# Is Copper Intra Uterine Contraceptive Device-Induced Menorrhagia Correlated with Changes in Transvaginal Ultrasound Findings before and after Insertion?

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# ABSTRACT

**Background:** Many women all around the world use the Cu T 380A for contraception as it is cheap and effective way for contraception. Menorrhagia is the most common cause of removal of the intra uterine contraceptive device (IUCD) and it is a very annoying side effect for IUCD users. Finding a way to avoid such a complaint is important to find a proper way for contraception.

**Objective:** To prove the correlation between the Cu IUCD-induced menorrhagia and the findings of the transvaginal Doppler ultrasound.

**Patients and Method:** It was a prospective cross-sectional study and it was conducted on eighty four women who were referred to the family planning clinic of Zagazig University Hospital and Zagazig General Hospital for Cu T-380A IUCD insertion. The study was conducted in the period from 1/1/2019 to 30/7/2019. Then, all specimen had been classified into 2 groups: Group 1 (n =37): with menorrhagia, and group 2 (n = 47) without menorrhagia.

**Results:** Uterine artery pulsatility index (PI) and resistance index (RI) after one month of insertion were significantly lower than at time of insertion among women with IUCD-induced menorrhagia. Endometrial thickness after one month of insertion was significantly higher than at time of insertion among women with IUCD-induced menorrhagia. PI and RI at time of insertion were significantly lower in women with IUD-induced menorrhagia than in those using IUD with normal menstrual bleeding. Uterine artery  $PI \le 1.99$  and  $RI \le 0.82$  have been associated with menorrhagia at time of insertion.

**Conclusions:** The transvaginal Doppler ultrasound is very helpful in prediction of menorrhagia among IUCD users. **Keywords:** Pulsatility index, Resistance index, Endometrial thickness, Cu IUCD, Transvaginal Doppler ultrasound.

### **INTRODUCTION**

More than fourteen percent of women around the world use the intrauterine device for contraception <sup>(1)</sup>. The IUCD is more effective than other contraceptives and it's a long standing and reversible way of contraception <sup>(2)</sup>.

The Pearl Index was introduced at the beginning of the 20<sup>th</sup> century as the first measure to describe the effectiveness of a contraceptive method. The Pearl Index is defined as the number of pregnancies per 100 woman-years of a contraceptive method's use. It still meets the essential criteria of an index, i.e. easy calculation, approximation of real probability and prediction accuracy. Since the mid-1960s, objections to the Pearl Index have been raised, mainly because it does not reflect the duration of use of the contraceptive method <sup>(3)</sup>.

The levonorgestrel and copper T380A T have remarkably low pregnancy rates that may be less than 0.2 per hundred women per year. Twelve-year data on the CU T380A showed a cumulative pregnancy rate of only 1.9 per one hundred women (4). The Cu IUCD increases amount of blood flow during the woman's menstrual periods. On average, the menstrual blood loss increases by 20-50% after insertion of a Cu T IUCD. Increased menstrual discomfort is the most common medical reason for the IUCD removal <sup>(5)</sup>.

correlation between the copper T intra uterine contraceptive device-induced menorrhagia and the change in findings of transvaginal ultrasound Doppler before and after one month of insertion.

#### PATIENTS AND METHOD

It was a prospective cross-sectional study, which was conducted on 84 women from 1/1/2019 to 30/7/2019. They had been classified into two groups according to presence or absence of menorrhagia: Group (1) included thirty seven cases with complaint of menorrhagia and group (2), which included forty seven cases without complaint of menorrhagia.

Site of study: Obstetrics and Gynecology Department and Family Planning Clinic, Zagazig University Hospitals and Zagazig General Hospital, Egypt.

### **Ethical approval:**

The study was approved by Institutional Review Board (IRB) and by the Ethical Committee, Faculty of Medicine, Zagazig University. All corresponding documents were declared for ethical and research approval by the Council of Obstetrics and Gynecology Department, Zagazig University. Informed verbal and written consents were obtained from all women included in the study. This work has been carried out in accordance with The Code of

The aim of the present study was to assess the



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### Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

### **Inclusion Criteria:**

Any woman attended to the Family Planning Clinic of Obstetrics and Gynecology Department who wanted to use a copper IUCD. Patients with regular menstrual cycle in child bearing period without any hormonal treatment for at least 3 months before IUCD insertion.

# **Exclusion Criteria:**

Nulligravidas, pregnancy, associated uterine, cervical or adnexal pathology, presence of cervical or endometrial polyp, generalized bleeding disorders, medication causing coagulation defects, cervicitis, genital tumor, copper allergy and PID, severe dysmenorrhea and hypertensive patients.

All patients were subjected to the following: Detailed history taking including personal history, past history of previous medication, history of medical diseases and drug intake, surgical history and contraceptive history. General examination including blood pressure, pulse and BMI, complete general examination of all body systems to find out any associated autoimmune diseases and medical conditions and to identify the uterine size and position.

Then, detailed gynecological examination had been performed for examination of any cervical lesion or infection using the Cusco speculum and examination of uterine tumors or pelvic inflammatory disease by the bimanual examination.

Insertion of TCu-380A had been done on the 4<sup>th</sup> or 5<sup>th</sup> day of the menstrual cycle the transvaginal ultrasound and Doppler had been performed at time of insertion and after one month then all women had been divided into 2 groups according to presence or absence of menorrhagia. Group 1 (thirty seven cases) with menorrhagia and Group 2 (forty seven cases) without menorrhagia.

### Transvaginal ultrasonography (TVUS):

The used ultrasound machine was GE Logiq P7 system with 5-8 MHz curved transvaginal transducer. A 2-dimensional B-mode real-time sonographic examination for the uterus and the adnexa had been carried out to study endometrial thickness, uterine size and shape and to exclude any uterine or ovarian pathology and for identifying the IUD position for displacement or not in the follow up visits.

# Transvaginal color Doppler on uterine artery (TVCD):

The uterine arteries were located < 2 cm from the vaginal fornices at level of internal OS. Then, the mode had been switched to the color Doppler and the blood flow velocity waveforms had been displayed and the image had been frozen including at least three

waveform signals. Then the calculations of PI and RI for both uterine arteries had been done.

# Statistical Analysis

All data were collected, tabulated and statistically analyzed using SPSS 22.0 for windows (SPSS Inc., Chicago, IL, USA) & MedCalc 13 for windows (MedCalc Software bvba, Ostend, Belgium). Continuous data were expressed as the mean  $\pm$  SD & median (range), and the categorical data were expressed as a number (percentage). Continuous variables were checked for normality by using Shapiro-Wilk test. Wilcoxon signed ranks test was used to compare between two dependent groups of non-normally distributed variables. McNemar's test was used for paired categorical data. Stuaright-Maxwell test (different generalization of McNemar test) was used for testing marginal homogeneity in a square table with more than two rows/columns with using nonconservative test if needed. All tests were two sided. P value  $\leq 0.05$  was considered significant.

### RESULT

Uterine artery PI and RI after one moth of insertion were significantly lower than at time of insertion among women with IUCD-induced menorrhagia. Endometrial thickness after one month of insertion was significantly higher than at time of insertion among women with IUCD-induced menorrhagia. PI and RI at time of insertion were significantly lower in women with IUD -induced menorrhagia than in those using IUD with normal menstrual bleeding. Uterine artery PI  $\leq$  1.99 and RI  $\leq$  0.82 have been associated with menorrhagia at time of insertion (Tables 1, 2, 3).

Table (1): Comparison between ultrasound and color			
Doppler measurements before and one month after			
IUCD insertion among the studied women (N=100)			

Ultrasound and color Doppler measurements	Before IUCD insertion	After IUCD insertion (N=84)	P-value (Sig.)
measurements	(N=84)	(11-04)	(Big.)
Endometrial			
thickness (mm)	$5.95\pm0.77$	$6.28\pm0.82$	< 0.001
Mean $\pm$ SD	5.93	6.16	(HS)
Median			
RI			
Mean $\pm$ SD	$0.84\pm0.08$	$0.83\pm0.09$	0.143
Median	0.86	0.86	(NS)
PI			
Mean $\pm$ SD	$2.12\pm0.24$	$2.09\pm0.25$	< 0.001
Median	2.15	2.13	(HS)

\* Wilcoxon signed ranks test. P < 0.05 is significant. Sig.: Significance.

This table showed that there was high significant change in endometrial thickness, RI and PI between before IUCD insertion and one month after IUCD insertion.

Ultrasound and color Doppler	IUCD- menor	P-value	
measurements before IUCD insertion	Absent (N=47)	Present (N=37)	(Sig.)
Uterine length			
(cm)	$8.02 \pm 0.76$	$7.98 \pm 0.96$	0.732
Mean $\pm$ SD	8	7.60	(NS)
Median			
Uterine width			
(cm)	$4.95 \pm 0.56$	$5.11 \pm 0.74$	0.464
Mean $\pm$ SD	5	5	(NS)
Median			
Endometrial			
thickness (mm)	$5.66 \pm 0.36$	$6.32 \pm 0.98$	< 0.001
Mean $\pm$ SD	5.82	6.10	(HS)
Median			
RI			
Mean $\pm$ SD	$0.89 \pm 0.05$	$0.76 \pm 0.05$	< 0.001
Median	0.88	0.76	(HS)
PI			
Mean $\pm$ SD	$2.31 \pm 0.11$	$1.88\pm0.10$	< 0.001
Median	2.31	1.85	(HS)

 Table (2): Comparison between women without and with IUCD-induced menorrhagia regarding ultrasound and color Doppler measurements before IUCD insertion

• Mann Whitney U test. P < 0.05 is significant. Sig.: Significance.

This table showed that there was high significant relation between IUCD–related heavy menstrual bleeding and endometrial thickness, RI and PI before insertion.

**Table (3):** Comparison between women without and with IUCD–induced menorrhagia regarding ultrasound and color Doppler measurements one month after IUCD insertion

Ultrasound and color Doppler	IUCD–induced menorrhagia		P-value
measurements after IUCD insertion	Absent (N=47)	Present (N=37)	(Sig.)
Endometrial			
thickness (mm)	$5.85\pm0.35$	$6.81 \pm$	< 0.001
Mean $\pm$ SD	6.02	0.94	(HS)
Median		6.63	
RI			
Mean $\pm$ SD	$0.90\pm0.05$	$0.75 \pm$	< 0.001
Median	0.89	0.05	(HS)
		0.73	
PI			
Mean $\pm$ SD	$2.29\pm0.11$	$1.83\pm0.10$	< 0.001
Median	2.30	1.81	(HS)

• Mann Whitney U test. P < 0.05 is significant. Sig.: Significance.

This table showed that there was high significant relation between IUCD–related heavy menstrual

bleeding and endometrial thickness, RI and PI one month after insertion.

**Table (4):** Comparison between before and after onemonth ICUD insertion ultrasound and color Dopplermeasurements among women with IUCD-inducedmenorrhagia

Ultrasound and color Doppler measurements	Before IUCD insertion (N=37)	After IUCD insertion (N=37)	P-value (Sig.)
<b>Endometrial</b> <b>thickness (mm)</b> Mean ± SD Median	$\begin{array}{c} 6.32\pm0.98\\ 6.10\end{array}$	$6.81 \pm 0.94$ 6.63	<0.001 (HS)
<b>RI</b> Mean ± SD Median	$\begin{array}{c} 0.76 \pm 0.05 \\ 0.76 \end{array}$	$\begin{array}{c} 0.75 \pm 0.05 \\ 0.73 \end{array}$	<0.001 (HS)
PI Mean ± SD Median	$\begin{array}{c} 1.88 \pm 0.10 \\ 1.85 \end{array}$	$1.83 \pm 0.10$ 1.81	<0.001 (HS)

• Wilcoxon signed ranks test. P < 0.05 is significant. Sig.: Significance.

This table showed that there was high significant difference between before IUCD insertion and one month after IUCD insertion regarding ultrasound and color Doppler measurements among women with IUCD-related heavy menstrual bleeding.

### DISCUSSION

IUCD-induced menorrhagia may be caused by the decrease in resistance of uterine artery that leads to the increase in blood flow to uterus <sup>(6)</sup>. Failure rate of the copper T380A IUCD is 0.6%- 0.8% within 1<sup>st</sup> year of the insertion <sup>(7)</sup>. So, uterine artery Doppler indices ,which are the pulsatility index (PI) and resistive index (RI) are used to find correlation between IUCD-induced menorrhagia and the uterine artery blood flow <sup>(8)</sup>.

Our study was conducted on eighty four women who had been referred to the family planning clinic of the Zagazig university hospital for insertion of an IUD (Cu T-380A). The Transvaginal ultrasound and Doppler had been done at time of insertion at 4th or 5th day of menstruation and after one month of insertion.

The women have been classified into 2 groups according to presence or absence of menorrhagia. According to our study, before insertion of the IUCD there was high significant difference between the two studied groups regarding the endometrial thickness. Furthermore, there was high significant difference between endometrial thickness at time of insertion and after one month of insertion. However, in **Mohamed and Abdel Hakim** <sup>(9)</sup> study there was no significant difference before insertion and a high significant difference appeared after 3 months of insertion, which disagrees also with our study. In the study of **Mohamed and Abdel Hakim** <sup>(9)</sup>, at time of insertion and after one month there was no significant difference between the 2 groups regarding PI and RI. However, there was a significant difference between the 2 groups regarding the PI after 3 months of insertion and there was a high significant difference between the 2 groups after 3 months of insertion regarding the RI as these indices were lower significantly in group 2 than in group 1 which disagree with our study as in our study there was a high significant difference between the 2 groups at time of insertion and after one month of insertion as the Doppler indices of the 1<sup>st</sup> group were significantly lower than that of the 2<sup>nd</sup> group.

According to our study results there is a high significant difference between the 2 groups regarding PI at time of insertion and after one month of insertion as this index is significantly lower in group I than in group II and these results run in agreement with **El Anwar** *et al.* <sup>(10)</sup>, as their study showed significant difference between the control group and the other 2 groups (II and III) regarding PI after one month of insertion as the PI of group I was  $2.6 \pm 0.8$ , PI of group II was  $1.8 \pm 0.41$  and PI of group III was  $1.1 \pm 1.0$ , which showed that PI of group II and III was significantly lower than that of group I.

In a study of **Mutlu** *et al.* <sup>(11)</sup> where they investigated 120 patients wanted to use the IUCD by the transvaginal color Doppler ultrasound before insertion of the device and after 6 months of insertion at the follicular phase. The recorded uterine artery Doppler indices showed no significant difference between before and after insertion in comparison with the group of patient who complained of IUCD-mediated side effects and the group with no side effects recorded. This study doesn't agree with our study results.

The results of this study revealed that uterine artery PI and RI after one month of insertion were significantly lower than at time of insertion among women with IUCD-induced menorrhagia. Endometrial thickness after one month of insertion was significantly higher than at time of insertion among women with IUCD-induced menorrhagia. PI and RI at time of insertion were significantly lower in women with IUD induced menorrhagia than in those using IUD with normal menstrual bleeding. Uterine artery PI  $\leq$  1.99 and RI  $\leq$  0.82 have been associated with menorrhagia at time of insertion

### CONCLUSION

There was a correlation between the copper T intra uterine contraceptive device-induced menorrhagia and changes in the findings of the transvaginal ultrasound Doppler before and after one month of insertion. Any women want to have a cu T 380A IUCD for contraception have to undergo transvaginal Doppler examination on the uterine artery and if they are with a PI lower than 1.99 and RI lower than 0.82 they should use another way for contraception. The Transvaginal Doppler ultrasound is very helpful in prediction of menorrhagia among IUCD users.

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