

Use of Gelatin Matrix for Hemostasis in Adult Tonsillectomy- A Study of 100 Cases

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ABSTRACT

Objective: The purpose of study was to study the efficacy of gelatin matrix in achieving homeostasis after Tonsillectomy.

Methods: 100 patients were enrolled (59 males and 41 females) between the age group of 18 to 50 yrs. 73 patients who underwent tonsillectomy for Chronic tonsillitis and 27 patients with Obstructive sleep apnoea who underwent tonsillectomy alone were included. The surgery was done in direction land snare method for all patients surgiflo was applied as the topical hemostatic material using an applicator over the tonsillar fossa on both sides

Results: Hemostasis was obtained in 97% of the study group within 3 minutes of product application The average blood loss was 12 ml and the duration of surgery was on average 24.57 5.22 minutes. Patients were able to take normal diet within 2 days after surgery. The follow up period of 4 weeks was uneventful with no evidence of complications 3 cases, in which there was uncontrolled bleed despite the use of surgiflo, were managed by conventional ligatures. These 3 cases had been planned for Interval Tonsillectomy after previous attack of quinsy.

Conclusion: Surgiflo gelatin based haemostatic matrix is very useful as a solo topical hemostat in obtaining hemostasis without the need for any other assisted methods and we did not have any adverse effects on the patients.

Key words: Surgiflo, Tonsillectomy, Haemorrhage

HOW TO CITE THIS ARTICLE: Sumitha, Use of Gelatin Matrix for Hemostasis in Adult Tonsillectomy-A Study of 100 Cases, J Res Med Dent Sci, 2022, 10 (9): 0141-144.

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Received: 20-Jul-2022, Manuscript No. JRMDs-22-57370;

Editor assigned: 22-Jul-2022, PreQC No. JRMDs-22-57370 (PQ);

Reviewed: 05-Aug-2022, QC No. JRMDs-22-57370;

Revised: 20-Sep-2022, Manuscript No. JRMDs-22-57370 (R);

Published: 27-Sep-2022

INTRODUCTION

The most commonly performed ENT surgical procedure till date is tonsillectomy [1]. Post tonsillectomy haemorrhage primary, reactionary or secondary is shown to be higher among adults as compared to children in several studies worldwide and is one of the important ENT emergencies that require immediate management. Numerous techniques are practiced over the year to attain hemostasis in head and neck surgeries with varying results. Techniques like ligature, cautery and laser are being followed to control bleeding in tonsillectomy. Though numerous techniques have evolved over the years, post tonsillectomy haemorrhage is still prevalent as same as earlier days and is the most dangerous complication that needs expertise management [2]. Studies have not shown any decline in the incidence despite the recent trends, mainly because of the limited studies proving the efficacy and safety of these agents. Techniques adopted to reduce bleeding like diathermy, laser cause charring of the tissue and higher incidence of postoperative morbidity.

In this study we use surgiflo a sterile absorbable hemostat for haemostasis. It is a topical agent applied over the bleeding surface. Gelatin induces the platelet aggregation leading to a clot formation [3]. Earlier it was used in functional endoscopic sinus surgery as nasal pack post operatively to control bleeding [4]. There is no need to remove the pack as it is absorbable.

CASE PRESENTATION

Patients and methods: This prospective study was done among 100 patients in Sree Balaji Medical College, Chennai between July 2017 and May 2018 after getting a written informed consent. Patients were seen after 24 hours, after 7 days and then 4 weeks after procedure for follow up. Inclusion criteria were adult patients, male or female, between 18 and 50 years of age suffering from chronic or recurrent tonsillitis and obstructive sleep apnea, who were candidates for tonsillectomy.

Exclusion criteria: It is included infection, bleeding disorders, bronchial asthma, hypertension metabolic disorders and other co morbid conditions. The primary end point measured was success in achieving hemostasis within 3 minutes of product (Surgiflo) application. The time interval from the anterior pillar incision to complete hemostasis of tonsillar fossa is calculated as the duration of procedure. Blood loss was measured by weighing the used gauze piece and cotton balls befriended after soaking

with blood and also measuring the blood collected in the suction apparatus. All patients were followed up for 4 weeks for adverse events.

Procedure: All 100 patients in the study group were evaluated pre-operatively by proper history taking and complete physical examination focusing on bleeding disorders and comorbid conditions. All patients underwent tonsillectomy by dissection and snare method. The procedure was done under general anesthesia by the same surgeon. The mucosa was incised using Waugh's forceps. In the superior pole, tonsil dissected and snared from the inferior pole using the Eves tonsillar snare.

After tonsillectomy, Surgiflo was immediately applied over the tonsillar fossa. Surgiflo consists of two components 2000 IU of sterile lyophilized human thrombin and flow able gelatin matrix components with suitable applicator. The thrombin was prepared in sterile field reconstituted with 5 ml saline and then mixed into the pre filled syringe containing flow able gelatin matrix. Once mixed, the haemostatic matrix resides in the 12 ml syringe with the straight white tip that was trimmed to desirable length before application. The process was done in sterile environment taking necessary aseptic precautions.

After 3 minutes, the excess surgiflo was removed except in areas where clots were formed around it. Patient was put back in supine position on the operating table after checking for complete hemostasis. The amount of blood loss in the intraoperative and postoperative period (if any) was recorded. In the intraoperative period, the amount of blood that was suctioned and the blood loss from soaked gauze were recorded separately to get the total blood loss. Following procedure, patient was kept under observation for 4 hours until complete recovery from anesthesia and ice cold diet was started if patient is stable. Patient was then examined to look for any expanding clots in the tonsil fossa, or bleed. Patient was then discharged within 8 hours of procedure and asked to follow up the next day, after 7 days and then after 4 weeks for postoperative assessment.

RESULTS

In this study, 100 adult patients, between 18-50 years of age were enrolled and followed up for 4 weeks postoperative. They were 59 males and 41 females, with a total of 200 operated sides (Figure 1).

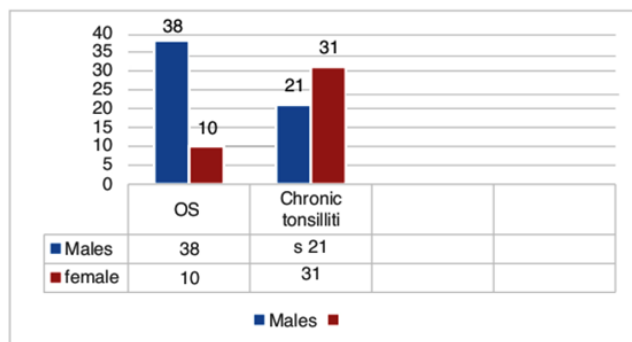


Figure 1: No. of patients in the study group and their indication for tonsillectomy

Out of 100 cases, we encountered intraoperative bleed that was not controlled by Surgiflo in 3 cases (Figure 2). These cases were planned for interval tonsillectomy alters an attack of Quinsy previously which may have contributed to the bleed. Patients started taking normal diet in 2 days, average being 1.8 days. Both genders showed no difference in recovery and the duration of the procedure was approximately 24.57 +/- 5.22 minutes.

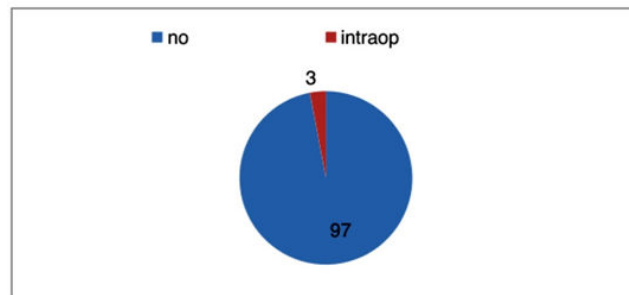


Figure 2: The incidence of intraoperative bleed in the study group after application of Surgiflo.

Patients were followed for period of 4 weeks at an interval of 1 day, 7 days and 4 weeks. No complication was evident in the follow up period.

DISCUSSION

Numerous complications are encountered after tonsillectomy including tongue injury, soft palate edema, dental issues, voice change, infection of adjoining spaces like Para pharyngeal space but hemaorrhage continues to be the most commonest and dangerous [1-8].

Over the centuries, surgical techniques and equipments have been evolved tremendously aiming at decreasing time of operation and the intra-operative blood loss [2]. In the late 18th century Tonsils were removed by Guillotine method and were very popular. It fell out of favour in early 19th century due to heavy bleeding and recurrence of sore throat. With advanced technology coablation and electro cautery with laser or diathermy is commonly used for tonsillectomy. These methods cause very minimal blood loss compared to cold dissection methods [5]. Hot knife like diathermy and laser cause reduced blood loss but more thermal injury to tissues. Temperature controlled coblation and RF knife cause less thermal injury but are very expensive. The need for hemostatic measures like tie, chemical cautery, electro cautery is determined by the dissection method and extent of tissue damage during the surgery.

Surgiflo is a sterile absorbable gelatin matrix used as a topical hemostat intending to aid with hemostasis. It consists of two components 2000 IU of sterile lyophilized human thrombin and flow able gelatin matrix components [10]. Gelatin causes platelet aggregation when in contact with blood forming clots which causes hemostasis [3].

Gelatin matrix is of animal origin but non antigenic and is absorbed within 6 weeks. Unlike regenerated oxidized cellulose, the pH of the gelatin matrix is neutral and therefore can be used in conjunction with thrombin or other hemostatic agents to enhance hemostatic action. Gelatin matrix is easily usable low cost hemostatic material to control hemorrhage with minimal morbidity [11]. Thrombin is a natural enzyme and plays an important step in hemostasis, inflammation and cell signalling. It is formed from prothrombin, as a result of the activation of intrinsic and extrinsic coagulation pathways, and forms the base of the fibrin clot, promoting the conversion of fibrinogen to fibrin [12].

Surgiflo works as a topical hemostatic pack without the need to remove it postoperatively due to its absorbable properties [4]. The main advantages of Surgiflo are that it takes less time to apply and has no disadvantage of trauma or thermal injury to tissue. This avoids post-operative charring and pain and accelerates wound healing.

In our study the results show 97% success in achieving hemostasis within 3 minutes using only surgiflo without tie, ligature or cautery. In addition the average estimated blood loss was 12 ml. This is much less as compared to the average estimated blood loss with other methods [6,7]. The less weight easy flowing gelatin matrix helps in easy application with optimal control [13]. The application helps in precise placement in difficult areas like superior and inferior poles near tongue base. Furthermore, the duration of operation is not increased and patients could be discharged the same day or next day.

The older techniques of surgical ligature and diathermy have a lot of disadvantages. Both require expert hands as reaching both poles of the tonsil and tongue base is difficult. Further, inappropriate use of diathermy can damage the surrounding tissues and particularly uvula, which causes postoperative oedema and odynophagia. Monopolar or bipolar diathermy is no more cost effective and causes severe charring of fossa and adjacent tissues [14]. This increases postoperative pain and delay in recuperation and commencement of oral intake. Patient feels very unsafe to get discharged without starting oral intake and this increases hospital stay. This clearly imposes a major economic burden for the patient and family, which gets cut off with the use of Surgiflo, which has excellent hemostasis with minimal handling of fossa. Excessive charring caused by diathermy also leads to a lot of unhealthy slough formation which increases the risk of infection and secondary haemorrhage. This makes Surgiflo most cost effective despite having an added cost for the material. In the case with surgical ties, the chance of slippage of ligature and dislodgement of clot is nullified with Surgiflo application thereby reducing the need for prolonged postoperative care and hospitalisation.

Recent techniques like Coblator and LASER can be used for removing the tonsil and maintaining hemostasis [3-14], but both need huge theatre equipment setup and

the cost is much more than conventional tonsillectomy. So, routine tonsillectomy with dissection and snare method and the use of Surgiflo is a simpler and cost efficient method to attain hemostasis.

Surgiflo cannot be used when there is an arterial bleed or if the patient is allergic to human products. Patients need to be counselled before surgery regarding adequate care to avoid violent coughing in postoperative period as it can dislodge the material. Very rarely thrombosis can occur if systemically absorbed [15].

The main objective of this study was to evaluate the success of Surgiflo haemostatic matrix alone in achieving hemostasis in adult patients undergoing tonsillectomy. A similar study was conducted among paediatric age group which showed similar results and 100 percent success with Surgiflo [9]. The technique avoids thermal damage of the tissues. Cases with previous history of Quinsy or recent history of an acute exacerbation of the infection may pose a difficulty in maintaining hemostasis with Surgiflo alone.

CONCLUSION

Surgiflo alone was successful in achieving hemostasis and safe in patients who underwent tonsillectomy. The technique avoids the need to use electrocautery, laser etc that causes thermal damage of the tissues. The reduced incidence of postoperative haemorrhage, reduced postoperative pain and faster recovery in the immediate postoperative period provides a more pleasant experience for patients in terms of physical wellbeing and comparatively less economic burden due to the reduced hospital stay and reduced equipment cost. Further studies are needed with appropriate sample size to compare the application and any possible adverse effects of Surgiflo haemostatic matrix and its substitute fibrin sealants in tonsillectomy with other conventional and nonconventional methods.

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