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# Change in mean postoperative pain in patients undergoing tonsillectomy with cold water versus usual practice: A pragmatic trial

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## Abstract

**Introduction:** Tonsillectomy is one of the most common procedures performed in otolaryngology. There are various methods to perform tonsillectomies (cold and hot). Thermal damage and inflammation of the surrounding tissue using monopolar cautery is said to point to increased pain whereas immediate cooling of the burnt area is thought to reduce pain owing to heat dissipation. Our objective was to determine the difference in mean post-tonsillectomy pain scores among patients irrigated with cold water (4°C) and in patients not irrigated with cold water.

**Material and Methods:** A quasi-experimental trial was conducted from January 2016 to December 2017 at a tertiary care hospital. All tonsillectomies were carried out with monopolar cautery at a power of 20 W. Patients either received cold water irrigation post tonsillectomy of the tonsillar bed (intervention arm) or no irrigation (control arm). The pain score was measured on Days 0, 1, 3, 5, and 7. Pain scores were charted on a visual analog scale on the respective days.

**Results:** Seventy-eight patients were included in the study. The mean age of our patients was 10.26 (4.24) years old in the intervention arm, and 11.95 (4.19) years old in the control arm. It was observed that the pain was significantly lower in patients with cold water irrigation of the tonsillar fossa on Days 1, 3, 5, and 7 (p = 0.001). There were no readmissions postprocedure and none of our patients developed any complications postsurgery.

**Conclusions:** In this trial, we report a reduced pain score at all days of observation in the intervention group. Irrigation of the tonsillar fossa is a safe, cost-effective, and less technically demanding technique that could be employed to reduce post-operative pain. Further studies with randomization, blinding and a larger sample size could further improve on our results.

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## KEYWORDS

cold water tonsillectomy, monopoalr tonsillectomy, postoperative pain, tonsillectomy

#### Highlights

- Tonsillectomy is one of the most common procedures performed in otolaryngology.
- There are various methods to perform tonsillectomies (cold and hot).
- Thermal damage and inflammation of the surrounding tissue using monopolar cautery is said to point to increased pain whereas immediate cooling of the burnt area is thought to reduce pain owing to heat dissipation.
- Our objective was to determine a difference in mean posttonsillectomy pain score amongst patients irrigated with cold water (≤10°C) and in patients not irrigated with cold water.
- A pragmatic trial was conducted from January 2016 to December 2017 at a tertiary care hospital.
- Seventy-eight patients were included in the study.
- In this pragmatic trial, we report a reduced pain score at all days of observation in the intervention group.
- Irrigation of tonsillar fossa is a safe, costeffective, and technically less demanding technique that could be employed to reduce postoperative pain.
- Further studies with randomization, blinding and a larger sample size could further improve on our results.

## INTRODUCTION

Tonsillectomy is one of the most common procedures performed in otolaryngology.<sup>1,2</sup> The surgical techniques and instruments used to perform tonsillectomy have evolved significantly over the years.<sup>3–5</sup> Currently, monopolar electrocautery is the most commonly used surgical instrument to perform tonsillectomy.<sup>6</sup> It generates heat up to 600°C and is highly cost-effective and readily available in the vast majority of hospital settings.<sup>7</sup>

Tonsillectomy is a short-day care procedure, however, one of its major drawbacks is postoperative pain which causes a hindrance to the patient in performing their daily activities and taking their usual diet for a few days.<sup>3–5</sup> Postoperative pain is greater among patients who have undergone cautery with instruments generating higher heat as it leads to greater damage to the surrounding structures. Tonsillar fossa is richly supplied by nociceptors and postoperative pain may persist for more than a week, thereby limiting daily activities.<sup>7</sup> Various methods have been shown to reduce post-tonsillectomy pain and immediate cooling of the burnt area on a body surface is one such method,<sup>1,8,9</sup> as was done by Galen and Rhazes back in the 2nd century AD.<sup>10,11</sup> Immediate cooling helps dissipate heat and reduces tissue damage and inflammation, thereby reducing postoperative pain.<sup>1,11</sup>

Therefore, in light of existing literature, the rationale of our study was to assess whether cold water irrigation is effective in reducing posttonsillectomy pain as compared to the usual practice. The objective of our study was to compare the mean posttonsillectomy pain scores of intraoperative cold-water irrigation of tonsillar fossa with the usual practice.

## MATERIAL AND METHODS

The study was a pragmatic trial to compare postoperative pain scores among patients undergoing tonsillectomies at a tertiary care hospital. All patients undergoing tonsillectomies from January 2016 to December 2017 were recruited for the study. Institutional ethical review committee approval was obtained before commencement of the trial and informed consent/assent was taken for participation in the study.

Only participants aged 5 years or above undergoing tonsillectomy for recurrent tonsillitis or obstructive sleep apnea were included in the study. Patients with coagulopathies and patients undergoing surgery due to suspicion of malignancy were excluded from the study. The sample size was calculated on open epi software. A minimum sample size of 78 patients with 39 in the intervention arm and 39 in the control arm (ratio 1:1) was determined to achieve 80% power, with an anticipated difference in mean pain scores of 1.71 at a 5% level of significance among patients who received cold water irrigation compared to those who receive the usual treatment. The sampling technique used was nonprobability consecutive sampling.<sup>7</sup>

The patients were nonrandomly distributed in the intervention arm (received cold water irrigation in tonsillar fossa) and control arm (not irrigated with cold water). All patients underwent tonsillectomy with monopolar cautery at a power of 20 W. Irrigation was carried out with normal saline at either 4°C for the intervention group or at room temperature for the control group. The tonsillar fossa was flushed three times with a 20 mL syringe following the removal of the tonsil on each side. Patients in both arms were prescribed weightadjusted analgesics (paracetamol 15 mg/kg and ibuprofen 10 mg/kg) postoperatively to be taken in three divided doses at regular intervals. Patients were asked to rate their pain on a scale from 1 to 10, with 1 being the lowest and 10 being the highest, on the next day as an average of the previous day to account for any discrepancies based on the pain medications being taken at slightly different times of day by the patients. For pediatric cases where an un-cuffed endotracheal tube was used, the throat was packed with a one-inch ribbon gauze. The surgery was performed by three different surgeons who had similar experience and qualifications to keep consistency. The patients in both groups were discharged on the

#### **TABLE 1** Patient demographics.

Variables	Intervention arm (n = 39, 50%) (with cold water irrigation)	Control arm (n = 39, 50%) (without cold water irrigation)
Age (in years, mean $\pm$ SD)	10.26 ± 4.24	11.95 ± 4.19
Gender, n (%)		
Male	31 (79.5)	22 (56.4)
Female	8 (20.5)	17 (43.6)
Surgical indication, n (%)		
Recurrent tonsillitis	29 (74.4)	32 (82.1)
Obstructive sleep apnea	10 (25.6)	7 (17.9)

same day as per protocol and were given a pain scale form to rate their pain intensity on a scale of 1-10 on Days 1, 3, 5, and 7. A visual analog scale was also handed over to patients at the time of discharge. The mean pain scores for both groups were calculated on their follow-up visit on Day 8.

Data analysis was performed on Stata version 12. Continuous variables were reported as means and standard deviations and independent *t* tests were used. Categorical variables were reported as frequencies and percentages and were assessed by  $\chi^2$ /fishers exact test where appropriate. Stratification was done based on age, gender, and surgical indications. *p* < 0.05 was considered significant throughout the study.

## RESULTS

A total of 78 patients were included in our study (Table 1). The mean age of our patients was 11.1 years old with a SD of 4.3. Most of our patients were male (67.9%) and the rest were female (32.1%). The most common surgical indication to undergo tonsillectomy was recurrent tonsillitis (78.2%) followed by obstructive sleep apnea (21.8%). The mean operative time for removal of both tonsils was 12.3 (3.5) min. We observed a decrease in mean pain score in both groups posttonsillectomy with Day 0 (9.1), Day 1 (8.6), Day 3 (7.6), Day 5 (6.4), and Day 7 (5.5).

Table 2 represents a comparison of the mean postoperative pain between the two groups. It was seen that the pain was significantly lower in patients with cold water irrigation of tonsillar fossa on Days 1, 3, 5, and 7 compared to their counterparts (p = 0.001).

In Table 3 patients were stratified based on age (5–15 and 16–22) and it was observed that the irrigation of the tonsillar fossa with cold water was significant for lower postoperative pain scores in the intervention group compared to their counterparts (p < 0.01 and p = 0.001, respectively).

TABLE 2	Comparison of age,	operative time,	pain at Days (	0, 1, 3, 5, and 7	) between both groups (	with CWI and without CWI)
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Variables	Intervention arm (with cold water irrigation, mean ± SD)	Control arm (without cold water irrigation, mean ± SD)	p Value
Age	10.25 ± 4.24	11.94 ± 4.19	0.081
Operative time	12.41 ± 3.40	12.25 ± 3.55	0.846
Day 0	8.92±0.80	9.20 ± 0.57	0.079
Day 1	8.28 ± 0.85	9.00 ± 0.56	0.001 <sup>a</sup>
Day 3	7.10 ± 1.33	8.17 ± 0.94	0.001 <sup>a</sup>
Day 5	5.76 ± 1.47	7.0 ± 1.23	0.001 <sup>a</sup>
Day 7	4.69 ± 1.90	6.33 ± 1.64	0.001 <sup>a</sup>
Overall pain score	6.95 ± 1.33	7.94 ± 1.07	0.001 <sup>a</sup>

Abbreviation: CWI, cold water irrigation.

<sup>a</sup>Significant at p < 0.05 by using two independent *t*-test.

Mean pain score at Day 7, when stratified based on gender, was significantly lower for males irrigated with cold water 4.54 (1.89) versus controls 6.68 (1.21) (p < 0.001). However, no such difference was observed among females (Table 4). Patients treated for recurrent tonsillitis with cold water irrigation had a lower mean postoperative pain score on Day 7 compared to those without cold irrigation (p < 0.001). However, we did not find any difference in pain scores in patients with or without cold irrigation who underwent surgery for OSA (p = 0.448, Table 5).

There were no readmissions postprocedure and none of our patients developed any complications postsurgery.

## DISCUSSION

Our study shows a significant reduction in mean posttonsillectomy pain in patients irrigated with cold water compared to patients not irrigated with cold water. Our findings are consistent with previous studies.<sup>7,8</sup>

**TABLE 3**Stratication of pain at 7th day w.r.t age between bothgroups.

Age groups (years)	Cold water irrigation		Pain at 7		
		n	Mean	SD	p Value
5-15	With	35	4.74	1.99	0.005 <sup>a</sup>
	Without	30	6.1	1.7	
16-22	With	4	4.25	0.95	0.001 <sup>a</sup>
	Without	9	7.11	1.16	

<sup>a</sup>Significant at p < 0.05 by using two independent *t*-test.

**TABLE 4** Stratication of pain at 7th day w.r.t gender between both groups.

Gender	Cold water irrigation	n	<u>Pain at 7t</u> Mean	h day SD	p Value
Female	With	8	5.25	1.98	0.471
	Without	17	5.88	2.02	
Male	With	31	4.54	1.89	0.001 <sup>a</sup>
	Without	22	6.68	1.21	

<sup>a</sup>Significant at p < 0.05 by using two independent *t*-test.

**TABLE 5** Stratication of pain at 7th day w.r.t surgical indications

 between both groups.
 Stratication of pain at 7th day w.r.t surgical indications

Surgical indications	Cold water irrigation		Pain at 7th day			
		n	Mean	SD	p Value	
OSA	With	7	5.28	1.7	0.448	
	Without	10	5.9	1.52		
Recurrent tonsillitis	With	32	4.56	1.94	0.001 <sup>a</sup>	
	Without	29	6.48	1.68		

<sup>a</sup>Significant at p < 0.05 by using two independent *t*-test.

Hypothetically, heat generated from a monopolar cautery would cause dissipation into the surrounding tissue, causing inflammation and irritation of nociceptors. Immediate cooling of the tonsillar fossa would therefore reduce this heat dissipation and reduce thermal damage to the surrounding tissue.<sup>1,11</sup> This was also shown by Sylvester et al. who observed a reduced pain score in children who were given ice popsicles immediately after their tonsillectomies.<sup>12</sup>

We included all patients more than or equal to 5 years old and most of our patients were of the pediatric age group (n = 65). Previous studies have either included only pediatric age groups or only adults in their study.<sup>1,7,8</sup> On subgroup analysis based on gender, it was observed that the male population which underwent cold water irrigation reported significant reduction in mean pain score on Day 7 compared to those who had not. However, there were no significant differences seen in pain scores among females. This could possibly be due to nonadherence of analgesics, a variable which was not assessed in our study. In addition, other postulations could include the subgroup having a higher pain threshold or being used for more potent analgesics, but this was not assessed in this present study, and is therefore a potentially confounding factor in this pragmatic trial. However, there was no difference in mean pain scores on Day 0, that is, 3 h posttonsillectomy in recovery between the two groups. A possible explanation for this is the immediate surgical trauma and inflammation of the surgical bed. Unfortunately, subgroup analysis based on gender was not reported in any previous study either, possibly due to a smaller sample size, making it difficult to compare results.

Moreover, we observed a significant reduction in mean pain score in the intervention (cold water irrigation) group versus control group on postoperative Day 1. Our results are consistent with a randomized study where significantly lower pain scores were observed in the irrigated group with normal saline at 4°C.<sup>7</sup> In another study, however, there were no significant differences seen in pain scores on Day 1.<sup>8</sup> We also observed a mean reduction in pain scores in the intervention group on Days 3, 5, and 7 and our results are consistent with findings from other studies.<sup>1,7,8</sup>

Our study results also show a significant reduction in pain in the intervention group versus the control group among patients who had undergone tonsillectomy for recurrent tonsillitis. A plausible explanation for this is that patients with recurrent tonsillitis have more fibrosis and therefore, electro-dissection with a monopolar cautery would lead to more inflammation and thus a greater irritation of nociceptors. However, there is limited information in the existing literature regarding this.<sup>7,8</sup>

Previous studies have had certain limitations. In one study, tonsillectomies were performed concomitantly with uvulopalatoplasties, and due to a small sample size in either group and lack of a subgroup analysis, the external validity of the study was low.<sup>1</sup> In another study, isotonic fluid at room temperature was used to irrigate one tonsil while the other tonsil was left untreated and due to the small sample size and lack of reporting the exact amount of fluid used and the time taken to irrigate,<sup>8</sup> it would be difficult to generalize the results. In another study, two different surgical techniques were compared, that is, bipolar scissors for cooling compared to cold

dissection, and it is uncertain whether cooling or the use of bipolar scissors reduced postoperative pain and to what extent.<sup>9</sup>

Our study had several limitations. First, our study was a quasiexperimental trial that lacked randomization. There were three surgeons who performed tonsillectomies with the same technique, and this might have led to some heterogeneity while performing the procedure, even though all the surgeons had an experience of over 5 years. In addition, in a few cases, irrigation was delayed while maintaining hemostasis. Furthermore, we did not encounter any complications in either arm, such as secondary hemorrhage, and this could be due to our small sample size. Use of intraoperative steroids by anesthetists to reduce inflammation of airways might also have confounded the results and was not analyzed in the present study. Although all the patients were given similar medication regimens for postoperative pain control, adherence to analgesics could have varied amongst the patients.

## CONCLUSIONS

In this pragmatic trial, we report a reduced pain score on Days 1, 3, 5, and 7 in the cold-water irrigation group. Irrigation of tonsillar fossa is a safe, cost-effective, and technically less demanding technique that could be employed to reduce postoperative pain. We would recommend that in the future, randomized control trials should be conducted with a larger sample size with blinding to reduce bias. We also suggest comparing pain scores at various temperatures of monopolar electrocautery.

#### AUTHOR CONTRIBUTIONS

Haissan Iftikhar: Study conception; study design. Nida Zahid: Study design, analysis, and interpretation of results. Adan Zubair: Data collection, analysis, and interpretation of results. Mohammad Wasif: Data collection; draft manuscript. Nabeel N. Baig: Data collection. Khadijah Abid: Analysis and interpretation of results. Muhammad Ozair Awan: Draft manuscript, critical revisions. Muhammad Sohail Awan: Critical revisions, final approval.

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The authors have nothing to report.

#### CONFLICTS OF INTEREST STATEMENT

The authors declare no conflict of interest.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

### ETHICS STATEMENT

Institutional ethical review committee approval was obtained before commencement of the trial and informed consent/assent was taken for participation in the study.

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