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Preliminary Clinical Study of a Polyherbal Formulation (Wh1) in the Treatment of Vaginitis

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Abstract

Vaginitis is a very common disease affecting millions of women each year with multifactorial etiology. If left untreated it can lead to various complications. Current medical therapy may temporarily reduce infection but tend to disrupt the normal vaginal flora. Hence, herbal therapy is gaining popularity in women on account of its reduced side effects and restoration of the normal vaginal flora. With this in view, a preliminary clinical study was conducted using a polyherbal formulation (WH I), containing herbs with antifungal, antibacterial, antiseptic and astringent properties. In this prospective clinical study, 36 patients presented with the symptoms of vaginitis of varying etiology were treated successfully with the polyherbal formulation (WH I) and was found to be safe and effective (83%). The results of this study were found to be significant, thus this study will be extended on a large patient population in future.

Key Words: *Vaginitis, Polyherbal preparation (WH 1), Clinical Study, Female, bacterial vaginosis, candidiasis,richomoniasis, leucorrhoea.*

INTRODUCTION

Vaginitis is described medically as an irritation and/or inflammation of the vagina. It is a very common disease affecting millions of women each year. The three most common vaginal infections reported each year are bacterial vaginosis (30-40%), candidiasis due to yeast infection (20-25%) and trichomoniasis caused by protozoal infection (15-20%). Vaginal infections can produce a variety of symptoms, such as abnormal or increased discharge, itching, fishy odor, irritation, painful urination or vaginal bleeding(1,2,3).

Though the infections are not serious in nature, they can become chronic and the eradication of such infections is often difficult. If left untreated, bacterial vaginosis may result in increased risk of pelvic inflammatory disease (PID), infertility, pre-term birth, premature rupture of membranes, low birth weight, intra-amniotic infections, endometritis, cervical intra-epithelial neoplasia (CIN), post-gynecological surgery infections and increased risk of sexually transmitted diseases (4,5).

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Vaginitis is identified by checking vaginal fluid appearance, vaginal pH and presence of volatile amines (the odor causing gas) and microscopic detection of clue cells 2 (6).

Current medical therapy for vaginitis includes the use of systemic or topical antibiotic and antifungal preparations. Vaginitis being a disorder of multifactorial etiology, a single-line therapy is often inadequate and recurrence is a common complication. Though these medications may temporarily reduce infection, they often disrupt the balance of good bacteria and frequently lead to recurrent infection. Studies shows that vulvovaginal candiasis(VVC) affects three-quarters of women during their lifetimes and use of antibiotics is an acknowledged trigger for VVC, which adversely affects women's physical and emotional health (7, 8, 9).

Therefore, as an alternative to these medications herbal therapy is gaining popularity in women on account of its reduced side effects and restoration of the normal vaginal flora (10,11,12).

Ayurvedic herbs are available, which have been listed in ayurvedic literatures like Dhanwanthri Nighantu, Bhavaprakash Nighandu, Ashtanga Hrdaya, Sushruta

Sanhita, Chakradatta and Nighandu Ratnakara which are of use in treating this condition.

Common herbs such as Dhataki Flower, Musta, Mocharas, Lodhra, Lata Karanja have actions that include antifungal, antimicrobial, antiseptic, astringent, and demulcents(13). Herbs with astringent activity may produce a protective coating on the tissue surface. Therapeutically, these herbs may reduce irritation, inflammation, and excessive fluid secretion, and provide a barrier against infection. Antiseptic and antimicrobial herbs may work to eliminate bacterial and viral infections, and antifungal herbs may help fight fungal infections. A list of herbs containing these qualities for the treatment of vaginitis is shown in Table-1.

Traditionally, a mixture of powder of the herbs listed in Table-1 in the medium of ghee as "Anupana" [vehicle of administration] has been used effectively in the treatment of vaginitis. However, there has been no documentation regarding its efficacy and safety.

Hence, the objective of this work was to take up a preliminary clinical study in a small patient group to confirm the efficacy and safety of this poly herbal preparation (WH1). Therefore, this mixture of powders in ghee base was formulated as soft gelatin capsules. The formula of this preparation is given in Table 2.

METHOD

Institutional Ethical committee clearance was obtained from Sri Sai Charitable Dispensary, Girinagar, Bangalore and Shreyas Poly Clinic & Laboratory, Chamarajpet, Bangalore, where the study was conducted for a period of six months, from November 2006 to April 2007.

Informed consent was taken from all patients included in the study after explaining to them the purpose of the study.

Inclusion Criteria: All patients presented with symptoms of vaginitis at the clinic during the study period of 6 months.

Exclusion Criteria: Patients with white discharge due to any other clinical condition like fibroid, malignancy etc and pregnant women.

All patients who met the inclusion criteria were recruited for the study. These patients were clinically examined and a swab was taken from the vaginal discharge and sent to pathological laboratory. All patients were prescribed the poly herbal formulation (WH 1) thrice a day for 10 days after food. Two fortnightly follow ups were conducted and progress was assessed by clinical improvements and confirmed by swab test. If the condition was not improved, another course of treatment was repeated and the sexual partner also treated simultaneously. Patients were encouraged to report any adverse reaction to the physician during the course of treatment.

RESULTS & DISCUSSION

36 patients completed the preliminary clinical study with the polyherbal preparation (WH1). WH1 reduced the amount of vaginal discharge significantly in all the patients both symptomatically and clinically. Significant results were seen microbiologically in 30 patients (83%). During the study period, 58 patients were enrolled; only 36 patients completed the study. 22 patients were therefore excluded from the study as per the protocol design. Hence, statistics of only 36 patients who completed the trial has been presented here and the results were summarized as percentages. Age of patients ranged between 18 and 55 years (Fig.1) which explains incidences of risk factors such as child birth, abortions, passage of infective organism by infected semen etc in this age group (14). Maximum patients belonged to low income group. Poor hygienic conditions, ignorance about the proper cleaning and toilet habits and bad nutritional status explains the higher incidence of this condition amongst this group (14). Duration of complaints varied from less than 1 month (4 days) to 8 years (Fig.2) which further confirms that women are busy in managing the household work without taking sufficient care regarding their own health. 25 patients improved with the first course of 10 days treatment (69%). 7 patients received 2 courses of medicine and 2 patients 3 courses of medicine. 2 patients received more than 4 courses of medicine without benefit (Fig.3). The etiology of patients observed by microbiological examination is given in (Fig.4). 17 patients were diagnosed as non specific vaginitis (47%), 14 as Bacterial Vaginitis (39%), 3 as vaginal candidiasis (8%) and 1 each as atrophic vaginitis and senile vaginitis (3%). The swabs taken after 15 days and after one month, which assessed the effectiveness of the treatment microbiologically, showed 83% (30/36) patients improved with treatment and no improvement was seen in 17% (6/36) of patients (Fig.5). None of the patients in this series experienced any adverse reactions. Thus, the polyherbal preparation (WH1) effectively produced clinical and microbiological relief in women with vaginitis of varied etiology.

CONCLUSION

The polyherbal formulation (WH1) has shown significant results in the treatment of vaginitis. But this

Table -1: List of herbs used in the treatment of vaginitis

List of herbs	Botanical name	Action & uses
Dhataki Flower	Woodfordia Floribunda flower	Stimulant Astringent and Tonic used in leukorrhea, mennorhagia
Musta	Cyperus scariosus root	Pungent, Bitter, Astringent with Carminative, antibacterial, antifungal and Stimulating properties used in treatment of inflammation, tumor and infection
Mocharas	Bombax malabaricum gum	Astringent, tonic, demulcent, contains tannic acid and gallic acid. Used in dysentery, leukorrhea and menorrhagia
Lodhra	Symplecos recemosus root	Astringent used in wound healing to reduce the bleeding, swelling and leukorrhea
Lata Karanja	Caesalpinia bonduc seed	Antiseptic, Anti parasitic and Cleansing action used in treatment of pain and skin diseases

Table -2: Formula of the soft gel capsules*.

Ingredients	Quantity/capsule
Ext. Dhataki Flower	eq. to 20mg
Ext Musta	eq.to 40mg
Ext. Mocharas	eq. to 22.5mg
Pulv.Lodhra	100mg
Pulv. Lata Karanja	50mg
Ghee	q.s
Total weight of each capsule	650mg

*** Poly herbal formula code : (WH 1)**

Fig.1: Age distribution of patients in the study population

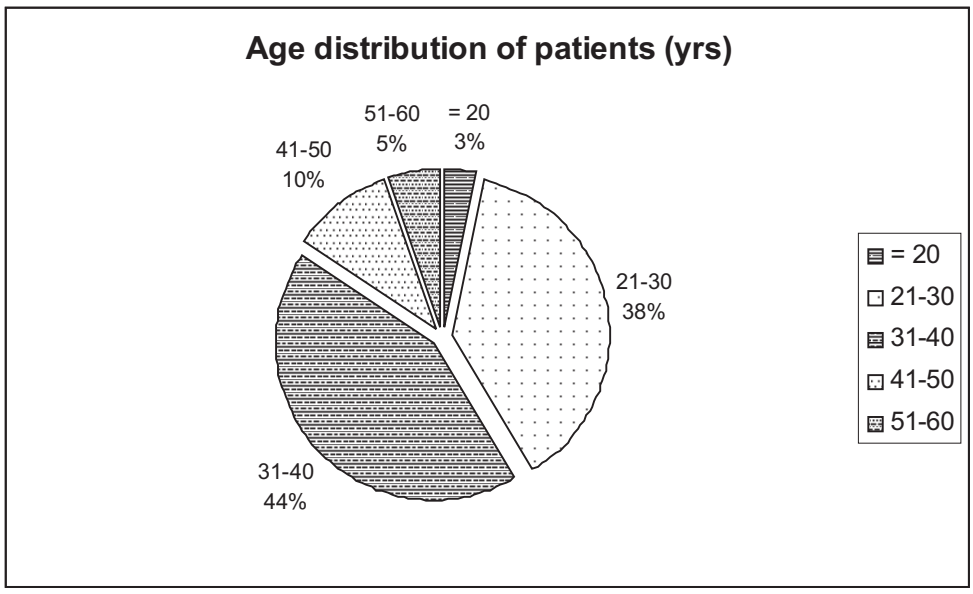


Fig.2: Duration of complaints reported by the patients.

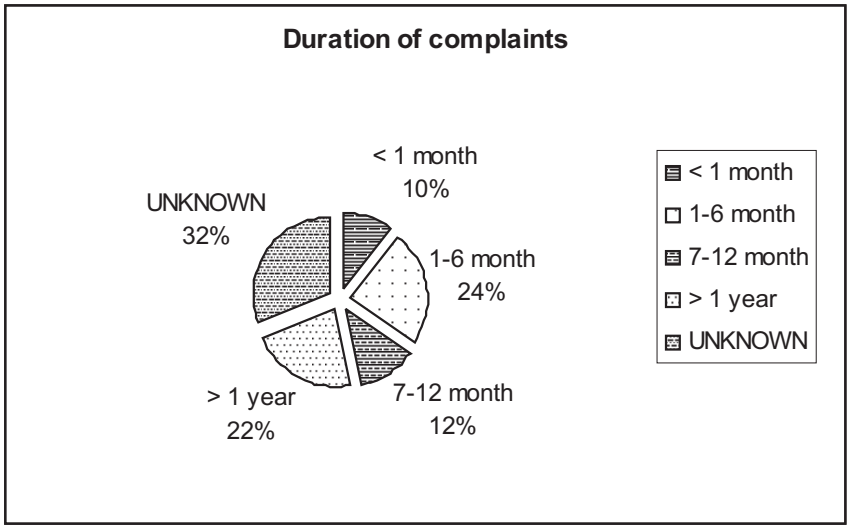


Fig.3: Number of medication courses given to the patients for the treatment of vaginitis.

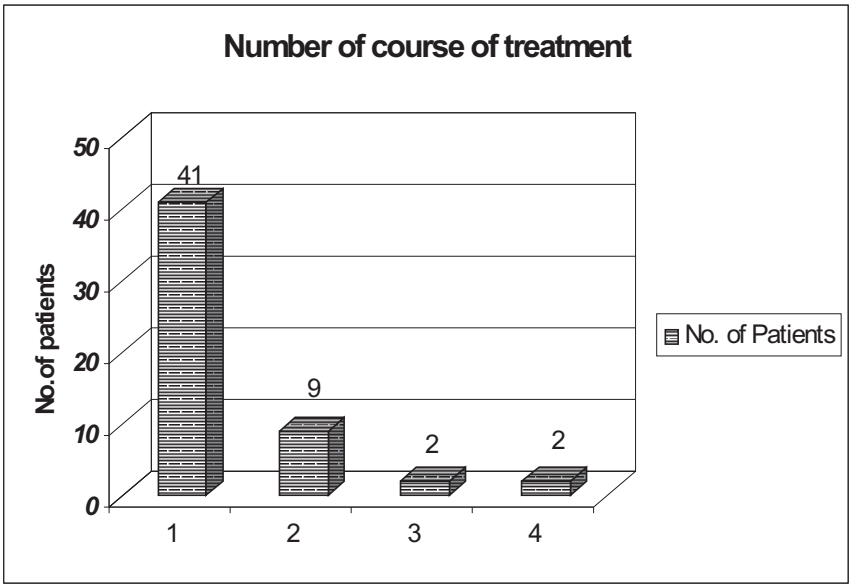


Fig.4: Conditions diagnosed in the patients included in this study

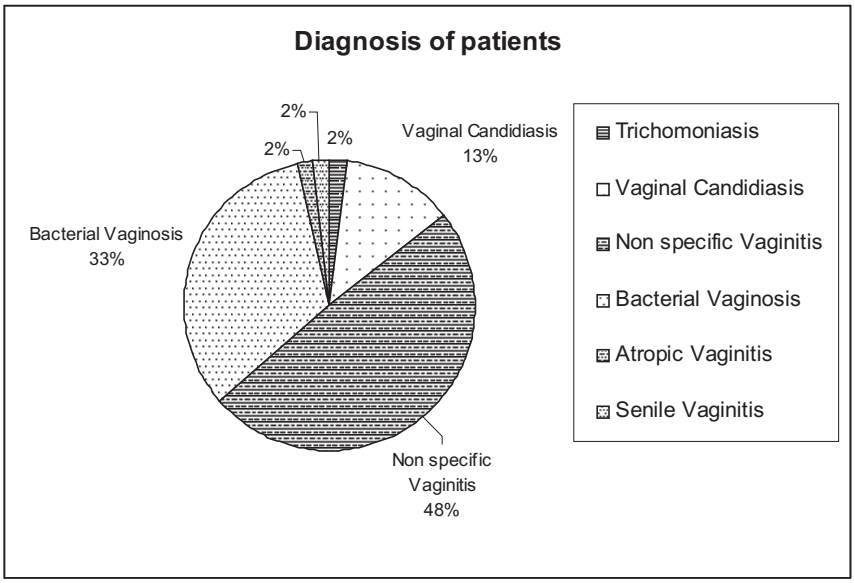
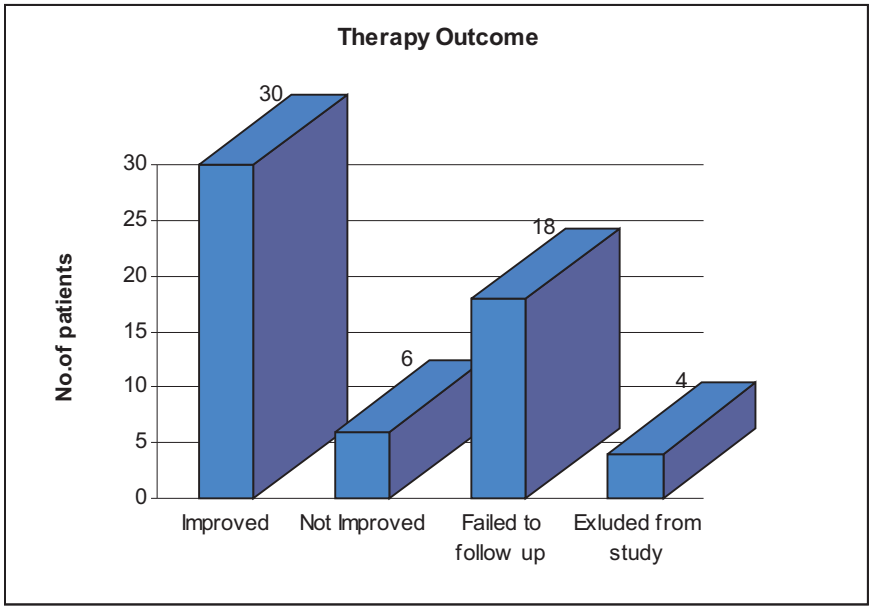


Fig.5: Outcome of therapy using a polyherbal formulation (WH 1) in vaginitis



clinical study throws up a gamut of questions regarding the specificity and sensitivity to each type of infection. Probably sensitivity and cultural studies may throw more light on the subject. Our observations are similar to some of the trials published earlier.[15,16, 17] In conclusion, the results of this study were found to be significant. Thus, this study will be extended in larger number of patients in future.

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