Master's Thesis of **Haolin Zheng**

Which topical agent is more efficacious in diminishing postoperative drainage following multi-level cervical laminoplasty/laminectomy: Tranexamic acid- versus Thrombin-soaked collagen sponge?

경추 다분절 후궁성형술/후궁절제술 후 배액량 저감 방법: 트라넥삼산 함유 콜라겐 스펀지와 트롬빈 함유 콜라겐 스펀지의 효과 비교

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Abstract

Objectives : To compare the efficacy of topically applied tranexamic acid (TXA)-soaked versus thrombin-soaked collagen sponges in diminishing postoperative drainage following cervical 4-6 level laminoplasty/laminectomy.

Summary of literature review : Both TXA-soaked and thrombin-soaked sponges are reported to be effective in decreasing postoperative blood loss following spine surgery. However, we could not find a report on which one is more efficacious.

Conclusions : Topical application of TXA-soaked collagen sponges before wound closure provides higher efficacy with similarly high safety compared with thrombin-soaked collagen sponges in decreasing postoperative drain output following multi-level cervical laminoplasty/laminectomy.

Keyword : cervical, postoperative drainage, tranexamic acid, thrombin, collagen sponge

Student Number : 2018-20238

Table of Contents

Chapter 1. Introduction

1.1. Study Background

Various materials and measures to diminish postoperative hemorrhage following spine surgery have been employed in order to prevent postoperative complications such as epidural hematoma and neurologic deficits and to minimize length of hospital stay. Recently, topical application of absorbable sponges soaked in hemostatic agent solutions at the end of the surgery has been reported [1–3]. Application of absorbable gelatin sponges soaked in tranexamic acid (TXA), an antifibrinolytic agent, has been reported to be safe and effective for reduction of postoperative blood loss in lumbar spine surgery [1,2]. Thrombin-soaked absorbable gelatin sponges placed before wound closure is reported to significantly decrease postoperative drain output following multi-level posterior cervical spine surgery [3]. Therefore, topical application of either TXA- or thrombin-soaked sponges is promising in decreasing postoperative hemorrhage or drain output.

1.2. Purpose of Research

To compare the efficacy of topically applied TXA-soaked versus thrombin-soaked collagen sponges in decreasing postoperative drainage following multi-level cervical laminoplasty/laminectomy.

1.3. STUDY DESIGN

A retrospective comparative analysis.

Chapter 2. Body

2.1. Materials and Methods

2.1. 1 Selection of the participants

In July 2016, the corresponding author started to topically apply absorbable sponges soaked in TXA (Tranexamic Acid, Shinpoong, Seoul, Korea) or thrombin (Thrombin Lyophilized Powder, Reyon, Seoul, Korea) before wound closure in posterior cervical spine surgery in an effort to minimize postoperative hemorrhage. Until April 2017 he did not establish a standardized protocol for the application of those sponges. Thus, intraoperative hemostasis strategy using the sponges had varied on a case by case basis. Either gelatin sponges (Spongostan Standard, Ferrosan Medical Devices, Soeborg, Denmark) or gentamicin-containing collagen

sponges (Collatamp G, EUSA Pharma, Oxford, UK) were arbitrarily used, and the size and number of the sponges varied in individual procedures. Either TXA or thrombin was chosen arbitrarily and their doses varied as well. In addition, in some of the patients, but not in all, TXA was intravenously administered at the beginning of the operation. Since a standardized protocol for hemostasis had not been established, all patients operated on during this period were excluded from this study (Fig. 1).

In May 2017 the corresponding author standardized a protocol for topical application of the sponges and intravenous administration of TXA, which will be described below. Thereafter, all consecutive patients who underwent posterior cervical spine surgery and met the indication/contraindications described in Table 1 were treated with topically applied TXA- or thrombin- soaked collagen sponges according to the standardized protocol. Regardless of the type of surgical procedures, TXA and thrombin was used alternatively. In all of these patients, TXA was intravenously injected just before the operation as well, according to the standardized protocol described below.Among the patients who underwent posterior cervical spine surgery following the standardized protocol

between May 2017 and March 2019, only those patients who fulfilled the selection criteria described in Table 2 were enrolled in this study. The selection criteria (Table 2) were strictly determined to minimize inhomogeneity of cases, which is one of the inherent limitations of retrospective analyses. Accordingly, only those who underwent a total of 4-6 level laminoplasty/laminectomy including 3-4 level open-door laminoplasty using plates (Centerpiece, Medtronic, Memphis, TN) were included, and all cases with larger or smaller number of those surgical levels were excluded. All fusion cases were excluded as well. The selected participants were categorized into 2 groups: TXA and Thrombin groups (Fig. 1).

For Control group, among the patients who underwent posterior cervical spine surgery between January 2015 and June 2016 without either topical TXA/thrombin-soaked sponge application or intravenous TXA injection, all consecutive patients who fulfilled the same selection criteria (Table 2) were initially chosen. Among them we enrolled only those who also met the same indication/contraindications for application of topical sponges and intravenous TXA injection (Table 1) even for this Control group for the

purpose of fair comparison.

2.1. 2 General surgical procedures

The following procedures were performed uniformly in all patients in any of the 3 groups. All operative procedures were performed by a single surgeon (the corresponding author) and partly by his fellows under his supervision at a single hospital.

In all patients included in this study, open-door laminoplasty was carried out using laminoplasty plates at least at all three levels of C4, C5, and C6 under microscopy. Any patients who had ≤2-level laminoplasty were excluded from this study. At C7, if it was operated on, cranial partial laminectomy with undercutting instead of laminoplasty was selected to minimize postoperative axial neck pain [4–6], except in one patient for whom laminoplasty was inevitable. At C3, total or caudal partial laminectomy was chosen according to the extent and degree of spinal cord compression. At this level, open-door laminoplasty, which might result in

C2-3 interlaminar fusion and/or limited range of neck extension [6,7], was not carried out in any patient. If the spinal cord compression extended to C2, dome-like laminoplasty of C2 [8] was added. Most common combination of the decompressive procedures was C3 total laminectomy; C4, C5, and C6 open-door laminoplasty; and C7 partial laminectomy (Figs. 2 and 3A). At all laminoplasty levels in all patients, spinous processes and any impinging bone between adjacent laminae were removed using a burr (Figs. 2 and 3A) to improve range of neck extension [6,9]. This procedure increased the area of bleeding bony surfaces.

After the main procedures were completed and massive irrigation was carried out, flowable gelatin-thrombin matrix sealant (Floseal, Baxter Healthcare, Westlake Village, CA) was applied over exposed epidural areas and bleeding bony surfaces and thrombin-soaked cottonoid pledgets were placed over the matrix sealant to achieve meticulous hemostasis (Fig 3A). Muscle bleeding was controlled with bipolar electrocautery. While the operative field was compressed using gauzes, two deep suction drain tubes (Hemovac, Zimmer, Warsaw, IN; or Barovac, Sewoon Medical, Seoul, Korea) were inserted and tagged. Thereafter, the gauzes and cottonoid

pledgets were removed (Fig. 3A). Then, in TXA and Thrombin groups, topical sponges were applied in a way described below (Fig. 3B). One gram of vancomycin powder was sprinkled into the surgical wound (Fig. 3C). The wound was closed in layers.

2.1. 3 Standardized protocol for topical sponge application and intravenous TXA injection

In TXA and Thrombin groups, all patients received intravenous bolus injection of 1-gram TXA at the time of surgical site skin preparation and draping. On the contrary, it was not injected in Control group.

In TXA group, after adequate hemostasis was achieved and the gauzes and cottonoid pledgets were removed at the end of the surgical procedures (Fig. 3A), two sheets of 5×5 cm gentamicin -containing collagen sponges soaked in 1-gram TXA solution (10 mL) were placed over the laminae (Figure 2B). Approximately 5 minutes of soaking time was required for the collagen sponges to change into a readily applicable form by losing its original tenacity. Afterwards, the collagen sponges became relatively mushy and clingy so that it was easily applicable over the laminae using 2 pairs of forceps, obliterating the space between the

irregular bony surfaces and the collagen sponges. We did not cover the exposed dura mater at the total/partial laminectomy sites in order to avoid possible dural compression by the expanded sponge. In the meanwhile, the laminoplasty plates on the open side were partially covered beacuse the plates could prevent dural compression by the sponges. Remaining TXA solution, which contained gentamicin released from the collagen sponge, was poured onto the paraspinal muscles after the deepest one of the 3 muscle layers was closed.

In Thrombin group, the same collagen sponges were soaked in 5,000-IU thrombin solution (5 mL) and topically applied in the same way. In Control group, neither intravenous TXA injection nor topical application of collagen sponges was applied.

After wound closure, negative pressure was immediately applied to the suction drain in Control group. On the contrary, in TXA and Thrombin groups, we temporarily clamped the drain to retain the topical agents and released it one hour later.

2.1. 3 Statistical analysis

Collected data were compared among the 3 groups using chi-square test; and one-way ANOVA test with post-hoc Student-Newman-Keuls test. The level of statistical significance was set at a 2-tailed $p<.05$. We used

MedCalc Statistical Software version 18.11.3 (MedCalc Software bvba, Ostend, Belgium) for statistical analysis.

2.2 Resluts

2.2.1 Participant population and baseline data

Among the 166 patients who underwent posterior cervical spine surgery between May 2017 and January 2019, 95 patients received the topical application of TXA- or thrombin-soaked collagen sponges and intravenous TXA injection according to the standardized protocol (Fig. 1). Among them 53 consecutive patients who met the selection criteria were enrolled in this study: 27 patients in TXA group and 26 patients in Thrombin group. All of the 56 patients who underwent posterior cervical spine surgery between July 2016 and April 2017 were excluded from the study, because in this period the standardized protocol for topical sponge application and intravenous TXA injection had not been established. All patients who underwent posterior cervical spine surgery between January 2015 and June 2016 did not receive either topical sponge application or intravenous TXA injection. Among those 142 patients, 31 consecutive patients who met the indication/contraindications and

selection criteria were enrolled in Control group.

Table 3 summarizes the baseline characteristics of enrolled patients in the 3 groups. There were no statistically significant differences among the 3 groups ($p>.05$, respectively).

2.2.2 Postoperative drain output

Table 4 summarizes the 4 parameters related to postoperative drain output. The time for the 8-hour drainage to decrease to <30 mL was 15±7, 23±10, 29±10 hours in TXA, Thrombin, and Control groups, respectively. The drain output until this time was 41±37, 88±60, 186±78 mL, respectively. The time for the 8-hour drainage to decrease to <20 mL was 29±9, 35±11, 41±10 hours in TXA, Thrombin, and Control groups, respectively. The drain output until this time was 77±41, 124±61, 215±66 mL, respectively. All of these 4 parameters were significantly different among the 3 groups ($p<.001$ on one-way ANOVA test, and $p<.05$ on post-hoc analysis in every pairwise comparison, respectively), with the most best results in TXA group sequentially followed by Thrombin and Control groups.

2.2.3 Related postoperative complications

There were no patients in any group who had (1) postoperative hematoma formation and/or neurologic deficits; (2) any other postoperative complications potentially attributable to topical hemostatic agents; or (3) reoperation and/or readmission within one month of the index surgery.

2.3 Discussion

Multi-level posterior cervical spine surgery tends to lead to considerable amount of postoperative hemorrhage and drainage unlike anterior cervical spine surgery. Even though epidural bleeding may be successfully controlled using flowable granulose gelatin-thrombin matrix sealant, bleeding from multi-layered paraspinal muscles and large exposed bony surfaces with/of relatively long/wide/large wound size may not be satisfactorily controlled with it. Physical coverage or compression using absorbable sponges may be more effective to control bleeding from them, and this effect may be enhanced when used in conjunction with biological effect of TXA or thrombin [1,3]. Even though both tranexamic acid- and thrombin-soaked sponges are reported to be effective in decreasing postoperative hemorrhage/drainage following

spine surgery [1–3], we could not find any report on which one is more efficacious. Therefore, in the current study, we sought to determine which one is more efficacious.

2.3.1 Findings of the current study

In our series, either TXA- or thrombin-soaked collagen sponge, in combination with intravenous TXA injection prior to the beginning of the operation, significantly decreased postoperative drainage. The time for the 8-hour drainage to decrease either to <30 mL or <20 mL and drain output until these times were significantly lower in TXA group than in Thrombin group, followed by Control group, respectively. There were no potentially related or attributable complications in any groups. These results demonstrate that TXA-soaked collagen sponge led to significantly better outcomes than thrombin-soaked collagen sponge.

2.3.2 Limitations of the study

As with any study, there are limitations with ours. First, this study is not a prospective randomized study. In order to overcome/minimize the inherent limitations of retrospective nonrandomized study, the authors set

strict criteria for participant selection (Table 2). As a result, many patients were excluded (Fig. 1), and demographic and surgical parameters of finally enrolled patients were highly comparable among the 3 groups (Table 3).

Second, all patients in TXA and Thrombin groups were operated on after all patients in Control group were, even though TXA and Thrombin group patients were operated on during the same period. As a result, the operating surgeon had more experience when he operated on TXA and Thrombin group patients, favoring these groups. However, the surgeon had performed more than 1,200 cervical operations for 16 years before he carried out the surgery for the first enrolled patient of the current study. In addition, he tended to allow his fellows to take more role in surgical procedures under his supervision as time went by during the study period, favoring Control group. As a result, there was no significant difference in operation time among the 3 groups (Table 3).

Third, the outcome measures to represent postoperative drain output were selected rather arbitrarily. We first chose the time for the 8-hour drainage to decrease to <30 mL and drain output until this time because the authors of previous reports [1,3] discontinued the drain at this time point. However, there is no standard protocol for discontinuation of the drain for the posterior cervical spine surgery [3]. Nowadays many surgeons in this country including the corresponding author's group discontinues the drain at a point when the 8-hour drainage decreases to <20 mL. Therefore, we added the time for the 8-hour drainage to

decrease to <20 mL and drain output until this time. On the other hand, we did not compare the total drain output until drain removal because the criterion to remove the drain was not fixed throughout the study period and the criterion itself was not strictly followed in all patients. The length of hospital stay was not analyzed as well, because it was not directly related with the drain removal in this country, where hospitalization cost is extremely low and many patients refuse to be discharged earlyafter surgery.

Fourth, it is not clear whether the collagen sponge, which was chosen in the current study, led to more favorable results with either TXA or thrombin. It is not clear whether the results of the study would be similar or different if gelatin sponge was used. We chose the collagen sponge instead of gelatin sponge because of two reasons. First, the collagen sponge that we used contained gentamicin, and therefore could possibly reduce the risk of postoperative infection. Second, while the main mechanism of action of gelatin sponge is physical coverage or compression of the bleeding surface [1,3], collagen sponge has an additional biologic hemostatic function by activating the platelets and accelerate coagulation process [10–12].

Fifth, the doses of TXA and thrombin, which were rather arbitrarily determined, could possibly influence the results. The results might have been different with different doses. Ideally, the optimal dose providing sufficiently high efficacy and safety should have been selected for each agent. Unfortunately, such optimal dosage for topical application is not

known yet. In the previous reports, 1.0 or 2.0 mg TXA was used for lumbar spine surgery [1,2], and 2,500-IU thrombin was used for posterior cervical spine surgery [3]. Compared with them, our dosage, 1.0 mg TXA and 5,000-IU thrombin favored Thrombin group. Nevertheless, the efficacy was better in TXA group.

Sixth, intravenous TXA administration could potentially affect the results. The half-life of the intravenously injected TXA is reported to be approximately 2 hours [13] and the average operation time was approximately 2.2 hours in TXA and Thrombin groups. Therefore, it might have given an additive effect in TXA group. On the other hand, in Thrombin group it is not clear whether it had additive, synergistic or negative effect.

Despite these limitations, we believe that this study has unique strengths. This is the first study to compare the efficacy of TXA- versus thrombin-soaked sponges, as far as we know. We used highly strict selection criteria to obtain as homogeneous groups as possible even though this is a retrospective study.

Chapter 3. Conclusion

3.1 Conclusions

To our knowledge, this is the first study to compare the efficacy of topically applied TXA- versus thrombin-soaked sponges in decreasing postoperative drain output following spine surgery. Our results demonstrate that topical application of either TXA- or thrombin-soaked collagen sponge before wound closure, in combination with intravenous TXA injection prior to the beginning of the operation, significantly decreased postoperative drainage following multi-level cervical laminoplasty/laminectomy. TXA-soaked collagen sponge was significantly more efficacious than the thrombin-soaked one. In the meanwhile, there were no complications potentially attributable to the use of those sponges and/or hemostatic agents. Therefore, the present study indicates that TXA-soaked collagen sponge provides significantly higher efficacy in decreasing postoperative drain output with similarly high safety compared with thrombin-soaked collagen sponge, when used in combination with intravenous administration of TXA. Further studies are required to determine dose dependent effects of TXA/thrombin and different hemostatic effects of various types of sponges. The optimal dosage of TXA/thrombin remains to be identified as well.

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Figure Legends

Fig. 1.

Flow diagram of patient selection

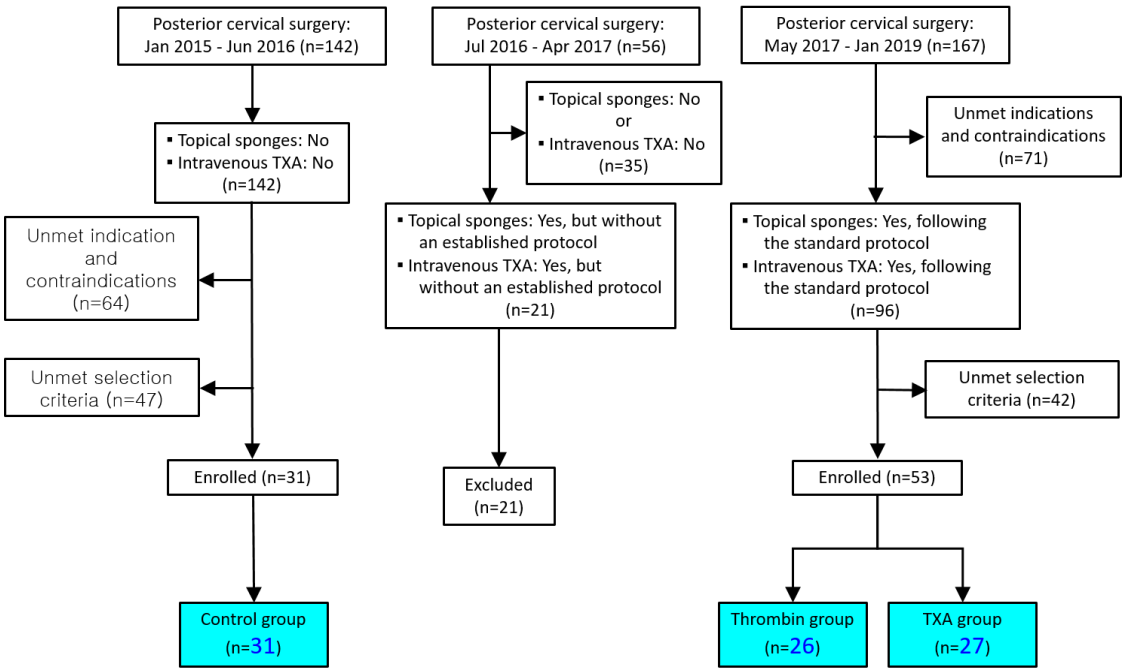


Fig. 2.

A postoperative lateral radiograph of a patient who underwent the most common combination of decompressive procedures is shown. Total laminectomy was performed at C3; open-door laminoplasty using plates at C4, C5, and C6; and partial laminectomy at C7.

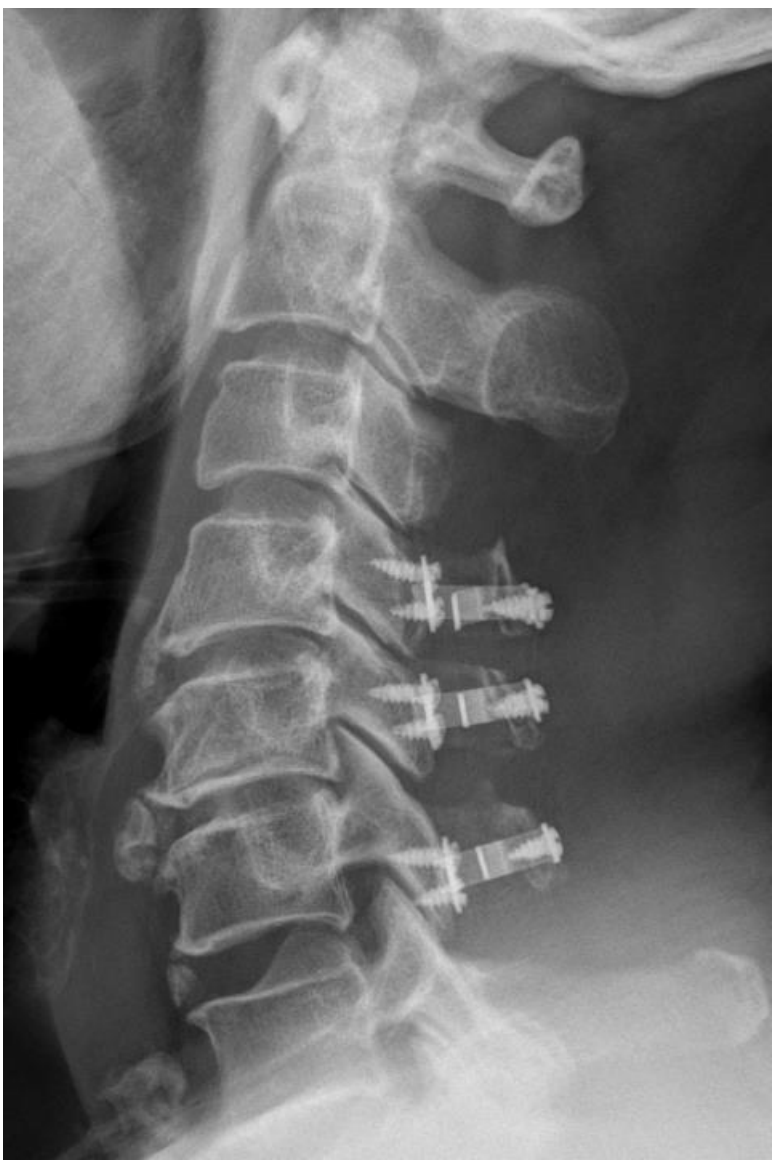
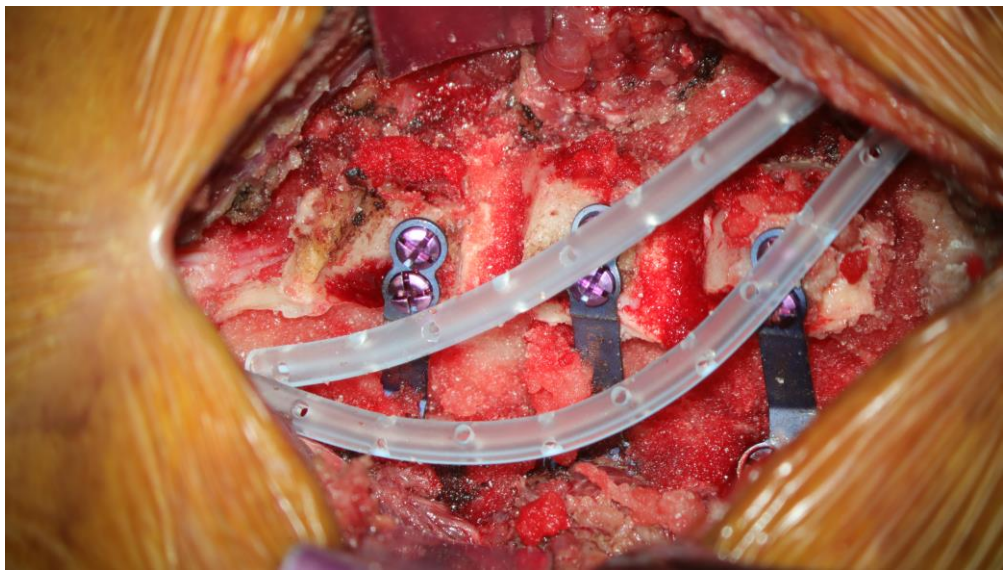
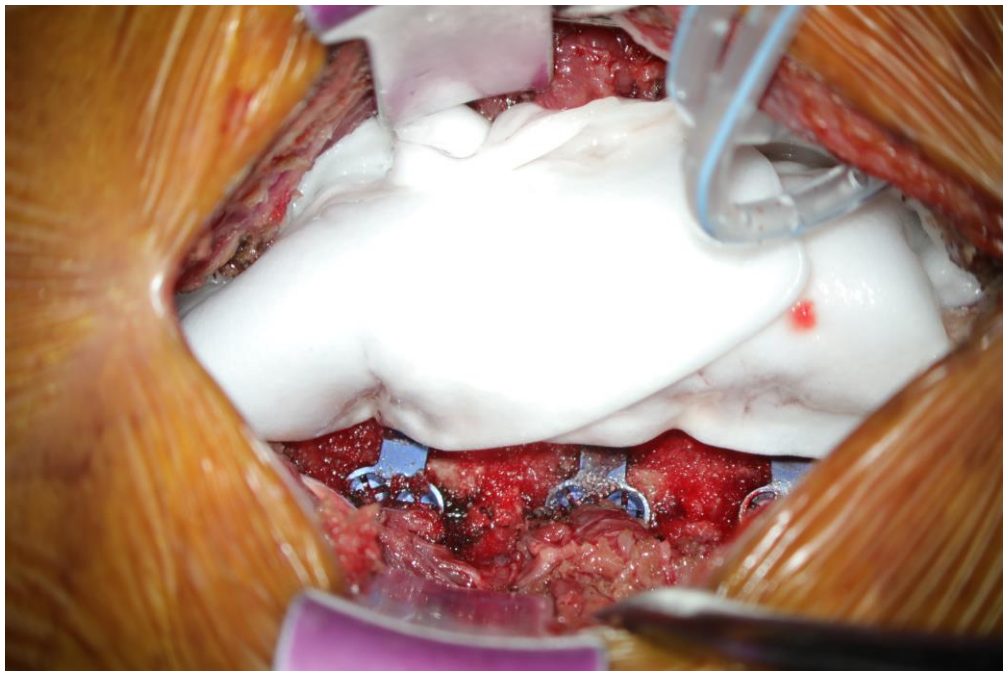


Fig. 3.

Intraoperative photographs of a patient in TXA group are shown.



(A) After flowable gelatin-thrombin matrix sealant is applied over exposed epidural areas and bleeding bony surfaces and muscle bleeding is controlled with bipolar electrocautery, two deep suction drain tubes are inserted.



(B) Two sheets of 5×5 cm gentamicin-containing collagen sponges soaked in 1-gram TXA solution are placed.

(C) One gram of vancomycin powder is sprinkled.

Table Legends

Table 1. Indication and contraindications for topical application of TXA- or thrombin-soaked collagen sponges and intravenous TXA injection

Indication
All posterior cervical surgery with ≥3 operation levels
Contraindications
Anticoagulant therapy for cardiovascular disorders, stroke, and/or stent insertion
History of thromboembolic events, including deep vein thrombosis and pulmonary embolism
History of coagulopathy
History of cerebrovascular or cardiovascular disorders
History of allergy for tranexamic acid or thrombin
Renal impairment with creatinine ≥2.0 mg/dL
History of epilepsy
Infection
Dural tear or dural opening during the index surgery

Table 2. Selection criteria for the current study

Inclusion criteria
4-6 level cervical laminoplasty/laminectomy, including 3-4 level open-door laminoplasty using plates
Age 20-80 years
F/U ≥1 month
Exclusion criteria
Number of operation level *≤3 or ≥7*
Number of laminoplasty level ≤2 or ≥5
Fusion and/or fixation except laminoplasty plates
Additional anterior cervical surgery during the same admission period
Additional thoracolumbar surgery during the same admission period
History of previous cervical surgery
Tumors and trauma
Unintended accidental removal of suction drain(s)

Table 3. Baseline characteristics of enrolled patients

Variables	Group			p-Value
	TXA (n=27)	Thrombin (n=26)	Control (n=31)	
Age (years)*	61 ± 12	62 ± 12	60 ± 8	.68‡
Gender†				.80§
Man	22 (81%)	20 (77%)	23 (74%)	.
Woman	5 (19%)	6 (23%)	8 (26%)	
Weight*	74 ± 12	71 ± 11	69 ± 12	.27‡
Height*	167 ± 8	165 ± 9	163 ± 8	.26‡
Body mass index*	26.5 ± 3.7	25.8 ± 3.2	25.8 ± 3.5	.65‡
Main disorder†				.57§
OPLL	18 (67%)	20 (77%)	20 (65%)	
CSM	9 (33%)	6 (23%)	11 (35%)	
Number of operation levels†				.66§
4	5 (19%)	7 (27%)	11 (35%)	
5	20 (74%)	18 (69%)	18 (58%)	
6	2 (7%)	1 (4%)	2 (6%)	
Number of laminoplasty levels†				.32§
3 (C4, C5, and C6)	27 (100%)	25 (28%)	30 (97%)	
4 (C4, C5, C6, and C7)	0 (0%)	1 (4%)	0 (3%)	
Operation time (min)*	2.20 ± 0.35	2.19 ± 0.58	2.16 ± 0.43	.94‡
Estimated blood loss (mL)*	200 ± 69	212 ± 119	213 ± 133	.90‡

OPLL, ossification of the posterior longitudinal ligament; CSM, cervical spondylotic myelopathy.

*Values are mean ± standard deviation.

†Values are n (%).

‡Derived with One-way ANOVA test

§Derived with Chi-square test

Table 4. Parameters related to postoperative drain output

Parameters	Group			p-Value*
	TXA (n=27)	Thrombin (n=26)	Control (n=31)	
Time for 8-hour drainage to decrease to ≤30 mL (hours)	15±7	23±10	`29±10	<.001**
Drain output until 8-hour drainage decrease to ≤30 mL (mL)	41±37	88±60	186±78	<.001**
Time for 8-hour drainage to decrease to ≤20 mL (hours)	29±9	35±11	41±10	<.001**
Drain output until 8-hour drainage decrease to ≤20 mL (mL)	77±41	124±61	215±66	<.001**

*Derived with one-way ANOVA test

**On post-hoc analysis using Student-Newman-Keuls test, there was a significant difference (p<.05) in each of the 3 pairwise comparisons.

Abstract in Korean

연구목적 : 경추의 4-6 분절 후궁성형술/후궁절제술 후에 H-vac 배액량을 저감시키는데에 있어서, 창상 봉합 직전에 국소 부위에 도포한 트라넥삼산 함유 콜라겐 스펀지와 트롬빈 함유 콜라겐 스펀지의 유효성을 비교해보고자 하였다.

선행연구문헌 요약 : 창상 봉합 직전에 국소 부위에 도포한 트라넥삼산 함유 콜라겐 스펀지와 트롬빈 함유 스펀지는 두가지 모두 척추 수술 후의 출혈량을 저감시킬 수 있음이 보고되어 있다. 그러나, 이 두가지 중에서 어느 것이 출혈량 저감에 더 효과적인지에 관한 보고는 찾을 수 없었다.

결론 : TXA 군은 28명, 트롬빈 군은 27명, 대조군은 31명의 환자로 구성되었다. 기초임상자료는 3 군간에 차이가 없었다($p > 0.05$). H-vac 배액량과 관련된 4가지 지표는 모두 TXA 군에서 가장 우수한 결과를 보였고 다음으로 트롬빈 군, 대조군 순이었으며, 모두 3군간에 유의한 차이를 보였다(각각 $p < 0.05$). 어떤 군에서도, 수술 후 트라넥삼산, 트롬빈 및 스펀지와 관련된 합병증을 보인 환자는 없었다.

주요어 : 경추, 수술 후 배액량, 트라넥삼산, 트롬빈, 콜라겐 스펀지

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