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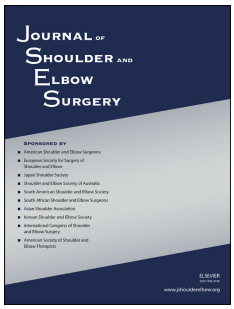


A Single Dose of Tranexamic Acid Reduces Blood Loss After Reverse and Anatomic Shoulder Arthroplasty: A Randomized Control Trial

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# A Single Dose of Tranexamic Acid Reduces Blood Loss After Reverse and Anatomic Shoulder Arthroplasty: A Randomized Control Trial

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This study was approved by the Human Research Ethics Committee at St Vincent's Hospital (file no. 16/105) and registered with the Australian New Zealand Clinical Trial Registry (ID no. ACTRN12616000723482).

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# Title

A Single Dose of Tranexamic Acid Reduces Blood Loss After Reverse and Anatomic Shoulder Arthroplasty: A Randomized Control Trial


## Abstract

**Background**: Hematoma formation and blood transfusions are commonly reported complications after shoulder arthroplasty. Tranexamic acid (TXA) has been widely used in hip and knee arthroplasty to decrease perioperative blood loss. The role of TXA is still being established in shoulder arthroplasty.

**Materials and Methods**: We conducted a double-blinded randomized controlled trial comparing intravenous TXA to placebo in 60 patients undergoing primary anatomic and reverse shoulder arthroplasty. 29 patients received a placebo whilst 31 received a single dose of 2g of intravenous TXA. Patient demographics as well as drain tube output, blood loss, hematoma formation, transfusion requirement, length of hospital stay and pain scores were recorded. Patients were followed up for 12 weeks to assess for complications.

**Results**: Patients who received TXA had lower drain tube outputs at all time points, 41ml compared to 133ml at 6 hours, 75ml compared to 179ml at 12 hours and 94ml compared to 226ml at 24 hours (all $P<0.001$). They also had higher postoperative Hb (12.3 vs 11.4; P=0.009), lower change in Hb (1.7 vs 2.3; $P=0.011$), lower total Hb loss (0.078g vs 0.103g; $P=0.042$) and blood volume loss (0.55L vs 0.74L; $P=0.021$), higher postoperative hematocrit (36.7 vs 34.6; $P=0.020$) and lower hematocrit change (5.4 vs 7.6; $P=0.022$). There was no significant difference in pain scores or length of hospital stay and no patients required a transfusion.

**Conclusion**: A single dose of 2g intravenous Tranexamic Acid decreases blood loss and drain tube output in primary anatomic and reverse arthroplasty of the shoulder. There were no

differences detected in occurrence of complications, need for transfusion, pain scores or length of hospital stay. With the mounting evidence now available, patients undergoing an elective primary shoulder arthroplasty should be given intravenous TXA to decrease peri-operative blood loss.

**Keywords:** shoulder arthroplasty; total shoulder arthroplasty; reverse shoulder arthroplasty; Tranexamic acid; TXA

**Level of evidence:** Level I; Randomized Controlled Trial; Treatment Study

Shoulder arthroplasty is becoming a more frequently performed procedure, increasing by 11.1% in Australia from 2015 to 2016, and by 115.5% since 2008. This is a steeper increase than either hip or knee replacements [3]. Perioperative management of blood loss and bleeding has also become an increasing area of interest in shoulder arthroplasty. Hematoma formation is one of the most commonly recorded complications of reverse shoulder arthroplasty [51, 11], whilst the blood transfusion rate following shoulder arthroplasty has a reported range from 3.9% to 43% [2, 7, 19, 20, 32, 39, 40]. An analysis showed an increase in rate of transfusions after shoulder arthroplasty in recent years [38], which may be due to the increased number of revisions [2, 51].

~~Decreasing peri-operative bleeding and limiting the rates of blood transfusion is therefore clearly important.~~ Allogenic blood transfusion has been linked to an increase in postoperative bacterial infections [23], respiratory tract infections and wound inflammation [12]. In shoulder arthroplasty specifically, it has been associated with increased rates of myocardial infarction, respiratory infections, sepsis, venous thromboembolism and cerebrovascular accidents as well as an increased rate of peri-prosthetic joint infection, which appears to be dose dependent [10, 18]. With the peri-prosthetic infection rate of around 1% remaining unchanged

between 2002 and 2011 [33], it is important to establish treatments that can affect infection rates such as improved peri-operative blood management.

Tranexamic acid (TXA) has been widely studied and used in lower limb arthroplasty as well as spine and trauma surgery to decrease perioperative blood loss and transfusion rates [5, 9, 24-26, 30, 37, 42, 46, 50].

TXA inhibits fibrinolysis indirectly, by competitively blocking lysine-binding sites on plasminogen. ~~Tranexamic acid acts by inhibiting fibrinolysis. It does this indirectly, by competitively blocking lysine binding sites on plasminogen, leading to a decreased affinity for plasminogen to bind to fibrin, decreasing the activation of plasmin~~ [44]. Its use and safety in shoulder surgery is currently being investigated ~~established~~, but it has been shown to be safe and effective in lower limb surgery without increasing the thromboembolic rate [5, 14, 22, 31, 42].

We conducted a prospective randomized double blinded trial to test our hypothesis that intravenous TXA would decrease drainage volume and bleeding, improve surgical field visibility and decrease surgical time and complexity, as well as decrease blood loss, need for transfusion, hematoma formation, hospital stay and improve postoperative pain, in primary total anatomic or reverse shoulder arthroplasty.

## Materials and Methods

*Study design and patient enrolment and randomization*

This is a double-blinded randomized controlled trial comparing intravenous TXA to placebo in 60 patients undergoing primary anatomic and reverse shoulder arthroplasty. 29 patients received a placebo whilst 31 received a single dose of 2g of intravenous TXA.

This study was approved by the Human Research Ethics Committee at St Vincent's Hospital (file number 16/105) and registered with the Australian New Zealand Clinical Trial Registry (ID number ACTRN12616000723482).

Between April 2016 and September 2018, all consecutive eligible patients who were to undergo shoulder arthroplasty after failed non-operative treatment were prospectively enrolled into the trial. The patients were given a standardized information sheet about the study and completed an Informed Patient Consent form.

Patients were randomized to either the treatment group of 2g TXA given intravenously or a saline placebo solution. They were block-randomized (n=6) in a double-blind fashion via a sealed, numbered envelope, which was opened by the anesthetist on the day of the surgery. Only the anesthetist and study coordinator were aware of the patient's allocated group. Each surgeon's patients were separately randomized (separate pile of envelopes) to avoid potential selection bias.

The inclusion criteria were any patient undergoing primary anatomic or reverse shoulder replacement who consented to participation in the study.

The exclusion criteria were allergy to TXA, history of seizure, revision arthroplasty, refusal to have potential blood transfusion, and any known coagulopathy or preoperative use of anticoagulant agents.

*Surgical and treatment protocol*

Shoulder replacements were performed by three high volume senior shoulder specialized surgeons, (**BC, AY, JH**, blinded for review purpose), who routinely perform shoulder replacements in the semi-beach chair position via a standard delto-pectoral approach. The procedure was performed under general anesthesia with an interscalenic block. Patients were administered either TXA or placebo (saline) before skin incision. At the end of the procedure each patient had a drain tube placed deep to the deltoid, exiting laterally to the distal part of the incision, which was then removed 24 hours post operatively. All patients received thrombo-prophylaxis with sequential calf compressors, graduated compression stockings and low molecular weight heparin. Postoperative protocols regarding use of sling and permitted

range of motion followed each surgeon's preference. All patients had standard follow-up appointments at 2, 6 and 12 weeks.

*Outcome measurement*

Patient demographics including age, sex, hand dominance, relevant comorbidities, BMI and ASA classification were recorded. Preoperative hemoglobin (Hb) and hematocrit were also recorded. Operative time was recorded, as well as subjective parameters rated by the surgeon, including intraoperative surgical field visibility (poor, fair, good, excellent) and procedure complexity (less than usual, as usual, more than usual).

Postoperatively all patients had their drain tube output recorded at 6, 12 and 24 hours, as well as need for a blood transfusion, hematoma formation, recovery room duration, overall hospital duration and pain visual analogue score (VAS) at 24 hours. Blood loss was also calculated using the Hb balance method [15]. Any adverse events were noted and reported until the 12-week mark. The threshold for blood transfusion was a postoperative Hb lower than 7.0g/dL, or 9.0g/dL with symptoms (fatigue, breathlessness, chest pain, tachycardia, fatigue).

*Statistical analysis*

All statistical analyses were performed using Stata 15. A sample size power calculation was performed with drain output as the primary variable and alpha set at 0.05. From previous studies on arthroplasty in other joints, we estimated that the drainage output would reduce 40% when TXA treatment was given. Using standard deviations in drainage reported in the literature (30%), a group number of 20 would be required to give a power of 99%. For blood loss as variable, a reduction of 25% with a 25% standard deviation requires a group n = 27 to give 95% power. A group number of 30 (60 total) was thus selected to ensure enough power to detect expected differences in these two variables.

Differences between treatment groups were determined using Students T tests (normally distributed continuous data), Chi-squared test of proportions or Mann-Whitney U ranked tests

(non-normally distributed or ordinal data) as indicated in the results tables. Subgroup analysis was carried out between the different types of prosthesis (reverse versus anatomic) using the same tests. The effect of demographic and treatment variables on surgery outcomes (operating time, procedural complexity, field visibility, postop pain, length of hospital stay) was measured using mixed model regression, correcting for site of operation (see Appendix). Any P value <0.05 was considered as statistically significant.

**Results**

Of the 100 patients screened to be enrolled in the trial, 26 were excluded and 11 chose not to participate (Figure I). There were 63 patients who qualified and were randomized. 31 patients were randomized to placebo, of which 2 were excluded (1 due to incorrect randomization and 1 whose drain tube dislodged and was removed early). 32 patients were allocated to receive TXA of which 1 was excluded because the procedure got cancelled due to concerns regarding infection. There was no loss to follow-up leaving 29 patients in the placebo group and 31 patients in the intervention group at 6 weeks. There were 19 reverse shoulder arthroplasties (RSA) and 12 total anatomic shoulder arthroplasties (TSA) in the TXA group, 22 RSA and 7 TSA in the control group. There was no significant difference between procedure type in both groups (P=0.11)

Patient demographics were similar in both groups (Table I). Patients who received TXA were found to have a higher postoperative Hb of 12.3 compared to 11.4 (P=0.009) and lower change in Hb from preoperative to postoperative of 1.7 compared to 2.3 (P=0.011). Using the Hb balance method, patients who received TXA had lower total Hb loss, 0.078g compared to 0.103g (P=0.042) and lower blood volume loss of 0.55L compared to 0.74L (P=0.021). Hematocrit postoperatively was higher in the TXA group at 36.7 compared to 34.6 (P=0.020) and hematocrit change from preoperatively was lower at 5.4 compared to 7.6 (P=0.022).

Drain tube output was significantly lower at all time points in patients that received TXA with the 6-hour measure being 41ml compared to 133ml (P<0.001), the 12-hour measure being 75ml compared to 179ml (P<0.001) and the 24-hour measure being 94ml compared to 226ml (P<0.001). There was one hematoma in the placebo group, clinically defined as a painful colored swelling of the operative site and/or arm, and none in the TXA group; this was not significant. No patient in either the placebo group or TXA group received a blood transfusion, and we found no significant difference in operative field visibility, operative complexity, operative time, time in recovery, hospital admission stay or pain scores at 24 hours (Table II).

When we analyzed the outcomes by procedure there was no statistically significant difference between anatomic or reverse total shoulder replacements (Table III). We also found that surgery time, procedural complexity, field visibility, postoperative pain, time in recovery and length of hospital admission was not affected by age (all P≥0.35 except for the length in PACU where P=0.01), gender (all P≥0.092), BMI (all P≥0.52), operated side (all P≥0.13), or ASA class (all P≥0.13) (see Appendix).

## Discussion

The results of this study show that a single dose of 2g of intravenous TXA provided a simple and effective dosing regimen to decrease blood loss and drain tube output. While we did not find any difference in the pain scores this may have been due to the timing of when these scores were taken as the nerve block may have still had some effect. We also did not have any transfusions in either group and only one hematoma in the placebo group. No adverse events were recorded, which is consistent with the recently published meta-analyses of TXA use in shoulder arthroplasty that found no adverse events across all studies [4, 21, 28, 43, 49]. This is also consistent with results from hip and knee arthroplasty [14, 16, 25, 36, 50].

TXA use in shoulder arthroplasty has shown significant recent interest. Gillespie et al in a prospective randomized trial demonstrated a decrease in drain tube output and drop in hemoglobin in patients given topical TXA intraoperatively compared to normal saline [17].

Intravenous TXA administration has also shown similar results [48]. Vara et al showed in their prospective randomized trial that two doses of intravenous TXA of 10mg/kg (one given 60 minutes before surgery and one given at wound closure) had significantly less blood loss, total Hb loss and drain tube output compared to placebo. 14.3% of the placebo group and 5.7% of the TXA group required a transfusion post operatively [45].

Pauzenberger et al also found similar results, with lower blood loss and lower drain tube output, using two doses of TXA (1g given within 30 minutes of skin incision and 1g given at wound closure). They also found lower hematoma rates and improved pain scores. There were no transfusions in either the TXA group or placebo group [34].

In a further randomized trial, Cvetanovich et al found that a single dose of 1g of TXA produced lower blood loss but no difference in drain output [6]. Single dose TXA administration was also found to be successful in non-randomized trials for decreasing blood loss and drain ~~tube~~ output, with Kim et al using 500mg in their South Korean population, Friedman et al using 20mg/kg and Abildgaard et al using 1g [1, 12, 27].

The ideal TXA dose regime is still yet to be established in arthroplasty surgery, with considerable variation in all published data for both lower limb and shoulder arthroplasty. Fixed dose and weight-dependent dosing have been used, as has single and multiple dosing with no clear consensus as to the most effective regime [4, 5, 14, 24, 28, 31, 41, 43]. There is also considerable debate in lower limb arthroplasty about intravenous versus intra-articular TXA dosing, with a recent meta-analysis by Gianakos et al showing that intra-articular dosing either on its own or combined with intravenous dosing led to less blood loss and drain tube output [16]. Recent studies seem to show similar results in shoulder arthroplasty ~~examined~~ [48].

According to another meta-analysis concerning lower limb arthroplasty, combined administration of tranexamic acid is associated with significantly reduced total blood loss, postoperative hemoglobin decline, drainage volume, and transfusion requirements in comparison with single application [35].

The role and safety of TXA in patients at high risk for thromboembolic events is still to be established. Three large database studies on hip and knee arthroplasty patients showed no increased risk of thromboembolic events in those with risk factors, however not all patients were given TXA, with some excluded due to their risk factors [8, 36, 47]. This study further adds to the published data about safety of the use of TXA in shoulder arthroplasty.

This study presented several strengths and limitations. Firstly, it is a multi-surgeon, randomized and controlled trial, including mixed type of procedures (RSA, TSA), with no loss to follow-up. Secondly, it also analyzed additional parameters than blood loss, such as hospital stay length, as well as subjective parameters including procedure complexity and surgical field visibility. Although no patient was lost to follow-up, a first limitation to this study was the rather limited number of patients. This is partly related to the strict exclusion criteria such as the use of preoperative anticoagulant or antiaggregant, which would have negated the results. Greater numbers of patients would be required to detect significant differences in some of the secondary variables. Based on the results presented here, a post-hoc analysis reveals that to get a significant difference in operating time or length of hospital stay with 80% power would have required 104 and 372 patients per group, respectively. With the number of patients used, it was not possible to carry out in-depth cost-effectiveness analysis. Secondly, the average patient BMI was 30.3 with an average weight of 82.5kg. The dose of 2g may not be applicable for all population groups. However, a recent metanalysis showed no difference when using a weight-adjusted dose than a fixed dose [29]. 2g appeared to

be as safe as 1g, which has been used in previous studies [1, 17]. Moreover, a fixed dose is easier to administer than a weight-corrected dose, limiting the risk of error.

**Conclusion**

A single dose of 2g intravenous Tranexamic Acid decreases blood loss and drain tube output in primary anatomic and reverse arthroplasty of the shoulder, with no significant difference between the latter. There was no difference in occurrence of complications, need for transfusion, pain scores or length of hospital stay. With the mounting evidence now available, patients undergoing an elective primary shoulder arthroplasty should be given TXA to decrease peri-operative blood loss.

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## Appendix

Correcting for site of operation (by mixed regression model) had no effect on the significance of treatment on operating time, PACU stay or days spent in hospital.

***Comments by objective***

Surgery time was not significantly affected by age ($P$=0.068), gender ($P$=0.43), BMI ($P$=0.81), side ($P$=0.13) or ASA class ($P$>0.13).

TXA did not significantly reduce surgery time ($P$=0.13; see table 2).

Procedural complexity was not significantly affected by age ($P$=0.062), gender ($P$=0.26), BMI ($P$=0.81), side ($P$=0.13) or ASA class ($P$>0.13).

TXA did not significantly change the proportion of surgeries in each category of procedural complexity ($P$=0.40; see table 2).

Field visibility was not significantly affected by age ($P$=0.35), gender ($P$=0.092), BMI ($P$=0.52), side ($P$=0.076) or ASA class ($P$>0.19).

TXA did not significantly change the proportion of surgeries in each category of field visibility ($P$=0.25; see table 2).

There were no transfusions given to any patient and only one hematoma (in the non-TXA group).

Postoperative pain (by VAS) was not significantly affected by age ($P$=0.60), gender ($P$=0.62), BMI ($P$=0.58), side ($P$=0.72) or ASA class ($P$>0.81).

Postoperative pain (by VAS) was not different between the treatment groups (P=0.74; table 2).

Length of hospital stay was not significantly affected by age ($P$=0.068), gender ($P$=0.26), BMI ($P$=0.81), side ($P$=0.13) or ASA class ($P$>0.13).

TXA did not significantly reduce length of hospital stay ($P$=0.13; see table 2).

***Not listed as objectives***

Length of time in PACU was not significantly affected by gender ($P$=0.11), BMI ($P$=0.80), side ($P$=0.21) or ASA class ($P$>0.48) but was affected by the patient's age (P=0.001).

TXA did not significantly reduce length of hospital stay time in PACU whether corrected for age (P=0.84) or not ($P$=0.70; see table 2).

Patients on TXA had a higher postop hemoglobin than those not given TXA ($P$=0.009) and thus had a smaller change in Hb from pre to postop ($P$=0.011; table 2).

Males have a significantly higher Hb (by 1.72 ± 0.26) than females ($P$<0.001).

Correcting for the difference between genders (in a linear regression model) the TXA difference in change in Hb from pre to postop more significant ($P$=0.006).

Hb total ($P$=0.042) and blood volume ($P$=0.021) losses were significantly less in patients on TXA.

Patients on TXA had a higher postop hematocrit than those not given TXA ($P$=0.020) and thus had a smaller change in hematocrit from pre to postop ($P$=0.022; table 2).

Males have a significantly higher Hct (by 4.1 ± 1.0) than females ($P$<0.001).

Correcting for the difference between genders (in a linear regression model) makes the TXA difference in change in Hct from pre to postop more significant ($P$=0.011).

TXA significantly reduced drain output at all three time points measured ($P$<0.001).

## Legends

**Figure 1**

Figure showing a CONSORT flowchart of the patient selection and randomization. *TXA*, Tranexamic Acid; *TSA*, Total Shoulder Replacement; *RSA*, Reverse Shoulder Replacement.

**Table 1**

Table illustrating the patient demographics in both groups.

*CS*, Constant Score; *ASA*, American Society of Anesthesiologists; *SD*, standard deviation; *TXA*, tranexamic acid

[a]Students t test; [b]Chi-squared proportions test; [c]Mann-Whitney U test

*Calculated by the Gross equation

**Table 2**

Table showing the results of the measured outcomes in both groups.

*Hb*, hemoglobin; *Hct*, hematocrit; *SD*, standard deviation; *TXA*, tranexamic acid; *PACU*: Post-Anesthesia Care Unit; *VAS*: Visual Analog Scale

[a]Students t test; [b]Chi-squared proportions test; [c]Mann-Whitney U test

*Using method 2 from Gao et al. (2015)

**Table 3**

Table displaying the results according to procedure type.

*SD*, standard deviation; *TXA*, tranexamic acid; *VAS*: Visual Analog Scale; *PACU*: Post-Anesthesia Care Unit

[a]Students t test; [b]Chi-squared proportions test; [c]Mann-Whitney U test

**Table I** Demographics

| | Non-TXA (N = 29) | | TXA group (N = 31) | | *P* |
|---|---|---|---|---|---|
| | No. | % or mean (SD) | No. | % or mean (SD) | |
| Age at surgery (years) | 29 | 73 (9) | 31 | 72 (8) | 0.60[a] |
| Gender | | | | | |
| Female | 23 | 79.3% | 20 | 64.5% | |
| Male | 6 | 20.7% | 11 | 35.5% | 0.20[b] |
| Body Mass Index | 29 | 31 (7.8) | 31 | 30 (7.0) | 0.51[a] |
| Blood volume (L)* | 29 | 4.6 ± 0.7 | 31 | 4.7 ± 1.0 | 0.73[a] |
| Side of Surgery | | | | | |
| Left | 12 | 41.4% | 13 | 41.9% | |
| Right | 17 | 58.6% | 18 | 58.1% | 0.97[b] |
| Pre Op CS | 25 | 25 (11) | 29 | 30 (12) | 0.11[a] |
| ASA class | | | | | |
| 1 | 1 | 3.4% | 1 | 3.2% | |
| 2 | 14 | 48.3% | 21 | 67.7% | |
| 3 | 14 | 48.3% | 9 | 29.1% | 0.30[b] |

*CS*, Constant Score; *ASA*, American Society of Anesthesiologists; *SD*, standard deviation; *TXA*, tranexamic acid

[a]Students t test; [b]Chi-squared proportions test; [c]Mann-Whitney U test

*Calculated by the Gross equation

**Table II** Outcome measures

| | Non-TXA (N = 29) | | | TXA group (N = 31) | | | *P* |
|---|---|---|---|---|---|---|---|
| | No. | Mean | SD, [range] or % | No. | Mean | SD or % | |
| Hb (g/dl) | | | | | | | |
| Preoperative | 29 | 13.8 | 1.1 | 31 | 14.0 | 1.3 | 0.57[a] |
| Postoperative | 29 | 11.4 | 1.1 | 31 | 12.3 | 1.3 | 0.009[a] |
| Change pre to post | 29 | 2.3 | 1.0 | 31 | 1.7 | 1.0 | 0.011[a] |
| Hb total loss (g)* | 29 | 0.103 | 0.044 | 31 | 0.078 | 0.049 | 0.042[a] |
| Blood volume loss (L)* | 29 | 0.74 | 0.29 | 31 | 0.55 | 0.34 | 0.021[a] |
| Hct change (%) | | | | | | | |
| Preoperative | 29 | 42.2 | 4.5 | 31 | 42.1 | 3.6 | 0.94[a] |
| Postoperative | 29 | 34.6 | 3.3 | 31 | 36.7 | 3.5 | 0.020[a] |
| Change pre to post | 29 | 7.6 | 4.4 | 31 | 5.4 | 2.7 | 0.022[a] |
| 6h drain output (ml) | 29 | 133 | 58 | 31 | 41 | 40 | <0.001[a] |
| 12h drain output (ml) | 29 | 179 | 70 | 31 | 75 | 49 | <0.001[a] |
| 24h drain output (ml) | 29 | 226 | 87 | 31 | 94 | 72 | <0.001[a] |
| Field visibility | | | | | | | |
| Poor | 1 | | 3.4% | 0 | | 0.0% | |
| Fair | 16 | | 55.2% | 12 | | 41.9% | |
| Good | 10 | | 34.5% | 11 | | 35.5% | |
| Excellent | 2 | | 6.9% | 6 | | 22.6% | 0.25[b] |
| Procedure complexity | | | | | | | |
| Less than usual | 3 | | 10.3% | 7 | | 22.6% | |
| As usual | 18 | | 62.1% | 18 | | 58.1% | |
| More than usual | 8 | | 27.6% | 6 | | 19.3% | 0.40[b] |
| Haematoma | 1 | | | 0 | | | |
| Transfusion | 0 | | | 0 | | | |
| Operation time (min) | 29 | 89 | 24 | 31 | 81 | 16 | 0.13[a] |
| Time in PACU (min) | 29 | 86 | 34 | 31 | 83 | 31 | 0.70[a] |
| Hospital stay (days) | 29 | 4.8 | 1.0 | 31 | 5.1 | 1.8 | 0.53[a] |
| Pain VAS score | 29 | 4 | [0,8] | 31 | 4 | [0,7] | 0.74[c] |

*Hb*, haemoglobin; *Hct*, haematocrit; *SD*, standard deviation; *TXA*, tranexamic acid
[a]Students t test; [b]Chi-squared proportions test; [c]Mann-Whitney U test
*Using method 2 from Gao et al. (2015)

**Table III** Outcome measures by procedure

| | Non-TXA (N = 29) | | | TXA group (N = 31) | | | *P* |
|---|---|---|---|---|---|---|---|
| | No. | Mean | SD, [range] or % | No. | Mean | SD, [range] or % | |
| Procedure | | | | | | | |
| Reverse | 24 | | 83 | 20 | | 65 | |
| Anatomical | 5 | | 17 | 11 | | 35 | 0.11[b] |
| Operation time (min) | | | | | | | |
| Reverse | 24 | 88 | 26 | 20 | 77 | 14 | 0.081[a] |
| Anatomical | 5 | 92 | 15 | 11 | 88 | 24 | 0.72[a] |
| Procedure complexity | | | | | | | |
| Reverse | | | | | | | |
| Less than usual | 2 | | 8.3% | 6 | | 30% | |
| As usual | 15 | | 62.5% | 10 | | 50% | |
| More than usual | 7 | | 29.2% | 4 | | 20% | 0.18[b] |
| Anatomical | | | | | | | |
| Less than usual | 1 | | 20% | 1 | | 9.1% | |
| As usual | 3 | | 60% | 8 | | 72.7% | |
| More than usual | 1 | | 20% | 2 | | 18.2% | 0.81[b] |
| Pain VAS score | | | | | | | |
| Reverse | 24 | 4 | [0,8] | 20 | 4 | [0,7] | 0.80[c] |
| Anatomical | 5 | 3 | [0,5] | 11 | 4 | [1,6] | 0.95[c] |
| Time in PACU (min) | | | | | | | |
| Reverse | 24 | 86 | 30 | 20 | 88 | 36 | 0.83[a] |
| Anatomical | 5 | 89 | 55 | 11 | 74 | 24 | 0.42[a] |
| Hospital stay (days) | | | | | | | |
| Reverse | 24 | 5.0 | 1.1 | 20 | 5.0 | 1.6 | 0.92[a] |
| Anatomical | 5 | 4.4 | 0.5 | 11 | 5.3 | 2.1 | 0.37[a] |

*SD*, standard deviation; *TXA*, tranexamic acid
[a]Students t test; [b]Chi-squared proportions test; [c]Mann-Whitney U test

**Figure 1**

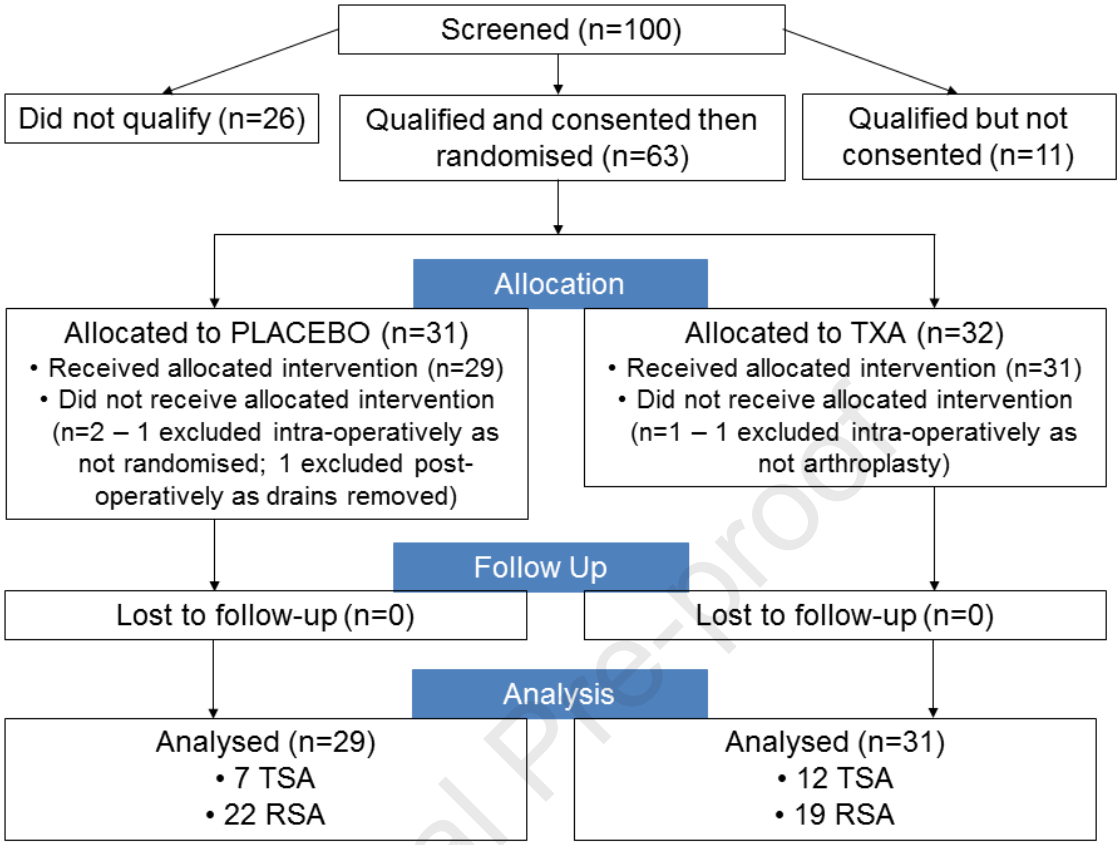


Figure showing a CONSORT flowchart of the patient selection and randomization. *TXA*, Tranexamic Acid; *TSA*, Total Shoulder Replacement; *RSA*, Reverse Shoulder Replacement.