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Original Research Article

Effect of pre-incisional infiltration of 0.5% ropivacaine versus placebo in post-operative pain relief among patients undergoing tonsillectomy under general anaesthesia: a comparative study

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ABSTRACT

Background: Pain is the most common complaint in the immediate post-tonsillectomy period. Inadequate post-tonsillectomy pain management has many drawbacks. Ropivacaine is a new long acting local anaesthetic, structurally closely related to bupivacaine.
Methods: It was a prospective double blinded randomized control trial on a total of 50 patients who were posted for tonsillectomy. Randomization of each patient was done into two groups one of which had received 4 ml of 0.5% ropivacaine hydrochloride solution and other 4 ml normal saline. Data entry and analysis was done with (SPSS IBM) version 21.0. Both univariate and bivariate analysis done. Proportions were calculated for qualitative variables and mean with standard deviation was done for quantitative variables. Required tests of significance such as Chi square test and independent test were applied. Significance of p value is taken as $p<0.05$. Postoperative pain, first post op oral intake, duration of post-operative hospital stay, and postoperative haemorrhage was assessed. The intensity of postoperative pain was assessed on behavioural observational pain Scale and Wong baker faces pain rating scale.
Results: Pre-incisional infiltration of 0.5% Ropivacaine was an effective method to reduce post-operative pain in patients undergoing tonsillectomy under GA. Effect of Ropivacaine was statistically significant ($p<0.05$).
Conclusions: We recommend the use of 0.5% ropivacaine pre-incisional infiltration in patients undergoing tonsillectomy.

Keywords: Ropivacaine, Tonsillectomy, Adenotonsillectomy, BOPS

INTRODUCTION

Various tonsillectomy studies have shown the advantage of local anaesthetic (LA) injection, perioperatively to prevent pain stimulus.[1] The reasons for using LA agents perioperatively are both to block peripheral nociceptive excitation after tissue damage and to prevent the sensitization of the central nervous system. Ropivacaine is a new long acting local anaesthetic, structurally closely related to bupivacaine. It is the first enantiomerically pure local anaesthetic, and exists as the S-enantiomer.[2] Ropivacaine exhibits less central nervous system and cardiovascular toxicity than bupivacaine in healthy volunteers.[3,4] The objective of the present study is to compare the efficacy of pre incisional infiltration of ropivacaine vs. placebo on

postoperative pain relief among patients undergoing tonsillectomy and to find out the possibility of any complication in relation to ropivacaine infiltration into the peritonsillar fossa.

METHODS

The study was a prospective, double blinded randomized controlled trial. All patients who had attended ENT outpatient clinic at Tata Main Hospital, located in Jamshedpur of Jharkhand State of India with a history of recurrent or chronic tonsillitis, from July 2018 to June 2020, included in this study, in whom 50 patients aged 5 to 18 years were planned for tonsillectomy.

The selection criteria were, age group between 5 and 18 years both sexes and patient undergoing tonsillectomy for symptomatic tonsillar enlargement. Exclusion criteria were, age group less than 5 years and more than 18 years, patients known for bleeding disorders, liver and kidney dysfunction, cardiovascular comorbid conditions making him/her unfit for general anesthesia, patients with histories of allergies and anaphylaxis and patients having active infections such as quinsy, acute pharyngo-tonsillitis.

The Wong-Baker pain scale (WBS) and behavioural observational pain scale (BOPS) were used to evaluate post operative pain. WBS is highly preferred by children and parents for reporting pain severity.[5] BOPS was used to evaluate post operative pain. It is tool which has been used to measure post-operative pain and it has been shown to be a particularly useful tool in pre-school children. Patients received the study drug as per randomization. Group 1-4 ml of 0.5% ropivacaine hydrochloride group 2-4 ml of 0.9N normal saline.

Required tests of significance such as Chi square test and independent test were applied at $p<0.05$.

RESULTS

Operation type

Among all 50 patients 47 (94%) patients underwent tonsillectomy and 3 (6%) underwent adenotonsillectomy.

Tonsillectomy

Among those who underwent tonsillectomy, 24 (51.1%) were on ropivacaine and 23 (48.9%) were on saline treatment.

Adenotonsillectomy

Three patients underwent Adenotonsillectomy among which 1 (33.4%) were in ropivacaine and 2 (66.6%) on saline treatment.

Intra-operative bleeding

Eleven (22 %) cases have intraoperative episode of bleed which required control by ligature. 6 (24%) were in ropivacaine group and 5 (20%) were in saline group. No Statistically significant difference observed in intraoperative bleeding time in both groups ($p>0.05$).

Behavioral observational pain score

The average pain score of all patients at 2nd hour, 6th hour and 10th hour is 2.52, 1.94 and 1.56 respectively. In ropivacaine group the average pain score at 2nd hour post-surgery is observed as 1.36, 1.24 at 6th hour and 1.08 at 10th hour. In saline group the average scores are found to be 3.68, 2.64, 2.04 at 2nd, 6th and 10th hour respectively. Statistically significant difference is observed in pain scores between both groups at all time intervals ($p<0.05$) (Table 1).

Table 1: Behavioural observational pain score.

	BOPS		
	2nd hour	**6th hour**	**10th hour**
All patients	2.52	1.94	1.56
Ropivacaine	1.36	1.24	1.08
Saline	3.68	2.64	2.04

Wong Baker faces pain scores

The WB pain score is observed as 5.52, 4.28 and 3.12 at 2nd, 6th and 10th hour in all patients respectively. In ropivacaine group pain is observed to be 3.76 after 2hrs, 3.2 after 6 hrs and 2.64 after 10 hours of operation. In saline group pain score is found to be 7.28, 5.36 and 3.6 after 2hrs, 6 hrs and 10 hrs. of operation respectively. Statistically significant difference is observed in WB pain score across ropivacaine and saline groups ($p<0.05$) (Table 2).

Table 2: Wong Baker faces pain scores.

Wong Baker pain scores	2nd hour	6th hour	10th hour
All patients	5.52	4.28	3.12
Ropivacaine	3.76	3.2	2.64
Saline	7.28	5.36	3.6

Oral intake

In present study 62% started oral intake at 6 hours' post-surgery and 80% started at 8 hours after surgery. In ropivacaine group 80% started oral intake after 6 hours and 96% started after 8 hours of surgery. Whereas 44% started oral intake in saline group at 6 hours and 64% at 8 hours after surgery. A statistically significant difference is found between both groups ($p<0.05$) (Table 3).

Table 3: Oral Intake.

Oral Intake	6 hours	8 hours
	N (%)	N (%)
Ropivacaine	16 (80)	24 (96)
Saline	11 (44)	16 (64)

Post-operative admission days

It is observed that average time of admission post operation is 3.78 days. In ropivacaine group the average time postoperative admission is 3.44 days and in saline group it is found to be 4.12 days. There is a statistically significant difference between duration of admission in saline and ropivacaine group ($p<0.05$) (Table 4).

Table 4: Total admission days.

Total admission days	Average
All patients	3.78
Ropivacaine	3.44
Saline	4.12

DISCUSSION

Despite advances in anaesthetic and surgical techniques, post tonsillectomy morbidity remains a major clinical problem. Hence studies are being performed to find treatments with fewer side effects, especially for paediatric patients who are more sensitive to pain. In a study by Arikan et al, it was found that the constant postoperative pain in the ropivacaine side at rest was significantly less than in the placebo side on days 1, 2, 5, and 6 ($p<0.05$). The post-tonsillectomy pain experienced in the ropivacaine side when swallowing was significantly less than that in the placebo side throughout the study period except on day 10 ($p<0.05$) and concluded that pre incisional infiltration of ropivacaine 2% appears to be effective against both early and late postoperative pain, especially on swallowing, following tonsillectomy in adults.[6] In a prospective study of day surgery care unit for children and a neurosurgical postoperative care unit, 76 chilthe study was divided into interrater reliability, concurrent validity, and construct validity and observed that interrater reliabilities of the observers were very good with a high agreement between the different nurses' BOPS scores and concluded that with BOPS, the caretaker can evaluate and document pain with high reliability and validity and thereby improve postoperative pain treatment in children.[7] In a study by Helgadóttir on 68 children undergoing tonsillectomy were taught to use the Wong-Baker faces pain rating scale.[8] The WB pain score was observed as 5.52, 4.28 and 3.12 at 2nd, 6th and 10th hour in All patients respectively. In ropivacaine group pain was observed to be 3.76 after 2 hrs, 3.2 after 6 hrs and 2.64 after 10 hours of operation. In saline group pain score is found to be 7.28, 5.36 and 3.6 after 2 hrs, 6 hrs and 10 hrs of operation respectively. Statistically significant difference is observed in WB pain score across ropivacaine and saline groups ($p<0.05$). Akoglu et al compared the effects of ropivacaine and bupivacaine on post-tonsillectomy pain in children and found that local ropiva-caine infiltration is a safe and effective method and equivalent to bupivacaine for post-tonsillectomy pain. In their study it was found that the pain scores were similar between the bupivacaine and ropivacaine groups ($p>0.05$). The pain scores in both analgesia groups were significantly ($p<0.05$) lower 1, 4, 12, 16, and 24h post-operatively compared to the control group. Analgesic requirements and the time to first analgesia were also significantly ($p<0.05$) different between the analgesia and control groups.[1]

In present study 62% started oral intake at 6 hours' post-surgery and 80% started at 8 hours after surgery. In ropivacaine group 80% started oral intake after 6 hours and 96% started after 8hours of surgery. Whereas 44% started oral intake in saline group at 6 hours and 64% at 8 hours.

In a study of 120 patients aged between 4 and 13 years, who were randomized into four groups. In group 1 (31 patients, mean age (8.40±4.05 years) received topical lidocaine hydrochloride with 1:100,000 epinephrine was applied to surgical bed following tonsillectomy. Group 2 (29 patients, mean age (8.15±4.20 years)) and group (31 patients, mean age (7.75±3.95 years)) were administered 0.25% bupivacaine hydrochloride with 1:200,000 epinephrine and 0.5% ropivacaine respectively. In Group 4 (29 patients, mean age 8.15±4.20 years) topical 0.9% saline was used. The difference between mean operative time of the three groups against saline injected group was statistically significant ($p<0.001$) in their study. The difference between mean pain score between ropivacaine and bupivacaine groups was not statistically significant ($p>0.001$), they concluded that ropivacaine infiltration is as effective as bupivacaine for post-tonsillectomy pain management in children.[9] In a study by Oghan et al, to determine whether post-operative administration of topical ropivacaine hydrochloride decreases morbidity following Adenotonsillectomy it was found that in first hour there was no significant pain-relieving effect seen in the ropivacaine group ($p>0.05$).[10] The other hours and days there were statistically significance between the two groups ($p<0.001$). Also, the other post-operative parameters such as nausea, fever, vomiting, odour, bleeding, otalgia and trismus were not statistically different between the two groups. They concluded that locally 1.0% ropivacaine administration significantly relieves the pain of paediatric tonsillectomy and, it is a safe and effective method. Also, high concentrations of ropivacaine may produce clinically significant pain relief.

CONCLUSION

With our study, we conclude that pre-incisional infiltration of 0.5 % ropivacaine is an effective method to reduce post-operative pain in patients undergoing tonsillectomy under GA. It is also effective for early start

of postoperative oral feed and also reduces the cost of postoperative hospital stay. There were no additional complication raised because of ropivacaine use and we recommend routine use of 0.5% ropivacaine as pre-incisional infiltration in patients undergoing tonsil-lectomy.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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