Original Article

Efficacy and Safety of Ultrasound Guided versus Blind Technique for Office Insertion of Intrauterine Contraceptive Device in Women with Previous Cesarean Section; A Randomized Controlled Clinical Trial

Ahmed M. Abdelraheem, Ahmed M. Mekled, Ola A. Abdel Razek and Gihan S. Elhawwary

Department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University, Egypt

ABSTRACT

Background: Intrauterine devices (IUD) are a highly successful type of contraception, if not the most effective, with normal use-related failure rates of 0.2-0.8 percent. Difficulties with IUD application, failure, and complications can reduce the use of this successful technique.

Objective: Comparison between ultrasound guided and blind IUD insertion technique as regards proper fundal location, incidence of complications, time consumption and patient satisfaction in women with previous cesarean section.

Methods: The randomized controlled comparative clinical was conducted of 100 women attended family planning clinic seeking contraceptive method. All eligible participants were randomly distributed into two equal groups. For both groups, Copper TCu-380A (Pregna®, DKT, Egypt) was inserted with withdrawal insertion technique blindly in group A and ultrasound guided in group B.

Results: The time needed for the procedure was statistically significant shorter, degree of pain during IUD insertion was lower and patient satisfaction was higher with ultrasound guided insertion technique compared with blinded one. On the other hand, there were no statistically significant differences between study groups as regard proper fundal device placement, degree of difficulty during insertion, post insertion infection, bleeding during and post insertion and rate of complications as perforation and expulsion.

Conclusion: Ultrasound guided IUD insertion is more effective than blind technique with lesser pain score and better patient satisfaction.

Key Words: Blind technique; cesarean section, intrauterine contraceptive device; ultrasound guided.

Received: 10 March 2024, **Accepted:** 30 April 2024

Corresponding Author: Ola A. Abdel Razek, Department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University, Cairo, Egypt, **Tel.:** +2 010 09065 0463, **E-mail:** olaemam164@gmail.com

ISSN: 2090-7265, 2025, Vol. 15

INTRODUCTION

The most popular reversible method of contraception at the moment is the intrauterine device (IUD). 15% of reproductive-age women worldwide are thought to use it[1].

IUDs offer a reversible and long-term method of contraception as a convenient, effective, comparatively safe, and affordable choice. Copper T-380A was demonstrated to be more effective in preventing conception than the other devices[2].

Application problems, failure, and complexities can limit the usage of this effective method. IUD insertion failure rates varied from 2.3 to 8.3 per 1000 insertions, and discomfort during the procedure was associated with a greater risk of failure[3].

In the first year after insertion, 5 to 15% of women will have their IUD removed because of erratic uterine bleeding. Before changing to a different birth control technique, it is important to rule out the possibility that bleeding is caused by an improper posture rather than the contraceptive method[4].

If an IUD can be safely and effectively used in the presence of a CS scar, it can enhance access to long-acting reversible contraception (LARC) options for women who have had prior caesarean sections (CS). On the other hand, a past CS scar may prevent access to insertion of an IUD if a prior CS may cause trouble with insertion and/or subsequent IUD issues[5].

The transvaginal method of pelvic ultrasonography, which is recognised as the gold standard for determining

DOI:10.21608/EBWHJ.2024.275927.1312

IUD location and related concerns, is the gold standard for this gynaecological condition[6].

Transvaginal ultrasonography is utilised in routine follow-up of asymptomatic IUD users as well as symptomatic patients to rule out IUD malposition and associated issues such perforation, expulsion, and pregnancy[7].

METHODS

This randomized controlled comparative clinical trial was carried out on 100 women attended in Ain Shams University Maternity Hospital asked for contraceptive method from January till September 2022.

Inclusion criteria

Women aged 18-40 years old, with body mass index less than 35 kg/m^2 with one or more previous cesarean sections desired IUD insertion either post- menstrual or postpartum after 6 weeks of delivery were enrolled.

Exclusion criteria

Pregnant women or whom with unexplained abnormal vaginal bleeding, untreated cervical, uterine or ovarian cancers, benign or malignant gestational trophoblastic disease, any uterine abnormalities as congenital anomalies, endometrial lesions, adenomyosis, fibroids, and intrauterine adhesions, pelvic infection, laboratory documentation of cervical infection with Neisseria gonorrhea or Chlamydia trachomatis, had pervious displaced IUD, any previous uterine scars other than CS were excluded

Sampling Method

A convenient sampling

Sample size

One hundred women who were subdivided into 2 groups.

Randomization

Randomization was guided by a table of random members by a computer-based program (using www.randomization.com).

Allocation and concealment

The appropriate letter designating the assigned group was placed in each of the 100 opaque envelopes, which were serially numbered, using a randomization table. Then, every envelope was sealed and placed in a single box. The first envelope was opened when the first patient came, and the patient was assigned based on the letter inside.

Study procedures

After approval of study protocol, women were enrolled into the study according to inclusion and exclusion criteria.

All women were subjected to thorough history taking and full clinical examination.

All eligible participants were distributed randomly in two equal groups. For both groups, the same IUD type Copper TCu-380A (Pregna®, DKT, Egypt) and the same insertion technique (withdrawal technique) was used.

For cases of group A, the blind technique for IUD insertion was used. On the other hand, IUD was inserted using ultrasound guided technique for cases of group B.

The Copper T380A IUD Insertion (withdrawal technique)

An assistance opened the copper T380A packing while preserving the sterility of the package contents.

The IUD was inserted through the insertion tube. This was performed by withdrawing the insertion tubing slightly and folding the IUD's horizontal arms down along the vertical arm with the thumb and index fingers.

The insertion tube was advanced until the horizontal arms were securely seated within the tubing.

The solid white rod was then inserted into the bottom of the insertion tubing and progressed until it met the bottom of the IUD.

The open end of the insertion tube was grabbed, and the blue flange was adjusted to the level at which the uterus sounds.

The insertion tubing was then turned so that the IUD's horizontal arms were parallel to the blue flange's long axis.

The loaded insertion tube was advanced through the cervical canal until it encountered resistance at the uterine fundus and the blue flange was at the external cervical os.

The insertion tubing was removed roughly 1 cm while holding the solid white rod steady, releasing the IUD.

The insertion tube was then carefully pulled up to the uterine fundus, ensuring that the IUD was placed at the fundus level.

The insertion tube was held constant before the white rod and insertion tubing were removed.

The IUD strings were easily visible in the vagina when the insertion device was removed. The threads were clipped with long-handled scissors so that roughly 3cm were seen extending from the external cervical os.

Before device implantation, a bimanual examination was performed in group A to examine the uterus in terms of position and size to assist the practitioner in planning the treatment. The same senior doctor used a Cusco speculum to visualise the cervix, which was then wiped with a povidone-iodine swab before tenaculum application to the cervix, and then uterine sound was introduced. Based on the measured uterine length, the shoulder of the IUD applicator was modified. The applicator for the device was introduced, and the gadget was placed inside the uterine cavity.

The urinary bladder was allowed to fill in group B in order to act as an acoustic window for high frequency sound waves and to straighten the angle between the uterine body and cervix. The uterine location was then seen using a MedisonSonoace abdominal transducer during trans-abdominal pelvic ultrasonography. An assistant held the transducer longitudinally in the suprapubic area to see the uterus in sagittal plain to measure the endometrial and cervical stripe lengths in this view, which were summed to get the real length of the uterus, which was used to adjust the IUD tube before insertion.

A Cusco speculum was used to see the cervix, which was then wiped with a povidone-iodine swab without making any attempts to introduce uterine sound; the treatment was completed in the same manner as the non-guided technique. The main difference was that we would not employ uterine sound, and the device was visible and modified throughout the introduction.

In both groups, after Cusco opening and visualisation of the cervix, a timer was started and stopped after the practitioner completed the operation with Cusco removal, and the duration of the treatment was recorded in seconds.

Transvaginal ultrasonography was performed on all patients in both groups at the ultrasound unit of Ain Shams Maternity Hospital to determine the appropriate position of the IUD immediately after insertion using a Samsung H60. A vaginal transducer was introduced through the vagina to provide a true longitudinal slice of the endometrial cavity. The distance in the sagittal plane between the superior edge of the IUD and the internal uterine wall was estimated.

The degree of difficulty of IUD insertion was graded in both groups using the following scale: easy, normal, mild, and severe difficulties.

Sharp pain and bleeding were examined clinically as indicators of perforation during device installation, and subsequently by ultrasonography, which revealed either an extra-uterine position of the IUD with complete perforation or a partial perforation of the myometrium.

Women in both groups were asked to rate their pain three times: immediately after vulsellum placement, during IUD insertion, and five minutes later. We used the Visual Analogue Scale (VAS) to assess pain experience at those periods in time. It was a 10-point scale, with 0 signifying no discomfort and 10 indicating the most severe pain. The VAS was explained to the participants prior to their participation in the study.

After the procedure , both groups' patient satisfaction was evaluated in a different office.

Patients were instructed to return to the study facility after one month and then again after six months for follow-up on device placement, which was validated by another trans-vaginal ultrasound, and late problems such as IUD expulsion, perforation, and infection.

STATISTICAL ANALYSIS

With the aid of the IBM SPSS software package version 20.0, data was input into the computer for analysis. (IBM Corp, Armonk, NY). Number and percentage were used to describe qualitative data. The normality of the distribution was examined using the Kolmogorov-Smirnov test. The range (minimum and maximum), mean, standard deviation, median, and interquartile range were used to characterise quantitative data (IQR). Chi-square test to compare results between groups for categorical variables Monte Carlo or Fisher's Exact test When more than 20% of the cells have an anticipated count of less than 5, the chi-square should be corrected. To compare two examined groups, use the Mann Whitney test for quantitative variables with anomalous distributions. The 5% threshold of significance was used to determine the results' significance.

RESULTS

of IUD insertion in our trial are illustrated in (Tables 1-4).

Background characteristics , evaluation and complications

Table 1: Demographic characteristics of study groups

Variables		Group A (blind technique) (n = 50)	Group B (US guided) (n = 50)
Age (years)	Mean ± SD.	30.24 ± 4.88	28.38 ± 6.20
BMI (kg/m^2)	Mean ± SD.	28.91 ± 3.39	30.77 ± 20.23
	Previous I section	18 (36%)	15 (30%)
Parity	More than one CS (>1)	32 (64%)	35 (70%)
	Mean ± SD.	2.02 ± 1.0	2.18 ± 1.08

Table 2: Proper fundal device placement post insertion among the studied groups

Proper fundal device placement	Group A (n = 48)	Group B (n = 49)	t	*P*
Immediately post-insertion				
Mean ± SD.	1.71 ± 0.38	1.82 ± 0.30	1.601	0.113
one month post-insertion.	(n = 46)	(n = 49)		
Mean ± SD.	1.72 ± 0.34	1.82 ± 0.30	1.504	0.136
6 months post-insertion	(n = 46)	(n = 49)		
Mean ± SD.	1.73 ± 0.34	1.82 ± 0.30	1.508	0.135

Table 3: Evaluation of the process of IUD insertion in both groups

		Group A (n = 50)	Group B (n = 50)	Test of sig.	*P*
The time needed for the procedure (minutes)	Mean ± SD.	3.95 ± 0.31	3.23 ± 0.35	U=255.0*	<0.001*
Difficulty	Mean ± SD.	2.90 ± 1.22	2.68 ± 1.10	U=1079.5	0.194
Pain	Mean ± SD.	51.64 ± 9.33	29.42 ± 9.94	U=115.50*	<0.001*
	Mild	44 (88%)	47 (94%)		
Bleeding during insertion	Moderate	6 (12%)	3 (6%)	X^2= 1.099	^{MC}p=0.487
	Severe	0 (0%)	0 (0%)		
	More difficult than expected	6 (12%)	5 (10%)		
Patient satisfaction after insertion	As expected	39 (78%)	24 (48%)	X^2= 13.508	0.001*
	Or easier than expected	5 (10%)	21 (42%)		

Table 4: Complications in both groups

Complications		Group A (n = 50)	Group B (n = 50)	□□	*p*
Perforation		2 (4%)	0 (0%)	2.041	^{FE}p=0.495
Expulsion		2 (4%)	1 (2%)	0.344	^{FE}p=1.000
	Mild	19 (39.6%)	23 (46.9%)		
Bleeding post insertion	Moderate	28 (58.3%)	25 (51%)	0.787	^{MC}p=0.771
	Severe	1 (2.1%)	1 (2%)		
Total complications		40 (80%)	42 (84%)	0.271	0.603

DISCUSSION

Our study evaluated the effect of use of transabdominal us guidance during IUCD insertion in patients with previous CS to make the procedure more easy for the doctor and the patient and to decrease the incidence of complications during the procedure.

There was no significant difference between both groups as regard age, BMI, parity and number of previous cesarean sections.

There was no significant difference between the two groups when we compared how difficult it was to slide the IUD through the cervical canal and cervico-uterine angel to reach the uterine

fundus while using ultrasound guidance. It was easy in 21 (42.0%) of the patients, normal in 25 (50.0%), mild difficulty in 4 (8.0%), and severe in 0 (0.0%) in Group A. While in Group B, it was easy in 28 (56.0 %) of the patients, normal in 19 (38.0%), mild difficulty in 3 (6.0%), and severe in 0 (0.0%) .

The time needed for the procedure was significantly shorter in Group B compared to Group A (the mean time was 3.95 ± 0.31 minutes in Group B versus 3.23 ± 0.35 minutes in group A, *p value* <0.001) .

According to the VAS score used to measure pain after IUD insertion, only three patients in Group B compared to 34 patients in Group A reported moderate to severe pain throughout the procedure. Regarding post-insertion patient satisfaction, the ultrasonography guided group fared much better. In group A 6 patients reported more difficult than expected, 29 as expected and 5 patients reported easier than expected while in group B 5 patients reported more difficult than expected, 24 As expected and 21 patients reported easier than expected .There was no significant difference in the bleeding amount during the procedure.

After IUCD insertion, proper positioning was assessed by ultrasonography by measuring the fundal distance (normal fundal distance is 3 mm); there was no significant difference between the two groups. In group A, the mean fundal distance was 1.71 0.38 mm, while in group B, it was 1.82 0.30 mm. After one month and six months of monitoring the IUCD position in the outpatient clinic, there was no discernible difference between the two groups' IUCD positions.

In terms of overall complication incidence, group A had a higher incidence, but the difference is statistically insignificant. Compared to group B, which had no perforations, expulsions, or persistent moderate to severe bleeding that required medical attention, group A had two cases of perforation, two cases of IUCD expulsion, and one case of persistent severe bleeding that required laparoscopic intervention.

At the Ain-Shams University Maternity Hospital's Birth Control Clinic, Elhoussieny and his colleagues conducted a comparison of the ultrasound guided and blind IUD insertion techniques on 100 women. After insertion, group U experienced proper fundal distances significantly more frequently than group B (p=0.009), and group U experienced total difficulties significantly less frequently than group B (p=0.016). Additionally, group U experienced much less pain (VAS-100), a shorter treatment, and lower dissatisfaction than group B[2].

El-Bahnasy and her colleagues evaluated the use of US-guided IUD insertion, 200 women scheduled to undergo IUD insertion at the outpatient clinics of Obstetrics and Gynecology insertion. Patients were classified into two equal groups: Group (A): were scheduled for trans abdominal ultrasound-guided IUD insertion; and Group (B): were scheduled for Non Guided method of IUD insertion. Patient's pain during IUD insertion in Group (A) was statistically significantly lower than group (B) (P<0.001). Patient's duration of the IUD insertion procedure (seconds) in Group (A) was statistically significantly lower than group (B) (P<0.001). In Group (A), 3% of the patients had failed insertion, while 96% of the patients had their IUDs implanted; in Group (B), 6% of the patients had failed insertion, 80% of the patients had their IUDs implanted, and 14% had their IUDs misplaced. Between groups, there were statistically significant differences (P 0.001). Regarding patient satisfaction, there were large statistically significant variations between groups (P 0.001)[8].

The advantages of employing ultrasound guidance for IUD implantation in women with RVF (retroverted flexed RVF uteri) were examined by Maged and his colleagues. 400 women who were eligible for IUD insertion and had RVF uteri participated in a randomised controlled experiment. They were split into two groups at random. While group 2 received no ultrasound guidance, group 1 received IUD insertion under ultrasound supervision. Women in the ultrasound guided group experienced much less discomfort than women in the control group (2.36 1.77 vs. 4.74 2.35, p 0.001), had much simpler insertion (scoring 4.0 0.9 vs. 2.5 1.27, p 0.001), and required significantly less time (5.82 2.56 vs. 9.4 4.99 min, P 0.001). When compared to the control group, the overall rate of complications was significantly lower (6 vs. 16%, p 0.001), specifically bleeding (2 vs. 9%, p = 0.002), stomach cramps (10.5 vs. 28%, P 0.012), and operation failure (0 vs. 3%, P = 005)[9].

In order to compare the results of the two approaches used to install copper intrauterine devices (IUDs), Ali and his colleagues used trans-abdominal ultrasound (TAS) guidance and uterine sound-sparing technique (USSA). The

eligible women (44 in each group) were randomly divided into two groups: group I (TAS-guided IUD insertion) and group II (USSA). Eighty-eight women from each group were examined. In comparison to the TAS-guided group, the VAS for satisfaction was considerably higher in the USSA group (7.80 1.27 vs. 5.45 1.42, *P* =.0001). In the USSA group compared to the TAS-guided IUD, there were significantly reduced VAS pain scores during IUD insertion (*P* =.001). The USSA group had a lower ES and an IUD insertion that lasted noticeably less time (*P* =.0001) as well. Conclusions: Compared to the TAS-guided IUD insertion method, USSA is related with more pleasure and reduced pain during insertion. However, both methods provide the best location for intrauterine devices[10].

Last but not least, a total of 85 subjects were randomly assigned: 42 to US-guided insertion and 43 to standard blind insertion. The visits lasting 4-6 weeks and 6 months were successfully completed by 69 and 52 participants, respectively. In the US and conventional arms, the malposition rate was 3/32 (9.4%) and 6/37 (16.2%), respectively, with a relative risk of 0.58 (95% CI 0.15, 2.18; *P*=0.41). In the US and conventional arms, the 6-month discontinuation rates were 6/33 (18.2%) and 8/32 (25.0%), respectively, with a relative risk of 0.73 (95% CI 0.28, 1.90; *P*=0.51). The 4-6 week follow-up appointment allowed for the identification of every malpositioned IUD. At the 4-6 week visit, two participants chose to keep using their misplaced IUDs, but both stopped using them before the 6-month visit (1 expulsion and 1 IUD removal). Two participants in the standard arm and three participants in the US-guided arm were discontinued for correctly positioned IUDs due to side effects. There was no statistically significant difference between the two arms for post-insertion discomfort or pleasure. Traditional and US-guided side effects were comparable in the following ways: vaginal bleeding (39% and 38%), pelvic pain (20% and 13%), menstrual alterations (5% and 0%), and hormonal side effects (7% and 0%)[11].

CONCLUSION

With less discomfort and higher patient satisfaction, ultrasound guided IUD insertion is more efficient than blind method.

ACKNOWLEDGMENTS

Authors would like to thanks to Ain Shams University and the patients recruited in the study.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee

CONFLICT OF INTERESTS

There are no conflicts of interest.

REFERENCES

1. Bolarinwa OA, Olagunju OS. Knowledge and factors influencing long-acting reversible contraceptives use among women of reproductive age in Nigeria. Gates Open Research. 2019;3.
2. Elhoussieny AS, Ibrahim AM, Hassanin AS, El-Azeem A, Shaimaa S. Efficacy and Safety of Ultrasound Guided versus Blind Technique for Office Insertion of Intrauterine Contraceptive Device: A Randomised Clinical Trial. Evidence Based Women's Health Journal. 2019 May 1;9(2):432-40.
3. Subathra Devi S. Study on PPIUCD Acceptors and their Follow Up (Doctoral dissertation, Government Theni Medical College, Theni).
4. Jayaprakasan K, Polanski L, Ojha K. Gynecological Ultrasound Scanning: Tips and Tricks. Cambridge University Press; 2020 Feb 27.
5. Goldstuck ND, Steyn PS. Insertion of intrauterine devices after cesarean section: a systematic review update. International journal of women's health. 2017;9:205.
6. Nijkang NP, Anderson L, Markham R, Manconi F. Endometrial polyps: Pathogenesis, sequelae and treatment. SAGE open medicine. 2019 Apr;7:2050312119848247.
7. Makena D, Gichere I, Warfa K. Levonorgestrel intrauterine system embedded within tubal ectopic pregnancy: a case report. Journal of Medical Case Reports. 2021 Dec;15(1):1-6.
8. El-Bahnasy H, Hanafy M, El-Mallah S. Role of Ultrasound Technique in Woman Satisfaction during Placement of Intrauterine Contraception (A Randomized Clinical Trial). Al-Azhar Medical Journal. 2022 Jan 1;51(1):135-46.
9. Maged AM, Nada AM, Abdelwahab H, Salah E, Soliman M, Hussein EA, Essam A, Nabil H. The value of ultrasound guidance during IUD insertion in women with RVF uterus: A randomized controlled trial. Journal of Gynecology Obstetrics and Human Reproduction. 2021 Apr 1;50(4):101875.
10. Ali MK, Ramadan AK, Abu-Elhassan AM, Sobh AM. Ultrasound-guided versus uterine sound-sparing approach during copper intrauterine device insertion: a randomised clinical trial. The European Journal of Contraception & Reproductive Health Care. 2022 Jan 2;27(1):3-8.
11. Li L, Wright T, Estes SJ. 31: Randomized controlled trial of ultrasound-guided intrauterine device insertion. American Journal of Obstetrics & Gynecology. 2020 Mar 1;222(3):S793-4.