

Study of Efficacy and Safety of Injection Depot Medroxy Progesterone Acetate In Lactating and Non-lactating Women

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ABSTRACT

Subject: This was a prospective study of efficacy and safety of injection depot medroxy progesterone acetate (DMPA) in lactating and non-lactating women. **Abstract:** The population of India is growing rapidly. The socio-economic problem of overpopulation is too well known. The use of safe and effective contraception is the need of the hour in India. Contraceptive advice is a vital component of good community health. **Aims and Objective:** The present study aims to study the establish safety and effectiveness of injection DMPA as a contraceptive method, acceptance, and continuation rate of injection DMPA in lactating mothers who had received first dose at postpartum period and non-lactating women and study the side effect of injection DMPA. **Methods:** A prospective study was conducted, at J K Lone mother and Child Hospital, Government Medical College Kota, Rajasthan, between April 2019 and April 2020. One hundred women were given injection DMPA 150 mg intramuscularly taken as study group and 100 women not using hormonal contraception were taken as controls group. They were followed at every 3 months. The comparison between the two groups was done using student t-test Chi-square test for calculation of p value. **Results:** The study was conducted to evaluate that women who were used DMPA mean age were 25.35 years. Overall accepted rate is 20%. No effect of literacy on acceptance rate. Significant menstrual irregularity found which was most common reason for attrition. Failure rate was zero among DMPA user. No significant effect on BP, blood sugar, and weight gain. No adverse effect on lactation. **Conclusion:** The study concludes that DMPA is a very effective contraceptive. Women accept it very easily without much degree of motivation. However, side effect decreases compliance.

Keywords: Depot medroxy progesterone acetate, Blood sugar, Weight gain

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INTRODUCTION

Today, as, ever, there is a pressing need for limiting the family size at the personal level and for the control of population at a national level. The need for family planning at personal level has arisen through increased cost of living, scarcity of accommodation, a desire for better education of children in the present competitive world, and an overall desire for an improved standard of living.

The population of India is growing rapidly. The socio-economic problem of overpopulation is too well known. World population is also a major problem with more than 7.8 billion on this earth. At present rates, the population of the world will double in 66 years and that of the United States will double in 75 years. For the individual and for the planet, reproductive health requires careful use of effective means to prevent both pregnancy and sexual transmitted disease.

Definition of Contraception

A method or a system which allows intercourse and yet prevents conception is called a contraception method. This contraception may be temporary when the effect of preventing pregnancy lasts while the couple uses the method but the fertility returns immediately or within a few months of its discontinuation.^[1]

The Choice of Contraception Depends Upon the Following

- Availability, cost
- Age and parity of the couple
- Reliability
- Side effects, contraindications to a particular method
- Advantage and disadvantage
- Requirement of follow-up
- Counseling and allowing the couple to make a suitable choice.

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Although use of contraception is high, a significant proportion of sexually active couple (7.4%) does not use contraception and each year, two of every 100 women aged 15–44 years have an induced abortion. Young women are much likely to experience unplanned pregnancy because they are more fertile than older women and because they are more likely to have intercourse without contraception. An ideal contraceptive should suit an individual's personal, social, and medical needs. Socio-economic factors and education are some of the factors that play an important role in family planning acceptance.

Depot medroxy progesterone acetate (DMPA) is a progestin only method of contraception. It is a 3 monthly intramuscular injectable that delivers 150 mg of medroxyprogesterone acetate in microcrystalline suspension form that delays absorption of the hormone after the injection. It provides long acting effective and reversible contraception.

Aims and Objectives

This study was designed for “Efficacy of DMPA in Lactating and Non-Lactating Women” at J. K. Lone Mother and Child Hospital and Associated Group of Hospitals, Govt. Medical College Kota (Rajasthan).

1. To establish safety and effectiveness of injection DMPA as a contraceptive method.
2. To determine the acceptance rate of injection DMPA in lactating mothers and non-lactating women.
3. To estimate the continuation rate as a contraception up to a year in a lactation and non-lactating patients.
4. To study side effects of injection DMPA.

MATERIALS AND METHODS

Study Design

This is prospective, comparative hospital-based study. The study was conducted in J. K. Lone Mother and Child Hospital, Medical College Kota.

Study Population

The study population included 100 patients who attended family planning outpatient department for contraception including lactating and non-lactating women and 100 patients were taken as control in J.K. Lone Hospital. The cases that fulfilled the inclusion criteria were selected.

Study Period

The study was conducted at J.K. Lone Hospital from April 2019 to April 2020.

Inclusion criteria

The following criteria were included in the study:

- Age 20–35 years
- Lactating women
- Non-lactating women (1st week of menses [5–7 days of last menstrual period])
- Weight 45–65 kg
- Low risk patients
- Patients not suffering from any chronic illness and no contraindication to progesterone.

Exclusion criteria

The following criteria were excluded from the study:

- Age more than 35 years
- High risk patients; medical diseases such as hypertension, diabetes mellitus, obesity, and hemoglobinopathy.
- Unexplained vaginal bleeding, etc.
- Patients who did not consent for enrolment or regular follow-up were excluded from the study
- Breast cancer
- History of myocardial infarction, ischemic heart disease, or stroke
- Cirrhosis (severe-decompensated)
- Liver tumors – adenoma or hepatoma

- Hypertension (>160 systolic or >100 diastolic)
- Other vascular disease or diabetes of >20 years duration
- Anti-phospholipid antibodies, and severe thrombocytopenia
- Rheumatoid arthritis-immunosuppressive therapy
- Migraine with aura at any age.

The present study was a prospective study conducted on 100 women who attended the hospital for contraception in family planning clinic.

Written and informed consent was taken from the patients who enrolled in this study. They will be given option and explained well about the benefits and side effects of each and every contraceptive which can be used. Those who chose DMPA were taken in this study. DMPA 150 mg IM given after explaining them well about how it is better than other method of contraception in restoring their hemoglobin (Hb) level and no effect on their lactation.

All the female were asked to maintain a diary so that they can remember the date of next appointment.

Women were counseled and a detailed physical and gynecological examination will be done. Exclusive breast feeding was strongly emphasized. Blood samples were taken in the fasting state for Hb, lipid profile, blood sugar, and liver function test.

Injection DMPA 150 mg was given deep IM in upper lateral gluteal region. The schedule consisted of injection within day 5 for menstruating women and lactating women. Subsequent injection was given at 3-month interval. All women were followed up for 1 year after the first injection for pregnancy rate, discontinuation, and patient satisfaction.

Side effects of the drug on mother such as headache, dizziness, acne, abdominal bloating, breast swelling, mood changes, alopecia, and weight gain were monitored and asked at each visit. Detailed evaluation of menstrual irregularity such as spotting, irregular bleeding, and menorrhagia was done. Irregular bleeding was graded as mild, moderate, and severe. Mild irregularity was taken as spotting only which is less than women's usual menstrual loss. Moderate bleeding was equivalent to woman's periods. Prolonged and heavy bleeding were considered as severe abnormality. Amount of bleeding was assessed with pictorial blood loss assessment chart score chart. They were evaluated for acceptance or discontinuation of injectable progestogens and reason thereof.

Data were entered into MS EXCEL work sheets version 2007 and analyzed by statistical software, SPSS version 21. $P < 0.05$ was considered statistically significant. Test of significant applied is – Chi-square test for calculation of P value. Descriptive statistics is presented as frequencies, percentages, mean, and bar charts. Pie chart and bar diagram also presented to show difference.

OBSERVATION AND RESULTS

A prospective study was conducted, at J K Lone Mother and Child Hospital, Government Medical College Kota, Rajasthan, between April 2019 and April 2020. A tertiary level teaching hospital and patients consent before joining this study.

A total of 100 women, who were apparently healthy, aged between 20 and 35 years, had lactating and non-lactating (interval) were ready to follow-up and wanted some form of reversible contraception were recruited in this study. Controls consisted of 100 women who were not using hormonal contraception.

RESULTS

Table 1: Age-wise distribution of cases

Age (Years)	Number	%	Mean age
<20	5	5	25.35 year
21–25	52	52	
26–30	34	34	
31–35	9	9	

Distribution of cases in relation to parity		
Parity	Number	%
1	30	30
2	53	53
≥3	17	17
Total	100	100

Distribution of cases according to educational status			
Education	Study group (%)	Control group (%)	P-value
Literate	66	43	0.9999
Illiterate	34	57	
Total	100	100	

DISCUSSION

Birth control methods have been used since ancient times, but effective and safe methods only became available in the 20th century (Hanson, 2010).^[2] Total fertility rate (TFR) of India has been declined from 3.6 to 2.2 (1991–2020) (National Family Health Survey).^[3] The contraceptive has been introduced under Mission Parivar Vikas across 145 districts in seven states that have TFR of more than or equal to 3, with the aim of reducing this to the replacement-level fertility rate of 2.1 by 2025.

The present study was conducted to assess the efficacy and safety of injectable progestogen (DMPA) contraception in lactating and non-lactating women. Because of prevailing custom of early marriage in our society, these were the group of women in reproductive age group, who attended family planning department in our center in large number. Hence, reception to contraceptive counseling was much better. The mean age of women in our study was 25.35 years which was comparable to Rai^[4] and Khan *et al.*^[5] (27 years) Table 1. In congruence with our finding Fonseca^[6] (53.5%), Mishra^[7] (72.66%), and Patel^[8] (54.44%) also found maximum patients in age group between 21 and 30 year. This shows that DMPA usage is more among young females rather than among teenage pregnancies. Teenage mothers tend to fear complications more and are not willing to accept DMPA usage and grand multipara go toward the permanent sterilization.

Parity has a close relationship to acceptance of contraception 53% were Para-2, 30% were primiparas, 17% had three living children, and more than three living children Table 2. In the present study, most of the women had 2 or more children, thus had completed their family size. They chose DMPA as they feared from using permanent sterilization or IUCD as per their religious and cultural beliefs. In primi patients acceptance of DMPA less because of myths associated with DMPA and they rely on absolute breastfeeding and they getting pregnant again. In the present study, better acceptance rates were found in multiparous females.

The perceived side effects of DMPA such as menstrual abnormalities are a frequent reason for discontinuation, and counseling for the same was done in current study.

Education of women had influenced the contraceptive use Table 1. Contraceptive use was shown to be increased as education of women was higher (Aggarwal [2005]).^[9] Nearly 66% of the subjects were high school pass but it was surprising that only 20% of the study population was continued injection DMPA up to 4th injection. It was found that they either relied on lactation

amenorrhea method or nothing. During counseling, the acceptors came up with various myths and misconceptions which were cleared by the counselor.

In our study, maximum patients (64%) were non-lactating Table 2 contrary to other study like Babre *et al.*^[10] None of the patients in the study have complained of decreased lactation. This reiterates that DMPA does not decrease the amount of lactation in a post-natal mother. Guiloff *et al.*^[11] studied progestin-only contraceptives do not impair lactation and, in fact, may increase the quality and duration of lactation. Thus, DMPA represents an appropriate choice for lactating women.

There was no effect of injectable DMPA on the blood pressure of the subjects in the study group Table 2 when compared with control group. Sikha *et al.*^[12] studied no significant rise or fall in BP was observed at 6 weeks, 3 months, and 6 months follow-up. According to the WHO medical eligibility criteria for starting contraceptive method, DMPA can be safely given in women with mild-to-moderate hypertension or in women with history of hypertension where BP cannot be evaluated (including hypertension during pregnancy). However, its use is not recommended in women having severe hypertension >180/110 or arterial disease

No significant rise or fall in blood sugar was observed in the study group as compared to base line values at subsequent follow-up Table 3. All women include in the study group were euglycemic. Furthermore, the women recruited in the study of Sikha *et al.*^[12] were normoglycemic, no significant rise or fall in blood sugar was observed in the study group at subsequent follow-ups also. Similarly in one study carbohydrate metabolism was assessed by intravenous glucose tolerance test reported that carbohydrate metabolism is not impaired by progestogens (Amatayakul [1985]).^[13]

The impact of DMPA on weight has been controversial. In our study, average 2–3 kg weight increase compares to control group which was non-significant ($P > 0.05$) Table 3. Weight gain has not been noted in many patients. This probably might have to do something with the socio-economic status they belong to due to which a post-natal mother is forced to look after her baby and the household activities herself. Weight gain was found to be the second major cause for discontinuation in various studies. Shao *et al.*^[14] is an open study done in 1985 for 1 year. The discontinuation due to weight changes is shown to be very less. Polanekzy *et al.*^[15] studied that 24% patients discontinued DMPA due to weight gain. The amount of weight gain can increase with longer use. Sirisha *et al.*^[16] the present study showed only 2% discontinuation rate due to weight gain.

In our study, no pregnancy was noted among patients used injection DMPA and in control group out of 100 women 19 used Cu-T and 2 women found UPT positive and barrier method used by 15 couple, among them nine women found UPT positive. The typical failure rate of condom^[1] is 18, which is higher than DMPA.66 women from control group who were not used any contraceptive among them 41 found UPT positive. Failure rate is 85 for unprotected intercourse.^[1]

On evaluating the reasons for discontinuation of the injection in 80% of the patients, menstrual disturbances (46.25%) were found to be the main reasons for discontinuation. Other study like Rai *et al.*^[4] had 43% discontinuation rate after 2nd injection Table 4. Among the menstrual disturbances, amenorrhea is the main reason stated for the cause of discontinuation even after the first dose. And other menstrual irregularities such as irregular spotting and profuse

Table 2: Distribution of study group according to the effect of DMPA on blood pressure

BP (mmHg)	1 st Injection		P value	2 nd Injection		P value	3 rd Injection		P value	4 th Injection		P value
	1 st visit	Control group		2 nd visit	Control group		3 rd visit	Control group		4 th visit	Control group	
	Study group	Control group	Study group	Control group	Study group	Control group	Study group	Control group				
SBP mean	118.98	119.3	0.764	120	119	0.407	121.42	122.71	0.3116	121.1	118.93	0.2692
SD	7.47	7.58		6.36	7.58		5.88	6.75		5.33	8.16	
DBP MEAN	78.5	79.37	0.178	79.05	78.89	0.876	79.57	79.46	0.8611	80.2	79.19	0.3533
SD	4.51	4.61		4.71	6.75		3.42	3.11		2.89	4.54	
Continuation status of DMPA in lactating women												
Lactating	36%	48%	0.9999	22 (40%)	44 (52.38%)	0.9997	14 (36.8%)	39 (62.90%) 23 (37.09%)	0.9992	08 (40%)	27 (58.69%)	0.9997
Non lactating	64%	52%		33 (60%)	40 (47.61%)		24 (63.15%)			12 (60%)	19 (41.30%)	

Table 3: Distribution of study group according to the effect of DMPA on blood sugar

Time from start of treatment	Mean blood sugar (mg%)±SD		P value
	Study group	Control	
I st injection	104.81±6.05	104.52±5.77	0.962
II nd injection	105.45±5.27	104.62±5.71	0.3694
III rd injection	105.42±5.81	104.57±5.96	0.4637
IV th injection	106.05±5.47	104.40±5.74	0.2168

Distribution of study group according to the effect of DMPA on body weight

	Average weight gain (in kg)±SD		P value
	Study group	Control	
I st injection	(n=100) 51.78±5.69	(n=100) 51.84±5.07	0.9373
II nd injection	(n=55) 53.52±4.90	(n=84) 51.97±3.93	0.332
III rd injection	(n=38) 53.13±4.89	(n=62) 53.35±4.035	0.7946
IV th injection	(n=19) 54.15±5.18	(n=46) 53.14±4.21	0.3893

Distribution of study group according to the continuation and discontinuation

Follow up rate	Continue no. of women	%	Discontinue no of women	%
I st injection	100	100	0	0
2 nd injection	55	55	45	45%
3 rd injection	38	38	17	30.90%
4 th injection	20	20	18	47.36%

Table 4: Distribution of study group according to the reason of attrition

Reason	No. of patients	%
Side effect	37	46.25
Loss of follow-up	25	31.25
Desire for pregnancy	12	15
Change of contraception	6	7.5
Total	80	100

Table 5: Distribution of study group according to the pattern of menstrual flow

	Amenorrhea	Irregular bleeding	Normal flow	Total
I st injection (n=100)	35 (35%)	2 (0.02%)	63 (63%)	100
II nd injection (n=55)	21 (38.18%)	32 (58.18%)	2 (3.6%)	55
III rd injection (n=38)	18 (47.36%)	19 (50%)	1 (2.6%)	38
IV th injection (n=20)	11 (55%)	9 (45%)	0	20

bleeding though were present in a larger number of patients that were the cause of discontinuation in only 0.03% of the patients.

Table 6: Distribution of study group according to the irregular bleeding pattern

	Mild	Moderate	Severe
I st injection	2	0	0
II nd injection	27	4	1
III rd injection	18	1	0
IV th injection	9	0	0

The major reasons for discontinuation are found to be the family pressure. These patients were comfortable with the injection initially but due to the various myths surrounding the injection in the surrounding people, mainly the belief of irreversibility of fertility; they have opted out of the study. This shows the requirement of adequate counseling not only to the patient but also to her 1st-degree relatives or creating a general awareness regarding the method and its myths.

The present study showed higher rates of discontinuation compared to other study Table 3 during 3rd injection (30.9%) and 4th injection (47.36%). This could be because of lockdown due to COVID pandemic and patients unable to reached hospital from off villages.

Menstrual changes occur in almost all women using DMPA and are the most frequent cause for discontinuation Table 4. In the present study, the main menstrual problems encountered were amenorrhea and irregular bleeding. In this study, 46.28% of the women had menstrual side effect which included amenorrhea, irregular bleeding, and oligomenorrhea and this was cited as the reason for discontinuation. There were 1% patient's reports of heavy bleeding in our study. In this study, lost to follow-up was 31.25% which was higher compared to other study could be due to COVID pandemic.

In our study, post-partum dose was administered after 6 weeks of delivery. The average number of days of spotting does come down progressively with each injection Table 5. Menstrual disturbances are the most frequent cause for dissatisfaction and discontinuation of the method in all studies. Discontinuation due to amenorrhea was less than due to irregular bleeding contrary to other study. Pattern of bleeding comparable to another study Sikha *et al.*^[12] which shows 73/125 women had mild irregularities, and in 24 women bleeding irregularities were moderate. Severe bleeding irregularities were seen in two women.

Compliance with DMPA is an issue mainly because of its menstrual side effects. Amenorrhea was the main side effect in study of Nautiyal *et al.*^[17] followed by spotting per vaginum. Irregular bleeding and disruption of menstrual cycle have also been observed by Aktun *et al.*^[18] and Rai *et al.*^[4] in 65–80% of women in their studies. Women can be counseled that amenorrhea

and reduction in menstrual cramps if develops as a side effect, can be viewed as an advantage. Menorrhagia which was common with first and second dose of injectable was reported by six clients in our study Table 6.

After 1st month of use, episodes of unpredictable bleeding and spotting lasting 7 days or longer are common. Bleeding decreases with use, and at 1 year, 55% of women experience amenorrhea. However, some women may view amenorrhea (along with a reduction or elimination of menstrual cramps) as one of the advantages of using this method. In the present study, 80 women did not complete the full follow-up. Irregular bleeding was the major troublesome factor responsible for discontinuation. At the end of present study, 20% of women were happy with DMPA and opted to continue it. Our study found a zero failure rate of DMPA, thus indicating its high efficacy (100%) and leading ultimately to a high patient satisfaction. Although this study addresses the concern of efficacy and safety of DMPA, the limitation was that these effects were studied only for a short period. It is also easy to administer and does not require compulsory follow-up of the woman after delivery. It is important; however, that DMPA be injected only after lactation has become established and breastfeeding has been properly initiated. Hence, it is concluded that DMPA should be available as a first line method to all who wish to make an informed choice about reversible methods of contraception. Pre use counseling regarding initial irregular bleeding and later amenorrhea will further improve acceptance, satisfaction, and continuation rate of DMPA as a postpartum contraceptive.

CONCLUSION

The present study concluded that DMPA is an effective contraceptive shown by the minimum or absence of failure rate. DMPA is a very acceptable method of hormonal contraceptive, which does not need a daily motivation and has absolutely no ill effect on lactation. About 20% of the subjects were satisfied with the method of contraception and were willing to recommend it to other women. Menstrual disturbances are the main reason for discontinuation. Irregular bleeding most common cause followed by amenorrhea was the 2nd most common cause for discontinuation.

In our study, weight gain was not found but literature had shown there was increase weight gain and osteoporosis for long-term use, not for short-term uses like our study. The study concludes that DMPA is a very effective contraceptive. Rural women accept it very easily without much degree of motivation. However, side effect decreases compliance.

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