www.jmscr.igmpublication.org
Impact Factor (SJIF): 6.379
Index Copernicus Value: 71.58
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossrefDOI: https://dx.doi.org/10.18535/jmscr/v6i7.173

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Original Article

Evaluation of Safety, Efficacy and Continuation Rates of Postpartum Intrauterine Contraceptive Devices (PPIUCD) (Cu-T 380 A)

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Abstract
Introduction: *Copper intrauterine devices (IUDs) are the most commonly used type of IUD. This study is aimed at assessing the safety, efficacy and continuation rates of postpartum Cu T380A in women delivering at our center.*
Methodology: *A longitudinal study of participants recruited from the antenatal clinic willing for postpartum insertion of Cu T380A was done. Participants were counselled about Cu T380A during the antenatal period. Baseline demographic information, medical and menstrual history and adverse effects were noted. Expulsions and continuation rates were assessed.*
Results: *During the study period 89 women were willing for IUCD insertion and regular follow up. Most common age group was 26 to 30 years and 73% were primipara. 53% of all participants had an immediate postpartum insertion of IUCD. Insertion of IUCD was easy in 87% of the cases and two thirds had a pain perception of 0 to 5 on the VAS. During the follow up period pf one year a total of 12 expulsions were observed. Additionally, five cases had their IUCD removed. So the total continuation rate in our patient population was 81%. Unplanned pregnancy was reported in one cases (1.1%). Five cases reported abnormal vaginal bleeding, three reported pain in abdomen and two cases reported the thread to be missing. No cases of pelvic inflammatory disease (PID) were reported in our patient population during the study period.*
Conclusions: *The benefits of Cu T380A should become better recognized with time. As part of routine antenatal services, counselling for post-partum family planning should be done for all women.*
Keywords: *Continuation rate, Expulsion, Intrauterine contraceptive devices, Post-placental.*

Introduction

Intrauterine devices (IUDs) are the most commonly used reversible contraception worldwide with 160 million women using it.[1] Copper IUDs are the most commonly used type of IUD and Copper T380A IUD (CuT380A) has been found to be the most effective among them.[2] As experience with the CuT380A has grown

across the globe, and vast amounts of scientific evidence has been produced, it has become a first line contraceptive option for women seeking intermediate to long term contraception. It is an excellent choice for women desiring to delay pregnancy with a non-hormonal contraceptives. IUD has been shown to be highly effective, private, long-acting, and rapidly reversible, with few side effects.[3] It is safe for most women, including teens and nulliparous women, though there are few contraindications to its use.[4]

Furthermore, it does not interfere with the spontaneity of sex, offers several non-contraceptive health benefits, has high user acceptability and continuation, and can be used by women who want or need to avoid exogenous estrogen. Moreover, it represents an effective alternative to surgical sterilization, which many women choose in order to avoid the side effects and frequent attention required by most reversible methods of contraception. Despite these attractive features, less than 10% of the women use any type of IUD,[5] and only a minority of those women utilizes the copper IUD. In part, this may reflect lack of professional enthusiasm for the method. A survey of clinicians reported that 40% did not offer IUDs to any patient seeking contraception.[6] This study is aimed at assessing the safety, efficacy and continuation rates of postpartum Cu T380A in women delivering at our center.

Methodology

Study design and sampling

This was a longitudinal study in which participants were recruited from the antenatal clinic. All antenatal mothers were counselled about the contraceptive options during their visits after 30 weeks of gestation. Those willing for postpartum insertion of Cu T380A were included in the study. Approval of the institutional ethics committee was taken and an informed written consent was taken from all participants. All antenatal mothers who were admitted for delivery in our indoor ward and were counselled antenatally for postpartum insertion of Cu T380A were included in the study. We excluded mothers from the study who had postpartum haemorrhage, active sexually transmitted disease, chorioamnionitis, history of fever during labor or delivery, purpeural sepsis or those who did not consent for the study. Refusal of consent to participate in the study did not affect the treatment management plan in any manner.

Method of IUCD insertion and follow up

Bimanual examination was performed to evaluate the cervix and the uterus after the delivery of the placenta and ensuring an empty cavity with contracted uterus. The copper T model Cu T 380 A was inserted with all aseptic precautions. Post-placental insertion was done either instrumentally (using forceps) or manually. Instrumental insertion of IUCD was done with long placental forceps. The forceps was inserted up to the fundus of the uterus and IUCD is released, allowing the woman to rest for few minutes. Manual insertion of IUCD was done with hand and inserted up to fundus and released. Intracesarean insertion was done after placenta was removed, IUCD was introduced through uterine incision and placed at the fundus. The strings of IUCD were left lower down in uterine cavity. Uterus was sutured taking care that the strings of IUCD do not get included in the same sutures. All study participants were advised to come for follow up at 6 weeks, 3 months and 6 months and one year. A follow up card containing information regarding type, insertion date, date of expiry of IUCD and date of follow up was given to all participants. During follow up, data was collected regarding complaints, willingness to continue and request for removal of IUCD. Efficacy of Cu T380A was assessed from expulsion rate and rate of unplanned pregnancy. From expulsion and removal rates, continuation rates were assessed. Safety profile of Cu T380A was assessed by observing adverse effects in the participants during the follow up period.

Results

During the study period 89 women were willing for IUCD insertion and regular follow up. Most common age group was 26 to 30 years (30%), followed by 21 to 25 years. More than half of all women were literate and approximately three fourths were unemployed (Table 1). Only 5% of all study participants belonged to upper socio-economic class and 35% to middle class according to the modified Kuppuswamy socioeconomic classification. Approximately three fourths of all participants were primipara and rest were multipara. Majority of the participants delivered vaginally (69%), while 31% underwent lower section caesarean surgery. Approximately half of all participants had an immediate postpartum insertion of IUCD (53%). All participants who underwent caesarean had IUCD inserted intra-operatively and fourteen participants had a delayed insertion (within 48 hours) of IUCD. Insertion of IUCD was easy in 87% of the cases (Table 2) and two thirds had a pain perception of 0 to 5 on the VAS. During the follow up period pf one year a total of 12 expulsions were observed. Additionally, five cases had their IUCD removed. So the total continuation rate in our patient population was 81%. Unplanned pregnancy was reported in one cases (1.1%). Five cases reported abnormal vaginal bleeding, three reported pain in abdomen and two cases reported the thread to be missing (Table 3). No cases of pelvic inflammatory disease (PID) were reported in our patient population during the study period.

Table 1. Baseline characteristics of the study subjects included in the study

Variables	N
Age structure (in years)	
≤ 20	12 (13%)
21 to 25	24 (27%)
26 to 30	27 (30%)
31 to 35	19 (21%)
≥ 35	7 (9%)
Literacy	
Literate	51 (57%)
Illiterate	38 (43%)
Occupation	
Employed	21 (24%)
Unemployed	68 (76%)
Socio-economic scale	
Low	53 (60%)
Middle	31 (35%)
Upper	5 (5%)
History	
Primipara	65 (73%)
Multipara	24 (27%)
Mode of delivery	
Vaginal	61 (69%)
Cesarean	28 (31%)
Time of PPIUCD insertion	
Immediate postpartum	47 (53%)
Intra-cesarean	28 (31%)
Delayed postpartum (within 48 hours)	14 (26%)

Table 2 Information regarding postpartum intra-uterine contraceptive device insertion in our patient population

Variable	N
Ease of insertion of PPIUCD	
Easy	78 (87%)
Difficult	11 (13%)
Pain perception on VAS	
0 to 5	59 (66%)
6 to 10	30 (34%)
Expulsion rate	
At 1 month	4 (4.4%)
At 3 months	5 (5.6%)
At 6 months	2 (2.2%)
At 12 months	1 (1.1%)
Total	12 (13%)
Removal of IUCD	5 (5.6%)
Total discontinuation	17 (19%)
Total continuation	72 (81%)
Unplanned pregnancy	1 (1.1%)

Table 3 Safety profile of Cu-T380A in our patient population

Adverse effect	N
Vaginal bleeding	5 (5.6%)
Pain abdomen	3 (3.3%)
Pelvic inflammatory disease	0 (0)
Missing thread	2 (2.2%)
Expulsion	12 (13%)

Discussion

A Cochrane Systemic Review concluded that the first year failure rate of the Cu T380A ranged from 0% to 1.0% and the cumulative pregnancy rate by 10 years was 2.1%.[2] Similar estimates were obtained by another review in which CuT380A was found to have a 5 year failure rate of 0.3%–0.5%.[7] The effectiveness has also been demonstrated in longer follow-up studies.[8] Success of IUDs is independent of the user's

behaviour, and there is practically no way to compromise its efficacy. Furthermore, the efficacy of the CuT380A has been demonstrated not to be affected by any drug interactions.[9] This has an important implication as pain and bleeding after IUD insertion are usually controlled with pharmacological agents. Additionally, copper containing IUDs increase serum copper levels, but no advese clinical effects have been shown due to that.[10] IUDs containing smaller amounts of copper have measurably higher failure rates than the CuT380A.[11] Though, higher copper concentrations may result in early spotting and bleeding, they have not demonstrated long term carcinogenic impacts on the endometrium.[12]

In the present study, 13% expulsion rate was observed over one year. Similar rates have been reported by previously published studies.[13] Risk factors for expulsion include nulliparity, menorrhagia, severe dysmenorrhea, prior expulsion and age less than 20 years.[13] A multi-centric trial in which women were followed up for 7 years found that the cumulative discontinuation rate due to expulsion was 1.8 per 100 women-years of use.[14] Additionally, expulsion rates are highest when IUDs are placed during menses and delaying IUD insertion until day 6 of the cycle can reduce expulsions in the first 3 months by 30%–50%.[15] Rare complications can occur with IUD placement. Perforation occurs in about 1 in 1000 cases.[16] Risk factors include inexperienced clinician, an immobile uterus, a retroverted uterus, and the presence of a myometrial defect. Ultrasound is used to determine the location of a perforated IUD and once identified treating the woman with antibiotics as for pelvic inflammatory disease is recommended. [17]

None of the patients in the present study had pelvic inflammatory disease or any other infection due to IUD insertion. PID is most strongly associated with the insertion process and with the user's risk of acquiring a sexually transmitted disease. [18] The risk of infection is greatest in the first 20 days after insertion (range 1 to 10 per 1000 women undergoing insertion and is rare thereafter (1.4 per 1000 women undergoing insertion), and does not increase with prolonged IUD use. [19] Furthermore, menstrual blood loss may increase by 35%–80% with use of the CuT380, though this rarely results in anemia. [20] In the first year of use, heavy menses and dysmenorrhea are the most common reasons for CuT380A removal and up to 15% of users discontinue use due to those side effects. Though, non-steroidal anti-inflammatory agents have shown to be effective for controlling bleeding, their prophylactic use is not sup- ported by evidence. Excessive bleeding is among the most common reason for IUD discontinuation and Stanback and Grimes found that women who complained of intermenstrual bleeding at their first visit were almost three times more likely to request early removal and those with excessive menstrual flow were 3.5 times more likely to discontinue use.[21] The authors based on these findings suggested that these women should receive more intensive counselling and treatment with non-steroidal anti-inflammatory drugs to reduce the risk of early discontinuation.

Conclusion

The benefits of CuT380A should become better recognized with time. As part of routine antenatal services, counselling for post-partum family planning should be done for all women. Clinicians should be trained in counselling, insertion of IUDs and be able to detect expulsions in a timely manner. New copper IUDs coated with NSAIDs or related agents may reduce early spotting or abnormal bleeding. Modified versions of copper IUD that rest in the cervix rather than in the endometrial cavity is another innovation worth investigating. Future research should explore the reasons for expulsion and discontinuation in general and find ways so as to reduce it.

Study Funding: None
Conflict of interest: None

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