

## **Title: Medical management of urolithiasis by novel Herbal Formulation- Research perspective**

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### **INTRODUCTION AND OBJECTIVE:**

Urolithiasis is a metabolic disorder for which surgery is the treatment of choice, although few herbal formulations developed on empirical basis are available for the treatment. We have developed a novel Herbal formulation based on traditional knowledge for the treatment of urolithiasis. In preclinical studies in rodents this formulation was found to be safe using OECD guidelines and the efficacy of antiurolithiatic activity was proved by ethylene glycol model. In the present study the results of the clinical evaluation of this formulation in the patients having calculi of size 4-9 mm after the treatment with above formulation are reported.

### **STUDY METHODS:**

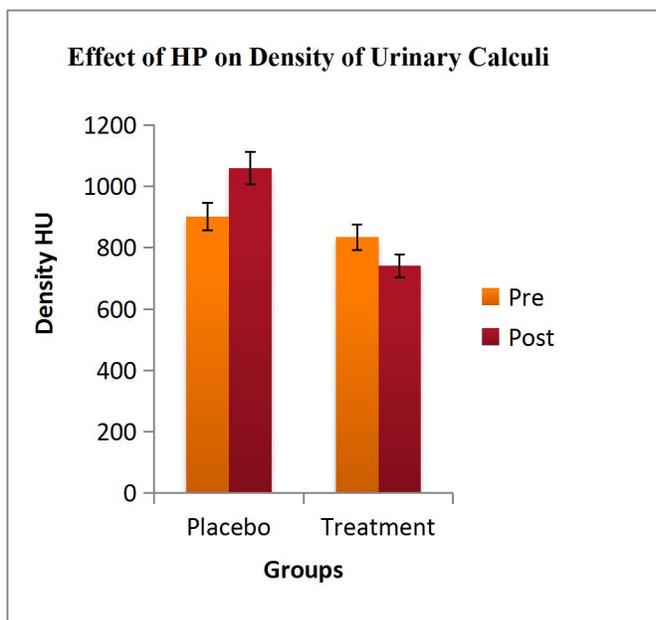
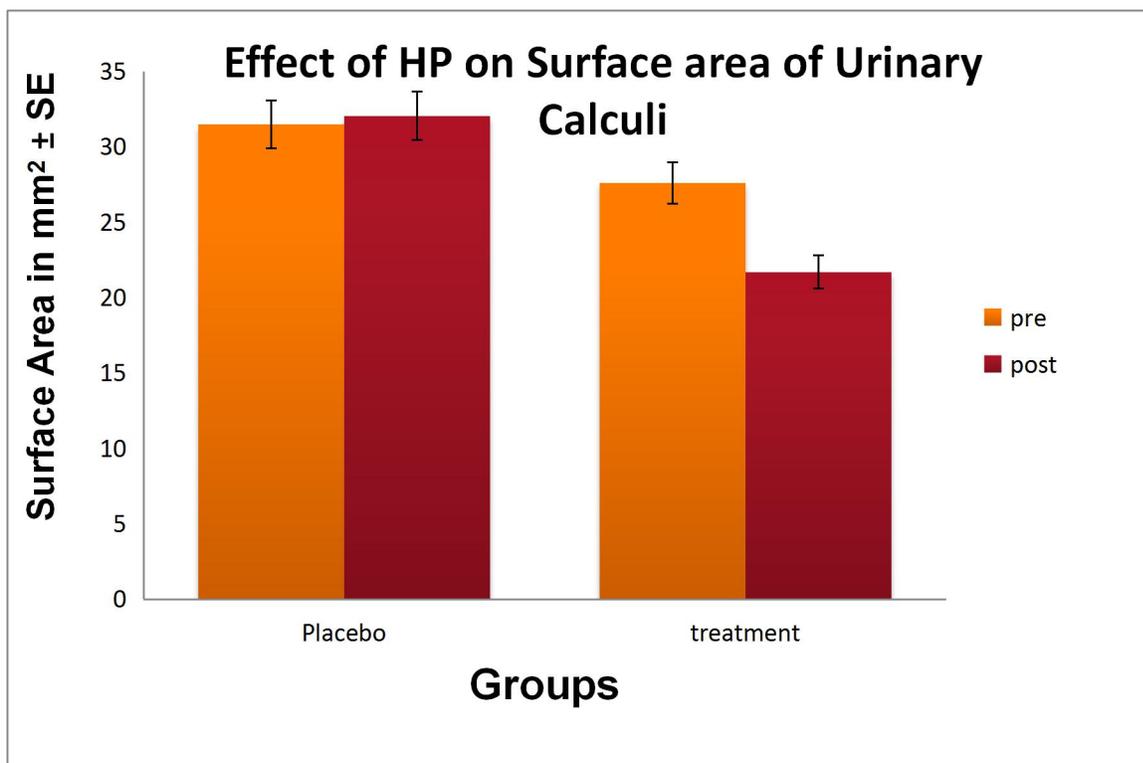
For the present study 'Herbmed plus' was used, which was formulated and manufactured at GMP certified facility using *Crataeva nurvala* bark and kshars of *Musa paradisiaca* stem, *Achyranthus aspera* plant and *Hordeum vulgare* seeds in certain proportion based on Ayurvedic knowledge. A prospective, phase II, randomized, double-blind, placebo-controlled clinical trial was conducted and registered with Clinical trials.gov (NCT01355341) after approval of the Institutional Ethics Committee. The effect of above formulation was studied in total 84 patients of 18-75 years age group, having calculi size of 4-9 mm after confirmation by CT scan were included, and those with complications requiring surgical intervention were excluded. The clinical assessment of subjects were carried out after six months treatment of one capsule of 500mg twice a day after meals for expulsion/ reduction in the size of calculi, simultaneously pain was assessed by VAS. The results were assessed by T-test and Chi-square test using 2013 GraphPad Software, Inc.

### **RESULTS:**

Total 65 patients completed the trial (Treatment group: n=34; Placebo group: n=31). The rate of expulsion was significantly higher ( $p < 0.03$ ) in the treatment group as compared to placebo group. It was observed that there was 21.34% reduction and 8.98% increase in the size of calculi in the treatment group ( $p < 0.02$ ) and the placebo group ( $p < 0.28$ ) respectively. In the treatment group there was statistically significant lower VAS as compared to placebo ( $p < 0.001$ ).

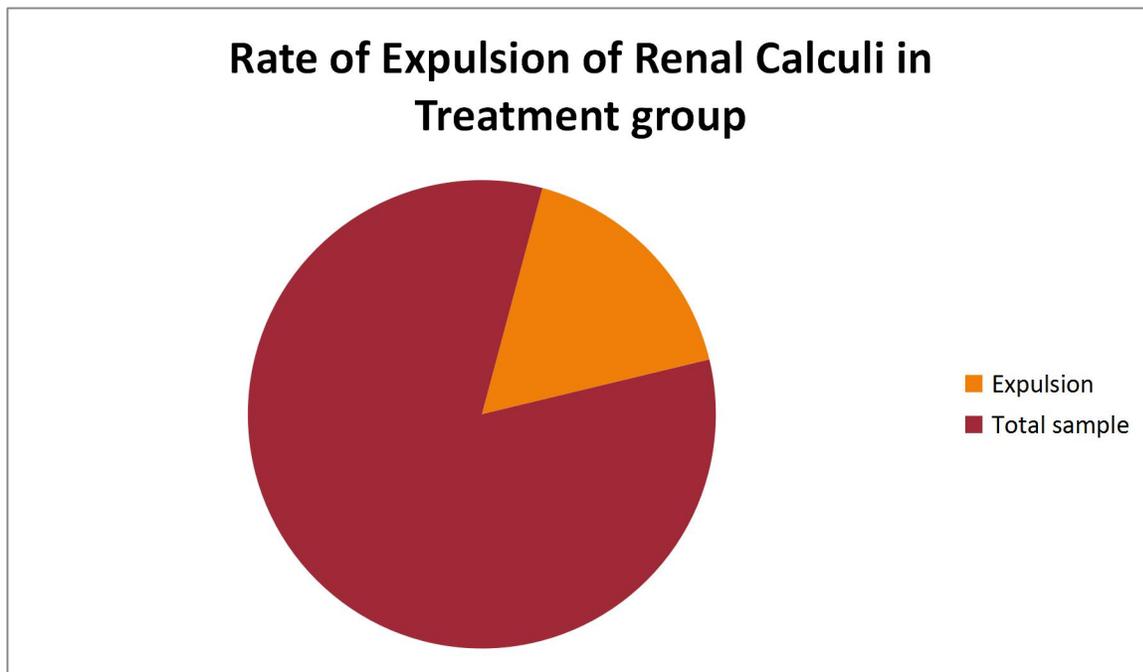
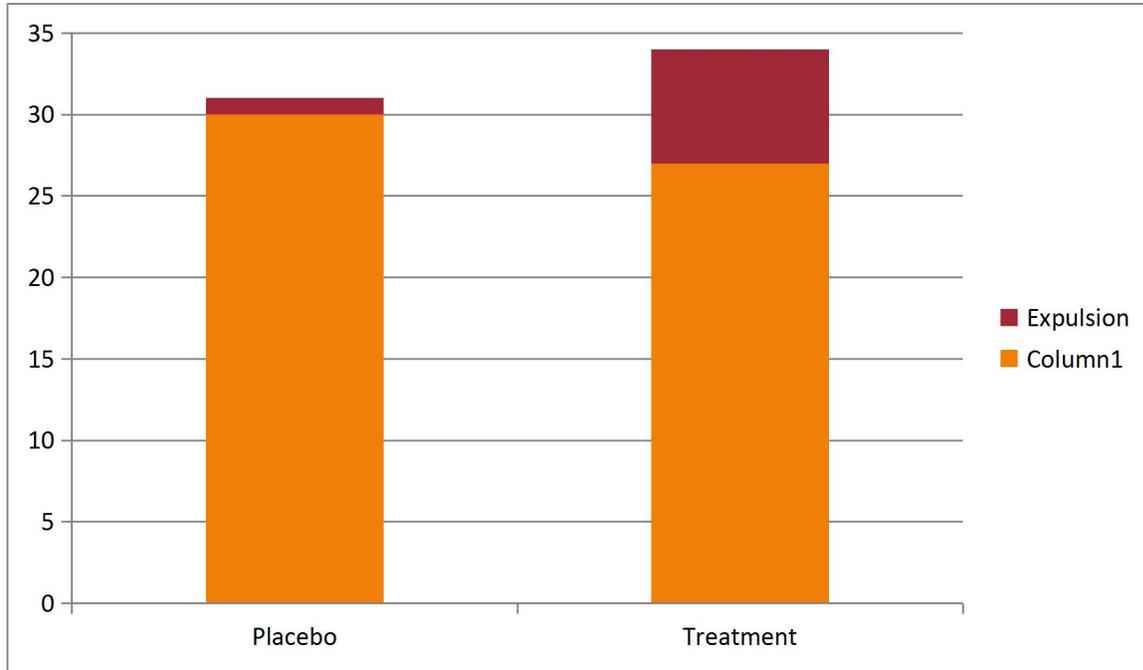
### **CONCLUSIONS:**

Possibly this formulation may be helpful to reduce the size of calculi thereby facilitate their passage and reduce the pain due to calculus disease. The antiurolithiatic activity of the formulation was observed in the treated group which may be due to synergistic activity of its ingredients. For further confirmation a phase III study is needed.

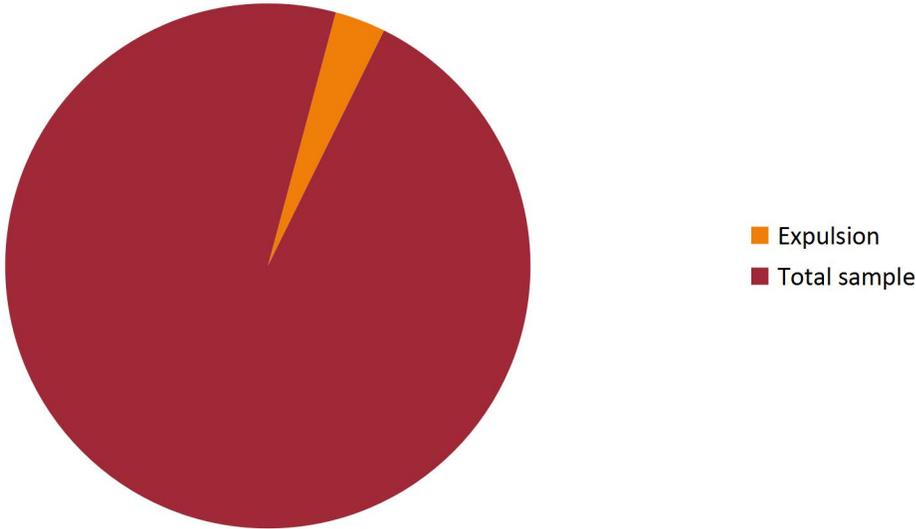


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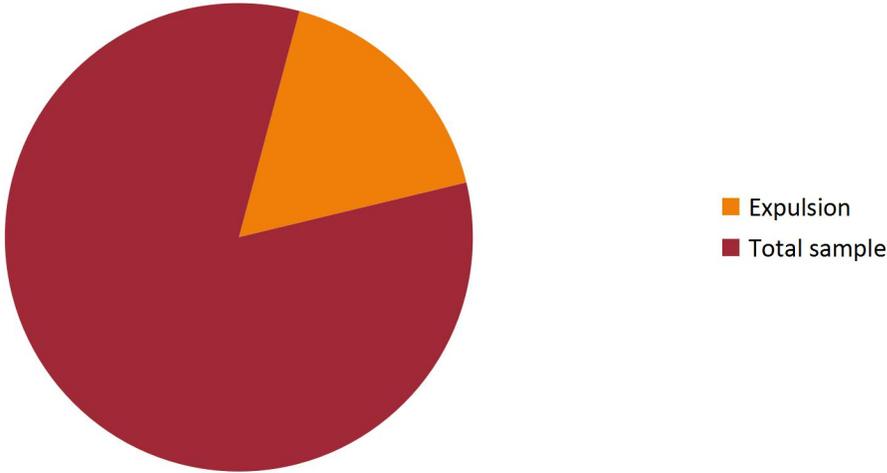
Urinary calculi are the third most prevalent disorder of the urinary system.<sup>2</sup>



### Placebo



### Rate of Expulsion of Renal Calculi in Treatment group



**Comparison of Surface Area in both Groups**

