STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Official Title:
Effect of Intravenously Administered Tranexamic Acid on Intraoperative Visual Clarity, Perioperative Blood Loss, and Early Postoperative Outcomes in Shoulder Arthroscopy Performed in the Beach Chair Position: A Randomized Controlled Trial

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1. Background and Rationale

Adequate intraoperative visual clarity is essential for safe and effective shoulder arthroscopy. Visualization quality depends largely on the amount of bleeding into the irrigation fluid and cannot be supported by tourniquet use, unlike arthroscopy of the extremities. Strategies to optimize visualization therefore include hypotensive anesthesia, modulation of irrigation pressure, meticulous hemostasis, and pharmacological interventions.

Tranexamic acid (TXA) is a synthetic antifibrinolytic agent that reduces blood loss by inhibiting plasminogen activation. It is widely used in orthopedic surgery and has demonstrated a favorable safety profile. However, evidence regarding its effect on intraoperative visual clarity during shoulder arthroscopy is limited and heterogeneous. Previous studies often relied solely on subjective assessment of visibility and rarely incorporated objective measures of intraoperative bleeding.

This prospective randomized controlled trial was designed to evaluate the effect of intravenously administered TXA on intraoperative arthroscopic visibility during shoulder arthroscopy performed in the beach chair position. Subjective assessments of visual clarity were supplemented with objective measurements of hemoglobin concentration in irrigation fluid and independent postoperative evaluation of intraoperative images by blinded expert assessors.

2. Objectives

Primary Objective

To assess the effect of intravenously administered tranexamic acid on intraoperative arthroscopic visual clarity during shoulder arthroscopy.

Secondary Objectives

- To evaluate interobserver agreement among independent assessors of arthroscopic visibility.
- To compare arthroscopic visibility ratings between the operating surgeon and independent assessors.

- To assess objective indicators related to visibility, including hemoglobin concentration in irrigation fluid, irrigation pressure adjustments, irrigation fluid volume, and mean arterial pressure.
- To assess intraoperative and perioperative blood loss parameters.
- To evaluate early postoperative recovery outcomes, including swelling, pain, analgesic consumption, and length of hospital stay.

3. Study Design

This was a prospective, single-center, double-blind, randomized controlled clinical trial conducted at the University Orthopaedic and Trauma Hospital Lovran, Croatia.

4. Participants

Inclusion Criteria

- Adults aged 18–65 years
- Indication for therapeutic shoulder arthroscopy with rotator cuff repair

Exclusion Criteria

- Known hypersensitivity to tranexamic acid
- History of venous or arterial thromboembolism
- Known coagulation disorders or thrombophilia
- Renal insufficiency
- Recent cerebrovascular or coronary events
- Chronic anticoagulant or antiplatelet therapy
- Uncontrolled arterial hypertension

5. Interventions

Experimental Group

Participants received 1 g of tranexamic acid diluted in 100 mL of sterile saline administered intravenously 10 minutes before the start of surgery.

Control Group

Participants received 100 mL of sterile saline administered intravenously using identical, non-specific packaging.

6. Randomization and Blinding

Participants were stratified by age and sex and randomized using simple randomization within strata. Allocation was performed by a research collaborator not involved in patient care or outcome assessment. Patients, surgeons, anesthesiology staff, physiotherapists, and outcome assessors were blinded to treatment allocation throughout the study.

7. Surgical Procedure and Perioperative Management

All procedures were performed in the beach chair position by the same surgeon using standardized arthroscopic equipment. A 4-mm 30° arthroscope was used. The arthroscopic pump was set to a baseline pressure of 50 mmHg, with temporary increases of 20 mmHg permitted for up to 2 minutes as needed. No adrenaline or tranexamic acid was added to the irrigation fluid.

8. Outcome Measures

Primary Outcome Measure

- **Intraoperative arthroscopic visibility (VAS)** rated by the operating surgeon every 15 minutes from skin incision to the end of the procedure.

Secondary Outcome Measures

- **Postoperative VAS ratings of intraoperative images** by three independent blinded expert assessors.
- **Interobserver agreement among independent assessors** for VAS ratings.
- **Comparison of VAS ratings between the operating surgeon and independent assessors.**

- **Hemoglobin concentration in irrigation fluid** as an objective indicator of intraoperative bleeding.
- **Number of irrigation pump pressure-boost events.**
- **Total irrigation fluid volume used.**
- **Intraoperative mean arterial pressure (MAP).**
- **Duration of surgery.**
- **Intraoperative blood loss.**
- **Total perioperative blood loss.**
- **Postoperative (hidden) blood loss.**
- **Perioperative hemoglobin decrease.**
- **Upper-arm circumference** as a marker of postoperative swelling.
- **Postoperative pain intensity (VAS).**
- **Total postoperative analgesic consumption.**
- **Length of hospital stay.**

9. Data Collection Procedures

At the beginning of surgery and every 15 minutes thereafter, the operating surgeon assessed arthroscopic visibility using the VAS-V scale (0–10). At the same time points, standardized photographs of the arthroscopic monitor were obtained and stored.

After completion of surgery, intraoperative images were independently evaluated by three experienced arthroscopic surgeons blinded to treatment allocation using the same VAS-V scale.

Irrigation waste fluid was collected, homogenized, and sampled for spectrophotometric determination of hemoglobin concentration. Intraoperative data included operative time, mean arterial pressure, number of irrigation pressure increases, and total irrigation fluid inflow and outflow volumes. All procedures, implants, and intraoperative technical issues were documented.

Postoperative assessments included shoulder circumference measurements, pain intensity scoring, analgesic consumption, venous blood sampling for complete blood count analysis, and length of hospital stay.

10. Statistical Analysis Plan

Descriptive statistics were used to summarize baseline characteristics and outcome measures. Normality of distribution was assessed using the Shapiro–Wilk test. Between-group comparisons were performed using independent samples t-tests or non-parametric equivalents as appropriate. Repeated intraoperative measurements were summarized per participant. Interobserver agreement among independent assessors was evaluated using reliability statistics. Correlations were assessed using appropriate correlation coefficients. Statistical significance was set at $p < 0.05$.

11. Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and approved by the relevant institutional ethics committee. Written informed consent was obtained from all participants. The trial was registered at ClinicalTrials.gov.