ORIGINAL RESEARCH PAPER

Volume-9 | Issue-1 | January-2020 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A COMPARATIVE STUDY OF EFFICACY AND SAFETY OF A UNANI FORMULATION WITH THE CURRENTLY AVAILABLE DRUGS (TAMSULOSIN & FINASTERIDE) IN THE MANAGEMENT OF LOWER URINARY TRACT SYMPTOMS (LUTS) DUE TO BENIGN PROSTATIC HYPERPLASIA

Unani Medicine

Mohd Tarique* Assistant Professor, Department of Jarahat, Glocal Unani medical college & Hospital *Corresponding Author

Tafseer Ali Professor, Department of Jarahat, Aligarh Muslim University, Aligarh

ABSTRACT

Background: Benign prostatic hyperplasia (BPH) is a common urological problem in aging men and Phytotherapy has become a popular treatment option, there are many different single and compound herbal products being used for the treatment of LUTS due to BPH.

Objectives: The present study compared the efficacy and safety of a Unani formulation in the management of LUTS due to BPH.

Materials and Methods: This was a single blind randomised controlled clinical trial on 73 men with moderate LUTS due to BPH who underwent the evaluation at the baseline and at the end of the treatment. The symptoms were assessed by IPSS.

Results: After three months treatment with Unani formulation there was a statistically significant decrease of IPSS Score, without any significant adverse effect.

Conclusion: Results demonstrate that the treatment with Unani formulation is safe and effective in the management of mild to moderate LUTS due to BPH.

KEYWORDS

BPH, IPSS

INTRODUCTION

Benign prostatic hyperplasia (BPH) is the most prevalent benign urological tumour in elderly men; there is a prevalence rate of more than 70% at 60 years age and 90% older than 70 years, BPH is characterized histopathologically by an increased number of epithelial and stromal cells in the periurethral zone of the prostate and therefore it is correctly referred as *hyperplasia* and not *hypertrophy*.

International Prostate Symptom Score (IPSS): IPSS is primarily based on the seven questions and its answers related to lower urinary tract symptoms (LUTS).

International Prostate Symptom Score (I-PSS)

Patient Name: _____ Date of birth: _____ Date completed _____

In the past month:	Not at All	Less than 1 in 5 Times	Less than Half the Time	About Half the Time	More than Half the Time	Almost Always	Your score
1. Incomplete Emptying How often have you had the sensation of not emptying your bladder?	0	1	2	3	4	5	
2. Frequency How often have you had to urinate less than every two hours?	0	1	2	3	4	5	
3. Intermittency How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
4. Urgency How often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5. Weak Stream How often have you had a weak urinary stream?	0	1	2	3	4	5	
6. Straining How often have you had to strain to start urination?	0	1	2	3	4	5	
	None	1 Time	2 Times	3 Times	4 Times	5 Times	
7. Nocturia How many times did you typically get up at night to urinate?	0	1	2	3	4	5	
Total I-PSS Score							

Score: 1-7: *Mild* 8-19: *Moderate* 20-35: *Severe*

Quality of Life Due to Urinary Symptoms	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6

MATERIAL AND METHOD

The aim of the study was to evaluate the efficacy and safety of a Unani Formulation in the management of LUTS due to BPH and to compare it with the currently available drugs i.e. Tamsulosin and Finasteride (Urimax F).

The Unani formulation included the following ingredients: Tribulus terristeris (Khar-e-khasak), Cucurbita pepo (Maghz-e-Tukhm-e-Kaddu shireen), Matricaria recutita (Babuna), Linum usitatissimum (Alsi), Pimpinella anisum (Anisoon) and Cucumis sativa (Khyarein).

Drug preparation: The tablets of 750 mg were prepared by Dawakhana Tibbiya College, Aligarh Muslim University, Aligarh. Dose: - 3 gms /day, two tablets of 750 mg BID.

Study procedure: At the initial visit, a detailed medical history, with special emphasis on history of urinary obstructive and irritative symptoms were obtained from all the patients. The severity of the urinary parameters was evaluated using I-PSS symptom score.

Patients were divided into two groups. Group A (test group) received a polyherbal Unani formulation for 3 months in the dose of 02 tablets twice a day with water. Group B (Controlled group) receive a capsule containing Finasteride 5 mg and Tamsulosin 0.4 mg once daily for 3 months.

The outcome of study was assessed by comparing urinary symptoms of BPH on IPSS score before and after the treatment.

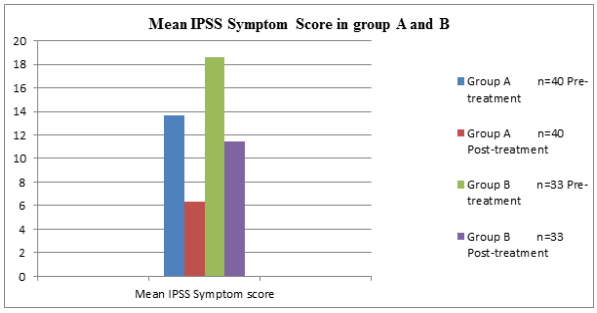
Results and Observation

The study was conducted on 73 diagnosed patients of LUTS due to BPH. The patients were divided into two groups, A and B having 40 and 33 patients, respectively. The symptoms were assessed by IPSS at the baseline and at the end of the treatment.

Table 1 Mean IPSS Symptom Scores in group A and B

IPSS symptom score	Group A n=40			Group B n=33		
	Pre-treatment	Post-treatment	Difference	Pre-treatment	Post-treatment	Difference
Incomplete Emptying	1.52±1.10	0.62±0.77*	0.90±0.74.	2.27±1.75	1.33±1.29*	0.93±0.70
Frequency	2.10±1.73	1.07±1.14*	1.02±0.89	2.60±1.49	1.48±1.06*	1.12±0.78
Intermittency	2.57±1.59	1.30±0.96*	1.35±0.89	3.09±1.28	1.81±1.01*	1.27±0.93
Urgency	1.32±1.42	0.62±0.83*	0.70±0.88	2.12±1.38	1.21±0.96*	0.90±0.63
Weak Stream	2.52±1.43	1.00±0.90*	1.52±1.03	3.15±1.27	1.93±1.17*	1.21±0.59.
Straining	1.57±1.48	0.57±0.71*	1.02 ±0.97	2.54±1.64	1.63±1.19*	1.00 ±1.01
Nocturia	2.30±1.36	1.27±1.03*	1.02±0.83	2.90±1.10	1.93±1.05*	0.96±0.76
Mean IPSS Symptom score	13.92±3.03	6.35±3.28*	7.57±2.07	18.63±5.04	11.45±4.28*	7.18±2.70

*($p<0.0001$)



Graph 1

Table 1 and **graph** 1 demonstrates the pre-treatment and post-treatment scores and there is highly significant difference ($p<0.0001$) between pre-treatment and post-treatment in both groups A&B.

On comparison, the two Groups A and B, showed almost equal reduction in IPSS obstructive and irritative scores and IPSS total score, scores decreased to 7.57±2.07 and 7.18±2.70 in Group A and B, respectively the Comparison of efficacy of test and control drug was tested by unpaired t test. The p value was found to be more than 0.5 indicating non-significant difference between the efficacies of two drugs. The findings showed that the test drug is as effective as the standard drug Tamsulosin and Finasteride.

DISCUSSION

The present study on a Unani formulation is important because it is being used by Unani physicians since long and has an age-old history of successfully treating the patients of LUTS. The scientific validation of the test drug may pave the way for the development of an effective and safe drug useful in the management of BPH.

The effectiveness of the Unani formulation was attributed to its anti-inflammatory [10,6] and anti- tumour [12] and 5α reductase inhibitor [15] properties of its ingredients and at the end the diuretic effects [10,6] of the administered Unani formulation can further improve the urinary flow rate without any effect on urgency.

There are about 50 phytotherapeutic agents have been identified and studied as a single or compound form in the management of BPH and the number is growing each day, most of the studies on these herbal agents have shown decrease in score of total IPSS symptom score. 90% of patients felt a very good or good improvement of their urinary symptoms (Hamvas et al, 1991) [2]. IPSS scores improved by 8.2 units (Klippel et al 1997) [7]. Himplasia containing Tribulus terristeris and other ingredients reduced the IPSS up to 64% and mean value reduced significantly from 23.73 to 8.52, the duration of treatment was three month **(**Sahu et al, 2003) [11]. IPSS decreased -3.67 ±1.56, -7.33 ±1.18, and -6.88 ±1.43 with placebo, 300mg and 600mg doses of flax seed extracts respectively (Zhang et al, 2008) [17]. IPSS declined from 19.0 to 4.7 by 14.3 points, indicating 75.3% improvement in symptoms (Hong et al 2009) [3]. IPSS declined from 17.0 (12.0-19.0) to 9.0 (5.0-13.0) (Sengupta et al, 2011) [13]. The mean AUA symptom score changed from 14.60 ± 3.20 to 9.2 ± 2.60 (Jeyaraman and Patki 2012) [4]**.** After the 1 year treatment period, the mean differences compared with baseline were –5.4 ± 5.1, –4.2 ± 5.4 and –4.0 ± 5.5 with pumpkin seed, pumpkin seed extract and placebo, respectively (Vahlensieck et al, 2014) [16]. A significant reduction in the overall IPSS scale was reported, before treatment it was 11 ± 12 and finally it was 4 ± 5 ($p<0.0001$) (Machado-Leiva et al 2016) [8]. The mean IPSS score before and after treatment was 14.30±3.92 and 12.04±1.19 respectively (Khesal et al, 2017) [5].

Results of tamsulosin and finasteride combination (control group) in our study are almost similar to other studies which showed decrease in total IPSS score with the treatment of tamsulosin and finasteride combination; values changed from baseline to follow up period. There was a significant reduction in the IPSS obstructive and irritative scores, after 12 weeks treatment it was -2.5 ± 2.3 & -2.1 ± 2.0 and after 24 weeks it was -3.5 ± 2.5 & -2.6 ± 1.9 respectively, vs the baseline ($P<0.001$), while the total IPSS, at the end of the 12 weeks was -4.8 ± 4.2 and after 24weeks it was -6.3 ± 4.1 ($P<0.01$) (Mohanty et al, 2006) [9]. Total AUA score decreased from 18.02 to 12.12 ($p<0.0001$) (Shrestha and Karmacharya et al 2015) [14]. Significant improvements observed in IPSS ($p < 0.05$), (Ghadian and Rezaei 2017) [1].

It was observed that compound herbal formulations have shown significant therapeutic results in short time period three to six months, and in case of single drug treatment duration must be 10-12 months or more and while it is also a well-known fact that BPH has a multifactorial etiology therefore the compound drug may be more beneficial in alleviating the LUTS due to BPH.

CONCLUSION

The present study has demonstrated the clinical equivalence of Unani formulation and combination of Tamsulosin and Finasteride in the management of LUTS due to BPH, both provide equal improvements in IPSS. Therefore the Unani formulation can be used as a safe and effective agent in the management of LUTS due to BPH. Further, since it is cost effective and relatively safer drug therefore it should ideally be used on preferential basis.

REFERENCES

1) Ghadian A, Rezaei M, Combination therapy with omega-3 fatty acids plus tamsulocin and finasteride in the treatment of men with lower urinary tract symptoms (LUTS) and benign prostatic hyperplasia (BPH) Inflammo pharmacology. 2017 Aug; 25(4):451-458.
2) Hamvas, A., Corradi, G.Y., Hegedüs, M. and Frang, D., 1991.Experience with the Peponen® capsule in the management of benign prostatic hyperplasia. International urology and nephrology, 23(1), pp.51-55.
3) Hong H, Kim C-S, Maeng S. Effects of pumpkin seed oil and saw palmetto oil in Korean men with symptomatic benign prostatic hyperplasia. Nutrition Research and Practice. 2009;3(4):323-327. doi:10.4162/nrp.2009.3.4.323.
4) Jeyaraman, R. and Patki, P.S., 2012. Clinical Evaluation of Efficacy and Safety of a Herbal Formulation in Benign Prostatic Hyperplasia: A Single Blind, Randomized, Placebo-Controlled Study. Open Journal of Urology, 2(03), p.157.
5) Khesal Ahmad, FA Najar, Mohd Faisal et al. Efficacy of Banadiqul-Buzoor in Improving the Quality of Life of Patients of Benign Prostatic Hypertrophy: An Open Labelled Observational Clinical Study. Research & Reviews: Journal of Surgery. 2017; 6(3): 7–11p.
6) KIRTIKAR, K. R., BASU B. D. Indian Medicinal Plants, volume -1, P. No.229-230.
7) Klippel KF, Hiltl DM, Schipp B, A multicentric, placebo-controlled, double-blind clinical trial of beta-sitosterol (phytosterol) for the treatment of benign prostatic hyperplasia. German BPH-Phyto Study group, Br J Urol. 1997 Sep;80(3):427-32.
8) Machado-Leiva et al, Clinical evaluation of patients with benign prostatic hyperplasia, treated with the natural product Calprost®: a randomized, controlled study 2016 Journal of Pharmacy & Pharmacognosy Research, 4 (5), 187-198 ISSN 0719-4250.
9) Mohanty, N.K., Singh, U.P., Sharma, N.K., Arora, R.P. and Amitabh, V., 2006.A comparative study of fixed dose of tamsulosin with finasteride vs tamsulosin with dutasteride in the management of benign prostatic hyperplasia. Indian Journal of Urology, 22(2), p.130.
10) Nadkarnis, K.M. Indian Materia Medica, volume- 1, P. No. 1229-1232, third edition 1976, Bombay popular prakashan private limited.
11) Sahu, M., Bhat, R. and Kulkani, K., 2003. Clinical evaluation of himplasia in benign prostatic hyperplasia: an open clinical trial. Med Update, 11, pp.75-78
12) Said, M.M., Hassan, N.S., Schlicht, M.J. and Bosland, M.C., 2015. Flaxseed suppressed prostatic epithelial proliferation in a rat model of benign prostatic hyperplasia. Journal of Toxicology and Environmental Health, Part A, 78(7), pp.453-465.
13) Sengupta, G., Hazra, A., Kundu, A. and Ghosh, A., 2011. Comparison of Murraya koenigii–and Tribulus terrestris–based oral formulation versus tamsulosin in the treatment of benign prostatic hyperplasia in men aged>50 years: a double-blind, double-dummy, randomized controlled trial. Clinical therapeutics, 33(12), pp.1943-1952.
14) Shrestha, B.B. and Karmacharya, M., 2015.Finasteride and Tamsulosin Combination in Benign Prostatic Enlargement in a Tertiary Hospital of Western Nepal. Journal of the Nepal Medical Association, 53(197).
15) Tsai, Y.S., Tong, Y.C., Cheng, J.T., Lee, C.H., Yang, F.S. and Lee, H.Y., 2006. Pumpkin seed oil and phytosterol-F can block testosterone/prazosin-induced prostate growth in rats. Urologia internationalis, 77(3), pp. 269-274.
16) Vahlensieck, W., Theurer, C., Pfitzer, E., Patz, B., Banik, N. and Engelmann, U., 2015. Effects of pumpkin seed in men with lower urinary tract symptoms due to benign prostatic hyperplasia in the one-year, randomized, placebo-controlled GRANU study. Urologia internationalis, 94(3), pp.286-295.
17) Zhang, W., Wang, X., Liu, Y., Tian, H., Flickinger, B., Empie, M.W. and Sun, S.Z., 2008. Effects of dietary flaxseed lignan extract on symptoms of benign prostatic hyperplasia. Journal of medicinal food, 11(2), pp.207-214.