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Original article

Epidural neuroplasty versus physiotherapy to relieve pain in patients with sciatica: a prospective randomized blinded clinical trial

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Abstract

Background. Epidural neuroplasty seems to be one of the promising minimally invasive techniques for adhesiolysis in patients with chronic sciatica with or without low back pain. However, because no data exist from randomized studies the aim was to investigate whether this procedure is superior to conservative treatment with physiotherapy.

Methods. A total of 99 patients with chronic low back pain were enrolled in this study and randomly assigned into either a group with physiotherapy ($n = 52$) or a second group undergoing epidural neuroplasty ($n = 47$). Patients were assessed before and 3, 6, and 12 months after treatment by a blinded investigator.

Results. After 3 months, the visual analog scale (VAS) score for back and leg pain was significantly reduced in the epidural neuroplasty group, and the need for pain medication was reduced in both groups. Furthermore, the VAS for back and leg pain as well as the Oswestry disability score were significantly reduced until 12 months after the procedure in contrast to the group that received conservative treatment.

Conclusions. Epidural neuroplasty results in significant alleviation of pain and functional disability in patients with chronic low back pain and sciatica based on disc protrusion/prolapse or failed back surgery on a short-term basis as well as at 12 months of follow-up.

Introduction

Sciatica results mainly from nerve root compression by a herniated disc or the formation of fibrosis/scar tissue after discectomy. Theoretically, direct decompression or excision of the compressing tissue is the best procedure. However, there is a moderate rate of failed back surgery after primary nucleotomy, and patients with failed back surgery have a higher risk of complications when operated on a second time.[1,2]

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Surgery for lumbar disc herniation provides satisfactory results, although conservative therapy is still the treatment of choice for lumbar disc herniation.[3–5] Weber mentioned that the results of surgical treatment were superior to conservative treatment at 1 year of follow-up but not significantly better at 4 years; however, at 10 years the outcomes of the two treatments were similar.[6] Moreover, the frequency of disappearance or marked reduction of the size of the lumbar disc herniation has been reported to be between 48% and 76%.[7,8] Therefore, an adequate period of conservative therapy before surgery is a widely accepted practice because of the well known natural improvement of lumbar disc herniation.[9,10] Epidural neuroplasty (ENP) is an interventional pain management technique that has been first described by Racz and Holubec.[11] The technique is a minimal invasive therapy, where a catheter is placed directly at the herniated disc or the scar tissue compromising the nerve root. Local anesthetic, steroid, and 10% saline is then injected through the catheter. Once on each of the next 2 days these agents are injected again (except the steroid), and the epidural catheter is removed. This procedure shows good results and is associated with only minor complications.[12,13] To our best knowledge, however, no randomized study has been done regarding whether this therapy is superior to controlled conservative physiotherapy over 3 months.

The aim of our study was to evaluate the outcome of epidural neuroplasty in patients with chronic sciatica due to nerve root compression by herniated disc or scar tissue after failed back surgery and to compare the results with those of conservative physiotherapy.

Patients and methods

Patients

A total of patients 99 patients with a history of chronic low back pain and sciatica were randomly assigned to

one of two groups: one group had conservative treatment with physiotherapy and the second underwent epidural neuroplasty. The randomization procedure was as follows: There were 150 cards with either "A" for conservative or "B" for ENP. Once the inclusion criteria of a patient were fulfilled, an independent assistant pulled a card to decide into which group the patient would be allocated.

Inclusion criteria were radicular pain with a corresponding nerve root compressing substrate found on magnetic resonance imaging (MRI) or computed tomography (CT) scans. Therapy before randomization included physiotherapy, local injections, and analgesics. All patients had to be evaluated for radicular pain by an independent neurologist. Exclusion factors were paralysis, spinal canal stenosis, rheumatologic disease, and malignancy.

Altogether, 99 patients were enrolled in the study: 47 (21 men, 26 women; 42 ± 23 years of age) were assigned to the group with epidural neuroplasty and 52 (24 men, 28 women; 45 ± 25 years of age) to the group with physiotherapy. Among the 99 patients enrolled in this study,[13] had previous (9 ± 13 months prior randomization) surgery (discectomy) corresponding to the level of sciatica (5 in the conservative group and 8 in the EPN group). All patients gave written consent, and the study fulfilled the criteria of the local ethics commitee.

Methods

The times of follow-up were set at 3, 6, and 12 months after the onset of the therapy. At each follow-up, visual analog scale (VAS) scores for back pain (VASbp) and leg pain (VASlp), Oswestry disability score (ODS), Gerbershagen score (GHS),[14] and a quantified score for the use of analgesics was assessed by a blinded observer. At 3 months after the onset, patients in the group with conservative treatment had the choice of crossing over into the ENP group; 12 patients switched into this therapy group 3 months after the beginning of therapy. The specific data of the groups at the time of follow-up are shown in Tables 1–4 (see later).

The ENP technique was performed as previously described according to the protocol of Racz.[11] The patient is placed prone on a fluoroscopy table in the operating room. Under local anesthetic the epidural needle is placed in the hiatus sacralis. Epidurography is performed to ensure correct localization of the catheter. The catheter is placed directly onto the herniated disc/scar under fluoroscopic control. Contrast medium is injected to exclude intradural placement of the catheter. A 10-ml dose of a mixture of 9 ml ropivacaine (2 mg)/1 ml triamcinolone (40 mg) is slowly injected (over 5 min). The catheter is sutured in place; and 30 min after the anesthetic/steroid injection, 10 ml of 10% saline is injected by a perfusion pump over 30 min.

Statistical analysis

All data are expressed as the mean ± SEM. Statistical significance was determined using Student's paired *t*-test within the groups. Differences between the two groups were determined using Student's unpaired *t*-test. $P < 0.05$ was considered significant.

Results

The 99 patients were randomized to a group undergoing EPN ($n = 47$) or a group with conservative treatment ($n = 52$). Patients had the choice to cross over into the ENP group after 3 months of unsatisfactory results with physical therapy. One patient of the ENP group had to be excluded, as it was impossible to position the catheter. Twelve patients of the conservative therapy group changed after 3 months to the ENP group, but for evidence-based statistical reasons they were excluded from the statistical testing of the study. Another 10 patients of the group with conservative treatment could not be reached for follow-up or refused to be reevaluated, and 3 patients underwent open discectomy elsewhere; therefore, only 27 patients could be investigated 6 and 12 months after randomization. Because of these patients and statistical reasons, the data for the 6- and 12-month follow-ups could not be used for statistical testing in this study.

There was a significant difference in the reduction of VAS bp and VAS lp ($P < 0.02$) as well as in the Owestry scores ($P < 0.01$) at 3 months in the ENP group compared to the conservatively treated group (Tables 1, 2). Moreover, after 3, 6, and 12 months the VAS bp and VAS lp (both $P < 0.01$) as well as the ODS ($P < 0.02$) were significantly reduced only in the group with ENP in contrast to the group with conservative treatment. Furthermore, 28 patients of the ENP group could be downgraded into one grade lower by the Gerbershagen score with regard to chronification-power, whereas this

Table 1. Results after conservative treatment, by the VAS score

Time of evaluation	VAS lp	VAS bp	ODS
Before ($n = 52$)	6.7 ± 2.0	6.0 ± 2.0	21.4 ± 8.1
3 Months ($n = 39$)	5.6 ± 2.4	5.4 ± 2.3	18.3 ± 8.1
6 Months ($n = 27$)	5.8 ± 2.2	5.6 ± 2.5	22.5 ± 8.9
12 Months ($n = 27$)	5.9 ± 2.3	5.7 ± 2.6	21.6 ± 8.7

VAS, visual analog scale score; lp, leg pain; bp, back pain; ODS, Oswestry disability score
Data are given as the mean ± SEM

Table 2. Results after epidural neuroplasty, by the VAS score

Time of evoluation	VAS lp	VAS bp	ODS
Before ($n = 47$)	7.2 ± 2.0	6.9 ± 2.2	23.1 ± 8.7
3 Months ($n = 46$)	2.4*† ± 2.2	2.2*† ± 2.2	10.6*† ± 7.1
6 Months ($n = 46$)	2.3* ± 2.1	2.2* ± 2.0	10.8* ± 7.4
12 Months ($n = 46$)	2.8* ± 2.8	2.7* ± 2.6	11.6* ± 10.0

Data are given as the mean ± SEM
*$P < 0.05$ in comparison to preoperative (before); †$P < 0.05$ vs conservative-treatment group

Table 3. Results after conservative treatment, by the GHS group

Time of evaluation	GHS I	GSH II	GSH III
Before ($n = 52$)	9	35	8
3 Months ($n = 39$)	8	29	2
6 Months ($n = 27$)	8	17	2
12 Months ($n = 27$)	7	18	2

GHS, Gerbershagen score
Results are the number of patients

Table 4. Results after epidural neuroplasty, by GHS group

Time of evaluation	GHS I	GSH II	GSH III
Before ($n = 47$)	8	34	5
3 Months ($n = 46$)	34	6	6
6 Months ($n = 46$)	31	10	5
12 Months ($n = 46$)	30	8	8

Results are given as the number of patients

was the case in only 2 patients of the group with conservative treatment (Tables 3, 4).

There were no serious complications in our patients (e.g., paralysis or intradural injections). However, 15 patients developed a transient sensory deficit inluding radicular numbness of the leg. In two patients contrast medium revealed intradural placement of the catheter, and consequently the therapy had to be retried after 4 weeks. One patient was excluded because there was no possibility of placing the catheter in the epidural space. Furthermore, the catheter ruptured during removal in one patient. The catheter was easily removed by local incision at the sacrum under local anesthesia.

Discussion

To obtain reliable results with various surgical strategies in patients with herniated disc of the lumbar spine and radiculopathy is difficult. Although many attempts have been made to investigate the effectiveness of these open techniques including minimally invasive techniques such as percutaneous automated discectomy or percutaneous laser discectomy,[15,16] no evidence-based data are available to prove that one of these therapies is superior to conservative treatment during a long-term follow-up.[17] Most of these procedures are based on mechanically decreasing the pressure of the herniated disc or of scar tissue in case of failed back surgery.

Racz was the first in 1989 to describe a new method by which certain drugs are applied via a epidural catheter directly to the herniated tissue or scar tissue compromising the nerve root. This technique, called epidural neuroplasty, epidural neurolysis, or lysis of epidural adhesions, has been proven in numerous prospective controlled clinical studies to be efficiacious and safe.[11–13] However, to our best knowledge, there are no data from a randomized clinical study investigating whether this therapy is superior to conservative treatment with physiotherapy.

To understand the theoretical backround of ENP, one has to elucidate the exact anatomical and neurophysiological facts as well as the pathophysiologic changes in the herniated disc or scar tissue in the lumbar spine. The ventral epidural space is between the ventral part of the dura, the dorsal part of the vertebra, and the dorsal part of the anulus fibrosus/nucleus. This space is separated by fibrous tissue into right and left compartments. The pain-sensitive structures of these compartments are the inner parts of the capsule of the facet joints, periosteum of the vertebra, dorsal longitudinal ligament, and the dorsal part of the fibrous anulus, as well as the tissue surrounding the nerve fibers.[18,19] Mechanical irritation of the nerve root can result in diminished nutrition of the fibers and intraneural edema formation, furthering the mechanical pressure on the nerve root. It has also been shown that biochemical mediators are produced by the herniated nucleus pulposus, such as proinflammatory cytokines, histamine, glycoproteins, and lactic acid, which in turn are able to create pain owing to their inflammatory actions.[20] Various cell types have been found to be present at the site of nerve root compression, such as mast cells, macrophages, fibroblasts, endothelial cells, and chondrocytes.[21] The role of pro-inflammatory cytokines as well as immunological cells and their mediators in degenerative musculoskeletal diseases is becoming more and more evident.[22–24] Thus, the pathophysiology of radicular pain in these patients includes mechanical stress, edema formation, fibrosis, microcirculatory alterations, and inflammation.

These pathophysiological changes at the site of nerve root compression led to the idea of local application of the following drugs without surgical trauma: local anesthetics for local pain relief; steroids for an antiinflammatory effect; and 10% saline as an analgesic and antiedema agent. The technique is performed

using an epidural catheter placed in the ventrolateral epidural space within the segment containing the nerve root compression.[11] The position of the catheter in the ventrolateral epidural space is critical, as it has been shown that the sensitive innervation of the dorsal annulus fibrosus and the dorsal longitudinal ligament is more pronounced because it is in the lateral and dorsal epidural space.[19] The nerve strucures localized in the ventrolateral space are directly connected to the central nervous system. Moreover, if the catheter is placed directly at the affected ventrolateral space, usually a positive memory pain is obtained by the patient when the first drug is injected. In fact, almost all patients who recognized a positive memory pain had good results after 1 year of follow-up in our study.

Optionally, hyaluronidase can be injected additionally, as described by Racz, for more effective adhesiolysis. However, in a prospective randomized study they showed that the use of hypertonic saline is more important than the use of hyaluronidase to obtain good results at the 1-year follow-up with this therapy.[13] Owing to these results, we did not use hyaluronidase in our study.

The local application of steroids in patients with chronic low back pain or radicular pain is controversial. Although there are data to support the idea that periradicular infiltration of corticosteroids leads to results similar to those achieved by saline, infiltration,[25,26] Viton and others showed that 3 months after periradicular infiltration 80% of their patients had significantly less pain than before therapy.[27]

Currently, the results of peridural injection of hypertonic saline seem to be similar to those of steroid application. Theoretically, the basis of this therapy is that water diffuses out of the surrounding tissue along the gradient of the NaCl content. There are not sufficient data that support this possibility, although the clinical data suggest its effectiveness.[13]

Nevertheless, one of the possible reasons for the overall good results of this technique is the effect of the lavage of pain mediators and pro-inflammatory cytokines.[28] Because these mediators lead to chemical, immunological, and inflammatory alterations of the epidural space, lavage of this area can help reduce the factors known to contribute not only to acute pain but also to the chronicity of the pain.[29]

Our results show for the first time that ENP using the technique first described by Racz is superior to conservative treatment in patients with radicular pain due to nerve root compression. Data from some prospective studies have also emphasized the good results in patients treated with this catheter technique.[11,12] In one of his first papers, Racz demonstrated that more than 70% of the patients were immediately pain-free after therapy and this remained so at 6 months after ENP.[12] In contrast, in a study by Devulder et al., no patient had significant pain reduction 6 months after ENP. They used a similar protocol but placed the catheter into the dorsal epidural space and did not use hypertonic saline. These data underline the importance of ventral positioning of the catheter and the use of hypertonic saline.[30]

To date, however, 49 (75%) of the patients in our study had still significant pain reduction 1 year after ENP. Furthermore, at 3 months all parameters were significantly reduced in the EPN group in contrast to the conservatively treated group.

Unfortunately, for various reasons, only 27 of the 52 patients could be reevaluated in the group treated conservatively 12 months after the beginning of the therapy. Twelve patients used the cross-over option to join the ENP group 3 months after therapy onset, ten patients discontinued physical therapy during the protocol owing to unsatisfactory results, and three patients had back surgery elsewhere. Therefore, we did not statistically compare these data with those from the ENP group at 6 and 12 months after the onset of therapy, although our data clearly suggest superior results of ENP in comparison with physical therapy 1 year after ENP. Although there was no improvement in the conservatively treated group, there is strong evidence that exercise therapy might be effective in decreasing pain and improving function in patients with chronic low back pain, (CLBP), particularly in populations visiting a health care provider.[31] In addition, the combination of exercise and massage seems to be beneficial in CLBP patients.[9]

However, one cannot decide on the best treatment regimen owing to a lack of sufficient data from placebo-controlled trials and prospective randmized double-blinded trials regarding therapy for disc herniation with sciatica or failed back surgery with fibrosis. Discectomy is undoubtedly the first choice for patients with acute radicular pain and motor deficit. For all others, one must thoroughly elucidate the best therapy for the individual patient. It is suggested from the literature that if pain continues for a period of 10 weeks, the risk of it becoming chronic is dramatically increased and an invasive method should be discussed.[33]

Conclusions

Taking into account that the results of open discectomy are not necessarily superior to conservative treatment often long-term follow-up, our data show for the first time that for patients with radicular pain due to disc protrusion and herniation or epidural fibrosis epidural neuroplasty seems to be an effective, safe alternative treatment. Furthermore, at least 3 months after

neuroplasty it is superior in comparison to conservative treatment with physiotherapy. Nevertheless, further prospective randomized double-blinded studies should be performed to prove the effectiveness of ENP in comparison to placebo and in comparison to open discectomy procedures.

References

1. Yorimitsu E. Long-term outcomes of standard discectomy for lumbar disc herniation: a follow up study of more than 10 years. Spine 2001;26:652–7.
2. Chiodo A, Haig AJ. Lumbosacral radiculopathies: conservative approaches to management. Phys Med Rehabil Clin N Am 2002; 13:609–21.
3. Atlas SJ, Keller RB, Robson D, Deyo RA, Singer DE. Surgical and nonsurgical management of lumbar spinal stenosis: four-year outcomes from the maine lumbar spine study. Spine 2000;25:556–62.
4. Davis RA. A long-term outcome analysis of 984 surgically treated herniated lumbar discs. J Neurosurg 1994;80:415–21.
5. Vroomen PC, de Krom MC, Knottnerus JA. When does the patient with a disc herniation undergo lumbosacral discectomy? J Neurol Neurosurg Psychiatry 2000;68:75–9.
6. Weber H. Lumbar disc herniation: a controlled, prospective study with ten years of observation. Spine 1983;8:131–40.
7. Cowan NC, Bush K, Katz DE, Gishen P. The natural history of sciatica: a prospective radiological study. Clin Radiol 1992;46:7–12.
8. Delauche-Cavallier MC, Budet C, Laredo JD, Debie B, Wybier M, et al. Lumbar disc herniation: computed tomography scan changes after conservative treatment of nerve root compression. Spine 1992;17:927–33.
9. Zentner J, Schneider B, Schramm J. Efficiacy of conservative treatment of lumbar disc herniation. J Neurosurg Sci 1997;41:263–8.
10. Morgan-Hough CV, Jones PW, Eisenstein SM. Primary and revision lumbar discectomy. a 16-year review from one centre. J Bone Joint Surg Br 2003;85:871–4.
11. Racz GB, Holubec JT. Lysis of adhesions in the epidural space. In: Ray P, (editor). Techinques of neurolysis. Boston: Kluwer Academic; 1989. p. 57–72.
12. Racz GB, Heavner JE, Raj PP. Percutaneous epidural neuroplasty: prospective one year follow up. Pain Digest 1999;9: 97–102.
13. Heavner JE, Racz GB, Raj P. Percutaneous epidural neuroplasty: prospective evaluation of 0.9% NaCl versus 10% NaCl with or without hyaluronidase. Reg Anesth Pain Med 1999;24: 202–7.
14. Gerbershagen HU. The concept of a multidisciplinary pain clinic. Anaesthesiol Intensivmed Notfallmed Schmerzther. 1992;27:377–80 (in German).
15. Kahanovitz N, Viola K, Goldstein T, Dawson E. A multicenter analysis of percutaneous discectomy. Spine 1990;15:713–5.
16. Scick U, Dohnert J, Richter A, Konig A, Vitzthum HE. Microendoscopic lumbar discectomy versus open surgery: an intraoperative EMG study. Eur Spine J 2002;11:20–6.
17. Weber H. The natural history of disc herniation and the influence of intervention. Spine 1994;19:2234–8.
18. Gries NC, Berlemann U, Moore RJ, Vernon-Roberts B. Early histologic changes in lower lumbar discs and facets joints and thier correlation. Eur Spine J 2000;9:23–9.
19. Nakamura S, Takahashi K, Takahashi Y, Morinaga T, Shimada Y, Moriya H. Origin of nerves supplying the posterior portion of the lumbar intervertebral discs in rats. Spine 1996;21:917–24.
20. Wolf CJ, Allchorne A, Safieh-Garabedian B, Poole S. Cytokines, nerve growth factor and inflammatory hyperalgesia: the contribution of tumour necrosis factor alpha. Br J Pharmacol 1997;121: 417–24.
21. Rothoerl RD, Woertgen C, Brawanski A. Pain resolution after lumbar disc surgery is influenced by macrophage tissue infiltration: a prospective consecutive study on 177 patients. J Clin Neurosci 2002;9:633–6.
22. Specchia N, Pagnotta A, Toesca A, Greco F. Cytokines and growth factors in the protruded intervertebral disc of the lumbar spine. Eur Spine J 2002;11:145–51.
23. Ozaktay AC, Cavanaugh JM, Asik I, DeLeo JA, Weinstein JN. Dorsal root sensitivity to interleukin-1 beta, interleukin-6 and tumor necrosis factor in rats. Eur Spine J 2002;11:467–75.
24. Veihelmann A. The significance of immunology in orthopaedics today. Orthopade 2003;32:736–43.
25. Karppinen J, Malmivaara A, Kurunlathi M, Kyllonen E, Pienimaki T, Nieminen P, et al. Periradicular infiltration for sciatica: a randomized controlled trial. Spine 2001;26:1059–67.
26. Carette S, LeClaire R, Marcoux S, Morin F, Blaise GA, St-Pierre A, et al. Epidural corticosteroid injections for sciatica due to herniated nucleus pulposus. N Engl J Med 1997;336:1634–40.
27. Viton JM, Peretti-Viton P, Rubino T, Delarque A, Salamon N, et al. Short term assessment of periradicular corticosteroid infections in lumbar radiculopathy associated with disc pathology. Neuroradiology 1998;40:59–62.
28. Omarker K, Myers RR. Pathogenesis of sciatic pain: role of herniated nucleus pulposus and deformation of spinal nerve root and dorsal root ganglion. Pain 1998;78:99–105.
29. Obata K, Tsujino H, Yamanaka H, Yi D, Fukuoka T, Hashimoto N, et al. Expression of neurotrophic factors in the dorsal root ganglion in a rat model of lumbar disc herniation. Pain 2002;99: 121–32.
30. Devulder J, Bogaert L, Castille F, Moerman A, Rolly G, et al. Relevance of epidurography and epidural adhesiolysis in chronic failed back surgery patients. Clin J Pain 1995;11:147–50.
31. Hayden JA, van Tulder MW, Malmivaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. Cochrane Database Syst Rev 2000;2:CD000335.
32. Furlan AD, Brosseau L, Imamura M, Irvin E. Massage for low back pain. Cochrane Database Syst Rev 2002;2:CD001929.
33. Fransen M, Woodward M, Norton R, Coggan C, Dawe M, Sheridan N, et al. Risk factors associated with the transition from acute to chronic occupational back pain. Spine 2002;27:92–8.