The Egyptian Journal of Hospital Medicine (January 2024) Vol. 94, Page 740-746

Ultrasound Assessment of Post Placental Insertion of (Cupper T380A) Intrauterine Device at Cesarean Section; Two Different Techniques

Ayman Elsayed Solyman, Ayman Abd ElKader Shabana,
Reham Salah Ahmed Elsotohy*, Ahmed Mohamed Tharwat
Department of Obstetrics and Gynecology, Faculty of Medicine, Menoufia University, Egypt
***Corresponding author:** Reham Salah Ahmed Elsotohy, Mobile**:** (+20) 01275508346, **E-Mail:** Amirmo777amed@gmail.com

ABSTRACT

Background: post placental intrauterine device (IUD) insertion is effective, convenient strategy to reduce the risk of rapid repeated pregnancy.

Objectives: To evaluate abnormal uterine bleeding (AUB), infection, loss of threads, displacement, expulsion, and pregnancy on top, regarding two post placental IUD insertion techniques.

Patients and Methods: Cohort prospective comparative study was conducted on 164 women in the Obstetrics and Gynecology Department, Menoufia University Hospital, during a period time from September 2022 to December 2022.

Results: Significant differences among the studied two groups regarding IUD displacement (p=0.029), AUB (p=0.001), loss of threads (p=0.036) and IUD expulsion (p<0.001) after 6 weeks of IUD insertion, and a significant difference regarding IUD displacement and loss of threads after 3 months of IUD insertion (P<0.05).

Conclusions: Because the new approach is linked to a decreased frequency of IUD displacement and non-visibility of IUD threads, it may become the standard procedure for intra-cesarean section IUD insertion.

Keywords: Cesarean section, Contraceptive device, Copper-T380A, Insertion, Post placental, Ultrasound.

INTRODUCTION

Higher rates of morbidity and death in children and mothers are associated with shorter gestational periods [1]. The avoidance of unwanted and closely spaced pregnancies during the first year after childbirth is known as postpartum family planning. A variety of efficient contraception techniques are necessary for postpartum women to be able to avoid an unintended pregnancy in a short amount of time [2].

Among the various alternatives, the Copper T380A IUD is one of the most economical and long-acting solutions due to its multi-year cost. Regardless of whether a woman is nursing during this time, she can safely utilise the highly effective, non-hormonal Copper T 380A intrauterine contraceptive device (IUCD) [1]. The rate of ejection and adverse effects, such pain and bleeding, are the primary drawbacks of IUDs as contraceptive devices and may need an early removal [3].

Since the 60s, the idea of early postpartum IUD implantation has been studied and is now well recognised [4, 5]. When it comes to contraception, early postpartum IUD implantation offers a number of benefits over alternative options. It offers contraceptive protection without interfering with nursing. Furthermore, putting in an IUD early can help prevent insertion-related pain. IUD implantation during birth is linked to increased expulsion rates, despite these benefits [4].

According to some publications, women who deliver by caesarean section and put their IUD immediately after the birth (within 10 minutes) through a hysterotomy may experience a lower expulsion rate than women who deliver vaginally and insert their IUD immediately [5].

The aim of the study was to record the complications after insertion of IUD by the two different techniques regarding, AUB, infection, loss of threads, displacement, expulsion, and pregnancy.

PATIENTS AND METHODS

Cohort prospective comparative study was conducted on 164 women to evaluate patient satisfaction of post-placental insertion of contraceptive device who attended to the Obstetrics and Gynecology Department, Faculty of Medicine, Menoufia University Hospital, during a period time from September 2022 to December 2022.

The study's patients were split into the following two groups: Group A: The IUD was placed by traditional method, and Group B: The IUD was placed by A modified method.

Method of randomization:

Using opaque envelopes, participants were divided into the two groups at random. Then, in order to preserve secrecy, the envelopes were opened one after the other right before the IUD was inserted. After then, a statistician who was not involved in this study created the randomization list using "computer software".

The 1:1 ratio was the basis for the participant's allocation. Subsequently, the researchers recruited individuals and allocated them to various therapies. In order to support analyses based on the intention to treat by protocol, a record of the intervention type and insertion technique was maintained. Ultimately, the group assignment was concealed from the participants.

Received: 15/10/2023
Accepted: 15/12/2023

Sample size:

Minimum sample size was calculated using statistical and sample size program and it was 164 participants divided into 2 groups, each of 82 participants at 80% power and at 95% confidence level.

Inclusion criteria:

Patients were delivered by caesarean section, after counseling for postpartum contraception, and consent to the immediate insertion of IUCD.

Exclusion criteria:

All cases with refusal by patient, uterine congenital anomalies, distorted uterine cavity (as fibroid), evident chorioamnionitis, ROM ≥18 hours, uterine atony, history of AUB, allergy to copper, history of ectopic pregnancy, history of PID, single tube, cervical dilatation >5 cm on admission, to avoid immediate spontaneous expulsion and hemorrhagic disorder.

All patients underwent the following:

Full history taking including personal,menstrual, obstetric history and contraceptive history. Counselling was done during antenatal visits or during early labor. As standard procedure at our hospital, 1 g of intravenous cefazolin sodium was administered to every woman having a caesarean surgery. Within ten minutes of the placenta was removed, a copper IUD (model TCu 380A) was inserted into the uterus' fundus. After examinationof fundus of the uterus to exclude uterine anomalies not diagnosed before.

Then insertion of IUD by traditional method in group A: The IUD was removed from the insertion tube and threads was trimmed then IUD was advanced through the hysterotomy to the fundus and IUD threads was directed manually into the cervix. A modified method in group B: We applied the same idea of the withdrawal technique used for IUD insertion in Gynecology.

We didn't remove IUD from insertion tube, arms remained unfolded then blue flange was removed. Finally, we slid the introducer with IUD threads downward via the cervical canal before lifting the IUD between the middle and index fingers to firmly press it on the fundal endometrium, directing the threads down the cervical canal and into the vagina, and finally closing the uterine incision.

Next, we carefully withdrew the insertion tube from the vagina while using the vaginal toilet. IUD recipients were evaluated before to hospital release, with follow-up appointments arranged at 6 weeks and 3 months, during which the strings were cut to reach just past the exterior cervical OS. The ultrasound scan determined that the IUD location was no more than 2 cm from the uterine fundus.

Outcome measurements: Primary outcomes: included patients' satisfaction and successful placement (insertion). Secondary outcomes (complication): as displacement, AUB, non-visibility of threads expulsion, infection, pregnancy on top and method use at study assessment.

Ethics approval:

The local Ethical Scientific Committee of Menoufia Faculty of Medicine approved the study proposal (IRB approval No.: 9/2022OBSG24). Following a detailed description of the study's aims, all participants completed an informed consent form. The Helsinki Declaration was observed throughout the study's duration.

Statistical Analysis

Utilising SPSS V.25 application for Microsoft Windows 10, the results were tallied and statistically examined. Quantitative data in the form of Mean ± SD, as well as frequency and percentage for qualitative data, were used to describe the data. When it is equal to or less than 0.05, a significant p-value was taken into account.

RESULTS

A flowchart of the study population is shown in figure 1. Of the 189 patients enrolled in our study to evaluate outcome and patient satisfaction of post-placental insertion of contraceptive device at cesarean section in the two different techniques at Menoufia University Hospitals. 10 patients were excluded from the study, and 15 of them lost the followup. 164 of them were analyzed, 82 of them subjected to traditional method and other 82 subjected to modified method **(Figure 1)**.

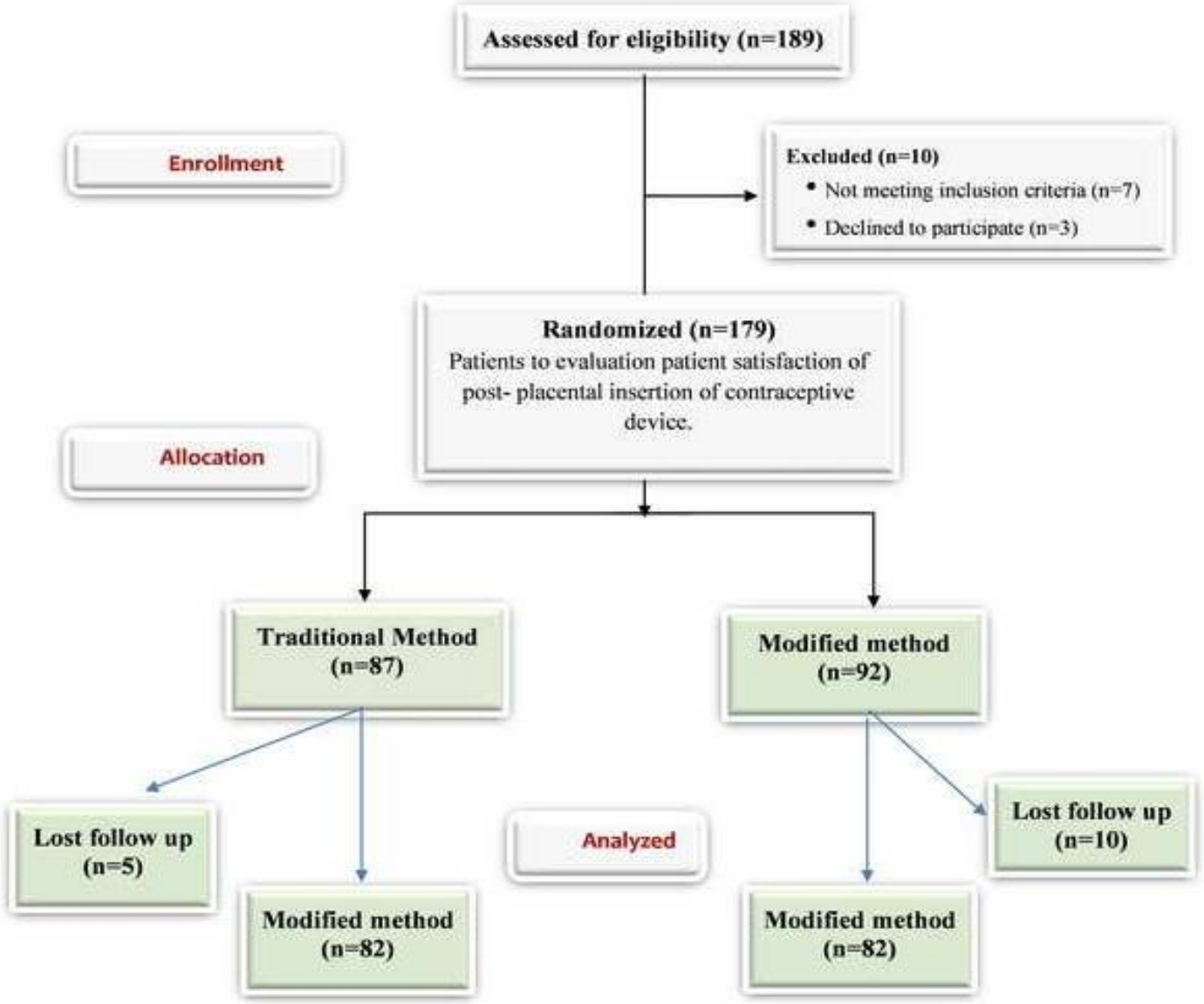

Figure (1): Flowchart of patients to evaluate patient satisfaction of post-placental insertion of contraceptive device. There were significant differences among the studied methods regarding previous delivery, complaint, and previous IUD use. While no significant difference was found between the studied groups regarding parity **(Table 1)**.

Table (1): Baseline characteristics data of included study groups (n=164).

	Variable	Traditional method (n=82)		Modified method (n=82)		*t*	*P-value*
Age/year (Mean ±SD)		31.73±8.35		30.73±7.57		0.804	0.423
Gestational age/weeks (Mean ±SD		38.41±1.35		38.16±1.05		U= 1.356	0.177
Parity	P0	16	19.51	5	6.10	p X^2= 5.774	0.056
	P1	11	13.41	20	24.39		
	P2	27	32.93	30	36.59		
	P3	22	26.83	17	20.73		
	P4	6	7.32	9	10.98		
	P5	0	0.00	1	1.22		
Previous delivery	PG	16	19.51	2	2.44	FE= 12.23	**<0.001***
	CS	66	80.49	80	97.56		
Complain	Elective CS	54	65.85	63	76.83	X^2= 1.760	**0.038***
	In labor	13	15.85	11	13.41		
Previous IUD use	No	21	25.61	8	9.76	X^2= 7.079	**0.008***
	Yes	61	74.39	74	90.24		

CS: Cesarean section. **PG:** primigravida, **IUD:** intrauterine device, **X^2:** Chi square, EF: Fisher exact test, ***:** Significant

There were significant differences among the studied methods regarding IUD displacement, AUB, loss of threads and IUD expulsion after 6 weeks of use IUD insertion. IUD expulsion was significantly less frequent among women of modified methods than women of traditional method. While there was no significant difference among the studied methods regarding infection and pregnancy on top after 6 weeks of IUD insertion **(Table 2)**.

Table (2): Follow up at 6 weeks after IUD insertion among the studied methods (n=164).

	Traditionalmethod (n=82)		**Modifiedmethod (n=82)**		***X2***	***P-value***
	N	**%**	**N**	**%**		
IUD Displacement						
No	67	81.71	75	91.46	6.496	**0.029***
Yes	15	18.29	7	8.54		
AUB						
No	52	63.42	72	87.80	15.589	**0.001***
Yes	30	36.58	10	12.20		
Infection						
No	27	32.92	35	42.68		
Endometritis	1	8.20	0	0.00	2.16	0.395
Cervicitis	11	13.41	11	13.41		
Vaginitis	43	52.44	36	43.90		
Loss of threads						
No	61	74.39	74	90.24	4.673	**0.036***
Yes	21	25.61	8	9.76		
IUD Expulsion						
No	65	79.27	80	97.56	FE=	**<0.001***
Yes	17	20.73	2	2.44	18.256	
Pregnancy on top						
No	82	100.0	82	100.00	FE= 0.0	1.00
Yes	0	0.0	0	0.00		

AUB: Abnormal uterine bleeding, **IUD:** intrauterine device, **X^2:** Chi square, EF: Fisher exact test, ***:** Significant

There were significant differences among the studied methods regarding IUD displacement and loss of threads after 3 months of IUD insertion. While there was no significant difference among the studied methods regarding AUB, infection, IUD expulsion and pregnancy on top after 3 months of use of IUD insertion **(Table 3)**.

Table (3): Follow up at 3 months after IUD insertion among the studied methods(n=164).

Variable	**Traditional method(n=82)**		**Modified method (n=82)**		**X^2**	**P-value**
	N	**%**	**N**	**%**		
IUD Displacement						
No	58	70.73	65	79.27	4.826	**0.032***
Yes	24	29.27	17	20.73		
AUB						
No	41	50.00	59	71.95	2.254	0.521
Yes	41	50.00	23	28.04		
Infection						
No	48	58.54	61	74.39		
Endometritis	0	0.0	2	2.43	4.02	0.063
Cervicitis	10	12.20	6	7.32		
Vaginitis	24	29.27	13	15.85		
Loss of threads						
No	47	57.32	70	85.36	23.50	**<0.001***
Yes	35	42.68	12	14.63		
IUD Expulsion						
No	61	74.39	72	87.80	13.82	**0.016***
Yes	21	25.61	10	12.20		
Pregnancy on top					FE=	
No	80	97.56	81	98.78	0.685	0.417
Yes	2	2.44	1	1.22		

AUB: Abnormal uterine bleeding, **IUD:** intrauterine device, **X^2:** Chi square, FE:Fisher exact test, ***:** Significant

Regarding traditional method, IUD displacement was significantly more after 3 months than after 6 weeks. While there were no significant differences among traditional method after 6 weeks and 3 months regarding AUB, infection, loss of threads, IUD Expulsion, and pregnancy on top **(Table 4)**.

Table (4): Follow up at 6 weeks and 3 months after IUD insertion among women of traditional method.

	Variable	**Traditional method**					
		At 6 weeks		**At 3 months**		***X²***	***P-value***
		N	**%**	**N**	**%**		
IUD Displacement	No	67	81.71	58	70.73		
	Yes	15	18.29	24	29.27	7.25	**0.001***
AUB	No	52	63.42	41	50.00		
	Yes	30	36.58	41	50.00	4.11	0.166
Infection	No	27	32.92	48	58.54		
	Endometritis	1	1.21	0	0.0		
	Cervicitis	11	13.41	10	12.19	1.88	0.670
	Vaginitis	43	52.44	24	29.27		
Loss of threads	No	61	74.39	52	63.41		
	Yes	21	25.61	30	36.58	1.82	0.0480
IUD Expulsion	No	65	79.27	57	69.51		
	Yes	17	20.73	25	30.48	3.20	0.67
Pregnancy on top	No	82	100.0	80	97.56		
	Yes	0	0.0	2	2.44	FE=0.41	0.92

X^2: Chi square, FE: Fisher exact test, ***:** Significant

There were no significant differences among modified method after 6-weeks and 3-months regarding IUD displacement, AUB, loss of threads, IUD expulsion and pregnancy on top. However, many patients had vaginitis (43.90%) after 6 weeks and (15.85%) of patients had vaginitis after 3 months **(Table 5)**.

Table 5. Follow up at 6 weeks and 3 months after IUD insertion among women ofmodified method.

Variable	**Modified method**				**X^2**	P-value
	At 6 weeks		**At 3 months**			
	N	**%**	**N**	**%**		
IUD Displacement						
No	75	91.46	65	79.27	3.80	0.075
Yes	7	8.54	17	20.73		
AUB						
No	72	87.80	59	71.95	0.140	0.920
Yes	10	12.20	23	28.04		
Infection						
No	35	42.68	63	76.83		
Endometritis	0	0.00	2	2.43	9.71	**0.001***
Cervicitis	10	12.20	6	7.32		
Vaginitis	36	43.90	13	15.85		
Loss of threads						
No	74	90.24	70	85.36	0.866	0.251
Yes	8	9.76	12	14.63		
IUD Expulsion						
No	80	97.56	72	87.80	0.83	0.273
Yes	2	2.44	10	12.20		
Pregnancy on top						
No	82	100.00	81	98.78	FE=	0.200
Yes	0	0.00	1	1.22	1.04	

X^2: Chi square, FE: Fisher exact test, ***:** Significant

DISCUSSION

IUDs are a good form of contraception for the postpartum period. They have an advantage over hormonal treatments in that they don't interfere with nursing or the coagulation system, and they are not dependent on the compliance of women [6]. In the current study, there was no significant difference among the studied methods regarding age and GA.

The results of our study are similar to those of **Mahmoud *et al.* [7],** who found that study participants' mean age was 29.17±4.56 years and that there was no significant age difference between the fixation and non-fixation groups. This is similar to the average age found in earlier research, such as **Levi *et al.* [8]** research; 30 years.

Ragab *et al.* [9] study conducted a 28.7-year research on the TCu-380A group. 27.9 years was the mean age in **Ariadi and Aulia [10]** research; and 27.4 years was in **Tjahjanto and Haryuni [11]** study.

In the present study, we found that there were significant differences among the studied methods regarding previous delivery, and previous IUD use, 90.24% of modified method had previous IUD use vs 74.39% of traditional method. In this concern a study by **Shahienaz *et al.* [12]** reported that in terms of future reproductive desire, 83.3% of patients desired fertility, whereas 36.7% of patients had previously used an IUD. Of the patients, 63.3% had no history of using an IUD. They also discovered that 36.7% of patients utilised the IUD because it had previously been difficult to re-implant, 23.3% because they had cervical stenosis, and 40% of patients chose the device after placental implantation because they were having trouble returning to using contraceptive methods.

In the present study, there were significant differences among the studied methods regarding IUD displacement, AUB, loss of threads and IUD expulsion after 6 weeksof IUD insertion, IUD displacement was found in 18.29% of traditional method vs 8.54% in modified method. Our study was close to the study obtained by **Fadiloglu *et al.* [13]** where the main issue with IUD use was IUD displacement, which can result in additional issues such unintended pregnancy, expulsion, bleeding, and uterine colic.

Women of traditional method significantly complained from AUB (30 women, 36.58%) vs women of modified method (10 women, 12.20 %), p=0,001. The current study showed that, loss of threads significantly increased among women of traditional methods (21 women, 25.61%) than women of modified method (8 women, 9.76%) with (P<0.001). In the same line **Levi *et al.* [6]** indicated that visible threads in 40%. IUD threads were evident in 29.1% of participants at the 6-week post-insertion consultation. If the wires are invisible in the exterior cervical OS, ultrasound imaging must be used to determine the intrauterine position of an IUD.

In this study, IUD Expulsion was significantly less frequent among women of modified method (2.4%, 12.2%) than women of traditional method (20.73%, 25.61%) at 6 weeks and 3 months respectively.

Our research closely matched that of **Ribeiro Simões *et al.* [14],** who discovered that the T copper 380A IUD placed during the immediate postpartum period, was expelled at a rate of 8.73% after a postpartum caesarean section. In terms of the rate of IUD malposition detected by early ultrasound, it was lower in the postpartum period following a caesarean section (4.57%). This is likely because of the insertion technique used during the procedure, which opens the uterus via hysterotomy and ensures that the IUD is properly implanted into the uterine fundus.

The current investigation revealed that there was no significant difference between the evaluated strategies for AUB, infection, and pregnancy on top after 3 months of IUD insertion. In this concern, **Çelen *et al.* [15]** found that after six weeks, two people (1.3%) in their trial experienced infections: one with endometritis and the other with vulvovaginitis.

Immediate post-placental IUD insertion during caesarean does not appear to raise the incidence of infection, and first clinical therapy does not affect the outcome. This study demonstrated that IUD displacement in the conventional approach occurred in 18.29% of patients after 6 weeks and 29.27% of patients after 3 months. While there was no significant difference between conventional method patients after 6 weeks and 3 months in terms of AUB, infection, thread loss, IUD expulsion, and pregnancy on top.

Welkovic *et al.* [16] examined post-partum bleeding and infection following post-placental IUD installation and found no difference in the incidence of severe bleeding, which is consistent with our findings. Additionally, **Shahienaz *et al.* [12]** discovered that 75% of patients who experienced bleeding did so in the form of menorrhagia and 25% in the form of metrorrhagia; 75% of patients experienced bleeding after puerperium and 25% during puerperium; and patients who experienced infection experienced endometritis in 4 cases and PID in 3 cases.

CONCLUSION

Because it is associated with a lower incidence of IUD displacement, non-visibility of IUD threads, and a higher rate of continuation without lengthening the surgical procedure, our new technique has the potential to become the standard for intra-cesarean section IUD insertion.

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