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Original Research Article

To Study the Safety and Efficacy of Post-Partum Intra-Uterine Contraceptive Device

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ABSTRACT

Background: Post-partum intra-uterine contraceptive device provides a safe and an ideal contraceptive choice that can be effectively implemented by optimizing the available hospital resources. Proactive advocacy of post-partum contraception has many fold health benefits and averts complications of unwanted pregnancies.
Methods: It is a prospective cohort study to assess the safety, efficacy, failure rate and feasibility of post-partum application of Cu-T 380 A in our service hospitals. After adequate counseling and valid consent; 150 patients were included in the study group. Amongst them; 27% as intra-caesarean, 30% as immediate post placental and 43% within 48 hours post normal delivery were provided with post-partum Copper T 380 A.
Results: During the follow-up period; 12% reported with bleeding per vaginum, 10% cited abdominal discomfort and 5% complained of discharge per vaginum. All these problems were managed conservatively without any complications. There was no history of any pregnancy in our study. Removal rate figured upto 13% including the expulsion rate of 4%. At the end of the study duration of 24 months; approximately 87% patients were found to satisfactorily continue PPIUCD.
Conclusion: Post-partum intra-uterine contraceptive device provides a safe, reversible and effective contraceptive method for our clientele.

Key Words: Post-partum, Copper T 380 A

INTRODUCTION

The time of delivery at a health-care centre offers a unique opportunity to address the need of a practical, low cost, reversible and easily compliable method of contraception. Return of fertility during the post-partum period is unpredictable and hence carries the potential fear of unwanted pregnancies. Post-partum contraception prevents unwanted pregnancies, abortions and fulfils the need of healthy birth spacing in young couples. [1] Birth spacing decreases maternal mortality and morbidity, pre-term birth and low birth weight babies. Recently, various studies have validated a positive outcome with the use of intra-uterine contraceptive device immediately after delivery. Post-partum intra-uterine contraceptive device (PPIUCD) has been used immediately after delivery of placenta (post placental) or within 48 hours after delivery and as intra-operative during caesarean delivery. An effective and reversible contraception during the post-partum period has been limited so far. Option for various contraception like condom, progesterone only pills, lactational amenorrhoea method, tubal ligation may be offered along with the option of post-partum intra-uterine device (Copper-T 380 A).

Time after delivery is the most motivated time for the decision of contraception but the turmoil of delivery can be a difficult time to decide amongst the various contraception methods. Hence, counseling should commence during the antenatal period about the feasibility of PPIUCD.

PPIUCD has been proved to be a safe, effective and an ideal contraceptive choice with manifold benefits. [2] Acceptability of this method of contraception depends upon substantial counselling by the care provider. Post-partum IUCD insertion has the advantage of assurance that the woman is not pregnant, provides a convenient health care setting and is the most motivated time for a clientele for IUCD application. Compared with the interval insertions, post-partum insertions of IUCD neither increase the risk of infection, bleeding, uterine perforations and sub-involution of uterus. [3, 4] Proper insertion techniques and adequate training of the provider has been shown to decrease the expulsion rate in post-partum IUCD. [5] Also this reversible method of contraception is as effective as that of tubal ligation. Large scale successful implementation of this family planning method in various countries like China, Mexico, Egypt and Kenya has been very encouraging for all of us. The present study has been undertaken to assess the feasibility, safety and efficacy of PPIUCD in the armed forces. Patient's safety, satisfaction and participation were given priority all throughout the implementation of this noble method of contraception in the hospital.

Xu J X et al conducted a study of the PPICUD Copper-T 380 A and they found an expulsion rate of 12.7 per 100 women using ring-forceps insertion. Discontinuation rates for medical reasons due to bleeding and pain were 1.0 per 100 women users. They found a higher expulsion and discontinuation rate in hand insertion techniques compared to the ring-forceps insertion. No uterine perforation, infection or pregnancy occurred and hence it was concluded that PPIUCD using Copper-T 380A was suitable for the Chinese women. [7]

In another Chinese study by Xu JX, Connell C, and Chi IC observed the one year life-table expulsion rates of PPIUCD inserted at caesarean section are lower than the rates for vaginal insertions after normal delivery. They also concluded that the PPIUCD has the advantage of providing the ideal time as the clients are most motivated after the delivery. [8]

Tatum HJ et al reported a randomized control study of PPIUCD given within 10 minutes of placental delivery and found an expulsion rate of 13.2 per 100 cases and continuation rate above 80 per 100 users. They concluded that PPIUCD is a safe and effective method of contraception. [9]

Nathalie Kapp and Kathryn M. Curtis concluded a search and systemic review of 15 relevant articles out of 297 related articles from Medline, Lilacs and Cochrane Collaboration databases. [10] They compared the outcomes of postpartum IUD insertion time intervals. They concluded that safety and efficacy of PPIUCD were statistically significant with no post-partum complications. Their search added that some increase in expulsion rates occurred with delayed postpartum insertion when compared to immediate insertion. Post placental placements during cesarean delivery are associated with lower expulsion rates than post placental vaginal insertions, without increasing rates of postoperative complications.

Copper-T 380 A:

This Copper-T device was developed and marketed first by the Population Council of U.S.A in 1982. They are made up of polyethylene impregnated with barium sulphate. They have 314 mm^3 copper wire on the vertical stem and two 33 mm^2 copper sleeves on each of the two transverse arms. The strings are made up of polyethylene. The approved life span of Cu-T 380 A is 10 years. Failure rate of Cu-T 380 A is less than 1 per 100 women users at the end of one year of use.

Advantages of Cu- T 380 A as PPIUCD

It is a low cost and freely available contraceptive in the hospital and requires one time motivation of the user. Hospital provides the most ideal setting and trained person are available for the insertion of Cu-T. Discomfort of Cu-T 380 A insertion as PPIUCD is less than during interval period because of the dilated cervix. It does not interfere with the sexual act and has no systemic side effects. The return of fertility is immediate following its removal. Copper bearing IUD have no effect on amount or quality of breast milk. It is more effective than other temporary contraceptive methods.

Disadvantages of Cu-T 380 A as PPIUCD

They need trained personnel for insertion and subsequent management. Complications like bleeding, pain, vaginal discharge, infection, perforation, unwanted pregnancy and ectopic pregnancy can occur. They cannot prevent transmission of HIV like barrier contraceptive (condom). Expulsion of Cu-T 380 A as PPIUCD is higher than during interval period and sometime users are not aware of expulsion leading to failure of contraception.

METHODOLOGY

This 24 months duration study was undertaken to assess the safety, efficacy and failure rate of post-partum intra-uterine contraceptive device.

Inclusion Criteria:

Study Population comprised all the antenatal patients visiting our outpatient department of the Obstetrics & Gynaecology. During the antenatal visits, counseling about various contraceptive measures has been imparted to every lady attending our antenatal out-patient department and also to the un-booked cases after in-hospital delivery. A written, informed and voluntary consent has been obtained before the insertion of the post-partum intra-uterine contraceptive device namely the Copper T-380 A as per the revised WHO eligibility criteria. [6] The insertion may be done post-placental (immediately after the delivery) or within 48 hours of delivery in the hospital (both after normal delivery) or as intra-operative during caesarean section.

Exclusion Criteria:

Patients with instrumental delivery, prolonged labour, leaking from rupture of membrane for more than 18 hours, post-partum haemorrhage, uterine anomalies, HIV infection, suspected genital neoplasia, heart disease and gestational diabetes mellitus have been excluded from the study population. Patients not meeting the revised WHO criteria have also been excluded.

MATERIALS & METHODS

This study was a prospective and a descriptive study. Sample size of 150 patients had been included in the study. Statistical analysis of the collected data had been performed using the standard statistical methods.

Counseling and option of PPIUCD was discussed during any opportunistic contact with the patient during the antenatal visit, early labour and after delivery. After obtaining the verbal and written consent from 150 patients; post-partum intra-uterine contraceptive device namely Copper T 380 A had been applied immediately after the delivery (post-placental) or within 48 hours of delivery or during caesarean section. The principal worker of this project undertook the PPIUCD training workshop conducted by the Ministry of Health and Family welfare.

Post delivery uterotonics (Injection Methergin 0.25 mg slow intravenous and/or Injection Oxytocin 10 units in 500 ml of Ringer's Lactate over 2 hours) had been used. We did not use injection Carboprost or tablet Misoprostol in any patient. After excluding the history of allergy to any drugs, inhalants and ingestants; antibiotics had been used. Caesarean section patients received prophylactic injectable Cefotaxime 1 gm intravenous - 3 doses and 12 hours apart. Normal delivery patients received capsule Amoxicillin 500 mg three times per day for 3 days. Most of the patients were

discharged within 5 days in caesarean delivery and within a day in case of normal delivery. All of them were told about the method of detecting expulsions and instructed to return for reinsertion or another method of contraception. Long strings of Copper-T coming out of vagina were advised to trim accordingly.

All of them followed exclusive breast feeding and adhered to the post-partum follow-up at 6 weeks, 6 months, 9 months and at 12 months following delivery in concurrence with the immunization of the newborn baby. Clinical examination and check ultrasonography had been done whenever required. During the follow-up period for one year (total duration of the study was 24 months); contraceptive failure rate, expulsion rate and complications like bleeding per vaginum, infection, perforation and the acceptance rate among our clientele had been evaluated.

RESULTS

The observations were described in terms of percentages with respect to clinical outcomes. Descriptive statistics was calculated, test of proportion (z test) and Chi-square test was assessed to measure the strength of association between variables; *P* <0.05 was considered as statistically significant at 95% confidence interval.

Table No 1: Details of distribution of PPIUCD

Intra-cesarean PPIUCD	40 (26.7%)
Immediate post placental PPIUCD	45 (30.0%)
PPIUCD within < 48 hours	65 (43.3%)

Table No 2: Profile of PPIUCD patients

Table No 2: Follow-up in PPIUCD patients		
Category	Sub-Division	Number of Patients
Age (Years)	<20	07 (4.7%)
	20-30	98 (65.3%)
	>30	45 (30.0)
Education	Secondary	74 (49.3%)
	Graduation	65 (43.3%)
	Post Graduation	11 (7.3%)
Occupation, p<0.0001	Housewife	108 (72.0%)
	Employed	42 (28.0%)
Spouse category	PBOR	135 (90.0%)
	JCO	12 (8.0%)
	OFFICER	3 (2.0%)
Parity	P1L1	103 (68.6%)
	P2L2	42 (28%)
	P3L3	59 (3.3%)

Table No 3: Reason of PPIUCD removal

Table No 3: Reason of PPIUCD removal				
Reason	Intra cesarean PPIUCD (40 OR 26.6%)	Immediate post placental PPIUCD (45 OR 30%)	PPIUCD < 48 HOURS (65 OR 43.3%)	Total (150 OR 100%)
Expulsion	1(2.5%)	2(4.4%)	3(4.6 %)	6 (4%)
Bleeding	0	2(4.4%)	3(4.6%)	5(3.3%)
Pelvic pain	1(2.5%)	1(2.2%)	2(3%)	4(2.6%)
Pelvic infection	0	1(2.2%)	2(3%)	3(2%)
Not cohabiting with spouse	0	0	2(3%)	2(1.3%)
Total Removal	2	6	12	20(13.3%)
Not Removed	38	39	53	130

DISCUSSION

There were about 55 eligible patients (satisfied inclusion criteria) but refused to give consent even after adequate counseling. They opted for other methods of contraception. Thus our study group comprised 150 motivated patients. It also reflects the need of more mass media awareness campaign for the success of family welfare programme. Out of 150 patients; 45(30%) patients were given IUCD soon after the delivery of the placenta and 65 (43.3%) patients were given IUCD within 48 hours of delivery. 40 (26.7%) patients were given IUCD during the caesarean section operation.

Approximately, 65% of the study population was between 20-30 years and all the study population completed primary level of education. 68% of our patients were P1L1, 28% were P2L2 and about 3% were P3L3 lady. Thus the study could actually target the ideal seekers (young and P1L1 patients).

During the follow-up, 18 (12%) patients reported with bleeding per vaginum and they were treated with Tab Tranexamic acid 1000 mg thrice daily. Exclusive breast feeding was encouraged as it has the potential of reducing the Cu-T induced bleeding. Expulsion was noticed in 6 (4%) patients and Cu-T strings were not visible per vaginum in 12 (8%) patients (used ultrasonography to confirm expulsion or clinically not visible strings per vaginum). Use of long Kelly's placental forceps for insertion ensures high fundal placement of Cu-T. This can be attributable to less expulsion rate in our study group compared to other reported studies. It is noticed that coiling of Cu-T threads was more in PPIUCD.

Abdominal pain was reported by 15 (10%) patients and they were treated orally with Mefenamic acid or/and Drotaverine. Altogether 8 (5.3%) patients reported with persistent white discharge per vaginum and they were treated with syndromic approach by giving vaginal pessary (Clotrimazole and Clindamycin) or/and oral antibiotics (Ofloxacin + Tinidazole). Vaginal culture and sensitivity was not done before starting the treatment. Infection due to lochial discharge was anticipated but post delivery use of antibiotics for every patient probably caused less infection in the patients.

All patients were reassured about the temporary nature of such initial problems. All such minor ailments were satisfactorily managed conservatively without any untoward complications. The findings are in concurrence with other existing studies. It is to be noted that none of the complaints were statistically significant. However, as much as 93 (62%) patients were asymptomatic or without any problems during the follow-up visits. This also gives a valuable insight that a standard follow-up management of complaints should be available in the hospital. Follow-up is an important component for the success of the PPIUCD programme.

Finally, in 20 (13.3%) patients, PPIUCD could not be continued due to persistent problems in spite of above treatment. It was expected that uterine contraction by use of utero-tonics (pitocin and methergine) and breast feeding would lead to more expulsion rate; but we found that the expulsion rate of about 4 % and comparable to other studies. There were 2 patients among these 20 patients who expressed unwillingness to continue the Copper-T as they were not regularly cohabiting with their husbands (husbands were posted out to field locations). Thus the continuation rate in the study was about 86.7 % at 12 months compared to 82% as reported in other studies. [11,12]

There was no reported pregnancy in 130 during the follow-up of 12 months. Thus there was zero failure rate at 12 months. The failure rate reported in the study ranged from 0.003% to 0.7%. [13,14] There was no case of perforation in any patient which was also highlighted in studies by Xu et al and Kapp et al (a thickened post partum uterus lessens the chance of perforation).There has been no case of reinsertion of Cu-T in our study.

There was inherent weakness in the study due to small sample size and absence of long term follow-up. Multi centric studies can further substantiate the results of the study.

CONCLUSION

Hospitals are ideal settings for this low cost, easily available, safe, effective and reversible contraceptive method. By sustained advocacy of the PPIUCD in the hospital; the acceptance rate among the clientele increases. Thus, PPIUCD offers an unique opportunity for all the hospital delivery patients and is a major policy shift in the concept of contraception and population control within the available resources. Thus there is more benefit to our clientele without any increase in the cost or extra burden to our existing infrastructure.

However, counseling and training of the care provider (doctors, nurses and health staffs) of a hospital form integral part in the success of this noble programme. Awareness about this post partum contraceptive programme through mass media will help in convincing and establishing the core benefits to all our prospective clientele. The impact and feasibility of this reversible method of contraception among our clientele were excellent in our clinical setup as shown by our study.

Conflict of Interest

The authors have none to declare.

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