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An Educational Module in the Usage of Tranexamic Acid (TXA) as an Alternative to Epsilon Aminocaproic Acid (EACA) in Cardiac Surgery to Reduce Perioperative Transfusion Requirements: A Quality Improvement Project

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Abstract

Background: Cardiac surgery is associated with significant perioperative bleeding and blood transfusion requirements. The effectiveness of antifibrinolytic therapy and financial concerns are carefully balanced in cardiac surgery in the United States. While TXA has stronger potency and fewer dose requirements than EACA, its higher cost impacts the choice of antifibrinolytic medication. Developing an educational module for anesthesia practitioners on the issue of TXA dosing in cardiac surgery can be an effective strategy. This project thus aimed to develop the educational module.

Method: The sample size for participants was selected based on the available pool of CRNAs from the FIU alumni list. This DNP project adopted a pre-/post-intervention design to evaluate the impact of an educational module on the knowledge and practices of CRNAs involved in providing anesthesia for cardiac surgery. These questionnaires captured quantitative and qualitative data, including demographic information. The project used the electronic Qualtrics system to streamline the process and improve data accuracy.

Results: This survey had a sample size of 15 participants. Of the participants, 57% (n = 8) were males, and 43% (n = 6) were females. Male participation was slightly higher. All participants were older than 25, with the highest % of participants older than 31 years, 79% (n = 11). Hispanics comprised the most prominent ethnic group of participants at 50% (n = 7). CRNAs with a doctoral level of education comprised 100% (n = 14) of the sample size. Of these providers, 54% (n = 7) had 1-5 years of experience, while the rest had less than a year or more than 5. Compared to the pretest, the posttest demonstrated a greater proportion of questions with the correct answers. The fact that this occurred suggests that the educational intervention was effective.

Discussion: The findings indicate the educational module's positive effect on improving clinical confidence and competency among healthcare workers. The most evident flaw in the educational initiative was the small sample size. A limited sample size may impact the study's validity and reliability. The project's findings might increase knowledge among CRNAs, minimize blood loss and transfusion requirements, and promote standardized TXA protocols.

Keywords: Tranexamic acid (TXA), cardiac surgery, antifibrinolytic therapy, epsilon aminocaproic acid (EACA)

Table of Contents

PICO

This research investigated a fundamental question in clinical practice: the role of TXA versus EACA in cardiac surgery. It specifically sought to evaluate whether TXA has the same effect on transfusion needs and intraoperative hemorrhage as EACA. To address this issue, the PICO question posed was, “In patients undergoing cardiac surgery, does the use of tranexamic acid infusion (TXA), compared to epsilon aminocaproic acid (EACA), have similar effects on transfusion requirements and intraoperative bleeding?”

Population: Patients undergoing cardiac surgery

Intervention: Usage of tranexamic acid (TXA)

Comparison: Usage of epsilon aminocaproic acid (EACA)

Outcome: Transfusion requirement and intraoperative bleeding

Problem Identification

Antifibrinolytics have long been shown to reduce surgical bleeding and, as a result, the requirement for blood product transfusions. On March 16, 2023, the National Hemophilia Foundation for All Bleeding Disorders announced the bankruptcy and closure of Akorn Pharmaceuticals, a manufacturer and marketer of epsilon aminocaproic acid (EACA). Despite assurances of supply protection, this event raised concerns about accessibility and availability.[1] On the verge of a possible supply and demand imbalance of EACA, tranexamic acid (TXA) may be substituted as the main therapy in cardiac surgery. Such a shift may require adjustments in dosing protocols. There has yet to be a universally agreed-upon consensus on the dosing of TXA in the context of cardiac surgery, and dosing regimens often vary between institutions and even among healthcare providers.[2] Even though research and clinical practice guidelines often provide recommendations or considerations for TXA dosing in cardiac surgery, its dosage and delivery

strategies have long been a source of contention. Drug administration varies widely among studies, and no unanimity has been achieved on the following issues: the optimal TXA dosage, whether TXA should be administered intravenously or topically, and whether continuous infusion or bolus injection should be employed.[2] Furthermore, the dosing of TXA in cardiac surgery typically depends on several factors, including the patient's weight, the procedure, and institutional practices. The current challenge is deciding what dose of TXA is equally efficacious and safe compared to aminocaproic acid in this setting.

Background

Cardiac surgery is a standard procedure nowadays. However, although it is commonly practiced, it continues to be associated with significant perioperative bleeding and blood transfusion requirements. The etiology is multifactorial.[3] Contributing risks are platelet dysfunction, hypotension, systemic anticoagulation, and fibrinolysis associated with cardiopulmonary bypass (CPB).[3,4] Antifibrinolytic drugs, such as lysine analogs and aprotinin, have reduced perioperative bleeding. In 2007, a randomized control trial (RTC) revealed that aprotinin was associated with a 53% increase in mortality. Subsequently, the drug was withdrawn globally by its manufacturer.[3] After aprotinin use ceased, TXA and EACA became the leading agents for bleeding reduction during cardiac surgery.[5]

The effectiveness of antifibrinolytic therapy and financial concerns are carefully balanced in cardiac surgery in the United States. While TXA has stronger potency and fewer dose requirements than EACA, its higher cost provides economic issues for institutions, perhaps impacting the choice of antifibrinolytic medication.[6] On average, the medication acquisition cost for EACA was found to be $2.23 per surgery, while TXA was significantly more expensive at

$39.58 per surgery.[6] Given TXA's considerable price tag, many institutions employ EACA as the mainstay anti-fibrinolytic therapy for their open-heart surgery protocols.

Scope

In 2016, the American College of Surgeons Database (ACSD) revealed that cardiac procedures such as coronary artery bypass graft (CABG), isolated aortic valve replacement (AVR), CABG+AVR, mitral valve surgery, and aortic aneurysm repair are among the most performed cardiac procedures worldwide. Approximately 156,931 CABG procedures were performed in 2016 alone in the United States.[7] These procedures share a common feature: the imperative use of antifibrinolytic therapies to prevent extensive bleeding and its associated complications. The prevalent use of antifibrinolytics in these surgeries has a worldwide impact on patient care, as these medications help reduce complications, improve outcomes, and decrease the need for blood transfusions.

The clinical problem posed would significantly impact millions of people globally. Due to a possible shortage of Amicar and a lack of agreement on TXA dose, healthcare facilities' antifibrinolytic medication choices may vary, resulting in uneven treatment regimens. Inconsistent dosage can compromise bleeding control, raising the risk of bleeding complications. Without successful antifibrinolytic medication, there may be a greater demand for blood products, putting a strain on blood bank supplies and increasing the risk of transfusion-related complications. Substituting TXA as the major antifibrinolytic may increase costs, affecting healthcare budgets and resource allocation. Without agreement on TXA dose, cardiac surgical centers may lack standardized care methods, impacting patient care quality and consistency.

Consequences of the Problem

Without appropriate analysis of the various ways EACA and TXA may differ, patients undergoing cardiac surgery will inevitably suffer the consequences of yet another drug shortage. A review of the literature noting the various ways drug shortages have impacted healthcare points out the potential challenges that may be faced in the future without enough EACA. From an economic perspective, institutions will have to absorb the increased expenses required to manage the change from EACA to TXA use.[8] Still, most frightening is the potential for near misses and medication errors that often follow sweeping medication practices surrounding drug shortages.[8] Furthermore, since drug shortages do not necessarily affect all hospitals equally, a decreased supply of Amicar can disproportionally impact vulnerable populations.[8] There is a lack of consensus and a gap in knowledge to practice because TXA is rarely used in open heart surgery. Practitioners and institutions may need more knowledge about this medication's appropriate dosing, contraindications, and side effects. To resolve this issue, it is imperative to compare the safety profile of TXA and its impact on transfusion requirements and intraoperative bleeding to those of aminocaproic acid.

Knowledge Gaps

The issue of antifibrinolytic therapy in cardiac surgery is characterized by information gaps, particularly in the absence of EACA and consensus on TXA dose. These include a lack of agreement on optimal dose regimens, a lack of comparative efficacy and safety trials, and a need for more evidence on patient-specific factors impacting medication selection.[9] It is also uncertain whether the dosing route should be intravenous or topical.[2] Long-term follow-up on the issue needs to be more extensive, as are cost-effectiveness assessments. More real-world evidence must be provided on antifibrinolytic use in cardiac surgery results and practices. Addressing

these knowledge gaps through clinical trials, systematic reviews, and collaborative initiatives is critical for enhancing patient treatment, maximizing resource use, and guaranteeing the long-term viability of the field.

Proposed Solution

This study addressed a critical issue anesthesia providers face in cardiac surgery. It aimed to provide evidence-based dosing recommendations for antifibrinolytic therapy, address existing knowledge gaps, and standardize practice. The results can improve patient care, reduce complications, and optimize healthcare resource utilization. Developing an educational module for anesthesia practitioners on the issue of antifibrinolytic medication dose in cardiac surgery, specifically TXA dosing, can be an effective strategy to address the identified knowledge gaps and solve the problem. Launching said module requires a thorough needs assessment, clear learning objectives, evidence-based content, and an accessible delivery platform. The module should cover topics like TXA and EACA mechanisms of action and recommended dosing in cardiac surgery scenarios. The module should also include an assessment to evaluate comprehension. Regular feedback and updates are crucial for the module's effectiveness.

Rationale

The closure of Akorn Pharmaceuticals, a major manufacturer of EACA, in March 2023 has raised concerns about its accessibility and availability.[1] As a result, tranexamic acid TXA may be used as the primary anti-fibrinolytic for cardiac surgery patients, potentially requiring adjustments in dosing protocols. There is no universally agreed-upon consensus on the dosing of TXA in this setting, and dosing regimens often vary between institutions and healthcare providers.[2] The optimal dosage, administration methods, and continuous infusion or bolus injection are all factors that must be considered.

This review aims to provide evidence-based dosing recommendations for antifibrinolytic therapy in cardiac surgery, address existing knowledge gaps, and standardize practice. An educational module on antifibrinolytic therapy dosing in cardiac surgery can efficiently manage these shortcomings. The results can improve patient care, reduce complications, and optimize healthcare resource utilization. This session covers the TXA mechanism of action, suggested dose in cardiac surgery, and side effects.

Literature Review

Methodology

Eligibility Criteria

The review was initially limited to RCTs published in English, chosen for their methodological rigor, and potential to demonstrate TXA efficacy in cardiac surgery. Later, systematic reviews and case studies were included to expand the scope and provide a more comprehensive understanding of the topic. Articles were included if they targeted the specific patient population, adults undergoing elective cardiac surgery, both with and without CPB. Children were excluded from the review due to potential differences in physiological responses, surgical requirements, and dosing considerations.

Information Sources

The outcome of this review was expected to yield information regarding the optimal dosage and delivery method of TXA with the most negligible adverse effects. A literature search strategy was designed to ensure a systematic and exhaustive approach. The databases of PubMed, Embase, and Cochrane Central Register of Controlled Trials (CENTRAL) were the primary sources for retrieving relevant research articles published between 2013 and 2023. These databases were chosen for their comprehensive medical and healthcare literature coverage,

including RCTs, systematic reviews, and scholarly publications. They are considered reliable sources of evidence-based practice in healthcare, making them ideal for the study's objectives.

Search Strategy

The search targeted Evidence Based Practice (EBP)-related articles using keywords and Boolean operators. Included within the search queries were the keywords; “patients undergoing cardiac surgery,” "tranexamic acid," "aminocaproic acid," "cardiac surgery," "transfusion requirements," and "intraoperative bleeding." These terms were combined with Boolean operators such as "AND" and "OR" to refine the search results and retrieve articles that addressed the particular elements of the practice query. According to the search strategy described above, the initial question found 179 articles from the Cochrane database, 585 from Embase, and 504 from PubMed.

The titles and abstracts of retrieved articles were screened for significance. Duplicates were removed to prevent redundancy. After assessing 31 full-text articles for eligibility, 9 papers were included for analysis, meeting the criteria and providing a clear, evidence-based assessment of the optimal dosage and delivery method while minimizing potential bias and ensuring relevance to the clinical context of cardiac surgery in adults. The following keywords were used to conduct the literature search: tranexamic acid (TXA), cardiac surgery, antifibrinolytic therapy, and epsilon aminocaproic acid (EACA).

Keywords: Tranexamic acid (TXA), cardiac surgery, antifibrinolytic therapy, epsilon aminocaproic acid (EACA)

Results

Study Characteristics

The appendix literature matrix table appraises several studies to gauge the role of TXA in cardiac surgery. Dearholt and Dang's principles and practice approaches for assessing research evidence were used to determine the strength of the evidence of the 9 included studies.[11] Eight randomized controlled trials and one systematic review gave valuable insights into various aspects of TXA administration, including dosages and their related outcomes. Each study's quality and validity were thoroughly assessed.

Results of Included Studies

The DEPOSITION study, a single-center, double-blind, parallel-group randomized controlled trial, aimed to reduce postoperative blood loss by topical vs. intravenous TXA in open cardiac surgery.[3] The study involved 97 adults undergoing elective on-pump cardiac procedures through a median sternotomy.[3] Patients were randomized to either an intervention group, which received intravenous (IV) placebo and intrapericardial (IP) TXA, or a control group, which received IV TXA and IP placebo.[3] This small Level II RCT found that IP TXA was as effective and safe as IV TXA, leading to decreased bleeding and transfusion requirements. [3,11]According to the study, employing IP TXA based on a small pilot study may overestimate its effectiveness, perhaps resulting in unforeseen clinical repercussions.[3] It underlines the importance of larger RCTs to establish the intervention's safety and efficacy, as applying the intervention without further validation may result in a less effective or risky intervention.

Makhija et al. conducted a prospective RCT comparing TXA and EACA in thoracic aortic surgery on CPB.[4] This study is categorized as a Level II RCT.[11] The study was conducted in a tertiary care center with 64 adult patients. Patients were randomized into 2 groups. Group

EACA received a bolus of 50 mg/kg of EACA after induction of anesthesia over 20 minutes, followed by a maintenance infusion of 25 mg/kg/h until chest closure.[4] Group TXA received a bolus of 10 mg/kg of TXA after induction of anesthesia over 20 minutes, followed by a maintenance infusion of 1 mg/kg/h until chest closure. Findings revealed that both interventions reduced blood loss and transfusion requirements. However, EACA was associated with higher renal injury.[4]

Verma et al. conducted a prospective, randomized, double-blind study comparing TXA and EACA in elective coronary artery bypass grafting (CABG).[10] It involved 80 patients admitted for elective CABG at a tertiary hospital between 2017 and 2018. The TXA group received 10 mg/kg IV at induction and 1 mg/kg/hr throughout the surgery. In contrast, the amino-caproic acid group received 100 mg/kg IV over 20 minutes and 10 mg/kg/hr through surgery completion.[10] The study concluded that TXA significantly reduced postoperative bleeding in off-pump CABG at 24 hours, compared to EACA, but it also had a slightly higher seizure rate. The study's main drawback is that the sample size is too small, making it difficult to accurately determine complication rates, suggesting that more extensive trials are needed for off-pump CABG surgeries.[10]

Shi et al. conducted a randomized clinical trial comparing the efficacy and adverse events of high-dose and low-dose TXA in cardiac surgery with CPB.[5] The study involved 3079 adult patients aged 18-70 undergoing cardiopulmonary bypass at 4 Chinese hospitals from 2018 to 2021. Participants received either a high-dose TXA regimen comprising a 30-mg/kg bolus, a 16-mg/kg/h maintenance dose, and a 2-mg/kg prime or a low-dose regimen consisting of a 10-mg/kg bolus, a 2-mg/kg/h maintenance dose, and a 1-mg/kg prime dose.[5] Results showed that the High-dose TXA infusion modestly reduced the proportion of patients receiving allogeneic red

blood cell transfusions after CABG, meeting noninferiority criteria for 30-day mortality, seizure, kidney dysfunction, and thrombotic events. This trial was limited to the Chinese population. Caution should be exercised when applying the findings to other ethnic groups. Additionally, the red blood cell transfusion rate reduction by high-dose TXA was smaller than the expected absolute rate reduction of 7.4%.[5]

Guo et al. conducted a meta-analysis of RCTs to determine the optimal TXA dosage and delivery method for elective heart surgeries.[2] This study is considered Level I on the hierarchy of evidence.[11] The study systematically searched Cochrane Central Register of Controlled Trials, MEDLINE, and EMBASE for relevant articles published before December 2018. As a drawback, only RCT comparing TXA with placebo was considered. After assessing 103 full-text articles for eligibility, the authors included 49 studies with 10,591 participants in this meta-analysis.[2] The study found that TXA significantly reduced blood loss, transfusion requirement, and re-operation rate in adult cardiac surgery. TXA was effective for off-pump and on-pump operations and did not increase the risk of thrombotic events or renal injury.[2] However, it significantly increased the risk of seizure, a rare occurrence in cardiac surgery patients. Intravenous delivery of TXA reduced the transfusion rate by 30%, while topical application showed no signs of lowering transfusion requirement.[2]

Myles et al. performed a large-scale 2-by-2 factorial RCT in patients undergoing coronary artery surgery to assess the effect of TXA.[9] Between 2006 and 2015, 4662 patients were randomly assigned to receive aspirin or placebo and TXA or placebo at 31 sites in 7 countries.[9] The study found that TXA reduced blood loss and transfusion requirements without increasing the risk of death or thrombotic complications. However, it was associated with a higher risk of postoperative seizures. The study reasoned that in a cardiac surgical practice

similar to the one in which the trial population was treated, TXA would save approximately 57 units of blood products for every 100 patients treated.[9] This study is classified as a Level II RCT.[11]

Monaco et al. conducted a double-blinded RCT to investigate the effect of TXA on blood loss in open abdominal aortic aneurysm (AAA) surgery.[12] The study included 100 patients over 50 years old. Patients were randomly assigned to receive a TXA loading dose of 500 mg and a continuous infusion of 250 mg/hr or placebo for elective open AAA repair.[12] This research found that TXA did not significantly reduce intraoperative blood loss but had a beneficial effect on postoperative bleeding. This Level II RCT had several limitations, including being underpowered to assess safety outcomes.[11,12] However, the findings agreed with recent literature that TXA does not increase the risk of thromboembolic events. Further trials should specifically focus on postoperative bleeding, including measurements of blood content in postoperative drainages.[12]

Choudhuri et al. compared the incidence of reopening after open heart surgeries in patients who received either EACA or TXA for controlling perioperative bleeding.[13] The study included 78 patients aged 18-65 with ASA physical status II-IV undergoing elective open heart surgeries under CPB. Patients were divided into 3 groups: group A received EACA, group B received TXA, and group C received intravenous 0.9% normal saline. Group A received EACA as a loading dose of 100 mg/kg body weight before the skin incision, followed by a continuous infusion of 100mL of diluted EACA up to 6 hours postoperatively. Group B received TXA at a loading dose of 10mg/kg body weight, followed by a continuous infusion of 100mL of diluted TXA up to 6 hours postoperatively.[13] Both groups received 0.9% normal saline for dilution. This Level II RCT found that both agents had minimal impact on the re-exploration rate due to

excessive bleeding.[11,13] Due to the small sample size, future studies with more power are needed to provide more data for critical comparison.

Tksaudom et al.[14] conducted a double-blind, prospective, randomized, controlled trial that aimed to assess the effectiveness of topical and intravenous tranexamic acid in reducing bleeding in cardiac surgery cases. The study involved 82 adult patients who underwent elective on-pump cardiac surgery between July 1, 2014, and September 30, 2015. The primary endpoint was 24-hour blood loss, with secondary endpoints including the volume of blood products transfused, reexploration rate, length of hospital stay, mortality, morbidity, and TA-related complications. Data was collected from cardiac surgery patients using research questionnaires and analyzed using the STATA statistical package.

The study found no significant difference between groups in surgical procedures, operative time, aortic cross-clamp time, or CPB time.[14] Postoperative hematologic profiles were comparable, except for postoperative hemoglobin level and hematocrit. The median blood loss 24 hours after surgery was 350.0mL, and there was no significant difference in the rate of decline of postoperative drainage between groups. The most common postoperative complication was de-novo atrial fibrillation in 12 patients. The study concluded that topical tranexamic acid is safe but does not enhance postoperative blood loss. In contrast, intravenous tranexamic acid alone is sufficient for improving hemostatic effects during on-pump cardiac surgery.

Appendix A: Literature Review Table

Citation	Design/Method	Sample/Setting	Major Variables /Definitions	Measurements / Data analysis	Findings	Results	Conclusions	Appraisal/ Worth to Practice Level
Habbab et al,[1] 2019	The DEPOSITION pilot study, a single-center, double-blind, parallel group randomized controlled trial, aimed to reduce postoperative blood loss by topical vs. intravenous tranexamic acid in open cardiac surgery. Patients were randomized to either an intervention group (received intravenous	The study involved 97 adults undergoing elective on-pump cardiac procedures through a median sternotomy. Exclusion criteria included minimally invasive valve surgery, off-pump procedures, emergency operations, and severe renal impairment.	The primary outcome was postoperative chest tube production 24 hours after surgery, with secondary outcomes including postoperative seizure rates, surgical re-exploration, total blood transfusions, ICU stay length, death, nonfatal myocardial infarction, stroke, and pulmonary embolism. Adverse events were	The study used continuous variables such as mean, standard deviation, median, and quartiles, and categorical data such as frequency distributions. Baseline characteristics were compared using $\chi 2$/Fisher's exact tests and analysis of variance for numerical variables, with analyses conducted	The IP TXA group showed comparable outcomes and adverse events to the IV TXA group, with decreased bleeding and reduced transfusion requirements. Secondary outcomes, including cardiac tamponade, bleeding reoperations, postoperative seizures, deep vein thrombosis, and pulmonary embolism,	The IP TXA group had comparable primary outcomes compared to the IV TXA group, with decreased chest tube drainage and less transfusion requirements. This was observed in all secondary outcomes at discharge and 30 days follow-up, including cardiac tamponade, reoperations, pneumonia/re	The study suggests that IP TXA application is as effective and safe as IV TXA in cardiac surgery, with potential for greater effectiveness and safety if studied in a larger patient population, but a larger RCT is needed.	Level II small RCT According to the study, employing IP TXA based on a small pilot study may overestimate its effectiveness, perhaps resulting in unforeseen clinical repercussions. It underlines the importance of larger RCTs to establish the intervention's safety and efficacy, as applying the intervention

	(IV) placebo and intrapericardial (IP) TXA) or a control group (received IV TXA and IP placebo).		recorded on discharge and at 30 days.	using SAS version 9.4, with a significance level of 0.05.	also decreased at discharge and 30 days post-intervention. These reductions were observed at both discharge and follow-up.	spiratory failure, postoperative seizures, deep vein thrombosis, and pulmonary embolism.		without further validation may result in a less effective or risky intervention.
Makhija et al,[2] 2013	A prospective randomized comparative study was conducted to evaluate the efficacy and safety of tranexamic acid (TXA) versus epsilon aminocaproic acid (EACA) on patients undergoing thoracic aortic surgery on CPB. Group EACA received a bolus of 50 mg/kg of	The study was conducted on a tertiary care center with 64 consecutive adult patients undergoing thoracic aortic surgery with cardio-pulmonary bypass (CPB).	The study compared perioperative data from 2 study groups, assessing blood loss, coagulation variables, and safety measures. Intraoperative blood loss was measured by the amount of blood collected and required for PRBC and blood products, while	The study used pre-trial power analysis with a sample size of 29 patients per group, assuming mean blood loss of 220.31 mL in EACA and 198 mL in TXA. Data were analyzed using SPSS version 15 software, with continuous variables expressed as mean and categoric	Both groups were comparable with respect to CPB time, aortic cross-clamp (AOX) time, minimum temperature on CPB, hemoglobin before coming off CPB, urine output, amount of conventional hemofiltrate, intraoperative blood and blood product requirement,	Cumulated mean blood loss, total packed red blood cells, and blood product requirement up to 24h postoperatively were comparable between groups. The study found that EACA patients experienced significant renal injury and increased risk of renal	EACA and TXA effectively reduced perioperative blood loss and transfusion requirements in thoracic aortic surgery patients, but EACA caused renal injury and TXA increased seizure incidence. Further confirmation and prospective placebo-	Level II RCT

	EACA after induction of anesthesia over 20 minutes followed by maintenance infusion of 25 mg/kg/h until chest closure. Group TXA received a bolus of 10 mg/kg of TXA after induction of anesthesia over 20 minutes followed by maintenance infusion of 1 mg/kg/h until chest closure.		postoperative blood loss through thoracic chest tubes was measured. Secondary endpoints included thrombosis, neurological dysfunction, renal dysfunction, mechanical ventilation duration, and death.	variables as medians. A significance level of $p < 0.05$ was considered.	inotropic support, vasopressor requirement, and doses of fentanyl, vecuronium, midazolam, heparin, and protamine. The median blood loss through chest tube drain was higher in the TXA group compared to the EACA group. The incidence of renal injury significantly higher in the EACA group compared to the TXA group. Both groups had comparable postoperative hbg, platelet, BUN, serum creatinine, creatinine clearance, D-dimer values, and use of rFVII.	failure compared to TXA patients. Additionally, there was a significant increase in D-dimer from preoperative to postoperative values in EACA.	controlled trials are needed.	

Verma et al,[3] 2020	A prospective, randomized, double-blind study randomized patients to receive tranexamic acid or epsilon-amino-caproic acid. The tranexamic acid group received 10 mg/kg IV at induction and 1 mg/kg/hr throughout surgery, while the amino-caproic acid group received 100 mg/kg IV over 20 minutes and 10 mg/kg/hr through surgery completion.	The study involved 80 patients admitted for elective CABG at a tertiary hospital between 2017 and 2018, excluding those with concomitant valvular heart disease, recent myocardial infarction, ejection fraction <40%, pre-existing neurological, pulmonary, renal, or hepatic dysfunction, or known drug allergy.	Postoperative bleeding at 4 and 24 hours as the primary outcome, and rate of postoperative transfusion, re-operations, complication rate, serum fibrinogen, and D-dimer levels as secondary outcomes.	The study used SPSS software to perform statistical analysis. A sample size of 32 was found to be sufficient for each group, with a 5% significance level and 80% study power. With a 10% dropout rate, 80 patients were enrolled. Nonparametric data was represented as median with interquartile range, while categorical data was represented as mean with standard deviation. Nominal data was analyzed	Bleeding at 4 hours did not show significant difference between groups, 180 ml (80–250) vs 200 ml (100–310). Bleeding at 24 hours was significantly lesser in tranexamic acid group as compared to epsilon-amino-caproic acid group, 350 ml (130–520) vs 430 ml (160–730) ($p = 0.0022$) The rate of transfusion, re-operations, seizures, renal dysfunction, fibrinogen levels, and	The study found no significant difference in postoperative bleeding between groups, but at 24 hours, group TXA showed significantly less bleeding than group EA, possibly due to TXA's potency. There was no difference in postoperative transfusion rates or reopening operations for excessive bleeding. There was no difference in thrombo-embolic complications, stroke, DVT, or PE. The	Tranexamic acid significantly reduced postoperative bleeding in off-pump CABG at 24 hours, compared to epsilon-amino-caproic-acid.	Level II RCT The study's main drawback is the lack of standardized, surgery-specific dosing for both agents, which could have caused differences in results. Standardization is also needed for drug administration timing. The sample size was small, making it difficult to accurately determine complication rates, suggesting larger trials are needed for off-pump

				using Chi-square tests, and a P value <0.05 was considered significant.	D-dimer levels did not show significant difference between the groups.	incidence of stroke and DVT was not statistically significant. The study did not report an increased incidence of renal dysfunction, possibly due to dose variation and sample size. There was no significant difference in seizures incidence between groups.		CABG surgeries.
Shi et al,[4] 2022	This double-blind, randomized clinical trial compared the efficacy and adverse events of high-dose vs low-dose tranexamic acid in	The study involved 3079 adult patients undergoing cardio-pulmonary bypass at 4 Chinese hospitals from 2018 to 2021 included those	The primary efficacy end point was the rate of allogeneic red blood cell transfusion post-operation, while the primary safety	The primary efficacy end point was compared using the full analysis set, while the primary safety end point was compared using	Allogeneic red blood cell transfusion occurred in 21.8% of high-dose patients and 26.0% in low-dose patients. Postoperative seizure,	A randomized clinical trial found that high-dose tranexamic acid infusion reduced the proportion of patients receiving allogeneic red	High-dose tranexamic acid infusion modestly reduced the proportion of patients receiving allogeneic red blood cell transfusions	Level II RCT The trial is limited to the Chinese population, so caution should be exercised when applying the findings to other ethnic

	patients undergoing cardiac surgery with cardiopulmonary bypass. Participants received either a high-dose tranexamic acid regimen comprising of a 30-mg/kg bolus, a 16-mg/kg/h maintenance dose, and a 2-mg/kg prime or a low-dose regimen comprising a 10-mg/kg bolus, a 2-mg/kg/h maintenance dose, and a 1-mg/kg prime dose.	aged 18 to 70, awaiting elective surgery, and willing to give informed consent. Patients could withdraw at any time. Exclusion criteria included acquired defective vision, active intravascular coagulation, thrombophilia, previous convulsions or seizures, allergy to intravenous transexamic acid, breastfeeding or pregnancy, terminal illness with a life expectancy of less than 3	end point was a composite of 30-day mortality, seizure, kidney dysfunction, and thrombotic events (noninferiority hypothesis with a margin of 5%). There were 15 secondary end points, including the primary safety end point components.	completed cases with 30-day follow-up data. The study used multiple imputation, $\chi 2$ test, *t*-test, and $\chi 2$ test for primary and secondary end points. Post=hoc subgroup analyses were performed to investigate the consistency of the primary efficacy of high-dose vs low-dose tranexamic acid across clinically important subgroups. The study also examined the influence of both high- and low-dose tranexamic	thrombotic events, kidney dysfunction, and death occurred in 17.6% of high-dose patients and 16.8% of low-dose patients. Fourteen of the 15 secondary end points were not significantly different between groups, including seizure, in high-dose patients and 0.4% in low-dose patients. The study highlights the importance of considering secondary end points in treatment planning.	blood cell transfusion by 21.8% compared to 26.0%. The high-dose group had a 17.6% composite safety end point rate of 30-day mortality, seizure, kidney dysfunction, and thrombotic events compared with a 16.8 in the low-dose group. The difference was within the noninferiority margin of 5%.	after cardio-pulmonary bypass surgery, meeting noninferiority criteria for 30-day mortality, seizure, kidney dysfunction, and thrombotic events in a composite primary safety end point.	groups. Additionally, the reduction of red blood cell transfusion rate by high-dose tranexamic acid was smaller than the expected absolute rate reduction of 7.4%.

		months, mental or legal disability, and current enrollment in another interventional study.		acid on seizures in non-open-chamber and open-chamber cardiac surgery. A 2-sided p <.05 was considered statistically significant.				
Guo et al,[5] 2019	This meta-analysis of randomized trials aimed to identify the optimal TXA dosage and delivery method in elective heart surgeries. The study systematically searched Cochrane Central Register of Controlled Trials, MEDLINE, and EMBASE	After assessing 103 full-text articles for eligibility, the authors included 49 studies with a total of 10,591 participants in this meta-analysis. Inclusion criteria were adult patients undergoing elective heart surgeries, and only RCT comparing TXA with	Primary outcomes included transfusion rate and volume during hospital stay, while secondary outcomes included postoperative blood loss, re-operation rate, mortality, and postoperative complications such as seizure, stroke, myocardial	For dichotomous outcomes, relative risk (RR) was calculated with 95% confidence interval (CI), while mean difference (MD) was calculated for continuous outcomes. The fixed-effect model was used for analysis with no heterogeneity,	The use of TXA in heart surgery has been shown to significantly reduce the need for allogeneic blood transfusion by 29% in 31 trials with 8925 patients. The overall transfusion rate was 35% for patients using TXA and 49% for the control group. TXA	The study found that TXA significantly reduced blood loss, transfusion requirement, and re-operation rate in adult cardiac surgery. TXA was effective for both off-pump and on-pump operations and did not increase the risk of	The meta-analysis shows that TXA significantly reduces blood loss and transfusion requirements in adult cardiac surgery without increasing the risk of serious adverse events, except for seizure. High-dose trials delivered	Level I Meta-Analysis of RCTs The meta-analysis has limitations, including missing data on transfusion rate and not performing a network analysis to compare high and low-dose regimens, which underpowered the results. The

	for relevant articles published before December 2018. Only RCT comparing TXA with placebo were considered	placebo were considered. There were mainly 2 types of intravenous administration methods. One was bolus infusion alone (14 trials) and the other was bolus injection followed by continuous infusion (22 trials).	infarction, pulmonary embolism, and renal dysfunction.	and the random-effect model was used for analysis with heterogeneity. For outcomes with heterogeneity, subgroup analysis was used. Statistical heterogeneity was assessed using the I2 test, with I2 values ranging from 0-40% to 75-100%. $p < 0.05$ was considered statistically significant for hypothesis testing. The publication bias was visualized using symmetry of funnel plots. All statistical	also reduced the volume of blood transfused in all patients, with a reduction of 0.6 units per patient. Postoperative blood loss was reduced by around 247 ml per patient compared to the control group. TXA significantly decreased the risk of reoperation by 38%, with a reduction in absolute risk of 0.01 (95%CI 0.01, 0.02). TXA was associated with a 3.21-fold increase in the risk of seizure, with a	thrombotic events or renal injury. However, it significantly increased the risk of seizure, a rare event in cardiac surgery patients. Intravenous delivery of TXA reduced transfusion rate by 30%, while topical application did not show any signs to reduce transfusion requirement. Low-dose intravenous TXA was effective in reducing transfusion requirements, while high-dose TXA	TXA intravenously, but high-dose TXA does not decrease transfusion rates and tends to cause more seizure attacks. They considered low-dose TXA (bolus injection<50 mg/kg, or 10 mg/kg + 1mg/kg/h)to be more preferable.	mentioned limitations in the meta-analysis, may raise concerns about the feasibility of directly applying the study's results to clinical practice.

				analyses were performed in RevMan and Stata.	rate of 0.62% for patients using TXA and 0.15% for patients in the control group.	was at least equally effective and may be even more effective in reducing transfusion rate. The use of TXA was significantly associated with an increase in seizure attacks.		
Myles et al,[6] 2017	A 2-by-2 factorial trial randomly assigned patients undergoing coronary-artery surgery at risk for perioperative complications to receive aspirin or placebo and tranexamic acid or placebo.	Between 2006 and 2015, 4662 patients were randomly assigned to receive tranexamic acid or a placebo at 31 sites in 7 countries. Out of these, 2311 patients in the tranexamic acid group underwent surgery, while	The trial aimed to determine the primary outcome of postoperative myocardial infarction, including death and thrombotic events. Secondary outcomes included death, stroke, pulmonary embolism,	Using a chi-square test with a 2-sided type I error rate of 5%, they calculated that a sample size of 4484 patients would be required; they aimed to recruit a total of 4600 patients. Analysis of the primary and	The primary outcome was death or thrombotic complications within the first 30 days after surgery in 386 patients (16.7%) and in 420 patients (18.1%) in the placebo group. Myocardial infarction was	The study found no evidence that tranexamic acid resulted in a higher risk of death or thrombotic complications than a placebo for patients undergoing coronary-artery surgery. The tranexamic acid group had a lower	Tranexamic acid was found to be associated with a lower risk of bleeding in patients undergoing coronary-artery surgery, without higher risks of death or thrombotic complications within 30 days, but with a higher risk	Level II RCT The trial had several limitations, including underpowered dose effects testing, limited inclusion of high-risk patients, and the presence of attending anesthesiolo-gists. Sensitivity analysis and

		2322 patients in the placebo group underwent surgery. After surgery, 2 additional patients in the placebo group were excluded, and the remaining 2320 patients were included in outcome analyses. Demographic, medical, and perioperative characteristics were similar between the 2 groups. Two patients in the tranexamic acid group had incomplete follow-up data.	renal failure, bowel infarction, reoperation, and transfusion requirements. In January 2012, seizures were added as a safety outcome, based on clinical observation.	dichotomous secondary outcomes was performed with the use of chi-square tests constructed from binomial regression with a logarithmic link; the results are expressed as risk ratios with 95% confidence. Time-to-event outcomes were assessed with the use of the Wilcoxon–Breslow–Gehan test, with data on length of stay in the hospital and intensive care unit censored at 30 days and in-	detected in 269 patients (11.6%) and in 300 patients (12.9%) in the placebo group, including 58 patients (2.5%) and 47 patients (1.9%), respectively, recovering from isolated coronary-artery bypass grafting. Postoperative seizures occurred in 15 patients who received tranexamic acid and in 2 patients who received placebo (0.7% vs. 0.1%; relative risk, 7.60; 95% CI,	risk of blood loss, blood transfusion, and reoperation but a higher risk of postoperative seizures. The results were consistent across patients treated with aspirin and those not. Patients in the tranexamic acid group received 46% fewer units of blood products than the placebo group.	of postoperative seizures.	blinded data on postoperative blood loss and transfusion were consistent with the study's results. The trial also included only a small proportion of patients undergoing off pump surgery, which may have led to clinically important differences. Despite these limitations, the point estimates of effects among these patients were generally consistent with those among on-pump surgery

				hospital deaths assigned the highest length of stay.	1.80 to 68.70; P = 0.002).			patients. In a cardiac surgical practice similar to the one in which the trial population was treated, the use of tranexamic acid would save approximately 57 units of blood products for every 100 patients treated.
Monaco et al,[7] 020	The study aimed to investigate the effect of tranexamic acid on blood loss in open abdominal aortic aneurysm (AAA) surgery. One hundred	This single-center, double-blinded, parallel-group, randomized clinical trial was open to patients over 50 years old who provided written	The primary outcome was intraoperative blood loss, which was calculated by combining blood volume aspired during surgery and absorbed in gauzes. Secondary	The study used SPSS Statistics software version 23 to analyze data. The distribution of continuous data was tested for normality using the	The tranexamic acid group experienced a median blood loss of 400 ml compared to 500 ml in the placebo group. The rate of patients receiving red	The study found no reduction in intraoperative blood loss in patients undergoing open AAA repair, although a reduction in postoperative	In conclusion, the use of tranexamic acid in major vascular surgery did not reduce intraoperative blood loss, although it might have had a beneficial	Level II RCT The study has several limitations and strengths, including a historical estimate of intraoperative blood loss during AAA surgery and being

	patients were randomly assigned to receive tranexamic acid (a loading dose of 500 mg and a continuous infusion of 250 mg/hr) or placebo for elective open AAA repair.	informed consent. Patients with known allergies to tranexamic acid, seizures, acute venous or arterial thrombosis, fibrinolytic conditions, severe renal insufficiency, hematuria, or ocular disturbances were excluded from the trial.	outcomes included patients receiving packed red blood cells, occurrence of thrombo-embolic events up to 28 days after surgery, and mortality 28 days and 1 year after surgery. A phone follow-up was performed 28 days and 1 year after surgery	Shapiro-Wilk test and other tests as appropriate. A *p*-value <0.05 was considered statistically significant. Continuous variables were compared using *t*-test or Mann-eWhitney U-test, and categorical values were compared using a 2-tailed c2 test with Yates correction. Two-sided significance tests were used in all analyses. Data were presented as mean or median, and the estimated	blood cell transfusion was 14% in the tranexamic acid group compared to 24% in the placebo group. No differences were found in the rate of thrombo-embolic events, acute kidney injury, pulmonary embolism, bowel infarction, or seizures. At 28 days, no death was recorded, while at the 1-year follow-up, 3 patients died in the control group.	bleeding was observed.	effect on postoperative bleeding.	underpowered to assess safety outcomes. However, the findings agree with recent literature in that tranexamic acid does not increase the risk of thrombo-embolic events. Further trials should specifically focus on postoperative bleeding, including measurements of blood content in postoperative drainages.

				effect size was assessed using Cohen's kappa statistic for continuous variables, Cliff's *d* for non-normal variables, and absolute risk difference for categorical variables.				
Choudhuri et al,[8] 2015	The study aimed to compare the incidence of reopening after open heart surgeries in patients who received either epsilon amino caproic acid (EACA) or tranexamic acid (TXA) for controlling perioperative bleeding. Patients were divided into 3 groups: group	The study included 78 patients aged 18-65 with ASA physical status II-IV undergoing elective open heart surgeries under CPB. Patients with redo-cardiac surgery, renal insufficiency, ant platelet therapy, haematological disorders, or hepatic dysfunctions	The primary outcome of the study is the incidence of reopening following open heart surgeries in patients who were administered either epsilon amino caproic acid (EACA) or tranexamic acid (TXA) for control of perioperative bleeding.	The study used a sample size of 26 subjects per group to detect a difference of 200mL in blood loss after bypass surgery. Numerical variables were compared using one-way analysis of variance and Bonferroni's test, while categorical	Two patients in each of the EACA and TXA groups had excessive bleeding requiring reopening after surgery, while 3 patients in the control group had undergone reopening for excessive bleeding. The differences in reopening rates among	The study found that demographic and preoperative physiological parameters, such as age, body weight, sex, and preoperative coagulation profiles, were comparable among groups. The duration of cardio-pulmonary bypass and	Epsilon aminocaproic acid and tranexamic acid show similar effects to placebo on the incidence of reopening for excessive bleeding following open heart surgeries under cardio-pulmonary bypass.	Level II RCT The study found that prophylactic administration of EACA or TXA during cardiac surgeries under CPB has minimal effect on the rate of re-exploration due to excessive bleeding. However, future studies will provide

	A received EACA, group B received tranexamic acid, and group C received intravenous 0.9% normal saline. Group A received EACA as a loading dose of 100 mg/kg body weight before the skin incision, followed by a continuous infusion of 100ml of diluted EACA up to 6 hours postoperatively. Group B received TXA at a loading dose of 10mg/kg body weight, followed by a continuous infusion of	were excluded from the study.		data was compared using Chi-Square or Fisher's exact tests. All analyses were 2-tailed, and a *p*-value <0.05 was considered statistically significant.	the groups were statistically insignificant ($p > 0.05$).	patient age were also similar, indicating no significant impact on results. The study followed uniform methods and had minimal bias.		more data for critical comparison and analysis. The study emphasizes the need for uniform methods and minimal bias from confounding factors.

	100ml of diluted TXA up to 6 hours postoperatively. Both groups received 0.9% normal saline for dilution.							
Tksaudom et al,[9] 2017	The study aimed to assess the effectiveness of topical and intravenous tranexamic acid in reducing bleeding in cardiac surgery cases. Patients undergoing elective on-pump cardiac surgery were divided into a tranexamic acid group and a placebo group. The TXA group received 1 g of tranexamic	The study involved 82 adult patients who underwent elective on-pump cardiac surgery between July 1, 2014, and September 30, 2015. The majority (43.75%) were male and the remaining (56.25%) were female. The primary endpoint was 24-hour blood loss, with secondary endpoints including	The primary endpoint was 24-hour blood loss, with secondary endpoints including volume of blood products transfused, reexploration rate, length of hospital stay, mortality, morbidity, and TA-related complications.	The study involved recording data from cardiac surgery patients using research questionnaires. The data was analyzed using the STATA statistical package, with categorical data presented as frequency and percentage, and continuous data as mean and standard deviation. The study used	The study found no significant difference in surgical procedures, operative time, aortic crossclamp time, or CPB time between groups. Postoperative hematologic profiles were comparable, except for postoperative hemoglobin level and hematocrit. The median blood loss 24 hours after surgery was	There was no significant difference in demographic and intraoperative data except for a significantly lower platelet count preoperatively in the tranexamic acid group (p.0.030). There was no significant difference in postoperative drainage volumes at 8, 16, and 24 h, postoperative bleeding over	Topical tranexamic acid is safe but doesn't enhance postoperative blood loss, while intravenous tranexamic acid alone is sufficient for improving hemostatic effects during on-pump cardiac surgery.	Level II. This was a double-blind, prospective, randomized, controlled trial. The study's small sample size, despite theoretically being a large enough sample, did not significantly differ from previous studies, suggesting that intravenous TXA administration alone is

	acid dissolved in 100 mL of normal saline solution during sternal closure, while the placebo group received 100 mL of saline.	volume of blood products transfused, reexploration rate, length of hospital stay, mortality, morbidity, and TA-related complications.		Fisher's exact test, student's *t*-test, or Wilcoxon's rank-sum test for comparison. Postoperative blood loss was compared using repeated measures with mixed models. A *p*>value of less than 0.05 was considered significant.	350.0mL, and no significant difference in the rate of decline of postoperative drainage between groups. The most common postoperative complication was de-novo atrial fibrillation in 12 patients, with no other complications found. The mean intensive care unit and hospital stay were not significantly different between groups.	time (coefficient.0.713, p.0.709), or blood product transfusion between the groups.		sufficient antifibrinolytic treatment to improve hemostatic effects during on-pump cardiac surgery.

Literature Review Discussion

Synthesis of the Evidence

Several studies have compared the efficacy of EACA and TXA as antifibrinolytic drugs in various surgical scenarios. Makhija et al. compared EACA and TXA in thoracic aortic surgery.[4] Verma et al. and Choudhuri et al. compared the 2 drugs in elective CABG surgery and elective open-heart surgeries under CBP, respectively.[10,13] There were primarily 2 types of IV administration: bolus infusion alone and bolus infusion followed by continuous infusion. Notably, the dosages utilized in this study follow a consistent trend. All 3 studies employed the same dosing regimens for TXA: a loading dose of 10mg/kg and a maintenance infusing of 1mg/kg/hr, emphasizing the consistency in results achieved with similar dosages.[4,10,13] Makhija et al., on the other hand, used a different dosage of EACA, highlighting the diversity in dosage among research.[4] The precise dosage varied between studies, but the researchers determined that TXA and EACA were non-inferior and successfully decreased perioperative blood loss and transfusion needs. Furthermore, Verma et al. argued that the TXA group showed significantly less bleeding, possibly due to its potency.[10]

Two studies compared different routes of TXA administration. Habbab et al. and Taksaudom et al. compared IV TXA versus IP TXA.[3,14] It should be noted that the IV TXA dose employed by Habbab et al. was not dependent on the patient's weight but on a conventional 100mg dose. This study suggested that IP TXA application is as effective and safe as IV TXA in cardiac surgery.[3] In contrast, Taksaudom et al. found that while intravenous delivery of TXA significantly reduced the transfusion rate by 30%, the topical

application showed no signs of lowering transfusion requirements.[14] This result is further confirmed by Guo et al., who debated that topical application of TXA did not reduce the need for allogeneic blood transfusion.[2]

TXA administration was compared to a placebo by Myles et al. and Monaco et al.[9,12] Monaco et al. observed that TXA did not minimize intraoperative blood loss in major vascular surgery.[12] It may, however, have had a favorable effect on postoperative bleeding. Myles et al., on the other hand, concluded that the TXA group had a lower risk of blood loss, transfusion, and reoperation.[9] Furthermore, the disparity in outcomes between these 2 studies could be attributed to the Myles et al. high-dose regimen, which gave either 50 mg/kg or 100 mg/kg of TXA to each patient.[9] A lower dose of TXA will be similarly beneficial while generating fewer side effects.

This research indicated that utilizing TXA was strongly related to increased seizure events. This incidence was linked to greater dosages of TXA rather than low-dose TXA. Shi et al. compared low-dose to high-dose TXA continuous infusion.[5] The authors defined low dose as an intravenous bolus and maintenance regimen of 10 mg/kg and 2 mg/kg/h, respectively, with a pump prime dose of 1 mg/kg and a high dose as 30 mg/kg after anesthesia induction and then maintenance dosage of 16 mg/kg/h throughout the operation with a pump prime dose of 2 mg/kg.[5] This trial substantiates previous findings by showing that high and low doses of continuously infused TXA in patients undergoing cardiac surgery were associated with similar adverse event rates. However, the high dose was more efficacious than the low dose in reducing the need for red blood cell transfusion.[5] The estimate for postoperative seizures was slightly higher in the high-dose TXA group.

Monaco et al. used an average of 1g of TXA to balance the anti-fibrinolytic effects and avoid the previously described neurological problems.[12] Makhija et al. reported a notable tendency for seizure (TXA10% v EACA 3.3%, $p = 0.19$) after the administration of TXA.[4] Yet the authors considered this difference as insignificant. According to Verma et al., there was no significant difference in the incidence of seizures between the groups.[10] This was consistent with the findings of the study conducted by Makhija et al.[4] Despite differences in dosage regimens and the specific context of the studies (e.g., different types of cardiac operations), the overwhelming opinion is that the incidence of seizures is not statistically different between TXA and control or comparison groups.

TXA and Its Impact on Transfusion Requirements in Cardiac Surgery

A significant topic addressed by this review is whether TXA successfully minimizes the requirement for blood product transfusions during and after cardiac surgery compared to other antifibrinolytic drugs. Multiple trials consistently reported reduced blood loss and transfusion needs in patients who received TXA, providing proof of TXA's effectiveness in this area. For example, in a trial comparing TXA with EACA in thoracic aortic surgery, Makhija et al. reported that both antifibrinolytic drugs successfully decreased blood loss and transfusion needs.[4] Similarly, Verma et al. observed that TXA substantially decreased postoperative hemorrhage relative to EACA in elective CABG.[10] This research synthesis emphasizes TXA's essential function in reducing transfusion demands and improving patient outcomes after cardiac surgery, which supports the use of TXA as an alternative to EACA despite its high cost.

Dosages Trends of TXA in Cardiac Surgery

The research highlighted an essential aspect: the general dose trends of TXA used in cardiac surgery. A consistent tendency appears throughout the included studies regarding TXA

dose, notably concerning bolus and maintenance infusions. For TXA, Verma et al., Makhija et al., and Choudhuri et al. used a 10mg/kg bolus followed by a 1mg/kg/hr maintenance infusion.[4,10,13] This consistent dosage method, reproduced in various investigations, provides a familiar and successful technique for attaining antifibrinolytic effects in cardiac surgery. While the actual dosage may differ somewhat between these trials, the agreement on a loading dose and maintenance infusion dosage highlights a common trend in improving TXA delivery in the setting of cardiac surgery.

Literature Review Conclusion

This literature review provides valuable insights into antifibrinolytic therapy in cardiac surgery, specifically TXA. The studies consistently show the effectiveness of TXA in reducing perioperative blood loss and transfusion requirements, with a standardized dosage regimen of 10mg/kg bolus followed by a 1mg/kg/hr maintenance infusion being a well-supported practice. The administration route of TXA is also crucial, with studies comparing IV to IP TXA administration suggesting that IP TXA application can be as effective and safe as IV TXA. However, Guo et al.'s findings indicate that topical application of TXA does not significantly reduce the need for allogeneic blood transfusion, calling for further exploration of the optimal route in different cardiac surgical settings.[2]

The incidence of seizures associated with TXA administration is another crucial aspect, with mixed insights from studies. High-dose and low-dose TXA infusions have similar adverse event rates. Monaco et al. used an average of 1g of TXA to balance anti-fibrinolytic effects and neurological concerns.[12] The variability in seizure incidence among these studies underscores the importance of carefully evaluating dosages to mitigate potential adverse effects. The literature

supports the efficacy of TXA in reducing bleeding and transfusion requirements in cardiac surgery, but further investigation is needed to optimize its use in this medical context.

Primary DNP Project Goal

The primary goal of this doctoral project was to enhance the knowledge of Certified Registered Nurse Anesthetists (CRNAs) FIU alumni practicing throughout the United States through an educational module that provides evidence-based dosing recommendations for antifibrinolytic therapy in cardiac surgery, address existing knowledge gaps, and standardize practice. The educational module was based on evidence-based research that evaluates the efficacy, relative significance, and similar outcomes of EACA and TXA in cardiac surgery. On the verge of a medication shortage, TXA has been proven superior in mitigating perioperative blood loss and transfusion requirements.[2] The current administration of TXA during cardiac surgery is not standardized and may not adhere to best practices.[2] The primary emphasis is on adhering to the well-established dosage regimen of a 10mg/kg preload followed by a 1mg/kg/hr maintenance infusion, as supported by the comprehensive findings of the literature review.[4,10] This assessment offers significant perspectives on the pragmatic implementation of TXA and its influence on enhancing patient outcomes across our country.

SMART Objectives

Specific

The project's objective is to ensure CRNAs clearly understand the appropriate administration and dosing of TXA in case of an EACA drug shortage. Implementing a standardized TXA protocol aims to decrease perioperative blood loss and the necessity for allogeneic blood transfusion among patients undergoing cardiac surgery.

Measurable

This endeavor's efficacy will be determined by examining the data collected through pre- and post-educational questionnaires, focusing on participants' understanding of TXA usage during cardiac surgery, dosage regimens, and potential side effects. The primary goal is to detect a significant enhancement in knowledge, and provider's confidence after the educational module's execution.

Achievable

This objective is attainable due to its dependence on the application of established and empirically supported methodologies within the domain of cardiac surgery. It also considers CRNA's commitment to continuous education and patient safety.

Relevant

Pertinent to the clinical environment, the project aims to educate CRNAs and enhance patient outcomes by mitigating medical errors, standardizing practice, and decreasing blood loss and transfusion requirements, which contribute to patient safety and satisfaction.

Time-Bound

The project will be concluded within 6 months, including developing the educational module, data acquisition, and analysis of pre- and post-questionnaires. This timeframe guarantees the project's timely completion and comprehensive evaluation.

Description of the Program Structure

Developing an online educational module initiative that educates CRNAs on administering TXA during cardiac surgery entailed collaboration among multiple disciplines. A meticulous assessment was conducted to pinpoint opportunities, evaluate the project's importance, and gauge its significance to all stakeholders within the context of cardiac surgery.

Employing the Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis was instrumental in scrutinizing internal and external factors that could impact the program's development.[15] The SWOT analysis is an instrument utilized in strategic planning wherein an organization's internal strengths, vulnerabilities, and external opportunities and threats are methodically assessed.[15] The SWOT analysis is of utmost importance in our practice, as it facilitates the translation of evidence into practice by identifying potential areas for enhancement to elevate the standard of cardiac surgery care.

The initial step of this project involved determining key stakeholders. These stakeholders will play an essential role in the future implementation of a framework for TXA administrations throughout the country. Healthcare stakeholders include patients, providers, insurance companies, funders, donors, and research committees.[15] Once stakeholders have been identified, participants of this educational initiative were given a pre-test to assess their existing understanding of TXA, EACA, and cardiac surgery-related factors that influence blood transfusion requirements. Subsequently, an educational course was administered. Post-intervention, participants completed a survey to assess for shifts in their knowledge levels before and after the educational course, ensuring the practical impact of the initiative.

Strengths

An outstanding aspect of this initiative was its dedication to enhancing the understanding and use of CRNAs in administering TXA during heart surgery. The initiative's primary goal was to improve perioperative outcomes and patient care. This strategy aligned with the project's objective of minimizing blood loss during surgery and the need for blood transfusion, fostering a safer and more efficient procedures. In addition, the initiative utilized technology and evidence-based approaches.

Weaknesses

Despite commendable attributes, the administration of antifibrinolytics across the nation possesses evident shortcomings, as discerned via the SWOT analysis. A notable deficiency lies in the absence of standardized protocols for administering TXA during cardiac surgery and a need for provider knowledge. This weakness gives rise to discrepancies in dosage regimens and routes of administration, potentially causing infidelity in patient care and adverse effects on patient outcomes.

Opportunities

Healthcare organizations can capitalize on several development opportunities to enhance cardiac surgery care. An opportunity exists to align TXA administration practices with guidelines grounded in empirical evidence.[10] TXA is considerably more expensive than EACA but also more potent. Its utilization can minimize blood loss and transfusion needs during cardiac surgery. Heyns et al. consistently supported specific TXA dosage regimens and administration routes. By implementing these evidence-based practices, hospitals nationwide can decrease complications and increase patient satisfaction and outcomes.[16]

Threats

The hazards recognized within this framework primarily pertain to the threats of neglecting to rectify the vulnerabilities and failing to exploit favorable circumstances. Potential consequences of non-compliance with TXA administration best practices include inconsistent patient care, increased complications, and patient dissatisfaction.[16] Furthermore, failure to improve TXA practices in cardiac surgery could potentially subject healthcare organizations to legal liabilities and reputational predicaments in the competitive healthcare industry. Another significant threat to the success of this project revolves around securing the support of cardiac

surgeons and pharmacy. Consistent compliance with the intervention hinges on a collaborative effort among these key stakeholders. Overcoming this challenge is paramount to the project's success, and ensuring the desired improvements in patient care.[15]

Conceptual Underpinning and Theoretical Framework

The importance of theoretical frameworks in nursing care and evidence-based practice cannot be overstated.[17] They provide an organized framework for comprehending and resolving intricate clinical matters besides serving as a guide for systematically implementing and assessing interventions.[17] This project used the Donabedian model in this context, as it is highly relevant to developing healthcare outcomes and quality assessment. The Donabedian model considers 3 fundamental facets of healthcare quality: structure, process, and outcome.[18] Applying this theoretical framework to assess the effects of an online educational module that aims to elevate the knowledge of FIU alumni regarding standardizing TXA administration on cardiac surgery outcomes will be of immense value. This enables a thorough evaluation of how modifications to the TXA administration process (intervention) impact the organizational components of care provision and, ultimately, the results observed in patients undergoing cardiac surgery.

Theory Overview

The Donabedian model, developed by Avedis Donabedian in the 1960s, is a crucial framework for evaluating healthcare quality and improving healthcare outcomes. It comprises 3 elements: structure, process, and outcomes, also known as the "Donabedian triad."[18] Structure refers to healthcare delivery's environmental and organizational aspects, including tangible assets, establishments, personnel, and machinery. The process element examines how healthcare is administered, including interactions, practices, and procedures during care provision. On the

other hand, outcomes assess the results of healthcare provision, including clinical, patient-reported, and functional outcomes. The model suggests that the interaction among these components influences healthcare efficacy, with changes in the care delivery process potentially affecting the structure and resources, leading to enhanced or diminished outcomes.[18] This model provides a comprehensive and systematic structure for assessing healthcare quality and identifying areas for improvement.

Theory/Clinical Fit

The Donabedian model is an essential conceptual framework for evaluating healthcare quality. It aligns with my Doctor of Nursing Practice (DNP) project, which focuses on educating CRNAs and enhancing the administration of TXA during cardiac surgery in the event of an EACA shortage. The clinical relevance of this model is remarkable for several reasons. It advocates for a comprehensive approach to evaluating healthcare quality, including structural elements, processes, and results. By educating CRNAs and possibly implementing a standardized protocol for TXA administration, which has the potential to impact patient outcomes, resource allocation, and operational processes, this all-encompassing strategy aligns with the characteristics of healthcare interventions. The Donabedian model is also frequently implemented in healthcare quality improvement endeavors. It provides a systematic approach to evaluate current methodologies and pinpoint opportunities for improvement.[18] The efficacy of my research is assessed by alterations in patient outcomes about blood loss and transfusion requirements, consistent with the theory's focal point on attaining superior healthcare delivery results.

The model is consistent with the growing focus on patient-centered care within the healthcare industry.[15] My project aligns with the principles of delivering patient-centered care by

utilizing optimized TXA administration to improve outcomes. This objective is consistent with the needs and expectations of the patients. This model is an all-encompassing, flexible, and patient-focused structure, providing a solid conceptual underpinning for this DNP project.[18] It directs the project's methodology in assessing the effects of standardized TXA administration practices on operational procedures, structural elements, and, above all else, patient results.[29] By facilitating the implementation of evidence-based modifications in TXA administration protocols, this framework ultimately contributes to improving patient care throughout cardiac surgery.

Theory Evaluation

Utilizing the framework developed by Peterson and Bredow[17], I can methodically evaluate the Donabedian model, the theoretical foundation of this project.

What is the conceptual definition of the theory, and is it congruent with the project?

Three elements comprise the Donabedian model's definition of healthcare quality: structure, process, and outcomes.[17] The project aligned closely with the goals of my DNP endeavor, which is to improve the quality of healthcare through modifications in the process of care (specifically, standardized TXA administration protocols), the structural component (TXA administration practices), and the intended results (a reduction in perioperative blood loss and transfusion requirements).

Is the theory relevant to nursing and healthcare?

The relevance of the Donabedian model to the fields of nursing and healthcare is undeniable.[18,19] Utilization in quality improvement, research, and healthcare quality assessment dates back many years.[19] As an essential component of the healthcare system, the nursing

profession stands to gain substantially from the all-encompassing methodology of this model for evaluating and improving the standard of care.

Is the theory appropriate for the specific setting and population in your project?

The Donabedian model is adaptable and suitable for various healthcare settings and populations.[18] This method also applies to various clinical settings, rendering it exceptionally suitable for my research project, which revolves around antifibrinolytic use during cardiac surgery.

Does the theory offer testable hypotheses for your project?

Although the Donabedian model does not produce testable hypotheses, it does offer a systematic framework for evaluating and enhancing quality.[19] By employing the model in my project, I generated hypotheses concerning the effects of an educational module regarding standardized TXA administration on transfusion needs and perioperative blood loss. This aspect facilitates a methodical pursuit in evaluating the efficacy of the intervention.

What variables in your project can be linked to the concepts in the theory?

Several variables in my undertaking can be associated with the concepts of the Donabedian model. For example, the protocols for TXA administration are structural elements comprising the "structure" component.[20] The care processes, including the administration of TXA, follow the "process" element. The intended results, which encompass a decrease in blood loss and transfusion requirements, are associated with the "outcomes" element of the model.[19]

Is there existing empirical support for the theory's relevance to your project?

A solid empirical foundation supports the Donabedian model in healthcare quality research and evidence-based practice. It has been implemented in numerous studies and quality enhancement initiatives across various healthcare settings.[20] Within the framework of my project,

the model's pertinence is empirically supported by an extensive collection of research that establishes a direct correlation between the quality of healthcare and the outcomes experienced by patients. These findings further support the suitability of the paradigm for my DNP project.

Setting and Participants

The educational initiative focused on creating a complete teaching module for CRNAs FIU alumni. The sample size for participants was selected based on the available pool of CRNAs from the FIU alumni list, guaranteeing a representative and practical cohort for the educational module. Participants for this online educational module were recruited voluntarily from the FIU alumni list through email invites. Because of the voluntary nature of involvement, individuals with a thorough comprehension of TXA procedures were identified, establishing a devoted cohort who actively participated in the educational endeavor.

Procedures

This DNP project adopted a pre-/post-intervention design to evaluate the impact of an educational module on the knowledge and practices of CRNAs involved in providing anesthesia for cardiac surgery. This research approach is widely recognized in healthcare research, as it measures outcomes before and after implementation.[21] This design is particularly effective in evaluating changes in knowledge, attitudes, or behaviors resulting from educational interventions or programs.[21] Numerous studies support the applicability and efficacy of pre-/post-intervention designs in healthcare education due to their ability to capture changes within the same group of participants, providing valuable insights into the immediate effects of an intervention.[21] The project aligned with best practices, allowing for a robust analysis of the intervention's effectiveness by comparing participants' understanding of TXA evidence-based recommendations after the educational module.

Protection of Human Subjects

This project aimed to engage anesthesia providers, specifically CRNAs, in an educational initiative to improve patient care during cardiac surgery. The recruitment strategy involved personalized email invitations and informational materials to clarify the project's objectives and expectations, outlining the project's purpose, significance, and role of CRNAs in contributing to the initiative. This initiative prioritized subject privacy and confidentiality. Participants were fully informed about the project's aim, projected time commitment, and voluntary nature of their participation. Responses were kept anonymous, with no way to link them to specific participants. Basic demographic information such as gender, age, and years of service was collected to understand the sample's makeup better. Participants could, however, choose to keep this information private.

Participants signed electronic consent forms showing their comprehension of the project contents and acceptance to participate as part of the informed consent process. The consent form explaining these facts was distributed to participants as part of the recruitment process and included in this document's appendices. Furthermore, participants were notified that the project findings would be presented collectively, preventing individual responses from being identified. To protect participant information further, the project followed the standards and requirements established by the Institutional Review Board (IRB).[21] Obtaining IRB permission was a vital step in guaranteeing the ethical conduct of the research.

Data Collection

The project used electronic data collection, specifically the Qualtrics system, to streamline the process and improve data accuracy. The platform administered pre- and post-educational intervention questionnaires to CRNAs, assessing participants' knowledge of

tranexamic acid administration during cardiac surgery, appropriate dosing, and potential side effects. The questionnaires captured both quantitative and qualitative data, including demographic information.[21] Post-education intervention, the data were graded for accuracy and compared to assess the effectiveness of the educational module. The analysis also explored whether participants planned to alter their current practices based on the insights gained from the educational initiative.

Data Management and Analysis Plan

The study adhered to strict confidentiality and security protocols in data management and storage. Electronic data collected through the Qualtrics system were stored on a password-protected laptop, ensuring only authorized personnel had access. Private information was managed vigilantly, with only essential personnel accessing identifiable information. Results were reported in an aggregated and de-identified format to protect participant privacy. These measures aligned with ethical standards and was communicated to participants during the informed consent process. After the project's completion, all data were securely disposed of, with electronic files permanently deleted.

The statistical evaluation of the data collected in this project involved a combination of descriptive and inferential statistical methods.[21] Descriptive statistics were employed to summarize and present the essential features of the dataset, offering a comprehensive overview of the CRNAs' knowledge levels regarding TXA administration during cardiac surgery. This provided a detailed understanding of the baseline knowledge and the extent of knowledge enhancement achieved through the educational module. In addition to descriptive statistics, inferential statistics were applied to conclude the observed data and to provide evidence of the

educational initiative's effectiveness in improving CRNAs' understanding of TXA administration protocols, dosing, and potential side effects.

Timeline

This project was expected to take 6 months to complete. The initial steps were dedicated to initiation and defining objectives. A literature review was also conducted to inform the project's design and proposal. Subsequent tasks involved preparing and submitting the Institutional Review Board (IRB) application, ensuring ethical compliance and participant protection. Once IRB approval was obtained, the next step was to work on participant recruitment and informed consent facilitation, emphasizing voluntary participation.

Pre-intervention data collection and implementation were conducted, with pre-intervention questionnaires and resources provided. Post-intervention data collection analyzed participants' responses to assess the module's impact. Data were examined in the final months, with findings organized into a cohesive document. The last steps were dedicated to the preparation and execution of the final defense, including a detailed presentation, refining communication skills, and addressing stakeholder queries.

Results

As mentioned before, upon receiving the official IRB and faculty approval, the Qualtrics survey containing the pre- and post-questionnaires and the educational module was launched. Emails containing an invitation to follow Qualtrics's link were submitted to the list of FIU CRNA alumni provided by the faculty. Participants had almost 2 months to complete the survey, with reminders sent every 2 weeks for a total of 3 reminders. Eighteen replies were collected; however, 3 were empty and subsequently invalidated from the results and data analysis.

This survey had a sample size of 15 participants. One participant declined to answer after consent, but 14 consented and completed the survey. Of the participants, 57% (n = 8) were males, and 43% (n = 6) were females. Male participation was slightly higher. All participants were older than 25, with the highest number of participants older than 31 years, 79% (n = 11). Hispanics comprised the most prominent ethnic group of participants at 50% (n = 7). CRNAs with a doctoral level of education comprised 100% (n = 14) of the sample size. Of these providers, 54% (n = 7) had 1-5 years of experience, while the rest had less than a year or more than 5. Participants' demographics are shown with details in the following tables.

Table 1. Sample Size

Response	Count	Percentage
Completed Survey	14	93
Declined to answer	1	7
Total Participants	15	100

Table 2. Demographic Characteristics

Characteristic	Count	Percentage
Gender		
Male	8	57
Female	6	43
Age		
25-30	3	21
31-40	7	50
41 and above	4	29
Ethnicity		
Hispanic	7	50
Caucasian	5	36
African American	1	7
Asian	0	0
Other	1	7

Level of Education		
Certificate	0	0
Bachelor's degree	0	0
Master's degree	0	0
DNP	14	100
PhD	0	0
Years of Experience		
Less than 1 year	5	36
1-5 years	7	50
6-9 years	0	0
More than 10 years	2	14

Summary

The pretest was crafted to identify knowledge disparities among providers. In the pretest, the vast majority of the providers identified a decrease in perioperative bleeding as the primary purpose of using antifibrinolytic therapy, such as TXA or EACA, during cardiac surgery (n = 11, 77%). Common missed knowledge was regarding the antifibrinolytic drug that was associated with a 53% increase in mortality and subsequently withdrawn globally in 2007. Most participants believe the drug to be aprotinin (n = 7, 50%), while others thought it to be lysine analogs or EACA. Most participants were able to correctly identify platelet dysfunction, hypotension, and systemic anticoagulation as contributing risks to significant perioperative bleeding in cardiac surgery (n = 8, 60%), while a minority wrongly chose hypertension and platelet aggregation. Regarding the adverse effects associated with a high dose of antifibrinolytics, only n = 6 (43%) were able to identify seizures during cardiac surgery as the answer. Less than half of the participants (n = 6, 45%) could pinpoint 10mg/kg as the loading dose of TXA commonly used in studies comparing TXA and EACA in cardiac surgery. When identifying 30 mg/kg loading dose

and 16 mg/kg/hr maintenance as the high-dose regimen of TXA recognized as more effective in reducing the need for red blood cell transfusion, only $n = 1$ (7%) could pick the correct answer.

CRNA (7%) knew the dosage method suggested by the research as the safer choice for TXA in cardiac surgery. These statistics showed that CRNAs are deficient in knowledge regarding proper dosing of TXA or antifibrinolytics in general.

Compared to the pretest, the posttest demonstrated a greater proportion of questions with the correct answers. The fact that this occurred suggests that the educational intervention was effective. Eighty-seven percent of the providers correctly identified seizures as the principal adverse effect associated with high doses of antifibrinolytics compared to 43% in the pretest. The high-dose regimen of TXA identified as more effective in reducing the need for red blood cell transfusion, and the dosage method suggested by the research as the safer choice for TXA in cardiac surgery, the 2 lowest scoring questions from the pretest, had score increases of 43% and 53%, respectively. However, the question with the most significant score improvement of 55% was the loading dose of TXA commonly used in studies comparing TXA and EACA. The educational intervention successfully addressed inadequacies in the providers' knowledge, as seen by the considerable improvement in the questions with the lowest scores.

Table 3. Pretest and Posttest Responses

Questions	Pretest (% of correct answers) $n = 14$	Posttest (% of correct answers) n =14	Difference
What is the primary purpose of using antifibrinolytic therapy, such as TXA or EACA, during cardiac surgery?	77%	100%	33%

Which antifibrinolytic drug was associated with a 53% increase in mortality and subsequently withdrawn globally in 2007	50%	87%	37%
What are some contributing risks to significant perioperative bleeding in cardiac surgery?	60%	100%	40%
Why might institutions choose EACA over TXA for open-heart surgery protocols?	72%	100%	28%
Which adverse effect has been associated with high doses of antifibrinolytic drugs, including TXA and EACA, during cardiac surgery?	43%	87%	44%
What loading dose of TXA is commonly used in studies comparing TXA and EACA in cardiac surgery?	45%	100%	55%
Which high-dose regimen of TXA has been identified as more effective in reducing the need for red blood cell transfusion?	7%	50%	43%
What dosage method is suggested by the research as the safer choice for TXA in cardiac surgery?	7%	60%	53%

Implementation

Before the educational material, most participants (n = 6, 42%) reported feeling either somewhat comfortable or extremely comfortable administering TXA during cardiac surgery. In comparison, 28% felt neither comfortable nor uncomfortable, and 14% felt somewhat uncomfortable. However, 75% of CRNA participants felt either somewhat comfortable or extremely comfortable with TXA administration after the educational module, marking a 33% improvement from previous responses. These findings clearly indicate the educational module's

favorable effect, underlining its significance in improving clinical confidence and competency among healthcare workers.

Limitations

The most evident flaw in the educational initiative was the small sample size. Although email invitations were initially distributed to over 100 FIU alumni, after multiple reminders were sent, merely 15 replies were collected. Of those, only 14 consented to participate in the survey. The study's validity and reliability may be impacted by a limited sample size. It is worth mentioning that only 9 articles were considered for inclusion in the initial literature review.

Discussion of the Results with Implications for Practice

The anticipated outcomes of this program will have far-reaching ramifications for advanced nursing practice in various ways. Implementing this module is expected to raise awareness and understanding among CRNAs. This might result in a more informed and trained workforce capable of providing evidence-based treatment in the ever-changing field of cardiac anesthesia, reducing perioperative blood loss and the need for allogeneic blood transfusions.

The next step of this educational module is to make the results available to hospital stakeholders. If a shortage of EACA were to occur, stakeholders may use the EBP information collected as a tool to make decisions regarding the care of cardiac surgery patients. While implementing new recommendations for best practices in this area may result in additional expenses, it might also involve a better surgical experience for the patient. It is advised to carry out more research on the use of TXA in cardiac surgery.

Conclusion

Cardiac surgery involves considerable perioperative bleeding and blood transfusions. Antifibrinolytics, such as TXA, have been demonstrated to prevent bleeding. However, their

greater cost may limit healthcare facilities' options. Inconsistent dosing may impair bleeding control and increase the risk of complications. Creating an educational module for anesthesia practitioners on TXA doses may fill knowledge gaps and enhance patient care. The project's findings might increase knowledge among CRNAs, minimize blood loss and transfusion requirements, and promote standardized TXA protocols. The project's success may establish the hospital as a leader in evidence-based cardiac surgical techniques, perhaps impacting more extensive healthcare policy.

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Appendix B: IRB Approval Letter

FLORIDA INTERNATIONAL UNIVERSITY

Office of Research Integrity
Research Compliance, MARC 430

MEMORANDUM

To:	Dr. Vicente Gonzalez
CC:	Lianet Ramirez
From:	Kourtney Wilson, MS, IRB Coordinator KMW
Date:	February 14, 2024
Protocol Title:	""An Educational Module on the usage of Tranexamic Acid (TXA) as an alternative to Epsilon Aminocaproic Acid (EACA) in cardiac surgery to reduce perioperative transfusion requirements: A Quality Improvement Project.""

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the **Exempt Review** process.

IRB Protocol Exemption #:	IRB-24-0057	**IRB Exemption Date:**	02/14/24
TOPAZ Reference #:	113928		

As a requirement of IRB Exemption you are required to:

1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fiu.edu/irb.

KMW

Appendix C: Participant Recruitment Letter

"An Educational Module on the usage of Tranexamic Acid (TXA) as an alternative to Epsilon Aminocaproic Acid (EACA) in cardiac surgery to reduce perioperative transfusion requirements: A Quality Improvement Project."

Dear FIU ALUMNI Perioperative Providers:

My name is Lianet Ramirez, and I am a student in the Anesthesiology Nursing Program Department of Nurse Anesthesiology at Florida International University. I invite you to participate in my quality improvement project. This project aims to increase healthcare providers' awareness of evidence-based dosing recommendations of TXA as an alternative to EACA with a focus on contraindications and side effects during cardiac surgery. You are eligible to participate in this project because you are a part of the FIU ALUMNI perioperative provider.

If you decide to participate in this project, you will be asked to complete and sign a consent form. Next, you will complete a pre-test questionnaire, which is expected to take approximately 5 minutes. You will then be asked to view an online educational presentation that is around 15 minutes long. After going through the educational module, you will be asked to complete the post-test questionnaire, which will take about 5 minutes. *No compensation will be provided.*

Remember, this is entirely voluntary. You can choose to be in the study or not. If you'd like to participate or have questions about the study, please email or contact me, Lianet Ramirez, at 786-447-4466 or lrami168@fiu.edu.

Thank you very much.

Sincerely,

Lianet Ramirez, SRNA
786-447-4466
lrami168@fiu.edu.

Appendix D: Informed Consent

FIU | FLORIDA INTERNATIONAL UNIVERSITY

CONSENT TO PARTICIPATE IN A QUALITY IMPROVEMENT PROJECT
An Educational Module on the usage of Tranexamic Acid (TXA) as an alternative to Epsilon Aminocaproic Acid (EACA) in cardiac surgery to reduce perioperative transfusion requirements: A Quality Improvement Project

SUMMARY INFORMATION
Things you should know about this study:

- **Purpose:** Educational module to increase providers' awareness of TXA dosing, contraindications, and side effects in the field of cardiac anesthesia.
- **Procedures**: If the participant chooses to participate, they will be asked to complete a pretest, watch a voice PowerPoint, and then a post-test
- **Duration:** This will take about a total of 25 minutes total.
- **Risks**: There will be minimal risks involved with this project, as would be expected in any type of educational intervention, which may include mild emotional stress or mild physical discomfort from sitting on a chair for an extended period.
- **Benefits:** The main benefit to you from this research is to increase the participants' knowledge of evidence-based dosing recommendations of TXA as an alternative to EACA during cardiac surgery.
- **Alternatives:** There are no known alternatives available to the participant other than not taking part in this quality improvement project.
- **Participation:** Taking part in this quality improvement project is voluntary.

Please carefully read the entire document before agreeing to participate.

NUMBER OF STUDY PARTICIPANTS:
If the participant decides to be in this study, they will be 1 of 20 people in this research study.

PURPOSE OF THE PROJECT
The participant is being asked to be in a quality improvement project. The goal of this project is to increase providers' knowledge of best practices in perioperative TXA administration during cardiac surgery, with a focus on dosage protocols, administration techniques, and associated benefits and risks. If you decide to participate, you will be 1 of approximately 20 participants.

DURATION OF THE PROJECT
The participation will require about 25 minutes.

PROCEDURES

If the participant agrees to be in the project, PI will ask you to do the following things:
1. Complete an online 10-question pre-test survey via Qualtrics, an Online survey product for which the URL link is provided
2. Review the educational PowerPoint Module lasting 15 minutes via Qualtrics, an Online survey product for which the URL link is provided.
3. Complete the online 10-question post-test survey via Qualtrics, an Online survey product for which the URL link is provided.

RISKS AND/OR DISCOMFORTS

The main risk or discomfort from this research is minimal. There will be minimal risks involved with this project, as would be expected in any type of educational intervention, which may include mild emotional stress or mild physical discomfort from sitting on a chair for an extended period.

BENEFITS

The following benefits may be associated with participation in this project: enhanced understanding of TXA administration in cardiac surgery, increased knowledge of dosage regimens, heightened awareness of potential side effects, and the chance to contribute to advancing evidence-based practices in perioperative care. The overall objective of the program is to increase the providers' knowledge based on the current literature.

ALTERNATIVES

There are no known alternatives available to the participant other than not taking part in this project. However, if the participant would like to receive the educational material, it will be provided to them at no cost.

CONFIDENTIALITY

The records of this project will be kept private and will be protected to the fullest extent provided by law. If any sort of report PI might publish, it will not include any information that will make it possible to identify the participant. Records will be stored securely, and only the project team will have access to the records.

PARTICIPATION: Taking part in this quality improvement project is voluntary.

COMPENSATION & COSTS

There is no cost or payment to the participant for receiving the health education and/or for participating in this project.

RIGHT TO DECLINE OR WITHDRAW

Participation in this project is voluntary. The participant is free to participate in the project or withdraw the consent at any time during the project. The participant's withdrawal or lack of participation will not affect any benefits to which you are otherwise entitled. The investigator reserves the right to remove the participant without their consent at such time that they feel it is in their best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research project, you may contact Lianet Ramirez at 786-447-4466/lrami168@fiu.edu and Dr. Vicente Gonzalez at 305-348-0062/ gonzalv@fiu.edu.

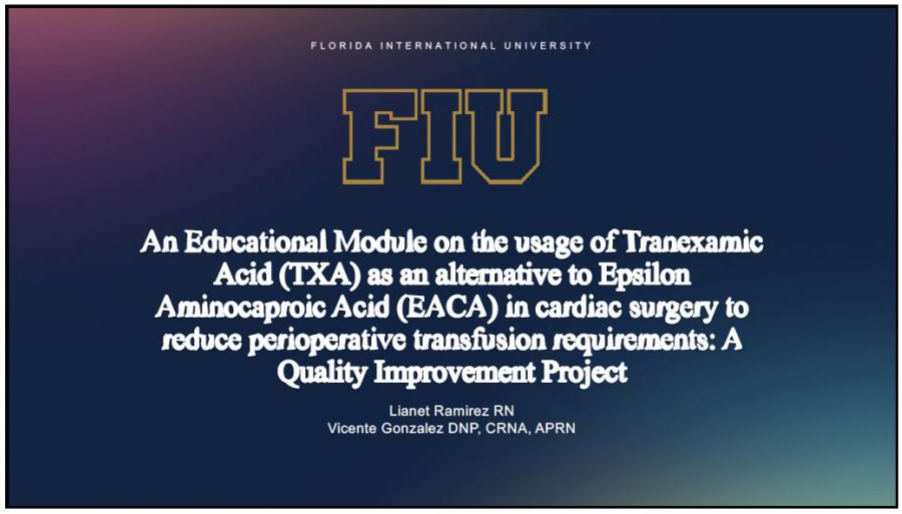
IRB CONTACT INFORMATION

If the participant would like to talk with someone about their rights pertaining to being a subject in this project or about ethical issues with this project, the participant may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. By clicking on the "consent to participate" button below, I am providing my informed consent.

Appendix E: Educational Module



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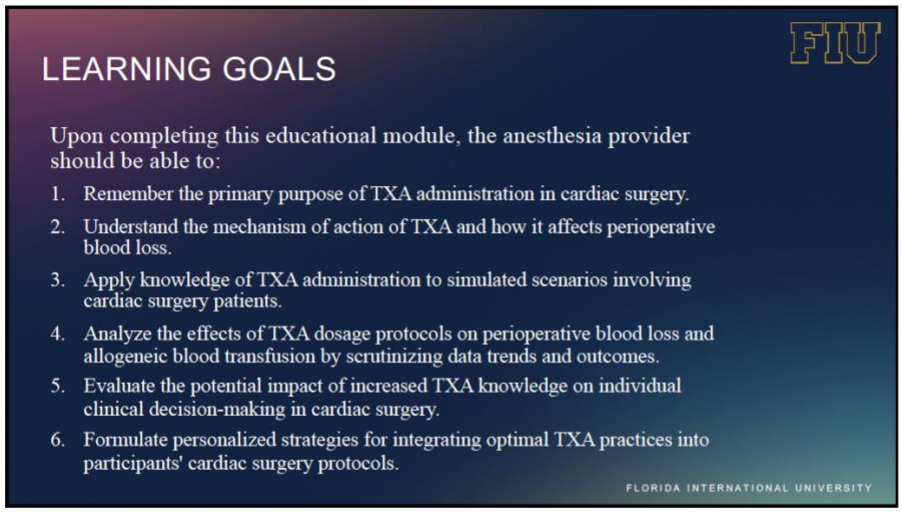

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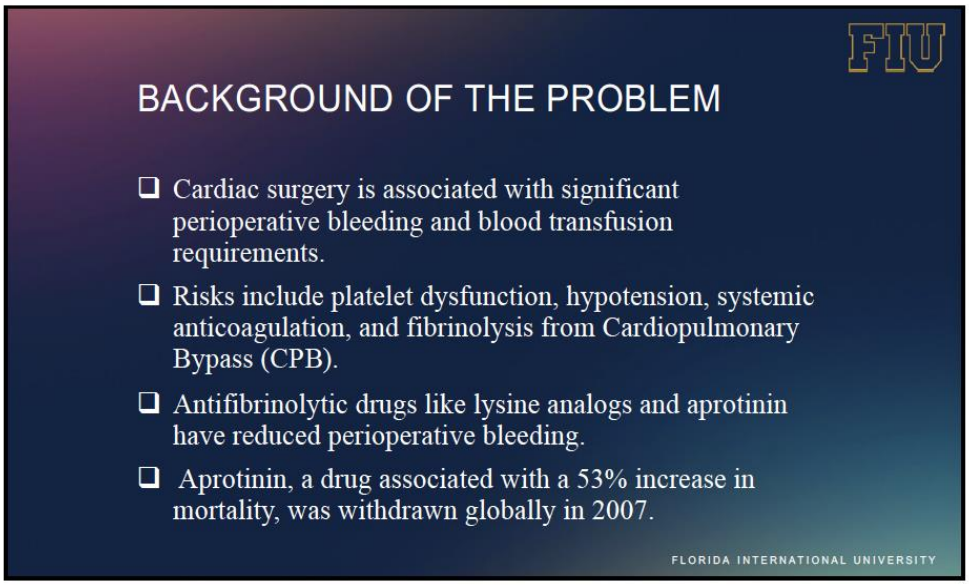
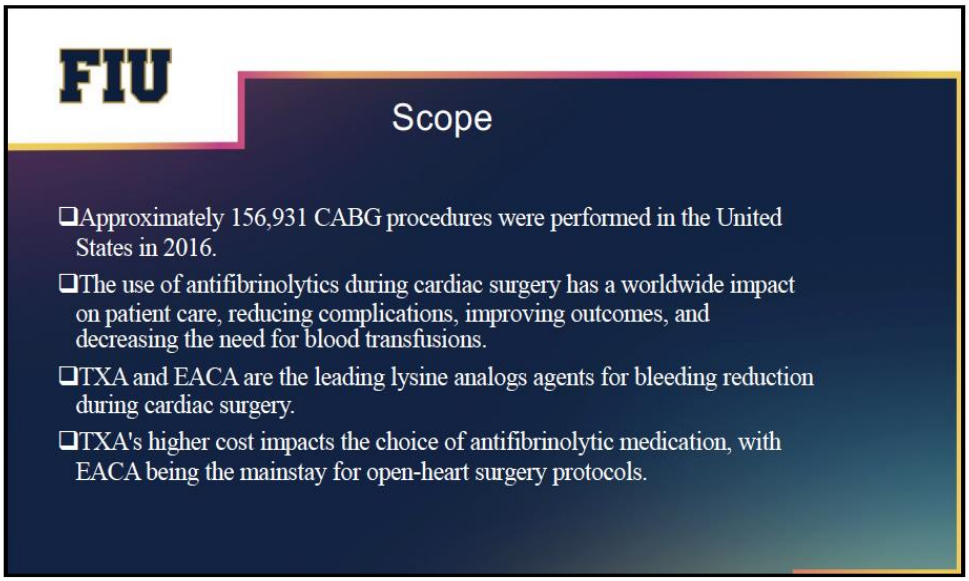

FIU
BACKGROUND OF THE PROBLEM
Cardiac surgery is associated with significant perioperative bleeding and blood transfusion requirements.
Risks include platelet dysfunction, hypotension, systemic anticoagulation, and fibrinolysis from Cardiopulmonary Bypass (CPB).
Antifibrinolytic drugs like lysine analogs and aprotinin have reduced perioperative bleeding.
Aprotinin, a drug associated with a 53% increase in mortality, was withdrawn globally in 2007.
FLORIDA INTERNATIONAL UNIVERSITY

3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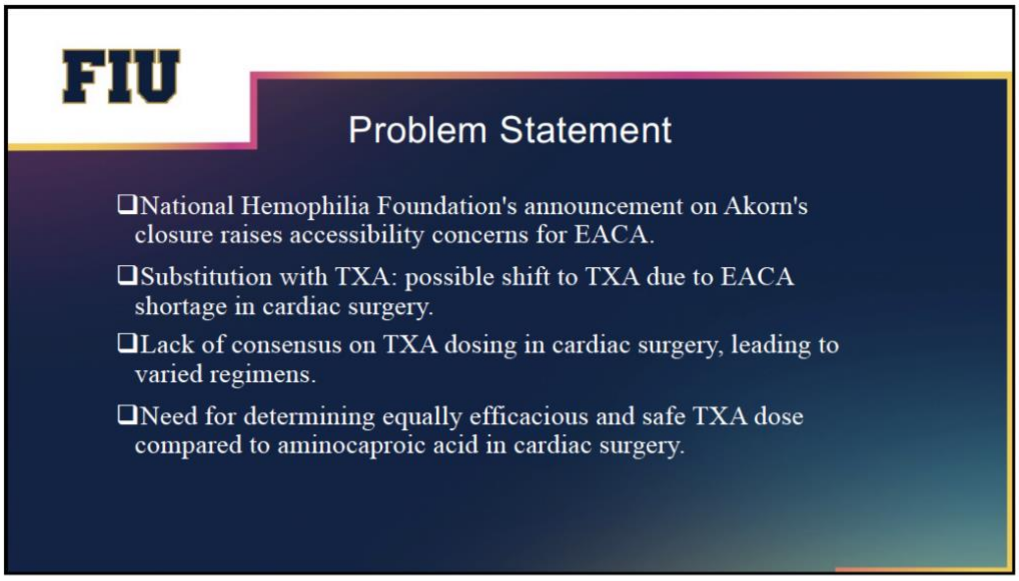
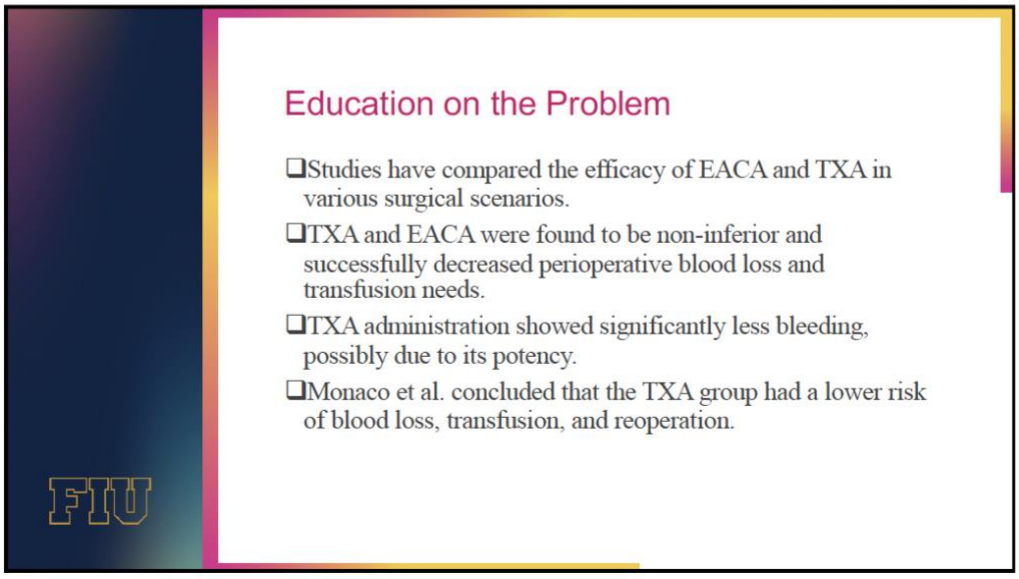
Scope
Approximately 156,931 CABG procedures were performed in the United States in 2016.
The use of antifibrinolytics during cardiac surgery has a worldwide impact on patient care, reducing complications, improving outcomes, and decreasing the need for blood transfusions.
TXA and EACA are the leading lysine analogs agents for bleeding reduction during cardiac surgery.
TXA's higher cost impacts the choice of antifibrinolytic medication, with EACA being the mainstay for open-heart surgery protocols.

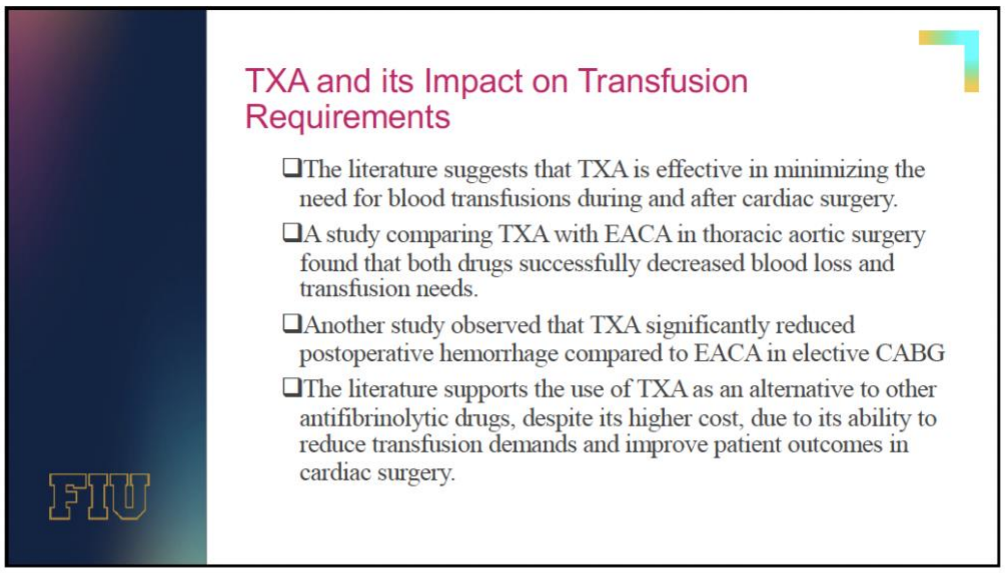
4


FIU
Problem Statement
National Hemophilia Foundation's announcement on Akorn's closure raises accessibility concerns for EACA.
Substitution with TXA: possible shift to TXA due to EACA shortage in cardiac surgery.
Lack of consensus on TXA dosing in cardiac surgery, leading to varied regimens.
Need for determining equally efficacious and safe TXA dose compared to aminocaproic acid in cardiac surgery.

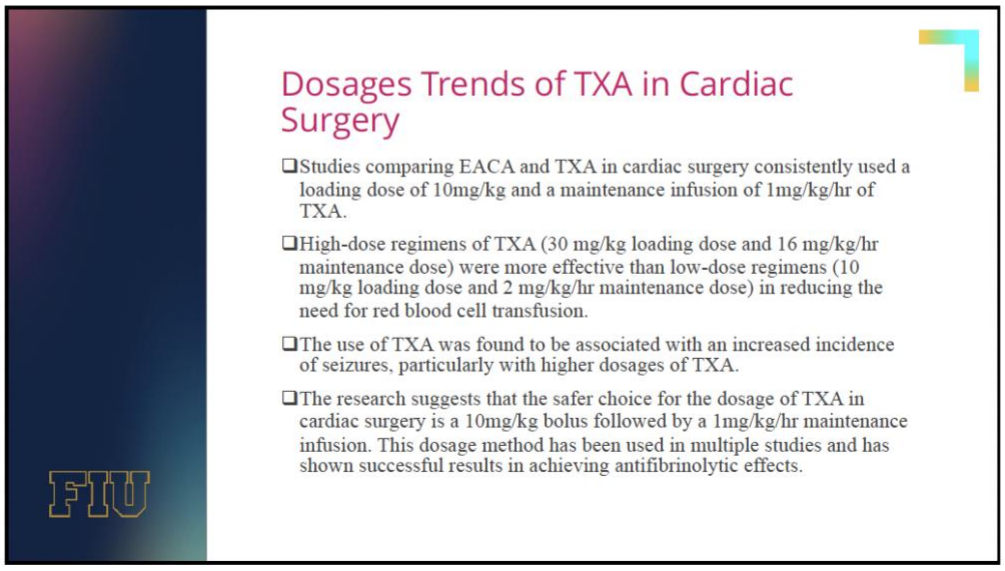
5


Education on the Problem
Studies have compared the efficacy of EACA and TXA in various surgical scenarios.
TXA and EACA were found to be non-inferior and successfully decreased perioperative blood loss and transfusion needs.
TXA administration showed significantly less bleeding, possibly due to its potency.
Monaco et al. concluded that the TXA group had a lower risk of blood loss, transfusion, and reoperation.
FIU

6


TXA and its Impact on Transfusion Requirements
❑The literature suggests that TXA is effective in minimizing the need for blood transfusions during and after cardiac surgery.
❑A study comparing TXA with EACA in thoracic aortic surgery found that both drugs successfully decreased blood loss and transfusion needs.
❑Another study observed that TXA significantly reduced postoperative hemorrhage compared to EACA in elective CABG
❑The literature supports the use of TXA as an alternative to other antifibrinolytic drugs, despite its higher cost, due to its ability to reduce transfusion demands and improve patient outcomes in cardiac surgery.
FIU

7


Dosages Trends of TXA in Cardiac Surgery
❑Studies comparing EACA and TXA in cardiac surgery consistently used a loading dose of 10mg/kg and a maintenance infusion of 1mg/kg/hr of TXA.
❑High-dose regimens of TXA (30 mg/kg loading dose and 16 mg/kg/hr maintenance dose) were more effective than low-dose regimens (10 mg/kg loading dose and 2 mg/kg/hr maintenance dose) in reducing the need for red blood cell transfusion.
❑The use of TXA was found to be associated with an increased incidence of seizures, particularly with higher dosages of TXA.
❑The research suggests that the safer choice for the dosage of TXA in cardiac surgery is a 10mg/kg bolus followed by a 1mg/kg/hr maintenance infusion. This dosage method has been used in multiple studies and has shown successful results in achieving antifibrinolytic effects.
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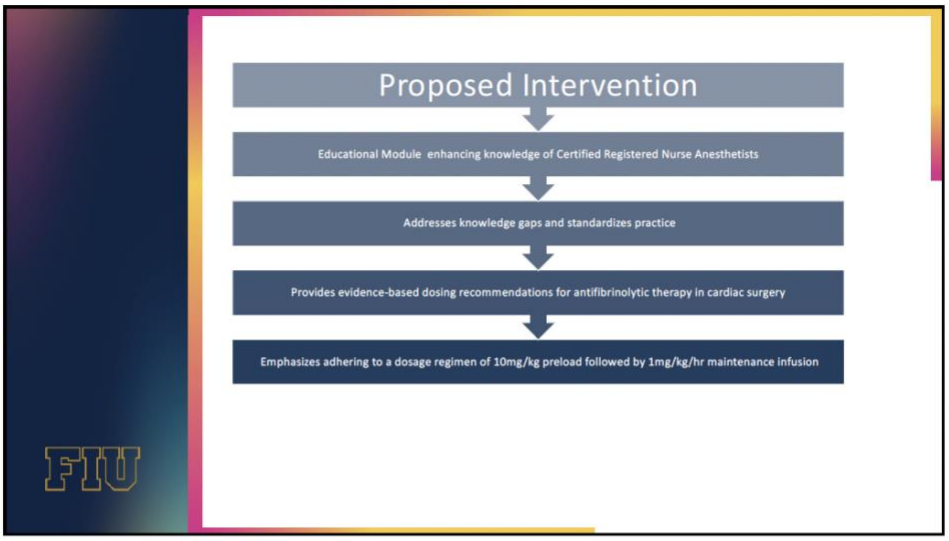
8


Proposed Intervention
Educational Module enhancing knowledge of Certified Registered Nurse Anesthetists
Addresses knowledge gaps and standardizes practice
Provides evidence-based dosing recommendations for antifibrinolytic therapy in cardiac surgery
Emphasizes adhering to a dosage regimen of 10mg/kg preload followed by 1mg/kg/hr maintenance infusion
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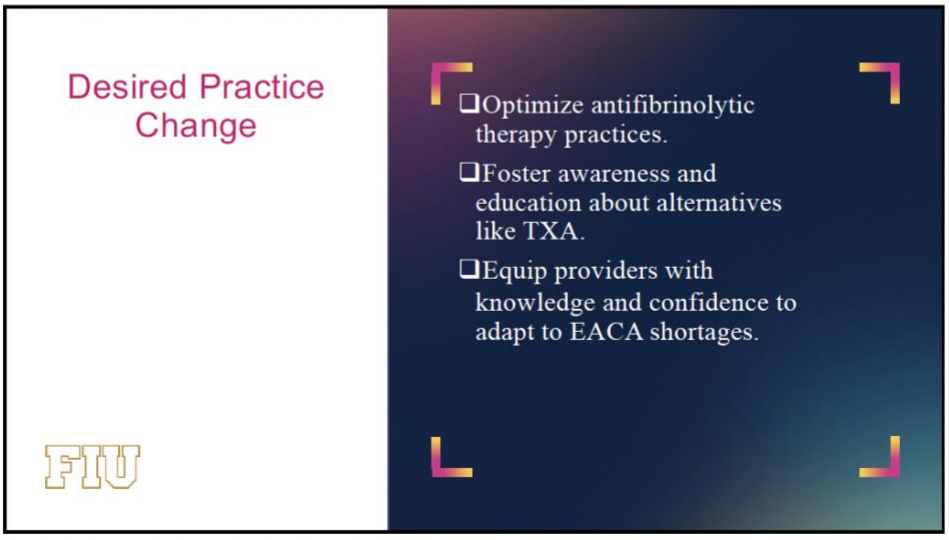
9


Desired Practice Change
Optimize antifibrinolytic therapy practices.
Foster awareness and education about alternatives like TXA.
Equip providers with knowledge and confidence to adapt to EACA shortages.
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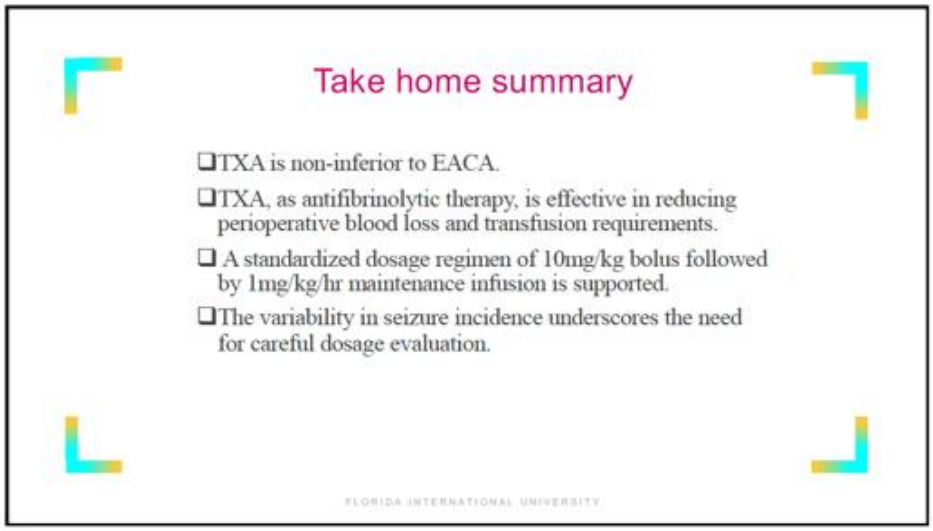
Take home summary
❑TXA is non-inferior to EACA.
❑TXA, as antifibrinolytic therapy, is effective in reducing perioperative blood loss and transfusion requirements.
❑ A standardized dosage regimen of 10mg/kg bolus followed by 1mg/kg/hr maintenance infusion is supported.
❑The variability in seizure incidence underscores the need for careful dosage evaluation.
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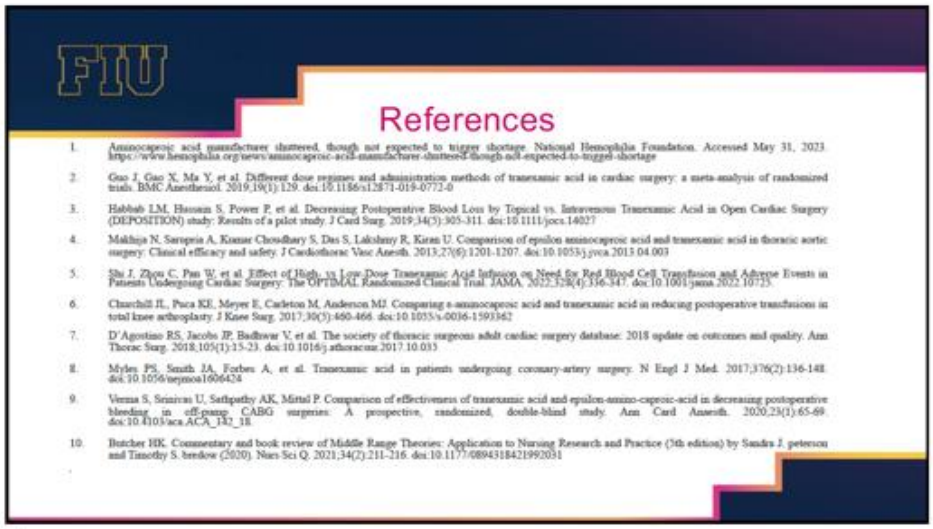
11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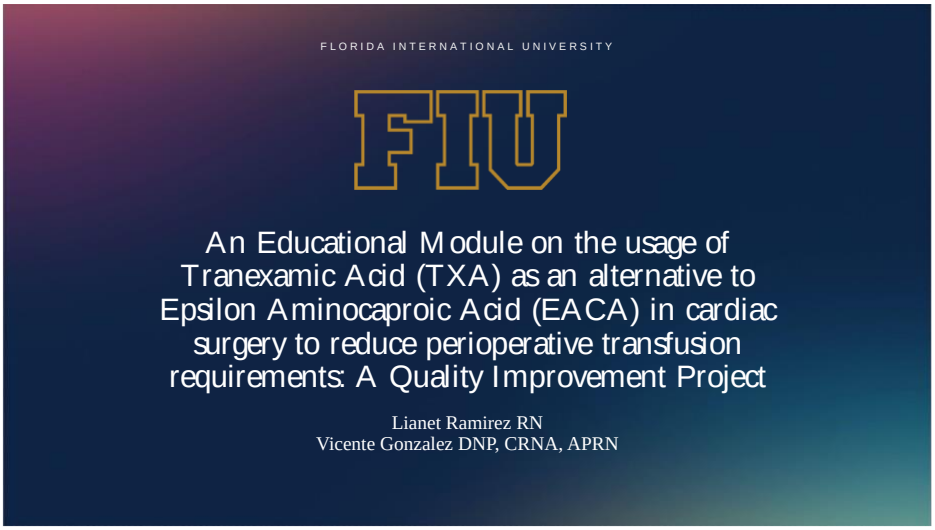
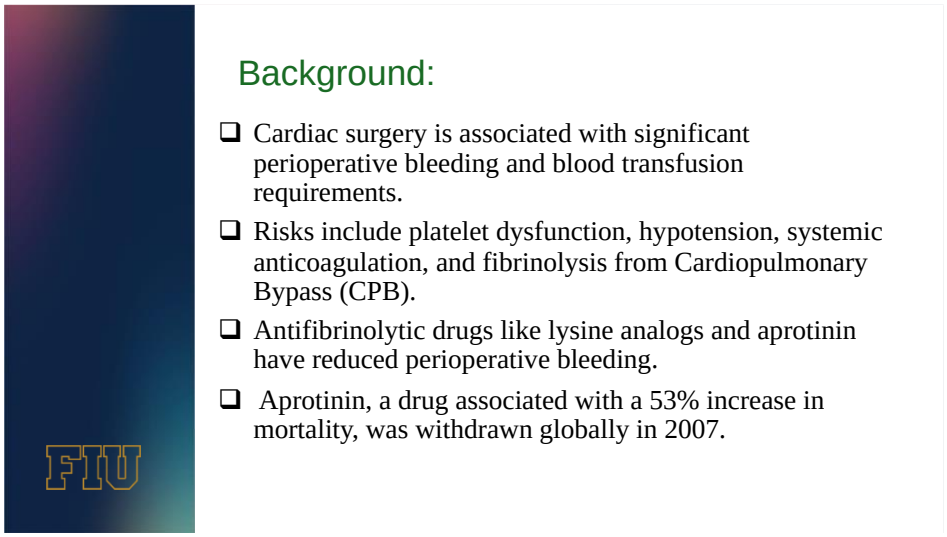
12

Appendix F: Dissemination PowerPoint





Background cont.:

- Approximately 156,931 CABG procedures were performed in the United States in 2016.
- The use of antifibrinolytics during cardiac surgery has a worldwide impact on patient care, reducing complications, improving outcomes, and decreasing the need for blood transfusions.
- TXA and EACA are the leading lysine analogs agents for bleeding reduction during cardiac surgery.
- TXA's higher cost impacts the choice of antifibrinolytic medication, with EACA being the mainstay for open-heart surgery protocols.

Problem:

- National Hemophilia Foundation's announcement on Akorn's closure raises accessibility concerns for EACA.
- Substitution with TXA: possible shift to TXA due to EACA shortage in cardiac surgery.
- Lack of consensus on TXA dosing in cardiac surgery, leading to varied regimens.
- Need for determining equally efficacious and safe TXA dose compared to aminocaproic acid in cardiac surgery.

PICO Question:

"In patients undergoing cardiac surgery, does the use of tranexamic acid infusion (TXA), compared to epsilon aminocaproic acid (EACA), have similar effects on transfusion requirements and intraoperative bleeding?"

- ❑Population: Patients undergoing cardiac surgery
- ❑Intervention: Usage of tranexamic acid (TXA)
- ❑Comparison: Usage of epsilon aminocaproic acid (EACA)
- ❑Outcome: Transfusion requirement and intraoperative bleeding

DNP Project Purpose:

- ❑Optimize antifibrinolytic therapy practices.
- ❑Foster awareness and education about alternatives like TXA, providing evidence-based practice recommendations.
- ❑Equip providers with knowledge and confidence to adapt to EACA shortages.

QI Methods:

Setting and participants:

- ❑Selection based on the FIU ALUMNI list.
- ❑Aims for representative, practical cohort.
- ❑The project complies with the Institutional Review Board (IRB) for ethical research.

Protection of Human Subjects:

- ❑Prioritizes subject privacy and confidentiality.
- ❑Participants were informed about the project aim, time commitment, and voluntary participation.
- ❑Responses are kept anonymous, with no link to specific participants.

QI Methods:

Design:

- ❑Pre-/Post-Intervention Design ⟹ Effectively evaluates changes in knowledge, attitudes, or behaviors from online educational intervention.

Data collection:

- ❑Utilization of Qualtrics system for efficient data collection.
- ❑Captures both quantitative and qualitative data, including demographic information.
- ❑Post-intervention data is compared for accuracy and effectiveness.

Results:

Response	Count	Percentage
Less than 1year	5	36
1-5 years	7	50
6-9 years	0	0
More than 10 years	2	14
Total	14	100

Response	Count	Percentage
25-30	3	21
31-40	7	50
41 and above	4	29
Total	14	100

Response	Count	Percentage
Certificate	0	0
Bachelors	0	0
Masters	0	0
DNP	14	100
PHD	0	0
Total	14	100

Questions	Pre-test (% of correct answers) n=14	Post-test (% of correct answers) n=14	Difference
What is the primary purpose of using antifibrinolytic therapy, such as TXA or EACA, during cardiac surgery?	77%	100%	33%
Which antifibrinolytic drug was associated with a 53% increase in mortality and subsequently withdrawn globally in 2007	50%	87%	37%
What are some contributing risks to significant perioperative bleeding in cardiac surgery?	60%	100%	40%
Why might institutions choose EACA over TXA for open-heart surgery protocols?	72%	100%	28%
Which adverse effect has been associated with high doses of antifibrinolytic drugs, including TXA and EACA, during cardiac surgery?	43%	87%	44%
What loading dose of TXA is commonly used in studies comparing TXA and EACA in cardiac surgery?	45%	100%	55%
Which high-dose regimen of TXA has been identified as more effective in reducing the need for red blood cell transfusion?	7%	50%	43%
What dosage method is suggested by the research as the safer choice for TXA in cardiac surgery?	7%	60%	53%

Discussion:

- ❑ The post-test showed a higher proportion of correct answers, indicating the effectiveness of the educational intervention.
- ❑ The educational intervention addressed inadequacies in providers' knowledge, leading to significant improvements in the questions with the lowest scores.
- ❑ The project's outcomes have implications for advanced nursing practice, shaping education, practice administration, and leadership in the evolving landscape of cardiac surgery.
- ❑ However, limited sample size may impact study validity and reliability.

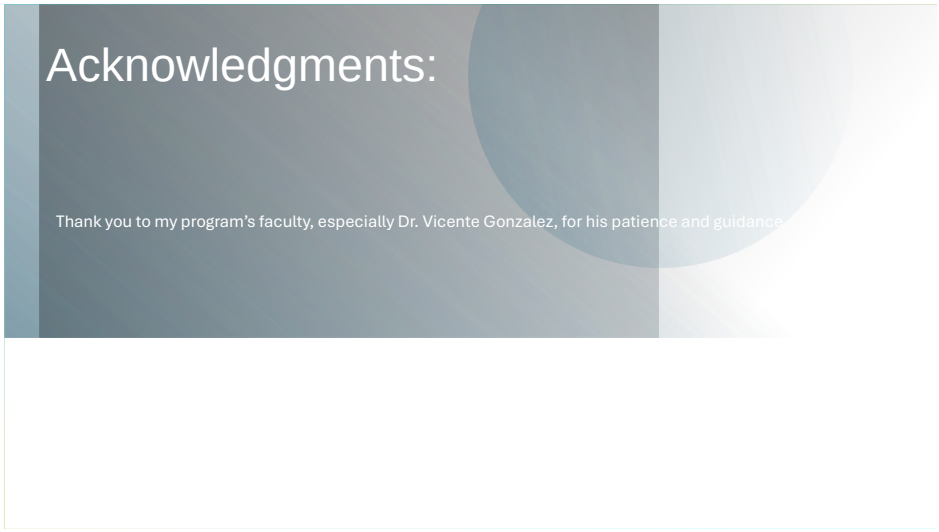
Discussion:

May pave the way for collaborative, multidisciplinary approaches to heart surgical treatment, improving the hospital's reputation.

Administratively, standardized TXA protocol could establish a uniform, evidence-based care framework, positioning the hospital as a leader in evidence-based cardiac surgery practices.

Conclusions:

- Cardiac surgery involves significant bleeding and blood transfusions.
- Antifibrinolytics like TXA prevent bleeding but cost limits options.
- Inconsistent dosing can impair bleeding control and increase complications.
- Educational module for anesthesia practitioners on TXA doses could improve patient care.
- Project findings could increase knowledge among CRNAs, minimize blood loss, and promote standardized protocols.
- Success could establish the hospital as a leader in cardiac surgical techniques.


Acknowledgments:
Thank you to my program's faculty, especially Dr. Vicente Gonzalez, for his patience and guidance.