ORIGINAL ARTICLE

Comparative study between Immediate Insertion of Intrauterine Device and 6 Weeks Post Caesarean Section

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Abstract

Background: Ovulation is extremely unpredictable for women who aren't breastfeeding and for women who aren't exclusively breastfeeding, making the postpartum period a particularly risky time for unintended pregnancies because of the lack of effective contraception options, particularly for women who are breastfeeding.

Aim and objectives: To compare the insertion of an intrauterine device (IUD) intra-operatively and the insertion of IUD post-puerperium (after 6 weeks) according to compliance pain during insertion, missed threads, and effectiveness.

Subjects and methods: One hundred pregnant women who had CS and were seeking a method of birth control that did not involve the use of an intrauterine device (IUD) were the subjects of this randomized controlled trial that ran from September 2022 through September 2023 at Qena General Hospital and El-wakf Hospital

Results: According to IUD status, in Group-A; 16.0% of them were Expulsed and 84.0% were Retained, while the Group-B; 8.0% of them were Expulsed and 92.0% were Retained, and this was statistically insignificant. In Group-A; 12.0% of them were partial expulsion and 4.0% were complete expulsion, while the Group-B; 6.0% of them were Partial expulsion and 2.0% were complete expulsion, and this was statistically insignificant.

Conclusion: Both methods were generally safe and effective for IUD insertion, in intra-operative insertion there was no pain but there was high rate of missed threads and in post operative insertion (after 6-weeks) there was some pain with less rate of missed threads, so its easily removed, with highly statistically significant increase in continuation rate among post operative insertion than intra operative insertion.

Keywords: Post caesarean section; Intrauterine device

1. Introduction

Family planning (FP) is a means to attain an individual's and a couple's reproductive life. Postpartum family planning (PPFP) is described as the prevention of unwanted pregnancy and closely spaced pregnancies through the first year after childbirth.

The effectiveness of long-acting reversible contraception (LARC) in lowering the rate of unwanted pregnancies is being acknowledged more. The American College of Obstetricians and Gynecologists describes LARC techniques, such as the contraceptive implant and copper and levonorgestrel (LNG) intrauterine devices (IUDs), as first-line methods of contraception for

adults and adolescents.2

Roughly fourteen percent of women throughout the world use an intrauterine device (IUD) as a method of pregnancy prevention.³

Easy insertion, few negative effects on breastfeeding, and low cost are only a few of the benefits of this coitus-independent, reversible, and effective method of birth control.⁴

While some gynecologists prefer to insert intrauterine devices (IUDs) immediately following placental removal during a cesarean section (CS), others recommend waiting 42 days or 6 months after the procedure, and the majority of doctors recommend waiting 3 months after the CS. The exact timing of the IUD insertion is a topic of debate.⁵

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The benefits of intrauterine devices (IUDs) include less discomfort and improved motivation for contraception when inserted within the first ten minutes after delivery, a time known as immediate post-placental insertion (IPU).

Concerning compliance discomfort, missing threads, and efficacy, this study compared intra-operative and post-puerperium (after 6 weeks) intra-uterine device (IUD) insertion.

2. Patients and methods

One hundred pregnant women who had CS and were seeking a method of birth control that did not involve the use of an intrauterine device (IUD) were the subjects of this randomized controlled trial that ran from September 2022 through September 2023 at Qena General Hospital and El-wakf Hospital.

Question of the study:

Does the instantaneous intrauterine device (IUD) work as advertised and pose no health risks to the user?

Ethical and legal considerations

All subjects were required to sign a written consent form and undergo ethical committee approval before they could take part in the study.

Sample size:

The following formula was used to calculate the sample size:

Where:

With n = sample size, $Z\alpha/_2$ = 1.96 (the critical value separating the central 95% of the Z distribution from the 5% in the tail), $Z\beta$ = 0.84 (the critical value separating the lower 20% of the Z distribution from the upper 80%), σ = the estimate of the standard deviation of the length of latent period, μ = mean in the study group, and μ_2 = mean in the control group, the sample size was calculated to be equal to 50 cases per group, for a total sample size of 100 cases.

Inclusion criteria:

Women who were pregnant and seeking a method of birth control, who did not have any contraindications for intrauterine devices (IUDs).

Exclusion criteria:

The patient presents with symptoms such as a fever, vaginal discharge with a foul odor, a history of prelabour membrane rupture (more than 8 hours), preterm labor, an upper segment or classical cesarean scar, a scar from a previous myomectomy, a cesarean on top of the placenta previa or placenta accreta, or a previous myomectomy. Hemoglobin levels below 8 g/dl, uterine anomalies (such as a uniconuate, bicornuate, didelphus, or septate uterus), postpartum bleeding, or the manual removal of the placenta.

Intervention (s):

A thorough medical history was taken from each patient, including their current and past medical conditions, any medications or surgeries they may have had in the past, the length of time since their last menstrual period (LMP), and any other relevant information. A clinical examination was also performed, and the mother's body mass index (BMI) was calculated. An abdominal examination and abdominal ultrasound were also performed.

Randomization:

Numbers were delivered in sealed envelopes in order to ensure randomization. Two groups were formed from the randomly selected patients (n=100) using an alternate allocation system: Fifty pregnant women who were anticipated and prepared for intraoperative IUD insertion were part of Group-A. Fifty pregnant women who were recommended to get an intrauterine device (IUD) after six weeks of gestation were part of Group B.

Interventions:

The first group, known as Group A, consisted of fifty women who were all subjected to the following procedures: a standard technique skin incision (the Pfannenstiel incision), an incision into the bladder and peritoneum, a lower-segment transverse cesarean section (CS) with an extension of the incision, the birth of the fetus, and finally, the placental delivery. In a cesarean section, the intrauterine device (IUD) was manually inserted into the uterine fundus. The strings were inserted into the lower uterine segment prior to the closure of the uterine incision. A tube for intrauterine device implantation was used to thread the strings through the cervix. The peritoneal suture in the bladder and the uterine incision are closed. Finally, the subcutaneous and epidermal layers were sealed.

Fifty people made up Group B, which served as a control group for the interval insertion (n=50). Standard procedure for lower-segment CS: (skin incision, Pfannenstiel incision, bladder peritoneal incision, lower-segment transverse CS and incision extension, fetus delivery, placental delivery, uterine incision closure, bladder peritoneal suture, subcutaneous and skin closure). Conventional intrauterine device (IUD) insertion occurred six weeks later.

Primary outcomes:

Compliance of patients for IUD, motivation of pregnant women for contraception, especially those in the previous section, and the importance of contraception for the health of women and their babies, and the effect of anesthesia in pregnant women for IUD insertion.

Secondary outcomes:

Rate of expulsion of IUD if insertion during CS and after puerperium. Assessment of pain if insertion during CS and puerperium. Other

complication such as perforation and missed threads.

Statistical Analysis

The data was entered into the Statistical Package for Social Science (IBM SPSS) version 20 after it had been revised and coded. Numbers and percentages were used for qualitative data, while means, standard deviations, and ranges were used for quantitative data with a parametric distribution. A Chi-square test was used to compare two groups with qualitative data. If the expected count in any cell was less than 5, Fisher's exact test was used instead of the Chisquare test. When comparing two groups with quantitative data and a parametric distribution, an independent t-test was employed. The confidence interval was set to 95% and the margin of error accepted was set to 5%. Therefore, the pvalue was deemed significant.

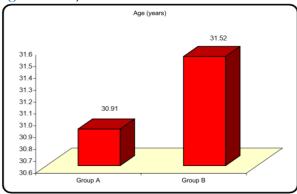
3. Results

Table1. Comparison between studied groups regarding age(years) and BMI(kg/m2)

	_	GROUP-A	GROUP-B	TEST	P-	SIG.
		No=50	No=50	VALUE•	VALUE	
AGE(YEARS)	Mean±SD Range	30.91±4.03 23-40	31.52±4.57 24-41	-0.711	0.479	NS
DMI(VC/M²)				1 414	0.160	NIC
BMI(KG/M ²)	Mean±SD	26.20±3.51	27.20±3.55	-1.414	0.160	NS
	Range	20-33	22-35			

**Chi-square test, **Independent t-test, P-value<0.05: Significant (S), P-value<0.01: Highly significant (HS), P-value>0.05: Non-significant (NS)

The mean of age (years) for patients of group-A was 30.91±4.03 and it was 31.52±4.57 for patients of group-B, and this was statistically insignificant. The mean of BMI (kg/m2) for patients of group-A was 26.20±3.51 and it was 27.20±3.55 for patients of group-B, and this was statistically insignificant, (table 1; figures 1&2).



Figure(1): Comparison of the age (years) of the groups under study.

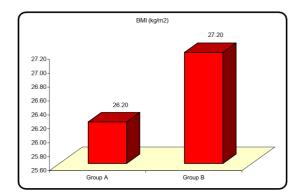


Figure 2. Comparison of the groups under study in terms of BM (kg/m2).

Table 2. Comparison between studied groups regarding parity and education.

		GROUP-	GROUP-	TEST	P-	SIG.
		A	В	VALUE	VALUE	
,		No=50	No=50			
PARITY	Mean±SD	2.86 ± 0.98	2.93 ± 0.85	-0.383•	0.702	NS
	Range	1-5	1-4			
EDUCATION	High	26(52.0%)	29(58.0%)	0.364*	0.546	NS
	Low	24(48.0%)	21(42.0%)			

*: Chi-square test, •: Independent t-test; P-value>0.05: Non-significant (NS); P-value<0.05: Significant (S); P-value<0.01: Highly significant (HS)

The mean of parity for patients of group-A was 2.86±0.98 and it was 2.93±0.85 for patients of group-B, and this was statistically insignificant. Twenty-six patients in group-A were high education and 24 low educations in comparison to 29, 21 patients had the same in group-B, and this was statistically insignificant, (table 2; figures 3&4).

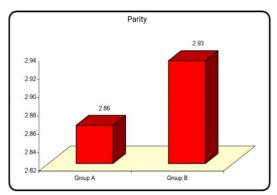


Figure 3. Comparison of the groups under study in terms of parity.

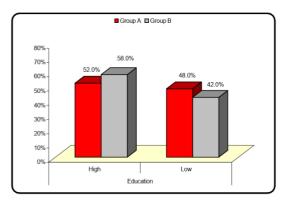


Figure 4. Comparison of the educational attainment of the groups under study.

Table 3. Comparison of the groups under study in terms of endometritis, PID, discomfort, and bleeding.

		GROUP-A		GROUP-B		TEST	P-	SIG.
		No.	%	No.	%	VALUE*	VALUE	
BLEEDING	Abnormal	12	24.0%	10	20.0%	0.233	0.629	NS
	Normal	38	76.0%	40	80.0%			
PAIN	No	38	76.0%	41	82.0%	0.542	0.461	NS
	Yes	12	24.0%	9	18.0%			
PID	No	44	88.0%	47	94.0%	1.099	0.295	NS
	Yes	6	12.0%	3	6.0%			
ENDOMETRITIS	No	48	96.0%	49	98.0%	0.344	0.558	NS
	Yes	2	4.0%	1	2.0%			

P-value>0.05:Non-significant (NS); P-value<0.05:Significant (S); P-value<0.01:highly significant (HS); *:Chi-square test, •:Independent t-test

In Group-A; 24.0% of them had abnormal bleeding (Menorrhagia and spotting) and 76.0% were normal bleeding, while the Group-B; 20.0% of them had abnormal bleeding and 80.0% had normal bleeding, and this was statistically insignificant.

In Group-A; 24.0% of them had pain, 12.0% were PID and 4.0% were endometritis, while the Group-B; 18.0% of them were pain, 6.0% were PD and 2.0% were endometritis, and this was statistically insignificant, (table 3;figures 5&6).

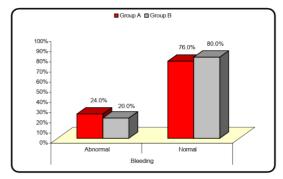


Figure 5. Comparison of the groups under study with respect to bleeding.

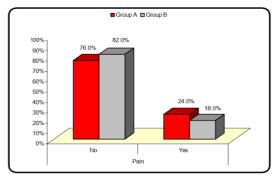


Figure 6. Comparison of the pain levels of the groups under study.

Table 4. Comparison between study groups regarding IUD status, incomplete expulsio (malpostion) and total expulsion.

		GROUP-A		GROUP-B		TEST	P-	SIG.
		No.	%	No.	%	VALUE*	VALUE	
IUD	Expulsed	8	16.0%	4	8.0%	1.515	0.218	NS
STATUS	Retained	42	84.0%	46	92.0%			
PARTIAL	No	44	88.0%	47	94.0%	1.099	0.295	NS
EXPULSION	Yes	6	12.0%	3	6.0%			
COMPLETE	No	48	96.0%	49	98.0%	0.344	0.558	NS
EXPULSION	Yes	2	4.0%	1	2.0%			

*: Chi-square test, •: Independent t-test; P-value>0.05: Non-significant (NS); P-value<0.05: Significant (S); P-value<0.01: Highly significant (HS)

According IUD status In Group-A; 16.0% of them were expulsed and 84.0% were retained, while the Group-B; 8.0% of them were expulsed and 92.0% were retained, and this was statistically insignificant.

In Group-A; 12.0% of them were partial expulsion and 4.0% were complete expulsion, while the Group-B; 6.0% of them were partial expulsion and 2.0% were complete expulsion, and this was statistically insignificant.

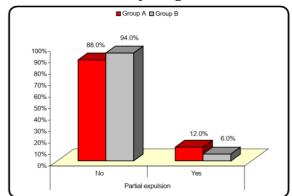


Figure 7. Comparison between investigated populations regarding partial expulsion.

Table 5. Comparison of the groups under study in terms of missing threads, perforation, continuation rate, and perforation during CS versus after 40 days.

		GROUP-A		GROUP-B		TEST	P-	SIG.
		No.	%	No.	%	VALUE	VALUE	
CONTINUATION	No	18	36.0%	5	10.0%	9.543	0.002	HS
RATE	Yes	32	64.0%	45	90.0%			
IMMEDIATE	No	50	100.0%	49	98.0%			
PERFORATION	Yes	0	0.0%	1	2.0%	1.010	0.315	NS
(DURING								
INSERTION)								
DELAYED	No	50	100.0%	48	96.0%	2.041	0.153	NS
PERFORATION	Yes	0	0.0%	2	4.0%			
DURING CS								
VERSUS AFTER								
40DAYS								
(FOLLOW-UP)								
MISSED	No	35	70.0%	45	90.0%	6.250	0.012	S
THREADS	Yes	15	30.0%	5	10.0%			

*: Chi-square test, •: Independent t-test; P-value>0.05: Non-significant (NS); P-value<0.05: Significant (S); P-value<0.01: Highly significant (HS) In Group-A; 64.0% of them were continuation rate, while the Group-B; 90.0% of them were continuation rate in the first year, and this was highly statistically significant.

In Group A; 0.0% of cases were perforated and remained so during follow up, while the Group-B; 2.0% of them were perforated during insertion and 4.0% were perforated during follow up after 40 days, and this was statistically insignificant.

In Group-A; 30.0% of them were missed threads, while the Group-B; 10.0% of them were missed threads, and this was statistically significant.

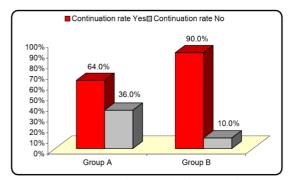


Figure 8. Comparison of the study groups' rates of continuation.

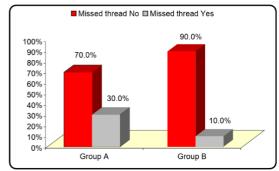


Figure 9. Comparing the groups under study in terms of missed threads.

4. Discussion

The cumulative pregnancy rate in the first year after the installation of intrauterine devices (IUDs) is less than 1%, making them a popular method of birth control. IUDs are also long-lasting, reversible, and affordable. Furthermore, their usage is unrestricted by any regulations, whether a woman is breastfeeding or not. If women get intrauterine devices (IUDs) soon after giving birth, particularly those without health insurance, they may save money in the long run.⁷

Conventional wisdom states that women should wait six weeks after giving birth before beginning postpartum birth control. Consequently, it has been advised that women refrain from having sexual relations for the next six weeks. Although some women experience sexual activity during this interval, it is more common in women who give birth via cesarean section than in those who give birth vaginally. So, there's a good chance of an unexpected pregnancy right after giving birth if you wait six weeks to start a form of birth control.⁸

Groups A and B did not differ significantly from one another in terms of age, body mass index (BMI), or parity, according to the present research.

Consistent with this, new studies have sought to compare and contrast the expulsion rate, pain, and amount of bleeding after puerperium and cesarean delivery with and without an intrauterine device (IUD; Pregna T Cu 380A). Elkholy et al., found no significant difference between the two groups when comparing prenatal care, age, and parity.

Although 24% of patients in group A reported experiencing pain, just 18% of patients in group B reported the same level of discomfort; our results showed no statistically significant variations in pain levels between the two groups (p>0.05).

Was the outcome the same when Elkholy et al.,⁹ found no statistically significant differences in postoperative discomfort between the two groups.

This was in conflict with Khurshid et al., 10 who mild spotting pain and as initial consequences with the installation of their intrauterine devices (IUDs). The presence of lochia prevented the detection of bleeding or spotting in the PPIUD group. In the PPIUD group, just eleven patients reported experiencing minor pain. In the IIUD group, 7.8% of patients reported little bleeding or spotting, and 39.9% reported mild to moderate discomfort. For both of the acute problems, there was a statistically significant difference between the two sets of patients. Incontinence discomfort of pelvic dysmenorrhea was also shown to be more prevalent in the IIUD group after 6 weeks.

Statistical analysis revealed a notable distinction between the two sets of participants. There was no statistically significant difference between the groups at 6 months and 1 year. They may have included patients with mild pelvic pain because their analysis reveals a relatively higher incidence of pelvic discomfort in both groups.

The increased risk of problems in Group A remains unclear. The cervix may dilate more easily during pregnancy, facilitating the insertion of the intrauterine device (IUD). On the other hand, the woman's general health and the specific IUD type might have a role.

According to the latest findings, the groups do not differ much in terms of PID. With a p-value of only 0.295, 12% of patients in group A had PID compared to 6% in group B.

Hubacher¹¹ notes that the best data suggest that the risk of PID among IUD users is minimal. While studies have shown that the insertion process increases the risk of PID, prophylactic antibiotic treatment appears to be necessary since PID rates are low even in the first month. New studies have shown that there is less of a definite relationship between IUD usage and later infertility.

Our results showed that, according IUD status In Group-A; 16.0% of them were expulsed and 84.0% were retained, while the Group-B; 8.0% of them were expulsed and 92.0% were retained, and this was statistically insignificant. In Group-A; 12.0% of them were partial expulsion and 4.0% were complete expulsion, while the Group-B; 6.0% of them were partial expulsion and 2.0% were complete expulsion, and this was statistically insignificant.

This disagreed with Khurshid et al., 10 who discovered a statistically significant difference in expulsion following post-placental insertion versus delayed insertion; the difference between groups was statistically significant (p=0.006) for cumulative expulsion, but not for interval expulsion rate (p=0.6). The only potential drawback of PPIUD insertion may be the higher expulsion rate in the PPIUD group compared to the interval insertion group; the groups' cumulative expulsion rates showed a statistically significant difference, and the difference remained throughout the study period; however, the interval expulsion rates were comparable between 6-months and 1-year, suggesting that interval expulsions are high in the PPIUD groups up to 6-months, and after a year, the risk of expulsion is the same in both groups.

The reason for the difference in these findings is not clear. It is possible that Khurshid et al., ¹⁰ had a longer follow-up period, which allowed them to detect more late expulsions. It is also possible that the two studies used different methods to define expulsion.

This also agrees with Shah et al., 12; and Gupta et al., 13 who discovered that PPIUCD had a higher expulsion rate.

According to our findings, Group B's continuation rate increased more than Group A's by a highly statistically significant margin.

This partially contradicts Khurshid et al., ¹⁰ who stated that although the PPIUD group appears to have greater continuation rates, the difference is not statistically significant.

The present study showed that, in Group-A; 24.0% of them were abnormal bleeding and 76.0% were normal bleeding, while the Group-B; 20.0% of them were abnormal bleeding and 80.0% were normal bleeding, and this was statistically insignificant.

In agreement with our result, Safty et al.,¹⁴ showed that there was no significant difference in abnormal bleeding between the groups (p>0.05), with group-A patients presenting with abnormal bleeding at a rate of 24% and group-B patients presenting with abnormal bleeding at a rate of 19%.

According to our findings, Welkovic et al. 15 the incidence of major hemorrhage after the insertion of a post-placental intrauterine device did not vary among the studies.

4. Conclusion

Both methods were generally safe and effective for IUD insertion, in intra-operative insertion there was no pain but there was high rate of missed threads and in post operative insertion (after 6-weeks) there was some pain with less rate of missed threads, so its easily removed, with highly statistically significant increase in continuation rate among post operative insertion than intra operative insertion.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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