

Therapeutic Device Reduces the Prostate Volume in Men with Benign Prostatic Hyperplasia, Easing Lower Urinary Tract Symptoms, Naturally

Ivan Gerasimovich Aghajanyan¹ and Simon Allen^{2*}

¹Professor, Head of the Department of Urology at the Yerevan State Medical University, Republic of Armenia
9 EzrasHasratyan St, Yerevan, 0052, Armenia

²Director of Fine Treatment, 29 Rewley Road, Oxford, OX1 2RA, United Kingdom

***Corresponding Author:** Allen Simon, MD, PhD, Director of Fine Treatment, 29 Rewley Road, Oxford, OX1 2RA, United Kingdom; Tel: +447958878300; Fax: +441865728255; E-mail: info@finetreatment.com

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Abstract

Background: Benign prostatic hyperplasia (BPH), a non-malignant enlargement of the prostate gland, is the most common benign tumour found in men. BPH is responsible for the development of lower urinary tract symptoms (LUTS). However, there have been contradictory reports about the correlation between the prostate volume (PV) and development of BPH symptoms. The aim of this study was to find if there is a link between PV and LUTS.

Methods: Before and after 6 months men older than 55 with LUTS and prostatic enlargement had the following tests twice: the International Prostate Symptom Score (IPSS), ultrasound measurement of PV and uroflowmetry maximum flow rate (Q_{max}). The effectiveness of Thermobalancing therapy enabled by therapeutic device was thoroughly investigated in 124 men with BPH and PV < 60 mL. We also present here case studies of 2 men with PV > 60 mL who used the device for 7 months.

Results: The outcomes of investigated tests in 124 men with the PV < 60 mL verified decrease of IPSS ($P < 0.001$) and improvement of quality of life (QoL) ($P < 0.001$), reduction of PV ($P < 0.001$) and increase of Q_{max} ($P < 0.001$). Furthermore, the prostate volume in men with PV > 60 reduced significantly after wearing the device for 7 months but numbers of PV were still abnormal.

Conclusions: The observed positive changes in PV and BPH symptoms under Thermobalancing therapy demonstrate that there is tight correlation between PV and IPSS. Men with PV > 60 require more time for therapy. As therapeutic device is side effects free and safe it can be used when enlarged prostate is diagnosed without waiting of LUTS to progress, i.e. in the watchful waiting stage.

Keywords: Enlarged prostate; BPH treatment; Prostate enlargement; Thermobalancing therapy; Prostate natural treatment; Lower urinary tract symptoms; BPH cause; Clinical trial.

Background

Benign prostatic hyperplasia (BPH) is the most common disorder affecting men worldwide and the most common cause of lower urinary tract symptoms (LUTS). The main factors of its development are age and the prostate volume. A positive correlation between age and LUTS is accepted by all researches [1, 2]. However there are contradictory opinions concerning the prostate volume, the progress of prostate enlargement and BPH symptoms until now. “Benign Prostatic Hyperplasia: Does Prostate Size Matter?” From one side there were reports: prostate size is completely unimportant in determining the need for treatment [3] or the size of prostate does not matter for developing symptoms of BPH [4]. From another side: “Size does matter!” [5]. Men with mild to no LUTS but enlarged prostate are at higher risk of incident LUTS presumed due to BPH [6].

Why do researches argue about the prostate size? 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 α -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 [7 - 9].

Prostate surgical procedures even “minimally invasive” or “laser surgery” are unsafe [10]. That is why EAU Guidelines on the Treatment and Follow-up 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 [11].

So, some of academics support the view that the PV is an issue, and believe that medical and surgical intervention in men with BPH/LUTS in an early stage of prostate enlargement is vital to prevent LUTS progression, whereas, other researchers think that PV should not be the start point of medical or surgery intervention in men with BPH as it can reduce men's quality of life. Therefore about 20 years ago watchful waiting stage in the BPH management was initiated.

However, it should be remembered that as with aging the bladder function became more complex with an increased percentage of patients with detrusor hyperactivity with impaired contractility (DHIC). Both bladder outlet and bladder functions are affected by age [12]. A study with trans-abdominal ultrasonography assessment of the lower urinary tract in a non-invasive manner showed the correlation between PV and the detrusor wall thickness (DWT), the larger prostate –the thicker DWT [13].

We investigated 124 men with BPH and PV < 60 mL to whom the therapeutic device was administered exclusively as a mono-therapy. This study has confirmed the effectiveness and safety of Thermo balancing therapy.

Thoroughly examined before and after a 6-month treatment period, the patients reported a significant improvement of LUTS. The treatment results compared favorably to other patients, also 124 men, in the control group [14]. In this article we also present the dynamics of the prostate size in men with BPH and PV > 60 before and after Thermobalancing therapy.

Materials and Methods

Study Design

The clinical controlled study was used. Enrolment began in 2013 at the Department of Urology of the Yerevan State Medical University. The Ethics Committee of the Yerevan State Medical University has approved the clinical study on Thermobalancing therapy enabled by therapeutic device, termed Dr. Allen's Device. Comparing men with BPH who received treatment with therapeutic device with the control group studied the effectiveness of Thermobalancing therapy. Dynamics of the symptoms and the indicators in each group were evaluated in comparison to their data in the beginning and end of the treatment or no-treatment.

Evaluation

The baseline evaluations included complete physical examination, medical history, DRE, serum biochemistry, and PSA measurements, electrolytes, urine and renal function tests. Evaluations were made at baseline and 6 months after the treatment. IPSS-QoL scored as follow: delighted = 0, pleased = 1, mostly satisfied = 2, about equally satisfied and dissatisfied = 3, mostly dissatisfied = 4, hopeless = 5 and poor = 6. PV was measured at baseline and at 6 months after the treatment by ultrasonography (US-9000E2 ultrasound scanner, Rising Medical Equipment Co. Ltd, Beijing, China) and uroflowmetry was used for the measurement of the rate of urine flow parameters (Sanuro2UL, SantronMeditronic, Maharashtra, India). The standard ellipsoid formula length \times width \times height \times 0.52 was used to determine prostate volume.

Participants and Interventions

The main group 124 patients selected for the 6-months clinical trial. Inclusion criteria: Men were eligible for enrollment if they were over the age of 55, in the absence of acute prostatitis, at the level of prostate-specific antigen (PSA) that is not more than 4 m.mol/l. It did not matter if they were treated at the time of enrollment with medicines. However, after the use of therapeutic device other treatments were cancelled gradually. Exclusion criteria: PV greater than 60 mL, co-morbidities, such as diabetes, heart failure, cancer, etc.

In this article we also present an individual data of men with PV over 60 mL who used Dr. Allen's Device for about 12-months. Men in treatment-group after the screening were given therapeutic device, termed Dr. Allen's Device, see figure 1.



Figure 1: The thermoelement of the therapeutic device is tightly attached to the coccyx area.

Statistical Analysis

Because Independent Samples t-Test and Pair Samples t-Test is only suitable for interval and ratio data, the Wilcoxon Signed- Ranks Test by using SPSS has been conducted.

Results

Figure 2: Dynamics Prostate volumes (mL) in 124 patients with benign prostate hyperplasia and control group at the beginning and at the end of the study.

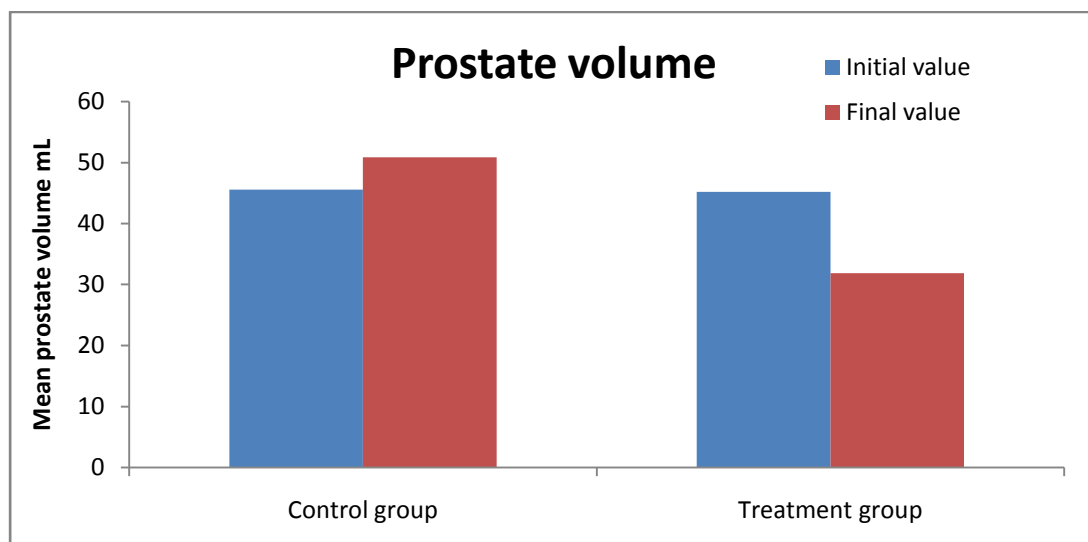


Figure 2 shows the changes in PV (mL) in men with BPH in the beginning and the end of the study. In the control group the mean prostate volume increases from 45.54 to 50.85 ml, whereas in the treatment group the mean prostate volume decreases from 45.19 to 31.86 ml. For the control group, the z value is -8.727 at the significance level of (<0.001). So there is a statistically significant increase in the prostate volume in the control group. For the treatment group, the z value is -9.669 at the significance level of (<0.001). So the treatment with therapeutic device reduces the prostate volume significantly, whereas in the no treatment group the prostate volume increases.

We also investigated the effect of the therapeutic device on alleviating urinary symptoms, as assessed using the IPSS. In the control group, the mean IPSS increased from 13.45 ± 3.254 to 14.35 ± 3.396 , whereas in the treatment group the mean IPSS decreased from 14.33 ± 3.399 to 4.73 ± 2.754 at the end of the observation period.

We assessed the QoL according to IPSS. In the control group, the mean QoL score increases from 3.43 ± 0.956 to

3.76 ± 0.983 , whereas in the treatment group the mean QoL score decreases from 3.91 ± 0.755 to 1.39 ± 1.110 .

The uroflowmetry Qmax (mL/s) in BPH patients, in the control group, the mean Qmax decreased from 7.95 ± 2.871 to 7.7 ± 2.695 mL/s, where as in the treatment group the mean Qmax increased from 8.10 ± 3.041 to 17.73 ± 4.392 mL/s.

Figure 3: Prostate volume (mL) dynamic in 2 patients with benign prostate hyperplasia and initial PV level over 60 mL.

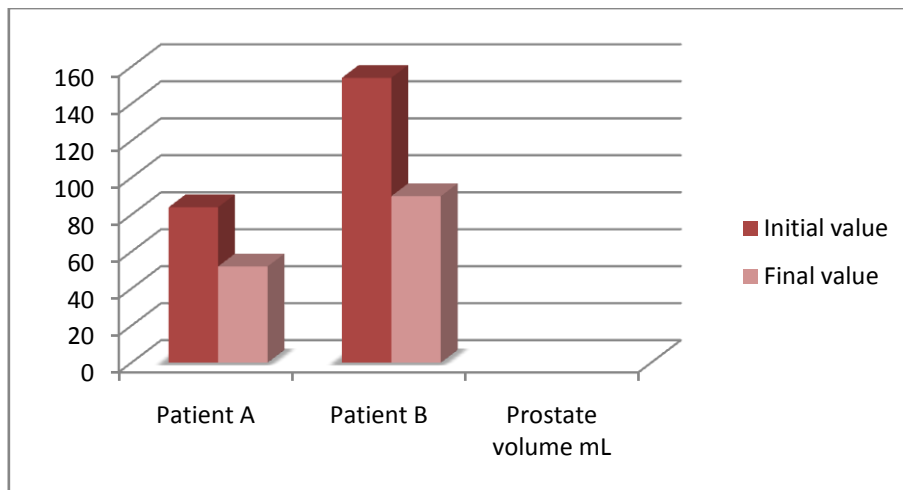


Figure 3 shows the changes in PV (mL) in 2 men with BPH in the beginning and the end of the treatment with therapeutic device. The prostate volume decreased in Patient 1, Galstyan L, 75, PV level decreased from 84 mL on 03/2/2014 to 52 mL on 03.11.2014; in Patient 2, Nersesyan T, 79, PV level decreased from 154 mL on 22/07/2014 to 52 mL on 18.02.2015. Accordingly to PV reduction, it was observed improvement of other clinical parameters, including, IPSS and QoL, the uroflowmetry Qmax increased.

Discussion

These obtained data indicate that the Thermobalancing therapy is effective for BPH/LUTS. It is important as this disorder has a major impact on men, their families, health services and society. Men with LUTS secondary to BPH should not simply accept their symptoms as part of ageing, but should be encouraged to consult their physicians if they have bothersome symptoms [15]. In the last decade, the opinion of the necessity of medical/surgical treatment of BPH has been challenged. BPH/LUTS should not be viewed as an inevitable disease of older people but part of the aging process which can be prevented [16]. Moreover, a research that included overall 2,620,269 patients with BPH which were treated within 5 years has shown that medical treatment was interrupted for approximately 16% of patients. So, it is necessary to improve the level of care for men with BPH [17].

As Thermobalancing therapy is free from side effects it can play an important role in the prevention of BPH development and progression. Thermobalancing therapy is different than common heating treatments because it regulates the affected organ's temperature locally, maintaining it within the normal body temperature range. As the thermoelement accumulates body heat, the temperature in it cannot exceed normal body temperature. Treatments with imposed heat can be damaging, because the high temperatures above 104 Fahrenheit (or 40°C) destroy living cells, while low temperatures decrease cellular metabolism and, as a result, interfere with a natural recovery.

Therapeutic device applies the thermoelement tightly to the skin in the projection of prostate, helping to overcome the skin barrier spreading the energy inside the body. It is not similar to treatments with wool or synthetic

fabric clothes, etc., as no other treatment method and material have been able to overcome the skin barrier delicately and precisely.

Dr. Allen's research on the Origin of Diseases suggests the causal root of prostate enlargement, namely capillary expansion. This conclusion is based on 2 functional physiological properties of capillaries which are activated by an irritating factor, i.e. a trigger. Constriction of capillaries in response to an irritating trigger develops local micro-hypothermia. It is this focus of hypothermia, which in turn becomes a constant irritant maintaining illness, i.e. making a disease chronic. In response to irritation (i.e. a trigger-initiator and later focus of hypothermia) and in order to eliminate them, the blood flow increases through the spontaneous expansion of the capillary net locally. The formation of new capillaries is essentially the growth of the excess tissue that leads to an increased pressure inside the prostate and its enlargement [18].

In the last decade, the pathogenesis of BPH began to consider from the perspective of vascular dysfunction, for instance, age might activate systemic vascular risk factors, resulting in disturbed blood flow [19], and with a correlation between pelvic ischemia and voiding dysfunction in elderly men [20], and also increasing the pressure in the prostate [21].

Thermobalancing therapy is the only external non-invasive treatment that targets pathological nidus continuously for a prolonged period of time, i.e. for days, months or even years [22]. We believe that the use of therapeutic device that maintains the accumulated temperature in the projection of a prostate acts on micro-focus of hypothermia and ischemia in it, removing the vicious cycle of spontaneous growth of capillaries in response to a trigger, micro-hypothermia, thereby relieving the pressure in the prostate gland and easing LUTS.

Conclusions

Thermobalancing therapy enabled by therapeutic device leads to greater access to BPH treatment and improved outcomes for those suffering from enlarged prostate. It is a new prospect for secure effective physio therapeutic intervention in the watchful waiting stage. The reduce of the prostate volume after use of therapeutic device, termed Dr. Allen's Device, correlates with significant decrease of urinary symptoms and improvement of quality of live in patients with enlarged prostate. We believe that decrease of PV volume in men with BPH shows the reversion of enlarged prostate.

Safety and Costs

None of the patients who received Thermobalancing therapy had side effects. Besides all of this, the important factor is

the cost of a new treatment compared to the cost of the standard treatment options.

Competing Interests:

The authors declare that they have no competing interests. Simon Allen application to USPTO in 2009 has been considered positively: "Therapeutic Device and Method" but he hasn't received reimbursements, fees, funding, or salary relating to the content of the manuscript.

Authors Contributions:

Both authors made substantive intellectual contributions to a presented study. They have made substantial contribution to conception and design, acquisition of data and interpretation of data; have been involved in drafting the manuscript and revising it critically for important intellectual content; and have given final approval of the version to be published.

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