

The cause of chronic prostatitis and prostate enlargement is a change in the vascular level and requires similar treatment: innovative Thermobalancing therapy

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ABSTRACT

INTRODUCTION: The outcomes of clinical studies show Thermobalancing therapy (TT) with Dr Allen's Therapeutic Device (DATD) successfully helps men treat chronic prostatitis / chronic pelvic pain syndrome (CP/CPPS) and lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). The purpose of this study is to compare the ratio of the causes of these diseases with their treatment.

METHODS: Two clinical trials observed dynamics of urinary symptoms, pain score and prostate volume in men with BPH and CP/CPPS after using the device for six months. There were 124 men with BPH and 45 men with chronic prostatitis investigated in the treatment groups and the same number of men were in the control groups.

RESULTS: These studies have shown that TT with DATD reduced prostate volume from 45 mL to 31 mL ($P < 0.001$) and, consequently, urinary symptoms from 14.2 to 4.9 ($P < 0.001$) in the treatment group of 124 patients with BPH. Pain score was reduced from 10.3 to 3.5 ($P < 0.001$) and prostate volume decreased from 31 mL to 27 mL ($P < 0.001$) in the treatment group of 45 men with CP/CPPS. In the control groups of 124 men with BPH and 45 men with CP/CPPS no difference in the symptoms and parameters was observed.

CONCLUSION: The clinical studies indicated that the cause of these chronic diseases lies at the vascular level, namely the pathological activity of capillaries. The focus of hypothermia in combination with the spontaneous expansion of capillaries creates pressure in the tissue of the prostate gland, causing inflammation in it as well as symptoms in men with CP/CPPS and prostate growth in men with BPH. TT with DATD proved to be effective in treating LUTS related to BPH and CP/CPPS. Therefore, the same therapy can be used for the treatment of both chronic prostatic diseases: BPH and CP/CPPS.

Keywords: cause of disease, Thermobalancing therapy; enlarged prostate; chronic prostatitis, prostate treatment

1 INTRODUCTION

Prevalence

Benign prostatic hyperplasia (BPH) is most often encountered in men over the age of 50 and can cause lower urinary tract symptoms (LUTS) [1]. Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a common, painful disease in men under 50. However, there is no useful

treatment for this problem due to the unknown cause of the disease [2, 3].

The cause, etiology and pathophysiology of BPH and CP/CPPS

Discovering the cause of prostate enlargement is crucial for BPH treatment. It was thought that hormones have a fundamental role in BPH/LUTS development, particularly that androgens must be present for BPH to occur [4]. However, castrated boys do not develop BPH as they get older [5], Some years ago, investigations of BPH pathogen-

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esis focused on vascular dysfunction. For instance, aging could activate risk factors for systemic vascular disease, resulting in disturbed blood flow [6]. Development of prostatic hyperplasia could be associated with prostatic hypoxia [7]. Also, a correlation between pelvic ischemia and LUTS in elderly males [8], and increased pressure in the prostate gland have been suggested [9].

The investigations on TT with DATD explored the etiology and pathophysiology of BPH and CP/CPPS, which can be explained by changes in small blood vessels in the affected tissues, namely the pathological activity of capillaries. In response to initial triggers—such as cold, infection, stress and other factors, the constriction of capillaries follows and that creates the focus of hypothermia, which is the secondary irritating trigger, thus leading to spontaneous expansion of a capillary net. Slowly this expansion of capillaries forms extra tissue in the prostate, which leads to prostate enlargement – BPH and LUTS [10]; or creates pressure and prostate inflammation - CP/CPPS with associated symptoms [11], including chronic pelvic pain [12]. This pressure inside the prostate tissue is responsible for the continuous compression of small vessels, which causes secondary local hypothermia and makes the problem chronic. This understanding of the pathophysiology of BPH and CP/CPPS is a core principle of TT [13].

Standard treatment options of BPH and CP/CPPS

Antibiotics, medications and alternative strategies for CP/CPPS are the subject of serious analysis as none of these treatment options are effective [14]. Medical treatments for BPH do not treat the prostate gland and have side effects negatively affecting the quality of life (QoL). Alpha blockers relax the bladder muscles, making it easier to urinate – but cause tiredness, headaches, dizziness, retrograde ejaculation and others. Another class of drugs, 5-alpha reductase inhibitors, such as finasteride and dutasteride, act at the hormonal level to ease urination – but cause impotence, depression, testicle pain, and even diabetes. [15].

TT with DATD for BPH and CP/CPPS

TT with DATD was developed for the treatment of chronic internal diseases by using the body's own energy. [16]. This therapy has demonstrated pain relief and improvement of QoL in men with CP/CPPS [17]. TT with DATD diminishes LUTS due to BPH by reducing the enlarged prostate volume [18]. This article is intended to show that TT with DATD is able to treat the cause of BPH and CP/CPPS in the same way.

2 METHODOLOGY

Dr Allen's Device was registered with the Medicines and Healthcare Products Regulatory Agency in the United Kingdom in 2010, as a class 1 medical device. The ethics committee of the Yerevan State Medical University approved the clinical study with TT and DATD. The studies were registered at the World Health Organisation via the German Clinical Trials Register (DRKS). TT with DATD

was used in 2 clinical controlled studies at the Department of Urology of the Yerevan State Medical University. One clinical trial in 124 men with BPH who received TT within a 6-month period examined 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. The second clinical trial of 45 men with CP/CPPS who received TT within a 6-month period examined their clinical parameters before and after therapy. This information was compared with the control group, i.e. data received from 45 men with CP/CPPS who did not receive TT. Patients with BPH were measured using the International Prostate Symptom Score – Quality of Life (I-PSS). In men with CP/CPPS the National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI) score was utilized. In both clinical studies, prostate volume (PV mL) was investigated. The parameters were compared between groups accordingly. Baseline evaluations were a full physical examination, medical history, digital rectal examination, serum biochemistry, measurement of prostate-specific antigen and electrolytes, urinalysis, and renal function tests. Dynamics of the symptoms and indicators in each group were assessed at the beginning and end of treatment using NIH-CPSI and I-PSS scores. Ultrasound was used to determine the volume of the prostate gland (PV mL). 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).

DATD

DATD applies a special mixture of waxes (thermoelement) topically to be projected toward the affected organ. In men with prostate problems, it would be directed to the coccyx area Figure 1. The thermoelement accumulates the emitted body heat and turns into a source of energy itself. DATD applies the thermoelement tightly to the skin, thereby overcoming the skin barrier and spreading the energy towards the prostate gland.



Figure 1. DATD tightly attaches a thermoelement to the coccyx area in a man for prostate treatment.

3 RESULTS

Figure 2 Dynamics of prostate volume (PV) mL, measured by ultrasound, and pain score in 45 men with CP/CPSP, measured by the National Institute of Health-Chronic Prostatitis Symptom Index (NIH-CPSI), in 45 men with CP/CPSP and in the control group.

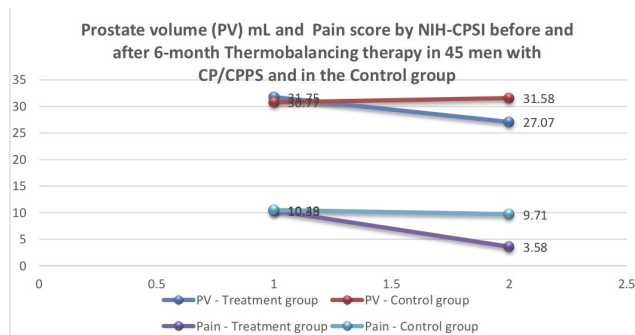


Figure 2. As indicated from this figure there was a significant decrease of PV (mL) from 31.75 ± 7.0 to 27.07 ± 4.5 mL ($P < 0.001$) and pain score from 10.38 ± 2.53 to 3.58 ± 2.54 ($P < 0.001$) in the treatment group. In the control group changes were insignificant. These results suggested that TT decreases PV and pain in men with CP/CPSP.

Figure 3 Prostate volume (PV) mL, measured by ultrasound, and urination symptoms (UrS), measured by the International Prostate Symptom Score (IPSS), in 124 men with BPH after 6-month Thermobalancing therapy, and in the control group.

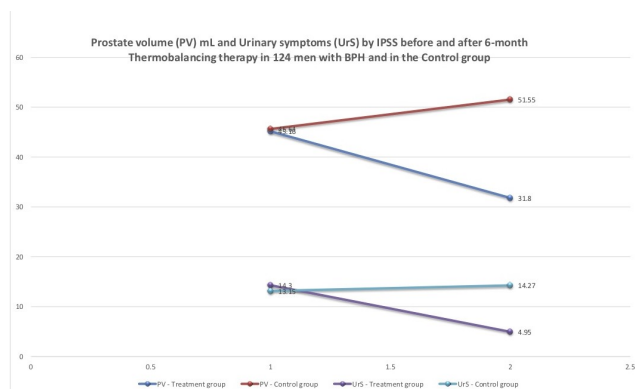


Figure 3. According to this figure, in the treatment group PV decreased from 45.1 mL to 31.8 mL ($P < 0.001$) and UrS score decreased from 14.3 to 4.9 ($P < 0.001$). In the control group changes were insignificant or even worse. These results suggest that DATD reduces PV and UrS significantly.

Side effects of Thermobalancing therapy with DATD

Side effects of Thermobalancing therapy with DATD were not observed.

4 DISCUSSION

The use of TT with DATD reduces volume of the inflamed prostate and pain score in patients with CP/CPSP dramatically, whereas in the control group changes were insignificant [19]. In men with BPH the size of enlarged prostate has been reduced greatly and, consequently, LUTS relief has been achieved [20]. At the same time, the prostate size in men with BPH in the control group increased and urinary symptoms worsened.

The importance of these studies also includes the high costs of CP/CPSP and BPH treatments. For instance, the annual per person costs of treatment of a man with CP/CPSP were estimated as \$6534 [21]; and annual cost of BPH medical treatment was lowest in the UK at about \$1000 and highest in Poland at approximately \$1500 [22]. *The use of TT with DATD, with the price for a unit less than \$200, would make significant changes in the costs of these common chronic diseases.*

The studies have proven that TT with DATD can be easily implemented in the medical practice in the primary health care system [23]. The use of DATD which redirects energy accumulated from the body in the projection of the prostate gland for a prolonged period, has deactivated the micro-focus of hypothermia and spontaneous expansion of capillaries, thereby relieving pressure in the prostate tissue and reducing the enlarged or inflamed prostate in size [24].

Although BPH and CP/CPSP have nasty symptoms, they are non-life-threatening conditions. Therefore, these chronic internal diseases should be treated with safe TT as first line therapy to aid in maintaining men's well-being [25, 26]. It should be noted that Thermobalancing therapy treats the cause of CP/CPSP and BPH by improving blood circulation in the prostate gland in similar ways.

5 CONCLUSION

TT with DATD is an economical solution for chronic prostate disease management, as the price is cost-effective compared to other treatment options. TT with DATD terminates the pathological activity of capillaries and enhances blood circulation in the affected prostate, thus treating the cause of BPH and CP/CPSP. DATD provides the same safe treatment using our own human body energy for BPH and CP/CPSP identically. The use of TT with DATD for the treatment of BPH and CP/CPSP can significantly improve men's quality of life and reduce pressure on the healthcare system.

Competing interests

These studies were not supported by grant and did not have financial interest.

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