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# **Non-drug local procedures for treatment of benign prostatic hyperplasia<sup>1</sup>**

## **Executive Summary**

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<sup>1</sup> Translation of the executive summary of the final report “Nichtmedikamentöse lokale Verfahren zur Behandlung der benignen Prostatahyperplasie” (Version 1.0; Status: 02.06.2008), Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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## EXECUTIVE SUMMARY

### Background

Urination disorders are relatively common in older men. The term “benign enlargement of the prostate” (benign prostatic hyperplasia, BPH) has previously been used to describe the frequent cause of these symptoms. Nowadays the term “benign prostatic syndrome” (BPS) is often used, as the size of the prostate has only a limited influence on whether and how severely the person affected perceives his symptoms. About 20% of 50 to 59-year-old men report moderate to severe symptoms; in men above 70, this rate is about 40%. These include “irritative symptoms”, which comprise symptoms related to controlling urination, such as a strong urge to urinate, frequent and/or nocturnal urination, and urge incontinence. “Obstructive” symptoms comprise difficulties in voiding the bladder, such as a weak urinary stream or incomplete voiding. Chronic urinary retention can lead to late complications such as urinary tract infections, bladder stones, or kidney damage.

Symptoms caused by BPS can lead to such distress that men seek treatment. Several treatment options are available, ranging from initial monitoring to see if symptoms resolve spontaneously, to drugs, or to various surgical procedures in which the prostate is partially removed. The prostatic capsule is always preserved. However, to date it is unclear which advantages and disadvantages these options have.

### Aims

The aim of this report was to compare non-drug local treatment procedures for BPS with regard to patient-relevant therapy goals. From the patient’s point of view, treatment should primarily relieve urination symptoms and improve quality of life, while at the same time cause as few adverse events as possible. For surgical procedures, it is also relevant whether hospitalisation is necessary, how long the patient has to stay in hospital, and whether or for how long he needs a urinary catheter.

For this report, the treatment procedures were organised into 3 groups. The first group comprised “standard” procedures, i.e. recognised surgical procedures such as transurethral resection of the prostate (TURP) (reference method), transurethral incision of the prostate (TUIP), and removal of the prostate gland (prostatectomy), which is sometimes performed in patients with BPS who have a very large prostate. In TURP, an endoscopic probe is inserted through the urethra into the prostate. The prostatic tissue is ablated little by little with a resection loop attached to the tip of the endoscope, and is flushed out of the prostate bed and bladder.

The second group comprises various newer treatment procedures that are regarded as less invasive and less burdensome for the patient. This includes holmium laser techniques, some of which use a laser probe to resect small pieces of prostate tissue, similar to the TURP method. In other laser techniques (e.g. contact laser ablation or visual laser ablation), a laser probe inserted via a cystoscope is used to heat areas of prostatic tissue to such an extent that they become necrotic. Other procedures such as microwave or ultrasound therapy also overheat prostatic tissue.

The third group includes the option of initially withholding treatment (watchful waiting) and other treatment procedures such as drug therapies.

## Methods

This report was based on a systematic literature search for comparative studies in international literature databases. In addition, an association of manufacturers was contacted. The search was focussed on controlled clinical studies with or without random allocation (randomisation).

## Results

A total of 56 studies were included in the benefit assessment, studies in which 6039 men with an average age of at least 60 years had participated. Patients had been randomised to treatment groups in 55 of the 56 studies. Despite the large number of randomised controlled studies, the evidential value of results was in part extremely limited because of the studies' methodological deficits. Most of the studies or publications were of low quality; 51 of the 56 studies were of such low quality that their conclusions must be challenged.

Standard procedures such as TURP were compared with a total of 15 other therapeutic procedures. None of these 15 comparisons indicated that any of the alternative procedures showed improved or equivalent symptom relief compared with standard therapy. However, one procedure (transurethral microwave thermotherapy; TUMT) showed greater symptom relief compared with a sham intervention. Another procedure (visual laser ablation of the prostate; VLAP) provided an indication that symptom relief was greater compared with no intervention (watchful waiting). This can be assumed at least indirectly for 2 further procedures (holmium laser resection of the prostate, HoLRP; holmium laser enucleation of the prostate, HoLEP).

Overall, hospitalisation time was longer after standard therapy compared with other therapies. One procedure (TUMT) can be performed on an outpatient basis and does not require a general anaesthetic.

No consistent conclusions on quality of life and catheterisation time can be made, neither can reliable conclusions be drawn on adverse event rates, as these rates were not recorded and reported systematically. However, there were indications that some non-drug local treatment procedures required repeated interventions compared with standard therapy, but that on the other hand, standard therapy led to more major bleeding events than less invasive procedures. The possibility of the occurrence of a transurethral resection (TUR) syndrome, caused by the performance of a TURP, was excluded for most of the procedures tested due to the type of technique applied.

## Conclusions

Men seek medical consultation for the treatment of BPS in order to achieve symptom relief and the related increase in quality of life. They also wish to undergo treatment with procedures that avoid adverse events (particularly serious ones such as major bleeding).

None of the 15 non-drug local procedures to treat BPS that were assessed in this report showed improved or equivalent symptom relief, i.e. an additional benefit, compared with standard therapy. The interpretation of data on adverse events was limited. If the main focus for the patient is symptom relief, then standard therapy should be used. However, if other factors are pivotal in the choice of treatment, such as hospitalisation time and the avoidance of serious adverse events, some non-drug local procedures are available that indicate that these aims can be achieved.

Some of the alternative procedures have the advantage of shorter hospital stays compared with standard therapy, and one procedure can be performed on an outpatient basis.

**Key words:**

BPH, BPS, benign prostatic hyperplasia, benign prostatic syndrome, prostate, non-drug, surgical procedure, systematic review