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Original Research Article

Effect of tonsillar fossa cooling with cold saline on early post-tonsillectomy pain: A randomized, double-blind controlled study

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ABSTRACT

Background and Aims: Postoperative pain following tonsillectomy is troublesome, and non-pharmacological methods can be a valuable adjunct to reduce the intensity of pain. Cooling can attenuate the damage done to tissues by hot dissection techniques.The study was aimed to assess the effect of tonsillar fossa cooling on post-tonsillectomy pain.

Materials and Methods: Forty patients aged 8-18 years of American Society of Anaesthesiologists physical status I and II scheduled for elective bilateral tonsillectomy with bipolar electrocautery under general anaesthesia were recruited. After obtaining consent and approval from the institutional ethical committee, they were randomly assigned to one of the two groups. At the end of tonsillectomy, the tonsillar fossa was packed for 10 minutes using gauze soaked in ice-cold 0.9% saline (5–10 ℃) in group T (test) and saline at room temperature in group C (control). The postoperative pain scores using Faces Pain Scale-Revised (FPS–R) and sore throat were evaluated at 15 minutes, 1 hour, 6 hours and 12 hours. All the data were analyzed using appropriate statistical tests. $P < 0.05$ was considered significant.

Results: Pain scores were significantly lower in group T as compared to group C at all time points. ($p<0.05$) The rescue analgesic consumption was lower in group T.($p<0.05$) There was no difference in of sore throat between two groups.

Conclusion: Cooling of the tonsillar fossa with ice-cold 0.9% saline after hot dissection tonsillectomy is a useful adjunct in reducing postoperative pain without any significant complications.

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1. Introduction

Tonsillectomy is a common surgical procedure performed in children and adolescents. It is associated with significant postoperative pain. Higher pain scores may result in nausea, vomiting, insomnia, lower parent satisfaction, inadequate diet intake, unplanned medical visits and re-hospitalizations.[1] Suboptimal analgesia can cause persistent postoperative pain which may last up to two weeks following surgery and also increase the risk of transitioning to chronic pain.[2] Thus, optimal management of post-tonsillectomy pain is of utmost importance.

The thermal injury by electric surgical devices and stimulation of pharyngeal nociceptors by inflammatory mediators are two proposed mechanisms for post-tonsillectomy pain.[3] Postoperative pain relief can be achieved by pharmacologic treatments, non–pharmacological interventions or a combination of both. The former technique includes opioids and non-opioid agents like acetaminophen and nonsteroidal anti-inflammatory drugs.[4] Both group of drugs have their advantages and side effects in children and adolescents. Non-pharmacological therapies relatively lack side effects

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and can be a potential adjunct for pharmacological treatments.

Non-pharmacological techniques such as behavioural and assimilated therapies, iced water drinking or rinsing the tonsillar fossae with cold saline, mouthwash with benzydamide hydrochloride, hydrogen peroxide, or lidocaine, chewing gum, consumption of honey, ice-cream, and cold diet, speech therapy, and acupuncture have been tried in different clinical settings.[5–7] The number of trials exploring the efficacy of non-pharmacological treatments are limited, and results are inconclusive. Intraoperative irrigation of tonsillar fossae and pharyngeal mucosa with cold saline after tonsillectomy has been reported to reduce immediate postoperative pain.[8,9]

Only a few studies have appropriately investigated the effect of tonsillar fossa cooling with cold saline on early post-tonsillectomy pain. Lack of adequate research prevents its recommendation as an adjunct therapy in perioperative multimodal analgesia regimen. The present study aimed to compare the effects of ice-cold 0.9% saline (at 5–10ºC) and 0.9% saline (at room temperature) on early postoperative pain and sore throat after hot dissection tonsillectomy under general anaesthesia (GA) in a population aged 8 to 18 years.

2. Materials and Methods

This study was conducted in a tertiary care academic hospital from December 2017 to August 2018. Prior ethical permission was taken from the institutional human ethical committee (dated 27/09/2017), and the trial was prospectively registered in the Clinical Trials Registry - India (www.ctri.nic.in) with the identification number CTRI/2017/11/010705. This prospective, randomized, double-blind study included 36 American Society of Anaesthesiologists (ASA) physical status I and II patients of either sex, aged 8–18 years, scheduled to undergo elective tonsillectomy under GA. Patients undergoing additional procedures like uvulopalatoplasty, re-exploration, or emergency surgery were excluded from the study.

After a thorough pre-anaesthetic checkup, patients satisfying the inclusion criteria were selected. Demographic parameters such as age, gender, bodyweight and ASA Physical Status were recorded. Written informed consent was obtained from the parents/legally authorized guardians of each patient after explaining the procedures in detail. Besides, verbal assent from children <12 years of age and written informed assent from children aged >12 years were also documented. Faces Pain Scale-Revised (FPS–R) was explained to the patients in the presence of parents. Those who refused to participate in the study or could not understand and follow the FPS-R were excluded from the study. The Consort diagram indicating the enrolment and progress of our patients throughout the course is shown in Figure 1.

The study participants were randomly allocated into one of the two predefined groups by using computer-generated random numbers. The group allocation was revealed only after completion of tonsillar dissection. The anesthesiologist who assessed the patients in the postoperative period was blinded to the group allocation.

Group T = Test Group: Following tonsillectomy, the tonsillar fossae were packed with gauze pieces soaked in cold saline (at 5–10 ºC).

Group C = Control Group: Following tonsillectomy, the tonsillar fossae were packed with gauze pieces soaked in 0.9% saline (at room temperature).

Each patient was kept nil per mouth for an adequate period according to the standard guidelines. On arrival in the operation theatre, ASA standard monitors were attached. Intravenous (IV) access was secured in all the patients and infusion of ringer's lactate was started as per the standard calculation of perioperative fluid replacement therapy.

All patients were pre-oxygenated with 100% O2 for 3 minutes and pre-medicated with IV Glycopyrrolate 0.004 mg/kg, Midazolam 0.5–1 mg, Dexamethasone 0.1 mg/kg, and Fentanyl 2 mcg/kg. GA was induced with IV Propofol (2 mg/kg) until the loss of verbal commands. Injection Atracurium (0.5 mg/kg) was used for the neuromuscular blockade. The trachea was intubated with an appropriate size preformed cuffed endotracheal tube (South Pole Ring Adair Elvin Tube, Rusch, Teleflex Medical Pvt Ltd.) in each patient. The cuff of the tube was inflated with air, and the correct placement was confirmed by auscultation of breath sounds and square waveform on capnography.

Anaesthesia was maintained with oxygen: air (50:50), titrated MAC (1.0) of Sevoflurane, the maintenance dose of IV Atracurium (0.1 mg/kg intermittent bolus) and positive pressure ventilation. All patients received IV Paracetamol 15 mg/kg and an additional bolus dose of IV Fentanyl (1 mcg/kg/hour) intraoperatively. IV Ondansetron 0.1 mg/kg was administered 15 minutes before the completion of surgery.

A single experienced surgeon performed all tonsillectomies. Following adequate exposure of the oral cavity, each tonsil was dissected in the extracapsular plane using bipolar electrocautery. Hemostasis was achieved by minimal spot electrocautery using bipolar forceps. After removal of each tonsil, the tonsillar fossa was irrigated with 0.9% normal saline at room temperature.

At the end of the surgery, two gauze pieces soaked with 100 mL 0.9% saline either cold (5-10 °C) or at room temperature according to group allocation was packed in each tonsillar fossa for a total of 10 minutes. Each gauze was left in place for 5 minutes and was replaced with a fresh gauze soaked with the same saline to keep the tonsillar fossa temperature as constant as possible. The packs were removed after 10 minutes.

Following the completion of the surgical procedure, Sevoflurane was discontinued, and gentle oral section was done. The patients were kept on 100% oxygen, and residual neuromuscular blockade was reversed with IV Neostigmine 0.05 mg/kg and Glycopyrrolate 0.01 mg/kg. Once the patient fulfilled the criteria for extubation, the ET tube was removed after deflation of the cuff. Patients were then transferred to the Post Anaesthesia Care Unit for monitoring and after that, to the ward, as guided by modified Aldrete's score.

All patients received IV Paracetamol 15 mg/kg 8^{th} hourly for postoperative analgesia. The postoperative pain was recorded at 15 min, then after 1 hr, 6 hr and 12 hr. IV Diclofenac 1.5 mg/kg was used as rescue analgesic whenever the FPS-R score was >4. Presence or absence of sore throat was also recorded at the same time intervals.

The sample size was calculated based on a pilot study and with the help of an online sample size calculation tool (https://sample-size.net). By comparison of pain relief in patients with the cooling of tonsillar fossa vs control, the response rate in intervention and control groups were 0.75 and 0.3, respectively. Assuming an alpha error of 0.05 and power of the study to be 80%, a minimum of 18 patients were required in each group. To compensate for attrition, we decided to take 25 patients in each group.

All data were entered into Microsoft Excel Spreadsheet (version 2019) and analyzed using IBM SPSS Statistics for Windows, version 27 (IBM Corp., Armonk, New York, USA). Appropriate statistical tests were applied as required such as t-test, chi-square test and Mann–Whitney U Test. Descriptive statistics were summarized using means with standard deviation, median and percentage. A p-value < 0.05 was considered statistically significant.

3. Results

We recruited 20 participants per group, and there were no dropouts. Final data analysis was performed on 40 patients (Group T = 20 patients, group C = 20 patients).

Demographic profile of the two groups was comparable with respect to age, sex, body weight and ASA physical status (Table 1). Majority of the patients in both groups were from 8-10 years age group.

Table 2 and Figure 2 show the postoperative pain scores (FPS-R) between two groups at different time points until 12 hours. Patients in Group T had lower pain scores as compared to group C, and the difference was statistically significant ($p \leq 0.001$).

The incidence of sore throat was comparable between the groups ($p > 0.05$). The highest incidence of sore throat was noted at 6 hours following the surgery in both groups (Table 3).

Postoperative rescue analgesic consumption was higher in the control group ($p < 0.001$) (Table 3).

4. Discussion

The result of the present randomized controlled trial suggests that cooling of tonsillar fossae with cold saline (5-10 °C) as an adjunct to systemic analgesic paracetamol significantly reduce postoperative pain without any change in the incidence of sore throat.

Cryotherapy or cryoanalgesia can be a useful adjunct in acute post-tonsillectomy pain management. Cold saline by promoting vasoconstriction and anti-oedema effect may play a vital role in reducing postoperative pain and inflammation. The drop in local temperature decreases cellular metabolism, which helps to reduce oxygen consumption and limitation of the damage.[10] It also affects peripheral nerve endings by diminishing the threshold needed to activate the tissue nociceptors and decreases the conduction velocity of nerve signals.[11] Cryotherapy has also been reported to reduce endothelial dysfunction and the inflammatory response by diminishing the number of leukocytes adhering to the endothelial wall of capillaries.[12]

Cryoanalgesia can be performed either with a cryotherapy probe (−20°C to −32°C) or ice-water cooling (4°C to 10°C).[8,13–15] In our study, intraoperative cryoanalgesia was done using gauze-soaked in ice-cold saline at 5-10 °C. In a recent systematic review, including three studies with a total of 153 participants, it was suggested that patients undergoing 'hot' tonsillectomy with cryoanalgesia experienced less average postoperative pain without any additional complications. However, the conclusions are limited by heterogeneous results and limited quality evidence, which needs further research. Our patients had significant pain relief as compared to the control group, and it correlates well with the systematic review.

In literature, a wide variation in the study population include preschool, school-age, adolescents and adults (1-68 years).[16] Different age groups have different threshold for pain, and thus the effect of cryoanalgesia would be different. So, we decided to select the target population from the pediatric and adolescent group (8-18 years) to maintain uniformity. In our study, the tonsillectomies were performed by a single experienced Otorhinolaryngologic surgeon to reduce the inter-operator variability. Thus, overcoming the limitation mentioned in the study by Horii et al.[8] where many surgeons with varied skill levels had performed the surgeries.

We used the FPS-R pain scale, unlike others where mainly visual analogue scale was used. FPS-R ratings of pain intensity appear to reflect both pain intensity (as measured by the Numeric rating scale) as well as pain interference and pain unpleasantness.[17] We observed a significant reduction in pain intensity at each of the specified time intervals in patients who had cooling of the tonsillar fossa. This was also reflected in the 12–hour rescue analgesic consumption. Patients in the control group

Table 1: Demographic profile

Parameters		Group T (n=20)	Control Group (n=20)	P-value
Age (years)		10.8 ± 3.6	11.7 ± 2.8	0.383
	8-10	13 (65%)	8 (40%)	
Age groups (years)	**11-13**	3 (15%)	8 (40%)	
	13-18	4 (20%)	4 (20%)	
Male/Female		11/9	9/11	0.527
Body weight (kg)		39 ± 15.56	37.5 ± 10.60	0.724
ASA-PS (I/II)		18/2	19/1	0.548

ASA-PS = American Society of Anaesthesiologists Physical Status, n = number of patients, Group T = 0.9% saline at 5-10 °C, Group C = 0.9% saline at room temperature

Table 2: Comparison of postoperative pain scores between two groups at different time points according to face pain Scale-Revised (FPS-R)

Time interval	FPS-R score	Group T (n=20)	Group C (n=20)	Z#	P-Value
15 min	0	16	5	3.46**	0.001
	2	4	14		
	4	0	1		
	Median	0	2		
1hr	0	17	2	4.72**	0.000
	2	3	11		
	4	0	7		
	Median	0	2		
6 hrs	0	16	0	5.3**	0.000
	2	4	7		
	4	0	10		
	6	0	3		
	Median	0	4		
12 hrs	0	16	0	5.12**	0.000
	2	3	6		
	4	1	8		
	6	0	4		
	8	0	2		
	Median	0	4		

Mann-Whitney U Test **: - Significant at 0.01 level, Group T = 0.9% saline at 5-10 °C, Group C = 0.9% saline at room temperature

Table 3: Comparison of incidence of sore throat

	Group T (n=20)		Group C (n=20)		
Time	**Yes**	**No**	**Yes**	**No**	**p-value**
15 min	3	17	0	20	0.072
1 hr	15	5	14	6	0.723
6 hrs	19	1	16	4	0.151
12 hrs	16	4	15	5	0.705

Group T = 0.9% saline at 5-10 °C, Group C = 0.9% saline at room temperature

Table 4: Comparison of 12–hour rescue analgesic consumption between two groups

Total Analgesic consumption	Group T (n=20)	Group C (n=20)	p-value
Diclofenac (mg)	21 ± 29.698	56.25 ± 15.909	<0.001

Group T = 0.9% saline at 5-10 °C, Group C = 0.9% saline at room temperature

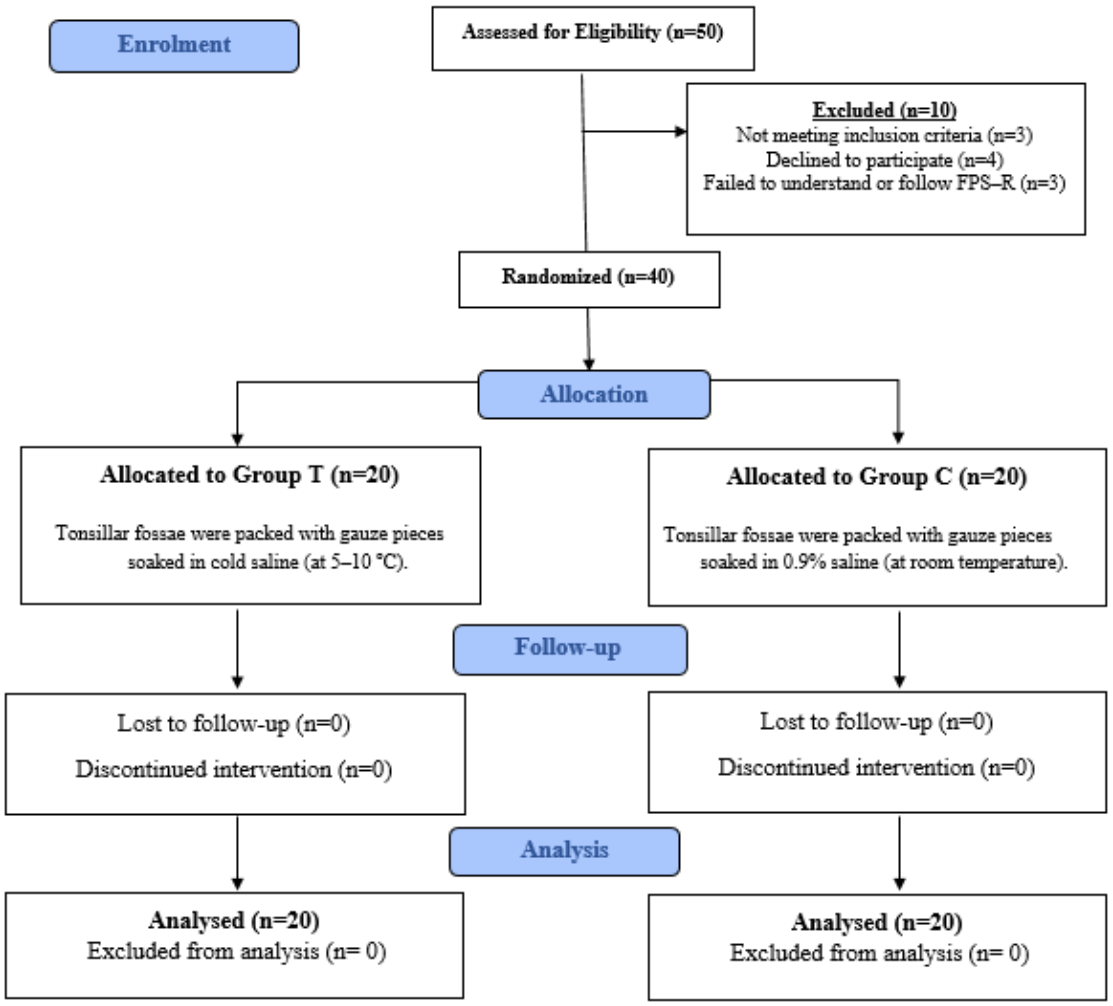

Fig. 1: Consort flow diagram of our study

consumed almost twice amount of rescue analgesia as compared to group T. Vieira et al.[14] performed irrigation of oral cavity with 500 mL of 0.9% saline (5-10°C) for 5 minutes after tonsillectomy. They observed a 21.4% reduction in the average values of VAS score. However, our study finding does not correlate with the observations of Karaca and colleagues.[18] They observed pain reduction from 3rd to 7th postoperative day but no statistically significant difference in postoperative pain scores between the study groups on the first postoperative day. Contrary to this, we evaluated the first 12h postoperative pain and found that the pain reduction was significant as compared to the control group. Our findings well-matches with the study by Sylvester et al.[19] The authors reported significant postoperative pain relief up to 4^{th} hour postoperatively in the patients aged 2-12 years who underwent tonsillectomy with or without adenoidectomy.

We observed no significant difference between two groups concerning the sore throat at specified time intervals following tonsillectomy. Sore throat is a common postoperative complaint following endotracheal intubation and GA. It could also be due to intraoperative pharyngeal manipulation and irrigation during surgery. Cold saline did not increase the incidence of sore throat in our patients.

Due to absorption of cold saline, the rare possibility of hypothermia exists, leading to shivering and delayed recovery. However, we did not observe any such effects in our patients as the contact time was minimal (10 minutes), and the ambient temperature was controlled.

Our study has a few limitations. We did not include children aged less than eight years because of difficulty in the assessment of postoperative pain. A similar study with a bigger sample size could add strength to our findings. We focused on the exclusive analysis of postoperative pain, without considering other factors such as duration of surgery

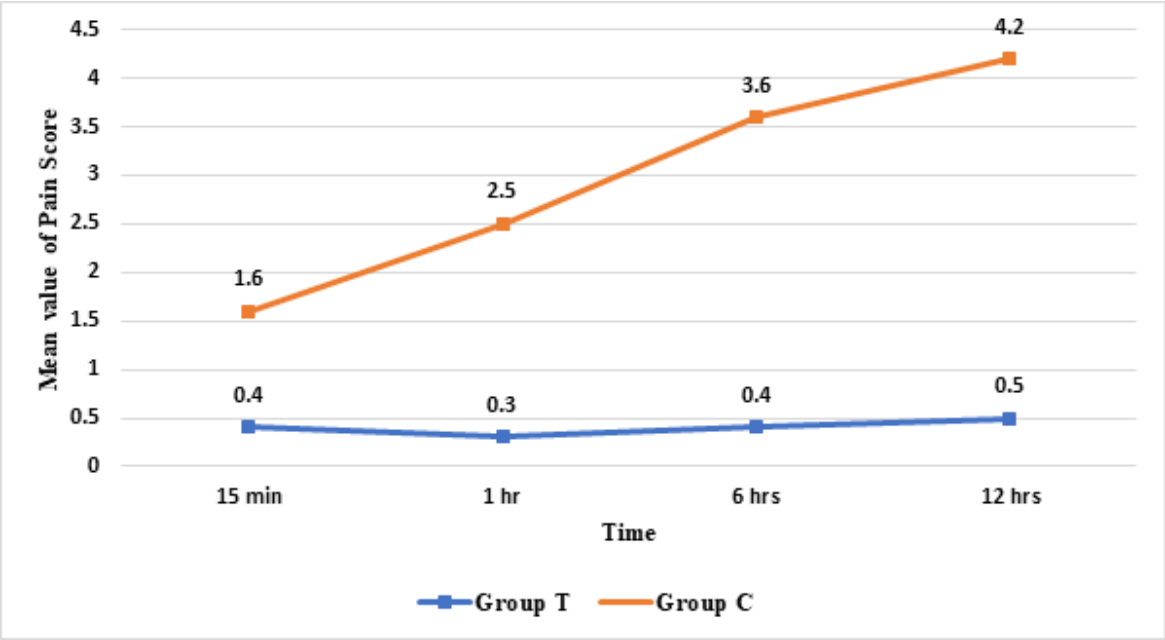

Fig. 2: Comparison of postoperative pain scores between two groups

and blood loss, which might influence the pain scores due to greater use of electrocautery.

5. Conclusion

Tonsillar fossa cooling with ice-cold saline helps in a significant reduction of early post-tonsillectomy pain without any major adverse effects. This technique can be used as a non-pharmacological adjunct therapy with systemic analgesics for effective management of postoperative pain.

6. Source of Funding

Nil.

7. Conflicts of Interest

Nil.

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