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Original Research Article

Ropivacaine 0.25% versus bupivacaine 0.25% in immediate post tonsillectomy pain management: a randomised control trial

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ABSTRACT

Background: Tonsillectomy is one of the most common surgeries performed by an otolaryngologist, with post operative pain during the initial 24 hours being one of the most common challenging concerns. This makes it a need to find a suitable mode for managing the post operative pain imperative. This study aims to: assess the post operative pain control with ropivacaine 0.25% and bupivacaine 0.25% and to assess which among these two drugs are better in controlling the post operative pain and safer.
Methods: The 70 patients were selected, randomized, double blinded into group 1 and group 2 and given intraoperative infiltration of either 0.25% ropivacaine or 0.25% ropivacaine respectively into the tonsillar bed after tonsillectomy. The surgeries were done by the same surgeon by cold steel method of tonsillectomy. Post operative pain was evaluated using VAS (visual analogue scale) at regular intervals. Other parameters like hemodynamic status, surgical duration, any adverse reactions to the medications are also recorded.
Results: There was a statistically significant difference seen in the post operative pain scores between the two groups at all time intervals, with group 1 having a lower score compared to group 2.
Conclusions: Intraoperative infiltration of local anesthetics into the tonsillar bed was effective in controlling the post operative pain, with ropivacaine suitable anesthetic agent as compared to bupivacaine due to its higher efficacy and safety.

Keywords: Tonsillectomy, Ropivacaine, Bupivacaine, Post operative pain management

INTRODUCTION

Tonsillectomy is one of the most common surgeries performed by an ENT surgeon with a multitude of techniques of the same. The main complications of this surgery are hemorrhage, pain, nausea, vomiting, and dehydration.[1] Surgery causes tissue damage and subsequent release of biochemical agents such as prostaglandins and histamine. These agents can then stimulate nociceptors, which will send the pain message to the central nervous system to generate the sensation of pain.[2] Management of post operative pain is one of the most common challenging concerns for the surgeon, especially in the immediate post operative period.

Postoperative pain immediately after surgery has not only a pathophysiologic impact but also affects the quality of patients' lives. Improved pain management might therefore speed up recovery and rehabilitation and consequently decrease the time of hospitalization.[2]

Various methods have been used to try and control this post operative pain. Methods like changing anesthesia regimens change in surgical techniques, use of corticosteroids, and use of local anesthetic infiltration. [3]

It has been suggested that injection of a local anesthetic agent may decrease pain by blocking the sensory pathways and thus preventing the nociceptive impulses.[4] Intraoperative local infiltration with Ropivacaine and Bupivacaine have been used in achieving pain control in the post operative period in separate studies, but have very few studies have compared their effects against each other. Therefore, this study was done to assess which among these drugs when used as intra operative local infiltration yields the better result in controlling the pain post operatively, hence this study assumes significance.

METHODS

Source of data

Those patients of either sex in age group of 10-40 years undergoing tonsillectomy were selected at a teaching hospital in Davanagere, Karnataka.

Sample size

The 70 patients undergoing tonsillectomy that fulfilled all inclusion criteria and exclusion criteria were selected and randomized and double blinded, with the patients who were given 0.25% ropivacaine allocated as group 1 and those that were given 0.25% bupivacaine as group 2.

Sampling procedure

The 70 patients undergoing tonsillectomy selected for the surgery were randomized, with group 1 taken as the patients who were given 0.25% ropivacaine infiltration into the tonsillar bed after removal of the tonsil and group 2 as those who were given 0.25% bupivacaine infiltration in the similar fashion.

Post operative pain was evaluated using VAS (Figure 1) at regular intervals. Other parameters like hemodynamic status, surgical duration, anesthesia duration, recovery period, any adverse reactions to the medications are also regularly recorded.

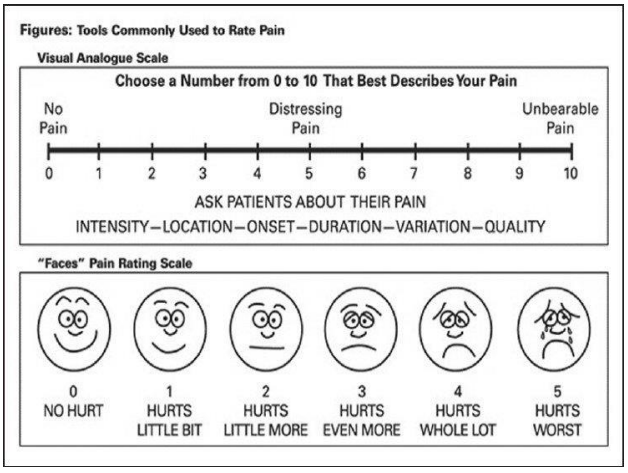

Figure 1: Visual analogue scale.

Study of design

Double blinded clinical trial study used as study design.

Study duration

Study conducted from August 2019 to June 2021.

Sampling criteria

Inclusion criteria

Patients undergoing tonsillectomy, either sex and age group between 10 to 40 years were included in study.

Exclusion criteria

Patients below 10 years of age, suspected cases of tonsillar carcinoma, patients with co morbid condition (hepatic, cardiac, endocrine) and patient who were not willing to take part in the study were excluded.

Data collection method

Patients who presented to ENT OPD who were diagnosed through history and clinical examination as cases chronic tonsillitis. And those that fulfilled the inclusion and exclusion criteria for the study was selected for the study. A written informed consent was taken from those who were willing to take part in the study.

The drug and the dosage were calculated and kept ready by the anesthetist so as to ensure the double blinding of the study. All patients underwent tonsillectomy by cold steel method done by the same surgeon to keep the surgery technique consistent in all cases. The infiltration was given over the upper and lower poles of the tonsillar fossa with a maximum of 5 ml in each fossa.[1] Following which the fossa was re-examined for any bleeders and once hemostasis is achieved the patient was extubated.

Among those selected 70 patients, either 0.25% ropivacaine or 0.25% bupivacaine infiltration was given into the tonsillar bed intraoperatively after removal of the tonsil. Group 1 were patients infiltrated with 0.25% ropivacaine using 23G spinal needle, with the appropriate amount of the drug by the surgeon and group 2 as the patients who were infiltrated with 0.25% bupivacaine using 23G spinal needle with the appropriate amount of the drug by the surgeon.[3] The patients were discharged after a minimum of 24 hrs/starting soft diet, whichever was later.

Postoperatively the patients were assessed for pain scoring using VAS scoring system at 2nd, 4th, 6th, 8th, 12th and 24th hours, along with duration of surgery and for any adverse effects during and post-surgery. Post operatively analgesics were only given to patients who complained of pain score above 8/if patient was unable to intake liquids orally to break NPO after 4 hours of surgery.

RESULTS

The average ages of the cases in group 1 and group 2 were 24.69±11.62 years and 24.34±10.08 years respectively with the mean weight being 46.29±20.46 kg in group 1 and 52.37±17.24 kg in group 2.

Group 1 had 10 (28.6%) males to 25 (71.4%) females and group 2 consisted of 14 (40%) males and 21 (60%) females which also showed no statistically significant difference in gender distribution among the two groups.

The most common grade of tonsil as shown in Table 1 was grade 2 tonsils with group 1 having 15 (42.9%) cases and group 2 having 14 (40.0%) cases with the same.

Table 1: Tonsil grading.

Tonsil	Group I, n (%)	Group II, n (%)	P value
1	08 (22.9)	05 (14.3)	0.46
2	15 (42.9)	14 (40.0)	
3	11 (31.4)	12 (34.3)	
4	01 (02.9)	04 (11.4)	

As shown in Table 2 and Figure 2, the average scores of groups 1 being 5.57±1.17, 4.11±1.18, 3.31±1.23, 2.00±1.16, 1.11±0.86 and 0.51±0.85, while that of Group 2 being 6.40±1.09, 5.31±1.05, 4.60±1.03, 3.49±1.09, 2.09±0.95 and 1.34±0.80, at 2nd, 4th, 6th, 8th, 12th and 24th hours respectively.

Table 2: Post operative pain scoring (VAS score).

Pain (Hour)	Group I, (Mean ± SD)	Group II, (Mean ± SD)	P value
2	5.57±1.17	6.40±1.09	0.003
4	4.11±1.18	5.31±1.05	0.001
6	3.31±1.23	4.60±1.03	0.001
8	2.00±1.16	3.49±1.09	0.001
12	1.11±0.86	2.09±0.95	0.001
14	0.51±0.85	1.34±0.80	0.001

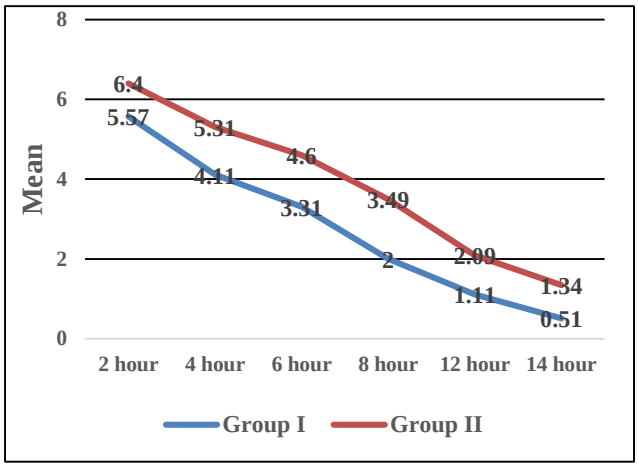

Figure 2: Post operative pain score (VAS score).

In our study intraoperative infiltration of local anesthetics like 0.25% ropivacaine and 0.25% bupivacaine into the tonsillar bed were both found to be effective in controlling the post operative pain experienced by the patient and aids in easier starting of oral feeds by the patient. There was no requirement of further use of other analgesics post operatively during the time of breaking the NPO status in both the groups.

The 0.25% ropivacaine was found to be a more suitable anesthetic agent for post tonsillectomy pain management as compared to 0.25% bupivacaine due to its higher efficacy and safety.

DISCUSSION

Ropivacaine

Ropivacaine is an amide (pipecoloxylidides) molecule which acts as a long-acting regional anesthetic. It is a pure S (-) enantiomer which was developed for reducing both the potential toxicity and to improve the sensory and motor anesthetic capabilities.[5] It acts by reversibly blocking the sodium influx and there in blocking the nerve impulse conduction. There is also a dose dependent blocking of the potassium channels as well. Due to its less lipophilic nature when compared to Bupivacaine, the drug has a selective action on the Aδ and C type nerve fibers which transmit pain signals.[5] This less lipophilic nature also contributes the higher cardio vascular and central nervous toxicity threshold for the drug.

As with most medications the plasma concentration of Ropivacaine will depend on the total dose and the rate of administration. In the plasma, ropivacaine is bound to α-1-acid glycoprotein up to 94%.[5] The mean half-life is about 14 minutes initially with a slower phase with 1/2 of about 4.2 hours which gives it long duration of action. Ropivacaine is metabolized in the liver by cytochrome P450 into 2', 6'-pipecoloxylidine and excreted in the urine by the kidneys. As compared to bupivacaine, ropivacaine has a smaller volume of distribution, greater clearance, and shorter elimination half-life than bupivacaine in humans.[1]

For the purpose of giving regional anesthesia in this study we have used 0.25% ropivacaine at a dose of 1 mg/kg with maximum dose of 5 ml, in each fossa which combined would correspond to 250 mg.[1,5,6]

Bupivacaine

Bupivacaine, like ropivacaine is an amide molecule, with long-acting anesthetic properties. It binds reversibly to specific sodium ion channels present over the neurons, thereby decreasing the voltage dependent membrane permeability to sodium ions, and preventing nerve impulse conduction.[7] With the duration of action on the surgical wound site as long as 20 hours, it is a widely used local anesthetic agent.[7] The drug though has a

drawback of being the most cardiotoxic among the other long-acting local anesthetics when used in larger amounts. Though the changes in the cardiac parameters like conduction, excitability and contractility are minimal when the drug concentration is within therapeutic doses, the toxic concentration causes depression of cardiac conduction, cardiac output and excitability.[7] The infiltration technique using bupivacaine carries the risk of accidental intravascular injection which can lead to cardiac arrest and convulsion.[5] In the blood bupivacaine is highly plasma protein bound, between 82-96%. The drug once administered has 3 phases of distribution; 1st is rapid intravascular distribution, which is followed by the 2nd stage of equilibration throughout the highly perfused organs and final 3rd stage of equilibration through the poorly perfused tissues like fat. After injection the peak drug levels in the blood is seen by 30-45 minutes and the decrease to insignificant levels by the next 3-6 hours.[7]

For the purpose of the study, we have used 0.25% bupivacaine with the same dose of 1 mg/kg with a maximum of 5 ml in each fossa to ensure comparability between the two study groups.

Tonsillectomy is one of the most common surgeries performed by an ENT surgeon with management of post operative pain is one of the most common challenging concerns. This makes it a need to find a suitable mode for controlling the post operative pain imperative.

Kuthiala et al showed that ropivacaine is a well-tolerated regional anesthetic effective for surgical anesthesia as well as the relief of postoperative and labour pain, with efficacy of ropivacaine is similar to that of bupivacaine and L-bupivacaine.[8] Clinically adequate doses of ropivacaine appear to be associated with a lower amount of motor block than bupivacaine.

Ozkiris et al showed that Ropivacaine infiltration is as effective as bupivacaine for post-tonsillectomy pain management in children.[1]

Akoglu et al showed that local ropivacaine infiltration is a safe and effective method and equivalent to Bupivacaine for post-tonsillectomy pain.[4]

Haksever et al showed that pain scores in topical bupivacaine hydrochloride group were significantly lesser than the topical saline group and pain scores of topical bupivacaine hydrochloride group were superior to Bupivacaine hydrochloride infiltration group.[3]

İhvan et al showed that intraoperative pre-incisional bupivacaine injection is useful in postoperative pain control at early period of time in children undergoing tonsillectomy. But it has no effect in pain reduction after 24 hours.[2]

Özmen et al showed that the pain scores in the bupivacaine and L-bupivacaine groups were significantly lower than those in the saline group and there was no difference between the L-bupivacaine and bupivacaine groups.[9]

Our study is there in agreement with the above-mentioned studies in the usage of intraoperative infiltration of the tonsillar bed with a local anesthetic to achieve post operative pain control. And we also have found that 025% ropivacaine is more effective and safer than 0.25% bupivacaine in achieving the same.

This study concentrates on the immediate post operative pain management alone; this leaves the status of post operative pain in the days following the surgery unaddressed. Further research into the longer-term control of post tonsillectomy pain management is needed. The smaller sample size of this study is also a limitation of the current study that needs to be addressed in future studies on this topic.

CONCLUSION

Intraoperative infiltration of local anesthetics into the tonsillar bed was effective in controlling the post operative pain, with ropivacaine suitable anesthetic agent as compared to bupivacaine due to its higher efficacy

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