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Evaluation of Safety, Efficacy and Expulsion of Post Placental Insertion of Intrauterine Contraceptive Device.

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Abstract

Aims: To determine the safety, efficacy and expulsion of post placental insertion of contraceptive device.

Materials and methods: The study population included all primigravida who were counselled both during antenatal period and during early labor and given consent and CuT 380A inserted within 10 minutes of placental delivery and were given post insertion counseling and were followed up at 6,12 and at 24 weeks

Results and Discussion: Totally 2630 primipara's was delivered of which 1828 women were included in the study. Acceptance rate is 69.50%. The mean age of women in the study was 24 year. Out of 1828 patients, 1450 patients (79.3%) delivered by labour natural, 318 patients (17.4%) delivered by caesarean section, 60 patients (3.3%) delivered by assisted deliveries. They are counselled for follow up at 6 weeks, 12 weeks and 24 weeks and issued a follow up card. Out of 1828 woman, only 922(50.4%) returned for first follow up and 780(42.7%) returned for second follow up and 703(38.4%) returned for third follow up. 276(15%) developed lower abdominal pain, 271(14.8%) developed excessive bleeding pervaginum,27 (1.5%) developed both lower abdominal pain and excessive bleeding pervaginum. 74 patients had expulsion of IUCD. Continuation rate at the end of 24 weeks is 38.1%.

Conclusion: PPIUCD is the most safe and highly efficacious mode of contraception and provides healthy birth spacing, thereby decreasing the unmet need for family planning.

Keywords: IUCD,Cu-T, abdominal pain, continuation rate, follow-up, parturients.

Introduction

India is world's 2nd largest populated country in the world with 121 million according to 2011 census. IUD-1.6%, natural method (LAM)-5.4%, condom use-5.3%, and female sterilization- 34.2%, male sterilization 1.9% are the methods of contraception among the married couple in India. Unmet need of Family Planning is 21.3% as per DLHS-III (2007-08) In India, 65% of women in the first year of post-partum period have an unmet need for family planning. Hence contraception needs to be practiced in this critical period. During the first year postpartum most women resume sexual activity, approximately 40% return to sexual activity within the first three months and by 10-12 months postpartum 90% have resumed sexual activity. Couples will not necessarily see themselves at risk of pregnancy at this time and will not fully recognize the need for family planning.

The use of intrauterine contraceptive device (IUCD) in the immediate postpartum period is an excellent option for meeting the need of these females regarding contraception.

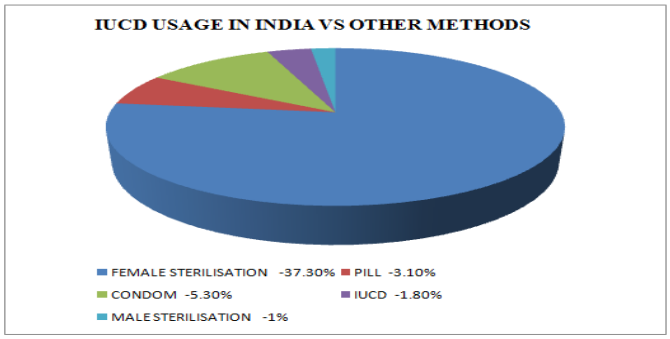
The postpartum period following three months after delivery, weaning from breast feeding and resuming sexual activity among married couple, is the risk period for unintended pregnancy. Poor spacing between pregnancies, the unmet need for post partum contraception may lead to intervention in an unwanted subsequent pregnancy. There are many options available for postpartum contraception i.e. LAM method, pills, IUD, condoms, sterilization but the women in the post partum period wants a efficacious, reliable, safe, easy to use, reversible and a contraceptive[1] method which provide long term protection. All these criteria's are fulfilled by IUCD

IUCD is most effective, safe, long acting and do not interfere with coitus. Inserted immediately or within 72 hours after delivery of placenta in a health care facility.

It is convenient for those who are in outreach area where family planning facilities are less available that may be utilized to overcome the unmet need of contraception, in a single hospital visit during institutional delivery. It's appealing for several reasons. The women are not pregnant and are motivated for contraception and situation is convenient for women and providers. PPIUCD has distinct advantage. It is free from systemic side effects and does not affect breast feeding as seen with hormonal methods.

It is a reversible method. PPIUCD does not require regular user compliance. It is also not coital dependent and there is no pain on insertion when used post placentally.

Indian scale of IUCD



Copper T 380A, acts primarily by preventing fertilization. The released Copper decreases sperm motility[10]. Copper acts as a spermicide within The uterus, increasing levels of copperions prostaglandins, and white blood cells within the uterine and tubal fluids.It alters the enzymatic and metabolic changes in the uterus and fallopian tube, thereby preventing sperm from reaching the fallopian tubes and fertilizing the ovum.It also stimulates foreign body reaction in the endometrium that causes macrophage release and prevents implantation of the fertilized ovum. Copper can also alter the endometrial lining, but studies show that while this alteration can prevent implantation of a fertilized egg ("blastocyst"), it cannot disrupt one that has already been implanted. The effectiveness is dependent on the annual failure (pregnancy) rate10. Copper T380 A has an effective life of upto 10 years. A woman's fertility returns immediately after an IUCD is removed.

Aim of Study

To determine the safety, efficacy and expulsion of postplacental insertion of contraceptive device (PPIUCD)

To determine the rates of complications, uterine perforation, expulsion, pelvic infection, lost strings and displacement following PPIUCD insertion among the acceptors by 6 months.

Type of Study

Descriptive cohort study

Duration of Study

August 2016 to july 2017

Materials & Methods

The study population included all primigravida who were counselled both during antenatal period and during early labor and given consent and delivered during six months period from August 2016 to January 2017 and CuT 380A inserted within 10 minutes of placental delivery and were given post insertion counselling and were followed up at 6weeks, 12 weeks and at 24 weeks ie till July 2017

Inclusion Criteria

All primigravida patients admitted for delivery to our hospital were counselled for PPIUCD. Consent was obtained from those, who opted for insertion. Among those who fulfilled the following criteria were considered for inclusion:

• 18–40 years old.

• GA 37–42weeks.

• Desire to have CuT after counseling before insertion.

• No infections.

• Hb>8 g/dl.

• AMTSL universally provided after the delivery of the baby

Exclusion Criteria

- Fever during labor and delivery.
- Having active STD or other lower genital tract infection or high risk for STD.
- Known to have ruptured membranes for more than 18 hours prior to delivery.
- Known uterine abnormalities e.g., Bicornuate/septate Uterus, uterine myomas,
- Manual removal of the placenta.
- Unresolved postpartum hemorrhage or postpartum uterine atony requiring use of additional oxytocicagents in addition to AMTSL.

Medical Eligibility Criteria

It describes IUCD use for women under specific medical conditions .The reproductive rights of the individual must be considered. It is essential that the provider has to screen the women based on theMEC[8] in order to provide the Quality Care In IUCD Services. There Are Four Categories.

Time of Insertion

There are three types of postpartum insertion of intrauterine device.

They are

1. Immediate post placental

- Insertion within 10 minutes of delivery of the placenta in vaginal delivery
- Intracesarean insertion

2. within 48 hours of delivery

Technique of IUCD Insertion

No Touch Technique of Ppiucd Insertion

Post Insertion Counselling

Post-insertion counseling is done and follow up card is issued with the details like date and type of insertion and type of IUCD inserted and follow up date and the date and month when the IUCD need to be removed. Examination done at the time of discharge and advice given about the Danger signs like heavy vaginal bleeding, severe lower abdominal discomfort, fever and not feeling well or suspected expulsion–feeling IUCD in the vagina or has expelled. They are advised to come for follow up at 6 weeks, 12 weeks and 24 weeks from delivery.

Follow Up

During the follow up a detailed history was taken as per the proforma enclosed and thorough general and systemic examination and speculum examination was done for the presence or absence of Copper -T inside the uterus by visualization of the copper T thread. If the threads were missing, then immediate Tran's abdominal ultra sonogram or x-ray abdomen and pelvis was done to identify whether copper-T was expelled, or perforated out of the followed up persons. Symptomatic treatment is given for their complaints if not responding or the clients insist on removal,IUCD is removed.

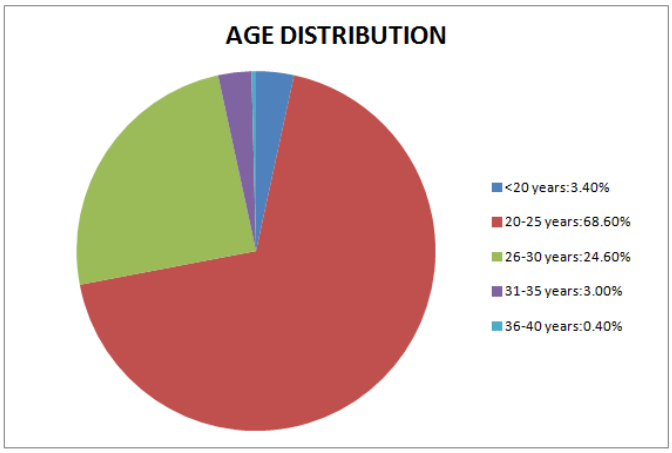
Removal of IUCD[1] is done

- partial expulsion
- Puerperal sepsis
- Perforation of the uterine wall
- Persistent uterine cramping of unknown origin
- Patient's request

Results & Analysis

Age Distribution

The total number of n in the study is 1828. The mean age is **23.99** years with standard deviation of 3.29 years. The median age is 21, minimum 18 and maximum 40 years.Majority ie 1254(68.6%) patients belong to the age group of **20-25 years**



1757(96.1%) clients were Hindus and 47(2.6%) clients were Christian 24(1.3%) clients were Muslims

Table 1: Education Distribution

S.No	Educational qualification	Frequency (n)	Percentage %
1	Illiterate	31	1.7
2	SSLC (Secondary school)	790	43.2
3	HSC (Higher Secondary)	376	20.6
4	UG (Under graduates)	429	23.5
5	PG (Post graduates)	202	11.1

Complications Distribution

Medical Disorder

Out of 1828 patients, **210 (11.5%)** patients had co-morbid conditions.

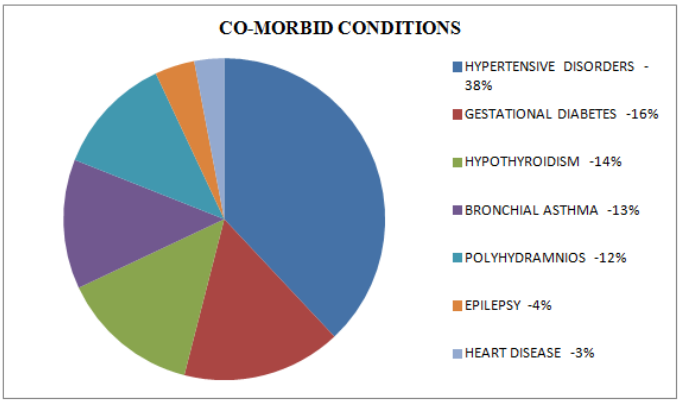


Table 2: Mode of Delivery Distribution

S.No	Mode of delivery	Frequency (n)	Percentage %
1	Labour naturalis with episiotomy	1450	79.3
2	LSCS	318	17.4
3	Outlet forceps delivery	30	1.6
4	Vaccum delivery	27	1.5
5	Assisted Breech delivery	3	0.2

Acceptance Rate

Total number of primipara's delivered : 2630

Total number accepted PPIUCD: 1828

Acceptance rate: **69.50%**

Table 3: Follow Up Distribution In Numbers

	First follow up	Second follow up	Third follow up
Followed up	922	780	703
Lost follow up	906	947	958
Excluded from study		101	167

Table 4: Follow Up Distribution in Percentage

	First follow up		Second follow up		Third follow up	
	n	%	n	%	n	%
Followed up	922	50.4	780	42.7	703	38.4
Lost follow up	906	49.5	947	51.8	958	52.4
Excluded from study			101	5.5	167	9.13

97 of clients had thread problems during the first follow up 70 of clients had thread problems during the second follow up67 of clients had thread problems during the third follow up 5.3%(97) of clients had thread problems during the first follow up3.8%(70) of clients had thread problems during the second follow up3.6%(67) of clients had thread problems during the third follow up. Out of the 97 patients with thread problems 49 had IUCD expelled ,6 clients had IUCD removed due to malposition of IUCD and normal position confirmed in 42 clients during the first follow up. Out of the 70 patients with thread problems 19 had IUCD expelled, 5 clients had IUCD removed due to malposition of IUCD and normal position confirmed in 46 clients during the second follow up

Out of the 67 patients with thread problems 6 had IUCD expelled and normal position confirmed in 61clients during the third follow up

Table 5: Overall Distribution among the Invisible Threads in Percentage.

	First follow up	Second follow up	Third follow up	n	%
Expelled	49	19	6	74	32
Removed	6	5	0	11	4.7
Normal position	42	46	61	149	63.3

Table 6: Distribution of Complications in Numbers.

	First follow up	Second follow up	Third follow up
Complaints	n	n	n
Pain	118	98	60
Bleeding	73	98	100
Pain and bleeding	18	0	9
Fever	3	0	0
Foul smelling discharge	0	0	0
Inability to feel thread	97	70	67
Perforation	0	0	0
Pregnancy	0	0	0
No complaints	591	530	510

Table 7: Distribution of Complications in Percentage.

				n	%
Pain	118	98	60	276	15
Bleeding	73	98	100	271	14.8
Pain and bleeding	18	0	9	27	1.5
Fever	3	0	0	3	0.2
Foul smelling discharge	0	0	0	0	0
Inability to feel thread	97	70	67	234	12.8
Perforation	0	0	0	0	0
Pregnancy	0	0	0	0	0

Table 8: Distribution of Investigations Done

	First follow up	Second follow up	Third follow up	n	%
USG	125	167	72	364	20
X –ray	153	36	42	231	13
UPT	9	3	18	30	1.6
CUL	6	51	0	57	3.1

Table 9: Distribution of Symptomatic Treatment

	First follow up		Second follow up		Third follow up	
	n	%	n	%	n	%
Treated	197	10.8	190	10.4	184	10.1
Not treated	725	39.7	590	32.3	519	28.4

Table 10: Distribution of Reason for Removal

Reason for removal	First follow up	Second follow up	Third follow up	Total	%
Pain	18	18	3	39	2.2
Bleeding	25	24	6	55	3
Pain and bleeding	0	0	0	0	0
Fever	3	0	0	3	0.2
Foul smelling discharge	0	0	0	0	0
Malposition	6	5	0	11	0.6
Perforation	0	0	0	0	0
Pregnancy	0	0	0	0	0
Total	52	47	9	108	6

Table 11: Combined Distribution of Complications and Removal

Complaints	Complaints(n)	%	Reason for removal(n)	%
Pain	276	15	39	2.2
Bleeding	271	14.8	55	3
Pain and bleeding	27	1.5	0	0
Fever	3	0.2	3	0.2
Foul smelling discharge	0	0	0	0
Inability to feel thread	234	12.8	11	0.6
Perforation	0	0	0	0
Pregnancy	0	0	0	0

Table 12: Distribution of Expulsion of PPIUCD

Expulsion	First follow up	Second follow up	Third follow up	n	%
By history	31	19	6	56	3
By investigations	49	19	6	74	4
Total	49	19	6	74	4

TABLE 13: Distribution of Time of Expulsion of PPIUCD

Time of expulsion	Frequency (n)	Percentage %
< 6 weeks	49	67
6 to 12 weeks	19	25
12 to 24 weeks	6	8

Table 14: Willingness to Continue PPIUCD

	n	%
Willing to continue	688	38%
Not willing to continue	182	10%

Table 15: Comparison of Mean Age

	Mean age
Our study	24 yrs
Sahaja kittur et al[22](2010)	20-25(45%)
Runjun Doley et al[32](2013-2015)	21-25 yrs (43.8%)
Sangeetha jairaj et al[28](2015)	23.7 yrs
Jisha Bai et al[31](2015)	20-30 yrs (80%)

Table 16: Comparison of Complications

	OUR STUDY	Jisha Bai et al[31](2015)	Runjun Doley et al[32] (2013-2015)	Sahaja Kittur et al[22](2010)	Anjali VivekKanhere et al[23](2012-2013)
PAIN	15%	2%	2.13%	43%	8%
BLEEDING	14.8%	3%	12.35%	6.2%	6%
THREAD PROBLEMS	12.8%	25.3%	15.12%	24.7%	3%
PID	0%	0	0.75%	0	0
PERFORATION	0	0	0	0	0
PREGNANCY	0	0	0	0	1.3%

Table 17: Comparison of Study Population

	Study population
Our study	1828
P. Malathi et al[30](2010-2015)	2850
Sudha T. R et al[21](2011-2013),	1832
AnjumAfshan et al[20](2013)	1238
Jisha Bai et al[31](2015)	100

21.7% of clients gave a score of 9 out of 10

9.1% of clients gave a score of 8 out of 10

6.7% of clients gave a score of 7 out of 10

10% of clients who were exit from the study due to expulsion or removal did not answer the level of satisfaction. Overall (37.5%) all those clients on IUCD were very well satisfied with the device inspite of minor complaints.

Discussion

In our study, total patients included in the study is 1828.In the study done by Sudha T. R et al[21](2011-2013),total patients included in the study is 1832.In the study done by AnjumAfshan et al[20](2013),total patients included in the study is 1238.In the study done by by P. Malathi et al[30](2010-2015), total patients included in the study is 2850.

In our study 50.4% returned for first follow up at 6weeks and 42.7% returned for second follow up at 12 weeks and 38.4% returned for third follow up at 24weeks.In the study done byAnjumAfshan et al[20](2013) The follow up rate at 6 weeks was 51% and 14% at 6 months.In the study done by Anjali VivekKanhere et al[23](2012-2013) 72%) reported for follow up at 6 WeeksIn our study, for 4.3% clients,threads were not visible.In the study done byJisha Bai C. P et al[31],IUCD thread of the device was not visible in 25.3%.In the study done by Mishra Sujnanendra et al[27](2012-2013),8.6% of patients had string problems.In our study 79.3% of patients delivered by labour natural with episiotomy, 17.4% delivered by caesarean section had PPIUCD.In the study done byAnjumAfshan et al[20](2013),56% of insertions were performed after vaginal delivery and 44% insertions were done at caesarean sections.In the study done byAruna Nigam et al[29](2013) 67% had insertion following vaginal delivery and 33% during cesarean section.In our study acceptance rate is 69.5%.

In our study Out of 74 patients who had expulsion of IUCD ,67% expelled at < 6 weeks,25% expelled at 6 to 12 weeks,8 % expelled at 12 to 24 weeks.In the study done bySudha T. R et al[21](2011-2013) Expulsion rate was 0.32 %.In the study done by AnjumAfshan et al[20](2013),expulsion rate is 6% at 6 months.In In the study done by Mishra Sujnanendra et al[27](2012-2013) expulsion rate is 6.9%.In our study 6% had IUCD removed.In the study done bySudha T. R et al[21](2011-2013),removal rate was 0.76% .In the study done by AnjumAfshan et al[20](2013),removal rate was 10% at 6 months.In the study done by Mishra Sujnanendra et al[27](2012-2013), Removal rate 7.6% In our study Continuation rate at the end of 24 weeks 38.1%.In the study done bySudha T. R et al[21](2011-2013) Continuation rate is 98.90%.Inthe study done byAnjumAfshan et al[20](2013), Continuation rate is 84% at 6months.In In the study done by Mishra Sujnanendra et al[27](2012-2013) Continuation rate is 62.4%.In our study 38% clients were willing to continue IUCD and 10% clients were not willing to continue IUCD.In our study 21.4% of clients were well satisfied with IUCD and given score of 90% satisfaction. In the study done by Jisha Bai[31]89% were well satisfied with IUCD and 11% were unsatisfied with IUCD.

Conclusion

As there are no untoward complications like pregnancy or perforations or pelvic inflammatory disease with minimal expulsion rate of 4% and removal rate of 6%, PPIUCD is the most safe and highly efficacious mode of contraception in period after the delivery of the baby and

population control and provides a healthy birth spacing, thereby decreasing the unmet need for family planning.

Review of Literature

1. Ory HW, for Women's Health study , Showed there is 80%-90%reduction in the risk of ectopic pregnancy due to higher dose ofcopperT380A

2. The Oxford study Vessey M, Doll R, PetoR , et al ,Found thatwomen gave birth just as promptly after IUCD removal as they didafter discontinuing use of the diaphragm.

3. A Cochrane data base – Grimes DA, Lopez LM et al 2006, Thediscontinuation for pain and bleeding is higher with copper IUCD.The worsened periods often occur with the first few menses andthey are treated with NSAID'S.

4. A Cochrane Database- CelenS ,Sucak A et al 2004, Clinicaloutcomes in early postplacental insertion of IUCD.It appears to besafe, effective and there were no bleeding, infection nor perforation. The main disadvantage was increased expulsion , and it was12.3% at 1 year with the copper T.10

5. A Randomised control trial Trusselet el 2004, Showed insertion ofIUCD after immediate postpartum period and before 4 weekspostpartum was associated with more perforations.

6. Walsh T, Grimes D, Friezieres R, Randomised Control Trial ofprophylactic antibiotics before insertion of IUCD-1998. No role inlowering the peri-insertion infections.

7. Rosenberg MJ, Waugh MS, A prospective evaluation ofdiscontinuation between oral contraception and IUCD 1998,Thecontinuation rate at the end of 1 year for Copper T 380A- 78%,OCP- 50%.

8. French R, Van Vliet H, Cowan F et al 2004- A Cochrane Databaseof pregnancy rates. The pregnancy rates at end of 1 year, CopperT380 A- 0.8-0.6 and LNG IUS- 0.1.per 100 woman years.

9. Otero- Flores JB , Guerrero- CarrenoFJ,Vazquez-Estrada LA2003. A large Comparative Randomised Control Study of threedifferent IUCD in nulliparous Mexican woman,Thehigheffectiveness with a failure rate at 1year and overall expulsionrates were 1.8%- T Null and multiload, compared with CopperT380A- 3.3%.

10. Hubacher D, Grimes DA 2005.In a recent cohort study of2,037,883 woman years of follow up in china was associated with adecreased risk of endometrial cancer with an adjusted odds ratio of0.6 (95% CI 0.3-0.9).although type of IUCD were not specified, itwas a combination of Copper T380A, and stainless steel ringswere most frequently used device.

11. Cole et al,Expulsions in Immediate Postpartum Insertions ofLippes Loop D and Copper T IUDs and their Counterpart DeltaDevices-- An Epidemiological Analysis1984. They have foundedhatpostpartm insertion to be a safe procedure. the magnitude ofIUD expulsions in postpartum depend upon the insertor's skill &experience.

12. Comparitive study between two techniques used in immediatepostplacental insertion of TCu 380A in china : Chen Y yang X et al1999 .

13. A women's Health study – kriplaniA,Buckshee K, Relan S, et al,showed the only pelvic infection that has been unequivocallyrelated to IUCD use is actinomycosis and that to occurred in thewomen who have multiple sexual partners.The rate increases withduration of use of plastic devices, and it is much less for copperreleasing IUCD's.13

14. O'hanley K, Huber Dh April 2007, New York. Insertion atimmediatepostplacental and postpartum periods are demonstrablysafe, because they have a low incidence of infection, few bleedingproblems, and low perforation rates.

15. In studies comparing immediate postpartum IUD insertions withinterval insertions, the removal rate due to bleeding is lower for theimmediate postpartum IUD

insertions, e.g., 13.7% vs. 23.6% in astudy in India. 90-95% of women are able to detect their own expulsions.

16. Randomised comparative study between immediate postpartum insertion of multiload Cut375 and Cut380A Lara ricalde et al 2006-

17. Randomised comparative study of two techniques used inimmediatepostplacental insertion of the Copper T-380A IUD inShanghai, Rivera R et al,1996-: IUD inserted by hand and IUD viaring forceps. Expulsions were the main reason for discontinuation. The six-month gross cumulative expulsion rates were 13.3 and 12.7per 100 women in the hand-insertion group and ring forcepsinsertion group respectively. Discontinuation rates for medical removals (bleeding/pain)were 2.1 and 1.0 in these two groups, respectively. Neither of the differences was statistically significant ($p > 0.05$). No uterine perforation, infection or pregnancy occurred.15

18. The IUD expulsion rate was higher in non-breast feeding women than in breast-feeding women (22.4% vs. 11.9%; p 0.05).

19. Comparison of efficacy and complications of IUD insertion inimmediatepostplacental/early postpartum period with intervalperiod: 1 year follow-up. Taskin L haberalAetal 2006.

20. In a longitudinal international study which was conducted by theWHO, where the average annual pregnancy rate was 0.4%, and theaverage cumulative pregnancy rate was 2.2% at the end of 12 yearsof use of CuT 380A, which is very similar to that of tubalsterilization (United Nations Development Programme et al. 1997).

21.In a Cross Sectional Study,Main reported complications were pain abdomen (17.14%), bleeding (14.28%). Expulsion rate was 6.8%. Most common reason (40%) for removal of IUCD was inclination to other methods

22.Awareness about post-placental IUCD was significantly low as compared to interval IUCD (5.79% versus 73.55%).

23.A randomized study by Nidhi Gupta et al[26] in 2010-2011,for two techniques of immediate post-partum intrauterine contraceptive device insertion statistically no significant difference in the mild discomfort during insertion by either technique There was no significant difference in the complication rate for the two groups

24.Ina prospective study acceptance of PPIUCD was higher in Cesarean deliveries than in vaginal deliveries. Acceptance was also higher in unplanned pregnancies

25.In a prospective study by Monica Soniet al[24] in 2016, There was higher rate of acceptance, no expulsion and high continuation rate in post-cesarean cases as compared to vaginally delivered cases

26. In a study by Neha Jain (2012-2013), immediate postpartum IUCD insertion is an effective, safe and even better means of contraception when compared with that of delayed insertion