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Thermobalancing conservative treatment for moderate-to-low-degree lower urinary tract symptoms (LUTS) secondary to prostate enlargement

Simon Allen^{1*} and Ivan Gerasimovich Aghajanyan²

Abstract: *Background:* The prostate undergoes gradual growth throughout men's lives, resulting in development of lower urinary tract symptoms due to benign prostatic hyperplasia (LUTS/BPH). The aim of this review was to determine whether Thermobalancing could be used for conservative treatment of LUTS/BPH. *Methods and Results:* Men older than 55 with LUTS derived to BPH used Thermobalancing therapy enabled by therapeutic device as mono-therapy. The main group consisted of 124 patients with the prostate volume (PV) up to 60 ml, however, there were also men with the prostate volume (PV) over 60 ml that were studied separately. Before and after six months Thermobalancing the International Prostate Symptom Score (IPSS) lessened ($p < 0.001$), quality of life (QoL) index improved, ultrasound PV reduced ($p < 0.001$) and uroflowmetry maximum flow rate (Q_{max}) increased ($p < 0.001$). The dynamics of the same measurements in the watchful waiting or active surveillance control group have shown negative outcomes. *Discussion and Conclusions:* The observed positive effect of therapeutic device for BPH has allowed us to recommend this side-effect-free therapy in watchful waiting or active surveillance approach. Therefore, Thermobalancing can be used as safe physiotherapeutic solution for men with enlarged prostate in order to reduce LUTS.



Simon Allen

ABOUT THE AUTHOR

Simon Allen, MD, PhD, is a highly experienced medical professional specialising in internal medicine. He has found a way of how people can get relief from a wide range of chronic diseases, including patients with prostate conditions, enlarged prostate and chronic prostatitis, spine ailments: upper/lower back pain and sciatica, metabolic disorders: after a heart attack and kidney stones disease by using Thermobalancing therapy enabled by therapeutic device, termed Dr Allen's Device. Fine Treatment ensures international availability of Dr Allen's Devices, services customers in over 100 countries worldwide, and engages in a constructive dialogue with medical professionals on the provision of the best healthcare to patients. The research that demonstrates positive outcomes in men with benign prostatic hyperplasia after Thermobalancing therapy would have immense impact on current BPH treatment options and a motivation for new investigations of the changes in prostate gland under use of therapeutic device.

PUBLIC INTEREST STATEMENT

Thermobalancing therapy and therapeutic device should have been used in men with moderate to low degree of lower urinary symptoms (LUTS) secondary to prostate enlargement before any long-term pharmacotherapy or surgical procedures are initiated. Many men over 50 years of age feel the need to urinate a lot, often at night, namely LUTS, and later it may lead to serious health problems. This happens because with ageing the prostate size increases, squeezing the urethra and leading to benign prostatic hyperplasia (BPH). It is supposed that almost every man will suffer from BPH. Current treatments for LUTS due to BPH include medication to relax the muscles near the gland and prostate surgery in order to improve the flow of urine. However, medical/surgical interventions have side effects. Therefore, positive outcomes from the study focused on Thermobalancing conservative prostate treatment enabled by therapeutic device show a new safe solution for LUTS/BPH.

Subjects: Chronic Diseases; General Medicine; Health and Social Care; Medicine; Nephrology; Physiotherapy; Prostatic Disease; Urology

Keywords: enlarged prostate; bph treatment; prostate enlargement; Thermobalancing therapy; lower urinary tract symptoms; bph cause; clinical trial; prostate natural treatment; bph

1. Background

Patients with mild symptoms or moderate-to-severe symptoms of benign prostatic hyperplasia (BPH) who are not bothered by their symptoms and are not experiencing complications of BPH should be managed with a strategy of watchful waiting (American Urological Association (AUA), 2015). According to The European Association of Urology (EAU) Guidelines on Conservative Treatment in 2010: conservative treatment of male LUTS should include self-management, however nobody is quite sure which key components of self-management are effective, but most experts believe the key components are: education about the patient's condition; reassurance that cancer is not a cause of the urinary symptoms; framework of periodic monitoring (Oelke, Bachmann, & Descazeaud, 2010). The latest EAU revealed that there now exists evidence that self-management as part of watchful waiting reduces both symptoms and progression. Men randomised to three self-management sessions in addition to standard care had better symptom improvement and quality of life (QoL) than men treated with standard care only for up to a year (Gravas, Bach, & Bachmann, 2015).

The importance of self-management and conservative approach in men with BPH increased after researches had found the link between BPH and metabolic syndrome. The eight studies enrolled 5,403 patients, of which 1,426 (26.4%) had metabolic syndrome (MetS) defined according to current classification, have shown that patients had significantly higher total prostate volume when compared with those without MetS. These studies verify the exacerbating role of MetS-induced metabolic derangements in the development of BPE (Gacci, Corona, & Vignozzi, 2015).

Investigating uncomplicated lower urinary tract symptoms (LUTS) in men who used a self-management programme in addition to standard care or standard care alone demonstrated that behavioural treatment reduced nightly nocturia by a mean of 0.97 episodes and was significantly more effective than drug therapy (Johnson et al., 2013). However, all attention in alternative approach for BPH was usually associated with the phytotherapeutic agents, as natural products, containing inherently vast structural diversity than synthetic compounds, have been the major resources for discovering new drugs (Aggarwal et al., 2014).

For the purpose of a targeted conservative treatment for men with BPH Allen suggested Thermobalancing therapy enabled by topically applied therapeutic device to the projection of prostate (Allen & Adjani, 2009). This device contains a natural thermoelement which accumulates body heat, becoming a source of the energy itself. A two-year study with this therapeutic device has shown decrease in urinary symptoms and prostate volume (PV). The uroflowmetry maximum flow rate (Q_{max}) increased and quality of life (QoL) improved (Aghajanyan & Allen, 2016; Allen & Aghajanyan, 2015). In this clinical review, we display the dynamics of the symptoms and parameters in men with BPH/LUTS after Thermobalancing therapy and debate the possible use of therapeutic device as the conservative treatment option in men with prostate enlargement.

2. Methods and results

2.1. Study design

The observational clinical controlled study for men with BPH from 2013 to 2015 was performed at the Department of Urology at 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. Men with BPH received treatment with therapeutic device and in the

control group men with BPH were in watchful waiting with no treatment. Dynamics of the symptoms and the indicators in each group were evaluated in comparison to their data at the beginning and end of the treatment.

2.2. 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 (maximum urinary flow rate- Q_{max} , mL/s was used for the measurement of the rate of urine flow parameters (Sanuro2UL, Santron Meditronic, Maharashtra, India). The standard ellipsoid formula length \times width \times height \times 0.52 was used to determine prostate volume.

2.3. Participants and interventions

From 226 men with BPH 124 patients with prostate volume (PV) < 60 ml were selected for the clinical trial. Eighty men were excluded, as their prostate volume was over 60 ml or they had severe comorbidities; 10 preferred operation; four were suspected prostate cancer; eight did not attend to the following examinations. Men in treatment group were given therapeutic device, termed Dr Allen's Device, see Figure 1.

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 > 60 ml, comorbidities, such as diabetes, heart failure, cancer, etc.

In this study we also included an individual data of men with PV > 60 ml who used Dr Allen's Device.

2.4. Statistical analysis

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

3. Results

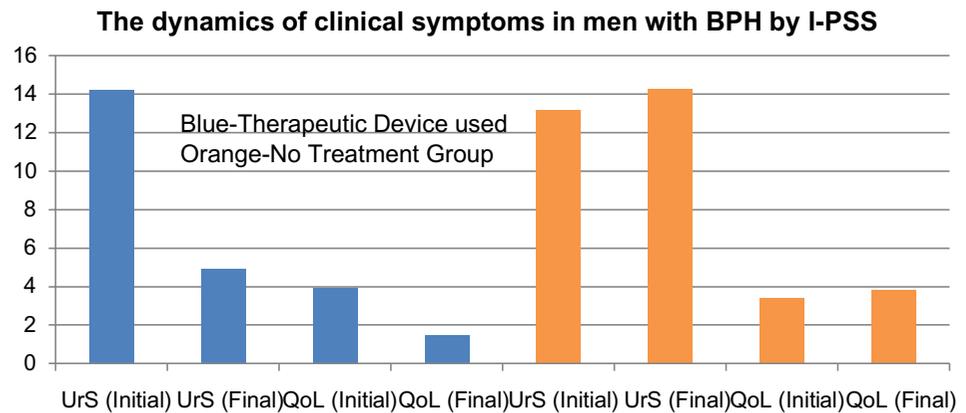
3.1. The clinical symptoms and parameters in treatment group, 124 men with BPH, PV < 60 ml, comparing compared with no treatment group

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

Figure 1. The therapeutic device alone (on the left) and the device tightly applied to the coccyx area in the projection of the prostate.



Figure 2. The changes of urinary symptoms by International Prostate Symptom Score (IPSS) and quality of life (QoL) in 124 patients with BPH on Thermobalancing therapy and in 124 men in the control group at the beginning and at the end of the six-month period.



with therapeutic device improved the QoL significantly, while in the control group the QoL worsened. Y-axis graph shows mean changes in scores according to IPSS (Figure 2).

3.2. PV volume and Q_{max} in 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} . Y-axis graph shows mean changes in PV and Q_{max} (Figure 3).

3.3. The clinical symptoms and parameters in men with BPH, PV > 60 ml

These cases show that the age of all men with BPH and PV > 60 ml, was over 70. Therapeutic device used as a long-term mono-therapy decreased PV and increased Q_{max} , consequently was observed improvement in IPSS and QoL. Despite the fact that the PV decreased significantly in all cases, the size of the prostate remained large. This means that these patients should use the device longer (Table 1).

3.4. Safety and costs

There were no side effects found during the clinical trial. Besides all of this, the important factor is the cost of therapeutic device compared to the cost of the standard treatment options.

4. Discussion and conclusions

This study's results have demonstrated that the conservative treatment with therapeutic device in the main treatment group with 124 men with BPH, PV < 60 ml decreased urinary symptoms score by IPSS, reduced PV, increased Q_{max} and improved QoL. The condition of men with BPH and PV > 60 ml

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 Thermobalancing therapy and in 124 men in the control group at the beginning and at the end of the six-month period.

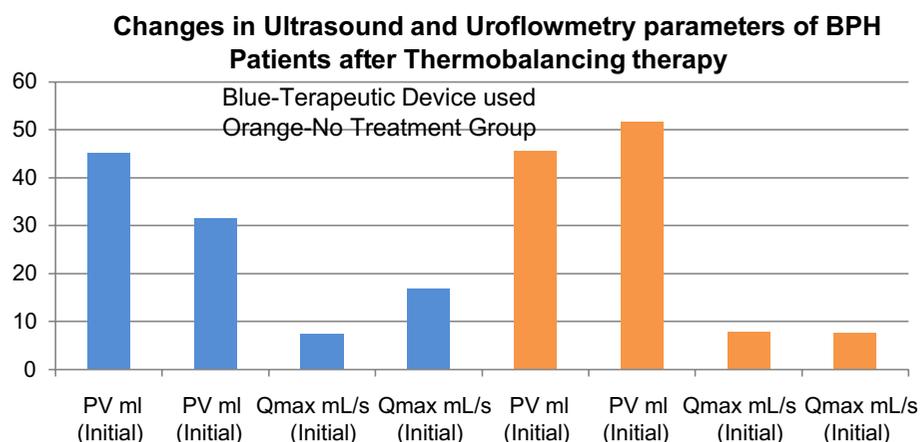


Table 1. The changes in prostate volume (PV) ml, uroflowmetry (maximum urinary flow rate (Q_{max}) mL/s and International Prostate Symptom Score (IPSS) in men with BPH and (PV > 60 ml) before and after Thermobalancing therapy

Patient 1, age 73	1 July 2014	3 November 2014
IPSS–Urinary symptoms	14	4
QoL index	4	1
Prostate volume ml	93	70
Q_{max} mL/s	11.2	14.0
Patient 2, age 79	22 July 2014	18 February 2015
IPSS	6	2
QoL index	3	1
Prostate volume ml	154	90
Q_{max} mL/s	13.0	14.4
Patient 3, age 75	3 February 2014	03 November 2014
IPSS–Urinary symptoms	12	3
QoL score	4	0
Prostate volume ml	84	52
Q_{max} mL/s	9.7	15.5
Patient 4, age 73	18 March 2014	10 March 2015
IPSS–Urinary symptoms	16.5	6
QoL score	3	1
Prostate volume ml	74	51
Q_{max} mL/s	7.2	10.3

also improved significantly. At the same time in the no treatment group the clinical symptoms and parameters worsened. These encouraging outcomes indicate that Thermobalancing therapy can be effective for men with BPH, particularly for the treatment of moderate-to-severe symptoms of BPH.

The observational clinical controlled study was used in this trial for men with BPH. The study was not randomised that may limit belief in the results. Of course having “placebo” or “sham” group as controls could provide more confidence in the outcomes. However, the health-related quality of life of BPH patients is considered as poor, and their psychological well-being is severely affected. For instance, postvoid residual urine, lower urinary tract symptoms, anxiety and depression are identified to be significant predictive factors of the health-related quality of life of patients with enlarged prostate (Pinto, He, Chan, & Wang, 2016). Thus, we suggested that men with enlarged prostate may not wear during six-months something on the body that is helpless. In our opinion as patients with BPH felt healthier within weeks they used the device as was required.

BPH is historically believed to be a consequence of the ageing process and the treatment of the destructive symptoms of enlarged prostate in men should be done with the medical or surgical intervention. At the same time, medications used for the treatment of BPH do not provide sufficient performance. For example, a recent study indicated that more than half (52.8%) of men with BPH were dissatisfied with the results of medical treatment conducted according to current international guidelines for BPH (Fourcade et al., 2012).

Furthermore, commonly used BPH medications have serious side effects, especially in the long-term use (Gacci et al., 2014). Surgical treatments of prostate were found to be safe, however, advanced age and non-Caucasian race were independent predictors of adverse outcomes after BPH surgery. In patients with these attributes, conservative treatment might be a reasonable alternative (Naeem, Giorgio, & Akshay, 2014). Additionally, the results of a survey of sexually active men after

three different laser surgeries from 2005 to 2010, concluded that these surgical techniques can have a negative impact on sexual function, and patients with normal preoperative sexuality are more at risk (Elshal, Elmansy, Elkoushy, & Elhilali, 2012).

Although many of medical/surgical interventions were advised to men with LUTS, it was generally done in a non-standardised and unsystematic way. Therefore, a research in this area described a self-management programme for men with uncomplicated LUTS using formal methods and assessed its effectiveness in a randomised controlled trial. Self-management significantly reduced the frequency of escalation through the treatment cascade and reduced urinary symptoms (as effective as medication), suggesting that self-management could be considered as first-line treatment for men with LUTS (Brown & Emberton, 2009).

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 ageing process which can be prevented (Corona et al., 2014). Therefore, the treatment of lower urinary tract symptoms in older men should be holistic, and may include conservative measures, lifestyle interventions and behavioural modifications as well as medication and surgery. Only treatments with a strong evidence base for their clinical effectiveness should be used (Abrams, Chapple, Houry, Roehrborn, & de la Rosette, 2009).

Thermobalancing therapy can be used as a preventative measure of prostate enlargement progression, particularly for moderate to low degree of LUTS secondary to BPH. This therapy is different from commonly addressed heating treatments, as the source of energy doesn't exceed the normal body temperature range. Treatments with imposed heat can be damaging, because the high temperatures above 104 Fahrenheit (or 40°C) can destroy the living organism. On the other side, low temperatures decrease cellular metabolism.

Therapeutic device applies the thermoelement tightly to the skin overcoming the skin barrier and spreading energy inside towards the prostate. There is no other treatment method that is able to overcome the skin barrier delicately and precisely. Thermobalancing therapy is the only external non-invasive treatment that targets the pathological point of origin continuously for a prolonged period of time, i.e. for days, months or even years.

We believe that the use of therapeutic device by keeping the body temperature in the projection of the prostate gland acts on micro-focus of hypothermia and ischaemia, removing the vicious cycle of spontaneous growth of capillaries in response to triggers, thereby relieving the BPH symptoms.

5. Conclusions

This review has shown that effective and safe of Thermobalancing therapy can be a useful solution for the conservative treatment of moderate to low degree of LUTS secondary to prostate enlargement. Therapeutic device should be tried before any long-term pharmacotherapy is initiated.

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Competing Interests

S Allen is an author of US Patent, US 9,408,744 B2, on Therapeutic Device and Method i.e. Thermobalancing therapy and therapeutic device. United States Patent and Trademark Office, USPTO have issued the patent, in August 2016.

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Corrigendum

This article was originally published with errors. This version has been corrected. Please see Corrigendum (<http://dx.doi.org/10.1080/2331205X.2016.1248332>).

Cover image

Source: Authors.

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