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A randomized standard controlled clinical study on overactive bladder and its management with Majoon Qust

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Abstract
Overactive bladder (OAB) is a chronic medical disease that affects the quality of life for a large percentage of the population. Many people who are afflicted do not seek medical assistance. Patients with OAB usually get it as they become older.[1] It is a condition in which various Lower Urinary Tract Symptoms (LUTS) related to urine storage coexist, with urinary urgency serving as the essential parameter and does not require confirmatory urodynamic evaluation. Urgency with at least one other symptom is essential to diagnose OAB. Thus, urgency is the pivotal symptom. Urgency incontinence is described as involuntary urine leakage that is accompanied or preceded by urgency in many OAB patients. this standardized definition abandoned the need that the leakage be a "social or sanitary problem" to be termed incontinence. In a prevalence survey, 69% of women had “any incontinence,” but only 30% found this a “social or hygienic problem”. In Unani Classical literature, the term Overactive bladder (OAB) as such is not traceable although there is much description of various lower urinary tract symptoms (LUTS). The Clinical features of the OAB can be compared with the symtoms of *zoaf-e-masana*, *sal-e-sul boul*, and *isterka-e- masana* described in Unani System of Medicine. According to Ibn Sina, causes of *zoaf-e-masana* are sue mizaj barid and weakness of bladder, because of which the patient cannot withhold urine, and passes it frequently. The treatment of OAB in Modern system of medicine is present but recurrence of the disease and side effects of the medicine are very troublesome. A compound polyherbal Unani formulation namely “Majoon qust” is selected from classical literature which have been used since very long but scientific data on safety purpose is not available.

Keywords: Majoon Qust, OAB, Zoaf-e-masana, sal-e-sul boul, isterkha-e-masana

Introduction
According to International Continence Society (ICS) definition, OAB consists of urinary urgency with or without urgency urinary incontinence (UUI), often accompanied by frequency and nocturia, in the absence of urinary tract infection (UTI) or other obvious pathology [1, 2]. The term overactive bladder (OAB) was not in common use until 15 years ago, it was famously introduced in 1997 by Dr. Paul Abrams and Dr. Alan Wein when they co-chaired a 1997 consensus conference titled, “The Overactive Bladder: From Basic Science to Clinical Management.” Patients with overactive bladder syndrome who have urgency are distinguished from those who have bladder pain syndrome by their "fear of leaking" and "fear of pain." Urgency is often felt in the perineum, base of penis, or vagina/urethra in overactive bladder syndrome. In bladder pain syndrome, on the other hand, suprapubic pain is common, however extra perineal (urethral/vaginal/penile) discomfort might occur. Increased daytime frequency is a complaint stated by patients who believe they void too frequently during the day. As there is significant overlap in actual voiding frequency between normal and overactive bladder syndrome, this standardized definition does not contain a minimum number of voids. Because there is currently insufficient data to define a threshold for identifying increased daytime frequency, the definition does not contain a minimum number of voids Nocturia is a complaint made by one who needs to get up one or more times throughout the night to void. Individuals with varying sleep habits, such as nightshift employees, have yet to achieve an accord [3]. Mixed urinary incontinence encompasses overactive bladder syndrome and stress urinary incontinence. The complaint is of involuntary leakage associated with urgency and with exertion, effort, sneezing, or coughing [4]. Although the prevalence of OAB is similar in both men and women, there are sex-specific differences in the prevalence of various symptoms within the OAB complex [5, 6].

Men have a higher prevalence of "overactive bladder syndrome dry", meaning urgency without urgency urinary incontinence, and women have a higher prevalence of "overactive bladder syndrome wet" [7]. The differing prevalence of incontinence is presumed to be due to the relative weakness of the bladder neck and urethral sphincter mechanism in women. In conventional system of medicine OAB has not been described as a disease rather it is a complex of the various symptoms pertaining to the lower urinary tract. According to Ibn Sina, causes of *zoaf-e-masana* are sue mizaj barid and weakness of bladder, because of which the patient cannot withhold urine, and passes it frequently [8]. According to Ahmad bin Ali bin Hubl Baghdadi, *sal-e-sul boul* is a condition when patient passes urine unknowingly [9]. He explained causes of sal-e-sul boul as when the muscles of bladder get affected by extreme cold or spinal injury resulting in bladder atony [9].
According to Abu Marwan Abdul Malik Ibn Zuhr, *sue mizaj barid masana* can be caused by various factors such as wearing a damp under wears especially in old age, sitting on a cold stone and excessive use of cold temperament drug(s) [10].
In allopathic system of medicine the main first-line medications for the treatment of OAB are anticholinergics (antimuscarinics). Hormone replacement therapies, tricyclic antidepressants, desmopressin, alpha blockers, and botox injections have also been used in certain cases.
The European Association of Urology and the Japanese Urology Society recommend non- pharmacological and pharmacological treatments for OAB. The aim of non-pharmacological treatment is to educate patients about OAB and help them to develop strategies to manage it, cessation of smoking, weight reduction, dietary and fluid intake changes, bowel regulation, and exercise are all included in this group.
The principle of treatment of *zoaf-e-masana*, *sal-e-sul boul*, and *isterka-e- masana* as described in classical unani text are use of Muqawwi-e-aasab (Nervine tonic), Qabiz (Astringent), Musakhin (Calorific), Muqawwi-e-masana (Bladder tonic), Masikul boul drugs.
A compound polyherbal Unani formulation namely "Majoon Qust" is selected from classical literature which have been used since very long but scientific data on safety purpose is not available.
A semisolid polyherbal Unani classical Formulation "Majoon Qust" having following constituents namely – Filfil siyah (Piper nigrum), Sonth (Zingiber officinale), Kundur (Boswellia serrata), Qust Shirin (Suassurea lappa), Nagar motha (Cyperus longus), Balut (Quercous incana), Peepal (ficus religiosa), and honey as a preservative is given to the patients of Test group.
While Control Group is treated with tablet Urikind (Flavoxate) 200 mg of Mankind Pharmaceuticals.

2. Objectives of the study

- To evaluate the safety and efficacy of the Unani polyherbal formulation in the treatment of Overactive Bladder.
- To provide cost effective drug for the management of OAB.
- To evaluate the efficacy of test drug in comparison to a standard control drug.

3. Material and Methods

3.1 Place of study: The present study entitled as "A Randomized Standard Controlled Clinical Study on Overactive Bladder and its Management with Majoon Qust." has been conducted in the Department of Moalijat, Ayurvedic and Unani Tibbia College and Hospital, Karol Bagh, New Delhi session 2018- 2021.

3.2 Study Design: The present study was designed as a randomized controlled clinical trial.

3.3 Randomization: Randomization was done by lottery method. 40 patients were allocated by using lottery method into two groups, comprising 20 patients in each of the test group and control group respectively.

3.4 Sample size: 40 Patients were included in the study. 20 Patients in each test and control groups.

3.5 Criteria for the selection of patients: Both male and female patients aged between 18-65 years with clinical signs and symptoms were enrolled from outpatient Department of Moalijat, Ayurvedic and Unani Tibbia College & Hospital, Karol Bagh, New Delhi.

3.5.1 Inclusion criteria

- Patient of either sex.
- Age group of 18 to 65 years.
- Patient suffering from the symptoms of OAB
- Patients willing to participate and sign the informed, understood consent form.
- Patients willing to discontinue the drugs already taking for the treatment of OAB.

3.5.2 Exclusion criteria

- Patient above the age of 65 years and below 18 years.
- Pregnant and lactating women.
- Patient having benign prostatic hyperplasia.
- Renal insufficiency
- Hepatic insufficiency
- Cardiovascular disorders
- Endocrinal disorders
- UTI
- Anxiety and depression
- Bladder stone
- Post bladder instrumentation
- Abnormal position of uterus
- Uterine fibroid
- Spinal injury

3.5.3 Withdrawal criteria

- Failure to consume the drug.
- Failure to report for follow up.
- Any marked adverse drug reaction or adverse event.

3.6 Duration of study: One and half years.

3.6.1 Duration of protocol therapy

4 weeks (28 days)

3.7 Clinical evaluation of disease

Patient is assessed on the basis of designed Case Record Form (CRF). A detailed history is taken to rule out any accompanying visible disease like e.g., diabetes, benign

prostatic hypertrophy (BPH), urinary tract infection (UTI), and or other symptoms of organic bladder disease. The patient's lifestyle, particularly, tobacco, coffee and alcohol consumptions etc. have also been taken into consideration, as personal habits can have significant impact on the symptoms.

3.8 Ethical consideration
After receiving approval from the Institutional Ethics Committee, and getting registered in Clinical Trial Registry (CTRI/2020/11/028812), the proposed study was started in the Department of Moalijat of A & U Tibbia College and Hospital, Karol Bagh, New Delhi.

3.8.1 CTRI NO.-CTRI/2020/11/028812[02/11/2020]
After getting approval from Institutional Ethics Committee, the trial was registered in clinical trial registry of India.

3.9 Criteria for diagnosis of OAB
- Diagnosis was made on the basis of clinical features of OAB and Overactive Bladder Symptom score.
- TLC, DLC, ESR, was also monitored.

3.10 Procedure
After thorough screening, diagnosed patients of OAB who fulfil inclusion criteria, were included in the study. Patients were randomly allocated in 2 groups after making them understand about the study and taking their voluntary informed written consent. Test group had 20 patients and Control group had the same number of patients. Those falling under test group were given the semisolid form of crude polyherbal formulation, 5gm twice a day orally and the control group were given Tab. Urikind (Flavoxate) 200 mg of Mankind pharmaceuticals twice daily after meal. Patients kept in follow up weekly. The data for both the groups were statistically analysed and compared with each other using appropriate statistical tests. The safety of the test and control drugs were ensured by monitoring the haematological indicators for kidney and liver functions.

3.11 Study Drug
3.11.1 Test drug
A semisolid polyherbal Unani classical Formulation "Majoon Qust" having following constituents namely – Filfil siyah (Piper nigrum), Sonth (Zingiber officinale), Kundur (Boswellia serrata), Qust shirin (Suassurea lappa), Nagar motha (Cyperus longus), Balut (Quercous incana), Peepal (ficus religiosa), and honey as a preservative was given to the patients of Test group.

3.11.2 Control drug
While Control Group was treated with tablet Urikind (Flavoxate) 200 mg of Mankind Pharmaceuticals.

3.11.3 Preparation of test drug
Test drug was polyherbal Unani classical Formulation i.e., "Majoon Qust". The originality and authenticity of the ingredients in the test drug were certified by Dr. Sunita Garg, Emeritus Scientist, CSIR- NISCAIR. Following proper identification, the components were cleaned and ground to make a semisolid form of majoon in precise accordance as mentioned in classical Unani Literature.

3.11.4 Procurement of control drug
Control drug, i.e., Tablet Urikind (Flavoxate) 200 mg of Mankind pharmaceuticals was obtained from market.

3.12 Dosage schedule
Test group (group A) received test drug (Majoon Qust) in Semisolid form. The drug was given to the patients, 5g two times in a day orally with plain water for 28 days. Control group (group B) was treated with one Tablet Urikind (Flavoxate) 200 mg, of Mankind Pharmaceuticals twice daily after meals for 28 days.

3.13 Follow Up
Clinical examination was performed and recorded at the baseline, 7th day, 14th day, 28th day.

3.14 Assessment of MIZAJ (temperament)
Temperament of each patient was assessed on the basis of ten classical parameters (Ajnas-e- Ashra) as prescribed in Unani Classical literature.

3.15 Criteria for assessment of efficacy
To assess the adequacy of treatment of OAB on patients in both groups, following subjective parameters were used in the study.

3.16 Subjective parameters: OABSS (OAB Symptoms Score) Homma, *et al*.

Question	Frequency	Score
How many times do you typically urinate from waking in the morning until sleeping at night?	≤ 7 8-14 ≥ 15	0 1 2
How many times do you typically wake up to urinate from sleeping at night until waking in the morning?	0 1 2 ≥ 3	0 1 2 3
How often do you have a sudden desire to urinate, which is difficult to defer?	Not at all Less than once a week Once a week or more About once a day 2-4 times a day 5 times a day or more	0 1 2 3 4 5
How often do you leak urine because you cannot defer the sudden desire to urinate?	Not at all less than once a week Once a week or more About once a day 2-4 times a day 5 times a day or more	0 1 2 3 4 5

3.17 Assessment of safety
To establish the safety of drugs, the following investigations were carried out at baseline, after one week and just after termination of treatment.

- Liver function test: S.G.O.T, S.G.P.T and Alkaline phosphatase.
- Kidney function test: Blood urea and Serum creatinine.
- Hemogram: Hb%, TLC, DLC.

3.18 Adverse event documentation
No adverse event observed during entire period of study.

3.19 Statistical analysis
After 4weeks of the treatment, pre-treatment and post-treatment values of subjective parameters in each group were analyzed and compared to evaluate the efficacy of the treatment by applying appropriate statistical tests.

3.20 Confidentiality
Confidentiality regarding patient's identity was truly maintained. The patient never identified by name in any of the related publications.

4. Observations and results
4.1 Effect of trial drug on urinary urgency

Table 1: Effect of trial drugs on urinary urgency

Urinary Urgency	(Mean ± SD)			t-value	p-value	Statistical Result
	0 Day	7th Day	28th Day			
Test Drug	2.9±0.85	2.7±0.86	1.65±0.93	8.75	<0.001	Extremely significant
Control Drug	2.8±0.69	2.6±0.82	1.5±0.6	10.17	<0.001	Extremely significant

In test group, mean score of Urinary Urgency reduced from 2.9 ± 0.86 at the baseline to 2.7 ± 0.86 on 7th day and 1.65 ± 0.93 on the termination of treatment (t=8.75; $p< 0.001$). While in control group, urinary urgency reduced from 2.8 ± 0.69 on the baseline to 2.6 ± 0.82 on 7th day, 1.5 ± 0.60 at the end of treatment (t=10.17; $p<0.001$). On applying unpaired t test in both the groups, no significant difference between the mean Urinary Urgency of both groups is found (t=0.617; $p> 0.10$).

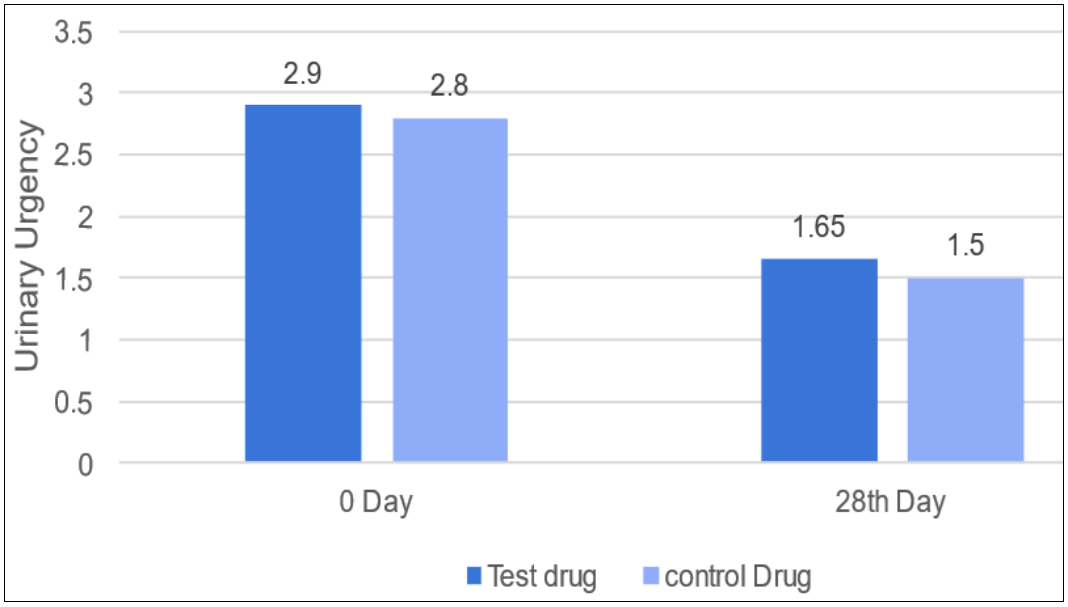

Fig 1: Effect of trial drugs on urinary Urgency

4.2 Effect of trial drugs on nocturia

Table 2: Effect of trial drug on nocturia

Nocturia	(Mean ± SD)			t-value	p-value	Statistical result
	0 Day	7th Day	28th Day			
Test Drug	1.85±0.67	1.5±0.76	0.95±0.68	7.28	<0.001	Extremely significant
Control Drug	1.3±0.73	1.1±0.78	0.65±0.48	4.95	<0.001	Extremely significant

In test group, mean score of Nocturia reduced from 1.85 ± 0.67 at the baseline to 1.5 ± 0.76 on 7th day and 0.95 ± 0.68 on the termination of treatment (t=7.28; $p< 0.001$). While in control group, nocturia reduced from 1.3 ± 0.73 on the baseline to 1.1 ± 0.78 on 7th day, 0.65 ± 0.48 at the end of treatment (t=4.95; $p< 0.001$).

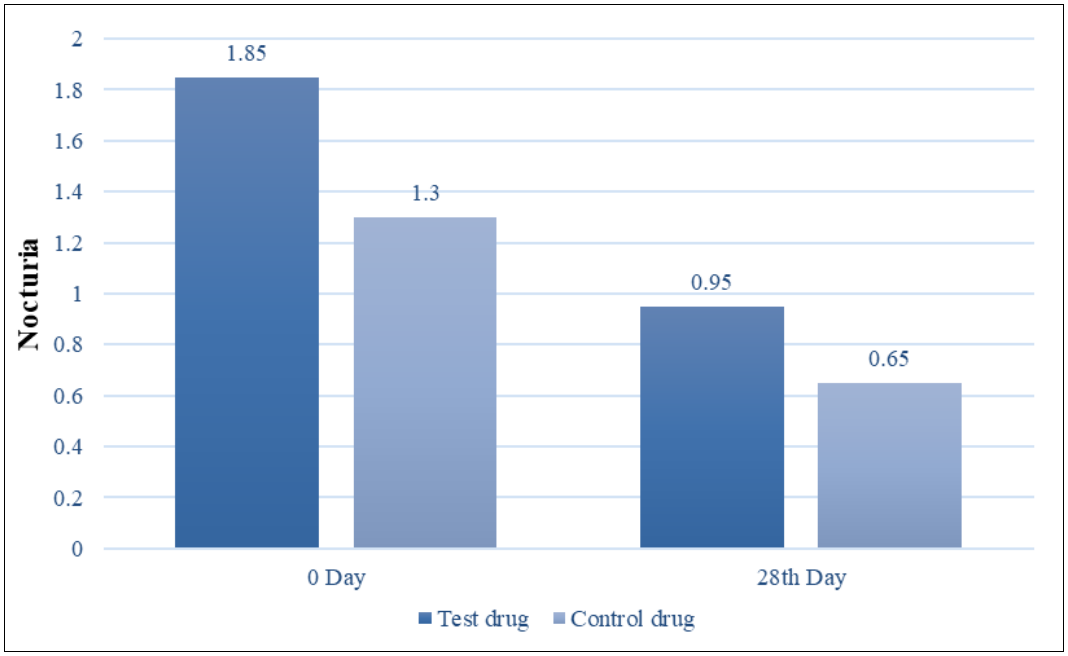

Fig 2: Effect of trial drug on Nocturia

4.3. Effect of trial drugs on Frequency

Table 2: Effect of trial drug on nocturia

Frequency	(Mean ± SD)			t-value	p-value	Statistical Result
	0 Day	7th Day	28th Day			
Test Drug	1.15±0.36	1.05±0.51	0.4±0.50	7.54	<0.001	Extremely significant
Control Drug	1.3±0.73	1.1±0.78	0.65±0.48	7.54	<0.001	Extremely significant

In test group, mean score of Frequency reduced from 1.15 ± 0.36 at the baseline to 1.05±0.51 on 7th day and 0.4 ± 0.50 on the termination of treatment. While in control group, frequency reduced from 1.3 ± 0.73 on the baseline to 1.1 ± 0.78 on 7th day, 0.65 ± 0.48 at the end of treatment.

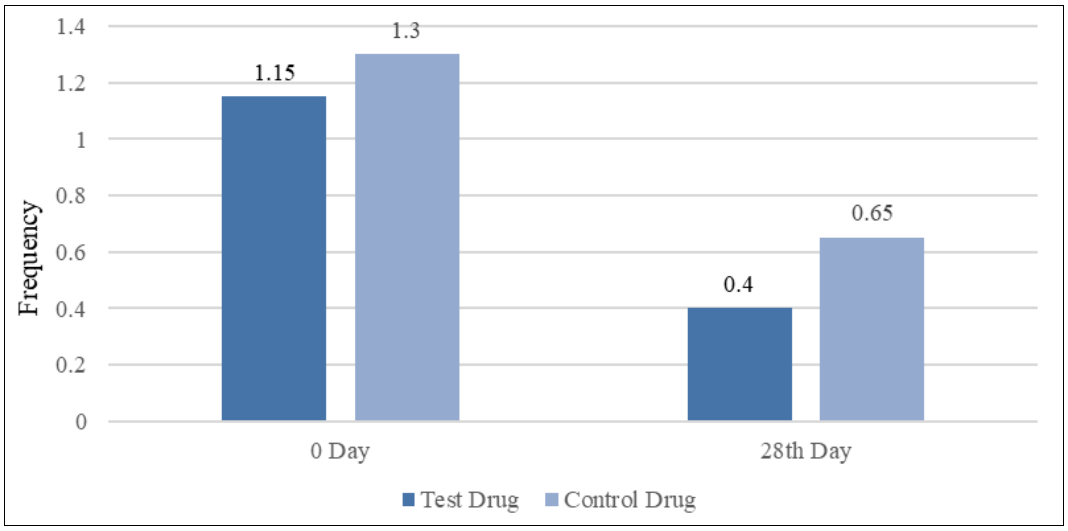

Fig 3: Effect of trial drug on frequency

Table 3: Effect of trial drugs on incontinence

Incontinence	(Mean ± SD)			t- value	p-value	Statistical Result
	0 Day	7th Day	28th Day			
Test Drug	0.95±0.99	0.75±0.91	0.5±0.51	3.32	<0.001	Extremely significant
Control Drug	0.6±0.88	0.55±0.82	0.3±0.47	2.85	<0.001	Extremely significant

In test group, mean score of Incontinence reduced from 0.95 ± 0.99 at the baseline to 0.75 ± 0.91 on 7th day and 0.5 ± 0.51 on the termination of treatment. While in control group, it reduced from 0.6 ± 0.88 on the baseline to 0.55 ± 0.82 on 7th day, 0.3 ± 0.47 at the end of treatment.

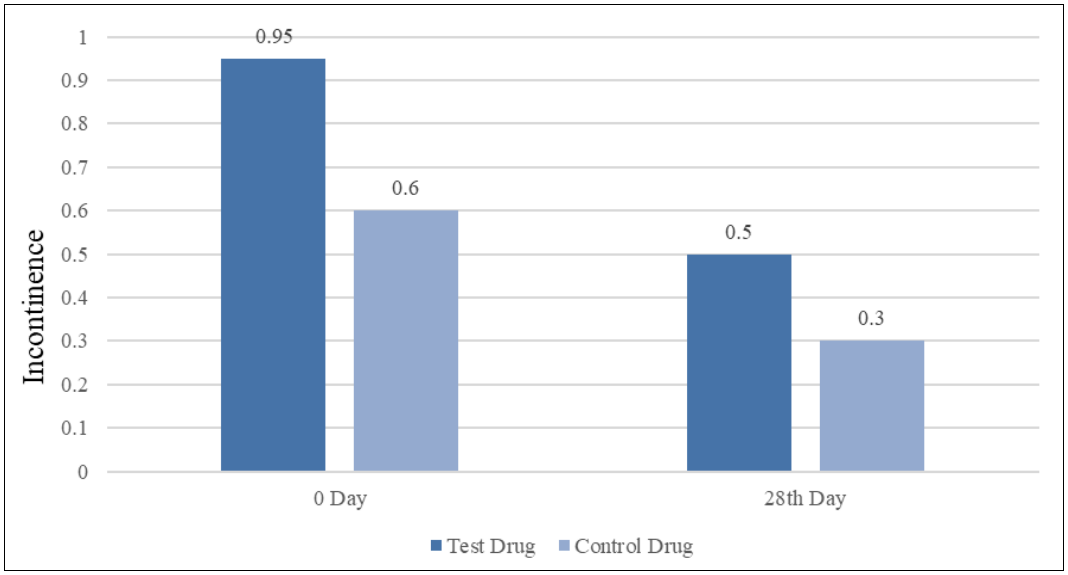

Fig 4: Effect of trial drug on incontinence

Table 4: Intergroup comparison of test group vs control group on urinary urgency

Urinary urgency (Mean ± S.D.)	Test Group	Control Group
0 day	2.9 ± 0.85	2.8 ± 0.69
7th day	2.7 ± 0.86	2.6 ± 0.82
28th day	1.65 ± 0.93	1.5 ± 0.60
t value	0.617	
p value	>0.10	
Statistical result	insignificant	

Table 5: Intergroup comparison of test group vs control group on nocturia

Nocturia (Mean ± S.D.)	Test Group	Control Group
0 day	1.85 ± 0.67	1.3 ± 0.73
7th day	1.5 ± 0.76	1.1 ± 0.78
28th day	0.95 ± 0.68	0.65 ± 0.48
t value	1.64	
p value	>0.05	
Statistical result	insignificant	

Table 6: Intergroup comparison of test group vs control group on frequency

Frequency (Mean ± S.D.)	Test Group	Control Group
0 day	1.15 ± 0.36	1.3± 0.73
7th day	1.05 ± 0.51	1.1 ± 0.78
28th day	0.4 ± 0.50	0.65 ± 0.48
t value	0.71	
p value	>0.01	
Statistical result	insignificant	

Table 7: Intergroup comparison of test group vs control group on incontinence

Incontinence (Mean ± S.D.)	Test Group	Control Group
0 day	0.95 ± 0.99	0.6 ± 0.88
7th day	0.75 ± 0.91	0.55 ± 0.82
28th day	0.5 ± 0.51	0.3 ± 0.47
t value	0.99	
p value	>0.01	
Statistical result	Insignificant	

Table 8: Safety assessment in test group (n=20)

Parameters		Assessments		
		0 Day	10th Day	28th Day
Hemoglobin		13.42 ± 0.98	13.08 ± 1.03	13.34 ± 0.76
RBC		4.44 ± 0.17	4.43 ± 0.05	4.49 ± 0.07
TLC		8525 ± 849.1	8830 ± 899.76	8595 ± 891.17
DLC	Neutrophils	74.51 ± 2.70	73.89 ± 3.25	72.51 ± 5.39
	Lymphocytes	24.08 ± 1.83	24.72 ±2.36	25.16 ± 2.46
	Monocytes	0.91 ± 0.91	0.84 ± 0.78	0.93 ± 0.60
	Eosinophils	1.01 ± 0.98	0.86 ± 0.64	0.93 ± 0.61
	Basophils	0.22 ± 0.12	0.24 ± 0.13	0.28 ± 0.07
LFT	SGOT	23.58 ± 3.03	23.69 ± 2.31	23.26 ± 2.41
	SGPT	27.61 ± 3.04	27.77 ± 3.05	27.04 ± 2.62
	S. Alk.Phos.	1102.52 ± 9.63	99.70 ± 9.91	98.6 ± 8.61
KFT	B. Urea	24.27 ± 5.01	22.65 ± 3.33	20.24 ± 1.06
	S. Creatinine	0.95 ± 0.25	0.9 ± 0.15	0.9 ± 0.05

*Values with plus/minus signs are expressed as Means + S.D.

Table 9: Safety assessment in control group (n=20)

Parameters		Assessments		
		0 Day	10th Day	28th Day
Hemoglobin		13.25 ± 0.98	13.22 ± 1.06	13.1 ± 0.81
RBC		4.50 ± 0.09	4.49 ± 0.08	4.52 ± 0.07
TLC		8660 ± 799.61	8545 ± 717.8	8020 ± 721.54
DLC	Neutrophils	73.65 ± 2.6	73.56 ± 2.34	72.04 ± 1.92
	Lymphocytes	24.87 ± 2.48	25.12 ±2.48	26.5 ± 2.39
	Monocytes	0.93 ± 0.6	1.08 ± 0.63	1.06 ± 0.36
	Eosinophils	1.03 ± 0.68	1.09 ± 0.63	1.21 ± 0.5
	Basophils	0.29 ± 0.03	0.29 ± 0.05	0.29 ± 0.04
LFT	SGOT	23.92 ± 2.37	23.08 ± 2.03	22.6 ± 2.28
	SGPT	28.25 ± 3.3	28.25 ± 3.5	25.73 ± 2.31
	S. Alk.Phos.	1049.52 ± 5.76	102.8 ± 4.57	98.05 ± 2.01
KFT	B. Urea	22.3 ± 1.83	20.75 ± 1.25	20.09 ± 1.06
	S. Creatinine	0.95 ± 0.06	0.91 ± 0.06	0.86 ± 0.06

*Values with plus/minus signs are expressed as Means + S.D.

5. Summary and Conclusion

The present study has been carried out in the Department of Moalijat of Ayurvedic and Unani Tibbia College and Hospital, Karol Bagh, New Delhi. The subjects were allocated into two groups, 20 in test group and 20 in control group on the basis of lottery method randomization. Those falling under Test group were given a semisolid polyherbal Unani classical Formulaton "Majoon Qust" twice a day

orally and Control Group is treated with tablet Urikind (Flavoxate) 200 mg of Mankind Pharmaceuticals two times in a day after meal. The duration of protocol therapy was 28 days/ 4 weeks. The efficacy of the drugs was evaluated on follow up visit on 7th day and 28th day on the basis of subjective parameters of Overactive Bladder Symptoms Score (OABSS) BY Homma *et al*. The safety evaluation was done on 10th day and 28th day based on hemogram, liver and kidney functions. Both the groups were compared for efficacy and safety parameters.

The observations were tabulated and statistically analysed by calculating the mean standard deviation followed by paired 't' test of the data recorded before and after the treatment.

The follow up observations and results are summarized as follows:

6. Demographic parameters: The sex ratio of the patients was typical for patients of Overactive Bladder i.e., belongs to female class (52.5%). Most of the patients were married (75%) and belonged to Home makers class (40%). The history of alcohol intake was positive only in 12.5% of cases. Majority of the patients had Phlegmatic temperament (Balghami mizaj) (50%).

7. Clinical Features: The clinical features of Overactive Bladder were recorded before treatment and during the follow up of the study to observe the improvement. In the test group, there was improvement of 43.2% in urinary urgency symptom, 65.3% in frequency, 48.7% in nocturia and 50% in incontinence at the end of study. In the control group, there was an improvement of 46.5% in urinary urgency, 68.2% in frequency, 50% in nocturia and 42.9% in incontinence at the termination of trial.

8. Safety Assessment: The safety and tolerability of the Test drug and the Control drug were tested and statistically analyzed at baseline, on the 7th, and on the 28th day. The outcomes of both trial groups were found to be statistically insignificant. Hence, both the Test and Control drugs are neither hepatotoxic, nephrotoxic nor has any hematological toxicity.

On the basis of above-mentioned observations, it may be concluded that the test drug was effective and safe in the management of Overactive Bladder. There was significant reduction in Urinary Urgency, Nocturia, Frequency, and Incontinence. There was marked improvement in the overall Quality of the Life of the patients suffering from the OAB.

9. Conclusion

- It may be concluded that the Test formulation and Control drug used in this study were found to be statistically effective in the management of Overactive Bladder as they have significantly reduced clinical parameters of the disease i.e., Urinary Urgency, nocturia, frequency and incontinence.
- The Test formulation was well tolerated and no adverse/ side effects were observed during the entire period of protocol therapy.
- The quality of the life of the patients participating in the test group was more improved as this group has better control in the symptoms of incontinence.

In view of the data in terms of efficacy and safety generated from present study, the Test drug has been found to be equally effective in the management of Overactive Bladder as of Control drug. However, the Test drug being natural and herbal in origin is more patient friendly in the long-term treatment of Overactive Bladder.

10. Limitations of the study

- In the present study, the sample size was very small due to shortage of time on account of post-graduation clinical research study.
- There was lack of sophisticated investigation facilities for diagnosis and efficacy assessment in the institution in respect of Overactive Bladder Syndrome.
- Owing to shorter duration of the clinical trial the sustained effect of Test drug in controlling the symptoms of OAB could not be evaluated.

11. Future scope of the study: To generate the comprehensive data of "Majoon Qust" in the management of Overactive Bladder Syndrome in terms of safety and efficacy, a large sample sized multicentric clinical trial with better research protocol by including more sophisticated investigations needs to be conducted.

12. References

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