International Journal of Medical and Health Research
ISSN: 2454-9142
Impact Factor: RJIF 5.54
www.medicalsciencejournal.com
Volume 3; Issue 9; September 2017; Page No. 17-22

A study on injectable DMPA (Depomedroxy progesterone acetale) isomg use as short-term contraception in immediate postpartum women

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Abstract
Depot medroxyprogesterone acetate (DMPA) provides long acting effective and reversible contraception in postpartum period.
Aims Objective: Present study aims to study the effects of DMPA injection in immediate postpartum period by asing it for six months for contraception just after delivery in postpartum patients.
Methods: Prospective case control study was done in which 250 women were recruited. One hundred and fifty woman were given injection DMPA 150mg intramuscularly before discharge from hospital and then at three months. One hundred postpartum women, not using hormonal contraception were taken as controls. They were followed at six weeks, three months & six months. The mean comparison between the two groups was done by using student t-test chi-square or Fisher extract test.
Results: There was a significant gain in weight after three months (p value<0.01) and six months was higher in DMPA user than controls [{3 months 0.77+0.42gm%vs0.48+0.48gm%, p value<0.01), (6 months 1.1+0.44 vs 0.46+0.49, p value <0.01)}]
In the study group, a progressive rise was observed in triglyceride (TGL, low density lipoprotein (LDL) and Total cholesterol (TC), with a fall in high-density lipoprotein (HDL) but the changes were clinically not significant.
No significant change was observed on blood pressure, blood sugar and liver function test (LFT). 72.5% women reported irregular bleeding at six weeks and 8% of women at six months. At six months, amenorrhea was significantly higher in study group than controls (% and 30%). There was no case of pregnancy in uses of DMPA while seven women among controls conceived during study period.
Conclusion: Injectable DMPA use in the immediate postpartum period is a safe and effective method of contraception.

Keywords: depot medroxyprogesterone acetate, injectable progestogens, immediate, metabolic effects, menstrual irregularity, weight gain

Introduction

Population explosion is a major issue especially in our country with the second largest population in world next only to china starting the use of contraception in immediate postpartum period is an effective method of increasing the gap between two pregnancies and hence reducing the family size. However, experience shows that contraception in postpartum period is a major challenge. Although the patients are receptive to advice concerning contraception just after delivery, as time lengthens, she is less concerned about it & may have an undesired pregnancy resulting in trouble for herself, the present baby & next pregnancy from the preceding one. Amongst popular methods offered like barrier contraceptions Pills, IUCD & sterilization, Depot medroxy progesterone (DMPA) has been found to provide effective, long acting and reversible contraception added advantage is that it is to be given by intramuscular route and hence not much training is needed for the person administering the injection. Therefore it seems to be a feasible option to increase family planning services at grass root level, It appears to be rational and effective method in temporarily motivated postpartum women specially in low resource settings, where patient training and follow up along with patient education is not optimal

There was a controversy in 2004 regarding the effects of DMPA on reduction in BMD on long use skeletal health resulting in overshadowing the many benefits of DMPA and making us clinicians reluctant to prescribe DMPA.

However, other studies by world health organization (WHO, 2005) and American college of obstetricians and gynecologists (ACOG, 2008) [6] have concluded that losses in BMD (bone mineral density) are largely reversed when DMPA is discontinued. The above studies have mentioned that DMPA should be available as a first line method to all those who wish to make an informed choice about reversible methods of contraception.

Now the timing of initiation of DMPA injection after delivery is controversial.

Product labeling recommends initiating DMPA 4-6 weeks postpartum regardless of breastfeeding status. WHO recommends DMPA in breastfeeding women to be initiated at 6 weeks. ACOG recommendation states that clinical judgment to start DMPA in postpartum women should be weighed against theoretical risk that endorse early initiation DMPA A large number of patients who do not turn-up for postpartum visit & hence are lost to contraception advice are benefited by early start of DMPA in immediate postpartum period and it also helps in avoiding the large number of undesired pregnancies during the period of lactational amenorrhea. Theoretical concerns with early postpartum administration of DMPA remain that of infant safety, premature inhibition of

lactation and its metabolic effects on mother. Studies indicate that the fears about effect of DMPA on infant health and lactation are unfounded. A number of investigations have been conducted on various metabolic effects of DMPA but the results are not consistent. Hence we aim to do this present study, giving DMPA for six months in the immediate postpartum period and study its effects and safety in immediate postpartum period and study its effects and safety in immediate postpartum period.

Materials and methods

A prospective case control study was conducted at MGM Medical College Hospital, Jamshedpur, a tertiary level teaching Hospital after approval from in institutional review board, and patients consent before joining this study.

A total of 250 women, who were apparently healthy, aged between 20 and 35 years, had term delivery, were breast feeding at the time of discharge, Were ready to follow and wanted some form of reversible contraception immediately after delivery were recruited in this study.

The women who were grand multipara, had preterm or intrauterine growth retardation (IUGR babies, or were undernourished or severely anemic or were unable to initiate lactation, were excluded from the study. All patients coming for delivery to labor room of MGM Medical College Jamshedpur were screened and a preliminary contact was made on the day of delivery. Using the cafeteria approach, le mothers were given information about all the available methods of delivery. To the prospective candidates, further details regarding study procedure were given.

Eligible candidates were short-listed as per the criteria mentioned below: i.e.

- willing for contraception in immediate postpartum period
- Apparently healthy with no anemia, diabetes, hypertension, cardiac disease or any other obvious illness.
- Age between 30 & 35 yr. old.
- Had term delivery
- Successfully breast feeding at the time of discharge.

After obtaining informed consent women were enrolled in the study. A total of 150 women had opted for hormonal contraception for study. Controls consisted of one hundred. Postpartum women who were not using hormonal contraception.

All women underwent a through general physical, examination.

Exclusive breast feeding was strongly emphasized. Blood samples were taken in the fasting state for hemoglobin (Hb), lipid profile, blood sugar and liver function test (LFT). Only the women with normal results who opted for DMPA received inject able DMPA 150mg intramuscularly before discharge from hospital (day two to day 10 of their deliver) and at three months.

They were followed up to complete a full six months follow up. All patients were given iron and calcium supplements.

a) All these patients were followed up at six months for the following :-
b) Menstrual irregularity
c) Duration and frequency of lactation
d) Effects on blood investigations

Side effects of the drug on mother like 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 like 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 was considered as severe abnormality. At the end of six months, all women were given a choice either to continue injectable contraception or change to another method.

They were evaluated for acceptance or discontinuation of injectable progestogens and reason thereof. Out of total 150 women who were included in the study group only 100 women completed full size months follow-up. Therefore, number of patients that was included for analysis at each visit was different. The statistical analysis was carried out by using software two groups was done by using student t-test. The association between two categorical variable was done by using chi-square or Fisher exact test. P value <0.05 was taken as significant.

Results: The mean (±SD) age of subjects in the study group was 25± 3.3 Years median 25 years, range 21-32 years). The mean (±SD) age of subjects in the control group was 26.56±456 years (median 26 years, range 21 to 32 years). Fifty four percent of women in the study group and 49% of women in the control group were illiterate.

In the study group 41% and in the control group 39% of women were educated up to the school level (5^{th} standard). 72.7% of women in the study group and 68% of women in the control group were homemakers.

Current pregnancy was unplanned in 65.3% and 58% of women in the study and control group respectively.

In the present study, 46% of women in the study group and 37% of women in the control group resumed their sexual activity earlier than 6 weeks after delivery.

There was a significant gain in weight after three months (p value <0.01) and six months (p value <0.01) of follow up in the study group, (Table1).

Table 1: Effect on weight gain

Time from start of treatment	Average weight gain (in kg) ± SD		P value
	Study group	Control group	
6 weeks	(n=125) -2.79±1.67	N=100 -2.61± 0.73	0.28
3 months	(n=121) 0.73±1.13	N=100 0.04±1.07	<0.01
6 months	(n=100) 1.33±1.22	N=100 0.38±1.19	<0.01

The mean (±SD) hemoglobin (Hb) rise was 0.45±0.30gm % in the study group at six weeks follow up and 0.46±0.42gm% in the control group. But this difference was not found to be statistically significant (p=0.84). However, the rise in Hb levels in study group at three months follow-up was 0.77± 0.42 gm % and in control group it was 0.48±0.49 gm%. This rise in Hb levels in DMPA group was found to be statistically significant (p value <0.01). The rise in Hb levels at six months follow up in study group was 1.1 + 0.44 and in control group, it was 0.46 ± 0.49. This difference was also found to be statistically significant (p value < 0.01).

In the study group, a progressive rise was observed in triglyceride (TG), low-density lipoprotein (LDL) and total cholesterol (TC), with a fall in high-density lipoprotein (HDL) in subsequent follow-ups, *(Table 2).* However, these changes were not clinically significant.

Table 2: Effects on Lipid Profile

		Triglycerides mg%	P value	LDL mg%	R-value	HDL	P value	Total Cholesterol mg %	P value
0 Week	Study (n=150)	110.13±12. 78	0.02	106.83112.02	<0.01	54.1518.01	0.534	183.64115.79	0.017
	Control (n=100)	106.83112. 68		113.06114.56		54.7817.5 6		178.72+16.13	
6 Weeks	Study (n=125)	111.22±13. 33	0.19	107.13+12.38	0.10	53.4016.6 2	0.428	182.78114.60	0.39
	Controls (n=100)	108.93112. 96		109.99113.52		52.6816.9 3		184.46+15.02	
3 months	Study (n=121)	114.27110. 72	0.31	112.39110.40	0.66	53.09±5.3 5	0.01	188.31+10.04	0.30
	Control (n=100)	116.02114. 97		111.49110.09		55.2617.0 2		189.96113.26	
6 months	Study (n=100)	117.1219.3 3	0.01	117.27±9.61	0.004	51.0214.4 4	<0.01	191.6118.46	0.20
	Control (n=100)	112.76114. 25		112.77112.23		54.1917.7 9		189.72112.23	

There was no effect of inject able DMPA on the blood pressure of the subjects in the study group when compared with control group *(Table 3).* The mean blood pressure (BP) was also comparable in the two groups *(Table 3).*

Table 3: Effect on Blood Pressure

BP[a] *(mm Hg)*	**0 weeks**		**P value**	**6 weeks**		**P value**	**3 months**		**P value**	**6 months**	
	Study (n=150)	Control		Study (n=125)	Control		Study (n=121)	Control		Study (n=100)	Control
SBP[b] mean	128.64	122.67	<0.001	129.12	127.48	0.05	128.84	121.86	<0.001	128.6	128.92 (p=0.008)
SD	7.86	7.54		7.63	5.23		8.57	7.64		7.80	8.17
DBP[C] mean	75.70	71.42	<0.001	75,48	75.83	0.74	76.26	74.75	0.12	75.08	78.54 (p=0.004)
SD	8.13	8.45		8.44	7.37		7.80	6.82		8.14	8.76

[a]BP; Blood Pressure, **[b]SBP:** Systolic Blood Pressure, **[C]DBP:** Diastolic Blood Pressure.

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 4). None of the subjects were found to have deranged liver function tests *(Table5).*

Table 4: Effect on blood sugar levels

Time from start of treatment	Mean Blood sugar (mg%) ± SD		P value
	Study group	Control group	
0 weeks	101.93± 11.50	103.30±11.93	0.36
6 weeks (n=125)	99.48±11.55	104.78±11.26	0.0007
3 months (n=121)	105.30±10.91	98.56±11.77	0.0001
6 months (n=100)	104.58+11.03	102.82+12.10	0.28

Table 5: Effect on Liver Function Test (LFT)

		Bilirubin mg%	P value	SGOT IU/L	P value	SGPT IU/L	P value	Alkaline Phosphatase IU/L	P value
	Study	0.49±0.25		23.36±6.40		23.53+5.31		75.32+13.39	
	Control	0.5610.24		26.4315.69		20.1914.36		78.62+16.35	
	Study	0.50+0.25		22.3914.96		23.014.52		72.37+13.13	
	Controls	0.62±0.30		24.5817.02		24.0615.36		75.22+18.02	
	Study	0.59+0.24		22.19+4.62		21.7615.37		74.90112.85	
	Control	0.52±0.28		20.58+4.22		22.1414.98		74.68112.54	
	Study	0.4910.25		22.4415.04		22.7614.37		70.98+12.22	
	Control	0.56±0.30		25.12±5.11		24.57+5.47		72.54+14.62	

Irregular bleeding was the major problem reported by 77.6% women in the study group at six weeks follow *up (Table 6).* But it was not troublesome and was managed by counseling or symptomatically in all women. At six months, follow up only 13% women complaint of irregular bleeding. At six months amenorrhea was significantly higher in study group than controls (Table 6,56 % and 30%). However, this was accepted as a physiological phenomenon in puerperium.

Table 6: Effect on menstrual pattern

Menstrual periods	6 weeks			3 Months			6 Months		
	Study n=125	Control n=100	P value	Study n=121	Control	P value	Study n=100	Control n=100	P value
Absent	26 (20.8%)	22	0.375	45 (37.19%)	44	0.018	56 (56%)	30	0.000
Irregular bleeding	97 (77.6%)	78		30 (24.79%)	10		13 (13%)	3	
Normal	2 (1.60%)	0		46 (38.02%)	46		31(31%)	67	

Pattern of irregular bleeding was also analyzed and it was observed that in study group at six weeks follow up 97/125 women had experienced bleeding irregularities. Out of these majorities *i.e.* 73/ 125 women had mild irregularities, and In 24 women bleeding irregularities were moderate. Severe bleeding irregularities were seen in two women *(Table 7).*

Table 7: Pattern of irregular bleeding

irregular bleeding	6 Weeks			3 Months			6 Months		
	Study (n=97)	Control (n=78)	P value	Study (n=30)	Control (n=10)	P value	Study (n=13)	Control (n=3)	P value
Mild	73 (75.67%)	54 (69.23%)		22 (73.33%)	8 (80%)		10 (76.92%)	3 (100%)	
Moderate	24 (24.4%)	23 (29.48%)		7 (23.33%)	2 (20%)		3 (23.07%)	0	
Severe	2 (2.06%)	1 (1.28%)		1 (3.33%)	0		0	0	

All prim gravidas in the study group and 95% in the control group were satisfied with their lactation amount (p value 0.22). In multigravidas 62% (65/105) in the study group and 75% in the control group felt no change in lactation amount as compared to their previous experience (p value 0.044). Other minor problems encountered during the study were headache, acne, bloating which were observed in six, three and seven women in study group at three months follow up but their incidence was not statistically significantly higher than control (p value 0.23, 0.11, 0.15 respectively). Features like depression, alopecia, breast tenderness were not complained by any patient.

There was no case of pregnancy in users of DMPA while seven women among controls conceived during study period. In the present study, 50 women did not complete the full follow up or received the two doses of DMPA and dropped out in between. Twenty-eight women among these were lost to follow up and hence no reason could be cited for discontinuation. However, in rest of them, irregular bleeding was the major troublesome factor responsible (in 10 out of 22). Other reasons observed for drop out were amenorrhea (in five patients) and acceptance of other contraceptive methods like intrauterine contraceptive device (three patients) and sterilization (four patients). At the end of the study i.e. at six months, 70% of women were happy with DMPA as contraceptive and opted to continue it. However 28 % switched to alternate methods of contraception.

Discussion

Present study was conducted to assess the metabolic effects of initiating inject able progestogen (DMPA) contraception in the immediate postpartum period. A high number of unplanned pregnancies in the current study are comparable to other studies, where 67%. [16], and 49% [17] of pregnancies were unplanned. This large number of unplanned pregnancies emphasize that either the current methods of contraception are not acceptable to couples or awareness of contraception is not adequate. Parity bears a close relationship to acceptance of contraception, while 68% of women with more than three living children use contraception, its usage by women with no living children is not more than 5%. [18]. Early resumption of sexual activity highlights the importance of early requirement of contraception even before scheduled follow up.

We observed a significant rise of Hb in study group at three and six months of follow up. In the study group Hb rise ranged from 0.2 to 2.1 gm/dl. Similar rise in hemoglobin varying between 0.3 and 0.6 gm % was observed in women using hormonal contraceptives [19]. The rise in Hb observed in DMPA users could be because of amenorrhea or reduced menstrual bleed observed in them.

The perceived side effects of DMPA such as weight gain and menstrual abnormalities are a frequent reason for discontinuation, and counseling for the same was done in current study. In the present study, initially there was a weight loss for the mother ranging from 1.5 kg to four kg at six weeks follow up which was comparable in both study and control groups. This weight loss is basically physiological during puerperium. Considering six weeks weight of women as baseline, weight gain at three months and six months was studied and there was a significant weight gain (p value<0.01) in the study group at three and six months post injection as compared to controls. The impact of DMPA on weight has been controversial. In a prospective study, two thirds of adolescent women using DMPA gained two kg, whereas another study reported that some adult DMPA users maintained their initial body mass index (BMI) over time [20]. The amount of weight gain can increase with longer use. A study of 700 women found that after three years, DMPA users who completed the study had more weight gain than did combined oral contraceptive (COC) users and nonusers of hormonal contraception [21]. A systematic review found that weight gain with DMPA was not associated with baseline weight or BMI in adults but that obese clients or overweight adolescents gained more weight than did nonusers or DMPA users who were not overweight [13].

In the study group although a progressive rise was observed in TG, LDL and total cholesterol, with a fall in HDL in subsequent follow ups but the difference in serum values was statistically significant as compared to controls. Also none of the women in present study crossed the cut off limit for hyperlipidemia. Other studies also reported similar results that DMPA usage had no significant effect on fasting TG and

phospholipids levels." HDL reduces by 15-20% but levels generally remain within normal range [22, 23]. Another review that evaluated plasma lipids among groups of women using DMPA also observed little or no change in mean triglyceride and total cholesterol levels, but in all seven studies in which mean HDL cholesterol levels were measured, the levels were lower among the DMPA users. Out of the five studies in which LDL cholesterol was measured, three noted an increase among the DMPA users [2]. It has been observed that DMPA users were at increased risk of developing an abnormally low HDL level as well as an abnormally high LDL level and an increase in the LDL to HDL cholesterol ratio [21]. However, these adverse effects on serum lipids were temporary and levels improved over time even if DMPA was continued [22].

In present study no significant rise or fall in BP was observed at six weeks, three months and six months follow up. According to WHO medical eligibility criteria for starting contraceptive method, DMPA can be safely given in women with mild to moderate hypertension or in women with past history of hypertension where BP cannot be evaluated (including hypertension during pregnancy) [24]. However, its use is not recommended in women having severe hypertension > 180/110 or arterial disease [24]. As the women recruited in the present study were normoglycaemic, 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 [25]. Another study where 80 uncomplicated diabetic women using DMPA reported significant rise in blood sugar levels at three, six and nine months follow up [26]. This difference from present study can be explained as women with high blood sugars were not included in our study.

In the present study none of the women were found to be having deranged liver function tests with DMPA usage. Also, no particular trend of rise or fall of serum bilirubin, SGOT, SGPT and serum alkaline phosphates were observed during six months follow up. Effect on liver function tests in women taking injections of DMPA 150 mg every three monthly for two years was studied and it was reported that specific activities of SGOT, SGPT and alkaline phosphates do not show any change with long term treatment." A cross sectional study described the metabolic changes in 57 women using DMPA for five years or more. They observed a higher alkaline phosphates levels in users than controls; however, no significant difference was observed in serum bilirubin, SGOT and SGPT values [28].

Menstrual changes occur in almost all women using DMPA and are the most frequent cause for discontinuation. In the present study, the main menstrual problems encountered were amenorrhea and irregular bleeding. A study reported the amenorrhea rate is 20% by three months of use and 70% after one year [29]. Ouring first month of use, episodes of unpredictable bleeding and spotting lasting seven days or longer are common. Bleeding decreases with use, and at one year, 50% of women experience amenorrhea; this rate increased to 75% with long-term use. In another study, the incidence of unscheduled bleeding or spotting days is about 70% in the first year and diminishes to about 10% thereafter [30]. About 50% of DMPA users experience amenorrhea by year one of use and about 70% after two years of use [31]. 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, 50 women did not complete the full follow up. Irregular bleeding was the major troublesome factor responsible for discontinuation (in 10 out of 22). In a study where 421 women who were using DMPA were analyzed the main reason for terminating DMPA was found to be menstrual changes [28].

At the end of present study, 70% of postpartum women were happy with DMPA and opted to continue it. One study found a zero failure rate of DMPA, thus indicating its high efficacy (100%) and leading ultimately to a high patient satisfaction. Effect of pre treatment counseling on continuation rate was explored and it was seen that at one year the total continuation rate was 89% in counseling group and 58% in non-counseling group [31]. Although this study addresses the concern of metabolic effects of DMPA in immediate postpartum period, however the limitation was that these effects were studied only for a short period. Long-term study in our set up with this population will require a very large cohort because of high dropout rates and poor birth spacing.

Conclusion

Injectable DMPA use in the immediate postpartum period is safe and effective method with no deleterious metabolic effects. 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 breast feeding 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.

Acknowledgements: None
Financial support and sponsorship: None
Conflict of Interest: None

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