Clin Rheumatol (2003) 22: 299–304
DOI 10.1007/s10067-003-0736-z

ORIGINAL ARTICLE

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Efficacy of transforaminal versus interspinous corticosteroid injection in discal radiculalgia – a prospective, randomised, double-blind study

Received: 30 September 2002 / Accepted: 28 February 2003

Abstract A prospective, randomised, double-blind study was carried out to compare the respective efficacies of transforaminal and interspinous epidural corticosteroid injections in discal radiculalgia. Thirty-one patients (18 females, 13 males) with discal radicular pain of less than 3 months' duration were consecutively randomised to receive either radio-guided transforaminal or blindly performed interspinous epidural corticosteroid injections. Post-treatment outcome was evaluated clinically at 6 and 30 days, and then at 6 months, but only by mailed questionnaire. At day 6, the between-group difference was significantly in favour of the transforaminal group with respect to Schober's index, finger-to-floor distance, daily activities, and work and leisure activities on the Dallas pain scale. At day 30, pain relief was significantly better in the transforaminal group. At month 6, answers to the mailed questionnaire still showed significantly better results for transforaminal injection concerning pain, daily activities, work and leisure activities and anxiety and depression, with a decline in the Roland–Morris score. In recent discal radiculalgia, the efficacy of radio-guided transforaminal epidural corticosteroid injections was higher than that obtained with blindly-performed interspinous injections.

Keywords Corticosteroids · Disc · Epidural · Herniation · Injection · Transforaminal

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Introduction

Interspinous epidural corticosteroid injection is a widely used technique for the treatment of discal radiculalgia despite controversy about its efficacy [1]. Low corticosteroid uptake by the compressed spinal nerve root due to poor injection targeting could explain the low efficacy of such treatments in some cases [2].

Transforaminal epidural corticosteroid injection techniques are more recent and were initially implemented for preoperative verification of root compression sites [3]. Documented relief of radicular pain after transforaminal injections has prompted many rheumatologists to use this technique in low back pain therapy [4]. Satisfactory results have been obtained in many open studies [5–7]. Interspinous epidural injections are easy to perform, even in the practitioner's office, with a low risk of complications [8]. Transforaminal injections are more technologically complex and require radioscopic or CT control [9], thus exposing the patient to radiation. Injection of an iodised tracer to accurately determine the injection site can also induce an allergic reaction in the patient. The relative efficacies of these two injection techniques have, to our knowledge, only been compared in one previous study, without any clear conclusions being drawn [10]. Moreover, in that study interspinous injections were controlled epidurographically, a technique that is not commonly used in our country (France), where interspinous infiltrations are generally performed blindly. We therefore decided to conduct a prospective, randomised, double-blind study of patients hospitalised in our Rheumatology Service to determine the first-line injection procedure (blindly performed interspinous injection or transforaminal injection with radioscopic control) to recommend for discal radiculalgia therapy.

Materials and methods

Thirty-one patients (18 females, 13 males, mean age 50.5 ± 15.4 years) hospitalised in our Rheumatology Service for treatment of

sciatica secondary to disc herniation of L4/L5 or L5/S1 spaces gave their written informed consent and were consecutively included in this study. It was carried out in agreement with our institutional guidelines for human experimental investigations. The inclusion and exclusion criteria were as follows.

Inclusion criteria: Subjects over 18 years old, with radicular pain of less than 3 months' duration, disc herniation confirmed by CT or MRI, radicular pain intensity above 30 mm scored on the Visual Analog Scale.

Exclusion criteria: Epidural corticosteroid injection within the previous month, a history of spinal surgery, motor or sphincter dysfunction requiring emergency surgery, iodine allergy, anticoagulant intake, clinical depression syndrome, employment disruption of more than 6 months, or occupational injury.

Clinical evaluation: After giving their written informed consent, patients underwent an initial clinical evaluation: pain intensity scored on the Visual Analog Scale, Schober's index, finger-to-floor distance, straight-leg raising test with angle at which pain was triggered, tests for sensory and/or motor dysfunction, and deep reflex anomalies. Patients were also asked to fill in a quality of life questionnaire (Dallas Pain Questionnaire [11] and Roland–Morris Low Back Pain Questionnaire [12]), validated by the Spinal Section of the French Rheumatology Society [13]. Although primarily developed for the evaluation of chronic low back pain, the Dallas pain questionnaire was used in this study for its sensitivity to change.

Randomisation and injection procedure: Patients were randomised using a system of numbered and sealed envelopes containing the type of injection to perform (transforaminal or interspinous). Each envelope was consecutively opened by the same skilled operator in the scanning room just prior to injection. Under identical conditions, irrespective of the type of injection, patients were placed on the radiology table in a procumbent position on a cushion to slightly elevate the painful side. Patients were then premedicated, disinfected, topically anaesthetised and draped. All injections were performed under opiate analgesic (alfafentanyl) and benzodiazepine (midazolam) therapy to maintain double-blinding by ensuring that the patient would not remember which type of injection they had received. For interspinous injection, a 22 gauge (L: 75 mm, Ø: 0.72 mm) spinal needle was inserted in the L4/L5 interspace, with brief radioscopic control to ensure the same conditions as those used for transforaminal injections, but without epidurographic control. The spinal needle was connected to a 10 ml glass syringe filled with physiological saline. The operator maintained steady pressure on the syringe plunger until there was a sharp drop in resistance, which meant that the epidural space had been reached. This saline syringe was then replaced by a syringe containing 5 mg dexamethasone acetate in 2 ml solution, which was all injected into the epidural space. For transforaminal injection, a single-needle paramedian technique was used. At the L4/L5 and L5/S1 levels the needle (L: 75 mm, Ø: 0.72 mm) was advanced obliquely towards the corresponding vertebral pedicle into the 'safe triangle' (composed of a roof made up by the pedicle, a tangential base that corresponds to the exiting nerve root, and a side that is made by the lateral border of the vertebral body). Both anteroposterior and lateral fluoroscopic projections confirmed correct needle placement [5]. At the S1 level the needle was advanced medially and cephalad towards the corresponding sacral foramen. After the injection of 0.5 ml contrast agent to produce a neurogram that identified the affected nerve root, a 5 mg/2 ml dexamethasone acetate solution was injected.

Injection evaluation and review: After injection, all patients underwent the same treatment of rest and lumbar physiotherapy. At day 6 (D6) post injection they were clinically assessed by the same person, who was blinded to the injection technique used. The patients were then sent home. At day 30 patients were clinically assessed again and filled in the same questionnaire. At 6 months (M6) they were sent a questionnaire to assess their outcome, but were not clinically evaluated; they were asked about:

- Surgical treatment undergone, between Day 30 and Month 6, for disc herniation. These patients were then excluded from the final evaluation.
- Persistence of pain (self-assessed ungraduated visual pain scale).
- Effects on quality of life (assessed according to Dallas and Roland–Morris questionnaires).

Statistical analyses

The statistical analyses were carried out in collaboration with the Medical Information Department using the SAS 6.12 software package (SAS Institute Inc.).

- Descriptive statistical analysis: calculation of frequencies for each qualitative variable condition. Means and standard deviations were determined for quantitative variables, while assessing the normality of the data distribution.
- Analytical statistical analysis: performed on the basis of the hypothesis of the independence of samplings corresponding to each solution. χ^2 or Fisher's exact tests were performed to find links between two qualitative variables when the sample population was too small. Means were compared via non-parametric Mann–Whitney, Wilcoxon or Kruskal–Wallis tests. A P value of 0.05 or less was considered to indicate statistical significance for each of these tests.

Results

A total of 31 patients were followed up, with 16 in the interspinous group and 15 in the transforaminal group. No treatment side effects were noted. All patients were followed up until 6 months post reatment (M6). The demographic and clinical characteristics of patients in both groups are presented in Tables 1 and 2. Both groups were comparable with respect to all clinical criteria studied.

Outcome at D6

In both groups there were significant improvements in several parameters (Table 3). In the interspinous group, pain relief, Schober's index and the pain angle in the straight-leg raising test were significantly improved. In the transforaminal group, pain relief, Schober's index,

Table 1 Patient characteristics in both groups (interspinous and transforaminal injection). Values are means with standard deviation

	Interspinous $n = 16$	Transforaminal $n = 15$	P
Age (years)	51.3 ± 17	49.8 ± 13.9	0.7
Sex (male/female)	5/11	8/7	0.2
Weight (kg)	73.5 ± 8.9	70.7 ± 11.5	0.6
Height (cm)	167.3 ± 9.4	170.4 ± 8.9	0.3
Symptom duration (weeks)	6.8 ± 4.1	6.5 ± 3.8	0.8
Herniation type (posterior/lateral)	12/4	10/5	0.7

Table 2 Radiculopathy characteristics in both groups (interspinous and transforaminal injection)

	Interspinous $n = 16$	Transforaminal $n = 15$	P
Intensity of pain (VAS)	71.8 ± 17.3	74 ± 12.4	0.6
Schober (cm)	2.2 ± 0.8	1.7 ± 0.8	0.1
Finger-to-floor distance (cm)	39.6 ± 18.2	39 ± 18.6	0.9
Straight-leg raising test (°)	35.9 ± 26.6	48.3 ± 29.7	0.7
Dallas (daily activities)	84.3 ± 16.2	84.2 ± 21	0.7
Dallas (work and leisure activities)	95.6 ± 8.3	98.6 ± 3	0.9
Dallas (anxiety, depression)	64.3 ± 23.4	50 ± 26.9	0.1
Dallas (sociability)	54.0 ± 23.5	47 ± 26.2	0.4
Roland–Morris	14.3 ± 5.2	11.6 ± 4.7	0.1

Table 3 Results at D6 after epidural corticosteroid injection in both groups (interspinous and transforaminal injection). Δ: score variations between D0 and D6. (DA) daily activities, (W&L) work and leisure activities, (A&D) anxiety–depression, (S) sociability. *P*: intragroup significance, *P** (interspinous and transforaminal injection): intergroup significance

Interspinous transforaminal	Day 0	Day 6	Δ D0–D6	P	P^*
VAS (mm)	71.8 ± 17.3	42.1 ± 23.8	29.6 ± 21.9	0.04	NS
	74 ± 12.4	30.2 ± 27.1	43.7 ± 29.5	0.002	
Schober (cm)	2.2 ± 0.8	2.6 ± 0.7	0.4 ± 0.6	0.03	0.009
	1.7 ± 0.8	2.9 ± 0.9	1.2 ± 1	0.01	
Finger-to-floor (cm)	39.6 ± 18.2	33.8 ± 20	5.8 ± 11.4	0.07	0.04
	39 ± 18.6	23.3 ± 15	15.6 ± 19.8	0.006	
Straight-leg raising test (°)	35.9 ± 26.6	65.8 ± 16	18.6 ± 21.8	0.02	NS
	48.3 ± 29.7	72.5 ± 14.3	15 ± 20	0.05	
Dallas (DA)	84.3 ± 16.2	79.5 ± 21.8	6.3 ± 20.3	NS	0.03
	84.2 ± 21	61.2 ± 29.1	24.8 ± 29	0.003	
Dallas (W&L)	95.6 ± 8.3	84 ± 19.2	6.8 ± 23.7	NS	0.03
	98.6 ± 3	85.6 ± 22.1	17.6 ± 26.3	0.01	
Dallas (A&D)	64.3 ± 23.4	60.9 ± 28.4	3.7 ± 27.4	NS	NS
	50 ± 26.9	40.6 ± 23.5	9.3 ± 28	0.01	
Dallas (S)	54 ± 23.5	46.5 ± 22.4	7.5 ± 27.4	NS	NS
	47 ± 26.2	43.6 ± 23.7	3.3 ± 16.9	0.03	
Roland–Morris	14.3 ± 5.2	13.3 ± 6	1 ± 3.8	NS	NS
	11.6 ± 4.7	7.5 ± 4.9	4.1 ± 4.6	0.005	

finger-to-floor distance and the pain angle in the straight-leg raising test were significantly improved. There were also significant improvements in the quality of life parameters in this group, i.e. according to the Roland–Morris questionnaire ($P = 0.005$) and for all items of the Dallas questionnaire, including daily activities ($P = 0.003$), leisure and work activities ($P = 0.01$), anxiety and depression ($P = 0.01$) and sociability ($P = 0.03$). In the interspinous group, none of the quality of life criteria was significantly improved at D6. A comparison of mean intergroup variations revealed a higher efficacy of transforaminal injections with respect to Schober's index ($P^* = 0.009$), finger-to-floor distance ($P^* = 0.04$), daily activities ($P^* = 0.03$) and leisure and work activities ($P^* = 0.03$) based on the Dallas questionnaire.

Outcome at D30

In the interspinous group we documented a significant improvement in all clinical and quality of life criteria (Table 4). In the transforaminal group, pain, Schober's index and finger-to-floor distance were improved, as were all items of the Dallas scale except anxiety and depression. A comparison of mean intergroup variations revealed a higher efficacy of transforaminal injections for pain relief.

Outcome at 6 months

All patients answered the mailed questionnaire to assess their medium-term outcome. Between the D30 and the M6 evaluations five patients in the transforaminal group had undergone a discectomy and four in the interspinous group. Fisher's exact test showed that the number of operated patients was not significantly different between the two groups. Furthermore, means comparison for quantitative variables, i.e. duration of disease, Schober's index, finger-to-floor distance, intensity of pain, via non-parametric Mann–Whitney Wilcoxon test, did not show any significant difference in each group (transforaminal and epidural) between operated and non-operated patients. These nine patients were therefore excluded from the analysis of the 6-month evaluation results.

Table 4 Results at Day 30 after epidural corticoid injection in both groups (interspinous and transforaminal). Δ: scores variations between D0 and Day 30. (DA) daily activities, (W&L) work and leisure activities, (A&D) anxiety–depression, (S) sociability. *P*: intragroups significance, *P** (interspinous and transforaminal injection): inter group significance

Interspinous transforaminal	Day 0	Day 30	Δ D0–D30	*P*	*P**
VAS (mm)	71.8 ± 17.3 74 ± 12.4	31 ± 26.2 17.2 ± 24	40.3 ± 24.4 56.8 ± 32.8	0.0001 0.0003	0.04
Schober (cms)	2.2 ± 0.8 1.7 ± 0.8	3.2 ± 0.7 3.5 ± 1.1	1 ± 1.2 1.8 ± 1.5	0.0004 0.001	NS
Fingers-to-floor (cm)	39.6 ± 18.2 39 ± 18.6	18.3 ± 13.76 17.7 ± 14.6	20.6 ± 18 21.3 ± 22.4	0.0009 0.004	NS
Straight-leg raising test (°)	35.9 ± 26.6 48.3 ± 29.7	76.2 ± 19.2 83.3 ± 8.1	24.3 ± 22.5 27.5 ± 21.8	0.03 0.06	NS
Dallas (DA)	84.3 ± 16.2 84.2 ± 21	59 ± 24.7 52.2 ± 18.1	22.8 ± 25.3 33.8 ± 29.2	0.004 0.001	NS
Dallas (W&L)	95.6 ± 8.3 98.6 ± 3	58.7 ± 27 55.3 ± 24.9	28.3 ± 29.1 35 ± 34.2	0.0007 0.002	NS
Dallas (A&D)	64.3 ± 23.4 50 ± 26.9	40.3 ± 22.9 36 ± 15.9	21 ± 21.2 14 ± 29.1	0.001 NS	NS
Dallas (S)	54 ± 23.5 47 ± 26.2	32.1 ± 20.8 33 ± 12.6	21.6 ± 26.7 14 ± 23.7	0.006 0.05	NS
Roland–Morris	14.3 ± 5.2 11.6 ± 4.7	9.6 ± 6.1 7.9 ± 5.8	4.5 ± 4.8 3.7 ± 7.4	0.005 NS	NS

Table 5 Variations in pain and quality of life. Results at 6 months postinjection in both groups. (DA) daily activities, (W&L) work and leisure activities, (A&D) anxiety–depression, (S) sociability. Δ: score variations between D0 and Month 6. *P*: intragroup significance, *P** (interspinous and transforaminal injection): inter group significance

Interspinous transforaminal	Day 0	Month 6	Δ D0–M6	*P*	*P**
VAS	71.8 ± 17.3 74 ± 12.4	43.7 ± 25.2 21.7 ± 21.7	25.4 ± 33.6 55.3 ± 28.8	0.02 0.003	0.04
Dallas (DA)	84.3 ± 16.2 84.2 ± 21	69 ± 26.3 46.5 ± 26.7	13.5 ± 33.8 43.8 ± 29.8	NS 0.005	0.05
Dallas (W&L)	95.6 ± 8.3 98.6 ± 3	59.5 ± 23.3 37 ± 29.7	30.4 ± 34.5 65.5 ± 31.1	0.004 0.002	0.02
Dallas (A&D)	64.3 ± 23.4 50 ± 26.9	55 ± 27.3 33.5 ± 25.7	6.2 ± 25.8 26 ± 24.2	NS 0.02	0.04
Dallas (S)	54 ± 23.5 47 ± 26.2	44.1 ± 26.7 29.5 ± 22.7	10 ± 28.9 26.5 ± 23.9	NS 0.01	NS
Roland–Morris	14.3 ± 5.2 11.6 ± 4.7	10.2 ± 6.7 5.3 ± 5.2	3.1 ± 7.2 7.7 ± 4.7	NS 0.003	0.05

In the interspinous group we documented a significant improvement in pain relief ($P = 0.02$) and leisure and work activities ($P = 0.0004$) according to the Dallas questionnaire (Table 5). In the transforaminal group, pain relief and all quality of life criteria were significantly improved. A comparison of mean intergroup variations highlighted a significant difference in favour of transforaminal injections with respect to pain relief ($P^* = 0.04$), daily activities ($P^* = 0.05$), leisure and work activities ($P^* = 0.02$) and anxiety and depression ($P^* = 0.04$). There was also a significant improvement in the quality of life parameters, i.e. according to the Roland–Morris questionnaire.

Discussion

Since the pioneer studies of Lièvre [14] in the 1950s, most epidural corticosteroid injections have been performed by the interspinous route, a technique commonly used in rheumatology for the treatment of lumbosacral radiculopathies. Early open studies reported 65% satisfactory results [1], whereas contradictory results have been obtained in more recent randomised controlled studies. In a systematic review of randomised clinical trials, Koes et al. [15] presented 12 studies of disparate methodological quality. Positive results in favour of corticosteroid injections were obtained in six of these studies, but in the remaining six studies these injections had equivalent or lower efficacy than the placebo. A recent study on epidural corticosteroid injections in 158 patients was reported by Carette et al. [16]. The group receiving interspinous epidural corticosteroid injections had better spinal mobility, lower sensitivity dysfunction after 3 weeks, and less radicular pain after 6 weeks than the control group. The difference with the placebo group was no longer significant at 3 months. After 1 year 25% of the patients in both groups had been operated on.

Buchner et al. [17] also demonstrated high short-term (2 weeks) efficacy of corticosteroid injections, but this efficacy had waned at 6 weeks and 6 months.

Transforaminal corticosteroid injections have been the focus of fewer studies. Between 1986 and 1995, Weiner and Fraser [6] conducted an open prospective study on 30 patients presenting with severe radiculopathy secondary to lateral disc herniation. Almost 80% of these patients were significantly improved after a mean follow-up of 3.4 years. Lutz et al. [5], in an open study involving 69 patients, obtained more than 75% positive outcome after a mean follow-up of 80 weeks. Vad et al. [18] compared the efficacy of transforaminal corticosteroid injections and paravertebral trigger-point saline injection in a prospective, randomised, controlled study. With a mean follow-up of 1.4 years, 84% of patients in the transforaminal group showed improvement, compared to only 48% in the control group ($P < 0.005$). Karppinen et al. [9], in a prospective, randomised, double-blind controlled trial, compared transforaminal injections of corticosteroids and of local anesthetics (saline) in two groups of 79 patients presenting with radicular pain of 3–28 weeks' duration. There was a significantly greater improvement in spinal flexibility, radicular pain relief and patient satisfaction for the corticosteroid group only at 2 weeks, but not at 3 or 6 months.

We compared the respective efficacies of radio-guided transforaminal and blindly performed interspinous epidural corticosteroid injections in discal radiculalgia of less than 3 months' duration. At D6, the efficacy of transforaminal injections was found to be higher than that of interspinous injections with respect to lumbar flexibility, daily activities and leisure and work activities scored on the Dallas pain scale. At D30, pain relief was significantly better in the transforaminal group. At M6, the efficacy of transforaminal injections was also higher than that of interspinous injections concerning pain relief, and all items except sociability on the Dallas pain questionnaire. There was also a significant improvement in the quality of life parameters, i.e. according to the Roland–Morris questionnaire.

To our knowledge, only one previous controlled test has compared the respective efficacies of interspinous and transforaminal epidural corticosteroid injections in disc-related sciatica [10]. This study assessed 30 patients with radiculalgia requiring hospitalisation. The main difference between our study and that of Kolsi et al. [10] concerned the interspinous injection technique. We performed all epidural injections without visual control, because in France interspinous epidural injections are widely performed in the rheumatology specialist's office without radioscopic control. In the trial of Kolsi et al. [10] interspinous injections were performed with epidurographic control. Epidurography ensured that the injection was actually epidural, because the injected contrast agent was visible, with brief radioscopic control, along the anterior wall of the epidural space. They highlighted a significant decrease in radicular pain at D7 and D28 in the interspinous and transforaminal groups, without any significant difference between groups. There was no medium-term follow-up evaluation. In our study, the lower efficacy of the epidural route was not related to a poorer injected corticosteroid location. Indeed, a success rate of above 90% has previously been obtained in trained hands [19].

We decided to perform interspinous injections without visual control to determine whether, in routine operating conditions for the treatment of recent discal radiculalgia, it would be better to perform transforaminal injection immediately (despite the drawbacks discussed above), or whether the same efficacy could be achieved by blindly performed interspinous epidural injection.

In our study, both interspinous and transforaminal epidural corticosteroid injections showed short-term efficacy in the treatment of discal radiculalgia. Our comparison of these two injection techniques revealed that transforaminal injections performed under radioscopic control had higher efficacy with respect to pain relief and quality of life criteria. In the medium term the need for surgery was not significantly different in the two groups. In unoperated patients, compared to interspinous treatments transforaminal injections revealed a higher efficacy concerning pain relief and most items of the Dallas pain questionnaire. There was also a significant improvement in the quality of life parameters, i.e. according to the Roland–Morris questionnaire. This should therefore be considered a first-line procedure in the treatment of discal radiculalgia, despite problems of irradiation and allergic reaction and the fact that these injections are more complex to perform.

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