PLACE OF LACTOBACILLUS SPOROGENES (MYCONIP) THERAPY IN THE MANAGEMENT OF LEUCORRHOEA

(Clinical Trial conducted at Dr. R. N. Cooper, Municial General Hospital)

by

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Introduction

Leucorrhoea is one of the commonest complaints encountered in gynaecology and obstetrics, accounting for about 10% of out-patient attendance. Though, not serious in nature, it can be an extremely distressing symptom.

When it is due to an increase in normal discharge, it can be caused by several physiological states like puberty, sexual excitement, ovulation, pregnancy, etc. and pathological conditions like cervical erosions, cervical polypi, pelvic congestive states, etc. Normal discharge never causes distressing symptom. When the type of discharge is abnormal, it can be due to several causes including foreign body, fistulae, malignancy, etc. but the basic etiological factor is always an infection. The infection may be trichomoniasis, moniliasis, Gonorrhoea, syphilis, Tuberculosis, or non-specific.

Treatment for the specific type of leucorrhoea is with specific drugs like Metronidazole, Nystatin, Penicillin, etc. Non-specific leucorrhoeas are treated with vaginal douches of antiseptics or sodium bicarbonate. Whenever any other associated pathology is present like polypi, erosions or malignant growths, they have to be treated primarily.

A new approach to the management of the infective and senile leucorrhoea is by increasing the vaginal acidity, because it is the normal protective mechanism against infection. This was achieved by introducing lactobacillus spores into the vagina in the form of tablets (Myconip). These bacilli concert the vaginal glycogen into lactic acid, thus increasing the acidity of the vagina in the same way as the Doderlein's bacilli do it naturally.

Patients with specific as well as non-specific infections were included in the study to see if such an increase in acidity would have a favourable effect on the treatment of the specific infections as well.

Material and Methods

One hundred and fifty patients with leucorrhoea, either as a symptom or as a sign were randomly selected. A preliminary assessment of the patient was made by recording symptoms and their severity.

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The symptoms noted were leucorrhoea, pruritus, vulval excoriation and burning micturition. The patient was then examined (avoiding the use of antiseptics) and the signs were similarly recorded (quantity and type of discharge, vaginitis, cervicitis and cervical erosion). A microscopic examination of the discharge was performed for trichomonas vaginalis and Candida albicans. Suspected cases were investigated for diabetes, syphilis and helminthiasis and were suitably treated (one case each of diabetes and syphilis).

The patient was then given ten vaginal tablets of Myconip (Uni-Sankyo), each tablet containing 150 million spores of Lactobacillus sporogenes. The patient was advised to insert one tablet in the morning and one in the evening for 3 days and then one every night for 4 days, constituting one course of Myconip. The patient was followed up every week and was reassessed every time.

The course was repeated if the discharge persisted. Those cases with microscopic evidence or clinical suspicion of Trichomonas or Monilial infection, showing no response to the first course, were given a course of specific drugs like Metronidazole or Nystatin respectively along with the course of Myconip tablets.

The follow-up was continued till a cure was achieved or the patient was lost to follow-up. The results were evaluated and analysed.

Results

The age distribution of 150 patients is shown in Table I.

TABLE I
Age Incidence

Age in Years	No.	%
15 and below	0	0
16 to 25	71	47.3
26 to 45	73	48.7
46 and above	6	4

TABLE II
Chief Complaints

Main Complaint	No.	%
Leucorrhoea	98	65.3
Pruritus only	7	4.7
Other (Prolapse, Pregnancy, etc.)	45	30

The type of patients are shown in Table III.

TABLE III
Type of Cases

Type of Case	No.	%
Antenatal	17	11.3
Gynaec. surgical	33	22.0
Others	100	66.7

Out of 150 patients, 4 did not complain of vaginal discharge. Of the remaining, 90 (60%) complained of mild discharge, 51 (34%) of moderate, and 5 (3.3%) of severe discharge. Sixty-five patients (43.3%) had mild itching and 14 (9.3%) had significant itching. Twelve patients (8%) complained of excoriation and 17 (11.3%) of burning micturition. On examination, 26 (17.3%) patients had no significant discharge, 70 (46.7%) had mild discharge, 47 (31.3%) moderate, and 7 (4.7%) severe. The clinical appearance of the discharge was recorded as "Trichomonial" if it was thin, frothy and greenish yellow; and "Monilial" if thick, white and curdy and "non-specific" if neither..

TABLE IV
Type of Discharge

Clinical Appearance of Discharge	No.	%
Non-specific	111	74
Trichomonial	20	13.3
Monilial	19	12.7

Signs of vaginitis were seen in 27 (18%) and cervicitis and/or erosion were detected in 22 (14.7%).

Response

This was evaluated in three separate ways:

1. *Symptomatic or subjective response*—

A positive response was recorded when the symptoms disappeared altogether (78, i.e. 52%) at the end of 2 courses and 1 patient (0.7%) at the end of 3 courses of Myconip alone. But 22 (14.7%) of the patients required some other drugs in conjunction with the Myconip tablets and 4 cases (2.8%) required cauterisation of the cervix for severe cervical erosion. Twenty-one cases (14%) showed no subjective response at all as long as they were followed up.

2. *Objective response (Clinical)*

This was decided from the observation of decreased discharge, vaginitis, cervicitis and erosion.

Response after one course of Myconip alone	73	(48.7%)
Response after two courses of Myconip alone	30	(20%)
Response after three courses of Myconip alone	1	(0.7%)
Thus, response to Myconip alone	104	(69.4%)
Required other therapy concomitantly	22	(14.7%)
Showed no objective response	24	(16%)

3. *Objective response (microscopic)*

Such a response was recorded when a positive smear became negative. Three consecutive negative smears were required to label a patient disease-free. But the adequate number of follow-up patients were not available for evaluation.

TABLE V

Slide-initial Findings	No.	%
Positive for Trichomonas	22	14.7
Positive for Candida	19	12.7
Negative for both Trichomonas and Candida	109	72.6
Total	150	100.0

Out of 22 patients who showed microscopic evidence of Trichomoniasis, 8 (36.4%) became parasite free after one course of Myconip alone and 1 (4.6%) after two such courses. However, 12 required a course of Metronidazole in addition, to clear the infection. One patient failed to appear for the third follow up visit.

Out of 19 patients who showed Candida on smear examination, behaved as follows:

Eight patients (42.1%) showed negative smear at the end of first course of Myconip alone and 11 (57.9%) required additional treatment with Nystatin pessaries along with Myconip.

Cure

A complete cure was recorded when either the symptoms or the signs or both disappeared completely. This was achieved as follows:

After one course of Myconip alone	42	(28%)
After two course of Myconip alone	29	(19.3%)
After three courses of Myconip alone	4	(2.7%)
Thus, cure with Myconip alone	75	(50%)
Other drugs required	22	(14.7%)
No cure achieved	53	(35.3%)

Conclusion

It is seen from both the subjective and objective response that about half the total number of cases responded to a single course of Myconip alone, a further 20% responded after the course was repeated without adding any other drug. About 15% required some additional therapy and some 15% failed to respond as long as they were followed up.

Non-specific leucorrhoea

Out of 111 cases of non-specific leucorrhoea, 87 (78.4%) patients responded to Myconip alone.

Specific leucorrhoea

Even when Trichomoniasis was conclusively proved, 40% of these cases responded to Myconip alone (36% after one course and 4% after two courses). However, more than half (55%) required specific therapy. A similar result was obtained from Candida positive cases, where 42% of whom responded to Myconip alone but 58% required antifungal treatment.

Analysing the cure rate, 50% were completely cured with Myconip alone (one, two or three courses). About 15% required some other therapy also, whereas as many as 35% did not achieve a complete cure as long as they reported for follow-up. Thus it is seen that in a substantial number of cases, Myconip alone could give significant relief even when definite evidence of Trichomonas or Candidiasis was present. Hence a new approach to the management of leucorrhoea may be evolved. It could be suggested that all cases after a preliminary check up should be first treated with Myconip for three courses. Only those 50% or so who fail to respond would then require further investigation and specific treatment.

Summary

The effect of Lactobacillus spores in the treatment of leucorrhoea was evaluated singly and in combination with the standard drugs in 150 randomly selected patients. The evaluation included microscopic examination of the discharge. The first course always consisted of Myconip (Lactobacillus spores) alone. Subsequent courses were given in combination with standard drugs as required if there was no response to the first course.

The results showed that about 70% of cases responded and 50% were completely cured with Myconip alone, when subjective and clinical response was considered. Even when microscopic evidence of specific leucorrhoea was assessed, about 40% responded to Myconip alone.

These encouraging results emphasize the significance and utility of this new mode of therapy which does not utilise any drug but instead, aims at increasing the inherent resistance of the vaginal mucosa to infections, by increasing vaginal acidity with use of Lactobacillus spores in tablet form per vaginum (Myconip tablets).

Acknowledgement

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