

To assess the efficacy & safety of Femiforte tablet in cases of non-specific leucorrhoea.

Subject of clinical study

“Femiforte tablet in a controlled series of 200 cases of Non-specific Leucorrhoea”.

The investigator of clinical study.

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The conclusion of clinical study.

Common causes of leucorrhoea are mentioned. 200 cases of non-specific leucorrhoea were treated with an oral indigenous drug Femiforte and results were noted. Additional 50 cases were kept as control on placebo. Results were vary encouraging 72.5% cured, 20.5% improved, with 7% failures, with minimum side effects and very low relapse rate. Possible mode of action of drug has been discussed. Being orally effective and economically acceptable to all young, old, orthodox or fastidious females, this drug is no doubt a very valuable remedy in the management of leucorrhoea.

MANAGEMENT OF NON-SPECIFIC LEUCORRHOEA

By

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INTRODUCTION

Vaginal discharge is one of the commonest complaints at a gynaecologist clinic. Normal vaginal discharge comes mainly from the glands of the cervix, but with the addition of a transudate through the vaginal epithelium and probably also of some discharge, thin, watery, alkaline and scanty, from the body of the uterus. Its volume should not be more than half a c.c. It is of semifluid consistency, is whitish or greyish in colour, has little or no smell, and it should not cause any vulval irritation or itching. It contains glycogen, and its pH is 4 to 4.5. Doderlein's bacilli and epithelial cells are numerous, and pyogenic organisms are nil.

Excessive vaginal discharge without blood or pus is termed as leucorrhoea. Leucorrhoea is not a disease, but a symptom-complex. This subjective symptom depends also on the patient's mental state regarding the hygiene. The amount of discharge, which may be a distress to one patient, may not draw any notice of another patient, unless asked directly about it.

Causes of leucorrhoea are multiple. They can be classified into local and general, or constitutional. The commonest cause is chronic cervicitis. The others are trichomonas infection, mycotic vaginitis, gonorrhoea, senile vaginitis, early cases of carcinoma cervix or carcinoma endometrium, retained foreign body and non-specific causes.

Treatment of leucorrhoea consist of eradicating the cause, but is often unsatisfactory, particularly when no specific organism or lesion can be found to account for it. In this study, an attempt has been made to assess the effectiveness of an oral drug “FEMIFORTE” in a controlled series of 200 cases of non-specific leucorrhoea. A form of treatment that is simple and carries reasonable assurance of success has long been needed. Early observations on the efficacy of this drug were reported by Surti, A. Phiroze, Thakur and Phadke.

MATERIAL AND METHODS

The study began at the “Chandrika Bhatia Memorial Clinic” Bombay. The total number of gynecological cases attending the clinic was 1,022, of which 498 complained of leucorrhoea - amounting to about 50%. These included females of prepubertal age group, childbearing age group and postmenopausal, age group. The cases were from this city as well as from the suburbs and belonged to different social, educational and economic strata. All the women complaining of leucorrhoea were scrutinized as under:

(a) History: -

- (i) Duration: In most of the patients of childbearing age group, the complaints dated back to any delivery, though a few cases complained of leucorrhoea since marriage.
- (ii) Color of discharge
- (iii) Irritation or not
- (iv) Is the discharge constant, or only before or after the periods?

It was at this juncture that we came to realize that the standards of cleanliness differ very much e.g. one patient may present a complaint of vaginal discharge and on examination, no abnormal discharge can be found, other, on routine questioning, deny that they have any discharge, but examination reveals an abundant, thick, mucopurulent discharge, quite abnormal in character and quantity.

- (v) History of treatment given before-vaginal tablets, douche, etc.
- (vi) Micturition: Pain or frequency.

(b) General Examination: was then carried out in detail.

(c) External Examination: Vulva was examined for the evidence of vulvulitis. Bartholin's glands were palpated and urethra examined.

(d) Internal Examination: - No lubricant was used for the examining finger. Forefinger was first introduced and with it, the posterior vaginal wall was depressed. The discharge was collected from the posterior fornix in a pipette and examined. A bivalve speculum was passed and vaginal walls exposed. Cervix was

inspected and smear was taken from the cervical canal. Speculum was then withdrawn and routine bimanual examination was carried out.

All the cases of specific origin were duly treated and are not included in the present series. The present series is comprised of 200 cases of leucorrhoea of non-specific origin, which were treated by Femiforte. A group of 50 cases was kept as control, by treating them with placebo and general line of treatment.

Tables 1, 2 and 3 show that most of the patients were married and of the child-bearing age group. Their symptom dated back to more than three months. But this is not of much statistical significance, because most of the patients attending this clinic are of the child-bearing age group, and of low socioeconomic status, and do not rush for treatment for leucorrhoea until it becomes distressing or chronic. Some of the patients have history of taking some local or general line of treatment for leucorrhoea prior to attending this clinic.

TREATMENT

All the 200 cases of this series were kept on Femiforte, and were not subjected to any other line of treatment during this course of therapy.

TABLE 1
Marital Status

Unmarried	---	42
Married	---	148
Widows	---	10
Total	---	200

TABLE 2
Age

Below 15	---	14
15 to 45	---	174
46 and over	---	12
Total	---	200

TABLE 3
Duration of complaint

Less than a month	---	12
1 - 3 months	---	34
3 months and over	---	154
Total	---	200

DOSAGE AND OBSERVATION

The patients under the present series were kept on two tablets of Femiforte three times a day for a period of one week, then maintaining to one tablet three times a day for three weeks, total course lasting for four weeks. During the course of therapy, the patient was called once a week when she was inquired about her complaint, general and local examination carried out simultaneously.

The course was not repeated before two months after completion of first course. Minimum period of two months was required for follow up.

RESULTS

The cases were labeled as cured, improved and unrelieved depending upon the symptoms and signs detected on every check-up. Those who were completely relieved of their symptom were termed as cured. Those who noticed definite reduction in the discharge, but who did not completely get rid of were termed a “cured”. Those who noticed definite reduction in the discharge, but who did not completely get rid of it were termed as “improved” and those who did not have improvement whatsoever were termed “unrelieved”.

TABLE 4

Result	Number of cases	Percent
Cured	145	72.5
Improved	41	20.5
Unrelieved	14	7.0
Total	200	100.0

TABLE 5

Result	Number of cases	Percent
Cured	1	2.0
Improved	9	18.0
Unrelieved	40	80.0
Total	50	100.0

Two percent cure rate and 18% improvement rate in the placebo group draws one's attention that the psychological factor also constitutes as one of the causes of leucorrhoea, but is not the only etiological factor of non-specific leucorrhoea as many gynecologists think.

SIDE EFFECTS

None of the patients had any severe side effects as to discontinue the drug. Eight patients in the present series complained of nausea, when the drug was initially started. As the dosage was reduced to one tablet three times a day, the nausea was no more felt. Other complaints like occasional headaches and giddiness were not considered as specific side effects of this drug, as these were often found even after stopping the drug.

DISCUSSION

In the management of leucorrhoea specially when there is no evident cause, the following are some of the important factors.

1. Co-operation of the patient to carry out the treatment correctly and regularly as directed for any length of time.
2. Efficacy of the drug-optimum concentration without side effects.
3. Relapse or recurrence due to various causes. Incorrect diagnosis, faulty or inadequate treatment, resistant strains or reinfection.

In the light of above factors, the drug we tried was acceptable to all ladies young and virgins or orthodox married and fastidious as it is oral, easy to administer, not requiring qualified supervision or privacy unlike local medication of pain power, tablet or a douche.

Drug was found efficacious in 186-145 cured and 41 improved making a percentage of 93% - 72.5% and 20.5% respectively as against placebo where correspondence figures are 10-1 cure-9 improved making 20%-2%-18% respectively with no major side effects except transient nausea, giddiness, headache which passed off on continuing the treatment or reducing the dosage. In no case the drug had to be discontinued before the schedule.

Relapse or recurrence rate was very low, but is difficult to give an opinion with a short-term study like this one.

The drug seems to be acting under synergistic effect of all constituents.

Improved general metabolism: Digestion, assimilation, evacuation, improving general health with gain in weight in case of undernourished, reduction in pelvic congestion correcting constipation - all these contributing reduction in leucorrhoea, reduced vascularity and permeability of vaginal walls due to decongestion and astringent action, improved nourishment of vaginal cells, restoring depleted glycogen content, leading to correction of pH, reducing chances of local infection. All these help in amelioration of leucorrhoea.

Low dosage trial was not carried out in the present series as most of the patients required prompt relief. But it is important to carry out such a study, as it will reveal the minimum effective dose of the drug.

SUMMARY AND CONCLUSION

Common causes of leucorrhoea are mentioned. 200 cases of non-specific leucorrhoea were treated with an oral indigenous drug Femiforte and results were noted. Additional 50 cases were kept as control on placebo. Results were vary encouraging 7.5% cured, 20.5% improved, with 7% failures, with minimum side effects and very low relapse rate. Possible mode of action of drug has been discussed. Being orally effective and

economically acceptable to all young, old, orthodox or fastidious females, this drug is no doubt a very valuable remedy in the management of leucorrhoea.

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REFERENCE

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|------------|---|--|
| Khudabux M | : | Antiseptic, May 1961 |
| Surti, B | : | Indian Practitioner, XVII : 8,194. |
| Phiroze, A | : | Current Medical Practice, IX :4, 1965. |
| Thakur, A | : | Antiseptic, 63 : 11, 1966. |
| Phadke, M | : | Current Medical Practice XI : 3, 1967. |
| Gupte, U | : | Indian Practitioner October 1967. |