



Therapeutic Effects of *Sufoofe sailan* in Bacterial Vaginosis: A Randomized, Standard Controlled Trial

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ABSTRACT

Bacterial Vaginosis (BV) is one of the common causes of *Sailanur rehm* (Abnormal Vaginal discharge). It is a complex clinical syndrome with multiple etiologies. It is an extremely distressful and unpleasant condition which affects quality of life in women of reproductive age group. This condition is also regarded as an important public health problem for its medical, social and economic implications. Its prevalence among Asian women varies from 32-84%. A randomized, standard controlled clinical study was carried out on "Efficacy of *Sufoofe sailan* in the management of Bacterial Vaginosis" in the Gynaecology out patient department of National Institute of Unani Medicine and Hospital, Bengaluru during the year of 2015-16. Out of 45 patients, 30 in test and 15 in control group were randomly assigned. In test group *Sufoofe sailan* 6 grams in two divided doses for three weeks and in control group standard drug tablet Metronidazole 500mg twice daily for five days was given. Analysis of the results was done to assess overall efficacy of test drug. In test group 83.3% and in control group 73.3% were cured with p value of 0.454, which was not significant whereas 10% in test and 13.3% in control group were relieved, while 6.67% in test and 13.3% in control group showed no response. *Sufoofe sailan* was found to be beneficial in relieving the sign and symptoms of Bacterial vaginosis. There was no significant difference between test and control drugs.

Keywords: Bacterial vaginosis; Abnormal vaginal discharge, *Sailanur rehm*, Amsel criteria, Metronidazole, *Sufoofe sailan*.

INTRODUCTION

Sailanur rehm (Abnormal Vaginal discharge) is a broad term commonly used in gynaecological disorders in Unani system of medicine. In this condition woman suffer from uterine, cervical and vaginal discharge other than blood due to genital tract infection or alteration in genital physiology. It is an extremely distressful and unpleasant condition which affects quality of life in women of reproductive age group. This condition is also regarded as an important public health problem for its medical, social and economic implications.¹

The women complain of offensive vaginal discharge, pruritus vulva, burning micturition, low back ache and lower abdominal pain. These symptoms are so common among them that they ignore and usually do not seek treatment. This is mainly due to lack of knowledge among women about the symptoms and morbidities associated with them, even if they are suspicious, they are unaware of the complications such as infertility and other pregnancy associated complications like premature labour, premature rupture of membranes etc. Even if the latter is known, unless the woman is suffering from alarming symptoms, they refuse to seek health care due to economic and time constrains. They are also too shy to reveal their problems.

Sailanur rehm (Abnormal vaginal discharge) have an additional element of shame and humiliation for many

women because they are considered unclean and so the fears of social consequences often take priority over fears of health consequences, making the infected women reluctant to inform their partners.² Of these women a significant portion will be predisposed to recurrent or chronic infections of this sort, which can be correlated with the symptoms of Bacterial vaginosis. It is one of the most common causes of *Sailanur rehm*.

Women in their reproductive period are commonly affected by Bacterial Vaginosis (BV), earlier it was known as non-specific vaginitis (NSV) or Gardnerella vaginitis in conventional system. This condition represents a mal-proportion of bacterial species in the vagina namely a decrease in lactobacilli and an increase in anaerobic organisms.³ Bacterial Vaginosis (BV) is an important public health problem because it is associated with HIV.⁴

Bacterial Vaginosis (BV) is treated with antibiotics or antifungal medications in modern system of medicine, which are effective temporarily, but the problem tends to reoccur once the medication is stopped. They are not sustainable option for women who are prone to develop chronic infections. As the number of women who are forced to deal with these disorders on a regular basis increases, lack of appropriate treatment options becomes less and less acceptable. As the symptoms of Bacterial vaginosis is similar to that of *sailanur rehm* in unani concept and view, a time tested formulation *Sufoofe sailan* is found to be effective in the management of this chronic



ailment. The magnitude of these gynecological and obstetrical consequences has stimulated a research effort towards therapeutic development of a unani formulation called *Sufoofe sailan*.

Sufoofe sailan is a polyherbal unani formulation described in various texts of Unani medicine and is used to treat various conditions like *Sailanur rehm* (leucorrhea), *uqr* (sterility), *kasrate tams* (Menorrhagia), (*surate inzal* (premature ejaculation) etc. It consists of the following ingredients; *Gule dhawa* (*Woodfordia fruticosa kurz*), *Gule fofil* (*Areca catechu linn*), *Mocharas* (*Salamalia malabarica DC.*) and *Gonde molsari* (*Mimusops elengi linn*) which has *qabid* (astringent), *mujaffif* (dessicant), *habis* (styptic), *muhallil* (anti-inflammatory) and *dafe taffun* (Anti-bacterial) properties.⁵ Hence this formulation has been selected with the objective to evaluate its therapeutic efficacy in the management of *Sailanur rehm* (Bacterial vaginosis).

MATERIALS AND METHODS

This was a single-blind, randomized standard controlled clinical trial. The study was conducted at Gynaecology OPD of National Institute of Unani Medicine, Bengaluru, India during the year of 2015-16. Forty five married participants aged between 18–45 years complaining of offensive vaginal discharge, pruritus vulvae were included in the study. Approval of study was taken from the Institutional Ethical Committee (IEC). The subjects were randomly assigned in test group (n = 30) and control group (n = 15) by Lottery method.

In test group *Sufoofe sailan* which contains *gule dhawa*, *gule fofil*, *mocharas* and *gonde molsari* was given 3 grams twice daily for 21 days and in control group standard drug tablet Metronidazole 500 mg twice daily for 5 days was given. Follow up was done weekly for three weeks for the assessment of subjective and objective parameters. Statistical analysis was done to compare the efficacy of test drug over standard control drug.

Consents were obtained from all the patients prior to the study. Clinical history regarding age, address, contact number, education, religion, occupation, socio-economic status and presenting complaints were interrogated. Assessment of *mizaj* was done according to unani parameters. Patients with pelvic pathology, systemic illness, unmarried, pregnant and lactating women, women on IUCD, OCPs and having history of previous antibiotic therapy were excluded. Systemic and pelvic examination was done. Simultaneously vaginal discharge was taken for smear was taken. Investigations include complete blood picture, erythrocyte sedimentation rates, random blood sugar, and complete urine analysis, VDRL & HIV I & II, pelvic ultrasound were done to exclude systemic and pelvic pathology.

The standard method for diagnosis of bacterial vaginosis is based on the clinical criteria developed by Amsel *et al.* known as the composite clinical criteria. Clinical diagnosis of bacterial vaginosis is made if three of the following four signs are present. Characteristics of discharge should be; homogenous greyish white discharge, fishy odour after addition of 10% potassium hydroxide (Whiff test), vaginal fluid pH more than 4.5 and presence of clue cells more than 20% on microscopic examination. Vaginal swab were collected from the interior vaginal wall for KOH whiff test, pH and clue cells.^{3,6}

Amsel criteria were done before and after trial. Progression and regression of symptoms were recorded. Compliance to therapy was assessed at every follow-up by examining the packets in which medication was dispensed at previous visit. Participants were advised not to take any other concomitant treatment during study. Effectiveness of trial drugs were assessed by improvement in subjective and objectives parameters. Subjective parameter comprises symptoms of offensive vaginal discharge and vulvo vaginal pruritus.

Vulvo-vaginal pruritus was graded as 1+, 2+ and 3+ and the discharge was graded as score: 0-No discharge; 1-Mild (streak/spotting on undergarments); 2-Moderate (stain on undergarments) and 3-Severe (using pads). Objective parameters were assessed by Amsel criteria. On the basis of improvement in subjective and objective parameters before, during and after the trial, the response was graded as cured, relieved and no response. The safety of the drug was assessed by LFT and RFT at baseline and after three weeks of trial in test group and after one week in control group.

RESULTS

Total 145 participants of vaginal discharge were screened during the study period. Out of which 70 participants refused to participate; 22 were excluded (10) due to systemic illness and (12) due to pelvic pathology and the rest of them (63) were randomized into experimental and standard control group groups. Six patients in test and twelve patients in the standard control group were dropped out due to lost to follow up. The final analysis was conducted on 45 patients. In the test group, a significant difference was observed in alleviation of subjective and objective parameters. (Table 1 & 2)

In the test group, out of 30 patients of Bacterial vaginosis, 25(83.3%) were cured completely and 3(10%) were relieved; 2(6.67%) showed no response while in control group 11(73.3%) patients were cured completely and 2(13.3%) were relieved but 2(13.3%) showed no response. Comparison was done by using student t test and fisher exact test and it revealed that there was no significant difference between test and control group with p value of 0.454. (Figure.1)

Table 1: Effect of test and standard drug on subjective parameters:

Vaginal Discharge	Before Treatment	After Treatment	p value (a)	Improvement
Test group (n=30)	30 (100%)	3 (10%)	<0.001	27 (90%)
Control group (n=15)	15 (100%)	2 (13.3%)		13 (86.7%)
p value (b)	1.000			
Vulvo vaginal Pruritus	Before Treatment	After Treatment	p value (a)	Improvement
Test group (n=30)	30 (100%)	2 (6.67%)	<0.001	28 (93.3%)
Control group (n=15)	15 (100%)	1 (6.67%)		14 (93.3%)
p value (b)	1.000			

p-value (a) was from Fisher Exact Test to test the significant difference before and after treatment in Test group, p-value (b) was from student 't' to test the significant difference between Test and Control groups after trial.

Table 2: Comparative evaluation of objective parameters

Vaginal Discharge	Before treatment	After Treatment	p value (a)	Improvement
Test Group (n=30)	30 (100%)	3 (10%)	<0.001	27 (90%)
Control Group (n=15)	15 (100%)	2 (13.3%)		13 (86.7%)
p value (b)	0.384			-
Whiff test	Before Treatment	After Treatment	p value (a)	Improvement
Test group (n=30)	30	2 (6.67%)	<0.001	28 (93.3%)
Control group (n=15)	15	2 (13.3%)		13 (86.7%)
p value (b)	0.384			
Wet mount test	Before Treatment	After Treatment	p value (a)	Improvement
Test group (n=30)	30 (100%)	3 (10%)	<0.001	27 (90%)
Control group (n=15)	15 (100%)	3 (20%)		12 (80%)
p value (b)	0.384			
Vaginal pH	Before Treatment	After Treatment	p value (a)	Improvement
Test group (n=30)	5.45±0.24	4.57±0.25	<0.001	--
Control group (n=15)	5.50±0.33	4.63±0.40		<0.001
p value (b)	0.564	0.498	--	--

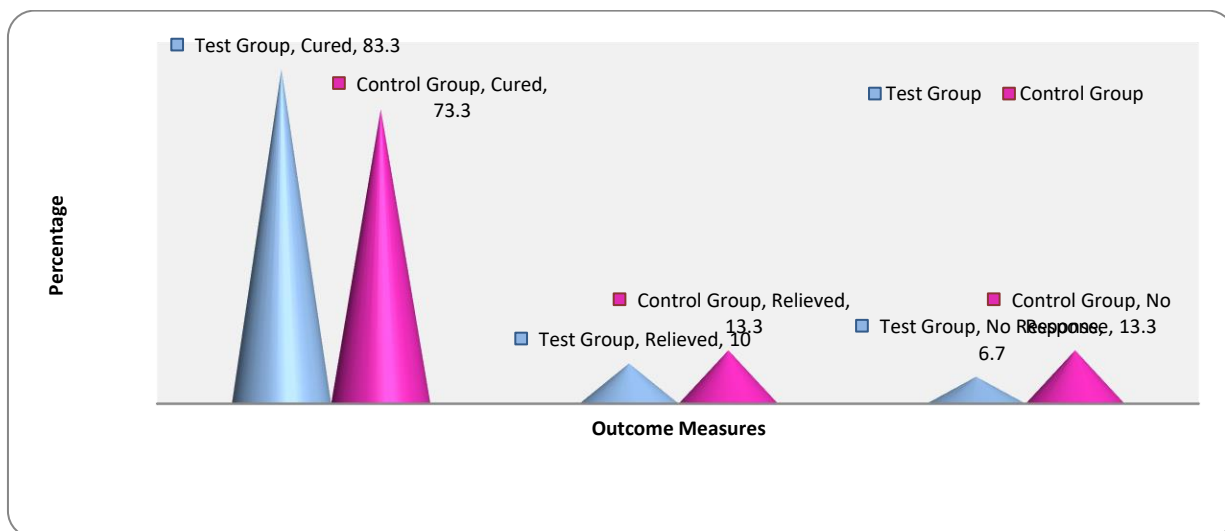


Figure 1: Comparison of outcome measures in test and control group

DISCUSSION

Bacterial vaginosis is probably the most frequent problem faced by gynecologist, which is more complex because of the polymicrobial etiologies. The incidence of bacterial vaginosis varies; the rates are 10–35% in patients visiting gynecological wards, 10–30% in patients visiting obstetric wards and 20–60% in patients visiting services of sexually transmitted disease.⁴ According to Unani concept, there is a defense mechanism potential in the body known as *tabi'at-e-mudabbir-e-badan* which keeps body immune from certain microbial diseases. It guides the body to produce certain specific substances which constitute humours like blood, phlegm, bile and black bile and thus maintaining balance in temperament of body. Any derangement in these humours either qualitatively or quantitatively leads to disease.⁷ According to ancient unani physicians any type of abnormal discharge which comes out of the uterus or vagina is termed as *Sailanur rehm*. The discharge may be *damwi* or *balghami* or *safravi* or *sawdawi* and may be mucoid, viscous or watery in character.⁸ Abnormal vaginal discharge is the most common factor which creates irritation in women and decreases Quality of life (QOL). Bacterial Vaginosis (BV) is one of the causes of *Sailanur rehm* in women of reproductive age.^{2,9}

According to Unani concept *sailanur rehm* is caused by *Zo'fe quwwate hadhima*, *ghadhiya* and *jadhiba* of *rehm* (derangement in cellular metabolism of uterus) leads to production of excessive *rutubat* (secretion) in the form of *balgham* (Phlegm). As *barid* (cold) and *ratab* (moist) temperament of *balgham* is more favorable to accept *ufunat* easily. If any sort of *ufunat* enters the uterus this *quwwate ghadhiya* of *rehm* gets disturbed and is manifested as fluid discharge from the birth canal.^{10,11} Hence, it should be treated with *barid wa yabis* (cold and dry) drugs having *dafe ta'fun* (antimicrobial) and *mohallil* (resolvent) properties to remove infections and associated symptoms of *sailanur rehm*.¹² The temperament of *Gule dhawa* (*Woodfordia fruticosa* kurz), *Gule fofil*, (*Areca catechu* Linn), *Mochras* (*Salamalia malabaricum* DC) and *Molsari* (*Mimusops elengi* L) is *barid wa yabis* which are the ingredients of *safoofe sailan* and assumed that these drugs reduce the inflammation or dominance of *khilt*.

Furthermore; improvement may also be due to various activities of the ingredients of *Safoofe sailan*, as these herbs possess *mohallil-e-warm* (anti-inflammatory), *dafe ta'fun* (anti-microbial), *mulattif* (demulcent), *mujaffif* (desiccant), *munzij* (concoctive) and *qabiz* (astringent) properties.⁵ These herbs would have inhibited the proliferation and growth of microorganism and resolved the inflammatory process that led to the overall improvement in Bacterial vaginosis. Recent studies also confirmed that these herbs possess antimicrobial, anti-inflammatory, antioxidant, analgesic, immuno-modulators and wound healing properties.^{13,14} Several Studies reveals *Gule dhawa* to have antimicrobial activity. Similar results of these herbs were seen in our study.

The patients were included into the trial after thorough assessment of clinical sign and symptoms such as offensive vaginal discharge, vulvo-vaginal pruritus and positive. Amsel criteria, which consists of homogenous vaginal discharge, whiff test, vaginal pH and wet mount test. Demographic data of the patients such as age, *mizaj*, education, socio economic status, occupation, parity and contraceptive practice in both groups were recorded in CRF. Baseline parameters were almost similar in patients of both groups. Routine and specific investigations were done before and after trial. In test group *Sufoofe sailan* was given 3 grams twice daily for 21 days and in control group standard drug tablet Metronidazole 500 mg twice daily for 5 days was given. Follow up was done weekly for three weeks for the assessment of subjective and objective parameters. Statistical analysis was done to compare the efficacy of test drug over standard control drug.

Assessment of results of both test and control drugs was done before and after trial. Results were analyzed on the basis of three categories i.e. cured, relieved and no response. Inter group comparison of test and standard drug was done by using fisher exact test. It revealed that 25(83.3%) patients in test and 11(73.3%) patients in control group were cured, whereas 3(10%) in test and 2(13%) in control group were relieved and equal number of patients i.e. 2 (6.7%) in test and 2 (13.3%) in control group showed no response to the treatment with a p value of 0.454, which indicates insignificant difference between test drug i.e. *Sufoofe sailan* and standard drug. From these results it can be inferred that both drugs have equal efficacy in curing the condition. In response and no response category the effect of both test and standard drugs were almost similar.

This study demonstrates that the Unani formulation was effective in the improving symptoms of Bacterial vaginosis. *Sufoofe sailan* was found to be beneficial in reducing the signs and symptoms of Bacterial vaginosis. No adverse effects were observed and the formulation was found to be safe and well accepted by the subjects.

CONCLUSION

It can be concluded that an Unani formulation *Safoofe sailan* was found to be effective and serves as an alternative therapy in the treatment of Bacterial vaginosis. Although the study showed remarkable response, its limitations include small sample size and lack of long term follow up. Therefore, studies with large sample size with long term follow-up period are need for further exploration of efficacy and safety of Unani formulation.

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