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Original Research Article

Evaluation of Post Placental Copper T380 A Insertion in Women during Caesarean Section

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Abstract

Objective: The study was carried out to evaluate the outcome of post placental COPPER T380 A insertion in women during caesarean section. ***Methods:*** A descriptive quasi-experimental study was carried out to evaluate the outcome of post-placental COPPER T380 A insertion in women during caesarean section. They were interviewed with a specific pre-designed questionnaire ***Results:*** The patients were asked to visit 1, 6 and 12 months after the insertion of COPPER T380 A to record the complaints during the follow-up period. It was found that only 2(1.33%) complaints of expulsion after 1 month of insertion and 1 (0.66%) after 6 months, and there was no complaint of expulsion at 12 months of follow-up. In case of PID, there were 3(2%) at 1 month, 1(0.66%) at 6 months and 1(0.66%) at 12 months follow up. The most frequent complaint was pain lower abdomen which accounted for 13 (8.67%), 12 (8.00%) and 8 (12.67%) at 1. 6 and 12 months of follow-up, respectively. The next common complaint was the vaginal discharge of 9 (6.00%) at 1 month, 8 (4.67%) at 6 months and 10 (6.67%) at 12 months of follow-up. No failure of COPPER T380 A insertion during cesarean section within 12 months of follow-up (No pregnancy within 12 months). ***Conclusion:*** Clients and providers can benefit from COPPER T380 A's high motivation, low risk of infection, and fast insertion speed when used after childbirth. The use of an intrauterine device as a form of birth control immediately after delivery has been shown to be effective and safe. Furthermore, considering the large number of puerperal who do not return for contraception, the use of a safe contraceptive method, provided quickly after delivery and before discharge from the hospital, is a far-reaching reproductive health strategy.

Keywords: COPPER T380 A, UNFPA, IUC.

INTRODUCTION

Evaluation of post placental COPPER T380 A insertion in women during caesarean section: New look and effective in our country. COPPER T380 A is an intrauterine device, a coitus-independent, reversible, effective form of contraception with immediate contraceptive action [1].

It is the most widely used contraception method, with approximately 160 million users worldwide [2]. 14.3% of female contraceptive users prefer the COPPER T380 A [3]. But in our country, it is only 0.7% of COPPER T380 A users. COPPER T380 A has COPPER threads in its arms. The device and the COPPER lon create a nonspecific inflammatory environment in the endometrium and prevent implantation. Ionized COPPER has an additional local anti-inflammatory effect and prevents blastocyst implantation through enzymatic interference; COPPER initiates the release of cytotoxic cytokines. During the postpartum period, it does not affect breast-feeding [2].

Previous data indicate that COPPER T380 A are as effective as tubal sterilization [4], despite well-known complications such as increased menstrual bleeding and pain. The long-term discontinuation rate is generally low. As a contraceptive used during the postpartum period, the COPPER T380 A has a distinct advantage: It does not affect breast- feeding, as do many systemic contraceptive methods. The postpartum period may also be a convenient time during a woman's

life to have a COPPER T380 A inserted since it may be one of the few times she is in contact with medical services.

In addition, COPPER T380 A does not require regular user compliance. Couples who think conception is less likely during this period may use coital-dependent methods consistently during the postpartum period. Also, if a woman says she wants no more children but has not had time to consider sterilization carefully. A COPPER T380 A offers a reversible alternative [5]. The timing of insertion is important primarily because it influences the risk of expulsion. Expulsion can leave a woman unprotected from pregnancy without her realizing it. Ideally, postpartum insertion should occur during caesarean section after placental delivery or at about six weeks after birth when women return for a routine postpartum care visit.

Studies have shown that postpartum COPPER T380 A insertions, including those done immediately after placental delivery during cesarean section, are generally safe and effective, compared with interval insertion (Interval insertions are done after the postpartum period of six weeks following delivery). Postpartum insertion does not increase the risk of infection or bleeding. Uterine perforation or endometritis does not affect the uterus's return to its normal size [6].

If we properly counsel the pregnant women who need birth spacing & no more pregnancy post placental COPPER T380 A during cesarean section is, safe. The patient is unaware of the procedure, easy to perform, has no adverse effect on puerperium (as the patient is with antibiotic coverage), and there is no hormone in COPPER T380 A, so no adverse effect can produce on maternal health and breast-feeding. In our country post, placental COPPER T380 A during cesarean section is a new look and there is hardly any documental study. Therefore, I planned to evaluate the procedure in our set-up.

OBJECTIVES

The study was carried out to evaluate the outcome of post placental COPPER T380 A insertion in women during caesarean section.

Specific Objectives:

- To observe the long-term contraceptive efficacy.
- Any complication following insertion within the follow-up period.
- To observe the proper position of the inserted COPPER T380 A at 7 postoperative day 1-, 6- and 12 months following insertion.
- To assess the acceptance of patients after insertion.

RESEARCH METHODOLOGY

Study Design: Descriptive longitudinal study.
Study Place: Department of Gynecology and Obstetrics, Rajshahi Medical College Hospital and MCWC, Rajshahi.
Study Period: January 2015 to December-2016.
Study Population: Pregnant woman undergoing caesarean section.

Data Analysis

Data were entered into the computer using Statistical Package for Social Sciences (SPSS) software (version 16). Student t-test was used to determine the significant difference between normally distributed variables. Statistical analysis between groups was performed with Fisher's exact test or odds ratio. Parameters with p-value less than or equal to $p<0.05$ were considered to be significant.

Ethical Consideration

Before the commencement of the study, the protocol of the following study was approved by the Ethical Review Committee (ERC) of Rajshahi Medical College. The respondents' informed consent was taken by describing the objectives and purpose of the study. They were also given the freedom to withdraw themselves from the study whenever they wanted and were ensured that the information obtained from them was kept confidential.

RESULT

None of the respondents complained of missing thread, perforation, or pregnancy failure during the entire follow-up period. Only a few respondents (2 each) experienced menstrual disturbances such as irregular bleeding, menorrhagia, and dysmenorrhea. Five respondents complained of pelvic inflammatory disease (PID), with 3 at 1 month, 1 at 6 months, and 1 at 12 months. The most common complaint was pain abdomen, with 13 (8.67%), 12 (8.00%), and 8 (12.67%) at 1, 6, and 12 months of follow-up, respectively. The next most common complaint was vaginal discharge, with 9 (6.00%), 8 (4.67%), and 10 (6.67%) at 1, 6, and 12 months of follow-up, respectively. The total number of discontinuations was 3, with 2 at 6 months and 1 at 12 months. Only 2 (1.33%) patients complained of expulsion after 1 month of insertion, which decreased to 1 (0.66%) after 6 months and there were no complaints of expulsion at 12 months of follow-up.

Table 1: Age group distribution among study patients

Age group	Frequency	Percentage
16-20 years	64	42.64%
21-25 years	44	29.33%
26-30 years	20	13.33%
31-36 years	44	14.67%
Total	**150**	**100%**

Table 1 shows 16-20 years age group (42.67%) followed by 29.33 % of were 21-25 years age group. 13.33% of patients were 26-30 years and 14.67 % were between 31-36 years old.

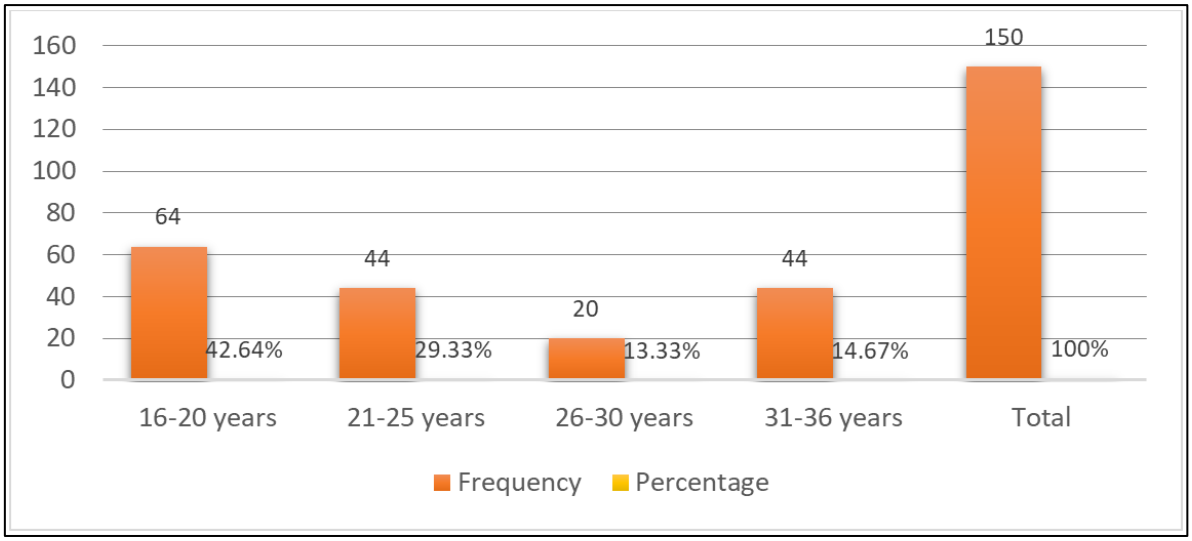

Fig. 1: Age group distribution among study

Table 2: Distribution of parity

Parity	**Frequency (n)**	**Percentage (%)**
Primi Para	91	60.67%
Para two	40	26.67%
Para three or more	19	12.67%
Total	**150**	**100%**

The table shows that out of the 150 study subjects, 60.67% (91) were primi para, 26.67% (40) had para two, and 12.67% (19) had para three or more. The total percentage sums up to 100%.

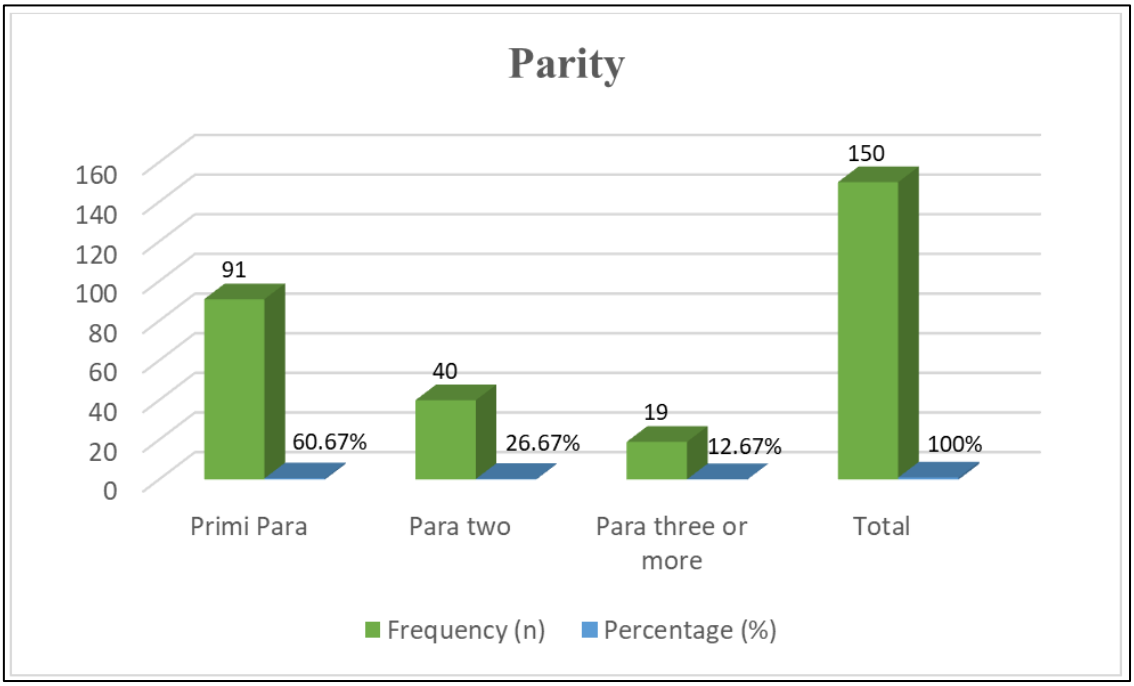

Fig. 2: Total percentage sums up to 100%

Table 3: Distribution of follow-up complaints (multiple responses) (n=150)

Complaints	Follow up			
	Within 7 days after C-section	1 month	6 month	12 month
Missing Thread	0	0	0	0
Expulsion	0	2 (1.33%)	1 (0.66%)	0
Menorrhagia	0	0	2 (1.33%)	0
Dysmenorrhea	0	0	2 (1.33%)	0
PID	0	3 (2.00%)	1 (0.66%)	1 (0.66%)
PPH	0	0	0	0
Irregular Menstrual cycle	0	0	2 (1.33%)	0
Perforation	0	0	0	0
Discontinuation	0	0	2 (1.33%)	1 (0.66%)
Pain abdomen	Pain only due to operative procedure	0	0	0
Vaginal discharge	0	9 (6.00%)	8 (5.33%)	10 (6.67%)
Failure (Pregnancy)	0	0	0	0
Number of Completion	0	18 (12.00%)	16 (10.66%)	22 (14.66%)
No complaints	150	132	134	128

The table indicates that within 7 days after cesarean section, none of the patients reported any problems except pain in the lower abdomen due to the operative procedure. After 1 month of follow-up, 132 patients had no complaints, and only 18 (12%) reported some complaints. After 6 months, 16 (10.66%) respondents reported some complaints, and after 12 months, 22 (14.66%) respondents reported some complaints. In total, 128 complaints were reported in the study, and 22 patients had no complaints at all.

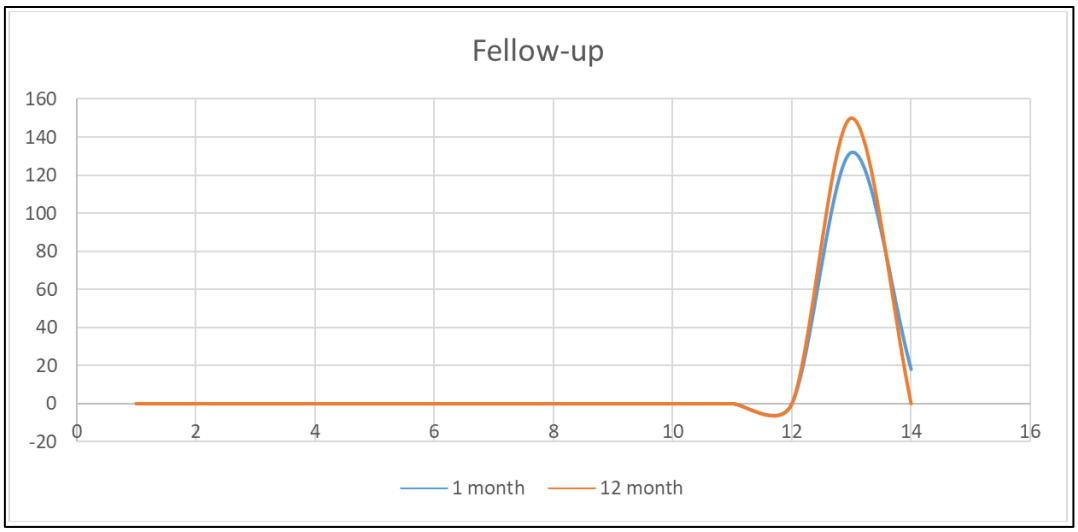

Fig. 3: Note that some complaints were not reported at certain follow-up periods.

DISCUSSION

This is a descriptive longitudinal study carried out to establish the method of a COPPER T380 A as a safe, effective and long-term contraceptive. The study population consisted of pregnant women who were under cesarean section. Most patients were 16-20 years old (42.67%), 29.33% were 21-25 years old. 13.33% of patients were 26-30 years old, and 14.67% were between 31 and 36 years old.

Arti Sharma *et al*., conducted one prospective study in the obstetrics and Gynaecology department, SGRR IM&HS, India, from September 2011 to August 2012. They found 20-25 years age group 45.13%, 26-30 years age group 43.36%- and 31-35-years age group 11.50%. Another study found that the age group ≤20 yr. of 5.33%, 21-25 years 65.33% and 26-30 years 29.33% [7]. All these are consistent with the present study.

Regarding educational status among study patients, more than fifty percent (66.67%) of patients had completed primary education, graduate and above were 13.33%. only 2.67% of patients were found illiterate. In contrast Singal *et al.*, found literate 64% and illiterate 36%. In our study 85.33% were housewives, 10.67% were service holders and only 4.00% patients were found student in our study 35.33% patients were lived in urban area, 37.33% in semi-urban and 27.30% inhabitant in rural area. Among the study subjects, 54.67% patient had received antenatal checkup regularly. On the other hand, only 15.33% of patients did not receive antenatal checkups. Antenatal

checkups and time of counselling were observed in some other studies. The checkup and counselling done during the antenatal period was 30.67% and at early labour/before LSCS was 69.33% [8].

The patients were asked to visit after 1, 6 and 12 months after the insertion of COPPER T380 A to record the follow-up complaints. It was found that only 2(1.33%) complaints of expulsion after 1 month of insertion came down to 1(0.66%) after 6 months and no complaint of expulsion at 12 months of follow-up. In most of the studies, the first follow-up visit was scheduled between 4-6 weeks, except in a study by Dahlke *et al.,* (2011), with a first visit at two weeks [9].

In our study PID developed in 3(2.00%) patients at 1 month, 1(0.66%) at 6 months and 1(0.66%) at 12 months follow up. The most frequent complaint was pain abdomen with operative procedure. The next common complaint was vaginal discharge of 9(6.00%) at 1 month, 7(4.67%) at 6 months and 10(6.67%) at 12 months of follow up. There was no failure (pregnancy) within the follow-up period.

The common adverse events, in some studies, observed during follow-up were menstrual complaints, excessive vaginal discharge and persistent pelvic pain. Post-insertion bleeding or spotting was reported at the first follow-up visit by 13.04%, while 20.07% of women had vaginal discharge [10]. According to an ICMR study on urban women, pelvic pain is a common symptom reported in 25% of users following interval COPPER T380 A insertion. Removal rate of COPPER T380 A 2(1.33%) at 6 months, 1(0.66%) at 12 months respectively. As reported, this was less than 10% at 10 weeks [9]. The commonest cause of removal was psychosocial (52.48%), followed by menstrual complaints (23.80%) and persistent pelvic pain (9.52%) [11].

The main side effects of COPPER containing COPPER T380 A are prolonged or excessive bleeding and abdominal pain. In one study, 16.66% of women had menstrual disturbances, and 13.54% had pain in the lower abdomen and back ache. There was one case of vaginal discharge and infection [12]. In a study using Cu T200B in the immediate postpartum period, 27.23% of women had heavy bleeding during menstruation. Neither of the women in their study complained of pain in the lower abdomen or abnormal vaginal discharge, nor did any of them have any sign of PID but the follow-up rate in that study was only 11.3% at 6 months [7] while in our study it was 84.95% at 6 months. In a systematic review, the outcome of postpartum insertion of COPPER T380 A at different time intervals was compared [13]. The evidence demonstrated no increase in the risk of complications among women who had a COPPER T380 A inserted during the postpartum period. Post-placental insertions during caesarean section were associated with lower expulsion rates than post-placental vaginal insertions, without any increase in other complications Welk [14].

Compared levonorgestrel intrauterine system (LNG-IUS) with COPPER T380 A insertion during caesarean section. The COPPER T380 A expulsion rate was 4.5% in each group. The safety of multi-load Cu 375 insertion at the caesarean section in terms of infection conception and perforation. In their study, the wound was infected in 10% of women, lochia was heavy in 4% of women, and 82% of women were willing to continue with COPPER T380 A, and they found it as a safe and effective method. In one study, intra-caesarean COPPER T380 A was associated with a lower rate of complications, removals and expulsions, in one study. Researchers did not encounter any serious complication, uterine perforation or misplaced COPPER T380 A in their study, which is similar with results of other study by Xu *et al.,* [15], which also showed the absence of any serious complication in their observations and found postpartum COPPER T380 A as a safe contraceptive method.

CONCLUSION

Postpartum insertion of COPPER T380 A has the advantages of high motivation, ease of insertion and convenience for both the clients and the service provider. Immediate postpartum intrauterine device insertion showed to be a useful and safe contraceptive method with low expulsion and a high continuation rate. Furthermore, the use of a safe contraceptive method, provided immediately after delivery and before discharge from the hospital, is a far-reaching reproductive health technique if we consider the high number of puerperal who do not return for contraception. Moreover, insertion at caesarean section also offers an alternative to tubal ligation in case of multiple repeat caesarean sections. Women who have had multiple caesarean sections at short intervals followed by tubal ligation at a relatively younger age may regret it later, especially in view of high perinatal and infant mortality rates in developing countries like Bangladesh. Therefore, a reversible but long-term method like COPPER T380 A in this group of women is a feasible option. Post-placental insertion of COPPER T380 A during caesarean section is safe and effective, with low expulsion and high continuation rates; it can contribute significantly to increasing the use of COPPER T380 A as a long-acting reversible contraception in our country.

RECOMMENDATION

- It is a long-term, safe, effective contraceptive method.
- It does not interfere with sexual relations. It improves marital relations because there is no fear of unwanted pregnancy.
- Thus it may be a popular contraceptive method among married couples in Bangladesh.

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