VOLUME - 12, ISSUE - 05, MAY - 2023 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Anaesthesiology

COMPARATIVE STUDY OF 0.2% ROPIVACAINE VERSUS PLACEBO FOR POST OPERATIVE ANALGESIA TO PATIENTS UNDERGOING TONSILLECTOMY UNDER GENERAL ANAESTHESIA

Dr. Velagala Ravi Tej Reddy MBBS

Dr. Ravi Shankar R.B* MBBS., MD., DA Anesthesia*Corresponding Author

ABSTRACT

BACKGROUND AND OBJECTIVE: Tonsillectomy is one of the most common surgical procedures performed worldwide in children and adults. Reducing post-operative pain is one of the most common taxing concern for anaesthesiologist as well as the surgeon, in the immediate post-operative period. This study aims in comparative evaluation of ropivacaine 0.2% and placebo for post-operative analgesia aged 10-30 years undergoing tonsillectomy under general anaesthesia. **METHODS:** 60 patients of either sex aged 10-30 years who diagnosed with chronic adeno tonsillitis undergoing tonsillectomy and are willing to participate in this study will be selected, informed and written consent will be taken from all patients. During study 60 patients are randomly divided into two groups (Group A and Group B). Group A (30 patients) are given 2ml of 0.2% Ropivacaine infiltration in each fossa after tonsillectomy and Group B (30 patients) are given 2ml of 0.9% saline infiltration in each fossa after tonsillectomy. Post-operative pain was evaluated using VAS (visual analogue scale) at regular intervals. **RESULTS:** Out of the 60 patients, 30 patients in each group were evaluated and compared. Patients demographic profile were similar in both groups. No significant difference was found among them with respect to age, sex, diastolic blood pressure, PR, Spo2, RR. SBP was statistically significant($p<0.05$) in study group at 1,3,6 and 8 hours respectively as compared to control group. VAS score was highly significant($p<0.05$) in study group at immediate post-operative period, 1,2,4,6 and 8 hours respectively as compared to control group. **CONCLUSION:** We conclude that patients who were infiltrated with 0.2% ropivacaine in the tonsillar fossa during tonsillectomy had lower post operative pain scores during immediate post operative period,1 hour, 2 hours, 4 hours, 6 hour and 8 hours respectively.

KEYWORDS : Postoperative pain; Blood Pressure; Pulse rate; SPO2; Respiratory Rate.

INTRODUCTION:

Patients who are having surgery often worry the most about postoperative discomfort. Numerous studies conducted with well-integrated health care infrastructures have indicated that even in the first decade of the twenty-first century, one-third to one-half of patient's postoperative pain was not well treated. But it appears that things are getting better with time. The treatment of postoperative pain is supported by a wealth of medications, pharmacological formulations, acute pain management techniques, and empirical data.[1] The hardest part is integrating this knowledge into daily life. Limited financial resources, a lack of time and resources, as well as the incapacity to handle this issue, and the absence of clear and consistent instructions all contribute to this situation.[2] For postoperative analgesia to be given to anybody who needs it, it is crucial to acknowledge that adequate analgesia is not only necessary but also a fundamental entitlement to any patient experiencing pain and a fundamental obligation to every healthcare professional who treats these patients.

OBJECTIVES OF STUDY:

1. To study and compare ropivacaine 0.2% and placebo for post-operative analgesia aged 10-30 years undergoing tonsillectomy under general anaesthesia with respect to the following parameters.
I. Relief from postoperative pain
II. Haemodynamic changes like BP, PR, RR, SPO2.

METHODOLOGY:

Patients of either sex in age group of 10-30 years undergoing tonsillectomy are selected at Bapuji Hospital and CG district Hospital, teaching hospitals attached to J.J.M. Medical College, Davangere.

Duration of study: August 2020 to June 2022

Study design: Prospective, Comparative study.

Sample size: 60 cases (Group R 30 patients; Group P 30 patients)

Method of Collection: Those patients undergoing tonsillectomy who fulfilled all inclusion criteria and exclusion criteria and are willing to participate in this study will be selected, informed and written consent will be taken from all patients.

Inclusion criteria:
1) Age – 10 years to 30 years.
2) Gender - male and female.
3) Patients posted for Tonsillectomy under GA.
4) ASA Grade 1 and 2.

Exclusion criteria:
1) Neurological or psychiatric diseases.
2) Coagulation disorders.
3) Patients with co morbid conditions (hepatic, cardiac, endocrine).
4) Patients not willing to take part in study.

Method: During study 60 patients are randomly divided into two groups (Group R and Group P). Group R (30 patients) are given 2 ml of 0.2% Ropivacaine infiltration in each fossa after tonsillectomy and Group P (30patients) are given 2ml of 0.9% saline infiltration in each fossa after tonsillectomy.

Postoperative pain was evaluated using VAS (visual analogue scale) at regular intervals. Other parameters like hemodynamic status, surgical duration, anesthesia duration, recovery period, any adverse reactions to the medications are also regularly recorded.

Investigations include: 1. Complete haemogram, bleeding time, clotting time. 2. Random blood sugar.3. Renal function test. 4. ECG, HIV, HBsAg. 5. Urine for albumin and microscopy. 6.Any other special investigations if necessary.

STATISTICAL ANALYSIS:

Categorical data will be represented in the form of frequency and percentage. Association between variables were

assessed with Chi Square Test. Quantitative data will be represented as Mean & Sd. Comparison of variables will be done with Unpaired *t*-test. A P-value of <0.05 was considered statistically significant. Data was analyzed with IBM SPSS Version 22 for windows.

RESULTS:

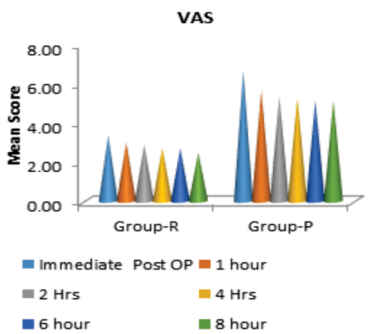
Out of the 60 patients, 30 patients in each group were evaluated and compared. Patients demographic profile were similar in both groups. No significant difference was found among them with respect to age, sex, diastolic blood pressure, PR, Spo2, RR, systolic blood pressure. VAS score was highly significant($p<0.05$) in study group at immediate post-operative period, 1,2,4,6 and 8 hours respectively as compared to control group.

There was a statistically significant difference seen in post-operative pain scores between the two groups at all-time intervals, with Group R having a lower pain Score as compared to Group P.

Average scores of Group R was found to be 3.37±1.43, 3.00±1.11, 2.87±1.33, 2.70±1.15, 2.70±1.32 and 2.47±1.22, while that of Group P being 6.67±1.03, 5.67±1.18, 5.33±1.12, 5.27±1.08, 5.13±1.04 and 5.13±1.04, at immediate post op period, 1st hour, 2nd hour, 4th hour, 6th hour and 8th hour respectively.

Table 1: VAS score

Time Interval	Group-R		Group-P		Unpaired t Test	
	Mean	Std. Deviation	Mean	Std. Deviation	P Value	Significance
Immediate Post OP	3.37	1.43	6.67	1.03	0.001	HS
1 hour	3.00	1.11	5.67	1.18	0.001	HS
2 hours	2.87	1.33	5.33	1.12	0.001	HS
4 hours	2.70	1.15	5.27	1.08	0.001	HS
6 hours	2.70	1.32	5.13	1.04	0.001	HS
8 hours	2.47	1.22	5.13	1.04	0.001	HS
HS = HIGHLY SIGNIFICANT						



Tonsillectomy is one of the most commonly performed surgeries and postoperative pain management is one of the biggest challenges. Therefore, it is imperative to find the appropriate mode of postoperative pain control.

After a tonsillectomy, pain is brought on by inflammation, nerve irritation, and pharyngeal muscle spasms, which produce the release of substance P, chemokines, and vasoactive intestinal peptide. Inadequate postoperative pain management can cause substantial discomfort, postoperative nausea and vomiting (PONV), which can limit oral intake, lengthen hospital stays, and potentially necessitate hospital readmission after discharge due to severe dehydration. By carefully administering a suitable analgesic drug, this can be avoided.[3]

To reduce the discomfort, a variety of efforts have been attempted, including the infusion of local anaesthetic drugs. By pharmacologically blocking sensory pathways before surgery, a LA is thought to lessen pain by preventing nociceptive impulses from accessing the spinal cord. The lingual nerve, lesser palatine nerve, and glossopharyngeal nerve all send fibres to the peritonsillar area. The rationale for LA injection is to inhibit these fibres.

POST OPERATIVE PAIN:

Our study has compared the effect of 0.2% ropivacaine infiltration in the tonsillar fossa against placebo infiltration in the tonsillar fossa, and we have found that 0.2% ropivacaine offers significant pain relief compared to placebo at immediate post-operative period, 1 hour, 2 hours, 4 hours, 6 hours and 8 hours respectively.

In our study, in comparison of VAS score at time duration Immediate post op (Z-value=1.43, p=0.001 <0.01), 1 hour (Z-value=1.11, p=0.001 <0.01), 2 hour (Z-value =1.33, p=0.001 <0.01), 4 hour (Z-value=1.15, p=0.001<0.01), 6 hour (Z-value =1.32, p=0.001 <0.01), 8 hour (Z-value=1.22, p=0.001 <0.01) which shows highly statistical difference at p<0.01 level.

In 2004 a study performed by Mehmet A. Somdas, *et al.*,[4] 30 patients were locally infiltrated with 0.5 per cent bupivacaine in the right tonsil bed and got local infiltration of 0.9 % normal saline in left tonsil bed. Patients were required to find pain on the most painful part of pharynx, 1st, 4th, 8th, 16th, 24th hour. In the Bupivacaine group, significant difference was found between the control periods (P<0.05). (Cochran's Q = 23,459) The major contribution to the difference lay in the contrast between the fourth and the eighth hours (P<0.05). Total pain score at the placebo side did not change significantly, but it decreased significantly after the 4th hour, on Bupivacaine side. There are significant differences between the two sides at 8th, 16th and 24th hours (P<0.05), Pain lateralizes to the placebo side at the mentioned hours. But in our study VAS score of Ropivacaine group comparing to placebo at Immediate post op ,1 ,2, 4, 6 and 8 hour are highly statistically significant p< 0.01 level.

Ertap Akoglu *et al.*,[5] showed that Local Ropin infiltration is a safe and effective method and equivalent to Bupin for post-Ton' pain.

Önder İhvan *et al.*,[6] showed that Intraoperative preincisional Bupin injection is useful in postoperative pain control at early period of time in children undergoing Ton'. But it has no effect in pain reduction after 24 hours.

Gaurav Kuthiala *et al.*,[7] showed that Ropin is a well-tolerated regional anesthetic effective for surgical anesthesia as well as the relief of postoperative and labour pain, with efficacy of Ropin is similar to that of Bupin and L-Bupin. Clinically adequate doses of Ropin appear to be associated with a lower amount of motor block than Bupin.

Ayatollahi *et al.*,[8] showed that tramadol had significantly better pain control with shorter time to the beginning of liquid regimen and led to less demand for analgesic than placebo and ketamine group.

Chhanya Bhandari *et al*[9], demonstrated that peritonsillar infiltration of ropivacaine during surgery promotes analgesia in the first few hours following surgery, with a subsequent decrease in the need for analgesia throughout the first 24 hours following surgery. Therefore, using it in adult patients having tonsillectomy is advised.

COMPLICATIONS:

Reported complications are namely bilateral vocal cord

paralysis lasting 5 h, severe upper airway obstruction with pulmonary edema due to vagal or hypoglossal block, life-threatening deep cervical abscess, and brain stem stroke[10] due to cardiac asystole intraoperatively necessitating tracheotomy and gastrostomy tube. These are seen especially after deeper and higher volume infiltrations of local anaesthetics with vasoconstrictors into tonsillar and adenoid beds. We experienced no complications probably because of superficial injection of ropivacaine which is not able to block the vagus nerve. Also the infiltrate was free of adrenaline, securing the cardiac rhythm.

In a study conducted by Ertap Akoglu *et al.*,[5] in 2005, 46 young children of age between 2 – 12 years who underwent tonsillectomy were included in the study. Group 1 got bupivacaine, group 2 got ropivacaine and group 3 (control) got 0.9 per cent of NaCl given around each tonsil. Subjective symptoms of nausea, abdominal pain, constipation, and otalgia were similar between the groups ($p > 0.05$). No major complications such as airway obstruction, haemorrhage, dehydration, or local anaesthetic toxicity developed. But in our study we encountered no such complications.

In a study conducted by Fatih Oghan *et al.*,[11] forty-one children aged 4 to 16 years undergoing tonsillectomy were included in the study. Patients received swabs soaked in 1.0% ropivacaine hydrochloride into the fossa tonsils, and control groups received swabs soaked in saline. Topical administration of 1.0% ropivacaine is a safe and effective method to significantly reduce the pain of paediatric tonsillectomy. Other postoperative parameters such as nausea, fever, vomiting, odour, bleeding, ear pain and trismus were also not statistically different between the two groups. There were no complications associated with ropivacaine hydrochloride. No patient in this study experienced any systemic side effects associated with the use of this drug.

CONCLUSION:

From our study, we conclude that 0.2% ropivacaine infiltration in the tonsillar fossa gives better post-operative pain relief in patients undergoing tonsillectomy during immediate post op period, 1st hour, 2nd hour, 4th hour, 6th hour and 8th hour respectively.

REFERENCES:

1. Giannoni, S. White, FK. Enneking, T. Morey. Ropivacaine with or without clonidine improves pediatric tonsillectomy pain. Arch Otolaryngol Head Neck Surg. 2001;127:1265-1270.
2. AH. Park, AL. Pappas, E. Fluder, S. Creech. Effect of perioperative administration of ropivacaine with epinephrine on postoperative pediatric adenotonsillectomy recovery. Arch Otolaryngol Head Neck Surg. 2004;130: 459-464.
3. Ju NY, Cui GX, Gao W. Ropivacaine plus dexamethasone infiltration reduces postoperative pain after tonsillectomy and adenoidectomy. Int J Pediatr Otorhinolaryngol. 2013;77(11):1881–5.
4. Somdas MA, Senturk M, Ketenci I, Erkorkmaz U, Unlu Y. Efficacy of bupivacaine for post-tonsillectomy pain: A study with the intra-individual design. International Journal of Pediatric Otorhinolaryngology. 2004;68(11): 1391-1395.
5. Akoglu E, Akkurt BC, Inanoglu K, Okuyucu S, Dagli S. Ropivacaine compared to bupivacaine for post-tonsillectomy pain relief in children: A randomized controlled study. International Journal of Pediatric Otorhinolaryngology. 2006; 70(7):1169-1173.
6. İhvan Ö. Evaluation of the duration of postoperative pain control obtained with bupivacaine injection into the tonsillar region in children who underwent tonsillectomy.
7. Kuthiala G, Chaudhary G. Ropivacaine: A review of its pharmacology and clinical use. Indian Journal of Anaesthesia. 2011;55(2):104.
8. Ayatollahi et al. Peritonsillar ketamine and tramadol and pain. Croat Med J 2012;53:155-61.
9. Bhandari C, Pokharel A, Mayya NJ, Thapa A. Peritonsillar Infiltration of Ropivacaine and Pain Control in Immediate Postoperative Period Following Tonsillectomy Surgery in Adult Patients. JCMS Nepal. 2022; 18(3); 215-20.
10. J. Colclasure, S. Graham. Complications of tonsillectomy and adenoidectomy, in: D. Eisele (Ed.), Complications in Otolaryngology–Head and Neck Surgery, Mosby, St. Louis, MO, 1993.
11. Oghan F, Harputluoglu U, Guclu E, Kocaman B, Ozturk O. Does topical ropivacaine reduce the post-tonsillectomy morbidity in pediatric patients?. Int J Pediatr Otorhinolaryngol. 2008;72(3):361-5.