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CLINICAL STUDY TO VALIDATE THE THE EFFICACY AND SAFETY OF UNANI FORMULATION IN U.T.I (E-coli induced)

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ABSTRACT

Urinary tract infection (UTI) refers to both microbial colonization of the urine and tissue invasion of any structure of the urinary tract, or the presence in an appropriately collected mid stream specimen of urine (MSU) of more than colony forming units per ml of urine. UTI occurs predominantly in females specially during the child bearing age. Its incidence among school girls is 1-2 %. It is only 0.03% in boys of the same age. Also the incidence in females rises about 1% per decade. Gram -ve bacteria E-coli is most commonly responsible, although yeast, fungi and viruses may produce UTI. In unani literature there is no specific term coined for Urinary tract infection. But the aetiopathogenesis, clinical features and managements have been described by most of the Unani Physicians under different heading i.e. *Warm-e-kuliya, Warm-e-masana, Hurqat-e-baul* and *Taqtir-ul-baul*. The general guidelines for the management of urinary tract infection (*Tadia-majra-e-baul*) in unani system of medicine include, use of anti- inflammatory drugs, excretion of rotten humour and use of diuretics. The unani drugs being safe, efficacious, easily available, cost effective and above all free from after effects of medications can play an important role in eradication of this problem if properly researched. Unani system of medicine uses holistic approach, the trial drug shows significant improvement overall in symptoms & signs and laboratory findings of the disorder as well as when compared to the standard control group. The formulation was found effective and completely safe in Urinary tract infection.

KEYWORD: *Warm-e-kuliya, Warm-e-masana, Hurqat-e-baul* and *Taqtir-ul-baul.*

INTRODUCTION

Warm-e-Majra–e-Baul means inflammation of urinary tract which may be infectious (*mutaaddi*) or non-infectious (*ghair mutaaddi*) in type. *Warm-e-majra–e-baul* is a term which has been adopted and used recently in unani literature[1] but in classical unani literature, this term does not exist as such but various descriptions of '*warm-e-majra-e-baul*' are available under different nomenclature such as *Warm-e-Masana* (Cystitis), *Warm-e-kulliya* (pyelonephritis),[2,3,4,5,6,10] '*Hurqat-e -baul*[2,4,5,6] and '*Warm-e-ahleel* (urethritis).[10],

Which may be considered as synonymous of urinary tract infection with clinical finding of urinary tract infections described in contemporary literature.

If we trace from antiquity to modern era there is substantial evidence that the disease existed even in ancient times "*Hurqat-e-baul*'(burning micturition) is described invariably as an important manifestation of disease in the ancient system of medicine in greek. A renowned physician of unani system of medicine, *Abu bakr mohammad bin zakaria al-razi* (838-925 A.D) has described *Hurqat-e-baul* in his book *Al-havi fi-al-tib (vol. 10). Ibn-sina* (avicenna) has described '*Hurqat-e-baul*' as a disease in his book '*Al-Qanoon*' (vol. 3). When we compare the modern concept, the concept perceived by '*Hurqat-e-baul*' is not very much different to U.T.I moreover, the concept of '*Ufoonat*' (sepsis) in relation to '*Hurqat-e-baul*' is described in many classical unani textbooks.

The term '*Hurqat-e-baul'* (burning micturition) is one of the symptoms of urinary tract infection. It was customary that time that the diseases were given nomenclature on their prominent sign or symptom. Though the term *Warm-e-majra-e-baul* (urinary tract inflammation or infection) has not been mentioned as such in Unani literature. but the etiology, symptoms and treatment with '*Muhallilat*' (anti inflammatory) and '*Daf-e-afoonat*' (antiseptic) clearly indicate that the term '*Warm-e-majra–e-baul*' has been described with the term '*Hurqat-e-baul*'.

Concept of infection and infestation are being postulated by various ancient as well as modern scholars dates back. Robert Koch (1843-1910) is supposed to be the pioneer for enlighting the concept of infection and its association with microbes.[7,8,9], Although there is no description of any kind of microorganism by name in the ancient literature, but from the

careful survey of the *Tibbi* literature it is evident that the Arab Physicians were well conversant with the process of infection to which they named as *Tadyiah* (infection) and *Ufoonah* (Putrifaction). The unique method adopted by *Al-Razi* (Rhazes) to choose the most suitable and healthiest site for construction of the hospital building also bears testimony to the fact that he was aware of the presence of microorganisms. Avicenna in his famous book *Al-Qanoon* has mentioned the microorganism as *Ajsam* khabisah.[11]

Urinary tract infection (UTI) refers to both microbial colonization of the urine and tissue invasion of any structure of the urinary tract, or the presence in an appropriately collected mid stream specimen of urine (MSU) of more than colony forming units per ml of **urine.** UTI occurs predominantly in females specially during the child bearing age. Its incidence among school girls is 1-2 %, it is only 0.03% in boys of the same age. Also the incidence in females rises about 1% per decade. With the advancement in medical science, the *concept* of infection came into existence. Various uropathogens were identified in the urine samples and then the word urinary tract infection as used as a disease. The urinary tract infection implies multiplication organisms in the urinary tract. It is usually associated with the presence of more than 100,000 organisms/ml in a midstream sample of urine (MSU) also termed as significant bacteriuria. It may or may not be symptomatic. When it is not symptomatic, the term asymptomatic bacteriuria is used which refer to large number of bacteria in the urine without producing symptoms. The urinary tract is common site for bacterial. It include upper urinary tract infection (Acute Pyelonephritis, Chronic Pyelonephritis) and lower urinary tract infection (Urethritis. Prostatitis, Cystitis).

The most common bacteria responsible for U.T.I is E. Coli (85%)[12] and staphylococcus Saprophyticus (10%) the other organism responsible for U.T.I are Pseudomonas, Klebsiella, Proteus, Enterococcus and Enterobacter etc. The symptoms of acute UTI depend on a large extent on the anatomical site of infection i.e., whether the patient has lower or upper U.T.I or both. Lower U.T.I (Acute cystitis) characterized by superficial bacterial infection of the bladder or urethra or both. These patients have a short duration of symptoms, including some combination of dysuria, frequency of urination, urgency, nocturia, haematuria and suprapubic pain or tenderness. Fever or flank pain or tenderness are absent. In contrast, patients with acute upper U.T.I (Acute pyelonephritis) classically present with localized flank pain or lower back or abdominal pain, and systemic symptoms such as varying degree of fever, headache, nausea, vomiting, rigors, sweats and malaise. A few patients may even develop

complications such as intrarenal or peninephric abscess and gram-ve sepsis. Not infrequently, such cases also have antecedent or concomitant symptoms of cystitis.[13]

As per the literature of Unani system of medicine, In management of *Tadia-e-majra-e-baul* the following *Usool-e-ilaaj* recommended.

- ***Muhallil-e-warm***(Anti-inflammatory)
- ***Muddir-e-baul*** (Diuretic)
- ***Musshil-e-akhlaat-e-khaam*** (excretion of rotten humour)
- ***Musakkin-alam*** **(**analgesic)
- ***Daff-e-ufoonat*** (anti-septic)
- ***Daff-e-humma*** **(**anti-pyeritic)

Therefore on the basis of above *usool-e-ilaaj*, compound drug ‘*’Qurs-e-Suzak*’’ is considered to be a novel combination for the treatment of disease of *Tadia-e-majra-e-baul* and it is also being used in the treatment of ‘*Suzak*’ from many decades as an Anti-microbial without any significant side effect.

This study is proposed to be conducted to generate data regarding the efficacy & safety of **‘*’Qurs-e-suzak*’’** in “***Tadia-e-majra-e-baul***”(E.coli induced U.T.I.), and to be given a scientific orientation so as to make it more acceptable to people in this scientific era.

MATERIAL AND METHODS

1. Study Site

The proposed study was conducted in the department of Moalijat Deptt. in A & U Tibbia College & Hospital, Karol Bagh, New Delhi–05,

2. Study Design

The study was designed as an Open, randomized, standard controlled trial.

3. Study Population

Individuals of both the sexes between the age group of 18-65 years.

4. Study Duration

Two Years.

5. Duration of Protocol Therapy

The treatment period in test and control groups was fixed as 21 days and 14 days respectively.

6. Sample Size

In the proposed study, number of the subjects participating were 40:20 in each group.

7. Trial Drugs & Dosage

Group-A (Test-group): Treated with '*Qurs-e-Suzak*' (Tibbi Dawakhana Aligarh) 2tab. B.D. orally for 21 days.

Group B (Control group.): treated with standard control drugs- Tab. Ofloxacine-200mg (Cipla co.) 1B.D orally for 14 days.

8. COMPOSITION OF THE TEST DRUG

S.No.	Ingredient	Scientific Name	S.No.	Ingredient	Scientific Name
1.	Shora qalmi	*Potassium nitrate*	10.	Habb-e-kaknaj	*Physalis alkeknegi linn*
2.	Hajrul yahood	*Lapis jaudaicus*	11.	Tabasheer	*Bambusa arundenacia*
3.	Raal safaid	*Vatera indica linn*	12.	Khar-e-khasak	*Tribulus terristris*
4.	Sang-e-jarahat	*Soap stone*	13.	Shakh marjaan sokhta	*Corallium Rubrum*
5.	Alu – balu	*Prunus.cerasus Linn*	14.	Busud Ahmar sokhta	*Corallium rubrum*
6.	Kaat safaid	*Acacia catechu wild*	15.	Zeher-e-mohra	*Serpentine*
7.	Dammul akhwain	*Dracaena ombet*	16.	Samag-e-arbi	*Acacia Arabica willd*
8.	Kateera	*Stericulia urenus*	17.	Arq-e-badiyaan	*Foeniculum vulgare mill*
9.	Bisbasa	*Myristrica fragrance houtt*			

9. Subject Evaluation

Subjective evaluation performed and recorded at the baseline, weekly and after completion of drug schedule.

Laboratory evaluation performed and recorded at the baseline, and after completion of drug Schedule.

10. Criteria for Selection of Patients

Diagnostic Criteria

Diagnosis made on the basis of

- Clinical presentation

- Urine- routine & microscopic(pus cells- above 4 in M & 5 in F)
- Urine-culture.

Inclusion criteria

- Diagnosed patients of E.Coli induced U.T.I. (by urine c/s test).
- Patients of either sex between the age group of 18-65 years.
- Patients not talking any other drugs for E.Coli induced U.T.I.
- Patients who are willing and able to provide informed consent.
- Patients who are willing and able to understand and follow the protocol for the duration of the study.

Exclusion criteria

- Patients taking any other drugs for E.Coli induced U.T.I.
- Patients with urinary tract stricture or any anatomical abnormality.
- Patients with diabetes mellitus.
- Patients with uncontrolled hypertension.
- Patients with cardiovascular complications.
- Patients with hepatic abnormality or renal disease.
- Pregnant and lactating women.
- Patient with STD`s or HIV 1 & 2
- Patients not willing to report for follow up.

11. Withdrawal Criteria

- Failure to consume the drug.
- Failure to report for follows up.
- Any significant adverse drug reaction or adverse event.
- Intake of any other concomitant drug for UTI.

12. Assessment of Temperament (*Mizaj*)

Temperament of each patient was assessed on the basis of ten classical parameters (*Ajnase-Ashra*) as prescribed in Unani medical literature.

13. Criteria For The Assessment Of Efficacy

Subjective Parameters will be used to assess the efficacy of the test drugs

- Dysuria

- Increased frequency of micturition
- Fever with chills and rigor
- Hematuria
- Pyuria
- Pain in loin & suprapubic region

These will be estimated on day 0, 7^{th}, 14^{th} 21^{th} day.

Objective parameters will be used to assess the efficacy of the test drugs:-

- Urine- routine & microscopic (pus cells)
- Urine-culture.

These will be estimated pre-treatment & post treatment.

Grading For Subjective Parameters

- **Burning micturition /Dysuria**

0=Absent/No Itching.

1=Mild burning and pain during voiding/Occasional episodes.

2=Moderate burning and pain during voiding /uncomfort to void.(In this grade pt. feel burning and pain more but not as much as it don't force to stop the voiding due to pain and burning.).

3=Severe burning and pain during voiding.

(In this grade pt. feel burning and pain during voiding as much as pt. desire to stop the voiding due to pain and burning.).

- **Frequency of micturition**

By the counting of no. of times micturition has done.

Grade 0= Micturition 1-3 times/day

Grade 1= Micturition 4-7 times/day

Grade 2= Micturition 7-9 times/day

Grade 3= Micturition >9 times/day

- **Fever with chill**

Grade 0=<99.0F^0

Grade 1=99-101F^0

Grade 2=101-103F^0

Grade 3=>103F^0

- **Pain in abdomen**

Grade 0=Absence of pain

Grade 1=Mild –donot disturb the routine

Grade 2=Moderate- disturb the routine

Grade 3=severe-Rolls on bed due to pain

- **Pus cells**

Grade 0=1-5

Grade 1=5-10

Grade 2=10-25

Grade3=>25

- **Hematuria**

Grade 0=0 rbc (clear)

Grade 1=0-3rbc (microscopic)

Grade 2=3-5rbc (pink in color)

Grade 3=>5 rbc

Bacteuria Grade

	Bacteuria	**Becteuria+ symtomps**		**Bacteuria**	**Becteuria+ symtomps**
Grade 0	<10^4CFU/ml urine	<10^2CFU/ml urine	Grade 2	<10^6CFU/ml urine	<10^4CFU/ml urine
Grade 1	<10^5CFU/ml urine	<10^3CFU/ml urine	Grade 3	>10^6CFU/ml urine	>10^4CFU/ml urine

The following examinations performed for the exclusion of any concomitant acute and chronic diseases.

- **Complete Blood Count-** To rule out infections.
- **Blood Sugar Random-**To rule out diabetes.
- **VDRL-**To rule out STD's.
- **HIV 1 & 2-** To rule out HIV infection.
- **KFT-** To rule out CRF.

These routine examinations was done before the commencement of protocol therapy.

14. Parameters For Assessment of Safety

The safety was assessed by monitoring adverse events either volunteered by the patients or elicited by the investigator by monitoring the following investigations at baseline, after one week and at the termination of the study.

- **Kidney Function Test (KFT):** Blood Urea, S. Creatinine.
- **Liver Function Test (LFT):** S. Bilirubin, SGOT, SGPT, Alk. Phosphatase.

Statistical analysis was restricted to those patients who completed the full duration of the study. Student't' Test was used to analyze the efficacy of unani formulation. The confidence level was set to be at $p<0.05$ for significant result of unani formulation.

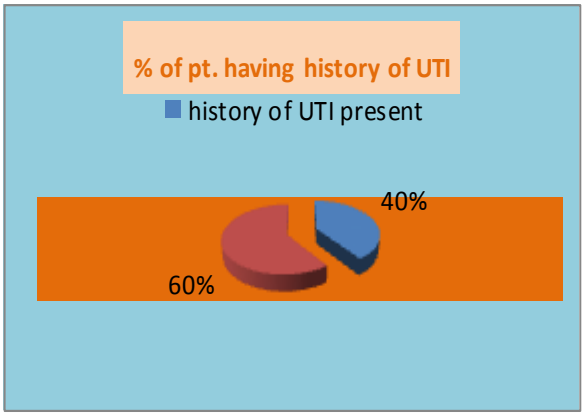
RESULTS AND DISCUSSION

Baseline characteristics

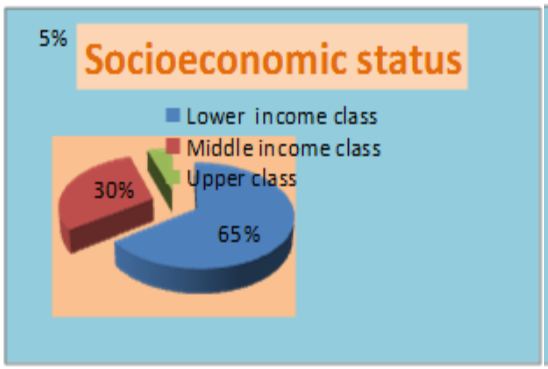
During the study all the patients were divided into five age groups viz 18-27 years, 28-37 years, 38-47 years, and 48-57 years, 57-65 years. It was observed that maximum number of cases 16 *(40.00%)*, belonged to age group of 18-27 years, 13 cases (32.5%) fell in the age group of 28-37 years. 7 cases (17.5%) in the age group of 38-47 years, 4 cases (10%) in the age group of 48-57 years and *0* cases in the age group of 58-65 years. Among the 40 patients, 25 cases (62.5%%) were females and 15(37.5%) were females. This shows Female predominance to develop Urinary tract infection.

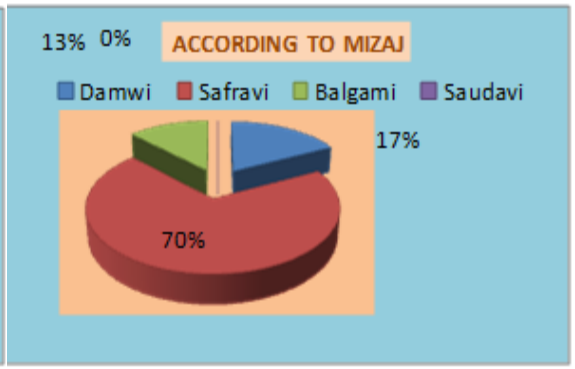
Age group	Number and Percentage Male	Female	Total number and %
18-27	8..20%	8..20%	16…40%
28-37	3…7.5%	10..25%	13….32.5%
38-47	2…5%	5..12.5%	7…..17.5%
48-57	2...5%	2..5%	4…..10%
58-65	0	0	
Total	15…37.5%	25….62.5%	40…..100%

In this study, all the cases were divided according to the present and not present the history of previous UTI. 16 cases (40.0%) had the history of previous attack of urinary tract infection.) Positive history of previous infection of urinary tract was present in 40 percent cases. This observation is quite similar to the description given in the various text books.



(According to the socio-economic status all the patients were divided into three groups i.e. Lower class, lower middle class and upper middle class. 26 cases *(65%)* belonged to lower class while the number of cases belonged to middle class and upper middle class were 12 cases (30.0%) and 2 cases (5%) respectively.





It is evident that maximum number of' patients belonged to lower middle class

While carrying out this study. all the patients were divided into two groups according to their mizaj . it was observed that only 7 pt. had damwi mizaj,28 safraavi mizaj,and 5 had balgami mizaj

RESULT: The presenting symptoms at baseline of selected person

	Presenting Symptom	No. of Subjects presented with % at baseline			
		Grade 1	Grade 2	Grade 3	Grade 4
Test grp.	Dysuria	0	12(60%)	8(40%)	
	Increased frequency of micturition	0	9(45%)	8(40%)	3(15%)
	Fever with chills and rigor	0	8(40%)	7(35%)	4(20%)
	Hematuria	0	5(25%)	4(20%)	0
	Pain in loin & suprapubic region	0	6(30%)	4(20%)	0
	Pyuria	0	8(40%)	7(35%)	5(25%)
	Urine culture	0	11(55%)	7(35%)	2(10%)

	Presenting Symptom	No. of Subjects presented with % at baseline			
		Grade 1	Grade 2	Grade 3	Grade 4
Cntrl grp.	Dysuria	0	11(55%)	8(40%)	1(5%)
	Increased frequency of micturition	0	12(60%)	7(35%)	1(5%)
	Fever with chills and rigor	0	7(35%)	6(30%)	2(10%)
	Hematuria	0	8(40%)	5(25%)	0
	Pain in loin & suprapubic	0	11(55%)	2(10%)	1(5%)

	region				
	Pyuria	0	8(40%)	7(35%)	5(25%)
	Urine culture	0	10(50%)	7(35%)	3(15%)

From the observations in the test group, it is evident that maximum effect was found on Pain in loin & suprapubic region (90%), followed by Hematuria which were subsided in 88% cases, followed by Fever with chills and rigor, Pyuria, and Urine culture (85% cases), Dysuria and Increased frequency of micturition (80% cases), (Table). In the present study, decrease in "pus cell" and bacteria in urine (urine culture) was found statistically extremely significant (p value <0.0001) using paired t-test in both test and control groups. While using unpaired t-test for the comparison of post study outcomes in both test and control groups, result found was not statistically significant (p value=0.9577).

	Presenting Symptom	Effect of drug(after trtmnt)		
Test grp		**0 day**	**21 day**	**% change**
	Dysuria	20	4	80%
	Increased frequency of micturition	20	4	80%
	Fever with chills and rigor	19	2	85%
	Hematuria	9	1	88%
	Pain in loin & suprapubic region	10	1	90%
	Pyuria	20	3	85%
	Urine culture	20	3	85%
			14 Day	
Cntrl grp.	Dysuria	20	5	75%
	Increased frequency of micturition	20	5	75%
	Fever with chills and rigor	15	3	80%
	Hematuria	13	2	85%
	Pain in loin & suprapubic region	14	2	86%
	Pyuria	20	3	85%
	Urine culture	20	2	95%

Whereas, extremely significance is, the decrease in "pus cell" and bacteria in urine (urine culture) was observed in both the groups, while using paired t-test between before treatment and after treatment values. Which is indicative of that "pus cell" and bacteria in urine (urine culture) has significantly decreased after treatment in both the groups Adverse Effects:

In the present study 2 (10%), 3(15%) and 2(10%) patients were reported for constipation, diarrhoea and abdominal pain respectively in control group. Whereas none of the patients in

test group reported for any adverse effects. It is observed that the test drug does not have any adverse effect.

Safety Assessment for both Groups

Safety Parameters	Test Group			Control Group		
	BT	OW	AT	BT	OW	AT
TLC	7827±1684	7980±1447	7297±1759	8680±1622	7600±1663	7330±1628
Poly	54.67±6.32	52.93±6.55	53±8.49	54.47±8.59	53.37±6.99	53.23±5.45
Lympho	31.70±5.79	30.20±5.20	30.40±8.08	30.03±7.23	29.33±4.25	28.63±5.46
ESR	17.77±3.39	15.73±4.33	13.33±4.36	18.33±3.78	16.63±4.04	14.33±3.22
S.Bil	0.7±0.16	0.7±0.15	0.6±0.22	0.8±0.18	0.8±0.19	0.6±0.21
SGOT	26±8.4	24±5.8	26±7.2	26±7.1	23±7.3	26±8.4
SGPT	30±6.6	31±5.79	35±8.1	32±7.2	29±7.7	29±6.8
S.Creat	0.8±0.15	0.8±0.29	0.8±0.15	0.8±0.12	0.8±0.18	0.7±0.13
B.Urea	22±7.4	24±4.1	21±6.1	22±7.6	22±5.3	21±7.5
BSR	95±11.4	98±13.2	89±15.7	92±10.2	96±13.1	95±14.5

CONCLUSION

The aim of the present study was to evaluate an alternative regimen for the management of UTIs. Tested Unani formulation comprising of *Sat-Behroza, Ral Safaid, Shora qalmi, Kaphoor* and other drugs showed significant antibacterial effect on the patients suffering from UTIs resulting in the change of urinary composition significantly.

The results were assessed for their statistical significance by using paired t-test and unpaired t-test. It was found that the test group patients had shown better response in most of the clinical sign and symptoms than control group. Statistically significant improvements were also recorded in hematological values in both groups by using paired t-test whereas, while applying unpaired t-test for post outcomes of both groups (test and control) for pus-cells and bacteuria result was not found statistically significant. None of the patient in test group reported any adverse effect attributable to test drug. Hence, it may be concluded that the test drug is effective and safe in the management of iron deficiency anemia.

Scope for Further Study

The present clinical trial to evaluate the Efficacy & Safety of Unani Formulation "*Qurs-e-Suzak*" in UTI was in itself, properly planned and executed according to the protocol. Best possible efforts were made to achieve accurate and conclusive results in the study. Nevertheless no research is complete and there is always room for further improvement. The present study, being a time bound programme, the sample size was small (40 patients). Looking at the positive and encouraging results in the present study, it is sincerely felt, that

with a larger sample size subjected to certain other sophisticated investigations, more in-depth analysis could be carried out.

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