Original Article / Çalışma - Araştırma

Management of pain after tonsillectomy: a prospective, randomized clinical study

Tonsillektomi sonrası ağrının tedavisi: Prospektif, randomize klinik çalışma

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Objectives: We evaluated the alleviation of post-tonsillectomy pain with systemic and topical applications.

Patients and Methods: Data obtained from 78 patients (28 females, 50 males) who had undergone tonsillectomy for recurrent tonsillitis by conventional cold surgery were reviewed with prospective, randomized clinical study. Initially, the patients were assigned into topical and systemic drug groups. These groups were then divided into three sub-groups; *(i)* clindamycin, dexamethasone, and control (saline) *(ii)* groups for the topical drug group; *(iii)* cefprozil, amoxicillin+clavulanate and control (no medications except analgesic) for the systemic drug group. The intensity of pain perceived by the patients at 21 different times was assessed by visual analog scale and facial scale.

Results: No significant relation was found between topical or systemic antibiotic use and pain intensity after tonsillectomy.

Conclusion: Neither topical application nor systemic administration is significantly superior to the other for postoperative management of pain.

Key Words: Analgesics, clinical trial; pain, postoperative; tonsillectomy.

Amaç: Tonsillektomi sonrası oluşan ağrının, sistemik ve topikal uygulamalarla ortadan kaldırılması değerlendirildi.

Hastalar ve Yöntemler: Tekrarlayan tonsillit nedeniyle, geleneksel soğuk cerrahi yöntem kullanılarak tonsillektomi uygulanan 78 hastanın (28 kadın, 50 erkek) bilgileri, prospektif, randomize klinik çalışma için değerlendirildi. Hastalar ilk olarak topikal ve sistemik ilaç gruplarına ayrıldı. Sonrasında bu gruplar, kendi içinde üç alt gruba ayrıldı; *(i)* topikal ilaç grubu klindamisin, deksametazon ve kontrol (salin), *(ii)* sistemik ilaç grubu sefprozil, amoksisilin-klavulanat ve *(iii)* kontrol (analjezik dışında ilaç verilmedi) gruplarına ayrıldı. Hastalar tarafından algılanan ağrının şiddeti 21 farklı zamanda görsel analog skala ve fasiyal skala ile değerlendirildi.

Bulgular: Sistemik ve topikal antibiyotik kullanımıyla tonsillektomi sonrası oluşan ağrının şiddetinde belirgin hiçbir etkileşimin olmadığı gözlendi.

Sonuç: Ne topikal uygulama ne de sistemik ilaç kullanımı ameliyat sonrası ağrı tedavisinde birbirine üstün değildir.

Anahtar Sözcükler: Analjezik; klinik çalışma; ağrı, ameliyat sonrası; tonsillektomi.

Some of the major negative effects of tonsillectomy are pain during swallowing, risk of secondary infection and dehydration.[1-4] Pain can be explained by two mechanisms: irritation of free nerve endings exposed in the tonsillar fossa and/or chemical mediators such as lactic acid, leukotrienes and prostaglandins produced during the inflammation in the tonsillar fossa and causing spasm of

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the pharyngeal muscles.[5,6] Postoperative inflammation and spasm of the pharyngeal muscles have been shown to cause ischemia in the tonsillar fossa and this prolongs the pain cycle.[6] Pain hinders mastication and swallowing, hence nourishment which, in turn, causes a delay in wound healing, dehydration, loss of several work or school days and weight.[4,7,8] These collectively lead to prolonged hospitalization, psycho-social problems in patients as well as placing a financial burden and causing loss of manpower.[9] Therefore, in the past 50 years, otorhinolaryngologists have been trying to improve the quality of postoperative life of the patients and reduce the economic losses. Among treatment protocols used for this purpose are various systemic/topical antibiotics and steroids. Though many studies endeavored to find answers to questions regarding the selection of the suitable antibiotic, its dose, route of administration and duration of the treatment, there is no universal agreement.

The objective of the present study was to determine the efficacies of topical clindamycin, topical dexamethasone, systemic cefprozil and systemic amoxicillin+clavulanate on pain following tonsillectomy.

PATIENTS AND METHODS

This study has been carried out on 78 tonsillectomy cases performed for recurrent tonsillitis over a period of 19 months in the Uludağ University, Faculty of Medicine, Department of Otorhinolaryngology Head and Neck Surgery. The criteria for recurrent tonsillitis were seven or more episodes of bacterial tonsillitis in the past year, or five or more episodes in each of the previous two years, or three or more episodes in each of the previous three years in the pediatric group, and two or more episodes of bacterial tonsillitis in the past year in the adult group. Patients who were operated due to another indication or those operated using a technique other than described below were not included in the study.

Patients over the age of four, the minimum age a person can gargle, were included in the study. The patients were divided into two groups: *(i)* children/adolescents (aged 18 years and under) and *(ii)* adults (aged 19 years and over). Among the 61 patients in children/adolescent group, 21 (35%) were female and 40 (65%) were male. In the adult group, seven of the 17 patients (41%) were female and 10 (59%) were male. Mean age of the children/adolescents group was 7.63 while that of the adult group was 33.58 years.

Prior to the operation, the patients were informed on "Visual analog scale" (VAS), (Fig. 1) and "Facial Scale" (FAS), (Fig. 2) used to measure the intensity of pain perceived during postoperative period.[10,11] The patients were instructed to indicate on VAS and FAS sheets the pain they perceived 1, 2, 3, 4, 6, 12 and 18 hours after the operation and twice a day for the next seven days, when they wake up in the morning and before they take their analgesic in the evening.

We employed "cold surgery" during tonsillectomy on all patients and used a 50-Watt bipolar electrocautery for homeostasis when needed. Starting four hours after the operation, all patients were given acetaminophen for analgesia (patients aged 4-12 years: oral suspension, 10 mg/kg qid; patients over 12 years of age: oral suspension, 500 mg qid). We do not use routine antibiotic therapy after tonsillectomy. Since hard foods exacerbate pain in the first few days after the operation, the patients were advised liquid and soft foods at room temperature for the first seven days and revert to regular diet subsequently.

Analgesic agents were used during perioperative period and anesthesia were standardized in all groups. Anesthesia in children started with inhalation induction using sevoflurane and in oxygen. After induction, an intravenous cannula was inserted and muscle paralysis was established using rocuronium to facilitate tracheal intubation. For intraoperative analgesia, intravenous fentanyl (1 μg/kg) was given prior to intubation. Anesthesia was maintained with sevoflurane in oxygen/nitrous oxide (2:1). Induction of anesthesia was performed with propofol (2-3 μg/kg), rocuronium (0.6 μg/kg), fentanyl (1-2 μg/kg) in adult patients.

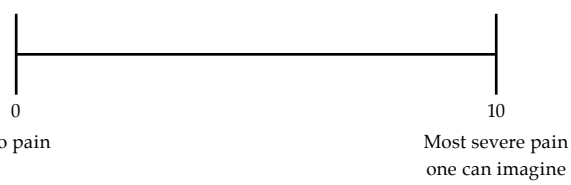

Fig. 1. *Visual analog scale.*

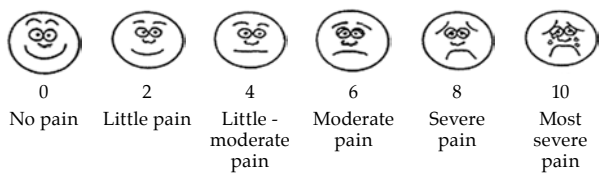

Fig. 2. *Facial scale.*

Table 1. Sex and age distribution of the groups

Group	Subgroup	Medications used	Number of patients		Mean age
			Male	Female	
A	A1	Clindamycin	17	11	13.4
	A2	Dexamethasone	8	2	12.9
	A3	Saline	6	4	9.1
B	B1	Cefprozil	5	5	11.3
	B2	Amoxicillin+clavulanate	6	4	22.1
	B3	Control	8	2	10.4
Total			50	28	13.2

The patients were randomly allocated into either topical (A) or systemic medication (B) groups. Topical medication group was further divided into three subgroups: clindamycin (Klindan; Bilim, İstanbul, Turkey) (A1), dexamethasone (Dekort flacon; Deva, İstanbul, Turkey) (A2), saline (A3). Systemic medication group was also divided into three subgroups: cefprozil (Serozil; Bristol Myers Squibb, İstanbul, Turkey) (B1), amoxicillin+clavulanate (Augmentin, GlaxoSmithKline, İstanbul, Turkey) (B2) and control group (B3) which received no medication except analgesics. Age and sex details of patient groups are presented in Table 1.

To reduce the morbidity of tonsillectomy, we have developed a method based on works of Mann et al.[12] with topical clindamycin; Grandis et al.[13] with systemic amoxicillin+clavulanate; Brook and Foote[14] with cefprozil; and Kaygusuz and Susaman[3] with dexamethasone injection into the tonsillar fossa. The use of dexamethasone is based on the work of Kutcher et al.[15] in which the authors used 0.5 mg/ml dexamethasone as gargle for recurrent aphthous stomatitis. Patients in groups A1, A2 and A3 gargled for one minute the solutions of 1.5 g clindamycin in 60 ml of saline, 30 mg dexamethasone in 60 ml of saline, and 60 ml of saline only, respectively, 30 minutes before the operation. During the operation, once the tonsils were extirpated, the tonsillar fossa was washed by the surgeon with clindamycin (A1) (900 mg clindamycin + 60 ml saline) or dexamethasone (A2) (30 mg dexamethasone + 60 ml saline) or saline only (A3) (60 ml saline) for one minute. After the wash, the excess fluid was aspirated. The patients also gargled clindamycin (A1) (1.5 g clindamycin + 60 ml saline), dexamethasone (A2) (30 mg dexamethasone + 60 ml saline), and saline only (A3) (60 ml saline) at the postoperative 8th hour, for one minute.

Patients in group B were also divided into three subgroups. Starting from the postoperative 4th hour, patients in group B1 were given cefprozil, a second generation cephalosporin for seven days (patients aged 4-12 years: oral suspension, 7.5-15 mg/kg bid; patients over 12 years of age: oral suspension, 500 mg bid). Patients in group B2 had amoxicillin+clavulanate for seven days (patients aged 4-12 years: oral suspension, 40 mg/kg tid; patients over 12 years of age: oral suspension, 500 mg tid). Patients in group B3, on the other hand, were not given any medication but acetaminophen to constitute the control group.

All patients who had tonsillectomy were hospitalized the night of the operation and discharged with recommendations the next day if there were no problems and scheduled for a follow-up control on the 7th postoperative day.

Data were analyzed with SPSS statistical software using Fisher's chi-square test, Kruskal-Wallis test and Mann-Whitney U-test.

Informed consents were obtained from all patients or their parents and the study was approved by the Ethical Board.

RESULTS

There were no statistically significant differences with regard to age distribution among six groups ($p>0.05$).

1. Analysis of the intensity of pain scores of the groups

a) Analysis of visual analog scale

Visual analog scale scores of 78 patients recorded at 21 different times postoperatively have been analyzed.

Figure 3 shows VAS pain intensity scores after topical medication use at 21 different times, span-

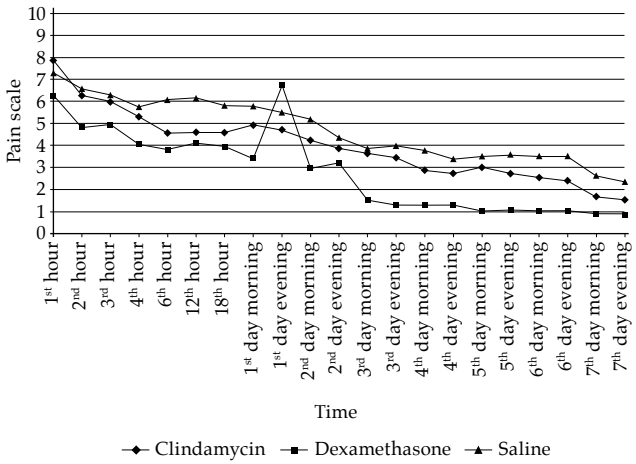

Fig. 3. Visual analog scale pain intensity scores after topical medication use (group A).

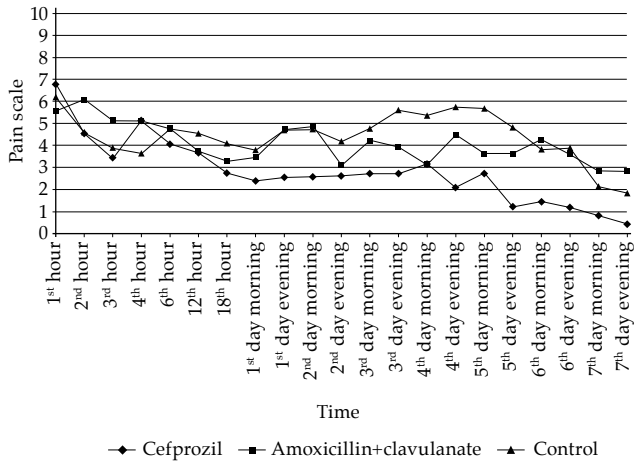

Fig. 4. Visual analog scale pain intensity scores after systemic medication use (group B).

ning a time period between the first postoperative hour and the evening of day seven.

There were no significant differences between VAS pain intensity scores of clindamycin, dexamethasone and saline groups ($p>0.05$).

Figure 4 shows VAS pain intensity scores after systemic medication use at 21 different times, spanning a time period between the first postoperative hour and the evening of day seven.

Comparison of VAS pain intensity scores of cefprozil, amoxicillin+clavulanate and control groups revealed a significant difference only on the evening of day four ($p=0.047$). Pairwise comparisons with Mann-Whitney U test showed that this difference stemmed from the difference between cefprozil and control groups ($p=0.04$). Mean pain intensity on the evening of day four in cefprozil group was 2.08±0.60 while that of the control group was 5.74±1.00, indicating that cefprozil alleviated the pain significantly more compared to the control group ($p<0.05$).

b) Analysis of facial scale

Facial Scale scores of 78 patients recorded at 21 different times postoperatively have been analyzed.

Figure 5 shows FAS pain intensity scores after topical medication use at 21 different times, spanning a time period between the postoperative first hour and the evening of day seven.

There were no significant differences between FAS pain intensity scores of clindamycin, dexamethasone and saline groups ($p>0.05$).

Figure 6 shows FAS pain intensity scores after systemic medication use at 21 different times,

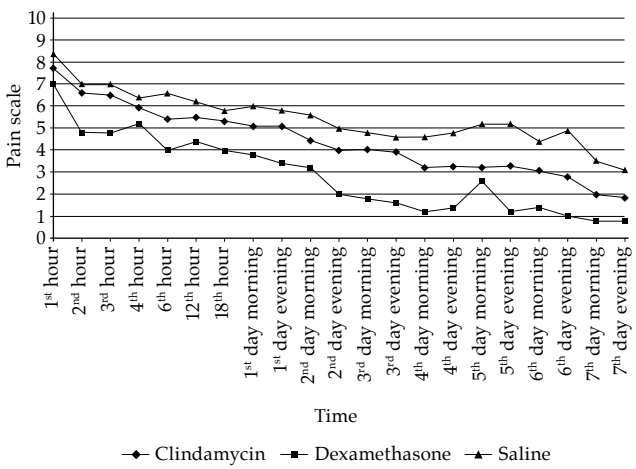

Fig. 5. Facial scale pain intensity scores after topical medication use (group A).

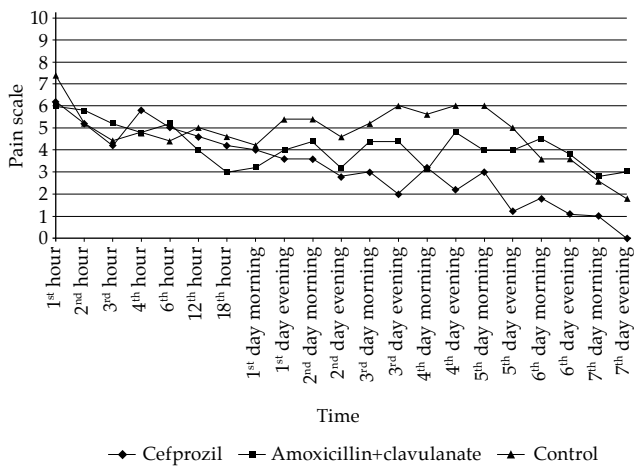

Fig. 6. Facial scale pain intensity scores after systemic medication use (group B).

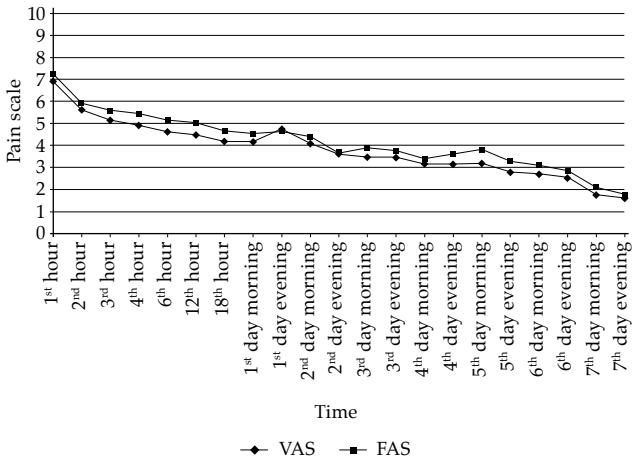

Fig. 7. *Comparison of VAS and FAS pain intensity scores of all patients at all times.*

spanning a time period between the postoperative first hour and the evening of day seven.

Comparison of FAS pain intensity scores of cefprozil, amoxicillin+clavulanate and control groups revealed no significant differences ($p>0.05$).

2. Statistical comparison of VAS and FAS

Comparison of the pain intensity scores of VAS and FAS at all times (Fig. 7) showed statistically significant differences between p values at 13 different times and VAS pain intensity was lower whenever the p value was significant.

DISCUSSION

Cornelius Celsus, who performed the first known tonsillectomy some 2000 years ago used various medications and irrigated the tonsillar fossa with vinegar to reduce pain and hemorrhage.[16]

Throat pain observed in tonsillectomy patients frequently results in inadequate food intake, otalgia, fever, dehydration and limited activity. Management of pain after tonsillectomy shortens the recovery time and decreases loss of manpower. Hence, there is ongoing research on finding methods to eliminate, or minimize post-tonsillectomy pain.[3,8]

Lee et al.[17] reported that post-tonsillectomy pain lasted more than five days in 90.4% of their patients and caused physical and behavioral changes in 36.8% of them. Comprehensive studies have been undertaken aiming to speed up healing and prevent morbidity. Towards the end of the 19th century, local anesthetics began to be used to reduce pain after tonsillectomy.[18] Before the turn of the 20th century, efficacies of various antibiotics to decrease bacterial colonization of the tonsillar fossa and promote healing were started to be explored. Telian et al.[19] reported that the incidence of peritonsillar cellulitis, and therefore morbidity, can be reduced by using antibiotics after tonsillectomy via decreasing the pathogen microorganisms in the fibrinous exudate around the tonsillar fossa and oral flora. Various studies showed that pain induced by inflammation after tonsillectomy can be alleviated by topical/systemic antibiotics, topical analgesics, steroid, sucralfate or fusafungine.[3,12-15,20,21] However, there is no consensus on the type of antibiotic to be used or the route of administration after tonsillectomy.

One of the factors that have an influence on pain after tonsillectomy is the surgical technique. Linden et al.[22] carried out a study on children in which they investigated the intensity of pain and found that patients perceived significantly more pain when electrocautery or laser was used, compared to blunt dissection. In order to eliminate differences due to surgical technique, we employed blunt dissection during tonsillectomy.

Assessing the intensity of throat pain after tonsillectomy

Stringel et al.[23] have demonstrated that local tissue concentration was higher with topical antibiotic application than that achieved by systemic administration. Polymicrobial oral flora is responsible for wound infection after the operations of the oral cavity. Systemic antibiotics can decrease postoperative morbidity by reducing the bacterial colonization of the exposed tonsillar fossa. Local inflammation is expected to decrease when the number of bacteria in open surgical wound is lessened. It has been shown in studies on head-neck surgery that topical clindamycin is a safe and effective tool in limiting the number of oral bacteria on wounds.[12] Therefore, with the use of topical antibiotics, the number of oral bacteria can be effectively reduced. As a result, morbidity due to bacterial colonization of the exposed tonsillar fossa can be diminished.[12] In such cases, topical application of antibiotics should be considered as an option for prophylaxis of wound infections, since infection, inflammation and consequently pain can be prevented by antibiotics suitable for the possible pathogenic microorganisms.[24-26] Prophylaxis with topical antibiotics is cheaper, easier to comply than systemic antibiotics, with fewer side effects.

In a study aiming to reduce pain after tonsillectomy using topical antibiotics, Mann et al.[12] divided their patients into four groups. The first three groups were given clindamycin (1500-900 mg), Augmentin (3.75 g)/Timentin (3.1 g) and topical saline while the fourth group had systemic amoxicillin (250 mg). They found that postoperative throat pain was significantly less in patients who had clindamycin or Augmentin/Timentin compared to saline or amoxicillin. But, no significant difference was observed in VAS and FAS pain intensity scores of topical clindamycin and topical saline groups ($p>0.05$). Therefore, we do not think that topical clindamycin is a good option after tonsillectomy.

In an attempt to reduce the intensity of post-tonsillectomy pain, triamcinolone acetonide has been injected to the tonsillar fossa and anterior pillar (a total of 40 mg) and the authors found that this approach caused significantly less pain compared to the placebo group.[27] Meanwhile, there are studies arguing that steroid use decreased edema by inhibiting vascular permeability, production of inflammatory cells and leukocyte extravasation and, consequently, promoted healing.[18,28] Kaygusuz and Susaman[3] injected dexamethasone into the tonsillar fossa following tonsillectomy to assess healing and found that dexamethasone, especially in children, decreased postoperative pharyngeal edema and the risk of obstructive sleep apnea due to upper respiratory tract obstruction and facilitated oral intake by its anti-inflammatory effects. In the present study, we preferred dexamethasone because it is absorbed in little amounts and exerts potent and long-acting local effects when applied to the mucous membranes. There were no statistically significant differences between pain intensity scores measured with VAS and FAS among dexamethasone and saline groups ($p>0.05$). These results collectively suggest that topical dexamethasone is not an effective option to reduce pain following tonsillectomy.

Systemic antibiotics reduce postoperative morbidity by reducing bacterial colonization of the exposed tonsillar fossa. Decrease in local inflammation and rapid healing of the surgical wound is expected when the number of bacteria is reduced. Brook and Foote[14] compared the efficacies of penicillin and cefprozil on tonsillar flora with placebo. The authors found that cefprozil was significantly more effective in reducing the numbers of β-hemolytic streptococci and β-lactamase producing bacteria than penicillin and placebo. In our study, statistically significant difference between VAS pain intensity scores of cefprozil and control groups was observed only on the evening of day four ($p=0.047$). Since the number of cases in systemic medication group was limited, this finding needs to be supported by comprehensive studies.

Grandis et al.[13] compared the pain intensity scores of patients who received perioperative Timentin (ticarcillin+clavulanic acid) and postoperative amoxicillin+clavulanate with those of placebo group and concluded pain was less severe in patients who used antibiotics. On the other hand, Mann et al.[12] reported that postoperative throat pain was less severe when Augmentin/Timentin solution was used topically compared to the placebo group. Telian et al.,[19] on the other hand, found that preoperative intravenous ampicillin and postoperative oral amoxicillin alleviated pain in the first two days only when compared to the control group. Colreavy et al.[29] reported that patients who had systemic amoxicillin+clavulanate experienced significantly less pain than those who did not have any medication. However, we did not find significant differences in VAS and FAS pain intensity scores between amoxicillin+clavulanate and control groups ($p>0.05$). This finding suggests that amoxicillin+clavulanate use after tonsillectomy is not effective in alleviating pain and, therefore, systemic use is not appropriate.

In a study by Warnock and Lander,[30] authors have reported severe throat pain, decreases in oral intake, physical activity when VAS pain score was 30 mm or higher after tonsillectomy. Based on this data; present study revealed that dexamethasone in the topical medications group and cefprozil in the systemic medications group decreased the morbidity earliest (after the evening of day two and after 12 hours, respectively). When all groups were considered, cefprozil decreased morbidity earliest but differences between groups were not statistically significant.

Comparison of VAS and FAS

Perception of pain is a complex process influenced by many sensorial, emotional and behavioral factors. The intensity of and decrease in pain can be measured by one-dimensional pain measurement methods. The magnitude of pain reflects how much pain is perceived by the patient and can be

quantified by various scales. Amongst these scales are VAS, category scales (FAS) and numerical rating scales[10,11] and there are significant statistical correlations between pain measurement scales. Carr et al.,[28] who conducted many researches on this matter, reported that these scales yield reliable results.

When pain intensity scores obtained at 21 different times using VAS and FAS were compared, statistically significant differences were found at 13 different times ($p<0.05$). We also noted that pain intensity scores obtained using VAS were lower at times when p values were significant. However, there were no distinct differences between VAS and FAS scores, neither among topical and systemic medication groups nor age groups. Nevertheless, we think that VAS is more reliable due to the tendency of the patients to select the middle facial expressions and words in FAS and ethnic and cultural differences in the population.

The results of the present study which analyzed the pain intensity scores obtained using VAS and FAS at 21 different times postoperatively showed that neither topical application nor systemic administration was significantly superior to the other for postoperative management of pain. Further studies are required in our quest to minimize the pain experienced following tonsillectomy.

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