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## ORIGINAL ARTICLE

# Transvaginal Spectral Doppler Analysis of Uterine Artery pre- and post- Copper Intrauterine Contraceptive Device (Cu-IUCD) Insertion to Predict Heavy Menstrual Bleeding

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## ABSTRACT

**Background:** Cu-IUCD is the most common method for long-acting reversible contraception, but its high potential use is hampered by menstrual complications especially heavy menstrual bleeding. So our work aimed to study the effect of Cu-IUCD on uterine artery blood flow through the assessment of uterine artery indices using transvaginal Doppler ultrasound (TVDU); and whether those potential findings could predict the risk of bleeding before insertion.

**Methods:** This prospective observational study had performed on 100 women in the Department of Obstetrics and Gynecology, Zagazig University Hospitals who requested insertion of a Cu- IUD for contraception and who met the inclusion criteria. Pulsatility (PI) and resistance index (RI) of the uterine artery were measured just before, three, and six months post-insertion.

**Results:** Forty-eight women came complaining of heavy menstrual bleeding and another 52 women were regularly menstruating. There was a substantial statistical variation concerning PI, and RI among women with IUD-induced heavy menstrual bleeding (n = 48) and those with the normal menstrual cycle (n = 52), while there was no difference as regards age, and abortion (P < 0.05). Uterine artery RI ≤ 0.809 and PI ≤ 2.078 was correlated with significant menstrual bleeding following insertion of IUCD.

**Conclusions:** Our results endorse our assumption that vascular changes may represent a critical part in the occurrence of heavy menstrual bleeding, so a study of TVDU of the uterine artery indices is a valuable adjuvant indicative means to predict the abnormal uterine bleeding for women pursuing the use of Cu-IUCD and lead to the proper choice for contraception and decrease the complications as possible.

**Keywords:** Heavy menstrual bleeding; Color Doppler Ultrasound; Copper IUCD; Uterine Artery Indices.



## INTRODUCTION

One of the most used birth control methods in the world is an intrauterine contraceptive device (IUCD). Interestingly the copper-IUD is the most popular and preferred method, especially for long-term reversible contraception, as it can be easily fitted and removed, with a 0.2 to 1 % failure rate [1], [2]. Heavy menstrual bleeding (menstrual bleeding > 80 ml per period) often combined with cramping is one of the major copper IUD-related side effects that can be extreme to the degree that it causes iron deficiency anemia and typically ends by requesting IUCD removal within the first year of insertion in so many cases (~ 5-15% of about 40 million women per year insert IUCD), [1], [3]. There is still no clear explanation of the impact

of copper IUD on uterine vascularization and its relation to IUD-pathophysiology inducing abnormal bleeding. The cause of heavy menstrual bleeding in women who used IUD can be explained by many potential mechanisms. Amongst those hypotheses, only a few studies that used two-dimensional (2D) power Doppler analysis have shown that IUD insertion induces increased endometrial development of prostaglandins, which improves vascular permeability, inhibits platelets, and thus increases bleeding of menstruation [4].

Applying spectral Doppler analysis in conjunction with 2D ultrasound offers the opportunity of quantifying uterine artery indices; PI and RI within a given volume of interest [5]. This technique may be a distinct non-invasive method for assessing

reproductive processes breeding methods; for analyzing the blood supply to the endometrium region [6]. The significance and goal of the present research were to assess the effectiveness of pre IUD insertion 2D-transvaginal Doppler ultrasound analysis of uterine artery in the prediction of a of a serious menstrual hemorrhage associated with IUCD to protect women at risk of bleeding.

## METHODS

This prospective observational study was handled in the family planning clinic at the Obstetrics and Gynecology Department in collaboration with the Radiology Department, Zagazig University Hospitals, Zagazig City, Sharika Governorate, Egypt, for a period of eight months from January 2019 to September 2019. The procedures of this study were approved by the Research Ethical committee, Faculty of Medicine, Zagazig University and to the obtained consent from the Institutional Review Board (IRB); (IRB Number: ZU-IRB#5037#03-12-2018). The study was done according to the code of ethics of the world medical association (Declaration of Helsinki) for studies involving humans. Before the beginning of the study, the suggested protocols were declared to all women, who wished to use (copper T-380A) IUD and met the inclusion criteria that mentioned below. History taking for the previous method of contraception had been used prior Cu-IUCD usage. General examination: involve body mass index (BMI), pulse, blood pressure, and examination of body systems were performed to discover any associated autoimmune diseases and medical conditions.

**Inclusion criteria:** young aged (20-35 years) old women, with normal menstrual bleeding cycle (24 and 35 days) who attends to the family planning clinic of obstetrics and gynecology department, and desired long-acting contraception, without hormonal therapy to at least 3 months prior IUCD insertion.

**Exclusion criteria:** Nulligravida, pregnancy, medication causing coagulation defects, severe dysmenorrhea, and associated uterine, cervical, or adenexal pathology. Detailed history taking including personal history (name, age, sex, and residence), history of previous medication, minor trauma, and history of drug intake or any past surgical operation. After exclusion of non-respondents and participants with the above-mentioned exclusion criteria, the patient's consent of all participants (100-woman) in this study was taking, then subjected to the following:

**Careful pelvic examination** to identify uterine size and position.

**Insertion of IUCD:** insertion of Cu-T380A was done postmenstrual or 6<sup>th</sup> week of postpartum by a gynecologist.

**Transvaginal ultrasonography (TVUS):** The woman was asked to evacuate the bladder before the examination and to lie in the supine position, with the knees bent on the upper level, and the feet rest on the lower level, and the uterus resumes its normal anteverted position. A binding gel was added to the vaginal probe, which was subsequently inserted into a sheath of rubber, and then inserted into the posterior vaginal fornix for uterus identification. Initially, an ultrasound (Siemens, Acuson X300 device with a Transvaginal convex probe (3.5-4.5 MHZ) frequency) 2-D B-mode real-time sonographic examination was performed to measure the uterine size and shape and exclude any uterine pathology, as well as IUCD position for displacement or not. Measuring the double layer of the endometrial thickness (EMT) was done by performing the measurement between the two basal layers of the anterior and posterior uterine walls.

**Transvaginal pulsed Doppler on uterine artery (TVPD):** After taking measures of the uterus, the mode was 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 Doppler color has been activated by 2D mode and established on the right and left uterine arteries. Then the mode was switched to pulsed Doppler and the blood flow velocity waveforms were displayed, and the image was fixed including three waveform signals at least. Calculations of RI and PI for both uterine arteries were done. TVUS was performed on women at the time of Cu-IUCD insertion, after three and six months follow up. All ultrasound scans were done on the fourth or fifth day of the menstrual period. At 2<sup>nd</sup> visit, all women had been classified into two classes based on the presence or lack of heavy menstrual bleeding:

**Group 1 (52 cases):** cases without complaint of heavy menstrual bleeding.

**Group 2 (48 cases):** cases with a complaint of heavy menstrual bleeding,

**Ethical consideration.** The study protocol was approved by the Institutional Review Board (IRB) and by the Research Ethical Committee in the faculty of medicine, Zagazig University (IRB Number: ZU-IRB#5037#03-12-2018).

**Patient consent** The suggested study protocols were conveyed to all participants, a verbal and an informed written consent document was signed by those who agreed to participate.

## STATISTICAL ANALYSIS

Results were displayed as a mean  $\pm$  standard deviation (SD) [95% confidence interval (CI)]. In both groups before and after IUD insertion, the Mann Whitney U test was used to match the respective variables. A difference at  $P < 0.05$  was deemed to be significant. The statistical study was

conducted using the Social Science Statistics Package (SPSS version 26.0 (SPSS Inc., Chicago, IL, USA).

**RESULTS**

A total of 100 women completed the study protocol; 52 had normal menstrual cycle after IUD insertion (group I; normal bleeding group), whereas 48 had menorrhagia (group II; heavy menstrual bleeding group). As presented in Table

(1), there was no significant difference with respect to the clinical aspects; age (P = 0.758), parity (P = 0.607) and basal hemoglobin concentration (P = 0.374) between the two groups, with a highly significant difference within the 2 groups concerning body mass index (BMI) and hemoglobin concentration at three- and six-months post IUCD insertion (p < 0.05).

**Table (1):** Participants’ data characteristics and its relation with heavy menstrual bleeding associated with IUCD.

	Number	Normal bleeding group (N = 52)		heavy menstrual bleeding group (N= 48)		Test	P-value
		Number	%	Number	%		
<b>Age (year)</b>		28.01 ± 5.51		28.43 ± 5.86		-0.308•	0.758 (NS)
<b>Body Mass Index (BMI kg/m2)</b>							
<b>Mean ± SD</b>		26.07 ± 4.51		28.58 ± 4.87		-2.671•	0.008 (S)
<b>Range</b>		20 – 34		20 – 36			
<b>Normal weight</b>	31	21	67.7%	10	32.3%	6.442‡	0.040 (S)
<b>Overweight</b>	45	23	51.1%	22	48.9%		
<b>Obese</b>	24	8	33.3%	16	66.7%		
<b>Parity</b>		2.04 ± 1.13		2.08 ± 1.02		-0.450•	
<b>Abortion</b>							
<b>Mean ± SD</b>		0.71 ± 0.91		0.60 ± 0.84		-0.514•	0.607 (NS)
<b>Range</b>		0 – 3		0 – 3			
<b>No</b>	57	29	50.9%	28	49.1%	1.694‡	0.638 (NS)
<b>One</b>	24	11	45.8%	13	54.2%		
<b>Two</b>	15	10	66.7%	5	33.3%		
<b>Three</b>	4	2	50%	2	50%		
<b>Hemoglobin (g/dl)</b>							
<b>At time of insertion</b>		10.894 ± 0.282		10.836 ± 0.370		* 0.893	0.3740 NS
<b>At 3 month</b>		10.616 ± 0.32		9.778 ± 0.370		* 12.23	0.000\ HS
<b>At 6 month</b>		10.796 ± 0.314		9.578 ± 0.372		* 17.73	0.000\ HS

‡ Chi-square test. •Mann Whitney U test. \* Student T-test P < 0.05 is significant. Sig.: Significance.

Also, the result of our study revealed that the uterine artery blood flow when menstruation is significantly higher in women with Cu-IUD induced bleeding reflected as decreased in uterine artery indices (PI and RI) with high EMT prior IUCD insertion, three- and six-months post-insertion relative to the normal non-bleeding group (1) (p < 0.05), as represented in Table (2).

**Table (2):** Comparison between women without and with heavy menstrual bleeding associated with IUCD regarding ultrasound and color Doppler measurements before IUCD insertion.

	Normal bleeding group (N = 52)	heavy menstrual bleeding group (N= 48)	Mann Whitney U test	p-value
<b>Endometrial thickness (EMT; mm) Mean ± SD</b>				
before insertion	5.749 ± 0.364	6.439 ± 1.01	-4.772	<0.001 (HS)
after 3 months	5.857 ± 0.358	6.852 ± 0.992	-5.900	<0.001 (HS)
after 6 months	5.979 ± 0.296	7.326 ± 0.98	-7.004	<0.001 (HS)
<b>Pulsatility index (PI) Mean ± SD</b>				
before insertion	2.433 ± 0.124	1.997 ± 0.122	-8.173	
after 3 months	2.381 ± 0.121	1.925 ± 0.126	-8.095	
after 6 months	2.335 ± 0.102	1.848 ± 0.133	-8.048	
<b>Resistance index (RI) Mean ± SD</b>				
before insertion	0.909 ± 0.091	0.776 ± 0.069	-7.091	
after 3 months	0.874606 ± 0.059	0.735 ± 0.063	-7.519	
after 6 months	0.873 ± 0.052	0.701 ± 0.065	-7.999	

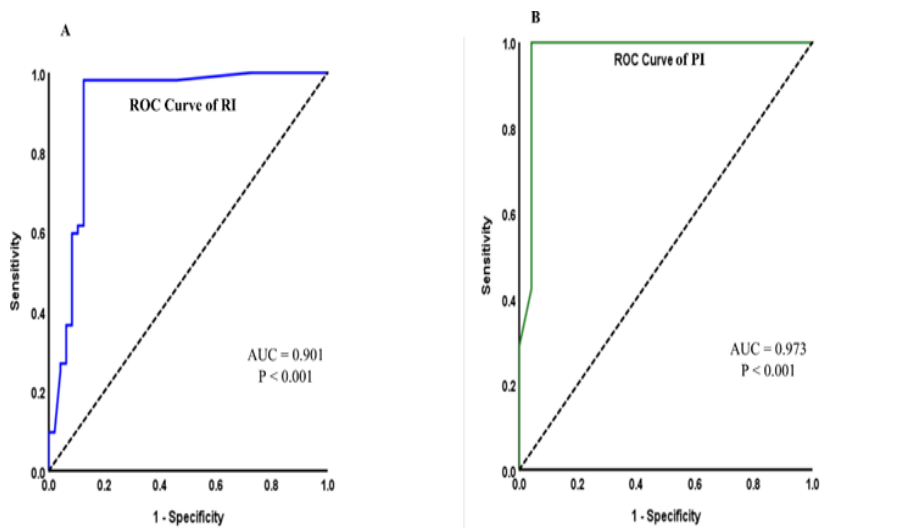
• Mann Whitney U test. p < 0.05 is significant. Sig.: Significance.

Multiple regression analyses of the participant's characters and heavy menstrual bleeding-related IUCD showed that the resistance index of the uterine artery (RI ≤ 0.809) was correlated with excessive menstrual bleeding post insertion of IUCD ( specificity 87.5% and sensitivity 98.1 %, with AUC 0.9101, at p-value < 0.001). Additionally, pulsatility index of the uterine artery (PI ≤ 2.078) was consistent with heavy menstrual bleeding following insertion of IUCD (sensitivity 100 % and specificity 85.4 %, with AUC of 0.973 at p-value < 0.001 as presented in Table (3) and revealed in ROC curve of RI (Figure. 1 A) and PI (Figure. 1 B) uterine artery indices.

**Table (3):** Multiple logistic regression interpretation of women’s properties and heavy menstrual bleeding associated with IUCD.

	AUC	Sensitivity %	Specificity %	Cut-off Values	p-value (Sig.)
<b>PI</b>	0.973	100	85.4	2.078	< 0.001
<b>RI</b>	0.9101	98.1	87.5	0.809	< 0.001

PI = Pulsatility index, RI = Resistance index, AUC = Area under the curve.

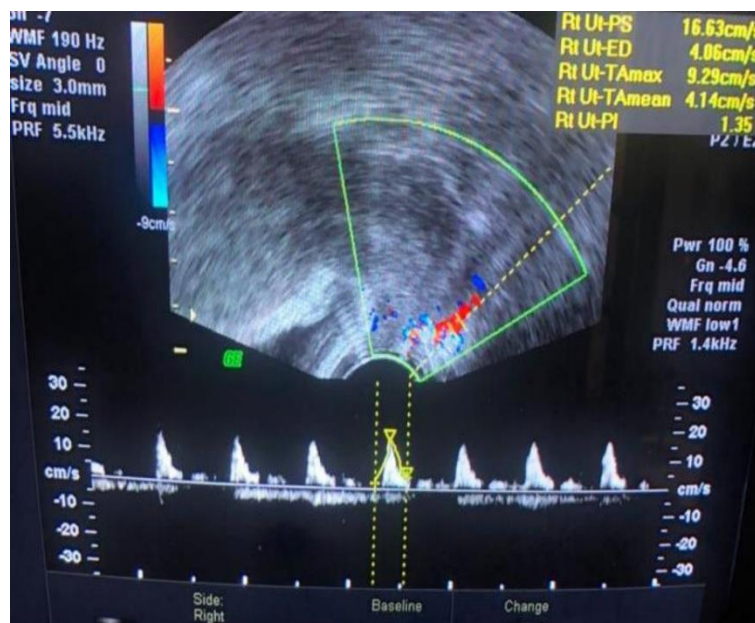




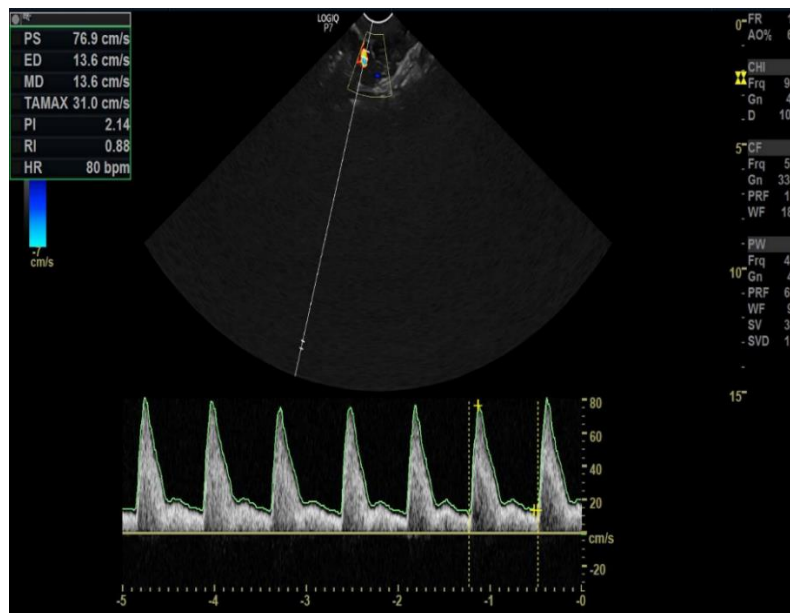
**Figure (1):** Receiver operating characteristic (ROC) curve of resistance (RI) index (A) and pulsatility (PI) index (B) before IUCD insertion as an indicator of heavy menstrual bleeding associated with IUCD.



**Figure (2):** Average uterine width, length, and endometrial thickness of the uterus of a woman in non-bleeding group.



**Figure (3):** Uterine artery indices in the bleeding group three months after insertion.



**Figure (4):** Average values of uterine artery RI and PI in the non-bleeding group three months after insertion.

## DISCUSSION

IUCD is a commonly accepted way of contraception for most women of reproductive age (~ 14.3 % worldwide with < 2% in some countries whereas more than 40% in others) who bypassing the systemic impacts of hormonal contraception and the inefficiency of local methods or other physiological techniques [7]. The mode of action of IUCD is not entirely known but many theories have been suggested that IUCD interfere with implantation and fertilization by making the endometrium unsuitable for implantation and through the daily release of foreign body (Copper T380 A release copper ions ~ equal to 1 % of the copper administered orally / day), which inhibit sperm motility and capacitation [8]. Besides, IUCD stimulates tubal peristalsis so the ovum reaches the uterine cavity before fertilization or before the endometrium is ready for implantation. It also, causes utero-tubal spasm preventing the meeting of the ovum and spermatozoa. The effect of IUCD may be pre and post-fertilization but the majority of its effect is pre-fertilization [9]. Unfortunately, the high potential use of Copper T380 A IUCD for contraception is hampered, and in the 1<sup>st</sup> year of usage, about 10% of IUD users require removal by menstrual complications, especially postinsertion bleeding, and heavy menstrual bleeding which are the most common adverse effects associated with the use of the IUCD [10]. IUD-related side effects such as abnormal uterine bleeding have been proposed as a secondary consequence of reduced arterial resistance or a result of changes in prostaglandin synthesis and an increased blood flow in the uterus, that both could be detected by a Doppler color sonography. However, none of these hypotheses are definitive, so from the viewpoint of

improving the quality of life for women, Doppler analysis of uterine artery indices (RI and PI) have a significant role in the prediction of heavy menstrual bleeding prior to IUD insertion.

To determine the relation between heavy menstrual bleeding following IUCD insertion and Doppler uterine artery to protect women at risk of bleeding, we try studying the vasculature of the endometrium of the uterus by measurement of uterine artery blood flow using Doppler ultrasound. One hundred women were involved in the current study; 52 with IUCD without heavy menstrual bleeding and 48 complain of heavy menstrual bleeding. In the current study, we found a non-significant difference between the study groups concerning the demographic data (age and parity) and sonographic findings related to uterine size at the beginning of the study as depicted in Table (1), which is agreed with the finding of Rezk et al., [11]. While the endometrial thickness was significantly higher in cases of heavy menstrual bleeding which was attributed to associated hormonal disturbance leading to increased thickness and vascularity that is in accordance with the finding of Ait-Allah et al., [6]. Also, the uterine blood flow was significantly higher and the Doppler indices (RI and PI), were significantly lower in cases of heavy menstrual bleeding in comparison to the normally menstruating women. This is in accordance with the findings of Lakhani and Hardiman [12]. The relation between PI, increase in uterine blood flow, and an increase in menstrual blood loss is explained in different mechanisms. Prostacyclins and prostaglandins perform a critical part in the Cu-IUD- induced heavy menstrual bleeding, besides, prostaglandins are known to influence the regulation of blood flow

in uterine arteries [4]. Women who complain of heavy menstrual bleeding also undergo substantial increases in the proliferation of endothelial cells due to disrupted angiogenesis [13]. Xin et al., also stated the postulated mechanism that describes the relation between low PI and RI in women who complain of heavy menstrual bleeding. The expression of the microvessel density (MVD), vascular endothelial growth factor (VEGF), and its receptor, besides kinase, inserted domain-containing receptor (KDR) is reported to have increased in the endometrium following the insertion of the cu-IUCD [14]. So it is possible that cu-IUCD (according to our study and Xin et al. base) induces a change in the production of the prostaglandins and enhances the angiogenesis in the endometrium, this contributes to an increase in blood flow in the uterine artery and inhibits the platelet activation, consequently increase menstrual bleeding. Our results are consistent with early studies [15], [16], and [17], which documented substantial changes in endometrial thickness and Doppler indices of a uterine artery; (RI, and PI) that recorded pre and post- IUCD insertion. Fouda et al., assessed uterine artery RI and PI in ninety-three women in three classes; group (I) of 32 women who had IUCD complaints of heavy menstrual bleeding, group (II) of 30 women who were with IUCD-normal menstrual cycle, and a control group of 31 women without IUCD. In group (I) the RI and PI uterine artery indices were substantially smaller than in group (II) and group (III) [18]. Also, in agreement with the results of Yigit et al., who noted a substantial increase in the systole/diastole ratio and PI of the uterine artery three to five months after copper IUD insertion. Even so, uterine artery PI was considerably lower in patients with high scores of bleeding than those without elevated bleeding levels [19]. While they agree with our finding and many other studies concerning the decreasing of RI and PI, their notice of the elevation of PI and RI after IUCD insertion is of discussion. Other earlier studies of the Doppler uterine artery showed contrary findings. Shen et al., stated the absence of any notable change in the blood flow as a consequence of the insertion of Cu- IUCD in both uterine arteries Doppler indices (PI and RI) pre and following insertion of Copper medicated IUD (Nova T) in either group with or without IUCD-related heavy menstrual individually [20]. Desauza and Geber, assessed the PI and RI indices of the uterine artery in both sides in 100 women, verified that there was no substantial difference in uterine blood flow among 100 participants who wanted to use the IUCD as contraception and experienced an increase in menstrual bleeding post copper IUD insertion when examined pre and post one month

of insertion, as there is not enough time for complications to occur and that they did not pick heavy menstrual bleeding cases [21]. But in our study, we presented the cases of heavy menstrual bleeding (N = 48) besides that there is a highly significant change in endometrial thickness, RI, and PI before and after 3 and 6 months of IUCD insertion. Additionally, there were not statistically relevant variations in RI and PI of the uterine artery among women with IUD-induced bleeding and women having the usual menstrual cycle, as recorded by, El-Mazny et al., [1] and Jamenez et al., [3]. Regarding the ROC curve of RI and PI before Cu-IUCD insertion, Figure (1), we found that  $RI \leq 0.83$  and  $PI \leq 2.02$  were correlated with excessive menstrual bleeding post insertion of IUCD which is in sound accordance with previous results reported by Rezk et al., (PI artery  $< 1.5$  and RI  $< 0.65$ , p-value  $< 0.001$ ) [11], and Mansour et al., (PI artery  $\leq 1.9$  and RI  $\leq 0.76$ , p-value  $< 0.001$ ) [2].

## CONCLUSIONS

In conclusion, RI and PI indices of the uterine artery were less in women with IUD-mediated menorrhagia than others who are not complaining of heavy menstrual bleeding, as indicated by 2D power Doppler sonography study pre the insertion of Cu-IUCD. The presented results prove our assumption that the uterine blood flow increases in patients with abnormal uterine bleeding correlated with Cu-IUD. We, therefore, recommended using TVD analysis before IUD insertion to classify women at risk of experiencing irregular uterine bleeding post insertion of Cu-IUD. For women with initial low values of uterine artery indices; RI and PI, another form of contraception should be considered.

**CONFLICT OF INTEREST:** None

**FINANCIAL DISCLOSURES:** None

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