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Comparison the efficacy of hemorrhage control of Surgiflo Haemostatic Matrix and absorbable gelatin sponge in posterior lumbar surgery

A randomized controlled study

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Abstract

Objective: To compare the hemostatic effect of hematostatic agent Surgiflo and absorbable gelatin sponge (AGS) in posterior lumbar surgery.

Methods: A total of 60 cases were recruited during August 2016 and June 2017 according to the inclusion and exclusion criteria. Patients were randomly allocated to the Surgiflo Haemostatic Matrix (SHM) group or the AGS group (AGS) by computer-generated randomization codes. The success rates of hemostasis for 3 minutes and 5 minutes, the time of operation, the amount of intraoperative bleeding, the volume of autogenously blood transfusion, the amount of blood during hemostasis, the amount of blood transfusion, and BP, RBC, HCT, HB of preoperative, 2 to 3 days, and 5 to 7 days following operation were recorded to compare. Daily drainage and all adverse events after operation were also compared.

Results: All the patients were followed up for at least 1 month. The RBC and HCT of the AGS group before operation were lower than those in the control group ($P = .039$, $P = .029$), but there was no difference after operation ($P > .05$). In the control group, 19 cases were successfully hemostatic in 3 minutes, 4 cases were successful in 5 minutes, and 7 cases were combined with hemostasis. In the SHM group, it was 22, 3, and 5 cases respectively. There was significant difference in blood loss during hemostatic process between the 2 groups ($P < .001$). There was no difference in the amount of blood loss and autologous blood transfusion between the 2 groups, and there was no difference in the operation time between the 2 groups. In the AGS group, allogeneic blood was infused in 1 case during operation, and no allogeneic blood was infused in the other patients. The drainage volume on the 1st day and the 2nd to 4th day after operation in the AGS group was less than that in the control group ($P = .015$, $P = .010$).

Conclusion: Compared with AGS, SHM could decrease the blood loss during hemostatic process and the postoperative drainage volume in posterior operation of lumbar degenerative disease. SHM is a safe and effective hemostatic agent in lumbar posterior surgery.

Abbreviations: AGS = absorbable gelatin sponge, HCT = hematocrit, RBC = erythrocyte count, SBP = systolic blood pressure, SHM = Surgiflo Haemostatic Matrix.

Keywords: absorbable fluid gelatin, absorbable gelatin sponge, hemostatic material, spine, surgery, Surgiflo

1. Introduction

Posterior lumbar fusion surgery has a high rate of success, although intraoperative concerns and complications exist. Bleeding during surgery was one of the most important problems that spinal surgeons often faced. The degree and location of bleeding in different spinal surgery are different. The main bleeding in the operation of epidural cavity is the rupture of the intraspinal venous plexus. Patients with lumbar spinal stenosis often suffer from long-term compression of the spinal canal. The vascular wall of the intraspinal venous plexus is thinner than normal. After decompression, the blood vessels of the veins are irritated and easily ruptured, which lead to bleeding. The improper hemostasis may lead to cauda equine syndrome, nerve root injury because of the small space operation. In elderly patients, the blood vessel sclerosis, the coagulation function is slightly abnormal, it is more difficult to stop bleeding of the intervertebral venous plexus bleeding during intervertebral decompression, which can lead to incomplete hemostasis during the operation, massive drainage of the wound after operation, and the need for continuous prevention of infection and blood transfusion treatment. This not only increases the economic burden of patients but also increases the risk of infection of blood-borne diseases. Prolonged use of antimicrobial agents may lead to a variety of adverse events as a result of a decrease in the patient's body resistance.

At present, the main hemostatic method for intervertebral venous plexus hemorrhage is filling of gelatin sponge, however,

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too much gelfoam may lead to compression of spinal cord, cauda equina nerve and nerve root,[1] there are also reported cases of emergency removal surgery due to gelfoam compression. Therefore, it is very important to find a convenient, fast and effective hemostatic method in posterior lumbar surgery. Absorbable hemostatic products, a new kind of hemostatic materials, have been widely used in various surgical operations to assist hemostasis.[2–9] Surgiflo Haemostatic Matrix (SHM) plus flextip (Surgiflo, Johnson & Johnson Wound Management, Somerville, NJ) is an absorbable gelatin matrix hemostatic material that has been widely used in other surgical procedures.[10–13] The liquid form allows injection to the place where hemostasis is required, and the fluid state can be dispersed into the local irregular cavity to have hemostatic effect on the local area. However, this new product has been little reported to be used in posterior lumbar surgery and the safety and efficacy remains controversial. A prospective, randomized and controlled study was conducted in our hospital to compare the hemostatic effect of hematostatic agent Surgiflo and absorbable gelatin sponge (AGS) (Fukangsen, Guilin fukangsen medical equipment co. LTD) in posterior lumbar surgery.

2. Materials and methods

All participants signed the informed consent form, applied and recorded to the ethics committee, fully respecting the principle of voluntary participation and withdrawal of the patients. This study was approved by medical ethical committee of our hospital.

Inclusion criteria: lumbar 3 to sacral segment 1 patients who underwent posterior spinal canal decompression, bone grafting, and internal fixation, the hemostatic material is fluid gelatin or gelatin sponge only. The operation is performed by a doctor only. Exclusion criteria: BMD ≤ -2.0, platelet $<50/109/L$, coagulation index more than normal 20%. Cerebrospinal fluid leakage patients were found during and after operation.

From August 2016 to June 2017, a total of 60 cases that underwent posterior lumbar decompression and fusion, and meet the inclusion and exclusion criteria were recruited at last. Patients were randomly allocated to the Surgiflo group or the control group. The random and blind methods were as follows: The number of patients undergoing posterior spinal surgery in the study was numbered in the order of operation. The sequence was randomly divided by statistical experts into 2 groups (the SHM group and the AGS group), the patient then enters the corresponding grouping, it was only before the operation began that the surgeon knew the hemostatic material used for the patient, if cerebrospinal fluid leakage occurred after operation, the patient will automatically be excluded until all effective patients have 60 cases. Blind method to a patient and a statistician. The SHM group (30 cases) was treated with absorbable fluid gelatin Surgiflo for hemostasis. The AGS group (30 cases) was treated with AGS Fukangsen for hemostasis. Fluid gelatin is a sterilized and absorbable porcine gel fluid matrix of 8 mL. After mixed evenly with 2 mL saline during the operation, it is sprayed on the wound to stop bleeding. The basic ingredient is porcine gelatin extract. The principle of hemostasis is to form a fluid gelatin matrix, which can be completely absorbed in the human body within 4 to 6 weeks by physical compression and physical stent for platelet aggregation. There is no compression effect on the spinal cord or cauda equina. Gelatin sponge is 60 mm $\times$ 20 mm $\times$ 5 mm in size. It is a white, sterile, absorbable sponge made of gelatin. It is hydrophilic and collagen for the common use of hemostatic materials in surgical procedures.

2.1. Surgical procedures and hemostasis

After general anesthesia, the patient was put in a prone position with abdominal suspension. The anesthesia used for 2 groups were same, the operation position was same, and the hypertension was adjusted to normal. All patients received the same degree of controlled hypotension during surgery. The lesion was marked with the help of X-rays, the electric knife dissects the paraspinal muscles on the spinous process and strips the paravertebral muscles along the surface of the vertebral lamina to both sides of the articular process joints and transverse processes. The pedicle screw was placed and the position of pedicle screw was confirmed by X-rays. The spinous process and ligamentum flavum were removed. The affected disc was removed and cartilage endplate was scraped off. Appropriately sized cage filled with autologous bone was inserted and confirmed by X-rays. Then the titanium rod was properly connected. Again, the fluoroscopy was used to finally confirm the position of implants. Bipolar electrocoagulation was used for hemostasis when bleeding during soft tissue incision. Autologous blood transfusion device is used during the operation, but another suction device is used during the hemostasis process to facilitate the collection of bleeding during the hemostasis process, meanwhile, it also helps to avoid hemostatic products from entering autologous blood recovery system so as to avoid patients with abnormal coagulation function. Internal bleeding in the spinal canal is hemostatic with gelatin sponge or fluid gelatin. Gelatin sponge hemostasis is as follows: assistant pruning gelatin sponge into long or square shape. Place 1 or more gelatin sponges on the lateral margin of the posterior spinal canal to avoid direct compression of the dura mater, and then apply 1:200 thousand epinephrine cotton slice to stop bleeding. Use the hemostatic product for 3 minutes and 5 minutes to observe the hemostatic effect. If 1 hemostasis is unsuccessful, repeat the procedure again, and if the hemostasis is still unsuccessful, use a combination of gelatin sponge and fluid gelatin to hemostasis until the hemostasis is successful. No matter which hemostatic material, the hemostatic material is not removed, the excess part is removed. After hemostasis, gelatin sponge covers the exposed dura. Drainage tubes were placed beside the incision to drain the hemorrhage in the incision. The muscle layer was sutured loosely and the deep fascia was sutured continuously to avoid the bleeding from the deep incision.

If the bleeding rate gradually slows so that there is no more obvious bleeding, the hemostasis is considered successful; otherwise, it is regarded as a hemostatic failure. The success rate of hemostasis for 3 minutes and 5 minutes is recorded, the operation time, the blood loss during the operation, and the amount of bleeding during the hemostasis process are recorded. Blood transfusion volume within 1 week after operation. The changes of systolic blood pressure (SBP), diastolic blood pressure (DBP), erythrocyte count (RBC), hematocrit (HCT), hemoglobin, platelet count, white blood cell count (WBC), neutrophil percentage (neutrophil) and lymphocyte percentage were recorded on the 2 to 3 days and 5 to 7 weeks after operation. The drainage volume was also recorded. All adverse events were recorded.

The data were managed by a single person. This study was based on the observation of different materials to hemostasis of intraoperative bleeding, followed up for 1 month, and observed the occurrence of adverse events after discharge.

2.2. Statistical analysis

The data were analyzed using statistical software (IBM SPSS Statistics for Windows, Version 17.0). The chi-square test was

Table 1

The basis data of 2 groups.

	Male	Female	Age, year	BMI	Length of hospital stay, day	Segment fused
AGS	14	16	57.7 ± 13.93	23.67 ± 2.41	15.3 ± 5.32	1.33 ± 0.48
SHM	12	18	58.37 ± 9.78	23.82 ± 2.41	15.2 ± 4.30	1.27 ± 0.45

No difference was statistically significant between 2 groups, all $P > .05$. AGS = absorbable gelatin sponge, SHM = Surgiflo Haemostatic Matrix.

used to classify variables, and the measured data were expressed as mean ± standard deviation. The Anova variance analysis was used to test the statistical significance of all the measured data ($P <$. 05).

3. Results

In the SHM group, there were 12 male cases and 18 female cases; and there were 22 cases operated on 1 segment, 8 cases operated on 2 segments. In the AGS group there were 14 male cases, 16 female cases; 1 segment fusion in 21 cases, 2 segmental fusion in 9 cases; the gender, age, BMI, fusion level, length of hospital stay, surgical segment of 2 groups were not statistically significant, $P > .05$ (Table 1).

The RBC in the SHM group before operation was less than that in the AGS group ($P = .039$), the HCT was less than that in the AGS group ($P = .029$), the SBP in the SHM group was higher than that in the AGS group on the 2 to 3 days after operation ($P = .006$), and the 5th to 7th day after operation($P = .037$). The other laboratorial data were no difference between 2 groups. See Table 2.

In the AGS group, the bleeding could not stop completely during the hemostasis process, and always found a little exudation, there were 7 cases with more exudation and with combined hemostasis in them. In the SHM group, there will be some cases that the bleeding is stopped immediately when the fluid gelatin is injected into the hemostatic par, without the need cotton flake to compress. And some needs local compression to stop bleeding and then no re-bleeding. However, few patients had the phenomenon of fluid gelatin being washed away by blood. At this time, only 3 cases successfully stopped hemostatic with fluid gelatin again, while the others (5 cases) needed to be filled with small pieces of gelatin sponge first and then taken the fluid gelatin on it and stop bleeding immediately (Table 3).

One patient in the AGS group transfused red blood cell of 2u and 150 mL fresh frozen plasma during operation, and none of the other patients received allogeneic blood transfusion. The amount of bleeding during the hemostasis process of the SHM group is less than that of the AGS group ($P < .001$). Patients in both groups were treated with subfascial wound continuous drainage and the drainage tube was removed if the drainage volume/24 hours is less than 50 mL. All drainage tubes were removed 2 to 4 days after operation. The patients were discharged from hospital on 5 to 7 days after operation. The drainage volume of the SHM group was less than that of the AGS group at first 24 hours after operation ($P = .015$), and the amount of drainage was also less than that of AGS group on the 2 to 4 day after the operation ($P = .010$). There was no statistical difference in the amount of bleeding, blood transfusion and operation time between the 2 groups, but the SHM group was less than the AGS group (Table 4).

Adverse events: the comorbidities in 2 groups were not significantly different. One case of intermuscular vein thrombosis in both groups disappeared after anticoagulant therapy. Cerebrospinal fluid leakage was observed in 3 cases in the AGS group and 2 cases in the AGS group after operation and they were excluded. All patients were followed up for at least 1 month. Including the 5 patients excluded, no patients were re-admitted to hospital because of postoperative complications and no adverse effects of fluid gelatin were observed in both groups.

4. Discussion

The intraspinal venous plexus, also known as the Batson venous plexus, is a part of the vertebral venous system and consists of a number of small valvular veins. These veins surround the ventral and dorsal side of the dural sac and then converge at the intervertebral foramen to form the extramedullary venous

Table 2

The blood pressure and laboratorial data of 2 groups in preoperative and postoperative time.

Time	group	SBP(mmHg)	DBP(mmHg)	RBC	HB(g/L)	HCT	PCT	WBC	N%	L%
Pre-operation	AGS	133.73 ± 15.48	78.43 ± 10.54	4.53 ± 0.46	136.30 ± 11.27	0.41 ± 0.03	175.50 ± 49.51	5.84 ± 1.47	59.56 ± 12.64	28.63 ± 8.54
	SHM	133.20 ± 19.30	80.47 ± 12.02	*4.30 ± 0.36	131.17 ± 15.53	#0.39 ± 0.04	158.73 ± 49.16	5.55 ± 1.25	60.42 ± 9.10	30.01 ± 8.72
The first day postoperatively	AGS	109.97 ± 13.57	64.97 ± 10.21	3.89 ± 0.53	117.30 ± 14.24	0.37 ± 0.07	163.97 ± 41.62	13.53 ± 3.60	88.46 ± 4.97	7.31 ± 3.91
	SHM	109.80 ± 13.90	61.53 ± 12.60	3.66 ± 0.42	111.47 ± 13.86	0.34 ± 0.03	149.47 ± 42.32	12.57 ± 3.99	89.28 ± 4.42	6.73 ± 2.89
The 2-3 day postoperatively	AGS	113.57 ± 13.74	65.33 ± 8.02	3.77 ± 0.56	113.80 ± 15.95	0.35 ± 0.07	163.78 ± 58.32	15.16 ± 14.34	85.16 ± 8.81	10.01 ± 6.46
	SHM	ε123.57 ± 13.20	69.10 ± 10.40	3.56 ± 0.47	108.43 ± 15.98	0.33 ± 0.04	157.80 ± 47.59	11.26 ± 2.97	83.39 ± 6.53	10.87 ± 5.70
The 5–7 day postoperatively	AGS	113.97 ± 11.70	66.13 ± 8.43	3.87 ± 0.50	115.67 ± 13.33	0.35 ± 0.04	222.73 ± 81.27	10.87 ± 2.93	74.24 ± 7.50	17.39 ± 6.06
	SHM	δ121.80 ± 14.88	69.00 ± 9.26	3.71 ± 0.41	112.83 ± 14.20	0.34 ± 0.04	190.40 ± 53.10	9.52 ± 2.92	74.57 ± 7.74	17.50 ± 6.94

AGS = absorbable gelatin sponge, SHM = Surgiflo Haemostatic Matrix.

* $P = .039$.

$P = .029$.

ε $P = .006$.

δ $P = .037$ compared with the AGS group, the difference was statistically significant $P < .05$.

Table 3

Success rates of hemostasis in 2 groups.

Group	The success rate of hemostasis for 3 minutes	The success rate of hemostasis for 5 minutes
AGS	19/30	4/30
SHM	22/30	3/30

AGS = absorbable gelatin sponge, SHM = Surgiflo Haemostatic Matrix.

plexus. When the intervertebral disc is herniated and the vertebral canal is narrow, the Batson venous plexus in the spinal canal is compressed and the reflux is limited, which results in the venous irritation. It is inevitable to touch or cut the vein of the angry opening during the operation, and the bleeding is difficult to control. The commonly used method of hemostasis is bipolar electrocoagulation. On the one hand, the effect on venous plexus hemorrhage is limited, and on the other hand, the local heat-producing effect has the risk of damaging the peripheral nerve. Local hemostatic preparation can achieve satisfactory hemostatic effect.[14]

The AGS, which is supported by gelatin in animal skin, is baked into a sponge. Although it is derived from animals, it has basically no antigenicity. It has a large absorbent surface and can inhale blood several times the weight of itself. The effect of local hemostasis was achieved by solidifying it in the sea surface.[15,16] Gelatin sponges can be absorbed in the body after 4 to 6 weeks, but since gelatin sponge absorbs more than 30 times its own volume, it is not recommended to keep it in the spinal canal. In order to avoid the nerve compression caused by blood-sucking swelling, the cases of postoperative acute paraplegia caused by gelatin sponge have been reported abroad.[17] Alander et al reported a case of acute quadriplegia after ACCF.[18] During the exploration, it was found that the blood-sucking swelling gelfoam filled the whole decompression area. Part of the gelatin sponge was removed after hemostasis, but the removal process often resulted in rebleeding and repeated hemostasis was required.

Absorbable hemostatic gelatin sponge (SurgifloTM), (short for short: fluid gelatin) is a sterile and absorbable porcine gel fluid matrix. After mixed evenly with 2 mL saline during the operation, it is sprayed on the wound for hemostasis. Stop the bleeding by physical compression and provide a physical scaffold for platelet aggregation, without forming a knot, without oppressive effects on the spinal cord or cauda equina nerve. The fluid matrix provides an environment in which platelets are adhered to and polymerized. In turn, a natural platelet-coagulation waterfall reaction occurs, and the patient's endogenous thrombin is activated, the particle state of gelatin matrix is consistent with the irregular wound, and the filling effect is produced in the expansion of the surgical site.[19] The hemostatic matrix is hydrophilic and melts well with the wet tissue. In contrast, other materials such as fibrin glue require a dry surface, and the fluid gelatin has a fluid state which allows it to enter an irregular cavity. The filling fluid gelatin fills the irregular gap between the dura mater and the spinal canal to stop bleeding. So, we found that the amount of bleeding during the hemostasis process of the SHM group is less than that of the AGS group. The preoperative RBC and HCT in the experiment group were less than those in the AGS group, but RBC and HCT were the same after operation, indicating that less RBC was lost during operation in the experiment group, The early postoperative SBP in the AGS group was lower than that in the AGS group, which may be related to more intraoperative bleeding. At the same time, the amount of intraoperative bleeding, the volume of autologous blood transfusion and the time of operation in the trial group were less than those in the AGS group, although the difference was not statistically significant, the postoperative drainage volume in the trial group was less than that in the AGS group. It shows that fluid gelatin has more advantages than gelatin sponge in hemostasis of spinal canal. In fact, solid hemostatic material cannot well touch or contact the errhysis wound compared with the liquid hemostatic material during the lumbar spine surgery, because hemostasis by compression is very dangerous for nerve and spinal cord. In a very small and irregular space, liquid hemostatic material has the theoretical superiority than solid hemostatic material. However, because of the hydrophilicity and fluid state of fluid gelatin, if the speed of bleeding in the spinal canal is very fast, the blood will be "washed away" because of the dilution of the fluid gelatin, which will not stop the bleeding. And in this case, a combination of Surgiflo and AGS can be used theoretically.

Some limitations should not be ignored. First, the sample size of this study is relatively small, the base line of 2 groups was approximately matched because of random allocation, but it is not completely matched since the limited sample size; Second, the hemostatic process is not blind because of different type of hemostatic material is so obvious to distinguish and observer bias may existed. Third, the hemostasis is influenced by so many factors and the confounding factors may have an impact on the results in this study.

In conclusion, compared with gelatin sponge, Surgiflo can decrease the blood loss during hemostatic process and the postoperative drainage volume in posterior operation of lumbar degenerative disease. Surgiflo is a safe and effective hemostatic agent in lumbar posterior surgery. Future prospective, randomized, controlled studies with larger sample sizes were needed for further investigation.

Author contributions

Conceptualization: Yi Yang.
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Table 4

The blood loss, transfusion, drainage volume and operation time between the 2 groups.

	The amount of bleeding, mL	Blood transfusion, mL	Blood loss during the hemostasis process, mL	The drainage volume of the first day after operation, mL	The drainage volume of the 2nd-4rd day after operation, mL	operation time, min
AGS	323.00 ± 183.32	158.67 ± 98.04	33.72 ± 13.23	321.33 ± 189.77	216.00 ± 95.18	178.43 ± 60.35
SHM	301.33 ± 189.24	142.33 ± 102.88	20.82 ± 10.05*	242.67 ± 81.28#	162.00 ± 97.25@	169.91 ± 66.37

Compared with the AGS group, the difference was statistically significant. AGS = absorbable gelatin sponge, SHM = Surgiflo Haemostatic Matrix.
* $P = .000$.
# $P = .015$.
@ $P = .010$.

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