

*Full Length Research Paper*

# The effects of post-operative topical chlorhexidine gluconate and benzydamine HCL spray (farhex) on post-operative pain and oral intake in tonsillectomied patients

\*Mahmut Özkırış and Cemil Mutlu

Department of Otolaryngology, Head and Neck Surgery, Private Hospital, Kayseri- Turkey.

Accepted 10 September, 2011

The current study was aimed to determine the effects of post-operative topical farhex oral spray on post-operative pain and oral intake in patients who underwent tonsillectomies. Eighty patients (40 patients in the farhex group and 40 patients in the control group) were included in the study. The mean age of the patients was  $9.07 \pm 3.33$  years (range, 6-13 years). Patients in the farhex group were given oral antibiotics and an analgesic solution, along with a farhex oral spray started to be applied 6 hours after tonsillectomy to the peritonsillar regions. The control group was only given oral antibiotics and an analgesic solution. Then, the two groups were compared in terms of post-operative pain (at 6, 12, 18, 24, 36, and 48 hours post-operatively) and oral intake. The mean pain scores at 6 hours post-operatively were similar between the two groups ( $p > 0.05$ ). Although the difference did not reach statistical significance, the 24 and 36 hour pain scores were lower in the farhex group. The mean pain score at 18 hours post-operatively was significantly lower in the farhex group compared to the control group ( $p < 0.01$ ). The use of topical farhex oral spray remarkably reduced post-operative pain in tonsillectomized patients, especially at 18 hours post-operatively.

**Keywords:** Tonsillectomy, topical farhex spray, post-operative pain.

## INTRODUCTION

Pain is a frequent complication of tonsillectomies and various techniques for reducing pain have been developed. Pain after a tonsillectomy may cause difficulties by restricting oral-intake. Thus, many studies have been conducted to determine the efficacy of steroids, local anesthetics, antibiotics, and oral analgesic preparations in pain control; however, there still is no consensus on the optimum approach to pain control (Ballenger, 1991; Parker et al., 1986).

Farhex spray (chlorhexidine gluconate [0.12%] and benzydamine HCl [0.15%]) is a topical agent that exhibits antiseptic, anti-inflammatory, and analgesic effects. Farhex spray is indicated for the treatment of oral infections, pharyngitis, tonsillitis, gingivitis. Additionally, it

can be used prophylactically in the post-operative period and for providing oral hygiene. Farhex spray is used in patients > 5 years of age. It is directly applied to the inflamed area in the mouth or throat. While the usual dose for children is 5 sprays per application, the recommended number of sprays per application is 5-10 for adults (Bieri et al., 1990). In the current study, we aimed to determine the effects of topical farhex oral spray on post-operative pain and oral intake in patients who underwent tonsillectomies.

## MATERIALS AND METHODS

Eighty patients (40 patients in the farhex group and 40 patients in the control group) who underwent tonsillectomies under general anesthesia between October 2008 and April 2010 in the Department of Otolaryngology of Kayseri Tekden Hospital were included

\*Corresponding author E-mail: [dramahmut@yahoo.com](mailto:dramahmut@yahoo.com);  
Phone: +90 505 7465238; Fax: +90 352 2224342

in the current study. The mean age of the patients was  $9.07 \pm 3.33$  years (range, 6-16 years). Children in whom tonsillectomy was indicated for chronic tonsillitis, recurrent tonsillitis, peritonsillar abscesses, and complications of tonsillitis were included. Children were excluded from the study for the following reasons: the presence of a bleeding diathesis; a history of medication use; a history of severe cardiovascular illness, severe pulmonary illness, and systemic illness. The pre-operative data of the patients, including age, gender, vital signs, tonsil sizes, indications for tonsillectomies, and medical histories were recorded. A standard general anesthesia protocol was followed for all patients. The same operative team of physicians performed the tonsillectomies using standard dissection techniques. The two groups were compared at 6, 12, 18, 24, 36, and 48 hours post-operatively regarding pain parameters and oral intake. All complications occurring before and after surgical intervention were recorded. The severity of pain was assessed using the 9-point Faces Pain Scale (FPS, 3), which composed of drawings of faces, ranging from happy/smiling to frowning/crying. Each drawing face in the FPS has been converted to a numerical value by correlating the FPS with the Visual Analogue Pain Scale (VAS). All of the patients and their parents were taught how to use the FPS during the pre-operative period. Pain was assessed six times in the post-operative period (at 6, 12, 18, 24, 36, and 48 hours) using the FPS by the patients under the supervision of their parents. The parents of the patients in the control group were instructed to use acetaminophen (paracetamol) syrup as needed for pain and/or fever at intervals not less than every 4 hours. The parents of the children in the farhex group were instructed to spray both tonsillar regions 5 times a day at most. Post-operative follow-up was performed using a 7-day questionnaire completed by the parents. Appetite was scored daily as good, moderate, or poor. Oral intake (liquid, semi-liquid, or solid foods), number of analgesic tablets, presence of fever, and morning and evening pain scores were recorded in the daily evaluation. Also, the date of return to normal daily activities/school was recorded.

Statistical analysis was conducted using SPSS for Windows (Version 10.0; SPSS Inc., Chicago, IL, USA). Descriptive data were presented as mean  $\pm$  standard deviation. A Student's t-test and Mann-Whitney U test were used for the comparison of quantitative data. A  $p < 0.05$  was considered statistically significant at the 95% confidence level.

## RESULTS

Eighty patients (40 patients in the farhex group and 40 patients in the control group) completed the study. While the amount of IV hydration was significantly lower in the farhex group than the control group, the amount of oral

fluid intake was significantly greater ( $p < 0.05$ ). Although the difference did not reach statistical significance, the duration of IV hydration was shorter in the farhex group. No significant differences were noted between the two groups regarding the time to oral intake. There was also no significant difference between the farhex and control groups regarding demographic characteristics, including age, gender, tonsil sizes, and indications for tonsillectomies ( $p > 0.05$ ). When the mean pain scores at 18 hours post-operatively were compared between the two groups, the mean pain score was significantly lower in the farhex group than the control group ( $p < 0.01$ ). The mean pain scores at 6 hours post-operatively were similar between the two groups ( $p > 0.05$ ). The 24, 36 and 48 hour pain scores were lower in the farhex group but the difference did not reach statistical significance ( $p > 0.05$ ).

There were no significant differences between the two groups in terms of post-operative analgesic intake, presence of fever, and vomiting ( $p > 0.05$ ). Additionally, no differences were observed between the two groups in terms of dietary regimen during a 7-day period of in-home monitoring of patients ( $p > 0.05$ ). The diet consisted mainly of liquid foods in the first two days after tonsillectomy. The children started consuming solid foods 3 days after tonsillectomy. At the end of 7 days, the diet consisted mainly of semi-liquid and solid foods. Appetite was similar between the two groups ( $p > 0.05$ ). While appetite was scored as poor or moderate on the first few days post-operatively, at the end of 7 days, appetite was mostly scored as moderate or good. The farhex and control groups did not differ regarding the presence of fever ( $p > 0.05$ ). There was no significant difference between the two groups regarding morning and evening pain scores ( $p > 0.05$ ). High pain scores noted on the first few days after tonsillectomies dramatically decreased by the end of 7 days in both groups. The number of analgesic tablets taken within the first 24 hours after tonsillectomy was significantly higher in the control group ( $p < 0.05$ ). Although this difference disappeared after the first day, the analgesic intake remained higher in the control group ( $p > 0.05$ ). The time to return to normal activities was 4.56 days in the farhex group and 5.11 days in the control group ( $p > 0.05$ ). No post-operative complications were observed in either group. Table 1 shows the distribution according to post-operative pain scores while Figure 1 shows post-operative pain scores according to the farhex and control groups.

## DISCUSSION

Pain, bleeding, infection, earache, dysphagia, voice and speech disorders are the most common symptoms experienced in the post-operative period following a tonsillectomy (Ballenger, 1991; Parker et al., 1986).

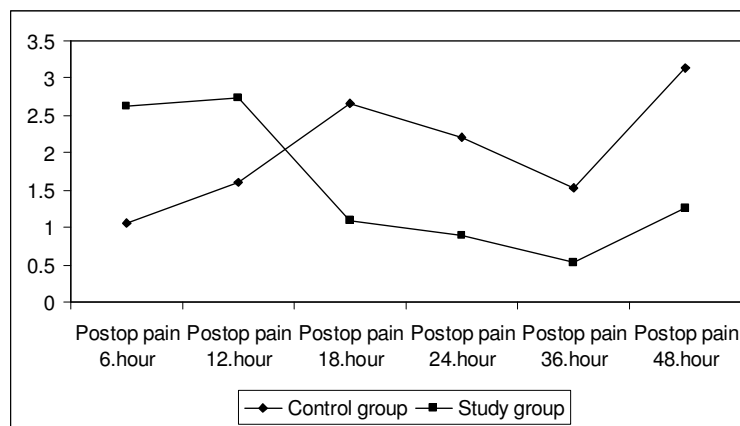
One of the most important reasons of pain in the post-

**Table 1.** Distribution according to postoperative pain scores

	Control group (n=40)	Study group (n=40)	P
Postop pain 6.hours	1,06 ± 1,43	1,83 ± 3,50	0,010*
Postop pain 12.hours	0,6 ± 1,18	1,33 ± 3,27	0,168
Postop pain 18.hours	2,66 ± 2,43	1,1 ± 2,05	0,129
Postop pain 24.hours	2,2 ± 2,56	0,9 ± 1,95	0,056
Postop pain 36.hours	1,53 ± 2,38	0,66 ± 1,82	0,129
Postop pain 48.hours	2,93 ± 3,23	0,26 ± 0,36	0,001**

\*P&lt;0,05 statistically significant

\*\*P,0,01 not statistically significant

**Figure 1.** Postoperative pain scores in the treatment groups

operative period following a tonsillectomy is the fact that, unlike the other surgical interventions, tonsillectomy creates an open wound that has to heal by secondary intention (Kerekhanjanarong et al., 2001). Healing after a tonsillectomy is an open wound healing that does not require primary closure. The wound surface is in contact with oral pathogens and foods for a long time, until the tonsillar fossae are filled in with granulation tissue, and scar. The subsequent irritation of nerve endings cause post-operative pain (Ballenger, 1991; Parker et al., 1986; Kerekhanjanarong et al., 2001)

Pain is the most disturbing complaint in rehabilitation of patients after tonsillectomies. Insufficient pain control may result in an increase in the time to return to normal activities, by restricting oral intake in the post-operative period. Pain occurs in nearly every patient undergoing tonsillectomy. Thus, several methods have been introduced for reducing pain (Kerekhanjanarong et al., 2001; Vasan et al., 2002; Steward et al., 2001; Goldman et al., 2000; Vosdoganis and Baines 1999; Carr et al., 1999). There are studies conducted with steroids, local anesthetics, and anti-inflammatory analgesics in the literature (Kerekhanjanarong et al., 2001; Vasan et al.,

2002; Steward et al., 2001; Goldman et al., 2000; Vosdoganis and Baines 1999; Carr et al., 1999).

Benzydamine is an anti-inflammatory analgesic agent that is structurally unrelated to the steroid group. Benzydamine has membrane stabilizing activity that may also be involved its mechanism of action. Benzydamine possesses local anesthetic action at the concentrations used for topical treatment. Chlorhexidine is a biguanide antiseptic agent and it is effective in decreasing plaque formation and gingivitis when oral hygiene cannot be maintained. Chlorhexidine is effective against most microorganisms, including gram-positive and gram-negative bacteria, yeasts, some fungi, and viruses. Chlorhexidine delays bacterial growth by a prolonged surface bacteriostatic action (Valijan, 1989).

Several methods, one of which is the FPS, have been developed for post-operative pain assessment in children. (Bieri et al., 1990) found that the FPS was a valid and reliable measure of the severity of pain in a study involving 553 children.

In the majority of studies on pain management with steroids after tonsillectomy, short-acting dexamethasone has been used. These studies have failed to demonstrate

the superiority of dexamethasone over other analgesic agents/placebo in pain control after tonsillectomy (Kerekhanjanarong et al., 2001; Vasan et al., 20024) however, dexamethasone has been shown to be effective in preventing post-operative vomiting (Vosdoganis and Baines 1999).

Dempster (1988) found no significant difference in analgesic intake or pain severity between the groups who did or did not receive benzocaine lozenges (10 mg) in a prospective placebo controlled trial involving 30 adult patients. In a study by Raj and Wickham (1986) involving 100 children and 100 adults, benzydamine hydrochloride spray, a local anti-inflammatory analgesic agent, was applied to the tonsillar beds after tonsillectomies. In that particular placebo-controlled study, analgesic intake was less in adults who received benzydamine hydrochloride compared to the controls, whereas there was no difference in analgesic intake between children who did or did not receive benzydamine hydrochloride. In a study by Young (1987) involving 56 children, benzydamine spray was more effective in the control of post-operative pain in the throat compared to the control group.

In conclusion, the efficacy of local anesthetics applied either by infiltration or topical spray to the tonsillar fossae during or after the surgical intervention is controversial. Even if they reduce pain, this relief is generally short-lived.

In the current study, the mean pain scores at 18, 24, and 36 hours post-operatively were lower in the farhex spray group compared to the control group, although the difference was only significant at 18 hours post-operatively ( $p < 0.05$ ). The time to return to a normal diet was 1.3 days shorter in the farhex spray group than in the control group ( $p > 0.05$ ).

The perception of pain depends on a number of factors, including personality, environment, individual pain perception, and expression. Thus, it is hard to measure

the severity of pain, especially in children. We recommend farhex spray after tonsillectomies for reducing pain and for an early return to a normal diet.

## REFERENCES

- Ballenger JJ (1991). Diseases of the Nose, Throat, Ear, Head and Neck, Lea-Febiger CO. 14: 259-71.
- Parker DA, Gibbin KP, Noydile RM (1986). Syrup formulation for post tonsillectomy analgesia. *J. Laryngol. Otol.* 100:1055-1060.
- Bieri D, Reeve RA, Champion GD (1990). The Faces Pain Scale for the self-assessment of the severity of pain experienced by children: development, initial validation, and preliminary investigation for ratio scale properties. *Pain* 41:139-50.
- Kerekhanjanarong V, Tang-On N, Supiyaphun P, Sastarasadhit V (2001). Tonsillar fossa steroid injection for reduction of the post-tonsillectomy pain. *J Med Assoc Thai. Suppl.* 84 (1):391-5.
- Vasan NR, Scott Stevenson S, Ward M (2002). Preincisional bupivacaine in posttonsillectomy pain relief. *Arch Otolaryngol. Head and Neck Surg.* 128:145-49.
- Steward DL, Welge JA, Myer CM (2001). Do steroids reduce morbidity of tonsillectomy? Meta-analysis of randomized trials. *Laryngoscope* 11(10):1712-1718.
- Goldman AC, Govindaraj S, Rosenfeld RM (2000). A meta-analysis of dexamethasone use with tonsillectomy. *Otolaryngol. Head Neck Surg.* 123(6):682-686.
- Vosdoganis F, Baines DB (1999). The effect of single dose intravenous dexamethasone in tonsillectomy in children. *Anaesth Intensive Care* 27(5):489-492.
- Carr MM, Williams JG, Carmichael L, Nasser JG (1999). Effect of steroids on posttonsillectomy pain in adults. *Arch Otolaryngol. Head Neck Surg.* 125(12):1361-1364.
- Valijan A (1989). Pain relief after tonsillectomy. Effect of benzydamine hydrochloride spray on postoperative pain relief after tonsillectomy. *Anaesthesia* 44:990-991.
- Dempster JS (1988). Posttonsillectomy analgesia. *J. Laryngol. Otol.* 102:813-814.
- Raj TB, Wickham MH (1986). The effect of benzydamine hydrochloride spray on posttonsillectomy symptoms. *J. Laryngol. Otol.* 100:303-306.
- Young JR (1987). A comparative study of benzydamine hydrochloride and placebo as analgesics following tonsillectomy. *Int. J. Tissue React.* 9:131-133.