The efficacy of TachoComb on reducing postoperative complications after tonsillectomy in children

Yong-Wan Kim, Myoung-Joo Kang, Hyung-Ju Lee, Chang-Ki Woo, Mi-Jin Mun, Kyu-Sup Cho

1. Introduction

Tonsillectomy is one of the oldest and most commonly performed otorhinolaryngologic procedures [1]. Despite generally being considered a safe procedure, tonsillectomy has significant morbidity and potential for complications. Among potential complications including postoperative pain, airway obstruction, aspiration, pulmonary edema, and hemorrhage [2,3], the major postoperative morbidity problems are pain and hemorrhage [3]. Severe postoperative pain may result in poor oral intake, dehydration, sleep disturbances, emesis, and late hemorrhage. Postoperative hemorrhage is the most common serious complications and may be fatal if not managed appropriately.

Numerous techniques, materials, and mediations have been introduced to decrease the considerable morbidity associated with post-tonsillectomy complications. Several studies have addressed the use of corticosteroids or local anesthetic agents, different surgical instruments or techniques, and topical application of fibrin glue to reduce post-tonsillectomy pain and bleeding [4–11]. However, because of the generally inconclusive results of these studies, the standard care after tonsillectomy remains a challenge to lack effective solutions.

A fibrinogen/thrombin-based collagen fleece (TachoComb; CSL Behring, Tokyo, Japan) is a powerful topical hemostatic agent that has been widely used in various surgical specialties with a favorable outcome [12–14]. The TachoComb consists of a sheet of collagen that is coated on one side with human fibrinogen, bovine

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ABSTRACT

Objective: A fibrinogen/thrombin-based collagen fleece (TachoComb) is a powerful topical hemostatic agent that has been widely used in various surgical specialties with a favorable outcome. The purpose of this study was to investigate the effect of TachoComb application on postoperative complications after tonsillectomy.

Materials and methods: A total of 1633 children had undergone tonsillectomy with or without adenoidectomy were included in this study. After removal of both tonsils, 1057 patients (64.7%) were treated with TachoComb on the tonsillectomy site and 576 without TachoComb. Post-tonsillectomy pain, hemorrhage rates, re-admission rates, and emergency surgery rates for post-tonsillectomy hemorrhage were evaluated between patients who received TachoComb and those who did not.

Results: TachoComb treatment significantly reduced post-tonsillectomy pain and emergency surgery rates for post-tonsillectomy hemorrhage. However, postoperative hemorrhage rate and re-admission rates for post-tonsillectomy hemorrhage were not statistically significant between TachoComb treatment group and control group. No patients had complications or adverse reactions after TachoComb treatment.

Conclusions: The use of TachoComb after tonsillectomy significantly reduces pain and emergency surgery for severe post-tonsillectomy hemorrhage without an apparent adverse effect. Therefore, TachoComb may be a useful adjuvant in terms of efficacy and safety after tonsillectomy.

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thrombin and aprotinin, and riboflavin (Fig. 1A) [15]. It is 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. However, there are few currently available studies in regard to its efficacy on reducing postoperative complications after tonsillectomy.

The purpose of this study was to investigate the effect of TachoComb application on patient’s subjective pain, hemorrhage, re-admission rates, and emergency surgery for hemorrhage following tonsillectomy.

2. Materials and methods

2.1. Subjects

Four institutions were included in this retrospective study involving 1633 patients from a total of 1680 enrolled patients had undergone tonsillectomy with or without adenoidectomy between March 2010 and May 2013. The institutional review board (IRB) approved this study before patient enrollment at each location.

Patients included in the study were aged 3–18 years and underwent elective tonsillectomy with or without adenoidectomy due to adenotonsillar hypertrophy, obstructive sleep apnea, and chronic tonsillitis. Exclusion criteria included a simultaneous performed uvulopalatopharyngoplasty, lateral pharyngoplasty, other pharyngeal surgery that would make comparison impossible, and additional use of a different hemostatic material. Additional exclusion criteria were patients with a history of previous peritonsillar abscess, anaphylaxis to bovine thrombin, bleeding disorders or anticoagulation therapy, pregnancy, and the presence of a severe medical or neuropsychiatric disorder.

2.2. Surgical procedures and intervention

Extracapsular tonsillectomy was performed by diathermy techniques under general anesthesia with oral intubation. The tonsils were completely removed from the underlying muscular bed. For diathermy technique, the power setting for monopolar and bipolar cautery was 20 and 20, respectively. An adenoidectomy was performed intraorally with a shaver under mirror visualization.

At the conclusion of surgery, a sheet of dry TachoComb was cut into two pieces by scissors. After both tonsillar bed were cleaned and wetted with gauze moistened with saline, each tonsillar bed was covered with a TachoComb strip (Fig. 1B). Wet gauze compression on the TachoComb strip was done for adhering tenaciously to the edges of the wound. All patients were discharged 3 day after surgery without acute complications and received postoperative antibiotics (second generation cephalosporin) and analgesics for 7 days.

2.3. Outcomes assessment

The difference in outcomes between TachoComb treatment and no treatment after tonsillectomy are mentioned below:

(1) Postoperative pain. The post-tonsillectomy pain was analyzed by visual analogue scale (VAS) pain scores with a range of 0 (no pain) to 10 (worst pain) that had been explained to the patients before surgery. Pain levels were checked in the morning before the intake of analgesic drugs at postoperative day (POD) 1, 2, 3, and 10. We obtained pain scores from nurse records of POD 1, 2, and 3 during hospitalization period to medical record of POD 10 during follow-up period.

(2) Postoperative hemorrhage. Post-tonsillectomy hemorrhage defined as an episode of bleeding requiring a visit to the emergency department or outpatient clinic after discharge.

(3) Re-admission for hemorrhage following tonsillectomy.

(4) Emergency surgery for severe post-tonsillectomy hemorrhage.

2.4. Statistical analysis

Data were presented as mean ± standard error of mean. Statistical significance was assessed by a chi-square test using the SPSS software package version 20.0 (SPSS Inc., Chicago, IL, http://www.spss.com). A p-value < 0.05 was considered significant.

3. Results

3.1. Clinical characteristics

Patient characteristics are summarized in Table 1. A total of 1633 consecutive tonsillectomy with or without adenoidectomy procedures were performed in four institutions. Males outnumbered females 1041–592. The mean age was 13.8 years (range, 3–18 years). Of these, 1057 patients (64.7%) were treated with TachoComb on the tonsillectomy site, 576 without TachoComb. A total of 84 patients (5.1%) visited emergency department or outpatient clinic due to delayed postoperative hemorrhage. There was no postoperative hemorrhage in any of the adenoidectomy sites. 51 patients (3.1%) received re-admission and 21

Fig. 1. TachoComb and endoscopic finding of tonsillar beds after TachoComb treatment. (A) TachoComb is covered by solid-type fibrinogen and thrombin on the collagen sponge. Riboflavin is present as a yellow colorant to indicate the active side of the patch. (B) Both tonsillar beds were coated with TachoComb after tonsillectomy (For interpretation of the reference to color in this figure legend, the reader is referred to the web version of this article).

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patients (1.3%) received emergency operation due to severe postoperative hemorrhage. There were no differences in age and gender between the groups.

3.2. Patients’ subjective pain after tonsillectomy

The mean pain score decreased between each time point following tonsillectomy, and continued to decrease by POD 10. The mean pain score at 1 day post-tonsillectomy was 4.03 ± 0.7 and 5.02 ± 0.8 in TachoComb treatment group and control group, respectively. Pain scores decreased to 3.95 ± 0.6 and 4.98 ± 0.6 at 2 days, 3.69 ± 0.4 and 4.78 ± 0.6 at 3 day, and 1.99 ± 0.4 and 2.82 ± 0.5 at 10 days post-tonsillectomy in TachoComb treatment group and control group, respectively. The pain scores were significantly lower in TachoComb treatment group than control group (Table 2).

3.3. Postoperative hemorrhage

Delayed post-tonsillectomy bleeding was identified in 47 (4.4%) of 1057 TachoComb treatment group and 37 (6.4%) of 576 no treatment group. Although postoperative hemorrhage rate was lower in TachoComb treatment group than control group, which was not statistically significant (Table 3).

3.4. Re-admission for post-tonsillectomy hemorrhage and dehydration

Re-admission rate for intravenous fluids secondary to dehydration and close observation was 2.6% in TachoComb treatment group and 4.0% in control group. Although TachoComb treatment decreased re-admission rate due to delayed post-tonsillectomy hemorrhage, there was no significant difference between TachoComb treatment group and control group (Table 3).

3.5. Emergency surgery for post-tonsillectomy hemorrhage

Seven patients (0.7%) of TachoComb treatment group and 14 patients (2.4%) of control group returned to the operating room for control of delayed post-tonsillectomy hemorrhage. TachoComb treatment significantly decreased emergency surgery rates for post-tonsillectomy hemorrhage (p < 0.001) (Table 3).

3.6. Adverse systemic reactions and complications

No major complications such as airway obstruction, aspiration, pulmonary edema, pneumonia, or local toxicity developed in any patients in this study. No TachoComb inadvertently fell out and no patients had immunologic responses with anaphylaxis related to the TachoComb treatment. The observation of the wound healing revealed no subjective differences in rapidity, cleanliness, or scarring. All wounds healed without complications within 21 days.

4. Discussion

Postoperative pain after tonsillectomy is a prominent problem. Severe pain can lead to poor oral intake, dehydration, and even hemorrhage which may deleteriously influence a patient’s physical state and recovery [16]. Furthermore, post-tonsillectomy hemorrhage delays recovery and may increase costs due to readmission and additional surgery. Tonsillectomy produces large areas of exposed muscle in the oropharynx, resulting in considerable pain from muscle spasm and irritation of nerve endings, and delayed hemorrhage. Therefore, sealing the surgical wound and thereby decreasing the exposure of traumatized tissue and sensory nerves may have a beneficial effect on minimizing both post-tonsillectomy pain and hemorrhage.

TachoComb has become widely used for the suture-free hemostasis of arterial and venous bleeding and hemorrhage in organ parenchyma [12–14,18,19]. When it makes contact with a bleeding or leaking wound surface, or triggered by the presence of physiological saline, the coating of the collagen sponge dissolves and subsequent thrombin-fibrinogen reaction initiates the last step of the coagulation cascade. Fibrinogen is converted by the action of thrombin into fibrin monomers which spontaneously polymerize to a fibrin clot. Thrombin could also activate endogenous factor XIII which covalently crosslinks the fibrin to create a firm and stable network.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Demographic and clinical characteristics.</th>
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<tbody>
<tr>
<td>Characteristics</td>
<td>Patients (n)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1041</td>
</tr>
<tr>
<td>Female</td>
<td>592</td>
</tr>
<tr>
<td>TachoComb treatment Yes</td>
<td>1057</td>
</tr>
<tr>
<td>No</td>
<td>576</td>
</tr>
<tr>
<td>Post-tonsillectomy hemorrhage Yes</td>
<td>84</td>
</tr>
<tr>
<td>No</td>
<td>1549</td>
</tr>
<tr>
<td>Re-admission Yes</td>
<td>51</td>
</tr>
<tr>
<td>No</td>
<td>1582</td>
</tr>
<tr>
<td>Emergency surgery Yes</td>
<td>21</td>
</tr>
<tr>
<td>No</td>
<td>1612</td>
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<table>
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<tr>
<th>Table 2</th>
<th>Effect of TachoComb on post-tonsillectomy pain.</th>
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<tbody>
<tr>
<td>Time point</td>
<td>TachoComb (−)</td>
</tr>
<tr>
<td>POD 1</td>
<td>5.02 ± 0.8</td>
</tr>
<tr>
<td>POD 2</td>
<td>4.98 ± 0.6</td>
</tr>
<tr>
<td>POD 3</td>
<td>4.78 ± 0.6</td>
</tr>
<tr>
<td>POD 10</td>
<td>2.92 ± 0.5</td>
</tr>
</tbody>
</table>

Data are expressed as the mean ± SD. POD: postoperative days.
The cost of the TachoComb (3 × 2.5 cm size) is $80,596 won ($74.6 US dollars), which is sufficient to cover both tonsillar beds in children. The present study showed that TachoComb treatment significantly decreased post-tonsillectomy pain. Moreover, the TachoComb treatment significantly reduced emergency surgery due to severe post-tonsillectomy hemorrhage, although there was no statistical significance in the rate of delayed post-tonsillectomy hemorrhage and re-admission between TachoComb treatment group and no treatment group. These findings may reflect the enhanced wound protection and effective hemostasis of TachoComb, resulting in decreasing severe postoperative hemorrhage necessary to be operated. To our knowledge, this study is the first to assess the usefulness of TachoComb in reducing postoperative complications after tonsillectomy on a large scale. Furthermore, we aimed to study children, a group that frequently experiences tonsillectomy, which excluded the variation in adhesion that could have resulted from the inclusion of adults.

Although American Academy of Otolaryngology-Head and Neck Surgery guidelines rejecting the efficacy of antibiotics after tonsillectomy for pain or infectious complications [21], we described antibiotics after tonsillectomy. Because multiple drug resistant bacteria would only be worsened through the use of the antibiotics, otolaryngologists need to rethink their use of postoperative antibiotics and further studies are required to clarify this problem. Although this study has the inherent limitations of a retrospective review, we believe that our collected data composed of validated outcomes measurements could offer further support to the benefit of TachoComb treatment following tonsillectomy. Additional well-designed randomized controlled prospective studies are needed to confirm our findings.

5. Conclusion

Although TachoComb has proven to be an effective hemostat in many surgical settings, its efficacy in tonsillectomy has not yet been definitely proven in large trials. Based on this study, TachoComb appears to be an effective painkiller and hemostat that works in tonsillectomy site. Therefore, TachoComb may be a useful adjuvant in terms of efficacy and safety after tonsillectomy.

Author's disclosure

The authors have no funding, financial relationships, or conflicts of interest to disclose.