

A Comparative Interventional Study To Determine The Side Effects Of Continuation And Discontinuation Among Women Using IUCD And DMPA Contraceptive

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ABSTRACT

India's National Family Planning Programme has evolved with a shift in focus from merely population control to more critical issues of improving the health of mothers and children through use of reversible spacing methods leading to reduction in closely spaced and unintended pregnancies and chances of unsafe abortions. A total of 105 women used DMPA and 105 women used IUCD as contraception in our study period. This study was conducted within our routine contraceptive services to compare proportion of women discontinuing the contraceptive method, and reasons for discontinuation, and adverse effects of the injectable method with that of copper T 380A (IUCD). In our study, 77.14% and 65.71% women used IUCD and DMPA respectively and were in 21-30 years of age. The mean age of patients was higher in DMPA with 29.34 year of age. Both the groups conferred statistical significance with p-value=0.0003, t-value=3.688 and degree of freedom was found to be 208. The frequency of acceptance to IUCD was 74.29% and DMPA was 69.52%, similarly, 30.48% and 25.71% of women declined the usage of DMPA and IUCD respectively. However, due to irregular bleeding, 44.45% and 40.63% of women discontinued using IUCD and DMPA respectively. This study concludes that, patients used IUCD and DMPA did not have any serious adverse consequences after using these contraceptive methods. Hence we recommend these methods to be safe and efficient to practice.

Key words: Intra Uterine Contraceptive Device, Depot Medroxy Progesterone Acetate, Contraception, Side effects, Continuation, discontinuation

INTRODUCTION

India has made considerable progress in reducing maternal mortality ratio, it still contributes 17% of maternal deaths globally, according to a 2012 report of World Bank, UNFPA, WHO. Family Planning can avert more than 30% of maternal deaths and 10% of child death if couples spaced their pregnancies more than 2 years apart.¹

Intra Uterine Contraceptive Device (IUCD) is highly effective, safe, reversible, long-acting and coital independent method of contraception with relatively low side effects. These devices are popular the method of contraception available at present due to their safety, efficacy, coitus independent and rapidly reversible nature.² In intra uterine contraceptive

device users, the relative risk for infection rate is 0.15-0.30%. The infection rate is very high for the initial 20 days of insertion. It is mainly due to infection with gonorrhoea or Chlamydia.³

Another reversible method of contraception added to basket of choices for contraception by government of India is Depot Medroxy Progesterone Acetate [ANTARA] which is also effective with long term contraceptive benefits. Convenient and easy to use (does not require daily administration). It acts for 3 months with a grace period of 4 weeks and completely reversible in 7-10 months from date of last injection.³

DMPA is an appropriate long acting contraceptive method suitable in majority of the women. It has also some limitations like it does not protect against STI/RTI and HIV infection. Return of fertility takes 7-10 months from date of last injection (Average 4-6 months after 3 months effectively of last injection is over).⁴ Side effect includes irregular bleeding, weight gain, decrease bone mineral density and headache. With a standard regimen, the first year effectiveness is 99.7%. The failure rate of DMPA is 0.3% is lower in comparison to 0.5% of female sterilization, 0.8% of IUCD and 3% of combined oral contraceptives.¹

It is necessary to determine the complications and reason for discontinuation of contraception to find ways to improve utilisation of contraception. Contraceptive discontinuation can be “active,” as when a woman needs to visit a clinic to have her IUD removed, or “passive,” requiring no extra effort, such as when an appointment for a re-injection is missed or forgotten, or a pill prescription is not re-filled.⁵ Proper counselling of method increases women adherence to method and acceptability. Acceptance of family planning methods are influenced by a variety of interrelated factors such as age at marriage, education, sociology-economic status, religion, number of living children. Proportion of couples using any method of contraception is found to be increased as the level of education and socio - economic status improves. It is not surprising that unmet needs still continue to be high with an overall unmet need of 13%, while in states like UP, Bihar and Jharkhand it continues to be over20%. This indicates that a large number of couples are unable to get the services to meet the needs.⁶

Contraceptive use continuation, switching and failure are important markers of how well programmes are meeting the family planning needs of women and couples. These methods are highly effective, safe for most women, cost effective and require little effort on the part of user. According to Indian incidence of abortion and unintended pregnancy survey conducted in 2015, approximately 2, 30, 88,000 pregnancies were intended. Unintended pregnancies can have many undesirable consequences. Unintended pregnancy is a strong indicator of the need for improvement in contraceptive services.⁷

This study conducted within our routine contraceptive services to compare proportion of women discontinuing the contraceptive method, and reasons for discontinuation, and adverse effects of the injectable method with that of copper T 380A (IUCD).

MATERIALS AND METHODS

Present study is a non-randomised comparative interventional study conducted at the Department of Obstetrics and Gynaecology, Umaid Hospital, Dr. S. N. Medical College Jodhpur for a period of one year.

INCLUSION CRITERIA: Women attending OPD in Umaid hospital who desire to use either Cooper T 380A or injectable DMPA for contraception, should be in age group of 18-45 year, with Hb >9gm%, Sexually active, non-pregnant, do not have desire of pregnancy within 12 months, given birth to one live baby, whose menstruation cycles are regular normal flow.

EXCLUSION CRITERIA: Women found to have heart disease, liver and kidney disease through her previous clinical records and history. Patients with previous allergic reaction to IUCD/injectable DMPA.

SAMPLE SIZE

Sample size was calculated at 95% confidence interval and 10% relative allowable error using the formula for sample size for estimation of a single sample proportion

$$N = \frac{(Z_{1-\alpha/2})^2 P (1 - P)}{E^2}$$

Where,

$Z_{1-\alpha/2}$ = standard normal deviate for 95% confidence interval (taken as 1.96)

P = Expected proportion of method discontinuation among contraceptive user either IUCD or injectable DMPA (taken as 15% as reported by Hofmeyer et al)

E = Relative allowable error (taken as 7% of P)

Sample size was calculated to be 105. Therefore, 105 are IUCD users and 105 are injectable DMPA users were included in this study.

METHODS OF COLLECTION OF DATA

The participants would be those who attended family planning clinic for contraception and meeting inclusion criteria. Participants were selected consecutively. All participants who were eligible were counselled in their native language and offered them contraception. Informed and written consent was taken from all the participants.

Discontinuation rate was defined as the proportion of women who did not continually use the allocated method in follow up period of 6 months out of women initiating the allocated method in follow up period of 6 month.

We measured weight of participant on a digital scale that was accurate to the nearest 0.1 kg. Weight was taken at 6week, 3month and 6 month from the date of using either IUCD or injectable DMPA during the follow up period. Height was calculated with wall audiometer that was accurate to the nearest 0.001 m.

Bleeding analysis: Participants record their bleeding pattern in diaries at the end of each day using a five point scale : 0- no flow , 1- minipad or no protection required ,2- bleeding less than usual (require sanitary pad),3- bleeding approximately same amount as usual, 4- bleeding more than usual. Number of days of menstruation cycle and Number of pads/ day used should be noted in their diaries at the end of the day of each cycle. Concepts and definitions used for measuring clinically important bleeding pattern changes.

REFERNCE PERIOD: Two 90-day periods based on day of initiating used method either IUCD or injectable DMPA.

BLEEDING OR SPOTTING DAY: 0-90days, 91-180days: Any single day when bloody discharge was recorded on the menstrual diary.

NORMAL PATTERN: Neither amenorrhea, infrequent bleeding, frequent bleeding or irregular bleeding.

NO BLEEDING: No days of bleeding/spotting entered throughout the reference period

PROLONGED BLEEDING: At least one bleeding/spotting episode lasting 10 days or more days.

FREQUENT BLEEDING: More than or equal to 4 bleeding/spotting episodes in one 90 day reference period

INFREQUENT BLEEDING: Less than 2 bleeding/spotting episodes in one 90 day reference period

IRREGULAR BLEEDING: A range of varying lengths of bleeding –free intervals more than 17 days within one 90 day reference period

RESULTS

In this study, maximum women were between 21-30 years age group, i.e., in IUCD group 81/105 (77.14%) and in DMPA group 69/105 (65.71%) (Table1).

It was observed that 78 out of 105 (74.29%) women from IUCD group and 73 out of 105 (69.52%) women from DMPA group accepted the chosen method (Table 2). Acceptance was more in IUCD users as no repeat visit required for the women using IUCD.

In our study, It was observed that major reason for decline in IUCD (44%) and DMPA (40%) user was irregular bleeding. Other reasons for discontinuation of IUCD were infection (14%), expulsion (14%), and weight gain (3%). Other reasons for discontinuation of DMPA were weight gain (37) % and amenorrhea (9%) (Table 3).

Average mean weight gain was also analyzed in women from IUCD (0.231±0.285 kg) and DMPA (0.442±0.365 kg) groups. A highly statistical significance was observed with p-value=0.0001, t-value3.981 (Figure 1).

Table 1: Age wise distribution of women in IUCD and DMPA users

Age group	IUCD	Percentage	DMPA	Percentage
18-20 years	6	5.71%	0	0%
21-30 years	81	77.14%	69	65.71%
31-40 years	17	16.19%	34	32.38%
41-50 years	1	0.96%	2	1.91%
Total	105	100%	105	100%

Table 2: Continuation of Method

Continuation of method	IUCD	Percentage	DMPA	Percentage
Decline	27	25.71%	32	30.48%

Acceptance	78	74.29%	73	69.52%
Total	105	100%	105	100%

Table 3: Reasons for discontinuation between IUCD and DMPA users

Reasons for discontinuation	IUCD	Percentage	DMPA	Percentage
Irregular Bleeding	12	44.45%	13	40.63%
Infection	4	14.81%	0	0
IUCD expulsion	4	14.81%	0	0
Weight gain	1	3.70%	12	37.5%
Amenorrhea	0	0	3	9.37%
No reason	6	22.23%	4	12.5%
Total	27	100%	32	100%

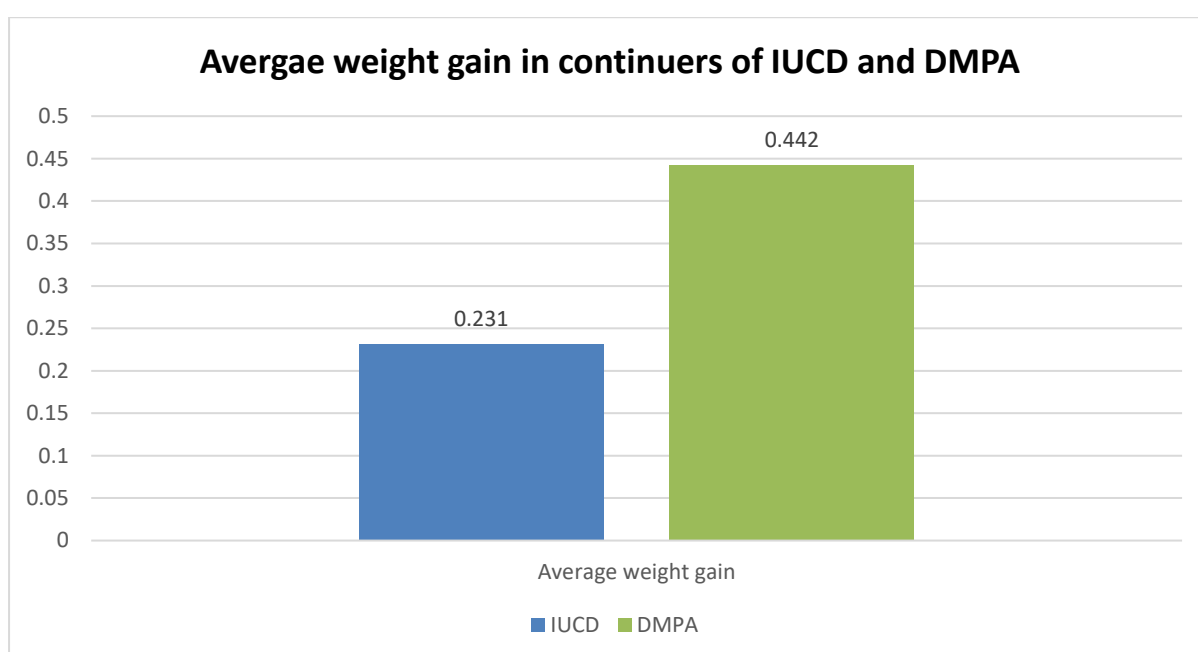


Figure 1: Average weight gain in IUCD and DMPA users

DISCUSSION

This study was conducted in the department of obstetrics and gynaecology, Ummaid hospital Jodhpur, aimed to evaluate and compare the menstrual irregularities, weight gain, and discontinuation of method in DMPA and IUCD users. A total of 105 cases were included in our study in each group (IUCD and DMPA).

Maximum number of patients preferred IUCD (77.14%) over DMPA (65.71%) having age between 21-30 years than other age groups. It was because repeat visits were not required for IUCD, does not cause significant weight gain and no delay in return of fertility. In the study done by M. Beksinka R et al,⁸ 63% are IUCD user and 64% are DMPA users. In the study done by Sugata kumar Burman et al⁹ in which 60% are IUCD users and 60.4% are DMPA users.

In our study, amenorrhea was observed in 9% women using DMPA. In the study done by Suvarna et al, amenorrhea was common with 10% to 30% of DMPA users within the first 3 months, 50% by the first year, and 80% by 5 years.¹⁰ Irregular bleeding pattern was observed in 28% IUCD users and 25% DMPA users. In the study conducted by Shilpa MN et al, nearly half of the DMPA users had irregular bleeding.¹¹

Our study results showed that 74% women from IUCD group and 69% from DMPA accepted the chosen method. This was supported by a cross-sectional study done by Jairaj S et al, where 67.12% majorly accepted the IUCD procedure and shared an opinion that IUCD is a reversible method.¹² The acceptance rate was also supported in another study performed by Kant S et al, overall acceptance rate among the eligible women for PPIUCD was 39%.¹³ Similarly, in our study, we observed discontinuation for DMPA method, which could be due to side effects on prolonged usage.¹⁴ O'Neil-Callahan ME et al, reported that, the continuation rate at 12 and 24 months (43% and 28%) of follow-up were lower for DMPA users from the US-based CHOICE study (58 and 38%).¹⁵ Veisi F et al¹⁶, in his study reported important side effects of DMPA as irregular bleeding (93.60%), weight gain (48%), bone pain (24%) and vaginal dryness (10.40%). Similar results were found in a study by Nautiyal R et al., where menstrual disturbances were the main reason for discontinuation of DMPA.¹⁷ Pre-use counselling was essential tool to minimize the effect of menstrual change which occurs in most of the patients.¹⁸

The mean average weight gain was significant and higher in DMPA in our study. An early collaborative study of DMPA use among 3857 women in the USA reported a mean weight gain of approximately 2.3 kg after 1 year, 3.7 kg after 2 years, and 6.3 kg after 4 years (Schwallie and Assenzo 1973).¹⁹ Another early trial among 138 women in Calcutta reported mean weight gains above 4.0 kg at 1 year and above 6.0 kg at 2 years (Mukherjee et al.1980). A WHO multicenter phase-III clinical trial of DMPA reported a mean weight gain of 1.5 kg per year (WHO 1986).²⁰ In a 36-month longitudinal study of 703 contraceptive women found that DMPA users had a 5.1 kg weight gain compared to 1.5 kg gain among oral contraceptive users ($p<.001$) and 2.1 kg gain among non-hormonal contraceptives users ($p<.001$). In addition, DMPA users had a greater increase in total body fat and percent body fat.²¹

CONCLUSION

Contraceptive induced bleeding was the most common reason of discontinuation encountered among DMPA and IUCD users. Pre-use counselling regarding expected menstrual bleeding pattern changes and regular follow up are crucial to increase the acceptance and complications of long acting contraception. Discontinuation rates with the IUCD were comparable with DMPA users suggesting that efforts for increased use of long acting contraceptive as birth spacing method are worthwhile.

We found average weight gain in DMPA users during follow up. Women using DMPA should be counselled about this side effect when choosing a contraceptive method. In our study, IUCD preferred over DMPA as repeat visit not required by women, doesn't causes significant weight gain and no delay in return of fertility.

We hereby conclude that, patients used IUCD and DMPA did not had any serious adverse consequences after using these contraceptive methods. Hence we recommend these methods to be safe and efficient to practice.

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