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## Development of Feedback Microwave Thermotherapy in Symptomatic Benign Prostatic Hyperplasia.

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# Microwave Thermotherapy in Patients with Benign Prostatic Hyperplasia and Chronic Urinary Retention

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## Key Words

Benign prostatic hyperplasia · Chronic retention · Indwelling catheter · Microwave thermotherapy · Transurethral microwave thermotherapy

## Abstract

**Objective:** To evaluate microwave thermotherapy as a treatment option for benign prostate hyperplasia (BPH) in patients with chronic retention and an indwelling catheter.

**Patients and Methods:** 24 unselected patients, 53–91 years old (mean age 73 years) with chronic urinary retention and an indwelling catheter were treated with ProstaLund Feedback Treatment®. Patients had had an indwelling catheter for 1–12 months prior to treatment. ProstaLund Feedback Treatment is an enhanced microwave treatment where the actual intraprostatic temperature is monitored and used to control the microwave power.

**Results:** 19 (80%) of the 24 patients were successfully relieved of their indwelling catheter with satisfactory peak flow, residual urine and symptom score. Treatment failed in 5 (20%) out of the 24 cases. The reasons of failure were identified in all 5 cases and indicate that the method may be less suitable in case of a median lobe or large protruding lobes into the bladder. There were no serious complications such as bleeding requiring hospital intervention, sepsis or urine incontinence. Isolated cases of urinary infection occurred.

**Conclusion:** The satisfying outcome of a 1-hour-long out-patient procedure for this patient category suggests that ProstaLund Feedback Treatment may be a good alternative to surgery for BPH patients with chronic retention and an indwelling catheter.

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## Introduction

Minimally invasive methods such as microwaves, varying forms of laser and transurethral needle ablation have all been developed in the 1990s. The underlying principle be-

hind these methods is to coagulate prostatic adenomatous tissue by means of heat. An advantage of microwaves compared to other minimally invasive techniques is their ability to heat the whole intended treatment volume simultaneously which makes the procedure easy to carry out. Efficacy

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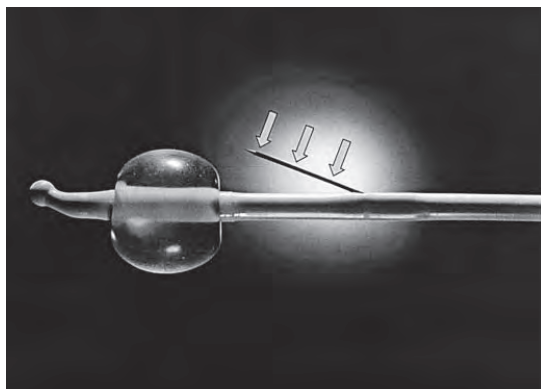
and safety studies of microwave treatment indicate that the subjective improvements are similar to surgery, while objective improvements relating to pressure/flow are less than after surgery [1]. Recent technological development and new treatment protocols have, however, led to further improvement in treatment outcome [2]. Posttreatment morbidity of microwave thermotherapy includes a rapidly developed oedema in the prostate, and catheterisation for up to 2 weeks is usually required. Retrograde and dry ejaculation are also seen but to lesser degree than after TURP. The safety of microwave thermotherapy seems high [3], and severe complications are rare in the literature.

Many BPH patients with chronic urinary retention are old and fragile and unsuitable for TURP or open surgery because of the operation risks involved. In a retrospective US study on 218,127 Medicare patients operated between 1984 and 1990, the 30-day mortality following TURP was assessed to be 0.4% for patients aged between 65 and 69 years and 3.5% for patients 85 years and older [4]. In a recent study, the overall intra-operative and immediate postoperative complications were 2.5 and 10.8%, respectively, while late postoperative complications were 8.5% [5]. Persistent incontinence may occur in about 4% and impotence in 5% [6].

From a patient perspective the exposure to risk is of central importance; studies on shared decision-making programmes teach that patients who are provided with objective information relating to benefits and risks associated with different treatments to a greater degree choose therapies where the risk is minimised [7]. The risks associated with microwave treatment appear to be substantially smaller than risks associated with surgery [8, 9]. It would thus be an important complement to the treatment arsenal of BPH if microwave treatment could be used successfully in this patient category.

At our hospital, we have experience of microwave treatment since 1993 and have found the method easy to perform with only a few undesirable side-effects. The waiting time for surgery for all BPH patients at our hospital is presently so long that microwave thermotherapy has become an important supplementary modality. In addition the indication to use microwave treatment is gradually changing from previously only offering it to patients with solely irritative symptoms to now also include patients with evident obstructive elements [1]. Reports of microwave treatment on patients with urinary retention are, however, rare in the literature [10, 11].

Due to the long waiting time for surgery at our hospital we have started to offer BPH patients with chronic retention and an indwelling catheter microwave treatment as an alter-



**Fig. 1.** The treatment catheter has an integral temperature probe that protrudes from the catheter into the prostate. The temperature probe contains three temperature sensors (arrows) to map the temperature distribution in the prostate along the probe.

native to surgery. This report presents the first results with this treatment modality.

## Method

24 unselected patients, 53–91 years old (mean age 73 years) with chronic urinary retention and an indwelling catheter underwent ProstaLund microwave feedback treatment between August 1997 and June 1999. Patients had had an indwelling catheter for 1–12 months prior to treatment. Patients were recruited in the order they registered to the clinic's surgery waiting list (waiting time >6 months) and were offered microwave treatment within a few weeks as an alternative to surgery. All 24 patients accepted the offer. No patient selection was made, but all patients with BPH and chronic urine retention who wished to be treated were given the microwave treatment. The prostate length pre-operatively exceeded 45 mm in all cases, well above the minimum recommended length of 35 mm as specified by the microwave device manufacturer.

All patients were investigated pre-operatively with S-PSA, transrectal ultrasound for morphometry and volume determination (B&K Medical 3535), and fluid cystometry. Before treatment, at least 1 attempt to remove the indwelling catheter was made, in most cases 2 or more attempts. The patients were followed up at 3 and 12 months after treatment with morphometry and volume determinations, IPSS, bother score, Madsen score, urinary flow measurement (Dantec Uro-dyn 1000) and residual urine. Patients who were relieved of their indwelling catheter and had a bother score  $\leq 2$  and a residual urine  $\leq 150$  ml were considered responders to the treatment.

Treatments were carried out using the ProstaLund Feedback Treatment™ protocol (ProstaLund, Sweden). The ProstaLund device is an enhanced microwave system where the actual intraprostatic temperature is monitored and used to control the microwave power. The treatment catheter contains a microwave antenna which focuses mi-

**Table 1.** Mean values of patient data before and at 3 and 12 months of follow-up

	Before (n = 19)	3 months (n = 19)	12 months (n = 16)
Prostate volume, ml	79.1 ( $\pm 40.2$ )	53.4 ( $\pm 32.5$ )	45.7 ( $\pm 28.7$ )
IPSS	indwelling catheter	4.8 ( $\pm 3.2$ )	4.0 ( $\pm 4.0$ )
Bother score	indwelling catheter	0.8 ( $\pm 0.95$ )	0.6 ( $\pm 1.03$ )
Madsen score	indwelling catheter	0.7/1.2 ( $\pm 1.5/1.6$ )	0.7/0.3 ( $\pm 1.4/0.5$ )
Max. flow, ml/s	indwelling catheter	12.5 ( $\pm 6.1$ )	14.7 ( $\pm 9.7$ )
Residual urine, ml	indwelling catheter	47 ( $\pm 36$ )	51 ( $\pm 34$ )
Figures in parentheses are the standard deviations $\sigma_{(n-1)} \dots$			

crowave energy to the prostate and a temperature probe with three sensors in an array that protrudes laterally into the prostate adenoma after the treatment catheter has been inserted (fig. 1).

During treatment the ProstaLund equipment continuously monitors the intraprostatic temperature and – by using the energy balance equation suggested by Pennes [12] – calculates the blood flow and the temperature distribution in the entire prostate. The system also estimates the amount of tissue being coagulated by using Henrique's damage integral which is based on the cytotoxic effect of heat on tissue [13, 14].

A microwave power of 40 W was applied at the start of the treatment and was gradually increased or decreased in order to reach an intraprostatic temperature of at least 50°C but not exceeding 70°C during the second half of the procedure. Treatment duration was nominally set to 1 h, but treatment was discontinued earlier if the calculated destruction of tissue shown by the system amounted to 30% or more of the total prostate volume. In a few cases the treatment duration was prolonged due to difficulty to reach high enough intraprostatic temperatures.

Treatment was carried out using gel anaesthesia, i.e. 2×11 ml Instillagel. All patients received 10 mg pethidine and 10 mg diazepam prior to treatment. On demand, 9 patients received an additional 10 mg of diazepam and 10–15 mg of pethidine. Other medication used was Toradol 30 mg i.v. (23 patients), Cetiprin nov 25 mg i.m. (14 patients) and oxybutynin hydrochloride 20–40 mg intravesically (10 patients). Treatments were performed as an office procedure and the patients returned home the same day.

## Results

19 patients (80%) of the 24 treated cases responded successfully to the treatment and were relieved of their indwelling catheter and had a satisfactory symptomatic picture, urinary flow and bladder control. Table 1 shows the prostate volume, IPSS, bother score, Madsen score, peak flow and residual volume at 3 and 12 months of follow-up for the responders. 16 patients have been followed for more than 1 year.

The average prostate volume measured by transrectal ultrasound prior to treatment was 79 ml (range 32–170 ml);

after 3 months it had decreased to 53 ml (range 22–138 ml), and after 1 year it had decreased further to 46 ml (range 18–123 ml). Eight patients had an initial volume of > 80 ml. The average reduction in prostate volume was 32% (26 ml) after 3 months and 42% (33 ml) after 1 year. According to the ProstaLund system's cell kill estimation which is displayed online during treatment, the calculated destruction of tissue averaged 27 ml. In the non-responder group, the average prostate volume was 69 ml (range 47–102 ml) pre-operatively and 38 ml (range 25–62 ml) at 3 months of follow-up, i.e. the volume reduction was in the same order as for the responder group. The residual urine in the non-responder group varied between 125 and 384 ml after treatment in 4 patients where it could occasionally be measured.

The average treatment time was 60 min (range 46–82 min) and the average microwave power during treatment was 59 W (range 30–77 W). The maximum prostate temperature recorded during treatment was on average 59.8°C (range 47.9–71.5°C). Posttreatment catheter time varied from 9 to 54 days for the responding group with an average of 26 days. Initially, we attempted to remove the catheter after 2 weeks, but this worked well only for about 1/3 of the patients. Later, we therefore decided to wait 4 weeks before attempting to remove the posttreatment catheter.

Patients tolerated treatment satisfactorily: 19 patients did not experience any discomfort, 3 patients experienced moderate discomfort, and 2 patients experienced significant discomfort mainly comprising urge sensation during treatment.

There were only a few posttreatment complications, and no patients required overnight stay or care in hospital: 1 patient experienced moderate haematuria for 2 weeks, 7 patients had urinary tract infection during the follow-up period (5 occurred in correlation with the draining of the catheter and 2 at later stages); 1 patient received temporary catheter care for 2 weeks/because of influenza 4 months after the treatment.

**Table 2.** Catheter time following treatment, treatment time and microwave power for those responding

	Mean Range
Catheter time after treatment, days	26 (9–54)
Treatment time, min	60 (46–82)
Microwave effect, W	58.7 (30–77)
Max. intraprostatic temperature, °C	59.8 (48–71)

It is possible to distinguish 5 of 24 patients (20%) who were not relieved of their indwelling catheter. Patient 1 had protruding side lobes into the bladder that after treatment fell down and formed a valve in the bladder neck. Patient 2 was actually relieved of his indwelling catheter after the treatment, but he was accustomed to an open catheter at night-time. Now suffering from nocturia 2–3 times per night he requested the indwelling catheter back in order to be able to sleep without interruptions. Patients 3 and 4 had a median lobe that was unaffected by the treatment, and patient 5 had an undiagnosed bladder neck sclerosis. Four of these later underwent TURP with a satisfactory result.

## Discussion

80% of the patients treated with the ProstaLund microwave system were relieved of their indwelling catheter, had low symptom and bother scores, adequate bladder emptying and acceptable urinary flow. There were no occurrences of serious complications such as bleeding requiring hospitalisation, sepsis or urinary incontinence. Surprisingly, the treatment appears to be insensitive to the prostate size. Outcome was equally satisfactory for patients with a severely enlarged prostate (>80 ml) where open prostate surgery would else have been the usually selected option. The satisfying outcome for this group of patients after a 1-hour-long out-patient procedure suggests that the ProstaLund Feedback Treatment can be a good alternative to surgery for patients with BPH and obstructive retention. The patient's relief of being able to void spontaneously again is probably the primary factor to understand the high patient satisfaction rate of the treatment.

Treatment failed in 5 (20%) of 24 cases. The reasons for failure were identifiable in all cases and indicate that the method may be less suitable for patients with a large median lobe or severely protruding lobes in the bladder. The

residual urine was considerably higher after treatment in the non-responder group suggesting that detrusor impairment is a contributing factor.

An interesting observation is that most patients experienced little or no discomfort during the treatment. An explanation can be that patients that carry an indwelling catheter for a long time become desensitised in the lower urinary tract. Postoperative catheter care and the weeks immediately following removal of the postoperative catheter were also endured without substantial discomfort or urge, despite the fact that the catheter period following microwave treatment was longer than usual, approximately 1 month compared to 1 or 2 weeks which is otherwise common for non-retention BPH patients that undergo microwave thermotherapy.

The underlying idea of thermotherapy is to create heat necrosis. The extent of the necrosis, or cell kill, is governed by two physical variables: the intraprostatic temperature and the duration of the heat exposure. Unfortunately, less relevant parameters that are secondary to the two fundamental ones are often seen in the literature to describe microwave thermotherapy, e.g. 'low energy' or 'high energy'. In the presented material, we saw large variations in treatment duration and microwave power between patients which reflects large individual differences in prostatic blood flow which in turn governs the intraprostatic temperature. Patients with a low blood flow may very well be successfully treated with 'low energy' whereas patients with a high blood flow need to be treated with high microwave power to reach therapeutic intraprostatic temperatures. This fact stresses that microwave thermotherapy should be regarded as an individualised treatment – the microwave power should in each case be adjusted to the actual intraprostatic temperature.

## Conclusion

The satisfying outcome of a 1-hour-long out-patient procedure for this patient category suggests that ProstaLund Feedback Treatment may be a good alternative to surgery for BPH patients with chronic retention and an indwelling catheter.

These positive preliminary findings will be followed by a randomised controlled multicentre study to further investigate the long-term efficacy, safety and health economy aspects of the ProstaLund Feedback Treatment compared to surgery for this patient category.

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