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Clinical Validation Of Efficacy And Safety Of Unani Formulation *Majoon Muqawwi-I-Rahim* In *Sayalan Al-Rahim* (Leucorrhoea)

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ABSTRACT

Sayalan al-Rahim (Leucorrhoea) is one of the common problem among the females visiting the Outpatient department of the hospital. It occurs in about 1-14% of all women of reproductive age group and is responsible for 5-10 million OPD visits per year. Due to white discharge, females are prone to other symptoms such as backache, itching in vulva, general weakness. The objectives of this clinical study was to assess the efficacy and safety of Unani Pharmacopoeial formulation *Majoon Muqawwi –i- Rahim* in patients of *Sayalan al-Rahim* (Leucorrhoea). A total of 100 cases in the age group of 13-45 years completed the study. Out of 100 patients 36 patients got relieved, 61 patients got partially relieved and 3 patients got no relief. The trial drug showed significant improvements in clinical parameters and showed statistically not significant effect on safety parameters. Thus it can be concluded that *Majoon Muqawwi-i-Rahim* is effective and safe in the management of *Sayalan al-Rahim* (Leucorrhoea).

Keywords: *Sayalan al-Rahim*, Leucorrhoea, *Majoon Muqawwi-i- Rahim*, Unani

Introduction

Leucorrhoea is an excessive vaginal discharge from the female genital tract and the term leucorrhoea should be restricted to mean and excessive normal vaginal discharge (**Guntoory et al., 2017; Eram, 2017**), consists mainly of cervical component, dries to leave a brownish yellow stain on clothing. (**Gul et al., 2013**) Leucorrhoea is a symptom, not a disease, and is an expression of some underlying disorder, either functional or organic (**Kumar, 2008**). It may be physiological or pathological. Physiological discharge is due to increased level of estrogen, occurs during pregnancy, around ovulation, premenstrual congestion and needs no treatment.**(Dutta, 2016)** Pathological discharge is mainly due to three causes: infective (non sexually transmitted) like bacterial vaginosis, candidiasis; non infective (sexually transmitted) like Chlamydia trachomatis, Neisseria gonorrhea, Trichomonas, Herpes simplex virus; and certain other non infective causes like foreign bodies, cervical polyp and ectopy, genital tract malignancy, fistulae, allergic reactions etc. It occurs in about 1-14% of all women of reproductive age group and is responsible for 5-10

million OPD visits per year. **(Khirodkar et al., 2015)**. Its prevalence is estimated to be about 30% **(Padubidri, 2008)** in India, 6% in urban and 7% in rural areas.**(Rajurkar et al., 2014).**

Due to white discharge, other symptoms, such as pain in lower abdomen, backache, painful menstruation, frequent micturition, general weakness and constipation may also present. **(Fahad, 2019)**

The eminent Unani scholars have described in detail about gynaecological problems including *Sayalàn al-Rahim*. Classical books of Unani Medicine like *Al Qanoon fit Tib, Kàmil al sanà'a, Kitab al-Hàwì, Firdaws al-Hikma, Tibb-i-Akbar, Al-iksìr* and many other authentic books it is mentioned that *Sayalàn al-Rahim* is due to poor *Quwwat-i-Ghàzia* (nutritional power) of the *Rahim* (uterus) resulting in accumulation of *Fuzlàt* (waste material). According to the humoural theory, *Sayalàn al-Rahim* is caused by the excess of humours (*Akhlàt*) and is of the following four types **(Sina,YNM; Jurjani, 2010; Khan, 2011; Majusi, 2010)**

- *Sayalàn al-Rahim Damwi*: It may be caused by excess of *Khilt-e-Dam* and the colour of the discharge in reddish.
- *Sayalàn al-Rahim Safràwì*: It is caused by excess of *Khilt-e-Safrà* and the colour of the discharge is yellowish.
- *Sayalàn al-Rahim Balghamì*: It is caused by excess of *Khilt-e-Balgham* and the colour of the discharge is whitish.
- *Sayalàn al-Rahim Sawdàwì* : It is caused by excess of *Khilt-e-Sawdà* and the colour of the discharge is blackish.

In Unani system of Medicine, there are many single as well as compound drugs, which are safe and effective in the treatment of *Sayalàn al-Rahim* (Leucorrhoea). *Majoon Muqawwi-i Rahim* is polyherbal preparation described in various texts of Unani Medicine .It is used to treat disorders like *Sayalan al Rahim* (leucorrhoea) since long by eminent Unani physicians but the scientific data on their safety and efficacy are lacking .Therefore, this study is undertaken to validate the safety and efficacy of *Majoon Muqawwi –i- Rahim* in the treatment of the *Sayalàn al-Rahim* (Leucorrhoea).

Material and Methods

An open –label multi centric clinical study with sample size of 100 completed patients of *Sayalan al Rahim* conducted at Central Research Institute of Unani Medicine (CRIUM), Lucknow during April 2016 to June 2017. The study started after ethical clearance from Institutional Ethical committee of CRIUM, Lucknow. Female patients in the age group of 13-45 years having excessive white discharge with or without backache and general weakness were included in the study. Patients having acute/sub acute/chronic Pelvic Inflammatory Diseases (PIDs), taking hormonal therapy, patients on long term medications, oral contraceptives/Intra Uterine Devices (IUDs), pregnant and lactating women were excluded from the study. The duration of treatment was 2 weeks while the duration of the study was 2 years. The test drug *Majoon Muqawwi-i- Rahim* was given 5 gm orally twice a day after meal for 2 weeks and the patients were evaluated weekly. During the treatment no concomitant medication was allowed. Haemogram (Hb, TLC, DLC, ESR), Urine examination (Routine and Microscopic), Liver Function Test (LFT) and Kidney Function Test (KFT) were carried out before starting and at the end of treatment for each case. VDRL and Random blood Sugar were carried out at the time of screening only.

The efficacy of *Majoon Muqawwi-i- Rahim* was assessed on the basis of improvement in the *Waja al Zahr* (backache), *Naqahat* (General weakness) for which a 10 point Visual Analogue scale (VAS) was applied while in Amount of vaginal discharge (rated according to number of pads used per day). The overall results of the study was recorded in terms of percentage efficacy as calculated from the improvement in the symptoms assessed on VAS.

Wilcox Signed Rank test was used in the analysis of clinical parameters while paired "t" test was used in the analysis of haematological and biochemical parameters. The values were considered statistically significant when the $p<0.01$.

The study drug *Majoon Muqawwi-i- Rahim* is a pharmacopoeial formulation mentioned in National Formulary of Unani Medicine (NFUM) Part I. The composition of *Majoon Muqawwi-i- Rahim* is as follows. **(Anonymous, 2006; Anonymous, 2009)**

S. No.	Ingredients	Part used	Quantity
1.	*Mochras (Salmalia malabarica)*	Gum	10 g
2.	*Fufal (Areca catechu)*	Seed	10g
3.	*Tabasheer (Bambusa bambos)*	Dried exudates	10 g
4.	*Nishasta- e- Gandum (Triticum aestivum)*	Starch powder	10 g
5.	*Gil- e- Makhtoom (Sealing clay)*	Powder	10 g
6.	*Gul –e- Surkh (Rosa damascena)*	Flower	10 g
7.	*Mazu (Quercus infectoria)*	Gall	10 g
8.	*Habb- ul- Aas (Myrtus communis)*	Fruit	10 g
9.	*Post-e- Halela Zard (Terminalia chebula)*	Fruit rind	10 g
10	*Post-e-Balela (Terminalia belerica)*	Fruit rind	10 g
11.	*Aamla (Emblica officinalis)*	Fruit	10 g
12.	*Musli Siyah (Curculigo orchiodes)*	Rhizome	10 g
13.	*Musli Safaid (Chlorophytum arundinaceum)*	Root	10 g
14.	*Post e Anar (Prunica granatum)*	Fruit rind	15 g
15.	*Aab e Behi Taza (Cydonia oblonga)*	Fruit extract	50 ml
16.	*Aab e Anar tursh (Prunica granatum)*	Seed extract	50 ml
17.	*Nabat Safaid (Sugar)*	Crystals	210 g
18.	*Asal (Honey)*		210 g

Observation and Results

The subjective and objective findings of the study are presented in the following tables

Table 1 Age Wise Distribution of patients

Age Group (In years)	No. Of cases	Percentage (%)
13-25	51	51
26-35	39	39
36-45	10	10
Total	**100**	**100**
Mean±SD	**26.75±7.33**	

Out of 100 patients, 51 patients were found in the age group of 13-25 years followed by 39 patients in the age group of 26-35 years and 10 patients in the group of 36-45 years. Mean age of patients was 26.75 years. (Table 1)

Table 2 Socio economic status wise Distribution of patients

Socio economic status	No. of cases	Percentage (%)
Lower class	57	57
Middle class	43	43
Upper class	--	--
Total	**100**	**100**

Out of 100 patients, 57 patients belong to lower class 43 patients belong to middle class and not any patient belongs to Upper class. (Table 2)

Table 3 Temperament wise Distribution of patients

Temperament	No. of cases	Percentage (%)
Balghami (Phlegmatic)	33	33
Damwi (Sanguine)	01	01
Safrawi (Bilious)	65	65
Saudawi (Melancholic)	01	01
Total	**100**	**100**

Out of 100 patients 33 patients were found *Balghami Mizaj*, 1 *Damwi Mizaj* 65 patients *Safrawi Mizaj* and 1 *Saudawi Mizaj*. (Table 3)

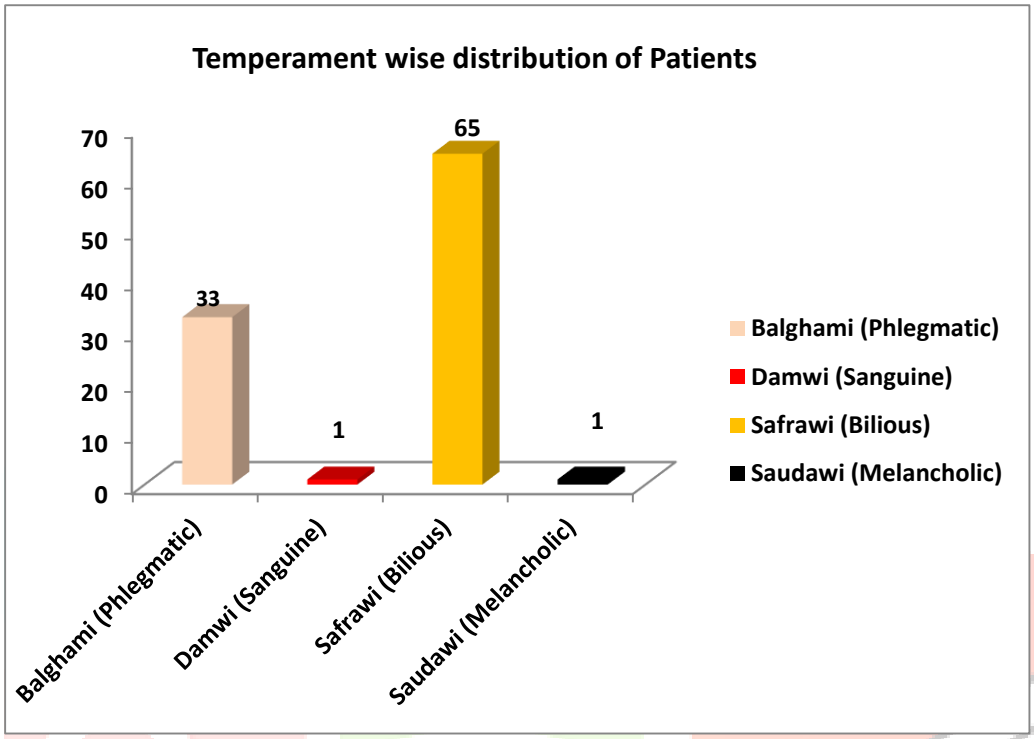

Table 4 Nutritional status wise Distribution of patients

Nutritional status	No. of cases	Percentage (%)
Poor	32	**32**
Average	63	63
Good	05	05
Total	**100**	**100**

Out of 100 patients 32 patients were found poor nutritional status 63 average nutritional status and 5 good nutritional status. (Table 4)

Table 5 Marital status wise distribution of patients

Marital status	No. of cases	Percentage (%)
Married	**68**	**68**
Un Married	**32**	**32**
Total	**100**	**100**

Out of 100 patients 68 patients were married while 32 patients were unmarried. (Table 5)

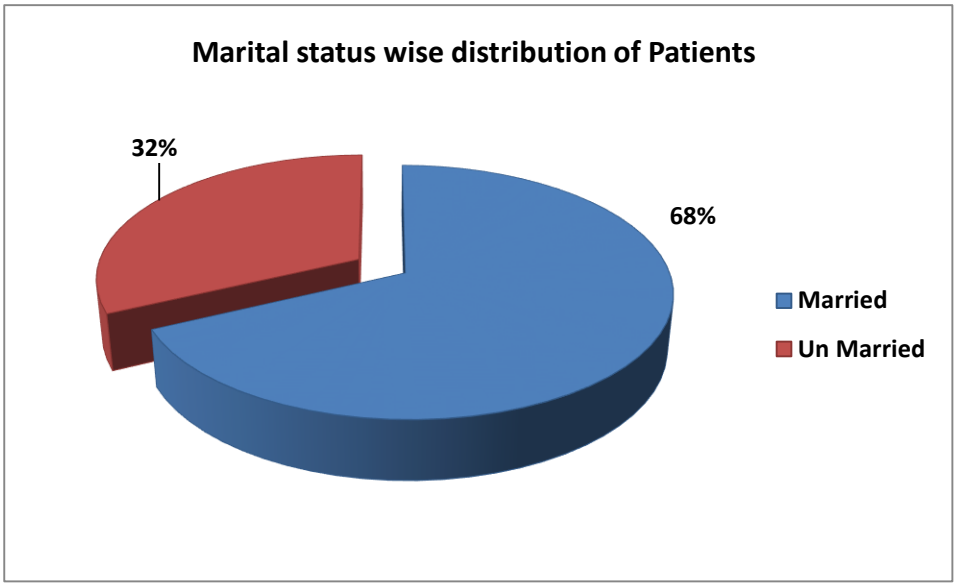

Table 6 Result wise Distribution of patients

Result	No. of cases	Percentage (%)
Relieved (61-100%)	36	**36**
Partially Relieved (10-60%)	61	61
Not Relieved (<10%)	3	3
Total	**100**	**100**

On the basis of percentage efficacy, out of 100 patients 36 patients got relieved, 61 patients got partially relieved and 3 patients got not relieved in clinical parameters. (Table 6)

Table 7 Effect of *Majoon Muqawwi-i- Rahim* on clinical parameters

Sr. No.	Clinical parameters	Mean±SD		Efficacy (%)	P-Value	Result
		BT	AT			
1	No. of Pads used /day	5.84±196	2.45±1.98	58.04	<0.0001	Extremely Significant
2	General weakness	5.82±1.73	2.68±1.33	53.95	<0.0001	Extremely Significant
3	Backache	5.73±1.69	2.74±1.48	52.18	<0.0001	Extremely Significant

Effect of *Majoon Muqawwi-i- Rahim* on clinical parameters showed that statistically extremely significant improvement occurred in No of Pads used/day, general weakness and Backache. $p<0.0001$ (Table 7)

Table 8 Effect *Majoon Muqawwi-i- Rahim* on HAEMOGRAM, LFT and KFT

	Name of the Parameters		No. of Observation (n)	Mean±SD		Percentage of Increase (↑) / Decrease (↓)		Paired "t" Test		Result
				BT	AT			Statistic value	P Value	
HAEMOGRAM	Hb (gm/dL)		100	11.09±1.27	11.13±1.23	0.36	↑	-1.16	0.25	Not Significant
	TLC (/mm)		100	9451±1163.28	9500±887.62	.51	↑	-0.62	0.54	Not Significant
	DLC	N (%)	100	58.03±8. 60	58.78±7.29	1.29	↑	-1.19	0. 24	Not Significant
		L (%)	100	35.34±7.86	35.31±7.24	0.08	↓	0.05	0.96	Not Significant
		E (%)	100	5.82±1.74	2.68±1.33	53.95	↓	20.78	0.00001	Significant
		M (%)	100	1.55±1.04	1.41±0.99	9.03	↓	1.02	0.31	Not Significant
		B (%)	100	0-0	0-0	0-0	--	--	--	--
LFT	S. Bilirubin (mg/100 ml)		100	0.54±0.53	0.56±0.47	3.70	↑	-1.09	0.27	Not significant
	SGOT (IU/L)		100	22.73±13.16	21.51±12.20	5.36	↓	1.30	0.19	Not significant
	SGPT (IU/L)		100	26.11±21.45	25.00±19.00	04.25	↓	0.73	0.46	Not significant
	S. Alkaline Phosphatase (KA)		100	232.98±78.32	228.56±77.32	1.89	↓	1.24	0.21	Not Significant
KFT	S. Creatinine (mg/100 ml)		100	0.61±0.11	0.62±0.10	1.63	↑	-1.31	0.19	Not significant
	S. Urea (mg/100 ml)		100	21.42±5.40	21.45±5.79	0.14	↑	-0.04	0.96	Not Significant
	S. Uric Acid (mg/dL)		100	4.20±0.69	4.14±0.58	1.42	↓	1.31	0.19	Not Significant

Effect of *Majoon Muqawwi-i-Rahim* on safety parameters (Haemogram, LFT and KFT) showed that no adverse effect was noted. (Table 8).

Discussion

This study showed that *Sayalan-al Rahim* is more common in the age group of 13-35 years and this finding is similar to the finding of previous study. **(Sehar et al., 2017)**. This study revealed that prevalence of *Sayalan-al Rahim* is more common in married women and this finding correlates with the findings of previous studies. **(Rehman et al., 2018; Sehar et al., 2017).**

In this study *Sayalan-al Rahim* is commonly seen in *Safrawi* and *Balghami* temperament this finding is similar to the findings of previous studies **(Sehar et al., 2017; Rehman et al., 2016)**.

On the basis of percentage efficacy, out of 100 patients 36 patients got relieved, 61 patients got partially relieved and 3 patients got not relieved in clinical parameters. This finding also similar to the finding of previous study **(Rehman et al., 2018).**

Effect of *Majoon Muqawwi-i- Rahim* on clinical parameters showed that statistically extremely significant improvement seen in Number of Pads used/day, General weakness and Backache. In classical literature of Unani Medicine *Majoon Muqawwi-i- Rahim* is indicated for the treatment of *Sayalan-al Rahim* (leucorrhoea) and other uterine disorders. **(Anonymous, 2006; Anonymous, 2009)**. The pharmacological actions of the ingredients of the formulation are *Qabiz* (Astringent), *Mumsik* (Retentive), *Muqaww-i-Rahim* (Uterine Tonic), *Mughalliz* on female genital tract. **(Ghani, YNM).** The improvement in clinical parameters occurred due to pharmacological actions of these ingredients.

Effect of *Majoon Muqawwi-i- Rahim* on Haemogram, LFT and KFT showed that not any adverse effect seen in Haemogram, LFT and KFT. This study revealed that *Majoon Muqawwi-i- Rahim* is safe in the treatment of *Sayalan-al Rahim* (Leucorrhoea).

Conclusion

On the basis of findings of this study it may be concluded that *Majoon Muqawwi-i- Rahim* is effective and safe in the treatment of *Sayalan-al Rahim* (leucorrhoea). In future multicentric Randomised Controlled trial may be conducted on *Sayalan-al Rahim* (leucorrhoea) on large sample size.

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