



Research Article

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CLINICAL STUDY OF YAVAKSHARADI YOGA IN THE MANAGEMENT OF MUTRASHMARI (UROLITHIASIS)

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ABSTRACT

Ashmari – Urolithiasis is one of the most common diseases found globally. It is found that this condition is having recurrence in nature in spite of removal of stone by surgical methods in large number of cases. In the present study an effort was made to evaluate the efficacy of 'Yavaksharadi yoga' (Ingredients : Gokshura -*Tribulus terrestris* and Yava -*Hordeum vulgare*) in the management of Ashmari. Sixty patients with diagnosis of Urolithiasis were taken for the study. Thirty patients received Placebo drug (Group A) and thirty patients were given trial drug i.e 'Yavaksharadi yoga' (Group B) for a period of four weeks. The subjects were asked for follow up once in a month for six consecutive months. The subjective and objective assessments were done after collecting data and analyzed with relevant statistical parameters. Pathya chart was given to all subjects keeping in view of stone promoters and inhibitors in terms of food and activities. After completion of the study, the results were encouraging in Group B (Trial drug), when compared with Group A (Placebo). The efficacy of Yavaksharadi yoga in relieving Pain abdomen was noted as 96.7 % of individuals, whereas in Placebo group result appreciated in only 46.7 %. (Significant level is < 0.001). Other major subjective parameters like Dysuria and Haematuria complaints got completely relieved (100 % and Significant level is 1.000) in both the group, but one week early response was appreciated in Group B than that of Group A. In objective parameter, stone expulsion was found with poor response in Group A (36.7 %) whereas fair response was seen in Group B (50 %). This shows that 'Yavaksharadi yoga' is effective in relieving the pain abdomen (Shulahara), Dysuria (Mutra kruchrata) and Haematuria (Sarudhira mutrata). It not only helps in expulsion of formed stone but also prevent new stone formation.

Keywords: Gokshur, Yavakshara, Ashmari, Urolithiasis

INTRODUCTION

Ashmari¹ (Urolithiasis) is a condition that affects homeostasis of the Urinary system.² It is a challenging clinical condition in the field of both medicine and surgery. In Bio-medical system, which is supposed to be the most advanced and highly scientific system, the problem of urolithiasis has no satisfactory solution. Despite advancement in modern techniques, the recurrence rate of Urolithiasis is approximately 50 % within 5 to 7 years.³ The preferred treatment is surgical removal or lithotripsy or palliative. But, this does not stop the formation of a subsequent stone. In Ayurveda, urinary stone diseases have been described in detail under the heading of Ashmari and it is considered as one among Astamagadha (Eight fatal conditions).^{4,5} Sushrut, "The Father of Surgery," being a surgeon himself has described in detail its etiopathogenesis, symptomatology, medical and surgical treatment and prognosis. Good number of drugs have been described that are very effective against urolithiasis, namely Shatavari (*Asparagus racemosus*), Gokshur (*Tribulus terrestris*), Varuna (*Crataeva nurvala*), Pashanabhed (*Bergenia lingulata*) etc. In the present work, an attempt has been made to determine the effect of 'Yavaksharadi Yoga'⁶ with placebo as a control group in the management of Ashmari.

MATERIALS AND METHODS

Selection of patients

The present study had been conducted by selecting patients from OPD and IPD of SDM college of Ayurveda

and hospital, Hassan, Karnataka, India. The patients were screened on clinical grounds and routine laboratory investigations to establish the nature of urinary problems. Study was carried out as per ethical guidelines with institutional ethical clearance SDM/IEC/03/2007-08 Dated 09/05/2007.

Grouping

A total number of 60 samples were randomly selected and allocated into two groups. Group A consists of 30 patients who received placebo treatment. Group B consists of 30 patients who received trial drug- Yavaksharadi Yoga. This is clinical study with pre-test and post-test study design. The patients were given 'Yavaksharadi yoga' for a period of four weeks in the dose of six gm thrice a day before food with buttermilk. Patients of both the group were advised for a follow up of every week for 4 weeks, during treatment and later once a month for next five consecutive months. The subjective and objective assessment was done after collecting data and analyzed with relevant statistical parameters.

Reason for selecting study design

For any scientific trial, a proper design is required so as to assess the efficacy of the therapy, in turn to meet the objectives. Here the drug 'Yavaksharadi yoga' was selected keeping in view of its each ingredient present in it. The yoga was prepared as described in classical textbook. As such there is no direct reference for the dosage i.e. six g thrice a day, that was decided based on

the observations made during pilot study. Anupana i.e. Vehicle with the trial drug was selected as buttermilk, since the particles are water-soluble and buttermilk is having lekha property (scarification).⁷ The drug was administered before meals so as to increase the bioavailability. Placebo consists of starch prepared out of rice and wheat flour. Patients of both the group were advised to drink 3-4 liters of water and to consume suitable diet with proper sleep and excretion of natural urges. Patients were advised to avoid milk, tomato, cauliflower, spinach, fish and meat (incompatible diets) during the period of treatment.⁸ Pathya (Wholesome and unwholesome diet and regimen) chart was prepared keeping in view of causative dietetic factors and also to avoid the recurrence of stone.⁹⁻¹¹ During the follow up of six months, the subjective improvement was assessed and this period was also important to check the recurrence of stones. The subjects underwent necessary investigations, before and after treatment so as to assess the objective parameters.

Objectives of the study

- To assess the efficacy of Yavaksharadi Yoga in the management of Urolithiasis
- To compare the impact of placebo in Urolithiasis with the trial drug

Selection Criteria

Inclusion Criteria

- Patients presented with general clinical features (samanya lakshan) of Urolithiasis as per classical texts.
- The patients between the age group of 16-60 years were selected irrespective of sex, occupation, race, chronicity and socio-economical status.

Criteria for assessment - Subjective criteria

Pain abdomen

Clinical features	Grading
Absence of pain abdomen	Grade 0 (no pain)
Present but does not disturbs routine	Grade 1 (mild pain)
Present, which disturbs routine	Grade 2 (moderate pain)
Patient rolls on bed due to pain	Grade 3 (severe pain)

Haematuria

Response obtained in days	Grading
In between 01 – 07 days	Grade 4 (Good response)
In between 08 – 14 days	Grade 3 (Fair response)
In between 15 – 21 days	Grade 2 (Poor response)
In between 22 – 28 days	Grade 1 (Very poor response)
Still persisting (>28 days)	Grade 0 (No response)

Pain abdomen

Response obtained in days	Grading
In between 01 – 07 days	Grade 4 (Good response)
In between 08 – 14 days	Grade 3 (Fair response)
In between 15 – 21 days	Grade 2 (Poor response)
In between 22 – 28 days	Grade 1 (Very poor response)
Still persisting (>28 days)	Grade 0 (No response)

Dysuria

Response obtained in days	Grading
In between 01 – 07 days	Grade 4 (Good response)
In between 08 – 14 days	Grade 3 (Fair response)
In between 15 – 21 days	Grade 2 (Poor response)
In between 22 – 28 days	Grade 1 (Very poor response)
Still persisting (>28 days)	Grade 0 (No response)

Criteria for assessment - Objective criteria

Response in stone expulsion	Grading
No stone expulsion	Grade 3 (No response)
Stone expulsion (< 50 %)	Grade 2 (Poor response)
Stone expulsion (between 50 to 75 %)	Grade 1 (Fair response)
Stone expulsion (> 75 %)	Grade 0 (Good response)

- Patients diagnosed as Urolithiasis and not responding for any other medical management were included.
- Patients of uncomplicated and under control diabetes mellitus and hypertension were also included.

Exclusion criteria

- Patients who are contraindicated for paniyakshara karma.
- Patients who were suffering with severe systemic disorders.
- Patients associated with complication of the diseases were excluded.¹²

Investigations

Blood examination

Hb %, Total count, Differential count, ESR, RBS, Blood Urea and Serum Creatinine

Urine analysis

Physical and Chemical - Colour, pH, Sp.Gravity, Reaction, Sugar, Albumin, Microscopic - RBC, Cast and Crystals, Epithelial and Pus cells.

Radiological study

Plain X-RAY KUB, IVP (If necessary)

Ultra Sonographical study

KUB

Diagnostic Phase

The selected patients were subjected to thorough general, systemic examination and investigations, after the diagnosis was confirmed the patients were registered for the clinical study.

Table 1: Age distribution of patients

Age in years	Group A		Group B	
	No	%	No	%
Upto 30	11	36.7	15	50.0
31-40	10	33.3	11	36.7
41-50	4	13.3	3	10.0
51-60	5	16.7	1	3.3
Total	30	100.0	30	100.0
Mean \pm SD	36.80 \pm 11.77		31.53 \pm 8.09	

Table 2: Gender distribution of patients

Gender	Group A		Group B	
	No	%	No	%
Male	23	76.7	20	66.7
Female	7	23.3	10	33.3
Total	30	100.0	30	100.0

Samples are gender matched with P = 0.390

Table 3: Diet distribution

Diet	Group A		Group B	
	No	%	No	%
Mixed	27	90.0	26	86.7
Vegetarian	3	10.0	4	13.3
Total	30	100.0	30	100.0

Table 4: Comparison of Clinical parameters before treatment in two groups

Clinical variables	Group A (n = 30)	Group B (n = 30)	P value
Pain abdomen			
No pain	0 (0 %)	1 (3.3 %)	0.577
Mild	3 (10 %)	2 (6.7 %)	
Moderate	16 (53.3 %)	12 (40 %)	
Severe	11 (36.7 %)	15 (50 %)	
Dysuria			
Absent	10 (33.3 %)	3 (10 %)	0.028
Present	20 (66.7 %)	27 (90 %)	
Haematuria			
Absent	25 (83.3 %)	24 (80 %)	0.739
Present	5 (16.7 %)	6 (20 %)	

Table 5: Type of stone in two groups of patients

Type of stone	Group A		Group B	
	No	%	No	%
Pittaja	4	13.3	6	20.0
Vathaja	26	86.7	24	80.0
Total	30	100.0	30	100.0

Type of stone is statistically similar in two groups with P = 0.488

Table 6: Site of Stone in two groups of patients

Site of Stone	Group A		Group B	
	No	%	No	%
Kidney	17	56.7	15	50.0
Ureteral	10	33.3	11	36.7
Both	3	10.0	4	13.3
Total	30	100.0	30	100.0

Site of stone is statistically similar in two groups with P = 0.875

Table 7: Side in two groups of patients

Side	Group A		Group B	
	No	%	No	%
Unilateral	24	80.0	20	66.7
Bilateral	6	20.0	10	33.3
Total	30	100.0	30	100.0

Distribution of side is statistically similar in two groups P = 0.243

Table 8: Size

Size	Group A (n = 50 stones)		Group B (n = 52 stones)	
	No	%	No	%
Unmeasured	6	12.0	7	13.5
< 6	21	42.0	23	44.2
6-10	21	42.0	22	42.3
>10	2	4.0	0	0.0

Table 9: Single / Multiple

Single / Multiple	Group A		Group B	
	No	%	No	%
Single	21	70.0	18	60.0
Multiple	9	30.0	12	40.0
Total	30	100.0	30	100.0

Distribution of single or multiple stones is statistically similar with P = 0.417

Table 10: Evaluation of two groups based on pain abdomen (includes follow up period)

Pain abdomen	Before treatment (n = 30)	After treatment (n = 30)	% Change
Group A			
No pain	0 (0 %)	14 (46.7 %)	46.7
Mild	3 (10 %)	7 (23.3 %)	13.3
Moderate	16 (53.3 %)	6 (20 %)	33.3
Severe	11 (36.7 %)	3 (10 %)	26.7
Group B			
No pain	1 (3.3 %)	29 (96.7 %)	93.4
Mild	2 (6.7 %)	1 (3.3 %)	3.4
Moderate	12 (40 %)	0 (0 %)	40
Severe	15 (50 %)	0 (0 %)	50
P value	0.577	< 0.001**	

Table 11: Response in days – Pain Abdomen

Pain abdomen (Responded in days)	Group A	Group B
1 to 7 days	0	2
8 to 14 days	2	5
15 to 21 days	6	10
22 to 28 days	6	6
> 28 days (still Persisting)	16	6

Table 13: Response in days – Dysuria

Dysuria (Responded in days)	Group A	Group B
1 to 7 days	1	1
8 to 14 days	3	15
15 to 21 days	10	11
22 to 28 days	6	0
> 28 days (still Persisting)	0	0

Table 15: Response in days – Haematuria

Haematuria (Responded in days)	Group A	Group B
1 to 7 days	2	1
8 to 14 days	2	5
15 to 21 days	1	0
22 to 28 days	0	0
> 28 days (still Persisting)	0	0

RESULTS AND DISCUSSION

Wholesome food and activities plays an important role in expulsion of the stones and hence subjects needs to adhere for those practices to minimize the recurrence of the diseases in future. This study also gives a ray of hope for the subjects suffering from Urolithiasis that they can go for Paneeya kshara before going for conventional approach, since it possesses Chedana (cutting/breaking), Bhedana (splitting), Lekhana (scarification) and Mutrala (diuretic) properties for facilitating in disintegration of the stone.¹³ The results were appreciable even in the placebo group which suggest that diet and lifestyle modifications do have major role to play in the management of the disease and in prevention. Onset of the results was delayed in placebo group against the trial group and mere expulsion of the stones may not contribute for the complete management of kidney stones without administrating any medications. Commonly it was observed that many of the subjects' carries stones in their urinary tract without any symptom (silent stones) and sometimes even they expel out without the knowledge of the individual and the same is observed in placebo group, hence expulsion wise there is no much difference in both the groups that is evident in the study with the help of the objective parameters. Urolithiasis drags the attention of the subjects mostly after the onset of the acute clinical features that makes them to rush to casualty ward. This trial compound has shown encouraging symptomatic relief in most of the clinical features with expulsion of calculi. Gokshura contains potassium nitrite in rich quantity which acts as an alkalizer. Further when it is combined with Yavakshara, synergistic action of alkalizer is enhanced and appreciating the results in disintegration

Table 12: Evaluation of two groups based on Dysuria

Dysuria	Before treatment (n = 30)	After treatment (n = 30)
Group A		
Absent	10 (33.3 %)	30 (100 %)
Present	20 (66.7 %)	0 (0 %)
Group B		
Absent	3 (10 %)	30 (100 %)
Present	27 (90 %)	0 (0 %)
P value	0.028*	1.000

Table 14: Evaluation of two groups based on Haematuria

Haematuria	Before treatment (n = 30)	After treatment (n = 30)
Group A		
Absent	25 (83.3 %)	30 (100 %)
Present	5 (16.7 %)	0 (0 %)
Group B		
Absent	24 (80 %)	30 (100 %)
Present	6 (20 %)	0 (0 %)
P value	0.739	1.000

Table 16: Stone Expulsion (Patients) (AT –After Treatment)

Stone Expulsion (AT)	Group A		Group B	
	No	%	No	%
No	19	63.3	15	50.0
Expelled	11	36.7	15	50.0
Total	30	100.0	30	100.0

Stone expulsion after treatment is statistically similar in two groups with P = 0.297

and elimination of urinary stones.¹⁴

Response in pain abdomen

In Group A, Out of 30 patients, 46.7 % of the patients got complete relief, whereas 53.3 % patients were persisted with either Severe (10 %), moderate (20 %) or mild pain (23.3 %) after treatment. In Group B, 96.7 % of the patients got complete relief, whereas only 3.3 % patients were persisted with mild pain and 'P' value shows highly significant (< 0.001 %). In Group A, no relief was obtained within 7 days of treatment. During second week 2 patients got relieved of their complaint, in between 15 – 21 days 6 patients responded, in between 22 – 28 days 6 patients responded and remaining 16 patients persisted with pain; mild (7), moderate (6) and severe (3). In Group B, 2 patients got relieved from pain within 7 days of treatment. During second week 5 patients got relieved of their complaint, in between 15 – 21 days 10 patients responded, in between 22 – 28 days 6 patients were responded and remaining 6 patients persisted with pain for few more weeks, later most of them got relieved completely from this complaint. (Table 10 and 11)

Response in Dysuria

In Group A, out of 20 patients, 100 % of the patients got complete relief, whereas in Group B, out of 27 patients 100 % of the patients got complete relief. In Group A out of 20 patients suffering from dysuria, 1 patient (5 %) got relieved within 7 days of treatment, whereas 3 patients (15 %) in 8 – 14 days, 10 patients (50 %) got relieved in between 15 to 21 days and remaining 6 patients (30 %) were responded in fourth week. But in Group B out of 27 patients of dysuria, 1 patient (3.7 %) was relieved within

7 days of treatment, whereas 15 patients (55.55 %) were relieved within second week i.e 8 – 14 days and remaining 11 patients (40.7 %), all of them, responded within third week itself. (Table 12 and 13)

Response in Haematuria

In Group A, out of 5 patients, all of them (100 %) were got complete relief, even in Group B, out of 6 patients, every one (100 %) has got completely relieved from this complaint. In Group A, out of 5 patients of haematuria, 2 (40 %) patients responded in first week, 2 (40 %) patients were got relieved in second week i.e 8 – 14 days and remaining 1 (20 %) patient responded in third week. Whereas in Group B out of 6 patients, 1 patient (16.67 %) responded in first week itself and remaining 5 (83.33 %) of them were got completely relieved from this complaint within second week i.e. 8 – 14 days. (Table 14 and 15)

Response in stone expulsion

In group A, out of 30 patients expulsion of stone observed in only 11 patients (36.7 % - Poor Response) whereas in group B, expulsion observed in 15 patients (50 % - Fair Response). Statistically 'p' value = 0.297 which denotes that in both the group response was similar after the treatment. (Table 16)

CONCLUSION

This comparative study clearly highlighted the efficacy of 'Yavaksharadi yoga' to overcome these clinical features. Hence mere expulsion of the stone is not a complete management and the administered drug 'Yavaksharadi yoga' was effective enough not only dealing with expulsion of stone but also in reducing symptoms like pain abdomen, haematuria and dysuria.

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