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A Single-blind Randomized Clinical Study of *Eladi Ghanvati* in the Management of Urinary Calculus & Modulation of S. Calcium Level

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ABSTRACT

Introduction

Urinary calculus is the most common afflict on the urinary system among other pathologies. It's a chronic disease with acute symptomatology i.e., severe pain incidence and dysuria.It's treatable with conservative management in the early stage with a good prognosis and speedy recovery. In the chronic phase, surgical intervention is essential in most cases though it comes with many complications and adverse effects. High S. Calcium level is a pathological stage, which can result in calcium crystal formation and deposition in the urinary tract leads to urinary calculus and obstruction of urinary pathway. Managing S. Calcium level can prevent further calculus formation and recurrence of calculus.

Materials & Methods

Total 32 patients, between the ages 18 to 70 years with classical symptomatology of urinary calculus and USG evident calculus in the urinary tract were registered& before treatment data was recorded. Patients were given *Eladighanvati*(500mg) each, 2 tablets 3 times a day with lukewarm water for 8 weeks. After treatment data was taken (Subjective & Objective) and assessed with proper statistical tests.

Results

In the subjective criteria,84.70% improvement was observed. In the USG investigation, 71.17% improvement was observed. In S. Calcium level, most of the subjects had slightly elevated S. Calcium levels, therefore no significant improvement was observed in it. In the overall assessment, 07 (21.88%) patients had marked improvement, 25 (78.13%) patients had moderate improvement.

Conclusion

Eladighanvati have a highly significant effect in the management of urinary calculus and have modulating effect for the S. Calcium level.

Key Words *Eladi Ghanvati, Urinary calculus, S. Calcium, Clinical study*

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INTRODUCTION

Urinary calculus is the most common afflict in the urinary system disorder after UTI & BPH and other pathologies. In the context of India, urinary calculus is prevalent, with an expectancy of 12% in a total population reported being prone to urinary stones and related pathologies. Total of

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50% of the population in above mentioned 12% of total population is severely affected by renal damage, which even leads to a loss of kidney function (End stage kidney disease)[1]. It's a chronic disease with acute symptomatology i.e., severe pain incidence and dysuria. Calcium is the major element of about 80–90% of all urinary stones along with different combinations[2]. They are usually made of calcium oxalate or calcium phosphate or mixtures of them detected in the chemical or infrared spectrometric analysis[3]. Uric acid stones constitute nearly 5–10% of urinary stones[4]. Cystine stones are very rare, constituting only 1–2% of urinary calculi[5]. Hypercalcemia with hypercalciuria causes the occurrence of calcium nephrolithiasis, by increasing the urinary saturation of calcium salts and by binding negatively charged inhibitors of stone formation[6]. Between 35% and 65% of hypercalciuric stone formers and up to 70% of subjects with hypercalciuria have relatives with nephrolithiasis pathologies[7].In Ayurveda 4 types of *Ashmari*and *related mutrakkruchhra*have been mentioned i.e., *shleshmaj, Vataj, Pittaj&Shukraj*[8]. In the early stage, *Ashmari*can be treated with medicines, but in the later stage when the disease progresses, surgical removal of *Ashmari* is essential to save the organ[9].*Ghanvati*form of *EladiKwatha*[10]has been used for this study, which was not applied for any other clinical study related with the urolithiasis.

AIMS & OBJECTIVES

A. Aims:

1. To study and observe the efficacy and effectiveness of *Eladighanvati*in the modulation of serum calcium levels.
2. To study and observe the efficacy and effectiveness of *Eladighanvati*in the management of urinary calculus.

B. Objectives:

1. To provide simple & effective measures to the patients with urinary calculus for the prevention and effective management of it along with the modulation of S. Calcium level.

MATERIALS & METHODS

Selection of patients:

Patients who attended the OPD of *kayachikitsa* department. Patients which were referred from other departments of IPGT & RA were screened. Out of these, patients suffering from *mootrashmari* (urinary calculus) fulfilling the below-mentioned inclusion criteria were randomly selected by a computer-generated randomization chart.

Inclusion criteria:

1. Pain in both, renal angle, and loin region, radiating (referring) towards the groin, specificallyprickingtype or dull-aching type of pain, which is an indication of obstruction by urinarycalculus.
2. Burning micturition with or without pain.
3. Intermittent mild to moderate haematuria.
4. Crystalluria. (Evident in Urine routine and microscopic investigation)

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5. Patients (research subject) with ages between 18 to 80 years irrespective of gender, caste, religion, and region.
6. Stone size up to 15 mm evident in USG.

Exclusion criteria:

Patients of urolithiasis having a disease or/and under any medication that affects study, study drug, and its result or prognosis were excluded.

1) Case of medical emergency or need of immediate surgical intervention.
2) Case with severe hydronephrosis.
3) Severe haematuria.
4) Acute or chronic renal disease.
5) Acute retention of urine for more than 12 to 24 hours.
6) Hyperparathyroidism.
7) Developmental defects or structural abnormalities of the kidney(s).
8) Neoplastic conditions.
9) Endocrinal diseases.
10) Staghorn stone or stone larger than 15 mm in size.

Washout period:

Minimum 3 days of washout period were given if the patient (research subject) was taking any herbal or conventional medicine which can interact with or interrupt the research study.

Treatment protocols:

Table 1 Ingredient of Eladighanvati: Chakradatt ashmaryadhikar-29

No.	*Classical Name &Latin name*	Part use	Proportion
1.	*Ela (Elettaria cardamomum Maton.)*	Seed	1 part
2.	*Pippali (Piper longum Linn.)*	Fruit	1 part
3.	*Yashtimadhu (Glycyrrhiza glabra Linn.)*	Root	1 part
4.	*Pashanbheda (Saxifraga ligulata Wall.)*	Root	1 part
5.	*Renuka (Vitex negundo Linn.)*	Seed	1 part
6.	*Gokshura (Tribulus terrestris Linn.)*	Fruit	1 part
7.	*Vasa (Adhatodavasica Ness.)*	Leaves	1 part
8.	*Eranda (Ricinus communis Linn.)*	Root	1 part
9.	*Shilajita (Asphaltumpunjabianum)*	*Niryasa*	500 mg
10.	*Sharkara*		Q.S.

Posology:

Method of preparation:

The decoction was made from all the herbal raw ingredients except, *Niryasa and Sharkara* for the *ghanvati*preparation as per table no. 1. A solid-state (*Rasakriya*) was achieved by continuously boiling the decoction, after that the *Prakshepadravya*was added to the formulation. *Ghanvati* was made from the mixture weighing 500 mg each.

Table 2 Posology

EladiGhanvati:	
Dose	2 Tab. (Each 500 mg)
Frequency	TDS
Anupana	Warm water
Root of administration	Oral
Duration	For 8 Weeks
Follow up	2 Weeks

Study design:

1. Study type: Interventional
2. Purpose: Treatment
3. Masking: Single-blind
4. Grouping: 1 Group
5. Timing: Prospective

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6. Endpoint: Efficacy and safety
7. Sample size: 32 patients in a group

Criteria for assessment:

Patients were assessed based on relief in signs-symptoms (subjective criteria), other imagining investigation, and findings of the laboratory (objective criteria) based on specially designed research proforma through the scoring pattern.

Objective Criteria:

1. Improvement in the s. calcium level, CBC and urine routine, and microscopic investigation
2. Size of stone (with the help of USG)
3. Number of stones (with the help of USG)
4. Hydronephrosis (with the help of USG)
5. Concretion of crystals (with the help of USG)

Table 3.1 Pain:

No.	Symptom	Score
1	No pain	1
2	Bearable pain (1 or 2 times in 1 month)	2
3	Bearable pain occasionally (average 2 to 3 times /week)	3
4	Bearable pain every day	4

Table 3.2 Burning micturition

No.	Symptom	Score
1	No burning micturition	0
2	Burning micturition (1 or 2 times in 1 month)	1
3	Regular burning micturition (average 2 to 3 times /week)	2
4	Regular burning micturition everyday	3

Table 3.3 Haematuria

No.	Symptom	Score
1	No Hematuria	0
2	Smoky black coloured urine	1
3	Bright red coloured urine	2

Table 3.4 Frequency micturition

No.	Frequency	Score
1	Up to 6 times	0
2	7-9 times	1
3	10-12 times	2
4	>12 times	3

DISCUSSION

In this study, total 32 subjects were enrolled according to inclusion criteria and given *Eladighanvati*for 8 weeks and with 2 weeks of follow up as per table no. 2. Before treatment and after treatment subjective data and objective data as per table no (3.1, 3.2, 3.3, 3.4) (investigations) were carried out and assessed statistically with ($p<0.05$) significance as per table no. (4.1, 4.2).*Eladighanvati*has10 ingredients as per table no. 1, all ingredients have mainly*vata-kaphanashaka*properties, and some have *pitta nashaka* property.

This formulation has pharmacological actions, i.e.,*Ashmarighna, bastishodhana, mootrala, bhedana, mootravirechaniya, deepana, paachana, aamdoshahara, vrushya, brumhana, anulomana, sugandhita, rasayana, snehana, shothahara, vranaropaka, krimighna, balya, mootrajanana, jvaraghna, vishaghna, yogavahi, chhardihara and sukshmasrotogami.*These all ingredients are individually indicated for the *ashmarichikitsa.* In the statistical analysis of subjective criteria (chief complaints), a significant improvement was observed in hematuria (96.15%), burning micturition (93.55%), pain (90.98%), frequency of micturition (75.47%) and dysuria (67.39%) as per table no. 4.1. In the objective criteria, for haematological investigations, no significant improvement was observed in Hb% (0.78%), and S. Calcium level (0.59%), for biochemical investigation significant improvement observed

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in U. Albumin level (82.35%), for ultra-sound sonography investigations, the significant improvement observed in a number of stones (40.57%), size of stones (46.58%), a concretion of crystals (97.56%), and hydronephrosis (100.00%) as per table no. 4.2.

Table 4 Criteria for total improvement for overall assessment**:**

No.	Total improvement	Criteria
1	Cured	100 % relief in sign & symptoms and change in size and number of stone(s).
2	Marked improvement	75 to 99% relief in sign & symptoms and change in size and number of stone(s).
3	Moderate improvement	50 to 74% relief in sign & symptoms and change in size and number of stone(s).
4	Mild improvement	25 to 49% relief in sign & symptoms and change in size and number of stone(s).
5	Impaired improvement	<25% relief in sign & symptoms and change in size and number of stone(s).
5	No improvement	No relief in sign & symptoms and no change in size and number of stone(s).

Table 4.1 Subjective parameters assessed by Wilcoxon matched-pairs sign rank test

Chief Complaints (Subjective parameters)	n	BT(Mean± S.D.)	AT (Mean± S.D.)	%	Sum of All Ranks (W)	P	Result
Pain (*Ruk)*	32	3.81 ± 0.39	0.34 ± 0.48	90.98	528	.0000 (<0.0001)	Extremely Significant
Burning micturition (*Mutradaha*)	32	2.90 ± 0.53	0.18 ± 0.39	93.55	496	.0000 (<0.0001)	Extremely Significant
Hematuria (*SaraktaMootrapravrutti*)	32	0.81 ± 1.02	0.03 ± 0.17	96.15	91	.000079 (<0.0001)	Extremely Significant
Dysuria (*Mootrakruchhra*)	32	2.87 ± 0.33	0.93 ± 0.24	67.39	528	0.0000 (<0.0001)	Extremely Significant
Frequency micturition (*Ati-mootrapravrutti*)	32	1.65 ± 1.51	0.40 ± 0.49	75.47	171	0.000136 (<0.001)	Highly Significant

Table 4.2 Objective parameters assessed by paired 't' test&Wilcoxon matched-pairs sign rank test:

Hematological, Bio-Chemical and USG Investigations	n	BT (Mean ± S.D.)	AT (Mean ± S.D.)	Mean Change	%	t value (or **Sum of ranks)	P value	Result
S. Calcium	32	10.13 ± .75	10.07 ± .61	.059 ± .98	0.59	.184	.340 (>0.01)	Not Significant
Hb%	32	13.99 ± 1.30	14.10 ± 1.29	-.10 ± .78	0.78	.791	.43 (>0.01)	Not Significant
Urine Albumin	32	.53 ± .62	.09 ± .29	.43 ± .50	82.35	4.91	.00002 (>0.01)	Extremely Significant
Number of Stones	32	3.31 ± 4.20	1.96 ± 3.53	1.34 ± 1.65	40.57	4.58	.00007 (>0.01)	Extremely Significant
Size of stones	32	12.44 ± 8.37	6.64 ± 7.35	5.79 ± 4.63	46.58	7.07	.00000 (>0.01)	Extremely Significant
Concretion of Crystals*	32	1.00 ± 0.00	0.03 ± 0.17	0.96 ± 0.17	97.56	496**	0.00000 (<0.0001)	Extremely Significant
Hydronephrosis*	32	0.96 ± 0.17	0.00 ± 0.00	0.96 ± 0.17	100.0	496**	0.00000 (<0.0001)	Extremely Significant

* Wilcoxon matched-pairs sign rank test applied (Data is not Normally Distributed & Grading pattern applied for the assessment)

On the assessment of overall effects of the treatment, 78.13 % (25) patients had moderate improvement as per table no. 5, which was in between 50 to 74% relief in sign & symptoms and change in size and number of stone(s) as per table no. 4. 21.88 % (07) patients had marked improvement as per table no. 5, which was in between 75 to 99% relief in sign & symptoms and change in size and number of stone(s) as per table no. 4.

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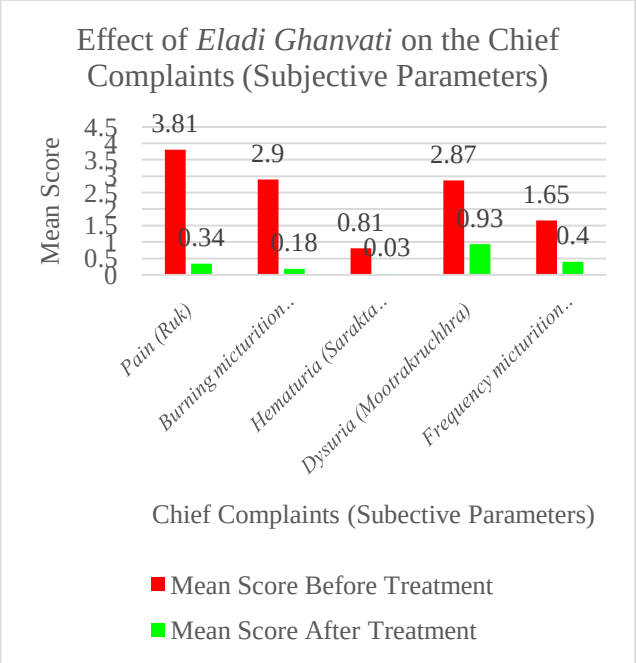

Chart 4.1 Chart presentation of statistical analysis of subjective parameters

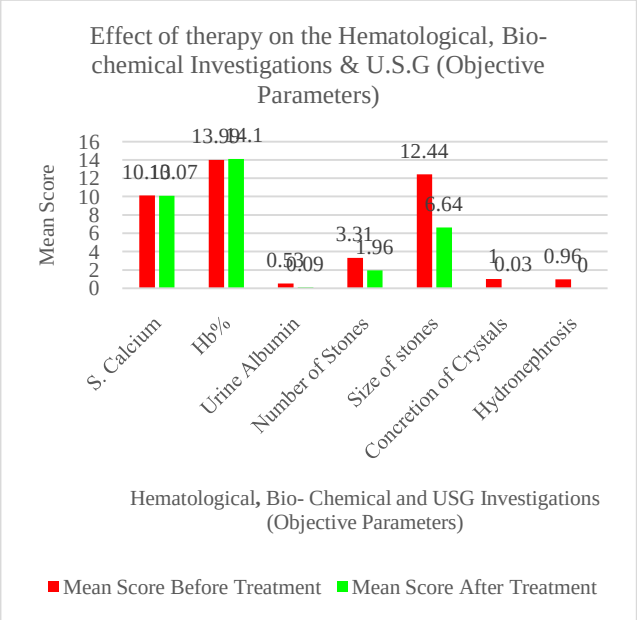

Chart. 4.2 Chart presentation of statistical analysis of Hematological, Bio- Chemical and USG Investigations (Objective parameters)

Table 5 Overall effects of the treatment

No.	Results	No. of patients	Percentage of patients
1	Cured	00	00
2	Marked improvement	07	21.88
3	Moderate improvement	25	78.13
4	Mild improvement	00	00
5	Impaired improvement	00	00
6	No improvement	00	00

CONCLUSION

These results suggest thatthe application of *Eladighanvati*for 8 weeks has a significant effect ($p<0.05$) on the management of urinary calculus and its expulsion, along with the modulation of S. Calcium level.

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