A. Alexandre, A. Bricolo,
and H. Millesi (eds.)

Advanced Peripheral Nerve Surgery and Minimal Invasive Spinal Surgery

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Preface

On behalf of the Committee for Peripheral Nerve Surgery of the World Federation of Neurosurgical Societies, and sponsored by EU.N.I., European Neurosurgical Institute, the Third Course on peripheral Nerve Microsurgery and on Minimally Invasive Treatments for Spinal Diseases was held in Treviso, February 9–11, 2004.

In the course, which was also supported by the European Association of Neurosurgical Societies (EANS), the Latin-American Federation of Neurosurgery, and the Italian Neurosurgical Society, the different minimally invasive techniques were analyzed which are presently used in order to minimize bone demolition, scarring, and risk of recurrence. The results of intradiscal techniques were compared with those of miscrodiscectomy, and new methods were discussed in face of problems such as epidural fibrotisation, microinstability, osteoporotic or neoplastic or postraumatic vertebral lesions. The different minimally invasive methods were discussed with participation of specialists from different countries. At the same time peripheral nerve problems were discussed and differential diagnosis problems highlighted.

As in past years, the course included conferment of the Hanno Millesi Award. This prize was conceived by the Committee of Peripheral Nerve Surgery of the World Federation of Neurosurgical Societies in honor of this Father of Surgery in the field. The prize consists of a financial support to a young researcher to help him going ahead with his studies on new perspectives in the field of nerve biology and surgery. The prize is financed by EU.N.I., European Neurosurgical Institute, and is assigned upon evaluation of the best paper presented.

This year Prof. Millesi, Dr. Giocoli, and members of the commission awarded Dr. A. Gravvanis and coworkers from the General State Hospital of Athens, Department of Plastic Surgery and Microsurgery & Burn Center of Hellenic Pasteur Institute, Greece. Dr A. Gravvanis presented the paper "The effect of genetically modified Schwann cells in end-to-side nerve grafting". The concept investigated by him is whether collateral nerve regeneration is feasible through silicone tubes, as previously he had demonstrated in rat models that Schwann cell lining of tubes improves significantly the regeneration rate and fiber maturation, but Schwann cell lining of tubes did not ensure collateral nerve regeneration in all cases. Hence the aim of the study was to improve these results by lining the silicone tubes with genetically modified Schwann cells with increased motility.

We are especially grateful to Acta Neurochirurgica for having dedicated this Special Issue to the Course in Treviso. In this volume we present papers on peripheral nerve surgery and on spinal surgery in order to underline the relevance of a common understanding of the clinical problems, in order to obtain a more perfect differential diagnosis between problems so closely related but so different in their management.

Alberto Alexandre, *Albino Bricolo*, and *Hanno Millesi*

Foreword

"This Special Issue of Acta Neurochirurgica is dedicated to the publication of the papers which were presented in the IIIrd Course on minimally invasive neurosurgery, held in Treviso under the organisation of the Committee for Peripheral Nerve Surgery of the WFNS. Discussion has moved through new trends on peripheral nerve surgery, and pain treatments, which are a challenging interdisciplinary matter for many professionals. Moreover analysis of differential diagnosis with spinal degenerative diseases has called the attention of participants. This Committee of the WFNS has increased his activities through the years, and symposia have been organized by it, in different continents. But the one in Treviso remains each year a regular recurring appointment open to interdisciplinary discussion and to the presentation of new trends and points of view.

Certainly Neurosurgery is a continuously evolving world, and each and everyone of us is compelled to critically consider the techniques he is employing and to analyze the results he is obtaining. There are diseases whose physiopathology is not yet clearly understood, and the mechanism of generation of such a difficult and complicate matter as pain remains under several aspects a dilemma. The discussion over these conditions involves interdisciplinary cooperation.

This is why similar meetings, during which we feel to be conducted through a careful analysis of new techniques and reconsideration of routinary trends, are useful and welcome. The participation of such a large group of experienced and outstanding professionals has made these days of great concern for all participants.

The special event of the attribution of the Hanno Millesi Award, conceived and offered by EU.N.I. to the WFNS, has further increased the interest of the appointment. An important paper on nerve regeneration stimulated by genetically modified Schwann cells, by Andreas Gravvanis has been awarded this year. This paper is in the line of the research awarded last year, the big progress that came from Fausto Viterbo who in Butucatu could demonstrate nerve regeneration by terminolateral anastomosis. We, who initiated the Committee of peripheral nerve surgery, are proud to observe that great attention is paid to young researchers."

Madjid Samii, M.D., Ph.D.
PastPresident of the WFNS
President of INI

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Neurolysis: Is it beneficial or harmful?

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Summary

The term internal neurolysis means removal of fibrotic tissue inside a nerve trunk. Unfortunately the term was used for procedures with complete isolation of fascicles with all consequences like damage of links between the fascicle and impairment of blood supply. The conclusion based on some negative experiences that all surgery within a nerve trunk has to be avoided cannot be accepted.

Neurolysis within a nerve trunk, id est within the epineurium, is a step-wise procedure to decompress fascicles from a constricting fibrosis. It stops immediately if this aim is achieved or continues with resection and reconstruction if an irreparable damage is present. It is better to use terms that describe exactly what was done and abandon the ill-defined term "internal neurolysis".

Fibrosis of the paraneurium remains outside the epineurium but causes the same consequences as fibrosis of the epineurium.

Keywords: Neurolysis; internal; nerve trunk.

Introduction

Neurolysis outside of the nerve itself is a common and frequently very successful procedure in order to remove an external compression like a bony fragment, scar tissue or a foreign body. A second very important indication is to liberate a nerve from adhesions and provide the possibility of passive motion for adaptation to the different position of an extremity.

The nerve itself must be intact if a good result is to be expected.

If the nerve is damaged and fibrosis of the different connective tissue layers has developed, external decompression alone is not able to produce functional recovery. It was therefore discussed for long (Babcock 1907, 1927, Lehmann 1936, John B. Murphy 1916) whether in such a case surgery within the nerve (internal neurolysis) to remove the fibrotic tissue which causes compression of the fascicles could solve the problem. The rather crude surgical techniques of those days might however have caused more damage than benefit.

An excellent survey of the historical development is given in the book of Susan Mackinnon and Lee Dellon (1988) on page 131 and 132.

Consequently, when microsurgical techniques became available, surgeons applied these techniques to operate within the nerve, convinced that the atraumatic procedure would minimize the surgical trauma. Without much hesitation fascicles were isolated, connections between the fascicles destroyed, and the circulation within the nerve impaired.

Curtis and Eversman (1973) applied internal neurolysis to all cases of carpal tunnel syndrome based on electromyographic criterias in regard to the severity of the case rather than on the local situation.

In the following years cases were observed in whom – after an internal neurolysis – a pain syndrome developed and internal neurolysis was condemned.

I have personally studied this problem intensively since 1975 and provided definitions and criterias to be followed to avoid problems. The results were summarized in 1995 (Millesi 1995).

Many surgeons are still afraid to enter a nerve trunk.

At a recent meeting I was asked whether I still do internal neurolysis or whether I have abandoned this procedure. My answer was that I still do surgery within a nerve trunk as I always did but I suggest to abandon the term "Internal Neurolysis".

For this reason I think it is necessary to outline again my approach to surgery within the nerve. In recent years fibrosis of the paraneurium has gained more and more significance especially in cases of brachial plexus lesions.

Therefore some information about this tissue is included in this paper.

Connective tissue components of a nerve trunk:

Endoneurium

The endoneural space is filled with a very delicate connective tissue framework, which is vulnerable and may become collagenized. We called this situation a fibrosis of type C. The involved fascicle are shrunken and hard. Regeneration is not possible in such an environment.

These fascicles have to be resected and the defect bridged by nerve grafts.

Perineurium

The perineurium surrounds the endoneural space and delineates it to the outside world. Fibrosis of the perineurium I have seen in cases of direct damage e.g. by injection of a toxic substance into the nerve. A perineuriotomy may be considered but I think it is the better solution to resect the involved fascicles and bridge the defect by nerve grafts.

Epineurium

This is the connective tissue which envelopes the fascicles and extends between the fascicles. It contains the vessels, provides space for movement of the fascicles within the nerve trunk and surrounds all the fascicles of a nerve trunk. Consequently we have to distinguish between an interfascicular (internal) and an epifascicular (external) epineurium. This is not specialized connective tissue like the endoneurium or the perineurium. It reacts easily against a traumatic damage of different kind with fibrosis. The fibrotic tissue shrinks and the fascicles within this tissue are compressed.

If the interfascicular tissue is involved (fibrosis of type B), it is more difficult to achieve decompression. If however the epifascicular epineurium alone is shrunken, the whole nerve is compressed like a too tight stocking (fibrosis of type A). The shrinkage of the epineurium is mainly directed in transverse direction.

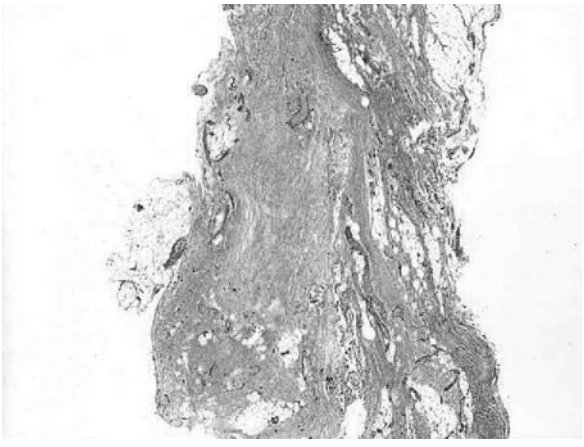

Fig. 2. Histologic section of a thickened fibrotic segment from a patient with a brachial plexus lesion. HE,Magn.:20x

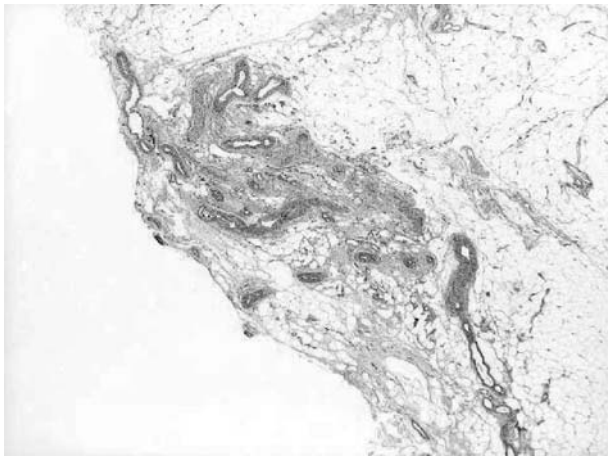

Fig. 1. Histological section of normal paraneurium. HE.Magn.:20x. Loose connective tissue with many vessels and fat lobules

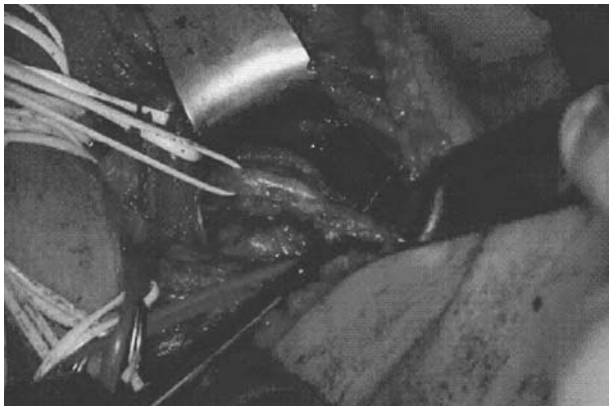

Fig. 3. Traumatic brachial plexus lesion. One of the structures of the brachial plexus with intact epineurium surrounded by a thick layer of fibrotic paraneurium. Paraneuriotomy has already been performed

Fibrosis of the paraneurium forms a subgroup of fibrosis of type A. We use the term fibrosis of type A*.

Paraneurium

It was mentioned above that the nerve has to be able to move passively in order to adapt to the movements of an extremity. The nerve needs also space to change its diameter. In full extension the nerve is extended and stretched and has a smaller diameter as compared to full flexion when the nerve becomes shorter with the same volume and has a larger diameter. This space has to be available for proper function. It is filled by a loose connective tissue, which extends between the epineurium and the surrounding tissue. If we isolate a nerve, we do it in this space and within this tissue. If we harvest a nerve as a graft, this is also done in this space and one part of this tissue remains always on the surface of the nerve.

This tissue is usually not described in textbooks. In cadaver dissections it is not impressive and may be overlooked. Since it is fixed to the epineurium and it contributes to the pathology (see below) it should be listed as part of the connective tissue frame work of a peripheral nerve.

This tissue was extensively described by Johannes Lang (1965) and called ''conjunctiva nervorum''. Van Beek and Kleinert (1977) referred to it as ''adventitia''. In the atlas of micro morphology by Krstic it is well described and called ''paraneurium''. On my question Krstic could not tell from where he had this term and who used it for the first time. I think this term is easier to handle than the two other terms. It corresponds to the term ''paratenon'' of tendons.

Therefore I shall continue to use paraneurium.

Surgical procedures to deal with a connective tissue problem of a peripheral nerve:

It was already mentioned that an *exploration* of a peripheral nerve is performed in the paraneurial space.

If there are adhesions and the paraneurial space is obliterated, an *external neurolysis* has to be done and everything compressing the nerve from outside has to be removed. At the end of this procedure the surface of the nerve (the epifascicular epineurium) should look normal and the nerve should give a soft impression by palpation.

If the surface of the nerve is irregular and the nerve is indurated, something more has to be done. This is the point when ''internal neurolysis'' comes into consideration. Doing nothing would mean neglect the possibility of significant improvement. It would be wrong to start with an interfascicular dissection coming from the sane tissue proximally and distally and to isolate the fascicles.

As a first step a longitudinal incision across the thickened tissue on the surface of the nerve has to be performed until fascicles are seen. This is an *epifascicular epineuriotomy*. Very often one will see the fascicles expand since the compression has subsided. In this case a fibrosis of type A is diagnosed and the surgery can be finished.

If, however, the decompression is incomplete and fibrous tissue can be seen extending between the fascicles into the depth, the epifascicular epineurium is removed all around the nerve to decompress fascicles which are located in a distance from the epineuriotomy. This would be an *epifascicular epineuriectomy*.

If there is more fibrous tissue between the fascicles and not all the fascicles can be decompressed by the last step, one continues with an *interfascicular epineuriectomy*.

The surgery is limited to those segments which have already developed fibrosis. In no case is it extended into normal tissues.

In these two cases the diagnosis would be: Fibrosis of Type B.

If the fascicles themselves were indurated the surgeon has to assume a fibrosis of type C. A neurolysis procedure cannot influence this condition. A more aggressive approach has to be elected: *Resection and nerve grafting*.

The same is true if the fascicular pattern has been lost. This would be a lesion of degree IV according to Sunderland.

One sees that the goal of neurolysis is to achieve decompression of compressed fascicular tissue. The surgical activity stops immediately if this goal is achieved or continues with resection and reconstruction if the damage is too far advanced. In no case are fascicles isolated and deprived from the blood supply.

The pathology of the paraneurium.

So far the paraneurium has not even been mentioned. The reason for that is the following:

The cause which initiates the pathologic changes involves at first the paraneurium if it acts from outside. Very soon the epifascicular epineurium is involved as well and the two layers fuse. The surgeon does not see the paraneurium but only the thickened epineurium.

This is one of the reasons why the paraneurium did not attract attention.

All cases of fibrosis of type A include a fibrosis of the paraneurium.

In a large casuistic, especially in brachial plexus cases, one can meet patients who have an isolated fibrosis of the paraneurium with intact epifascicular epineurium. Shrinkage of this tissue can produce a loss of function and in contrast to the epifascicular epineurium a contracture in longitudinal direction. It is treated in similar fashion:

Paraneuriotomy as a first step and
Paraneuriectomy as a second step.

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TOS pathophysiology and clinical features

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Summary

The authors present 280 patients operated on for thoracic outlet syndrome (TOS). In a first group of patients anatomical variants were the striking findings. The underlying factor for TOS development is therefore a well defined structural condition and its pathogenetic mechanism is known to be a nerve fibre compression.

In a second group there was no specific salient finding but a postural deviation. The unique pathological features were adhesions of the brachial plexus to the scalenus muscle. Consequently its pathogenetic mechanism is generally recognized as nerve fibre distraction.

In all patients neurological, vascular and myofascial pain symptoms were observed before the operation. Neurological and vascular pain disappeared after surgery, while the myofascial pain remained.

The authors believe that especially in the second, larger group of patients enhancement of the pain-immobility-fibrosis loop is the central pathogenetic factor on which surgical therapy is successful, and that myofascial hemisyndrome – probably arising from a longstanding postural deviation – is not a TOS dependent symptom. In TOS, therefore, there is a pain loop that cannot be resolved by surgical therapy alone.

The connection between myofascial pain syndrome and TOS might explain the many controversial opinions regarding frequency, results and surgical possibilities of this lesion.

Keywords: Thoracic outlet syndrome; myofascial pain; brachial plexus entrapment; trigger point; surgery; posture.

Introduction

The authors present 280 patients operated on for thoracic outlet syndrome (TOS) at the Neurosurgical Department of the University of Milan from 1982 to 1990 and from 1995 to 2000, at the Neurosurgical Department of San Gerardo Hospital of Monza from 1990 to 1995, and at the Neurosurgical Department of the University of Sassari from 2000 to 2003.

Patients were divided into two distinct groups. Fifty-two belonged to a first group where the striking findings from the clinical, diagnostic and pathological points of view were elements described as anatomical variants (cervical ribs, transversal mega-apophysis, fibrous bands, scalenus minimus). The underlying factor for development of TOS is therefore a well defined structural condition, and its pathogenetic mechanism is known to be a neural compression.

The second group of 228 patients was characterized by the absence of diagnostic or intraoperative features mentioned above. The salient finding is not a specific one and could also be observed in the first group, i.e. a postural deviation: tilting or side sliding of the pelvic joint and rotation of the spine. In this group, the unique pathological features were adhesions of the brachial plexus to the scalenus muscle, its pathogenetic mechanism is therefore generally recognized as nerve fibre distraction.

In all 280 patients neurogenic, vascular and myofascial pain symptoms were observed before the operation. Neurogenic and vascular pain disappeared after surgery, while the myofascial pain remained.

The authors believe that especially in the second, larger group of patients, enhancement of the pain-immobility-fibrosis loop is the central pathogenetic factor on which surgical therapy is successful, and that myofascial hemisyndrome, probably arising from a longstanding postural deviation, is not TOS provocated but a TOS independent symptom. In TOS there exists therefore another pain loop that cannot be resolved with surgical therapy alone.

The connection between myofascial pain syndrome (MPS) and TOS may explain the controversial opinions about frequency, results and surgical possibilities.

Materials and methods

Two hundred and eighty patients are reported, 220 females and 60 males, between 27 and 78 years old. 184 patients had surgery on the right side, 96 on the left. 248 patients had follow-up, 196 of them over more than one year.

Pain and other symptoms

Pain is the leading factor in the clinical history of these patients. Complaints consist of lumbago, sciatica and tension headaches. It was always possible to recognize one side of the body to be more affected. Finally a unilateral brachial pain arose with sudden onset in 64 cases and gradual onset in 216 cases.

Other constantly reported symptoms were insomnia, unsteadiness of gait, dizziness without vertigo and visceral disorders grouped under the general heading of ''bowel irritation''. The irritative symptoms (paresthesia) and the neurological deficit occurred later.

In order to select the patients for surgery, we wanted to distinguish personal subjective symptoms (pain and paresthesia) and interpersonal objective symptoms (impairment of function, reduced activity, modification of habits, hand muscle atrophy, hypesthesia).

Pain

The pain described by the patients covered the full range of possibilities from throbbing to dull, burning and stabbing. In general patients complained about different types of pain with different patterns. Location of the pain varied greatly: hand, forearm, or hemithorax irradiating also to the controlateral hand, neck and head.

We distinguished three specific pain patterns from different origins:

1) ''Neurogenic pain'': found in all cases, irradiating to radicular dermatomes (in 252 cases C8–T1, in 28 cases C5–C6). This pain appeared in paresthetic areas and occurred like a parossystic spike (shooting pain).

2) ''Vascular pain'': was present in 216 patients (80%), rather varied in intensity, endurance and extension. It spreads over areas remote from the radicular dermatomes. Sometimes it is characterized by psychological enhancement (chest pain, angor). The area overlaps one or more vascular territories and the pain is always accompanied by physical changes like rubor, tumor, calor, or pallor to the fingers, to the whole hand, limb, neck, breast region up to the contralateral hand. Typical is the ''glove'' pattern. Vascular pain has a slow climbing up to a plateau that can persist for many hours. The characteristic attribute is described as ''throbbing''.

3) ''Myofascial pain'': was present in 252 patients (90%) and is described as tension ache or burning. It extends along the fascias and is commonly perceived on biceps, triceps, trapetius, scalenus and pectoralis muscles up to the muscles of the arm. Distribution of spontaneous (myofascial) pain was identical in all patients. It overlaps an equal pattern of tender points on the periosteous attachment or on the belly muscles. Tapping some of these, around the scapula, triggers the referred pain similarly when occurring spontaneously. The area of myofascial pain generally covered the upper quarter of the body, extending to the arm in segmental distribution. In the temporal pattern, the myofascial pain was represented by the baseline (''underground'' pain), sometimes with parossystic outbursts.

Paresthesia

Paresthesia was present in all patients day and night. In 10% of cases (28 patients) paresthesia was distributed on the radial side of the hand/forearm, while in 90% of cases (252 patients) it was found on the ulnar side.

Impairment of performance and change in habits

Conscious and unconscious avoidance of certain movements or postures, e.g. those involving the upper quarter of the body (washing windows, painting ceilings, static load bearing on the shoulder), was a common feature in all patients. It is difficult to set the borderline between avoiding pain dysfunction of movement and neurologic deficit.

Symptoms of lesion

Only in 20 of our patients impairment of performance was clearly due to motor deficit (interosseous muscle atrophy); in the other patients there was no evidence neither clinical nor electrophysiological of denervation, even with an important functional limitation. In 45 patients there was an almost insensate hand.

Clinical features

General clinical evaluation

Based on Viola's typology, our patients could be divided into: asthenic longitype: 28 cases (10%), sthenis normotype: 20 cases (7%), brachitype: 232 cases (83%), picnic (none).

All patients observed presented a postural habit with forward bending of the head-neck complex on the sagittal plane. 252 patients (90%) showed a lateral tilt of the pelvis toward the injured side on the frontal plane, and 28 patients (10%) toward the opposite. All patients presented an enhancement of the supraclavear cavities and a lateral flexion of the head toward the injured side. On the same side, a constellation of tender points marked the bone attachment of peculiar muscles (enthesytis). Above the levator scapulae and the trapezius, trigger points (TPs) for referred pain to shoulder/arm were found. A postural scoliosis C-type was observed in 224 patients (80%), in 140 patients (50%) homolateral, in 84 patients (30%) contralateral to the painful limb. In 56 patients (20%) we observed a postural scoliosis S-type.

In 192 cases (68%) homolateral, in 88 cases (32%) contralateral the tender temporo-mandibular joint was always included in this algic pattern. Coccigodinia was present in 140 patients (50%). An amplified cutaneous reactivity, as for example enhancement of the stria alba or stria rubra after gentle cutaneous stroke was always evident.

Local clinical evaluation

All patients had a postural lateral tilt of the head toward the injured side and Tinel's sign with irradiation along the ulnar or radial side of the limb by tapping on Erb's point.

Neurological evaluation

All patients presented hypesthesia with radicular distribution, in 8 patients in the C5-C6 region and in 62 patients in the C8–T1 region. Two patients presented a severe interosseous muscle atrophy.

Strumental evaluation

X-rays of the cervical spine showed bilateral cervical rib in 28 cases. EMG demonstrated interosseous muscle denervation in two cases. Doppler sonography was performed in 88 cases and was positive only in one, showing digital artery flow impairment. Angiography was performed in 28 cases and a slow-down of the flow of the subclavian vein was always demonstrated. An analogous finding was seen in 60 cases on enhancement-CT. In no other case did the strumental diagnosis confirm TOS diagnosis but in all cases was valuable for exclusion of other pathologies.

Surgical indication

All our patients with TOS diagnosis were referred to physiotherapeutic treatment for at least three months. Persisting symptoms

were an indication for interventional therapy. Patients had to have brachial pain for more than 6 months to be operated. Subjective symptoms should be severe enough to disturb life style, objective symptoms must comprise three cardinal signs: 1) dermatomeric hypesthesia, 2) positive supraclavear Tinel's sign, 3) positive brachial plexus tension test (Elvey's test).

Surgical findings and etiopathogenetic correlations

During our study we encountered a number of anatomical vagaries: 28 cervical ribs, 12 scalenus minimus, 4 strengthening of Sibson's fascia, 12 anomalies of the attachment of the scalenus medius, 8 neurovascular conflicts between the lower trunk and the arteria transversa profunda colli. However, these anatomical variations do not have the same pathogenetic weight. While we put emphasis on the cervical rib (28 cases) or on the arteria transversa profunda colli (8 cases) for plexus injury, we are not sure that the other observed anomalies play a role in the pathogenesis of TOS. In another 244 patients we did not have immediate evidence of any compressing or offending structure and therefore we should look for the shape of the attachment of the scalenus anterior muscle on the first rib and its angle of inclination. In 120 patients out of this group, scalenus anterior lies near or merges with the scalenus medius in the caudal attachment. In such a situation the interscalenic triangle becomes progressively thin up to a suspended eyelet from which the neurovascular plexus hangs up thus complicating the clinical pattern. In 200 patients out of 244, verticalisation of the first rib reduced the angle between the scalenus anterior and the first rib with pinching of the subclavian artery and of the C8–T1 trunk. The lower trunk is more at risk due to its location: there is the pulsating artery in front and the firm posterior pillar of the tunnel entry located behind; i.e. the edge of the bare first rib or the scalenus medius at its attachment. This latter feels very taut when probing with palpating finger. Therefore in 212 cases out of 244 we assumed that a neurovascular conflict was evident. When adding to these 212 patients the first 36, we would find that in 248 out of 280 patients (88%) compressing or pulsating forces played a role in the pathogenetic mechanism. In 32 patients no feature of compression was found at all. In all patients we found a fibrillar net, bridging the interscalene gap and strangling the neurovascular plexus inside. This tangle of fibrillar lacinia was visible both in micro and in eye vision. In all cases (100% of patients) it was possible to see for example how the trunks of the plexus were stretched by pulling the scalene muscles with forceps: this test provides evidence that distraction also plays an important role in the pathogenetic mechanism. Traction force accounted for plexus injury in all cases and may be considered the chief offender in those 32 patients without evidence of compression.

Results

All patients within few hours after awakening from the operation had complete remission of the neurogenic pain. Two hundred and eight patients with follow-up of more than 1 year were assessed. In 52 patients (24%), vascular pain disappeared suddenly and totally after awakening, In 164 patients (76%) pain endured but at a more reduced distribution, scarcer and more tolerable than before. Eventually, after 3–4 weeks, all patients had complete remission of the vascular pain. Myofascial pain was completely remitted after the operation in 20 patients (10%), dragged on for weeks or months in 88 patients (40%) and endured until 1 year in 108 patients (50%), however, easier to bear than before. In all patients paresthesia and hypesthesia resolved within a few days following surgery. Patients with muscular atrophy did not show EMG and ENG evidence of improvement but fist grip and precision grip were more effective. It must be stressed that in all patients daily performances and mood improved.

Discussion

The most interesting issue emerging from this clinical report was the astonishingly large lot of patients in which symptoms started acutely. The sudden onset could easily be connected with traffic accidents in 20 cases and a change of occupational activity in 12 cases. However, the precipitating factor couldn't be recognized in 32 cases. The second interesting point was the presence and persistence of the myofascial pain pattern which should be correlated with surgical features. We assume that the pathogenetic mechanism is doomed to be misunderstood if we look for a compressing offender only. We believe that compression and distraction alternate in hurting neural primary trunks and that both forces are effective to a higher or lower degree for producing TOS. In the group of patients with cervical rib, anomalous compressive bone surely is the chief offender, but in the other patients it is tethering of the plexus by myofascial adhesions. We cannot say if these mechanisms are activated or enhanced during the day by movement or at night in a typical disturbed sleep. The presence of synechia between the plexus and scalene muscles is a constant pathological feature in the surgical field. We propose two theses regarding their nature: either they are physiological answers to a chronic nerve compression (starting from the thickened epineurium and going toward the fascia or vice versa) or they are offspring of a paraphysiological reaction of the connective tissue and therefore evident everywhere in the surgical field, on the platisma and on the homogeneous planes. The basic pathology, according to this thesis, would be a kind of connectivitis. Prior to surgery we found in our patients a diashesic tendency to sympathetic overactivity (long-standing stria alba and stria rubra); this could explain the enhancement of the pain-immobility-fibrosis loop [3]. For long time upon operation, our TOS patients presented an unchanged pattern of myofascial pain. This

impressively resembles in type and localization of tender points the fibromyalgic patients; fibromyalgia syndrome (FS) is a chronic pain disorder characterized by diffuse musculoskeletal soreness, non restorative sleep, psychological disturbance. It is more appropriate with an array: fibrositis, myo-fibrositis, fasciomyositis primaria (FMP), indicating a kind of pararheumatic illness; its histopathologic findings are a matter of debate particularly regarding the relationship with sleep. The overlapping of TOS and FS symptoms becomes more striking through the history (sleep troubles and bowel irritation are present in both). We have indeed the impression that the enduring myofascial pain, poorly modified by brachial plexus release, shows that this component of pain should not be a secondary phenomenon but a primary one. We stress that myofascial pain is able to independently rule among different symptoms related to plexus dysfunction. If we consider only this feature of pain in TOS patients, we find a striking analogy with pain arising from a cryptic form of pathology of the muscle or from a postural long-standing deviation (myofascial pain syndrome, MPS). We believe that the latter is very common in a large group of population, but if this coincides with a specific, particular anatomic situation, like a climbing first rib or a large basis of scalenus anterior, finally TOS could arise. To test this theory, we sampled within a few months other 240 patients (mostly female) who came to our department for pain symptoms in limbs, neck and trunk. Their general complaints (acrodynia, pectoral pain, no dermatomeric type brachialgia, sleep disturbances, bowel irritation, musculo-tensive cefalea) reflected analogous symptoms as in TOS operated patients, but the trigger points and myofascial pain pattern focused on FS. All patients of this type, also with minimal neurological signs indicating an irritative plexus were recruitable. In practice we easily found a large group of FS or MPS patients more or less bordering TOS. The high frequency of FS or MPS versus low frequency of TOS induces the authors to believe that these are the ''via finalis communis'' of different situations and that TOS is only a collateral, striking part of this phenomenon, an evolution regarding few patients only. It remains to explain how a ubiquitous MPS or FS with bilateral symptoms evolves in unilateral, upper quarter affecting TOS. We emphasize that both MPS and FS have actually symptoms prevailing one side and vice versa, many clear-cut TOS present a bilateral glove pattern of pain and paresthesia. Just the contralateral glove pattern of paresthesia which features a ubiquitous sympathetic overflow remitted quickly after unilateral operation. X-Ray finding showed a bilateral cervical rib in 28 patients. Also in this small group of patients this anatomical variant could not explain the one sided appearance of symptoms. We could track down in a few TOS patients the onset of clinical history to a whiplash injury, to a forcibly abducted shoulder or to a change of occupational activity, where the vascular nerve plexus was probably affected by unilateral stretching of soft tissues. But in many patients we did not find precipitating factors like these. We believe that in those cases trivial stretch or movement on overloaded muscles (e.g. scalene) could activate a latent trigger point and lock some fibres in ''taut bands''. So the thoracic outlet got suddenly more narrow by contracture on the scalene. In our opinion, this mechanism accounts for an abrupt onset of clinical history. Later on the transient early entrapment can be perpetuated by mechanical stress due to structural inadequacy or to postural imbalance. We report that all TOS patients had a lateral tilt of the pelvis, and we noted a close relation between the lateral down-slip of the pelvis and the side of arising symptoms. 248 patients (90%) had a homolateral TOS, 32 patients (10%) a contralateral TOS. We know that a tilted pelvis without rotation of the spine is due to an anatomical inadequacy for any of the body structures of the lower extremity kinetic chain, (anatomical length-limb difference – ''anatomical'' LLD-), and that meanwhile a tilted pelvis with rotation of the spine is due to muscular imbalance (postural scoliosis, or ''functional'' LLD).

LLD (structural inadequacy): this heading fits to sizable anisome. We found LLD in 128 patients (48%). The LLD about 1 cm or less, coupled with C-type scoliosis, in 88 cases, the LLD more than 1 cm, coupled with S-type scoliosis, in 40 cases. The technique used in our patients was the standing anterio-posterior X-ray examination, knee extended. We know that the muscular tone is greater in the ''short leg'' because the stance phase there is shorter, the swing phase is longer and the momentum of heel impact is greater. Therefore LLD accounts for unilateral raising of the muscular tone. Furthermore tilted pelvis corresponds with tilted shoulder girdle axis and the neck muscles must instantly compensate to maintain the head upright and eyes at level which leads to chronic overloading. In other cases (148 patients) we had a postural scoliosis. The overloading on the neck muscles was due to the

same mechanism. But in these cases we did not know the cause for which the unilateral overtonus had begun. Anyway, arising muscular imbalance applies torsional forces to the spine and results in lateral tilt of the pelvis. Bruxism was reported in 124 patients (48%) on admission. All examined patients were submitted to a dental check and a malocclusion was found in all cases. We believe that the temporo-mandibular joint dysfunction (TMJD), a very ancient muscular tension triggering mechanism, is the most important factor in raising muscular tone and in driving it toward one side. Perhaps the cause of producing torsional forces has not been acting for long, but the body maintains the same posture (postural neglect) from which the muscular overtone in the upper quarter is perpetuated.

Conclusions

We believe that in TOS patients two pain loop mechanisms, one specific for TOS the other a-specific, are interconnected. In the specific loop the pain is neurological and vascular and is maintained by compressing bone, band, or tethering fibrosis on the surrounding vascular nerve plexus soft tissues. We cope with vascular or true neurological TOS by severing this loop and the surgical removal of the offending cause is very successful. In the a-specific loop the pain is myofascial and is maintained by postural neglect with unilateral overtone. Unreliable response to surgery. In most of cases, the myofascial pain starts alone and heralds a pathological entity very difficult to define (''Disputed'' Neurological TOS) – and which borders with MPS are very blurred. Initially this is no indication for surgery. The problem can be settled with a correct conservative treatment. Without or despite this, minimal adhesions by chronic entrapment progressively build up around the nerve structures. Vascular and neurological pain loop mechanisms are eventually coupled. At this point we have to deal with a true TOS and must add the surgical treatment to the therapeutical panoply. However, we must inform the patients that the same pain symptoms remain because the myofascial loop mechanism cannot be severed by surgery. Therefore TOS, in which surgical treatment is mandatory, often is regarded a failure in preventive medicine, an example of a not timely corrected situation. TOS should be considered a multidisciplinary pathology, not only falling into the neurosurgeon's competence but also of other specialists such as rheumatologist, physiatrist and the maxillo-facialis. Their support is indispensable in caring for these patients. TOS needs to be approached without hubris by surgeons: neurological and vascular symptoms remitted easily after the operation; conversely myofascial pain may demonstrate to be very difficult to be resolved. We think that a poor chronic posture triggers continuously muscular tension anywhere in the upper quadrant or in hemibody and so myofascial pain has a self-maintained mechanism untouchable by surgery. Therefore a physiatric approach is fundamental because there are problems in this pathology which surgery does not fit. Interventional therapy should be only a step in the treatment. From this point of view we suppose that lacking awareness of this issue accounts for old and actual controversies in epidemiology, diagnosis, treatment, results of TOS.

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Post-traumatic thoracic outlet syndrome (TOS)

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Summary

TOS is a compressive non-tumorous syndrome of the brachial plexus. It is possible, however, to consider as TOS the irritative and lesional plexus syndrome following trauma as long as compression (or traction) on the nerves is triggered by long-lasting pathological changes of the area after trauma. Overload work of judges and lawyers after traffic accidents does not help to remind the real victim's problem, that is stretching of the neck soft tissues during head acceleration-extension. This movement is due to a forward acceleration. Both the car and the victim's trunk are violently pushed forward while the head does not move fast enough so that it is actually pushed backwards. The mandibula is even slower than the head and this leads to an opening of the mouth with possible temporomandibular joint (TMJ) dislocation. If there is nothing stopping the neck extension, like an appropriate headrest, the momentum is only resisted by cervical soft tissue stretching. Prolonged antalgic contracture and motor neglect may contribute to connective tissue changes and development of microadherences. Final result is fibrosis of paraneurium. The pain-immobility-fibrosis loop is of basic importance in the development of this syndrome.

Keywords: Post-traumatic TOS; whiplash injury; temporomandibular joint dysfunction; paraneurium; entrapment.

Introduction

TOS is a compressive non-tumorous syndrome of the brachial plexus. In the sense proper it does not refer to traumatic damage of the plexus, therefore a direct injury on the posterior triangle of the neck with subsequent immediate deficit cannot be considered as TOS. It is possible, however, to describe TOS as irritative and lesional plexus syndrome following a trauma as long as compression (or traction) on the nerves is triggered by long-lasting pathological changes of the area after trauma. TOS can therefore be regarded not as a primary traumatic lesion but as a secondary one, and the onset of its clinical features can variably be delayed. As matter of fact, from a legal point of view, a post-traumatic TOS can begin after an asymptomatic period. The same concept has been accepted for ulnar nerve after elbow fractures. Palsy can arise immediately, early and late. In all cases the canalicular syndrome is considered a post-traumatic neuritis (Mumenthaler).

Discussion

If we consider the thoracic outlet as a canal, we properly distinguish in it inlet, walls and outlet. The interscalenic triangle is the inlet and the anterior and middle scalene muscles form the walls of the tunnel, the space between the clavicula and the first rib is the outlet. The neuro-vascular bundle runs inside the canal. This latter is made of soft and hard tissues. The outlet of the canal is entirely made of hard tissues. Among post-traumatic TOS we may categorize those due to compression at the outlet level, pathophysiologically quite different from the neurological ones, and those due to entrapment by the walls, very similar to neurological postural TOS.

Costo-clavicular space

There is usually no compression at this level in spontaneous syndromes (walls of the canal are usually involved in neurological TOS) but in cases of traumatic fracture of the clavicula the size of canal outlet can be reduced. A compression of plexus with related clinical features may follows in variable time. Clinical features of an enduring compression can be overshadowed by trauma sequelae and surgical indication is based on radiological findings only. Especially in

war lesions we must keep in mind the possibility of a post-traumatic fake of subclavian or axillary artery aneurysm. In this case of a space occupying lesion in an inextensible space, plexus compression symptoms appear at very short time.

Inlet and walls of the canal

Different from hard tissue outlet, soft tissue changes of walls during trauma are extremely frequent. In particular, soft tissues (scalene muscles) are involved in the acceleration-extension lesions of the cervical spine.

This pathology was first described (in the forties) in aviators during catapult assisted take-off from ships. These pilots presented with chronic cervical pain so severe that they were forced to retire from service. It is reported that some of them lost consciousness after take-off and crashed. The problem was solved by providing them with a headrest. In the fifties this pathology was observed again with the growing diffusion of cars. The aforesaid trauma is in fact very common because it is involved in a big number (20%) of traffic accidents. Acceleration-extension injury of cervical spine, as definition, has long been neglected by the more fashionable whiplash injury. The latter was more propagated owing to its truculent name but it is based on a wrong concept (as if the medulla was whipped by spine ligaments). Protean features of this syndrome arise from troubled peripheral receptors. Acoustic, vestibular and visual systems are involved. Complaints of the victims caused an increasing importance of this syndrome more in legal aspects than in scientific ones. Overload work of judges and lawyers after traffic accidents does not help to remind the real victim's problem, that is stretching of the neck soft tissues during head acceleration-extension. This movement is due to a forward acceleration. Both the car and the victim's trunk are violently pushed forward while the head does not move fast enough so that it is actually pushed backwards. Moreover the mandibula is even slower than the head and this results in an opening of the mouth with possible temporomandibular joint (TMJ) dislocation. If there is nothing to stop neck extension, such as an appropriate headrest, the momentum is only resisted by stretching of the cervical soft tissues. The reduction of the anterior-posterior length of the car during a crash is linked to an increase in height. The victim is pushed not only backward but also vertically. Very often, at the moment of thrust from behind the head is above the headrest, which so becomes useless. The situation may be worsened through the car seats' being pushed forward. Applied force is only one of the elements causing damage in a crash. Some other elements are: weight of the car, surface of the road (much worse if slippery), etc. Stretched among the neck soft tissues during an extension injury are the scalene muscles. However, it would not be correct to consider the scalene muscles as the only ones involved. All anterior muscles of the neck may be stretched and damaged. They may be found ruptured and bloodied after serious injuries. In case of less serious lesions they appear microscopically damaged but we don't have pathologic-anatomic reports. In a "whiplash injury" commonly shoulder, neck and upper limb pain is referred together with hand paresthesia, especially at the 2 last fingers. Obviously it is not due to root compression because vertebral foramens increase rather than decrease their size during extension of the cervical spine. All the above symptoms derive from entrapment of nerve trunks by contracted scalene muscles. The lesion is considered as TOS when this transitory situation turns into a permanent one. Many of our TOS patients experienced a traumatic onset. The temporomandibular joint dysfunction can also be the perpetuating factor. In case of a unilateral syndrome, it should be noticed that TMJ dysfunction is often asymmetric after a traumatic event in which the cervical spine has asymmetrically been extended. This can be attributed to the standing rotation of the spine at impact. TOS clinical features do not necessarily start immediately after the traumatic event. Often a long period follows during which different symptoms are evident (dysphagia, vertigo). It is possible also, to have a completely asymptomatic period before the onset of TOS. Complex post-traumatic TOS patients are different from spontaneous TOS patients. Even if most of them are females, leptosomic ones are more often involved. It is obvious that muscular strength is pivotal in resisting cervical spine extension. "Bull necks" are coping more easily than "swan necks" with this type of trauma. Apart from the different pathogenesis, psycho-physical background may be the same in both postural and post-traumatic TOS. Prolonged antalgic contracture and motor neglect may contribute to connective tissue changes and development of microadherences. Final result is fibrosis of paraneurium. As a consequence the nerve loses its gliding property. The pain-immobility-fybrosis loop is of basic importance in the development of this syndrome.

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Brachial plexus injuries: regeneration timing and prognosis in patients without need for urgent operation. Preliminary results on truncus primarius superior

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Summary

Background. In Italy, and more generally in the industrialised countries, traumatic nerve lesions have become more frequent. It is commonly accepted that it is necessary to wait 6 months after injury to suggest surgery if movement does not appear. In the scientific literature, there is no systematic clinical evidence of nerve regeneration timing after trauma., especially regarding brachial plexus.

Method. We have performed a follow-up study of 15 consecutive patients with traumatic brachial plexus injuries involving truncus primaries superior without need for urgent surgery. In each patient an extensive clinical and neurophysiological evaluation was performed to detect the kind of lesion, level of lesion, severity of lesion and the outcome.

Findings. In our sample, some cases improved within a few weeks. This rapid improvement may be attributed to resolution of neuroapraxic block, in other cases slower improvement occurred due to rearrangement of motor units and axonal regeneration. In some cases voluntary activity clinically appeared after more than 6 months following injury.

Conclusions. The current study is preliminary, but it provides evidence that a period of 6 months may not be sufficient for the reappearance of clinical movement. Moreover, current results confirm that neurophysiological evaluation may be a highly prognostic tool in traumatic nerve lesions. We hope that our study together with other data may provide us a timetable for expected nerve regeneration.

Keywords: Brachial plexus; injuries; nerve regeneration; timing.

Introduction

In Italy, and more generally in industrialised countries, traumatic nerve lesions have become more frequent for several reasons: in Italy, for example, one of the most important reasons is to make wearing of crash helmets compulsory for motorbikers. This law has reduced mortality but it has subsequently increased incidence of brachial plexus lesions we currently observe [12].

The purpose of the present study was to document recovery of nerves from traumatic injuries and to evaluate timing of regeneration in patients without need for urgent operation. In this paper the preliminary results on troncus primaries superior are reported.

Materials and method

We have performed a follow-up study of 15 consecutive patients with traumatic brachial plexus injuries involving the truncus primarius superior without need for urgent surgery. Patients with at least one of the following features were classified "without need for urgent surgery":

- partial integrity of nerve fibers (demonstrated by clinical examination or EMG)
- nerve conduction block
- no root avulsion (confirmed by neurophysiological and neuroimaging evaluations)
- no plexus interruption evidence or haematoma at MRI

In each patient an extensive clinical and neurophysiological evaluation was performed to detect the kind of lesion, level of lesion, severity of lesion and outcome [1–3, 10, 14]. In all patients the following neurophysiological tests (according to procedures recommended by IFCN commitee International Federation of Clinical Neurophysiology) [3] were carried out:

1. Sensory nerve conduction studies in digit-wrist segments (radial nerve in the first digit-wrist segment, median nerve in the first and third-wrist segments, ulnar nerve in the fifth digit-wrist segment).
2. Motor nerve conduction studies of ulnar nerve (segments: erb point-axilla, arm, across elbow, forearm, wrist-abductor digit minimi), median (erb point-axilla, elbow-wrist, wrist-thenar eminence) and musculocutaneous nerves (erb-axilla, axilla-biceps brachii)
3. Needle EMG evaluation of the following muscles: deltoid, biceps brachii, extensor digiti communis, abductor digiti minimi
4. F wave response of ulnar nerve through wrist stimulation (recording from abductor digiti minimi)

Table 1. *Clinical neurophysiological mixed scale*

Score mixed scale	
−1	no voluntary activity at EMG (BMRC = 0)
0	BMRC = 0 but presence of voluntary activity
1	BMRC scale: 1
2	BMRC scale: 2
3	BMRC scale: 3
4	BMRC scale: 4
5	BMRC scale: 5

In many cases, these tests were associated with a motor evoked potential study through magnetic stimulation of cortex and cervical roots (recording from biceps brachii, abductor digiti minimi and thenar eminence) and a somatosensory evoked potential evaluation registering from scalp, cervical spine, and Erb point (median and ulnar nerve stimulation).

In case of suspected root avulsion or complete lesion of parts of plexus, neuroimaging was performed; if neuroimaging confirmed occurrence of that kind of lesion, the patient was excluded following the above mentioned criteria.

The outcome was based on a mixed scale we developed by using BMRC score (British Medical Research Council) [9] and EMG findings: we scored −1: muscles where no motor units potential (MUP) were detectable at EMG (and BMRC was 0); score 0: muscles where BMRC was 0 but EMG showed MUP; the other scores were the same as of BMRC scale (see Table 1). Each patient was evaluated with a mean of every 4 months.

Results

Results of this study are summarized on graphs with evolution of the clinical-neurophysiological outcome measure. The figures show the outcome evolution of deltoid, biceps brachii and brachioradialis muscles in patients with brachial plexus damage. Given that in clinical practice it is commonly accepted that it is better to wait for 6 months after injury to suggest surgery if movement does not appear, the graphs include a box to highlight some cases where clinical movement appeared after 6 months [11]. Some cases improved within a few weeks. This rapid improvement may be attributed to resolution of the neuroapraxic block; in other cases there was a slower improvement due to the rearrangement of motor units and axonal regeneration.

Regarding the outcome of deltoid (Fig. 1), excluding cases with rapid improvement due to resolution of neuroapraxic block, in many cases movement appeared after 6 months and complete improvement occurred after about 1.5 years.

Concerning the outcome of biceps brachii and brachioradialis (Figs. 2 and 3, respectively), excluding cases with rapid improvement due to resolution of neuroapraxic block, in many cases movement ap-

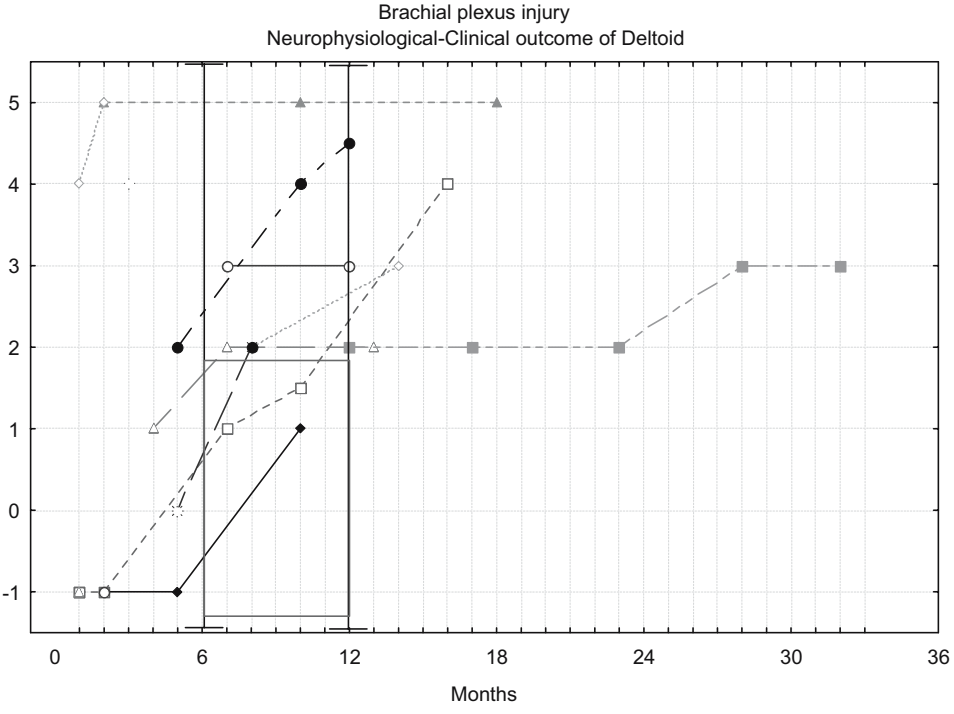

Fig. 1. Shows the neurophysiological-clinical outcome of Deltoid

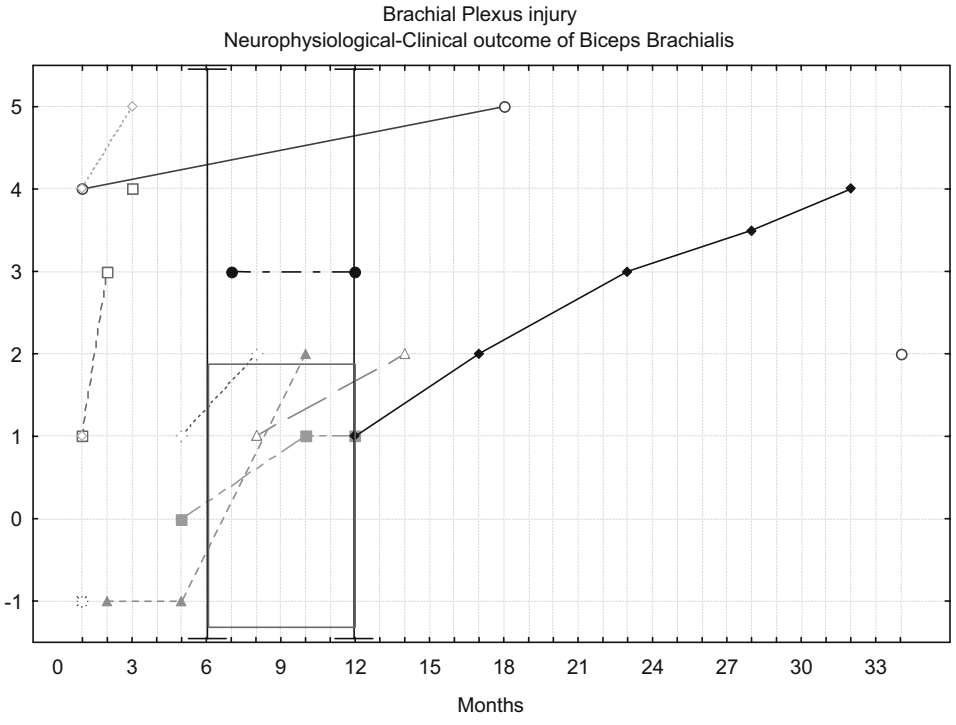

Fig. 2. Shows the neurophysiological-clinical outcome of biceps brachii

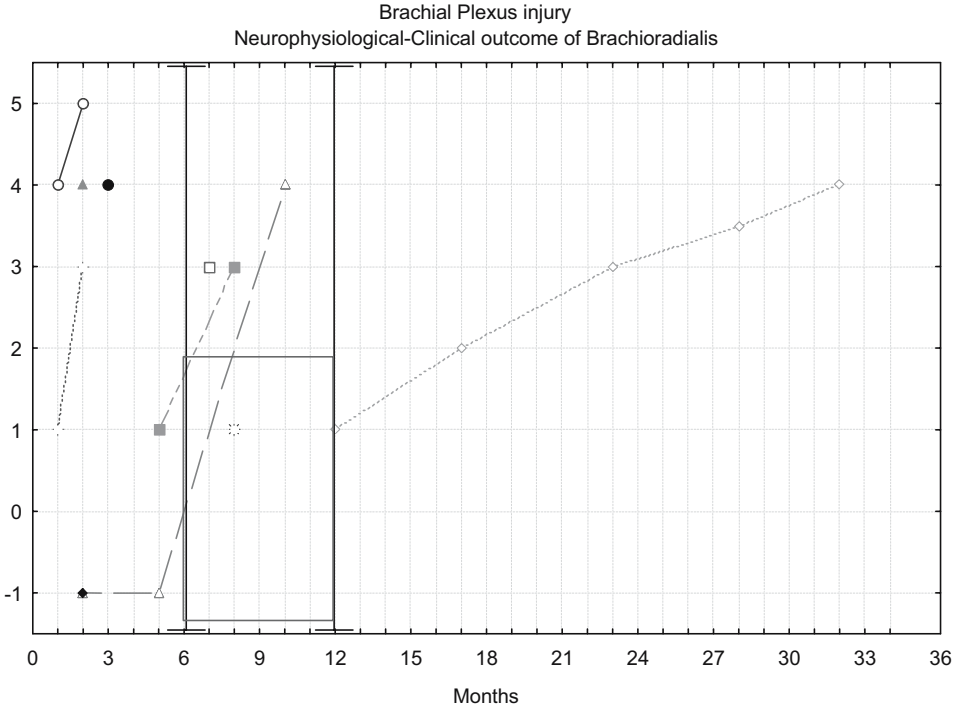

Fig. 3. Shows the neurophysiological-clinical outcome of brachioradialis

peared after 6 months and complete improvement occurred after about 2 years.

Discussion

Brachial plexus lesion is a complex diagnosis. The role of neurophysiological evaluation is crucial in the diagnosis and prognosis of brachial plexus lesion [4–8, 13]. To know the time period needed for recovery after injury is fundamental for the clinical (and surgical) approach, for the rehabilitation program and obviously for the patients. In the scientific literature, there is no systematic clinical evidence of timing of nerve regeneration after trauma, especially regarding brachial plexus. We followed up patients with non-operated brachial plexus injury.

Our results confirm that timing of regeneration is different according to the length of the damaged nerve segment (of course recovery of a short segment is faster than that of a longer one). The current study is preliminary but it provides evidence that a period of 6 months may not be sufficient for reappearance of clinical movement. Moreover, current results confirm that neurophysiological evaluation may be a highly prognostic tool in traumatic nerve lesions. In several cases, even 6 months after injury no clinical movement was present but EMG showed voluntary activity; in all these cases we observed improvement with clinical appearance of voluntary activity.

We hope that our study, together with other data, may provide us a timetable for expected nerve regeneration and possibly criteria for surgical indication. In our opinion this study may represent a preliminary step toward an evidence based therapeutic approach for brachial plexus injury, but further fundamental steps should be taken. When comprehensive information on therapeutic effects and natural evolution of this lesion is available and brought together, an evidence-based standardization of the therapeutic approach to brachial plexus injury will be at hand. Our study does not question the importance and necessity of therapy. In fact, until further data are available, the therapeutic decision must be taken case by case, on the basis of the clinical picture. We hope our data spurs on more studies, possibly multicentre, about the natural course and the evolution of this disease after surgery.

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Thoracic outlet syndrome due to hyperextension-hyperflexion cervical injury

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Summary

Posttraumatic brachial plexus entrapment in fibrotic scarring tissue is taken into consideration as the cause of complaints for patients who suffered a hyperextension-hyperflexion cervical injury. All 54 patients included in this analysis where symptom-free before the accident and subsequently complained for pain, paresthesia and slight weakness in the arm. In 14 neurological signs of brachial plexus entrapment were observed. Electroneurophysiological, summary index testing was positive for a brachial plexus involvement in all cases. Conservative measures, comprising physical therapy and vasoactive drugs were applied for a period of 6 to 12 (mean 8.4) months; surgical procedure of neurolysis was then proposed in 39 cases to solve the problem. Thirty-two patients were operated on. Twenty of these had a neat improvement on a 6-month to 1-year follow-up. Seven patients had refused surgery; of these 6 patients had clinical worsening at the same follow-up period while 1 remained unchanged. All patients with clinical symptoms not reversed after some time post-injury should be investigated for a possible brachial plexus entrapment.

Keywords: Brachail plexus; entrapment; thoracic outlet; hyperflexion; hyperextension; whiplash injury.

Introduction

Posttraumatic thoracic outlet syndrome, i.e. brachial plexus entrapment in fibrotic scarring tissue, may be the physical basis for prolonged complaints of patients who suffered hyperextension-hyperflexion, non structural cervical injury due to vehicular, slow-speed, rear-end accidents. The mechanisms of traction and distortion of cervical bony, ligamentous, and nerve structures have changed since safety systems have improved.

Patients and methods

Patient population included those patients who had suffered mild car accidents mostly rear-end crash. Included in the analysis were only patients who reported no other injuries. Concomitant head injury, back injury or arm injury were factors for exclusion of the patient from this analytic study. Our data were taken from a careful patient examination as well as from emergency unit documentation. Patients who suffered neck pain and stiffness or had symptoms of brachial plexus entrapment prior to injury were excluded from the study as well as patients whose MRI or/and CT scans revealed disc herniations which could be responsible, even if partially, for the symptoms presented. Patients with postural factors and anatomic anomalies seen on radiological investigation were also excluded from the study.

All patients included in the analysis underwent an X-ray of the cervical spine and possibly MRI or CT scan, as well as electrodiagnostic testing by summary index for the upper extremities on both sides. The time gap between injury and the moment patients came to our attention was 10 months (2 to 27 months). There were 31 female and 23 male patients. Age range was between 19 and 57 years with an average of 36.5 years. There was no significant difference in age between the male and female group.

The brachial plexus entrapment was seen on the right side in 13 patients, on the left in 9 patients and in 2 patients the entrapment was seen bilaterally.

The superior trunk alone was affected in 5 patients, the inferior trunk in 3 patients while 8 patients all three trunks were involvedt. Other combinations of trunk involvement were superior and middle in 4 patients and superior and inferior in 4 cases. Middle trunk was never affected alone.

Results

Clinical symptoms

All patients complained of neck pain and stiffness. Seventeen complained also of headache alone or in association with shoulder and/or arm pain. Twenty-seven patients referred shoulder pain associated with neck pain and/or headache. Arm pain was present in 10 patients. Most of the patients whose neurophysiologic findings indicated primary superior trunk involvement had pain in the suprascapular nerve territory on the affected side. Tingling in arm and hand augmented during sleep was frequently reported. Dizziness was present in 8 patients while one had also blurred vision.

Neurological findings

All patients showed tenderness and various degrees of muscular stiffness in the supraclavicular region as well as reduced motion amplitude of the neck in all directions. The Adson and "signe du plateau" test was positive in all patients. In 39 patients there were signs of neurological disturbances while 15 patients were free from any neurological sign to be correlated with a brachial plexus entrapment. When present, neurological findings were almost always slight and depended largely on the brachial plexus trunk affected. If just the superior trunk was involved, the most common finding was hypoesthesia of the skin covering the deltoid muscle and in the interscapular region. There was a decrease of strength in the supraspinatus muscle. When also the middle trunk was involved, hypoesthesia of the skin on the outer side of the forearm and a slight decrease of strength in the triceps muscle and the extensor communis of the fingers was seen. When the inferior trunk was affected, the most common neurological finding was a slight decrease of force in the hypothenar muscle group and interossei muscles as well as mild hypesthesia of the ulnar side of the hand, the inner side of the forearm and, occasionally, of the arm. When more than one trunk was involved various degrees of combination of the aforementioned signs was observed.

Radiological findings

All patients had an X-ray of the cervical spine taken immediately after the injury. Forty-five patients presented a straightening of the cervical vertebral column. None of the patients had an inversion of the curve, while 9 patients had a normal X-ray exam. MRI and/or CT scanning was performed in 48 patients. In 39 patients the scanning was negative for disc disease and/or other traumatic or degenerative problems that could explain the symptomatology. In 9 patients a disc herniation was found which did not correspond to the level of radicular symptoms or could not explain completely the radicular symptoms. Six patients had no CT or MRI imaging exams as their neurological signs clearly indicated the presence of a brachial plexus entrapment.

Neurophysiological findings

Electrodiagnostic testing was performed by using the summary index test proposed by Robinson *et al.* evaluating the summary results of nerve conduction studies and not the single tests.

Electrophysiological tests were of the F wave type from median and ulnar nerves, SSEP (N9) from median and ulnar nerves, motor and sensory nerve conduction studies from median, ulnar and medial antebrachial cutaneus nerves and electromyography.

The summary indexing of these paramethers in all the patients were positive for TOS.

A control study (submitted for revision) was done with patients affected by true neurological TOS and with normal control group. The results showed no difference between the true and whiplash groups while the control group of patients showed normal parameters.

Treatment

Before coming to our attention, all patients had already received some conservative treatment addressed to the cervical spine. The majority of patients had been treated by cervical dressing for a period from 1 week to 1 month and various modalities of physical therapy, postural corrections as well as analgesic and muscular relaxation drugs. Many patients were submitted to laser and ultrasound treatment of cervical paravertebral musculature. Our local medical treatment consisted for all patients of vasoactive (Naftidrofurile) and local anaesthetics (Bupivacaine) injected directly in the laterocervical area, either in the loose connective tissue or in the scalene muscles. These treatment modalities led to significant, lasting improvement in 15 cases.

Consequently, surgery was proposed in 39 patients. Seven patients refused surgery, while 32 were operated on. A supraclavicular approach allowed neurolysis of the offended nerve trunks. Occasionally, scalenotomy or other soft tissue removal was performed when found to be interfering with the nerve trunks. The intraoperative finding was that of a moderate to dense scar tissue surrounding completely the offended nerve trunks at the point of their exit from the interscalenic space. The primary superior trunk was rarely involved, while the middle trunk was frequently concerned. The subclavian artery was frequently observed to be hardly adherent to the middle trunk, as the scar tissue had formed a sheet around both structures incorporating them. Sometimes the different anatomical components where hardly distinguishable before neurolysis. This situation engendered a neurovascular conflict. The inferior trunk was frequently in touch either with the

ventral margin of the subclavian artery, or with the ventral aspect of the middle trunk.

Follow-up

Of the 7 patients not operated on, 6 worsened at a six month to one year follow-up, while one patient remained unchanged. The worsening generally involved a decrease in muscular strength, increase of pain and tingling in the radicular territory as well as arousing of unspecific disturbances such as dizziness and face pain.

In the operated group, 24 patients at the six month to one year follow-up showed a neat improvement. A longer time interval from injury to surgery entailed a reduced quality of result. Time was needed for the nerve trunk to regain its normal function. The improvement primarily concerned the dysfunction signs of the neck and more proximal segments of the upper extremity while the distal parts improved later. In the two patients who had suffered dizziness preoperatively, the problem solved after surgery. The one patient that remained unchanged after surgery had a repeated electromyography three months later, but no improvement with regard to the preoperative examination was observed.

Pathophysiological mechanism

When a car is hit from behind, the body, supported by the seatback and seatbelt, accelerates while the head, not supported, remains still. Thus the head actually is pushed backwards and the neck becomes hyperextended [4]. The headrest limits excessive movements and so prevents structural damage to the column but it permits enough movement to induce the stretching of the neck muscles and brachial plexus trunks.

The suspected pathophysiological mechanism is based on the fact that at the moment of the traumatic event two different, yet interrelated, events take place:

1) sudden and forceful anterior contraction of neck muscles due to their sudden and intense stretching
2) lenghtening of brachial plexus trunks to adjust to neck movement

The sliding capacity of the nerve trunks inside the interscalenic space becomes limited due to muscular contraction and, consequently, two different types of nerve injury develop:

1) compression injury due to forceful muscular contraction (continued contraction)
2) traction injury due to limited mobility of nerve trunks at compression site.

Moreover, it is well known that an intense and sudden muscular contraction leaves the muscles in a state of a prolonged contracture with development of myofascial syndrome and trigger points [6, 11]. These present clinically with stiffness, pain and, on palpation, the presence of hard muscular strings. This post-traumatic, time-lasting contraction may eventually play a secondary role in a prolonged compression of the nerve trunks [3].

Discussion

Olsson has studied the anatomical details of the nerve structures which may be the base for fibrotisation processes. The epineurium is similar to other connective tissue rich parts in the body, and its extracellular fluid is free to diffuse. The walls of the endoneurium are entirely covered by a basal lamina which surrounds the outer plasma membrane surface of the Schwann cells, the endoneurial vessels and the perineurial cells apparently forming a stabilizing structure.

Endoneurial fluid circulation depends on two major forces, net hydrostatic pressure and net osmotic pressure. The lack of lymphatics in nerve fascicles might render the removal of endoneurial fluid difficult. Also clearing of intrafascicular oedema occurring in many neuropathies is a rather slow process.

The frequent occurrence of anastomosis between the intrinsic (intrafascicular) and the extrinsic (nutrient arteries and epineurial vessels) system combined with a vascular organization in the form of plexA are of great importance for the oxygen supply. Experiments by staining have revealed the existence of a blood-nerve barrier in the fascicles. This barrier is composed of two components, the endoneurial vessels and the perineurium and is not as efficient as the blood-brain barrier. Perineurium creates a fluid environment around the nerve fibres of optimal composition for transmission of electrical impulses. Peripheral ganglia are surrounded by a perineurium with the same structural and functional features. It has thus a role in the homeostasis of the intraganglionic compartment. Nerve damage due to an injury may be further aggravated by oedema increasing endoneurial pressure which might compromise blood flow in the fascicles. Fibrosis, either at the site of the primary injury or in the distal part undergoing Wallerian degeneration may

so be marked that axonal regeneration and nerve repair are interfered with. The events provoked by an injury possibly induce a chronic compression of nerve trunks which interferes with their adequate blood supply. This initially induces changes in the small vessels of the endo- and perineurium and, consequently, changes in permeability of perineurium with swelling and oedema formation [5]. Early and late oedema of the vasogenic type is associated with elevated endoneurial fluid pressure and microcirculatory disturbances. Proliferation of fibroblasts, changes in the composition of the matrix and collagen formation may result in endoneurial fibrosis at the site of the lesion and distal to it.

If fibrosis is not solved, thinning of the myelin sheath is observed [1, 9]. The hypothesis is also that ischemia primarily affects the orthograde and retrograde axonal transport, which is very susceptible to oxygen deprivation and whose inadequate function interferes with adequate nerve conduction [1]. The process becomes selfmaintaining and, if not interrupted, deteriorates even if the muscles relax [1, 7]. During surgery fibrotic scar tissue enveloping the nerve trunks was found, and the site of greatest scarring was lateral and posterior to the anterior scalene muscle. This is in conformity with the statement that the maximal swelling and oedema formation is situated at the edges of the compression site [9]. Depending on the myelin and/or axonal derangement, the clinical expression of entrapment may present as pain and paresthetic disturbance or it may, in more severe situations, consist in muscle wasting and fibrillation potentials in the wasted muscles [2, 8, 10]. This pathological sequence of entrapment is well known to surgeons involved in peripheral nerve surgery and was described in 1964 by Weisl and Osborne [12]. The process of entrapment is a progressive one, and if persisting for time after injury, it will reach a point were the changes become irreversible [1].

Not all individuals develop this problem. It may be related to the anatomical conformation and pretraumatic posture and working habits. The brachial plexus, probably, becomes injured just in those patients who have some anatomical variations and/or have daily working and posture attitudes with a faint equilibrium of the nerve trunks in the thoracic outlet and in whom the cervical injury comes to disrupt this homeostatic equilibrium.

We suppose that, if diagnosis is made in time, a conservative approach by postural training, revascularization, appropriate drug application and other physiotherapeutic and pharmacological measures addressed to brachial plexus treatment, could solve this problem in many cases.

The surgical treatment to be performed is a small supraclavicular incision. External neurolysis is needed in the great majority of cases. Large exposures are not indicated because of increased scar formation which might compromise the result of surgery. Anyway, the surgical performance (neurolysis, scalenotomy, Sibson's ligament resection etc.) is highly variable from patient to patient and must be suited as to perform just the minimally indispensable surgical act.

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Whiplash injury. TOS and double crush syndrome. Forensic medical aspects

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Summary

In this article the author wants to specify that the whiplash syndrome is underestimated, even by the specialists. In particular the complications aren't taken into correct consideration, above all if they concern the brachial plexus, especially regarding the TOS syndrome and double-crush syndrome. This is a problem also among the experts who have to make an evaluation in the field of insurance.

Keywords: Whiplash injury; TOS; double crush syndrome.

The denomination "Whiplash Injury" (WI) derives from the etiopathogenic description of the sudden sharp whipping movement of the head and neck, produced at the moment of a traffic accident, particularly following collisions from behind, head-on or side collisions.

WI is characterised by a collection of symptoms that occur following damage to the neck usually as a result of a sudden strain affecting the discs, muscles, nerves, or tendons of the neck caused by a sudden acceleration or deceleration of the head and neck. The head is violently thrown back, forwards or sideways followed by reflex contraction in the opposite direction. Swelling and inflammation occur due to damage caused by the rapid movement which leads to pressure being placed on the nerves often resulting in the classical symptoms of whiplash. Damage to the bones in the neck rarely occurs [9].

Symptoms following an accident may be present immediately or may develop gradually over hours, days, or weeks after the injury. Pain and stiffness is caused by pressure being placed on the nerves as a result of tissue swelling which causes muscle spasms. Symptoms of injury may include.

Range of lesions seen with whiplash

- Single-multiple cranial nerve palsies
- *Peripheral neuropathy*
- Dizziness and otoneurological disorders
- *Thoracic outlet syndrome (TOS)*
- Visual disturbances
- Post-traumatic sympathetic dystrophy (PTSD)
- *Double-Multiple crush syndrome*
- Discopathy
- Rim lesions
- Spinal cord injury
- Retropharyngeal hematoma
- Damage to subarachnoid space
- Mediastinitis
- TMJ injury
- Hypopharyngeal, tracheal, or esophageal perforation
- Brain injury
- Hypothalamic-pituitary-thyroid axis disorder
- Damage to sympathetic nerves
- Menstrual disorders

Most people respond to whiplash treatment and recover in a few months, however a substantial percentage will have painful symptoms for much longer especially the elderly or those with pre existing neck problems who may develop chronic long-term problems which may never resolve [10].

Persistent symptoms lead to chronic whiplash syndrome which is defined as presence of symptoms for longer than six months. Most of the controversies over WI are related to arguments about the validity of chronic cases [5].

The evaluation and treatment of chronic cases often are obscure by a shroud of litigation and issues of long term disability. As a result, some investigators have concluded that many people who experience chronic syndrome are "malingering" to obtain the monetary benefits of litigation.

It may be more useful to include chronic whiplash into a group of disorders referred to as functional somatic syndromes.

It may be an oversimplification to conclude that sufferers of chronic whiplash syndrome are consciously exaggerating their symptoms or malingering. Moreover, studies demonstrate that symptom persistence (or worsening) occurs even when litigation issues have been resolved.

The type and extent of injury varies greatly and diagnosis of whiplash is often one of exclusion.

The effectiveness of seatbelts in preventing neck injury has not yet been determined. Some authors suggest that seatbelts may increase the incidence of a whiplash injury: with the strap over one shoulder, the body rotates during impact [9].

Neck pain occurs in 62% to 100% of whiplash injuries [4] and is the hallmark symptom. The pain can radiate into the occipital, shoulder, or midscapular area. Moreover, anterior neck pain syndromes have been described. Headaches, typically in the suboccipital region, occur in up to 82% of cases.

Other common complaints include thoracolumbar back pain (35% to 42% of cases) and paresthesia of the upper extremities (45%). A variety of theories have been proposed to explain paresthesia, *including thoracic outlet syndrome*, myofascial injuries, stretch injuries of the brachial plexus, central cord injuries, *double-multiple crush syndrome*. Dysphagia (7% to 18% of cases), dizziness, vertigo, visual and auditory disturbances, and cognitive impairment have also been reported to occur after whiplash. The pathophysiologic explanation for these symptoms has thus far eluded investigators.

No characteristic signs are associated with whiplash injuries. About 12% to 20% of patients present overt neurologic signs. Sensory impairment following a particular nerve root distribution of the upper extremities, reduced motor strength of the upper extremities, and diminished reflexes have been described.

Many patients have sensations of tingling and numbness in the hands, particularly of the ulnar two fingers. These symptoms can be attributed to nerve root stretch or compression. More commonly they are intermittent and aren't associated with overt neurologic signs [1]. The paresthesiae may be due to thoracic outlet syndrome arising from stretch or compression of the lower cords of the brachial plexus as they pass between the scalenus anterior muscle and the scalenus medius muscle, and under the clavicle. That injury can cause a fibrosis of the plexus because of the changement of microenvironment of the nerves. Trauma to various parts of the peripheral nervous system is associated with the formation of vasogenic oedema (in the epi-peri- and the endoneurium). Oedema may influence microcirculation in nerves and disturb the normal nutrition of the nerve parenchyma. It may be a stimulating factor for production of connective tissue which eventually might lead to endoneurial scar tissue [11]. Direct physical injury to a peripheral nerve readily increases the perineural permeability in some situations. The increased perineural permeability has an early onset and duration of several weeks. A focal axonal lesion which will result in wallerian degeneration upsets the normal bidirectional axonal transport mechanisms and the distal stump will suffer and initiate a series of biochemical events leading to axonal destruction [6]. A severe trauma is enough to cause an irreversible damage to the axons, wallerian degeneration will take place *distal* to the injury. Proliferation of fibroblasts changes in the composition of the matrix and collagen formation may result in endoneurial fibrosis at the site of the lesion *and distal to it*. This procedure has a duration of several weeks [3]. This can explain a late beginning of symptoms in a distal region (from the neck) and justify the rejection of the plaintiff's request by most medical examiners in their legal medical reports. The double-multiple crush syndrome (D-MCS) can explain some of these questions [8].

This syndrome occurs when a single nerve is compressed (crushed) at two separate levels, proximal and distal; the nerve being irritated at some proximal location like the thoracic outlet (in the shoulder) or in the neck is suffering a peripheral nerve entrapment like carpal tunnel or ulnar entrapment at the elbow:

- Median Cervical radiculopathy and CTS*
- Thoracic outlet and CTS
- Pronator syndrome and CTS
- Ulnar Cervical radiculopathy and cubital tunnel syndrome
- Thoracic outlet and cubital tunnel syndrome
- Cubital tunnel and Guyon's canal syndrome

– Radial Cervical radiculopathy and radial tunnel syndrome

**CTS* Carpal tunnel syndrome.

After a WI, patients may suffer from a double crush syndrome [2]. The symptoms are similar to carpal tunnel pathology and/or thoracic outlet syndrome pathology. Cervical disc disease predisposes patients to carpal tunnel syndrome as well as a cubital tunnel syndrome. Compression in the thoracic outlet or at the level of the cervical disc predisposes the median nerve to compression at the level of the pronator teres and the carpal tunnel. Similarly, thoracic outlet with compression of the lower trunk predisposes a patient to compression of the ulnar nerve at the cubital tunnel and in Guyon's canal [7, 13].

Double crush can be seen post traumatically after a whiplash injury. For instance, a hand specialist may overlook a double crush syndrome originating in the neck. Treatment by surgical release of the carpal tunnel syndrome alone is frequently unsuccessful in the long term because of the unrecognized presence of more proximal compression neuropathy [12].

Also the thoracic outlet syndrome is most often produced by hyperextension neck injuries, especially after side impacts in the case of car accidents. When the neck is hyper-extended in the whiplash injuries, the scalene muscles, which hold the neck in place, are torn, causing blood and other fluids to leak into the brachial plexus injury. This causes scar tissue in the brachial plexus.

TOS involves proximal neurovascular structures, symptoms are often confused whith various distal compression neuropathies or cervical radiculopathies. Also the imaging studies (RX-MRI-CT) usually fail to demostrate focal pathology. Electrodiagnostic studies aren't always enough to prove the damage, especially if the physicians aren't very experienced.

For all these reasons: the outbreak of the symptoms could be delayed, symptoms are vague, symptoms are far from the neck, tests usually don't demonstrate the lesions, the insurance companies deny the link between the symptoms and the accident.

Diagnosis and treatment of whiplash will remain a medical enigma [14] as long as the assessment of the damage is made superficially.

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Vascular thoracic outlet syndrome staging and treatment

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Summary

Thoracic Outlet Syndrome (TOS) is a well known lesion. Sophisticated imaging techniques can clearly highlight any anatomical damage and a wide range of therapeutic choices are available.

It would seem obvious that any given patient should obtain the same treatment irrespective of the medical institution he contacts, but this is not the case. Instead each specialist may recommend different treatments: physiatrist, neurologist, surgeons (thoracic, vascular, neuro, orthopedic). Everyone preserves his specific language and there is no univocal treatment plan consensus for this complex syndrome. Evidently, the correct staging of TOS is still an unresolved question.

In order to solve this problem, we collected all clinical and instrumental aspects of the syndrome into a clear, precise classification. Similar to TNM staging of malignant diseases, we used a grouping model based on the three mainly involved anatomical structures: N (= Nerves; brachial plexus and sympathetic fibers), A (= Artery; subclavian-axillary), V (= Vein; subclavian-axillary). We named it the NAV staging of TOS.

A retrospective examination of our case records confirmed a valid and useful correlation between the proposed NAV staging and the therapeutic procedures that were actually applied. It is now essential to perform a multi-centre study to extend the validity of our staging.

Keywords: Thoracic outlet syndrome; first rib.

Introduction

Today most has been analyzed and written about TOS and no unresolved questions seem to exist regarding its etiology, pathology or therapy. Nevertheless, TOS remains a complex syndrome and different specialists are supposed to work together to achieve the best treatment.

Therefore an emerging problem is to find a universal language, comprehensible to every physician. We classified all TOS cases treated by us in the past by grouping clinical and instrumental data according to their anatomical pertinence, so that any given case was depicted by the status of three parameters: N, A, V (as listed below). For any parameter, four grades of involvement were defined.

Staging system

Nerves (brachial plexus, sympathetic fibres)

⇒ N_0. No symptoms or signs of injury.

⇒ N_1. Only mild sensitive symptoms: non-invalidating paresthesia or pain; no electrical abnormalities (negative EMG, nerve conduction velocity and *SEP's recordings*).

⇒ N_2. Severe sensitive symptoms: invalidating pain or sympathetic irritation; mild electrical abnormalities (sensitive conduction velocity loss).

⇒ N_3. Motor symptoms: weakness even with muscular atrophy; serious electrical abnormalities (sensitive and motor conduction velocity loss).

Subclavian-axillary artery

⇒ A_0. No symptoms or signs of injury.

⇒ A_1. Intermittent compression: irregular appearance of arm "claudicatio" symptoms; no anatomical local lesions.
- Documented by ultrasound imaging (Doppler and plethysmography).

⇒ A_2. Minimal anatomical local lesions: minimal stenosis with mild post-stenotic dilatation (less than twice the size of normal arterial diameter).
- Ultrasound can only suspect the anatomical damage.
- Confirmation requires spiral CT or MRI

arteriography (traditional arteriography is reserved to particular questions).

⇒ A_3. Severe anatomical local lesions: intimal damage with aneurysmal evolution (post-stenotic dilatation more than twice the size of normal arterial diameter) ± mural thrombosis; possible distal vascular damage (brachial or cerebral embolization).
- A detailed investigation is possible with traditional arteriography only.

Subclavian-axillary vein

⇒ V_0. No symptoms or signs of injury.

⇒ V_1. Chronic intermittent compression: irregular appearance of arm swelling without any sign of acute or chronic thrombosis.
- Documented by ultrasound imaging.

⇒ V_2. More advanced disease not amenable to surgical revascularization: chronic thrombosis (diagnosed more than 2 weeks after onset) with long segment of vein obstructed (more than 20 mm).
- Confirmed by venography.

⇒ V_3. More advanced disease with predictable surgical revascularization: chronic thrombosis with short segment of vein obstructed (less than 10 mm); acute (diagnosed within 5 days) or sub-acute (between 6 days and 2 weeks) thrombosis.
- Confirmed by venography.

Taking into account the degree of involvement of each of the above parameters, the patient's clinical state is classified into one of the following four stages. As stage increases, therapy becomes gradually more complex: first conservative, than mild surgery and, finally, heavy surgery.

Stage I: N_{0-1} A_{0-1} V_{0-1}. Intermittent neurovascular compression.

- Only conservative treatment is indicated: physiokinesitherapy (FKT).

Stage II: N_2 A_{0-1} V_{0-1}. Early neurological involvement (invalidating sensitive symptoms) without irreversible anatomic damage.

- FKT.
- When ineffective, 10–30%, mild surgery becomes necessary: simple thoracic outlet decompression (scalenectomy, first rib resection, subclavian artery adventitiectomy, complementary maneuvers when particular osteo-muscular anomalies are present).

Stage III: N_3 or A_2 or V_2. Advanced neurological involvement and/or vascular damage that require "mild" surgery.

- FKT is not indicated.
- For N_3: decompression and possible neurolysis.
- For A_2 or V_2: decompression ± sympathectomy (when coexisting sympathectomy N_2) ± neurolysis (when coexisting N_3).

Stage IV: *every N* with A_3 or V_3. Advanced neurological involvement and/or vascular damage that require "heavy" surgery.

- FKT is not indicated.
- For A_3: decompression + arterial reconstruction (resection-reanastomosis or by-pass) ± sympathectomy (when coexisting sympathetic N_2) ± neurolysis (when coexisting N_3) ± brachial embolectomy (when coexisting distal brachial embolism) ± thrombolysis (when coexisting retrograde cerebral embolism).
- For V_3: pre-operative pharmacological thrombolysis; subsequent decompression ± venous angioplasty (if residual obstruction is left) ± neurolysis (when coexisting N_3).
- The role of percutaneous transluminal angio or venoplasty is still debated in the literature and, therefore, these procedures are not included in our protocol.

Methods and materials

178 patients with TOS where entrusted to our Centre (Thoracic, Neuro and Vascular Surgery Units of Umberto I° General Hospital, Mestre-Venice, Italy), from 1984 to 2003 and they where grouped as follows, according to stages:

Stage I: 67 cases (38%).
Stage II: 77 cases (43%).
Stage III: 24 cases (13%).
Stage IV: 10 cases (6%).

Results

Stage I: FKT for every case with good results in 60% of patients; the remaining 40% didn't consult our department for follow-up.

Stage II: FKT for every case with good results in 42%; 36% needed minimal surgery (with subsequent good results); the remaining 22% didn't consult our department for follow-up.

Stage III: Minimal surgery for every case with good results in 79%, fair in 13%, poor in 8%.

Stage IV: Heavy surgery for every case with good results.

Conclusion

A precise, synthetic and reproducible staging of TOS, based on the three parameter (TNM-like) grouping model, is still not present in the literature. Classifications can be found regarding some particular aspects of the syndrome [2, 3, 5] but a systematic one was only tested by Pang and Ass. [4], with quite a useless outcome.

Our NAV staging system is a new proposal and a retrospective study (based on our past cases) has revealed a good correlation between stages and applied therapy.

Using our parameters everyone can easily depict the actual status of a patient and thus a universal language is at last determined.

It is now important to apply the NAV staging to a sufficient amount of new TOS cases. Since TOS is quite a rare syndrome, a multi-centre study is needed with the aim to obtain a sufficient amount of cases.

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Suprascapular nerve entrapment

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Summary

It is important to be aware of neuropathy involving the suprascapular nerve. While direct trauma to the suprascapular nerve is the usual cause (direct blow to the base of the neck or posterior shoulder, shoulder dislocation or fracture), the problem may result from overuse injuries (such as repetitive tennis serving or spiking of a volley ball), excessive horizontal adduction, weight lifting, backpacking or no apparent reason.

These last three years we have operated 8 cases of suprascapular nerve neurolysis at the level of suprascapular incision, and section of the transverse scapular ligament through the back supraspinal approach.

Keywords: Suprascapular nerve; neuropathy; neurolysis; suprascapular notch.

Anatomy

The suprascapular nerve (SS) is a motor nerve originating from C5 and C6 nerve roots. It is the only lateral branch of the lateral upper trunk of the brachial plexus. It passes through the suprascapular notch which is covered by the transverse scapular ligament into the supraspinous fossa where it supplies the supraspinatus muscle.

The nerve continues around the lateral border of the spine of the scapula to supply also the infraspinatus. Depending upon where the compression occurs (suprascapular notch or spinoglenoid notch) either both or individual muscles may be involved.

It is noteworthy (see below) that after it leaves the suprascapular notch, it also passes the subacromial bursa and gives off sensory fibers to the capsular and ligamentous structures of the shoulder and acromioclavicular joint [6].

This area is moving continuously due to the scapular outing at every change of arm position. Therefore the SS nerve is subject to friction and thence to inflammatory reaction with oedema and nerve compression just on the most critical point of its way (suprascapular notch) [2].

Clinic

The patient may present with only vague posterior or posterolateral shoulder pain or diffuse pain with weakness.

Inspection of the shoulder may show atrophy of either or both the infraspinatus and supraspinatus muscle. Atrophy of the infraspinatus is easier to detect because the supraspinatus is covered by the trapezius muscle.

Diagnosis can usually be confirmed by EMG and nerve conduction studies or by magnetic resonance imaging (MRI) [7].

The conservative treatment of the suprascapular injury is directed at rehabilitation (strengthening and flexibility) of the supraspinatus, infraspinatus, and scapular rotators. At times, surgical decompression may be necessary.

Physiopathology

There are numerous clinical and experimental studies [3, 5] showing the way the initial oedema gives rise to the following succession of events: slackening of blood circulation, increase of extra/intra fasciculate pressure following further progression of the oedema and the supervening ischemia, the activation of fibroblasts epi/peri neural fibrosis and consequently a further increase of the oedema that augments the phenomenon just described.

Olsson [6] studied the anatomical details of nerve structure which may be the base for fibrotisation pro-

cesses. Epineurium is similar to other connective tissue rich parts in the body, and its extracellular fluid is free to diffuse [9]. The walls of the endoneurium are entirely covered by a basal lamina which surrounds the outer plasma membrane surface of the Schwann cells, the endoneurial vessels and the perineurial cells apparently forming a stabilizing structure.

Endoneurial fluid circulation depends on two major forces, net hydrostatic pressure and net osmotic pressure. The lack of lymphatics in nerve fascicles might render the removal of endoneurial fluid difficult. Perineurium creates a fluid environment around the nerve fibres of optimal composition for transmission of electrical impulses [1].

Early and late oedema of the vasogenic type is associated with elevated endoneurial fluid pressure and microcirculatory disturbances. Proliferation of fibroblasts, changes in the composition of the matrix and collagen formation may result in endoneurial fibrosis at the site of the lesion and distal to it.

Nerve damage due to an injury may be further aggravated by oedema increasing endoneurial pressure which might compromise blood flow in the fascicles.

All segmentary compressions in nerves are accompanied by a component of ischemia.

In front of a progressive or repetitive deforming force, the nerve becomes mechanically ''ribbon like'' [8].

The increase of the intraneural pressure causes a venous slow down with oedema of the affected segment, adding a greater deforming pressure [4]. So the area affected by oedema is invaded by fibroblasts that will produce a greater epineural and perineural fibrosis.

Case summary

These last three years we have operated 8 cases of SS neurolysis at the level of suprascapular incision and section of the transverse scapular ligament through the back supraspinal approach (4 patients were treated positively by conservative methods).

All patients were involved in professional and sport activities [10] which caused strong pressures on the shoulder articulation: 2 road workers, 3 volleyball players, 2 rugby players, 1 climber.

From the clinical point of view there was a pain insisting in all cases in the shoulder region which was greatly augmented by some particular movements and the atrophy of the super/under spinal muscles combined with a partial deficiency of the abduction/rotation of the shoulder.

EMG (before and after – about 4/6 months later – the surgical treatment) and RMI (before) studies have been applied to all patients.

Results

In 6 patients clinical symptoms were recovered (both pain and motion: M3 $\rightarrow$ M4); one patient reached partial recovery only (M2 $\rightarrow$ M3) while only one patient had no improvement at all (M2 = M2).

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Multicenter study on carpal tunnel syndrome and pregnancy incidence and natural course

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Summary

Objective. To evaluate the incidence of carpal tunnel syndrome (CTS) in pregnancy through a validated and multiperspective assessment of CTS and to assess the course of carpal tunnel syndrome after pregnancy.

Methods. During 2000–2001, the Italian CTS study group in 7 Italian centers studied the occurrence of CTS in women during the last period of pregnancy. The group enrolled and followed-up (10–15 months) 63 women during and after pregnancy with multiple measurements of CTS. In addition to the physician-centered and neurophysiologic traditional evaluations, a validated patient-oriented measurement to obtain more comprehensive and consistent data for severity of symptoms and functional impairment was adopted.

Results. CTS was clinically diagnosed in more than half of women (62%). Neurophysiological evaluation provided diagnosis of CTS in around half of women (43% were positive in one hand at least). Comparison of baseline and follow-up data showed a significant spontaneous improvement of patient-oriented and neurophysiologic measurements. Nevertheless, about half of women with CTS during pregnancy still complained of CTS symptoms one year after delivery.

Conclusions. Our observations confirmed the frequent occurrence of CTS in pregnancy. At follow-up we observed that most CTS cases improve spontaneously without treatment but only in half of women CTS symptoms disappeared one year after delivery.

Keywords: Carpal tunnel syndrome; natural history; pregnancy; delivery; multicenter; outcome; neurophysiology.

Introduction

One of the most frequent physiological conditions associated with carpal tunnel syndrome (CTS) is pregnancy [2, 5, 8]. CTS frequently causes disability [10] and hand disability in a woman during puerperium may be particularly severe. Therefore evolution of CTS after delivery is an important issue.

During 2000 and 2001 [11, 12], the Italian CTS study group studied

1) the incidence of CTS during pregnancy in women enrolled in 7 Italian centers
2) the evolution of CTS after delivery and lactation
3) the predictive factors for occurrence of CTS during pregnancy and evolution of CTS after delivery

In addition to the physician-centered and neurophysiologic traditional evaluations the group used a validated patient-oriented measurement to obtain more comprehensive and consistent data for the clinical picture.

Study design

Data collection at the initial evaluation

Each center had to provide at least 10 consecutive women, who were in their 8th and 9th months, monitored in the Department of Obstetrics and Gyneacology.

Study design was extensively reported previously [11, 12].

Clinical diagnosis of CTS

Clinical diagnosis of CTS was based on the AAN (AAN, 1993a) clinical diagnostic criteria summarized here: paresthesia, pain, swelling, weakness or clumsiness of the hand provoked or worsened by sleep, sus-

* Investigators and centers of the Italian CTS Study Group are listed in the Appendix.

tained hand or arm position, repetitive action of the hand or wrist that is mitigated by changing posture or by shaking of the hand; sensory deficits in the median innervated region of the hand and motor deficit or hypotrophy of the median innervated thenar muscles.

A detailed clinical history, a careful clinical examination and extended neurophysiologic evaluation (described later) were always performed to exclude the presence of other diseases that could be related to CTS.

For clinical examination, a historic and objective scale (Hi-Ob) of CTS was used [8]. This scale includes the following two measures. The first measure is a score (Hi-Ob) determined by clinical history and objective findings: 1) nocturnal paresthesia only, 2) nocturnal and diurnal paresthesia, 3) sensory deficit, 4) hypotrophy or motor deficit of the median innervated thenar muscles, and 5) plegia of the median thenar eminence muscles. The second measure of the scale evaluates, by patient-oriented measurement, the presence or absence of pain (PAIN) as dichotomous categoric score obtained from the patient with a forced-choice answer (yes or no).

Patient-oriented data: Boston Carpal Tunnel Questionnaire (BCTQ)

A patient-oriented validated measurement was used: the Italian version of the BCTQ [10, 15]. The BCTQ evaluates two domains of CTS, namely ''symptoms'' (SYMPT), assessed with an 11-item scale and ''functional status'' (FUNCT) assessed with an eight-item scale (each item has five possible responses). Each score (SYMPT and FUNCT) is calculated as the mean of the responses of the individual items.

Electrodiagnostic evaluation

Electrodiagnostic studies were performed according to a protocol [17, 18] inspired by AAN and AAEM recommendations [1–4]. When standard tests (median sensory nerve conduction velocity in two digit/wrist segments and median distal motor latency from the wrist to thenar eminence) yielded normal results, segmental (over short distance of 7 to 8 cm) or comparative studies (e.g. median/ulnar comparison) were always performed. The severity of neurophysiologic CTS impairment was assessed by a previously reported neurophysiologic classification [18, 19]. CTS hands are divided into six groups on the basis of neurophysiologic findings: extreme, absence of motor and sensory responses (EXT); severe, absence of sensory response and abnormal distal motor latency (SEV); moderate, abnormal digit/wrist sensory nerve conduction velocity and abnormal distal motor latency (MOD); mild, abnormal digit/wrist sensory nerve conduction velocity and normal distal motor latency (MILD); minimal, abnormal segmental and comparative tests only (MIN); and negative, normal findings on all tests (NEG).

Follow-up

Each centre had to re-evaluate at least 75% of the initially enrolled CTS hands, with a latency between 12 and 15 months from the first evaluation (therefore around one year after delivery).

The evaluation of the evolution was based on the following CTS severity measurements: SYMPT, FUNCT, PAIN, Hi-Ob and neurophysiologic class. In other words, the evolution was assessed by the perspective of the patient (FUNCT, SYMPT and PAIN), and the physician/neurophysiology assessment (Hi-Ob and neurophysiologic class). When the woman was not able to come to the neurophysiologic laboratory she was given a phone interview in which the following data were acquired: 1) historical follow-up data; 2) SYMPT and FUNCT scores (by BCTQ patient-oriented evaluation performed on the phone).

Predictive factors

To judge whether some factors, evaluated at the baseline, may predict the CTS course, CTS severity measurements (SYMPT, FUNCT, Hi-Ob and Neurophysiologic class, as dependent variables) were related to the following data: increment of weight, CTS symptoms before the current pregnancy, smoking and alcohol use, edema, beginning of symptoms. For statistical analysis (multiple regression), these last measurements were considered as independent variables.

To evaluate the percentage of CTS hands with a tangible ''improvement'', ''worsening'' or those remaining ''stationary'', we arbitrary considered: 1) meaningful neurophysiologic worsening or improvement in the CTS hands in which at follow-up (T1) the class moves from the baseline (T0) class to another class (for example: a case is neurophysiologically considered worse when presenting mild class at T0 and mod class at T1); 2) meaningful worsening or improvement on patient-oriented measurements

(SYMPT or FUNCT) of the CTS hands in which at T1 the score was increased or decreased by 0.5 or more; and 3) meaningful clinical worsening or improvement of the CTS hands, in which at T1 evaluation the clinical score (Hi-Ob) moves from the baseline class to another class. This kind of analysis was adopted in a previous CTS follow-up study [12].

In case of bilateral CTS we considered the hand with more severe symptoms at initial evaluation.

Statistical analysis

Statistical analysis was performed by using the STAT-SOFT (Statistica 4.5, Tulsa, OK) package. Complex statistical analysis was performed and was extensively reported [12, 13].

Results

Seventy-six women in their 8th and 9th months were studied (mean age 31.3, ranging from 20 to 41 years).

Occurrence of CTS: neurophysiological and clinical findings

In our study 59% of cases complained of paresthesia at least in one hand (85% of these had positive electrodiagnostic findings for CTS at least in one hand). Clinical CTS was diagnosed in more than half of women (62%). Neurophysiological evaluation provided diagnosis of CTS in around half of women (43% were positive in at least one hand).

Edema was related with neurophysiological picture of CTS (right hand $p < 0.01$, $r = 0.3$; left hand < 0.05, $r = 0.3$) and with right BCTQ symptom score ($p = 0.02$, $r = 0.3$); no other significant correlations with CTS measurements were detected.

Follow-up

Table 1 reports the follow-up data and statistical results in the re-evaluated pregnant sample with clinical CTS at first evaluation (37 women).

Table 2 reports the percentage of pregnant women with clinical CTS at initial evaluation with meaningful (as stated above) ''improvement'', ''worsening'' or ''stationary'' evolution at T1.

Table 3 summarizes the statistical results of multiple regression: the relationships between CTS severity measurements and the factors analysed are reported.

Table 1. *Mean values of CTS severity measurements at baseline and follow-up in 37 women with clinical CTS during the last period of pregnancy and statistic analysis results (matched comparison)*

	Baseline (T0)	Follow-up (T1)	Statistical analysis (test and p value)
SYMPT, mean (SD)	2.1 (1.0)	1.6 (0.8)	Wilcoxon matched pairs: $p = 0.011$
FUNCT, mean (SD)	1.6 (0.7)	1.3 (0.5)	Wilcoxon matched pairs: $p = 0.037$
Hi-Ob, mean (SD)	1.5 (1.1)	1.0 (1.2)	sign: $p = 0.015$
PAIN	48%	26%	Mc Nemar: $p = 0.025$
*Neurophysiol. Class**			
Negative	40.0%	41.7%	
Minimal	22.9%	20.8%	
Mild	14.2%	20.8%	sign test: $p = 0.18$
Moderate	22.9%	16.7%	
Severe	0%	0%	
Extreme	0%	0%	

SYMPT Symptoms, patient-oriented assessed; *FUNCT* hand functional status, patient-oriented assessed; *Hi-Ob* historic and objective scale.

* Note that only 24 patients were neurophysiologically evaluated.

Table 2. *Pregnant clinical CTS sample: percentage of women improved, worsened or stationary at follow-up*

CTS severity measurement	Evolution	Percentage
NF class*	improvement	32%
	stationary	59%
	worsening	9%
SYMPT	improvement	38%
	stationary	46%
	worsening	16%
FUNCT	improvement	32%
	stationary	60%
	worsening	8%
Hi-Ob	improvement	37%
	stationary	55%
	worsening	8%
PAIN	improvement	24%
	stationary	71%
	worsening	5%

* Note that only 24 patients were neurophysiologically evaluated.

The following analysis was performed only in 37 re-evaluated women who had clinical CTS at initial evaluation (in 95% the more symptomatic hand was the dominant hand).

Totally, at follow up, 20 out of the 37 women (54%) who presented clinical CTS at initial evaluation, presented clinical CTS. No woman out of the 37 with clinical CTS at first evaluation was operated on.

All patient-oriented measurements showed significant improvement of the CTS picture (Table 1). Con-

Table 3. *Evolution of CTS in pregnant women: relationships between severity measurements of CTS and analyzed factor (statistical results of multiple regression)*

CTS severity measurements improvement at T1 (dependent variable)	Predictive factors (independent variable)	B	P
Neurophysiologic class	neurophysiologic class (T0)	0.48	0.003
	increment of weight	−0.12	0.002
SYMPT	SYMPT (T0)	0.96	0.0000001
	beginning of symptoms #	0.16	0.01
FUNCT	FUNCT (T0)	0.85	0.0000001
	beginning of symptoms #	0.13	0.0006
	smoke	−0.26	0.003
	previous CTS symptoms	0.37	0.02
Hi-Ob	Hi-Ob (T0)	0.61	0.003
	beginning of symptoms #	0.18	0.04

Beginning of symptoms during pregnancy (month).

versely, the comparison of neurophysiologic picture between the baseline and the follow-up did not show differences, but note that only 24 of the 37 patients had initial and follow-up neurophysiologic evaluation. Note that according to all measurements, around one third of patients (from 24% to 38%) with CTS ''improved''; around half of patients remained ''stationary'' (from 46% to 71%) (see Table 2).

Discussion

Some papers focus on the incidence of CTS during pregnancy. Nevertheless the data reported are discordant. (Melvin *et al.*, 1969, Stolp-Smith *et al.*, 1998; 7, 9, 22).

In our study around half of the women in their 8th and 9th months presented clinical and neurophysiological CTS.

Some authors previously reported the correlation between edema in pregnancy and CTS symptoms [7, 22, 23]. Our study confirmed this association and provides evidence never reported before of the correlation between edema and neurophysiologic picture. Similarly, our study provides a correlation between validated patient-oriented measurement and edema. In conclusion our observations confirm that the edema of the tissues in the carpal tunnel, as a result of the tendency for fluid retention, could induce a mechanical compression of the nerve and then it could be an important factor of CTS during pregnancy.

With regard to the evolution after pregnancy, it is common opinion that most CTS resolve after delivery. Only one study systematically evaluated the evolution of untreated CTS through neurophysiologic evaluation, but a test with low sensitivity was used (the study was performed in 1978 and only motor conduction evaluation was performed) [9]. No study assessed the clinical evolution of CTS after delivery through a multiperspective protocol including validated patient-oriented evaluation.

As expected, our data showed that in the sample with CTS at initial evaluation, clinical (Hi-Ob) and patient-oriented (PAIN, SYMTP and FUNCT) measurements significantly improve 1 year after delivery. Conversely, the neurophysiologic picture does not improve, but most patients who improved refused the neurophysiologic evaluation at follow-up; therefore neurophysiologic evaluation at follow-up was performed in a smaller sample and usually in women with CTS symptoms [34]. Although CTS severity measurements improved at follow-up, more than half of the women who had CTS symptoms during pregnancy complained of CTS symptoms one year after delivery [5].

In our study, multiple regression (table 3) analysis showed a strong dependence of each severity measurement at T1 with its T0 value. Severe baseline pictures were associated with a higher probability of improvement at follow-up. Moreover, the factor that is most predictive of untreated CTS evolution is the onset of CTS symptoms during pregnancy. An earlier onset of symptoms is a negative prognostic factor according to all patient-oriented and clinical measurements. According to the neurophysiologic evolution, weight gain appeared predictive: a higher gain implies a lower probability of improvement at follow-up.

Appendix

The members of the Italian CTS Study Group include the following investigators and centers:

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Endoscopic carpal tunnel release surgery: retrospective study of 390 consecutive cases

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Summary

Endoscopic carpal tunnel release (ECTR) surgery was developed by Okutsu and Chow in 1989. Many reports indicated that the endoscopic technique reduces postoperative morbidity with minimal incision, minimal pain and scarring, a shortened recovery period and high level of patient satisfaction. To evaluate these reports, a retrospective study was conducted with 390 procedures of two-portal Chow technique for idiopathic carpal tunnel syndrome. Follow-up was performed at 1, 3 and 6 months and overall results were backed up by telephone questionnaire (Health Outcomes Carpal Tunnel Questionnaire, Health Outcomes, Bloomington, MN, USA). Results were favourable in 98% and 2% unfavorable for persistent pain. Rate of satisfaction of the patients was 90%. Average time of patient's return to work was 20 days. Eleven procedures (2.8%) were converted to open release. There was one case (0.2%) of incompleted section of the perineurium due to failure of endoscopic visualization of the ligament. In this case the procedure was converted to open and was completed with perineurium sutura. In six cases (1.5%) there were injury to superficial palmar arch. During the follow-up period there were no recurrences and no re-exploration. The mean preoperatively obtainable distal motor latency (DML) and sensory conduction velocity (SCV) values were 6.7 m/s and 29.2 m/s, respectively. The mean DML and SVC values at final follow-up were 3.8 msec and 42.3 m/s, respectively. In conclusion, ECTR can be used in the carpal tunnel syndrome and is a reliable alternative to the open procedure with excellent self-report of patient satisfaction. Reduced recovery period with minimal tissue violation and incisional pain can be expected.

Keywords: Carpal tunnel syndrome; endoscopic release; electromyographic evaluation.

Introduction

Endoscopic carpal tunnel release (ECTR) was introduced by Okutsu in 1987 [21]. He developed a single-portal technique with a system called "The Universal Subcutaneous Endoscopic System". In 1989, James Chow first reported the use of two incisions (Dual-Portal Technique) to dissect the transverse carpal ligament (TCL) endoscopically [12]. This technique had significant success in the following years and many reports described modifications in instrumentation and surgical procedures. Several controversies arose between the proponents of open and endoscopic surgery. Certain disadvantages have been associated with open transaction, including sensitive and scar tenderness, muscular injuries, hand weakness, anterior displacement of the median nerve and prolonged recovery time [4, 16, 18, 19, 22, 27]. In recent years, a tendency has developed to use minimal open surgery to reduce postoperative complications [1, 3, 7, 9, 12, 18, 25]. The proponents of the endoscopic release indicate patient satisfaction as one of the most important parameters in the evaluation of the surgical results. Other benefits include: minimal incision, less incisional postoperative pain, better healing, shortened recovery period and accelerated return to work [4, 6, 9, 11, 13, 15, 16, 18, 23]. However, controversy still exists between supporters of the open vs the endoscopic technique.

This paper reports the overall results and complications of a retrospective study on ECTR with two-portal technique in patients at the Neurosurgical Unit of the General Hospital of Cosenza (Italy).

Materials and methods

This study involved a total of 390 surgical procedures in 356 patients (34 bilateral) performed between July 1999 and December 2002 at our institution. There were 283 females and 73 males. Age range was 20–86 with an average age of 49.8 years. ECTR surgery was performed in patients on the basis of classical clinical symptoms in association with neurophysiological (EMG/NG) findings of carpal tunnel syndrome (CTS). The neurophysiological protocol utilized standard test and segmentary test and/or comparative test if standard test was negative (Fig. 1) [10, 17, 24]. Neurophysiological signs were classified into the following categories:

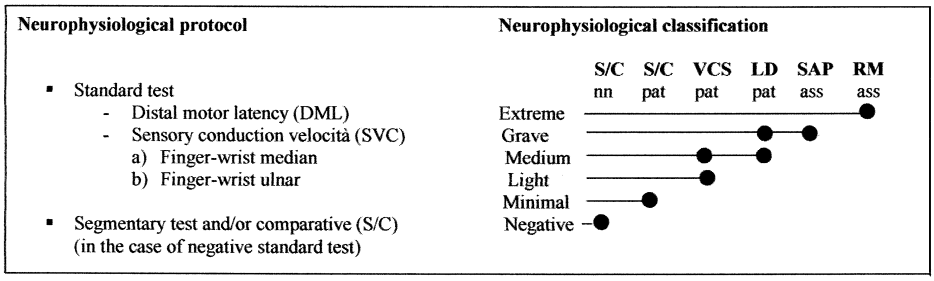

Fig. 1. Neurophysiological protocol

A) distal motor latency (DML) =/> 4.3;
B) sensory conduction velocity (SVC) =/< 28.1;
C) SAP absence;
D) MAP absence.

The procedure was performed in day-surgery under local anaesthesia using approximately 6–7 cc of bupivacaine hydrochloride 0.5% in association with lydocaine injected along the surgical field. The follow-up was conducted after 1–3 and 6 months whereas the overall results were evaluated after one year with a telephonic interview (modified Health Care Outcomes Institute Carpal Tunnel Questionnaire, Health Outcome Institute, Bloomington, MN, USA) [16]. This questionnaire measures a wide spectrum of variables symptoms pre and post-surgery, co-morbidities, ability to complete activities of daily living and ability to maintain the previous work. In fifty patients a neurophysiological study 6 months after treatment was conducted.

Surgical procedure

The biportal technique was used as described by James Chow in 1989 [12]. The entrance and exit wounds were <1.5 cm (Fig. 2). After introduction of a fenestrated cannula deep into the transverse carpal tunnel, a 4.0 mm 30 degree angle endoscope was introduced. The TCL was transected with a retrograde hook knife under direct visualization. The skin incisions were closed using either #4.0 nylon suture and the wrist was draped in an ice bendage which was removed after eight days. Immediate finger movements were encouraged to perform a range of gentle and active motion exercises.

Results

The average time of surgery was 15 min. and patients were discharged after two hours. Overall results analysis was performed based on the modified questionnaire with 15.8 months average follow-up (range 6–36 months). Sixty-five percent (n = 230) answered the questionnaire and 50 patients (14.5%) were studied with neurophysiological examination with a follow-up of 6 months. Clinical results were subdivided into 4 groups (Fig. 3). Ninety-eight percent reported excellent or good results. Only 2% of the patients reported poor results. At final follow-up there were no recurrences or new surgical exploration. Average time to return to daily life activities and work were 10 and 20 days, respectively. In the eleven cases (2.8%) the technique was changed to open because of difficulties with introduction instruments. In these cases persistent pain at the wrist for 6 months was observed. However, at final control the results were satisfactory. Figure 4 demonstrates the level of patient satisfaction: approximately 90% of patients indicated in the questionnaire that they were completely or very satisfied. To informatively compare neurophysiological results hands were classified into three groups: those with DML 4.3–6.0 msec and SVC 32.1–29.2 m/s as group I; those with MLD 6.0–8.5 msec and SVC 29.2–26.2 m/s as group II; those with MLD 8.5/> msec and SVC 26.2/< m/s as group III. Postoperatively, 98% of group I and 86% of group II reported excellent results. In group III only 21% reported favourable results

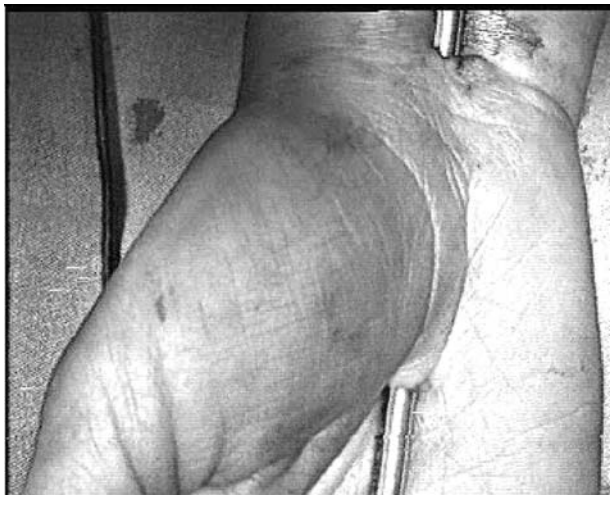

Fig. 2. The procedure of Chow's endoscopic biportal technique after introduction of fenestrated cannula

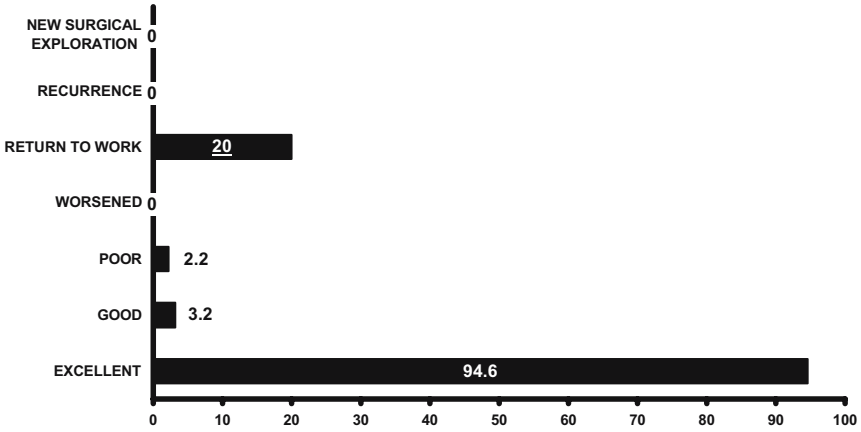

Fig. 3. Results (average follow-up 15,8 months – range 6–30 months). *Excellent* absence of pain in the first week; *Good* absence of pain in the first 20 days; *Poor* persistent paresthesia > 6 months; *Worsened* new sign; *20* days return to work

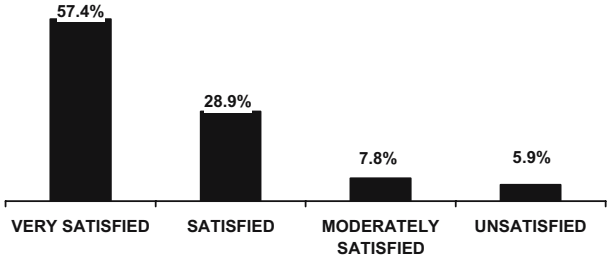

Fig. 4. Graph showing patient satisfaction with results of surgery

(Table 1). Complications encountered in this series included 14 cases (3.6%): five cases of wound infection with resolution after antibiotic therapy. In six cases there were injuries to the superficial palmar arch and two cases of wound haematomas (Table 2). In one case there was laceration of the perineurium sutured in open surgery. After two years of physiotherapy treatment the patient presented transient paresthesia.

Discussion

The carpal tunnel syndrome is currently the most common peripheral nerve compression neuropathy. The incidence, as reported by Nordstrom *et al.* [20], is of 3.46 cases per 1,000 person-year (95% confidence interval = 3.07–3.84). Tanaka *et al.* [26] reported that an estimated 1.55% (2.65 million) of 170 million adults self-reported CTS in 1988, based on a sample of 44,233 households (response rate, 91.5%). According to these authors, the incidence of CTS appears to be increasing in computer workers. Baldasseroni *et al.* [5] showed in this report a statistically significant risk for some ISTAT (Italian National Institute of Statistics) job classes, in particular class 53, 54, 742, 45, 63 and 85 (spinners, weavers, tailors, knitters, tanners, hotel and restaurant cooks, carpenters and similar job).

Surgical treatment for CTS may be performed by open or endoscopic techniques. In recent years, there has been a growing interest in minimally invasive surgery and ECTR has gained a great deal of popularity. Major controversy has ensued between the camps (open vs endoscopic) and within these camps regarding safety, success and complication rates of the two procedures. In the literature, the success rate of the open surgery (OCTR), minimally or standard, is greater than 95%, with a complication rate of less than 3% [18]. The results of ECTR techniques are comparable to those of OCTR procedures with overall success and complication rates of 98% and 0.97–2.67% with iatrogenic injury of 0.8% respectively. The endoscopic technique is associated with less incisional pain and scarring, faster recovery time and return to work [4, 11, 13, 15, 16, 18].

Table 1. *Outcome|EMG|patients%*

EMG	Excellent (LD </= 3,8 msec.)	Good (LD >/= 4,0 msec.)	Poor (LD > 4,0 msec.)	Worsened
Group I	97,8	2,2	0	0
Group II	86,3	10,9	2,8	0
Group III	21,4	73,8	4,8	0

Table 2. *Complications*

Wound infection	5 (1.3%)
Transitory tendon pain	4 (1%)
Transitory thenar pain	9 (2.3%)
Injury superficial palmar arch	6 (1.5%)
Injury perinuerium	1 (0.2%)

Since July 1999, to achieve less surgical invasiveness and early rehabilitation, we selectively performed ECTR using a biportal technique as described by Chow. Our findings are comparable with the results reported in the literature. The average time to return to activities of daily living and work were 10 and 20 days respectively and 97.8% of the cases reported excellent results. Moreover, 86.3% of the our patients were completely or very satisfied with the surgical results (Fig. 4). The most important risk encountered in our experience is injury of the superficial palmar arch that occured in six cases (1.5%). This iatrogenic damage occurs when the TCL is released. We believe that this potential vascular injury from ECTR can be prevented by direct visualization and by superficial palmar arch during the procedure before the ligament is released. Another important complication in our experience is injury to the perineurium of the median nerve for which an incidence has been reported of 0.3 to 2% [2, 8, 14]. Inaccurate insertion of the cannula and insufficient identification and visualization of the undersurface of the ligament accounts for these damages. Following Chow *et al.* [13] we believe that these complications are often found in early stage cases and the incidence being inversely proportional to the number of years of experience. In fact, our case happened in the first three months of training with ECTR. Release of the TCL under complete endoscopic vision via two small incisions is important to prevent injury to the median nerve. Moreover, to assure the best results of endoscopic technique, we believe that it is necessary to respect several principles:

A) Appropriate patient selection: only patients with classic CTS should be considered candidates. Controindications include patients with anatomical anomalies, synovial cysts, neuromas, previous trauma or surgery. Patients with very large, bulky hands or with longer preoperative symptomatology are sometimes technically difficult to operate because of adherences.
B) Adequate learning curve and familiarity with endoscopic techniques and instruments.

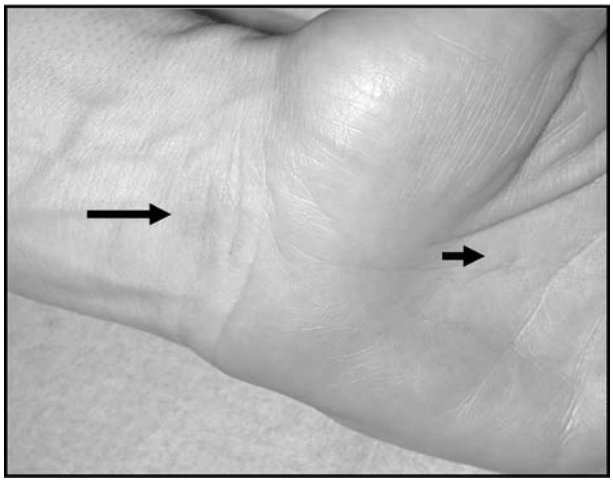

Fig. 5. Typical appearance two months following the biportal technique

C) Good knowledge of open surgery. The surgeon should not begin with endoscopic surgery.

Conclusion

Our study demonstrated that the endoscopic carpal tunnel release is a safe technique with overall results and complications comparable to those of open surgery. This method presents minimal postoperative morbidity with faster return to work, reduced disability time and better cosmetic results (Fig. 5).

In our experience, correct positioning of the hand with proper anatomical landmarks, correct use of instruments, perfect knowledge of the anatomy and possibility of conversion to open surgery at the slightest doubt concerning visibility of the carpal ligament, are essential for a safe and successful procedure.

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Wrist median nerve motor conduction after end range repeated flexion and extension passive movements in Carpal Tunnel Syndrome. Pilot study

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Summary

Carpal Tunnel Syndrome (CTS) can be due to a variety of different pathological conditions. These etiological and epidemiological differences may explain the non-homogeneous response to ordinary conservative therapeutical options observed in this syndrome. The aim of our study was to investigate on the possibility of identifying different sub-groups of patients among conservatively treatable CTS with different susceptibility to physiotherapeutic treatments. We decided to utilize an objective approach measuring some median motor nerve function parameters.

Short term variations of Compound Motor Action Potential (CMAP) from the thenar eminence were compared in two groups of 55 hands (CTS patients and normal controls) after performance of two different types of end range passive movement.

We found a different distribution of CMAP amplitude modifications within a sub-group of patients that suddenly improved more than the controls after two series of 10 end range passive flexions or after two series of ten end range passive extensions.

Amplitude changes proved to be much more useful than latency variation studies in the provocative test neurophysiological approach. The method we propose appears to be useful for better surgical indication and/or for improvement of conservative therapeutic choice.

Keywords: Carpal Tunnel Syndrome; compound motor action potentials; electromyography; physiotherapy; provocative tests.

Introduction

A variety of conditions may cause carpal tunnel syndrome (CTS) by increasing volume of tissue within the carpal tunnel and/or decreasing of the section area of carpal canal. CTS is associated in fact with inflammatory arthritis, Colles' fracture, amyloidosis, Kienboeck's disease, change of hormonal balance (pregnancy, diabetes, ipotiroidism, steroid or estrogens therapy) [6, 16] and with repetitive and forceful activities that cause thickening of the synovial lining of the tendons that traverse the carpal tunnel along with the median nerve [21].

Controversy still exists regarding the pathophysiology, assessment, diagnosis and treatment of CTS [14, 20]. In a multiperspective, multicentre follow-up study on untreated CTS published in 2001 several affected hands unexpectedly improved spontaneously. This study also showed that cases with initial low severity might tend to get worse, whereas severe patterns may improve [11].

Because of the high prevalence of CTS (reported to be between 2,7% and 5,8% of the general population) [3, 9] accurate diagnosis and effective treatment are important to physician, therapist, employers, and third-party payers.

Especially useful are those criteria that may help to predict the natural clinical course of the disease (toward spontaneous improvement or not) and to select the best individual treatment. In fact, in some cases an earlier surgical decision might save time, pain, further examination, working days and finally money.

The solution of this clinical enigma is often based on a long or short period of conservative treatment with a monitoring of symptoms and signs and sometime neurophysiological parameters.

Several conservative treatments may be used for this purpose: NSAD, Steroids (oral or infiltrative), physical therapy (ultrasound, ionophoresis), immobilization, mobilization, change of daily activities (ergonomical interventions, work changes), tendon and nerve gliding exercises, general conditioning therapies such as yoga or stretching.

Data concerning usefulness of these treatment methods aren't satisfactory: in fact only oral steroids, splinting, ultrasound, yoga and carpal bone mobilization show real short-term benefit. The other non-surgical treatments don't seem to produce improve-

ments according to the 2002 Cochrane Review which analysed the efficacy of non-surgical treatment (steroid injection excluded) for CTS [10].

Especifically regarding nerve and tendon gliding exercises it has been shown that neurodynamic mobilization doesn't change significantly the symptoms while carpal bone mobilization causes a short term improvement without any statistical difference between the two methods [18].

Moreover, according to other authors there is a tendency towards a decrease in surgical operations (only 57%) in patients who underwent tendon mobilization as opposed to patients that received only conventional treatment (71% surgery) [15, 19].

Akalin prospectively analysed a randomized group of 28 patients treated with splinting alone versus splinting and tendon and nerve mobilization and found better outcomes in the second group but with no statistical difference [2].

Our impression is that the lack of any statistical significance reported in the literature concerning the usefulness of methods that logically would appear effective may be due to a bias in patient selection. In our experience, there are in fact several sub-group of patients that may show a different clinical evolution pattern based on the treatment of tendon and nerve mobilization.

To verify our hypothesis we used a simple neurophysiological method: the study of compound motor action potential (CMAP). Our method evaluates the short-term variations of this parameter following two different types of passive movement and compares these variations in patients and controls. Our aim was to check the possibility of finding a few easy markers correlated with a different sensitivity to treatment of nerve and tendon mobilization in two different movement directions.

Methods

38 consecutive patients (55 hands) who had been referred to the Neurophysiological Laboratory of the Neurosurgical Clinic of the Siena University, Medical School, for evaluation of CTS were studied (*group B*). All of them exhibited symptoms of CTS (eg. Pain, numbness, tingling). A screening history and physical examination was conducted to ensure that the referring diagnosis of CTS was warranted, and to exclude those individuals who were not suitable for the study (i.e. those with peripheral neuropathy or obvious entrapment neuropathy other than median nerve).

55 hands of 32 hospital staff and healthy adult age matched volunteers served as control subjects (*group A*). These individuals did not show any signs or symptoms of CTS and their conventional NCS were within normal limits.

Procedure

A standard electrodiagnostic examination including conventional motor and sensory median and ulnar nerve NCS was performed in both groups.

The active recording position at the motor point of the thenar eminence was carefully controlled for the exact stimulation on the motor point in order to decrease pseudofacilitation phenomena that could be due to change of muscle length [17].

After having measured the baseline medial nerve distal motor latency (DML) and maximal compound muscle action potential (CMAP) from the thenar muscles at rest, 2 series of 10 passive wrist flexions were performed, followed by two series of 10 wrist extensions. After each series of ten passive movements a new measurement of DML and maximal CMAP of the median nerve was obtained. Both passive movements (flexion and extension) were performed until the end range of motion in the required direction.

Amplitude values (negative to positive peak) were measured after exercise performance were normalized and expressed as percentage of rest amplitude. The mean of the two values obtained after the first and the second flexion series and similar mean value after the two extension series were expressed as number value M-test, and values obtained were arbitrarily classified as worsened (lower or equal to 95% of rest value), unchanged (between 95% and 105%) and improved (equal or superior to 105%). Statistical analysis was performed with parametric and non-parametric test (Chi-square, Fisher's exact test and McNemar's) by the SPSS program (SPSS Inc.).

Results

Table 1 and Fig. 1 show mean and standard deviations of Distal Motor Latency and amplitude changes in patients and controls. The first analysis doesn't show any significant difference.

A normalization of values expressed as percentage of rest value (Fig. 2) showed a more elevated standard deviation in the patient group as compared to normal controls. In our opinion, this increased variation in patients is due to the presence of subjects with different disease typologies and therefore with different responses after movement performance.

To test if the distribution of the various responses after repeated movements could be different in subgroup of patients, we calculated the mean of the two values obtained after two series of extension and after two series of flexion movements. Obtained values were classified as worsened if they were lower than 95% of rest value, unchanged if between 95% and 105% and improved if superior to 105%.

The contingency table obtained (Table 2) is composed of three groups, classified according to CMAP change after repeated passive movements. The statistical analysis showed a difference in patient distribution via-à-vis normal controls in both directions of movement.

Table 1. *Modifications of mean distal motor latency (DML) and amplitude (AMP) of Compound Motor Action Potential (CMAP) registered from thenar eminence in patients and control subjects. Values were obtained at rest and after each of two groups of 10 repeated end range passive flexion movement (10 Flex) and two groups of 10 repeated end range passive extension movements (10 Ext). Standard deviation (SD)*

CMAP Changes	CONTROLS					PATIENTS				
	Rest	10 Flex	10 Flex	10 Ext	10 Ext	Rest	10 Flex	10 Flex	10 Ext	10 Ext
DML ms (SD)	3.49 (0.50)	3.50 (0.51)	3.49 (0.49)	3.53 (0.50)	3.51 (0.51)	4.62 (0.95)	4.62 (0.88)	4.64 (0.89)	4.65 (0.89)	4.66 (0.86)
AMP ms (SD)	10.0 (2.98)	10.0 (3.19)	10.1 (3.18)	10.1 (2.87)	10.1 (2.94)	6.93 (3.47)	6.72 (2.85)	6.61 (2.77)	6.79 (3.01)	6.57 (2.80)

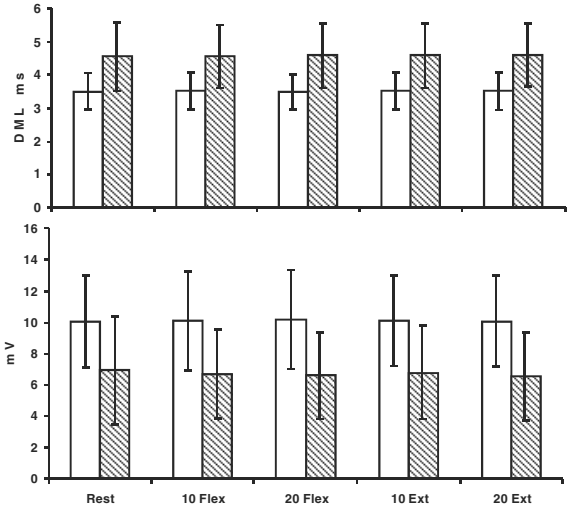

Fig. 1. Graphic representation of Table 1 value. Same Abbreviations

Moreover, comparing distributions of patients after flexion and extension we found a clear difference between the two movement directions. In Fig. 3, in fact, in the histogram of changes after flexion movements we may see a worsening of a wide group of patients without a significant behavioural change in control subjects. End range passive extension on the other hand resulted in a wider distribution also towards improvement in the patient group.

Figure 4 and Table 3 compare the presence of covariations (after flexion and extension) and their consistency between the two groups.

11 hands (32%) of patients and only 3 hands (5%) of controls showed worsening both with repeated flexion and extension movements. In total 31 hands of patients (56%) showed worsening in one and no variation in the other direction of movement or worsening in both directions. In the control group only 8 hands (14,5%) showed a similar response.

Regarding improvements 12 affected hands (22%) were improved after extension and unchanged after flexion against the 12% of controls (7 hands) showing a probable general tendency but without any statistical significance.

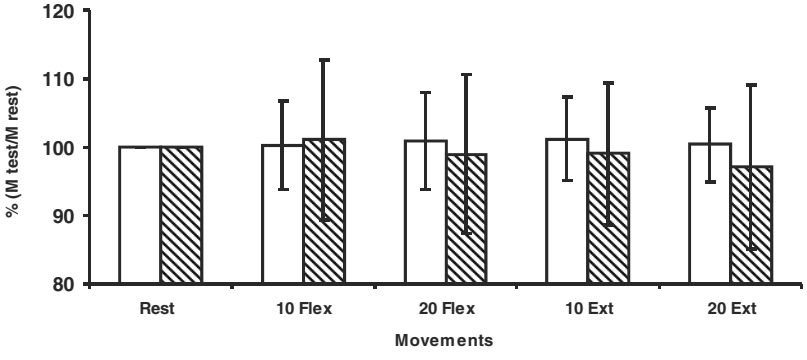

Fig. 2. Normalized Compound Motor Action Potential in Normal Controls (white) and Patients (dashed) shows a wider standard deviation in the patient category

Table 2. *Contingency table of three arbitrary categories of changes of compound muscle action potential after test movement*

	Flexion		Extension	
	Control	Patients	Control	Patients
CMAP < 95%	7	13	8	20
95% < CMAP < 105%	38	22	37	23
105% < CMAP	10	20	10	12

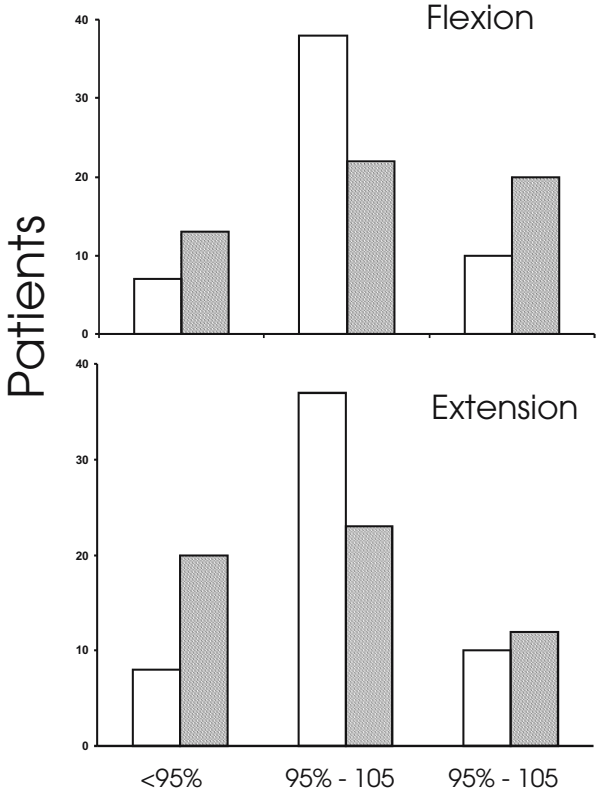

Fig. 3. Histogram of Table 2 values. White: normal control. Dashed: patients

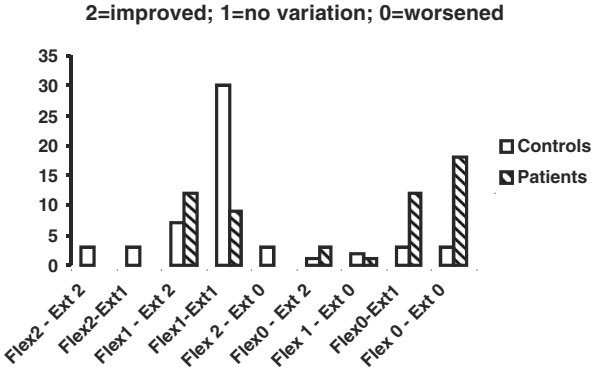

Fig. 4. As in Table 3. Covariation of compound motor action potential above 105%, below 95% or unchanged with respect to baseline in the two movement directions

Table 3. *Co-variation of compound motor action potential above 105% (improved), below 95% (worsened) or unchanged with respect to baseline in the two movement directions*

Flexion	↑	↑	↔	↑	↔	↓	↔	↓	↓
Extension	↑	↔	↑	↓	↔	↑	↓	↔	↓
Controls	3	3	7	3	30	1	2	3	3
Patients	0	0	12	0	9	3	1	12	18

↑ improved; ↓ worsened; ↔ unchanged

Discussion

According to the literature, recent prospective studies have shown that in a consistent group of patients affected by CTS a spontaneous improvement can be observed [11]. On the other hand, studies analyzing the efficacy of non surgical treatments in CTS show a very low success rate for the majority of the different conservative methods, [20] even though a tendency towards improvement with the use of non surgical and non infiltrative methods is generally accepted [10].

Most of the studies aimed at verifying the efficacy of the different conservative approaches in the treatment of CTS fail to show a statistical significance: this could be due, in our opinion, to a wide variation of responses in the samples studied.

Owing to a progressively improved health education many patients affected by CTS certainly receive an early diagnosis and seek prompt treatment. On the other hand, many patients still come late to a clinical evaluation [13, 22].

It is well known that CTS can be caused by several different diseases. Therefore, since there are many different stages of the disease and many different physiopathologic entities, it seems logical to suppose that there are wide differences in treatment responses in the group of patients studied.

In fact, the group of patients studied showed important variations in the amplitude of PAMC and significantly different responses as compared to the control group.

Moreover, within the group of patients studied, it seems possible to distinguish single and consistent subgroups of variations. Thirty-two percent of patients as compared to only 5% of controls showed worsening both with repeated movements of flexion and extension. Also, 22% of patients, compared with only 12% of controls, showed improvement after extension exercises and no variations after flexion exercises.

It is surprising that a series of flexion and extension

movements actually creating an increase in pressure within the carpal tunnel in the range of 30–110 mmHg [4], can determine an amplitude increase and hence an improvement in the impulse conduction in the motor axons of patients with CTS.

Since only a sub-group of patients showed such a response, it seems to be worth using this method to optimize the criteria for selection of best physiotherapeutic treatment for each patient.

In fact, the conservative treatment with exercises of nerve and tendon mobilization could be a good choice for many patients, but not for all. In our study, for example, a sub-group of patients, showed severe worsening (at least transitory) after a series of these exercises.

In the case reports of other authors individual patient sensitivity to a specific treatment could have been known in advance if a dynamic neurophysiologic evaluation like the one we propose had been performed at the start point of treatment selection in order to obtain a more homogenous group of patients for study with more reliable statistical results.

A dynamic test as proposed by us could also be used as provocative test to discover alterations remaining undetectable by using conventional neurophysiologic studies.

The validity of neurophysiologic methods using provocative tests is still under debate in the literature: the question is whether these tests could really be helpful detecting patients otherwise negative at EMG examination. Currently a significant percentage of patients with CTS (ranging from 16 to 51% according to different authors) are not discovered by common neurophysiologic tests: this is particularly true for the mild forms of CTS [1].

The poor results presently obtained by provocative tests could be due to the fact that they almost always analyse only response latency, which usually shows very weak and poor relevant variations, as we demonstrated in our study [23].

The different contributions of axonal attenuation, ischemia, demyelination and remyelination to the pathophysiology of carpal tunnel syndrome is still unresolved but recent evidence showed that demyelination may not be a critical factor for the slow down of impulse conduction in mild to moderate carpal tunnel syndrome. Hence it is reasonable to suppose that latency variations are not the ideal parameter to be studied by provocative tests.

Sometimes a surgical decision is made only on the basis of clinical symptoms with negative neurophysiologic examination [7]. Surprisingly, surgical procedures performed without considering the outcome of neurophysiologic examinations don't show different long term results [5, 8]. Anyway, the aim is to reduce as much as possible therapeutic decisions made only on the basis of clinical symptoms, without confirmation of positive objective, reliable, sensitive and specific diagnostic tests so that the failure rate of surgery is reduced and unnecessary surgical risk is avoided.

In our study, only a few subjects showed an amplitude decrease of PAMC both in flexion and extension in the control group (but the normal subjects were chosen in a pseudo-random manner). However, these people when subsequently investigated for the presence of typical symptoms of CTS revealed mild symptomatology in 3 out of 4 cases. These subjects behaved in a way similar to a sub-group of patients treated with early surgical intervention. Probably there is a subgroup of people, like pregnant women [12], who could benefit from a preventive surgical treatment. In such particular cases, a provocative test like the one we propose, could be very useful to best identify those people to be operated on.

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Microsurgical treatment of lumbosacral plexus injuries

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Summary

Surgical treatment of lumbar and sacral plexus lesions is very rarely reported in the literature.

The incidence of the involvement of these nervous structures in traumatic lesions of different etiology is probably much higher than believed, and surgical treatment should be taken into consideration more often.

In this paper the experience derived from the surgical treatment of 15 cases is reported. Different surgical approaches have been employed according to ethiology, to level of nerve lesion and concomitant lesions of other organs.

Patients who suffered a lesion in the lumbar or sacral plexus may have a very severe problem with deambulation since the leg may not be stable or may be unable to withstand the weight of the body. Pain syndrome in these patients may be a very severe obstacle to rehabilitation programs and to deambulation and everyday activity.

Microsurgical nerve treatment in the retroperitoneal space is demanding both for the surgeon and for the patient but neurolysis and grafting procedures are possible also in this area. The resulting improvement of motor performance and the relief of pain are strong arguments in favor of this choice. Muscles benefitting most from surgery are the gluteal and femural muscles; more distant muscles, and particularly the anterior tibial nerve dependent muscles will gain minimal benefit from surgery. The relief from pain is relevant in all cases.

Keywords: Lumbosacral plexus; peripheral nerve surgery; nerve injuries; microsurgery.

Introduction

Injuries to lumbar and sacral plexuses are very rarely reported in the literature. Their incidence is estimated very low [25, 29]. Probably incidence of this pathology is underestimated which may be due to the difficulty of such diagnosis and possibly also the lacking awareness that such a lesion may exist.

Analogous nerve lesions in the upper limb are well understood and well approached all over the world thanks to an enormous number of anatomical, experimental and clinical studies. Not so much attention has been payed to lumbosacral plexus injuries, for reasons discussed in this paper.

Such patients are often simultaneously affected by damage to several soft, parenchymatous [10, 13, 20, 21, 29, 30] and bony tissues [1, 2, 10, 12, 15, 19, 30, 31, 32], and this may makes neurological diagnosis difficult. This is particularly true for patients who in emergency receive treatment by general, urological, or obstetrical surgeons. In other cases diagnosis may be hindered by superimposing symptoms due to pathology of other organs, or by interposition of a long time span between injury and specialised clinical examination. The long time interval may be accompained by a sketchy clinical history and by incomplete or superficial surgical reports. A different case are iatrogenic nerve lesions which may long remain misunderstood or underestimated.

Nerve surgery in the abdominal retroperitoneal area is rarely performed [3, 5, 6, 11, 22, 23, 26] both because of the aforementioned problems and because of technical difficulties due to deep location of the nerve structures to be reached by a laborious approach with the risk of haemorrhage and infection. For the neurosurgeon this is an unusual anatomical area.

In the literature surgical treatment is reported to have been done in small series of patients: 14 cases have been published in the last years [5, 6, 11, 25]. Recently Kline and Hudson [22] presented their wide experience with a first relevant series of surgically treated cases.

In this paper a revision of the personal casistic is given, with some comments on surgical approaches.

Anatomical considerations

A careful anatomical study has been performed on 14 adult cadavers in order to collect data on the microsurgical anatomy of the region and to verify surgical possibilities. Lumbosacral plexus is composed of nerve roots L1 to S2. As for brachial plexus, nerve roots also in this anatomical area located anteriorly provide flexor functions, posterior ones extensor functions [8, 14, 23, 33].

Lumbar and sacral plexuses are to be considered separately because of the completely different destiny of their terminal branches and because of the differences in topographical anatomy which entail different surgical approaches.

The lumbar plexus originates from the spinal roots L2, L3 and L4 and receives contributions from L1 and L5 roots.

It is located in the corner between the vertebral bodies and lateral apophyses. It is covered by the ascending iliac and cava veins and by the aorta and common iliac arteries on the right side and by iliac arterial and venous plexuses on the left. Posterior to these structures is the psoas muscle which covers entirely the plexus. In the space between the psoas muscle and the spine, together with the plexus, lumbar arteries and lumbar and azygos veins which form the ascending lumbar vein are met.

While most cranial nerve roots and trunks have a fairly horizontal direction, the more caudal ones are obliquely oriented and in the plexus are located posterior to the more cranial ones.

Several terminal branches take origin from the lumbar plexus: iliohypogastric, ilioingiunalis nerves, nervous branches to psoas and ileous muscles, genitofemoralis, lateral femorocutaneous, obturatorious, obturatorius accessorius, and femoral nerves.

Three of these nerves, namely ileohypogastricus and ileoinguinalis proximally and femorocutaneous more distally, emerge from the lateral border of psoas muscle, and run on the posterolateral muscular wall of abdomen. Genitofemoralis nerve on the contrary emerges from the anterior surface of psoas muscle, in a virtual septum between minor and major psoas and runs subfascial on this muscle. Obturator nerves remain in a hidden position, behind psoas belly, running parallel to the lumbosacral trunk.

Thus the subserved muscles are: abdominal, psoas, iliac, pectineus, sartorius, quadriceps femoris, and adductors of the thigh.

The sacral plexus originates from the spinal roots L5-S1-S2 and S3; some fascicles coming from L4 contribute to this plexus, joining L5.

Sacral plexus lies on the sacroiliac junction, and on the piriformis muscle; it is located medially to the psoas muscle, between the latter and the column.

Hypogastric artery intermingles witzh the nerve trunks, and ascending veins cover the plexus. Nerve fibers have a fairly vertical orientation, and go deep into the pelvis following the bony profile. Most caudal components are located posteriorly to the most cranial ones.

The radicular components from L4 and from L5, together, form the lumbosacral trunk. Receiving fascicles by S1, S2, and S3 roots, lumbosacral trunk contributes to the formation of common peroneal and tibial nerves, which may unite to form sciatic nerve or remain indipendent and parallel all the way to the popliteal fossa. From the sacral plexus also superior and inferior gluteal nerves, and motor branches to quadratus femoris, biceps and semitendineous muscles take origin.

Thus the subserved muscles are: major, middle and minor gluteal, obturator, piriform, gemelli and quadratus, the muscles of the posterior aspect of the thigh; anterior tibial and peroneal muscles, abductors and extensors of the foot; triceps surae and plantar flexors of the foot.

Patients and methods

Patients

This paper reports our surgical experience with 15 patients operated on from 1987 to 1996. Some of these patients were subject of previous reports [5, 6]. Mean age was 30; nine were males, six female.

In seven patients the lesion was due to road or work injuries; five out of these were males. In other 4 cases (all males) the lesion was due to bullets, while in 4 females the lesion was the consequence of abdominal or gyneacologic surgery.

Patient features are detailed on Table 1.

Diagnostic methods

All patients where referred because of the diagnosis of lumbosacral plexus lesion at distance from the lesional event. EMG recordings and Sensory Evoked Potentials were regularly repeated monthly in order to monitor the clinical evolution and get an understanding of the possibilities of spontaneous recovery.

EMGraphic signs of dysfunction in muscles innervated by different terminal branches were studied to make a map of the possible site of damage; SEP recordings from specific cutaneous areas were analyzed in order to identify possible root damage.

As indicated by Harris [19] and some other authors [9, 22, 28] myelography and TC myelography were performed in cases in which

Table 1. *The features of patient's lesion, and the surgical treatment which has been performed*

Pat.	Sex-age	Cause*	Level of lesion	Preoperative picture	Surgical approach	Surgical treatment
1-L.R.	M 20	1	L3-L4	Femoral M1 Obturator M3	extraperit.	neurolysis
2-N.R.	F 21	1	L5-S1-S2	Gluteal M2 Ant.Tib M3 Post. Tib M2	transperit	neurolysis
3-E.V.	M 32	2	L4	Femoral M2 Obturator M3	extraperit	graft
4-D.J.	M 28	2	sciatic trunk	Gluteal M0 Sciatic(thigh) M0 Ant.Tibial M0 Post.Tibial M0	sacrectomy + gluteal approach	graft
5-D.M.	F 42	3	lumbar pl. & term. branches	Femoral M3 Obturator M3	transperit	neurolysis
6-A.A.	F 40	3	lumbar pl. & term. branches	Femoral M2-3 Obturator M2	transperit	neurolysis
7-Y.D.	M 22	2	L4-Femoral n.	Femoral MO Obturator M2	extraperit	graft
8-M.E.	M 30	2	L5-S1	Gluteal M2 Ant.Tib. M0 Post.Tib M2	transperit	graft
9-A.C.	F 38	3	femoral + obturator + femorocutaneous	Femoral M3 Obturator M3	extraperit	neurolysis
10-R.S.	M 37	1	L5-S1-S2	Gluteal M1 Ant.Tib M2 Post.Tib M3	transperit	neurolysis
11-S.F.	F 27	3	femoral & obturator	Femoral M3 Obturator M3	transperit	neurolysis
12-A.B.	F 16	1	L3-L4-L5	Femoral M2 Obturator M2 Gluteal M4 Sciatic(thigh) M3	transperit	neurolysis
13-R.G.	M 18	1	L3-L4	Femoral M3 Obturator M3	extraperit	neurolysis
14-C.A.	M 63	1	L4-L5-S1-S2	Femoral M3 Sciatic(thigh) M1 Ant.Tib. M0 Post.Tib. M0	transperit	graft
15-G.G.	M 54	1	L3-L4-L5	Femoral M3 Obturator M3 Ant.Tib. M3	transperit	neurolysis

* Cause 1 is traumatic event in road or work accidents; cause 2 is bullet; cause 3 is gynecologic or abdominal surgey.

a suspicion of root avulsion was present because of the mechanism of injury: palsies associated with lumbar, sacral or pelvic fractures which my entail stretch injury to the nerves.

Patients were studied also by CT and/or MR imaging. These imaging tools provided information about alterations of anatomy [4, 16, 17], about the presence of bone displacements or fibrotisation in the retroperitoneal space, and about muscular atrophy.

Surgical methods

The approach to the lumbosacral plexus area may be a difficult matter because of the deep location of nervous structures, which in the retroperitoneal space are covered by major arteries, veins, and venous plexuses. Fibrotisation following retroperitoneal haematomas and traction – distortion lesions may become very compact because of frequent participation of bone repair processes and because of the involvement of thick muscles with very numerous tendinous insertions.

Owing to the level of lesion three different approaches are described in the literature: [7, 14, 18]:

- anterior extraperitoneal via a lumbotomy, for reaching L2-L3-L4 roots and lumbar plexus
- anterior transperitoneal via a xifopubical incision for reaching L5-S1-S2 roots and sacral plexus
- posterior via L5 laminectomy and sacrectomy for reaching the nerve toots and the deep intrapelvic origin of sciatic nerve from sacral plexus.

Combined anterior and posterior approach is described only from a theoretical point of view: no reports on patients treated by this double approach could be found in the literature.

Millesi recently realized a very new approach which goes along the inner bony surface of iliac bone and enlarges the margins of foramen ischiaticus in order to expose the sacral plexus and sciatic nerve at the passage through the foramen [27].

In this series of 15 patients, surgical approach was chosen following the aforecited criteria, and also considering the previously performed surgical operations for each individual patient, which in some cases imposed the transperitoneal approach.

After neurolysis, nerve grafting procedures were performed in 2 of the lesions due to trauma, in all four due to bullet injury, and in 1 of the four iatrogenic lesions.

Surgical procedures

The anterior extraperitoneal approach

The patient lies on lateral decubitus on the healthy side with the bed forming a 30 degree angle corresponding to the lumbar area. The arm on the affected side is kept elevated over the head.

A lumbotomic incision is performed: the arciform skin incision and section of oblique muscles gives exposure of the peritoneal sac, which is gently retracted medially and downwards. The kidney is visible on the cranial limit of the operative field, on the posterior abdominal wall. Attention must be payed to the ureter, which runs inside a duplication of the peritoneal wall and must not be hurted in dislocating the peritoneum. By this way the plane of psoas and ileum muscles are exposed; femorocutaneous, femural and genitofemoralis nerves are easily identified and the appropriate microsurgical procedures can be performed. Tracing posteriorly the femoral nerve, we usually elevate the psoas muscle by a strong retractor, in order to reach L2, L3, and L4 roots at the foramina. In this point electrical stimulation is given while evoked cortical potentials are recorded for demonstrating the absence of root avulsion. Distally the terminal branches of the lumbar plexus are followed up to their way out of the pelvis. If needed femoral nerve is neurolysed by dividing the ligamentum inguinalis on the lacuna musculorum, and coming into the Scarpa's triangle in the thigh.

The same can be done for the femorocutaneous nerve by dividing the ligamentum inguinalis laterally, close to the anterior superior spina iliaca, and opening the fascia lata.

The obturator nerve can be traced distally: it is medial to the psoas muscle, and lateral and posterior to the iliac vein, and goes towards the canalis obturatorius.

In this series this approach was applied in 5 cases. In 3 out of them the target was a lesion of L3 and/or L4 roots. This site of lesion was associated with femoral nerve involvement in patient n° 7, and with femoral, obturator and femorocutaneous nerves lesion in patient n° 9.

Microsurgical treatment consisted in neurolysis in 2 cases, which showed that grafting procedures were needed in patients

The anterior transperitoneal approach

The patient lies on its back, the bed forming a 20 degree angle corresponding to the lumbar area. A long xifopubic skin incision allows bringing apart the two recti abdominis muscles. The anterior wall of the peritoneal sac is opened and bowels are retracted. For maintaining a central free space we have employed a circular autostatic spreader which can retract bowels in any direction without danger.

The posterior peritoneal wall is opened and major vessels are exposed. Once the vessels are gently retracted, the promontorium, that is the body of L5 vertebra and L5-S1 disk, can be palpated. This is the landmark for identifying the L5 nerve root. Nerve roots L4 and L5 can be reached medial to the psoas muscle, and their fusion in the lumbosacral trunk is exposed by partial resection of the muscle from medial to lateral. S1 root can be brought into vision more distally. Surgical procedures on its junction to the sacral plexus become extremely difficult; we believe that only neurolysis is possible at this level. Up to some millimeters exposure becomes impossible because of the very deep location and the presence of not movable vascular structures. So this is the distal limit of the surgical field. This is why more distal lesions at the passage from the pelvis to ischiatic foramen are to be approached by the posterior route.

Out of our 15 patients this approach has been used in nine cases. In 3 the target was a lesion located in L5 root and in more distal roots. In other complex lesions in which L5 root was involved together with the upper roots composing the lumbar plexus, the choice was in favour of this approach rather than the extraperitoneal one (patients n° 12 and 14).

In four patients the choice for this surgical approach was dictated by preexisting abdominal scar, even if the goal was to reach the lumbar plexus and its terminal branches (patients n° 5, 6, 11 and 15).

The posterior approach

The patient lies prone, with the the legs maintained in hip and knee flexion as for lumbar disk surgery. This position allows sacrectomy and L5 emilaminectomy, careful muscular resection from sacral insertions and intrapelvic plexus exposure. Also sciatic nerve exposure distal to the foramen ischiaticus underneath gluteal muscles is easyly performed by a distal separate approach [7, 24].

After medial lumbar skin incision, L5 and S1 roots are exposed by laminectomy and sacrectomy followed by foraminotomy. The paravertebral muscles are to be partially sectioned in order to gain a lateral extension of the surgical field and exposure of the retroperitoneal space. Neurolysis can be performed by this approach and if needed nerve grafting can be performed with connection to the sciatic nerve at foramen ischiaticus. Nerve grafts are brought beneath the gluteal muscles, outside the pelvis.

This approach was employed in only one case, in which the sciatic trunk was lesioned in the pelvis, and had to be repaired by grafts (patient n° 4).

Results

We had no complications from surgery, all postoperative courses were uneventful.

Follow up in our series of patients was at seven years for 3 cases, three years for 2, two years for 4 and 18 to 12 months for 6. In Table 2 the legend "postoperative picture" refers to the situation as observed at present, after the mentioned follow-up period after surgery.

EMG recordings demonstrated that gluteal muscles regained significantly useful innervation in neurolysis cases as well as in graft cases. Particularly the medium gluteus muscle, which is an important stabilizer of articulation, regained useful activity within one year after surgery. Muscles of the thigh showed an analogous improvement.

In general, most proximal muscles improved much more than the more distal ones. Among these the muscles subserved by the anterior tibial nerve had the worst results.

Table 2. *The correlation of results with kind and site of injury, and with the preoperative condition*

Patient	Sex-age	Cause	Surgical treatment	Preoperative picture	Postopertive picture
1-L.R.	M 20	1	neurolysis	Femoral M1	M4
				Obturator M3	M5
2-N.R.	F 21	1	neurolysis	Gluteal M2	M4
				Ant.Tibial M3	M3
				Post.Tibial M2	M4
3-E.V.	M 32	2	neurolysis + graft	Femoral M2	M3
				Obturator M2	M3
4-D.J.	M 28	2	neurolysis + graft	Gluteal M0	M3
				Sciatc(thigh) M0	M3
				Ant.Tibial M0	M0
				Post.Tibial M0	M0
5-D.M.	F 42	3	neurolysis	Femoral M3	M5
				Obturator M3	M4
6-A.A.	F 40	3	neurolysis	Femoral M2–3	M4–5
				Obturator M3	M4
7-Y.D.	M 22	2	neurolysis + graft	Femoral M0	M3
				Obturator M2	M3
8-M.E.	M 40	2	neurolysis + graft	Gluteal M2	M4
				Ant.Tibial M2	M2
				Post.Tibial M0	M3
9-A.C.	F 38	3	neurolysis	Femoral M3	M4–5
				Obturator M3	M4
10-R.S.	M 37	1	neurolysis	Gluteal M1	M4
				Ant.Tibial M2	M4
				Post.Tibial M3	M5
11-S.F.	F 27	3	neurolysis	Femoral M3	M5
				Obturator M3	M5
12-A.B.	F 16	1	neurolysis	Femoral M2	M4
				Obturator M2	M4
				Gluteal M4	M5
				Sciatic(thigh) M4	M5
13-R.G.	M 18	1	neurolysis	Femoral M3	M4
				Obturator M3	M4
14-C.A.	M 63	1	neurolysis + graft	Femoral M3	M4
				Sciatic(thigh) M1	M3
				Ant.Tibial M0	M0
				Post.Tibial M0	M2
15-G.G.	M 54	1	neurolysis	Femoral M3	M5
				Obturator M2–3	M4
				Ant.Tibial M3	M3

The woman treated by grafting because of a surgical lesion of the obturator nerve had a very good recovery, probably because of the clearcut lesion, and of the correct timing for reconstruction.

Among the graft cases one did not show improvement 18 months postoperatively. We cannot exclude that a root avulsion was the cause of this failure, but since the repaired structure was the L5 component of the lumbosacral trunk we think that muscle distance may have played as primary role.

For all patients surgery meant improvement in pain sensation; in the great majority pain disappeared, and this result was achieved almost immediately in the postoperative period. This is ascribed to neurolysis which allows resolution of ischemia.

Conclusions

Patients suffering a lumbosacral plexus lesion may have a very severe problem whith deambulation since the leg may not be able to withstand the body wheight. Also in cases of partial lesion impairment of various muscles from the gluteus to the foot will engender problems with motion. Moreover, the pain syndrome following nerve lesions will be exacerbated by posture and will hinder walking and rehabilitation programs.

As for any peripheral nerve lesion, the entity of damage may vary greatly from trunk to trunk and even inside a single nerve structure. Neurolysis, either as a first step procedure for studying the lesion or as a per se complete treatment, is a useful technique to facilitate nerve regeneration and appease neurogenic pain.

The problem in lesions of lumbar and sacral plexuses is the relevant distance to the depending muscles. Only some muscle groups are near enough to be reached by nerve regeneration in a time short enough to prevent postatrophic fibrotisation. The muscles with the best results are the gluteal muscles, with the medium gluteus in particular. This muscle is very important for standing and walking since it gives stability to the hip joint.

Concerning the lumbar plexus, psoas and ileopsoas muscles are the most proximal: the psoas muscle will be reinnervated by branches of the lumbar plexus joining it directly at L2 and L3, while the ileopsoas muscle will receive regrowing fascicles through the femoral nerve.

As regards the sacral plexus, gluteal muscles and muscles of the posterior aspect of the thigh can be reinnervated via the gluteal nerves and via the specific short branches of the sciatic nerve.

Function improvement of these muscular masses deriving from neurolysis or from nerve grafting in more severe nerve lesions offers to the patient the enormous advantage of regaining strength for the leg. To be able to stand on it whithout external support will be the basis for starting walking again. Great enthusiasm of the patient who also enjoys reduction of pain will facilitate the rehabilitation program.

All the other more distal muscles of the inferior limb are too far distant and we should not expect useful reinnervation of this area when planning nerve grafting for lumbosacral plexus lesions. Anyway, posterior tibial depending muscles have shown significant degrees of reinnervation.

Neurolysis has proved to be a useful procedure in the retroperitoneal area since it could be achieved to gain 1 or 2 M points, making deambulation possible without external support and since it has almost completely eliminated pain in all cases.

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Femoral nerve entrapment

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Summary

We present 30 cases of femoral nerve entrapment (1999–2003, age range 35–65 yrs), in 13 patients with diagnosis of idiopathic compression and 7 patients of neurovascular conflict. The compression, in the other 10 patients, was iatrogenic: 3 patients following cardiac catheterization for balloon valvotomy, 2 patients following intra-abdominal vascular surgery and 5 patients following laparoscopic hernia treatment. Microsurgical nerve decompression, and the elimination of neurovascular conflict gave satisfactory results. The best result has been observed in neurovascular conflict cases.

Keywords: Femoral nerve; entrapment; lumbar plexus.

Introduction

The femoral nerve, the largest branch of the lumbar plexus, is formed in the substance of the psoas major muscle where it derives its fibres from the posterior divisions of the L2, L3, L4 nerves. This nerve has both motor and sensory functions. The motor function involves control of iliopsoas and quadriceps muscles and the sensory function involves skin sensation over the medial-anterior shin. The femoral nerve may be involved in open (penetrating injuries) and closed (iatrogenous; neurovascular conflict or idiopathic) injuries in the femoral triangle.

Pathology

All segmentary compressions in nerves are accompanied by a component of ischemia. In front of a progressive or repetitive deforming force, the nerve becomes mechanically ''ribbon like'' [4, 8]. The increase of the intraneural pressure causes a venous slow down with oedema of the affected segment, adding a greater deforming pressure [2, 9]. So, the area affected by oedema is invaded by fibroblasts that will produce a greater epineural and perineural fibrosis.

Olsson [3] has studied the anatomical details of nerve structure which may be the base for fibrotisation processes. Epineurium, is similar to other connective tissue rich parts in the body, and its extracellular fluid is free to diffuse [5]. The walls of the endoneurium are entirely covered by a basal lamina which surrounds the outer plasma membrane surface of the Schwann cells, the endoneurial vessels and the perineurial cells apparently forming a stabilizing structure.

Endoneurial fluid circulation depends on two major forces, net hydrostatic pressure and net osmotic pressure. The lack of lymphatics in nerve fascicles might render the removal of endoneurial fluid difficult [6, 7]. Perineurium creates a fluid environment around the nerve fibres of optimal composition for transmission of electrical impulses [1].

Early and late oedema of the vasogenic type is associated with elevated endoneurial fluid pressure and microcirculatory disturbances. Proliferation of fibroblasts, changes in the composition of the matrix and collagen formation may result in endoneurial fibrosis at the site of the lesion and distal to it. Nerve damage due to an injury may be further aggravated by oedema increasing endoneurial pressure which might compromise blood flow in the fascicles. Fibrosis, either at the site of the primary injury or in the distal part undergoing Wallerian degeneration may be so marked that axonal regeneration and nerve repair are interfered with.

Clinical history and physical findings are the most important factors for diagnosis. To localize the site of the compression, the conduction velocity study by means of EMG and the Tinel sign are used.

Indications for treatment

- Persistence of an irritative syndrome that is not solved within a reasonable period of time with postural treatment and anti-inflammatory drugs.
- Either motor or severe and painful sensitive deficitary syndrome.

The surgical technique is composed of macro and microsurgical procedures.

Materials and methods

We present 30 cases of femoral nerve entrapment (1999–2003, age range 35–65 yrs).

In 20 patients the compression of the femoral nerve was not dependent upon external factors: 13 patients with diagnosis of idiopathic compression and 7 patients with neurovascular conflict. The compression of the other 10 patients was iatrogenic: 3 patients following cardiac catheterization for balloon valvotomy, 2 patients following intra-abdominal vascular surgery and 5 patients following laparoscopic hernia repair.

Surgical technique

We prefer general anaesthesia with intraoperative nerve electrostimulation.

The macrosurgical procedure is performed in order to release the extrinsic cause of the nerve's compression. On the other hand, an objective of the microsurgical approach is the detailed observation of the lesions produced by compression on the surface and within the femoral nerve.

The release of the fibrotic tissue allowed in 7 cases to separate the artery from the nerve, allowing solution of the neurovascular conflict. In these cases deformation of the nerve structure was observed in the site of continuous microtrauma due to vascular pulsation.

Results and conclusion

The outcome was simple with complete motor and pain recovery in the lower limb. The best result has been observed in neurovascular conflict cases.

Sensory recovery was rapid and rather good in iatrogenic cases, and was obtained after 12 months in the "pure" entrapment cases.

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Italian multicentre study of peroneal mononeuropathy at the fibular head: study design and preliminary results

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Summary

Background. The most common entrapment in the lower extremity is peroneal mononeuropathy (PM) at the fibular head. Several studies of this condition have been published but, until now, no wide multicenter clinical-neurophysiological studies on PM are available. In recent years, multicenter studies have been suggested; moreover it is commonly accepted that a multiperspective approach provides more comprehensive results.

Method. The *Italian CTS and other entrapments Study Group* has designed a strict clinical and neurophysiological protocol to carry out a wide multicentre study on PM at the fibular head. In addition to traditional clinical-neurophysiological evaluation, the group has also adopted validated disability and patient-oriented measurements in order to obtain more comprehensive and reliable data about this entrapment. The study was designed: 1) to identify predisposing factors; 2) to better assess the clinical picture; 3) to evaluate relationships between etiological, clinical and neurophysiological findings; 4) to evaluate the natural evolution of the entrapment. Study design is described.

Findings. During the period from November 2002 to January 2004, 69 patients were enrolled consecutively in eleven Italian centres. Our preliminary data show that PM involves men more frequently than women (M : F = 3.9 : 1). With regard to the predisposing factors, PM is idiopathic (16%) or due to surgery (21.7%), prolonged posture (23.2%), weight loss (14.5%), external compression (5.8%), arthrogenic cyst at the fibula (1.4%), trauma (10.1%); it also occurred in bedridden patients (7.3%). Unexpectedly, peroneal nerve lesions were due not only to surgical operation close to the peroneal region, but were also associated with thoracic-abdominal surgery. Usually PM involves both terminal branches; patients complain of motor deficit in 99.5% of cases, sensory symptoms in 87.9% and pain in 19.7%.

Conclusions. Our preliminary results provide some interesting information and confirm the usefulness of multicentre and multiperspective studies to standardise the approach to nerve entrapment.

Keywords: Peroneal mononeuropathy; multicentre study; predisposing factor; patient-oriented; neurophysiology; group.

Introduction

The most common mononeuropathy in the lower extremity is of the peroneal nerve. The common peroneal nerve arises from the sciatic nerve at the popliteal fossa, winds around the fibular neck and then divides into two terminal branches. Both terminal branches may be impaired but the superficial peroneal nerve is usually less involved than the deep peroneal nerve [13].

Electrodiagnostic evaluation is extremely useful: 1) to confirm the clinical diagnosis, 2) to establish the site of the peroneal nerve lesion, 3) to assess the features of the neurophysiological damage and 4) to predict the prognosis and the expected course of recovery [13].

Several studies have described different predisposing factors of peroneal mononeuropathy (PM) [4, 5, 7–12, 15, 20–22] but few data are available on the correlation between the predisposing factors of the lesion

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and clinical-neurophysiological findings [3]. It is commonly accepted that multicentre studies provide a better representative population and, to our knowledge, until now no wide multicentre and multiperspective study on PM has been carried out. This kind of study can contribute useful data to the current attempt to standardise the approach to nerve entrapment [17, 18].

The *Italian CTS and other entrapments Study Group* designed a multiperspective protocol to perform a wide multicentric study on PM. In addition to the clinical-neurophysiological evaluation, the group also adopted a validated disability and patient-oriented measurements in order to obtain more comprehensive and reliable data on this entrapment.

The study was designed: 1) to identify predisposing factors; 2) to better assess the clinical picture; 3) to evaluate the relationships between the etiological, clinical, neurophysiological findings; 4) to investigate the natural evolution of the PM at the fibular head.

Study design

A careful review of the literature was made before developing the methodology plan. The collaboration of the group was carried out according to the recently proposed guidelines for multicentre collaboration and clinical research in neurology [6, 16].

Definition of cases and clinical diagnosis

According to previously reported clinical criteria [23], clinical diagnosis of a probable PM at the fibular head was made when there was weakness, with or without a sensory deficit, in any muscle supplied by the peroneal nerve, with no abnormalities in the distribution of other peripheral nerves in the limb and no historical evidence to suggest lumbosacral radiculopathy, plexopathy, or sciatic neuropathy. Patients with clinical or electrophysiologic evidence of a generalised peripheral neuropathy were excluded.

Definition of centre and data collection

Each centre consisted of a neurophysiological laboratory with the following characteristics:

1) *Staff*. At least one trained clinical neurophysiologist; when possible, a neurophysiology technician should be included in the staff.

2) *Neurophysiological instrumentation*. A commercially available electromyography (EMG) instrument with the following equipment: a) calibration signal output (motor and sensory); b) signal averager; c) electrical stimulator with isolation unit (constant current or constant voltage); d) internal cursor for latency and amplitude measurements; e) hard copy output.

Each centre had to provide at least 5 cases of peroneal mononeuropathy at the fibular head referred consecutively to the laboratory.

Diagnostic procedures and data collection were performed according to the following steps:

1. patient fills in two self-administered questionnaires (patient-oriented data)
2. investigator acquires the patient's personal data and history of pathology and completes a case form
3. clinical examination
4. electrodiagnostic examination
5. disability evaluation.

Patient-oriented evaluation

Two patient-oriented validated measurements, the SF-36 and the NASS, were used.

The *Medical Outcome Study 36-item Short Form (SF-36)* is the most widely used generic health tool [24]. The Official SF-36 Italian version [2] was administered to the patients in agreement with standardised methodologies [25]. SF-36 consists of 36 questions that inquire about the general health status of patients. This questionnaire provides eight specific categories of physical and emotional scores (Physical Function-PF, Role Physical-RP, Bodily Pain-BP, General Health-GH, Vitality-VT, Social Functioning-SF, Role Emotional-RE, Mental Health-MH) which are summed up in two main scores: Physical Composite Score (PCS) and Mental Composite Score (MCS). Very low PCS indicates severe physical dysfunction, distressful bodily pain, frequent tiredness and unfavourable evaluation of health status. Very low MCS indicates frequent psychological distress, and severe social and role disability due to emotional problems.

The *NASS questionnaire analyses* neurological symptom and function of inferior limbs and provides two specific scores: lumbar spine pain/disability (Lpain) and lumbar spine neurogenic symptoms (Lneur). Higher NASS scores (range 0–100) indicate better health. We used the Italian version of the American Academy of Orthopedic Surgeon (AAOS) [1] lumbar cluster self-administered questionnaire [19]

which includes the NASS questionnaire (validated Italian version).

Personal data and patient history

Before examination, the neurophysiologist acquires data for each patient according to a case form.

The form includes the following clinical data: 1) name of the patient (this was immediately replaced with an identification code); 2) sex; 3) age; 4) potential predisposing factors (weight loss, habitual leg crossing or other prolonged posture, recent prolonged hospitalisation for a major illness, surgery operations, trauma or compression at the leg, etc.); 5) concomitant pathology (diabetes, metabolic or toxic diseases); 6) duration of symptoms; 7) type of onset; 8) trend of symptoms; and 9) therapies administered.

Clinical examination

Clinical examination included: muscle strength of knee flexor muscles (biceps femoris, semitendinosis, semimenbranosis), tibialis anterior, extensor hallucis, extensor digitorum, peroneus longus, gastrocnemius (graded using the Medical Research Council); trophysm of the tibio-fibular muscles; light touch and pinprick sensation were tested in the cutaneous distributions of the lateral cutaneous nerve of the calf and in the superficial and deep sensory branches of the common peroneal nerve; moreover, extended neurological examination is always performed.

Electrodiagnostic protocol and methods

Two different electrodiagnostic protocols could be adopted: a ''standard electrodiagnostic protocol'' and a ''detailed electrodiagnostic protocol''. The centres were given this choice of electrodiagnostic approach so as to include centres which otherwise would not have participated because they were unable to apply the more time consuming detailed protocol. This allowed us to have a larger number of participating centres.

The ''*standard electrodiagnostic protocol*'' included:

1) *Motor nerve conduction studies*: Surface recordings were made from two common peroneal-innervated muscles, the extensor digitorum brevis and tibialis anterior. Nerve conduction velocity from the popliteal fossa to the fibular head was always assessed. Moreover, latencies to initial deflection and amplitude (negative phase) of all compound motor action potentials (CMAP) were measured.
2) *Sensory nerve conduction studies*: Sural nerve conduction studies were performed using surface electrodes.
3) *Electromyographic evaluation*: tibialis anterior, peroneus longus and gastrocnemius muscles were examined with a concentric needle electrode. The muscles were examined at rest and during voluntary activation.

In the ''*detailed electrodiagnostic protocol*'', besides the standard electrodiagnostic evaluation, the following tests were also performed: motor nerve conduction study of the peroneal nerve from peroneus longus; sensory nerve conduction study of the superficial peroneal nerve (performed bilaterally); electromyographic evaluation of the short head of the biceps femoris, extensor hallucis longus and gluteus medius.

The following neurophysiological criteria for different pathophysiologic processes affecting the peroneal nerve were used: 1) *conduction blocking*: a drop in CMAP amplitude of more than 50% and in the CMAP area of more than 40% when recorded above or at the fibular neck compared with that recorded distally; 2) *axonal damage*: (a) denervation signs at rest (fibrillation potentials and/or positive sharp wave) and neurogenic recruitment during full effort in the needle EMG evaluation and/or (b) the amplitude of the peroneal CMAP (extensor digiti brevis, peroneus longus, tibialis anterior) was unelicitable, low compared with normal values for age, or relatively low (less than 50%) compared with the corresponding contralateral response; 3) *mixed involvement* (conduction block plus axonal damage): the nerve conduction studies and the electromyography results fulfilled both criteria.

Disability evaluation

To assess disability we used the Deambulation Index (DI).

The *Deambulation Index* is an adapted form (8-point scale) of the physical therapy portion of the Patient Evaluation Conference System.

The 8-point scale is: 0 = not assessed; 1 = needs maximal assistance from 2 people or an assistive device + 1 person; 2 = requires minimal assistance from another person with or without an assistive device; 3 = requires supervision and an assistive device; 4 = requires supervision for safety, no assistive device

needed; 5 = independent but cannot walk at a reasonable rate and/or has poor endurance (i.e., 10 m or less with or without an assistive device). Difficulty ambulating outdoors; 6 = independent with assistive device. No supervision required. Person can ambulate indoors and outdoors under different conditions (i.e. ramp, carpet, curb, uneven surface, any season); 7 = within normal limits, functionally independent [16].

Statistical analysis

Statistical analysis will be performed by using the STAT-SOFT (OK-USA) package.

Kolmogorov-Smirnov and Liliefors probabilities tests are used to assess distribution.

In the case of a normal distribution and interval scale, the correlation is assessed by using Pearson's product-moment correlation coefficient, while the comparison of the groups is performed by using Student's T Test.

In the case of a non-normal distribution or measurement by ordinal or nominal scale, non-parametric analysis of the correlation is assessed by using Spearman's R test and the comparison of the groups is performed by using the U-Mann Whitney test.

In order to evaluate the relationship between two dichotomous variables and to evaluate the difference between two groups in the frequency of one dichotomous variable, the standard Pearson Chi-square test (2×2 table) is performed.

Results

Patient enrolment began in November 2002 and ended in January 2004. A total of 69 cases of PM at the fibular head (67 patients, of whom 2 were studied bilaterally) were consecutively studied in 11 centres distributed throughout Italy (see Fig. 1) with a mean of 6.3 cases per centre. Of the 67 patients, 20.9% were women and 79.1% were men. Age distribution was normal (mean 47.9, SD 20.6, range 11–80 (Kolmogorov-Smirnov $p < 0.10$, Lilliefors $p < 0.01$). The mean age at diagnosis in men (46.6 years) was significantly lower than in women (52.7 years) ($p < 0.000001$).

The patients presented motor deficit in 99.5%, sensory deficit in 87.9% and pain in 19.7% of cases.

An overall involvement of the common peroneal nerve was observed in 62 cases (89.9%), an involvement of deep peroneal nerve was observed in 6 cases (8.7%), and an exclusive involvement of the superficial peroneal nerve in 1 case (1.4%).

Fig. 1. Geographic distribution of the 11 participating centres of the Italian CTS and other entrapment study group

Dr.ssa I. Aprile, Roma
Dr. A. Colleluori, Milano
Dr. A. Insola, Roma
Dr. A. Morini, Trento
Dr.ssa D. Murasecco, Perugia
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Dr.ssa G. Bogliun, Monza
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Dr. M. Mondelli, Siena
Dr. L. Padua, Roma

Thirty-four PM were right and 35 left.

As previously reported, in most cases (84%) a clear predisposing factor was identified [3].

With regard to the predisposing factors, PM was frequently perioperative (21.7%): 4 out of 15 cases underwent hip prothesis surgery, 3 cases tibia osteotomy, 3 cases coronarography, 2 cases abdominal surgery, 1 case thoracic surgery, 1 case thyroid surgery and 1 case prostate surgery. In all cases, on the basis of clinical history and examination, we could surely ascertain that the nerve impairment started immediately after surgery.

Prolonged posture preceded the onset of symptoms in 23.2% of cases, while PM was due to rapid weight loss in 14.5% of cases (we considered in this group patients with weight loss greater than 5 kg in 1 month). PM was due to trauma in 7 cases (10.1%), to prolonged bedridden state in 5 cases (7.3%), to external compression from casts in 4 cases (5.8%) and to arthrogenic cyst at the fibula in 1 case (1.4%).

Discussion

Several articles have described cases of peroneal mononeuropathy (PM) [4, 5, 7–12, 15, 20–22] but few data are available on the correlation between the predisposing factors of the lesion and clinical-neurophysiological findings [13] and no data are reported on multicentre studies. It is commonly accepted that multicentre studies provide a better representative population and can contribute useful data to the current attempt at standardising the approach to nerve entrapment.

The group designed a multiperspective protocol with clinical-neurophysiological, disability and patient-oriented measurements. The use of a patient-oriented evaluation made it possible to obtain a standardised clinical picture (standardisation is one of the most important advantages of this kind of measurement, which in turn facilitates wide and multicentric studies) and to compare clinical-instrumental objective findings with the ''voice of the patient''.

The preliminary results showed that PM is more frequent in men than women. As previously reported, sensory manifestations were common (87.9%) but pain was rare (19.7%) [12]. In most cases an overall involvement of the common peroneal nerve was observed (89.9%); an involvement of the deep peroneal branch alone (8.7%), or an exclusive involvement of the superficial peroneal nerve (1.4%) was rare.

With regard to the predisposing factors, this study confirms our data previously published: in most cases of peroneal mononeuropathy (84%) a clear predisposing factor can be identified. PM was frequently perioperative (21.7%). Unexpectedly, peroneal nerve lesions were due not only to surgical operation close to the peroneal region but were also associated with hip, cardiac or thoracic-abdominal surgery [3].

In conclusion our preliminary results provide some interesting information and confirm the usefulness of multicentre and multiperspective studies to standardise the approach to nerve entrapment.

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Entrapment of crural branches of the common peroneal nerve

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Summary

Failed back surgery syndrome (FBSS) occurs in 30% of operated patients and represents a heavy problem both regarding disability and costs in first world countries. Among FBSS we found the possibility of a double crush syndrome: a disco-radicular conflict and a peripheral nerve entrapment. The latter, disguised by root compression symptoms, becomes evident only after spinal surgery. Clinical features are the same as for the restless leg syndrome. We found peroneal nerve crural branches entrapped where they crossed the fascia to reach the subcutaneous layer. Venous stasis during immobility caused presentation of symptoms. Neurolysis was performed, all cases were successful. Most of the patients were found to have myofascial pain syndrome (MPS). MPS patients "feel" entrapments more frequently than others not because of their specific pain tolerance but because they are more prone to develop them.

Keywords: Crural branches; peroneal nerve; entrapment; failed back surgery syndrome; lumbar disc hernia; myofascial pain syndrome; trigger point; neurolysis; restless leg syndrome.

Introduction

Failed back surgery syndrome (FBSS) occurs in 30% of operated patients and represents a heavy problem both regarding disability and costs in first world countries. Patient's complaints may have different causes. Some of them are not really correlated to surgical treatment (the psycho-socio-economical syndrome with pain gain adverses patient's recovery). Others certainly are connected with surgery. The neuropathic pain from nervous damage occurring during surgery, the musculo-skeletal pain from post-surgery instability syndrome, the neural compression pain by remnants of hernia. Malpractice also includes wrong surgical indication. Often surgery is not mandatory and does not tackle the real back pain conundrum. In fact, in the majority of cases, the disco-radicular conflict is overrated and FBSS originally was a myofascial pain syndrome. All these causes of FBSS have thoroughly been described and discussed in previous studies but we think that another one should be considered. We name the possibility of a double crush syndrome, a disco-radicular conflict, and a peripheral nerve entrapment. The latter, disguised by root compression symptoms, becomes evident only after spinal surgery.

Materials and methods

Of 300 patients operated on for lumbar disc hernia in a time period of three years in our clinic, three patients referred specific pain syndrome after surgery. Symptoms were of lower grade intensity with different temporal and spatial patterns than pre-operatively. Pain, rather described as annoyance, was vaguely distributed to the lateral part of the leg and temporarily resolved by movement. It was not worsened by coughing but by extended knee manoeuvre. Long standing posture in orthostatism and clinostatism were disagreeable to the patients. In bed most had difficulty with induction of sleep. Clinical features were the same as for the "restless leg syndrome" but they were bilateral in one case. In the remaining two cases the annoyance-pain was located at the same side of the precedent L5 compression. Exquisite tender point behind femoral biceps tendon. Erratic trigger point in this area for paresthesias on the lateral region of the leg. We based our assessment on MacKinnon's description of peroneal nerve's crural branches entrapment and explored the trigger area. We found the crural branches and performed their neurolysis. Distally we also enlarged the Hirsch's canal until the nerve became divided into its three terminal branches. Operations were performed under local anaesthesia, both legs were operated in one case. All cases were successful.

Discussion

Peroneal nerve's crural branches entrapment (firstly described by MacKinnon) can be disguised as FBSS and must not be overlooked. Restless leg syndrome (known everywhere: "unruhige Beine", "jambes sans repos") is accredited to a widely accepted pathogenesis. It originates from a cryptic polineuropathy

and its only confounding borders are with Parkinson's acatisia. Nevertheless, the hypothesis of a polineuropathy is no alternative to a nervous entrapment. Metabolic and carential pathologies, alcohol, diabetes increase the risk of entrapment by damaging both myelin and axon. The same mechanism comes into play when a proximal neural compression occurs (C5–C6 arthrosis is very common and is surely related to carpal tunnel syndrome in harming the sixth spinal nerve). Both factors, spatial conflict and poor metabolic condition, concur for development of nerve entrapment. If the restless leg syndrome is unilateral, the spatial factor would be predominant on the metabolic one and vice versa. We also believe that this syndrome is strongly related to the patient's chronic poor posture because myofascial pain syndrome (deriving from the latter) is often associated with multiple nervous entrapments. In this particular case, nervous entrapment originates from its adherence to fascial foramen borders. The above mentioned foramens are formed at the meeting point of soleal and bicipital fascias. Peroneal nerve crural branches cross the fascia to reach the subcutaneous layer. Venous stasis during immobility causes presentation of symptoms. This is the reason why the patient is impaired to fall asleep. The patient is restless with his legs, continuously moving them. The target of movement is the angle of the knee. The fascial foramens change their shape when this angle is changed. With extended knee, foramens are a slit, with flexing knee, foramens are a circle. In this changing process venous drainage is temporarily improved and endoneural pressure goes down. The clinical result is a long period of alternate movements before sleep. We had already noticed frequent clinical hints in connection with this entrapment in myofascial pain syndrome patients. At first we thought that a certain nervous irritation, sublime for healthy people, could be evident in the respective individuals because of a supposed diminished pain tolerance. We changed our mind when it was noticed that not only this entrapment is more frequent in ''myofascial'' patients but is also frequently associated with the entrapment of the lateral femorocutaneus nerve. For the latter, there is a typical target-like anaestethic-ipoaestethic area on the lateral side of the thigh, independent of pain. In normal patients entrapment accompanying pain and autonomic dysfunction could be found in 50% of patients. In MPS patients, with more frequent entrapments, we have the same percentage of pain-free entrapped patients. Therefore MPS patients have not at all a lesser pain tolerance than others. To sum up, myofascial pain syndrome patients ''feel'' entrapments more frequently than others not because of their specific pain tolerance but because they are more prone to develop them. It is their chronic poor posture rather than their supposed poor pain tolerance that is responsible for high entrapment frequency. The link between MPS (and other pararheumatic syndromes: fybromialgia, fibrositis primaria) and nervous entrapment has to be found in a cryptic psychophysical diathesis. Its expression is the chronic poor posture. This latter gives a boost to the connective overgrowth, most when the patient is coping with some injury. Despite back surgery with successful removal of neural compression, a fascial contracture can last forever. In the follow-up a nervous entrapment could become evident. Prolonged contracture would cause connective hypertrophy and nerve entrapment as a result of adherences between the nerve and its surrounding fascias. The paraneurium with its gliding property is the first component of the nerve at risk. The pathomechanism is neural distraction more than neural compression. Biochemical dysfunctions due to excess in lactic acid and concentration of other substances might be involved. Our hypothesis would also explain hypertrophic scars found in FBSS. They would not be the cause of FBSS but the result of prolonged antalgic muscular contracture (the ''frozen back''). Since all patients with lumbar disc hernia have an ''antalgic'' chronic poor posture, they may be suspected of having a nerve entrapment (more easily on the same nervous fibre in double crush kind). This entrapment is asymptomatic as long as radicular pain persists. Once radicular epicrithic pain has been removed, peripheral nerve entrapment pain appears (protopathic and slowly transmitted), disinhibited by central modulation. This is what we call a misinterpreted FBSS.

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Part II: Minimal invasive spinal surgery

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Percutaneous cervical nucleoplasty using coblation technology. Clinical results in fifty consecutive cases

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Summary

Conventional open cervical discectomy, with or without bony fusion, in common neurosurgical knowledge is considered the standard treatment for cervical disc herniation. Percutaneous procedures are minimally invasive and offer decreased morbidity, require no bone graft and promise shorter recuperation time. Nevertheless, candidates for a percutaneous procedure as inclusion criteria must complain of symptoms related to contained herniated disc or focal protrusion. It does not substitute conventional open procedures required for extruded discs. We used the coblation technology for nucleoplasty of the cervical intervertebral discs. Early and long-term effects and/or complications observed with this procedure have not been reported yet. Fifty consecutive patients presenting with contained herniated cervical disc or focal protrusion causing compression of the cervical roots or cervical pain underwent a nucleoplasty procedure on the pathological disc. A randomized control group of twenty patients was treated conservatively with medical and physical therapy in the same period and completed the identical *follow-up form*. In the nucleoplasty group results were complete resolution of symptoms in 80% of cases, only 10% referred some residual cervical or radicular pain and are still under *follow-up* with a *wait-and-see* prospective. Patients who did not have a clinical resolution were treated with alternative traditional methods (10%).

Despite the relative low cases number and the limited *follow-up* the encouraging results induce us to utilize this technique in well-selected cases.

Keywords: Nucleoplasty; coblation; percutaneous; cervical; disc.

Introduction

For more than five decades despite various disadvantages, open nucleotomy has been a beneficial treatment for prolapse of the intervertebral disc. Hence minimally invasive treatment for vertebral disc diseases has increasingly been applied in the last three decades, starting with chemonucleolysis, followed by endoscopic nucleotomy, automated draw-off nucleotomy and percutaneous mechanical nucleotomy. However these methods are limited. Choy and Ascher experimentally produced the non-endoscopic percutaneous laser disc decompression and nucleotomy with good results, beneath its potential complications regarding the high level of temperatures reached.

Conventional open cervical discectomy in common neurosurgical knowledge, with or without bony fusion, is considered the standard treatment for cervical disc herniation. However, open discectomy with fusion is associated with significant local inflammation, graft donor site pain (when autologous bone graft is used), and lenghty period of convalescence. Percutaneous procedures are minimally invasive and offer decreased morbidity, require no bone graft and promise a shorter recuperation time.

Nevertheless patient candidates for a percutaneous procedure as inclusion criteria must complain of symptoms with regard to contained herniated disc or focal protrusion. It does not substitute conventional open procedures required for extruded discs.

Percutaneous decompression for treating lumbar disc herniation is a well-established technique which has demonstrated good clinical success in properly selected patients.

Plasma-mediated electrosurgery, used in other medical fields [4, 5], has proven useful for this application. Two independent outcome studies by Sharps and Isaac [2] and Singh and colleagues [3] have shown statistically significant reduction in pain up to one-year after percutaneous disc decompression using plasma-mediated electrosurgery (nucleoplasty) in the lumbar spine. Chen *et al.* [1] experimentally demonstrated in cadaveric specimens that intradiscal pressure is reduced following a decompression procedure using the coblation technology.

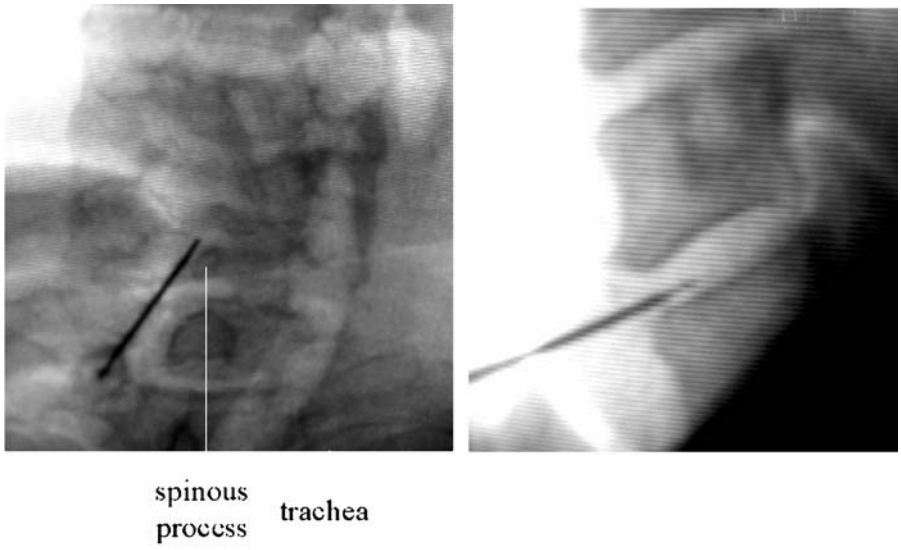


Fig. 1. Intraoperative fluoroscopic imaging in antero-posterior and lateral views during needle introduction. Appropriate positioning of the needle within the nucleus in the C5–C6 level

Nevertheless, early and long-term effects and/or complications observed with this procedure on the cervical spine have yet remained unreported. Objective of this study was to prospectively evaluate the effects and complications observed with nucleoplasty in the cervical spine as compared to conservative medical and physical treatment.

Materials and methods

From January to September 2003 fifty consecutive patients who reported having contained herniated cervical disc or focal protrusion causing compression of the cervical roots or cervical pain underwent a nucleoplasty procedure on the pathological disc. A randomized control group of twenty patients was treated conservatively with medical and physical therapy in the same period and completed the identical *follow-up*.

Inclusion criteria for the nucleoplasty procedure were disc protrusion or contained herniated disc not larger than 3 mm and not compromising more than 1/5 of the central spinal canal demonstrated on a magnetic resonance imaging (MRI). All patients reported to have persistent cervical or unilateral arm pain for a minimum of three months and had failed previous conservative treatment. Patients affected by spinal fractures, acquired stenosis, tumor, advanced spondylosis resulting in osseous foraminal stenosis or disc space collapse or with previous spinal surgery on the same level were excluded from this procedure. Presence of a radicular deficit, such as hypoesthesia or objective motor deficits or hyporeflexia were candidates for open procedure excluding nucleoplasty. Paresthesias were frequently associated with pain.

The Perc-DC SpineWand 126 mm connected to a System 2000 generator (ArthroCare Corp., Sunnyvale, CA, USA) was used to perform the nucleoplasty procedure. The device functions via plasma-mediated (coblation) electrosurgery, which fundamentally differs from traditional electrocautery and other thermal methods utilized for tissue treatments. Plasma-mediated electrosurgery uses high voltage, between 100 and 300 Volts depending on the controller setting selected, across the active and return electrodes of the device. When combined with an electrically conductive fluid (e.g. isotonic saline), the interaction creates an ionized vapor layer, or plasma, approximately 75 μm thick. Charged particles in the plasma are accelerated by the intense electric field within the plasma and carry enough energy to induce molecular dissociation, as opposed to the thermal denaturation attributed to standard electrosurgical tools. With plasma-mediated electrosurgery, a precise pathway can be produced with minimal thermal penetration into surrounding tissue. The diameter of the active tip of the Spine Wand is 0.8 mm.

The nucleoplasty procedure was always performed under intravenous sedation (Fentanyl and Propofol) with facial mask (oxygen 40%, air 60%, sevorane MAC 0,81%) via a medial approach to the sternocleidomastoideus muscle in an oblique right anterior direction to the target disc. Fluoroscopic imaging was used during the insertion of the introducer needle (19 gauge, 7,6 cm length) and wand placement with antero-posterior and lateral views. The needle was introduced until the annulus/nucleus junction was reached, the stylet was then withdrawn and replaced by the SpineWand. The wand was advanced until its tip was extended approximately 5 mm beyond the tip of the needle, which ensured that the active portion of the wand was deployed into the annulus when activated (Fig. 1). A short initial coagulation was performed when the wand was inserted, the ablation used three cycles of 8 seconds rotating the tip of the wand for 180 degrees each when withdrawal was started, the controller setting of 125 Volts caused a thermal reaction of 52 °C.

Patients were discharged 24 hours later with instructions for *follow-up* visits and placed on a standard rehabilitation program as routine following interventional spinal procedures.

Clinical status was recorded immediately postoperatively, 24 hours, 7 days and 60 days later. All patients were also asked to perform a visual analogue scale (VAS) from pre operative until their last *follow-up*. Changes in outcome measures were evaluated with Students T-test for coupled data.

Results

Nucleoplasty group

Fifty patients underwent a cervical nucleoplasty procedure for radicular unilateral or cervical pain derived from pathologic disorders of the cervical spine such as protrusions or contained herniated discs. A total number of 54 procedures were performed (4 on two adjacent levels). The C4–C5 disc level was treated in 12 cases (22%), C5–C6 in 33 (61%) and C6–C7 in 9 (17%) with the procedure described above. All patients were immediately mobilized and dismissed within 24 hours, antibiotic prophylaxis with a common cephalosporin was given in all cases.

In the immediate post-operative period and after 24 hours clinical status was almost similar to preoperative with a low percentage of patients referring amelioration of symptoms (20%).

In the precocious *follow-up* visit (one week later) 38 patients (76%) reported complete resolution of symptoms (mean VAS under 3,5), 7 patients observed a satisfactory amelioration of symptoms (14%, mean VAS varying from 3.5 to 4.8) and in 5 patients the intervention did not change clinical status (10%). In particular, patients treated on two adjacent levels had a resolution of symptoms in 3 cases (75%), one did not present amelioration of symptoms.

In the last *follow-up* (60 days) we observed a stabilization of the clinical results confirming the quota of patients with complete resolution of symptoms (40/50, 80%), only 5/7 patients (10% of all) referred some residual cervical or radicular pain and are still under *follow-up* with a *wait-and-see* prospective. Patients who did not have a clinical resolution remained stable and a month later were treated with microdiscectomy (4 cases, 1 on two adjacent levels) and with a selective analgesic treatment with Naropine and Cortisonics of the involved root (1 case).

Two patients (4%), one initially classified as complete resolution and the other one as partial, returned to our observation 3 months later declaring worsening of symptoms, MRI of the cervical spine documented persistence of the herniated disc. For these cases a microdiscectomy was proposed.

Mean *follow-up* was 3,8 months (varying from 2 to 9) and an MRI examination of the cervical spine was performed in all cases at the 4-month *follow-up*. Regression of the herniated disc shown on the MRI was confirmed in those cases with prolapsed disc and clinical resolution (Figs. 2, 3). On the other hand, when disc protrusion was the cause of persistence of symptoms, the MRI did not show a significant resolution. Nevertheless clinical improvement induced us to continue in a *wait-and-see stand-by* (see Table 1).

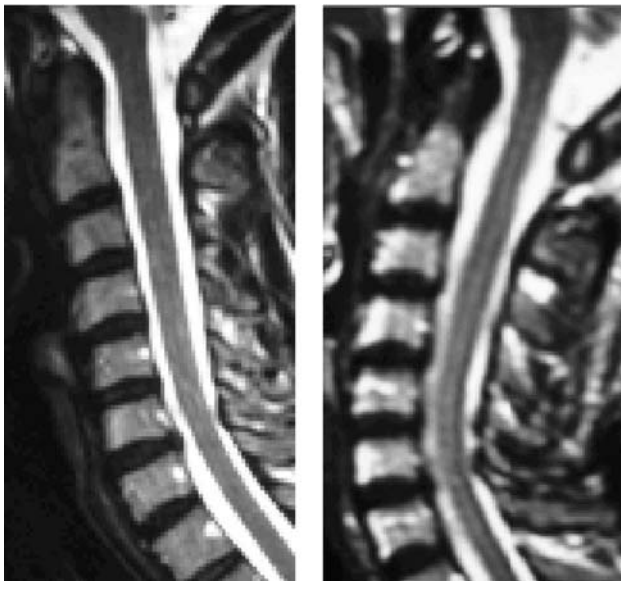


Fig. 2. Magnetic Resonance Imaging, T2 sagittal reconstruction, of the cervical spine in a young woman affected by a cervicobrachialgic pain. Preoperative imaging is shown on the left of the figure and post operative on the right. Cervical disc protrusion is evident at C6–C7 level. Nucleoplasty was performed with resolution of symptoms. On the post-operative MRI regression of the protruded disc is shown

Patients treated with nucleoplasty and having a complete resolution of symptoms returned to work after a period varying from 15 to 36 days (mean 21).

Control group

Twenty patients affected by cervical or unilateral arm pain secondary to a contained herniated cervical disc were treated conservatively for a minimum *follow-up* of three months (min. 3, max. 6, mean 4). No patients were affected by double space pathology. Medical therapy consisted of anti-inflammatory drugs and cortisonics for a period between 20 to 45 days, physical therapy included wearing of a Schanz collar for at least 30 days. All these patients were referred to a neurologist for *follow-up* as a random and "double blind" study.

At the first *follow-up* visit (one week later) 12 patients (60%) reported no change in their clinical status, 5 (25%) observed a sharp amelioration in pain and 3 (15%) had good results with the therapy. At the last

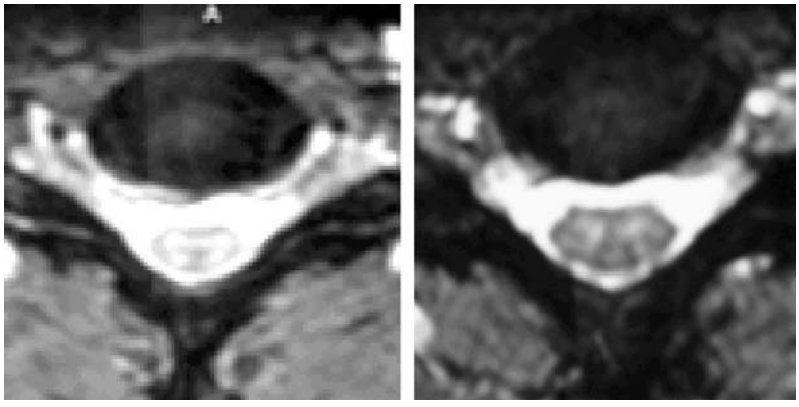
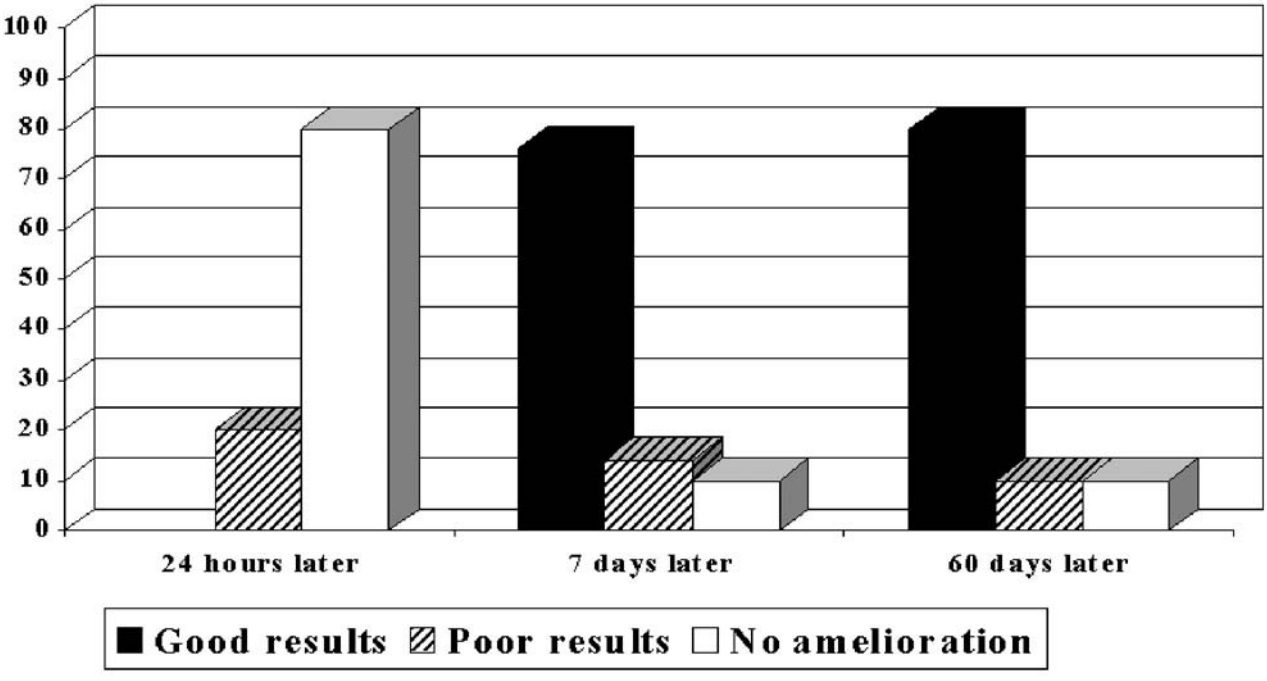


Fig. 3. Magnetic Resonance Imaging, T2 axial reconstruction of the same case as in Fig. 2. Resolution of the disc protrusion is shown

Table 1. *Clinical results. Nucleoplasty group*



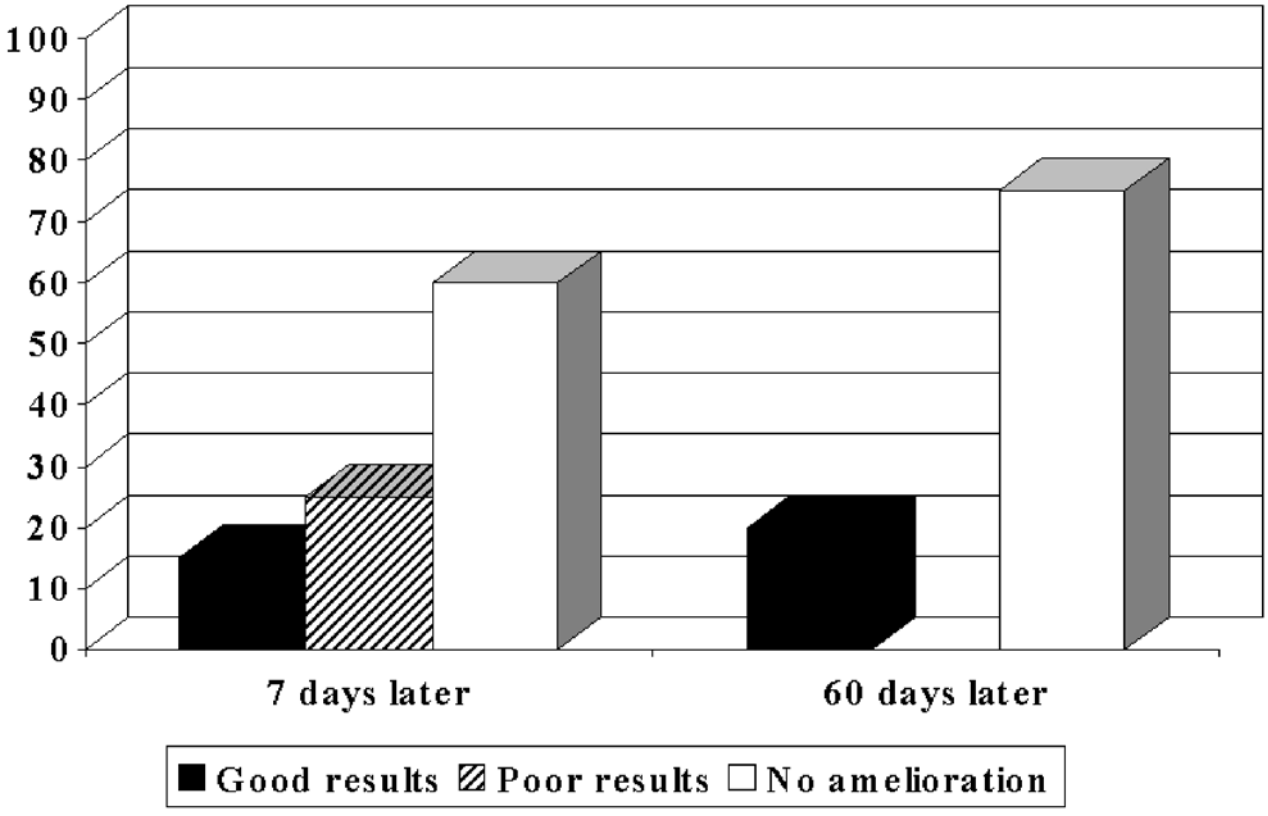
follow-up (60 days) 15 patients (75%) returned to our observation because of persisting symptoms of cervical or radicular pain, 4 patients (20%) reported complete wellness and healthy status and were submitted to a physical rehabilitation program, one patient (5%) refused prosecution of medical therapies and preferred to be followed by another center, a traditional microdiscectomy was then performed and the patient was considered as *lost at last follow up* (see Table 2). All patients repeated MRI at 3-month *follow-up*. No spontaneous regression of disc prolapse was observed, confirming it as rare incidence in cervical spine.

Patients treated conservatively returned to work after a period varying from 25 to 50 days (mean 46), nevertheless persistence of symptoms revealed their wellness to be very limited and healing could not be defined as complete.

Technical notes

Technical difficulties were encountered at the time of needle introduction into the C6–C7 space in brachytypical patients secondary to the scarce fluoroscopic visualization of the intervertebral disc, also in

Table 2. *Clinical results. Control group*



some cases where an anterior osteophyte or calcification of the anterior longitudinal ligament was present.

Discography with iodate contrast was not performed and no intraoperative prognostic indicators, such as the provocative discography, were described regarding clinical results.

No patients had the same operation again. No complications such as hemorrhages or infections were observed.

Discussion

The low temperatures used during the coblation technique is one of the most important factors for the low percentage of possible complications during surgery when compared to other methods. The three channels created with the ablative energy of the wand allow an internal decompression of the target disc with secondary reduction of intradiscal pressure.

Spontaneous regression of herniated disc is a common natural history in lumbar spine; in cervical spine this incident is rare and respective reports are few. The control group of this study confirms the importance of nucleoplasty and the non-relevant role of conservative medical or physical treatments.

The rate of patients who returned to normal quality of life and work is almost double for patients operated on with nucleoplasty than for those treated conservatively.

Clinical improvement is not always followed by complete regression of the herniated disc on MRI, nevertheless the *follow-up* confirms stabilization of recovery and clinical healing.

Statistical analysis of these data confirmed the clinical results revealing a significant improvement in percentage of patients treated with nucleoplasty ($p \leq 0{,}001$) as if compared to the control group where clinical resolution was not always reached ($p = 0{,}172$).

The possibility for the surgeon to observe neural tissue or vascular damage is almost zero.

In spite of the relatively low case numbers and the limited *follow-up* the encouraging results induce us to utilize this technique in well-selected cases.

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Intradiscal injection of oxygen-ozone gas mixture for the treatment of cervical disc herniations

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Summary

For disc herniations the use of open surgical approaches is reduced since new percutaneous methods allowing shrinkage of the disc and improvement of the radicular function are gaining interest. Studies on the spontaneous disappearance of disc fragments have demonstrated autoimmune responses with a chronic inflammatory reaction. Also radicular pain has been shown to be mostly due to biochemical mechanisms [10]. Researchers in different fields surprisingly noticed that a brief, calculated, oxidative stress by ozone administration may correct a persistent imbalance due to excessive, chronic oxidative injury [4]. Oxygen-ozone gas injection in painful patients has a dramatic effect on clinical symptoms. On these bases the intradiscal injection of oxygen-ozone gas has been conceived [1, 7, 9]. We report the treatment on a series of patients affected by cervical disc pathology, treated by intradiscal injection of oxygen-ozone gas mixture. The effects both on pain and on radicular dysfunction are impressive. The morphological effect of the treatment was also evaluated by pathological examination.

Keywords: Intradiscal injection; disc herniation; oxygen-ozone.

Introduction

In cases of radicular dysfunction due to discal-radicular conflict, the classical surgical treatment by open surgery has shown to entail a number of complications or of partial results. Neurosurgeons have always been searching for a method that allows shrinkage of the herniated or protruded disc in order to solve the problem of severe pain and dysfunction found in an enormous amount of patients. Thus a number of percutaneous non-invasive techniques have been conceived with the aim to remove or provoke shrinkage of the discal tissue. The common principle of these techniques is that of acting directly on the discal structure without access to the spinal canal. This drastically reduces the epidural formation of scar tissue, which may lead to compression of the nerve root and adherence to the moving bones. In the last years percutaneous techniques applied in the lumbar area have become increasingly the subject of research with regard to the various aspects of disc pathology and the possible solutions of the problem. Studies on pain originating from this pathology show that it may be due to biochemical mechanisms of acid intoxication of the nerve, which may be somehow independent from the mechanical problem but may result either from an autoimmune reaction, producing a chronic inflammatory response engendering an acid environment, or a situation of ischemia [10]. These problems may be solved by biochemical treatment, reducing the need for surgical intervention [1–3, 7]. On the other hand, the mechanism of disc shrinkage and elimination of herniated fragments have carefully been studied and the development of an autoimmune response against a "non-self" material, leading to a chronic inflammatory reaction has been demonstrated [6].

The mixture of oxygen and ozone gases has been employed in medicine since the 30s for the treatment of pain and dysfunction in patients affected by thrombotic and ischemic diseases. After decades of experience in these fields, the empirical observations of powerful and long lasting effects of this gas mixture injected in paravertebral muscles for the treatment

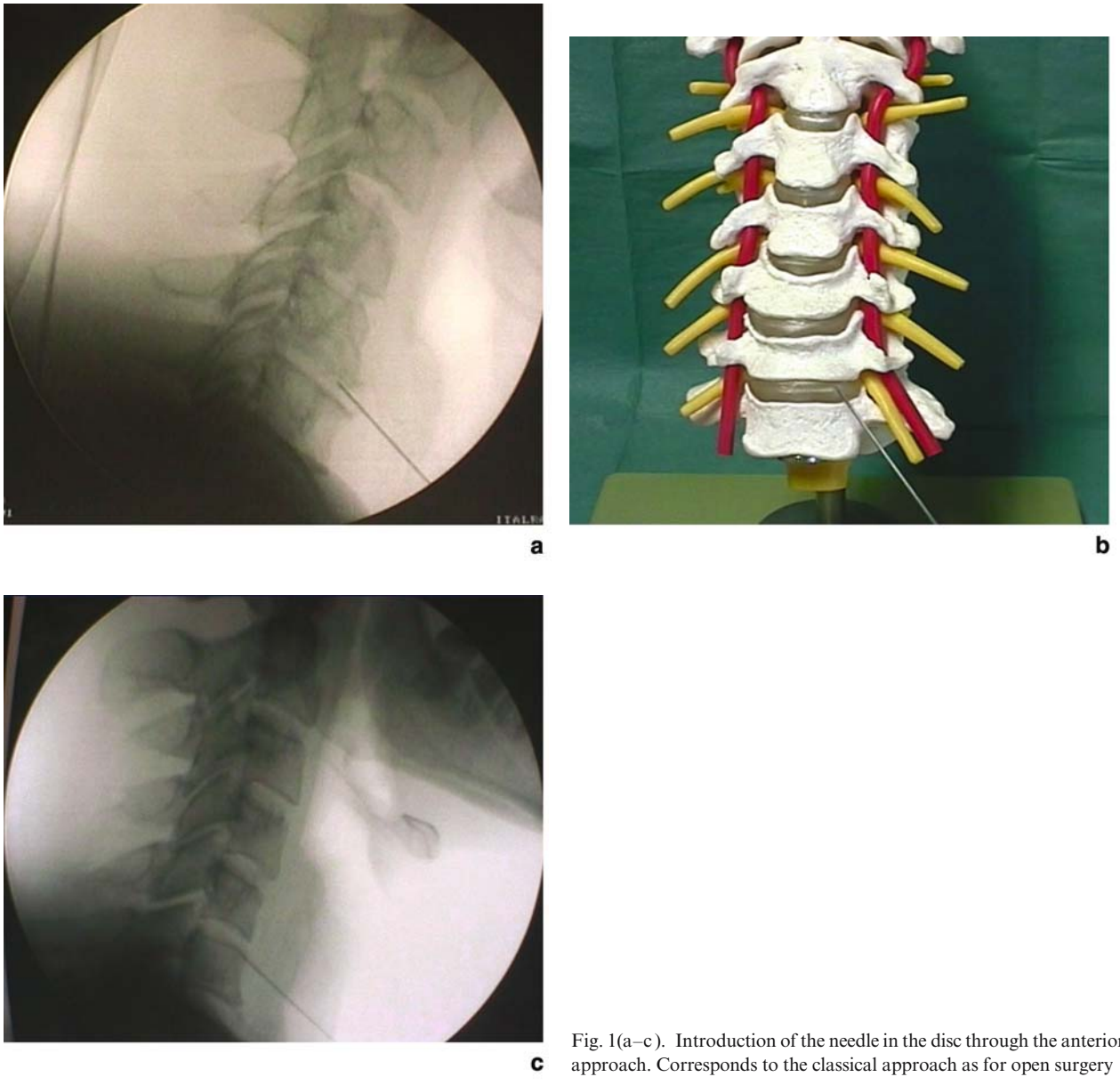

Fig. 1(a–c). Introduction of the needle in the disc through the anterior approach. Corresponds to the classical approach as for open surgery

of pain and radicular dysfunction due to a discal-radicular conflict have led to detailed studies on the subject. Working in different fields, researchers surprisingly noticed that a brief, calculated, oxidative stress, achieved by ozone administration, may correct a permanent imbalance caused by excessive or chronic oxidative injury. It has evolved that modest, repeated ozone treatment increases the activity of superoxide dismutase, catalase, and glutathione peroxidase, inducing a state of oxidative stress adaptation with very important therapeutic implications [4]. The mixture is produced by an apparatus (ozone generator) which activates the molecules of diatomic oxygen in a voltaic arch. Ultraviolet spectrophotometry allows a precise quantification of ozone percentages in the obtained mixture. Jacobs in 1982 reported [8] the absence of side effects in over five million ozone therapy sessions for different pathologies. The paravertebral intramuscular treatment produces pain relief in the majority of patients, together with decongestion, reabsorption of oedema and increased mobility. This has triggered the idea of injecting the oxygen-ozone mixture in the intervertebral disc and the conjugation foramen in order to obtain a powerful effect directly on the pathological mechanism [1, 7, 9]. Recently application of these gases has been used also in cervical disc pathology.

Patients and methods

From 1997 to 2003, a total of 252 patients were treated by intradiscal oxygen-ozone (0_20_3) injection for cervical disc disease in the different centres participating in this study. Mean patient age was 38 years, 47% were males. Each patient underwent clinical and electrophysiological and neuroradiological investigation in order to establish a precise diagnosis. In each case the presence of a disc herniation was demonstrated. In 67 (39.8% of cases) multiple level herniation was observed. Patients affected by cervical spinal canal stenosis, discarthrosic processes, osteophytes or concomitant CSN pathologies were not included in the series. Patients enrolled had received pharmacological and physical therapy without remedial of the clinical picture. The perspective of solving the problem reducing drug administration and without conventional surgical treatment was offered to the patients who consented after detailed explanation. Dexamethasone administration, if pre-existing, was interrupted when starting 0_20_3 injection. It was never associated with 0_20_3 treatment. Non steroid drugs were allowed, if occasionally needed. The treatment consisted of an intradiscal injection of 0_20_3 preceded and followed by 5 paravertebral injections.

- paravertebral injection consisted of administration of 20 ml of 0_20_3 at 10 micrograms/ml concentration, divided into 2 sites of injection: in the paravertebral muscles bilateraly, in the methameric level of the pathology.
- intradiscal injection is performed via the classical anterior cervial approach. Its execution requires operative room equipment, allowing safe asepsis and anaesthesiologic tools, a radiological apparatus for direct vision of the spine, and the source of the oxygen-ozone mixture. Two to three ml of gas are injected, at 20 micrograms/ml concentration.

Results

1. Among the 252 patients pain symptomatology was completely abolished in 79.3% (200 patients), amelioration was obtained in 9.9% (25 patients) and the result was poor in 10.7% (27 patients).
2. Sensory dysfunction was abolished in 78.1% (197 patients) and improved in 16.6% (42 patients). This makes a total of 94.7%. Dysfunction remained unchanged in 5.1% (13 patients).
3. Various degrees of motor dysfunction were present in 78.9% of our 252 patients, i.e. 199 cases. In the great majority of cases it was the question of a mild strength defect and was particularly evident when compared to the non-affected side. The motor defect had pre-existed with a mean pre-duration time of 14 days. Among the total group of 252 patients we observed complete regression of motor deficit in 61.9% (156 patients), partial in 21.4% (54 patients), and insufficient in 13.4% (34 patients). This means a total of positive results in 83.3% of cases.
4. Multiple level disc pathology was present in 67 patients. The treatment was performed simultaneously in all pathological discs. The results obtained do not differ from those obtained for single level pathology.
5. Patients underwent CT/MRI control 7 months after treatment. In 39.6% (100 cases) we observed a significant reduction in volume of the hernia, but correlation with clinical signs was not statistically significant.

Discussion

Experimental models suggest that material from the nucleus pulposus may act as a chemical or immunologic irritant to the nerve and that these mechanisms may produce inflammatory response [10]. Up to now, studies have hypothesized that injection of such a powerful oxidant such as ozone induces overexpression of antioxidant enzymes, which neutralise excessive reactive oxygen species (ROS) formation [4]. Ozone seems to reactivate immune system response. Several investigations have demonstrated that modest, repeated ozone treatment increases the activity of superoxide dismutase, catalase, and other enzymes for antioxidant defence.

After intradiscal injection, ozone can accelerate the degradation of proteoglycans in the degenerated nucleus pulposus, leading to its reabsorption and dehydration with the consequent reduction of herniated material responsible for nerve root compression [3, 4]. In our opinion, the most important aspect is the biochemical modification of the medium in the extradural space. Studies on pain, which often is disproportionate to the morphological evidence of discal-radicular conflict, have demonstrated that it is provoked by the presence of acid metabolites coming from the degenerative processes inside the disc, and from ischemia of the nerve root and of the ganglion. In the 90s attention was brought to A2 phospholipase. Saal demonstrated that A2 phospholipase is the cause of radicular pain, independent of the immunological response or a direct inflammatory process [10]. A2 phospholipase is responsible for the arachidonic acid liberation, and hence prostaglandines. High levels of A2 phospholipase have been demonstrated in herniated discs. Ozone injected in the disc and in the peridural space of the conjugation foramen and along the posterior longitudinal ligament acts as a powerful stimulus to the activation of antioxidant defence, favouring the normalisation of redox balance with neutralisation of acidosis, increased synthesis of ATP, Ca2+ reuptake and resolution of oedema [4, 6, 10]. The complete bio-

chemical mechanism is not yet understood, but there is strong clinical evidence that the effect is dramatic, and long lasting. Benefit is rapidly obtained on pain, and on nerve dysfunction, with progressive reduction of tingling. EMG controls have confirmed the recuperation of nerve function. We presume that this is achieved by amelioration of nerve ischemia.

Injections even in cases of extruded cervical disc pathology were performed and had good results. This is probably due to the fact that the isolated fragment is separated from normal tissues, has higher tendency to dehydration, and a degeneration process is engendered in the course of time.

Much remains to be done, but the possibility of treating patients by an easy method which is rapidly effective for solving clinical problems is at hand. This treatment is useful in patients who did not respond to physical therapy and conventional pain therapy, as a last step in conservative treatment before taking the decision of open surgery. Most of these patients will not need more surgery anymore, since ozone may act directly on the cause eliminating clinical symptoms. The target of the doctor must be to solve clinical problems, not to correct a morphological aspect of a radiological image. This technique is simple, has no risks, offers to the patient a solution without the discomfort of surgery and the possible risks it entails.

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Percutaneous nucleoplasty for discoradicular conflict

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Summary

Minimally invasive techniques for the treatment of degenerative pathology of the spine have come to be preferred by surgeons since the destructive effect on bony structures is eliminated and scar formation is dramatically reduced. A critical review of the pathogenetic mechanisms for low back pain and sciatalgia has recently yielded that mechanical compression is one but non essential component of the matter. The importance of chemical irritative processes is stressed. Coblation nucleoplasty is one of these minimally invasive techniques. It provokes ablation of the nucleus of the disk by a controlled thermal effect produced by radiofrequency. By this procedure one to two ml of tissue are colliquated in a few minutes. From February 2001 to May 2003 we treated 1390 patients for of lumbosciatalgic pain caused by disc pathology. The alteration consisted of disc bulging or contained disc herniation. Exclusion criteria as provided by the protocol of the multicentric study conceived by Conor O'Neill have been respected. This technique has been conceived in order to obtain progressive results in cases of contained disc herniation which has scanty natural tendency to shrinkage, as demonstrated by several studies on the natural history of evolution of this pathology. Contained disc herniation is a pathology most difficult to manage by conservative procedures, physiotherapy and drugs, but we all agree that open surgery should be avoided. By this minimally invasive procedure the patient will not be compelled to abandon physiotherapy and his normal daily activities for more than a few days.

Keywords: Percutaneous nucleoplasty; disc pathology; sciatic pain.

Introduction

Lumbar and sciatic pain concern 35% of the European people, and these problems are often due to degenerative intervertebral disc pathology.

For 50 years neurosurgeons have searched for a method to allow shrinkage of herniated or protruded discs, in order to resolve the problem of severe pain and dysfunction in an enormous amount of patients. Recently, in consideration of the pathogenetical mechanisms of the disease, surgeons have reduced the indication for traditional open surgery and have turned their choice to minimally invasive techniques with the aim of respecting anatomy and of solving the problem without producing epidural scars [1, 11, 13].

The review of the reliable data concerning the clinical and pathomorphological evolution of the problem [2, 15], together with the causative biological mechanisms, has lead to important considerations.

1. The evaluation of relevant surgical casuistic shows that the percentage of success of open surgery for lumbosacral disc herniation is roughly 93–98% upon short term evaluation, but 5 to 7 years later it significantly decreases (75–80%). The so-called failed back surgery syndrome (FBSS) is caused by fibrosis or by recurring hernia [15].
2. Data provided by studies on natural history of lumbar disc herniation and radiculopathy indicate that large and migrated herniations tend to decrease in volume to a greater extent than protrusions or small contained herniations which have less tendency to spontaneous regression [18]. Morphologic changes are usually observable after 6 months and correspond to a favourable clinical outcome but they tend to lag behind improvement of leg pain.
3. Studies on the efficacy of serotonin receptor blocker for symptomatic lumbar disc herniation [5] show that patients with uncontained disc herniation responded more favourably to the 5-HT(2A) blocker treatment than patients with contained disc herniation. A 5-HT(2A) blocker has the potential to block the cascade of acute nerve root inflammation and to alleviate symptoms in lumbar disc herniation [16].
4. Studies on pain originating from this pathology show that it may be the consequence of biochemical mechanisms of acid intoxication of the nerve, which may be somehow independent from the mechanical problem, but may depend either from autoimmune

reaction, producing a chronic inflammatory response which engenders an acid environment, or a situation of ischemia [17, 20]. These problems may be solved by biochemical treatment, reducing the need for surgical aggression [1, 2, 22]. On the other hand the development of an autoimmune response against a ''non-self'' material, leading to a chronic inflammatory reaction, is demonstrated [12].

From these considerations the evolution has derived towards the need for a specific treatment of contained herniations. A number of percutaneous non-invasive techniques have been conceived with the aim to provoke shrinkage of the discal tissue. The common principle of these techniques is that of acting directly on the discal structure, without access to the spinal canal [3, 13]. This drastically reduces epidural formation of scar tissue, which may risk to compress nervous tissues and adhere to the moving bones.

Nucleoplasty by coblation (a system developed by Arthro Care) tackles this problem, allowing removal of discal nucleus by radiofrequency with a controlled thermal effect [1, 2, 4, 19, 21, 23].

The process takes place at temperatures ranging from 40 to 70 degrees due to the effect of a layer of ''ionized plasma'', engendered around the extremity of the Spine Wand. The ''plasma'' has sufficient energy to break molecular bridges thereby disrupting molecules. Degradation products will spontaneously come out from the operative canal.

This radiofrequency ablation, which utilizes low temperatures over a short time (2 to 3 minutes) without damaging surrounding tissues allows reduction of the discal volume by about 10 to 20%.

Patients and methods

Patients

We have followed the Protocol for Nucleoplasty in lumbar pathology as proposed by Conor O'Neill [1, 19]. Inclusion criteria for patients were:

1. Age between 18 and 65, for patients convinced to search for a solution of the problem by this technique, and to work with physiotherapy and gymnastic.
2. Chronic lumbar pain with or without radicular pain, lasting more than three months and with failure of medical and physical conservative treatments
3. absence of neurological deficit
4. One level positive provocative discography and negative control level.

Exclusion criteria for this outcome analysis included disc herniation with sequestration, large contained herniation occupying one-third or more of the spinal canal, severe spinal stenosis due to extensive osteophytosis, presence of secondary pain issues, psychological disorders, gait disorders depending on different neurological or orthopaedic pathology.

Contraindications to the procedure were evidence of infection, severe coagulopathies or impossibility of interrupting anticoagulation treatment.

From February 2001 to May 2003 we treated 1390 patients, males 43.5% and females 56.5%. They presented with lumbalgia and/or lumbosciatalgia due to disc bulging or partially contained disc herniation (989 cases in L4-L5 and 234 in L3L4, 167 in L5-S1) as shown by TAC and/or NMR investigations.

These patients had been resistant to previous conservative treatments such as drugs, physiotherapy, and TENS.

There was no or only minor neurological deficit in all cases.

Surgery

Mild endovenous anaesthesia is applied to the patient in lateral decubitus. The approach is from postero-lateral as for discography, using a 17 Gauge needle. Under fluoroscopy we identify the involved disc, and the guiding needle is located at the annulus – nucleus junction.

Trough the needle the Spine Wand electrode is introduced, calibrating its length in order to move from one to the opposite margin of the annulus.

After the fluoroscopic control of the correct positioning of the electrode coblation is performed. Advancing the wand in ablation mode a channel is obtained up to the opposite anular margin. Retraction of the wand in coagulation mode will complete the individual channel preparation. Six channels are created thanks to the shape of the wand, turning around the clock positions.

The working protocol pinpoints the possible risks:

1. Damage to the root along with puncture.
2. Conduction of the electric stimulus to nervous structures when the Spine Wand is not perfectly located.

For these two reasons the procedure should be executed under mild sedation, in order to evidentiate the irritation of nerve roots.

3. Perforation of vessels.
4. Infections.

Postoperatively patients were allowed to perform walking and sitting as needed during their daily activities, but were instructed to limit bending, rotating, and lifting more than 5 kg for two weeks. A qualified instructor showed them physical exercises to be started thereafter.

Results

From serial follow-up at 15 days, 1 month, 6 months and 1 year, we have collected the following results:

Results	15 days	1 month	6 months	1 year
Excellent	50.8%	53.3%	51.5%	55.8%
Good	23%	26.6%	31.5%	24.9%
Scanty	13.9%	10%	8.5%	12.4%
None	12.3%	10%	8.5%	6.9%

Excellent Total resolution of the clinical picture, and full re-uptake of daily activities.

Good Fairly total resolution of pain, with rather good quality of life.

Scanty Insignificant pain resolution and inability to take up normal daily activities.

None No results both on pain and clinical field.

Evaluation of the results was based on the JOA Score Scale:

(Hirabayashi Method: (JOA final − JOA preop)/(15 − JOA preop) × 100 = % value of recuperation).

By this method a percentage superior to 70% is considered a very good result, and 50 to 70% a good result.

MRI and/or CT were performed 6 months after the procedure. These investigations have shown that bulging was eliminated in 34%, significantly reduced in 48% and unvaried in 18% of cases.

Comment and conclusions

Safety and efficacy of this technique was carefully analyzed by Chen *et al.* They concluded that a safe volumetric removal of the nucleus is achieved and that no disruption or necrosis of the surrounding vital structures occurs [8] no change in temperature is detected at 5 mm away from the tip of the wand [9], and after 2 channels are created within the disc intradiscal pressure decreases dramatically [10].

Sharp and Isaac [21] reported an overall success rate of 79%, with 67% success in the group of patients who had previous surgery, and 82% success in the group that had no prior surgical intervention at 12 months.

Evaluation of the results as far as the immediate postoperative period is concerned has shown that 5% of patients as long as about ten days complained about lateralized postural lumbar pain and hypertone – contraction of paravertebral muscles, probably due to irritation of the methameric Lushka nerve. We had no kind of complications related to the procedure, and patients never suffered from radiculopathy. This in spite of the fact that during the procedure at the moment of coblation rapid muscular contractions of muscles depending from the involved nerve root have occasionally been observed. This fact never occurred during the coagulation phase. The observed muscular contractions, in our opinion, are related to the diffusion of radiofrequencies along the nerve.

The most recent experimental studies by O'Neil [19] showed that coblation due to the physical and thermal effects on the pathological disc, entails biochemical effects. These findings have been evaluated and demonstrated. They consist, in the first postoperative period, of a decrease of interleukin 1, a substance which is known to have hyperalgesic effects, and in a subsequent (at 12 weeks) augmentation of interleukin 8, which may express the reparatory response of the disc.

These changes are in line with the clinical observation that amelioration will progressively occur, starting from the first weeks. The initial immediate recovery, followed by the rapid decrease in disc volume, is not the entire result.

This technique has good results in cases of contained disc herniations. This kind of herniation has a scanty natural tendency to shrink and loss of compressive effect on the nerve root, as demonstrated by several studies on the natural history of the evolution of disc herniation.

These cases are the most difficult to manage by conservative procedures, physiotherapy and drugs and we all agree that open surgery should be avoided.

It has become imperative to search for therapeutic techniques which are minimally disruptive to the anular structure, in view of the growing knowledge regarding the factors affecting anular healing and disc integrity. Mochida *et al.* [18] during their analysis of disc material removal have concluded that nucleotomy to reduce disc herniation should mimic asymptomatic disc degeneration and should therefore produce a gradual degenerative course, which is not achieved with removal of a large amount of disc material. A two-fold decrease in success rates for discectomies form 71 to 36% was seen in patients with a large amount of disc material removed averaging 3.8 grams including the central area of the nucleus, in contrast to removal of migrated material, averaging 1 g.

Percutaneous disc decompression, irrespective of the technique, is based on the principle that a small volume loss in a closed hydraulic space, like an intact disc, results in a disproportionately large drop of pressure.

Case *et al.* [7] have studied the matter and showed that a large rise in pressure will regularly result from a small increase in volume and vice versa. Chen *et al.* [10] have shown that after 2 coblation channels have been created within the disc, intradiscal pressure decreases dramatically.

Fagan and co-workers have recently described in detail discal innervation. They have identified areas where innervation is most concentrated. These include the perianular connective tissue and the central endplate. As they underline, this does not necessarily imply that these are the most important sources of pain, but some of the nerves identified may function as nociceptors [14]. Thus it is likely that coblation nucleoplasty has an effect on discogenic pain since it denervates in a concentrated manner the central endplate area.

Many of the nerves in the loose perianular connective tissue are ramii communicantes passing over the disc to connect the spinal nerves with the sympathetic chain. They do not directly supply the anulus, but they are potentially affected by mechanical or chemical noxious stimuli associated with disc degeneration, particularly if sensitized by prior release of inflammatory mediators [6, 14, 17]. Nucleoplasty will act on these nerves too, reducing discal pressure.

Although this outcome analysis may receive criticism since it is neither randomized to a placebo-controlled group nor double-blinded, the data is nevertheless compelling. We must remark that several reports indicate that the results of observational studies do not differ significantly from the results of randomized controlled trials [5, 12].

By this minimally invasive procedure the patient is not compelled to do without physiotherapy and abandon his normal daily activities for more than a few days.

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CT-guided oxygen-ozone treatment for first degree spondylolisthesis and spondylolysis

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Summary

Aim of this study was to assess the therapeutic outcome of CT-guided periganglionic infiltration of oxygen-ozone and injection of the gas mixture into the lysis points in patients with first grade spondylolisthesis and spondylolysis. We selected 18 patients presenting with low back pain and sciatica resistant to physical and medical management with a radiological diagnosis of spondylolisthesis and spondylolysis subsequently confirmed on CT scan. Following CT-guided bilateral periganglionic O_2-O_3 infiltration and injection into the lysis points, 15 patients (83.3%) obtained a complete remission of pain. None of the patients reported pain recurrence at clinical follow-up visits one, three and six months after treatment.

Oxygen-ozone therapy administered in this way is even more effective than CT-guided periganglionic infiltration alone as it has an additional anti-inflammatory and analgesic effect on the nerve structures in the neural arch, namely Luschka's recurrent nerve.

Keywords: Spondylolisthesis; spondylolysis; oxygen-ozone therapy; low back pain; sciatica.

Introduction

Spondylolysis is a bony defect of the neural arch, i.e. the part of the vertebral arch between the superior and inferior spinal processes. If the bony defect results in a forward shift of one vertebral body on another, this is called spondylolisthesis (a term coined by Kilian in 1854) [1, 25]. Symptoms include local pain varying in intensity and hyperlordosis of the lumbar spine. Spondylolisthesis is not a constant finding but when present it tends to gradually worsen. Diagnosis of spondylolysis is based on neuroradiological investigation, namely standard lateral and oblique x-ray views. Axial CT scan is an additional imaging technique used to determine the listhesis and demonstrate other lesions to the neural arch likely to supply information on the state of the intervertebral disc [11, 23, 24, 26].

Treatment varies in relation to the time of diagnosis [21]. During childhood and adolescence, i.e. the period of peak evolution and hence exacerbation of listhesis, an aggressive approach is required, warning relatives of possible evolution and the need for regular clinical and radiological monitoring even in the absence of symptoms. Conservative treatment involves physical exercises aimed at strengthening the abdominal and gluteal muscles to correct the exaggerated pelvic antiversion which often accompanies spondylolysis and is the result and also the cause of further worsening. Patients must avoid lifting heavy loads and sports or work entailing functional overload of the lumbosacral girdle [15]. When symptoms are present or forward subluxation is demonstrated, surgical decompression is necessary. The operation consists in fixing the sliding vertebra to the vertebral bodies above and below. For mild or moderate spondylolisthesis, the surgical treatment is in situ arthrodesis, i.e. fusion without reducing the forward shift. The postoperative course entails prolonged bed rest (from three to six months) until the graft has taken and fusion is complete [3, 4, 10, 14, 18, 20, 22]. Further vertebral dislocation leads to spondyloptosis, i.e. the sliding vertebral body falls in front of the underlying vertebra. Treatment for this severe condition is still the subject of controversy. Attempts at reducing spondyloptosis by different methods (Harrington, Bradford, Scaglietti) carry a high risk of neurological defects and caudal symptoms due to stretching of the nerves or roots during reductive manoeuvres. For these reasons, in most cases the spine is stabilized in position or the fifth lumbar vertebral body is removed fixing the fourth body to the sacrum.

We assessed the outcome of oxygen-ozone treatment in patients with first grade spondylolisthesis and spondylolysis administered by CT-guided periganglionic infiltration and injection of the gas mixture into the lysis points in the neural arch.

Classification

Congenital

Type A: abnormalities of the lumbosacral region are associated with occult L5-S1 spina bifida and incomplete development of the spinous processes with axial orientation of the facet joints. These combined factors preclude excess weight-bearing and lead to listhesis. The neural arch may be intact if the forward shift of the vertebral body does not exceed 35%. The male-female ratio shows a slight male prevalence for congenital forms. Both dysplastic abnormalities and neural arch spondylolisthesis have a genetic mechanism.

Type B: impaired congenital orientation of the spinous processes whose posterior parts are underdeveloped. Subluxation occurs due to instable orientation of the facet joints which are rotated rather than sagittally oriented.

Type C: other congenital abnormalities giving rise to a predisposition towards spondylolisthesis are: congenital kyphosis and abnormal development of the vertebral bodies.

Neural arch (fractures of the pars interarticularis)

Type A: are due to a separation of the pars interarticularis caused by a stress fracture. The lesion is rare below the age of five years and most commonly encountered between the ages of 5.5 and seven years. Already children may well have an anatomical predisposition for pars fracture. It is not known whether the pars is fractured in flexion or extension.

Type B: lengthening of the neural arch without fracture. This is secondary to repeated microfractures which allow the pars to recover in elongation when the body of L5 is shifted forward. A common congenital component may underlie all variations of congenital and neural arch forms of spondylolysis.

Degenerative

Lesions are due to longstanding intersegmental instability following multiple small fractures resulting from compression by the inferior spinous processes of the vertebra which is shifted forward. Tropism of the facet joints is important: when present one side slides more than the opposite one with rotation of the vertebra at the level of the listhesis. This form is six times more common in women than men and from six to nine times more common at L4. Forward displacement does not exceed 33%.

Post-traumatic

The lesion is secondary to acute injury which breaks the weight-bearing bony structures causing forward shift of one vertebral body on another. It is always the result of severe trauma.

Pathological

This form is encountered in local or disseminated bone disease.

Post-surgical

The lesion is due to a complete or partial loss of posterior bone support or disc support or a stress fracture of the inferior spinous processes following surgery.

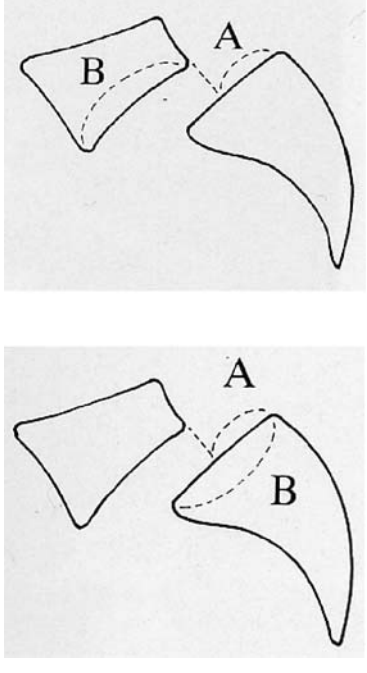

Fig. 1. Meyerding's grades.
1° = A/B = 0–33%
2° = A/B = 34–66%
3° = A/B = 67–99%
4° = 100% and spondyloptosis

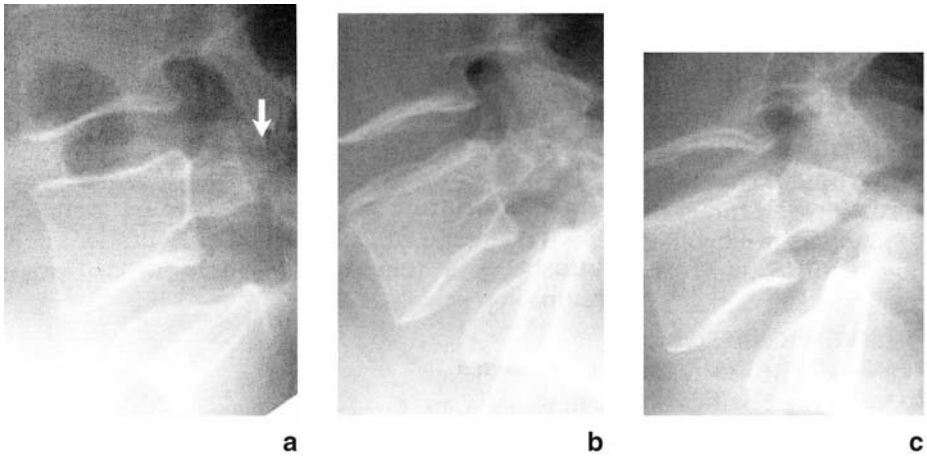

Fig. 2(a–c). Standard x-ray with morphodynamic tests (flexion-extension): First grade spondylolisthesis according to Meyerding with bilateral isthmic spondylolysis (a) standard view, (b) flexion, (c) extension

Meyerding's classification

The degree of forward shift of one vertebral body on another is measured as a percentage according to Meyerding's classification (Fig. 1 A–B) [19]:

Grade I 0–33%
Grade II 34–66%
Grade III 67–99%
Grade IV 100% and spondyloptosis

Materials and methods

In our series, from November 2001 to September 2002 we treated 18 patients aged between 24 and 42 years (mean 32.6), 12 men and six women with low back pain and sciatic secondary to first grade spondylolisthesis with spondylolysis. On enrolment, a case record was drawn up for each patient listing: name, date of birth, date of enrolment, date of treatment and information on the clinical examination defining the type of pain, irradiation, possible parasthesias, Lasègue's sign, degree of sensitivity, leg reflexes, plantar extension and dorsal extension of the big toe. All patients had previously undergone standard spine x-ray investigation including morphodynamic tests (flexion-extension) (Fig. 2) subsequently completed by computed tomography (CT) of the lumbosacral spine demonstrating spondylolisthesis complicated by spondylolysis (Fig. 3).

All patients were treated by CT-guided bilateral periganglionic infiltration of O_2-O_3 [2, 9, 12, 13] and O_2-O_3 injection into the lysis points in the neural arch. Treatment was administered in the day-hospital using the same infiltration technique adopted for discography after CT examination to fix the point of infiltration on the skin and subsequent measurement of the distance between the point marked and the root canal. The injection area was anaesthetised using ethyl chloride spray. A 22G 9 cm needle was used in all cases. Further CT scans were done to check the correct positioning of the needle in the periganglionic region and then in the lysis points (Fig. 4). We injected 3/4 cc of O_2-O_3 gas mixture at 25 µg/ml into the periganglionic area followed by another 3/4 cc of gas mixture into the lysis points. Another CT scan was done to display the correct distribution of the O_2-O_3 mixture (Fig. 5). All patients were monitored clinically for two hours before being discharged. The clinical benefit of treatment was almost immediate. Patients were then reassessed clinically one, three and six months later without repeating the treatment. No long-term CT follow-up was done. Treatment involved L5-S1 in 11 patients and L4-L5 in the remaining seven.

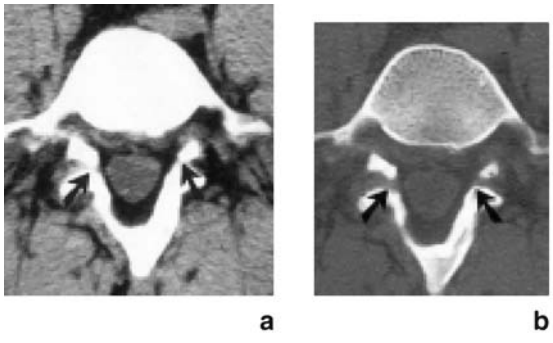

Fig. 3(a,b). CT diagnosis of isthmic spondylolysis (arrows) (a) standard reconstruction algorithm; (b) bone reconstruction algorithm

Results

Treatment outcome was assessed by a modified version of MacNab's method with clinical follow-up at one, three and six months after treatment as follows (table):

a) excellent: resolution of pain and return to normal working activity carried out before pain onset
b) good or satisfactory: more than 50% reduction of pain
c) mediocre or poor: partial reduction of pain below 70%.

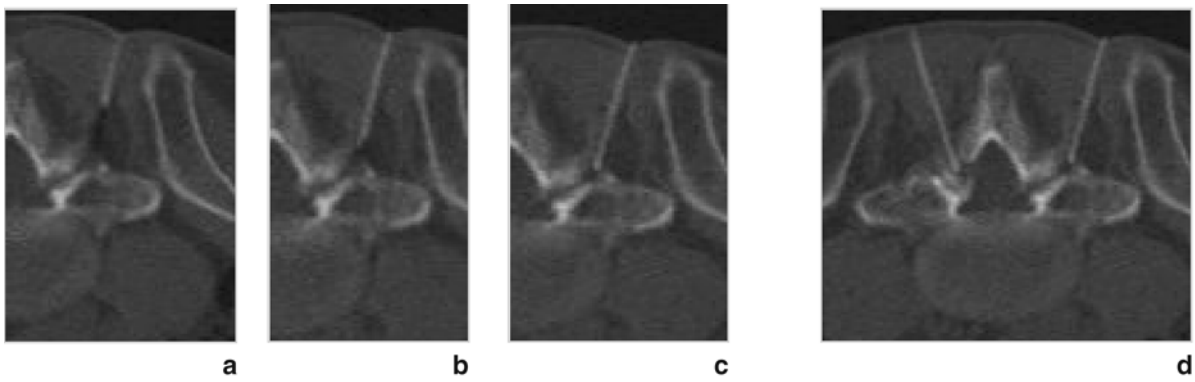

Fig. 4(a–d). Needle penetration to the lysis points under CT guidance (a–c) and correct needle placement (d) (arrowheads)

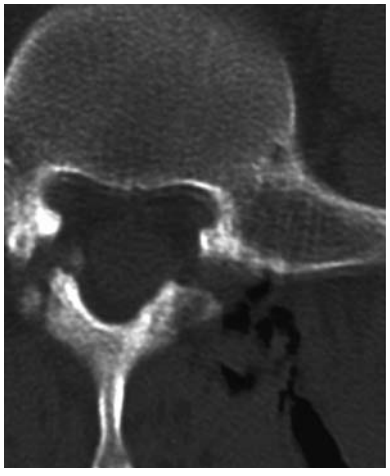

Fig. 5. CT image showing distribution of the gas mixture in the lysis points (arrowhead)

Of the 18 patients treated, 15 (83.3%) had a complete remission of pain immediately after treatment (Figs. 6, 7) subsequently confirmed at clinical follow-up one, three and six months later, whereas two patients (11.1%) had only a slight clinical improvement and one patient failed to benefit from O_2-O_3 administration. Of the 15 patients with excellent clinical outcome, two subsequently complained of sporadic episodes of ''bar-like'' back pain, but it was well tolerated and relieved by non-steroidal anti-inflammatory drugs when required. All the patients in the study were advised to consult a physiatrist/rehabilitation specialist to devise a programme of postural exercises for the purposes of treatment and prevention.

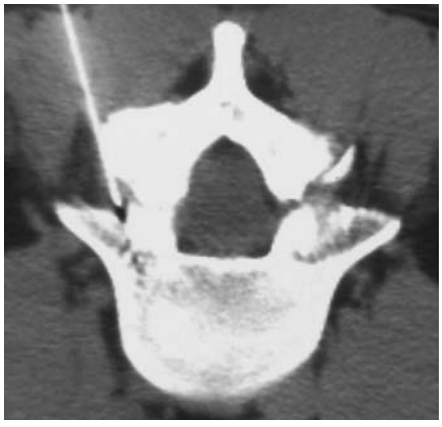

Fig. 6. A 31-year-old man was referred to us with several years' history of bilateral back pain and sciatica mainly on the right caused by Meyerding's first grade spondylolisthesis and bilateral isthmic lysis demonstrated on multiple radiograms (standard x-rays, CT and MR scans) which also disclosed accompanying marked concentric protrusion of the intervertebral disc with involvement of both root canals. No sensory or motor deficit was evident and for this reason none of the specialists consulted by the patient had proposed stabilizing surgery by means of intersomatic arthrodesis with interpedicular osteosynthesis.

Over the years, the patient had undergone numerous treatments in an attempt to relieve pain (massotherapy, laser therapy, postural exercise, ionophoresis, acupuncture and chiropractic) with little benefit. Pain-killers were not fully effective and had given rise to side effects poorly tolerated by the patient. The patient underwent O_2-O_3 infiltration in an attempt to achieve pain relief. CT display of correct positioning of the needle in the point of isthmic lysis

Discussion – conclusions

An explanation for such fast pain relief may be the twofold action of ozone in the perganglionic region

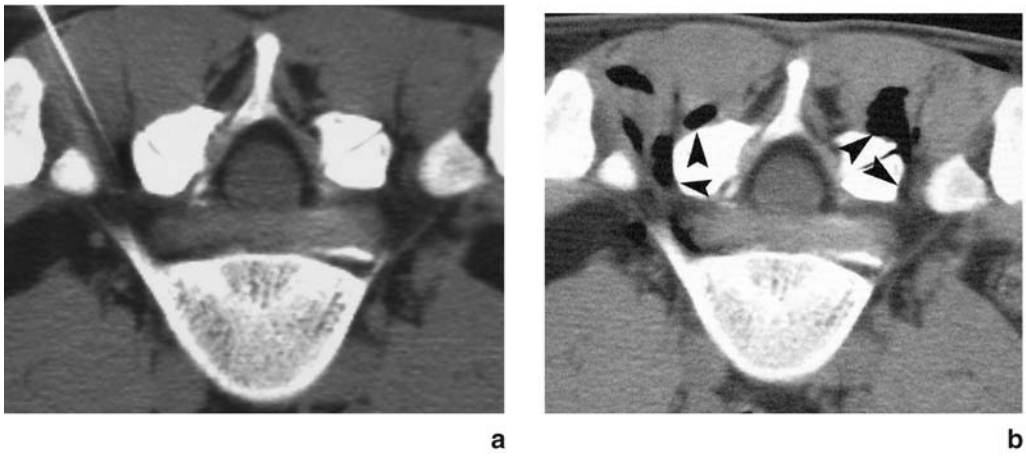

Fig. 7(a,b). (a) CT image of the needle (arrowhead) inserted into the periganglionic region, (b) distribution of the gas mixture in the periganglionic region and facet joints (arrowheads)

Table 1. *Assessment of therapeutic outcome at the time of treatment and one, three and six months later*

	Excellent	Good or satisfactory	Mediocre or poor
Immediate	15 (83.3%)		3 (16.7%)
At one month	15 (83.3%)		3 (16.7%)
At three months	13 (72.2%)	2 (11.1%)	3 (16.7%)
At six months	13 (72.2%)	2 (11.1%)	3 (16.7%)

(eutrophizing effect on the nerve roots compressed by protrusion accompanying listhesis) [16] and in the lysis points of the neural arch or pars interarticularis region innervated by Luschka's recurrent nerve.

The spine is innervated by the posterior primary branch and vertebral plexus or Luschka's recurrent nerve. The main posterior branch arises from the spinal nerve just outside the root canal: its medial branch innervates the capsule of the intertransverse joint, the dorsal muscles and the adjacent portions of the joint capsules of the metameres above and below; its lateral branch innervates the posterior skin of the trunk. Luschka's vertebral plexus, derived from the anterior part of the spinal nerve, moves medially to enter the spinal canal through the root foramen. It then exits to shunt with similar controlateral branches and those of the metameres above and below. The plexus innervates the vertebral bodies, end plates, external disc layers, posterior longitudinal ligament, dura and relative peridural tissues in particular the neural arch or pars interarticularis region (Fig. 8) [17].

Infiltration of the gas mixture directly proximal to the lysis points acts on Luschka's nerve by exploiting the well-known analgesic and anti-inflammatory effects of the oxygen-ozone mixture. Cytokine and

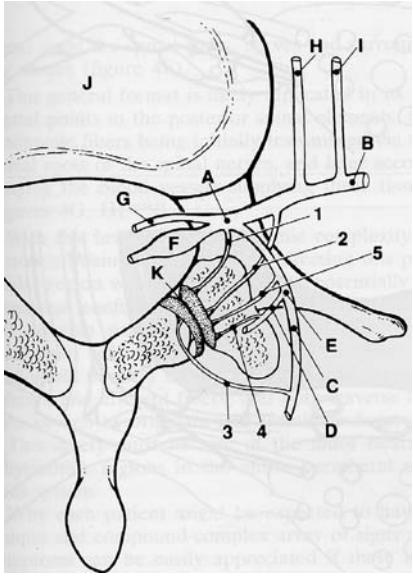

Fig. 8. Schematic diagrams outlining innervation of structures in the dorsal aspect of the spine: A) somatic-autonomic neural network innervating the dorsal spinal elements at or above the level of L2. (*1* neural fibers from the main trunk of the spinal nerve (*A*), *2* neural fibers from the ventral ramus (*B*) of the spinal nerve, *3* neural fibers from the lateral branch of the dorsal ramus (*C*), *4* neural fibers from the medial branch of the dorsal ramus (*D*), *5* neural fibers from the dorsal ramus (*E*) of the spinal nerve, (*F*) dorsal nerve root and ganglion, (*G*) ventral nerve root, (*H*) gray ramus communicans, (*I*) white ramus communicans, (*J*) intervertebral disc). From Jinkins JR "The pathoanatomic basis of somatic, autonomic and neurogenic syndromes originating in the lumbosacral spine" Rivista di Neuroradiologia 8 [Suppl 1]: 35–51, 1995

postaglandin levels are normalized with an increase in superoxide dismutase production and a reduction of reactive oxidant species [5–8]. Subsequent infiltration into the periganglionic region improves local circulation with a eutrophizing effect both adjacent to the nerve root compressed and injured by accompanying disc protrusion *and at the level of muscle spasm. The combined action accounts for the good final outcome*.

Fast pain relief without complications, relatively easy technical execution and full control of infiltration under CT guidance make oxygen-ozone administration a valid alternative to conservative treatment of first grade spondylolisthesis with spondylysis.

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Ozone chemonucleolysis in non-contained lumbar disc herniations
A pilot study with 12 months follow-up

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Summary

Study design. Prospective case series with six and twelve months follow up.

Objective. To observe clinical and morphological results of the intradiscal ozone chemionucleolysis in patients affected by non-contained lumbar disc herniations.

Methods. 30 patients were included in the study on the base of precise inclusion and exclusion criteria. The patients were followed on 6 and 12 months period by Visual Analogic Scale (VAS), Roland Morris Disability Questionnaire (RMDQ) and Overall Patient Rating Scale (OPRS). Disc herniation volume morphology was evaluated at 5 months by control MRI scanning.

Results. Twenty-seven patients (90%) showed a statistically significant improvement in pain ($P < 0.001$, Wilcoxon test) and function ($P < 0.001$, Wilcoxon test), on VAS and RMDQ evaluation, respectively. The mean satisfaction with the treatment on OPSR was 79.3%, with 24 patients referring satisfaction equal or greater than 80%. There were no major complications related to the procedure.

Conclusions. The results of this study indicate the ozone chemonucleolysis as a possibly effective modality of treatment in patients affected by signs and symptoms of non-contained lumbar disc herniations that have overpassed conservative measures and have not yet fulfilled the indications for open surgical treatment.

Keywords: Disc herniation; chemonucleolysis; ozone; percutaneous surgery.

Introduction

Lumbar disc herniation is a pathologic condition most commonly responsible for lumboradicular pain for which lumbar surgery is carried out most frequently [23]. For more than 50 years, standard discectomy followed by microdiscectomy have been used to manage this pathology. The majority of patients suffering from lumbo-radicular symptoms due to disc herniation recuperate spontaneously and the herniation, eventually disappears in a few months without any treatment [14]. In a number of reports on the long-term outcome of lumbar discectomy for lumbar disc herniation, success rates were fairly consistent (between 76% and 93%), although evaluation methods varied, and approximately 10–12% of patients underwent revisions [1, 7–9, 19, 20, 25, 31].

Also for 50 years, surgeons have been searching for a method to reduce or eliminate the herniated disc material without the need for open surgery. Hence a number of minimally-invasive percutaneous techniques have been developed which can be divided into two main types: mechanical removal (endoscopic discectomy, automated discectomy, laser discectomy) and chemical disruption of the nucleus pulposus (chimopapain, collagen, hydrocortisone, aprotin).

Recently, laboratory results showed that epidural application of autologous nucleus pulposus can induce pronounced morphological and functional changes in the nerve roots due to an increase in endoneurial fluid pressure of the nerve root and decrease of blood flow in the dorsal root ganglia with concomitant increase in its excitability and mechanical hypersensitivity [26, 30]. Phospholipase A2, tumor necrosis factor α, metalloproteinases and some other substances were found to be possibly responsible for this [6, 21].

Medical ozone is a trivalent form of oxygen that has been used for medical treatment mostly in European countries from the early 20th century. In 1885 the Florida Medical Association published *Ozone* by Dr. Charles J. Kenworthy, M.D. detailing the use of ozone for therapeutic purposes. In 1911, Dr. Noble M. Eberhart published *"A Working Manual of High Frequency Currents" (New Medicine Publishing Co, chapter IX)* where he describes the use of ozone for medical purposes. There are numerous other Med-

ical reports on the use of ozone in the treatment of different human diseases. For a comprehensive review one should search the web pages at www.iaqara.us/mccabe/. The experimental studies performed until today seem to indicate that the ozone, at appropriate doses, induces the development of excessive amounts of reactive oxidative substances (ROS). These, by inducing excessive production of antioxidant enzymes, have a modulating effect on production of pro-inflammatory cytokines as well as on inhibition of synthesis of prostaglandines, bradikinines and other algogenic composites [2, 24].

Patients and methods

Patients and selection criteria

From January 2002 to December 2002, 30 patients, 16 males and 14 females, aged between 19 and 77 years (mean 45 ± s.d.14.2) underwent chemonucleolysis with ozone for non-contained lumbar disc herniations. Each patient was selected on the basis of the following criteria.

Inclusion criteria: low back and leg pain not responsive to conservative treatment modalities; non-contained disc herniation at one or more levels between L3 and S1; level of disc herniation corresponding to the level of symptoms; discography positive for annular disruption; confirmation of pathology by MRI scanning.

Exclusion criteria: severe motor palsy (Fisher < 4); contained disc herniation; other spinal pathologies such as tumours, lyses, fractures, deformities, stenosis, instability, etc; previous spinal surgery; use of drugs or history of mental diseases.

Six patients (20%) underwent multilevel treatment while 24 patients (80%) underwent single level treatment. The symptom duration ranged from 21 to >365 days with a mean duration of 203.9 days (s.d. ± 129.6). One patient presented with pure lumbar pain, 24 had low back pain irradiated in the lower extremity and 5 patients just had leg pain. All patients had symptoms of pain and/or paraesthesia, with 19 patients presenting signs of slight sensitive and/or motor disturbance. The straight leg raising test was positive for all patients with mean angle of evocation being 51.3° (s.d. ± 20.5°). All the patients had an MRI imaging positive for non-contained disc herniation with outer diameter larger then ~4 mm. In all patients provocative discography proved positive for annular disruption.

All the patients were informed in detail about the procedure, the possibilities of success as well as the risk factors, and all of them accepted the treatment by signing an informed consent.

Percutaneous technique

The procedure was performed in the operating theatre under moderate sedation. No preventive antibiotic therapy was given. The patient was prepared by the anaesthesiologist with pharmacological sedation and then brought to the operating room and positioned in lateral decubitus; the affected side remained upwards; the legs folded. The operating table was folded, too as to assume an upward convex shape. This allowed the surgeon to have easier access to the lower discal space (L5-S1) even in the patients with a high iliac crest. The Beckton-Dickinson, Chiba type 22 G, 27 cm, needle was introduced by the standard postero-lateral, extra-articular percutaneous approach. The whole procedure was performed under continuous fluoroscopic control. Once in place, the position of the needle was confirmed by latero-lateral, oblique and antero-posterior imaging. The ozone-oxygen mixture was produced in real-time by a medical ozone generator Ozonline E 80 (Medica srl) CE certified. The gas concentration range was ι40 μg 0_3/ml 0_2 in quantity between 10–15 ml for a single level. The syringe used was a Terumo type – 50 ml. Between the siring and the needle a bacteriological Millipore filter was positioned before infiltrating the gas mixture inside the disc space. The ozone-oxygen mixture was infiltrated inside the disc space at an approximate velocity of 10 ml/min. The gas mixture inside the disc space appeared on fluoroscopic imaging as a positive contrastography. Some of the gas mixture escaped from the disc space and run into the epidural space both in cranial as well as in caudal directions. During gas infiltration the patient was sedated by Propofol. The patient was dismissed the following morning.

Follow-up

The patients were prospectively followed by compilation of pre and post-procedure questionnaires. The pain was evaluated by Visual Analogic Scale (VAS). Dysfunction and disability were followed by self-administered Roland-Morris Disability Questionnaire (RMDQ). Overall treatment satisfaction was evaluated by a 100 point Overall Patient Satisfaction Rating (OPSR).

The VAS was submitted to patients as a coloured scale divided into 10 different tonalities of the same colour and each tonality further divided into 10. The clearer the colour the lesser the pain and vice versa. The RMDQ form used was approved and validated for the use in the Italian language. The Pain Rating Scale of the same questionnaire was not used as it was found less valuable than the VAS evaluation for pain. The OPSR was used as a simple scale from 0 to 100 where the patient indicated the percent of his/her general feeling of satisfaction with the treatment. The above tests were filled in before the treatment (on the day of treatment), at six months and one year follow-up.

Seventeen patients underwent control MRI between 3 to 5 months after the procedure. The volume reduction was measured by an independent observer and expressed in % of volume reduction.

Statistical method

Statistical analysis was performed using the STATA 7.0 software (Stata Corporation, USA). The significance of the difference of the VAS score and the RMDQ score at time 0, 6 and 12 months was tested by using non-parametric statistics (Wilcoxon sign-rank test). Then 95% confidence interval of the differences of the VAS score and RMDQ score were calculated.

Results

Twenty-eight patients were available at 12 month follow-up. Two patients were dropped because of aggravation of symptoms and were operated upon by microdiscectomy.

VAS

Overall, at 12 month follow-up, 27 patients (90%) showed pain improvement, 1 patient (3.3%) remained unchanged while 2 patients (6.6%) worsened (operated) ($P < 0.001$, Wilcoxon test) (Table 1). The mean

Table 1. *Pre-treatment values* vs. *12 months follow-up values*

Variable	N (pts.)	Pre-treatment value	Post-treatment value	Difference (mean)	Difference (95% CI)	P
VAS	30	5.3 ! 2.2	0.9 ! 1.0	4.0	2.9–5.0	$P < 0.001$
VAS	27 (improved)	5.4 ! 2.1	0.85 ! 0.87	4.5	3.5–5.4	$P < 0.001$
RMDQ	30	9.1 ! 3.5	2.4 ! 2.7	6.9	5.3–8.4	$P < 0.001$
RMDQ	27 (improved)	8.9 ! 3.6	1.1 ! 1.4	7.6	6.1–9.1	$P < 0.001$

pre-treatment value for all patients was 5.3 $\pm$ s.d. 2.2 and the overall mean 12 month follow-up value was 1.3 $\pm$ s.d. 1.6 with a change of 4.0 (95% CI = 2.9–5.0). Among the 27 improved patients, mean pain reduction was 4.5 (95% CI = 3.5–5.4). The maximum improvement was seen within the first six months with a mean improvement of 4.2 points (95% CI = 3.4–5.0), while on the follow-up between 6 to 12 months the improvement was minimal for the value of 0.8 (95% CI = 0.4–1.1).

RMDQ

Overall, at 12 month follow-up, 27 patients (90%) had improved in function, 2 patients (6.6%) had worsened while 1 patient (3.3%) remained unchanged ($P < 0.001$, Wilcoxon test) (Table 1).The mean pre-treatment value for all patients was 9.1 $\pm$ 3.5 and the overall mean 12 months follow-up value was 2.2 $\pm$ s.d. 3.2 with a change of 6.9 (95% CI = 5.3–8.4). Among the 27 improved patients, the mean function improvement was 7.6 (95% CI = 6.1–9.1). Maximum improvement was seen within the first six months with a mean improvement of 6.8 points (95% CI = 5.4–8.2), while at the follow-up between 6 to 12 months the improvement was minimal for the value of 1.9 (95% CI = 1.0–2.8).

No significant difference was found in patients treated at one or more levels regarding pain reduction or functional improvement. Highest range of improvement was observed within the first 6 weeks after procedure and then changed very little until the 12 month follow-up. The only one patient with low back pain did worse than the others but there was not enough statistical evidence to ascertain the validity of the statement.

OPRS

Mean satisfaction with treatment at 12 months was reported by 79.3% $\pm$ 28.7. Twenty-four patients (80%) referred satisfaction equal or greater than 80%, 3 patients (10%) referred satisfaction from 50 to 80% while 3 patients (10%) were not satisfied with the treatment of whom two were operated upon.

Morphological changes

Seventeen patients out of 30, all of whom were clinically improved, underwent control MRI imaging. In 8 of them a substantial reduction (> 50%) of the herniation volume was found. Two patients showed reduction inferior to 50% while 5 patients had no substantial variation of the herniation volume. The mean volume reduction for 17 patients was 49% $\pm$ s.d. 42.5%.

There were no complications observed related to the procedure in the immediate post-procedural period as well as at 12 month follow-up.

Discussion

The 1999 Cochrane study group found that there is considerable evidence (Strength A) of the clinical effectiveness of discectomy for carefully selected patients with sciatica caused by lumbar disc prolaps. Discectomy was found to provide faster relief from the acute attack (Strength A), although any positive or negative effects on the lifetime natural history of disc problems remain unclear (Strength C). There was strong evidence (Strength A) that chemonucleolysis with chymopapain produced better clinical outcomes than placebo while there was limited and inconclusive evidence (Strength C) of the relative efficacy of different doses of chymopapain, chymopapain compared with collagenase, and collagenase compared with placebo. Automated percutaneous discectomy was found less effective (strength B) than standard discectomy or chemonucleolysis. No acceptable evidence (Strength D) was found for laser discectomy [10].

In view of these facts, any new treatment with low invasiveness and associated with a reasonably high percentage of results should be taken into consider-

ation. As the equation large herniation = big symptoms, small herniaton = small symptoms is not true, it seems quite natural to suppose that clinical signs and symptoms of disc herniation are not caused mainly by mechanical compression but that biochemical factors play an important role in inflammatory sensitation of the nerve root [13, 18, 23, 29]. The results of this study indicate that disc volume is not the most important but probably just one of the factors influencing the arousal of symptoms. For these reasons it is to presume that a mechanical removal of the herniated tissue by an open or percutaneous surgical procedure may not always be needed and that biochemical treatment may eventuall, be sufficient for symptom treatment.

Ozone has a dose-related biological action [4, 5, 22, 27, 28]. At high concentrations (30–70 μg 0_3/ml 0_2), it may cause alterations of tissue structure; at medium concentrations (20–30 μg 0_3/ml 0_2) it seems to affect the regulation of the immune system and at low concentrations (< 20 μg 0_3/ml 0_2) it improves the microcirculation. The following seem to be the primary effects of ozone inside the intervertebral disc: inflammation improvement due to oxygenation of algogenic pro-inflammatory mediators; direct interaction with the mucopolisaccarides of the nucleus and consequent reduction in disc water content; improvement of local microcirculation with reduction of the venous stasis and improved arterial supply, i.e. diminution of ischemic changes of the nerve root [11, 17]. Histological studies performed on animal models demonstrated that intradiscal ozone induces degeneration of cytosol and cell shrinkage of the nucleus [12, 16]. If applied in adequate concentrations, ozone produced no toxic effects, both in vitro and in vivo [24]. The primary condition is the dose range as the ozone quantity must not exceed the enzymatic antioxidant (superoxid dismutase and catalase and glutatione) capacity of the organism. Experimental tests in animals and humans did show essentially a lack of negative effects [15] indicating that the ozone application to the human body if in adequate concentration has no mutagenic properties [3]. However, special attention should be paid to patients affected by hyperthyroidism, unstable arterial hypertension, kahectic patients as well as patients affected by phavysm.

The authors are convinced that the treatment of disc herniation pathology has to be proportionate to the severity of clinical signs and symptoms. In this context, the ozone chemonucleolysis may have an important impact on the treatment of symptoms of disc herniation as it seems to have quite a high clinical success rate and may as well resolve the cause. It is a very simple and low-cost method both in terms of procedure as well as in terms of social cost. This coincides with an almost total absence of risks and complications both in short and long-term follow-up. The ozone chemonucleolysis is not meant to be a method aimed at eliminating any of to-date gold-standard treatments (pharmacological, physiatrist and surgical treatments). As for the chemonucleolysis with chymopapain, this preliminary study supports ozone chemonucleolysis as a possible, minimally invasive option to be planned as an intermediate stage of treatment situated in between conservative management on the one side and open surgical intervention on the other. That means that it is applicable to patients that have outpassed conservative treatment modalities but have not yet reached indications for surgical treatment. Particularly as it has been shown that when clinical indications are uncertain, postponing surgery for further assessment of clinical progress may delay recovery but will not produce long-term harm.

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Micro-endoscopic-discectomy (MED) for far lateral disc herniation in the lumbar spine. Technical note

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Summary

This study describes a new experience of the authors in the treatment of extraforaminal disc herniation via the micro-endoscopic far lateral approach to establish a less traumatic approach to extraforaminal disc herniation with less stay in hospital and less cost. Seventeen patients who underwent surgery for extraforaminal disc herniation were analysed and long-term follow up was done revisiting all of them in hospital. The results of surgical decompression via the micro-endoscopic far lateral approach were good in all patients with minimal discomfort. There was complete resolution of leg pain presented. Dysesthesia subsided after 2–3 weeks. Extraforaminal disc herniation can be diagnosed with the aid of CT scan and MRI. The minimally invasive surgical treatment via the micro-endoscopic far lateral approach, in our initial experience, has a high rate of succes.

Keywords: Lateral disc herniation; paramedian approach discectomy; micro-endoscopic approach.

Introduction

About 7–10% of lumbar disc herniations are localized in the intervertebral foramen and extraforaminally with compression signs of the extraforaminal nerve root and lumbar pain [1, 2, 7, 11, 15, 16, 20, 26, 27]. Foley and Smith recently have described a new technique of micro-endoscopic-discectomy for disc herniation excision with minor tissue damage, reduced scarring as compared to standard microdiscectomy [10, 13, 14, 19]. This technique is commonly used in our Department with good results. Standard microdiscectomy for lateral, intra and extraforaminal disc herniation is more traumatic, the surgical skin incision is larger and muscle traction and damage is more important [6, 8, 21–24].

Materials and methods

17 patients with extraforaminal disc herniations were operated with far lateral micro-endoscopic discectomy; 10 in L4-L5 and 7 in L3-L4 (Fig. 1). In L5-S1 space this approach is not possible.

Following induction of general endotracheal anaesthesia, the patient is placed in the prone position on a lumbar frame with thighs flexed at 30 degrees permitting the use of x-ray in lateral and anteroposterior position. The operative site is prepared in the usual fashion. A needle guide is introduced directly to the transverse process [12, 25] with x-ray control (CT scan and MRI images were evaluated before to calculate the distance from the midline). The correct position of the needle is on the supero-medial portion of the inferior transverse process to the level of approach, few millimetres lateral of the articular process. Under x-ray confirmation the dilators are inserted over the guide needle reaching the bigger of 17 mm of diameter (Figs. 2–3). The last dilator is positioned with the inferior border to the superior portion of the transverse process. After the introduc-

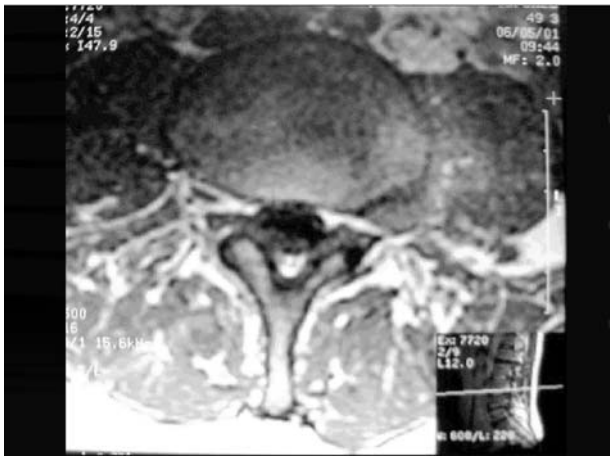

Fig. 1. Magnetic resonance imaging obtained of a left L3-L4 far lateral disc herniation

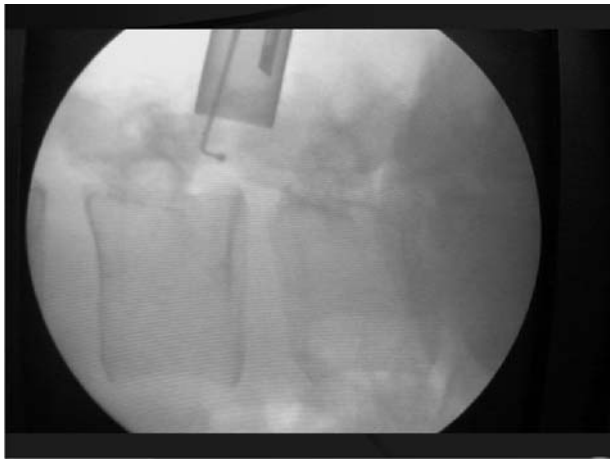

Fig. 2. Fluoroscopic lateral control of the ball-tip probe medial to the exiting nerve root searching for more disc fragments

Fig. 3. Fluoroscopic AP control of straight ball-tip probe under the pedicle and exiting L3 nerve root

tion of the optic fibers the intertransverse muscle is dissected exposing the intertransverse ligament. This is divided with accuracy in the supero-external portion. In this way we can see the root superiorly pushed from the disc herniation. Care must be taken to avoid traumatizing or transmitting electrical energy from the coagulation apparatus to the underlying root and ganglion. Disc fragments are removed using small grasping instrumentation. It is also possible to reach the disc space and to remove additional disc material.

Results

In our series, 17 patients presented with a voluminous far lateral disc herniation confirmed at surgery. Removal was easy in all cases using the endoscopic technique. Operative time ranged from 45 to 120 minutes. All patients were discharged home within 35 hours. The results were good and reported according to Macnab criteria (Table 1). The follow up period ranged from 1 to 4 years. There was no postoperative pain or dysesthesia secondary to the trauma of dissection and/or coagulation. The patients were immediately mobilized and discharged the day after surgical treatment. In the operated patients there was no neurological impairment and all of them had complete regression of radicular pain.

Table 1. *Outcome after endoscopic discectomy*

Outcome	N° of patients
Macnab criteria	
– Excellent	9
– Good	8
– Fair	0
– Poor	0

Discussion

The incidence of far lateral lumbar disc fragments is approximately 7–10% of all lumbar disc herniations [4, 17, 18]. The wide use of CT scan and lumbar MRI detect the disc fragments with increasing frequency [3, 5]. These herniation produce pain and radicular symptoms. In the past, the most common surgical approach was via a midline hemilaminectomy exposure that often requires destruction of the facet joint with subsequent instability. The other possibility is now the paramedian muscle splitting approach with microdiscectomy avoiding the facetectomy and instability [9, 11, 20]. This is the new concept of minimally invasive surgery with little discomfort, cosmetic disfigurement and towards day hospital surgery. A recent new evolution of this technique is the microendoscopic discectomy (MED) using dilators. This muscle splitting approach is the most direct route to the lumbar disc herniations lateral to the neural foramen and is greatly implemented by the use of video assisted microendoscopic technique. Radiographic view of the transverse process is mandatory for the correct position of the guide needle and dilators to avoid lesions to the root. Another point is the fat tissue that has to be measured before on the CT scan and MRI to permit the use of dilators that have now a limited length of 20 cm. This problem can be solved in the future by modifying the length of dilators. We are also working to change from general to spinal anaesthesia reducing

both hospital stay and cost. An absolute contraindication for this approach is the hypertrophic articular process that doesn't permit medial positioning and view of the optic fibers inside dilators. We never performed an approach at level L5-S1 because of the iliac crest.

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A long-term review of 50 patients out of 506 treated with automated percutaneous nucleotomy according to onik for lumbar-sacral disc herniation

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Summary

At the Orthopaedics and Traumatology Unit of the Palmanova Hospital, between 27 October 1989 and 31 December 2003 we performed 506 automated percutaneous nucleotomies according to Onik [6] for the treatment of lumbar disc hernia.

The survey of 50 reviewed cases after evaluation of the subjective and objective clinical pictures according to the Cabot method allowed us to come to the conclusion that this percutaneous methodology is suitable to relieve damaged discs from compression. It is also well accepted by patients because it is not too traumatic, it requires short-term hospitalisation, presents no risk of post-operative fibrosis and does not create complications for the eventual traditional operation when unsuccessful.

It is extremely important to accurately select the candidates keeping in mind the original indications given by Onik for percutaneous discectomy for which – in case of contained disc herniation – leg pain (sciatalgia) is more severe than low back pain affecting the lumbar region.

Keywords: Nucleotomy; lumbar disc herniation; automated.

Introduction

At the Orthopaedics and Traumatology Unit of the Palmanova Hospital, between 27th October 1989 and 31st December 2003 we performed 506 automated percutaneous nucleotomies according to Onik [6] for the treatment of lumbar disc herniation.

With this method good results are achieved particularly when patients are accurately selected [1] and when the original indications given by Onik [4, 5] for percutaneous discectomy are retained. According to these indications, leg pain (sciatalgia) is more severe than low back pain affecting the lumbar region when in connection with a contained disc herniation.

Already in October 1991, at the 2nd Meeting on ''Percutaneous Discectomy According to Onik'', held in Santa Margherita Ligure, we could report excellent or good results achieved in 93% of 75 cases we had treated. Since we had become absolutely enthusiastic about this method, we started also applying it in the treatment of patients considered out of the suggested limits and in fact, at the SERTOT meeting in the spring of 1992 in San Marino, we referred about good results we had achieved with this method in 17 cases not fitting the protocol of Onik, out of 121 patients treated before March 1992, which caused great perplexity in the audience.

Materials and methods

Only with difficulty we were able to randomly review 50 cases of patients aged between 33 and 74 years, treated in 1993 and 1994, that out of the 506 patients treated with the methodology proposed by Onik between October 1989 and December 2003.

Disc spaces involved were (Table 1):

in 4 cases L3-4 (3 on the right and 1 on the left) resulting in a total of 8% (Table 2)
in 30 cases L4-5 (15 on the right and 15 on the left) resulting in a total of 60% (Table 3)

Table 1. *Disc spaces involved were*

L3-4	4	cases (8%)
L4-5	30	cases (60%)
L5-1	13	cases (26%)
L3-4/L4-5	2	cases (4%)
L4-5/L5-1	1	case (2%)

Table 2. *L3-4*

Right	Left	%
3	1	8

Table 3. *L4-5*

Right	Left	%
15	15	60

Table 4. *L5-1*

Right	Left	%
5	8	26

Table 5. *L3-4/L4-5*

Right	Left	%
–	2	4

Table 6. *L4-5/L5-1*

Right	Left	%
–	1	2

Table 7. *Results*

Excellent	28 cases	56%
Good	10	20
Fairly good	6	12
Bad	6	12

in 13 cases L5-1 (5 on the right and 8 on the left) resulting in a total of 26% (Table 4)
in 2 cases L3-4/L4-5 on the left resulting in a total of 4% (Table 5)
in 1 case L4-5/L5-1 on the left resulting in a total of 2% (Table 6)

Results

Given the low availability, patients were evaluated on the subjective and objective clinical pictures following the methodology according to Cabot [2].

We considered (Table 7):

28 cases as *excellent* (resulting in a total of 56%) which means all patients who in the last 10 years did not present any episode of low back pain, had recovered to normal working life and had never turned to periodic physiokinetic therapy even though suggested when dismissed;

10 cases as *good* (resulting in a total of 20%) which means all patients who referred periodical low back pain that diminished after medical treatment and physiokinetic therapy or simply by using an orthopaedic corset;

6 cases as *fairly good* (resulting in a total of 12%) which means all patients who presented with partial regression of the symptoms, periodically took FANS and underwent physiokinetic therapy, hydrotherapy or fangotherapy.

The 6 cases we considered as bad (resulting in a total of 12%) underwent microdiscectomy according to Casper [3] with excellent results, respectively 1 after 7 days, 1 after 15 days, 2 after 1 month, and 2 after 1 year with periodical low back pain alternated with periods of reasonable well being.

Of these 6 cases,

2 presented a peridural extrusion at the moment of the discography

2 presented a CT report with L4-5 disc herniation, on the right and on the left respectively, and vertebral stenosis with the symptomatology localized on S1 (Lasègue, pain and paresthesia);

1 presented a CT report with large L4-5 disc herniation on the left with symptomatology localized along the root of SI and at the moment of the discography a filiform peridural extrusion floating towards the higher part of the root;

1 presented a CT report with L4-L5 disc herniation on the left and lateral recess stenosis.

Discussion

In conclusion, we achieved excellent and good results in 76% of the treated cases (compared to 93% of the 75 cases treated between 1989 and 1991).

We were presented with very few *complications and* the unsatisfactory results were corrected by performing microdiscectomy according to Caspar.

Our opinion on automated percutaneous nucleolisis according to Onik remains positive overall (and is, in our opinion, equivalent to other percutaneous treatments such as discectomy, discography, and nucleoplasty using radiofrequency energy which we also use, but have a limited number of casistics) particularly when patients are accurately *selected* according to the following symptoms:

unilateral pain in the lower limb more severe than in the lower back; positive Lasegue's sign;

alteration at the neurological level and no improvement after six weeks of conservative therapy;
paresthesia in a specific portion of the dermatome.

The main *means of survey*, apart from taking a complete x-ray of the lumbosacral region, are surely CT (without or with contrast medium) and MR scans which confirm the presence of subligamental herniation (contained disc herniation) as indicated in the clinical reports, in dubious cases also an EMG scan.

Nevertheless, the *ultimate preoperational evaluation* is based on a discogram test which allows us to evaluate the disc referring to the following 4 parameters:

mass evaluation
manometric evaluation, if needed
radiographic evaluation (how the contrast medium flows within the nucleus pulposus of a disc);
evaluation of the type of pain

Relying on our twenty years of experience (in consideration of the fact that from 1985 through to 1992 we satisfactorily treated 450 disc herniation performing chemonucleosis [7] resulting in a total of 77% of the cases), we can affirm that the *contraindications* of this method are:

pure low back pain, x-ray evidence of severe arthrosis of the articular facets, vertebral canal and lateral recess stenosis, hypertrophy of the yellow ligament, presence of spondylolysis and spondylolisthesis, congenital and acquired anomalies particularly lumbosacral transition disorders, severe degenerative discopathies such as the narrowing of some intervertebral spaces due to spondyloarthrosis, tumoral localisations, evidence of displaced fragment in the vertebral canal, cauda equina syndrome, disc extrusion, disc calcification.

In conclusion, the automated percutaneous nucleotomy methodology according to Onik is conceptually as suitable as other percutaneous methods to relieve damaged discs from compression and therefore to prevent formation of disc extrusion. It is well accepted by patients because it is not too traumatic, it requires short-term hospitalisation, there is no risk of post-operative fibrosis and does not create complications for a possible traditional operation when unsuccessful.

Finally, after ten years, we are still able to confirm the enduring benefits.

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Surgical intradiscal decompression without annulotomy in lumbar disc herniation using a coblation device: preliminary results

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Summary

Annulotomy is a mandatory step to perform intradiscal decompression to resolve a disco radicular conflict. However, this manoeuvre can lead to post surgical complications such as vertebral instability and back pain.

Coblation assisted microdiscectomy (CAM procedure) allows a quoted removal of disc without anulus damage.

Keywords: Coblation; lumbar disc herniation; annulotomy; vertebral instability; postsurgical back pain.

Introduction

In the last years with modern microdiscectomy techniques surgeons have reached many important goals in spine surgery: the incidence of intraoperative bleeding is now very low, time of hospitalization is short, the postoperative pain is low and the radicular symptoms are eliminated in a very high percentage of patients.

However, today we still have a 10% recurrence and postoperative back pain in 40% of cases.

The cause of recurrence can be sought in a loss of tension of the disc, that is even more weakened by the surgical annulotomy preceding microdiscectomy.

Postsurgical back pain can be caused by an excessive removal of disc contributing to the basis of vertebral instability and its first consequence: back pain.

The CAM procedure allows the surgeon to perform microdiscectomy without annulotomy with a defined amount of disc tissue removed.

Coblation technology removes tissue by using low-energy radiofrequency wave to create an ionic plasma field from sodium atoms within the nucleus. This low-temperature plasma converts tissue into gases by a molecular dissociation. Coblation is not temperature-driven and does not rely on heat energy to remove tissue. Thus thermal damage and tissue necrosis can be avoided.

Materials and methods

The coblation device which uses plasma energy to remove tissue and to create small channels within the disc, is of a bi-polar design allowing a fully contained plasma field at the tip to provide highly targeted tissue removal without injury to the surrounding tissue. For coagulation the device uses higher energy to create heat in the tissue (Figs. 1a and 1b).

The surgical steps for the CAM procedure are the same as for the classic microdiscectomy up to the intervertebral disc (the patient is under general anaesthesia, in genupectoral position). Thereafter we do not perform the annulotomy but a 17-gauge needle is inserted under direct control into the annulus (Fig. 2). Through this microsurgical approach the electrode is introduced which removes a defined amount of intradiscal tissue at each passage and in every planned direction determined by the surgeon.

Through this procedure a decompression inside the disc is achieved without damaging the integrity of the annulus. The extent of decompression can be verified by direct inspection or with palpation instruments.

After extraction of the needle we perform a classical closure layer by layer.

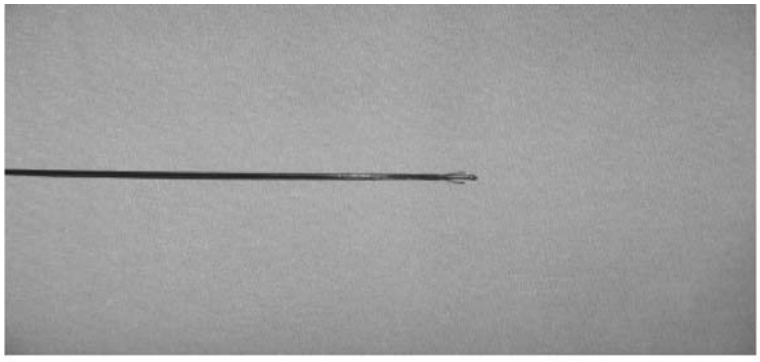
The inclusion criteria for patients were

- Leg pain greater than back pain
- MRI evidence of contained posterior-lateral disc protrusion
- Failed conservative therapy for at least 3 months

The exclusion criteria were

- Disc Height less than 50%
- Evidence of severe disc degeneration
- Spinal fracture or tumor
- Moderate/severe spinal stenosis

In the period August 2003 to September 2003, 6 patients underwent the CAM procedure. In 4 cases the herniated disc was at L4/L5, in 2



a

b Fig. 1(a–b). Micro DisCoblator (MDC) SpineWand

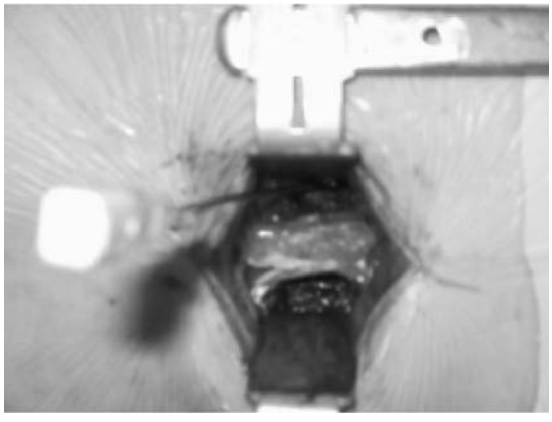


Fig. 2. Intraoperative needle insertion

at L5/S1. In 4 cases the herniation was left, in 2 right. One patient had a previous microdiscectomy at the same side and at the same level. We did not use topic steroids in any patient.

The referred symptoms were back pain with sciatic pain in 3 cases, 3 patients had only radicular symptoms.

Only one patient presented weakness in the tibialis anterior muscle.

All patients were discharged on the third day with orthopaedic corset.

Results

During the surgical procedure we achieved in all cases an important intradiscal decompression, aimed at disappearance of the radicular conflict. The annulus, after pulling out the needle, was macroscopically intact.

The immediate results (at discharge) were excellent: the pain had disappeared in all cases from the day of surgery.

The short term follow-up and the small number of treated cases does not allow quantification of recurrence frequency but we think the intradiscal decompression obtained and the annulus preservation are important to improve results and to minimize post surgical complications.

Conclusions

We think that the CAM procedure is a useful technique for intradiscal decompression without damage to the annulus (which would be the base of a low percentage of recurrence) and a predetermined tissue removal procedure (the basis for a low percentage of vertebral instability). The limited series and the short follow-up period does not permit the authors to provide definitive results. This is left to the future through further studies.

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CAM versus nucleoplasty

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Summary

In recent years the general trend in spinal surgery has been reduction and minimalization.

In general, all these have shown a moderate or good clinical result but they have been associated with serious sequelae. Plasma-mediated electrosurgery, widely used in other medical fields, has demonstrated to be well suited for this new indication. To perform the *Nucleoplasty* (Coblation) and the *CAM* (Coblation-Assisted Microdiscectomy) is use the Perc-DLE SpineWand connected to a System 2000 generator (ArthoCare Corp., Sunnyvale, CA) was used. The device functions via plasma-mediated electrosurgery (Coblation) and differs from traditional electrosurgery.

From a small sample 64 operated patients with contained disc herniation were analysed and classified into those who underwent percutaneous disc decompression (PDD) using coblation technology and patients who underwent CAM. All patients who presented with PDD were considered candidates for open surgery but all of them opted for the new technique. There was no contraindication. They had discogenic low back pain and/or leg pain and the procedure was performed on an outpatient basis. Follow-up data was of 1 to 12 months. Patients' gender distribution for PDD was 65% (41,6) male, 35% (22,4) female with a mean age of 43 years. The average duration of pain before nucleoplasty was of 18 months and none of them had previous lumbar surgery. At 6 to 12 months, 80% of the patients demonstrated an improvement in pain scores (75% very good, 5% good, 15% improved but not good, and 5% no effect). None of the patients was worse. Results indicate that Nucleoplasty may be an efficacious minimally invasive technique for the treatment of symptoms associated with contained herniated disc. However, randomized controlled studies are required to know with more precision the role of this procedure. CAM procedure (13 cases) is an excellent method in cases of root compression that needs liberation or in spine stenosis.

Keywords: Percutaneous disc decompression; minimally invasive surgery; coblation by radiofrequency; nucleoplasty; disc herniation.

Introduction

Seventy years ago Mixter and Barr [8] established in their paper the relationship between herniated discs and sciatica, and how disc excision relieves pain associated with leg pain.

Chronic low back pain from discogenic origin continues to represent a diagnostic dilemma for spine specialists, secondary to the difficulty of accurately verifying the pain generator. In addition there is uncertainty as to whether discogenic pain mediates via chemical, neural, or a combination of above mechanisms.

Percutaneous decompression to treat disc herniation is a well-established technique which has demonstrated good clinical success in properly selected patients. In the last decade, several different approaches have been developed for performing this procedure. All of these techniques were designed to remove intradiscal nucleus pulposus in order to relieve pressure on sensory structures, and produces an enzymatic break of the disc nucleus using chymopapain [2, 5], vaporization with laser-based technology [4], mechanical tissue resection with manual or automatic nucleotomy [9] or with endoscopic technique [7]. In general all these techniques have shown good clinical results but have been associated with serious sequelae. The chymopapain would produce spinal instability and disc collapse, possible root damage and allergic reaction, it can even cause death. Percutaneous nucleotomy may be difficult to carry out because sometimes correct positioning may be unpleasant and therefore is frequently uncomfortable for the patient. The laser technique generates high levels of heat within the disc and to adjacent tissues and has been associated with osteochondral defects and intense postoperative pain and lumbar spasm.

Plasma-mediated electrosurgery, widely used in other medical fields, has demonstrated to be well suited for this new indication [13]. For nucleoplasty the Perc-DLE or the Micro Discoblator (MDC) Spine Wand connected to a System 2000 generator (ArthoCare

Corp., Sunnyvale, CA) is used. The device functions via plasma-mediated electrosurgery (Coblation), which differs from traditional electrocautery. Plasma-mediated electrosurgery is initiated by inducing a high voltage current, between 100 and 300 V. When combined with an electrically conductive fluid (like isotonic saline), the interaction produces an ionized vapor layer, or plasma, of about 75 μm thick. Charged particles in the plasma are accelerated by intense electrical field within the plasma and carry enough energy to induce molecular dissociation, which is opposed to the thermal denaturation attributed to standard electrosurgery tools. So with plasma-mediated electrosurgery, a precise pathway can be produced with minimal thermal penetration into surrounding tissue [11].

Percutaneous nucleoplasty or coblation tries to reduce the intervertebral pressure in order to reduce or remove the disc prolaps and the radicular compression [3]. This is achieved by vaporization of the proteoglicans of the nucleus pulposus through coblation (coagulation with controlled temperature). This procedure is "blind", so for nucleoplasty it is not possible to assure efficacy in reducing the discal prolaps and liberation of the radicular compression. However it is a safe technique which takes place under "out patient regime" and under local anaesthesia and sedation. Coblation-Assisted Microdisc (CAM) offers security in radicular decompression aided by foraminotomy and by amplification of the lateral spinal canal and reduction of the discal prolaps under direct vision through a microscope due to coblation. All the above methods try to avoid possible instabilisation and reccurrence of the disc hernia through incision in the anulus fibrosus. In both cases it is essential to have a correct diagnosis from the clinical report and the findings from additional examinations, fundamentally Magnetic Resonance (MRI), as well as d failure of conservative treatment.

Nucleoplasty is *indicated* in:

Contained disc herniation under the fibrosus ring, in a lateral, lateroforaminal, and extraforaminal position, with a "black" disc on MRI and without an acute compression irritation symptoms from the nervous root without neurological deficits, especially motor deficits.

Nucleoplasty is *contraindicated* in:

Cases of severe degenerative disc with loss of disc height greater than 1/3, segmental stenosis of spinal canal with associated facet symptoms in older people in whom radicular mechanical decompression is required and where other methods like ozonetherapy would be more relevant. (Table 1)

CAM is *indicated* in:

Contained disc herniations with root compression or segmentary stenosis that needs liberation. The big contained disc herniations situated in the middle or midlateral with a high compression syndrome in young people with a "black" disc on the MRI who require maximum security concerning results or because they have sensorial or motor neurological deficits. In exchange, the patient must accept the typical risks of microsurgery (especially epidural high compression syndrome of fibrosis), epidural anaesthesia and hospitalization of 12 to 24 hours. (Table 2)

Table 1. *Selection criteria for Nucleoplasty*

Indications: Radicular/axial pain
MRI evidence of contained disc herniation (DH)
Failure of at least 6 weeks of conservative therapy
Extraforaminal DH without neurological deficits
When patient like minimal almost innocuous therapy
Contraindications:
Severe degenerative disc with 1/3 loss disc height
Segmental stenosis and associated facetary symptoms
Root compression needing liberation in older patients
Sequestrated disc fragment, tumours, etc.

Table 2. *Selection criteria for CAM*

Indications: Radicular pain + motor deficits
MRI evidence of contained DH + root compression
HD associated to spinal stenosis + root compression
Contained DH with "black" symptomatic disc in younger patients
Contraindications:
Disc extrusion or sequestration, tumours, etc.

Materials and methods

From January to December 2003, 64 patients who met the inclusion criteria, were recruited for PDD with coblation technology (nucleoplasty) and data was collected on a prospective basis. To be included in the study patients had to satisfy specific inclusion and exclusion criteria. *Inclusion* criteria were complaints of back pain with or without radicular pain, and failure of conservative care for at least six weeks (physical therapy and lumbar stabilization exercises, the use of posture and activity modifications, and oral NSAIDs). *Exclusion* criteria were previous surgery in the region, presence of a sequestered herniation free into the spinal canal, larger than 1/3 of the sagittal diameter of the spinal canal, severe spinal stenosis and the presence of progressive neurological deficits. Nucleoplasty was performed on an outpatient basis with local anaesthesia and endovenous sedation in an operating room using sterile technique and

fluoroscopic guidance. The patient received antibiotic prophylaxis of 1 gm of intravenous Cefazolin as unique dose. Patients were positioned in lateral decubitus, right or left according to the side of pain. This facilitates the work of the anaesthetist easy access to air duct is needed. A 17-gauge six-inch long needle was then introduced into the posterolateral corner of the disc using a posterolateral extrapedicular approach with fluoroscopic guidance in semi-oblique position to localize the Kambin's Triangle just anterior to the ear of the "shootish dog" [6]. The AP projection was checked to determine that the needle had correct position. The 17-gauge needle was then introduced through the annulus and the spine wand was inserted through the needle after checking with the aid of discography that the disc herniation is captured. A total of 6 channels were created at the 2, 4, 6, 8, 10 and 12 o'clock positions. Because of the C shaped curve at the tip of the wand these six channels decompress a cone shaped area of nucleus. Patients were discharged home within one hour of the procedure. Patients were allowed unlimited walking, standing and sitting and instructed not to perform any lifting, bending or stooping for 2 weeks and formal physical therapy for lumbar stabilization exercises starting 3 weeks post intervention was recommended.

In the same period of time, 13 cases of CAM were operated under epidural anaesthesia with coblation technology using the approach as described by Williams [12] but changing the annulus incision by just direct puncture on the disc herniation through the microscope after the root was liberated and separated. Then the Perc-DLE Spine Wand was introduced to create the same coblation canals for disc decompression. This technique avoids an instabilisation and offers to the surgeon to watch disc retraction through the microscope. Patients were discharged home within the first 24 hours after the procedure and were allowed unlimited walking. Formal physical therapy for lumbar stabilization exercises starting three weeks post procedure was recommended.

Questionnaires were filled out by the patients pre-procedure, at one week, one month, six, nine and twelve months. It contained patient satisfaction, absence of narcotic and NSAIDs use, as well as return to usual work life. Patient's satisfaction was measured with a scale ranging from 0 to 3 with 0 = equal or worse, 1 = satisfactory, 2 = good, and 3 = very good. Satisfaction score greater or equal to 1 was considered a success for this parameter. Patients were considered a failure if they did not meet a better situation or proceeded to surgery.

Results

Sixty four coblation procedures of percutaneous nucleoplasty (PDD) were performed and 13 cases of CAM (Coblation-Assisted Microdisc). Given here are preliminary results since data collection is still ongoing. None of the patients were referred to open surgery in that region. (Table 3)

From the 64 cases of nucleoplasty, 41,6 (65%) were male and 22,4 (35%) were female with a mean age of 43 years, age ranging between 23–57 years old. Fifteen were followed for one year, 35 for 9 months, 47 were followed for 6 months, 58 for 3 months and 62 for at least one month. The average duration of symptoms prior to nucleoplasty ranged from 2 months up to 124 months. Two patients were lost to follow up. Eighty per cent of all cases were satisfied with significant improvement at the one, three, six, and twelve-month follow-up visits when compared with baseline values (Table 4).

Table 3. Demographic *characteristics*

Gender	Male	41,6 (65%)
	female	22,4 (35%)
Age (years)	Mean ± SD range	43 ± 9,8 23–57
Duration of pain (years)	Mean ± SD range	1,3 ± 1,6 0,2–1,3
Surgery levels	L3-L4	3 (4,3%)
	L4-L5	38 (59,3%)
	L5-S1	23 (35,9%)
Two levels	L3-4 + L4-5	2 (3%)
	L4-5 + L5-S1	5 (8%)

Table 4. *Numeric pain score results reported in PDD*

Percentage of improvement in numeric pain score	
Follow-up	percentage
Baseline (N = 64)	–
1 month (N = 62)	83
3 months (N = 58)	82
6 months (N = 47)	80
9 months (N = 35)	79
12 months (N = 15)	78

Functional improvement was observed for sitting, standing, and walking abilities in more than 75% of patients. No complications were observed during or after the PDD procedure. Although this outcome analysis is neither randomized to a placebo-controlled group nor double-blinded, several reports indicate that results from observational studies do not differ significantly [1].

Of the patients treated with CAM (13 cases), 10 were male and 3 female with a mean age of 30 years old. Only one case had a poor outcome after the procedure and was re-operated with a classic microdiscectomy with good results. An extruded fragment of disc was found one month after nucleoplasty. It is impossible to establish further conclusions with such a limited number of cases but in general CAM is a good technique, especially when root liberation in addition to disc decompression is necessary.

Conclusions

Our initial data indicates that although long-term data is not available, using coblation (nucleoplasty)

technology is a promising treatment option for patients with contained disc hernia who have failed conservative treatment and are not considered candidates for open surgery or simply because they do not want to accept the risks of microdiscectomy, especially epidural high compression syndrome of fibrosis. CAM is considered the best technique for contained disc herniation in mid or mid-lateral situations in the spinal canal with a high compression syndrome in young people.

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Paraspinal approach to the far lateral disc herniations: retrospective study on 42 cases

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Summary

Forty-two patients underwent surgery for far-lateral disc herniations. Average patient age was 45.1 years, 28 patients were male and 14 female. The level concerned most was L4-5 disc (55%). A paramedian muscle-splitting intertransverse approach is described for this type of disc herniation. This method allows direct visualization of the disc and root involved and does not provide bone resection and important surgical manipulation. Ninety-one percent of the patients reported excellent or good results according to Macnab outcome criteria with an average follow-up of 32.5 months (range 1–5 years). Twelve patients (28.6%) developed postoperative transient radicular pain that disappeared in 15–21 days after analgesic therapy. There were no recurrences or spinal instability.

The paramedian muscle-splitting intertransverse approach is a rational technique. Its advantages are that the spine is not opened and spinal stability is maintained. It requires minimal soft-tissue and bone resection and the herniated disc is directly visualized. Moreover, it contains minimal manipulation of the neuro-vascular structures and avoids significant muscle retraction. However, it requires an adequate learning curve and good familiarity with microsurgical techniques.

Keywords: Far-lateral disc herniation; paramedian approach; microdiscectomy.

Introduction

Far lateral disc herniation occurs with a frequency between 0.7–11.7% of all lumbar disc herniations [1, 2, 6, 10, 17, 19, 20, 23, 29]. Abdullah *et al.* [1] first described the corresponding clinical syndrome in 1974. These herniations, previously considered rare, are increasingly being identified by improved imaging techniques [8, 10, 16, 25, 27–29]. Different surgical approaches can be used to treat extraforaminal disc herniations. Previous techniques included: 1) conventional approach via midline laminectomy with medial or total facetectomy; 2) combined intertransverse technique; 3) anterolateral retroperitoneal approach; 4) percutaneous technique; 5) a paramedian extraforaminal approach [4, 5, 7–9, 17, 20, 24, 29, 31, 34–37]. Midline approaches may provide inadequate exposure to the foraminal region and may require extensive removal of bone structures and needs spinal fusion for instability. The paramedian approach has become popular during the last decade and provides better visualization of the abnormality without significantly disturbing the facet joint. The target of this approach is the lateral part of the isthmus through a para- or transmuscular approach. In recent years, Foley KT *et al.* [12, 13] described a new surgical technique called microendoscopic discectomy. This approach combines endoscopic and standard open microsurgical techniques.

The paper presents the long-term outcome in 42 patients with far-lateral herniated disc who were surgically treated via the paramedian muscle-splitting intertransverse approach.

Material and methods

Forty-two consecutive patients underwent paramedian surgical removal of far-lateral lumbar disc herniations between January 1995 and December 2002 at the Neurosurgical Unit of General Hospital of Cosenza (Italy). These procedures represented 2.2% of the 1956 lumbar disc surgeries performed during that period. Preoperatively all patients presented radicular pain and variable neurological signs and symptoms and had unilateral, single level, far-lateral disc herniation demonstrated on computerized tomography and/or magnetic resonance imaging (Table 1). There were 28 men (65.1%) and 14 women (34.9%) with an average age of 45.1 years (range 22–65 years).

Table 1. *Summary of patient data*

Characteristics	No. of patients (%)
Male	24 (65.1%)
Female	14 (34.9%)
Preoperative signs	
Radicular pain	42 (100%)
Motor deficit	13 (30.9%)
Sensory deficit	25 (59.5%)
Decreased deep tendon reflex	35 (83.3%)
Level of herniation	
L3-L4	8 (19%)
L4-L5	23 (54.9%)
L5-S1	11 (26.1%)
Diagnosis	
C.T.	11 (26.2%)
M.R.	14 (33.3%)
C.T.+M.R.	21 (50.5%)

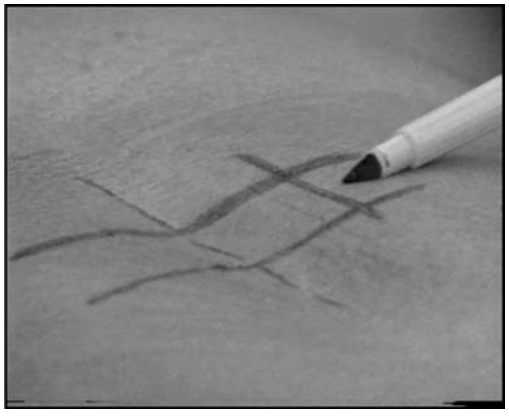

Fig. 1. Preoperative picture showing skin incision ( ) ▲

Surgical technique

Following induction of general anesthesia, the patient is positioned prone on a lumbar frame. All patients received prophylactic antibiotics before surgery. A paramedian skin incision, approximately 5 cm lateral to midline and 3–4 cm long, is made between two skin landmarks after the appropriate level has been identified using a spinal needle and a fluoroscope (Fig. 1). After incision of the erector spinae aponeurosis, the fibrous separation between the multifidus and longissimus muscles is dissected. Blunt dissection is used to expose the lateral aspect of the facet joint and the transverse process above and below the disc level to be explored. To maintain the exposure the self-retaining Caspar retractor is positioned. After x-ray confirmation of the correct interspace, the operating microscope is introduced and the intertransverse fascia and muscle is identified and divided (Fig. 2). At this point, the radicular artery and vein, the nerve root and the dorsal root ganglion are disclosed extraforaminally. Often the exposure is too far lateral and one must continue to work medially. In these cases, care must be taken regarding exposure of the nerve root in order to avoid injuring. The herniated disc is exposed and removed with the microscissors and, using small straight rongeurs, the nucleus pulposus tissue is removed as far as possible. In L5-S1 cases additional medial exposure is indispensable which may be obtained by removing the lateral part of the iliac crest.

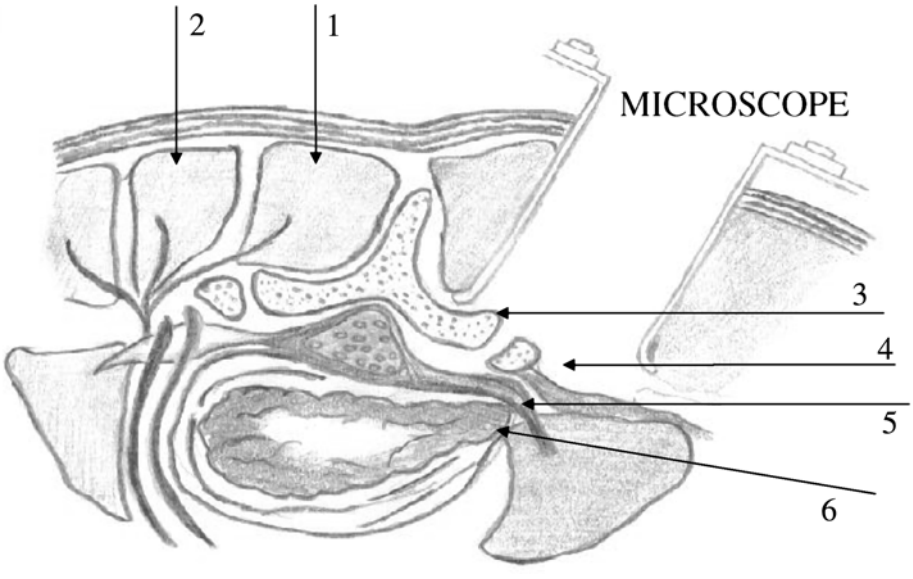

Fig. 2. Artist's diagram showing the area of paraspinal approach after the insertion of a self-retaining Caspar retractor and introduction of the operative microscope: (*1*) multifidus and (*2*) longissimus muscle; (*3*) the facet joint, (*4*) the transverse process, (*5*) the spinal nerve root, (*6*) herniated disc

Table 2. *Macnab outcome criteria*

Classification	Criteria
Excellent	no pain; no restriction of activity
Good	occasional back or leg pain of sufficient severity to impair patient's ability to do normal work or capacity to enjoy leisure
Fair	improved functional capacity but handicapped by intermittent pain of sufficient severity to curtail or modify work or leisure activities
Poor	no improvement or insufficient improvement to enable increase in activities; further operative intervention required

Results

The average surgery time was 55 minutes and the patients were discharged after two days. The mean follow-up period was 32.5 months (range 1–5 years). Overall analysis of results was based on the Macnab outcome criteria [23] (Table 2). Excellent results were documented in 32 cases (76.2%), good results in 6 (14.3%), and fair results in 4 (9.5%). In the immediate postoperative period 12 patients (28.6%) developed radicular pain and 3 (7.1%) showed burning dysesthesia in the zone of the nerve root involved. The pain was transitory and disappeared after 15–21 days following medical treatment with indomethacin. Burning dysesthesia was also transient and never persisted longer than 2 months. No patients experienced residual motor deficits. Of the 25 patients with preoperative sensory abnormalities, only 3 (7.1%) had residual decreased sensation. There were no surgery related complications or recurrences or lumbar instability in this series of patients during follow-up period.

Discussion

Far-lateral lumbar disc herniations, first described by Abdullah *et al.* [1], previously considered rare, are increasingly being identified by improved imaging techniques [8, 10, 16, 18, 25, 27–29], and represent an incidence of 0.7–11.7% [2, 5, 25, 29, 30] of all lumbar disc herniations. They can show at any age, but usually occur in older patients [1–5, 7–12, 17, 21, 22, 24, 26, 32]. Level L4-5 is the most common lumbar herniated level (30–60% of the cases) [2, 4, 5, 10–12, 17, 24, 26, 32]. The clinical presentation and requisite diagnostic imaging are well documented in the literature [1, 2, 4, 5, 7–12, 17, 21, 22, 24, 26, 30, 32, 33].

Although many different surgical approaches have been described to treat the far-lateral lumbar disc herniations, there is a continued debate regarding the better surgical method for this entity. One of the most common approach is posterior midline hemilaminectomy exposure combined with partial or complete facetectomy. This is an attractive option because it involves a well-known midline approach. It provides an important bone resection that undoubtedly determines good visualization of the involved nerve root but may also lead to destabilization of the spine. Many authors, in fact, have reported instability in motion segments following facetectomy [10, 17, 22, 29]. Moreover, even without significant instability, this approach determines altered paths of loading in the three columns of the spine. It is responsible for postoperative low-back pain due to degeneration in the adjacent discoligamentous structures [14, 15, 17]. To avoid the extensive bone resection, several Authors proposed and developed a paramedian alternative approach [14, 31, 34–37]. In 1953 Watkins [35] first proposed the lateral approach and Wiltse *et al.* [36] modified the technique by splitting the paraspinal muscles between the multifidus and longissimus muscles [37]. With this method, the dissection remains immediately lateral to the facet joint and retraction is minimized. The nerve root is directly beneath the intertransverse ligament and the microsurgical technique aids in the dissection with minimal resection of bone, when necessary, and little risk of injury to neurovascular structures. In addition, the minimal soft-tissue dissection and retraction determines faster postoperative mobilization of the patients. Despite these advantages, the approach is not familiar to many spinal surgeons and sometimes is not simple to carry out.

Since January 1995, to achieve less surgical invasiveness, we selectively performed the paraspinal approach as described by Watkins and Wiltse. The most important perplexing clinical problem encountered is that some patients developed severe pain postoperatively and burning dysesthesias, as several authors reported [4–10, 24, 29, 34]. The mechanism by which these manifestations are produced in not known. It is possible that the manipulation of the spinal nerve and especially the traction of the dorsal ganglion at the time of dissection might be responsible for the disabling pain. Fortunately, these manifestations were transient and disappeared after 15–21 days or two months, respectively, in our patients. Another difficulty encountered in our experience concerned level L5-S1. This intervertebral space is close to the

prominent alae sacralis or iliac crest which may render sight into the depth of the operative field impossible. In these cases more extensive far-lateral bone resection of the sacral structures and greater angle-shot of the operating microscope is appropriate.

Reported excellent or good outcomes with the use of a paramedian approach of the far-lateral lumbar herniations range from 70 to 100% compared with 67–100% in series with the use of a midline or combined approach [2, 4, 5, 7–12, 17, 22, 24, 26, 30].

Our findings are comparable to results reported in the literature. Ninety-five percent of the patients in our series showed excellent or good long-term outcome. There were no cases of postoperative lumbar instability and no cases of recurrences at final follow-up. Moreover, there were no complications related to surgery.

Conclusion

The paramedian muscle-splitting intertransverse approach to far-lateral lumbar disc herniations is a safe and minimally invasive surgery and offers a valid alternative to the midline approach. It requires minimal soft-tissue and bone resection and the herniated disc is directly visualized. Moreover, it determines minimal manipulation of the neuro-vascular structures and avoids significant muscle retraction and potential spinal instability due to excessive bone resection. However, it requires an adequate learning curve and good familiarity with microsurgical techniques. Sometimes the paramadian approach is not easy to carry out and it is necessary to utilize a combined approach.

Acknowledgments

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Surgical radio-frequency epiduroscopy technique (R-ResAblator) and FBSS treatment: preliminary evaluations

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Summary

Failed back surgery syndrome represents a heterogeneous situation that suggests a fibrosis or neuroinflammatory genesis. The social cost related to this issue are enormous. Several surgical techniques have been applied to FBSS patients with controversial effectiveness. In 1998 we evaluated the efficiency and limits of epiduroscopy treatment; it proved to be effective in 75% of cases, but in 45% of cases it needed to be repeated after 12 months. Therefore we subjected 14 patients, who had previously experienced a short temporary benefit by using a traditional epiduroscopic approach, to a new epiduroscopy fibrolysis using a radio-frequency device named "R-Resablator Epiduroscopy". Clinical evaluation was performed before myeloscopy and after 1–3–6 months. After myeloscopy, 93% of patients reported a general improvement. Among the latter, pain was reduced by 90% in 8 patients, by 60–70% in 5, and by less than 30% in 1.

Conclusion. It can be concluded that RF-Epiduroscopy offers greater therapeutic benefit than traditional epiduroscopy or other surgical techniques. Furthermore, RF-Epiduroscopy is more easily performed and repeated.

Keywords: Epiduroscopy neurolysis; back pain; epiduroscopy FBSS treatment.

Introduction

Despite the improvement of surgical practices for painful spine pathology, there is still a high percentage (10–40%) of pain recurrence [1], called "Failed Back Surgery Syndrome" (FBSS). The expression Failed Back Surgery Syndrome groups up very different clinical situations (pain in lumbar axial site – radicular pain with or without claudication – instability of the posterior compartment) which only have in common persistent pain and radiological iconography (MRI-CT) characterised by the presence of fibrous tissue. According to Burton [7], however, only among 24% of patients suffering from FBSS does pain have an etiogenesis from fibrosis, with the formation of adhesions among tissues and compression or "tethering" of nerve roots; no evidence is reported in the literature of linear correlation between epidural scars and radicular pain, unless the fibrosis is very large [16]. It can therefore be assumed that other mechanisms as well as the described mechanical-compressive one, are responsible for pain in FBSS [4]. Neuro-inflammatory factors play a more substantial role [21], even when there are no compressive causes [20]. This has been detected in an interesting way, by means of myeloscopic investigation [13]. Our experience has shown how morphological pictures of the epidural area in FBSS patients are much more complex and heterogeneous than what can be identified with traditional investigation. The relation between pain and fibrosis depends on fibrosis distribution within the epidural specum and the strain generated on the surrounding tissue. Recurrence of pain-free intervals suggest that the phenomenon is biochemical and is generated by stress in an area which is made anatomically sensitive by adhesion fimbria.

Nevertheless, pain persistence, negative economical impact, and patients' poor quality of life do not seem to be affected by pharmacological approach [7–11–19]. The social cost related to this issue is still huge [5]. Several surgical techniques have been applied to FBSS patients displaying controversial effectiveness [6–8–22], while Spinal Cord Stimulation (SCS) seems to be more effective [12]. As for the latter, one must bear in mind that tolerance, especially in young adults, may develop in 6 to 8 years. Which therapy should be implemented [9] and with what progression? Based on our experience, we have evaluated in 1998 the effectiveness and limits of this method [18]. Myeloscopy proved to be effective in 75% of FBSS cases, but in

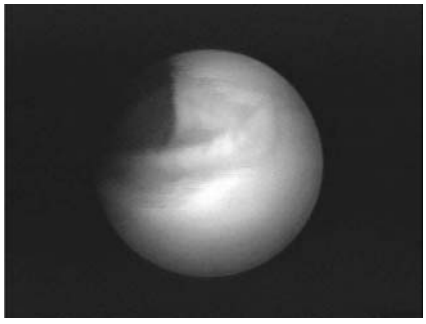

Fig. 1. Dura with false septa. The surface of the dura appears wrinkled (see arrows) with 'sail-like' aspects as dura was probably pulled by above or underlying fibrous traction

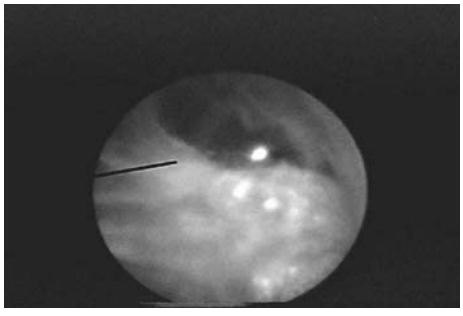

Fig. 2. Jagged or cotton-candy-like structures. Fibroid elements of transparent nature like bluish flaps interfere with the view of the dura. These structures adhere onto the surrounding tissues while exhibiting low adhesiveness onto the dura

45% of cases [13–14–15] it needed to be repeated after a 12-month period, so we introduced a new technique for the lesion of strangulation fimbria by using an RF thermo-knife inserted by means of the endoscope in order to improve the outcome.

Morphologic considerations [13–14]: endoscopic pictures (Figs. 1, 2): myeloscopy shows that there are very different morphological pictures, but they can be classified according to the presence of inflammatory situations and vessel alterations, which normally generate an axial lumbar pain, or scarring and adhesion bands with no flogosis element. The fibrotic component can also be divided into four subgroups based on the distribution of the pattern adhesion fimbria in the epidural channel: median connective sedimentation, diffused "honeycomb", blind transversal fimbria with total or partial stenosis, parallel to the side walls.

It can then be divided into 2 categories based on adhesiveness on dural structures: it adheres to the dura with painful distension of meninges and perineural tissue from traction that we have defined as "functional instability" or it can adhere to inert tissue without any distension, defined as "stable stenosis".

Table 1. *The morphological features %*

Morphological features	%
Fibrosis	55
Flogosis and hyperaemia	37
Stasis	29

The morphological features in our experience show the presence of functional stenosis from fibrosis in 55% of cases, flogosis and hyperaemia in 37%, alteration of microcirculation with stasis in 29% (Table 1).

Depending on the prevalence of the two pictures there will be a different therapeutic response to the procedure. The possibility of pain relief just with the infusion of liquids (antibiotics and saline) justifies a neurochemical-bacterial pathogenesis, which could be generated by the structural pericicatrical strain, since after different lengths of time there is a reappearance of the same pain. *Sacral pathology*. We would also like to stress an important factor which regards the scarce consideration often given by authors to the sacral component as site of pain genesis and presence of pathology. The presence of structural anomalies in the sacral compartment is common (50%) which can be the cause of a portion of the clinical pictures in FBSS patients, due to the co-existence in clinical correspondence areas, when they are subject to liquid dilation.

Materials and method

Patients. We have studied 14 patients (average age: 48 years). Primary pathology: secondary FBSS resulting from multiple spine surgeries (a minimum of two, discectomy/emilaminectomy – stabilization). Inclusion criteria were: presence of persistent radicular back pain related to previous rachis operations. Pain duration: at least two years after surgery.

Pain intensity: VAS > 5 (average VAS: 7).

Patients

- Had no pain relief after physical or invasive analgesic treatments, such as administration of drugs (NAISDs-weak Opioids) on a twice a week basis;
- Were subject to a first traditional epiduroscopy with a transitory (less than 3 months) partial pain relief;
- Displayed epiduroscopic morphological evidence of connective fibrosis with "Functional Instability";
- Responded well to active drug after "Intrathecal tests" (injection in the subarachnoid space of anaesthetic-opioids/paravertebral placebo) which excluded psychological pathology;
- Did not display imaging (MRI-CT) and electrophysiological (EMG) red flags.

Subjective evaluation of methods' outcomes. Patients before epiduroscopy (T0) and at the first (T1), third (T2) and sixth (T3) month after it, were evaluated by a blinded investigator. Patients were asked to estimate pain intensity by using an analog scale (VAS), and whether they had any benefit from epiduroscopy (yes/no). Those who responded in the affirmative were asked to rate their pain reduction using three categories: over 70%, 70–50%, 50%. Less than 50% was recorded as a negative result. A second question regarded reduction in analgesic drug consumption (100% – more than 50%).

Materials and technique

Optical fibre instruments commonly used are: single use with re-sterilizable optic fibre and protection single use videocatheter – manufactured by Myelotec (0.8 mm).

Patient preparation: Pre-anaesthesy with fentanyl and atropine (intra-operative use of propofol at sub-hypnotic doses); prone position on the radio transparent bed.

Sacral-elective approach to ease and lower invasiveness of execution [14–19]: identification and insertion in the iatus sacrale, after the fluoroscopy L/L guide of the dilation instrument through which a video-catheter with the optic fibre is positioned. If it is impossible to use the sacral path (due to a blocked stenosis iatus or to sacro-coccygeal ligament's ossification), one has to use a cranio-caudal interlaminar lumbar approach, two metamers above the site of the pathology (this is a more invasive technique) [13]. Dilation of the channel by means of liquid: infusion with a 20 ml syringe, with individual bolus at time intervals every 3–4 boluses (perforaminal diffusion time) – total dose from 180 to 350 ml – average dose 220 ml. Contrastography with Iopamiro (5 ml) after identification of the pathological space – purpose: to assess how the fluids are distributed and identify the presence of total channel stenosis and patency of sacral foramens.

Raffaeli-Righetti Technique (RR Myeloscopy technique)

1st phase adhesion subsidising

Preparation of the site by cleaning the channel structures by mechanical dilation and skeletization, removal of fat and low-adhesivity fimbria by selective pressure of fluids in situ and traction/dilation with Fogarty 3 F float.

Mechanical dissection of connective structures: by dragging with the endoscope tip in rotation and dilation of the fogarty float (Fig. 3).

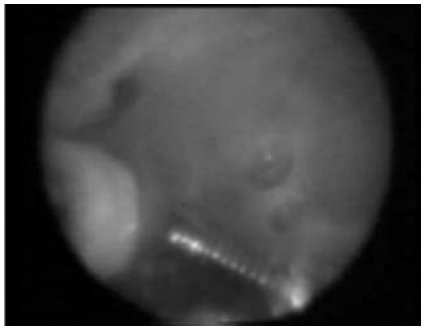

Fig. 3. Fogarty float

2nd phase – resection by radio frequency ablation

Surgical instrument: Res-ablator 50. Introduction through the video-catheter's operative channel. Ablative fibre type 0.8 mm reseflex. Spherical ablative tip. Modulated 4 Mhz output frequency in coagulation. Working depth: 1 mm beyond the tip.

Technique: Preparation of the channel and visualization of tissues by means of the first procedural phase. Identify, by means of skeletization with video-catheter tip, the newly-formed vascular component which appears blurred with the scar connective network/reticulum and proceed to insulating the individual fibrous septa with the application of RF, in the median fibrosis site for 2/3 times, until complete resection and disconnection from the base. Cleaning with fluids and float to isolate the fibroses in progression. Do not proceed to lesion if the dura/fimbra interconnection point is not visible. Avoid lesion of the structures at the insertion base with dural pannus. Proceed to removing septa and dilation of the channel until completely isolating the dural pannus from fibrous shoots. Dilation with float – cleaning with liquids and assessing any bleeding sites to be selectively coagulated by RF and removal of system after local application in inflammatory sites of steroids – (80 mg) and antibiotics – 100 mg (Ciprofloxacina).

Surgical time: 35 minutes.

Results

Anatomical effects: As we can see in Fig. 4 the Resablator epiduroscopy technique permits to remove the connective tissue totally in those conditions in which traditional epiduroscopical approach is not effective.

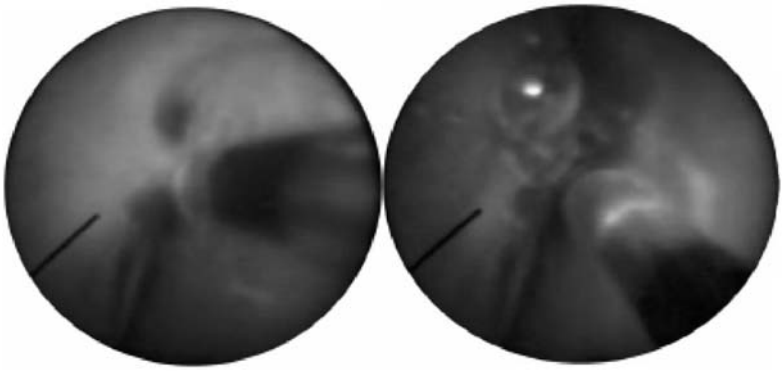

Fig. 4. During and post RF lesion

Table 2. *Pain reduction*

Pain reduction %	n. patients
<30%	1
60–70%	5
>90%	8

Subjective evaluation.

Compliance with the clinical investigation was total as all patients responded to the questionnaire. After myeloscopy, 93% of patients (n = 13) reported a general pain relief. Among the latter, pain reduction was over 90% in 8 patients, of 60–70% in 5, and less than 30% in 1 patient. For a quarter of patients [5] benefit lasted <1 month; for the other groups benefit was over 80% at the sixth month. Six patients: all patients stopped weekly analgesic use and half of them used weekly opioids sporadically (less than 10 days in a month): tramadol (9.4%) (Table 2).

Complications: short-long term: none.

Discussion

Surgical approach to FBSS patients is reported to have a low success rate. Some authors [2] report that repeated surgery in FBSS cases fails to give any pain relief in 60% of cases, worsening in another 20% of cases and sufficient benefit in only 20% of cases. Similar results were found more recently [11] making this approach highly inadvisable, except when instability of the rachis is involved. As previously reported [14–15] we believe that fibrosis is not the only cause of persistent pain in FBSS. So in our series, patients in whom fibrosis was not removed reported pain relief as just the same. Thus we are in agreement with those authors who attribute pain to fibrosis only in 24% of cases [1]. Hence, fibrosis generation by itself is not a synonym of FBSS [18]: often, before symptoms arise, there is a pain free window during which alongside fibrosis, other painful neuro-inflammatory phenomena and local fibrous impairments may develop. We have described extensively these phenomena in the epidural space and reported in accordance with other authors [10–15–16] the effective pain relief obtained by traditional epiduroscopy [13–15–16]. The peridural scar, especially when extensive, has widely been considered responsible for FBSS by Ross [16] who found that increasing scar scores led to an increased likelihood of experiencing recurrent radicular pain. We know that epidural structures upon which fibrous tissue anchors may determine during some conditions (e.g. increased SCF pressure) a traction on the inflamed dura and elicits pain (“dynamic instability”), so in this morphological condition we think it is indispensable to remove the fibrosis, otherwise there would not be persistent benefit. Epiduroscopy results proved to be effective in FBSS pain relief [15–16] but is poor in more than half over the years and the technique is no longer indicated.

Our preliminary findings show that in patients with dynamic instability it is important to remove the link with the dura to obtain a prolonged pain relief.

We need to gain further experience to find out which is the best epiduroscopy approach and select the patient patterns.

Conclusion

It has been shown that epiduroscopy has a specific therapeutic value. The effectiveness in FBSS patients

proved to be not inferior than other non-surgical techniques, with the advantage of easy implementation, limited invasiveness and repeatability. Given the variability of the identified pathological features, the technique is essential for a morphological diagnosis.

The set-up phase of the new technique allowed us to verify its limits and advantages as well as to define its technical features and to facilitate interventions. We think that introduction of the RF lesion method will lead to higher therapeutic benefits; it must be implemented in all conditions (Raffaeli) named "functional instability" in which fibrotic/connective banding takes place in the epidural space, causing traction on the dural pannum and where its perinervous structures increase or cause traction on the roots during intracanicular pressure. Rf myeloscopy represents a further development which allows to increase and optimize the positive results obtained with traditional myeloscopy, especially as regards reduction of long-distance pain recurrence. Compared with traditional surgical procedures, it has the advantage of easy execution and repeatability. We tend to recommend this method as first procedural step in patients with persistent FBSS pain with no signs of instability of the posterior compartment.

Using the Resablator Epiduroscopy Technique we can reduce the quantity of fluid used and avoid excessive fluid irrigation of the ES, taking care not to forget monitoring patients' cervico-cranial discomfort [10].

Hence epiduroscopy can be considered as a feasible and safe method when avoiding excessive fluid irrigation of the ES and preventing patients cervico-cranial discomfort.

Ethics

The study was approved by the Hospital Ethics Committee and conducted according to the Helsinki declaration principles on human clinical studies. All the patients were thoroughly onformed of the procedure and the study written consent was obtained.

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Disc coablation and epidural injection of steroids: a comparison of strategies in the treatment of mechanical spinal discogenic pain

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Summary

In this study two strategies in the treatment of Mechanical Spinal Discogenic Pain have been compared: Disc Coablation and Epidural Injection of Steroids.

In 2003 50 patients treated with one or two epidural injections have been selected "ad random" and 50 patients treated with disc coablation.

Comparison of the data indicated an improvement of average VAS when relaxed for both groups ($p < 0.01$), while after slight-moderate strain, this value was significant only after coablation ($p < 0.001$). Finally, average VAS was clearly lower ($p < 0.01$) after coablation as compared to epidural injections.

Keywords: Discogenic pain; epidural injection; disc coablation.

Introduction

In the anterovertebral compartment (anterior space of the transverse process) pain may be caused by stretching or spraining of the discal annulus fibrosus, by thickening or partial destruction of the yellow ligament, and by anterior periduritis.

According to a recent study, the incidence of Mechanical Spinal Discogenic Pain (MSDP) occurs in 39% of the population with low back pain and from the clinical point of view it is an axial nociceptive or laterolumbar pain aggravated by flexure, valsalva and the digital pressure on the spinous processes on algic level.

It may or may not be associated with radiculitis (neurophatic component of pain) and may be related to the superoanterior part of the thigh (L1-L2) since many roots of the principal segments on this level contribute to innervation of the discal annulus posterior. Radiologically (CAT and NMR) bulging of disc is always present, which in a more or less marked manner may interact with muscle-ligament and adjacent nerve structures.

Until about a year and a half ago, patients who came to our Pain Therapy Centre suffering from MSDP were treated with a cycle (on average two) of Selective Epidural Injections (S.E.I.) of depo-cortisone while the practice of lumbar disc coablation (L.D.C.) was subsequently introduced.

The purpose of this paper was to compare the two therapeutic approaches in terms of pain relief when relaxed and after slight-moderate strain.

Materials and methods

In 2003 we randomly selected 50 patients suffering from MSPD with an average age of 55 years (22–74), who were treated with an S.E.I. cycle of steroids (two segmentary infiltrations 15 days apart with 80 mg of Depo-cortisone) and 50 patients who were treated with L.D.C. (Perc-DLE probe and ArthroCare System 2000 generator, AMS, Italy), making 6 channels in the disc nucleus pulposus with an ablation time of 10 seconds and a coagulation time of 20 seconds.

All the patients had developed algic symptoms for at least 3 months and the average VAS (VASm, considering the neuropathic and nociceptive component) was 8.57 when relaxed and 9.72 after slight-moderate strain.

The evaluation of the entity of strain was made considering the "Quality of Life" parameters expressed in the "Brief Pain Inventory", Italian version, modified by Caraceni in 1996.

Lumbar pain was present in 80% of the patients and was mostly accentuated by flexure, while 20% of the patients exclusively had radicular and low back pain and radiculitis was associated with 40% of the patients.

The NMR was positive in all patients for degenerative discopathy associated with bulging or contained slipped disk, and the main exclusion criterion for coablation was when disc thickness was reduced by more than 50% of the normal value and when severe neurological deficiencies were present.

In all the patients that underwent coablation a preoperative discography was performed and a "chemical" lesion (congruent severe

pain after intradiscal infusion of 1–2 ml of water soluble contrast) was found in 25% of patients and partially in the remaining patients who underwent treatment.

Levels treated most were L4-L5 (70%) associated with L2-L3 in 10% and L5-S1 in 20% of the cases, and at the end of procedure 40 mg of triamcinolone acetate was infused into the homolevel radicular pouch on the affected side.

Results

Two follow-ups were done at three and eight months by means of a direct interview conducted by a physician not participating in the study.

The VAS when relaxed and after slight-moderate strain was required, considering the parameters of the latter expressed as "Quality of Life" in the "Brief Pain Inventory", modified Italian version [1].

The statistical analysis was carried out considering the Interval Confidence by difference of two averages compared with the Student "t" test, and the physical entity of relative improvement of the VAS (Mbefore-Mafter/Mbefore) was evaluated.

At three months the patients treated with S.E.I. of cortisone showed a VASm when relaxed of 3.25 and after strain of 6.82, while at eight months, the VASm when relaxed was 4.75 and after strain 7.52 and the percentage of patients treated again in this period was 57%.

In the patients treated with disc coablation, VASm at three months when relaxed was 0.65 and after strain 2.51, while at eight months the values were 1.55 and 3.52, respectively.

From comparison of the data it can be deduced that the relative improvement of VASm when relaxed is statistically significant at three and eight months for both the patients treated with S.E.I. and for those treated with coablation ($p < 0.01$), while after slight-moderate strain, this value is significant only after coablation ($p < 0.001$).

Finally, the VASm values were clearly lower ($p < 0.01$) after coablation as compared to epidural injection.

Conclusions

Analysis of the gathered data shows that coablation allows obtaining greater and more constant pain relief over time as compared to epidural injection of cortisone and, above all, allows a valid functional recovery with improvement of the quality of life in the largest part of the patients treated, without the need for another operation.

These positive results can also be obtained with patients that have partially degenerated and not completely continent discs without signs of chemical irritation, provided that they do not have grave discal degeneration or a slipped disk.

The lumbar pain component (nociceptive) is more sensitive to the treatment as compared to the radicular neuropathic component and for this reason the depocortisone is injected into the homolevel radicular pouch on the affected side.

In the partially successful cases, in diabetic patients or in patients allergic to corticosteroids, the treatment can be complemented with Pulsed Radio Frequency of Incturae zigapophyseales and the posterior dorsal ganglion on level L2.

In conclusion, we believe that the disc coablation method is the best approach for treating MSDP when compared with epidural injection of cortisone because of the particular simplicity of the method together with a low incidence of side effects and greater therapeutic efficacy.

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Preliminary results of a soft novel lumbar intervertebral prothesis (DIAM) in the degenerative spinal pathology

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Summary

The authors report a series of 43 patients suffering from lower limb pain, almost constantly associated with chronic or acute backpain, treated by microsurgical nerve root decompression and by implantation of a soft intervertebral prothesis (DIAM). Satisfying results were obtained in 97% of cases, inducing the authors to consider the device a reliable tool for curing low-back pain and sciatica. Selection criteria are exposed and discussed.

Keywords: Spinal degenerative pathology; spinal instability; soft lumbar prothesis; DIAM.

Introduction

Correction of lumbar vertebral instability remains a major challenge in spinal degenerative pathology. Clinical evidence of pain relief when pathologic motion is eliminated by immobilization or arthrodesis has led to consider spinal fusion as the method of choice for surgically relieving spinal pain. Consequently, a plethora of techniques have been introduced involving transpedicular screws, plating and wiring. Despite these concerns, the outcome is not successful in all patients. That is particularly true in cases of minimal instability as rigid fixation leads to many problems concerning: a) the surgical insertion of the devices as well as all the inherent complications associated with mechanical failure and loosening; b) the long-term stiffness either of the stabilized segment or the adjacent levels.

In order to obviate these drawbacks, we have used a novel soft implant [5] (DIAM*) in 51 patients suffering from lower limb pain, almost constantly associated with chronic or acute backpain, and suspected of harbouring low grade spinal instability.

Clinical materials and methods

Fifty-one patients with pain in the lower limbs, very frequently accompanied by persistent low-back pain, were admitted to our Neurosurgical Institute during the period May 1999 to February 2004. As first useful follow-up examination the one at 12 months after surgery was chosen, 8 patients were excluded from the study. Of the remaining 43, 26 were male and 17 female, with age varying from 34 to 80 years; mean age was 54,49 years. Clinical complaints ranged from low-back pain (39 cases) to sciatica (31 cases), cruralgia (2 cases), lower limb paresthetic sensations (7 cases). The diagnostic work-up variously included the clinical examination, plain and dynamic radiological x-rays, neuroradiological (CAT and MRI) studies, trial external immobilization in plastic jacket. In the last 30 patients an intra-operative evaluation concerning the mutual articular relationship between contiguous vertebral bodies (by pulling up the spinous process through clamping their proximal extremities) became an integral part of the patient's whole examination. Pathological entities discovered during neuroradiological assessment were: significant disc prolapse associated with lateral and foraminal stenosis (36 cases), single level or multilevel narrowing of the spinal canal (7 cases). Mild degenerative spondylolisthesis grade 1, never reaching the extreme dislocation, was found in 8 patients affected either by herniated disc or spinal stenosis. Minimal or mild retrolisthesis was found in other 15 cases. All the patients were operated on by the same surgeon (A. M.) using microsurgical discectomy or multiple microsurgical interhemilaminectomy. The soft prosthesis implantation was single-level in 31 cases and multiple in the remaining patients. Pre and post-operative pain and quality of life of patients were evaluated using the Dallas Questionnaire [3]. Results were further refined integrating them into the four categories of the Henderson Classification of Functional Results (Table 1). The post-operative time of observation varied between 12 months and 5 years (mean: 34,7 months). Two patients were lost at follow-up and excluded from the study.

Results

With regard to symptoms best results were collected in patients suffering from low-back pain with (27

* Cousin Biotech, France

Table 1. *Functional results according to Henderson*

Level	Functional capacity
Excellent	no pain
class 1	no restriction regarding precedent activity
	no limitation for physical activity
Good	occasional pain (< 12 hour)
class 2	possibility to take up again precedent work
	minimal limitation for physical activity
Middle	pain reduced by intervention
class 3	reduction of professional activity
	reduction of physical activity
Bad	identical symptoms as preoperatively
class 4	not able to work
	necessity for a continuous pharmacological support

cases) or without (8 cases) sciatica. Half of the subjects were in class 1, the remaining in Class 2. The four patients complaining of sciatica without back pain did well, only one patient was in class 1, the others in class 2. Patients with low-back pain and cruralgia did worse: one was in class 2, the other in class 3.

In relation to spinal pathology, 67% of patients harbouring spinal stenosis were in class 1, all the others in class 2. Patients suffering from herniated disc prolapse were either in Class 1 (43%) or in class 2 (57%), while those with disc herniation and canal stenosis had a wider distribution: 36% in class 1, 57% in class 2, 7% in class 3.

Overall analysis of the data rendered the following information: 18 patients (44%) are in class 1, 22 patients (53%) are in class 2, the remaining patient (2,3%) is in class 3.

Assuming as satisfying results the first two classes of Henderson, we collected useful outcomes in 97% of cases.

Discussion

Clinicians think that they know the cause of sciatica and treat it by surgical removal of whatever is pressing on the nerve root, emphasizing to the patient that the procedure is to relieve leg pain and not back pain. Consequently, many patients are left with debilitating back pain after surgery and the options of anti-inflammatory medications, additional surgery and/or physical therapy. In these conditions segmental instability of the lumbar spine is regarded as one of the sources of low back-pain. Indeed, when the abnormal motion between two or more vertebrae is extensive, the movement may cause mechanical deformation of the intraspinal nerve tissue and, thereby, induce pain and/or neurological deficits. But even minor instability may cause irritation of receptors related to facet joints or other components of the motion segment, resulting in local pain and/or painful muscular reflex spasm.

This may especially concern patients operated upon both at single or multiple levels, but is very frequently observed also in degenerative conditions. Although the disc is a major structural component of the spinal column, a spinal segment should be viewed as a three-joint complex consisting of the disc and the two facet joints. Disc degeneration is thought to precede all other changes within aging motion segment [1]. With disc dehydration and narrowing of the disc space, the anular fibres of the disc are no longer under tension loading but, rather, sustained compression loading from the vertebra above. Furthermore, the alignment between the facets change with reduced disc height and the facets begin to undergo subluxation until the tip of the inferior facets impinges on the lamina below. Throughout movement, the center of rotation within the motion segment no longer follows its expected path and subsequently becomes erratic. At that time, a patient not only may have back pain at forward flexion but also may have significant reproduction of pain when attempting to extend from a forward-bent position. This satisfies the three criteria of instability suggested by Kotilainen and Valtonen [2]: 1) instability catch; 2) painful catch; 3) apprehension.

During the process of three-joint complex degeneration, surgical intervention may be necessary to alleviate disabling symptoms but we must consider that all surgical interventions, violating the integrity of the three-joint complex, affect the biomechanical stability of the motion segment. Consequently, the surgical procedure may exaggerate a pre-existing degenerative instability, maintaining low-back discomfort.

It is obvious that procedures performed for pathologic alterations in the late degenerative phase, such as wide decompressive laminectomies or facetectomies, disturb load-bearing ability significantly and may lead to clinically relevant instability. In these instances, it may be necessary to perform a fusion to stabilize the unstable spine. Procedures performed for pathologic changes occurring during early degenerative and early instability phases, such as partial laminectomies and discectomies for disc herniations, cause only low-grade segmental instability. Such cases are more difficult to treat as rigid fixation represents an overtreatment

while the mere discectomy may be insufficient to cure backache.

In order to reduce the failed-back surgery rate in the latter group of patients, we tried to improve patient selection by forcing especially clinical examination of the back. Even though lumbar instability can be verified both clinically and radiologically, radiological findings do not always correlate with clinical symptoms and vice versa.

In our study spinal instability was evaluated by the three criteria mentioned previously: 1) instability catch; 2) painful catch; 3) apprehension. A further evaluation was made directly in the operative room inspecting the mutual relationship between the operated vertebral bodies. Patients with spinal instability present an abnormal excursion of the vertebrae when these are pulled up by a clamp branching their spinous processes.

In addition to nerve root decompression, all patients suffering from nerve root pain associated with significant low-back pain and satisfying the above mentioned four criteria, were stabilized by DIAM prosthesis, which was implanted into the segment affected by the disc-root conflict. Indeed, biomechanic tests [4] have demonstrated that a posterior shock-absorbing implant in lumbar spine is able to: 1) reduce intradiscal pressure; 2) re-tighten posterior elements of the vertebral bodies; 3) reduce rotatory dislocation. This represents an attractive alternative for stabilizing the painful segment and yet allow some spinal mobility. Also, the soft device is able to maintain the disc height and to prevent the facet impingement.

Although results of this study are very favourable, we realize that our procedure is somewhat empirical and lacking constant sensitivity. Nevertheless, the DIAM prothesis has demonstrated to be very biocompatible and either safely or easily implantable. Thus its use is not a harmful procedure. Consequently, we assume that whenever the diagnosis of back pain remains in doubt it is more useful for the patient to be implanted. No negative consequences can arise from the prosthesis even if the patient has not been selected correctly. It would be much worse to prevent using DIAM in an unstable patient who remains undetected by clinical and radiological selection.

This is our experience and the satisfying operative results seem to support our judgement. Nevertheless, improvements are necessary to further our knowledge on selection criteria. This is in the foreground for developing techniques with highest probability for success in a given low-back pain disorder.

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Lumbar spinal decompression with a pneumatic orthesis (orthotrac): preliminary study

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Summary

Aim. We present a preliminary study on the conservative treatment of chronic low back pain (LBP) using an easy to manage and extremely practical orthesis. It consists of a pneumatic custom made lumbar vest (Orthotrac), which permits both support-stabilisation and decompression. This system is versatile since the patient is not impeded and can perform any activity while wearing it.

Material. The study included 41 patients (23 males and 18 females, aged between 19 and 25 years) with radicular pain due to degenerative discopathy including: dark disc, discal protrusion with neural foramina involvement, stenosis of the foramina, syndrome of the facets, Grade 1 listhesis.

Patients had to wear the Orthotrac vest according to a precise protocol, 60 minutes 3 times a day for 5 weeks.

Results. 32 patients (78%) have showed a significant subjective and clinical improvement with subsequent better quality of life. All patients referred a decrease or disappearance of radicular pain. Outcome measures were evaluated according to SF-36 system which is used in clinical practice and research. As in any innovative therapy, selection of patients is extremely important. The pneumatic vest is not indicated in all patients, but it can play an important role in non-surgical therapy for LBP.

Conclusion. The system seems to give an effective spinal decompression and deserves a careful consideration when lumbar discal disease is treated conservatively. Further multicenter and interdisciplinary studies on a greater number of patients are obviously needed to confirm these preliminary results.

Keywords: Traction; degenerative discopathy; auto-traction; low back pain; SF-36 health survey.

Introduction

LBP is an extremely frequent clinical manifestation is continuously increasing in industrial countries; the high social cost due to missed working days and the increase of periodical or permanent disabilities justify the high interest in research on the treatment. LBP is responsible for the loss of 12 million working days a year in the UK. In the US in 1990 the cost due to LBP was around 0.5% of the gross national product (GNP). In the US it is the second common cause of illness. Although the causes are different, only the understanding of the pathophysiology of the intervertebral disc and the lumbar rachis will allow a rational treatment in patients with LBP. Up to now the major cause responsible for LBP is the degenerative discopathy with loss of intradiscal pressure, of the necessary tension of the lumbar anulus fibres and consequent posterior overload with degeneration and hypertrophy of the articular facetsjoints: the concept of the ''degenerative cascade'' introduced by Kirkaldy-Willis.

It is well known that 80% of population suffer LBP at least once and that 35% develop a hernia of the disc and 0.1% will undergo surgery. The remaining percentage will be treated conservatively. With overload being one of the main causes of lumbar degenerative discopathy, we have scrutinized the literature for the various treatments of chronic LBP. We found many therapeutic approaches and this demonstrates the high rate of chronic LBP and the great interest in its treatment due to the high social cost. These approaches range from surgery with few or many but more and more innovative instruments to various conservative treatments, sometimes questionable. Among the conservative treatments, the use of lumbar vests is the most frequent. In order to better understand our therapeutic proposal, it should be remembered what happened to surgical treatment of lumbar diseases over time. In the 70s the trend was to demolish, while in the 80s fusion with pedicle screw cages was up-to-date in

order to improve results. In the 90s the transitional syndrome was understood and the discs (natural stress-breakers) were replaced using prostheses or inter-spinous stress-breakers made of metal alloys or bio-polymers. In 2000 it was found that the best way was to repair the disc and where possible to restore its specific functions in different ways (injection of polymers, hydrogel, BMPs, staminal cells) to regain the integrity and height of the disc.

The challenge of biological repair (combined use of genic therapy on tissue engineering) of the intervertebral disc is still open.

Each specialist offers a different solution for LBP, not in pathologies with neurological damage or in severe stenosis or instability where surgery is out of question, but in those more frequent forms which should be treated conservatively.

Among the conservative treatment modalities, we wanted to study a reproducible method, efficacious and easy to apply. Treatments with reduction of load are the traction techniques which lighten the weight on the lumbar segments. Lumbar traction which we define as dynamic support is taking over the lumbar support with elasticised corsets with rigid sticks which we could define as static.

In the literature it is shown that traction induces a flattening of the lumbar lordosis, a distraction of the vertebral bodies, an increase in height of the intervertebral spaces, lengthening of the spinal muscles and ligaments, and widening of the conjugation foramens. Traction is based on the application of a force along the axis of the spine. The traction used since ancient times (Fig. 1) has recently been rediscovered with the introduction of new techniques of extreme efficacy: the

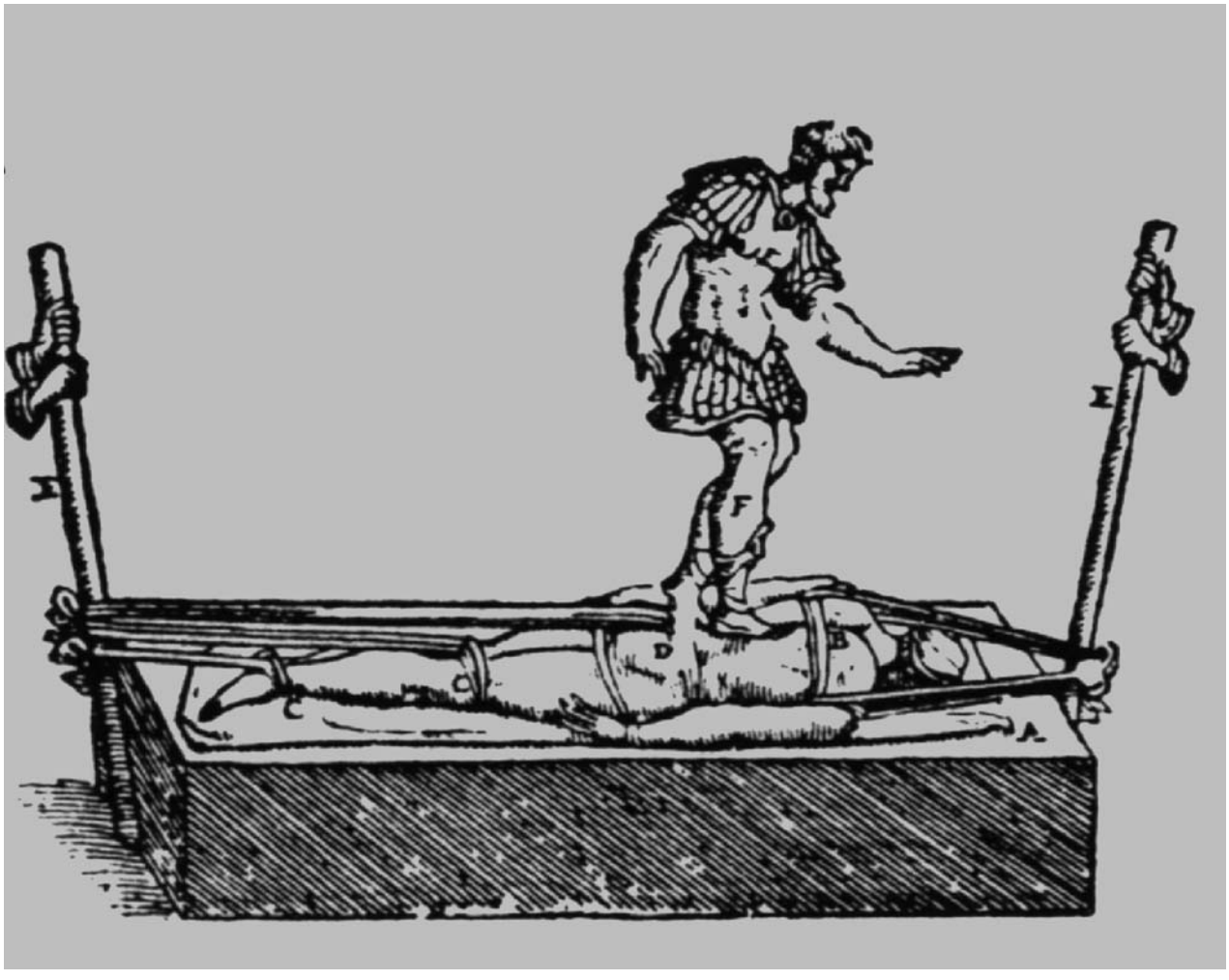


Fig. 1. History of traction

Fig. 2. Orthotrac Pneumatic Vest

auto-traction introduced by Lind in 1974 and further modified by Natchev in 1984 [5].

We analyzed about 150 papers about lumbar traction in different forms for chronic LBP treatment and we found 10 different types of lumbar traction. The majority of papers judged negatively the utility of traction in treating LBP, while a great number of papers were in favour of using lumbar traction. When analysing the papers, we realized that the indications were not homogeneous, the traction techniques and traction times were different and in the vast majority of the studies traction was applied in patients with acute LBP. This necessitates further studies. We all agree that if the human body was not subjected to gravity or if it could live all the time in water or air (without body weight) there would not be the problem of degenerative discopathy and therefore LBP. It should be remarked that the common feature of all these types of conventional traction (gravitational, auto-traction, in water, passive) is that the patient body is immobilised or constrained by the traction systems. All these systems influence the time and frequency of application of traction and the use is limited due to the discomfort of these distractional methods.

There was the need for a traction system which allowed lumbar distraction whilst permitting free movement. This could be achieved by applying a distractional force unconditioned by external constraints but linked to the body itself of the patient and so to permit free movement.

The pneumatic vest (Orthotrac) (Fig. 2) meets these characteristics. It is a vest which by means of pneumatic pistons transfers a load of 30–50% of the body weight from the spine to the iliac crests. It should be worn 3 hours a day (also intermittently) for a period of 5 weeks.

This type of traction could be defined as ''dynamic walking traction'', to be opposed to the traction with lumbar support vest which could be defined as ''static'' (Fig. 3).

The philosophy of the treatment with Orthotrac Pneumatic Vest coincides with recent research on interspinous devices to reduce both the intradiscal pressure and the pressure on the articular facets. Spinal surgery tends to improve its technology since it is clear that it is necessary not only to demolish and remove but also to reconstruct and recover function. Already the intersomatic cages recovered the disc height, supported the neural foramina, tensioned, where possible, the anulus fibres. Surgeons understood that it was incorrect to fuse and fix only with instruments. For this reason stress breaking systems of ''dynamic fusion'' were proposed which recover height, tension the annulus fibres with restoration of a partially stress

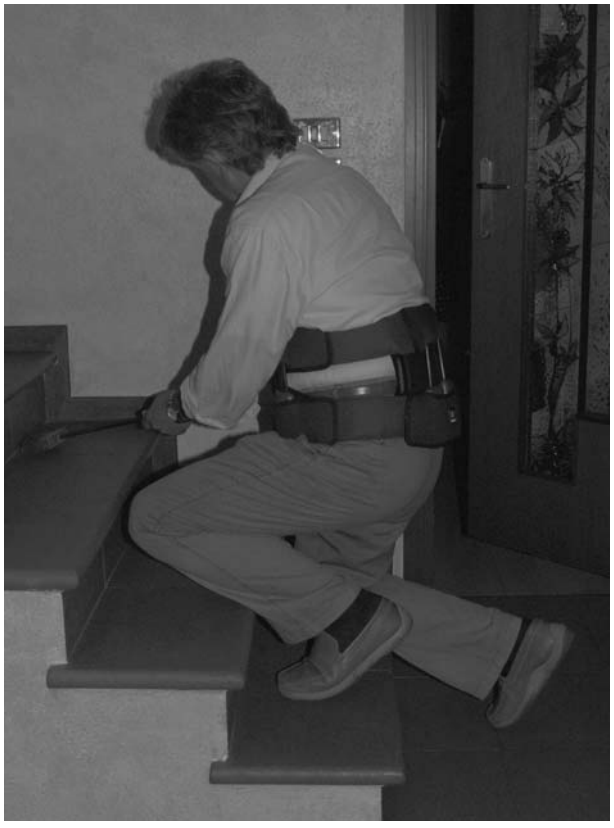


Fig. 3. Ambulatory treatment

breaking effect. In this study the efficacy of the pneumatic Orthotrac vest has been studied by testing the changes in pain and quality of life with the SF-36 questionnaire.

Material and methods

Candidates to Orthotrac are those patients with mechanical LBP, defined as lumbar or radicular pain which changes upon postures and activities; previous surgery is not contraindication. Furthermore, those patients in which LBP did not improve after conventional conservative treatments and pain was present for at least 3 months with or without irradiation to the lower limb were included in this study. Hernia or disc protrusion at one or more levels, listhesis with spondylolysis or degenerative listhesis documented by CT or MRI can be associated.

Exclusion criteria are: tumors, infective or metabolic causes of LBP, indications for surgery due to neurological ingravescent deficit, osteoporosis and pregnancy.

Patients included in the study:

41 Patients with chronic LBP with age between 19 and 65 years, 23 males and 18 females. 9 (22%) patients affected by disc hernia at one level with pain present for more than 3 months; 11 (27%) patients with 1st degree listhesis: 14 (34%) patients with multilevel discopathies and dark disc with Modic 1 and 2 signs; 7 (17%) with stenosis of the lumbar spine. Each of the 41 patients, following an appropriate information and consensus, had a custom made Orthotrac vest for a minimum of 40–60 minutes three times a day 5 weeks. The correct recommended use of Orthotrac is to start the treatment with a distraction force corresponding to 30% of the body weight for the first 2 weeks which should be increased up to 50% in the remaining weeks. The patients had to fill in 2 outcome questionnaires (according to SF-36 Health Survey); the first questionnaire (baseline) before the treatment and the second one (follow-up) at the end of treatment.

Both questionnaires included 2 scales to measure the following symptomatologic variables:

Neurogenic Symptoms Score: this scale included 6 scores to measure pain of the lower limb

Pain/Disability Score: this scale included 11 score to measure quality of life in all its aspects.

Results

The results of the questionnaires were as follows:

2 Patients (5%) were excluded from the study because they were not collaborative.
7 Patients (17%) had no improvement and subjectively they referred unchanged symptoms.

The remaining 32 patients (78%) had noticed a decrease in pain with percentages between 15 and 66%. Orthotrac seems to reduce pain more in elderly patients; the group of younger patients complained about the vest due to discomfort and difficulty in driving (Tables 1 and 2).

Table 1. *Pain/disability scale results*

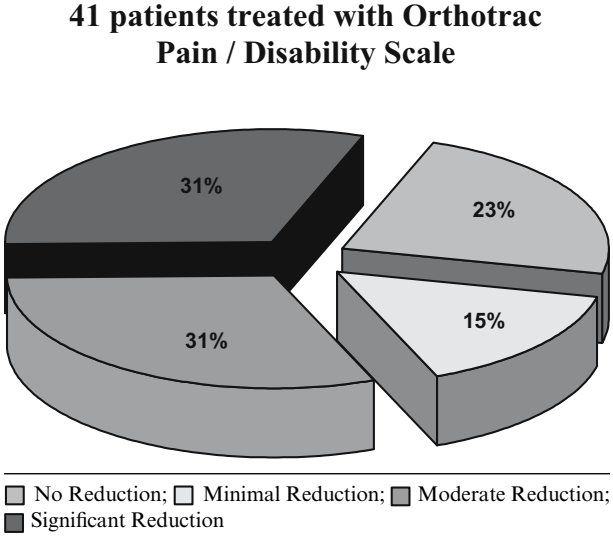
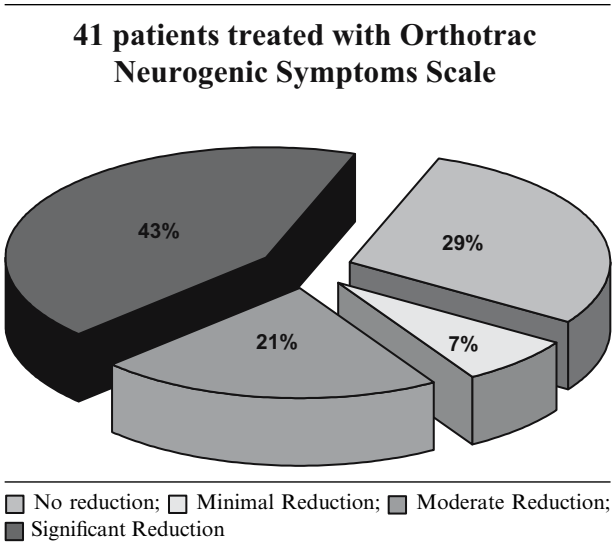


Table 2. *Neurogenic symptoms scale results*



Conclusion

Following the indication of less invasiveness, unconstrained traction while walking (similarly to walking in water without the constraint of water) could be an important further therapeutic support alone or associated with other procedures in order to regain as much as possible the initial characteristics of the intervertebral disc.

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The different outcomes of patients with disc herniation treated either by microdiscectomy, or by intradiscal ozone injection

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Summary

Disc herniation with radiculopathy and chronic discogenic pain are the result of degenerative processes. Treatment approach in face of this problem has largely been debated in the last years. A number of reviews on surgical treatments in the '80s and '90s have been published and various new techniques have been introduced among which ozone discolysis is one non-invasive intradiscal treatment method. In a 3-year follow-up period we have investigated the different outcomes of 150 patients who received microdiscectomy and 150 patients who received intradiscal ozone injection. In this series results are in favour of discolysis for contained disc herniations and of microdiscectomy for large migrated fragments with pain so severe that open surgery was obligatory. Apart from this, our results with the two techniques are equivalent also concerning mild neurological motor deficits.

Keywords: Disc herniation; microdiscectomy; ozone injection; discolysis.

Introduction

Lumbar disc degeneration occurs because of a variety of factors and results in a multitude of conditions and of clinical alterations. Structural modifications in the vertebral endplate cause derangement of nucleus nutrition and disc degeneration. Aging, apoptosis, abnormalities in collagen, vascular ingrowths, loads placed on the disc, and abnormal proteoglycan all contribute to disc degeneration. Disc herniation with radiculopathy and chronic discogenic pain are the result of this degenerative process. The treatment approach in face of lumbar disc herniations has largely been debated in the last years. A number of reviews on surgical treatments in the '80s and '90s have been published and various new techniques have been introduced. Criticism has grown regarding long term results of discectomy and a large number of neurosurgeons focused their attention on minimally invasive percutaneous intradiscal procedures. Ozone discolysis is one non invasive intradiscal treatment method which has shown to be effective and safe for these problems [1–3]. On the basis of these considerations we investigated in a three year follow-up period the different outcomes of 150 patients who received microdiscectomy and 150 patients who received intradiscal ozone injection. The aim was to find out whether injection of this substance in the disc is effective and useful.

Patients and methods

Out of a series of 1.180 patients treated by microdiscectomy and 1.050 treated by percutaneous O_2-O_3 discolysis due to lumbar disc herniation (R.P. operator) we selected 150 patients in each group with most similar characteristics.

Only patients affected by lumbar disc herniation at just one level were included in this study.

Age distribution for microdiscectomy was 25 males and 19 females up to an age of 30, 32 males and 35 females up to 60, 21 males and 17 females over 60; for discolysis 26 males and 24 females up to the age of 30, 34 males and 38 females up to 60, 16 males and 12 females over 60. Patient distribution according to the level of pathology is shown on Table 1. Kind and site of herniation in both groups are found in Tables 2 and 3. All 300 patients were examined by plain lumbo-sacral Xrays, EMG, lumbo-sacral CT/NMR before surgery, and 4

Table 1. *Patient distribution based on level*

	Microdiscectomy cases	Discolysis cases
L1-L2	1 (0.6%)	2 (1.3%)
L2-L3	3 (2%)	2 (1.3%)
L3-L4	15 (10%)	18 (12%)
L4-L5	79 (52.6%)	83 (53.3%)
L5-S1	52 (34.6%)	45 (30%)

Table 2. *Kind and type of herniation*

Patients treated by microdiscectomy			
Kind of herniation		Site of herniation	
Contained	98 (65.3%)	posterior median	16 (10.6%)
Extruded	47 (31.3%)	posterior paramedian	49 (32.6%)
		posterior median-param.	32 (21.3%)
Migrated	5 (3.3%)	posterolateral	41 (27.3%)
		intraforaminal	12 (8%)

Table 3. *Kind and type of herniation*

Patients treated by 0_20_3 discolysis			
Kind of herniation		Site of herniation	
Contained	102 (68%)	posterior median	14 (9.3%)
Extruded	44 (29.3%)	posterior paramedian	53 (35.3%)
		posterior median-param.	36 (24%)
Migrated	4 (2.6%)	posterolateral	34 (22.6%)
		intraforaminal	13 (8.6%)

to 6 months, 1 year and 3 years after surgery. Clinical data were collected preoperatively and postoperatively at the above time intervals and were classified according to the JOA Scale; evaluation of pain was done according to the VAS Scale.

Results

Results obtained for pain are presented in Table 4. Pain modification is related to the level of pathology in Table 5. Pain regression in respect to the level and location of the herniation is analyzed in Table 6. Regression of sensory dysfunction at 3 years is shown in Table 7.

As shown in Table 8, 9 and 10 motor deficit improvement is similar in the two groups among which we didn't find significant differences, not even in EMG recovery.

Morphological results are obviously different in the two series. Discolysis led to an unstable situation since total elimination of herniation was observed modest in percentage in the first months (38.6%) and to grow relevant after one year (57.3%) or after two years (68%).

Table 4. *Pain regression at controls*

Controls	Microdiscectomy	Discolysis
4–6 months	147 (98%)	139 (92.6%)
1 year	137 (91.3%)	131 (87.3%)
3 year	128 (85.3%)	119 (79.3%)

Table 5. *Pain regression with respect to level of herniation*

	Microdiscectomy	Discolysis
L1-L2	1 (100%)	2 (100%)
L2-L3	2 (66.6%)	2 (100%)
L3-L4	11 (73.3%)	13 (72.2%)
L4-L5	66 (83.5%)	67 (80.7%)
L5-S1	48 (92.3%)	35 (77.7%)
Total	128	119

Table 6. *Pain regression related to kind and location of herniation*

Kind of herniation	Microdiscectomy	Discolysis
Contained	81 (82.6%)	85 (68%)
Extruded	42 (89.3%)	44 (77.2%)
Migrated	5 (100%)	0 (0%)
Location		
Post. median	12 (75%)	11 (78.5%)
Post. paramedian	42 (85.7%)	42 (79.2%)
Post median paramedian	25 (78.1%)	28 (77.7%)
Post lateral	38 (92.6%)	27 (79.4%)
Intraforamina	11 (91.6%)	11 (84.6%)

Table 7. *Regression of sensory dysfunction at 3 years*

	Microdiscectomy	Discolysis
Complete	80 (82.5%)	74 (80.4%)
Partial	12 (12.4%)	11 (11.9%)
Insignificant	5 (5.15%)	7 (7.6%)
Total	97	92

Table 8. *Regression of motor deficit after 3 years*

	Microdiscectomy	Discolysis
Complete	71 (86.6%)	48 (85.7%)
Partial	8 (9.8%)	4 (7.4%)
Insignificant	3 (3.6%)	4 (7.1%)
Total	82	56

Table 9. *Regression of an initially severe motor deficit after 3 years*

	Microdiscectomy	Discolysis
Complete	4 (44.4%)	2 (40%)
Partial	2 (22.2%)	1 (20%)
Insignificant	3 (33.3%)	2 (40%)
Total	9	5

Table 10. *EMG improvement 3 years after treatment*

	Microdiscectomy		Discolysis	
	Initial EMG damage	improved	Initial EMG damage	improved
L4	5 (5.6%)	4 (80%)	9 (10.7%)	7 (77.7%)
L5	44 (50%)	37 (84.1%)	38 (45.3%)	33 (86.8%)
S1	39 (44.4%)	38 (97.4%)	37 (44%)	32 (84.2%)
Total	88	79	84	72

Table 11. *TC/MRI controls of reduction of discal herniation volume*

	Microdiscectomy		
	4–6 Months	1 year	3 years
Total		128 (85.3%)	
Partial		7 (4.6%)*	
Unchanged		15 (10%)**	
	Discolysis		
Total	58 (38.6%)	86 (57.3%)	102 (68%)
Partial	34 (22.6%)	16 (10.6%)	17 (11.33%)
Unchanged	58 (38.6%)	48 (32%)	31 (20.6%)

* Severe scarring and fibrosis.
** Recurrence and fibrosis.

In this series results were in favour of discolysis for contained disc herniations and of microdiscectomy for large migrated fragments, for which pain was so severe that open surgery had become a must. Apart from that, the results we obtained with the two techniques were equivalent also with regard to mild neurological motor deficit.

Comment and conclusions

Greenfield and coauthors [4] reported on the 1-year outcome for 80 patients who were randomly assigned to surgical or non-surgical groups for treatment of single-level lumbar disc herniations. All patients complained of back and radiating leg pain. Patients with major neurologic deficits and incapacitating pain were excluded from his study. Patients in the surgical group had a microdiscectomy, and the non-surgical group was treated conservatively with aerobic exercise and education. Measurement tools to evaluate outcomes included visual analogic scales for pain and Oswestry Disability Index for disability. Patients treated with microdiscectomy had a greater reduction in both back and leg pain and had greater improvements in their Oswestry Disability Index scores at all study intervals. This prospective study established the efficacy of microdiscectomy in the first 12 months for treatment of patients with small-to-moderate lumbar disc herniations and moderate complaints of back and leg pain.

Other non-randomized studies demonstrated the benefits of non-surgical treatment for lumbar disc herniations at a 10-year follow-up: long-term outcomes approach those of surgery, and some authors stress that the early benefits of surgery in the first 12 months may outweigh the risks of surgery.

Our results show that, after time, discolysis lead to an unstable situation regarding morphology since total elimination of herniation was observed modest in percentage in the first months (38.6%) and to grow relevant after one year (57.3%) or after two years (68%), but this doesn't correlate with the clinical course. This is probably due to the fact that progress of disc degeneration entails a loss in volume within the nucleus pulposus due to a decrease in proteoglycan and water concentration [5]. Percutaneous intradiscal entry is a technique which gives minimal disruption of the anular structure, and will therefore produce minimal epidural scarring [6]. This is confirmed by the images we obtained one year after treatment in the two groups of patients. It is too early yet to comment on recurrences within this series, but we think that the entity of fibrotic tissue will play a role in clinical significance.

Regression of pain and of motor dysfunction three years after surgery is quite similar in the two groups. In severe pain cases who presented with a large disc herniation open surgery offered an advantage in the short term, but after time there is no significant difference between the techniques employed for treating the problem.

Discolysis is a very simple method to practice and is safe. It can be employed also in elderly patients without danger. In consideration of the long term results, the technique is a practical alternative for those cases in which surgery can be avoided and a solution can be offered without fear of future complications such as scarring and peridural fibrosis.

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Quality of life, clinical and neurophysiological picture in patients operated on for lumbar stenosis

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Summary

Background. In lumbar stenosis (LS) patients, clinical, neuroradiological and neurophysiological findings were not related to validated measurements of the outcomes that are more relevant to patients such as functional status and symptoms.

Method. We have retrospectively studied 30 patients surgically treated for LS. We have evaluated the patients by means of self-administered questionnaires (SF-36), clinical examination, and neuroradiological and neurophysiological measurements and we have registered preoperative and follow-up clinical and neurophysiological findings. Finally we evaluated the relations between patient-oriented data and validated conventional clinical and neurophysiological measurements.

Findings. The comparison between pre- and post-operative clinical picture showed an improvement of most parameters tested. The comparison between pre- and post-operative neurophysiological picture revealed worsening of most tested parameters. The comparison between the current sample and the Italian normative data for the SF-36 showed a worsening of physical aspects of health related quality of life; conversely there was an improvement of some mental domains.

Conclusions. In our sample of LS patients the most compromised SF-36 domain was Role-Physical that measures the difficulty in every-day activities due to physical problems. Conversely, the clinical findings showed a significant improvement after surgery: patients reported in particular lower sciatica after surgical treatment, but the neurophysiological evaluation did not show any improvement.

Keywords: Patient-oriented; lumbar stenosis; surgery outcome; quality of life; SF-36.

Introduction

Lumbar stenosis (LS) affects middle-aged people and may cause severe symptoms and functional impairment at lower limbs. These neurological deficits may greatly impair patients' quality of life.

History and clinical examination findings, in particular the evaluation of osteotendoneous reflexes and muscle strength, are considered essential for diagnosis and a good measure to assess the severity of the disease [3, 4]. Neuroimaging provides information concerning the anatomy of the lumbar canal and is also considered fundamental for the diagnosis. Neurophysiological evaluation assesses the root axonal function and therefore provides information on the neurological damage due to stenosis.

We retrospectively evaluated [7] a sample of patients affected by LS and have related the clinical and neurophysiological findings to the perception that patients had of their own health-related quality of life (HRQoL) measured by using the Short Form-36 Health Survey (SF-36) [11].

Methods and materials

From 1992 to 1998, we retrospectively re-evaluated 30 patients surgically treated for Lumbar Stenosis (LS) at the Orthopaedic Department of "A. Gemelli" Hospital in Rome. All patients agreed to undergo the clinical examination and subjective analysis with SF-36 questionnaire. Twenty-six out of 30 patients agreed to undergo electromyographic evaluation (EMG).

Our sample was composed by 13 women and 17 men, mean age at follow-up was 67.7 years (SD: $\pm$9.2, range from 47 to 85 years). Follow-up period ranged from 15 to 88 months (mean 44.6 $\pm$ 19.4).

The indications and level of surgical approach were established according to clinical findings, confirmed by imaging (MRI and/or CT Scan) and neurophysiological measurements. All the operations were conducted with the patients in prone position. Decompression of the dural sac was accomplished by removal of laminae and lateral recesses were opened by tangential undercutting facetectomy. Each compressed nerve-root was always examined along its course to the foramen and then a partial foraminotomy was performed. No arthrodesis was performed and no patient was reoperated.

Follow-up evaluation

Long-term results were evaluated through self-administered questionnaires, clinical examination and EMG. Each patient underwent the following protocol.

Patient-oriented evaluation

The Short Form- 36 Health Survey (SF-36) [11], the most used generic health tool, was chosen to perform subjective analysis. The official Italian version of the SF-36 was administered to the patients. The SF-36 consists of 36 questions about patients' general health status. This questionnaire provides eight specific physical and emotional categories (physical function, role-physical, bodily pain, general health, vitality, social function, role-emotional, mental health), and two main scores (the physical composite score and the mental composite score). A very low physical composite score indicates severe physical dysfunction, distressful bodily pain, frequent tiredness, and an unfavourable evaluation of health status. A very low mental composite score indicates frequent psychological distress and severe social and role disability because of emotional problems.

Clinical examination

A comprehensive clinical evaluation was performed both pre-operatively and during follow-up.

Examination included clinical personal data (kind of onset and duration of low back pain, sciatica and thigh pain) and objective findings (straight leg raising and Wassermann test, neurogenic claudication, motor and sensory testing, muscular strength and deep tendon reflexes of the lower extremities). For evaluation of the muscular strength, we clinically checked the function of quadriceps femoris (QF), tibial anterior (TA) and Gastrocnemius (GR) by means of the British Medical Research Council (BMRC) scale [5]. We decided to evaluate QF, TA and GR because they are the main active muscles during deambulation.

In addition to these objective clinical findings, we acquired the following data as dichotomous categorical scores obtained from the patient with a forced-choice answer ('yes' or 'no'): presence or absence of low back pain (LBP), presence or absence of sciatica (SCIAT), presence or absence of thigh pain (THIGH), presence or absence of claudication, monolateral or bilateral symptoms.

Clinical personal data and objective findings were scored with a dicothomic numeric scale used in statistical analysis [7].

Neurophysiological evaluation

We performed an extensive and multi-metameric EMG evaluation detecting in each metamer fibrillation potentials at rest which means denervation, the presence of neurogenic recruitment and the amplitude of motor unit potentials (MUP), as expression of past damage of the root. Neurophysiological findings were scored with a dicothomic numeric scale used in statistical analysis. A more detailed description of the neurophysiological evaluation has previously been reported [7].

Statistical analysis

Statistical analysis was performed by using the STAT-SOFT (Statistica 4.5, OK) package.

Since ordinal or nominal scales were used for measurement, non-parametric analysis of the correlation was assessed by Spearman's rank correlation coefficient. The comparison of stenosis measurements at initial and follow-up evaluations was assessed by means of the Wilcoxon Matched Pairs test and 2×2 table Chi Square test.

To compare the current sample of SF-36 scores with mean values of SF-36 for the normal Italian population, the one sample T-Test was used. Throughout the statistical analysis, the level was set at 0.05.

Results

Table 1 shows the comparison between the pre and post-operative symptomatic picture. Table 2 shows pre- and post-operative clinical findings in the examined sample. Table 3 shows the comparison between pre and post-operative neurophysiological picture. Table 4 shows SF-36 mean scores in the LS operated sample and Italian healthy subjects population at the same age.

Table 1. *Shows the pre- and post-operative symptomatic picture in the examined samples*

	Pre-operative		Post-operative		P value
Measurement	Mean	(SD)	Mean	(SD)	
LBP	0.90	(0.30)	0.60	(0.49)	0.01
SCIAT	1.0	(0.00)	0.46	(0.50)	0.0004
THIGH	0.43	(0.50)	0.20	(0.40)	0.017
SIDE	1.6	(0.49)	0.7	(0.83)	0.00020
CLAU	0.80	(0.40)	0.30	(0.46)	0.0006

LBP Low Back Pain; *SCIAT* Sciatica; *THIGH* Thigh pain; *SIDE* Side of radiculophathy symptoms; *CLAU* Claudication.

Table 2. *Shows pre- and post-operative clinical findings in the examined samples*

	Pre-operative		Post-operative		P value
Measurement	Mean	(SD)	Mean	(SD)	
Laseg	0.73	(0.44)	0.03	(0.18)	0.045
Wass	0.26	(0.44)	0.03	(0.18)	0.001
Sens	0.2	(0.24)	0.31	(0.42)	0.19
Refl	0.70	(0.47)	0.40	(0.50)	0.016
Refl Side	1.16	(0.87)	0.70	(0.91)	0.01
QF dx	4.1	(0.40)	4.6	(0.68)	0.004
QF sn	4.1	(0.36)	4.5	(0.63)	0.002
TA dx	4.8	(0.43)	4.9	(0.35)	0.224
TA sn	4.7	(0.48)	4.9	(0.35)	0.03
GR dx	3.9	(0.52)	4.5	(0.77)	0.0009
GR sn	3.9	(0.49)	4.5	(0.86)	0.0002

Laseg Lasegue; *Wass* Wassermann test; *Sens* Sensibility; *Refl* presence of pathologic deep tendon reflexes; *Refl Side* presence of unilateral or bilateral pathologic deep tendon reflexes; *QF dx* Quadriceps Femoris dx strength; *QF sn* Quadriceps Femoris sn strength; *TA dx* Tibial Anterior dx strength; *TA sn* Tibial Anterior sn strength; *GR dx* Gastrocnemius dx strength; *GR sn* Gastrocnemius sn strength.

Table 3. *Shows pre- and post-operative neurophysiological findings in the examined samples*

	Pre-operative		Post-operative		P value
Measurement	Mean	SD	Mean	SD	
Fibr	0.77	(0.43)	0.66	(0.48)	0.5
Pat Rec	0.38	(0.49)	0.79	(0.41)	0.01
Pat MUP	0.14	(0.35)	0.70	(0.46)	0.003

Fibr Presence of fibrillation; *Pat Rec* presence of pathological recruitment; *Pat MUP* presence of pathological MUP (increased amplitude).

Clinical picture evolution

Referred symptoms and almost all evaluated clinical objective findings showed a comprehensive, significant improvement, only sensory testing was unchanged (see Tables 1 and 2).

The evolution of muscular strength showed an improvement of the following muscles: QF (p: 0.004 and p: 0.002 respectively for the right and left side), TA sn (p: 0.03), GR (p: 0.0009 and p: 0.0002 respectively for the right and left side). The strength of the right side TA did not improve at all (p: 0.224).

Neurophysiological picture evolution

Fibrillation measurements did not show any significant differences between the pre- and post-operative picture (p: 0.5). Conversely, recruitment and MUP measurements showed significant worsening of neurophysiological picture at follow-up (respectively p: 0.01 and p: 0.003) (see Table 3).

Patient-oriented evaluation

Comparison of SF-36 mean scores in the current LS sample versus the Italian normal population at the same age, showed that most physical aspects of HRQoL are significantly deteriorated in the LS sample (in particular the LS sample referred higher limitations of various kinds in everyday role activities due to physical health problems, as assessed by role-physical domain). Conversely, General Health domain is similar in both groups.

The mental aspect of HRQoL in LS patients on the contrary has a different behaviour: most emotional domains are similar in the two samples, while vitality is even significantly better in the LS sample than in the healthy Italian population (see Table 4).

Discussion

Lumbar stenosis (LS) may cause neurological deficits such as severe symptoms and functional impairment at lower limbs, which may greatly affect patients' quality of life. Traditional assessment of LS has been based on clinical, neuroradiological, and neurophysiological findings. Over the last two decades, clinical researchers outlined the need for a thorough evaluation of concepts such as HRQoL especially in those pathologies that may affect the patients' general status (such as LS) [1, 2, 6, 8–10, 13]. It has been suggested that **a** more widespread use of standardized health measures may improve clinical practice [12].

Four years after surgical treatment, physical aspects of HRQoL mildly deteriorated in patients operated for LS (with regard to the Italian norms) [7]. In our sample of LS patients the most compromised SF-36 domain was Role-Physical that measures the difficulty in every-day activities due to physical problems.

Conversely, clinical findings showed a significant improvement after surgery, in particular patients reported lower sciatica after surgical treatment, but the neurophysiological evaluation did not show any improvement.

In a previous paper we did not consider the evolution of the muscular strength among clinical parame-

Table 4. *Comparison between the people operated on the current LS sample and Italian healthy population*

		PF	RP	BP	GH	VT	SF	RE	MH
Control sample	*Mean*	67,28	60,01	62,81	51,63	55,01	72,86	70,45	60,44
	SD	26	40,43	29,05	21,54	21,09	24,86	36,82	21,04
LS sample	*Mean*	55,33	36,66	51,5	49,96	63,33	65,63	57,76	66,8
	SD	28,49	40,32	27,44	17,68	22,6	26,07	46,28	25,43
Statistical analysis, p		0,019	0,0030	0,040	0,68	0,043	0,13	0,080	0,13

PF Physical Function, *RP* Role-Physical, *BP* Bodily Pain, *GH* General Health, *VT* Vitality, *SF* Social Functioning, *RE* Role Emotional, *MH* Mental Health.

ters. Comparing the muscular strength, as measured by the physician, in the pre- and post-operative phase, we observed a general improvement and the mean value of the score of the BMRC scale for each muscle was close to normal (but according to the patient-oriented evaluation patients complained of a limitation in their every-day performance due to physical problems).

In conclusion, our study did not cover the important and necessary therapy in question, but it might represent one step towards a thorough assessment of the disease in order to better define the therapeutical approach. In this context, patient-oriented questionnaires represent a good instrument to supply useful information in evaluating the outcome of surgical treatment in patients operated for LS.

We do believe that it would be necessary to perform further studies to have an evidence based approach to LS. These studies should be focused on the natural history of LS and on the relationship between the different outcome measures: patient-oriented evaluation, physician-oriented evaluation and neurophysiological techniques.

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Myofascial pain mimicking radicular syndromes

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Summary

Myofascial pain is very often underscored and misunderstood in clinical practice. In many cases the localization of myofascial pain may resemble other diseases, such as radicular syndromes (e.g., low back pain from herniated disc) and even diseases of internal organs (e.g., angina pectoris, bowel diseases or gynaecological disturbances). In pain clinics one can routinely see patients with myofascial painful disorders showing a radicular topography and normal CT and MRI: as a consequence, when vertebral abnormalities are present on CT or MRI, it should be checked whether the cause of pain is radicular, myofascial, or both. On the other hand, the conventional approach to painful disorders may lead to errors and wrong diagnosis, depending on several factors: a) pain is often considered a symptom of an organic disease; b) the diagnosis is usually directed towards the structural cause of pain only; c) the functional components of the suffering patient are underscored; d) the site of pain may introduce some bias. When the latter is concerned, it is usually admitted that a neck pain may depend on muscle contraction (e.g. torticollis), while such a cause is less commonly admitted for leg, where the attention is first directed towards the sciatic nerve; myofascial origin of pain is even less considered in abdominal or pelvic painful disorders, where patients with no structural detectable diseases are often considered as neurotic and referred to the psychiatrist. The reason for this topographical dependence of diagnosis lies in the conventional attitude to focus on the most relevant and frequent organic diseases, thus introducing a bias with relevant epistemological implications.

Keywords: Myofascial pain; radicular syndrome; epistemological factor; pain diagnosis.

Introduction

Myofascial pain is very often underscored and misunderstood in clinical practice. In many cases the localization of myofascial pain may resemble other diseases, such as radicular syndromes (e.g., low back pain from herniated disc) and even diseases of internal organs (e.g., angina pectoris, bowel diseases or gynaecological disturbances). In pain clinics one can routinely see patients with myofascial painful disorders showing a radicular topography and normal CT and MRI: as a consequence, when vertebral abnormalities are present on CT or MRI, it should be checked whether the cause of pain is radicular, myofascial, or both. On the other hand, the conventional approach to painful disorders may lead to errors and wrong diagnosis, depending on several factors: a) pain is often considered a symptom of an organic disease; b) the diagnosis is usually directed towards the structural cause of pain only; c) the functional components of the suffering patient are underscored; d) the site of pain may introduce some bias. When the latter is concerned, it is usually admitted that a neck pain may depend on muscle contraction (e.g. torticollis), while such a cause is less commonly admitted for leg, where the attention is first directed towards the sciatic nerve; myofascial origin of pain is even less considered in abdominal or pelvic painful disorders, where patients with no structural detectable diseases are often considered as neurotic and referred to the psychiatrist. The reason for this topographical dependence of diagnosis lies in the conventional attitude to focus on the most relevant and frequent organic diseases, thus introducing a bias with relevant epistemological implications.

The crucial epistemological factor affecting the diagnosis of pain in clinical practice is the so called rule of "Occam Razor", or "Rule of Thrift" [2]: when a phenomenon may depend on different causes, one is inclined to choose the most evident or the preferred one, skipping the others. This is routinely seen in patients with herniated disc and myofascial pain in the lower limb, were many doctors perform the (wrong) diagnosis relying on CT or MR only. Conversely, in patients with pain resembling part of a radicular syndrome one should check whether myofascial components are present, what is their role and whether the structural abnormality is a cause or coincidence only.

Only this approach can avoid useless operations and disappointing surgical treatments of recurrent pain. In fact, failed surgery may depend on two main facts: a) the operation was correctly indicated and performed, but the apparently recurrent pain depends on new myofascial components; b) the operation was targeted to a coincident lesion in a patient with myofascial pain only.

The topic of myofascial syndromes resembling neurogenic in origin is quite a wide complex; here we can only recall the definition of neurogenic pain and shortly outline the essentials of myofascial pain, focussing on the most relevant syndromes resembling those of radicular origin (for further details see [7, 8]).

Neurogenic pain

Neurogenic pain may be acute or chronic: the latter may be the result of properly operated vertebral lesions which had caused a lesion of spinal roots or cord.

Chronic neurogenic pain is defined as pain arising from dysfunction within the peripheral or central nervous system with the following features: a) free interval from the time of nerve injury to the onset of pain (usually 1–3 months); b) a structural lesion may not be detected; c) pain is usually burning; d) intermittent bursts of pain may be present; e) paresthesia and dysesthesia, allodynia, hyperalgesia and/or hyperesthesia are usually present.

It is emphasized that paresthesia and dysesthesia, although essential features of neurogenic pain, may be found in myofascial pain too.

Fibromyalgia

Fibromyalgia is a chronic disorder of unknown origin characterized by bilateral musculoskeletal pain associated with tender points (TPs) in at least 11 of 18 anatomically defined positions [9] (Table 1). Most patients are women of 40–50 years of age. Trauma, surgery, infection and, mainly, psychological factors (such as insomnia, depression) and functional disorders of internal organs (such as colitis or urodynia) may be associated with fibromyalgia. Pain is widespread and seems to be related to a pain threshold lower than normal, probably depending on a nociceptive dysfunction.

There is a tendency to consider fibromyalgia and myofascial pain as two members of the same family with some overlapping [3, 4]: in fact, several patients with fibromyalgia have both myofascial trigger points (MPTs) and TPs. Despite this, fibromyalgia is not a neurogenic pain disorder, it may be associated with allodynia and dysesthesia.

Table 1. *Anatomic locations of tender points in fibromyalgia syndrome [9]*

1–2	Suboccipital muscle insertion at the occiput
3–4	Anterior aspects of the intertrasverse spaces of C5-C7
5–6	Midpoint of the upper border of trapezius
7–8	Near the origin of supraspinatus above the spine of scapula
9–10	Upper surface of II rib, just lateral to the 2nd costochondral junction
11–12	2 cm distal to the epicondyle on the extensor muscle
13–14	Upper outer quadrants of buttocks in anterior fold of muscle
15–16	Greater trochanter (posterior to the prominence)
17–18	Medial fat pad of the knee, proximal to the joint line and condyle

Myofascial pain

Myofascial pain includes a wide range of acute or chronic painful conditions, the features of which are the presence of MPTs in one or several muscles, pain, rigidity, weakness, spasms and/or autonomic abnormalities. The symptoms are usually reported in areas far from the MPT. There is virtually a specific syndrome for each muscle of the body. These syndromes are the most common cause of severe pain located in the head, neck, shoulder, arms, legs, thorax, and even abdomen: they are often misdiagnosed and thus taken for neuralgia, arthritis, radiculopathy, visceral diseases. Misdiagnosis may lead to wrong and unsuccessful therapies, even invasive (like surgery), which apparently leave pain intractable, thus frustrating the patient and giving rise to reactive depression. On the other hand, some patients with no detectable structural lesions are considered neurotic and are referred to the psychiatrist further worsening their frustration.

Several factors may yield myofascial pain such as psychological disorders, physical conditions, acute or repetitive trauma or microtrauma, cold or heat, stress, concurrent diseases, fatigue.

MPTs are discrete, focal, hyperirritable spots located in a taut band of skeletal muscle [6, 7]; They produce pain locally and in a referred pattern. The physical finding typically associated with an MPT is a hypersensitive bundle or nodule of muscle fiber with a consistency harder than normal where palpation elicits

pain directly over the affected area and/or may cause radiation of pain toward a zone of reference and a local twitch response. Muscle dysfunction resulting from MPTs may lead to weakness and decreased range of motion; the decreased use of muscle sooner or later leads to overload and new MPTs in other muscles. Pain often increases over night and on waking up, when the muscle shortens in resting conditions. Sometimes MPTs may be associated with autonomic symptoms (such as local vasoconstriction or vasodilation, lacrimation, local sweating, rhinitis), vertigo, tinnitus, visual disturbances. For example, an MPT in sternocleidomastoid muscle may yield a frontotemporal headache, associated with lacrimation, resembling an atypical cluster headache.

Patient's suffering may be deeply affected by emotional and cognitive aspects of pain experience, including its persistence, intractability and wrong diagnosis: the image of the persistent, intractable pain cause a reactive depression and leads to a vicious circle (Fig. 1), where pain and psychological malaise are the two facets of the same medal, calling for a holistic approach to the suffering patient.

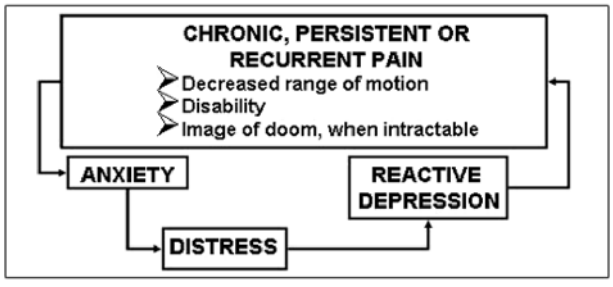

Fig. 1. Relationship between chronic pain and depression

Myofascial syndromes resembling radiculopathies

Any muscle of the body may virtually cause a specific myofascial syndrome. Pain in the neck, shoulder and arm and low back pain caused by MPTs may often resemble a radiculopathy, with a wide range of pictures (see [7, 8]); in this paper we briefly analyse only the most outstanding.

It is worth recalling once again that checking structural vertebral lesions is of course an essential step but it is not enough and functional components of pain should be evaluated as well. In other words, pain in the leg does not always depend on sciatic radiculopathy, whatever the CT or MR finding, but may be caused by MPTs.

The most outstanding myofascial syndromes resembling radiculopathies are those caused by MPTs of pectoralis minor, scalene, serratus anterior, gluteus minimus and piriformis. Anyway, all other muscles of arm and leg may cause local pain in the areas of the suspected radiculopathy.

The *pectoralis minor syndrome* causes shoulder pain, which may irradiate along the arm simulating a radiculopathy C_7-C_8 (Fig. 2); furthermore, a contracted

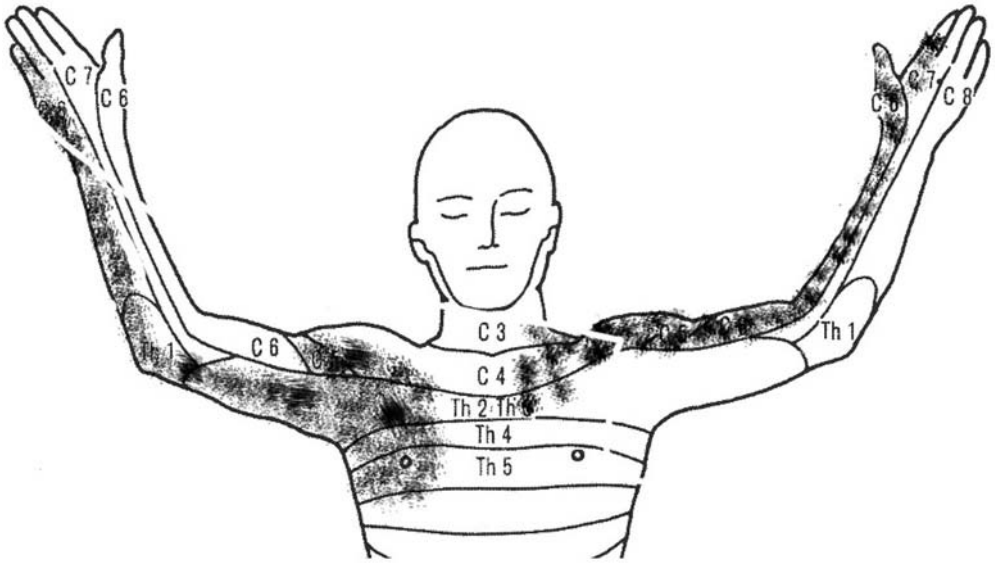

Fig. 2. Site of pain in the pectoralis minor syndrome (left) and in scalene syndrome (right)

pectoralis minor may compress the axillary artery and the brachial plexus close to its insertion to coracoid process during arm abduction, thus adding a neurovascular syndrome to pain. When pain is irradiated toward the precordial region, the myofascial pain may be taken for angina pectoris: thus, according to the main symptoms, the patient may be referred to the neurologist, neurosurgeon or cardiologist.

In the *scalene syndrome* the pain is radiated to the radial part of the arm down to the I and II finger, simulating a C_6 radicular pain (Fig. 2). This is also true for the pectoralis minor syndrome, here one can suffer from paresthesia, too when the contracted scalene compresses the brachial plexus.

The *serratus anterior* usually causes pain in the chest under the axilla, causing sometimes dyspnea, which increases during deep breaths. However, pain may radiate down the ulnar part of the arm, simulating a C_7-C_8 radicular pain.

When low back pain is concerned, pain from *gluteus minimus* radiates down the posterior or lateral part of the leg and may reach the ankle: therefore, the site of pain may simulate a radiculopathy L_4-L_5 or L_5-S_1 (Fig. 3). Pain may be severe, hampering both walking and resting in bed.

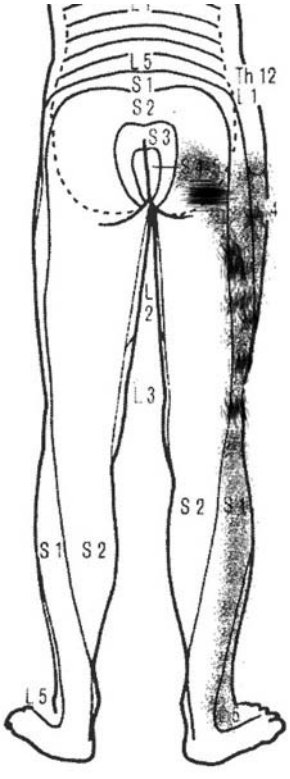

Fig. 3. Site of pain in the gluteus minimus syndrome

The *piriformis* may yield a pain radiating down the leg, which may be associated with paresthesia when the sciatic nerve is compressed by the contracted muscle, thus resembling low back pain from herniated disc. In fact, in about 10–20% of cases the whole sciatic nerve or its peroneal component crosses the piriformis muscle and may be compressed by its contraction [1, 5].

In conclusion, the painful myofascial syndromes radiating to the arm or leg may look like radicular pain, calling for a careful differential diagnosis, especially when vertebral abnormalities are present on CT or MR: pain is a complex phenomenon including many functional implications, which cannot be detected by radiological investigations and involve the whole patient. A structural abnormality may be the cause of pain, but pain may not depend on structural lesions and in many instances only a multidisciplinary approach allows for a right diagnosis and treatment, thus avoiding useless and disappointing surgical treatments.

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Prevention of recurrent radicular pain after lumbar disc surgery: a prospective study

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Summary

Background. Postoperative epidural fibrosis is a major causative factor of low-back pain even if microsurgical techniques are adopted to reduce this phenomenon. To prevent the recurrent radicular pain caused by this problem, we utilized adipose tissue drawn from the same patient; at the end of surgical procedure, the fat was placed around the spinal root or the dural sac. This procedure was evaluated by a prospective, randomised study.

Method. From 180 patients operated on for lumbar discectomy between January 2000 to December 2001, 74 were enclosed in the study. In 37 patients, the spinal root was covered by autologous fat (group A), in the other 37 (control group, B), this procedure was not adopted. One year after surgery, all the patients were evaluated with clinical and radiological (Magnetic Resonance Imaging) follow-up. Only two patients were lost to follow-up.

Findings. 71% of the patients in group A had 100% of clinical and radiological post-operative outcome score; this result was obtained only in 35% of the patients in group B. A clinical score evaluating pain syndrome (from grade 0 to 5) and a radiological score evaluating postoperative fibrosis (from grade 0 to 4) was adopted. Therefore, group A had best outcome as compared to control group.

Conclusions. The authors found a positive effect in the reconstruction of epidural fat with autograft of adipose tissue to prevent postoperative scarring and failed-back syndrome related to post-operative fibrosis.

Keywords: Fibrosis; lumbar disc surgery; recurrent pain; discectomy; postoperative scar.

Introduction

The surgical treatment of lumbar disc herniation is successful in low-back pain and prevents or limits neurological damage in the majority of patients.

Nevertheless, in 15% to 20% of these cases late postoperative pain is present, causing the phenomenon called failed-back syndrome. This event may lead to a worsening of the quality of life. Possible causes may be foraminal stenosis worsened by discectomy, ganglial damage by intra-extra-foraminal herniation, but the postoperative epidural fibrosis is a major causative factor of low-back pain, even if microsurgical technique is adopted to reduce this phenomenon.

Post-surgical fibrosis is part of normal healing after a surgical procedure, but the excessive presence of this fibrous tissue may limit surgical results.

Minimally invasive surgery reduces post-operative fibrosis and the has lowered the number of patients presenting with lumbar pain related to this complication.

To reduce the rate of patients affected by this problem, we utilized adipose tissue drawn from the same patient after the surgical procedure. The fat is placed around the spinal root or the dural sac in those cases where natural coverage and protection by epidural fat is lacking. This procedure was evaluated by a prospective, randomised study.

Clinical materials and methods

Seventy-four patients were included in this study, affected by lumbar disc herniation, admitted at the Department of Neurosurgery in Reggio Calabria, from January 2000 to December 2001. All the patients presented severe algo-paresthetic syndrome and mild radicular damage. Surgical indications were as reported by the Study Group for Spinal Surgery of the Italian Society of Neurosurgery.

Patients were selected for surgery when affected by pain syndrome resistant to medical treatment and with clinical and electrodiagnostic signs of neurological damage. Patients suffering from concomitant pathologies such as diabetes or polyneuropathies of different origin were excluded.

Only 74 patients out of 180 were included in this study. All

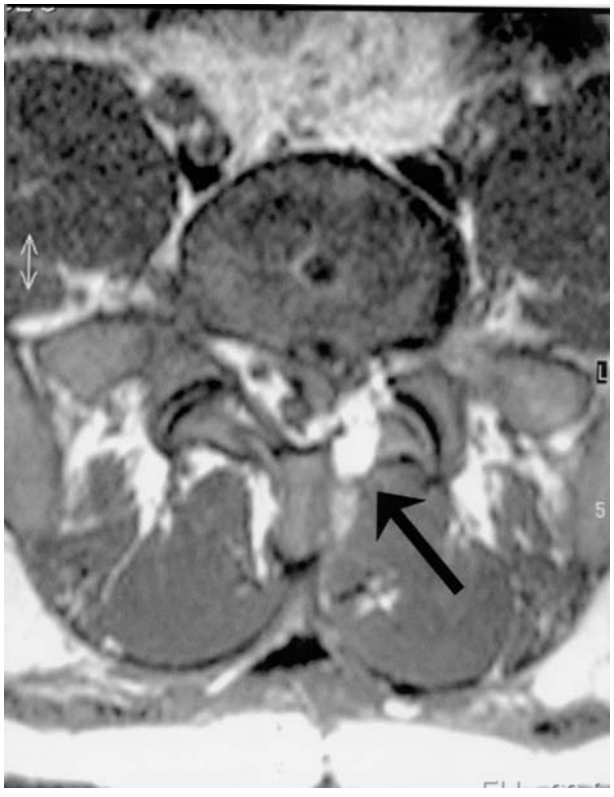

Fig. 1. Illustrative case: Post-operative MR image of one L5-S1 level operated case, shows the autologous fat graft (arrow) in the epidural space, to perform an impermeable barrier to fibrosis. Visible is the small opening of the yellow ligament

patients were operated by the same surgeon (the first author, GG) utilising the same microsurgical procedure for discectomy.

These patients presented a spinal root lacking natural epidural fat due to a voluminous herniation or scarcity of epidural fat or caused by the adopted procedures.

Total surgical removal of the herniation, documented by post-operative CT (Computerised Tomography) in the first month after surgery, was another criteria for inclusion in the study.

Finally 74 patients were selected, 41 males and 33 females, ranging from 16- to 74-old-years.

The herniations were located: 5 at L2-L3 level (2 right, 3 left), 19 at L3-L4 level (10 right, 9 left), 23 at L4-L5 level (12 right, 11 left), 27 at L5-S1 level (15 right, 12 left).

All the patients signed a detailed informed consent to the procedures.

In 37 patients the spinal root was covered by autologous fat (group A), in the other 37 (control group B), this procedure was not utilised.

The microsurgical placement of autologous fat graft in the epidural space together with a small opening of the yellow ligament achieved an impermeable layer to the coagula and the blood coming post-operatively from the superficial layers (Fig. 1).

One year after surgery all cases were clinically evaluated by a different neurosurgeon (OG, CZ, EP), filling a file-card for each patient and classifying the post-operative symptomatology into five groups (Table 1).

All patients were also radiologically evaluated by a radiologist, who was blinded as to whether patients had been submitted to the reconstruction procedure with epidural fat. One year after surgery all patients underwent MRI (Magnetic Resonance Imaging) examination and each case was graded by the radiologist according to the presence of fibrous epidural tissue showing on MRI scan (Table 2).

Table 1. *Grading system for post-operative symptomatology*

Grade	Symptomatology
0	absent
1	algesic episodes of small entity *, max monthly frequency persisting not more than 24 h
2	as above, but lasting more than 24 h
3	small entity, but more than one per month, lasting more than 24 h
4	algesic episodes of great entity **, max monthly frequency, lasting not more than 24 h
5	great entity, more than one per month, persisting more than 24 h

* *Small entity* Respondent to common analgesics.
** *Great entity* Non-respondent to common analgesics.

Table 2. *Grading system for post-operative fibrosis, detected by MRI*

Grade	Fibrosis
1	no signs of fibrosis
2	small signs*
3	great signs**
4	severe fibrosis, with radicular dislocation

* *Small* Fibrous tissue close to surgical field, not involving the spinal root.
** *Great* Spinal root enveloped by fibrous tissue.

Results

No-one of the 74 patients had post-surgical major complications. In one case, the surgical wound healed later, about 20 days after surgery. In one case, subcutaneous haematoma was present and was removed by transcutaneous aspiration. All patients benefited from the surgical treatment that reduced both pain and neurological damage, if present. Only two patients were lost to follow-up and were not considered in this study. Both patients lost to follow-up were in group A. Hence the total number of cases submitted was 72.

According to the grading system reported in Table 1, patients showed the following score: 38 presented a score of 0, 12 a score of 1, 8 a score of 2, 5 a score of 3, 6 a score of 4, 3 a score of 5.

Patients were successively evaluated also according to the inclusion criteria in groups A or B. Results are summarised in Table 3.

Table 3. *Post-operative outcome score*

Grade	Group A	Group B
	Patient number (percent)	Patient number (percent)
0	25 (71.4%)	13 (35.1%)
1	6 (17.1%)	7 (18.9%)
2	2 (5.7%)	6 (16.2%)
3	1 (2.8%)	4 (10.8%)
4	1 (2.8%)	4 (10.8%)
5	0	3 (8.1%)

Table 4. *Post-operative radiological score*

Grade	Group A	Group B
	Patient number (percent)	Patient number (percent)
1	13 (37.1%)	7 (18.9%)
2	19 (54.2%)	11 (29.7%)
3	3 (8.5%)	14 (37.8%)
4	0	5 (13.5%)

Seventy one % of the patients in group A had 100% of clinical post-operative outcome score; this result was obtained only in 35% of the patients in group B; 37,1% of the patients in group A had 100% of radiological post-operative score, compared to 18,9% in group B with the same result. A good correlation between clinical and radiological outcome was present. All the patients with radiological score 1 were in group 0 of the clinical outcome score. None of the patients in group A had clinical outcome score 5 or radiological score 4, whereas this was present in 8,1% and 13,5% respectively of the patients in group B. Therefore group A had best outcome as compared to control group.

Discussion

The analysis of results shows that the patients submitted to epidural fat reconstruction had a better outcome than those without a normal fat coverage.

Physiologically, the epidural fat permits gliding of the roots and the dural sac on the osteo-ligamentous structures. It allows that the dura of roots and sac move freely in the spinal canal. The epidural fat is an ensemble of lipocytes, surrounded by fibrous tissue with very broad meshes. Thus the adipose tissue is like a gliding fluid.

If this fluid is replaced by fibrous tissue which causes tight adherence between dura and the surrounding osseous structures, the environmental conditions significantly worsen.

The voluminous lumbar disc herniations, particularly if lasting for a long time period, cause a decrease in epidural fat, well visible on MRI. Mechanic and trophic factors play a role in this phenomenon: the herniated disc compression displaces the fat, gliding into regions of lesser pressure and the small, reticular feeding vessels of the adipose tissue are stopped by increased pressure. Finally, the local inflammatory process stimulates the fibroblasts, performing a fibrotic change in adipose tissue. The final consequence is the absence of adipose tissue covering the spinal root and the dural sac and the beginning of peri-radicular fibrosis. This problem is present in at least 50% of the surgically treated patients. Surgical intervention for the removal of disc herniation aggravates this condition, and, at the end of the operation, the dural sac and the spinal roots are further lacking protective epidural fat. The coagula in the surgical field region may also stimulate fibrotic tissue formation. It is common experience that in patients operated for recurrence of disc herniation, tight and thick fibrotic adherences are commonly found firmly involving the spinal root.

Previous studies [1, 7] showed that the posterior lumbar epidural fat is neither a simple incidental tissue nor a filling tissue but has specific histologic features: its sliding spaces and semifluid features suggest a functional role in the lumbar spinal unit and this explains the different distribution in fetal and adult epidural fat. At first distribution is circumferential, in the end it is limited to the posterior portion of the vertebral canal and the fascicles are reduced in number and thin [1]. Particularly the main location at the level of the mobile segment of the lumbar spine, at the intervertebral disc level, in a triangular space limited by the ligamenta flava laterally and posteriorly and by the dural sac anteriorly, suggests its role as sliding structure between the posterior surface of the dural sac and the anterior surface of the vertebral arch [7].

In the reported cases fibrosis was reduced by means of a microsurgical procedure, but in the patients not submitted to epidural fat reconstruction, 17 (46%) of 37 of group B had an unsatisfactory clinical outcome with a score from 2 to 5. Only 7 (19%) had a satisfactory outcome and 13 (35%) complete absence of the symptomatology. In group A on the contrary 25 patients (71%) of 35 had a good outcome with score 0, 6 (17%), an unsatisfactory outcome and 4 (11%) a poor

score between 3 and 5. These results are related to radiological outcome by MRI one year after surgery.

Extent of fibrosis was small in group A, severe in group B.

Previous reports [4, 5] showed that on MRI 1 year after surgery the fat graft utilized is alive and reshaped along the dura mater in relation to its re-expansion and thus is effective in protecting the spinal nerve. Size and quality of fat globules were reduced, lower than normal fat tissue, but was confirmed alive and effective over the long term.

It is important, however, to limit grafting to those cases where natural fat is absent upon the operation in order to avoid complications [2].

In other, previous reports the use of free fat grafts have been described as clinically ineffective [3, 6] but in our opinion there were some important critical technical issues:

- The *microsurgical* placement of autologous fat graft in the epidural space, performed by a small opening of the yellow ligament, forms an impermeable layer to the coagula and the blood coming postoperatively from the superficial tissues. The blood macrophages, transforming into fibrocytes, are responsible for the formation of fibrous tissue.
- Maintenance of a low venous pressure intra- and post-operatively.
- A good post-operative analgesia to achieve maintenance of a low intra-abdominal venous pressure.

Conclusions

To prevent postoperative scarring and failed-back syndrome related to postoperative fibrosis, the authors found a positive effect by reconstructing the epidural fat with autograft of adipose tissue.

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