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CLINICAL EVALUTAION OF "ASHMARI BHEDAN YOG" IN MUTRASH-MARI

Dhiraj Kumar Sharma[1], Pradeep Kumar[2], Vishal Verma[3], Sanjay Kumar. Singh[4]

[1]Reader, Department of Shalyatantra J.D. Ayurvedic Medical College & Hospital G.T. Road Aligarh, Uttar Pradesh, India

[2]Professor Depatrment of Shalya Tantra IMS BHU, Varanasi, Uttar Pradesh, India

[3]Associate Professor Depatrment of Shalya Tantra, [4]Associate Professor Depatrment of Rog Nidan, UttarakhandAyurved University, Rishikul Campus, Haridwar, UttaraKhand, India

ABSTRACT

Urolithiasis is a common disorder with few effective non surgical therapies available. Present study was undertaken to evaluate litholytic property of herbal drug formulation *AshmariBhedanYog* containing, *Gokshur, Talmakhana, Kantkari, Brihati& Erand*.[1] Thirty patients were enrolled in the study and randomly assigned into three groups. Groups 1st received *AshmariBhedanYog*& 2nd Group Placebo. At the end of three months symptomatic improvement and decrease in crystalluria in group 1st were noticed. However there was no significant reduction in stone size in any of groups. We conclude that *AshmariBhedanYog* have useful role in preventing renal stone formation but have no pridominantlitholytic property.

Keywords:*Gokshur, Tribulusterrestris,Talmakhana, Astercanthalongifilia*.

INTRODUCTION

Renal calculus defined as solid concentration in urinary system affects 2- 3% of general population and males have higher incidence than females, ratio being 3:1[2]. Urolithiasis is a global problem and an age old anguish of human body. Unfortunately, few effective non surgical therapies are available for Urolithiasis[3]. In Ayurveda, *Ashmari*can be correlated to Urolithiasis and *Sushruta*, the father of surgery had elaborately described aetiopathogenesis, symptomatology and management of *Ashmari* by drugs and surgery.[4]A number of traditional Indian medicinal plants have been claimed to have litholytic and lithopreventive properties. We undertook present study to evaluate litholytic properties of *AshmariBhedanYog*

Material and Methods: Thirty patients attended the OPD of PG Deptt. Of *Shalya-Tantra, Rishikul Ayurveda College &Hospital, Hardwar* were included in this study after taking informed consent. Patient having renal calculus less than 10 mm without any other diseased conditions like renal failure or obstruction were included. Therapy was considered to be effective when reduction in size of stone was assessed on radiology or patient passed stone in urine. Patients were advised to take antispasmodic drug on development of severe renal colic. Dietary restriction was also suggested during the course of drug trial. Detailed history, physical examination were performed and investigations done on all patients, included estimation of Total and Differential Leucocyte count, Hae-

moglobin, ESR, Blood glucose, Blood urea, Serum creatinine, serum uric acid, serum calcium, serum magnesium and phosphorus. Urine analysis was done for pH, albumin, sugar, phosphate and microscopic examination for crystals, pus cells, epithelial cells, casts and RBC_s were performed. 24 hrs urinary protein, excretion of urinary calcium andPhosphorus was estimated, culture and sensitivity test of urine was also performed whereas needed. Radiological examination included a plain x- ray of abdomen (KUB region) and ultasonography for KUB region. Intra venous Pyelogram (IVP) was also performed in special circumstances. Patients were randomly distributed into two groups. The patients in Ist group (n = 20) recieved*AshmariBhedan Yoga* and 2nd group (n = 10) re-cieved placebo. Patients were advised to follow up for three months at one month interval. During the course of trial clinical improvement, dietary assessment and routine haematological, bio-chemical and urine examinations were performed monthly, whereas Radiological procedures were repeated at the end of therapy. The trial drug '*AshmariBhedan Yoga'* was prepared in the pharmacy of department of *Rasa shastra*. The contents of *AshmariBhedan Yoga* were air dried and made into crude powder. One part powder was mixed with 8 times of water and boiled till its volume became 1/4th of initial volume, it was *kwath* which was again dried on low temperature and water extract was prepared , dried and made into fine powder and dispensed into gelatin capsules.The drug was given in dose of 1 gm thrice a day & patients were instructed to take this drug with *dadhi as anupan*.

Observation

Total 30 patients were registered in the study and divided into two groups.

Group 1st- Trial group: Total no. of '20' patients 16 males 04 females were kept under this group for trial of Drug.

Group 2nd- Placebo group: Total no. of '10' patients 08 males 02 females were kept under this group & given sugar in capsule form.

In group first, pain abdomen was present in 80% of patients, improved in 60% of patients at 3 months , vomiting was present in 40% of patients ,improved in 30% of patients, dysuria was present in 60% of patients, improved in 45% of patients, haematuria present in 20% of ,improved in 10% of cases, burning micturition present in 25% , improved in 20% cases, fever was present in 40% of cases ,improved in 30% cases, frequency of urine present in 70% cases, improved in 60% of patients. Symptoms did not deteriorate in any of the patients.

In group second (placebo), pain abdomen was present in 80% of patients , vomiting in 40%, dysuria in 60%, haematuria in 20%, burning micturition in 30%, fever in 60%, frequency of Urine in 60% cases. Pain abdomen improved in 20% of cases, Vomiting, haematuria in none, burning micturition in 20% and fever in 20%, dysuria improved in 10% cases only, frequency of urine improved in 20% of cases. (Table¬ 1)

Table1: Symptoms at start and completion of study.

Symptoms	Group I (n=20)		Group II (n=10)	
	0 months	**3 months**	**0 months**	3

Pain abdomen **Absent Present Improved Deteriorated**	04 (20%) 16 (80%) - -	04 (20%) 02 (10%) 12 (60%) 02 (10%)	02(20%) 08(80%) - -	**02(20%) 06(60%)**
Vomitting**Absent Present Improved Deteriorated**	12(60%) 08(40%) - -	12(60%) 02(10%) 06(30%) -	06(60%) 04(40%) - -	**06(60%) 04(40%)**
Dysuria **Absent Present Improved Deteriorated**	08(40%) 12(60%) - -	08(40%) 03(15%) 09(45%) -	04(40%) 06(60%) - -	**04(40%) 05(50%)**
Haematuria**Absent Present Improved Deteriorated**	16(80%) 04(20%) - -	16(80%) 02(10%)	08(80%) 02(20%) - -	**08(80%) 02(20%)**
Burning Micturition **Absent Present Improved Deteriorated**	15(75%) 05(25%) - -	15(75%) 01(05%) 04(20%	07(70%) 03(30%) - -	**07(70%) 01(10%) 02(20%**
Frequency of Urine **Absent Present Improved Deteriorated**	06(30%) 14(70%) - -	06(30%) 02(10%) 12(60%	02 (20%) 08(80%) - -	**02(62%) 06(60%) 02(20%**
Fever **Absent Present Improved Deteriorated**	12(60%) 08(40%) - -	12(60%) 02(10%)	04(40%) 06(60%) - -	**04(40%) 04(40%)**
Weakness **Absent Present Improved Deteriorated**	**06(30%) 14(70%)**	**06(30%) 02(10%)**	**07(70%) 03(30%)**	**07(70%) 01(10%)**

Table.2: Improvement of Therapy in signs and symptoms in First group

S.n.	Signs and symp-	Mean score			S.D.	S.E.	't'	'p' Val-
		BT	AT	%				
1.	Pain	3.6	0.55	85	0.8	0.29	10.67	**<0.001**
2.	Burning micturi-	1.08	0.75	30	0.49	0.14	2.35	**<0.05**
3.	Haematuria	1.2	0.58	53	0.6	0.19	3.52	**<0.01**
4.	Frequency of urine/day	9.14	12.00	31.26	1.80	0.68	4.18	**<0.01**
5.	Dysuria	2.6	0.40	69.2	0.7	0.33	5.38	**<0.01**
6.	Vomiting	2.7	0.62	77.2	0.7	0.27	7.69	**<0.001**
7.	Fever	2.0	0.43	85.7	0.4	0.17	10.04	**<0.001**
8.	**Weakness**	**2.0**	**0.66**	**66.6**	**0.4**	**0.19**	**6.92**	**<0.001**

Table.3: Improvement of Therapy in signs and symptoms in second group (placebo)

S.n.	Signs and symp-	Mean score			S.D.	S.E.	't'	'p' Val-
		BT	AT	%				
1.	Pain	2.00	1.33	33.3	0.4	0.27	2.45	**>0.05**
2.	Burning micturi-	1.25	0.58	53	0.65	0.19	3.52	**<0.01**
3.	Haematuria	1.33	1.33	0.00	0.0	0.00	0.00	-
4.	Frequency of urine/day	10.44	12.00	14.89	2.63	0.87	1.77	**>0.05**
5.	Dysuria	2.00	1.00	50	0.0	0.00	0.00	-
6.	Vomiting	0.25	0.08	33	0.2	0.08	1.00	**>0.05**
7.	Fever	1.77	1.55	12.4	0.0	0.00	0.00	-
8.	**Weakness**	**2.00**	**1.16**	**41.6**	**0.6**	**0.28**	**2.92**	**<0.05**

Comparison of Effect of Trial drugs in both groups: On comparison the effect of trial drugs in both group, the effect of trial drug in group 1st over the symptoms pain, vomiting, fever was highly significant (P<0.001) While significant effect (P <0.01) was observed on haematuria, frequency of urine/day and dysuria. The effect was also significant (P<0.05) on symptom of burning micturition. (Table.2)

While on the other hand the effect of drug in 2nd group (Placebo group) over pain, frequency of urine/day and vomiting burning micturition (P<0.01) and weakness (P<0.05) was significant but the effect on haematuria, dysuria and fever was insignificant (P value not recordable). (Table.3)

The overall effect of trial drug in group 1st was highly significant (P<0.001) while in group 2nd (Placebo group) effect of formulation in majority of symptoms was statistically insignificant (P>0.05).

There was no significant difference in following parameters in both groups during study period. Mean TLC, Haemaglobin, blood urea, blood sugar, S.creatinine, S.calcium, S.uric Acid, S. phosphorus.

Mean urinary calcium at the start of the study was 326.16±10.6 mg/dl in groups Ist and 235.7±19.6 mg/dl in group 2nd and at the end of study declined to 254.23±48.7 in group Ist. This apparent decline in calcium excretion was not statistically significant. In IInd group urinary calcium excretion remained almost same at completion

of study. The size of the stone did not show any significant change in both the groups during the study period.
(Table.4)

Table 4: Investigational parameters at start (o month) and at the end (3 months) of study (Mean ± SD)

	0 months	3 months	0 months	3 months
TLC (/cu mm)	6154.60± 1233.46	6440.84± 1068.80	7450.70 ± 1366.10	**7120.50 ± 1232.38**
Hb% (gm/dl)	12.76±0.54	12.82±0.46	12.26±0.61	**12.33±0.36**
ESR (mm 1st hr)	16.30 ±5.16	11.48±4.55	18.88±4.30	**16.40±2.35**
Fasting Blood glucose	82.63±16.72	78.86±7.58	80.22±12.57	**81.06±11.88**
Blood urea (mg/dl)	27.58±8.76	23.60±11.48	25.60±12.27	**24.77±11.96**
Serum creatinine (mg/dl)	1.15±0.20	1.17±0.16	1.16±0.10	**1.15±0.17**
Serum uric Acid (mg/dl)	5.46±0.21	6.10±0.26	4.88±0.19	**5.30±0.20**
Serum calcium	8.2±0.11	8.6±0.22	8.10±0.10	**9.2±0.24**
Serum Phosphorus (mg/dl)	3.2±0.14	3.68±0.21	3.76±0.18	**3.88±.22**
Urinary calcium (mg/dl)	326.16±10.6	254.23±48.7	235.7±19.6	**242.64±15.70**
Size of stone (mm^2)	**6.34.±0.78**	**6.13±0.54**	**5.8±0.67**	**5.3±0.63**

These observation show a marked and statistically significant reduction in crystalluria at
3 months of treatment of*AshmariBhedan Yoga.*

DISCUSSION

This study was designed to evaluate the effect of *AshmariBhedanYog* on renal calculus disease included 30 patients divided into two groups. In group I[st], 20 patients were treated with *AshmariBhedanYog*, in Group 2nd, 10 patients recieved placebo for three months.

In 1st group, there were significant improvements in symptoms including pain abdomen, nausea, vomiting, dysuria and crystalluria, while in group 2nd (Placebo group) there was no significant improvement. Improvement observed in symptoms in group 1st was statistically significant as compared to patients in placebo. There was no evidence of any deterioration of renal functions in patients treated with *AshmariBhedanYog*, suggesting that the trial drug formulation is not nephrotoxic. The drug formulation also had no effect on Blood urea, S.creatinine, S. uric acid, Blood glucose etc levels.

Mean stone size did not change in both groups during study period and none of the patient passed stone in urine suggesting that the trial drug do not have major lithotryptic properties. However, significant decrease in crystalluria and stabilization of Stone size with no further increase in size suggests a positive role of *AshmariBhedanYog*in preventing renal calculus formation.

CONCLUSION

It is evident from the present study that *AshmariBhedanYog* is safe and nontoxic. The drug improves symptomatology of

urolethiasis disease & arrest further progression of urinary stones and abolishescrystalluria in majority of patients. Hence it can be used for prevention of urolethiasis in high risk cases. However, the drug does not have predominant lithotryptic properties and cannot be suggested for treatment of wellformed renal stones of greater than 10mm of size. As sample size was very small and follow up was relatively short (3 months) further long term study is required to establish the efficacy of the AshmariBhedanYog.

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CORRESPONDING AUTHOR

Dr. Dhiraj Kumar Sharma
Reader, Department of Shalya Tantra
J.D. Ayurvedic Medical College & Hospital G.T. Road Aligarh, Uttar Pradesh, India
Email: dheeraj.sharma326@gmail.com

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