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Homoeopathic therapy for lower urinary tract symptoms with benign prostatic hyperplasia: An open randomized multicentre placebo controlled clinical trial

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Objectives: The primary objective was to compare the changes in IPSS (International Prostate Symptom Score) within the three groups enrolled for the study (Constitutional remedy/Constitutional + Organ remedy/Placebo). The secondary objectives were to compare the changes in Prostate volume, Post Void Residual Urine (PVRU), Uroflowmetry and in WHOQOL-BREF.

Material & Methods: The study was done in an open randomized placebo controlled setting at six research centers under Central Council for Research in Homoeopathy. The patients in the age group of 50-80 years presenting with the symptoms of incomplete emptying, frequency, intermittency, urgency, weak stream, straining and nocturia were screened from the general OPD as per ICD-10 Classification Code N40.0. The participants who qualified the inclusion criteria were enrolled in the study after obtaining the 'Informed Written Consent'. Intervention was administered as per the randomization chart for three groups i.e. homoeopathic constitutional medicine in LM potency (Group 1), homoeopathic constitutional medicine in LM potency with organ remedy (Group 2) and placebo (Group 3). The patients were assessed for IPSS monthly and for prostate volume, post void residual urine, Qmax and Qavg, PSA and QOL, at third and sixth month. Primary safety endpoint was any adverse event which may be life threatening, requires prolonged hospital stay, results in significant disability, an injury, accident or any other important medical event. 395 patients were screened and 208 patients were enrolled in the study. An interim analysis of 163 patients who have completed the study follow up period of six months as per protocol was carried out using repeated measures ANOVA.

Results: Interim analysis of the data showed statistically significant improvement in IPSS scoring, QOL due to LUTS and in three out of four domains of WHOQOL-BREF in the medicine (1st and 2nd) group. Qmax value comparison at baseline with 6 months was statistically significant i.e. $P < 0.05$ in intervention with homoeopathic constitutional medicine (Group 1) and $P < 0.01$ in intervention with homoeopathic medicine and organ remedy (Group 2). The prostate volume and post void residual urine however, remained unaffected in all the three groups.

Discussion: Results from this trial will help in constructing treatment strategy for BPH patients with lower urinary tract symptoms and to present the results of these assessments to the fraternity and the patient so that he can make an informed decision about available alternatives for the management of LUTS in BPH. RCT with longer follow up may be undertaken to analyze the role of homoeopathic treatment on pathological and pathophysiological parameters such as prostatic volume and post void residual urine.

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The systems pharmacology method and its application in traditional Chinese medicine

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Traditional Chinese medicine (TCM) is known to be essential in maintaining and improving human health for thousands of years. The strategy to discover new drugs from TCM has proved to be very successful. However, due to the complexity of chemical components and mechanisms of action, a search and understanding of therapeutic molecules from TCM based on the traditional method is extremely difficult. In recent times, the confluence of spectacular advances in systems pharmacology has led to the discovery and development of numerous novel potential drugs and therapeutic agents for the treatment of a wide spectrum of diseases. In this work, we attempted to introduce how to apply systems pharmacology for the novel drug discovery from TCM. The systems pharmacology integrated ADME/t prediction, pharmacokinetics and systems biology to uncover the action mechanisms of TCM. The new advances of systems pharmacology could be widely applied in investigation the basic theory of TCM, optimization of old formulae and novel drug development. Our study is not intended to be an exhaustive one of comprehensive approach for TCM, but rather is aimed at highlighting the invaluable role that natural products have played, and continue to play, in the drug discovery process and its future perspectives.

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