

SPINE SECTION

Original Research Articles

The Efficacy of Transforaminal Injection of Steroids for the Treatment of Lumbar Radicular Pain

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Abstract

Background. Transforaminal injection of steroids is used to treat lumbar radicular pain. Not known is whether the route of injection or the agent injected is significant.

Study Design. A prospective, randomized study compared the outcomes of transforaminal injection of steroid and local anesthetic, local anesthetic alone, or normal saline, and intramuscular injection of steroid or normal saline. Patients and outcome evaluators were blinded as to agent administered.

Methods. The primary outcome measure was the proportion of patients who achieved complete relief of pain, or at least 50% relief, at 1 month after treatment. Secondary outcome measures were function, disability, patient-specified functional outcomes, use of other health care, and duration of relief beyond 1 month.

Results. A significantly greater proportion of patients treated with transforaminal injection of steroid (54%) achieved relief of pain than did

patients treated with transforaminal injection of local anesthetic (7%) or transforaminal injection of saline (19%), intramuscular steroids (21%), or intramuscular saline (13%). Relief of pain was corroborated by significant improvements in function and disability, and reductions in use of other health care. Outcomes were equivalent for patients with acute or chronic radicular pain. Over time, the number of patients who maintained relief diminished. Only some maintained relief beyond 12 months. The proportions of patients doing so were not significantly different statistically between groups.

Discussion. Transforaminal injection of steroids is effective only in a proportion of patients. Its superiority over other injections is obscured when group data are compared but emerges when categorical outcomes are calculated. Over time, the proportion of patients with maintained responses diminishes.

Key Words. Lumbar; Radiculopathy; Radicular Pain; Transforaminal; Injection; Steroids

Introduction

For the treatment of lumbar radicular pain, conservative therapy (analgesics, physical therapy, traction) has been shown to be no more effective than natural history [1–4]. Surgery provides prompt relief of severe pain, and is more effective than conservative therapy, in the long term [5,6].

Lumbar radicular pain (otherwise and previously known as sciatica [7]) can be caused by foraminal stenosis and space-occupying lesions in the lumbar spine, but the most common cause is lumbar disc herniation. Laboratory evidence implicates inflammation of the affected nerve roots in the mechanism of pain [8–14]. The involvement of inflammation has attracted the use of steroids (corticosteroids) to reduce the inflammation and, thereby, relieve the pain. Injections of steroids, by various routes, have been used as an alternative to surgery, and as an alternative or complement to conservative therapy, for the treatment of lumbar radicular pain.

The simplest treatment is intramuscular injection of steroids, either into the gluteal muscles or the paraspinal muscles. However, the few controlled trials of this therapy cast doubt on its efficacy [15–17].

The most widely used injection therapy [18] is epidural injection of steroids, by either the interlaminar route or the caudal route. For the relief of pain, interlaminar injections have repeatedly been shown to be no more effective than sham injections (of normal saline into an interspinous ligament) [19–21], and studies of caudal epidural injections of steroids have failed to show superiority of steroids over local anesthetic alone [22,23].

More contentious are transforaminal injections of steroids. These involve the injection of steroids directly and accurately onto the affected spinal nerve, under radiologic guidance [24]. Initial observational studies showed that transforaminal injection of steroids spared patients from surgery [25] or provided greater than 50% relief of pain in over 70% of patients [26]. A controlled study confirmed the surgery-sparing effect [27], which persisted at 5-year follow-up [28]. Other controlled studies showed no greater effect from transforaminal injection of steroids than from transforaminal injection of local anesthetic alone [29–32], but another controlled study showed superiority of transforaminal injection of steroids over paraspinal injection of normal saline [33]. Meanwhile, transforaminal injection of steroids has been shown to be more effective than interlaminar injection of steroids, with respect to relief of pain and improvement of disability [34]. The evidence on transforaminal injection of steroids is therefore conflicting.

Transforaminal injection of steroids is a compound intervention. It is not known if the transforaminal route of injection is critical for its effectiveness, or if the agent injected is critical. If the treatment effect is from systemic uptake of steroids, the route of injection would be immaterial. If the treatment effect is due to the site of injection, it is not known if the use of steroids is critical, if the co-administration of local anesthetic is critical, or if the injection is effective because it simply irrigates the affected nerve and washes away the inflammatory exudate.

The present study was designed to test these various conjectures. Transforaminal injection of steroids was compared with transforaminal injection of local anesthetic, to test for a local anesthetic effect; with transforaminal injection of normal saline, to test for an irrigation effect; with intramuscular injection of steroids, to test for a systemic effect; and with intramuscular injection of normal saline, to test for nonspecific (placebo) effects of an elaborate injection.

Methods

The study was conducted at two sites. The majority of patients were recruited and treated at a major teaching hospital in a rural city (Newcastle, Australia) that served a population of some 600,000. Additional patients were also

recruited at a teaching hospital in a national capital city (Canberra, Australia), when the senior author was transferred to that site. Approval for the study was obtained from the Human Research Ethics Committee of the Hunter New England Area Health Service. The trial was registered with the Australian Clinical Trials Research Network (ACTRN 12608000401358).

Patients for the study were drawn from those presenting to spine surgeons (largely neurosurgeons) in the hospitals in which the study was conducted. Upon encountering a patient who satisfied the inclusion criteria, the participating neurosurgeons offered participation in the study to the patient. Eligibility was then assessed by either the first or third author, who obtained informed consent from the patients.

The inclusion criteria were as follows: adult patient capable of providing consent and capable of complying with the outcome instruments used, with pain radiating into the lower limb, of a lancinating, burning, stabbing, or electric quality; associated with limitation of straight-leg-raise to less than 30°; and demonstration of a disc herniation by computerized tomography (CT) or magnetic resonance imaging (MRI) at a segmental level consistent with the clinical features. (Patients with a straight-leg-raise greater than 30° but less than 45° were included only if they gave a clear history of lancinating pain and imaging demonstrated a disc herniation.) Pain of appropriate quality was the primary indication for treatment. Neurological signs of radiculopathy were not required, but served to consolidate the diagnosis when they were present. All patients had been classified by their referring surgeon as eligible for surgery, meaning that surgery would be the next intervention if injections did not relieve the pain.

Exclusion criteria were foraminal stenosis, severe motor deficit, a history of substance abuse, inability to comply with the instruments for outcome assessment, previous surgery at the affected segmental level, or conditions that rendered the conduct of an injection unsafe such as pregnancy, recent infection, or spinal deformity. Excluded also were patients who did not have lancinating pain in the lower limb; i.e., they had only deep aching pain characteristic of somatic referred pain. Although foraminal stenosis was an exclusion criterion, lateral recess stenosis was tolerated provided that the patient also had a disc herniation that was affecting the target nerve. Patients were not excluded on the basis of duration of pain. Pain was defined as acute if it had lasted less than 3 months and chronic if it had lasted longer than this [7].

At the primary study site, all consecutive patients who satisfied the inclusion criteria were invited to participate in the study. Only eight patients declined participation. During the period of recruitment (February 2007–November 2008), 130 patients were recruited at this site. At the secondary site, an additional 20 patients were recruited between March 2008 and November 2008. The size of the population from which these latter patients

were drawn was not disclosed to the investigators by the neurosurgeons who referred patients to the study.

As each patient was enrolled, baseline data were obtained by one of the principal investigators or a research nurse. Patients estimated the intensity of their radicular pain using a numerical pain-rating scale, on which 0 represented no pain and 10 represented worst pain imaginable [35]. They also completed an SF36 (version 1) [36–38], a Roland–Morris disability questionnaire [39], and the Patient-Specified Functional Outcome instrument [40–42]. This latter instrument asks patients to specify four activities of daily living that are limited by their pain and which they would most dearly want restored. Patients also indicated what other health care they were using for their radicular pain and their work status for those of working age.

The segmental level to be treated was determined by the referring surgeon, based on the results of imaging. The nerve targeted for treatment was the one that was affected by the disc herniation as seen on CT or MRI. Typically, this meant the nerve that entered the intervertebral foramen of the segment below the affected disc. The protocol allowed for nerves to be targeted if a far lateral herniation affected the nerve at the same segment as the herniation, but no instances of this possibility were encountered. The physician responsible for the injection was entitled to question the referring surgeon’s suggestion as to which nerve should be targeted, but no instance of disagreement arose.

All treatments were performed in the same procedure room (at each site). At the primary site, various operators performed the injections, but the majority of patients were treated by either one of two operators. At the secondary site, all patients were treated by the same operator.

Irrespective of the nature of the injection eventually performed, all patients lay on a fluoroscopy procedure table, most in a prone position, but some in a lateral position when they could not assume a prone position. The skin of the back was prepared as for an aseptic procedure. Based on the pre-procedural imaging, the operator identified the target level on a postero-anterior fluoroscopy view of the lumbar spine. The view of the target level was “squared off” (i.e., the X-ray beam passed parallel to the vertebral endplates of the target level).

Initially, a randomization code was consulted, which instructed the operator as to which route to use. If the code called for intramuscular injection, the needle was placed into the erector spinae opposite the interval between the transverse processes of the target level. Intramuscular placement was verified by injecting a small volume (0.2–0.5 mL) of contrast medium (Figure 1). If the code called for transforaminal injection, the needle was placed in the intervertebral foramen of the target level, according to the practice guidelines of the International Spine Intervention Society [24]. Whenever possible, the needle was placed on the back of the vertebral body

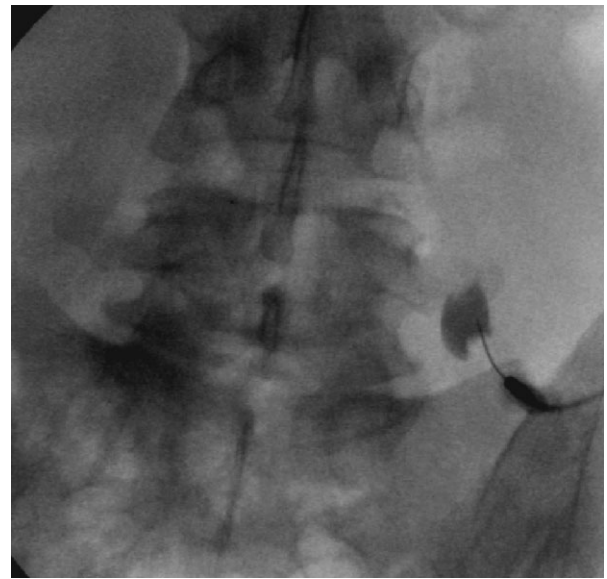


Figure 1 A postero-anterior fluoroscopy image of an injection of contrast medium prior to intramuscular injection of steroids or normal saline.

immediately below the pedicle. When the spinal nerve prevented access to this target point, the needle was placed behind or above the spinal nerve. Correct placement was verified by the injection of a test dose of contrast medium. The contrast medium had to outline the course of the target nerve and simultaneously show no vascular uptake of the injectate (Figure 2).

Once the needle had been placed, a second randomization code was consulted, which instructed the operator as to which agent to administer. This measure was adopted in order to ensure that operators correctly and accurately placed needles without bias, before and without knowing the agent to be used.

The randomization schedule was based on a series of random numbers, allocated sequentially to patients as they enrolled. A research nurse was the only member of the team who had knowledge of the randomization schedule. So that no subliminal cues might be transmitted to the patients during treatment, instructions from the nurse to the operator, about which route to use and which agent to use, were communicated by disclosing printed cards that carried the information, out of sight of the patient. As far as possible, all procedures were performed at a similar pace, with due attention being paid to accurate placement of the needle, recording the placement on postero-anterior and lateral fluoroscopy views, and gentle administration of the allocated agent.

For each injection, a standard volume and dose were used for each patient. For patients allocated to receive transforaminal injection of steroids, 0.75 mL of 0.5% bupivacaine

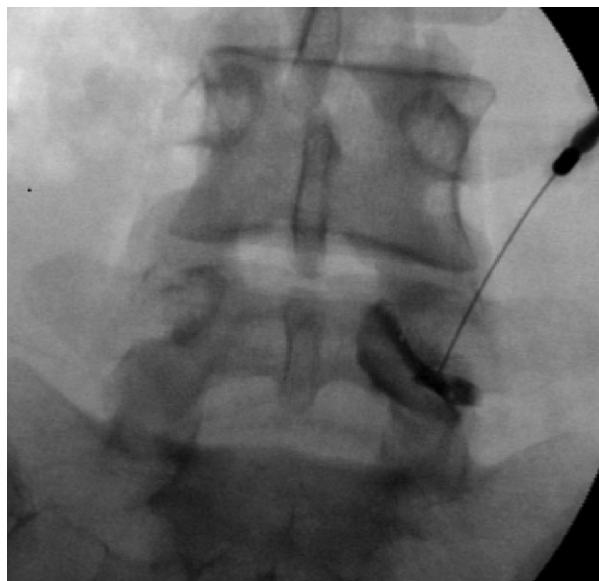


Figure 2 A postero-anterior fluoroscopy image of an injection of contrast medium prior to transforaminal injection of steroids, local anesthetic, or normal saline.

was injected followed by 1.75 mL of triamcinolone in a concentration of 40 mg/mL. (Bupivacaine was injected for two reasons. First, it is common practice for operators to administer both a local anesthetic and a steroid, and we sought to mimic common practice. Second, the preliminary injection serves as a putative safety measure to avoid spinal cord infarction when particulate steroids are to follow.) For patients allocated to receive transforaminal local anesthetic, the operator injected 2 mL of 0.5% bupivacaine. For patients randomized to receive normal saline, the operator injected 2 mL of the agent. Those patients allocated to intramuscular steroids received 1.75 mL of triamcinolone (40 mg/mL). Patients randomized to receive intramuscular normal saline received a volume of 2 mL.

The senior author or a research nurse, neither of whom was involved in the conduct of the treatment, conducted the follow-up assessment. Both were blind to the treatment administered.

Patients were checked on the day following the procedure and at 1 week, for any adverse effects. If patients felt that they had benefited from their treatment, they were invited and encouraged to continue with formal follow-up. If patients felt that they had partial benefit, they were invited to have a repeat of their allocated treatment, in order (ostensibly) to boost the response. In this regard, patients were entitled to have up to three injections of their allocated agent by their allocated route, if they wanted. Repeat injection was at the discretion of the patient. No patient was subjected to routine repetitions, or a prescribed "series" of injections. If patients felt they had not

benefited from their allocated treatment and felt that they wanted further treatment for their pain, once they had registered their response and had completed the outcome instruments, they were entitled to pursue rescue therapy. According to the preference of the patient, this could be analgesics, surgery, or open-label transforaminal injection of steroids.

Patients who felt that they had benefited from their allocated treatment commenced formal follow-up at 1 month after treatment. At this time, the outcome instruments were administered. Patients with continuing relief were assessed at 3, 6, and 12 months, or until relief of pain ceased. If relief ceased, at any time after 1 month, patients were entitled either to have a repeat of their allocated agent or to avail themselves of rescue treatment. Patients were not followed if, and once, they registered their failure with the allocated treatment or rescue treatment. All patients who reported a successful outcome were followed until relief ceased.

The primary outcome measure was the proportion of patients, who underwent each treatment, who obtained complete relief or at least 50% relief of pain for at least 1 month after treatment. The secondary outcomes were scores on the SF36 and Roland–Morris instruments, use of other health care, and improvements in activities of daily living as measured by the Patient-Specified Functional Outcomes Scale. Subsequent outcome measures were the duration of relief in those patients who obtained relief, or the proportion of patients who required rescue treatment or surgery.

The proportions of patients from each treatment group were compared using 95% confidence intervals of a proportion. For proportions to be considered significantly different statistically, their 95% confidence limits must not overlap. Group data on baseline features and outcomes were also collected. Nonparametric tests were applied when the data obtained were not normally distributed. Median values and interquartile ranges were calculated. For comparisons between groups, a Mann–Whitney test was used. For comparisons within groups, a paired *t*-test was used.

Although data were collected and calculated for all subscales of the SF36, only those for physical functioning, social functioning, bodily pain, general health, and mental health are reported below. The scales for vitality, role personal, and role emotional showed no meaningful change and did not contribute to establishing outcome.

For the Patient-Specified Functional Outcome Scale, patients were asked to report, for each of their four nominated activities, if they could perform them not at all, a bit, a lot, or fully. These grades were allocated a score of 0, 1, 2, and 3, respectively. These scores were totaled to yield a composite value, such that 0 indicated no restoration of activities, and 12 indicated completed restoration of all activities.

For use of other health care, treatments were classified into four classes: opioids, analgesics and nonsteroidal anti-inflammatory drugs, physical therapy, or nil. Agents classified as analgesics included paracetamol, compound analgesics, and tramadol. Physical therapy encompassed exercises and massage. If patients used opioids together with analgesics, they were regarded as using opioids. The numbers of patients using various treatments before and after treatment were tabulated and compared graphically.

The study initially targeted a sample size of 50 in each group, which would have been sufficient to distinguish proportions such as 0.20 from 0.48, or 0.30 from 0.60, or 0.40 from 0.70, should these proportions arise. However, the ethics approval also allowed for an interim analysis, under blinded conditions, when the number of patients in each group was about 30. This provision was applied in order not to have an unnecessary number of patients to continue to undergo treatments that could be shown, with statistical confidence, not to be sufficiently effective.

Results

A total of 150 patients were enrolled. Prior to registering their response to treatment, no patient was lost to follow-up. In accordance with the ethics provisions, patients were not required to participate in follow-up once they had registered failure to respond to either their allocated treatment or to rescue treatment. All patients who had a successful outcome, however, completed follow-up until their relief lapsed.

After randomization, the five treatment groups showed no statistically significant differences in demographic features such as age, gender balance, segmental levels treated, or the proportion of acute or chronic cases (Table 1). Certain differences arose in the duration of complaints in some groups. Patients randomized to intramuscular steroids had a significantly shorter duration of acute pain than did patients allocated to transforaminal normal saline ($P = 0.04$) or intramuscular saline ($P = 0.01$) (although not those allocated to transforaminal local anesthetic or transforaminal injection of steroids), and a significantly shorter

Table 1 Baseline demographic and clinical features of patients with lumbar radicular pain randomized to treatment by transforaminal injection of steroids (TFST), transforaminal injection of normal saline (TFNS), transforaminal injection of local anesthetic (TFLA), intramuscular injection of steroids (IMST), or intramuscular injection of normal saline (IMNS)

Feature	Treatment Group					P
	TFST	TFNS	TFLA	IMST	IMNS	
Male	17	19	17	15	21	0.567
Female	11	18	10	13	9	
Age						0.379
Median	49	44	43	49	46	
IQR	39–61	33–54	35–66	38–62	37–64	
Acute	19	21	13	12	15	0.379
Chronic	9	16	14	16	15	
Duration (weeks)						0.498
Acute						
Median	6	6	4	3	8	
IQR	2–12	4–8	1–8	1–6	4–12	
Chronic						
Median	96	42	48	32	72	
IQR	42–560	24–138	23–120	24–48	24–96	
Affected segment						0.498
L2	0	1	0	0	0	
L3	0	1	2	0	1	
L4	3	2	3	7	2	
L5	13	15	10	9	15	
S1	10	16	12	10	10	
L3 and L5	0	0	0	0	1	
L4 and L5	1	2	0	2	0	
L5 and S1	1	0	0	0	0	

IQR = interquartile range.

Table 2 Baseline scores for leg pain, disability, and quality of life of patients with lumbar radicular pain randomized to treatment by transforaminal injection of steroids (TFST), transforaminal injection of normal saline (TFNS), transforaminal injection of local anesthetic (TFLA), intramuscular injection of steroids (IMST), or intramuscular injection of normal saline (IMNS)

Feature	Treatment Group					<i>P</i>
	TFST	TFNS	TFLA	IMST	IMNS	
N	28	37	27	30	28	
Leg pain (0–10)						
Median	7	7	7	7	8	0.094–0.870
IQR	5–8	5–8	6–10	6–8	6–9	
SF36						
PF						
Median	20	20	35	20	30	0.062–0.987
IQR	6–39	10–35	15–45	10–43	24–46	
SF						
Median	38	38	25	30	38	0.188–0.926
IQR	25–50	19–50	25–63	25–63	25–60	
BP						
Median	22	22	21	22	22	0.287–0.960
IQR	10–29	12–31	10–31	12–32	12–32	
GH						
Median	52	60	72	47	57	0.114–0.844
IQR	40–65	41–67	42–77	36–77	44–83	
VIT						
Median	28	35	35	40	35	0.08–0.827
IQR	16–40	12–43	20–65	16–49	23–45	
MH						
Median	50	52	48	58	50	0.196–0.949
IQR	40–75	32–68	36–84	45–79	36–73	
Roland–Morris (0–24)						
Median	17	17	19	17	15	0.028–0.942
IQR	11–20	13–20	14–21	13–21	11–18	

Where a range of *P* values are shown, they pertain to the various permutations of comparisons between groups.

IQR = interquartile range; PF = physical functioning; SF = social functioning; BP = bodily pain; GH = general health; VIT = vitality; MH = mental health.

duration of chronic pain than patients allocated to transforaminal steroids ($P = 0.01$) (but not any other group).

Prior to treatment, the five groups had similar scores for pain and disability (Table 2). The patients had moderate to severe levels of pain. On the SF36, they were seriously impaired in physical functioning and social functioning, had reduced vitality, but were in reasonable general health and mental health. The Roland–Morris instrument indicated moderate levels of disability. On this latter instrument, the patients allocated to intramuscular normal saline were slightly but significantly less impaired than those allocated to transforaminal local anesthetic, but there were no statistically significant differences between any other pairs of groups.

After treatment, no complications occurred that could be attributed to the treatment. One patient developed

bladder incontinence, for 1 week, after a transforaminal injection of local anesthetic, but it was not evident that the complication was attributable to the injection, rather than worsening of her disc herniation.

The worst outcomes were reported by the patients treated with transforaminal local anesthetic. Only two patients in the group reported at least 50% relief of pain at 1 month after treatment. Both had complete relief of pain. These patients reported substantial, concurrent improvements in physical functioning, social functioning, and bodily pain, but although these improvements were large in absolute magnitude, statistical significance was not reached because of the small sample size, other than for disability on the Roland–Morris instrument (Table 3). The remaining patients (25) had no improvements in pain, and no changes of clinical or statistical significance in disability, general health, or mental health (Table 3).

Table 3 Outcome measures of patients, with unsuccessful and successful outcomes, at inception and 1 month after treatment with transforaminal injection of local anesthetic for lumbar radicular pain

Transforaminal Local Anesthetic

Outcome Measure	Outcome Category		P
	Unsuccessful (N = 25)	Successful (N = 2)	
Leg pain			
Inception, median (IQR)	7 (6–10)	8	0.938
1 month, median (IQR)	8 (6–9)	0	*
P	0.731	0.126	
SF36			
Physical functioning (0–100)			
Inception, median (IQR)	35 (15–45)	35 [15,55]	0.746
1 month, median (IQR)	35 (15–45)	63 [60,65]	0.058
P	0.668	0.361	
Social functioning (0–100)			
Inception, median (IQR)	25 (19–63)	75 [75,75]	*
1 month, median (IQR)	25 (19–57)	95 [88,100]	0.064
P	0.435	0.195	
Bodily pain (0–100)			
Inception, median (IQR)	12 (10–31)	32 [22,41]	0.211
1 month, median (IQR)	22 (10–31)	63 [41,84]	0.047
P	0.369	0.235	
General health (0–100)			
Inception, median (IQR)	72 (41–77)	71 [67,75]	0.926
1 month, median (IQR)	65 (41–79)	75 [72,77]	0.517
P	0.436	0.686	
Mental health (0–100)			
Inception, median (IQR)	48 (36–80)	70 [48,92]	0.309
1 month, median (IQR)	52 (38–80)	72 [48,96]	0.331
P	0.389	0.500	
Roland–Morris (0–24)			
Inception, median (IQR)	19 (15–21)	16 [10,21]	0.746
1 month, median (IQR)	18 (14–21)	8 [2,14]	0.105
P	0.142	0.042	

*P value not calculable because the scores of the two patients were the same.

IQR = interquartile range.

P values within the columns pertain to comparisons within groups, using a paired t-test. P values along the rows pertain to comparisons between groups, using a Mann–Whitney test.

Values in square brackets are the actual scores of the two patients in the sample.

Outcomes were little better in the group treated with intramuscular saline. Four patients achieved at least 50% relief of pain. Two had complete relief and two had 80% relief. These patients expressed large improvements in function and disability, but the small sample size precluded statistical significance in all measures except physical functioning (Table 4). Nevertheless, in all measures, the scores for these patients after treatment were significantly better, both clinically and statistically, than those of the patients who did not respond, for leg pain, physical functioning, social functioning, bodily pain, mental health, and disability (Table 4). The patients who did not respond (26) showed

no significant changes in any outcome measure; they remained in pain and disabled.

Somewhat better outcomes occurred in the group treated with intramuscular steroids. In this group, six patients achieved at least 50% relief of pain. Three obtained complete relief, and three obtained between 60% and 75% relief. Their scores for physical functioning, social functioning, bodily pain, and disability improved substantially and significantly, but their scores for general health and mental health did not alter significantly (Table 5). In these same measures, the outcomes of these patients were

Table 4 Outcome measures of patients, with unsuccessful and successful outcomes, at inception and 1 month after treatment with intramuscular injection of normal saline for lumbar radicular pain

Intramuscular Normal Saline

Outcome Measure	Outcome Category		<i>P</i>
	Unsuccessful (N = 26)	Successful (N = 4)	
Leg pain			
Inception, median (IQR)	7 (6–8)	6 (6–8)	0.626
1 month, median (IQR)	7 (5–8)	1 (0–3)	0.002
<i>P</i>	0.073	0.022	
SF36			
Physical functioning (0–100)			
Inception, median (IQR)	30 (19–47)	43 (29–85)	0.259
1 month, median (IQR)	30 (19–53)	85 (66–89)	0.004
<i>P</i>	0.635	0.004	
Social functioning (0–100)			
Inception, median (IQR)	38 (22–63)	63 (39–96)	0.161
1 month, median (IQR)	50 (25–63)	88 (75–100)	0.010
<i>P</i>	0.026	0.090	
Bodily pain (0–100)			
Inception, median (IQR)	22 (12–24)	31 (17–52)	0.190
1 month, median (IQR)	22 (12–41)	73 (65–74)	0.002
<i>P</i>	0.132	0.009	
General health (0–100)			
Inception, median (IQR)	57 (44–78)	70 (45–96)	0.464
1 month, median (IQR)	64 (48–83)	75 (64–88)	0.272
<i>P</i>	0.085	0.600	
Mental health (0–100)			
Inception, median (IQR)	48 (36–73)	60 (37–80)	0.692
1 month, median (IQR)	56 (36–77)	90 (85–95)	0.007
<i>P</i>	0.304	0.058	
Roland–Morris (0–24)			
Inception, median (IQR)	16 (11–19)	10 (3–16)	0.161
1 month, median (IQR)	15 (11–19)	5 (0–12)	0.026
<i>P</i>	0.373	0.926	

P values within the columns pertain to comparisons within groups, using a paired *t*-test. *P* values along the rows pertain to comparisons between groups, using a Mann–Whitney test.

IQR = interquartile range.

significantly better than those of the patients who did not obtain relief of pain. The scores for these latter patients (22) remained unchanged for all outcome measures (Table 5).

Similar outcomes were achieved in the group treated with transforaminal injection of normal saline. In this group, seven patients achieved at least 50% relief of pain (Table 6). Three obtained complete relief; two obtained between 60% and 100% relief; and two obtained 50% relief. They improved their scores substantially and significantly in physical functioning, bodily pain, general health, and disability; their substantial improvements in social functioning and mental, almost reached statistical significance. In all measures, their outcomes were significantly

better than those of patients who did not respond (Table 6). The latter patients (30) did not improve significantly in any outcome measure.

The most successful outcomes were achieved in the group treated with transforaminal injections of steroids (Table 7). In this group, 15 patients achieved at least 50% relief of pain. Three achieved 50% relief; nine achieved between 60% and 100% relief; and three achieved complete relief. These patients substantially and significantly improved their scores on all other measures (Table 7); and on all measures, their outcomes were significantly better than those of patients who did not respond. The latter patients (13) showed no improvements in any outcome measure (Table 7).

Table 5 Outcome measures of patients, with unsuccessful and successful outcomes, at inception and 1 month after treatment with intramuscular injection of steroids

Intramuscular Steroids

Outcome Measure	Outcome Category		P
	Unsuccessful (N = 22)	Successful (N = 6)	
Leg pain			
Inception, median (IQR)	8 (6–9)	8 (6–9)	0.823
1 month, median (IQR)	8 (6–10)	1 (0–2)	0.000
P	0.803	0.004	
SF36			
Physical functioning (0–100)			
Inception, median (IQR)	28 (10–85)	8 (0–46)	0.327
1 month, median (IQR)	30 (14–46)	60 (38–93)	0.014
P	0.039	0.003	
Social functioning (0–100)			
Inception, median (IQR)	38 (22–63)	32 (19–56)	0.933
1 month, median (IQR)	38 (25–63)	75 (56–100)	0.013
P	0.031	0.010	
Bodily pain (0–100)			
Inception, median (IQR)	22 (19–32)	16 (0–32)	0.327
1 month, median (IQR)	22 (21–34)	74 (50–88)	0.001
P	0.261	0.002	
General health (0–100)			
Inception, median (IQR)	46 (35–76)	62 (31–90)	0.557
1 month, median (IQR)	50 (35–76)	71 (44–82)	0.263
P	0.888	0.267	
Mental health (0–100)			
Inception, median (IQR)	62 (51–77)	40 (23–81)	0.300
1 month, median (IQR)	60 (48–77)	66 (56–79)	0.484
P	0.881	0.050	
Roland–Morris (0–24)			
Inception, median (IQR)	17 (14–21)	17 (10–20)	0.845
1 month, median (IQR)	16 (14–20)	5 (0–11)	0.012
P	0.102	0.036	

P values within the columns pertain to comparisons within groups, using a paired t-test. P values along the rows pertain to comparisons between groups, using a Mann–Whitney test. IQR = interquartile range.

Of those patients who reported relief of pain, nearly all did so after only one injection (irrespective of the route or agent used). Two patients in the intramuscular steroid group and one in the intramuscular normal saline group required a second injection within 1 month of the first, before registering success. Five of the 15 patients in the transforaminal injection of steroids group required two injections. No patient required more than two injections. Of the patients who reported unsuccessful outcomes, only two underwent two injections of the allocated agent (intramuscular normal saline); all others wanted only one injection.

Irrespective of the treatment undergone, nearly all patients who reported relief of pain also reported

substantial improvements in physical functioning, social functioning, and disability (Tables 3–7). They also reported substantial restoration of their desired activities of daily living (Table 8) and reduction of other health care (Figure 3). The magnitudes of improvements in desired activities were not significantly different between treatment groups. The patterns of reduction in other health care were similar. All patients who had been taking opioids ceased taking them; most patients who had been taking analgesics ceased to do so, although some persisted. Most patients required no other health care, while the remainder relied on only analgesics or simple physical therapy such as home exercises or occasional massage.

Table 6 Outcome measures of patients, with unsuccessful and successful outcomes, at inception and 1 month after treatment with transforaminal injection of normal saline

Transforaminal Normal Saline

Outcome Measure	Outcome Category		<i>P</i>
	Unsuccessful (N = 30)	Successful (N = 7)	
Leg pain			
Inception, median (IQR)	7 (5–8)	6 (4–8)	0.727
1 month, median (IQR)	7 (5–8)	1 (0–3)	0.001
<i>P</i>	0.354	0.003	
SF36			
Physical functioning (0–100)			
Inception, median (IQR)	20 (10–35)	30 (0–40)	0.587
1 month, median (IQR)	20 (10–35)	65 (45–70)	0.001
<i>P</i>	0.463	0.007	
Social functioning (0–100)			
Inception, median (IQR)	25 (22–38)	63 (17–63)	0.229
1 month, median (IQR)	38 (25–50)	88 (75–100)	0.001
<i>P</i>	0.203	0.051	
Bodily pain (0–100)			
Inception, median (IQR)	22 (12–31)	22 (0–41)	0.522
1 month, median (IQR)	22 (12–32)	61 (31–74)	0.001
<i>P</i>	0.104	0.020	
General health (0–100)			
Inception, median (IQR)	60 (40–67)	60 (42–72)	0.473
1 month, median (IQR)	61 (40–72)	82 (72–90)	0.002
<i>P</i>	0.201	0.019	
Mental health (0–100)			
Inception, median (IQR)	48 (31–68)	64 (32–80)	0.194
1 month, median (IQR)	48 (35–68)	84 (68–100)	0.003
<i>P</i>	0.775	0.056	
Roland–Morris (0–24)			
Inception, median (IQR)	17 (16–20)	12 (11–17)	0.081
1 month, median (IQR)	19 (16–20)	6 (2–7)	0.000
<i>P</i>	0.402	0.006	

P values within the columns pertain to comparisons within groups, using a paired *t*-test. *P* values along the rows pertain to comparisons between groups, using a Mann–Whitney test.

IQR = interquartile range.

Chronicity did not affect response to treatment. In each treatment group, the proportions of patients with acute or chronic radicular pain who responded did not differ statistically (Table 9).

Although the proportions of patients treated with transforaminal normal saline (19%), transforaminal local anesthetic (7%), intramuscular steroids (18%), or intramuscular normal saline (13%) who reported a successful outcome differed in absolute magnitude, their 95% confidence intervals overlapped and so were not significantly different from one another statistically (Figure 4). Based on a weighted mean average, the representative success rate across these four groups was 15% (8–22%).

In contrast, the proportion of patients who responded to transforaminal injection of steroids (54%) was larger and significantly greater than the proportion in any other group (Figure 4). This response rate was more than twice the rate for intramuscular steroids, and nearly three times the rate for transforaminal normal saline. In terms of initial yield, transforaminal injection of steroids was clearly more effective than any of the other injections.

Meanwhile, the response rate for intramuscular steroids was not significantly greater than that for intramuscular saline, nor did the response rate for transforaminal local anesthetic differ significantly from that for transforaminal normal saline.

Table 7 Outcome measures of patients, with unsuccessful and successful outcomes, at inception and 1 month after treatment with transforaminal injection of steroids

Transforaminal Steroids

Outcome Measure	Outcome Category		P
	Unsuccessful (N = 13)	Successful (N = 15)	
Leg pain			
Inception, median (IQR)	8 (7–8)	7 (5–8)	0.250
1 month, median (IQR)	7 (7–8)	2 (1–2)	0.000
P	0.165	0.000	
SF36			
Physical functioning (0–100)			
Inception, median (IQR)	15 (5–35)	20 (10–40)	0.549
1 month, median (IQR)	15 (5–42)	55 (40–65)	0.012
P	1.000	0.013	
Social functioning (0–100)			
Inception, median (IQR)	38 (13–44)	38 (38–50)	0.189
1 month, median (IQR)	38 (13–57)	88 (50–100)	0.001
P	0.188	0.000	
Bodily pain (0–100)			
Inception, median (IQR)	12 (0–22)	22 (12–31)	0.129
1 month, median (IQR)	21 (0–27)	62 (52–74)	0.000
P	0.692	0.000	
General health (0–100)			
Inception, median (IQR)	60 (41–71)	52 (40–62)	0.596
1 month, median (IQR)	60 (40–71)	62 (50–82)	0.420
P	1.000	0.027	
Mental health (0–100)			
Inception, median (IQR)	44 (28–68)	52 (40–80)	0.197
1 month, median (IQR)	40 (28–68)	84 (68–96)	0.001
P	0.240	0.002	
Roland–Morris (0–24)			
Inception, median (IQR)	17 (12–23)	17 (10–19)	0.565
1 month, median (IQR)	14 (10–23)	4 (0–9)	0.001
P	0.170	0.000	

P values within the columns pertain to comparisons within groups, using a paired t-test. P values along the rows pertain to comparisons between groups, using a Mann–Whitney test. IQR = interquartile range.

Not all patients maintained their response. Some relapsed after 1, 3, or 6 months, but thereafter, the remainder maintained relief of pain for 12 months, and some continued to have relief beyond a year, when last reviewed (Figure 5). Seven patients maintained their relief for 12 months after transforaminal injection of steroids; five did so after intramuscular steroids; two after transforaminal injection of normal saline, three after intramuscular saline, and one after transforaminal local anesthetic. The median durations of relief did not differ significantly between groups (Table 10). The greater number of patients with short durations of relief in the transforaminal injection of steroids group was balanced by the greater number of patients with durations exceeding 12 months.

Among the patients who obtained no relief from their initial treatment, similar numbers in each treatment group elected to undergo rescue treatment with transforaminal injection of steroids (Table 11). Four patients who had undergone transforaminal injection of steroids remained blinded as to their treatment and, after registering their lack of response, elected to have rescue treatment with transforaminal injection of steroids. The success rates of rescue treatment were similar in each group and statistically compatible with the success rate of transforaminal injection of steroids in the blinded phase of the study (Table 11).

Similar numbers in each treatment group elected to undergo surgery either when they did not benefit from their initial treatment or from rescue treatment (Table 12).

Table 8 The quantitative improvements in restoration of Patient-Specified Functional Outcomes (activities of daily living) of patients with lumbar radicular pain who were treated with transforaminal injection of steroids (TFST), transforaminal injection of normal saline (TFNS), transforaminal injection of local anesthetic (TFLA), intramuscular injection of steroids (IMST), or intramuscular injection of normal saline (IMNS)

Patient-Specified Functional Outcome Score	Treatment Group				
	TFST (n = 15)	TFNS (n = 7)	TFLA (n = 2)	IMNS (n = 4)	IMST (n = 6)
Median	8	6	6	10	10
IQR	6–9	2–12	[4,9]	6–12	6–12
Between-group <i>P</i> value, Mann–Whitney test	0.502				
	0.937				
	0.367				
	0.433				
		0.884			
		0.299			
		0.317			
			0.488		
			0.505		
				0.831	

Minimum possible improvement: 0. Maximum possible improvement: 12.
IQR = interquartile range.

The proportions of patients who eventually elected to have surgery (and, reciprocally, the proportions who avoided surgery) were similar in each group (Table 12). Of the 18 patients who avoided surgery after treatment with transforaminal injection of steroids, 9 (50%) did so because they benefited from their injection. In the other groups, between 5% and 23% avoided surgery because of their response to their initial treatment, and a further 26% to 36% did so because of their response to rescue treatment with transforaminal injection of steroids. The remaining patients relied on analgesics or coped by means undisclosed to the study (Table 12).

Discussion

Several previous studies of transforaminal injection of steroids have reported no demonstrable superiority over control injections, such as transforaminal injection of local anesthetic alone [29–32]. However, to assess their outcomes, these studies followed the convention of reporting and comparing mean values of scores for pain and other outcomes. Doing so can be a disservice to an otherwise valuable treatment.

When evaluated using mean values of a group response, treatments emerge as significantly more effective only if all patients consistently benefit to some degree, or if a substantial majority of patients benefit to at least a moderate degree. However, group data can camouflage good responses when they occur in a subgroup of patients. The poor outcomes of the other patients statistically cancel the good responses of the subgroup.

Indeed, if the data of the present study are subjected to analysis of group means, transforaminal injection of steroids emerges as significantly more effective than transforaminal injection of local anesthetic, intramuscular normal saline, and intramuscular steroids but fails to be more effective than transforaminal normal saline (Table 13). Such an analysis, however, is not appropriate, for the data are not normally distributed, and the distributions of outcomes differ in the different treatment groups.

As shown in Figure 6, few patients who had intramuscular saline or transforaminal local anesthetic achieved low pain scores, and the scores of patients who had intramuscular steroids or transforaminal normal saline are widely distributed across the possible range of values. In contrast, the distribution of scores of patients who had transforaminal steroids is distinctly bimodal: half the patients either responded or they did not. Moreover, the calculated mean score for the transforaminal steroid group (4.1) is represented by no patient and is representative of no patient.

Significant differences in favor of transforaminal injection of steroids do emerge when the data are subjected to categorical analysis, namely success rates. In the present study, success was defined by at least 50% reduction of pain, corroborated by improvements in function, reduction in disability, restoration of patient-specified activities, and reduction in use of other health care. A criterion of 50% reduction of pain was selected because this magnitude has been established as the change that patients regard as equating to “much improved” for pain in general [35], and which is the minimal clinical important change for radicular

Transforaminal Steroids

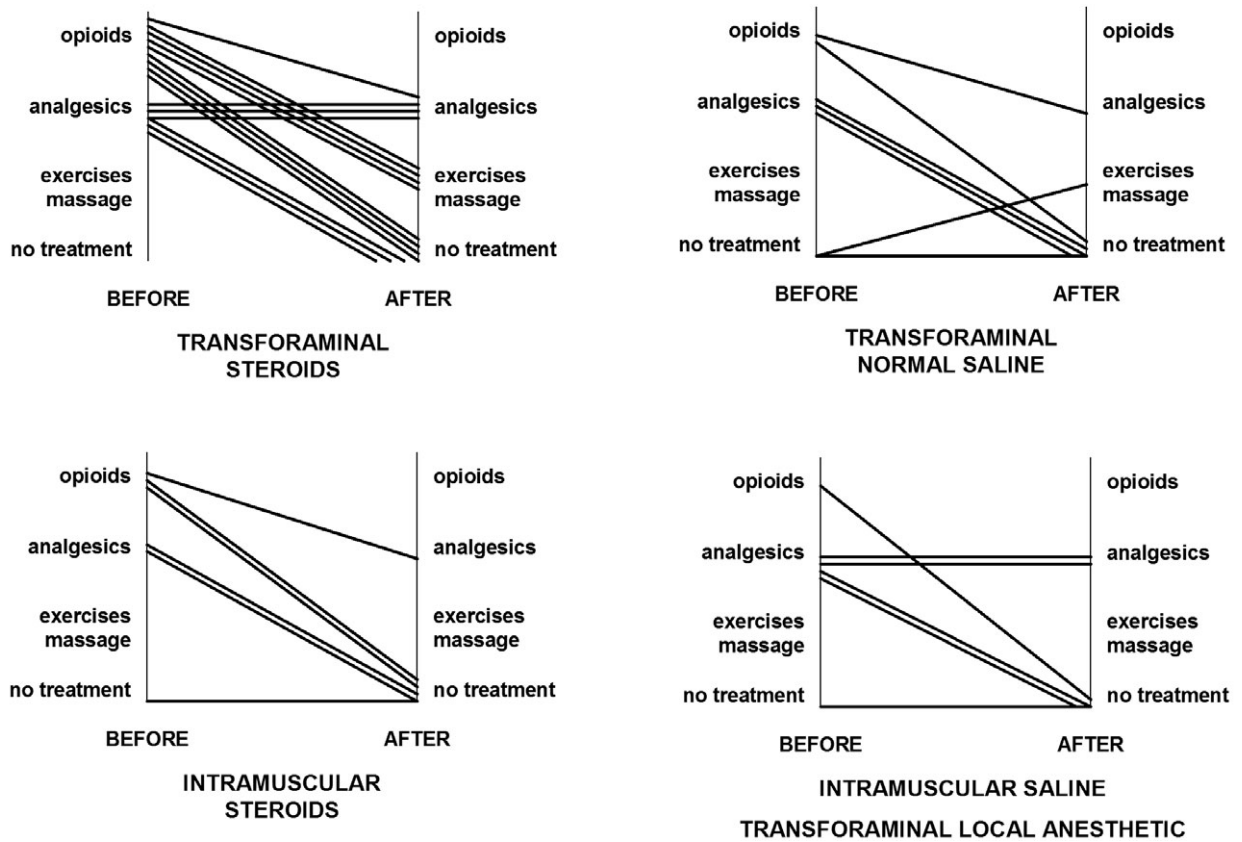


Figure 3 A graphic representation of the change in use of other health care from before to after treatment by patients with lumbar radicular pain who had greater than 50% relief of pain after treatment with transforaminal injection of steroids, transforaminal injection of normal saline, intramuscular injection of steroids, intramuscular injection of steroids or transforaminal injection of local anesthetic. Each line depicts the progress of an individual patient.

pain in particular [43]. As well, the simultaneous improvements in all secondary outcomes were not just statistically significant but substantial and were shared by nearly all patients. There were only three exceptions to this simulta-

neity: one patient whose back pain impaired improvements in function and other measures, one with rheumatoid arthritis, and one with multiple comorbidities, all of whom nevertheless reported major reductions in their radicular pain.

Table 9 The proportions and 95% confidence intervals of patients with acute or chronic lumbar radicular pain who responded to treatment with intramuscular normal (IMNS), intramuscular steroids (IMST), transforaminal local anesthetic (TFLA), transforaminal normal saline (TFNS), or transforaminal steroids (TFST)

	Treatment Group				
	IMNS	IMST	TFLA	TFNS	TFST
Acute	0.07 0.00–0.20	0.25 0.00–0.50	0.00 0.00–0.21	0.24 0.06–0.30	0.47 0.25–0.69
Chronic	0.20 0.00–0.40	0.19 0.00–0.38	0.13 0.00–0.33	0.13 0.00–0.29	0.55 0.22–0.88

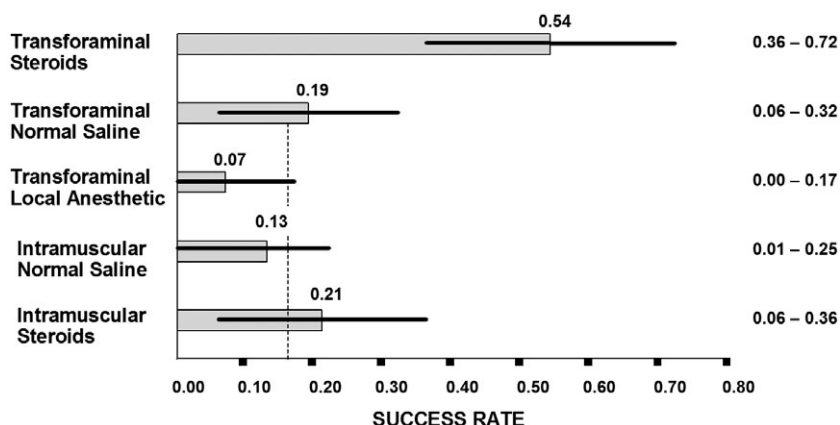


Figure 4 The proportions of patients (and 95% confidence intervals) who reported relief of lumbar radicular pain at 1 month after treatment with transforaminal injections of steroids or normal saline, or local anesthetic, or intramuscular injections of normal saline or steroids. The dotted vertical line is the representative average response rate of the latter four interventions, which stand in contrast to the success rate of transforaminal injection of steroids.

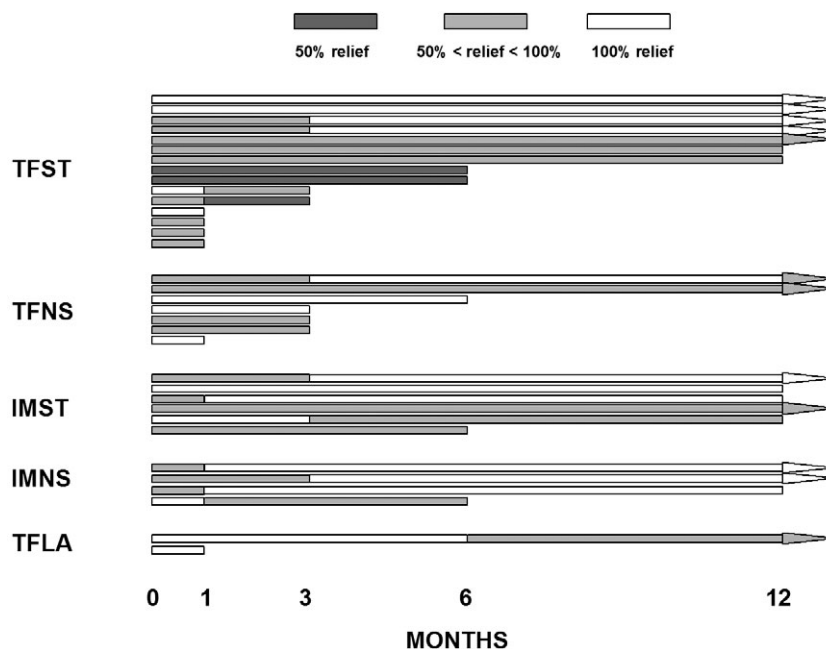


Figure 5 The duration and grade of relief of radicular pain following successful treatment with transforaminal injection of steroids (TFST), transforaminal injection of normal saline (TFNS), intramuscular injection of steroids (IMST), transforaminal injection of local anesthetic (TFLA), or intramuscular injection of normal saline (IMNS). Each horizontal bar represents an individual patient. White bars represent complete relief of pain; light gray bars represent greater than 50% relief but less than complete relief (typically between 60% and 80%); and dark gray bars represent 50% relief. Changes in color across a line represent improvement or deterioration of the relief over time. Arrows indicate that relief continued beyond 12 months.

Table 10 The median duration of relief of radicular pain in patients treated with lumbar radicular pain who were treated with transforaminal injection of steroids (TFST), transforaminal injection of normal saline (TFNS), transforaminal injection of local anesthetic (TFLA), intramuscular injection of steroids (IMST), or intramuscular injection of normal saline (IMNS)

Duration of Relief	Treatment Group				
	TFST (n = 15)	TFNS (n = 7)	TFLA (n = 2)	IMNS (n = 4)	IMST (n = 6)
Median (months)	6	6	7	12	12
IQR	1–12	3–12	[1,12]	8–12	11–12
Between-group <i>P</i> value, Mann–Whitney test	0.972				
	0.882				
	0.271				
	0.139				
		0.884			
		0.299			
		0.175			
			0.643		
			0.505		
				0.915	

Values in square brackets are the actual scores of the two patients.
IQR = interquartile range.

Table 11 An account of the response and subsequent progress, over 12 months after treatment, of patients with lumbar radicular pain treated with intramuscular normal saline (IMNS), intramuscular steroids (IMST), transforaminal local anesthetic (TFLA), transforaminal normal saline (TFNS), or transforaminal steroids (TFST)

Outcome	Original Treatment				
	IMNS (n = 30)	IMST (n = 28)	TFLA (n = 27)	TFNS (n = 37)	TFST (n = 28)
Relief	4	6	2	7	15
No relief	26	22	25	30	13
No rescue	2	1	2	4	3
Surgery	2	3	5	3	6
Rescue with TFST	22	18	18	23	4
Relief after rescue (proportion of rescue)	8 (0.36)	8 (0.44)	6 (0.33)	7 (0.30)	2 (0.50)
95% confidence intervals	0.16–0.56	0.21–0.67	0.11–0.55	0.11–0.49	0.01–0.99
No relief					
Surgery	7	5	5	6	0
No surgery	2	1	0	1	1
Withdrew	1	1	0	0	0
Died	0	1	0	1	0
Lost to follow-up	4	2	7	8	1
Surgery after initial relief lapsed	0	0	0	0	4

Patients who were lost to follow-up were on record as not having had surgery.

Table 12 An account of the surgery-sparing effects, at 12 months after treatment, of patients with lumbar radicular pain treated with intramuscular normal saline (IMNS), intramuscular steroids (IMST), transforaminal local anesthetic (TFLA), transforaminal normal saline (TFNS), or transforaminal steroids (TFST)

Outcome	Original Treatment				
	IMNS (n = 30)	IMST (n = 28)	TFLA (n = 27)	TFNS (n = 37)	TFST (n = 28)
Surgery (Proportion)	9 (0.30)	6 (0.21)	7 (0.26)	10 (0.27)	10 (0.36)
95% confidence intervals	0.14–0.46	0.06–0.36	0.10–0.43	0.13–0.41	0.18–0.54
No surgery	21	22	20	27	18
Rely on analgesics	2	6	6	9	8
Unknown	5	4	7	9	1
Response to initial treatment (Proportion)	4 (0.13)	5 (0.23)	1 (0.05)	2 (0.07)	
95% confidence intervals	0.01–0.24	0.05–0.41	0.00–0.15	0.00–0.17	
Response to TFST (Proportion)	8 (0.36)	8 (0.36)	6 (0.30)	7 (0.26)	9 (0.50)
95% confidence intervals	0.14–0.58	0.16–0.56	0.10–0.50	0.09–0.43	0.27–0.73

The table shows the means by which the patients who avoided surgery did so. Response to TFST encompasses response to rescue treatment and lasting response to initial treatment with TFST.

Table 13 The pain scores, before and 1 month after treatment, of patients with lumbar radicular pain who were treated with transforaminal injection of steroids (TFST), transforaminal injection of normal saline (TFNS), transforaminal injection of local anesthetic (TFLA), intramuscular injection of steroids (IMNS), or intramuscular injection of normal saline (IMNS)

Scores for Leg Pain (0–10)	Treatment Group				
	TFST (n = 28)	TFNS (n = 37)	TFLA (n = 27)	IMNS (n = 30)	IMST (n = 28)
Inception					
Mean	7.0	6.6	7.4	7.0	7.6
SD	1.7	2.2	2.1	1.5	2.0
At 1 month					
Mean	4.1	5.5	6.7	6.0	5.9
SD	3.0	2.6	2.8	2.5	3.4
Within-group <i>P</i> value of paired <i>t</i> -test	0.000	0.011	0.168	0.015	0.012
Between-group <i>P</i> value of two-sample <i>t</i> -test	0.071				
	0.002				
	0.015				
	0.043				
		0.070			
		0.423			
		0.549			
			0.279		
			0.340		
				0.962	

SD = standard deviation.

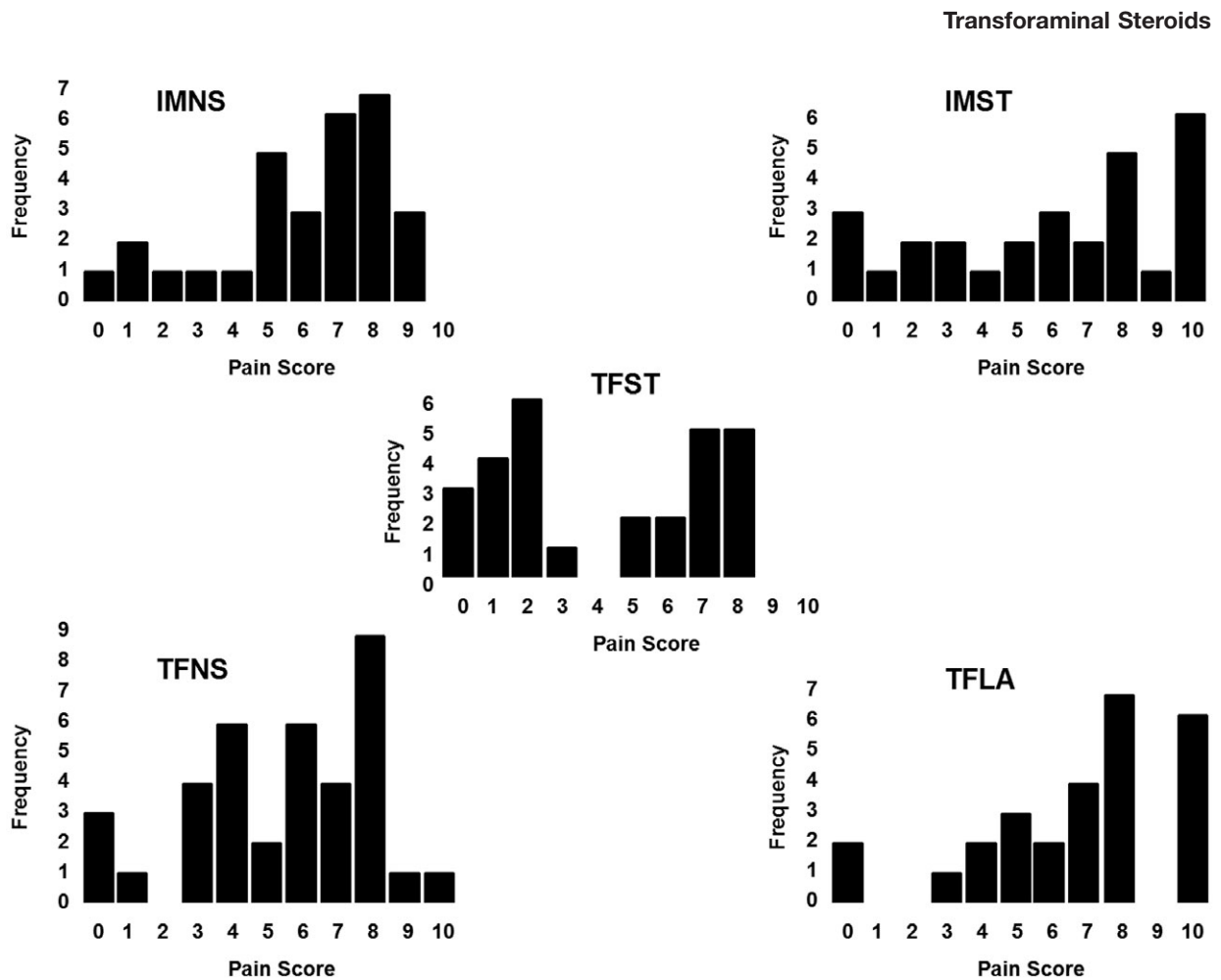


Figure 6 Histograms of the pain scores achieved by patients with lumbar radicular pain after treatment with transforaminal injection of steroids (TFST), transforaminal injection of normal saline (TFNS), transforaminal injection of local anesthetic (TFLA), intramuscular injection of steroids (IMST), or intramuscular injection of normal saline (IMNS).

Under those conditions, transforaminal injection of steroids was significantly more often successful than any of the other injections at providing relief of radicular pain—initially. However, it is not necessarily more successful at providing relief for 1 year.

A greater number and a greater proportion of patients treated with transforaminal steroids had long-term relief than did patients treated with intramuscular steroids or transforaminal normal saline (Figure 5). However, the proportions are not significantly different because of the small number of patients with sustained, long-term relief, and the relatively small sample sizes studied. This creates a conundrum concerning long-term success.

The proportion of patients with good long-term outcomes after transforaminal steroids was 7 of 28 (0.25), whereas that after transforaminal normal saline was 2 of 37 (0.05), and that after intramuscular steroids was 5 of 28 (0.18). To

prove beyond all reasonable doubt that 0.25 is greater than 0.05 would require a sample size of at 121 in each group. To prove that 0.25 is greater than 0.18 would require 550 in each group. Alternatively, to prove that intramuscular steroids are equivalent to transforaminal steroids would require over 2,000 in each group. These numbers are prohibitive.

Purists might call for such large studies to be conducted, and they might cite examples from cardiology where studies of such size have been conducted. However, lumbar radicular pain is not as dire a condition as coronary artery occlusion or other cardiovascular diseases. Its public health burden would neither warrant nor attract huge research expenditure.

The present data leave practitioners with some intriguing choices. Those interested in long-term outcomes only, might decide that intramuscular steroids are virtually as

effective as transforaminal steroids, but are less demanding technically; so, it might seem pragmatic to use intramuscular steroids in the first instance. However, two caveats apply. The data of the present study did not show superiority of intramuscular steroids over intramuscular normal saline. Nor has any other study. Only one study came close to showing superiority [17]. Moreover, the present study did not test the summary administration of intramuscular steroids at the bedside; it tested intramuscular steroids in the context of an elaborate procedure in a procedure room, using fluoroscopy. Bedside administration may not be as effective, as experienced in other studies [15–17].

Alternatively, practitioners might decide to adopt or continue with transforaminal steroids. The short-term yield of these injections is definitely greater than that of the other injections. That yield cannot be dismissed as simply due to an irrigation effect, systemic effect, or placebo effect. Using transforaminal injection of normal saline as the control, the number needed to treat (NNT; [44]) of transforaminal steroids is 3, which is a respectable value. Against intramuscular steroids, the NNT is just over 3.

However, more demanding practitioners might be more concerned about long-term outcomes. In that regard, the present data show that the yield of transforaminal steroids is small, but not negligible. Some 25% of patients treated experience satisfying relief for 12 months, together with restoration of function and activity, and reduction of other health care. For a 1 in 4 yield, transforaminal injection of steroids is patently cost-effective, whenever the cost of the alternative—surgery—is greater than four times the cost of an injection.

Furthermore, the data of the present study might understate the actual success rate of transforaminal injection of steroids. The data are internally consistent. The success rate in the randomized arm of the study was 54% (36–72%), and that in the rescue arm was between 25% and 50% (Table 11). In practice, this success rate could be greater if repeat injection was pursued more aggressively than it was in the present study. In that regard, it is notable that two of the four patients who had rescue treatment with transforaminal injection of steroids after initial failure of the same treatment nevertheless achieved relief from the second injection, with one lasting 21 months.

This proposition is not license to insist that every patient must routinely undergo two or more injection despite failing to respond to previous injections. Rather, it is a call for others to examine the possibility that a second, booster injection might increase the yield. The available literature hints that this occurs. The studies with negative results all used only one injection [29–32], whereas those with better results used up to three injections, with an average of about two [26–28,33].

Transforaminal injection of steroids can be hazardous [45–47], but only if carelessly performed. Guidelines for

the safe conduct of transforaminal injections have been published [24], emphasizing particularly the need to be vigilant for unintended, intra-arterial injection of particulate steroids.

Other studies have reported a surgery-sparing effect of transforaminal injection of steroids [25,27,28]. For that outcome measure, the present study was not as dramatically successful as these other studies. Nevertheless, it was evident that of the patients who avoided surgery after initial treatment with transforaminal steroids, some 50% did so because of the response to treatment, and some 30% or more of patients avoided surgery because of rescue treatment with transforaminal injection of steroids (Table 12). However, avoiding surgery is a capricious outcome measure. It can be affected by whether surgery is portrayed as an immediate, instant cure, or a hazardous undertaking. It can be affected by the availability of alternatives, or the nature of the population being treated. Many patients in the present study preferred to avoid surgery and relied on analgesics when injections failed to provide relief (Table 12).

In essence, transforaminal injection of steroids is a viable alternative to surgery for lumbar radicular pain due to disc herniation. Its immediate yield is modest, but substantial, and is not simply a placebo effect. For long-term efficacy, proof beyond reasonable doubt would require prohibitively large studies.

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References

- 1 Coxhead CE, Inskip H, Meade TW, North WRS, Troup JDG. Multicentre trial of physiotherapy in the management of sciatic symptoms. *Lancet* 1981;1:1065–8.
- 2 Pal B, Mangion P, Hossain MA, Diffey BL. A controlled trial of continuous lumbar traction in the treatment of back pain and sciatica. *Br J Rheumatol* 1986;25:181–3.
- 3 Weber H, Holme I, Amlie E. The natural course of acute sciatica with nerve root symptoms in a double-blind placebo-controlled trial evaluating the effect of piroxicam. *Spine* 1993;18:1433–8.
- 4 Matthews JA, Hickling J. Lumbar traction: A double-blind controlled study for sciatica. *Rheumatol Rehabil* 1975;14:222–5.

- 5 Weber H. Lumbar disc herniation: A controlled, prospective study with ten years of observation. *Spine* 1983;8:131–40.
- 6 Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus nonoperative treatment for lumbar disc herniation: Four-year results for the Spine Patient Research Trial (SPORT). *Spine* 2008;33:2789–800.
- 7 Merskey H, Bogduk N, eds. *Classification of Chronic Pain. Descriptions of Chronic Pain Syndromes and Definitions of Pain Terms*, 2nd edition. Seattle: IASP Press; 1994.
- 8 Olmarker 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.
- 9 Byröd G, Rydevik B, Nordborg C, Olmarker K. Early effects of nucleus pulposus application in spinal nerve root morphology and function. *Eur Spine J* 1998;7:445–9.
- 10 Olmarker K, Størkson R, Berge OG. Pathogenesis of sciatic pain: A study of spontaneous behaviour in rats exposed to experimental disc herniation. *Spine* 2002;27:1312–7.
- 11 Brisby H, Olmarker K, Larsson K, Nufu M, Rydevik B. Proinflammatory cytokines in cerebrospinal fluid and serum in patients with disc herniation and sciatica. *Eur Spine J* 2002;11:62–6.
- 12 Hou SX, Tang JG, Chen HS, Chen J. Chronic inflammation and compression of the dorsal root contribute to sciatica induced by the intervertebral disc herniation in rats. *Pain* 2003;105:255–64.
- 13 Murata Y, Onda A, Rydevik B, Takahashi K, Olmarker K. Distribution and appearance of tumor necrosis factor-alpha in the dorsal root ganglion exposed experimental disc herniation in rats. *Spine* 2004;29:2235–41.
- 14 Koboyashi S, Baba H, Uchida K, et al. Effect of mechanical compression on the lumbar nerve root: Localization and changes of intraradicular inflammatory cytokines, nitric oxide, and cyclooxygenase. *Spine* 2005;30:1699–705.
- 15 Naylor A, Flowers MW, Bramley JED. The value of dexamethasone in the postoperative treatment of lumbar disc prolapse. *Orthop Clin North Am* 1977;8:3–8.
- 16 Haimovic IC, Beresford HR. Dexamethasone is not superior to placebo for treating lumbosacral radicular pain. *Neurology* 1986;36:1593–4.
- 17 Friedman BW, Esses D, Solorzano C, et al. A randomized placebo-controlled trial of single-dose IM corticosteroid for radicular low back pain. *Spine* 2008;33:E624–9.
- 18 Manchikanti L, Singh V. Interventional pain management: Evolving issues for 2003. *Pain Physician* 2003;6:125–37.
- 19 Dilke TFW, Burry HC, Grahame R. Extradural corticosteroid injection in management of lumbar nerve root compression. *BMJ* 1973;2:635–7.
- 20 Carette S, LeClaire R, Marcoux S, et al. Epidural corticosteroids injections for sciatica due to herniated nucleus pulposus. *N Engl J Med* 1997;336:1634–40.
- 21 Valat JP, Giraudeau B, Rozenberg S, et al. Epidural corticosteroid injections for sciatica: A randomised, double blind, controlled clinical trial. *Ann Rheum Dis* 2003;62:639–43.
- 22 Breivik H, Hesla PE, Molnar I, Lind B. Treatment of chronic low back pain and sciatica. Comparison of caudal epidural injections of bupivacaine and methylprednisolone with bupivacaine followed by saline. In: Bonica JJ, Albe-Fessard D, eds. *Advances in Pain Research and Therapy*. Vol. 1. New York: Raven Press; 1976:927–32.
- 23 Bush K, Hillier S. A controlled study of caudal epidural injections of triamcinolone plus procaine for the management of intractable sciatica. *Spine* 1991;16:572–5.
- 24 International Spinal Intervention Society. Lumbar transforaminal injections. In: Bogduk N, ed. *Practice Guidelines for Spinal Diagnostic and Treatment Procedures*. San Francisco, CA: International Spinal Intervention Society; 2004:163–87.
- 25 Weiner BK, Fraser RD. Foraminal injection for lateral lumbar disc herniation. *J Bone Joint Surg* 1997;79B:804–7.
- 26 Lutz GE, Vad VB, Wisneski RJ. Fluoroscopic transforaminal lumbar epidural steroids: An outcome study. *Arch Phys Med Rehabil* 1998;79:1362–6.
- 27 Riew KD, Yin Y, Gilula L, et al. The effect of nerve-root injections on the need for operative treatment of lumbar radicular pain. A prospective, randomized, controlled, double-blind study. *J Bone Joint Surg* 2000;82A:1589–93.
- 28 Riew KD, Park JB, Cho YS, et al. Nerve root blocks in the treatment of lumbar radicular pain. A minimum five-year follow-up. *J Bone Joint Surg* 2006;88:1722–5.

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- 29 Karppinen J, Malmivaara A, Kurunlahti M, et al. Periradicular infiltration for sciatica. A randomized controlled trial. *Spine* 2001;26:1059–67.
- 30 Karppinen J, Ohinmaa A, Malmivaara A, et al. Cost-effectiveness of periradicular infiltration for sciatica. Subgroup analysis of a randomized controlled trial. *Spine* 2001;26:2587–95.
- 31 Ng L, Chaudhary N, Sell P. The efficacy of corticosteroids in periradicular infiltration for chronic radicular pain. *Spine* 2005;30:857–62.
- 32 Tafazal S, Ng L, Chaudhary N, Sell P. Corticosteroids in periradicular infiltration for radicular pain: A randomised double blind controlled trial. One year results and subgroup analysis. *Eur Spine J* 2009;18:1220–5.
- 33 Vad VB, Bhat AL, Lutz GE, Cammisa F. Transforaminal epidural steroid injections in lumbosacral radiculopathy. *Spine* 2002;27:11–6.
- 34 Thomas E, Cyteval C, Abiad L, et al. Efficacy of transforaminal versus interspinous corticosteroid injection in discal radiculalgia – a prospective, randomized, double-blind study. *Clin Rheumatol* 2003;22:299–304.
- 35 Farrar JT, Young JP, La Moreaux L, Werth JL, Poole M. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain* 2001;94:149–58.
- 36 Ware JE, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual framework and item selection. *Med Care* 1992;30:473–83.
- 37 McHorney CA, Ware JE, Rogers WH, Raczek AE, Lu JFR. The validity and relative precision of MOS Short- and Long-Form Health Status Scales and Dartmouth COOP charts: Results from Medical Outcomes Study. *Med Care* 1992;30:MS 253–65.
- 38 McHorney CA, Ware JE, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and Clinical tests of validity in measuring physical and mental health constructs. *Med Care* 1993;31:247–63.
- 39 Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine* 2000;25(24):3115–24.
- 40 Stratford P, Gill C, Westaway M, Binkley J. Assessing disability and change on individual patients: A report of a patient specific measure. *Physiother Can* 1995;47:258–63.
- 41 Westaway MN, Stratford PW, Binkley JM. The patient-specific functional scale: Validation of its use in persons with neck dysfunction. *J Orthop Sports Phys Ther* 1998;27:331–8.
- 42 Chatman AB, Hyams SP, Neel JM, et al. The patient-specific functional scale: Measurement properties in patients with knee dysfunction. *Phys Ther* 1997;77:82–829.
- 43 Giraudeau B, Rozenburg S, Valat S-P. Assessment of the clinically relevant change in pain for patients with sciatica. *Ann Rheum Dis* 2004;63:1180–1.
- 44 Cook RJ, Sackett DL. The number needed to treat: A clinically useful measure of treatment effect. *BMJ* 1995;310:452–4.
- 45 Bogduk N. Complications associated with transforaminal injections. In: Neal JM, Rathmell JP, eds. *Complications in Regional Anesthesia and Pain Medicine*. Philadelphia, PA: Saunders Elsevier; 2007:259–65.
- 46 Bogduk N, Dreyfuss P, Baker R, et al. Complications of spinal diagnostic and treatment procedures. *Pain Med* 2008;6:S11–34.
- 47 Kennedy DJ, Dreyfuss P, Aprill CN, Bogduk N. Paraplegia following image-guided transforaminal lumbar spine epidural steroid injection: Two case reports. *Pain Med* 2009;10:1389–94.