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Original Article

Intracesarean Postpartum Insertion of Intrauterine Contraceptive Device as an Alternative to Delayed Insertion: Safety and Complications

Ahmed Hisham Ahmed Al-Mahmoudi [1*], Muhamed Ahmed Abdelmoaty [2], Mofeed Fawzey Mohamed [2]

[1] Department of Obstetrics and Gynecology; Isis Specialized Hospital, Luxor, Egypt

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

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*Corresponding author

Email: ahmedhisham7788@gmail.com

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ABSTRACT

Background: Family planning [FP] describes the proper spacing and prevention of unintended pregnancies and seems to improve the couples' quality of reproductive and overall life. Different modalities are available to achieve such goal.

Aim of the work: This work aimed to evaluate the safety and efficacy profile of postpartum intrauterine contraceptive device [IUCD]. Thus, it could be recommended as a reasonable and effective modality for the family planning.

Patients and methods: A randomized controlled study that included 120 pregnant females, selected from the Department of Obstetrics and Gynecology, Faculty of Medicine, Al-Azhar University [Egypt]. All females were clinical evaluated by inquiry about their personal, medical, obstetric and contraception history. This was followed by general and local examination. An abdominal ultrasound was carried out for all. Females of Group-I underwent lower segment cesarean section by standard technique followed by IUD insertion after placental delivery. In the other group, the insertion was done 3 months after delivery. The successful IUD insertion and expulsion rate represented the primary outcome. The secondary outcomes included pregnancy, perforation and other adverse events.

Result: Female's age ranged between 18 and 37 years and previous cesarean section was the commonest indication of CS. The expulsion rate at 3 and 6 months after insertion was higher for group I than group II. However, the difference was non-significant. In addition, there was no significant differences found between groups I and II regarding post-CS complications at 3 or 6 months after CS. The frequency of pain and bleeding in the follow up duration was statistically increased in Group I than Group II after 3month and after 6 months.

Conclusion: Interval insertion of the IUD is an easy, safe, and effective method and could replace the post-placental insertion. Additionally, it could be the first line contraceptive agent in eligible patients.

Keywords: Intracesarean; Postpartum; Intrauterine; Contraceptive Device; Delayed Insertion

INTRODUCTION

The unintended pregnancy had a high chance during the postpartum period. This is attributed to the limited options of contraceptive, especially for breast-feeding women. In addition, ovulation is highly non-predictable in non-breast or exclusive breast-feeding women. Pregnancy and childbearing is associated with high mortality attributed to pregnancy and child-birth associated complications. Countries in the developing world had 99% of these deaths. Proper family planning [FP] could reduce pregnancy and child-birth associated complications and subsequently reduced associated mortality [1].

Long acting reversible contraception [LARC] is increasingly used to decrease the unintended pregnancies LARC methods, including the copper and levonorgestrel [LNG] intrauterine devices [IUDs] and the contraceptive implant, are described as first-line contraceptives for adolescents and adults by the American College of Obstetricians and Gynecologists [2].

LARC methods require little action on the part of the patient after insertion, resulting in typical-use effectiveness of 99.8% in the first year of use. The oral contraception, patch or ring methods are associated with 22 times more likely to get pregnancy in the first year than LARC method [3].

The intrauterine device [IUD] is an effective and popular method for contraception. It is used by 14% of women all over the world [4]. Its advantages are related to its nature as a coitus-independent, effective and reversible form of contraception. It had an immediate contraceptive action, easily inserted, had minimal side effects, did not affect breast-feeding and cost effective [5].

The complications of IUD include menstrual irregularities, heavy menstrual bleedings and infectious complications. These could be reduced by using strict aseptic techniques during insertion. The most distressing complication is the IUD displacement, especially extra-uterine displacement, as the patient requires a surgical intervention [endoscopic usually] for displaced-IUD extraction. Displacement of IUDs puts a financial and psychological burden to the patient. It also increased the risk of unwanted pregnancies and its related risks. IUD insertion at a wrong timing may increase the IUD displacement risk. So it is crucial to insert IUDs at the proper time with the proper method [6].

Timing of IUD insertion after cesarean delivery is an issue of debate; a few gynecologists insert IUDs at some point of cesarean section after placental delivery. However, others opt of IUD insertion for a long postpartum period [6 months]. However, many of them insert IUC after 3 months of cesarean delivery [7]. The rationale about three months postpartum IUD insertion was to guarantee that the SC scar had completely healed and the uterus is completely involuted to the pre-pregnancy size [8].

Cesarean sections [CS] are growing in all countries. IUD insertion on the time of CS creates a possibility to get right of entry to LARC methods. Conversely, a CS scar may prevent the proper insertion of IUD during CS [7]. Women who need to begin birth control at some point of the postpartum period may benefit from IUC insertion without delay after delivery. Post-placental delivery IUD insertion notably reduces the risk of unplanned pregnancies and helps in the process of birth control [9].

The postpartum length is doubtlessly a super time to start birth control as ladies are greatly stimulated to achieve birth control at this time [10, 11]. The usage of IUD immediately after delivery is extraordinarily beneficial for family planning, irrespective of the higher risk of complications. In order to mitigate risks, the International Federation of Gynecology and Obstetrics [FIGO] 2015 guidelines recommended a postpartum IUD insertion as a recurring carrier in antenatal and maternity units. However, the length of time to assure safety, continuation and approach effectiveness is controversial [12].

AIM OF THE WORK

This study was designed to address the safety and efficacy profile of postpartum intrauterine contraceptive device [IUCD], and possible role in family planning.

PATIENTS AND METHODS

This was a randomized controlled study, that included 120 pregnant females who underwent an elective cesarean section [CS] and were looking for contraception. They had no contraindications for IUD insertion.

The study had been completed during the period from April 2021 till February 2022, at the Department of Obstetrics and Gynecology, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

Ethical and legal consideration: Approval of ethical committee was obtained after a full review of

the study protocol. In addition, a written consent was signed from each patient before participation in this study. The study was conducted in the line of Helsinki declaration codes for research conduction and reporting.

Sample size calculation and randomization: Epi Info STATCALC was used to calculate the sample size by considering the following assumptions: 95% two-sided confidence level, with a power of 80%, & α error of 5% odds ratio calculated = 1.115. The final sample size taken from the Epi- Info output was 113. Thus, the sample size was increased to 120 cases to assume any drop-out during follow up. Randomization was achieved using specific computer programs with numbers distributed in closed envelops. Selected patients [n = 120] were randomly allocated 1:1 with alternate allocation into two groups, **Group I [the Study group]** underwent intra-operative post-placental insertion of IUD, and *the Group II* [Interval insertion or control group] who underwent delayed insertion of IUDs after a three-month interval following cesarean section.

Inclusion criteria were pregnant women who attended for elective cesarean section, and desiring contraception, with no contraindication for IUD insertion. Otherwise, the exclusion criteria were presence of upper segment or classical cesarean scar, previous myomectomy scar, CS on top of placenta accrete, evident fever and infections at time of cesarean section as chorioamnionitis. [foul smelling vaginal discharge, history of pre-labour rupture of membrane > 8 h], preterm labor, uterine anomalies [unicornuate, bicornuate, didelphus, or septate uterus], severe anemia [hemoglobin concentration lower than 8 g/dl], postpartum hemorrhage and when placenta was manually removed.

Methods

All females were clinical evaluated by inquiry about their personal, medical, obstetric and contraception history. This was followed by general and local examination. An abdominal ultrasound was carried out for all.

Females of Group-I underwent lower segment cesarean section by standard technique [skin incision [Pfannenstiel incision], bladder peritoneal incision, lower-segment transverse cesarean section and extension of the incision, delivery of the fetus then placental delivery]. Then, the IUD was manually positioned at the top of the uterine fundus. Before closure of the uterine incision, the strings were placed in the lower uterine segment. Then, they were passed through the cervix with IUD insertion tube. The uterine incision was closed and bladder peritoneal suture was applied. Finally, the subcutaneous tissues and skin were closed in layers.

On the other side, in group-II, delivery was achieved by CS with IUD insertion. Females were scheduled for postnatal visits and at the end of the third months, IUD was inserted.

Radiologic testing: Prior to discharge, follow-up all patients were re-examined, including abdominal ultrasonography. Transvaginal ultrasonography at 6 weeks, 3 and 6 months postpartum. Patients were instructed to contact one physician immediately if they experienced pelvic pain, fever, excessive bleeding or unusual vaginal discharge.

Outcome: the primary outcome of the current work was the successful placement of IUD, and percentages of subsequent expulsion. The secondary outcome included pregnancy, perforation and other adverse events.

Statistical Analysis: collected data were revised, coded [to conceal patient identity] and fed to a personal computer. We used the Statistical Package for Social Science, standard version 20 [IBM® Inc., Armonk, Chicago, USA]. Relative frequencies and percentages were the representative values for qualitative data. Otherwise, arithmetic means and standard deviations [for normally distributed data] were the representatives for the quantitative variables. Median and interquartile ranges were used for representation of quantitative non-normally distributed data. Comparison between study and control groups was achieved by Chi square [or its equivalent Fisher Exact] and unpaired samples "t" test for categorical and continuous variables. The paired "t" test was used to compared values in the same group at two different points of time. P value < 0.05 was considered significant.

RESULTS

Selected patients were randomly allocated 1:1 with alternate allocation into 2 groups: Group I [Study group] who undergone intra-operative post-placental insertion of IUD. Group II [Interval insertion or control group] who undergone delayed insertion of IUDs after a three-month interval following cesarean section.

Results of the current study showed that there were no statistically significant differences between Groups I and II regarding female age, parity, living children, indications for CS or data about family

planning. Female's age ranged between 18 and 37 years and previous cesarean section was the commonest indication of CS [Table 1].

In the current work, post CS clinical profile and the mean number of different unwanted manifestations was significantly different between both groups. The expulsion rate at 3 and 6 months after insertion was higher for group I than group II. [Table 2].

In addition, there was no significant differences found between groups I and II regarding post-CS complications [e.g, Pain/dysmenorrheal and Irregular bleeding/spotting, vaginal discharge or PID] at 3 or 6 months after CS [Table 3].

Table [4] showed that there was highly statistically significant difference found between After 3 month and After 6 months regarding Bleeding/pain, other medical reasons, Planned pregnancy, Expulsion rate and Continuation rate in group I and II.

Table [5] shows that there was no statistically significant difference found between After 3 month and After 6 months regarding Pain/dysmenorrheal, Irregular bleeding/spotting and Abnormal vaginal discharge/PID, and there was highly statistically significant difference found between After 3 month and After 6 months regarding Menorrhagia I group I and II.

Table [1]: Comparison between Group I and II regarding patient characters, indications for CS and family planning data

		Group I [PPIUD] No.= 60	Group II [DIUD] No.= 60	Test	P-value
Age [years]		26.59 ± 5.62; 18-37	25.10 ± 5.92; 18-37	1.41	0.159
Parity	I	14 [23.3%]	22 [36.7%]	6.844	0.077
	II	18 [30.0%]	12 [20.0%]		
	III	16 [26.7%]	8 [13.3%]		
	IV	12 [20.0%]	18 [30.0%]		
Living children	I	20 [33.3%]	28 [46.7%]	3.111	0.375
	II	22 [36.7%]	14 [23.3%]		
	III	10 [16.7%]	10 [16.7%]		
	IV	8 [13.3%]	8 [13.3%]		
Indication for cesarean section	Previous cesarean section	26 [43.3%]	25 [41.7%]	0.034	0.853
	In vitro fertilization treatment	8 [13.3%]	9 [15.0%]	0.069	0.793
	Previous myomectomy	4 [6.7%]	5 [8.3%]	0.120	0.729
	Placenta previa	3 [5.0%]	2 [3.3%]	0.209	0.648
	Advanced primigravid age	1 [1.7%]	2 [3.3%]	0.342	0.559
	Breech presentation	10 [16.7%]	8 [13.3%]	0.261	0.609
	Macrosomia	5 [8.3%]	4 [6.7%]	0.120	0.729
	Multiple fetuses	3 [5.0%]	6 [10.0%]	1.081	0.298
Family planning data	Previous use of IUD	40 [66.7%]	38 [63.3%]	0.147	0.702
	Wants more children	37 [61.7%]	35 [58.3%]	0.139	0.709
	Time to desired pregnancy [years]	3.47 ± 1.35	2.93 ± 1.52	2.05	0.062
	Prenatal care	23 [38.3%]	20 [33.3%]	0.326	0.568
	Family planning counseling	39 [65.0%]	36 [60.0%]	0.320	0.572

Table [2]: Comparison between Groups I and II regarding clinical outcome after 3 and 6 months after delivery

		Group I [PPIUD]	Group II [DIUD]	Test	P-value
Clinical outcome after 3 months	Bleeding/pain	0.81 ± 0.13	0.67 ± 0.20	4.306	<0.001*
	Other medical reasons	0.40 ± 0.12	0.20 ± 0.16	7.703	<0.001*
	Planned pregnancy	0.40 ± 0.13	0.20 ± 0.16	7.613	<0.001*
	Personal reasons	-	-	NA	NA
	Unplanned pregnancy	-	-	NA	NA
	Expulsion rate	5[8.3%]	1[1.7%]	2.807	0.094
Clinical outcome after 6 months	Bleeding/pain	4.11 ± 1.22	2.51 ± 1.18	7.257	<0.001*
	Other medical reasons	1.20 ± 0.86	0.73 ± 0.62	3.396	<0.001*
	Planned pregnancy	1.20 ± 0.87	0.73 ± 0.58	3.517	<0.001*
	Personal reasons	1.20 ± 0.77	0.74 ± 0.58	3.697	<0.001*
	Unplanned pregnancy	0.00 ± 0.00	0.00 ± 0.00	NA	NA
	Expulsion rate	7[11.7%]	1[1.7%]	4.821	0.088

Table [3]: Comparison between Group I [PPIUD] [no. =60] and Group II [DIUD] [no. =60] regarding Complications after 3 month and after 6 months

		Group I [PPIUD]	Group II [DIUD]	Test	P-value
After 3 months	Pain/dysmenorrhea	5 [8.3%]	10 [16.7%]	1.905	0.168
	Menorrhagia	0 [0.0%]	0 [0.0%]	NA	NA
	Irregular bleeding/spotting	3 [5.0%]	9 [15.0%]	3.333	0.068
	Abnormal vaginal discharge/PID	0 [0.0%]	0 [0.0%]	NA	NA
After 6 months	Pain/dysmenorrhea	11 [18.3%]	11 [18.3%]	0.000	1.000
	Menorrhagia	10 [16.7%]	10 [16.7%]	0.000	1.000
	Irregular bleeding/spotting	4 [6.7%]	9 [15.0%]	2.157	0.142
	Abnormal vaginal discharge/PID	1 [1.7%]	4 [6.7%]	1.878	0.171

Table [4]: The Clinical outcome after 3 month and Clinical outcome after 6month

	After 3 months	After 6 months	Test	P-value
	No.= 60	No.= 60		
Group I [PPIUD]				
Bleeding/pain	0.81 ± 0.13	4.11 ± 1.22	-21.041	<0.001*
Other medical reasons	0.40 ± 0.12	1.20 ± 0.86	-6.788	<0.001*
Planned pregnancy	0.40 ± 0.13	1.20 ± 0.87	-7.500	<0.001*
Personal reasons	0.00 ± 0.00	1.20 ± 0.77	-11.991	<0.001*
Unplanned pregnancy	0.00 ± 0.00	0.00 ± 0.00	NA	NA
Expulsion rate	5.38 ± 1.66	10.63 ± 2.96	-10.824	<0.001*
Continuation rate	93.96 ± 15.41	81.60 ± 17.86	4.980	<0.001*
Group II [DIUD]				
Bleeding/pain	0.67 ± 0.20	2.51 ± 1.18	-11.589	<0.001*
Other medical reasons	0.20 ± 0.16	0.73 ± 0.62	-6.477	<0.001*
Planned pregnancy	0.20 ± 0.16	0.73 ± 0.58	-6.808	<0.001*
Personal reasons	0.00 ± 0.00	0.74 ± 0.58	-9.889	<0.001*
Unplanned pregnancy	0.00 ± 0.00	0.00 ± 0.00	NA	NA
Expulsion rate	4.06 ± 2.20	6.52 ± 2.92	-5.006	<0.001*
Continuation rate	63.62 ± 19.82	70.97 ± 11.78	-2.392	<0.001*

Table [5]: Comparison between Complications after 3 month and Complications after 6 months

	After 3 months	After 6 months	Test	P-value
	No.= 60	No.= 60		
Group I [PPIUD]				
Pain/dysmenorrhea	5 [8.3%]	11 [18.3%]	2.596	0.107
Menorrhagia	0 [0.0%]	10 [16.7%]	10.909	<0.001*
Irregular bleeding/spotting	3 [5.0%]	4 [6.7%]	0.152	0.696
Abnormal vaginal discharge/PID	0 [0.0%]	1 [1.7%]	1.008	0.315
Group II [DIUD]				
Pain/dysmenorrhea	10 [16.7%]	11 [18.3%]	0.058	0.809
Menorrhagia	0 [0.0%]	10 [16.7%]	10.909	0.000
Irregular bleeding/spotting	9 [15.0%]	9 [15.0%]	0.000	1.000
Abnormal vaginal discharge/PID	0 [0.0%]	4 [6.7%]	4.138	0.061

DISCUSSION

An intrauterine device [IUD] is the most effective intervention for reversible birth control. The post-placental IUD insertion refers to direct intrauterine insertion of the device shortly after the placental delivery. It is remarked as immediate if inserted within 10 minutes after placental delivery or early postpartum when the insertion was performed within < 48 h after delivery. Immediate insertion could prevent the discomfort related to interval insertion, and any bleeding will be washed out by lochia. However, higher expulsion rate was reported as disadvantage, which outranked by the highly effective contraception [13]. However, others reported that, the expulsion rate is lower for immediate post-placental than early postpartum IUD insertion, especially with skilled healthcare providers inserting the IUD. The method of insertion [right forceps or by hand] did not affect the expulsion rate [14]. The susceptibility of unintended pregnancy in the first postpartum year is

highly susceptible [10-44.0%]. In non-lactating women, anovulatory infertility lasts about 5 weeks, that increased to 8 weeks in fully lactating women. The pregnancy rate with lactation is about 1-2% in the first postpartum year [15].

Postpartum IUD insertion is an opportunity particularly in developing countries where delivery may be the only chance when a healthy woman contacted healthcare providers. This option is attractive due to several factors: 1] at that time there is high acceptance rate for contraception, 2] it is actually non-pregnant, 3] she is highly motivated for contraception, 4] the method is free from systemic side effects and does not affect breast-feeding, 5] the pain of IUD insertion is masked by the pain after delivery, 6] lower infection rate, uterine perforation, postpartum bleeding, or uterine sub-involution; 7] avoid delay in contraception due to care for new baby [16].

The aim of this work was to assess the safety and efficacy of postpartum IUCD so that it is recommended as an effective family planning technique. The results showed that there was no significant difference found between Groups I and II regarding age and parity. However, there was statistically significant difference found among Group I than Group II regarding Bleeding/pain, after 3 and 6 months after intervention. These results are in line with **Khurshid *et al.*** [13] who reported that, their patients age was between 19 and 38 years. They added that, the majority of patients were multipara. Furthermore, their results reflected that, in the PPIUD group, there was no bleeding/ spotting demonstrable as it was washed by the lochia. Mild pain was seen in only 11 patients in this group. On the other side, slight bleeding/ spotting was reported among 7.8% of patients in the IIUD group, while mild to moderate pain was seen in 39.9% patients [$p < 0.05$]. These results reflected that, the IUD insertion is more comfortable and usually asymptomatic in patients when inserted immediately following placental delivery, because the pain if any is masked by the after-labor pains. Further dilatation was not needed in the PPIUD group. This make the technique quick and easy for the healthy worker and more comfortable for the patient.

Our study shows a comparatively higher incidence of pelvic pain in both the groups, possibly due to the fact that we also included patients having only mild pelvic pain. On contrary, other researcher could not significant difference regarding pain in PPIUCD and interval insertions [17-19]. This could be explained by different inclusion criteria and sample size. **Çelen *et al.*** [20] reported that the rate of IUD removal due to bleeding/pain was 8.2% per year.

Our results showed that, there was no significant difference found among Group I and Group II regarding Expulsion rate after 3 month & 6 months. However, **Khurshid *et al.*** [13] found a significant difference in expulsion after post-placental IUD insertion than delayed insertion. Increased expulsion rate in PPIUD group as compared to the other group is possibly the only disadvantage of PPIUD insertion; cumulative expulsion rates showed a significant difference between the groups. Between 6 months and 1 year, however, the interval expulsion rates were comparable. In addition, **Bonilla-Rosales *et al.*** [21]**, Bednarek *et al.*** [22] **and Gupta *et al.*** [23] found that expulsion rate was more in PPIUCD [24]. However, **Lucksom *et al.*** [25] reported a higher expulsion rate in delayed IUD insertions. **Levi *et al.*** [26] followed 90 women who had no expulsions. However, that study reported a higher rate [47%] with long term follow-up. Thus, the overall expulsion rate was limited.

Other researchers suggested that expulsion is less frequent for immediate post placental IUD insertion during cesarean section compared to vaginal delivery [27, 28]. In another study including cesarean [26%] and vaginal deliveries [74%], TCu 380A model IUD was immediately inserted after the placental delivery, and a cumulative 1-year expulsion rate of 12.3% was observed [29]. Unfortunately, we did not include insertion after normal delivery**,** but this topic was discussed to point to the role of delivery mode on the same studied topic, reflecting the complexity of the topic and point to different factors affecting the process. Other studies have also reported that, social factors, changing contraceptive method and psychological factors as additional causes of IUCD removal [30-32].

Conclusion: Interval IUD insertion is an easy, safe and effective alternative to post-placental insertion of the IUD. It could be used as the first-line contraceptive method due to its immediate and long-term contraceptive benefits, safety and convenience. However, the results of the study could be generalized due to a limitation step of small sample size. Future studies on large scale of patients are warranted.

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