

Epidural steroid injection for nerve root compression

A RANDOMISED, CONTROLLED TRIAL

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We have assessed whether an epidural steroid injection is effective in the treatment of symptoms due to compression of a nerve root in the lumbar spine by carrying out a prospective, randomised, controlled trial in which patients received either an epidural steroid injection or an intramuscular injection of local anaesthetic and steroid. We assessed a total of 93 patients according to the Oxford pain chart and the Oswestry disability index and followed up for a minimum of two years. All the patients had been categorised as potential candidates for surgery.

There was a significant reduction in pain early on in those having an epidural steroid injection but no difference in the long term between the two groups. The rate of subsequent operation in the groups was similar.

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Epidural steroid injection is widely used for patients with nerve root pain, and some studies suggest that it has adequate efficacy in the short term at least. Few patients have been followed up for long periods after such treatment but some papers suggest that the longer the follow-up the less difference there is between patients in the treated and control groups.^{1,2} The incidence of subsequent surgery may be low,^{1,3,4} but there is controversy as to the ability of epidural steroid injection to reduce the need for operation in these patients.^{1,4,5} We were not convinced that the long-term outcome was significantly altered by this treatment and therefore undertook a study to investigate its effect on pain and the rates of operation in patients with significant symptoms of nerve root compression. Our hypothesis was that epidural steroid injection would lessen the pain at one month and if efficacious would reduce the need for surgery in the long term. We studied a group of patients who had been offered lumbar decompression because we believed that operation was a defined endpoint which could be measured unequivocally. If long-term pain relief could be achieved these patients would have a lower rate of operation than those in a control group.

Patients and Methods

All patients who attended a spine clinic between June 1996 and April 1999 with lumbosacral nerve root pain which had not resolved within a minimum of six weeks and

was of an intensity to warrant surgery were considered for the study. They were followed up for a minimum of two years after the epidural injection. All had MRI evidence of a disc prolapse, spinal stenosis or a combination of the two. Patients who were unable for any reason to be considered for surgery or for the epidural, those with a cauda equina syndrome or deteriorating neurological function requiring more urgent operation and those who did not wish to take part in the study were excluded.

In total 93 patients were entered into the trial. Only one patient who did not attend for a proposed operation was lost to follow-up. Two patients died during the period of the study.

Approval of the ethics committee was obtained and the patients and their General Practitioners received a letter outlining the trial and its purpose. Patients were also placed on the waiting list for surgery at the same time on the assumption that they might not see an improvement in their symptoms.

Patients who were offered the possibility of surgical treatment were randomly allocated to receive an epidural with local anaesthetic and steroid or an intramuscular injection of local anaesthetic and steroid. These procedures were performed in the Day Surgery Unit at the Nuffield Orthopaedic Centre by one of the authors (GB) in blocks of up to six. At each session, all patients had either the epidural or the intramuscular injection in order to prevent them comparing their response since numbness and weakness are associated with the epidural and

not the intramuscular injection. The patients were placed in the lateral position with the affected side dependent. After infiltration of the skin and subcutaneous tissues with 1% Lidocaine, a 16-gauge Touhy needle was inserted to make contact with the lamina of the vertebra below the affected nerve root. The needle was then either withdrawn a few millimetres and an intramuscular injection performed or redirected into the ligamentum flavum and advanced into the epidural space. All patients received Bupivacaine 0.5% 8 ml (40 mg) with Methylprednisolone 2 ml (80 mg). The patients recorded their pain intensity and pain relief following the injections daily for 35 days using the Oxford pain chart.²

The unit of randomisation was the individual patient, and allocation was made by opening sequentially numbered sealed envelopes. These had been filled by someone not involved in the care of the patients using a random number table. Concealment of allocation was maintained until the time of the injection.

We made considerable efforts to ensure masking of allocation from patients and doctors. Patients were not informed of their allocation. The injections were performed by an anaesthetist (GB) who was not otherwise involved in the care of the patients and their surgeon was unaware of their allocation until completion of the study.

The records made by the patients were collected at a follow-up clinic six weeks after injection when their response was assessed. Since we considered it unethical to withhold a potentially beneficial epidural steroid injection which might allow the patient to avoid surgery, we offered this procedure to all patients who had not been helped by the first injection. Patients who accepted this offer were given a single unmasked epidural steroid injection using the technique described above.

Patients were followed up for at least two years after the first injection. We recognised that the offer of a second injection to some patients would lead to cross-over from the control to the intervention group and therefore planned analysis of the proportion who had surgery both by allocation and by the treatment received. These analyses were of proportions using the chi-squared test.

The planning of the sample size was pragmatic. We estimated that about 100 patients could be recruited in two years and felt that this and two years of follow-up was as long as the study could reasonably be maintained. Those patients who still wished to have surgery underwent operation and were followed up thereafter.

Operative technique. In the patients with an isolated disc prolapse, operation was carried out through a unilateral laminotomy under general anaesthetic using microsurgical techniques, with decompression of the affected nerve root. In patients with spinal stenosis, the procedure was carried out either through bilateral laminotomies where there was lateral stenosis alone, or through a laminectomy where there was central stenosis. Radiographic control was always used to confirm the level and, where appropriate,

Table 1. Variables among patients in epidural and control groups

Variable*	Group	
	Epidural (n = 44)	Control (n = 48)
Mean age in yrs (range)	49.1 (26 to 76)	48.6 (23 to 79)
Manual or non-manual worker (%)	20 (45)	26 (54)
Diagnostic (%):		
Disc	23 (52)	19 (40)
Stenosis	18 (41)	14 (29)
Disc + stenosis	3 (7)	15 (31)
Levels (%):		
1	35 (80)	42 (87)
2	7 (16)	6 (13)
3	2 (4)	0 (0)
Oswestry score before treatment	43.5	39.5
Positive sciatic stretch test (%)	13 (29)	19 (39)
Weakness (%)	14 (32)	9 (19)
Numbness (%)	21 (47)	16 (33)
Previous treatment (%)	5 (12)	9 (19)
Second epidural (%)	7 (16)	9 (19)
Operation (%)	18 (41)	15 (31)

* no variable was considered significant

suction drainage was used. Patients were allowed to mobilise on the first day after operation and were discharged at two to seven days after. All patients who had surgery were followed up for a minimum of one year.

Results

In total 92 patients were included in the study of whom 44 were in the epidural group and 48 received intramuscular injections (control). There were 37 men and 55 women. Their mean age was 49 years (23 to 79); 46 were in manual work, 28 in non-manual and 18 had retired. The diagnosis was disc prolapse in 43, spinal stenosis in 32 and a combination of these in 17. One level was affected in 77 patients, two in 13 and three in two. On neurological assessment 23 patients (25%) had some motor weakness of MRC grade 3 or 4 and 37 patients (40%) had some dermatomal sensory disturbance. A positive sciatic stretch test was elicited in 29 (31%). The mean Oswestry score⁶ before treatment was 41.0. Sixteen patients (17%) had undergone previous invasive management for nerve root pain including an epidural, chemonucleolysis or surgery. Seven received epidural steroid injection and nine were in the control group.

A total of 79 patients (85%) returned their pain forms. At 35 days there were complete records of 36 patients in each group. There was a significant difference in pain relief between the two groups at 35 days with the epidural group being better ($p < 0.004$). This difference had become significant ten days after the injection.

A second epidural was given to 16 patients, seven in the epidural group and nine who had received an intramuscular injection of whom three eventually underwent surgery. A total of 33 patients (35%) had some form of operation with a discectomy, decompression or a combination of decompression and fusion depending on the underlying diagnosis.

Table II. Summary of the results of previous trials of epidural steroid injection for sciatica

Author/s	Number of patients	Diagnosis*	Random	Control steroid	Follow-up (mths)	Pain relief at 3 mths	Pain relief at 1 yr	Surgery†
Current study	92	Yes	Yes	Yes	>24	yes	no	no
Dilke et al ⁷	100	No	Yes	No	3	?§	?	n/a‡
Ridley et al ¹⁰	39	No	Yes	No	6	yes	?	n/a
Snoek et al ¹⁵	51	Yes	Yes	No	14	no	no	n/a
Cuckler et al ³	73	No	Yes	No	20	no	no	n/a
Bush and Hillier ¹	23	No	Yes	No	12	yes	no	n/a
Helliwell et al ¹⁴	39	No	Yes	No	3	yes	?	?
Carette et al ⁵	158	Yes	Yes	No	12	no	no	n/a

* accurate diagnosis by investigation e.g. myelogram/MRI

† reduction by ESI in need for surgery demonstrated in trial

‡ n/a = not assessed in study

§ ?, no information in study

Included in this group were four patients who had chemonucleolysis and one patient with decompression and spinal fusion for associated back pain. One patient was offered surgery in the form of decompression and fusion but fell into the control arm of another randomised study on spinal stabilisation, and was randomised to non-operative treatment.

When the two groups were compared there were no differences in the variables prior to treatment (Table I). In addition there were no significant differences in the outcome measurements between the two groups and in the rate of operations. More patients in the epidural group underwent surgery than in the control group, but this difference was not significant.

We were unable to find any difference in outcome between those with spinal stenosis and those with disc prolapse. This probably reflects the small numbers of patients in each group when treatment and control groups are compared.

The proportion who had surgery in the ESI group was not significantly different to that in the control group (41% vs 31%; $p = 0.45$; relative risk = 1.3; 95% confidence interval (CI) 0.76 to 2.27).

Of the 16 patients who underwent a second injection, including nine in the control group, only one subsequently had surgery. Taking into account this crossover, an 'as treated' analysis showed no significant difference in the proportion who had surgery among those who had at least one epidural steroid injection compared to those who did not (36% vs 36%; $p = 0.82$; relative risk = 1; 95% CI 0.57 to 1.74).

A *post-hoc* power calculation for the 'as allocated' analysis was performed. For the observed control rate of surgery, the sample size achieved and with the significance set at $p < 0.05$, the study had 60% power to demonstrate a halving of the rate of surgery.

Discussion

This study was carried out in a relatively large group of patients where an accurate diagnosis had been made with MRI prior to epidural injection. Patients with both disc prolapse and spinal stenosis were included in the study

which was carried out as a randomised, controlled trial with blinding of both the patients and the surgeon. Although most other studies have a group of patients who have gone on to have surgery, there has been considerable variation among them in terms of the severity of symptoms and in diagnostic accuracy. Our patients all had symptoms severe enough for both the patients and the surgeon to consider surgical intervention.

One of the strengths of this study is the randomisation of the patients. The only significant difference between the two groups was the diagnosis. There were more patients with both disc pathology and stenosis in the epidural steroid injection group. This occurred by chance, and we do not believe that it has affected the results in this study. The incidence of eventual operation in the two groups was of little difference.

Many studies show short-term improvement in nerve root pain after epidural steroid injection.^{1,4,5,7-13} Koes et al¹⁴ reviewed the results of the 12 randomised clinical trials, and assessed the methods employed by a score. Four had scores above 60% for method, and of these two reported positive outcomes and two negative. They concluded that the best studies showed inconsistent results and that the efficacy of epidural steroid injection had not been confirmed, but noted that there was a trend for short-term improvement in symptoms.¹⁴ The majority of randomised studies have demonstrated useful improvement in the level of pain in the first three months after epidural steroid injection^{1,3,5,8,11,15,16} (Table II). This has been our experience and in the first five weeks after epidural injection a useful improvement in nerve root symptoms was seen in our patients which was statistically significant. However in the longer term there was no useful improvement in symptoms when compared to the control group. More recently Carette et al⁵ were not able to demonstrate improvement at three months after epidural steroid injection, but no steroid was given in their control group. This study was confined to patients with disc prolapse and excluded those with spinal stenosis. Epidural steroid injection appears to offer no long-term benefit for patients with nerve root pain, but probably reduces pain in the first three months. It appears to be useful in patients in whom improvement is likely to occur

spontaneously; the epidural steroid injection may simply accelerate the rate of recovery.

Many studies have been criticised because the steroid injected by the epidural route is spread over a wide area and not directly around a single affected nerve root. Up to 30% of these injections can be misplaced.¹⁷ In our trial the epidural steroid was injected with local anaesthetic and all the patients experienced paraesthesiae, suggesting that the injection was indeed in the epidural space. It has been suggested that a nerve root block may be more effective in the management of sciatica. Karpainen et al¹⁸ demonstrated that either local steroid injection or saline injection around a nerve root would improve referred pain, but found that when a combination of steroid and local anaesthetic were used there was a rebound phenomenon after three to six months, with increasing deterioration of symptoms the longer the period between the injection and follow-up. A more recent prospective randomised study of this technique was carried out in a relatively small group of patients who were not blinded. This study demonstrated a significant improvement in pain following transforaminal steroid.¹⁹ The evidence is therefore contradictory. Many studies on the efficacy of epidural steroid injection have been carried out only in those with disc prolapse, which may have affected the outcomes. Both epidural steroid injection and transforaminal steroid injection are useful in the management of nerve root pain in the lumbar spine.

We found a surprisingly low rate of operation in both groups of patients, especially since all were being considered for surgical treatment. This may reflect the natural history of nerve root compression, where in the majority of patients symptoms will improve with time.^{1,3,4,8,10} Only 10% to 15% of patients with sciatica presenting to a specialist eventually require operation.²⁰ Because of the method of selection our patients probably had more severe symptoms than those in most studies. It is also possible that the steroid may have had some effect on the pain even when injected at a site remote from the nerve root. It has been shown that epidural steroid injection with local anaesthetic is better than injection of local anaesthetic alone²⁰ and thus the steroid does appear to be important in reducing pain in these patients. However, it is unlikely that steroid placed outside the spinal canal as a single injection would have any long-term effect. The other reason for the low take up of surgery may have been that many of the older patients did

not wish to undergo surgical treatment. A small number of patients refused to have surgery despite the failure to improve over the course of time because of the perceived risks.

We have shown that epidural steroid injection does not affect the ultimate need for surgery in this group of patients, but it is useful for reducing symptoms in the acute stages of nerve root compression.

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