

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20242065>

Original Research Article

Depot medroxyprogesterone acetate injection as contraceptive method

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Received: 24 April 2024

Revised: 11 July 2024

Accepted: 15 July 2024

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ABSTRACT

Background: Depot medroxyprogesterone acetate (DMPA) injection is a reversible longer acting contraceptive method. One injection every three months makes compliance better and lesser side effects makes this contraception acceptable.

Methods: This is a prospective study done at our institute between July 2021 to September 2023. After prior approvals, each patient of study group had been given Inj. DMPA 150 mg intramuscularly at the time of enrolment. They were given DMPA every 3 months. All participants were followed for efficacy, side effects and continuation rates.

Results: Out of 104 participants, 49.05% belonged to 18-25 years of age group, 36.53% were 2nd paras and 41.35% took injections post-delivery. In this study 51.92% patients took ≥ 4 injections where as 45.19% discontinuation rate was found at the end of 1 year. Irregular bleeding seen in 50.96% was the most common side effect. 40.42% of total drop out was due to irregular bleeding. Efficacy of DMPA was found to be 100% in this study.

Conclusions: The study concludes that DMPA is a preferable contraceptive method in all the groups of patients for spacing and to avoid unplanned pregnancy. Education and socio-economic factors play key role in acceptance and continuation of DMPA. Menstrual irregularities were found to be most common cause of discontinuation. Use of DMPA has no permanent impact on fertility and it was found to be a safe alternative method with no deleterious effect on mother's milk secretion in lactating participants. It is reversible, non coitus dependent and long acting.

Keywords: Continuation rate, Contraception, DMPA

INTRODUCTION

Contraception is the use of artificial methods or other techniques to prevent pregnancy because of sexual intercourse. An ideal contraceptive should suit an individual's personal, social, and medical needs. The high rate of unintended pregnancies and relatively higher failure rate with typical use of reversible method of contraception are strong indications for the use of long-acting contraception like inj. DMPA, IMPLANTS etc. DMPA has been part of contraceptive programs of many countries for more than 25 years. It is proven to be safe, effective, reversible and acceptable. In 1956, Medroxy

progesterone acetate was discovered by Syntex and the Upjohn Company.³ In 1992, FDA approved use of intramuscular DMPA as a long-acting contraceptive under the brand name Depo-provera (150 mg/ml MPA) after the publication of reassuring World Health Organization (WHO) studies regarding gynecological cancer risk. It is now a widely used contraceptive and is approved for use in more than 130 countries.² In June 1993, DMPA was approved by the Drug Controller General of India (DCGI) for marketing and use as an injectable contraceptive method. Rodrigues MI et al in 2009 reported safety of immediate depot medroxyprogesterone acetate (DMPA) use in lactating postpartum women.³ In 2016, Under the

National Family Planning program, DMPA injectable contraceptive have been added to the basket of contraception as ANTARA.⁴ Following study has been done to establish safety, efficacy, acceptance and continuation rate in reproductive age group patients. Injectable Contraceptive (DMPA) is an aqueous suspension of microcrystal for depot injection of pregnane 17 alfa – hydroxyprogesterone – derivative progestin medroxyprogesterone acetate. DMPA is a progestin-only, long-acting reversible injectable method of birth control can be given via 2 routes: (1) Intramuscular DMPA: It is 1 cc crystalline suspension of 150 mg depomedroxyprogesterone acetate that is injected intramuscularly (IM) every three months. (2) Subcutaneous DMPA: Prefilled auto disable syringe in Uniject system (squeezing bulb pushes the fluid through the needle).⁵ It is low dose 104 mg of medroxyprogesterone acetate in a 0.65 ml solution that is injected Subcutaneously (subQ) every three months.

Mechanism of action

Injectable DMPA inhibits follicular development and prevent ovulation as their primary mechanism of action. The progesterone decreases the pulse frequency of (GnRH), which decreases the release (FSH) and LH leading to inhibition of follicular development, preventing an increase in estradiol levels.^{6,7} Thickening of cervical mucus - due to depletion of oestrogen and thinning of endometrial lining - due to high progesterone and depleted oestrogen adds to its contraceptive action.^{8,9}

METHODS

Study type

The type of study was prospective, interventional, longitudinal and a single centered study done at our institute Ananya College of Medicine and Research, Kalol, Gandhinagar, Gujarat.

Study method

Prior approval to conduct the study was taken from the Head of the unit and concerned authorities and then patients were enrolled in the study. Each patient of study group had been given Injection DMPA 150 mg intramuscularly at the time of enrolment. According to inclusion criteria, they were given DMPA every 3 month. The study was conducted for a total duration of 27 months from July 2021 to September 2023. The cases enrolled in the study during initial 12 months and each case was followed up approximately for a period of 15 months thereafter on the OPD basis.

Inclusion criteria

We have included Female patients age 18 years above in post-partum periods (at 6 weeks) or post abortal period(immediately) or other normally menstruating

women (non-postpartum, non-post abortal) desiring contraception. Patients included in study should not be suffering from any chronic illness or having any Contraindication to Progesterone. We have only included those patients who have given a written informed consent and willing to report for regular follow up and Patients desiring long-term, highly efficacious, non-coitus dependent, private contraceptive method.

Exclusion criteria

Patients who did not consent for enrolment or regular follow up were excluded from the study. In addition to that post-partum patients of less than 6 weeks duration were also excluded. Patients with unexplained vaginal bleeding, breast cancer, history of myocardial infarction, ischemic heart disease or stroke, cirrhosis (severe-decompensated), liver tumours-adenoma or hepatoma, hypertension (>160 systolic or >100 diastolic), diabetes with nephropathy/ retinopathy/ neuropathy, antiphospholipid antibodies, and severe thrombocytopenia, rheumatoid arthritis-immunosuppressive therapy, and migraine with aura at any age were also excluded. Women were counselled and a detailed physical and gynaecological examination was done. Inj. DMPA 150 mg was given deep intramuscular in the upper lateral gluteal region using 23–24-gauge needle after explaining them about the whole procedure. They were instructed about post inj. care and follow up procedure. All women were followed-up for 16 months after the first injection for pregnancy rate, side-effects, discontinuation, and patient satisfaction. Every time they came for their appointments, they were asked general questions like effect of DMPA in their sexual life, menstrual irregularities weight gain, milk secretion and about the symptoms to rule out pregnancy to rule out failure of DMPA. A total of 104 women who were included in the study over a period of 27 months and data of their follow-up visits were noted subsequently. The collected data was represented as graphs, tables, and charts in following section. Data were analysed using SPSS data analysis software. Data from our study was compared to other reference studies. The following data was obtained from present study.

RESULTS

Part 1 of Table 1 shows age and parity distribution among DMPA users. Majority of patients 51 (49.05%) belonged to 18-25 years age group while 42 patients were in the age group of 26-35 years where as 11 (10.57%) were more than 35 years of age. Above given table shows maximum number of patients studied were in age group of 18-25 (49.05%), because of prevailing custom of early marriages in our society. Part 2 of table 1 shows number of patients as per their parity. No nulligravida was offered this contraceptive method as method for birth spacing. Maximum of the woman recruited in this study, 38 were 2nd para (36.53%), 8 (7.96%) patients were nulliparous, 10 (9.61%) were primiparous, 27 (25.96%) patients were 3rd para, 16 (15.38%) were 4th para and 5 (4.80%) patients

were >4th para. Most of the women 86 (82.69%) had 2 or more children, thus had completed their family size.

Table 1: Age and parity distribution of patients (n=104).

Characteristics	No. of patients	Percentage
Age (Years)		
18-25	51	49.05%
26-35	42	40.38%
>35	11	10.57%
Parity		
Nulliparous	8	7.96%
Primipara	10	9.61%
2 nd para	38	36.53%
3 rd para	27	25.96%
4 th para	16	15.38%
>4 th para	5	4.80%

In present study, out of 104 Patients, 43 (41.35%) patients were post-partum when they took 1st dose of injection and 33 (31.73%) took it post abortal.

Table 2: Time of injection (n=104).

Time of injection	No. of patients	Percentage
Post delivery (at 6 weeks)	43	41.35%
Post abortal	33	31.73%
Others - B/W day 2-day 7 of menses (non post partum non post abortal subjects)	28	26.92%

In present study out of 104 patients recruited in the study, 57 took 4 or more injections, and continued in the study for more than 1 year. In our study, out of total 38 2nd para patients 27 continued for 4 or more injections and remained in the study for 1 year. (continuation rate for 2nd para = 71.05%). Out of 27 involved 3rd para patients 11 had taken 4 or more injections. (continuation rate for 3rd para = 40.74%). In present study comparatively higher continuation rate was seen in 2nd para and 3rd para patients, as these patients had already completed families and they use DMPA as alternative to permanent sterilization method. Out of 25 total patients enrolled with secondary education, 13 continued for 4 or more injections. (continuation rate = 52%). Total 19 graduates were included in the study out of which 16 took 4 or more injections. (continuation rate = 84.21%) Comparatively higher continuation rate was seen in patients having higher education as they were easily counselled about side effects and necessity of regular follow up. Out of 10 patients from upper class, 7 had taken 4 or more injections and continued using DMPA for more than 1 year. Almost half of the patients from lower socioeconomic class left the study earlier than rest of the patients, as they preferred to use

natural contraceptive methods, lack of knowledge, less likely to take decision regarding contraceptive use.

Table 3: Continuation rate (4 or more injections) in relation to parity, education, and socio-economic status (n=57).

Socio-demographic factors	No. of patients enrolled in the study	No. of patients took 4 or >4 injections
Parity	Nulliparous	8
	Primipara	10
	2 nd para	38
	3 rd para	27
	4 th para	16
	>4 th para	5
	Total	104
Education	Illiterate	23
	Primary	37
	Secondary	25
	Graduates	19
	Total	104
Socio-economic status	Upper	10
	Middle	36
	Lower	58
	Total	104

Table 4: Side effects of DMPA

Side effects	No. of patients	Percentage
Amenorrhea	31	29.8%
Irregular bleeding	53	50.96%
Heavy bleeding	7	6.73%
Scanty menses	8	7.69%
Weight gain	10	9.61%
Mood changes including anxiety	6	5.76%
Headache and others (backache, erythema nodosum, dyspareunia)	9	8.65%
No problem	15	14.4%

In present study irregular bleeding was most common side effect seen in 53 (50.96%) patients. Another major side effect observed was amenorrhoea seen in 31 (29.8%) patients. Irregular bleeding was more common with initial 2-3 injection, gradually it subsided. In present study it was seen in approximately in 50.96% of patients. In present study, weight gain noted in 10 patients over 1-year, other side effects were headache, backache, dyspareunia, erythema nodosum in 9 patients. Menorrhagia which was common with first and second dose of injectable was reported by 7 patients in our study. It was managed with tablet of tranexamic acid (500 mg) along with iron tablets. Though these effects are self-limiting. It is established that pretreatment counselling on expected side effects and their

management improves acceptability of DMPA. Pretreatment counselling of the couple can further improve DMPA acceptability.

Table 5: Reason for drop out from the study (n=47).

Reason	Present study no of patients (n=47)	Percentage
Irregular bleeding	19	40.42%
Heavy bleeding	4	8.51%
Amenorrhea	5	10.63%
Husband's insistence	4	8.51%
Husband away	6	12.00%
Weight gain	2	4.25%
Tubectomy	2	4.25%
Plan conception	5	10.63%

In present study out of 47 patients who dropped out of study, Irregular bleeding PV was main reason for discontinuation of DMPA contributed to 19 (40.42%) of total drop out. In our study out of total 104 patients' amenorrhea was observed in 31 patients. Among them 5 (10.63%) patients left study as they believed that their normal menstrual cycle regularity was essential for them, others 26 patients agreed with counselling and found it beneficial. Other causes responsible for discontinuation were, heavy bleeding in 4 (8.51%) patients, husband insistence in 4 (8.51%) patients and Husband living away in 6 (12%) patient's cases. 2 (4.25%) patients underwent permanent sterilization and 5 (10.63%) patients left study because they wanted to plan conception. In present study out of 47 patient who discontinue DMPA before 1 year, 14 patients conceived. They were studied for return of fertility. 6 patients conceived in 6-12 months of last DMPA injection, 4 patients conceived within 6 months of last injection, 4 patients conceived after 12 months of last injection. The number of injections did not affect the return of fertility. Women can conceive as early as within 4-6 months after last DMPA injection. In present study out of 43 postpartum women 40 (93.02%) were satisfied with their lactation, 3 (6.97%) women were not satisfied.

Most studies have shown an increase or no effect on milk volume, without any effect on quality of breast milk in terms of nutrition. Out of 104 patients 27 (25.96%) patients said they would recommend because of convenience and privacy and another 26 (25%) patients recommend it because lack of daily intake like combined pills and 27 (25.96%) patients recommend DMPA method as it is coitus independent. 19 (18.26%) patients preferred it for the non-contraceptive benefit like reduction in dysmenorrhea, premenstrual symptoms etc. 5 (4.80%) patients preferred DMPA because of Amenorrhea. Out of 104 patients involved in the study, no case of pregnancy reported in patients on DMPA injection. Effectivity of the DMPA in the study is 100%

DISCUSSION

Out of 104 patients, Majority 51 (49.05%) patients were in the age Group of 18-25 years while 42 (40.38%) patients were in the age group of 26-35 years where as 11(10.57%) were of more than 35 years of age. Out of 104 patients, majority of patients 38 (36.53%) were 2nd para and 8 (7.96%) patients were nulliparous, 10 (9.61%) patients were Primi para, 27 (25.96%) patients were 3rd para, 16 (15.38%) patients were 4th para and 5(4.80%) patients were >4th para where as in Rai L et al study percentage of multiparous patients were 27%, while primipara were 73%.¹⁰ In Fonesca et al and Nautiyal et al studies number of multiparous patients were more than primipara patients which is comparable to our study.^{11,12} In present study out of 104 patients, 43 (41.35%) patients took injection post-delivery at 6 weeks, 33 (31.73%) patients took it post abortion immediately and 28 other (normally menstruating, non-postpartum non post abortal) patients took it between day 2 to day 7 of menses. Maximum number of patients belonged to postpartum group which is comparable to Rai L et al study.¹⁰ In present study out of 104 patients, 57 (51.92%) patients took 4 or more injection, remained in the study for >=1 year. 16 (15.38%) patients took only one injection and left the study. In present study, out of 38 2nd para patients involved in the study, 27 patients had taken 4 or more injections and continued in the study for the year or more (continuation rate of 2nd para=71.05%). out of 27 3rd para patients involved in the study 11 patients had taken 4 or more injections and continued for more than 1 year. (continuation rate of 3rd para = 40.74%). Out of 25 patients having secondary level of education involved in the study 13 patients had taken 4 or more injections and continued for the year or more (continuation rate = 52%). out of 19 graduate patients involved in the study 16 patients had taken 4 or more injections and continued for the 1 year or more continuation rate 84.21%).

Rai L et al study was conducted in area where literacy rate is quite high, so they had major study subjects(nearly70%) educated above secondary level while Nautiyal et al study was conducted in rural to semi urban camp setting nearly 50% patients had education level of primary level which was very low. Out of 10 patients from upper class 7 patient continued using DMPA for 1 year or more. (continuation rate-70%) Discontinuation rate at one year in our study was 45.19% which is comparable to other studies.^{10 11} This rate was found to be on higher side in Aktun et al (discontinuation rate 70%) study whereas Nautiyal et al study had lower discontinuation rate of approximately 32%.^{12,13} In present study irregular bleeding was most common side effect seen in 53 (50.96%) patients (which is comparable to Rai L et al study and Fonesca et al study), amenorrhoea seen in 31 (29.8%) patients, weight gain noted in 10 (9.61%) patients over 1 year, mood changes in 6 (5.76%) patients other side effects were headache, backache, dyspareunia, erythema nodosum seen in 9 patients.^{10,11} In present study out of 47 patients who dropped out study, Irregular bleeding P.V contributed to

19 (40.42%) patient's drop out which is comparable to Rai L et al study, amenorrhea contributed 5 (10.63%) patient's drop out, heavy bleeding accounted for 4 patient's drop out, 4 patients left study because of husband insistence, 6 patients left study because husband was away.¹⁰ 2 patients had undergone permanent sterilization and 5 patients left study because of planning conception. In present study out of 47 patients who discontinued DMPA 14 patients conceived, 6 patients conceived in 6-12 months of last DMPA injection, 4 patients conceived within 6 months of last DMPA injection and another 4 patients conceived after 12 months of last DMPA injection. In present study out of 43 postpartum women 40 (93.02%) were satisfied with their lactation, 3 (6.97%) women were not satisfied. Out of 104 patients 27 (25.96%) patients said they would recommend because of convenience and privacy and another 26(25%) patients recommend it because lack of daily intake like combined pills and 27 (25.96%) patients recommend DMPA method as it is coitus independent. 19 (18.26%) patients preferred it for the non-contraceptive benefit like reduction in dysmenorrhea, premenstrual symptoms etc.¹⁴ 5 (4.80%) patients preferred DMPA because of Amenorrhea. It is established that pretreatment counselling on expected side effects and their management improves acceptability of DMPA.¹⁵⁻¹⁷ Out of 104 patients involved in the study, no case of pregnancy was reported in patients on DMPA injection. Effectivity of the DMPA in the study is 100%.

CONCLUSION

The study concludes that DMPA is a preferable contraceptive method in all the groups of patients including postpartum and post abortal patients for spacing and to avoid unplanned pregnancy with 100% effectivity. DMPA has higher acceptance and continuation rate in multipara women who fear to use permanent sterilization or IUCD as per their religious and cultural beliefs and as an alternative to permanent sterilization. Education and socio-economic factors play key role in acceptance and continuation of DMPA. Women having higher education and belonging to upper socio-economic class tend to be more compliant to DMPA. Menstrual disturbance was major side effect associated with DMPA use. Pretreatment counselling on expected side effects and proper treatment of side effects helps in better continuation of DMPA. Use of DMPA has no permanent impact on fertility. It may cause a delay in the return of fertility, the return of fertility takes 7-10 months from date of last injection, but it is completely reversible. Use of injectable DMPA as a contraception method in the postpartum Period (at 6 weeks) was found to be a safe and effective alternative method with no deleterious effect on mother's milk secretion, milk quality and infant's growth. Patients prefer DMPA because it is non coitus dependent, convenient, long acting, no need of daily use of pill or other methods and because of its other non-contraceptive benefits.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Patel RR, Sheth PN, Mehta AS. Depot medroxyprogesterone acetate injection as contraceptive method. *Int J Reprod Contracept Obstet Gynecol* 2024;13:2030-5.