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Assessment of the role of Transvaginal color Doppler ultrasound in prediction of menorrhagia among copper intra uterine device users

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Abstract

Objective: *to evaluate the effect of copper T IUCD on the uterine artery blood flow causing menorrhagia and to assess the role of Transvaginal color Doppler ultrasonography in prediction of this menorrhagia.****Method:*** *it was a prospective cross sectional study which was conducted on 84 patients referred to the obstetrics and gynecology family planning clinic of the Zagazig University Hospital and Zagazig General Hospital for insertion of an IUD (Cu T-380A) from 1/1/2019 to 30/7/2019. The Transvaginal ultrasound and Doppler had been done at time of insertion on the 4th or 5thday of menstruation. The patients had been classified into two groups the according to presence or absence of menorrhagia****;*** *group 1 (n =37): with menorrhagia, group 2 (n = 47) without menorrhagia.* ***Results:*** *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 (p-value <0.001). Uterine artery PI ≤1.99 (sensitivity 97.3% and specificity 100%, with area under the curve, AUROC of 0. 981and p-value <0.001) and RI ≤0.82 (sensitivity 94.6%and specificity 100%, with area under the curve, AUROC of 0.957and p-value <0.001) have been associated with menorrhagia after IUD insertion.* ***Conclusions:*** *any women tend to have a cu T 380A IUCD for contraception with a PI lower than 1.99 and RI lower than 0.82 will have menorrhagia after insertion, so they should use another way for contraception.*

Key words*: pulsitality index, resistance index, CuIUCD, Transvaginal Doppler ultrasound.*

I. INTRODUCTION:

All over the world about 14.3% of women use the intra uterine contraceptive device (IUCD) [(1)]. The intra uterine contraceptive device is more effective and safer without a lot of side effects than other ways of contraception and proved that it's reliable in family planning and it'sa reversible long lasting way of contraception [(2)]. The copper T380A and the levonorgestrel T have remarkably low pregnancy rates which may

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reach less than 0.2 per 100 women/year. Total pregnancies over a 7 year period were only 1.1 per 100 for levonorgestrel T and 1.4 for the copper T380A IUCD. Twelve-year data on the CU T380A showed a cumulative pregnancy rate of only 1.9 per 100 women [(3)].

The most common medical reasons for the IUCD discontinuation are abnormal uterine bleeding, so this discontinuation affects a large number of women, 40 million women estimated each year having an IUCD insertion. About 5%-15% of women discontinue the usage of IUCD within the 1st year because of bleeding [(4)]. There is a persistent increase in the loss of the menstrual blood which is revealed by recent studies with the Cu T380A but it didn't cause iron deficiency anemia. The increased bleeding may be unacceptable to many women but some women consider it as an annoyance only [(5)].

*The following indices were developed to represent flow:***Resistance index (RI):** Defined as the difference between the peak systolic flow velocity & the end-diastolic flow velocity divided by the peak systolic flow velocity. This index indicates state of the peripheral resistance in vascular bed distal to point of measurement. The index value decreases as peripheral resistance decreases and when the end diastolic flow is approaching zero, the index approaches unity,**Pulsatility index (PI):** Defined as the difference between the peak systolic flow velocity & the end-diastolic flow velocity divided by the mean of both. Mean is calculated by Doppler machine and thus, to obtain the accurate measures, the frequency shift should be processed in high accuracy, so this index may be the most difficult to measure [(6)].PI values of the women with IUCD having an abnormal bleeding are significantly lower than those of patients without IUCD[(7)].

II. METHODS:

Before the beginning of the study and in accordance with the local regulation followed, the protocol and 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 had been taken from all women included in the study. It was a prospective cross sectional study which had been conducted on 84 women from 1/1/2019 to 30/7/2019 and they had been classified into two groups according to presence or absence of menorrhagia; **Group 1 (37 cases):** cases with complaint of menorrhagia, **Group 2 (47 cases):** cases without complaint of menorrhagia.

Site of study: Obstetrics and Gynecology department; family planning clinic at Zagazig University Hospitals and Zagazig General Hospital, Egypt.

The study was approved by Institutional Review Board (IRB) and by the ethical committee in the faculty of medicine and verbal and signed written consent from all participants will be included in the study.

Inclusion Criteria: Any woman attended to the family planning clinic of obstetrics and gynecology department who wanted to use a copper IUCD: Patient 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: Personal history, family history, past history of previous medication, history of medical diseases and drug intake, surgical history and contraceptive history. General examination: Blood pressure, pulse and BMI, complete general examination of body systems will be performed to discover any associated autoimmune diseases and medical conditions and to identify uterine size and position.

Then detailed gynecological examination had been done for examination of any cervical lesion or infection using Cusco speculum and examination of any uterine tumors or PID by bimanual examination.

Insertion of TCu-380A had been done on the 4^{th} or 5^{th} day of the menstrual cycle the Transvaginal ultrasound and Doppler had been performed at time of insertion then all women had been divided into 2 groups according to presence or absence of menorrhagia:

Group 1 (37 cases): cases with menorrhagia, Group 2 (47 cases): cases without menorrhagia.

Transvaginal Ultrasonography (TVUS):

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

Transvaginal color Doppler on uterine artery (TVCD):

- After taking measures of the uterus, the mode had been shifted to color Doppler and the uterine arteries are located less than 2 cm from the vaginal fornices at the level of the internal OS.
- The color Doppler was activated in the 2D mode; the right and left uterine artery were identified.
- Then the mode had been switched to color Doppler and the blood flow velocity waveforms had been displayed and the image had been frozen including at least three waveform signals. Then calculations of PI and RI for both uterine arteries had been done.

STATISTICAL ANALYSIS:

All data were collected, tabulated and statistically analyzed using the 2018 SPSS 20.0 for windows (SPSS Inc., Chicago, IL, USA) and MedCalc 13 for windows (MedCalc Software bvba, Ostend, Belgium).

III. RESULTS:

The results of our study revealed that PI and RI at time of insertion were significantly lower in women with IUD -induced abnormal uterine bleeding than in those using IUD with normal menstrual bleeding.

Table (1): Comparison between women without and with IUCD–induced menorrhagia regarding Transvaginal color Doppler ultrasound measurements at time of IUCD insertion:

Ultrasound and color Doppler measurements before IUCD insertion	IUCD–induced menorrhagia		Test•	p-value (Sig.)
	Absent (N=47)	Present (N=37)		
RI				
Mean ± SD	0.89 ± 0.05	0.76 ± 0.05	-7.483	<0.001 (HS)
Median (Range)	0.88 (0.86 – 1.01)	0.76 (0.70 – 0.98)		
PI				
Mean ± SD	2.31 ± 0.11	1.88 ± 0.10	-7.578	<0.001 (HS)
Median (Range)	2.31 (2.15 – 2.55)	1.85 (1.75 – 2.39)		

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

This table shows that there is high significant difference between the 2 studied groups regarding RI and PI at time of insertion.

Table (2): Diagnostic performance of RI at time of ICUD insertion as a predictor for IUCD–induced menorrhagia; ROC curve analysis:

Cut-off Values	SN % (95% CI)	SP % (95% CI)	PPV % (95% CI)	NPV % (95% CI)	Accuracy (95% CI)	AUROC (95% CI)	p-value (Sig.)
RI ≤0.82	94.6% (81.8-99.3)	100% (92.5-100)	100%	95.9% (85.9-98.9)	97.6% (87.8-99.7)	0.957 (0.890-0.989)	<0.001 (HS)

ROC curve: Receiver Operating Characteristic curve; SN: Sensitivity; SP: Specificity; PPV: Positive Predictive Value; NPV: Negative Predictive Value; AUROC: Area under Receiver Operating Characteristic curve; 95%CI: 95% Confidence Interval; p< 0.05 is significant.

Table (3): Diagnostic performance of PI at time of ICUD insertion as a predictor for IUCD–induced menorrhagia; ROC curve analysis:

Cut-off Values	SN % (95% CI)	SP % (95% CI)	PPV % (95% CI)	NPV % (95% CI)	Accuracy (95% CI)	AUROC (95% CI)	p-value (Sig.)
PI	97.3%	100%	100%	97.9%	98.8%	0.981	<0.001

≤1.99	(85.8-99.9)	(92.5-100)	(87.2-99.7)	(89.6-100)	(0.924-0.998)	(HS)

ROC curve: Receiver Operating Characteristic curve; SN: Sensitivity; SP: Specificity; PPV: Positive Predictive Value; NPV: Negative Predictive Value; AUROC: Area under Receiver Operating Characteristic curve; 95%CI: 95% Confidence Interval; p< 0.05 is significant.

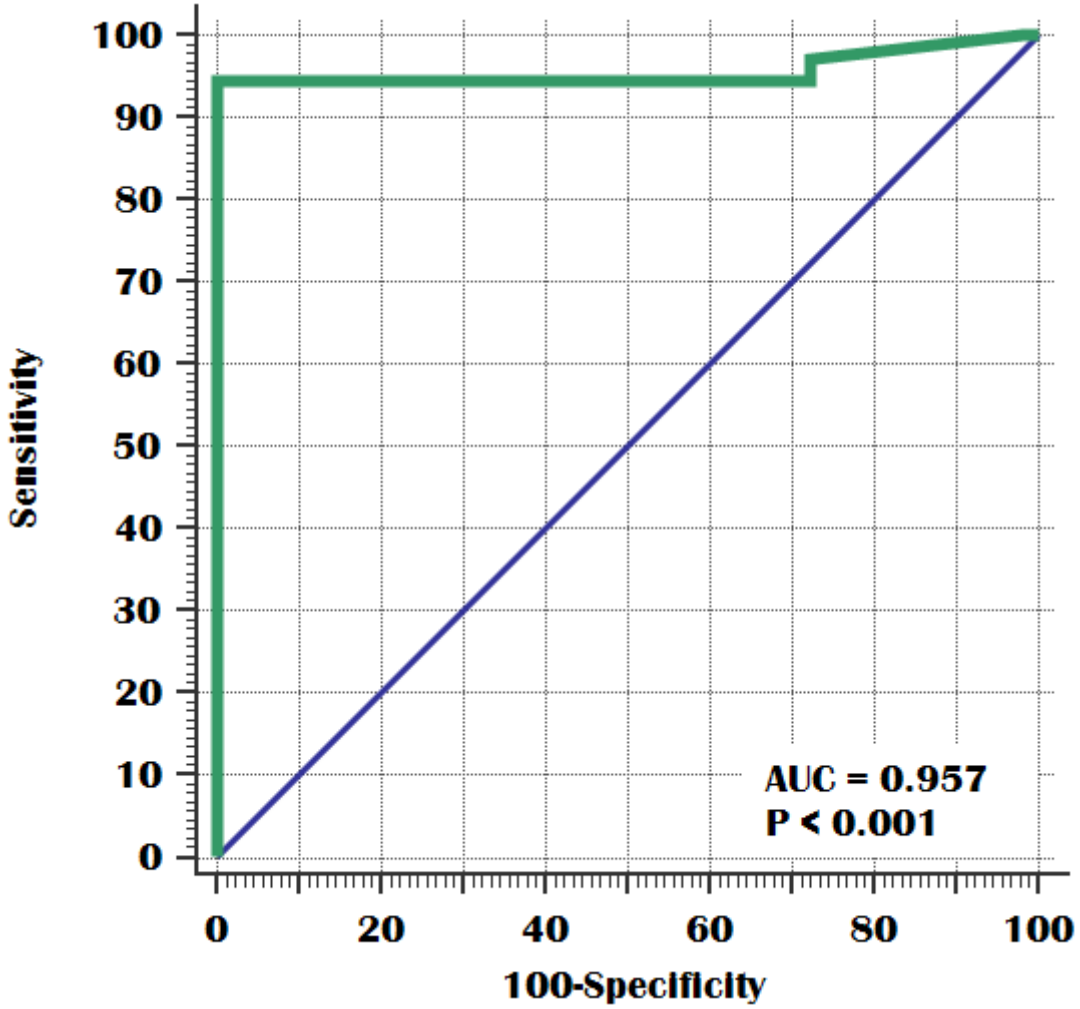

Figure (1): Receiver operating characteristic (ROC) curve of RI before ICUD insertion as a predictor for IUCD–induced menorrhagia.

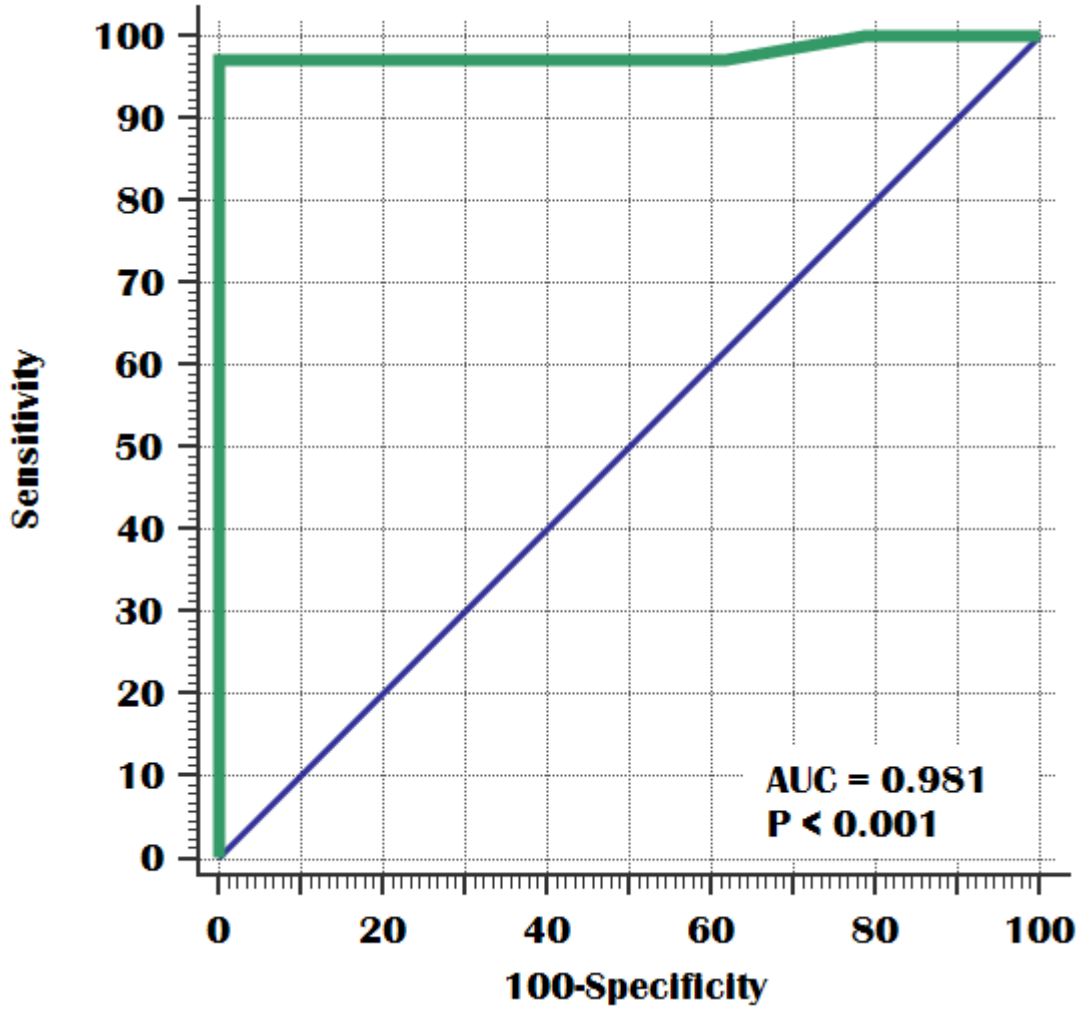

Figure (2): Receiver operating characteristic (ROC) curve of PI before ICUD insertion as a predictor for IUCD–induced menorrhagia.

IV. DISCUSSION:

IUCD-induced menorrhagia may be caused by decrease the resistance of the uterine artery which leads to increase in the blood flow to the uterus[(7)].

The rate of failure of copper T380A IUCD is (0.6%- 0.8%) within the 1st year of insertion, 0.2% for 20-mcg levonorgestrel IUD (Mirena) and 0.9% for 14-mcg levonorgestrel IUD (Skyla)[(8)].

So the uterine artery Doppler indices which are the pulsitality index (PI) and resistive index (RI) are used to find the correlation between the IUCD- induced menorrhagia and the uterine artery blood flow [(6)].

Our cross sectional study was conducted on 84 patients referred to the obstetrics and gynaecology family planning clinic of the Zagazig university hospital for insertion of an IUD (Cu T-380A). The transvaginal ultrasound and Doppler has been done at time of insertion at 4th or 5th day of menstruation.

The patients have been classified into two groups according to presence or absence of menorrhagia (increased duration and/or amount of menstrual bleeding).

The results of our study revealed that PI and RI at time of insertion were significantly lower in women with IUD -induced abnormal uterine bleeding than in those using IUD with normal menstrual bleeding.

Frajndlich et al, (2000) has made his study on 101 patients; 27 patients were control group (group I) and 74 patients were using the IUCD. The 74 patients have been divided into 3 groups; group II: 34 patients with normal bleeding, group III: 16 patients with abnormal uterine bleeding without medications, group IV: 24 patients with AUB corrected with prostaglandin inhibitors. In this study there was significant difference between the group III and the other 3 groups regarding the PI and RI as these indices were significantly lower in group III than the other 3 groups. In comparison to our study, this study agrees with our study regarding the PI and RI as in of our study, there is a high significant difference between 1st group and the 2nd group at time of insertion.

Fouda et al., 2010, has made a study on 93 women. They examined patients with Transvaginal color Doppler ultrasound and recorded the PI and RI of them then they divided into 3 groups; group I: 32 women with cu IUCD and complain of menorrhagia, group II: 30 women using CIUCD with normal menstruation, group III: 31 women who were a control group. This study revealed that PI and RI were significantly lower in group I than other 2 groups which agree with our study as there is significant difference between the 2 studied groups of our study and the PI and RI of group I are significantly lower than in group II.

The women with menorrhagia showed increase in endothelial cell proliferation leading to disturbed angiogenesis which may be a possible mechanism explaining the correlation between the PI and the increased menstrual blood loss and the disturbed angiogenesis possibly cause other vascular abnormalities. In these abnormal vessels the poor contractibility and the dysfunction of hemostatic system may lead to menorrhagia [(9)].

De Souza and Geber, 2006, have made a prospective study on 100 patients wanted to use the IUCD as contraception as they recorded the Doppler indices at time of insertion and after one month. They concluded that there is no change in uterine artery blood flow resistance after one month of IUCD insertion as there is not enough time for complications to.

V. Conclusions:

Our thesis concluded that any women tend to have a cu T 380A IUCD for contraception with a PI lower than 1.99 and RI lower than 0.82 will have menorrhagia after insertion, so they should use another way for contraception.

The present study which had been conducted on 84 cases may help in prediction of a serious side effect which is menorrhagia among the Cu IUCD users and helps to avoid such complications in the future. So the Transvaginal Doppler ultrasound is very helpful, easy, noninvasive and cheap tool for choosing the perfect contraception and for follow up.

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