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Innovative Thermobalancing therapy can help millions of men with enlarged prostate gland to improve the quality of life and well-being throughout the world

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ABSTRACT

Millions of men across the world suffer from enlarged prostate or benign prostatic hyperplasia (BPH) that causes lower urinary tract symptoms (LUTS). Medications and surgical procedures for BPH have serious side effects, reducing quality of life and wellbeing. 10 years empirical evidence and outcomes of a clinical study have shown effectiveness of innovative Thermobalancing therapy (TT) with Dr Allen's therapeutic device (DATD) to treat the cause of BPH. Dynamics of urinary symptoms by International Prostate Symptom Score, quality of life (QoL), ultrasound prostate volume (PV mL) and uroflowmetry (maximum flow rate, Q_{\max} mL/s) were evaluated at the beginning and end of the study in 124 patients who received TT for 6 months, comparing with no-treatment group. TT has diminished PV from 45 mL to 31 mL ($P<0.001$) and the urinary symptoms from 14.2 to 4.9 ($P<0.001$), increased Q_{\max} 8.1 to 17.7 mL/s ($P<0.001$) and improved QoL from 3.9 to 1.3 ($P<0.001$). Thus, the obtained data explores the substantial positive changes in PV and urine flow rate and, consequently, the significant improvement of urinary symptoms and QoL after use of TT with DATD as mono-therapy. Given the lack of side effects after use of DATD, which should be expected after BPH drugs and operations, it should be stated that TT should be used worldwide as first line treatment for men with LUTS due to BPH to improve men's health and wellbeing.

Keywords: aging men, longevity, lower urinary tract symptoms, thermobalancing therapy, bph treatment, enlarged prostate

1. INTRODUCTION

In the USA lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) prevalence rates ranged from 50% to 75% among men 50 years of age and older to 80% among men 70 years of age and older [1]. LUTS/BPH occurs in almost all men as they age, it affects $\approx 3\%$ of men aged 45–49 years, rising slowly up, reducing quality of life of the patient and their partner [2]. As the population ages, the urinary symptoms prevalence increases and increased resources will be needed to address this growing problem [3].

That is why impeding of LUTS/BPH progression by changing lifestyle or adding supplements and drugs has priority for researches. Epidemiological data show a possible relationship between healthy eating habits and regular physical activity level with a lower risk for LUTS, but nor healthy food neither exercises ever have protected men from BPH [4].

It was found that men getting older may start to have lower sex drive and sense of vitality, erectile dysfunction, decreased energy, reduced muscle mass and bone density, which are usually symptoms of low testosterone that require testosterone replacement therapy (TRT). TRT results in improvements in residual voiding volume and obesity parameters, however prostate volume may increase [5, 6].

LUTS due to BPH usually are treated by a medical treatment or surgery. However, BPH drugs have serious side effects, especially in the long-term, and furthermore do not provide sufficient performance [7, 8]. Surgical procedures were found to be safe for BPH, however adverse outcomes after surgeries indicate the need for conducting medical treatment, which may reduce use of surgical procedures [9, 10]. And a survey of sexually active men after different laser surgeries from 2005 to 2010 has observed a negative impact of surgeries on sexual function, concluding that patients with active preoperative sexuality are more at risk [11].

Some suggestions were made that NSAIDs have the potential to improve LUTS due to BPH, though at the same underlining that their long-term effectiveness and safety, and ability to prevent BPH complications are not known [12, 13]. However, NSAIDs should be prescribed very carefully especially in older people for their renal, cardiovascular and gastrointestinal side effects [14, 15].

For the targeted treatment of LUTS due to BPH, which has been recognized follows the chain of vascular changes inside the prostate tissue, Thermobalancing therapy (TT) enabled by Dr Allen's therapeutic device (DATD) has been proposed and investigated with the positive outcomes [16]. The *United States Patent and Trademark Office* (USPTO) has granted a patent US 9,408,744 B2 to "Therapeutic device and method", i.e. TT and DATD that is an acknowledgement of its uniqueness [17].

Thermobalancing therapy - TT

TT enabled by DATD treats the affected prostate by keeping the source of energy in the projection of the prostate gland during the prolonged period, for 6 months and longer. This unique therapy is contrasting commonly addressed heating treatments, as the source of energy it provides does not exceed the normal body temperature range. Treatments with higher heat can be damaging, because the extreme temperatures above 104 Fahrenheit (or 40°C) can destroy the living cells in the organism. On the other side, the low temperatures decrease cellular metabolism. So, aforementioned approach allows to use DATD without interruption harmlessly.

Dr Allen's therapeutic device for prostate treatment - DATD

DATD facilitates treatment of the affected region by the topical application of a special mixture of waxes that can collect the naturally emitted body heat, thus turning into a source of energy itself. This special wax mixture is called the thermoelement. DATD comprise also from an elastic belt that keeps the thermoelement in the projection of the prostate for a prolonged duration. Thus, thermoelement acts as the natural heat source for the prostate. The neoprene belt keeps the thermoelement tightly applied to the coccyx area and prevents heat dissipation (**Figure 1**).



Figure 1. DATD tightly attaches thermoelement to the coccyx area for a prolonged period of time.

DATD applies the thermoelement tightly to the skin overcoming the skin barrier and spreading energy inside toward the prostate. There is no other treatment method that is able to overcome the skin barrier delicately and precisely. TT with DATD is the only external non-invasive treatment that targets chronic prostate disease continuously for a prolonged period of time, i.e. for days, months or even years.

What is the essence of TT?

Thermobalancing therapy is based on a new understanding of the Origin of Diseases, which states: all chronic internal diseases have the same root, namely, a pathological activity of capillaries. Two functions of small blood vessels, as termed by physiologists, namely constriction and spontaneous expansion of capillaries, are responsible for the development of the pathological activity of capillaries. The initial triggers for constriction of capillaries can differ: cold, infection, stress, stagnation of its own secretion, metabolism products, etc.

Constriction of capillaries in the prostate tissue creates the micro-focus of hypothermia. In order to eliminate this focus of micro-hypothermia, blood flow increases through spontaneous expansion of the capillary network locally. The nervous system does not regulate spontaneous expansion of capillaries, so the expansion can continue and continue [18].

Formation of new capillaries is, essentially, the growth of excess tissue. Thus, chain reaction sets up between local micro-hypothermia and the spontaneous expansion of capillaries making the enlargement process and disease chronic. DATD by spreading energy towards local micro-hypothermia in the prostate tissue terminates it, stopping enlargement gradually [19].

2. METHODS

TT with DATD was used in the clinical controlled study in the Yerevan State Medical University and Mikaelyan Institute of Surgery where 124 men with BPH received TT within 6-month period and their clinical parameters before and after therapy. This information was compared with the control group, i.e. data received from 124 men with BPH who were in watchful waiting during the same period. Ethics committee of the Yerevan State Medical University approved the clinical study on TT.

Dr Allen's Device was registered with the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK in 2010, as a class 1 medical device. A class 1 medical device without a measuring function and supplied in non-sterile condition does not require the involvement of a notified body. So, it is permitted to be used by everyone at home.

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 International Prostate Symptom Scale (I-PSS) assessed the dynamics of the patients' conditions: urinary symptoms and quality of life (QoL). Prostate volume (PV mL) was measured by ultrasonography and maximum urinary flow rate (Q_{max}, mL/s) by uroflowmetry. The standard ellipsoid formula length×width×height×0.52 was used to determine prostate volume. 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.

Statistical analyses

The independent-samples t-test and paired-samples t-test are suitable only for interval and ratio data, so the Wilcoxon signed-rank test was employed. $P < 0.05$ was considered significant. Statistical analyses were carried out using SPSS v22 (IBM, Armonk, NY, USA).

3. RESULTS

The results of changes of urinary symptoms and QoL in men with BPH after Thermobalancing therapy and in the control group are presented in **Figure 2**.

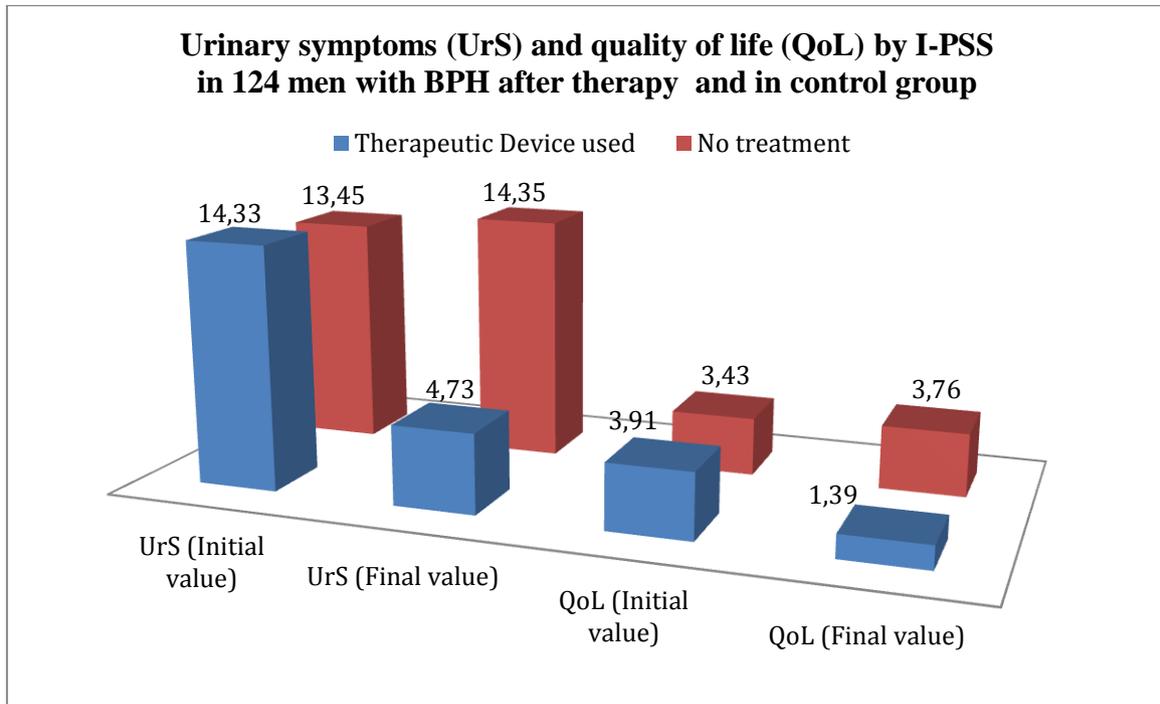


Figure 2. Urinary symptoms and QoL measured by IPSS in 124 men with BPH after Thermobalancing therapy and in the control group.

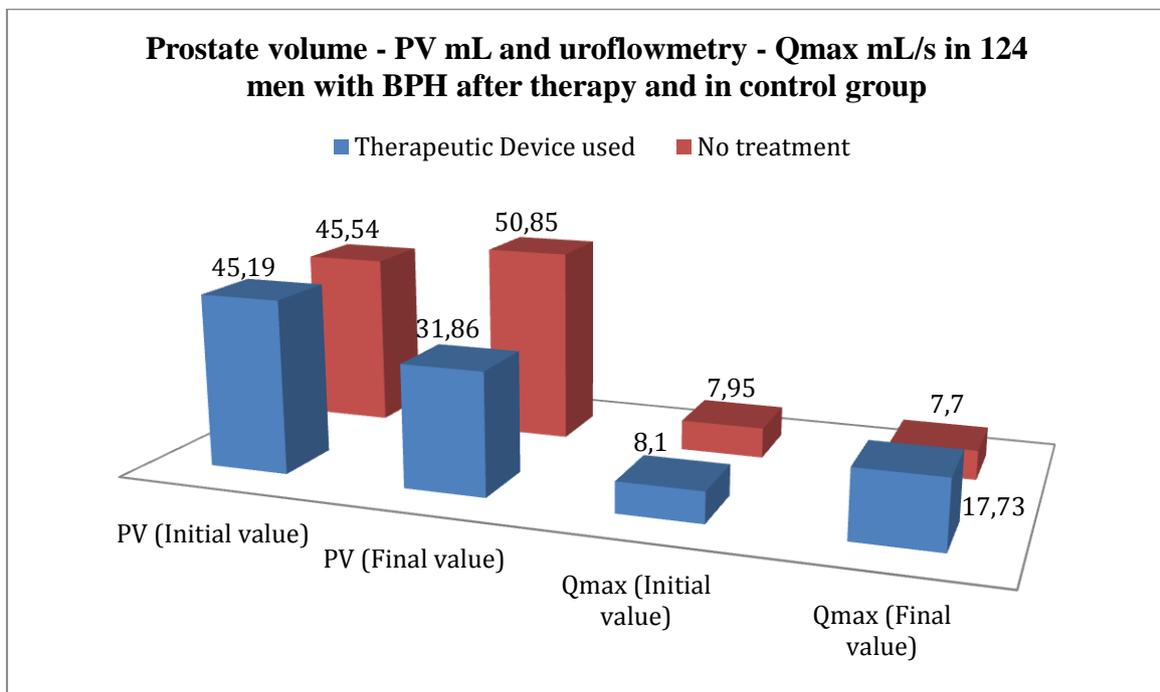


Figure 3. Prostate volume measured by ultrasound and Qmax - uroflowmetry level in 124 men with BPH after Thermobalancing therapy and in the control group.

In the treatment group the level of urinary symptoms by IPSS decreased from 14.33 ± 3.39 to 4.73 ± 2.75 and IPSS–QoL score decreased from 3.91 ± 0.755 to 1.39 ± 1.110 , both ($P < 0.001$). In the absence of treatment urinary symptoms and QoL scores worsened. Hence, DATD decreases urinary symptoms and improves QoL.

The results of changes of PV and Q_{\max} in men with BPH after Thermobalancing therapy and in the control group are presented in **Figure 3**.

In the treatment group prostate volume decreased from 45.19 mL to 31.86 mL and Q_{\max} increased from 8.10 ± 3.041 to 17.73 ± 4.392 mL/s, both ($P < 0.001$). In the control group changes were insignificant or even worse. These results suggest that DATD reduces PV and increases Q_{\max} significantly.

4. DISCUSSION

The results of clinical trial demonstrate that long-term use of TT with DATD could reduce BPH symptoms and the prostate size, while Q_{\max} increases significantly. Decrease urinary symptoms improves the quality of life. This indicates that the TT is effective for LUTS due to BHP. Positive changes in the ultrasound and uroflowmetry parameters with clinical improvement in men with BPH, who used TT for 6 months, could be explained by positive changes in the prostate tissue due continuous application of the source of energy to the projection of prostate. DATD by keeping the substantial temperature acts on micro-focus of hypothermia in the prostate gland tissue removing spontaneous growth of capillaries, which is in the core BPH and LUTS [20].

Prevalence

Urinary symptoms and decrease QoL are common complaints in older men. Berry with colleges in 1984 have established that histologic BPH occurs in 8% of men aged 31 to 40 years, 42% of men aged 51 to 60 years, 71% of men aged 61 to 70 years, and 88% of men aged 81 years and older [21]. Thus, it is estimated that 90% of men between 45 and 80 years of age have LUTS [22]. Increase in the number of elderly people raises the burden of urinary problems and LUTS has worsened with age [23]. It should be expected, as larger prostate volumes are positively associated with increased age [24].

Prostate volume

Some urologists suggest that prostate volume, which is visibly the main parameter of prostate enlargement, might be unimportant in determining the need for treatment, as the size of prostate does not matter for developing symptoms [25]. However, men suffering mild to no LUTS but with enlarged prostate are at higher risk of incident and complications from LUTS due to BPH, so the size does matter [26]. That is why today men are treated with medications straightaway when BPH is diagnosed, even though patients with symptoms which are not bothered should be managed with a strategy of watchful waiting [27].

Medication and surgeries

However, continuous use of BPH medications may develop irreversible side effects. Thus, finasteride or dutasteride often lead to loss or reduced libido, erectile dysfunction,

orgasmic and ejaculatory dysfunction, development of high-grade PCa tumors, potential negative cardiovascular events, and depression [28, 29, 30]. The health issues can be expected from surgical procedures even minimally invasive or/and laser surgeries [31]. That is why EAU Guidelines on the treatment of non-neurogenic male LUTS advises: prostate surgery should be used in men with LUTS who are resistance to drugs due to benign prostatic obstruction [32]. In normal practice, urologists have recommendations for the use of various BPH medications: alpha-blockers, 5-alpha-reductase inhibitors and combination therapy, even if men have a risk of serious side effects [33].

Metabolic syndrome

Russo and colleges stated that modifying metabolic factors in age after 40th could prevent the progression of LUTS due to BHP, so the use of drugs and surgeries should not be seen as the main treatment for this chronic condition. In their point of view, LUTS/BPH may be considered as a complex disorder, so called metabolic syndrome (MetS). Epidemiological evidence exposed the link between MetS, BPH and LUTS. Thus, MetS can be discovered in the earlier stage and treated accordingly, preventing prostate enlargement. Therefore, countering metabolic changes should be a new target in LUTS treatment [34].

Vascular factor in BPH development

Increasing evidence of association between BPH/LUTS and cardiovascular disease in elderly patients suggests that age might activate systemic vascular risk factors, resulting in disturbed blood flow that develops chronic ischemia in the pelvic organs inducing BPH [35]. Transrectal color Doppler ultrasonography has shown a significant decrease in bladder and prostatic blood flow in comparison of elderly men with younger controls [36]. A decrease in pelvic blood flow have been reported in the spontaneously-hypertensive-rat (SHR) indicating that development of prostatic hyperplasia may be associated with prostatic hypoxia, which is a possible mechanism of development of BPH [37].

Observation

It should be noted that TT has shown effectiveness in clinical trial in 45 men with chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) [38]. It was discussed that similar changes at the capillary level increase pressure into the inflamed prostate tissue that results with pain, which is the main symptom of CP/CPPS. DATD by spreading energy terminates hypothermia and spontaneous expansion of capillaries in the tissue, relieving pain and other symptoms of CP/CPPS gradually (39). Thus, the long-term application of the source of emitted body heat with DATD removes prostatic hypoxia and micro-focus of hypothermia at the capillary level that improves blood circulation in the prostate tissue influencing the underlying cause of BPH. Furthermore, in both trials with prostatic non-malignant diseases significant improvement of QOL was observed, moreover, there were not recognized any adverse side effects. At the same time a recent study has explored that a surgery that doesn't involve the heart may cause damage to the heart in people with known or at high risk of developing heart disease and was associated with an increased risk of death. 1 in 7 patients 65 years of age or older undergoing non-heart surgery experience heart cell damage during or after surgery [40].

5. CONCLUSIONS

- The prevalence of LUTS due to BPH among men aged 50–80 goes up to 90%.
- Mechanism of enlarged prostate can be explained via vascular changes at the capillary level with the continuous growth of the prostate tissue.
- TT with DATD for the first time removes the cause of BPH, reducing prostate volume and improving QoL of men.
- BPH drugs have serious side effects and do not protect patients from the surgical procedures relief follows in the future.
- BPH surgeries may harm health of aging men.
- TT and DATD has no adverse side effects, therefore it should be used as the first line treatment for BPH promoting men's health and wellbeing for years.

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There was no additional funding for this clinical study.

Conflicts of Interest

The author declares that there are no competing interests in writing this article. The US Patent and Trademark Office (USPTO) granted patent US 9,408,744 B2 in 2016. Dr Simon Allen has not received reimbursements, fees, funding, or salary relating to the content of this manuscript.

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