URICARE

Evaluation of efficacy and safety of UriCare Capsules in the management of urinary calculi: A prospective double blind randomized placebo-controlled clinical trial

INVESTIGATOR

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OBJECTIVES OF THE STUDY

To evaluate the efficacy and safety of UriCare Capsules in urinary calculi.

STUDY DESIGN

A randomized double blind placebo-controlled clinical study.

PRIMARY ENDPOINTS

Relief from symptoms of urolithiasis (pain, dysuria, burning micturition, hematuria, and increased frequency of micturition). Expulsion of the stone.

SECONDARY ENDPOINTS

Incidence of adverse events. Overall patient compliance to the drug therapy.

INCLUSION CRITERIA

- Adult (above 30 years) patients of both the sex
- Patients diagnosed with renal or bladder stones
- Size of stone less than 0.5 cm in diameter, determined radiologically
- Willing to sign informed consent form.

EXCLUSION CRITERIA

- Patients who have developed any complication of stone such as severe pain, hematuria or obstruction requiring immediate surgery
- Patients with developmental abnormalities (e.g., posterior urethral valves, exstrophy bladder, etc.
- Patients presenting with pyonephrosis.
- Patients with urinary tract infections
- Patients with history of renal insufficiency
- Patients who have had a renal transplant
- Children
- Pregnant and nursing women.

COMPOSITION

Each UriCare capsule contains:

NAME OF ACTIVE INGREDIENT	QTY. PER CAPSULE
Didymocarpus pedicellata	130 mg
Saxifraga ligulata	98 mg
Rubia cordifolia	32 mg
Cyperus scariosus	32 mg
Achyranthes aspera	32 mg
Onosma bracteatum	32 mg
Vernonia cinerea	32 mg
Shilajit (Purified)	16 mg

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METHODOLOGY

Fifty radiologically diagnosed patients (37 male and 13 female) of urinary calculi attending the Ratkal Specialty Clinic were included in the study provided they fulfilled the inclusion and exclusion criteria. They were randomly categorized into UriCare group and placebo group comprising 25 patients each. Patients' characteristics on entry is given in Table 1.

Table 1

DEMOGRAPHIC DATA OF PATIENTS ON ENTRY

PARAMETERS	GROUP A (n=20) Uricare	GROUP A (n=20) Placebo
Age in years (mean ± SD)	50.63 ± 12.5	50.11 ± 10.6
Weight (kg) (mean ± SD)	51.80 ± 7.8	53.32 ± 5.86
	NUMBER OF PATIENTS	
Sex ratio (M:F)	20:5	17:8
Pain	25	24
Dysuria	19	15
Increased frequency of micturition	17	14
Burning micturition	15	13
Hematuria	20	23

Pain in the abdomen was the main presenting symptom in all the cases. Difficulty in micturition was the next common. Apart from these, burning micturition, increased frequency and hematuria were among the associated symptoms.

Table 2 shows the number of cases having different types of calculi.

Table 2

TYPES OF UROLITHIASIS

	NUMBER OF CASES	
CALCULI TYPE	Uricare Group	Placebo Group
Renal calculi	3	4
Ureteric calculi	22	21
TOTAL	25	25

Both the groups were comparable on entry. All the patients in UriCare group received UriCare in the dosage of 2 capsules twice a day, while the patients in placebo group received identical looking placebo in the same dosage, for 4 weeks. Patients were evaluated clinically at entry and at the end of the study period, i.e. 4 weeks. They were subjected to a thorough clinical examination and their case histories were recorded. X-ray K.U.B was taken in all the patients before starting therapy and at the end of the study period. Adverse effects, if any, were noted. The study was initiated only after getting informed consent from the patients. Patients were free to withdraw from the study, if they desired.

STATISTICAL ANALYSIS

Results were analyzed statistically by using Fisher's exact test.

Results continued on next page...

RESULTS

The passage of stone was taken as the criterion for "cure" and only symptomatic relief for the "relieved".

Symptomatic relief

In UriCare group, 19 out of 25 patients were relieved from pain (76%). While in placebo only 4 patients were relieved from pain (16%) (Table 3).

In UriCare group, 14 out of 19 patients (73.7%), 12 out of 17 patients (70.6%), 10 out of 15 patients (66.6%), and 14 out of 20 patients (70%) were relieved from dysuria, increases frequency of micturition, burning micturition, and hematuria respectively (Table 3).

While in placebo group, 5 out of 15 patients (33%), 3 out of 14 patients (21%), 3 out of 13 patients (23%) and 4 patients out of 23 patients (17.4%) were relieved from dysuria, increased frequency of micturition, burning micturition, and hematuria respectively (Table 3).

Table 3

EFFECT OF URICARE THERAPY

PARAMETERS ASSESSMENT MEASURES	NUMBER OF PATIENTS					
	UriCare Group (n=25)			Placebo Group (n=25)		
	Before Therapy	After Therapy	Response (%)	Before Therapy	After Therapy	Response (%)
Pain	25	6*	76%	24	20	16%
Dysuria	19	5*	73.7%	15	10	33%
Increased frequency of micturition	17	5*	70.6%	14	11	21%
Burning micturition	15	5*	66.6%	13	10	23%
Hematuria	20	6*	70%	23	19	17.4%

From Table 3, it is clear that UriCare group showed 71.9% results as compared to placebo group, which showed 21.3% results.

Stone expulsion

In UriCare group, 11 patients were having stone size up to 0.2 cm. All the 11 patients expelled the stone in an average time of 14 days of therapy. Out of 8 patients with stone size 0.21 to 0.3 cm, 1 case was having renal calculi who failed to expel the stone while remaining 7 patients required on an average 21 days to expel the stone. Out of 6 patients with calculi size 0.31 to 0.5 cm, 4 expelled the stones in an average time of 29 days of therapy and remaining 2 with renal calculi failed to expel the stone. But in placebo group none of the patients expelled the stone at the end of the study (Table 4). In UriCare group, out of 25 diagnosed patients with urinary calculi, 22 expelled stones ($p<0.05$) while 3 cases of renal calculi failed to expel the stone.

Table 4

EFFECT OF URICARE ON STONE EXPULSION

SIZE OF THE STONE	UriCare Group (n=25)		Placebo Group (n=25)	
	Number of Cases	Average time required for stone expulsion (days)	Number of Cases	Average time required for stone expulsion (days)
Up to 0.2 cm	11	14 ± 2.5	10	no expulsion
0.21 to 0.3 cm	8**	21 ± 3.0	7	no expulsion
0.31 to 0.5 cm	6***	29 ± 2.0	8	no expulsion

*Radiological breadth of the stone, irrespective of its longitudinal dimensions
**1 patient having renal calculi
***2 patients having renal calculi; failed to expel the stone

Adverse effects: No adverse drug reactions were reported following treatment with UriCare Capsules for a period of 30 days. There were no drop outs.

DISCUSSION

Even after extensive research in the field of urology, urolithiasis is still a mysterious disease. Urolithiasis or renal calculi are crystal aggregations of dissolved materials in the urine. Various sophisticated investigations, radiological and others have failed to pinpoint the exact cause and mechanism of urolithiasis. However, various factors attributable to urolithiasis have been extensively studied in recent times. It is believed that when the urine becomes saturated with insoluble materials, crystals form and may grow and aggregate with one another to form a stone. Stones that are larger in size and produce obstruction sufficient enough to produce damage, require surgery or endoscopic removal. When the stone is less than 6-8 mm in size and does not produce obstructive changes, it should be treated conservatively. Recurrent stone formation is also a problem in patients having urolithiasis. The expulsion of stones in 22 out of 25 patients following UriCare therapy is a significant observation in the present study. Besides, UriCare provided symptomatic relief in majority of the patients.

CONCLUSION

This study indicates good clinical efficacy of UriCare Capsules in the management of urolithiasis. It is also well tolerated and safe.