Can Post-tonsillectomy Pain be Reduced by Topical Bupivacaine? a Prospective Randomized Trial

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ABSTRACT: INTRODUCTION: Post-operative pain and delayed oral intake can delay discharge after day-care tonsillectomy. OBJECTIVE: To assess the effectiveness of topical bupivacaine application in the tonsillar fossae for the relief of post-operative pain after tonsillectomy. STUDY DESIGN: Double blind prospective randomized trial. STUDY SETTING: Liaquat National postgraduate medical center, Karachi. SUBJECTS: 60 patients, aged 7 to 35 years, both male and female, attended otolaryngology clinic with history of recurrent tonsillitis admitted for day-care tonsillectomy. METHOD: After written informed consent from patient or parents/ guardian, patients were randomized into two groups, i.e. Group I and II both comprising 30 patients in each using sealed envelopes. Patients underwent tonsillectomy under general anesthesia according to standard procedure. At completion of procedure, Group I received bupivacaine 0.5% topical application with soaked swab tightly packed in both tonsillar fossae while Group II received topical 0.9% saline in both tonsillar fossae for 5 minutes. Main outcome measures: Postoperative pain in throat (visual analogue scale), need of analgesia, delay in start of oral food and water intake and need of readmission. RESULTS: The bupivacaine group was found to drink (p<0.001) and eat (p<0.001) earlier than the control group. The pain scores at one (p<0.001) three (p<0.001) and six (p<0.001) hours post-operatively were also found to be lower in the bupivacaine group than control group. Control group patients ask for analgesia earlier and more frequently than Bupivacaine group. Duration of stay in hospital was less in bupivacaine group than control group. CONCLUSION: Topical application of 0.5% bupivacaine provides better pain relief for post-tonsillectomy and facilitates early discharge in day-care tonsillectomy as compared to control group.

Key Words: Tonsillectomy; Pain; Postoperative period; Bupivacaine

INTRODUCTION: Tonsillectomy is one of the most commonly performed procedure in Otolaryngology. Nowadays tonsillectomy is carried out more as a day care surgery and this trend is increasing. Occasionally discharge from the day care surgery unit is not possible in these patients. The factors responsible for this include post-tonsillectomy pain, inadequate oral intake, nausea & vomiting and reactionary hemorrhage. It may cause post-operative depression in children who are unable to express themselves. Published data indicate that about 14-15% of day care tonsillectomy discharges are delayed due to inadequate pain control. Therefore such pain is challenging to manage effectively, and achievement of adequate analgesia is not only important but leads to an early return to eating which further reduces pain. The search for the ideal potent pain relieving drugs continues, although for many years it seemed as if analgesia, emesis, cardio respiratory depression, and addiction go hand in hand and are inseparable. Nowadays the trend towards controlling acute pain after tonsillectomy is increasing and instead of relying on the anesthetist to control pain in the post operative period by giving pain killers and sedatives; newer techniques have surfaced whereby post op pain can be controlled effectively after tonsillectomy. The good postoperative analgesia has attained an important role in oropharyngeal operations like tonsillectomy where quick return of cough reflex is essential with calm, quiet and co-operative patient. Various methods have been recommended to control post tonsillectomy pain e. g. sewing the faucial pillars, local anesthetic agents(topical or infiltrate), infiltration with local anesthetic and adrenaline, use of topical or systemic steroids injections and non-narcotic analgesics like diclofenac and paracetamol have also been tried for post tonsillectomy analgesia. All surgical procedures whether minor or major are followed by a degree of postoperative pain and discomfort. Pain begins with local tissue damage during surgery that causes the release of inflammatory substances. These substances lead to generation of electrical impulses at peripheral nociceptors. The electrical impulses are conducted by a delta fiber and C fibers to the spinal cord (transmission). Local anesthetics can block the transmission of the electrical impulses when applied to the wound. It is hypothesized that surgical trauma produces a barrage of pain signals to the spinal cord that act as a primary mechanism in sensitizing the central nervous system. The rationale behind several studies is that by providing analgesia using local anesthesia, these sensitizing neuroplastic changes can be reduced within spinal cord, leading to diminished post-operative pain. Less post-operative pain will result in early response to oral intake and early discharge. 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 Visual analogue scale (VAS) at repeated interval, the overall score of which would represent the contribution of constant pain and dynamic pain. HYPOTHESIS: Topical application of 0.5% bupivacaine in the tonsillar fossae after tonsillectomy can reduce pain, thus avoiding the use of systemic analgesia and facilitate drinking and eating during immediate post-operative period.

**SUBJECT AND METHODS:** Double blind prospective randomized trial.

**SETTING:** Liaquat National postgraduate medical center, Karachi. **DURATION OF STUDY:** The study was completed in one year. **SAMPLE SIZE:** 60 patients, 30 in each group. To detect significant difference on comparison of two means, considering time patient first drank in minutes m1=104.3, m2=159.5, s1=61.8, s2=48.8 (1 Hung et al. 2002), keeping power at 90% and significance level 5%, using formula n=((adv2)(s12+s22))/(m1-m2)2 (source: CPSP manual), a total of 21 patients is required in each group, and we decided to take 30 patients in each group.

**SAMPLING TECHNIQUE:** Non-Probability Convenience Sampling.

**SAMPLE SELECTION:** **INCLUSION CRITERIA:**

a) Patients undergoing tonsillectomy as a day care surgery for recurrent tonsillitis.
b) Patients between ages of 7 to 35 years.
c) Those using regular analgesics medications
d) Patients with language, visual, hearing, and cognitive impairment.
e) Illiterate enough not to understand the VAS
f) Patients undergoing following procedures.
g) Unilateral tonsillectomy
h) Tonsillar biopsy
i) Tonsillectomy for known carcinoma
j) Tonsillectomy in conjunction with palatal surgery
k) Tonsillectomy for peri-tonsillar abscess
l) Surgery in addition to tonsillectomy.

**Data Collection Procedure:** All the patients were instructed how to complete the VAS, a day before surgery. Proforma was filled in and the patients were instructed to do it in the same manner after the procedure. Patients were randomly assigned by drawing lots. A marked and coded envelopes for each patient (either soaked in 0.5% bupivacaine or 0.9% saline i.e. isotonic sodium chloride solution) was given to the anesthetist before he entered the operating room to be tightly packed in the tonsillar fossae by surgeon in both the tonsillar fossae for five minutes at the end of the procedure. In group I bupivacaine 0.5% and in group II a saline swab was used. The surgeon, patient, and other doctor in the ward who collected the data on proforma/questionnaire were all blinded to the solution used on the tonsil swab, as the opening of the sealed envelope and mixing of the swab with local anesthetic agent or saline was performed by anesthetist. Both groups underwent surgery with a standardized surgical and anesthetic technique. The surgical procedure involves removal of both the tonsils by cautery method performed by single surgeon.

**DATA COLLECTION TOOL:** All relevant information regarding the study was gathered onto the proforma (appendix) before being transferred to the computer for further analysis. **MAIN OUTCOME MEASURES:**

- Pain scores which were assessed at fixed interval i.e. one, three and six hours postoperatively using visual analogue scale (VAS)
- Time when patient first ate, drink
- Need for systemic analgesia.
- The delay in discharge and need for readmission due to pain were also recorded.

Patients complaining of pain or asking for pain relief were given analgesics drug. In our hospital we routinely prescribed Syrup Brufen (Ibuprofen) for post-operative analgesia after 4 hours when oral intake is allowed or injection I/M Diclofenac sodium, and to evaluate the intake, all the patients were reminded that IV fluids should be cancelled when they felt well enough to eat.

**DATA ANALYSIS:** Statistical analyses performed with statistical package for Social Sciences (SPSS) version 13.0. Results are presented as mean ± SD for continuous variables i.e. age, duration of symptoms and frequency/ percentage for qualitative variables. The Mann-Whitney test is used to compare the bupivacaine and saline groups with respect to the amount of analgesic drugs and need for readmission. The two –tailed unpaired Student t test is used to compare the delay until patient first drink/ate after the procedure. The VAS score of the placebo group and the bupivacaine is compared with a repeated-measures analysis variance. On the remaining variables, chi-squared test is used to compare two proportions. P-Value < 0.05 is considered significant.

**RESULTS:** There were 60 patients, 30 in Group I and 30 in the Group II. Age range was 7 to 35 years.

**Figure 1:** Scores for treatment and control group.

<table>
<thead>
<tr>
<th>Pain scores</th>
<th>Bupivacaine Mean ± SD</th>
<th>Control Mean ± SD</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>First hr</td>
<td>4.07 ± 1.78</td>
<td>6.47 ± 1.54</td>
<td>-37%</td>
</tr>
<tr>
<td>Third hr</td>
<td>2.80 ± 1.24</td>
<td>6.80 ± 1.78</td>
<td>-59%</td>
</tr>
<tr>
<td>Sixth hr</td>
<td>1.67 ± 2.10</td>
<td>5.31 ± 2.15</td>
<td>-68%</td>
</tr>
</tbody>
</table>
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Patients are more likely to swallow when they are in less discomfort. After starting oral intake post-operatively, patients are more likely to eat and drink more comfortably. This study shows that both eating and drinking started earlier following topical application of bupivacaine. Use of bupivacaine did not significantly affect rate of discharge. None out of 60 patients reported any other complication like hemorrhage or readmission due to pain. Because this study is not large enough to assess whether topical application would have an effect on post-operative admission rates. However admission and post-tonsillectomy hemorrhage rates were not the primary outcomes measures in this study.

**DISCUSSION:**

Tonsillectomy is a commonly performed procedure and can be associated with significant morbidity including pain, difficulty in swallowing, dehydration and bleeding. It may cause post-operative depression in children who are unable to express themselves. The raw area left after tonsillectomy operation is a source of pain postoperatively through the release of certain chemicals and enzymes. These allogeneic substances bring about hyperalgesia, characterized by a decrease in pain threshold and often spontaneous pain. The peripheral biochemical mechanism at the site of operation with arachidonic acid metabolites to mediate pain and inflammation may explain the post-tonsillectomy pain. Magnitude and standard deviation of age bupivacaine group is 14.20 ± 5.22 while mean and standard deviation of control group who received 0.9 percent saline is 15.13 ± 6.78. Mean and standard deviation of duration of stay in hospital is 0.43 ± 0.62 in bupivacaine group while its 1.47 ± 0.62 in control group. So duration of stay in hospital was less in bupivacaine group than control group. The mean (standard deviation SD) of the time of first ate for the bupivacaine group was 4.80 (SD =1.267Hours) and for control group was 7.03 (SD=2.356 Hours) with p value of (p<0.001). The mean of the time of first drank for the bupivacaine group was 4.13 (SD=0.730 Hours) and for control group was 5.90 (SD=1.971 Hours) with p value of (p<0.001) which shows significant reduction in mean time first drink and first eating between the bupivacaine group and the control group. There was significant reduction in mean pain score at one hour (p<0.001), three hours (p<0.001) and six hours (P<0.001) post-operatively in bupivacaine group. Request for analgesia by the patient is one of the indicators for subjective pain. Overall percentage of need of analgesia for 60 patients found out to be 28 patients (46.7%), whereas 32 (53.3%) did not need analgesia. Out of these 28 patients Control group 25 patients demanded for analgesia earlier and frequently than Bupivacaine group 3 patients. We found that the pain score was significantly lower in the bupivacaine group compared to control group in day-care tonsillectomy.
of postsurgical pain can be minimized by reducing the tissue damage. Post-operative use of balanced analgesia, regular assessment and assurance of patient can control the pain successfully. Here local analgesic drug in our study that is bupivacaine 0.5% proved itself to be effective in relieving post-tonsillectomy pain when applied locally as infiltration method carries life threatening risks. This protracted pain relief resulting by single use of bupivacaine cannot be explained by prolonged presence of the local anesthetic in the area of the surgery. An explanation for this long acting pain relief might be that the neural blockade prevents nociceptive impulses from entering the central nervous system immediately after the surgery when applied to raw area and this suppresses formation of the sustained hyper excitable state responsible for the maintenance of post-operative pain. Local anesthetics induce the anti nociceptive effect by acting on the nerve membrane; however, these affect many membrane-associated proteins in any tissue. They can inhibit the release and action of agents like (prostaglandin, lysosomal enzymes, etc.) which sensitize and stimulate the nociceptors participating in inflammation. Previous, in different studies certain approaches to post tonsillectomy pain reduction were reported which include: Attempts to reduce tissue stimulation and irritation by sewing of faucial pillars have been advocated for post tonsillectomy analgesia but Ramjitam & Singh have reported that suturing of pillars on raw tonsil bed by three zero catgut does not relieve pain and take more time. Sub capsular injection of 10ml of 0.5% lignocaine with adrenaline in 84 adult tonsillectomy patients halved the blood loss and made the dissection easier but there was a rise of blood pressure and heart rate due to systemic effect of adrenaline. This method would have an additional disadvantage in our setup where we use Halothane for maintenance of general anesthesia. Effect of tonsilar infiltration with local anesthetics Bupivacaine on post tonsillectomy pain has been documented. Moliex et al have shown that post-operative infiltration of 0.25% Bupivacaine lowers the postoperative pain also supplemental analgesics consumption is reduced while as Strubb et al did not report any reduction in postoperative pain in there study but blood loss was definitely reduced due to the local bupivacaine infiltrated.

A single preoperative IV dose of Dexamethasone for tonsillectomy in children 10 facilitate an earlier return to a full/semi full diet on 3/4th postoperative day. There was no difference in postoperative pain and nausea/emesis. Use of anesthetic gargling solutions had been employed to prevent post-tonsillectomy pain but these anaesthetize the pharynx, exposing the patient to the danger of diminished gag reflex and aspiration. Injection of penicillin-steroid local anesthetic mixture into the tonsilar fossae was believed to have ideal analgesic effect but Rundle conclude that this method did not alleviate pain any more than IM injection of Depo-Penicillin. NSAIDS have been employed for post tonsillectomy analgesia. In the treatment of postoperative pain after tonsillectomy the combination of pre and post-operative administration of Diclofenac suppositories resulted in significantly lower consumption of rescue analgesia and is thus preferable to administration solely postoperative. Oral paracetamol has been shown to be superior analgesic than the suppository. Ketorolac has been found to reduce the postoperative use of morphine for post tonsillectomy analgesia. But Jugkin & al have advocated that intraoperative ketorolac should be avoided because in there study of post tonsillectomy bleeding, intraoperative ketorolac caused 17% postoperative bleeding compared to 4.4% and in patients who received traditional opioid analgesic. Tonsillectomy because of its low primary hemorrhage rate (0.14-3.5%) was thought appropriate for day care surgery. Pringle showed in his study that 80% parents thought postoperative one night stay is suitable for pain, nausea, and vomiting and postoperative course. In our study we tried to search for an effective method of postoperative analgesia without necrosis and sedation in tonsillectomy. Children below the age of 7 years are excluded as it was difficult to assess the effect of the treatment on postoperative pain. We use VAS scoring using faces and descriptive words to assess the patients’ pain at repeated intervals. The absolute visual analogue scores can be difficult to interpret, but when focusing mainly on the repeated measures on the same patient, interpretable comparison between different stages can be made. Different researchers use different methods to assess the postoperative pain score, which might be the reason for variance in the result obtained. The operative technique and experience of the surgeon may also cause variance in the results. To avoid these confounding variables, a single surgeon was selected to perform tonsillectomy by means of a fixed protocol. Intra operative blood loss was not quantified because the purpose of the study was only to assess post tonsillectomy pain. There was no report of excessive bleeding intraoperative or any post-operative hemorrhage seen. And it was also noted that patients who were pain free were discharge earlier.

CONCLUSION: Our study has shown that topical use of local analgesic, Bupivacaine 0.5% can effectively reduce pain, avoid use of systemic analgesics and allow patients regain consciousness without pain in the throat in early post-operative period following tonsillectomy. In this way patient remains co-operative, approachable and has intact pharyngeal and laryngeal reflexes postoperatively and this facilitates eating and drinking earlier. A larger prospective study of similar design is required to assess whether this could make an impact on day-case tonsillectomy admission rate or shorter hospitalization time.

REFERENCES:
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