Percutaneous Pin Removal in the Outpatient Clinic—Do Children Require Analgesia?

A Randomized Controlled Trial

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Background: Percutaneous pins used in the surgical fixation of fractures in children are often removed in the outpatient clinic without the administration of analgesia. Pin removal can be a cause of anxiety for children, parents, and caregivers. Relatively little is known about the requirement of analgesia for this procedure. In a randomized controlled trial, we evaluated whether oral acetaminophen or ibuprofen reduced the pain experienced during pin removal.

Methods: Participating in the study were 240 children between the ages of five and twelve years who had two or three percutaneous pins in the elbow following treatment of a supracondylar humeral fracture or a lateral humeral condyle fracture with closed reduction and percutaneous pinning. The patients were randomized into one of three groups (n = 80) allocated to receive acetaminophen, ibuprofen, or vitamin C (placebo) an hour before pin removal. A pain score was obtained and heart rate measured before pin removal, immediately following the procedure, and ten minutes after pin removal.

Results: No significant differences were found among the study groups in terms of the demographic data of sex, age, side of injury, or number of pins. Pain score and heart rate did not exhibit differences that were either statistically significant or clinically relevant. The change from baseline did not differ significantly among the groups for either measure at either of the follow-up times post pin removal. Immediately after pin removal, the mean difference in pain score (and 95% confidence interval [CI]) between the acetaminophen group and the ibuprofen group was 0.10 (−1.03 to 1.23); between the acetaminophen group and the placebo group, 0.35 (−0.78 to 1.48); and between the ibuprofen group and the placebo group, 0.25 (−0.88 to 1.38). The CIs excluded a clinically relevant difference. Pain scores and heart rates returned to preprocedural baseline levels within ten minutes following pin removal.

Conclusions: Neither acetaminophen nor ibuprofen significantly reduced the pain score or heart rate associated with percutaneous pin removal in children as compared with the placebo. The oral analgesics administered were clinically equivalent to the placebo. These results suggest that non-narcotic analgesia use does not significantly reduce pain or heart rate associated with percutaneous pin removal in children.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Closed reduction and percutaneous pinning with smooth Kirschner wires is the mainstay of treatment today for displaced and unstable supracondylar fractures in children. Closed reduction and percutaneous pinning is also used for the stabilization of displaced lateral humeral condyle fractures and transphyseal fractures of the distal part of the humerus in young children. The percutaneous pins are usually removed three to four weeks post fixation, once the fracture has united.
In many centers around the world, this procedure is performed in the clinic setting without the use of analgesia. Although straightforward and not regarded as excessively painful, pin removal is a cause of anxiety for children, parents, and caregivers. Indeed, questions relating to the pain associated with the procedure and whether any analgesia would be administered are commonly encountered in the clinic.

Relatively little is known about the analgesia requirement for this procedure. The widespread practice of reassuring children and their families that the procedure is quick and mildly uncomfortable is one that has been passed from one generation of orthopaedic surgeons to the next and assumed to be best practice. To the best of our knowledge, there are no published articles that report on the analgesia requirement for this procedure. However, in a previous study conducted at this institution, parents or adult caregivers perceived that their children had pain during pin removal: among forty-one caregivers surveyed, ten (24%) thought that oral analgesia might have lessened the pain associated with the procedure, and one (2%) would have opted for sedation; none opted for general anesthesia.

The present study was an extension of our initial study. We wished to ascertain whether oral acetaminophen (a simple analgesic) or ibuprofen (a nonsteroidal anti-inflammatory medication) reduced the pain experienced during this procedure. Sedatives, such as midazolam and chloral hydrate, were not included for study. Sedative administration would have further stretched clinic resources and lengthened visit times because the children would have needed observation and monitoring of vital signs following the administration of such sedatives. Additionally, the risks associated with sedative agents may be serious and even life-threatening.

To our knowledge, this is the first randomized controlled trial to study this important issue relevant to every pediatric orthopaedist’s daily practice and the first study in which the children themselves were surveyed. Because the reporting of pain scores is subjective, we also recorded heart rate in order to have an objective measure.

**Materials and Methods**

This was an institutional review board-approved, randomized controlled trial conducted in a single tertiary referral center. The study is registered with ClinicalTrials.gov (identifier: NCT01944085).

All children who had undergone closed reduction and percutaneous pinning for a supracondylar humeral fracture or a lateral humeral condyle fracture between the ages of five and twelve years (inclusive) and who had two or three percutaneous pins in the elbow were invited to participate. Children with documented allergies to either of the medications or with documented cognitive impairments were excluded. Patient disposition is indicated in a CONSORT (Consolidated Standards of Reporting Trials) flow diagram (Fig. 1).

Results from our pilot study were used for the sample-size calculation. Sample size was calculated on the basis of our using a two-sample t test and \( \alpha = 0.05 \), for which \( n = 76 \) per group provided 90% power to detect an effect size of 0.53. As there were three groups, the sample size was increased to \( n = 80 \) per group.

**Protocol**

At the three or four-week visit following closed reduction and percutaneous pinning, all patients who fulfilled the inclusion criteria were invited to participate. Parents and caregivers were counseled beforehand to ensure no pain-relief medication was given to the child prior to the appointment.

On acceptance, informed consent was obtained from the parents or caregivers and the child was randomized to one of the three treatment groups.
by drawing a sealed envelope containing a ticket (labeled A, B, or C) from a box. The child was given the body-weight-appropriate medication (acetaminophen, ibuprofen, or the placebo, vitamin C) by a nurse in the treatment room and asked to return an hour later for pin removal. This nurse would be the only investigator who would know which treatment was administered. All participants and other members of the team were successfully blinded to the random assignment of each child to a treatment group.

The pin-removal procedure was performed by either one of two trained members of the team (S.N.S.A. and L.-L.O.), each using the same method. Each child was shown the Wong-Baker scale and asked to report a pain score at three time points: before pin removal, immediately following pin removal, and ten minutes after pin removal. The child’s heart rate was also recorded at these three time points with the use of a pulse oximeter (NPB-40; Nellcor Puritan Bennett, Pleasanton, California). No additional analgesic was prescribed to the child after pin removal.

**Statistical Analysis**

Demographic data and patient characteristics were summarized across treatment groups using the mean, standard deviation (SD), and range for patient age, and number and percentage of patients for categorical variables (see Appendix). A parametric (F-test) and nonparametric (Kruskal-Wallis) one-way analysis of variance (ANOVA) were used to compare pain scores and heart rates across treatment groups at baseline and at the two follow-up times (Figs. 2-A and 2-B, Table I). Change from baseline in pain score and heart rate were compared among groups using mixed-model longitudinal analysis of variance, adjusting for baseline values (Table II). In the mixed-model analysis, subjects were modeled as random effects; analgesic groups, follow-up times, and group × time interaction were modeled as fixed effects; baseline values were incorporated as a continuous covariate. Pairwise differences (95% confidence intervals [CIs]) in change from baseline among analgesia groups were calculated for the follow-up times immediately after and ten minutes after pin removal (Table III). Unadjusted p values are presented.
with the intent of deferring to the reader the choice of a multiple comparison approach. All analyses were performed using SAS version 9.2 statistical software (SAS Institute, Cary, North Carolina).

Source of Funding
Our institution’s research center provided the grant funding for this study.

Results
The study population comprised 240 children between the ages of five and twelve years (mean age, 7.4 ± 1.9 years), who were recruited over a thirty-eight-month period (October 2008 through December 2011). One hundred and fifty-six (65.0%) of the patients were male. No significant differences were found among the treatment groups for age, sex, ethnicity, number of pins, or side of injury (see Appendix).

Prior to pin removal, the mean baseline pain score (scale of 0 to 10) was 0.20 in the acetaminophen group, 0.18 in the ibuprofen group, and 0.20 in the vitamin C group (p = 0.974). Immediately after pin removal, mean pain score increased to 5.30, 5.19, and 4.95 (p = 0.825), respectively, and ten minutes after the procedure, diminished to 1.53, 0.88, and 1.10 (p = 0.135), respectively (Fig. 2-A and Table I). Heart rate followed a similar trend, increasing from mean baseline values of 90.3, 87.3, and 88.6 beats per minute (bpm) for acetaminophen, ibuprofen, and vitamin C, respectively, to 97.7, 94.8, and 95.3 bpm immediately following pin removal and 89.5, 88.5, and 87.1 bpm at ten minutes following removal (Fig. 2-B and Table I).

Comparisons of change from baseline in pain score and heart rate are presented in Table III. The estimated mean difference in pain score (and heart rate) between the acetaminophen group and the ibuprofen group was 0.10 (1.02 bpm) immediately following pin removal and 0.64 (2.03 bpm) ten minutes after pin removal, not exceeding 1.23 (4.97 bpm) and 1.29 (2.01 bpm) in respective absolute values with 95% confidence; the difference in pain score (and heart rate) between the acetaminophen group and the vitamin C group was 0.35 (1.31 bpm) immediately following pin removal and 0.43 (1.37 bpm) ten minutes after pin removal, not exceeding 1.48 (5.25 bpm) and 1.07 (2.41 bpm) in respective absolute values with 95% confidence; and the difference in pain score (and heart rate)
is required in exceptional circumstances. The clinic setting is reasonable, unless sedation or general anesthesia is associated with percutaneous pin removal in children. There-

Discussion

Our findings suggest that oral acetaminophen or ibuprofen does not significantly reduce the pain score or heart rate associated with percutaneous pin removal in children. Therefore, the current practice of pin removal without analgesia in the clinic setting is reasonable, unless sedation or general anesthesia is required in exceptional circumstances.

Confidence intervals provide a means of assessing the clinical relevance of a difference. Because the CIs obtained excluded a clinically relevant difference between acetaminophen, ibuprofen, and vitamin C, the three treatments can be said to be clinically equivalent. For all practical purposes, our study showed that there is no difference between acetaminophen and placebo, ibuprofen and placebo, or acetaminophen and ibuprofen as an analgesic for percutaneous pin removal in children. Regardless of which treatment was administered, children from all of the groups reported pain immediately after pin removal. On average, this resolved within ten minutes of the procedure. The emotional component of anxiety and fear generated from undergoing this procedure may itself manifest as perceived pain. In addition, we have never had to prescribe narcotic analgesics for pain control postoperatively or following pin removal in the outpatient clinic. Parents and caregivers at our clinic are advised to give acetaminophen and/or ibuprofen, guided by the amount of pain experienced by the child. No child has required stronger analgesia or narcotics, in our experience.

Limitations of the Study

From a psychological perspective, there appears to be a substantial component of fear and anxiety from undergoing this procedure, giving rise to the perception of pain as evidenced by the increase in pain scores and heart rates from baseline immediately after pin removal. Because we only measured subjective pain scores along with heart rate, we were unable to distinguish the physiological aspects from the emotional aspects of pain perception. Given the young cohort of patients, it would be difficult to assess to what degree pain was from actual noxious stimuli or from anxiety and fear.

A pain score and heart rate were obtained before both cast removal and pin removal. Thus, it is difficult to determine how much pain or anxiety originated from the cast removal, per se, compared with pin removal. Nevertheless, cast removal is routinely done in the clinic setting and is generally a well-tolerated, pain-free, and straightforward procedure.

Another limitation of this study is that the visual analog scale for pain that was provided to guide patients in this study could not account for the individual variability of pain interpretation. A possible fourth group in the study, one in which children would not receive any analgesia or placebo, would have added an additional dimension to this study. This was considered in the planning stages of this study but was subsequently decided against because many families whose child was randomized to this group probably would have withdrawn from the study. While the analgesic response in all three groups could reflect a placebo effect, in our opinion, this was unlikely for two reasons. First, for a child, the anticipatory anxiety associated with the procedure would almost certainly nullify, or substantially blunt, any placebo effect emanating from the memory of taking a prior analgesic medication. Second, the observed reactions in children who participated in this study and those who did not were very similar. Hence, we feel that any placebo effect from receiving the medication was minimal.

Recommendations

Better education of patients and parents may mitigate the anxiety and fear associated with the pin-removal procedure. Seeing the pins for the first time may be sufficient to frighten young children. Suggestions include incorporating play therapy involving dolls at earlier visits to demonstrate to younger children how the procedure would be carried out. Older children can be shown a video clip on a computer or tablet device as a distraction from looking at the pins or observing the procedure. Other nonpharmacological interventions may reduce situational anxiety and perceived pain intensity. Often, children perceive anxiety in their parents and this, in turn, increases their own anxiety. It is important to explain the procedure to children and their parents, so as to set expectations at the outset.

TABLE III Change from Baseline Differences in Pain Score and Heart Rate Among Groups

<table>
<thead>
<tr>
<th>LS Mean Change from Baseline*: Group Differences (95% CI)</th>
<th>Acetaminophen Minus Ibuprofen</th>
<th>Acetaminophen Minus Vitamin C</th>
<th>Ibuprofen Minus Vitamin C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediately after pin removal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain score</td>
<td>0.10 (−2.53 to 1.23)</td>
<td>0.35 (−0.78 to 1.48)</td>
<td>0.25 (−0.88 to 1.38)</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>1.02 (−2.94 to 4.97)</td>
<td>1.31 (−2.63 to 5.25)</td>
<td>0.29 (−3.65 to 4.24)</td>
</tr>
<tr>
<td>Ten minutes after pin removal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain score</td>
<td>0.64 (−0.002 to 1.29)</td>
<td>0.43 (−0.22 to 1.07)</td>
<td>0.22 (−0.86 to 0.43)</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>−0.83 (−3.68 to 2.01)</td>
<td>1.37 (−1.46 to 2.41)</td>
<td>2.21 (−0.63 to 5.04)</td>
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*Adjusted for baseline values. LS = least squares.
In conclusion, percutaneous pin removal can be done safely in the outpatient clinic without analgesia and is generally well tolerated by children. The risks and unwanted effects of general anesthesia, sedation, and stronger medication may be avoided. In addition, there are cost savings, shorter visit times for families, and better utilization of resources in the clinic when general anesthesia/stronger medication is not used.

This study demonstrated that the use of non-narcotic analgesia did not significantly reduce the pain score or heart rate associated with percutaneous pin removal in children. Therefore, the use of analgesia may not be necessary for pin removal in children.

Appendix

A table showing demographic data and patient characteristics is available with the online version of this article as a data supplement at jbjs.org.

References