White Paper

Seal Foam® Polysaccharide - Hemostat in arresting bleeding during spine surgery

July 1, 2011

OBJECTIVE:

Various techniques have been used to stop venous bleeding from the epidural space, vertebral and venous plexus. Here, we describe our experience with the use of Seal Foam® and Tachoseal® to stop venous bleeding in these areas.

METHODS:

Between February 2011 and June 2011, 51 patients undergoing elective, risk of bleeding spine operations were studied. The operation procedures included the approach to the spine for the posterior lumbar intercorporal fusion (PLIF) and transforaminal lumbar intercorporal fusion (TLIF) and decompression-operations . Patients who had acetylsalicylic acid ingestion recent (<5 days) thrombolytic therapy, or anticoagulant therapy (heparin <4 hours preoperatively or warfarin <3 days preoperatively), were excluded. Successful intra-operative haemostasis, intra- and post-operative bleeding, operative time, hospital discharge were evaluated.

RESULTS:

Tube drainage in the first 24 hours was 60 ± 40 mL in the Seal Foam® group and 90 ± 30 mL in the Tachoseal® group. Total postoperative tube drainage was 160 ± 120 mL (range, 140-330mL) in the Seal Foam® group and 190 ± 90 mL (range, 170-440 mL) in the Tachoseal® group. In addition, tube drainage was compared between the 2 groups every 3 hours after operation. Blood loss in the first 3 postoperative hours was less in the Seal Foam® group (40 ± 30 vs 60 ± 100 mL. In the following 3-hour interval, this difference persisted (10 ± 20 vs 20 ± 20 mL).

CONCLUSION:

The high risk of bleeding in high-risk procedures necessitates the use of drugs to reduce postoperative bleeding and transfusion requirements. The aim of this study was to determine if Sealfoam® was efficacious in reducing blood loss and transfusion requirements compared with Tachoseal® in spine operations associated with risk of bleeding.

PATIENTS AND METHODS:

Between between Febuar 2011 and June 2011, 51 patients undergoing elective, risk of bleeding operations were studied. The spine operation procedures included the laminectomy, the approach for the posterior lumbal intercorporal fusion (PLIF) or transforaminal lumbar intercorporal fusion (TLIF) and foraminotomy. Patients who had acetylsalicylic acid ingestion recent (<5 days) thrombolytic therapy, or anticoagulant therapy (heparin <4 hours preoperatively or warfarin <3 days preoperatively), were excluded.

Also, subjects with preexisting coagulation defects (including abnormal preoperative coagulogram [prothrombin time (PT) >18 seconds or partial thromboplastin time (PTT) >50 seconds] or platelet count <109/L, preexisting renal dysfunction (serum creatinine >200 mmol/L), or had autologous donation of blood, were excluded from the study. Consenting subjects were randomized to receive either Sealfoam® or Tachoseal®.

TachoSil® is the only ready-to-use fixed combination of a patch sponge coated with a dry layer of the human coagulation factors fibrinogen and thrombin. The sponge is manufactured from horse tendons. TachoSil® reacts on contact with blood, body fluids or saline to a clot. The sponge is absorbed by the body within a few weeks.

SealFoam® Absorbable Polysaccharide Hemostat is a plant based, absorbable hemostatic foam and is absorbed by the body in 3 days.

51 Patients who need access to decompression and fusion surgery with PLIF or TLIF in at least two segments, were included in the study.

The anesthetic management was standardized. During first the decompression and laminectomy was carried. Thereafter, the access to PLIF or TLIF Cage was created and the cages were placed in the usual manner. The bleeding occurs from the epidural veins were each supplied of the group affiliation.

The Groups were randomized to the use of a topical haemostatic agent (SealFoam® Group 1 or Tachoseal® Group 2) to compare their efficacy in achieving hemostasis. During the operation and after the application of the haemostatic agent, time to hemostase (primary endpoint) was measured in seconds. Also operative time and hospital discharge were evaluated.

After the patient was transferred to the intensive care unit, the drainage was measured hourly. The drains were removed when the total drainage was less than 50 mL over the previous 24 hours. Uniform transfusion criteria were adhered to in all patients. Blood and blood components were administered when the hematocrit level fell to less than 0.24 or the hemoglobin level fell to 7.5 g/L in the postoperative period.

RESULTS:

During the study period (between Febuar 2011 and July 2011), 51 patients (9 women and 42 men) were included and randomized (SealFoam® group, n = 25; TachoSeal® group, n = 26). With respect to surgical procedures performed, the difference between the 2 groups was nonsignificant.

Efficacy was assessed by comparing intraoperative time to hemostasis (primary endpoint) during the operation.

Table 5. Time to hemostasis (primary endpoint)

	SealFoam® group	Tachoseal® group
Patients	(n=25)	(n=26)
hemostasis (sec.)	17.2 ± 3.0	18.9 ± 2.9

In both groups at each of four patients, the procedure had to be repeated after a period of 5 minutes. The reason was a persistent bleeding.

The clot in the Sealfoam Group was removed in all cases after 10 minutes by saline lavage.

Table 1. Operative profile

Procedure	SealFoam® group	Tachoseal® group
Dorale Spondylodesis, PLIF 2 Level	8	12
Dorale Spondylodesis, PLIF 3 Level	7	8
Dorale Spondylodesis, PLIF 4 Level	10	6
Total	25	26

The mean (± SD) ages in the groups were 64 ± 6 and 62 ± 6 years (Table 2).

Patients	SealFoam® group	Tachoseal® group
Age (y)	64 ± 6	62 ± 6
M/F	20/5	22/4
Operative time (min)	185 ± 11	191 ± 17
Hospital death	0	0
Revision Operation	0	0
Hospital stay (d)	9.9 ± 0.98	10.1 ± 1.0

Preoperative and postoperative hemoglobin concentrations, hematocrit levels, platelet counts, PT, and PTT were not significantly different between the 2 groups (Tables 3 and 4).

Table 3. Preoperative hematologic profile

Patients	SealFoam® group	Tachoseal® group
Platelets (10^3)	161 ± 28	158 ± 44
Prothrombin time (s)	11.3 ± 0.8	13.4 ± 1.5
Partial thromboplastin time (s)	28.5 ± 4.1	33.2 ± 13.2
Hemoglobin (g/dL)	12.0 ± 0.7	11.5 ± 1.3
Hematocrit (%)	35 ± 3.7	35.2 ± 3.8

Table 4. Postoperative hematologic profile

Patients	SealFoam® group	Tachoseal® group
Platelets (10^3)	109 ± 31	109 ± 28
Prothrombin time (s)	16 ± 2.5	15.7 ± 1.4
Partial thromboplastin time (s)	39.7 ± 16	42.1 ± 34
Hemoglobin (g/dL)	9.9 ± 1.2	9.6 ± 1.1
Hematocrit (%)	25.8 ± 3.5	24.5 ± 2

No differences were found in the dosage of heparin during and after the operations.

Tube drainage in the first 24 hours was 60 ± 40 mL in the Seal Foam® group and 90 ± 30 mL in the Tachoseal® group. Total postoperative tube drainage was 160 ± 120 mL (range, 140-330mL) in the Seal Foam® group and 190 ± 90 mL (range, 170-440 mL) in the Tachoseal® group. In addition, tube drainage was compared between the 2 groups every 3 hours after operation. Blood loss in the first 3 postoperative hours was less in the Seal Foam® group (40 ± 30 vs 60 ± 100 mL. In the following 3-hour interval, this difference persisted (10 ± 20 vs 20 ± 40 mL.

In the remaining 3-hour intervals, the blood loss in the SealFoam® group was lower compared with the Tachoseal® group, but the differences did not reach a significant level. None of the patients received packed red blood cells.

CONCLUSION:

Spine surgery can be associated with a significant consumption of allogenic blood products, often as a result of acquired hemostatic defects and/or incomplete surgical haemostasis. Management of the abnormal bleeding exposes the patient to the morbidity of reoperation and/or excessive, and sometimes inappropriate, blood-product transfusions. However, some patients or operations are at an increased risk for allogenic transfusions because of excessive bleeding perioperatively. The risk factors include repeat spine operation; complex procedures, such as multiple level decompression PLIF or TLIF procedures or corporectomy and procedures requiring long operation times, such as combined procedures (ventro-dorsal-ventral approach).

Topical HAs composed of a gelatine-based matrix and thrombin have been reported to be effective, in addition to traditional means, in terminating bleeding during spine operations in comparison with haemostatic patches or sponges composed of either oxidized regenerated cellulose or purified porcine skin gelatine. In animal models, comparing safety, efficacy, presence of residual material and foreign body reaction of commonly used agents such as microporous polysaccharide hemospheres (Arista®), oxidized cellulose (Surgicel®), microfibrillar collagen (Avitene®) and gelatin matrix thrombin sealant (FloSeal®).

Avitene® and FloSeal® demonstrated a propensity for causing granuloma formation. [Hait MR. Comparative evaluation of Avitene microcrystalline collagen hemostat in experimental animal wounds. Am J Surg. 1973;125:284].

SealFoam® Absorbable Polysaccharide Hemostat is a plant based, absorbable hemostatic foam and is absorbed by the body in 3 days.

A special advantage the plant origin of the material has to be seen. This eliminates the usual remaining-risks of infection or reactions to animal or human products. In addition, a complete absorption of the material within 3 days was operated in studies.

In conclusion, the significant blood-loss reduction effect of the polysaccharide Hemostat SealFoam®, easy application and low cost, renders this agent attractive for spine operations associated with high risk of bleeding.

In the present study, there was a difference between the Sealfoam® and the Tachoseal® groups in terms of intraoperative blood loss and postoperative drainage volumes but did not reach a significant level.

No major immediate or delayed complications were observed in either group. SealFoam® is an excellent option for hemostasis in the epidural space and vertebral venous plexus.

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Brief Curriculum

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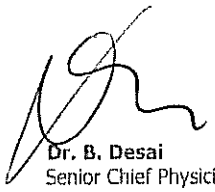
I hereby authorize the SMI, the white paper titled: "Seal Foam polysaccharides - Hemostat in arresting bleeding during spine surgery" from July 1, 2011 to use for marketing purposes.



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Medical education
1989 -1996: Medical School, Bonn University, Germany and Innsbruck University, Austria

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Promotion (MD)
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Medical training

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Board certification
2002-02 General surgery

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