

IQWiG Reports – Commission No. N09-01

**Non-drug
local procedures
for treatment of
benign prostatic
syndrome - update¹**

Executive Summary

¹Translation of the executive summary of the rapid report “Nichtmedikamentöse lokale Verfahren zur Behandlung des benignen Prostatasyndroms - Update” (Version 1.0; Status: 14.12.2009). Please note that 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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Background

On 2 June 2008 the Institute for Quality and Efficiency in Health Care (IQWiG) produced a final report commissioned by the Federal Joint Committee (G-BA) on assessing the benefit of non-drug local procedures for treatment of benign prostatic hyperplasia (BPH) – nowadays better known as benign prostatic syndrome (BPS). This was sent to the contracting agency (commission N04-01) [1]. The last update search for this report took place on 13 December 2007. Following the decision on 3 September 2009 of the sub-committee responsible, the G-BA commissioned IQWiG in its letter dated 14 September 2009 to produce a rapid report as an update to the IQWiG report. The objective was to collect and analyse literature published since 13 December 2007 on the benefit and medical necessity of non-drug local procedures for treatment of benign prostatic syndrome. The update search necessary for the rapid report was to match the system used in the original search in order to ensure uniformity in the procedure; the same applied in analysing the evidence obtained.

Research question

The aim of this investigation was:

- to find out whether the literature since published on the topic (using the same system of search and analysis as in the original final report) changes the conclusion of the final report on any of the individually assessed procedures.

Methods

Basically, the same methods were to be applied in this rapid report as in the benefit assessment in the final report N04-01. Accordingly, reference is simply made here to Chapter 4 of the final report N04-01 (pp. 19 ff.) [1].

The only deviations compared to the final report are adapting the search strategy (primarily due to changes in the thesaurus of the databases) and an additional search in PubMed.

Results

On the basis of the systematic literature search, 14 new controlled trials (described in 17 publications) were included, of which 9 were randomized controlled trials (RCTs) and 5 clinical controlled trials (CCTs). However, after closer inspection, the latter could not be included in the assessment as none of these non-randomized trials appeared to have considered prognostic factors, without which the results essentially cannot be interpreted. This

left 9 RCTs (described in 12 publications) with a total of 799 patients. This increased the total number of all patients included in the final report N04-01 by approximately 13%. In addition, new data were available on 3 procedures that had not yet been assessed or could not be assessed in the final report N04-01. These procedures were PVP,² HIFU,³ and TmLRP.⁴ However, new data were available only for the holmium laser procedure already assessed in the final report N04-01 (on HoLAP⁵ and HoLEP⁶). Consequently, no new studies were identified on the following procedures: CLAP,⁷ VLAP⁸ (including VLAP DB⁹), hybrid laser therapy, ILC,¹⁰ HoBNI,¹¹ HoLRP,¹² TUMT,¹³ TUNA,¹⁴ WIT,¹⁵ TEAP.¹⁶

The report quality of the included studies was inadequate, as was the case in the final report N04-01, where approximately 90% of studies included had relevant quality deficits.

The observation period in the studies was 3 to 18 months, so that long-term data in particular were lacking in the application of the following procedures assessed for the first time in this rapid report: PVP, HIFU and TmLRP. The baseline characteristics of the patients in the studies were mostly comparable with those of the final report N04-01. Only the IPSS¹⁷ was used to measure irritative and obstructive symptoms; the 1-item question in the IPSS was mainly used to ascertain the deterioration in quality of life caused by irritative and obstructive symptoms. In the majority of studies, sexual function was also measured, mainly using the IIEF¹⁸ in the 5-item version.

For the comparison of HoLEP vs. standard treatment, 2 new RCTs were identified, each with a low number of patients (altogether 90) and relevant quality deficits. The studies yielded no new conclusions beyond those found in the final report N04-01.

An RCT with a moderate number of patients (109) and relevant quality deficits was identified for the comparison of PVP vs. HoLAP. There was no indication of an advantage for any of the interventions.

² photoselective vaporization of prostate

³ high intensity focused ultrasound

⁴ thulium laser resection of prostate

⁵ holmium laser ablation of the prostate

⁶ holmium laser enucleation of the prostate

⁷ contact laser ablation of the prostate

⁸ visual laser ablation of the prostate

⁹ visual laser ablation of the prostate with debridement

¹⁰ interstitial laser coagulation

¹¹ holmium laser bladder neck incision

¹² holmium laser resection of the prostate

¹³ transurethral microwave therapy

¹⁴ transurethral needle ablation

¹⁵ water-induced thermotherapy

¹⁶ transurethral ethanol ablation of the prostate

¹⁷ International Prostatic Symptom Score

¹⁸ International Index of Erectile Function

For the comparison of PVP vs. standard treatment, 3 RCTs with a low or moderate number of patients (altogether 320) and relevant quality deficits were included. For this reason and linked to the inexplicable heterogeneity in the results, no robust conclusions can be drawn at the present time concerning the value of PVP as superior, inferior or equivalent to the standard treatment when considering irritative and obstructive symptoms. Thus, the relevance of indications of advantages in shorter hospital stays and catheterization times when compared with the standard treatment remains as yet unclear (i.e. until more data with less potential for bias are available on symptom reduction).

For the comparison of HIFU vs. standard treatment (TURP¹⁹), an RCT was identified with a low number of patients (80) and major quality deficits. Due to these two aspects, no robust conclusions can be drawn from the study; moreover, the transferability of the results from this study is doubtful.

For the comparison of TmLRP vs. standard treatment (TURP), 2 RCTs with a moderate number of patients (altogether 200) and relevant quality deficits were included in this rapid report. There is no indication from this procedure that symptoms are relieved equally (“maximal irrelevant inferior”) or better when compared to standard treatment, so that the relevance of indications of advantages in shorter hospital stays or catheterization times when compared to TURP remains unclear. However, there is an indirect indication of benefit of TmLRP compared to a (putative) sham treatment in ameliorating irritative and obstructive symptoms.

A summary of the 2 laser resection procedures (HoLRP and TmLRP) provides the following information: there are 3 studies on the comparison with TURP as standard treatment with a moderate number of patients (altogether 320) and relevant quality deficits. Despite the uncertainty of data in Fu 2009, there are indications at 6 and 12 months of a maximal irrelevant inferiority when applying the irrelevance criterion of 0.25 units of standard deviation as laid down in the final report N04-01. When considering both procedures together, however, no indications can be derived of an advantage in quality of life. The indications of advantages in length of hospital stay and of catheterization with HoLRP compared to TURP as standard treatment are strengthened by the results with TmLRP. The results on adverse events and complications also correlate (no indication of a difference).

Conclusions

This assessment has provided no indication that new scientific findings not yet included in the final report N04-01 (Non-drug local procedures for treatment of benign prostatic hyperplasia) qualitatively alter the conclusion of the final report.

¹⁹ transurethral resection of the prostate

As no pertinent new studies were identified, there are no changes compared to the final report N04-01 for the following procedures: CLAP, VLAP (including VLAP DB), HoBNI, hybrid laser therapy, ILC, TUMT, TUNA, WIT, TEAP.

Despite newly identified studies, there were no assessments that qualitatively altered the conclusion of the final report N04-01 for:

- **HoLAP**
The newly identified study on the comparison with PVP does not permit any conclusions on the (additional) benefit of the procedure, as the two procedures are not standard procedures and no advantage in favour of either of the two procedures could be identified.
- **HoLEP**
The two newly identified studies did not provide any new conclusions beyond those found in the final report N04-01.
- **HIFU**
The newly identified study did not permit any robust conclusions due to the major quality deficits. Furthermore, it is doubtful whether the results of this study from China can be transferred to the treatment context here.
- **PVP**
The 3 studies included do not permit any robust conclusions on whether PVP is inferior, superior or equivalent compared with the standard procedure when considering the irritative and obstructive symptoms. As this is a prerequisite for a considered appraisal of the indications of an advantage in shorter hospital stays, shorter catheterization times and fewer occurrences of bleeding requiring treatment (serious adverse event) compared to the standard treatments, there is no fundamental change in the assessment.
- **HoLRP**
Although no new study was identified on HoLRP, when it was considered together with TmLRP, there were increased indications of maximal irrelevant inferiority (therapeutic equivalence) compared to standard treatment, and the advantages in shorter hospital stays and catheterization times. However, indications of an advantage in quality of life are no longer sustainable.

Resection using a thulium laser (TmLRP) was included initially as a new procedure in this rapid report. Assessing this procedure together with HoLRP seems justified; as a result, it provides no fundamental change in the conclusion of the final report N04-01, either.

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

The full report (in German) is available on www.iqwig.de/index.958.html