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Tranexamic Acid Effect on Doppler Indices of the Uterine Artery in Patients with Menorrhagia Related to Copper IUCD (Cu 380) Insertion

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Abstract

Background: The intent of this survey was to inquire the tranexamic acid effects on Doppler indices of the uterine artery in patients with menorrhagia due to IUD insertion.

Aim of Study: The aim of the study was to assess the effective role of treatment by tranexamic acid on uterine artery vascular resistance in cases of menorrhagia associated with copper IUCD (Cu380) insertion.

Patients and Methods: The study was implemented in outpatient clinics of the Gynecology Department on patients with menorrhagia. We studied 212 cases of menorrhagia after 3 months of IUCD insertion to exclude insertion related bleeding and fulfilled the inclusion, they were appraised for 6 menstrual cycles. During the first 3 control cycles, the magnitude of bleeding was recorded on the Pictorial Blood Assessment Chart to affirm heavy menses. During the next 3 cycle, random assignment of cases into tranexamic acid and placebo groups was done. They were divided into two equal groups, group 1 (tranexamic acid group) and group 2 (placebo group). The group 1 received 500mg tranexamic acid four times daily from first to fifth days of the cycles, PI (Pulsatility Index) and RI (Resistance Index) were measured from Rt. and Lt. uterine arteries on the first month of the control cycles and during the third month of intervention cycles. MBL (Menstrual Blood Loss) was appraised using a validated pictorial blood chart during the intervention. SPSS version 15 for Windows was used for data analysis.

Results: In group 1, the mean PI and RI fell significantly with treatment (PI 2.26-1.78, p=0. 001); (RI 0.87-0.68, p= 0.031). There was a reduction of approximately 48% in MBL with treatment (120.0-65ml, p=0.001). In group 2, there was an insignificant change in either the PI or the RI and there was no significant reduction in menstrual blood loss.

Conclusion: Tranexamic acid significantly reduces uterine artery vascular resistance in patients with menorrhagia due to IUD insertion. This effect is afield to be the main role of tranexamic acid in the reduction of the menstrual blood loss.

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Key Words: *Menstrual blood loss – Tranexamic acid – Intra-uterine device – Uterine artery Doppler.*

Introduction

INTRAUTERINE Device (IUD) is one of the virtually effective contraceptive methods as it is simple, reversible and practicable; failure rate is 0.8% for the first year after insertion and for a 10-year period **[1]**. The copper IUD is more effective than inert IUDs, because of its safety, contraceptive action and declining risk of PID. The most common copper (IUD)-related side effects are uterine bleeding and/or menstrual pain, these side effects often directly affect compliance and consequently the continuation rates of this method **[2,3]**. Therefore, it is essential to prevent IUD users enduring extra loss of menstrual blood in order to ameliorate the acceptance and continuance of IUD use.

IUD-related side effectsmay be owned to increased prostaglandin synthesis in the endometrium that could change endometrial blood flow and capillary permeability and such change may lead to menorrhagia **[3,4]**. Bleedingwhich is thought to beincited by an IUD may be subsidiary to anincrease in uterine blood flow and a decrease in uterine arterial resistance, both could be detected by color Doppler ultrasound **[4,5]**.

Routine follow-up of IUD users and evaluation of symptomatic patients including transvaginal

Abbreviations:

IUD : Intrauterine Device.
MBL : Menstrual Blood Loss.
PBAC : Pictorial Blood Assessment Chart.
PI : Pulsatility Index.
RI : Resistance Index.
SPSS : Statistical Package for the Social Sciences.

ultrasonography are recommendedto exclude IUD related bleeding and other complications [6]. Tranexamic acid has been shown to be an effectual non-hormonal treatment that decreases menstrual blood loss in cases of menorrhagia [7,12]. The mechanism of action may be owned toa reduction of fibrinolysis in the endometrium, but other possible mechanisms, such as an effect on vascular flow, have not been investigated.

Methods

This was a randomized, placebo-controlled clinical trial study of the therapeutic effect of tranexamic acid on blood flow of uterine artery in patients with menorrhagia with IUD insertion.

This study was done between May 2016 and November 2017, women attending the family planning clinic of the Gynecology Department, Zagazig University Hospitals were recruited and inclusion criteria were: (I) Age 20-45 years old; (II) Normal findings of cervical smear test; (III) Normal ovulatory cycles; (IV) No history of renal or hepaticimpairment, inflammatory bowel disease, GIT ulceration, thromboembolic disease or coagulation or fibrinolytic disorders; (V) Normal results for laboratory investigations (including PT, PTT and TSH); (VI) Nohistory of hormonal treatment or NSAIDs with no contraindications for tranexamic acid taking; and (VII) Insertion of IUCD was done >3 months to exclude insertion related bleeding.Exclusion criteria included: (I) Infertility; (II) Overweight or obesity (body Mass Index (BMI) >25kg/m^2) or underbuilt (BMI <18.5kg/m^2); (III) Polycystic ovarian syndrome; (IV) Vaginitis and/or pelvic inflammatory disease; (V) Uterine polyps and/or fibroids; and (VII) Being perimenopausal (increased serum FSH levels suggesting the approach of menopause).

Gynecological investigations, which included vaginal & abdominal ultrasound scans, hysteroscopy, and endometrial biopsy, were executed in the luteal phase to exclude endometrial pathology and confirm normal ovulation. Also, a cervical smear test was carried out to exclude any organic causes of menorrhagia. Excluded cases were counseled for further assessment and appropriate treatment. Women who complained of menorrhagia and met all the inclusion criteria were recruited. A total of 250 eligible women were claimed to join the study, 20 cases refused participation, 5 cases discontinued using the IUD and 13 missed during the first treatment cycle. Finally, the study comprised 212 participants and divided into two groups, group 1 (tranexamic acid group) containing 106 patients and group 2 (placebo group) containing 106 patients.

The participants were assessed for 6 consecutive menstrual cycles, during which all of them used the same type of pads given by the researchers. During the first 3 control cycles, heavy bleeding was confirmed after recording the amount of bleeding on the Pictorial Blood Assessment Chart (PBAC). The PBAC was developed by Higham et al., in 1990, evaluated menstrual bleeding was scored based on the visual aspect of soiled towels, tampons and the existence of clots [13].

The study procedures were explained to the participants after the first 3 assessment cycles. They were asserted of voluntary participation and data confidentiality. Informed consent was signed by those who agreed to participate. Then they took tablets from days 1 to 5 of their menstrual period for the 3 consecutive intervention cycles.

The women in the first group received tablets containing 500mg tranexamic acid (Kapron, Amoun Company, Egypt) 4 times per day (2gm total daily intake), and those in the second group placebo tablets 4 times per day. Both types were typical in appearance apart from packages codes, only known by a person, not in the research team and couldn't be identified by the participants or the researchers until the study completed, statistical analysis and codes revelation. PBAC was accomplished by all participants during the intervention cycles and any adverse effects were recorded.

Tablets were advised to be taken with meals and a sufficient amount of water and used pads were thesame provided throughout the study cycles. Doppler blood flow assessment of the uterine arteries was performed in the mid-follicular phase (days 5-8 of the menstrual cycle) in the first month before and the third month during the intervention. The ultrasound equipment used was a Voluson E6 B 12 system with 6-9MHz transvaginal transducer. The same observer used the same equipment between 8 and 10AM to avoid interobserver, interultrasound transducer, intercycle variation, and circadian rhythm effects on the results [15]. Also, all patients had an empty bladder to avoid modification of artery impedance. A transverse ultrasound scan was done at the level of the internal os of the cervix to identify the uterine artery. Transvaginal pulsed color Doppler assessment and real-time imaging of the blood flow were performed to measure the uterine artery blood flow indices [15]. For the Doppler indices, we used the PI (A-B/mean) and the RI (A-B/A), in which A is the systolic

(maximum) Doppler frequency shift; B is the diastolic (minimum) Doppler frequency shift, and mean is the average Doppler frequency shift. Three waveforms were studied for each artery, and the mean value was considered for statistical analysis when the 3 intervention cycles completed and all the participants were convenedto compile the questionnaires in the final visit.

SPSS version 15 for Windows was used for data analysisafter completion of the 3 intervention cycles. One-way ANOVA was used to compare MBL and uterine artery indices in the two groups before and during the intervention. Demographic data were summarized by using descriptive statistics. p-value of <0.05 was considered statistically significant.

Results

A total of 250 eligible women were invited into the study, 20 cases refused participation, and 5 cases discontinued the use of IUD and 13 missed during the first treatment cycle. Finally, 212 participants fulfilled the inclusion criteria and were selectedfor this study, patients were divided into two equal groups. Group 1 (tranexamic acid group) and group 2 (placebo group) both containing 106 patients with menorrhagia.

Data regarding age, parity, BMI,and mode of last delivery were of no statistical significance (Table 1). Also, the relationship between MBL and demographic data had nosignificant differences. Mean blood loss at baseline was similar in bothstudy groups, ranging from 119.7 to 121.2ml per menstrual cycle (p>0.05 between groups) (Table 2).

Table (1): Comparison between the studied groups in socio-demographic characteristics.

Variable	Group 1 (tranexamic acid) (106)	Group 2 (placebo) (106)	*t*-test	*p*
Age (years):				
Mean ± SD	29.1±4.3	28.4±4.2	0.3	0.7
Range	(20-40)	(19-39)		
BMI (Kg/m ^{2}):				
Mean ± SD	26.2±2.5	25.9±2.2	0.4	0.7
Range	(20.6-30)	(21-30)		
Parity:				
Mean ± SD	4.3±0.7	57	0.6	0.5
Range	(1-5)	(1-5)		
Mode of last delivery:	N (%)	N (%)		
Vaginal	81 (76.4%)	82 (77.4%)	15.6	0.6
Cesarean section	25 (23.5%)	24 (22.6%)		

Statistically no significant difference (p>0.05).

Table (2): Menstrual blood loss in the two groups before the intervention.

Variable	Group 1 (tranexamic acid) (106)	Group 2 (placebo) (106)	*t*-test	*p*
Bleeding in the first month (ml), mean ± SD	120.5±3.4	119.7±0.9	1.8	0.61
Bleeding in the second month (ml), mean ± SD	119.71±6.1	121.2±5.8	7	0.59
Bleeding in the third month (ml), mean ± SD	119.2±3.2	120.6±6.1	2.8	0.58

Statistically no significant difference (p>0.05).

In the tranexamic acid group, there wasa markeddecrease in bleeding during the first month of intervention cycles, bleeding continued to decrease during the following 2 months but to a lesser extent. However in the placebo group no significant changes in blood loss during the three months of intervention (Table 3). The decrease in the total amount of blood lost was much more remarkable in the group 1 (48%) versus (4.8%) in group 2, and this difference was of statistical significance (p<0.05) (Table 4).

In participants receiving the placebo, the mean blood loss duringthe first month was slightly lowered, this decrease was lost in the second month of intervention (p>0.05); while in the third month, bleeding increased slightly again, though it was still less than it had been before intervention (p>0.05) (Tables 3,4).

Table (3): Menstrual blood loss in the two groups during the intervention.

Variable	Group 1 (tranexamic acid) (106)	Group 2 (placebo) (106)	*t*-test	*p*
Bleeding in the first month (ml), mean ± SD	82.5±4.4	115.7±0.9	1.8	0.001 **
Bleeding in the second month (ml), mean ± SD	68.9±8.4	111.6±5.8	7	0.01 *
Bleeding in the third month (ml), mean ± SD	65.3±5.2	114.2±6.3	2.8	0.01 *

* : Statistically significant difference (p≤0.05).
**: Statistically high significant difference (p≤0.001).

Table (4): Changes in blood loss before and during the intervention.

Variable	Group 1 (tranexamic acid) (106)	Group 2 (placebo) (106)	*p*-value
Bleeding before intervention (ml)	120.5±3.4	119.7±0.9	0.61
Bleeding after intervention (ml)	65.3±5.2	114.2±6.3	0.001 *
Mean decrease in bleeding (%)	48%	4.8%	0.001 *

* : Statistically significant difference (p≤0.05).
**: Statistically high significant difference (p≤0.001).

For both groups, the PI and RI of the left and right uterine arteries were similar before the intervention cycles (Tables 5,7). Therefore, we used the mean value of both arteries to make the comparison of the PI and RI before and after intervention (Table 9). When we compared the PI of the patients in group 1 (2.26±0.37) and group 2 (2.33± 0.22) before the intervention, the result was not statistically significant (p=0.297). On the other hand,the PI of both groups after the intervention was (1.78±0.20) versus (2.35±0.22) for groups 1 and 2 respectively (p=0.001).

Table (5): Comparison of uterine artery Pulsatility Index (PI) in the two study groups before the intervention.

	Group 1 (tranexamic acid) (106)	Group 2 (placebo) (106)	p-value
Rt. uterine art. PI:			
Mean ± SD	2.23±0.31	2.21±0.36	0.000
Range	1.83-2.69	1.68-2.76	
Lt. uterine art. PI:			
Mean ± SD	2.33±0.48	2.45±0.30	0.000
Range	1.62-2.98	1.93-2.97	
Uterine artery PI:			
Mean ± SD	2.26±0.37	2.33±0.22	0.297
Range	1.73-2.84	1.81-2.87	

Data are presented as mean ± (SD).

Table (6): Comparison of uterine artery Pulsitility Index (PI) in the two study groups after the intervention.

	Group 1 (tranexamic acid) (106)	Group 2 (placebo) (106)	p-value
Rt. uterine art. PI:			
Mean ± SD	1.77±0.18	2.24±0.36	0.000
Range	1.41-2.11	1.65-2.76	
Lt. uterine art. PI:			
Mean ± SD	1.79±0.22	2.30±0.30	0.000
Range	1.27-2.3	1.95-2.97	
Uterine artery PI:			
Mean ± SD	1.78±0.20	2.35±0.22	0.001

Data are presented as mean ± (SD).

Table (7): Comparison of uterine artery RI in the two study groups before intervention.

	Group 1 (tranexamic acid) (106)	Group 2 (placebo) (106)	p-value
Rt. uterine art. RI:			
Mean ± SD	0.89±0.11	0.86±0.10	0.000
Range	0.69-1.09	0.69-1.03	
Lt. uterine art. RI:			
Mean ± SD	0.86±0.10	0.86±0.07	0.000
Range	0.62-0.98	0.73-0.96	
Uterine artery RI:			
Mean ± SD	0.87±0.16	0.86±0.08	0.34
Range	0.66-1.04	0.71-1	

Data are presented as mean (SD).

No significant difference (p=0.34) when analyzing the RI before intervention, group 1 and 2 had similar results (0.87 ±0.16) and (0.86±0.08), but the opposite occurred when the RI of both groups were compared after the intervention (0.68 ± 0.16) and (0.87±0.55) for groups 1 and 2 respectively (p=0.031.

Table (8): Comparison of uterine artery RI in the two study groups after intervention.

	Group 1 (tranexamic acid) (106)	Group 2 (placebo) (106)	p-value
Rt. uterine art. RI:			
Mean ± SD	0.66±0.06	0.85±0.13	0.000
Range	0.57-0.75	0.69-1.09	
Lt. uterine art. RI:			
Mean ± SD	0.70±0.08	0.85±0.19	0.000
Range	0.57-0.83	0.63-0.98	
Uterine artery RI:			
Mean ± SD	0.68±0.16	0.87±0.55	0.031
Range	0.57-0.79	0.69-1.4	

Data are presented as mean (SD).

Table (9): Changes in uterine artery Doppler indices before and during the intervention.

Variable	PI before intervention	PI after intervention	RI before intervention	RI after intervention
• Group 1 (tranexamic acid) (106)	2.26±0.37	1.78±020	0.87±0.10	0.68±0.07
• Group 2 (placebo) (106)	2.33±0.22	2.35±0.22	0.86±0.08	0.87±0.55
• p	0.297	0.001	0.34	0.031

Data are presented as mean (SD).

Discussion

Tranexamic acid is widely used in many countries **[16,17]** and has been recommended as the first-line treatment of menorrhagia of unknown origin **[18]** . Clinical efficiency of tranexamic acid in decreasing MBL was confirmed by the study results.

Womentreated by Tranexamic acid (study group) had a significantly lower incidence of menorrhagia compared with the placebo group, this is due tothe significantreduction in average MBL and PBAC score. 2gm were applied in this study, however, identifying a proper dose for the purpose of a specific treatment has always been of interest. Vermylen et al., **[16]** found a 38% reduction in blood loss with 12gm total dose per cycle, but with an increased dose of 24gm (6gm per day for 4 days), the mean reduction raised to 51%. In our study 2gm daily were applied for 5 days with a mean reduction of 48%, this may the recommended for the Egyptian women, however, less than that

recorded in other studies **[19-22]**. This difference may reflect the semi-quantitative method for measuring MBL used in this study, together with natural variation in MBL between cycles or the difference in the drug dose.

It was shown in western countries studies that orally taken Tranexamic acid as well as the IUD loaded, can effectively reduce MBL after IUD insertion **[23]** but this conclusion had not been asserted in other studies.

The therapeutic effect of tranexamic acid in patients with menorrhagia is thought to result from its anti-fibrinolytic activity **[25]**. Surprisingly, our results demonstrated a reduced impedance of the uterine arteries blood flow. It is likely that this effect is incidental to the tranexamic acid effect in reducing menstrual blood loss. The mechanism by which tranexamic acid may influence vascular resistance is not known. There is no evidence of increased incidence of stroke or myocardial infarction related to treatment by tranexamic acid in the general population **[25]**. This is surprising for a drug that causes thrombogenic changes in clotting factors **[19]**. If the effect that we have demonstrated in the uterine arteries is seen in the systemic vasculature, this may provide a mechanism for a tranexamic acid protective effect on the risk of stroke or myocardial infarction. Reduced resistance to blood flow decreases the likelihood of the acute episodes of vasospasm in coronary vessels that often precede myocardial infarction, and reduces turbulence at vessel bifurcations associated with atheroma formation.

Conclusion:

Treatment with a recommended dosage of tranexamic acid was able to effectively decrease the amount of MBL related to IUD insertion, inhibit menorrhagia and reduce the impedance of uterine arteries blood flow.

Ethics approval and consent to participate: Institutional review boards approval was obtained and written consent was taken from all participants.

Consent for publication: All participants was informed about their data confidentiality and they agreed for results publication.

Availability of data and material: All materials and data were available and recruited from the same source (Outpatient of Gynecological Department) and evaluated by single observer and sonographer.

Competing interests: No competing interests was found.

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Authors' contributions: All authors participated in sampling, data collection, intervention and statistical analysis.

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تآثير حمض ترانيكساميك على مؤشرات الدوبلر لشريان الرحم فى المرضى الذين يعانون من النزف الرحمى بعد تركيب اللولب النحاسى

وكان الهدف من هذه الدراسة الإستقصائية الإستفسار عن الآثار الحمضية الجانبية على مؤشرات دوبلر لشريان الرحم فى المرضى الذين يعانون من النزف الرحمى بسبب إدخال اللولب النحاسى.

طرق الدراسة: وكانت النزيف الرحمى بعد الدراسة فى العيادات الخارجية فى قسم آمراض النساء على المرضى الذين يعانون من تركيب اللولب النحا سى. درسنا ٢١٢ حالة تعانين من النزيف الرحمى بعد ٣ آشهر من تركيب اللولب النحاسى حجم النزيف على الرسم حيث تم تقييمها ل ٦ دورات الحيض. خلال دورات التحكم الثلاثة الأولى تم تقييم البيانى بيكتوريال لتقييم الدم التصويرى لتآكيد الحيض الثقيل. خلال الدورات الثلاثة التالية، تم القيام بإعطاء عشوائى للحالات آما حمض الترانيكسيميك آو دواء بلاسيبو. وكانت تنقسم إلى مجموعتين متساويتين، مجموعة ١ (مجموعة ممتحن آو حمض الترانيكسيميك) ومجموعة ٢ (مجموعة البيلاسيبو آو الغفل). آعطيت المجموعة الأولى ٥٠٠مجم من الترانكسيميك ٤ مرات يومياً فى آول خمسة آيام من الدورة. وتم حساب معاملى النبض والمقاومة للشريان الرحمى الآيمن والآيسر فى آول شهر من دورات التحكم وفى الشهر الآخير من فترات العلاج.

النتائج: تبين فى المجموعة الأولى آن متوسط معاملى النبض والمقاومة للشريان الرحمى ينخفض بدرجة معتبرة مع العلاج بحمض الترانيكسيميك مع تناقص فى كمية النزف الرحمى بنسبة ٤٨٪ بينما لم يحدث تغيرات معتبرة فى المجمعة الثانية سواء فى مؤشرات الدوبلر آو كمية النزف الرحمى.

الخلاصة: وجد آن حمض الترانيكسيميك يقلل بدرجة قوية المقاومة الشريانية للرحم ومن ثم يساعد فى تقليل النزف الرحمى الناتج من تركيب اللولب النحاسى.