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Evaluation of the outcome of post-partum intrauterine contraceptive device insertion in patients following normal vaginal delivery and lower segment cesarean section

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Abstract
Background: Being the second most populous country in the world after china, around 17 percent of the world's population resides in India while it has just around 2.4 percent area of the world. Contraception is one effective way to control population explosion. In country where delivery may be the only time when a woman comes in contact with health care personnel, approach of immediate post-partum contraception is more applicable.
Material and Methods: This is a prospective interventional study conducted over a period of time from August 2018 to May 2019, on patients visiting labor room of the tertiary care centre in the national capital of India.
Results: The PPIUCD was most accepted in the age group of 21-25 years, educated women, home makers, parity status P2 for willingness to have no pregnancy and spacing. The insertion of PPIUCD had no negative impact on Hb level. The incidence of irregular bleeding, increased duration of bleeding, missed threads, foul smelling vaginal discharge, abdominal discomfort, removal, expulsion, uterine perforation, satisfaction level was variable in each group.
Conclusion: Being second most populous country in the world, India needs to promote use of contraceptives for reducing population growth as well as improving maternal and child health. PPIUCD can one of be the most easily available and used postpartum contraception in India.

Keywords: PPIUCD, contraception, postpartum contraception, missing threads

Introduction
India is the second most populous country in the world sustaining around one fifth population of the world. In spite of availability of wide range of contraceptives, the unmet need for family planning is 12.9% in 2015-16 (NFHS4, MoHFW) [1]. Trussell [2] found that pregnancies taking place within 24 months of previous birth have higher risk of adverse outcome like abortion, premature labour, postpartum hemorrhage, low birth weight babies, fetal loss, and maternal death [2]. Lactational amenorrhea is temporary and natural method of family planning, as highlighted by Trussell [2]. However, during postpartum period, women use barrier methods, progesterone only pills, sterilization and intrauterine contraceptive device (IUCD) as methods of family planning apart from natural method. Studies show that IUCD is an ideal method for birth control and limitations. Copper-T 380A, an IUCD, is a highly effective with pregnancy rates 0.6 to 0.8 per hundred women in first year of use and it can be used continuously for ten years [3]. Specific limitations of post-partum intrauterine contraceptive device (PPIUCD) are increased risk of spontaneous expulsion and uterine perforation. In the hands of the skilled clinicians using right technique of insertion, risk of perforation is less and it is associated with lower expulsion rate [4, 5]. However, the outcomes/occurrence of complications after PPIUCD insertion may differ in cases of normal vaginal delivery and lower segment cesarean section. Further, there are only few studies in Indian context pertaining to evaluation of outcome of PPIUCD insertion in patients following normal vaginal delivery and lower segment cesarean section.
The present study aims to evaluate the outcome of PPIUCD insertion in patients following normal vaginal delivery and lower segment cesarean section at 48 hours, 2 week, 6 weeks and 3 months follow-up. Copper-T 380A has been used as an IUCD. Around 1500 patients were counselled and out of which around 500 agreed for Copper-T 380A insertion during a period of 10 months (August 2018 to May 2019).

Method

This is a prospective interventional study conducted over a period of time from August 2018 to May 2019, on patients visiting labor room of the tertiary care centre and fulfilling the inclusion and exclusion criteria.

Inclusion criteria

The inclusion criteria of this study are following:

1. Age 18 -40 year old
2. More than37 week of gestation
3. Haemoglobin>8.0 gm per cent
4. Willing for follow-up for three months

Exclusion criteria

The exclusion criteria of this study are followings:

1. Prolong and obstructed labour
2. Rupture of membrane>18 hours prior to delivery
3. Post-partum Hemorrhage
4. Ante-partum Hemorrhage
5. Sexually Transmitted disease
6. Severe Thrombocytopenia
7. HIV infected patient
8. Distorted uterine cavity by fibroid or by congenital malformations
9. Infection during time of birth

The full term pregnant women attending emergency and in labour room of department of obstetrics and gynaecology, DDUH, who fulfil the required criteria were recruited for the study. After proper counselling, a written informed consent was taken from all selected patients. A detailed history was taken and complete clinical examination was done for all patients. Routine investigations like CBC, blood grouping, and ultrasound to note gestational age, placenta, AFI were done if not already done. In cesarean section post-partum intrauterine contraceptive device was inserted after removal of placenta and before closure of uterine incision. After placental delivery and controlling bleeding, presence of uterine malformations was ruled out. The IUCD was held between middle and index finger and it was inserted through uterine incision and it was released at the fundus. String was gently guided towards lower uterine segment without disturbing the IUCD's position.

In normal delivery, bimanual examination was performed to evaluate the cervix and the uterus after the delivery of the placenta and ensured empty cavity with contracted uterus. The cervix and the vaginal walls were cleansed with the antiseptic solution. The anterior lip of the cervix was held with ring forceps gently. The IUCD was removed from the inserter tube with Kelly's forceps using no touch technique. Once the IUCD was placed in the lower uterine segment, other hand was moved to the woman's abdomen and pushes the uterus upward towards the uterine fundus. To help preventing the IUCD being drawn downward in the uterus, the instrument was swept to the right to ensure that the instrument is away from the IUCD. Then the instrument was slowly withdrawn, keeping it slightly open against lateral wall of uterus. Post insertion counselling was done.

Follow UP

The patients were followed-up at 48 hours, 2 week, 6 weeks and three months. At each visits, patients were asked for irregular or increased bleeding, any foul smelling discharge, severe lower abdominal discomfort, and patient's satisfaction. Further, general examinations, per speculum examination and per vaginal examination were done to see for any cervical erosion, foul smelling discharge, excessive bleeding, missing thread and any tenderness. Haemoglobin test was done at each visit.

Measurement of outcomes

During four follow-up visits of the patients, mentioned above, the outcomes of this study were measured in following terms - Haemoglobin (Hb), irregular bleeding, increased duration of bleeding, foul smelling vaginal discharge, severe lower abdominal discomfort, removal, expulsion and satisfaction. Their methods of measurement are shown in the Table 1.

Table 1: Outcome Measures and Methods of Measurements

S. No.	Outcome Measures	Measurement of Outcomes
1	Haemoglobin	gm/dl
2	Irregular Bleeding	Yes=1; No=0
3	Increased Duration of Bleeding	Yes=1; No=0
4	Foul Smelling Vaginal Discharge	Yes=1; No=0
5	Severe Lower Abdominal Discomfort	Yes=1; No=0
6	Removal	Yes=1; No=0
7	Expulsion	Yes=1; No=0
8	Patient's Satisfaction	5-point likert scale (Very Satisfied -1, Satisfied-2, Neutral-3, Dissatisfied-4, Very Dissatisfied-5) [21]

Statistical analysis

Categorical variables were presented in number and percentage (%) and continuous variables has been presented as mean and standard deviation. Normality of data has been tested by Kolmogorov-Smirnov test. In case, the normality was rejected then non parametric test was used. The analysis was done using statistical tools such as frequency, mean, standard deviation, percentage, occurrence rate, correlation coefficient, chi squire test and probit model regression. Wherever possible, a comparative analysis of findings was done for following three groups of patients –

- Lower segment cesarean section Patients
- Normal Vaginal Delivery Patients
- All Patients

For calculating correlation coefficients and regression analysis, satisfaction was measured in terms of Yes (1 for very satisfied and satisfied) and No (0 for neutral, dissatisfied and very dissatisfied). Assuming that satisfaction has potential to motivate the patients to return for followup, dropped out cases considered "not satisfied". Therefore, 0 was assigned for such cases. Further, outcome measure such as 'irregular bleeding' and 'increased duration of bleeding' were clubbed together as 'bleeding' for calculating correlation coefficients and regression analysis. A probit model regression was done to identify the causal relationship between dependent variable (satisfaction) and explanatory variables *viz*. age, education, occupation, bleeding, foul smelling vaginal discharge, severe lower abdominal discomfort, removal, and expulsion.

Statistical significance of coefficients of correlation and probit model regression were studied at 1 percent, 5 percent and 10 percent level of significance.

Result

The present study was conducted to evaluate the outcomes of PPIUCD insertion in patients following normal vaginal delivery

(NVD) and lower segment caesarian section (LSCS) on 513 patients, 213 in LSCS and 300 in NVD in the Obs. & Gynaecology Department of DDU Hospital, Delhi during August 2018- May 2019. The observations and discussions in previous sections may be summarized as follows:

- The PPIUCD was most accepted in the age group of 21-25 years.
- The PPIUCD was more accepted educated women
- The PPIUCD was more accepted in home makers
- The PPIUCD was more accepted in women with parity status P2
- The PPIUCD was mainly preferred for willingness to have no pregnancy and spacing
- The insertion of PPIUCD had no negative impact on Hb level

Irregular Bleeding: after PPIUCD insertion, the occurrence rate of irregular bleeding was 3.70 percent. It was marginally high in LSCS patients (3.76 percent) than those in NVD patients (3.67 percent).

Increased Duration of Bleeding: After PPIUCD insertion, the occurrence rate of increased duration of bleeding was 1.56 percent. It was marginally high in LSCS patients (1.88 percent) than those in NVD patients (1.33 percent).

Missed Thread: After PPIUCD insertion, the occurrence rate of missed thread was 7.21 percent. It was marginally high in LSCS patients (9.39 percent) than those in NVD patients (5.67 percent).

Foul Smelling Vaginal Discharge: After PPIUCD insertion, the occurrence rate of foul smelling vaginal discharge was 3.51 percent. It was marginally low in LSCS patients (2.35 percent) than those in NVD patients (4.33 percent).

Severe Lower Abdomen Discomfort: After PPIUCD insertion, the occurrence rate of severe lower abdomen discomfort was 4.09 percent. It was marginally low in LSCS patients (3.29 percent) than those in NVD patients (4.67 percent).

Removal: After PPIUCD insertion, the occurrence rate of removal was 1.95 percent. It was marginally low in LSCS patients (1.41 percent) than those in NVD patients (2.33 percent).

Expulsion: After PPIUCD insertion, the occurrence rate of expulsion was 2.53 percent. It was marginally low in LSCS patients (1.41 percent) than those in NVD patients (3.33 percent).

Uterine Perforation: No cases of uterine perforation were reported.

Satisfaction: After PPIUCD insertion, the satisfaction of patients was 95.16 percent. It was marginally low in LSCS patients 92.66 percent) than those in NVD patients (97.03 percent).

- The main causes of removal were bleeding, foul smelling vaginal discharge and severe lower abdominal discomfort.

The satisfaction of patients may be increased by reducing occurrence of bleeding, missed thread foul smelling vaginal discharge and severe lower abdominal pain

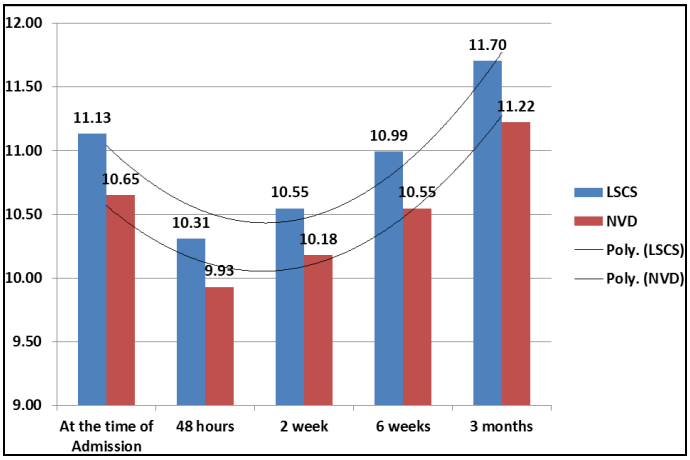

Fig 1: Trend of Hb Measurement during Follow-up

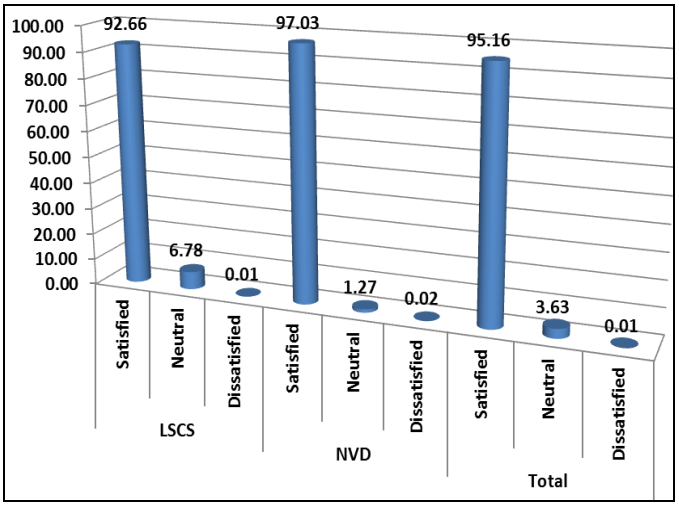

Fig 2: Satisfaction of Patients (% of Patients Followed-up After 3 Months)

Table 2: Outcome Measures and Methods of Measurements

S. No.	Outcome Measures	Measurement of Outcomes
1	Haemoglobin	gm/dl
2	Irregular Bleeding	Yes=1; No=0
3	Increased Duration of Bleeding	Yes=1; No=0
4	Foul Smelling Vaginal Discharge	Yes=1; No=0
5	Severe Lower Abdominal Discomfort	Yes=1; No=0
6	Removal	Yes=1; No=0
7	Expulsion	Yes=1; No=0
8	Patient's Satisfaction	5-point likert scale (Very Satisfied -1, Satisfied-2, Neutral-3, Dissatisfied-4, Very Dissatisfied-5) [21]

Table 3: Occurrence of Outcome Measures

Types of Complications	LSCS			NVD			Total		
	No. of Cases	% of Total Cases of Complications	% of Total Patients in the Group	No. of Cases	% of Total Cases of Complications	% of Total Patients in the Group	No. of Cases	% of Total Cases of Complications	% of Total Patients in the Group
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Irregular bleeding	8	24.2	3.76	11	20.00	3.67	19	21.59	3.70
Increase duration of bleeding	4	12.1	1.88	4	7.27	1.33	8	9.09	1.56
Missed thread	20	60.6	9.39	17	30.91	5.67	37	42.05	7.21
Foul Smelling Vaginal Discharge	5	15.2	2.35	13	23.64	4.33	18	20.45	3.51
Severe lower abdominal discomfort	7	21.2	3.29	14	25.45	4.67	21	23.86	4.09
Removal	3	9.1	1.41	7	12.73	2.33	10	11.36	1.95
Expulsion	3	9.1	1.41	10	18.18	3.33	13	14.77	2.53
Uterine perforation	0	0.0	0.00	0	0.00	0.00	0	0.00	0.00
Total	50		23.47	76		25.33	126		24.56
Total Number of Patients Reported Complications	33	100.0	15.49	55	100.00	18.33	88	100.00	17.15

***Source*:** Author's Calculation

Discussion and Conclusion

The United Nations adopted the 2030 Agenda of Sustainable Development Goals in 2015. It aims to create a better future for all by ending poverty and hunger including other goals. Being second most populous country in the world, India needs to promote use of contraceptives for reducing population growth as well as improving maternal and child health. According to the NFHS4, despite availability of wide range of contraceptives, the unmet need for family planning is 12.9% in 2015-16. Pregnancies taking place within 24 months of previous birth have higher risk of adverse outcome like premature labour, postpartum hemorrhage, low birth weight babies, fetal loss, abortion and maternal death. Therefore, there is a need to promote use of contraception.

Among many available contraceptives, PPIUCD is cost effective and a very safe means of contraception. The present study has evaluated the outcomes of PPIUCD insertion in patients following normal vaginal delivery (NVD) and lower segment caesarian section (LSCS). Based on the findings and discussions, it may be concluded that the PPIUCD is most accepted in the age group of 21-25 years. The PPIUCD is more accepted educated women. The PPIUCD is more accepted in home makers. The PPIUCD is more preferred in women with parity status P2 due to willingness to have no pregnancy and spacing. The insertion of PPIUCD has no negative impact on Hb level. After PPIUCD insertion, the occurrence rate of irregular bleeding, increased duration of bleeding, foul smelling vaginal discharge and severe lower abdominal discomfort is low and lies in the range of 3-5 percent. The occurrence rate of missed thread is around 7 percent. The rates of occurrence of removal and expulsion are around 2 and 2.5 percent respectively. Uterine perforation is a rare event. As a result of these outcomes, patients have very high satisfaction level -more than 95 percent in general. However, in general, the occurrences of medical complications are high for normal vaginal delivery in comparison to lower segment caesarian section.

The occurrence of complications has negative impact on the satisfaction level of patients after PPIUCD insertion. The main causes of removal are bleeding, foul smelling vaginal discharge and severe lower abdominal pain. The satisfaction of patients may be increased by reducing occurrence of bleeding, missed thread foul smelling vaginal discharge and severe lower abdominal pain. Proper counselling and medication after occurrence of any medical complications may reduce dissatisfaction among patients and increase the rate of success of PPIUCD insertion.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee.

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