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Efficiency and predictive parameters of outcome of a multimodal pain management concept with spinal injections in patients with low back pain: a retrospective study of 445 patients

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Abstract

Low back pain is one of the most common diseases of modern civilization. Multimodal pain management (MPM) represents a central approach to avoiding surgery. Short-term results are published rarely and often incomparable because of different treatment concepts. This study compared the subjective and objective parameters as well as the anamnestic and clinical parameters of 445 patients with low back pain before and after inpatient MPM to investigate the influence of this type of therapy on short-term outcome. The majority of patients were very satisfied (39%) or satisfied (58%) with the treatment outcome. The median pain reduction for back pain was 3.0 (IQR 2.88) (numeric rating scale, NRS), thus 66% and 2.75 (IQR 3.38, 62%) for leg pain. The main pain reduction occurred within the first 10 days of treatment and was clinically significant from day 5 onwards. The outcome for patients with hospitalization of more than 10 days was significantly worse. The parameters female sex, BMI of > 30, local pain, and pain duration of 3–24 months had a significantly better outcome. In contrast, age, treatment cause, depression, anxiety, and other diseases had no statistically significant influence on outcome. MPM therapy for more than 5 days seems to be an efficient short-term approach to treating low back pain. Knowledge of some of the outcome predictors helps to early identify patients who require more intensive individual care. In the case of no clear indication for surgery, MPM can be an appropriate treatment option.

Keywords Lumbar spinal stenosis · Multimodal therapeutic treatment · Spinal injection · Injection therapy · Conservative treatment

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Introduction

Low back pain represents an increasing problem in modern societies throughout all age groups. The incidence of low back pain is 60–90%, and low back pain is the main cause of working disability in most countries [1–3]. Elderly people present the largest population with degenerative lumbar spine diseases, mostly caused by spinal stenosis or herniated discs. The main symptom in the elderly is claudicatio spinalis that decreases walking distances. However, irritation or compression of the sciatic nerve as well as facet joint degeneration may also result in radicular pain.

Individually tailored treatment options are vitally important to patients affected by low back pain. Because of the side effects involved in surgical interventions, conservative treatment should always be preferred over surgery. Pain chronification due to long-term pain should be avoided. Clinical studies have shown the positive effect of conservative treatment options, but these studies were not standardized

and are thus not comparable. In addition, no standardized measurement tool for patient-related outcome is yet available [4]. However, the advantage of a multimodal pain management concept in comparison to a unimodal approach has been shown [5, 6].

The authors of this paper have achieved good mid-term results with MPM both in treating lumbar radicular pain syndrome as well as with regard to socioeconomic factors [7, 8]. Injection therapy is often accompanied by multimodal treatment such as physical therapy and psychological counseling, if patients fulfill the inclusion criteria of the respective country. MPM has already been shown to be a very beneficial treatment option [9, 10] for avoiding surgery in patients with radicular nerve route compression. However, no studies are yet available showing the overall effect in a large cohort of patients with low back pain, without any special regard to the specific underlying cause of pain.

One of the most common interventions in chronic low back pain are epidural injections, although the effectiveness has been controversially discussed in many systemic reviews [2]. The aim of nerve root injections is to reduce pain and symptoms faster than with other conservative treatment options, thus enabling patients to benefit from exercise programs and the behavioral approach within the hospital stay [11, 12].

Nowadays, other important treatment aspects are socioeconomic factors and cost effectiveness [7]. Therefore, as in any intervention [13, 14], it is very important to identify predictors for a positive outcome to choose the correct conservative treatment concept for each individual patient. A recent literature review by Yang et al. has suggested that conservative care is poorly defined and studies should explicitly define conservative care [15]. Therefore, we aimed at showing the effects of our specific multimodal pain management concept for patients with low back pain and leg pain.

Aim of the study

The study aimed at proving the positive short-term effect of a multimodal therapeutic inpatient concept based on drug injections for patients with low back pain and radicular pain and at establishing parameters for predicting outcome.

Methods

This retrospective clinical study included male and female patients aged between 29 and 77 years who had been treated for lumbar radiculopathy according to a multimodal therapeutic concept at the Department of Orthopedics of the University Medical Center Regensburg in 2015. Participation in the study was voluntary. The inclusion criterion was low back pain with and without radiculopathy. Low back pain or leg pain must have been > 4 on a numeric rating scale (NRS 0–10). At least two psychological sessions during therapy must have been visited to fulfill the German criteria for a multimodal pain management concept. A clear indication for conservative inpatient treatment was required, and an absolute indication for surgery had to be absent.

Exclusion criteria were post-discectomy syndrome, rheumatic or inflammatory spinal disorders, tumors with spinal involvement, and congenital spinal deformities. The study was approved by the Ethics Committee of the University of Regensburg (24 February 2015, Reference no. 16-101-0014) and carried out in accordance to the approved guidelines of the Helsinki Declaration of 1975. Written informed consent was obtained from all study participants. The study was registered on 22 February 2017 with the German Clinical Trials Register (Deutsches Register Klinischer Studien; DRKS) under the Number DRKS00011788 (WHO register).

Patients

After the evaluation of the patient files for exclusion criteria and completeness of the data set, 445 patients remained. 245 women (55.1%) and 200 men (44.9%) with a mean age of 66 years (29–77) were included (Table 1). The treatment causes are given in Table 2.

Intervention

The intervention has already been described by the authors elsewhere [8]: the treatment of every patient lasts 8–12 days (mean 10.8 days). On average, each patient receives two injections daily, one in the morning and one at noon. The injections consist of lumbar spinal nerve root analgesia (LSPA) into the affected nerve root in freehand technique [16]. Additional treatment consists of one injection into the facet joints under X-ray and one epidural injection in loss-of-resistance technique per stay. LSPA injections only contain 0.5% of scandicaine, whereas translaminar epidural injections and therapeutic facet joint injection (level L4/L5, L5/S1) also contain 40 mg of triamcinolone [7, 11, 17–19].

Physiotherapy and sports therapy as part of the inpatient concept include group exercises and aqua training; accompanying measures consist of electrotherapy for muscle relaxation and thermotherapy. In addition, patients are instructed in progressive muscle relaxation according to Jacobsen and take part in coordination training. The most effective exercises are isometric exercises for strengthening the back muscles that is further aided by medical training therapy with any workout equipment. The main goal is recovery of the load-bearing capacity and reducing pain-avoidance behavior. The success of MPM depends on accurate patient

Table 1 Demographic data of the patient group (mean and range)

	Women ($n=245$)	Men ($n=200$)	Together ($n=445$)
Age (years)	68 (32–77) SD ± 13.2 ($n=181$)	64 (31–77) SD ± 13.6 ($n=134$)	66 (29–77) SD ± 13.5 ($n=315$)
BMI	27.9 (19.5–43.2) ($n=211$)	29.1 (18.1–43.1) ($n=175$)	28.52 (18.1–50.8) ($n=387$)
HADS anxiety	Normal 115 (54.5%) Borderline 48 (22.7%) Abnormal 48 (22.7%)	Normal 108 (61.7%) Borderline 38 (21.7%) Abnormal 29 (16.6%)	Normal 223 (58.0%) Borderline 86 (22.0%) Abnormal 7 (20.0%)
HADS depression	Normal 124 (58.8%) Borderline 34 (16.1%) Abnormal 53 (25.1%)	Normal 111 (63.4%) Borderline 36 (20.6%) Abnormal 28 (16.0%)	Normal 235 (61.0%) Borderline 70 (18.0%) Abnormal 82 (21.0%)

Table 2 Data on the treatment cause of the patient group

	Women ($n=245$)	Men ($n=200$)	Together ($n=445$)
Facet joint syndrome	$n=78$ 32.0	$n=53$ 36.5	$n=131$ 29.4
Spondylolisthesis	$n=37$ 15.2	$n=20$ 10.0	$n=57$ 12.8
Herniated disc	$n=48$ 19.7	$n=50$ 25.0	$n=99$ 22.2
Spinal canal stenosis	$n=40$ 16.4	$n=36$ 18.0	$n=76$ 17.1
Other reason	$n=41$ 16.8	$n=41$ 20.5	$n=82$ 18.4

The total number and the percentage (%) of the different degenerative reasons for treatment are shown as total and gender dependent

information and consultation, continuous motivation, a systematic increase in load, and permanent feedback [20].

Data

Similar to the authors' description for cervical problems [11], data were recorded daily in a standardized manner. The data obtained before, during, and after treatment were compared to assess the treatment success at the end of hospitalization. Besides the numerical rating scale (NRS) for back and leg pain as a main evaluation criterion, the validated German version of the Oswestry Disability Index (ODI) [21–23] was assessed at the beginning and at the end of therapy. The minimum of clinically significant pain reduction was set to NRS 2.0 [24–26]. Treatment success was defined as NRS < 50% of the initial pain at the end of hospitalization [27]. Using the ODI, a score from 0 to 20% stands for light disabilities, 21–40% for medium, 41–60% for severe, and 61–80% for severest disabilities. 81–100% describes bedridden patients [22, 28, 29]. The Hospital Anxiety and Depression Scale-German version (HADS-D) were only evaluated on the first day of therapy, because no changes were expected during hospitalization. Scores from 0 to 7 are considered normal, scores from 8 to 10 borderline abnormal, and scores higher than 10 abnormal for both anxiety and depression [30, 31].

To assess the effect of epidural injection as conducted with triamcinolone but without any local anesthetics, pain reduction was evaluated 2 days after injection [32] and 1 day after facet joint injection. At the end of the hospital stay, all collected data were saved in a pseudonymized manner. The primary outcome was pain reduction > NRS 2 for back and leg pain.

Statistical analysis

Statistical analysis was done with SPSS (IBM SPSS Statistics, Version 23.0., Armonk, NY: IBM Corp.). Metric variables were reported descriptively as mean and standard deviation. Statistical data were not normally distributed. Data were compared with the non-parametric Wilcoxon test and reported with the median and interquartile range (IQR). The level of significance was set at $p < 0.05$. A sample size of $n=445$ resulted in 90% power to detect a significant effect, if the true effect size of the total population was $d=0.29$, which can be considered small. The corresponding significance level was adjusted according to Bonferroni. The datasets generated and/or analyzed during the current study

Table 3 Data on pain treatment of the patient group (median and interquartile range; mean and standard deviation)

	Women ($n=245$)	Men ($n=200$)	Together ($n=445$)
Treatment days	10.0 (2.0) 10.2 (±1.7)	10.0 (2.0) 10.0 (±1.6)	10.0 (2.0) 10.16 (±1.7)
Back pain on day 1 (NRS)	6.2 (3.2) 6.0 (±2.0)	5.5 (2.7) 5.4 (±2.1)	6.0 (3.2) 5.8 (±2.1)
Leg pain on day 1 (NRS)	5.25 (3.4) 5.1 (±2.7)	5.0 (4.5) 4.7 (±2.6)	5.2 (4.0) 4.9 (±2.7)
Back pain on day of discharge (NRS)	2.0 (2.4)* 2.4 (±2.1)	2.0 (2.6)* 2.4 (±1.9)	2.0 (2.5)* 2.4 (±2.0)
Leg pain on day of discharge (NRS)	2.00 (3.4)* 2.3 (±2.3)	1.8 (3.5)* 2.0 (±1.9)	2.0 (3.5)* 2.2 (±2.2)
Days of hospitalization needed for relief of back pain > 2 (NRS)	5.0 (4.0) 5.1 (±2.4)	5.0 (3.0) 5.1 (±2.4)	5.0 (3.0) 5.0 (±2.6)
Days of hospitalization needed for relief of leg pain > 2 (NRS)	4.0 (4.0) 4.9 (±2.3)	5.0 (4.0) 5.3 (±2.3)	5.0 (4.0) 5.1 (±2.4)

The course of back and leg pain and the days needed to treat to reduce the pain > 2 (NRS) are shown as total and gender dependent; both, back and leg pain were reduced significantly

*$p < 0.001$

are available from the corresponding author on reasonable request.

Results

Questionnaires

The Oswestry Disability Index (ODI) was used on day 1 and on the day of discharge to analyze the overall development of a patient's disability. At the first examination on day 1, the mean ODI was 42.8% that had decreased to 37.2% on the day of discharge.

The Hospital Anxiety and the Depression Scale (HADS-D) was additionally used to detect abnormalities regarding depression or anxiety [30]. Table 1 shows the HADS results. 82 out of 387 (21.5%) patients completing the HADS form had a depression score, and 57 of them were treated with anti-depressive medication (69.5%) (Table 1).

Pain

Before treatment, the median NRS value for back pain was 6.0 (IQR 3.2) that had been reduced to 2.4 (2.0) at discharge. The NRS for leg pain had been reduced from 5.2 (4.0) to 2.0 (2.5) (Table 3; Figs. 1, 2). Over time, median pain reduction was 3.0 (2.9) for back pain and 2.7 (3.4) for leg pain. These figures represent a reduction of back pain by 61.5% and of leg pain by 60.0%; both percentages are statistically significant ($p < 0.05$). Back pain reduction in women was significantly higher than in men (0.75 more in median), but there was no difference in leg pain. As described above, the minimum of clinically relevant reduction of NRS was set at 2. This value was reached after 5.0 (3.0) days for back pain and after 5.1 (2.4) days for leg pain. According to the IMMPACT definition a treatment success has a NRS decrease by 50% at the end of hospitalization. 286 patients (64.3%) were treated successfully for back pain and 53.9% of those with leg pain [27].

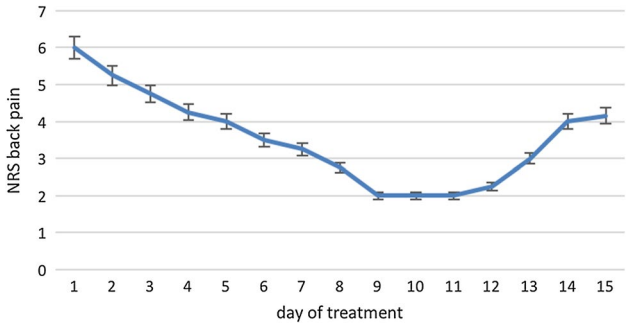

Fig. 1 Course of back pain during hospitalization (median and IQR)

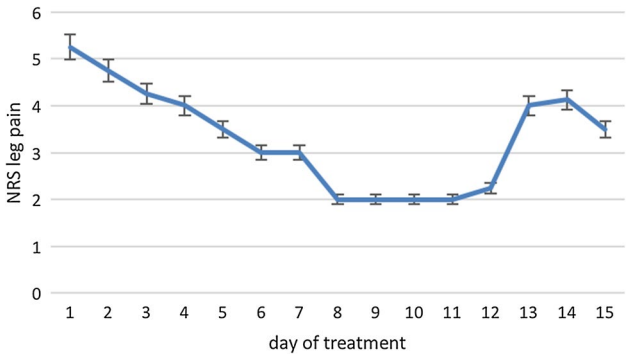

Fig. 2 Course of leg pain during hospitalization (median and IQR)

Patients who had to stay in hospital up to 10 days or longer also showed significant differences in pain reduction. The pain level on the first day was 5.7 (2.7)/5.0 (4.5) (back/leg) in the 10-day group but higher in the other group [back pain 6.0 (3.5)/leg pain 5.5 (3.5)]. Patients staying at the hospital longer than 10 days had significantly ($p < 0.001$) less overall reduction of back and leg pain and did not show any further improvement even after longer hospitalization (Figs. 3, 4).

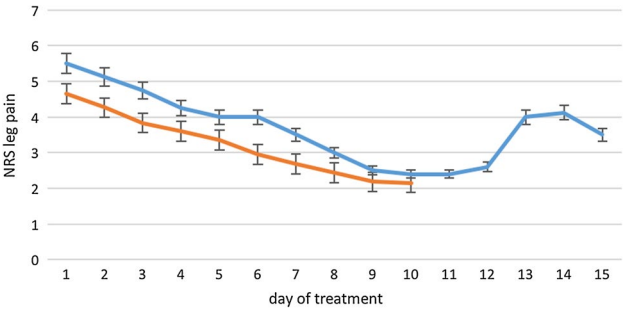

Fig. 4 Course of leg pain during hospitalization: ≤ 10 days (red line), > 11 days (blue line) (median and IQR)

Influence of special injections on pain

Translaminar epidural steroid injection

Translaminar epidural injections were given in the mean on day 4.2 (±2.45) of the therapy, but the time of injection ranged between day 1 and day 9. 2 days after epidural steroid injection, back pain was reduced by 33.0% and leg pain by 34.0%.

Facet joint injection into L4/5 and L5/S1

Facet joint injections were given for L4/L5 and L5/1. The mean day of application was day 3.6 (SD ± 3.23). 1 day after injection, back pain was reduced by 22.3% and leg pain by 19.3%.

Adverse events during injections

Minor adverse events were reported in 49 patients (11%) (Table 4). The most reported problem was hyposensibility. No major adverse events occurred during therapy.

Parameters influencing outcome

The comparison of the different groups regarding the reduction of back and leg pain showed significant improvements in some sub-groups. Women reported a higher level of back pain reduction than men. Patients with a BMI of > 30 [median reduction of back pain: 3.7 (3.0); of leg pain: 3.0 (3.5)] had significantly higher reduction of back and leg pain than patients with a BMI of < 30 [median reduction of back pain: 3.0 (3.0); of leg pain: 2.0 (3.5)]. The rate of improvement for patients with back pain for less than 6 weeks was 3.0 (4.0) and for patients with back pain for 3–24 months 3.7 (3.0) ($p < 0.05$). The comparison of pseudo-radicular back pain and local back pain showed significant improvement in the pseudo-radicular group [1.2 (3.0) and 2.2 (3.0)]. (Table 5) The parameters age, treatment cause, depression, anxiety, or presence of other diseases had no statistically significant influence on the outcome.

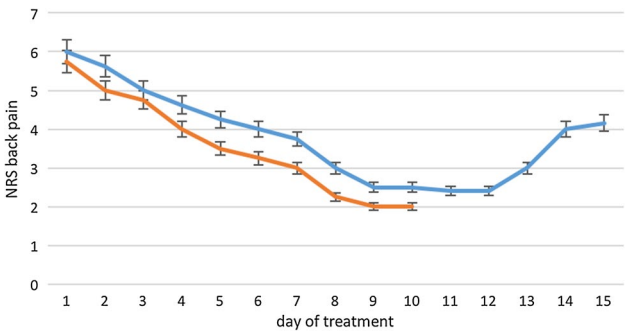

Fig. 3 Course of back pain during hospitalization: ≤ 10 days (red line), > 11 days (blue line) (median and IQR)

Discussion

The study aimed at showing the positive short-term effect of a multimodal therapeutic inpatient concept based on drug injections for patients with low back pain or radicular pain and at establishing parameters predicting outcome.

Table 4 Adverse events during hospital stay (frequency, percentage (%))

	(*n* = 445)
Paraesthesia	*n* = 31 7.0
Headache	*n* = 8 1.8
Local reaction	*n* = 1 0.2
Pain	*n* = 6 1.3
Dizziness	*n* = 2 0.4
Flush	*n* = 1 0.2
No adverse events	*n* = 396 89.0

Table 5 Predictive parameters for total pain reduction (mean and IQR)

	Back pain	Leg pain
Male/female	3.00 (3.00)/3.75 (2.75)*	2.75 (3.25)/2.75 (3.50)
BMI < 30/BMI > 30	3.00 (3.00)/3.75 (3.00)*	2.00 (3.50)/3.00 (3.50)*
Pain: < 6 weeks/3–24 month	3.00 (4.00)/3.75 (3.00)*	3.00 (4.25)/3.00 (3.13)
Referred pain/local pain	3.75 (3.00), 3.25 (2.75)	2.25 (3.00)/1.25 (3.00)*

*$p < 0.05$

This study showed that median low back pain decreased from NRS 6.0 to 2.0 and leg pain from 5.25 to 2.0. Both values represent significant pain reduction ($p < 0.001$). Other studies evaluating different types of conservative treatment as part of a multimodal approach have also shown positive effects [33–35].

72.1% ($n = 321$) of the treated patients had experienced pain for more than 3 months. Avoiding pain chronification or trying to reverse the effects is very important for the affected patients. The ODI score as a value for daily life disabilities had also decreased during the hospital stay [22, 28].

The high percentage of patients with pain chronification necessitate the use a combination of multimodal treatment concepts to reduce pain as fast as possible [8, 36, 37]. Fast pain reduction is often the problem of low-frequency outpatient treatment. Particularly, elderly people with low back pain have poorer physical performance; thus, further decrease in performance should be avoided [38].

As previously described by the authors for neck and arm pain, the positive effect of MPM could also be shown in this study including a large cohort of 445 patients with low back pain and leg pain. 'Therefore, these data also support our concept of interrupting the vicious circle of pain–stress–malposition–pain. The full capacity of the spine-stabilizing muscles cannot be achieved after just 10 days, but this intensive treatment should be the cornerstone for further exercises' [11].

In this study, the time points of the first clinically relevant success with regard to pain reduction by more than NRS 2 were 5.0 (3.0) days for back pain and 5.0 (4.0) for leg pain. Another study showed that patients with low back pain had not undergone evidence-based conservative treatments before consultation on spine surgery [39]. This is a common problem because, in many countries such as Germany, the reimbursement for conservative inpatient treatment is insufficient, and patients are discharged after 3 days of conservative treatment without any improvement of their condition. The consequence in these cases may be surgery that could have been avoided by extending the stay up to 10 days. On the other hand, we showed that patients who had no sufficient pain relief after 10 days did not benefit from prolonged hospitalization, which means that this specific treatment option is not successful in such patients. Identification of the group of non-responding patients before treatment was not possible.

Another focus of this study was the effect of special injections, i.e., the translaminar epidural joint injection and the therapeutic facet joint injection into L4/L5 and L5/S1. Each patient received both injections once during hospitalization in the mean on day 4. For epidural injections, many different techniques and effects have been discussed in the literature [2, 40–43]. The latest study showed a very good short-term effect (up to 3 months) of a single lumbar epidural steroid injection independent of the approach (midline, transforaminal, or paramedian) [44].

Two days after epidural translaminar (midline) steroid injection in our study, back pain was reduced by 33% and leg pain by 34%. Such good results have been described before, also for local back pain [2]. Back pain, which can be reduced by epidural injection, mainly constitutes discogenic pain [45]. In contrast, 'the posterior branches of the lumbar spinal nerves are the anatomic substrate of pain in the lower back' [46]. In our concept, facet joint pain is therapeutically addressed by facet joint injections into L4/L5 and L5/1. 1 day after injection, back pain was reduced by 22.3% and leg pain by 19.3%.

Another focus of this study was establishing predictive parameters for a positive outcome of pain reduction. Total reduction of back pain in women was better than in men, but no differences were found for leg pain. Many studies have described the differences in pain perception between men and women. All studies have shown that women have increased low back pain and leg pain [47] and that their pain is more attributed to psychological factors [48]. Our data correspond to these findings. The higher decrease in total pain of women in our study was probably caused by their higher level of pain on day 1. Therefore, the higher total pain reduction in women in comparison to men in our study was probably due to the psychological treatment provided within the concept of MPM.

Interestingly, patients with a BMI of > 30 had a significantly higher reduction of back and leg pain in comparison to patients with a BMI of < 30. We have no explanation for these findings, because the freehand injection technique is usually more exact in patients with a lower BMI [33, 49]. In the literature, a high BMI is associated with some kind

of weight bias on the perception of likeability, personality attributes, and functional impairment [48, 50].

Patients who had experienced pain for 3–24 months showed a significantly higher benefit from MPM than patients with pain for less than 6 weeks or for longer than 2 years. Patients with pain for less than 6 weeks also showed very good results, but absolute pain reduction was smaller due to the lower pain level on day 1. Patients who have experienced pain for more than 2 years usually suffer from chronified pain, so that an injection therapy lasting 10 days might not just be sufficient anymore.

Another significant improvement could be seen in patients with pseudo-radicular back pain or—as termed today—referred back pain in comparison to patients with local back pain. Because of a degenerative facet joint, referred back pain has many different causes and a higher proportion of functional problems than pain due to a local problem [51–53]. Breaking the vicious circle by means of a multimodal approach is more successful in decreasing functional problems than structural problems.

Parameters age, treatment cause, depression, anxiety, or other diseases had no statistically significant influence on the outcome in this cohort. In the literature, depression is always described as a negative predictor for outcome [54–57]. In our study population, 21% of patients had depression, but 69.5% of them took medication; therefore, the influence of depression may not be shown in our cohort.

The biggest limitation of this study is the lack of a general control group who did not receive any therapy to control the natural history, especially for patients who had only experienced pain for less than 6 weeks. However, implementation of a control group is difficult when evaluating the overall concept of MPM and not just the sub-item 'injections'. Also, a selection bias may exist in this population, because patients were only included after failed unimodal outpatient therapy. A trend towards chronification can be observed, yet the results are satisfying. Another limitation is the inclusion of all types of causes of back pain, not just specific ones. However, the aim was to evaluate MPM therapy in the cohort of patients with back pain. Another limitation is the short follow-up and the unknown effect after discharge, although the authors have already described the mid-term effects in another study [8]. Future studies will have to show the long-term effect of this therapy.

Conclusion

In summary, MPM based on injections can be an efficacious treatment option for low back and leg pain after failure of unimodal outpatient treatment. The first clinical relevant treatment effect can be seen after 5 days. No further improvement can be achieved after 10 days of treatment. To know some positive predictors for successful pain reduction helps to identify patients who may require additional treatment. Before surgery and in the absence of an absolute indication for surgery, MPM should be tried as a treatment option.

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Author contributions MB, TS, MK, JG and AB made substantial contributions to the conception and design of the study. MB, FZ, MK and AB participated in the acquisition of data, analysis and statistics. All authors made contributions to the interpretation of data and have been involved in drafting the manuscript. All authors read and approved the final manuscript.

Compliance with ethical standards

Conflict of interest The authors declare that they have no competing financial interests.

Ethical approval The study was approved by the Ethics Commission of the University of Regensburg and carried out in accordance with the approved guidelines. Registration in Deutsche Register Klinischer Studien (DRKS), German Clinical Trials Register DRKS00011788.

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