Does wound irrigation with triamcinolone reduce pain after surgery to the lumbar spine?

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This prospective, randomized study compared postoperative pain scores, morphine consumption and length of stay in 95 adults who underwent elective lumbar spine surgery via a posterior incision. Immediately prior to closure the wound was irrigated with triamcinolone 40, 20 or 0 mg. Visual analogue scale pain scores at 24 h after surgery were median 12 (interquartile range 3–24), 15 (6–34) and 33 (20–59) mm for patients receiving triamcinolone 40, 20 mg or no steroid, respectively (P<0.0005, Kruskal–Wallis test). Total morphine usage after 24 h was 26 (21–39), 27 (17–43) and 43 (27–73) mg for the same groups (P<0.001, Kruskal–Wallis test). The proportion of patients discharged from hospital on the first day after surgery was 83.9, 77.4 and 54.8% for patients receiving triamcinolone 40, 20 mg and no steroid, respectively (P<0.028, chi-squared test). Extra-dural triamcinolone reduces pain after lumbar spine surgery and reduces time to discharge from hospital.

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Pain after surgery is distressing for patients and may delay their mobilization. Although the use of opiate analgesia for pain relief is widespread, its uptake by patients may be limited by side effects, notably nausea, vomiting and sedation. Although wound infiltration with bupivacaine towards the end of surgical procedures on the lumbar spine is commonly undertaken, reports on its efficacy are equivocal.1–7 We have previously reported that in a non-random subset of patients to whom extra-dural steroid was administered during wound closure, there was a significant reduction in pain after surgery.1 However, this was an unexpected finding in a post hoc analysis of data from an investigation of the efficacy of para-vertebral wound infiltration with bupivacaine. The present study was designed to rigorously and prospectively investigate the efficacy of extra-dural triamcinolone as an adjuvant therapy to reduce pain after surgery to the lumbar spine.

Methods
All patients admitted to the Department of Neurosurgery at Derriford Hospital, Plymouth, UK in anticipation of surgery for benign conditions of the lumbar spine were approached to participate in this trial. Written consent was obtained. Patients who were under 18, pregnant, or in whom it was expected that the dura would be opened were excluded. Prior approval was obtained from the South and West Devon Health Authority Ethics Committee. In addition, as extra-dural administration of triamcinolone is not a licensed indication, we obtained a Clinical Trials Exemption certificate (CTX) from the Medicines Control Agency of the UK.

Patients were pre-medicated with temazepam 10–20 mg and anaesthetized with propofol and fentanyl, 2 µg kg⁻¹ followed by 0.5–1.5% isoflurane (end tidal concentration) and 66% N₂O in oxygen administered by mechanical ventilation. Additional fentanyl was given as clinically indicated. Paralysis was achieved with vecuronium or atracurium, and reversed at the end of surgery using glycopyrronium and neostigmine. Droperidol 0.5 mg was given as a prophylactic anti-emetic.

Treatment allocation (40, 20 or 0 mg triamcinolone) was determined by a computer-generated randomization scheme. Study allocation was held in individually numbered sealed opaque envelopes which were not opened until after the surgical procedure had been completed and wound closure was about to commence. If the dura was inadvertently opened before the end of the surgical procedure, the patient was not randomized.

Triamcinolone injection is an opaque white suspension, and after discussion with the pharmacy we could not identify a suitable inert substance with a similar appearance which...
could be safely administered as a placebo. It was therefore not possible to blind the operating surgeon or the operating room staff. However, implementation of the standardized prescriptions for postoperative analgesia and collection of outcome data were the responsibility of nursing staff who were blind to the treatment allocation.

The study protocol dictated randomization only immediately prior to wound closure. This allowed the exclusion of patients in whom the dura was inadvertently opened and also ensured that the administration of the standardized anaesthetic was not biased by prior knowledge of the patient’s treatment allocation. Anaesthetic interventions after administration of study drug were limited to reversal of neuromuscular block and extubation. No additional fentanyl was administered after wound closure had commenced.

All patients were operated on in the prone position on an extension frame. Before surgical incision, the skin and subcutaneous tissues were infiltrated with 20 ml 1% lidocaine with epinephrine 1/200 000. Immediately prior to wound closure, the randomization envelope was opened, and according to the instructions inside, triamcinolone 40, 20 mg or no steroid was placed in the wound under direct vision. The triamcinolone (40 mg ml$^{-1}$) was drawn up in a sterile 1-ml syringe and infused in such a way as to coat the paraspinal muscles and drain down into the extradural space.

In the postoperative recovery area, patients received i.v. morphine 2 mg at 5-min intervals until comfortable, and subsequently used a patient control analgesia (PCA) system with morphine 50 mg and droperidol 2.5 mg diluted to 50 ml with 0.9% saline. The system was set to give a bolus injection of 1 ml (containing morphine 1 mg and droperidol 50 µg) with a lockout period of 5 min and no background infusion.

After giving written informed consent, preoperative variables including age, gender, weight, duration of symptoms, operative indication and preoperative pain scores (VAS) were recorded. A baseline pain score was obtained from the patient using a 100-mm visual analogue scale (VAS) ranging from ‘no pain’ to ‘the worst pain I can imagine’. It was emphasized that we were collecting data on spinal pain only, not radicular symptoms.

Operative variables recorded included the number of levels operated upon, the length of the incision, the duration of the operation, the grade of operating surgeon, whether the operation was unilateral or bilateral, and the dose of fentanyl.

Outcome measures collected were pain scores (VAS), 24 h morphine usage and length of stay. VAS pain scores were recorded at 3, 12 and 24 h by nurses blinded to the study drug. Again it was emphasized that we were scoring spinal pain not radicular symptoms. At 24 h, total morphine consumed during the postoperative period was read from the PCA machines and this was added to the morphine given in the recovery room to obtain 24 h morphine usage.

Decisions on discharge were made according to strict criteria by doctors, physiotherapists and nurses blinded to study allocation. Patients were discharged when they were independent for self-care, fully mobile including the stairs, comfortable on oral non-opioid analgesics, and able to pass urine unaided. Decisions about patient discharges were made during a ward round on the morning immediately after surgery.

Statistical analysis was undertaken with SPSS for Windows Version 8.0 on a personal computer. The three groups were compared with a one-way ANOVA or Kruskal–Wallis test for continuous variables as appropriate. The Bonferroni method was used to correct for multiple comparisons. Categorical variables were compared with the chi-squared test. To evaluate any dose–response relationship between study group and outcome, the chi-squared test for trend and polynomial linear contrasts (ANOVA) were used. Factorial analysis of variance was used to test the influence of certain preoperative factors on outcome. Pain scores at 24 h and total morphine consumption end-points were not normally distributed, so these variables were square root transformed prior to factorial analysis of variance and polynomial linear contrasts. The null hypothesis was rejected when $P<0.05$.

Sample size was determined by an a priori power calculation based on our earlier study of patients undergoing lumbar spine surgery.$^1$ We felt the smallest clinically significant difference in VAS scores and morphine usage over 24 h would be 15 mm and 15 mg, respectively. Three groups of 31 patients were sufficient to detect both these differences with an alpha error of 0.05 and a power of 80%.

**Results**

One hundred and two consecutive patients were approached to participate in the trial and all gave consent. Two patients suffered a CSF leak during the procedure and there was no PCA apparatus available for another three. On two occasions the protocol was violated when an analgesic (diclofenac) was prescribed as a part of premedication. None of these seven patients was randomized. Two patients were randomized to triamcinolone 20 mg but did not complete the protocol. One became hypotensive and the morphine PCA was discontinued, and one was given diclofenac (an accidental protocol violation) during the first 24 h. These two patients were excluded from subsequent analysis. Ninety-three patients completed the trial and full data sets were available for all of them.

Patient characteristics and preoperative pain scores for the 93 evaluable patients are shown in Table 1. The patients who received triamcinolone had a shorter duration of symptoms and lower preoperative pain scores than those who did not receive steroid. However, these differences were not statistically significant.

Operative variables are summarized in Table 2. The incision length was slightly longer in the group that did not receive steroid but this was not statistically significant. All
Triamcinolone and back surgery

Table 1 Patient characteristics, duration of symptoms and preoperative pain scores. Data are mean (SD or range) or number. *One-way ANOVA. **Chi-squared

<table>
<thead>
<tr>
<th></th>
<th>No steroid (n = 31)</th>
<th>Triamcinolone 20 mg (n = 31)</th>
<th>Triamcinolone 40 mg (n = 31)</th>
<th>P-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>44.5 (23.3–78.5)</td>
<td>44.8 (22.7–69.7)</td>
<td>46.3 (24.0–76.6)</td>
<td>0.904*</td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>18/13</td>
<td>17/14</td>
<td>12/19</td>
<td>0.264**</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>74.1 (15)</td>
<td>74.6 (15.7)</td>
<td>78.3 (13.4)</td>
<td>0.484*</td>
</tr>
<tr>
<td>Duration of symptoms (months)</td>
<td>16.8 (14.4)</td>
<td>13.8 (13)</td>
<td>11 (9.6)</td>
<td>0.206*</td>
</tr>
<tr>
<td>Preoperative pain score (mm)</td>
<td>52.9 (23.6)</td>
<td>44.3 (28.8)</td>
<td>38.2 (30.2)</td>
<td>0.117*</td>
</tr>
</tbody>
</table>

Table 2 Duration of surgery and details of surgical procedure. Data are mean (SD) or number. *One-way ANOVA. **Chi-squared. ***Kruskal–Wallis test

<table>
<thead>
<tr>
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<th>Triamcinolone 40 mg (n = 31)</th>
<th>P-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision length (cm)</td>
<td>6.3 (2.6)</td>
<td>4.8 (1.1)</td>
<td>5.1 (2)</td>
<td>0.07***</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>68.1 (28.8)</td>
<td>62.4 (26.7)</td>
<td>62.4 (24.6)</td>
<td>0.656*</td>
</tr>
<tr>
<td>Levels operated upon</td>
<td>1.2 (0.51)</td>
<td>1.1 (0.37)</td>
<td>1.1 (0.45)</td>
<td>0.623*</td>
</tr>
<tr>
<td>Bilateral/unilateral</td>
<td>6/25</td>
<td>3/28</td>
<td>5/26</td>
<td>0.555**</td>
</tr>
</tbody>
</table>

Table 3 Visual analogue pain scores (VAS), morphine usage and duration of hospital stay after lumbar spine surgery. Data are percentage, mean (SD) or median (interquartile range). *One-way ANOVA. **Chi-squared. ***Kruskal–Wallis test. †ANOVA polynomial linear contrasts (square root transformation for 24 h pain scores and total morphine usage). ‡Chi-squared for trend.

<table>
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<tr>
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<th>Triamcinolone 20 mg (n = 31)</th>
<th>Triamcinolone 40 mg (n = 31)</th>
<th>Between group differences (P-values)</th>
<th>Dose–response relationship (P-values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS (3 h)</td>
<td>41.1 (26.2)</td>
<td>38.1 (25.6)</td>
<td>29.3 (19.4)</td>
<td>0.126*</td>
<td>0.056‡</td>
</tr>
<tr>
<td>VAS (12 h)</td>
<td>32.9 (18.7)</td>
<td>28 (20.8)</td>
<td>23.6 (18.4)</td>
<td>0.174*</td>
<td>0.062†</td>
</tr>
<tr>
<td>VAS (24 h)</td>
<td>33 (20–59)</td>
<td>15 (6–34)</td>
<td>12 (3–24)</td>
<td>0.0005***</td>
<td>0.001†</td>
</tr>
<tr>
<td>24 h morphine usage (mg)</td>
<td>43 (27–73)</td>
<td>27 (17–43)</td>
<td>26 (21–39)</td>
<td>0.001***</td>
<td>0.007†</td>
</tr>
<tr>
<td>Length of stay (days)</td>
<td>1.48 (0.57)</td>
<td>1.22 (0.42)</td>
<td>1.16 (0.37)</td>
<td>0.025***</td>
<td>0.007‡</td>
</tr>
<tr>
<td>Discharged on first day after surgery (%)</td>
<td>54.8</td>
<td>77.4</td>
<td>83.9</td>
<td>0.028**</td>
<td>0.011†</td>
</tr>
</tbody>
</table>

other measures of operative complexity of the three groups were comparable.

Table 3 shows the outcome variables. There was no significant difference in pain scores at 3 or 12 h after surgery. Twenty-four hour pain score, 24 h morphine usage, length of stay and the probability of being discharged from hospital more than 24 h after surgery were all significantly lower in patients who had received triamcinolone than in those who had not (ANOVA). Post hoc analysis showed that both the groups which received 20 or 40 mg of triamcinolone were significantly different from the group that received no steroid (P<0.05), but they were not different from each other. Tests for trend show a significant linear dose–response relationship for all outcome variables except VAS at 3 and 12 h. The results for these two variables are only just outside statistical significance.

Despite rigorous randomization, there were some interesting, albeit, non-significant differences between groups in terms of preoperative factors. In view of the lower preoperative pain scores and shorter histories in those patients who received steroids (Table 1), additional statistical analysis was carried out to explore the possibility that preoperative differences in the study groups may have contributed to our findings. In a factorial analysis of variance with 24 h morphine consumption as the dependent variable, steroid group as a co-factor and both preoperative VAS score and length of history as co-variants, only the steroid group significantly predicted outcome. The same result was obtained when 24 h VAS was used as the dependent variable.

**Discussion**

The efficacy of epidural injection of steroids for selected patients with sciatica is well established. However, their use is not without risk and reported complications include infection and paralysis. Extra-dural administration of triamcinolone with lidocaine in a cat model did not cause significant damage to neural tissues. Extra-dural administration of steroids after surgery to the lumbar spine reduces postoperative fibrosis in an animal model, and individual neurosurgeons have used steroids in this way for some years although the practice is not universal.

Few studies have investigated whether triamcinolone can modify acute pain outwith the spine. Local injection of
steroid into the pillar of the fauces and the tonsil bed reduces pain after tonsillec-
yomy. However, adding triamcinolone to bupivacaine did not reduce postoperative morphine consumption in men undergoing elective inguinal hernia repair under general anaesthesia. Some small studies have evaluated the use of extra-dural steroids to relieve pain after spinal surgery. In a non-randomized study, Foulkes and Robinson reported that 22 patients who received wound irrigation with dexamethasone acetate suspension 16 mg after lumbar hemi-laminectomy or micro-discectomy used less narcotics than historic controls. Ang and colleagues randomized patients to receive extra-dural dexamethasone 4 mg or no steroid after ‘lumbar laminotomy’ and reported that the steroid group experienced less pain and requested less pentazocine than the controls. Our study confirms these findings and extends them to suggest a dose–response relationship with the higher 40 mg dose of triamcinolone giving the greatest reduction in pain scores and morphine usage. We found no statistically significant effect of triamcinolone at 3 and 12 h after surgery, although the pain scores at these times were lower amongst those patients who had received steroid. The smallest difference between groups was 9 mm at 12 h. If this was to be considered clinically significant it would have taken three groups of 85 patients to test the hypothesis that such a difference was statistically significant.

Although the use of steroid after lumbar hemi-laminectomy or micro-discectomy has previously been shown to reduce hospital stay from an average of 8.7 to 6.4 days, the relevance of such findings to modern surgical practice with aggressive early discharge was unknown. We have demonstrated that triamcinolone offers a shorter stay in hospital and an increased chance of discharge on the first day after surgery when early discharge protocols are already routine.

This prospective, randomized, controlled study has rigorously tested the hypothesis that wound infiltration with triamcinolone can reduce pain after surgery to the lumbar spine, and has demonstrated an effect which is both statistically and clinically significant. In support of this finding is a dose–response relationship for all outcome variables. Additional work might usefully determine the optimum dose of triamcinolone, although this might require an unfeasibly large number of patients.

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