

NEW NON-DRUG AND NON-INVASIVE THERMOBALANCING THERAPY FOR THE MANAGEMENT OF LOWER URINARY TRACT SYMPTOMS SECONDARY TO BENIGN PROSTATIC HYPERPLASIA

Background

Lower urinary tract symptoms (LUTS), such as daytime urinary urgency, nocturia, urinary hesitancy, weak stream, straining, and prolonged voiding, are the manifesting signs of benign prostatic hyperplasia (BPH) that are prevalent among aging men. Trends in management of LUTS/BPH have changed over the last 25 years. Current literature has not been able to consistently prove the efficacy of physiotherapeutic agents, therefore they are not included in the treatment protocol for LUTS associated with BPH. The primacy of prescriptions of medications used for LUTS/BPH has dramatically increased. Due to serious side effects from BPH drugs some of patients discontinue their intake. Also, gradually medications become helpless and different surgical procedures for LUTS/BPH patients are offered. However, invasive techniques may have various complications and also men with LUTS/BPH often have other health concerns common in older men. 'Therapeutic device and method' have been introduced recently for the treatment of chronic internal conditions [1]. The aim of this study is to find out whether topically applied therapeutic device that enables Thermobalancing therapy is able to reduce LUTS secondary to prostate enlargement.

Study design, materials and methods

The observational clinical controlled study for BPH/LUTS lasted from 2013 to 2015 [2]. 124 men older than 55 with LUTS/BPH and with the prostate volume (PV) up to 60 mL received Thermobalancing therapy enabled by therapeutic device during 6 months as mono-therapy. The therapeutic device tightly attaches a natural thermoelement that accumulates the body heat to the coccyx area in the projection of prostate, Fig. 1.



Figure 1. The thermoelement, belt, therapeutic device is tightly attached to the coccyx area.

Before and after treatment were investigated the International Prostate Symptom Score (IPSS), including quality of life (QoL) index, ultrasound measurement of PV and uroflowmetry maximum flow rate (Q_{max}). Men in the control group on the watchful waiting approach did not receive any treatment.

Results

After treatment the dynamics of clinical parameters in 124 men with PV < 60 mL have shown positive results: urinary symptoms, according to IPSS, reduced significantly ($P < 0.001$) and improved QoL.

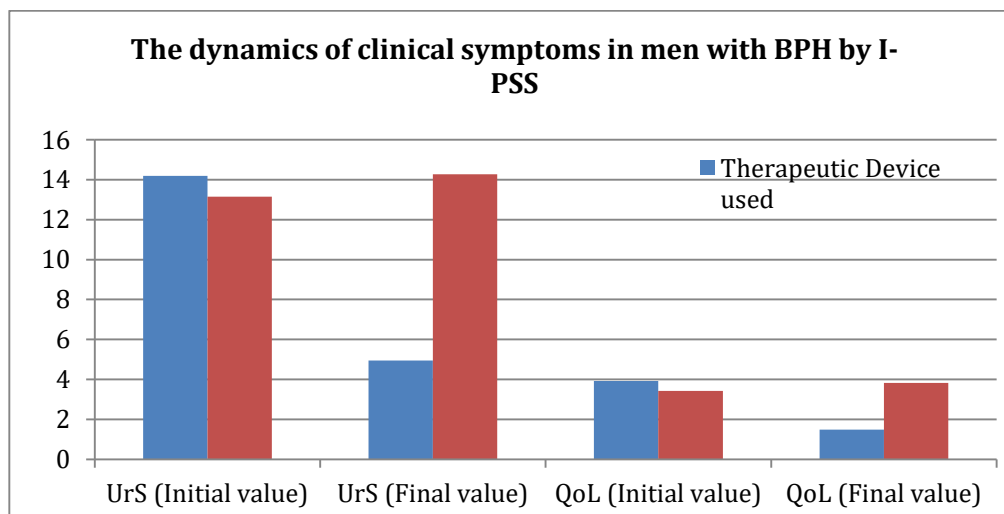


Figure 2. International Prostate Symptom Score (IPSS), urinary symptoms (UrS) and quality of life (QoL), in patients with BPH on Thermobalancing therapy and in the control group at the beginning and at the end of the study.

The PV level reduced ($P < 0.001$) and Qmax ($P < 0.001$) increased.

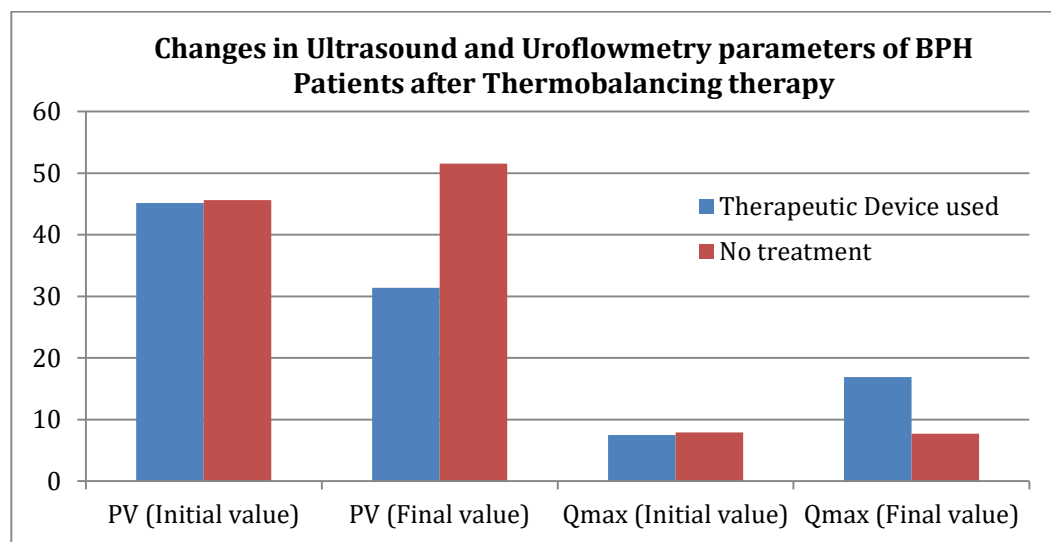


Figure 3. The changes in prostate volume (PV) mL and the uroflowmetry (maximum urinary flow rate (Qmax, mL/s) in men with BPH on Thermobalancing therapy and in the control group at the beginning and at the end of the study.

The dynamics of the same measurements in the control-group without treatment have shown negative outcomes.

Interpretation of results

Thermobalancing therapy enabled by therapeutic device helped men with enlarged prostate to reduce PV gradually and got LUTS relief in safe, without drugs and surgery. The data received in the control-group suggested the necessity of active management of LUTS/BPH in the earlier stage of prostate enlargement.

Concluding message

The positive clinical outcomes in men after use of therapeutic device indicate that Thermobalancing therapy is effective for BPH and the device should be considered as a new physiotherapeutic tool for the treatment of moderate to low degree LUTS.

References

1. Allen S, Adjani A 2009 Therapeutic Device and Method, US 20110152986 A1, <http://www.google.com/patents/US20110152986>
2. Allen S, Aghajanyan IG Benign Prostatic Hyperplasia Treatment with New Physiotherapeutic Device, Urol J. 2015 Nov 14;12(5):2371-6.

Disclosures

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Subjects: HUMAN **Ethics Committee:** The Ethics Committee of the Yerevan State Medical University **Helsinki:** Yes **Informed Consent:** Yes