

Pain Related Secondary Outcomes Associated with Cold Tonsillectomy and Role of Topical Sucralfate in Mitigating Their Severity: A Comparative Observational Study

Sadaqat Momand

Department of ENT, Nangarhar University Teaching Hospital, Jalalabad, Afghanistan

Momina Zeb

Department of ENT & HNS, Pakistan Institute of Medical Sciences, Islamabad, Pakistan

Wajih Ud Din Shinwari

Department of ENT, Frontier Medical College, Abbottabad, Pakistan

Wasim Ahmad (Corresponding Author)

Department of Allied Health Sciences, SHS, Peshawar, Pakistan

Email: vazim4847@gmail.com

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Abstract

The **aim** of the study was to assess the pain related secondary outcomes associated with cold tonsillectomy and role of topical sucralfate to reduce their intensity. **Material and Methods:** This comparative observational study was conducted in the ENT department of Pakistan Institute of Medical Sciences (P.I.M.S.), affiliated with the Shaheed Zulfiqar Ali Bhutto Medical University (SZABMU), Islamabad, spanned from December 2016 to August 2017, following institutional ethical approval. The study comprised 112 patients with recurrent tonsillitis, evenly assigned to group A (subjects) and group B (control). Tonsillectomy, employing the cold steel dissection method, was administered to all patients. Group A received 10ml of topical sucralfate every 8 hours on the zero and first postoperative days, while group B received a placebo. Comparative analysis between the groups focused on pain-related secondary outcomes, including referred otalgia and the ability to initiate a regular oral diet on the morning of the first postoperative day. SPSS version 21 facilitated data analysis, with significance set at $p < 0.005$. **Results:** In group A, the mean age was 12.14 ± 5.17 , and in group B, it was 11.53 ± 3.95 , resulting in an overall mean age of 11.83 ± 4.59 for both groups. Among 112 patients, 55.4% ($n=62$) were male, and 44.6% ($n=50$) were female. The frequency of referred earache was significantly lower in group A (15, 26.8%) compared to group B (25, 54.6%) [$n_1=n_2=56$, $p=0.049$]. Intolerance to start a normal diet was significantly lower in group A (17, 30.4%) compared to group B (39, 69.6%) at the first post-op day [$n_1=n_2=56$, $p=0.034$]. **Conclusion:** Utilizing topical sucralfate alongside other pain management strategies proves to be an effective approach in reducing the intensity of pain related secondary complication i.e. referred otalgia and intolerance to oral intake among patients undergoing tonsillectomy using the cold steel dissection technique.

Keywords: Bio- imitative; Bio- stimulated; Self-curing Composites; Material science.

1. Introduction

Tonsillectomy, whether performed alone or alongside adenoidectomy, stands as one of the most frequently carried out surgical procedures in the field of otorhinolaryngology. The surgical process involves the complete removal of a tonsil, along with its capsule, achieved by dissecting the peritonsillar space situated between the tonsil capsule and a muscular wall [1]. Research has increasingly revealed that tonsillectomy offers the potential to improve upper airway passage, treat obstructive sleep apnea, decrease the frequency of recurring pharyngitis, and ultimately lead to better overall health and a higher quality of life [2]. Tonsillectomy, despite its benefits for breathing and overall health, presents a significant burden of morbidity in the form of postoperative pain. (Problem statement) This pain, predominantly experienced in the throat, can manifest as difficulty swallowing (dysphagia), earache (otalgia), and jaw stiffness (trismus). This pain can be most severe in the initial days following surgery, potentially leading to reduced oral intake and subsequent dehydration, which may necessitate hospital readmission. Recent studies suggest the etiology of post-tonsillectomy pain lies in the inflammation and irritation of nerve endings coupled with pharyngeal muscle spasm. This discomfort subsides with time as the exposed and inflamed tissues undergo re-epithelialization, forming a new mucous membrane [2, 3]. Optimizing postoperative pain management strategies is crucial for ensuring patient comfort, facilitating early return to regular oral intake and nutritional status, and expediting a swift resumption of normal daily activities. Various pharmacological interventions, including preoperative, intraoperative, and postoperative administration of different medications, are being investigated alongside the exploration of novel surgical techniques. These efforts aim to identify the most effective approaches for minimizing postoperative pain [4, 5]. Following tonsillectomy, systematic administration of paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs), frequently in combination, represents the mainstay of postoperative analgesia. Additionally, systemic or local corticosteroids and local anesthetics may be employed [6].

However, the use of NSAIDs remains a subject of debate despite evidence supporting the efficacy of certain NSAIDs and paracetamol in mitigating post-tonsillectomy pain. This controversy stems from the potential adverse effects of NSAIDs on platelet function, which could theoretically contribute to increased postoperative bleeding [7]. Sucralfate, which is a basic amino salt derived from sucrose octasulfate, proves to be an effective agent in treating peptic ulcers. Sucralfate exerts its therapeutic effect through a multifaceted mechanism of action. Primarily, it fixes to the protein matrix of the ulcer, forming a protective barrier that fosters a conducive environment for healing [8]. Additionally, evidence suggests that sucralfate stimulates the local production of prostaglandin E2, a factor known to enhance blood flow, mucous membrane production, cell division (mitotic activity), and the migration of cells towards the wound surface. Furthermore, sucralfate has been demonstrated to accelerate epithelial wound healing by promoting the bioavailability of growth factors, particularly fibroblast growth factor. This specific growth factor plays a critical role in angiogenesis, the initial stage of epithelial wound healing. Finally, sucralfate's ability to induce prostaglandin production and protect cells from programmed cell death (apoptosis) may contribute to facilitating re-epithelialization, the process of regenerating the surface layer of the stomach lining during wound healing [9]. The study is significant because of the sucralfate use in effective pain management and accelerated healing may help reduce the risk of post-operative complications, such as bleeding or infection. The objective of the study was to assess the pain related secondary outcomes associated with cold tonsillectomy and role of topical sucralfate to reduce their intensity.

2. Methodology

2.1. Aim of the Study

To assess the pain related secondary outcomes associated with cold tonsillectomy and role of topical sucralfate to reduce their intensity.

2.2. Hypothesis of the Study

Topical Sucralfate is effective in mitigating post-operative cold tonsillectomy pain and other related outcomes.

2.3. Study Design

Comparative observational study

2.4. Study Setting

The 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.

2.5. Sample Size

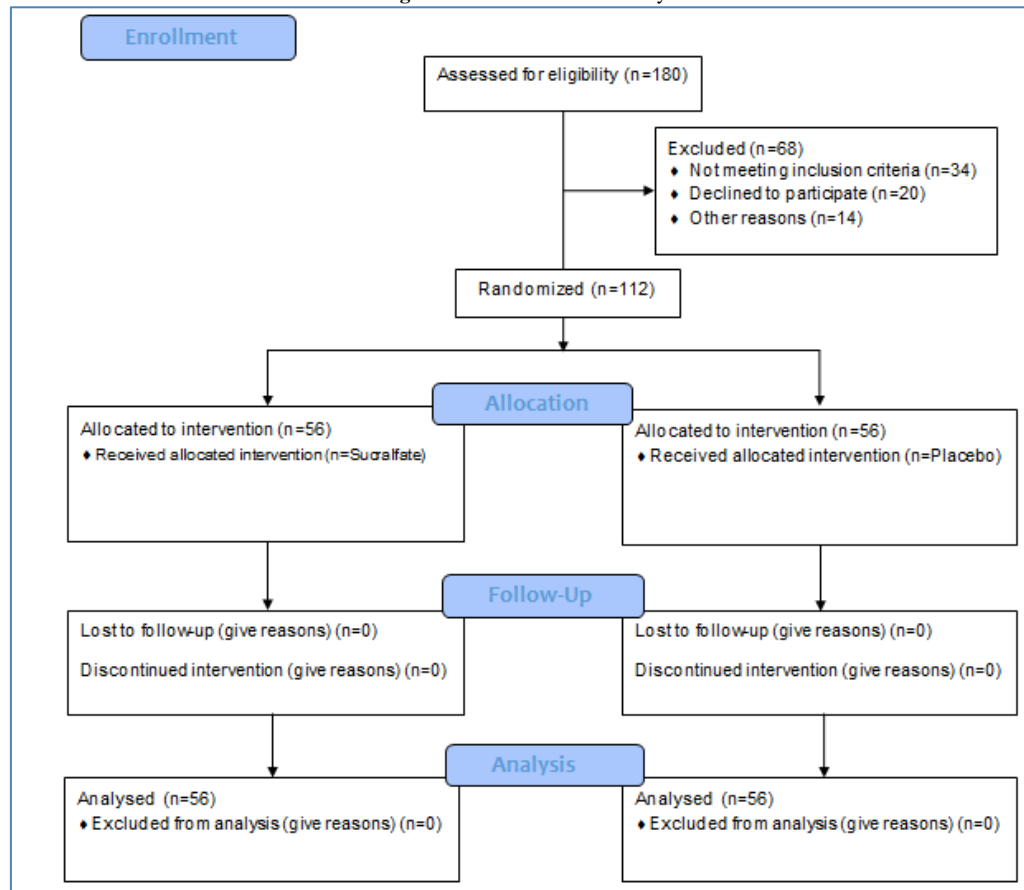
180 individuals were assessed out of which, one hundred and twelve patients having recurrent tonsillitis or hypertrophied tonsils were enrolled in the study. The sample size was calculated using WHO calculator with 5% margin of error and 95% confidence interval.

2.6. Data Collection

The patients aged more than 8years, fit for general anesthesia, suffering from recurrent tonsillitis or hypertrophied tonsils causing obstructive symptoms, which have been planned for tonsillectomy were included in the study (n=112). 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 (n=68).

We divided the patients randomly into two groups (A & B) using a lottery method. 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. We asked the patients about earache and food intake intolerance on first post-op day, and recorded if any.

Figure-1. Flow chart of the study



2.7. Statistical Analysis

The analysis of the data was conducted utilizing the statistical software SPSS version 21. Descriptive statistical methods were employed to compute the mean and standard deviation for numerical variables. For categorical variables such as gender and the occurrence of post-tonsillectomy referred earache and intolerance to oral food intake within the first post-operative day, frequency percentages were calculated. A comparison between the presence of earache and intolerance to oral food intake was performed using the Chi-square test. A significance level of $p < 0.05$ was used to determine statistical significance.

3. Results

The age is displayed in mean for each group separately, as well as for the whole sample. We found homogenous age data that 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. There was no statistically proven difference between age of both the groups and the p value was found to be 0.487.

The baseline characteristics of the study population are mentioned in table 1.

Table-1. Study population Baseline Characteristics

Characteristics		Group A (Sucralfate) n=56	Group B (Placebo) n=56	P value
Gender	Male	32 (57.14%)	30 (53.57%)	0.242
	Female	24(42.86%)	26 (46.43%)	
Age (years) (mean \pm SD)		12.14 \pm 3.54	11.53 \pm 2.21	0.487
Weight (kg) (mean \pm SD)		26.4 \pm 2.88	26.8 \pm 4.10	0.642

3.1. Post-operative referred Otolgia

We inquired about the occurrence of otalgia in participants from both groups on the first day after surgery and recorded the results. Among the 56 patients in group A, 15 patients (26.8%) experienced postoperative referred otalgia on the first day after surgery without any cause of primary ear pain, while 41 patients (73.2%) did not report any ear pain. Conversely, in group B, 25 patients (54.6%) reported referred otalgia, while the remaining patients in the same group, 31 patients (55.4%), did not indicate any ear pain on the first day after surgery. To assess the significance of the difference in post tonsillectomy earache occurrence between the two groups, a Chi-square test was employed. The resulting P value was 0.049, signifying statistical significance. Table 2 presents a comparison of the frequency of post tonsillectomy referred ear pain between the two groups.

Table-2. Frequency of post-operative referred otalgia in different group

Variables		Total (n=112)	Group A (n=56)	Group B (n=56)	P- value
Frequency of post-operative referred otalgia	Yes	40 (35.7 %)	15 (26.8 %)	41 (73.2 %)	0.049
	No	72 (64.3 %)	25 (54.6 %)	72 (64.3 %)	

3.2. Intolerance to start normal diet at first post-op day

Patients were advised and motivated to initiate their regular diet on the morning of the first day after surgery. However, certain patients in both groups experienced difficulty in consuming the diet due to painful swallowing (odynophagia). A noticeable contrast was observed between group A and group B in the number of patients who faced challenges in consuming a regular diet on the first morning following surgery [10] (30.4%) in group A compared to 28 (50%) in group B]. To determine the statistical significance of this difference, the Chi-square test was employed. The resulting P value was 0.034, which was deemed statistically significant. The findings regarding the incidence of diet intolerance are presented in table 3.

Table-3. Comparison of groups according to inability to start normal diet at first post-op day

Variables		Total (n=112)	Group A (n=56)	Group B (n=56)	P- value
Comparison of inability to start normal diet	Yes	45(40.2%)	17(30.4%)	28(50%)	0.034
	No	67(59.8%)	39(69.6%)	28(50%)	

4. Discussion

Despite its frequent application, tonsillectomy carries a non-negligible risk of postoperative complications. These complications primarily include pain, particularly localized to the throat and radiating to the ears, as well as difficulty with oral intake leading to potential dehydration. It is noteworthy that the intensity of postoperative pain appears to be greater in adults compared to the pediatric population [11-13].

Effective pain management is crucial to address these challenges. In the case of children, effective pain relief is particularly important to prevent heightened bleeding. Additionally, improving the post-tonsillectomy recovery process can enhance patient satisfaction and have positive impacts on emotional, social, and economic aspects [14]. While there isn't a perfect medication yet to minimize pain related post-tonsillectomy complications, it's important to extensively explore any potential drugs with minimal to no side effects for their effectiveness [15]. The incidence of referred ear pain was asked at first post-operative day from participants of both groups which was significantly lower in patients who received post-operative topical sucralfate. Out of 56 patients of group A, 15 patients (26.8 %) were suffered from post-operative referred otalgia at first post-operative day, while 41 patients (73.2 %) did not complain of any earache. On the other hand, the referred otalgia was reported by 25 patients (54.6 %) in group B, while 31 patients (55.4 %) did not report any ear pain at first post-operative pain. The P value was found 0.049. According to a report [16], a notable distinction was only evident on the third day after surgery concerning postoperative ear pain referred to the throat with a P value of 0.000. In a separate study [17], it was demonstrated that postoperative otalgia exhibited significant reduction in the placebo group when compared to the sucralfate group, with a p value of under 0.05. However, unlike our research, they quantified postoperative referred ear pain using a scoring system rather than its frequency, making direct comparison with our study challenging [18]. The resumption of a regular diet post-surgery is a crucial aspect of patient aftercare. Our findings indicate a noteworthy distinction between the two groups in terms of resuming normal oral intake on the morning of the first postoperative day. This implies that the sucralfate group demonstrated significantly lower intolerance compared to the placebo group; [10] (30.4%) versus 28 (50%), P=0.034, n1=n2=56]. A report focused on determining the average duration it took for patients to resume their regular diet, rather than the proportion of patients capable of doing so on the first day after surgery. Siddiqui, *et al.* [16] Their findings revealed that there was no statistically significant distinction between the sucralfate and control groups in terms of the average time it took to return to a normal diet, as indicated by a p-value of 0.09 [10, 16, 17, 19]. Conversely, the researchers arrived at a different conclusion, stating that patients who were administered sucralfate returned to their normal diets significantly sooner during the postoperative period compared to those who did not receive topical sucralfate [19]. This was a single centered study that do not reflex the results of the entire population. More multi-centered studies should be conducted for the validation of our mentioned results.

5. Conclusion

The application of topical sucralfate, combined with other pain-relieving approaches, proves to be a successful strategy for reducing the intensity of secondary effects in individuals undergoing tonsillectomy using the cold steel dissection technique. As previously noted, our evaluation was limited to the initial day after surgery, and the outcomes closely align with findings from prior investigations.

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Conflicts of interest

No potential conflicts of interest were disclosed by the author(s) about the research, authorship, and/or publication of this paper.

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