## Do we need watchful waiting for BPH as a natural therapeutic device can prevent prostate enlargement?

Ivan Gerasimovich Aghajanyan<sup>1</sup>, Simon Allen<sup>\*2</sup>

<sup>1</sup>Professor, Head of the Department of Urology at the Yerevan State Medical University, Republic of Armenia 9 Ezras Hasratyan St, Yerevan, 0052, Armenia

<sup>2</sup>Director of Fine Treatment, 29 Rewley Road, Oxford, OX1 2RA, United Kingdom \* *info@finetreatment.com* 

**Keywords:** *enlarged prostate, bph treatment, prostate enlargement, thermobalancing therapy, prostate natural treatment, lower urinary tract symptoms, luts, bph cause, clinical trial, watchful waiting.* 

People are living longer and if in 2006 almost 500 million people worldwide were 65 and older by 2030 this number is projected to increase to 1 billion <sup>(1)</sup>. Benign prostatic hyperplasia (BPH), also known as benign prostate enlargement (BPE), is a condition in aging men in whom the prostate gland is enlarged and not cancerous. BPH causes lower urinary tract symptoms (LUTS) because the prostate growth places pressure on the bladder and urethra gradually. A positive correlation between age and LUTS is accepted by all researches <sup>(2)</sup>. Many of them are beginning to treat this disorder as a metabolic disease <sup>(3)</sup>. As BPH occurs in almost all men as they age, it has been always managed with special care.

**Watchful waiting is a well-known approach to the management of benign prostatic hyperplasia.** However, the longitudinal studies and randomized placebo-controlled trials have confirmed the progressive nature of BPH, with symptom progression being the most common manifestation. Variables such as baseline prostate-specific antigen, prostate volume, symptom score and bother score, decreased flow rate, and increased postvoid residual have all been linked to progression to acute urinary retention and need for surgery <sup>(4)</sup>.

But it is impossible to decline watchful waiting approach for men with BPH without suggesting something that can keep their quality of life up. Widely used conventional treatment options such as BPH medications may develop irreversible side effects. For instance, a substantial body of evidence exists which points to serious and potentially ill-health effects of  $5\alpha$ -RIs' therapy, namely finasteride or dutasteride. These include loss or reduced libido, erectile dysfunction, orgasmic and ejaculatory dysfunction, development of high-grade PCa tumors, potential negative cardiovascular events, and depression<sup>(5,6)</sup>.

Prostate surgical procedures are unsafe<sup>(7)</sup>. That is why EAU Guidelines on the Treatment and Followup of Non-neurogenic Male Lower Urinary Tract Symptoms Including Benign Prostatic Obstruction suggests: Prostate surgery is indicated in men with absolute indications or drug treatment–resistant LUTS due to benign prostatic obstruction<sup>(8)</sup>.

A recent clinical trial at the Department of Urology of the Yerevan State University involving 124 men with BPH, to whom the therapeutic device was administered exclusively as a mono-therapy, has confirmed the effectiveness and safety of Thermobalancing therapy. Thoroughly examined before and after a 6-month treatment period the patients reported a significant improvement to the disturbing lower urinary tract symptoms (LUTS). Their treatment results compared favourably to other patients, also 124 men, in the control group who didn't receive treatment <sup>(9)</sup>.

According to this study, the effect of the therapeutic device on alleviating urinary symptoms in men with BPH, as assessed using the International Prostate Symptom Score (IPSS) were, in the control group, the mean IPSS increased from  $13.45 \pm 3.254$  to  $14.35 \pm 3.396$ , whereas in the treatment group the mean IPSS decreased from  $14.33 \pm 3.399$  to  $4.73 \pm 2.754$  at the end of the observation period.

The dynamic of quality of life (QoL), according to IPSS was as follows: in the control group, the mean QoL increased from  $3.43 \pm 0.956$  to  $3.76 \pm 0.983$ , whereas in the treatment group the mean QoL decreased from  $3.91 \pm 0.755$  to  $1.39 \pm 1.110$ .

Changes in prostate volume (PV) mL in the beginning and the end of the study; thus in the control group the mean of PV increased from 45.54 to 50.85 mL, whereas in the treatment group the mean PV decreased from 45.19 to 31.86 mL.

The uroflowmetry maximum flow rate (Qmax mL/s): in the control group the mean Qmax decreased from  $7.95 \pm 2.871$  to  $7.7 \pm 2.695$  mL/s, where as in the treatment group the mean Qmax increased from  $8.10 \pm 3.041$  to  $17.73 \pm 4.392$  mL/s.

The obtained data indicated that Thermobalancing therapy was effective for men with BPH, as it improved QoL, reduced the PV level and IPSS, whereas in the no treatment group the dynamics of indexes were negative.

It must be time for urologists to update guidance for BPH management, especially when the problem is diagnosed, i.e. in watchful waiting. As conventional treatment options have serious side effects, approximately 30% of men diagnosed with prostate disease take supplements, and doctors in Europe typically use such remedies as first-line treatment for urologic conditions <sup>(10)</sup>. The most common for LUTS due to BPH are extracts of the saw palmetto. The most recent data from double-blind clinical trials do not support efficacy superior to that of placebo, but the saw palmetto extract showed no evidence of toxicity <sup>(11)</sup>. Natural therapies have a long history of use in India to support optimal prostate health. Varuna, khadir, and punarnava have been shown to be effective for BPH <sup>(12)</sup>.

## CONCLUSIONS

The results of the 2-year clinical trial suggest that Thermobalancing therapy should be viewed as a new physiotherapeutic treatment option for BPH. Not all men with BPH need medication or surgery, so self-care with Dr Allen's Device should be an option. Furthermore, urologists have to monitor their patients in the 'watchful waiting' systematically using in addition various natural remedies in order to support men's wellbeing.

## **COMPETING INTERESTS**

The authors declare that they have no competing interests.

## REFERENCES

- [1] Why Population Aging Matters: A Global Perspective, National Institute of Aging, NIH, 09/2011-01/2015, https://www.nia.nih.gov/publication/why-population-aging-matters-global-perspective/overview-our-aging-world.
- [2] Baruah SK, Nath SJ, Puthenveetil RT et al Prostate Volume, Serum Prostate-Specific Antigen, and Serum Testosterone in Indian, Benign Prostatic Hyperplasia Patients, UroToday Int J. 2012 October;5(5):art 43.
- [3] Vignozzi L, Rastrelli G, Corona G Benign prostatic hyperplasia: a new metabolic disease? J Endocrinol Invest. 2014 Apr;37(4):313-22.
- [4] Wiygul J, Babayan, RK Watchful waiting in benign prostatic hyperplasia, Current Opinion in Urology: January 2009, 19-1-3-6
- [5] Torre AL, Giupponi G, Duffy D et al Sexual Dysfunction Related to Drugs: a Critical Review. Part V: α-Blocker and 5-ARI Drugs, Pharmacopsychiatry 2016 Jan;49(1):3-13.
- [6] Traish AM, Mulgaonkar A, Giordano N The Dark Side of 5α-Reductase Inhibitors' Therapy: Sexual Dysfunction, High Gleason Grade Prostate Cancer and Depression, Korean J Urol. 2014 Jun;55(6):367-379.
- [7] Elshal AM, Elmansy HM, Elkoushy MA, Elhilali MM. Male sexual function outcome after three laser prostate surgical techniques: a single center perspective. Urology. 2012;80:1098-104.
- [8] Oelke M, Bachmann A, Descazeaud A EAU Guidelines on the Treatment and Follow-up of Nonneurogenic Male Lower Urinary Tract Symptoms Including Benign Prostatic Obstruction, Eur Urol. 2013 Jul;64(1):118-40.
- [9] Allen S, Aghajanyan IG Benign Prostatic Hyperplasia Treatment with New Physiotherapeutic Device, Urol J. 2015 Nov 14;12(5):2371-6.

- [10] Jackson CB, Taubenberger SP, Botelho<u>E</u> et al Complementary and Alternative Therapies for Urinary Symptoms: Use in a diverse population sample qualitative study, Urol Nurs. 2012 May-Jun; 32(3): 149–157.
- [11] Avins AL, Lee J Y, Meyers CM et al Safety and Toxicity of Saw palmetto in the Complementary and Alternative Medicine for Urological Symptoms (CAMUS) Trial J Urol. 2013 Apr; 189(4): 1415–1420.
- [12] Shrivastava A, Gupta VB Various treatment options for benign prostatic hyperplasia: A current update, J Midlife Health. 2012 Jan-Jun; 3(1): 10–19.