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Ultra Low Dose Oral Contraceptives in Indian Women

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Summary

The acceptance of a contraceptive depends largely on it's lack of side effects, low failure rate and good cycle control. It was believed that good cycle control needs higher hormone (specially estrogen) content in an OCpill. On the other hand to reduce the side effects the hormone content of the pill needs to be reduced. After extensive research and trials the pill containing ethinyl estradiol 20 microgram and desogestrel 150 microgram has been found to satisfy the criteria of lesser side effects and good cycle control, reliability remaining the same. The studies were done mainly on Western women. This study done in 1062 Indian women shows the pill to be extremely reliable with lesser side effects and comparable cycle control.

Introduction

The combined oral contraceptives are the most popular form of contraception in the developed world. Almost 80 million women per day are using oral contraceptives throughout the world. In a developing country like India oral contraceptives are yet to become popular. Lack of education plays the pivotal role, though social, religious, cultural and ethical considerations and governmental policies all play important role in determining the acceptance of particular contraceptive method. However the fear of side effects and health hazards are the principal barriers against the oral contraceptive usage. With decrease in the estrogen content of the OC pills and incorporation of newer and better type of progestogen, the acceptance of OC pills have increased. The majority of study reports on oral contraceptives are available from the developed world. The reliability, side effects and cycle control of low dose OC pills in Indian women are assessed in the present study.

Materials and Method

The study was conducted in 30 centres spread all over India. It included the medical colleges, private hospitals and private clinics. It was aimed at including 1800 women and following them for 3 cycles. The completed reports, that is the reports on all the four visits, were available in 1062 women which means 3186 cycles could be studied.

The women who attended the out patient's department for contraception as well as those who were advised contraceptives after abortion and 6 months after delivery were all included in the study. Both nulliparous and multiparous women were included.

The screening was done on the first visit which included history taking and clinical examination. History of jaundice, thromboembolic episodes and hormone dependent tumour in the body excluded the women from the study group. The history of previous

pill intake, its effect and side effects and why it was discontinued were asked. Menstrual history was elicited thoroughly and cycle length, amount of bleeding, dysmenorrhoea and history of irregular bleeding were noted. The body weight and blood pressure were measured. After one month, two months and three months the women were assessed. Apart from body weight and blood pressure measurements questions were asked to find out any side effect. Guided questions were asked for each known side effect. The cycle control, amount of withdrawal bleeding were also noted. The women were instructed to inform immediately if there was any failure of the pill eg if pregnancy occurred.

Results

Total number of cases under study	1062
Total number of cycles studied:	3186

Table I shows the distribution of age. As expected more number of women were of the age group 20 to 29 years followed by the age group 30 to 39 years. Teenagers and those more than 40 years rarely accepted oral contraceptives.

Table I
Distribution of age

Age Group	No. of women	% of women
< 20 yrs	42	4
20-29 yrs	595	56
30-39 yrs	372	35
40-45 yrs	32	3
> 45 yrs	21	2

Table II shows the distribution of parity. As expected maximum number of women in the study had one child followed by the parity group with two children. The nulliparous women accepting OC pill were mostly attending the private clinics rather than the pills outdoors.

Table II
Distribution of parity

Parity	No. of women	% of women
Nulliparous	21	2
One	456	43
Two	330	31
Three or more	255	24

Table III shows the problems of cycle control. With the reduction of estrogen content of the oral pill it was apprehended that the problems of cycle control i.e. breakthrough bleeding and spotting will increase in the users. In the present series however the results were quite comparable with the incidence of breakthrough bleeding and spotting in women taking OC pills with higher estrogen content. In the first month irregular bleeding was present in 12% of women. However with the use of low dose pill for 3 months it decreased to 9% of women. Table IV shows the nature of bleeding problems. When a woman needs one or more sanitary napkin per day then the type of irregular bleeding is called breakthrough bleeding. When she needs less than one sanitary napkin then it is called spotting. After 1 month of ultra low dose OC pills usage 11.1% of women complained of spotting which decreased to 8.5% after 3 months of continuous use. Breakthrough bleeding was complained by 0.9% of women at end of 1 month and it reduced to 0.5% after 3 months. These are the women in whom higher estrogen containing pills had to be prescribed.

Table III
Problems of cycle control

Problem	After one month		After three months	
	No. of women	Percentage of women	No. of women	Percentage of women
Present	127	12	96	9
Absent	935	88	966	91

P: 0.005

Table IV. Nature of bleeding problems

Type of problem	After 1 month		After 3 months	
	No. of Women	% of Women	No. of Women	% of Women
Spotting	117	11.1	91	8.5
Breakthrough Bleeding	10	0.9	5	0.5

P: 0.005

Table V: The incidence of the different amounts of withdrawal bleeding

Amount of Withdrawal Bleeding	After one month		After three months	
	No. of women	% of women	No. of women	% of women
No bleeding	01	0.1	0	0
Normal bleeding	1009	95	910	85.6
More than normal bleeding	04	0.4	14	1.31
Less than normal bleeding	48	4.5	138	12.99

P<0.005

Table VI
The incidence of side effects

	After 1 month		After 2 months		After 3 months	
	No. of women	% of women	No. of women	% of women	No. of women	% of women
Nausea	132	12.4	55	5.18	19	1.79
Headache	86	8.1	45	4.24	30	2.82
Breast Tenderness	81	7.63	52	4.9	27	2.54

P<0.005

Table V shows the incidence of the different amounts of withdrawal bleeding. In most of the women i.e. 95% after 1 month and 85.6% after 3 months, the amount of withdrawal bleeding did not change. In 4.5% after 1 month and 13% after 3 months, the amount of bleeding was less than before. In only 0.4% women after 1 month and 1.3% after 3 months, the amount of bleeding was stated to be increased. Amenorrhoea was reported in only one woman after one month. However, after three months no case of amenorrhoea was reported.

Table VI shows the incidence of side effects. The usual side effects encountered with OC pills usage were noted with lesser incidence in the women on ultra low dose pill. Nausea, the commonest side effect was present in 12.4% women in the first month. With continued usage it decreased to 1.79% only. Headache was complained in 8.1% after first month and only in 2.82% after 3 months. Breast tenderness was common in 7.63% women after first month and 2.54% after 3 months.

Table VII shows the changes in body weight in the women under study. In majority of women no weight change was noted. Weight remained same in 54% of women after 2 months and in 73% of women after 3 months. The weight gain was in the range of 0.5 to 1.5 kg. The loss of weight was also noted, which was in the range of 0.5 to 1 kg.

Table VIII shows the range of weight gain in 3

Table VII
The changes in body weight

	After 2 months		After 3 months	
	No. of women	% of women	No. of women	% of women
No change	573	54	775	73
Weight gain	414	39	244	23
Weight loss	75	07	43	04

P<0.005

Table VIII
The range of weight gain in 3 mths

Weight gain (in Kg)	No. of women	% of women
< 0.5	191	18
0.5-1.0	48	4.5
1.1-1.5	05	0.5

Table IX
The incidence of blood pressure changes after 3 months

	No. of women	% of women	5-10mm systolic / diastolic	10-15mm systolic/ diastolic
No change	764	72	-	-
Increase	180	17	176 (16.6%)	4 (0.4%)
Decrease	118	11	102 (9.6%)	16 (1.4%)

P<0.005

Table X
The reliability of the pill

No. of cycles	User Failure	Method Failure
3186	01	00

months. Out of 244 women 191 gained upto 0.5kg weight, 48 women gained more than 0.5 kg but less than 1kg in 3 months. Remaining gained more than 1kg but less than 1.5 kg in 3 months.

Table IX shows the incidence of blood pressure changes after 3 mths. The increase in blood pressure was marked in only 17% of women, of which 16.6% had an increase less than 10mm of Hg either in systolic or in diastolic blood pressure. In 0.4% the increase was more than 10mm but less than 15mm of Hg. The decrease in blood pressure was also noted in 11% of women.

Table X confirms the reliability of the pill under study. The ultra low dose pill had very low failure rate. Only one case was found to become pregnant due to her faulty intake of OCpills.

Discussion

The progesterones used in oral pills are capable enough to suppress hypothalamo-pituitary axis and prevent ovulation and thus prevent pregnancy. The estrogen has to be added to control the cycles. Therefore, decreasing the dose of estrogen in an combined OC pill does not interefere with the reliability of the pill. Thus when problem of cycle control remains at an acceptable level the lowest dose of estrogen in the OCpill is preferred. In this study the OCpill used contained ethinyl estradiol 20 microgram and desogestrel 150 microgram. The side effects were found to be low as compared to OCpills containing 30 mcg or more estrogen Tuimala et al (1987). The incidence of irregular bleeding was also comparable to OC pills with higher estrogen content. The problem of post pill amenorrhoea was not encountered with except in one case where no withdrawal bleeding occurred in the first month but after completion of second cycle of pill intake withdrawal bleeding occurred. Regarding weight gain the result was quite encouraging. At the end of 3 months only 5% of women reported to have gained more than 0.5kg. The recorded weight loss in 4% women could not be explained. The change in blood pressure was also insignificant. In 72% users no change could be noted. The increase or decrease in blood pressure at the end of 3 months was only 17% and 11% respectively, of which majority was in the range of 5 to 10mm of Hg either systolic or diastolic. It should also be mentioned here that the follow-up of the users in the hospital outpatient clinics was not always done by the same personnel or by the same instruments. The woman who conceived was reported to have had taken the pill.

In the US multicentre study (Morris Notelowitz (1995) with desogestrel 150 mcg and ethinyl estradiol 30 mcg, 809 women were observed for 4096 cycles. Only 1 user failure pregnancy was recorded. The overall incidence of breakthrough bleeding was 1.7% and of spotting 8.1% and only 1% of patients had to be withdrawn from the study for menstrual irregularity. In our study, breakthrough bleeding was in 0.5% and spotting in 8.5%. The women in whom higher estrogen containing pill had to be prescribed were only 5 in number i.e.0.5%. The results therefore are quite comparable between the 30 mcg EE and 20 mcg EE containing pills. On the other hand the side effects causing discontinuation of the pill were seen in 6.6% in the US study whereas in the present study discontinuation due to side effects was not required since at the end of 3 months nausea was present only in 1.8%, headache in 2.8% and breast tenderness in 2.5%. Absence of withdrawal bleeding was very rare in US and European (Bilotta & Favilli, 1988) trials occurring in <2% of the cycles. In the present study only one woman had absence of withdrawal bleeding in the first cycle. Overall, there were no significant changes in mean body weight in the US study. Five of their cases discontinued the study

because of weight gain. In our study, weight gain was not significant in majority of cases. Only in 0.5% the weight gain was between 1 kg to 1.5 kg. In the US study, the effect on blood pressure was also not significant. Two patients presented with clinically significant blood pressure values (systolic > 140mm Hg or an increase of 15 mm Hg from base line or diastolic > 90 mm Hg and an increase of 10 mm Hg from base line). In our study clinically significant blood pressure changes of 10-15 mm Hg systolic or diastolic were noted only in 4 cases (0.4%).

In the multicentre European study (Bilotta & Favilli, 1988) 13,290 women were followed up for 74,967 cycles and put on 30 mcg EE and 150 mcg of desogestrel preparation. The irregular bleeding was noted in 1.5%. At the end of 3 months 0.4% had breakthrough bleeding and 6.7% had spotting. This is also quite comparable to the ultra low dose preparation containing 150 mcg desogestrel and 20 mcg EE. In the present study, with the Indian women the ultra low dose pills have been found to be quite suitable regarding reliability, acceptability (due to less side effects) and cycle control.

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