

CHOICE OF TREATMENT METHOD FOR SYMPTOMATIC BLADDER OUTLET OBSTRUCTION IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA AFTER KIDNEY TRANSPLANTATION

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The paper presents a comparative assessment of different methods of treating symptomatic bladder outlet obstruction (BOO) in patients with benign prostatic hyperplasia (BPH) who underwent kidney transplantation (KT).

Keywords: bladder outlet obstruction, benign prostatic hyperplasia, kidney transplantation.

INTRODUCTION

Ninety-one years ago, on April 3, 1932, Soviet surgeon, Yury Voronoy, performed the first kidney transplantation (KT) in the world. Since then, there have been major breakthroughs in the field of KT in Russia and around the world [1–3]. KT is championed as the gold standard treatment for patients with end-stage kidney failure [3].

In 2018, over 95,000 KTs were performed worldwide [1]. In the Russian Federation, the number of kidney transplant surgeries increases every year [2].

In the early and late post-KT period, there is a high likelihood of various complications [4–8]. Urological complications in KT recipients, whose incidence is 3–14%, causes longer hospital stay, graft dysfunction and increased mortality [5–10]. One of the complications is bladder outlet obstruction (BOO) in the background of benign prostatic hyperplasia (BPH) [5, 6, 8, 11].

At the same time, the incidence of BPH-associated BOO in the postoperative period increases every year, as the age of recipients increases [4–8, 11, 12]. Urological problems in transplanted kidney recipients are associated with decreased graft survival and lead to higher morbidity and mortality [13–17].

The age of kidney transplant recipients increases every year and, on average, exceeds 55 years [14]. However, it should be taken into account that 50–70% of men over 50 years of age present with lower urinary tract symptoms (LUTS) associated with BPH; LUTS prevalence reaches 80% in men aged 80 [17].

In the pre-transplant period, against oliguria accompanying chronic kidney disease, symptoms of chronic urinary fade into the background and do not bother the

patient. The patient may have no characteristic complaints. Whereas after successful KT, manifestations of BOO on the background of BPH increase and significantly worsen the quality of life (QoL) of patients.

In recent years, there have been significant advances in the treatment of urological complications, largely due to advances in therapy [6–16, 18–21]. A comparative analysis of the availability and efficacy of different methods of treatment of BOO against BPH in kidney transplant recipients is presented in this review.

METHODS OF TREATING SYMPTOMATIC BOO IN BPH PATIENTS WHO UNDERWENT KIDNEY TRANSPLANTATION

Treatment of BOO in KT recipients can be therapeutic, surgical, or combined [18, 19].

It is necessary that the above approaches be personalized after analyzing the comorbidities, age of the patient, size of the prostate gland, etc. [20–27]. After careful examination, the patient's management tactics are determined: dynamic monitoring, drug therapy or surgical treatment [20–26]. Surgical treatment is indicated if conservative approaches to BOO therapy fail [20–27].

Drug therapy for BOO in BPH patients who underwent kidney transplantation

Given the progressive nature of the disease, BPH medication therapy is carried out for a long time, in some patients – for the entire life. In BPH treatment in all patients, several kinds of medicines are used. However, the basic therapy consists of three groups of drugs: alpha-1 blockers (A1Bs, adrenergic alpha-1 receptor ant-

agonists), 5-alpha-reductase inhibitors (5-ARIs), phosphodiesterase type 5 (PDE5) inhibitors [20–26, 28–31].

In the general population, drug treatment of BPH-associated LUTS in kidney transplant recipients initially includes alpha blockers and finasteride in most cases [31]. Medication therapy with AIBs can be used as the first stage of treatment. Adrenergic alpha-1 receptor antagonists are first-line drugs and are used for moderate to severe lower urinary tract syndromes. The action of these drugs begins 48 hours after intake [28, 30].

Currently, five drugs of this group are used in clinical practice: alfuzosin, doxazosin, silodosin, tamsulosin, terazosin [28, 30, 32–34]. The differences between the listed drugs lie in their tolerability, which is due to their pharmacodynamics and pharmacokinetics. AIBs are effective in correcting LUTS symptoms, but do not reduce prostate size or protect against the development of acute urinary retention in the long term. Tamsulosin is the most commonly used AIBs in the world [28, 33].

Several randomized, placebo-controlled clinical trials (RPCCTs): three phase III RPCCTs and two phase IV RPCCTs have been performed to investigate the effectiveness of AIBs in a subgroup of patients with severe BOO [28, 30, 32, 33].

Disease severity was assessed by two or more of the following criteria: International Prostate Symptom Score (IPSS), QoL score, maximum urinary output (Q_{\max}) <5 mL/s or residual bladder volume ≥ 100 mL, prostate volume ≥ 50 mL [30]. The main endpoint of the study was the change in IPSS score relative to baseline.

Comparison of silodosin and placebo among patients with severe LUTS revealed statistically significant differences in favor of the active treatment group compared to the placebo group in terms of improvements in QoL, IPSS, its subscores, and Q_{\max} . 53% of patients with severe LUTS and a baseline total IPSS score ≥ 20 included in a phase III placebo-controlled RPCCT showed an 8–19 improvement in IPSS scores after treatment, 10.2% improved their IPSS score by 0–7 points, and 36.8% showed no significant improvement from baseline. The corresponding figures for patients receiving placebo were 36.6%, 4.8%, and 58.6%. The proportion of patients receiving silodosin who reported improvement (5–6 to 0–4), no effect, and worsening (0–4 to 5–6) of QoL scores was 44.2%, 54.7%, and 1.1%, respectively, and the same rates among patients receiving placebo were 26.4%, 70.6%, and 3.0% ($p = 0.0009$) [30].

Thus, silodosin monotherapy provides statistically significant clinical improvement in the group of patients with severe BOO. These results correlate with the data obtained in the study of patients receiving tamsulosin or alfuzosin, and confirm the favorable pharmacodynamic effect of this class of drugs [30, 32]. It was noted that IPSS scores in patients with severe LUTS against the background of tamsulosin therapy at a dose of 0.4 mg/day improved by an average of 5.8–14.3 points [30].

AB are more effective in severe than in minor manifestations of LUTS [31]. Debruyne et al. [30] found mean improvements in IPSS scores assessing bladder filling and emptying by 1.9 and 3.9 points, respectively, among patients with severe BOO who received tamsulosin at a dose of 0.4 mg/day. These results support the assumption that the effect of AB is mainly to reduce obstruction. Also Debruyne et al. [30] showed an improvement in QoL after 12 months of treatment with tamsulosin 0.4 mg/day. Improvement in Q_{\max} was clinically insignificant. This conclusion is consistent with previously published data demonstrating non-significant correlations between improvements in IPSS parameters and changes in Q_{\max} results against the background of AB therapy [32].

Incomplete reported data on prostate volume, residual urine volume, adverse events (AEs), and isolated outcomes and consequences constitutes a limitation of the aforementioned RPCCTs [28, 30, 32, 33]. As a consequence, results must be interpreted with caution, since severe BOO symptoms may be associated with late stages of bladder wall remodeling [34].

Nevertheless, it can be concluded that daily AB administration significantly improves QoL against the background of reduced severity of BOO, especially in patients with severe LUTS [23, 33]. In this group, drugs provide a 30–40% reduction in the IPSS score and remain effective for several years [35, 36]. Adverse events associated with the use of alpha-blockers include abnormal ejaculation due to decreased or absent seminal fluid, dizziness, and postural hypotension [35, 36].

In moderate to severe LUTS, prostate volume exceeding 40 cm³, 5-alpha-reductase inhibitors, dutasteride and finasteride, are prescribed and are associated with a reduced risk of BPH progression against a reduced incidence of acute urinary retention [36–39].

5-alpha-reductase inhibitors help to reduce IPSS by 15–30%, reduce prostate volume threefold from the initial volume, increase in Q_{\max} by 1.5–2 ml/s, reduce the risk of acute urinary retention, and reduce the frequency of surgical interventions in a long-term (more than 1 year) run. The effect of this group of drugs comes slower than that of 5-ARIs, and is more noticeable with large prostate volumes. Adverse events observed in patients receiving 5-ARIs, include erectile dysfunction, decreased libido and less often ejaculatory dysfunction, retrograde ejaculation and gynecomastia [23].

Muscarinic receptor antagonists can be used against a background of moderate to severe LUTS, although this group of drugs is associated with increased incidence of acute urinary retention [20, 22–24].

With BPH progression and with large prostate gland volume, large residual urine volume, low Q_{\max} , and age >62 years, surgical treatment should be considered [40].

Non-drug methods of treatment of symptomatic BOO in BPH patients who have undergone kidney transplantation

Until the 1970s, the only available treatment and relief for LUTS was open adenectomy (for very large prostate) or endoscopic surgery in the form of transurethral resection to remove or resect prostatic tissue [41].

In the general population, surgical procedures performed for infravesical obstruction in patients with BPH who have undergone renal transplantation include minimally invasive surgical treatments, such as laser techniques, vaporization techniques, mono- and bipolar resections, open, laparoscopic and robotic adenectomy, etc. [18, 19, 21, 42, 43].

Transurethral resection of the prostate (TURP) is one of the methods of surgical treatment of BOO against BPH in kidney transplant recipients [44–47]. Against the background of the high efficiency of TURP in controlling LUTS, long-term adverse effects or adverse events, such as erectile and ejaculatory dysfunction, risk of urinary incontinence, and other complications, have been noted [44–48].

Minimally invasive surgical treatments have emerged as an alternative to TURP, successfully reducing BOO symptoms, while minimizing side effects and complications, and reducing the length of hospital stay [43]. These include transurethral electrovaporization (Rezūm technique), transurethral enucleation, laser enucleation, urolifting, and temporary implantable nitinol device [43].

Electrovaporization involves vaporization of the prostate using high-frequency and high-power currents with coagulation of the underlying layers, without capillary bleeding and without coagulation of large vessels and venous sinuses [49, 50]. *Bipolar vaporization* involves simultaneous bipolar resection and vaporization [49, 50].

Rezūm water vapor thermal therapy (Rezūm System, Boston Scientific, Marlborough, Massachusetts) is an innovative minimally invasive surgical treatment approved by the US Food and Drug Administration (FDA) in 2015 to reduce prostate tissue volume associated with BPH, including central zone and/or middle lobe hyperplasia [49–50]. The accumulated thermal energy (540 calories/ml H₂O) is transferred as vapor to the prostate tissue. Thermal effects do not occur beyond the target treatment area [49, 50], thus eliminating the limitations of conductive heat transfer seen in transurethral needle ablation of the prostate (TUNA) and transurethral microwave thermotherapy (TUMT) [51–54].

The most unique feature of this technique is the possibility to influence the lateral and central zones of the prostate gland. Complex anatomical variants, such as intravesical prostatic protrusion, can be treated without affecting sexual function [53]. This technique has been used throughout the United States and Europe for 5 years since FDA approval [49–58]. According to the multi-

center, prospective, blinded, controlled trial of water vapor heat therapy (Rezūm II Study, NCT01912339), the wide use of this technique is attributed to sustained relief of LUTS, improved QoL, and long-term response to treatment [49–58]. An RPCCT (Rezūm II Study, NCT01912339) showed that BPH heat therapy has clinically significant results and a proven long-term effect [49, 51–53]. Five years after the procedure, a 30% improvement in IPSS and no recurrence of BPH were found [49–57]. Despite the fact that the majority of patients had pronounced manifestations of LUTS at inclusion in the study (72.5% with IPSS 19–35), these parameters improved in comparison with the initial ones 3 months after a single water vapor heat therapy procedure, without a negative effect on erectile function [49–58].

Other minimal surgical techniques, such as prostatic urethral lift (PUL) or other implantable devices, provide symptomatic relief without tissue removal [59–61]. However, repeated interventions are required to achieve a permanent reduction in LUTS severity with urethral lift surgery [60, 61].

Patients in the general population who may be candidates for water vapor thermal therapy are often referred for more invasive surgical techniques such as TURP, holmium laser enucleation of the prostate, or other treatments that have a high risk of bleeding, longer recovery time, reduced erectile function, and other undesirable side effects [62–65].

In 2018, a study was performed on the long-term outcomes of treatment of lower urinary tract symptoms caused by BPH using a single Rezūm® System water vapor thermotherapy treatment with daily drug therapy: doxazosin and/or finasteride [63]. Thermal therapy resulted in a 50% improvement in IPSS scores at 36 months ($p < 0.0001$). The improvement in symptoms was more pronounced than with one of the drugs, but similar to that with the combined drugs ($p \leq 0.02$ and 0.73 , respectively). Q_{\max} improved by 4–5 mL per second after thermal therapy and doxazosin, while thermal therapy was superior to finasteride and combination drugs at 24 and 12 months.

Thus, a single session of water vapor thermal therapy provided effective and sustained improvement in symptom scores with a lower observed rate of clinical progression compared with daily long-term use of pharmaceuticals [63].

High-tech methods of LUTS treatment, such as transurethral enucleation of the prostate with a holmium or thulium laser, are now widely used [66–69].

Laser enucleation involves excising the prostate gland up to its surgical capsule, and the enucleated tissue is then moved into the bladder and removed [66–69]. *Holmium laser enucleation of the prostate (HoLEP)* is used for moderate to severe LUTS against a prostate volume exceeding 80 cm³ [67, 68], and the risk of bleeding against anticoagulant therapy is reduced.

In 2020, data from a multicenter, retrospective pilot comparative study of the efficacy, safety and complications, registered within 1 year, after the following interventions were published: holmium laser enucleation of the prostate, greenlight photoselective vaporization of the prostate (GL-PVP) and TURP performed after KT [70].

From January 2013 to April 2018, 60 BPH endoscopic surgical procedures in KT recipients were performed: 17 patients in the HoLEP group, 9 in the GL-PVP group, and 34 in the TURP group. Age, body mass index, preoperative serum creatinine, preoperative IPSS score, preoperative Q_{max} , preoperative prostate-specific antigen, medical history of acute urinary retention, urinary tract infection and indwelling urethral catheter were similar in all study groups. Mean preoperative prostate volume was higher in the HoLEP group. The rate of overall postoperative complications was statistically higher in the HoLEP group (11/17 [64.7%] vs 1/9 [11.1%] vs 12/34 [35.3%] in HoLEP group, GL PVP group, and TURP group, respectively, $p = 0.02$). After interventions, Q_{max} were comparably improved in both groups [70].

Considering the above data, it can be concluded that the rate of postoperative complications is higher with HoLEP procedure, in comparison with GL-PVP, for the treatment of BPH after KT [70]. One-year efficacy is similar in HoLEP, GL PVP, and TURP groups [70].

One year later, data from a study was published to compare the efficacy and safety of water vapor thermal therapy using the Rezūm™ system and PUL using the Urolift™ system in men with lower urinary tract symptoms due to BPH [71].

From December 2017 to November 2019, consecutive patients who underwent Rezūm™ and Urolift™ procedures in two urology centers were retrospectively considered. Only patients with a prostate size less than 80 mL were included.

A total of 61 (52.1%) and 56 (47.9%) patients underwent Rezūm™ and Urolift™ procedures, respectively. At 12 months, higher IPSS improvement was observed in the Rezūm™ group (median:4 [IQR 3–5]) than in the Urolift™ group (median:8 [IQR 7–12]), without statistical difference ($p = 0.08$). Improvement in QoL at 12 months was similar in the two groups ($p = 0.43$). Reintervention rates were 25% (Urolift™) and 8.3% (Rezūm™), $p = 0.24$. Erection and ejaculatory function scores did not change significantly in either treatment group.

Results have shown that both Rezūm™ and Urolift™ provide clinically significant improvements in symptoms and QoL, although the Rezūm™ procedure appeared to be more effective in the immediate and long-term postoperative period [71].

TURP is the gold standard treatment for BPH in 30–80 cm³ prostate volumes with moderate to severe LUTS [18–21]. *Monopolar TURP* is a well-established option

for surgical treatment of BOO due to benign prostatic enlargement. However, this intervention continues to be associated with a significant risk of postoperative complications [72]. In the light of this, new techniques have been developed to reduce the risk of complications. Unlike monopolar TURP, *bipolar TURP* uses energy confined between the active electrode (resection loop) and the return electrode located on the resectoscope tip or sheath, and lower voltage, theoretically eliminating the risk of TURP syndrome and reducing thermal damage to surrounding tissue [72].

Despite existing studies on the efficacy and safety of monopolar and bipolar TURP over the past decade, there remains uncertainty about the differences between these two surgical techniques. Systematic reviews published prior to 2020 that compared these surgical techniques [73–78] did not include a significant number of recently published randomized controlled trials and did not always adhere to strict methodological standards.

A comprehensive systematic electronic literature search was carried out up to 19 March 2019 via CENTRAL, MEDLINE, Embase, ClinicalTrials.gov, PubMed, and WHO ICTRP. Handsearching of abstract proceedings of major urological conferences and of reference lists of included trials, systematic reviews, and health technology assessment reports was undertaken to identify other potentially eligible studies. No language restrictions were applied. Randomized controlled trials, comparing monopolar and bipolar TURP in men (>18 years) for the treatment of LUTS secondary to BPH, were selected.

A total of 59 RPCCTs with 8924 participants were included. The mean age of the included participants was 67 years; mean prostate volume was 39–83 cm³.

Based on the results of this review, it was shown that bipolar TURP and monopolar TURP relieve LUTS both to a similar degree. Bipolar TURP probably reduces the severity of clinical manifestations of TURP syndrome and postoperative blood transfusion compared to monopolar TURP. The impact of both procedures on erectile function is probably similar. The moderate certainty of evidence available for the primary outcomes of this review suggests that there is no need for further RPCCTs comparing bipolar TURP and monopolar TURP [70]. The most severe complication after prostate gland TURP, with an incidence >7%, is bleeding requiring blood transfusion [70].

In patients in the general population with prostate gland volume <30 cm³, *transurethral incision* of the prostate (TUIP) [79], in which electrosurgical dissection of the prostate gland tissue is performed using a resectoscope loop, is indicated [79].

According to a small study [80] of the early and long-term outcomes of TURP and TUIP procedures performed in the first month following KT, at a median of 19 days

(range 8–30 days), due to BOO against BPH, no AEs were found.

In the early postoperative period, 5 patients (13.1%) developed urinary tract infection. The mean Q_{\max} (22.4 ± 11.1 mL/sec) increased significantly ($p < 0.001$). At the end of follow-up, the groups did not differ in Q_{\max} and IPSS scores ($P = .89$, $P = .27$, $P = .08$, and $P = .27$). Among postoperative complications, the incidence of urinary tract infections and retrograde ejaculation was higher in the TURP than in the TUIP group (12.7% versus 6.2% and 68.1% versus 25%, respectively), whereas urethral strictures were more common in the TUIP group (12.5% versus 6.3%).

Thus, TURP and TUIP techniques have been shown to be equally safe and effective in the surgical treatment of BPH-induced urinary retention in KT recipients with a prostate volume <30 cm³ [80, 81].

As shown above, prostate volume is the main criterion for choosing the method of surgical treatment of BPH [49–82].

Open adenectomy is the most effective and unfortunately, the most invasive method of surgical treatment of BPH in patients with a prostate volume >80 cm³. After this intervention, the effect is most durable [19–21].

Laparoscopic adenectomy is a minimally invasive surgical procedure that is an alternative to open adenectomy in patients with a prostate volume ≥ 90 – 100 cm³ [19–21].

TUNA is less effective than TURP among patients in the general population; it is reserved for patients with severe comorbidities, as this procedure does not require hospitalization of the patient and general anesthesia [84].

In *prostate artery embolization*, blood arteries of the prostate gland are occluded by introducing emboli [85, 86]. With this intervention, acute urinary retention episodes are more frequent in the postoperative period [87].

Prostatic stent is used in patients with contraindications to surgical intervention. This procedure is accompanied by a temporary reduction in LUTS and frequent AEs, so its use is limited.

Robotic surgery has shown high efficiency on the background of significant correction of LUTS, exclusion of postoperative complications and fast recovery after surgery [83].

CONCLUSION

The kidney is the most transplantable organ in the world. In the early post-KT period, urinary retention caused by BOO can directly affect the success of transplantation. Accurate assessment and optimal treatment of LUTS in renal transplant candidates and recipients is crucial for improving the QoL and preserving allograft function [88–98].

LUTS should be carefully evaluated before KT. Postoperative symptoms of moderate to severe LUTS should be carefully investigated so that early intervention can

prevent graft compromise and associated complications. If indicated, BOO surgery can be performed early after renal transplantation [99–101].

Evidence suggests that many of the proposed treatments for BPH-associated BOO developing after KT can offer effective relief of LUTS. Nevertheless, a number of factors may influence the personalized choice of a particular intervention for each patient. This decision depends on patient characteristics like age, comorbidities, severity of LUTS, concomitant treatment such as ongoing anticoagulant therapy and unpredictable drug interactions. It is necessary to balance the desired results with possible risks. Possible effects on sexual function, frequency of reoperation, and the cost of treatment must be considered.

Despite all the advantages of minimally invasive obstruction therapies, several obstacles limit their wider adoption, the first of which are equipment limitations. For example, urolifting requires a special elongated lens, and Rezūm requires a special computerized radiofrequency steam generator [102].

The second limitation in the new technology is the cost, which is well over €1,000 just for the equipment, in addition to the requirement to perform the procedures in specially designated operating conditions [102]. As cost-benefit analysis has shown, the cheaper minimally invasive methods were €900 more expensive than drug therapy for 2 years [102].

Based on a review of disparate literature data, there is insufficient evidence to offer a reliable recommendation for a specific treatment technique for BOO in all BPH kidney recipients. Further clinical trials with longer follow-up comparing different interventions with routine and evidence-based methods are required.

The authors declare no conflict of interest.

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