

A CLINICAL STUDY TO EVALUATE THE EFFICACY AND SAFETY OF GOKSHUR EXTRACT CAPSULE IN RENAL CALCULUS

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ABSTRACT

Kidney stones [renal calculi] are solid concretions formed in the kidney from dissolved urinary minerals. The incidence of renal calculi ranges from 55-60 % in males and 40-45% in females. The most advanced non-invasive surgical procedure in conventional therapy like lithotripsy developed certain complications in later period. Hence there is an urgent need to look into an alternative method to treat renal calculi. For this reason, a single blind placebo controlled clinical study is conducted on 200 patients attending the OPD of Shalyatantra, at Govt. Astang Ayurvedic College, Indore, Madhya Pradesh, India diagnosed with renal calculus. They were randomly allotted into two groups i.e. Group A and Group B comprising 100 patients in each. Two capsules of Gokshura extract of 500 mg each were given thrice daily for group A and two capsules of sugar powder of 500 mg each were given thrice daily for group B. Results were assessed based on the improvement in the clinical features, laboratory and radiological investigations. In this study, 62.63, 86.74, 86.66 and 91 percent of the subjects were completely relieved of symptoms of frequency of micturition, dysuria, haematuria and intermittent colicky pain in Group A. 95.12 and 84.74 percent of the subjects of Group A were found with absence of calculi through radiological investigation after treatment with sizes 4-6 mm and 7-10 mm before treatment respectively. In Group B, there was no considerable relief in either the symptoms or in the expulsion of stone. No adverse drug reactions were observed during or after the study. Hence it can be concluded that the Gokshura extract capsules were effective and safe in the cure of renal calculus as compared with the sugar powder capsules.

Key words: Renal calculi, *Gokshura*.

INTRODUCTION

Kidney stones [renal calculi] are solid concretions formed in the kidney from dissolved urinary minerals. The incidence of renal calculi ranges from 55-60 % in males and 40-45% in females. Among the various types of calculi, the prevalence of Calcium stones is 75-85%, uric acid stones 5-6%, cysteine stones 21% and struvite stones 10-15%. The majority of calcium stones comprise of calcium-oxalate stones followed by calcium phos-

phate stones. Some people with metabolic abnormalities may produce uric acid stone and cysteine stone.

Kidney stone typically leave the body by the passage in urine stream and many stones are formed and passed without causing symptoms. If stones grow more than 2-3 mm they can cause dilation and stretching of upper ureter and renal pelvis as well as muscle spasm of ureter, trying to move stones. It causes renal colic which is

associated with nausea and vomiting. There can be blood in urine also. The non-invasive surgical procedure of Conventional therapy like lithotripsy developed diabetes 3.75 times and hypertension 1.47 times than those whose kidney stone were treated with other methods.

To overcome this, there is an urgent need to peep into alternative systems of medicine for safe, effective and economical therapies. Ayurveda, an indigenous Indian system offers vast scope for the successful treatment for urinary tract problems like renal calculus. Acharya Charak and Sushruta identified a disease named *Asmari*. It is mentioned in *Ashta Mahagadas*. *Slesmaasmari* described in Ayurveda resembles with calcium phosphate stone, *Pitta asmari* with uric acid stones and *Vata asmari* with calcium oxalate stone. Large numbers of indigenous drugs are mentioned for the treatment. Hence there is a need for systematic investigation and evaluation and of their efficacies.

Aims and objectives

To evaluate the efficacy and safety of *Gokshura* extract capsules in renal calculus.

Materials and methods

Subjects

Patients attending the OPD of *Shalyatantra* at Govt. Astring Ayurvedic College, Indore Madhya Pradesh, India, were diagnosed with renal calculus. They were randomly allotted into two groups i.e. Group A and Group B consisting of 100 patients in each.

Inclusion criteria

Patients aged between 20 to 60 years of either sex with the complaint of the following signs and symptoms.

- Haematuria
- Dysuria
- Frequency of micturition

- Colicky pain
- Evidence of calculus more than 4mm up to 10mm in either X-ray KUB or USG KUB region.

Exclusion criteria

Patients with hypertension, severe UTI, Hydro nephrosis, pyelonephrosis and chronic renal failure

Criteria for withdrawal

If any adverse events developed during course of the treatment

Drug administration

Two capsules of *Gokshura* extract of 500 mg each were given thrice daily for group A and two capsules of sugar powder of 500 mg each were given thrice daily for group B for three months.

Drug preparation

Dry fruits of *Gokshura* were pounded to coarse powder and water is added in the ratio of 1:8. It was boiled till $\frac{1}{4}$ of it is remained. It was filtered and the *kwatha* was boiled till the evaporation of water and dried. Dry *Gokshura panchang* is collected and powdered. 100 mg of dried extract powder and 400 mg of *panchang* powder is filled in the empty capsules. They were administered for group A. Sugar was powdered. It was filled in empty capsules and was administered for group B.

Routine Examination and assessment

Patients were informed of the study design thoroughly. A detailed history was taken, the data on physical examination, laboratory investigation were recorded monthly and assessment was made. X-ray KUB or USG KUB was done before treatment and after treatment.

Criteria for the assessment of results

Results were assessed based on the improvement in the clinical features, laboratory and radiological investigation.

A scoring system was adopted for gradation of severity of the disease as 3, 2, 1 respectively for severe moderate and mild

nature of symptoms while 0 was regarded as absence of symptoms.

Observations and Results

Demographic Data

Table 1: Distribution of cases according to age and sex

Age in yrs	Group A				Group B			
	Male	%	Female	%	Male	%	Female	%
21-30	12	12	06	06	10	10	08	08
31-40	28	28	13	13	30	30	15	15
41-50	22	22	12	12	20	20	14	14
51-60	3	3	04	04	01	01	02	02
Total	65	65	35	35	61	61	39	39

Table 2: Distribution of cases according to Prakriti

Prakriti	Group A		Group B	
	No. of Patients	Percentage	No. of Patients	Percentage
Vataj	4	4	03	03
Pittaj	5	5	04	4
Kaphaj	1	1	2	2
Vatapittaj	20	20	22	22
Vatakaphaj	49	49	50	50
Pittakaphaj	13	13	16	16
Sannipataj	8	8	3	3
Total	100	100	100	100

Table 3: Distribution of cases according to nature of work

Nature of work	Group A		Group B	
	No. of Patients	Percentage	No. of Patients	Percentage
Sedentary	64	64	61	61
Active	36	36	39	39
Total	100	100	100	100

Table 4: Distribution of cases according to dietary habits

Diet	Group A		Group B	
	No. of Patients	Percentage	No. of Patients	Percentage
Vegetarian	42	42	44	44
Non-Vegetarian	58	58	56	56
Total	100	100	100	100

Table 5: Distribution of cases according to duration of disease

Duration	Group A		Group B	
	No. of Patients	Percentage	No. of Patients	Percentage
6months	68	68	72	72
01Yrs	22	22	19	19
Above1Yrs	10	10	9	9
Total	100	100	100	100

Clinicaldata

Table 6: Distribution of cases according to the symptoms before treatment and their relief after treatment in Group A

Symptoms	Severe		Moderate		Mild		Nil		%of the pts relieved
	BT	AT	BT	AT	BT	AT	BT	AT	
Frequency of micturition	30	2	46	12	15	20	9	66	62.63
Dysuria	15	1	40	4	28	6	17	89	86.74
Haematuria	5	0	12	1	13	3	70	96	86.66
Intermittent Colicky pain	50	0	49	0	1	9	0	91	91

Table 7: Distribution of cases according to the symptoms before treatment and their relief after treatment in Group B

Symptoms	Severe		Moderate		Mild		Nil	
	BT	AT	BT	AT	BT	AT	BT	AT
Frequency of micturition	30	26	46	48	15	13	9	13
Dysuria	15	14	40	38	28	29	17	19
Haematuria	10	9	5	6	15	13	70	72
Colicky pain	42	41	22	20	34	37	2	2

Table 8: Distribution of cases according to size of Renal Calculi before treatment and their relief after treatment

Size of calculi in mm	Group A			% of the pts relieved	Group B	
	BT	AT	Nil		BT	AT
4 -6mm	41	2	39	95.12	38	38
7-10mm	59	9	50	84.74	62	62
Total	100	11	89		100	100

Table 9: Distribution of cases according to laboratory parameters in Group A

Laboratory parameters	Nil		Up to 5		6-10		11 -20		21-30	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Pus cells	0	0	59	86	31	14	10	0	0	0
Epithelial cells	0	0	4	98	78	2	16	0	2	0
Calcium Oxalates	0	0	86	91	10	7	4	2	0	0
RBCs	58	82	24	18	10	0	0	0	0	0

Table 10: Distribution of cases according to laboratory parameters in GroupB

Laboratory parameters	Nil		Up to5		6-10		11 -20		21-30	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Pus cells	0	0	12	15	54	52	30	30	4	3
Epithelial cells	0	0	6	6	80	90	12	3	2	1
Calcium Oxalates	0	0	2	6	60	58	24	22	14	14
RBCs	64	70	28	26	8	4	0	0	0	0

Observations and Results

In this clinical study the following observations were noted

In the age group 31-40 maximum number of males were seen compared to females in both the Groups A and B (Table 1)

In Group A the maximum subjects were with *vatakaphaj prakriti* (49) followed by *vatapitta prakriti* (20). In Group B it was 50 and 22 respectively (Table 2).

The patients with sedentary life style were more prone to this disease than active subjects in both the Groups (Table 3)

The non-vegetarian were observed as 60 percent whereas vegetarian were 40 percent (Table 4)

It was observed that the patients with less duration were more than with that of longer duration in both the Groups (Table 5)

In Group A the symptoms of frequency of micturition, dysuria, haematuria and intermittent colicky pain before treatment were complained by 91, 83, 30, 100 subjects respectively. After treatment complete relief was seen in 57, 72, 26, and 91 patients while the percentage is 62.63, 86.74, 86.66 and 91 in the above symptoms respectively (Table 6). Whereas there was no considerable relief in Group B (Table 7).

In the laboratory parameters pus cells, epithelial cells, Calcium Oxalates from 6-10 and beyond was seen in 41, 32, 14 and 10 patients respectively and complete relief was observed in 27, 10, 5 and 24 while the percentage is 65.85, 31.25 and 35.75 respectively. In case of RBCs 34 patients were from 1-5 and above before treatment whereas 24 were completely relieved and the percentage of the same is 70.58.

Before the treatment, it was observed that 41 cases had a size 4-6 mm and 59 cases had a size of 7-10 mm in Group A. Complete relief was observed in 39 and 50 subjects while the percentage is 95.12 and 84.74 respectively in above sizes. In Group

B 38 were falling in the size 4-6 mm and 62 in the size of 7-10 mm, there was no relief in this Group (Table 8).

DISCUSSION

On analysing the data it is evident that males are more prone to the disease as compared to females as the maximum subjects were males. The study suggests that the persons with *vatakaphaj prakriti* followed by *vatapittaj prakriti* are more prone to as the maximum number of subjects was having these *prakritis*. The study hints that the sedentary life style and non-vegetarian diets can cause the disease.

In this study, 62.63, 86.74, 86.66 and 91 percent of the subjects were completely relieved of frequency of micturition, dysuria, haematuria and intermittent colicky pain of Group A. It supports the *Pramehahara*, *Mutrakricchrahara*, *Vata pitta samaka* and *Asmarihara* properties of *Gokshura*⁴.

In the laboratory parameters 65.85 and 70.58 percent of the subjects were found with normal pus cell count and RBCs in Urine After treatment in Group A. It supports the *Vastisodhaka* and *Vata pitta samaka* properties of *Gokshura*.

In this study, 95.12 and 84.74 percent of the subjects of Group A were found with absence of calculi through radiological investigation after treatment with sizes 4-6 mm and 7-10 mm before treatment respectively. It strongly supports the *Asmarihara* property of *Gokshura*.

Various other studies also support the above properties of the drug. *Gokshura* inhibits the growth of urinary calcium hydrogen phosphate dehydrate crystals. *Gokshura* is a diuretic drug useful in dysuria, renal dysfunction and renal calculus⁵. The aqueous extract of *Tribulusterrestris*, in oral dose of 5gm/kg elicited a positive diuresis, which was slightly more than that

of frusemide. In addition to its diuretic activity *T. terrestris* had evoked a contractile activity on Guinea pig ileum⁶.

The positive diuresis and contractile activity of may aid in the expulsion of renal calculus.

In Group B, there was no considerable relief in either the symptoms or in the expulsion of stone. No adverse drug reactions were observed during or after the study.

CONCLUSION

In this study, the demographic data supports that males are more prone to the disease. The persons with *vatakaphaj prakriti* and *vata pitta prakriti* are affected more. Sedentary life style and non-vegetarian diet may favour the occurrence of this disease.

In the aspect of clinical data the percentage relief in the symptoms and pass out of the stone did not reflect the percentage relief in the laboratory parameters in Group A. whereas in Group B there was no considerable change.

Hence it can be concluded that the *Gokshura* extract capsules were effective and safe in the cure of renal calculus as compared with the glucose powder capsules.

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