Evaluation of V-Gel in Vaginitis and Cervicitis

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ABSTRACT
Thirty five females diagnosed with vaginitis, clinically and microbiologically, were enrolled in the study to evaluate the efficacy of V-Gel. Patients were assessed subjectively for symptoms of vaginal discharge, pruritus, soreness of vulva, inflammation, foul odour and scratch marks. Vaginal discharge was subjected to microbiological diagnosis. The patients were advised to apply V-Gel with an applicator once daily, at night, for two weeks.

At the end of two weeks, a significant number of patients showed evidence of clinical relief from the 7th day onwards.

Thirty patients showed inhibition of inflammation of vagina, cervix, vulva and disappearance of scratch marks. Twenty eight patients showed a reduction in foul odour of the discharge, 25 showed significant reduction of vaginal discharge, 18 showed relief in soreness and 16 showed relief from pruritus and itching. The results were optimum at second week where 14 females showed eradication of Trichomonas vaginalis, 15 showed eradication of Candida, 5 showed eradication of Gardnerella vaginalis and one patient showed eradication of non-specific cocci. Thus, V-Gel significantly produced symptomatic relief and microbiological eradication in patients with vaginitis. Various constituents of V-Gel have anti-inflammatory and antimicrobial properties reported to be useful in the treatment of Leucorrhoea. Multiple components of V-Gel have produced synergistic effects with each other as seen from these results.

Key words: Leucorrhoea, Trichomoniasis, Candidiasis, Vaginitis, Non-specific vaginitis, Cervicitis.

INTRODUCTION
Vaginitis and cervicitis are among the most common problems that challenge a gynaecologist. During the menstrual years, the most frequent offenders are Monilia, Candida, Trichomonas vaginalis, Haemophilus vaginalis, etc. In the pre-pubertal and post-menopausal years, the thin vaginal epithelium becomes vulnerable to many specific and non-specific organisms. A number of systemic diseases also predispose to vaginitis. Cervicitis is a similar inflammation of the cervix which can be caused due to improper management during labor or may be a consequence of ascending infection during vaginitis. A patient with vaginitis or cervicitis is posed with a number of symptoms such as leucorrhoea (excessive vaginal discharge), vulvar itching and irritation, which are not only embarrassing but also cause immense discomfort and hindrance to normal daily activities.
Due to the frequency of this infection and the common problem of recurrence, several treatment schemes have been used over the years. While the use of substances such as vaginal douches, Betadine, etc. is beneficial, their action, however, is short-lived. Systemic administration of metronidazole and other drugs though effective, have side effects and are not prescribed for pregnant women. These limitations necessitate a safer and more effective remedy in this field.

Ayurveda, the esteemed Indian system of medicine, with its abundant herbal remedies, has provided a number of combination preparations for various disorders with little or no side effects. V-Gel, comprising highly potent herbs like *Berberis aristata*, *Boerhaavia diffusa*, *Vitex negundo*, *Lawsonia inermis*, *Azadirachta indica* and *Cedrus deodara*, is a formulation which is comparable to modern medicine and used for vaginal infections. It has exhibited profound antimicrobial and antifungal action in experimental trials. Its effect on skin and mucosal inflammation has been proved by various studies conducted on animals and no side effects have been reported. It is safely used during pregnancy.

**MATERIAL AND METHODS**

Thirty five female patients between the age of 20-55 years were included in the trial. All the patients had clinical signs and symptoms of vaginitis and cervicitis. These were patients with leucorrhoea, inflammation of vulva, foul odor, pruritus and soreness. Complete medical, gynaecological and obstetrical examinations of all patients were carried out to rule out any evidence of malignancy and genetic disorders to exclude them from the trial. A positive microbiological diagnosis was also confirmed in all the patients.

Patients were advised to apply V-Gel once daily at night (before retiring to bed) with an applicator for two weeks.

The patients were examined on the 7th, 14th and 21st days to assess symptomatic relief. A microbiological test was repeated on day 14 for microbiological evidence of cure and followed up for 21 days to determine the degree of therapeutic response as complete relief, partial relief or no response.

All the patients were advised to observe abstinence during the study period. This was an open clinical trial using V-Gel on all the patients for assessing clinical response on post-treatment.

Relief in clinical symptoms (pruritus, soreness, discharge and inflammatory signs along with reduction in microbiological count) was considered as the criteria of efficacy. Follow-up was done twice weekly for three weeks to note if any side effects occurred with topical application of vaginal gel. Patients were also followed up for the next 3 months to note the recurrence of symptoms and requirement of other therapeutic drugs, if necessary.

**RESULTS**

Thirty five patients with clinical signs and symptoms of vaginitis were included and all of them completed the trial. At the end of two weeks, the results were analysed.
All the patients had signs of inflamed vulva, vagina and cervix before treatment. However only 33 had vaginal discharge and scratch marks, 31 complained of itching or pruritus, 30 patients had foul odour in vaginal discharge and vaginal soreness was present in 30 patients (Table 1).

On microscopic examination, 17 patients had Candida albicans, 9 were positive for Trichomonas vaginalis, 5 had Gardnerella vaginalis and 2 had non-specific organisms. On application of V-Gel every day for two weeks, a significant number of patients showed evidence of symptomatic relief from day 7 onwards.

Thirty patients showed relief from inflamed vagina, vulva, cervix and scratch marks on the 7th day. Twenty eight patients showed improvement in foul odour and 25 showed significant reduction of vaginal discharge. Eighteen patients showed improvement in soreness and 16 got relief from pruritus and itching. On day 15, all the patients showed evidence of anti-inflammatory effects on the vulva, vagina and cervix, 33 showed relief from scratch marks, 31 showed a reduction of vaginal discharge, 30 showed disappearance of foul odour, 28 experienced relief from itching and pruritus and 23 displayed disappearance of soreness (Table 1).

On microscopic examination on day 14, 8 patients showed disappearance of Trichomonas vaginalis, 15 Candida albicans, 5 Gardnerella vaginalis and 1 a non-specific organism (Table 2). Complete relief of signs and symptoms was seen in 28 patients at the 3rd week follow-up (Table 3). The remaining patients who still had a few symptoms required a longer duration of treatment and the healing response was gradual.

Thus, V-Gel is effective in both symptomatic relief and microbiological cure in a significant number of patients.

**DISCUSSION**

Vaginal gel on topical application was found very effective in relieving signs and symptoms of vaginitis caused by multiple organisms. Application of the gel for two weeks had no side effects. There was a significant reduction of vaginal discharge in 75.75% patients on day 7...
and 93.93% on day 15. Similarly foul odour reduced in 93.33% on day 7 and 100% on day 15.

The quantity and odour of the vaginal discharge are two important clinical symptoms of vaginitis, which were relieved by the vaginal gel after two weeks of topical application.

Pruritus and itching are also important clinical symptoms of vaginitis in all age groups of patients, which were relieved in 51-61% on day 7 and 90.32% on day 15. The relief from pruritus is significant and is confirmed by the disappearance of scratch marks in 90.90% on day 7 and 99% on day 15. Vaginal and cervical soreness disappeared in 72% on day 7 and 92% on day 15. Vaginal and cervical inflammation was also significantly reduced in 85-71% on day 7 and 100% on day 15. Thus, the vaginal gel has shown potent anti-inflammatory and anti-infective activity in patients with vaginitis.

Its antimicrobial properties are confirmed by its effect on vaginal and cervical flora on microscopic examination of cervical flora. 66.66% showed disappearance of *Trichomonas vaginalis* on day 7 and 88.88% on day 15. *Candida albicans* also disappeared in 88.20% on day 15. The effect of V-Gel on *Candida albicans* was found gradual as only 45.57% were eradicated by day 7. *Gardnerella vaginalis* was eradicated 100% by day 7. Non-specific organisms were eradicated on day 7 in 50% and 100% on day 15.

Partial cure of signs and symptoms were seen in 94.28% on day 7 and 80% were completely cured on day 21 (Table 3).

**REFERENCES**