Preincisional Bupivacaine in Posttonsillectomy Pain Relief

A Randomized Prospective Study

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Objective: To determine the effect of preincisional bupivacaine hydrochloride infiltration on postoperative pain after tonsillectomy.

Design: Prospective, randomized, double-blind clinical trial.

Setting: A secondary/tertiary referral center in Christchurch, New Zealand.

Patients: A volunteer sample of 70 patients, aged 16 to 42 years, with recurrent tonsillitis. Seven patients were excluded.

Interventions: After randomization, one group received 5 mL of 0.5% bupivacaine hydrochloride in the peritonsillar space, with the patient under general anesthesia. The other group received 5 mL of isotonic sodium chloride solution, with the patient under general anesthesia. Both groups underwent surgery with a standardized surgical and anesthetic technique.

Main Outcome Measures: Postoperative pain was assessed with a visual analog scale at 15 minutes and 1, 4, 12, 16, and 24 hours after the procedure. Postoperative analgesic requirement, length of admission, and antiemetic requirement were also assessed.

Results: No statistical difference was found between the 2 groups for postoperative pain by means of the visual analog scale at any time interval, nor was any statistical difference found for the other variables measured. A trend toward less pain in the immediate postoperative period in the group receiving bupivacaine was noted.

Conclusion: No statistically significant benefit is found for use of preincisional bupivacaine in tonsillectomy.


THE ROLE of local anesthetic (LA) infiltration in tonsillectomy is controversial. Studies have been published that support and refute the use of LA during tonsillectomy. Proponents of LA infiltration claim a reduction in postoperative pain that in some studies has shown a benefit up to 10 days postoperatively.1,2

Local anesthetic is thought to act by impeding noxious stimulation of C-fiber afferent neurons, thereby diminishing the excitability of dorsal horn neurons.1 The excitability produced by nociceptive stimuli may contribute to postoperative pain, even when procedures are performed under general anesthesia.1 Confirming the benefit of preincisional LA analgesia statistically has been difficult.

Tonsillectomy is known to cause severe pain postoperatively. The pain affects the patient’s nutrition, ability to return to work or school, discharge from the hospital, and satisfaction with the whole process. Our study was designed to determine whether LA has an effect on postoperative pain after tonsillectomy. Only older teenagers and adults were recruited to ensure that participants could understand and complete a visual analog scale (VAS). We excluded children to avoid observer bias when assessing pain.

RESULTS

Seventy patients were randomized into the LA and placebo groups. Seven patients were excluded because of breaches of anesthetic protocol (2 patients), postoperative analgesia protocol (2 patients), and changes in surgical technique (3 patients). A total of 31 patients (8 male) received LA. Thirty-two patients (9 male) received isotonic sodium chloride solution. The mean (SD) age was 23.4 (6.7) years and 23.1 (6.4) years for the LA and placebo groups, respectively. Of the 63 patients in the study, only 46 pa-
PATIENTS AND METHODS

Ethical approval was obtained from the Canterbury Ethic Committee (Christchurch, New Zealand); 70 patients, aged 16 to 42 years, were recruited for the study. All patients had attended an otolaryngology outpatient clinic with a history of recurrent tonsillitis. Patients with allergies, those with bleeding disorders, those using regular analgesic medication, and those with significant comorbidities were excluded. Patients were enrolled between May 1, 1998, and September 30, 1999.

All patients gave consent and were instructed on how to complete a VAS before surgery. A 100-mm horizontal VAS was used, where 0 mm represented no pain, and 100 mm, the worst pain imaginable. Patients were given a new VAS at each testing interval and were instructed to mark on the line the approximate level of their pain at that moment. The VAS has been found to be reliable and easily used in a number of studies.3,4 A standard anesthetic protocol was constructed for the study patients and administered by a number of anesthetists. The protocol consisted of the following:

- Premedication: acetaminophen, 20 mg/kg (up to 1.5 g) orally 40 minutes to 1 hour preoperatively; intravenous induction: fentanyl citrate (1 µg/kg), propofol (2 to 3 mg/kg), and midazolam chloride (0.1-0.2 mg/kg).
- Maintenance: oxygen and nitrous oxide in a ratio of 1:2 (oxygen saturation >94%), isoflurane (0.25%-2.00% end-tidal), and morphine, 0.1 mg/kg (maximum, 10 mg).
- Antiemetic: cyclizine hydrochloride, 1 mg/kg (maximum, 50 mg).
- Recovery: analgesia: morphine (0.02 mg/kg as needed to every 5 minutes if pain score ≥60 mm and respiratory rate ≥8/min); antiemetic: ondansetron (0.15 mg/kg as needed 1 time for nausea or vomiting; maximum, 8 mg).

The tonsillectomy was performed by 1 of 3 surgeons (N.R.V., S.S., and M.W.) with a standardized blunt dissection technique. No concurrent procedures were performed. All patients had been randomized into the LA group or placebo group (isotonic sodium chloride solution) by means of a sealed envelope to determine which solution was required, assuming a 2-tailed significance test at \( p = .05 \) than 0.81 (SD of 15 mm), 30 patients in each group were needed, to have a power greater than 0.81 (SD of 15 mm), 30 patients in each group were required, assuming a 2-tailed significance test at \( \alpha = .05 \).

Results between the 2 groups for each time were compared by means of a repeated-measures analysis of variance. No statistical difference between the 2 groups was found (\( F = 3.03, p = .09 \)). At 15 minutes, the LA group had a lower mean score (45 mm) than the placebo group (60 mm), but this was not significant. The overall mean for the LA group was less (36 mm) than that for the placebo group (42 mm), but again this was not significant.

The Figure shows a trend toward less pain in the LA group that was not statistically significant. All other variables (Table 2), including postoperative analgesic consumption, time to first codeine tablet, length of admission, and antiemetic requirement, showed no significant difference between the 2 groups. No patient suffered any adverse effect from LA infiltration (ie, respiratory obstruction or local anesthetic toxic effects).

This double-blinded, randomized, prospective study did not demonstrate any statistical benefit with preincisional bupivacaine treatment in patients undergoing tonsillectomy. The hypothesis behind preemptive analgesia is to prevent or reduce any “memory” of the painful stimulus in the nervous system.3 Subsequently, this re-

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The peritonsillar region is innervated by fibers from the glossopharyngeal nerve, the lesser palatine nerves, and the lingual nerve. The premise for LA injection is to block the glossopharyngeal nerve and lesser palatine nerve contributions to the fossa. That group did not mention injection technique was included. In our study, 3 surgeons performed tonsillectomy by means of a fixed anesthetic protocol, injection method, and operative technique. The method was constructed to closely resemble techniques in common practice in New Zealand. The VAS and postoperative analgesic requirements failed to show any benefit with LA.

Many studies have addressed the question of the effect of LA in tonsillectomy, with a marked variance in results. Jebeles et al assessed adenotonsillectomy in 1993 and found a statistically significant improvement in postoperative pain in 22 children with the use of LA. A reduction in pain in some cases within the LA group persisted until day 10. The same authors in 1991 had shown similar results with LA in 14 children undergoing tonsillectomy. Unfortunately, these studies suffer from inclusion of children and small sample sizes and lack detail regarding injection technique. Pain is a subjective and complex expression, and its assessment depends on personal experience, social and ethnic factors, and anxiety level as well as the patient's ability to describe the type and degree of pain on the basis of some frame of reference. The inclusion of children into such studies makes the assessment of pain even less precise. Our study was constructed to minimize the number of variables; only an older teenage and adult patient population was used, who completed their own VAS.

Dynamic assessments of pain, such as drinking water or opening the jaw, have been used in past studies, in an attempt to measure pain objectively. We elected to assess the patients’ pain by using a VAS at repeated intervals, the overall score of which would represent the contribution of constant and dynamic pain.

The majority of previous studies used electrocautery as the dissection method; however, recent evidence has shown that an electrocautery dissection technique increases postoperative morbidity in terms of pain, otalgia, and poor diet when compared with blunt dissection technique. The electrocautery dissection method used in other studies may have altered their results.

The peritonsillar region is innervated by fibers from the glossopharyngeal nerve, the lesser palatine nerves, and the lingual nerve. The premise for LA injection is to obtain blockade of these fibers. Descriptions of injection technique and amount of solution injected have been variable. In Jebeles and coworkers’ initial 1991 article, no mention of injection technique was included. In our study, 5 mL of 0.5% bupivacaine hydrochloride was injected into each peritonsillar space. Our assumption was that a high volume of solution within this area would anesthetize the multiple pain fibers supplying the tonsillar bed. In a recent study, the injection technique attempted to block the glossopharyngeal nerve and lesser palatine nerve contributions to the fossa. That group did
not mention the amount of LA administered at each site, however. In 2 studies by Schoem et al,6,10 small volumes of LA were used. In their adult study, only 1.8 mL of 0.5% bupivacaine hydrochloride was used. There was a concern in their study regarding toxicity, but the dose they used fell well short of the 225-mg adult toxic dose. Violaris and Tuffin11 assessed LA in patients by using the con-tralateral side as a control. We believe assessing pain in this way after tonsillectomy is difficult. Studies investigating the role of LA in tonsillectomy are limited in number; research using the structures outlined in this study may give answers to these issues.

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Studies showing a difference

<table>
<thead>
<tr>
<th>Source, y</th>
<th>No. of Patients</th>
<th>Participants</th>
<th>Pain Measure</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jebeles et al,1 1991</td>
<td>14</td>
<td>Children (6-18 y)</td>
<td>VAS</td>
<td>Showed benefit 10 d postoperatively</td>
</tr>
<tr>
<td>Jebeles et al,2 1993</td>
<td>22</td>
<td>Children (8-18 y)</td>
<td>VAS objective 100-mL water swallow</td>
<td>Significant decrease in pain 5 d postoperatively with smaller difference on day 10</td>
</tr>
<tr>
<td>Stuart et al,12 1994</td>
<td>44</td>
<td>Children (2-12 y)</td>
<td>VAS: 5 h postoperative then twice daily for 10 d</td>
<td>Significant decrease in pain 10 min postoperatively only</td>
</tr>
<tr>
<td>Johansen et al,13 1996</td>
<td>26</td>
<td>Adults (18-40 y)</td>
<td>VAS; assessment by independent observer</td>
<td>Significant difference on days 4, 6, 7, and 9 postoperatively</td>
</tr>
<tr>
<td>Molliex et al,4 1996</td>
<td>68</td>
<td>Children and adults (8-65 y)</td>
<td>VAS</td>
<td>Three groups: preincisional LA, placebo, and postinfiltration LA; LA groups showed decrease in pain in first 24 h</td>
</tr>
</tbody>
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Studies showing no difference

<table>
<thead>
<tr>
<th>Source, y</th>
<th>No. of Patients</th>
<th>Participants</th>
<th>Pain Measure</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Violaris and Tuffin,11 1989</td>
<td>15</td>
<td>Age ≥16 y</td>
<td>Self-assessment</td>
<td>Patients had LA- or placebo-soaked gauze in tonsillar fossa and were asked to compare sides</td>
</tr>
<tr>
<td>Broadman et al,14 1989</td>
<td>42</td>
<td>Children (4-12 y)</td>
<td>Pain 10-point objective scale</td>
<td>Patients divided into 4 groups; no pain difference but significant decrease in bleeding in epinephrine group</td>
</tr>
<tr>
<td>Schoem et al,10 1993</td>
<td>50</td>
<td>Children (3-16 y)</td>
<td>Subjective assessment by parents</td>
<td>No difference between groups; slightly less acetaminophen in LA group (not significant); very small amount of LA infiltrated</td>
</tr>
<tr>
<td>Schoem et al,6 1993</td>
<td>51</td>
<td>Age ≥16 y</td>
<td>Pain intake (subjective), oral intake, frequency of postoperative analgesia, pain on jaw opening (no VAS)</td>
<td>No difference; small amount of LA infiltrated; patients all had preincisional lidoceaine/epinephrine; posttonsillectomy infiltration</td>
</tr>
<tr>
<td>Ørntoft et al,15 1994</td>
<td>35</td>
<td>Age 15-36 y</td>
<td>Additional analgesia VAS</td>
<td>Measured 4 h postoperatively; 3 groups: preand post-LA infiltration, placebo</td>
</tr>
<tr>
<td>El-Hakim et al,9 2000</td>
<td>92</td>
<td>Age ≥16 y</td>
<td>VAS; frequency of postoperative analgesia; pulse rate and blood pressure changes</td>
<td>Measured 4, 6, and 8 h postoperatively and following day; 3 groups: LA, isotonic sodium chloride solution, and no injection</td>
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*LA indicates local anesthetic; VAS, visual analog scale.

There is no clear advice in the literature on what is an acceptable reduction in pain, measured with a VAS, in any situation. Most authors use a 100-mm VAS; some then seek a difference of 20 mm between the means of the 2 groups, whereas others accept a difference of 15 mm. Many previously published articles lack power.17 In our study, a difference of 15 mm between the means of the 2 groups gives a power of 0.81. Research into ways to improve tonsillectomy continues to be troubled by issues of this nature, as institutions seek to evaluate different operative techniques, anesthetic protocols, the benefit of perioperative corticosteroids, the benefit of perioperative antibiotics, and the use of nonsteroidal anti-inflammatory drugs. Randomized, prospective, double-blind studies in all of these areas are limited in number; research using the structures outlined in this study may give answers to these issues.

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REFERENCES


