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Effect of *Gule Dhawa* and *Mocharas* in *Sailan al Rahim*: A randomized controlled trial

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Abstract
Introduction: *Sailan al rahim* is not a single entity but a wide term, and its description is similar to bacterial vaginosis, which is considered as the most common vaginal infection among women of childbearing age. This condition is notorious for causing severe complications related to the reproductive health of women. The objective of this study was to evaluate the efficacy of *gule dhawa* and *mocharas* in the management of *sailan al rahim* (bacterial vaginosis).
Methods: A single blind randomized placebo controlled clinical trial was conducted at Institute's Hospital. Diagnosed cases (n=60) were included and randomly allocated to test (n=30) and control (n=30) groups. In test group, powder prepared from *gule dhawa* (*Woodfordia fructosa* L. Kurz) and *mocharas* (*Bombax malabaricum* DC) was administered orally in a dose 6 g in capsule form twice daily for 4 week and in control group, placebo was given for the same duration. The subjective and objective parameters (Amsel's criteria) were assessed for improvement. Chi square and Fisher's exact test were used for statistical analysis.
Results: *Gule Dhawa* and *Mocharas* showed better response than placebo in eliminating clue cells, fishy odour and reducing homogenous vaginal discharge (P<0.01) after completion of trial.
Conclusion: *Gule Dhawa* and *Mocharas* were effective in the management of *sailan al rahim;* hence, it can be used as an alternate therapy.

Keywords: *sailan al rahim*, bacterial vaginosis, amsel's criteria, *gule dhawa*, *mocharas*

1. Introduction

Sailan al rahim is an excessive vaginal discharge from the female genital tract [1]. In classical Unani text, *sailan al rahim* include any discharge other than blood coming out from the uterus; thus it covers almost all types of discharges caused by infection of female genital tract [2] *Ibn Sina* states that *aurame rahim* (uterine inflammations) and presence of morbid material within the uterine vessels causes *sailan al Rahim* [3]. *Majoosi* [2] *Ibn hubal*, [4] *Azam Khan* [5] states that *rahim* contains excessive *rutubat* and any infection in these *rutubat* may leads to *zoafe quwate hazema* of *rehm* resulting in *sailan al rahim.* The clinical symptoms of *sailan al rahim* coincides well with the symptoms of vaginal infection such as excessive vaginal discharge, pruritus vulvae, low backache, lower abdomen pain, and frequent urination etc. [4-6] Vaginitis is caused mainly by bacterial vaginosis (40-50%), candida vaginitis (20-25%) and trichomonas vaginitis (15-20%) of cases [7]; among all these causes, bacterial vaginosis is the most common cause of vaginal discharge in reproductive age women. [8, 9]. Bacterial vaginosis (BV) is the most common vaginal infection among women of childbearing age, which is characterized by replacement of vaginal lactobacilli with predominantly anaerobic polymicrobials [9]. This replacement causes an imbalance in the vaginal microflora, which is the pathophysiologic process responsible for the discharge. A large women population in the world is suffering from bacterial vaginosis [10]. It is estimated that 20–30 % of women with vaginal discharge have BV, although the prevalence can be as high as 50–60 % in some high-risk sexual behavior populations. [11] Risk factors associated with BV includes multiple sex partners, a new male sex partner, early exposure to sexual activity, frequent vaginal douching, use of vaginal foreign bodies or perfumed soaps, cigarette smoking, low socioeconomic status, use of antibiotic for another condition etc [9]. It is more common among women who have an STI or who use intrauterine devices. Bacterial Vaginosis is associated with severe gynecologic complications, such as cervicitis, endometritis, salpingitis, post-operative infections, pelvic inflammatory disease, oophoritis with or without tubo-ovarian abscess and obstetric complications, such as chorioamnionitis, preterm deliveries, postabortion and postpartum endometritis [7, 8, 12, 13]. The symptoms of BV include an abnormal malodour and increased vaginal discharge, which is highly distressing and embarrassing to women, impacting significantly on their self-esteem and sexual relationships [14]. Amsel's criteria are used world-wide for the diagnosis of BV which includes four parameters: (1) vaginal pH > 4.5, (2) homogenous milky vaginal discharge (3) fishy odour after addition of 10% KOH (Whiff test) and (4) presence of "clue cells" [15]. Presence of 3 out of 4 parameters of Amsel's criteria is necessary for the diagnosis of bacterial vaginosis. In the presence of abnormal vaginal discharge, both vaginal pH and Whiff test has 100% sensitivity [16]. The sensitivity and specificity of > 20% clue cells in the diagnosis of BV is 81-99% and clue cells are said to be the single most reliable predictor of BV on microscopic examination [17]. In conventional medicine, the recommended

first line treatment for BV includes oral metronidazole or topical clindamycin creams, which are effective with > 90% cure rate in one week, [18] but adverse side-affects, are common and include nausea, vomiting, an unpleasant metallic taste in the mouth and vaginal candidiasis [14, 19]. Further, they may induce bacterial resistance with repeated use[9] and relapse rates are high after the completion of treatment [10, 19]. Hence, there is a need for alternate therapy which is to be safe, effective, easily available and free from side effects. Many single drugs and compound formulations are available in Unani system of medicine for the management of *sailan al rahim*. Out of several drugs available, *gule dhawa* (*Woodfordia fructosa* L. Kurz) and *mocharas* (*Bombax malabaricum* DC) were selected as test drugs as they possess the properties of *qabiz, mujaffif*, [20,21,22,23] *jazib-i-rutubat rahim*, [21, 24] *muqawwi Rahim* [23] and *musaffi-i- khun* [21]. Moreover, pharmacological studies suggest that these drugs exhibit astringent, styptic, uterine sadative [25, 26], antimicrobial [27, 28], and anti-inflammatory [29] activities. The objective planned for this study was to evaluate the efficacy of *gule dhawa* and *mocharas* in the management of *sailan al rahim* and hypothesis framed was test drugs may be as effective as control drug in the management of *sailan al rahim.*

2. Materials and Methods

2.1 Study Design: A single blind randomized placebo controlled study was conducted at the Institute's Hospital after obtaining ethical clearance from the Institutional Ethical Committee and the study was completed with in the duration of one and half year.

2.2 Participants: Sixty diagnosed cases of *sailan al rahim* were randomly allocated in two equal groups by computer generated random table.

2.3 Eligibility Criteria: Married women in the age of 18-45 years presenting with c/o abnormal vaginal discharge were evaluated thoroughly by detailed history and clinical examination and patients with positive Amsel's criteria of bacterial vaginosis, who are willing to participate in the study were included in the study. Patients with trichomoniasis, candidiasis, gross lesions on cervix, upper genital tract infection, sexually transmitted diseases, intra uterine contraceptive devices, malignancy, systemic illnesses, pregnant and postmenopausal women were excluded after performing CBC, CUE, RBS, VDRL, USG Pelvis, and Pap smear. Written consent was taken from each participant who fulfilled the inclusion criteria before the commencement of the study.

2.4 Procedure of study: All patients with h/o abnormal vaginal discharge were subjected to gynecological examination using a speculum to find out the signs of vaginitis and abnormal discharge. Vaginal pH was assessed using pH–meter paper (Ranbaxy Co) with a range of 4.5-7, the paper was applied to anterior vaginal fornix, withdrawn and colour was matched with the colour scale provided. Vaginal discharge was taken with a sterile cotton swab from the posterior fornix and smeared on 2 glass slides. On one slide, one or two drops of normal saline were put & on other slide 10% KOH was added. Both slides were covered with cover slip and examined under the microscope. Saline mount was observed for the motile flagellated organism of T. vaginalis & clue cells. While, the other slide was examined for Whiff test (p/o fishy odour by adding 10% KOH on vaginal discharge was interpreted as positive test, while its absence as negative test) and also to detect *candida albicans.* Criteria for diagnosis of BV were based on the presence of 3 out of 4 Amsel's criteria: thin, grey-white homogenous discharge, vaginal pH >4.5, presence of clue cells on wet mount test and positive Whiff test [15]. Assessment of *mizaj* of every patient was done as per the parameters mentioned in classical Unani literature [30]. All included patients underwent biochemical investigation (Blood urea, Serum Creatinine, SGOT, SGPT, Alkaline phosphatase,) during the trial to assess the safety of test drugs. All findings were recorded on case record form structured for the study.

2.5 Intervention: In test group, powder prepared from equal quantity of *gule dhawa* and *mocharas* was administered orally in a dose of 6g/day in capsule form (1capsule is of 1 g), 2 capsules three times daily for 4 weeks and in control group, placebo capsule (wheat flour) was given for the same period of time.

2.6 Blinding and Compliance: Blinding of patients in either group was maintained as medicine was dispensed in similar pack to one patient at a time. For maintaining drug compliance, self locking pack was examined for any left over capsules in subsequent follow up visit.

2.7 Assessment cum Follow up: Patients were followed weekly once for four weeks during the treatment and subjective (white discharge per vaginum, malodour, pruritus vulva, lower abdomen pain, low backache, dyspareunia, dysuria) & objective parameters (Amsel's criteria) [15] were assessed for improvement; In follow up visit, whole of the diagnosis procedure were repeated again and successful treatment was demonstrated by the presence of one or no Amsel's criteria. Patients were also enquired for any adverse effect of drug during the study. After treatment, patients were followed once in 15 days for a month to look for recurrence; pre and post treatment analysis of signs and symptoms were done and subjected to comparison statistically to evaluate the response to treatment.

2.8 Statistical Analysis: Chi square test and Fisher exact test were used to analyze the results. The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc**.**

3. Results

Table 1: Comparison of baseline characteristic in two groups:

Baseline characteristics	Test group (n=30)	Control group (n=30)
Mean age (yrs)	29.56±4.41	30.16±6.07
Mizaj	No (%)	No (%)
Balghami	13(43.3%)	16(53.3%)
Damvi	10 (33.3%)	7 (23.3%)
Safravi	7(23.3%)	7(23.3%)
Socioeconomic status		
Middle class	5(16.6%)	6(20%)
Lower class	25(83.3%)	24(80%)
Educational status		
Illiterate	8(26.6%)	6(20%)
Primary	6(20%)	12(40%)
Secondary	12(40%)	9(30%)
Higher secondary	4(13.3%)	3(10%)
Occupation		
Housewife	28(93.3%)	29(96.6%)
Teacher	1(3.33%)	0
Farmer	1(3.33%)	1(3.33%)
Mean parity	2.6±1.52	2.7±1.26
Contraception		
Not using contraception	10(33.3%)	6(20%)
Barrier contraceptive	2(6.66%)	2(6.66%)
Tubectomy	18(60%)	22(73.3%)
Vaginal discharge duration (months)		
1-3	5(16.6%)	9(30%)
4-6	13(43.3%)	4(13.3%)
7-9	5(16.6%)	7(23.3%)
10-12	7(23.3%)	10(33.3%)

Data were presented as mean ±SD and number (percentage);

Table 2: Comparison of subjective parameters in two groups

Subjective parameters	Test group			Control group		
	BT	AT	% change	BT	AT	% change
	No. (%)			No. (%)		
Vaginal discharge	30(100%)	9(30%)	70%	30(100%)	26(86.6%)	13.4%
Malodour	10(33.3%)	2(6.66%)	26.6%	14(46.6%)	12(40%)	0.6%
Pruritus vulvae	14(46.6%)	2(6.66%)	39.9%	6(20%)	5(16.6%)	3.4%
Lower abdomen pain	9(30%)	2(6.66%)	23.3%	5(16.6%)	4(13.3%)	3.3%
Low backache	18(60%)	6(20%)	40%	16(53.3%)	14(46.6%)	6.7%
Dyspareunia	3(30%)	0	3(30%)	2(6.66%)	2(6.66%)	0
Dysuria	1(3.33%)	0	1(3.33%)	0	0	

Data were presented as number (percentage).

Table 3: Comparison of objective parameters in two groups

Objective parameter	Test group		Control group		*P* value
(Amsel's criteria)	BT	AT	BT	AT	
	No. (%)		No. (%)		
Clue cells on wet mount	30(100%)	11(36.6%)	30(100%)	28(93.3%)	< 0.01
Positive whiff test	26(86.6%)	8(26.6%)	28(93.3%)	24(80%)	< 0.01
pH>4.5	28(93.3%)	28(93.3%)	29(96.6%)	29(96.6%)	>1.0
Homogenous vaginal discharge	30(100%)	9(30%)	30(100%)	26(86.6%)	< 0.01

Data were presented as number (percentage); Fisher exact test *P* value significant at <.05

4. Discussion

4.1 Baseline Characteristics: Most of the patients (43.33%) were in the age group of 26-30 years. Mean age of the patients was 29.56±4.41and 30.16±6.07 in test and control groups respectively, which matched well with the studies of Mohammadzadeh F *et al.* [31] reported 29.58± 6.30 and 30.30±5.58, Thulkar J *etal* [16] reported 29.9±4.2yr, Rumaiza *et al.* [32] reported 31.90±6.22 and 29.73±6.16 and Simber M *et al.* [33] reported 32.2±5.82 and 32.7±6.51 respectively. Maximum patients, 43.3% in test and 53.3% in control groups possessed

balghami mizaj, which is in accordance with the theories proposed by eminent *Unani* physicians, who have quoted that this disease is more common in individuals with dominance of *khilte balgham* [5]. Majority of the patients, 83.3% in test and 80% in control groups were from lower SES which is in conformance with the study of Rumaiza *et al.* [32] Most of the patients, had education up to secondary (40% in test and 30% in control) and primary level (20% in test and 40% in control), while 26.6% in test and 20% in control were illiterate. Majority of the patient's occupation were housewife (93.3%) which is in consonance with Rumaiza *et al.* [32] who reported 91.1%. Mean parity were 2.6±1.52 and 2.7±1.26 in test and control groups respectively, which is in agreement with Simber M *et al.* [33] reported 2.07±1.12 and 2.25±1.45. Most of the patients, 60% in test and 73.3% in control groups underwent tubectomy operation, while 6.66% patients in each test and control groups were using barrier method of contraception and no h/o contraception was observed in rest of the patients. Duration of vaginal discharge ranges from 1-12 months, most of the patients, (43.3%) in test and (13.3%) in control group had vaginal discharge from 4-6 months, while (23.3%) in test and (33.3%) in control had from 10-12 months, 16.6% in test and 30% in control had from 1-3 month, while 16.6% in test and 23.3% in control had from 4-6 months. (Table -1)

4.2 Subjective parameters

Vaginal discharge: At baseline, 100% patients in both groups had vaginal discharge, which persist in 30% with a percentage change of 70% in test and 86.6% in control with a percentage change of 13.4% after treatment.

Malodour: At baseline, 33.3% patients in test group and 46.6% in control group had complained of malodour vaginal discharge, which persist in 6.66% in test and 40% in control after treatment with a percentage change of 26.6% and 0.6% in test and control group respectively.

Pruritus vulvae: At baseline, 46.6% patients in test group and 20% in control group had pruritus vulvae; which persist in 6.66% with a percentage of 39.9% in test and 16.6% in control with a percentage of 3.4% after treatment.

Lower abdomen pain: At baseline, 30% patients in test group and 16.6% in control group had pain in lower abdomen, which persist in 6.66% with a percentage change of 23.3% in test and 13.3% in control with a percentage of 3.3% after treatment.

Low backache: At baseline, 60% patients in test group and 53.3% in control group had low backache; which persist in 20% with a percentage change of 40% in test and 46.6% with a percentage change of 6.7% in control group after treatment.

Dyspareunia & dysuria: It was observed in few cases during the trial. (Table -2)

4.3 Objective parameters

Clue cells: At baseline, wet smear was positive for clue cells in 100% patients in both the groups, which remains positive in 36.6% in test (P<0.01) and 93.3% in control group.

Whiff test: At baseline, 86.6% patients in test group and 93.3% in control group had positive whiff test which remains positive in 26.6% in test with P<0.01and 80% in control group.

Vaginal pH: No significant change in vaginal pH was observed during the trial (P>0.05). Vaginal pH in a number of cases remains elevated for several weeks following successful therapy, and persistent pH elevation cannot be taken as the indicator of poor response [34].

Homogenous vaginal discharge: At baseline, 100% patients in both the groups had homogenous vaginal discharge, which persist in 30% in test with P<0.01and 86.6% in control group. (Table -3)

The improvement in subjective and objective parameters in test group is credited to *qabiz*, *mujaffif* [21, 22, 23], *jazib-i- rutubate rahim* [21, 24], *muqawwi rahim* [22] and *musaffi-i- khun*[21] properties of test drugs. Moreover, pharmacological studies suggest that these drugs exhibit astringent, styptic, utreine sadative [25,26], antimicrobial [27, 28], and anti-inflammatory [29] activities due to the presence of phenols, flavonoids, glycosides, tannins, carbohydrates, saponins and steroids [28,29, 35]. Further, astringent drugs reported to decrease the secretion due to its inhibitory effect and even tannins having antimicrobial and antioxidant properties may further useful in this condition [36].

5. Conclusion

Gule Dhawa and Mocharus were effective in the management of *sailan al rahim* as significant reduction (P<0.01) was observed in 3 out of 4 Amsel's criteria in test group as compared to control group. Moreover, the test drugs were safe as safety parameters were normal during the study and no abnormal clinical manifestation was observed during the study and overall compliance to the treatment was good. Hence, the inference suggests that the test drugs are safe, effective, and serve as a better alternative medicine in patients who like to use herbal medicine for bacterial vaginosis. This study was first of its kind, which showed that *Gule Dhawa and Mocharus* were effective in relieving bacterial vaginosis based on Amsel's criteria. Limitation of the study was short duration of intervention and short follow up. Future trials for longer duration with long term follow up are required to confirm the efficacy of test drugs.

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