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Tranexamic Acid Should be Considered for High Risk Arthroplasty Patients

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Abstract

Background: Tranexamic acid significantly reduces blood loss and transfusion requirements in arthroplasty patients. However, it is often avoided in patients who have had previous arterial and thromboembolic disease despite the absence of evidence of hazard in this group of patients. We examined the use of tranexamic acid in unselected hip and knee arthroplasty patients including those considered to be 'high risk'.

Methods: A 2-year retrospective multicentre study was performed with patients who underwent hip or knee arthroplasty surgery. A blood management protocol included universal tranexamic acid use for all patients. Blood loss, transfusion volumes and complications were analysed.

Results: A total of 958 patients were included in the study, 130 patients were considered 'high risk' of thromboembolic complications and 828 patients were considered 'low risk'. 879 patients received tranexamic acid with a significant reduction in blood loss ($p<0.001$) in these patients.

Conclusions; The efficacy of tranexamic acid is overwhelming and outweighs any potential risks. Tranexamic acid should be considered for use in all arthroplasty patients including those with prior history of venous or arterial thrombosis.

Background

Antifibrinolytic agents have been used since the 1960's for bleeding dyscrasia, gastrointestinal bleeds, menorrhagia, epistaxis, urological bleeds, hyphemas and haemophilias and have a well-defined safety profile [1]. Tranexamic acid (TXA) has been widely adopted for routine use in joint replacement surgery and its effectiveness in reducing perioperative blood loss in arthroplasty patients has been well demonstrated in the literature [2–7].

Tranexamic acid is a fibrin clot stabiliser and theoretically should not be prothrombrotic [8]. However, there remains a concern within theatre when a decision is made to provide TXA to a patient with a higher risk of arterial or venous thromboembolism, that they may be subject to additional harm. This accounts for the frequent exclusion of these patients in clinical practice and research studies. Therapeutic Goods Administration guidelines include active or previous history of arterial or venous thrombosis, cerebral thrombosis, subarachnoid haemorrhage and acquired disturbances of colour as a contraindications for TXA use [9].

A multidisciplinary association of American Societies have recently conducted a safety meta-analysis and recommended guidelines which included the routine use of TXA for arthroplasty patients with routine risks [10]. Whilst they found that here is no evidence of an increased risk in high-risk patients (Patients with venothromboembolism (VTE), myocardial infarction, cerebrovascular accidents, transient ischemic attacks, or presence of cardiac stents), they acknowledge that there is limited data on patients in this group and the consensus was inconclusive [11].

Keywords*: TXA; Tranexamic acid; Arthroplasty; VTE; Venothromboembolism; Joint replacement*
Level of Evidence*: III*

Tranexamic acid has been used sporadically with arthroplasty surgery patients who have had previous arterial and thromboembolic disease and there is no evidence of hazard in this group of patients [10]. The aim of this study was to evaluate the complication rate following the use of tranexamic acid in unselected arthroplasty patients including patients with previous histories of cerebrovascular, cardiovascular and thromboembolic disease.

Material and Methods

A retrospective interrogation of a prospective patient database from two independent Australian institutions was examined. All consecutive patients who had total hip arthroplasty or total knee arthroplasty were included over a two-year period from a single surgeon private hospital (St John of God Murdoch) and a multi-surgeon series from a public hospital (Queen Elizabeth Hospital). 518 consecutive patients from the private hospital and 440 patients from the public hospital were included. In the private hospital tranexamic acid was administered to all patients 1 gram orally one hour prior to surgery and 1 gram via peri articular injection. VTE prophylaxis included post-operative mechanical calf pumps and enoxaparin 40mg daily until discharged from hospital when enoxaparin was exchanged for aspirin 150mg daily for 4 weeks. In the public hospital 15mg per kilogram (rounded to 1-1.5 gram ampule) intravenous tranexamic acid was administered at induction of anaesthesia and 8 and 16 hours post operatively. VTE prophylaxis included postoperative mechanical calf pumps and either aspirin 100mg EC or enoxaparin 40mg daily, patients were discharged on aspirin 150mg daily for 4 weeks (table 3). A restrictive transfusion trigger of < 7gram/decilitre (g/dl) and 7-9g/dl for cardiac and symptomatic patients was used in both institutions.

Demographic data included age, sex, body mass index (BMI), past medical history including previous thromboembolic events (stratified into a risk profile) and American Society of Anaesthesia (ASA) scores. High risk patients were defined as those with a history of VTE or arterial thromboembolic events whilst the remaining patients were considered low risk. Patients who did not receive tranexamic acid were further investigated as to the reasons of withholding the medication.

Outcome data included pre-operative and day one post-operative Hb, transfusion volumes and postoperative complications. A restrictive VTE investigation protocol was used with imaging if there was clinical suspicion of VTE with either doppler ultrasound or computed tomography pulmonary angiogram.

Statistical Analysis

Patient demographic data were obtained for this study and where normally distributed; mean and standard deviation were used. Categories were reported as frequency and percentages. Logistic regression analysis was used for analysis of VTE rate post arthroplasty whilst controlling for potential confounding variables of patient demographics, ASA, risk score and BMI.

Ethics

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee. An ethical review was performed by the Central Adelaide Local Health Network Human Research Ethics Committee as a quality assurance project and was exempt from ethical approval. The Human Research Ethics Committees (HREC) Reference number for this review is HREC/18/CALHN/704.

Results

958 knee and hip arthroplasty patients were identified between the two institutions (table 1). There was no significant difference between all demographic data and the independent variables (table 2). There were 36 patients (3.6%) who had a previous deep vein thrombosis or pulmonary embolus, 52 patients (5.4%) had ischemic heart disease, 42 patients (4.4%) had a history of a previous cerebral vascular accident. These patients were all considered high risk for the purpose of this study.

130 patients were considered ‘high risk’ and 828 patients were considered ‘low risk’. 92% of ‘high risk’ patients and 92% of ‘low risk’ patients received TXA. In the public hospital there was a significantly lower rate of TXA compliance with 59 of 440 patients (13%) not receiving TXA whilst in the private hospital 20 of 518 patients (4%) did not receive TXA ($p<0.01$) (table 1). Of the 79 patients who did not receive TXA, four of these patients had a post-operative VTE (5%) and of the 879 patients who received TXA, 12 of these patients had a post-operative VTE (1%). This difference was significant $P=0.04$.

When these patients were split into their risk profiles, two of 130 (1.5%) ‘high risk’ patients and 14 of 828 (1.7%) ‘low risk’ patients had post-operative VTE. Of those who received TXA, one of 120 (0.8%) ‘high risk’ patients and 11 of 759 (1.4%) ‘low risk’ patients had post-operative VTE. There was no significant difference in rate of VTE between the ‘high risk’ and ‘low risk’ patients overall ($p=0.6$) or in the subgroup of patients who had only re-

Table 1: Demographic data and risk groups split by institution

	Hospital 1	Hospital 2	Total
n	518	440	958
Age (mean +/- SD)	65.16 +/- 11.9	68.2	
Age (median + IQR)	66 (58 - 73)	69 (61 - 76)	
Male (%)	220 (57%)	163 (43%)	383
Female (%)	298 (52%)	277 (48%)	575
TXA compliance	87%	96%	92%
High risk	**69**	**61**	**130**
VTE	11	25	36
CVA	18	24	42
IHD	40	12	52
Low risk	**449**	**379**	**828**
Transfusion	6	8	14
VTE rate	5	11	16

Table 2: Demographic data and independent variables split by tranexamic acid use

	TXA	No TXA	P-value
Age (mean +/- SD)	66 +/- 14.1	67 +/- 10.8	P=0.69
Age (median + IQR)	66 (56 - 76)	69 (59 - 75)	
BMI (mean +/- SD)	32.49 +/- 6.49	32.55 +/- 7.48	P=0.94
BMI (median + IQR)	32 (27 - 38)	32 (28 - 37)	
Female (%)	523 (91%)	52 (9%)	P=0.57
Male (%)	356 (93%)	27 (7%)	
TKR (%)	481 (90%)	50 (10%)	P=0.14
THR (%)	398 (93%)	29 (7%)	
ASA 1&2 (%)	566 (92%)	50 (8%)	P=0.7
ASA 3&4 (%)	288 (91%)	28 (9%)	
High Risk	120 (92%)	10 (8%)	P=0.96
Low Risk	759 (92%)	69 (8%)	

ceived TXA (p=1) (table 4).

Despite a significant difference between no TXA use and post-operative VTE, after controlling for other independent variables and a multiple logistic regression model did not demonstrate a significant difference (Age, Sex, BMI, Joint, Risk group, ASA score) (p=0.2). Independently there was a significant reduction in blood loss (p=0.0001) and transfusions (P=0.002) in patients who received TXA. Controlling for independent variables (age, sex, joint, BMI, ASA) the subsequent reduction in blood loss (P< 0.001) and transfusion rate remained significant (P=0.009) (table 5). ASA score was found to significantly increase the chance of transfusions (p=0.01) but not blood loss (p=0.129).

Table 3: Institutional differences in prescription and application of thromboprophylaxis

	Charles Gardner Hospital	Queen Elizabeth Hospital
N	518	440
Recruitment method	Consecutive	Consecutive
Period	2014-2016	2016-2018
Private/Public	Private	Public
Surgeons	Single Surgeon	Multi-Surgeon
TXA route	Oral and Topical	IV
TXA dosage	1g PO and 1g Top	15mg/kg
TXA timing	PO 1 hour prior and Top intra-operative injection	IV at induction, 8 hours and 16 hours post
Transfusion trigger	< 7gm/dl or 7-9g/dl for cardiac and symptomatic patients	< 7gm/dl or 7-9g/dl for cardiac and symptomatic patients
Mechanical VTE prophylaxis	Post-operative calf compressors	Post-operative calf compressors
Chemical VTE prophylaxis	Enoxaparin 40mg as inpatient and aspirin 150mg as outpatient	Mixture of aspirin 100mg or enoxaparin 40mg as inpatients and aspirin 150mg as outpatients
Chemical duration	4 weeks total	4 weeks total

Table 4: Venous thromboembolic events in high and low risk groups and stratified by tranexamic acid use

	Post op VTE	No post op VTE	P-value
High risk	2	128	P=0.6
Low risk	14	814	
High risk who received TXA	1	131	P=1
Low risk who received TXA	11	736	

Table 5: VTE rate, blood loss and transfusion rates following tranexamic acid application controlling for independent variables

	TXA	No TXA	P-value
VTE (%)	12 (1.4%)	4 (5%)	P=0.2
Blood loss (mean)	29.9	35.7	P<0.001
Transfusions	9 (1%)	5 (6.3%)	P=0.009
Controlling for age, sex, joint, BMI, ASA, risk profile			

Discussion

Tranexamic acid was again shown to be effective in reducing blood loss and transfusion after total joint arthroplasty in this study which is consistent with every prior report on the use of tranexamic acid in arthroplasty patients. Paradoxically our data showed an independent significant reduction in VTE post-operative TXA administration however this significance did not carry over after controlling for independent variables. Specifically, our findings showed that tranexamic acid even in these 'high risk' patients was safe and in our study was not associated with an increased risk of venous thromboembolism or thromboembolic complications such as myocardial infarction or cerebrovascular accident [13]. This finding in our Australian population is consistent with larger international registry studies such as the matched outcome study performed by the Mayo group in 2017 [14].

Our results demonstrate less blood loss and less transfusions with tranexamic acid use regardless of age, sex, knee or hip joint, BMI or ASA. Patients with more complex medical conditions recorded with an ASA greater than 2 had the same blood loss but were more likely to receive a transfusion which is an anticipated finding as the ASA grade and cardiac comorbidities alter the transfusion trigger.

This study has a number of limitations particularly the relative number of participants required to measure uncommon sentinel events such post-operative myocardial ischaemia, cerebral ischemia and clinically important venous thromboembolic events. A post hoc analysis would suggest that many tens of thousands of patients would be required to detect a difference in the context of these relatively uncommon complications. The Mayo group [15] have recently published the results of 1262 knee arthroplasty patients with a history of venous thromboembolisms in a matched outcome study. Patients that received tranexamic acid had a VTE rate of 2.3%, which compared to 1.8% in matched controls, and they concluded that tranexamic acid was safe to use in patients with a history of VTE. In 2018, the Mayo group expanded this work to include 16 hospitals with 38,220 patients including 8,877 patients that had a prothrombotic history [13]. They found that TXA use was not associated with increased rates of adverse outcomes.

The Danish national database was interrogated to determine the risk of cardiovascular events and death after hip arthroplasty in 45,290 patients [2]. 38,586 patients had received tranexamic acid including 1,176 that had a prior history of venous thromboembolism and there was no difference in VTE risk. In that study the hazard ratio of tranexamic acid for arterial thrombosis was 0.64 and all-cause mortality was 0.61 suggesting clinically important improvements of mortality and morbidity. Tranexamic acid may be protective in 'high risk' patients because of the reduction of blood loss, which is an independent variable for perioperative myocardial ischemia. These patients measurably benefit from a decrease in all-cause mortality and protection against arterial thrombosis that overrides any theoretical concerns of increased VTE.

The safety of tranexamic acid in the high risk patient has been looked at from a registry level in anaesthesiology by Poeran et al [12] who found that tranexamic acid was not associated with an increase in complication irrespective of patient risk status whether these be vascular, renal or cardiac risks.

The mode of administration remains an uncertain variable and was a limitation of this study where one hospital used parenteral administration exclusively and the other used a combination of oral and intra-articular injection. The optimal dosing regimen of TXA for total knee replacement (TKR) and total hip replacement (THR) is considered in the recent clinical guide on TXA administration in arthroplasty patients, specifically guideline questions 1-4 and found equivalency in efficacy between the modes of administration [10]. The dosing regimen continues to be debated and the guidelines concluded that the dosage regime did not have a clinically important impact on blood loss or VTE risk in patients without a pro-thrombotic history [10]. Whilst MacDessi et al examined the efficacy and safety of topical TXA compared to parenteral administration with TKA and demonstrated similar efficacy and safety in patients with routine risk [16], a knowledge gap exists for THR patients.

In our study, 8% of ' high risk patients' and 9% of 'routine risk patients' did not have tranexamic acid. We were unable to identify documented reasons for these exclusions and believe most were due to oversight or logistical errors. There was a difference in compliance of tranexamic acid administration between the public and the private hospital. We felt that this difference is probably due to the continuity of surgeon and anaesthetist at the private hospital whilst there were multiple surgeons and anaesthetists at the public. We recommend increased scrutiny to ensure all patients receive tranexamic acid in association with joint arthroplasty surgery.

Before the widespread use of perioperative blood management strategies approximately 1/5th of knee arthroplasty patients and 1/3rd of hip replacement patients received a transfusion [17]. With the evolution of blood management strategies, which include the routine use of tranexamic acid, transfusion following arthroplasty surgery is an infrequent occurrence [18]. Newman et al report a reduction

in the transfusion rate in Victorian arthroplasty patients between 2009 and 2015 with THA transfusion incidence decreasing from 38.5% to 12.5% and TKA transfusion rates decreasing from 12.4% to 2.1% [17]. Kildow et al proposed THR patients with a normal pre-operative haemoglobin (Hb) that had tranexamic acid did not require a routine postoperative Hb test [19]. Halawi et al found post-operative laboratory results did not change the course for 96% of patients and recommend a restricted approach to post-operative laboratory testing [20]. In our series, 8 patients (1.8%) received a transfusion and a total of 11 units were transfused (transfusion index of 0.025). Frank et al proposed group and holding blood is not required when less than 5% of patients are transfused and the transfusion index is less than 0.3 [21]. In this study the transfusion requirement was below this threshold and we believe it is unnecessary to hold serum for these patients where transfusion is a rare event.

The national blood authority recommends a three-pillar approach to peri-operative blood conservation [22–25] that includes optimizing red blood cell mass, minimizing blood loss, and managing anemia. Kearney et al [26] demonstrated that 17% of Orthopaedic arthroplasty patients were anemic, with half of these being iron-deficient. It is recommended that patients found to have a low red cell mass have preoperative investigations and optimisation which is more likely to occur if the haemoglobin assessment is available when booking their surgical procedure rather than the current time frame which is foreshortened to allow a group and save. The practical consequence of not venesecting a patient immediately before surgery for an unnecessary group and save should be considered. Patients should instead have a pre-operative Hb assessment early prior to surgery with potential advantages to electively correct red cell mass, and saves the cost of an unnecessary test.

Conclusion

We recommend that tranexamic acid be routinely administered to all elective arthroplasty patients, including those patients considered “high risk”. The data regarding the safety of tranexamic acid is overwhelming and the proven benefits of use outweigh any potential risks.

We recommend that the use of tranexamic acid as part of a perioperative blood management regime obviates the need for routine group and hold testing.

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AUTHOR DISCLOSURES

- The authors declare that there is no conflict of interest in connection with this submitted article.

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