

# THE EFFECT OF DEPOT MEDROXYPROGESTERONE ACETATE CONTRACEPTIVE ON BODY WEIGHT AND BLOOD PRESSURE IN INDIGENOUS KENYAN WOMEN

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## ABSTRACT

**Background:** Concern has been raised that depot medroxyprogesterone acetate (DMPA) contraceptive leads to weight gain and possibly rise in blood pressure among its users.

**Objectives:** The objectives of this study were to determine the magnitude of body weight and blood pressure changes in indigenous Kenyan women on DMPA contraceptive and assess whether these changes lead to stoppage of its use as a contraceptive.

**Study Design:** This was a prospective cohort study

**Study Setting:** Family Welfare Centre at Kenyatta National Hospital, Nairobi, Kenya

**Subjects and Methods:** The study subjects were 50 black normotensive Kenyan women aged 20-40 years newly accepting DMPA as a method of contraception while the control group comprised 50 black normotensive Kenyan women aged 20-40 years newly accepting non-hormonal copper-bearing intrauterine contraceptive devices (IUCD) for contraception. The subjects and control group were chosen through simple random sampling technique.

**Results:** The mean age of DMPA users was 27.880 years vs 30.260 years for IUCD users, 2-tailed p-value 0.0269. The mean parity, marital status, occupation, religion and number of years in school were similar among DMPA and IUCD users.

*The mean weight change from baseline remained significantly higher among DMPA users compared to IUCD users up to the end of the study. The total mean weight change from baseline to 12 months was 2.919kg for DMPA users vs 1.550kg for IUCD users, 2-tailed, p-value 00000, which is significant. Mean systolic and diastolic blood pressure changes were minimal at every visit in the 2 groups and no significant differences were appreciable throughout the study period.*

*By the end of the 1 year of study, 26.0% of DMPA users had quit using the method and the commonest reasons were Irregular menses (30.8%), amenorrhoea (23.1 %) and weight gain (23.1 %) At the end of the study period 20% of rUeD users had quit using the method and the commonest reasons were pelvic inflammatory disease (400%), cramping and spotting (30%) and no obvious reason (20%)*

**Conclusions:** *There is a significant weight gain among indigenous Kenyan women on DMPA contraception after 1 year of use. However, there is no significant increase in both systolic and diastolic blood pressure after the same period of use. Hence DMPA is a safe enough contraceptive that can be recommended for those willing and fit to use it.*

## INTRODUCTION

Injectable contraceptives are approved for use in over 100 countries and have been used for many years by millions of women. They represent a safe and effective option for women seeking reversible contraceptive protection (1,2,3)

Injectable contraceptives are popular with many women because they are highly effective and do not require effort (like oral contraceptives) or use at the time of sexual intercourse (like barrier methods). They do not require an expert (like insertion of intra-uterine contraceptive device) and furthermore, some injectables can be used by women who cannot use methods that contain estrogen, including breastfeeding women(10,11)

In some cultures, injectable contraceptives are favoured over other methods because they can be used without the knowledge of family and friends( 2)

Injectable contraceptives contain hormonal drugs that provide women with safe, highly effective, and reversible contraception. Two types of injectable contraceptives are available (1) progestogen-only formulation that contain a progestogen hormone and are effective for 2 or 3 months; and (2) combined formulations that contain both a progestogen and a estrogen and are effective for I month.

Progestogen -only formulations consist of DMPA (depot medroxyprogesterone acetate) and NET-EN (norethisterone enanthate). DMPA is the injectable formulation most widely used worldwide. DMPA is injected every 3 months. NET-EN is injected every 2 months (14,15)

Injectable contraceptives prevent pregnancy primarily by stopping ovulation by effectively blocking LH surge and by thickening the cervical mucus, thus forming a barrier to sperm). They are administered by a deep intramuscular injection into the muscle of the arm or buttock and are effective immediately, provided they are taken at specified times (for DMPA is ISOmg every 90 days with a 14 days margin for the follow-up re-injection, early or late). The first injection of DMPA should be given within 5 days of the current menstrual cycle, otherwise a back-up method is necessary for 2 weeks.

All injectable contraceptives are slowly absorbed into the bloodstream from the injection site, with the body maintaining a sufficient level of hormone to provide contraception( I 3 months, depending on the type of injectable used. The efficacy of DMPA for contraception is equivalent to that of sterilization with a typical first-year failure rate of 0.1-1.4%.The search for an effective and safe contraceptive has been going on for a long time.

The study aims to evaluate the safety and complications of Depo Provera

## Material and methods

The study was conducted at Kenyatta National Hospital , Nairobi, Kenya

The sample size was calculated using EPI Info version 5 and was 100, 50 for the study group and 50 for the control group.

The first mother newly accepting DMPA for contraception from the date of commencement of the study. Other study subjects were recruited alternatively i.e. every other mother newly accepting DMPA for contraception was taken until 50 subjects were obtained. A similar method was used to choose the control group amongst mothers newly accepting IUD for contraception until 50 mothers were obtained over the same period. The first control group mother was the first mother newly accepting IUD for contraception immediately after the first study group mother. Both groups were followed up 3-monthly for a total duration of 12 months.

Data was collected by completion of a set out precoded questionnaire by the principal investigator. Data was up-dated as required on follow-up visits.

On the day(s) of recruitment, height (cm), weight (kg) and blood pressure (mmHg) were taken and recorded. Accurate measurement of blood pressure was done by a nurse trained to use the same sphygmomanometer for all mothers in the study.

At follow-up visits weight and blood pressure records were taken and recorded in a tabulated form. Information on smoking history, alcohol intake and menstrual history was also updated.

## RESULTS

**Table 1: Study Group by Socio-Demographic Characteristics**

Socio-Demographic Characteristic		Depo Provera	IUCD	p-value
Age (Mean age in years)		27.880	30.260	0.02
Marital status	Single	2 (4%)	2 (4%)	
	Married	48 (96%)	47 (94%)	
	Divorced/Separated/ Widowed	0 (0%)	1 (2%)	
Occupation	Housewife	5 (10%)	10 (20%)	
	Professional	16 (32%)	14 (28%)	
	Unskilled	29 (58%)	26 (52%)	
Religion	Christians	50 (100%)	48 (96%)	
	Muslims	0 (0%)	0 (0%)	
	None	2 (4%)	0 (10%)	
Mean Parity		1.800	2.143	0.3
Mean Number of Years in School		12.000	12.120	0.9

The mean age of DMPA users (27880 years) was significantly lower compared to that of IUCD users(30260), p-value 002.

Most of the DMPA users(96%) were married and so were the IUCD users(94%) There were no significant differences in occupation among DMPA and IUCD users. There was no significant differences in religion between DMPA and IUCD users. The mean parity showed no significant difference between the two groups There was no significant difference in the number of years spent in school between DMPA and IUCD users

**Table 2: Height, Weight and Blood Pressure of DMPA and IUCD Users**

**(a) DMPA**

Months of DMPA use	0	3	6	9	12
Mean Height (cm)	153.480	153.480	153.480	153.480	153.480
Mean Body Weight (kg)	62.740	63.574	64.439	64.658	65.459
Mean Systolic Blood Pressure (mmHg)	112.520	113.617	113.780	113.947	115.270
Mean Diastolic Blood Pressure (mmHg)	70.400	70.745	70.854	71.053	71.351
Number of Subjects	50 (100%)	47 (94%)	41 (82%)	38 (76%)	37 (74%)

**(b) IUCD**

Months of IUCD use	0	3	6	9	12
Mean Height (cm)	155.220	155.220	155.220	155.220	155.220
Mean Body Weight (kg)	65.694	65.500	66.404	67.095	67.725
Mean Systolic Blood Pressure (mmHg)	112.653	113.100	114.043	115.238	117.500
Mean Diastolic Blood Pressure (mmHg)	70.000	69.200	69.043	69.643	71.500
Number of Subjects	50(100%)	50(100%)	45(90%)	41 (82%)	39(78%)

**Table 3: Comparison of Baseline Mean Height, Weight, BP, and Cigarette Smoking Between DMPA and IUCD Users**

Variable	DMPA	IUCD	p-value
Mean Height at Baseline in cm	153.480	155.220	0.01
Mean Weight at Baseline in kg	62.740	65.694	0.4
Mean Systolic BP at Baseline in mmHg	112.520	112.653	0.8
Mean Diastolic BP at Baseline in mmHg	70.400	70.000	0.7
Cigarette Smoking %	2.4%	2.2%	0.9

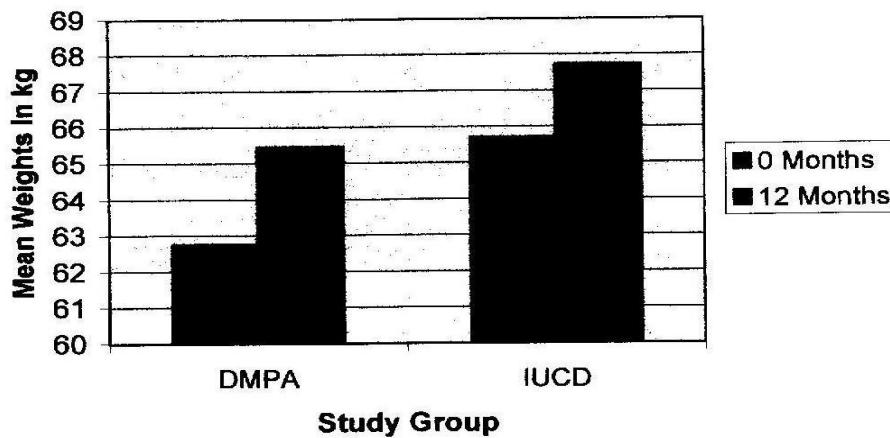
The DMPA users were generally shorter (153.480cm) compared to IUCD users to IUCD users 155.20 cm, 2-tailed p-value 0.01. However, there was no significant difference in weight at baseline, DMPA 62.740kg and IUCD 65694, 2-tailed p-value 0.4 Similarly, there were no significant differences between the 2 groups in their baseline systolic and diastolic BP and also In cigarette smoking.

Table 4: Comparison of Weight Changes among DMPA and IUCD Users

Variable	DMPA	IUCD	p-value
Mean Weight Change: Baseline and 3 months in kg	0.872	0.122	0.003
Mean Weight Change: Baseline and 6 months in kg	1.293	0.787	0.004
Mean Weight Change: Baseline and 9 months in kg	1.895	1.000	0.0001
Mean Weight Change: Baseline and 12 months in kg	2.919	1.550	0.0000

As shown by the table above and the graph that follows, the mean weight increase among DMPA users was significantly higher than among IUCD users throughout the study period

Bar Graph Showing Mean Weights at 0 and 12 months



**Table 5:****(a) Comparison of Systolic Blood Pressure Changes among DMPA and IUCD Users**

Variable	DMPA	IUCD	p-value
Mean systolic BP Change and Baseline and 3 months in mmHg	1.362	0.714	0.6
Mean systolic BP Change Baseline and 6 months in mmHg	1.683	1.277	0.6
Mean systolic BP Change Baseline and 9 months in mmHg	1.947	1.905	0.8
Total Mean Systolic BP Change from 0 months to 12 months in mmHg	3.216	4.250	0.4

**(c) Comparison of Diastolic Blood Pressure Changes among DMPA and IUCD Users**

Variable	DMPA	IUCD	p-value
Mean Diastolic BP Change Baseline to 3 months in mmHg	0.532	-0.612	0.2
Mean Diastolic BP Change Baseline to 6 months in mmHg	0.610	-0.951	0.2
Mean Diastolic BP Change Baseline to 9 months in mmHg	0.789	0.833	0.2
Total Mean Diastolic BP Change 0 months to 12 months in mmHg	1.216	1.250	0.7

As noted in the tables above, there were no significant differences in the systolic and diastolic BP changes from baseline through to 12 months among the DMPA and IUCD users.

**Table 6: Discontinuation of Contraceptive Use at 1 year N=100**

Study Group	Discontinuation		p-value
	Number	%	
DMPA	13	26.0	0.4
IUCD	10	20.0	

At the end of the 1 year of study, 26% of DMPA users had discontinued the method while 20.0% of IUCD users had stopped using it as a method of contraception, p value 0.4.

**Table 7:****(a) DMPA Users Reasons for Quitting N=50**

Reason	Number	%
Amenorrhoea	3	23.1
Weight gain	3	23.1
Irregular menses	4	30.8
Quit to conceive	1	7.7
Amenorrhoea and Weight gain	2	13.0

**(b) IUCD users Reasons for Quitting N=50**

Reason	Number	%
No obvious reason	2	20.0
PID	4	40.0
Cramping and Spotting	3	30.0
Increased bleeding	1	10.0

Majority of DMPA users discontinuing use at the end of 1 year did so because of irregular menses (30.8%), amenorrhoea (23.1 %) or weight gain (23.1 %).

Majority of IUCD discontinuing used at the end of 1 year did so because of PID (40.0%), cramping and spotting (30.0%) or for no obvious reason (20.0%)

**DISCUSSION**

Two of the common concerns regarding DMPA use have been possible weight gain and rise in blood pressure (1,2, 3,4,9,13) . This study was designed to look at these 2 issues prospectively and compare with non-hormonal copper-bearing intra-uterine contraceptive device (IUCD) which is not known to affect weight nor blood pressure of its users.

In socio-demographic characteristics such as marital status, occupation, religion, mean parity and mean number of years in school, the DMPA and IUCD users were comparable with no significant differences in the listed characteristics.

The weight increase at every visit, except between 3 and 6 months, was significantly larger for DMPA compared to IUCD users. The weight increase between 6 months and 9 months, and 9 months to 12 months, were significantly larger among DMP A users compared to IUCD users, with 2-tailed p-value 0[0.0014 and 0.0193 respectively. The total mean weight gain among DMPA users over the 1 year period of study was 2.919kg while for IUCD users was 1.550kg, 2-tailed p-value 0.0000.

The total mean weight gain of 2.919 kg found in this study among DMPA users at the end of 1 year of use was slightly higher than the 2.44938kg average weight gain outlined in the DMPA package insert by



Pharmacaria and Upjohn. This is perhaps because the weight quoted in the package insert was derived in large part from studies in non-African populations (9,10).

The importance of weight gain as perceived by contraceptive users was underlined by the fact that of all DMPA users quitting the method, weight gain contributed 23.1 %, second only to the contribution of irregular menses (30.8%). These findings differed significantly from those of Waweru Mathu (1980) S which had shown that only 2% of DMPA users discontinued because of bleeding irregularities and there was no mention of those doing so because of weight gain. The main difference between the 2 studies was that while this was a prospective cohort study, Waweru's was a retrospective descriptive study. The overall first year discontinuation rate of DMPA use of 26% in this study was comparable to the KDHS 2003 national rate of 31.8% (5)

Weight gain in DMPA is due to fat deposition rather than water retention (16) The aetiology of weight gain in hormonal contraceptors has been thought to be due to increased appetite secondary to a hypothalamic effect or through an increase of insulin, glucocorticoid-like activity of DMPA and or general improvement of health especially reduction of blood loss and therefore an increase in haemoglobin 16.

At baseline, the mean BMI for DMPA users was 26.657 compared to 27.311 for IUCD users, 2-tailed p-value 0.8310. At the end of 12 months of use, the mean BMI for DMPA users was 27.985, while that of IUCD users was 28.172, 2-tailed p-value 0.7250. The mean BMI % change was 4.612% for DMPA users and 2.377% for IUCD users at the end of 12 months of use, 2-tailed p-value 0.0000.

The BMI (Quetelet's index) compares with the KDHS 2003 BMI for Nairobi Province which showed that 56.4% of Nairobi's women aged 15-49 had normal BMI of 18.5 to 24.9 while 39.1 % were overweight/obese with BMI >25. The baseline BMIs and the ones at the end of 12 months are in the overweight category for both groups of contraceptive users. This suggests that other underlying factors such as dietary habits and sedentary lifestyles have a contribution to the baseline weight and subsequent weight changes.

The total mean systolic BP rise from baseline was small among DMPA users (3.216mmHg) and also among IUCD users (4.250mmHg) with no significant difference detected, 2-tailed p-value of 0.4976. This finding agreed with a similar study carried out by Nyansera in 19889 which showed that there was a significant rise in mean systolic BP among oral contraceptive users but none among DMPA users (7)

The total mean diastolic BP rise from baseline among DMPA users was 1.441mmHg while that among IUCD users was 1.250mmHg, 2-tailed p-value of 0.7412. Thus, there was no significant difference in diastolic BP rise among DMPA and IUCD users. This differed from Nyansera's finding that there was a significant rise in diastolic BP among DMPA users (7)

The discontinuation rate among the DMPA users at the end of the I year period of study was 26% while for IUCD was 20%, 2-tailed p-value of 0.47592. This compared well with Waweru-Mathu's (1980) findings of discontinuation rate of 28.9% among DMPA users at the end of I year of use 5. It also compared favourably with the Kenya Health Demographic survey 2005 national rate of 31.8% (6) This study has largely shown that DMP A is a safe contraceptive with modest rise in both systolic and diastolic blood pressure at the end of 1 year of use. However, great attention needs to be exercised while monitoring weight gain since the study has indicated a significant weight gain among DMP A users at the end of 1 year of use (8). This is important especially for those clients who will use the method for longer periods in order to avoid potential risks of cerebrovascular accidents (stroke) and ischaemic heart diseases.

## Conclusions

There is a significant weight gain among indigenous Kenyan women DMP A contraceptive users at the end of 1 year of use. There is no significant systolic nor diastolic blood pressure rise among indigenous Kenyan women DMPA contraceptive users at the end of 1 year of use. Menstrual irregularities are the more common reasons for stoppage of DMPA as a contraceptive among indigenous Kenyan women.

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