

Review

I-wave Transcutaneous Thermotherapy for the Treatment of Benign Prostate Hypertrophy and Pelvic Dysfunction in Men

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ABSTRACT

I-wave heat therapy produces microwave-like energy using a high-frequency electromagnetic field to achieve an optimal hyperthermia effect on the targeted organs. One of the advantages of this non-invasive and effective method is that it uses the body's natural response to the application of heat to produce a desired therapeutic effect. This innovative, non-invasive and very promising method, which also requires no anesthesia, is performed in the practitioner's office on an outpatient basis. Regarding urological indications, it is Benign Prostate Hypertrophy and inflammatory prostatitis including pelvic dysfunction that will be mainly treated. However, many other indications are applicable and some are under evaluation. In this paper, we present a review of one of these techniques concerning the principle of i-wave external thermotherapy. In a separate article we will present our patient group and the first clinical results in Switzerland.

Keywords: *Non-invasive external thermotherapy; Benign prostate; Hypertrophy; Safe and efficient treatment; Inflammatory prostatitis; Pelvic dysfunction.*

INTRODUCTION

For many years, transurethral thermotherapy has been recognized as a safe and alternative method in the treatment of benign prostatic hyperplasia in men.^{1,2} Despite the minimally invasive aspect of the application of microwaves, some surgeons even used this technique for external application in obstructive patients with bladder catheters in whom a transurethral procedure could not be performed.^{3,4} The authors therefore report excellent and very promising results, which according to the studies would allow 65% of patients a significant improvement during 8 years after the application of external thermotherapy.^{4,5} Based on its results, many engineers and physicists have worked to develop a technique that can be safely used routinely applicable on an outpatient basis and that could provide quality functional results. Principles of i-wave Thermotherapy (Eugeniux)

I-wave heat therapy produces microwave-like energy using a high-frequency electromagnetic field to achieve an optimal hyperther-

mia effect on the targeted organs. The radiofrequency type of energy generated by the applicator enables deep tissue treatment up to 15 cm. The application of this energy allows the practitioner to maintain throughout the duration of the treatment a temperature which can oscillate between 39 and 44 degrees Celsius. The optimal and therapeutic temperature is obtained very quickly (from 8 to 10 minutes from the beginning of treatment) and is maintained constantly during the entire application of the radiofrequency. One of the advantages of this non-invasive and effective method is that it uses the body's natural response to the application of heat to produce a desired therapeutic effect. Throughout the treatment, the power generator is used to control and regulate the applied temperature in order to maintain a surface temperature 3.9 degrees Celsius lower (and therefore allowing safety) than the internal temperature.

Therapeutic Indications

I-wave transcutaneous thermotherapy conceptualized by its engineer

Dr. G. Aknine from the company Eugeniux, makes it possible to apply efficiently and sequentially during a period of one hour a temperature of 44 degrees Celsius coupled with neuromodulation at the level of strategic and targeted organs in order to obtain a therapeutic response. This innovative, non-invasive and very promising method, which also requires no anesthesia, is performed in the practitioner's office on an out-patient basis. Regarding urological indications, we were able to consider

so far Benign Prostate Hypertrophy (BPH) and inflammatory prostatitis including pelvic dysfunction. In the latter indications the results were good and the response of the patients in term of tolerance and satisfaction was very high. Thus, many other indications are applicable and some are under evaluation, allowing and opening a wide and interesting window of opportunity. (Table 1&2)

Table 1. Below shows the many indications, non-exhaustive, related to the application of i-wave transcutaneous thermotherapy

Indications	Advantages
BPH	Improvement of irritative symptoms
Bladder retention	Removal of the catheter and / or reduction of the post-void residual
Erectile dysfunction	Improvement of erectile function by regulating blood flow to the perineum and the cavernous bodies. Reduction in the intake and dosage of oral treatments (PDE5-inhibitors)
Cystitis and prostatitis	Decreased prevalence of infections and improvement of inflammatory symptoms
Libido	Regulation of androgen levels circulating by acting on the relaxation of prostate muscles
Pelvic dysfunctions	Reduction of pain and tension by cellular regulation of muscles and fibroblasts
Testicular pain and tension Inflammatory epididymitis	Decreased congestion of the ducts and glands of the vas deferens and epididymis by regulation of the blood flow
Postoperative dysuria and / or irritative symptoms	Alleviation of symptoms and improvement of urine flow by regulating blood flow and reducing inflammation

Table 2. IPSS or Symptomatic Score of the Prostate to assess the degree of severity of symptoms related to benign prostatic hyperplasia

Q 1. In the past month, how often have you had the feeling that your bladder was not completely emptied after urinating?
0 points = never
1 point = approximately 1 in 5
2 points = approximately 1 in 3
3 points = approximately 1 in 2
4 points = approximately 2 times out of 3
5 pts = almost always
Q 2. In the past month, how often did you need to urinate within 2 hours after having finished urinating?
0 points = never
1 point = approximately 1 in 5
2 points = approximately 1 in 3
3 points = approximately 1 in 2
4 points = approximately 2 times out of 3
5 pts = almost always
Q 3. During the past month, how often have you had an interruption in the flow of urine, ie starting to urinate then stopping then restarting?
0 points = never
1 point = approximately 1 in 5
2 points = approximately 1 in 3
3 points = approximately 1 in 2
4 points = approximately 2 times out of 3
5 pts = almost always
Q 4. In the past month, after you felt the need to urinate, how often have you had difficulty holding on to urinate?
0 points = never
1 point = approximately 1 in 5
2 points = approximately 1 in 3
3 points = approximately 1 in 2
4 points = approximately 2 times out of 3
5 pts = almost always
Q 5. During the past month, how often have you had a decrease in the size or strength of the urine stream?
0 points = never
1 point = approximately 1 in 5
2 points = approximately 1 in 3
3 points = approximately 1 in 2

4 points = approximately 2 times out of 3
5 pts = almost always
Q 6. During the past month, how often did you have to force or push to start urinating?
0 points = never
1 point = approximately 1 in 5
2 points = approximately 1 in 3
3 points = approximately 1 in 2
4 points = approximately 2 times out of 3
5 pts = almost always
Q 7. During the past month, how many times per night, on average, did you get up to urinate (between when you went to bed at night and when you got up completely in the morning)?
0 points = never
1 point = approximately 1 in 5
2 points = approximately 1 in 3
3 points = approximately 1 in 2
4 points = approximately 2 times out of 3
5 pts = almost always

Recruitment of Patients for Therapy

After a careful history and prostate examination, patients are selected for therapy based on clinical symptoms on one hand and the I-PSS score (prostatic symptom score) on the other hand. Additional examinations such as free flowmetry, urethroscopy or urodynamic evaluation are only performed in doubtful cases or in order to clarify the diagnosis. To date, we can list the indications of benign non-obstructive prostatic hyperplasia in patients presenting mainly irritative symptoms as well as inflammatory prostatitis and pelvic dysfunction as the major indications for this type of treatment. Indeed, these pathologies respond best to the application of i-wave heat therapy. In addition, some patients who have been operated on for transurethral resection of the prostate (by ND- Yag Laser, Holmium or Plasma Edge) for obstructive BPH and presenting post-operative irritative and inflammatory symptoms, also respond very well to a few treatment sessions. allowing to spare anti-inflammatory treatments or corticosteroids.

Depending on the intensity of the IPSS score, patients are scheduled for 6 to 8 treatment sessions, or even more, if necessary. Depending on the progress, some patients may repeat the sessions after a few months of break.

The IPSS Score is calculated by adding the scores obtained by answering the 7 questions: Depending on the score, a severity scale can be established:

0 - 7 Little symptomatic
8 - 19 Moderately symptomatic
20 - 35 Severe symptoms

This score, although very simplistic, but very useful in current urology practice, makes it possible to identify patients according to their symptoms and especially to follow the progress of therapy.

On the day of treatment, the patient completes an IPSS score to monitor the progression of symptoms and the progression of treatment effects. The patient also performs a flow measurement and a measurement of the post-voiding residual before the start of the session.

For the follow-up, apart from the clinical and ultrasound evaluation of the prostate, we suggest performing a control flow measurement as well as blood PSA assay. These tests are carried out at 3 and 6 months allowing progress to be monitored.

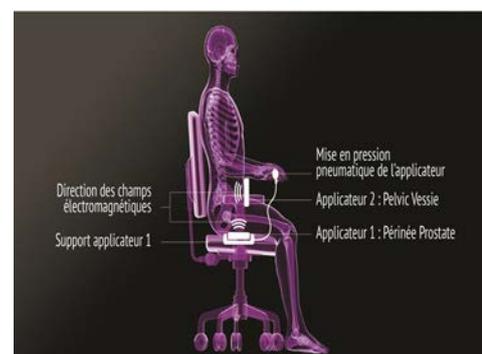
Course of Therapy

During therapy, which lasts in principle one hour of time, the patient is comfortably installed in a chair (Figures 1a-1b & 2) allowing the pads to be put in place including the external electrodes (digital multipoint temperature sensors) connected to the treatment console. These applicators are ultra-flexible and comfortable and allow heat distribution to a depth of 15 cm at tissue level. During the session, the specialist can at any time activate neuromodulation to reduce the sensation of pain due to the rise in temperature. This non-invasive, real-time temperature control with autofocus system is a real gain in energy application and therapeutic safety control.

Figure 1a&1b. Console and monitor with electrodes connected externally to the pelvic-prostatic area and the bladder area



Figure 2. Patient positioning showing the course of the session with an automatic biological tissue adaptation system and maintaining a low skin temperature



Promising Preliminary Results

As we have already specified, the purpose of this article is above all to present this innovative and non-invasive method that we have been using in our clinic since March 2019. To date, several hundred patients have been treated with excellent functional and very promising results.

In a future article we will present our first clinical results in Switzerland. Over time, we were able to refine our indications and the choice of patients eligible for therapy as well as the optimal number of sessions for each indication.

CONCLUSION

I-wave heat therapy is an innovative, non-invasive and very promising method of treatment for benign prostatic pathologies using molecular thermal wave therapy and providing excellent functional results. Indeed, this molecular therapy system coupled with ultra-high radiofrequencies allowing optimal penetration into biological tissues helps to improve tissue trophicity and to regulate blood circulation in order to obtain an optimal therapeutic effect. In addition, a low frequency modulation close to the heart rate of the main wave beam allows hyper-vascularization. This gives the therapy the ability to improve blood flow optimally when reaching the therapeutic 44 degrees Celsius. Thus, even if transurethral thermotherapy remains an excellent alternative in non-invasive surgery for BPH [5,6] and other benign prostate pathologies, external transcutaneous application thanks to the i-wave form gives a new and very promising dimension. This new application of the thermotherapy in the treatment of benign prostatic conditions can be safely done in a one day

clinic without any kind of anesthesia and completely painless and convenient for the patient.

CONFLICTS OF INTEREST

None.

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