Therapeutic Evaluation of Safuf Mudir and Sharbat Bazuri Motadil in Urinary Tract Infections (Tadiya Majra-e-Baul)

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Abstract

Urinary tract infection is an inflammatory response of urothelium to bacterial invasion. These infections fall into two anatomic categories; the lower urinary tract infections comprising of urethritis and cystitis and the upper urinary tract infections comprising of pyelonephritis, prostatitis, and intrarenal and perinephric abscesses. In patients of such ailments Safuf mudir and Sharbat Bazuri motadil plays a drastic role. This study is therefore carried out to assess the efficacy and safety of the said drugs. Sixty patients satisfying the inclusion criteria were selected for the randomized single blind standard controlled study in the department of Moalijat Ajmal Khan Tibbiya College and hospital. All the patients were divided into test and control groups by random table numbers. 6 gm of Safuf Mudir and 20 ml of Sharbat Bazuri motadil were prescribed twice daily for 21 days to 40 patients (Group A). The study was designed by a control group of 20 patients in which Ofloxacin 200 mg was prescribed twice daily for the same duration (Group B). The assessment was carried out at weekly intervals. The data were analysed biostatstically.

Key words: Urinary tract infection, Safuf Mudir, Sharbat Bazuri

Introduction

Urinary tract infections (UTIs) account for a vast majority of patients attending the outpatients department. Throughout the world, there are about 150 million cases of symptomatic UTI per year. Such infections have plagued mankind since even before the establishment of urology as a separate branch of medicine. They affect both males as well as females, but females are at a higher risk due to the anatomy of their urinary tract. The prevalence of UTI in females is about 3% at the age of 20, increasing by about 1% in each decade (Boon, 2006). It may be defined as an inflammatory response of the urothelium to bacterial invasion. Although the concept of infection was not so clearly mentioned in Unani literature, their clinical presentations are vividly described by our ancient Unani physicians. It has been mentioned by various names in Unani text like warm-e-kulliya, warm-e-masana, and hurqatul baul. The names are either according to the site of infection or according to one of the most distressing symptoms. They may be collectively known as tadiya majra-e-baul. According to modern medicine UTIs fall into two general anatomic categories: the lower urinary tract infections comprising of urethritis, and cystitis, and the

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upper urinary tract infections comprising of pyelonephritis, prostatitis, intrarenal and perirenal abscesses. From a microbiologic perspective, it has been defined as the presence of more than one lakh organisms per ml in a midstream clean catch urine sample (Fauci *et al.*, 2008). The Infectious Diseases Society of America (IDSA) gave a slightly more relaxed consensus definition, requiring 10^3 organisms /ml to diagnose cystitis and 10□/ml for pylonephritis. In women with symptoms of uncomplicated cystitis, significant bacteriuria is now defined as 100 or more CFU (colony forming units) /ml in midstream urine plus pyuria, while in patients with uncomplicated pylonephritis and in men with UTI significant bacteriuria is defined as 10□ CFU/ml plus pyuria. In patients with complicated UTI 10□ or more CFU /ml with or without pyuria is taken into consideration (Goldman Lee, 2004). It is commonly caused by gram negative bacilli. Nearly 80% of infections are caused by *E.coli*, followed by *Proteus, Klebsiella,* and *Pseudomonas* species. Gram positive cocci play a lesser role. They include *Staphylococcus aureus, Sterptococcus epidermidis,* and *Enterococci*. The patient may present with dysuria, urgency, increased frequency of micturition, pain in abdomen, fever with chills nausea, vomiting, diarrhea, tachycardia, hematutria, pyuria (Fauci *et al*, 2008). According to the unani concept it is due to the disturbance in asbab-e-sitta zaruria and weakening of tabiyat mudabbir-e-badan, which may be regarded as the predisposing factors for derangement in kamiyat (quantity) and kaifiyat (quality) of akhlat or humors (Ahmad, 1980). This derangement may favour the growth of ajsam-e-khabisa. Among its causes weakness of excreatory function and inflammation of the neck of urinary bladder are also mentioned (Kanturi, 1889). Hippocrates, in his treatise Al-fasul, described taqtirul baul and stated that this disease is characterized by increased frequency of micturition which is due to the debility of the urinary bladder. Burning micturition as well as sepsis of the urinary tract also occurs (Razi, 2002). Tadia majra-e-baul may also occur due to exposure to cold and rain water. Other causes include consumption of alcohol and certain toxic drugs. Renal trauma and pregnancy may also predispose to the disease. Sometimes it occurs as a complication of certain infectious diseases like humma-e-mewi (tyhoid), khasra (measles), humma-e-ajamia (malaria), sarsam (meningitis) and khunnaq (diphtheria). Ufoonat-e-dam is also included among its causes. Warm-e-masana haad (acute cystitis) occurs due to deranged safra that is bile (Kabiruddin, 2009). Dysuria, burning micturition, cystitis and nephritis are not only described in detail but their management was also not beyond the approach of Unani scholars. Several regimes are mentioned in Unani pharmacopoea both in single as well as in compound formulations which have been in practice by Unani physicians. Now it is the need of the hour to test these drugs on modern parameters and to

make them evidence based. We therefore undertook this study to clinically evaluate the efficacy and safety of Safuf Mudir and Sharbat Bazuri Motadil, in the patients of UTIs. Composition of both the drugs is given in table-6.

Material and Method

This study was an experimental randomized controlled trial performed over the period extending from 2010 to 2011 i.e. one year at the outpatients and inpatients department of Moalijat, A.K. Tibbiya College & Hospital, AMU, Aligarh. All the GCP-ICMR guidelines were followed before and during the trial. Informed written consent was taken from the patients before their participation into the study. Sixty diagnosed patients, who met the criteria of age between 10-60 years, and belonged to either sex were selected for the study. Patients were diagnosed on the basis of subjective parameters like burning micturition, urgency, increased frequency of micturition, fever with chills, pain/tenderness in suprapubic region and loin. Objective parameters included haemogram, urine-routine and microscopic examination as well as culture, X-ray abdomen, random blood sugar, and USG abdomen. Liver function tests and kidney function tests were also done before and after the treatment. Patients below 10 years and over 60 years of age, those suffering from diabetes mellitus, hypertension, nodular hypertrophy of prostate and other concomitant diseases of the urinary tract were excluded from the study. Mentally retarded persons, pregnant and lactating mothers were also excluded from the study. All the patients were randomly divided into two groups, with forty patients in the test group and twenty patients in the control group. Safuf mudir (6 g) and Sharbat bazuri motadil (20 ml) were orally administered twice daily to the patients of the test group, while ofloxacin 200 mg was prescribed to the patients of the control group. Safuf Mudir is a herbomineral formulation, prepared at the pharmacy of Ajmal Khan Tibbiya Hospital, while Sharbat Bazuri Motadil is a herbal formulation from Bayaz-e-kabir Vol.II. Duration of treatment was three weeks and assessment was done at weekly intervals. Follow up was also maintained up to one month even after termination of the therapy in both the groups to observe any recurrence or re-infection. The data were analysed biostatistically by applying X^2 test.

Result and Discussion

Clinical evaluation was carried out on the basis of subjective and objective parameters. However, during the course of study it was observed that out of 60 patients enrolled in the study, the highest incidence (51.66%) was found in

the age group of 21-30 years, while the least incidence (6.6%) was found in the age group of 51-60 years. Gender wise 20 (33.33%) patients were males, while 40 (66.66%) patients were females. This shows female preponderance and it is in accordance with the established fact (Table -1). Also, 38 (63.33%) patients were married and 22 (36.66%) patients were unmarried. According to the socioeconomic status 44 (73.33%) patients belonged to the low income group (LIG), 15 (25%) belonged to medium income group (MIG), while, only 1 (1.6%) belonged to the high income group (HIG). High incidence among the LIG may be attributed to poor personal hygiene. Various nutritional deficiencies also predispose to develop UTIs. Out of 60 patients 35 (58.3%) had a previous history of UTI while 25 (41.6%) patients had no such history (Table-2). This may be due to re-infection rather than relapse. As far as temperament is concerned the highest incidence (53.33) was found in the patients belonging to the safrawi temperament, followed by damwi (23.3%), balghami (20.00%) and the least incidence (3.33%) was found in the patients of saudawi temperament (Table-3). This also in accordance with the established fact as most of the unani physicians maintain that it is mainly caused by Safra.

Table 1: Distribution of patients according to age and sex

Age groups (in years)	Males		Females		Total	
	No	% age	No	% age	Total	% age
10-20	3	5	5	8.3	8	13.3
20-30	10	16.7	21	35	31	51.7
30-40	4	6.7	5	8.3	9	15.0
40-50	2	3.3	6	10	8	13.3
50-60	1	1.7	3	5	4	6.6
Total	20	13.3	40	66.7	60	100.0

Effect of the drugs on dysuria (Table-4)

During the study maximum number of patients complained of dysuria. 95% patients in the test as well as in the control group had this complaint at the outset. But after the treatment 84.21 % patients in the test group and 84.12% in the control group showed improvement. The effect in the test group may be attributed to the soothing and cooling properties of tukhm-e-khayarain, tukhm-e-kharpaza, and bekh-e-kasni (Baitar, 2000; Chopra, 1958; Chugtai, 2000; Sala, 2003).

Table 2: Distribution of patients according to Social status, Marital Status, and H/O previous UTI

Social status	No.	% age
LIG	44	73.3
MIG	15	25.0
UIG	1	1.7
Total	60	100.0
Marital status		
Married	38	63.3
Unmarried	22	36.7
Total	60	100.0
H/O Previous UTI		
Present	35	58.3
Absent	25	41.7
Total	60	100.0

Effect of the drugs on Fever (Table-4)

In the test group 27 (67.50 %) had fever before the commencement of the treatment which was relieved in 70.37% cases after the treatment. It may be due to the antipyretic and cooling properties of tukhm-e-khayarain, tukhm-e-kharpaza (Baitar, 2000; Sala, 2003). In the control group, 13 (65%) patients had the same complaint, which was relieved in 84.81% cases.

Table 3: Distribution of patients according to Temperament

Temperament	No.	% age
Damwi	14	23.3
Balghami	12	20.3
Safrawi	32	53.3
Saudawi	2	3.3
Total	60	100.0

Effect of the drugs on pain and tenderness (Table-4)

About 45% patients in both the groups presented with pain in lower abdomen before the treatment. There was improvement in 72.22% and 88.88% patients

in the test and the control groups respectively. However, tenderness was present in 26 (65%) patients of the test group and improvement was observed in 76.92% patients. In the control group, tenderness was observed in 12 (60%) patients and it was improved in 83.333% patients after the treatment. The improvement in the test group may be due to the anti-inflammatory effect of tukhm-e- khayarain, tukhm-e-kharpaza, and heel kalan (Khan, YNM).

Effect of the drugs on pus cells and urine culture (Table-5)

Pus cells were present in 67.50% cases in the test group, which after the treatment became normal in 66.66% patients. While in the control group, they were present in 70% cases and became normal in 78.57% patients ($X^2 = 0.03$). Urine culture being a reliable objective parameter was positive in 34 (85%) cases in the test group, which after the termination of therapy became negative in 64.71% cases. In the control group it was positive in 18 (90%) patients and became negative in 77.77% cases after the termination of therapy ($X^2 = 0.29$).

In addition to the above-mentioned results, regression in other symptoms like urgency, nausea, vomiting and foul smelling urine was also noted. In the beginning urgency was present 15 (37.5%) and 6 (30%) of patients in the test and the control groups respectively. After the treatment, it was relieved in 66.6% and 83.3% patients in the respective test and control groups. Foul smelling urine was observed in 5 (12.5%) patients of test group and 4 (80%) patients were relieved by the test drug. While, 3 (15%) patients in the control group had this complaint and after the treatment there was 100% cure. Nausea and vomiting were present in least number of patients. Only two (5%) patients of test group complained it and one patient in the control group had this symptom. However, after the treatment with the test drug it was relieved in both the patients, that is, the cure was 100%, but it was not relieved in the patient of the control group. The effect may be attributed to the digestive properties of shora qalmi, jawakhar, heel kalan, and barg-e turb (Khan N.G. YNM). Above all, the effect of the test drug may be due to nuzuj and tanqiya as they are the main principles described by various eminent unani physicians. As far as UTI is concerned, the tanqiya may be mainly in the form of diuresis and most of the drugs in both the said compounds are diuretic like shora qalmi, jawakhar, barg-e-turb, tukhm-e-khayarain, tukhm-e-kharpaza, bekh-e-kasni and bekh-e-badiyan (Baitar, 2000; Khan, 1313H; Khan, YNM; Kirtikar, 1981; Lubhaya, 1982). These drugs may also alter the pH of urine. The overall effect of the test and the control drug is almost similar in both objective and subjective and parameters but during and after the termination of the treatment, several patients of the control group complained of abdominal discomfort, nausea

and decreased appetite, while in the patients of the test group there were no such complaints. The effect of the test drug is solely cumulative in relieving the symptoms and signs along with the improvement in appetite as well as general well-being.

Table 4: Effect of Drugs on Symptoms & Signs

Sings & symptoms	Test group n = 40				Control group n = 20			
Dysuria Increased frequency Urgency Fever Pain in abdomen Haematuria Nausea/ Vomiting Foul Urine Tenderness	No & % age				No. & % age			
	0day 38 95% 35 87.5 15 37.5% 27 67.5% 18 45% 4 10% 2 5% 5 12.5% 26 65%	7 day 19 47.5% 21 52.5% 12 30% 20 50% 11 27.5% 2 5% 1 2.5% 2 5% 18 45%	14day 12 30% 12 30% 8 22.5% 16 40% 9 22.5% 2 5% 0 0% 1 2.5% 13 32.5%	21 day 6 15% 7 17.5% 5 15% 8 22.5% 5 12.5% 1 2.5% 0 0% 1 2.5% 6 15%	0 day 19 95% 18 90% 6 30% 13 65% 9 45% 1 5% 1 5% 3 15% 12 60%	7 day 9 45% 5 25% 4 20% 7 20% 4 20% 1 5% 1 5% 2 10% 7 20%	14 day 4 20% 3 15% 4 20% 3 15% 2 10% 0 0% 1 5% 1 5% 3 15%	21 day 3 1.5% 3 15% 1 5% 2 10% 1 5% 0 0% 1 5% 0 0% 2 10%

Table 5: Effect of Drugs on Pus Cells and Urine Culture

Investigation	Test Group n = 40		Control Group n = 20	
Pus Cells	Before Treatment	After Treatment	Before Treatment	After Treatment
Present	27 (63.5%)	9 (35%)	14 (70%)	3 (15%)
Absent	13 (32.5%)		6 (30%)	
Total	40 (100%)	9 (35%)	20 (100%)	3 (15%)
X2 = 0.03				
Urine Culture				
Positive	34 (85%)	12 (30%)	18 (90%)	4 (20%)
Negative	6 (15%)		2 (10%)	
Total	40 (100%)	12 (30%)	20 (100%)	4 (20%)
X2 = 0.29				

Table 6: Composition of Test Drugs

Drug	Scientific name	Part used/Form
Safuf Mudir (All ingredients in equal quantities)		
Shora Qalmi	Potassium nitrate	Salt
Jawakhar	*Hordeum vulgare*	Salt
Heel Kalan	*Elitteria cardamomum*	Fruit
Berg-e-turb	*Raphanus sativus*	Leaf
Sharbat Bazuri Motadil (All ingredients equal except Bekh-e-Kasni which is twice)		
Tukhm-e-kasni	*Cichorium intybus*	Seed
Tukhm-e-khira	*Cucumis sativus*	Seed
Tukhm-e-kakri	*Cucumis utilissimus*	Seed
Tukhm-e-kharpaza	*Cucumis melo*	Seed
Bekh-e-badyan	*Foeniculum vulgare*	Root
Bekh-e-kasni	*Cichorium intybus*	Root

Conclusion

It is obvious from the study that the test and the control drugs have similar efficacy in almost all the subjective and the objective parameters. As for data analysis, X^2 test was applied and it was found that there is no significant difference between the test and the control groups regarding the efficacy (Table- 5). The test drugs also showed no apparent adverse effects as evident by laboratory investigations, which were done before and after the trial and showed no remarkable change. Therefore, we can conclude that the test drugs are effective as well as safe when prescribed to the patients of UTIs. But, after all, the exact mechanism of action is not known. Therefore, for any final conclusive data, it is mandatory to study more objectively with the collaborative approach and the involvement of modern pharmacologists and microbiologists.

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