

Clinical efficacy of Unani medicine Renax for treatment of Urolithiasis

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Abstract: Stone formation occurs most commonly in acute and chronic renal failure. A kidney stone is a solid lump made up of crystals that separate from the urine and build up on the inner surfaces of the kidney. The current study was conducted to investigate the clinical efficacy of Unani medicine Renax in comparison with allopathic medicine (Spironolactone + Furosemide) to treat urolithiasis. The study was conducted in District Dera Ghazi Khan, South Punjab region. This was case control, randomized, double blind clinical study. All patients were examined by the Physician and given either herbal or allopathic medicine for Urolithiasis. The patients were divided “into two groups” a control group and test groups. A Total of 24 patients were completely cured out of 50 by use of Renax while a total of 9 patients was cured out of 50 with allopathic medicine (Spironolactone + Furosemide). This study validated the claim of traditional healer for use of Unani medicine in the treatment of urolithiasis.

Keywords: Urolithiasis, allopathic medicine (spironolactone + furosemide), renax, comparative study, clinical trial.

INTRODUCTION

Urolithiasis is the oldest disease in human beings. Egyptian mummies have been found Urolithiatic back as far as 7000 years and symptoms of this disease were described by Hippocrates. In ancient times, only ureter stones were known and the stones of the kidney were not known. Roman scientists stated that diet, eating habits, climate, gout, race and some other factors cause urolithiasis (Saita *et al.*, 2007). Prevalence of urolithiasis is 15% in men and 6% in women. The ratio increases due to changes in eating habits, lifestyle, and obesity. Renal failure is a major risk factor for the development of urolithiasis. Some stones are hard and some are soft. In many cases, the stone may not come from the ureter. Stones cause pain, obstruction and blocking the flow of urine from the kidney (Victoriano *et al.*, 2010). The symptoms of the stones are severe pain or aching in the back on one or both sides, bloody, cloudy or smelly urine, feeling of being sick, urge to urinate or a burning sensation during urination, fever and frequent urination (Andrew, 2010). Mostly 50% of patients with stones suffer recurrences. There are various factors that may influence stone formation (Curhan *et al.*, 2005). In those people who have a low urine pH suffer from uric acid stones. Cysteine stones occur in cystinuria, a hereditary disorder of amino acid transport (Amato *et al.*, 2004). Allopathic medicine has better efficacy but exert side effects. Therefore, it is needed to investigate alternative

medicine, which would have better efficacy with fewer or no side effects and also cost effective. Various chemical ingredients obtained from medicinal plants have proven their efficacy and safety in the management of urolithiasis.

MATERIALS AND METHODS

Methodology

This study was conducted on the basis of clinical trials performed on the human beings with its comparisons to the modern allopathic drugs (Spironolactone + Furosemide). This was a double blinded, case control, a clinical study conducted on the patients belonging to the District Dera Ghazi Khan, Pakistan.

Ethical issues and clinical trial approval

A Study was conducted under the rules of the Ethical Committee (EC) of the Faculty of Pharmacy and Alternative Medicine, Islamia University of Bahawalpur, Pakistan.

Study design and protocols were presented to the board members of the Ethical Committee (EC) and Board of Advance Studies and Research (BASR) for their clearance and permission before the start of clinical trials.

The study has been conducted according to the principles of good clinical practice, i.e., a written informed consent was obtained from the patients before enrollment.

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Clinical evaluation proforma was filled up before starting the treatment and was consequently updated during the course of the treatment.

Diagnostic technique

Patients having urolithiasis related symptoms were enrolled in the study. Clinical trial proforma was filled up accordingly and changes were recorded during each follow-up visit. Further diagnosis of urolithiasis was made on the basis of urine examination and ultrasonography. The urine test was also done at baseline for the confirmation of infection and stone formation. Urine culture was also performed.

Methods/design

The current study was based on a double-blinded and randomized fashion. All included patients were examined by a physician. The patients with urolithiasis were treated with either herbal or allopathic medicine agents.”

Setting

The therapeutic investigations of these drugs were performed after the diagnoses of urolithiasis on clinical and biochemical evaluation at Eastern Medicine Clinic District Dera Ghazi Khan.

Eligibility

Age group: 10-60 years

Sex: Both men and women

Inclusion criteria

The patients included in the study were;

1. The patients suffering from urolithiasis.
2. Patients living in District Dera Ghazi Khan and its adjacent areas.
3. Patients who have no other chronic disease.

Exclusion criteria

The criteria for exclusion were:

1. Patients having chronic diseases such as hypertension and diabetes mellitus.
2. Patients having a surgical history of the kidneys.
3. Pregnant females were also excluded due to safety measures.

Sample size

This study comprises of 100 patients, 50 of the test drug and the 50 of control drug. This was a 3 week study. The patients were called back after every one week for follow up in 3 weeks of treatment.

Data collection

Data was collected by physicians through trial proforma at the start of the study, then patients were asked to come for follow up after every one week up to 3 weeks of treatment and changes in the clinical features were noted in the trial proforma.

STATISTICAL ANALYSIS

Statistical analysis was performed using statistical package for social sciences. Parametric Student’s t-test was applied to determine the p-value. The results were assumed to be significant if the p-value < 0.05.

Dosage form design

Control drug

The allopathic medicine (Spironolactone + Furosemide) 40mg tablets twice daily was prescribed to control group.

Test drugs formulation

Unani medicine, Renax 500mg tablets twice daily was prescribed to test group.

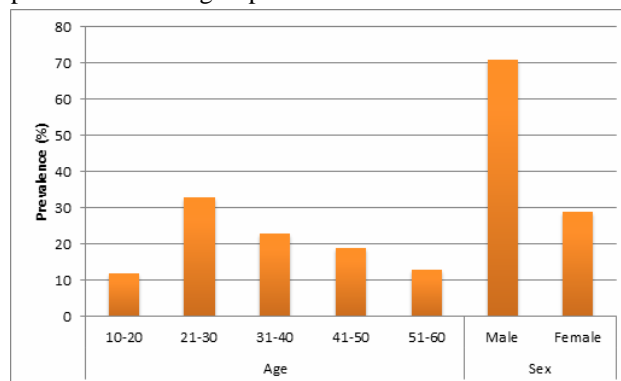
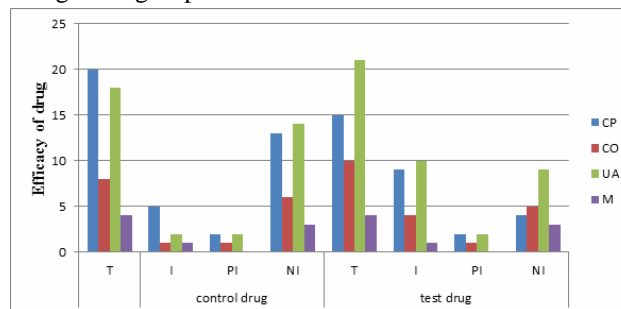


Fig. 1: Prevalence of Urolithiasis patients in different age and gender groups.



CP: Calcium phosphate stones; CO: Calcium oxalate stones; UA: Uric acid stones; M: Miscellaneous; T: Total Number; I: Improvement; PI: Partial improvement; NI: No improvement

Fig. 2: Efficacy of control and test drugs on various kinds of stones.

Renax

All the ingredients (*Cumunim cyminum* seeds, *Raphanus sativus* seeds, *Rheum officinale* seeds, *Citrullus lanatus*, Natrium phosphate and Potassium nitrate) of Unani medicine Renax were purchased from the Zakria Herbal Store Multan and were identified by Prof. Dr. Muhammad Zuhaib, Department of Botany, Govt. Post Graduate College District Dera Ghazi Khan. All the ingredients were cleaned thoroughly and ground to make a powder form. While the control drug (Spironolactone + Furosemide) was purchased from City Medical Store

Table 1: Experimental Design

Age distribution	10-20	21-30	31-40	41-50	51-60	Total	
Test drug	09	22	11	02	06	50	
Control drug	03	11	12	17	07	50	
Sex	Male			Female			
Test drug	33			17			50
Control drug	38			12			50

Table 2: Effect of test and control drug on sign and symptoms of urolithiasis

Sign and symptoms	Test drug			Control drug			P value
	First Round	2 nd Round	3 rd Round	1 st Round	2 nd Round	3 rd Round	
Pain in back	45	18	8	43	24	13	<0.05
Burning micturition	40	21	11	46	23	11	
Frequency of micturition	41	24	09	34	10	3	
Nausea and vomiting	42	27	2	37	18	3	
Fever	21	08	02	26	15	03	
Hematuria	37	21	5	29	11	2	

District Dera Ghazi Khan. The two drugs were packed in the same size and same color tablets and were coded for making them double blind. The renax name for Unani Medicine was suggested by all authors.

RESULTS

Age is one of the most important factors for the urolithiasis in human beings. Prevalence of urolithiasis is more in patients of 21-30 years of age. Patients were distributed gender wise. Prevalence of urolithiasis is more in men than women (table 1 and fig. 1).

In present study, there was significant reduction in signs and symptoms of urolithiasis in patients treated with Unani medicine Renax as compared to patients treated with (Spironolactone + Furosemide) (table 2).

DISCUSSION

Herbal medicine Renax contains medicinal plants which are usually used in the management of kidney stones and different disorders of the urinary tract. These medicinal plants contain a rich source of active constituents. In this study, an attempt has been made to investigate efficacy of this medicine to treat kidney stones. The prevalence of urinary stone across the world is high and alarming. Usually the urinary stones are common in hot climate areas of the world and in the people of low socioeconomic status (Sharma and Filler 2010). The areas with greater incidence of urinary stones are said to be "Stone belt" areas. Pakistan is also included in the "Stone belt" area. The urinary stone disease is very common in Pakistan with a highest incidence rate in southern Punjab and interior Sindh (Rizvi *et al.*, 2007). The patients were divided into 5 groups on the basis of their age; each group's age ranges between ten years (table 1 and fig. 1). There was no single patient under the age of ten years.

There were three major types of stones such as calcium phosphate, calcium oxalate and uric acid were diagnosed. Number of cases with uric acid, calcium phosphate, calcium oxalate and miscellaneous stones was 39, 35, 18 and 8 respectively. In the current study, the prevalence of urolithiasis is more common in 21 to 30 years of age. High prevalence of urolithiasis in District Dera Ghazi Khan and its adjacent areas may be due to dehydration in the hot climate of South Punjab. This observation is in accordance with previous study in which prevalence of upper tract urolithiasis in young adults was more in the fall and summer than in spring and winter (Sternberg *et al.*, 2005). Corresponding to high temperatures, The peak prevalence of urolithiasis occurs in July, August, and September in the Northern hemisphere (Pietrow *et al.*, 2002; Al-Eisa *et al.*, 2002; Soucie *et al.*, 1996). In the current study, 71 patients were male and 29 were female that indicated high prevalence of urolithiasis in male than female. This observation is in agreement with the previous study conducted by Hizbullah *et al.*, (2008)., in which prevalence of urolithiasis was 12.6% in male and 6.3% in female in Charsadda, Pakistan. Similar observations were made by Charles *et al.*, (2012)., which showed that prevalence of urolithiasis was 10.6% in men and 7.1% in women in the United State. This is due to the lifestyle, hormonal differences, diet habits and water requirement difference between male and female. Renax was more effective in treating calcium phosphate, uric acid, calcium oxalate and miscellaneous stones than spriomide. Renax was most effective against calcium phosphate stones and least effective against calcium oxalate and miscellaneous stones (fig. 2). Reduction in signs and symptoms of urolithiasis was more in the test group than control group (table 2). Significant reduction in signs and symptoms of urolithiasis by use of Renax may be due to the synergistic effects of ingredients present in Renax.

CONCLUSION

Unani medicine Renax exhibited significant efficacy than allopathic medicine (Spironolactone + Furosemide). The study indicated that *Cuminum cyminum* seeds, *Raphanus sativus* seeds, *Rheum officinale* seeds, *Citrullus lanatus*, Natrium phosphate and *Potassium nitrate* have some active ingredients that are involved in lithotriptic activity. This study validates the therapeutic use of Unani medicine in the treatment of urolithiasis.

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