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"Comparative clinical study of Nagaradi kwath and polyherbal preparation (Cystone) in the management of Mootrashmari w.s.r. to Urolithiasis."

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Abstract: Urolithiasis or urinary calculus means a presence of calculus single or multiple in the urinary tract**.** Body is composition of these *dosha, dhatu and mala*. These *Mala* are produced as result of a digestion and metabolism of food and those should be eliminated from the body through their respective channels. In these three *mala*, *Mutra* is one of the *Drava mala*. Mootrashmari is a disease of mootravaha srotas and according to Sushruta it is formed due to the drying up of kapha because of the action of vata and pitta. Acharyas mentioned 4 types mootrashmari. Depending upon the nidana for which a particular Doshas get vitiated and leads to that of mootrashmari.The present study has been conducted by selecting patients from OPD and IPD of Shalya. A total number of 60 samples were randomly selected and allocated into two groups i.e. Trial and Control groups, 30 samples in each group. This is clinical study with pre-test and post-test study design. Group – A Trial group with *Nagaradi kwath* while Group - B Control group with standard polyherbal proprietary drug cystone (Himalaya).The duration of treatment for both groups was 15 days.. it was found that in Trial group the main clinical features like pain, burning micturition, dysuria, and haematuria were reduced remarkably in both groups but control group got better result than trial group.

Key words: mootravaha srotas, kapha ,Ashmari. *Nagaradi kwath*, cystone,

INTRODUCTION: Urolithiasis or urinary calculus means a presence of calculus single or multiple in the urinary tract and this disease is prevailing all over the world. Urolithiasis is a global problem. However hereditary and dietary factors like imbalance of electrolyte such as calcium, phosphates, oxalate, magnesium, abnormal metabolism, and deficiency of vitamin-A etc. have their key role to play in formation of calculus Calculi are crystalline aggregates of one more components, mostly calcium oxalate. It is necessary to take efforts; either long term or short term to control intra renal or extra renal causes causative to stone

formation. And lots merely accept that the patient is cured when a stone is voided. Hence there is a need to understand the disease and to fiend an effective and economical remedy for this widely prevalent disease.*Ayurveda* is an ancient science of life. *Ayurveda*, the System of Indian medicine and science of life deals with the welfare of mankind. According to *Ayurveda*, body has some vital constituents like *Tridosha, Sapt-dhatu and Trimala*. Body is composition of these *dosha, dhatu and mala*. These *Mala* are produced as result of a digestion and metabolism of food and those should be eliminated from the body through their respective channels. In these three *mala*, *Mutra* is one of the *Drava mala*. Forthe production and excretion of *mutra* specialized system is present in our body that is called as *mutravaha strotas* In our ayurvedic classics and purana Granthas lot of references about mootrashmari are present.Mootrashmari is a disease of mootravaha srotas and according to Sushruta it is formed due to the drying up of kapha because of the action of vata and pitta. Acharyas mentioned 4 types mootrashmari. Depending upon the nidana for which a particular Doshas get vitiated and leads to that of mootrashmari. These are Vataja ashmari, Pittaj ashmari, Kaphaja ashmari and Shukrashmari. Sushruta, Charaka, Bhela and Harita devoted separate chapter for Ashmari, where Harita says formation of ashmari is hereditary.

All most all Acharyas described its Nidana, Purvaroopa, Roopa, Chikitsa (Aushadhi and shastra karmas) and Upadravas. For the same purpose so many yogas of medicines have been explained in our ancient ayurvedic literatures, which are easy to prepare, easily available, affordable and effective. Our Acharyas have after their vast experience mentioned there yogas in these books.Hence from the various available references one, of such formulation "*Nagaradi kwath*" from "*Gadanigrah*" has been taken for comparison with standard polyherbal proprietary drug cystone (Himalaya).

The effect of the drug in both groups was observed on various parameters and compared by using statistical methods. From collected statistical data was summarized and presented as a conclusion of the study

AIM AND OBJECTIVES

Aim :

To compare the efficacy of Nagaradikwath and polyharbal preparation (Cystone) in management of Mootrashmari w.s.r to Urolithiasis.

Objectives :

1. To study the disease Mootrashmari according to Ayurvedic science and modern medicine.

2. To study the efficacy of trial drug Nagaradikwath on Urolithiasis

3. To study the efficacy of Cystone on Urolithiasis

4. To compare the results of the trial drug with standard proprietary Formulation.

MATERIAL AND METHODS

Selection of Patients:

The present study has been conducted by selecting patients from OPD and IPD of Shalya. The patients were screened on clinical grounds and routine laboratory investigations to establish the nature of urinary problems.

Grouping:

A total number of 60 samples were randomly selected and allocated into two groups i.e. Trial and Control groups, 30 samples in each group. This is clinical study with pre-test and post-test study design.

Selection Criteria

Inclusion Criteria-

1) Subjects attending OPD and IPD of Shalya Tantra Department of Our Institute
2) Subjects of the age in between 15-70years.
3) Either sex.
4) Calculus of size less than 10mm anywhere in the urinary system, single or multiple .

Exclusion Criteria

1) Subjects requiring immediate intervention like severe colicky pain, sepsis.
2) Subjects having Diabetes, hypertension & other systemic diseases.
3) Impaired renal functions.
4) Gross hydronephrosis, Pyelonephritis

Withdrawal Criteria

During the course of the trial treatment if any adverse events occurred, or subject sensitive to formation or subjects unwilling for treatment should withdraw from the study

INVESTIGATIONS:

Urine Examination:

Urine was subjected for **routine and microscopic** examination **USG of KUB** was done before and after treatment. The changes occurred were taken into consideration for the assessment.

TREATMENT PLAN:

For the evaluation of efficacy of *Nagaradikwath* study was divided into two groups **(Trial Group) Group A** and **(ControlGroup) Group B.**

Each group contains 30 patients selected on the basis of selection criteria.

Groups	**(Group A)**	**(Group B)**
Name of drug	Nagaradikwath	Cystone
Form	Kwath	Tablet
Dose	20 ml with Yavakshara	2 Tablets (500mg)
Frequency	Twice before meals	Twice before meals
Duration	15 days	15 days
No of Subjects	30	30

Pathya	Pathyakar ahar vihar to be followed.	Pathyakar ahar vihar to be followed.

Assessment Criteria –

Subjective criteria for assessment

1) Pain-

No pain- 0

Occasional pain required no treatment- 1

Occasional pain required treatment – 2

Constant dull pain required treatment -3

2) Burning micturition-

No burning micturition - 0

Occasional burning micturition required no treatment - 1

Occasional burning micturition required treatment - 2

Constant burning micturition required treatment- 3

3) Dysuria-

No dysuria-0

Occasional dysuria required no treatment -1

Occasional dysuria required treatment -2

Constant dysuria required treatment -3

Objective criteria for assessment-

1. Presence of Stone: After treatment

	Present	Absent
Group A		
Group B		

2. Size of Stone:

	Before Treatment	After Treatment
Group A		
Group B		

3. Haematuria: On basis of microscopic urine analysis.

No RBC/Hpf – 0

0-5 RBC/Hpf – 1

6-10 RBC/Hpf – 2

11-15 RBC/Hpf – 3

Overall Effect of Therapy-

For the assessment of the total effect of the therapy following four categories were taken into considerations.

1) Good Change (75% to 100%)

Complete relief in subjective signs and symptoms.

Absence of any calculus in urinary tract with radiological Evidence.

2) Moderate Chnge (50% to 74.9%)

Relief in subjective signs and symptoms.

Reduction in calculus size with radiological evidence.

3) Mild Change (25% to 49.9%)

Relief in subjective signs and symptoms without any change

in size of stone confirmed with radiological evidence.

4) No Change (Up to 25%)

No relief in subjective signs and symptoms.

DIETIC REGIME:

Avoid food with high oxalate content, which encourages calcium oxalate stone formation, the most common type of renal stone. If level of urinary oxalate is high, limiting high oxalate foods reduce risk of forming renal stone.Food rich in uric acid and purines increases urinary excretion of uric acid, which predisposes to both uric and oxalate stones.

Apathya:

Avoid or reduce intake of palak, chulai, tomatoes, amla, chiku, cashew nuts, cucumber, as they have high oxalate contents. Cut down the intake of

cauliflower, pumpkin, and mushroom, brinjal, as they are high in uric acid and purine contents.

Pathya:

Old rice, barley, kulattha, green gram (mudga), white gourd melon, ginger (adraka), Coconut water as it contains dialyzable biomolecules.Cornsilk tea is rich in tartrates acting as good inhibitor of stone formation.Bananas are rich in vitamin B6 which breakdown oxalic acid. Almonds provide rich source of magnesium and potassium, which act as stone inhibitors.

MATERIAL

The following are the materials used for study.

1) Nagar
2) Varun
3) Gokshur
4) Pashanbhed
5) Kapotvankaj (Bramhi)
6) Yavakshara

Properties of these drugs are already discussed in drug reviewcontext.

Authentication:

Authentication of all the ingredients of *Nagaradikwath* was done at an ISO certified pharmacy with the help of microscopic study according to API and *Bhavaprakash Samhita.*

Standardization of raw material

Standardization of all the ingredients of *Nagaradikwath* was done at an ISO certified pharmacy with the help of microscopic study according to API and *Bhavaprakash Samhita.*

Preparation of Nagaradikwath - According to Sharangdhar

- First all ingredients were identified and authenticated by reliable

source then standardized in laboratory were taken and dried properly

- Coarse powder of all ingredients in equal quantity taken (Nagar, Varun, Gokshur, Pashanbhed ,Bramhi each 2 grm)
- Soak them for few hours in sufficient quantity of water
- Add 160 ml of water and boil on moderate flame to reduce water to 1/8 (20 ml)
- Filter it and collect in flask . add Yavakshar(0.5 gm) in it.

Standardization of final product:

To ensure the quality of preparation it is necessary to standardize that before using in experiment.

The study was done at GMP Certified Pharmacy.

Certificates of authentication and standardization of raw material as well as final product are attached in annexure.

2) Cystone

This is the Control drug used in the study.

NOC is taken from Himalaya Pharmacy and it attached in annexure.

OBSERVATIONS

'Wilcoxon signed ranks test' and 'Mann – Whitney U Test' were applied to compare the score of data before treatment and after treatment.**Paired and unpaired 't' tests** were applied for the analysis of actual quantitative data between the two groups.

Showing result on Pain

Pain	Mean difference score	Sd	Mann-Whitney U	P
Group-A	1.766	0.935	384	0.3059 NS
Group-B	2.033	0.889		

Pain was seen to be reduced in both the groups. When subjected to Wilcoxon Rank Sum Test and Mann – Whitney U Test, both the groups were equally effective. Hence there was no significant difference found between the efficacies of both Group A and Group B.

Burning Micturition

Burning Micturation	Mean difference score	Sd	Mann-Whitney U	P
Group-A	1.60	0.838	235	0.6641 NS
Group-B	1.72	0.631		

Burning micturation was seen to be reduced in both the groups extremely significant. When subjected to Wilcoxon Rank Sum Test and Mann – Whitney U Test, both the groups were equally effective. Hence there was no significant difference found between the efficacies of both Group A and Group B.

Dysuria

Dysuria	Mean difference score	Sd	Mann-Whitney U	P
Group-A	1.55	0.783	169	0.7396 NS
Group-B	1.50	0.827		

Dysuria was seen to be reduced in both the groups Extremely significantly. When subjected to Wilcoxon Rank Sum Test and Mann – Whitney U Test, both the groups were equally effective. Hence there was no significant difference found between the efficacies of both Group A and Group B.

Haematuria

Haematuria	Mean difference score	Sd	Mann-Whitney U	P
Group-A	1.00	0.632	73	0.5873 NS
Group-B	1.13	0.516		

Haematuria was seen to be reduced in group A is very significantly but in group B it is Extremely significant . When subjected to Wilcoxon Rank Sum Test and Mann – Whitney U Test, both the groups were equally effective. Hence

there was no significant difference found between the efficacies of both Group A and Group B.

Size of Stone

Size of Stone (mm)	Mean difference	Sd	Unpaired T	P
Group-A	3.713	2.862	0.3565 Df-58	0.7227 NS
Group-B	3.953	2.324		

In the above table, there is no significant difference in the results of both groups on size of stone at the 5% level of significance.Hence, both the groups are equally effective on the size of stone.

Overall Effect of Therapy on Both Groups

Symptoms	% Relief	
	Group-A	Group-B
Pain	71.66	80
Burning Micturation	81.06	88.63
Dysuria	79.62	78.33
Haematuria	77.27	92.85

DISCUSSION

Effect in Pain: In Trial Group after accomplishment of treatment 3 patients had severe pain abdomen, 4 patients had moderate pain and 7 patients had mild pain. 16 patients had no pain in abdomen after completion of treatment. In Control Group, after accomplishment of treatment none of the patient had severe pain in abdomen, 5 patients had moderate pain and 5 patients had mild pain. 20 patients had no pain in abdomen after completion of treatment.After Statistical Analysis, we got there is no significant difference in the results of both groups on Pain.

Effect in Burning Micturition: In Trial Group after accomplishment of treatment 01 patient had moderate complaint. 07 patients had mild complaint of burning micturation. 22 patients had no complaint about burning micturition.In Control Group after accomplishment of treatment 01 patient had moderate complaint 04 patients had mild complaint about burning micturation, whereas 25 patients had relieved from the complaint of burning micturation.After Statistical Analysis, there is no substantial difference in the result of both groups on Burning Micturition.

Effect on Dysuria: In Trial Group after accomplishment of treatment 02 patients had moderate complaint about dysuria, 03 patients had mild complaint about dysuria. 25 patients had no complaint about dysuria.In Control Group after completion of treatment 01 patients had moderate complaint, 06 patients had mild complaint whereas 23 patients had no complaint at all.After Statistical Analysis, there is no substantial

difference in the result of both groups on Dysuria.

Effect on Haematuria: In Trial Group, after accomplishment of treatement 03 patients had mild haematuria, whereas 27 patients were relieved completely from haematuria. In control group, after accomplishment of treatement mild haematuria was seen in 02 patient and 28 patients were relieved from the haematuria completely. After statistical analysis, there is no significant difference in the result of both groups on Haematuria.

Effect on size of stone: In Trial group, 54.70% change in size of stone was observed. The mean score of size of stone in trial group before treatment was 7.053, which was reduced to 3.34 after treatment. After employing Paired- 't test' from the given data the result was found statistically significant at the level of $p<0.05$.In control group, 67.91% change in size of stone was observed. The mean score of size of stone in control group before treatment was 6.426, which was reduced to 2.473 after treatment. After employing Paired- 't test' from the given data the result was found statistically significant at the level of $p<0.05$.By equating the results of both trial and control groups on the size of stone statistically analysed by using the Unpaired –'t test'; there was no significant difference in the results of both groups on size of stone at the level of $p<0.05$.Hence, the efficacy of both Group A and Group B is same. Both the drugs are effective in mostly same manner in the management of mootrashmari.

Overall Response of Therapy in Both Groups:Results show recovering action on all the subjective and objective symptoms of patients in both the groups. Some symptoms were persevering in some patients and rest of all had reduced their symptoms within predetermined period.Statistical analysis shows enhancement in their overall symptoms in both groups and hence, it may be quantified that both drugs of trial and control group comparatively having no significant action with p –value (< 0.05). After the completion of study we found both The Drugs are more or less equally significant on urolithiasis in which Nagaradikwath contain Nagar, Varun, Gokshur , Pashanbhed, Bramhi & Yavakshar . where Cystone contain Shilapushpa, Pashanbhed, Manjishtha, Apamarga, Gojiha, Sahadevi, Hajral yahud Bhasma & Shilajeet. Drugs in both groups act like Kaphahara, Ashmaribhedana, Lekhana, Mutral & Vedanasthapana . Due to these reasons both the drugs showing same efficacy.Advantage of Nagaradikwath is coastwise it is cheaper than Cystone .

CONCLUSION: The current data of the series uncovers that in **Trial group,** there is 71.66% relief in pain, 81.06% relief in burning micturation, 79.62% relief in dysuria, 77.27% relief in haematuria and 54.70% changes in the size of stone. As per the overall effect of therapy, out of 4 subjective parameters, there is good change in 3 parameters and moderate change in only 1 parameter.In **Control Group**, there is 80% relief in pain, 88.63% relief in burning micturation, 78.33% relief in dysuria,

92.85% relief in haematuria and 67.91% changes in the size of stone. As per the overall effect of therapy, out of 4 subjective parameters, there is good change in all 4 parameters.The improvement is statistically significant in both the groups.But as comapring the results of both the groups with each other, there is no statistical significance noticed in the study.No side effects were observed in this study.To triumph more significant results we can rise the dose of Trial drug and duration of treatment.

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