

# Long Term Evaluation of Post-Partum Intrauterine Device (PPIUD) In Terms of Safety and Efficacy

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## Abstract

**Objectives:** The purpose of this study was to evaluate the long term safety and efficacy of postpartum IUCD at a tertiary level hospital.

**Materials & Methods:** This cross sectional study was carried out in Shaheed Suhrawardy Medical College & Hospital (ShSMCH) from March 2019 to December 2019. International Federation of Gynecology and Obstetrics (FIGO) in collaboration with Obstetrical and Gynecological Society of Bangladesh (OGSB) have been launched a project in Bangladesh to foster family planning activities by postpartum IUCD insertion since July 2015 in this hospital. All patients who were inserted PPIUD following delivery under FIGO- PPIUD project since 1<sup>st</sup> January 2017 to 31<sup>st</sup> December, 2017 were included in this study. Phone number of those PPIUD inserted women were collected from the register book. Clients were evaluated after 2 years of insertion. The outcome measures analyzed were safety measures – menstrual irregularities, vaginal discharge, pelvic infection, perforation and efficacy measures – continuation, removal, expulsion and failure rate.

**Result:** Total number of patients delivered at ShSMCH in 2017 were 2,593. Out of them deliveries, 329 (12.70%) were introduced PPIUD. Among 329 PPIUD users, after about 2 years, 175 (53.20%) could be traced for follow up and rests couldn't be reached by repeated attempts on phone call. After telephone call they attended our hospital and thorough interview and examination was done. All the informations were collected in a predesigned data collection sheet. Among 175 study population, 25 (14.28%) IUCD introduction were following vaginal delivery and 150 (85.71%) were during cesarean section operation. Those who are continuing PPIUD, 100 (82.0%) had no complications and few, 22 (18.0%) had some minor complaints for which they received treatment. The most common adverse event was the menstrual irregularities. There was no case of perforation.

By the end of 2 years, out of 175 PPIUD inserted clients, missing string was found in 85 (69.7%) cases, continuation rate of PPIUD was 122 (69.7 %), spontaneous expulsion was 10 (5.7%), removal was 43 (24.6%) and failure rate was 3 (1.7%).

**Conclusion:** PPIUCD is a safe, effective and convenient method of contraception and should be encouraged after both vaginal and Cesarean deliveries.

**Keywords:** Postpartum Contraception, Post-Partum Intrauterine Device, PPIUD

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**Introduction:**

Optimal birth spacing and birth control are issues that caught the attention of global reproductive health services. Spacing birth-to-pregnancy intervals by at least 2 years and birth-to-birth intervals by at least 3 years could prevent more than 30% of maternal and 10% of infant mortality<sup>1</sup>. Postpartum period is a highly vulnerable period for unintended pregnancy as there are limited contraceptive options for breastfeeding mothers. In postpartum period, ovulation is highly unpredictable and, it can occur as early as 45 days after delivery in non-breast feeding and partially breast feeding women and couples often underestimate the likelihood of pregnancy.

Postpartum family planning (PPFP) is defined as the prevention of unintended pregnancy and closely spaced pregnancies through the first 12 months following childbirth<sup>2</sup>. According to an analysis of Demographic and Health Surveys data from 27 countries, 95% of 0–12 months postpartum women who want to avoid a pregnancy in the next 24 months; 70% of them are not using contraception. Most women are unclear about contraceptive usage in postpartum period. This results in unplanned and undesired pregnancies, which in turn increases induced abortion rates and consequently maternal morbidity and mortality<sup>3</sup>.

Globally, intrauterine devices (IUDs) are cited as the second most widely used contraceptive method according to a WHO study<sup>4</sup>. The IUD recommended by WHO is CuT380A which got USFDA approval in 1984.

Post-partum IUCD insertion refers to IUCD insertion within 48 hours of delivery. IUCD insertion within 10 minutes of placental expulsion is known as post placental IUCD insertion. The concept of post-partum IUCD insertion arose in 1970's<sup>1</sup> but it was not commonly used in general practice before 21st century because the previous studies showed very high rates of expulsion<sup>5</sup>.

Various studies have proved safety of IUCD when inserted post-placentally. It has good acceptability because of the safety and being reversible<sup>6</sup>. WHO has approved IUCD use even in breast-feeding women since it has no effect on lactation, not even in terms of any increased copper in milk.

Recognizing the potential impact of improved family planning programming on maternal and child health,

the Government of Bangladesh has committed to expanding access to family planning as part of achieving Millennium Development Goals 4 and 5 related to reduction of child and maternal mortality. With increased number of women electing to give birth in health institutions, the Government of Bangladesh decided to strengthen PPFP and to introduce PPIUCD services. Previously, concerns about the PPIUCD focused on high expulsion rates. Studies published in the nineties and early 2000 reported rates of about 9-13%<sup>7-10</sup>. However, lower expulsion rates have been reported more recently with improvements in insertion technique<sup>11, 12</sup>. PPIUCDs are still emerging as a relatively new contraception choice in Bangladesh.

A project on PPIUD in collaboration with International Federation of Gynaecology and Obstetrics (FIGO) and Obstetrical and Gynecological Society of Bangladesh (OGSB) has been launched in Bangladesh to foster family planning activities by postpartum IUCD insertion. ShSMCH is one of the centre among six tertiary level hospitals where the project activity is going on since July, 2015. According to FIGO-PPIUD project the follow-up schedule is up to 6 weeks, but long term follow-up is not evaluated. Follow-up schedule on problems and complications with PPIUCD insertions are available from International sources, but it is scarce in Bangladesh. It is important to generate evidences on the outcome in respect to safety and efficacy after introduction of PPIUCD program.

Though the device has lot of advantages like reversible, long acting, low-cost; the device has not attained much popularity due to the myths and misconceptions amongst the general public and health care personnel. Besides, due to the fear of perforation and infection and also, lack of proper training, most health care providers are reluctant in performing interval IUCD insertion in women with previous caesarean delivery<sup>13</sup>.

The purpose of the study is to evaluate the long term safety and efficacy of postpartum IUCD at a tertiary level hospital.

**Methodology:**

This study was a cross sectional study carried out in the Department of Obstetrics & Gynecology of Shaheed Suhrawardy Medical College & Hospital from March 2019 to December 2019. All patients who

were inserted PPIUD following delivery under FIGO-PPIUD project since 1<sup>st</sup> January 2017 to 31<sup>st</sup> December, 2017 were initially included in this study. Phone number of those PPIUD inserted women were collected from the register book. Among them, those who received the phone and were willing to participate in this study were finally included in the study. Clients were evaluated after 2 years of their PPIUD insertion. Clients who had completed 2 years after insertion were asked to come for follow-up. If any woman could not come physically in hospital for follow up, data were collected over phone. During evaluation, a detailed history regarding irregular or excessive menstrual bleeding, pelvic pain, foul smelling vaginal discharge or any other complaint were taken along with general physical & pelvic examinations. If the thread of IUCD was not visible during pelvic examination, then Ultra sonogram (USG) was done to ascertain the location of Cu-T. USG was done in the department of Obstetrics & Gynaecology free of cost. Along with evaluation if any patient had any complain, were managed at that time.

Data were collected in a predesigned data collection sheet, data was validated, entered into the computer & statistical analysis using SPSS V.20.

The outcome measures analyzed were safety measures like menstrual irregularities, vaginal discharge, pelvic infection and perforation. Efficacy measures were continuation, removal, expulsion and failure rate.

### Result:

Total number of patients delivered at ShSMCH in 2017 were 2,593, among them 823 delivered vaginally and 1770 (68.20%) underwent caesarean section. Out of these deliveries, 329 (12.70%) clients were introduced PPIUD. Among 329 PPIUD users, after about 2 years, 175 (53.20%) could be traced for follow up and rests couldn't be reached by repeated attempts at phone call. So, our sample size was 175.

Socio demographic profile of 175 clients are shown in Table – I. Maximum number 71 (40.57%) of our clients were of age group 21 – 25 years, 60 (34.3%) completed primary education, 153 (87.4%) were housewife, 91 (52%) clients belonged to 10,000-20,000 Tk. per month income category, 124 (70.8%) came from urban area and 168 (96%) were Muslim. Majority of the clients i.e. 92 (52.6%) had two living

children after present child birth (Table II). Among total PPIUD inserted women 58 (33.14%) were booked and counselled during antenatal period, other 117 (66.8%) were not booked case and counselled after admission during delivery (Table II).

**Table-I**  
*Socio demographic profile of acceptors (n=175)*

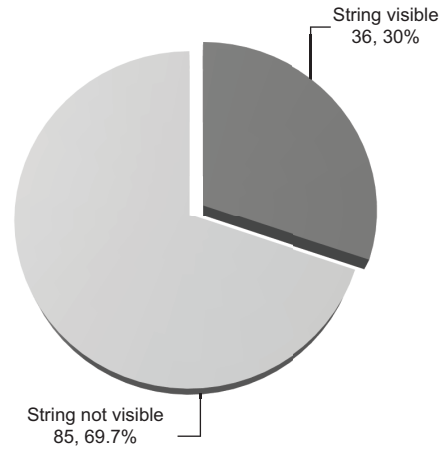
Parameters	Number	Percentage
Age Group (yrs.)		
< 20	9	5.14
21 – 25	71	40.57
26 – 30	58	33.14
31 – 35	28	16.00
> 35	9	5.14
Literacy		
No formal education	15	8.57
Primary	60	34.28
Secondary	26	14.85
SSC	31	17.71
HSC	16	9.14
Graduate	14	8.0
Masters	13	7.4
Occupations		
Service	19	10.8
Housewife	153	87.41
Day labor	3	1.7
Monthly Income (Tk.)		
Low income group < 10,000	30	17.14
Middle Income group – 10,000-20,000	91	52
High Income group - > 20,000	54	30.85
Residence		
Rural	51	29.14
Urban	124	70.86
Religion		
Muslim	168	96
Hindu	7	4

**Table -II**  
*Obstetric Profile of acceptors (n=175)*

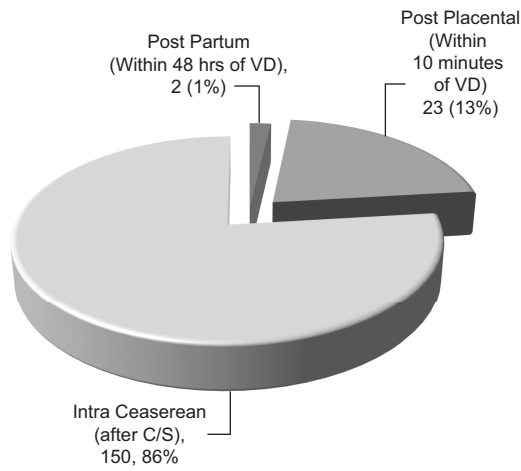
Parameters	Number	Percentage
Number of Children		
One	50	28.57
Two	92	52.57
Three	24	13.71
Four or more	9	5.14
Time of Counseling		
Antenatal period	58	33.14
Early labour / before C/S	117	66.85

Among 175 studied population 150 (85.7%) were intrauterine PPIUD insertion, 23 (13.1%) were post placental within 10 minutes of vaginal delivery and & 2 (1.1%) were post-partum within 48 hrs of vaginal delivery (Fig-1).

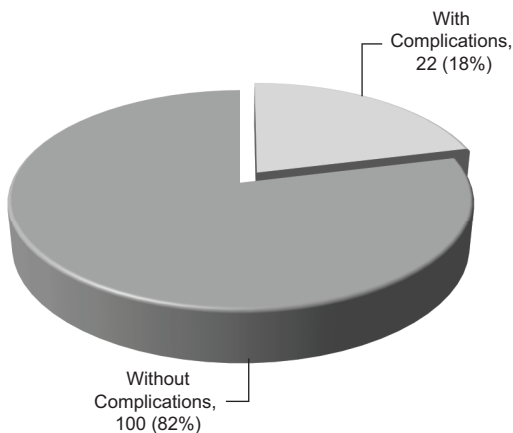
Among 175 clients, 122 clients were continuing PPIUD. Out of 122 clients who were continuing PPIUD, 100 (82.0%) had no complications and 22 (18.0%) had some minor complaints for which they received treatment (Fig-2). The most common adverse event, was the menstrual irregularities (Table III). There was no case of perforation (Table III). Here more than one complaint was present in many cases. Missing string was found in 85 (69.7%) cases, but by USG it was proved that Cu-T was in Situ (Fig-3).



**Fig-3: String visibility**



**Fig-1: Route and Time of Insertion**



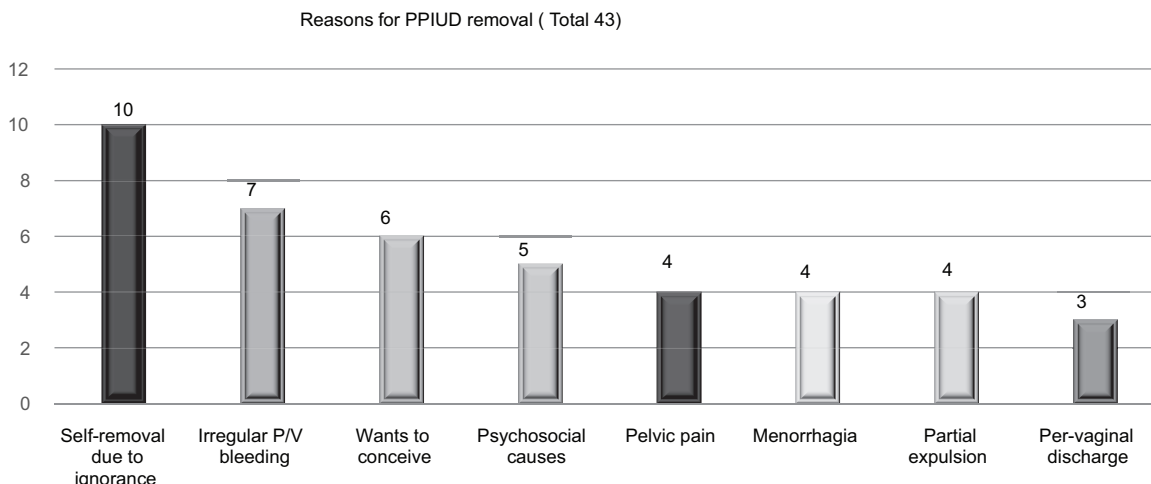
**Fig-2: Complications of PPIUD**

**Table-III**  
*Adverse events (n = 22)*

Parameters	Number	Percentage
<b>Adverse events</b>		
Irregular pervaginal bleeding	9	7.4
Menorrhagia	6	5.0
pervaginal discharge	8	6.5
Pelvic pain	5	4.1
Dyspareunia	3	2.4
Husband complain during coitus	2	1.6
Dysmenorrhea	2	1.6
Perforation	0	0

**Table-IV**  
*Main outcome measures (n = 175)*

Parameters	Number	Percentage
Continuation	122	69.7
Removal	43	24.6
Expulsion	10	5.7
Failure	3	1.7

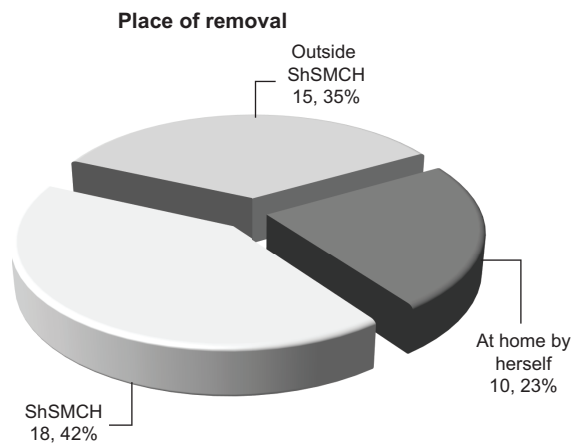


**Fig-4: Reasons for removal**

In this study, at the end of 2 years of insertion of PPIUD, out of 175 clients 122(69.7%) clients were continuing PPIUD, 43(24.6%) clients removed this contraceptive method and 10(5.7%) clients had spontaneous expulsion (Table IV). Among those 10 spontaneous expulsion cases 3 clients became pregnant who were unaware of expulsion and who didn't come for any follow up. So, the overall failure rate was 1.7% (Table IV).

Among total 43 removal, 10 (23.2%) clients removed PPIUD due to self ignorance by pulling the thread, 7(16.3%) clients removed it due to irregular per vaginal bleeding, 6(14%) clients removed due to seeking next pregnancy, 5(11.6%) due to psychosocial causes, 4(9.3%) due to pelvic pain, 4(9.3%) due to menorrhagia, 4(9.3%) due to partial expulsion and 3(7%) due to pervaginal discharge (Fig-4).

were removed at this hospital, 15(35%) were removed at other health facilities and 10(23%) were removed at home by themselves (Fig-5).



**Fig-5: Place of removal**

**Table-V**

*Time interval between insertion and removal of PPIUD (n = 43)*

Parameters	Number	Percentage
Time of interval		
Within 6 weeks	4	9.33
6 weeks - 3 Months	7	16.27
3 Months - 6 Months	11	25.58
6 Months - 1 year	5	11.62
> 1 year	16	37.20

Most of the PPIUD removal 16(37.2%) were done after 1 year of insertion (Table V). Eighteen (42%)

**Table -VI:**

*Time of spontaneous expulsion (n = 10)*

Parameters	Number	Percentage
Spontaneous expulsion		
Within 6 weeks	1	10
6 weeks – 3 months	1	10
3 months – 6 months	2	20
6 months – 1 year	1	10
Un noticed	5	50

Time of expulsion of PPIUD was shown in (Table VI) which shows 5 spontaneous expulsions occurred within 1 year of insertion but 5(50%) were unnoticed by the patient.

## Discussion

Bangladesh has made remarkable and rapid progress in many family planning and other health indicators<sup>14</sup>. According to BDHS 2014, Bangladesh has achieved substantial success to increase in Contraceptive Prevalence Rate (CPR) to 62% and reduction of Total Fertility Rate (TFR) to 2.2 per woman in last 10 years. Despite this progress, unmet need for family planning is still 12% among currently married women and all method discontinuation rate is 30% within 12 month of starting<sup>15</sup>.

Bangladesh is committed to achieve the Sustainable Development Goal. The recently approved 4th Health Sector Programme, 2017-2021, of the health ministry, will put the country on track to attain the targets by 2030<sup>16</sup>.

The family planning 2020 commitment (revitalized in July 2017)<sup>16</sup> activities are to reduce TFR from 2.2 to 2.0, increase CPR from 62% to 75%, increase share of Long Acting Permanent Method (LAPM) from 8.1% to 20%, reduce unmet need from 12% to 10% and reduce discontinuation rate of FP method from 30% to 20%.

Our government is trying to change in the method use more towards long acting and reversible contraceptives and permanent methods. For this, new strategies have been implemented which included post-partum family planning and involvement of obstetricians in family planning program<sup>17</sup>. These strategies necessitate a shift in paradigm of family planning services more towards strengthening maternal health care services.

Birth spacing is an effective way to reduce maternal, perinatal and childhood morbidity and mortality. FIGO's postpartum family planning programme in partnership with OGSB has trained more than 1,653 providers in postpartum IUD counselling and insertion, and enabled 66,181 women to make as informed choice for themselves and their families<sup>18</sup>.

In the present study maximum number of patients (40.6%) belonged to age group 21 – 25 years which is similar to the study by Kumar et al<sup>19</sup> and Bansal et al<sup>20</sup>. In this study majority (34.3%) patients who accepted PPIUCD were educated up to primary level. Acceptance rate was 7.4% and 8.5% in uneducated and postgraduate patients which were similar to study done by Mishra who found 7.7% and 8.2% acceptance in these patients<sup>21</sup>. These findings

indicates the importance of certain level of education for increased awareness and acceptance of postpartum IUCD. This study found that the acceptance of PPIUCD was more (70.9%) among urban people. This reflects the easy accessibility for urban people to this hospital. Though women of urban areas has easy access to other methods of contraception, they still prefer PPIUD because of its various benefits like free of cost, availability, long acting reversibility and fewer side effects.

In the present study, acceptance of PPIUD was more common among multipara (71.4%) compared to primipara (28.6%) which is similar to the study done by Grimes et al<sup>22</sup> and Aswathys et al<sup>23</sup> where higher acceptance were found in multiparous client about 65.1% and 73.3% respectively. Present study emphasizes on the fact that our women who have completed their family are in need of long acting, immediate and safe contraceptive method which is reversible too, till they could decide about option for the permanent method.

In this study 33.14% client were booked and counselled during antenatal period, rest 66.85% accepted the method where they were given information during early labour or before caesarean section. Whereas in the study done by Celen, 64% had received family planning counseling during antenatal period<sup>24</sup>. This highlights the role of proper counseling during antenatal period as well as during labour since the patients are highly motivated at that time.

In the present study, most of the patients, 100 (82.0%) had no complications which is similar to Pandher et. al<sup>25</sup>. Few patients (18.0%) had some minor complaints that were managed by medication and counselling. The common adverse events were menstrual irregularities (7.4%), menorrhagia (5%), per vaginal discharge (6.5%) and pelvic pain (4.1%). There was no case of perforation. Parikh and Gandhi reported an excessive bleeding rate of 6.6% with intra cesarean insertions<sup>26</sup>. Shukla et al indicated a higher incidence of menorrhagia (27.2%) with use of Copper T 200 as interval insertion<sup>27</sup>. While Gupta et al observed bleeding in only 4.3% PPIUCD cases using Copper T 380A<sup>28</sup>. Women with IUCDs are more apprehensive regarding the symptom of vaginal discharge. In women reporting with symptoms of unusual discharge actual infection was extremely low on clinical evaluation. A multicentric study from India

reported an overall infection rate of 4.5% with PPIUCD<sup>29</sup>. Welkovic et al compared the infection rate among IUCD users and non-users but found no difference<sup>30</sup>.

Visibility of string is important as it assures both the health care provider and IUCD user about the proper position of IUCD and during removal of the device. In the present study IUCD string were visible at 30.0% of client after 2 years of PPIUCD insertion. Strings were not visible in 70.0% cases despite ultrasonography confirmation of IUCD being in place. Hooda et al.<sup>3</sup> reported missing string in 22.1% cases following vaginal delivery & 55.1% cases following caesarean section after 2 years. As most of our insertions were following caesarean section, string visibility was less. The result of string visibility differ from Sunita et al.<sup>31</sup> where missing string was 14.66% cases after 1 year of study and by Aswarthy et al.<sup>23</sup> missing string was in 34.5% cases (48.5% in C/S versus 25% in vaginal delivery). The difference in missing string in different study may be due to the different types of IUCD and also due to variation in placement of IUCD string during caesarean section.

The continuation rate of 2 years was 69.7% in the present study, Mishra<sup>21</sup> reported 81.1% at 6 months, Celen et. al<sup>24</sup> reported 62% at 12 months and Pandher<sup>25</sup> reported 85% at 2 years. So emphasis should be given on counseling, regarding awareness of the doctors and patients about postpartum IUCD and regular training of the health care providers for proper insertion technique.

In the current study, the removal rate was 24.6% which was higher than study done by Pandher et. al<sup>25</sup>, where it was 12.8% after 2 years and by Sunita et. al<sup>31</sup> 7% after 1 year, Celen et al<sup>24</sup> 10.6%. Menstrual abnormality were the prime cause of removal which is similar to other studies<sup>20, 21, 25</sup>. In this study, the high removal rate was due to the fact that the study was done after 2 years of insertion when among 43, 6 removal were due to desire for pregnancy, 5 were due to psychosocial causes, having no actual problem. Interestingly 10 clients removed the IUCD by pulling the thread by themselves when string was felt in the vagina due to ignorance. This findings were not seen by other studies which indicates a counseling problems regarding the PPIUCD thread. Also it is assumed that when they came for removal due to any complaints

they might be properly counseled and appropriate management of the problem could be given without removing the IUCD. About 35.0% removal done in other health facilities, probably they were not well oriented about postpartum IUCD at that time.

Expulsion of IUCD is an important factor affecting efficacy of the device. In the present study 10 IUCD were expelled, making expulsion rate as 5.7% which is similar to the study done by Sunita et al<sup>31</sup> (5.33%). Expulsion rates of PPIUCD insertion has been reported from 0 – 5.7% in various studies<sup>32, 33</sup>. On the contrary, Celen et al. have reported a higher cumulative expulsion rate of 17.6% per 100 women per year<sup>24</sup>. Maximum expulsion in previous studies have been detected during first follow-up visit<sup>10, 34</sup>. In this study expulsion rate at 6 weeks was found to be 0.57%, which were 2.3% by Pandher et al<sup>25</sup> and 3.6% by Kumer et al<sup>19</sup>. In this study, among total expulsion 10% occur within 6 weeks. In 50% (n=5) cases of expulsion, client were unaware about the expulsion and they came to know it when they consulted with doctors for other reasons. Thus the first follow up at 6 weeks is very important to know the presence of IUCD in right place. WHO-RHL study has emphasized that expulsion rate can be minimized by the expertise of the doctor. Thus programs should be conducted regularly to train the clinicians and special IUCD insertion kit should be provided to the health centers conducting deliveries<sup>35</sup>.

In this study failure rate was 1.7%. Failure rate less than 1% within one year were reported by different studies<sup>29, 31</sup>. There were no failure case reported by Pandher<sup>25</sup> and Aswathy<sup>23</sup>. There were three cases of unintended pregnancy with spontaneous expulsion of Cu-T which they were unaware about it, because they didn't came for follow-up at 6 weeks.

### Conclusion:

PPIUD is a safe and effective reversible method of contraception. To make it more effective, face to face follow-up at 6 weeks is very important. Proper counselling of the clients regarding the IUCD string and probable minor side effects along with proper insertion technique increase the continuation rate. Appropriate orientation and motivation of health care providers of all level can reduce the removal rate. So, PPIUD insertion is an opportunity while the woman is in a health care centre and that not to be missed.

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