ORIGINAL ARTICLE

Calcuim vs Tranexemic Acid to Decrease Postpartum Haemorrhage in Ceaserian Section

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Abstract

Background: ***Post-partum hemorrhage (PPH) is one of the most frequent complications following vaginal & cesarean deliveries.***

Aim: ***To assess the efficiency of calcium versus tranexamic acid in decreasing postpartum blood loss in the elective cesarean section.***

Patient and Methods: ***This randomized control research conducted on 135 cases allocated randomly into 3 groups: Group I: 45 females who taken tranexamic acid in the form of injectable ampoules (1 Ampoule by IV drip method on 0.9% normal saline) 1 hour before the procedure, Group II: 45 women who received one ampoule (10 ml 10% Ca Gluconate on 0.9% normal saline by slow IV drip method) with incision of the uterus & Group III (Control Group): 45 females taken oxytocin 5 units only at Al-Azhar University (Assiut) hospital & Akhmim hospital from April 2022 till October 2022.***

Results: ***There wasn't statistically significant variance among the studied groups in the indication of cesarean section (CS) and pre-operative vital signs, statistically significant variance within the examined groups in post-operative vital signs, Hb post-operative, and change in Hb, and highly statistically significant variance among the studied groups according to total blood loss. We concluded that calcium has a better probability of preventing atonic postpartum hemorrhage & is more efficient at regulating the volume of blood lost during delivery.***

Conclusion: Tranexamic acid is an affordable, safe medication that has no immediate adverse effects on either the mother or the fetus, so it can be used safely and effectively when calcium is contraindicated.

Keywords: Calcium; Tranexemic acid; Ceaserian section

1. Introduction

The number of CS has increased in developed & developing nations in recent decades.[1]

Worldwide, PPH is a significant complication following both vaginal & cesarean deliveries that significantly increases maternal mortality & near-misses. Approximately 140,000 fatalities occur annually due to "PPH" worldwide. Every four minutes, a woman passes away from PPH; therefore, PPH ranks fifth among the leading causes of death among women.[2]

PPH can be described as blood loss exceeding 500 milliliters subsequent to a normal delivery or 1000 milliliters subsequent to a caesarean section.[3]

Treatment of hemorrhage following CS includes blood transfusions & oxytocic administration, as well as more radical measures like hysterectomy. By utilizing an anti-fibrinolytic agent like tranexamic acid (TXA), one can avoid the potential risks associated with blood transfusions & the prolonged adverse effects of hysterectomy.[4]

Tranexamic acid is the antifibrinolytic agent that is most frequently utilized globally. Further benefits of being cheap and easy to handle & stock. In women with menorrhagia, TA reduces uterine blood loss significantly & is suggested "as a treatment for intractable postpartum hemorrhage.[5]

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Oxytocin is stored in the pituitary gland's posterior lobe after its production by the hypothalamus. It induces smooth muscle contraction in the uterus, a critical process for regulating hemorrhage subsequent to uterine emptying. Oxytocin functions by elevating the calcium concentration within the muscle cells, which is responsible for regulating uterine contraction. Elevated calcium levels stimulate uterine contraction.[6]

The objective of the work is to evaluate the efficacy of Calcium VS TXA to decrease postpartum blood loss in elective cesarean section.

2. Patients and methods

The randomized control research carried out 135 cases allocated randomly into 3 groups: Group I: 45 females who taken TXA in the form of injectable ampoules (1 Ampoule by IV drip method on 0.9% normal saline) 1 hour before the procedure, Group II: 45 Women who received one ampoule (10 ml 10% Ca Gluconate on 0.9% normal saline by slow IV drip method) with incision of the uterus and Group III (Control Group): 45 women receive oxytocin 5 units only at Al-Azhar University (Assiut) hospital & Akhmim hospital from April 2022 till October 2022.

Inclusion criteria: Age ≥ 18 & < 35years, ≥ 35 & < 42 weeks of pregnancy, singleton gestation, living fetus & hemoglobin ≥ nine gram%

Exclusion criteria: History of venous (pulmonary and/or deep venous thromboembolism) or arterial (myocardial infarction, stroke, angina pectoris) thrombosis, documented case of clotting conditions, twin pregnancy, serious anemia, TXA allergy, serious medicinal & operating complications including the hepatic, renal, heart, brain, & blood disorder, abnormal placenta including placental abruption, & placenta previa pregnancy associated complication including multiple pregnancy, serious preeclampsia, polyhydramnios, & macrosomia, history of seizure or epilepsy, autoimmune disease sickle cell disease, & woman on anticoagulant medication one week prior to delivery.

Sample size: This research base on study performed on by Farber et al.,[7] & Sekhavat et al.,[8] Using Epi Info STATCALC, the sample size was computed with the following assumptions in mind: With a 95% confidence level, an odds ratio of 1.115 is calculated, assuming an error of 5% & a power of 80%. The final maximum sample size extracted from the Epi- Info output was forty-three. Subsequently, the number of subjects in each group was raised to forty-five.

$N = [(4\sigma 2) (Z(1-(\alpha/2)) + Z(1-ß))2] \div E2$

N = total sample size (number of experimental units within treatments)

σ = assumed standard deviation of each treatment response.

$Z(1-(\alpha/2))$ = related to the chosen significance criterion

Z(1-ß) = related to the chosen power, or sensitivity of the experiment

E = minimum detectable difference between treatment means.

We assumed the difference does not exceed: -113

The least estimated sample size is 45 in each study group.

Administrative design: Verbal consent was obtained from the cases after they were informed & information confidentiality was ensured. A formal written letter of administrative permission was obtained from the dean of Al Azhar University's Faculty of Medicine, Head of the Obstetrics & Gynecology department at Assiut University. The title & purposes of the research were explained to them to assure their participation. Additionally, approval from the institutional review board & the faculty medicine ethical committee was obtained.

Methods:

All patients were subjected to the following: All groups will receive oxytocin 5 ml IV as a bolus on 10ml saline with incision of the uterus after extraction of the fetus.

Group I (Study Group): Includes 45 Women who will receive tranexamic acid in the form of injectable ampoules (1 Ampoule by IV drip method on 0.9% normal saline) 1 hour before the procedure.

Group II (Study Group): 45 Women who will receive one ampoule (10 ml 10% Ca Gluconate on 0.9% normal saline by slow IV drip method) with incision of the uterus

Group III (Control Group): 45 women received oxytocin 5ml only.

Detailed personal, obstetric, and medical history, examinations, assessment of fetal well-being, and ultrasound prior to the operation, an indwelling catheter was inserted and extracted within twenty-four hours. Additionally, the preoperative hematocrit was calculated. Each surgery was carried out under general anesthesia by second-year residents. A cesarean section of the lower segment was conducted, either with or without bilateral tubal ligation. During the procedure, adhesions, whether present or absent, & their severity were assessed. Supervising nurse of the labor room randomly assigned cases enrolled in the study to either receive 1.2 g of amoxycillin-clavulanic acid or two grams of ampicillin intravenously (i.v.) immediately following umbilical cord clamping. An envelope including either group was selected by a nurse for each case who participated in the study. Breaking the randomization code occurred only after the final patient had finished the study. The management of

this postoperative patient was identical to that of other postoperative cases.

Measuring blood loss: Blood loss (mL) equals (the product of the towel's weight utilized in cesarean sections - towel's weight before the procedures) plus the amount sucked in the suction bottle following placental delivery in mL. Furthermore, the pads utilized from the time CS was concluded until two hours postpartum were evaluated individually. The hematocrit & hemoglobin levels of both groups were recorded within twenty-four hours following the procedure. The equation for converting the weight (g) of towels to their volume (ml) is as follows: (1000 g =962 ml). Heart rates, respiratory rates, & Blood pressure were measured & recorded prior to the operation, immediately following placental delivery & between one and two hours following birth, respectively.

Methods of estimating blood loss:

Estimating blood loss by number of towels, HB% (CBC), and change in general condition. Number of towels, HB%(CBC), change in general condition

Statistical analysis: The data analysis was conducted utilizing version 20 of the Statistical Program for Social Science (SPSS Inc., Chicago, USA, IL). The description of quantitative variables consisted of the mean & standard deviation. Descriptive units of qualitative variables were numbers & percentages. The Student's t-test was utilized for comparing parametric quantitative variables across 2 groups. When the frequencies of qualitative variables were less than five, the chi-square (X2) test or Fisher's exact test was utilized to compare them. The Pearson correlation coefficients were utilized to determine whether or not two variables that followed a normal distribution were related. When a variable doesn't follow a normal distribution, a significance level of P less than 0.05 is applied.

3. Results

Table 1 detected that within the examined groups there wasn't statistically significant variance as regard personal data.

Table 1. Comparison among studied cases according to baseline data

	GROUP I (N = 45)		GROUP II (N = 45)		CONTROL GROUP (N = 45)		TEST OF SIG.	P
AGE (YEARS)								
RANGE.	24 – 33		24 – 33		24 – 33		F=	0.589
MEAN ± SD.	28.4 ± 2.43		28.96 ± 3.04		28.44 ± 3.02		0.531	
PARITY	No.	%	No.	%	No.	%		
PG	11	24.4	9	20.0	11	24.4	χ^2=	0.298
1	8	17.8	15	33.3	7	15.6	4.896	
>1	26	57.8	21	46.7	27	60.0		
PREVIOUS ABORTION	5	11.1	7	15.6	4	8.9	χ^2= 0.993	0.609

SD: Standard deviation, χ2: Chi square test , F: Oneway ANOVA test, p: p value for comparing among studied groups, *: Statistically significant at p ≤ 0.05

Table 2 detected that within the examined groups there wasn't statistically significant variance according indication of CS.

Table 2. Comparison among studied cases regarding to indication of CS

	GROUP I (N = 45)		GROUP II (N = 45)		CONTROL GROUP (N = 45)		TEST OF SIG.	P
	No.	%	No.	%	No.	%		
ELECTIVE CS	22	48.9	16	35.6	23	51.1	χ^2=	0.842
BREECH	5	11.1	11	24.4	8	17.8	5.675	
CORD AROUND NECK	5	11.1	3	6.7	4	8.9		
CEPHALO-PELVIC DISPROPORTION	3	6.7	3	6.7	3	6.7		
MECONIUM STAINED LIQUOR	6	13.3	8	17.8	4	8.9		
NON-PROGRESS OF LABOR	4	8.9	4	8.9	3	6.7		

Table 3 showed that within the examined groups there wasn't statistically significant variance regarding to pre-operative vital signs.

Table 3. Comparison among studied cases regarding to pre-operative vital signs

	GROUP I (N = 45)	GROUP II (N = 45)	CONTROL GROUP (N = 45)	TEST OF SIG.	P
SYSTOLIC BP					
RANGE.	106 – 130	108 – 130	107 – 128	F= 0.150	0.861
MEAN ± SD.	117.67 ± 6.96	117.49 ± 6.83	116.91 ± 6.76		
DIASTOLIC BP					
RANGE.	67 – 84	67 – 84	67 – 84	F= 1.768	0.175
MEAN ± SD.	76.2 ± 5.76	74.36 ± 4.62	76.02 ± 4.95		
HEART RATE					
RANGE.	72 – 97	75 – 97	72 – 98	F= 0.910	0.405
MEAN ± SD.	83.73 ± 6.68	85.11 ± 7	85.69 ± 7.49		

Table 4 detected that within the examined groups there was statistically significant variance regarding to post-operative vital signs.

Table 4. Comparison among studied cases regarding to post-operative vital signs

	GROUP I (N = 45)	GROUP II (N = 45)	CONTROL GROUP (N = 45)	TEST OF SIG.	P
SYSTOLIC BP					
RANGE.	102 – 127	103 – 126	99 – 122	F= 6.959	0.001*
MEAN ± SD.	114.62 ± 7.05	113.09 ± 7.1	109.31 ± 6.69		
POST-HOC	p1=0.297, p2<0.001*, p3=0.011*				
DIASTOLIC BP					
RANGE.	68 – 85	67 – 84	61 – 80	F= 9.203	<0.001*
MEAN ± SD.	76.16 ± 5.81	74.42 ± 4.31	71.58 ± 5.1		
POST-HOC	p1=0.110, p2<0.001*, p3=0.009*				
HEART RATE					
RANGE.	70 – 96	72 – 98	81 – 111	F= 36.012	<0.001*
MEAN ± SD.	84.16 ± 6.9	85.27 ± 7.38	95.96 ± 7.56		

POST-HOC	p1=0.471, p2<0.001*, p3<0.001*

SD: Standard deviation, F: Oneway ANOVA test, p: p value to compare among studied groups, p1: p value for comparing among group I & group II, p2: p value to compare among group I & group III, p3: p value to compare among group II & group III, *: Statistically significant at p ≤ 0.05

Table 5 detected that within the examined groups there was statistically significant variance regarding to Hb post-operative and change in Hb.

Table 5. Comparison among studied cases regarding to Hb readings

	GROUP I (N = 45)	GROUP II (N = 45)	CONTROL GROUP (N = 45)	TEST OF SIG.	P
HB PRE-OP					
RANGE.	9.9 – 13.6	9.9 – 13.6	9.7 – 13.7	F= 0.906	0.407
MEAN ± SD.	11.54 ± 1.19	11.72 ± 1.24	11.89 ± 1.28		
HB POST-OP					
RANGE.	8.5 – 13.3	8.7 – 13.3	7.7 – 12.8	F= 3.348	0.038*
MEAN ± SD.	10.54 ± 1.21	11 ± 1.32	10.29 ± 1.46		
POST-HOC	p1=0.099, p2=0.377, p3=0.012*				
CHANGE IN HB					
RANGE.	0.1 – 1.8	0.2 – 1.4	0.6 – 2.4	F= 47.376	<0.001*
MEAN ± SD.	1 ± 0.49	0.72 ± 0.31	1.6 ± 0.49		
POST-HOC	p1=0.003*, p2<0.001*, p3<0.001*				

Table 6 detected that within the examined groups there was high statistically significant variance regarding to total blood loss.

Table 6. Comparison among studied cases regarding to total blood loss

	GROUP I (N = 45)	GROUP II (N = 45)	CONTROL GROUP (N = 45)	TEST OF SIG.	P
TOTAL BLOOD LOSS (ML)					
RANGE.	390 – 770	310 – 700	370 – 910	F= 14.005	<0.001*
MEAN ± SD.	585.56 ± 109.76	502.22 ± 106.34	642.22 ± 156.36		
POST-HOC	p1=0.002*, p2=0.035*, p3<0.001*				

4. Discussion

In the present research, we found that there was no statistically significant alteration among the studied groups according to parity, age (years) & previous abortion.

These findings were compatible with Perveen et al.[9] who showed that average age of TXA intervention group was 28.80 ± 3.72 years with no significant variance among the examined groups. The mean pregnancy age was 38.94 ± 0.814 weeks in TXA group & 39.02 ± 0.864 weeks in control group with no statistical variance.

This was in agreement with Abd El-Samie et al.[10] who documented that there was no significant variance among the studied groups regarding patients' parity, age, or history of previous abortions.

In the current research, we detected that there was no statistically significant variance within the examined groups regarding indications of CS.

Goswami et al.[11] illustrated that regarding Indications for surgical intervention were similar across all groups examined. The number of breech presentations was the highest among the 3 groups. A significant differential existed in the period of surgery across the 3 groups, with group T2 enduring the longest at 67.80±9.704 minutes.

Our current findings clearly revealed that within the examined groups there was no statistically significant difference regarding pre-operative vital signs, while there was statistically significant variance according to post-operative vital signs.

Our results agree with Shakur et al.[12] that showed that a statistically significant variance among TA & placebo groups was found regarding any vascular occlusive event, myocardial infarction, systolic blood pressure (mmHg), respiratory rate (/min), and HR (beats/min).

However, our results disagree with the study done by Sekhavat et al.[8], who found there wasn't statistically significant variance in the HRs, blood pressures, & respiratory rates in the 2 groups.

In the recent research we detect that within the examined groups there was statistically significant variance regarding to Hb post-operative and change in Hb.

This was in agreement with El-Sttar et al.[13] who detected that postoperative HCT & Hb were significantly greater in group B than group A. Decrease in HCT & Hb was significantly lower in group B than in group A.

Also, Sekhavat et al.[8], which was mostly due to the significant decrease in the amount of blood from the termination of CS to two hr.

Our current findings clearly detected that within the examined groups there was great statistically significant variance regarding total blood loss.

In agreement with our outcomes, Abd El-Samie et al.[10] documented that a highly significant variance was found in the 3 groups according to the mean volume of blood loss.

In a study done by Chong et al.[14] to compare methergine & calcium, the average loss of the blood was detected to be higher in the calcium group in comparison with the methergine group however, the variance wasn't statistically significant.

Also, Larciprete et al. [15] compare methergine & calcium, there was no significant variance in the amount of estimated blood loss among the 2

groups.

Also, Gungorduk et al.[16], who obtained that the average measured loss of the blood was significantly less in the TA group than in the control group, & the average calculated loss of the blood from placental delivery to two hours postpartum in the intervention group was fewer than in the control group.

4. Conclusion

Calcium exhibits greater efficacy in regulating blood loss during delivery, thereby increasing the likelihood of averting atonic postpartum hemorrhage. Calcium is an affordable & safe that doesn't cause any immediate adverse effects in either the fetus or the mother. Calcium is well alternative to tranexamic acid with low side effects so may be utilized safely & efficiently when TXA is contraindicated.

Disclosure

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Authorship

All authors have a substantial contribution to the article

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