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ORIGINAL ARTICLE

The Effect of Intravenous Tranexamic Acid on Reducing Blood Loss during Myomectomy Operation; Randomized Controlled Study

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ABSTRACT

Background: The most frequent benign tumor in females is uterine myoma, which is derived from the myometrium of the uterus. Multiple studies have reported rates of occurrence were varying between twenty percent and forty percent. The histological diagnosis indicates a significantly higher frequency compared to the clinical diagnosis. Therefore, the treatment of the hemorrhage is contingent upon the estimation of the hemorrhage and the alterations that happen during the operation. **So we aimed** to compare the effectiveness of placebo and tranexamic acid during transabdominal myomectomy for reducing the bleeding. **Methods:** Blinded randomized controlled research, while 50 females with uterine fibroids were divided and equally classified among two groups, each group contained 25 females. Prior to the abdominal myomectomy, each woman received a slowly intravenous injection of tranexamic acid fifteen milligrams per kilogram or placebo over a period of between five and ten minutes. The amount of blood loss was assessed. **Results:** The tranexamic acid group showed low blood loss, participants needing blood transfer, or additional intervention, in comparison to the placebo group. Furthermore, the participants that received tranexamic acid injections showed higher hemoglobin and hematocrit levels than those that received placebo injections following surgery. **Conclusions:** The parameters that were assessed together with the adverse and beneficial consequences of the study drugs, showed as follows: The hematologic profile and hemodynamics may be established, which might result in tranexamic acid being more efficient compared to a placebo in reducing the need for blood transfusions.

Keywords: Tranexamic acid; Uterine fibroids; Placebo; Transabdominal myomectomy; Blood loss.

INTRODUCTION

The most frequent benign tumor in females is uterine myoma, which is derived from the myometrium of the uterus. Multiple studies have reported rates of occurrence were varying between twenty percent and forty percent. The histological diagnosis indicates a significantly higher frequency compared to the clinical diagnosis. Harboring myoma is present within around sixty percent of females over the age of forty-five [1].

The majority of myomas are asymptomatic. The primary determinants of whether a myoma results in complications and symptoms are its site and size. Abnormal uterine bleeding, bloating, abdominal discomfort, backache, painful defecation, frequent retention or urination, and infertility are all significant symptoms. It's correlated to impairment in the quality of life in terms of health [2].

Myomectomy is a medical operation that is performed through an invasive approach, such as laparoscopic, robotic or abdominal technique. Typically, abdominal incisions are utilized for carrying out myomectomy operations, which enable the uterus to be simply closed in layers. Extra machinery, such as a morcellator, is necessary for laparoscopic myomectomy due to its small port hole. Outcomes of robotic myomectomy have nevertheless to be demonstrated to be preferable to those of the laparoscopic technique [3].

Within myomectomy operations, bleeding is a significant problem. When dissection is performed through the avascular cleft or is reduced through mechanical or pharmacological

techniques, hemorrhage may be avoided. A new Cochrane Library review examined a variety of medications that can be used to minimize the bleeding during myomectomy [4].

Tranexamic acid is one of the compounds that are utilized. Tranexamic acid has been utilized to decrease the necessity for allogeneic blood transfusions, particularly in cardiac operations, transplantation of the liver, and certain orthopedic surgical procedures, with variable outcomes [5].

The current research objected to compare the effectiveness of placebo and tranexamic acid during transabdominal myomectomy for reducing bleeding.

METHODS

The current research was a blinded randomized controlled trial on 50 women with uterine fibroids attending to Zagazig Unversity Hospital in the Obstetrics and Gynecology Department at maternity Unit during the time of the study.

Inclusion criteria: women uterine fibroids submitted to elective Abdominal myomectomy; estimation the bleeding during surgery and following surgery in patients administrated by tranexamic acid vs. placebo.

Methods

The selected candidates have been classified into 2 groups: A single dose of IV tranexamic acid fifteen milligram per kilogram has been administered to the 1st group just before incision of skin, while the 2nd group received a standard IV fluid injection just before incision of skin. Also. The investigation involved cases between the ages of 30 and 50, having a single symptomatic uterine myoma with the myoma's maximum diameter is five to ten centimeters. The uterine size is less than twenty-four weeks during pregnancy, and all myomas are submucosal or intramural. Through a sufficient history, appropriate local and general examinations, and acceptable transvaginal or abdominal ultrasonography outcomes, as well as appropriate laboratory findings. In addition, from cases that were diagnosed with pulmonary illnesses, hypertension, and cardiac, and cases with bleeding conditions, anemia (hemoglobin less than ten-gram percent). Diabetes and obesity (body mass index greater than thirty kilogram per meter square) are examples of chronic endocrine or metabolic illnesses. Cases necessitating during surgery change from myomectomy to hysterectomy.

Outcomes

The main goal of the present research was to determine the frequency of bleeding intra-operation. This was achieved through the use both methods: the first mean has been determined by the variance among the weight of wet towels and dry towels that had been suctioned of blood and any additional fluid prior to their use. A different strategy is to compare the hemoglobin values prior to and following the operation, as well as the hematocrit percent prior to and twenty-four hours following the operation. The percent of participants that had hemorrhage which occurs after delivery and required a transfusion of blood had been the 2ry outcomes.

Statistical analysis

The statistical package for social sciences (SPSS) version 21 (SPSS Inc, Chicago, USA) has been utilized to organize, tabulate, and assess the obtained data. Percentage and frequency distributions have been determined for qualitative data. The mean and standard deviation are estimated for quantitative data. The independent samples test was set up to facilitate comparisons among the two groups. A p-value of less than 0.05 was presented significant for all tests.

Ethical approval: Approval from the Faculty of Medicine's ethical committee (Institutional Research Board IRB). Number of IRB approval: 11023-10-09-2023. Written informed assent has been obtained from each case.

RESULTS

Statistically insignificant variance was observed among the examined groups regarding age, weight, height and BMI P-value >0.05. (Table 1)

Statistically insignificant variance was observed among the examined groups according to Obstetric history P-value >0.05. (Table 2)

Statistically insignificant variance was observed among the examined groups according to HR, RR, SBP and DBP P-value >0.05. (Table 3)

Statistically insignificant variance was observed between the examined groups according to Uterine size, myoma diameter, myoma location and Previous scar P>0.05. (Table 4)

Statistically insignificant variance was observed among the examined groups according to pre-operative investigations P>0.05. (Table 5)

Highly statistically significant variance was observed among the examined groups according to operative data P<0.0001. (Table 6)

Statistically insignificant variance was observed between the examined groups according to hemoglobin after 2hrs and hemoglobin after 48hrs P-value <0.05 and highly statistically significant variance was observed among the examined groups according to hematocrit test P-value <0.0001. (Table 7)

Statistically insignificant variance was observed among the examined groups according to hospital Stay (day) P>0.05, whereas statistically insignificant variance was observed among the examined groups

according to blood transfusion P-value <0.05. (Table8)

Table 1: show distribution of general characteristic among studied groups.

	Group 1 Number= twenty-five	**Group 2 Number = twenty-five**	**P value**
Age Mean ± SD	41.24 ± 5.79	39.52 ± 5.57	0.28
Weight (kg) Mean ± SD	69.28 ± 7.1	69.5 ± 6.89	0.911
Height (cm) Mean ± SD	163.3 ± 5.02	163.6 ± 5.08	0.83
BMI Mean ± SD	25.86 ± 2.78	25.9 ± 2.79	0.95

P value < 0.05 is statistically significant

Table 2: show distribution of obstetric history among studied groups.

	Group 1 Number= twenty-five	**Group 2 Number= twenty-five**	**P value**
Gravidity Mean ± standard deviations	2.44 ± 0.82	2.16 ± 0.8	0.22
Parity Mean ± standard deviations	2.08 ± 1.11	1.84 ± 0.89	0.40

Table 3: show distribution of vital signs among studied groups.

	Group 1 Number= twenty-five	**Group 2 Number= twenty-five**	**P value**
HR Mean ± standard deviations	75.68 ± 9.36	73.2 ± 9.29	0.35
RR(breath/min) Mean ± SD	13.96 ± 0.97	13.6 ± 0.95	0.191
SBP (mmHg) Mean ± SD	105.2 ± 6.21	103.2 ± 9.05	0.36
DBP (mmHg) Mean ± SD	68.24 ± 3.91	66.44 ± 3.94	0.11

P value < 0.05 is statistically significant. SBP: systolic blood pressure, RR: respiratory rate, HR: heart rate, DBP: diastolic blood pressure.

Table 4: show ultrasonography among studied groups.

	Group 1 Number= twenty-five	**Group 2 Number= twenty-five**	**P value**
Uterine size (week) Mean ± standard deviations	18.67± 2.43	19.59± 2.69	0.210
myoma diameter (cm) Mean ± SD	7.84± 1.59	8.08± 1.8	0.619
myoma location			
sub mucosal	13 (52%)	12 (48%)	0.777
intra mural	12 (48%)	13 (52%)	
Previous scar			
Yes	10 (40%)	9 (36%)	0.770
No	15 (60%)	16 (64%)	

Table 5: show distribution of pre-operative investigations between studied groups.

	Group 1 Number= twenty-five	**Group 2 Number= twenty-five**	**P value**
Hb (g/dl) Mean ± standard deviations	11.84 ± 0.67	12.13 ± 0.81	0.17
Hct % Mean ± SD	40.32± 2.58	39.44± 2.74	0.25
PT Mean ± SD	12.06 ± 1.01	11.85 ± 0.86	0.43
PTT Mean ± SD	31.56 ± 1.68	30.92 ± 1.89	0.21
INR Mean ± standard deviations	1.014 ± 0.03	1.007 ± 0.02	0.34

P value < 0.05 is statistically significant. Hct: hematocrit test, Hb: Hemoglobin, PTT: Partial thromboplastin time, PT: prothrombin time, INR: international normalized ratio.

Table 6: show distribution of operative data among studied groups.

	Group 1 Number= twenty-five	Group 2 Number= twenty-five	P-value
Intraoperative blood loss (milliliter) Mean ± SD	635.9 ± 204.1	969.4 ± 125.8	**<0.0001***
Operative time (min) Mean ± SD	68.28 ± 12.27	98.72 ± 7.03	**<0.0001***

Table 7: show distribution of post-operative investigations between studied groups.

	Group 1 Number= twenty-five	**Group 2 Number= twenty-five**	**P-value**
Hb after 2hrs (gram per deciliter) Mean ± standard deviations	10.5±1.1	9.4±1.42	**0.004**
Hb after 48hrs (g/dl) Mean ± standard deviations	10.1±1.07	1.5±8.9	**0.002**
Hct % Mean ± SD	32.6±2.2	29.68±2.69	**<0.0001***

Hct: hematocrit test.

Table 8: show distribution of outcomes among studied groups.

	Group 1 Number= twenty-five	**Group 2 Number= twenty-five**	**P-value**
Blood transfusion			
Yes	6 (24%)	16 (64%)	**0.004**
No	19 (76%)	9 (36%)	
Hospital Stay (day) Mean ± SD	3.4±0.81	3.64±1.03	0.36

DISCUSSION

Myomectomy is a typically a bloody operation, myomectomy is one of the most bloody gynecologic surgeries carried out, and the most significant morbidity correlated with the resulting bleeding [6].

Reducing bleeding during myomectomy is still the subject of many studies to reach the ideal and

the most effective method to decrease the morbidities of the surgery and blood transfusion as well [7].

Additional investigations have compared the administration of placebo and tranexamic acid during abdominal myomectomy [8]. Additionally, the comparison of placebo vs. oxytocin during abdominal myomectomy was done [9].

Fifty cases with uterine fibroids pleasing the exclusion and inclusion criteria underwent abdominal myomectomy in Zagazig University Hospital during period time from.

Patients were randomly categorized into both groups: Group A (Tranexamic acid group)which involve twenty-five cases is going to administrated single dose of IV tranexamic acid fifteen milligram per kilogram just prior to skin incision and Group B (Saline group) which involve twenty-five cases is going to administrated normal saline IV just before skin incision.

An intraoperative bleeding comparison between both groups was the main goal of this investigation. The following subsequent results have been additionally compared: the period of hospitalization within days, the variance among before and following surgery hematocrit and hemoglobin concentrations, the requirement for transfusions of blood during surgery, and the duration of surgery within min.

Statistically insignificant variances was observed among both groups according to parity, height, age, weight, BMI, size of uterine, myoma diameter, myoma location, and previous scar. Additionally, statistically insignificant difference was observed among both groups according to the cases' showing symptoms.

Our results were supported by research of Alanwar & Gamal, [10] because they stated which insignificant variance was observed according to case features (weight, age, gestational, age and BMI) among control and research groups. The final examination contained sixty-four females, who were randomly assigned to both groups: thirty-two females within the research group administrated ethamsylate and tranexamic acid, and thirty-two females within the control group administrated placebos.

In the present study, fibroid type, diameter of largest fibroid and fibroids numbers, weren't independent indicators of bleeding.

Also in this present research statistically insignificant variance was observed among the examined groups according to HR, RR, SBP and DBP.

In the current study discovered which the bleeding during surgery was significantly reduced in the females who were randomized to administrate 15 mg/kg of tranexamic acid versus a saline solution. This may be due to the reason that tranexamic acid functions as an antifibrinolytic, which reduces blood loss through the mechanism of fibrinolysis suppression.

The method of loss of blood assessment utilized by Mousa couldn't be accurate; rather, it involved the counting of the mops that were utilized during the surgery. The amount of blood in each mop has been determined to be between 100 and 150 milliliter, based on the degree of soaking. In this investigation, we utilized an accurate technique by collecting the weight differences among the dry and soaked linen towels prior to and following the surgery, presuming that one milliliter of blood is equivalent to one gram of blood [11].

The present research determined only the loss of blood during surgery, because it has been performed in the research of Mousa, regardless of the variant methods of estimating the loss of blood. Within the investigation of Shady, the postoperative bleeding has been determined as well, defined as the amount of blood in the suction drain that was maintained for forty-eight hours postoperatively. This represented limitations of the present research.

The current research supports the research by Shady et al., [8] who discovered which the blood loss during the operation was significantly reduced in the females who were randomized to be administered tranexamic acid during abdominal myomectomy compared with the placebo groups.

In accordance with our outcomes Shaaban et al. [12] assess the effectiveness of TA in reducing bleeding following and intra-open myomectomy in cases with three or more uterine fibroids. 132 females underwent abdominal myomectomy. The tranexamic acid group demonstrated a lesser amount of blood loss (407 milliliter) than the control group (677 milliliter; P-value < .01). The probability of blood loss after surgery was reduced by forty percent because an outcome of therapy with tranexamic acid. Within the control group, twenty-three (34.8%) cases needed blood transfusions, whereas thirteen (19.7%) cases within the research group did so (P-value < .01). On the third day following surgery, the control group demonstrated significantly lesser hematocrit and hemoglobin concentrations (P value = .001).

Within the current research, there were more cases in the Saline group who needed a transfusion of blood compared to the tranexamic acid group.

In addition, also supported by the study of Opoku-Anane et al., [13] which declared According to the reduction of blood loss during myomectomy by during surgery given tranexamic acid, the operating techniques used were all least invasive. Because the incision form and the quantity of blood loss have been influenced by the operating technique, every case in the present research have been selected from those that underwent surgery via the Pfannenstiel incision.

Tranexamic acid was administered prophylactically to decrease the frequency of severe hemorrhaging following delivery and bleeding in a systematic review with meta-analysis. A randomized, double-blind, placebo-controlled investigation carried out on 660 females demonstrated which IV administration of one gram of tranexamic acid significantly decreased the loss of blood during cesarean section in comparison to the placebo control group (499 ± 206.4 milliliter vs. 600.7 ± 215.7 milliliter, respectively [p-value <0.001]. Within a prospective case-control randomized investigation carried out at a single center, Goswami U et al. [14] discovered which the decrease in the loss of blood with intravenous tranexamic acid ten milligrams per kilogram was 146.34 ± 56.32 milliliters and 262 ± 31.5 milliliter, respectively, for ninety anemic cases undergoing LSCS with hemoglobin levels between seven to ten grams percent.

The duration of surgery in the present research was significantly quicker in the tranexamic acid group than in the saline group due to the reduced bleeding and improved operating site and These outcomes supported by clinical trials of Kathopoulis et al., [15], which declared that The utilization of tranexamic acid resulted in a significant decrease in the overall duration of surgical. Although tranexamic acid had the ability to decrease bleeding, it didn't have a beneficial effect on the hematocrit following surgery, hemoglobin alter, or rate of transfusion.

We conducted a comparison of the hemoglobin prior to surgery and following surgery, as well as the hematocrit prior to surgery and following surgery, in the current investigation. Our findings indicated which the tranexamic acid group noticed a significantly fewer decrease in hemoglobin compared to the saline group, and the tranexamic acid group additionally showed a significantly lesser decrease in hematocrit.

Also within our research, significant variance is observed among groups within concentration of hemoglobin following surgery.

The present outcomes in accordance with Shabaan et al., [16] discovered the statistically significant variance approximately the alteration within hemoglobin level within tranexamic acid group.

Tranexamic acid and saline have been administered to cases in the present research, and insignificant negative consequences have been found. The saline group and the tranexamic acid group failed to demonstrate a statistically significant difference. This conclusion is consistent with the research conducted by Mousa et al. [11].

This may be due to the reason that we gave a single dose of saline or tranexamic acid, and the cases were either remaining anesthetized or under the influence of an analgesic following the operation.

In contrast to vasopressin, TXA provides numerous benefits. However, the safety and economic considerations associated with vasopressin therapy are partially valid. The application of vasopressin during surgery was associated with the following negative consequences: the temporary elevation of blood pressure during local vasopressin administrations, accidental intravascular infiltration and bleeding at the injection site [17].

Furthermore Obaji et al. [18] stated myocardial infarction and stated that they observed pulmonary edema following the administration of local vasopressin.

CONCLUSION

According to the Current study, we can conclude which, the injection of the tranexamic acid could be of some benefits in reducing the loss of blood during and following surgery through the operation of myomectomy and it also could be beneficial value for reduction of transfusion requirement than the Saline.

Conflict of interest statement: The authors declared that there were NO conflicts of Interest.

Disclosure: The authors have no financial interest to declare in relation to the content of this article.

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