Clinical Evaluation of PD-959 Vaginal Gel: An Open Trial

Renuka Kulkarni, MD, Lecturer, Department of Pharmacology and Therapeutics
Nandita Kashalikar, MD, Professor, Department of Gynaecology & Obstetrics
Vinita Salvi, MD, DGO, DNB, FCPS, DSP, Professor, Department of Gynaecology & Obstetrics
Vanita Raut, MD, DGO, Professor, Department of Gynaecology & Obstetrics
Urmila Thatte*, MD, DNB, PhD, Associate Professor, Department of Pharmacology & Therapeutics,
and
Sharadini Dahanukar, MD, DNB, PhD, F.I.I.M., Professor & Head, Department of Pharmacology & Therapeutics
Seth G.S. Medical College & KEM Hospital, Parel, Mumbai, India.
(*Corresponding author)

ABSTRACT
An open clinical trial was conducted in 30 women with clinical and microbiological evidence of vaginitis to evaluate the efficacy of a polyherbal preparation, PD-959, vaginal gel, on topical application. Seventeen women had inflammatory vaginitis and 13 showed evidence of microbial infection produced by Candida, Trichomonas and other non-specific bacteria. Soreness, pruritus and vaginal discharge were considered as clinical symptoms. There was a significant improvement in clinical symptoms after 2 weeks of treatment with the topical application of vaginal gel, twice daily with a remarkable clinical improvement seen especially in women with candidal infection. No side effects were reported. Thus, the vaginal gel effectively produced clinical and microbiological relief in women with vaginitis of varied aetiology.

Key words: Trichomoniasis, vaginitis, leucorrhoea

INTRODUCTION
Vaginitis is one of the most common gynaecological problems in clinical practice. Though the infections are not serious in nature, they can become chronic and the eradication of such infections is often difficult1. Various causative organisms during the reproductive years are *Trichomonas vaginalis*, *Monilia* or *Candida albicans*, *Haemophilus vaginalis* and the Herpes virus2. In the prepubertal and postmenopausal years, infection is mostly produced by gonococci and non-specific organism.

Usually a large percentage of *Trichomonas vaginitis* (*T. vaginitis*) patients are asymptomatic. *Trichomonas* alone cannot produce vaginal inflammation. The infection tends to be chronic, transmitted by sexual contacts and infection is more common during pregnancy.

The organisms responsible for producing *Monilia vaginitis* are fungi of the yeast group. *Candida albicans* is the most common and the use of systemic or local antibiotics promotes the growth of *Candida*3.

Antibiotic therapy, pregnancy, diabetes mellitus, oral contraceptives and immunocompromised states have all been associated with an increased risk of *Candidal vaginitis*. Non-specific vaginitis caused by *Gardnerella vaginalis* is also a sexually
transmitted infection\textsuperscript{4,5}. \textit{Emphysematous vaginitis} is a rare condition, seen during pregnancy and heart failure and is usually associated with other infection mainly \textit{T. vaginitis}\textsuperscript{6}.

During the postmenopausal period, atrophy of the vaginal mucosa makes it prone to infections, discharge, itching, burning and soreness in the vaginal region. In postmenopausal vaginitis, the discharge is thin and may be blood tinged. This type of vaginitis responds to local or systemic oestrogen therapy.

Most of the conventional medicines available are applied topically and may be administered systemically, but have limited utility due to the recurring nature of the clinical problems. Hence, it is decided to evaluate the topical efficacy of a polyherbal formulation with minimal systemic hazards (if any) and thus clinical trial was conducted in a small population of patients.

\textbf{MATERIAL AND METHODS}

This was an open clinical trial in 30 patients in the age group of 30-55 years suffering from both inflammatory and infective vaginitis. Seventeen had inflammatory vaginitis, 9 had \textit{Candida vaginitis}, 3 had \textit{Trichomonas vaginitis} and 1 had non-specific vaginitis in the infective vaginitis group.

Patients were assessed symptomatically for soreness, itching and discharge and for signs like inflamed vulva, scratch marks, odour and vaginal discharge for two weeks. A microscopic examination of vaginal smears was done to determine the causative organisms. Patients were advised abstinence during the 2 week study period.

All the patients were instructed to apply 2 gm vaginal gel twice daily for 2 weeks.

The benefit of the gel application was relief from symptoms like soreness, pruritus, vaginal discharge, decrease in erythema and a reduction in microbial count. These patients were examined every week for two weeks.

All the patients were followed-up weekly for two weeks, for any adverse effects like burning, pain, hypersensitivity reactions, pruritus and menstrual abnormalities. These were recorded on data sheets, if observed.

\textbf{RESULTS AND DISCUSSION}

Thirty patients completed the open clinical trial with PD-959 vaginal gel. PD-959 reduced the amount of vaginal discharge significantly in all the patients both symptomatically and clinically. It also produced symptomatic relief from vaginal pruritus and soreness. Microbiologically the most remarkable effect was seen in women with \textit{Vaginal candidiasis}, in that, all 9 patients showed eradication of the organism by the end of the two week period. One patient of \textit{T. vaginitis} also showed disappearance of \textit{Trichomonas} in one week (Tables 1-3). Although the degree of inflammation decreased in most patients with inflamed vaginitis, it did not reach statistically significant values.
There were no side effects observed with topical application of PD-959 vaginal gel and it was thus found safe for the symptomatic management of vaginitis.

Our observations are similar to some of the trials published on V-Gel earlier\(^7\)-\(^9\). The symptomatic relief starts after 3 to 4 days of application and microbiological homeostasis appears within two weeks. All patients treated with PD-959 gel were followed up for the next 3 months for any evidence of relapse and recurrence.

The herbs used in the gel are effective in vaginal tract infections. *Berberis aristata* possesses antimicrobial activity against *E. coli* and antifungal activity against *Candida albicans*. Berberine, an alkaloid from Berberis, possesses antibacterial and anti-inflammatory activities\(^10\). *Cedrus deodara* oil has anti-inflammatory and antifungal activity\(^11,12\). The various components of PD-959 vaginal gel have synergistic interactions with each other and result in symptomatic relief and control of mixed infections.

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**REFERENCES**


