

Hemostasis using Gelatin-based Hemostatic-Matrix in Pediatric Tonsillectomy and/or Adenoidectomy

Abdulmohsen E Al-Terki*

Chairman of ENT College for Post-Graduate Training, Kuwait Institute of Medical Specialization (KIMS), General Secretary of the Kuwait ENT Society, Head of Unit and Consultant, ENT Department, Zain and Al-Sabah Hospitals, State of Kuwait, Kuwait

*Corresponding author: Abdulmohsen E Al-Terki, PO Box: 3764, Mishref, 40188, State of Kuwait, Kuwait, Tel: 9659888 3648; E-mail: q8ent@hotmail.com

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Abstract

Objective: The aim of this study was to evaluate the applicability and safety of gelatin-based hemostatic matrix in children undergoing tonsillectomy and/or adenoidectomy.

Study design: This study was prospective, single-arm case series study conducted in a three tertiary care centers in Kuwait, from August to December 2011.

Methods: Seventy five children were enrolled (48 male and 27 female) with average age of 3.80 ± 2.14 years. Sixty six underwent tonsillectomy and adenoidectomy, seven tonsillectomy alone and two adenoidectomy alone; by same surgeon and same procedures. Surgiflo was applied for 214 surfaces with an average of 2.85 surfaces/patient via an applicator tip connected to the 12 ml syringe pre-filled with Surgiflo mixed with 5 ml normal saline.

Results: Hemostasis was achieved in all 75 patients within 5 minutes of product application without stitches, ties or cautery. The mean blood loss was 11.63 ± 4.40 ml, with a 95% CI (10.61-12.64). The mean duration of operation was 20.57 ± 4.22 minutes, with a 95% CI of (19.60-21.55). The mean time to return to normal diet after operation was 2.11 ± 0.80 days, with a 95% CI of (1.92-2.29). The incidence of adverse events and postoperative complications including hemorrhage in the follow up period was 0%.

Conclusion: Gelatin-based hemostatic matrix (Surgiflo) alone was successful in achieving hemostasis and safe in all patients who underwent tonsillectomy and/or adenoidectomy. Further RCTs are needed to compare the application of Surgiflo in tonsillectomy and/or adenoidectomy to other conventional methods.

Keywords: Tonsillectomy; Adenoidectomy; Surgiflo; Post-tonsillectomy hemorrhage; Hemostasis

Introduction

Tonsillectomy with or without adenoidectomy is still one of the most common performed surgical procedures in the pediatric age [1].

Whereas postoperative complications after tonsillectomy with or without adenoidectomy may be in the form of hemorrhage, tonsillar fossa hematoma, tongue and soft palate edema, airway obstruction, hoarseness, persistent vomiting, infection of the parapharyngeal space or dental complications; the postoperative hemorrhage is still the most serious complication [1,2].

Post-tonsillectomy hemorrhage has been divided into primary (in the first 24 hours) and secondary (after 24 hours) hemorrhage, with the first being the most serious of the two [3]. This is because of the reason that the initial vascular spasm of the injured artery makes bleeding not to occur in all cases immediately but instead with some sort of delay [4].

So, sufficient hemostasis is a prerequisite in any type of surgery, so as to prevent dramatic postoperative hemorrhage and their subsequent hazards. For this reason, different methods of hemostasis including variable local hemostatic agents have been developed [5].

In the past, tonsillectomy was called by the Greeks the antiades. They were picked up with a little hook and excised with a scalpel. Afterwards, the tonsil bed were washed out with vinegar and painted with a medication to reduce bleeding [6].

Despite the various techniques that have been developed over the years, the percentage of post-tonsillectomy hemorrhage is still almost the same and is considered to be the most significant complication [1,7].

Above all, none of the techniques discussed in the literature give an overall of zero percent of post-tonsillectomy hemorrhage. Accordingly, there is still a room for new techniques or hemostatic agents to be searched for and studied.

Surgiflo hemostatic matrix (a gelatin-based matrix, Johnson & Johnson Wound Management, A division of Ethicon Inc, Somerville NJ), is a sterile, absorbable gelatin intended to aid with hemostasis when applied to a bleeding surface. Gelatin induces the platelet aggregation leading to a clot when in contact with blood [5]. It was initially used for functional endoscopic sinus surgery, and it works as a pack applied to a bleeding surface gently without the need to remove it intra-operatively, due to its absorbable properties [8].

In addition to being used for and showed success in achievement of hemostasis in endoscopic sinus surgery, Surgiflo has been used for and showed success in partial nephrectomy, chronic compression of

lumbar dorsal root ganglia, and for venous malformations of the tongue [8-11].

Most of the modern hemostatic agents contain more or less human and animal components. Moreover, the residual presence of these agents may behave as foreign bodies, induce inflammation and infection. Therefore, safety is an important concern [5].

Thus, the rationale intended for this study was to evaluate the applicability of using Surgiflo as a hemostatic agent in tonsillectomy and / or adenoidectomy and studying the outcome in term of success of hemostasis, time-to-hemostasis, duration of surgery, need for extra method for hemostasis, estimated blood loss, incidence of post-operative hemorrhage, incidence of any adverse events, and time-to-return to normal diet.

Patients and Methods

The study was prospective, single-arm, multi-center case series study. The study adopted the globally accepted standards of GCP and in conformity with the latest revision of the Declaration of Helsinki. In addition, it conformed to national laws and regulations of Kuwait and approved by the Local Ethics Committee.

A total of 75 patients from 3 tertiary centers in Kuwait were enrolled and signed the informed consent form in the period from August 2011 to December 2011. Follow up of patients took 4 weeks. Patients were seen 24 hours after operation, 7 days and 4 weeks.

Inclusion criteria were; children patients, male or female, under 12 years suffering from recurrent tonsillitis, obstructive sleep apnea, recurrent otitis media or delayed speech who were candidate for tonsillectomy and/or adenoidectomy.

Exclusion criteria included infection, bleeding, metabolic disorders, dysmorphic features including Trisomy 21, or any chronic disease such as asthma, diabetes, and hypertension.

The primary end point measured was success in achieving hemostasis within 5 minutes of product (Surgiflo) application. Hemostasis was defined as the complete arrest of the accumulation of blood at the treated operative site. Time to hemostasis, including manual compression time, was measured. The proportion of success in achieving hemostasis within 5 minutes of product application was computed.

Secondary end points included the time to hemostasis, duration of operation, estimated blood loss, time to return to normal diet and incidence of postoperative hemorrhage. Duration of operation was measured from the anterior pillar incision or beginning of dissection until complete hemostasis of tonsillar fossa was achieved. The time of adenoidectomy was measured from starting using the curettage until complete hemostasis was achieved. Blood loss was measured by the use of gauge piece and weighing it before and after soaking with blood.

All patients were followed up for adverse events, postoperative hemorrhage, infection, and any unanticipated adverse effects.

Procedure

All patients underwent pre-operative evaluation included a thorough history and physical examination with emphasis on past episodes of bleeding and family history. Patients with bleeding disorders, malnutrition and co-existing systemic diseases were excluded from the study. Moreover, the hemoglobin level, total and

differential blood counts, the clotting time and blood group were determined.

The surgical technique was uniform amongst all patients. All the surgeries were performed by the same surgeon using the cold dissection method. The procedure was done under general anesthesia with the patient lying in the rose position. A Davis-Boyle mouth gag was used to keep the mouth open and was supported with Draffin Bipodes.

Primarily, the nasopharynx was examined indirectly with a laryngeal mirror, if the adenoid blocked the posterior choanae; a curette was passed to the caudal end of the septum, and pressed down until the posterior pharyngeal wall was met. Then, the curette was brought forward with a seesaw motion to remove the adenoid pad; this was followed by the application of Surgiflo to establish hemostasis.

For tonsillectomy, the mucosa was then incised using Woods tonsil scissors. The tonsils were dissected from the upper pole using the Gwynne Evans dissector until the lower pole was reached, the palatine tonsil was then removed, and Surgiflo immediately applied after preparation using 5 ml saline. No ties, no stitching and no electrocautery were used for hemostasis.

Once the tonsils or the adenoid is removed, Surgiflo is applied to the tonsillar fossa bi-latellary, and into the post-nasal space where the adenoid was removed. Once hemostasis is achieved, where it takes 2 to 3 minutes, the excess material of Surgiflo is removed except the portion in the tonsillar bed, where it forms like a small clot. And then the procedure is terminated.

Surgiflo, manufactured by Johnson & Johnson Wound Management, A division of Ethicon Inc, Somerville, NJ were used and applied to the bleeding surface, via an applicator tip connected to a pre-filled 12 ml syringe.

Statistical analysis

The analysis of the primary end point - the success of hemostasis within 5 minutes or less-was done by using descriptive statistics (frequency and 95% CI when applicable).

A value for $P < 0.05$ was considered statistically significant. SPSS software (Statistical Package for the Social Sciences, version 20.0, SSPS Inc, Chicago, IL, USA) was used for the statistical analyses. Data were presented as (mean \pm SD) for continuous variables after testing for normality of data and as frequency for categorical variables. Moreover, for further analysis, the sample was sub-grouped by age (≤ 3 years and 3-10 years) and gender (male & female). Difference between groups was tested using unpaired two-sided t-test. The 95% Confidence interval (CI) were calculated whenever applicable.

Results

Baseline characteristics and Indications for tonsillectomy and / or adenoidectomy

In this study, 75 patients were enrolled and followed up for 1 year postoperative, with average age of 3.80 ± 2.14 years. They were including 48 (64.00%) males and 27 (36.00%) females, with a total of 214 operated sides (for tonsillectomy; 73 right and 73 left and adenoidectomy 68). The baseline characteristics of patients as well as diagnosis classification and specification are shown in Table 1.

Parameter	Number	%
Patients enrolled	75	100%
Patients completing study	75	100%
Number of treated operative sides	214	100%
Mean (SD) age (year)	3.80 (2.14)	
Age range (year)	0.11-10	
Age groups		
≤3 years	38	50.67%
3-10 years	37	49.33%
Gender		
Male	48	64.00%
Female	27	36.00%
Race		
Arab/Oriental	71	94.67%
American	4	5.33%
Diagnosis classification		
Primary*	73	97.33%
Revision	2	2.67%
Diagnosis specification		
Recurrent tonsillitis	47	62.67%
Obstructive sleep apnea (OSA)	19	25.33%
Recurrent otitis media (OM)	6	8.00%
Delayed speech	3	4.00%

*Indicates no prior surgery, SD: Standard deviation.

Table 1: Demographic and baseline characteristics

Patients were grouped by age into two groups; ≤ 3 years (38 patients, 50.67%) and 3-10 years (37, 49.33%). In addition, they were grouped by gender; males (48 patients, 64.00%) and females (27, 36.00%).

Surgeries conducted in the study

Sixty six (88.00%) patients underwent both tonsillectomy and adenoidectomy either alone or in addition to bilateral myringotomy or bilateral ventilation tubes. Only 2 (2.67%) underwent adenoidectomy with bilateral ventilation tubes. Further details about surgeries done are shown in Table 2.

	Number of patients	Number of surfaces	%
T & A & Tubes	45	135	63.08%
T & A & M	13	39	18.22%
T & A	8	24	11.21%

T & M	4	8	3.74%
T & Tubes	2	4	1.87%
A & Tubes	2	2	0.93%
T	1	2	0.93%
Total	75	214	100.00%

T = Tonsillectomy, A = Adenoidectomy, M = myringotomy

Table 2: Operations conducted in the study and number of surfaces where Surgiflo applied

Surgiflo was applied for 214 surfaces with an average of 2.85 surfaces/patient. The minimum number of surfaces where Surgiflo applied was 1 and the maximum was 3. The product was applied via an applicator tip connected to the 12 ml syringe pre-filled with Surgiflo and mixed with 5 ml normal saline.

There were no significant difference in the number of surfaces where Surgiflo was applied between the two age groups (p=0.819) and between the two gender groups (p=0.982), as shown in Table 3.

	Number of patients	Number of surfaces	p*
		mean (SD)	
Age group			
≤3 years	38	2.84 (0.50)	0.819
3-10 years	37	2.86 (0.35)	
Gender			
Male	48	2.85 (0.41)	0.982
Female	27	2.85 (0.46)	

Table 3: Number of surfaces by age group and gender

Hemostasis and intra-operative assessment

All the 75 patients achieved hemostasis within 5 minutes of product application (100% success rate) without stitches, ties or cautery. The mean total time to hemostasis for all 75 patients was 4.05 ± 0.84 minutes, with a 95% CI (3.86-4.26). There was a significant difference (p=0.026) in time to hemostasis between the two age groups with 3.84 ± 0.79 minutes for the age group ≤ 3 years and 4.27 ± 0.84 minutes for the age group 3-10 years. No gender difference was seen regarding time to hemostasis (p=0.309), as shown in Table 4.

The mean estimated blood loss was 11.63 ± 4.40 ml, with a 95% CI (10.61-12.64). No significant difference in the estimated blood loss was seen in different age groups (p=0.505) or in different gender (p=0.267), as shown in Table 4.

The mean duration of operation was 20.57 ± 4.22 minutes, with a 95% CI of (19.60-21.55). There was a highly significant difference (p<0.001) in the duration of operation between the two age groups with 22.39 ± 4.12 minutes for the age group ≤ 3 years and 18.70 ± 3.49 minutes for the age group 3-10 years. No gender difference was seen regarding the duration of operation (p=0.671), as shown in Table 4.

	Age group			Gender		
	≤3 years	3-10 years	p	Male	Female	p
N	38	37		48	27	
Intra-operative assessment						
Success of hemostasis n (%)	38 (100%)	37 (100%)		48 (100%)	27 (100%)	
Time to hemostasis (min)	3.84 (0.79)	4.27 (0.84)	0.026	3.98 (0.84)	4.19 (0.83)	0.309
Duration of operation (min)	22.39 (4.12)	18.70 (3.49)	0	20.42 (4.31)	40.85 (4.13)	0.671
Estimated blood loss (ml)	11.29 (4.82)	11.97 (3.97)	0.505	11.21 (4.39)	12.37 (4.41)	0.276
Ties, n (%)	0 (0%)	0 (0%)		0 (0%)	0 (0%)	
Stitches, n (%)	0 (0%)	0 (0%)		0%	0 (0%)	
Cautery, n (%)	0 (0%)	0 (0%)		0 (0%)	0 (0%)	
Post-operative assessment						
Time to return to normal diet (days) mean (SD)	2.03 (0.82)	2.19 (0.78)	0.381	2.10 (0.81)	2.11 (0.80)	0.971
Postoperative hemorrhage, n (%)	0 (0%)	0 (0%)		0 (0%)	0 (0%)	
Postoperative complications, n (%)	0 (0%)	0 (0%)		0 (0%)	0 (0%)	

Table 4: Intra-operative and post-operative assessment

Postoperative assessment, haemorrhage and complications

The mean time to return to normal diet after operation was 2.11 ± 0.80 days, with a 95% CI of (1.92-2.29) days. There was no significant difference in the time to return to normal diet between the two age groups (p=0.381) nor between the two genders (p=0.971), as shown in Table 4.

The incidence of postoperative hemorrhage was 0%. Moreover, no complications or adverse events were encountered in the study follow up period.

Discussion

Synopsis of key/new findings and comparisons with other studies

Over the centuries, surgical techniques and equipments have been evolved tremendously aiming at decreasing time of operation and the intra-operative blood loss [7]. That is because excessive intra-operative blood loss is considered to be one of the significant risk factors for post-tonsillectomy hemorrhage [12]. Currently, cold dissection, hot knife dissection and bipolar diathermy dissection are the most commonly used techniques all over the World. Moreover, intra-operative blood loss is far less with electrocautery than with cold dissection technique [13].

Variations in technique usually revolve around the method of dissection, which involves cold knife, hot knife with Monopolar cautery, ultrasonic scalpel, microscopic bipolar cautery, temperature controlled radiofrequency tonsil reduction and Coblation, and the methods of homeostasis which include cautery, chemical, laser, or suture and ties [10].

In this current study, the results showed a 100% success in achieving hemostasis within 5 minutes using only Surgiflo without ties, stitching or cautery by the cold dissection method. In addition, the average estimated blood loss was 11.63 ± 4.40 ml. This is comparable to the average estimated blood loss in other studies [14,15]. Furthermore, the duration of operation (20.57 ± 4.22 minutes) is within the range that reported in the literature in other studies [14-21].

Episodes of post-tonsillectomy hemorrhage are still unpredictable and potentially life-threatening. One of the important observations in this study is that, the overall incidence of postoperative hemorrhage is 0% which appears to be within the rates described in the literature which ranges from 0% to 20% [10,15-24]. However, the exact incidence of postoperative tonsillar bleeding is very difficult to determine due to the heterogeneity between the studies which is reflected in the differences in the size and structure of age population, as well as the indication for tonsillectomy and above all, the duration of postoperative follow up. Such differences make it difficult to compare their results. Furthermore, the term “postoperative hemorrhage” has no uniform definition [25].

Strengths and weakness of the study

The main objective of this study was to evaluate the success of Surgiflo hemostatic matrix alone in achieving hemostasis in pediatric patients undergoing tonsillectomy and/or adenoidectomy. The technique is novel because this can obviate the need to use cautery, hence avoid thermal damage of the tissues. On the other hand, one important limitation of the study is being single-arm and non-comparative, hence, we cannot rely on it alone to draw a conclusion without doing further RCTs.

Clinical applicability of the study

In summary, despite the limitations of such type of study being single-arm and non-comparative; the study showed that Surgiflo can be used in such types of surgeries as it is effective in achieving hemostasis, safe and well-tolerated agent, in the medical practice.

Conclusion

Surgiflo alone was successful in achieving hemostasis and safe in all patients who underwent tonsillectomy and/or adenoidectomy. Further randomized controlled trials are needed with appropriate sample size to compare the application of Surgiflo hemostatic matrix in tonsillectomy and/or adenoidectomy with other conventional and nonconventional methods.

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