THE EFFECT OF TOPICAL TRANEXAMIC ACID IN REDUCTION OF POSTOPERATIVE BLOOD LOSS AFTER POSTERIOR INSTRUMENTED CERVICAL SPINAL FUSION:

A RETROSPECTIVE COMPARATIVE STUDY

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INTRODUCTION

- POSTERIOR CERVICAL INSTRUMENTED FUSION IS USEFUL FOR MANY CERVICAL SPINE CONDITIONS.
- PERIOPERATIVE BLOOD LOSS IS ONE OF THE MOST COMMON COMPLICATIONS.
- VARIOUS MEASURES : INTRAOPERATIVE CELL SAVER MACHINE, DELIBERATE HYPOTENSIVE ANESTHESIA, AND *ANTI-FIBRINOLYTIC AGENTS*.
- **SYSTEMIC TRANEXAMIC ACID** CONTROLS PERIOPERATIVE BLEEDING AND REDUCES POSTOPERATIVE BLOOD TRANSFUSION, BUT IT RESULTS SYSTEMIC THROMBOTIC EVENTS.
- **TOPICAL TRANEXAMIC ACID** ELIMINATES THROMBOTIC EVENTS AND REDUCE PERIOPERATIVE BLOOD LOSS IN MANY ORTHOPEDIC PROCEDURES.
- FEW EVIDENCE OF TOPICAL TRANEXAMIC ACID USAGE IN CERVICAL SPINE TO DATE.

OBJECTIVES

- TO EVALUATE THE EFFICACY OF TOPICAL TRANEXAMIC ACID ON POSTOPERATIVE BLOOD LOSS AND BLOOD TRANSFUSION RATE IN POSTERIOR INSTRUMENTED CERVICAL SPINE FUSION COMPARED WITH A CONTROL GROUP.

- TO OBSERVE THE PERIOPERATIVE COMPLICATIONS ASSOCIATED WITH THE LOCAL TRANEXAMIC ACID ADMINISTRATION.

MATERIAL AND METHODS

- A RETROSPECTIVELY NON-RANDOMIZED OBSERVATIONAL STUDY
- THE CLINICAL DATA OF PATIENTS RECEIVING POSTERIOR CERVICAL SPINE FUSION FROM 1 OCTOBER 2016 TO 31 MARCH 2021 WERE ANALYZED.
- 20 PATIENTS WITH LOCALLY TRANEXAMIC ACID ADMINISTRATION AND 20 PATIENTS WITH NOT GIVEN TRANEXAMIC ACID AS A CONTROL GROUP WERE INCLUDED.
- THE STUDY WAS APPROVED BY THE UDON THANI HOSPITAL ETHICS COMMITTEE (REGISTRATION NUMBER: I055/2563).

INCLUSION CRITERIA

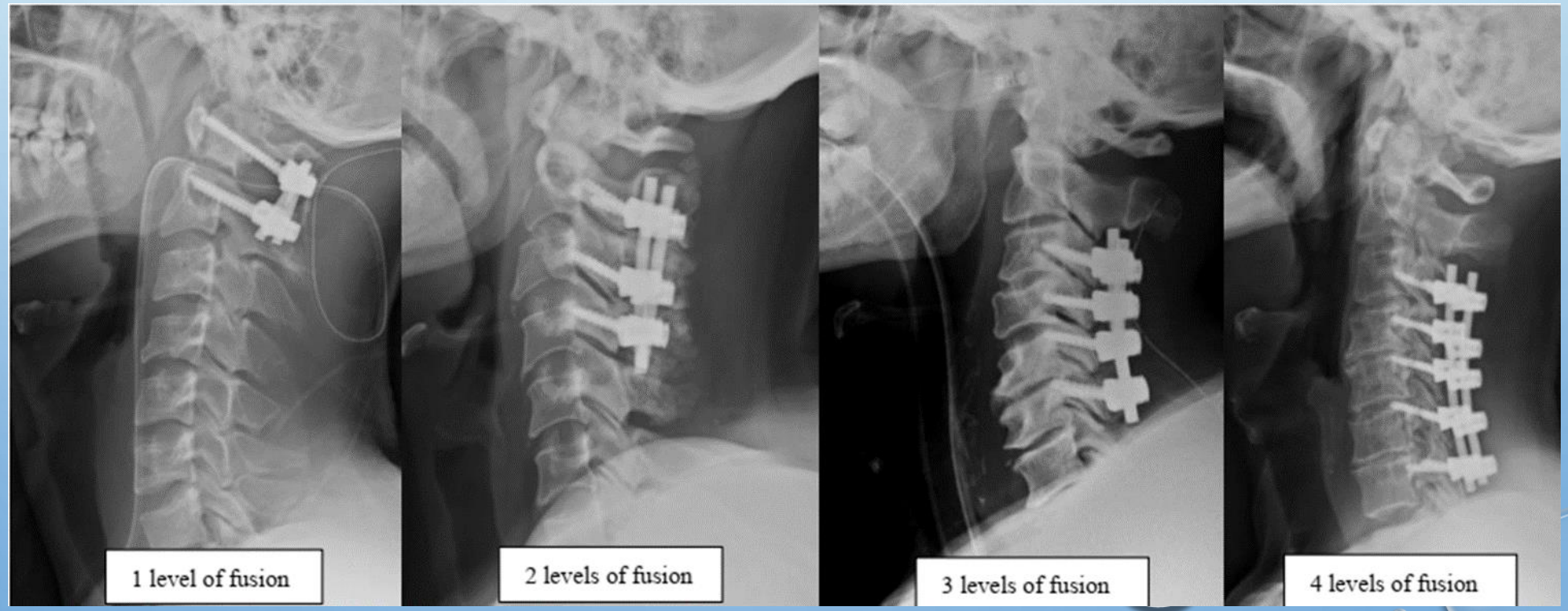
- MALE OR FEMALE, AGE OF 18 TO 80-YEARS-OLD
- CERVICAL SPINAL DISEASES AND/OR CERVICAL SPINE TRAUMA RECEIVING POSTERIOR INSTRUMENTED CERVICAL SPINE FUSION

EXCLUSION CRITERIA

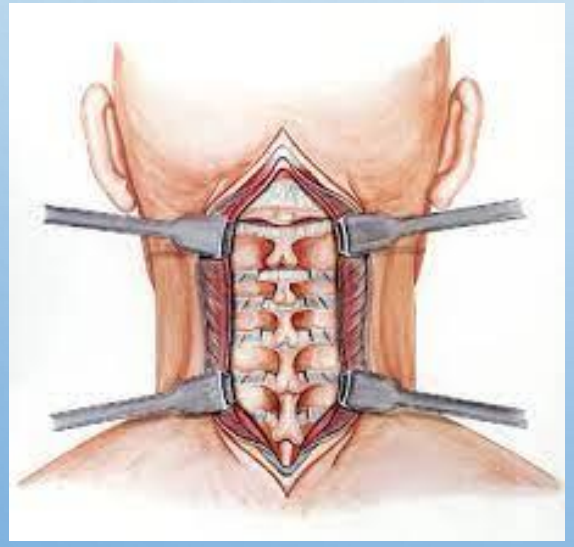
- PREVIOUS HISTORY OF THROMBOEMBOLIC EVENTS
- PREVIOUS HISTORY OF USING NSAIDS
- COAGULATION DISORDERS
- CERVICAL SPINE INFECTION OR MALIGNANCY
- RENAL INSUFFICIENCY
- CARDIOVASCULAR DISEASES
- INTRAOPERATIVE DURAL TEAR
- HISTORY OF TRANEXAMIC ACID ALLERGY
- PREOPERATIVE HEMOGLOBIN<10 G/DL
- PREOPERATIVE PLATELET COUNT <100×109/L
- COMBINED ANTERIOR AND POSTERIOR CERVICAL SPINE SURGERY OR COMBINED CERVICAL SPINE FUSION WITH OTHER SURGICAL PROCEDURES

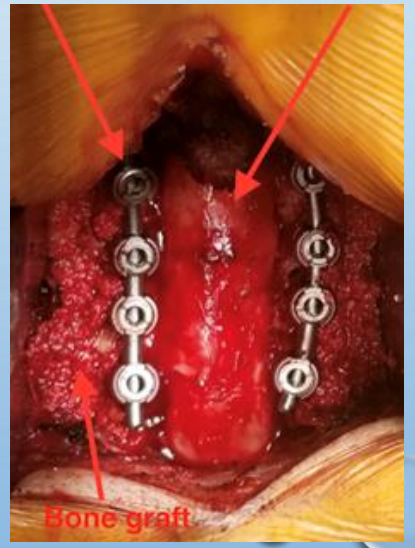
SURGICAL PROCEDURES

- ALL PATIENTS WERE POSITIONED PRONE ON THE OPERATING TABLE.
- THE ANESTHETIC TECHNIQUE IN ALL PATIENTS WAS SIMILAR.
- OPERATIVE PROCEDURES WERE PERFORMED BY THE SAME SPINE SURGEON.
- ALL PATIENTS UNDERWENT STANDARD OPEN POSTERIOR CERVICAL SPINE APPROACH.



- BEFORE SURGICAL WOUND CLOSURE, IN THE TRANEXAMIC ACID GROUP, WOUND SURFACE AND PARASPINAL MUSCLE, LIGAMENT, LATERAL GUTTER FOR GRAFT SITE OF BOTH SIDES WAS SPRAYED WITH TRANSAMIN® (OLIC THAILAND, AYUTTHAYA, THAILAND) 500 MG IN 10 ML FOR 5 MINUTES BEFORE WOUND CLOSURE.
- STANDARD SURGICAL WOUND CLOSURE WAS PERFORMED WITH A SAME TECHNIQUE IN BOTH GROUPS.
- A NEGATIVE-PRESSURE DRAINAGE (RADIVAC® DRAIN) WAS PLACED, AND A LAYER-TO-LAYER SUTURE WAS CARRIED OUT TO CLOSE THE WOUND.





EVALUATION

- THE PRIMARY OUTCOME : DRAINAGE VOLUME (RECORDED EVERY 8 HOURS UNTIL REMOVAL)
- THE SECONDARY OUTCOMES :
    1. POSTOPERATIVE HEMOGLOBIN IN 24 AND 48 HOURS
    2. TIME TO DRAIN REMOVAL
    3. DURATION OF POSTOPERATIVE HOSPITALIZATION
    4. RATE OF BLOOD TRANSFUSION
    5. COMPLICATIONS

- THE BLOOD TRANSFUSION CRITERIA

  POSTOPERATIVE HB ≤8.5 G/DL

  POSTOPERATIVE HB WAS <10 G/DL WITH ANEMIC SYMPTOMS.

- PATIENT'S DISCHARGE CRITERIA

  1) STABLE CLINICAL STATUS AND VITAL SIGNS

  2) REACHED GOALS OF POSTOPERATIVE REHABILITATION PROTOCOL

  3) NO COMPLICATION AT THE TIME OF DISCHARGE.

- AT LEAST ONE MONTH FOLLOW-UP DATA

DATA ANALYSIS

- EXCEL VERSION 2013 (MICROSOFT COOPERATION) FOR DATA REGISTRATION
- SPSS STATISTICS FOR WINDOWS, VERSION 25 FOR DATA ANALYSIS
- MEAN ± STANDARD DEVIATION (SD) AND FREQUENCY (PERCENTAGE).
- STATISTICAL DIFFERENCES BETWEEN THE TWO GROUPS WERE COMPARED USING FISHER'S EXACT TEST FOR CATEGORICAL VARIABLES AND STUDENT T TEST FOR CONTINUOUS VARIABLES.
- TWO-SIDED VALUE OF $P < 0.05$ WAS CONSIDERED STATISTICALLY SIGNIFICANT.

RESULTS

DEMOGRAPHIC DATA

Characteristic	Control group (n=20)	Topical tranexamic acid (n=20)	p-value
Gender (male/female)	15/5	18/2	0.407
Age, year ± S.D.	58.4±15.2	51.7±14.38	0.161
BMI, kg/m^2	25.5±10.7	24.3±3.3	0.648
Preoperative hemoglobin, g/dL	12.5±1.5	13.0±1.2	0.169
ASA classification, n (%): **1 and 2** **3** **4**	20 (100)	18(90) 2(10)	0.487

DEMOGRAPHIC DATA

Characteristic	Control group (n=20)	Topical tranexamic acid (n=20)	p-value
Diagnosis, n (%):			0.258
Cervical spondylotic myelopathy	11 (55)	7(35)	
Ossified posterior longitudinal ligament	1 (5)	4(20)	
Cervical spine trauma	8 (40)	9(45)	
C-segment level of fusion*, n (%)			0.493
1 level	3 (15)	2(10)	
2 level	1 (5)	3(15)	
3 level	11 (55)	13(65)	
4 level	5 (25)	2(10)	
Number of decompressive levels, n (%)**			0.774
No laminectomy	5(25)	4(20)	
3 laminae	1(5)	1(5)	
4 laminae	14(70)	14(70)	
5 laminae	0(0)	1(5)	

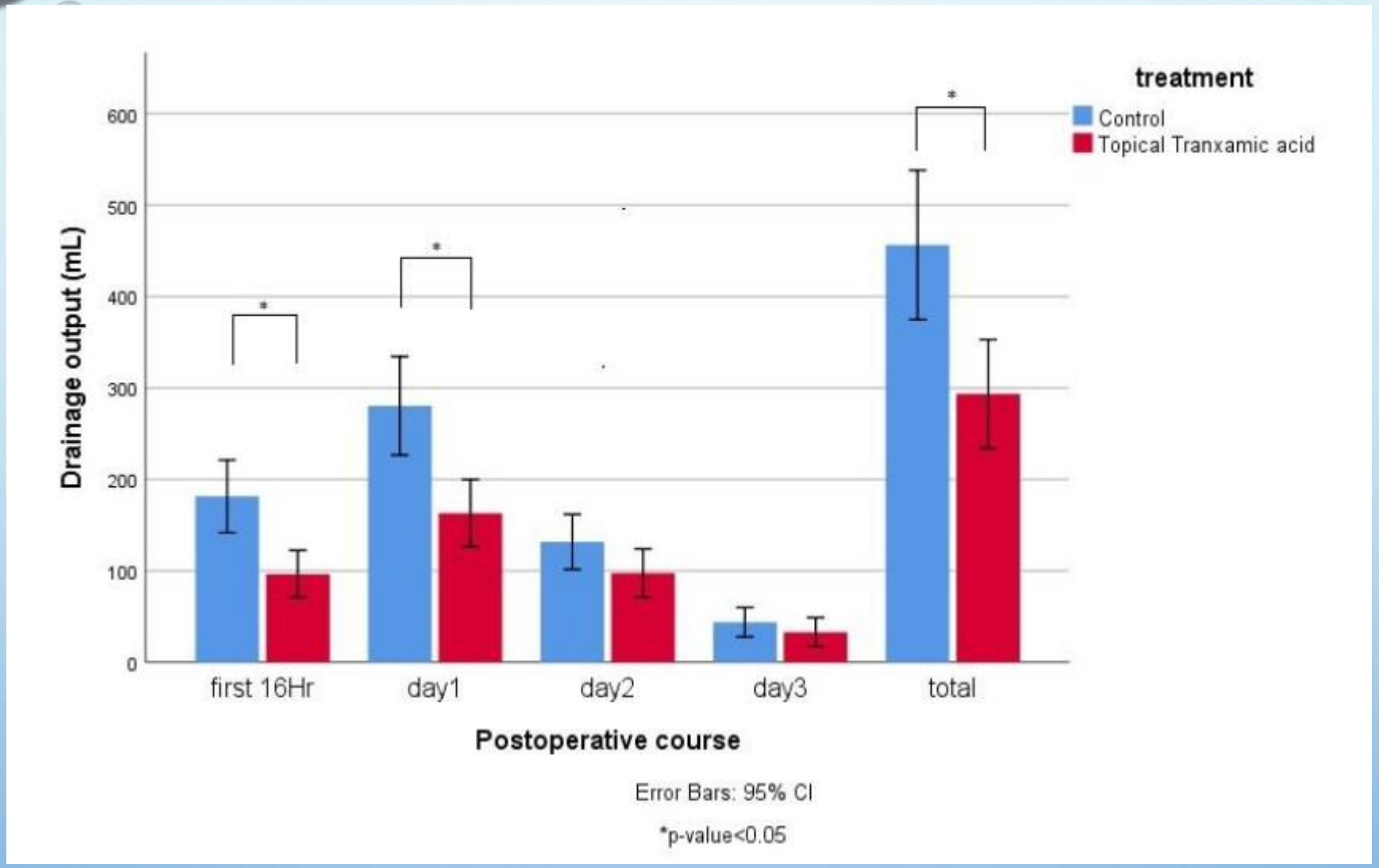
DEMOGRAPHIC DATA

Characteristic	Control group (n=20)	Topical tranexamic acid (n=20)	p-value
Duration of operation, minute	169±28.3	168±46.8	0.935
Intraoperative fluid replacement, ml	1,485±622.6	1,757±877.4	0.264
Intraoperative blood loss, ml	155±105.0	197.5±170.6	0.349

POSTOPERATIVE BLOOD LOSS VOLUME

Postoperative drainage output	**Topical tranexamic acid (ml)**	**Control group (ml)**	**p-value**
0-16 hours 0-24 hours	96.5±55.4 163.0±78.8	181.5±84.7 280.5±115.1	0.001* 0.001*
24-48 hours	97.5±56.5	131.7±64	0.082
48-72 hours	33.0±34.0	44.0±34.2	0.315
Total drainage	293.5±126.71	456.3±174.56	0.002*

* Statistically significance: p-value less than 0.05



POSTOPERATIVE BLOOD LOSS WAS DEMONSTRATED BY MEAN DRAINAGE OUTPUT AND 95% CI DURING THE FIRST 16 HOURS AND THE SUBSEQUENT DAY 1, DAY 2, DAY 3 AND TOTAL DRAINAGE AFTER OPERATION.

POSTOPERATIVE HB LEVEL

	Topical tranexamic acid group	Control group	P-value
Postoperative Hb level (g/dL) Day 1 Day 2	 11.7±1.27 11.2±1.12	 10.5±1.64 11.3±0.89	 0.015* 0.757
Number of days to drain removal (days)	2.8±0.49	4.0±0.92	0.000*
Duration of hospitalization (days)	6.8±4.58	11.6±7.37	0.019*

* Statistically significance: p-value less than 0.05

- ONE PATIENT IN THE TOPICAL TRANEXAMIC ACID GROUP (5%) RECEIVING BLOOD TRANSFUSION COMPARED TO 7 PATIENTS (35%) OF THE CONTROL **(ODD RATIO 0.0977, 95% CONFIDENCE INTERVAL 0.0107 TO 0.8918; P-VALUE 0.03).**

- THE AVERAGE FOLLOW-UP PERIOD WAS 9.0 MONTHS (1- 33 MONTHS).
- THERE WAS NO IMPLANT FAILURE.
- ONE ADJACENT LEVEL DEGENERATION OF LOWER PART OF FUSION SEGMENT AT 12 MONTHS.

COMPLICATIONS

Topical tranexamic acid	Control	p-value
4 pneumonia (2 UTI)	1 unilateral temporary C5 palsy	Odd ratio 0.2105, 95% CI 0.0213 to 2.0790 with p-value 0.1823
No thrombotic related complications (deep vein thrombosis, pulmonary embolism, cerebrovascular accident or myocardial infarction) in both groups No tranexamic acid adverse reaction (seizure, renal failure nausea, diarrhea or rash)		

DISCUSSION

- EVIDENCE OF TOPICAL TRANEXAMIC ACID REDUCED BLOOD LOSS IN TOTAL KNEE ARTHROPLASTY BY ZEKCER AND COLLEAGUES IN 2017
- TOPICAL TRANEXAMIC ACID IN LUMBAR SPINE SURGERY: SABERI ET AL IN 2010, REN ET AL IN 2027
- BENEFIT OF TOPICAL USAGE IN LUMBAR SPINE SURGERY IN META-ANALYSIS STUDY IN 2018 BY LUO AND COLLEAGUE IN 2018
- CLINICAL APPLICATION IN THORACOLUMBAR SPINE FRACTURE FIXATION BY SUDPRASERT AND COLLEAGUES IN 2019

- THE STRENGTH OF THE STUDY :

  NO STUDIES OF THE USE OF TOPICAL TRANEXAMIC ACID IN POSTERIOR CERVICAL SPINE SURGERY

  THE STUDY PROTOCOL RECRUITED TWO CONSIDERABLY HOMOGENEOUS GROUPS.

  ALL CASES WERE OPERATED BY THE SAME SURGEON AT THE SAME HOSPITAL WITH THE SAME FUSION AND INSTRUMENTATION TECHNIQUE.

- LIMITATION OF THE STUDY

  STUDY DESIGN

  CLINICAL APPLICATION FOR CERVICAL PEDICLE SCREW FIXATION

CONCLUSION

THE LOCAL ADMINISTRATION OF 500 MG OF TRANEXAMIC ACID TO THE SURGICAL SITE IN POSTERIOR INSTRUMENTED CERVICAL SPINE FUSION REDUCES POSTOPERATIVE DRAINAGE VOLUME SIGNIFICANTLY AND DECREASES POSTOPERATIVE BLOOD TRANSFUSION, SHORTEN TIME UNTIL DRAIN REMOVAL AND LENGTH OF HOSPITAL STAY AFTER SURGERY WITHOUT A SIGNIFICANT INCREASE IN THE RISK OF SYSTEMIC THROMBOSIS OR OTHER COMPLICATIONS.

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The Effect of Topical Tranexamic Acid in Reduction of Postoperative Blood Loss after Posterior Instrumented Cervical Spinal Fusion: A Retrospective Comparative Study

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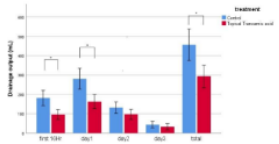
Keywords: topical tranexamic acid, postoperative blood loss, cervical spine surgery



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โรงพยาบาลอุดรธานี

The Effect of Topical Tranexamic Acid in Reduction of Postoperative Blood Loss after Posterior Instrumented Cervical Spinal Fusion: A Retrospective Comparative Study

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Purpose: *to evaluate the efficacy of topical tranexamic acid on postoperative blood loss reduction, risk of blood transfusion and postoperative complications in patients undergone posterior cervical spine surgery compared with a control group.*
Methods: *Retrospectively non-randomized observational study was conducted. The clinical data of patients who underwent posterior cervical spine instrumented fusion in Udon Thani hospital from October 2016 to March 2021 were included. Perioperative and postoperative outcomes were analyzed to compare between 20 patients received local tranexamic acid before wound closure and another 20 patients with no tranexamic usage as a control group.*
Results: *A total of 40 cases undergone posterior cervical spinal instrumented fusion procedure were enrolled, of which male to female ratio was 33:7 and mean age was 55.0±15 years. The mean of drainage volume was significantly lower in the topical tranexamic acid group than in the control group during the first 24 hour after surgery (163.0±78.8 versus 260.5±115.1 ml, p-value 0.001). The mean total drainage volume was significantly lower in the topical tranexamic acid group than in the control group (293.5±126.71 ml versus 456.3±174.56 ml, p-value 0.002). Postoperative blood transfusion rate was lower in the tranexamic acid group (5%) than the control group (35%) (Odd ratio 0.0977, 95% confidence interval 0.0107 to 0.8918; p-value 0.03). The mean duration of postoperative hospitalization was significant shorter in the topical tranexamic acid group (6.8±4.58 days) than the control group (11.6±7.37 days), p-value 0.019.*
Conclusion: *The local administration of 500 mg of tranexamic acid to the surgical site in posterior instrumented cervical spine fusion reduces postoperative blood loss from drainage output, decreases risk of blood transfusion, and shortens postoperative hospital stay without an increase in the risk of systemic thrombosis or other complications.*

Keywords: *topical tranexamic acid, postoperative blood loss, cervical spine surgery*

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Introduction

Posterior cervical instrumented fusion can be used to treat cervical spine conditions because it provides rigidly immediate stabilization and early rehabilitation including fastened ambulation to patients. Perioperative blood loss is one of the most common complications for the surgery. This condition causes surgical wound hematoma, wound infection, prolonged retained drainage leading to prolonged hospitalization and postoperative anemia followed by risks of blood transfusion[1]. Potential problems associated with blood transfusion include disease transmission, transfusion reactions, and infections[2]. The causes of perioperative blood loss lie in surgical techniques such as multilevel cervical spinal fusion requiring a longer operative time, extensive soft tissue dissection associated multiple level of surgical address, and a difficult level of fusion (upper cervical spine surgery).

Various measures have been used to decrease perioperative blood loss and reduce risks of blood transfusion, such as intraoperative cell saver machine[3], deliberate hypotensive anesthesia[4], and anti-fibrinolytic agents. An anti-fibrinolytic agent, tranexamic acid, has been investigated in many clinical trials including systemic review[5] and proven that systemic tranexamic acid can control perioperative bleeding and reduce postoperative blood transfusion significantly[6]. Nevertheless, many surgeons are concerned whether the effects of systemically administered tranexamic acid can result systemic thrombotic events such as myocardial infarction, stroke, deep vein thrombosis and pulmonary embolism[7]. To eliminate thrombotic events from systemic administration, topical tranexamic acid has been used in many studies[8] and appeared to be effective to reduce perioperative blood loss significantly in many orthopedic procedures including lumbar spine

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THANK YOU