Conference presentation

HOMOEOPATHIC TREATMENT FOR LOWER URINARY TRACT SYMPTOMS IN MEN WITH BENIGN PROSTATIC HYPERPLASIA: AN OPEN RANDOMIZED MULTICENTRIC PLACEBO CONTROLLED CLINICAL TRIAL

Dr Raj K. Manchanda, Dr Bindu Sharma, Dr Pritha Mehra, Dr Parveen Oberai, Dr Varanasi Roja, Dr Deepti Singh, Dr G. Ravi Chandra Reddy, Dr D. D. Arya, Dr B. S. J. Rajakumar, Dr P. G. Mohanan, Dr A. K. Prusty.

Central Council for Research in Homoeopathy, Ministry of AYUSH, Government of India.

Background: Benign Prostatic Hyperplasia (BPH) associated with Lower Urinary Tract Symptoms (LUTS) is the most common condition in ageing men. The epidemiological studies estimate that 90% of men between 45 and 80 years of age suffer some type of LUTS.¹ There is paucity of such epidemiological data from India but one study reports the prevalence of BPH among rural elderly of India as 11.8%².

Although LUTS secondary to BPH (LUTS/BPH) is not often a life-threatening condition, the impact of LUTS/BPH and its complications on Quality of Life (QoL) can be significant and should not be underestimated.³ When the effect of BPH-associated LUTS on QoL was studied in a number of community-based populations, for many, the most important motivations for seeking treatment were the severity and the degree of bother associated with the symptoms.⁴ LUTS include storage and/or voiding disturbances common in ageing men. Although voiding symptoms are most common, storage symptoms responsible for daytime frequency, urgency and nocturia interfere the most with life activities. Homoeopathic constitutional treatment is useful in the treatment of a constellation of symptoms due to BPH and LUTS. Along with constitutional medicine homoeopathic practitioners are using organ medicines having special affinity for prostate and urinary bladder with good results. Traditionally the primary goal of treatment is to alleviate bothersome LUTS that result from prostatic enlargement. The literature review indicates that both homoeopathic constitutional medicines as well as organ specific remedies show positive results in relieving the symptoms of BPH but the study was not randomized and there was no control group to show its efficacy. In this backdrop the present study was undertaken to evaluate the storage and voiding symptoms of men having BPH through an internationally validated scale IPSS and the role of homoeopathic intervention, both constitutional and organ remedies on LUTS due to BPH and QoL of the patient.

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.⁵

Material and Methods: The study was done in an open randomized placebo controlled setting at five 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 following the predefined inclusion and exclusion criteria. A consultant Urologist was appointed at each center to screen and follow up the enrolled cases. The participants who qualified the inclusion criteria were enrolled in the study after obtaining the 'Informed Written Consent'. It was a three armed randomized clinical trial where Intervention was administered as per the randomization chart for three groups i.e.

Cite as: Manchanda RK, Sharma B, Mehra P, Oberai P, Roja V, Singh D, Reddy GRC, Arya DD, Rajakumar B, Mohanan PG, Prusty AK. Proceedings of the XXX GIRI Meeting; 2016 Sep 09-11; Netherland. *Int J High Dilution Res.* 2016;15(4):12-13

homoeopathic constitutional medicine in LM potency (Group 1), homoeopathic constitutional medicine in LM potency with organ remedy in mother tincture and 3X (Group 2) and placebo (Group 3) in 2:2:1 ratio. The patients were followed for six months and the outcome of intervention was assessed monthly for IPSS (Primary objective) and at third and sixth month for prostate volume, post void residual urine, Qmax and Qavg, PSA and WHOQOL-BREF, (Secondary objectives). Internationally validated scales (IPSS & WHOQOL-BREF) were used to assess the outcome. 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.

474 patients were screened and 252 patients were enrolled in the study. The analysis of these patients as per protocol and as per intention to treat was carried out using repeated measures ANOVA and paired T test.

Results: Out of 254 patients enrolled in the study (HC=103, HC + O = 102 and Placebo = 49), 152 were analyzed as per protocol (HC=71, HC + O = 53 and Placebo = 28) as they completed a follow up period of 6 months whereas, 241 patients were analyzed as per ITT (HC=101, HC + O = 92 and Placebo = 48). 13 patients were excluded from analysis for reasons such as protocol violation and incomplete baseline information. There was statistically significant improvement in all the seven components of IPSS, WHOQOL- BREF and Q max values of uroflowmetry in both per protocol as well as ITT analysis.

Discussion: Results from this trial will help in constructing treatment strategy for BPH patients with lower urinary tract symptoms to enable them to make an informed decision about available alternatives for the management of LUTS in BPH. The limitation of the study was that it was not blinded. The inhibition for not making it blinded was the use of mother tinctures of organ specific medicines in liquids of different colors and odours which could not be blinded. Pragmatic trial with longer follow up and a parallel arm comprising of conventional treatment may be undertaken in future to compare their role on LUTS due to BPH on pathological and pathophysiological parameters such as prostatic volume and post void residual urine.

Trial Registration: Clinical Trial Registry - India: CTRI/2012/05/002649.

References:

1. McVary K: BPH: Epidemiology and Comorbidities. Am J Manag Care 12 2006; 5 Suppl: S122.
2. AUA symptoms score: A simple tool for assessment of Benign Prostatic Hyperplasia in rural setting; Indian Journal of Community Health, Vol. 25, No.2, April 2013-June 2013; 147.
3. Wei J, Calhoun E, Jacobsen S: Urologic diseases in America project: benign prostatic hyperplasia. J Urol 2005; 173: 1256.
4. O'Leary M: LUTS, ED, QOL: alphabet soup or real concerns to aging men? Urology 2000; 56: 7
5. Central Council for Research in Homoeopathy. Homoeopathic Therapy for lower urinary tract symptoms in men with Benign Prostatic Hyperplasia: An open randomised multi-centric placebo controlled trial. Indian J Res Homoeopathy 2014; 8:75-80.

© International Journal of High Dilution Research.
Not for commercial purposes.

Cite as: Manchanda RK, Sharma B, Mehra P, Oberai P, Roja V, Singh D, Reddy GRC, Arya DD, Rajakumar BSI, Mohanan PG, Prusty AK. Proceedings of the XXX GIRI Meeting; 2016 Sep 09-11; Netherland. *Int J High Dilution Res.* 2016;15(4):12-13