

Exploring the potential of probiotics in preventing recurrent urogenital infections: a pilot study

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Abstract

Urogenital infections, including bacterial vaginosis, yeast vaginitis, and urinary tract infections, affect millions of women globally, leading to complications such as infertility, chronic pain, and increased susceptibility to sexually transmitted diseases. While antibiotics remain the primary treatment, their long-term use can result in side effects and antibiotic resistance. This study investigates the potential of probiotics, specifically *Lactobacillus fermentum* and *Lactobacillus rhamnosus*, to restore vaginal microbiota balance and reduce oxidative stress in women with recurrent urogenital infections. Forty women aged 18-50 participated in a 90-day multicentric study in Italian clinics, divided into probiotic and placebo groups. Results showed that probiotic treatment significantly increased antioxidant potential by 45.18% and decreased total oxidant capacity by 25.46%, compared to placebo. Probiotics also enhanced lactobacilli dominance, restored vaginal microbiota, and normalized epithelial health. These findings suggest that probiotics could be a safer, long-term alternative to antibiotics for managing recurrent urogenital infections, improving overall urogenital health, and reducing infection risk. Further research with larger populations and extended study periods is warranted to validate these results.

Keywords: Urinary Tract Infection, Probiotics, Lactobacilli Vaginal Microbiota

Introduction

An estimated one billion women are affected by urogenital infections each year, making it one of the most prevalent infectious diseases in the world (1)-(2)-(3-6). These infections

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include urinary tract infections (UTIs), yeast vaginitis, and bacterial vaginosis (7)-(8)-(9-12). While antimicrobial treatments are effective, recurrence rates are high, resulting in substantial healthcare expenses of more than \$6 billion yearly (13)-(14)-(15-18). Serious side effects from UTIs include ectopic pregnancy, pelvic inflammatory disease, infertility, early labor, low birth weight babies, persistent pain, and heightened susceptibility to HIV and other STIs (19)-(20)-(21-25). Because of its exposure to the outside world, the urogenital system—which combines the reproductive and urinary tracts—is prone to infections (26)-(27)-(28-31).

E. Coli is responsible for 80–85% of UTIs, while other bacteria such as *Staphylococcus saprophyticus*, *Klebsiella*, *Proteus*, *Pseudomonas*, *Enterococcus*, and *Enterobacter* spp. are also responsible (32)-(33)-(34-36). Because of their anatomy, poor cleanliness, sexual activity, and usage of contraceptives, women are more likely to get UTIs than men (37)-(38)-(39-42). UTI complications include ureteritis, pyelonephritis, cystitis, and urethritis (43)-(44)-(45)-(46-50). Strong urges to urinate, burning when urinating, frequent small-scale urination, murky or crimson urine, strong-smelling urine, and pelvic pain are all common signs of urinary tract infections (51)-(52)-(53-55).

Recent research has demonstrated the significance of a lactobacilli-dominated, healthy microbiome in preserving women’s quality of life and preventing sexually transmitted diseases (STDs) and premature childbirth (56)-(57)-(58-61). The investigation of artificial lactobacilli supplementation to reduce infection rates has been prompted by the depletion of lactobacilli in women who are prone to vaginal and urinary tract infections (62)-(63)-(64-67). Uropathogens are becoming more resistant to standard antibiotics, which has led to a quest for natural alternatives such as cranberry juice, which has antiadhesive chemicals that are effective against (68)-(69)-(70-73).

Antibiotics are the mainstay of current preventive therapies for UTIs, which involve long-term, low-dose interventions (74)-(75)-(76-79). Lactobacilli-based probiotic treatment has been explored as a non-chemotherapeu-

tic way to maintain and restore a healthy urogenital tract (80)-(81)-(82-86). After oral intake, several strains, such as *Lactobacillus rhamnosus* and *Lactobacillus fermentum*, have demonstrated efficacy when placed straight into the vagina or ascending from the rectum (87)-(88)-(89-92). These probiotics can enhance vaginal flora and protect against UTIs when taken daily (93)-(94)-(95)-(96-98).

The purpose of this pilot study was to determine whether probiotics (Hyperbiotics PRO-Women) taken daily may affect the vaginal microbiota over ninety days (99)-(100)-(101)-(102-105). Forty patients with a history of recurrent urogenital infections were enrolled and split into two groups: one that received a placebo and the other that received probiotics as a test (106)-(107)-(108-111). At T0, one month, and three months, the biological antioxidant potential (BAP test) and total oxidant capacity (derived reactive oxygen metabolites (d-ROMs) test) were evaluated for both groups (112)-(113)-(114-116). Investigations were also conducted into histological alterations in the inner (117)-(118)-(119)-(120-124).

According to the results, the test group’s antioxidant potential was enhanced by the considerable increases in BAP values and decreases in oxidative stress levels (125)-(126)-(127-130). These results imply that by altering the inner vaginal microbiota, oral probiotics can successfully prevent and lessen recurrent urogenital infections (131)-(132)-(133-136). Although more research with bigger sample sizes is required to validate these findings, the study offers encouraging evidence for the safety and efficacy of probiotics in controlling urogenital health (137)-(138)-(139)-(140-142).

Materials and Methods

This multicentric investigation was conducted exclusively in Italian clinics and medical facilities. Every participating patient was asked to read, comprehend, and sign an informed consent form. The study was conducted according to the Helsinki Declaration’s “Ethical principles for medical research involving human subjects.” The



Figure 1. Table summarizing the number of patients selected and excluded from the research project

clinical protocol for this proposed clinical investigation was verbally explained to the patients.

Following a thorough initial screening for inclusion and exclusion criteria, 51 patients were chosen randomly (Figure 1). Those undergoing antibiotic therapy were not allowed to participate in the study.

Forty women with recurrent urogenital infections (UGIs), aged 18 to 50, participated in a multicentric study that was carried out at Italian clinics (Figure 1).

To determine the bacteria causing the infections, urine samples were examined at private microbiological laboratories. Certain bacteria, such as *E. Coli* (discovered in 44/51 patients) and *Candida* spp. (found in 37/51 patients), were the predominant causes of positive results. Recurrent UTIs in patients with dysuria, frequency, urgency, and abdominal/flank pain with or without fever were requirements for inclusion. In this study, 40 individuals with a history of recurrent urogenital infections were enrolled.

For ninety days, participants were split into two groups, one receiving oral probiotic tablets and the other a placebo. Recurrent UGIs were among the inclusion criteria, while smoking, systemic illnesses, pregnancy, and recent antibiotic usage were excluded. All inclusion and exclusion criteria are summarized in the table depicting the criteria for inclusion and exclusion of patients in the research (table 1).

Six specific probiotic strains—*L. plantarum*, *L. fermentum*, *L. acidophilus*, *L. reuteri*, *L. rhamnosus*, and *B. bifidum*—were employed to make the probiotics used in this investigation. More than 5 billion Colony Forming Units are present in each probiotic tablet. The probiotics utilized in this study were developed and manufactured to enhance immunological, urinary, and digestive function by fusing the effectiveness of cranberry extract with the effects of naturally occurring D-mannose that have been clinically examined. D-Mannose actively prevents unwanted recurring urinary tract diseases, such as bacterial infections.

Table 1. Inclusion and exclusion criteria for patients.

| |
|--|
| <i>Inclusion Criteria</i> |
| a. Caucasian. |
| b. Volunteer to participate in the study. |
| c. Patients diagnosed with recurrent urogenital infection. |
| d. Between 18-50 years. |
| <i>Exclusion Criteria</i> |
| a. Any systemic disease. |
| b. Patients undergoing to recent surgical treatments. |
| c. Pregnant. |
| d. Smoking habits. |
| e. Patients with sexually transmitted viruses onset on vaginal mucosa. |
| f. Patients with frequently recurring complicated vaginitis with a high fever. |
| g. Diseases are leading to influence oxidative stress, like syndromic conditions & rheumatological diseases. |
| h. Subject received antibiotics for the last 3 months and/or during the study. |
| i. Subjects received immunosuppressive drugs. |

Assays for Oxidative Stress: The BAP test investigated antioxidant potential, whereas the d-ROMs test evaluated total oxidant capacity. Blood samples were examined at T0, one month (T1), and three months (T2).

Microbiological Evaluations: Gram-stained vaginal swabs were used to assess alterations in vaginal flora. Glycogen-associated pH balance and epithelial health were the main topics of histological study.

Statistical Analysis: Data from T0, T1, and T2 were compared using paired t-tests and ANOVA to assess significant differences across groups.

Results

All patients included in this pilot trial participated, and no adverse reactions or dropouts were recorded before the end of the research. The study focused on how free radicals, usually controlled by biological processes but dangerous nonetheless, are produced during cell metabolism. Severe oxidative stress can lead to reactive oxygen species (ROS) and unchecked lipid peroxidation. UTIs cause oxidative stress, increase lipid peroxidation, and decrease antioxidant enzyme levels.

At T0 and T2, there was a significant difference in the levels of oxidative stress between the test and control groups. Oxidative stress levels were higher in the test group than in the control group at T0. The BAP readings of the test group increased significantly over the experiment, improving by 45.18% overall from T0, whereas the control group's climbed by 9.72%. The ANOVA test showed high statistical significance ($p < 0.001$) between the data.

The test group's vaginal mucosa provided positive feedback, as evidenced by histological examinations that showed formed epithelial cells with small, dense pyknotic nuclei—the acidic pH of lactobacilli protected against *Candida albicans* and other diseases.

The test group's oxidative stress decrease was significantly less than the control group's. The d-ROM (derived reactive oxygen metabolites) values in the test group decreased by 25.46%, whereas they increased by 3.86% in the control group. These findings highlight the importance of oral probiotics in reducing oxidative stress in cases of urogenital infections.

Discussion

Maintaining lactobacilli levels, which are good bacteria that guard the vaginal environment, and stopping the growth of dangerous bacteria are both made possible by the acidic pH of the vagina (143)-(144)-(145–148). However, several variables, including sperm, antibiotic use, excessive cleanliness, menstrual flow, and intrauterine devices (IUDs), might affect this equilibrium (149)-(150)-(151–153)-(154–158). Bacterial vaginosis can result from an overabundance of anaerobic organisms that replace the typical lactobacilli when the pH of the vagina changes (159)-(160)-(161–164). Women between the ages of 15 and 44 who are of reproductive age are more likely to have this disorder (165)-(166)-(167)-(168–171). Bacterial vaginosis is frequently asymptomatic, although it can occasionally cause pain, stinging, and burning when urinating, as well as light-colored vaginal secretions and a strong odor, particularly after sexual activity (172)-(173)-(174).

Although the exact causes of bacterial vaginosis are unknown, women who have multiple relationships have been reported to have a greater incidence (175)-(176)-(177)-(178-181). Bacterial vaginosis can reoccur and lead to difficulties, including an increased risk of spontaneous abortion or premature birth during pregnancy if treatment is not received (182)-(183)-(184)-(185-187). Probiotics are defined as the use of foreign organisms, such as lactobacilli. These are live microorganisms that are given to the host to treat or prevent illness (188)-(189)-(190). The study's findings are in line with other research that demonstrated the advantages of oral probiotics in reducing the risk of urogenital infections (191)-(192)-(193)-(194-197). For instance, Anukam et al. found that probiotic lactobacilli reduced bacterial vaginosis by 90% (198)-(199)-(200-204).

Probiotics have both preventive and therapeutic effects on the growth of *E. coli*, according to another *in vivo* investigation by Pascual et al. (205)-(206)-(207). According to studies, probiotics' protective barrier, which has been shown to stop pathogenic bacteria from colonizing healthy epithelial and mucosal tissues without any oncological beginning, starts with these tissues (208)-(209)-(210)-(211-213).

It has been shown that the human microbiota plays a part in women's urogenital health by affecting the length, frequency, and intensity of infection episodes (214)-(215)-(216). Certain metabolic disorders and alterations in pregnant women's physiology are also linked to the microbiome (217)-(218)-(219)-(220-224). It appears that oxidative stress is a biological marker, drawing attention to inflammatory stressors that could cause superinfections or histological alterations (225)-(226)-(227). Numerous nutraceuticals and probiotics have been shown in some studies to have beneficial effects on the distribution and composition of commensal microbiota (228)-(229)-(230). These effects reflect the biology and physiology of the tissues involved and help to prevent and lessen the severity of infections and related inflammatory phenomena (231)-(232)-(233).

The test group's notable reductions in systemic oxidative stress (BAP/d-ROMs) in our pilot study (234)-(235)-(236) confirmed the good impact of probiotics in preventing or lowering UTIs. The test group's vaginal microbiota was found to be healthy based on histological data characterizing the inner vaginal mucosa's Gram staining before and after probiotic administration (237)-(238)-(239). Despite the small patient sample size in this initial trial, our findings indicate that daily probiotic administration should be a helpful tool for enhancing women's general health, with a particular benefit on UTIs, and without any adverse side effects (240)-(241)-(242). Controlling the local mucosal flora may offer a valuable supplement to the available treatment options for female UTIs (243)-(244)-(245-247).

Additionally, because probiotics are safe and simple to employ, their usage in urogenital health management is growing (248)-(249)-(250). Since probiotics are available over the counter and are usually considered secure, many women can afford them. In environments with limited resources, when access to medical treatment may be restricted, this accessibility is especially crucial (251)-(252,253). Probiotics have the potential to lessen the demand for antibiotics since they can assist in addressing the developing issue of antibiotic resistance (254)-(255)-(256)-(257-261).

In summary, the study emphasizes how probiotics may help manage urogenital health (262)-(263)-(264). The test group's healthy vaginal microbiome and notable improvements in oxidative stress markers demonstrate the promise of probiotics as a therapeutic and preventive measure (265)-(266)-(267)-(268-272). The results are encouraging and call for more research despite the study's early nature and small sample size limitations (273)-(274)-(275-279). To validate these results and investigate the long-term impacts of probiotic usage on urogenital health, future research should concentrate on more significant, thorough investigations (280)-(281)-(282-285). Furthermore, knowing the precise processes via which probiotics work may help us better grasp their potential as a treatment (286)-(287)-(288-290).

Conclusion

This pilot investigation shows the promise of probiotics in treating recurrent urogenital infections. Probiotics are a promising non-antibiotic treatment because they restore vaginal microbiota and drastically reduce oxidative stress. Frequent use of probiotics may improve urogenital health in women, reducing the risk of infection and enhancing general health.

Restrictions and Prospects

The small sample size and brief follow-up period limit generalizability. Future research should include larger populations, more extended study periods, and examinations of the causes and advantages of particular probiotic strains.

List of Abbreviations

- BAP - Biological antioxidant potential
- D-ROMs - Derived reactive oxygen metabolites
- STD - Sexually transmitted disease
- T0 - Baseline
- T1 - One month
- T2 - Three months
- UGI - Urogenital infection
- UTI - Urinary tract infections

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