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

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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).

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 terrestris (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

<table>
<thead>
<tr>
<th>IPSS symptom score</th>
<th>Group A n=40</th>
<th>Group B n=33</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incomplete Emptying</td>
<td>1.52±1.10</td>
<td>1.33±1.29*</td>
</tr>
<tr>
<td>Frequency</td>
<td>2.10±1.73</td>
<td>1.48±1.06*</td>
</tr>
<tr>
<td>Intermittency</td>
<td>2.57±1.59</td>
<td>2.12±1.38</td>
</tr>
<tr>
<td>Urgency</td>
<td>1.32±1.42</td>
<td>1.21±0.96*</td>
</tr>
<tr>
<td>Weak Stream</td>
<td>2.52±1.43</td>
<td>1.21±0.96*</td>
</tr>
<tr>
<td>Straining</td>
<td>1.57±1.48</td>
<td>2.54±1.64</td>
</tr>
<tr>
<td>Nocturia</td>
<td>2.30±1.36</td>
<td>1.93±1.05*</td>
</tr>
<tr>
<td>Mean IPSS Symptom score</td>
<td>6.35±3.28*</td>
<td>11.45±4.28*</td>
</tr>
</tbody>
</table>

*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 [10] properties of its ingredients and at the end the diuretic effects [10,6] of the administered Unani formulation to 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 (Klippe et al 1997) [7]. Hemplasia containing Tribulus terrestris 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 (Vahlsieck 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 ± (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 provided 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