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

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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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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.

Postoperative pain was recorded using a Faces Pain Scale [22] with seven schematic faces depicting changes in severity of expressed pain from no pain to the most pain possible (scored 0–6). It was registered during the first six postoperative hours and at discharge from the hospital (12 h). Peritonsillar-uvular edema and the presence of red pillars were evaluated before discharge using a four-grade scale (very slight, slight, moderate, and severe). At home, the parents recorded on a checklist the time to returning to normal activities and when the patient was able to eat solid food. No restriction was made on food intake. Throat condition was evaluated with respect to degree of healing at the postoperative visit, 10 d after discharge.

Safety of the KG was evaluated by the percentage of patients experiencing complications, defined as return to operating room for primary or secondary PTB, readmissions, duration of readmission period, liquid reposition, or number of blood products required during the control of PTB. An adverse event was defined as any undesirable change, either clinical or in laboratory values, in relation with using KG, occurring throughout the postoperative course with a minimum follow-up of 6 wk.

For comparisons of parametric data, unpaired Student *t*-test was used, with a significance factor of $P < 0.05$. Chi-square or Fisher test was used for nonparametric data with a significance level of $P < 0.05$. The mean (standard deviation) and confidence interval (CI) of 95% were calculated for each set of results.

3. Results

During the 27-mo evaluation time, a total of 230 patients underwent tonsillectomy with or without adenoidectomy by CDT + ligature and standard curettage adenoidectomy. There were 138 patients in the KG group and 92 in the CG group. Obstructive symptoms with chronic adenotonsillar hypertrophy were the most common indications for surgery overall. The average age was 8.0y ± 3.9 y (range, 3–20 y), and 51.7% of enrolled patients were female. The gender distribution and mean age were not significantly different.

All intraoperative measurements were significantly reduced in the KG group. The mean operative time was 18.6 min for the KG group and 27.1 min for the CG group ($P < 0.0001$). The average of intraoperative blood loss was 34.4 mL for the KG group and 54.6 mL for the CG group ($P < 0.0001$). The number of sutures ligation was significantly reduced in the KG group (Table 1). In both tonsillar fossae, the CG group had 6.7 ± 1.5 ligatures *versus* 4.6 ± 0.8 of the KG group ($P < 0.0001$). The use of KG resulted in a significant improvement of the TCH and overall hemostatic success. Patients treated with the KG successfully achieved complete hemostasis at 5 min in 84.8% of cases (95% CI = 77.6–90.3), whereas only 34.8% (95% CI = 24.1–44.3) of patients in the CG group had partially stopped bleeding ($P < 0.0001$). At 10 min, 91.3% (95% CI = 85.3–95.4) of patients of the KG group had hemostatic success *versus* 51.1% (95% CI = 40.4–61.6) in the CG group ($P < 0.0001$; Fig. 1). After 10 min of observation, only 8.7% (95% CI = 4.5–14.6) patients in the KG group were still bleeding in comparison with 48.9% (95% CI = 38.3–59.5) patients in the CG group ($P < 0.0001$).

Table 1 – Patient demographics and operative measures*.

Characteristics	Kaolin $n = 138$	Control $n = 92$	*P* value
Age	7.7 ± 3.8	8.5 ± 4.2	0.27
Sex			
Female	8.1 ± 3.5	9.2 ± 4.3	0.15
Male	7.3 ± 4.0	7.9 ± 3.9	0.94
Operative time, min	18.6 ± 3.2	27.1 ± 5.9	0.0001†
Intraoperative blood loss, mL	34.4 ± 10.5	54.6 ± 16.8	0.0001†
Number of sutures (r/l)	2.3 ± 0.6/2.2 ± 0.4	3.7 ± 1.0/2.9 ± 0.7	0.001†

l = left; r = right.
* mean (±SD).
† t-test.

Figures 2 and 3 display the hemostatic success after the use of KG or CG. The tonsillar fossae and adenoid bed were covered completely with enough KG, which came in contact with blood vessels and other anatomical structures (muscle and pharynx mucosae) until complete hemostasis (Fig. 2A–C). Furthermore, in some tonsillectomies, KG was applied a second time in each tonsillar fossae to allow the surgeon to quickly obtain bleeding control, leaving a clear and dry operative field in all cases (Fig. 2B and C). These characteristics of the operative field allowed the vessels from superior and inferior poles of each tonsillar fossae to be ligated easily. Afterward, the entire operative area was carefully watched, and no clinical evidence of tissue damage was observed (i.e., burns, edema, or necrosis) caused by the KG; the mucosa showed little inflammation or no edema (Fig. 2D). In contrast, in the control group, CG was applied and immediately becomes saturated with blood. In addition, the tonsillar fossae continued to bleed (Fig. 3A–C). This effect required the application of extra ligatures for controlling the bleeding;

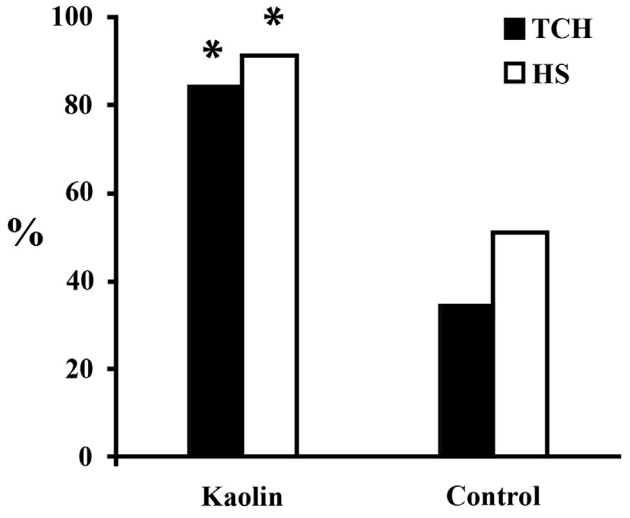

Fig. 1 – Efficacy of hemostasis between kaolin-impregnated gauze and standard cotton gauze groups. TCH, time to complete hemostasis (5 min); HS, hemostatic success (<10 min). *Chi-square test ($P < 0.0001$).

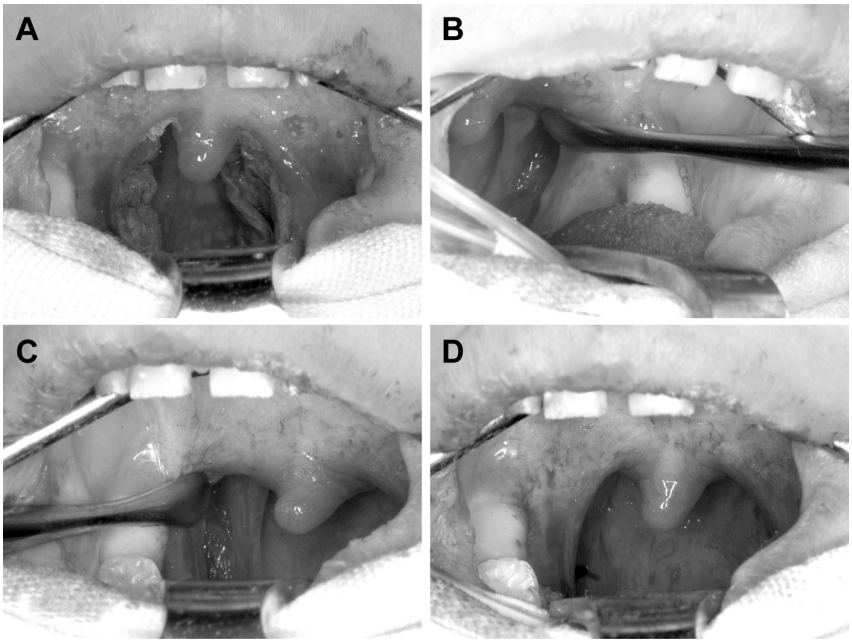

Fig. 2 – Kaolin-impregnated gauze (KG). (A) Initial application of KG to tonsillar fossae after tonsillectomy; (B, C) appearance of the right- and left-side tonsillectomy after removal of KG (TCH), there was no further bleeding and both tonsillar fossae were very clean; (D) ligation of vessels of superior and inferior poles of each tonsil. The operative field shows little inflammation or no edema.

furthermore, inflammation and edema were present at the end of surgery (Fig. 3D).

Postoperative recovery is summarized in Table 2. During the first 12 postoperative hours, a greater proportion of patients in the CG group had throat discomfort with vomiting and otalgia in comparison with KG group (67.9% *versus* 32.1%; $P < 0.001$). Furthermore, patients in the KG group required less oral and intravenous analgesic for pain relief and they get out

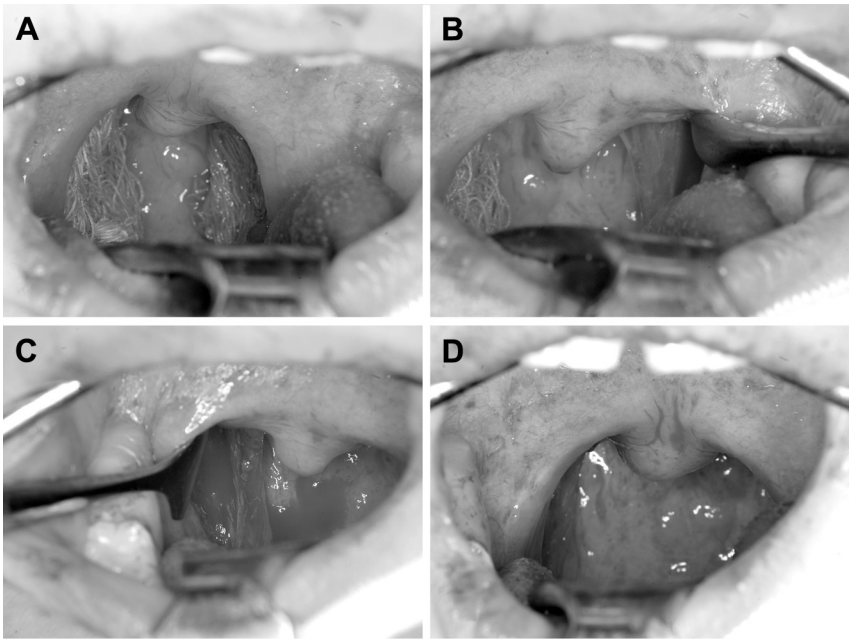

Fig. 3 – Standard surgical cotton gauze (CG). (A) The application of CG to tonsillar fossae after tonsillectomy appear to be saturated with blood; (B, C) after removing CG (TCH), the tonsillar fossae continued bleeding; (D) after ligation of vessels of the superior and inferior poles the mucosa shows inflammation and edema.

Table 2 – Postoperative outcome measures after kaolin or CG in tonsillectomy.

Recovery measures (12-h hospital stay)	Kaolin	Control	*P* value
Emesis (%)	32.1	67.9	0.001†
Oral analgesic doses	1.8 ± 0.5	2.6 ± 0.7	0.001*
Intravenous analgesic doses	1.5 ± 0.6	2.7 ± 0.5	0.02*
Time to first drink, h	3.2 ± 1.4	3.7 ± 1.6	0.38*
Time to go out of bed, h	5.3 ± 1.3	7.5 ± 2.1	0.001*
Peritonsillar edema, very slight (%)	70.5	29.5	0.001†
Days near normal diet	4.0 ± 1.0	5.4 ± 1.9	0.001*
Days return activity	3.5 ± 1.0	5.2 ± 2.0	0.001*

*mean (±SD), *t*-test.
†Chi-square test.

of bed faster in comparison with patients of CG group ($P < 0.001$). No significant difference in time to oral intake was noted between the groups ($P > 0.05$). At home, the KG group took a mean of 4.0 d to reestablish a normal diet and to return to regular activities, which was faster than the CG group ($P < 0.001$; Table 2).

Pain assessment using Faces Pain Scale during the first 12 postoperative hours show that there was a significantly less pain in the KG group *versus* the CG group at 6 and 12 h after surgery ($P < 0.0001$; Fig. 4). During the first six postoperative hours more patients in the KG group reported "slight pain" (scale 1, 2) *versus* "moderate pain" (scale 3) recorded in the CG group. On release, there was a clear difference in general behavior with respect to pain between groups. Most patients

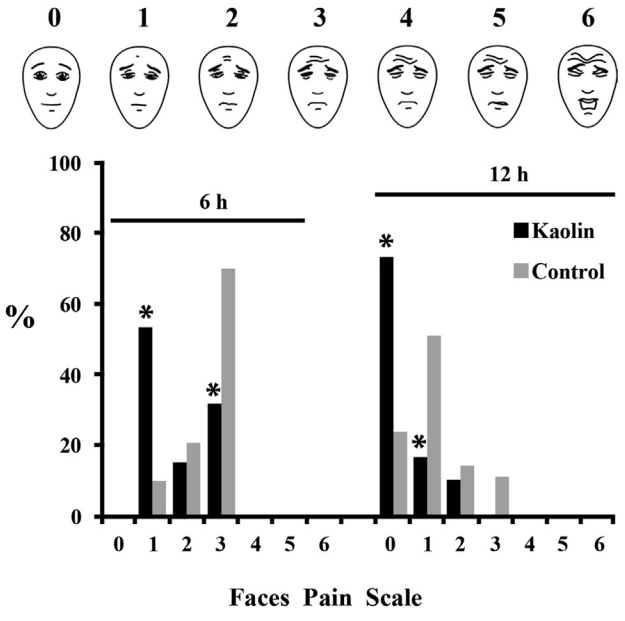

Fig. 4 – Faces Pain Scale, numbered 0 to 6 from left to right and the seven-point verbal pain rating scale. (0 = no pain, 1 = slight pain, 2 = pain, 3 = moderate pain, 4 = severe pain, 5 = very severe pain, and 6 = most pain possible). It was marked during the first 12 postoperative hours. *Chi-square test ($P < 0.0001$).

treated with the KG were noticed to have moderate activity, friendly disposition and were able to eat soft food, whereas the patients in the CG group were much sadder and more withdrawn. When the groups were discharged from the hospital, a score of 0 *versus* 1 was recorded between groups ($P < 0.01$; Fig. 4). Furthermore, the exploration of oropharynx showed no evidence of allergic reactions or intolerance and both tonsillar fossae were covered with white fibrin. Patients in the KG group were observed to have a higher significant percentage of very slight peritonsillar-uvular inflammation or no edema (67.3%, 95% CI = 58.8–75.1) than patients in the CG group (42.3%, 95% CI = 32.1–53.1; $P < 0.0001$; Fig. 5).

Although this study was not designed to analyze postoperative healing, patients in the KG group showed a significantly improved tissue healing at 10 d postoperatively. Both tonsillar fossae were completely healed and fully epithelized without any sign of injury, swelling, infection, or adverse effect. In contrast, the CG group showed minimal gray eschar in the tonsillar fossae (Fig. 5). Additionally, there was no PTB in any of the patients, and no patient required hospitalization or intravenous fluids for more than 12 h. Also, there were no readmissions and no postoperative mortality was observed in this study.

4. Discussion

The findings in the present study demonstrate that KG is effective for adenoidectomy and tonsillectomy. Benefits of KG started to be evident to reduce intraoperative bleeding and became statistically significant within 10 min of KG application compared with the control group. Furthermore, the use of KG led to significant improvement in operative time, pain, and the absence of PTB, which were important parameters that improved the patient recovery time and overall satisfaction. These findings are important because KG has shown to be safe allowing the surgeon to quickly obtain surgical control of bleeding within 60 s and complete hemostasis within the first five critical minutes, which are usually associated with the maximum bleeding after the disruption of vessels during tissue removal. Interesting findings with the use of KG was the easy application and the clean and dry operative area that is rapidly accessible for hemostasis by ligature when necessary. Moreover, no toxicity or adverse reactions were observed with the use of KG during the time of application and follow-up.

The Department of Defense Committee on Tactical Combat Casualty Care recently selected this KG (Combat Gauze; Z-Medica Corporation, Wallingford, CT) as the first-line hemorrhage treatment for tourniquet-resistant wounds. It has shown significant promise for controlling severe arterial hemorrhage, and it was recently approved for use in the prehospital, combat environment [23]. We were able to find few experimental studies and only one clinical case report, regarding the use of KG and to our knowledge, there are no data in the literature on the use of KG in elective human surgical procedures. These investigators demonstrated its hemostatic efficacy in lethal models of extremity and visceral hemorrhage [16–18,20]. In pigs with severe hemorrhage from hepatic injuries, they observed a trend toward reduced blood loss, lower resuscitation requirements and less mortality. Sena *et al.* [19] described in a 20-y-old man, the first report of

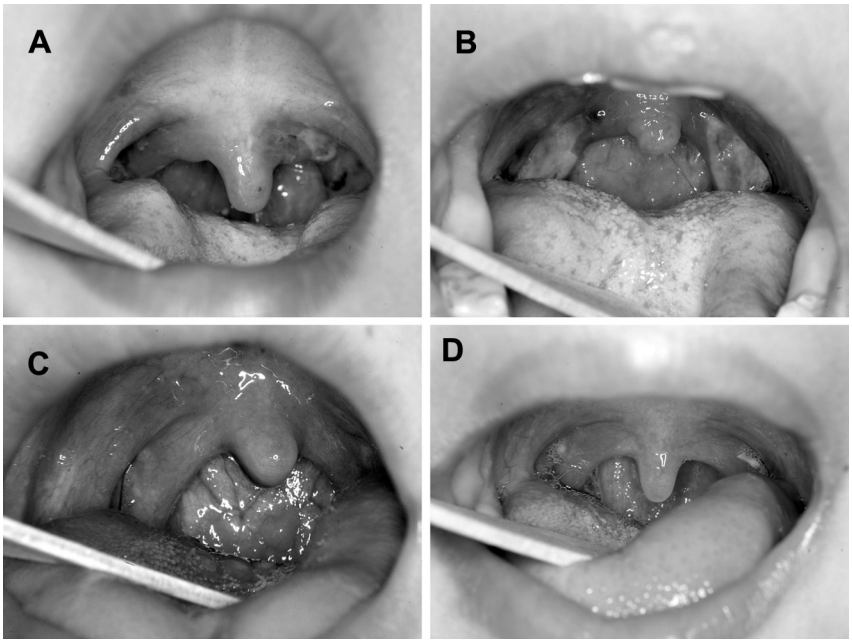

Fig. 5 – Healing in kaolin-impregnated gauze and standard cotton gauze groups. (A) On release (12-h postoperative), patients of KG group show little peritonsillar-uvular inflammation and no red pillars; (C) on day 10 postoperative, the throat anatomical structures and the degree of healing appear normal. In contrast, 12-h postoperative, the patients of CG group (B) show edema, red pillars, and inflammation; (D) on day 10 postoperative, minimal gray eschar may be seen in both tonsillar fossae.

direct application of KG in a life-threatening episode of massive hemorrhagic from stress gastritis that failed medical management (intracavitary bleeding). A longitudinal gastrotomy was made, and the stomach was packed using KG and it was removed in 12 h later without evidence of further gastrointestinal bleeding.

The manual compression with CG or sponges is the most common method to initially address bleeding areas in all surgical procedures, but often this technique is not effective and remains time consuming. For this reason, topical homeostatic agents are being increasingly used across all surgical disciplines as adjunctive measures to reduce the occurrence of operative morbidity and mortality after excessive surgical bleeding. Furthermore, the choice of surgical technique and postoperative treatment for reducing bleeding is often determined by surgeon preference and can potentially influence the intraoperative and postoperative morbidity [21].

Some reports have shown the beneficial effect of topical hemostatic in tonsillectomy with regard to operative speed, pain, and PTB [12,14,15,24–28]. Jo *et al.* [24] demonstrated that Floseal as a hemostatic sealant *versus* the traditional electrocautery after CDT reduced significantly the operative time (16 *versus* 31.2 min), intraoperative blood loss (49.2 *versus* 70 mL), pain (2 *versus* 11 d), return to regular diet (5.5*versus* 7.9 d), and activity (5.3 *versus* 7.8 d). Blackmore *et al.* [25] reported the effect of CDT + Floseal on posttonsillectomy pain using the paired study design in patients aged >16 y. One tonsillar fossa was treated with Floseal, and the other one with ligatures for hemostasis. Results show no significant difference in postoperative pain scores between the control and treatment side in the first 10 postoperative days. In addition, a PTB rate of 6.7% on the Floseal side was recorded. Other publications in recent years have demonstrated the efficacy of fibrin glue in reducing PTB and pain. However, it was found that there was no significant beneficial effect of fibrin glue in postoperative pain, PTB, use of analgesic medications, and return to regular diet between groups [14]. Bismuth subgallate is another topical hemostatic agent historically used as an astringent in tonsillectomy. It has been demonstrated to decrease the operative time and intraoperative blood loss, but it poses risks such as broncoaspiration [26]. Calcium alginate and other local hemostatic agents such as ethamsylate (dicyone) have been used in tonsillectomies without significant effects on blood loss [27–29]. These studies confirm that the use of KG allows better results in terms of operative time, pain, return to regular diet, activity, and PTB. The beneficial effects of KG may be attributed to the immediate effect in control bleeding, which allow less blood loss, operative time, and use of ligatures, hence decreasing the surgical trauma in the operative field and a faster return to normal diet and activities. Moreover, it is possible that kaolin possesses anti-inflammatory properties since there was a clear difference in tissue healing at 12 h and 10 d postoperatively, but further studies are needed to determine these anti-inflammatory properties.

More recently, several studies with other surgical methods using electrocautery and electrosurgery have compared the CDT with the hope of reducing operative time, time to intraoperative hemostasis, bleeding complications, thermal injury, and pain. Nonetheless, different variations of techniques have not been able to reduce discomfort and the risk of complications. The results of these studies emphasize that after surgery patients continue to experience some type of

postoperative morbidity such as pain, PTB, readmissions, and delay in returning to normal diet and activities [13,30–32]. In contrast, CDT has been recognized to potentially minimize thermal injury, has yielded excellent results, and it is the current standard technique in our department.

The advantage of KG over new technologies is that it does not require an investment in more expensive equipment and special training. The combination of CDT and the application of KG allowed complete removal of tonsils with minimal intraoperative blood loss and faster postoperative recovery. Its use with every patient undergoing a tonsillectomy benefits not only the surgical team by reducing any complications during the procedure and providing a safer alternative but also the patient by reducing the chance of complications during surgery and avoiding any secondary costs from a prolonged hospital stay and the use of hematic products. In addition, the characteristic of KG to be lightweight and manageable allows it to be adjusted in the small and irregular areas when dissecting the nasopharynx or nasal cavity. Moreover, KG shows no toxicity, and it is designed in different shapes and sizes to be used in all surgical specialties and is inexpensive. The disadvantage of KG is that it is not replacement the use of sutures and ligatures and it is not biodegradable as other topical hemostatic agents. Some limitations in our study need to be considered. Because of the exploratory design, it was nonrandomized and included children and adults. Both operative fields (tonsillar fossae) were treated with the same hemostatic method (KG or CG). In this study, it was observed that bleeding is different in each one of them according to the degree of chronicity. It is common to find unilateral encapsulated abscesses, with fibrosis and friable tissue with a contralateral tonsil hypertrophic; because of this, it would be a disadvantage and probably inclusion bias to use the common design where the new hemostatic agent is used on one side and compared to a different agent on the other side.

In conclusion, this is the first report of a large clinical experience using KG in human. The beneficial effects obtained with the use of KG during this study have made it the standard of practice for us and other ear, nose and throat surgeons. The results of this study show decreased bleeding complications with the subsequent reduction of overall postoperative morbidity and warrant further investigation of this hemostatic agent in surgical procedures involving larger bleeding.

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Authors' contributions: M.E.C.H.-D. and R.-C.M. contributed to conception and design. M.E.C.H.-D and G.-S.P analyzed and interpreted the data. M.E.C.H.-D. wrote the article. K.-S.C.V. and R.-C.M. made the critical revision of the article. A.-R.X.N. collected the data. G.-S.P. was in charge of obtaining the hemostatic agent by Z-Medica and Loorita Met Medical.

Disclosure

The authors reported no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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