Comparison of Anti BPH capsule (herbal) and Terazosin HCl in the treatment of benign prostate hyperplasia

Hafiz Mohammad Rashid Nadeem[1]*, Ejaz Mohiuddin[1], Shahab-ud- Din[1], Muhammad Daniyal[1] and Khan Usmanghani[2]

[1]Faculty of Eastern Medicine, Hamdard University, Karachi, Pakistan
[2]Department of Research and Development, Herbion Pharmaceutical (Pvt.) Limited, Karachi, Pakistan

Abstract: Benign prostatic hyperplasia (BPH) is a disease of senile age, usually occurring> 60 years of age. BPH is a disease that involves cell proliferation of the prostate. Pathological hyperplasia affects the elements of the glandular and connective tissue of the prostate. This study is designed to scrutinize the efficacy and tolerability of herbal drug Anti BPH capsule for the management of benign prostate hyperplasia (BPH), in this study we select the 100 patients in which 50 received the Anti BPH capsule and 50 received the Terazosin HCl. We use the American Urological Association BPH Symptom Score Index Questionnaire to measure the quality of life of the patients. We compare the before treatment and after treatment results for each symptom. We record the following symptoms, incomplete emptying of bladder, Frequency, Intermittency, Urgency, Weak stream, Straining, Nocturia and weight of prostate gland by USG. We compare the both drug by using paired sample t-test. The level of significance of incomplete emptying of bladder before treatment and after treatment is 0.013 in test group and 0.032 in control group. Similarly the level of significance of Frequency before treatment and after treatment in test groups in, intermittency, Urgency, Weak stream, staining, Nocturia and mean weight of prostate gland are 0.007, 0.015, 0.044, 0.012, 0.017, 0.004 and 0.020; where as in control group afford as 0.031, 0.044, 0.044, 0.032, 0.024, 0.009 and 0.035 respectively. The herbal drug Anti BPH capsule is more effective in the treatment of BPH than Allopathic medicine Terazosin HCl.

Keywords: Anti BPH, herbal treatment, efficacy, tolerability, comparison.

INTRODUCTION

Benign prostate hyperplasia (BPH) is a disorder of senile age, most often occurs >60 years of age. BPH is less common in Asian countries. Particular etiology of BPH is unidentified. BPH is an illness that comprises the cellular proliferation of the prostate gland. Pathologically, hyperplasia affects the glandular and connective tissue elements of the prostate gland (Wei *et al.,* 2007). Clinically BPH present with distal urinary tract symptoms that includes increase frequency, intermittency, urgency, weak stream, straining and nocturia (Barry *et al.,* 1992). Distal urinary tract symptoms have a very bad influence on patient's quality of life and this impairment in quality of life encourage the patients to seek the treatment (Jacobsen *el al.,* 1993). The prevalence of men's who seek treatment in USA is 23.8% in 2004 (Jacobsen *el al.,* 1995). In Japan more than 250,000 patients with distal urinary tract symptoms are treated per year and this fig. is expected to increase in the future (Tsukamoto *el al.,* 1997). Prevalence of distal urinary tract symptoms is 53.8% in Pakistan (Hassan *et al.,* 2012). Prostate is an exocrine gland which present immediately under the bladder base and enclosed by the some portion of urethra. Prostate secretes the fluid which is important for fertilization because this fluid enhance the viability of the sperms in both male and female reproductive tract. This secretion are released into urethra at the time of ejaculation (Haynes *et al.,* 2005). BPH is an intensifying disorder that starts with the distal urinary tract symptoms. Histologically this is stromal glandular hyperplasia of prostate gland (Alan *et al.,* 2011). BPH is the disease of ageing men, which may be connected with enlargement of the prostate gland. BPH bothers the patient due to lower urinary track symptoms (LUTS) and bladder outlet obstruction. BPH also causes the sexual dysfunction in patients due to LUTS (Nordling *et al.,* 2005). BPH is increase the morbidity of the patients but it didn't increase the mortality (De Rejike *et al.,* 2004). In Pakistan, the scope of herbal medicine is not popular than allopathic medicine due to less data available on Pakistan community. This study aimed to evaluate the efficacy and tolerability of herbal medicine anti BPH capsule versus allopathic medicine Terazosin HCl in the treatment of symptomatic BPH.

**Corresponding author:* e-mail: hakeem_m.rashid@yahoo.com

METHODS

This clinical trial was carried on the patient of BPH. This is randomized clinical case control study. This study is conducted on the outdoor and indoor patients in Govt. Tibbia College Bahawalpur, B.V. Hospital and Civil Hospital Bahawalpur. The age range of patient was 40 to 80 years. Subjects were divided in two groups one received the study drug (Anti BPH capsule) called as test group and another receive the patented medicine (Terazosin HCl) called as control group. Ages Eligible for

Study: above 40 Years, Genders Eligible for Study: Males. Subjects are selected after seeing inclusion and exclusion criteria. This study is conducted on 100 patients in which 50 received the anti BPH capsule and 50 received the Terazosin HCl. The patients were registered from the Govt. Tibbia College Bahawalpur, B.V.Hospital and Civil Hospital Bahawalpur. This study is approved by the Ethical Board of the Hamdard University Karachi, Pakistan. In this study 50 patients were received Anti BPH and 50 patients were received Terazosin HCl. The American Urological Association BPH Symptom Score Index Questionnaire was used to evaluate the sign and symptoms of the patients. The parameters that were taken are incomplete emptying of bladder, Frequency, Intermittency, Urgency, Weak stream, Straining, Nocturia and weight of prostate gland by ultrasound sonography test (USG).

STATISTICAL ANALYSIS

All the data acquired from Govt. Tibbia College Bahawalpur, B.V.Hospital and Civil Hospital Bahawalpur, were subjected to statistical analysis (SPSS version 21.0) to conclude the level of significance of this clinical trial. The sample paired t-test were applied.

RESULTS

The aim of this study was to evaluate efficacy and safety of this Anti BPH capsule for the treatment of BPH. The clinical effect of this therapy is conducted on 100 patients which were diagnosed patients of BPH at Govt. Tibbia College Bahawalpur, B.V.Hospital and Civil Hospital Bahawalpur. Study design is shown in table 1 and ingredients of test and control drug are shown in table 2.

Clinical response

History taking and physical examination was carried out before, during and after give treatment with both drugs. The drug response was noted on sign and symptoms improvement level i.e. (Complete improvement, moderate improvement, mild improvement and no improvement).

Incomplete emptying of bladder

Incomplete emptying of bladder has been recorded in both test and control group patients. Patients presenting with incomplete emptying of bladder observed complete improvement in 32% of patients, moderate improvement in 20% of patients, mild improvement in 8% of patients and 6% of patients did not improve with control drug and the *p* value is 0.032 when compared with paired sample t-test, before and after treatment. The effects of test drug only 32% of the patient indicated complete improvement,42% shows moderate improvement, 10% shows mild improvement and 8% of patients did not improve and the *p* value is 0.013 when compared with paired sample t-test, before and after treatment. The test drug is more significant than control drug as shown in table 3.

Frequency of Urine

Frequency has been recorded in both test and control group patients. Patients observed complete improvement in 17% of patients, moderate improvement in 24% of patients, mild improvement in 30% of patients and 12% of patients did not improve with control drug and the *p* value is 0.031 when compared with paired sample t-test, before and after treatment. The effects of test drug only 26% of the patient indicated complete improvement,44% shows moderate improvement, 10% shows mild improvement and 20% of patients did not improve and the *p* value is 0.007 when compared with paired sample t-test, before and after treatment. The test drug is more significant than control drug as shown in table 4.

Intermittency

Intermittency has been recorded in both test and control group patients. Patients observed complete improvement in 34% of patients, moderate improvement in 40% of patients, mild improvement in 12% of patients and 14% of patients did not improve with control drug and the *p* value is 0.044 when compared with paired sample t-test, before and after treatment. The effects of test drug only 26% of the patient indicated complete improvement,44% shows moderate improvement, 12% shows mild improvement and 18% of patients did not improve and the *p* value is 0.015 when compared with paired sample t-test, before and after treatment. The test drug is more significant than control drug as shown in table 5.

Urgency

Urgency has been recorded in both test and control group patients. Patients observed complete improvement in 32% of patients, moderate improvement in 30% of patients, mild improvement in 30% of patients and 8% of patients did not improve with control drug and the *p* value is 0.044 when compared with paired sample t-test, before and after treatment. The effects of test drug only 34% of the patient indicated complete improvement,40% shows moderate improvement, 12% shows mild improvement and 14% of patients did not improve and the *p* value is 0.09 when compared with paired sample t-test, before and after treatment. The test drug is more significant than control drug as shown in table 6.

Weak stream

Weak stream has been recorded in both test and control group patients. Patients observed complete improvement in 30% of patients, moderate improvement in 38% of patients, mild improvement in 22% of patients and 10% of patients did not improve with control drug and the *p* value is 0.032 when compared with paired sample t-test, before and after treatment. The effects of test drug only 40% of the patient indicated complete improvement, 24%

Table 1: Design of the study

Number of Drugs	1. Test drug 2. Control drug	1. Anti BPH capsule 2. Terazosin HCl
Total Patients	50+50	50 Test+ 50 Control
Number of Tests	History, Physical Examination, Prostate gland weight by USG	Follow up 8 week after treatment
Duration of Treatment	8 weeks	Post treatment follow up

Table 2: Test and Control drug ingredients

Disease	Test drug	Ingredients of Test drug	Control Drug
BPH	Anti BPH capsule	Seronarepens (Standardized Extract) 80 mg UrticadioicaL.(Standardized Extract) 60 mg Cucurbitopepo Linn. (Standardized Extract) 50 mg Pygeumafricanum (Standardized Extract) 25mg	Terazosin HCl (Terazosin)

Table 3: Comparative data between test and control drug (Incomplete emptying of bladder)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	*p* value
Control group	16(32%)	20(40%)	8(16%)	6(12%)	.032
Test group	16(32%)	21(42%)	5(10%)	8(16%)	.013

Table 4: Comparative data between test and control drug (Frequency)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	*p* value
Control group	17(34%)	12(24%)	15(30%)	6(12%)	.031
Test group	13(26%)	22(44%)	5(10%)	10(18%)	.007

shows moderate improvement, 4% shows mild improvement and 32% of patients did not improve and the *p* value is 0.012 when compared with paired sample t-test, before and after treatment. The test drug is more significant than control drug as shown in table 7.

Staining

Staining has been recorded in both test and control group patients. Patients observed complete improvement in 22% of patients, moderate improvement in 42% of patients, mild improvement in 26% of patients and 10% of patients did not improve with control drug and the *p* value is 0.024 when compared with paired sample t-test, before and after treatment. The effects of test drug only 34% of the patient indicated complete improvement,30% shows moderate improvement, 10% shows mild improvement and 26% of patients did not improve and the *p* value is 0.017 when compared with paired sample t-test, before and after treatment. The test drug is more significant than control drug as shown in table 8.

Nocturia

Nocturia has been recorded in both test and control group patients. Patients observed complete improvement in 28% of patients, moderate improvement in 12% of patients, mild improvement in 22% of patients and 16% of patients did not improve with control drug and the *p* value is 0.009 when compared with paired sample t-test, before and after treatment. The effects of test drug only 40% of the patient indicated complete improvement,20% shows moderate improvement, 22% shows mild improvement and 18% of patients did not improve and the *p* value is 0.004 when compared with paired sample t-test, before and after treatment. The test drug is more significant than control drug as shown in table 9.

Mean weight of prostate gland by USG

Mean weight of prostate gland has been recorded by USG in both test and control group patients. The Mean weight before treatment is 53.16g and after treatment with control drug is 51.5g, and the *p* value is 0.035 in control group when compared with paired sample t-test, before and after treatment. The mean weight of prostate gland before treatment is 51.32g and after treatment is 49.5g and the *p* value is 0.020 in test group when compared with paired sample t-test, before and after treatment. Test group shows more improvement than control group as shown in table 10.

Comparison of treatment before and after

Complete results of before treatment and after treatment of each symptom are given in table 11 test group and table 12 control group. The comparisons are made by using paired sample t-test and *p* value is analyzed. Test drug is more significant in controlling the symptoms of BPH than control drug.

Table 5: Comparative data between test and control drug (Intermittency)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	*p* value
Control group	17(34%)	20(40%)	6(12%)	7(14%)	.044
Test group	13(26%)	22(44%)	6(12%)	9(18%)	.015

Table 6: Comparative data between test and control drug (Urgency)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	*p* value
Control group	16(32%)	15(30%)	15(30%)	4(8%)	.044
Test group	17(34%)	20(40%)	6(12%)	7(14%)	.019

Table 7: Comparative data between test and control drug (Weak stream)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	*p* value
Control group	15(30%)	19(38%)	11(22%)	5(10%)	.032
Test group	20(40%)	12(24%)	2(4%)	16(32%)	.012

Table 8: Comparative data between test and control drug (Staining)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	*p* value
Control group	11(22%)	21(42%)	13(26%)	5(10%)	.024
Test group	17(34%)	15(30%)	5(10%)	13(26%)	.017

DISCUSSION

This clinical trial is designed to evaluate the efficacy of Anti-BPH capsule in comparison to allopathic treatment Terazosin HCl. BPH is a progressive disease of senile age, it impair the patients quality of life due to distal urinary tract involvement and obstruction to the bladder outlet. The enlargement of the prostate gland sometimes associated with distal urinary tract symptoms and sometimes it is not associated with distal urinary tract symptoms. All men with histological present BPH did not consult the doctor due to less degree of prostate enlargement (Girman *et al.,* 1998).The gold standard test for measurement of prostate enlargement is ultrasound, computerized tomography and magnetic resonance imaging (Oesterling *el al.,* 1993). In the last few decades the treatment option for BPH has increasing, new medicines and new surgical approaches are developed to treat the BPH. The range of treatment is wide as the BPH present with large range of sign and symptoms. BPH is not the life threatening condition that's why its treatment should be safely improves quality of life (Gonzalez *et al.,* 2006). Subsequently, there is need to develop the safe and cost effective treatment for BPH. This study shows that herbal medicine anti BPH capsule is effective in the treatment of BPH when compare with the Terazosin HCl (Terazosin). The level of significance between both treatments is compare with paired sample t-test and Anti-BPH group shows high significance than Terazosin HCl (Terazosin) group. Consequently, here is necessity of herbal medicine that is safe and effective for the treatment of BPH. It has been observed that herbal drug Anti-BPH proven as well tolerated and has shown better efficacy without any side effects. None of the patient obsoletes the clinical trials due to any of adverse events or for any other reason.

CONCLUSION

It has been observed that Anti-BPH capsule is effective and well tolerated when compare to Terazosin HCl. None of patient shows any adverse effect. Recent studies accompanied on adults also proven that these type of products can potentially improve the BPH symptoms. It is recommended to conduct large scale clinical trial in future to use this product to large number of patients in terms to prove its efficacy more authentic way.

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