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Evaluation of Intra-Cesarean Insertion of Cu-T380 IUCD (Safety, Efficacy, Expulsion and Continuation Rates)

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ABSTRACT
Background: Interval contraception with Copper T 380A has been shown to be highly effective and reversible, providing ten years of reliable protection. Multiple studies have demonstrated that intra-caesarean implantation of an intrauterine contraceptive device (IUCD) is effective and poses no increased risk of infectious morbidity.
Aim and Objectives: We aimed to study the clinical outcomes (safety, effectiveness, expulsion, and continuation rates) of post placental Copper T 380A insertion in women after cesarean section.
Patients and methods: This case-control study was conducted in the Department of Obstetrics and Gynecology, AL-Azhar University Hospitals (Assiut), a Tertiary Care Hospital. The study included 67 pregnant women who were scheduled for elective Cesarean section.
Results: The statistical significance (p-value< 0.001)) was extremely high increased percentage of lost follow at 6 months (19 patients, 39.6%) and 3 months (12 patients, 21.8%) when compared to 3 weeks (0 patients, 0%). Concerning the problems that were evaluated, there was no discernible difference (p value > 0.05) between the two time periods of follow-up.
Conclusion: Intra caesarean IUCD insertion is a promising approach. It is safe and effective with remarkable low failure rate and minimal side effects over the users.
Keywords: Intra-cesarean insertion, Cu-T380 IUCD, Pregnancy.

INTRODUCTION
Some women are at risk for rapid, recurring, and unwanted pregnancy if they wait until their postpartum visit to start using effective contraception [(1)]. Approximately 50% of women who do not breastfeed will have ovulated by 6 weeks postpartum [(2)]. Furthermore, greater than half of women resume sexual activity within 6 weeks postpartum [(3)]. Many women who want to use an IUCD for postpartum contraception never get one because they avoid the doctor after giving birth out of fear of the potential pain and discomfort of the experiment [(4)]. Because of their lower socioeconomic status [(5)], these women are more likely to have trouble getting to and from medical appointments and communication with their doctors [(6)].

With a verified success rate, Copper T 380A (IUCD) is a long-acting, reversible spacing treatment that can prevent pregnancy for up to ten years [(7)]. Several studies have shown that IUCDs can be successfully implanted through an incision made during Caesarean section with no increase in the risk of infectious morbidity [(8, 9)]. This method allows the obstetrician to put the IUCD into the uterus under direct visualization, removing any potential risk of perforating the uterus. Nonetheless, obstetricians are reticent to offer the benefits of Copper T 380A IUCD to women undergoing surgical delivery, despite reports of its safety and effectiveness. The benefits of starting IUCD use during Caesarean section include skipping the postpartum waiting period of six weeks and the subsequent hospital visit [(8)].

Women undergoing Cesarean sections will participate in this trial to assess the clinical results (safety, effectiveness, expulsion, and continuation rates) of post placental Copper T 380A insertion.

PATIENTS AND METHODS
Sixty-seven pregnant women who were scheduled for elective Cesarean section were included in this case-control study. The study was conducted at Tertiary Care Hospital, AL-Azhar University Hospital (Assiut).
The sample size was calculated by using the following formula:
$N = (Z / \Delta)^2 \times P (100 - P)$.

Inclusion Criteria: Those interested in using the CuT-380 IUCD for contraception must be between the ages of 18 and 40, have no uterine malformations and genital or pelvic lesions, or genital cancer.

Exclusion criteria: Refusal of the patient, age less or more than 18-40, Patients with intra-partum fever, congenital uterine abnormality, amniotic sac rupture lasting more than 18 hours, history of postpartum haemorrhage and Allergy from any component of the CuT-380A IUCD.

Methodology
Every patient was subjected to: Detailed history taking (age, obstetric history, menstrual history, residence,

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occupation, medical history, surgical history, and family history). Clinical examination and Proper investigations are asked to the patients for preparation for undergoing Cesarean section. All patients signed informed consents to apply the Cu-T380A IUCD intra-Cesarean, and also gave explanation and informed consent to use their data in the study and Duration of patient follow-up was 6 weeks to 6 months to detect the efficacy of the device in contraception, safety of the device continuation and expulsion rates.

Insertion of TCu-380A: Only medical professionals with the necessary skills and knowledge placed IUCDs. After the newborn, its placenta, and membranes were removed through a cesarean section, the TCu-380A IUCD was placed through the incision made in the lower uterine segment. After removing it from the applicator, the IUD was inserted into the uterine fundus as close to the cervix as possible.

Figure (1): IUCD

Figure (2): Cusco speculum.

Ethical approval:

Approval of research by Ethics Committee of AL-Azhar University (Assiut) Faculty of Medicine was obtained. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans. Consent was given both verbally and in writing after proper education will be taken from all participants.

Statistical analysis

SPSS version 24 was used for the statistical analysis of the data. Quantitative data were summarized as a mean ± SD. Frequency and percentages were used to represent qualitative information. The mean (or average) is the value at the mathematical center of a discrete set of numbers, calculated by dividing the total by the total. A set of numbers' dispersion was measured by its standard deviation (SD). A smaller standard deviation (SD) implies that the values cluster around the set's mean, while a larger SD suggests that the values are more widely dispersed. The significance level is set at $p<0.001$X2: Chi-square test. NS: p-value > 0.05 is considered non-significant.

RESULTS

Table (1) listed the demographic information for all patients who were the subject of the study. The average age of all the patients in the study was 30.2 ± 5.6 years, with a minimum age of 21 and a maximum age of 40 years. In terms of parity, all patients that were studied had a mean parity of 3.4 ± 1.72, with a minimum parity of 1 and a maximum parity of 8. Regarding the number of CS, the mean number in all patients who were evaluated was 2.2 ± 1.05, with a minimum number of 1 and a high number of 5. It was found that 61.2% of the patients tested were from rural areas, whereas 38.8% were from urban areas. There were 36 educated patients (53.7% of the total) among those who were studied.

Table (1): Description of demographic data in all studied patients

		Studied patients (N = 67)	
Age (years)	**Mean ±SD**	30.2 ± 5.6	
	Min – Max	21 – 40	
Parity	**Mean ±SD**	3.4 ± 1.72	
	Min – Max	1 – 8	
No of CS	**Mean ±SD**	2.2 ± 1.05	
	Min – Max	1 – 5	
Residence	**Rural**	41	61.2%
	Urban	26	38.8%
Education	**No**	31	46.3%
	Yes	36	53.7%

Table (2) showed the six-week evaluation for each patient in the study. There was bleeding in 7 patients (10.4%), pelvic infection in 1 patient (1.5%), discharge in 3 patients (4.5%) visible by Cusco in 39 patients (58.2%), not visible in 28 patients (41.8%), in site (US) in 55 patients (82.1%), expulsion in 4 patients (6%), displaced in 8 patients (11.9%) and removal in 8 patients (11.9%) while there were no patients with perforation or got pregnant in the subjects of the studies.

Table (2): Description of 6 weeks assessment in all studied patients

		Studied patients (N = 67)	
6 weeks assessment	**Bleeding**	7	10.4%
	Pregnancy	0	0%
	Pelvic infection	1	1.5%
	Discharge	3	4.5%
	By Cusco Visible	39	58.2%
	Not visible	28	41.8%
	In site (US)	55	82.1%
	Expulsion	4	6%
	Displaced	8	11.9%
	Removal	8	11.9%
	Perforation	0	0%
	Lost follow	0	0%

Three-month results for all patients in the study were summarized in table (3). There had been bleeding in 7 patients (12.7%), pelvic infection in 2 patients (3.6%), discharge in 4 patients (7.3%), visible by Cusco in 30 patients (54.5%), not visible in 25 patients (45.5%), in site US in 48 patients (87.3%), expulsion in 3 patients (5.5%), displaced in 4 patients (3.6%) and removal in 4 patients (7.3%). While, there were no patients with perforation or got pregnant in the studied patients and there were 12 patients (17.9%) lost follow-up.

Table (3): Description of 3 months assessment in all studied patients

		Studied patients (N = 55)	
3 months assessment	**Bleeding**	7	12.70%
	Pregnancy	0	0%
	Pelvic infection	2	3.60%
	discharge	4	7.30%
	Visible	30	54.50%
	Not visible	25	45.50%
	In site (US)	48	87.30%
	Expulsion	3	5.50%
	Displaced	4	7.30%
	Removal	4	7.30%
	Perforation	0	0%
	Lost follow	12	21.80%

Table (4) showed the description of 6 months assessment in all studied patients.

There was bleeding in 11 patients (22.4%), pelvic infection in 2 patients (4.2%), discharge in 4 patients (8.3%), visible by Cusco in 30 patients (62.5%), not visible in 18 patients (37.5%), in site US in 45 patients (93.8%), expulsion in 2 patients (4.1%), displaced in 1 patient (2%) and removal in 1 patient (2.1%).

While, there were no patients with perforation or got pregnant in the studied patients and there were 19 patients (39.6%) lost follow up.

Table (4): Description of 6 months assessment in all studied patients

		Studied patients (N = 48)	
6 months assessment	**Bleeding**	11	22.9%
	Pregnancy	0	0%
	Pelvic infection	2	4.2%
	Discharge	4	8.3%
	Visible	30	62.5%
	Not visible	18	37.5%
	In site (US)	45	93.8%
	Expulsion	2	4.2%
	Displaced	1	2.1%
	Removal	1	2.1%
	Perforation	0	0%
	Lost follow	19	39.6%

Increased percentage of lost follow-up at 6 months with a very high level of statistical significance (19 patients, 39.6%) and 3 months (12 patients, 21.8%) when compared to 3 weeks (0 patients, 0%).

Concerning the examined complications, there was no significant distinction (p value > 0.05) between the two time points of follow-up (Table 5 & figure 3).

Table (5): follow-up

	Follow up						X^2	P-value
	6 weeks (n = 67)		3 months (n = 55)		6 months (n = 48)			
Continuation Rate								
Bleeding	7	10.4%	7	12.7%	11	22.9%	3.7	0.155 NS
Pregnancy	0	0%	0	0%	0	0%	====	=====
Pelvic infection	1	1.5%	2	3.6%	2	4.2%	0.83	0.657 NS
Discharge	3	4.5%	4	7.3%	4	8.3%	0.77	0.679 NS
Visible	39	58.2%	30	54.5%	30	62.5%	0.66	0.716 NS
Not visible	28	41.8%	25	45.5%	18	37.5%	0.66	0.716 NS
In site (US)	55	82.1%	48	87.3%	45	93.8%	3.3	0.184 NS
Expulsion	4	6%	3	5.5%	2	4.2%	0.18	0.911 NS
Displaced	8	11.9%	4	7.3%	1	2.1%	3.8	0.144 NS
Removal	8	11.9%	4	7.3%	1	2.1%	3.8	0.144 NS
Perforation	0	0%	0	0%	0	0%	====	====
Lost follow	0	0%	12	21.8%	19	39.6%	**30.1**	**< 0.001 HS**

HS: The significance level is set at p<0.001 **X^2:** Chi-square test. NS: p-value > 0.05 is considered non-significant.

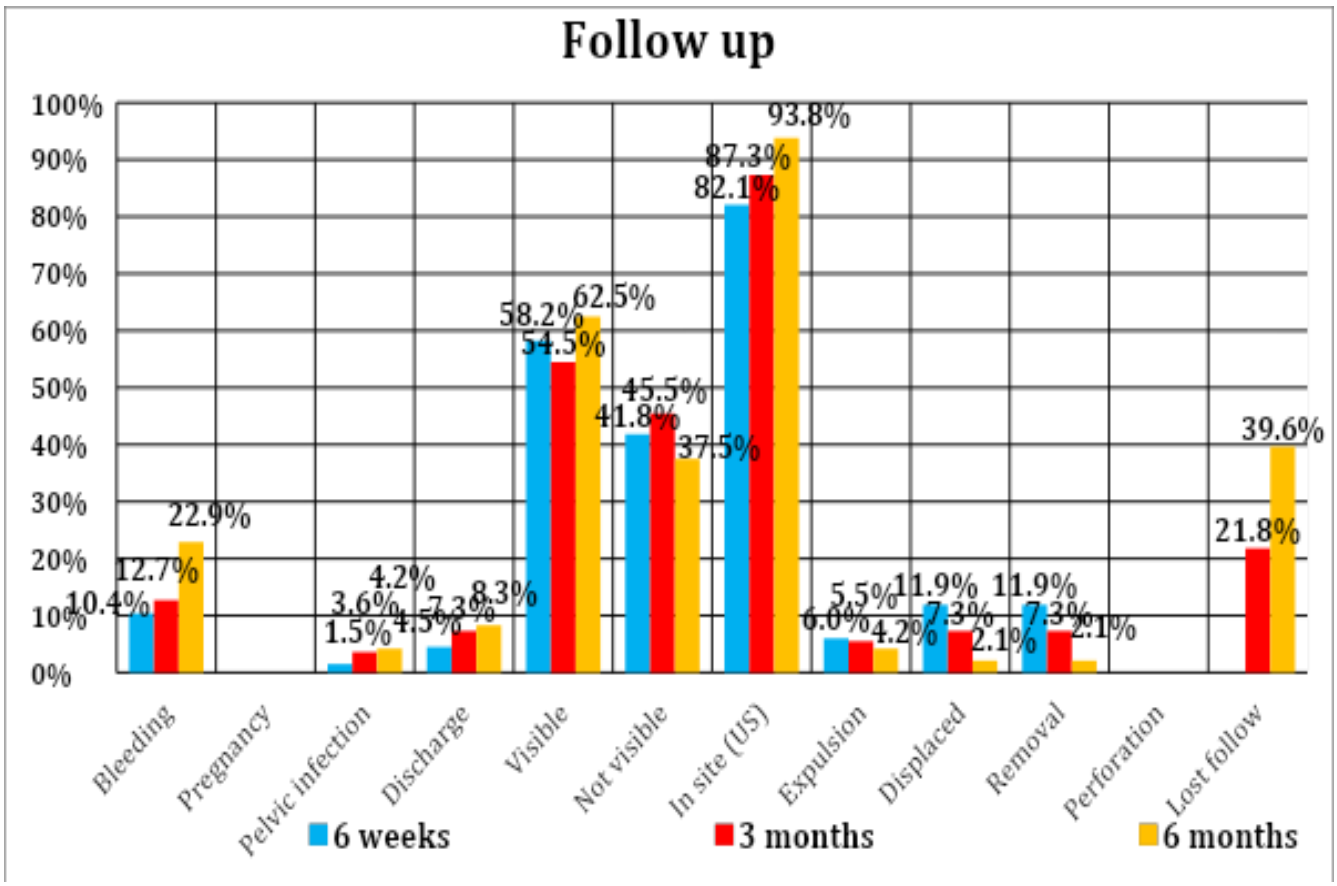

Figure (3): follow up

DISCUSSION

In this study, acceptance of post-partum intra uterine contraceptive device (PPIUCD) is higher in age of 30.2 ± 5.6 of the studied women, which is higher than in **Singal *et al*. [(10)]**, which was 23.12 ± 2 .42, and also higher than **Abhijit *et al*. [(11)]**, which was 24.84 ± 4.79 . And more than half of women in the study lived at the rural around the city where our hospital is located. This high mean of ages involved in the study, and the high number of rural ladies may conflict the lower acceptance of the PPIUCD at lower ages as the common believes to counseling proof of permanent sterilisation.

53.7% of the studied women had a primary level of education, which is much lower than in **Mishra Sujnanendra [(12)]**. According to a study conducted in Zimbabwe, increased access to education increases the prevalence of contraceptive use. Females with a secondary education (12 years or more) were the only ones who noticed it. Women with a secondary school diploma were nearly twice as likely to utilize modern contraceptive methods as women with a primary school diploma [(13)].

Most of our patient underwent 2.2 ± 1.05 Caesarean sections, which comes in a midway between the belief to permanent sterilization and the post-caesarean conception fear.

Outcomes of PPIUCDS at follow-up visits:

Safety:

Zero cases had perforation during the full time of the study, which is same as **Hooda *et al.* [(14)]** has found in a study over 171 women at Department of Obstetrics and Gynecology, Pt. BD Sharma Post Graduate Institute of Medical Sciences, Rohtak, Haryana, India [(14)].

This supports the rational of our study that inserting the IUD CU-T 380 post placental intra-caesarean keeps the obstetrician away from the probability of uterine perforation during application of IUCD any time after.

Unusual vaginal discharge was reported in 3 cases in the 6 weeks visit, one of those patients had history of fever, pelvic pain and scanty whitish discharge treated with proper antibiotics. This finding is higher than what was found in **Hooda *et al*.[(14)]** and could be explained by the lower sample of patients we studied, while the two other cased had itching, scanty cheesy discharge with acidic PH positive weff test and received the fungal vulvovaginitis treatment.

Different forms of vaginal bleeding were experienced by the patients varying from spotting to heavy menstrual bleeding representing 10.4%of patients which is almost the same as in **Hooda *et al*. [(14)]**, but a much less than **Mishra Sujnanendra. [(12)]** Who had 23.5% of his patients with different forms of bleeding led 14.71% of them to remove the device, which hadn't occur in our study. But effective treatment with hematinics and nonsteroidal anti-inflammatory drugs.

Efficacy

Another zero cases is found in detecting the pregnancy rate among the studied patients, which is corresponded to what **Hooda *et al*. [(14)]** has found. **Singal *et al*. [(10)]** has a case got pregnant in his 6 months follow up visit and another case in the 12 months follow up .both ladies had medical termination of pregnancy unfortunately.

Encouraging women to use the contraceptive device immediately before leaving the hospital in case of Caesarean delivery give them a great chance to avoid unwanted unspaced pregnancy, which puts mother, current fetus and future pregnancy in a great risk of multiple comorbidities.

Expulsion of the IUCD occurred completely in 4 cases in the 6 weeks visit, 3 cases in the 3 months visit, which is higher than IUCDs expulsed in **Abhijit *et al*. [(11)]** which was 2%, and near to what **Singal *et al*. [(10)]** had found with expulsion rate of 5.33%. Pushing a concern about the efficacy of the device.

An ultra-sonographic finding was presence of the IUCD more than 4 mm away from uterine fundus in 8 cases after 6 weeks, 4 cases at 3 months and one case at 6 months, which was removed once discovered by crocodile forceps. This is much higher per 100 woman than what happened with **Singal *et al*. [(10)]**. This finding (displacement) was the main cause of removing the device and patients were counseled to re insert the IUCD or have another method. The removal rate in our study is higher than in **Singal *et al*. [(10)]** who had 7% removal rate for reasons like menstrual complains and psychological causes.

Fortunately we had all of our studied women continued the study except for who had terminal events like expulsion or removal of the device. Which is lower than the 23.05% of lost to follow-up cases in **Mishra Sujnanendra [(12)]**.

One of the components of the follow-up visit is inspecting the cervical opening through a Cusco speculum to detect any abnormal vaginal discharge, confirm the presence or absence of the IUCD strings, and to cut them 2 cm away from the cervical opening. 41.8% of the studied cases had no visible strings by Cusco speculum examination, which push some worries for both the user and the physician about the presence of the device either intra uterine, extra uterine, or completely expulsed outside, which necessitate the next step of using the ultrasound to locate the device or further more investigations of missed IUCD. But it is noticed that number of those cases are reduced along the 6 months, which suggested that the descend of the threads may improve by time. Our finding is corresponding to the

Hooda *et al*. [14] finding of 38% undescended strings and slightly higher than **Singal *et al*. [10]** who has a close manner in progression in strings decent along months.

CONCLUSION

Intra-caesarean IUCD insertion is a promising approach. Incredibly few incidents of failure characterize its reliability and minimal side effects over the users.

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- **Availability of data and material:** Available
- **Competing interests:** None
- **Funding:** No fund
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