

ORAL CONTRACEPTIVES—ACCEPTABILITY AND SIDE EFFECTS WITH COMBINATION PILLS

by

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Introduction

The clinical trials with combination pills as a contraceptive, started in 1958. Evaluation of coincidental medical problems and side effects still continue to be a pressing issue in women on pills. Contraceptive steroids are not natural hormones and they induce a pharmacological state and not a physiological change of pregnancy (Speroff *et al* 1973). We have therefore tried to evaluate the acceptability and side effects of this contraceptive in our clinic.

Material and Methods

This is a prospective analysis of 6211

cycles of 849 women enrolled on Primovular (a combination type of pill containing norgestrel 0.5 mg and ethinyl oestradiol 0.05 mg) in our clinic during the years 1974 and 1975. A detailed history was recorded and a complete physical examination was done. Haemoglobin and urine analysis for albumin and sugar and vaginal cytology for cancer screening was done for all the women. Suitable women were kept on this contraceptive after proper explanation. A 3 monthly follow up was done and records maintained.

Results

Six hundred and thirty-nine (75%) of

TABLE I
Education

Education	Interval	%	M.T.P.	%
Illiterate	132	20.66	38	18.10
Primary School	244	38.18	67	31.89
Secondary School	85	13.30	39	18.57
S.S.C.	138	21.60	52	24.76
Undergraduate	16	2.50	6	2.85
Graduate	24	3.76	8	3.83
Total	639		210	

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the patients were interval cases and 210 (25%) were post M.T.P. cases.

Of the women who opted for oral contraceptives, 18-20% were illiterate. Very few under-graduates and graduates attend K.E.M. Hospital, O.P.D. hence they form 6% of the cases in this group (Table I).

70-80% of the cases were from the age group of 21-30 years (Table II).

66-72% of the cases had 1 or 2 living children. Very few nulliparous patients came for a contraceptive to our clinic. Women having more than 4 children were advised oral contraceptives only

when they refused sterilisation (Table III).

80% of the women had no complaints (Table IV).

Table V indicates the menstrual history of women on oral contraceptives. 85% of the cases had regular menstrual cycles.

TABLE II
Age Group

Age Group	Interval	%	M.T.P.	%
Less than 20	83	12.99	18	8.57
21-25	263	41.16	100	47.62
26-30	191	29.89	70	33.33
31-35	66	10.33	14	6.67
36-40	23	3.60	6	2.85
41-45	10	1.57	1	0.48
More than 45	3	0.46	1	0.48
Total	639		210	

TABLE III
Living Children

Living children	Interval	%	M.T.P.	%
0	26	4.07	16	7.62
1	194	30.36	75	35.71
2	235	36.78	79	37.62
3	116	18.15	28	13.33
4	42	6.57	7	3.34
5	15	2.35	5	2.38
6 and more	11	1.72	-	-
Total	639		210	

TABLE IV
Side Effects (O.C.)

Side Effects	No. of Cases	Percentage
Nil	679	80
Symptoms	170	20
Nausea	26	2.9
Vomiting	17	2.0
Headache	26	2.9
Dizziness	18	2.1
Leucorrhoea	15	1.7
Pain in Abdomen	21	2.4
Pain in legs	35	4.9
Breast Discomfort	4	0.5

In 9.7% of the women previous regular cycles changed to scanty flow. In all our patients of amenorrhoea, spontaneous return of menstruation occurred on stopping the oral pills.

TABLE V
Menstrual Cycles (O.C.)

Menstrual Cycles	No. of Cases	Percentage
Regular Cycles	542	63.5
Menorrhagia-Regular	66	21.5
Irregular Cycles-Regular	114	
Regular-Scanty Flow	83	9.7
B.T.B.	38	4.5
Amenorrhoea	6	0.7
Total	849	100

About 60% continued the oral contraceptives, the discontinuation rate being 40%. However, 32% of the patients discontinued the pills for social reasons. Table VI indicates the Social reasons for discontinuation of the pills. Most of these women discontinued the pills in the first 3 months.

9.4% discontinued the pills for medical reasons. Twenty-three patients accepted Copper T due to hypomenorrhoea while on O.C. or underwent sterilisation. Twenty-seven patients changed their

methods due to side effects like nausea, vomiting, headache, dizziness etc. Three patients stopped the pill on family doctor's advice for reasons of weakness, pain in legs etc. (Table VII).

Discussion

The advantages of oral contraceptives are multiple sites of action, ease of administration, feeling of well-being in women, regular menstrual function, relief of dysmenorrhoea and premenstrual tension and improvement of endometrial

TABLE VI
Reasons for Discontinuation (Not Related to O.C.)

Cycles Studied	1	2-3	4-6	7-12	13-18	25 & More	Total	%
Reasons								
Out of Bombay	17	13	8	7	2	-	47	7.36
Change of Address	14	6	2	10	1	-	33	5.16
Indifferent	18	3	-	5	2	-	28	4.38
Lost to follow up	11	1	2	4	2	-	20	3.13
Inconvenient to visit	17	6	8	4	-	1	36	5.63
Husband's Objection	5	1	-	-	-	-	6	0.94
Desired Pregnancy	5	11	4	8	-	1	29	4.54
Taking Pills								
From Outside	5	1	-	-	-	-	6	0.94
Total	92	42	24	38	7	2	205	32.08

There were no cases in the Cycles Studies 19-24 group. One patient developed Jaundice.

TABLE VII
Reasons for Discontinuation (Medical)

Cycles Studied	1	2-3	4-6	7-12	13-18	19-24	25 & More	Total	%
Reasons									
Pregnant	-	-	-	1	-	-	-	1	0.16
Change of Method	8	6	4	2	3	-	-	23	3.60
Side Effects	11	3	3	7	3	-	-	27	4.23
Family Doctor's									
Advice	1	1	1	-	-	-	-	3	0.47
B.T.B.	-	3	1	-	-	-	-	4	0.63
Amenorrhoea	-	1	-	1	-	-	-	2	0.31
Total	20	14	9	11	6	-	-	60	9.40

hyperplasia or endometriosis.

The disadvantage of oral contraceptives are pregnancy-like reaction, menstrual disturbances in some women, daily ingestion in calendar pattern, medical problems and metabolic effects.

The failure rate of oral contraceptives is only 0.05/100 women years and most often it is due to patient failure.

Weighing against the remarkable effectiveness of O.C. is the growing concern to both patient and physician about the side effects and the major metabolic effects.

From a woman's point of view the side effects of O.C. can be roughly divided into:

(a) Symptoms of pseudopregnancy, mimicking pregnancy or lactation and those usually attributed to an excess of oestrogen are nausea, vomiting, dizziness, headache, enlarged and tender breasts, oedema or fluid retention, weight gain. Symptoms attributed to progestogen excess are increased appetite, tiredness, depression and some form of weight gain.

(b) Menstrual side effects: On the whole O.C. have a beneficial effect on the menstrual pattern. However, there are few patients who discontinue the pills because of menorrhagia, hypomenorrhoea, spotting, menstrual irregularity and dysmenorrhoea etc.

A survey of British women who are and were on combination pills is reported by population studies series 3. They are summarised in Table VIII.

There were no symptoms in 39% of the women, only. Symptoms were twice more common in those women who stopped taking pills compared to those who continue with it. Headache is reported as the most common reason for discontinuation.

TABLE VIII
Symptoms in Women Using Oral Contraceptives

Symptom	% Reporting Symptom
None	39
Nausea	16
Depression	13
Putting on Weight	13
Headache	12
Bleeding	11
Breathlessness	3
Dizziness	2
Other	25

In the present study, menstrual symptoms accounted for 14% of the cases. Other side effects in our series were much less, occurring in only 20% of the cases. Weight gain was not a problem in our cases.

Breakthrough bleeding (B.T.B.) in the first few months of use is usually insignificant and disappears with proper use of pills. B.T.B. in women who are on pills for many months can be treated effectively by additional oestrogens. Menorrhagia responds to treatment with additional oestrogen for 5 days and should not be treated by increasing the dosage of combination type of pill. Any irregular bleeding that does not respond to treatment should be properly investigated.

Post-pill amenorrhoea is well reviewed by (Shearman, 1975). He studied 103 cases of Post-pill amenorrhoea. In 30% of the patients amenorrhoea was persistent.

It is difficult to identify and evaluate the serious and sometimes irreversible hazards that may be associated with prolonged daily use of steroids. These include thrombo-embolic episodes, hypertension, carcinogenic potential, effects on diabetes, liver disorders, gall bladder disease, urinary tract and vaginal infection, possibilities of foetal abnormalities and various other metabolic effects.

Speroff *et al* (1973) estimate a possibility of 12-15 deaths 100 million women years due to oral contraceptives. However, according to them the death rates among women using safer but less reliable contraceptives such as condom, jelly, diaphragm etc. are much more due to a greater chance of pregnancy as pregnancy involves a much higher risk to life.

Dosage and Choice of Pills

In order to minimise the metabolic effects and side effects with combination pills, minipills were introduced with a new hope. However, because of the high incidence of failure rate and disturbances of the menstrual cycles, their use became restricted only to the lactating mothers. Lebach and Svendsen (1969) and Borglin and Staland (1975) emphasized the role of Natural Oestrogens to replace the synthetic oestrogens in combination pills. He claims that natural oestrogens minimise the metabolic changes.

A W.H.O. sponsored double blind trial is being carried out at this hospital with NETAGEN Tablets containing either natural or synthetic oestrogen and some progestogen i.e. Norethisterone Acetate.

Summary

(i) 6211 cycles of 849 women on oral combination pills were studied.

(ii) 80% of these women had no symptoms, 20% had pregnancy-like symptoms and menstrual disturbances occurred in

15%. There were no cases with serious side-effects endangering the life of the woman.

(iii) The discontinuation rate was 41% but only 9% had medical reasons for discontinuation.

(iv) The age, parity, educational level, percentage of side effects as well as the discontinuation rate were the same in the interval as well as in the post M.T.P. group.

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References

1. Borglin, N. E. and Staland, B.: Oral treatment of Menopausal Symptoms with natural oestrogens—Acta Obstetrica Gynaecologica Scandinavia. Page 1-11, Supplement 43, 1975.
2. Lebach, P. E. and Svendsen: Oral treatment with Oestradiol, Acta Endocrinologica (Kbh) (Suppl) 138: 22, 1969.
3. Sherman, R. P.: Contraception, 11: 123, 1975.
4. Speroff, L., Glass, R. H. and Kase, N. G.: Steroid Contraception in Clinical Gynaecologic Endocrinology and Infertility. The Williams and Wilkins Company, Baltimore, 1973, page 152-169.