



# The Origin of Chronic Diseases Can Be in Capillary Pathology: An Evidence From Clinical Trials on Thermobalancing Treatment of Prostate Reveals

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## ABSTRACT

**Aim:** Etiology and pathophysiology of chronic internal disease was unknown until last days. This article challenges that two clinical trials have discovered the origin of chronic prostate diseases.

**Methods:** The hypothesis of the chronic internal diseases cause due to pathological activity of capillaries with emerging micro-focus of hypothermia, a continuous trigger for disease development in any affected organ, was declared in the US patent “Therapeutic Device and Method”, i.e. thermobalancing therapy (TT) and therapeutic device. Two clinical trials before and 6 months after TT for chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) and benign prostatic hyperplasia (BPH) with the device, namely Dr. Allen's therapeutic device (DATD) confirmed the effectiveness of TT. This device was used as mono-therapy for 124 patients with BPH and 45 men with CP/CPPS.

**Results:** Compared to controls, the TT groups showed significant improvements from baseline to endpoint. TT in men with BPH decreased urinary symptoms and PV, increased  $Q_{max}$  and improved quality of life index (QoL). At the same time, another clinical trial on TT in men with CP/CPPS has demonstrated decrease of pain score and PV mL, improvement of QoL and increase of  $Q_{max}$  mL/sec. **Conclusions:** The long-term application of the source of emitted body heat with DATD, i.e. TT, to the projection of affected prostate removes “micro-focus” of hypothermia at the capillary level that improves blood circulation in the organ and its function. Thus this article shows that the underlying cause for different chronic internal diseases, such as BPH and CP/CPPS is the same and is positioned at the microvascular level. More studies with thermobalancing therapy needed.

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## Introduction

Chronic diseases are poorly defined problems, for instance investigations on chronic prostatitis/chronic pelvic pain syndrome (CP/CPSP) have usually focused on peripheral-end-organ mechanisms, such as inflammatory or infective conditions, however, the potential etiologies and pathogenesis for CP/CPSP still remains unclear (Liao et al., 2016). Absence of knowledge of the pathogenesis of benign prostate hyperplasia (BPH) makes investigators look for its development in several mechanisms including increased intra-abdominal pressure, altered endocrine status, increased sympathetic nervous activity, increased inflammation process, and oxidative stress (Parikesit et al., 2016).

For many years has been suggested that in CP/CPSP pathogenesis has been proposed immunological, neurological, endocrine, or psychological basis (Cho and Min, 2015). In the last decade the cause of CP/CPSP has been also considered from the view of vascular dysfunction (Shoskes et al., 2011), chronic ischemia in the prostate tissue (Kogan et al., 2011), and increased pressure in the prostate gland (Mehik et al., 2003). The same situation was seen with the etiology of BPH, where the metabolic syndrome (MetS) (Demir et al., 2009), inflammation (Bostanci et al., 2013) and hormones (Bhasin et al., 2003) were discussed, and recent investigation found the vascular factor in pathogenesis of BPH (Saito et al., 2014).

It has been suggested that all chronic internal diseases, including BPH and CP/CPSP, originate at the capillary level. This conclusion is based on 2 functional physiological properties of capillaries that are activated by a trigger, thereby leading to violation of the microcirculation along with emergence of a focus on hypothermia, which in itself becomes a continuous trigger leading to chronic disease. Thus it was proposed that continuous application of a natural source of energy could treat the chronic disorder and thermobalancing therapy (TT) with therapeutic device (DATD) were created (Allen and Adjani, 2016).

The use TT with DATD for the treatment of LUTS and BPH led to a marked improvement and symptomatic relief (Allen and Aghajanyan, 2015). Furthermore, TT with DATD has shown to be effective for CP/CPSP (Allen and Aghajanyan, 2016a). The symptoms' improvement in men with BPH and CP/CPSP after using TT can be explained by positive changes in the prostate gland. So, it can be suggested that pathological capillary activity plays the crucial role in the etiology and pathophysiology of these prostate diseases.

## Methods

### *Ethical Approval of the Study Protocol*

The Ethics Committee of Yerevan State Medical University approved the study protocol, and all participants provided written informed consent to be included in the study.

### *Study Design*

Two clinical controlled studies undertaken in 2013–2015 that measured: International Prostate Symptom Score–Quality of Life (I-PSS) in 124 men with BPH and National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI) in 45 men with CP/CPSP, and also prostate volume (PV mL), and maximum urinary flow rate ( $Q_{max}$  mL/sec). The parameters were compared between groups: treatment groups, which underwent TT, and control groups, which did not have such treatment.

### *Participants*

Over a 2-year period, 45 men (age <55 years) with CP/CPSP (NIH category III) and 124 men with BPH were selected for a clinical trial at the Department of Urology of Yerevan State Medical University. Patients were selected in conjunction with urologists.

### *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.

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