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ORIGINAL ARTICLE

The efficiency and safety of intravenous tranexamic acid administration in open reduction and internal fixation of pelvic and acetabular fractures

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Abstract

Purpose This study aimed to investigate the efficiency and safety of tranexamic acid use in open reduction and internal fixation of pelvis and acetabulum fractures.

Materials and methods 73 consecutive patients were included. 1000 mg TXA was administered intravenously to all patients before surgery. The patients were evaluated on the basis of preoperative, postoperative first and third day hemoglobin-hematocrit values, amount of drainage collected, total blood loss, transfusion rates and complications.

Results Mean operative time was 120.1 min. Average decrease in hematocrit levels between preoperative and postoperative first day was 2.1 g/dL. Average collected blood from the drain was 177 mL. Mean total blood loss was 1137 mL. Transfusion rate of the patients was 21%. Mean transfused units was 0.9 units. Three patients died within 3 weeks after the operation due to myocardial infarction, acute kidney failure and pneumonia. There were no cases of symptomatic venous or pulmonary thromboembolism during the 90 days of follow-up.

Conclusion Use of TXA in pelvic and acetabular fractures was found to be effective in reducing total blood loss, hemoglobin drop and transfusion rates without increasing venous and pulmonary thromboembolism in our series.

Keywords Tranexamic acid · Pelvis · Acetabulum · Fracture · Blood loss · Transfusion

Introduction

Pelvis and acetabulum fractures are infrequent and complex injuries that require major orthopaedic intervention. Both the initial injury and the required major surgery can lead to substantial blood losses and the total blood loss has been reported as high as 1232–2818 mL in previous studies [1, 2]. To prevent anemia and hypovolemic shock, blood transfusion is often required but massive transfusions can cause serious complications such as lifethreating immunologic response, cardiovascular damage, acute lung injury, HIV and Hepatitis C transmission [3].

It has been demonstrated that transfusions have harmful immunomodulatory effects via disrupted T-cell mediated immunity [4, 5]. Impaired immunity leads to an increased risk of postoperative infections in trauma, spine, and arthroplasty patients [6–10]. This increased risk has also been shown in acetabulum fractures [11, 12].

Furthermore, blood transfusion has been demonstrated as an independent predictor of mortality after controlling for severity of shock in trauma patients [13].

On the other hand, intraoperative bleeding increases surgical risk via affecting safe surgical exposure, increasing operative time and causes additional morbidity. Thus, reducing the amount of blood loss is our top priority in the treatment of pelvic and acetabular fractures.

Postoperative blood loss and allogeneic blood transfusion can be reduced with several procedures. These procedures include autologous blood transfusion, hypotensive

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anesthesia, apply of fibrin tissue adhesive, clamping of the drain and administration of tranexamic acid (TXA) [14]. TXA saturates lysin-binding sites of plasminogen molecules, delays fibrinolysis and inhibits clot degradation [15].

Especially in recent years, to reduce morbidity and blood loss, TXA is widely used in arthroplasty and trauma surgeries in orthopaedics [16–18]. An analysis of 26 randomized controlled trials have shown that TXA can reduce blood loss at least 300 mL and reduce the transfusion rate by 52% in patients undergoing orthopedic surgery [19]. Meta-analyses of randomized clinical trials have demonstrated that administration of TXA reduces blood loss and blood transfusion rate without increasing the risk of thromboembolic events in total hip and total knee arthroplasty [14, 16, 20]. Benefit has also been shown both in adult and pediatric spinal surgery [21, 22].

In published literature, majority of studies regarding fracture and TXA have focused on hip fractures and do not address pelvic or acetabular fractures [23, 24]. The effect of TXA on pelvis and acetabulum fractures remains unclear. So, this study was designed to investigate the efficacy and safety of the TXA use in open reduction and internal fixation of pelvic and acetabular fractures.

Materials and methods

Patients

From August 2017 to October 2019, 73 consecutive patients (56 male, 17 female) who were diagnosed as having pelvic and acetabular fractures and treated with open reduction and internal fixation were included in this retrospective study. Patients were excluded if their fracture was treated with external fixation, C-clamp, trans-sacral or sacroiliac screw placement without open approach. No other exclusion criteria applied. Any postoperative complications up to 90 days were recorded.

Blood management

Preoperatively, patients were prepared to surgery to have a hemoglobin value of at least 10 mg/dL. Postoperative Hb threshold for blood transfusion was 8 mg/dL in our institution; however, all patients who demonstrated symptomatic acute blood loss anemia were transfused.

Surgical procedures

1000 mg TXA was administered for all patients 30 min before surgery. The TXA administration dose in our study was determined according to previously published cohort and randomized controlled studies [25, 26]. All operations were applied by single senior surgeon (author). Acetabular fractures were operated via ilioanterior [27] or Kocher Langenbeck [28] approaches according to the fracture pattern and pelvic ring fractures were also treated with open approach. Patients operated with ilioanterior approach were given general anesthesia (41 patients, 58%). Other patients were given spinal anesthesia. Drain was removed at postoperative 48th hour. Subcutaneous low molecular weight heparin was given preoperative 12 h ago and throughout postoperative 4 weeks.

Outcome measures

The patients were evaluated on the basis of preoperative, postoperative first and third day Hb-Hct values, amount of drainage collected, total blood loss and transfusion rate. Total blood loss was calculated on the basis of hemoglobin balance according to equations described by Good et al. [29] using the Nadler's formula for blood volume [30]. This calculation method takes into consideration both the evident and hidden losses.

Statistical Analysis

Data were included in a database created by the Excel 2007 programme by Microsoft (Microsoft Corporation, Redmond, Washington, USA). Statistical analysis was performed using PASW statistics for Windows (version 18, USA). Descriptive analysis of the frequencies was performed via calculating the distribution of frequencies for qualitative variables and mean and standard error of mean for the quantitative variables. The chi-square test and the Student *t*-test were used to compare differences between variables. A p value < 0.05 was considered statistically significant.

Results

Mean trauma age of the cohort was 44.3 ± 19.1 (range, 18–88). Mean body mass index (BMI) was 25.8 ± 5.0 (range, 17.6–45.5). Fracture type was isolated pelvis in 15 (20%) patients, isolated acetabulum in 29 (40%) patients. Twenty-nine (40%) patients had both pelvic and acetabular fractures. Except one patient, all isolated acetabulum fractures were unilateral. The most common accompanying trauma was lower extremity fracture and the most common injury mechanisms were falling from high and motor vehicle accident. Accompanying medical diseases included hypertension, diabetes mellitus, history of cardiac operation, history of cerebrovascular and pulmonary event (Table 1).

Mean operative time was 120.1 ± 53.6 min. Average hematocrit (Hct) drop between preoperative and postoperative first day was 2.1 g/dL. Average collected blood

Table 1 Baseline demographic and clinical features of patients ($n=73$)

Age, years	44.3 ± 19.1
Male gender	56 (77%)
Body Mass Index, kg/m^2	25.8 ± 5.0
Comorbidity	
History of cardiac operation	4 (5%)
History of cerebrovascular accident	3 (4%)
History of pulmonary embolism	1 (1%)
Hypertension	9 (12%)
Diabetes mellitus	5 (7%)
Fracture type	
Isolated pelvis fracture	15 (20%)
Isolated acetabulum fracture	29 (40%)
Combined pelvis and acetabulum fracture	29 (40%)
Additional trauma involvement[a]	
Lower extremity	17 (23%)
Upper extremity	14 (19%)
Maxillofacial	5 (7%)
Vertebrae	5 (7%)
Urethra	1 (1%)
No additional injuries	39 (53%)
Mechanism of injury	
Falling from high	27 (37%)
Motor vehicle (in car)	26 (36%)
Low energy trauma	9 (12%)
Motor vehicle (pedestrian)/motorcycle	7 (10%)
Crush injury	4 (6%)

*The levels are expressed as mean ± standart error of the mean

[a]Sum greater than 100% because of combined injuries

Table 2 Outcomes ($n=73$)

Preoperative Hct, g/dL	32.8 ± 4.6
Postoperative 1.day Hct, g/dL	30.7 ± 4.8
Postoperative 3.day Hct, g/dL	28.7 ± 4.3
Mean drained blood volume, mL	177 ± 147.9
Total blood loss, mL	1137 ± 972
Transfusion rate	21% (15 patients)
Mean transfused units	0.9 ± 2.1
Surgical time, minutes	120.1 ± 53.6
Length of hospital stay, days	7.5 ± 7.3
DVT/PE cases	0/0

Hct hematocrit, *DVT* deep vein thrombosis, *PE* pulmonary embolism

*The levels are expressed as mean ± standart error of the mean

from the drain was 177 mL. Mean total blood loss was 1137 mL. Transfusion rate of the patients was 21%. Mean transfused units was 0.9 units. Mean hospitalization duration was 7.5 days (Table 2).

There was no significant difference in age and gender between patients who received transfusion and those who did not ($p>0.05$). However, transfused patients had significantly lower body mass index, body weight and blood volume than those who were not transfused ($p<0.05$) and patients with a body mass index < 25 were transfused significantly higher units than the patients with a body mass index ≥ 25 (1.63 units versus 0.24 units, $p<0.05$).

The avarage number of days between injury and surgery was 4.8 ± 2.4 (range, 0–12) days. There was no statistically significant difference in transfusion rates, total blood loss and Hct drop between patients who were operated for < 5 days and ≥ 5 days ($p>0.05$).

Complications included superficial infection (four patients), deep infection (two patients), Moral Lavallee lesion (one patient), obturator vein injury (one patient), superior gluteal artery injury (one patient) and myocardial infarction (three patients). Superficial infections were treated with antibiotics. Deep infections and Moral Lavallee lesion were successfully treated with debridement. Arterial and venous injuries were treated with ligation of the vessels. There were no cases of symptomatic deep vein thrombosis or pulmonary embolism during the 90 days of follow-up. Three patients died within 3 weeks after the operation due to myocardial infarction, acute kidney failure and pneumonia. The age of these three patients were 71, 88 and 82, respectively, and the patients had no history of ischemic heart disease.

Discussion

Pelvic and acetabular region has a complex anatomical structure surrounded by abundant venous plexuses. Initial injury and required major intervention causes substantial blood losses and massive blood transfusions. Transfusion rate has been reported 24% in isolated pelvis fractures, 35% in isolated acetabulum fractures and 57% in combination of these two injuries, with a mean transfusion of 4.81 units [31]. A recent study reported that blood transfusion increases mortality even 3 months after surgery for hip fracture [32].

Recent meta-analysis studies have demonstrated that TXA reduces hemoglobin drop, total blood loss and transfusion rate in trauma patients without increasing venous thromboembolism rate [17, 18, 33, 34]. The biggest study that investigates the role of TXA on trauma patients was the CRASH-2 trial. 20,221 patients in 40 countries were evealuted and the authors found significant reduction in all-cause mortality and bleeding associated mortality with the use of TXA in trauma patients [26]. However, there is still uncertainty regarding the benefit and safety of TXA in fracture surgeries and in United States TXA is not included in routine practice for orthopaedic fracture repair operations. The reason why clinicians are hesitant to administer TXA is

the theoretical concern of increased thromboembolic complications [18].

One recent randomized controlled trial reported no benefit of TXA in terms of transfusion incidence, transfusion volume and estimated blood loss in open reduction and internal fixation of acetabulum fractures [35]. Another randomized controlled trial reported no reduction in overall transfusion rates, although a significant reduction was found in total blood loss with the use of TXA in high-energy fractures of the pelvis, acetabulum and femur [36]. To our knowledge, these studies are the only two published studies directly evaluating intravenous TXA use in pelvic or acetabular fracture patients. Wayne et al., investigated combination of holding preoperative thromboembolism chemoprophylaxis and using intraoperative TXA in pelvic and acetabular fracture patients. They concluded that this combination is safe and effective in reducing operative time and blood transfusion rates [37]. In a placebo-controlled study, Sandeep et al. [38] reported reduced blood loss and transfusion rate with the use of topical TXA in acetabular fracture patients. In our series, TXA was effective in reducing total blood loss, Hct drop and transfusion rates with respect to the reference for the series that TXA did not administered (Table 3).

Patients with increased BMI in our series had significantly lower transfusion rates ($p < 0.05$). This may be secondary to losing smaller percentage of the total blood volume. Similarly previous studies have reported a significant decrease in transfusion rates with increasing BMI in arthroplasty and trauma patients [39, 40].

To our knowledge, TXA have not been shown to cause an increased risk of myocardial infarction. In a recent meta-analysis of 10 studies involving 842 patients, investigators found no significant difference between the TXA and placebo groups in terms of myocardial infarction in hip fractures [23]. In the CRASH-2 trial investigating the effects of TXA on vascular occlusive events in trauma patients, 213 (1.05%) of 20,211 patients experienced an arterial occlusive event (myocardial infarction or stroke) and there was no statistically significant difference between TXA and placebo groups [26]. Our study group consisted of patients with pelvic and acetabular fractures, and the myocardial infarction rate of our study (1.3%) was compatible with the literature.

Compared to the total knee and total hip arthroplasty patients, trauma patients have increased risk of fatal pulmonary embolism [41]. The reason is these patient group is immobilized preoperatively and postoperatively. In pelvic fracture patients, venous thromboembolism has been reported to occur 61% without prophylaxis and 2–33% with prophylaxis [42–44]. On the other hand, TXA inhibits fibrinolysis and creates a prothrombotic state. As many surgeons have theoretical concern of increased thrombotic events, they are hesitant to use TXA in trauma patients [18]. To our knowledge, there have been no reported significant

Table 3 Comparison of current series and published studies regarding the use of TXA in pelvic/acetabular fractures

	Year	Dose	*N*	Surgical time (mins)	Hct drop postop 1.day	Hct drop postop 3.day	TBL (mL)	Transfusion rate (%)	Units transfused	DVT/PE
Current series	2020	1000 mg	73	120	− 2.1 g/dL	− 4.1 g/dL	1137	21	0.9	0/0
William et al. [35] (TXA group)	2017	10 + 10 mg/kg	42	251	–	–	–	50	2.65	1/1
William et al. [35] (Placebo group)	2017	0	46	212	–	–	–	33	2.36	0/0
Clay et al. [36] (TXA group)	2019	15 + 15 mg/kg	47	306	− 3.1 g/dL	− 6.7 g/dL	952	55	1.51	2/0
Clay et al. [36] (Placebo group)	2019	0	46	284	− 5.6 g/dL	− 9.6 g/dL	1325	43	1.17	1/0
Sandeep et al. [38] (TXA group)	2019	Topical	31	206	–	–	988	42	–	0/0
Sandeep et al. [38] (Placebo group)	2019	0	30	215	–	–	1356	97	–	1/0

TXA tranexamic acid, *Hct* hematocrit, *Postop* postoperative, *TBL* total blood loss, *DVT* deep vein thrombosis, *PE* pulmonary embolism

relationship between intravenous administration of TXA and deep vein thrombosis or pulmonary embolism in trauma patients. We reported no cases of symptomatic deep venous thromboembolism or pulmonary embolism in our cohort.

The limitation of this study was the lack of a control group. Therefore, we compared our results with previously published studies. In these studies, various races from different countries were included, and there may be differences between races in terms of efficacy and side effects of TXA and the coagulation system of patients.

In conclusion, the use of TXA in pelvic and acetabular fractures was found to be effective in reducing total blood loss, hemoglobin drop and transfusion rates without increasing venous and pulmonary thromboembolism in our series. More studies are needed to prove the effect of TXA administration in pelvic and acetabular fractures.

Author contributions All authors contributed to the study conception and design. Performing surgeries was done by SAG. Material preparation, data cata collection and analysis were performed by SAG, ZEÇ and SA. Review and editing of the study were performed by TO and HBÇ. The first draft of the manuscript was written by ZEÇ and all authors on previous versions of the manuscript. All authors read and approved the final manuscript.

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Code availability Available.

Availability of data and material Available.

Compliance with ethical standards

Conflict of interest The authors report no conflict of interest.

Ethics approval This research has been approved by the institutional review board of the authors' affiliated institutions.

Informed consent Written informed consent was obtained from all patients.

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