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RANDOMISED CONTROL STUDY OF EFFECT OF PROBIOTICS IN NON-INFECTIVE VAGINAL DISCHARGE

Obstetrics & Gynaecology

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ABSTRACT

Introduction- Normal vaginal discharge is watery, white in color, non odorous with pH around 4. Abnormal vaginal discharge may be infective or non infective. Non infective excessive vaginal discharge is nonpurulent, nonoffensive and non-irritant.

Objective- This study is done to monitor effect of probiotics in non-infective vaginal discharge and about the myths that brought the patient to hospital with the complaint of vaginal discharge.

Results- A total of 100 patients were recruited for study. 54 patients were given probiotics and 46 were given placebo. 62.9% were improved after treatment with probiotics and 34.7% were improved after placebo (P-value-0.009), which is statistically significant. In cases of mucoid discharge, role of probiotics is not statistically significant. In case of non mucoid discharge, the effect of probiotics is significant with p value of 0.01.

Conclusion- The findings indicate that Probiotics are effective in reducing the non infective and non mucoid vaginal discharge.

KEYWORDS

INTRODUCTION

The human vagina is inhabited by a range of microbes from a pool of over 50 species. [1] Lactobacilli are the most common particularly in healthy women. Lactobacilli maintains vaginal pH <4.5. [1] The microflora can change composition rapidly due to various reasons e.g. during and after menses, after sexual contact, diabetes, antibiotics use etc. [1] Normal vaginal discharge is watery, white in color, non odorous with pH around 4. Abnormal vaginal discharge may be infective or non infective. Non infective excessive vaginal discharge is nonpurulent, nonoffensive and non-irritant. The infective vaginal discharges are Bacterial Vaginosis, Vulvovaginal Candidiasis & Trichomoniasis mainly. The most common urogenital infection is bacterial vaginosis, a condition characterised by depletion of lactobacilli population and presence of gram negative anaerobes and in some cases gram positive cocci and aerobic pathogens. [1] Vulvovaginal candidiasis is second most common type of vaginitis, caused by fungus Candida Albicans. It is characterised by itching, pain and thick curdy white discharge. [2] Trichomoniasis is caused by parasite trichomonas vaginalis. Symptoms are diffuse, malodorous, yellow-green vaginal discharge with vulvar irritation.[3]

Probiotics are regarded as "Live microorganisms which when administered in adequate amounts confer a health benefit on the host". [4] The Food and Agriculture Organization of the United Nations and the World Health Organization Working Group has developed guidelines for what constitutes a true 'probiotic', and very few so-called health products currently meet these criteria because they have no published clinical studies showing a benefit of their strains on the host. [4] Probiotic *Lactobacillus rhamnosus* GR-1 and *Lactobacillus fermentum* RC-14 have been shown in open studies to colonize the vagina following oral intake.[4]

Aims & Objectives

1) To monitor effect of probiotics in non-infective vaginal discharge.
2) Myths that brought the patient to hospital with the complaint of vaginal discharge

Materials and methods

This was a randomised control study in department of Obstetrics and Gynaecology, IGIMS, Patna over a period of one year. Total of 100 patients were selected. All women were selected on the basis of clinical symptoms, per speculum examination, Amsel's criteria, Wet film preparation and KOH mount. According to these criteria, patient either had

1) **Infective vaginal discharge-** In this case antibiotic treatment were given according to the species OR

2) **Non Infective excessive vaginal discharge**

After signing the informed consent form, all non infective cases having complaints of excessive vaginal discharge were divided randomly into two groups. The randomisation was done according to registration number of patient, even number was given probiotics and odd were given placebo. In group - 1, probiotic was given orally twice daily for 10 days and in group - 2, placebo was given. Follow up was done after one month & three months. The outcomes were observed by cure of symptoms of patient & per speculum examination.

Inclusion criteria

1) Women of reproductive age group
2) Sexually active female
3) Regular menstrual cycle
4) No Gynaecological pathology

Exclusion criteria

1) Before menarche and after menopause
2) Women with Bacterial vaginosis, Trichomoniasis, Vulvovaginal candidiasis
3) Pregnancy and lactation
4) Women with hormonal IUCD, OCP users

RESULTS

110 Women with mean age of 32 years were selected. 10 patients lost to follow up. A total of 100 patients were recruited for study. They were randomly divided in two groups. Maximum no of patients were of age group 25-29 years (Table1). Most of the patients were of average socioeconomic group (Table1). 74% of patients' complaints of white discharge per vaginum, other complaints were watery discharge per vaginum, pain abdomen and itching per vaginum. Some patients had more than one complaint (Table2). The most common myth regarding discharge per vaginum is weakness (54%). Other myths were osteoporosis, backache & cancer (Table 2).

54 patients were given probiotics and 46 were given placebo in the form of multivitamins (figure1). 62.9% were improved after treatment with probiotics and 34.7% were improved after placebo (P-value-0.009), which is statistically significant (Table 3).

Regarding type of discharge, 37 patients were having mucoid discharge and 63 were having non-mucoid discharge (Figure 2). Among 37 with mucoid discharge, 15 were given probiotics and 22 were given placebo. In probiotics group, 10 were improved. In placebo

group, 10 were improved and 12 were not improved (P- value- 0.349). (Table-4)

Among 63 with non-mucoid discharge, 39 were given probiotics and 24 were given placebo. In probiotics group, 24 were improved. In placebo group, 6 improved (P-value- 0.01). (Table-5)

TABLE-1

AGE in years	No. of pts.	%
<20	2	
20-24	20	
25-29	35	
30-34	26	
35-39	6	
40-44	5	
45-49	6	
>50	0	
Socioeconomic status		
Poor	25	25
Average	74	74
High	1	1

Table- 2

	Complaints	No. of patients	%
1	White discharge per vaginum	74	74%
2	Watery discharge per vaginum	7	7%
3	Pain abdomen	18	18%
4	Itching PV	9	9%
	MYTHS		
1	Osteoporosis & Backache	50	50
2	Cancer	20	20
3	Weakness	54	54

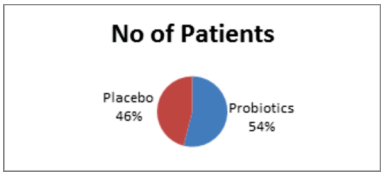

FIGURE-1

Table-3- Effect of Probiotics & placebo on vaginal discharge

Outcome	Probiotics	Placebo	Total	P-value
Improved	34(62.9%)	16(34.7%)	50	
Not improved	20(37.03%)	30(65.2%)	50	
Total	54	46	100	0.009

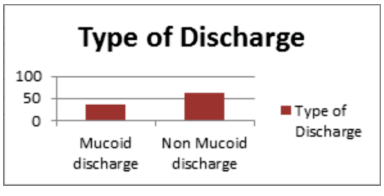

Figure - 2

Table-4- Effect of Probiotics & Placebo on Mucoid discharge

	No. of patients treated with probiotics	No. of patients treated with placebo
Improved	10(66.6%)	10(45.45%)
Not improved	5(33.3%)	12(54.54%)
	15	22
P-value		0.349

Table-5- Effect of Probiotics & Placebo on Non-Mucoid discharge

	No. of patients treated with probiotics	No. of patients treated with placebo
Improved	24(61.5%)	6(25%)
Not improved	15(38.4%)	18(75%)
	39	24
P-value		0.01

DISCUSSION

Many women have what they perceive as an abnormal vaginal discharge at some point in their lives, but usually it is just a normal physiological discharge. This is a white or clear, non-offensive discharge that varies with the menstrual cycle. Cervical ectopy can be associated with a mucoid discharge and if symptomatic is widely treated with cryotherapy or diathermy, although evidence to support the effectiveness of these treatments is poor.

This study was done to demonstrate effect of probiotics in non infective vaginal discharge and it has shown that there was significant improvement in vaginal discharge after taking probiotics. (p=0.009) This is due to that probiotics alters vaginal microflora and maintain normal pH results in decrease in excessive vaginal discharge. Previous studies have shown that whilst oral therapy with probiotics does not appear to mount peripheral immune response[5], it can induce an intestinal antibody and phagocytic response that appear to benefit the host in terms of reduced impacts on pathogens[6]. In our study, we were giving probiotics orally twice daily for 10 days.

Studies have shown that the vaginal microflora is constantly in a state of flux and at many time points during the menstrual cycle it can be dominated by Bacterial Vaginosis pathogens in the absence of lactobacilli without symptomatic infection developing[7, 8]. While this so-called abnormal microflora obviously does not always convert to a symptomatic infection, it increases the risk of that happening by several fold[9, 10]. Thus, the higher levels of coliforms and yeast indicate that even women, who appear healthy, are indeed at some risk of urogenital infection each month.

In our study, in cases of cervical ectopy, where mucoid discharge present, probiotics seems to be effective (66.66%) and in cases of non mucoid discharge, it was effective in 61.5%.In cases of mucoid discharge, role of probiotics is not statistically significant. In case of non mucoid discharge, the effect of probiotics is significant with p value of 0.01.

In summary, Probiotic combination taken orally to reduce vaginal colonization by pathogenic bacteria and yeast and to maintain normal vaginal flora. Probiotics use could provide a natural, safe and effective means to stabilize the fluctuating vaginal flora. The sample size in this study was rather small, therefore; our results need to be confirmed in a larger cohort.

CONCLUSION

The findings indicate that probiotic can restore and maintain the urogenital health of women. Probiotics are effective in reducing the non infective and non mucoid vaginal discharge.

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