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Randomized Trial

Long-term Efficacy of Percutaneous Epidural Neurolysis of Adhesions in Chronic Lumbar Radicular Pain: 10 Year Follow-up of a Randomized Controlled Trial

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Background: No long-term follow-up data exist in any treatment for chronic radicular pain occurring with disc pathology and after failed back surgery. A previous randomized controlled trial (RCT) has proven efficacy in short-term follow-up as an evidence-based effective therapeutic option.

Objectives: Long term data is needed to determine the efficacy and cost- effectiveness of minimal invasive procedures. The present study reports 10 year follow-up results from the randomized trial.

Study Design: A prospective, randomized, placebo-controlled, interventional clinical trial. A power calculation was based on a previous feasibility trial.

Setting: University medical centers.

Methods: After a 4 year enrollment phase, 381 patients with chronic radicular pain persisting beyond 4 months, who failed conservative treatments, were screened. Ninety patients were enrolled. Patients were randomly assigned to receive percutaneous epidural lysis of adhesionsor placebo with concealed allocation in permuted blocks of 4 to 8 patients each, and stratified by treatment center. The primary outcomes were a mean change of the Oswestry Disability Index (ODI) scores and Visual Analog Scale (VAS), one and 10 years after intervention. For each rating scale an analysis of variance with the within-patient factor time (baseline, one year follow-up, 10 year follow-up) and the between-patient factor treatment (lysis, placebo) was used.

Results: Homogeneity was shown at baseline between the groups. The ODI and VAS scores were significantly better one and 10 years in the lysis group vs the control group. The ODI in the lysis group improved from 55.3 ± 11.6 to 9.6 ± 9.3 after one year and to 11.7 ± 14.2 after 10 years. The placebo group also improved from 55.4 ± 11.5 to 30.7 ± 14.2 after one year and to 24.8 ± 12.0 after 10 years. The VAS improved from 6.7 ± 1.1 to 1.2 ± 1.1 after one year and to 1.5 ± 1.4 after 10 years in the lysis group and from 6.7 ± 1.1 to 2.8 ± 1.5 after one year and to 2.9 ± 1.3 after 10 years after placebo intervention. The statistical difference of the ODI and VAS between the treatment and control groups remain significant up to 10 years. No treatment-related severe adverse effects occurred within the 10 years, but minor transient neurological effects were seen directly after the intervention.

Limitations: The long-term effects of single treatment components cannot be specified as no imaging examination was performed at 10 year follow-up. A large variety of unanalyzed noninvasive treatments were done within the 10 years. Some patients did not clearly remember the intervention after 10 years. Uncontrolled effects such as higher in homogeneity of biometric properties, concomitant therapies, pain tolerance level, or just social effects could occur, but were not analyzed in the trial.

Conclusion: This is the first 10 year follow-up report of a placebo-controlled RCT showing

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efficacy of the minimally invasive percutaneous adhesiolysis procedure for patients with chronic lumbosacral radicular pain. No alternative evidence-based treatment modality with 10 year follow-up is available to be recommended. This procedure should be considered as the first treatment option for patients with chronic lumbosacral radicular pain.

Key words: Disc herniation, RCT, disc disease, radiculopathy, back pain, failed back syndrome, epidural, lysis of adhesions, adhesiolysis

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Over the past 30 years, the lysis of epidural adhesions procedure has been pioneered and refined by Racz and Heavner (1-3). Later, McCarron (4) showed that the nucleus pulposus produces local inflammation and scarring in the epidural space in dogs. In humans, microstructural defects accumulate over time as a person ages and the disc pulposus protrudes deeper into the annulus. These defects can result in frank tears of the annulus and disc material can enter the epidural space (5). This may result in epidural adhesion formation and pain related to it. The posterior longitudinal ligament is highly innervated and is an important source of back pain associated with epidural adhesions (6).

The technique is based on several premises: 1) adhesions occur in the epidural space of surgical and nonsurgical patients with low back pain and/or radicular pain; 2) the adhesions are thought to cause pain by entrapping or immobilizing nerve roots; 3) the adhesions prevent injected medications from reaching the intended targets in the epidural space; 4) pain relief can be achieved by removing these adhesions that prevent therapeutic medications from reaching the target site and prevent the normal movement of nerve roots (7).

The epidural lysis catheter has to be placed into the ventrolateral epidural space, close to the target pain generator structure such as the posterior longitudinal ligament, dura mater, nerve root and neural foramina (1,3). Significant device-related adverse events, such as catheter shearing, was addressed by modifying the catheter to the RX-2™ Coudé® needle (Epimed, Dallas, TX) which has reduced shearing risk due to its larger opening and noncutting back edge. The goals of the lysis of adhesions technique include injecting fluid into the ventrolateral epidural space to dissect adhesions and separate the dura from the posterior longitudinal ligament to allow free dural and nerve root movement. Multiple medications are injected to disrupt and prevent reformation of adhesions. Multiple investigators have studied the technique with encouraging results (8-11). A definitive prospective, randomized, sham controlled trial was reported in 2013 with significant improvements in pain severity and functional status one year after treatment (7). Multiple systematic reviews about the procedure have summarized that the lysis procedure is now considered to be the first interventional treatment option for chronic lumbosacral radicular pain (12-17).

Based on these reviews, long-term follow-up is lacking. Up to now, no 10 year follow-up has been published to determine the long-term efficacy of any low back treatment from any cause. Furthermore, this is the first published study to report the long-term outcome of patients with chronic low back pain treated with placebo. Furthermore, the effect sizes of any placebo intervention observed during randomized placebo-controlled trials are still a topic of discussion. In 2017, a randomized placebo-controlled trial was published to determine the effect size of real placebos (13). The authors reported significant and clinically relevant effect sizes within a short-term follow-up. It is known that placebo responses in randomized controlled trials can be confounded by spontaneous symptom improvements and time (13). The natural history of radicular pain is often favorable and nonspecific responses to treatments can be significant.

The purpose of this study is to assess the long-term efficacy of lumbar epidural lysis of adhesions in patients with chronic radicular pain with a 10 year follow-up.

Methods

The study design is a multicenter prospective, randomized, double-blind trial comparing the outcomes of patients with chronic lumbosacral radicular pain after lysis of epidural adhesions versus a sham procedure. Three hundred eighty-one patients were screened in the enrollment phase and 90 patients were enrolled: 46 in the lysis group and 44 in the sham group (Fig. 1). Patients were randomly assigned to receive either percutaneous lysis of epidural adhesions or a sham procedure using concealed allocation of permuted blocks of 4 to 8

patients, stratified by treatment center (n = 4), using a computer generated randomization list. Opaque envelopes were used to conceal the randomization results. Patients, care providers, and outcome assessors were blind to the patients' assigned treatment group. The study was conducted in 4 orthopedic surgery universities specializing in interventional pain management. A feasibility trial was completed beforehand to perform a power analysis and prove the study's setup (18).

The protocol was submitted and approved by the Ethics Committee of the Technical University of Munich (project number: 842/03). Guidelines of Good Clinical Practice from the International Conference on Harmonization and Consolidated Standards of Reporting Trials (CONSORT) were followed (19-21).

Inclusion criteria included chronic lumbosacral radicular pain of at least 4 months duration; a positive Laségue test; clinical examination confirming the presence of lumbosacral radicular pain; and presence of congruent computed tomography or magnetic resonance imaging pathology. Exclusion criteria included abnormal blood coagulation history or laboratory parameters; severe spinal stenosis; motor deficits; neoplasia involving the spine; diabetes mellitus; or a history of allergy to medications used for the procedure (Table 1).

The epidural lysis procedure was performed using a caudal approach and a 3 day protocol. Using fluoroscopic guidance, a 16-gauge RK epidural needle was placed into the sacral canal via the sacral hiatus. Ten ml of radiopaque contrast medium (Solutrast 300 [Iopamidol], ALTANA Pharma AG Byk-GuldenStraße 2, 78467 Konstanz, Germany) was injected to confirm epidural placement and to visualize filling defects associated with epidural adhesions (epidurogram). A TunL-Kath® (Epimed International, Dallas, TX) was placed through the RK epidural needle and positioned to the anterolateral epidural area of the filling defect. Ten mL of 0.25% bupivacaine was injected through the catheter followed by150 U/mL of hyaluronidase in 10 mL of preservative-free saline. After monitoring for the absence of subdural local anesthetic blockade, hypertonic saline (10 mL, 10%) was injected slowly with 40 mg triamcinolone and 2 mL of 0.25% bupivacaine. The catheter was secured and on each of the subsequent 2 days, 0.25% bupivacaine, 10 mL was injected through the catheter, followed by slow injection of 10 mL of 10% saline and 2 mL of 0.25% bupivacaine. Finally, the catheter was carefully removed. In the sham procedure control group, an identical needle and catheter were inserted similarly except the needle and catheter were

Table 1. *Inclusion and exclusion criteria.*

Inclusion criteria	Exclusion criteria
• Chronic lumbar radicular pain without neurologic motor deficits after disc protrusion or after failed disc surgery • Age > 18 years • Ability to give written informed consent after being told of the potential benefits and risks of participating in the study • Signed patient informed consent paper • 4 months of unsuccessful conservative treatment i.e., must have undergone at least 1 unsuccessful nonpharmacological treatment and at least 2 unsuccessful pharmacological treatments • Time gap of at least: • 6 weeks since the last corticosteroid injection • 4 weeks since the last anesthetic injection; iontophoresis, ultrasound and electromyostimulation • One week since the last nonsteroidal anti-inflammatory drugs • 2 days since the last prescription or nonprescription analgesics, heat, ice, massage, stretching • Score of > 4 on the VAS scale • Score of > 45 on ODI • Time interval of > one week after last pain medication except rescue medication of 14g acetaminophen max / week or 14g metamizole / week • Time interval of 6 weeks after epidural injections	• Patients with chronic lumbar radicular pain with neurologic motor deficits after disc protrusion or after failed disc surgery • Rheumatoid disease, collagenosis, diabetes mellitus • Cancer • Inflammation (acute, subacute, chronic) with significant pathologic laboratory findings, • Vertebral body fracture • Immunsupressive therapy • Long-term cortisone therapy • Clinically relevant heart and lung disease • Disturbance of coagulation • Spinal stenosis • Polysegmental disc disease • Previous epidural catheter interventions. • Time interval of > 1 week after last pain medication except rescue medication of 14g acetaminophen max / week or 14g metamizole / week • Time interval of 6 weeks after epidural injections • Hypersensitivity to local anesthetics, hyaluronidase, contrast medium • Liver disorders • Poor physical conditions • Pregnancy • Peripheral nerve entrapement • Workers' compenstion • Urogentital or sexual disfunction

placed epifascial into the subcutaneous tissue superficial to the afflicted level. Each patient was injected with 10 mL of preservative-free saline daily for 3 days, then the catheter was removed. Following the series of 3 injections, all patients were prescribed physical therapy with no activity limitations. Patients were prescribed analgesics of 14 g of acetaminophenmaximum per week (not to exceed 2 g per day) or 14 g of metamizole (recently banned in the United States) maximum per week, if requested. The primary outcome measures were the difference in percent change of Oswestry Disability Index (ODI) scores and Visual Analog Scale (VAS) 10 years after the procedure. Secondary outcome measures were mean differences of ODI scores and VAS 6 and 12 months after the intervention.

Statistics

For each rating scale an analysis of variance (ANOVA) with the within-patient factor TIME (baseline, one year follow-up, 10 year follow-up) and the between-patientfactor TREATMENT (lysis placebo) was used. Indeed, Shapiro-Wilk tests showed that rating data were not normally distributed. However, given the sample size and based on the central limit theorem, this violation of the normality assumption can be considered to be negligible (22). In case of a significant interaction TIME x TREATMENT post hoc t-tests for independent samples were performed. Note that for ANOVA calculations only those patients were included that provided full data sets (ODS: n = 52, VAS: n = 52). In case of comparisons of single means, however, all available data were used. To account for multiple testing, the conservative Bonferroni correction was applied: since 2 rating scales were used, the alpha level was set to .05/2 = .025. Descriptives are reported as a mean (M) and standard deviation (SD). As measure of effect sizes for ANOVA main effects and interactions, the η^2 and for t-tests the Cohen's d was computed. Data analysis was performed with SPSS for Windows, version 25 (IBM Corp., Armonk, NY).

Results

Ninety adult patients (50% women, aged between 26 and 83.5 years) participated in this multicenter study. Groups did not differ with respect to age [t(88)= 0.6, P = .579], BMI [t(88) = 0.8, P = .440], gender ratio (V = 0.18, P = .092), duration of treatment [t(88) = 0.6, P = .571), body side of pain/treatment (V = 0.05, P = .658), or ratio of participating study center [χ^2 = 0.8, P = .846]. Table 2 summarizes demographic data at baseline. Fifty-two patients completed 10 years follow-up. In the neurolysis group, 17 were lost to follow-up; in the placebo group 21 patients were lost to 10 years analysis. Reasons are displayed in the flow chart according to the CONSORT statement (Fig. 1). The ODI and VAS scores were significantly better one and 10 years in the lysis group vs the control group. The ODI in the lysis group improved from 55.3 ± 11.6 to 9.6 ± 9.3 after oneyear and to 11.7 ± 14.2 after 10 years. The placebo group improved from 55.4 ± 11.5 to 30.7 ± 14.2 after one year and to 24.8 ± 12.0 after 10 years. VAS improved from 6.7 ± 1.1 to 1.2 ± 1.1 after one year and to 1.5 ± 1.4 after 10 years in the active group and from 6.7 ± 1.1 to 2.8 ± 1.5 after one year and to 2.9 ± 1.3 after 10 years after placebo intervention. All differences remained significant up to 10 years (Table 4 and Figs. 2,3).

For ODI the ANOVA revealed a main effect for TIME (F[2,104] = 239.9. P < .001, η^2 = .822) and TREATMENT (F[1,52] = 19.8, P < .001, η^2 = .276). Most importantly, however, the interaction TIME x TREATMEANT was significant (F[2,104] = 21.4, P < .001, η^2=.291). Regarding the VAS, the main effect for TIME (F[2,100] = 347.6, P < .001, η^2 = .874), the main effect for TREATMENT (F[1,50] = 17,1 P < .001, η^2 = .255), as well as the interaction TIME x TREATMENT (F[2,100] = 6,4 P = .002, η^2 = .114) became significant.

Subsequent t-tests confirmed that the baseline rating did not differ between groups, neither for ODI (t[88] = 0.04, P = .966, d = 0.01), nor for VAS (t[88] = 0.2, P = .822, d = 0.005). In contrast, there were clear group differences in ratings after one year showing that pain in the treatment group was lower than in the placebo group (ODI: t[55*] = 6.7, P < .001, d = 1.75; VAS: t[55] = 4.8, P < .001, d = 1.25). After 10 years pain ratings of the treatment group were lower than ratings of the placebo group, which was true for every scale (ODI: t[52] = 3.6, P = .001, d = 0.99; VAS: t [50] = 3.6, P = .001, d = 1.03). All significant group comparisons survived a Bonferroni alpha correction.

The same significant difference in outcome was found concerning the benchmark of 50% improvement in ODI and VAS, defined as a clinically relevant benchmark of improvement.The difference between the active and control groups remained significant up to 10 years (Table 3).

Transient neurologic deficits were observed more frequently in the lysis group immediately after the intervention as an expected treatment-related side effect (42 vs 6). All neurological deficiencies resolved spontaneously within the hospitalization period. No

adverse event or side effect was found up to 10 years follow-up. Dura puncture of the catheter into the spinal canal and shearing of the outside catheter coating were observed once in each group. In the case of dura puncture, the catheter was removed and replaced in the correct position. In the case of shearing, the outside catheter coating, resistance to maneuvering the catheter was perceived, and the RK needle and catheter were removed and the procedure was performed with a new catheter and RK epidural needle.

Discussion

Many treatment modalities for back pain have appeared on the market within the last 3 decades. Minimally invasive procedures became attractive because of less invasiveness, higher safety, and maintenance of function and mobility and to avoid surgery (12,23,24). Most techniques are still lacking evidence-based proven efficacy and almost no long-term data are available. Our study analyzed the first 10 year follow-up data after a minimally invasive lysis procedure in patients suffering chronic radiculopathy. The results demonstrate long-term maintenance of the improvements measured one year after lumbar epidural lysis of adhesions in the original trial (7). This study found clinically meaningful improvements in pain and function 10 years following lumbar epidural lysis of epidural adhesions in patients with single level lumbar radicular pain that had not responded to at least 4 months of usual treatments. The average ODI score in treated patients was in the minimal disability range, while the sham group scored in the moderate disability range. Pain severity was almost doubled in the sham group compared to the treatment group at long-term follow-up. The effect sizes for pain and function are large and clinically relevant. The clinically relevant level of improvement was defined as 50% improvement or more, scored as a success. A significantly higher number of patients in the lysis group reached the 50% benchmark of improvement after one year and also after 10 years, which demonstrates the long-term success rate up to 10 years after this minimally invasive lysis procedure. A tendency of pain reoccurrence was found within the 9 year period after the one year follow-up date, but this tendency was insignificant. Surprisingly, the same minor pain reoccurrence was found in the placebo group. For the first time, a 10 year sustained placebo effect was found after a placebo minimally invasive lysis procedure in patients with chronic back pain. Still, 69% of patients reached the 50% improvement benchmark measured on the VAS and 65% reached improvement on the clinically relevant 50% benchmark measured on the ODI.

The improvement in the sham control group was significant and sustained as well as in the treatment

Table 2. *Demographic data at baseline.*

Patient Demographics			
	Placebo	**Treated**	***P* value**
Number of Patients	44	46	
Men (%)	41	59	0.14
Age (years)	47 ± 13	49 ± 13	0.58
BMI	25.9 ± 3.2	25.4 ± 3.4	0.44
Duration of radicular pain (months)	7.1 ± 2.8	6.7 ± 2.6	0.57
ODI	55.4 ± 11.5	55.3 ± 11.6	0.97
VAS	6.7 ± 1.1	6.7 ± 1.1	0.82

BMI, body mass index; #t-test; *Cramer-V; +χ^2

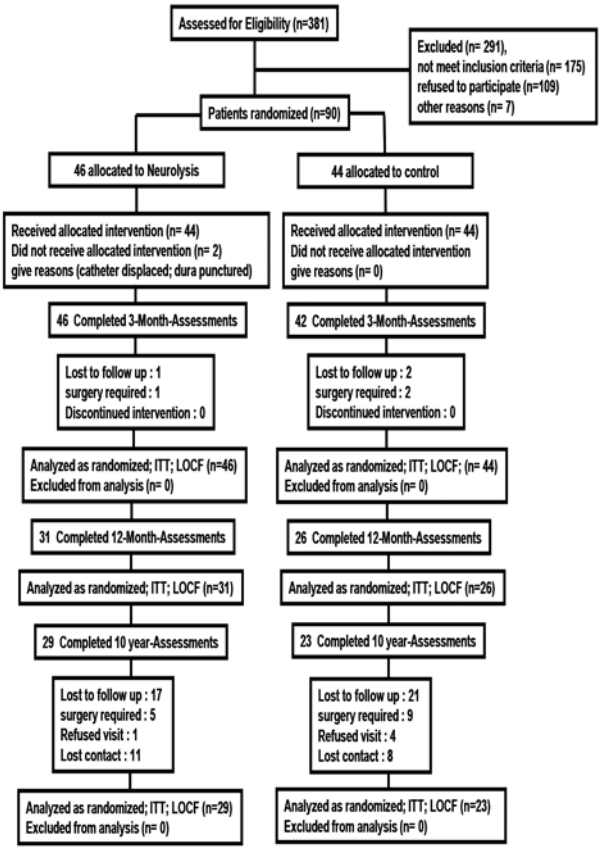

Fig. 1. *Flow chart of a the randomized controlled trial in accordance to the CONSORT Statement.*

Table 3. *Follow-up data 50% improvement one year and 10 years after intervention.*

	Placebo group	Lysis group	*P* value
Clinically relevant improvement > 50% one year after intervention			
> 50% improvement ODS {ODI?}	9/26 (34%)	28/31 (90%)	< 0.01 **
>50% improvement VAS	18/26 (69%)	29/31 (93%)	< 0.032 **
Clinically relevant improvement > 50% 10 years after intervention			
>50% improvement ODS{ODI?}	15/23 (65%)	25/29 (86%)	< 0.01 **
>50% improvement VAS	16/23 (69%)	25/29 (86%)	< 0.01 **

** indicates significance $P < 0.05$

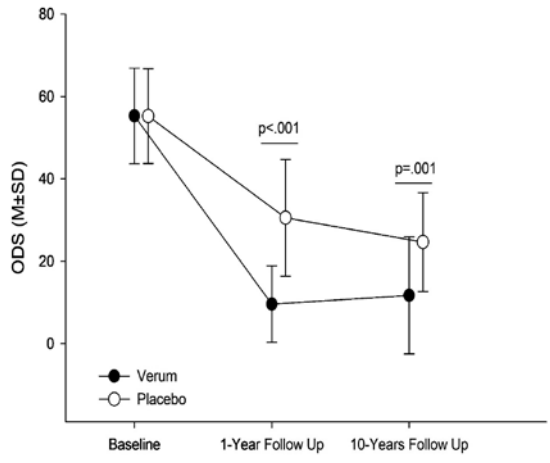

Fig. 2. *Pain ratings on the ODS (Oswestry Disability Score).*

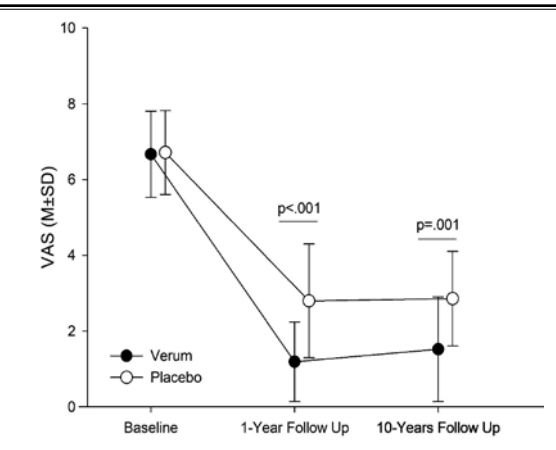

Fig. 3. *Pain ratings on the VAS (Visual Analog Scale).*

group. The placebo response or nonspecific response was usually short-lived; however, this study suggests that for the first time, a long-term placebo response is possible which was almost negated until today. Further research into this is attractive since the risk and cost of a sham procedure are minimal. It is also possible that the natural history of radicular pain is favorable in many patients. Patients may have episodes of chronic pain that eventually improves. TWENTY-FIVE percent (11/44) of patients in the sham control group had surgery over the 10-year follow-up period. This compares to 9% (4/46) in the treated group.

While the number of patients is not large enough to achieve statistical significance, the 2.8-fold higher surgical rate in the sham group is an important observation. The potential cost savings from avoiding surgery are significant and compelling. The technique has been modified over decades. While a midline catheter placement in the posterior epidural space has been successfully used, ventrolateral epidural catheter placement is now recommended (25). A lateral view during contrast medium injection is used to visualize spread into the ventrolateral epidural space (26). This is because a lack of ventral spread is associated with treatment failure (7). Additionally, achieving contrast medium runoff through one or more neural foramina correlates with an improved outcome (27). Achieving lateral runoff is now a specific goal of the procedure.

While small volume injections have been effective for radicular leg pain, larger volume injections are necessary for effective treatment of back pain (28). Each medication used in this lysis technique has a specific rationale for use. Myelogram grade contrast medium is used to identify adhesions and initiate the lysis of adhesions process. Epidurography demonstrates epidural scarring areas by injecting contrast medium into the epidural space. The areas of scarring are not filled with contrast medium (29). Hyaluronidase is used to enhance the spreading of medications in the epidural space and hyaluronidase also has an important inhibitory effect on neutrophil infiltration (30). Local anesthetic is used to produce fluid dissection of epidural adhesions and for analgesia for the procedure as hypertonic saline is quite painful when injected in the epidural space.

The use of epidural steroid injections for sciatica was reported in the early 1950s by Robecchi, Capra, Lievre and others (31,32) Corticosteroid is used to reduce inflammation and pain. Methylprednisolone was used in the early years but triamcinolone and dexamethasone are used now. Hitchcock (33,34) used subarachnoid hypothermic and hypertonic saline to

treat intractable pain . Hypertonic saline 10% is used to reduce swelling in adjacent tissue and to block C fibers long-term. Hypertonic saline was originally diluted with normal saline from a 23.4% hypertonic solution used for sclerosis veins. Now dilution is with lidocaine to a final concentration of 0.6% lidocaine and slightly less than 10% saline. The combination of hypertonic saline and hyaluronidase has provided the best results for epidural lysis of adhesions (35,7). Hypertonic saline has a long-term effect on back pain probably by blocking C fibers in the sinuvertebral nerves.

Treatment of epidural adhesions in the scarring triangle is an additional technique of importance. Teske (36) firstly described the space known as the scaring triangle. The cavity is approximately one mL in volume and is bounded cranially by the L5 nerve root, caudally by the sacral bone, laterally by the facet, and medially by the S1 nerve root and dural sheath. This space is large enough and positioned to collect disc material and is a site of dense scar formation after disc trauma or surgery. Conventional epidural catheters and epidural scopes are probably not able to enter this scarring triangle. However, Matsomuto (37) has reported a successful technique using a specific 21-gauge Versa-Kath® (Epimed, Dallas, TX) via a transforaminal approach.

Despite lacking lysis procedure studies in acute cases, this option should be offered much earlier to prevent chronicity. This evidence-based treatment showed significant improvement within one year follow-up (7,12) and preventing chronic cases should be strongly recommended. Preventing pain chronicity has to be brought into focus for clinical and economic reasons. Patients with surgical problems inevitably have surgery and it is important to identify these patients as early as possible to avoid overtreatment with remedies that essentially have no chance of success. However, some patients have medical contraindications for surgery and this situation may call for a trial of treatment with lysis of adhesions.

While interventional pain procedures have an important role in pain management, education, surgical skill, medical pain management, rehabilitation and psychological care are needed to maximize improvement (38). Dural flossing exercises should be performed before and after the procedure to promote movement between the dura and adjacent structures (38). A dural tug maneuver is performed by flexing the spine and reproducing localized back pain. The dural tug sign may be positive in patients with multilevel injury to discs in isolated cases or in significant trauma like athletic injury in young athletes. Relief of axial back pain is thought to be a consequence of epidural C fiber disconnection during neuroplasty. Nonmyelinated C fibers are affected by 10% sodium chloride. Ten repetitions of dural flossing exercise maneuvers should be performed 3 times per day by the patient to promote movement between the dura and adjacent structures. Dural tug exercises pre- and postprocedure, help identify the side of the spine of the dural adhesion and postneuroplasty resolution of residual pain (38).

This study is characterized and also limited by the long time period after the initial intervention. After 10 years many confounders could have significant effects. Simple, uncontrolled over-the-counter medication, physical intervention, change of biometric characteristics such as body mass index, activity level, comorbidities such as stroke or cardiac infarct, or a simple change of physical work load were not analyzed in this trial but may have significant effect on outcome. Some patients were found to have mental illness, such as dementia, and hardly remember the lysis treatment they got. This is the first time that a long-term follow-up was done in minimallyinvasive neurolysis interventions. Further long-term follow-up studies are needed to confirm in mostly all procedures, but will be hard to perform nowadays when speed, short time results, and fast track science are mostly the focus.

Table 4. *Subjective ratings and Oswestry Disability Index scoring.*

		Placebo M (SD)	Lysis M (SD)	Lysis vs. Placebo *P* value#	Effect size d
ODI	Baseline (n = 90)	55.4 (11.5)	55.3 (11.6)	.966	0.01
	1 year follow-up (n = 57)	30.7 (14.2)	9.6 (9.3)	**< .001**	1.75
	10-years follow-up (n = 52)	24.8 (12.0)	11.7 (14.2)	**.001**	0.99
VAS	Baseline (n = 90)	6.7 (1.11)	6.7 (1.14)	.822	0.005
	one year follow-up (n = 57)	2.8 (1.50)	1.2 (1.05)	**< .001**	1.25
	10 years follow-up (n = 52)	2.9 (1.25)	1.5 (1.38)	**.001**	1.03

ODI, Oswestry Disability Index; VAS, visual analog scale; # -t-test; bold values indicate significant groups difference ($P < .0167$).

Limitations

Due to the very long period, a significant percentage of our patients were lost to follow-up, which was expected. However, the percentage of these patients was balanced and similar in both groups.

Conclusion

In the future, modifications to the lumbar epidural lysis of adhesions technique may include 3 dimensional imaging to facilitate placement and positioning, catheters with imaging capacity, biological injection materials and selective anti-inflammatory drugs and techniques to prevent scar re-formation.

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