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THEORETICAL ARTICLE

Open Access



Innovative Thermobalancing therapy and Dr Allen's Device for the first time employ body energy to treat chronic prostatic diseases effectively

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Abstract

Benign prostatic hyperplasia (BPH) and chronic prostatitis / chronic pelvic pain syndrome (CP/CPPS) are common chronic diseases. None of the available treatments are effective in the management of these diseases. The purpose of this study was to assess the efficacy of Thermobalancing therapy (TT) with therapeutic Dr Allen's Device (DATD) for the treatment of BPH and CP/CPPS. Retrospective analysis of 2 clinical studies employing 6-month TT for the treatment of BPH ($n = 124$) and CP/CPPS ($n = 45$) was conducted. The efficacy of the TT with DATD was assessed using validated and widely accepted parameters. Results were compared with corresponding control groups comprising of subjects who did not receive any treatment. In BPH treatment group, urinary symptoms decreased (14.3 to 4.7) and QoL improved (3.9 to 1.39). In CP/CPPS treatment group, pain score decreased (10.3 to 3.5) and QoL improved (8.1 to 2.9). The results in the 2 treatment groups were statistically significantly better than the results obtained for the corresponding control groups ($P < 0.001$). Innovative TT with DATD provides an effective treatment that uniquely employs body energy for the management of BPH and CP/CPPS.

Keywords: Chronic pelvic pain, Benign prostatic hyperplasia (BPH), Chronic prostatitis, Thermobalancing therapy and Dr Allen's Device, Body energy

Introduction

Benign prostatic hyperplasia (BPH) is one of the most common chronic disorders in elderly men, the incidence of which increases with age. Clinically, it is a non-malignant progressive proliferation of prostatic epithelial tissue and smooth muscles resulting in an increased prostate volume beyond the normal value of 20–30 mL. According to an estimate, the age-related prevalence of BPH in the United States (US) ranged from 50 to 75% among men > 50 years of age and to 80% among men > 70 years of age, which corresponds to approximately 15 million men [1]. The age-related prevalence of BPH has been reported to be 8% in men aged about 40 years and it reaches 90% by 90 years of age [2]. Similar trends have been reported from different parts of the world

[3]. Increases in prostate size exert pressure on the nearby organs and block the passage of urine from the urethra.

Thus, BPH is generally associated with a constellation of urinary symptoms that are divided into 2 major classes: (1) bladder storage symptoms such as increased urgency, frequent urination, urgency incontinence, and urine leakage at night; and (2) emptying and voiding difficulties such as weak urinary stream, incomplete emptying, and straining while urination. These symptoms are referred to as lower urinary tract symptoms (LUTS) in literature [4]. These symptoms cause a significant personal and societal burden because of both direct medical costs and reduced functioning due to decreased quality of life (QoL) of patients and their partner [5]. As the population ages, the prevalence of LUTS increases, and additional resources will be needed to solve this growing problem [6]. Various comorbidities are also usually found to be associated with BPH, such as cardiovascular events, diabetes mellitus, digestive disorders, and inflammation accompanied by pain [7–9].

The LUTS due to BPH are usually treated by a medical or surgical intervention. The use of nonsteroidal anti-inflammatory drugs (NSAIDs) for the management of LUTS symptoms associated with BPH is still debatable [10, 11]. The use of medication for the management of BPH is inversely related to the frequency of surgical intervention, which is believed to be due to the post-surgical complications associated with the surgical interventions available for BPH management [12]. Surgical procedures for BPH, such as transurethral resection of the prostate, laser vaporization of the prostate, and laser enucleation of the prostate, are considered safe in cases of low prostate volume; however, many adverse outcomes may occur after these surgeries that supports the use of conservative management, especially in advanced age individuals [13, 14].

Prostatitis syndrome is another poorly understood condition that produces prostatitis-like symptoms (for example, pelvic pain). The prostatitis-like symptoms are highly prevalent affecting about 10% of men during their lifetime [15]. The US National Institutes of Health (NIH) has classified prostatitis syndrome into 4 major categories: I—acute bacterial prostatitis, II—chronic bacterial prostatitis, III—chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) (this category includes two subcategories, IIIa—inflammatory CPPS and IIIb—noninflammatory CPPS), and IV—asymptomatic inflammatory prostatitis [16]. The CP/CPPS is responsible for prostatitis-like symptoms in most patients (> 90%). Researchers have proposed that the chronic inflammatory processes in the prostate may play a role in the development of BPH [17]. Many researchers think that this syndrome may have multifactorial causes such as infection, inflammation, central nervous system changes, alteration in the microbiome of the urinary system, stress, and central sensitisation.

Thus, the typical treatment for it is a multimodal approach based on phenotyping, including medical intervention (alpha-blockers, antibiotics, anti-inflammatory medication, hormonal therapy, phytotherapy, and antispasmodics) and nonmedical strategies, such as psychotherapy and attempts to improve relaxation of the pelvic floor [18, 19]. The management of CP/CPPS is frustrating for both the patient and physician since standard treatments often fail [20] and as there has been no successful treatment available for this health problem [21]. Therefore, there has been a need in a treatment modality is needed for chronic prostatic diseases, like CP/CPPS and BPH, which is free from serious side-effects and easy to use at home by the elderly population.

Thermobalancing therapy (TT) is a term used for elucidating the mechanism of action of the device known as therapeutic Dr Allen's device (DATD) [22, 23]. The device has been invented and used for over 10 years in people with various chronic internal diseases, including BPH and CP/CPPS [24]. The device was registered with the Medicines and Healthcare Products Regulatory Agency in the UK in 2010, as a class 1 medical device (medical device without a measuring function and supplied in a non-sterile condition and does not require the involvement of a notified body).

The DATD has been patented in the USA as a "Therapeutic device and method." The patent is an acknowledgment that it is indeed a completely new treatment option for chronic internal diseases [25]. The TT enabled by DATD facilitates the treatment of an affected area by the topical application of a special thermoelement, consisting of a mixture of waxes that accumulates the naturally emitted body heat and projects the accumulated heat to the affected body part. The device comprises an elastic belt with a pocket that houses the thermoelement and maintains it in the projection of the affected body part. Thus, TT with DATD is the first ever non-invasive treatment that employs body energy for the treatment of chronic diseases. It should be used for a prolonged period of time, ranging from days to months [26, 27].

This study aims to assess the effectiveness of this innovative therapy uniquely employing body energy for the management of chronic prostatic conditions, such as BPH and CP/CPPS.

Methods

This is a retrospective analysis of data obtained from 2 clinical investigations that were registered at the World Health Organization via the German Clinical Trials Register: DRKS00009271 — Effect of the Physiotherapeutic Device compared to no treatment on prostate volume, urinary symptoms, and quality of life in men with Benign Prostatic Hyperplasia (BPH), and DRKS00009352 — Effect of the physiotherapeutic device and thermobalancing therapy compared with no therapy on pain, urinary symptoms, quality of life and prostate volume in men with chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS).

The ethics committee of the Yerevan State Medical University approved these 2 studies. The 2 clinical investigations included 124 men with BPH and 45 men with CP/CPPS all with age above 50 years and who were naive for the intended treatment (TT). These study participants constituted the treatment group and received TT for a period of 6 months. The TT was administered with the help of DATD applied to project a single thermoelement over the prostate gland (as shown in Fig. 1).

The results of the treatment groups were compared with those of the control groups comprising the same number of age-matched participants (124 men with BPH and 45 men with CP/CPPS) who were in the control groups of participants who were either on watchful waiting or did not receive any treatment.

Various baseline evaluations were carried out, which included complete physical examination, medical history, digital rectal examination, serum biochemistry, prostate-specific antigen measurements, electrolytes, urine examination, and renal function tests. The efficacy of TT was evaluated by using the following parameters that were measured



Fig. 1 Dr Allen's Device for prostate treatment comprises an elastic belt and one thermoelement

before starting the treatment and after completing the 6-month treatment (in the treatment groups) and no treatment (in the control groups):

1. The International Prostate Symptom Scale (I-PSS) is a validated and widely accepted tool that is used to assess the dynamics of urinary symptoms and quality of life (QoL) in BPH patients. The I-PSS consists of an 8-item questionnaire that measures urinary symptoms (seven questions evaluating incomplete bladder emptying, frequency, intermittency, urgency, weak stream, straining, and nocturia) on a scale of 0–35 with a higher score indicating higher severity of the urinary symptoms. The I-PSS consists of another component (1 question) that measures QoL on a scale of 0–6 with a lower score indicating a better quality of life.
2. The National Institutes of Health chronic prostatitis symptom index (NIH-CPSI) is a validated and widely accepted tool that is used to assess the dynamics of pain and QoL in CP/CPPS patients. The NIH-CPSI assesses pain using 4 questions (evaluating pain location, frequency, and severity) on a scale of 0–21 with a higher score indicating more severe pain. The NIH-CPSI consists of another component that helps in assessing QoL using 3 questions on a scale of 0–12 with a lower score indicating a better quality of life.
3. Prostate volume (PV; in mL) was measured using ultrasonography. The standard ellipsoid formula $\text{length} \times \text{width} \times \text{height} \times 0.52$ was used to determine the prostate volume.

The results obtained for the treatment group participants who received TT were compared with those of control group participants who did not receive any treatment. The Wilcoxon signed-rank test was employed for the comparison of results between the treatment group and the control group. $P < 0.05$ was considered significant. Statistical analyses were carried out using SPSS version 22 software (IBM, Armonk, NY, USA).

Results

Impact of TT with DATD on urinary symptoms and QoL measured by I-PSS score

In the treatment group comprising 124 subjects with BPH who received TT using DATD, the urinary symptoms (UrS) decreased from 14.2 to 4.95 as measured by I-PSS

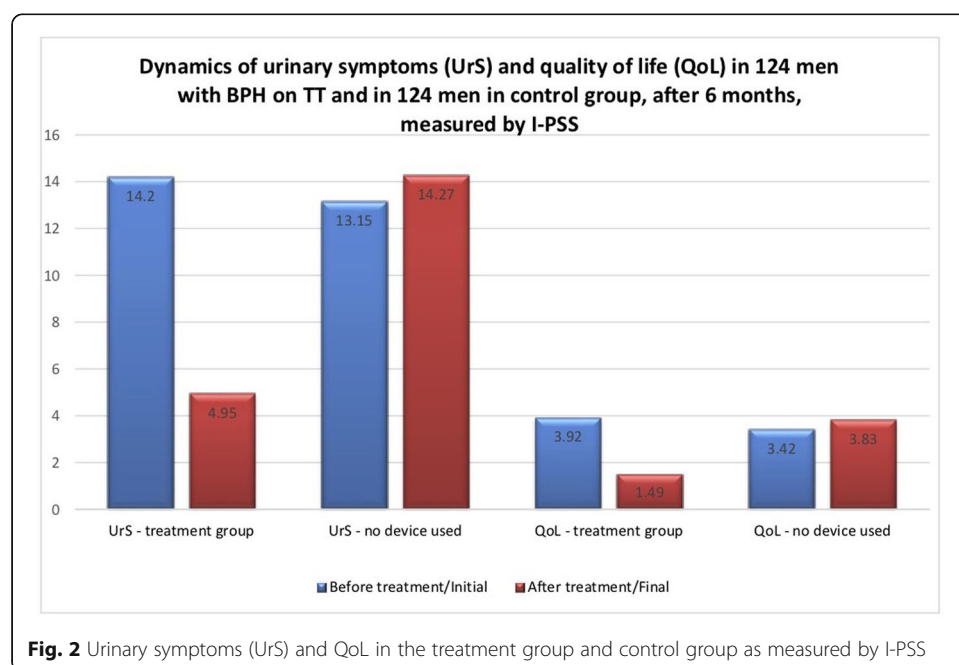
score, while an increase in the urinary symptoms from 13.15 to 14.27 as measured using I-PSS was observed in the control group also comprising 124 subjects with BPH who did not receive any treatment. Similar results were obtained for the IPSS–QoL score that decreased from 3.9 to 1.49 in the treatment group but increased from 3.42 to 3.83 in the control group. The comparison of results between the 2 groups indicated that there was a statistically significant difference ($P < 0.001$) in the results obtained for the 2 groups (Fig. 2). Thus, the results indicate that DATD significantly decreases urinary symptoms and improves QoL in patients with BPH, while watchful waiting may worsen the urinary symptoms and QoL in this patient population.

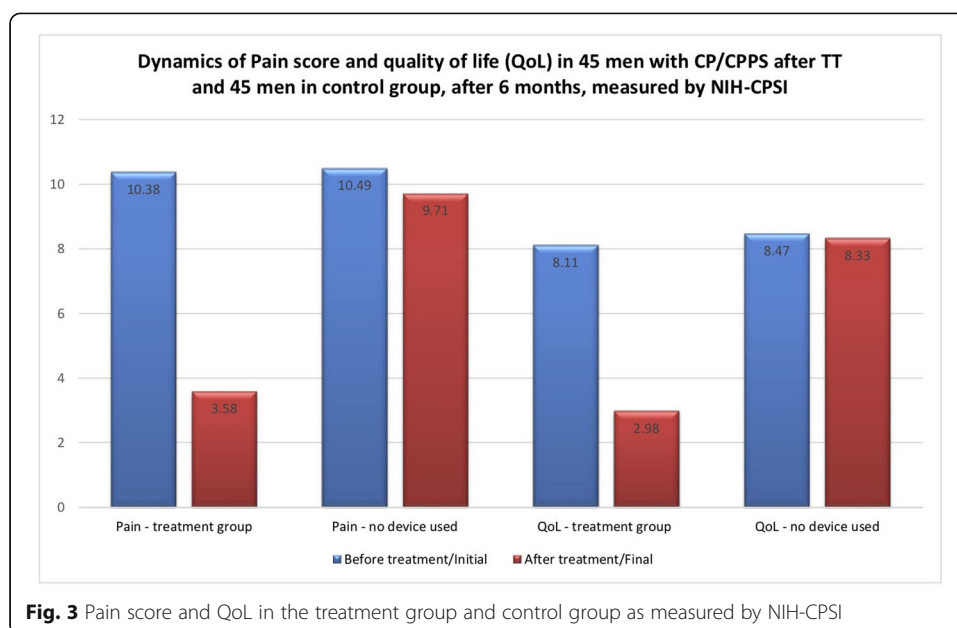
Impact of TT with DATD on pain and QoL measured by NIH-CPSI

In another treatment group comprising 45 subjects with CP/CPPS who received TT using DATD, the pain score decreased from 10.38 to 3.58 as measured by NIH-CPSI questionnaire, while a marginal decrease in the pain score from 10.49 to 9.71 as measured using NIH-CPSI was observed in the control group also comprising 45 subjects with CP/CPPS who did not receive any treatment. Similar results were obtained for the QoL score that decreased from 8.11 to 2.98 in the treatment group but only marginally decreased from 8.47 to 8.33 in the control group. The comparison of results between the 2 groups indicated that there was a statistically significant difference ($P < 0.001$) in the results obtained for the 2 groups (Fig. 3). Thus, the results indicate that DATD significantly decreases pain and improves QoL in patients with CP/CPPS, while no treatment may not be effective in this patient population.

Impact of TT with DATD on prostate volume (PV)

An increase in the PV from 45.5 to 50.85 mL was noted in the control group comprising 124 subjects with BPH who did not receive any treatment. However, there





was a marked decrease in the PV from 45.1 to 31.8 mL in the treatment groups comprising 124 subjects with BPH. The PV change in the treatment group was statistically significantly different when compared with that of the control group ($P < 0.001$). Thus, the results indicate that DATD significantly decreases prostate volume (PV) in patients with BPH, while watchful waiting may not be effective in this patient population. Similarly, in the treatment group comprising 45 men with CP/CPPS who received TT, PV reduced from 31.7 to 27.0 mL; however, in the control group comprising 45 men with CP/CPPS who did not receive any treatment, PV increased from 30.7 to 31.5. The comparison of results among the two CP/CPPS groups indicated a statistically significant difference between the results obtained for the two groups ($P < 0.001$). Thus, the results indicate that DATD significantly decreases prostate volume (PV) in patients with CP/CPPS, while no treatment may not be effective in this patient population.

Overall, the results indicate that the treatment with DATD reduces prostate volume and LUTS in men with BPH and decreases pain and prostate volume in men with CP/CPPS. Also, QoL improved significantly in both treatment groups, while there were no positive changes in the control groups.

Discussion

Historically, BPH was considered an outcome of the aging process and treatment modalities were devised merely to reduce the symptoms of the diseases with the help of different medicines or surgical interventions. However, developments in the last decade have indicated that vasculature plays an important role in the pathophysiology and etiology of this chronic disease [28]. Physiologists have found that constriction and spontaneous expansion of capillaries occur [29, 30]. These processes are responsible for the build-up of pressure inside the prostate that results in abnormal growth of the prostate tissue. The constriction of capillaries in response to different triggers such as infection, cold, excess of certain elements, stress, and others creates focal hypothermia in the

prostate tissue. To improve blood circulation in the affected area, spontaneous expansion of a capillary net occurs. The expansion of the capillaries, known as angiogenesis, slowly forms additional tissue, which creates pressure in this area and the prostate gland continues to grow in size [31]. These findings support the fact that etiology and pathophysiology of BPH are associated with prostate hypoxia, pelvic ischemia, increased pressure inside the prostate, and vascular dysfunction [32–35].

Similarly, the etiology and pathophysiology of CP/CPPS can be viewed as a chain of events in which constriction of capillaries in the prostate tissue, due to different initial triggers (such as cold, infection, and stress) leads to spontaneous capillary expansion. This leads to increased pressure in the prostate gland that sets up a secondary trigger, namely the focal hypothermia [36]. Chronic ischemia and vascular dysfunction in the prostate tissue has already been indicated to be involved in the pathophysiology of BPH and CP/CPPS [37, 38]. Also, the development of pain in men with CP/CPPS has been reported to occur due to increased intra-prostatic pressure [39]. Constant pressure in the prostate gland due to the disturbance in the prostate vasculature leads to chronic pelvic pain [40].

The current study highlights the effectiveness of innovative employment of body energy with DATD and TT in the treatment of chronic prostatic diseases, as it reduces PV and improves QoL in men with BPH and CP/CPPS. It was demonstrated that effective local energy management with DATD leads to improvement in the blood circulation within the prostate gland; consequently, a decrease in PV was observed accompanied by a reduction in the urinary symptoms in men with BPH and a reduction in the pain score in men with CP/CPPS. The studies on TT with DATD in men with BPH and CP/CPPS have demonstrated that TT is effective because it treats the actual cause of these disorders, and since the cause of these chronic diseases is identical, they should be treated in the same way [41, 42]. DATD helps in improving blood circulation in the prostate gland due to its constant exposure to the optimal amount of heat accumulated by the thermoelement from the body's own radiated heat or energy, and no external heat source is used by the device. This is a novel mechanism of action.

The innovative approach for treating chronic prostate diseases with non-invasive Dr Allen's Device by improving blood circulation locally is important. Although there are many medical options for treating BPH, their safety and effectiveness against older people are still under consideration [43]. For instance, silodosin, known as Rapaflo in the US, was approved by the FDA for BPH in 2008 [44] and recommended for men with CP/CPPS in 2011 [45]. However, even though the efficacy of silodosin appears to be similar to that of other alpha-blockers (tamsulosin and alfuzosin), its rate of sexual side effects is likely higher [46]. Moreover, a study published in 2020 suggests that silodosin was associated with increased digestive symptoms such as diarrhea and loose stools [47]. Therefore, oral drugs for chronic prostate diseases need to be selected by taking into consideration the possibility of their side effects.

The efficacy of Dr Allen's Device for the treatment of BPH and CP/CPPS has confirmed that the heat emitted by the body can serve as a source of energy, which, when directed at the prostate over a long period of time, gradually eliminates the focal hypothermia and thus alleviates LUTS symptoms of BPH and pain associated with CP/CPPS. Thus, TT removes a permanent trigger in the tissue of the prostate gland, termed focal hypothermia, which is responsible for chronic pelvic pain and continuous

prostate growth. This improves the health and well-being of men [48]. The positive changes in the prostate gland, absence of any side effects, and improved QoL achieved through this innovative treatment modality make it more attractive compared with other treatment modalities. The use of DATD as a single self-management tool for the at home treatment of BPH and CP/CPPS can significantly reduce the need for other interventions, reduces contact with healthcare providers and patient visits to clinics and hospitals, which is particularly important during a pandemic and cost-effective for both the patients and the society [49, 50].

Limitation

This is a retrospective analysis of 2 non-randomized clinical trials. The presence of a “placebo” or “sham” group as control could have provided more statistical rigor with respect to results. However, the results of a cohort study showed a bi-directional relationship between controlled anxiety/depression and LUTS due to BPH [51], and many researches since 1995 are viewing CP and/or CPPS as a psychoneuromuscular disorder driven by protective pelvic floor guarding and psychosocial stress [52]. Thus, most men with CP/CPPS and BPH have psychological problems, including depression and anxiety [53, 54]. A 6-month period may be considered an appropriate time for taking tablets/placebo, but not for using something tied to the body. Therefore, suggesting that patients should wear a “placebo-belt” for 6 months, which does not alleviate the symptoms, would be very difficult. Typically, patients included in the study felt relief of symptoms several days or weeks after wearing DATD and continued using the device as needed.

Conclusion

Innovative TT with DATD is an effective treatment modality for the management of chronic diseases of internal organs, including BPH and CP/CPPS. The pathophysiology of BPH and CP/CPPS is related to vascular changes at the level of capillaries that lead to the development of focal hypothermia, spontaneous expansion of capillaries, and pressure in the affected tissue, which in turn leads to chronic prostate disease. TT with DATD is the first treatment modality of its kind that can effectively treat the capillary changes employing body energy and, thus, it can be used as a personalised care method that improves wellbeing naturally and cost-effectively. Moreover, this at home treatment with DATD reduces the number of patient hospital visits and contact with healthcare providers, minimising the risk of infection transmission during a pandemic. Additional clinical trials should be conducted to assess this innovative treatment modality in comparison with other standards of care approved for the treatment of chronic diseases, like BPH and CP/CPSS.

Abbreviations

TT: Thermobalancing therapy; DATD: Therapeutic Dr Allen's Device; BPH: Benign prostatic hyperplasia; CP/CPPS: Chronic prostatitis/chronic pelvic pain syndrome; *n*: Number; QoL: Quality of life; PV: Prostate volume; LUTS: Lower urinary tract symptoms; I-PSS: International Prostate Symptom Scale; NIH-CPSI: National Institutes of Health chronic prostatitis symptom index; US: United States; NSAIDs: Nonsteroidal anti-inflammatory drugs; UrS: Urinary symptoms

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Author's contributions

SA made a significant contribution to the concept and design of the studies. SA analysed and interpreted patient data and wrote the manuscript. SA approved the final manuscript.

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Availability of data and materials

Data available at the public World Health Organization International Clinical Trials Registry <http://apps.who.int/trialsearch/Trial2.aspx?TrialID=DRKS00009271> and <http://apps.who.int/trialsearch/Trial2.aspx?TrialID=DRKS00009352>

Competing interests

The author declares that there are no competing interests.

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