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New Method of IUD Insertion During Cesarean Section

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ABSTRACT

Background: There is currently no accepted method for inserting an IUD during a Cesarean section. According to previous research, the traditional method of inserting an IUD during Cesarean section involves manually inserting the device into the fundus of the uterus and guiding the IUD strings through the cervix.

Objectives: This study aimed to compare between the standard method and a new method for IUD placement during CS. **Patients and methods:** This prospective randomized controlled trial included 624 female patients coming for either elective or emergency cesarean delivery. They were subjected to intra-caesarian CU T380 IUD insertion. **Group A (standard method):** consisted of 312 pregnant patients who underwent manual insertion of the CU T380 IUD using the standard technique of intracesarian IUD insertion; **Group B (new method):** consisted of 312 pregnant women who underwent IUD insertion utilizing the novel approach for placing the IUD (CU T380). **Results:** Our results showed significant statistical differences between the two groups regarding visibility of the threads, IUD displacement, discontinuation rate & overall patient satisfaction (p-values < 0.001, 0.008, 0.004 & 0.002 respectively).

Conclusion: Intra-partum IUD insertion during Cesarean section using the new technique is more effective than using the standard approach in terms of visibility of threads and better accuracy post-Cesarian and at 6 weeks follow up, hence higher patient satisfaction.

Key words: Intrauterine device, Contraception, New method, CS delivery, Expulsion.

INTRODUCTION

Less than 1 in 100 women experience failure with the copper IUD in its first year of usage, making it one of the most popular reversible techniques of contraception in Egypt. It is recommended due to its high efficiency, convenience of use, safety record, and lack of adverse effects [(1)].

It's critical to place IUDs according to practice and at the appropriate time to reduce the chance of displacement. It's arguable when, exactly, to implant the IUD following a Cesarean section. The majority of gynecologists favor inserting IUDs three months or right after puerperium (6 weeks) [(2)].

According to recent studies, about 50% of moms resume sexual activity six weeks after giving birth, and many of these women do not take contraception [(3)]. By inserting IUDs, less manipulation and discomfort are required during Cesarean sections. According to one study, using it as soon as possible after birth has benefits such as convenience and ease of insertion and is safe for both the mother and the baby [(4)]. The insertion of an intrauterine device (IUD) can be performed under eyesight, eliminating the risk of uterine perforation [(5)]. IUD strings drop and become visible due to the uterus's involution; nevertheless, occasionally, threads become coiled inside the uterus, making visibility impossible [(6)]. The invisibility of IUD strings might cause anxiety among women, as they may worry about an uncommon consequence of an IUD puncturing into their abdominal cavity [(7)]. Visualizing IUD strings during a follow-up appointment rules out expulsion and gives women and the service provider confidence regarding in utero IUD presence. It's also simple to remove an IUD with visible strings only needs to be pulled gently with the strings grasped [(8)]. Our study compared a novel intracesarian IUD insertion technique to the conventional IUD insertion procedure.

PATIENTS AND METHODS

This prospective randomized controlled trial was performed to evaluate the effectiveness of a new method for placement of CU T380 intrauterine contraceptive device during Cesarean delivery versus the standard manual approach of post-placental IUD insertion.

Study setting and duration: This study took place at the Obstetrics and Gynecology Department, Kasr Al-Ainy Hospital, Cairo University, Egypt. The study was carried out through a 12-month duration, starting from December 2021 to February 2023.

Study subjects: 684 pregnant women who were counseled to have an IUD implanted during a Cesarean delivery, were included in the study. Based on the insertion technique, cases were divided into two equal groups at random as follows: **Group A (standard method)** consisted of 342 pregnant women who underwent manual insertion of the Copper T380 IUD using the standard technique of intracesarian IUD placement and **group B (new method)** that consisted of 342 pregnant women who underwent IUD insertion utilizing the novel approach for placing the device at the top of the fundus of the uterus. Sixty patients dropped out during follow-up and were removed from the trial, leaving 312 women in each group who finished the follow-up (Figure 1, consort flow chart).

Inclusion criteria: Pregnant patients between the ages of 18 and 45 who were admitted for emergency or elective Cesarian delivery, consenting for an IUD to be inserted immediately after placental removal.

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Exclusion criteria: Women who had a placenta previa or placenta accreta, who had an upper segment Cesarean scar, or who had a Cesarean section due to obvious infections such as chorioamnionitis, uterine abnormalities, uterine myomas, or bleeding diathesis, were not included in our analysis.

Method of randomization: Using opaque envelopes, participants were divided into 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 is the basis for the participant's allocation. Subsequently, the researchers recruited individuals and allocated them to various therapies. To improve analyses based on the method intended to be used for intervention, a record of the intervention type and insertion technique was maintained. Lastly, the group assignment was concealed from the participants.

Intervention: Following a comprehensive clinical evaluation, lower segment cesarean delivery was performed for each subject. After the placenta was delivered, IUDs were placed inside the uterus as follows:

- **Group A (standard method): (*n* = 312) (Figure 2):** Initially, we carried out an evaluation and confirmed that the inserting of an IUD was not contraindicated. Then, we took the IUD out of the introducer and cut the IUD threads to a length of 12 cm after opening the packaging. We securely gripped the IUD by its stem and introduced the IUD through the hysterotomy to the fundus after stabilizing the uterus with the non-dominant hand or with the help of an assistant surgeon. We removed the hand and manually guided the IUD threads into the cervix. Finally, we closed the uterine incision, being careful not to entangle the IUD threads.

- Group B (the new method): (*n* = 312) (Fig. 3): We utilized the same concept as the gynecological IUD insertion removal approach in the novel method. Using this method, the IUD was pushed with its arms unfolded to a high position in the uterine fundus and then removed without dragging the IUD down with it. The limbs of the IUD stay unfolded during the procedure in the novel approach. I**nitially**, we shortened the introduction device to 12 cm after eliminating the distance indicator (the blue flange on the introducer). This was done to make sure that, in the unlikely event that the cervix was pointed acutely posterior, as in the case of elective Cesarean sections, the introducer could pass smoothly through the cervix without running into the posterior wall of the vagina. To ensure that the IUD threads could get through the cervix's external os without requiring to be cut immediately the abdomen was closed, we also cut them. Then, we grasped the uterus and steadied it with the non-dominant hand. Next, we pressed the introducer up against the uterine fundus first. Then, we carefully moved the IUD downwards through the cervical canal to the vagina, making sure that the IUD remained in the fundus and that the IUD threads were in the cervical canal. Lastly, we carefully closed the uterine incision, making sure that neither the introducer nor the threads were within. Following the sealing of the skin and wound ceiling, we next carefully removed the introducer manually from the vagina. This procedure was thought to lower the rate of IUD thread invagination into the uterus and uterine incision, which aided the patient's self-examination in the event that an ultrasound was not accessible.

Post-operative:

- Each woman received a card indicating the type and date of insertion prior to being released from care. Women were made aware of the risks associated with IUDs.

One week Postpartum: Pelvic ultrasonography was performed to confirm in situ IUD and rule out malposition.

Six weeks after giving birth: Patients were asked if they had any indications of adverse consequences or problems. Speculum examination was carried out. The length of the IUD threads were trimmed to 2 cm from the external os if speculum examination revealed longer ones.

- Pelvic ultrasonography (Figure 4) was performed to confirm in situ IUD and rule out malposition if they were not visible. Rotation or inferior position in the cervix or lower uterine section is called displacement. IUD to endometrium, IUD to uterine myometrium, and IUD to uterine fundus distances of 7, 11, and 27 mm respectively were applied as a definition of normal IUD position [(9)].

- IUD complications such as endometritis or pregnancy were assessed by US. Missed threads and pain were assessed using VAS score to gauge patient satisfaction.

Ethical considerations: The Ethical Committee of Faculty of Medicine, Cairo University approved this study. written informed consent outlining the purpose of the investigation and the procedures that were initiated was obtained from each participant. The Helsinki Declaration was adhered to over the entirety of the research.

Statistical analysis

The statistical program for social science version 23 (SPSS) was used. Quantitative data were expressed as mean ± standard deviation (SD). Whilst, frequency and percentage were used to describe categorical data. Quantitative data comparison was conducted using the Mann Whitney U test for independent samples, and, when appropriate, the Fisher exact test or the Chi squared test was used to compare categorical data. A probability value (p-value) ≤ 0.05 was deemed statistically significant, and a p-value ≤ 0.001 was deemed statistically highly significant. The correlation coefficient test was used to rank various variables against one another.

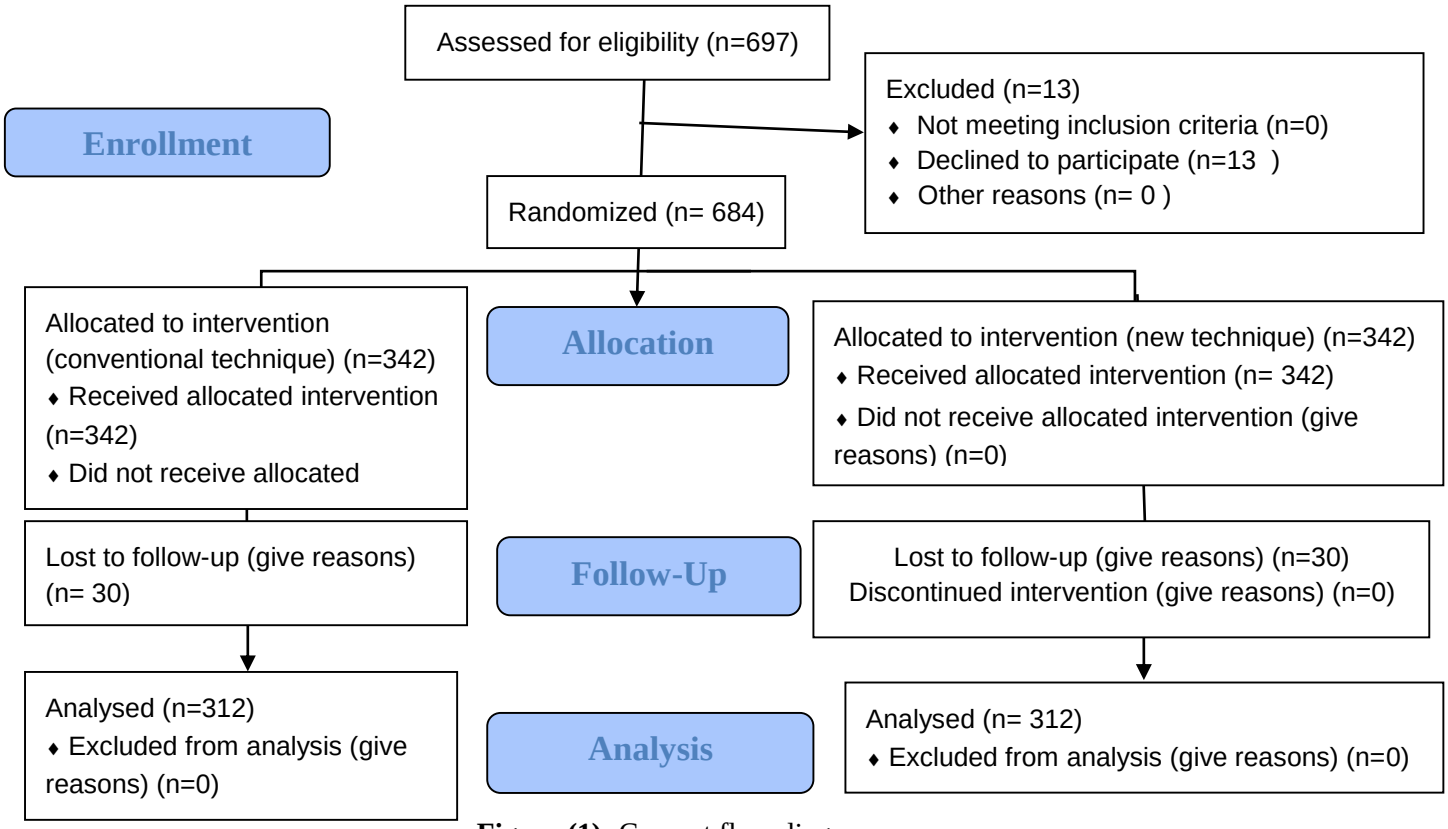

Figure (1): Consort flow diagram.

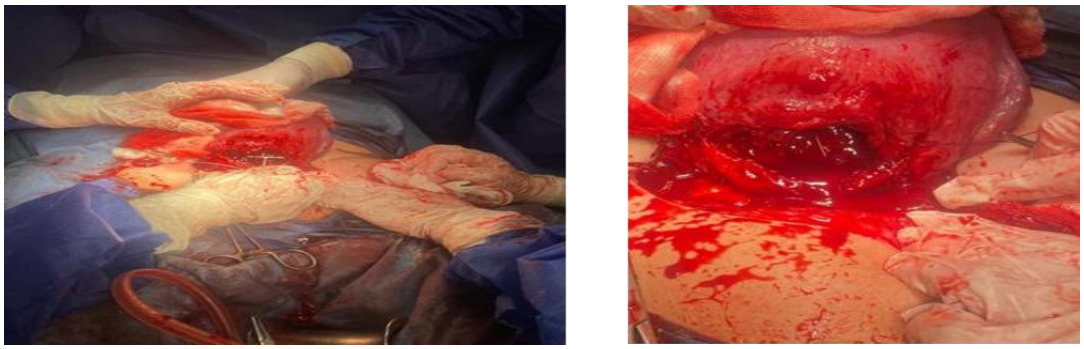

Fig (2): CuT380 IUD inserted intra-caesarean using standard approach. (Kasralainy Obgyn Operation theatre)

Fig (3): CuT380 IUD inserted intra-cesarean using our new technique. (Kasralainy Obgyn Operation theatre).

Fig (4): Trans vaginal US 6w follow up of CuT380 IUD inserted intra-caesarean (Kasralainy Obgyn Outpatient clinic).

RESULTS

Table (1): revealed that there was no significant statistical difference between new technique and the standard technique group as regards BMI, number of previous CS, history of menorrhagia/ dysmenorrhea, history of PPH, previous use of IUD (p-values 0.321, 0.420, 0.139, 0.69, 0.745) respectively.

Table (1): Basic Data of the patients

	Group (A) Standard Technique (N=312)	Group (B) New Technique (N=312)	P value
Age	27.57±5.13	28.87±6.22	0.212
BMI	29.37±5.93	30.49±6.54	0.321
Gest. Age	38.23±1.11	37.96±1.17	0.083
Parity	2.32±1.12	2.47±1.22	0.442
Prev. CS **Prev. 1 cs** **Prev. 2 cs** **Prev. 3 cs** **Prev. 4 cs** **Prev. 5 cs**	248(79.5%) 128(41.5%) 60(19.2%) 36(11.5%) 24(7.7%) 0(0%)	256(82.05%) 108(34.6%) 92(29.5%) 36(11.5%) 16(5.1%) 4(1.3%)	0.420
Prior IUD use	188(60.3%)	176(56.4%)	0.745
Dysmenorrhea /menstrual irregularities	40(12.8%)	20(6.4%)	0.139
H/O of PPH	8(2.6%)	8(2.6%)	0.69
Pre-operative hemoglobin	11.13±0.625	11.22±0.704	0.427

Table (2) showed that there was no statistically significant difference between the studied groups regarding estimated intra-operative blood loss & post-operative hemoglobin (P values 0.298 & 0.088 respectively). However, there were statistically significant differences regarding the mean duration of CS & post-operative mean VAS score of pain (P values 0.01 & 0.006 respectively).

Table (2): Intra-operative data

	Group (A) Standard Technique (N=312)	Group (B) New Technique (N=312)	P value
CS duration	41.66±6.39	38.32±7.34	0.01
EBL during CS	575.6±103.9	554±92.815	0.298
Post-operative Hemoglobin	10.38±0.643	10.49±0.75	0.088
PPH	7(2.2%)	8(2.6%)	0.414
VAS score **Mean ±SD** **Mild (1-3)** **Moderate (4-7)** **Sever (≥8)**	 5.43±1.25 8(2.6%) 284(91%) 20(6.4%)	 4.85±1.065 28(9%) 280(89.74%) 4(1.3%)	 0.01 0.105

Table (3) showed that there were statistically significant differences between the new technique and the standard technique group as regards visibility of the threads ($p < 0.001$), displaced IUD position ($p = 0.008$) and discontinuation rate ($P = 0.004$). Patient satisfaction was in favor of new technique group ($p = 0.002$).

Table (3): outcome of IUD technique

	Group (A) Standard Technique (N=312)	Group (B) New Technique (N=312)	P value
Visibility of threads	188(60.3%)	276(88.5%)	<0.001
Displaced IUD position	32(10.3%)	19(6.1%)	0.008
Post-insertion bleeding	72(23.1%)	56(17.9%)	0.276
Infection	13(4.2%)	8(2.6%)	0.138
Expulsion	28(8.9%)	12(3.8%)	0.083
Pregnancy	0(0%)	0(0%)	
Discontinuation	32(10.3%)	9 (2.8%)	0.004
Overall satisfaction	188(60.3%)	224(83.3%)	0.002

Table (4) showed that patient satisfaction was mainly correlated to visibility of threads ($p < 0.001$). The discontinuation was correlated to infection & expulsion in the standard method (p values < 0.001 & 0.001 respectively). On the other hand, infection, expulsion & post-insertion bleeding were the leading motives for discontinuing method use after the new technique (p value 0.001, 0.001 & 0.001 respectively).

Table (4): Correlation between Patient satisfaction & outcome

Satisfaction	Standard technique	New technique
Visibility	<0.001	<0.001
VAS score	0.929	0.237
Post-insertion bleeding	0.317	0.192
Infection	0.023	0.001
Expulsion	<0.001	0.001
Discontinuation		
Visibility	0.538	0.364
VAS score	0.103	0.394
Post-insertion bleeding	0.893	0.001
Infection	<0.001	<0.001
Expulsion	<0.001	<0.001

DISCUSSION

As one of the highest quality options for contraception in the postpartum period, the American College of Obstetrics and Gynecology (ACOG) recommends the CU-T 380 IUD, a long-acting reversible contraception (LARC). The purpose of the ACOG guidelines for this technique is to increase the spacing between pregnancies, which will enhance the care provided to mothers and children, particularly in developing nations. IUD placement during cord clamping (CS) immediately after placental separation can provide direct contraception, stop recurrent unintended situations, and potentially lessen the likelihood of further CS. Nevertheless, the high ejection displacement rates of postplacental IUD installation [(10)].

There is currently no accepted method for inserting an IUD during a Cesarean section. According to previous research, the traditional method of inserting an IUD during a cesarean section involves manually inserting the device into the fundus of the uterus and guiding the IUD strings through the cervix [(11)]. To guarantee that the IUD was inserted into the uterine fundus, certain research employed the IUD introducer, ovum forceps, or long curved Kelly's forceps**.** Without providing a clear explanation for this procedure, the introducer was utilized in a different investigation to direct the strings in the cervix. The impact of procedure adjustments on IUD problems and side effects was not examined in any of the prior trials. Consequently, it is evident that a standard procedure with the fewest potential side effects and problems is required for IUD implantation during cesarean delivery [(12)].

In 2023, Seleem *et al.* [(13)] conducted a comparative trial that compared IUD insertion using a new technique versus the standard method. However, they did not provide a detailed description of the operative & postoperative outcome of this new technique and if there are factors impacting this outcome. Because of this, the purpose of our study was to evaluate the safety and effectiveness of inserting an IUD using this novel methodology against the conventional method in terms of thread visibility, IUD position accuracy, and the emergence of any issues both immediately after delivery and six weeks later. The rationale of this new approach is the use of the introducer to make sure that the IUD is inserted into the fundus of the uterus and that the strings of the IUD travel through the cervix into the vagina. Pushing the IUD's unfolded arms up to the fundus with an introducer guarantees that the arms are securely in the uterine fundus, something that is not guaranteed by the traditional manual placement maneuver of gripping the IUD from the stem. We also need to be aware that pushing the IUD is not the same as holding and releasing it.

Inserting an IUD that has been grabbed into the uterine fundus may result in some IUD bringing downward during the withdrawal of the grabbing tool or even the snapping hand because of the restricted space available, which creates some negative pressure, and being unable to entirely ungrasp the IUD. However, because the introducer is no longer attached to the IUD, withdrawal of the introducer will not cause the IUD to pull downward as is typically the case with standard IUD insertion-removal methods practiced in gynecology.

In another investigation, the introducer was employed during the insertion method; however, the IUD was placed in the fundus first, followed by the cervix, and neither the introducer nor the threads were trimmed. We can anticipate that resistance from the posterior vaginal wall was encountered if the cervix was directed posteriorly, and that they had trouble inserting the introducer because of the length of the cavity of the uterus, which may make it difficult for the entire introducer to enter before being pushed through the cervix. Additionally, they contrasted interval insertion and intra-cesarean insertion in this investigation [(12)]**.**

The key issue with IUD utilization is IUD displacement, that can lead to other concerns such as lower abdominal colic, bleeding, expulsion, and unwanted pregnancy [(14)]**.** In our study, the new procedure resulted in a 6.1% probability of IUD displacement at the completion of puerperium, while the usual post-placental placement of the IUD method had a 10.3% rate. This difference in percentage was statistically significant. According to a study by **Seleem *et al*.** [(13)] at the end of puerperium, the incidence of intrauterine displacements using the novel approach

was 9.9%, while the proportion using traditional methods was 15.5%. There will be reduced risk of displacement if the IUD is fixed after being inserted into the uterine fundus. The least displacements and expulsion rates of the Gyne-T 380 postpartum IUD and the GyneFix® CS for intra-cesarean installation by **Wildemeersch *et al.*** [15] are 2.7% and 9.5% respectively.

However, by using the widely available IUD types and the standard IUD insertion equipment included in every package, we wanted to standardize a method that may be applied in underdeveloped nations with low resources. Furthermore, the risk of bleeding, the lengthening of the surgical procedure, and the excessive difficulty of the procedure may all rise with suturing and fastening the IUD to the uterus. However, since prior research only used the traditional manual method for IUD fixation, more research will be required to determine the benefits of switching to this new method.

A potential issue with post-placental IUD insertion could be thread visibility. IUD thread non-visibility makes it challenging to solve the missed IUD problem. Our research revealed a highly significant statistical difference (p-values < 0.001) in the visibility of the threads between the novel method group and the standard method group, which had an impact on patient satisfaction since the patient feels reassured when they feel the threads. The **FIGO** investigation documented the prevalence of missing threads in about one-third of mothers, this was among both vaginal and cesarean deliveries [16]. After a year of post-placental conventional method, the incidence of missed IUD threads was 48.15% in one study [17]; after a year, the incidence was 13% in another study [12].

In a different study, even though the researchers guided the IUD strings through the cervix using ring forceps, 44% of the threads were invisible. The prevalence of missed IUD strings varied from zero to 72% in a systematic review updated in 2017, depending on the kind of the contraceptive device and the small number of patients in certain studies [2]. Based on our discussion, one of the main benefits of the new method was the use of the introducer to guarantee that the IUD threads pass through the cervical canal and are visible in the vagina.

In our study, acceptability, side effects, and problems were measured by stopping the IUD use after six weeks. IUD usage was discontinued at a slightly greater rate in the group using the usual approach (10.3% versus 2.8%, which was statistically significant). This agrees with what **seleem *et al.*** [13] concluded. According to their findings, the novel technique group continued to use IUDs at a higher rate than the standard method (88.1% versus 79.9%, with a significant statistical difference).

In a prior study, where the IUDs were placed in the fundus using an introducer and the threads were guided into the cervical canal by ring forceps, 17% of the participants stopped using IUDs after six months, despite using a variety of IUD forms [17].

In terms of the study's intraoperative portion, we compared the length of time each group spent during surgery to determine whether our novel technique added significantly to the time required for the procedure. Surprisingly, we found a statistically significant difference between the two groups, with the new technique resulting in a shorter operative duration. Further evaluation of the procedure with various IUD varieties and obstetricians with varying degrees of training is nevertheless required. This novel technique was easier and required less uterine manipulations, which was also reflected post-operatively. There was a significant statistical difference between groups regarding post-operative mean VAS score of pain (P value 0.006), which was also in favor of the new technique. Thus, patient satisfaction was statistically higher in the new technique group (p-value 0.002).

There were some constraints on our research. Because the clinical personnel and patients were not blinded to the trial, observation bias may have arisen. Every attempt was made to ensure that the evaluation of thread visibility was unbiased as feasible. More time was needed to assess complications as pregnancy on IUD. Post- insertion bleeding and cramping pain weren't accurately assessed due to difficulty to distinguish them from post-operative pain and lochia. Sixty patients dropped out of the study during the follow up period.

CONCLUSION AND RECOMMENDATIONS

We came to the conclusion that utilizing the new technique instead of the standard one for post-placental IUD insertion, produced better results in terms of thread visibility and accuracy and increased patient satisfaction. In the light of all of the available data, we advise that intra-cesarean CuT380 IUD insertion to be considered a very safe, effective, and practical approach of postplacental (Intracesarian) contraception. This will help to address the unmet need for family planning in developing nations such as Egypt, where women do not seek out postnatal contraception.

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***Authors of this manuscript state that:**

1) the paper is not under consideration elsewhere,
2) none of the paper's contents have been previously published and
3) all authors have read and approved the manuscript.

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