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Efficacy of topical 0.5% bupivacaine in pain reduction in pediatric tonsillectomy patients

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ABSTRACT

BACKGROUND & OBJECTIVE: Palatine tonsils are lymphoid organs in the oropharynx part of the Waldeyer's ring and serve as host defence organs with maximum immunological activity from 3-10 years. Tonsillectomy is associated with considerable postoperative pain and requires significant consumption of analgesia. This study aimed to determine effect of topically suffused 0.5% bupivacaine on postoperative tonsillectomy pain.

METHODOLOGY: This double-blind interventional experiment was done on 120 patients 5-15 years of age at the ENT Department, Shaikh Zayed Hospital, Lahore, Pakistan from February-August 2019. Tonsillectomies were performed by conventional blunt dissection method and tonsillar fossae were packed with 0.5% bupivacaine (Group-A) and 0.9% normal saline (Group-B) for 5 minutes. Postoperative pain scores were recorded by Faces Pain Scale-Revised 24 hours postoperatively. Routine postoperative analgesia (diclofenac-sodium 3mg/kg/day) as intramuscular-injection was given immediately after surgery to all patients. A patient who would have difficulty in communicating his/her pain levels, with history of bleeding disorders or INR of ≥ 1.5 , who suffered fever, sore-throat (in last 4-weeks) or underwent tonsillectomy after quinsy and patients allergic to bupivacaine on history or medical record were excluded.

RESULTS: One hundred & twenty (120) patients with 61 males and 60-patients in each group with age range of 5-15 years (Group-A=8.63 \pm 2.63 and Group-B=8.32 \pm 6.60 in). Mean BMI of Group-A and group-B was 15.18 \pm 1.60 and 14.96 \pm 1.34 respectively ($p=0.417$). Mean pain score in group-A and group-B was 2.63 \pm 0.938 and 6.07 \pm 0.800 respectively ($p<0.001$).

CONCLUSION: Tonsillectomies performed using bupivacaine-soaked packs postoperatively are associated with lower postoperative pain compared with those packed with normal saline.

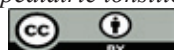
KEYWORDS: Palatine tonsil, Tonsillectomy, Postoperative pain, Bupivacaine.

INTRODUCTION

Tonsillectomy is among the commonest surgeries in Ear Nose & Throat (ENT) practice and the majority of the patients are of paediatric age group [1]. Pain is the most important cause of postoperative morbidity after tonsillectomy. Pain in the throat restricts oral intake and results in less activity in the constrictor muscles of the pharynx. It further increases pain, and thus a vicious cycle starts [2]. Effective pain management helps the patient for early resumption of oral intake and thus early discharge from the ward [3,4]. Pain results from local tissue damage, which in turn causes a

release of inflammatory mediators. The throat is innervated by multiple sensitive cranial nerves. Excision of the tonsils exposes the tonsillar bed, mainly comprising of the superior constrictor and styloglossus muscles. The postoperative morbidity directly relates to delayed recovery and a higher rate of complications. The exposed tonsillar bed is prone to bacterial infection & release endotoxins which results in enhanced inflammatory reaction. Haemostasis is achieved by bipolar cauterisation resulting in thermal injury. As a result of these factors, i.e. muscle exposure, thermal injury, and bacterial toxins, many patients experience severe pain after a traditional tonsillectomy. These electrical impulses generated at pain receptors are conducted to the spinal cord,

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and their transmission can be blocked by local anaesthetics applied to the wound bed, possibly resulting in pain reduction [5]. Various options for pain reduction have been tried after tonsillectomy, like the use of topical lignocaine [6], ropivacaine [7], daflon [8], dexamethasone [9], bupivacaine [10], pregabalin [11] etc. in addition to systemic use of NSAIDs, narcotic analgesics and steroids [12,13].

Different sealants have been used to cover the surgical wound in order to prevent sensory nerves from being exposed to reduce pain. Another study achieved good using sucralfate in adult patients [14]. Stoeckli et al. used fibrin glue to cover the surgical wound but reported no benefit with this technique [14]. Few studies have been undertaken reflecting mixed results, one of the earlier studies, Violaris and Tuffin, applied topical bupivacaine to the surgical wounds of adult patients and compared it with the application of normal saline and reported the side treated with normal saline showed less pain than the side coated with 0.5% bupivacaine [15].

Bupivacaine, because of its rapid onset and prolonged action, is gaining popularity as an effective method for pain reduction after tonsillectomy. Serious life-threatening complications have been reported by local infiltration of bupivacaine like cardiac arrhythmia, airway obstruction, cervical osteomyelitis, facial nerve paralysis, Horner's syndrome and vocal cord paralysis [16-18].

The first to examine the effect of peritonsillar infiltration of bupivacaine and pethidine on post-tonsillectomy pain demonstrated that administration of lidocaine combined with pethidine to the peritonsillar fossa pre-operatively could result in significant postoperative pain relief in paediatric patients. It can be hypothesised that combination of pethidine and bupivacaine would offer more reliable pain relief, at least in the early postoperative period [16].

This study was aimed to determine the efficacy of bupivacaine applied topically through a pack in the tonsillar fossa, in reducing postoperative pain and also eliminating the risks associated with infiltration of the local anaesthetic.

METHODOLOGY

This double-blind interventional experiment was done on 120 patients at the ENT department, Shaikh Zayed Hospital, Lahore. They were registered Indoor. Approval of this study had already been taken from the Institutional review board (IRB No. 1554) of the hospital regarding ethical issues. Fitness for general anaesthesia was obtained from the anaesthesia department. The parents/guardians of the patients were fully explained about the purpose, procedure, risks and the benefits of surgery and informed written consent was taken for the study from parents/ guardians. They were also explained that all the information taken will be confidential. Patients were randomly allocated using lottery method to 2 groups; Group-A and Group-B. There were 60 patients in each group. These groups were randomized by using lottery method. Group-A tonsillectomy patients were topically suffused with bupivacaine 0.5% soaked swabs packed in the tonsillar bed for 5 minutes, and similarly, group B had 0.9% saline-soaked swabs for the same duration.

Conventional blunt dissection tonsillectomy was done by using sharp and blunt dissection by using a knife and tonsillar dissector. Hemostasis was secured by silk ligation and bipolar electro cautery (set at 15 watts). All of these tonsillectomies were done by consultants to avoid the expertise related bias. Routine postoperative analgesia Diclofenac Sodium 3mg/kg/day as an injection was given intramuscularly immediately after surgery to all patients. Postoperative pain scores were recorded by Faces Pain Scale-Revised 24 hours postoperatively.

This study included patients male and female from 5 – 15 years of age who suffered from chronic tonsillitis and were listed for an elective tonsillectomy. Patients excluded from the study were who did not consent to the study/procedure, a patient who would have difficulty in communicating his/her pain levels, patients with a history of bleeding disorders or showing INR of 1.5 or more, who suffered fever, sore throat (in last 4 weeks) or underwent tonsillectomy after quinsy and patients allergic to bupivacaine on history or medical record.

The collected data were analyzed statistically by using SPSS version 20. Quantitative variables like post-operative pain score and age will be presented in the form of mean \pm SD.

Qualitative variables like gender will be presented in the form of frequency and percentage. Data was stratified for age, gender and BMI to deal with effect modifiers. Normality testing was done and the data were found to be skewed to the right with p value for Shapiro-Wilk's test < 0.05 (Table-I). So, non-parametric test for two independent samples i.e. Mann-Whitney's U- test was applied and mean ranks were compared for the two samples.

RESULTS

One hundred & twenty (120) patients were included in the study, 61 males and 59 were females. 60 patients were given bupivacaine post-tonsillectomy (Group-A), while the other 60 served as controls (Group-B).

The age range was 5-15 years. The mean & standard deviation was 8.63 ± 2.63 in group A and 8.32 ± 6.60 in group B. The mean BMI of Group A patients was 15.18 ± 1.60 , while that of Group B patients was 14.96 ± 1.34 with $p=0.417$ (Table-II).

The mean pain Score with Bupivacaine was 2.63 ± 0.938 , while the mean pain score without Bupivacaine was 6.07 ± 0.800 . Median pain scores without Bupivacaine was 6.00, while median pain scores with Bupivacaine was 3.00. Mann-Whitney's U test was applied to determine the differences between the two groups. $U = 14.00$, $p \leq 0.001$. From this data, it can be concluded that pain scores in the bupivacaine groups were statistically significantly lower than in the control group ($U = 14.00$, $p \leq 0.001$).

Age stratification of pain in both groups was done. The results show that the mean pain score of patients between 5-10 years was 2.68 ± 0.959 in Group A, while 5.06 ± 0.835 in Group B. Similarly mean pain score of patients between the age of 11-15 years was 2.50 ± 0.894 in Group A, while it was 5.38 ± 0.744 in Group B. This shows that in patients who

Table-I: Tests of Normality.

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Pain Score - With bupivacaine	.234	60	0.000	0.889	60	0.000

Table-II: Age, Gender and Body Mass Index of Patients (n=120).

		Group A (n=60)		Group B (n=60)	
Parameters		No.of patients	%	No.of patients	%
Age (years)	5 – 10	44	73.3	51	85
	11–15	16	26.7	9	15
	Mean±SD	8.63±2.63		8.32±6.60	
Gender	Male	31	51.7	30	50
	Female	29	48.3	30	50
Body Mass Index (kg/m ²)	Mean±SD	15.18±1.60		14.96±1.34	

received Bupivacaine, mean postoperative pain is slightly more in younger children. On the other hand, in patients who did not receive Bupivacaine, the mean postoperative pain is relatively less in younger children. Gender stratification of pain in both groups shows mean pain score in male patients was 2.74 ± 0.930 in Group A, while it was 5.13 ± 0.776 in Group B. Similarly, the mean pain score in Female patients was 2.52 ± 0.949 in Group A, while it was 5.10 ± 0.885 in Group-B. This show that the mean postoperative pain score in male patients was slightly more than females in both groups (Table-III).

The mean duration of illness (weeks) in Group A patients was 13.5 ± 6.3 , while that in Group-B was 12.4 ± 6.4 .

DISCUSSION

Post tonsillectomy pain management has always attracted special attention and presents a challenge, as pain attenuation not only improves patient comfort but also improves oral intake, reducing the chances of dehydration and eventually minimizing the risk of postoperative bleeding [19]. This is especially significant during the pandemic and the COVID-19 crisis, as early recovery results in prompt discharge and shorter hospital stay [20]. The definition of pain recognizes the interplay between the objective, physiological sensory elements and its subjective, emotional and psychological components. Pain threshold is highly variable among individuals and in the same person at different times, making it difficult to quantify. Due to this, a number of pain scores have been developed and tried. Visual Analog Scale is one of the simplest, efficient and minimally intrusive methods that correlate well with other reliable methods and hence was used in this study.

Bupivacaine-amide local anaesthetic is frequently used for epidural, spinal and peripheral nerve blocks. It has high

protein binding and lipid solubility with an upper limit of a safe dose of 2 mg/kg. In order to achieve its analgesic effect, it needs to be in contact with tonsillar bed for about 10 seconds. It has been used as an effective method to reduce post-tonsillectomy pain. The premise for its use is to obtain blockade of the nerve fibers of the peritonsillar region, innervated by the glossopharyngeal nerve, the lesser palatine nerves, and the lingual nerve. It has been applied peri-operatively in three different ways (1) pre-incisional peritonsillar infiltration (2) post-tonsillectomy wound infiltration, and (3) post-tonsillectomy packing with soaked gauze. Topical application of bupivacaine, rather than infiltration in tonsillar bed, is considered safer. Serious and life-threatening complications had been reported after bupivacaine injection, including convulsions, paraesthesia's, arrhythmias and allergic reactions [22].

In our study, the mean age of patients was 8.63 ± 2.63 in group-A and 8.32 ± 6.60 in Group-B. The age range was 5-15 years, and most of the patients were between 5-10 years of age. In a study done by S. Yilmaz et al, the mean age in Group with bupivacaine was 7.5 ± 2.6 while that in group without bupivacaine was 7.9 ± 3.9 . Sabbar S., did a study where the mean age group of patients receiving bupivacaine was 17.88 ± 4.775 , and that of patients not receiving bupivacaine was 16.6 ± 3.95 . The age range was 10-30 years. In a study done by Haq E et al. the age range was 5-30 years with a mean age 9.23 years.

The male to female ratio in our study was 1:1.07 in group A and 1:1 in group B. The male to female ratio in a study done by Hydri AS et al, was 1:1.2, which is comparable to our results. In a study done by Haq E the ratio was 2:3. In another study done by Sabbar S, the male to female ratio was 1.17, which is again comparable to our study.

We calculated the mean BMI in each group, which was 15.18 ± 1.60 in group A and 14.96 ± 1.34 in group B. None of the other studies have described BMI, which is a feature unique to our study.

Vasan NR studied pre-operative infiltration of 5 ml of 0.5% bupivacaine hydrochloride and used the Visual Analogue Scale to assess the postoperative pain in the first twenty-four hours [21]. However, he found no statistically significant benefit with its use. Similarly, post-tonsillectomy wound infiltration with Bupivacaine and again did not find any statistically significant difference in pain levels, oral intake or full jaw opening between the two groups [22].

Most of the studies done to assess postoperative packing of tonsillectomy fossae with bupivacaine-soaked gauze divided the patients in two groups (one group was given bupivacaine, other acted as control) and measured pain scores at regular intervals i.e., at 1, 4, 8, 16 and 24 hours after surgery in both the groups and they found bupivacaine effective in reducing pain during the first 24 hours but not after that. Our study also assessed the effect of postoperative packing of tonsillar fossa with bupivacaine but we only measured the pain scores at 24 hours after the surgery, unlike most of the other studies. The mean pain score of group A in our study was 2.63 ± 0.938 , and that of group

Table-III: Mean & median pain scores of group-A and group-B.

Parameters		Median Pain Score	Group A	Group B	p-value
			n=3	n=6	
Age (years)	5-10	Mean Pain Score±SD	2.68±0.959	5.06±0.835	<0.001
	11-15		2.50±0.894	5.38±0.744	
Gender	Male		2.74±0.930	5.13±0.776	<0.001
	Female	Mean Pain Score±SD	2.52±0.949	5.10±0.885	
Duration (weeks)		Mean Duration±SD	13.5±6.3	12.4±6.4	

B was 6.07 ± 0.800 . The difference in pain scores was found to be statistically significant. This reduction in pain was noted in both younger (5-10 years) and in older groups (11-15 years), irrespective of their gender. Heward E measured the pain scores between two groups at 1, 4, 8, 16 and 24 hours [20]. The pain scores at 24 hours was 5.01 ± 1.27 in the bupivacaine group and 5.61 ± 1.24 in patients who did not receive bupivacaine. This is not comparable to our study but is statistically significant. The pain score at 24 hours in their tested group was 2.09 ± 0.95 and in bupivacaine group was 1.97 ± 0.95 . This is again not comparable to our results but is still statistically significant.

Contrary to our results, Hydri A S et al. packed only one tonsillar fossa with 3 ml of 0.5% bupivacaine, and the other one acted as control [23]. They measured pain scores using VAS during the first eight hours of surgery and found no statistically significant difference. The pain score of the untreated fossa was 5.97 ± 1.14 , and the pain score of the treated fossa was 5.82 ± 0.64 , which was not statistically significant. This may be a better method since it compared to pain in both tonsillar fossae in the same patient.

CONCLUSION

It is concluded from this study that tonsillectomies performed by dissection method using bupivacaine-soaked packs postoperatively are associated with lower postoperative pain as compared with those packed with normal saline. Thus, we believe that the use of this technique after tonsillectomy reduces postoperative pain and may result in additional benefits to the patients, such as early recovery and shorter hospital stay. This may be highly significant for uncertain situations such as the COVID-19 pandemic.

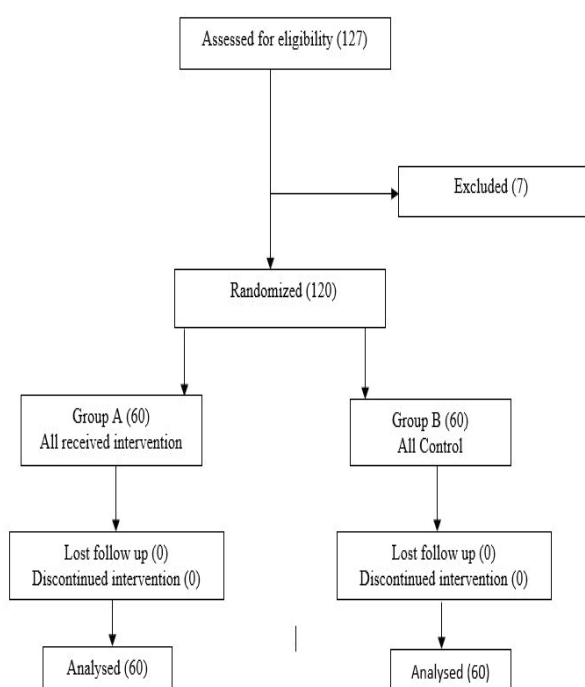
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Sabih Nadeem Qamar: Conception, design, analysis, literature review, and manuscript writing.
Zia us Salam Qazi: Surgeon, and data collection.
Sarfraz Latif: Data Collection, critical review, and supervision.
Sadia Maqsood Awan: Data analysis, and critical review.
Saulat Sarfraz: Literature review and data Processing.
Riffat Saeed: Data collection, anaesthetist, and literature review.

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