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Original Research Article

A COMPARATIVE PRE CLINICAL IN VITRO AND IN VIVO EVALUATION OF EFFICACY OF PANCHAVALKALA VAGINAL CREAM IN MANAGEMENT OF DIFFERENT VAGINAL MICRO-ORGANISM

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Abstract: ***Background:*** Vaginal infections, including bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis, are among the most common gynecological disorders affecting women of reproductive age. Frequent recurrence, antimicrobial resistance, and disruption of the normal vaginal microbiota have created a need for safer and effective alternative therapies. Panchavalkala, a classical Ayurvedic polyherbal formulation prepared from the bark of five Ficus species, possesses antimicrobial, anti-inflammatory, astringent, and wound-healing properties, making it a promising candidate for the management of vaginal infections. ***Aim:*** To evaluate and compare the preclinical in vitro and in vivo efficacy of Panchavalkala vaginal cream against Candida albicans, Gardnerella vaginalis, and Trichomonas vaginalis. ***Methodology:*** A comparative experimental preclinical study will be conducted in two phases. The in vitro phase will evaluate antifungal, antibacterial, and antiprotozoal activities using minimum inhibitory concentration (MIC) determination and agar well diffusion methods. The in vivo phase will utilize standardized vaginal infection models in Wistar female rats. Animals will be allocated to Panchavalkala vaginal cream, standard drug, saline control, and untreated control groups. Outcomes will include microbiological clearance, vaginal pH, vaginal discharge, microscopic findings, and inflammatory changes. Data will be analyzed using appropriate statistical tests, with $p < 0.05$ considered statistically significant. ***Conclusion:*** This study is expected to generate preclinical evidence regarding the antimicrobial efficacy and local safety of Panchavalkala vaginal cream against common vaginal pathogens. The findings may support its development as a safe and effective local therapeutic option or adjunct for the management of vaginal infections.

Keywords: Panchavalkala, Vaginal cream, Vaginal infections, Candida albicans, Gardnerella vaginalis, Trichomonas vaginalis, Antimicrobial activity, Preclinical study.

INTRODUCTION

Vaginal infections and dysbiosis are among the most frequent causes of abnormal vaginal discharge, itching, burning, malodor, and dyspareunia in women

of reproductive age. Clinically, a significant proportion of symptomatic episodes are associated with bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomoniasis, and mixed infections are frequent as well. Biologically, vaginal well-being is strongly associated with the vaginal microbiome such that Lactobacillus-rich communities promote low vaginal pH-maintaining and inhibiting pathogen overgrowth and Lactobacillus loss promotes BV, inflammation, and susceptibility to further reproductive tract infections. (1)

BV is defined from its origins as a shift in Lactobacillus dominance to a polymicrobial anaerobic community (as exemplified by species such as Gardnerella), associated with recurrence, treatment failure, and downstream reproductive and obstetric sequelae. (2)

In addition to BV, VVC (usually from Candida species) along with protozoal infections such as Trichomonas vaginalis are associated with substantial symptomatology and recurrences; interestingly, interactions between Lactobacillus spp., Candida, and Trichomonas are thought to govern disease expression and persistence. (3)

Although classic therapies (e.g., metronidazole for BV and trichomoniasis and azoles for candidiasis) are effective for many cases, recurrence risks, tolerance problems, and antimicrobial resistance and microbiome disturbance have raised interest in a number of evidence-based interventions, locally used non-antibiotics or add-on, and for instance adjuncts to minimize pathogen load with the aim of reducing the burden of pathogenicity and to return the vaginal flora to ecological balance. {Citation},{Citation}

So in this respect, Panchavalkala a polyherbal combination known as an Ayurvedic blend that is traditionally made from the bark of five Ficus species—became the source of interest on account of its reported astringency (tannin rich) and anti-inflammatory, antimicrobial, and wound healing properties as well as good wound healing role. The preclinical and translational findings of Panchavalkala-promoted formulations suggest the possibility of lowering the microbial load and tissue repair in infected and nonhealing injured, possibly through the local infection control and mucosal healing when tailored to the gynecological context. (5) Beyond the “kill” effects, it is of interest the polyherbal formulations which have been proposed to control virulence as well as biofilm-promoting activity of pathogen (including quorum-regarding effects), especially since vaginal pathogens usually thrive via biofilm and polymicrobial cooperation, particularly in the context of repeating BV. (6)

Additionally, individual Ficus constituents have documented antimicrobial and anti-infective activities in diverse experimental models, supporting biological plausibility for a combined formulation. (7)

Thus, a comparative preclinical (in vitro and in vivo) of Panchavalkala vaginal cream is needed to ensure: (1) spectrum and potency against diverse vaginal microorganisms in combination with BV/VVC/trichomoniasis and mixed infections, (2) impact on outcomes related to biofilm/virulence when feasible, (3) local safety and mucosal compatibility, and (4) visual signs of efficacy in vivo, including reduced microbial burden and inflammation. Such data could help establish Panchavalkala vaginal cream as a valuable independent or additional local treatment for pathogen resistance, consistent with the modern objectives of reinstating and maintaining a healthy vaginal environment. (8)

Panchavalkala studies are largely from wound or dermatological models and do not directly evaluate activity against major vaginal pathogens (Gardnerella-associated BV flora, Candida spp., Trichomonas vaginalis). Hence, focused in-vitro vaginal microorganism testing is required.

Review of Literature :-
Bhat et al. (2014) presented antimicrobial activity of Panchavalkala cream in infected wound models: they exhibited decrease in microbial presence and ameliorated healing.

Chen et al. (2021) and Lev-Sagie (2022) demonstrated that vaginal health is supported by a Lactobacillus-dominated microbiota and success in treatment relies on the control of pathogens while retaining a balance of protective flora.

Machado et al. (2016) and Gustin et al. (2021) characterized bacterial vaginosis as a polymicrobial disorder that is biofilm mediated where there is also a polymicrobial persistence and recurrence.

AYUSH Panchavalkala monograph notes formulation development and animal safety/clinical evaluation for a Panchavalkala vaginal cream in uncomplicated leucorrhoea, but the broader literature still lacks robust comparative preclinical mapping of (a) dose–response antimicrobial spectrum across different vaginal organisms, (b) local mucosal irritation/safety endpoints, and (c) head-to-head comparisons with standard agents in in vivo vaginal infection models. Thussupports the research gap for a combined in vitro + in vivo comparative preclinical study.

Therefore, there is scientific justification for a systematic analysis of Panchavalkala vaginal cream against heterogeneous vaginal microorganisms using

modern experimental models. Vaginal infections are microbiologically driven illnesses and must be adequately suppressed with effective repressing pathogenic bacteria while protecting against protective Lactobacillus-dominated flora, the evidence suggests. Conventional antimicrobial treatments have shown effectiveness, but are also often associated with recurrence and disruption of vaginal ecology, especially in biofilm infections (bacterial vaginosis). Panchavalkala is a traditional polyherbal formulation that includes anti-microbial, anti-inflammatory and wound healing components that have exhibited local infection control potential. As demonstrated by proven safety information, the Panchavalkala vaginal cream has a good scientific basis for systematic preclinical assessment against common vaginal pathogens in vitro and in vivo experimental models.

AIM AND OBJECTIVES

In vitro

• To evaluate the antifungal action of Panchavalkala vaginal cream on Candida albicans. Antibacterial effect of Panchavalkala vaginal cream with bacterial vaginosis–associated organisms. Antiprotozoal effect of Panchavalkala vaginal cream on Trichomonas vaginalis.

In vivo (Wistar female rats)

• To assess the effect of Panchavalkala vaginal cream against Candida albicans, bacterial vaginosis and Trichomonas vaginalis.

OBJECTIVES

• To evaluate the in vitro efficacy of Panchavalkala vaginal cream against Candida albicans, Gardnerella vaginalis and Trichomonas vaginalis.

• To evaluate the in vivo activity of Panchavalkala vaginal cream on Candida albicans, Gardnerella vaginalis and Trichomonas vaginalis in Wistar female rats.

• To compare Panchavalkala vaginal cream versus clotrimazole for Candida albicans infection.

• To establish a comparison of Panchavalkala vaginal cream and clindamycin in bacterial vaginosis.

• Evaluate Panchavalkala vaginal cream and tioconazole in Trichomonas vaginalis infection.

MATERIALS AND METHODS

Present study will take place at Mahatma Gandhi Ayurveda College, Hospital & Research Centre (MGACH&RC), Wardha and Central Preclinical Research Facility, Datta Meghe Institute of Medical Sciences (DMIHER-DU), Sawangi (Meghe), Wardha or any centre accredited by DMIHER. Pharmaceutical preparation will be done at Practical Pharmacy, MGACH&RC; analysis at MGACH&RC or other DMIHER-approved laboratory; animal study at DMCP, Wardha or other recognized animal facility. The study was approved previously by the Institutional Ethics Committee (IEC/IAEC) of DMIHER (DU), and all animals treatment protocol will comply with CPCSEA.

Study planned as a comparative experimental preclinical trial with two stages. Phase I (in vitro) will be performed in a microbiology laboratory to assess the antifungal, antibacterial, and antiprotozoal activity of Panchavalkala vaginal cream against Candida albicans, Gardnerella vaginalis, and Trichomonas vaginalis. Minimum inhibitory concentration (MIC) will be established from standard broth dilutions by serial two-fold dilution and antimicrobial activity evaluated by a reduction in turbidity after incubation at 37°C for 48–72 hours. The zone of inhibition will be determined by agar well diffusion method in Sabouraud Dextrose Agar. Zones will be given in millimeters after the incubation period. Phase II (in vivo) will be carried out on Wistar female rats. Only positive microbes that are active in vitro can be selected. A total of 72 rats (6 rats per group and 12 groups) will consist. Specific experimental vaginal infection models of Candida albicans, Gardnerella vaginalis and Trichomonas vaginalis will be set up applying standardized inoculation protocols. Animals will be randomly assigned to: experimental (Panchavalkala vaginal cream), standard control (clotrimazole/clindamycin/tioconazole), saline control, and no-treatment conditions. The study drug will be provided intravaginally for 6 days, followed by monitoring of outcomes up to Day 15. Measures of outcome include vaginal white discharge, microscopic identification of fungal hyphae, Gram staining and whiff test for Gardnerella vaginalis, hanging drop test for Trichomonas vaginalis, and vaginal pH ≥4.5 pre- and post-treatment.

Statistical Analysis Plan

The data from the in-vitro and in-vivo phases will be arranged and analyzed using suitable statistical tools (SPSS / GraphPad Prism). Descriptive statistics will be written as mean ± standard deviation (SD). For in-vitro experiments, MIC (Minimum Inhibitory Concentration) and zones of inhibition among various concentrations will be detailed descriptively and compared using one-way ANOVA with corresponding post hoc tests. In-vivo animal studies will assess pre-test vs post-test results (vaginal discharge, microscopic findings, Gram stain/whiff test and vaginal pH) within groups based on paired t-test or, again, repeated-measures ANOVA as indicated. Between-group comparisons (Panchavalkala vs standard drug vs saline vs no treatment) will be carried out using one-way ANOVA, which will be followed by post hoc multiple comparison tests. When nonparametric, appropriate tests like Kruskal–Wallis test or Mann–Whitney U test will be used. A p-value < 0.05 will be considered statistically significant.

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