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Study of *Hasate Kulya* (Renal Calculus) with Therapeutic Evaluation of Unani Formulation (*Sufoof Hajrul Yahud*) in its Management

Rajesh

Research Officer (U) Scientist L-1, Regional Research Institute of Unani Medicine, Patna (Bihar), India

Abstract: Hasate Kulya (Renal calculus) disease occurs worldwide and has been recognized as a medical problem even from the BC era. It is a solid accumulation of material that forms in the tubal system of the kidney. It varies in the size from as small as grains to a large as a golf ball. The great majority of stones 80% are composed of calcium oxalate crystals. Pain is the most common symptom and varies from a mild and barely noticeable ache to severe pain. This study was a single blind to evaluate the efficacy and safety of Unani formulation (Sufoof Hajrul Yahud) in renal stone. The test drug was given 3 gm in the form of powder orally thrice a day with water for 75 days. The data was analyzed statistically used Friedman test and student t test. The test drug was found significantly effective in both subjective and objective parameters. Hence, it can be concluded that the test drug is effective.

Keywords: Hasate Kulya (Renal calculus), Sufoof Hajrul Yahud, Pain

1. Introduction

Renal calculi are known as *Hasate Kulya* In Unani medicine and Asmari in Ayurveda. Renal stone is a crystalline mass or a concretions or a solid accumulations of material that formed by precipitation of various urinary solutes in the tubal system of the kidney. It can vary in size from as small as grains of sand to large as golf ball. ^[1, 2, 3, 4, 5]

Renal stone, with a life time risk of 7-13%, results in significant morbidity as well as substantial economic costs, not only directly from medical treatment but also indirectly through time lost from work. Prevalence of renal calculi varies according to the geographical area & socio-economic conditions. Calculi in the urinary tract has been known since of Hippocrates and the ancient recorded example of urinary stones detected by the at el Amrah dated to 4800 B.C. India has high incidence of renal calculi especially in Gujarat, Rajasthan, Punjab and Madhya Pradesh. An extrapolated incidence statistics of 3,915,700 renal stone has been estimated from a population of 1,065,070,607 persons in India, an indication of its high prevalence. The renal stones increases with age and commonly present between 2nd and 3rd decade. These stones are more common in men than women with the ratio of 7 to 8:1. [1, 6, 7, 8, 9]

They are mainly four types. The commonest type of stones contains calcium in combination with either oxalate or phosphate. Calcium oxalate and calcium phosphate make at least 80% of all kinds of stones. Struvite stones are composed of magnesium, ammonium and phosphate and its make up approximately 15%, 5-10% uric acid and 1-2% Cystine of kidney stone disease. [1, 3, 6-18]

Stone formation starts by the aggregation of crystals on a nidus. The nidus can be glycoprotein matrix, injured epithelium, foreign body or another crystal. Once such a nidus is formed and the urine saturation remains in the metastable zone or it is supersaturated, aggregation of the

crystals occurs over the nidus and the crystal grows in size to form a stone. [19]

Pain is the most common symptom and varies from a mild and barely noticeable ache to sever pain requiring parenteral analgesics. It is typically waxes and wanes in severity, and develops in waves or paroxysms that are related to movement of the stone in the ureter and associated ureteral spasm. ^[2]

In Ancient literatures described broadly the pathology, manifestations and treatment of its. According to Majoosi, renal calculi is formed due to increased *hararate ghareezi* and *madda* (matter) of these calculi derived from viscous and mucous matter, these matters may be the phlegmatic or viscous blood or pus. Razi mentioned the symptoms of calculi i.e. renal pain, incontinence of urine, dysuria and the persons passing sandy precipitate in their urine must have the calculus in his kidneys or in urinary bladder.

Unani physicians adopted a well organized line of treatment in the management of *Hasate Kulya*. The line of treatments is 1) Remove the *Asbabe Maddi* (causative material), 2) Use of *Mufattite Hasat advia* (lithotriptic drugs) and 3) Use of *Mudire Bol advia* (diuretics drugs).

Accumulation of morbid matter can be removed by *mushil*, further it can be avoided by restriction of diets (*ghaleez aghzia*), which are responsible for the formation of *hasat* e.g. concentrated milk, paneer and meat (old camel, old bull, old goat), roasted meat and fish meat which has the properties of *ghaleez* and sangeen, roti (feteeri, leshdar, maida) etc. [1, 6, 18-23]

The test drug Sufoof Hajrul Yahud [24] has the ingredient of Hajrul Yahud, Sang Saremahi, Habbul Qilt and Namak Turb and it possess the main properties of Mufattite Hasat (lithotriptic) and Modire Bol (diuretic).

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2. Methodology

The clinical study was conducted in Hospital of National Institute of Unani Medicine, Bangalore. Before embarking upon the patients, a comprehensive protocol was chalked out with the ethical clearance for bio-medical research from institutional ethical committee. After the ethical clearance, clinical study was started by enrolling eligible patients from the OPD and IPD of National Institute of Unani Medicine Bangalore. This was a single blind study, with 20 patients belonging to 20 to 60 years of age either in sex and diagnosed as case of Hasate Kulya (Renal Calculus) were enrolled. The patient before 20 years and after 60 years, Diabetic patient, Pregnant and lactating women, Renal Carcinoma and Renal Tuberculosis patients were excluded from the study. The patients between 20-60 years of age of both sexes with well established clinically Diagnosed cases of Hasate Kulya (renal calculi) upto 10 mm and the Patient who has agreed to sign the informed consent form and follow up the protocol were included in the study. All the drugs were purchased from Bangalore. Before preparing the formulation, all the ingredients were properly identified by chief pharmacist of NIUM Bangalore to insure their originality and authenticity. Make the fine powder of all the ingredients of Sufoof Hajrul Yahud [24], in the quantity of Hajrul Yahud, Sang Saremahi, Habbul Oilt each 10 gm and Namak Turb 20 gm. The drug was packed in sachets weighing 3 gm each. The drug was given 3 gm (one sachet) orally thrice a day to the patients after the meal as for 75 days. Duration of treatment of 75 days was divided into 6 visits of follow up, at an interval of 15 days. At every visit, patients were asked about the progression or regression in their symptoms and subjected to assess the clinical findings. Concomitant treatment was not allowed during study.

The efficacies of the treatment were assessed on the basis of subjective parameters (pain at renal angle, Burning micturition, Haematuria, Nausea and Vomiting) and objective parameter (USG) and safety was assessed with LFT and KFT. Pain and Burning Micturition were assessed by VAS scale and haematuria, nausea and vomiting based on arbitrary grading system as severe, moderate, mild and no symptoms.

Appropriate statistical tests were analyzed by Friedman Test and Student t-test (paired) and difference in the treatment was considered significant at p < 0.05.

3. Result And Discussion

It was the evaluation of *Sufoof Hajrul Yahud*. The 16 patients were completed the study out of 20 patients because 4 patients were drop out in this study.

In this study a maximum of 11 (55%) of the patients aged between 20-30 years and 7 (35%) patients in 31-40 years, 1 (5%) patients in 41-50 years, 1 (5%) patients in between 51-60 years were found. This coincides with API's description as the highest prevalence of renal calculus is in persons aged between 20-30 years. [1, 2, 4]

This study reveals the disease is more in male as because 15 (75%) of the patients were male and only 5 (25%) were

female, which is highly contrary to the description of Robert and Carl in Diseases of the Kidney. [8, 22, 23]

The religion wise distribution of *Hasate Kulya* patients shows that out of 20 (100%) patients, 15 (75%) patients were Muslims and 5 (25%) patients were Hindus No convincing data is available to demonstrate the existence of this disease among different religious communities in the society. It may be absolutely due to the patients attending NIUM hospital are mainly from Muslim community which reflected in my study.

The highest number 9 (45%) patients were found to be in upper lower class followed by 8 (40%) in lower middle, 1 (5%) in lower, 1 (5%) in upper middle and 1 (5%) patient in upper class in socio-economic status. This study supports the statement that renal stone is more prevalent among the low socio-economic class as observed by Sundhya et al. [25]

According to distribution of occupation the maximum 7 (35%) patients were found to be in shop keeper/Sales man and 4 (20%) in driver/mechanic/carpenter, 1 (5%) in house wives, 3 (15%) in teachers, 2 (10%) in students, 1 (5%) in laborers, 1 (5%) in engineer and 1 (5%) in unemployed. This is coincides with Sundhya et al. that manual workers have a high incidence of stone formation in comparison to sedentary workers. [25]

As far as the family history of *Hasate Kulya* is concerned, out of 20 patients, 3 (15%) patients had positive family history and 17 (85%) patients had no such family history. Gary C. described that kidney stone developed more frequency in individuals with a family history of kidney stone. This is not contrary by in this study because it may be due to small number of sample size. [26, 27]

According to distribution of diet, all the 20 (100%) patients were mixed diet, which coincides with Ibn Sina and other unani physicians that mixed diet are more prone for the renal calculus. [10, 28]

The highest incidence of BMI >25.0 found to be in 10 (50%) patients and 9 (45%) patients had 18.5-25.0 BMI and only 1 (5%) patient in < 18.5% BMI. This coincides with Barry M. in The Kidney that obese persons are more prone for the *Hasate Kulya*. $^{[6,10]}$

A maximum of 15 (75%) patients were found to be having a damvi mizaj, followed by only 5 (25%) patients having balghami mizaj, and no patients were found to be from saudavi and safravi mizaj.

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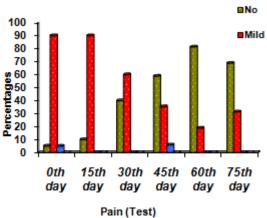


Figure 1: Evaluation of Burning Pain

In the beginning of the study, out of 20 (100%) patients, 1 (5%) had no pain, 18 (90%) mild and 1 (5%) patients had moderate pain, at the end of the study out of 20 (100%) patients, 11 (68.8%) had no pain, 5 (31.3%) mild and no patients had moderate pain. This improvement may be due to the astringent property of the drug. (Figure No. 1)

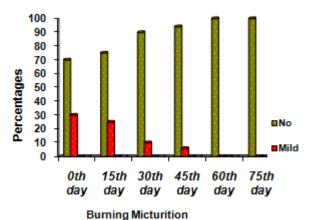


Figure 2: Evaluation of Burning Micturition

Burning micturation was observed out of 20 (100%) patients, before the treatment 14 (70%) had no burning micturation and 6 (30%) patients had burning micturation but after the treatment no patient had the burning micturation. This may be due to the *Mudire Bol* (diuretics) properties of drug. (Figure No. 2)

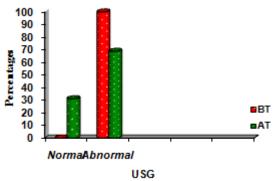


Figure 3: Evaluation of Uro-Radiology in Test

The results indicate that USG finding was after treatment 31.2% normal out of 100% abnormal USG of Renal Stone.

Through the evaluation in drug was statistically significant in USG (p > 0.50), the size of stone is reduced. Before the treatment the size of stone was 3, 4, 5, 8, 14 mm after treatment the size of stone was reduced 0, 0, 0, 0, 4 mm respectively. It shows that the trial drug has the properties of *Mufattite Hasat* (lithotriptic) and *Modire Bol* (diuretic). (Figure No. 3)

The assessment of safety parameters, by using student t-test (paired) was not significant (p > 0.50). There was no difference between before and after the treatment.

4. Conclusion

The overall effect of the *Sufoof Hajrul Yahud* was found effective in the treatment of *Hasate Kulya* (Renal calculus). The drug was effective in both subjective and objective parameters, no clinically side effects were observed in the study. The evaluation of subjective and objective parameters was statistically significant (p < 0.01) by using Friedman Test and using the student t-test (paired) for safety parameters. There was no difference between before and after the treatment. So it indicates that the drug is safe and effective.

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