EAS Journal of Anaesthesiology and Critical Care
Abbreviated Key Title: EAS J Anesthesiol Crit Care
ISSN: 2663-094X (Print) & ISSN: 2663-676X (Online)
Published By East African Scholars Publisher, Kenya

OPEN ACCESS

Volume-1 | Issue- 6| Nov-Dec-2019 | DOI:10.36349/EASJACC.2019.v01i06.002

Research Article

Comparative Differential Dose of Topical Bupivacaine for Post-Operative Pain Management in Paediatric Ambulatory Tonsillectomy: A Prospective Randomized Study

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Abstract: **Introduction:** Tonsillectomy is one of the most commonly performed procedures in Otolaryngology. Nowadays tonsillectomy is carried out more as a day care surgery and this trend is increasing, Discharge from day case surgery may not be possible in some of the patients.The factors responsible for this include post-tonsillectomy pain, Bupivacaine when used topically for post tonsillectomy pain relief in children, has been shown to be safe with no complications. This study aims to determine effective dose of 0.5% bupivacaine and 0.25% Bupivacaine topically applied in reducing post tonsillectomy pain. **Material and methods:** This is a prospective randomized, double blind study of sixty patients ASA I and II patients aged between 5 to 12 years scheduled for ambulatory tonsillectomy. Anaesthesia was standardized for all patients fentanyl 1µ/kg was used as intra operative analgesia, patients were randomized into group A, who received 0.5% Bupivacaine and group B received 0.25% Bupivacaine both solutions were prepared and labeled by the research assistant who is in custody of the envelopes. After haemostasis was achieved, group A patients had both sides of their tonsillar fossae tightly packed for 5 minutes with a standard gauze of 10cm dimension folded twice to make it 2.5 by 2.5cm and fully soaked with 5ml of 0.5% bupivacaine. Group B patients received 5mls of 0.25% of bupivacaine soaked gauze was applied for 5 minutes as applied in group A. In both groups both the patients/parents or guardian and the researcher were blinded to the agent being used. **Results:** There was significant reduction in pain intensity among patients that received topical application of 0.5% bupivacaine 1.46(±1.17) & 2.80(±0.81) compare to those received 0.25% bupivacaine 3.16(±1.38) & 3.02(±1.62), time to first analgesic request (TFA) was longer in group A 8.84 (3.24) hours, when compared to group B which had a mean duration of 6.72(1.56) hours, with a p-value of 0.036. The cumulative dose of paracetamol consumption (CDP) was also lower among patients who had 0.5% bupivacaine (group A) with a mean of 150.84(±19.44) mg while those that received 0.25% bupivacaine (group B) had a mean of 228.60(±30.14) mg (p-value = 0.018). Mean first oral intake time (FOT), which was reduced in the group A when compared to group B even though not statistically significant, with a mean minutes 194.40 (114.652) and 288.20 (91.245)minutes respectively. **Conclusion:** This study demonstrated an improvement in pain intensity with topical application of bupivacaine; however 0.5% Bupivacaine may provide superior post-operative analgesia, early resumption to oral intake than topical application of 0.25% Bupivacaine without any side effect.

Keywords: Otolaryngology haemostasis, paracetamol consumption (CDP).

INTRODUCTION

Tonsillectomy is one of the most commonly performed procedures in Otolaryngology. Nowadays tonsillectomy is carried out more as a day care surgery and this trend is increasing, (Hung, T. *et al.*, 2002) occasionally discharge from the day care surgery unitis May 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. (Klauser, R.D. *et al.*, 1995) Published data indicate that about 14-15% of day care tonsillectomy discharges are delayed due to inadequate pain control.

Quick Response Code

Journal homepage:
http://www.easpublisher.com/easjacc/

Article History
Received: 03.11.2019
Accepted: 16.11.2019
Published: 28.12.2019

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.(Homer, J.J. *et al.,* 2002) The International Association for the Study of Pain (IASP) defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. (Merskey, H., & Bogduk, N.1994) Assessment of pain in paediatric patients has been a challenging task, especially due to issues related to verbal communication and to the development of associative thinking. Poor pain assessment usually leads to inadequate pain treatment in this patient age group and realization of this has increased awareness of the need to use objective pain measurement, (Silva, F.C., & Thuler, L.C. 2008) self - reported and observational/physiological assessments are the major tools widely used in the field of pain assessment. Self-reported remains the gold standard for assessing acute pain in both children and adults. (Voepel-Lewis, T. *et al.,* 2005)

Topical application of Bupivacaine is gaining popularity as a multimodal approach for post tonsillectomy pain relief due to its longer duration of action when compared with lidocaine which is the most widely studied.[7-9] Bupivacaine when used topically for post tonsillectomy pain relief in children, has been shown to be safe with no complications reported in most of the literatures. (Sabbar, S. *et al.,* 2009; Bukhari, M. A., & Al-Saied, A. S. 2012) Topical application of Bupivacaine is acheived by soaking the gauze piece in 5ml of 0.5% and 0.25% of bupivacaine solution before packing; one can achieve both goals of achieving hemostasis and analgesia by locally blocking the exposed nerve endings on the raw surface of the tonsillar bed. (Sabbar, S. *et al.,* 2009; Bukhari, M. A., & Al-Saied, A. S. 2012; Sharma, S.*et al.,* 2015) Bupivacaine requires only 10 seconds of contact with the raw area to exert its local anesthetic effect.

Several studies have been conducted to evaluate the efficacy of topical bupivacaine in relieving post-tonsillectomy pain with variable outcomes. (Hung, T. *et al.,* 2002; Klauser, R.D. *et al.,* 1995; Homer, J.J. *et al.,* 2002) Effective postoperative pain relief is an essential part of peri-operative management, adequate pain relief may hasten postoperative recovery, decrease length of hospital stay and reduce cost of care especially in developing countries were majority of the populations are living below the poverty line. Following tonsillectomy. Non- Steroidal Anti Inflammatory Drugs (NSAIDS) are commonly used for postoperative pain relief. Occasionally opioids are used but some of their side effect such as nausea & vomiting, sedation, constipation, cough reflex suppression and respiratory depression limited their used especially in day ambulatory anaesthesia while NSAIDS may increase bleeding tendencies. On the other hand, use of topical local anesthetics for relieving post-tonsillectomy pain is relatively simple, cheap, and devoid of major complications. The use of differential dose of topical bupivacaine may guide the appropriate dose needed to achieve effective reduction of dosages of systemic analgesics with resultant reduction in their side effects, better post -operative analgesia and reduce un- plan admission.

MATERIAL AND METHODS

This is a prospective randomized, double blind study of sixty ASA I and II patients aged between 5 to 12 years scheduled for ambulatory tonsillectomy. Following Hospital Research and Ethics Committee all patients scheduled for ambulatory tonsillectomy. Patient/parents/guardian not willing to participate, proven or suspected allergy to local anaesthetics, patients for combined adenotonsillectomy, inability to understand the Faces Pain Scale-Revised (FPS-R) and patients with sickle cell disease were excluded.

All the patients were review using pre-anaesthetic preforma before the surgery during which a detailed pre-anaesthetic evaluation was done, study protocol explained to parents/guardian, and a written informed consent obtained from them. Patients were educated on the use of FPS-R and instructed to fast according to fasting guidelines. Routine laboratory investigations including full blood count, Serum electrolytes, urinalysis and and coagulation studies were conducted. Sixty (60) were randomly assigned using sealed envelope technique into two groups (groups A and B) of 30 each in a double blind fashion. Sixty sealed envelopes were prepared, 30 of which contains a letter A received 0.5% while the remaining 30 contains a letter B received 0.25%. Anaesthesia was standardized for all patients fentanyl 1µ/kg was used as intra operative anagesia, envelopes were given to the surgeon before each case for random selection until they were exhausted. Both solutions were prepared and labeled by the research assistant who is in custody of the envelopes. After haemostasis was achieved, group A patients had both sides of their tonsillar fossae tightly packed for 5 minutes with a standard gauze of 10cm dimension folded twice to make it 2.5 by 2.5cm and fully soaked with 5ml of 0.5% bupivacaine (marcaine Astra-Zeneca brand). Group B patients received 5mls of 0.25% of bupivacaine soaked gauze was applied for 5 minutes as applied in group A. In both groups both the patients and the researcher were blinded to the agent being used..

Postoperative analgesia was provided using a single dose of intravenous paracetamol 10mg/kg on patients demand. Restlessness or crying was considered as demand for analgesics in patient less than 6 years, while those above 6 years were allowed to report pain and seek for pain relief. For breakthrough pains (FPS-R score >4) rescue analgesia was administered as a

repeated dose of intravenous paracetamol. After 6 hours patient were converted to oral ibuprofen 5mg/kg/dose and oral acetaminophen 15mg/kg every 8 hours. Pain severity was measured in each patient by the researcher and another anaesthetist who is conversant with FPS-R at 1, 2, 4, 6,8 and 24 hours postoperatively, patients were discharge home based on discharge criteria: tolerating oral feeding with pain score FPS-R < 3, no vomiting, no bleeding, none of the patient had un plan admission. At 24 hours patients were follow up through their parents/guardians phone contact. Statistical analysis of data collected was performed using SPSS version 22.0 statistical package. Results were expressed as the mean ± SD. FPS-R score taken at each time interval (1, 2, 4, 6,8 and 24) was compared between the two. Differences in demographic and postoperative data between the two groups was sought out by using the χ^2 test and unpaired Student's *t*-tests for nonparametric and parametric variables, respectively. Differences in FPS-R scores between the two groups was evaluated with Student's *t*-tests. The time to first analgesic request, defined as interval of time between the end of surgery and the first administration of paracetamol was analyzed with the unpaired Student's t-test after logarithmic transformation to ensure a normal distribution. A *P* value <0.05 was considered significant.

RESULTS

Sixty patients were recruited for the study and were randomly allocated into two (2) groups of 30 each. Group A had their tonsillar fossae packed with 0.5% Bupivacaine soaked gauze while group B had 0.25% Bupivacaine.

DEMOGRAPHIC PROFILE

Table 1 shows the demographic profile of the patients; age, sex and ASA physical status. The age range of the entire patients was between 5 and 12 years. The mean age was 5.0 (±3.26) years for group A and 5.5 (±3.92) years for group B.

The sex distribution of patients in both groups was 19(63.3%) and 21(70%) male patients in group A and B respectively.

The ASA physical status classification distribution revealed 28(93.3%) in group A and 26 (86.7%) in group B as ASA I, two (6.7%) and 4(13.3%) were ASA II for group A and B respectively.

POSTOPERATIVE PAIN SCORE

Table II showed FPS-R score at 1 and 2 hours postoperatively were significantly lower in group A with a mean score of 1.46(±1.17) & 2.80(±0.81) indicating lower pain intensity compare to 3.16(±1.38) & 3.02(±1.62) for patients in group B with p-value of 0.03 and 0.034 respectively. The table also shows the mean FPS-R score of group A patients to be lower than that of group B throughout the period of the postoperative pain assessment, however no statistically significant difference was found at 4, 8, and 24 hours follow up.

Postoperative Analgesic Requirement Pattern and Oral Intake Tolerance

Table III showed the time to first analgesic request (TFA) was longer among group A which was 8.84 (3.24) hours, when compared to group B which had a mean duration of 6.72(1.56) hours indicating better pain control among group A patients, with a p-value of 0.036. The cumulative dose of paracetamol consumption (CDP) between the two groups also showed a statistically significant reduction among patients who had 0.5% bupivacaine (group A) with a mean of 150.84(±19.44) mg while those that received 0.25% bupivacaine (group B) had a mean of 228.60(±30.14) mg (p-value = 0.018).

Table III also showed the mean first oral intake time (FOT), which was reduced in the group A when compared to group B even though not statistically significant, with a mean minutes 194.40 (114.652) and 288.20 (91.245)minutes respectively. Bupivacaine toxicity were looked out for such as confusion, tinnitus, convulsions, hypotension.but none was recorded in this study.

Table 1: Population Demographic Profile

Variables	Group A n =30 Mean (±SD)	Group B n = 30 Mean (±SD)
Age (years)	5.0(3.26)	5.5(3.92)
Sex male/female (%)	19/11 (63.3/36.7)	21/9 (70/30)
ASA status (I/II) (%)	28/2 (93.3/6.7)	26/4 (86.7/13.3)

Table 2: Postoperative FPS-R scores

Time	Group A Mean (±SD) N= 30	Group B Mean (±SD) N=30	Significance level (*p*-value)
1st hour	1.46 (1.17)	3.16 (1.38)	0.044
2nd hour	2.80 (0.81)	3.02 (1.62)	0.013
4th hour	2.94 (1.21)	3.12 (1.54)	0.547
8th hour	3.01 (1.26)	3.46 (1.02)	0.625
24th hour	3.51 (0.52)	3.88 (0.80)	0.146

P- value < 0.05 indicates statistical significance

Table 3: Time of first analgesic requirement, cumulative paracetamol dose and time to first oral intake

Variables	Group A Mean (±SD) N= 30	Group B Mean (±SD) N = 30	Significance level (p- value)
TFA (hour)	8.84 (3.24)	6.72(1.56)	0.036
CDP (mg)	150.84 (19.442)	288.60 (10.140)	0.018
FOT (min)	194.40 (114.652)	288.20 (91.245)	0.542

P< 0.05 indicates statistical significance

DISCUSSION

This study revealed significant decrease in pain intensity among patients that received 0.5% bupivacaine group compared to those with 0.25% bupivacaine group with mean pain scores of 1.46 (±1.172) and 3.16 (±1.38), p = 0.044, at 1 hour and 2.80 (±1.00) and 3.72 (±1.621), p < 0.05, at 2 hours respectively. The relatively lower values obtained in both groups at 1 hour postoperatively is likely due to the residual effect of anaesthesia and the intraoperative analgesia, while the peaking of the mean pain score of the group A at 1 hour can be attributed to higher dosage used compared to group B. The subsequent 2nd 4th 8th, and the 24th hours, showed no significant difference between the two groups in terms of their FPS-R scores. This is can be attributed due to wearing out of bupivacaine's effect, and relative decrease in pain scores of group B due to early commencement of paracetamol, hence, reducing the difference in pain intensity of the two groups. Though the effect of bupivacaine was expected to have worn out by 4th hours after surgery, lower pain scores were still observed in group A 2.94 (±1.21) compared to group B indicating 3.12 (1.54) likely association between higher dose and longer effect . However the difference was not significant (p = 0.147). This can be explained by the fact that almost all patients irrespective of the group they belong to, have had a dose or more of paracetamol, and the analgesic effect seen at this period was assumed to be mainly due to paracetamol but was potentiated in group A. Hence, the relatively lower FPS-R scores observed in the group.

Bukhari *et al.,* (2012), randomized 35 patients age ranging between 3-53 years (mean age 10.3 years). They found that 4ml of 0.25% bupivacaine soaked gauze, reduction in pain at 2 and 4 hours was not statistically significant when compared with the control side with P-value of 0.078 and 0.146 respectively. However, at 6, 12 and 24 hours after surgery, the reduction in pain was statistically significant with P-value of 0.024, 0.001 and 0.001 respectively. The conclusion drawn from their findings was that 0.25% bupivacaine appears to give considerable degree of analgesia within the first 24 hours postoperatively. Saki *et al.,* (2015) injected 0.5 mg/ kg of 0.5% bupivacaine in one group and sterile water in another group into the tonsillar bed of children aged between 4 to 13 years, coming for tonsillectomy, immediately after induction. 30 patients were randomly assigned to each group and pain was assessed using faces pain scale (FPS) postoperatively. Pain was assessed at 6 and 24 hours after the surgery. Time to first analgesic request and time to first oral intake were also noted. Similar to the present study, they found the bupivacaine group to have a significantly lower pain scores at both 6 and 24 hours (P< 0.001). Sabbar *et al.,* (2009) in their randomized double-blinded placebo-controlled study, reported that there is a significant reduction in pain scores (VAS) of patients who had 5ml of 0.5% bupivacaine soaked gauze applied to their tonsillar bed after tonsillectomy when compared to the control group who had normal saline. The difference in VAS score between the bupivacaine and saline group was highest at 2 hours postoperatively, with a value of 1.43(p<0.001), indicating period of maximal effect of the intervention which is similar to our findings above. However, a pain score of >4 was observed in Sabbar's study at 2 hours postoperatively in contrast to our study that showed lower pain score although in our study both patients received different dosages of bupivacaine. Similarly, different pain assessment scale was used in both studies that may results in the variation observed.

In contrast to our study, Manal *et al.,* (2012) in their study concluded that an even lower concentration of Bupivacaine (0.25%) was effective in providing post tonsillectomy analgesia. It is worth noting that there is no statistical evidence that Bupivacaine in a 0.25% concentration provides the same degree of analgesia as a 0.5% concentration. Sharma *et al.,* (2015) found that topical bupivacaine has no benefit in managing post

tonsillectomy pain, as no statistically significant difference was found in the VAS scores between the bupivacaine group and the control group who had nothing even though marginally lower pain scores were obtained in bupivacaine group 6.22 ±1.01 P=0.34 at 1hr, 6.63 ±1.17 P=0.81 at 4hrs, 5.22 ±1.30 P=0.31 at 8hrs and 4.73 ±1.19 P=0.41 at 24hrs when compared to the saline group 6.48 ±1.23 at 1 hr, 6.72 ±1.84 at 4hrs, 4.88 ±1.51 at 8hrs and 4.48 ±1.39 at 24hrs. Though, it can be argued that the unequal number of patients in the two groups (54 to 24) with the test group having more patients and lack of a placebo, may be the reason why no statistically significant difference was found in the Sharma's study.

This study also showed that 0.5% bupivacaine group with mean time of 194.40 (114.652) minutes was found to commence oral intake earlier than the 0.25% bupivacaine group 288.20 (91.245) minutes but the difference was found not to be statistically significant. Both Feroz *et al.,* (2013) and Saki *et al.,* (2015) found the bupivacaine group to commence oral intake significantly earlier than the saline group in their respective studies. Generally, most of the clinical trials used Bupivacaine in a 0.5% concentration. However, in1994 a clinical trial was conducted using Bupivacaine in a0.25% concentration. They prospectively compared pre-incision Bupivacaine infiltration, post-operative Bupivacaine infiltration, and pre-incision normal saline infiltration and found no statistically significant differences between all 3 groups. (Ong, C. K. S. *et al.,* 2005)

This study has also been able to demonstrate a significant reduction in systemic analgesic requirement in the 0.5% bupivacaine group with mean TFA of 8.84 (3.24) compare to 6.72(1.56) among 0.25% bupivacaine group *P*=0.036. This is similar to the findings reported by Feroz *et al.,* (2005), which showed that only 28(46.7%) patients in the entire studied population requested for analgesia, of which 25 (41.7%) were from the saline group and only 3 (5%) were from the bupivacaine group. This means that 27 (45%) patients in the bupivacaine group did not require any analgesic, which was contrary our findings. However, this is not surprising since the patients were assessed for just 6 hours when bupivacaine's effect is expected to be present, while the longer duration of our study of up to 24 hours (beyond the expected duration of action of bupivacaine) made all patients in our study to have at least one dose of paracetamol irrespective of the group., the findings would have been similar if our study was for 6 hours. Saki *et al.,* (2015) also found the bupivacaine group to have spent longer time before requesting for analgesics (P=0.002) compared to the placebo group. This further shows the systemic analgesic sparing effect of topical bupivacaine after tonsillectomy surgery in children.

This study did not find any complication related to bupivacaine toxicity. This finding is comparable with that of similar studies (Klauser, R.D. *et al.,* 1995; Merskey, H., & Bogduk, N. 1994; Silva, F.C., & Thuler, L.C. 2008; Voepel-Lewis, T. *et al.,* 2005; Sabbar, S. *et al.,* 2009; Saki, N. *et al.,* 2015) where bupivacaine soaked gauze as topically applied in the tonsillar fossa after tonsillectomy in children. Some of the limitation to our study include: Vital parameters like PR, BP and SPO_2 were not analyzed. These are important indicators of pain whose values could correlate well with FPS-R scores. The sample size used in this study may have reduced the power of the study to reflect its significance in achieving the set objectives.

CONCLUSION

This study demonstrated an improvement in pain intensity with topical application of bupivacaine, however 0.5% Bupivacaine may provide superior post-operative analgesia, early resumption to oral intake than topical application of 0.25% Bupivacaine without any side effect.

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