THE EFFECTIVENESS OF TACHOSIL PATCH AS A DRAINAGE AND HAEMOSTATIC AGENT IN THYROID AND SALIVARY GLANDS SURGERIES

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ABSTRAK

Objektif: Tujuan penyelidikan ini adalah untuk mengkaji keberkesanan pelekat TachoSil® sebagai agen pemberhentian pendarahan dan peredaran dalam pembedahan tiroid dan kalenjar air liur.

Kaedah: 27 orang pesakit yang menjalani pembedahan tiroid dan kelenjar air liur dari bulan Jun 2018 hingga Mei 2020 untuk ketumbuhan bukan kanser telah dilibatkan dalam penyelidikan ini. Pesakit-pesakit dibahagikan kepada 2 kumpulan. Kumpulan yang tidak menggunakan pelekat TachoSil® dinamakan sebagai kumpulan 'non- Tachosil' dan kumpulan yang menggunakan pelekat Tachosil dinamakan sebagai kumpulan 'Tachosil'. Jangka masa untuk pembedahan, jangkaan jumlah pendarahan, jumlah aliran selepas pembedahan, jumlah masa pengalir, dan jumlah masa di hospital digunakan untuk sebagai perbandingan di kedua-dua kumpulan.

Keputusan: Purata jumlah aliran 24 jam selepas pembedahan adalah lebih rendah dalam kumpulan 'Tachosil' (20mL, berbanding 45mL dalam kumpulan 'non-Tachosil', p=0.049). Tiub pengalir dapat dikeluarkan lebih awal dalam kumpulan 'Tachosil' (2 hari, berbanding 2.5 hari dalam kumpulan 'non-Tachosil', p=0.045) dan ini menyumbang kepada pengurangan tempoh waktu pesakit perlu berada di wad (2 hari, berbanding 2.5 hari dalam kumpulan 'non-Tachosil').

Kesimpulan: Penyelidikan ini membuktikan bahawa TachoSil® berkesan dalam mengurangkan jumlah aliran selepas pembedahan, dan seterusnya mengurangkan tempoh tiub aliran dalam badan dan akhirnya dapat juga mengurangkan tempoh berada di dalam wad. Penyelidikan ini tidak dapat membuktikan bahawa TachoSil® dapat mengurangkan jumlah pendarahan semasa pembedahan, maka jumlah pesakit yang lebih banyak diperlukan untuk kajian akan datang.

KATA KUNCI

Pelekat fibrin, alat pemberhentian darah, pembedahan tiroid, pembedahan kalenjar air liur, pembedahan kepala dan leher.

ABSTRACT

Objectives: The aim of this study is to evaluate the effectiveness of TachoSil® patch as a drainage and haemostatic agent in thyroid and salivary glands surgeries

Method: Twenty-seven patients who undergone thyroid and salivary glands surgeries between June 2018 and May 2020 for benign pathology were included in the study. They were classified into 2 groups; those who did not use TachoSil® patch intraoperatively (known as non-Tachosil group) and those who used TachoSil® patch intraoperatively (known as Tachosil group). Parameters such as duration of surgery, estimated blood loss, post-operative drain amount, duration of drain and duration of hospital stay were used to measure the outcomes in both groups.

Result: After 24 hours of surgery, mean drainage volume was reduced in Tachosil group (20mL vs 45mL in non-Tachosil group, p=0.049). Drain removal occurred earlier in the Tachosil group (2 days, as opposed to 2.5days in non-Tachosil group, p=0.045), which resulted in a shorter duration of hospital stay (2 days, as opposed to 2.5d days for non-Tachosil group).

Conclusion: This study demonstrated that TachoSil® is beneficial in reducing post-operative drainage volume, which lead to reduction of drain duration, and eventually a reduction in hospitalisation time. Considering that it was significant in providing haemostasis intra-operatively, a bigger sample size future study is needed to adequately assess its effectiveness.

KEYWORDS

Fibrin sealant patch, haemostatic agent, thyroid surgery, salivary gland surgery, head and neck surgery.

Chapter 1

INTRODUCTION

1.1 INTRODUCTION

Head and neck surgeries encompass salivary gland surgery, thyroid surgery, lymph nodes biopsy, oral cavity and oropharyngeal surgery, laryngeal surgery as well as nasal cavity and paranasal sinuses surgeries. These surgeries are unique, largely due to its proximity to vital organs that are responsible for respiration, swallowing and speech. Without appropriate procedures, complication related to surgeries in head and neck area can potentially be debilitating, affect patient's quality of life and in the worst-case scenario cause fatality. Intra operative and postoperative bleeding is one of the most severe complications of head and neck surgeries. A surgical procedure with inadequate haemostasis may lead to blood transfusion or other bleeding related complications. In head and neck surgeries, parotidectomy is the most often associated with bleeding, followed by thyroidectomy[(1)]. Significant, uncontrolled haemorrhage can lead to substantial morbidity and mortality[(2)]. Blood transfusion are often costly as they require a vast amount of clinical and staff resources and simultaneously poses a high risk of complications that add an additional cost to hospitalization and post discharge medical care[(3)]. Many conventional methods are being used to control bleeding intraoperatively, mainly compression with adrenaline, suture, ligation, and electrocauterization. With the advancement in technology, more products are invented to facilitate optimum hemostasis in surgical procedure, namely liquid fibrin, synthetic glues, and topical hemostatic patches.

The hemostatic agent of interest, TachoSil®, is a ready-to-use patch with two different sides that act as hemostatic and sealant agent. One side of the patch is coated with active biological ingredients of human fibrinogen and thrombin, while the other side of the

patch is made with horse collagen and has a honeycomb-like structure[4]. It is a sterile and bioabsorbable product[4]. The side of the patch that contains human-derived fibrinogen and thrombin is called the active side. Once in contact with bleeding wound surface, the fibrinogen and thrombin coating will be dissolved and partly diffused into the wound surface[4]. It will subsequently trigger the last step of coagulation cascade, converting fibrinogen into fibrin and eventually a fibrin clot at the site of bleeding[4]. The formed fibrin clot will patch the collagen layer to the wound surface and provide a physical barrier to bleeding and thus, achieving hemostasis[4]. The other side of the patch is made with horse collagen and has a honeycomb-like structure[4]. The honeycomb-like structure with its closed cell formation is structurally stable thus acts as mechanical barrier, while at the same time remains flexible and will not swell on exposure to liquid[4].

This study focuses on the effectiveness of TachoSil® in establishing haemostasis and drainage for minor head and neck surgeries. TachoSil® is recommended to be used as adjunctive haemostasis to control mild-to-moderate intraoperative bleeding, but it is not to be used for major arterial and venous bleeding[4]. The effectiveness of TachoSil® to controlled bleeding has been studied in various fields, namely neurosurgery[5], kidney tumour resection[6], lumbar spine surgery[7], with its sealant property has been used to prevent lymphocele in gynecologic cancer[8].

Chapter 2

OBJECTIVES OF THE STUDY

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GENERAL OBJECTIVE

1. To determine the effectiveness of TachoSil® patch as a hemostatic agent and drainage in thyroid and salivary glands surgeries.

SPECIFIC OBJECTIVES

1. To determine the effects of TachoSil® patch as hemostatic agent in thyroid and salivary glands surgeries.
2. To determine the effects of TachoSil® patch for drainage in thyroid and salivary glands surgeries.

Chapter 3

MANUSCRIPT

3.1 Title Page

The Effectiveness of Tachosil Patch as A Drainage and Haemostatic Agent In Thyroid And Salivary Glands Surgeries.

Running title: Tachosil in Head and Neck Surgery.

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3.2 ABSTRACT

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Method: Twenty-seven patients who undergone thyroid and salivary glands surgeries between June 2018 and May 2020 for benign pathology were included in the study. They were classified into 2 groups; those who did not use TachoSil® patch intraoperatively (known as non-Tachosil group) and those who used TachoSil® patch intraoperatively (known as Tachosil group). Parameters such as duration of surgery, estimated blood loss, post-operative drain amount, duration of drain and duration of hospital stay were used to measure the outcomes in both groups.

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KEYWORDS

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3.3 INTRODUCTON

Head and neck surgeries encompass salivary gland surgery, thyroid surgery, lymph nodes biopsy, oral cavity and oropharyngeal surgery, laryngeal surgery as well as nasal cavity and paranasal sinuses surgeries. These surgeries are unique, largely due to its proximity to vital organs that are responsible for respiration, swallowing and speech. Without appropriate procedures, complication related to surgeries in head and neck area can potentially be debilitating, affect patient's quality of life and in the worst-case scenario cause fatality. Intra operative and postoperative bleeding is one of the most severe complications of head and neck surgeries. A surgical procedure with inadequate haemostasis may lead to blood transfusion or other bleeding related complications. In head and neck surgeries, parotidectomy is the most often associated with bleeding, followed by thyroidectomy[(1)]. Significant, uncontrolled haemorrhage can lead to substantial morbidity and mortality[(2)]. Blood transfusion are often costly as they require a vast amount of clinical and staff resources and simultaneously poses a high risk of complications that add an additional cost to hospitalization and post discharge medical care[(3)]. Many conventional methods are being used to control bleeding intraoperatively, mainly compression with adrenaline, suture, ligation, and electrocauterization. With the advancement in technology, more products are invented to facilitate optimum hemostasis in surgical procedure, namely liquid fibrin, synthetic glues, and topical hemostatic patches.

The hemostatic agent of interest, TachoSil®, is a ready-to-use patch with two different sides that act as hemostatic and sealant agent. One side of the patch is coated with active biological ingredients of human fibrinogen and thrombin, while the other side of the patch is made with horse collagen and has a honeycomb-like structure[(4)]. It is a sterile

and bioabsorbable product[4]. The side of the patch that contains human-derived fibrinogen and thrombin is called the active side. Once in contact with bleeding wound surface, the fibrinogen and thrombin coating will be dissolved and partly diffused into the wound surface[4]. It will subsequently trigger the last step of coagulation cascade, converting fibrinogen into fibrin and eventually a fibrin clot at the site of bleeding[4]. The formed fibrin clot will patch the collagen layer to the wound surface and provide a physical barrier to bleeding and thus, achieving hemostasis[4]. The other side of the patch is made with horse collagen and has a honeycomb-like structure[4]. The honeycomb-like structure with its closed cell formation is structurally stable thus acts as mechanical barrier, while at the same time remains flexible and will not swell on exposure to liquid[4].

This study focuses on the effectiveness of TachoSil® in establishing haemostasis and drainage for minor head and neck surgeries. TachoSil® is recommended to be used as adjunctive haemostasis to control mild-to-moderate intraoperative bleeding, but it is not to be used for major arterial and venous bleeding[4]. The effectiveness of TachoSil® to controlled bleeding has been studied in various fields, namely neurosurgery[5], kidney tumour resection[6], lumbar spine surgery[7], with its sealant property has been used to prevent lymphocele in gynecologic cancer[8].

3.4 MATERIAL AND METHOD

Patients' data on those who undergone thyroid and salivary glands surgery between June 2018 and May 2019 were compiled from existing researcher's hospital database. These patients did not use TachoSil® patch during the surgeries and were classified into non-Tachosil group. The information pertaining to the surgeries were obtained based on the hospital admission and their clinic visitation documents.

Patients who undergone thyroid and salivary gland surgery between June 2019 and May 2020 were recruited and classified into Tachosil group. Patients were given comprehensive explanation of the study and their consent was obtained by the research team. Patients were consulted prior to before, during and post-operatively.

Our inclusion criteria included those aged 7 to 60 years old who underwent parotidectomy, submandibulectomy, thyroidectomy and Sistrunk procedure for benign pathology. This study excluded patient who had surgical site infection at time of surgery, known coagulopathy, developing disseminated microvascular bleeding during surgery, known history of allergic reaction on application of fibrinogen/ thrombin/ collagen of any origin, carcinomatous pathology, pregnant and lactating females. Data on surgical outcome and adverse events incidents, particularly on major bleeding and inadequate drainage following exposure to TachoSil® were recorded.

Study Design and Outcome Measurement

The study was approved by the Medical Research and Ethics Committee of Universiti Sains Malaysia (USM/JEPeM/19010001) and was performed parallel with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research involving Human Subjects. For Tachosil group, patients were evaluated pre-operative, informed consent was obtained from patients or parents of underage patients.

Intraoperatively, after excision of thyroid gland or salivary gland, haemostasis was achieved using the standard methods of controlling bleeding that is local compression, vessels ligation, and thermal cauterization using monopolar or bipolar diathermy. TachoSil® patch was later placed on the bed of surgical site resection with its active side (containing human fibrinogen and thrombin) in direct contact with the surgical site to help with haemostasis. Duration of surgery, estimated blood loss and amount of blood transfusion were recorded. Drainage tube size 8 or 10Fr was inserted. Muscle, subcutaneous tissue, and skin were approximated using sutures. The drainage tube was connected to vacuum bottle.

Post-operatively, drain volume, duration of drain, hospital stay, blood transfusion and details of complications were documented. Clinic visits up to 6 weeks post-operatively were reviewed.

Data Collection

The data was entered and analysed using IBM SPSS Statistics for Windows (Version 26.0, IBM Corp). The data obtained was expressed as mean with standard deviation (SD) for numerical variables and frequency (n) with percentage (%) for categorical variables. Mann-Whitney and Pearson Chi-square test were used to compare the mean difference of related variables between the two studied groups. A p value < 0.05 was considered as statistically significant.

3.5 RESULTS

3.5.1 General result

A total of 27 samples were obtained for this study. The obtained data were expressed as mean with standard deviation (SD) for numerical variables and frequency (n) with percentage (%) for categorical variables as tabulated in Table 1. The result of the data showed that the mean age of the total 27 samples were 43.15 years old with standard deviation of 18.62. Predominantly, there were 74.1% Malay (n=20) from the total population studied.

Our data involved 15 cases of hemithyroidectomy (55.5%) and three Sistrunk excision (11.1%), which together we pooled as thyroid surgeries that made up 66.7% of cases, seven cases of parotidectomy (25.9%) and two cases of submandibular gland excision (7.4%). For hemithyroidectomy and Sistrunk excision, eight of the cases uses TachoSil® (29.6%) while ten cases did not used TachoSil® and thus served as control. For parotidectomy, four cases (14.8%) used TachoSil® while the other three cases (11.1%) did not. For submandibular gland excision, a case (3.7%) used TachoSil® and the other one (3.7%) did not.

3.5.2 To determine the effects of TachoSil® patch as haemostatic agent in thyroid and salivary glands surgeries.

The first objective of the study was, to determine the effects of TachoSil® patch as haemostatic agent in thyroid and salivary glands surgeries. The parameters that we considered were: duration of surgery, estimated blood loss intraoperatively, amount of blood transfusion intraoperatively, presence of swelling, hematoma or bleeding at

operative site and the need for post-operative blood transfusion. Mann-Whitney and Pearson chi square test were used to compare the mean difference of related variables between the two studied groups (Table 2).

The duration of surgeries was slightly longer in Tachosil group with the median time of 170 minutes as compared to the non-Tachosil group of 157 minutes (Table 2). Estimated blood loss from both groups had the same median of 200ml, but higher in Tachosil group with interquartile range (IQR) of 50 as compared to non-Tachosil group of 9. There was no significant mean difference of all related parameters between Tachosil and control group (all $p>0.050$). Each group reported one incident of swelling post-operatively secondary to hematoma and seroma.

3.5.3 To determine the effects of TachoSil® patch for drainage in thyroid and salivary glands surgeries.

The second objective of the study was to determine the effects of TachoSil® patch for drainage in thyroid and salivary glands surgeries. Parameters that were taken into account are total post-operative drainage volume, post-operative volume within 24 hours of surgery, drainage volume after 24 hours of surgery, total duration of drain in situ post-operatively and duration of hospital stay. Mann-Whitney and Pearson chi square test were used to compare the mean difference of related variables between the two studied groups (Table 3).

Both groups reported a median of 51mL and 50mL of total post-operative drainage. The drainage volume within 24 hours of surgery did not show any significance (both $p>0.050$). However, a significant difference was seen at drainage volume after 24 hours

of surgery, in which the Tachosil group only recorded 20mL of drainage as compared to non-Tachosil group with 45mL of drainage volume, ($p=0.049$). Significant findings were also recorded on the duration of post-operative drainage with $p=0.045$, where the use of TachoSil® proved to reduce the duration of drain and duration of hospital stay. There was no significant mean difference in other related parameters between TachoSil® and control group ($p>0.050$).

3.6 DISCUSSION

Head and neck surgeries uniquely differs from other systems or organs. The thyroid and salivary glands are in proximity with major vessels and numerous cranial nerves. Injury to cranial nerves by excessive traction or accidental ligation can lead to organ dysfunction, including but not limited to facial asymmetry in parotid surgeries, impaired swallowing, speech and even airway compromised in cases of bilateral vocal cord palsies in post-thyroidectomies. As head and neck region has extensive vascular network, injury can often result in haemorrhage. Intra-operative bleeding can make these miniscule nerves difficult to visualise, thus leading to a higher chance of injury. Post-operative hematoma that is rapid and massive can also compress the nerves, leading to nerve ischaemia and dysfunction. Massive hematoma can also compress air conducts to the lungs, causing life threatening airway compromised. Thus, surgeries in the head and neck area are to be handled carefully and delicately to avoid catastrophic complications.

In our study, after excision of thyroid gland or salivary gland, haemostasis was achieved using the standard methods of controlling bleeding that was local compression, vessels ligation, and thermal cauterization using monopolar or bipolar diathermy. TachoSil® patch was subsequently gently placed on the bed of surgical site resection with its active side (containing human fibrinogen and thrombin) in direct contact with the surgical site to help with haemostasis. It was followed by placement of drainage tube that is connected to vacuum bottle. Muscle, subcutaneous tissue, and skin were later approximated using sutures.

Intra-operatively, we documented the duration of surgery from skin incision to skin closure and estimation of blood loss to gauge the effectiveness of TachoSil® patch in providing haemostasis. We did not detect any significant difference between Tachosil group and non-Tachosil group in terms of reducing the duration of surgeries. The median duration of surgery in Tachosil group were 157 minutes as compared to 170 minutes in Tachosil group ($p=0.395$). This phenomenon could be linked to multiple factors. Although our study included surgeries over the head and neck region, the thyroidectomies, Sistrunk excisions, parotidectomies and submandibulectomy are different from each other with their own set of possible complications. Complexity of procedure contributes to longer hours of surgery. In the Tachosil group, there were 2 cases that recorded long surgical duration. A total parotidectomy requiring removal of pleomorphic adenoma from the deep lobe of parotid gland, which took 280 minutes because there was difficulty in removing the mass in the deep lobe of parotid that has intimate relationship with other important structures of the parapharyngeal space, namely the great vessels of carotid, internal jugular veins and the lower cranial nerves. Another case was superficial parotidectomy for Kimura's Disease that took 545 minutes, as there were difficulties in separating the disease from the normal surrounding tissues. The exact location of the tumour to be operated and the nature of the tumour itself affected the time taken in operation theatre.

In general, superficial parotidectomy with facial nerve preservation will generally be lengthier compared to submandibular gland excision or a hemithyroidectomy, considering that the facial nerve preservation intra-operative requires careful dissection with identification of each branch of the facial nerve itself. It is a time consuming procedure, and even when facial nerve monitoring used intra-operative may reduce the

operative time and risk of facial nerve injury[9], it is still comparatively a lengthier surgery compared to others.

There is also no significant reduction of intraoperative blood loss in Tachosil group as compared to non Tachosil group. The longer the surgery, the higher the blood loss will be. As the Tachosil group has longer operative time, the blood loss is greater, and this justify why there was no significance difference in homeostatic effects of TachoSil® patch between the two groups.

It is also worth noting that the cases, both in Tachosil and non-Tachosil group were operated by different surgeons. Some were undertaken by experienced surgeons, while others were performed by surgical resident under a close supervision of a more experienced surgeon. In a case of hemithyroidectomy performed by surgical resident, the surgery took 210 minutes, as compared to a hemithyroidectomy performed by experienced endocrine surgeon that took only 105 minutes. Cases that were operated by surgical resident usually took longer time compared to more experienced surgeons. Longer surgery, especially more than 4.3 hours is also associated with more complications like greater blood loss. This can be contributed to complexity of procedure and longer exposure of wound to the environment[10]. High volume blood loss leads to low post-operative haemoglobin level which will impaired oxygen and nutrient delivery to surgical wounds causing poor wound healing[10]. Longer operative time is also shown to increase wound infection risks, thus it is critical to repeat the antibiotic dosage during surgery at its appropriate interval dosing time[10]. Some extant studies illustrate that a

more experience surgeon are associated with better surgical outcome and lesser complication rates as compared to surgeons with less experience[11][12].

In post-thyroidectomy, development of haemorrhage or hematoma was rare. Incidence were reported around 1.08%-1.5%[13][14][15], but not without life threatening consequences. Failure to drain the blood from surgical site will lead to formation of hematoma that eventually can compress airway and cause airway obstruction[13][14]. Most of patient tend to notify pressure on the neck and dyspnoea, which was associated with increase in neck circumference[14]. This prompted return to the operation theatre and re-exploration of surgery as early as ten minutes after skin closure and up to 22 days following thyroidectomy[14] to stop the ongoing haemorrhage and relieve airway obstruction[15]. Most of the re-exploration, however, took place within 6 hours post-surgery[14]. In majority of the cases, surgeons were able to identify the source of bleeding, which commonly occurred from skin, subcutaneous tissue, muscles of the neck and thyroid stump[14]. Placement of TachoSil® patch at the surgical wound bed would activate the last step of coagulation cascade, by converting fibrinogen into fibrin and eventually a fibrin clot at the site of bleeding, thus ensuring haemostasis[16][17]. Doing so would help prevent development of hematoma that can compress the cranial nerves, more specifically recurrent laryngeal nerve in thyroidectomy thus prevents vocal cord palsy that can lead to airway obstruction. Returning patient to theatre for re-exploration and evacuation of hematoma post-operative is associated with increased risk of ICU admission, blood transfusion and prolonged hospital stay[14].

A single drainage tube was inserted on each case, both for non-Tachosil group and Tachosil group and connected to a vacuum bottle. The drainage volume was documented by the nurses in ward during each shift. We tabulated the measurements into drainage within 24 hours post-surgery and total drainage volume after 24hours of surgery. The drainage volume within 24 hours for both non-Tachosil and Tachosil group had a median measurement of 5ml. For most cases, the drainage volume was documented to be 'in tubing', means the actual amount of drainage could not be properly measured due to limitation of equipment. This might have contributed to the non-significance result ($p>0.05$) for both groups.

The drainage tubing was removed once the drainage volume reached less than 10ml within 8 hours (corresponding to nurses' shift). Our study demonstrated a significant difference in non-Tachosil and Tachosil group. Non-Tachosil group recorded 45mL of drainage, compared to Tachosil group with 20mL of drainage volume, ($p=0.049$). As the volume was much lesser for the Tachosil group, it allowed the drainage tubing to be removed earlier and allowed for shorter hospital stay post-operative as patient usually discharged home once the drainage tubing is removed. These findings were consistent with existing study that uses TachoSil® patch[16][18].

The study size was notably limited as it was partially conducted during the global COVID-19 pandemic in 2020, in the last few months of the study duration. Most of the elective cases had to be cancelled and that some of our patients were not able to attend follow up appointments. A bigger sample size may reflect the true advantages of TachoSil® patch in terms of haemostasis and drainage in head and neck surgeries.

3.7 CONCLUSION

Head and neck surgery are a complex procedure which can result in various complications especially bleeding related if haemostasis is not secured properly. This study demonstrated that TachoSil® had been beneficial in reducing post-operative drainage volume which led to reduced duration of drain, and eventually reduced hospitalisation time. Hence, the TachoSil® patch is an effective adjunct in head and neck surgery. As it does not prove to be significant in providing intra-operative haemostasis, a bigger sample size study is required to further assess its effectiveness.

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