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Intra Uterine Contraceptive Device Insertion and Fixation versus Insertion Only During Cesarean Section

Mahmoud Abdeen Ahmed Mahmoud [1,*] Msc, Hossam Hassan Elkatatny [2] MD, Abd Elhalim Mohamed Abd Elhalim [2] MD

** Corresponding Author:*
Mahmoud Abdeen Ahmed Mahmoud
mahmoudabdeen9090@gmail.com

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[1]*Resident at Obstetrics and Gynecology Department, sohag general hospital, Egypt.*

[2]*Obstetrics and Gynecology Department, Faculty of Medicine , Al-Azhar University, Cairo, Egypt.*

ABSTRACT

Background: Women who have a caesarean section (CS) have a special chance to get the IUD (IUD).
Aim of the study: : to assess the efficacy, safety, convenience, and complications of a copper IUCD inserted instantly following the expulsion of the placenta through the lower segment of the caesarian section and comparison of the results according to whether the IUCD is fixed or not. This is carried out by clinical assessment and follow-up by ultrasound.
Patients and Methods: This randomized control trial that conducted at the Sohag General Hospital's Department of Obstetrics and Gynecology (Sohag, Egypt), on 200 pregnant women, during twelve months (December 1st, 2019 – November 30 th , 2020).
Results: there was statistically significant increase expulsion in insertion of IUD without stitch.
Conclusion: IUCD insertion and fixation with absorbable suture (fixation group) was the best healthy results at all study points and the less expulsion rate than IUCD insertion only without fixation (no-fixation group).

Keywords: *issing IUD threads; post-placental IUD; cesarean section; IUD expulsion.*

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INTRODUCTION

Just after the baby is delivered is the optimal time to begin utilising postnatal control, either as a preventative precaution or as a family tool for planning. Instant contraception is both practical and timely when a woman is actively considering her present and future health choices. The return of a female's fertility after childbirth is unpredictable, as it could happen in as little as three weeks in women who are not breast-feeding and is not always followed by menstruation. The prenatal period is a near-ideal time for discussing contraception with women, in terms of requirements, the nature of the products accessible, and other topics, as well as the advantages and disadvantages of each. The willingness of the patient to pick a certain type of contraceptive is an important aspect in assisting a woman in appropriately managing her contraceptive requirements. [1] Females who have caesarean sections with less than 18 months between deliveries have a higher risk of uterine rupture [2]. Using contraceptives as soon as feasible after delivery to prevent uterine rupture following a caesarean section would allow the wound to heal and the woman to recover completely from her gestation. Efficient contraception will help such women avoid undesired pregnancies, and it may even allow them to have natural births instead of caesareans.

Intrauterine devices (IUDs) are largely regarded as the near-ideal contraception type, with advocacy organizations, clinicians, as well as gynaecological organisations all advocating for them. IUDs have high effectiveness and a low rate of failure, owing in part to the female's lack of participation. Rapid postpartum IUD insertion is worth considering since it could offer rapid contraceptive methods, prevent unintended pregnancies, as well as decrease the requirement for a second caesarean birth [3]. Unfortunately, the high expulsion and displacement rates of traditional T-shape IUDs limit their usage right after placental delivery [4, 5].

With T-shape devices, the timing of implantation after placenta delivery is crucial. According to studies, when the catheter was put in more than 10

minutes after delivery, rates of expulsion have been greater than in usual women

PATIENTS AND METHODS

This was a randomized controlled clinical trial performed at Sohag General Hospital's Department of Obstetrics and Gynecology (Sohag, Egypt) for twelve months (December 1st, 2019 – November 30th , 2020).

Patients: The study included 200 pregnant women scheduled for elective CS and desired immediate postpartum IUCD insertion during CS at Sohag General Hospital during the period of the study.

Inclusion criteria: Gestational age between 36 – 40 weeks, singleton pregnancy, elective CS, normal findings on ultrasound scanning, and request of the Cu T380A IUD for immediate postpartum contraception.

Exclusion criteria: Gestational age < 36 weeks or > 40 weeks, distorted uterine cavity, multiple gestations, abnormal placenta (e.g., previa, accreta), ruptured membranes for more than 12 hours or evidence of chorioamnionitis, emergent CS, uterine fibroid, history of ectopic pregnancy, bleeding tendency, repeated PID, allergy to copper and wilson disease.

Methods: All participating pregnant women were subjected to the following:

Complete history taking: including the following data: Sociodemographic data: including age, residence, and socioeconomic status. Menstrual history: including age at menarche, and details of menstrual cycles. Obstetric history: including number of pregnancies and deliveries, mode of delivery, and previous obstetric complications. Medical history: including diabetes mellitus, hypertension, and other medical conditions.

Antenatal counselling and consent: All women have been counselled about contraception throughout prenatal care with a full description of different methods of contraception, different types of IUCDs, and the advantages and disadvantages of each of them.

Examination: All study participants underwent complete general examination, abdominal examination, and pelvic examination.

Investigations: All study participants underwent pelvic Ultrasound for thorough assessment of uterus and ovaries. Moreover, blood samples were obtained for complete blood counts and hemoglobin levels, kidney functions, liver enzymes, and coagulation profiles.

Insertion of TCu-380A: The TCu-380A (Pregna International Ltd, Mumbai, India) is a T-shaped device with a vertical measurement of 32 mm and a horizontal measurement of 36 mm. The monofilament polyethylene tail strings are threaded into a 3 mm bulb at the vertical stem base, allowing the patient to check for the device's continued presence and facilitating the IUCD's later removal. All IUCDs were put by physicians who had undergone adequate training. The TCu-380A IUCD was placed via the lower uterine segment incision after delivery of the baby, placenta, and membranes through caesarean section. The IUD was manually inserted into the most proximate portion of the uterine fundus after being detached from its applicator. **In the fixation group**, A single absorbable stitch was used to anchor the TCu-380A to the fundal wall. At the connecting arm of the TCu-380A, the anchor ring was tied. Both IUCD strings were lengthened before being placed in the uterine cavity by threading 10 cm of Vicryl threads number 0 through the cylinder and out the other end. The cylinder is progressively pushed downwards through the threads after being inserted near to the fundus, passing through the cervix and being withdrawn vaginally after delivery.

Assessment & follow-up: Follow-up appointments were scheduled for 3, 6, 9, and 12 months after birth for the women who took part. They were shown how to check for IUCD threads and told that if they couldn't feel them, they should seek medical help right once. The Vicryl suture knot emerged beneath the cervix during the puerperium, and the threads were reduced to 2 cm from the cervix. The IUCD was detected via ultrasonography.

Measured outcomes: The rate of IUCD expulsion at 3, 6, 9, and 12 months following CS was the primary endpoint in this study. This was determined by collecting a medical history, performing a pelvic examination, and using an ultrasound. When the IUCD's longitudinal arm is partly or completely within the cervix or vagina, it was considered complete ejection. When the IUCD was more than 10 millimetres away from the fundus but remained completely contained inside the uterine cavity, it was considered partial ejection or displacement [5; 6]. The incidences of intrauterine pregnancy on top of an IUD, ectopic pregnancy, menstrual disturbances, and PID were among the secondary outcomes. Pregnancy was determined by taking a medical history (e.g., missed periods), a pregnancy test, hCG titration, and an ultrasound. PID was defined as chills, fever (temperature N38°C), foul-smelling lochia, spontaneous uterine discomfort or tenderness, and/or delayed uterine involution.

Ethical Considerations: The study was accepted by Al-Azhar University's Faculty of Medicine's Ethical Research Committee (Assiut). Pregnant women gave their informed consent to participate in the study. All data were kept confidential and used for only scientific purposes.

Statistical Analysis: The collected data has been coded, reviewed, and entered into IBM SPSS version 20 (Statistical Package for Social Science). The Chi-square test was used to compare two groups with qualitative results, but the Fisher exact test has been employed rather when the predicted count in any cell was < 5. The independent t-test was employed to compare two groups having quantitative data as well as a parametric distribution, whereas the Mann-Whitney test has been employed to compare two groups having quantitative data as well as a non-parametric distribution. The acceptable margin of

error has been established at 5%, with a 95% confidence interval.

RESULTS

Address of 28.5 of patients (57) elbaliana, of 20.5% (41) was sohag, of 36% (72) was almonshaa. Mean of age was 29.01 with range from 20 to 42 years. (Table 1)
95 patients (47.5%) were have previous use of IUD,25% of patients (50) had Prev use of another method of contraception, Insertion of IUD of 100 patients (50%) was with stitch, of 100 patients (50%) was without stitch. (Table 2)
5 patients (2.5%) had pelvic infection and 71 patients (35.5%) had menstrual complications.(Table 3)
In the case of IUD insertion without stitching, there was a statistically significant increase in expulsion. (Table 4)
In regards to occurrence, there were no statistically significant differences between IUD insertion with stitch versus IUD insertion without stitch. In regards to pelvic infection and menstrual complaints, there were no statistically significant differences between IUD insertion with stitch versus IUD insertion without stitch.(Table 5)

		No	%
Address	Akhmim	4	2.0%
	Almonshaa	72	36.0%
	Elbaliana	57	28.5%
	Gerga	7	3.5%
	Maragha	19	9.5%
	Sohag	41	20.5%
Age	Mean± SD	29.01 ± 4.67	
	Range	20 - 42	

Table 1: Demographic data

		No	%
Prev use of IUD	No	105	52.5%
	Yes	95	47.5%
Prev use of another method of contraception	No	150	75.0%
	Yes	50	25.0%
Insertion of IUD with or without stitch	With stitch	100	50.0%
	Without stitch	100	50.0%

Table 2: Prev use of IUD, Prev use of another method of contraception and Insertion of IUD with or without stitch

		No	%
Pelvic infection	No	195	97.5%
	Yes	5	2.5%
Menstrual complaints	No	129	64.5%
	Yes	71	35.5%

Table 3: Pelvic infection and menstrual complaints

Expulsion	**Insertion of IUD with or without stitch**					
	with stitch		**without stitch**		**Chi square test**	
	No	**%**	**No**	**%**	**x^2**	**p value**
Expulsion after 3 months	1	1.0%	8	8.0%	5.701	0.017
Expulsion after 6 months	5	5.0%	15	15.0%	5.556	0.018
Expulsion after 9 months	10	10.0%	21	21.0%	4.619	0.032
Expulsion after 12 months	15	15.0%	24	24.0%	2.58	0.048

Table 4: Comparison between Insertion of IUD with or without stitch as regards expulsion

		Insertion of IUD with or without stitch					
		with stitch		**without stitch**		**Chi square test**	
		No	**%**	**No**	**%**	**x^2**	**p value**
Occurrence							
Occurrence of intrauterine Pregnancy on top of the iud	No	97	97.0%	98	98.0%	0.205	0.651
	Yes	3	3.0%	2	2.0%		

Occurrence of ectopic pregnancy on top of the iud	No	99	99.0%	99	99.0%	0.000	1.000
	Yes	1	1.0%	1	1.0%		
Pelvic infection and menstrual complaints							
Pelvic infection	No	97	97.0%	98	98.0%	0.205	0.651
	Yes	3	3.0%	2	2.0%		
Menstrual complaints	No	64	64.0%	65	65.0%	0.022	0.883
	Yes	36	36.0%	35	35.0%		

Table 5: Comparison between Insertion of IUD with or without stitch as regards occurrence and Pelvic infection and menstrual complaints

DISCUSSION

Immediate postplacental insertion of IUCD during CS can deliver direct contraception, prevent repeated unintentional conditions, and may help to decrease the occurrence or need for another CS. Even so, postplacental IUCD insertion is limited by its great exclusion and movement rates [7; 8].

The intent of this study was to evaluate the efficacy, safety, convenience, and complications of copper IUCD (TCu-380A) inserted instantly after expulsion of the placenta during lower segment CS and to compare the results between fixed and non-fixed IUCD.

The present randomised controlled trial was carried out at Sohag General Hospital's department of obstetrics and gynaecology from December 2019 to November 2020. Our study included 200 pregnant women scheduled for elective CS and desired immediate IUCD insertion during CS. Participants was equally randomized to undergo either: Group 1 (fixation group): IUCD insertion and fixation with absorbable suture (n = 100). Group 2 (no-fixation group): IUCD insertion only without fixation (n = 100).

In the present study, we used copper IUCD (TCu-380A). The TCu-380A and TCu-380S copper IUDs are more successful than other copper IUDs at preventing pregnancy, according to a Cochrane systematic review [9].

The mean age of study participants was 29.17±4.56 years; the age difference between the fixation and non-fixation groups was not significant.

This is comparable to the mean age of previous studies, such as 30 years in Levi et al. [10] study, 28.7 years for the TCu-380A group in Ragab et al. [5] study, 27.9 years in Ariadi & Ade Aulia. [11] study, 27.4 years in Tjahjanto & Indah. [12] Study.

However, some studies included participants with lower mean ages, such as 26.4 years in Çelen et al. [13] study, 24.9 years in Jakhar & Singhal. [14] Study, and 23.12 years in Singal et al. [15] study. In contrast, the median age of the TCu380A group in Unal et al. [16] study was 32 years.

The variation in the participants' mean ages could be attributed to the differences in inclusion criteria among studies.

Regarding number of deliveries and number of previous C.S our results show that number of deliveries of 5 patients (2.5%) was one times, of 64 patients (32%) was two times, of 73 patients (36.5) was three times, of 16 patients (8%) was five times, number of previous CS of 12 patients (6%) was one time, of 82 patients (41 %) was two times, of 72 patients (36 %) was three times, of 28 patients (14%) was four times and of 6 patients (3%) was five times. So all women in this study were multiparous, and most (98.5%) underwent ≥ 2 CS. The number of deliveries and CS across the two study groups was not significantly different.

The participants' parity widely varies among previous studies. In Çelen et al. [13] study, 73% were multiparous. In Tjahjanto & Indah [12] study, 50.9% were multiparous. In Ragab et al. [5] study, 48% of the TCu380A group was multiparous. In contrast, Singal et al. [15] study included only primiparous women.

Parity could be an important determining factor for the rate of IUCD expulsion. Some studies have demonstrated that higher parity is linked to higher rates of IUCD expulsion regardless of the mode of delivery [17].

In contrast, previous use of IUCD was reported by 67% of participants in Çelen et al. [13] study. Data on previous use of contraceptives have not been reported in most previous studies.

In the present study in no-fixation groups show statistically significant increase expulsion rate of IUCD than fixation groups, we expected that suturing IUCD into the fundal wall could hold it during the involution process of the uterus; therefore, reducing the rate of IUCD expulsion.

Various trials have been undertaken to reduce the expulsion rate of IUD inserted during CS. This includes the use of absorbable sutures (delta-T) and the inclusion of extra appendages [1].

Similar to the previous study, Unal et al. [16] conducted a study on 140 women underwent immediate postpartum IUD insertion during CS, half of which using anchored frameless GyneFix-CS300 and the half by TCu-380A. The expulsion rate at 6 weeks was significantly lower in the anchored frameless GyneFix-CS300 (1.4%) compared with the TCu-380A (11.4%).

There are several factors affecting the expulsion rate of IUCD after its insertion, including the delivery mode, IUD type, and time of insertion. The experience of the operator could be an important determining factor. Parity has been also suggested to

affect expulsion. Moreover, the physiological and anatomical changes that occur throughout the puerperium may increase the likelihood of expulsion. Excessive contractions, uterine subinvolution, and chronic cervical dilation caused by excessive lochia passage may all raise the expulsion risk [1; 5].

Regarding demographic data of Insertion of IUD, the difference between IUD insertion with stitch and IUD insertion without stitch was not statistically significant regarding demographic data with Address (P-value = 0.606) and age (P-value = 1.000).

Similar data had been recorded by Ade Aulia., [11] noted that several studies have reported that from women who show their desire around the time of delivery for interval postpartum IUD, only a small percentage actually return for IUD insertion.

Previous research has shown that the usage of copper IUDs is related to lower rates than levonorgestrel IUD [8; 18]; however, studies on different types of copper IUDs are limited. In an open-label randomized controlled study, Ragab et al. [5].

Regarding expulsion in insertion of IUD, there was statistically significant increase expulsion in insertion of IUD without stitch, expulsion after 3 months were 1 patient (1.0%) with stitch and 8 patient (8%) without stitch (P-value = 0.017); expulsion after 6 months were 5 patient (5.0%) with stitch and 15patient (15%) without stitch (P-value = 0.018); expulsion after 9 months were 10 patient (10%) with stitch and 21patient (21%) without stitch (P-value = 0.032); expulsion after 12 months were 15 patient (15%) with stitch and 24patient (24%) without stitch (P-value = 0.048).

The expulsion rate for immediate postplacental IUCD placement is higher than the 6-weeks interval postpartum or at times unrelated to pregnancy[8; 11; 18].

Regarding occurrence in insertion of IUD, the difference between IUD insertion with stitch and IUD insertion without stitch was not statistically significant, regarding the occurrence of intrauterine pregnancy on top of the IUD (P-value = 0.651). Similar data has been recorded by [12]

In our study, there were two cases of ectopic pregnancy, one of them with stitches and the other case without stitches. The difference between IUD insertion with stitch and IUD insertion without stitch was not statistically significant regarding the occurrence of ectopic pregnancy on top of the IUD (P-value = 1.000); regarding pelvic infection and menstrual complaints, pelvic infection was in five patients there were no statistically significant differences between the insertion of the IUD with stitch (3 cases) and the insertion of the IUD without stitch (2 cases) (P-value = 0.651) and menstrual complaints (P-value = 0.883).

Our findings are generally in accordance with previous studies. The incidence of unintended pregnancy on top of IUCD was 0.4% in Çelen et al. [13] study and 0.7% in Singal et al. [15] study. Likewise, the incidence of PID was 2.3% in Singal et al. [15] study and 3% in Ragab et al. [5] study.

CONCLUSION

Based on our findings, Copper IUCD (TCu-380A) which inserted immediately after expulsion of the placenta during lower segment CS was with high efficacy, safety, and convenience specially fixed IUCD than non-fixed IUCD. IUCD insertion and fixation with absorbable suture (fixation group) was the best healthy results at all study points and the less expulsion rate than IUCD insertion only without fixation.

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