

Effectiveness of powder of *Tribulus Teristrus* in the management of urinary calculi

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Abstract: Urinary calculi is a common genito-urinary disorder in the modern era. They may cause pain, nausea, vomiting, hematuria and possibly chills and fever due to secondary infection. Diagnosis is based on urinalysis and radiological imaging usually non-contrast helical CT imaging. In Ayurveda, urinary calculi are known as *Mutrāshhari*. This study was aimed to evaluate the efficacy of *Gokshurabija choorna* (GBC) comparatively with Cystone[®] in the management of *Mutrāshhari*. The formula was prescribed in *Bhaishajya Rathnāvali* under the chapter of *Mutrāshhari chikitsa*. Twenty patients with urinary calculi were randomly selected from Gampaha Wickramarachchi Ayurveda (Teaching) hospital, Yakkala and D. B. Welagedara Ayurveda (Provincial) hospital, Kurunegala. They were divided into two groups (Control and Test) using the simple random sampling method. Test group was treated with 10g of GBC with hot water twice daily for a period of seven days. Two tablets of Cystone[®] was recommended twice daily for a period of seven days to the control group. Appropriate *patyāpatya* were instructed to follow during the period. Data was collected before treatment, after treatment and after seven days follow-up period using USG (for objective parameters) and self-prepared questionnaire (for subjective parameters). Results were analyzed by using IBM SPSS v22 statistical software. After fourteen days of treatment, both groups showed a significant effect to some clinical symptoms. But calculated p values of GBC were less significant than Cystone[®] comparatively. It was concluded that GBC has got effectiveness as a treatment of *Mutrāshhari*. No adverse reaction was observed during treatment, proving the formulation is safe and effective.

Key-words: urinary calculi, *Mutrāshhari*, *Gokshurabija choorna*

I. INTRODUCTION

Urinary stone is a rock particle or a crystal in the urinary tract formed by substances in urine (Robbins & Cotran, 2005). Monotonous diet based on rice, water quality and hot climate which contribute to this high incidence are curable in Sri Lanka too, making it likely to be a part of the stone belt. Stones are commoner in the young and the effects of absenteeism from work due to stones on economy and family is great. Furthermore, urinary calculi are the commonest cause of obstructive uropathy and renal impairment in Sri Lanka (Abeygunasekera, 2004). Therefore, it is essential to know the pattern of calculi in a country and region when planning treatment. A study done in Sri Lanka has shown that the stone composition of Sri Lankan staghorn calculi is likely to be different to that described in literature which are based on

studies done in the western world. However, there is a paucity of published data about composition of renal stones especially those of staghorn calculi in Sri Lankan patients (Pethiyagoda et al., 2015)

In Ayurveda, lot of classics explained various types of formulations. *Gokshurabija choorna* (GBC) is one of the successful treatment formulae mentioned in *Bhaishajya Rathnāvali*. It is also a simple formula for *Mutrāshhari*. In this classic *Gokshurabija choorna* prescribe with sheep milk. But in this present study ,it is prescribed with warm water according to *choorna paribhāshā*. Therefore, it can be prepared easily. Hence, evaluation of the efficacy of this drug is important in current society.

II. METHODOLOGY/MATERIALS AND METHODS

Prospective Randomized comparative clinical trial to determine the effect and efficacy of *Gokshurabija choorna* and Cystone[®] in the management of *Mutrāshhari* (Urinary calculi). 19 patients who are diagnosed with any type of urinary calculi were randomly selected from the out-patient department (OPD) of Gampaha Wickramarachchi Ayurveda (Teaching) Hospital, Gampaha and W. D. Welagedara Ayurveda Hospital, Kurunegala. Urinary calculi were diagnosed by ultrasonography (KUB).

Patients with renal stones greater than 5mm in size but <12mm, presenting with or without symptoms such as dysuria, pain in the renal angle or flanks radiating to the groin, and burning micturition were included in the study. Subjects with severe urinary tract infection, uretero-hydronephrosis, diabetes, ulcer disease, history of hypersensitivity to herbal formulation, and pregnant women were excluded from the study.

Study was conducted as per ethical consent. The aim of study was explained to all patients. After collecting detail patient history and physical examination only those who gave written consent were included in the study.

After that they were randomly separated two groups as test group (group A) and control group (group B). Group A patients were treated with 10g of *Gokshurabija choorna* with warm water two times a day for a period of 7 days. And, group B patients were treated with Cystone[®] tablets two times a day for a period of 7 days. After treatment of both A and B

groups were further studied for a period of 14 days as follow-up period.

Patients who desired to recruit to the study were selected. Any gender between 15 to 65 years and radiological evidence of stone (up to 5mm) in kidney, ureter or urinary bladder.

Patients with age below 15 years and above 65 years, stone size more than 12mm, impacted stone, uncontrolled DM and HTN, malignancy, impaired or decreased renal function, patients undergoing treatments for any other serious illnesses, pregnancy or lactation patients were excluded according to the exclusive criteria.

All patients could use symptomatic therapy with pain killers, if required and were advised to drink a minimum of 3L of water daily. The follow up was limited to 2 weeks. All patients were examined at before and after treatments clinically and by ultrasonography. Patients were evaluated for amelioration in the relief of clinical symptoms like pain in the abdomen, number of pain episodes, frequency of urination, dysuria, hematuria, painful micturition, and tenderness in KUB area at entry, after treatments and after follow-up period. All the parameters except number of pain episodes and frequency of urination were evaluated using a 5-point grading scale (0: Absent; 1: normal; 2: mild; 3: moderate; and 4: severe).

General symptoms score

Complete absence of the signs and symptoms	0
Mild degree of the signs and symptoms	1
Moderate degree of the signs and symptoms	2
Severe degree of the signs and symptoms	3
Very severe degree of the signs and symptoms	4

The patients complaining of pain in abdomen and other related symptoms like burning micturition, painful micturition, urinary retention, hematuria was selected as subjective diagnostic criteria and USG (KUB) was considered as basic objective diagnostic criteria.

Number of calculus and total size of calculi were taken as objective criteria from the ultrasonography. All the diagnostic criteria were graded by scoring method and statistical analysis of these scores was done before starting the treatment and after the treatment.

Patients were instructed to take 2 full teaspoons of powdered drug and transferred into 100ml of hot water and mixed well as a 1 dosage form. This should be taken two times a day before meal for 1 week.

The patients were advised to drink 3-4 L of water per day and to consume suitable diet with proper sleep and excretion of natural urges. Patients were advised to avoid cow's milk, tomato, cauliflower, spinach, fish and meat (incompatible diets and regimen) during the period of treatment.

Data was collected and the statistical analysis was performed using Microsoft Office Excel 2016 professional plus and IBM SPSS v22 software. Values were expressed as mean \pm SD for calculi size and relief of clinical symptoms. The minimum level of significance was fixed at $p < 0.05$.

III. DATA ANALYSIS AND RESULTS

All cases were analyzed for the incidence of *Mutrāshhari* in relation to age, sex, socio-economic status etc. In test group, it was found that 33.33% of patients were in the age group 26-35 yrs., 22.22% of patients were in the age group 36-45, 22.22% of patients were in the age group 46-55 and 22.22% in the age group 56-65 yrs. In control group, it was found that 20% of patients were in the age group 26-35 yrs., 30% of patients were in the age group 36-45, 30% of patients were in the age group 46-55 and 20% in the age group 56-65 yrs. This indicates that the incidence is higher in 3rd to 5th decade of life. Excessive work and by the excessive sweating lead to decrease in urine output in turn helps for the formation of stone. The effectiveness of the treatment adopted in both the groups in respect to each parameter is tabulated based on the difference between the scores before treatment and after treatment.

Pain:

The effectiveness of test group is 44.44% with the level of significance of p-value is 0.829 (>0.05), which is not significant. The effectiveness of control group is 50% with the level of significance of p-value is 0.707 ($p > 0.05$), which is not significant.

Haematuria:

The effectiveness of test group is 100% with the level of significance of p-value is 0.000 ($p < 0.01$), which is highly significant. The effectiveness of control group is 90% with the level of significance of p-value is 0.035 ($p < 0.05$), which is moderately significant.

Painful micturition (Dysuria):

The effectiveness of test group is 77.77% with the level of significance of p-value is 0.012 ($p < 0.05$), which is moderately significant. The effectiveness of control group is 60% with the level of significance of p-value is 0.124 ($p > 0.05$), which is not significant.

Burning micturition:

The effectiveness of test group is 55.55% with the level of significance of p-value is 0.013 ($p < 0.05$), which is moderately significant. The effectiveness of control group is 30% with the level of significance of p-value is 0.040 ($p < 0.05$), which is mild significant.

Urinary retention

The effectiveness of test group is 55.55% with the level of significance of p-value is 0.019 ($p < 0.05$), which is moderately significant. The effectiveness of control group is 50.00% with

the significance of p-value is 0.078 ($p>0.05$), which is not significant.

Size of stone:

The effectiveness of test group, the level of significance of p-value is 0.000 ($p<0.05$), which is highly significant. The effectiveness of control group, the level of significance of p-value is 0.068 ($p>0.05$), which is not significant.

Number of stones:

The effectiveness of test group, the level of significance of p-value is 0.000 ($p<0.01$), which is highly significant. The effectiveness of control group, the level of significance of p-value is 0.000 ($p<0.05$), which is highly significant.

IV. DISCUSSION

From the present study it becomes evident that the urological problems form an important part of medical deliberations. Perhaps, this can be the reason for detailed description of the urinary system related disease i.e. *Mutrāshhari* (Urolithiasis) in Ayurvedic texts. Old literature gives a clear idea of the disease that it has come into existence from the very beginning. In Ayurveda Madhura (sweets) and guru (heavy for digestion) diets and hot climate are the main cause for the formation of *Ashhari* (stones). As this can be understood hypothetically with the present contemporary science that these types of food may reduce the solubility crystals in the urine, this may lead into precipitations and formation of the stone. Whereas in modern Science, they have considered many causative factors for the stone formation, but stone has been seen even in those patients also, where these factors are absent. So, in total, the etiology of the disease is still unknown.

V. CONCLUSION/S AND RECOMMENDATIONS

It was found that, the lithotryptic action of the *Gokshurabija choorna* was showing significant effect than Cystone®. *Gokshurabija choorna* and Cystone® was not capable of

reducing Pain intensity. But it was capable of reducing Hematuria, reducing dysuria, reducing size of stone, reducing burning micturition and minimize urinary retention than Cystone®.

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