



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



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ARTICLE INFO

Article history:

Received 19 February 2015

Received in revised form 2 June 2015

Accepted 4 June 2015

Available online 12 June 2015

Keywords:

Tachocomb

Postoperative hemorrhage

Postoperative pain

Tonsillectomy

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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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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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 \pm 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

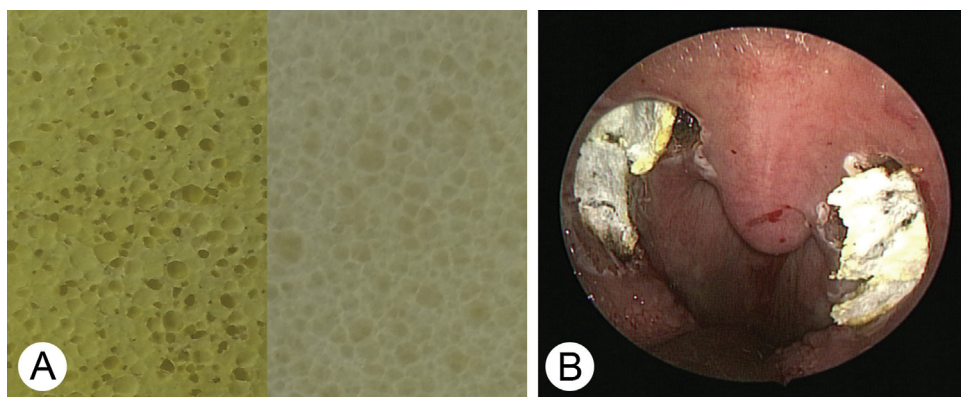


Fig. 1. TachoComb and endoscopic finding of tonsillar beds after TachoComb treatment. (A) TachoComb is covered by solid-type fibrinogen and thrombin on the collagen sponge. Riboflavin is present as a yellow colorant to indicate the active side of the patch. (B) Both tonsillar beds were coated with TachoComb 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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