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Determining the Effectiveness of Tranexamic Acid on Hemorrhage During Abdominal Hysterectomy

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ABSTRACT

Background & Objective: Hysterectomy is the most common gynecological surgery. Every year, numerous women around the world undergo this type of surgery for various reasons. Regardless of the type of surgery, bleeding during surgery and after surgery is the most common consequence? Tranexamic acid is a cheap, available and low-complication drug that has been considered in recent years to control bleeding. The present study investigated the effectiveness of Tranexamic acid on the bleeding during laparotomy hysterectomy in women aged 35 to 55 years.

Materials & Methods: This study was a randomized, double-blind clinical trial performed on 80 patients undergoing laparotomy hysterectomy. Using a random number table, patients were divided into two groups A (receiving Transid) and the other group receiving drug B (not receiving Transid), both of which received 100 ml of normal saline prepared to reduce bias in the prepared syringe.

Results: Mean age of the patients was 46.24 ± 5.21 years. Based on the results of mean hemoglobin before surgery, the rate of infection, infusion and induction in the control and intervention groups were not statistically different ($P > 0.05$). Also, the mean hemoglobin variables before and after hemorrhage were estimated by the surgeon and hemorrhage estimated according to Hernandez formula were not statistically different in the two groups ($P > 0.05$).

Conclusion: Tranexamic acid administration has no effect on the amount of bleeding during hysterectomy laparotomy.

Keywords: Tranexamic acid, Hysterectomy, Laparotomy, Hemorrhage

Introduction

Hysterectomy is the most common gynecological surgery. Every year, a large number of women around the world undergo this type of surgery for various reasons. It is estimated that about 33% of women undergo a hysterectomy during their lifetime **(1)**. Hysterectomy is mostly required in women aged 40-49 years. Problems such as severe pelvic pain, heavy and irregular menstrual bleeding, or uterine cancer are some cases that sometimes leave no choice but to remove the uterus through surgery **(2)**. Hysterectomy is done to treat some gynecological conditions that have not responded well to medication. In addition, this method can be desirable for women who no longer intend to have children or to use ineffective and numerous treatments for cases such as uterine myomas, uterine prolapse, cervical dysplasia, menstrual disorders, cancer, endometriosis and endometrial hyperplasia **(3, 4)**.

Hysterectomy can be performed in various ways, including through the abdomen, vaginally and by laparoscopic technique **(5)**. Currently, only 10-30% of hysterectomies are performed vaginally, 5% as laparoscopy and the rest in laparotomy **(6)**. Regardless of the type of surgery, bleeding during surgery and after surgery is the most common and the most dangerous complication of the surgery **(7)**. In recent years, various techniques have been invented and patented in this field, including mechanical sutures and electrical coagulations **(5, 7)**. Several drugs have been studied in this field, including the use of misoprostol and gonadotropin agonists **(7)**. Sometimes the tools of these techniques may not be available or the patient may not be able to use these methods due to special circumstances, so a more appropriate solution should be sought.

Tranexamic acid is a cheap, available and low-complication drug that has been considered in recent

years to control bleeding. This drug is widely used to control abnormal vaginal bleeding in women, but its use to control bleeding during surgery and after surgery has been approved by certain groups of surgeons. This drug is one of the drugs that inhibit fibrin degeneration and can be used orally, slow intravenous injection or serum infusion **(8)**. Tranexamic acid prevents blood clots from breakdown by blocking fibrinolysis. Nausea, diarrhea, headache, sinus and nasal symptoms, back pain, abdominal pain, muscle aches, anemia and fatigue are some of its complications **(9, 10)**. Side effects of this drug include visual disturbances, hypotension and anaphylaxis in case of rapid injection, nausea and vomiting and diarrhea **(8)**.

It is approved and used by orthopedic surgeons for hip surgery **(11)** and heart surgeons in open-heart surgery **(12)**. The use of this drug in gynecological and obstetric surgeries has been discussed countless times and few studies have been done. In this study, the aim is to prove or disprove the effect of the drug in surgeries related to uterine manipulation, which, if confirmed, can be generalized to most gynecological surgeries by open or laparoscopic methods. If approved, this method could save lives and reduce the need for blood transfusions, especially in emergencies or areas with limited facilities. According to the above, the present study investigated the effectiveness of Tranexamic acid on the bleeding during laparotomy hysterectomy in women aged 35 to 55 years and candidates for hysterectomy referred to Rasoul-e-Akram hospital in 2020.

Methods

Design and setting

This study is a double-blind randomized trial performed on 80 patients who were candidates for laparotomy hysterectomy. The sample size in this study was calculated by considering the first type error of 2% and 95% power. The sample size was considered by the following formula for each group of 11 people, to increase the study accuracy, 40 people in each group or a total of 80 people were randomly selected.

$$TP + FN = Z^2 * \frac{[SN(1-SN)]}{W^2}, N(sn) = \frac{TP+FN}{P}$$

P= 0.10, Sen=0.96, W= accuracy = 0.02 and finally N=80.

Inclusion and exclusion criteria

Inclusion criteria included females who needed hysterectomy following abnormal vaginal bleeding aged 35-55 year. Exclusion criteria was having no allergy to Tranexamic acid, having no history of coagulopathy, suffering from hypertension, diabetes, renal disorders, cancer, uterine size > 12 weeks and body mass index less than 30 kg/m^2.

Intervention

The patients took enoxaparin (40 mg) 12 hours before surgery time. One group (intervention) 30 minutes before skin incision received Tranexamic acid and the control group received normal saline. The surgeon was unaware of the allocated groups for the patients. The amount of bleeding during the surgery was estimated by measuring the amount of blood collected in the suction along with the changes in the weight of the gauzes used. The effect of the drug on platelet count, postoperative fever and the need for blood transfusion, which was decided based on the patient's vital signs and the opinion of the anesthesiologist, were other objectives studied in this study.

Statistical analysis

Qualitative data was presented as a percentage and frequency, and quantitative data was presented as mean ± SD. Independent t-test was used to compare the two means and in case of abnormal data distribution, Mann-Whitney U test was used. Chi-square test was also used to examine the differences in qualitative variables. P value < 0.05 was significant. The data were analyzed through SPSS software, version 21, SPSS Inc., USA.

Results

The mean age of the patients was 46.24 ± 5.21 years. Patients were randomly divided into control (n=40) and intervention (n=40) groups. Basic characteristics were examined for both groups. The results showed that the variables of mean age, BMI, parity, and laparotomy were not statistically different in the control and intervention groups ($P > 0.05$) (Table 1).

Table 1. Results of baseline characteristics for both control and intervention groups

Variable	Group	Mean	SD	P Value
Age	Intervention	46.83	4.976	0.160
	Control	47.65	5.117	
BMI	Intervention	27.973	3.2523	0.942
	Control	28.025	3.2125	
Parity	Intervention	2.53	1.261	0.889
	Control	2.75	1.691	

Laparotomy	Intervention	1.03	1.025	0.556
	Control	1.05	1.339	

Preoperative hemoglobin of the patients for the control and intervention groups was assessed using independent t-test. The mean of preoperative hemoglobin in the control and intervention groups were not statistically different ($P > 0.05$) (Table 2).

Table 2. Mean and standard deviation of hemoglobin before surgery for both control and intervention groups.

Variable	Group	Mean	SD	P Value
Preoperative hemoglobin	Intervention	12.018	1.1681	0.365
	Control	12.278	1.3768	

The mean bilirubin and uterine weight for the control and intervention groups were evaluated using independent t-test. The mean bilirubin and uterine weight in the control and intervention groups were not statistically different ($P > 0.05$) (Table 3).

Table 3. Mean and standard deviation of bilirubin and uterine weight for the control and intervention groups

Variable	Group	Mean	SD	P Value
Bilirubin	Intervention	342.28	191.228	0.083
	Control	412.53	165.437	
Uterine weigh	Intervention	148.90	60.015	0.237
	Control	165.28	62.801	

Infection, infusion and indication rates for the control and intervention groups were assessed using Chi-square test. The results showed that the infection, infusion and induction rates in the control and intervention groups were not statistically different ($P > 0.05$) (Table 4).

Table 4. Distribution of infection, infusion and indication for the control and intervention groups

Variable		Total	Group		P value
			Control	Intervention	
Infection	NO	67(83.8)	31(77.5)	36(90.0)	0.225
	YES	13(16.3)	9(22.5)	4(10.0)	
Infusion	NO	77(96.3)	38(95.0)	39(97.5)	1.000
	YES	3(3.8)	2(5.0)	1(2.5)	
Indication	A	12(15.0)	6(15.0)	6(15.0)	0.901
	B	16(20.0)	10(25.0)	6(15.0)	
	C	19(23.8)	8(20.0)	11(27.5)	
	D	13(16.3)	7(17.5)	6(15.0)	
	E	8(10.0)	4(10.0)	4(10.0)	
	F	6(7.5)	3(7.5)	3(7.5)	
	G	6(7.5)	2(5.0)	4(10.0)	

The mean of hemoglobin variables before and after hemorrhage estimated by the surgeon and hemorrhage estimated according to Hernandez formula were evaluated. There was no statistically significant difference regarding three mentioned variables ($P > 0.05$) (Table 5).

Table 5. Mean and standard deviation of hemoglobin before and after, hemorrhage estimated by the surgeon and hemorrhage estimated according to Hernanders formula

Variable	Group	Mean	SD	P value
Hemoglobin before and after	Intervention	1.148	0.8252	0.851
	Control	1.115	0.7167	
Hemorrhage estimated by the surgeon	Intervention	292.50	189.990	0.205
	Control	342.50	158.337	
Hemorrhage estimated according to Hernanders formula	Intervention	442.33	290.372	0.270
	Control	512.83	276.537	

Discussion

In this study, infection, Infusion and Indication rates for the control and intervention groups were not statistically significant. The mean of hemoglobin before and after, hemorrhage estimated by the surgeon and hemorrhage estimated according to Hernanders formula were not statistically significant for the two groups of control and intervention, i.e. this study did not confirm the effect of Tranexamic acid in reducing bleeding.

We know that the hysterectomy is frequent in women 40-49 years, and sometimes there is no way to treat them other than surgical removal of the uterus **(2)**. In this study, the mean age of patients was 46 years. One of the ways to reduce bleeding in recent years was the use of Tranexamic acid **(13)**, which has been reported in various studies on various actions with contradictory results, which are mentioned in a few cases. In a study by Choi et al. performed on 73 patients with bilateral maxillary osteotomy, they administered Tranexamic acid 20 mg/kg or the equivalent of normal saline before surgery and at the same time used mild controlled hypotension. Postoperative bleeding, duration of operation, transfusion of blood products, hemoglobin, and preoperative hematocrit were recorded. In the Tranexamic acid group, bleeding was significantly reduced (878 ± 577.7 ml vs. 1257± 817.2 ml), which was a significant difference (P <0.05). However, there was no statistically significant difference regarding blood transfusion and duration of operation **(14)**.

These results were not consistent with the results of our study, which can also be affected by controlled hypotension and play a distorting role in the study. In another clinical trial, Choi et al. performed orthographic surgery on patients aged 17-30 years and administered intravenous Tranexamic acid 10 mg/kg preoperatively and 1 mg/kg intra-operatively and compared with controls. Intraoperative hemorrhage transfusion and complications were low in patients received Tranexamic acid) (P <0.01). The quality of the operation field was much better in light of bleeding in the study group than the control group, but there was no statistically significant difference between the duration of the operation and the need for transfusion (P<0.05) **(14)**. Tranexamic acid in controlled hypotension has much better efficacy **(15)**.

In a consistent study by Mohammadi et al. to re-evaluate the efficacy of Tranexamic acid in reducing bleeding during percutaneous nephrolithotomy (PCNL) surgery, 132 patients undergoing PCNL were randomly divided into two groups. The intervention group received one gram of intravenous Tranexamic acid before induction of anesthesia and then for two days every 8 hours one gram of Tranexamic acid. In the control group, normal saline was used as a placebo. There was no significant difference in the demographic characteristics of the two groups. The mean decrease in hemoglobin in the Tranexamic acid group was 2.2 g/dl and in the control, group was 2.4 g/dl, which was not statistically significant (P =0.312). Regarding bleeding amount, a mean of 751 ml was recorded in the Tranexamic acid group and 826 ml in the control group, which was not statistically significant (P=0.416). They concluded that Tranexamic acid was not associated with reduction of intraoperative bleeding and had no significant effects, and suggested further studies in this field **(16)**.

Also in another study, Abrisham et al., compared the effect of topical use of Tranexamic acid versus intramedullary injection on bleeding rate after knee arthroplasty in a double-blind randomized clinical trial in primary osteoarthritis patients. The groups were divided locally for injection of placebo into the drain, injection of Tranexamic acid into the drain and receiving Tranexamic acid locally. Demographic information and then preoperative hemoglobin, 12 and 48 hours postoperatively were recorded and 75 patients (67 females and 8 males) with a mean age of 63.26±5.15 years were included in the study. The hemoglobin level of patients before surgery was 13.29±1.23 g /deciliter and there was no significant difference in hemoglobin of patients before surgery (P =0.891). By examining the hemoglobin 48 hours after surgery in the study groups, it was concluded that the hemoglobin level in the patients of the placebo group decreased significantly and this decrease was significant compared to the other two groups (P =

0.001). Topical injection as well as intra-drainage injection of Tranexamic acid can have a greater effect on reducing the need for blood transfusion and anemia in patients after knee arthroplasty than placebo, but the difference between the two methods in the present? study was not significant **(17)**.

In orthopedic applications, beneficial effects of Tranexamic acid have been observed. In a study by D'Ambra et al, on 64 patients undergoing spinal reconstruction surgery at a dose of 2 g Tranexamic acid, in children 30 mg / kg, and infusion of 100 mg / hr. in adults, or 1 mg / kg / hr. in children, were used during surgery and 5 hours after surgery, 49% reduction in bleeding and 80% less need for transfusion was observed (P = 0.007). However, no side effects were reported despite high doses **(18)**. Also, intravenous Tranexamic acid administration after induction of anesthesia reduces the amount of bleeding during traumatic mandibular **(19-21)**. Consistent with the results of our study, no significant difference was observed in the study of Wong et al. in which patients underwent spinal fusion and the two groups of control and intervention consumed Tranexamic acid **(22)**. Finally, anti-fibrinolytic trials performed on women around the world provide ample evidence for the effectiveness of tranexamic acid in reducing bleeding during hysterectomy **(23-26)**.

During the COVID-19 pandemic, it should be noted that the administration of Tranexamic acid can worsen the condition of COVID-19 patients, so anticoagulant therapy should be considered along with the use of Tranexamic acid, because COVID-19 affects not only the main organs of the body, including the kidneys, eyes, heart, lung and others but with changes in the blood coagulation system, it also causes susceptibility to disseminated intravascular coagulation (DIC) **(27-34)**.

Conclusion

It seems that Tranexamic acid administration has no effect on the amount of bleeding during hysterectomy laparotomy. It is recommended that tests with a larger sample size be performed to elucidate the exact effectiveness of Tranexamic acid use on the bleeding during laparotomy.

Acknowledgments

None.

Conflict of Interest

The authors declare that there is no conflicts of interest in this study.

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