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Topic usage of kaolin-impregnated gauze as a hemostatic in tonsillectomy

Maria Estela Chávez-Delgado, MD, DSc,[a,*] *Celina Verónica Kishi-Sutto, MD,*[b] *Xellic Nallely Albores de la-Riva, MD,*[c] *Manuel Rosales-Cortes, MD, DSc,*[d] *and Paulino Gamboa-Sánchez, MD*[e]

[a] *Research Department, Instituto Jalisciense de Cirugía Reconstructiva "Dr. José Guerrerosantos", Guadalajara, Jalisco, México*

[b] *Research Division, Ethical and Research Department, Instituto Jalisciense de Cirugía Reconstructiva "Dr. José Guerrerosantos", Guadalajara, Jalisco, México*

[c] *Department of Plastic Surgery and Reconstructive, Instituto Jalisciense de Cirugía Reconstructiva "Dr. José Guerrerosantos", Guadalajara, Jalisco, México*

[d] *Biological Sciences Division, CUCBA, Universidad de Guadalajara, Zapopan, Jalisco, Mexico*

[e] *Department of Surgical Oncology, Hospital General Regional 46, IMSS, Guadalajara, Jalisco, México*

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ABSTRACT

Background: The main postoperative complications after tonsillectomy are due to bleeding, and effective hemostasis may lead to a reduction of overall postoperative morbidity. This study was undertaken to determine the efficacy and safety of a novel kaolin-based hemostatic dressing in tonsillectomy.

Methods: A pilot, single-blind, open label study was performed in patients aged 3–20 y with history of chronic or hypertrophic tonsillitis. Cold dissection tonsillectomy (CDT) + ligature was performed by the same surgeon. Hemostasis on each tonsillar fossa was achieved using kaolin-impregnated gauze (KG; study group) or standard surgical cotton gauze (CG; control). Time to complete hemostasis, operative time, intraoperative blood loss, pain score, analgesic use, and return to normal diet and activity were recorded for all children.

Results: A total of 230 patients with a mean age of 8.0 y (138 in the study group and 92 in the control group) were included in the study. Both operative time and intraoperative blood loss were significantly reduced in the KG group ($P < 0.0001$) *versus* the CG group. At 5 min, 84.8% patients using the KG successfully achieved complete hemostasis *versus* 34.8% in the CG group where standard gauze controlled bleeding only partially. Results show significantly less pain for the KG group at 6- and 12-h postoperative when compared with the CG group ($P < 0.0001$). Also, the KG group required less analgesic medications, returned to normal diet and normal activities faster than the CG group ($P < 0.01$).

Conclusions: Preliminary findings show that the KG is effective and safe in managing surgical bleeding after tonsillectomy. In addition to rapid bleeding control, the dressing causes minimal inflammation and pain and allows patients to quickly return to normal activities. This novel dressing is a promising tool for ear, nose and throat surgical hemostasis.

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* *Corresponding author*. Instituto Jalisciense de Cirugía Reconstructiva, Av. Federalismo Norte 2022, CP 44210, Guadalajara, Jalisco, México. Tel.: +52 33 3823 3723; fax: +52 33 3823 3723.

E-mail address: draestelachavez@live.com.mx (M.E. Chávez-Delgado).

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1. Introduction

In Mexico, like in other parts of the world, tonsillectomy with or without adenoidectomy constitute the most common surgical operation performed on children. Although its history dates back more than 2000 y, both surgeries still can cause high morbidity intra- and post-operatively, including bleeding, pain, diminished oral intake, and reduced activity [1–3]. Posttonsillectomy bleeding (PTB), which is described as occurring during surgery or in the first 48 h (primary) or between postoperative days 5 and 15 (secondary) is a potentially life-threatening morbidity. The rate of PTB varies with different methods, and the incidence of combined primary and secondary bleeding varies between 0% and 20% [4–9]. Despite the numerous topic on hemostatic methods such as bismuth subgallate, calcium alginate, surgicel, fibrin glue (Quixil), collagen and thrombin sealant (Floseal), as well as novel instruments (cautery or electrosurgery) introduced to perform tonsillectomy with the hope of provide operative speed and intraoperative hemostasis, minimization of postoperative pain and bleeding complications, to date, no optimal technique has been successful in reducing the hemorrhage rate and postoperative pain [10–15].

Recently, a novel kaolin-coated hemostatic gauze (KG) has demonstrated efficacy in controlling bleeding in lethal models of extremity and visceral hemorrhage with the advantage to apply and remove easily [16,17]. Sena *et al.* [18] demonstrated in pigs with severe hepatic injury that KG reduced blood loss and resuscitation requirements. Furthermore, they reported in a 20-y-old man the first case of direct application of KG in a life-threatening episode of hemorrhagic gastritis (intraluminal bleeding) [19]. Kaolin, the active ingredient of KG is a layered silica mineral with no biological property of its own and containing no human, animal, or botanical protein. It is bonded to the surface of nonwoven polyester and rayon gauze for easy application and it has been shown to activate Factor XII and platelets to begin the clotting cascade [18–20]. Thinking about the prospective beneficial effects of KG in controlling hemorrhage, this study was undertaken to determine the efficacy and safety of KG in tonsillectomy.

2. Materials and methods

2.1. Design

A prospective pilot study was undertaken to evaluate the safety and efficacy of a novel hemostatic dressing consisting of rayon surgical gauze impregnated with kaolin (KG) compared with standard surgical cotton gauze (CG) during the removal of tonsils. The study protocol and the consent form were approved by the Institute Jalisciense de Cirugía Reconstructiva "Dr. Guerrerosantos" (R-002/2011) and patients were provided with written consent before the surgical procedure.

2.2. Patients and procedure

From January 2011 through May 2013, patients aged 3–20 y were selected with history of chronic or hypertrophic tonsillitis. Exclusion criteria included systemic disease, coagulation disorders, hematologic wound–healing disorder, and patients with impaired ability to express their degree of pain (motor/developmental delays).

All procedures were performed by the same surgeon. The surgical techniques were standardized, and classical cold dissection tonsillectomy (CDT) with or without curettage adenoidectomy were performed. All patients were orally intubated, and tonsillectomy was performed using a no. 15 scalpel blade to enter the peritonsillar space, blunt dissection to remove the tonsil from superior to inferior and a wire snare to divide the inferior pole. Pressure was applied with packs of KG (study group) or CG (control group) in each tonsillar fossae for hemostasis, and the time to complete hemostasis (TCH) was measured. Ligation of vessels of the superior and inferior poles of each tonsillar fossae was then performed. No further hemostasis method was used on tonsillar fossae. Each group had both tonsils removed by the same technique and hemostatic method (unpaired study design). Because in our experience, it was observed that bleeding is different in each one of them according to the degree of chronicity (fibrosis, encapsulated abscess, tonsilloliths, and friable tissue) and to avoid a likely bias, the same hemostatic method was used on both tonsils. Likewise, curettage adenoidectomy was performed until complete adenoid tissue removal, and pressure was applied with packs of KG or CG to the nasopharynx for hemostasis. Patients were transported to the postoperative unit in the lateral decubitus position and were routinely administered oxygen by face mask for the initial postoperative period. One dose of dexamethasone dosed by body weight was administered and intravenous analgesic (metamizol) was given three times daily or until the patient was pain free. During hospital stay, oral intake consisted of liquid diet and lemon ice. The patients were discharged from the hospital 12 h postoperative with therapeutic doses of paracetamol (20 mg/kg body weight) and amoxicillin/clavulanate every 8 h for 7 d postoperatively with an appointment for a control visit 10 d later.

2.3. Outcome measures

Data collected included demographic characteristics (age and gender). The efficacy of KG was evaluated by intraoperative and recovery measures. The intraoperative data included TCH (defined as time to complete bleeding cessation after application of the KG or CG), hemostatic success was defined as cessation of bleeding within 10 min of KG or CG application [21], surgery time was estimated as the time of initiation of tonsillectomy including time to hemostasis with ligation, intraoperative blood loss was recorded by the anesthesiologist and it was estimated by weighing the gauzes that were used during the surgical procedure (assuming that 1 mL of blood weighs 1 g) and including the net suction volume after subtraction of irrigation fluids. The number of sutures ligation used in the bleeding sites after applying the hemostatic agent (KG or CG) was also recorded. Recovery measures included throat pain, number of emesis events, oral analgesic doses, intravenous analgesic doses, time to resuming oral intake, time to ambulation, and peritonsillar edema.

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