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Original Research Article

COMPARATIVE EVALUATION OF THE EFFICACY FOR CU375 AND CU T 380 CONCERNING FAILURE RATES AS A POSTPARTUM INTRAUTERINE CONTRACEPTIVE DEVICE

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ABSTRACT

Background: The family planning program in India is now focused on raising awareness concerning the use of postpartum contraception methods with special emphasis on postpartum intrauterine devices as a reversible and long-acting method. The use of copper UCD in the immediate postpartum period has limited literature data. The present study was aimed at a comparative evaluation of the efficacy of Cu375 and Cu T 380 concerning failure rates as a postpartum intrauterine contraceptive device. The study also assessed concerns, acceptability, expulsion rates, and side effects of the two intrauterine devices.

Materials and Methods: The present study assessed 640 postpartum females that were ready for insertion of PPIUCD (postpartum intrauterine contraceptive device) after normal vaginal delivery. The study subjects were divided into two groups with 320 subjects each where Group I subjects were inserted with IUCD Cu T 380 A and Group II subjects were inserted with Cu 375. The subjects were followed at 6 weeks, 6 months, and 1 year.

Results: The study results showed a high acceptability of PPIUCD in both groups with 72.5% (n=228) and 79.38% (n=254) subjects from Group I and II respectively. At the end of 1-year follow-up, menorrhagia was seen in 62.5% and 11% of subjects from Groups I and II respectively. Expulsion of IUCD over 1 year was reported in 15.28% (n=44) and 12.85% (n=36) females from groups I and II. The IUCD removal rate was 18.75% (n=60) and 14.38% (n=46) in groups I and II. The overall continuation rate at 1 year was 57.5% and 62.5% respectively in Group I and II. No failure was seen in any subject.

Conclusion: The present study concludes that both Cu T 380 A and Cu 375 are similar concerning expulsion rates, complications, and efficacy. However, overall satisfaction was higher in Cu375 using females compared to Cu 380 A device.

Keywords: Copper T, intrauterine contraceptive device, long-acting reversible contraceptive, PPIUCD, postpartum

INTRODUCTION

India is one of the most populous countries across the globe with the population of India being the youngest across the world. Even though the fertility rates in India have declined, a large number of young reproductive females continue to increase the overall population leading to the continued increase in overall population leading to a continued higher need for family planning services. In India, family size limitations are largely dependent on permanent contraception methods such as female sterilization and there is an unmet need for temporary contraception methods.[1]

Another major concern in India is shorter intervals of interpregnancy that lead to higher maternal mortality and morbidity. It is expected that long-acting reversible contraception use can increase birth intervals and decrease the incidence of maternal death, fetal loss, low birth weight infants, PPH, premature labor, abortions, and anemia incidence.[2]

The present rate of contraceptive prevalence in married females aged 15-49 years is nearly 54%. In the Indian community, early conception after marriage is very common. The majority of couples avoid contraception use. It is also seen that following childbirth, couples do not consider contraception methods and consider breastfeeding as a natural contraception method. With time, contraception either is not needed or demand remains unmet. It is reported that only 26% of females use contraception in 1st post-partum year. These factors lead to a load of unintended pregnancies. Hence, there is a compelling need for long-acting and reversible contraception methods for both family size limitations and spacing.[3]

In India, family planning programs are now promoting the use of postpartum contraception, especially postpartum intrauterine devices as a long-acting reversible method. The use of copper IUCD in immediate postpartum time including cesarean delivery has a category 1 rating in the WHO medical eligibility for contraceptive use.4 Hence, the present study aimed to comparatively evaluate the efficacy of Cu375 and Cu T 380 concerning failure rates as postpartum intrauterine contraceptive devices. The study also assessed concerns, acceptability, expulsion rates, and side effects of the two intrauterine devices.

MATERIALS AND METHODS

The present prospective case-control clinical study was aimed to comparatively evaluate the efficacy of Cu375 and Cu T 380 concerning failure rates as postpartum intrauterine contraceptive devices. The study also assessed concerns, acceptability, expulsion rates, and side effects of the two intrauterine devices. The study subjects were from the Department of Obstetrics and Gynecology of the Institute. Verbal and written informed consent were taken from all the subjects before participation.

The present study assessed 640 postpartum females that were ready for insertion of PPIUCD (postpartum intrauterine contraceptive device) after normal vaginal delivery. These females were divided into two groups of 320 subjects each where Group I subjects were inserted with Cu T 380A and Group II subjects with Cu375. Females were routinely counseled for insertion of PPIUCD in the antenatal clinic during early labor and the immediate postpartum period.

Inclusion criteria for the study were females that were within 48 hours of delivery and came under WHO MEC categories 1 and 2 and were willing to participate in the study. The exclusion criteria for the study were subjects in WHO MEC category 3 with prolonged rupture of membranes >18 hours, chorioamnionitis, and between 48 hours and 6 weeks postpartum, and category 4 subjects with unresolved PPH and puerperal sepsis for PPIUCD.

Demographic data of all the subjects was noted including age, education, and socioeconomic status. In all subjects, detailed history was noted including any past surgical illness, medical history, history of STD, history of IUCD usage, chorioamnionitis, PROM (prolonged rupture of membranes), unhealthy vaginal discharge, and/or fever. A complete general physical and systemic examination was done to rule out any active infection.

Insertion was done following a standard protocol based on the guidelines of the Government of India using Kelly's forceps. After insertion initial assessment was done after 72 hours. The experience of females concerning PPIUCD insertion was asked for any complaints if recorded. Pelvic inflammation signs were assessed. After that, females were called for follow-up at 6 weeks, 6 months, and 1 year.

History of feeling the IUCD thread, PID, menstrual irregularity, dysmenorrhea, pain, and any other problem was assessed and recorded. Females were told to report back if the thread was missing or any other sign of period or infection. If a female requested IUCD removal, the cause for IUCD removal was assessed and if considered right, females were counseled against IUCD removal. The females who did not visit the hospital were telephonically followed.

Statistical analysis of the gathered data was done using SPSS (Statistical Package for the Social Sciences) software version 24.0 (IBM Corp., Armonk. NY, USA) for assessment of descriptive measures, Student t-test, ANOVA (analysis of variance), and Chi-square test. The results were expressed as mean and standard deviation and frequency and percentages. The p-value of <0.05 was considered.

RESULTS

The present prospective case-control clinical study was aimed to comparatively evaluate the efficacy of Cu375 and Cu T 380 concerning failure rates as postpartum intrauterine contraceptive devices. 640 study subjects were divided into two groups with 320 subjects each where Group I subjects were inserted with IUCD Cu T 380 A and Group II subjects were inserted with Cu 375. The majority of the stud subjects from Group I and II were in the age range of 20-30 years with 84.38% (n=270) and 78.75% (n=252) subjects respectively followed by <20 years with 10% (n=32) and 13.75% (n=44) subjects respectively and 5.63% (n=18) and 7.50% (n=24) subjects from Group I and II respectively. The difference was statistically non-significant with p=0.432. There were 72.19% (n=462) subjects from

lower and 27.81% (n=178) subjects from middle socioeconomic status with p=0.903 [Table 1].

On assessing the expulsion of PPIUCD in study subjects, IUCD expulsion at 6 weeks, 6 months, and 1 year was 10.92% (n=62), 2.46% (n=14), and 0.70% (n=4) in study subjects respectively. Total expulsion was done in 13.45% (n=80) of study subjects. The difference in expulsion rate in Groups I and II study subjects was statistically non-significant with p=0.943 [Table 2].

It was seen that for outcomes of PPIUCD in study subjects at 1 year, expulsions were done in 13.75% (n=44) and 11.25% (n=36) subjects from Group I and II respectively and removal was done in 18.75% (n=60) subjects from Group I and 4.38% (n=46) subjects from Group II. The difference was statistically non-significant in the two study groups with p=0.592. The total continuation was done in 57.50% (n=184) subjects from Group I and 62.50% (n=200) subjects from Group II respectively. The difference was statistically non-significant with p=0592 [Table 3].

The study results showed that for causes of removal of PPIUCD in study subjects, females opting for other methods of contraception was reported in no subject from Group I and 4.35% (n=2) subjects from Group II, conception in 23.33% (n=14) and 17.39% (n=8) subjects from Group I and II, menorrhagia in 26.6% (n=16) and 43.48% (n=20) subjects from Group I and II, vaginal discharge in 13.3% (n=8) and 1.05% (n=6) subjects from Group I and II, abdominal pain in 3.33% (n=2) and 4.35% (n=2) subjects from Group I and II, and social issues in 33.3% (n=20) and 17.39% (n=8) subjects from Group I and II subjects respectively. The difference between the two groups was statistically non-significant with p=0.352 [Table 4].

Table 1: Demographic data of study subjects.

S. No	Characteristics	Group I		Group II		Total		p-value
		n	%	n	%	n	%	
1	Age (years)							
A	<20	32	10	44	13.75	76	11.88	0.432
B	20-30	270	84.38	252	78.75	522	81.56	
C	>30	18	5.63	24	7.50	42	6.56	
2	Socioeconomic status							
A	Lower	232	72.50	230	71.88	462	72.19	0.903
B	Middle	88	27.50	90	28.13	178	27.81	

Table 2: Expulsion of PPIUCD in study subjects

S. No	IUCD expulsion	Group I		Group II		Total		p-value
		n	%	n	%	n	%	
1	6 weeks	34	11.81	28	10	62	10.92	0.943
2	6 months	8	2.78	6	2.14	14	2.46	
3	1 year	2	0.69	2	0.71	4	0.70	
4	Total expulsion	44	13.28	36	12.85	80	13.45	
5	No expulsion	244	84.72	246	87.84	490	85.92	
6	Total	288	100	242	100	570	100	

Table 3: Outcomes of PPIUCD in study subjects at 1 year

S. No	IUCD expulsion	Group I		Group II		Total		p-value
		N	%	n	%	n	%	
1	Expulsions	44	13.75	36	11.25	80	12.50	0.592
2	Removals	60	18.75	46	4.38	106	16.56	
3	Total continuation	184	57.50	200	62.50	384	60	

Table 4: Causes of removal of PPIUCD in study subjects

S. No	IUCD removal causes	Group I		Group II		Total		p-value
		N	%	n	%	n	%	
1	Other methods of contraception	0		2	4.35	2	1.89	0.352
2	Conception	14	23.33	8	17.39	22	20.75	
3	Menorrhagia	16	26.6	20	43.48	36	33.96	
4	Vaginal discharge	8	13.3	6	13.05	14	13.2	
5	Pain abdomen	2	3.33	2	4.35	4	3.77	
6	Social issues	20	33.3	8	17.39	28	26.42	

DISCUSSION

The present study assessed 640 study subjects who were divided into two groups with 320 subjects each where Group I subjects were inserted with IUCD Cu T 380 A and Group II subjects were inserted with Cu 375. The majority of the stud subjects from Group I and II were in the age range of 20-30 years with 84.38% (n=270) and 78.75% (n=252) subjects respectively followed by <20 years with 10% (n=32) and 13.75% (n=44) subjects respectively and 5.63% (n=18) and 7.50% (n=24) subjects from Group I and II respectively. The difference was statistically non-significant with p=0.432. There were 72.19%

(n=462) subjects from lower and 27.81% (n=178) subjects from middle socioeconomic status with p=0.903.[4] These data were comparable to the previous studies of El-Shafei MM et al,[5] in 2000 and Singh U et al,[6] in 2017 where authors assessed subjects with PPIUCD insertion and demographics comparable to the present study in their respective studies.

The study results showed that on assessing the expulsion of PPIUCD in study subjects, IUCD expulsion at 6 weeks, 6 months, and 1 year was 10.92% (n=62), 2.46% (n=14), and 0.70% (n=4) study subjects respectively. Total expulsion was done in 13.45% (n=80) of study subjects. The difference in expulsion rate in Groups I and II study subjects was statistically non-significant with p=0.943. These results were consistent with the studies of Xess S et al,[7] in 2018 and Lara RR et al,[8] in 2006 where the expulsion rate of PPIUCD reported by the authors in their studies was comparable to the results of the present study.

Concerning the outcomes of PPIUCD in study subjects at 1 year, expulsions were done in 13.75% (n=44) and 11.25% (n=36) subjects from Group I and II respectively and removal was done in 18.75% (n=60) subjects from Group I and 4.38% (n=46) subjects from Group II. The difference was statistically non-significant in the two study groups with p=0.592. The total continuation was done in 57.50% (n=184) subjects from Group I and 62.50% (n=200) subjects from Group II respectively. The difference was statistically non-significant with p=0592. These findings were in agreement with the previous studies by Goswami G et al,[9] in 2015 and Maluchuru S et al,[10] in 2015 where outcomes of PPIUCD similar to the present study were also reported by the authors in their respective studies.

It was seen that for causes of removal of PPIUCD in study subjects, females opting for other methods of contraception was reported in no subject from Group I and 4.35% (n=2) subjects from Group II, conception in 23.33% (n=14) and 17.39% (n=8) subjects from Group I and II, menorrhagia in 26.6% (n=16) and 43.48% (n=20) subjects from Group I and II, vaginal discharge in 13.3% (n=8) and 1.05% (n=6) subjects from Group I and II, abdominal pain in 3.33% (n=2) and 4.35% (n=2) subjects from Group I and II, and social issues in 33.3% (n=20) and 17.39% (n=8) subjects from Group I and II subjects respectively. The difference in the two groups was statistically non-significant with p=0.352. These results correlated with the findings of El Beltagy NS et al,[11] in 2011 and Jairaj S et al,[12] in 2016 where causes of removal of PPIUCD reported by the authors in their studies were comparable to the results of the present study.

CONCLUSION

Within its limitations, the present study concludes that both Cu T 380 A and Cu 375 are similar concerning expulsion rates, complications, and efficacy. However, overall satisfaction was higher in Cu375 using females compared to Cu 380 A device.

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