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Original Research Article

Observational Study to Analyze Acceptance and Expulsion Rates of Post Placental Intra Uterine Contraceptive Device (PPIUCD) - CuT380A

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Abstract:

Background: The challenge of population explosion hinders socio-economic development, leading India's Ministry of Health to focus on refined strategies, emphasizing non-invasive approaches in its 2020 plan. Post Placental Intra Uterine Contraceptive Devices (PPIUCD), specifically CuT380A, are promoted for safe, long-acting contraception. CuT380A, a Copper IUCD, offers a decade of effectiveness with minimal side effects.

Objectives: The main objectives of the study are to assess the acceptance rates, expulsion rates before 6 weeks and before 6 months and associated complications of Post Placental Intrauterine Contraception Device PPIUCD (CuT380A) insertion.

Methods: Contraceptive counselling was given to 1380 eligible couples during the antenatal period. A proforma was filled out for all participants. Women who accepted the Post Placental Intrauterine Contraception Device (PPIUCD) CuT380A in the antenatal period were inserted with the device immediately after delivery of the placenta. These women were followed up at 6 weeks and 6 months for expulsion and complications. Women who declined Post Placental Intrauterine Contraception Device (PPIUCD) CuT380A were asked for the reason and documented. The acceptance rate of Post Placental Intrauterine Contraception Device (PPIUCD) CuT380A and expulsion rate were recorded.

Results: Of the 1380 women counselled, a total of 202 (15%) were inserted with Post Placental Intrauterine Contraception Device (PPIUCD) CuT380A. Women who had higher education and who underwent vaginal delivery had greater acceptance of the Post Placental Intrauterine Contraception Device (0.032 & 0.006 respectively). Preference to other methods of contraception, partner refusal, need to discuss with partner and family, fear of pain and heavy bleeding were the most common reasons for declining use of Post Placental Intrauterine Contraception Device. The common complication at 6 weeks interval was lower abdominal pain. The common complication at 6-month interval was menstrual disturbance. Expulsion rates at 6 weeks and 6 months were 0.9%.

Conclusion: The Post Placental Intrauterine Contraception Device (PPIUCD) CuT380A was demonstrably safe, effective, has a high continuation rate. The expulsion rate was not very high and it can be reduced with practice and insertion techniques.

Keywords: PPIUCD, Acceptance rate, Expulsion rate, Complications of PPIUCD.

Introduction

The persistent challenge of population explosion poses a formidable obstacle to the socio-economic development of nations, communities, and families. In response to this demographic challenge, the Ministry of Health and Family Welfare in India has continually refined its strategies within five-year plans, with a specific focus on population control, maternal and child health.

The strategic approach of 2020 underscores a shift towards non-invasive procedures, acknowledging the inherent morbidity and mortality associated with permanent sterilization. However, the effectiveness of these programs has been hindered, prompting an emphasis on promoting spacing methods over invasive operative procedures. As part of this evolving strategy, the Government of India advocates for the utilization of Post Placental Intra Uterine Contraceptive Devices (PPIUCD), with a particular emphasis on the CuT380A—a long-acting, safe, and coitus-independent contraceptive method. [1,2]

The historical trajectory of Intra Uterine Contraceptive Devices (IUCDs) traces back to ancient practices, such as placing a pebble in a camel's uterus during long desert journeys, evolving into contemporary developments featuring

diverse shapes and sizes. [3] The CuT380A, a representative of Copper IUCDs, is characterized by a T-shaped polyethylene frame with an exposed copper surface. This device stands out as a highly effective and reversible contraceptive option designed to last for a decade. With minimal side effects and low expulsion rates, it has emerged as a preferred choice for women seeking reliable contraception.[4]

In the evolving landscape of family planning, immediate postpartum IUCD insertion has gained prominence as a practical and effective option for women. The postpartum period presents a unique window of opportunity for women to access long-acting contraceptive methods, a particularly crucial consideration for those with limited access to medical care. The CuT380A can be seamlessly inserted immediately post-placentally, during a cesarean section, or within the first 48 hours after delivery, ensuring not only ease of placement but also high retention rates.[5–7] However, despite the evident benefits, challenges persist, and the importance of thorough counselling and informed consent cannot be overstated in the context of successful post-placental IUCD insertion. This method, while highly effective, demands careful consideration and discussion with women, taking into account their physical and emotional readiness for such decisions [6,8,9].

Against the backdrop of India, the most populous country globally, with a burgeoning population surpassing 1.42 billion, the imperative for effective population control measures becomes increasingly urgent [10]. Despite the low failure rate of IUCDs, their adoption in India remains relatively modest, with merely 2.1% of current contraception users opting for this method [11]. Addressing the unmet need for family planning, particularly in the first year postpartum, emerges as a critical imperative to avert adverse outcomes linked to closely spaced pregnancies.

The Study aims at assessing acceptance, expulsion, and complications of Post Placental Intra Uterine Contraceptive Device (PPIUCD) CuT380A. Wherein primarily we measured the proportion of women who could not accept Post Placental Intra Uterine Contraceptive Device (PPIUCD) CuT380 and identify the reasons for non-acceptance and complications associated with it. By comprehensively understanding the factors influencing contraceptive choices and proactively addressing barriers to utilization, this research seeks to contribute meaningfully to the on-going efforts of the Ministry of Health and Family Welfare. The ultimate goal is to advance the promotion of effective and accessible family planning methods, thereby mitigating the morbidity and mortality associated with unwanted pregnancies.

Methods:

The study, conducted at D. Y. Patil University School of Medicine & Hospital, Nerul, Navi Mumbai from October 2020 to March 2022 with follow-up until September 2022, aimed to assess the acceptance rate, expulsion rate, and complications of the Post Placental Intra Uterine Contraceptive Device (PPIUCD) CuT380A in women after delivery. Pregnant women received counselling during the antenatal period, and written informed consent was obtained from those willing to participate.

After obtaining ethics committee approval from Institutional Ethics committee with no. IECBH No. - EC/NEW/INST/2019/473 data collection considering inclusion and exclusion criteria was initiated. Inclusion criteria encompassed women delivering at D. Y. Patil Hospital, Navi Mumbai, willing to undergo PPIUCD without contraindications. Exclusion criteria involved patient refusal, chorioamnionitis, atonic postpartum haemorrhage, rupture of membranes >18 hours, temperature >38°C, fibroid uterus, uterine anomalies, AIDS without ARV therapy, extensive genital trauma. Trained doctors inserted the PPIUCD.

The study utilised universal sampling method. Data collection utilized a structured proforma, capturing social-demographic, obstetric, and gynaecological variables, awareness of PPIUCD, reasons for declination, and follow-up details. Follow-up cards were issued to monitor expulsion, warning signs, insertion details, and principal investigator contact. Data analysis involved coding, entry into MS Office Excel, and statistical analysis using SPSS v26. Descriptive statistics and chi-square tests were employed, with significance set at $p<0.05$.

The study included 1812 deliveries, and the acceptance rate for PPIUCD was 15% (202 individuals). Follow-up at six weeks achieved a 100% participation rate, with 16 losses to follow-up at six months. Stratification based on demographics and obstetric characteristics revealed significant trends, including higher acceptance among women with higher education ($p=0.032$) and variations related to gravidity and mode of delivery ($p=0.006$). Complications were minimal, and the expulsion rate at six weeks was 0.9%, with a continuation rate of 98%.

Data analysis was performed using SPSS v26, incorporating descriptive statistics and chi-square tests. Significance was set at $p<0.05$. The study spanned from October 2020 to September 2022, involving 1812 deliveries. PPIUCD acceptance was 15%, with 100% follow-up at six weeks and 16 losses at six months. Stratification revealed significant acceptance trends based on education, gravidity, and mode of delivery. Complications

were minimal, with a 0.9% expulsion rate at six weeks and a 98% continuation rate. Statistical analyses employed SPSS v26, applying descriptive statistics and chi-square tests with a significance threshold of $p<0.05$.

Results

During the study period (October 2020 to September 2022), 1812 deliveries occurred, with 1380 women eligible for Post Placental Intra Uterine Contraceptive Device (PPIUCD) insertion. Within the cohort of 1380 eligible subjects, a notable 15% (202 individuals) embraced PPIUCD insertion as a contraceptive method of choice. The subsequent follow-up at the six-week mark demonstrated a commendable 100% participation rate, providing valuable insights into the immediate post-insertion period. However, as the study extended to six months, a regrettable loss to follow-up occurred for 16 individuals.

Stratifying the population based on age revealed intriguing trends, with statistically significant acceptance rates observed among women with higher educational attainment (p=0.032). The role of gravidity emerged as a pivotal determinant, showcasing distinct acceptance patterns among primigravida and multigravida. Additionally, the mode of delivery exerted a significant influence, with a pronounced preference for PPIUCD among individuals with vaginal deliveries compared to those undergoing caesarean sections (p=0.006). (Table 1.) Exploring the reasons behind declining PPIUCD uncovered a spectrum of considerations, including preferences for alternative contraception methods, partner refusal, and the desire for further discussion with family or partners. (Table 2) Complications remained minimal, with no instances of uterine perforation, genital tract infections, or contraceptive failure reported. (Table 3), Figure 1-3.

The expulsion rate at six weeks stood at 0.9%, reflecting a high continuation rate of 98%. However, at the six-month juncture, the continuation rate slightly decreased to 88.12%. (Table 4) Notably, the primary reasons for PPIUCD removal were lower abdominal pain at six weeks and subsequent occurrences of menstrual disturbance and social considerations at six months.

Table 1: Association between demographic Variables and Acceptance of CU380A

	Variables	Accepted (N=202) n (%)	Declined (N=1178) n (%)	Total N = 1380n (%)	P value
Age (years)	≤20	4 (2)	19 (1.6)	23 (1.7)	0.445
	21 – 29	153 (75.7)	894 (75.9)	1047 (75.9)	
	30 – 39	45 (22.3)	263 (22.3)	308 (22.3)	
	≥40	0 (0)	2 (0.2)	2 (0.1)	
Educational status	Primary	59 (29.2)	232(19.7)	291(21.1)	0.032
	Secondary	47 (23.3)	182(15.4)	229 (16.6)	
	Higher	96(47.5)	764(64.9)	860(62.3)	
Parity	Primipara	41(20.3)	519(44.1)	560 (40.6)	0.067
	Multipara	161(79.7)	659(55.9)	820(59.4)	
Mode of delivery	Vaginal Delivery	128 (63.4)	286 (24.3)	414 (30)	0.006
	LSCS	74 (36.6)	892(75.7)	966 (70)	

Table 2: Reasons for Non-Acceptance of PPIUCD

Reason	N	%
Prefer to use another method	390	33.1
Need to discuss with partner/family	169	14.3
Fear of pain and heavy bleeding	167	14.2
Partner refusal	185	15.7
Don't want contraception immediately	113	9.6
Not enough knowledge about PPIUCD	55	4.7
Fear of cancer	4	0.3
Interferes with intercourse	57	4.8
Religious belief	38	3.2

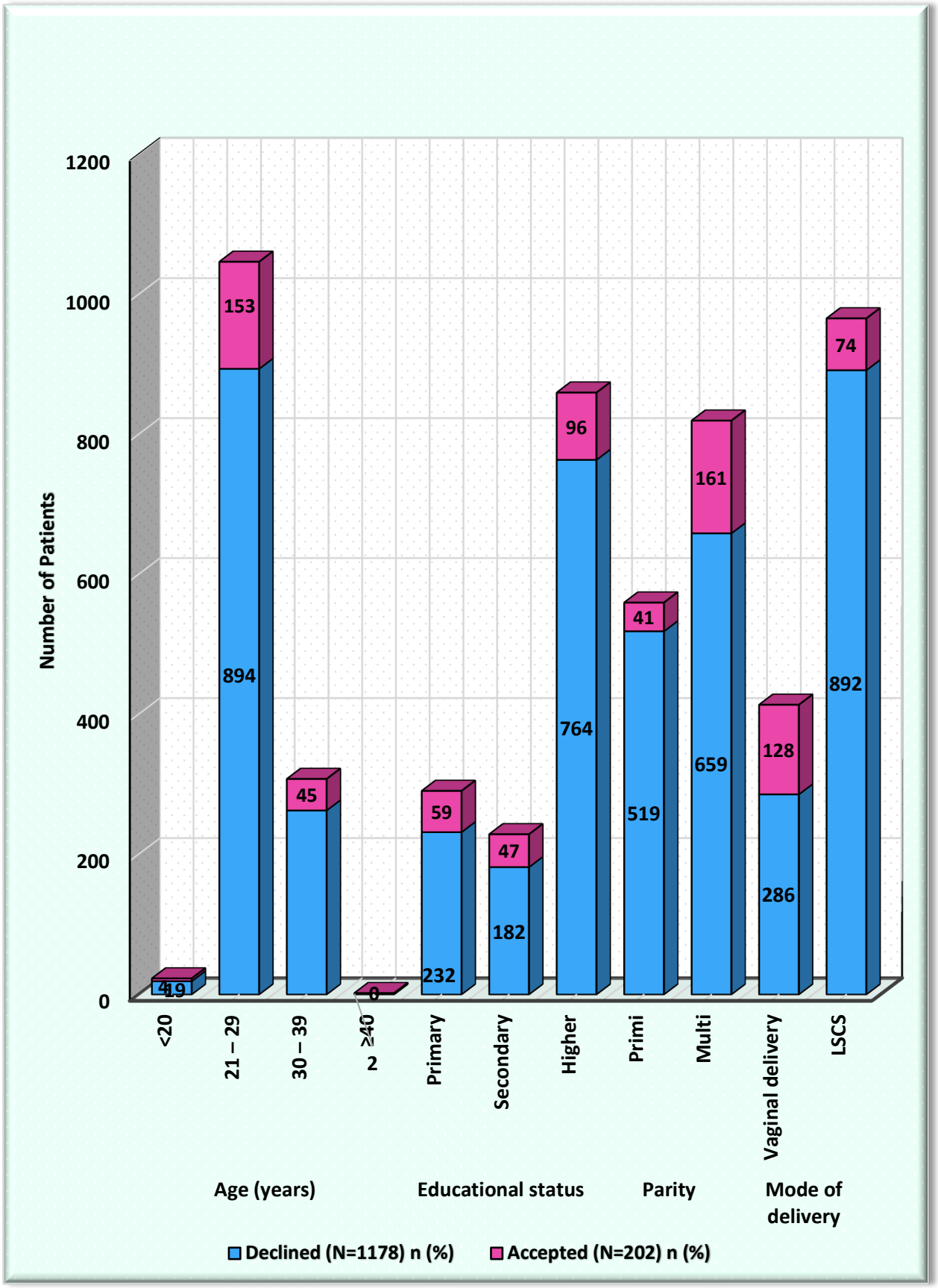

Figure 1: Association between demographic Variables and Acceptance of CU380A

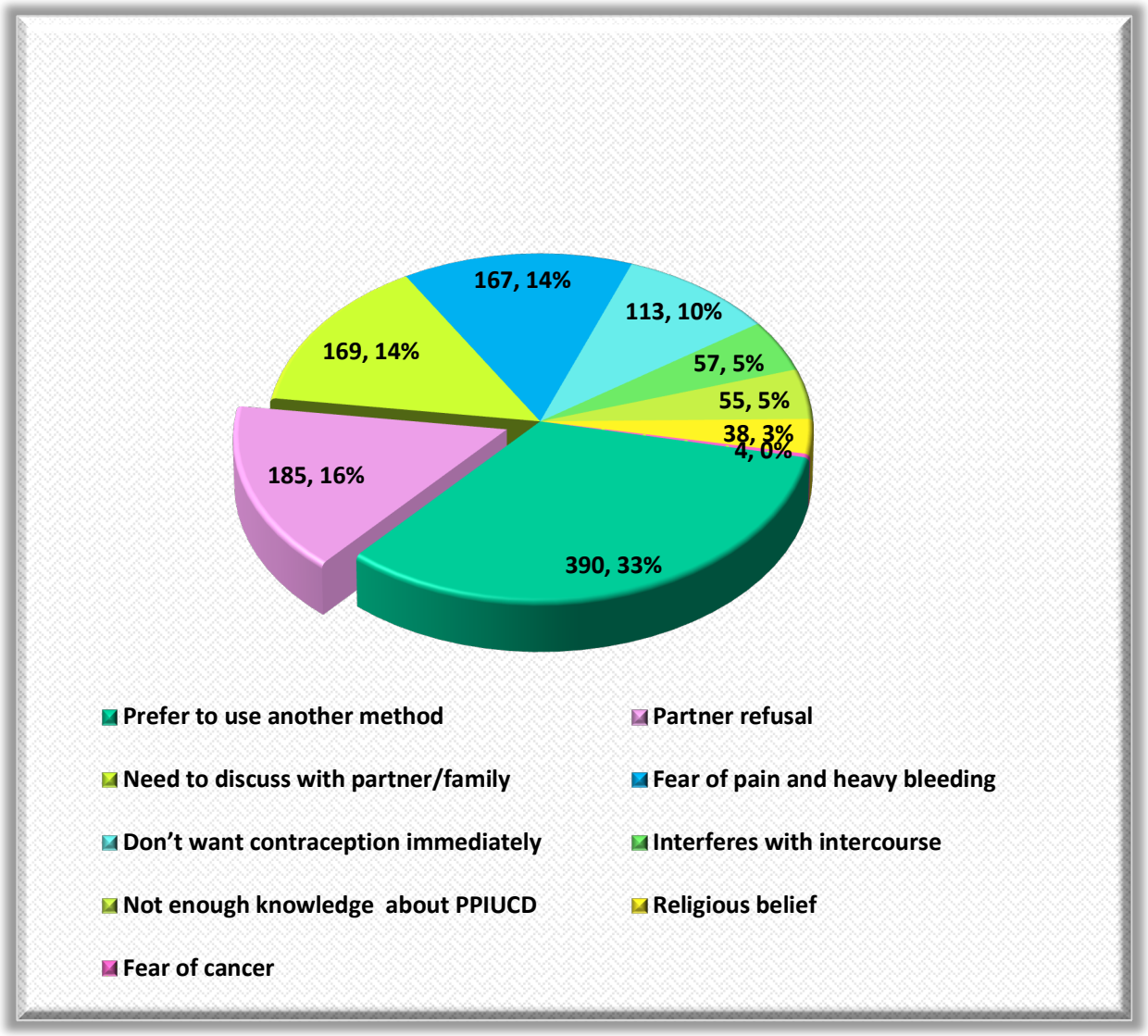

Figure 2: Reason for Non-Acceptance of PPIUCD

Table 3: Complications and Efficacy of PPIUCD at follow up visits (6 Weeks and 6 months)

		At 6 Weeks	At 6 months
		Frequency (%) (n=202,)	Frequency (%)(n=186)
Complications	Uterine Perforation	0	0
	Genital Tract Infection	0	0
	Menstrual Disturbance	0	8 (4.3%)
	Lower Abdominal Pain	1 (0.5%)	2 (1.6%)
	Missing Threads	0	1 (0.5%)
Efficacy	Expulsion	2 (1%)	2 (1%)
	Removal	1 (0.5%)	6 (3%)
	Pregnancy	0 (0.0%)	0 (0.0%)

Table 4: Expulsion rate and Continuation rates of PPIUCD between 6 weeks to 6 months in vaginal and intra caesarean insertion group

	Vaginal delivery	Cesarean section	Total
No. of PPIUCD insertion	128	74	202
Lost to follow up	9	7	16
Removal	3	3	6
Expulsion	2	0	2
Expulsion rate	1.56%	0%	0.90%
Continuation Rate	89.06%	86.49%	88.12%

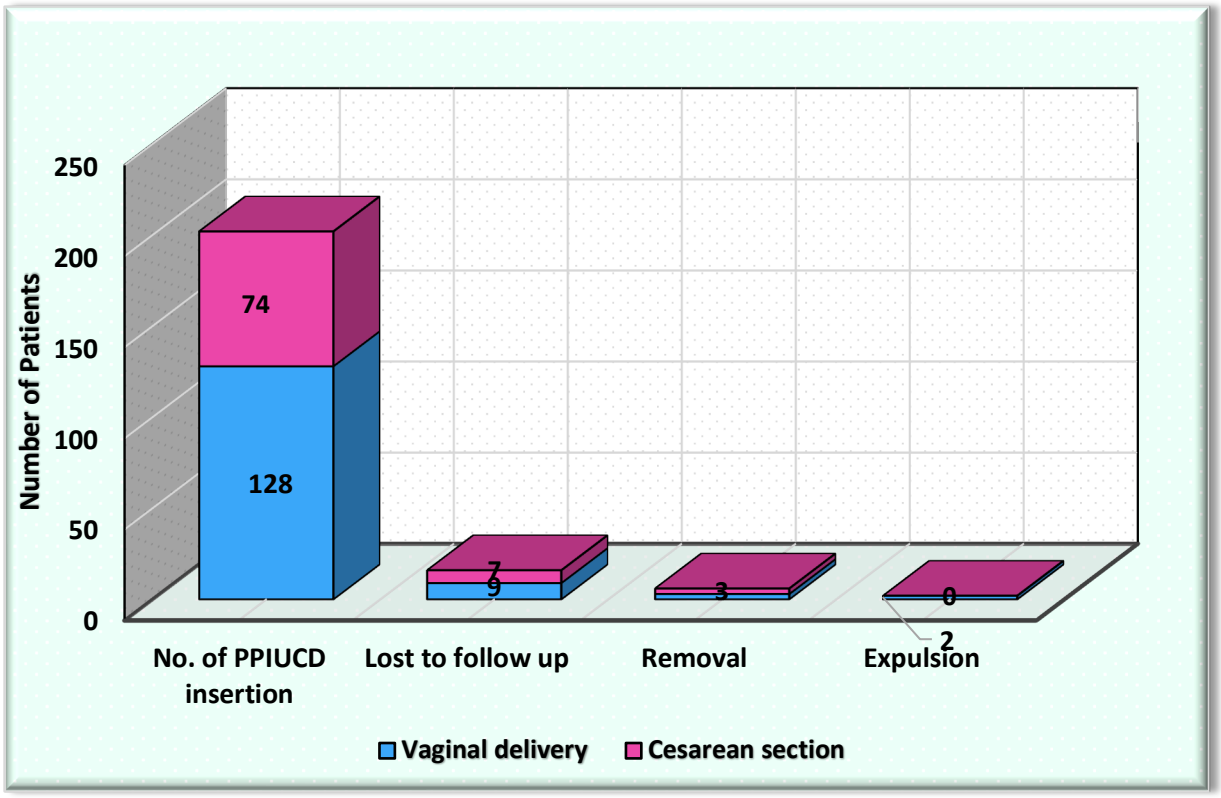

Figure 3: Expulsion rate and Continuation rates of PPIUCD between 6 weeks to 6 months in vaginal and intra cesarean insertion group

Discussion

The global challenge of population explosion, particularly in third-world countries, necessitates robust family planning measures to curb its impact on maternal and child health. The post-partum intrauterine contraceptive device (PPIUCD) emerges as a pivotal, safe, effective, cost-efficient, long-term, and reversible alternative, especially in countries like India where childbirth might be the only healthcare encounter for women.

In our study, a significant proportion of women in the 21-29 age group, with at least primary education, demonstrated a higher acceptance of PPIUCD, aligning with findings from Mishra et al. [12], Anjali et al.[13] , Gunjan Goswamy et al. [14], and Vidyaramana et al.[15]. Educational status consistently emerged as a crucial factor influencing PPIUCD acceptance, echoing the broader impact of education on healthcare decision-making [8,16,17].

Multiplicity emerged as a prevailing factor in PPIUCD acceptance, particularly in our setting where slum-dwelling, low-literacy populations displayed higher acceptance rates among multiparous women (80%). Religious and socio-cultural factors, especially among Muslim communities, played a role in this observation, resonating with similar findings in studies conducted by Shukla et al.[18], Celen et al. [19], and Kittur et al.[20]. However, with strategic antenatal and intrapartum counseling, there is potential to shift this trend and encourage PPIUCD acceptance among primiparous women for better birth spacing.

Contrary to some studies, Sharma N et al [21], Chaudhari P et al.[22] and Kant S et al.[23], our findings indicated a higher acceptance rate among women undergoing vaginal delivery, challenging the conventional belief that acceptance is higher in the cesarean delivery group.

This suggests the need for tailored counseling based on the mode of delivery.[24] Maharashtra's acceptance rate of 35%, surpassing the national average of 20%, highlights the impact of education and counseling, emphasizing the role of regional context in PPIUCD acceptance.[25] The low expulsion rates (0.9%) in our study, in contrast to Mishra et al.'s findings (83), may be attributed to our meticulous insertion technique, ensuring fundal placement. However, the high decline rate (85%) underscored prevailing myths and misconceptions, with a majority citing a preference for other contraceptive methods (33.1%). Adequate counseling, therefore, emerges as a critical intervention to dispel myths and address concerns surrounding PPIUCD.[20,21,26]

Safety outcomes were favorable, with no serious complications noted. The absence of uterine perforation, infections, and limited menstrual disturbances reinforces PPIUCD's safety profile.

Lower abdominal pain and menstrual disturbances emerged as the primary reasons for removal, reflecting findings in many other studies [27–30].

The continuation rates at 6 weeks (98%) and 6 months (88%) were encouraging, emphasizing the method's sustained effectiveness. Vidya ramana et al.'s study also observed high follow-up rates (93%)[31]. The minimal expulsion and removal due to complications further support PPIUCD's efficacy in real-world scenarios [17,29,32].

In conclusion, our study underscores the pivotal role of education, tailored counseling, and partner involvement in promoting PPIUCD acceptance. Addressing myths and ensuring proper insertion techniques enhance safety outcomes. While challenges persist, PPIUCD emerges as a promising strategy for postpartum contraception, offering a balance between safety, effectiveness, and long-term usability. Further research and advocacy efforts are warranted to integrate PPIUCD seamlessly into family planning programs, especially in resource-constrained settings.

Conclusions:

Post Placental Intra Uterine Contraceptive Device (PPIUCD)-CuT380A emerges as a safe and effective long-term contraception option, offering advantages over invasive permanent methods. Integration with national health programs, particularly in rural areas, could enhance awareness and acceptance. Education and training for ground-level health workers are crucial, along with targeted antenatal and postpartum counseling. The study noted higher acceptance among educated women and those undergoing vaginal delivery, with an overall acceptance rate of 15%. Despite a relatively low acceptance rate, the high continuation rate and minimal expulsion emphasize PPIUCD's safety, efficacy, and patient acceptability as a postpartum contraceptive method. Limitations of the study include the study's focus on a tertiary center, potentially limiting generalizability, and a cohort with higher education levels than the broader population.

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