ORIGINAL ARTICLE

Effect of fibrin-coated collagen fleece (TachoComb) on pain and bleeding after adenotonsillectomy in children

JUNG GWON NAM, TAE-HOON LEE, JOONG KEUN KWON, JONG CHEOL LEE, SEONG ROK LEE, SANG MIN LEE & HO MIN LEE

Department of Otolaryngology-Head and Neck Surgery, University of Ulsan College of Medicine, Ulsan University Hospital, Ulsan, Korea

Abstract

Conclusion: Even though the use of TachoComb does not decrease pain after tonsillectomy, it is safe and useful to reduce bleeding after tonsillectomy. Objectives: Sealing the post-tonsillectomy wound would be expected to reduce pain and bleeding by decreasing the exposure of the traumatized tissue and sensory nerves. TachoComb is a powerful topical hemostatic agent. The objectives of this study were to evaluate the effect of TachoComb on reduction of pain and bleeding after tonsillectomy. Methods: A prospective randomized double-blind study was performed on 120 pediatric patients undergoing adenotonsillectomy. The patients were randomized into two groups: use/non-use of TachoComb. In the study group, each tonsillar bed was covered with a TachoComb strip at the end of operation. No hemostatic agents were used in the control group. After surgery, patients were monitored for pain, bleeding, oral intake, medication administration, activity, and complications using a 10-day diary. Results: In all, 110 patients returned and filled in the diary. The use of TachoComb did not decrease pain, reduce the use of analgesic drugs or speed recovery to normal everyday life. Post-surgery bleeding was not experienced by any of the TachoComb patients, but occurred in five of the control patients. The result had borderline statistical significance (p < 0.1).

Keywords: Tonsillectomy, postoperative pain, postoperative hemorrhage, sealant, fibrin glue

Introduction

Tonsillectomy is one of the most common surgical procedures in children. Yet, post-surgical pain, which usually lasts for more than 7 days and is especially severe for the first 3 days, and bleeding, which afflicts 0.5–10% of tonsillectomy patients [1,2], remain challenges that lack effective solutions. Bleeding within 24 h of surgery is typically due to inappropriate technique and insufficient hemostasis. Secondary bleeding that occurs 7–10 days after surgery results from events that include the removal of the crust from the operative site, injury due to hard food, the onset of infection, and the use of nonsteroidal anti-inflammatory drugs.

Numerous techniques have been devised to decrease the considerable morbidity associated with post-surgical complications of tonsillectomy. Strategies developed to reduce post-tonsillectomy pain include the use of corticosteroids, different surgical instruments or techniques, and the use of local anesthetic agents. Several studies have addressed the topical application of fibrin glue to reduce post-tonsillectomy pain and bleeding [3–11]. Sealing the surgical wound would be expected to reduce pain and bleeding by decreasing the exposure of the traumatized tissue and sensory nerves. However, the results have been mixed.

A fibrin-coated collagen fleece, TachoComb® (Nycome International Management, Zurich,
Switzerland), is a powerful topical hemostatic agent that has been widely used in various surgical specialties with a favorable outcome [12,13]. The TachoComb consists of a sheet of collagen that is coated on one side with human fibrinogen, bovine thrombin, bovine aprotinin, and riboflavin [12]. It is very easy to handle, and is flexible, adhesive, and glutinous, which are all advantages over fibrin glue in wound protection. Collagen protects the operative site by forming an outer membrane. It has been anticipated that TachoComb will prove superior to fibrin glue. But, until the present study, the use of TachoComb in tonsillectomy has not been reported. This study explored the effectiveness of TachoComb on reducing post-tonsillectomy bleeding and pain for children.

**Material and methods**

From March 2010 to February 2011, 120 pediatric patients aged 3–15 years who had undergone tonsillectomy and adenoidectomy due to adenotonsillar hypertrophy, obstructive sleep apnea or chronic tonsillitis were entered in this prospective, randomized, and double-blind trial. Institutional Review Board approval was obtained from the Ulsan University Hospital and informed consent was obtained from the legal guardians of all patients. Patients who had known bleeding disorders, a history of known anaphylaxis to bovine thrombin or a previous peritonsillar abscess or who could not clearly express pain because of developmental delays were excluded. Patients who underwent only a tonsillectomy were also excluded.

All operations were performed under general anesthesia by ENT faculty and residents. An adenoidectomy was performed intraorally with a shaver under mirror visualization and hemostasis was obtained by a saline-moistened adenoid pack. Tonsillectomy was then performed using blunt or sharp dissection with bipolar electrocautery hemostasis. The patients were randomized into two groups: use/non-use of TachoComb. The surgeon was blinded as to whether or not patients were to receive TachoComb until just before the application.

In the study group, a sheet of dry TachoComb was cut into strips (1.5 cm wide, 2.5 cm long) by scissors (Figure 1). After both tonsillar beds were cleaned and wetted with gauze moistened with saline, each tonsillar bed was covered with a TachoComb strip. Wet gauze compression on the TachoComb strip was done for about 3 min. No hemostatic agents were used in the control group.

After surgery, patients were monitored for pain, bleeding, oral intake, medication administration, activity, and complications using a 10-day diary compiled by the patient's legal guardians. The pain level was assessed using the Wong-Baker FACES Pain Rating Scale (Figure 2) [14] in the morning before the patient had received any pain medication or food. Normal oral intake or activity was defined as the same type and amount of food or activity as before surgery. The 10-day diary was collected at the time of patient follow-up in the clinic on postoperative day 10.

Analyses were conducted using SPSS version 17.0 statistical software (SPSS, Chicago, IL, USA).

![Figure 1. TachoComb strips. The face coated with fibrin glue (left strip) is applied on the wound. The slightly wider side covers the upper tonsillar bed.](image1)

![Figure 2. Wong-Baker FACES Pain Rating Scale. Point to each face using the words to describe the pain intensity. Ask the child to choose the face that best describes their own pain and record the appropriate number. From Hockenberry MJ, Wilson D: Wong’s essentials of pediatric nursing, ed. 8, St Louis, 2009, Mosby. Used with permission. Copyright Mosby.](image2)
Comparison between the two groups was made using student’s t test, \( \chi^2 \) test, and Fisher’s exact test. A value of \( p < 0.05 \) was considered statistically significant.

**Results**

Of the 120 patients, 10 who did not complete their surveys were excluded. The 110 patients (35 females, 75 males) were randomly assigned to TachoComb treatment (study group, \( n = 53 \)) and conventional treatment (control group, \( n = 57 \)). There were no differences in age, gender, and operating conditions between the groups (Table I).

Pain score and times of analgesic drug administration decreased with time. At post-surgery day 4 and 8, the average scores decreased to \(<2\) and \(<1\), respectively. Analgesic drugs were provided an average of 6.94 times, and were administered for about 3 days following surgery. There were no statistical differences between the two groups as regards the aforementioned parameters (Figures 3 and 4). In the study and control groups, resumption of normal oral intake required 6.50 days and 5.77 days, respectively, and return to normal activity required 3.89 days and 3.40 days, respectively. These differences were not statistically significant (Table II). Post-surgery bleeding was not experienced by any of the TachoComb patients, but occurred in five of the control patients; the result was not statistically significant (Table II). Neither group developed complications such as edema of the lung, pneumonia, velopharyngeal insufficiency, nasopharyngeal stenosis, or Eustachian tube damage.

**Discussion**

Severe pain after tonsillectomy can cause dehydration and improper nutrition or stress, and can deleteriously influence a patient’s physical state and recovery [15,16]. Also, post-surgical bleeding delays recovery and can increase costs due to prolonged hospitalization and additional surgery. Various surgical methods and medications have been explored with the aim of decreasing post-surgical pain and bleeding [17–19].

![Figure 3. Change in pain score after surgery. The differences were statistically insignificant \( (p > 0.05) \).](image)
The application of fibrin glue to tonsillar fossa has been reported in several studies [3–11]. Consistently, studies that utilized fibrin glue in the absence of electrocautery reported decreased pain. However, the combinational use of electrocautery and fibrin glue has produced mixed results (Table III).

The present study, which exclusively involved children, reported pain scores using the Wong-Baker

Table II. Time for normalized diet and activity, and incidence of postoperative bleeding.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>TachoComb group</th>
<th>Control group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normalized diet (days)</td>
<td>6.50</td>
<td>5.77</td>
<td>0.202</td>
</tr>
<tr>
<td>Normalized activity (days)</td>
<td>3.89</td>
<td>3.40</td>
<td>0.691</td>
</tr>
<tr>
<td>Bleeding</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence (n)</td>
<td>0</td>
<td>5 (8.8%)</td>
<td></td>
</tr>
<tr>
<td>Absence (n)</td>
<td>53</td>
<td>52</td>
<td>0.058</td>
</tr>
</tbody>
</table>

Table III. A brief review of the previous studies.

<table>
<thead>
<tr>
<th>Author</th>
<th>Control group</th>
<th>Fibrin group</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moralee et al. (1994) [6]</td>
<td>Electrocauterization</td>
<td>Fibrin glue</td>
<td>Positive</td>
</tr>
<tr>
<td>Gross et al. (2001) [7]</td>
<td>Electrocauterization</td>
<td>Fibrin glue</td>
<td>Negative</td>
</tr>
<tr>
<td>Vaiman &amp; Shlamkovich (2003)</td>
<td>Electrocauterization</td>
<td>Fibrin glue</td>
<td>No result</td>
</tr>
<tr>
<td>Jo et al. (2007) [8]</td>
<td>Electrocauterization</td>
<td>Fibrin glue</td>
<td>No result</td>
</tr>
<tr>
<td>Stoeckli et al. (1999) [3]</td>
<td>Electrocauterization</td>
<td>Electrocauterization + fibrin glue</td>
<td>Negative</td>
</tr>
<tr>
<td>Stevens et al. (2005) [10]</td>
<td>Electrocauterization</td>
<td>Electrocauterization + fibrin glue</td>
<td>Positive</td>
</tr>
<tr>
<td>Segal et al. (2008) [4]</td>
<td>Electrocauterization</td>
<td>Electrocauterization + fibrin glue</td>
<td>Negative</td>
</tr>
</tbody>
</table>
FACES Rating Scale. The pain score in patients who received electrocautery differed by 3 points by post-surgery days 2 and 3, and 2 points by day 7, which was superior to results in the two previous studies [7,8] that addressed post-tonsillectomy pain. In a previous study, the use of analgesic drugs was reduced to <1 after 5 days and 10 days in the study group and control group, respectively [8]. Presently, the time to achieve a similar level of use was markedly less (1 day and 2 days, same respective order). The study also reported a time of 7.9 days and 7.8 days for normal oral intake and recovery, respectively, in the control group of patients receiving electrocautery treatment [8]. The present respective times of 5.8 days and 3.4 days were superior. The improvement may reflect the surgeon involved and/or cultural differences between West and East concerning diet and lifestyle.

In the present study, the effect of TachoComb versus conventional treatment was not significantly different for pain and bleeding reduction. But the effect of TachoComb for bleeding was only of borderline significance. The effect of pain reduction with the enhanced wound protection likely did not counterbalance the pain caused by electrocautery. Post-tonsillectomy pain is a greater influence on the damage of mucous membrane, muscles, and peripheral nerves caused by electrocautery than by an open wound [5,20].

A 3 × 2.5 cm size TachoComb that costs USD$68.70 is sufficient to cover both tonsillar beds in children. When post-tonsillectomy bleeding occurs, the additional hospitalization (typically approximately 3.5 days) costs USD$120.50 in Korea. Thus, the use of TachoComb represents a considerable saving in medical costs. The gap between TachoComb price and hospital fees may be much wider in other developed countries such as the United States. For post-tonsillectomy bleeding, the use of TachoComb is less expensive than hospitalization and safer, when considering the risk, discomfort, anxiety, and stress of the patient.

To our knowledge, this study is the first to assess the usefulness of TachoComb in tonsillectomy. Also, we aimed to study children, a group that frequently experiences tonsillectomy; this excluded the variation in adhesion that could have resulted from the inclusion of adults. To exclude the possible confounding influence of adenoidectomy, we only evaluated patients who underwent an adenotonsillectomy.

There were, however, several limitations to the current study. The difference in bleeding rate between the study and control patients was only of borderline significance, given the small number of patients who experienced bleeding. In addition, the study was limited by the use of children, since they might be less able to verbalize the pain they experienced, which could introduce subjective bias.

**Conclusion**

This randomized, double-blind study indicates that the use of TachoComb does not decrease pain after tonsillectomy, reduce the use of analgesic drugs or speed recovery to normal everyday life. Even though the results concerning bleeding were superior in patients who received TachoComb treatment, the results only had borderline statistical significance ($p < 0.1$). This may reflect the small sample size rather the absence of an appreciable benefit, and further studies are needed to confirm this.

**Declaration of interest:** The authors have no financial conflicts of interest. The authors alone are responsible for the content and writing of the paper.

**References**


