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Original Article

A Randomized Control Study on Primary Outcomes and the Effectiveness of Topical Sucralfate to Reduce Post-Tonsillectomy Throat Pain

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Abstract

Objective: The objective of the study was to assess the effectiveness of topical sucralfate to reduce post-tonsillectomy throat pain and associated primary outcomes.

Methods: This randomized control study was conducted in the department of ENT, Pakistan Institute of Medical Sciences (P.I.M.S.), Shaheed Zulfiqar Ali Bhutto Medical University (SZABMU), Islamabad from December 2016 to August 2017. The ethical approval was obtained from the ethical committee of the institution. One hundred and twelve patients having recurrent tonsillitis or hypertrophied tonsils were equally distributed into twin clusters. All the patients experienced tonsillectomy procedure (cold dissection method). The participants in-group A maintained on 10ml topical sucralfate (8 hourly during zero and first post-operative days) whereas the participants in-group B maintained on placebo. A comparison of both thestudy groups was done for post-tonsillectomy throat pain score as primary outcome, at zero and first post-operative days, as well as for the intolerance of tkaing normal oral diet at the morning of first post-operative day as secondary outcomes. Data was analyzed using SPSS version 21. A p value <0.005 was considered as significant.

Results: The mean age of the study participants in group A was 12.14+5.17 whereas, in group B, it was recorded as 11.53+3.95. The overall mean age of both the groups participants was calculated as 11.83+4.59. Out of 112 patients, 55.4% (n=62) were male and 44.6% (n=50) were female. Mean age was recorded as 11.83+4.59. The mean pain scores at day zero post-operatively were calculated for both the groups and were compared through independent simple t test. The difference between groups was found statistically significant with p value of less than 0.001. Similarly, the mean pain scores at day first post-operatively were calculated for both the groups and were compared using an independent simple t test. The difference between both the groups was found statistically significant with a p value of less than 0.001. General mean pain score after tonsillectomy procedure was significantly lower in-group A, as compared to group B (5.11+1.08 Vs 6.76+1.18, p<0.001).

Conclusion: The intensity of throat pain in study participants who are considered for tonsillectomy procedure using cold dissection method might be reduced with the use of topical sucralfate, additionally with the other analgesic measures. This can increase the compliance levels of patients undergoing cold tonsillectomy procedure.

Keywords: tonsillectomy, post-tonsillectomy pain, sucralfate.

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Introduction

Tonsillectomy is one of the most communal surgical procedures in otorhinolaryngology. Numerous techniques are being used to remove tonsils such as the electrocauterization methods, sharp dissection method, lasers, the tonsil guillotine as well as newer technologies including Harmonic Scalpel technique, Coblation and the Micro-debrider technique. The two most commonly used techniques are cold dissection and electro dissection.[1,2] With respect to patient's health, pain indicates a significant post-op morbidity during first week of the surgery because; it leads to many secondary complications. These might include painful swallowing, pain in the throat, problems in swallowing, halitosis, referred ear pain, fever and reduced oral intake.[3] Post-tonsillectomy pain immerges due to inflammatory conditions, nerve exasperation and spasm of visible pharyngeal muscles. The painful condition does not entirely reduce

until the appurtenance of mucosal layer on the muscles. More or less, 20-60% of patients nitpicks about Spartan post-op pain. Severe pain can lead to poor oral intake, dehydration, longer hospital stay and late return to regular daily activities.[4] In many cases, pain strength is dropped after the first post-op week, but it can continue for more than two weeks in some patients. Different studies have shown different mean pain scores in post-tonsillectomy patients, dependent on their age, surgical practices incorporated, administration of diverse analgesic agents etc.[5] Different medical and surgical approaches have been suggested to reduce post-op pain intensity. These approaches may include the use of narcotics, local anesthetic drugs, fibrin glue, acetaminophen, NSAIDs and honey, but persistent pain is still the most common grievance following tonsillectomy.[6,7] In this scenario, the post-op pain and other associated complications management in of utmost importance to every working ENT surgeon performing tonsillectomy.

Sucralfate has been a proven positive effect on post-op pain following diverse surgical procedures. A clinical study conducted in Iran, displayed a statistically significant pain reducing effect of topical sucralfate in post-tonsillectomy children.[8] The annals of Eurasian Medicine has published a study showing a minor post-op pain score, lesser referred otalgia score, lesser odynophagia score and lesser return time to normal diet for the patients who received topical sucralfate post-operatively, as compared to control group. [9]

The objective of the study was to assess the effectiveness of topical sucralfate to reduce post-tonsillectomy throat pain and associated primary outcomes.

Methods

This randomized control study was conducted in the department of ENT, Pakistan Institute of Medical Sciences (P.I.M.S.), Shaheed Zulfiqar Ali Bhutto Medical University (SZABMU), Islamabad from December 2016 to August 2017. A sample size of one hundred and twelve patients was calculated by using WHO calculator having recurrent tonsillitis or hypertrophied tonsils were enrolled in the study.

Inclusion criteria

The patients aged more than 8 years, fit for general anesthesia, suffering from recurrent tonsillitis or hypertrophied tonsils causing obstructive symptoms, which have been planned for tonsillectomy.

Exclusion criteria

The patients with known allergy to sucralfate, amoxiclave and paracetamol, Mentally retarded patients, the patients with history of bleeding disorders, the patients having Impaired renal and liver functions, the patients presenting suffering from acute tonsillitis, or acute upper respiratory tract infection and pregnant patients were excluded.

We divided the patients randomly into two groups (A & B) using a lottery method. Group A was called sucralfate whereas group B was termed as placebo group. Both the groups contained equal number of participants. We used Cold steel dissection method for the tonsillectomy Cauterization was done as little as possible in order to decrease the chances of confounding, as it has been reported that cauterization itself increases the severity of post-op pain. All the patients received oral Co-amoxiclave 40mg/kg/dose TDS and suspension paracetamol 15mg/kg/dose TDS, post-operatively. No patient received pre-op antibiotics, at least after hospitalization period. Starting 6 hours after surgery, patients were asked to keep 10mL of solution in the throat, either sucralfate or placebo, 8 hourly for one minute during zero and first post-op days.

Patients were asked about pain severity as a primary outcome by zero post-op day (12 hours after surgery) and first post-operative day (24 hours after surgery) using the Visual Analogue Scale, on a scale of zero to ten. Zero denoted no pain and 10 denoted the most severe pain. Mean throat Pain score of both readings was calculated for each patient and was recorded in an already prepared structured Performa.

Statistical analysis

We analyzed the collected data by subjecting it to statistical software SPSS version 21. Descriptive statistics were used to calculate mean and standard deviation for numerical variables like age and post-tonsillectomy throat pain score at zero and first post-operative days as well as overall mean pain score. Frequency (%) was calculated for qualitative variables like gender and intolerance to oral food intake by start of first post-op day. Mean pain Scores of both the groups, at zero and first post-operative day, as well as overall mean pain scores were compared by applying independent sample t test while presence of earache and intolerance to oral food intake were compared using Chi square test. A p value $<0.05\%$ was considered to be significant. In addition, the patients of both groups were divided into two groups of age categories and the pain scores were compared between both groups.

Results

We displayed the age in range and mean for the each group separately, as well as for the whole sample. The age data was homogenous which was verified by applying the Levene's test. ($p=0.111$). The overall mean age was 11.83+4.59. The mean age of both the groups were compared by using independent sample t test.

Table 1: *Age and Gender wise distribution of the study participants*

Age (year) Wise Distribution							
Groups	**Age range**			**Mean Age**		**P value**	
Group A	8-30			12.14±5.17		0.487	
Group B	8-25			11.53±3.95			
Overall	8-30			11.83±4.59		--	
Gender Wise Distribution							
Groups	**Male**		**Female**			**Total**	
	Number	**Percentage**	**Number**	**Percentage**	**P value**	**Number**	**percentage**
Group A	33	58.9 %	23	41.1 %	0.447	56	50 %
Group B	29	51.8 %	27	48.2 %		56	50 %
Total	62	55.4 %	50	44.6 %	--	112	100 %

There was no statistically proven difference between age of both the groups and the p value was found to be 0.487.

Out of 112 patients, 55.4% (n=62) were male and 44.6% (n=50) were female. Mean age of the patients was 11.83 + 4.59. The gender was shown in frequency and percentage for both groups separately, as well as for whole sample. Both groups were compared from gender point of view by using the Chi Square test. No statistically significant dissimilarity was found and the p value was 0.447. The data of age and gender is concised for each group, as well as for whole sample in table1.

The mean pain scores at day zero post-operatively (12 hours after surgery) were calculated for both the groups and were compared through independent simple t test. The difference between groups was found statistically

Table 2: *Comparison of the Mean Pain Score at day Zero post-operatively*

Groups	**Mean Pain Score at day Zero post-operatively**		**P value**
	Mean	**SD**	
Group A	6.08	1.21	<0.001
Group B	7.62	1.16	

significant with p value of less than 0.001. The results are displayed in table II.

Similarly, the mean pain scores at day first post-operatively (24 hours after surgery) were calculated for both the groups and were compared using an independent simple t test. The difference between both the groups was

Table 3: *Comparison of the mean pain score at day 1 post-operatively*

Groups	**Mean pain score of first post operative day**		**P value**
	Mean	**SD**	
Group A	4.16	1.15	<0.001
Group B	5.94	1.32	

found statistically significant with a p value of less than 0.001. The results are displayed in table III.

The overall mean pain scores i.e. at day zero and day first post-operatively was calculated as well. The overall mean pain score was recorded as 5.11+1.08 for group A and 6.76+1.18 for group B with proven statistical significance after applying an independent sample t

Table 4: *Comparison of the overall mean pain score among the groups*

Groups	**Overall mean pain score**		**P value**
	Mean	**SD**	
Group A	5.11	1.08	<0.001
Group B	6.76	1.18	

test. (p<0.001). The comparison of overall mean pain scores is potted in table IV.

It should be pointed out that than pain scores data was tested for variance through Levene's test which presumed the data to be of equal variance at both day zero and day first, post-operatively.The comparison of both the groups in term of mean pain scores at day zero and day first post-operatively as well as overall mean pain scores is shown in figure 1.

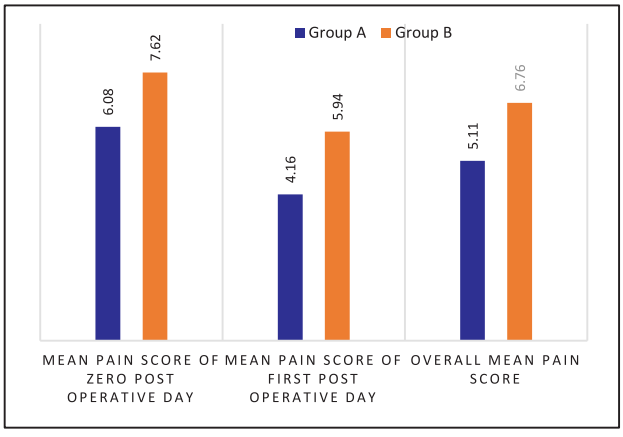

Figure 1. *Comparison of mean pain score among different groups at various intervals*

The overall mean pain score was also calculated for different age groups and were compared within the same group. Age of eleven years was considered the cut off, so the age was divided into two categories including <11 and >11. The mean scores of each category were comparable to each other within groups. After applying the independent sample t test, statistically significant difference was not found for age categories, within any of the two groups. (P=0.674 for group A, and 0.292 for group B) The comparison of pain scores between different age categories is shown in figure V.

Table 5: *Comparison of overall mean pain score among the groups*

Groups	Age	Number of patients	Overall mean pain score		P value
			Mean	SD	
Group A (n=56)	<11	32(57.1%)	5.06	1.01	0.674
	>11	24(42.9%)	5.18	1.19	
Group B (n=56)	<11	31(55.4%)	6.91	0.99	0.292
	>11	25(44.6%)	6.58	1.38	

Discussion

A mutual consensus is there among the clinical researchers that as of any surgical procedure, tonsillectomy is also linked with the incidence of numerous post-op morbidities. The patients who undergo tonsillectomy procedure, most commonly complain for severe painful conditions[10]. According to our results, the mean pain score at day zero post-operatively was 6.08+1.21 in group A and 7.62+1.[16] in group B, while the mean pain score was recorded to be 4.16+1.15 and 5.94+1.32 in group A and group B on day first post-operatively, respectively (P<0.001). The results of our study are comparable with some of the other published reports, but not with all of them, due to some important differences between the studies. For instance, some of the published studies have assessed the pain score for seven consecutive post-op days, while our evaluation for pain score was only at the day zero and day first post-operatively. This was done in order to complete the questionnaire before discharging the patient from the hospital, as it is too difficult to follow a patient for seven consecutive days on OPD basis, especially in our setup[11,13]. The overall mean pain score of group A was recorded 5.11+1.08 for group A and 6.76+1.18 for group B with proven statistical significance (P<0.001).

In most of the available related studies, the mean score of each day is recorded separately without calculating the overall mean pain score. There is only one available related study which includes the overall mean post-op pain score, in comparison to our study[14].

Sucralfate is a drug that is used in the treatment of duodenal ulceration. It is a complex of sulfated disaccharide sucrose and Aluminum hydroxide. This synthetic compound is insoluble in water and therefore, it serves as an appropriate coating over the tonsillar bed. The compound's protecting ability in ulceration is because of its combination with protein that stick to the raw surface[15]. We hypothesized a chemical barrier formation can be resulted over the exposed raw bed which could prevent stimulus of nerve endings and thus, relieving painful condition of the patients. Due to sucralfate cytoprotective effects, healing and epithelization can also be indorsed[16]. Therefore, it produces a native atmosphere for earlier wound healing. The results of our study shows the benefits of Sucralfate by the start of 2nd post-op day. We observed a substantial decrease in the pain score amongst both the groups with an increase in post-op days. The variance between the groups continued till their follow up period. Freeman et al had followed up patients for ten days, so he had reported pain difference between the two groups even up to ten post-op days[17]. Some of the researchers reported pain relief on 1st post-op day with the use of Dexamethasone[18]. Correspondingly, Kaan MN reported a less pain score in patients with the pre-operative use of dexamethasone during the first 6 hours post-operatively[19]. The frequent and immediate analgesic effects of sucralfate are not prominent because it does not have any analgesic property. Similarly, some of the researchers have reported its beneficial effects because of its use from intra-operative to post-operative period[20]. Sampaio reported a substantial decrease in pain score in the sucralfate group only in the initial six hours post-operatively and no difference after that. He had therefore, concluded that Sucralfate may not be effective in reducing post-surgery morbidity[19].

Conclusion

The intensity of throat pain in study participants who are considered for tonsillectomy procedure using cold dissection method might be reduced with the use of topical sucralfate, additionally with the other analgesic measures. This can increase the compliance levels of patients undergoing cold tonsillectomy procedure.

Conflict of Interest: None

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