VOLUME - 10, ISSUE - 08, AUGUST- 2021 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Obstetrics & Gynecology

TO EVALUATE THE EFFECT OF PROPHYLACTIC USE OF TRENEXAMIC ACID ON BLEEDING DURING ELECTIVE LSCS. A STUDY CONDUCTED IN TERTIARY CARE HOSPITAL OF CENTRAL INDIA.

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ABSTRACT

Background: Recent guidelines of the World Health Organization (WHO) indicated administering tranexamic acid (TXA) in order to treat postpartum bleeding (PPH). Therefore, finding low-cost and low-risk alternative methods to control obstetric bleeding is of great importance. The present study aimed to evaluate the prophylactic effect of TXA on bleeding during and after the LSCS. In addition, it was attempted to explore the impact of TXA as a safe and inexpensive method for decreasing bleeding during and after CS so that to decrease the hazard of blood transfusion or hysterectomy in these patients.

Material and Methods: This prospective study conducted on 100 women in Department of Obstetrics &gynecolgy for one year period. They were divided in two groups: Cases: (n=50; women receiving prophylactic Tranexamic Acid) and Control: (n=50; women receiving saline). Estimated the amount of blood loss during surgery. The amount of blood loss during surgery were calculated Estimation of weight of dry towels and mops before autoclaving is noted.

Results: Most common age group among Cases and Control was 26-30 years .%. Mean age among cases group (26.69±7.51 years) was significantly lesser compared to control study cohort (29.75±7.72). Post operativehemoglobin level was significantly higher among Case (11.26±12.03) as compared to Control (8.56±1.01). Comparing post operative complications revealedno significant changes. Use of topical hemostatics was higher among the control (77%) as compared to Cases (57%). Conclusion: Prophylactic treatment with TXA in relation to elective LSCS reduces the overall total blood loss, and the risk of reoperations owing to postoperative hemorrhage as revealed by higher hemoglobin level among cases.

KEYWORDS : Prophylactic, intravenous, tranexamic acid and hysterectomy.

INTRODUCTION

Nearly 530 000 maternal deaths annually occur due to pregnancy and childbirth worldwide. Obstetric bleeding which often happens after the delivery is one of the chief reason for maternal mortality (1). Based on recent reports, cesarean delivery causes more bleeding than vaginal delivery (2). The World Health Organization (WHO) defined postpartum hemorrhage (PPH) as > 500 mL blood loss from the canal of birth in 24 hours after birth (3). It is inevitable to prevent PPH, particularly after cesarean delivery. Nowadays, systemic antifibrinolytic agents are increasingly administered during the surgery in order to decrease the volume of blood loss and prevent fibrinolysis, namely, dissolution of the blood clot. Numerous studies were conducted regarding the prophylactic impact of administering tranexamic acid (TXA) on bleeding throughout the surgery and consequently less need for blood transfusions during anesthesia in liver transplantation and spinal, urologic, orthopedics, and cardiac surgeries (4). Fibrinogen and fibrin quickly dissolve as the placenta is expulsed during the cesarean delivery. After placental expulsion, activation of fibrinolytic system prompted clinicians to apply TXA. Meanwhile, activating the fibrinolytic system can increase the activators of plasminogen and fibrin degradation products (FDP). In addition, fibrinolytic activation system may endure 6 to 12 hours, causing further bleeding. Since TXA is an antifibrinolytic drug (4), recent guidelines of the WHO recommended administering TXA for PPH treatment if oxytocin and uterotonics were ineffective to halt the bleeding or trauma as the potential causes of bleeding. As the WHO noted the need for a modified guideline consequent to further researches (5), more in-depth studies are suggested about the effect of TXA on controlling the PPH. Further, the WHO and the Iranian ministry of health and medical education (MoHME) have made huge investments in preventing maternal mortality. Hence, it is crucial to identify low-cost and low-risk alternative methods of controlling obstetric hemorrhage. Therefore, the current study sought to investigate the prophylactic effect of TXA on haemorrhage Introduction Nearly 530 000 maternal deaths annually occur due to pregnancy and childbirth worldwide. Obstetric bleeding which often happens after the delivery is one of the chief reason for maternal mortality (1). Based on recent reports, cesarean delivery causes more bleeding than vaginal delivery (2). The World Health Organization (WHO) defined postpartum hemorrhage (PPH) as > 500 mL blood loss from the canal of birth in 24 hours after birth (3). It is inevitable to prevent PPH, particularly after cesarean delivery. Nowadays, systemic antifibrinolytic agents are increasingly administered during the surgery in order to decrease the volume of blood loss and prevent fibrinolysis, namely, dissolution of the blood clot. Numerous studies were conducted regarding the prophylactic impact of administering tranexamic acid (TXA) on bleeding throughout the surgery and consequently less need for blood transfusions during anesthesia in liver transplantation and spinal, urologic, orthopedics, and cardiac surgeries (4). Fibrinogen and fibrin quickly dissolve as the placenta is expulsed during the cesarean delivery. After placental expulsion, activation of fibrinolytic system prompted clinicians to apply TXA. Meanwhile, activating the fibrinolytic system can increase the activators of plasminogen and fibrin degradation products (FDP). In addition, fibrinolytic activation system may endure 6 to 12 hours, causing further bleeding. Since TXA is an antifibrinolytic drug (4), recent guidelines of the WHO recommended administering TXA for PPH treatment if oxytocin and uterotonics were ineffective to halt the bleeding or trauma as the potential causes of bleeding. As the WHO noted the need for a modified guideline consequent to further researches (5), more in-depth studies are suggested about the effect of TXA on controlling the PPH. Further, the WHO and the Iranian ministry of health and medical education (MoHME) have made huge investments in preventing maternal mortality. Hence, it is crucial to identify low-cost and low-risk alternative methods of controlling obstetric hemorrhage. Therefore, the current study sought to investigate the prophylactic effect of TXA on haemorrhage.

MATERIALS AND METHODS

This prospective study conducted on 100 women in Department of Obstetrics & Gynaecology at Tertiary care

center in Central indiafor period of one year. They were divided in two groups: Cases: (n=50; women receiving prophylactic Tranexamic Acid) and Control: (n=50; women receiving saline). Patient undergoing Elective LSCS were included in the study and family history of thromboembolism, thrombophilia, previous or active thromboembolic disease, malignant disease, patients on anti coagulant drugs, ascites and ovarian cyst which may likely to rupture/rupture during surgery were excluded from study.

Methodology

Estimated the amount of blood loss during surgery. The amount of blood loss during surgery were calculated Estimation of weight of dry towels and mops before autoclaving is noted. The amount of saline used during surgery in surgical field is noted. The weight of wet mops will be measured (in gms).The estimated blood loss can be calculated by weight of wet mopsweight of dry mops +saline in gms. This value in gms is converted to volume (ml) by following formula Volume=weight/density. Any additional blood collected in suction machine/tray, etc Statistical analysis All the data analysis was done using IBM SPSS ver. 20 Software. Cross tabulation and frequency distribution was used to prepare tables. Microsoft office 2010 was used to prepare the graphs. Paired sample t test was used to compare the mean where as categorical data was compare using Chi square test. Level of significance was assessed at 5%.

RESULTS

Based on the results, no significant difference was observed between the groups regarding the age (P = 0.685). Furthermore, there was no significant difference between the women aged < and > 30 years in term of mean age. The results indicated that the volume of blood collected during the cesarean delivery for the experimental group was 140 mL less than that of the placebo-receiving group.

Table 1: Comparing Age (years)-

Age Group	Cases	Control	P.Value
19-24	10	09	0.685
25-29	21	19	
30-34	16	17	
>35	03	05	
Total	50	50	

Most common age group among Case and Control group was 26-29 years .Second most common age group was 30-34 years. The comparison was statistically insignificant (p=0.685).

Table 2: Comparing Pre-OP & Post OP Hemoglobin-

Mean Hemoglobin	Cases	Control	P Value
Pre-op	10.11	10.19	<0.001
Post-op	9.56	8.59	

Comparing pre and post operativehemoglobin among Cases and Control revealed that post operative (10.11±0.77) hemoglobin was statistically significantly lower as compared to preoperative hemoglobin (9.56±0.65) (p<0.001).

Table 3: Comparing blood transfusion-

Blood tranfusion	Mean	N	St.Dev	P Value
Case	0.64	50	0.57	<0.001
Constrol	1.06	50	0.74	

No of blood transfusion were statistically significantly lower in Cases (0.64±0.57) compared to Control group (1.06±0.74) (p<0.001).

Table 4: Comparing number of MOPS used-

No.of MOPS used	Mean	N	St.Dev	P Value
Case	1.14	50	4.47	<0.001
Constrol	1.91	50	0.84	

Number of MOPS used were similar among Cases (1.14±4.47) and Control (1.91±0.84).

Table 5: Comparing Total amount of Blood loss-

Total amount of Blood loss	Mean	N	St.Dev	P Value
Case	602.31	50	175.88	<0.001
Constrol	844.64	50	211.95	

Total amount of Blood loss were statistically significantly lower in Cases (602.31±175.88) compared to Control group (844.64±211.95) (p value <0.001)

Table 6: Use of topical hemostatics-

Use of topical hemostatics	Case(%)	Control(%)	P Value
NO	66	18	<0.001
YES	34	82	

Use of topical hemostatics was statistically significantly more in Control (82%) as compared to Cases (34%) (p<0.001).

DISCUSSION

Massive bleeding after surgical interventions or severe trauma continues to be one of the most frequent life-threatening emergencies. Trauma-associated hemorrhagic shock is the most frequent cause of avoidable deaths, with hyperfibrinolysis (HF) at the time of hospitalization having been identified as an independent predictor of mortality (Pabinger I, 2017) [7] . A total of 100 participants were included. All Elective LSCS were done in spinal and all participants received preoperative antibiotic and anticoagulation treatment 4- 12 hours postoperatively, according to national guidelines (Dansk Hysterektomi Database 2009) [8] . The vast majority of the elective LSCS were performed by a senior gynecologist assisted by a resident under training, but no data concerning the surgeon's experience were collected. Most common age group among Cases and Control was 26-29 years.Age among Case and Control were equally distributed (p=0.684). In a similar study by Shady NW et al., (2018) [9] reported that there was no significant difference between the control and Case group with respect to their age (p>0.05). In present study preoperative hemoglobin level were comparable among the study groups (p=0.879). Shady et al., (2018) [9] studied 105 women and reported that preoperative hemoglobin was comparable in all the groups. In present study post operativehemoglobin level was significantly higher among Case (11.26±12.03) as compared to Control (8.56±1.01) (p=0.030) Shady NW et al., (2018) [9] showed no significant difference between the three groups (Control, IV and Topical Tranexamic Acid Group) related to their post-operative hemoglobin (p=0.752). Among control group hemoglobin level was significantly decreased from 10.25±0.77 preoperatively to 8.56±1.01postoperatively (-1.69gm%) (p present study. In present study comparing post operative complications revealed that among both the groups post operative complications were comparable (p=0.989) In agreement to present study findings post operative complications reported by Shady et al., in both Control and Tranexamic acid group in terms of the incidence of nausea, vomiting, and diarrhea were comparable (Shady NW et al., 2018) [9] . TopsoeeMF et al., (2016) [11] in a similar study reported that diagnosis of or readmission for postoperative hematoma/ hemorrhage or abdominal pain did not reach significant difference between both the groups. No incidence of thromboembolic event or mortality emerged in any of the participants which is in agreement to present study findings where post operative complication were comparable between both the groups. Present study has few limitations. First cross sectional nature of the present study was the main limitation which restricts the use of present study findings to large population. Second is the small sample size; a large randomize clinical trial is required to strengthen the present study findings.

CONCLUSION-

Our results indicate that prophylactic treatment with TA in relation to Elective LSCS reduces the overall total blood loss, and the risk of postoperative hemorrhage as revealed by higher post op hemoglobin level among cases. No incidence of thromboembolic events or death was observed in any of the groups.

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