Immediate Post-placental Insertion of the Intrauterine Contraceptive Device during Cesarean delivery versus 6 Week Post-Cesarean Insertion: R.C.T

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Abstract

Background: Insertion of the IUCD immediately is likely to have a high motivation for accepting contraception, and the health-care center provides a convenient setting for inserting the IUCD. Aim of the study is to compare between immediate post-placental insertion of IUCD during cesarean delivery versus 6 weeks post-cesarean insertion delivery Design This study is a prospective randomized controlled trial study. Methods: This study was conducted at Ain Shams university maternity hospital. Women were randomly assigned into two groups; 1st group (Postplacental) containing 100 women in whom IUCD were inserted during cesarean section after delivery of the placenta, The second group (Postpartum) included 100 women where the IUCD were inserted after six weeks postpartum. Primary outcome was the expulsion rate while secondary outcomes were infection, perforation, bleeding, displacement for follow up visits at one month and three months. Data were analyzed by SPSS version 20.

Results: The result of the current study showed there is no significant difference between the two groups as regard expulsion rate also there is not any significant difference regarding infection, perforation, displacement and abnormal bleeding between the both groups. However, perforation rate between both groups is statistically insignificant, it is clinically high significant.

Conclusion: immediate post placental IUCD insertion during caesarean delivery is equal safe and effective method of contraception as IUCD insertion in puerperium, however it may be better as regard patient convenience because easy insertion, no expulsion no complications in using contraceptive method.

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Keywords: IUD, post placental, perforation, displacement, infection, bleeding .

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Introduction

Each year, more than One Hundred million women make decisions about beginning contraception after child birth.

The main concern during the postpartum period is the occurrence of pregnancy in this short period of time, which may cause maternal-fetal complications and also have serious social, economic and psychological and repercussions. [1]

Intrauterine Contraception Device (IUCD) is the one of most frequently used method of reversible contraception in the world. Over One Hundred million women all over the world use it for contraception. It is regarded as one of the most reversible and effective contraceptive method. It is estimated that approximately 130 million women are using it worldwide. [2]

IUD is a very attractive to women as a contraceptive method because it is safe , reversible and effective. No follow up is required daily or monthly and it is a cost effective. The main drawback are failure, abdominal cramps, expulsion from the uterus, uterine perforation, menorrhagia , increased incidence of ectopic pregnancy, [3]

Instructions are given to the women to regularly feel the IUD strings, presence of the strings usually means that the IUD is in place. The first sign of perforation is the absence of threads in almost 80% of cases. The incidence of perforated uterus caused IUD is 0.87/1000 women and the perforation usually occurs during insertion.[4]

Previous studies assumed that Immediate post-placental application of intrauterine contraceptive device (IUCD) provides a more effective, reversible and long-term method of contraception . Previous trials of IUCD placement at the time of delivery by cesarean section have demonstrated low levels of complications and higher incidence of device retention.[5]

World Health organization (WHO) stated that risks generally outweigh benefits when insertion of IUD occurs between 2 days and 4 weeks. However, immediate post-placental IUCD insertion (within ten minutes) during delivery by cesarean section provides a good way to achieve minimal discomfort to the patient and also provides long-term contraception. There are no studies reporting any increase in the incidence of infection or any other complication related to immediate placement of IUD) during delivery by cesarean section.[6]

The aim of this study is to compare between immediate post-placental insertion of IUCD during cesarean delivery versus 6 weeks post-cesarean insertion delivery. The ethical committee at Ain Shams University has approved the study protocol. The paper was registered in clinicaltrial.gov NCT03404622

PATIENT AND METHODS

This study is a randomized clinical trial study conducted in Ain Shams University Maternity Hospital from May 2017 – December 2017 on 200 pregnant women.

Inclusion criteria of selected patients were; Age: 18-45, Singleton pregnancy at ≥32 weeks gestation at time of enrollment, voluntarily requesting to IUD placement for postpartum contraception. While the exclusion criteria were Uterine anomaly that preventing replacement of IUD, Chorioamnionitis (such as prolonged rupture of membranes >18 hours, prolonged labor >24 hours, fever >38C), Partum sepsis and unresolved postpartum hemorrhage, IUD allergy (copper), Systemic lupus erythematosus with severe thrombocytopenia.

Primary outcome

Expulsion [Time Frame:3 months] which is defined as the time until expulsion of the IUD beginning from the time of insertion until expulsion occurred, if known. If the date of expulsion was not known, this was documented as the day after the IUD was last known to be in place. If a pregnancy was detected and the IUD was absent (and the participant was unaware of expulsion), the expulsion was assumed to have occurred

at the time of conception, as determined by gestational age on ultrasound. Expulsions were measured as total expulsions and separately noted whether complete or partial,

Secondary outcomes

Displacement [Time Frame: 3 months]: The displacement was diagnosed by doing trans-vaginal ultrasound that showed IUCD that displaced up or down word

Infection [Time Frame: 3 months]: The diagnosis of PID was made based on the 2006 CDC guidelines and the criteria used in the PEACH study.

Bleeding [Time Frame: 3 months]: Irregular bleeding (including spotting, light bleeding, heavy or longer menstrual period) were common in the first 3 months and may persist.

Perforation [Time Frame: 3 months]: The diagnosis of a perforation was made by a transvaginal sonogram that shows no IUD within the uterus and an abdominal radiograph that show IUD within the abdominal cavity.

Sample Size calculation

Sample size was calculated using STATA program (Stata Corp. 2001. Statistical Software: Release 7.0. College Station, TX: Stata Corporation), setting the type-1 error (α) at 0.05 and the power (1-β) at 0.9. Results from a previous study (Lester et al., 2015) showed shows the IUD expulsion at 3 months was lower in the immediate insertion group compared to delayed insertion (93% vs. 50% after delayed Insertion p<.0001). Calculation according to these values produced a minimal sample size of 100 cases per each group.

Randomization

200 women have been allocated in this study, randomized in two groups: Group I (Postplacental): IUCD was inserted immediate post-placental removal during caesarean section and include 100 pregnant women. Group II (Postpartum): IUCD was inserted 6 weeks post cesarean delivery and include 100 pregnant women. Randomization was done using a computer-generated randomization table using Research Randomizer Version 4.0 software in a 1:1 ratio, using a case code written in a piece of paper and put in an opaque concealed enveloped which carried the case number. Closed opaque envelop method was applied as 100 envelops contained letter I (immediate insertion) and another 100 envelops would contain letter S (six weeks insertion). All patients with letter S (six weeks insertions) were followed up by phone to ensure they come to our hospital to insert the IUD by us. Allocation concealment was ensured as the service did not release the randomization code until the patient was recruited into the trial, which took place after all baseline measurements have been completed.

Procedures Done

Written consent Was obtained from all the participants and they were informed about the objectives of the study. Detailed complete history (personal, menstrual, obstetric and surgical history) taking, General and abdominal examination, Per vaginal examination and U/S before delivery were taken for all participants.

Surgical procedure: pre-operative antibiotics were given to all participants of both groups according to our hospital protocol. Group (1): this group included 100 women in whom IUCD were inserted during cesarean insertion, after delivery of the baby, placenta was removed then the IUCD was placed at the top of the uterine fundus with ring forceps or manually, Before closing the uterine Incision, the strings were placed in the lower uterine segment, The strings were usually descended spontaneously through the cervix during the partum period, If the cervix was closed, dilatation from above with ring

forceps and Strings were passed through the cervix with ring forceps, If this was done, rechecked to make sure IUCD was remained at the fundus of the uterus prior to closing the uterine incision, Trim strings at a follow-up visit. Group (2): this group included 100 of women who had elective lower segment cesarean section in whom the IUCD were inserted in the usual sterile fashion as described in the manufacturer's instructions at the 6-week postpartum visit.

All the participants were instructed about side effects, possible complications, and warning signs about the use of IUCD (TCu380) as a method of contraception and informed consent were taken from all recruited patients enrolled in the study. They were educated to recognize IUCD expulsion and to return to clinic for reinsertion or an alternative contraceptive method. Almost all expulsions occur in the first three months after insertion. She should also be advised that within several weeks, the IUCD strings may protrude through the internal os.

Follow up: Followed up was at interval of 1st week, one month and three months after insertion of IUCD. Follow up of participants was done by history taking, general and vaginal examination including speculum to visualize the strings of IUCD, CBC. In cases of missed IUCD an extra transvaginal ultrasound and pelvi-abdominal X-ray were done. Follow up was concise to primary and secondary outcomes.

Statistical methods: The collected data were revised, coded, tabulated and studies Statistical package for Social Science (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). Data was presented and suitable analysis was done according to the type of data obtained for each parameter. Student T Test was used to assess the statistical significance of the difference between two study group means. Chi-Square test was used to examine the relationship between two qualitative variables. Fisher's exact test: was used to examine the relationship between two qualitative variables when the expected count is less than 5 in more than 20% of cells. P>0.05: Non significant (NS), P< 0.05: Significant (S) and P<0.01: Highly significant (HS).

Results

The mean of age in group I (Postplacental) was 25.74±4.29 years while it was 26.02±4.63 years in group II (Postplartum). The mean of body mass index (BMI) was 31.85±4.27 and 32.37±1.46 kg/m2 in Postplacental group and II respectively. The mean of hemoglobin was 10.02±0.81 gm/dl in Postplacental group versus 10.07±0.65 gm/dl in postpartum group . The mean of gestational age was 38.89±0.71 and 38.9±0.74 weeks in Postplacental group and postpartum group respectively. And all these differences were statistically not significant (data not tabulated).

Our results showed that Postplacental group included 85 multiparous patients (85%), 80 patients (80%) with history of cesarean section, 59 of them (59%) had 2 or more sections while postpartum group included 82 multiparous patients (82%), 81 patients (81%) with history of cesarean section, 61 of them (61%) had 2 or more cesarean section. These differences were statistically not significant (data not tabulated).

Table 1 shows the rates of primary and secondary outcomes in both groups in period of follow up (1 week, 1 month and 3 month). Comparison between the incidence of expulsion, infection bleeding and displacement in time of follow up in Postplacental group and postpartum group were statistically not significant.

The correlations between mean age, BMI, hemoglobin, gestational age and parity, and complications in Postplacental group (immediate post-placental IUCD insertion) and postpartum group (6 weeks postpartum IUCD insertion) as regards patients with complications 3 months after IUCD insertion

were statistically not significant. (Table 2)

The correlations between parity, previous number of cesarean sections, and IUCD expulsion in both groups were statistically not significant. (Table 3)

DISCUSSION

The copper-T IUD is considered a long-acting reversible contraceptive (LARC) and is recommended by the ACOG (American College of Obstetrics and Gynecology) as one of the best options contraceptive methods during early postpartum period . ACOG's guideline on using IUD aims to improve the pregnancy-spacing that leads to the improvement of child health and maternal care, especially in developing countries. [2]

Our results demonstrated that there was no statistically significant difference between 2 groups as regard the incidence of expulsion, infection bleeding and displacement in time of follow up (one week, 1 month and 3 month duration).

Also there was no statistically significant difference between 2 groups as regard the correlations between mean age, BMI, hemoglobin, gestational age and parity, and complications in Postplacental and postpartum group in period of follow up. The correlations between parity, previous number of cesarean sections, and IUCD expulsion in both groups were statistically not significant.

Interpretation of our results and their comparison to similar studies

The CS rate was estimated at 55.1% for the 2019, 2020 and 2021 , the highest rate reached 67.8% in Behira and the lowest rate was 49.0% in Assiut. This higher rate of CS should encourage obstetricians to apply IUD immediate after delivery of placenta in CS, the main objection of obstetricians is that uterus size in immediate postdelivery is large and their increased rate of expulsion compared to 6 weeks insertion. The Expulsion was the was the primary outcome in our study in 3 month follow up. In Postplacental group, expulsion rate was about 6.0%, in three of those cases IUCD was not found at one month follow up and in the other three cases IUCD was not found at three month follow up but fortunately pregnancy had not occurred in any them may be due to exclusive breast lactation. The expulsion of IUD differs according to parity and number of previous CS as it increases in cases of postpartum insertion, but in our study, we found no statistically significant difference in rate of expulsion and previous number of CS which favors the insertion of IUD in post placental. The study done by levi et al. (2015), 112 women were randomized into their trial for post placental insertion vs 6 weeks insertion, they had four expulsions in the post placental group that occurred in the first three weeks postpartum which is almost similar to our study that 3 patients in Postplacental insertion had her IUD expelled. They explained that these women had a dilated cervix of 0-1cm at the time of cesarean section and IUD insertion [7] In the study of Zaconeta et al., (2019), which was a prospective cohort study including 100 women where Postplacental IUD was inserted during CS (it included only one group). The expulsion rate in the first 6 weeks was not different from that between 6 weeks and 6 months (9 vs 9.1%, respectively) which is different from our study 3% after first month and 6% after 3 rd month. Five of 9 patients in Zaconeta at al., study had spontaneous IUD expulsion, while one patient had the IUD removed due to PID. The remaining 4 cases were as follow 2 women IUD were removed due to excessive bleeding, and one was removed because was rotated to a transverse position and one patient asked removal to change to another way of contraception. During their 6 month follow up only 3 (3.4%) of 88 patients had IUD expulsion, so these results are in line with our results in both 6 weeks and 6 months follow up.[8]

In postpartum group , the expulsion rate was about 9.0%, six of those cases IUCD was not found at one month follow up and other three cases IUCD was not found three month follow up and by comparing both groups in our study; there was no statistical significant between both groups as regard expulsion of IUCD in the present study, these results are in line with RCT of Lester et al., 2015 where there was no statistical significant difference between 34 Postplacental women versus 18 women in postpartum period.[9] while in study by Mohamed et al. (2015) immediate postpartum IUCD insertion had higher expulsion rate 6.2% compared to 1.2% among post partum which is statistically significant. [10] In contrary to our study is the study of Gupta et al., (2016) where the Expulsion rate was significantly higher in Postplacental group as compared to postpartum insertion group (4.3% v/s 2.0%; p value< 0.05).[11]

In the present study there were no cases of perforation in Postplacental group while there was only one case in our study of uterine perforation in postpartum group (1%) had been occurred during insertion and managed conservatively. The comparison between both groups revealed no statistically significant difference which is comparable to study by Gutgutia et al. (2017) in which there were no cases of perforation in Postplacental insertion of IUCD. [12]

In Postplacental group, there was 15% of women complained of abnormal bleeding, eight of those cases were at one month follow up and other seven cases at three month follow up. 5% of those women were required removal of IUCD, in postpartum group there were about 19% complained of bleeding, ten of those cases at one month follow up and other nine at three month follow up. only 9% of those women were required removal of the IUCD and shifting to another method because of this complaint. There was no statistical difference between both groups as regard abnormal bleeding. Our results agree with study by Gupta et al. (2016) where number of women complain of bleeding was 5.3% and all of them remove the IUCD because of this complaint [11]

In Postplacental group, the displacement rate was about 9%, five of those cases IUCD were displaced at one month follow up and other four cases were displaced at three month follow up, so transvaginal and abdominal ultrasound were done to exclude perforation. While in postpartum group, the displacement rate was about 11%, nine of those cases IUCD were displaced at one month follow up and other two cases were displaced at three month follow up. No statistical significant difference was found between 2 groups , similar results were recorded in the study of Lester et al., 2015 where no statistical significant difference was found between 34 Postplacental women versus 18 women in postpartum period as regard rate of displacement (p>0.05). [9]

Regarding vaginal infection, in Postplacental group , the infection rate was about 5% at three month of follow up, although in postpartum group, the infection rate was 10%. Five of those cases were at one month follow up and other five cases were at three month follow up, in this study there was no cases of PID, comparable to study by Gupta et al. (2016) [11]. As regard cases of PID; the present study revealed that there was no statistically significant difference in both groups. This may be attributed to that 6-weeks postpartum participants resuming their sexual life after puerperium that make them risk for pelvic infection, also immediate post placental participants recently had a complete course of antibiotic that decrease the incidence of their risk of have pelvic infection. These results are in line with Gupta et al. (2016),[11] and Zaconeta et al., (2019). [8]

Strength and limitation of our study

The current study had the advantages of having a high power (90%) and of being randomized controlled trial; however. The

main weak point of this study is the absence of long term follow-up after the second visit between seven and ten days after birth, and the use of pain -which is a subjective measure- as the only variable for patient's satisfaction; however, efforts were made to minimize this bias by explaining how to fill the follow up sheet another limitation of the study is that it is not multicenter which may cause statistical bias

Clinical Implication of our study

We highly recommend the doctors to insert the IUD immediately post placental delivery in CS to decrease the fear felt by the patients as many patients refuse to insert IUD just from fear, also due to easier application during CS

Recommendations for future studies

Further studies are needed with a long term follow up and to study satisfaction of the patient towards the post placental IUD insertion and the decrease of psychological fear of pain from the inserting the IUD

Conclusion: immediate post placental IUCD insertion during caesarean delivery is equal safe and effective method of contraception as IUCD insertion in puerperium, however it may be better as regard patient convenience because easy insertion, no expulsion no complications in using contraceptive method

Ethics approval

Study approved by Research Ethical Committee, faculty of medicine , Ain shams University

Registration

The paper was registered in clinicaltrial.gov NCT03404622

Consent for publication:

Non applicable

Availability and data material:

The datasets used and/or analyzed during the current study are available from

the corresponding author on reasonable request.

Competing interests:

The authors report there are no competing interests to declare

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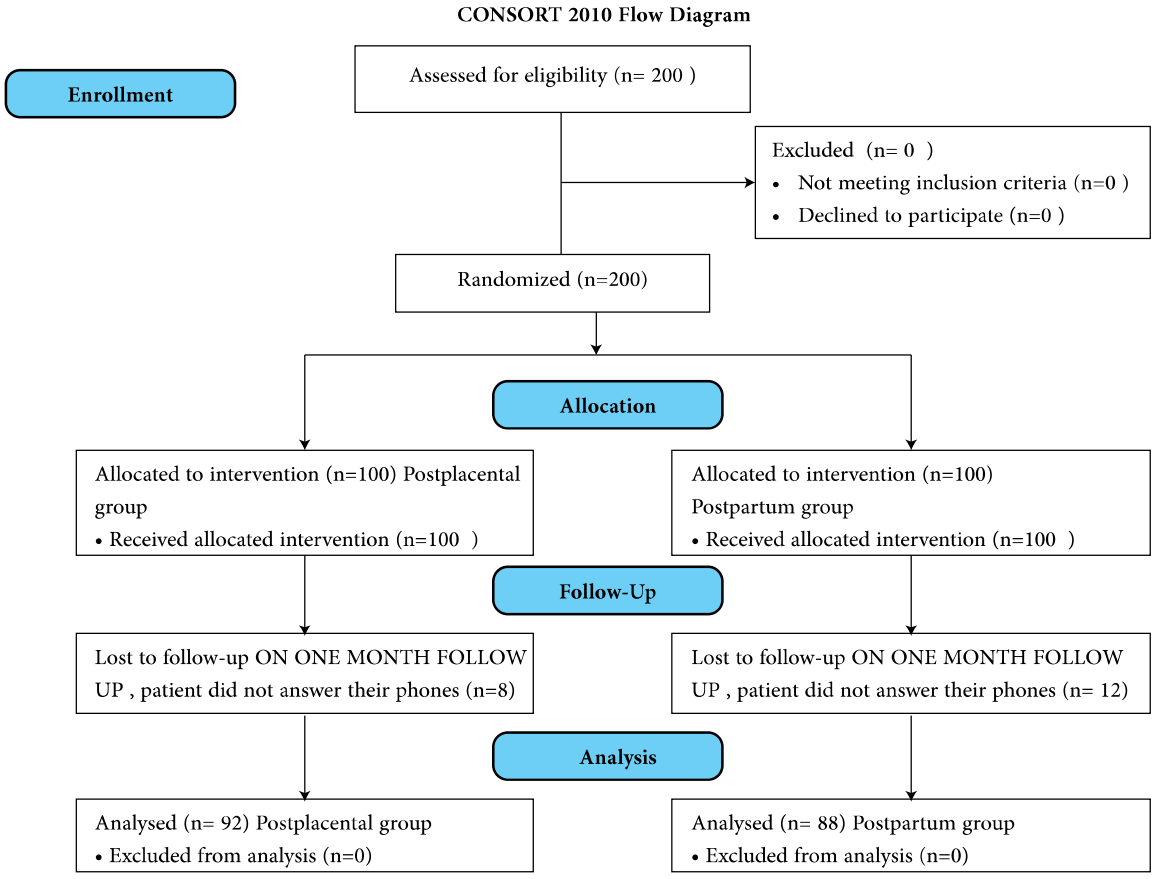

Table (1): Comparison between group I and Group II as regard Primary and secondary outcomes; one week, 1 month and 3 month duration.

Group I (n=100)	**1 week after insertion (n=100)**	**1 month after insertion (n=100)**	**3 months after insertion (n=92)**	
Expulsion	0 (0%)	3 (3.0%)	6 (6.5%)	
Infection	0 (0%)	0 (0%)	5 (5.4%)	
Bleeding	0 (0%)	8 (8.0%)	15 (16.3%)	
Perforation	0 (0%)	0 (0%)	0 (0%)	
Displacement	0 (0%)	5 (5)	9 (9.8%)	
Group II (n=100)	**1 week after insertion (n=100)**	**1 month after insertion (n=100)**	**3 months after insertion (n=88)**	
Expulsion	0 (0%)	6 (6.0%)	9 (10.2%)	
Infection	0 (0%)	4 (4.0%)	10 (11.4%)	
Bleeding	0 (0%)	10 (10.0%)	19 (21.6%)	
Perforation	0 (0%)	0 (0%)	1 (1.1%)	
Displacement	0 (0%)	9 (9.0%)	11 (12.5%)	
	Post placental Group I (n=100)	**Post puerperal Group II (n=100)**	**P**	**Sig**
Expulsion 1 month after IUCD insertion	3 (3.0%)	6 (6.0%)	0.307	NS
Infection 1 month after IUCD insertion	0 (0%)	4 (4.0%)	0.053	NS
Bleeding 1 month after IUCD insertion	8 (8.0%)	10 (10.0%)	0.622	NS
Perforation1month after IUCD insertion	0 (0%)	0 (0%)	---	---
Displacement 1 month after IUCD	5 (5.0%)	9 (9.0%)	0.269	NS
	N=92	**N=88**		
Expulsion 3 month after IUCD insertion	6 (6.5%)	9 (10.2%)	0.370	NS
Infection3 month after IUCD insertion	5 (5.4%)	10 (11.4%)	0.147	NS
Bleeding3 month after IUCD insertion	15 (16.3%)	19 (21.6%)	0.365	NS
Perforation3 month after IUCD insertion	0 (0%)	1 (1.1%)	0.315	NS
Displacement 3 month after IUCD	9 (9.8%)	11 (12.5%)	0.566	NS

Using: Chi-square test; with p-value >0.05 is insignificant

Table (2): Correlations between mean of age, BMI, Hemoglobin (HB) , Gestational age (GA) and parity in post-placental group I (immediate post-placental IUCD insertion) and post puerperal group II (6 weeks postpartum IUCD insertion) as regards patients with complications 3 months after IUCD insertion.

	Groups		p-value	Sig
	Post placental Group I	Post puerperal Group II		
	Mean ± SD	Mean ± SD		
Correlation between mean of age of the patients and 3-month complications				
Expulsion	25.83 ±3.87	28.33 ±6	0.386	NS.
Infection	25 ±3.81	24 ±4.69	0.687	NS
Bleeding	27.07 ±3.26	25.53 ±3.92	0.230	NS
Perforation	--	27.0±0.0	--	--
Displacement	28 ±4.64	30.55 ±3.91	0.199	NS
Correlation between mean of BMI of the patients and 3- month complications				
Expulsion	31.94 ±1.45	32.63 ±1.58	0.404	NS.
Infection	31.86 ±1.44	32.09 ±1.42	0.778	NS
Bleeding	30.31 ±7.6	32.69 ±1.31	0.188	NS
Perforation	--	32.47±0.0	--	--
Displacement	32.56 ±0.85	33.37 ±1.02	0.074	NS
Correlation between mean of HB of the patients and 3- month complications				
Expulsion	10.25 ±0.99	10.06 ±0.58	0.637	NS.
Infection	10.2 ±0.91	10.15 ±0.63	0.902	NS
Bleeding	9.43 ±0.59	9.42 ±0.56	0.951	NS
Perforation	--	9.5±0.0	--	--
Displacement	9.56 ±0.88	10.14 ±0.6	0.096	NS
Expulsion	39.17 ±0.98	39 ±0.71	0.707	NS.
Infection	39 ±0.71	38.9 ±0.88	0.829	NS
Bleeding	38.93 ±0.26	38.63 ±0.68	0.089	NS
Perforation	--	39±0.0	--	--
Displacement	38.89 ±0.78	38.73 ±0.65	0.619	NS
Correlation between mean of parity of the patients and 3- month complications				
Expulsion	1.67 ±1.63	2 ±1.32	0.670	NS.
Infection	1.6 ±0.89	1.6 ±1.26	1.000	NS
Bleeding	2.27 ±1.1	1.95 ±0.85	0.346	NS
Perforation	--	3±0.0	--	--
Displacement	2.56 ±1.81	3±1.1	0.506	NS

Using: Independent sample t-test; with p-value >0.05 is insignificant

Table (3): Comparison between two groups according to outcome relation with history of previous CS after 3 months.

			Group				p	Sig
			Post placental Group I		Post puerperal Group II			
			N	%	N	%		
Expulsion	History of previous CS	No	3	50.0%	2	22.2%	0.280	NS
		Yes	3	50.0%	7	77.8%		
Infection	History of previous CS	No	1	20.0%	3	30.0%	0.690	NS
		Yes	4	80.0%	7	70.0%		
Bleeding	History of previous CS	No	0	.0%	1	5.3%	0.373	NS
		Yes	15	100.0%	18	94.7%		
Perforation	History of previous CS	No	0	.0%	0	.0%	----	----
		Yes	0	.0%	1	100.0%		
Displacement	History of previous CS	No	2	22.2%	0	.0%	0.108	NS
		Yes	7	77.8%	11	100.0%		

Using: Chi-square test; with p-value >0.05 is insignificant

Table (4) Relation between expulsion at 3 months with parity and previous number of cesarean section in all patients (n=180).

		Expulsion				Chi square test	P value
		Yes (n=15)		No (n=165)			
		N	%	N	%		
Parity	PG	2	13.3%	38	23.0%	8.461	0.076
	One	5	33.3%	17	10.3%		
	Two	4	26.7%	50	30.3%		
	Three	4	26.7%	40	24.2%		
	>three	0	0.0%	20	12.1%		
Previous number of cesarean section	1	8	53.3%	82	49.7%	0.239	0.887
	2	5	33.3%	65	39.4%		
	3	2	13.3%	18	10.9%		
	4	0	0.0%	0	0.0%		
	More 4	0	0.0%	0	0.0%		

Using: Chi-square test; with p-value >0.05 is insignificant