Doppler Ultrasound in Prediction and Follow up of Copper 380 IUCD Induced Excessive Menstrual Bleeding

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Abstract

Objectives: This research aimed to evaluate Doppler Ultrasound value in prediction and follow up of copper 380 intrauterine contraceptive device (IUCD) induced excessive menstrual bleeding. **Patients and methods:** This was a prospective study performed on a total of 120 cases seeking 380 IUCD insertion. All the cases were subjected to 1) Full history taking, 2) General examination, 3) pelvic examination, 4) Abdominal exam, 5) Speculum examination to detect and exclude any bleeding local cause as erosion and polyp, 6) Menstrual history, 7) Obstetric history and 8) Doppler US. **Results:** Uterine artery resistance index (RI) and pulsatility index (PI) before and after IUD were negatively correlated with IUCD induced bleeding ($P < 0.001$). The RI and PI of sub-endometrium prior and following IUD were negatively correlated with the IUCD induced bleeding ($P < 0.001$) while visual field index (VFI) and vascularization index (VI) before and after IUD were positively correlated with the IUCD induced bleeding ($P < 0.001$). Also, endometrium flow index (FI), VFI and VI before and after IUD were positively correlated with the IUCD induced bleeding ($P < 0.001$). The uterine artery RI and PI prior and following IUD were negatively correlated with the IUCD induced bleeding ($P < 0.001$). **Conclusions:** Medical professionals should give women unbiased information on the potential variations in bleeding they may face if there is no extremely successful medication for excessive bleeding in the first few months following copper IUD placement.

Keywords: Doppler Ultrasound; Copper 380; IUCD-Induced Excessive Menstrual Bleeding.

1. Introduction

The most widely used kind of long-acting reversible contraception in the world is the copper intrauterine contraceptive device (IUCD) [1]. The average menstrual cycle lasts 3 to 6 days and can result in up to 30 ml of blood loss. Menstruation that lasts more than seven days or that results in blood loss over 80 ml is considered menorrhagia [2] **.**

The most significant copper IUCD adverse reaction is elevated menstrual bleeding by 30–50%, which is frequently accompanied by cramps. The amount of menstrual blood may be large enough to lead to iron deficiency anaemia [3]. Four to fifteen percent of IUCDs are removed during the first year after insertion as a result of these modifications [4].

The increased release of prostaglandins in the endometrium, that results in an elevation in vascular permeability, platelet activity, vascularity as well as other potential processes, shed light on the reason for the heavy monthly bleeding in women using IUCD. Another explanation is that the capillary plexus injury caused by the IUCD causes it to promote fibrinolysis [5].

The micro-vascularization of the sub-endometrium has also increased in the women who claimed heavy bleeding caused by IUCD [6].

In women with IUCD-induced excessive menstrual bleeding, only a small number of studies have shown a sub-endometrial vascularization elevation [7]. PI and RI, two Doppler uterine artery indices, have been extensively studied to determine the relationship between excessive menstrual haemorrhage related with IUCD and enhanced blood flow in the uterine artery [8].

This research aimed to evaluate Doppler Ultrasound value in prediction and follow up of copper 380 IUCD induced excessive menstrual bleeding.

2. Materials and Methods:

This was a prospective study conducted on 120 cases seeking 380 IUCD insertion, patients were collected and examined from gynecology and obstetrics Department, Benha University Hospitals among October 2021 and October 2022. After receiving approval from the Benha University Faculty of Medicine Research Ethics Committee, the study was performed. All individuals including in the study provided their informed consent.

Inclusion criteria were patients with age between 20–40 years old, who desired long-acting contraception, multiparous women and regular menstrual cycles with average amount of bleeding.

Exclusion criteria were pregnant women, lactating women, Nulligravida, women who have experienced protracted menstrual bleeding, history of congenital or inherited uterine abnormalities, idiopathic amenorrhea, or both (e.g., septate uterus, uterine polyp, or fibroid), present-day inflammation of the pelvis, women with a bleeding tendency (such as those with thrombophilia or anticoagulant diseases), women with diabetes mellitus (DM), hypertension, hyperthyroidism, or hypothyroidism, any contraindication to IUCD insertion, women on anticoagulant drugs, or those who are sensitive to copper.

All the cases were subjected to **1) Full history taking** include Age, occupations, habits, and past history of medical or surgical problems, OCP uses. **2) General examination:** including Vital signs: capillary filling

time, respiration rate, temperature, pulse, and blood pressure before and after the operation. **3) pelvic examination** that also involved a bimanual inspection to look for any unusual finds. **4) Abdominal exam. 5) Speculum examination** for detection and excluding of bleeding local causes as erosion and polyp. **6) Menstrual history**: Amount, duration of menstrual cycle, dysmenorrhea regularity, inter menstrual or spotting or contact bleeding and cycle length. **7) Obstetric history**: parity and abortion

8) Doppler US: was done to all women prior IUCD placement then at 3 months following placement on days 5 and 12 of the cycle to rule out menstrual cycle phase and the study should be conducted between 9:00 and 10:00 AM to prevent circadian rhythm variance & to detect size of uterus and thickness of endometrium **to assess the following:** Correct IUCD placement within the uterus, Uterine length and width, Uterine artery PI and RI, Measure the endometrium and sub-endometrial region, VI: represents number of colour voxels to all voxels (percent), that indicates blood vessels presence (vascularity), FI represents the average blood flow intensity and estimates the mean power Doppler signal intensity (0–100).

9) Recording of number of pads per day, pads soaked or not, passage blood clot during menstruation and presence of symptoms as palpitation, fatigue, drowsiness and blurring of vision. **10) CBC: prior** insertion and 3 ,6 months after insertion to measure HB concentration

IUCD insertion precautions: We performed prior placement. Cu-T380A placement ought to be done postmenstrual or six weeks after delivery. Under complete aseptic condition. Under obstetric and gynaecologist supervision.

Heavy menstrual bleeding was diagnosed with score more than 80 as if during the menstrual period fewer than 4 soaked pads or 16 unsoaked pads will be utilised and/or the duration lasts fewer than seven days, blood clots form, and one or more of the symptoms following are present (easy fatigue, palpitation, drowsiness, blurring of vision and fainting).

Since the early 20th century, assessment of MBL has sparked a persistent controversy among gynecologic academics and practitioners. Higham and Shaw first published the pictorial blood assessment chart (PBAC) in 1990, then Janssen and colleagues modified and confirmed it in 1995. The PBAC is a semi-quantitative tool for evaluating MBL. PBLAC has been employed in clinical research more frequently lately, particularly in pivotal trials that assessed the efficacy of non-hysteroscopically-dependent endometrial ablation devices.

Participants were told to raise their intake of iron- and vitamin B12-rich foods and completely relax throughout their periods if severe bleeding happened. But, they should seek medical attention right once if the bleeding persisted. If the bleeding was twice as heavy or twice as frequent as usual, the bleeding alterations were very bothersome, there was significant anaemia present,

or the bleeding alterations continued longer than six months, withdrawal of the IUCD should be considered.
Statistical analysis:

The obtained data were statistically analysed using SPSS statistics for windows (Statistical Package for the Social Sciences), version 26 (IBM, Armonk, NY, USA). The Shapiro-Wilk test was employed to determine whether the data distribution was normal. 95 percent confidence intervals were used for all tests. Statistical significance was defined as P (probability) value < 0.05. The SPSS chart builder and Microsoft Excel for Windows 2019 were used to create the charts. Whereas categorical variables were represented as frequency and percentage, quantitative variables were expressed as mean and standard deviation, median, inter-quartile range, minimum and maximum as applicable. For inter-group (between participants) comparison of parametric and non-parametric continuous data without follow-up readings, independent sample T and Mann Whitney tests, correspondingly, were utilised. The follow-up readings were compared to their matching basal value utilising paired samples for pair-wise data comparison (within individuals). T test, Wilcoxon signed ranks test with matched pairings, or related-samples Rank-based two-way Friedman's analysis of variance with Bonferroni correction for multiple comparisons. Depending on the type of data, Pearson's or Spearman's correlation coefficients were used to evaluate bivariate correlations. In this investigation, a significance level of (p < 0.05) was considered appropriate.

3. Results

Table 1 showed patients' demographics, parity, number of gestations, Menarche and duration of menstruation and Incidence of IUCD induced excessive menstrual bleeding PBAC score at three months after IUD and its change in the studied sample. **Table (1)**

A substantially considerable change was present among baseline PBAC score and three months after IUD in the studied samples (mean ± SD= 45.98 ± 12.885 vs 70.52 ± 35.618, P < 0.001). **Figure (1)**

A substantially critical change was seen among IUD RI and PI of the uterine artery at baseline and after (P < 0.001), among baseline and after IUD PI, RI, FI, VI and VFI of the sub-endometrium (P < 0.001) and between the baseline and after IUD VI, FI and VFI of the endometrium (P < 0.001). No substantial change was present among IUCD induced bleeding and PBAC baseline score (P = 0.237). A substantially critical change was found among IUCD induced bleeding and PBAC score three months after IUD (P < 0.001) and between IUCD induced bleeding and PBAC change (P < 0.001). Substantially critical changes were present among baseline Doppler assessment according to the presence of IUCD induced bleeding as follows: PI and RI of the uterine artery (P < 0.001), the sub-endometrium PI, VI, VFI and RI (P < 0.001) and the endometrium FI, VFI and VI (P < 0.001). Substantially critical changes were seen among Doppler assessment after 3 months according to the presence of IUCD induced bleeding as

follows: PI and RI of the uterine artery (P < 0.001), PI, RI, VI and VFI of the sub-endometrium (P < 0.001) and VI, FI and VFI of the endometrium (P < 0.001). **Table (2)**

PBAC score three months after IUD was positively correlated with IUCD induced bleeding (P < 0.001) and the PBAC score change was also positively correlated with the with IUCD induced bleeding (P < 0.001). **Table (3)**

The uterine artery RI and PI before and after IUD were negatively correlated with the IUCD induced bleeding (P < 0.001). The sub-endometrium RI and PI before and after IUD were negatively correlated with the IUCD induced bleeding (P < 0.001) while VFI and VI before and after IUD were positively correlated with the IUCD induced bleeding (P < 0.001). Also, the endometrium FI, VFI and VI before and after IUD were positively correlated with the IUCD induced bleeding (P < 0.001). The PI and RI of the uterine artery before and after IUD were negatively correlated with the IUCD induced bleeding (P < 0.001). The PI and RI of the sub-endometrium before and after IUD were negatively correlated with the IUCD induced bleeding (P < 0.001) while the VI and VFI before and after IUD were positively correlated with the IUCD induced bleeding (P < 0.001). Also, the endometrium FI, VFI and VI before and after IUD were positively correlated with the IUCD induced bleeding (P < 0.001). **Table (4)**

Table (1) Demographic characteristics, parity, number of gestations, Menarche and duration of menstruation, PBAC score at three months after IUD and its change in the studied sample.

		Mean & SD	Median	Range	IQR
Age		30.88 ± 6.081	31.00	20.00, 40.00	26.00, 37.00
BMI		30.44 ± 2.590	30.10	25.73, 38.50	28.59, 32.12
Occupation	Housewife	70		58.3%	
	Worker	50		41.7%	
Residency	Urban	38		31.7%	
	Rural	82		68.3%	
DM		29		24.2%	
HTN		12		10.0%	
Parity		2.00 ± 0.870	2.00	1.00, 4.00	1.00, 3.00
Number of Gestations		2.74 ± 1.073	3.00	1.00, 5.00	2.00, 4.00
Menarche (years)		10.92 ± 1.713	10.00	7.00, 16.00	10.00, 12.00
Duration (days)		4.92 ± 2.007	5.00	2.00, 8.00	3.00, 7.00
IUCD induced excessive menstrual bleeding		29		24.2%	
Three months after IUD		70.52 ± 35.618	60.50	30.00, 166.00	43.25, 77.75
Change		24.54 ± 33.178	9.00	3.00, 136.00	7.00, 12.00

Data is expressed as mean and standard deviation, median, range and interquartile range or as percentage and frequency.

Table (2) Comparison of baseline Doppler assessment and three months after IUD and PBAC score before and after IUD and baseline/3 months Doppler assessment according to presence of IUCD induced bleeding in the studied sample

		Baseline	After IUD	95% CI	P
Uterine artery	PI	2.33 ± 0.456	2.20 ± 0.459	0.12, 0.14	< 0.001
	RI	0.92 ± 0.191	0.88 ± 0.194	0.04, 0.05	< 0.001
	PI	1.73 ± 0.266	1.63 ± 0.266	0.10, 0.11	< 0.001
	RI	0.67 ± 0.152	0.64 ± 0.151	0.03, 0.03	< 0.001
Sub-endometrium	VI	3.64 ± 1.825	4.07 ± 1.820	-0.47, -0.40	< 0.001
	FI	31.95 ± 5.459	33.62 ± 5.460	-1.74, -1.60	< 0.001
	VFI	1.22 ± 0.717	1.47 ± 0.720	-0.27, -0.23	< 0.001
	VI	0.72 ± 0.271	0.77 ± 0.270	-0.06, -0.05	< 0.001
Endometrium	FI	22.46 ± 6.523	23.68 ± 6.590	-1.29, -1.14	< 0.001
	VFI	0.20 ± 0.067	0.22 ± 0.070	-0.02, -0.02	< 0.001
IUCD induced bleeding		**Absent (n= 91)**	**Present (n= 29)**	95% CI	P
PBAC Baseline		45.19 ± 13.109	48.45 ± 12.037	-8, 2	0.237
PBAC Three months after IUD		52.97 ± 13.285	125.59 ± 26.125	-79, -65	**< 0.001**
PBAC Change		7.78 ± 2.624	77.14 ± 29.631	-75, -63	**< 0.001**
IUCD induced bleeding		Absent (n= 91)	Present (n= 29)	95% CI	P
Baseline Uterine artery	**PI**	2.52 ± 0.310	1.72 ± 0.281	0.67, 0.92	< 0.001
	RI	1.00 ± 0.142	0.69 ± 0.130	0.25, 0.36	< 0.001
Baseline Sub-	**PI**	1.80 ± 0.238	1.54 ± 0.256	0.16, 0.36	< 0.001

endometrium	**RI**	0.72 ± 0.122	0.52 ± 0.129	0.16, 0.26	< 0.001
	VI	2.75 ± 0.718	6.43 ± 1.349	-4.07, -3.30	< 0.001
	FI	31.53 ± 5.485	33.26 ± 5.255	-4.02, 0.56	0.138
	VFI	0.89 ± 0.368	2.26 ± 0.530	-1.54, -1.19	< 0.001
	VI	0.61 ± 0.171	1.06 ± 0.242	-0.53, -0.37	< 0.001
Baseline Endometrium	**FI**	21.25 ± 5.959	26.27 ± 6.849	-7.63, -2.41	< 0.001
	VFI	0.17 ± 0.051	0.27 ± 0.063	-0.12, -0.07	**< 0.001**
IUCD induced bleeding					
Uterine artery after 3 months	**PI**	2.39 ± 0.313	1.59 ± 0.264	0.68, 0.93	< 0.001
	RI	0.95 ± 0.144	0.64 ± 0.133	0.25, 0.37	< 0.001
	PI	1.69 ± 0.241	1.43 ± 0.247	0.16, 0.36	< 0.001
Sub-endometrium after 3 months	**RI**	0.69 ± 0.122	0.49 ± 0.132	0.15, 0.26	< 0.001
	VI	3.18 ± 0.716	6.84 ± 1.383	-4.05, - 3.27	< 0.001
	FI	33.21 ± 5.474	34.89 ± 5.306	-3.97, 0.62	0.150
	VFI	1.14 ± 0.383	2.50 ± 0.527	-1.54, -1.18	< 0.001
Endometrium after 3 months	**VI**	0.67 ± 0.172	1.11 ± 0.245	-0.53, -0.36	< 0.001
	FI	22.47 ± 6.030	27.50 ± 6.915	-7.67, -2.39	< 0.001
	VFI	0.19 ± 0.052	0.29 ± 0.066	-0.12, -0.07	< 0.001

Data is expressed as mean and standard deviation. 95% CI: 95% confidence interval of the mean difference between both readings. P is significant when < 0.05.

Table (3) Correlation between of PBAC score before and after IUD in the studied sample and IUCD induced bleeding:

IUCD induced bleeding	Correlation coefficient	P
PBAC Baseline	0.109	0.237
PBAC Three months after IUD	0.876	< 0.001
PBAC Change	0.899	< 0.001

P is significant when < 0.05.

Table (4) Correlation between of Doppler assessment before and after IUD in the studied sample and IUCD induced bleeding.

IUCD induced bleeding		Baseline		3 months		Change	
		r	P	r	P	r	P
Uterine artery	**PI**	-0.749	< 0.001	-0.755	< 0.001	-0.091	0.323
	RI	-0.687	< 0.001	-0.691	< 0.001	-0.193	0.034
Sub-endometrium	**PI**	-0.422	< 0.001	-0.421	< 0.001	0.007	0.941
	RI	-0.586	< 0.001	-0.576	< 0.001	0.136	0.138
	VI	0.868	< 0.001	0.864	< 0.001	-0.058	0.532
	FI	0.136	0.138	0.132	0.150	-0.051	0.578
	VFI	0.820	< 0.001	0.812	< 0.001	-0.026	0.779
Endometrium	**VI**	0.715	< 0.001	0.707	< 0.001	-0.082	0.372
	FI	0.331	< 0.001	0.328	< 0.001	0.009	0.920
	VFI	0.605	< 0.001	0.605	< 0.001	0.111	0.227

P is significant when < 0.05.

Table (5) Diagnostic performance of PI and RI before ICUD insertion as an indicator for the heavy menstrual bleeding associated with IUCD; ROC curve analyses.

Cut-off values	Sensitivity	Specificity	PPV	NPV	Accuracy	AUROC	P-value (Sig.)
PI (≤2.02)	95.8 (85.7-99.5)	100 (93.2-100)	100	96.3 (87-99)	98 (89.6-99.8)	0.971 (0.916-0.994)	<0.001
RI (≤0.83)	93.8 (82.8-98.7)	100 (93.2-100)	100	94.5 (85.3-98.1)	97 (88.2-86.5)	0.949 (0.885-0.983)	<0.001

Values are presented as percent (95% CI) unless otherwise indicated. PI, pulsatility index; RI, esistance index; IUCD, intrauterine contraceptive device; ROC curve, receiver operating characteristic curve; PPV, ositive predictive value; NPV, negative predictive value; AUROC, area under receiver operating characteristic curve; 95% CI, 95% confidence interval; Sig., significance; P<0.05.
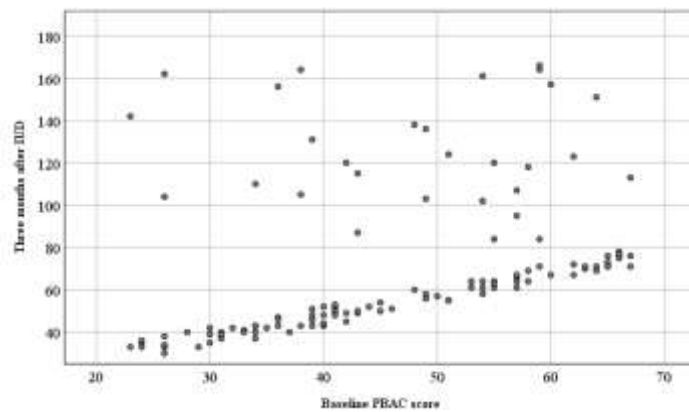
Fig. (1) Relation between Baseline PBAC score and three months after IUD in the studied sample.

4. Discussion

IUCD is a widely utilized contraceptive technique for family planning. Notably, the most popular method of long-acting, reversible contraception is the use of copper intrauterine devices (Cu-IUDs), which have extremely low failure rates of between 0.2 percent and 1.0 percent (LARC). Cu-T380A is favoured because of its low failure rate and long lifespan **[9].**

El-Mazny et al., 2013 evaluated endometrial and sub-endometrial micro-vascularization, employing 3D power Doppler ultrasound, in women with IUD-induced menorrhagia, found that Endometrial thickness before IUD insertion was 5.29 ± 1.78 (4.87–5.71), Uterine artery PI was 2.09 ± 0.58 (1.95–2.23), Uterine artery RI was 0.86 ± 0.20 (0.81–0.91), Endometrial VI was 0.73 ± 0.24 (0.67–0.79), Endometrial FI was 23.80 ± 4.93 (22.65–24.95), Endometrial VFI was 0.16 ± 0.07 (0.14–0.18) .Sub-endometrial VI was 1.79 ± 0.51 (1.67–1.91). Sub-endometrial FI was 24.79 ± 5.27 (23.56–26.02). Sub-endometrial VFI was 0.38 ± 0.12 (0.35–0.41) [10].

Jiménez et al., 2006 also found that Three months after the IUD was placed, seven of 25 patients reported either feeling like their monthly bleeding had elevated or experiencing excruciating pain (5 with pain, and 2 with bleeding). The IUD was subsequently taken out of two individuals who had adverse symptoms, including one who had heavy monthly bleeding and the other who had excruciating pain. When compared to patients who had no adverse reactions, subgroup analysis revealed higher sub-endometrial blood flow following IUD installation in those who experienced adverse reactions (P=0.016) [11].

In contrast, **Sanders et al., 2018** found that Over the course of the trial, haemorrhage dramatically decreased (by about 23 percent), from an expected PBAC equals 195 at one month after implantation to PBAC equals 151 at six months (t = -2.38, P < 0.05). Furthermore, IUD user satisfaction increased by time (t = 2.65, P < 0.01), over the course of the six-month trial, rising from "Neutral" to "Satisfied," then "Satisfied." [12].

As opposed to our study**, El-Mazny et al., 2013** found no critical change in the endometrial thickness (P= 0.349), uterine artery PI (P= 0.526) and RI (P= 0.537), endometrial volume (P= 0.552), endometrial VI (P= 0.326), FI (P= 0.159), and VFI (P= 0.356), and sub-endometrial VI (P= 0.354), FI (P= 0.172), and VFI (P= 0.336) before and after IUD insertion [10].

Jiménez et al., 2006 found that prior to and following IUD placement, the power Doppler sub-endometrial examination showed no discernible differences (P = 1.00). Prior to and following IUD placement, PI and RI were not critically different (P = 40 and P = 19, respectively). However, endometrial thickness (median: 25th–75th percentiles) was less before (7: 6 – 9 mm) than after IUD insertion (9: 7.5 – 10 mm) (P< 0.001) [11].

Attia et al., (2021) revealed that Doppler indices of the uterine artery (RI and PI) prior IUCD placement and at three and six months following placement have a highly significant correlation with severe menstrual bleeding related to IUCD implantation (P<0.001) [8].

Analysis of participant characteristics and heavy menstrual bleeding in relation to IUCD using multiple regression done by **Attia et al., (2021)** appeared that the uterine artery PI (PI $\leq$ 2.02) was appropriate for menorrhagia after IUCD placement (sensitivity 95.8 % [85.7-99.5] and specificity 100% [93.2-100]), with an AUC of 0.971 (0.916-0.994) at P < 0.001 [8].

5. Conclusions

3D power Doppler analysis showed that endometrial and sub-endometrial micro-vascularization was elevated in women with IUD-induced menorrhagia. But prior to IUD placement, this data had no prognostic significance. For a better knowledge of the IUD's mode of action and the pathophysiology of its adverse reactions, additional research is advised. Medical professionals should give women unbiased information on the potential changes in bleeding they may experience if there is no extremely successful therapy for excessive bleeding in the first few months following copper IUD placement. The results of this study are valuable and comforting in that regard.

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