

INFLUENCE OF MODERATE WORM INFESTATION ON SELECTED BIOCHEMICAL PARAMETERS IN THE WOMEN ENROLLED FOR TRIALS ON CONTRACEPTIVES

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Worm infestation is very common in tropical countries like India and is mainly due to soil contamination, unhygienic conditions and other environmental factors. Persistent worm infestation is known to impair the health of an individual which in turn affects certain biochemical parameters.

In evaluating the effect of any drugs in general, it is advisable to carry out trials in healthy normal population. This is also true for trials on steroidal contraceptives. Most of the studies involving metabolic effects of contraceptive steroids are done in normal healthy women in the reproductive age. Although it is very difficult to define a 'normal population', it is assumed that any asymptomatic condition with no clinical signs could be regarded as normal. We had an opportunity on a Task Force study under W.H.O. to evaluate the effect of oral combination contraceptives and injectable contraceptive steroids on such normal individuals, some of whom were likely to have asymptomatic worm infestation.

The contraceptives given were oral combination pills and once-in-three months injection. For ethical reasons, stool examination was done at the end of the study period. We were appalled to see the percentage of women having worm infestation of one sort or the other (Table I). Since it is likely that the re-

TABLE I
Results of Stool Examination
Number of specimens seen : 223
Cyst and/or ova present in 117 (52.4%)

Type of infestation seen:	
Ascaris Lumbricoides	80%
Ascaris Lumbricoides and Trichuris Trichiura	} 11%
Trichuris Trichiura	
Trichuris Trichiura	4%
Giardia Lambliia	2%
Entamoeba Histolytica	2%
Ankylostoma Duodenale	1%

sults of a clinical trial may get vitiated due to the presence of worm infestation, we separated out the results of pertinent biochemical parameters in women who had infestation and compared with those who had not.

Methods

Biochemical parameters estimated were

plasma glucose (glucose tolerance test), serum proteins with electrophoretic pattern, plasma iron, haemoglobin and haematocrit. Plasma glucose was estimated by glucose oxidase method (Trinder, 1969). Serum proteins were estimated by using biuret reagent (Varley, 1963) while electrophoretic separation was obtained by using Beckman Microzone Electrophoresis apparatus with recorder (Model R-101). Plasma iron was estimated by sodium bathophenanthroline reagent using assay kits supplied by WHO (Roche, Product No. 1006). Haemoglobin was estimated by cyanmethaemoglobin method using modified Drabkin's reagent (Varley, 1963) while PCV was determined on microhaematocrit (IEC/Demon Model No. MB). Morning stool specimens were examined for the presence of ova/and or protozoa. Three smears (from saline suspension, with iodine solution and concentration with saturated sodium chloride solution) were seen under the microscope. Presence of 0 to 4 ova per high power field in the smear prepared by the concentration method was con-

sidered to be moderate infestation according to WHO Task Force Protocol.

Although biochemical studies for the women enrolled for trial were carried out prior to, at 1, 3, or 6 months and also at 12 months intervals after taking contraceptives the results of biochemical tests at 12 months interval only have been compared since the stool examination was done at the end of the study period.

Results

Tables II and III show the results obtained. It can be seen that plasma glucose levels at fasting state and after a glucose load were significantly lower in the women with infestation. Serum total proteins and albumin levels were nearly the same. Serum γ -globulin levels were significantly higher in the women with infestation. Plasma iron levels were lower in the women with infestation and they were significantly reduced in the infested women who were enrolled for trials on oral combination contraceptives. Haemoglobin and haematocrit levels in the women with infestation were signi-

TABLE II
Biochemical Investigations in Women With and Without Infestation Who Had Completed the Trial on Oral Contraceptives
(Mean \pm S.D.)

Parameter	Women with infestation	Women without infestation	Probability 'P'
Glucose Tolerance Test:			
0 hr mg %	89.85 \pm 8.8	93.7 \pm 9.8	0.02
60 mins. mg %	141.3 \pm 35.7	150.2 \pm 39.3	N.S.
120 mins. mg %	100.3 \pm 41.5	121.5 \pm 30.3	0.001
Serum total protein gm %	7.22 \pm 0.50	7.18 \pm 0.14	N.S.
Serum Albumin (gm %)	3.50 \pm 0.31	3.51 \pm 0.28	N.S.
Serum γ -globulin (gm %)	1.78 \pm 0.25	1.70 \pm 0.28	>0.1 <0.05
Plasma iron (μ gm %)	78.7 \pm 27.5	88.3 \pm 28.3	0.05
Haemoglobin (gm %)	12.6 \pm 1.35	12.5 \pm 1.10	N.S.
Haematocrit %	37.5 \pm 3.1	38.0 \pm 3.2	N.S.

TABLE III

Biochemical Investigations in Women With and Without Infestation Who Had Completed the Trial With DMPA Injection for Contraception
(Mean \pm S.D.)

Parameter	Women with infestation	Women without infestation	Probability 'P'
Glucose Tolerance Test:			
0 hr mg %	88.7 \pm 9.6	94.3 \pm 9.2	0.01
60 mins. mg %	97.8 \pm 25.7	109.3 \pm 20.2	0.05
120 mins. mg %	81.8 \pm 19.2	93.3 \pm 20.8	0.02
Serum total protein gm %	7.21 \pm 0.44	7.20 \pm 0.41	N.S.
Serum Albumin (gm %)	3.55 \pm 0.26	3.61 \pm 0.29	N.S.
Serum γ -globulin (gm %)	1.79 \pm 0.32	1.65 \pm 0.28	0.05
Plasma iron (μ gm %)	86.3 \pm 28.8	91.2 \pm 27.8	N.S.
Haemoglobin (gm %)	12.8 \pm 0.93	13.1 \pm 0.50	>0.1 <0.05
Haematocrit %	38.5 \pm 2.6	40.1 \pm 2.88	0.02

N.S.: 'P' not significant.

ificantly low in those women recruited for trial on injectable contraceptives.

Discussion

None of the women at the time of stool analysis showed any signs and/or symptoms of worm infestation. Majority (80%) of the women with infestation had ascariasis. Only 1 and 2 per cent respectively had ankylostomiasis and amoebiasis. A significant difference in plasma glucose, iron, haemoglobin, haematocrit and γ -globulin in the women with infestation as seen in this study may be due to malabsorption of nutrients. Since the biochemical tests were carried out 12 months after taking oral contraceptives they may be influenced by two factors viz. effect of pills and presence of worm infestations. Intestinal helmenthis and parasites are known to produce such a condition (Monroe, 1976). Changes in hosts' circulatory inorganic substances, carbohydrate and protein metabolism due to worm infestation has been reported earlier (Brand, 1973). Mechanical blockage of microvilli by the parasites, competi-

tion between host and parasites for nutrients, altered intestinal motility and mucosal invasion have been suggested as the possible mechanism for such a change leading to malabsorption (Beeson and McDermott, 1975). In the present study, though the worm infestation was of a moderate type it produced some degree of malabsorption as evident by biochemical parameters. We have not carried out specific intestinal absorption tests in these women to check this possibility.

The data obtained suggests that the results of clinical trials conducted for the metabolic effects of contraceptive steroids are likely to be influenced if moderate worm infestation is present in the subject population.

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