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# Role of Probiotics in Vaginitis as Adjuvant Treatment to Augment the Women Health

P. Slome Satya Vani [1] *, P.Mounika Goud [2], Nazmeen Saba[2], P. Susmitha [2]
Dr. Vrm Gupta[3], Dr. subash sahoo[4]
[1]*4 Associate professor, Pulla Reddy Institute of Pharmacy*
[2] *VI-Pharm.D Interns, Pulla Reddy Institute of Pharmacy, Dommadugu, sangareddy ( dt), Telangana (s).*
[3] *Principal, Pulla Reddy Institute of Pharmacy*
*Corresponding Author: P. Slome Satya Vani*

***Abstract:*** *The aim of the study is developing women health in association with the use of probiotics as an adjuvant therapy in vaginitis treatment. The study is open label, randomized trial, pilot study conducted during the period of 6 months, it involved 37 women of child- bearing age (18-55) who were diagnosed as vaginitis either bacterial, fungal or trichomonial, each of them were randomly prescribed an antimicrobial with probiotics or an antibiotic/anti-fungal alone, labeled under two groups- group A (with probiotic) and group B (antibiotic/anti-fungal alone). Each subject was followed up to a period of 28 days. The swab test was done on day1 for diagnosis and repeated the swab test on day 28 for checking out the improvement and to monitor the recurrence. ECOFLORA, BIFILAC, BIOVAG are the different brands of probiotics used in the study along with local or oral antibiotic/anti-fungal. The 6-month cure rate for vaginitis in group A was 90.9% and group B was 33.33%. Among all the probiotics prescribed, ECOFLORA (brand name) was administered to more number of subjects (14). The prevalence rate observed among the age group 28-33 years was high (32.4%). The most common sign white discharge was (62.1%), which was high compared to other color discharges. The prescribed probiotics for the subjects in our study mainly contain L.rhamnosus and in small amounts other lactobacilli species. The most prevalent microorganism was candida species (70.2%) among all subjects. The study suggests that treatment with antimicrobial with probiotic provides long term cure against vaginitis*.

***Keywords:*** *vaginitis, antibiotics, recurrence, probiotics, antimicrobial, antifungal.*

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## I. Introducction

The composition of urogenital micro flora of women is crucial for health and well-being of women[1]. The healthy vaginal ecosystem is inhabited by many different groups of micro-organisms, among them Lactobacillus species are found to be most common[4] .There are several pathogens that colonize the urogenital tract that affects the women and their general health. [11, 12 13, 14.] Women face many gynecological problems in their child bearing age such as incontinence, infertility (evaluation/treatment), mastitis (lactation), menorrhagia (heavy periods), ovarian cysts, pelvic pain, premenstrual syndrome (PMS), polycystic ovarian syndrome (PCOS), urinary tract infection, vaginitis, vulvodynia etc. [18, 19, 20.]

In the women of child bearing age the most common infection was vaginitis [26, 38.] . There is a difference in between the Indian and western scenario in the number of hospital visits for treatment of vaginitis. Vaginitis is often self- diagnosed and self- treated due to various social and ethical barriers between the women and medical practionor that hinders their exposure H54leading to lack of appropriate treatment which, when unnoticed leads to recurrences. This makes vaginitis prevalence and incidence uncertain [27, 28.]

The useful live microorganisms (probiotic) have its prime importance. Among the useful live microorganisms various species of lactobacillus are highly prevalent. Of, these *Lactobacillus rhamnosus* is a bacterium that originally was considered to be a subspecies of *L. casei*, but later genetic research found it to be a species of its own. It is a short Gram-positive facultative anaerobic rod that often appears in chains. Some strains of *L. rhamnosus* bacteria are being used as probiotics, and are particularly useful in treating female-related infections, most particularly very difficult to treat cases of bacterial vaginosis (or "BV"). The *Lactobacillus rhamnosus* and *L. reuteri* species are most commonly found in the healthy female genito-urinary tract and are most helpful to supplement in order to regain control over dysbiotic bacterial overgrowth during an active infection. *L. rhamnosus* sometimes is used in yogurt and dairy products such as fermented and un-pasteurized milk and semi-hard cheese. While frequently considered a beneficial organism, *L. rhamnosus* may

not be as beneficial to certain subsets of the population; in rare circumstances, especially those primarily involving weakened immune system or infants, there may be no advantage.[29, 30, 31, 32.]

**1.1**VAGINITIS**:**

Vaginitis is the inflammation of vagina is associated with discharge, itching, and abdominal pain. The most common vaginal infections are bacterial vaginosis, trichomoniasis and vaginal yeast infections [33]. The change in the normal balance of vaginal bacteria leads to vaginitis.[34, 35]

**1.2** SHOWING CLASSFICATION WITH DIFFERENTIATION OF SIGNS AND SYMPTOMS OF VAGINITIS

| *TYPE* | *ETIOLOGY* | *CLINICAL SYMPTOMS* | | | *CLINICAL SIGNS* | |
|---|---|---|---|---|---|---|
| | | *DISCHARGE* | *PAIN* | *PRURITUS* | *VAGINA* | *VULVA* |
| Bacterial vaginosis | *Gardnerella vaginalis*, *Mycoplasma hominis* Anaerobic bacteria: *Prevotella* species, *Mobiluncus* species | Malodorous; homogenous; clear, white, or gray; fishy odor | Not primary symptom | Not primary symptom | No signs of inflammation | Unaffected |
| Trichomoniasis | *Trichomonas vaginalis* | Green-yellow, frothy | Pain with sexual intercourse,vaginal soreness, dysuria | Not primary symptom | Signs of inflammation, "strawberry cervix" | Vestibular erythema may be present |
| Vulvovaginal candidiasis | *Candida albicans, Candida krusei, Candida glabrata* | White, thick, lack of odor | Burning, dysuria, dyspareunia | Frequent | Signs of inflammation, edema | Excoriations |
| Atrophic vaginitis | Estrogen deficiency | Yellow, greenish, lack of odor | Vaginal dryness, pain with sexual intercourse | Rare | Vagina mildly erythematous, easily traumatized | Vestibule thin and dry; labia majora lose their subcutaneous fat; labia minora irritated and friable |
| Erosive lichen planus | Etiology is unknown | Yellow or gray | Intense pain, dyspareunia, postcoital bleeding | Intense | Erythema with friable epithelium | Erosions, white plaques |
| Irritant or allergic contact dermatitis | Contact irritation or allergic reaction with episodic flares | Minimal | Burning on acute contact, soreness | More likely in allergic reaction | Vulvar erythema possible | Erythema with or without edema; vesicles or bullae rare |

**TABLE: 1**

**1.3** ANTIBIOTIC TREATMENT:

The standard treatment option for bacterial vaginosis and trichomoniasis is metronidazole and an alternative treatment option is clindamycin, and for candidial infection is clotrimoxazole and alternative treatment is fluconazole, terconazole creams.

**1.4** PROBIOTICS:

Probiotics, as defined by WHO-2002, are "live microorganisms which, when administered in adequate amounts, confer a health benefit on the host." [36, 37]

Generally, people often think of bacteria and other microorganisms as **germs,** many microorganisms help our body to function properly. For example, bacteria that are normally present in our intestine help to digest food, destroy disease causing microorganism and produce vitamins. Large amount of microorganisms live on and in our body. In fact, microorganisms in the human body out number human cells by 10 to 1. Many of the live microorganisms in probiotic products are same as or similar to microorganism that naturally lives in our body.[38]

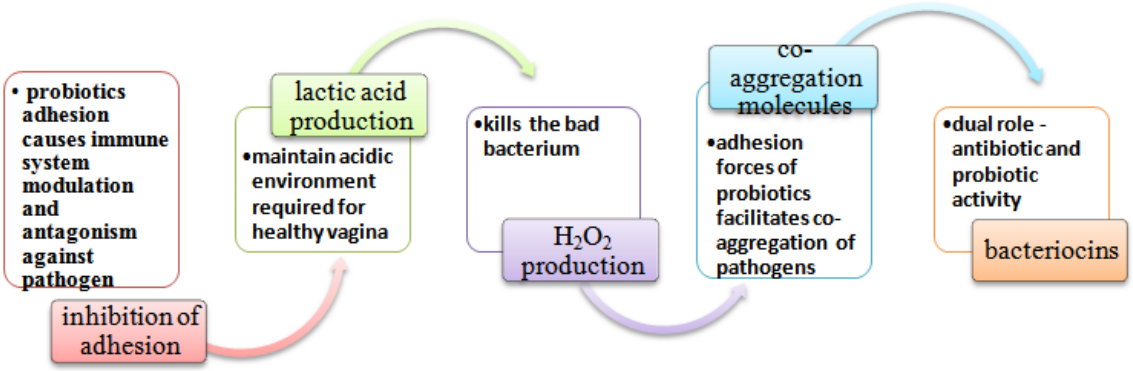



**FIGURE: 1**

**1.5** EXAMPLES :

**1. Lactobacillus 2.Streptococcus .3.Bifidobacterium 4.Sacharomyces boulardii(non-human)**

| | |
|---|---|
| | infantis |
| reuteri | |
| casei | lactis |
| rhamnosus | |
| acidophilus | longum |

Probiotics are found to improve digestive function,reduces diarrhea associated with antibiotic therapy and also helps to reduce risk of certain acute common infectious diseases. They improve lactose tolerance and enhance immune function. It plays a role in reducing crying time in colicky babies. Probiotics play a role in reducing the development of allergy in children, decrease Helicobacter pylori colonization of the stomach and manage relapse of some inflammatory bowel conditions.[39, 40]

## II. Aims And Objectives:

- To study the use of probiotics as adjuvant therapy in treatment of vaginitis
- To evaluate the prophylaxis & the therapeutic efficacy of probiotics along with antimicrobial agents in vaginitis
- To promote an initial step in overcoming the social and ethical barriers for improvising the women health during the treatment of vaginitis and its associated complications.
- To improve the quality of life of women by recognising the use of bio-therapeutic agents and minimising the use of anti-microbial agent (pathogen resistance).
- To emphasise the need for development of strategies in preventing the reoccurrence of vaginal infections using probiotics by maintaining or reconstructing the normal composition of vaginal micro flora.
- To normalize the healthy vaginal pH with probiotics.

**2.1** Inclusion criteria**:**

- Premenopausal women of age bearing 18-55.
- Sexually active women.
- No use of any vaginal drugs, antibiotics and immune-suppressive drugs 14 days before the start of study.
- Women with PID(pelvic inflammatory disease)

**2.2** Exclusion criteria**:**

- No intercourse or vaginal bath during last 24 hours, no use of alcohol, anticoagulant drugs such as Coumadin and disulfiram.
- Women with lactobacillus intolerance
- Patient with STD's
- Use of systemic or intra-vaginal Antimicrobial agents currently or from 14days

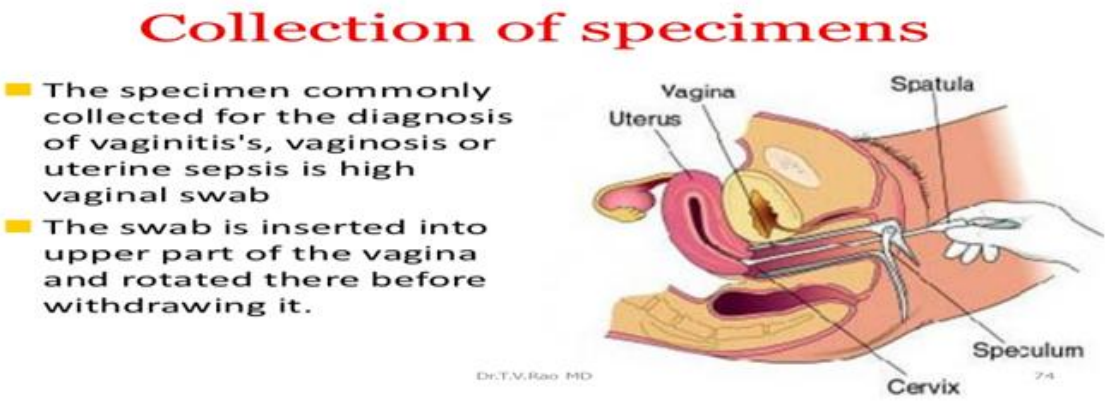
- Hypersensitive to Antimicrobial agents
- Pregnant women
- Lactating mother

## III. Methodology:

This is an open label, Pilot study with randomized study done within a period of 6months in Hyderabad, from October 19'2016 to March 15'2017 in multicenter secondary care hospitals.

The 37 subjects were randomly divided into two groups -group A and group B. Group A includes the subjects who were prescribed an antibiotic with a probiotic and Group B includes subjects with just an antibiotic. On day one the subject was explained about the study and informed consent form was signed and dated ,prior to this vaginal examination was done (p/v) for type of discharge, its nature, odour with any signs of inflammation or redness, these were noted, after which the patient was advised for vaginal swab culture test. Based on the conclusion made from the report the prescription is randomly written to the subjects. They are monitored constantly through phone calls and checked on for adherence. They are also advised with some life style and diet modifications which were further reminded to them. On day 28, after the completion of the course of medications prescribed they were followed up on the 28$^{th}$ day for checking out the recurrence. Same as on day one per vagina examination was done and second swab culture test was advised. These reports predicted if the condition has improved or if they were possible recurrences seen. Based on these 2 reports, conclusions were withdrawn for the prescription orders of individual subject and they were compiled at the end**.**

**FIGURE: 2**



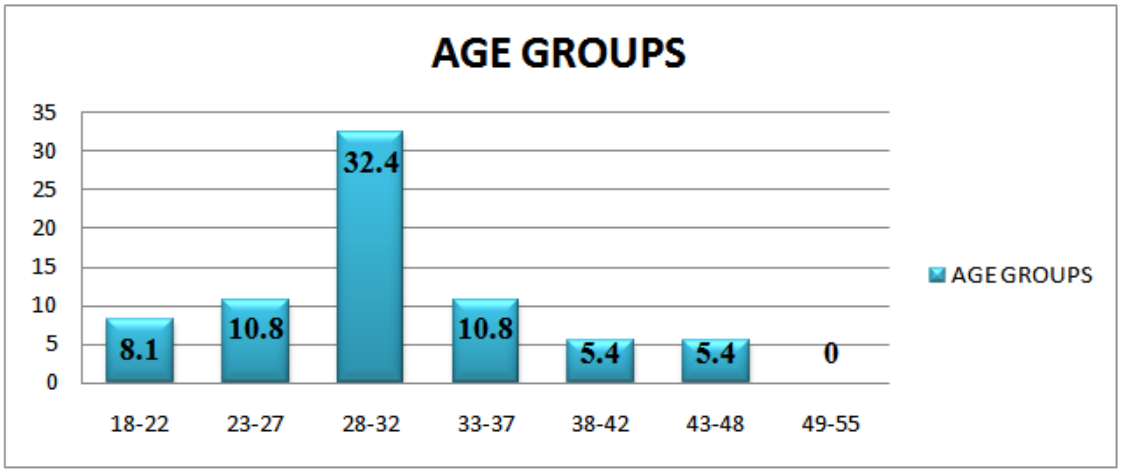

**3.1** MICROSCPIC EXAMINATION**:**

Using a sterile swab, swab the vagina region and immerse the swab into the vial containing 2ml of sterile 0.9% sodium chloride and label. A wet prep by mix the sample in vial and place on drop of the solution onto a slide and examine microscopically using a high power (40x) objective for the presence of trichomonas and clue cells. **Trichomonas**: scan the entire slide on low power magnification with reduced light for motile trichomonas. If motility is observed, switch to high power to positively identify trichomonas. The flagella or undulating membrane should be visible. If seen, reports were positive, if motile trichomonas are not seen the reports are negative. **Clue cells**: clue cells are epithelial cells covered with bacteria giving the cell 'fur-like' appearance. Clue cells areported as few, moderate, or many on low powers.

## IV. Results And Discussion:

Vaginitis is a common problem faced by every woman at least once in life time. In our study we have chosen 37 patients, all of which comply with the inclusion and exclusion criteria.

**GROUPING OF SUBJECTS BASED ON AGE (IN YEARS)**



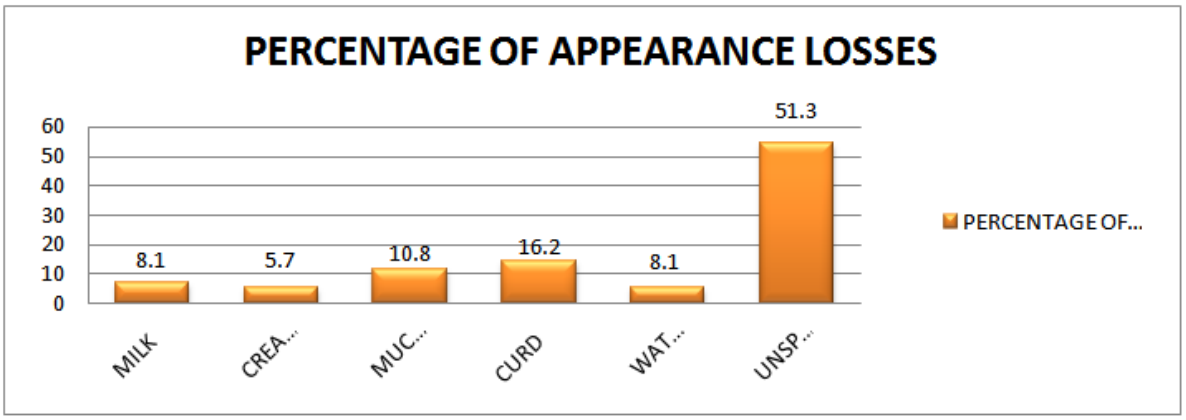

**On Y- Axis = No. Of Subjects (%)*
*On X-Axis = Age Groups*

**GRAPH: 1**

| AGE GROUPS | NUMBER OF SUBJECTS | PERCENTAGE |
|---|---|---|
| **18-22** | 3 | 8.1 |
| **23-27** | 4 | 10.8 |
| **28-32** | 12 | 32.4 |
| **33-37** | 4 | 10.8 |
| **38-42** | 2 | 5.4 |
| **43-48** | 2 | 5.4 |
| **49-55** | 0 | 0 |

**TABLE: 2**

The prevalence rate of vaginitis in the age group of 18-22 was found to be 8.1% , where as in 23-27 age group women it was found to be 10.8%. The highest prevalence was found between the age group of 28-32 (32.4%). The women in the age group of 33-37 the prevalence rate was found to be 10.8%, whereas between age group of 38-42 and 43-48 the prevalence rate was found to be same 5.4%.




**GRAPH: 2**

**TYPES WITH PERCENTAGE OF APPEARANCE OF LOSSES IN SUBJECTS**

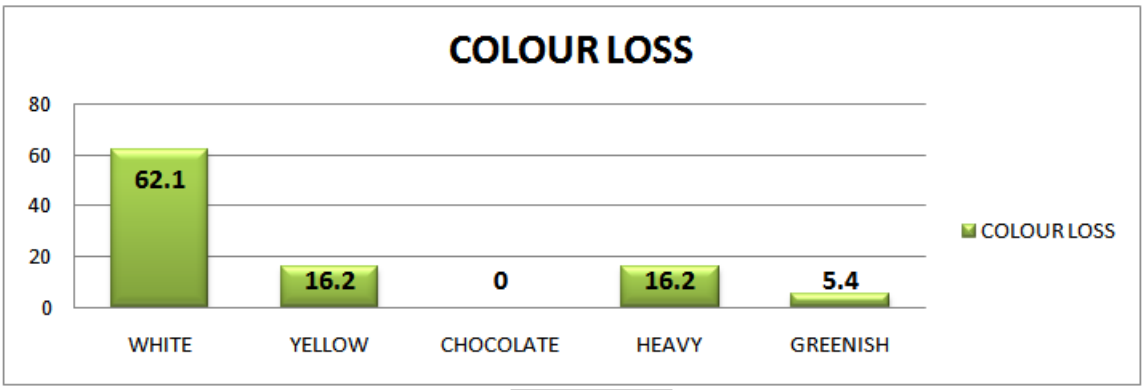
**On Y- Axis = No. Of Subjects (%)*
*On X-Axis = Appearance Losses*

| APPEARANCE LOSSES | NUMBER OF PATIENTS | PERCENTAGE |
|---|---|---|
| MILKY | 3 | 8.1 |
| CREAMY | 2 | 5.4 |
| MUCOID | 4 | 10.8 |
| CURDY | 6 | 16.2 |
| WATERY | 3 | 8.1 |
| UNSPECIFIED | 19 | 51.3 |
| TOTAL | 37 | 100% |

**TABLE:3**

The above table gives a complete view of the nature of discharges in 37 subjects which were characterized as follows: milky discharge was found in 3 women (8.1%), creamy discharge was found in 2 women (5.4%), mucoid discharge was found in 4 (10.8%), curdy discharge was found in 6 women (16.2%), watery kind of discharge was found in 3 women (8.1%) and unspecified discharge in 19 women holds 51.3%.

**TYPES WITH PERCENTAGE OF DIFFERENT COLOR DISCHARGE IN SUBJECTS**




**Graph: 3**

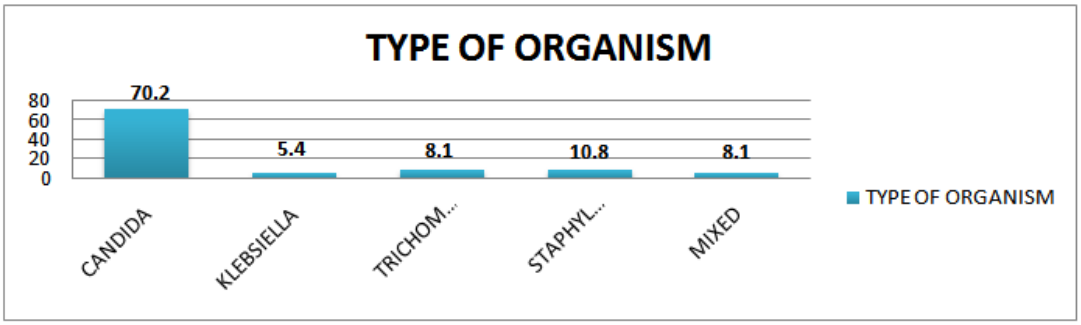
**On Y- Axis = No. Of Subjects(%)  On X-Axis = colour loss*

| COLOUR LOSS | NUMBER OF PATIENTS | PERCENTAGE |
|---|---|---|
| WHITE | 23 | 62.1 |
| YELLOW | 6 | 16.2 |
| CHOCOLATE | 0 | 0 |
| HEAVY | 6 | 16.2 |
| GREENISH | 2 | 5.4 |
| TOTAL | 37 | 100% |

**TABLE: 4**

In total of 37 patients the women with complaints of white colour discharge were 23 (62.1%), and those who came up with complaints of yellow and heavy color discharge after P/V examination were 6 (16.2%). No women came with complaints of light bloody brown or chocolate colour discharge. There were 2 women who came up with complaints of greenish discharge (5.4%) .

**TYPES AND PERCENTAGE OF ORGANISAM FOUND IN SUBJECTS**



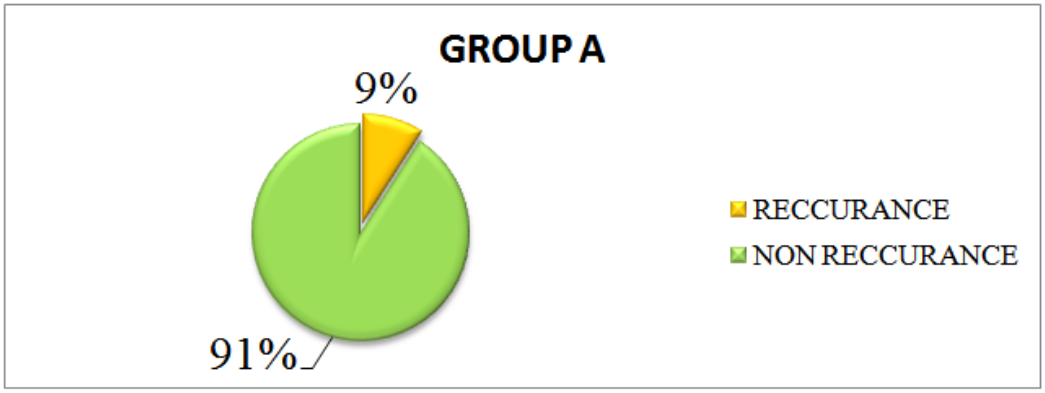

**GRAPH: 4**

**On Y- Axis = No. Of Subjects (%), On X-Axis = Type Of Organism*

From the data available from day 1 to day 28 Candida sps were found to be high , being reported in 25 women (70.2%) and reports showing Klebsiella were 2 (5.4%), where as trichomonas and mixed type of infection was reported in 3 women each (8.1%) . Staphylococcal was reported in 4 women (10.8%) all making up a total of 37.

From the above represented pie chart we can conclude the total percentage of recuurance and non reccurence in subjects included in group A and as well as group B. The percentage of recuurance was 32.4% in 12 subjects and non reccurence was 67.5% in a 25 subjects from a total of 37.

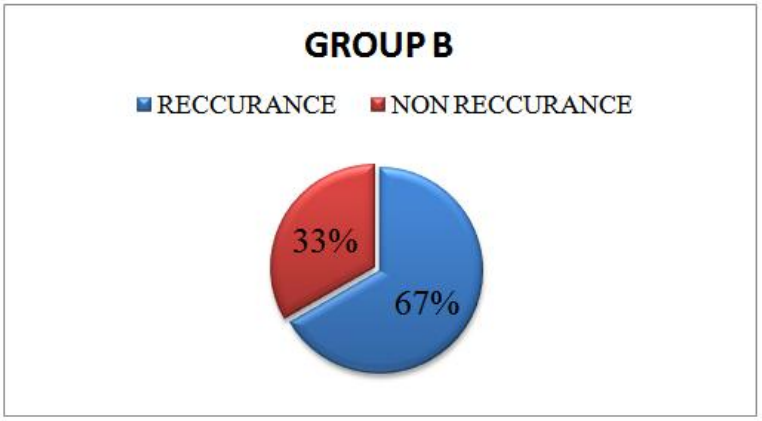
**REOCCURANCE V/S NON-REOCCURANCE IN GROUP A**




**GRAPH: 5**

In group A which includes subjects treated with a probiotic as an adjuvant therapy along with an antibiotic/ antifungal the recurrence found was 9% and the condition was improved in the remaining women showing beneficial impact of the adjuvant therapy (91%).

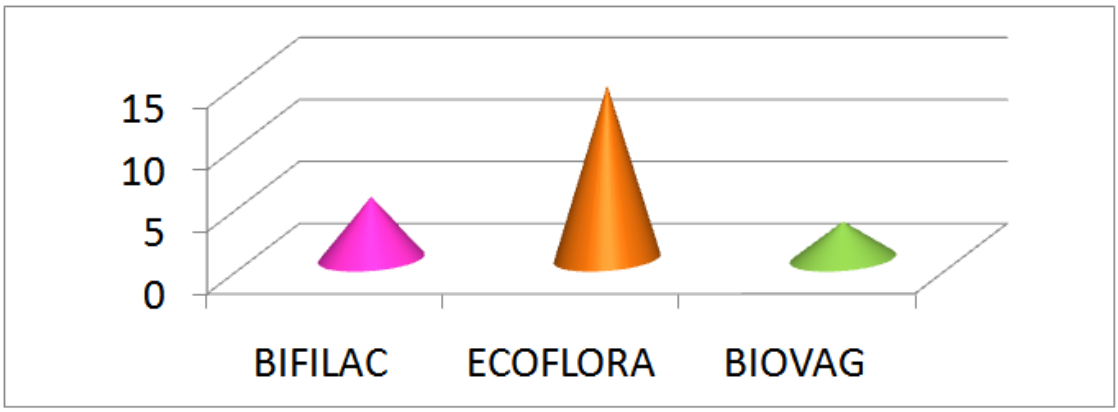
**RECCURANCE V/S NON-RECCURANCE IN GROUP B**




**GRAPH: 6**

In group B which includes subjects treated with an antibiotic/ antifungal alone, the recurrence found was 33% and the condition was improved in the remaining women showing beneficial impact of the adjuvant therapy (67%) which was low compared to the non-recurrence found in group A.

**PROBIOTICS PRESCRIBED IN GROUP A**




**GRAPH: 7**

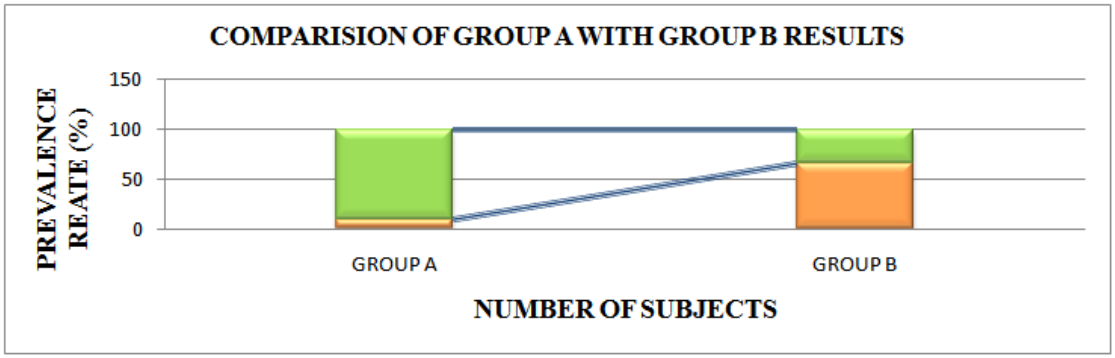
**On x axis – name of probiotic, on y- axis – number of subjects*

Probiotics were randomly prescribed by the doctors where ECOFLORA (***Lactobacillus rhamnosus, Lactobacillus reuterii***) was highly prescribed (14 women) when compared to the other probiotics used BIFILAC (***Bacilus mesentericus, Lactobacillus sporogens, Clostridium butyricum, Streptococcal faecalis***) in 5 women and BIOVAG ( ***lactobacillus gasseri, Lactobacillus fermentum, Lactobacillus plantarum*** ) in 3 women. The change in brands dint not show any effect on their adjuvant use.

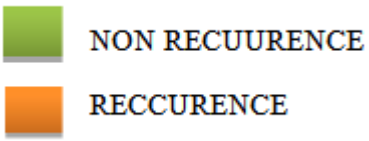
**GROUPING OF SUBJECTS WITH ILLUSTRATION OF BENEFICIAL EFFECT OF PROBIOTIC:**

| | RECUURANCE | NON RECUURANCE |
|---|---|---|
| **GROUP A** | 9.09 | 90.9 |
| **GROUP B** | 66.66 | 33.33 |

**TABLE: 5**




**GRAPH: 8**




**On Y- Axis = prevalence rate (%)*
*On X-Axis = Number of subjects*

This graph reflects the comparison in treatment of both the groups for better understanding of the results. This shows group A has better positive results in comparision to group B where group A has only 9.09% of reccurence while the other shows 66.66%. By this we can conclude that the use of probiotic as an adjuvant

therapy has better, positive results and is beneficial to prevent reccurence and maintain healthy vaginal health in women. All variables are analyzed and the applied descriptive statistical key data, the p values are greater than 0.05 the outcomes are significant.

## V. **Conclusion:**

This study suggests that the treatment with antibiotics or antifungal agent medication in combination with probiotics strains (Lactobacillus) strains provide long term cure against Vaginitis as compared to other published studies.

Further studies needed with larger sample size as to be performed by using quantitative molecular methods to confirm extensive results. The use of probiotic lactobacilli to prevent infection has a good rationale, and an excellent safety record, but so far only a few strains have been clinically proven to be effective, in particular to prevent Vaginitis.

An advantage for women is that they can self-administer the probiotics. Many more studies are needed to optimize the defensive properties of the vaginal microbiota, but the potential remains that the health of many women can be improved by probiotic intervention. Although the results this study have been in favor of the probiotics in the prevention or treatment of vaginitis. and no adverse effects have been reported.

Therefore, it may be helpful to recommend daily consumption of probiotic products to improve public health among women.

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