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Effect of Flurbiprofen spray on postoperative tonsillectomy pain

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Abstract

Background and objectives: Tonsillectomy is one of the most frequently performed surgical procedures. Up to date there are no guidelines for pain control following tonsillectomy. The aim was to determine whether oral spray flurbiprofen reduces pain and has an influence on wound healing following tonsillectomy. **Methods:** A Prospective, randomized study was done in Rizgary Teaching Hospital (Erbil-Iraq). This study was conducted on 60 patients who underwent tonsillectomy between July 2017 and July 2018. Patients were randomly chosen and they were divided into two groups (thirty patients included in test group received flurbiprofen spray, other thirty included in control group). For test group oral spray flurbiprofen was used 3 times a day, every time three puffs. Postoperative pain was evaluated on the 1st, 4th, 7th and 10th postoperative days. The Efficacy was evaluated by universal pain assessment tool. Wound healing was evaluated on the 1st, 4th, 7th and 10th postoperative days. **Results:** The flurbiprofen group include 30 patients (18 males, 12 females) with a mean age of 23 years (range 12-40 years); the control group consisted of 30 patients (16 males, 14 females) with a mean age of 22 years (range12- 40 years). The severity of throat pain was lower in the flurbiprofen group when compared with the control group, and this difference was statistically highly significant for the 4th and the 7th day. W ound healing was not significantly different between the two groups **Conclusions:** The use of flurbiprofen oral spray decreases postoperative tonsillectomy pain.

Key words: Flurbiprofen spray, Tonsillectomy pain.

Introduction

Tonsillectomy is a common surgical procedure that may cause significant postoperative pain. Pain following tonsillectomy is the major cause of morbidity that may lead to decrease oral intake, dysphagia and dehydration. Maximum pain control methods following tonsillectomy continue to be a challenge for both anesthesiologists and otorhinolaryngologists. Over all there are three commonly used treatments for management of postoperative pain following tonsillectomy: non-steroidal anti- inflammatory drugs (NSAIDs), acetaminophen and opioids. Acetaminophen may not be powerful enough for controlling post-tonsillectomy pain[1]. Although the Cochrane Collaboration concluded that NSAIDs could be safely used for the postoperative treatment of pain following tonsillectomy, their use after tonsillectomy has been controversial because of adverse effects on platelet function that may prolong bleeding time[2]. Opioid analgesics may cause respiratory depression. Ibuprofen provides pain control that is at least equivalent to narcotic and is not associated with respiratory depression[3]. Direct injection of local anesthetic into the tonsillar bed has been shown to be effective in improving pain control, however, there is concern that local anesthetic could be erroneously injected into the carotid artery and lead to devastating consequences[4]. Others used steroids, GaoW1et al used steroid and concluded that local infiltration of dexamethasone was more effective than systemic administration to decrease pain and time to food intake, but the antiemetic effect was less[5]. Flurbiprofen 8.75 mg delivered as a spray or lozenge provides effective relief of the pain associated with sore throats due to upper respiratory tract infection. Oral spray of flurbiprofen has been approved for adults and children above 12 years old. Non-inferiority of the spray versus the lozenge formulation was established, and both formulations demonstrated comparable efficacy and safety profiles[6]. The mechanism of action of NSAIDs in form of oral sprays or lozenges is similar to that of topical (transdermal) NSAIDs (like diclofenac gel). They inhibit the enzyme cyclooxygenase an early component of the arachidonic acid cascade resulting

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in decreased formation of prostaglandins thromboxanes, and prostacyclin.

Pain after tonsillectomy is thought to be due to a combination of nerve irritation, inflammation, and pharyngeal muscle spasm[7]. Meta-analysis suggests that there is no increased risk of bleeding with NSAIDs when used following tonsillectomy. In addition, it is noticeable that aspirin is contraindicated in children due to the increased risk of Reye's syndrome[8].

Edema and pain are greatest immediately after surgery, probably as a result of thermal effects

and expression of inflammatory mediators that stimulate pharyngeal nociceptors. Pain gradually

decreases over time, with an increase in analog pain measures on postoperative days 3 to 5

corresponding to the maximal wound inflammation documented in experimental models.

Epithelial ingrowth beneath a fibrin clot begins shortly after wounding. Separation of the fibrin clot about 7 days after surgery exposes vascular stroma. Involution of the vascular stroma and completion of epithelial coverage correlates with decreased pain levels and a decreases risk of bleeding[9]. The aim in post tonsillectomy pain management was to establish appropriate oral intake as early as possible, to mobilize the patient and to decrease the risk of postoperative hemorrhage.

Patients and Methods

Sixty patients between the ages of 12 and 40 years who underwent tonsillectomy in Rizgari Teaching Hospital between the period of July 2017 and July 2018 were included in this study. Patients were randomly divided into two groups, randomly chosen. Test group (30patients) received flurbiprofen spray; control group (30 patients) didn't receive flurbiprofen. Flurbiprofen oral spray was used 3 times a day, every time three puffs. Pain was evaluated using universal pain assessment tool on the 1st, 4th, 7th and 10th postoperative day. Wound healing was evaluated on the 1st, 4rd, 7th and 10th postoperative day.

Tonsillectomy indications were 7 attacks of tonsillitis in the past year or at least 5 episodes per year in the past 2 years, or at least 3 episodes per year for 3 years, with symptoms of fever, snoring, sore throat, and inability to take normal diet and sleep disorder.

Exclusion criteria: Known hypersensitivity to flurbiprofen or NSAIDs in general, and patients with medical or coagulation disorders.

Written informed consents were taken from all adults and parents signed the consent for participants who were under18 years old. Preoperatively, as a routine procedure, complete blood counts, bleeding time and clotting time were performed. Clinical parameters including name, age, and sex were obtained. The same surgeon performed cold steel tonsillectomy. Tonsillectomy was performed under general anesthesia by blunt dissection; hemostasis was accomplished by ligation and bipolar cautery at 25W of power. Each patient was followed up in the hospital for 6 hours, proper use of the spray was taught by a nurse. Universal pain assessment tool was given to the patients or the parent and were instructed how to fill the chart. Patients were advised to visit the hospital on 4th, 7th, 10th postoperative days. They were examined for wound healing. Postoperative instructions included cold and soft diet for seven days. Oral antibiotic suspension (Amoxicillin with calvulanic acid, 30 mg/kg twice a day or azithromycin, 10 mg/ kg, in case of a history of penicillin allergy) was given postoperatively to both groups for a week. Paracetamol (10 mg/kg) suspension or tablet was given postoperatively to both groups three times daily for a week.

A universal pain assessment tool was used to illustrate how much pain the patients were feeling. On the day before surgery, patients were instructed to use the Numeric Pain Rating Scale (NRS) to express pain at swallowing 100 mL of water (0 = no pain, 5 = moderate pain, 10 = worst pain imaginable)10. Patients were clinically examined on postoperative days 1st, 4th, 7th and 10th for tonsillar bed healing. The healing was scored depending on the percent of tonsillar bed which is covered with slough as follow: (0), complete healing; (1), 1%-25%; (2), 26%-50%; (3), 51%-75%; (4), 76%-100%11.

Statistical analysis of data was performed using the chi-square test for relationship and t test for differences. p-value $\leq$ 05 was considered significant. The study was approved by the ethical committee of Hawler Medical University /College of Medicine.

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Results

The flurbiprofen group consisted of 30 patients (18 males, 12 females) with a mean age of 23 years (range 12-40 years); the control group consisted of 30 patients (16 males,14 females) with a mean age of 22 years (ranges from 12- 40 years). The severity of throat pain was lower in the flurbiprofen group when compared with the control group, and this difference was statistically highly significant for the 4th and 7th day, Table (1).

Table (1): Post tonsillectomy pain evaluation.

Days	Flurbiprofen Group		Control Group		p-value
	Mean	SD	Mean	SD	
1st Day	3	0	3	0	1
4th Day	2.06	0.36	2.7	0.46	<0.001
7th Day	1.33	0.47	1.9	0.30	<0.001
10th Day	0.6	0.49	0.63	0.49	0.795

As demonstrated in Figure (1), the difference in average pain level was significant during the follow-up period (days 4 and 7, p-value <0.001, p-value <0.001, respectively).

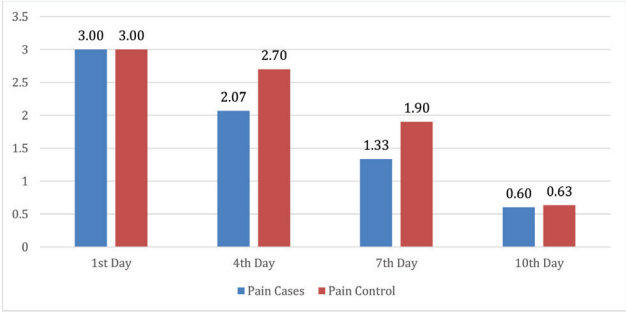

Figure (1): Post tonsillectomy pain evaluation graph.

The patients were examined for epithelialization on days 1, 4, 7, 10 postoperatively. Healing of the tonsil bed was not significantly different between two groups, as shown in Table (2), Figure (2).

Table (2): Statistical comparison of wound healing in flurbiprofen and control groups.

Days	Flurbiprofen Group		Control Group		p-value
	Mean	SD	Mean	SD	
1st Day	4	0	4	0	1
4th Day	2.7	0.46	2.6	0.49	0.42
7th Day	1.33	0.47	1.33	0.47	1
10th Day	0.13	0.34	0.1	0.30	0.69

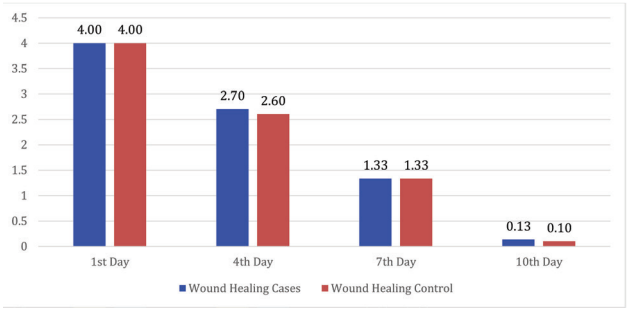

Figure (2): Mean Wound Healing Score in flurbiprofen and control groups.

Discussion

Post tonsillectomy involves period of pain which affects quality of life so it is very important, yet strenuous to manage posttonsillectomy pain. In this prospective randomized study we evaluated the clinical efficacy of oral spray flurbiprofen, which is a member of NSAIDs, in reducing post tonsillectomy pain and morbidity. Topical lidocaine, bupivacaine and topical analgesic were used for post tonsillectomy pain relief in otolaryngology literature. But there is no ordinary use of NSAIDs oral sprays in post tonsillectomy. In review of literature we found only one paper assessing the effect of oral flurbiprofen spray in post tonsillectomy pain. In our study the pain difference between both groups were statistically significant on day 4th and 7th which is similar to the study done by Muderris et al[12]. While on the 1st and 10th day there was no difference in pain between both groups which is contradiction to Muderris et al results. We suspect the absence of effect of flurbiprofen spray on the 1st day is due to edema and pain is greatest immediately after surgery, probably as a result of thermal effects and excretion of inflammatory mediators that stimulate pharyngeal nociceptors as mentioned by Isaacson[11]. While on 10th day pain difference was not significant between both groups because wound healing is nearly completed and there is no or minimal raw area therefore there is mild discomfort in both groups.

Although it is not the same material but in the literature, it was written that Lidocaine spray appeared to be effective in reducing the severity of post tonsillectomy pain but only until the third postoperative day[13]. While a prospective study by Valijan demonstrated that benzydamine hydrochloride spray does not relieve the symptoms of post tonsillectomy patients when compared with placebo[14].

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Regarding wound healing, there is no statistically significant difference between both groups in all postoperative days which means that flurbiprofen spray doesn't have effect on wound healing. This result is similar to the results of Muderris et al[12].

In review of literature we found that some substance enhances wound healing like the study done

by Hancı et al which evaluated the effectiveness of hyaluronic acid on wound healing on 7th , 10th and 14th postoperative days[15].

Conclusions

This study showed that the use of oral flurbiprofen spray in post tonsillectomy patients decreases pain to a good extent meanwhile it is safe and can easily applied.

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