

TITLE: An exploratory study on novel herbal formulation for the treatment of recurrent urinary stone
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ABSTRACT:

INTRODUCTION AND OBJECTIVE:

Recurrence of Urolithiasis is second most common concern for Urologist's all over the world. The incidence of recurrence over a period of five years without any treatment is estimated to be 35 to 50 %. The treatment of choice to avoid above incidence is usually Thiazides, Chlorthalidone indapamide and oral Potassium citrate for calcium oxalate stone and Allopurinil for hyperuricosuria. Lithorisk Profile- a 24 hours urine analysis parameter is considered as guideline for recurrence of renal calculi. The incidence and risk factors are usually hyperoxaluria, hypercalciuria, low level of citrate and magnesium in recurrent stone formation. This condition can be treated by employing number of herbal remedies supplemented with following a typical lifestyle to slow down the rate of recurrence in known urolithiatic patients. We have developed a novel herbal combination for the management of recurrent stone. The preclinical safety profile of this formulation was evaluated by OECD guidelines and efficacy by Ethylene glycol model in rodents. The results of exploratory studies of above formulation in recurrent stone patients are presented.

STUDY METHODS:

The formulation 'Herbmed plus' was prepared using *Crataeva nurvala* bark and kshars of *Musa paradisiaca* stem, *Achyranthus aspera* plant and *Hordeum vulgare* seeds in certain proportions at GMP certified facility. This certified formulation was clinically validated by prospective, exploratory, controlled study in 30 patients without any major complications having recurrent stone after the approval of Institutional Ethics Committee. The patients were divided into Group A (n=15) and Group B (n=15) and were evaluated by Lithorisk profile at baseline and end of the study with treatment period for three months. The parameters like pH, Uric acid, Calcium, Oxalates, Citrate, Sodium, Potassium, Magnesium, Phosphates and Saturation Index for CaOx were considered in 24 hrs urine samples. The results were analyzed by employing T-test using 2013 Graph Pad Software, Inc.

RESULTS:

The baseline results of 24 hrs urine analysis revealed no significant difference in pH, Uric acid, Calcium, Oxalates, Citrate, Sodium, Potassium, Magnesium, Phosphates and Saturation Index for CaOx between control and treatment group. However, significant difference is observed in treatment group after three months medication in values of oxalate ($p<0.03$), calcium ($p<0.04$), citrate ($p<0.02$), magnesium ($p<0.02$) and saturation index for CaOx ($p<0.005$) and there was no such difference in the control group patients.

CONCLUSIONS:

The herbal formulation 'Herbmed plus' is showing promising results in correction of the parameters responsible for formation of recurrent stones. However, a proper study in large sample size is proposed to confirm the above results.