

## Pumpkin seed oil (Prostafit) or Prazosin? Which one is better in the treatment of symptomatic benign prostatic hyperplasia

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### Abstract

**Objective:** To assess the efficacy of drugs containing herbal extracts in the treatment of Benign Prostatic Hyperplasia.

**Methods:** The clinical trial study was performed in 2011-2012 at Imam Reza Hospital, Mashhad, Iran. One hundred patients with Benign Prostatic Hyperplasia were randomly divided into 2 equal groups receiving prostafit and prazosin, respectively. Quality of life and International Prostatic Symptom Score questionnaire were filled and prostate specific antigen level, uroflowmetry and prostate volume were measured at baseline, 3 and 6 months after the medication. The data was analysed using SPSS 15 and repeated measure analysis of variance.

**Results:** No complications were observed during and after the treatment. International Prostatic Symptom Score had significant differences at baseline and 6 months after the treatment in both groups, specially in group 2 18 vs 22 (36% versus 44%). Quality of life was better in group 2, 25.5 vs 31.5 (51% versus 63%). prostate specific antigen level did not change after the treatment and there was no remarkable difference in either group.

**Conclusion:** Prostafit is an effective and safe treatment in Benign Prostatic Hyperplasia but not as much as prozasin.

**Keywords:** Benign prostatic hyperplasia, Prazosin, Pumpkin seed oil, International Prostatic Symptom Score, Prostate specific antigen. (JPMA 64: 683; 2014)

### Introduction

Benign Prostatic Hyperplasia (BPH) is the most common benign tumour in males. The prevalence of BPH increases with age. It is reported in the biopsy of transitional zone among 50% of males in the 5th decade and more than 90% of males in the 9th decade.<sup>1</sup> Lower Urinary Tract Symptoms (LUTS) are age-related and 25% of 55 years old and 50% of 75 years old males have obstructive symptoms.<sup>1-3</sup> Obstructive symptoms are divided into mild, moderate and severe groups, according to the International Prostatic Symptom Score (IPSS). There are many different treatment options, including watchful waiting, medical ( $\alpha$ -blockers and  $5\alpha$  reductase inhibitors) and surgical treatment. Medical treatment has some side effects, including orthostatic hypotension, dizziness, headache, loss of libido and low volume of semen. EuRho® Vital Prostafit® Pumpkinseed-oil Capsules (Germany) is a safe and effective method of treatment.<sup>4</sup> Pumpkin with the scientific name of Cucurbita pepo is a form of cucurbita ceae family. Pumpkin seeds have 50% lipid, 30% protein and a high amount of potassium and iron. Phytosterole, tocopherol, cucurbitin and fatty acids such as omega 3 and 6 has been extracted

from that.<sup>5</sup> It has the effect of inhibition of  $5\alpha$  reductase and lowers the amount of di-hydrotestosterone which can arrest the prostate growth and improve urinary obstructive symptoms due to BPH.<sup>6</sup> The mechanisms of prostafit function may include changes in cholesterol metabolism, inhibition of  $5\alpha$ -reductase activity, a decrease in sex hormone binding globulin and anti-inflammatory effects.<sup>7</sup> A study on 60 patients and another on 245 patients showed that the obstructive symptoms had decreased.<sup>8,9</sup> In this study, the effectiveness of pumpkin seeds (prostafit) was compared with prozacin on patients with BPH.

### Patients and Methods

The prospective randomised clinical trial was conducted at Imam Reza Teaching Hospital in Mashhad, Iran, from 2011 to 2012, and 100 patients with symptomatic BPH were included. The patients were randomly divided into two equal groups using a random number table and treated with either prostafit (group 1, 2 tablets daily) or prazosin (group 2; 2 capsules daily). Both prostafit and prazosin were obtained from EuRho® Vital (Germany).

The study was conducted in accordance with the principles of Declaration of Helsinki 1996 version and Good Clinical Practice standards.<sup>10</sup> The study protocol, informed-consent form, and the other study-related documents were reviewed and approved by the Human Research Ethics Committee of Mashhad University of Medical Sciences. All patients were able to read, and voluntarily signed the informed consent,

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which was in the same language as that of patient.

Patients more than 50 years old with symptomatic BPH who were resistant to watchful waiting treatment options were included. Those with urinary system infection, urolithiasis, urinary retention, urinary incontinence, urethral stricture, urinary system malignancies, physical and mental disabilities, participation in another research, hernia, haematuria, cancer of prostate and neurogenic bladder were excluded.

Eight patients were lost to follow up. Finally, ninety two patients completed the study, 47 patients in Pumpkin group (A) and 45 in Prazocin group (B).

At the baseline after complete history, physical examination, including rectal examination, routine lab tests including prostate specific antigen (PSA), urine analysis and culture were performed. The measurement of prostate volume was done by transabdominal ultrasonography. Also, all patients were subjected to uroflowmetry to measure the maximum flow rate. Then, Quality of Life and IPSS questionnaires, which were translated into native language, were filled. Validity of the questionnaire was confirmed with content validity and reliability of a pilot study and was also calculated with Alpha Cronbach ( $\alpha=0.80$ ). IPSS questionnaire<sup>11</sup> contained 7 questions related to urinary symptoms and 1 question related to the quality of life. The questions related to incomplete emptying, frequency, intermittency, urgency, weak stream, straining and nocturia in the preceding month. Each one had 5 scores from zero onwards in ascending order. Overall maximum score was 35; 0-7, 8-19, 20-35 respectively showing mild, moderate and severe symptoms. Prostate volume, uroflowmetry and PSA level were measured and IPSS questionnaire were filled before the prescription and at 3 and 6 months of medication. The data was analysed using SPSS software and a repeated measure analysis of variance (ANOVA). For the comparison between groups, two-way ANOVA was used. Values were expressed as mean  $\pm$  standard deviation, while p value less than 0.05 were considered significant.

## Results

Of the 100 patients, 8 (8%) were lost to follow-up, and 92

(92%) completed the study. There was no morbidity during and after the study. The average height, weight and Body Mass Index (BMI) of patients were not significantly different between the 2 groups. Mean age of patients was  $64.28 \pm 8$  and  $63.69 \pm 8.8$  in group 1 and 2, respectively ( $p < 0.73$ ). In group 1, mean IPSS score was  $14.50 \pm 3.49$ ,  $11.90 \pm 4.09$  and  $9.24 \pm 3.60$  at the baseline, 3 and 6 months after treatment, respectively. It had a significant difference before and after the start of the medication ( $p < 0.001$ ). In group 2, mean IPSS score was  $14.54 \pm 5.36$  at the baseline,  $8.30 \pm 1.93$  at 3 months and  $8.08 \pm 2.93$  at 6 months, which showed a remarkable difference ( $p < 0.001$ ). Also, there was a significant difference between group 1 and 2 after the treatment ( $5.26 \pm 1.06$  and  $6.46 \pm 2.64$ , respectively) ( $p < 0.001$ ).

There was no significant difference between the IPSS score of the two groups ( $p < 0.28$ ), whereas within group differences over time was significant ( $p < 0.05$ ).

There was no remarkable difference in PSA and prostate volume (PV) before and after the medication in both groups ( $p > 0.05$ ). Uroflowmetry showed remarkable difference from  $14.5 \pm 1.3$  ml/s to  $19 \pm 1.7$  ml/s in group 1 and from  $14.2 \pm 1.3$  ml/s to  $22.1 \pm 1.4$  ml/s in group 2, respectively, that showed the improvement of 31% in group 1 and 48% in group 2, respectively. PV and PSA were not significant between the groups ( $p > 0.05$ ) (Table).

## Discussion

The results showed that IPSS score and quality of life in the second group was better than the first. PSA level and PV did not change after the treatment and without remarkable difference in both groups.

In a study published in 2008, the results of two  $\alpha$ -blocker was examined on BPH symptoms. In this study, 40 male patients with a mean age of 63.5 received daily 5mg terazosin for 3 months. After one month washout, they received alofosocin for 3 months. The results showed that both drugs significantly reduced IPSS values. Similarly, our findings showed that prazosin is a good  $\alpha$ -blocker.<sup>12</sup>

**Table:** Comparison between groups.

Parameter	Pumpkin group (N=47)			Prazosin group (N=45)			Group
	Baseline	3 Months	6 Months	Baseline	3 Months	6 Months	
IPSS	$14.50 \pm 3.49$	$11.90 \pm 4.09^*$	$9.24 \pm 3.60^*$	$14.54 \pm 5.36$	$8.30 \pm 1.93^*$	$8.08 \pm 2.93^*$	0.28
Uroflowmetry (ml/s)	$14.5 \pm 1.3$	$16.2 \pm 2.1$	$19 \pm 1.7^*$	$14.2 \pm 1.3$	$21.3 \pm 1.7^*$	$22.1 \pm 1.4^*$	0.23
QoL	$4.63 \pm 0.48$	$4.21 \pm 1.48$	$2.28 \pm 1.33^*$	$4.64 \pm 0.48$	$2.08 \pm 1.12^*$	$1.73 \pm 1.02^*$	0.29
PV (ml)	$22.1 \pm 2.2$	$23.1 \pm 1.8$	$22.9 \pm 2.3$	$23.2 \pm 1.9$	$22.2 \pm 2.4$	$21.9 \pm 1.7$	0.73
PSA (ng/ml)	$1.76 \pm 0.86$	$1.77 \pm 0.51$	$1.89 \pm 0.79$	$1.80 \pm 0.90$	$1.78 \pm 0.40$	$1.77 \pm 0.88$	0.68

Values expressed as mean  $\pm$  SD, \* $p < 0.05$ . Between two group were compared using two-way ANOVA in column "group".  
IPSS: International Prostate Symptom Score. QoL: Quality of Life. PV: Prostate volume. PSA: Prostate specific antigen.

Another study in 2010 assessed the effects of  $\alpha$ -blockers on LUTS by IPSS. In this study, 395 patients aged 40 years and older were enrolled with IPSS greater than or equal to 8. The mean age was 66 years. IPSS was significantly decreased in both groups, and the study confirmed a significant effect of  $\alpha$ -blockers on IPSS values. PSA levels decreased slightly in both groups. But this decrease was not significant. Hence, none of the drugs were effective on PSA level. These results are similar to our results.<sup>13</sup>

A study in 2000 examined the therapeutic effects of Prosta Fink Forte capsule containing extracts of pumpkin seeds in the treatment of BPH symptoms. In this study, 2245 patients over 12 weeks received 2 capsules per day. IPSS decreased 41.4% and 96% of patients did not report any side effects. The findings of this study, similar to our results, reported 36% reduction in IPSS values and no report of side effects.<sup>9</sup>

Another study investigated the effects of pumpkin extract Saw palmetto on BPH symptoms. This study was carried out for 12 months, and comprised 63 patients with a mean age of 53 years. Patients were divided into 4 groups. First group was the placebo group, the second group received pumpkin extract, third group received Saw palmetto, and the fourth group was given a mixture of extract of Saw palmetto and pumpkin seeds. IPSS in the second group was significantly decreased after 3 months. IPSS was 20.7 and 8.7 respectively before and after treatment. The treatment had no effect on the PSA level. In this study, no side effects were reported. Findings of pumpkin extract impact on IPSS (down 58%) confirmed the results of our study. In our study, IPSS after 6 months had a reduction of 36 per cent. Also, the effect of the drug on PSA levels and no reported side effects were similar to the results of our study.<sup>14</sup>

In another 2007 study, the treatment effect of various drugs were investigated on the symptoms of BPH. In this study, 906 patients were divided into 7 groups, receiving terazosin, doxazosin, tamsulosin, naftopidil, finasteride, and herbal product Cemilton, respectively. Patients were followed for 6 months at the end of which significant reduction in IPSS was obtained. But there was no significant difference among the groups. In other words, different drugs had the same effect. These findings are in contrast with our results that  $\alpha$ -blockers are better than phytotherapy.<sup>15</sup>

The placebo effect of drugs in treating LUTS may range from 20% to 40%, but there was no placebo arm in this study, which was a limitation.

## Conclusion

Both prazosin and prostafit are useful in the treatment of symptoms of BPH, and result in a better quality of life for patients. But in these fields, prazosin is more effective than Prostafit. None of these drugs have any effect on PSA levels.

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