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COMPARISON BETWEEN TRANEXAMIC ACID AND MISOPROSTOL FOR THE PREVENTION OF HEMORRHAGE FOLLOWING CESAREAN DELIVERY

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ABSTRACT

Background: Cesarean section (Cs) is the most common major surgical procedure performed on females worldwide, and it is the main cause of the rising numbers of deaths due to cesarean-related hemorrhage. Despite the advances in the medical field, obstetric hemorrhage remains a well-recognized complication of childbirth in both developed and developing countries. **Objective**: this study compares the effectiveness of administering sublingual Misoprostol combined with oxytocin to that of IV Tranexamic acid combined with oxytocin to reduce intra and post-operative blood loss. **Materials and Methods**: This prospective randomized clinical trial was performed in Tishreen university hospital, Syria, between 2024 and 2025. A total of 150 pregnant women aged 19-40 years with a gestational age of 37-40 weeks were included and assigned into Two groups (n=75 in each group): Group A received Tranexamic acid, ten minutes before the skin incision, one ampoule (1 g) was injected. group B received Misoprostol, immediately after the delivery two sublingual pills (400 mg) were administrated. In both groups, immediately after the delivery 20 units of oxytocin was injected. After the operation, the Cs duration was recorded, the amount of bleeding was measured based on the number and differences in weight of the mops before and after the procedure, the blood in the suction container excluding the amniotic fluid, and the difference of patient's hemoglobin before and 24 h after surgery. Need for added uterotonics, need of blood transfusion, and adverse effects of drugs was also assessed. **Results**: The preoperative and postoperative hemoglobin in Tranexamic group were identified as 12.59±0.8, 11.19±0.7 respectively, whereas it was identified as 12.81±0.5, 10.35±0.2 respectively in Misoprostol group. Hemoglobin level reduction in the Misoprostol group was higher than the Tranexamic group - 2.46 ± 0.4 vs - 1.4 ± 0.2. The mops weight and count were recorded higher in Misoprostol group compared to Tranexamic acid group 271.11±84.7 vs 214.22±91.6 and 4.19±2.1 vs 3.42±1.1 respectively. blood suction in the Misoprostol group was significantly higher compared to Tranexamic acid group 258.82 ± 77.6 vs 206.19 ± 84.2 respectively. The common side effects identified in the Misoprostol group was chills and fever 13.3%, and 10.7% respectively. while, it was 2.7%, and 2.7% respectively in the Tranexamic acid group. **Conclusion**: In clinical practice, both Tranexamic acid and Misoprostol are effective in reducing blood loss during and after cesarean section; But Tranexamic acid was better as there were significantly lesser blood loss and fewer side effects especially in uncomplicated cases.

KEYWORDS: Postpartum hemorrhage, Cesarean Section, Tranexamic Acid, Misoprostol, Blood loss.

1. INTRODUCTION

Cesarean Section is one of the most commonly performed major operations in women throughout the world[1], The increasing incidence of cesarean section has contributed to postpartum hemorrhage (PPH), as the average blood loss during cesarean section is twice that during vaginal delivery.[2] Despite the advances in the medical field, obstetric hemorrhage remains a well-recognized complication of childbirth in both developed and developing countries[3,4], Syria serves as a prominent example of this issue. To lower the occurrence rate of this complication, preventive measures should be taken to reduce blood loss during and after CS. Different uterotonics agents administration, mainly oxytocin, has been routinely used to reduce the frequency of CS-related hemorrhage.[5] However, despite the routine use of oxytocin, 10-40% of women still need secondary uterotonics, which have been used to reduce blood loss during caesarean section.[6] As a result, exploring alternative therapeutic agents in addition to oxytocin with lower adverse effects and higher efficacy is needed for the prophylaxis against PPH following CS. Recently, a number of studies reported a correlation between fibrinogen decrease and cesarean-related hemorrhage.[7] Also the trauma during caesarean section provokes fibrinolysis, Therefore, anti-fibrinolytic agents, such as Tranexamic acid (TA), was recommended to prevent and treat uncontrollable blood loss following delivery.[8]

Tranexamic acid is an antifibrinolytic medication that acts by blocking lysine binding sites on plasminogen molecules. Several studies have showed the effectiveness of Tranexamic acid when added to oxytocin in preventing blood loss.[9,10]

Misoprostol is a prostaglandin E1 analogue which has been introduced as an uterotonics agent for preventing postpartum hemorrhage following Cesarean section[11], due to its multiple routes of administration, stability to temperature changes, availability, and cost[6] Studies have shown that intra-operative and post-operative blood loss was less in the Misoprostol group than in the placebo group. Therefore, they have recommended its use during caesarean section to prevent postpartum hemorrhage.[12,13] A Cochrane review has concluded that the combination of Misoprostol and oxytocin was one of the most effective combinations in reducing blood loss compared to oxytocin alone.[14]

Even after reviewing the latest available evidence, it became evident that there is a shortage of studies concerning the efficacy of intravenous TA and sublingual Misoprostol on reducing bleeding during and after CS; Therefore, we compared the effectiveness of the combined use of sublingual Misoprostol and oxytocin with that of the combined use of IV Tranexamic acid and oxytocin.

2. MATERIAL AND METHODS

2.1 Study population

A prospective randomized clinical trial was conducted in Tishreen university hospital, Syria, between February 2024 and February 2025, Informed consent was obtained from all participants after explaining the nature of the study, expected value, outcome, and possible adverse effects. The Study included 150 pregnant women who were candidates for lower segment cesarean section (LSCS).

Inclusion criteria consisted of participant's referral to the obstetrics and gynecology department, age 19 to 40 years, Gestational age between 37 and 40 weeks, Singleton pregnancy, and Elective cesarean delivery with a lower uterine incision. On the other hand, The exclusion criteria consists of having underlying disease (cardiac, liver, kidney, lung, etc.), Eclampsia or preeclampsia, Allergy to Tranexamic acid or Misoprostol, Thromboembolic event during pregnancy, Coagulation disorders, Placental pathology (placental abruption, placenta previa, etc.), Risk factors for postpartum hemorrhage (such as multiple pregnancy, polyhydramnios, and a history of uterine rupture), Uterine fibroids, Obesity (BMI greater than 30), and Restricted fetal growth or intrauterine fetal death. The researchers also excluded participants with incomplete data or inadequate information, or unwillingness to complete the study.

All participants went through the following procedures to verify their eligibility for this study: (1) a comprehensive medical and obstetric history review, (2) a general and obstetric physical examination, (3) an obstetric ultrasound, and (4) pre-operative lab tests, which included a complete blood count (CBC), a coagulation profile, and assessments of liver and kidney functions.

One hundred and fifty pregnant women with indication for elective CS, diagnosed by an obstetrician-gynecologist, based on both clinical and para-clinical evaluations and adherence to the study's inclusion and exclusion criteria, were selected to participate in the research. The Participants were randomly assigned into two groups using the computer-generated randomization: group 1 (75 women), who received Tranexamic acid was given intravenously at a dose of 1 gram (10 ml) slowly over two minutes, at least 10 minutes before the skin incision. and group 2 (75 women), who received Misoprostol was given sublingually at a dose of 400 mcg (two tablets) immediately after birth. Both groups were given oxytocin at a dose of 20 units per liter of lactated Ringer's solution at a rate of 1000 cm^3/hour.

After the operation, the Cs duration was recorded, the amount of bleeding was measured based on the number and differences in weight of the mops before and after the procedure, the blood in the suction container excluding the amniotic fluid, the difference of patient's hemoglobin before and 24 h after surgery, and the level of blood loss two hours after the procedure. Need for added uterotonics, need of blood transfusion, and adverse effects of drugs was also assessed.

2.3 Ethical Consideration

Signed informed consents were obtained from all participants. The researchers were committed to the ethical guidelines of the Declaration of Helsinki (1964), and approval for the study was obtained from the Ethics Committee of Tishreen University hospital.

2.3 Statistical Analysis

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency, and proportion for categorical variables. Categorical outcomes were compared between study groups using the Chi-square test /Fisher's Exact test. For normally distributed Quantitative parameters, the mean values were compared between study groups using an independent sample t-test. The change in the quantitative parameters before and after the intervention was assessed by paired t-test. $P<0.05$ was considered statistically significant. IBM SPSS version 25 was used for statistical analysis.

3. RESULTS

In this clinical trial, 150 pregnant women who visited the Obstetrics and Gynecology Department at Tishreen University Hospital during the period 2024-2025 met the inclusion criteria.

Table 1 shows the basic demographic and obstetric characteristics of the participants. The women's ages ranged from 19 to 40 years, with a mean of 28.32±2.1 years, the highest percentage was in the 20-35 age group, representing 78%, followed by <20 (12.7%), and >35 (9.3%).

116 (77.3%) participants BMI was within the Normal weight range, for 20 (13.3%) it was Underweight and 14 (9.3%) was Overweight. Most of the studied cases had one previous birth 96 (64%), followed by two previous births, primigravida, and three previous births 28(18.7%), 22(14.7%), 4(2.6%) respectively.

Table 1: Basic demographic and obstetric characteristics of the participants.

Variables	Result (n,%)
Age groups (Years)	
<20	19(12.7%)
20 – 35	117(78%)
>35	14(9.3%)
Mean ± SD	28.32 ± 2.1
BMI (kg/m^2)	
Underweight	20(13.3%)
Normal weight	116(77.3%)
Overweight	14(9.3%)
Parity	
Primigravida	22(14.7%)
One Previous birth	96(64%)
Two previous births	28(18.7%)
Three previous births	4(2.6%)

Pregnant women participating in the study will be randomly divided into two groups: (n=75 in each group): Group A received Tranexamic acid, group B received Misoprostol. During Cesarean section, all patients received 20 unit of oxytocin, and the final outcome compared between them.

In Tranexamic acid group, the mean age of women was 28.67±2.9 years, and the age group 20-35 years represented the most frequent group (80%), followed by <20 (13.3%), and >35 (6.7 %). The mean gestational age was 38.91±0.4. 61.3% of the participants had one previous birth, and 74.6% of Women were in normal weight range. In Misoprostol group, the mean age of women was 29.45±3.3 years, and the age group 20-35 years represented the most frequent group (76%), followed by >35 (12%), and <20 (12%). The mean gestational age was 39.42±0.5. 66.7% of the participants had one previous birth, and 80% of Women were in normal weight range. The mean duration of caesarean sections was 38.52±2.6 minutes and 39.11±1.8 minutes for Tranexamic acid and Misoprostol groups respectively. No statistically significant differences were observed between patients in either treatment group regarding women's age, mean gestational age, parity, body mass index, or mean surgical duration (p>0.05) (Table 2).

Table 2: Basic demographic and obstetric characteristics of the participants by comparison of the two groups.

Variables	Tranexamic Acid (75)(n,%) (Mean ± SD)	Misoprostol (75)(n,%) (Mean ± SD)	p-value
Age (years)			0.09
<20	10(13.3%)	9(12%)	
20-34	60(80%)	57(76%)	
>35	5(6.7%)	9(12%)	
Mean ± SD	28.67±2.9	29.45±3.3	0.4
Gestational age (weeks)	38.91±0.4	39.42±0.5	0.7
parity			0.1
primigravida	12(16%)	10(13.3%)	
Previous birth	46(61.3%)	50(66.7%)	
Two previous births	15(20%)	13(17.3%)	
Three previous births	2(2.7%)	2(2.7%)	
BMI (kg/m^2)			0.1
Underweight	11(14.7%)	9(12%)	
Normal weight	56(74.6%)	60(80%)	
Overweight	8(10.7%)	6(8%)	
CS duration (minutes)	38.52±2.6	39.11±1.8	0.4

The preoperative and postoperative hemoglobin in Tranexamic acid group were reported as (12.59±0.8, 11.19±0.7 respectively), whereas it was reported as (12.81±0.5, 10.35±0.2 respectively) in Misoprostol group. There is a reduction in post-operative hemoglobin in both groups when compared to preoperative hemoglobin, however Hemoglobin level reduction in the Misoprostol group was higher than the Tranexamic group (- 2.46 ± 0.4 vs - 1.4 ± 0.2 g/dL) (P< 0.05) (Table3).

Table 3: Comparison of hemoglobin pre to post of the participants by comparison of the two groups.

Hgb (g/dl)	Tranexamic acid (Mean ± SD)	Misoprostol (Mean ± SD)	P-value
Before Cs	12.59±0.8	12.81±0.5	0.9
After Cs	11.19±0.7	10.35±0.2	0.03
Hgb reduction	- 1.4±0.2	- 2.46±0.4	0.01

The mean of mops weight and count used per cesarean section were recorded higher in Misoprostol group compared to Tranexamic acid group (271.11±84.7 vs 214.22±91.6 and 4.19±2.1 vs 3.42±1.1 respectively). And The difference between study groups was statistically significant ($p<0.05$). Blood suction in the Misoprostol group was significantly higher compared to Tranexamic acid group (258.82 ± 77.6 vs 206.19 ± 84.2 respectively) ($P< 0.05$), There were statistically significant differences in the mean blood loss values two hours after cesarean section, which were higher in the Misoprostol group (92.14±16.4) compared to the Tranexamic acid group (58.14±11.2).

There were no statistically significant differences in the need for blood transfusion, with only 4(5,3%) women in the Misoprostol group had blood transfusion while it was 3(4%) in the Tranexamic acid group. additional uterotonics was used for 9 women in the Tranexamic acid group vs 7 in the Misoprostol group (Table 4).

Table 4: Estimated blood loss and indicators of the participants by comparison of the two groups.

	Tranexamic acid (n=75)(n,%) (Mean ± SD)	Misoprostol (n=75)(n,%) (Mean ± SD)	P-value
Mean difference in the weight of the mop (g) (mean blood loss from mop -ml) *	214.22±91.6	271.11±84.7	0.006
Mops count	3.42±1.1	4.19±2.1	0.04
Suction volume (ml)	206.19±84.2	258.82±77.6	0.0001
Blood Loss after 2h (ml)	58.14±11.2	92.14±16.4	0.0001
Blood transfusion			0.8
Yes	3(4%)	4(5.3%)	
No	72(96%)	71(94.7%)	
Additional uterotonics			0.2
Yes	9(12%)	7(9.3%)	
No	66(88%)	68(90.7%)	

g- Gram, *each unit weight gain in grams is equivalent to 1 milliliter of blood los.s[15]

As shown in Figure 1, The common side effects identified in the Misoprostol group was chills, fever and nausea with 13.3%, 10.7% and 9.3% respectively. while, it was 2.7%, 2.7% and 5.3 % respectively in the Tranexamic acid group. There were statistically significant differences in both fever and chills, which were higher in the Misoprostol group compared to the Tranexamic acid group. However, there were no statistically significant differences in the remaining side effects, such as nausea, vomiting, and headache (Table 5).

Table 5: Side effects of the participants by comparison of the two groups.

Side Effects	Tranexamic acid (n=75)(n,%)	Misoprostol (n=75)(n,%)	P-value
Nausea	4(5.3%)	7(9.3%)	0.06
Vomiting	3(4%)	6(8%)	0.8
Headache	8(10.7%)	6(8%)	0.5
Fever	2(2.7%)	8(10.7%)	0.04
Chills	2(2.7%)	10(13.3%)	0.01

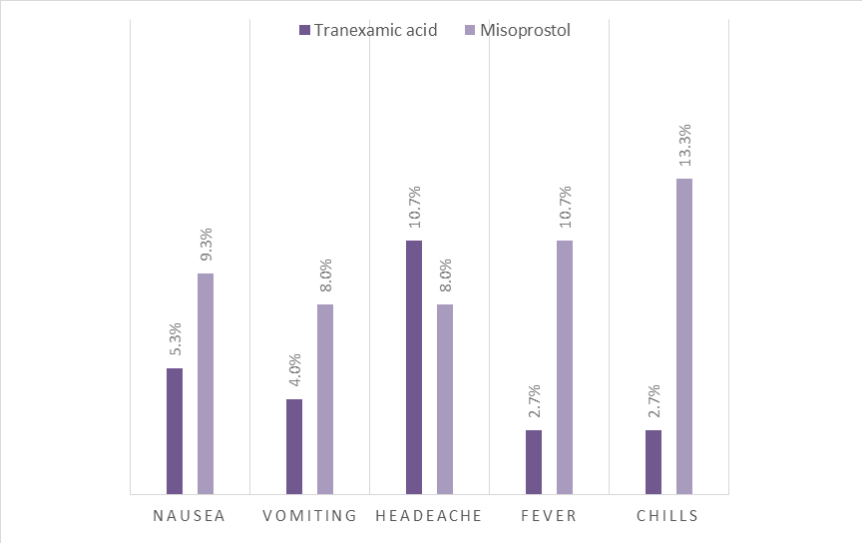

Fig. 1: Side effects of the participants by comparison of the two groups.

4. DISCUSSION

According to the results of our study, intravenous Tranexamic acid was significantly more effective in reducing total bleeding during and after cesarean section as compared to the sublingual Misoprostol.

Rao DM et al. (2023) found similarly to our study, significant differences between misoprostol and Tranexamic acid group regarding hemorrhage during cesarean section, mops count and hemoglobin reduction level, and stated that Tranexamic acid has proven better than Misoprostol.[16] In contrast to the results of our study, Seyed Saleh Tabatabaie et al. (2021), showed that Misoprostol is superior to Tranexamic acid in reducing bleeding during and after cesarean section, by used 600 mcg of rectal Misoprostol and 10mg/kg of intravenous Tranexamic acid after cord clamping[17], Unlike in our study, in which Tranexamic acid was given intravenously at a dose of 1 gram (10 ml) slowly over 2 minutes, at least 10 minutes before the skin incision. Whereas Misoprostol was given sublingually at a dose of 400 mcg (two tablets) immediately after birth. These differences in results may be due to the sample size and the type and dose of the drugs used in the intervention. The results of the study conducted by Deepak Bose et al. (2017) showed no statistically significant difference between the two drugs in terms of bleeding during and after cesarean section in high-risk patients. whereas, in low-risk patients, reached similar results to our study, with Tranexamic acid being superior to Misoprostol in reducing bleeding.[18] One possible explanation is that Tranexamic Acid performs better than misoprostol in low-risk, uncomplicated cesarean sections where bleeding is mainly due to surgical trauma. However, in high-risk patients experiencing hemorrhage, there was no statistically significant difference in blood loss reduction between the two drugs, suggesting that multiple factors may contribute to the overall blood loss.

The need for additional uterotonics and blood transfusions was similar in both groups. The proportion of women that were transfused blood was only (5,3%) for the Misoprostol group and (4%) for the Tranexamic acid group. The use of additional uterotonics to control bleeding was (9,3%) of the misoprostol group and (12%) of the Tranexamic acid group. No statistically significant differences were observed between the two groups regarding the need of uterotonics or blood transfusions, as in related studies performed by Ogah et al. (2022) and Pakniat et al. (2018).[19,20] This is a positive and uplifting development, particularly in our community where access to blood products is limited. Any intervention that helps decrease the reliance on blood transfusions is highly valued. While Tranexamic acid has demonstrated benefits in reducing blood loss, there are still concerns regarding its potential risk of causing thrombosis. Nevertheless, previous studies have confirmed the safety of this medicine for pregnant and non-pregnant women.[21] Similar to the results of our study, ogah et al. (2022), confirmed the effect of Tranexamic acid on reducing blood loss without thromboembolism events or other side effects.[19]

In present study, Misoprostol had higher side effects, with 10 (13.3%) participants experiencing chills, 8 (10.7%) having fever, and 7 (9.3%) having nausea. While, it was 2 (2.7%), 2 (2.7%) and 4 (5.3 %) respectively in the Tranexamic acid group. Similarly, Rao DM et al. (2023), was reported the more frequent side effects, including chills and fever, with sublingual Misoprostol use.[16] Saedda Safi et al. (2021) and Dawoud et al. (2023), on the other hand noted no significant difference in side effects between the two drugs.[22,23] These differences between studies could be due to the different doses of sublingual Misoprostol and Tranexamic acid, or different inclusion and exclusion criteria between studies.

5. CONCLUSIONS

Both intravenous Tranexamic acid and sublingual

Misoprostol are prescribed to prevent bleeding during and after cesarean delivery. However, Tranexamic acid has been shown to be superior, resulting in significantly less blood loss and fewer side effects than Misoprostol.

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Ethical approval

The study protocol was approved by Tishreen University Ethical Committee. All methods were carried out following the relevant guidelines and regulations. Informed consent was obtained from all participants.

Informed consent

The authors declared no conflict of interest. The authors have no financial conflict of interest to declare.

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