

**A CROSS SECTIONAL STUDY ON SIDE EFFECTS OF INJECTABLE
CONTRACEPTIVE DMPA IN WOMEN AT A TERTIARY HOSPITAL****Dr. J. Sarala¹, Dr. Prema Elizabeth Jeyanthi David^{*2}, R. Mothilal³**^{1,2}Professor of O&G, Institute of Obstetrics and Gynecology, Egmore, Chennai-600008.³Lecturer in Statistics and Demography, Govt. Kilpauk Medical College Hospital, Chennai-10.***Corresponding Author: Dr. Prema Elizabeth Jeyanthi David**

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ABSTRACT

Background: Depo provera, the long acting injectable formulation DMPA, is a crystalline suspension of this hormone. DMPA is extremely effective, the pregnancy rate 0-1/100 women years. This study was done to estimate the side effects of DMPA among mothers who accepted DMPA 150 mg with mode of injection through 6 weeks after child birth, after abortion / MTP and as a contraceptive method (after excluding pregnancy) as a cafeteria approach and to assess the association between the menstrual problems and doses of DMPA. **Methods:** It is an analytical cross sectional retrospective study on women who were accepted DMPA after 6 weeks after child birth, after abortion / MTP and as a contraceptive method (after excluding pregnancy) as a cafeteria approach. The study was conducted at a tertiary care hospital on 136 patients between July 2008 and July 2010. **Results:** About 136 patients were studied and all the women were followed-up to know the current status of DMPA was made to them. About 67.6 % of the women were continued DMPA. The side effects namely menstrual problems, headache, hot flushes, weight gain, breast changes and nervousness were noticed among the women who had DMPA contraceptive injections. Of the cases, menstrual problems were the major reason for drop out. **Conclusions:** In present study, disruption of menstrual was the major side effects observed. On an average amenorrhea was seen in 10.4% of the patients, irregular cycles were seen in 14.7% of the patients after 3 doses. Average weight gain of 6 kg was observed in 6.5% of the patients after 3 doses. The dropout rate was increasing with every dosage. Majority of the patients had come back for follow-up.

KEYWORDS: DMPA, Effects.**INTRODUCTION**

India is the first in the world to take up government sponsored family planning program as early as 1951. Since 1962 effort has been to impart mass education and set targets aim to achieve 'Health for all 2020'. The WHO collaborative study of neoplasia and steroid contraceptives examined the risk of cancer among users of hormonal contraceptives and reached the following conclusions published largely in 1991, about DMPA and cancer.

Family planning and its importance in Indian society is widely known and well established. There are many forms of contraception that can be practiced by either sex. Each method has its relative advantages and disadvantages. It follows that each family should be able to choose the method that suits them best. No method is either perfect or universal. Depo provera, the long acting injectable formulation DMPA, is a crystalline suspension of this hormone.^[1] The effective contraceptive dose is 150mg. 3 monthly given by deep IM injection into gluteal/deltoid muscle, after which the progestin is

released slowly into systemic circulation.^[2,3]

Depo provera is suited for women who are in one / more of the following situations.

1. Ideal postpartum contraceptive method
2. Wishes to practice contraception while breast feeding
3. Cannot remember to take pill every day.
4. Wishes to practice contraception in private.

DMPA Side Effects

1. Menstrual changes – most commonly reported side effect.
2. Irregular bleeding / spotting
3. Prolonged / heavy bleeding
4. Amenorrhoea
5. Weight gain
6. Headache, Dizziness and mood changes.

With appropriate counseling and adequate follow up measures, this could be a safe and convenient method of long term reversible contraception. Approximately 50% of women will have amenorrhea after one year of use⁴.

The aim of this study is to analyze the side effects of injectable contraceptive DMPA 150mg and to assess the association between menstrual problems that irregular cycles regular cycles and doses of DMPA.

METHODS

This study is an analytical cross sectional retrospective study. This study was conducted in a tertiary care hospital, Chennai on 136 patients between July 2008 and July 2010. The cases were grouped into three groups as follows:

Group A: Women who have taken the injection (Depo provera) 6 weeks after child birth

Group B: Women who have taken the injection immediately after abortion / MTP

Group C: Women who have taken the injections as a contraceptive method (after excluding pregnancy) as a cafeteria approach.

Depo provera injection was given either 6weeks after delivery / immediately after abortion or MTP. Patients were given a file in which the date of the first injection, due date for the next injection, and last child birth or abortion, and will be advised to come for follow up, to family planning OPD once in a month until the next injection or any time, if they develop any such symptoms. If they do not turn up on scheduled date, they will be reminded by contacting them by phone. The patients namely History of unexplained bleeding PV, History of lump in the breast, DVT, Known sensitivity to Depo provera, Hypertension and Diatetes were excluded from the study. Detailed history was taken and patients were counseled about the advantages and disadvantages of the inject able and were advised to try it. Advantages and disadvantages which are explained to patients are as follows:-

Advantages

1. Convenience to use once in 3 months
2. Most effective method of temporary contraception better than oral contraceptive and some IUCDs.
3. Does not interfere with sex
4. No bad estrogenic effect
5. Reduces menstrual flow and prevents anaemia
6. Most suitable for lactating women
7. Causes weight gain
8. It cures and ameliorates menorrhagia, and dysmenorrhoea as well as endometriosis.
9. Prevents sickling episodes
10. Reduces the risk of PID and vaginal candidiasos
11. Protects against endometrial cancer for atleast 8 years after its discontinuation.
12. Prevents ovarian cancer
13. Suitable in cases of myoma and endometriosis as contraception is provided without oestrogen effect.
14. Helps prevent ectopic pregnancies and fibroids.

Disadvantages

1. Change of menstrual pattern, like irregular bleeding, spotting and amenorrhoea.

2. Weight gain
3. Impaired glucose tolerance
4. Delay in return to fertility, DMPA users may have to wait two or three months longer than the former OC Users.
5. Does not protect against STD including HIV/AIDS

A thorough general examination was done for the presence of any pallor. Lump in the breast, heart and lungs are auscultated for any murmurs or additional sounds and blood pressure was recorded. A routine gynecological examination was done including per speculation and per vaginal examination. Under aseptic precautions, 150 mg of Depo provera injection was given in the gluteal region (upper outer quadrant) after cleaning the area with a spirit swab, via deep intramuscular route. Depo provera 150mg was given every three months. If the patient was more than 6 weeks postpartum, injection was given after making sure that she is not pregnant. If the interval between the two injections is greater than 14 weeks, pregnancy was ruled out before giving next dose.

Follow up: Patient was advised to come for a follow up once a month up to the next dose and at the time of follow up, examination of the patient was done for pallor, breast examination and Blood Pressure are recorded. Patients are questioned regarding side effects of Depro provera injection. They were advised to come for the next visit and for the following injections. During each visit, patients were repeatedly counseled regarding the menstrual disturbances that are likely to occur.

The statistical Chi-square test was used and also the statistical tools that percentage were used for discreet and continuous variable in this study. It is an analytical cross sectional prospective study.

RESULTS

H_0 = The attributes that doses of DMPA and menstrual problems that irregular and regular are independent

H_1 = The attributes that doses of DMPA and menstrual problems that irregular and regular are not independent

Table 1: Menstrual problems verses stages of doses.

Menstrual problems	Doses of DMPA			Total
	First	Second	Third	
Irregular cycles and amenorrhea	24	17	37	78
Regular cycles	106	72	55	233
Total	130	89	92	311

There exist an association between the doses of DMPA and the menstrual problems that irregular, regular and doses of DMPA since the chi- square value is 15.94 at degrees of freedom is 2; the level of significance is 0.05. The p- value is 0.000346.

RESULT

Since the calculated chi-square value 15.94 is greater than the table value 4.99. So, the attributes that doses of DMPA and menstrual problems that irregular and regular

are not independent and the result is significant at p -value < 0.05 . This proved that as the doses of DMPA increases the menstrual problems are also increases.

Table 2: No. of women who had DMPA and discontinued.

Group	Dose 1	Dose 2	Dose 3	Discontinued	%
A	100	84	72	28	28.0
B	30	22	20	10	33.3
C	6	2	0	4	66.7
Total	136	108	92	44	32.4

Table 2 shows the women who had DMPA and discontinuation rate. Maximum doses were taken by Group A followed by Group B shows that postnatal women accepted this contraceptive method better in

comparison to post abortal women. It also states that discontinuation rate was higher in Group C followed by group B and group A. The average discontinuation rate was 32.4%.

Table 3: Distribution of cases according to the Menstrual Problems.

Follow up periods	Regular cycles	Irregular Cycles	Amenorrhea	Mennoragia	Lost
0-3 months	106	14	10	-	6
4-6 months	72	11	6	-	19
7-9 months	55	20	17	-	0

Table 4: Menstrual Problems (%).

Follow up periods	Regular cycles	Irregular Cycles	Amenorrhea	Mennoragia
0-3 months (1 st dose)	77.9%	10.2%	7.3%	-
4-6 months (2 nd dose)	66%	10.1%	5.5%	-
7-9 months (3 rd dose)	59.7%	21.7%	18.4%	-

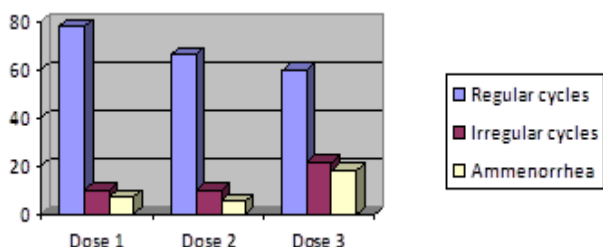


Figure 1: Percentage of menstrual problems according to doses of DMPA.

The table 3 shows the distribution of cases according to the menstrual problems during their follow up period.

Table 4 and Figure 1 shows the percentage of menstrual problems occurred during their follow up periods or doses given. It reiterates that as the dose was increased the menstrual problem also increased.

Table 5: Mood Changes.

Follow up periods	Total	Mood changes	%
0-3 months	136	11	8.08
3-6 months	108	9	8.33
6-9 months	92	7	7.6

Table 6: Mood changes and its cons.

Follow up periods	Nervousness	Insomnia	Depression
0-3 months	6	3	2
3-6 months	3	1	2
6-9 months	3	2	2

The table 5 & 6 shows the mood changes and its consequence. Among the symptoms of mood changes nervousness was the most common complaint and as the number of doses was increased there was a decrease in the complaints of mood changes.

Table 7: Headache.

Follow up periods	Total	Headache	%
0-3 months	136	10	7.3
3-6 months	108	7	6.4
6-9 months	92	5	5.4

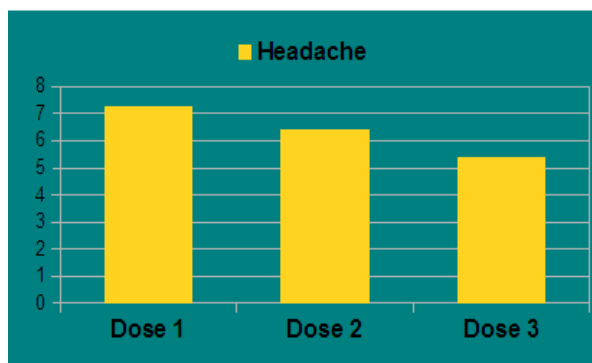


Figure 2: Headache according to Doses of DMPA.

The Table 7 and Figure 2 shows the symptoms of headache showed a decline as the number of doses

Table 9: Weight gain.

Follow up periods	Total	Weight Gain > 3 kg	%
0-3 months	136	8	5.8
3-6 months	108	6	5.5
6-9 months	92	6	6.5

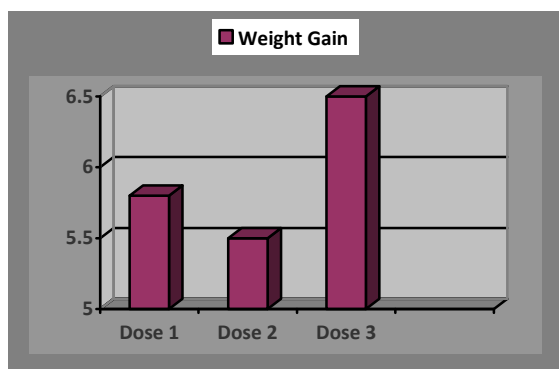


Figure 3: Weight Gain by Doses of DMPA.

The table 9 and Figure 3 shows the weight gain by the women who had doses of DMPA and how much they had gained weight during the follow up periods was noticed.

Table 11: Effects (%).

Side Effects	Dose I	Dose II	Dose III	Total	Average
Regular cycles	77.9	66	59.7	59.7	67.86
Irregular cycles	10.2	10.1	21.7	21.7	14
Amenorrhoea	7.3	5.5	18.4	18.4	10.4
Mood changes	8.08	8.33	7.6	7.6	8.0
Head ache	7.3	6.4	5.4	5.4	6.36
Hot Flushes	5.8	6.4	5.5	5.5	5.9
Weight Gain	5.8	5.5	6.5	6.5	5.93
Breast Changes	10.2	9.2	8.6	8.6	9.33

The above table shows that at the end of 3 doses the average percentage of regular menstrual cycles – 67.86%, irregular cycles – 14%, Amenorrhea – 10.4%, mood changes – 8%, headache – 6.36%, hot flushes – 5.9%, Weight gain – 5.93% and breast changes – 9.33% .

increased. The above table shows that 7.3% of the cases complaint of headache with the first dose and there was a decrease with the 3rd dose to 5.4%.

Table 8: Hot Flushes.

Follow up periods	Total	Hot Flushes	%
0-3 months	136	8	5.8
3-6 months	108	7	6.4
6-9 months	92	6	6.5

As shown in the above table and diagram the symptoms of hot flushes increased as the number of doses were increased.

Weight gain of more than 3kg were seen in 6.5% of the cases following 3 doses.

Table 10: Breast changes.

Follow up periods	Total	Breast Changes	%
0-3 months	136	14	10.2
3-6 months	108	10	9.2
6-9 months	92	8	8.6

The table 9 shows the breast changes were noticed during their follow up period for having the doses of DMPA by the women. The symptoms of breast pain and breast swelling decreased as the number of doses increased.

Of the cases, menstrual problems were the major reason for drop out.

DISCUSSION

Study Group: Institute of Obstetrics and Gynecology, Egmore, Chennai-8.

Other Groups: WHO multicenter studies, Lady Harding Medical College, New Delhi.

Menstrual Pattern

	Regular	Amenorrhea	Irregular
Study Group	67.8%	10.4%	14%
WHO	50%	37%	13%
Lady Harding	55%	22%	23%

As shown in the above table, amenorrhea was seen in an average of 10.4% of the cases in the study group, 37% in the WHO group and 22% in the Lady Harding. In the Reference manual for Injectable Contraceptive DMPA, it is stated that approximately 50% of women will have amenorrhea after one year use of DMPA.^[4] In the present study it was 18.4% of women suffered by amenorrhea after one year use of DMPA. Irregular periods were more seen in the study group compared to amenorrhea. Menstrual problems were the reason for the maximum number of drop outs. Regular cycles were seen in 67% of the cases in the study group with an approximate 15% difference from the other groups. In the study group menstrual disturbances were observed as the most common side effect. Even in the other groups amenorrhoea and irregular cycles were the cause of discontinuation. Various studies have been conducted to evaluate injectable contraceptive DMPA, Benglano G et al in 1983 studied about long acting contraceptive and found that the most important side effect with DMPA was complete disruption of menstrual bleeding pattern. Ajmal F et al in 1987 studied bleeding patterns of DMPA given intramuscularly every 3 months and found that abnormal bleeding patterns was responsible for discontinuation of DMPA in majority of patients.

Weight Gain

Study group	6.5%
WHO Group	10%
Lady Harding	12%

In the study group following 3 doses 6.5% of the cases had a weight gain of more than 3 kgs. Maximum of weight gain seen was upto 9 kgs.

Mood changes, head ache, hot flushes, breast changes

Study Group	5-10%
WHO Group	3-12%
Lady Harding	10-12%

In this study group 5-10% users reported headache, mood changes (nervousness, insomnia, depression), hot flushes, breast changes. Percentage of users with the above complaints were almost same as WHO study group and Lady Harding study group. In the WHO trial

few women discontinued use of the contraceptive for the above reasons.

DMPA and Discontinuation Rate.

	Study Group	WHO	Lady Harding
After 3 doses	33%	25%	20%

As seen in the above table 33% of the cases discontinued usage as compared to 25% of WHO and 20% of Lady Harding.

CONCLUSION

In present study, disruption of menstrual was the major side effects observed. On an average amenorrhea was seen in 10.4% of the patients, irregular cycles were seen in 14.7% of the patients after 3 doses. Average weight gain of 6 kg was observed in 6.5% of the patients after 3 doses. Majority of the patients had no effects of moods changes, headache, hot flashes or breast changes. The dropout rate was increasing with every dosage. Majority of the patients had come back for follow up. Bone mineral density studies are to be conducted in patients receiving injection DMPA, on a large scale, before the safety of this injection is accepted. This study proved that menstrual problems increases as the doses increases and it statistically significant at p value is <0.05.

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