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Comparison of local infiltration of ropivacaine, bupivacaine, topical application of sucralfate in the tonsillar fossa on post-tonsillectomy pain

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Abstract:

<u>Background</u>: Tonsillectomy is one of the most common surgeries performed in paediatric otorhinolaryngology. The most common morbidity of the surgery is the post operative pain. As there is increase in trend of tonsillectomy as day care surgery adequate postoperative analgesia becomes a very important issue.

<u>Objective</u>: To compare the efficacy of infiltration of ropivacaine 0.2% and bupivacaine 0.25% and topical application of sucralfate in to the tonsillar fossa in postoperative pain management.

Method: 120 patients aged 5–12 years, undergoing tonsillectomy were enrolled in the study. They were randomized into 4 groups. In group A (n=30) cases were infiltrated with ropivacaine into the tonsillar fossa; in group B (n=30), bupivacaine was infiltrated and in group C (n=30), the fossa was painted with sucralfate solution after the surgery; group D (n=30) was the control group where normal saline was infiltrated to the fossa following surgery. Visual analogue scale & Wong Baker facial pain scale were used to measure the intensity of pain postoperatively.

Results: At 4h postoperatively, the pain scores of all 3 study groups were significantly lesser (p<0.05) than control group (Group A - 3.53, B - 3.70, C- 3.80, D- 5.20). The VAS & facial pain scores over the entire postoperative period were consistently lower in the study groups than in the control. The reduction of throat pain was significantly lower in the ropivacaine & sucralfate group compared with bupivacaine & control groups.

<u>Conclusion</u>: Our study demonstrates that topical sucralfate and ropivacaine are equally effective and safe and improves post tonsillectomy analgesia. They provide better analgesia compared to bupivacaine.

Keywords:

- 1. Tonsillectomy
- 2. Post tonsillectomy pain
- 3. Visual analogue scale
- 4. Wong Baker Facial Pain Scale

Introduction

One of the major negative effects of tonsillectomy is pain during swallowing.¹ Pain may be either by irritation of free nerve endings exposed in the tonsillar fossa and/or chemical mediators such as lactic acid, leukotrienes and prostaglandins produced during the inflammation in the tonsillar fossa and causing spasm of the pharyngeal muscles. Postoperative inflammation and spasm of the pharyngeal muscles have been shown to cause ischemia in the tonsillar fossa and this prolongs the pain cycle.^{2,3}

Despite the use of different surgical and anesthetic techniques in the search for safe and effective post-tonsillectomy pain relief, this problem remains a clinical dilemma. Pain hinders mastication and swallowing, hence nourishment which, in turn, causes a delay in wound healing, dehydration, loss of several work or school days and weight. These collectively lead to prolonged hospitalization, psycho-social problems in patients as well as placing a financial burden and causing loss of manpower.⁴

Pain is mainly treated with analgesics, antibiotics, steroids and local and topical anaesthetics.⁵ Many studies have reported that it is necessary to utilize more than one analgesic medication. However, various topical solutions such as sucralfate have also been used for pain relief. The objective of the present study is to determine the efficacy of bupivacaine, ropivacaine and topical sucralfate in alleviating post tonsillectomy pain.

PATIENTS AND METHODS

The study was a randomized, single-blinded prospective clinical study to evaluate the efficacy of ropivacaine, bupivacaine & topical sucralfate in comparison with placebo for the reduction of postoperative pain after tonsillectomy in children. The study was conducted in the department of ENT & HNS in our institution over a period of 2 years from March 2011 to March 2013.

120 patients aged 5-12 yrs (65 males & 55 females) undergoing tonsillectomy was randomized into four groups, each containing 50 patients. The patients were informed on "Wong Baker Face Scale" & "Visual analog scale" (Fig. 1), used to measure the intensity of pain perceived during postoperative period. The patients above 10 years used VAS, whereas patients below 10 years used face scale.⁶

All operations were performed under general anesthesia early in the morning by the same experienced surgical team using dissection and snare method. Haemostasis was achieved by ligation method. In group A (n=30), the tonsillar fossa was infiltrated with 0.2% ropivacaine (fig 3) in weight related dose. In group B (n=30), 0.25% bupivacaine was infiltrated into the tonsillar fossa. In group C (n=30), sucralfate solution, was applied to the oropharynx, including the tonsillectomized area, for 2 minutes. For the following 7days, the patients used 10 ml of the Sucralfate solution as swish and swallow four times a day. In group D (n=30) was the control group where normal saline was infiltrated to the fossa following surgery. The patient and doctor in the ward who collected the data on proforma / questionnaire were blinded to the analgesic used.

The same prescriptions were given to all children for analgesics (paracetamol) and antibiotics (cefixime/clavulanic acid) in weight-related doses. The patients were instructed to indicate the pain they perceived on Face scale or Visual analogue scale (VAS) sheets, 4, 8, 24 and 48 hours and 7 days after the operation (fig 4). In VAS, the patient indicates the intensity of his pain by marking on a line 10 cm long. It is measured from no pain to the point indicated by the patient and then a numerical value is given (0=no pain to 10 cm = point of worst pain. In Face Scale, the patient indicates to various facial smileys depending upon the severity of the pain (0 = no hurt to 10 = hurts worst).

Analysis: Statistical Analyses: The data was collected from the proformas and was analyzed by statistical package for social sciences (SPSS) version 16. Mean pain scores of all groups at time intervals of 4, 8, 24, 48 hrs and 7 days post operatively were presented. Pain scores of all the groups were calculated and compared by using "t" test. A p value of <0.05 was considered statistically significant.

Result:

No difference was found in the demographic data among the groups. There were 65(54%) males and 55(46%) females in the study. The mean age in Group A (ropivacaine) was 8.50 ± 4.05 years, Group B (bupivacaine) 7.9 ± 3.95 years, Group C (sucralfate) 8.1 ± 4.2 years, Group D (control) 8.25 ± 3.8 years.

The mean pain scores at 4h post operative period in Ropivacaine, Bupivacaine & Sucralfate groups were almost similar (*Group A-3.53*, B-3.70, C-3.80, D-5.20). The pain scores in all 3 analgesia groups were significantly (p<0.05) lower at 4h postoperatively compared to the control group. Thus at 4h post operative period all three methods proved to be equally effective in alleviating the pain. At 8^{th} , 24^{th} & 48^{th} post operative hours, the pain scores in group A & C were significantly (p<0.05) lower compared with B & D (Table 1). Thus ropivacaine & sucralfate provided better pain relief after 4^{th} post operative hour. These patients were more comfortable & able to eat

earlier. They required lesser analgesics compared with Group B & D. The pain scores were almost similar in all 4 groups at follow up after 1 week. The overall mean pain scores were also less in group A& C compared with group B & D (*Group A*= 3.18 ± 1.50 , $B=3.82 \pm 1.98$, $C=3.11 \pm 1.59$, $D=4.37 \pm 2.21$.).

Conclusion:

The effect of Bupivacaine reduced significantly 4h post surgery. Ropivacaine and sucralfate consistently lowered postoperative throat pain, otalgia, and trismus. There were no complications related to Ropivacaine & Sucralfate. Thus they are safe and well-tolerated analgesics even in paediatric population. They provide better analgesia compared to bupivacaine in post tonsillectomy pain. Sucralfate may also promote healing of the fossa.

The patients receiving Ropivacaine and Sucralfate as analgesics can be discharged in the evening of surgery as they show significant pain relief even at 8th post operative hour. These patients with no pain or tolerable pain can be discharged on the same evening, provided the patient has access to telephone and stays within a couple of hours from the hospital. The patients who are from far off places are advised overnight stay irrespective of the pain scores.

Discussion:

Tonsillectomy is one of the most common ear, nose and throat surgical procedures, and in many institutions it is carried out as a short-stay operation. Unfortunately, tonsillectomy is often associated with intense pain that may not only delay discharge of the patient but also influence his ability to return to normal daily activities. Patients may even be reluctant to eat and drink due to painful dysphagia. Throat pain after pediatric tonsillectomy is mainly due to irritation of open nerve endings (the glossopharyngeal and vagus nerve) and spasm of the exposed pharyngeal and palatal muscles as a result of mechanical or thermal damage of surrounding tissue. Oral flora may also increase throat pain via inflammation and infection.

To allow a smooth recovery and a peaceful return to normal activities, treatment of pain after tonsillectomy should be effective. Therefore, surgical techniques and medications are still being developed to diminish post-adenotonsillectomy morbidity and to decrease the risk of complications. Among these surgical techniques, cold dissection is the most widely performed with the advantages of cost-effectiveness and less trauma to surrounding tissues. Other tonsillectomy techniques are electrocautery, bipolar diathermy, harmonic ultrasonic scalpel, Coblator, laser or radiofrequency excision and thermal welding. Perioperative local anaesthetics are often used to reduce the postoperative pain in tonsillectomy. There are different ways of applying local anaesthetics, include: pre-incisional peritonsillar infiltration, post-tonsillectomy wound infiltration and post-tonsillectomy packing with soaked gauze.

Sucralfate has a cytoprotective effect and increases mucosal renewal by stimulating prostaglandin E synthesis. ⁹ By adhering to mucoproteins at the ulcer site and by forming a protective coating against gastric acid and pepsin bile salts, sucralfate promotes healing. Sucralfate is not absorbed, and is effective locally for 5 hours. Due to its lack of absorption in the circulation, there are few incidences of adverse effects. If a similar protective coating could be created at the area of tonsillectomy, morbidity may be diminished, and although sucralfate is mainly used for peptic ulcers, it has been used locally for the reduction of postoperative tonsillectomy pain. Sucralfate significantly lowered the need for analgesic drug, postoperative throat pain, otalgia, and trismus. ^{1,10}

Transmission of electrical impulses can be blocked by local anaesthetics when applied to wound producing analgesia. Local anaesthetics like lignocaine, bupivacaine & ropivacaine have been applied by infiltration, by topical spray and also by placing soaked swabs in tonsillar fossae. The onset of action of bupivacaine & ropivacaine is usually 2 to 10 minutes and anesthesia may last two or three times longer than lidocaine and may last up to 6-7 hours.

Study by Ankolu, Akkurt et al shows that the pain scores were similar between the bupivacaine and ropivacaine groups. The pain scores in both analgesia groups were significantly lower 1, 4, 12, 16, and 24h postoperatively compared to the control group. Analgesic requirements and the time to first analgesia were also significantly different between the analgesia and control groups. Local ropivacaine infiltration is a safe and effective method and equivalent to bupivacaine for post-tonsillectomy pain.¹¹

According to Ozkiriş, Kapusuz & Saydam, Ropivacaine infiltration is as effective as bupivacaine for post-tonsillectomy pain management in children. In view of potential side effects of bupivacaine-epinephrin combination, ropivacaine is a safer choice, for post-tonsillectomy pain relief. ¹²

Study by Freeman & Markwell on 34 adult patients shows that, Sucralfate is a safe and well-tolerated topical agent that offers significant pain reduction and may promote healing in tonsillectomy patients.¹

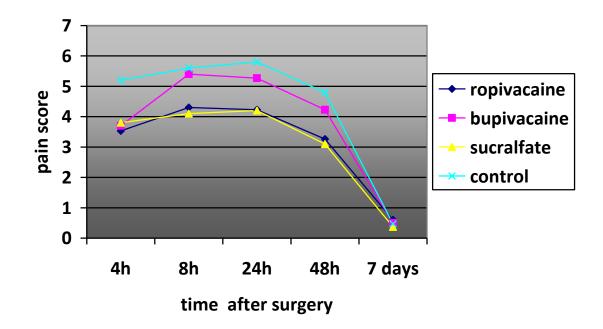
According to Miura, Saleh et al sucralfate was beneficial in reduction of pain in the postoperative period but cannot be utilized as a single agent for pain relief in children. It is simple, safe, tolerated, and low-cost; it is an important tool as adjuvant treatment of post-tonsillectomy pain. ¹⁰

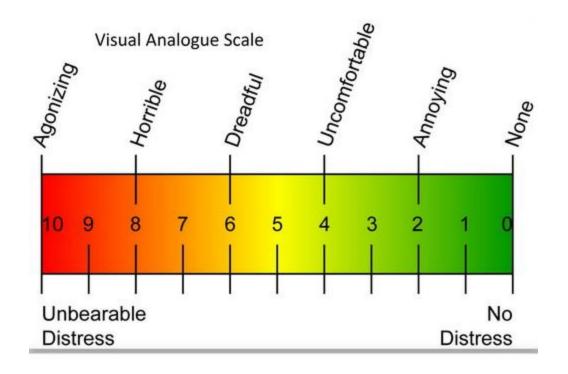
In the present study, Bupivacaine is effective up to 4h post operatively, following which the effect decreases significantly. Ropivacaine & Sucralfate provides analgesia for longer duration. These patients can be discharged early, even as day care surgery. No complications were seen in these groups. Thus ropivacaine & Sucralfate are safe in paediatric age group & are better compared to Bupivacaine.

Table 1: Mean VAS/ face scale scores in all the 4 groups.

Post op	Group A	Group B	Group C	Group D
period	[n=30]	[n=30]	[n=30]	[n=30]
	(ropivacaine)	(bupivacaine)	(sucralfate)	(control)
After 4 hrs	3.53	3.70	3.80	5.20
After 8 hrs	4.30	5.40	4.10	5.60
After 24	4.23	5.27	4.20	5.80
hrs				
After 48	3.26	4.23	3.10	4.80
hrs				
After 7	0.60	0.50	0.37	0.47
days				
Overall	3.18 ± 1.50	3.82 ±1.98	3.11 ±1.59	4.37 ± 2.21
mean				
P value	< 0.05	< 0.05	< 0.05	
compared				
with				
control				

Graph 1: mean pain scores at various time intervals postoperatively.





Wong Baker Face Scale O 1 2 3 4 5 6 7 8 9 10 No Hurts Hurts Hurts Hurts Hurts Hurts Whole Lot Worst

Fig 1 VAS and Wong Baker Facial Pain score



Fig 2: Ropivacaine 0.2% & Bupivacaine 0.25% & topical Sucralfate used for local anaesthesia

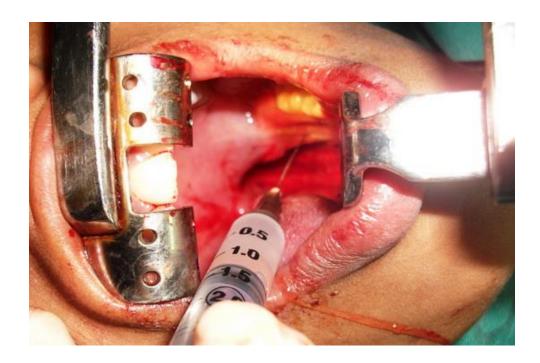


Fig 3: 0.2% Ropivacaine being infiltrated in the tonsillar fossa after tonsillectomy

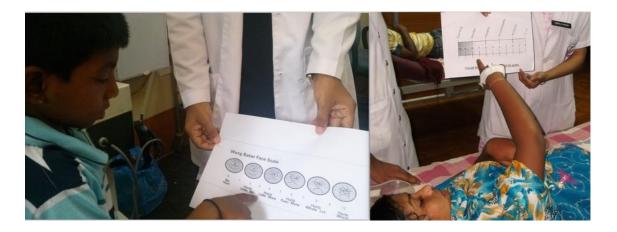


Fig 4: Patient denoting level of pain on VAS & Face scale

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