CLINICAL INVESTIGATION OF A NEW LOW DOSE ORAL CONTRACEPTIVE

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Introduction

One of the most widely used products of the present day is the oral contraceptive pill. It has been reported that at least 80 pharmacologically different oral contraceptives are available on the world market (Rudel and Kinel 1970), while the total current world usage has been estimated at about 50 million women (Piotrow and Lee 1974). The new lowest dose combination pill containing 150 mcg. levonorgestrel and 30 mcg. ethinyl estradiol was clinically evaluated at the Cama and Albless Hospital, Bombay.

The advantages of the low dose contraceptive pill are obvious. Many worldwide studies have demonstrated without doubt that this pill causes the least metabolic disturbances in a woman taking the pill (Briggs 1975; Briggs and Briggs 1976). There is minimum weight gain and a low incidence of thromboembolic phenomena, the latter side effect being the most serious one as demonstrated by the Committee on Safety of Drugs (1970) some time ago.

The aim of our study was to evaluate the efficacy, cycle control and patient acceptance of this new low dose contraceptive in Indian women.

Materials and Methods

Nordette was given to 60 women attending the Out-Patient Department of the Cama and Albless Hospital. Twenty five women who attended the private clinic were also put on Nordette.

In our study we found that the best motivated patients were those undergoing Medical Termination of Pregnancy. Almost 90% of our patients were selected after MTP. All women were otherwise healthy without any history of jaundice, high blood pressure or a previous history of thromboembolic disorders. Patients living near the hospital were selected to prevent a significant drop out rate. Care was also taken to enrol only those who would come back to the clinic for a minimum period of six months. None of the patients were on any other oral contraceptive pill in the last four months. Table I gives the age and parity of the women who were enrolled for the trial.

@This pill has since been marketed as OVRAL®L.

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TABLE I

Age	Patients	Parity					
20-25 years	42	0	I	II	III	IV	V
26-30 years	37	11	30	30	8	5	1
31-35 years	6						

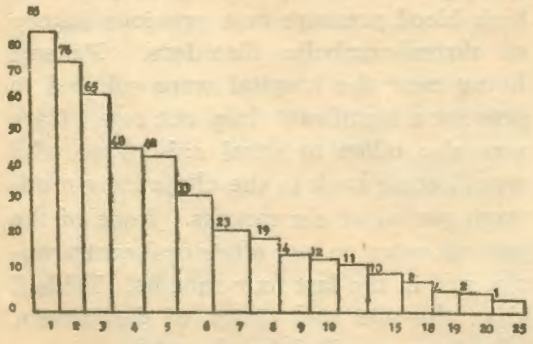
Most patients were below 30 years and had an average of 1 or 2 children. In the total of 85 patients majority were Hindus. We however had 14 Muslim women and 4 Christians. Although we initially had a problem motivating this group, most women accepted the pill readily.

Routine blood count, urine examination and PAP smears were performed on all patients before they were put on the pill. Smears were repeated in individual cases at the end of 6 and 12 months.

Results

A total of 502 cycles were completed by 85 women. There were no pregnancies reported while the patents were on the pill, thus gving the pill a 100% efficacy. The drop out rate in the trial was considerable. Table II shows the total number of cycles completed against the number of patients.

TABLE II



Despite repeated home visits some patients were reluctant to continue on the pill. However, once convinced women continued to take the pill from 6 months to 2 years. We feel that once the women is on the pill for 6 months without any significant side effects, she is likely to continue taking it for at least 2 years.

Most patients had good cycle control and 99% of the recorded cycles were in the range of 25-31 days. The mean durations of withdrawal bleeding was 4 ± 1 day. In 5 patients there were scanty periods (6%). The incidence of breakthrough bleeding was 6% and that of spotting about 1.8%. However, breakthrough bleeding and spotting were not the reasons for withdrawal. Some degree of breakthrough bleeding is to be expected with the lower dose of estrogen in this pill. In addition, all our patients were enrolled immediately folowing MTP which may contribute to a slightly higher incidence of breakthrough bleeding. It was possible to control the breakthrough bleeding by asking the patient to double the dose of the contraceptive pill should irregular bleeding occur. Once controlled in this way, bleeding rarely recurred in subsequent cycles.

Other side effects were mild in nature, i.e. slight nausea, vomiting and dizziness which was seen in about 8% of cases. The symptoms were common in the first month and usually disappeared once the patient continued with the pill for 2 or 3 months.

Hematological investigations and PAP smears did not show any alteration in women on the pill.

Table III gives the reasons for closure.

There was a prompt return of ovulation after the discontinuation of the pill. We know of at least 6 pregnancies in the pre-

TABLE III

Reason	No. of patients
Wanted pregnancy	10
Changed residence	2
Changed to loop	5
Husband fell ill	8
Unknown	25
Total	50

sent series within 3 months of stopping the pill. One patient had an ectopic gestation which was diagnosed and treated. One patient came for a subsequent Medical Termination of Pregnancy at which time tubal ligation was done.

Conclusions

Our clinical evaluation demonstrated that the pill Nordette, a combination of 150 mcg. levenorgestrel and 30 mcg. ethinyl estradiol is a reliable, safe and acceptable oral contraceptive. It induces few undesirable side effects and is well suited to the Indian women.

The most striking aspect of this low dose contraceptive pill was a significant low incidence of breakthrough bleeding and spotting as against the reports from other countries (Foss and Fotherby 1975; Moggia *et al*, 1974; Rozenbaum, 1974; Wouterrz, 1974). This may probably be related to the lower weight of Indian women and needs to be substantiated by a more extensive field trial.

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