

Ropivacaine versus Bupivacaine for Post-Tonsillectomy Pain Management in Pediatric Cases – A Randomized Double-Blind Comparative Study

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Conflict of interest: Nil

Abstract

Introduction: Post tonsillectomy pain management is important to mitigate common postoperative morbidity. The effective postoperative analgesia is important in reducing postoperative pain. The present study was designed to assess the efficacy of preoperative infiltration of ropivacaine and bupivacaine in postoperative analgesia in pediatric cases undergoing tonsillectomy.

Materials and methods: A total of 36 children undergoing elective adenotonsillectomy between 2-12 years of age belong to ASA grade I and II were considered. Participants were randomly divided into two groups i.e. group A (3 ml of 0.25% of bupivacaine hydrochloride) and group B (0.2% ropivacaine hydrochloride 3ml). Postoperative pain score was assessed by Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) till 24 hours after procedure.

Results: The mean levels of hemodynamic parameters and rate of postoperative complications was comparable between two drug groups. The ropivacaine group showed low pain scores at all time intervals than bupivacaine group. The mean difference of pain scores was significant at 1 hour, 2 hours, 8 hours, 12 hours and 24 hours between two study groups ($p < 0.05$)

Conclusion: Both drugs are effective in minimizing the postoperative pain; however, ropivacaine was superior in postoperative pain relief as compared to bupivacaine.

Keywords: Bupivacaine, Ropivacaine, Postoperative pain, efficacy, tonsillectomy

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Introduction

Postoperative pain is an unpleasant sensory experience, also triggers various biochemical and physiological stress response [1]. Tonsillectomy is frequently observed in children that associated with postoperative pain which lasts for 7 to 10 days after procedure [2]. Management of postoperative pain and post-tonsillectomy morbidities have

significant clinical concern and may challenge to the anesthetist [3,4]. Intraoperative seize of peripheral nerve pain impulses to central nervous system can control its hyperexcitability state that diminishes postoperative pain [5]. Tonsillectomy procedure damages local tissue with release of inflammatory

mediators to activate C fibres transmitting pain [6].

Studies suggested several options for post-tonsillectomy pain reduction including use of topical lignocaine, pethidine, bupivacaine and ropivacaine [7]. Infiltration of local anesthetic agent into tonsillar bed facilitates analgesia with less adverse effects and helpful for controlling postoperative pain [8]. Ropivacaine is a amino amide group of local anesthetics which blocks the generation and conduction of nerve impulses like bupivacaine and has vasoconstriction property [9]. However, bupivacaine is two to three time less soluble and has a lesser volume of distribution and less elimination half-life than ropivacaine in human beings [10]. Few studies have been reported that ropivacaine is safer and more effective in postoperative pain management in tonsillectomy [11].

With limited availability of literature, the present study was designed to assess the efficacy of preoperative infiltration of ropivacaine and bupivacaine in postoperative analgesia in pediatric cases undergoing tonsillectomy.

Material and Methods

The present randomized double-blind study was conducted in the Department of Anaesthesia at MNR Medical College and Hospital, Sangareddy during January 2021 to August 2022. A total of 36 children undergoing elective adenotonsillectomy surgery between 2-12 years of age were recruited. Children belong to ASA grade I and grade II, undergoing elective adenotonsillectomy and willing to participate in the study were included. Children with contraindications to the study drugs, with oral

Results

and pharyngeal infection, asymmetric tonsillar enlargement, with coagulation disorders, with chronic diseases and not willing to participate were excluded. Study procedure was explained and written informed consent was obtained from parent or guardian. The study protocol was approved by institutional ethics committee.

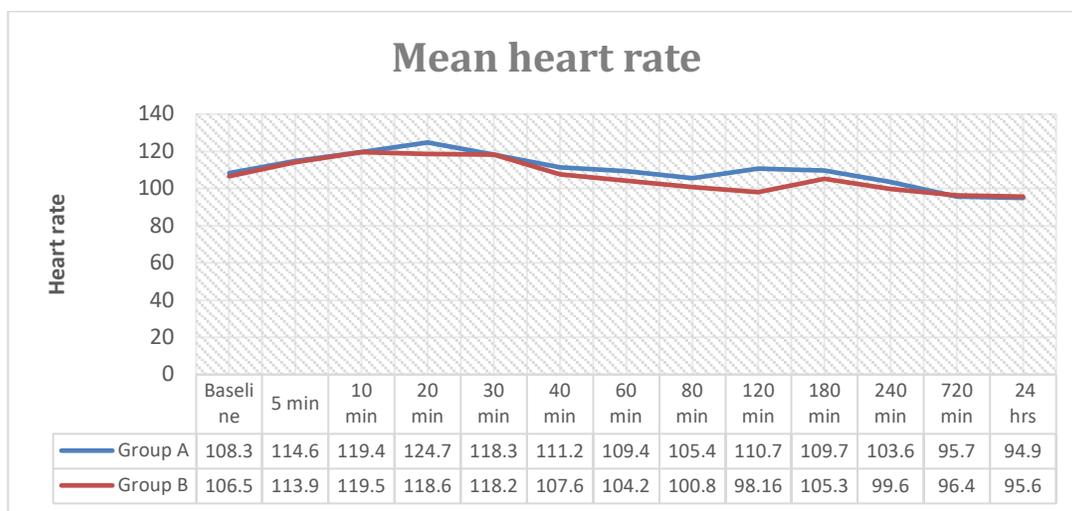
Study participants were randomly divided into two groups. Group A (n=18) cases were administered with 3 ml of 0.25% of bupivacaine hydrochloride and group B (n=18) cases administered with 0.2% ropivacaine hydrochloride 3ml. All participants were undergone necessary laboratory investigation and radiological examination. Cases were advised for fasting 6 hours prior to the surgery and premedicated with Inj. Glycopyrrolate 5µg/kg and Inj. Midazolam 0.02mg/kg.

The study drugs were infiltrated into each tonsil in the anterior pillar at lower and upper poles. Postoperatively, pain scores were assessed using Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) at different time interval i.e. 1 hour, 2 hours, 4 hours, 8 hours, 18 hours and 24 hours. CHEOPS Scale is behavioural scale for evaluating postoperative pain in young children. Rescue dose of fentanyl was given if pain score was above 5. Intraoperative hemodynamics and postoperative incidence of nausea and vomiting, pain and other adverse effects were recorded.

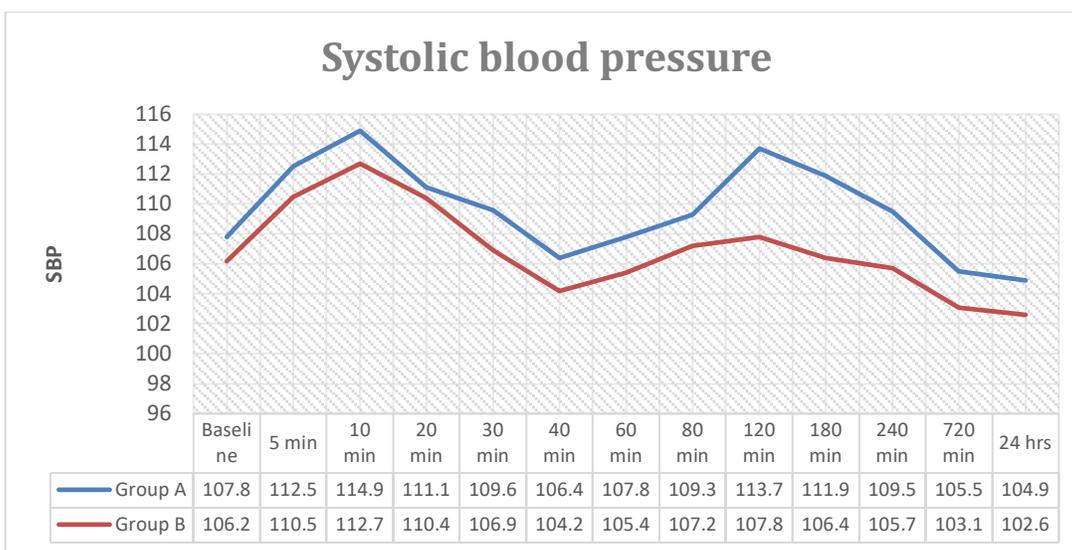
The collected data was analyzed by SPSS 23.0. Descriptive statistics were used to analyse demographic data. Chi-square test and unpaired student 't' test was used to compare the group. P<0.05 was considered statistically significant outcome.

Table 1: Demographic data of study participants

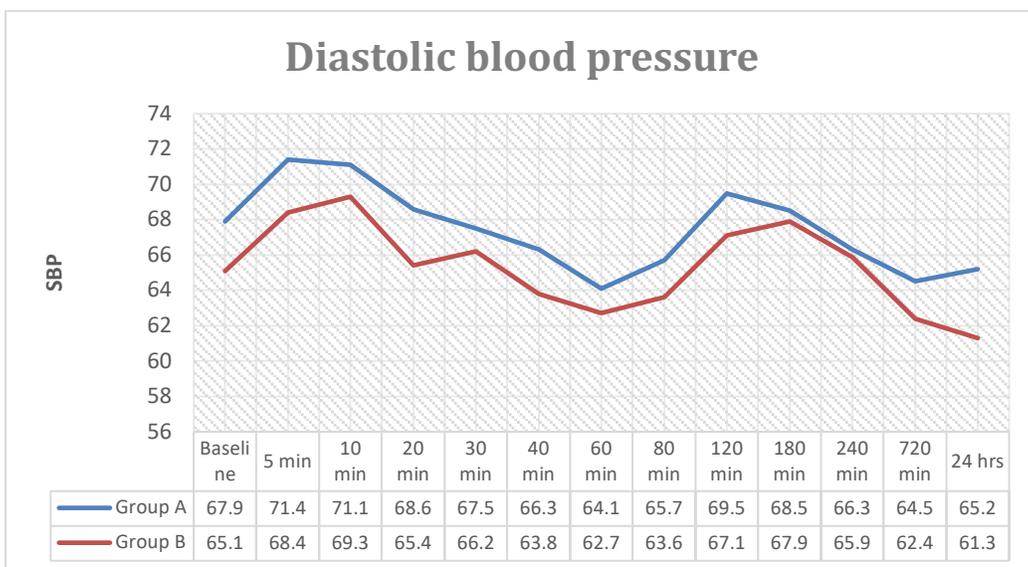
Demographic data	Group A (n=18)	Group B (n=18)
	Frequency (%)	Frequency (%)
Age (In years)		
≤6	02 (11.1%)	03 (16.67%)
7-9	06 (33.3%)	06 (33.33%)
10-12	10 (55.56%)	09 (50%)
Gender		
Boys	8 (44.44%)	8 (44.44%)
Girls	10 (55.56%)	10 (55.56%)
Weight (In Kgs)	32.94±6.25	33.67±5.02
ASA Grade		
Grade I	12 (66.67%)	13 (72.22%)
Grade II	06 (33.33%)	05 (27.78%)



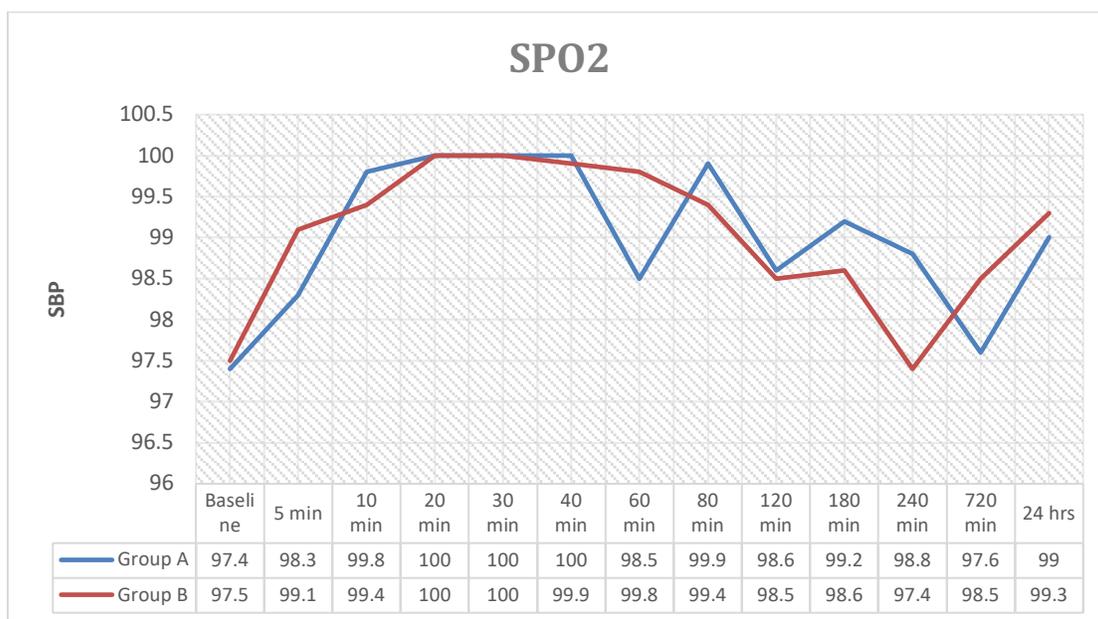
Graph 1: Mean heart rate among two study groups



Graph 2: Mean systolic blood pressure



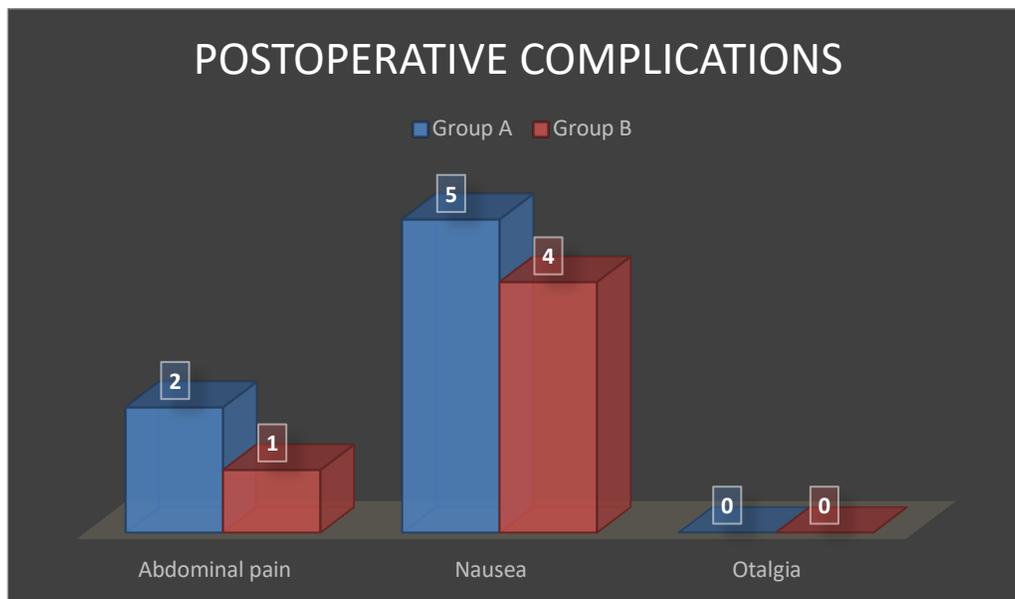
Graph 3: Mean diastolic blood pressure



Graph 4: Mean SPO2.

Table 2: Comparison of postoperative pain score by Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)

Demographic data	Group A	Group B	p-value
1 hour	3.1±0.78	2.9±0.90	0.001
2 hours	2.8±0.52	2.6±1.15	0.001
4 hours	2.4±0.94	2.2±0.98	0.675
8 hours	2.1±0.86	1.8±0.85	0.001
12 hours	1.7±0.48	1.3±0.74	0.001
18 hours	0.5±0.71	0.4±0.67	1.723
24 hours	0.2±0.66	0.1±0.88	0.001



Graph 5: Post-operative complications in the study groups

Discussion

Majority children were between 10-12 years (55.56% in group A & 50% in group B) of age followed by 7-9 years (33.33% in group A & 33.33% in group B) and 2-6 years (11.1% in group A & 16.67% in group B) in both study groups. Girls were common in both groups. The mean weight in group A was 32.94kg and in group B was 33.67 kg. 66.67% cases in group A and 72.22% cases in group B were belonged to ASA grade I and 33.33% in group A and 27.78% in group B belonged to ASA grade II (Table 1). A study by Akoglu E et al., found mean age of cases in bupivacaine group was 6.0 ± 2.5 years and in ropivacaine group was 6.1 ± 1.0 years [10].

The mean heart rate was comparatively high in group A. But 24 hours after surgery, the mean heart rate was high in ropivacaine group than bupivacaine group. The mean difference was significant at 5 min, 20 min, 30 min and 40 min of intraoperative period and 120, 180, 240 and 720 min of postoperative periods ($p < 0.05$) (Graph 1). The mean systolic blood pressure was high in bupivacaine group than ropivacaine group during intraoperative end postoperative timelines. The mean difference was

significant at 5 min and 60 min to till 24 hours after surgery ($p < 0.05$) (Graph 2)). Similar to SBP, the mean DBP was comparatively low in ropivacaine group than bupivacaine group. The difference was significant at 5 min, 10 min, 20 min, 60 min of intraoperative period, and 180 min, 720 min and 24 hours of postoperative period ($p < 0.05$) (Graph 3). The mean levels of SPO₂ were low in bupivacaine group at 720 min and 24 hours after surgery than ropivacaine group. The mean difference was statistically significant at 5 min, and 30 min. (Graph 4)

A prospective study by Manvi mehata on 60 children reported that locally infiltrating ropivacaine significantly relieves pain and reduces post operative analgesic requirement than bupivacaine in pediatric age group [12]. Goutham MK et al., assessed mean pain score by VAS/face scale scores found pain score 3.53, 4.30, 4.23, 3.26, 0.60 in ropivacaine group and 3.70, 5.40, 5.27, 4.23 and 0.50 in bupivacaine group at 4, 8, 24, 48 and after 7 days of surgery. The mean difference between study groups was statistically significant ($p < 0.05$) [13]. A study by Akoglu E et al., on 46 children, to assess effect of

ropivacaine and bupivacaine on post tonsillectomy in paediatric cases found that similar pain scores between both drugs groups assessed by mCHEOPS. The mean pain score was 4.2, 2.1, 1.9, 1.5, 1.0 and 0.8 in bupivacaine group and 4.0, 2.5, 1.4, 0.9, 0.7 and 0.6 in ropivacaine group at 15 min, 1 hr, 4 hr, 12 hr, 16 hr, and 24 hrs respectively. The mean difference of pain score was statistically significant at all postoperative time ($p < 0.05$) period except on 15 minutes ($p > 0.05$) [10]. The present study outcome was comparable with above findings where post-operative assessment of pain score by Children's Hospital of Eastern Ontario Pain Scale (mCHEOPS) showed that the cases treated with ropivacaine had reported comparative low pain at all time intervals than bupivacaine group. The mean difference was significant at 1 hour, 2 hours, 8 hours, 12 hours and 24 hours between two study groups ($p < 0.05$) (Table 2). A study by Akoglu E et al., found postoperative nausea, abdominal pain, constipation in 6, 2, 5 cases of bupivacaine group and 7, 1, 3 cases in ropivacaine group [10]. However, in current study bupivacaine group showed nausea, abdominal pain in 5 and 2 cases and ropivacaine group showed 4, 1 cases respectively.

A study by Akoglu E et al., concluded that local ropivacaine infiltration is effective, safe for post-tonsillectomy pain same as bupivacaine [10]. The ropivacaine is effective, safe and improves post tonsillectomy analgesia [12]. Sood AS et al., reported that ropivacaine infiltration was effective methods for pain management in children under post tonsillectomy [14]. Ravi KS et al., reported that post-tonsillar infiltration of 0.75% of ropivacaine with 1:200000 adrenaline is safe, effective in minimizing the post-operative pain on 24 hours after surgery, but significant effect on 7th day post-operative day [15]. A study by Bhandari C et al., on 80 adult cases to assess peritonsillar infiltration of ropivacaine in

postoperative pain control stated that ropivacaine is effective in providing immediate analgesic effect and minimizes the requirement of analgesia in first 24 hours of procedure [16]. Afman CE et al., reported that ropivacaine is effective, safe and efficient in minimizing postoperative pain in cases undergoing tonsillectomy [17]. Ahmed El Daly et al., reported that ropivacaine is effective in minimizing postoperative pain on 24 hours after procedure [18].

Conclusion

Effective postoperative analgesia is important in the pediatric cases undergoing tonsillectomy. Studies reported that ropivacaine and bupivacaine are similarly effective in the postoperative pain management after tonsillectomy. In present study, both drugs showed minimal postoperative complications. Both drugs are effectively reducing the postoperative pain; however, ropivacaine showed effective postoperative pain relief compared to bupivacaine.

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