Steroid injection for heel pain: evidence of short-term effectiveness. A randomized controlled trial

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Abstract

Objectives. To compare the effectiveness of a steroid injection (25 mg/ml prednisolone acetate) with a local anaesthetic control in the treatment of heel pain and to determine any advantage for patients' comfort of using a posterior tibial nerve block to anaesthetize the heel prior to infiltration.

Methods. A double-blind randomized controlled trial using a 2 × 2 design in a hospital-based rheumatology clinic. Subjects comprised 106 patients with heel pain referred by general practitioners and other rheumatologists working in Camden and Islington Health Authority. Main outcome measures: heel pain reduction at 1, 3 and 6 months, and patient comfort at the time of injection. All outcomes were measured using a 10 cm visual analogue scale.

Results. A statistically significant reduction in pain was detected at 1 month (P = 0.02) in favour of steroid injection, but thereafter no differences could be detected. Patient comfort was not significantly affected by anaesthesia of the heel (P = 0.5).

Conclusions. A steroid injection can provide relief from heel pain in the short term. There appears to be no increase in patient comfort from anaesthetizing the heel prior to infiltration.

Key words: Steroids, Heel pain, Plantar fasciitis, Enthesopathy, Randomized controlled trial, Clinical practice.

Patients with plantar heel pain commonly present in rheumatology clinics and general medical practice. The aetiology is poorly understood, but is believed to be partly inflammatory and partly biomechanical. It has been suggested that patients' occupations and lifestyles [1], body mass indices [2], biomechanical characteristics [3] and the duration of the pain [4] are involved in the aetiology and can affect the outcome.

In common with other musculoskeletal conditions, steroid injections have been used to treat plantar heel pain since the 1950s [5] and are one of the most frequently described treatments for painful heels in the medical literature [6]. In a survey of orthopaedic surgeons, 73% reported using steroids to treat painful heels [7]. Rheumatologists also regularly administer this therapy; as a prelude to this study, 100 randomly selected consultant rheumatologists were sent a questionnaire to assess their current management of heel pain. Steroid injections were the most frequently reported treatment, often in conjunction with heel pads, ultrasound and stretching exercises.

Systematic reviews evaluating steroids for painful shoulders and elbows show that evidence of effectiveness is scant [8, 9]. Robust evaluations using randomized, double-blind designs are rare for painful heels, making beneficial or detrimental treatment effects difficult to estimate. Three randomized evaluations of steroid injections have either reached conflicting conclusions about their superiority in relation to heel cups and orthoses [10, 11] or shown similar cure rates using injected saline [12].

There are drawbacks in injecting the heel with steroids: mainly rupture of the plantar fascia and atrophy of the fat pad [1, 13]. In an observational study, Acevido and Beskin [14] reported a plantar fascial rupture rate of 10% in patients after steroid injection for heel pain. Another drawback is the extreme pain experienced by some patients during an infiltration of the tissues surrounding the calcaneum.

This paper reports a double-blind randomized controlled trial of steroid injection used to treat plantar heel pain. The aim of this study was to produce evidence of the effectiveness of one steroid injection for plantar heel pain using local anaesthetic as a control, and to assess the value of administering a tibial nerve block to improve patient comfort and pain outcomes.

Method

The trial was conducted between January 1995 and December 1998. After ethical committee approval, general practitioners (GPs) and rheumatologists in Camden and Islington Health Authority were contacted and asked to refer patients with heel pain to the Middlesex Hospital, the site of the trial. Patients with a clinical
diagnosis of heel pain were invited to participate if they reported pain and tenderness centred on the medial tubercle of the calcaneum on weight bearing after rest which resolved, either partly or fully, after activity. Patients using orthoses, insoles, pads or analgesia were also included and not advised to discontinue these therapies. After verbal and written information, all included patients gave written consent.

Patients were excluded from the study if they were pregnant, under the age of 18 yr, had received a steroid injection for heel pain within the previous 6 months, were receiving anticoagulants or were unable to give consent.

Patients were allocated to one of four interventions using a computer-generated randomization schedule stratified to ensure equal numbers of participants in each group. The unit of randomization was individual episodes of heel pain. The four interventions were: (A) 1 ml of 25 mg/ml of prednisolone acetate with 1 ml of 2% lignocaine; (B) 1 ml of 25 mg/ml of prednisolone acetate with 1 ml of 2% lignocaine given after a tibial nerve block; (C) 2 ml of 1% lignocaine hydrochloride; (D) 2 ml of 1% lignocaine hydrochloride given after a tibial nerve block.

All heels were infiltrated through the medial aspect of the heel pad. In order to assess the accuracy of placement, a small sample of patients had MRI to confirm needle position. Five cases were assessed using a dedicated, small-part low-field-strength MRI scanner. In these five, the tip of the needle was confirmed to be within the body of the flexor digitorum brevis muscle just deep to the heel fascia and immediately distal to its origin from the calcaneus.

**Primary outcomes**

Ten-centimetre visual analogue scales were used for all primary outcomes. Patients who met the inclusion criteria were asked to score their level of heel pain at the time of entry to the trial. Participants immediately received treatment according to the random allocation, after which they were asked to score the degree of pain from the heel injection. Outcome reassessments were taken at 1, 3 and 6 months post-treatment to measure pain in the treated heel. At the termination of the trial, all participating patients were sent a questionnaire to determine whether they were cured by the trial treatment allocation, had sought further treatment for heel pain from a different health provider (e.g. GP) and whether they still suffered from heel pain.

**Prognostic variables**

Data were collected about the duration of heel pain, weight, height [body mass index (BMI)], occupation (sedentary or active) and the presence of Helbing’s sign (a soft-tissue indication of excessive subtalar joint pronation).

An a priori power calculation indicated that 90 patients randomized to receive either steroid or a local anaesthetic control would allow a 30% difference in efficacy between the two allocations to be identified with 80% confidence.

Treatment allocation was concealed from both the clinician (DA) who took all outcome measurements and the physician (JE) who administered all injections, by an independent observer (FC) who was responsible for the treatment allocation. The independent observer also prepared the injections and, in order to obscure the syringe contents from the physician and patients, masked the syringes using white dressing tape. An empty syringe was used to aspirate the injection site before it was disconnected, leaving the needle in situ; the masked syringe containing the allocated treatment was then connected to the needle. Only the clinician taking outcome measurements was blind to the administration of the tibial nerve block. The codes for the allocation schedule were known only to the independent observer and were held in file by the departmental secretary. The code was broken at the end of the trial.

**Results**

One hundred and six patients with heel pain entered the trial; 69 females and 37 males. The age range was 30–87 yr, the mean age was 57 yr (± 12.9). The range of heel pain duration for all trial participants was 1–120 months, the median duration was 6 months (± 20.6). The mean pain score of patients at the time of entry to the trial was 5.7 (± 2.4). Table 1 shows baseline characteristics for trial patients analysed at group level. Only two patients had been diagnosed with seronegative pathology.

**Primary outcomes**

The mean pre-treatment pain scores and mean pain scores at 1, 3 and 6 months are presented in Table 2. The comparison of outcomes at 1 month shows a statistical difference in favour of treatment with steroid (P = 0.02). No statistically significant difference in pain reduction could be detected between the injected substances for pain outcomes taken at 3 and 6 months; the P values were 0.9 and 0.8, respectively.

The number of patients lost to follow-up at 1 month was 4%. This rose to 25% at 3 months and by 6 months was 48% (51 patients). No statistical difference existed in the numbers of patients lost to follow-up between the four groups (P = 0.7), but made an intention-to-treat analysis impractical.

Sixty-two patients returned end of trial questionnaires, 38 (75%) of them were patients for whom the outcome at 6 months was unknown. Nineteen of those still had heel pain and 16 had sought treatment from other health care providers. These outcomes did not differ significantly from those patients with known 6 month outcomes; 11 patients still had heel pain and nine sought treatment elsewhere. Thus, 28% of the entire trial population reported having heel pain at the end of the trial.

**Prognostic variables**

A regression analysis did not detect a relationship between the duration of heel pain and pain scores at
1 month ($P = 0.3$). The patients’ perception of pain from the steroid injection did not appear to be significantly altered by the prior administration of tibial nerve block ($P = 0.5$). No statistical differences in pain scores were detected between patients who had their heel anaesthetized and those who did not ($P = 0.5$). No relationship was found between BMI and pain reduction at 1 month ($P = 0.6$).

Pain and sedentary or active occupations did not appear to be associated ($P = 0.6$), nor was a relationship apparent between patients’ age and pain ($P = 0.3$). Twenty-five per cent of participants had a positive Helbing’s sign, indicating excessive subtalar joint pronation, but no relationship was found to exist between pain reduction and the presence or absence of Helbing’s sign ($P = 0.3$). Thirteen per cent of participants wore insoles at entry to the trial, but no relationship was detected between insole wearing and pain scores ($P = 0.2$).

### Discussion

The comparability of baseline characteristics (age, duration of pain and initial pain scores) of patients in each group indicates that the randomization procedure was successful (Table 1). The range of participants’ ages reflects the findings of non-randomized studies of the condition [15–17] and there can be little doubt that plantar heel pain predominantly affects adults, often in mid to late life.

The analysis did not detect any relationship between pain reduction and patient characteristics. Patients’ age, BMI, occupation and the duration of their pain prior to treatment did not seem to be associated with their outcome nor did the use of orthoses or the presence of excessive subtalar joint pronation. According to these findings, patients’ heel pain does not benefit from weight loss or prompt treatment after the onset of symptoms. Indeed, it was not possible to distinguish any features associated with a good or poor outcome.

The pain perceived by patients at the time of injection did not differ between those who had a tibial nerve block and those who did not, and there seems to be no value in undertaking this additional procedure to increase patient comfort or improve outcomes. There are two possible explanations for this conclusion. The first is that direct contact with the nerve during the administration of the anaesthetic can occur and is painful. The second is the variable success in achieving anaesthesia of the posterior tibial nerve in a relatively short period of time (out-patient appointment).

The large loss to follow-up at the 6 month outcome reduced the trial’s power and it is not possible to make valid statistical conclusions about the efficacy of the treatment at 6 months, but the outcomes are reported for completeness.

Of the 52% of trial patients who did document pain scores at 6 months (Table 2), the reductions in pain were uniform across all four intervention groups, suggesting that, for half of the trial patients, the condition resolved naturally over time. From patients’ responses to the end of trial questionnaire, it is clear that for 28% the natural history of the condition was not one of improvement.

Reductions in patients’ pain scores were significantly greater in the two arms that received steroid at 1 month, but at 3 months no therapeutic advantage could be detected. The short-term nature of the benefit from steroid injections has previously been reported in the treatment of painful shoulders [8] and in observational

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**Table 1. Baseline characteristics for the trial patients**

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>s.d.</th>
<th>Mean</th>
<th>s.d.</th>
<th>Mean</th>
<th>s.d.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corticosteroid + tibial nerve block</td>
<td>53.69</td>
<td>14.28</td>
<td>14.85</td>
<td>23.87</td>
<td>5.5</td>
<td>2.1</td>
</tr>
<tr>
<td>Local anaesthetic</td>
<td>56.88</td>
<td>13.02</td>
<td>18.96</td>
<td>25.72</td>
<td>5.5</td>
<td>2.1</td>
</tr>
<tr>
<td>Corticosteroid</td>
<td>59.41</td>
<td>11.84</td>
<td>11.65</td>
<td>19.49</td>
<td>5.6</td>
<td>2.3</td>
</tr>
<tr>
<td>Local anaesthetic + tibial nerve block</td>
<td>58.81</td>
<td>12.48</td>
<td>8.59</td>
<td>9.93</td>
<td>5.8</td>
<td>2.8</td>
</tr>
</tbody>
</table>

*Significance levels: *$P = 0.39$; *$P = 0.32$; *$P = 0.64$.  

**Table 2. Mean heel pain scores at 1, 3 and 6 months**

<table>
<thead>
<tr>
<th>Intervention group</th>
<th>Mean pain score</th>
<th>At trial entry</th>
<th>1 month after injection</th>
<th>3 months after injection</th>
<th>6 months after injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local anaesthetic (LA) alone</td>
<td></td>
<td>5.5 ± 2.1</td>
<td>4.0 ± 2.9</td>
<td>3.7 ± 3.3</td>
<td>3.3 ± 2.7</td>
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<tr>
<td>n = 27</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corticosteroid and LA + tibial nerve block</td>
<td></td>
<td>5.5 ± 2.1</td>
<td>4.5 ± 2.6</td>
<td>3.4 ± 2.7</td>
<td>2.5 ± 3.2</td>
</tr>
<tr>
<td>n = 26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corticosteroid and LA</td>
<td></td>
<td>5.6 ± 2.3</td>
<td>2.9 ± 2.5</td>
<td>3.6 ± 2.8</td>
<td>2.4 ± 2.6</td>
</tr>
<tr>
<td>n = 27</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local anaesthetic + tibial nerve block</td>
<td></td>
<td>5.8 ± 2.8</td>
<td>5.3 ± 2.9</td>
<td>3.1 ± 2.7</td>
<td>0.6 ± 1.1</td>
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<tr>
<td>n = 26</td>
<td></td>
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</table>

*Significance levels: *$P = 0.02$; *$P = 0.9$; *$P = 0.8$.  

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