

Efficacy of V-Gel, a polyherbal vaginal gel, in the management of vaginitis.

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ABSTRACT

A clinical study was conducted to evaluate the efficacy of V-Gel, a polyherbal vaginal gel in 38 women between the age group of 22 and 35 years who were diagnosed with clinical evidence of vaginitis. Patients were assessed subjectively for symptoms of soreness of vulva, pruritus and vaginal discharge. All the patients were advised to apply V-Gel locally with an applicator twice daily for two weeks and return for follow-up on day 7 and day 15. On examination prior to initiation of treatment, symptoms of soreness and itching were present in 29 (75.31%) patients and discharge in 34 (89.47%) patients. Vaginal examination findings revealed inflamed vulva, scratch marks, discharge and foul odour in 60.52%, 34.21%, 94.73% and 36.84% patients respectively. Following 7 days of treatment with V-Gel, symptoms of soreness, itching and discharge was significantly reduced to 28.94%, 39.47%, and 73.68% respectively. On examination, signs of inflamed vulva, scratch marks, discharge and foul odour were present in only 39.47%, 15.78%, 71.05% and 2.63% patients respectively. After completion of two weeks of treatment with V-Gel, symptoms of soreness, itching and discharge were absent in 94.73%, 94.73% and 63.15% respectively. Signs of inflamed vulva, scratch marks, discharge were found to be relieved in 89.47%, 97.36%, 71.10% respectively in patients when examined on the 14th day of treatment. The foul odour was not observed in any patient on 14th day of treatment. The study showed that V-Gel significantly alleviates the symptoms of vaginitis and does not produce any adverse reactions and hence can be safely recommended in the treatment of vaginitis.

INTRODUCTION

Vaginitis is the most common gynecologic diagnosis in the primary care setting. The prevalence and causes however are uncertain, because the condition is so often self-diagnosed and self-treated. In addition, vaginitis is frequently asymptomatic or has more than one cause. Reports reveal that in approximately 90% of the affected women, this condition occurs secondary to bacterial vaginosis, vulvovaginal candidiasis or trichomoniasis.¹ Noninfectious causes include vaginal atrophy, allergies and chemical irritation. In most cases however accurate diagnosis can be obscure, complicating treatment.²⁻⁴

Vaginitis develops when the vaginal flora has been altered by introduction of a pathogen or by changes in the vaginal environment that allow pathogens to proliferate. Antibiotics, contraceptives, sexual intercourse, douching, stress and hormones can change the vaginal environment and allow pathogens to grow.⁵ The evaluation of vaginitis requires a directed

history and physical examination, with focus on the site of involvement and the characteristics of the vaginal discharge.

Bacterial vaginosis is currently the most common cause of vaginitis. This infection is believed to be caused by proliferation of a number of organisms, including *Gardenella vaginalis*, Mobiluncus species, *Mycoplasma hominis* and Peptostreptococcus species.⁶ Determining the prevalence of bacterial vaginosis is difficult because one third to three quarters of affected women are asymptomatic.⁷ Even though higher rates of bacterial vaginosis have been reported in sexually transmitted disease clinics and in women with multiple sexual partners, the role of sexual transmission is unclear. Studies indicate that treating the male sexual partner of a woman with bacterial vaginosis is not beneficial and that even women who are not sexually active can have the infection.⁸ Additional risk factors for bacterial vaginosis include the use of intrauterine devices (IUDs), douching and pregnancy.⁹

Vulvovaginal candidiasis is the second most common cause of vaginitis. An estimated 75% of women have vulvovaginal candidiasis at some time in life, and approximately 5% of women have recurrent episodes.¹⁰⁻¹² *Candida albicans* is the infecting agent in 80-90% of atients.¹³ Recently, the frequency of non-albicans species (e.g., *Candida glabrata*) has increased, possibly secondary to greater use of over-the-counter antifungal products.¹⁴ Establishing *Candida* species as the cause of vaginitis can be difficult because as many as 50% of asymptomatic women have candidal organisms as part of their endogenous vaginal flora.¹⁵ Further, risk factors for uncomplicated vulvovaginal candidiasis are difficult to determine.¹⁶

The protozoan *Trichomonas vaginalis* is the third most common cause of vaginitis. It affects 180 million women worldwide and currently accounts for 10-25% of vaginal infections.¹⁷ From 20-50% of women with trichomoniasis are asymptomatic.¹⁸ Trichomonads are transmitted sexually and may be identified in 30-80% of the male sexual partners of infected women.¹⁹

This clinical study was designed to evaluate the efficacy of the polyherbal V-Gel in women diagnosed with clinical evidence of vaginitis. V-Gel, a polyherbal formulation contains multiple herbs, each of the constituents providing antibacterial, antifungal and anti-inflammatory properties.

MATERIAL AND METHODS

Thirty-eight women aged between 20 to 35 years with history of signs and symptoms of vaginitis and cervicitis were enrolled in this study. Informed consent and detailed history was obtained from all the patients. Complete gynecological examination was done to assess the extent of the inflammation before initiation of the therapy. The enrolled patients were dispensed V-Gel with an applicator and advised to apply 2 gms of the gel to be squeezed into the calibrated applicator and applied deep inside the vagina twice a day for 7-14 days. Participants were requested to note down for signs of irritation or any other side effects if encountered during the trial period. Patients were advised to return for follow up on day 7 and day 15. Detailed history and gynecological examination was scheduled to be performed on all the patients on follow-up.

RESULTS

All of the recruited 38 patients completed the study. Before commencement of treatment, 29 patients had complaints of soreness and itching and 34 complained of discharge. Gynecological examination prior to therapy revealed signs of inflamed vulva in 23 patients, scratch marks in 13, discharge in 36 and foul odour in 14 patients. Subsequently, treatment was started and the patients were evaluated for assessment of symptomatic response. Follow-up vaginal examination was scheduled on 7 and 14th day. The scoring was done as: Severe - 4, moderate - 3, mild - 2, occasional - 1 and nil - 0. Observations revealed that symptomatic relief score reduced from the initial 1.522 ± 0.9482 to 0.5862 ± 0.8245 on day 7 and further reduced to 0.0697 ± 0.2579 on day 14 for soreness. Severity of itching reduced from the initial score of 1.448 ± 0.7831 to 0.6207 ± 0.7277 on day 7 and further reduced to 0.06897 ± 0.2579 on day 14. Similar response was seen in the symptom score for vaginal discharge, which was noted as 2.029 ± 0.9996 initially reducing to 1.206 ± 0.8083 on day 7 and further reducing to 0.4412 ± 0.5609 on day 14.

Vaginal examination before initiating treatment revealed a score of 1.957 ± 1.065 for signs of vaginal inflammation, that was significantly reduced to 0.9565 ± 0.8779 on day 7 showing further improvement on day 14 at 0.1739 ± 0.3876 . A similar encouraging response in the score was seen with the regard to signs of scratch marks, which was recorded as 1.462 ± 0.9674 before treatment, reducing to 0.6923 ± 1.109 after 7 days and 0.07692 ± 0.2774 following 14 days of treatment. Signs of discharge also showed significant improvement in the score from 2.000 ± 0.9562 initially to 1.083 ± 0.8409 on day 7 and 0.3611 ± 0.5426 on day 14. There was good response to bad odour, where the initial score was 1.357 ± 0.06333 before treatment, reducing to 0.2143 ± 0.4258 on day 7 and was found completely absent by the 14th day of treatment (Tables 1 and 2). The percentage of relief was also quite significant. Treatment with V-Gel was viewed as completely safe as none of the women complained of any untoward side effects.

Table 1: Symptomatic response score to V-Gel treatment

	Day 0	Day 7	Day 14
Soreness (n= 29)	1.522 ± 0.9482	0.5862 ± 0.8245	0.0697 ± 0.2579
Itching (n=29)	1.448 ± 0.7831	0.6207 ± 0.7277	0.06897 ± 0.2579
Discharge (n=34)	2.029 ± 0.9996	1.206 ± 0.8083	0.4412 ± 0.5609
Score: severe - 4, moderate -3, mild -2, occasional - 1, Nil - 0			

Table 2: Vaginal examination score during the course of V-Gel treatment

	Day 0	Day 7	Day 14
Inflamed vulva (n=23)	1.957 ± 1.065	0.9565 ± 0.8779	0.1739 ± 0.3876
Scratch marks (n=13)	1.462 ± 0.9674	0.6923 ± 1.109	0.07692 ± 0.2774
Discharge (n=36)	2.000 ± 0.9562	1.083 ± 0.8409	0.3611 ± 0.5426
Bad odour (n=14)	1.357 ± 0.06333	0.2143 ± 0.4258	0.00 ± 0.00
Score: severe - 4, moderate -3, mild -2, occasional - 1, Nil - 0			

DISCUSSION

V-Gel is a polyherbal formulation containing multiple herbs, each of the constituents providing antibacterial, antifungal and anti-inflammatory properties. V-Gel consists of the following herbs *Triphala*, *Rosa damascena*, *Elettaria cardamomum*, *Boerhavia diffusa*, *Parmelia perlata*, *Vitex negundo* and *Curcuma longa*. *Triphala* is a composite herbal preparation containing equal proportions of the fruits of three myrobalans, *Emblica officinalis*, *Terminalia chebula* and *Terminalia bellirica*. *Elettaria cardomomum* has anti-inflammatory activity.²⁰ The extracts of *Curcuma longa* possess anti-inflammatory, antibacterial and antifungal activity.²¹⁻²³ *Cedrous deodara* oil has anti-inflammatory property and is a good antifungal agent. The active principle of neem possesses antibacterial, antiviral and antifungal properties. *Vitex negundo* leaves have antibacterial properties effective against *E. coli* and are commonly used in excessive vaginal discharge. The extracts of *Curcuma longa* possess anti-inflammatory, antibacterial and antifungal activity. *Nelumbium speciosum* possesses bacteriostatic action against gram-positive and gram-negative bacteria.

Earlier studies have found V-Gel to be a clinically effective formulation for the treatment of vaginitis and cervicitis. In a study that was conducted in 26 women suffering from vaginitis and cervicitis, V-Gel was applied topically twice daily for 15 days. Signs and symptoms of soreness, pruritus, inflammation of vulva, vaginal discharge was significantly reduced within two weeks of treatment. Majority of patients showed microbiological cure after treatment with V-Gel.²⁴ Similar response was seen in another open clinical trial that was conducted in 30 women with clinical and microbiological evidence of vaginitis. Seventeen women had inflammatory vaginitis and thirteen showed evidence of microbial infection produced by *Candida*, *Trichomonas* and other non-specific bacteria. The vaginal gel effectively produced clinical and microbiological relief in women with vaginitis of varied aetiology²⁵.

In another hospital trial that was conducted with V-Gel on 50 patients with vaginitis, 48 patients showed an excellent response with complete cessation of symptoms and repeat microbiological evaluation showed absence of causative organisms by the end of 2 weeks treatment.²⁶

In the present study V-Gel on topical application was found to be very effective in relieving the signs and symptoms of vaginitis. On examination prior to initiation of the treatment, symptoms of soreness and itching were present in 29 (75.31%) patients and discharge in 34 (89.47%) patients. Vaginal examination findings revealed inflamed vulva, scratch marks, discharge and foul odour in 60.52%, 34.21%, 94.73% and 36.84% patients respectively. Following seven days of treatment with V-Gel, symptoms of soreness, itching and discharge was significantly reduced to 28.94%, 39.47%, and 73.68% respectively. On examination, signs of inflamed vulva, scratch marks, discharge and foul odour were present in only 39.47%, 15.78%, 71.05% and 2.63% patients respectively. After completion of two weeks of treatment with V-Gel, symptoms of soreness, itching and discharge was absent in 94.73%, 94.73% and 63.15% respectively. Signs of inflamed vulva, scratch marks, discharge were found to be relieved in 89.47%, 97.36%, 71.10% respectively in patients when examined on the 14th day of treatment. The foul odour was not observed in any patient on 14th day of treatment.

CONCLUSION

In conclusion, the study shows that there is a significant alleviation in the symptoms of vaginitis when treated with V-Gel for a period of 7-14 days applied twice daily. Because of the encouraging findings and patient compliance complimented with absence of side effects, we can safely recommend this herbal gel as a treatment of choice in the treatment of vaginitis.

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