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A multicentre randomized controlled trial of epidural corticosteroid injections for sciatica: the WEST study

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***Objective*. To determine the effectiveness and predictors of response to lumbar epidural corticosteroid injections (ESI) in patients with sciatica. We performed a 12-month, multicentre, double-blind, randomized, placebo-controlled, parallel-group trial in four secondary pain-care clinics in the Wessex Region.**

***Methods*. Two hundred and twenty-eight patients with a clinical diagnosis of unilateral sciatica of 1–18 months' duration were randomized to either three lumbar ESIs of triamcinolone acetonide or interligamentous saline injections at intervals of 3 weeks. The main outcome measure was the Oswestry low back pain disability questionnaire (ODQ).**

***Results*. At 3 weeks, the ESI group demonstrated a transient benefit over the placebo group (patients achieving a 75% improvement in ODQ, 12.5 *vs* 3.7%; number needed to treat, 11.4). No benefit was demonstrated from 6 to 52 weeks. ESIs did not improve physical function, hasten return to work or reduce the need for surgery. There was no benefit of repeated ESIs over single injection. No clinical predictors of response were found. At the end of the study the majority of patients still had significant pain and disability regardless of intervention.**

***Conclusions*. In this pragmatic study, ESIs offered transient benefit in symptoms at 3 weeks in patients with sciatica, but no sustained benefits in terms of pain, function or need for surgery. Sciatica is a chronic condition requiring a multidisciplinary approach. To fully investigate the value of ESIs, they need to be evaluated as part of a multidisciplinary approach.**

KEY WORDS: Sciatica, Epidural injection, Corticosteroids, Pain, Surgery.

Sciatica is defined as unilateral, well-localized leg pain which approximates to the dermatomal distribution of the sciatic nerve and normally radiates to the foot or toes. It is often associated with numbness or paraesthesia in the same distribution. It is a common condition that is associated with significant pain and disability. The lifetime prevalence is at least 5.3% in men and 3.7% in women, representing 6% of total work disability [1]. Sciatica has traditionally been regarded as a self-limiting condition with a good prognosis for complete recovery; however, 30% of patients still have significant symptoms at 1 yr, with 20% out of work and 5–15% requiring surgery [2, 3]. The cost of conservatively treated sciatica was estimated at £30 000 in a 1997 US study [4].

Sciatica was initially thought to occur predominantly as a result of a prolapsed lumbar vertebral disc causing compression of the nerve root, leading to neural ischaemia, oedema and eventually to chronic inflammation, scarring and perineural fibrosis. Similar symptoms can occur secondary to facetal osteoarthritis, leading to nerve root compression. It is now evident that sciatica can occur in the absence of direct nerve root compression, possibly as a result of the release of phospholipase A2 and other pro-inflammatory agents from a damaged disc, leading to nerve root inflammation and oedema [5]. Epidural corticosteroid injections (ESIs) are commonly used to treat sciatica, as the perceived wisdom is that the corticosteroid will reduce perineural inflammation and prevent perineural fibrosis and hence prevent chronic pain. ESIs are one of the commonest procedures performed in the UK, with 45 948 ESIs recorded in the National Health Service in 2002/2003 [6].

Although there have been a number of trials of ESI, firm conclusions are difficult to draw due to their relatively small size and heterogeneity of design. Some [7–11], but not all [12–16], trials have suggested that ESIs offer short-term benefit in terms of pain relief, but there is little evidence of long-term benefit [13, 14, 17]; others suggest further benefit by repeating epidurals [18, 19]. Few studies have looked for clinical predictors of patients likely to respond to ESIs, although several studies have suggested that the chronicity of the symptoms may be a factor in determining response to injection.

We have therefore performed a large, randomized, placebo-controlled clinical trial with long-term follow-up of patients to assess the effectiveness and predictors of response of lumbar ESIs in the management of patients with sciatica.

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Methods

Study design

The WEST (Wessex Epidural Steroids Trial) Study is a multicentre, double-blind, randomized, placebo-controlled, parallel-group trial of lumbar epidural injections of corticosteroid or interligamentous saline on a 1:1 basis. The study was conducted at four centres within the Wessex region. The ethics committees at each centre approved the protocol.

All eligible patients, aged 18–70 yr, presenting to orthopaedic, rheumatology and pain clinics at the participating hospitals with a clinical diagnosis of unilateral sciatica of between 4 weeks' and 18 months' duration were approached. Sciatica was defined as leg pain radiating below the knee, reduced straight leg raising, and a positive sciatic nerve stretch test. Exclusion criteria included spinal canal stenosis or previous lumbar spine surgery; ESIs; depression; bleeding diathesis; use of anticoagulants; and current litigation. All patients had received physiotherapy and analgesics for this episode of sciatica.

After written informed consent, patients were randomized, using sealed envelopes, by random number generation, balanced after every 10 assignments and stratified by centre and by duration of symptoms: acute (4 weeks to 4 months) or chronic (4–18 months). The active group received ESIs via the lumbar route of 80 mg triamcinolone acetonide and 10 ml of 0.25% bupivacaine at weeks 0, 3 and 6. The placebo group received injections of 2 ml of normal saline into the interspinous ligament. Injections at 3 and 6 weeks were omitted if the patient's score for the Oswestry Low Back Pain Disability Questionnaire (ODQ) [20] had improved by more than 75% from baseline. Anaesthetists experienced in the procedure, who were not involved in the patients' further assessments, performed all injections; the patient and assessor were blind to the procedure. At the 52-week visit or at the withdrawal visit, patients were asked which procedure they thought that they had received.

Follow-up

The patients were assessed at 0, 3, 6, 12, 26 and 52 weeks by a trained research nurse, who administered the questionnaires and performed a physical examination and physical performance tests (Fig. 1). The primary outcome measure was the ODQ [20], and the criterion of response was a reduction of 75% from baseline. The score ranges from 0 to 100, a score of over 40 representing severe disability [20]. Secondary outcome measures included: a 100 mm visual analogue scale (VAS) for leg and back pain; Likert scales measuring improvement in leg pain and back pain; the SF-36 questionnaire; days off work due to sciatica; return to work; surgery; and physical function (measured walk time, timed stair climb and chair stands).

If a patient's Oswestry score had not improved by 10% at 12 weeks or they experienced any significant neurological deterioration at any point, they were withdrawn from the study. This was for ethical reasons as it was felt that these patients could not be denied further treatments, which were precluded in the study design. These patients were included in all intention-to-treat statistical analyses even those following the 12 week visit, using the last observation carried forward technique. Patients were free to use analgesics and NSAIDs, and they completed a diary. All patients were approached to attend the 52-week visit to collect data on current symptoms in addition to data on any additional interventions performed.

Statistical analysis

Power calculations suggested that 240 patients would be needed, allowing for a dropout rate of 20%, to give 90% power to detect a difference of 7.25 points (<0.5 S.D.) on the ODQ at the 5% significance level. All analyses were performed using an intention-to-treat basis. Patients withdrawn from the study according to protocol or for other reasons or who were lost to follow-up were analysed using the technique of last observation carried forward. An analysis of secondary completers was also performed.

Continuous variables were analysed using regression models, entering baseline values as covariates and treatment as an explanatory variable. Binary outcome measures were analysed using the χ^2 test. To examine the treatment effect over time in a more complete manner, repeated measures analyses were also performed including the data from each visit simultaneously. To examine predictors of response to treatment, the groups were stratified according to possible predictors; the above tests were performed on each stratum and a formal interaction test was performed. All statistical analyses were performed using Stata Version 7.0 (Stata Corp. 2001, Stata Statistical Software, College Station, Texas, USA).

Results

Table 1 shows demographic data for the 228 recruited patients. The ESI and placebo groups were well matched for baseline clinical characteristics. Approximately one-third of the patients were acute and two-thirds chronic. Ninety-one (40%) patients had a previous episode of sciatica. Only 40% of those screened were accepted into the study. Questionnaires were completed at the 52-week visit by 208 patients (Fig. 1). Sixty patients achieved a 75% improvement in ODQ before week 6 and therefore did not receive three injections. There were no significant clinical differences between patients who achieved an early 75% improvement and those that did not. There was no difference between groups in the number of dropouts or protocol withdrawals. At the end of the study period, 55% of patients in the active group and 45% of the placebo group thought that they had received an epidural injection.

Effectiveness of the intervention

ESI produced a statistically significant improvement in self-reported function compared with placebo at 3 weeks [improvement in ODQ adjusted for baseline, 10.3 (14.8) *vs* 6.6 (15.6); $P = 0.017$] (Fig. 2). The number of patients achieving a 75% improvement in the ODQ, although small, was greater in the active group compared with the placebo group [15 (12.5%) *vs* 4 (3.7%); $P = 0.016$] (Fig. 2). ESIs did not produce a significant improvement in VAS leg pain, but did increase the number of patients reporting any improvement in leg pain using the Likert scale (61 *vs* 40%, $P < 0.01$). At 3 weeks, the number needed to treat to achieve a 75% improvement in the ODQ over and above the placebo injection was 11.4. If all of the improvement in the placebo group is assumed to be a placebo response, and not spontaneous improvement, the number needed to treat compared with standard medical care was reduced to 8.

By six weeks the benefit of ESI was lost (Fig. 2, Table 2). At all subsequent visits, there were no differences between the groups on any measure of outcome (Fig. 3). At 52 weeks, 32.5% of the active group and 29.6% of the placebo group had achieved a 75% improvement in ODQ. The repeated measures analyses on the ODQ and VAS scores replicated these findings (data not shown). Repeating these analyses using only the completers made no appreciable difference to the results (data not shown). After 12 months only 26 patients were pain-free, with no difference between treatment groups.

Patients reported lower levels of back pain than leg pain at baseline using VAS scales. Back pain improved to a modest degree throughout the study, but there was no benefit of ESIs.

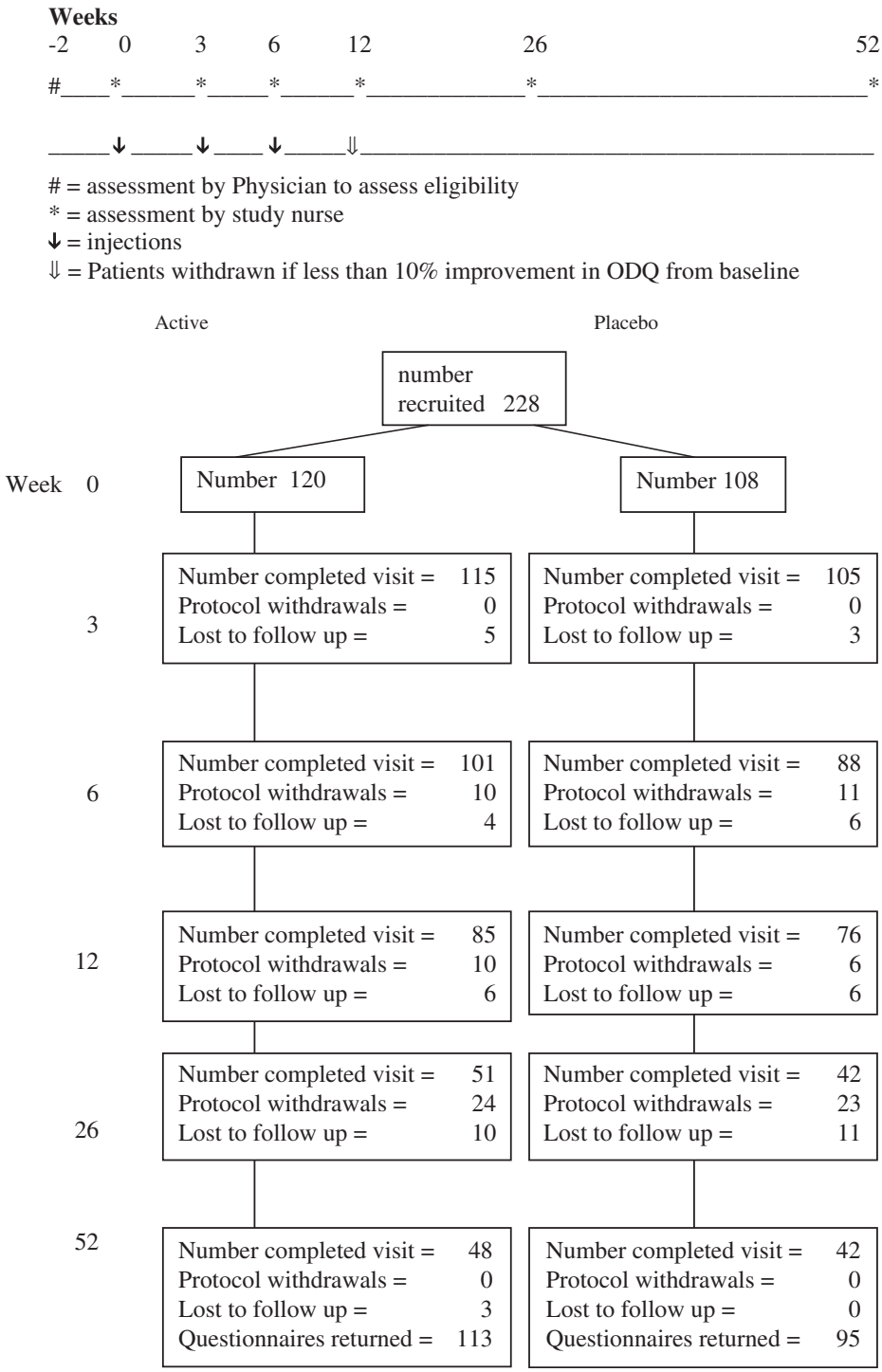

FIG. 1. Study design and participant flow chart.

Neurological symptoms and signs tended to improve throughout the trial; however, at the end of the study 44.8% of patients still had decreased sensation and 24.6% decreased power. ESIs did not reduce the degree of neurological signs or symptoms (Table 2). There was no difference in analgesic use throughout the study. Quality of life measures and objective physical function improved throughout the study period, with no significant differences between groups (data not shown).

Several baseline clinical variables were examined as predictors of response to ESIs. Patients with symptoms for less than 4 months tended to fare better than those with more chronic symptoms; however, this did not achieve statistical significance (Fig. 4). Chronicity of symptoms had no discernible effect on the response to ESI. Other variables examined and not found to predict response to treatment included anxiety or depression scores, SF-36, baseline ODQ, neurological abnormalities, previous episodes of sciatica, coexistent back pain, work status, gender and centre. There were few reported side-effects. Four patients in each group reported a non-specific headache after injection. The other reported side-effects included postdural puncture headache, nausea (two active, two placebo) and 'other' (five active, five placebo).

Health-care utilization and absenteeism from work

Table 3 shows the utilization of health-care resources by the groups. The numbers did not differ significantly between the groups in terms of surgery, physiotherapy and pain management programmes. The number of analgesics used in the 3 weeks before the baseline visit did not differ significantly between the two treatment groups and decreased during the study. Approximately a third of all patients were not working as a result of their sciatica at entry into the study. By the end of the study, this had fallen to just under one-quarter of patients, with no difference between the two treatment groups.

TABLE 1. Baseline clinical characteristics of 228 patients with sciatica

	Active	Placebo
Number of subjects	120	108
Age (yr)[a]	43 (12)	44 (12)
Height (m)[a]	1.7 (0.1)	1.7 (0.1)
Weight (kg)[a]	80 (16)	81 (18)
Sex (female %)	48.3	46.3
Duration of symptoms (%)		
<4 months	32.5	33.3
4–12 months	53.3	43.5
12–18 months	14.2	23.2
Oswestry score[a]	44 (15)	45 (18)
VAS leg pain[a]	52 (23)	56 (22)
VAS back pain[a]	40 (24)	44 (25)
HAD anxiety[a]	9 (3)	9 (4)
HAD depression[a]	7 (4)	8 (4)
SF-36[a]	46 (12)	46 (15)
Number of analgesics used in previous week[b]	37 (14–56)	34 (14–58)
Off work with sciatica (%)	34.2%	31.5%
Previous sciatica (%)	40.0%	39.8%
Acute (%)	38.3	35.2
Decreased sensation (%)	78.3	63.0
Absent/decreased ankle reflexes (%)	32.5	32.4
Decreased power (%)	41.7	42.6

[a]Mean (S.D.).
[b]Median (interquartile range).

Discussion

For the first time in a single large randomized controlled trial, our results confirm the duration of benefit afforded by epidural injections of corticosteroids. They offer short-term relief of symptoms in patients with sciatica at 3 weeks with a number needed to treat of 11.4. However, they do not offer any medium- or long-term benefit in terms of symptoms, function, return to work or the need for surgery. The majority of patients with sciatica referred to secondary care still have significant pain and disability 12 months later. Sciatica that is referred to secondary care should therefore be regarded as a chronic disease and be managed using a chronic disease framework.

This was a pragmatic study and as such was designed to mirror current clinical practice, approaching all eligible patients passing through the hospital service with a clinical diagnosis of sciatica. We did not use cross-sectional imaging as a recruitment criterion; however, the patients recruited had clinical characteristics similar to those in studies that have required a proven prolapsed disc on cross-sectional imaging in their inclusion criteria [11, 13]. This study was powered to detect even small clinical differences in symptoms. The dropout rates of 13.1 and 23.7% at 12 and 52 weeks, respectively, were similar to those in previous studies. Other patients were withdrawn according to the protocol, but as they had reached a formal study endpoint their analysable data were complete. Furthermore, these patients were contacted at 52 weeks to obtain further data to allow an accurate assessment of health resource use to be performed. To be certain that our loss to follow-up had not obscured any benefit of ESIs, we performed a formal completers analysis, which produced virtually identical results.

Previous studies of ESI in sciatica have shown discordant results due to the marked heterogeneity in their design, showing both no benefit in pain reduction [11–15] and significant benefit [9, 10, 17, 20]. Many studies were underpowered and used different patient populations and different approaches to the epidural space; most importantly, however, they assessed outcome at different time periods. Two negative studies used 24 h as an outcome time [13, 14], which is probably to early to detect an effect. Other positive studies had short- to medium-term follow-up periods [9, 10, 17, 21]. A meta-analysis of these studies had reported significant short- and long-term benefit of ESIs in sciatica [21],

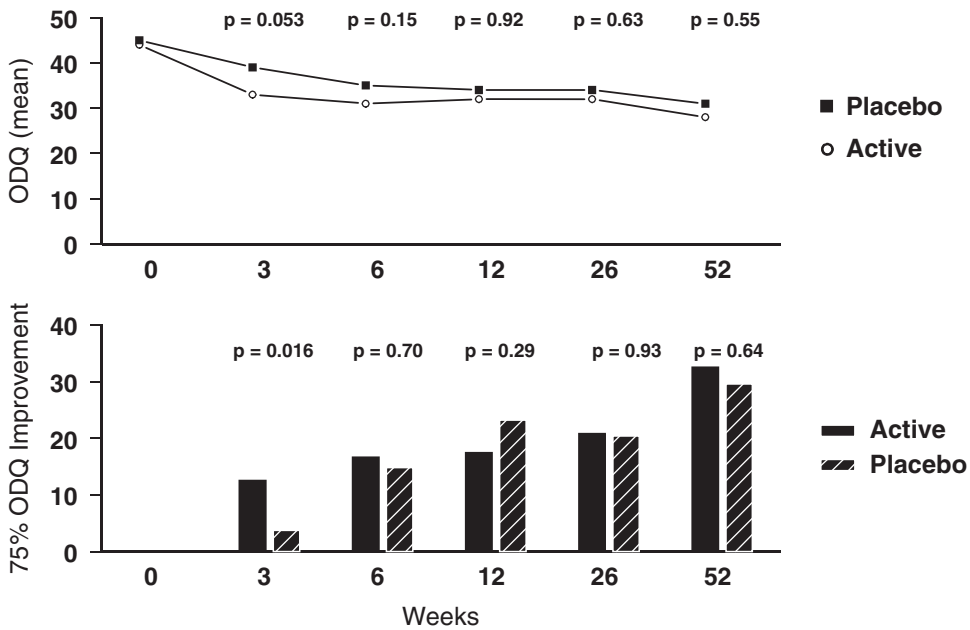

FIG. 2. ODQ scores and percentage of patients achieving a 75% improvement in ODQ by treatment group.

TABLE 2. Change in clinical outcomes throughout the follow up according to treatment group[a]

	Weeks									
	Baseline		3		6		12		52	
	A	Pl	A	Pl	A	Pl	A	Pl	A	Pl
Number of subjects			120	108	120	108	120	108	120	108
Continuous outcomes (decrease from baseline)										
Oswestry Disability Score	44 (15)	45 (18)	10 (15)*	7 (16)	13 (17)	10 (18)	12 (19)	12 (21)	16 (23)	14 (24)
VAS leg pain	52 (23)	56 (22)	12 (28)	10 (28)	15 (32)	15 (32)	13 (33)	18 (33)	17 (36)	20 (34)
VAS back pain	40 (24)	44 (25)	6 (27)	2 (27)	6 (28)	8 (30)	4 (28)	7 (32)	8 (31)	9 (33)
Dichotomous outcomes (actual percentages)										
Improvement on leg pain (Likert scale)	–	–	60.8**	39.8	56.7	50.9	52.5	50.0	55.8	47.2
Improvement on back pain (Likert scale)	–	–	45.8	37.0	50.0	48.1	46.7	46.3	48.3	43.5
Paraesthesia	45.8	40.7	34.2	38.9	29.2	38.9	26.7	31.5	21.7	30.6
Decreased sensation	78.3	63.0	60.8	59.3	59.2	52.8	50.0	45.5	46.7	42.6
Decreased reflex	32.5	32.4	25.8	25.9	25.0	23.2	25.8	21.3	25.8	22.2
Reported weakness	80.0	78.7	68.3	67.6	63.3	63.0	62.5	61.1	55.8	51.9
Decreased power	41.7	42.6	32.5	27.8	25.8	25.9	29.2	22.2	28.3	20.4

[a]A, epidural corticosteroid injection; Pl, placebo injection.
*$P < 0.05$; **$P < 0.01$.

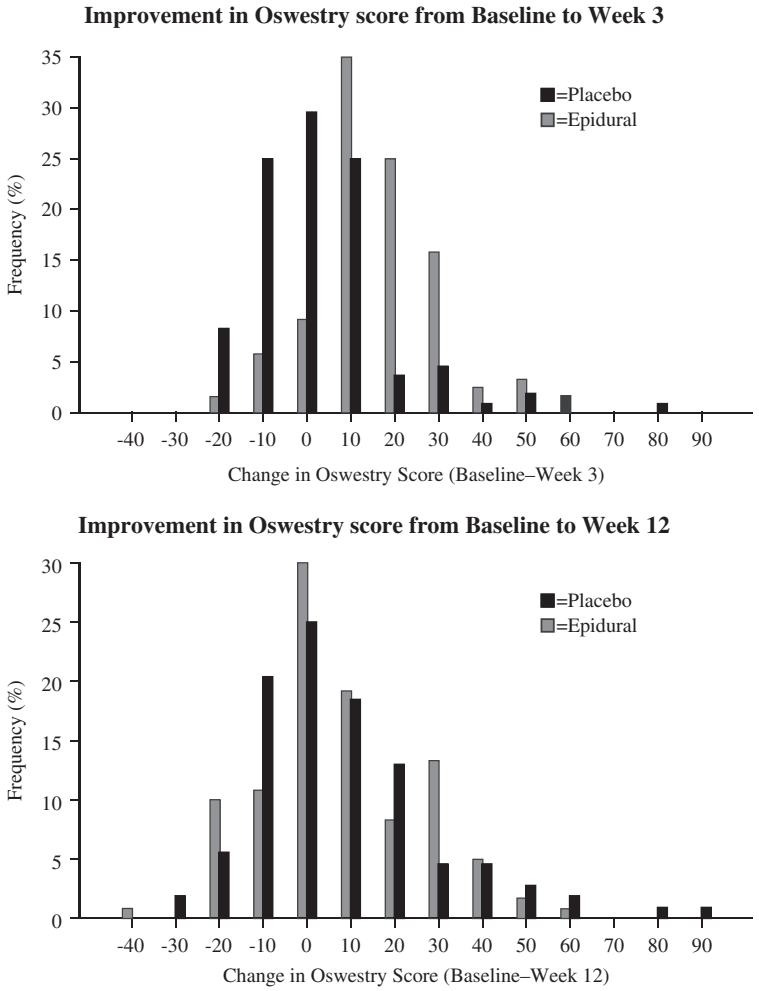

FIG. 3. Improvement* in Oswestry score from Baseline to Week 3 and Week 12.

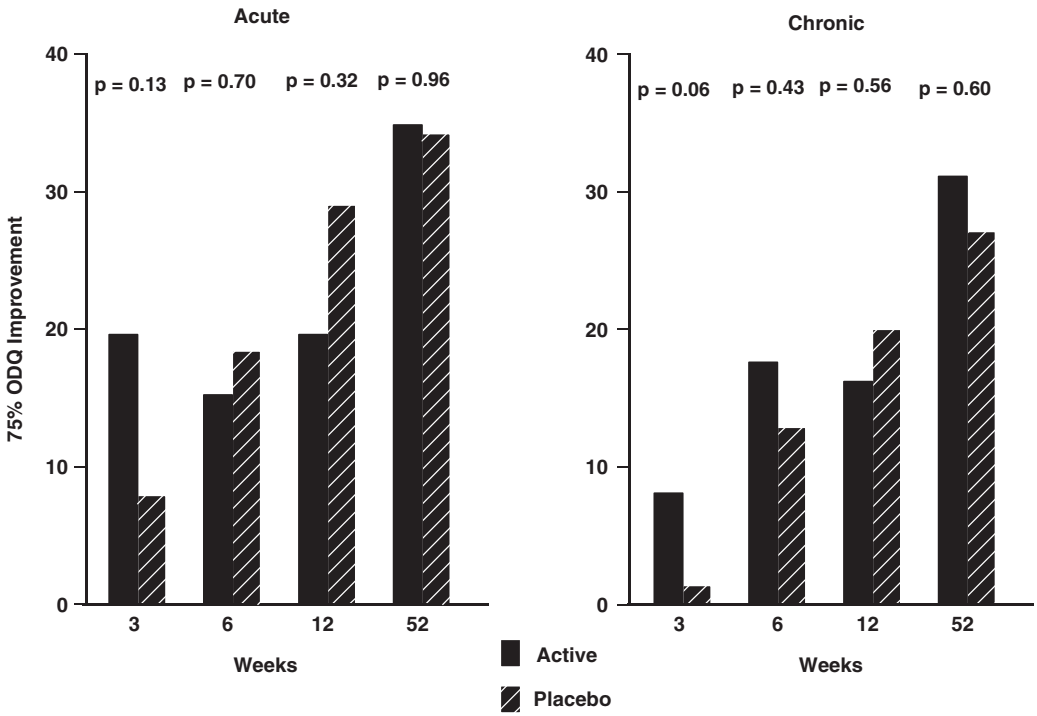

FIG. 4. Percentage of patients achieving a 75% improvement in ODQ by chronicity of symptoms.

TABLE 3. Change in health economic outcomes over study period

	Time 0		3 weeks		6 weeks		12 weeks		52 weeks	
Group	A	Pl	A	Pl	A	Pl	A	Pl	A	Pl
Off work with sciatica (%)	34.2	31.5	34.2	29.6	30.0	28.7	27.5	24.1	24.1	22.2
Days off work with sciatica: median (range)	98 (6–240)	93 (8–352)	21 (6–240)	21 (5–352)	21 (6–266)	21 (11–352)	37 (6–266)	23 (11–352)	65 (6–311)	33 (11–352)
Analgesic use (average number/week)[a]	37 (30)	48 (58)	6 (23)	11 (39)	8 (24)	13 (46)	9 (25)	16 (43)	14 (28)	16 (48)
Surgery (%)									15	14
Further physiotherapy (%)									31	25
Pain management (%)									0	2
Other injections (%)									16	12

[a]Mean (S.D.).

confirming the dangers of performing this type of statistical analysis when there is marked heterogeneity in study design. A critical appraisal of the literature concluded that there was insufficient evidence to determine the efficacy of ESIs in sciatica [22]. Our study, being the first to follow patients regularly from 3 weeks to 52 weeks, clarifies the situation in a single, large, well-designed randomized controlled trial: ESIs can lead to short-term benefit but not medium- or long-term benefit.

More than one ESI has often been given, both in clinical practice and in previous studies [10–12, 14, 17, 20]. Our results show that there is little point in performing repeat injections. An assumption was made of accurate needle placement. Previous studies have demonstrated that 93% of injections are correctly placed when using the lumbar approach to the epidural space, increasing to 97% when the operator was confident of the placement [23]. In cadavers, it has been shown that epidural injectates flow freely within the epidural space and are directed into the lateral recesses and surround the nerve roots [24]. Despite this, doubts have been aired about whether the steroid reaches the affected nerve root and in adequate quantities [25], and many doctors are abandoning lumbar ESIs in favour of foraminal or nerve root injections, first described 30 yr ago [26]. It is unclear whether transforaminal injections are more effective than ESIs. Some evidence suggests that they may reduce the need for surgery and that they are successful in cases of lumbar radiculopathy [27]. However, other evidence suggests similar outcomes to blind lumbar ESIs [28, 29]. Transforaminal injections are more complex to perform and more costly. It has also been suggested that, unless research shows a decrease in complications with the transforaminal approach, it would be difficult to recommend this approach [30]. In summary, given that pain relief is transient, it is unlikely that the transforaminal approach would have improved the long-term outcome of the group.

In order to aid clinical decision-making, it is important to identify predictors of response in order to target treatments effectively. It has been suggested that ESIs are more effective in

patients with acute sciatica; however, our results demonstrate that even though the acute group generally fared better than the chronic group, there was no difference in the effect of ESIs between the two groups. Despite a thorough search for clinical predictors of response, none could be found, and we conclude that there is no simple, clinically identifiable group of patients with sciatica that can be identified as being appropriate for an ESI.

ESIs did not reduce the number of patients off work due to their sciatica, which is contrary to previous studies [10, 20]. In one study [10], all patients were treated as in-patients with periods of bed rest and structured physiotherapy, contrary to current practice. The second study was small and had a crossover design, and hence it was difficult to interpret [20]. Our data demonstrate that ESIs did not reduce the need for surgery, nor did it reduce the need for any other interventions, including physiotherapy, pain management programmes or other injection techniques. The number of patients requiring surgery in this study was the same in both groups and consistent with previous studies of sciatica [17].

Traditionally sciatica has been considered to be a self-limiting condition by many clinicians. However, our results suggest that this is not the case as most patients had significant pain and disability at the end of the study. The majority of patients in this pragmatic study had been in pain for over 3 months at the time of referral to secondary care and can therefore be defined as suffering from chronic pain and its associated sequelae. It is now widely accepted that chronic painful conditions should be managed using a multidisciplinary approach. Currently, many patients with sciatica receive ESIs as an isolated intervention outside this framework. Our study, being pragmatic, reflected this practice and we cannot exclude benefits of ESIs as part of a multidisciplinary package.

ESIs are often used in the management of sciatica and incur considerable costs to the health-care system. In this study there was no benefit of ESI in the medium or long term in terms of pain relief, utilization of further health services (including surgery) or return to work. Because of the high cost, the use of ESIs in the medium to long-term patient management strategies can therefore be regarded as an insufficient use of resources by the health provider.

In conclusion, the use of epidural corticosteroid injections, as used in this pragmatic study, offered limited short-term benefit but no sustained benefits to patients with sciatica in terms of pain, function or need for surgery. Alternative management strategies need to be implemented for these patients.

Rheumatology	Key messages
	• Epidural corticosteroids offer only short-term benefit in the management of sciatica. • By the time patients reach secondary care, sciatica is a chronic condition requiring a multidisciplinary management strategy.

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