



## Treatment of Kidney Stone Disease, Benign Prostatic Hyperplasia and Chronic Prostatitis with Thermobalancing Therapy should be listed in the Guidance for Health Professionals

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**Abstract:** The prevalence of kidney stone disease, chronic prostatitis / chronic pelvic pain syndrome (CP/CPPS) and benign prostatic hyperplasia (BPH) increases around the world. Long-term medications and surgical procedures for these non-life-threatening chronic conditions can develop serious side effects and complications. At the same time, Thermobalancing therapy (TT) with Dr Allen's therapeutic Device (DATD) has shown its high effectiveness in the treatment of chronic internal diseases. Discussion at many international conferences in 2017-2018 was aimed at treating various chronic non-malignant diseases with the help of Thermobalancing therapy, such as BPH, CP/CPPS, kidney stones and cardiovascular diseases.

In the conferences were presented cases of TT with DATD of patients with kidney stone disease that confirm the ability of DATD to dissolve any type and size of kidney stone; discussed the outcomes from the clinical trials of TT in 124 men with BPH and 45 patients with CP/CPPS, before and after 6-month period they used DATD. The assured results of the cases and clinical trials reveal that TT with DATD treats the cause of kidney stone disease, CP/CPPS and BPH. Implementation of this therapy is needed today, as it helps patients avoid long-term drugs and surgical procedures, including extracorporeal shock wave lithotripsy (ESWL) with their risks and complications. In addition, it is a cost-effective solution. Therefore, conference participants proposed that TT with DATD should be included in the Guidance for health professionals.

**Keywords:** Enlarged Prostate, Kidney Stones, Prostatitis, Thermobalancing Therapy

### 1. BACKGROUND

Thermobalancing therapy (TT) enabled by Dr Allen's therapeutic device (DATD) is able to treat chronic internal disease. 2 clinical studies on TT in men with benign prostatic hyperplasia (BPH) and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) were completed. They confirmed the high effectiveness of this safe therapy that has no adverse side effects [1,2]. There is many empirical evidence that DADT dissolves any type of kidney stones and prevents their recurrence. TT with DATD is effective because it eliminates the constant trigger in the tissue of affected organ, namely the focus of hypothermia, maintaining the source of energy obtained from the body in its projection, stopping the pressure inside the organ, which leads to relief of pain and other symptoms[3]. Discussions at the International Conferences in Spain, China, Italy, London, Paris and other countries (2017-2018) were aimed at better understanding the origin of

disease of chronic internal diseases and their treatment.

#### 1.1. Kidney Stone Disease

Kidney stone disease or nephrolithiasis is a highly prevalent disease worldwide with rates ranging from 7 to 13% in North America, 5–9% in Europe, and 1–5% in Asia [4]. This disease is also prevalent in mainland China, and the prevalence increases with age. Due to high rates of new and recurrent stones, management of stones is expensive and the disease has a high level of acute and chronic morbidity. There has been a rising incidence in stone disease throughout the world with a narrowing of the gender gap [5,6]

Most patients with ureteral stones present with typical symptoms, although many stones in the renal calices remain asymptomatic. Not every asymptomatic caliceal stone needs to be treated immediately [7]. Ureteral stones <6 mm can pass spontaneously in controlled patients, while medical expulsive therapy, without prior

extracorporeal shock wave lithotripsy (ESWL), supports the chance of successful passage and reduces the need for analgesics [8].

Nowadays, the competition for priority in the treatment of kidney stones between ESWL, percutaneous nephrolithotomy (PCNL) and retrograde intrarenal surgery (RIRs) turned on [9]. After ESWL was implemented it was supposed that 85% of all patients with kidney stones could be cured by nonsurgical means [10]. The initial promising results of ESWL were challenged with common side effects caused by this procedure, such as bleeding, severe pain, or urinary tract infections [9], rare complications, such as spleen rupture or intrarenal hematoma [11,12,13], and long-term medical effects: hypertension and diabetes mellitus [14,15,16].

A prospective-randomized study with asymptomatic caliceal stones <15 mm did not find any statistical advantage of ESWL over observation in terms of stone free rate (SFR), quality-of-life, kidney function and symptoms during a 2.2-year follow-up [17]. Therefore, watchful waiting can be suggested with yearly follow-up examinations over a period of 2-3 years. Asymptomatic calyceal stones may be observed but there is a higher risk of symptoms and a need for intervention within 5 yr. [18,19].

The cause of pain in kidney stone disease is understood for thousands of years. Kidney stones can cause pain as they pass through ureter, stretching the proximal ureter and renal collecting system. This physical stretch activates nociceptive nerve fibers within an entire neuronal network located submucosally in the renal pelvis, calyces, capsule and ureter [20].

Kidney stones can occur due to excess of elements in blood, infection, dietary changes and other factors. Nevertheless, the pathophysiology of kidney stones is still unknown, and a more complete understanding of stone formation is needed to develop prevention strategies [21]. Only after it was shown that the origin of diseases in all chronic internal diseases has the same root, the formation of kidney stones can be explained as a chain of changes at the microvascular level, and it is supported by evidence that TT with DATD dissolves kidney stones [22].

### **1.2. Benign Prostatic Hyperplasia**

Lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH)

most often encountered in men over the age of 50 [23]. Many men with CP/CPHS and BPH are not satisfied with conventional treatment options and they try alternative therapies: diet and lifestyle modifications, phytotherapy and acupuncture [24]. Thus, in the last decade, the necessity of medical/surgical treatment of BPH has been challenged. BPH/LUTS should not be viewed as an inevitable disease of older people but as part of the aging process that can be prevented [25].

It was shown that acupuncture can relieve the clinical symptoms of prostate hyperplasia and raise the patients' quality of life [26]. The following investigations also demonstrate that the effect of electroacupuncture (EA) on the urinary symptoms was positive but it doesn't improve clinical parameters in patients with moderate to severe BPH [27]. Statistically significant changes were observed in short-term follow-up endpoints in favor of acupuncture in moderate to severe BPH. However, it is not certain whether clinically significant outcomes can be achieved by acupuncture [28].

Phytotherapy doesn't significantly improve symptoms of enlarged prostate against placebo, despite being largely safe for ingestion. However, it can be used in patients with mild BPH symptoms who are reluctant to take standard pharmaceutical medications provided that men understand their current limitations [29]. Therefore, recommendations on the evaluation and treatment of LUTS in older men are in demand. BPH treatment should be holistic, and may include conservative measures, lifestyle interventions and behavioral modifications, as well as medication and surgery [30].

Many researchers have tried to understand the etiology and pathophysiology of BPH in order to find the optimal treatment for this frequent disease, but they concluded that the exact cause of BPH remains largely unknown [31,32].

TT with DATD by using continuous heat exposure that does not exceed the normal body temperature terminates the trigger of BPH development, the micro-focus of hypothermia, and the following spontaneous expansion of capillaries; stops and even reverses prostate enlargement. Thus, it was confirmed that the

BPH cause related to the chain of changes at the microvascular level [33].

### **1.3. Chronic Prostatitis/Chronic Pelvic Pain Syndrome**

CP/CPPS is a common condition that causes severe symptoms and worsens quality of life (QoL) in 8.2% of affected men [34]. Chronic pain, the main symptom of CP/CPPS, which is characterized by pelvic pain and voiding symptoms, is poorly defined [35]. Pelvic pain may have a close relationship with the pelvic floor, as it has been established potential therapeutic benefit from pelvic floor therapy for men with CP/CPPS [36]. However, chronic pain is a multifactorial condition, caused by the complex interplay of nociceptive, neuropathic or mixed pathogenic mechanisms [37]. It maybe because of pain CP/CPPS also takes a substantial toll on physical and mental health, and remains a major challenge and is a source of frustration to both the patient and physician since standard treatments often fail and a “panacea” is still lacking[38].

Different etiologies and mechanisms of CP/CPPS pathogenesis have been proposed with a suggested immunological, neurological, endocrine, or psychological basis [39]. For instance, hypogonadism, a treatment of which is raise in the aging population [40] with the appropriate use of testosterone replacement therapy [41], today may be suggested as target in men with CP/CPPS [42]. However, as there is no successful treatment for this common health problem, a treatment methodology for CP/CPPS is needed [43].

TT with DATD by providing continuous application with a natural source of energy to the prostate gland reaches a marked improvement of quality of life (QoL) and symptomatic relief in men with CP/CPPS [44]. The initiating factors for CP/CPPS may differ but the trigger for the development of chronic disease is the focus of hypothermia and, consequently, ischemia, sets up a vicious cycle of spontaneous growth of capillaries and continuous pressure inside the prostate tissue that leads to CP/CPPS. DATD terminates the focus of hypothermia improves microcirculation in the prostate, affecting the etiology of this disease [45].

### **1.4. The Purpose of the Research Review**

The purpose of this review is to find an optimal treatment option for people with chronic internal

diseases, such as kidney stones disease, BPH and CP/CPPS. Clinical empirical evidence and trials have confirmed that the use of DATD is incredible effective for patients with these chronic conditions. TT with DATD received a patent in the US. The patent is an acknowledgement that it is indeed a completely new treatment option for chronic internal diseases. This review includes discussions at international conferences in Spain, China, Italy, the United Kingdom and France (2017-2018) aimed at a better understanding of the origin of kidney stone disease, BPH, CP/CPPS and recommendations for optimal treatment of these conditions.

## **2. METHODS**

Dr Simon Allen in his speeches at the conferences explained the essence of TT and demonstrated supporting data of its effectiveness. Therefore, below are presented the case studies in patients with kidney stone disease and the outcomes of clinical trials on TT with DATD in men with BPH and CP/CPPS.

### **2.1. Study Protocol**

Dr Allen’s Device was registered with the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK in 2010, as a class 1 medical device. A class 1 medical device without a measuring function and supplied in non-sterile condition does not require the involvement of a notified body. So, it is permitted to be used by everyone at home. Therefore, Dr Allen has opened Fine Treatment Company in the United Kingdom that distributes Dr Allen’s Device worldwide.

Today we have satisfied customers from over 100 countries. Ethics committee of the Yerevan State Medical University approved the clinical studies on TT with DATD. The studies on BPH and CP/CPPS were registered at the World Health Organisation via the German Clinical Trials Register (DRKS).

### **2.2. Study Design**

TT with DATD was used in the clinical controlled studies at The Department of Urology in Yerevan State Medical University. 124 men with BPH and 45 men with CP/CPPS received TT during 6-month period and their clinical parameters before and after therapy were examined. This information was compared with the control groups, i.e. data received from 124 men with BPH who were in watchful waiting

and 45 men with CP/PPS who did not receive TT with DATD. Also, data of patients with kidney stones is presented in this study.

**2.3. The Baseline Evaluations**

It included complete physical examination, medical history, DRE, serum biochemistry, and PSA measurements, electrolytes, urine and renal function tests. Evaluations were made at baseline and 6 months after. The International Prostate Symptom Scale (I-PSS) assessed the dynamics of the BPH patients' conditions; and the condition of 45 men was assessed by measurement of the National Institute of Health chronic prostatitis Symptom index (NIH-CPSI). Prostate volume (PV mL) was measured by ultrasonography. The standard ellipsoid formula length×width×height×0.52 was used to determine prostate volume. Dynamics of the symptoms and the indicators in each group were evaluated in comparison to their data in the beginning and end of the treatment.

**2.4. 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).

**2.5. TT and DATD**



**Picture1.** DATD tightly attaches thermoelement to the coccyx area for a prolonged period of time.

TT enabled by DATD for the first time in the world treats the affected organ using own energy of the human body. Natural thermoelement(s) in the device accumulates the body heat and becomes a source of energy itself. Thus, it treats a prostate gland by keeping the source of energy, which has been accumulated from the body, in the projection of the prostate during the prolonged period of time, for 6 months and longer, see Picture 1.

The same happens with patients who suffer with kidney stone disease, when the device applies thermoelements to both kidneys it dissolves stones by keeping the source of energy, which has been accumulated from the body, in the projection of both kidneys during the prolonged period of time, see Picture 2.



**Picture2.** Dr Allen's Device for kidney treatment consists of 2 thermoelements and a belt that applies these thermoelements to the projection of both kidneys.

**3. RESULTS**

**Table1.** Data in this table demonstrates that DATD is effective tool for kidney stone disease. DATD can be used in men and women.

Table 1. The empirical evidence in patients with kidney stone disease before and after TT				
Patient A. 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 B. Male 56 years old	Kidney stones history for 30 years.	Had 3cm renal stone, lithotripsies in history, CKD	Used DATD from March to December 2014.	3cm stone was dissolved, kidneys function improved.

We have collected many cases provided to me by the users and should note that not a single user of Dr Allen's Device for kidney treatment has complained that this treatment method has not worked for him or her. Table 1. presents data from 2 patients with kidney disease who have suffered from this disease for many years and dissolved kidney stones using TT with DATD.

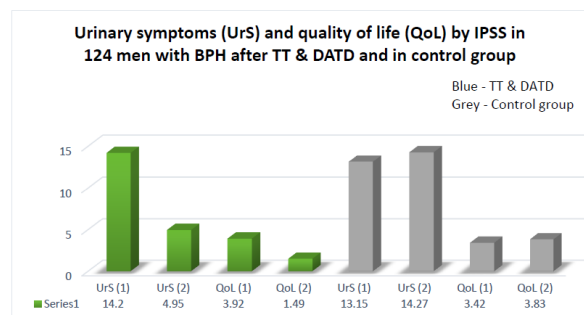
The outcomes of the clinical trial on TT in 124 men with BPH are presented in **Figure 1** and **Figure 2**.

In the control group, the mean IPSS – UrS score increased from 13.45±3.254 to 14.35±3.396 (P<0.001) whereas, in the treatment group, it

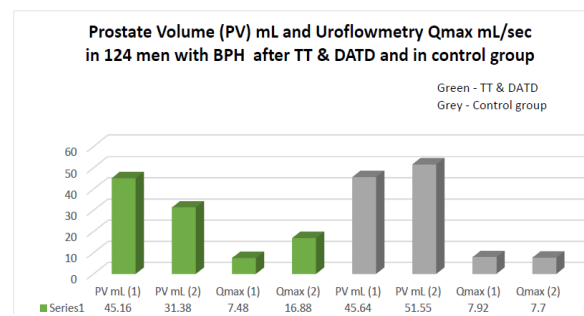


decreased from  $14.33 \pm 3.399$  to  $4.73 \pm 2.754$  ( $P < 0.001$ ) at the end of the observation period. Hence, DATD decreased urinary symptoms significantly whereas, in the absence of treatment, urinary symptoms worsened significantly.

In the control group, the mean IPSS–QoL score increased from  $3.43 \pm 0.956$  to  $3.76 \pm 0.983$  ( $P < 0.001$ ) whereas, in the treatment group, it decreased from  $3.91 \pm 0.755$  to  $1.39 \pm 1.110$  ( $P < 0.001$ ). These results suggested that DATD treatment improved QoL whereas, in the control group, QoL worsened.



**Figure1.** Dynamics of the IPSS for urinary symptoms (UrS) and QoL in 124 patients with BPH after TT with DATD, and in the control group, at the beginning and at end of the study demonstrated:



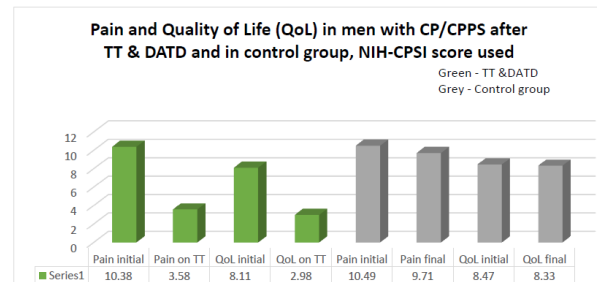
**Figure2.** Changes in prostate volume (PV, mL) and uroflowmetry,  $Q_{max}$  mL/s) in 124 men with BPH after TT with DATD and in the control group, at the beginning and at end of the study demonstrated

In the control group, the mean PV increased from 45.54 mL to 50.85 mL ( $P < 0.001$ ) whereas, in the treatment group, it decreased from 45.19 mL to 31.86 mL ( $P < 0.001$ ). Hence, DATD reduced PV significantly whereas, in the control group, PV increased.

In the control group, the mean  $Q_{max}$  decreased from  $7.95 \pm 2.871$  to  $7.7 \pm 2.695$  mL/s (no significant difference) whereas, in the treatment group, the mean  $Q_{max}$  increased from  $8.10 \pm 3.041$  to  $17.73 \pm 4.392$  mL/s ( $P < 0.001$ ). These results suggested that DATD increased  $Q_{max}$  significantly whereas, in the control-group, a significant difference in  $Q_{max}$  was not

observed.

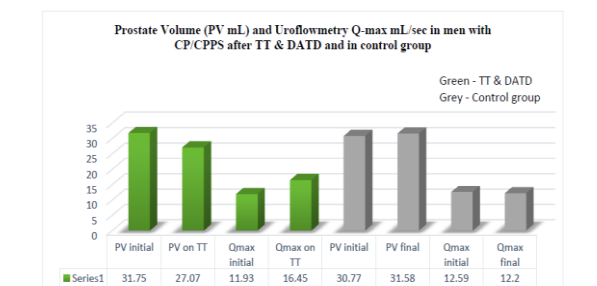
The outcomes of the clinical trial on TT in 45 men with CP/CPSP are presented in **Figure 3.** and **Figure 4.**



**Figure3.** Dynamics in Pain and Quality of life evaluation scores in 45 men with CP/CPSP according to the NIH-CPSI before and after TT with DATD and in the control group demonstrated

In the control group, the mean pain score decreased from 10.49 to 9.71 ( $P < 0.05$ ) at the end of the study period, whereas in the treatment group the mean pain score decreased from 10.38 to 3.58 ( $P < 0.001$ ). These data suggest that although the pain score decreased in both groups, the difference between scores was considerably higher (8.72:1) in the treatment group than the control group.

In the control group Estimation of quality of life showed a decrease from 8.47 to 8.33 (no significant difference), whereas in the treatment group the mean quality of life went from 8.11 to 2.98 ( $P < 0.001$ ). We concluded that the treatment improved the quality of life significantly, whereas in the control group there was no significant difference.



**Figure4.** Changes in ultrasound measurement of prostate volume (PV mL) and uroflowmetry  $Q_{max}$  mL/sec in 45 men with CP/CPSP before and after TT with DATD and in the control group demonstrated

In the control group, the mean prostate volume increased from 30.77 to 31.58 ( $P < 0.05$ ), whereas in the treatment group the mean prostate volume decreased from 31.75 to 27.07 ( $P < 0.001$ ). This indicated that the treatment reduced the PV significantly, whereas in the control group the prostate volume increased over time.

In the control group  $Q_{max}$  value decreased from 12.59 to 12.20 (no significant difference), whereas in the treatment group the mean uroflowmetry  $Q_{max}$  increased from 11.93 to 16.45 ( $P < 0.001$ ). Thus, the treatment had a significant increase in the uroflowmetry  $Q_{max}$ , while the control group had no change in its value overtime.

#### **4. DISCUSSIONS**

The study highlights the effectiveness of TT with DATD in the treatment of chronic internal diseases, as it dissolves kidney stones, reduces pain and improves QoL in patients with CP/CPPS; reduces symptoms of urination and improves QoL in men with BPH and reduces PV and increases  $Q_{max}$  in both treatment groups with CP/CPPS and BPH.

This study was not randomized. The presence of a "placebo" or "sham" group as a control could provide more statistical rigor with respect to results. However, most men with CP/CPPS have psychological problems, they largely do not respond to medical interventions, and pain syndrome is associated with a decrease in QoL [46,47]. Similar problems are observed in men with BPH suffering from depression and anxiety, their health-related QoL is considered poor, and their psychological well-being is seriously affected [48,49]. A 6-month period may be considered as a short period of time for taking tablets / placebo, but not for using something attached to the body. Therefore, suggesting that men with CP/CPPS and BPH should wear a "placebo-belt" for 6 months, which does not alleviate the symptoms, it would be very difficult. Typically, patients with CP/CPPS and BPH felt relief of symptoms for several weeks after wearing DATD and used the device as needed.

This effectiveness of DATD can be explained in the following way: that TT treats the underlying cause of these chronic diseases, tackles the origin of disease.

##### **4.1. The Origin of Diseases, Including Kidney Stones, BPH, CP/CPPS and TT with DATD**

The vascular factor plays a decisive role in the pathophysiology and etiology of chronic diseases, so all chronic internal diseases have the same root, namely, a pathological activity of capillaries. Two physiological properties of small blood vessels, named by physiologists: constriction of capillaries and spontaneous

expansion of capillaries are responsible for the pathological activity of capillaries. First is the constriction of capillaries in response to different triggers, such as infection, cold, excess of elements in blood, stress and others. It creates the focus of hypothermia in the affected tissue, which gradually becomes a trigger itself, irritating the affected tissue [50].

To improve blood circulation in this affected tissue, the second factor, namely spontaneous expansion of a capillary net occurs [51]. Slowly the expanded capillaries form extra tissue that creates pressure in this area of the organ leading to its malfunction. Thus, the conclusion is that this physical factor is responsible for the development of chronic internal disease. In order to eliminate the focus of hypothermia and, consequently, the pressure inside the organ, and ultimately, its malfunction TT enabled by DATD have been developed [52].

##### **4.2. Management of Kidney Stone Disease**

Kidney stones may lead to chronic kidney disease (CKD) and stone formers are at increased risk for end-stage renal disease (ESRD) [53,54]. However, the management of kidney stones should be evaluated according to severity of side effects and complications after treatments. This conclusion has been created slowly while researches have understood that the stone-removing procedure may itself negatively impact the functional integrity of the targeted kidney and perhaps its mate [55].

That is why today researches try to find a connection between dietary factors and the risk of incidence of kidney stones, as they see that lifestyle and dietary factors seem to be increasingly important in prevention of stone disease [56,57]. As the incidence of kidney stones is common in the United States and treatments for them are very costly, researches advise stone removal using surgery or ESWL, and aftermedical and dietary treatments to prevent recurrence of stone [58]. However, there is no point in recommending dietary management of kidney stones, as it cannot stop the formation of kidney stones without offering useful alternatives to surgical interventions.

Therefore, the introduction of TT with DATD as a first line treatment in the Guidelines for Nephrology and General Practitioners should be

carried out as soon as possible, as it stops the formation of kidney stones, extremely safely and economically.

### **4.3. Management of Benign Prostatic Hyperplasia**

Even though BPH now is considered a consequence of aging, treatment of this disease centered on medical/surgical intervention to counteract LUTS. Medical treatment of BPH is not efficacious as 52.8% of men with BPH were dissatisfied with the results of medical treatment conducted according to current international guidelines for BPH [59]. BPH medications have serious side effects, especially in the long-term [60]. Surgical treatments of prostate were found to be unsafe for non-Caucasian race, so for them conservative treatment might be a reasonable alternative [61]. Additionally, the results of a survey of sexually active men after three different laser surgeries from 2005 to 2010, concluded that all these surgical techniques can have a negative impact on sexual function, and patients with normal preoperative sexuality are more at risk [62].

Although many of medical/surgical interventions were advised to men with LUTS, it was generally done in a non-standardised and unsystematic way. A self-management programme could significantly reduce the frequency of escalation through the treatment cascade and reduce urinary symptoms (as effective as medication), suggesting that self-management could be considered as first-line treatment for men with LUTS [63].

The self-management of LUTS due to BPH with the DATD demonstrated its high efficacy and, therefore, therapeutic device should be used before any long-term pharmacotherapy is initiated [64]. Therefore, implementation TT with DATD as the first-line BPH treatment into the Guideline for Urologists and General Practitioners should be carried out as soon as possible.

### **4.4. Management of Chronic Prostatitis/Chronic Pelvic Pain Syndrome, CP/CPPS**

The results of the systematic review and meta-analysis confirmed the current inability to effectively manage CP/CPPS, suggesting the identification of the etiology and role of therapeutic intervention in CP/CPPS in the first place [65]. The lack of effective therapy for CP/CPPS forces health professionals to implement different treatment strategies. For

example, illness-focused coping as an important biopsychosocial goal in the management of CP/CPPS or transrectal triple physiotherapy in combination with pharmacotherapy in patients with CP/CPPS [66,67].

Rees with colleagues in the Guidelines recommend that multimodal/combined therapy should be uniquely designed for each individual patient, adding to first-line antibiotic therapy:  $\alpha$ -blocker and/or an NSAID; and an agent targeting neuropathic pain (e.g. pregabalin); and phytotherapy, which, has a modest beneficial effect on symptom improvement in CP/CPPS, and may be considered as a treatment option in treatment-refractory patients [68]. Several studies of acupuncture have provided positive results as well as transcutaneous electrical nerve stimulation comparing with traditional treatments for CP/CPPS [69,70]. Acupuncture, compared with standard treatment, it is more effective, so it can also serve as a standard treatment option when it is available [71]. However, the duration of the effect after acupuncture is not clear.

Today, with invention of TT with DATD, the quality of life of men with chronic pelvic pain should be changed positively. The vascular changes with the focus of hypothermia in affected prostate tissue play the main role in the cause the pain in CP/CPPS. TT eliminates this constant trigger that backs chronic process. By maintaining a source of energy that does not exceed body temperature in the projection of a prostate, DATD reduces the pressure inside its tissue, relieving pressure on stress nociceptors, which results in relief of chronic pelvic pain. Therefore, TT with DATD can be recommended as an independent treatment option for patients with CP/CPPS [72].

## **5. CONCLUSION**

TT with DATD is an effective tool for the treatment of kidney stone disease, BPH and chronic prostatitis. Kidney stone disease ought to be treated therapeutically by Thermobalancing therapy in the first instance, helping patients to dissolve kidney stones and to avoid surgical procedures, including lithotripsy, with their risks and complications. The treatment of LUTS due to BPH should start with DATD, as TT can stop and reverse prostate enlargement. TT with DATD provides pain and other symptoms relief in men with CP/CPPS. TT

with DATD is safe and cost-effective. Therefore, it is important to include TT with DATD in the Guidance for health professionals for the treatment of kidney stones, BPH and CP/CPSP.

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