Review Article

Investig Clin Urol 2021;62:148-158.
https://doi.org/10.4111/icu.20200392
pISSN 2466-0493 • eISSN 2466-054X

INVESTIGATIVE AND CLINICAL UROLOGY
ICUROLOGY

A state-of-art review on the preservation of sexual function among various minimally invasive surgical treatments for benign prostatic hyperplasia: Impact on erectile and ejaculatory domains

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There is a strong association between benign prostatic hyperplasia (BPH)/lower urinary tract symptoms (LUTS) and sexual dysfunction. While transurethral resection of the prostate (TURP) is considered the standard BPH treatment, it is however associated with a high rate of erectile and ejaculatory dysfunctions. Over the past decade, new and novel minimally invasive BPH therapies have been shown to improve various parameters of voiding domains while minimizing adverse sexual effects. These minimally invasive BPH therapies can be largely be divided into those with cavitating technology (Rezum, Histotripsy, Aquablation), intra-prostatic injections (Botulinum neurotoxin Type A, Fexapotide Triflutate, prostate specific antigen-activated protoxin PRX-302), and mechanical devices which include intraprostatic stents (Urospinal 2™, Memotherm™, Memokath™, and Allium triangular prostatic stent™) and intraprostatic devices (iTIND™, Urolift™), as well as prostatic artery embolization. Published literature on these technologies showed reasonable preservation of erectile function with limited data reported on ejaculatory domain. Further validation of the performance of these novel minimally invasive treatment options for LUTS due to BPH in well-designed and multi-centre studies are desired, to evaluate their role (or lack of such a role) in clinical practice and whether these BPH therapies can provide equivalent standard or better than TURP.

Keywords: Benign prostatic hyperplasia; Clinical outcomes; Sexual dysfunction; Surgery

INTRODUCTION

Benign prostatic hyperplasia (BPH) contributes to lower urinary tract symptoms (LUTS) such as urinary hesitancy, dribbling, weak stream and frequency [1]. Epidemiological studies showed that 50% of men in their fifties will have BPH symptoms [2], and the incidence of LUTS in this age group is estimated as high as 25% in some studies [2,3]. Erectile dysfunction (ED) and ejaculatory disorders are prevalent in sexually active men with LUTS and both conditions

Received: 1 September, 2020 • **Revised:** 11 October, 2020 • **Accepted:** 8 November, 2020 • **Published online:** 9 February, 2021
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correlate with LUTS severity independently of age and cardiovascular comorbidities [3,4]. The prevalence of ED and concurrent BPH has been reported to be as high as 40% and men with ED are 6 times more likely to have BPH than men without BPH [5]. Moreover, it is known that the severity of LUTS and sexual dysfunction are both independently correlated with lower quality of life (QoL) scores [6].

The link between LUTS and ED has been explained through several pathophysiological pathways involving nitric oxide guanosine monophosphate and RhoA/Rho-kinase, metabolic syndrome, autonomic hyperactivity, pelvic ischaemia, sex hormones imbalance, inflammatory pathway, and psychological factors [7]. Clinically, the resolution of LUTS appears to correlate with an improvement in sexual function but not in a linear fashion [8]. There appears to be an intricate balance between adequate prostatic tissue resection to improve the bladder outflow tract and preservation of critical structures responsible for sexual function.

Although transurethral resection of the prostate (TURP) is considered the surgical standard for BPH therapy, it is however associated with a high rate of male sexual dysfunction such as ED (3.4%–32%) and ejaculatory dysfunction (53%–72%) [9]. The proposed pathophysiologic mechanisms for retrograde ejaculation and/or decreased ejaculation are related to inadvertent resection of tissue paracollicular and supracollicular tissue at the verumontanum and decreased volume of prostate tissue following resection respectively [1,8]. Furthermore, the use of high-frequency generated energy current close to the prostate capsule may cause neuropraxia injury to the nearby neuromuscular bundles, resulting in the development and/or progression of ED [1,9]. Additionally, some studies highlighted the potential psychosocial factors or ensuing urinary symptoms such as urgency or incontinence as contributing factors to the subsequent development of male sexual dysfunction [2-4, 6].

Hence, over the last decade, there is a paradigm shift towards effective yet minimally invasive BPH surgical therapy with minimal sexual dysfunction postoperatively. The following article reviews the current minimally invasive BPH surgical treatments with an emphasis on the impact of these therapies on sexual function preservation (Table 1).

MATERIALS AND METHODS

PUBMED was screened for English language publication of relevant clinical trials including systematic review and meta-analysis articles up to July 2020 using the following keywords namely "benign prostatic hyperplasia", "lower urinary tract symptoms", "minimally invasive surgery", "sexual

Table 1. Minimally invasive BPH surgical treatments with known limited or no adverse impact on sexual function

BPH treatment	Manufacturer	Mechanism of action	Erectile function	Ejaculatory function	Reference
Rezum system	Boston Scientific	Convective water vapour energy therapy	Minimal or no ED	1.5%–2.9% has reduced ejaculatory volume	[13,14]
Histotripsy (VortxRX™)	HistoSonics	Extracorporeal ultrasound technology	Minimal or no ED	Better ejaculation	[16]
Aquabeam system	PROCEPT BioRobotics Inc.	Heat-free, high pressured-saline jets	Minimal or no ED	0%–11% ejaculatory dysfunction	[18-25]
Onabotulinum toxin A	Multiple companies	Inhibition of acetylcholine release and pro-apoptotic	Minimal or no ED	No information	[27-33]
Fexapotide Triflutate	Nymox Pharmaceutical Corporation	Prostatic apoptosis	Minimal or no ED	No information	[37]
PSA-Activated protoxin (PRX-302)	Sophiris Bio Corp.	Prostatic apoptosis	Minimal or no ED	No information	[39,40]
Urospinal 2™	Coloplast, Inc.	Intraprostatic stent	No information	No information	[43]
Memotherm™	Angiomed Gmbh & Co.	Intraprostatic stent	No information	No information	[44-47]
Memokath™	Pnn Medical	Intraprostatic stent	No information	No information	[48-51]
Allium™ TPS	Allium Medical Solutions Ltd.	Intraprostatic stent	No information	No information	[52]
iTIND™	Medi-Tate	Prostatic lateral compression	Minimal or no ED	Minimal ejaculatory dysfunction	[54,55]
Urolift™	Neotract Inc.	Prostatic lateral compression	Minimal or no ED	No ejaculatory dysfunction	[66-71]
Prostatic artery embolization	None	Embolization of prostatic vessels	Minimal ED	Minimal ejaculatory dysfunction	[76-99]

BPH, benign prostatic hyperplasia; ED, erectile dysfunction.

function", "erectile dysfunction", "ejaculatory function", and "adverse event". Each article's title and abstract were reviewed for their appropriateness and their relevance for inclusion due to limitation in number of references allowed for this review paper.

Emphasis is placed on the report of validated sexual outcomes specific questionnaires such as the International Index of Erectile Function (IIEF); Sexual Health Inventory for Men (SHIM) and Male Sexual Health Questionnaire for Ejaculatory function (MSHQ-EjD). A detailed description of the actual surgery is not included in this review paper.

RESULTS

1. Cavitation technology or techniques

Similar to conventional TURP which resects prostate tissue to open the prostatic urethra and bladder outlet, these novels minimally invasive BPH devices cause prostatic tissue cavitation through various energy sources.

1) Rezum™ - convective water vapour energy therapy

The Rezum system, originally pioneered by NxThera (Maple Grove, MN, USA) in 2015, was subsequently acquired by Boston Scientific (Marlborough, MA, USA) in 2018. It delivers a lethal dose of steam as generated by the radiofrequency current into the prostate lobes, causing localised tissue necrosis and cavitation of the prostate gland [5].

The majority of published studies on Rezum system is industry-sponsored [10-12] and a multi-centre randomised sham-controlled trial involving 197 men (with an active arm of 136 men) has been updated with a 4-year follow-up data recently [12]. While there was no reported incidence of *de novo* ED, 2.9% of patients reported reduced ejaculatory volume which subsequently decreased to 1.5% at 3 months while the initial 4% risk of anejaculation immediately postoperative disappeared 3 months later [13]. The sexual impact of Rezum across the IIEF scores (based on the minimal clinically important difference) were 11.5±3.5 for severe, 11.2±4.4 for moderate and 5.3±2.8 for mild groups at 12 months [13]. Other treatment-related adverse events (TRAE) of Rezum include dysuria (16.9%), haematuria (11.8%), frequency and urgency (5.9%), acute urinary retention (3.7%), and urinary tract infection (UTI) (3.7%). Another retrospective study with shorter follow of 12 months duration involving similar patient demographics reported similar improvement in IPSS (International Prostate Symptom Score) and Qmax without significant change in sexual function scores [14].

2) Histotripsy

Histotripsy (VortxRX™, human prototype device; HistoSonics, Inc, Ann Arbor, MI, USA) is an extracorporeal ultrasound technology that delivers short high-intensity pulses of acoustic energy to a targeted volume of the prostate gland causing tissue fractionation and subsequent debulking of prostate tissue (as seen in canine models) [15]. The *in vivo* study based on histotripsy of canine prostate gland showed a 31% reduction in prostate volume with a limited inflammatory and fibrotic response [15].

The only single-arm prospective clinical trial involving 25 patients showed an actual improvement in sexual function based on MSHQ-EjD questionnaire (7.5±3.8 vs. 10.0±4.2; $p<0.005$) at 6-month postoperative review [16]. The most serious TRAE reported was acute urinary retention lasting 8 days in one patient, while no sexual dysfunction was reported. A larger, multi-center clinical study with placebo-controlled arm is required to provide further evidence and confirm safety profile.

3) Aquablation system

The Aquabeam system (PROCEPT BioRobotics Inc, Redwood Shores, CA, USA) uses a robotically guided heat-free, high pressured-saline jets to ablate prostatic tissue in animal model based on pre-defined volume on transrectal ultrasound whilst sparing the anatomical landmarks responsible for urinary continence and ejaculatory function [17].

Gilling et al. [18] described the first human clinical trial of aquablation in a prospective study involving 15 men with a 6-month follow-up. There was no reported incidence of retrograde ejaculation, ED, or incontinence. The 30-days TRAE were dysuria (20%), haematuria (20%), pelvic pain or discomfort (20%), need for re-catheterisation for urinary retention (25%), post-operative cardiac arrhythmia (6.6%), and bladder spasms (6.6%). A multi-centre phase 2 trial involving 21 patients with 12 months follow-up with comparable baseline characteristics was subsequently conducted by the same group [19]. Similarly, no subjects reported ejaculatory dysfunction, while 11 sexually active subjects demonstrated an improvement in their sexual function as noted on the IIEF-15 questionnaire. An acute UTI (1 patient) and meatal stenosis (1 patient) were two newly identified TRAE. Desai et al. [20] reported data on a single institution study involving 47 patients and at 3 months follow-up review, no patients developed ED, retrograde ejaculation or urinary incontinence postoperatively. The TRAE include haematuria (1 patient), UTI (2 patients), urinary retention (6 patients), haematuria requiring transfusion (1 patient), infection (1 patient), and stricture (2 patients). Pivotal phase III double-blinded ran-

https://doi.org/10.4111/icu.20200392

domized-controlled trials comparing aquablation to TURP such as WATER [21] and WATER 2 [22,23] reported MSHQ 7.5±4.8 (vs. 8±4.1) and IIEF-5 score 14.6±7.9 (vs. 14.6±7.8) respectively. Treatment-related sexual dysfunction was ejaculatory dysfunction (11%) but no report of ED postoperatively [24,25]. The 30-days TRAE included bleeding (5.9%), dysuria (7.9%), meatal stenosis (1%), sexual dysfunction (1%), UTI (1%), urethral stricture (1%), urinary incontinence (1%), cardiac (2%), stroke (1%), and multi-system organ failure (1%) [21-25].

2. Intra-prostatic injectables

Intra-prostatic injections with different agents have been explored with proposed advantages of being administered under local anaesthesia in an outpatient setting, and is suitable for older and co-morbid patients who are not suitable or fit for surgery. These injectable drugs include Botulinum neurotoxin type A, Fexapotide Triflutate (FT) (NX-1207; Nymox Pharmaceutical Corporation, Hasbrouck Heights, NJ, USA) and PRX-302 (Topsalysin; Sophiris Bio Corp, La Jolla, CA, USA). Of note, the ethanol injection has been abandoned due to significant TRAE.

1) Botulinum neurotoxin Type A

Onabotulinumtoxin A (BoNT-A) is one of the most powerful neurotoxins produced by the anaerobic Clostridium bacteria and causes flaccid paralysis of injected muscles due to the inhibition of acetylcholine release [26]. *In vitro* studies showed impairment of smooth prostate muscle hyper-contractility, induction of prostate cells apoptosis, inhibition and down-regulation of alpha-1A adrenergic receptors in murine prostate [26].

While there are no reported sexual adverse effects in published studies to date [27-33], the large placebo effect as shown in both large multi-centre studies [32,33] has diminished the interest in the use of BoNT-A as an effective treatment for BPH.

2) Fexapotide Triflutate (NX-1207)

FT is a protein with selective pro-apoptotic properties which is administered by transrectal intraprostatic injection under ultrasound guidance into each left and right transition zones of the prostate, causing selective apoptosis of prostate glandular cells with complete sparing of adjacent structures [34].

Published data has been mixed [35,36] and recent multi-centre placebo-controlled study with subsequent open-label cross-over involving 995 men [37] showed that the TRAE were similar between the 2 groups with no transient or persistent NX-1207 related sexual side-effects. Larger Phase III trials are ongoing to further confirm the efficacy, safety and tolerability for this minimally invasive, FT injected BPH treatment.

3) Prostate specific antigen-activated protoxin (PRX-302)

Prostate specific antigen (PSA)-activated protoxin (PRX-302) is an engineered proaerolysin, which is activated by the PSA and in the animal model, when injected into monkey's prostate, it causes rapid lytic prostatic cellular death [38].

Early phase clinical study [39] showed erectile function was preserved based on IIEF scores although ejaculatory dysfunction was not assessed. The double-blinded vehicle-controlled study [40] reported no sexual dysfunction related to PRX-302 injection. Common TRAE were dysuria, pollakuria, micturition urgency, perineal pain, and malaise; all of which had a duration of fewer than 2 days. Another multi-centre safety and efficacy study of intraprostatic PRX-302 injection was conducted in 2013, but the clinical outcomes have yet to be published [41].

3. Mechanical devices

1) Intraprostatic stents

The first experiment on the use of expandable metallic stent as a valid treatment for BPH was published by Fabian in 1980 [42]. Since then, there have been multiple intraprostatic stents, either temporary non-epithelialising type or a permanent type which fasten onto the prostate stroma through epithelialization, have been introduced and tested to keep the prostatic urethra patent. Given the dearth of robust evidence, some of these stents have been phased out and withdrawn from the commercial market.

(1) Urospinal 2™

Urospinal 2™ (Coloplast, Inc, Rosny-sous-Bois, France), is a temporary spiral urethral stainless-steel stent with a theoretical life expectancy of 6 months and is placed under direct urethroscopy vision. A phase I trial which enrolled 94 patients who were deemed unfit for conventional ablative surgery [43] showed no report of sexual dysfunction postoperatively. However, four patients needed stent replacement due to early device migration as noted on pelvic imaging.

(2) Memotherm™

Memotherm™ (Angiomed Gmbh & Co., Karlsrube, Germany) is a thermo-reactive nitinol based, permanent wire mesh prostatic urethra stent. Published studies [44-47] did not report on sexual function outcome among the frail and surgically unfit candidates. The TRAE such as migration

of the stent causing acute urinary retention and need for retrieval, removal or replacement; and intermittent haematuria have diminished the initial enthusiasm for its use.

(3) Memokath™

Memokath prostatic stent (Memokath™; Pnn Medical, Kvistgaard, Denmark) is a temporary thermo-expandable, nickel-titanium alloy spiral stent, which has a memory-shape effect and is purported to mitigate against the migration of the stent. To date, there are no documented sexual adverse event published in any of the clinical studies [48-51]. Nonetheless, some patients discontinued treatment due to either urinary retention, persistent urinary incontinence or progressive voiding LUTS and reported TRAE include stent migration (13%), urinary retention after the procedure (10%), urinary incontinence (6%), infection (6%), pain (3%), bleeding (3%), stone formation (2%), and occlusion (1%) [49]. Furthermore, the relatively short-term functional outcomes and high complication rates have significantly hampered the usefulness of Memokath prostatic stent in young, fit and sexually active men with BPH.

(4) Allium™ triangular prostatic stent

The Allium™ triangular prostatic stent (TPS) (Allium Medical Solutions Ltd, Caesarea Industrial Park South, Israel) has a triangular cross-section body that fit into the prostatic urethra and is designed to circumvent some of Memokath limitations since its nitinol and copolymer sheath is thought to prevent tissue ingrowth and reduce stent encrustation [52]. The only published BPH study in 2016 did not report on postoperative sexual function [52].

2) Intraprostatic devices

(1) iTIND™ (i-Temporary Implantable Nitinol Device)

The iTIND™ (Medi-Tate, Hadera, Israel) is a temporary implantable nitinol device that expands and exerts localized ischemic pressure on the prostate tissue once placed to create three longitudinal channels within the prostatic urethra and it is entirely removed at 5 to 7 days later. The radial pressure from its expanded struts is thought to result in ischaemic necrosis, causing an incision of the bladder neck and prostatic urethra, to open the bladder outlet [53]. Published studies [54,55] showed none of the sexually active patients who completed the 12-month follow-up period reported any sexual or ejaculatory dysfunction. Despite its relative safe implantation, the efficacy of iTIND is yet to be ascertained and further multi-centre studies are currently underway [56,57].

(2) Prostatic urethral lift (Urolift™)

Prostatic urethral lift (PUL) (Urolift™; Neotract Inc., Pleasanton, CA, USA), is a procedure whereby small suture-based implants are inserted to lift and retract away from the coapting prostate lobes, creating a channel through the anterior aspect of the prostatic fossa [58].

Earliest published study on PUL [59] found a slight increase in erectile function as measured by SHIM score (18.2±4.9 vs. 19.4±5.3; p=0.01), with no reported incidence of retrograde ejaculation at 12 months. Clinical evaluation of the effect of PUL on BPH was also assessed in the same cohort and their 2-year outcomes showed durable improvement in urinary symptoms whilst preserving sexual function [60]. Positive benefits observed during earlier clinical trials were confirmed in many studies conducted across different countries [60-65].

Studies comparing PUL and TURP showed superior preservation of ejaculation and quality of recovery with PUL [66-68]. The BPH6 study [66] conducted across 10 European centres with 80 men demonstrated not only noninferiority but also a superiority of PUL over TURP on the BPH6 endpoint such as symptom relief, quality of recovery, erectile function preservation, ejaculatory function preservation, continence preservation, and safety. Similarly, a multi-centre German study [68] reported no change in sexual function postoperatively. The Cochrane review [69] found that whilst PUL preserved erectile function and is associated with better ejaculatory function, the actual improvement in urinary symptoms was inferior compared to TURP. The MedLift study [70] which was an extension of the LIFT randomized study found that men with middle lobe prostatic obstruction can be treated with PUL with ≥40% of sexually active men reporting an improvement in erectile function at 12 months review. A recent systematic review and meta-analysis also confirmed PUL is associated with no postoperative sexual dysfunction in the intermediate-term [71].

4. Prostatic artery embolization

Prostatic artery embolization (PAE) is a technique initially developed to control prostatic bleeding [72]. Sun et al. [73] evaluated the feasibility of transcatheter arterial embolization of the prostate in pigs and found a significant reduction in the mean prostate volume following PAE compared to the control group. Subsequent histopathology study on PAE confirmed observed areas of ischaemic prostatic necrosis much like the animal models [74].

The first human trial had human subjects who had an injection of polyvinyl alcohol particles to occlude the prostatic arteries [75] to the phase I trial [76], PAE was technically

https://doi.org/10.4111/icu.20200392

feasible and no significant ED was recorded post-procedure. Nonetheless, reported TRAE can vary from mild such as UTI (13.3%) and acute urinary retention (6.6%), to serious complications such as ischemia of the bladder, rectum and glans of the penis as well as prostatic abscess [77-80].

Since the initial phase I studies, a myriad of studies has been published including multiple open-label studies using various embolization agents, instruments or techniques [77-90], 3 comparative studies [91-93] and 4 randomised controlled trials (vs. sham, or vs. TURP) [94-97]. A recent meta-analysis comparing PAE versus TURP [98] demonstrated that PAE was inferior to TURP with respect to post-operative urinary scores despite relatively safe sexual profile. While PAE appears to preserve erectile function, it is reported to have a lower incidence of anejaculation when compared to TURP (16% vs. 52%) [99].

DISCUSSION

Current and novel minimally invasive BPH therapies have been shown to improve various parameters in voiding domains while minimizing adverse effects in sexual function. At present, there is a lack of direct comparative clinical trials between these minimally invasive BPH therapies and published sexual function outcomes have been hampered by restricted methodology and incomplete reported outcomes. Furthermore, the use of various validated sexual health-related outcome measures may not be applicable if these men with BPH are not sexually active or concerned about sexual function postoperatively. Therefore, it is difficult to ascertain which of these minimally invasive BPH technologies is/are truly superior since factors such as clinician's expertise, device registration and availability of technology, as well as cost-effective analysis need to be taken into account.

Male sexual function is a highly complex neurobiological and neurophysiological interaction, and any disruption of endocrine, neural, or vascular response, caused by aging, medical illness, neurological diseases, surgery, or drugs, can lead to various male sexual dysfunctions [100]. Given the strong association among the underlying pathophysiologic mechanisms between BPH and ED, and that ED and ejaculatory/orgasm function is closely interlinked, it is likely that physical, psychological, and emotion changes relating to BPH therapy will invariably affect male sexual function. The presence of complications such as urinary urgency, stricture or incontinence, will directly impact of sexual outcomes too.

While some of these minimally invasive technologies can be performed in an office or outpatient setting, with minimal recovery time, some of these TRAE can be devastating. Presence of stricture disease either urethral stricture or bladder neck contracture, will necessitate additional surgical intervention, while stress incontinence from damage external urethral sphincter with ensuing climacturia or significant urinary incontinent, can adversely impact across various QoL domains beyond just sexual function alone.

Careful patient selection, adequate informed consent and stringent application of these promising BPH treatment modalities are essential to ensure favourable outcomes beyond those achieved by the current TURP surgical standard. Further validation of the performance of these novel minimally invasive treatment options for LUTS due to BPH in well-designed and multi-centre studies are desired, to evaluate their actual role in clinical practice and potentially replace TURP as the new standard of surgical care.

CONCLUSIONS

It has become evident that an improvement in LUTS coupled with the preservation of male sexual function especially erectile and ejaculatory functions are of paramount importance for many sexually active men who are contemplating BPH surgery. To date, there are very little direct comparative clinical trials among these minimally invasive BPH technologies, and further studies are required to ensure optimal patient selection, analyze cost-effectiveness and counsel patients on longer-term clinical outcomes and safety profile.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

AUTHORS' CONTRIBUTIONS

Research conception and design: Eric Chung. Data acquisition: Brian Hung Shin Ng and Eric Chung. Data analysis and interpretation: Brian Hung Shin Ng and Eric Chung. Drafting of the manuscript: Brian Hung Shin Ng and Eric Chung. Critical revision of the manuscript: Eric Chung. Approval of the final manuscript: Brian Hung Shin Ng and Eric Chung.

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https://doi.org/10.4111/icu.20200392