

ORIGINAL RESEARCH

A Prospective Randomized Double-Blinded Study to Evaluate the Effect of Intraoperative Bupivacaine Use on Post-Tonsillectomy Analgesia

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ABSTRACT

Introduction: Post-tonsillectomy pain is the major cause of morbidity after the tonsillectomy, and it also leads to increased chances of complications. The use of local anaesthetic agents for this pain control is debated in literature. The objective of the present study is to evaluate the effect of local anaesthetic bupivacaine on post-operative pain relief with visual analogue scale. **Methods:** In the present study, 60 patients were randomized to 1 of the 4 groups: bupivacaine infiltration, normal saline infiltration, bupivacaine packing and normal saline packing. Post-operative morbidity in terms of pain on rest, speaking and swallowing was assessed using VAS at 4, 8 and 24 hours. **Results:** The post-tonsillectomy pain in the patients receiving bupivacaine infiltration and packing was significantly low as compared with placebo group ($p < 0.05$). There were no post-operative complications in the majority of patients. The requirement of analgesics within the first 24 hours post-surgery was less in the patient's receiving bupivacaine. **Conclusion:** We conclude that the use of bupivacaine infiltration or packing following tonsillectomy is effective in postoperative analgesia.

Keywords: Tonsillectomy, Pain, Local Anaesthetic, Bupivacaine.

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INTRODUCTION

The palatine tonsils are a collection of secondary lymphoid tissues in the tonsillar fossa. The palatine tonsils, the adenoids, the tubal tonsils, the lingual tonsils, and the sub-mucosal aggregates of lymphoid tissues in the pharynx form the Waldeyer's ring. The tonsils play an important immunological role in children, it produces IgG, IgA plasma cells on exposure to allergens. It thus enhances the local immunity and contributes to the development of systemic immunity. Tonsillectomy is the most common surgery in the otolaryngology practice and this is mainly performed for obstructive symptoms and rest for infections.[1] Even though being the commonest surgery performed in otolaryngology, surgeons are always concerned about adequate control of post-operative pain which is the most common morbidity.[2] The post-tonsillectomy pain

management remains a challenge for both the treating surgeon and the anaesthetist as it produces raw area in the pharynx with impairment of swallowing, leading to dehydration, infection of tonsillar bed and subsequently secondary haemorrhage.[3]

The literature describes various methods for adequate control of post-operative pain and decreased morbidity after tonsillectomy. Pre-operative use of local anesthetics and nerve blocks is one of the methods, the other includes the use of nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and dexamethasone.[4,5] The use of systemic analgesics and opioids provides pain relief but are associated with adverse effects like nausea, vomiting and constipation, which further decreases oral intake and adds to dehydration. Because of these reasons, the use of local anesthetic agents for adequate post-tonsillectomy pain control is being

increasingly studied. Pre-incisional peritonsillar infiltration, post-tonsillectomy wound infiltration and post-tonsillectomy packing with soaked gauze are the different ways of using local anesthetic agents.[3] Local infiltration of local anesthetic agents in the tonsillar fossa may lead to complications due to inadvertent intravascular injection, whereas topical application in the form of soaked gauze is considered safe.

Bupivacaine is a long-acting anaesthetic and potent analgesic most commonly used for paediatric regional anaesthesia because it has a lower toxic threshold as compared to other local anesthetics.[6,7] Bupivacaine has been used as a peripheral nerve block agent for post-tonsillectomy pain relief due to its above attributes.[8,9] The results of pre- and post-operative use of bupivacaine infiltration and post-operative packing of tonsillar fossa are conflicting. There is scarcity of data on the use of local anaesthetic agents in the post-tonsillectomy pain control. The present study has been done to evaluate the role of bupivacaine, in injectable and topical form in achieving post-tonsillectomy pain relief.

MATERIALS AND METHODS

The present study was carried out in the Department of Otorhinolaryngology and Department of Anaesthesiology, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, India from January 2018 to April 2020. The study comprised of 60 patients suffering from chronic tonsillitis. The age of patients ranged from 5 to 46 years and male to female sex ratio of 1.2:1. The patients were subjected to detailed history, general as well as systemic examination, which includes clinical examination of the ear, nose, paranasal sinuses, larynx and pharynx. The grade of the tonsillar enlargement was recorded and any signs suggestive of acute inflammation was checked. Diagnostic nasal endoscopy was performed whenever possible to evaluate the status of adenoid. Complete laboratory evaluation was done, and radiological evaluation was done if needed. Institutional ethical committee approval was taken, and informed written consent was obtained from the patient or their parents before enrolment into the study.

Data Collection Technique and Tools

Inclusion Criteria:

1. Patients suffering from chronic tonsillitis with or without adenoids.
2. Patients between 5 to 50 years of age.
3. Patients of chronic tonsillitis in whom the last episode occurred before 6 weeks.
4. Patients having American Society of Anesthesiologists (ASA) physical status I or II.

Exclusion Criteria:

1. Patients with an acute attack of tonsillitis, peritonsillar abscess,
2. Patients found to have systemic disease e.g. bleeding disorder and anaemic status.

3. Patients aged less than 5 years and more than 50 years
4. Patients having an ASA status of III and above.

Randomization and Methods

The patients were given four unnamed envelopes to select one of them. The envelopes were preassigned with codes for every group. In this way, the patients were randomly allocated to one of the four groups, namely bupivacaine infiltrate, normal saline infiltrate, bupivacaine pack, and normal saline pack. Each group comprised of 15 patients. The infiltration or the pack of bupivacaine and normal saline was used after the completion of surgery and just before the extubation of the patient. However, the nurse in the operation theatre was instructed to prepare the infiltration or pack with the secret codes and give it to the operating surgeon in an unnamed envelope before the procedure started. The surgeon and the patient were unable to identify the medication being used because all of them were clear liquids. Hence, the present study was a double-blinded clinical study. The patients enrolled in our study were operated on by the dissection and snare method to avoid confounding. In the first post-operative 24 hours, patients were not given any systemic analgesics.

Outcome Measures

The patients were asked about visual analogue scale (VAS) scores at different time intervals after surgery (4, 8 and 24 hours). These findings were recorded in a pre-designed proforma and were kept for analysis. The pain at rest, difficulty in speaking and difficulty in swallowing were assessed by the VAS at different time intervals mentioned above.

Statistical Analysis

Data was analyzed by using SPSS 20. The mean visual analogue score for pain at rest, difficulty in speaking and difficulty in swallowing at 4, 8 and 24 hours after surgery was compared using repeated measures analysis of variance (ANOVA) test. Tukey's Honest Significant Difference post hoc test was used after ANOVA. P value of <0.05 was considered significant while p value <0.01 was considered highly significant.

RESULTS

The present study comprised 60 patients and they were included in the study over 28 months between January 2018 to April 2020. The age of the patients ranged from 5-50 years; the mean age of participants was 12.6 years. Out of total 60 patients 32(53.3%) were male and 28(46.7%) were female, with male to female ratio of 1:1.1. The highest prevalence was seen in patients between 11-20 years of age. In our study out of total 60 patients, 22 patients were from the rural background whereas 38 patients were from the urban population. The demographic variables of the study are summarized in Table 1.

The patients enrolled in our study were operated on by the dissection and snare method. The intra-operative time for the patients ranged between 10 minutes to 30 minutes with the maximum number (58.3%) of patients having a duration of 20 minutes. In the present study, the intra-operative blood loss was 15 to 75 ml in most of the patients. All the patients in our study were given intravenous co-amoxiclav in the post-operative period for first 24 hours after surgery and then switched to oral co-amoxiclav therapy at discharge. In the first 24 hours after the surgery the patients were not given any systemic analgesics to study the effect of bupivacaine on post-operative pain relief. After the initial 24 hours of surgery, IV Paracetamol was the most common analgesic used. About one-third of the patients required the addition of a second analgesic for adequate pain control. The requirement for the second analgesic was more in the group of patients who received placebo treatment in the form of saline infiltration or packing.

The mean VAS scores for pain at rest, difficulty in speaking and difficulty in swallowing in the group of the patients receiving bupivacaine infiltration was significantly lower than the group of the patients receiving normal saline infiltration, bupivacaine pack and normal saline pack with a P value of ($p < 0.05$). The results of mean VAS scores at 4, 8 and 24 hours after surgery are given in Table 2-4.

The application of repeated measures analysis of variance (ANOVA) revealed that infiltration of bupivacaine has statistically significant relief from pain at 4, 8 and 24 hours. The difficulty in speaking was also significantly low in the group of patients receiving bupivacaine infiltration. As the patients have less pain and will resume quickly to normal activities. The difficulty in swallowing VAS scores showed a statistically significant impact of bupivacaine infiltration.

Table 1: Classification of cases based on demographic variables.

	No. of cases	Percentage (%)
Age group (Years)		
5-10	9	15.0
11-20	19	31.7
21-30	14	23.3
31-40	11	18.3
41-50	7	11.7
Sex		
Male	52	53.3
Female	48	46.7
Population		
Rural	22	36.7
Urban	38	63.3

Table 2: Mean of visual analogue scale for different groups after 4 hours of surgery

	Pain at rest (Mean±SD)	Difficulty in speaking (Mean±SD)	Difficulty in swallowing (Mean±SD)
Bupivacaine infiltrate	1.23 ± 0.26	1.04 ± 0.48	1.18 ± 0.41
Normal saline infiltrate	3.61 ± 0.92	4.34 ± 0.74	3.71 ± 0.78
Bupivacaine pack	1.75 ± 0.42	1.63 ± 0.51	2.03 ± 0.48
Normal saline pack	4.79 ± 0.78	4.41 ± 0.64	5.18 ± 0.78

Table 3: Mean of visual analogue scale for different groups after 8 hours of surgery

	Pain at rest (Mean ± SD)	Difficulty in speaking (Mean ± SD)	Difficulty in swallowing (Mean ± SD)
Bupivacaine infiltrate	1.47 ± 0.25	1.54 ± 0.51	1.63 ± 0.47
Normal saline infiltrate	3.26 ± 0.89	3.26 ± 0.72	4.21 ± 0.79
Bupivacaine pack	1.81 ± 0.41	1.89 ± 0.44	2.27 ± 0.53
Normal saline pack	2.89 ± 0.74	3.47 ± 0.67	3.41 ± 0.85

Table 4: Mean of visual analogue scale for different groups after 24 hours of surgery

	Pain at rest (Mean ± SD)	Difficulty in speaking (Mean ± SD)	Difficulty in swallowing (Mean ± SD)
Bupivacaine infiltrate	1.27 ± 0.32	1.54 ± 0.46	1.52 ± 0.52
Normal saline infiltrate	2.61 ± 0.87	3.03 ± 0.68	2.89 ± 0.83
Bupivacaine pack	1.52 ± 0.41	1.97 ± 0.45	2.69 ± 0.61
Normal saline pack	2.19 ± 0.69	2.94 ± 0.61	2.97 ± 0.78

DISCUSSION

Post-tonsillectomy pain has been a challenge for otolaryngologists as it is difficult to measure accurately because of the reasons like most of the patients are of pediatric age group and the variety of methods of surgery available.[10] The reduction of post-tonsillectomy pain is vital for both the patient's comfort and for prevention of complications. As reducing pain enhances oral intake, reduces chances of dehydration, infection and post-tonsillectomy hemorrhage.[11] Various modalities, both medical and surgical have been used for optimum pain relief following tonsillectomy. The use of local anaesthetic agents for post-tonsillectomy pain relief has been widely studied. All local anaesthetic agents including bupivacaine act by inhibition of c-fiber afferent neuron stimulation which results in decreased stimulation of dorsal horn neurons of the spinal cord.[12]

The literature suggests that the post-tonsillectomy pain is most severe in intensity on the first post-operative day and then it diminishes slowly over the period of time with a transient increase at 3-4 post operative days. Which is due to the development of scar tissue during healing process.[13] The usefulness of local anaesthetic agents for post-tonsillectomy pain relief has been a topic of debate. If local anaesthetics could provide effective post-tonsillectomy pain control, they may obviate the requirement of systemic analgesics and opioids in the post-operative period and also avoid side effects associated with these agents. The results of our study strongly support the use of bupivacaine as an effective agent for post-tonsillectomy pain relief.

In our study, it was seen that the mean pain score was significantly lower in the patients who received bupivacaine as compared to the patients in the placebo group at 4, 8 and 24 hours after surgery. This finding supports the hypothesis that bupivacaine has significant analgesic effect and could be efficiently used for post-tonsillectomy pain relief. The findings of our study are in concurrence with the studies of Goldsher M et al[9], Johansen M et al[8], Hollis LJ et al[14] and Cakar Turhan KS et al.[15] In the studies conducted by Stuart JC et al[16] and Wong Ak et al[17], they found that peritonsillar infiltration of bupivacaine has moderate relief in post-tonsillectomy pain. According to them bupivacaine infiltration reduces pain in immediate post-operative period only and has no significant effect later on. The study conducted by Vasani NR et al[18] found no statistically significant benefit for use of preincisional infiltration of bupivacaine in tonsillectomy. This finding was not in concurrence with the finding of our study.

The difference in the results of these studies may be attributed to the variability in use of the surgical techniques, pre-anaesthetic medications and different strengths of the local anaesthetics used. In our study, all the patients were operated by dissection and snare

method of tonsillectomy. This method of tonsillectomy in expert hands produces minimal inflammation after surgery and hence post-operative pain. In our study the surgical technique, pre- and post-operative management of all the patients remained the same, it is therefore observed that the difference in the post-operative pain is due to the effect of the local anaesthetic bupivacaine used.

The use of the local anaesthetic agent bupivacaine is associated with cardiac arrhythmias if it is inadvertently administered to the blood vessels. Its deep peritonsillar injection may cause bilateral vocal cord paralysis lasting for many hours. It may also cause vagal or hypoglossal nerve blockage, life-endangering deep cervical abscess, and brain stem stroke as a result of cardiac asystole leading to tracheostomy and gastrostomy tube placement. These are seen especially after infiltration of a deeper and higher volume of local anaesthetics with vasoconstrictors into the tonsil and adenoid beds.[19-21] The patients included in our study do not have any major complications.

CONCLUSION

Tonsillectomy is one of the most common operations performed by otolaryngologists worldwide. Post-operative pain management remains a challenge to the operating surgeons and anaesthetist. Post-tonsillectomy use of local anaesthetic bupivacaine in the form of infiltration and packing at the surgical site has a statistically significant role in reducing pain after surgery. In our study pain severity in the bupivacaine group of the patients was significantly lower than the normal saline group. Our study concludes that bupivacaine, both as an infiltration and packing at local site after tonsillectomy is effective in achieving post-operative analgesia.

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