Tranexamic Acid in Reducing Perioperative Blood Loss in Lumbar Spinal Stenosis Surgery: A Double-Blind Randomized Controlled Trial

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Objective: *To compare peri-operative surgical blood loss in laminectomy with spinal fusion surgery, using tranexamic acid (TXA) in one group, versus a control group given a placebo.*
Methods: *A prospective double-blind randomized controlled trial studied lumbar spinal stenosis patients who underwent decompressive laminectomy with spinal fusion at Maharat Nakorn Ratchasima Hospital from 2009 to 2010.*
Results: *Forty three patients were included in the study. The intra-operative and peri-operative blood loss was insignificantly reduced in the TXA group versus placebo group (mean: 493.2 ml. VS 526.2 ml. p=0.74) (mean: 932.9 ml. VS 1127.6 ml. p=0.19), respectively. However, post-operative blood loss was reduced significantly in the TXA group compared to placebo group (mean: 439.8 ml. VS 601.2 ml. p=0.04). However, there was no difference in blood transfusion requirements between the two groups. The number of decompressed levels and surgical duration were two factors related to perioperative blood loss.*
Conclusions: *Intravenous tranexamic acid connot significantly reduce total peri-operative blood loss in laminectomy and spinal fusion surgery. It does however, significantly reduce post-operative blood loss. We found no difference in the number of blood transfusions required between the TXA and placebo groups.*

Keywords: *Tranexamic acid, blood loss, laminectomy, spinal fusion, spinal stenosis*

The Thai Journal of Orthopaedic Surgery: 35 No.3-4: P1-7
Full text. e journal: *http://www.rcost.or.th/journal, http://thailand.digitaljournals.org/index.php/JRCOST*

Degenerative spinal stenosis is a common disorder in middle-aged and older patients. Symptoms including backache, claudication, or neurological impairment cause patients to visit a physician. The onset is insidious. Conservative treatment is initially considered, with good to excellent results in more than 50% of patients during the first 12 weeks. If conservative treatment fails, or there is further neurological impairment, operative treatment is indicated[1].

Surgical treatment including decompressive laminectomy with or without fusion/ instrumentation is usually accompanied by greater than 1000 ml. of blood loss.

At Maharat Nakhon Ratchasima Hospital, total blood loss in decompressive laminectomy averages approximately 1100 ml., which can cause post hemorrhagic anemia and shock. Blood transfusion is required to correct these problems, which may risk blood transfusion allergy, or infection, or both.

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Several methods exist to diminish the risk of blood transfusion: proper preoperative preparation, blood conservation intervention (such as cell saver, preoperative erythropoietin, preoperative autologous donation and acute normovolumic hemodilution), anesthetic techniques, surgical technique, medications, especially antifibrinolytic agents such as tranexamic acid (TXA), Amicar (Epsilon aminocaproic acid), and Aprotinin[7]. Tranexamic acid is widely used in Thailand because of its low cost and low incidence of adverse effects. Furthermore, TXA is used in open heart surgery [2,3,8], dental surgery[4,5], gynaecological surgery[6] ,and orthopaedic surgery eg. total knee replacement [17,18], and pediatrics scoliosis[13-15].

Tranexamic acid (trans-4-(aminomethyl) cyclohexanecarboxylic acid (C8H15NO2) is a low molecular weight antifibrinolytic drug, affecting the lysine binding site of plasminogen and plasmin. It inhibits enzyme activation of plasminogen, such as is seen with streptokinase, urokinase, and tissue activator. The inactive complex resulting from the binding of plasmin with TXA inhibits fibrin clot lysis.

In pediatric patients, two prospective studies found that TXA reduced perioperative blood loss,[14] and reduced the total amount of blood transfused in patients having scoliosis surgery without thromboembolic complications[9,12-16]. However, the blood-conservation effect is still uncertain in adult spine surgery[19-21]. There are no comparative studies using TXA in decompressive laminectomy with spinal fusion.

The purpose of this study is to compare peri-operative blood loss in laminectomy with spinal fusion surgery, using two groups: those given Tranexamic acid (TXA), and a control group given a placebo.

Material and Method

This study was performed at Maharat Nakhon Ratchasima Hospital from 1st May 2009 to 31st May 2010. Forty three patients who underwent decompressive laminectomy and spinal fusions were included and enrolled in the study. Exclusion criteria were: patients with renal insufficiency, previous spinal surgery, previous thromboembolic events (eg. deep vein thrombosis, pulmonary embolism), coagulation disorder, history of acquired defective color vision, history of hematuria, history of drug allergy to tranexamic acid, and those who received NSAIDs within the week prior to surgery. If intraoperative surgical complications such as uncontrollable surgical bleeding from broken vertebral laminae, or dural tears, etc. occurred, the patients were excluded from the study. The Ethics Board of the Maharat Nakhon Ratchasima Hospital approved this study, after which informed consent was obtained from all participants.

Patients were randomized to receive either TXA or placebo (normal saline). Random numbers were computer-generated and the randomization schedule was kept inaccessible throughout the study period. Patient assignments were placed into sequentially numbered opaque sealed envelopes. A research assistant, not involved with care of the patients, prepared the placebo and treatment medications which were identical in appearance. Research personnel, anesthesiologists, surgeons, and operating room staff were blinded to the randomization.

Patients in the TXA group received a bolus of 10 mg/kg IV of TXA after anesthetic induction, and before surgical incision. A maintenance infusion of 1 mg/kg/hr of TXA was continued until skin closure. Patients in the control group were given a bolus of an equivalent volume of placebo (normal saline), and a maintenance placebo infusion until skin closure.

All patients were positioned prone on the operating table with the abdomen free. Intraoperative blood loss was measured by the blood volume in the suction bottles. The surgeon performed the operation without using sponges or gauze, using instead cottonoids which held a very small volume. Thus intraoperative blood loss was measured by suction bottle volume, after deducting the volume of irrigation fluid used in the surgical field. This was done by the operating room nurse. The surgical Radivac drainage was measured for 72 hours by a ward nurse to give a close estimate of postoperative blood loss. Blood loss in the wound dressing was minimal because a watertight suture technique was employed.

The guideline for transfusion of packed red cells (PRC) was to give one unit at a time to maintain a hemoglobin concentration of 7 g/dL or a hematocrit of 27%. A higher hematocrit level was maintained if continuing blood loss occurred, or signs or symptoms of anemia developed. If the anesthesiologist/surgeon considered it clinically unsafe to withhold transfusion of RBC, FFP or platelets before laboratory confirmation of anemia, coagulopathy, or thrombocytopenia, blood products were given.

The primary outcome measured was the total perioperative blood loss occurring intraoperatively, and 72 hours postoperatively. Secondary outcomes recorded were the numbers of blood transfusions required, including PRC, and coagulation components i.e. FFP, and platelets administered during the hospitalization, duration of hospital stay, and complications. Patients were assessed daily for any clinical symptoms of deep vein thrombosis (DVT) and if suspected, venous Doppler ultrasonography was performed to confirm the diagnosis.

Statistical analysis

Demographics, type of treatment, length of hospital stay, and complications were analyzed by descriptive analysis. The independent two-sample Student's *t*-test was used to compare the preoperative and postoperative laboratory tests, perioperative blood loss, and operative time between the placebo and TXA group. Continuous variables were expressed as mean and SD. The number of patients receiving blood transfusion was reported. Two sided tests were used to determine the *P* value. A P value < 0.05 indicated statistical significance.

The independent variables included in the analyses were demographic characteristics (age, gender, body weight, ASA classification, number of levels fused), preoperative factors (hematocrit, hemoglobin) and intraoperative factors (treatment with TXA, surgical duration). All statistical analyses were performed with SPSS statistical software.

The sample size calculation for this trial was based on a previous study in our institution where the mean blood loss for patients having spinal fusion was 858.75+206.6 mL. Hence, the total sample size required to demonstrate a 20% reduction in perioperative blood loss, i.e. 216.6 mL.

in the treatment group was 15 patients, assuming a type I [*alpha*] error of 0.05 (two-tailed), and a statistical power of 0.8.

Results

Forty-three patients were recruited: twenty-eight females and fifteen males, aged 41-70 years, were included in this study. Twenty-two patients were enrolled in the TXA group and twenty-one patients in the placebo group. Patient demographics such as age, sex, and body weight were not significantly different.

Most cases underwent laminectomy and fusion with instrumentation.

There were no differences in type of treatment between the two groups, nor in the numbers of decompressed levels, or operative time. (Table 1)

Table 1 Demographics and baseline characteristics

Demographic data	TXA group (N=22)	Placebo group (N=21)
Age; mean(years)(SD)	57.6 (8.3)	55.5 (7.6)
Sex; - Male - Female	 8 14	 7 14
Body weight; mean(kg.)(SD)	61.9 (7.9)	60.8 (8.9)
Pre-operative Hemoglobin; mean (g/dL)(SD)	11.90 (1.34)	11.98 (1.31)
Pre-operative Hematocrit; mean (%)(SD)	36.16 (3.93)	36.01 (3.65)
Pre-operative Platelet count; mean (/mm^3)(SD)	267.86 (56.64)	273.95 (95.84)
INR; mean (s)(SD)	0.96 (0.08)	0.98 (0.09)
ASA status: I/II/III	6/11/5	6/9/6
Type of treatment: - non-instrumentation - Instrumentation	 6 16	 3 18
No. of decompressed levels - 1-2 levels - $\geq$ 3 levels	 12 10	 12 9
Operative time: mean(min)(SD)	93.6 (26.7)	98.3 (31.8)

There are no significant differences between the two groups (parameters) ($p > 0.05$)

In the primary outcome, there is no significant difference in total peri-operative blood loss between the TXA group and the placebo group (1128$\pm$573 ml. and 933$\pm$370 ml., respectively) (p = 0.19), nor in intra-operative blood loss (493$\pm$322 ml. and 526$\pm$330 ml., respectively) (p = 0.74). The post-operative blood loss was significantly reduced in the TXA group versus placebo group (440$\pm$170 ml. VS 601$\pm$315 ml. respectively) (p = 0.04). (Table 2). There is no significant difference in the perioperative blood transfusion requirements. (Table 3)

Table 2 Mean blood loss

	Mean blood loss (ml.)(SD)		p-value
	Placebo group (N=21)	TXA group (N=22)	
Intra-operative	526.2 (330.4)	493.2 (321.6)	0.74
Post-operative	601.2 (314.6)	439.8 (169.6)	0.04
Peri-operative (total)	1127.6 (572.6)	932.9 (369.8)	0.19

Table 3 Blood transfusion requirements

Number of units of blood component	Number of patients	
	Placebo group (N=21)	TXA group (N=22)
0	10	13
1	6	6
2	3	3
3	2	0
p = 0.25		

Table 4 Other factors related to mean blood loss

Factors	Mean blood loss (ml.) (SD)		
	Intra-op	**Post-op**	**Total**
No. Decompressed levels			
≤ 2 levels (N=24)	410.4 (318.6)	427.7 (194.9)	838.1 (385.8)
> 2 levels (N=19)	634.2 (288.7)	633.6 (292.5)	1267.9 (497.4)
Operative time			
< 120 min. (N=38)	471.1 (314.1)	499.8 (257.0)	970.9 (392.5)
> 120 min. (N=5)	800.0 (167.3)	698.0 (138.5)	1498.0 (457.6)
	$p < 0.05$		

The other significant factors affecting total blood loss in this study were numbers of decompressed levels, and operative time. More than two decompressed levels, or more than 120 minutes of operative time significantly increased perioperative blood loss. (Table 4)

There were no complications such as drug allergy, venous thromboembolism, re-operation due to further neurological deficit, or hematoma collection and infection.

Discussion

In the current study, intravenous tranexamic acid (TXA) administration significantly reduced the post-operative blood loss in spinal stenosis patients who underwent decompressive laminectomy, but TXA did not reduce the total perioperative and pre-operative blood loss when compared to our control group who received placebo. TXA did not reduce the number of blood transfusions required significantly.

Our findings are consistent with previous randomized controlled trials in adult patients who had spinal fusion, and pediatric patients who had scoliosis surgery[12,14]. From a recent meta-analysis[29], tranexamic acid was found to significantly reduce total blood loss, and blood transfusion requirements in four studies[14,21,30,31]. However, our study results are consistent with the report of Neilipovitz et al.[13], Bednar et al.[20], and Shapiro et al.[15] for insignificant total blood loss reduction. This current study's results are the same as that of Sethna et al., and Neilipovitz et al. whose reports for blood transfusion requirement reduction were not significantly different [13,14].

The dose of TXA in this study was the recommended dose for noncardiac surgery[7,22]. This dose is consistent with that used in other spinal surgeries[12,13,20,21]. The optimal dose regimen in adult patients having spine surgery has not been determined in randomized controlled trials[19]. A randomized, controlled study by Elwatidy et al.[16] had has shown that even large doses of TXA (loading dose of 2 g (for adults) or 30 mg/kg (for children), followed by continuous infusion of 100 mg/h (for adults) or 1 mg/kg/h (for children) during surgery, and for 5 hours after the operation) provided both safety and an effective method without complications. A meta-analysis of 18 trials of TXA versus placebo in cardiac surgery[23] and a Cochrane review did not find an increase in mortality, stroke, or MI[7].

The etiology of perioperative bleeding during spinal reconstructive surgery is multifactorial[24,25]. The exposed bony surfaces are not amenable to standard hemostatic maneuvers used during soft tissue surgery, and bleeding can continue after the wound is closed[26]. TXA can decrease the bleeding by attenuating the enhanced fibrinolytic activity, and mediated by the blockade of lysine binding sites on plasminogen molecules, thereby inhibiting the interaction of plasminogen and the heavy chain of plasmin with lysine residues on the surface of fibrin. Thus plasmin is unable to bind to and degrade fibrin, leading to a decrease in clot dissolution as well as an increase in thrombus formation and thrombus weight[11].

Our results indicated that number of decompressed levels and surgical duration were two factors in predicting total perioperative blood loss, that being consistent with previous reports [12,27,28]. More than two decompressed levels, or more than 120 minutes of operative time significantly increased perioperative blood loss.

There are some limitations to this study: small sample size did not allow subgroup analysis such as instrumentation versus non-instrumentation. In our study, venous thromboembolism was diagnosed by clinical examination. Therefore asymptomatic deep vein thrombosis was not detected.

We controlled the confounding factor of surgical hemostatic technique by using only one surgeon. However, that increased the time needed to complete this study. A future, randomized study using several surgeons could determine any differences. Future dose ranging studies may be necessary to determine the dose dependent effects of TXA in spinal surgery.

Conclusions

The use of intravenous tranexamic acid does not reduce total perioperative blood loss in laminectomy and spinal fusion surgery significantly. However, it's use does reduce post-operative blood loss. There was no difference in blood transfusion requirements between the TXA and placebo groups.

Acknowledgement

The authors wish to thank Dr. Pensri Ruckwong, Medical Education Center, Maharat Nakhon Ratchasima Hospital.

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การศึกษาแบบสุ่ม ควบคุม ปกปิดสองทาง เปรียบเทียบการใช้ยา Tranexamic acid ในการลดปริมาณการเสียเลือดจากการผ่าตัดกระดูกสันหลังส่วนเอวตีบ

ไพรัตน์ สุขสโมสร, พบ. วว., จิธายุทธ เสือจุ้ย, พบ., ศุภมาส ลิ่วศิริรัตน์, พบ. วว.

วัตถุประสงค์ : *เพื่อศึกษาเปรียบเทียบปริมาณการเสียเลือดรวมจากผ่าตัด decompressive laminectomy with spinal fusion ในผู้ป่วยกลุ่มที่ใช้ยา intravenous Tranexamic acid (TXA) และ กลุ่มที่ใช้ยาหลอก*

ระเบียบวิธีวิจัย : *เป็นงานวิจัยแบบ prospective double-blind randomized controlled trial ศึกษาในผู้ป่วยโรค Spinal stenosis ที่ได้รับการรักษาโดยการผ่าตัด decompressive laminectomy with spinal fusion ที่ รพ.มหาราชนครราชสีมา ในระหว่างปี พ.ศ.2553-2554*

ผลการศึกษา : *มีผู้ป่วย 43 คนที่ได้เข้าร่วมในการศึกษานี้ ผลปรากฏว่า การเสียเลือดในห้องผ่าตัดและการเสียเลือดรวมจากการผ่าตัด ในกลุ่มที่ใช้ยา TXA ลดลงอย่างไม่มีนัยสำคัญเมื่อเทียบกับกลุ่มที่ใช้ยาหลอก (ค่าเฉลี่ย ; 493.2 มล. เทียบกับ 526.2 มล. โดย p=0.74) (ค่าเฉลี่ย ; 932.9 มล. เทียบกับ 1127.6 มล. โดย p=0.19) ตามลำดับ แต่การเสียเลือดหลังจากการผ่าตัด ในกลุ่มที่ใช้ยา TXA ลดลงอย่างมีนัยสำคัญเมื่อเทียบกับกลุ่มที่ใช้ยาหลอก (ค่าเฉลี่ย ; 439.8 มล. เทียบกับ 601.2 มล. โดย p=0.04) อย่างไรก็ตาม ไม่พบความแตกต่างเกี่ยวกับเรื่องการให้เลือดแก่ผู้ป่วยระหว่างทั้งสองกลุ่ม และพบว่า จำนวนระดับของกระดูกสันหลังที่ได้รับการผ่าตัดและระยะเวลาในการผ่าตัดเป็นปัจจัยที่เกี่ยวข้องกับการเสียเลือดจากการผ่าตัด*

สรุป : *การใช้ยา Tranexamic acid ทางหลอดเลือดดำ ไม่สามารถลดการเสียเลือดรวมจากการผ่าตัด Laminectomy and spinal fusion อย่างมีนัยสำคัญ แต่สามารถลดการเสียเลือดหลังการผ่าตัดได้อย่างมีนัยสำคัญ แต่อย่างไรก็ตาม ไม่พบความแตกต่างเกี่ยวกับเรื่องการให้เลือดแก่ผู้ป่วยระหว่างกลุ่มที่ได้รับยา Tranexamic acid และกลุ่มที่ได้รับยาหลอก*