ORIGINAL ARTICLE

Comparison effect of intravenous tranexamic acid and misoprostol for postpartum haemorrhage

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ABSTRACT

Background: Postpartum haemorrhage (PPH) is the third-most common cause of maternal death in the United States and it is still the first prevalent cause of maternal death in developing countries. Active prevention of haemorrhage with an uterotonic or other new drugs leads to a decrease in postpartum vaginal haemorrhage. The aim of this study was to compare anti-haemorrhagic effect of Tranexamic acid (TXA) and Misoprostol for PPH. **Patients and Methods:** In a double-blinded randomised control clinical trial, 200 women were included after Caesarean or natural vaginal delivery with abnormal PPH. They were divided into two equal intervention and control groups. Effect of intravenous TXA and Misoprostol for postpartum haemorrhage was examined. **Results:** The mean age of patients was 26.7 ± 6.5 years which ranged from 14 to 43 years. The sonographic gestational age in the group treated with TXA was 37.7 ± 3.4 weeks and it was 37.4 ± 3.3 weeks for the other group (P = 0.44). The haemorrhage in the TXA and Misoprostol groups was 1.2 ± 0.33 litres and 1.18 ± 0.47 litres, respectively (P = 0.79). The haemoglobin levels after 6-12 hours of labour, in TXA group was more than that of the Misoprostol group, but this difference was not statistically significant (P = 0.22 and P = 0.21, respectively). **Conclusion:** Regarding to the superior results in Misoprostol group in one hand and lack of significant differences between two groups in haemorrhage during labour, post-partum haemoglobin level and discharge haemoglobin level, we can state that Misoprostol has no specific preferences to TXA, but more studies with greater population are needed.

Key words: Maternal death, misoprostol, postpartum haemorrhage, tranexamic acid

INTRODUCTION

Obstetrical haemorrhages are the most common cause of morbidity and mortality of women. Annually about 530000 women die in world as a consequence of pregnancy or child birth.[1-4] Annually 14 million women suffer postpartum haemorrhage (PPH); 2% of deaths occur 2-4 hours after haemorrhage starts. In other words, of 14 million PPH cases each year, 2% leads to death. Although most of mortalities occur out of health care centres but a considerable amount of deaths occur in hospitals, where effective facilities are used to prevent this event.[5-7]

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PPH is defined as 500 ml or more haemorrhage via genital tracts in the first 24 hours after child birth, but about severe postpartum haemorrhages (SPPH) this amount goes beyond 1000 ml or higher. Main reasons for PPH are the lack of ability for postpartum sufficient contraction (Atonic PPH) which includes 90% of cases in most of countries, trauma of genital tracts (traumatic PPH) in about 7% of cases and haemorrhage resulted from remaining placenta and coagulopathy (3%).[3,8-11] Although obstetric haemorrhages are often an unpredictable event but predelivery preparation and intervention could reduce severity of haemorrhage and decrease rate of morbidity of mother and child. This type of haemorrhage is often a sudden and life-threatening event. Finally, successful management is related to awareness about surgery interventions and pre-surgery preparation, if haemorrhage is expected.[5,12,13]

Currently, a wide range of haemostatic drugs are available commercially. In spite of limited information about this, these drugs are simultaneously used with some surgical methods to control intraoperative haemorrhage.

Haemostatic drugs are categorised into local haemostats and advanced drugs including fibrin sealers and underlying haemostatic drugs. Information about all available haemostatic drugs, is limited and has been obtained based on studies with low sample size.[5] Tranexamic Acid (TXA) is a synthetic derivative of lysine amino acid which inhibits fibrinolysis via reversible blocking of lysine-binding sites on plasminogen.[14] This drug has been used for menorrhagia treatment which results in considerable reduce (45-54%) in menstrual haemorrhage.[15] Homeostasis of placenta bed after child birth is a considerable physiological procedure, but this physiological procedure is not efficient enough.[16,17] TXA has been used since 1960 in most of the clinical cases whenever anti-fibrinolytic therapy have been appropriate. This is used to reduce haemorrhage and reduce the need for allogeneic blood transfusion especially in cardiac surgeries, liver transplantation and some orthopaedic surgeries with different results.[18-22] Also World Health Organization (WHO) has suggested TXA administration in uncontrollable PPH.[8,19,20] TXA decreases postpartum blood loss after vaginal birth and after Caesarean section based on a meta-analysis which reported on only a few outcomes.[23]

Regarding that different studies have been conducted on this field in world research centres and on the other hand it seems like that there was not such a study on patients in our region, therefore, considering the importance of this subject, it was tried to investigate the effect of intravenous TXA and Misoprostol on PPH and its complications. Haemodynamic status was the main factor being examined in both groups.

PATIENTS AND METHODS

During present double blinded randomised clinical trial, 200 women with PPH (500-1500 ml) diagnosis after caesarean or normal delivery, according to their haemorrhage level after usual therapies for controlling haemorrhage, after doing a consent were enrolled in study. For patients who had not filled the consent, WHO gold standard treatment was administered. Collecting bag method of sponges was used for measuring amount of haemorrhage.[24] They were divided into two equal intervention and control groups randomly. Patients in group A were treated with intravenous TXA and patients in group B with rectal Misoprostol. This study was conducted in Alzahra Educational-Medical centre related to Tabriz University of Medical Sciences (Tabriz, Iran). This study was performed in a 24 months period (from June 2011 to June 2013) and it was composed of collecting primary information, evaluating patients and data analysis.

Qualified patients are randomly divided into two equal groups using Randlist (version 1.2) Software. Intervention group (group A) which were receiving intravenous TXA (1gr) and if there was relieve in haemorrhage, next TXA dose was repeated after 30 minutes and in patients of control group (group B) after usual therapies, 5 rectal 200 micrograms Misoprostol pills were used. To determine sample size, results of similar studies were examined. The bladder was emptied before therapy in both groups. In a study the haemorrhage volume had been considered as primary variable and was 25% less in intervention group (receiving intravenous TXA) than that of the control group. For 15% reduction and α = 0.05 and 80% power, 190 patients were determined and in order to increase credit of study, 200 samples were studied. In this study, either patient or physician were not aware of drug given to each group and questionnaire was also filled in a blinded manner.

The routine therapy protocol to control haemorrhage in Tabriz Alzahra Educational-Medical hospital is prescribing 20 IU syntocinon in one litre of Ringer serum, which its infusion takes half an hour. This therapy was implemented immediately after removal of placenta if this therapy failed to control haemorrhage, birth canal was investigated in terms of cervical and vaginal lacerations to determine origin of haemorrhage. Then retraction of uterus was investigated and if uterus was not retracted, monomanual uterine compression and then bimanual uterine compression was performed, and in case of lack of haemorrhage by these methods, patients were included into the study.

In each group of patients, in case of Misoprostol or TXA therapy failure, F2α prostaglandin injection was used. Finally in case of F2α prostaglandin injection failure, surgery methods such as artery ligation, uterine compression sutures, balloon tamponade, selective arterial embolisation and finally hysterectomy were available options to control haemorrhage. Before starting therapy with TXA, we assured that usual therapies for PPH has been conducted and then determined haemorrhage level was more than normal level or patient's haemodynamic was yet unstable. After starting therapy with TXA and Misoprostol, next evaluation was compared for determining effect of TXA and Misoprostol on PPH and its complications. Any side effects due to misoprostol and TXA was investigated in both groups. Women with medical diseases or severe surgery including diseases of heart, liver, kidney and blood disorders, allergies to TXA, thromboembolic disorders and high-risk pregnancy complications such as severe preeclampsia were excluded from the study.

The study was approved by the Regional Ethics Committee (Ethics committee, Tabriz University of Medical sciences, Tabriz, Iran) which was based on Helsinki declaration and the patients information was kept as secret.

Analyzing data collected from the study was done by descriptive statistic methods (frequency, percentage, mean ± standard deviation) and by SPSS™ statistical

software version 16.0 using Chi-square test or Fisher's Exact test and Independence samples t-test. *P*-value less than 0.05 was considered as statistically significant.

This study has been registered in the Iranian Registry Clinical Trail (IRCT.ir) (ID: IRCT2012122411862N1).

RESULTS

Mean age of all studied patients was 26.7 ± 6.5 years which ranged from 14 to 43 years. As distinct groups mean age of women in group A, was 27.1 ± 6.3 years (17-41) and in group B it was 26.7 ± 6.8 years (14-43). Mean age difference between two groups of under study patients was not statistically significant (*P* = 0.97). Based on sonography mean gestational age in group A, was 37.7 ± 3.4 (23-41) and in group B, was 37.4 ± 3.3 weeks (23-40). Difference of two groups in terms of gestational age and amount of haemorrhage, was not statistically significant (*P* = 0.44 and *P* = 0.57 respectively).

Of all 246 patients with PPH, 200 patients who met inclusion criteria and filled consent were included in study. Included patients were divided into two equal groups randomly; CONSORT flowchart of study is shown in Figure 1.

Table 1 compares some demographic information of patients in two groups.

In group A, natural vaginal delivery (NVD) was performed, while in group B there in 96 patients (96%) NVD and in 4 patients (4%) caesarean delivery was performed. According to analysis, the difference between two groups was not statistically significant considering mentioned aspects. NVD in 76 cases (76%) in group A and in 88 patients (88%) in group B, was together with episiotomy or laceration and its difference was statistically significant (*P* = 0.004). Estimating the amount of haemorrhage during delivery, Hb at hospitalisation time, during haemorrhage, 6-12 hours after delivery and during discharge were investigated and its description in women and their comparison are presented in detail in Table 2.

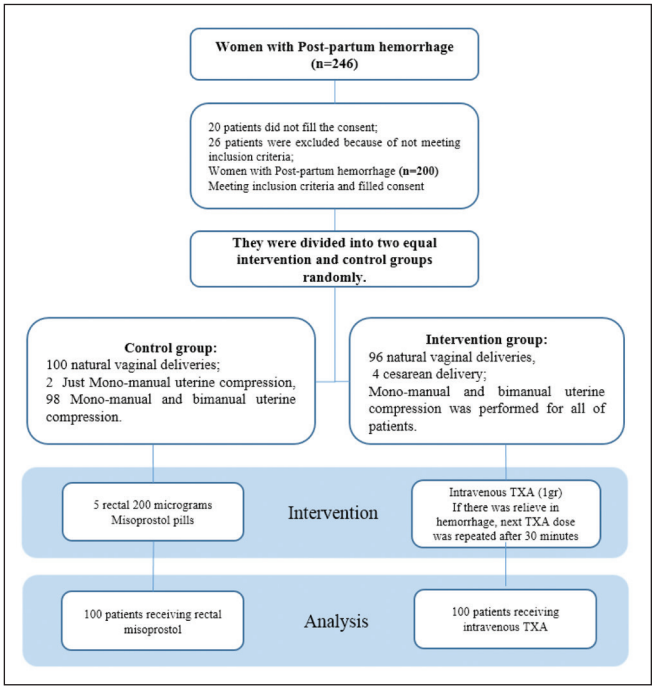

Figure 1: CONSORT flowchart of study

Table 1: Basic information of patients in study groups

Groups variable	Group receiving Tranexamic Acid (*N* = 100)	Group receiving Misoprostol (*N* = 100)	*P*
Weight (kg)	68.4±6 (58-81)	68±7.2 (54-81)	0.66
Height (m)	1.60±0.03 (1.51-1.70)	1.61±0.03 (1.55-1.67)	0.056
Body mass index (Kg/m²)	26.6±2.1 (21.5-31.6)	26±2.5 (21.5-32.4)	0.12
Gravidity	2.1±1.2 (1-6)	1.9±1.2 (1-6)	0.35
Parity	1±0.2 (0-5)	1±0.2 (0-4)	0.24
Abortion	0.2±0.1 (0-3)	0.2±0.1 (0-1)	0.76
Alive	0.8±0.1 (0-4)	0.7±0.1 (0-5)	0.25
Hospitalisation duration (h)	8.5±3.9 (1-96)	13.5±5.8 (1-72)	0.01
Hospitalisation duration after delivery (h)	38.2±18.8 (2-96)	45.5±41.2 (2-240)	0.10

*Data was shown in Mean ± Standard Deviation (Min-Max) Pattern

Table 2: Haemodynamic Status and Administered Products of Study Groups

Groups variable	Group receiving Tranexamic Acid (*N* = 100)	Group receiving Misoprostol (*N* = 100)	*P*
Haemorrhage (litres)	1.20±0.33 (1-2)	1.18±0.46 (1-3)	0.79
Hb during hospitalisation (g/dl)	11.4±0.8 (9.4-13)	11.6±0.8 (9.4-13.4)	0.11
Hb during haemorrhage (g/dl)	10.1±0.9 (7.5-12.4)	10.4±0.9 (8-12.4)	0.02
Hb 6-12 hours after delivery (g/dl)	8.9±0.9 (7-10.9)	9±0.9 (7-11)	0.22
Hb during discharge (g/dl)	9±0.7 (7.8-11)	9.2±0.7 (7.4-11)	0.21
Administered serum (lit)	1±0.7 (0-2.5)	0.9±0.7 (0-2)	0.24
Administered pack Cell (UI)	0.6±0.2 (0-5)	0.7±0.2 (0-6)	0.64
Administered fresh frozen plasma (UI)	0.2±0.1 (0-3)	0.3±0.1 (0-6)	0.53

*Data was shown in Mean ± Standard Deviation (Min-Max) Pattern

Before drug administration, uterine massage to control haemorrhage was performed. In 98 cases (98%) of patients in group A, one-handed massage and two-handed massage was performed and only in 2 cases (2%) just one-handed massage had been given. Also in group B in all cases one-handed and two-handed massage was given, Difference between two groups was not significant (P = 0.49). Mean massaging time for patients in group A was 24 ± 18.9 minutes (10-180) and in group B, was 24.5 ± 12.6 minutes (15-60). In conducted statistical analysis the difference between two groups in terms of massage duration was not statistically significant (P = 0.82). In terms of clinical consequence, 93 patients (93%) in group A and 91 patients in group B, were discharged without any specific problem.

No side effects such as nausea, vomiting, diarrhea or hypotention was detected due to TXA administration was not detected in group A. No side was detected due to rectal misoprostol administration was not detected in group B, except one case of disseminated intravascular coagulation which was due to preeclampsia. In group A, ICU admission frequency was 7 cases and in group B, it was 8; In conducted analysis, the difference between two groups was not significant (P = 0.58).

DISCUSSION

Currently, a wide range of haemostatic drugs are available commercially. In spite of limited information about this, these drugs are simultaneously used with some surgical methods to control intraoperative haemorrhage.[5] Beigi *et al*., in a clinical trial study investigated the effects of sublingual Misoprostol and intravenous oxytocin on controlling PPH. Results of this study shows that PPH in patients undergoing therapy with Misoprostol is significantly lower than group undergoing therapy with oxytocin. Duration of the third delivery stage was also less in Misoprostol group than that of oxytocin group. Although our study was on comparing the effects of haemorrhage controlling by TXA and Misoprostol but similar to study of Beigi *et al*.,[25] in our study haemorrhage level was lower in group receiving Misoprostol. Despite the study of Beigi *et al*., also the difference between two groups in terms of haemorrhage and haemoglobin level was not statistically significant. In spite of the study of Beigi *et al*.,[25] in our study Misoprostol has been used as 5 rectal 200micrograms pills. Also in our study, in checked serial haemoglobin level, haemoglobin level was slightly higher in group receiving Misoprostol than that of group receiving TXA but two groups had no significant statistical difference except urgent Hb level during haemorrhage.

In another study, efficacy of TXA in reducing blood loss after Caesarean section was investigated; according to this study, TXA statistically reduces blood loss from end to 2 h after Caesarean and its use was not associated with any side effects or complications.[26]

Nasr *et al*., concluded that two groups had no difference in terms of PPH and the need for blood transfusion and loss of more than 10% in blood haemoglobin makes that study different from present study.[27] In the study of Nasr similar to the study of Beigi *et al*., misoprostol had been used sublingually. It has been mentioned that misoprostol has rapid mucosal absorption; especially when it is used sublingually it reaches to a high concentration in blood. So this is a very useful drug for controlling PPH especially in far suburbs and rural areas where there is no access to hospital, personnel and trained midwives. Misoprostol is cheap, light and easily transportable. It is stable at room temperature and does not need to be kept in refrigerator and to be injected, so it is a preferable drug to control PPH.[25]

Abbaspour *et al.,* studied the sensitivity and specifity of method of blood collecting with bag for evaluating PPH, according to the results in PPH, sensitivity level of collected blood bag was 80%, specifity was 95.7%, value of positive prediction was 88.9%, value of negative prediction was 95.7%, and its accuracy was 91%. Finally in this study it has been concluded that collecting bags are rapid and accurate tools for recognising PPH. So considering the proper price, simplicity and ease of use it could be suggested to be used in labour centres of country.[28]

Zhang *et al.,* in their study on 25381 women in 13 European countries in 2010 using collecting blood bags showed that PPH prevalence was 1.71% in intervention group (using collecting bag) and 2.06% in control group. So collecting bag could not decrease severe PPH level comparing to visual estimation, which based on the ideas of authors due to the vast extent of study, there was probability of error in way and time of using collecting blood bags.[29] So according to the results of the above study and considering numerous problems in using bags for evaluating PPH level, we decided to estimate severity of PPH in women visually and alongside it, measure serial haemoglobin level to evaluate the effects of two used drugs and the estimation method of our study that is in contrast with the studies of Abbaspour[28] and Zhang.[29]

Samimi *et al.,* studied the effect of rectal misoprostol and muscular syntometrine in preventing PPH and it was concluded that rectal suppository misoprostol is more effective and less harmful than syntometrine injection for reducing PPH. So it could be used as a selective drug for preventing PPH;[30] it was in contrast with results of present study which had PPH diagnosis. In study of Samimi *et al.,* the mentioned drugs have been used as primary prophylaxis; which is in contrast with our study. Zafarghandi *et al*., studied haemorrhage duration and its relationship to different factors.[31] The results of

this study showed that count of deliveries, history of abortion, weight of birth, gestational age, preoperative haemoglobin, method of placenta removal and uterine height had no statistically significant relationship with haemorrhage duration.

Some studies have mentioned that side effects of misoprostol drug are more adverse comparing to other factors which are effective for controlling PPH.[25,27] In our study, except one case of DIC in group undergoing therapy with misoprostol which was a result of pre-eclampsia, there was no side effect in patients of both groups during study and two groups had no difference in terms of side effect.

CONCLUSIONS

According to better results in misoprostol group and on the other hand lack of significant difference between two groups in terms of haemorrhage level during delivery and postpartum and discharge haemoglobin, it is possible to state that misoprostol has no specific preference over TXA, but it is better to investigate its effect with other studies with more sample size and associated with misoprostol. Also, it must be mentioned that both insurance coverage for TXA and misoprostol makes these drugs equal in financial aspect. Since delivery of most of the women in our study was normal and had lower tissue trauma than Caesarean delivery, the lack of significant difference between two groups would be related to this issue, considering the fact that TXA has more effect on haemorrhage that has resulted from cut tissues.

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