

A DOUBLE BLIND PLACEBO CONTROLLED TRIAL OF

'PELVORIN'

IN PATIENTS OF EXCESSIVE VAGINAL
DISCHARGE (LEUCORRHOEA)

INVESTIGATOR

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OBJECTIVE

The aim of the study was to see the efficacy and safety of a Homoeopathic medicine 'Pelvorin' in patients suffering from excessive vaginal discharge.

ABSTRACT

A double blind placebo controlled trial was conducted in 104 patients suffering from vaginal Discharge of different etiology. All the patients were allotted randomly Group A and Group B respectively. In Group A patients received Pelvorin in dosage of 4 tablets 4 times a day for 1st week, 4Tablets 3 times a day for second week and then 4 tablets 2 times a day for 2 weeks. One bottle was sufficient for one month for 1 patient. Patients of the Group B were given placebo tablets in the same dosage for the same duration. Patients were examined regularly. General examination and per vaginal (PV) examination were done. Hb was estimated at 1st visit. Microscopic examination of vaginal smear was done and discharge was sent for culture also. It was noted that vaginal discharge (Leucorrhoea) was significantly cured in Pelvorin Group as compared to Placebo group ($p < 0.01$). Other associated signs and symptoms e.g. pain in back, pain in abdomen, itching, redness, burning micturition, weakness, mental problem were also remarkable attenuated by the end of 4 weeks in Pelvorin group. Thus this study confirms that Pelvorin is highly beneficial for prompt management of Leucorrhoea and other associated symptoms.

INTRODUCTION

The amount of normal vaginal discharge varies with age, in health and in disease. In healthy adult women in child bearing age group, the vaginal discharge consist of white coagulated material which when examined is seen to consist of squamous cells, Doederlein's bacilli and coagulated secretion. Normal discharge increases at the time of ovulation, immediate premenstrual phase, during pregnancy and under the stimulus of sexual excitation. Normally the discharge is 0.5 to 1 cc and consists of:

1. Secretions of sweat and sebaceous glands of vulva and bartholin's gland.
2. Transude of the vaginal epithelium and desquamated cells.
3. Mucous secretion of endocervical glands.

4. Endometrial glandular secretions.

In leucorrhoea the normal vaginal secretions are increased which can be non-pathogenic and pathogenic. Sometimes it can be due to specific infections like gonococcal and trichomonas vaginalis. Non-sepcific infections due to streptococcus, staphylococcus, E. Coli. Other causes are cervical erosion, carvical polyp, patient taking oral contraceptives and chemical contraceptives used locally.

Excessive vaginal discharge is found in 50% of gynaecological patients and is a very common symptom in every woman at one time or other.

COMPOSITION & ACTION OF INDIVIDUAL COMPONENTS OF PELVORIN

1. Alumina	6CH
2. Borax	6 CH
3. Sepia	6CH
4. Kreosotum	6X
5. Pulsatilla nigricans	6X

ACTION OF INDIVIDUAL DRUGS

1. Alumina - Leucorrhoea, acrid profuse, transparent ropy with burning, worse during day time worse after menses.
2. Borax - Leucorrhoea like white of egg.
3. Sepia - Leucorrhoea, yellow, greenish with much itching.
4. Kreosotum - Corrosive itching, leucorrhoea yellow acrid worse between periods.
5. Pulsatilla nigricans - Leucorrhoea acrid burning creamy, pain in back, tired feeling.

MATERIALS & METHODS

The design of study was randomised placebo controlled double blind trial. Drug code was provided in a sealed envelop which was kept secret till final analysis of trial was over.

PATIENT SELECTION

One hundred and four patients attending O.P.D. at Gupta Medical Centre were included in the study. 40 patients had specific vaginitis - Monilia trichomonas infection, 30 patients had non-specific vaginitis - streptococcal and staphylococcal infection. 20 patients had cervical erosion, 4 patients had cervical polyp-10 patients had leucorrhoea of unknown etiology. Diagnosis was made by vaginal discharge. Signs and symptoms were noted.

- I. **Type**
 1. Acrid, corroding, burning
 2. Albuminous, slurry and mucous
 3. Thick, viscid, string, tough
 4. Thin and watery

- | | |
|---------------------------|---|
| II. Colour | <ol style="list-style-type: none"> 1. Blackish 2. Bloody 3. Brown 4. Flesh coloured like washing of meat 5. Greenish 6. Milky white 7. Purulent, staining, yellow |
| III. Flow | <ol style="list-style-type: none"> 1. Gushing 2. Intermittent 3. Profuse |
| IV. Smell | <ol style="list-style-type: none"> 1. Bland and non offensive 2. Offensive |
| V. Pain | <ol style="list-style-type: none"> 1. Painless 2. Painful |
| VI. Accompanied by | <ol style="list-style-type: none"> 1. Itching 2. Lumpy |
| VII. Occurrence | <ol style="list-style-type: none"> 1. After coitus 2. After menses or between periods 3. After stools 4. After urination 5. At climaxis 6. At night 7. Before menses 8. Better from washing with cold water. 9. From movements/walking 10 From rest 11. From sitting relieved by walking 12. From urine, contact of 13. In daytime 14. In little girls 15. In old weak woman 16 Instead of menses |
| VIII. Concomitants | <ol style="list-style-type: none"> 1. Abdominal pain, colic preceding & attending. 2. Backache and weak feeling, preceding and attending. 3. Cervical erosion, bleeding easily. 4. Debility, weakness 5. Diarrhoea 6. Feeling as if water running 7. Feeling of fulness, heat relieved by cold water |

8. Haemorrhage, obstinate 'intermittent'
9. Hepatic derangement
10. History of abortion
11. Hysterical spasm in uterus and abdomen
12. Mental symptoms
13. Moth spots on forehead
14. Metorrhagia following
15. Pruritus vulva
16. Relaxation of genitals
17. Spasmodic contraction of vagina
18. Urinary irritation

Thorough general examination of patients was done, PS & PV was done to exclude any pelvic pathology. P/R was done in selected patients having thread worm infection.

DOSAGE OF PELVORIN

A total of 104 patients were randomised for the trial and 52 patients were assigned to Group 'A' (containing Pelvorin) and 52 patients were included in Group 'B' (containing placebo Tablets). Randomisation was done. Both drugs A & B were dispensed in tablets form of the same colour, consistency and flavour. Each patient was given 4 tablets 4 times a day for 1st week and 4 tablets 3 times a day for 2nd week. 4 tablets 2 times a day for another 2 weeks. One bottle was sufficient for one patient for one month. Group 'A' patients were given 'A' tablets and Group B patients were given 'B' tablets for one month.

INITIAL EVALUATION AND FOLLOW UP

Each patient was subjected to detailed clinical evaluation to establish the etiology of vaginal discharge. The signs and symptoms were recorded on pre-designed proforma. The follow up was done from 0 day, 1st week, 2nd week, 3rd week and 4th week.

DATA ANALYSIS

For assessing the impact on efficacy of a drug, it is important to know the cause of excessive vaginal discharge.

Age distribution -All the patients were between 18-40 years of age. (Child bearing age group in both the groups).

DISTRIBUTION OF PATIENTS ACCORDING TO DISEASE AND TREATMENT

S. No.	DISEASE	PELVORIN	PLACEBO	TOTAL
1.	SPECIFIC VEGINITIS	20	20	40
2.	NON-SPECIFIC VEGINITIS	15	15	30
3.	CERVICAL EROSION	10	10	20
4.	LEUCORRHOEA OF UNKNOWN ORIGIN	5	5	10
5.	CERVICAL POLYP	2	2	4

RESULTS

A total of 104 patients in age group of 18–40 years constituted the study sample. Group A received Pelvorin while group B received Placebo.

SIGN AND SYMPTOMS PROFILE : Total number of patients 104

S. No. Symptoms	Pelvorin					Placebo				
	0 Day	1st wk	2nd wk	3rd wk	4th wk	0 Day	1st wk	2nd wk	3rd wk	4th wk
1 Discharge	52 (100%)	50 (96.15%)	18 (34.61%)	16 (30.7%)	10 (19.2%)	52 (100%)	50 (96.15%)	49 (94.2%)	45 (86.6%)	44 (84.6%)
2. Pain in back	50 (100%)	48 (96%)	36 (72%)	20 (40%)	12 (22%)	48 (100%)	46 (95.8%)	45 (93.7%)	42 (87.5%)	40 (83.3%)
3. Pain in abdomen	48 (100%)	46 (95.8%)	38 (79.1%)	30 (62.5%)	15 (31.2%)	46 (100%)	45 (97.8%)	40 (86.50%)	38 (82.6%)	30 (65.2%)
4. Itching	48 (100%)	45 (93.7%)	36 (75%)	30 (62.5%)	10 (20.8%)	45 (100%)	40 (88.8%)	38 (84.4%)	36 (80%)	30 (66.6%)
5. Redness	30 (100%)	28 (93.3%)	20 (66.6%)	12 (40%)	10 (30.3%)	31 (100%)	29 (93.5%)	28 (90.3%)	20 (64.5%)	15 (48.3%)
6. Burning during urination	15 (100%)	14 (93.3%)	9 (60%)	8 (53.3%)	6 (40%)	12 (100%)	10 (83.3%)	8 (66.6%)	7 (58.3%)	6 (50%)
7 Weakness	40 (100%)	35 (87.5%)	30 (75%)	21 (52.5%)	10 (25%)	41 (100%)	39 (95.1%)	38 (92.6%)	35 (85.3%)	30 (73.3%)
8. Mental problems	28 (100%)	26 (92.8%)	20 (71.4%)	12 (42.8%)	10 (35.7%)	26 (100%)	24 (92.3%)	20 (76.9%)	18 (69.2%)	16 (61.5%)

Distribution patients according to relative efficacy of drugs (Pelvorin & Placebo)

	Group A (Pelvorin)		Group B (Placebo)		Relative efficacy & P Value
	Cured	Not Cured	Cured	Not Cured	
Vaginal Discharge	42 (80.7%)	10	8 (15.3%)	44	$X^2 = 14.36$
n=104	n==52		n=52		p<0.01

Efficacy of treatment was greater among patient receiving Pelvorin compared to that of Placebo (80.7% against 15.3%)
 $X^2 = 14.36$ p<0.01

GROUP 'A' PATIENTS

All the patients had vaginal discharge. At the end of 1 st week with treatment, it was seen that out of 52 patients, 50 had vaginal discharge. At the end of 2nd week 18 patients (34.6%) complained of vaginal discharge. At the end of 3rd week, 16 patients (30.7%) complained of vaginal discharge. At the end of 4th week only 19.2% complained of vaginal discharge.

Pain in back was present in 50 patients. At the end of 1st week, it was present only in 48 patients (96%) At the end of 2nd week, it was present in 36 patients (72%). At the end of 3rd week, pain in back was present in 20 patients (40%) and at the end of 4th week, pain in back was present in 12 patients (22%).

Pain in abdomen was present in 48 patients. At the end of 1st week 46 patients (95.8%) complained of pain in abdomen. At the end of 4th week with treatment only 15 patients (31.2%) complained of pain in abdomen.

Itching was associated in 48 patients. At the end of 1 st week, 45 patients (93.7%) had itching. At the end of 2nd week, 36 patients had itching. At the end of 3rd week, 62.5% had itching. At the end of 4th week only 10 patients (20.8%) complained of itching.

Redness was present in 30 patients. At the end of 1 st week, 20 patients complained of redness, At the end of 2nd week, 20 patients had redness. At the end of 3rd week, 12 patients had redness and at the end of 4th week, 10 patients (30.3%) had redness.

15 patients complained of burning micturition. At the end of 1 st week, 14 patients had burning. At the end of 2nd week, 9 patients had burning micturition. At the end of 3rd week, 8 patients complained of burning micturition. At the end of 4th week, only 6 patients (40%) complained of burning micturition.

General weakness was noticed by 40 patients. At the end of 1 week with treatment only 35 patients (87.5%) had general weakness. At the end of 2nd week 30 patients had weakness At end of 3rd week, 21 patients (52.5%) had weakness. At the end of 4th week, only 10 patients (25%) complained of weakness.

Mental problems were associated in 28 patients. After one week with treatment, 26 patients (92.8%) had mental problems. At the end of 2nd week, 20 patients (71.4%) had mental problems. At the end of 3rd week, 12 patients (42.8%) had mental problems. At the end of 4th week, 10 patients (35.7%) had mental problems.

GROUP 'B' PATIENTS

In Group B patients, after 1 week of treatment with placebo tablets, 50 patients (96.15%) had vaginal discharge. At the end of 2nd week, 49 patients (91.2%) had vaginal discharge. At the end of the 3rd week 45 patients (86.5%) had vaginal discharge. At the end of 4th week 44 patients (84.6%) had vaginal discharge.

Pain in back was present in 48 patients. At the end of 1 st week treatment 46 Patients (95.8%) had pain in back. At the end of 2nd week, 45 patients had pain in the back. At the end of 3rd week with treatment 42 patients (87.5%) had pain in back. At the end of one month treatment with placebo, 40 patients (83.3%) had pain in back.

Pain in abdomen was present in 46 patients of Group B. After 1 month, treatment with placebo 30 patients had pain in abdomen.

Itching was present in 45 patients. After 1 month of treatment with placebo 30 patients (66.6%) had itching.

Redness was noticed in 31 patients. After one month of treatment with placebo 15 patients (48.3%) had redness.

Burning micturition was noticed by 12 patients. After one month of treatment with placebo tablets, 6 patients (50%) had burning micturitions.

Weakness was noticed by 41 patients. After one month of treatment 30 patients (73.1%) had weakness.

Mental problems were present in 26 patients. After one month of treatment 16 patients (61.5%) had mental problems.

DISCUSSION

No scientific explanation of the mechanism of action of homoeopathy currently exists. However, the numerous anecdotal reports of its efficacy at its use by millions of people worldwide suggest the need for a thorough scientific examination of this modality. In this study our intention was to document whether there was a clinically and statistically significant treatment associated with Pelvorin, a homoeopathic medicine said to alleviate excessive vaginal discharge in women. Leucorrhoea is one of the commonest problem in women. It is commonly associated with pain in the back, pain in abdomen, itching, redness, burning micturition, weakness and mental problems.

Total 104 patients were selected for the study who complained of Leucorrhoea, 52 patients were given 'Pelvorin' (Group A) and 52 patients were given placebo tablets in the same dosage (Group B). Signs and symptoms at the end of one month of treatment with 'Pelvorin' and Placebo were compared. It was found that at the end of one month with treatment of Pelvorin, relief was found in 80.8% patients while in patients receiving placebo tablets, relief was found in 15.4% patients only.

The other symptom associated with Leucorrhoea, pain in back was relieved in 78% patients While in patients receiving placebo only 16.7% patients got relief.

Pain in abdomen was alleviated in 68% in Group A patients while in Group B only 34.8% got relief.

Itching reduced to 20.8% at the end of one month treatment in Group A patients. Thus itching was relieved in 79.2% patients of Group A while in Group B patients relief was obtained only in 33.4% of patients.

Redness was relieved in 69.7% of Group A while in Group B it got cured only in 51.7% of patients. Burning micturition was present in 40% of patients after one month of treatment with Pelvorin while it was present in 50% of patients in Group B.

Weakness was present in 25% of patients of Group A at the end of one month while in Group B it was present in 73.1 % of patients in Group B.

Mental problems were found in 35.75% of patients in Group A while in Group B they were present in 61.5% of patients at the end of one month treatment with placebo tablets.

Thus the above study confirms that Pelvorin helps in controlling Leucorrhoea and other symptoms associated with Leucorrhoea.



Signature

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