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ORIGINAL ARTICLE

Forceful sacrococcygeal injections in the treatment of postdiscectomy sciatica. A controlled study versus glucocorticoid injections*

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Summary – The role of epidural fibrosis in postoperative sciatica is unclear. Few therapeutic trials have been published. We evaluated the mechanical effects of forceful saline injections through the sacrococcygeal hiatus comparatively with glucocorticoid injections. ***Patients and mehods.*** Forty-seven patients with postdiscectomy sciatica but no evidence of compression by computed tomography or magnetic resonance imaging were included in a multicenter, randomized, controlled, parallel-group study comparing forceful injections of saline (20 ml) with or without prednisolone acetate (125 mg) to epidural prednisolone acetate (125 mg) alone. Each of the three treatments was given once a month for three consecutive months. Outcome measures were pain severity on a visual analog scale (VAS) and the scores on the Dallas algofunctional self-questionnaire on day 0, day 60, and day 120. Analysis of variance for repeated measures and Student's t test for paired series were used to evaluate the data. ***Results.*** Forty-seven patients were evaluated. The VAS score improved significantly between day 0 and day 30 in the glucocorticoid group as compared to the forceful injection group ($P = 0.01$). No other significant differences were found across the groups. The VAS score improved steadily in the forceful injection group, producing a nearly significant difference on day 120 as compared to baseline ($P = 0.08$). ***Conclusion.*** Forceful epidural injections produced a non-significant improvement in postdiscectomy sciatica four months after surgery. Epidural glucocorticoids used alone induced short-lived pain relief. Joint Bone Spine 2001 ; 68 : 43-9. © 2001 Éditions scientifiques et médicales Elsevier SAS

epidural fibrosis / epidural injection / failed back surgery syndrome / sacral hiatus / sacrococcygeal injections

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The role of epidural fibrosis in recurrent sciatica after back surgery is highly controversial. Surgical removal of the fibrotic lesions fails to improve the pain in the medium and long term [1-3] and fibrosis is demonstrable by computed tomography (CT) [4] and post-gadolinium magnetic resonance imaging (MRI) [5] in similar proportions of symptomatic and asymptomatic patients. However, two prospective studies [6, 7] involving quantitative evaluation of fibrosis using the same MRI protocol found a statistically significant increase in the risk of recurrent postoperative nerve root pain in patients with abundant fibrosis. In another study [8], persistent fibrosis around the lumbar root six months after surgery was associated with a significant increase in the rate of postoperative sciatica (83% vs 31% in patients without this feature). In support of this finding, a low rate of radicular fibrosis has been reported six months after surgery in asymptomatic patients [9]. By preventing the lumbar root from sliding easily during movements, fibrosis may cause nerve root pain with a predominantly mechanical time pattern [6, 10, 11].

When no mechanical compression is evident, post-discectomy sciatica is treated conservatively. The results are disappointing, however. Transcutaneous electrical nerve stimulation is not effective in all patients and tends to be followed by an escape phenomenon [12, 13]. Psychotropic agents have not been evaluated in this indication, although they are widely used because of the frequent presence of psychological disturbances. Oral morphine has been found more effective than naproxen in a controlled study [14]. Intrathecal and epidural glucocorticoid injections are used primarily because no better treatment is available: in a controlled study versus epidural morphine, glucocorticoid injections were effective for less than one month [15], and in an open study they improved only about 25% of patients [16]. D-penicillamine has been suggested because it is known to inhibit fibrosis, but its efficacy remains unproven [17].

We conducted a study to determine whether mechanical disruption of fibrosis by epidural lavage alone or in combination with epidural glucocorticoid injections was effective in relieving postdiscectomy sciatica, as compared to epidural glucocorticoid injections without epidural lavage.

PATIENTS

Patients aged 18 to 75 years who developed postoperative sciatica with or without low back pain were eligible. Exclusion criteria were as follows: evidence on the postoperative CT or MRI study of nerve root compression by residual disk tissue or lumbar spinal stenosis or of a nondegenerative disease (tumor, infection, or inflammation); clotting disorders; skin lesions at the potential injection site; and severe hypersensitivity to iodine.

METHOD

Study design

This was a multicentre prospective double-blind controlled parallel-group study. The patients were randomly assigned to injection once a month for three consecutive months of saline alone (disruption group: D), of saline followed by prednisolone (D + P group), or of prednisolone alone (P group). All injections were into the epidural space through the sacrococcygeal hiatus. The study protocol was approved by the appropriate ethics committee (Rennes Teaching Hospital). Informed consent was obtained from all the patients.

Sacrococcygeal hiatus injection technique

The patient was prone with a block under the antero-superior iliac spines to facilitate perception of the hiatus as a hollow between the lateral horns of the sacrum. A long 21G intramuscular needle (21G) or a 22G lumbar puncture needle was used. The superficial tissues were anesthetized by injection of 2 mL of 1% lidocaine. A lateral roentgenogram was taken to check that the tip of the needle was midway between the anterior and posterior walls of the spinal canal and was under the S2–S3 disk. The patient was then replaced in the prone position and asked to cough as a test for leakage of cerebrospinal fluid. If the test was positive, indicating puncture of the dura mater, the procedure was postponed for one or two weeks. If the test was negative, 2 to 3 mL of Iopamidol® 200 were injected, and roentgenograms were taken in the anteroposterior and lateral projections *(figures 1* and *2)*. It has been shown that epidurography reduces the risk of technical failure from 15% [18] to less than 3% [19, 20]. In group P, 125 mg of prednisolone acetate were injected. In group D, 20 mL of saline were injected forcefully; the speed of the injection was modulated according to the severity of the pain elicited by the procedure. In group D + C, 20 mL of saline were injected forcefully after 125 mg of prednisolone acetate.

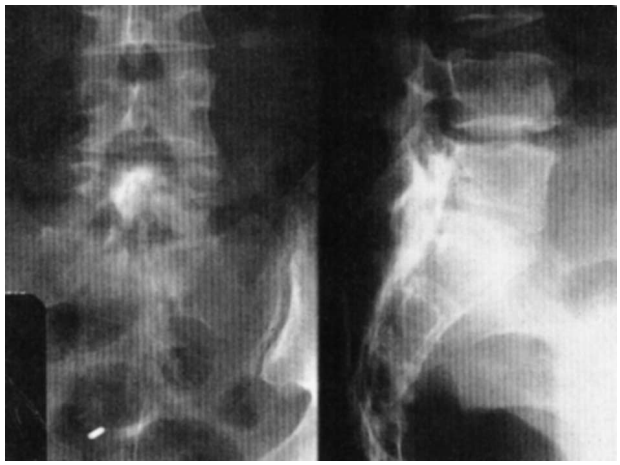


Figure 1. Epidurography by injection of a iodinated contrast agent through the sacrococcygeal hiatus. The contrast agent opacifies the sacral canal and reaches the surgical site.

Outcome variables

The evaluations were conducted on a double-blind basis during outpatient visits on day 0, day 30, day 60, and day 120 after the first injection. On day 0, the following data were recorded: age, sex, time since surgery, sciatica duration, and the treatments used prior to study inclusion (level 2 and 3 analgesics, nonsteroidal anti-inflammatory drugs, psychotropic agents, epidural injections, bracing).

The primary outcome variable was the change over time in the pain severity score on a visual analog scale (VAS). The secondary outcome variables were pain severity on a verbal scale (VS), Schöber's index, the finger-to-floor distance, and the score on the Dallas questionnaire (DRAD). The DRAD self-questionnaire is a multidimensional tool that assesses the impact of pain on activities of daily living (ADLs), work and recreational activities (WR), anxiety and depression (AD), and social activities (SAs) [21]. Its French translation has been validated in low back pain.

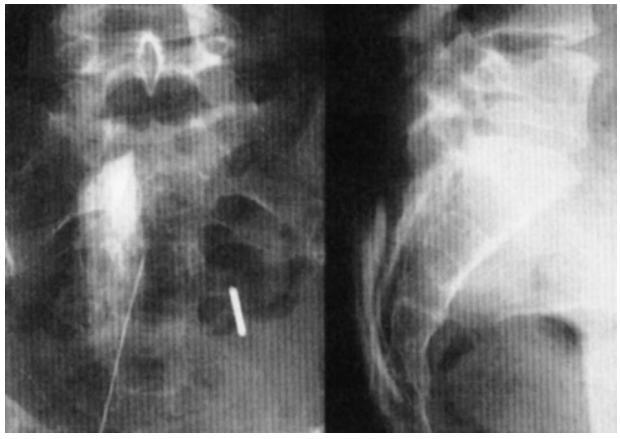


Figure 2. Failed epidurography. The contrast agent was injected into the subcutaneous space and traveled behind and on either side of the sacral canal.

Statistical analysis

The sample size calculation yielded 54 patients with a 5% risk of type I error and a 20% risk of type II error [22]. The assumption used in this calculation was that the nerve root pain would improve in 20% of the patients in the C group and in 45% of those in the D and D + C groups. Analysis of variance (ANOVA) for repeated measures was used to evaluate between-group comparisons of changes in quantitative variables over time. Within-group comparisons of these same quantitative variables were done using Student's *t* test for paired data.

RESULTS

Fifty-eight patients with postoperative sciatica were preselected for the study (Pitié-Salpêtrière, $N = 12$; Lille, $N = 11$; Strasbourg, $N = 11$; Rennes, $N = 9$; Rouen, $N = 5$; Amiens, $N = 4$; Brest and Bourges, $N = 3$). Eleven patients were excluded from the analysis either because they were not fully evaluated on day 0 (in particular, missing VAS score) or because they failed to respond to any of the injections.

This left 47 patients for the study, 19 men and 28 women. Fifteen were randomly assigned to the D + C group, 16 to the C group, and 16 to the D group. Mean age was 44.9 ± 8 years with a range of 21 to 62 years. Mean time since surgery was 38.1 months, and mean sciatica duration was 28.6 months *(table I)*.

A number of differences were found among the three groups at baseline (day 0). The pain was more severe in group D: the difference was significant for the VS score ($P = 0.03$) and non-significant for the VAS score ($P = 0.89$) *(table II)*. The VAS score improvement between D0 and D30 was significantly greater in group C than in groups D and D + C ($P = 0.02$). This difference disappeared over time. Between D0 and D120, the time-course of the VAS score was not significantly different among the three groups. In group D, however, the VAS score decreased steadily, from 70.24 ± 23.5 mm on day 0 to 59.53 ± 24.2 mm on day

Table I. Demographic data and comparison of the three groups in day 0.

Groups		*Disruption*		*Disruption + glucocorticoids*		*Glucocorticoids*		P-*value*
Number of patients		16		15		16		
Age (years)		47.46 ± 8		44.53 ± 24		42.86 ± 36.7		0.35
Sex		M	F	M	F	M	F	0.39
		8	8	4	11	7	9	
Time since surgery (months)		42.8 ± 37.9		33.5 ± 24		37.84 ± 36.7		0.96
Sciatica duration (months)		34.9 ± 44.6		20.28 ± 10.6		31 ± 24		0.52
Prior treatment with	Local glucocorticoid injection	yes	no	yes	no	yes	no	0.9
		12	3	12	2	12	3	
	Brace	10	4	12	2	11	3	0.65
Treatment on D0	Level 2 or 3 analgesic	13	3	11	4	7	9	0.06
	NSAID	6	10	4	11	6	10	0.76
	Psychotropic agent	2	14	6	9	8	8	0.06

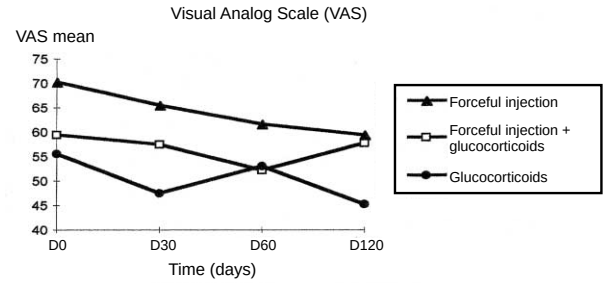
120, a difference near the threshold of statistical significance ($P = 0.08$) *(figure 3)*. No significant differences were found for any of the secondary criteria, including the Dallas ADL subscore *(figure 4)*. However, a close correlation was demonstrated between the Dallas scores, particularly the Dallas ADL score, and the VAS score (significant Spearman's correlation was significant: Rho = 0.66, $P < 0.0001$). The treatment was considered successful if the VAS score improved by 15% or more between day 0 and day 120. The mean VAS improvement in the overall population was 12.5%. The treatment was successful in 43.7% of group D patients, 25% of group C patients, and 20% of group D + C patients *(figure 5)*. The difference between group D and the other groups was not significant because of the small sample size ($P = 0.3$). The pain induced by the injections was evaluated. The number of injections that induced pain was higher in group D and in group D + C than in group C *(figure 6)*. Rather than the insertion of the needle, it is the forceful injection of saline that produced pain at the surgical site, which was reached in 73.4% of cases overall with no significant difference across the three groups (73.3% in group D, 70% in group D + C, and 76.4% in group C); a follow-up epidurography was performed in every case prior to the injection.

DISCUSSION

In this study, some favorable effects were obtained with each of the treatments: although there was no significant difference regarding the VAS score improvement after four months, the epidural glucocorticoid injections alone produced a significantly greater improvement during the first month than the other two treatments, but this difference was not found at the

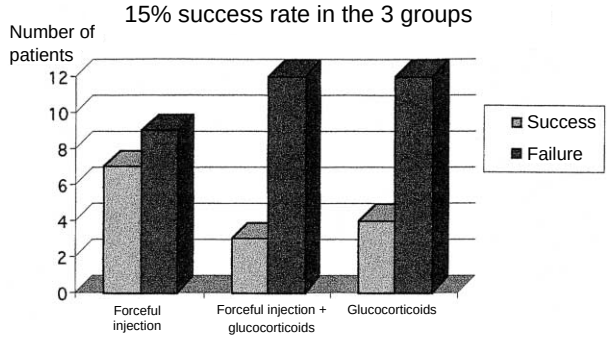
Table II. Comparison of the clinical data in the three groups on day 0.

Groups		*Disruption*	*Disruption + glucocorticoid*	*Glucocorticoid*	P-*value*
VAS (0–100)		70.2 ± 23.5	59.5 ± 19.9	55.4 ± 13.9	0.089
Verbal scale			Number of patients		0.03
	Extremely severe	5	0	0	
	Very severe	6	8	7	
	Moderately severe	4	7	8	
	Mild	0	0	1	
	No pain	0	0	0	
Schöber (in cm)		2.5 ± 1.15	2.6 ± 1.1	2.4 ± 1	0.87
Finger-to-floor distance		34.1 ± 17.4	32.8 ± 16	35.0 ± 11.8	0.99
Dallas score	Activities of daily living	71 ± 12.6	60.8 ± 16.4	65.6 ± 14.1	0.26
	Work, recreation	74 ± 17.4	73.5 ± 16.6	78.7 ± 16.5	0.62
	Anxiety, depression	43.3 ± 25.6	47.3 ± 31.1	47.8 ± 20.4	0.93
	Social activity	41 ± 20	36.3 ± 24.8	41.2 ± 27.7	0.73



	D0	D30	D60	D120
Disruption	70.2±23.5	65.6±22.4	61.6±24.4	59.5±24.2
Disruption + Corticoids	59.5±19.9	57.5±17.8	52.5±22.5	57.6±24.7
Corticoids	55.4±13.9	47.6±20.4	53.0±24.7	45.3±24.0

Figure 3. Time course of the visual analog scale pain score in each group (mean ± SD).



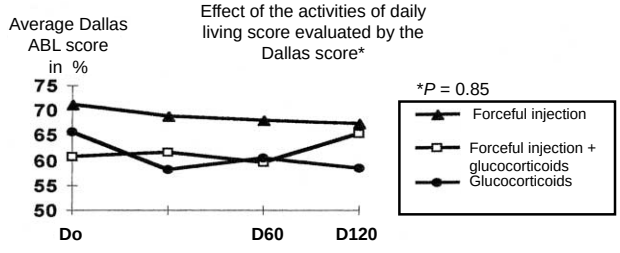
	Forceful injection	Forceful injection + glucocorticoids	Glucocorticoids
Success	7 (43.75%)	3 (20%)	4 (25%)
Failure	9 (56.25%)	12 (80%)	12 (75%)

Figure 5. Number of patients (%) with a 15% or greater improvement in the visual analog scale pain score between day 0 and day 120.

subsequent time points; on the other hand, the VAS score improved steadily throughout the four-month study period in the patients treated with repeated saline injections, producing a nearly significant difference with the other groups ($P = 0.08$). This improvement noted in group D was modest, of about 15%, and was seen in 43.75% of subjects versus 25% of those given glucocorticoid injections.

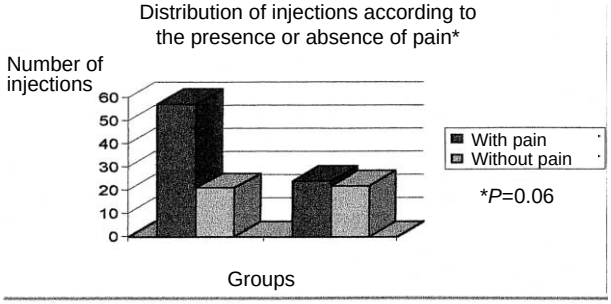
We found a single previous controlled study [23] comparing the effect on pain of forceful epidural saline injections to epidural glucocorticoid injections via the sacrococcygeal hiatus. The results were comparable to ours: 45% of the patients reported an improvement in their nerve root pain after six months in the forceful injection group, versus only 19% in the glucocorticoid group. The between-group difference was statistically significant [23].

Our study has a number of methodological weaknesses. The sample size was too small to allow demonstration of significant differences across the three groups. Our sample size calculations based on the results of the above-mentioned study [23] yielded about 50 patients per group. However, the pace of recruitment into our



	D0	D30	D60	D120
Forceful injection	71.2±12.6	68.8±17.2	68.0±14.6	67.3±18.9
Forceful injection + glucocorticoids	60.8±16.4	61.6±11.8	59.6±16.5	65.3±18.5
Glucocorticoids	65.6±14.1	58.2±18.7	60.3±23.4	58.4±22.8

Figure 4. Time course of the activity of daily living score on the Dallas questionnaire in each group (mean ± SD).



Groups	Total number and percentage of pain: With pain	Without pain
Forceful injection Forceful injection + glucocorticoids (D and D+C)	57 (73%)	21 (27%)
Glucocorticoids (C)	24 (52%)	22 (48%)

Figure 6. Clinical adverse effects of the injections (comparison of the disruption and disruption + glucocorticoid groups to the glucocorticoid alone group; percentage of injections with adverse effects in each group).

study remained on target during the first six months then slowed during the next year, for two main reasons: some of the study centers had a large number of procedural failures, injection through the sacrococcygeal hiatus being fairly difficult, and the injections were frequently painful. The less favorable results in the D + C group as compared to the D group may be ascribable to the higher rate of psychological disturbances in the former. Although randomization was used, the groups were not strictly comparable at baseline: in particular, a larger proportion of patients used psychotropic agents in the D + C group than in the D group, the difference being near the threshold for statistical significance ($P = 0.06$).

Although we found no significant differences, our results confirm those reported by Revel et al. [23] and shed some light on the pathophysiology of postoperative sciatica not caused by residual compression and accompanied by imaging study evidence of epidural fibrosis. Loss of sensory afferents due to prolonged compression before surgery or intraoperative injury to the nerve root may be a less common cause than is usually thought. Abundant epidural fibrosis located around a nerve root may cause pain directly by impinging on or stretching the nerve root. This possibility is consistent with the fact that the time pattern of the pain is more often mechanical than neuropathic. Two to three forceful injections of saline may be effective in disrupting fibrous bands [6]. However, the improvement afforded by forceful saline injections in our study was only about 15% on the visual analog scale. Thus, forceful saline injections must be used in combination with other treatments such as analgesics, psychotropic agents, and psychotherapy.

A new controlled study in a larger number of patients could be performed with the goal of identifying factors associated with a good response to forceful saline injections. In particular, it is worth investigating whether a large amount of fibrosis on MRI scans is associated with a good response to this treatment.

CONCLUSION

Epidural glucocorticoid injections have a significant but short-lived (one month) effect on postoperative sciatica with epidural fibrosis but no evidence of residual nerve root compression. Two to three epidural injections of saline injections induce a steady but modest (although nearly significant) improvement in pain over a four-month period.

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