Role of Ultrasonography in Intrauterine Contraceptive Device Utilization in Mansoura University Hospital

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Abstract

Background: More often than any other type of contraception, intrauterine contraceptive devices (IUCDs) are used in Egypt. In most cases, a non-guided procedure is used to insert IUCDs in office settings. Blind insertion possibly causes various complications including perforation. It is recommended to conduct TVUS prior to insertion in order to determine the uterus's size and orientation, as well as to rule out the possibility of pregnancy or pathology. Moreover use of TVUS during regular follow up may improve outcomes and help reduce IUCD related complications.

Aim of the work: Compare ultrasound-guided and non-ultrasound-guided IUCD insertion techniques for proper placement, problems, time, and patient satisfaction during insertion and follow-up.

Patients and methods: The study recruited 200 women using copper TCu-380A that were randomly divided into two groups (Each of 100 females), subgroup U (where ultrasound guided technique before insertion, during insertion and follow up and subgroup B (with non-ultrasound guided technique for IUCD insertion). The primary outcome was measuring the proper device placement post-insertion and after the next menstruation. Secondary outcomes included measuring the incidence of complications including perforation, expulsion, cervical problems, bradycardia, syncope, measuring patient satisfaction, assessment of difficult IUCD insertion and pain scores.

Results: The overall incidence of complications was statistically significantly higher in the non-ultrasound guided technique group as compared to the ultrasound group. The duration for insertion was statistically significantly longer in the non-ultrasound guided technique group as compared to the ultrasound group. The Pain score during insertion was statistically significantly higher in the non-ultrasound guided technique group as compared to the ultrasound group. The degree of satisfaction was statistically significantly higher in the ultrasound technique group.

Conclusions: Several positive outcomes were linked to the use of TVUS during the insertion of IUCD, including a shorter insertion duration, lower pain levels, a higher degree of satisfaction, and a smaller frequency of problems. Also, TVUS scan during regular follow up substantially help reduce IUCD related complications and improve continuity of the method.

Key words: IUCD, Ultrasound, Blinded, Insertion, Satisfaction.

Introduction

Negative effects on maternal and fetal health can result from unwanted pregnancies in a number of ways, including unsafe abortion, postponed prenatal care, negative consequences for children, and diminished educational and economic possibilities for the pregnant woman [1].

The Intrauterine Device (IUCD) is the most used reversible contraception worldwide with a prevalence usage rate of 15%. IUCDs offer simple, efficient, safe, and low-cost reversible and long-term contraception [2].

Traditional technique of IUCD insertion and lack of regular follow up approach may result from problems, failure, or difficulties associated with intrauterine contraceptive device insertion [3]. Five to fifteen percent of women will have their IUCD removed in the first year following insertion due to irregular uterine bleeding caused by device-endometrium contact and uterine muscle pressure. Most bleeding problems are caused by the IUCD's disharmonious interaction with the uterus, hence inappropriate position should be ruled out before switching birth control methods [4].

TVUS is the gold standard choice for guidance of insertion and assessing IUCD position and consequences [5].

Researchers have conducted a comparison between ultrasound guided and blind IUCD insertion techniques in terms of the correct placement of the IUCD in the uterus, the occurrence of problems, the time required for the procedure, and patient satisfaction. According to their findings, ultrasonography-guided IUCD insertion is superior to blind techniques in terms of achieving the desired fundal position of the device with a lower risk of problems, less discomfort, and higher patient satisfaction [6, 7].

It is intended in this current study to compare both techniques and use of TVUS during follow up visits.

Patients and Methods

Over the course of a year, researchers at Mansoura University Hospital's Obstetrics and Gynecology Department performed a prospective randomized interventional trial.

The study included 200 women using copper TCu-380A in Reproductive and Fertility Unit at Mansoura University Hospitals. The females were randomly divided into two groups (Each of 100 females), **subgroup U** (Ultrasound guided technique before insertion , during insertion and follow up and **subgroup B (Blind technique)**

The current study included regularly menstruating women before IUCD insertion in the age between 20 and 45 years who didn’t receive non-steroidal anti-inflammatory at 24 hours before the examination.

The cases with the following criteria were excluded; septic abortion, unexplained abnormal vaginal bleeding, cervical cancer, malignant, benign gestational trophoblastic disease, uterine cancer, uterine anomalies, endometrial polyps and uterine fibroids, pelvic infection within the past three months and presence of pelvic pathology as ovarian cysts, pelvic endometriosis.

All procedures adhere to the 2013 Helsinki Declaration [8]. All subjects provided written informed consent after the study was approved by the Mansoura university faculty of medicine's institutional review board.

Full medical history, detailed physical examination and routine laboratory investigations were conducted to all the included females.

Ultrasound

TVUS was conducted before insertion for both subgroups (B and U) for measurements of dimension of the uterus, determination of the position of the uterus (RVF, lateral position) and to detect any associated abnormalities (cervical, uterine or adnexal). Ultrasound was also used during the insertion for U subgroup to assure proper fundal placement of the device. US guidance helps prevent uterine perforation.

Technique for IUCD insertion:

- Encourage women to micturate for emptying the bladder.
- Placing women in a lithotomy position.
- Under aseptic and antiseptic measures the cervix was seen with sterile Cusco's speculum.
- We used a vulsellum to tract the cervix and introduce uterine sound to assess uterine length and orientation.
- TVUS scan was performed to confirm uterus position and its measurments .
- Inserting IUCD in the uterine cavity without touching it. Safety is best with "no-touch" implantation. This includes keeping the loaded IUCD and uterine sound away from unsterile surfaces.
- The no-touch technique involves:
  - IUCDs should be loaded into the inserter when still in their sterile package to avoid direct contact.
  - Prior to inserting the IUCD, make sure to clean the cervix well with antiseptic.
  - When using the uterine sound or loaded IUCD inserter, avoid touching the vaginal wall or speculum blades.
  - Making just one trip through the cervical canal with the uterine sound and the loaded intrauterine contraceptive device (IUCD) inserter.
- Following insertion, TVS was performed to verify proper placement of the IUCD.

Follow up was performed for both groups at the following time points, after one month or next menstruation, after 3 regular cycles or 3 months, after 6 months, after 9 months and after 12 months for both groups or when complications occur as bleeding, pain, pregnancy, malposition and missed threads.

Study outcomes

The main outcomes after insertion and following the subsequent menstruation, measure the appropriate positioning of the device.

The secondary outcomes were to asess the incidence of the associated complications included perforation, expulsion, cervical problems, bradycardia, syncope, measuring patient satisfaction, identification of difficult IUCD insertion and assesment of pain score during insertion.

Difficulty of IUCD insertion was measured by whether uterine sound with a diameter of 4 mm or smaller can pass through the internal cervical os or not. Internal cervical os resistance as a measure of IUCD insertion difficulties. Using the following scale, researchers were to ascertain how challenging it was to pass both the sound and the IUCD: Easy (1-2) Normal (3-4) Mild difficulty (5-6), Severe difficulty (9-10).

All women were taught how to express their pain (during insertion) on an eleven-point scale (VAS), from 0 to 10, with 0 for no pain, and 10 for the maximum pain ever felt [9].

Any intrauterine contraceptive device (IUCD) that was more than 3 mm away from the fundal endometrial surface was deemed misplaced [10]. It was determined that expulsion had occurred if the intrauterine contraceptive device had passed through the external cervical os, even marginally [10].

Statistical analysis

Coding, processing, and analysis of the data

were carried out using the SPSS 26 for Windows® application. The qualitative data was presented in percentage and number form. To compare groups, researchers used the Chi-Square test, which is also known as Fischer's Exact test or the Monte-Carlo test. Quantitative data was examined for normalcy using the Kolmogorov-Smirnov test. The range and mean ± SD were the ways the data was shown.

A Mann Whitney U test was employed in the event that the data did not follow a normal distribution, and an independent samples t-test was utilized to compare the two groups with normally distributed quantitative variables. P values <0.05 are considered significant.

Results

The study included 200 women using copper TCu-380A in Reproductive and Fertility Unit at Mansoura University Hospitals. The females were randomly divided into two groups (Each of 100 females), **subgroup U** (Ultrasound guided technique) before insertion, during insertion and follow up and **subgroup B (Blind technique)**.

Table (1) shows that there was no statistically significant difference between the two study groups regarding the Age, BMI, parity, previous vaginal delivery, and previous CS. The mean age in the ultrasound technique group was 31.02 ± 7.20 years while in the non-ultrasound guided technique group, the mean age was 33.15 ± 8.26 years. The mean BMI in the ultrasound technique group was 30.26 ± 4.90 kg/m2 while in the non-ultrasound guided technique group, the mean BMI was 31.04 ± 6.54 kg/2.

Table (1): Demographic characteristics among the studied groups

Variables		Groups		P value
		Ultrasound technique (Subgroup U) (N=100)	Non ultrasound guided technique (Subgroup B) (N=100)	
Age (years)	Mean ± SD	31.02 ± 7.20	33.15 ± 8.26	**0.153**
	Range	19 - 42	19 – 41	
BMI (Kg/m^2)	Mean ± SD	30.26 ± 4.90	31.04 ± 6.54	**0.340**
	Range	20.48 – 34.15	20.28 – 35.12	
Parity	Mean ± SD	2.76 ± 1.14	2.93 ± 1.27	**0.352**
	Range	1- 6	1- 6	
Previous vaginal delivery	Mean ± SD	1.71 ± 0.92	1.95 ± 0.97	**0.137**
	Range	0 - 5	0 – 6	
Previous CS	**Mean ± SD**	**1.36 ± 0.90**	**1.24 ± 0.92**	**0.234**

Table (2) reveals that there was no statistically significant difference between the two study groups regarding the sounding status. Successful sounding was reported in 97% and 94% in the ultrasound technique group and blinded technique group respectively

Table (2): Sounding status among the studied group

	Groups				Test of significance
	Ultrasound technique (Subgroup U) (N=100)		Non ultrasound guided technique (Subgroup B) (N=100)		
Sounding status					
Success	97	97 %	94	94 %	0.306
Failure	3	3 %	6	6 %	

Table (3) discloses that at the baseline, the fundal distance was statistically significantly higher in the non-ultrasound guided technique group as compared to the ultrasound technique group (5.70 ± 3.40 mm versus 3.30 ± 1.02 mm respectively).

Table (3): Fundal Distance (D) immediately after insertion among the studied groups

		Groups				Test of significance
		Ultrasound technique (Subgroup U) (N=100)		Non ultrasound guided technique (Subgroup B) (N=100)		
Fundal distance	Mean ± SD	3.30 ± 1.02		5.70 ± 3.40		0.001*
	Range	1.5 – 5		-4 – 12.4		
Fundal distance grades						
0 – 3 mm		41	41 %	27	27 %	
3.1 – 10 mm		59	59 %	68	68 %	0.001*
> 10 mm		0	0 %	5	5 %	

Table (4) records that at one month follow up, the fundal distance was statistically significantly higher in the non-ultrasound guided technique group as compared to the ultrasound technique group (6.68 ± 2.58 mm versus 5.75 ± 2.32 mm respectively).

Table (4): Fundal distance (D) at follow up postmenstrual after one month among the studied groups.

Variables		Groups				Test of significance
		Ultrasound technique (Subgroup U) (N=100)		Non ultrasound guided technique (Subgroup B) (N=100)		
Fundal distance	Mean ± SD	5.75 ± 2.32		6.68 ± 2.58		0.014*
	Range	2.7 - 10		2.7 – 13.3		
Fundal distance grades						
0 – 3 mm		22	22 %	15	15 %	0.016*
3.1 – 10 mm		78	78 %	78	78 %	
> 10 mm		0	0 %	7		7 %

Table (5) demonstrates that follow up downward displacement (mm) postmenstrual after one month didn't show a statistically significant difference between the two groups.

Table (5): Follow up downward displacement (mm) postmenstrual after one month among the studied groups.

		Groups				Test of significance
		Ultrasound technique (Subgroup U) (N=100)		Non ultrasound guided technique (Subgroup B) (N=100)		
Displacement	Mean ± SD	2.74 ± 1.75		2.80 ± 1.89		z = - 0.310 p= 0.756
	Range	- 0.6 – 5.4		- 1.5 – 5.9		
Displacement > 5 mm		9	9 %	14	14 %	c^2 = 1.228 P = 0.268

Table (6) reveals that the overall incidence of complications was statistically significantly higher in the non-ultrasound guided technique group as compared to the ultrasound group (12% versus 2%). In the ultrasound group, complications were bradycardia in 2% while in the non-ultrasound guided technique group, complications were bradycardia 4%, partial perforation 6%, Low lying IUCD in 6%, cervical displacement in 2% and expulsion in 2%.

Table (6): Complications in the two studied groups

	Groups				Test of significance
	Ultrasound technique (Subgroup U) (N=100)		Non ultrasound guided technique (Subgroup B) (N=100)		
Bradycardia	2	2 %	4	4 %	FET = 0.338 P = 0.561
Syncope	0	0 %	0	0 %	----------
Partial perforation	0	0 %	6	6 %	FET= 3.046 P = 0.081
Low lying IUCD	0	0 %	6	6 %	FET= 3.046 P = 0.081
Cervical displacement	0	0 %	2	2 %	FET= 1.005 P = 0.316
Expulsion	0	0 %	2	2 %	FET= 2.020 P = 0.155
Overall	2	2 %	12	12 %	FET= 5.664 P = 0.002*

Table (7) the following table discloses that the duration for insertion was statistically significantly longer in the non-ultrasound guided technique group as compared to the ultrasound group (7.58 ± 0.90 minutes and 5.94 ± 1.19 minutes respectively).

The Pain score during insertion was statistically significantly higher in the non-ultrasound guided technique group as compared to the ultrasound group (1.77 ± 0.72 and 0.98 ± 0.65 respectively). The degree of satisfaction was statistically significantly higher in the ultrasound technique group.

Table (7): Evaluation of pain and patients' satisfaction in the two study groups.

		Groups				Test of significance
		Ultrasound technique (Subgroup U) (N=100)		Non ultrasound guided technique (Subgroup B) (N=100)		
Time (minutes)	Mean ± SD	5.94 ± 1.19		7.58 ± 0.90		t = - 11.001 p < 0.001*
	Range	4 - 8		6 – 9		
Pain score during insertion	Mean ± SD	0.98 ± 0.65		1.77 ± 0.72		z= - 6.920 p < 0.001*
	Range	1 (0 -2)		2 (1 – 3)		
Degree of satisfaction						
Dissatisfied	16	16 %	38	38 %		C^2 = 15.742 P < 0.001*
Satisfied	84	84 %	62	62 %		

Discussion

The purpose of this research was to evaluate the efficacy of ultrasonography-guided versus non-ultrasound-guided intrauterine contraceptive device insertion procedures with respect to the following: correct fundal positioning of the IUCD, frequency of problems, time required for insertion and follow-up, and patient satisfaction.

The study included 200 women using copper TCu-380A and were randomly divided into two groups (Each of 100 females), subgroup U (where ultrasound guided technique before insertion, during insertion and follow up and subgroup B (with non-ultrasound guided technique for IUCD insertion).

The current study showed that both groups are comparable regarding demographic data as Age, BMI, parity, previous vaginal delivery, and previous CS.

This was similar to the trial that randomized 300 eligible women for IUCD insertion into two groups of 150 women, TAS-guided IUCD insertion versus non-TAS-IUCD insertion (no ultrasonography). The mean age, parity, number of previous CSs, BMI, and IUCD insertion time did not differ between the two groups (P=0.9, P=0.08, P=0.1, and P=0.9, respectively) [11].

This was also confirmed by another study (Abbas), who randomly assigned 102 female IUCD implantation patients to the TAS-guided and traditional groups (51 in each group). Compared to age, gravidity, parity, BMI, previous deliveries, IUCD history and duration, and IUCD-associated problems, there was no statistical significance [6].

This indicates the process of effective randomization to avoid the selection bias and exclude this effect on the results.

In this study, sounding status did not differ statistically between groups. Successful sounding was reported in 97% and 94% in the ultrasound technique group and non-ultrasound guided technique group respectively.

According to Elhoussieny et al., the ultrasound-guided and non-ultrasound-guided method groups had 98% and 96% success rates, respectively, with no statistically significant difference [7]

In contrast, El-Bahnasy et al. found that 3% of women who had ultrasound-guided IUCD insertion had failed insertion and 96% had it in place, while in traditional IUCD insertion, 6% had failed insertion, 80% had it in place, and 14% had it low lying. High statistical differences existed between groups (P<0.001) [12].

Elsedeek examined the effectiveness of trans-abdominal ultrasonography guidance in IUCD insertion identification in her cohort study. She evaluated 80 parous women's IUCD after the operation and one week later. Proper IUCD fitting and placement were accomplished in 32 (80%) and 27 (68%) women compared to 39 (98%) and 38 (95%) women in the non-ultrasound guided and ultrasound guided groups (P = 0.04 and 0.02). Ultrasound guidance improved IUCD placement and fit compared to non-ultrasound guidance [13].

In the current study, the fundal distance was statistically significantly higher in the non-ultrasound guided technique group as compared to the ultrasound technique group (5.70 ± 3.40 mm versus 3.30 ± 1.02 mm respectively). At one month follow up, the fundal distance was statistically significantly higher in the non-ultrasound guided technique group as compared to the ultrasound technique group (6.68 ± 2.58 mm versus 5.75 ± 2.32 mm respectively).

According to Elhoussieny et al., fundal distance (distance between the IUCD and inner uterine wall) 0.0 -0.3 mm was substantially more prevalent in group U than group B (P=0.009) shortly after insertion [7].

The current results showed that the Pain score during insertion was statistically significantly higher in the non-ultrasound guided technique group as compared to the ultrasound

group (1.77 ± 0.72 and 0.98 ± 0.65 respectively).

This matches a recent meta-analysis of seven RCTs involving 1267 subjects. In the ultrasound-guided group, IUCD insertion reduced VAS pain (P = 0.001) [14].

In agreement with Samaha et al., TAS-IUCD insertion resulted in considerably decreased mean pain scores (1.3 ± 1.02 vs. 1.6 ± 0.76, P=0.0001) [11].

According to El-Bahnasy et al., ultrasound-guided IUCD insertion patients reported discomfort between 1-5 with Median (IQR). 4 (3–5); conventional IUCD insertion group: 3-8 (IQR). 7 (6 – 8). Significant differences were found between groups (P<0.001) [12].

Elhoussieny et al. showed that pain perception (VAS-100) was significantly lower among group ultrasound guided group than among group non ultrasound guided technique group [7]

Abbas observed that TAS-IUCD insertion was statistically superior to regular IUCD insertion in participant pain assessments (P<0.001) [6].This is because ultrasound-guided IUCD insertion eliminates unwanted manipulations (touch/push) of the cervix or uterus, which can cause additional pain.

In this study, the duration for insertion was statistically significantly longer in the non-ultrasound guided technique group as compared to the ultrasound group (7.58 ± 0.90 minutes and 5.94 ± 1.19 minutes respectively).This supported Baradwan et al.'s finding that ultrasonography guided reduced procedure insertion time compared to control (P < .001) [14].

El-Bahnasy et al. found that ultrasound-guided IUCD insertion took 25-45 seconds, with a mean ±S.D. of 35.56 ±6.323, while traditional IUCD insertion took 56-110 seconds, with a mean ±S.D. of 82.44±17.545. Significant differences (P < 0.001) were found between groups, supporting our findings [12]. This also was in the same line with Abbas who reported that the mean time for IUCD insertion in the TAS-guided IUCD insertion was 32.2 ± 14.8 seconds versus 77.7 ± 30.6 seconds in the traditional group (p < 0.001) [6].

In agreement with our findings, Elsedeek et al. (2016) found that US-guided procedures were shorter [13].

A key distinction between the two techniques, in favor of the new methodology, was the number of stages and instruments needed by the old method. When a patient is in a lot of pain, they tend to move around a lot, which makes the treatment more difficult and takes longer.

However, according to Ali et al. (2019). Examined the time and pain of intrauterine contraceptive device insertion using trans-abdominal ultrasound (US-guided) and the Uterine Sounding Sparing Approach (USSA). According to their research, USSA is a superior method that significantly reduces treatment time and pain while increasing patient satisfaction [15].

Our results showed that the degree of satisfaction was statistically significantly higher in the ultrasound technique group. According to El-Bahnasy et al., there was no statistically significant difference between groups (P=0.436) in patient satisfaction, with 89% satisfied and 11% unsatisfied in the ultrasound-guided IUCD insertion group and 41% with 59% in the traditional group [12]. Additionally, the ultrasound-guided group had a higher rate of satisfied women, according to Baradwan et al. [14].

According to Elhoussieny et al., there was a marked decrease in patient dissatisfaction in the group that had ultrasonography guidance compared to the group that did not [7]

In the current study, the overall incidence of complications was statistically significantly higher in the non-ultrasound guided

technique group as compared to the ultrasound group (12% versus 2%) (p= 0.002). This agrees with the findings of Baradwan et al., who demonstrated that problems and misplaced IUCDs were significantly reduced when the insertion was guided by ultrasonography [14].This aligns with El-Bahnasy et al.'s findings of substantial differences (P< 0.001) in IUCD insertion complications between groups. Ultrasound-guided IUCD side effect 71% of IUCD-inserted women had no complications, 16% suffered bleeding, 7% pelvic pain, and 6% backache. In traditional IUCD insertion, 69% of women experienced no complications, 20% bleeding, 9% pelvic pain, and 2% backache [12].

Maged et al. found that ultrasound-guided group ladies had fewer problems, including bleeding and procedure failure, than controls. In terms of other problems, such as infection and perforation, both groups were comparable [16].

The overall complication rate was much lower in the group who underwent ultrasonography guidance compared to the group that did not.

With just two cases recorded in the group using the non-ultrasound guided approach, there was no statistically significant difference in the incidence of expulsion between the two groups (p= 0.155).This was in line with the findings of Samaha et al., who found no statistically significant difference in the rate of IUCD expulsion between the groups who had TAS-IUCD insertion and those that did not (0.7% (1/150) versus 1.3% (2/150), respectively, P=0.6) [11].

A number of complications, including uterine colic, bleeding, unplanned pregnancies, expulsion, and IUCD displacement, can arise from the use of IUCDs [17, 18]. In this study, one-month postmenstrual downward displacement (mm) did not differ between groups statistically. The incidence of cervical displacement was not statistically significant (p= 0.155) and only two cases of expulsion were documented in the non-ultrasound guided method group. This contradicted Samaha et al., who found that TAS-IUCD insertion considerably reduced cervical IUCD displacement (0% (0/150) versus 2% (3/150), P=0.03) [11].

Also, TAS-guided IUCD insertion enables for correct IUCD placement and decreases the danger of expulsion and mal-positioning, according to Balica et al., Which could lead to fewer cases of unwanted pregnancies, less pain after the procedure, and happier patients who get intrauterine device [19].

In a study by McCool, 21% of symptomatic women needed IUCD removal (19% due to incorrect IUCD position) and 18% of asymptomatic women needed it based on ultrasound findings.

While perforation of the uterus during intrauterine device insertions occurs in 0.6–16% of all insertions, it is more likely to occur if the device is inserted within four to six weeks following either the delivery of the baby or an elective abortion [20].Neither the incidence of low-lying IUCD (p=0.081) nor the incidence of partial perforation (p=0.081) differed significantly between the two groups in the present work. The non ultrasound guided technique group, complications were bradycardia 4%, partial perforation 6%, Low lying IUCD in 6%.

Samaha et al. did not find any perforations, pregnancies, or mal-positioned IUCDs in their investigation, which is in line with the current findings [11].

The main limitation of the study is that is a single center study that couldn't reflect the variations in the technical skills of the operator that could affect the results.

Conclusion

The use of ultrasound during the insertion of IUCD was associated with some favorable outcomes such as shorter duration of insertion, less pain scores and higher degree

of satisfaction lesser incidence of complications. Although the overall success rate was higher in the ultrasound group, it showed no statistically significant difference compared to the non-ultrasound guided technique group. A multicentric study is recommended based on regular follow up of IUCD,being guided by TVUS scan.

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