

# World News of Natural Sciences

An International Scientific Journal

WNOFNS 23 (2019) 84-93

EISSN 2543-5426

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## Thermobalancing therapy as a self-management tool

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### **ABSTRACT**

People live with one or more chronic diseases, medical and surgical treatments of which may affect their quality of life negatively. Thermobalancing therapy (TT) and Dr Allen's therapeutic Devices (DATD) for the first time use own body energy to treat chronic internal diseases. This invention was received a US patent. Here we observe condition of people with benign prostatic hyperplasia (BPH), kidney stone disease, and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) before and after use of TT and DATD. 10 years of empirical evidence has been studied in people with kidney disease, CP/CPPS and BPH. 2 clinical controlled trials on TT with DATD were conducted. The dynamics of clinical characteristics and parameters, such as pain, urinary symptoms and ultrasound prostate volume (PV), were compared with the no-treatment control groups. 124 men with BPH and 45 men with CP/CPPS used DATD for 6-month period, as mono-therapy, in clinical trials. The outcomes confirmed that TT with DATD reduced pain and PV in men with CP/CPPS and PV and urinary symptoms in men with BPH, while there were no positive changes in the control groups. 4 people with kidney stones, random from the 10-year follow-up, confirmed that after using DATD kidney stones were dissolved without side effects and complications. DATD is a class-1 medical device, which does not need an involvement of notified body, and it is easy use this device. Therefore, people with kidney stones, CP/CPPS and BPH should use DATD, as a tool for self-management in the first place.

**Keywords:** thermobalancing therapy, disease management, kidney stone, benign prostatic hyperplasia, chronic prostatitis

## **1. INTRODUCTION**

### **1. 1. Management of chronic diseases**

Treatment of people with chronic diseases is complex, as they are characterized by a long duration and usually a slow progression. Various models for the treatment of chronic diseases are widely discussed without a clear understanding of the priority of one of them [1]. Integrated chronic disease management, which is a responsive, person-centred, system of care, has shown positive economic impacts for people with chronic diseases [2]. Over the past few years, more attention has been paid to self-management activities in patients with chronic diseases with different results [3]. Physiotherapists and occupational therapists, who were focused on self-management programmes for fatigue, pain, joint protection, etc., made a moderate contribution to self-management [4]. Thus, aging people need a tailored self-management, and care providers should be better equipped to promote motivational change in their patients [5].

### **1. 2. Thermobalancing therapy (TT) and Dr Allen's therapeutic device (DATD)**

TT and DATD has been designed as a new treatment for chronic internal diseases. TT and DATD received a patent in the U.S., as "Therapeutic device and method", which is an acknowledgement that it is indeed a completely new treatment option. For the first time, natural body heat is used to treat chronic diseases [6]. A thermoelement in the device accumulates body heat and turns into a source of energy, spreading this energy to the affected organ. TT is based on a new understanding of The Origin of Diseases, i.e. the vascular factor plays a decisive role in the pathophysiology and etiology of chronic diseases, namely, a pathological activity of capillaries. In the results of these changes a focus of hypothermia inside the affected tissue becomes a continuous trigger, developing swelling and pressure in the organ, leading to its malfunction [7].

### **1. 3. The aim of this study**

This study presents data on how patients with benign prostatic hyperplasia (BPH), chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) and kidney stone disease have managed to use TT with DATD and discuss the role of innovation therapy as a strategy to manage these problems.

## **2. MATERIALS and METHODS**

### **2. 1. Study Protocol**

During last 10-years DATD was used by people with chronic internal diseases in more than 100 countries. There were not complains about this safe therapy. 2 clinical trials were conducted at the Department of Urology of the Yerevan State Medical University. 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). Dr Allen's Device is registered with the Medicines and Healthcare Products Regulatory Agency in the United Kingdom in 2010, as a class 1 medical device. The class 1 medical device without a measuring function and supplied in non-sterile condition does not require the involvement of a notified body.

## **2. 2. Study design**

2 clinical studies were completed. One clinical trial in 124 men with BPH who used DATD during 6-month period and their clinical parameters before and after therapy were examined. This information was compared with the control group, i.e. data received from 124 men with BPH who were in watchful waiting. Second clinical trial in 45 men with CP/CPPS who used DATD during within 6-month period and their clinical parameters before and after therapy were examined.

This information was compared with the control group, i.e. data received from 45 men with CP/CPPS who did not receive TT. International Prostate Symptom Score (I-PSS) was measured in a patient with BPH, and in men with CP/CPPS, with National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI) score. In both clinical studies, prostate volume (PV) was investigated.

## **2. 3. Participants**

For about 3-year period, 45 males (age <55 years) with CP/CPPS (NIH category III) and 124 men with LUTS due to BPH with PV <60 mL were received treatment with DATD at the Department of Urology of the Yerevan State Medical University. Patients were selected in conjunction with urologists.

## **2. 4. Evaluation**

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. Evaluations were made at baseline and 6 months after treatment. Dynamics of the symptoms and indicators in each group were assessed at the beginning and end of treatment using NIH-CPSI and I-PPS scores. Ultrasound was used to determine the volume of the prostate. Evaluation at baseline shows that characteristics of men were identical between treatment and control groups in the CP/CPPS and BPH studies.

## **2. 5. 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).

## **2. 6. DATD**

DATD applies a special mixture of waxes (thermoelement) topically to the projection of affected organ, in men with prostate problems to the coccyx area. In people with kidney stones disease to the projection of kidneys in the back.

No look at **Figure 1**, and **Figure 2**. DATD applies thermoelement to the skin tightly, thereby overcoming the skin barrier and spreading the energy towards the prostate gland or kidneys.

It is comfortable to wear these devices.



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

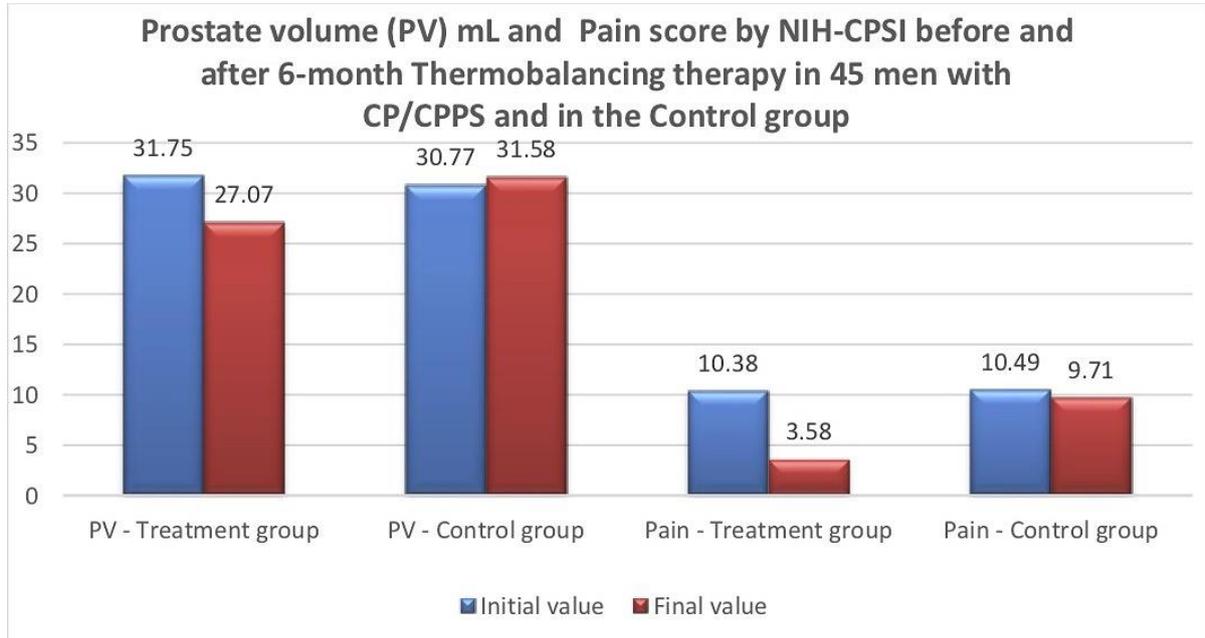


**Figure 2.** DATD tightly attaches thermoelements to the back of a woman in the projection of kidneys to dissolve kidney stones.

### **3. RESULTS**

#### **3. 1. Prostate Volume (PV) mL, and Pain score in men with CP/CPPS**

Dynamics of Prostate volume (PV) and Pain score in 45 men with CP/CPPS and in the control group were measured by the National Institute of Health-Chronic Prostatitis Symptom Index (NIH-CPSI) (**Figure 3** and **Table 1**).



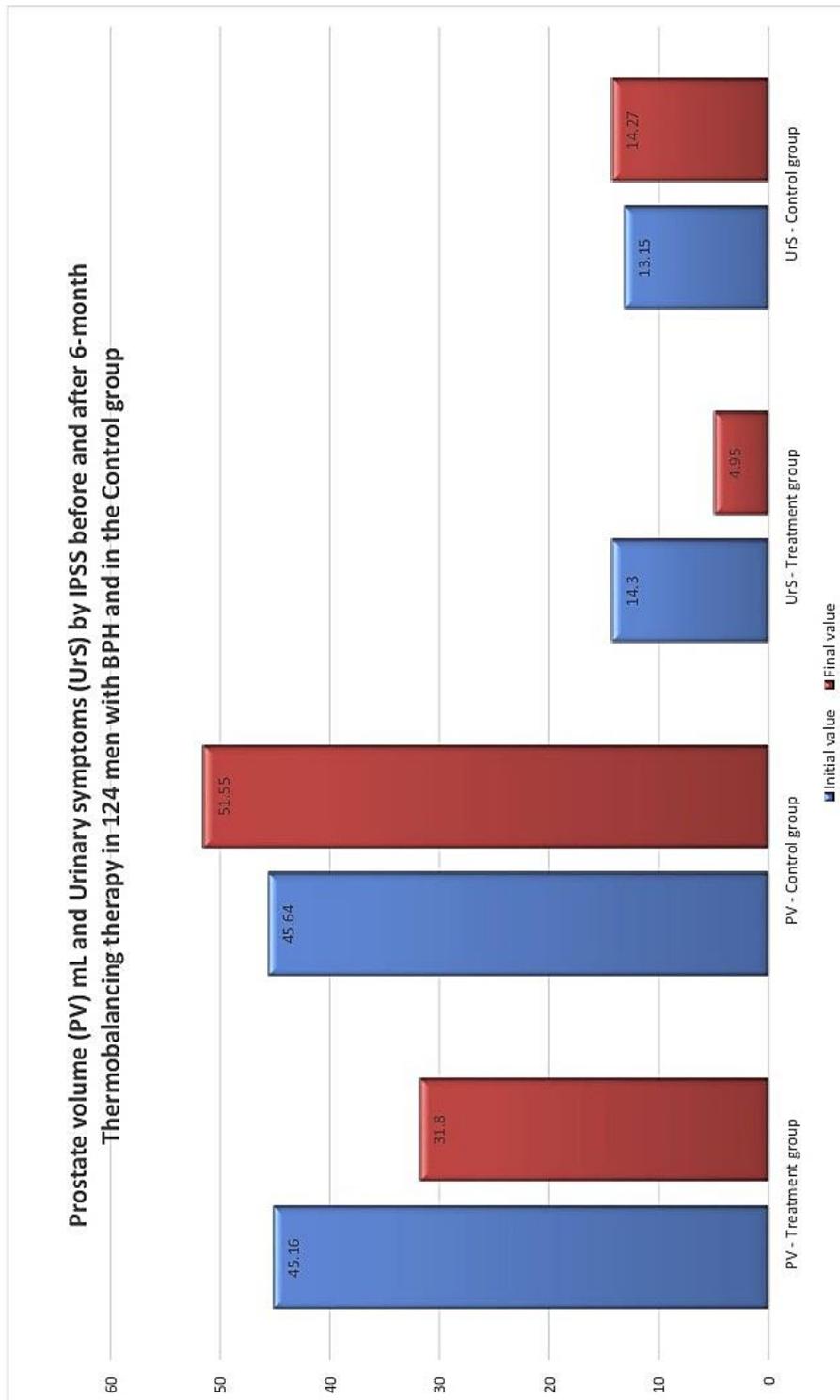
**Figure 3.** There was a significant decrease of PV (mL) from 31.7 to 27.07 ( $P<0.001$ ) and pain score from 10.3 to  $3.58 \pm 2.5$  ( $P<0.001$ ) in the treatment group. In the control group changes were insignificant. These results suggested that TT decreases PV and pain in men with CP/CPPS.

**Table 1.** Presents data from patients with kidney stone disease. People suffered from this disease for many years have dissolved kidney stones using TT with DATD. The empirical evidence in patients with kidney stone disease before and after wearing DATD for prolonged period.

Patient A. Male 52 years old	Kidney stones in both kidneys, large in left.	Renal colic often from 1995.	Used DATD periodically from 2000.	Renal calculi were dissolved, no renal colic after 2002.
Patient B. Female 44 years old	Kidney stones history for 20 years.	Had renal colic every year.	Used DATD from January to May 2016.	After 2 weeks pain and other symptoms are gone, until now.
Patient C. Male 58 years old	Kidney stones history for 30 years.	3cm renal stone, lithotripsies in history, CKD	Used DATD from March to December 2014.	3cm stone was dissolved, kidneys function improved.
Patient D. Male 41 years old	Was diagnosed with kidney stone Nov 2009.	Several renal colic within 5 months.	Used DATD from March to December 2010.	Some twinges first 2-3 months but no recurrences since.

In Table 1, the data demonstrate that DATD is effective for kidney stone disease. DATD can be used in men and women and can dissolve any size and type of kidney stones.

### 3. 2. Prostate Volume and Urinary symptoms score in men with BPH



**Figure 4.** Prostate volume (PV) mL and Urinary symptoms (UrS) measured by the International Prostate Symptom Score (IPSS) in 124 men with BPH after 6-month Thermobalancing therapy & in the control group.

The Prostate volume (PV) mL and Urinary symptoms (UrS) were measured by the International Prostate Symptom Score (IPSS) in 124 men with BPH after 6-month Thermobalancing therapy and in the control group (**Figure 4**).

### **3. 3. Side effects of Thermobalancing therapy with DATD**

Side effects of Thermobalancing therapy with DATD were not observed in all patients.

## **4. DISCUSSION**

The results of the study confirm that the use of TT with DATD reduces volume of the inflamed prostate and pain score in patients with CP/CPPS. DATD. In men with BPH the use of TT with led to reduction of the size of enlarged prostate and, consequently, urinary symptoms relief. People with kidney stone disease have dissolved kidney stones gradually, without renal colic, side effects and complications.

TT with DATD is effective as improves blood circulation in the tissue of the affected prostate or kidney. Thus, the elimination of focus-hypothermia in the prostate tissue leads to chronic pelvic pain relief that is the main symptom of CP/CPPS [8]. DATD treats the cause of CP/CPPS gradually, terminating chain of pathological activities at the capillary level, i.e., constriction and spontaneous expansion of capillaries that are responsible for pressure in the prostate [9].

By stopping the pathological activity of capillaries characterised by spontaneous expansion of capillaries, which in long term leads to the prostate growth, DATD stops prostate enlargement [10]. TT with DATD, eliminating the focus of hypothermia, stops the expansion of capillaries, the pressure inside the affected kidneys contributes to the process of dissolution of stones [11].

### **4. 1. Prevalence**

The prevalence of the studied chronic conditions: CP/CPPS, BPH and kidney stones are high, and in general these problems develop in about 30% of the population. In a large healthy population, CP/CPPS-like symptoms are common with a greater detrimental effect affecting QoL, even more than pain [12]. The occurrence rate of BPH in China in the age groups 40–49 years was 2.9%, 50–59 years - 29.0%, 60–69 years - 44.7%, 70–79 years and 80 years and older was 58.1% and 69.2%, respectively [13]. Kidney stones affect about 1 in 11 people in the United States [14]. So, high incident rate of these chronic disease requires a substantial response from the health care services.

### **4. 2. Management strategies for chronic diseases**

Management of chronic diseases is a major burden for health professionals, since the improvement of it is mainly focused on adherence to medicines [15]. Decision makers facing implementation of measures to improve the use of consumer drugs should find out what interventions can be most promising for improving the specific results [16].

Of course, the most actual treatment option for chronic internal disease should be the one which is helpful, safe and cost-effective.

TT with DATD meets all three basic standards [17, 18].

#### **4. 3. TT with DATD for a self-management strategy for chronic diseases**

Self-management is a dynamic process in which individuals actively manage their chronic illness. The use of TT with DATD gives people this opportunity. For instance, in men with CP/CPPS the use of DATD led to pain relief without side effects [19]. Therefore, it is appropriate to implement this therapy with DATD as an independent treatment for CP/CPPS [20]. The use of TT with DATD for LUTS due to BPH led to significantly reduce the prostate size, urinary symptoms relief [20], stating that it can be a useful solution for the conservative treatment of LUTS secondary to prostate enlargement, instead watchful waiting, prior to any long-term pharmacotherapy [22]. The use of TT with DATD for kidney stone disease dissolved any type and size of kidney stones, without adverse side effects and complications that follow the standard surgical procedures, so it should be implemented in primary care services [23].

#### **5. CONCLUSION**

Since DATD used on the body, patients can easily participate in self-management strategies with an initial point of treatment. BPH, CP/CPPS and kidney stone disease are non-life-threatening conditions, therefore they should be treated therapeutically with the safe therapy in the first instance. The self-management strategy for these chronic internal diseases should include DATD, which should be used from the starting point of their treatment. This strategy, involving people in the treatment of their own chronic diseases, will make them more confident in the treatment they receive and more accurate for its implementation. A successful treatment of these common chronic diseases is expected to improve their health for years to come.

#### **Acknowledgments**

I am grateful to Professor IG Aghajanyan, the founder Armenian Association of Urology, for his support in conducting clinical studies.

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