

Efficacy of V-Gel in Vaginitis and Cervicitis

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ABSTRACT

An open clinical trial was conducted with V-Gel on 31 patients with vaginitis in the age group of 24-62 years. After initial screening of symptomatology and aetiological organisms the patients were enrolled in the trial. All the patients were advised to apply V-Gel twice daily for a period of 2 weeks. A weekly follow-up was done in all the patients to assess the clinical response and side effects, if any. Complete relief in symptoms was observed in patients (73.3%) within 7-14 days. A repeat microbiological evaluation revealed the complete eradication of causative organisms in all the patients in 14 days of treatment. There were no untoward manifestations associated with the use of V-Gel in any of the cases. Thus, the vaginal gel is effective and safe for vaginitis caused by different micro-organisms.

Key words: V-Gel, Vaginitis, *Candida albicans*, *Trichomonas vaginalis*, Non-specific vaginitis.

INTRODUCTION

Vaginitis is one of the most common problems that poses a challenge to the gynaecologists. The vaginal epithelium in healthy adult women undergoes constant desquamation and the discharge of vaginal origin is characterised chiefly by the presence of epithelial cells. Vaginal secretions are largely oestrogen dependent and the amount of normal vaginal secretion varies with age and the time of menstrual cycle, with a physiological increase at ovulation, in the premenstrual phase and during pregnancy and other conditions¹. In addition to these physiological variations, the vagina may be infected pathologically by microbes such as *Trichomonas vaginalis*, *Candida albicans*, *Gonococcus*, *Gardnerella vaginalis* and other non-specific organisms, which result in increased vaginal secretions. Systemic diseases such as diabetes, cardiovascular diseases and other debilitating illnesses may also predispose to vulvo vaginitis.

Vulvo vaginal candidiasis, in 85-90% of presenting cases, is caused by *Candida albicans*². It is one of the most prevalent vaginal infections, which appears to be increasing in incidence and is possibly related to the increased use of broad-spectrum antibiotics³. The other prevalent causative organism of vaginitis is *Trichomonas vaginalis*, which is common among women with other sexually transmitted diseases and the infection rates with Gonococci have been reported to be as high as 60%^{4,5}. *Trichomonas* is also linked to preterm labour in

pregnant women. The current methods of treatment involving the use of nitroimidazoles or synthetic hormone preparations, though curative, are not free from side effects.

The drawbacks of the existing modes of treatment and increasing prevalence of infections has led to an exploration of other modalities especially herbal remedies, keeping in view their safety and efficacy. V-Gel is one such herbal formulation, chiefly comprising *Curcuma longa*, *Vitex negundo*, *Azadirachta indica*, *Elettaria cardomomum*, *Cedrus deodara*, *Boerhaavia diffusa* and *Nelumbium speciosum*. Keeping this in view an open clinical trial was conducted to evaluate the efficacy of V-Gel in vaginitis and cervicitis.

The extracts of *Curcuma longa* possess anti-inflammatory, antibacterial and antifungal activity⁶⁻⁸. *Vitex negundo* leaves are found to have antibacterial activity against *Micrococcus pyogenes*, *E. coli*, etc. and are beneficial in the treatment of excessive vaginal discharge. It also accelerates the healing process in inflammatory conditions⁹. *Azadirachta indica* is widely used in traditional medicine for its beneficial antibacterial, antifungal, antiviral and anti-inflammatory properties¹⁰⁻¹³. *Elettaria cardomomum* is found to have anti-inflammatory activity¹⁴. *Cedrus deodara* exhibits anti-inflammatory and antifungal activity¹⁵. *Boerhaavia diffusa* is found to have anti-inflammatory activity¹⁶. *Nelumbium speciosum* possesses bacteriostatic action against gram-positive and gram-negative bacteria¹⁷.

MATERIALS AND METHODS

Thirty one patients in the age group of 24 to 62 years with excessive vaginal discharge secondary to vaginitis and/or cervicitis were included in the study after obtaining a written consent. Patients with mild to severe degree of dysplasia, genetic disorders and other debilitating conditions were excluded from the study. A detailed history with reference to the characteristics of discharge such as amount, colour, odour, consistency, etc. was recorded for each patient. General, systemic and local examinations were carried out, considering the vaginal lesions, areas of inflammation, irritation and tenderness. Abnormal secretions were collected in sterile swabs and the samples were sent for microscopy. One swab was used for wet preparation and staining and the other swab for culture.

The wet preparation was used to identify pus cells, epithelial cells, *Candida albicans* and *Trichomonas vaginalis*. The fontana stain was used to identify *Trichomonas vaginalis* with flagella, which are motile parasites. Culture for *Candida* was done on the Sabourad dextrose agar with antibiotics. Positive growth of *Candida* was identified by germ in the tube and biochemical tests based on cultural characteristics. Culture for other organisms was done on McConky's agar and Thayer Martin Media and identified by biochemical tests.

After initial screening, the patients were advised to apply V-Gel twice daily, intra-vaginally, for 7 to 14 days and return for follow-up on the 7th and 14th day. During follow-up improvement in signs and symptoms, changes in the microbiological picture and side effects, if any, were recorded. Cases with persistence of symptoms were followed up to 21 days.

The signs and symptoms in patients were recorded based on a rating scale of 0=absent, 1=mild, 2=moderate and 3=severe.

The microbial status was assessed based on the rating scale of 0=no growth of organisms, 1=mild growth of organisms and 2=prominent growth of organisms. The overall clinical response to V-Gel was presented as percentage of patients with complete response, partial response and no response.

Statistical Analysis: The data was analysed statistically using repeated measures of analysis of variance (RMANOVA). The minimum level of significance for all inferences was set at $p < 0.05$.

RESULTS

The number of patients with symptomatology, clinical manifestations of aetiological organisms and findings of the microbiological evaluation both before and after the study are presented in Tables 1 and 2, respectively. The clinical assessment of V-Gel in vaginitis of varied aetiology showed a complete response in 22 patients (73.3%), partial response in 7 patients (23.3%) and no response in 1 patient (3.4%).

A significant decrease in signs and symptoms was observed on day 7 and a further decrease was observed on day 14 (Table 3). Microbiological examination of the patients revealed negative results in 58.3% of patients within 7 days of treatment and a 100% response in 14 days. The assessment of microbial status is shown in Table 3.

Signs and Symptoms	No. of patients
Abnormal vaginal discharge	31
Soreness	21
Itching	23
Vulval inflammation	20
Scratch marks	18
Bad odour	19

Organism isolated	No. of patients	Percentage
Trichomonas vaginalis	11	35.5
Candida albicans	7	22.6
Non-specific	6	19.4
Mixed	4	12.8
Senile vaginitis	3	9.7

Parameters	Baseline	Day 7	Day 14
Abnormal vaginal discharge	2.45 ± 0.11	1.28 ± 0.11*	0.66 ± 0.10*
Soreness	1.10 ± 0.16	0.58 ± 0.10*	0.29 ± 0.08*
Itching	1.61 ± 0.20	0.84 ± 0.14*	0.27 ± 0.08*
Vulval inflammation	0.97 ± 0.16	0.42 ± 0.11*	0.13 ± 0.06*
Scratch marks	0.97 ± 0.18	0.57 ± 0.13*	0.30 ± 0.14*

Bad odour	0.90 ± 0.17	0.38 ± 0.09*	0.10 ± 0.08*
Microbial growth	1.17 ± 0.08	0.63 ± 0.12*	0.00 ± 0.00*
* $p < 0.001$ as compared to respective base line rating scores.			

DISCUSSION

The existing modes of treatment for *Candida albicans* include multiple topical imidazole or triazole compounds which are 80-90% effective, when given in courses ranging from one dose or up to 14 days^{17,18}. Treatment for *Trichomonas vaginalis* consists of metronidazole either in a single 2 g dose or multidose course (500 mg orally b.i.d. for 7 days)^{19,20}.

However, cases of resistance to metronidazole have been reported^{21,22} and the available chemotherapeutic regimes though effective, are not free from side effects^{23,24}.

In the present study, it was observed that local application of V-Gel provided symptomatic relief within 4-5 days of treatment. There was complete relief in majority of cases (73.3%) in 7-14 days of application. In this trial, cases of vaginitis had various aetiological factors such as fungal, bacterial and mixed infections. Application of V-Gel for 7-14 days showed a complete eradication of the causative organism. There were no untoward manifestations associated with the use of V-Gel in any of the cases.

It can be concluded from the above observations that V-Gel is of immense value in the treatment of vaginitis of varied aetiology.

CONCLUSION

The clinical trial has proved that V-Gel is effective in treating patients with vaginitis of different aetiology on topical application for 2 weeks. The efficacy was observed to relieve the symptom as well as eradicate the causative micro-organisms. None of the patients complained of any side effects. These patients were followed up subsequently for up to 3 months to rule out the evidence of recurrence in infection. V-Gel produced long term remission in most of the patients, as there was no evidence of recurrence.

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