

Research Article

Benign Prostatic Hypertrophy Management Strategy Should Include Thermo Balancing Therapy

Ivan Gerasimovich Aghajanyan¹ and Simon Allen^{2*}¹Department of Urology, Yerevan State Medical University, Armenia,²Director of Fine Treatment, UK

*Corresponding author

Simon Allen, Director of Fine Treatment, 29 Rewley Road, Oxford, OX1 2RA, UK; Tel: 447-958878300; Fax: 441-865728255; Email: info@finetreatment.com

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Abstract

Introduction: Phytotherapy often used for lower urinary tract symptoms (LUTS) however contemporary treatment recommendations for benign prostatic hypertrophy or hyperplasia (BPH) usually start with alpha-blockers and 5 α -reductase inhibitors isolated or in combination, and once medical therapy becomes helpless different surgical procedures are used. The aim of this evidence-based clinical review is to discover if Thermo balancing therapy enabled by therapeutic device can useful in the LUTS due to BPH management.

Methods and Results: For 3-year period men with BPH/LUTS were using therapeutic device. Before and after 6 months patients with BPH were investigated on: the International Prostate Symptom Score (I-PSS), ultrasound measurement of prostate volume (PV) and uroflowmetry maximum flow rate (Q_{max}). The effectiveness of therapeutic device was examined in 124 men with BPH and PV < 60 ml. We also included the dynamics of 5 men with PV > 60 ml who used this device. 124 men with 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} ($P < 0.001$). The similar positive outcomes were found in men with PV > 60 ml. In the control no-treatment group the condition of men with BPH worsened.

Discussion and Conclusions: The positive changes in LUTS/BPH symptoms after 6-month period of using therapeutic device were observed. The obtained results challenge standard concept of the only medicine/surgical management for LUTS due to BPH, adding therapeutic device as a valuable and cost-effective treatment option for men with prostate enlargement. Moreover, Thermo-balancing therapy enabled by therapeutic device is side effects free.

INTRODUCTION

Epidemiological studies have shown that age is the principal firm risk factor of lower urinary tract symptoms, however the traditional dogma that BPH related LUTS is an immutable consequence of old age is no longer acceptable, but whether promoting healthier lifestyles can really alter a man's propensity to develop BPH/LUTS remains to be clarified [1]. The prevalence of metabolic syndrome in men aged ≥ 50 years with and without clinical BPH differ, as the presence of clinical BPH was associated with a 37% increased odds of having metabolic syndrome [2].

Thus, the process of prostate enlargement is similar to the development of cardiovascular/cerebral or other internal chronic diseases with aging. From the point of view that metabolic

syndrome is associated with BPH it is understandable that 12 months of treatment with pumpkin seed, which is a rich natural source of antioxidant, led to a clinically relevant reduction in the International Prostate Symptom Score (I-PSS) compared with placebo [3]. At the same time the correlation between BPH and metabolic diseases also explains situation that current medical therapies are not always adequate in controlling LUTS or slowing disease progression, and there is unmet need for new effective therapeutic options. Therefore, most researches are looking for establishing new BPH drugs [4].

It has been suggested that the two functional physiological properties of capillaries: constriction and spontaneous expansion of the capillary net are responsible for the cause of chronic internal diseases, including prostate. These functions

Table 1: The changes in International Prostate Symptom Score (I-PSS) and quality of life (QoL), in prostate volume (PV) ml and uroflowmetry maximum urinary flow rate (Q_{max}) mL/s in men with BPH, PV > 60 ml, on Thermo balancing therapy.

Patient 1, age 75	03/2/2014	03.11.2014
IPSS - Urinary symptoms	12	3
QoL score	4	0
Prostate volume ml	84	52
Q_{max} mL/sec	9.7	15.5
Patient 2, age 73	01/07/2014	03/11/2014
IPSS - Urinary symptoms	14	4
QoL index	4	1
Prostate volume ml	93	70
Q_{max} mL/sec	11.2	14.0
Patient 3, age 79	22/07/2014	18/02/2015
IPSS	6	2
QoL index	3	1
Prostate volume ml	154	90
Q_{max} mL/sec	13.0	14.4
Patient 4, age 73	18/03/2014	10/03/2015
IPSS - Urinary symptoms	16.5	6
QoL score	3	1
Prostate volume ml	74	51
Q_{max} mL/sec	7.2	10.3
Patient 5, age 77	31/03/2014	24/03/2015
IPSS - Urinary symptoms	12.5	7
QoL score	4	3
Prostate volume ml	110	88
Q_{max} mL/sec	5.8	6.8

are activated by an irritating factor, i.e. a trigger. Constriction of capillaries in response to irritating trigger develops local focus of micro-hypothermia. It is this focus of hypothermia, which in turn becomes a constant irritant maintaining illness, i.e. making a disease chronic [5]. 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 [6].

The continuous formation of new capillaries is essentially the growth of the excess tissue that leads to an increased pressure inside the prostate and its enlargement. For the purpose of a targeted treatment for the secondary trigger, i.e. focus of hypothermia inside the organ; Dr Allen suggested Thermo balancing therapy enabled by therapeutic device. This device contains a natural thermo element which accumulates body heat becoming a source of the energy itself [7]. Previous articles have shown that Thermo balancing therapy decreases urinary symptoms and improves quality of life in men with BPH after 6-month using of this physiotherapeutic device [8,9].

In this study we investigate the influence of topically applied therapeutic device to the projection of prostate by defining changes in urinary symptoms and prostate volume (PV) quality of life (QoL) and uroflowmetry maximum flow rate (Q_{max}). In this clinical review we would like to show the dynamics of the symptoms and parameters in men with BPH/LUTS after Thermo balancing therapy and discuss the possible changes in the recommendations for patients with LUTS/BPH by including therapeutic device to the arsenal of urologists against BPH.

METHODS AND RESULTS

Study design

From April 2013 at the Department of Urology of the Yerevan State Medical University men with LUTS/BPH were used therapeutic device under supervision of urologists. The Ethics Committee of the Yerevan State Medical University has approved the clinical controlled study on Thermo balancing 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 Thermo balancing therapy. Dynamics of the symptoms and the indicators in each group were evaluated in comparison to their data in the beginning and after 6 months of 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 by ultrasonography, the standard ellipsoid formula $length \times width \times height \times 0.52$ was used to determine PV, (US-9000E2 ultrasound scanner, rising Medical Equipment Co. Ltd, Beijing, China) and maximum flow rate Q_{max} by uroflowmetry was measured (Sanuro2UL, Santron Meditronic, and Maharashtra, India).

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.

Participants and interventions

124 patients with BPH were observed during 2-year clinical trial arranging the main treatment group. The control group comprised 124 men with BPH received no treatment. 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 4m.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> 60 ml, co-morbidities, such as diabetes, heart failure, cancer, etc.

This article also explores the treatment group that includes men with PV > 60 ml who were excluded from the main group but

used Dr Allen's Device even for a longer period of time. Men in the treatment groups after the screening were given therapeutic device, Figure 1.

RESULTS

The changes of clinical symptoms and parameters in treatment group, 5 men with BPH, PV >60 ml

These cases show that all men with BPH, PV > 60 ml, were over 70. It is big dissimilarity between initial PV, from 154 ml to 110 - 93 - 84 - 74 ml. It was also recorded that a man with the largest prostate (154 ml) had fewer complain, IPSS - 6 and Quality of Life score - 3, whereas a patient with the smallest PV in this group (74 ml) had high IPSS - 16.5 and QoL - 4. Therapeutic device used as a long-term mono therapy and improved IPSS and QoL index in all men. The PV level decreased and Q_{max} increased. Despite the fact that the PV decreased significantly in all cases, the size of the prostate remained large: from 90 ml to 88 - 70 - 52 - 51 ml. This means that these patients should use the device even longer than a year under supervision of urologist.

The clinical symptoms and parameters in the treatment group, 124 men with BPH, PV <60 ml, comparing with no treatment group

The treatment with therapeutic device decreased the urinary symptoms significantly, while in absence of treatment the symptoms increased significantly. The results indicated that the treatment with therapeutic device improved QoL significantly, while in the control group the QoL worsened.

The PV level and QoL in the treatment group, 124 men with BPH, PV < 60 ml, comparing with no treatment group

The treatment with therapeutic device reduced PV significantly, whereas in the no treatment group PV increased. The results demonstrated that the therapeutic device increased uroflowmetry Q_{max} significantly, whereas in the control group there was no significant difference in uroflowmetry Q_{max} .

DISCUSSION AND CONCLUSIONS

Therapeutic device that was administered as a mono-therapy to men with LUTS/BPH demonstrated positive outcomes as in urinary symptoms as well in parameters PV and Q_{max} . It is important as BPH is a highly prevalent and costly chronic condition that affects older men worldwide, developing LUTS,

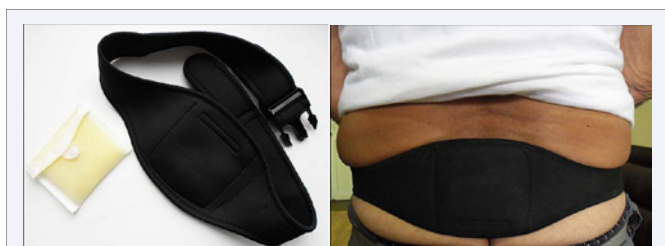


Figure 1 The thermo element, belt, therapeutic device is tightly attached to the coccyx area.

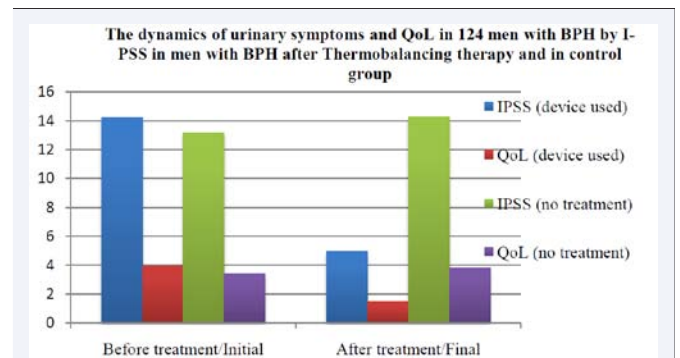


Figure 2 The changes of urinary symptoms by International Prostate Symptom Score (I-PSS) and quality of life (QoL) in 124 patients with BPH on Thermo balancing therapy and in the control group at the beginning and at the end of the 6-month period.

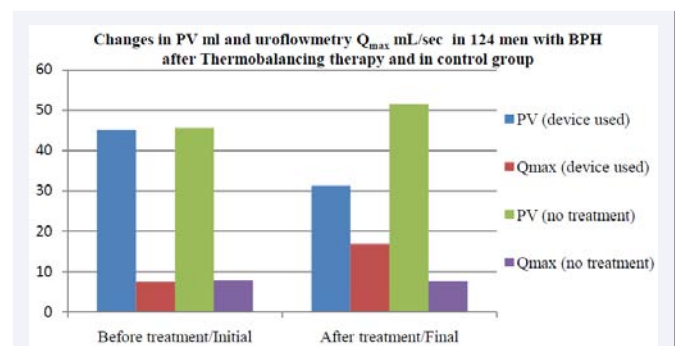


Figure 3 The changes in prostate volume (PV) ml and uroflowmetry maximum urinary flow rate (Q_{max} mL/s) in 124 men with BPH on Thermo balancing therapy and in the control group at the beginning and at the end of the 6-month period.

which can have a negative impact on their quality of life and even their families, and the management of BPH in a not-so-far future can become a public health problem in many countries [10,11].

Thermo balancing therapy with therapeutic device decreased urinary symptoms improved QoL significantly, reduced PV significantly and increased uroflowmetry Q_{max} . None of the patients who received Thermo balancing therapy had side effects.

The outcomes from our clinical trial are convenient for consideration that this therapy is a valuable physiotherapeutic treatment option for the LUTS/BPH management strategy, particularly in its early stage

Thermo balancing therapy is the only non-invasive external treatment that targets pathological nidus in the enlarged prostate gland continuously for a prolonged period of time. 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 stopping its growth and easing LUTS [12,13].

Phytotherapeutic agents in management of BPH-related LUTS

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 [14]. The most common for LUTS due to BPH is saw palmetto berry (SPB), also known as Serenoa repens. The 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 [15]. Natural therapies have a long history of use in India to support optimal prostate health. Gokshura has been traditionally used in treating urogenital conditions; varuna, khadir, and punarnava have been shown to be effective for BPH [16]. In the University of Ghana a recent study indicated that ethanolic root extract of *C. membranaceus* is one of the few monoherbal products that remarkably reduced PSA levels, prostate volume, and subsequently improved the QoL of patients with BPH [17].

However, there is no standard of care about the management of patients with LUTS/BPH by using phytotherapeutic agents, despite the fact that more than 30 phytotherapeutic compounds were proposed for the management of BPH. The current literature has not been able to consistently prove the efficacy of these supplements. Individuals should be advised that while many of phytotherapeutic agents demonstrate acceptable safety profiles, the efficacy and mechanisms of action are still not defined [18].

That is why the BPH/LUTS management currently programmed on the medicine/surgical base: mild or non-bothersome symptoms of BPH do not require treatment; bothersome symptoms are managed with lifestyle modifications, medications, and surgery; **and dietary supplements, such as saw palmetto, pygeum, cernilton, and beta sitosterols, and acupuncture are not recommended for the management of BPH** [19].

Costs of management BPH-related LUTS

The overall cost for the diagnosis and treatment of LUTS/BPH in the US has been estimated at approximately 1.1 billion US\$/year, compared to total annual expenditure for urological conditions of some 9 billion, and this cost continues to increase [20].

The costs of contemporary treatment options for LUTS/BPH vary; for instance, the price of the single-dose combination therapy is £19.80 (\$30) per month, compared with £26.09 (\$38) per month for dutasteride plus tamsulosin; the average cost of mini invasive procedures such as Holmium laser enucleation of the prostate (HoLEP) or transurethral resection of the prostate (TURP) varies from \$3000 to \$3500, and the price can be doubled in the private clinics [21,22].

The costs of treatments for benign prostatic hyperplasia were compared, including pharmaceuticals (finasteride, tamsulosin, and combined therapy), transurethral laser resection of the prostate and TURP, and it **has been found that the cost of operative group was lower than 5-year cost of pharmaceutical group** [23].

Besides all of this, the important factor is the cost of a new Thermo balancing therapy is affordable for people at any country, if it is compared to the cost of the standard treatment options.

Drugs in management of BPH-related LUTS

In men with bothersome LUTS related to BPH, medical treatment usually represents the first line. The usual plan of drug therapy is as follows: Alpha-blockers usually prescribed to men with LUTS with small prostates and 5-alpha reductase inhibitors (5-ARIs) are recommended in men with large symptomatic prostates. While, phosphodiesterase-5 (PDE-5) inhibitors are the mainstay of erectile dysfunction therapy, they also play a role in treating LUTS/BPH. If men have persistent irritative storage symptoms after first line BPH therapy then overactive bladder (OAB) medications can be added or substituted. Combination therapies can be used to provide short-term symptom relief with long-term disease management [24].

Due to serious side effects from BPH drugs that include loss or reduced libido, erectile dysfunction, orgasmic and ejaculatory dysfunction, development of high-grade PCa tumors, potential negative cardiovascular events, and depression, some of patients discontinue their intake [25]. It has been found that the adherence to pharmacological therapy for BPH is low and discontinuation of drug treatment can be an independent risk factor for hospitalization for BPH and BPH surgery [26]. Furthermore, a research that included overall 2,620,269 patients with BPH which were treated within 5 years has shown that the α 1-blockers were prescribed most frequently, but phototherapy surprisingly accounted for 27% of all mono therapies and 54% of all combination therapies; also **medical treatment was interrupted for approximately 16% of patients**. So, it is necessary to improve the level of care for men with BPH [27].

Surgical procedures in management of BPH-related LUTS

To compare outcome of medical and surgical treatment in men with BPH in the population-based study, operative treatment seemed to relieve LUTS, whereas medical treatment only slowed down their progression, so men with surgical treatment experience a more favourable outcome in LUTS than those receiving medical treatment [28].

Prostate surgical procedures even "minimally invasive" or "laser surgery" are unsafe [29]. 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** [30].

This short review shows that all treatment options are necessary for men with BPH during development and progression of LUTS. The study we discuss here demonstrates that physiotherapeutic device should have been tried in patients with prostate enlargement before any long-term pharmacotherapy is initiated [31].

CONCLUSIONS

Phytotherapeutic agents are safe but their effectiveness for

men with LUTS/BPH is questionable for many years. Medications are essential in the acute stage of BPH but have not proven to be helpful in the long-term; furthermore, their continuous intake is expensive and may develop serious side effects decreasing men's QoL. Surgical interventions in men with BPH provide better outcomes than drugs but complications are narrowing their implications for the LUTS/BPH management. Thus, Thermo balancing therapy, which has shown promising outcomes in our clinical study, can become an important tool for LUTS/BPH management. Moreover, therapeutic device is cost-effective and safe.

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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