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## Research Article

### CLINICAL EVALUATION OF UNANI DRUGS *MAJOON MUQAWWI RAHIM* IN THE *SAYALAN AL RAHIM* (SIBYANI) PRE PUBERTAL VAGINAL DISCHARGE: A PRELIMINARY STUDY

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#### ABSTRACT

The pre-pubertal vulvo vaginal discharge (sayalan al rahimsibyani) is increasing slowly but steadily in young girls has been a well-known disease among young women since ages. Now a day's almost all Unani physicians at from Hippocrates 360 BC down to Shiekh Abu Ali Sina 910 AD Ibn -ul-Nafees, Ibn e Zuhr and Indian origin physicians like Hakeem Shareef Khan, Hakeem Akbar Arzani, Hakeem Mohd Azam Khan and Hakeem Abdul Aziz have mentioned the disease in there treatise and suggested single as well as compound drugs for internal and external use, The study has been conducted successfully by the Central Research Institute of Unani Medicine Lucknow, to evaluate the efficacy and safety of Unani drugs in the treatment of the disease. The pre pubertal vaginal discharge is not a new phenomenon in young girls, but due to the social stigmit is discussed in Indian society. Some studies suggest that various internal and external factors are causing the disease but to the best of over knowledge only a few studies have been conducted in the Indian sub-continent hence the Central Research Institute of Unani Medicine, ministry of AYUSH Govt. of India took upon itself the responsibility and conducted a clinical trial on 22 young girls with consent of their parents and *Majoon muqawwi rahim* an Unani pharmacopeial formulation was administrated orally in semi solid form and the results are so encouraging that CCRUM may plan a bigger study in large scale and lead the country in the treatment of PPV through herbal Unani formulation and provide relief the suffering young girls.

#### INTRODUCTION

The *Sayalan-al-Rahim* (Leucorrhoea) is an excessive vaginal discharge from the female genital tract and is a frequent gynecological complaint of women that accounts for more than 1/4<sup>th</sup> gynec patients who visit to the gynecologist [1]. The discharge may range from what is called as excess of normal to one, which is a part of wide spectrum of ailments. It may be blood-stained or contaminated with urine or stool. [2] The normal discharge is actually fluids form of all worn out and dead cells in the vaginal tract along with other toxic materials that are eliminated continuously from the vagina. The abnormal vaginal discharge may be whitish, yellowish, reddish and

blackish in colour.[3,4] The vaginal discharge with foul smell makes it embarrassing to women to get into social gatherings and even engage in her personal affairs. The abnormal condition of the reproductive organs of women, if not treated in the initial stages then it may become chronic and leads to PID (Pelvic Inflammatory Diseases), which may cause infertility. Women with pale color vaginal discharge are unable to conceive.[5] Peculiar vaginal discharge is generally associated with body aches and thirst. [6]

Leucorrhoea is physiological when associated with various phases of menstrual cycle. But, when it

turns into pathological condition, it produces associated problems like low backache, itching, burning sensation of vulva, poor appetite, discomfort, general weakness and pain in legs etc. Chronic illness, fatigue, malnutrition, emotional disturbances, unhygienic condition, improper diet, constipation and chronic retroverted uterus are responsible for leucorrhoea. The most common cause of excessive secretion is physiological excess due to increase in conditions, when the oestrogen levels become high during the puberty, menstruation cycle, pregnancy and sexual excitement; followed by vaginal and cervical causes. The vaginal infections are due to bacteria, virus, fungi and parasites. Other causes include foreign bodies, cervicitis and atrophic vaginitis.<sup>[2,7]</sup> Infections of vaginal mucosa by *Trichomonas vaginalis* and *Candida* are the most common cause of leucorrhoea. These are treatable as well as preventable causes as both these infections are transmitted sexually. Although, 25% of both infections are asymptomatic. <sup>[2,8]</sup>

The Unani scholars have described *Sayalan-al-rahim* (Leucorrhoea) and its treatment in various Unani classical literatures like Kamil al Sana'a, Al Hawi, Firdaus al Hikmat and Tibb-e-Akbar etc. According to them, the disease occurs due to poor quwwat-e-ghadhiya (nutritive faculty) of the rahim (uterus) that causes accumulation of fuzlaat (waste materials)<sup>[3]</sup>. Hakim Mohammad Azam Khan has

described the disease in his famous book 'Akseer Azam. According to humoral theory, sayalan-al-rahim is caused by the excess of humors with discharge colours reddish, yellowish, whitish or blackish depending on the humors <sup>[3, 4]</sup>. The health of females is spoiled by the excessive vaginal discharge just as the health of adult male is spoiled by the spermatorrhea <sup>[9]</sup>. General examination of the patients may reveal ill health. The patient often states the discharge as cause of ill health but in reality, the ill health is due to leucorrhoea <sup>[2]</sup>.

The health of women is considered to be the back bone of the society and gynaecological morbidity is an important health issue among all women in India. Gynaecological morbidity in women can range from life threatening diseases such as malignancies to debilitating and psychologically distressing problems like leucorrhoea. This study was done to focus on the concept and management of sayalan-al-rahim (leucorrhoea) in Unani system of Medicine because the disease has been described in the various Unani classical literatures and Unani drugs are being used for the management of the disease since ancient times without causing any side effect on the human body <sup>[10]</sup>. Before puberty it also occurs in young girls due to the vulvo vaginitis, poor hygiene and foreign body.<sup>[11]</sup>

## MATERIAL AND METHOD

### Study drug

**Table 1: Composition Majoon Muwawwi Rahim<sup>[13]</sup>**

S. No.	Ingredients	Botanical Name	Quantity
1.	Mochras	<i>Salmalia malabarica</i>	10 g
2.	Fufal	<i>Areca catechu</i>	10 g
3.	Tabasheer	<i>Bambusa arundinacea</i>	10 g
4.	Nishashta-e-Gandum	<i>Triticum</i>	10 g
5.	Gil-e-Makhtoom	Silicate of alumina	10 g
6.	Gul-e-Surkh	<i>Rosa damascus</i> mill	10 g
7.	Mazu	<i>Quercus infectoria</i>	10 g
8.	Habb-ul-Aas	<i>Myrtrus communis</i>	10 g
9.	Post HaleelaZard	<i>Terminalia chebula</i>	10 g
10.	Post-e-Baleela	<i>Terminalia bellerica</i>	10 g
11.	Aamla	<i>Phyllanthus emblica</i>	10 g
12.	MusliSiyah	<i>Curculigo orchoides</i>	10 g
13.	MusliSafaid	<i>Chlorophyllum borivilianum</i>	10 g
14.	Post Anar	<i>Punica granatum</i>	15 g
15.	Aab-e-Behitaza	<i>Cydonia oblonga</i>	50 ml
16.	Aab-e-AnarTursh	<i>Punica granatum</i>	50ml
17.	NabatSafaid	Rock candy	210 ml
18.	Asal or QandSafaid	<i>Saccharum officinarum</i>	210 g

### Study Design

The present pilot study was carried out from April 2018 to October 2018 on 22 complete cases of pre pubertal vaginal discharge, who came for treatment in the General OPD of Central Research Institute of Unani Medicine, Lucknow.

### Patients Selection

The patients presenting sign and symptoms of vaginal discharge from the age group of 5 years to 13 years, were subjected to inclusion and exclusion criteria before their final selection for the study.

### Inclusion Criteria

- Patients with complaints of vaginal discharge
- Patients between the age group of 5 years to 13 year
- Patients who did not reached to the puberty.

### Exclusion Criteria

- Patients who experienced menstruation
- Patients suffering from helminthiasis
- Patients whose haemoglobin is less than 8 gram /dl.
- Patients suffering from multiple diseases
- Any other condition that in the investigator's opinion makes the patient participation in the study difficult.

### Diagnosis Criteria

The patients were diagnosed with the help of history in respect of selected patients i.e. previous similar episode, physical and systemic examinations.

### Patients Enrolment in the Study

All patients of pre pubertal vaginal discharge selected for the study as per inclusion and exclusion criteria were diagnosed and enrolled for the study.

### Dosage and Administration

All selected patients were given Unani Pharmacopoeial classical formulation in the dose of 5gram twice daily for the period of 15 days. No concomitant treatment was given.

### Place of Study

The present pilot study was carried out at Central Research Institute of Unani Medicine, Lucknow, after obtaining the consent of patients parents to enrol in the study.

### Efficacy Assessment

The patients were assessed clinically on 7<sup>th</sup> day and 15<sup>th</sup> day of the treatment and the efficacy of Unani Pharmacopoeial classical formulation on the ground of reduction in the sign and symptoms. The severity of symptoms was recorded in numbers as per the Visual Analogue Scale (VAS).

### Safety Assessment

The safety was assessed by monitoring adverse effect volunteered by the patients or observed during the course of the study. No adverse effect of *Majoon Muqawwi Rahim* was either reported by the patients or observed during the course of the study.

## RESULT AND DISCUSSION

During the course of the study, patients were divided into three age groups 05 to 07 years, 08 to 10 years, 11 to 13 years (Table 2). It was observed that 03 cases (13.63 %), 05 cases (22.73) and 14 cases (63.64 %) belongs to the age group respectively. Distribution of patients according to the dietary habit among 22 cases 17 (77.27 %) cases were non vegetarian and 05 cases (22.73 %) were vegetarian (Table 3). High incidence of the disease was among the age group of 11 to 13 years.

The patients were further divided into three categories according to their consistency, odor and colour of vaginal discharge (Table 4).

Observation on reduction in intensity of the vaginal discharge including odor, consistency and colour at the base line and after the treatment with *Majoon Muqawwi Rahim* have been depicted in table 3, 4 and 5. Mean±SD score of Amount of vaginal discharge, generalised weakness and Backache respectively were found significantly reduced after the treatment.

The efficacy of study drug (Unani pharmacopoeial formulation) on clinical parameters of pre pubertal vaginal discharges are depicted in table 7. After the treatment, Mean±SD score of clinical parameter of the disease including vaginal discharge generalised weakness and backache, were found decreased from 5.36±1.87 to 3.18±1.71, 5.86±1.75 to 3.68±1.76 and 4.55±1.99 to 2.73±1.76 respectively. The reduction score in percentage of the clinical parameter 40.67 %, 37.20 %, 40 % respectively p< 0.01 as compared to base line. No adverse effect was detected by clinical examination and or laboratory examination.

In the present study it was found that the incidence of the disease in female of age 05 years (13.63 %). The prevalence of vaginal discharge was found increasing with increasing of age and the observation that high prevalence in the female who follow the non vegetarian diet the finding is similar and agree with the study of Sehar et al [12].

In the present study the efficacy of *Majoon Muqawwi Rahim* was evaluated over a period of three weeks (21 days) on the basis of symptoms wise improvement. Before treatment 8 patients reported that the colour of discharge is white, 13

were reported whitish, 1 patient reported yellowish. After the treatment, the colour of discharge was changed. Efficacy of the drugs was evaluated on the basis of consistency of vaginal discharge, the two types of consistency was reported by the patients, thick and thin. After the treatment it is found that the consistency is also converted to normal. The odor of the vaginal discharge is also documented, before treatment 19 patients have no odour in vaginal discharge, and after treatment it is reported by 22 patients. The efficacy of the Unani Pharmacopoeial formulation statistically analyzed on the symptoms of the vaginal discharge that are amount of discharge, generalized weakness and back ache. There was significant improvement found in amount of discharge 40.67%, generalized weakness 37.20% and backache 40% show in table 7. Response of the

drugs by reducing the symptoms of pre pubertal vaginal discharge due to the treatment and can be attributed to ingredients used in the formulation. *Majoon Muqawwi Rahim* has *Mochras* which has astringent and styptic (*habisqabis*) properties<sup>[14]</sup> *Supari* has therapeutic effect of phytochemical effect of its bio chemical on various disease conditions. Antioxidant, anti-inflammatory and antidepressant properties. *Tabasheer* has astringent, refrigerant and desiccant/siccative effect. *Gul-e-surkh* has anti-inflammatory and laxative effect.<sup>[15]</sup> *Muslisyah* (black) and *muslisafaid* (white) has *mulattif* (demulscent) and *mughazzi* (nutritive) effect.<sup>[16]</sup> Over all compliance of the Unani pharmacopoeial formulation is *muwallidkhoon* (Heamopoeitic), *muqawwi-e-rahim* (urine tonic).

**Table 2: Age-wise Distribution of patients**

Age Group ( In years)	No. of cases	Percentage
5-7	03	13.63
8-10	05	22.73
11-13	14	63.64
Total	22	100.00

**Table 3: Dietary Habits wise Distribution**

Dietary Habits	No. of cases	Percentage
Non-Vegetarian	17	77.27
Vegetarian	05	22.73
Total	22	100.00

**Table 4: Colour of Vaginal Discharge wise Distribution**

Colour	Before Treatment	After Treatment
White	08	13
Whitish	13	07
Yellowish	01	-
No colour	0	02
Total	22	22

**Table 5: Consistency of Vaginal Discharge wise Distribution**

Consistency	Before Treatment	After Treatment
Thick	09	03
Thin	13	17
No Consistency	0	02
Total	22	22

**Table 6: Odour of Vaginal Discharge wise Distribution**

Odour	Before Treatment	After Treatment
Absent	19	22
Present	03	-
Total	22	22

Table 7: Analysis according to clinical parameter

Parameters	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Reduction Percentage	P. Value	Results
Amount of Discharge	5.36±1.87	3.18±1.71	40.67 %	0.000025	significant at P<0.1
General Weakness	5.86±1.75	3.68±1.76	37.20 %	0.000012	significant at P<0.1
Backache	4.55±1.99	2.73±1.75	40 %	0.000028	significant at P<0.1

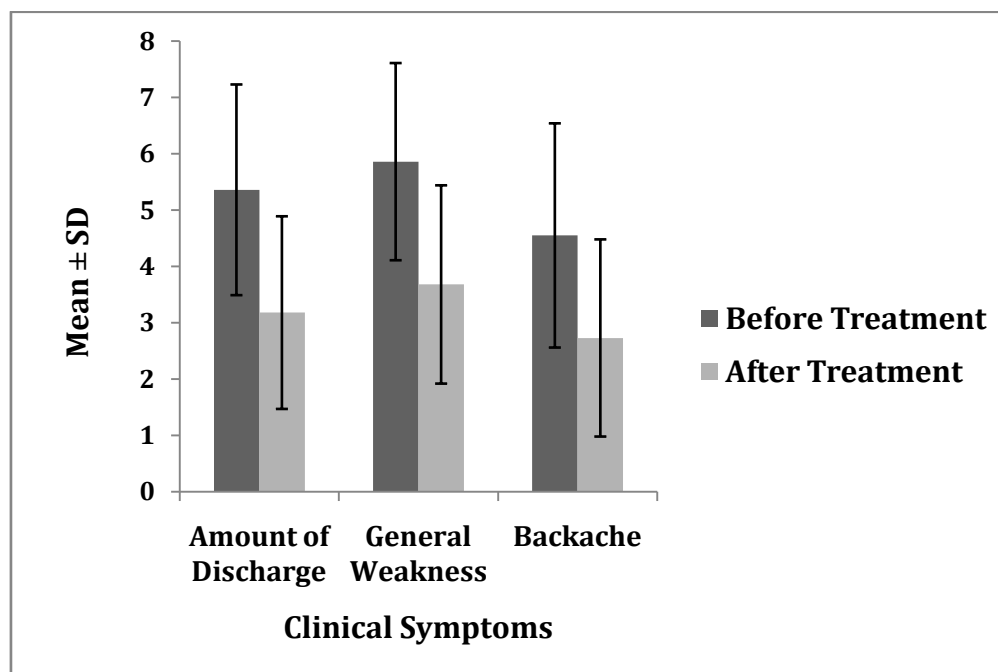


Figure 1: Efficacy of Unani formulations Majoon muqawwi-e-rahim.

The data are expressed as the Mean ± SD. P. value is Significant P<0.1

### CONCLUSION

On the ground of above observation and findings, it can be concluded that Unani pharmacopoeial formulation *Majoon Muqawwi-e-Rahim* is safe and effective in the management of prepubertal vaginal discharge and hence this can be prescribed to the patients in the management of prepubertal vaginal discharge. This Unani formulation is cheap, easily available and can be easily tolerated by the patients without any adverse effect on them.

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