

CLINICAL TRIAL

“OVOUTOLINE” FOR THE TREATMENT OF LEUCORRHOEA AND DYSMENORRHOEA (A STUDY OF 50 CASES)

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INTRODUCTION

Ovoutoline is a combination of extract of various indigenous herbal drugs known to have beneficial effects in leucorrhoea and dysmenorrhoea, such as Ashok (*Saraca indica* linn), Lodhra (*Symplocos racemosa*), Guduchi (*Tinospora Cordifolia* Miers), Shatavari (*Asparagus racemosus* wild), Kurchi (*Hollarrhena antidysenterica*), Tagar (*Valeriana wallichii* D.C.) and Yashtimadhu (*Glycyrrhiza glabra* linn). These herbal drugs are known for their action as uterine relaxant and uterine tonic. These drugs have been used from ancient times for a variety of gynaecological disorders. Of the various ingredients particularly Ashok bark is a uterine sedative and is known to act directly on the muscular fibres of the uterus. Similarly 'Lodhra' in combination with sugar is recommended for treatment of menorrhagia and other uterine disorders.*

MATERIAL & METHOD AND OBSERVATION

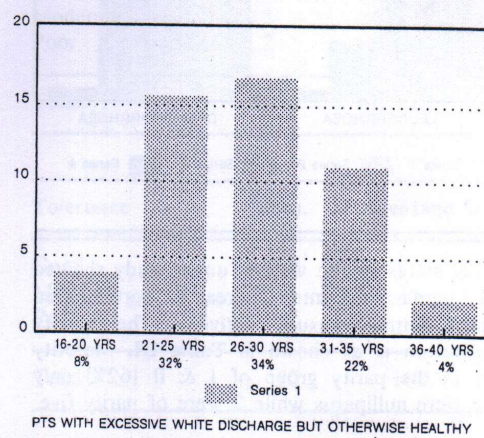
A total number of 50 cases in the age group of 18 to 40 were studied. (Table I)

Patients with organic diseases of the cervix such as cervical erosion, pelvic inflammatory disease, cervical fibroids, polyps etc. were not included. In every case a thorough gynaecological examination was done to rule out any pathology. Similarly, cases with chronic metabolic disorders like diabetes mellitus, endocrine disorders, pregnancy etc., were not included for obvious reasons.

TABLE I
Age Wise Distribution

Age	No.	Percentage %
16-20	4	8
21-25	16	32
26-30	17	34
31-35	11	22
36-40	2	4
Total	50	100

STUDY OF THE EFFICACY OF OVOUTOLINE AGEWISE DISTRIBUTION OF PATIENTS



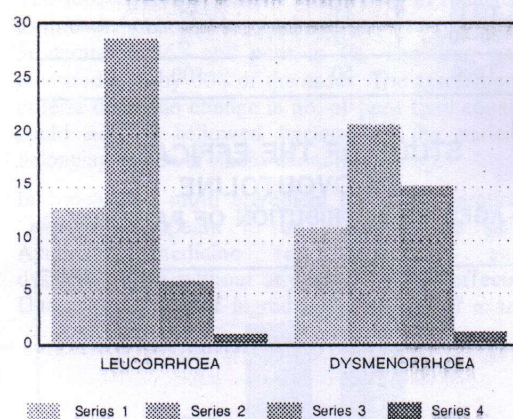
PTS WITH EXCESSIVE WHITE DISCHARGE BUT OTHERWISE HEALTHY

Patients were observed for three consecutive menstrual cycles. The evaluation of the symptoms was based on subjective interrogations. Evaluation was done before starting the Ovoutoline therapy and after the cycle. **Subjective grading of evaluation** is as shown in Table II. Ovoutoline was administered in the dose of 1 to 2 tablets three times a day.

TABLE II
Subjective Evaluation Grading

LEUCORRHOEA	DYSMENORRHOEA
Mild reduction (+)	Mild (+)
Moderate reduction (++)	Moderate (++)
Satisfactory reduction (+++)	Satisfactory (+++)
Complete Relief (++++)	No pain (++++)

STUDY OF EFFICACY OF OVOUTOLINE RESULTS AND ANALYSIS

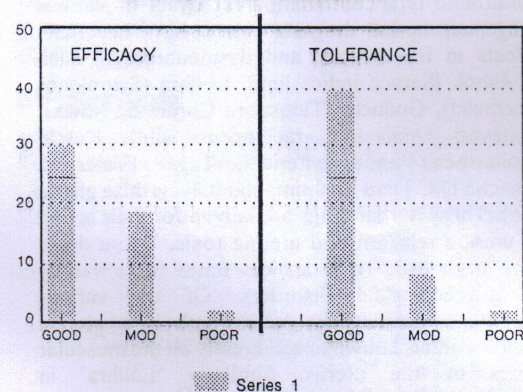


Marital status of the women under study showed only 3 unmarried women whereas 47 were married having normal sexual activity. The **parity distribution** is as shown in Table III. Majority were in the parity group of I & II (62%) only three were nulliparus while 2 were of parity five.

TABLE III
Parity Distribution

Parity	Number	Percentage %
Nulliparus	3	6
I & II	31	62
III & IV	14	28
V	2	4
Total	50	100

OVOUTOLINE SUBJECTIVE ASSESMENT



As regards socio-economic status majority were from lower and middle socio-economic group. Only 2 were from higher socio-economic group. (Table IV). Associated clinical features in addition to leucorrhoea (100%) and dysmenorrhoea (96%) included infertility (12%) dysfunctional uterine bleeding (12%) seven (14%) presented history of recent medical termination of pregnancy. Nine (18%) were lactating and post partum, six had undergone laproscopic sterilisation (12%) in recent past. While nine had CUT 200 inserted in the recent past. Table V.

TABLE IV
Socio-Economic Status

Socio-economic Group	Nos.	Percentage %
Higher Income Group	2	4
Middle Income Group	22	44
Lower Income Group	26	53
Total	50	100

TABLE V
Clinical Features

	Nos.	Percentage %
Leucorrhoea	50	100
Infertility	6	12
Dysmenorrhea	48	96
D.U.B.	6	12
Post M.T.P.	7	14
Post I.U.D.	9	18
Post Lap. T.L.	6	12
Post partum	9	18
Nonspecific vaginitis	36	72
Atrophic vaginitis	1	2
Nonspecific cervicitis	13	26

Clinical examination revealed nonspecific vaginitis and cervicitis in 36 & 13 cases respectively. Only 1 had atrophic vaginitis. She was 40 years of age and was administered local oestrogens in addition.

RESULTS & ANALYSIS

Table VI shows that improvement in symptoms of leucorrhoea was judged as excellent in 13 (26%), good in 28 (56%). Only 1 did not show any improvement while 2 had marginal improvement.

TABLE VI
Results Following Ovoutoline Therapy

Leucorrhoea	Nos.	Percentage %
Excellent	13	26
Good	28	56
Fair	6	12
Poor	2	4
No improvement	1	2

Dysmenorrhoea **Nos.** **Percentage %**

Excellent	11	22
Good	20	40
Fair	15	30
Poor	1	2
No improvement	1	2

As regards symptoms of dysmenorrhoea 11 (22%) had excellent results 20 (40%) had good results while no improvement was seen in 1 and marginal in another. Overall efficacy and tolerance of Ovoutoline therapy for treatment of leucorrhoea and dysmenorrhoea is shown in Table VII. None of the patients discontinued drugs therapy for drug intolerance or any side effect. Vaginal cytology was taken before, during and after the therapy in 40 cases. It showed dramatic decrease in inflammatory cells in the smear (Table VIII).

TABLE VII
Efficiency & Tolerance of Ovoutoline Therapy.

Efficiency	Nos.	Percentage %
Good	30	60
Moderate	18	36
Poor	2	4
Total	50	100

Tolerance **Nos.** **Percentage %**

Good	40	80
Moderate	8	16
Poor	2	4
Total	50	100

TABLE VIII
Cytological Findings Before & After Ovoutoline Therapy.

Percentage decrease in inflammatory cells.	Nos.	Percentage %
More than 50%	28	56
More than 25%	10	20
No change	2	4
Cytology not done	10	20
Total	50	100

CONCLUSIONS

Ovoutoline appears to be safe and effective Ayurvedic remedy for patients with leucorrhoea and dysmenorrhoea, especially in non-specific vaginitis and primary dysmenorrhoea.

The subjective assessment of the drug in reducing dysmenorrhoea and leucorrhoea was good in 60%, moderate in 36% and poor in 4%. The drug was tolerated well by 80% of the cases. The assessment criteria based on change in no. of pads (pad count) could not be followed because of the patient belonging to lower socio-economic group.

In conclusion, multi ingredient herbal preparation Ovoutoline appears to be effective and safe Ayurvedic medicine for leucorrhoea and dysmenorrhoea without any alarming side effects. Due to a number of ingredients and lack of exact

pharmacodynamic profile of the ingredients and availability of analytical facility, it is difficult to establish exact mode of action of Ovoutoline. The specific mechanism of action of Ovoutoline is not known. However it is believed to sedate and tone up uterine musculature, reduce secretion and make the environment less conducive for the growth and multiplication of pathogens.

The investigators feel that there is a definite need to undertake multicentric trials with more number of patients to determine the statistical significance of therapy and to decide minimum duration of therapy.

ACKNOWLEDGMENT

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