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Review – Bladder Outlet Obstruction

Techniques and Long-Term Results of Surgical Procedures for BPH

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Abstract

Objective: To provide an overview on the current status of the long-term outcomes of instrumental treatment options for patients with lower urinary tract symptoms that are suggestive of bladder outlet obstruction.
Methods: Based on MEDLINE database searches, we performed a systematic review of the literature with a focus on peer-reviewed articles about surgical benign prostatic hyperplasia (BPH) therapy published between 2000 and 2005. Special emphasis was given to randomized controlled trials on long-term outcome with a minimum follow-up of five years.
Results: Data on clinical outcome with a follow-up of more than 10 years are available for open prostatectomy (OP), transurethral resection of the prostate (TURP), and transurethral microwave therapy. Studies with a follow-up of at least five years are obtainable for transurethral incision of the prostate, transurethral vaporisation of the prostate, transurethral needle ablation of the prostate, Holmium:YAG laser enucleation of the prostate, potassium-titanyl-phosphate laser vaporization of the prostate, and interstitial laser coagulation of the prostate. Among these long-term reports, OP and TURP provide the most durable results.
Conclusions: The most substantial long-term data on surgical procedures for BPH are available for conventional therapy, namely TURP. Concerning the techniques that have emerged within the last decade, there is clear evidence that the outcomes are more sustainable for truly ablative and thus deobstructing procedures.

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1. Background

The urologist's armamentarium for treating lower urinary tract symptoms (LUTS) that are suggestive of bladder outlet obstruction (BOO) has been expanded dramatically within the last decade. Besides specific medical therapy options, various novel or distinctively modified instrumental procedures have been

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introduced. Many of these emerging techniques are considered minimally invasive therapies because of their favourable safety profile compared to conventional ablative therapy. Nevertheless, the primary goal of benign prostatic hyperplasia (BPH) therapy must be an effective relief of symptoms associated with BOO. The treatment of choice may be adapted for the individual patient, taking into account essential matters like potential morbidity, probable clinical outcome, need for hospitalisation, necessity for anaesthesia, and costs. Increasing economic restraints make the issue of long-term efficacy of utmost importance for assessing upcoming instrumental BPH procedures. In most countries, health authorities warrant long-term information on the durability of interventional techniques.

Many of the novel minimally invasive therapy options are characterised by the absence of long-term data on efficacy. Of note, the idiom *long-term* is used variably in the literature, and ranges from 12 months to 22 years [1,2]. Most reports about long-term outcomes of surgical BPH procedures, even conventional techniques as transurethral resection of the prostate (TURP) or open prostatectomy (OP) represent open, uncontrolled, often single-centre experiences. Data from randomised controlled trials (RCTs) about durability longer than three years for interventional BPH therapies are scarce.

This lack of true long-term reports can be explained for novel ablative laser procedures like Holmium:YAG laser enucleation of the prostate (HoLEP) [3] or 80-W potassium-titanyl-phosphate laser vaporization of the prostate (KTP laser) [4] by their more recent introduction. Also, formal and legal matters as well as staff fluctuations (especially in academic settings) make RCTs with significant long-term follow-up difficult to initiate and retain.

This article was based on MEDLINE database searches. A systematic review of the literature on surgical BPH therapy published between 2000 and 2005 was performed. Long-term outcome in our view presumes a minimum follow-up of five years; thus, we gave attention to those reports with a special emphasis on RCTs.

2. Transurethral resection of the prostate

TURP has been the benchmark therapy for BPH and for decades has been considered the reference standard of surgical treatment. This idiom in particular applies to long-term considerations, since several reports provide durable follow-ups from eight to 22 years [5–12]. There are no similar data on durability for any other instrumental BPH treatment option, including OP. In a very recent large-scale study Madersbacher et al. presented the long-term outcome of 20,671 men who underwent TURP in Austria [8]. The nationwide data were provided by health authorities. They report an overall incidence of a secondary procedure associated with the initial TURP of 5.8%, 12.3%, and 14.7% at one, five, and eight years of follow-up. These figures include secondary TURP, urethrotomy, and bladder neck incision. Specifically, secondary TURP had to be performed in 2.9%, 5.8% and 7.4% of patients for the same follow-up periods. In terms of reintervention, these more contemporary data show a superior outcome compared to the landmark study by Roos et al. [9], who reported reoperation rates of 12%–15.5%, eight years after TURP. Moreover, they extensively discussed the increased incidence of myocardial infarction at eight years (relative risk: 2.5), which led to a higher mortality after TURP compared to OP reported by the latter group. This could not be confirmed by the current study (4.8% resp. 4.9%). These findings are comparable to work published by Shalev et al., who could demonstrate no significant difference in an eight-year actuarial cumulative incidence of myocardial infarction between TURP (6.3%) and OP (6.9%) [11].

These results are comparable to reports by Wasson et al., who identified 188,161 Medicare beneficiaries in the United States who underwent TURP [12]. They assert a reoperation rate of less than 5% at five years. In another recent publication, Varkarakis et al. presented long-term morbidity of 577 patients with a minimum follow-up of 10 years [6]. They describe a reintervention rate of 6% within that period. Specifically, 2.4% required surgery for bladder neck contracture, 1.9% for recurrent prostatic obstruction, and 1.7% for urethral strictures. As far as patient contentment is concerned, they state excellent functional outcome with a mean IPS score of 4.9 and a mean quality of life (QOL) score of 1.2 more than 10 years after TURP.

Less current, but noteworthy because of an impressive follow-up 12–22 years later are findings by Koshiba et al. that states a reoperation rate of 5.6% within this period [2]. Concerning mortality, actuarial survival rates did not differ substantially for patients who underwent TURP and OP, and exceeded the expected survival rates in the general male population in Japan.

A similar report from Zwergel et al. with a follow-up of more than 15 years after TURP yields low rates of urethral strictures (1.7%) and bladder neck contractures (2.7%) [10]. Questionnaires about the patient's contentment after that period showed 79% of the patients still satisfied, 12% neutral, and 9%

dissatisfied with their micturition. Overall the patients reported a generally favourable view of TURP outcome in the long-term follow-up.

In a recent elaborate long-term urodynamic study by Thomas et al., 217 men underwent TURP with a mean follow-up since surgery of 13.0 years [7]. A significant, sustained decrease in most symptoms and improvements in urodynamic parameters could be seen. Of note, long-term symptomatic failure and decreased flow rate were principally associated with decreased detrusor contractility rather than obstruction. The authors demonstrate that patients with clear BOO benefit most from deobstruction. In conclusion, the outstanding long-term treatment efficacy of TURP is well documented.

3. Transurethral incision of the prostate

Some authors advocate transurethral incision of the prostate (TUIP) as an ideal treatment option for younger, sexually active men with prostate volumes <30 ml. In a meta-analysis of six RTCs that compared TUIP with TURP with a follow-up of more than six months [13–18], Madersbacher et al. concluded that efficacy of TUIP in that subgroup is comparable or slightly inferior to TURP [19]. Nonetheless, reintervention rates were clearly favourable for TURP compared to TUIP (2.6% vs. 15.9%). Concerning morbidity, TUIP provided superior results in terms of blood transfusions (TUIP: 0.4% vs. TURP: 8.6%) and retrograde ejaculation (TUIP: 18.2% vs. TURP: 65.4%).

Similar overall findings are reported in another meta-analysis performed by Yang et al. [20]. They conclude that for small prostates, TUIP yields effectiveness for the first 12 months (comparable to TURP), but with decreased morbidity. However, they add that there is little evidence on the long-term effectiveness of TUIP two to 10 years after the intervention.

In a more recent study by Tkozc and Prajsner, patients with prostates smaller than 30 ml were randomised to TUIP or TURP and were re-evaluated after 24 months [21]. Follow-up included pressure-flow examinations. In summary, the clinical results mentioned earlier could be confirmed by urodynamic parameters. The authors conclude that TUIP is effective and safe for patients with small prostates. For such patients TUIP is recommended in the European Association of Urology (EAU) [22] and American Urological Association (AUA) [23] guidelines on BPH. However, given a ratio of 1 to 36 for TUIP vs. TURP in the U.S. Medicare program for 1999 [20], some urologists believe that TUIP is an underused technique. However, candidates for TUIP form a select patient group.

4. Open prostatectomy

If conservative treatment fails in patients with benign prostatic syndrome, OP at the moment represents the only validated approach in the treatment of large prostates. OP has been described via perineal, retropubic, and suprapubic routes. Also, the technique of laparoscopic retropubic prostatectomy has been described [24,17]. There are few data in the recent literature about its long-term efficacy. Varkarakis et al. evaluated data of 232 patients who underwent open transvesical prostatectomy for BPH during a five-year period [5]. Improvement in International Prostate Symptom Score (IPSS), postvoid residual (PVR) urine volume, and maximal flow rate was statistically significant at eight to 12 months and remained statistically significant at the last follow-up visit. Long-term complications included bladder neck contraction in five (3.3%) that occurred at a mean of 10 months, urethral strictures in one (0.6%), and meatal stenosis in two (1.3%). Re-operation was required in six patients (3.9%). Adam et al. evaluated the patient files of 201 patients retrospectively for operation outcome parameters [25]. They found significant differences in pre- and postoperative median residual urine volume (85 vs. 0.0 ml) and pre- and postoperative median urinary flow (6.0 vs. 20.8 ml/s). Postoperative complications were rarely seen in either group. The rates of postoperative complications were permanent incontinence 0.5%; endoscopic revision (bleeding) 3%; open revision 1%; urinary tract infection 13%; and secondary wound healing 5.5%. In conclusion, transvesical prostatectomy is an effective technique with a low rate of complications with durable success.

5. Transurethral vaporization of the prostate

Transurethral vaporization of the prostate (TUVP), a technique that employs well-known electrosurgical principles, was introduced approximately 10 years ago [26]. At the moment data about two RCTs with a follow-up of more than five years are available. In a prospective study Hammadeh et al. compared TUVP with conventional TURP and followed their patients for five years [27]. They conclude that TUVP is as effective as standard TURP in the treatment of medium-size prostates. The reintervention (13% at five years in each arm) and complication rates were comparable and initial improvement could be maintained during a five-year period for most patients who underwent TUVP. Of note, prostate size was rather

small with 27 ml (TURP) resp. 32 ml (TUVP). The fairly excessive energy application during TUVP [28], an issue that has been associated with postoperative dysuria, urge incontinence, and erectile dysfunction generated no adverse events. New onset impotence was higher in the TUVP group (17%) than in the TURP group (11%) but did not reach statistical significance.

These findings are confirmed by van Melick et al., who prospectively randomised men to TUVP or TURP with a mean follow-up of 4.3 years [29]. They demonstrate durable subjective and objective results for patients with LUTS who were treated by TUVP. Again, prostate sizes were noticeably small, averaging 37 ml (TURP) resp. 35 ml (TUVP).

Because of the limited numbers of long-term reports and the decreasing clinical employment, in our view TUVP should, because of its favourable safety profile, be reserved for patients at higher risk, as recommended by EAU [22] and AUA [23] guidelines for the treatment of BPH.

6. Transurethral vaporization-resection of the prostate

Evolving from TUVP, Transurethral vaporization-resection of the prostate (TUVRP) was introduced 1996 [30]. This modification contains a thicker resection loop that claims to combine the hemostatic properties of TUVP with the efficacy of conventional TURP. Despite single centre experiences [31], RCTs are scant, particularly those with a longer follow-up. In such a randomised study of TURP with a follow-up of 12 months Gupta et al. concluded that TUVRP for prostates >40 cc is beneficial, as it significantly reduces operating time, blood loss, irrigant requirement, and duration of catheterisation [32]. Similar results were obtained in a different RCT that compared TUVRP with conventional TURP with a limited follow-up of nine months [33]. On the other hand Holmes in their study with short follow-up found that TUVRP offers no advantage over standard TURP [34].

7. Transurethral microwave thermotherapy

Long-term data about transurethral microwave thermotherapy (TUMT) are to be interpreted cautiously due the high drop-out rate of patients at the end of the study. Several studies were performed with a study length of 2.5–11 years [35,36]. Symptom score changed between 5.9 and 13 points, Qmax improved from 10.5 ml/s to 15.5 ml/s, depending on the specific device that was used.

Daehlin et al. reported on a five-year follow-up after TUMT with a lower power treatment protocol [36]. Ninety-one patients were treated in a one-hour session with the PRIMUS U + R device. Twenty-nine (32%) of the patients were evaluable after five years, but 42 had received additional treatment for their lower urinary tract symptoms. The decrease in IPSS was 37% compared with the pretreatment value. A moderate increase in peak uroflow one year after TUMT was not confirmed in an extended follow-up. Patients still on TUMT monotherapy after five years had smaller prostates than the group who received additional treatment. No serious side effects were observed. Francisca et al. evaluated the long-term results of lower-energy TUMT using the Prostasoft 2.0 and determined predictors for a favourable treatment outcome [37]. A total of 1,092 patients were evaluated. Re-operation rate was the primary endpoint for further evaluation. After treatment the improvement in uroflow was 2–3 ml/s. This was maintained for up to five years after treatment for the patients who remained in follow-up. The overall improvement in the Madsen symptom score was five to six points for these patients. The absolute instrumental retreatment rate appeared to be 26%; however, when patients no longer in follow-up were taken into account, the calculated retreatment rate was 39.6%. The authors concluded that TUMT gives a sustained objective and subjective improvement in patients with moderate symptoms and a low-grade bladder outflow obstruction; patients with larger prostates, severe symptoms, low rates of maximal uroflow, and large residuals are not the ideal candidates for this treatment. The absolute instrumental retreatment rate after five years was 26%.

Vesely et al. evaluated the durability of the effect of TUMT for BOO in 841 patients who used the Prostatron device [38]. The mean follow-up after TUMT was 8.8 years for Program 2.0 and 2.5 years for Program 3.5 In this study, two treatment programs were used: low-energy Program 2.0 and high-energy Program 3.5. At the end of follow-up, 67% of the patients treated with Program 2.0 were satisfied with the TUMT. During the follow-up period, 37% of patients experienced worsened symptoms, 18% various complications (e.g., haematuria), 25% transient urinary tract infection, and 16% went into retention. Secondary treatment (repeat TUMT, transurethral resection, medical therapy) was needed in 32% of patients. The mean IPSS was 13.5 and QOL score decreased to 2.1. Only 7% of patients needed secondary treatment. The IPSS and QOL scores decreased to 11.4 and 1.6, respectively. Ohigashi et al. presented a study in 102 patients who

were treated with TUMT and used a Prostatron device (Prostasoft version 2.0 J) [39]. Sixty-seven percent of the patients received additional treatment within five years. The patients with a peak flow rate greater than 6.5 ml/s, with a prostatic urethral length <40 mm, or who were older than 64 all demonstrated a significantly longer period before receiving additional treatment. These three factors were also significant for predicting long-term outcome. This study concluded that overall durability of TUMT was limited; aged patients with a relatively high peak flow rate or with a short prostatic urethral length resulted in lower risk of receiving additional treatments after TUMT.

Taken all into account, long-term treatment with TUMT seems to be promising, especially concerning modifications in third-generation systems, which allow for better tissue ablation.

8. Transurethral needle ablation

Transurethral needle ablation (TUNA) creates cavities in the inner region of the prostate and preserves the prostatic urothelium. Five-year efficacy and safety of TUNA were evaluated recently. Zlotta described five-year-follow-up results in 188 patients with symptomatic BPH [40]. The authors reported at a mean follow-up of 63 months a significant increase in mean urinary peak flow (from 8.6 ml/s to 12.1 ml/s; IPSS and PVR decreased from 20.9 and 179 ml to 8.7 and 122 ml, respectively). Medical treatment was given to 12 patients (6.4%), a second TUNA performed in seven patients (3.7%) and surgery indicated in 22/186 (11.1%). In this study, more than 75% of the patients needed no additional treatment. Hill et al. compared TUNA with standard TURP in a randomised multicentric clinical trial in 121 men [41]. Improvements in IPSS, QOL, peak flow rate, and PVR volume were statistically significant at all time points for TURP and for TUNA after five years. Ejaculation disorders and the incidence of erectile dysfunction, incontinence, and stricture formation were greater in TURP than in TUNA.

In conclusion, the follow-up of five years of treatment revealed that the risk of adverse events was lower for the TUNA group and the overall improvement was superior in the TURP group. Boyle et al. conducted a meta-analysis based on data abstracted from two RCTs, two nonrandomized observational protocols, and nine single-arm studies conducted on TUNA therapy [42]. There was a significant improvement in symptoms and flow rate after one year that persisted for at least five years. A second meta-analysis based on more than 30 studies showed a significant reduction of symptoms and voiding parameters for TUNA; complication rates were significantly lower than for TURP [43]. The authors concluded that patients with predominant irritative voiding symptoms and a moderate obstruction and high-risk patients who could be treated only under local anaesthesia would be suited ideally for TUNA.

Very recently, Naslund et al. compared the cost of medical management with TUNA therapy for a five-year period [44]. During that time, TUNA generated less expense than combination medical therapy (5alpha-reductase inhibitor together with an alpha-blocker), with a break-even point at approximately two years, seven months, but was more expensive than alpha-blocker monotherapy. 5alpha-reductase inhibitor monotherapy was approximately equivalent to TUNA for five years. In conclusion, TUNA seems to be a safe and effective technique in the treatment of BPH; nevertheless, studies with a longer follow-up are awaited.

9. Interstitial laser coagulation of the prostate

Interstitial laser coagulation of the prostate (ILC) was introduced into clinical practice 12 years ago [45]. Nevertheless, comparative long-term data are scant. Most findings derive from uncontrolled studies with a rather limited follow-up. In a review of the few RCTs that compared ILC with TURP, Laguna et al. found that morbidity associated with ILC is minimal, whereas instant postoperative complications include acute urinary retention and irritative voiding [46]. They report retreatment rates of 15% at one year, which further increases to 40% at three years after surgery.

Similar outcomes of an RCT of ILC versus TURP after one year follow-up are presented by Liedberg et al. [47]. ILC patients had significantly more irritative symptoms, higher incidence of urinary tract infections, and lower urinary peak flows. On the other hand, in a long-term study with a mean follow-up of seven years, Knoll et al. demonstrated a significant decrease in IPSS from 18.8 preoperatively to 8.8 as well as in QOL (3.3 to 1.5) [48]. Also, 68.4% of the patients were satisfied with their micturition. The reoperation rate (all patients received conventional TURP) was 15.8% at a mean of seven years after ILC.

In another recent publication with a mean follow-up of 48 months by Terada et al., 72% of the patients needed no additional treatment at 12 months and 37% required no additional treatment during the entire follow-up period [49]. Twenty-nine patients

(35%) were retreated during follow-up. They found that short-term improvement of subjective symptoms predicted favourable long-term outcome.

10. Holmium Laser Enucleation of the Prostate

Several systematic reviews on laser prostatectomy in general and holmium prostatectomy in particular were published recently [50,51]. They concluded that HoLEP was at least as effective as TURP in improving LUTS. However, because of the lack of studies with long-term follow-up data, no final statement was made about the long-term efficacy of HoLEP compared to TURP.

Short-term outcome of HoLEP and its forerunner Holmium laser resection of the prostate was assessed in several studies and described as a safe and effective alternative to TURP and OP [50,52–55]. HoLEP also represents an effective treatment with low morbidity in patients with BPH who present with urinary retention [56,57].

Very recently, Elzayat et al. reported a seven-year follow-up of HoLEP that included 552 patients with symptomatic BPH [58]. The authors detected a significant improvement in voiding parameters with a 200% increase in Qmax, as well as a 75% improvement in IPSS one year postoperatively, which continued to improve during subsequent follow-up. Eleven patients required blood transfusion; eight of these were on anticoagulant therapy. Irritative symptoms were noted in 9.4% and transient stress incontinence in 4.2% of patients. Bladder neck contracture and urethral stricture developed in 1.3% of patients.

Thus, HoLEP represents a safe and effective procedure for treating symptomatic BPH independent of prostate size, with low morbidity and short hospital stay. Nevertheless, a limitation of this technique is the long learning curve associated with the rather small number of experts in this field.

11. Potassium-titanyl-phosphate laser vaporization of the prostate

The first clinical report on the contemporary 80 W (KTP) laser was published in 2003 by Hai and Malek [4]. The promising results in terms of efficacy and safety could be confirmed by others [59–62]. However, these data derive from uncontrolled clinical trials with very limited follow-up with a maximum of 12 months. At the moment, only one nonrandomised controlled study has been undertaken to prospectively compare KTP laser vaporization with conventional TURP [63]. The functional results of KTP laser compare well with TURP but provide an essentially superior complication and morbidity profile. The mean follow-up of six months is certainly limited and does not permit any statement on durability.

Malek et al., who pioneered this technique, very recently reported on results with a follow-up of up to five years [64]. They state excellent clinical outcome, without necessity of reintervention and sustained symptomatic and urodynamic improvements. Complications are described as mild and rare with transient dysuria (6%), delayed haematuria (3%), bladder neck contracture (2%), and retention (1%). However, this report has to be judged cautiously, since 79 of the 94 patients were treated with the 60-W unit; only the last 15 received therapy with the contemporary 80-W setting. Moreover, of the total number of patients, only 14 (15%) were actually evaluated five years after surgery. Even at three years, only 32 patients (34%) were available for examination. Furthermore, the outstanding data on outcome, which clearly seem to be superior to those known for TURP, will doubtfully be confirmed by all future studies, as some report on retention rates of 5%–11%, as well as the necessity for reinterventions even after a limited follow-up of six to 12 months [65,63,60]. To conclude, prospectively randomised trials with long-term data are warranted for this very promising procedure.

12. Conclusions

Obviously, the most substantial long-term data on surgical procedures for LUTS that is suggestive for BOO are available for conventional ablative treatment, namely TURP. Concerning relief of BOO, there is clear evidence that the outcomes are more sustainable for those procedures that are truly ablative and thus deobstructing. Nevertheless, randomised controlled long-term evaluations are not yet available for several techniques even though they were introduced enough time ago. Partly because of this lack of long-term data, conventional TURP and its modifications are experiencing a renaissance.

Unfortunately, urodynamic data for minimally invasive techniques are scarce and thus many of the reports are of inferior value. OP and TURP yield the best outcomes because of urodynamically proven deobstruction.

KTP laser vaporization achieves genuine instant tissue ablation, promising for durable results. However, as with the other treatment alternatives, its

potential has to be confirmed by randomised controlled long-term studies in the future.

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Editorial Comment

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This paper is a timely review of the techniques and long-term results of surgical procedures for BPH. The relevance of this paper to practising Urologists cannot be over emphasised due to the rapid adoption and diffusion of innovative technologies using different sources of energy in ablating prostatic tissue.

The review focuses on the long-term outcome of various interventional procedures in the management of benign prostate enlargement causing bladder outflow obstruction.

It points out that ablative techniques appear to give better long-term results but randomised controlled trials of other techniques are still lacking. Urologists and health service organisations must guard against ''going with the tide'' in adopting new technologies without solid evidence of their clinical and cost effectiveness over known alternatives. There are compelling arguments against the presumption that randomised clinical trials of surgical procedures are not possible or unethical [1].

The usefulness of this review for decision-making is limited due to deficiencies in the method of reporting. A formal systematic review would involve a search strategy, mention of electronic databases, study selection criteria, defined outcomes, data collection/analysis and quality assessment of the literature. The outcome would be an evidence based ''bottom line'' message for the readers, with identification of areas for future research and details of the practical implications of the results for health care. Such a review is certainly needed as we enter yet another possible 'new dawn' of technological advance in the treatment of BPH with the advent of 'green light' laser.

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