IJFANS INTERNATIONAL JOURNAL OF FOOD AND NUTRITIONAL SCIENCES
ISSN PRINT 2319 1775 Online 2320 7876
 Journal UGC CARE Listed (Group-I) Volume 10, Iss 04 2021

"CLINICAL EVALUATION OF SHUNTHYADI KWATHA AND TRIVIKRAM RAS IN THE MANAGEMENT OF MOOTRAASHMARI (UROLITHIASIS)"

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ABSTRACT

Ayurveda, is the system of Indian medicine and science of life which deals with the wellbeing of mankind, it explains all the aspects of diseases like causes, types, treatment etc of many diseases, the disease of urinary stone is explained under the heading of Mootraashmari. The reference regarding it can be found in all most all the Samhitas, Acharya Sushruta has described nidana, samprapti, laxanas, chikitsa etc in most scientific manner in separate chapter. Objectives of the study is to evaluate the efficacy of Trivikram rasa in the management of mootraashmari. Study Design: open labelled clinical study. Patients of diagnosed with mootraashmari satisfying inclusion criteria was included in study from OPD and IPD of Nitishwar Ayurveda Medical College & Hospital & P. G. Research Institute, Muzaffarpur 841226, (Bihar) India. They registered under different groups for the assessment of effect of Shunthyadi Churna and Trivikram ras on Mootraashmari also called as Urolithiasis. Based on the assessment criteria the parameters are graded and statistically analysed using Paired t‟ test. Results: In this study, the subjective and objective parameter shows significant results. As the drug caused reduction in size of calculus in some patients and even expulsion of calculus in some others, hence bypassed the operative procedures this drug can be considered as cost effective and safe regarding management of calculus.

Key Words: Mootraashmari, Shunthyadi Churna, Trivikram ras, Urolithiasis

NTRODUCTION

Ayurveda, is the system of Indian medicine and science of life which deals with the wellbeing of mankind. It explains all the aspects of diseases like causes, types, treatment etc of many diseases, the disease of urinary stone is explained under the heading of Mutrashmari. [1] In India this disease affect all age group, prevalence is more in men, approximately 5-7 million patients suffer from this disease and at least 1/1000 of Indian population need hospitalization due to Renal calculi disease. In India this disease is found more in stone belt area like Gujarat, Maharashtra, Rajasthan. In these regions the disease is so prevalent that most of the family will suffer from renal calculi sometime in their lives. In Ayurveda various formulation are mentioned for the Mootrashmari management one among them said by sharangadhar samhita is trivikram ras, It has unique properties like lekhana and vedanasthapana So, it has been used effectively and economically on Mootraashmari. No research found on evaluate effect of trivikram ras in the management of Mootraashmari. So, study on "**CLINICAL**

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EVALUATION OF SHUNTHYADI KWATHA AND TRIVIKRAM RAS IN THE MANAGEMENT OF MOOTRAASHMARI (UROLITHIASIS" is undertaken.

MATERIALS AND METHODS

AIMS AND OBJECTIVES

- To evaluate the clinical effect of Shunthyadi Kwatha and Trivikram rasa in the management of Mootraashmari.
- To study the Aetiopathogenesis of Mootrashmari as per Ayurveda and contemporary sciences.

Ashmari is a disease related to mutravaha strotas in which an 'ashma' meaning stone is formed in urinary system. It is a tridoshaj vyadhi with predominant kapha dosha. This disease is classified on the basis of signs and symptoms as well as morphology of stone that are formed in different part of mutravaha strotas. Acharya Sushruta has mentioned it in Ashta Mahagada (eight most dangerous diseases), number of drugs, kshara and ghrita are proved to be useful in ashmari. These drugs act as bhedana and patana, vedana shamak, basti shodhak. A relapse rate of 50% in 5-10 year and 75% in 20 year is seen in urolithiasis. It is estimated that 12% of world population experiences renal stone disease. The functions of Mutravahasrotas (urinary system) is also regulated by Apanavayu one among the five types of Vayu. Obviously, any derangement of Apana Vayu leads to the pathology of the urinary system. So, the treatment principle is to correct the vitiated Apana Vayu, thereby attaining the normal physiology of the urinary system. This controls the symptoms of the Mutravaha Shrotas (urinary system).

Method of preparation of drug

Shunthyadi kwatha prepared as per method6 i.e. Kwath was prepared by boiling the powder of drugs (shunthi + gokshura 10 gm each) in 320 ml of water on low heat and reduced to 40 ml and stained in cloth. The Tamrabhasma was heated in 8 times of ajadugdha initially. When all of milk was evaporated, parada and the gandhak were added to it and the solid mass was obtained. "Bhavna" with nirgundi patrasvarasa was given and the obtained solid portion was transfered to Valukayantra and heated for 3 hours. It was allowed to cool by itself. Fine powder of drug was made in khalvayantra, The obtained drug was filled in capsules in the dose of 250 mg each.

Study design

A randomized, open labeled single arm, clinical trial study**.**

INTERVENTIONS

Patients were assessed before and after treatment as per assessment criteria and data was recorded in a special case sheet proforma. The nature of study was explained to the patient in detail and written informed consent as per WHO guidelines was taken. The patient was having full right to quit the study at time. The data was maintained confidentially and subjected to statistical analysis.

INCLUSION CRITERIA

• Patients having classical signs and symptoms of Mootraashmari (Renal calculi)

• Size of calculus less than 9 mm was taken.

• Patients age between 16 to 60 years.

• Bilateral and unilateral renal calculi

EXCLUSION CRITERIA

• Patient having Urinary Calculus of size more than or equal to 10mm.

• In case, Patient requires immediate surgical intervention.

• Chronic systemic illness, DM, HTN, HIV and other renal diseases.

• Pregnant and Lactating women.

ETHICAL CLEARANCE

Ethical clearance was obtained from the Institutional Ethical Committee of P. G. Department of Shalya Tantra, Nitishwar Ayurveda Medical College & Hospital & P. G. Research Institute, Muzaffarpur 841226, (Bihar) India.

FOLLOW UP STUDY: 15 days.

ASSESSMENT CRITERIA

Subjective parameters have recorded on 1st 15th & 30th day and objective parameter were recorded on 1st and 30th day

SUBJECTIVE PARAMETERS

1. Fixed renal pain posteriorly at renal angles or anteriorly at hypochondriac region
2. Vomiting
3. Burning micturition
4. Dysuria

OBJECTIVE PARAMETERS

1. Size
2. Number of calculus
3. Haematuria Pain was assessed by VAS scale.

INVESTIGATIONS

Urine routine and microscopy Routine haematological investigation like cbc Blood urea, Creatinine, Uric acid, X-ray Kidneys, ureters, and bladder(KUB) USG (Abdomen, pelvis).

OBSERVATIONS

Patients suffering from mootraashmari from OPD of Shalya Tantra, Nitishwar Ayurveda Medical College & Hospital & P. G. Research Institute, Muzaffarpur 841226, (Bihar) India, were participeted in the clinical trial, the size of sample was 30 excluding the dropouts. In this study maximum 43.33% patients were from age group of 20-30, 36.67% patients from 31-40 age group, followed by 10.00% from 41-50 and 10.00% from 51-60 age group. In this study maximum percentage of enrolled patients are male 56.67% and the percentage of female were

43.33% In this study maximum percentage of enrolled patients are hindu 93.33% and the percentage of muslim patients were 6.67% maximum percentage of enrolled patients are married 76.67% and the percentage of unmarried patients are 23.33% 33.33% were graduated, followed by 26.67% were uneducated, 23.33% were post- graduate and 16.67% were under graduated 30% patients were housewife, 26.67% patients are Students, followed by 23.33% were in service, 13.33% were labour and 6.67% were farmer.

According to Socio-economic status maximum patients i.e. 66.67% were from middle class & 23.33% patients belonged to poor class, & 10.00% were from rich class. According to diet wise classification maximum patients i.e. 53.33% were vegetarian & 46.67% patients were consuming mixed diet maximum percentage of the patients i.e. 30% were habitual of consuming madhura rasa, & amla rasa by 20%, kashaya rasa by 16.67%, and katu rasa by 13.33% and least of lavan rasa by 10.00%. Among total registered 30 patients, only 10% were having family history of this disease and rest 90.00% was having negative family history. Maximum patients enrolled in this study were from i.e. 66.67% Jangala Desha, while 20.00% patients were from Anupa and 13.33% of sadharana Desha. Maximum number of patients (50.00%) in this were habitual of eating viruddhaahara, followed by adhyashana 23.33%, and vishamashana (16.67%). According to chief complaints all 100% of patients had abdominal pain, and vomiting was complained by 23.33% of patients, dysurea was present in 26.67% of patients & burning micturation was present in 63.33% of individuals. According to frequency of micturation wise classification maximum patients i.e. 56.67% micturition of 5-6 times per day, followed by 33.33% micturate 7-8 times per day and finally only 10.00% micturate 3-4 times a day ie 24 hrs. Among the 30 patients, 66.67% of patients were having unilateral calculi while 33.33% of patients have bilateral calculus. Maximum 76.69% of patient had the complained pain of calculi from 1-6 months, followed by 16.65% of patients from 6-12 months, and only 6.66% had the pain in chronic origin ie more than 1 year In this study maximum 66.67% patient had moderate pain, followed by 30.00% patients complained of mild pain and lastly only 3.33% patient complained of severe pain.

RESULT

The paired t test has been applied to the mean score of before treatment and after treatment Assesment of result through subjective parameter: Pain (vedana) -0.001, Burningmicturation -0.001, Vomiting – 0.001, Dysurea – 0.001, Assesment of result through objective parameter: Size of calculi - 0.001, No of calculi – 0.001.

DISCUSSION

The purvarupa said by acharyas are Bastipeeda, Mutrakricchaetc were found in some patients as when USG, and X-ray was done no calculus was seen but after some days 4 months when usg was done due to abdominal pain calculus was seen on 5*7 mm in VUJ so it was found that even purvarupa said by acharyas was evident. The pain is the important factor in this disease, and it was seen when the calculus was stuck on the junction of the ureter the intensity of pain was more on the VAS scale it was up to 8, so rescue medication of intramuscular injection dicyclomine 1ampule was given when intensity of pain was more, and tablet dicyclomine was given alternative to IM dicyclomine if needed. The total number of drop out were 4 in this study from them 3 were due to pain they got operated for URS and 1 patient

failed to came on follow up. Not all the calculi present in KUB can be diagnosed as per its composition, only the evidence can be found in urine examination, so it becomes challenge for the doctors to treat this disease. Also considering the Sonological diagnosis, the size of calculi can vary from technician to technician and the size of calculus is also not every time possible for the technician to give in 2 dimension, the 2 dimensional image of calculus really helps to manage it as a calculus of size 4*4mm can pass easily but the calculus of size 4*9mm is difficult to pass. Again the shape of calculus plays the important role, but as there is problem in giving 2 dimensional details of calculus how can the sonologist give 3 dimensional details (which are required to demonstrate the shape of calculus). The drug used in this study is trivikrm rasa, which is a herbomineral drug there were many important steps in making this drug, In the nature there are mainly 3 formes of mercury (Elemintal, organic & inorganic) among which parada can be correlated to inorganic mercury, and among the route in body the inhallation is considered as the most dangeraous route as it effects on lungs which can cause death, so precautions were taken in production of drug some of them was the cap mask was worned when parada was produced by damruyantra, and while chandelling the parada the gold items was removed from hands for eg gold ring. This drug was made as said in sarangdharsamhita to take equal quantity of ajakshir and the tamtrabhasma which was practically impossible so the quantity of ajakshir was taken 8 times of tamrabhasma, all other ingrediants were taken in equal quantity. After the preparation of drug the drug the drug was filled in capsules in the 250 mg each and prescribed in 1 od with luke warm water in morning empty stomach as it was easy to fill this drug in capsules then to make vati of 250 mg which was difficult task and time consuming. Subjective parameter pain shows None of the patient had severe pain abdomen after completion of treatment and 80.00% patients were get relief from pain. With the t value of 21.00 and P value of less tha 0.001 which is highly significant, It is showing that trivikram rasa act as vedanashamaka due to ushnaveerya and vatashamana properties and it also possess significant anti-inflammatory (analgesic) activity. Dysuria The effectiveness in this parameter is 70.00% with tvalue 3.00 and the level of significance of p-value is less than 0.01 which is highly significant, this may be due to increased blood flow, vasodilatation, or an inhibition of tubular secretion contributes to an increased excretion, dysuria subside and large intake of water also helps in this process. Burning micturition The effectiveness in this parameter is 69.00% with tvalue 7.13 and the level of significance of p-value is less than 0.01 which is highly significant. Vomiting 87.00% patients were get relief from the symptoms. with t -value 5.89 and the level of significance of p-value is less than 0. 01 which is highly significant. Discussion on objective criteria In this study Before treatment, mean size of calculi was 6.50 and after completion of treatment it reduced to 3.87 i.e. reduced by 2.63% with (p value = 0.001) which is significant. This probable mechanism change in this may be following. There was decrease in size of calculi due to lekhana property of drug and the size of larger calculi was reduced in some patients and in some cases the calculi was broken due to lithotriptic action of drug, significant result was obtained in calculus which has single chemical composition rather than triple phosphate calculi. Discussion on number of calculi Before treatment, mean value of Stone number was 2.20 and after completion of study it was reduced to 1.27 i.e. reduced by 68.00% (p value = 0.000) which is also statistically significant. Trivikram rasa have eliminated the stone and causing reduction in the number of stone due to its kapha-vatashamaka properties.

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CONCLUSION

The aim of the present study was to assess the effect of trivikram rasa in the patients of mootraashmari. The sample size of 30 patients, they were administered the Shunthyadi churna and the capsule containing trivikramrasa 250mg once daily in morning empty stomach with luke warm water for the duration of one month 30 days. As the drug caused reduction in size of calculus in some patients and even expulsion of calculus in some others, hence bypassed the operative procedures this drug can be considered as cost effective and safe regarding management of calculus. The statistical analysis has proven that drug was significantly effective in management of the subjective criteria like pain, vomitting, burning micturation, dysurea and the objective criterias like size and number of calculus and hematuria. Hence, regarding management of calculus Null hypothesis (trivikram rasa is not effective) was rejected and the alternative hypothesis (trivikram rasa is effective) was accepted.

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