LYNESTRENOL 1 mg.—MESTRANOL 0.1 mg. A NEW LOW DOSE ORAL CONTRACEPTIVE. A CLINICAL STUDY

by

I. KAMAL, F. HEFNAWI and N. YOUNIS

From the department of Obstetrics and Gynaecology. Cairo & Al-Azher University

The development of new contraceptives is an indispensable adjunct to the solution of the world wide problems related to the explosive population growth.

It is generally agreed that an optimum ratio should be present between the progestogen and the oestrogen part of any pill. Lowering too much the oestrogen will lead to ovulation escapes. Lowering of the progestogen part is supposed to lower the side effects and leads to a commercially cheap preparation. The present report presents our experience with a new preparation combining 1 mg. of Lynestrenol and 0.1 mg. of Mestranol per tablet.

MATERIAL AND METHOD

The material of this study comprised 39 women. Twenty three of them were randomly selected from those attending the family planning clinic at Cairo University Hospital. Sixteen cases were private patients attending the private clinic of the senior author. All of them received no hormonal contraception for the last 3 months before joining the trial but almost all of them were using another oral contraceptive for a period of 6—12 months and stopped using it for the last three months because of side effects. All were multiparae with an average number of children 7—8 in the hospital group and 1—9 in the private clinic group. Their age ranged between 20 and 36 years. A thorough history and a careful general and pelvic examination with a premedication vaginal and cervical smears were routine in all cases.

Participants were instructed to use the pills cyclically for twenty two days, starting from the 5th day of the first menstrual flow and then to continue taking the pills for 22 days and stop taking them for 6 days. They were followed up monthly for a period of 6 to 12 months ; the total follow up cycles were 336 cycles. At each follow up visit any complaint was first recorded then an inquiry was made about the menstrual pattern and any break-through bleeding, changes in the gastro intestinal, vasomotor, nervous and emotional functions together with any changes in the breast, in libido or any skin manifestations. At each visit, the weight was recorded and compared to that of the previous visits.

At 6 months intervals, participants were re-examined both generally and gynecologically and the vaginal and cervical smears were repeated.

RESULTS

I.—Menstrual Pattern

The interval between the end of tablets and onset of flow varied between 0—5 days with an average of 3.9 for the hospital group and 2.95 for the private clinic group.

1. *Cycle Length :* varied between 24—34 days with an average of 30.3 for the hospital group and 28.1 for the private clinic group. In 5 cycles of the hospital group and 3 cycles of the private clinic group no withdrawal bleeding occurred and these were regarded as amenorrheic. In all such cases a withdrawal bleeding occurred in next cycles.

2. *Duration and Amount of Flow :* The duration of menstrual flow varied between 1—5 days with an average of 3.6 in the hospital group and 3.39 in the private clinic group. The amount of flow was moderate in 67.2% of the cycles ; slight in 27.8%, and severe in 2.9%.

3. *Break-through Bleeding :* spotting occurred in 4 cycles and bleeding occurred in 2 cycles out of the 244 cycles of the hospital group. The incidence of spotting was slightly higher in the private clinic group (11 out of 92 cycles), but no actual bleeding occurred in any of the cycles in this group.

4. *Dysmenorrhea :* in 70% of the whole cycles no dysmenerrhea occurred ; in 29% of the cycles the participants complained of colic and in 1% of heaviness.

II.—Gastro Intestinal Manifestations

Loss of appetite occurred in 3.3% of the cycles in the hospital group, while none of the private clinic grop complained of loss of appetite.

Nausea occurred in 8 cycles of the hospital group and 19 cycles of the private clinic group. Vomiting occurred in only 2 cycles of the first group and 3 cycles of the 2nd group.

Gastric discomfort was complained of in 4% of the cycles in both groups.

III.—Headache and Dizziness

Headach occurred in 34.8% of the cycles in the hospital group and 15% of the cycles in the private clinic group. Dizziness was a complaint in 17% of the cycles of the first group, while none of the participants of the 2nd group complained.

IV.—Skin Manifestations

An increase in the incidence of fall of hair occurred in 11.8% of cycles in both groups.

No acne or cloasma occurred.

V.—Breast Changes

Breast discomfort occurred only in one cycle of the hospital group while it occurred in 25 cycles of the private clinic group.

No change in size nor any nodularity was reported in both groups.

VI.—Changes in Libido

All cases of the hospital group reported no change in libido or in the average number of sexual intercourses per week (1.6/w). In the private clinic group an increase in libido was reported in 5 cycles while a decrease was reported in 6 cycles ; in the remaining 81 cycles no change occurred. These changes did not reflect themselves on the average number of sexual intercourses per week which was almost constant during the whole treatment cycles (2.3/w).

VII.—Weight Changes

In both groups, the average increase in weight was 2.1 Kg./year. This increase occurred in 32.6% of the cases only, 53.2% had no change and 14% decreased in weight.

VIII.—Blood Pressure and Vascular Changes

The blood pressure on admission ranged between 100—130/70—90. Estimations at six and twelve months showed no significant changes. No thromboembolic manifestations occurred during the treatment cycles.

IX.—Cytological Findings

Tow cases showed atypical cell (Class II). No suspicious or malignant smears were found in any participant before or during the course of the trial.

DISCUSSION

The low dose pills used in this trial proved to be fully effective in preventing pregnancy. In 336 cycles not one unplanned pregnancy occurred. This was also the experience of Meyrelles et al. (1968).

The cycle length of participants before joining the trial was 28.8 days. Its average during treatment was 30.3 in the hospital group and 28.1 in the private clinic group.

The amount and duration of flow before the trial was moderate in 73% of the cases and lasting for an average of 4.2 days. It did not vary significantly during the treatment ; both scanty and heavy flows were minimal.

Break-through bleeding (B.T.B.) in the form of spotting was higher in the private clinic group than in the hospital group, while it occurred in 2 out of the 244 cycles of the hospital group.

The incidence of B.T.B. was much less in both groups when compared to its incidence while using other formulations.

In the author's experience, the present preparation proved to have lesser side effects than other preparation having larger doses. It is to be noted that the incidence of these side effects was higher in the private clinic group than in the hospital group except for headache and dizziness which were higher in the hospital group. But still, a subjective improvement of the symptoms was reported by almost all participants when comparing these symptoms with those occurring during medication with higher doses oral pills.

REFERENCES

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