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ORIGINAL ARTICLE

Use of Tranexamic Acid in Arthroscopic Instability Repairs: A Prospective Study on Requirement of Hypotensive Anaesthesia and Clarity of Vision

Wg. Cdr. Shivani Mahajan[1], Lt. Col. Satish Kumar[2], Col. Nikhil Sood[3], Parikshat Gopal[4]

[1]Classified Specialist Anesthesia, MH Amritsar
[2]Classfied Specialist, [3]Sr Adviser Orthopaedics, Dept. of Orthopaedics Command Hospital, Chandimandir
[4]Professor, Dept. of Orthopaedics, Army College of Medical Sciences, New Delhi, India

Abstract

Background: Shoulder instability repairs are one of the commonest arthroscopic surgeries performed in the shoulder. It is always challenging to perform the repair both for want of skills and for requirement of a clear field of vision. A prospective study was conducted for assessment of the requirement of hypotensive anaesthesia and visual clarity as primary outcomes. Also as secondary outcomes operative time and post-operative shoulder swelling were studied.

Methods: A prospective study was conducted for Use of Tranexamic Acid in Arthroscopic Instability Repairs on requirement of Hypotensive anaesthesia and Clarity of vision. Forty cases of recurrent dislocation of shoulder requiring Bankart's repair were divided randomly into two groups of twenty each. One group was scoped using tranexamic acid 500mg in each of the 3ltrs of Normal saline used for arthroscopy and the other group was scoped without the use of tranexamic acid. The results were tabulated and statistically analysed.

Results: The study on these 40 patients revealed that the requirement of hypotensive anaesthesia and the time taken to carry out the repair was significantly lower in patients who were scoped with arthroscopic fluid with tranexamic acid.

Conclusion: The administration of a 500mg of tranexamic acid in each of the 03-04 arthroscopic fluids during instability repairs of the shoulder led to better clarity at higher readings of mean arterial pressure with significant reduction in the operative time. Although maintaining a bloodless field still remains a challenge therefore further studies with larger sample sizes would be required to confirm the claims of our study.

Keywords: TKA - Total Knee Arthroplasty, TXA -Tranexamic acid, MAP - Mean arterial pressure, DVT - Deep Venous Thrombosis.

Introduction

Tranexamic acid is a drug that effectively reduces blood loss and helps clot formation. Its safety and benefits have been well documented.Tranexamic acid (TXA) has been used successfully in other surgical fields and numerous studies on total knee (TKA) andhip arthroplasty (THA) have explored the efficacies and safeties of intravenous systemic or topical tranexamic acid with respect to reducing blood loss and transfusion rates [1-6].

The use of tranexamic acid in shoulder surgery is becoming more popular and has shown many advantages. Although transfusion and blood loss are not common in shoulder arthroscopy.

Address for Correspondence
Dr. Parikshat Gopal, Professor, Dept of Orthopaedics,
Army College of Medical Sciences, New Delhi, India
E-Mail: docpgopal@gmail.com

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Currently, no literature exists looking at local use of tranexamic acid in shoulder arthroscopy. The published evidence on tranexamic acid use in shoulder surgery is limited to arthroplasty procedures, which shows a decrease in blood loss and drain tube output.[7-10] Therefore, there is a need for studies to support the use of intravenous tranexamic acid in arthroscopic shoulder surgery. For creating a bloodless field inside the gleno-humeral joint often one or all of these methods have been used in the past i.e. use of arthropump, radio frequency ablation, hypotensive anaesthesia and use of epinephrine in irrigation fluid.

Hypotensive anesthesia is considered to be a suitable anesthetic technique for those patients who will be undergoing spinal surgery, hip or knee arthroplasty, craniosynostosis, hepatic resections, robotic surgery, and major maxillofacial operations [11-16]. In hypotensive anesthesia, the patient's

baseline mean arterial pressure (MAP) is reduced by 30% [17]. Consequently, the systolic blood pressure values are about 80–90 mmHg and the MAP is reduced to 50–65 mmHg [18]. Various pharmacological agents have been used for induced hypotension during orthognathic surgery. Appropriate patient evaluation and selection, proper positioning and monitoring, and adequate fluid therapy are stressed as important considerations in patients undergoing induced hypotension during orthognathic surgery.

The study aimed to determine whether local use of tranexamic acid (TXA) during shoulder arthroscopic instability repair surgery can improve arthroscopic visual clarity without the use of arthroscopic pump. Primary Outcome was to test the hypothesis that use of tranexamic acid in doses of 500 mg in each of the 3 ltrs of Arthroscopic fluid reduces bleeding and the requirement of hypotensive anesthesia. Secondary outcomes included estimated operative time and degree of shoulder swelling.

Methods

Study Design

A prospective study was conducted at Command Hospital Western Command, Chandimandir during the year 2017-2019 for assessment of the requirement of hypotensive anesthesia and visual clarity as primary outcomes. Also as secondary outcomes operative time and post-operative shoulder swelling were studied. Forty cases of recurrent dislocation of shoulder requiring Bankart's repair were divided randomly into two groups of twenty each and one group was scoped using tranexamic acid 500mg in the 3000 ml of Normal saline and the other group was scoped without tranexamic acid. In both the study groups arthro pump was not used.

Study population

Inclusion Criteria

- Patients with recurrent dislocation of shoulder warranting a Bankart repair were included.

Exclusion Criteria

- The Hillsach's lesion was assessed pre- operatively using MRI and CT scan. Those patients requiring Latarjet for Bony Bankart and Remplissage were excluded from the study group.
- History of coagulopathy.
- Under anticoagulation therapy before surgery.
- Abnormal coagulation profile (prothrombin time or activated partial thromboplastin time) before surgery.
- Renal or liver disorder.
- Uncontrolled hypertension.
- Allergy to local anesthetic agent or TXA.
- Pre - existing CAD or more than Grade II ASA.

Study procedure

The patient group was divided into two groups of 20 each. Ethical clearance was obtained from institutional ethics committee of the hospital before start of study. Informed written consent was taken from all the patients before surgery. All the patients were operated in a lateral decubitus position with the affected side up. Fixed skin traction was applied using an abductionpully with 04 kg weight. Standard posterior viewing portal was created. The repair was carried out using anterior and anterolateral portals. In all the cases 03 X 2.8 mm knotless anchors were used to repair the capsulo-labral complex. Bites were taken using a suture lasso after adequate release of the capsulo-labral complex. A radiofrequency ablator was used in all the cases without an arthropump.

- This study was carried out to assess the requirement of hypotensive anesthesia and visual clarity as primary outcomes and operative time and shoulder swelling as secondary outcomes. Finding of our study of 40 patients is tabulated below:

Outcome Measures

- **Primary Outcome Measures**:

  Requirement of hypotensive anesthesia: (Time Frame: Measured during the surgery). The average of MAP as calculated every 15 minutesduring the surgery was compared between the test and the control group.

  Visual clarity during shoulder arthroscopic surgery:(Time Frame: Measured during the surgery). We use 3-grades visual clarity. Grade 1 means poor visual clarity or red out (active bleeding that the vision was too poor to perform the arthroscopic repair); Grade 2 means fair clarity (minor bleeding that interferedvision but surgery can still be performed) and Grade 3 means good clarity. The visual clarity was scored every 15 minutes during the during arthroscopic surgery and the mode (most commonly occurring grade) was taken as the overall Grade for that particular repair.

- **Secondary Outcome Measures**:

  Operative time: Timing of surgery was calculated in minutes from the time the incision for the viewing portal was placed to the time when the last skin staple was applied.

  Post operation shoulder swelling: Was measured

Table 1: Assessment of Primary Outcome measures

Group 1 patients without Tranexamic Acid.	Number Of patients.	Mean Arterial Pressure required calculated every 15 mts during the surgery. Average of all readings.	Clarity of Vision (Graded 1 to 3).
Group 1	20	79.33 mm Hg	Mode was Grade 2- (12 out of 20 patients had Grade 2 visual clarity and 8 out of 20 had grade 3 visual clarity).
Group 2 patientswithTranexamic Acid	**Number Of patients**	**Mean Arterial Pressure required calculated every 15 mts during the surgery . Average of all readings.**	**Clarity of Vision (Graded 1 to 3).**
Group 2	20	71.664 mm Hg	Mode was Grade 3- (14 out of 20 patients had Grade 3 visual clarity and 6 out of 20 had grade 2 visual clarity).

Table 2: to assess Secondary Outcome measures

Group 1 patients without Traneximic Acid	Number Of patients	Post op shoulder swelling in (cms)- Average of three readings.	Average quantity of Arthroscopic Fluid used.	Time taken for repair in minutes.
Group 1	20	41.66	3.8 ltrs	65.7 minutes
Group 2 patients withtraneximic Acid	**Number Of patients**	**Post op shoulder swelling in (cms)- Average of three readings.**	**Average quantity of Arthroscopic Fluids used.**	**Time taken for repair (in minutes).**
Group 2	20	41.33	3.7 ltrs	58.2 minutes

immediatepost-operative period and 06 hours and 24 hours after the surgery. The girth of the shoulder was measured at the level of the edge of the acromion and the average of three readings was taken.

Result

The study on these 40 patients revealed that the requirement of hypotensive anaesthesia and the time taken to carry out the repair was significantly lower in Group 2 patients (with tranexamic Acid) with a p-value of < 0.0001. It was also noted that the post - operative swelling and clarity of vision in both groups was statistically insignificant although the clarity of vision was nearly significant with a p-value of 0.057. However, the clarity of vision mostly is a subjective criterion and was amenable to operative surgeon bias as it was not a single blinded study. Furthermore the swelling of the shoulder was far from significance with a p value of 0.718. Although the number of arthroscopic fluids used in the surgery was not part of primary / secondary outcomes but was tabulated and statistically investigated. It was inferred that the quantity of 03 ltr saline used for the arthroscopic repair in both the groups was statistically insignificant with a p value of 0.355. It was concluded that since there was no significant difference in the amount of arthroscopic fluid used in both the groups there was no difference in the post-operative swelling of the shoulders in both the groups.

The analysis included profiling of patients on visual clarity grade, requirement of hypotensive anesthesia (MAP), number of arthroscopic fluids used, operative time and post operation shoulder swelling during shoulder arthroscopic surgery. Quantitative data were presented in terms of means and standard deviation. Qualitative/categorical data were presented as absolute numbers and proportions. Cross tables were generated and chi square test was used for testing of significance for association. All quantitative variables were tested for outliers and normality using box plot analyses and the Shapiro-Wilk test of normality, respectively. Independent Student t test was used for comparison of quantitative outcome parameters between two study groups. P-value < 0.05 was considered statistically significant. SPSS software Version 24.0 was used for statistical analysis.

Table 3: Association between Study groups and Clarity of Vision Grade

Clarity of Vision Grade	Group 1 (n=20)	Group 2 (n=20)	Total (n=40)
Grade - 2	12 (60.0%)	6 (30.0%)	18 (45.0%)
Grade - 3	8 (4.0%)	14 (70.0%)	22 (55.0%)

Chi Square Value = 3.636; p-value = 0.057; Group 1 - Patients without Traneximic Acid; Group 2 - Patients with Traneximic Acid

Table 4: Comparison of Mean value of Study Parameters between Study Groups

	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	(Mean ± SE) of Difference	95% C.I. of the Difference		t - value	p - value
				Lower	Upper		
Mean Arterial Pressure	79.3 ± 2.9	71.7 ± 2.8	7.67±0.90	5.84	9.50	8.490	< 0.0001*
Post op shoulder swelling in (cms)	41.6 ± 3.4	41.3 ± 2.6	0.35±0.96	-1.60	2.30	.363	0.718
Time taken for repair in minutes	65.8± 5.4	53.2 ± 6.1	12.55±1.83	8.84	16.26	6.857	< 0.0001*
Number of Arthroscopic Fluids used	3.6 ± 0.5	3.4 ± 0.5	0.15±0.16	-0.17	0.47	.936	0.355

SE - Std. Error; p-value < 0.05, statistically significant; Group 1 - Patients without Traneximic Acid; Group 2 - Patients with Traneximic Acid

Discussion

Although the sample size was small but the study showed that the requirement of hypotensive anaesthesia and the time taken to carry out the repair was significantly lower in Group 2 patients (with tranexamic Acid) mainly because of its inhibition of activation of plasminogen. The above lead to better vision at higher readings of mean arterial pressure consequently translating into faster repairs. Also, the time taken by the operating surgeon in achieving hemostasis by other means such as radiofrequency ablation also was less as compared to Group 1 patients.

The swelling of the shoulder in both the Groups remained the same as it is mostly due to extravasation of saline in the inter-tissue planes. Therefore, the sole factor responsible for swelling of the shoulders was the number of arthroscopic fluids used during the surgery which also did not reveal any significant difference between the two groups. Therefore, it can be inferred that because of the better clarity of vision in Group2 patients it would have facilitated the surgeons in carrying out more meticulous and accurate repairs although the above would require further studies to assess the functional outcomes of both the Groups.

The side effects of tranexamic acidnamely DVT, pulmonary thromboembolism, nausea, vomiting and color vision problems, are known to occur with systemic use but none of these complications were encountered in the present study mostly because the drug was used locally in the arthroscopic fluid. In view of the low cost of tranexamic acid and its safety, it would appear to be suitable for use in shoulder arthroscopic surgeries.

Tranexamic Acid acts as an antifibrinolytic that competitively inhibits the activation of plasminogen and thereby reduces the conversion of plasminogen into plasmin. In addition, at higher doses, tranexamic acid also directly inhibits plasmin activity and may improve platelet function in patients administered dual antiplatelet therapy [19, 20].

Gillespie et al. reported on the similar effectiveness of topical tranexamic acid (100ml of normal saline with 2g tranexamic acid) on reducing blood loss and evaluated the effect of topical tranexamic acid on hemovac drain output after shoulder arthroplasty [21]. Abildgaard et al. retrospectively analyzed the effect of tranexamic Acid(1g) after total shoulder arthroplasty and found that tranexamic Acid diminished drain outputs postoperatively [22]. In a retrospective study, Friedman et al found tranexamic (20mg/kg) effectively reduced Hb and Hct level changes and hospital stays after total shoulder arthroplasty and reverse total shoulder arthroplasty [23].

Tranexamicacid has been used for some time for arthroplasties of the hip and knee, and published results have allowed systematic reviews and meta-analyses to be undertaken [24-26]. These studies concluded that administration of intra-articular tranexamic acidis safe and effective in reducing blood loss and blood transfusion

requirements without increase in the risk of postoperative DVT. The postoperative blood-saving effect of tranexamic acid after TKA has been previously reported to be between 20% and 48%, that is, equivalent to as much as 833 ml [27-29]. It has also been suggested that topical administration may be superior to the intravenous route [22]. However, further research is required to determine the optimum route or dose for administration.

The present study has several limitations. First, the sample size was small, nevertheless significant results were obtained. Second, the study was inherently limited its prospective design without being blinded which predisposes it to biases which could not be eliminated. Thirdly, visual clarity which was a primary outcome was subjective and was subject to biases of the operative surgeon.

Conclusions

The administration of a 500mg of tranexamic acid in arthroscopic fluids during instability repairs of the shoulder lead to better clarity at higher readings of mean arterial pressure with significantly reducing the operative time. The study shows the local use of tranexamic was not associated with any complications of its systemic use while having all its benefits on hemostasis.To maintain a bloodless field still remains a challenge and further studies with bigger sample sizes would be required to confirm the claims of our study.

Conflict of interest:	All authors declare no COI
Ethics:	There is no ethical violation as it is based on voluntary anonymous interviews
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