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Original Article

# Usefulness of Tranexamic Acid in Reducing Blood Loss in Obstetrics and Gynecology: A Prospective Observational Study

**Akanksha Yadav, Kalpana Mahadik**

Department of Obstetrics and Gynecology, R D Gardi Medical College, Ujjain, Madhya Pradesh, India

## Abstract

**Introduction:** Uterine bleeding in reproductive age is due to hormonal causes in 14% of women as a whole which is medically treatable. Hemorrhage is a major killer in obstetrics. Uterine bleeding is a main cause of modifying health related quality of life in child bearing age group. To avoid major surgical intervention, there is a need for a medical modality which will act quickly and effectively. Here, we address outcomes of use of tranexamic acid (TXA) in mild postpartum hemorrhage (PPH), abnormal uterine bleeding (AUB), and threatened abortion.

**Purpose:** In this study, we intended to find effect of various doses and routes of drug in improving blood loss, hemoglobin, and hematocrit increase.

**Methods:** 145 gynecology and 40 obstetric patients were recruited in C.R. Gardi Hospital, Ujjain over 20 months in 2017–2020 having various types of bleeding pathology. In gynecology pictorial blood loss assessment chart (PBAC) was used to assess blood loss improvement and visual blood loss assessment was used in Obstetrics. Assessing blood loss, hemoglobin and hematocrit; before and after treatment was observed. Doses of 1.5–10 g/day of TXA were used. In PPH 1–5 g was used.

**Results:** About 65% and 35% women with ≤120 and ≥120, respectively, showed improvement in PBAC. Increase in hemoglobin, hematocrit, and reduction in PBAC score ($P$ = 0.00) are major findings. No significant difference was found in improvement of hemoglobin in mildly and severely bleeding patients. Average gain in hemoglobin was 0.5 g% and hematocrit of 7.4 in 1 week. In 33% of PPH, patient's major surgery could be postponed.

**Conclusion:** Improvement in pictorial PBAC score in AUB patients, hemoglobin, and hematocrit with avoidance of major surgical treatment in mild PPH are major findings of this study.

**Key words:** Tranexamic acid, Capillary bleeding in obstetrics and gynecology, Abnormal uterine bleeding, PBAC score

## INTRODUCTION

In this observational study, we have evaluated the usefulness of tranexamic acid (TXA) in reducing blood loss in various obstetric conditions, such as threatened abortion and minor post-partum hemorrhage (PPH), as well as its usefulness in abnormal uterine bleeding (AUB). Hemorrhage as a whole, both in obstetrics and gynecology, in addition to mortality risks, causes trauma to woman's mental and physical health. It is a major contributor of maternal mortality.[1] Nearly all (99%) of these deaths are in low- and middle-income countries.[2] Estimated prevalence of PPH varies widely, from 3% to 15% of deliveries globally.[3-6] In India, PPH is a major cause of maternal mortality and is responsible for 30% of all maternal deaths.

TXA is a lysine analog that binds to lysine receptors on plasminogen and plasmin, thereby inhibiting plasmin-mediated fibrin degradation and hence prevents fibrinolysis. None of the previous trials reported any significant increase in adverse events related to the use of TXA, including thromboembolic events. Thus, it appears that TXA is a safe and effective agent for the prevention and treatment of hemorrhage. The WOMAN trial conducted from 2009 to

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**Corresponding Author:** Kalpana Mahadik, Department of Professor Obstetrics and Gynaecology, Kotwali Road, Ujjain, Madhya Pradesh, India.

2017 strongly recommends early use of this drug to control PPH. In India, there is no fixed guideline for use of TXA. In this study, we intended to observe the efficacy of its use in the treatment of PPH. Besides PPH, early pregnancy bleeding has negative impact on the growing fetus, as well as on maternal health. Approximately 25% of pregnant women experience bleeding before 12 weeks of gestation, that is, in early pregnancy.[7] TXA was used in these women as a first line therapy in addition to progestogens.

Addressing AUB, 14% of women in reproductive age suffer from AUB. It impairs quality of life by creating significant physical, social, emotional, and sexual life disturbances and is a major material and financial burden.[8-10] Women with AUB make up 32.7% of clinical visits in gynecological outpatients.[11] About 30% of women overall consult a physician for heavy menstrual bleeding (HMB). HMB creates a clinically significant burden for affected women by interfering with daily activities and negatively impacting health-related quality of life (HRQL). The impact of HMB on HRQL derives from both the mechanics of managing bleeding and the consequences of excessive blood loss, such as fatigue and iron deficiency anemia.[12] Women with HMB appear to have higher number of endometrial plasminogen activators and more local fibrinolytic activity than women with normal menses. In the treatment of HMB, TXA has proven to be superior to placebo, mefenamic acid, and luteal-phase progestins.

We aim to study AUB patients with milder symptoms, without structural and pathological abnormalities; mostly having idiopathic etiology, who do not require immediate surgical intervention and will not progress to severe one. Around 35% of women with HMB will undergo a hysterectomy, which is a definitive cure for menorrhagia. Many guidelines of different nations consider medical alternatives as a first-line treatment, especially for idiopathic HMB. Women who are of younger age, who want to preserve their fertility, and who are nearing menopause are candidates for conservative treatment. There is no single line drug available to use as a short-term therapy in management of menorrhagia, to conserve the fertility of women, to arrest bleeding and to avoid surgical intervention. The purpose of this study is to assess the effectiveness of TXA in less severe obstetric and gynecological hemorrhage in patients in rural India.

## MATERIALS AND METHODS

This was a prospective cross-sectional study conducted on 185 women at the Department of Obstetrics and Gynaecology, R.D. Gardi Medical College Ujjain between 2017 and 2019. The study began after researchers obtained ethical approval from the Institutional Ethics Committee at R.D Gardi Medical College, Ujjain, M.P. The aims of the study and procedure were clearly explained to all participants and confidentiality was assured.

Study subjects were women from both obstetrics and gynecology.

### Recruitment of Gynecology Patients

One hundred and forty-five women attending C.R. Gardi Hospital, Obstetrics and Gynecology outpatient department with complaints of menorrhagia, menometrorrhagia and metrorrhagia were recruited. All women underwent estimation of complete blood count and ultrasonography evaluation. Physical examination was done to rule out any organic and endometrial pathology; and women with fibroids <2 cm in size were included in the study. Women with fibroids of more than 2 centimeter in size, polyps, adenomyosis, and endometrial or cervical carcinoma were excluded from the study. Women with coagulopathy, ovulatory dysfunction and iatrogenic causes were also excluded from the study. Menstrual blood loss was graded by self-assessment of the amount of blood loss using a pictorial blood loss assessment chart (PBAC).[13] A score was completed by multiplying the number of lightly, moderately, and heavily soiled pads. The score also has different points for different sizes of blood stains. A PBAC score of more than 100 refers to a blood loss of more than 80 ml and is considered heavy bleeding. Premenopausal women (18–45 years) with complaints of heavy period, or irregular and heavy period and reporting PBAC score of more than 100 for two consecutive cycles were included in the study. In our study, TXA was used as an adjunctive treatment, along with conventional treatment. PBAC score was noted in all participants before starting TXA. Patients included in the study were given 500 mg of TXA orally, three to four 3 times a day/4 times a day (TDS/QID) times daily according to the estimated bleeding at the time of examination. Total doses of 1.5–2.0 g/day for the first 5 days (i.e., total of 7.5–10 g) were given. Patients were asked about improvement in the condition by history and were examined 7 days and 1 month following the treatment. PBAC scoring was done at the time of follow-up visit. Women with the previous PBAC scores between 100 and 120 were classified as bleeding less heavily, and those with scores >120 were classified as bleeding heavily. A PBAC score below 100 signifies a reduction in menstrual blood loss of <80 ml. Patient satisfaction was assessed by asking the patient to indicate (yes or no) whether they were satisfied with the treatment. We categorized the patients in different subgroups of anemia based on hemoglobin levels at the time of first visit: Mild anemia hemoglobin 10–11.9 g/dl, moderate anemia 7.0–9.9 g/dl, and severe anemia <7 g/dl. Hemoglobin and hematocrit levels were

measured after 1 month of treatment, and thereafter again if patients followed up with some complaint. We noted the changes in hemoglobin levels according to category, after treatment with TXA. Total doses of TXA given were noted in the outcome.

### Recruitment of Obstetric Patients

In obstetrics, 16 women attending C.R. Gardi Hospital, Obstetrics, and Gynecology OPD with complaints of minor ailment such as threatened abortion, and post medical abortion bleeding were recruited and given TXA (500 mg TDS) orally for 4–5 days, depending on the clinical blood loss at the time of examination. In admitted patients, 24 women of PPH having more than average blood loss by our clinical judgment (average blood loss in vaginal delivery is 500 ml and in cesarean section 1000 ml) were recruited. In both the conditions, conventional treatment with TXA was given. For PPH, patients were given 1 g of TXA by IV injection over a period of 20 min. A second dose of 1 g of TXA was given if bleeding continued after 30 min following the first dose, or if bleeding stopped and restarted within 24 h of the first dose. A third dose was given to women who continued to bleed more than average after the second dose or if bleeding stopped and restarted within 24 h after the second dose. The patients with less bleeding received TXA (500 mg TDS) orally for 4 days. All patients received TXA as an adjuvant therapy. The primary therapy for each obstetric patient was noted in the outcome. The time of stoppage of bleeding was noted in all patients receiving TXA as an adjuvant therapy. The outcome variable is the number of obstetric cases of bleeding in which bleeding stopped after the first dose, second dose, and third dose of intravenous TXA. Another secondary outcome is the number of patients requiring other adjuvant therapy and the number of patients requiring operative intervention after the third dose of TXA.

Analysis of patients with respect to the above parameters was done for each group of patients separately. Data were analyzed using the student t-test, student paired t-test, and one-way ANOVA test and Shewhart control chart for mean. Data were represented by suitable diagrams and graphs and significance was defined as $P < 0.05$, to assess the efficacy of drug.

The study proposal was approved by Institutional Ethics Committee at R D Gardi Medical College, Ujjain (34/2019).

## RESULTS

A total of 185 patients were recruited in the study, out of which 145 were gynecology patients and 40 were obstetrics patients.

### Gynecology Results

Out of 145 cases of gynecology, patients with menstrual blood loss of more than 80 ml (i.e., PBAC score >100) were included in the study after excluding those having exclusion criteria. Of 145 cases, three women did not follow-up and one underwent a hysterectomy (opted for surgical treatment in the middle of the study), and were excluded from the analysis. Thus, there were 141 patients in gynecology group.

### Response in Terms of PBAC Score after Treatment

Out of a total of 141 patients, 92 had PBAC scores of <120 before treatment with TXA. In this category, the score reduced to <100 in 78 patients, and to >100 in 14 patients after treatment. Before treatment, 49 patients had scores ≥120, of which 41 patients had reduction of scores to <100 and 8 patients had reduction of scores to >100, that is, between 100 and 120.

This table signifies that improvements in PBAC scores, and hemoglobin and hematocrit levels are all statistically significant ($P = 0.0$ in all parameters).

### Obstetrics Results

C. A total of 40 patients were recruited in obstetrics, out of which 24 are PPH cases and 16 are abortion cases, in which we have given TXA at different doses according to the clinical condition and severity of bleeding**.** We will observe the results of the characteristics of study subjects in obstetrics and then we will observe the results in PPH patients, followed by the results in threatened abortion and post medical abortion cases separately.

Out of 24 patients, 14 (58%) were given 1 g of TXA and bleeding stopped within 1 h of treatment, 7 (29%) were given 2 g of TXA and bleeding stopped within 2 h of treatment and 3 (12.5%) were given 3 g of TXA and bleeding stopped within 3 h of treatment. The changes were all significant, with $P =$ of 0.000.

### Women Requiring Operative Interventions

Out of 24 women, eight cases (33.33%) required operative intervention and 16 cases (66.66%) recovered without surgery – in the latter group, bleeding stopped after TXA was given.

Out of 16 women, bleeding stopped 1 day after giving 3 g or less of TXA in three women, bleeding stopped 2 days after giving 3 g or less of TXA in six women, bleeding stopped 3 days after giving more than 3 g of TXA in three women, and 4 days after giving more than 3 g of TXA in four patients. The patients whose bleeding stopped early required three grams or less of TXA relative to those whose bleeding stopped after 2 days, who required more than 3 g

of TXA. After applying Chi-square test, the p value of the change is significant ($P = 0.001$) for all groups.

## DISCUSSION

Serum concentration of tissue plasminogen activator doubles, possibly because of tissue damage during childbirth within 1 h of giving birth. Thereafter, the concentration of plasminogen activator falls. Increased fibrinolytic activity has been described in obstetric hemorrhage secondary to uterine atony, placental abruption, and placenta accrete.[14] This concept provides the basis for a plausible role of antifibrinolytic agents (i.e., TXA) for the prevention, treatment, or both of PPH. In this study, we have given oral and injectable TXA in different doses, from 1 g to 10 g, over periods of 1 h–5 days in obstetrical and gynecological patients. Study subjects belong to various strata of society, representing diversity in economical and literacy backgrounds. For women who are ambulatory, it is difficult to assess improvement in blood loss. PBAC is a pictorial PBAC that is simple, yet more accurate method for the assessment of menstrual blood loss. Fraser *et al.* in 1984 devised PBAC, in addition to recording the number of towels and tampons used, and considered the degree to which individual items were soiled with blood. PBAC is not as accurate as objective methods like the standard hematin method. It provides simple and useful adjuvant therapy to enable clinician to identify women who require treatment and those who should be counseled. It also avoids unnecessary drug therapy, hospital stay, and surgical interventions in quite a significant number of women.

We found PBAC score to be a good criterion for assessing blood loss. The final charting of PBAC score was carried out after extensive questioning of women to assess blood loss and counseling was done in a contusive atmosphere. We feel a woman always tells her own story when she is allowed to talk to the gynecologist for some length of time. As such, for measuring improvement in blood loss, the subjective criteria of PBAC were used. Two objective criteria: Improvement in hemoglobin and hematocrit levels after 1 month was used. These two are definite and standard criteria to assess improvements in status of patients following treatment. In acute PPH, visual assessment by an obstetrician of time required to stop bleeding was used.

### Gynecology Patients

#### *Improvement in PBAC Score*

For comparison, we divided patients into two groups: Those having PBAC scores before treatment of more than 120, and those with PBAC scores between 100 and 120. In gynecology patients, the overall improvement in PBAC score was 116 ± 8.32–95.90 ± 5.44 ($P < 0.00$) [Table 1]. This significant improvement was present in 84% of women having PBAC scores of more than 120 before study [Table 2]. Out of this, 65% of women were having heavy bleeding (PBAC scores of more than 120). Another 35% of patients who had moderate menorrhagia (PBAC scores between 100 and 120) showed an improvement following treatment by TXA. Other studies documented improvements of 38% and 60%, respectively, in heavily and moderately bleeding women. Figure 1 shows that changes

**Table 1: "t-test" Comparison of Means of hemoglobin level, PBAC score, and hematocrit level before and after treatment with TXA**

| Variable | | Mean | (*n*) | *P* value |
|---|---|---|---|---|
| 1 | Hb before | 9.55±0.45 | 141 | 0.000 |
| | Hb after | 10.06±0.39 | 141 | |
| 2 | PBAC before | 116.63±8.32 | 141 | 0.000 |
| | PBAC after | 95.90±5.44 | 141 | |
| 3 | Hematocrit before | 24.73±4.18 | 141 | 0.000 |
| | Hematocrit after | 32.149±4.82 | 141 | |

**Table 2: Improvement in PBAC score in gynae patients**

| PBAC score before treatment | PBAC score after treatment (*n*) | | Percentage |
|---|---|---|---|
| | <100 | >100 | |
| <120 | 78 | 14 | 65 |
| ≥120 | 41 | 8 | 35 |
| Total | 84% | 16% | 100 |

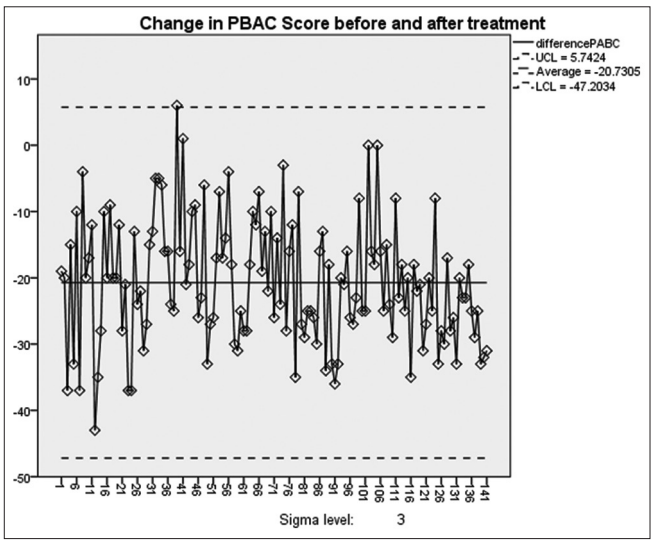


**Figure 1: Statistical quality control list for change in pictorial blood loss assessment chart (PBAC) score before and after treatment. The average change in PBAC score is 20. After plotting all the patients on a control chart, the maximum patients experienced a change in PBAC score that was close to the average. PBAC scores decreased in almost all patients; in only four patients, PBAC scores were not reduced; signifies that tranexamic acid appears to stop the bleeding effectively**

in PBAC scores occurred in all but four patients. The previous studies, dating back to 1995–1996, documented a reduction in menstrual blood loss of <80 ml/cycle in 56–100% patients following treatment with TXA.[15]

### *Improvement in hemoglobin level*

In 85% of women having PBAC scores of 120 or more, there was a significant improvement in hemoglobin levels 1 month following treatment of 1-week duration. Improvement in hemoglobin levels was seen in each different category of patients (mild, moderate, and severe anemia) following treatment with TXA. Most women who were in the moderate anemia category before treatment shifted to the mild anemia category and women in the mild anemia category shifted to normal hemoglobin levels [Tables 1 and 3]. Average improvement in hemoglobin was 0.5 g % [Figure 2]. A previous study found a reduction in menstrual blood loss of 47% and a rise in hemoglobin level in none.[16] Another study found a reduction in PBAC scores of 60% ($P < 0.005$) and a rise in hemoglobin level ($P < 0.003$).[17]

An Indian study comparing TXA and ethamsylate use in dysfunctional uterine bleeding demonstrates the superiority of TXA in terms of effectiveness, reduction in blood loss and improvement in quality of life.[17] The geographical setting of this study is the same as ours (i.e., India).

## Obstetric Patients

### *Improvement in PPH patients*

In our study, bleeding stopped in 58% of patients within 1 h of receiving one gram of TXA, while bleeding stopped after 2 h in 29% of patients after a dosage of 2 g, and in 12.5% of patients, bleeding stopped after 3 h after a dosage of 3 g [Table 4]. Other researchers have given TXA as a preventive measure for PPH, and found that the treatment significantly reduced bleeding.[18] Some studies report infusion of more than 800 ml of TXA in women with PPH.[19] Other reports measuring blood loss between enrollment and 6 h after TXA found that TXA significantly reduced bleeding ($P = 0.041$).[20] These findings are comparable to those of our study. A big trial on 20060 patients with a diagnosis of PPH and being given TXA or placebo demonstrated a reduction in deaths due to bleeding by one third with use of TXA. This multicentric WOMAN trial was carried out over 6 years and analyzed on narrative data reporting deaths due to PPH. Collaborators of the same trial measuring outcome measures of mortality, hysterectomy, and other morbidities in women with clinical PPH and use of TXA in a placebo-controlled trial report significant difference between TXA and placebo groups ($P = 0.045$).[21-23] In our study, 66% of patients did not need any operative intervention and 33% patients needed operative intervention after treatment with

**Table 3: Improvement in hemoglobin levels under various anemia categories before and after treatment with TXA**

| Anemia status | Treatment with TXA | |
|---|---|---|
| | Before | After |
| Normal | 1 | 2 |
| Mild anemia | 24 | 81 |
| Moderate anemia | 116 | 58 |

**Table 4: Correlation of TXA dose and time of stoppage of bleeding in PPH patients**

| Time of stoppage of bleeding | | Dose of tranexamic acid | | | *P*-value |
|---|---|---|---|---|---|
| | | 1 g | 2 g | 3 g | |
| 1 h | | (n) 14 | 0 | 0 | 0.000 |
| | % within time of stoppage of bleeding | 100.00% | 0.00% | 0.00% | |
| 2 h | | (n) 0 | 7 | 0 | |
| | % within time of stoppage of bleeding | 0.00% | 100.00% | 0.00% | |
| 3 h | | 0 | 0 | 3 | |
| | % within time of stoppage of bleeding | 0.00% | 0.00% | 100.00% | |

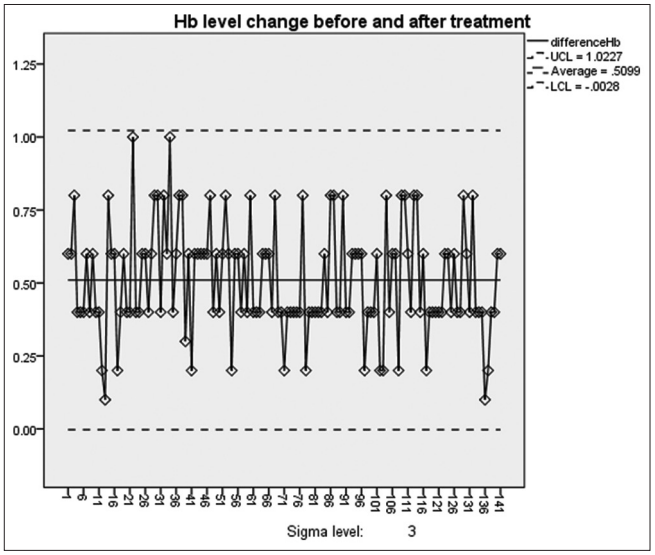


**Figure 2: Statistical quality control list for changes in hemoglobin levels before and after treatment. The average change in hemoglobin level is 0.5 g%. After plotting all the patients on a control chart, all the patients experienced close to an average change in hemoglobin level, and experienced positive changes in hemoglobin levels. A reduction in hemoglobin was not seen in any patient, signifying that tranexamic acid improves hemoglobin status**

TXA. Use of TXA within the first 3 h of birth in women with PPH is recommended by the International Federation of Obstetrics and Gynecology and the International Confederation of Midwives.[24] A very recent report has also mentioned a very positive outcome of the early use of TXA in PPH. In this study, administration of TXA was

the dominant strategy at all probability of maternal deaths due to hemorrhage >0.00002.[25]

Hemoglobin levels may not increase with TXA, but TXA will definitely prevent a decrease in hemoglobin, and provide early control of bleeding, hence stabilizing hemoglobin and prevent the development of anemia. In our study, the peripartum reduction in hemoglobin was −0.171 ± 0.33, with a $P = 0.02$, which is comparable to some researchers who in 2018 found reductions in mean hemoglobin levels of −0.77 ± 1.23, with $P = 0.64$.[16]

TXA also reduced the surgical treatment rate [Figure 3]. About 66.6% of patients did not require surgical treatment, while 33.3% did require a hysterectomy following treatment.

### *Improvement in abortion patients*

No previous studies have been reported on the use of TXA in abortion. There were five women having threatened abortion, out of which two cases (40%) needed 3 g or less of TXA, while three women (60%) required more than 3 g of TXA [Table 5]. 11 women were suffering from medical abortion, out of whom seven women needed 3 g or less, while four women needed 3 g or more. Threatened abortion patients needed higher doses of TXA relative to those with post abortal bleeding. $P = 0.377$ is not significant while comparing doses for threatened abortions and post medical abortion. In 18.7% of patients, bleeding stopped after 1 day of treatment, in 38% after 2 days of treatment, in 18.7% after 3 days of treatment and in 25% after 4 days of treatment with TXA. Mean hemoglobin levels prior to TXA treatment was 9.56 ± 0.51, and following TXA treatment for various days to stop the bleeding was 10.13 ± 0.34. There is a rise in hemoglobin of 0.57, which is significant ($P = 0.001$). Out of all the abortion patients, only 6% had undergone evacuation and in the remaining 94% of patients, treatment with TXA stopped the bleeding in medical abortion patients, and helped continue the pregnancy in other patients.

**Table 5: Correlation of dose of tranexamic acid with no. of days of stoppage of bleeding in threatened abortion**

| Days of stoppage of bleeding | Dose of TXA given | | *P* value |
|---|---|---|---|
| | ≤3 g | >3 g | |
| One | *n*=3 | *n*=0 | 0.001 |
| % Days of stoppage of bleeding | 100.00% | 0.00% | |
| Two | *n*=6 | *n*=0 | |
| % Days of stoppage of bleeding | 100.00% | 0.00% | |
| Three | *n*=0 | *n*=3 | |
| % Days of stoppage of bleeding | 0.00% | 100.00% | |
| Four | *n*=0 | *n*=4 | |
| % Days of stoppage of bleeding | 0.00% | 100.00% | |

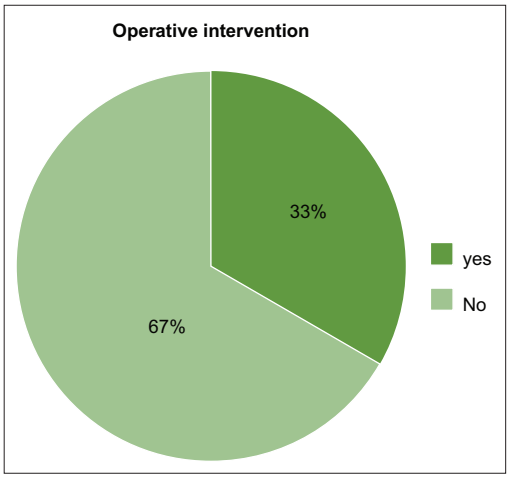


**Figure 3: Obstetric patients requiring surgical Treatment**

Recently, a recommendation has been made for all perinatal nurses to administer TXA as early as possible following a slightest prediction of PPH. Identifying the nurse's role in the management of PPH and its implementation is a best practice for treatment of PPH.[26,27]

## CONCLUSION

Improvement in PBAC score in AUB patients, improvement in hemoglobin and hematocrit levels; and avoidance of major surgical treatments in AUB and mild PPH are major findings of this study. We conclude that TXA is a very good adjuvant tool for milder forms of bleeding in obstetrics and gynecology. Improvement of 0.5 g% hemoglobin in 1 week in gynecology patients and significant improvement in reducing menstrual blood loss in AUB patients are major findings of this study. Its role in optimizing management of PPH at the stage of uncertainty is appreciable.

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### Institutional Committee Approval

This study was approved by Institutional Ethics Committee at R D Gardi Medical College, Ujjain, India (Approval no.-34/2019). We all authors confirm that informed written consent was obtained from all participants to carry out this work.

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