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Original Research

Application of Mirena Intrauterine Device in Cesarean Section: Experience from a Private Hospital in Saudi Arabia - A Prospective Cohort Comparative Study

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Abstract

Background: Postpartum application of an intrauterine device (IUD) is often challenging to many women and induces fear, especially when performed without general anesthesia. This renders insertion difficult, which may predispose to complications, or the women to delay her decision for contraception. Our study compared the complications of Mirena IUD insertions during cesarean section (CS) *versus* 42 days postpartum. **Methods**: This study is a prospective cohort comparative study conducted in a private hospital in Saudi Arabia, from May 2021 to December 2021. Women were assigned into two groups. The first group (post-placental) contained 48 women in whom Mirena IUDs were inserted during CS, after placental delivery. The second group (postpartum) included 48 women where the intrauterine contraceptive device (IUCD) was inserted after 42 days postpartum. The primary outcome was the expulsion rate of IUD, while secondary outcomes were infection, perforation, bleeding, and displacement. The patients were followed up one month and three months after Mirena's insertion. **Results**: There was no significant difference between the two groups regarding the expulsion rate ($p = 0.646$). Also, there was no significant difference between the two groups in terms of secondary outcomes ($p > 0.05$). **Conclusions**: Post-placental application of Mirena IUD is more accessible, more convenient, and less fearful for the patients.

Keywords: Mirena; intra-cesarean; perforation; PID; post-placental

1. Introduction

Concerns about contraception are increasing every day. Early initiation of contraception methods right after childbirth helps prevent the occurrence of conception in the early postpartum period. Long-acting reversible contraception (LARC) is considered the best solution for this situation [1].

Mirena intrauterine device (IUD) is one of the world's most frequently used reversible contraception methods. Over one hundred million women worldwide use intrauterine contraceptive devices (IUCDs) for contraception. It is regarded as one of the most popular, reversible, and effective contraceptive methods. It is estimated that approximately 120 million women are using it worldwide [2].

IUD is considered a safe, reversible, and effective method, making it a great choice for women as a contraceptive method. It does not require long-term follow-up, and it is cost-effective. The main concern for the women is the fear of pain during its application. Its complications are related to the application, such as perforation or displacement, and other complications such as excessive bleeding, or pelvic inflammatory disease (PID) [3,4]. It has been assumed in previous studies that immediate post-placental application of an IUD provides a more effective, safe, reversible, and long-term method of contraception. Immediate post-placental application of IUD in different studies has demonstrated low complications [5,6].

Herein, we sought to compare the complications of Mirena IUD insertion during cesarean section (CS) versus 42 days postpartum.

2. Patients and Methods

Design: a prospective cohort study conducted in a private hospital in Saudi Arabia, from May 2021 to December 2021, on 96 pregnant women who met the eligibility criteria. All patients provided informed consent, and the study has been approved by the Ethic Committee of the Hassan Muhammed Abu Bakr Al Bar Hospital.

The inclusion criteria of the selected patients were age between 20–45 years, singleton pregnancy, previous IUD application history, and requesting IUD placement for contraception. The exclusion criteria for IUD application excluded patients with contraindications, such as uterine anomalies or obstetric infections (e.g., chorioamnionitis or puerperal sepsis).

2.1 Primary Outcomes

The primary outcome of this study was the IUD expulsion rate, which was monitored for a duration of three

months. We recorded the time period between device insertion and expulsion. If the women were unaware of the exact date of expulsion, it was recorded as the last day of follow-up, indicating the last known presence of the device.

2.2 Secondary Outcomes

Displacement rate, which was followed up for three months. This was measured using transvaginal ultrasounds, done at one month and three months.

Infection and bleeding, were followed up for three months. Uterine bleeding symptoms (including spotting, light bleeding, and heavy or longer menstrual period) were recorded. In addition, symptoms suggestive of PID, such as lower abdominal pain, or vaginal discharge were recorded.

Perforation rate was calculated over a three month period. It was diagnosed using transvaginal ultrasound and confirmed by an abdominal radiograph, showing IUD within the abdominal cavity.

The sample size calculation was based on the following equation: $n = Z^2 \times p(q)/d^2$ [7]. Here, n represents the sample size, Z is the standardized degree of 95% which is equal to 1.96, p is the proportion of target women estimated to be expelled one month after IUCD insertion (0.045), q is the complement of p, and d is the degree of accuracy required, usually 0.05. The result of the calculation was 66 patients, but we increased the sample size to 96 patients to improve the study's strength and to account for expected dropouts.

2.3 Procedures

One consultant applied the IUD postpartum (group II), while the other performed a post-placental application in the first group (group I). Grouping of the patients was done according to the patient's choice of device application.

The private hospital's ethical committee approved the study, and patients provided informed consent. Patients were subjected to full history (personal, menstrual, detailed obstetric, and past surgical history) and physical (general, obstetric and local pelvic examination) examination process.

Surgical procedure: at the time of induction of anesthesia, pre-operative antibiotics were given to all women of both groups according to the hospital protocol.

Group I (post-placental): this group included 48 women in whom IUCD was inserted during the cesarean application after delivery of the baby (Fig. 1). The placenta was removed, then the Mirena IUD was placed at the fundus of the uterus using the regular applicator, the strings were then placed in the lower uterine segment downward through the cervix. If the cervix was closed, manual opening of the cervix by surgeon's fingers, then the strings were passed through the cervix with ring forceps, and the uterus was closed. In the first follow-up visit, trimming of long threads was done.

Group II (postpartum): this group included 48 women who had elective lower-segment CS where the Mirena IUD was inserted in the traditional steps after a six-week postpartum visit (Fig. 1).

All the women were instructed about side effects, possible complications, and warning signs about using the Mirena IUD. They were taught how to recognize IUCD expulsion and how to feel strings.

The first follow-up visit was in the first week, then one month, and three months after the Mirena IUD was inserted. Follow-up of women was done by vaginal examination, including speculum examination to visualize the threads of the Mirena IUD. An extra trans vaginal sonography (TVS) and abdominal X-ray were done in cases of missed IUD.

2.4 Statistical Methods

The data collected was reviewed, organized, tabulated, and analyzed using the Statistical Package for Social Science (SPSS20.0, IBM, Armonk, NY, USA). The Student's *t*-test was used to determine the statistical significance of the difference between the means of the two groups. The Chi-square test was applied to qualitative variables, while Fisher's exact test was used for qualitative variables. A *p*-value greater than 0.05 was considered non-significant, and a value less than 0.05 was considered significant.

3. Results

The mean age in group I (post-placental) was 25.74 $\pm$ 4.29 years, while it was 26.02 $\pm$ 4.63 years in group II (postpartum). The mean body mass index (BMI) was 31.85 $\pm$ 4.27 and 32.37 $\pm$ 1.46 kg/m^2 in groups I and II, respectively. The mean hemoglobin was 10.02 $\pm$ 0.81 gm/dL in the post-placental group *versus* 10.07 $\pm$ 0.65 gm/dL in the puerperal group. In the post-placental and puerperal groups, the mean gestational age was 38.89 $\pm$ 0.71 and 38.9 $\pm$ 0.74 weeks (data not shown). These differences were statistically not significant. No patients were excluded in the first month follow-up in both groups, while 6 were excluded in the third-month follow-up in the post-placental group, and 7 in the postpartum group (Fig. 1).

The study found that the post-placental group had 26 multiparous patients (54.2%), 37 patients (77.1%) with a history of CS, and 15 of them (31.3%) had three or more CSs. On the other hand, the puerperal group had 34 multiparous patients (70.8%), 40 patients (83.3%) with a history of CS, and 17 of them (35.4%) had three or more CSs. However, these differences were not statistically significant (data not shown).

Table 1 shows the primary and secondary outcome rates of both groups during the follow-up period (one week, one month, and three months). The comparison of incidence rates for expulsion, infection, bleeding, and displacement between the post-placental and puerperal groups during the follow-up period was statistically insignificant (*p*

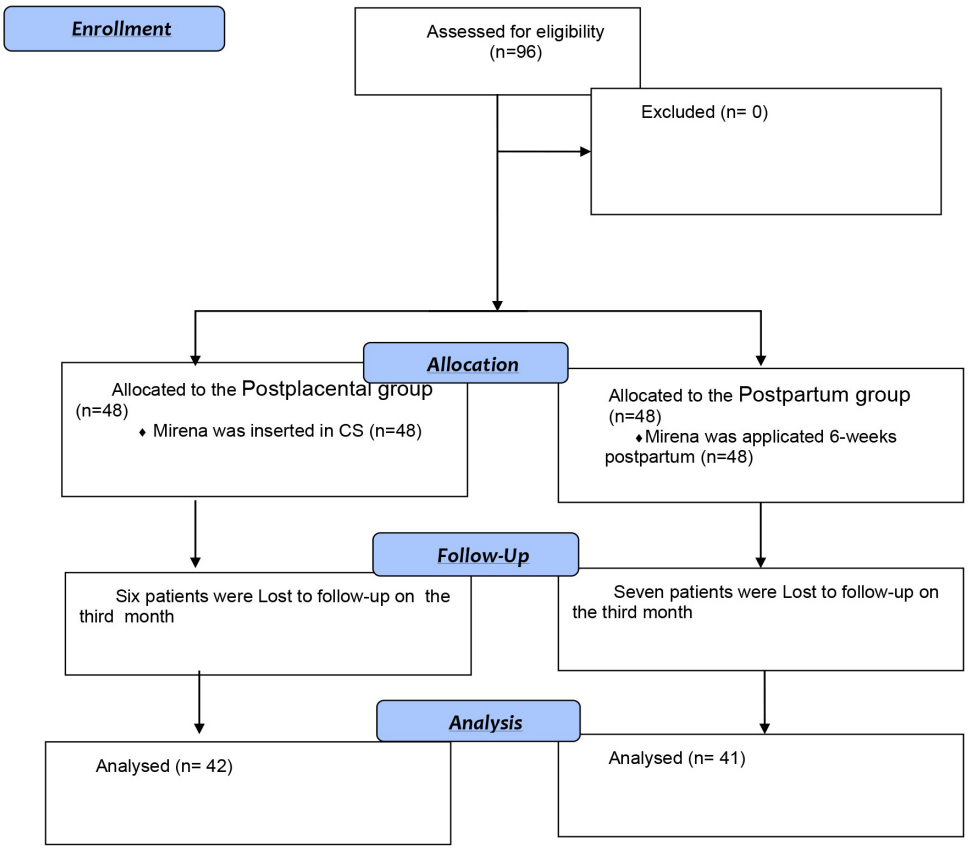

Fig. 1. Patient flow diagram. CS, cesarean section.

> 0.05). Additionally, there were no significant differences ($p > 0.05$) between the demographic criteria (mean age, BMI, hemoglobin, gestational age, and parity) and the occurrence of complications (expulsion, perforation, displacement, bleeding, and infection) in both groups (data not shown).

Based on the data that was collected, there were no statistically significant differences ($p > 0.05$) found between the history of CS and the complications of IUD application, such as expulsion, infection, bleeding, displacement, and perforation. Unfortunately, the data was not shown. Table 2 demonstrates that there is also no statistically significant difference ($p > 0.05$) when it comes to the expulsion and number of previous CS in all patients.

4. Discussion

The Mirena IUD is considered one of the most successful long-acting reversible contraception (LARC), and is recommended by the American College of Obstetrics and Gynecology (ACOG) as one of the best options for contraceptive methods during early puerperium, to improve child healthcare and maternal care [8].

It is important to apply the IUD early on, in order to avoid the need for delayed contraception until six weeks after childbirth. Some women may continue to have sexual activity during this time, which increases the risk of unintended pregnancy [9]. Non-breastfeeding women who resume ovulation in the fourth week after childbirth are also at a higher risk of unintended pregnancy [10].

4.1 Interpretation of the Present Study Results and Their Comparison to Similar Studies

The present study found no significant differences between groups, regarding IUD displacement, or expulsion rates. There were no statistically significant differences in the expulsion rate and previous number of CSs, which supports the application of an IUD during a CS.

The Mirena device has a wider diameter and is inert, making it less likely to be expelled than the copper (Cu) IUD. However, obstetricians are concerned about the larger size of the uterus after delivery, which increases the risk of expulsion during the postpartum period [11].

In a cohort study of 90 patients who received an IUD during cesarean delivery, Levi *et al.* [11] reported very low expulsion rates. Additionally, 80% of the women reported high satisfaction with this method. In Levi *et al.*'s study conducted in 2015 [12], 112 women were randomly assigned to receive an IUD, either immediately after giving birth, or six weeks later. The researchers reported only 4 cases of IUD expulsion in the post-placental group, which is comparable to the findings of the present study [12]. However, their study used a different methodology, in which they inserted another IUD for the four women who pre-

Table 1. Comparison between group I and group II in terms of primary and secondary outcomes: one-month and three-months duration.

	Post-placental group I (N = 48)	Post-puerperal group II (N = 48)	*p*-value	Sig
Expulsion one month after IUCD insertion	2 (4.2%)	3 (6.3%)	0.646	NS
Infection one month after IUCD insertion	0 (0.0%)	2 (4.2%)	0.153	NS
Bleeding one month after IUCD insertion	4 (8.3%)	5 (10.4%)	0.725	NS
Perforation one month after IUCD insertion	0 (0.0%)	0 (0.0%)	–	–
Displacement one month after IUCD	3 (6.3%)	4 (8.3%)	0.708	NS
	N = 42	N = 41		
Expulsion three months after IUCD insertion	3 (7.1%)	4 (9.8%)	0.636	NS
Infection three months after IUCD insertion	2 (4.8%)	5 (12.2%)	0.196	NS
Bleeding three months after IUCD insertion	7 (16.7%)	9 (22.0%)	0.513	NS
Perforation three months after IUCD insertion	0 (0.0%)	1 (2.4%)	0.283	NS
Displacement three months after IUCD	4 (9.5%)	5 (12.2%)	0.672	NS

Using: Chi-square test; *p*-value $>$ 0.05 is insignificant.

IUCD, intrauterine contraceptive device; NS, non-significant.

Table 2. Relation between expulsion, parity, and previous number of CSs in all patients at three months (N = 83).

		Expulsion				Chi-square Test	*p*-value
		Yes (N= 7)		No (N = 76)			
		N	%	N	%		
Parity	PG	1	14.3%	16	21.1%	3.883	0.422
	One	1	14.3%	15	19.7%		
	Two	4	57.1%	18	23.7%		
	Three	1	14.3%	23	30.3%		
	>Three	0	0.0%	4	5.3%	3.797	0.284
Previous number of CS	0	1	14.3%	16	21.1%		
	1	5	71.4%	27	5.5%		
	2	1	14.3%	22	28.9%		
	3	0	0.0%	11	14.5%		

PG, primigravida; CS, cesarean section.

sented the device expulsion, explaining the cases of IUD permanence at six months for the remaining patients.

The prospective cohort study by Zaconeta *et al*. [13] supports our findings. The study involved 48 women who had IUDs inserted during CS. According to their findings, the expulsion rate during the first six weeks was not significantly different from that between the period of six weeks and six months (9% and 9.1%, respectively). This, however, differs from our study where the expulsion rate was found to be 4.2% within the first month and 7.1% after the third month.

In the present study, in the puerperal group, the expulsion rate was about 6.3% (3 patients) during the first month follow-up and 4 patient (9.8%) in the three-month follow-up. There was no statistically significant difference between both groups in regards to the expulsion of IUCD. These results are in line with the randomized control trial (RCT) of Lester *et al.* [14], where there was no statistically significant differences between 34 post-placental women versus 18 women in the postpartum period [14].

Contrary to the present study is the study of Mohamed *et al.* [15], in which immediate postpartum IUCD insertion had a higher expulsion rate, of 6.2% compared to 1.2% postpartum, which was statistically significant. These results were similar to the study of Gupta *et al.* [16], where the expulsion rate was significantly higher in the post-placental group compared to the postpartum insertion group.

In the current study, there were no instances of perforation in the post-placental group. However, only one perforation was observed in the puerperal group (2.4%), which occurred three months after insertion and was managed conservatively. This can be attributed to the fact that Mirena is inserted under vision, and the myometrium is thicker immediately after the delivery of the placenta in comparison to the myometrium after six weeks. Accordingly, Gutgutia *et al*. [17] (2015) reported no cases of Cu IUD perforation in the post-placental insertion of IUCD. Moreover, in a study of IUD insertion in CS in six different countries, 17,000 women were observed, and there was not a single case of perforation [18].

In our study, we found no statistically significant differences between both groups in terms of excessive bleeding. This finding is in line with Gupta *et al.*'s research [16] in 2013, where only 5.3% of women complained of bleeding, and all of them had to remove the IUCD due to this issue. There are several factors that can explain this result, such as Mirena's ability to imitate the normal involution of the uterus during the postpartum period. This may help reduce dysfunctional bleeding and lochia [19].

In the group of women with IUDs inserted postpartum, there was no statistically significant differences in the rate of displacement between those who received the IUD immediately after delivery, and those who received it later. In both the first- and third-month follow-ups, the rate of displacement was similar in both groups. However, in cases where the IUD was displaced, it was removed, and the women were offered an alternative form of contraception. This result was consistent with the findings of a study conducted by Lester *et al*. [14], which also found no statistically significant differences in the displacement rates between post-placental and postpartum women [14]. Another study by Puzey [20] found that 6% of patients experienced malposition of the IUD, conducted among 33 patients who had Mirena inserted intra-cesarean [20]. In a randomized controlled trial by Zaconeta *et al.* [13], 8 out of 91 women (8.8%) exhibited IUD rotation to a transversal situation inside the endometrial cavity during sonographic follow-up [13].

Our study found no statistically significant differences between groups in regard to pelvic infection. This may be due to the Mirena's inert nature, which reduces the local inflammatory response, that is common with the Cu device. Additionally, participants who had an immediate post-placental insertion, recently completed a course of antibiotics, which lowered their risk of developing a pelvic infection. Our results are consistent with Zaconeta *et al*. (2019) and Gupta *et al*. (2013) [13,16].

4.2 Strengths and Limitations of the Present Study

The advantage of the current study is that it was conducted in a private hospital and the consultants applied Mirena at the same level of experience, which reduced statistical bias. However, there are some weaknesses in the study. Firstly, there was no long-term follow-up due to the fact that most patients being non-Saudi, i.e., non-residents who only visited Saudi Arabia for three to six months before returning to their countries. Secondly, there was a lack of randomization, as most private patients refused the idea of randomization and preferred to make their own decisions.

4.3 Clinical Implication of the Present Study

We highly recommend that obstetricians insert the IUD immediately after delivery for an easier application, safety, early contraception, and patient convenience.

4.4 Recommendations for Future Studies

There have not been any large or long-term randomized controlled trials on the insertion of the levonorgestrel intrauterine system (LNG-IUS) during a CS. Further studies are necessary to evaluate patient satisfaction with post-placental IUD insertion and the reduction of psychological fear related to pain during IUD insertion, with a long-term follow-up.

5. Conclusions

Inserting an IUCD immediately after childbirth through cesarean delivery is just as safe and effective as inserting it in the postpartum period. However, it may be more convenient for patients due to its easy insertion process, lack of expulsion, and low risk of complications associated with using this contraceptive method.

Availability of Data and Materials

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

Author Contributions

All authors jointly contributed to the conception and design of the study. NA: helped in the review of literature, revision of results and data analysis, writing the manuscript. SN: review of literature and revision of the manuscript. SA: design of the study, obtaining ethical committee approval, reviewing the literature, sharing in the collection of data, revision of results and data analysis, and contributing to writing the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Following local regulations, the protocol gained ethical and research approval from the Hassan Muhammed Abu Bakr Al Bar Hospital (8/2023). Written informed consent was obtained from every candidate after explaining the procedure before enrollment. We Confirm that all methods were performed by the relevant guidelines and regulations according to the Declaration of Helsinki.

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Conflict of Interest

The authors declare no conflict of interest.

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