

Efficacy of Sucralfate in the Early Postoperative Improvement of Pediatric Thermal Welding Adenotonsillectomy Morbidity

Pediatric Thermal Welding Tonsilektomide Erken Dönem Morbiditelerin Azaltılmasında Sukralfatın Etkinliği

Original Investigation ►
 Özgün Araştırmalar

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Abstract ►

Objective: Many surgical techniques and solutions have tried to improve the morbidity of pediatric adenotonsillectomy. Pain is mainly treated with analgesics, steroids and anaesthetics. However, various topical solutions such as sucralfate have been used for pain relief.

Methods: We investigated the efficacy of sucralfate together with the TW technique on post-tonsillectomy morbidity in children. Our hypothesis was that the advantages of the TW technique might be improved by the protective coating effect of sucralfate on post-tonsillectomy morbidity. Patients were examined and scored clinically by their parents on the day of the operation and at the end of the day for the next 7 days. Throat pain was estimated by parents using the Faces Pain Scale-Revised from 0 to 10 with 0 representing the absence of

pain and 10 maximal pain on postoperative days 1 to 7 while swallowing, speaking and resting.

Results: The daily pain scores over the entire 7-day postoperative period were consistently lower in the sucralfate group than in the placebo group. The reduction of throat pain was significantly lower in the sucralfate group compared to the placebo group from the 1st to the 3rd postoperative day.

Conclusion: Our study demonstrates that sucralfate is safe and improves post-tonsillectomy analgesia in combination with the TW technique in children.

Key Words: Pediatric tonsillectomy, sucralfate, morbidity, thermal welding, Faces Pain Scale, quality of life

Özet ►

Amaç: Pediatrik adenotonsilektomi sonrası morbiditeyi azaltmak için birçok ameliyat tekniği ve ilaç denemektedir. Ağrının esas tedavisi analjezikler, steroidler ve anesteziplerdir. Ayrıca sukralfat gibi bazı topikal solüsyonlar ağrının azaltılmasında kullanılmıştır.

Yöntemler: Çalışmamızda Thermal Welding (TW) yöntemi ile sukralfatın topikal kullanımının pediatrik tonsilektomiye bağlı morbidite üzerine etkisini araştırmayı planladık. Hipotezimiz TW tekniğinin avantajlarını sukralfatın yüzey kaplayıcı etkinliğini kullanarak arttırmaktır. Aileler çocukları gözlemledi ve skorlamayı yaptı. Ağrı skorlaması Yüz Ağrı Skalası kullanılarak post

operatif 1 ve 7. günlerde yutarken, konuşurken ve istirahat halinde iken ağrı için 0'dan 10 kadar puan verildi.

Bulgular: Sukralfat grubunda ağrı skorları plasebo grubuna göre belirgin olarak düşüktü. Özellikle 1. ve 3. postoperatif günlerde sukralfat grubunda belirgin bir üstünlük vardı.

Sonuç: Çalışmamız sukralfatın çocuklarda postoperatif tonsilektomi morbiditesinin azaltılmasında etkili ve güvenli olduğunu gösterdi.

Anahtar Kelimeler: Pediatrik tonsilektomi, sukralfat, morbidite, thermal welding, Yüz Ağrı Skalası, yaşam kalitesi



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Introduction

Pediatric adenotonsillectomy is the most common surgery applied in pediatric otorhinolaryngology. Pain, the most trouble some morbidity of pediatric adenotonsillectomy, is the most powerful in the first 24 hours after surgery, and its severity decreases over subsequent days (1). Quality of life in children is mainly associated with the severity of pain. Their daily activities are affected by pain. With the relief of pain, quality of life suddenly improves, and children usually return to normal life earlier than adults.

Many surgical techniques have tried to improve the morbidity of adenotonsillectomy, including cold dissection, laser tonsillectomy, ligature tonsillectomy, ultrasonographic removal, mono-bipolar diathermy dissection and harmonic tonsillectomy (2, 3). Thermal welding (TW) tonsillectomy is a new surgical device that uses direct heat by coagulating and cutting soft tissue. This method is described as being

less traumatic to adjacent tissues than other methods and is hypothesized to cause less postoperative pain and faster recovery (4). Although post-tonsillectomy pain has been improved with recent tonsillectomy techniques, it is still the main problem for surgeons. Therefore, new methods are still being developed for pain recovery.

Pain is mainly treated with analgesics, antibiotics, steroids and local and topical anaesthetics (2). Many studies have reported that it is necessary to utilize more than one analgesic medication (5). However, various topical solutions such as sucralfate have also been used for pain relief. Sucralfate, a basic amino salt of sucrose octasulfate, is an effective agent in the treatment of peptic ulcer by binding the protein matrix of the ulcer and forming a protective barrier. Tonsillectomy leaves two large ulcerous wounds, and sucralfate may diminish morbidity by binding these wounds. There have been a few studies on sucralfate in pediatric tonsillectomy analgesia. Most reported that sucralfate decreased post-tonsillectomy pain, but that additional analgesics were required. In these studies, tonsillectomy was performed with cold dissection. However, there has been no report about the combination of pediatric TW tonsillectomy and topical sucralfate application in the relief of pain and the improvement of morbidity.

In the present study, we investigated the effect of sucralfate together with the TW technique on post-tonsillectomy morbidity in children. Our hypothesis was that the advantages of the TW technique might be improved by the protective coating effect of sucralfate on post-tonsillectomy morbidity.

Methods

The study was a randomized, double-blinded prospective clinical study to evaluate the efficacy of topical sucralfate in comparison with placebo for the reduction of postoperative pain after TW tonsillectomy in children. One hundred and seventy children who underwent TW adenotonsillectomy were randomized into two groups (sucralfate and placebo). All children were adenotonsillectomized with indications of chronic obstructive tonsillitis. Children with acute, recurrent or chronic tonsillitis with obstructive symptoms or with a history of peritonsillar abscess were not included in the study, because chronic inflammation might cause additional pain and damage to surrounding tissue during surgery, causing extra pain. All operations were performed under general anaesthesia by the same experienced surgical team. The surgical technique of TW tonsillectomy was based on dissection of the tonsil with a Bayonet UltraSlim Forceps (110-005D), which was used as a haemostatic and dissection tool. Haemostasis was performed with the UltraSlim forceps using the 1 setting of the power supply unit. A solution of sucralfate was prepared at a concentration of 1 g in 60 mL of distilled water. Placebo was 1 g of lactose diluted in 60 mL of distilled water. All patients were randomized into groups according to a random-number table. The random number table list and code was given to a recovery room anaesthesiologist who was blinded to patient grouping. The code was revealed to the researchers once recruitment and data collection were complete. All subjects and their parents were blinded to group assignment

for the duration of the study. At the end of surgery, after haemostasis, sucralfate or the placebo solution, which was prepared by an anaesthesiologist, was applied to the oropharynx, including the tonsillectomized area, for 2 minutes and then washed with isotonic solution and aspirated. On the following days, the patient used sucralfate or the placebo solution by rinsing his or her mouth with 10 mL of the solution and then swallowing four times a day for a period of 7 days. The same prescriptions were given to all children for analgesics (paracetamol) and antibiotics (amoxicillin/clavulanic acid) in weight-related doses. Patients were examined and scored clinically by their parents first on the day of the operation with the guidance of an experienced nurse and at the end of the day for the next 7 days. Throat pain was estimated by parents using the Faces Pain Scale-Revised (FPS-R) from 0 to 10, with 0 representing the absence of pain and 10 maximal pain on postoperative days 1 to 7, while swallowing, speaking and resting (6). All patients received a follow-up chart on which they were instructed to record the total daily analgesic requirements for the next 7 days, the last day of taking analgesics, the time of return to normal diet and any adverse events during recovery such as otalgia, nausea, vomiting, bleeding and fever. All questions on the chart were answered as yes or no. The time of return to normal diet was defined as the time within which the patients postoperatively returned to their diet without pain sensation during solid food intake. For analgesia, 200 mg/mL of paracetamol solution was prescribed, every 6 hours, when necessary. Paracetamol use was to be recorded on the chart, varying from zero up to four times a day. The patients, parents, surgeons and investigators were blinded to the sucralfate and placebo groups. The placebo was a lactose solution with the same density, colour and taste as sucralfate and was prepared in the hospital pharmacy.

The study was fully approved by the local ethics committee of the Istanbul Education and Research Hospital. Informed consent was received from the parents of all children enrolled in this study.

Statistical analysis

Statistical analysis was performed using the SPSS 12.0 and Advanced Models software (SPSS, Inc., Chicago, IL). Data with regard to throat pain, otalgia and analgesic use were analysed as means and standard deviation (SD). The differences between the two groups concerning continuous, ordinal variables such as age, pain scores, day of cessation of significant pain, total analgesic requirements and the last day of taking analgesics were evaluated using Student's t-test. The differences between groups in terms of frequency of nausea, vomiting and bleeding were analysed using Fisher's exact test. P values below 0.05 were considered to indicate significance.

Results

A total of 170 children (86 male, 84 female) who underwent TW adenotonsillectomy were enrolled in the study. The sucralfate and placebo groups consisted of an equal number of children to allow randomization. In the sucralfate group, 10 children were excluded from the study due to a lack of cooperation. There was no intolerance of or adverse events related to the medication.

Ages ranged from 3 to 12 years; the mean age was 7.25±1.90 years in the sucralfate group and 8.44±2.41 years in the placebo group (Table 1).

The overall mean pain score for the sucralfate group was 5.44±1.11, while for the placebo group, the overall mean pain score was 6.99±1.11. This difference was statistically significant (p=0.001). The daily pain scores over the entire 7-day postoperative period were consistently lower in the sucralfate group than in the placebo group, as seen in Table 2 and Figure 1. The reduction in throat pain was significantly lower in the sucralfate group compared to the placebo group from the 1st to the 3rd postoperative day (Table 2). However, although pain was consistently lower in the sucralfate group, the pain scores did not differ significantly between the two groups (Table 2) from the 4th to 7th postoperative day. There was no significant difference in the severity of pain while eating, resting and speaking.

Otalgia was statistically significant in the placebo group during the first 3 days postoperatively (p=0.000). Otalgia diminished in both groups over the following days, but the difference was not statistically significant (p=0.225).

The average duration of analgesic requirement after surgery was 7.83±2.60 hours in the sucralfate group and 5.22±1.56 hours in the placebo group; this difference was significant (p=0.001). There was a significant reduction in analgesic use in the sucralfate group compared to the placebo group (p=0.005) from the 1st to the 3rd day postoperatively. However, analgesic use was higher in the placebo group during subsequent days, and the day of the last analgesic dose was earlier in the sucralfate group (sucralfate group 5.50±3.35 days, versus the placebo group 6.50±3.0 days), but the differences were not statistically significant (p=0.225). The mean time to return to normal diet was 6.7±2.2 days for the sucralfate group and 7.11±2.11 days for the placebo group. The difference was not significant (p=0.09) (Table 2).

Fever was a rare event, and there was no significant difference between the groups (p>0.05). A few patients experienced nausea and/or vomiting, mainly during the 1st and 2nd days postoperatively.

Discussion

Throat pain, one of the most important morbidities 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 (7). Oral flora may also increase throat pain via inflammation and infection. The objective measurement of pain in children is difficult. The visual analogue scale is the most frequently applied method in adults, but is not suitable for children, especially those under the age of 7. The Faces Pain Scale was developed and validated by Bieri et al. (8), and is easy to perform and understand in children. Later, the FPS-R was adapted from the Faces Pain Scale in order to make it possible to score on the widely accepted 0-to-10 metric. This scale shows a close linear relationship with visual analogue pain scales across the age range 4 through 16 years. The FPS-R is easy to administer

Table 1. Throat pain levels over 7 days on Faces Pain Scale

Post-op day	Sucralfate Group (n=85)	Placebo Group (n=85)	p value
	Mean pain score±SD		
1	5.50±1.85	7.00±1.41	0.003
2	4.75±1.90	5.89±1.45	0.001
3	3.95±1.60	5.78±1.35	0.001
4	3.15±1.63	3.65±1.92	0.083
5	2.58±1.60	2.56±1.08	0.225
6	1.50±1.26	1.80±1.42	0.167
7	0.65±1.31	0.35±1.00	0.187
Overall mean throat pain score	5.44±1.11	6.99±1.11	0.001

SD: Standard deviation, P: Student t test

Table 2. Mean time to return to normal diet, last analgesic use and mean analgesic requirement after tonsillectomy results

	Sucralfate Group (n=85)	Placebo Group (n=85)	p value
	Mean±SD		
Mean analgesic requirement after tonsillectomy (hrs)	7.83±2.60	5.22±1.50	0.001
Last analgesic use (days)	5.50±3.35	6.50±3.0	0.225
Main return to normal diet (days)	6.70±2.20	7.11±2.11	0.09

SD: Standard deviation, P: Student t test

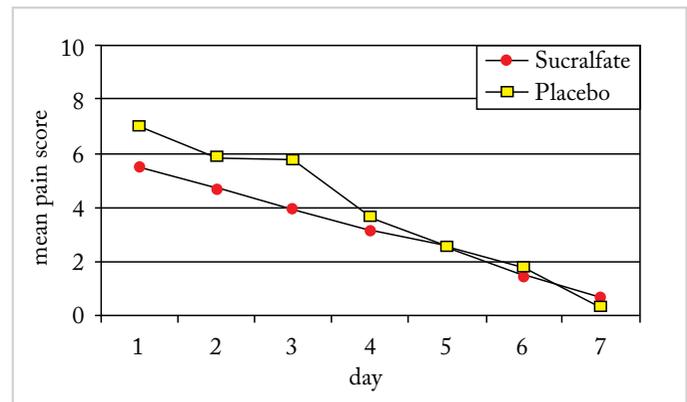


Figure 1. Mean post-tonsillectomy throat pain scores

and requires no equipment except for the photocopied faces. The absence of smiles and tears in this scale may be advantageous. The FPS-R that we used in our study is recommended for use with younger children in parallel with numerical self-rating scales (0 to 10) for older children and behavioural observation scales for those unable to provide self-report.

Despite the use of various medications, pain is still one of the most important morbidities after pediatric adenotonsillectomy.

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 (2). Few studies have reported on the advantages and disadvantages of thermal welding over the cold dissection technique in children. Chimona et al. (9) reported that there is less blood loss, and that thermal welding tonsillectomy is less time-consuming; however, there is more throat pain and difficulty in swallowing due to thermal damage of the surrounding tissues, causing excessive uvula and soft palate oedema. In contrast, other studies have reported that the thermal welding technique is considered less traumatic to adjacent tissues with less thermal damage, so this technique may be associated clinically with less pain and faster recovery (10, 11). The healing time with thermal welding technology should be faster than with the cold dissection technique. Due to earlier recovery, pain abates earlier after TW tonsillectomy.

In addition to different surgical techniques, various solutions have been applied to the tonsillectomized area for pain relief. Of these, sucralfate has been used in pediatric cold dissection tonsillectomy. Sucralfate has a cytoprotective effect and increases mucosal renewal by stimulating prostaglandin E synthesis (12). 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, and in patients who have undergone uvulopalatoplasty (7, 13). Sucralfate significantly lowered the need for analgesic drug use in these studies (14, 15).

The difference in our study was that, because of the reported advantages of the TW technique over cold dissection, we preferred TW tonsillectomy. In addition, all published studies have reported a significant pain reduction effect of sucralfate during tonsillectomy. However, all these studies performed cold dissection tonsillectomy. We used sucralfate with TW tonsillectomy to see this reduction value than control group and compare it with current published data. Our study found a lower intensity of pain in the sucralfate group, and this difference was significant in the first 3 days postoperatively. However, when we compared VAS scores with the results of Miura MS, using the same methodology but with cold dissection, the severity of pain was higher on all 7 days of our study. This showed us the reduction effect of sucralfate than control group whenever with negative effect of the TW technique on post-tonsillectomy pain (15). Otolgia is mostly due to reflection throat pain through the glossopharyngeal and vagal nerve. As throat pain diminishes, the intensity of otalgia should also decrease. In the present study, patients in the sucralfate group had significantly less otalgia than those in the placebo group during

the first 3 days postoperatively. Although Miura (15) reported that there was no reduction of otalgia in his series using sucralfate, we found a significant reduction of otalgia in children after sucralfate use, as shown in other studies (7). However, scores of otalgia in our study were also higher than those of Miura et al. (15).

There was no significant difference in the frequency of use of an analgesic and the number of days of analgesic use between the two groups, as found in some studies, although other studies have reported that analgesic requirements are lower in the sucralfate group (16-18). This implies that, although children feel pain, they do not decide on their analgesic requirements because the analgesic is administered by parents and parents may not realize that the child is in pain. Therefore, there may be no difference between the two groups in analgesic requirements even though the pain scores differ. Sucralfate is responsible for this difference. Our results showed that the analgesic requirement was lower in the sucralfate group than the placebo group. The first analgesic requirement was seen later after surgery in the sucralfate group than in the placebo group and the difference in timing was statistically significant. There were no severe complications of sucralfate such as abdominal pain, drowsiness, vertigo, nausea, dry mouth, pruritus, rash, constipation, diarrhoea or dizziness. Because only 2% to 5% is absorbed through the gastrointestinal tract, the incidence of adverse effects is very low.

A major limitation of our study was the lack of a cold dissection tonsillectomized group for determining the additive effect of the thermal welding technique. However, previous studies conducted using the same methodology showed a negative analgesic effect of TW on tonsillectomy pain.

Conclusion

Our study demonstrates that sucralfate is safe and improves post-tonsillectomy analgesia in children. Sucralfate also enables an earlier return to normal diet in tonsillectomized children, reduces the amount of analgesics required, and prevents dose-related adverse effects that can be caused by analgesic agents. This treatment is also easy to perform without any complications.

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Conflict of interest

No conflict of interest was declared by the authors.

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