

## Analgesic Efficacy of Topical 0.25% Levobupivacaine in the Control of Postoperative Pain in Children After Tonsillectomy: A Double Blind, Prospective, Randomized, Controlled Study

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### Abstract

**Background:** Tonsillectomy or adenotonsillectomy have a high incidence of postoperative pain. Topical approaches have the advantage of local pain control with minimal systemic side effects and good patient acceptability. Levobupivacaine may be useful in pediatric practice. We preferred topical levobupivacaine in our study because of the lack of enough data in the literature about its topical use in pediatric tonsillectomy cases for postoperative analgesia. **Material & Methods:** A double blind prospective randomised controlled clinical trial conducted in 54 children aged between 4 and 12 years, ASA I-II, of both sex, suffering from recurrent tonsillitis, chronic tonsillitis, tonsillo-adenoid syndrome, scheduled for elective tonsillectomy and/or adenotonsillectomy in Department of Anaesthesiology, M B Government Hospital, attached to RNT Medical College, Udaipur, Rajasthan, India. Informed written consent from parents of each patient participating in the study was obtained. Patients were evaluated using behavioural scale (FLACC scale) Face, Legs, Activity, Cry, consolability at the 1<sup>st</sup>, 4<sup>th</sup>, 12<sup>th</sup>, 18<sup>th</sup>, 24<sup>th</sup>, 48<sup>th</sup> hrs, 3<sup>rd</sup> day, 4<sup>th</sup> day and 7<sup>th</sup> day postoperatively. The total number of doses of rescue analgesic required by each patient in the first 48 hrs was noted. Postoperative complications like post-tonsillar bleeding from the operating site was noted and re-explored. A post hoc test was used to assess intergroup differences, P<0.05 was considered as statistically significant. **Results:** In the present study, the two groups (control versus levobupivacaine group) were statistically comparable regarding mean age, mean weight, sex, mean body weight, ASA grading, diagnoses, surgery performed and the duration from induction to placement of swabs (completion of surgery) which was statistically non-significant (P>0.05) in between groups. Pain scores in Group L v/s Group C at 4<sup>th</sup> hr were 1.22 ± 0.698 v/s 2.85 ± 2.143; at 12<sup>th</sup> hr were 1.44 ± 1.188 v/s 4.52 ± 0.935; at 18<sup>th</sup> hr were 1.30 ± 1.353 v/s 4.33 ± 1.209; at 24<sup>th</sup> hr were 1.37 ± 1.214 v/s 4.30 ± 1.37; and at 48<sup>th</sup> hr were 1.11 ± 0.698 v/s 2.89 ± 0.698 respectively (P<0.001). Pain scores were comparable in the rest of the hours and days, P>0.05. The total number of doses of rescue analgesic was significantly higher in Group C (58 doses) as compared to Group L (18 doses), P<0.001. **Conclusion:** We conclude that topical application of swabs soaked in 10 ml of 0.25% levobupivacaine for 5 min after tonsillectomy in the tonsillar bed is a simple and effective approach and therefore be safely recommended as a safe and reliable method of postoperative pain relief after tonsillectomy.

**Keywords:** Tonsillectomy, Pain Score, Levobupivacaine, FLACC Scale.

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### Introduction

Adenotonsillectomy is one of the most common ambulatory surgical procedures performed to children. Tonsillectomy or adenotonsillectomy have a high incidence of postoperative pain. Significant pain associated with tonsillectomy is reported in 20-50% of children undergoing tonsillectomy[1]. Pain can affect patients' nutrition, ability to return to work/school, discharge from hospital and overall satisfaction of the procedure. Pain results in the activation of physiologic stress response, which causes significant changes in the cardiovascular system, metabolism, the immune system, and organs. Despite the use of different surgical techniques, the problem of effective post tonsillectomy pain relief remains a clinical challenge[2].

These surgical procedures are associated with increased risk of respiratory adverse events, bleeding, pain after surgery, and postoperative nausea and vomiting (PONV)[3-5].

Analgesia is often provided with a combination of small dose opioid and non-steroidal anti-inflammatory drugs (NSAIDs)/acetaminophen, as they have opioid sparing effect. The route of administration of the above-mentioned group of drugs still remains uncertain for post tonsillectomy pain control. We know that analgesic effects of anti-inflammatory drugs are effective for post tonsillectomy patients but these agents are also strong inhibitors of prostaglandins and platelets and may cause significant postoperative bleeding[6].

Intraoperative Peritonsillar infiltration with local anaesthetics has been proposed for post-operative analgesia, but the results are conflicting. Some studies showed that local anaesthetics reduce the intensity of post-operative pain[7] while others, found no significant effect of local anaesthetic infiltration[8]. The infiltration technique carries the risk of accidental intravascular injection which can lead to convulsions and cardiac arrhythmias. Indeed, life-threatening upper airway obstruction after bupivacaine infiltration has been reported in

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children[9]. In order to avoid potential side effects of the infiltration technique, topical use of local anaesthetics has been proposed.

Topical approaches have the advantage of local pain control with minimal systemic side effects and good patient acceptability. Local anaesthetics, anti-inflammatory agents and opioids are given in solution form by rinsing the oral cavity for oropharyngeal pain control[10]. Also local anaesthetics are infiltrated to the base of the tonsils for analgesia. Studies regarding topical swab application of local anaesthetics[11,12] in the tonsillar fossa have been carried out. Similarly, lidocaine, ketamine and morphine in the form of spray at tonsillar fossa were found effective for postoperative analgesia[13] without any complications. Tramadol has also been used topically to control the post tonsillectomy pain[14]. For this reason we selected the topical route for post-tonsillectomy pain relief.

Levobupivacaine is the S-enantiomer of bupivacaine and is believed to have some advantages like less motor blockade and more prolonged postoperative analgesia compared with bupivacaine[6]. Levobupivacaine may be useful in pediatric practice. We preferred topical levobupivacaine in our study because of the lack of enough data in the literature about its topical use in pediatric tonsillectomy cases for postoperative analgesia.

### Materials & methods

A double blind prospective randomised controlled clinical trial conducted in 54 children aged between 4 and 12 years, ASA I–II, of both sex, suffering from recurrent tonsillitis, chronic tonsillitis, tonsillo-adenoid syndrome, scheduled for elective tonsillectomy and/or adenotonsillectomy in Department of Anaesthesiology, M B Government Hospital, attached to RNT Medical College, Udaipur, Rajasthan, India. Informed written consent from parents of each patient participating in the study was obtained. All patients under study were subjected to a detailed pre-anaesthetic examination and routine preoperative investigations were carried out.

### Exclusion Criteria

Patients with a known history of allergy, sensitivity, or contra-indication to opioids or local anaesthetic, renal or liver impairment, acute pharyngeal infection, a history of asthma, or clotting disorder were excluded.

### Methods

As per study protocol, the patients who could be followed up for the 7 days for postoperative analgesia were included for the data analysis of two groups. Hence 67 patients were included randomly in the study initially in both the groups. 54 patients (27 in each group) who could be followed up for 7 days were statistically analysed. The study patients were randomly divided using opaque sealed envelope technique based on the swab applied as follows:

**Group L (n=27) Levobupivacaine Group:** received cotton swabs soaked with 10 ml of 0.25 % levobupivacaine (preservative free 0.25% levobupivacaine 2.5 mg/ml; Neon Laboratories Limited) in both the tonsillar fossae (5 ml each) post tonsillectomy.

**Group C (n=27) Control Group:** received cotton swabs soaked in 10ml saline in both the tonsillar fossae (5 ml each) post tonsillectomy.

### Anaesthesia Technique

All patients were fasted for 4 hrs. All patients were premedicated with oral midazolam 0.5 mg/kg (preservative free midazolam hydrochloride syrup 2mg/ml; Ranbaxy Pharmaceutical Inc.) and intravenous cannulation was done.

All operations were performed by the same surgeon, who was blind to the study drug, using a standardized snare dissection technique.

In the operating room: Routine monitoring (ECG, non-invasive blood pressure, pulse rate, oxygen saturation and temperature) was used. Patient was premedicated with Inj. glycopyrrolate (0.01mg/kg), tramadol (2mg/kg), ondansetron (0.1mg/kg) given intravenously. After induction with intravenous propofol 2 mg/kg and atracurium 0.5 mg/ kg, patient was intubated with an appropriately sized, cuffed/uncuffed, naso-tracheal tube under direct laryngoscopy. Anaesthesia was maintained with O<sub>2</sub> and N<sub>2</sub>O (50:50 ratio), propofol 2 mg/kg/h and atracurium 0.1mg/kg intermittently. After tonsillectomy but before reversal, swabs soaked in 0.25% levobupivacaine (Group L) or saline (Group C) were applied for 5 min. Then patient was reversed using Inj. neostigmine 0.08 mg/kg and Inj. glycopyrrolate 0.02 mg/kg IV. The trachea was extubated after proper oropharyngeal suctioning and adequate reversal of muscle power.

Injection Tramadol (2 mg/kg) diluted in 50 ml saline, infusion over 15 min was given as a rescue analgesic, when the patient complaints of pain or FLACC score >4 or both, any time after surgery within the first 48 hrs with a minimum duration of 6 hours between each dose.

All patients received oral paracetamol (20 mg/kg) and amoxicillin (45 mg/kg) in form of paediatric suspensions/tablets at 6 hrs postoperatively which was repeated every 6 hourly. Amoxicillin was given for 5 days and paracetamol for 3 days as a routine clinical protocol in our setup.

The patient was observed in the ward until 48 hrs postoperatively and then discharged. Patient was called for follow-up on the 3<sup>rd</sup>, 4<sup>th</sup> and the 7<sup>th</sup> postoperative days. The patients who had complete follow up for 7 days regarding postoperative analgesia and complication were enrolled in the study. If a patient is lost to follow up was excluded from the study. Hence topical swabs were applied to a larger number of patients to compensate for drops outs.

### Data Recording

The time of application of topical swabs at tonsillar site at the end of surgery was considered as 0 hrs. Data related to postoperative analgesia were recorded referring to this time of 0 hrs.

#### A. FLACC Score[15]

Patients were evaluated using behavioural scale (FLACC scale) Face, Legs, Activity, Cry, Consolability at the 1<sup>st</sup>, 4<sup>th</sup>, 12<sup>th</sup>, 18<sup>th</sup>, 24<sup>th</sup>, 48<sup>th</sup> hrs, 3<sup>rd</sup> day, 4<sup>th</sup> day and 7<sup>th</sup> day postoperatively.

FLACC Behavioral Scale

| Categories   | flacc scoring                                |   |  |
|--|--|---|--|
|  | 0  | 1   | 2  |
| <b>Face</b>  | No particular expression or smile            | Occasional grimace or frown, withdrawn, disinterested.                      | Frequent to constant frown, clenched chin            |
| <b>Legs</b>  | Normal position or relaxed                   | Uneasy, Restless, tense   | Kicking or legs drawn up                             |
| <b>Activity</b>  | Lying quietly, normal position, moves easily | Squirming, shifting back and forth, tense                                   | Arched, rigid, or jerking                            |
| <b>Cry</b>   | No cry (awake or asleep)                     | Moans or whimpers occasional complaint                                      | Crying steadily screams or sobs; frequent complaints |
| <b>Consolability</b>   | Content, relaxed                             | Reassured by occasional touching, hugging, or being talked to; distractable | Difficult to console or comfort                      |
| <b>How to use the FLACC; In patients who are awake:</b> observe for 1 to 5 minutes or longer. Observe legs and body uncovered. Reposition patient or observe activity. Assess body for tenseness and tone. Initiate consoling interventions if needed. |  |   |  |
| <b>In patients who are asleep:</b> observe for 5 minutes or longer. Observe body and legs uncovered. If possible, reposition the patient. Touch the body and assess for tenseness and tone   |  |   |  |

Minimum score is 0 (no pain), maximum score is 10 (maximum pain) FLACC score of more than 4 indicates pain, requiring analgesic.

**B. Rescue analgesic**

Injection Tramadol (2 mg/kg) diluted in 50 ml saline, infusion given over 15 min was given as a rescue analgesic, whenever the patient complains of pain or FLACC >4 or both, at any time after surgery within the first 48 hrs with a minimum duration of 6 hours between each dose.

The total number of doses of rescue analgesic required by each patient in the first 48 hrs was noted. The time interval in which the rescue analgesic was given was also noted.

**C. Postoperative Complaints**

Postoperative complaints like fever, nausea, vomiting, otalgia, pain in the throat were asked for at the 1<sup>st</sup>, 4<sup>th</sup>, 12<sup>th</sup>, 18<sup>th</sup>, 24<sup>th</sup>, 48<sup>th</sup> hrs, 3<sup>rd</sup> day, 4<sup>th</sup> day and 7<sup>th</sup> day postoperatively. The complaints were noted and treated accordingly.

Fever was treated with tepid sponging and paracetamol was given every 6 hourly; nausea and vomiting with ondansetron (2mg/kg); otalgia and pain in throat with dexamethasone (0.5mg/kg) IV.

**D. Postoperative Complications**

Postoperative complications like post-tonsillar bleeding from the operating site was noted and re-explored.

**Statistical Analysis**

Data were entered and analysed with the help of MS Excel, Epi info 6 and SPSS. Qualitative or categorical data like patient distribution according to sex, age, airway assessment, indication for surgery, surgery performed, FLACC score, rescue analgesic requirement, post-operative complaints and complications were presented as number (proportion) and compared with Chi-square test. A post hoc test was used to assess intergroup differences, P<0.05 was considered as statistically significant.

**Results**

In the present study, the two groups (control versus levobupivacaine group) were statistically comparable regarding mean age, mean weight, sex, mean body weight, ASA grading, diagnoses, surgery performed and the duration from induction to placement of swabs (completion of surgery) which was statistically non-significant (P>0.05) in between groups (table 1-3).

**Table 1: Distribution of patients according to different age groups**

| Age (yrs)                | Group C (n=28) | Group L (n=28) | Total      | P-value    |
|--------------------------|----------------|----------------|------------|------------|
| <b>Age (yrs)</b>         |                |                |            |            |
| 4-8                      | 10(37.03%)     | 13(48.14%)     | 23(50%)    | P>0.05(NS) |
| 8-12                     | 17(62.96%)     | 14(62.96%)     | 31(50%)    |            |
| Mean ±SD                 | 9±2            | 7.8±1.9        | 8.4±2.5    |            |
| <b>Sex</b>               |                |                |            |            |
| Male                     | 14(51.85%)     | 18(66.66%)     | 32(59.3%)  | P>0.05(NS) |
| Female                   | 13(48.14%)     | 9(33.33%)      | 22(40.7%)  |            |
| <b>Body weight (kg)</b>  |                |                |            |            |
| 5-<15                    | 10(37.03%)     | 11(40.74%)     | 21(38.88%) | P>0.05(NS) |
| 15-30                    | 17(62.96%)     | 16(59.25%)     | 33(61.11%) |            |
| Mean ±SD                 | 14±5.2         | 15±5.55        | 14.8±5.3   |            |
| <b>Diagnosis</b>         |                |                |            |            |
| Tonsilloadenoid syndrome | 14(51.9%)      | 17(63.0%)      | 31(57.4%)  | P>0.05(NS) |
| Recurrent tonsillitis    | 6(22.2%)       | 5(18.5%)       | 11(20.4%)  |            |
| Chronic tonsillitis      | 7(25.9%)       | 5(18.5%)       | 12(22.2%)  |            |
| <b>Type of Surgery</b>   |                |                |            |            |
| Adenotonsillectomy       | 14(51.9%)      | 17(63.0%)      | 31(57.4%)  | P>0.05(NS) |
| Tonsillectomy            | 13(48.1%)      | 10(37.0%)      | 23(42.6%)  |            |

**Table 2: Distribution of patients according to airway examination**

| Variable                     | Group C (n=27) | Group L (n=27) | Total     | P-value     |
|------------------------------|----------------|----------------|-----------|-------------|
| <b>1.Dentition</b>           |                |                |           |             |
| -Normal                      | 25(92.6%)      | 25(92.6%)      | 50(92.6%) | P>0.05 (NS) |
| -Missing Tooth               | 2(7.4%)        | 2(7.4%)        | 2(7.4%)   |             |
| <b>2.Mallampatti grading</b> |                |                |           |             |
| I                            | 1(3.7%)        | 1(3.7%)        | 2(7.14%)  | P>0.05 (NS) |
| II                           | 24(88.9%)      | 25(92.6%)      | 49(90.7%) |             |
| III                          | 2(7.4%)        | 1(3.7%)        | 3(5.6%)   |             |
| IV                           | 0(0%)          | 0(0%)          | 0(0%)     |             |

**Table 3: Distribution of patients according to the duration from induction to placement of swabs (at completion of surgery)**

| Duration (min) | Group C (n=28) | Group L (n=28) | Total     | P-value     |
|----------------|----------------|----------------|-----------|-------------|
| 20-<35         | 15(55.6%)      | 15(55.6%)      | 30(55.6%) | P>0.05 (NS) |
| 35-<50         | 9(33.3%)       | 9(33.3%)       | 18(33.3%) |             |
| 50-<65         | 3(11.1%)       | 3(11.1%)       | 6(11.1%)  |             |

Postoperative pain scores in the present study were significantly low in the Levobupivacaine group (Group L) as compared to the control group (Group C) at the 4<sup>th</sup>, 12<sup>th</sup>, 18<sup>th</sup>, 24<sup>th</sup> and 48<sup>th</sup> hr postoperatively (P<0.001). Pain scores in Group L v/s Group C at 4<sup>th</sup> hr were 1.22 ± 0.698 v/s 2.85 ± 2.143; at 12<sup>th</sup> hr were 1.44 ± 1.188 v/s 4.52 ± 0.935; at 18<sup>th</sup> hr were 1.30 ± 1.353 v/s 4.33 ± 1.209; at 24<sup>th</sup> hr was 1.37 ± 1.214 v/s 4.30 ± 1.37;

and at 48<sup>th</sup> hr were  $1.11 \pm 0.698$  v/s  $2.89 \pm 0.698$  respectively ( $P < 0.001$ ). Pain scores were comparable in the rest of the hours and days,  $P > 0.05$  (figure 1).

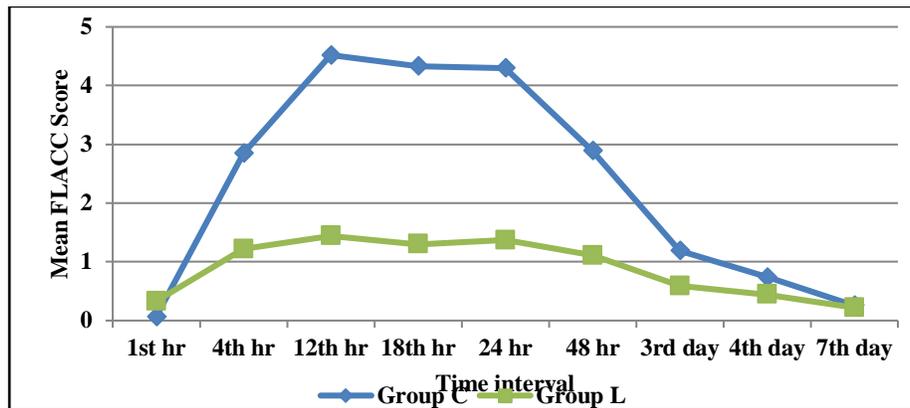


Fig.1: Comparison of post-operative pain as assessed by Face, Leg, Activity, Cry, Consolability (FLACC) score

Overall rescue analgesic requirement during the first 48 hrs postoperatively was noted. It was found that only 11 patients (39.29%) of Group L [10 patients (37.03%) - 1 dose; 1 patient (3.7%) - 2 doses; 2 patients (7.40%) - 3 doses] required rescue analgesic as compared to all 27 patients (100%) in Group C [2 patients (7.47%) - 1 dose; 19 patients (70.37%) - 2 doses; 6 patients (22.2%) - 3 doses]. The difference was highly significant,  $P < 0.001$ . The total number of doses of rescue analgesic was significantly higher in Group C (58 doses) as compared to Group C (18 doses),  $P < 0.001$  (table 4).

Table 4: Comparison of rescue analgesic requirements at various time intervals in the two groups

| Time interval | Number of doses                                | Number of patients |                | P-value                |
|---------------|--|--------------------|----------------|------------------------|
|               |  | Group C (n=27)     | Group L (n=27) |                        |
| 0-12 hrs      | No. of patients requiring rescue               | 24(88.88%)         | 6(22.22%)      | <b>0.001 HS</b>        |
|               | Patient distribution according to no. of doses |                    |                |                        |
|               | 1 dose   | 15(55.6%)          | 5(18.51%)      |                        |
|               | 2 doses  | 8(29.62%)          | 1(3.7%)        |                        |
|               | Total doses of rescue analgesic                | 31                 | 7              | <b>0.0000 HS</b>       |
| >12-24 hrs    | No. of patients requiring rescue               | 21(77.77%)         | 6(22.2%)       | <b>0.003 HS</b>        |
|               | Patient distribution according to no. of doses |                    |                |                        |
|               | 1 dose   | 21(77.77%)         | 6(22.2%)       |                        |
|               | 2 doses  | 0(0.00%)           | 0(0.00%)       |                        |
|               | Total doses of rescue analgesic                | 21                 | 6              | <b>0.003 HS</b>        |
| >24-48 hrs    | No. of patients requiring rescue               | 6(22.22%)          | 5(18.51%)      | <b>&gt;0.05 NS</b>     |
|               | Patient distribution according to no. of doses |                    |                |                        |
|               | 1 dose   | 6(22.22%)          | 5(18.51%)      |                        |
|               | 2 doses  | 0(0.00%)           | 0(0.00%)       |                        |
|               | Total doses of rescue analgesic                | 6                  | 5              |                        |
| 0-48 hrs      | No. of patients requiring rescue               | 27(100%)           | 13(48.14%)     | <b>0.02 &lt;0.05 S</b> |
|               | Patient distribution according to no. of doses |                    |                |                        |
|               | 1 dose   | 2(7.47%)           | 10(37.03%)     |                        |
|               | 2 doses  | 19(70.37%)         | 1(3.7%)        |                        |
|               | 3 doses  | 6(22.2%)           | 2(7.40%)       |                        |
|               | Total doses of rescue analgesic                | 58                 | 18             | <b>&lt;0.001 HS</b>    |

In the present study there was minimal occurrence of post operative complaints like nausea, vomiting, fever, otalgia, pain in the throat and complications like post-tonsillectomy bleeding. All the complaints except pain in the throat were statistically comparable in both the groups ( $P > 0.05$ ) at all times (hours and days). Incidence of pain in the throat was significantly higher ( $P < 0.001$ ) in Group C [ $n=26(96.29\%)$ ] on the first day as compared to Group L [ $n=5(18.51\%)$ ]. Later on, till 7 days throat pain was statistically comparable in two groups  $P > 0.05$  (table 5).

Table 5: Comparison of Post-operative morbidity in both the groups

| Complaints         | 1 <sup>st</sup> day |    | 2 <sup>nd</sup> day |   | 3 <sup>rd</sup> day |   | 4 <sup>th</sup> day |   | 7 <sup>th</sup> day |   |
|--------------------|---------------------|----|---------------------|---|---------------------|---|---------------------|---|---------------------|---|
|                    | Group               |    | Group               |   | Group               |   | Group               |   | Group               |   |
|                    | C                   | L  | C                   | L | C                   | L | C                   | L | C                   | L |
| Nausea             | 4                   | 7  | 0                   | 0 | 0                   | 0 | 2                   | 2 | 0                   | 0 |
| Vomiting           | 9                   | 7  | 2                   | 2 | 0                   | 0 | 0                   | 0 | 0                   | 0 |
| Fever              | 4                   | 3  | 1                   | 3 | 1                   | 0 | 0                   | 0 | 0                   | 0 |
| Otalgia            | 2                   | 2  | 3                   | 1 | 1                   | 1 | 0                   | 1 | 0                   | 0 |
| Pain in the throat | 26*                 | 5* | 4                   | 2 | 0                   | 0 | 1                   | 0 | 0                   | 0 |

\*  $P < 0.001$  (HS)

## Discussion

Tonsillectomy is one of the most commonly performed operations in children, and pain after tonsillectomy still remains to be a frequent and frustrating problem[16], which can affect the duration of inpatient care, analgesic consumption, oral intake, ambulation, and return to regular activity[17]. Relief of pain after tonsillectomy is thus a major concern in order to improve the patient quality of life in the postoperative period[18].

The oropharynx and the tonsillar fossae are exquisitely sensitive. They are well innervated locally by the branches of the trigeminal and glossopharyngeal nerves and are highly represented in the somatic cerebral cortex[19]. Many treatment modalities for post-tonsillectomy pain have been used, ranging from systemic opioids to different surgical techniques, even radiation[20]. Because of the absence of any respiratory depressant effect, there has been a renewed interest in local anesthetic techniques as an effective means of postoperative pain control[19].

Injury creates a 'C' fibre afferent barge (discharge)[20,21] which causes increased central hyper- excitability at the level of dorsal horn neuron's and finally pain is perceived in CNS. Once the C-fibres are anaesthetised by bupivacaine (local anaesthesia) no pain will be perceived. This is a very simplified view. In reality, however, another second afferent barge is created, which is attributed to the inflammatory reaction to the damaged tissue. This inflammatory reaction produces certain chemicals which sensitise threshold nociceptors. This phase occurs during the process of healing and can cause pain. Hence even if pre-emptive blockage exists pain can still occur due to second barge[22]. It should also be pointed out that pre-emptive analgesia is a time dependent concept[23]. This has now led to the concept of post-surgical analgesia and continuous analgesia. Both however are integral part of pre-emptive analgesia. In this study we have clearly used the concept of post-surgical topical anaesthesia (swabs) and continuous analgesia in the form of NSAID drugs.

Several investigators have evaluated the effect of pre-incisional and postoperative injection of local anaesthetics at tonsillar site, on postoperative pain following tonsillectomy[24,25]. With regards to the results of the cited studies, there exist three different ways of applying the local anaesthetics: pre-incisional peritonsillar infiltration[26,27] post-tonsillectomy wound infiltration[28,29] post-tonsillectomy packing with soaked local anaesthetic` gauze[11].

At present it is not clear which application method is the most effective, because of the wide range of results, i.e., from "no difference"[28] to "highly significant difference"[26].

Injection of a local anesthetic agent is believed to decrease pain by producing pharmacologic blockade of the sensory pathways and prevent the nociceptive impulses from reaching the spinal cord, thus decrease the occurrence of complication, such as postoperative bleeding and laryngospasm induced by crying[30].

Topical application of drugs in the tonsillar fossae for postoperative analgesia after tonsillectomy has been evaluated previously using bupivacaine[11], levobupivacaine[6], ropivacaine[12] and tramadol[13].

Levobupivacaine is the S-enantiomer of bupivacaine[31,32] and is believed to have some advantages like less motor blockade and more prolonged postoperative analgesia[33,34] compared with bupivacaine. Levobupivacaine may be useful in pediatric practice. We preferred topical levobupivacaine in our study because of the lack of enough data in the literature about its topical use in pediatric tonsillectomy cases for postoperative analgesia.

The infiltration technique carries the risk of accidental intravascular injection which can lead to convulsions and cardiac arrhythmias, so we preferred the topical application of levobupivacaine which is a safe alternative technique to topical infiltration.

Most previous studies have used a visual analogue scale (VAS), dynamic pain assessments (e.g., when drinking water or opening the jaw) or CHEOPS to evaluate post-tonsillectomy pain[35,36]. It is generally accepted that evaluating pain in children is difficult, especially in children unwilling or unable to verbalize. We preferred

the FLAAC, a valid and reliable method of assessing pain in children[15].

Our study showed that the mean age, mean weight, sex, mean body weight, ASA grading, diagnoses, surgery performed and the duration from induction to placement of swabs (completion of surgery) which was in accordance with the previous studies conducted by authors: Akbay B K[13] et al in 2010, Yilmaz S[6] et al in 2009, Oghan F[12] et al 2008.

Findings of our study were supported by the following studies in which local application of tramadol[13], bupivacaine[11], levobupivacaine[6] and ropivacaine[12] were found effective in providing postoperative analgesia.

Yilmaz S<sup>6</sup> et al (2009) used swabs soaked in 5 ml levobupivacaine hydrochloride (25 mg/10 ml) in group I and 5 ml saline swabs in group II into each of the two tonsillar fossae after tonsillectomy for 5 min. They used McGrath's face scale to compare the two groups in respect of pain control. They found that there was statistically significant pain-relieving effect in the levobupivacaine group in the first 24 hrs (p < 0.05). But after 24 hr, pain relieving effect of levobupivacaine was not significant (p > 0.05).

Akbay et al[14] (2010) used swabs soaked in 2mg/kg tramadol diluted in 10ml saline and applied to both tonsillar fossae for 5 min (Tramadol group) and compared it with swabs soaked in 10 ml saline (saline group). They observed that pain scores were significantly lower at the 21st hour and on seventh postoperative day, in the tramadol group compared with the control group (P < 0.05). Mean daily pain scores ranged from 0.34 ± 0.21 on day 1 to 0.11 ± 0.08 on day 7 in the tramadol group and 0.53 ± 0.14 on day 1 to 0.42 ± 0.15 on day 7 in the control group.

OghanF[12] et al (2008) used 1% ropivacaine hydrochloride-soaked swabs packed in tonsillar fossae in the test group and the control group received saline-soaked swabs. Mc-Grath's face scale was used to compare the two groups in respect of pain control. Only at first hour there was no significant pain-relieving effect seen in ropivacaine group (P>0.05); while the other hours and days there were statistically significance between the two groups (P<0.001).

Other studies[11] convincingly demonstrated that topical application of bupivacaine in tonsillar fossa after surgery, reduces post-operative pain at all stages of the trial upto the discharge of the patients; although the local effect of bupivacaine can last only for 6-9 hours. It has been noticed that analgesia effects last beyond the expected duration of the local anaesthesia. This protracted pain relief resulting by a single use of bupivacaine cannot be explained by prolonged presence of the local anaesthetic in the area of surgery. An explanation for this long-lasting pain relief might be that neural blockade prevents nociceptive impulses from entering the central nervous system during and immediately after surgery and this suppresses formation of the sustained hyperexcitable state responsible for the maintenance of post-operative pain. Local anaesthetic induces the antinociceptive effect by acting on the nerve membranes; however, these affect many membranes associated proteins in any tissue. They can inhibit the release and action of agents (prostaglandins, lysosomal enzymes, etc.) sensitizing or stimulating the nociceptors and participating in inflammation[11].

In the present study there was minimal occurrence of post operative complaints like nausea, vomiting, fever, otalgia, pain in the throat and complications like post-tonsillectomy bleeding. All the complaints except pain in the throat were statistically comparable in both the groups (P>0.05) at all times (hours and days). Incidence of pain in the throat was significantly higher (P<0.001) in Group C [n=26(96.29%)] on the first day as compared to Group L [n=5(18.51%)]. Later on, till 7 days throat pain was statistically comparable in two groups P>0.05. Yilmiz S et al<sup>6</sup> also found that postoperative morbidity was comparable in two groups i.e., the group receiving topical levobupivacaine v/s the group receiving normal saline.

Akbay BK[14] et al also found that postoperative morbidity was comparable in the two groups i.e., the group receiving topical ropivacaine v/s the group receiving normal saline.

OghanF[12] et al also found that postoperative morbidity was comparable in the two groups i.e., the group receiving topical ropivacaine v/s the group receiving normal saline.

### Conclusion

We conclude that topical application of swabs soaked in 10 ml of 0.25% levobupivacaine for 5 min after tonsillectomy in the tonsillar bed is a simple and effective approach and therefore be safely recommended as a safe and reliable method of postoperative pain relief after tonsillectomy.

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