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Benign Prostatic Hyperplasia

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Disclosures

- Grants/Research Support: Boston Scientific, Bard, Teleflex, Abbvie, Zenflow
- Consulting: BSCI, Olympus, Femselect, ARMs, Prodeon Medical, Sumitomo, Teleflex, Zenflow
- Advisor: Promaxo, Bright Uro, COSM

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What is BPH?

- **Benign prostatic hyperplasia (BPH):**
  - Refers to an increase in the number of prostatic stromal and epithelial cells, resulting in the formation of large, discrete nodules in the transition zone of the prostate
- **Benign prostatic hypertrophy:**
  - Refers to a growth in the size of individual cells

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Epidemiology of BPH

- **Age as a percentage:**
  - 50% by 50 and prevalence rises 10% with each decade
- **Growth factors and genetic predisposition**
  - Growth factors (FGF-1,2,7,17; VEGF, IGF; TGF-β)
  - Stromal Hypertrophy
- **Lower Urinary Tract Symptoms (LUTS)**
  - Chronic obstruction with compensatory bladder changes
  - Storage, Voiding

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Roehrborn, C.: Benign Prostatic Hyperplasia: Etiology, Pathophysiology, Epidemiology, and Natural History. In: Campbell-Walsh Urology.. Edited by A. Wein: Elsevier Saunders, vol. 3, pp. 2570-2610, 2011

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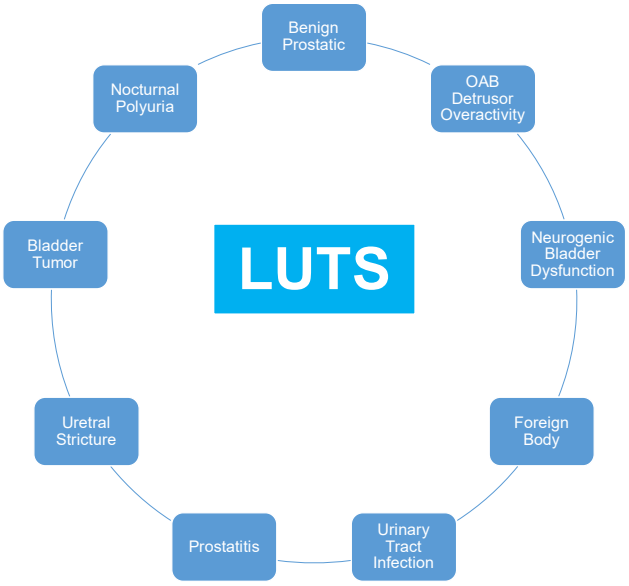
Multifactorial Etiology of LUTS

- LUTS are non-specific
- Occurs in men and women
- Caused by many conditions
- Describes ailments without implying their cause



Chapple, C.R., Tubaro, A. (Ed), Male LUTS/BPH Made Easy. Springer-Verlag London 2014

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AUA Guidelines: Evaluation Statements

Initial Evaluation

1. In the initial evaluation of patients presenting with bothersome LUTS possibly attributed to BPH, clinicians should obtain a medical history, conduct a physical examination, utilize the International Prostate Symptom Score (IPSS), and perform a urinalysis. (Clinical Principle)
2. Patients should be counselled on options for intervention, which can include behavioral/lifestyle modifications, medical therapy and/or referral for discussion of procedural options. (Expert Opinion)

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Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART I-Initial Work-up and Medical Management [published correction appears in J Urol. 2021 Nov;206(5):1339]. *J Urol.* 2021;206(4):806-817. doi:10.1097/JU.0000000000002183

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AUA Guidelines: Evaluation Statements

Follow-up Evaluation

1. Patients should be evaluated by their providers 4-12 weeks after initiating treatment (provided adverse events do not require earlier consultation) to assess response to therapy. Revaluation should include the IPSS. Further evaluation may include a post-void residual (PVR) and uroflowmetry. (Clinical Principle)
2. Patients with bothersome LUTS/BPH who elect initial medical management and do not have symptom improvement and/or experience intolerable side effects should undergo further evaluation and consideration of change in medical management or surgical intervention. (Expert Opinion)

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AUA Guidelines: Pre-Operative Testing Statements

1. Clinicians should consider assessment of prostate size and shape via transrectal or abdominal ultrasound, cystoscopy, or cross-sectional imaging (i.e., magnetic resonance imaging [MRI]/ computed tomography [CT]) if such studies are available, prior to intervention for LUTS/BPH. (Clinical Principle)
2. Clinicians should perform a PVR assessment prior to intervention for LUTS/BPH. (Clinical Principle)
3. Clinicians should consider uroflowmetry prior to intervention for LUTS/BPH. (Clinical Principle)
4. Clinicians should consider pressure flow studies prior to intervention for LUTS/BPH when diagnostic uncertainty exists. (Expert Opinion)
5. Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally-invasive treatments for LUTS/BPH. (Clinical Principle)

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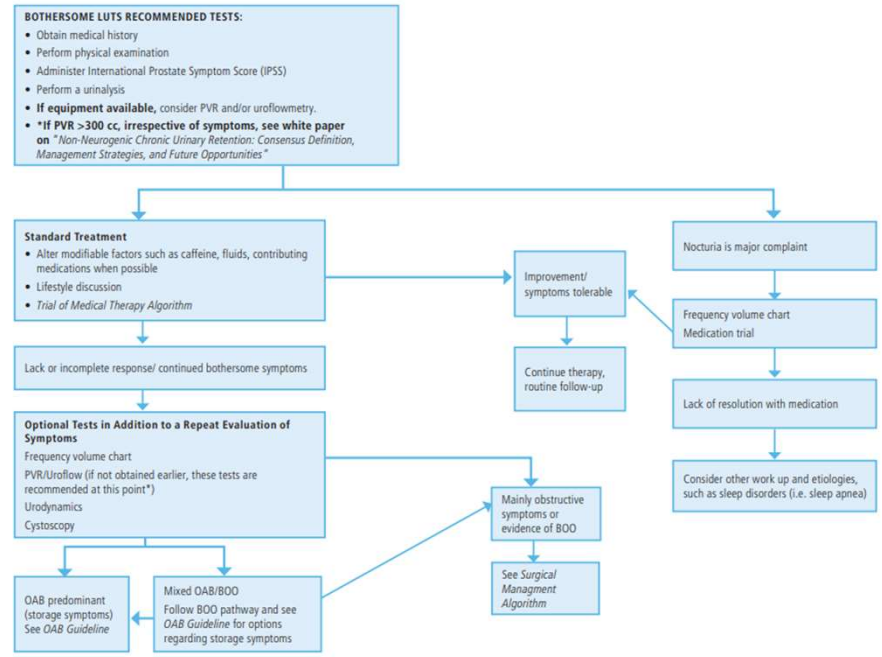
Basic Management of LUTS in Men



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Subjective Metrics

IPSS:
- 0-7 mildly symptomatic
- 8-19 moderately symptomatic
- 20-35 severely symptomatic

AUA symptom score expected improvement
- Placebo (1-2)
- Alpha-Blocker (1-4)
- Combination therapy (2-9)
- PUL/Rezum
- TURP
- HoLEP

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International Prostate Symptom Score (IPSS)

Name: Date:

	Not at all	Less than 1 time in 5	Less than half the	About half the time	More than half the	Almost always	Your score
Incomplete emptying Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5	
Frequency Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
Intermittency Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
Urgency Over the last month, how difficult have you found it to postpone urination?	0	1	2	3	4	5	
Weak stream Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
Straining Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	

	None	1 time	2 times	3 times	4 times	5 times or more	Your score
Nocturia Over the past month, many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning?	0	1	2	3	4	5	

Total IPSS score	

Quality of life due to urinary symptoms	Delighted	Pleased	Mostly satisfied	Mixed - about equally satisfied and dissatisfied	Mostly dissatisfied	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that?	0	1	2	3	4	5	6

Total score: 0-7 Mildly symptomatic; 8-19 moderately symptomatic; 20-35 severely symptomatic

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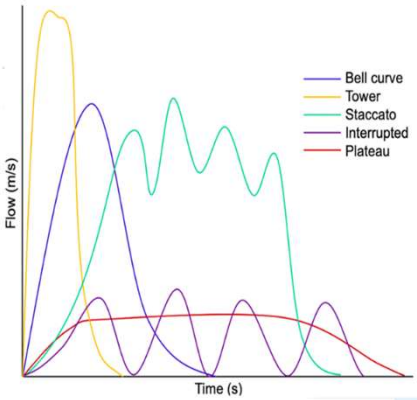
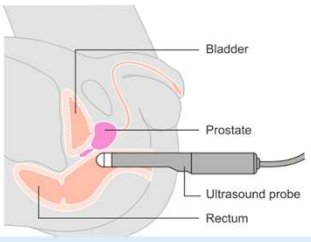
Objective Metrics

- Includes **flow rate (Qmax)** and **post-void residual (PVR)**
- **Cystoscopy** not routinely recommended in otherwise healthy patients with an initial eval consistent with BOO
  - But can offer a visual inspection of the urethra, prostate, & bladder to further evaluate BOO in men undergoing treatments where success may depend on anatomic configuration
- **Urodynamics are considered optional per AUA guidelines prior to intervention**
  - Can be useful in quantifying the degree of bladder outlet obstruction (BOO) and/or detrusor overactivity and are typically used to further evaluate voiding function in the context of multiple lower urinary tract symptoms.[6]





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Urodynamics in the Evaluation for BPH

To identify patients who will not benefit from outlet procedure and avoid potential side effects DDx- BPO, OAB and underactive bladder

UPSTREAM Trial 1: use of UDS to identify candidates for prostate surgery

Addition of UDS did not improve decision making

Suggested better to dx BOO in men with Qmax > 10

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1. Young GI et al European Urology Focus. 8(5):1331-1339, 2022

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Urodynamics in the Evaluation for BPH

High Pdet with low Qmax = bladder outflow obstr. (BOO)

Low Pdet with low Qmax = detrusor underactivity.

BOO index (BOOI): = Pdet @ Qmax − 2 Qmax

>40 is obstructed

<20, no obstruction exists

BCI = Pdet Qmax + 5 Qmax

> 150 suggests strong contractility

100–150 normal; and less than 100 weak.

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1. Abrams P et al, Proc 4th Int Consultation on BPH. 1998. pp. 323–377

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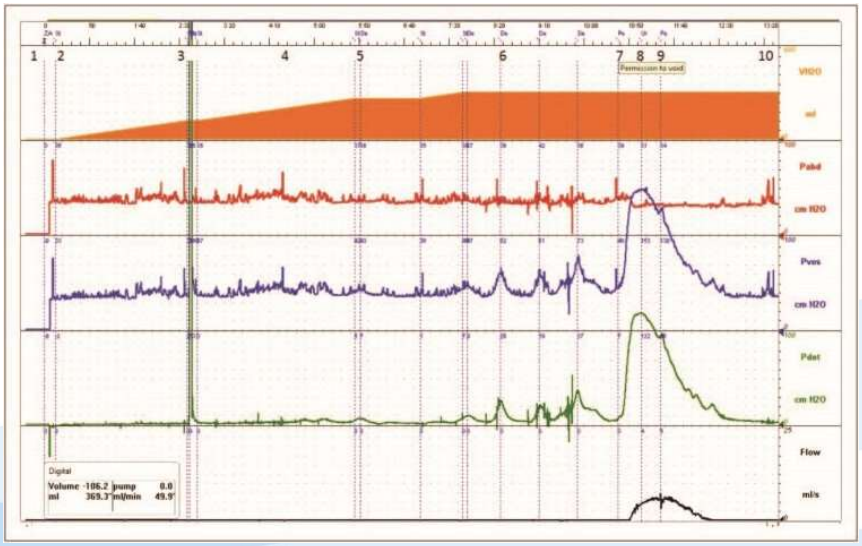
Urodynamics in the Evaluation for BPH



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Optional Tests

Post void residual: PVR

PVR > 300: consult white paper on Non neurogenic chronic urinary retention

Do prior to any intervention

Uroflowmetry: > 150 ml

<10 mL/s :specificity of 70%, a positive predictive value of 70%, and a sensitivity of 47% for BOO

Pressure flow studies for complex cases

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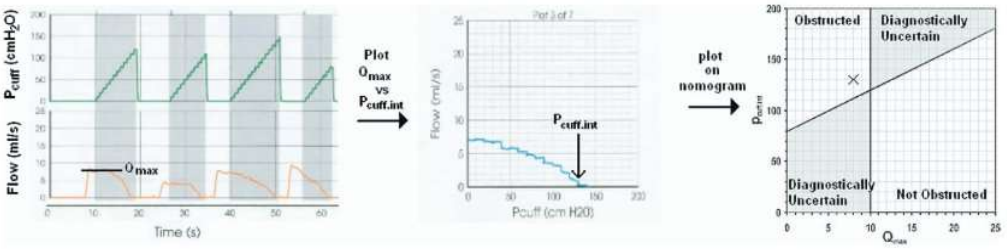
Penile Cuff Test

The penile cuff test (PCT) is a noninvasive pressure flow study

A pressure cuff is placed around the penis
As the patient voids into a flowmeter, the cuff is inflated until voiding is interrupted
The cuff then deflates, allowing voiding to resume
This process is repeated until the patient has finished voiding



Clarkson, B., Robson, W., Griffiths, C., McArdle, F., Drinnan, M., & Pickard, R. (2008). Multisite evaluation of noninvasive bladder pressure flow recording using the penile cuff device: Assessment of test-retest agreement. *Journal of Urology*, *180*(6), 2515–2521. https://doi.org/10.1016/j.juro.2008.08.076

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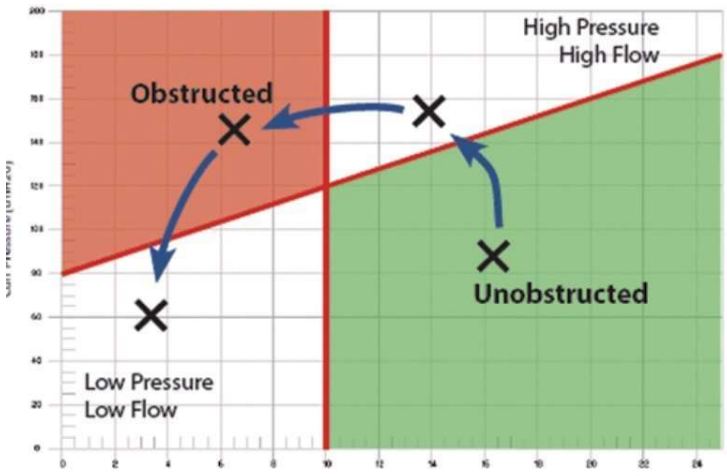
Penile Cuff Test: Nomogram



Griffiths CJ, Harding C, Blake C, et al. A nomogram to classify men with lower urinary tract symptoms using urine flow and noninvasive measurement of bladder pressure. *J Urol*. 2005;174(4 Pt 1):1323-1326. doi:10.1097/01.ju.0000173637.07357.9e

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***Post Obstructive Diuresis

Urine production exceeding 200 mL/h for two consecutive hours or urine output exceeding 3,000 mL/day

Physiological response to the accumulated solutes and volume expansion that occurred with obstruction.

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Post Obstructive Diuresis

Pathologic POD: inappropriate renal handling of water and/or solutes. Get disruption of the medullary interstitial solute gradient due to

- downregulation of sodium transport channels
- downregulation of aquaporin channels
- poor responsiveness of the collecting duct to vasopressin (nephrogenic DI)

- altered regulation of ANP

- atrial natriuretic peptide (ANP), exerts a vasodilator effect on the kidney and also reduces tubular reabsorption of sodium

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Post Obstructive Diuresis

Risk factors for who will develop

signs of fluid overload including edema, CHF and HTN

high serum creatinine, high serum bicarb [1]

residual urine > 1150 [2]

Note: no role for gradual decompression of bladders. Should be emptied as quickly as possible.

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1. Hamdi A et al. BJU Int. 2012;110(11c):E1027–1034.
2. Leinum LR et al. Scand J Urol 54(3):253-257, 2020

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Assessment in Post Obstructive Diuresis

Mental status

Vital sings- high or low BP, temperature

Serum electrolytes: Na+ normal or high, creatinine, K+

Get renal US if creatinine does not improve **

Risk of hypokalemia **

- Urine osmolality < 150 mOsm/kg is a water diuresis; 150-300 is a mixed diuresis and 300-500 is a salt diuresis (normal plasma osmolality is 290mOsm/kg)

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1. Hamdi A et al. BJU Int. 2012;110(11c):E1027–1034.
2. Leinum LR et al. Scand J Urol 54(3):253-257, 2020

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Treatment of POD

Normal mental status and BP- free access to PO fluids, not IV

IV fluids are administered to:

- patients with inability to tolerate oral fluids
- mental status changes
- clinical hypotension

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1. Hamdi A et al. BJU Int. 2012;110(11c):E1027–1034.
2. Leinum LR et al. Scand J Urol 54(3):253-257, 2020

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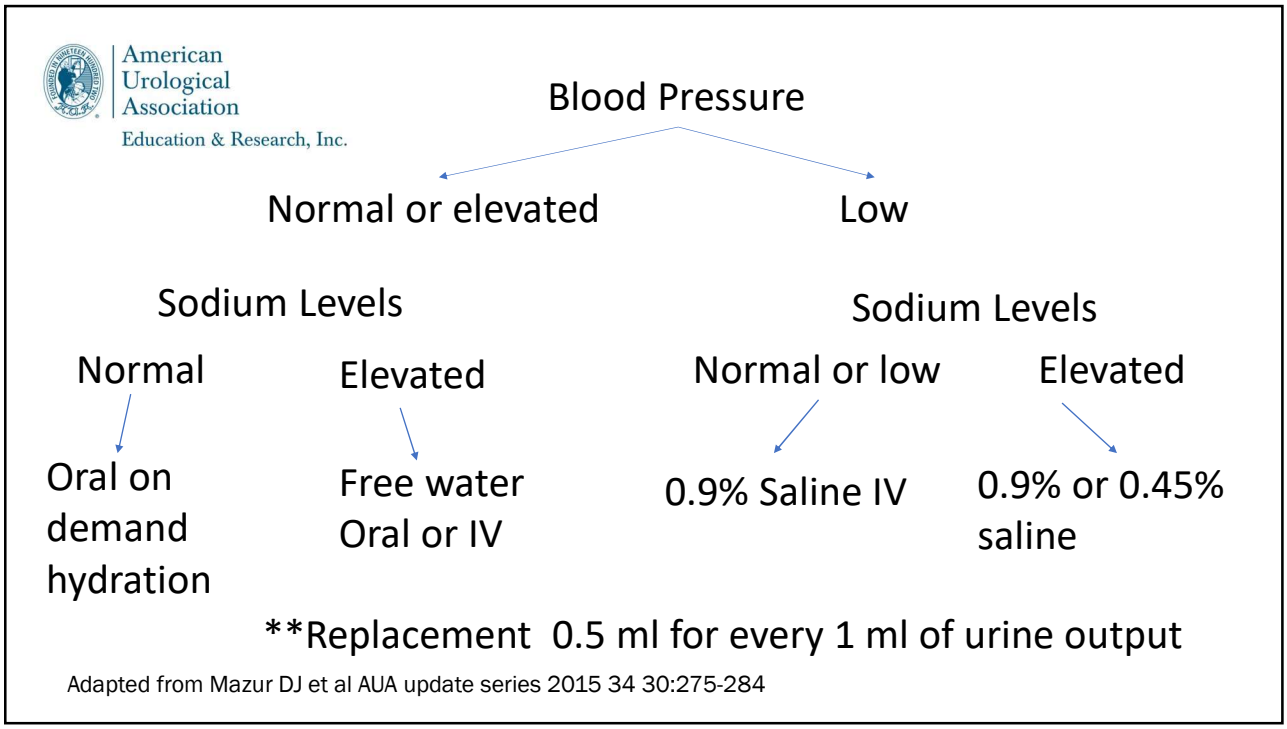

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Back to Evaluation

Counseling on options

Behavioral therapy: fluids, caffeine, exercise

Medical Therapy

Surgical/procedures: discuss possibility of retreatment

Follow-up 4-12 weeks with IPSS*

PVR, Uroflow as indicated

Change meds, consider procedures if not improved

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Medical Therapies

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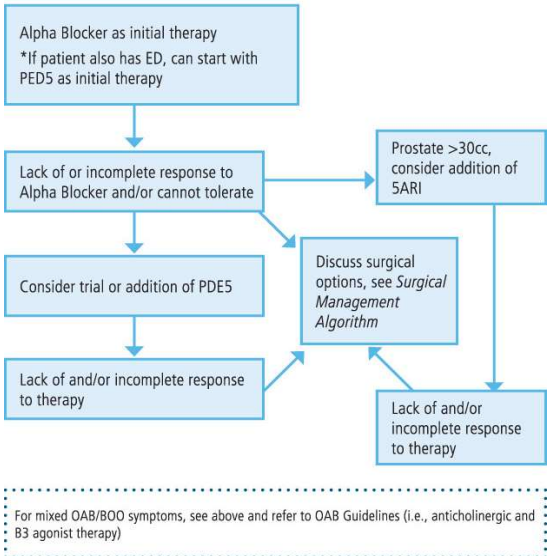
AUA Guidelines: Trial of Medical Therapy Algorithm



Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

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Complementary & Alternative Methods

- Over 30 phytotherapeutic compounds have been described in the management of BPH
- Given their classification as foods by the US Food and Drug Administration, there is little regulation of production and distribution of these herbal supplements
- Studies have demonstrated extreme variations in active compounds in products sold OTC[9]
- One of the most common, **saw palmetto**, is derived from Serenoa repens
- Other examples : beta-sitosterols from the Hypoxis rooperi plant[10] and pygeum from the Prunus africana plant.[11]
- There is no convincing evidence that pumpkin seed (Cucurbita pepo) or stinging nettle (Urtica dioica) are effective for BPH.[12]

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α-Blockers

Alpha Blockers

1. Clinicians should offer one of the following alpha blockers as a treatment option for patients with bothersome, moderate to severe LUTS/BPH: alfuzosin, doxazosin, silodosin, tamsulosin, or terazosin. (Moderate Recommendation; Evidence Level: Grade A)
2. When prescribing an alpha blocker for the treatment of LUTS/BPH, the choice of alpha blocker should be based on patient age and comorbidities, and different adverse event profiles (e.g., ejaculatory dysfunction [EjD], changes in blood pressure). (Moderate Recommendation; Evidence Level: Grade A)[8]

Alpha Blockers and Intraoperative Floppy Iris Syndrome (IFIS)

1. When initiating alpha blocker therapy, patients with planned cataract surgery should be informed of the associated risks and be advised to discuss these risks with their ophthalmologists. (Expert Opinion)

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Outcomes of α-Blockers

- 1st generation agents: phenoxybenzamine (irreversible) and prazosin (frequent daily dosing) no longer used.[15,16]
- Second generation agents: **terazosin** and **doxazosin**, allow for once-daily dosing but need to be titrated to effect[17,18,19,20,21]
- $\alpha 1_a$-selective blockers: **tamsulosin**,[22,23] **alfuzosin**,[24] and **silodosin**,[25,26] developed to avoid the systemic side effects associated with α-blockade
- Improvements in Qmax with use of α-blockers range from **0.59-4.8ml/s** (**Table on Next Slide**)
- Symptom score reductions range from **1-4.2 points**.
- Direct comparisons between different types of alpha blockers are limited
- In 2011, a large RCT involving 1228 patients compared tamsulosin, silodosin and placebo
  - Found silodosin to be non-inferior to tamsulosin in improving storage and voiding LUTS while allowing for greater alpha 1a selectivity.[27]

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α-Blockers

Table 1. Summary of α-Blocker Efficacy

Agent	Reference	N	Change in Qmax (ml/s)	Change in Boyarsky symptom score	Change in AUA symptom score
Prazosin 2mg bid	Kirby, et al.[15]	55	+4.8*	N/A	N/A
Prazosin 2mg daily	Chapple, et al.[16]	75	+1.6	N/A	N/A
Terazosin Up to 10mg daily	Lepor, et al.[17]	285	+1.9*	-2.3*	N/A
Doxazosin 4mg daily	Chapple, et al.[18]	135	+1.5*	N/A	N/A
Doxazosin Up to 8mg daily	Fawzy, et al.[20]	100	+2.2*	N/A	-3.2*
Doxazosin Up to 12mg daily	Gillenwater, et al.[21]	248	+3.5*	-2.1*	N/A
Tamsulosin 0.4mg daily	Lepor, et al.[22]	756	+1.23*	-1.6*	-2.8*
Tamsulosin 0.4mg daily	Narayan, et al.[23]	735	+0.59*	-1.08*	-3.84*
Alfuzosin 10mg	Roehrborn, et al.[24]	955	+1.2*	N/A	-2.2*
Silodosin 8mg	Marks, et al.[25]	661	+2.8*	N/A	-4.2*

* denotes p<0.05

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Adverse Effects of α-Blockers

- Most common side effects associated with alpha blockade[22] :
  - a decline in blood pressure that can result in dizziness (5 to 15% with $\alpha 1_a$-selective agents)
  - retrograde ejaculation (6%),
  - rhinitis (12%)
- The cardiovascular effects particularly seen when less selective drugs and higher doses of α-blockade are used (tamsulosin 0.8mg daily)
- Silodosin is felt be less likely to cause orthostasis given its high $\alpha 1_a$-selectivity
- In regard to ejaculatory dysfunction, alfuzosin is thought to pose a reduced risk when compared to other means of alpha blockade[28]

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5 α-Reductase Inhibitor

1. For the purpose of symptom improvement, 5-ARI monotherapy should be used as a treatment option in patients with LUTS/BPH with prostatic enlargement as judged by a prostate volume of > 35cc on imaging, a prostate specific antigen (PSA) > 1.5ng/dL, or palpable prostate enlargement on digital rectal exam (DRE). (Moderate Recommendation; Evidence Level: Grade B)
2. 5-ARIs alone or in combination with alpha blockers are recommended as a treatment option to prevent progression of LUTS/BPH and/or reduce the risks of urinary retention and need for future prostate-related surgery. (Strong Recommendation; Evidence Level: Grade A)
3. Before starting a 5-ARI, clinicians should inform patients of the risks of sexual side effects, certain uncommon physical side effects, and the low risk of prostate cancer. (Moderate Recommendation; Evidence Level: Grade C)
4. Clinicians may consider 5-ARIs as a treatment option to reduce intraoperative bleeding and peri- or postoperative need for blood transfusion after transurethral resection of the prostate (TURP) or other surgical intervention for BPH. (Expert Opinion)

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Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

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5 α-Reductase Inhibitor

Mechanism of action:

- Reduces prostate volume to unobstruct the bladder neck
- 5-ARIs suppress androgen synthesis by blocking the conversion of testosterone to dihydrotestosterone
- This is associated with reduction in prostate volume and decrease in bladder outlet obstruction
- Contrary to alpha-blockers, these drugs have a slow onset of action and a clinical benefit is not noticed before at least 6 months of therapy in most patients[22]

Names

- Finasteride, Dutasteride

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5 α-Reductase Inhibitor Studies

PLESS Study

Findings at 4 year f/u:[30]

- Finasteride arm: **57%** risk reduction in AUR & **55%** risk reduction in the need for surgery
- Qmax increased by 0.2ml/s in the placebo group vs. 1.9ml/s in the finasteride arm ($p<0.001$)
- Decrease in symptom score of 1.3 in the placebo group vs. 3.3 in the finasteride group ($p<0.001$)
- 5α-reductase inhibitors reduced prostate volume **15-32%.**

REDUCE Trial

Post-hoc analysis of the Reduction by Dutasteride of Prostate Cancer Events:

- Dutasteride in asymptomatic or mildly symptomatic men decreased the risk of BPH-related symptoms, episodes of urinary retention and need for BPH-related surgery.[31]

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5 α-Reductase Inhibitor Studies

Table 2. Summary of 5α-Reductase Inhibitor Efficacy

Agent	Reference	N	Change in Qmax (ml/s)	Change in symptom score	Change in prostate value
Finasteride Up to 5 mg daily	Gormley, et al.[33]	895	+1.6*	-0.8*	-13cm³*
Finasteride 5 mg daily	Andersen, et al.[34]	707	+1.5*	-2.0*	-19.2%*
Finasteride 5 mg daily	Marberger, et al.[35]	3,270	+1.5*	-3.2*	-15.3%*
Finasteride 5 mg daily	Stoner, et al.[36]	1,645	+2.3*	-3.6*	-27%*
Finasteride 5 mg daily	McConnell, et al.[37]	3,040	+1.7*	-2.0*	-32%*
Dutasteride 0.5mg daily	Roehrborn, et al.[38]	4,325	+2.2*	-4.5*	-25.7%*
Dutasteride 0.5mg daily	Roehrborn, et al.[39]	2,340	N/A	-1.9*	N/A
* denotes p<0.05					
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Adverse Effects of 5 α-Reductase Inhibitor

Adverse Effects

- Decreased libido (6.4%)
- Erectile dysfunction (8.1%)
- Ejaculatory disorder (0.8%)
- Gynecomastia (0.5%)
- Breast tenderness (0.4%)
- Rash (0.5%)[32]
- Case reports linking finasteride use to IFIS development have been published, although it is unclear what alpha-blocker exposure these patients had experienced[33,34]
- Despite a change in label for these agents, there currently exists no robust evidence regarding any causal link between 5-ARIs and persistent or long-term sexual side effects

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Anticholinergic Outcomes

Tolterodine and Tamsulosin for Treatment of Men with Lower Urinary Tract Symptoms and Overactive Bladder (TIMES) trial:

- Randomized, double blind, placebo-controlled study designed to evaluate the efficacy and safety of using an antimuscarinic agent (tolterodine ER) alone or in conjunction with a α-blocker (tamsulosin) in the treatment of LUTS with OAB symptoms[36]
- Combination therapy resulted in improved number of nocturia, daytime frequency, and urgency episodes
- There was no significant difference in Qmax or PVR between the four arms

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Anticholinergic Outcomes

- A meta-analysis of trials that studied the effects of anticholinergics on men with BPH was conducted, pooling data from 5 randomized controlled trials and 15 observational studies[37]
- Although total IPSS scores did not change with anti-cholinergic therapy, IPSS storage sub-scores, which account for the majority of subjective bother, were improved.
- Anticholinergic use was found to be safe, with a low acute urinary retention rate of **0.3%** at 12 weeks of follow-up.
- Overall, the addition of antimuscarinics to therapy for BPH improved symptom scores by 6-8.5 with mixed effects on Qmax and PVR

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Anticholinergic Outcomes

Table 4. Summary of Anti-Cholinergic Efficacy

Agent	Reference	N	Change in Qmax (ml/s)	Change in Boyarsky symptom score	Change in AUA symptom score
Tolterodine ER 4mg daily	Kaplan, et al.[44]	43	+1.9*	-6.1*	-22*
Tolterodine ER 4mg + tamsulosin 0.4mg daily	Kaplan, et al.[45]	879	+0.07	-8*	N/A
Tolterodine ER 4mg + tamsulosin 0.4mg daily	Kaplan, et al.[50]	851	+0.07	-8.5*	+6.42
* denotes p<0.05					
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Beta-3 Adrenoreceptor Agonist

Mechanism of action

- Hypothesized dual mechanism of action involving β3 adrenoceptor activation and possible α1 blockade leading to relaxation of urethral smooth muscle as has been demonstrated in animals models
- The mechanism by which mirabegron contributes to α_1-adrenoceptor blockade is still not well understood[38,39]

Name:

- Mirabegron (Only available Beta-3 Agonist in US)

Side Effects

- Urinary retention
- Hypertension

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Beta-3 Adrenoreceptor Agonist

- In 2013, Nitti et al. conducted a randomized, double-blind, parallel group, placebo controlled, multicenter phase II study with 12 weeks duration, 200 men more than 45 years of age with LUTS and BOO were randomized (1 : 1 : 1) into three groups (mirabegron 50 mg/mirabegron 100 mg/placebo)[40]
- After 12 weeks of treatment, it was found that mirabegron 50 or 100 mg did not compromise PdetQmax or Qmax as compared to placebo
- Both treatment arms showed a significant decrease in voiding frequency versus placebo
- In addition, the 50 mg mirabegron group showed a statistically significant decrease of urgency.
- Across all three groups, rates of adverse events were similar
- These findings suggest an emerging safe and promising treatment for men with BPH/LUTS[40]
- HTN, UTI, Headache, Nasopharyngitis equivalent

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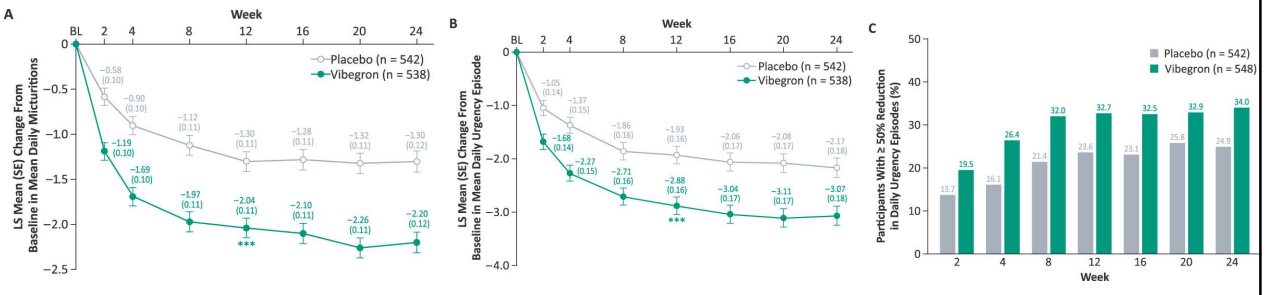
COURAGE Trial

- Phase 3 randomized control trial to evaluate safety and efficacy of virabegron treating OAB in n=1105 men ≥ 45 years of age with medically treated BPH
- Significant reductions in average daily micturitions & episodes of urgency
- Improved IPSS Storage scores, nocturia, UUI, and voided volume per micturition



Staskin, D., Owens-Grillo, J., Thomas, E., Rovner, E., Cline, K., & Mujais, S. (2024). Efficacy and Safety of Vibegron for Persistent Symptoms of Overactive Bladder in Men Being Pharmacologically Treated for Benign Prostatic Hyperplasia: Results From the Phase 3 Randomized Controlled COURAGE Trial. *Journal of Urology*, *212*(2), 256–266. https://doi.org/10.1097/JU.0000000000003999 (Original work published August 1, 2024)

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Slide 42

AC0 ADD MORE STUDY DETAILS
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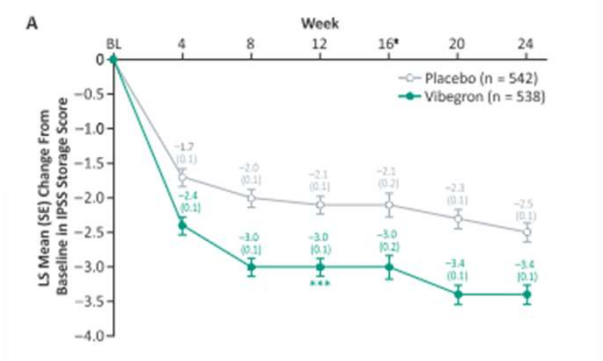
COURAGE Trial



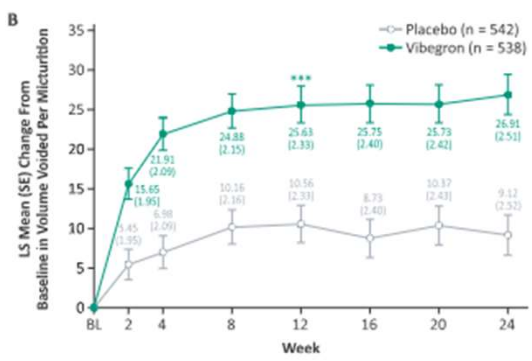


Figure 4. Least squares (LS) mean (SE) change from baseline in International Prostate Symptom Score (IPSS) storage score (A) and volume voided per micturition (full analysis set; B). ***$P < .001$. [a]Includes data collected from 170 participants in the vibegron arm and 173 participants in the placebo arm who completed the week 16 visit in clinic before a protocol amendment changing the visit to virtual. BL indicates baseline.

Staskin, D., Owens-Grillo, J., Thomas, E., Rovner, E., Cline, K., & Mujais, S. (2024). Efficacy and Safety of Vibegron for Persistent Symptoms of Overactive Bladder in Men Being Pharmacologically Treated for Benign Prostatic Hyperplasia: Results From the Phase 3 Randomized Controlled COURAGE Trial. *Journal of Urology, 212*(2), 256–266. https://doi.org/10.1097/JU.0000000000003999 (Original work published August 1, 2024)

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PDE5I

Mechanism of action

- Blockade of phosphodiesterase cGMP —> GMP; Nitric Oxide, Endothelial/Vasodilator
- PDE5i function by blocking the breakdown of cGMP to GMP by phosphodiesterase, thus leading to vasodilation
- There are 11 PDE families and the prostate contains several, most abundantly 4, 5 and 11
- All PDE5I have significant cross-reactivity on PDE enzymes other than PDE5
- They have classically been utilized for the treatment of erectile dysfunction (ED), but an age-independent link between LUTS and ED has recently been demonstrated
- Improvements in LUTS have been observed in patients using **sildenafil**,[41,42,4344] **tadalafil**,[45,46,47] and **vardenafil**[48]

Names

- Tadalafil, Sildenafil, Vardenafil

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Efficacy of PDE5I

Table 5. Summary of PDE5i Efficacy

Agent	Reference	N	Change in Qmax (ml/s)	Change in Boyarsky symptom score	Change in AUA symptom score
Sildenafil on deman	Sairam, et al.[47]	112	N/A	N/A	N/A
Sildenafil on deman	Mulhall, et al.[48]	48	N/A	-4.6*	N/A
Alfuzosin 10mg daily + sildenafil 25mg every other day	Kaplan, et al.[50]	62	+2.0*	-4.3*	-21*
Sildenafil 50mg titrated to 100mg daily	McVary, et al.[51]	366	+0.31	-6.3*	N/A
Tadalafil 5mg titrated to 20mg daily	McVary, et al.[52]	281	+0.5	-2.8*	+1.4
Tadalafil up to 20mg daily	Roehrborn, et al.[53]	1,058	+1.96	-5.2	-3.95
Tadalafil 20mg daily	Dmochowski, et al.[54]	200	-0.1	-9.2*	-13
Vardenafil 10mg twice daily	Stief, et al.[55]	222	+1.6	-5.8*	-1.0
Tadalafil 5 mg	Oelke 61	511	2.4*	-2.1*	-4.6
Tadalafil 5mg	Roehrborn 62	1500	+1.8*	1.6*, 2.5*,4.1*	N/A
* denotes p<0.05					
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PDE5I Outcomes

- The largest study was reported by Roehrborn et al. who examined the use of 2.5, 5, 10, or 20 mg tadalafil vs. placebo in 1,058 men with BPH-related LUTS.[46] Significant improvement was seen in IPSS score in a dose-related fashion with the maximum improvement seen in the 10 and 20 mg dosing albeit at the cost of a greater number of adverse events
- No impact on Qmax was seen
- Dmochowski et al. studied 200 men randomized to 20 mg tadalafil vs. placebo over 12 weeks, focusing specifically on urodynamic parameters[47]
- Despite improvements in IPSS score over placebo, no significant changes were seen in urodynamic parameters, specifically $P_{detQmax}$, Qmax, Qavg, or maximum Pdet.

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PDE5I Outcomes

- In 2012, Oelke et al conducted a randomized, double-blind, multicenter placebo controlled study with randomization to either placebo, tamsulosin 0.4mg or tadalafil 5mg
- Results revealed similar improvements versus placebo in IPSS and BPH Impact Index in both tamsulosin and tadalafil groups and compared to previous literature Qmax increased significantly compared to placebo (2.4ml/s p=0.009).[48]
- Roehrborn et al conducted a randomized placebo controlled trial including 1500 patients
- Found a small but statistically significant median Qmax improvement that increased with voided volume[49]

For patients with LUTS/BPH irrespective of comorbid erectile dysfunction (ED), 5mg daily tadalafil should be discussed as a treatment option.
(Moderate Recommendation; Evidence Level: Grade B)

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PDE5I

- Pooled analysis of 4 studies investigating the use of tadalafil 5mg did however show IPSS improvement in two-thirds of patients with at least 50% of patients with significant response at 1 week and at least 70% demonstrating improvement at 4 weeks. These results suggest speed of onset comparable with alpha blockade.[50]
- Symptom score improvements have been observed in the 4.3-9.2 range (**see table on next slide**)
- While no consensus currently exists regarding what role PDE5i should play in the BPH-related LUTS treatment pathway, daily tadalafil 5 mg has been approved in the US for daily use in men with BPH/LUTS.

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Combination Therapy

1. 5-ARI in combination with an alpha blocker should be offered as a treatment option only to patients with LUTS associated with demonstrable prostatic enlargement as judged by a prostate volume of > 35cc on imaging, a PSA >1.5ng/dL, or palpable prostate enlargement on DRE. (Strong Recommendation; Evidence Level: Grade A)
2. Anticholinergic agents, alone or in combination with an alpha blocker, may be offered as a treatment option to patients with moderate to severe predominant storage LUTS. (Conditional Recommendation; Evidence Level: Grade C)
3. Beta-3-agonists in combination with an alpha blocker may be offered as a treatment option to patients with moderate to severe predominate storage LUTS. (Conditional Recommendation; Evidence Level: Grade C)
4. Clinicians should not offer the combination of low-dose daily 5mg tadalafil with alpha blockers for the treatment of LUTS/BPH as it offers no advantages in symptom improvement over either agent alone. (Moderate Recommendation; Evidence Level: Grade C)

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Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

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Combination Therapy

Table 1.2. Differences in MTOPS and CombAT Study Characteristics

	Medical Therapy of Prostate Symptoms Study (MTOPS)	Combination of Avodart and Tamsulosin (CombAT)
Treatments	Placebo vs finasteride vs doxazosin vs combination	Dutasteride vs. tamsulosin vs. combination
Setting	United States; select centers	International > 100 centers
Total number enrolled	*N*=3047	*N*=4844
Follow-up time	Up to 5.5 years	4 years (2-year data available)
Endpoints	Composite progression	International Prostate Symptom Score at 2 years; progression at 4 years
Prostate size (mean)	36.3 mL	55.0 mL
Prostate-specific antigen (mean)	2.4 ng/mL	4.0 ng/mL

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Nickel JC, Méndez-Probst CE, Whelan TF, Paterson RF, Razvi H. 2010 Update: Guidelines for the management of benign prostatic hyperplasia. Can Urol Assoc J. 2010 Oct;4(5):310-6. doi: 10.5489/cuaj.10124. PMID: 20944799; PMCID: PMC2950766.

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Combination Therapy

Table 3. Summary of Combination Therapy Efficacy

Agent	Reference	N	Change in Qmax (ml/s)	Change in symptom score	Change in prostate volume
Finasteride 5mg + terazosin up to 10mg daily	Lepor, et al[37]	1,229	+3.2*	-4.4*	-7.5cm3*
Finasteride 5mg + doxazosin up to 8mg daily	Kirby, et al[38]	1,007	+3.8*	-8.5*	N/A
Finasteride 5mg + 5mg alfuzosin twice daily	Debruyne, et al[39]	1,051	+2.3	-6.3*	-4.9
Finasteride 5mg + doxazosin up to 8mg daily	McConnell, et al[42]	3,047	+5.1*	-7.4*	-19%*
Dutasteride 0.5mg + tamsulosin 0.4mg daily	Roehrborn, et al[43]	4,844	+2.4*	-6.3*	-27.3%*
* denotes p<0.05					
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AUR Outcomes Statements

1. Physicians should prescribe an oral alpha blocker prior to a voiding trial to treat patients with AUR related to BPH. (Moderate Recommendation; Evidence Level: Grade B).
2. Patients newly treated for AUR with alpha blockers should complete at least three days of medical therapy prior to attempting trial without a catheter (TWOC). (Expert Opinion)
3. Clinicians should inform patients who pass a successful TWOC for AUR from BPH that they remain at increased risk for recurrent urinary retention. (Moderate Recommendation; Evidence Level: Grade C).

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Clinical Pathway for BPH

Patients should first be thoroughly evaluated with a history, physical exam, IPSS, and objective measures such as Qmax and PVR

Urodynamics (represents the most definitive way to diagnose BOO) is an invasive test

- But may be helpful in patients with complex symptoms (co-existing OAB and BOO), co-morbid neurologic conditions, or those with equivocal obstructive LUTS and concomitant bothersome OAB symptoms considering outlet surgery

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Clinical Pathway for BPH

- For patients with (i) mild symptoms (IPSS≤8) or (ii) moderate to severe symptoms without significant bother, watchful waiting is reasonable assuming no evidence of **recurrent infection, bladder stones, urinary retention, or renal compromise**
    - These patients can be seen annually for f/u visits and symptom assessment with PVR's

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Clinical Pathway for BPH

For patients with moderate to severe symptoms with significant bother, physicians should engage in a discussion with patients regarding treatment options

- Patients may choose from medical therapy (typically first line) or surgical therapy in the event of medication failure
- For those with small prostates (<30g), initial therapy with α-blockers is reasonable
- Should symptoms not improve sufficiently, the addition of an anti-cholinergic is beneficial in patients with OAB
- For patients with larger prostates (≥30g), combination therapy with an α-blocker and 5α-reductase inhibitor should represent the first line of treatment
- An anti-cholinergic may be added for further symptom control if necessary
- The use of PDE5i monotherapy may be beneficial in reducing urinary symptoms, particularly in patients with concomitant ED.

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Surgical Therapies

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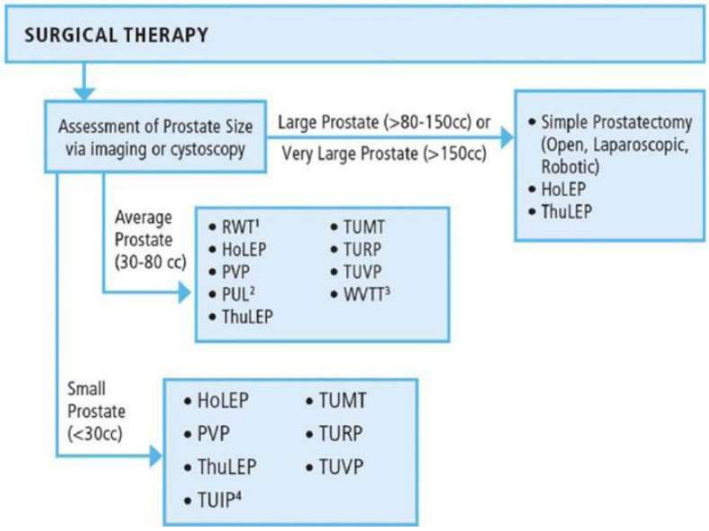
AUA Surgical Pathway



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Prostatic Urethral Lift (PUL) - UROLIFT

PUL should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g and verified absence of an obstructive middle lobe. (*Moderate Recommendation; Evidence Level: Grade C*)

PUL may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (*Conditional Recommendation; Evidence Level: Grade C*)

Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

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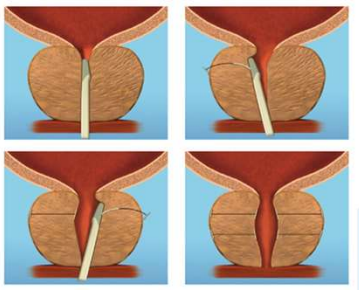
Urolift – (PUL)

The UroLift System	The UroLift ATC® System Advanced Tissue Control	The UroLift® 2 System
Delivery Device is inserted transurethrally through a rigid sheath under cystoscopic visualization in order to reach the targeted area of obstruction	**Enhanced Delivery Device tip** that makes it **easier** to treat BPH patients with challenging anatomies, including an **obstructive median lobe**[1]	Innovative delivery system that **reduces waste** and **streamlines the procedure** with the same implant with proven outcomes[2-4]
		



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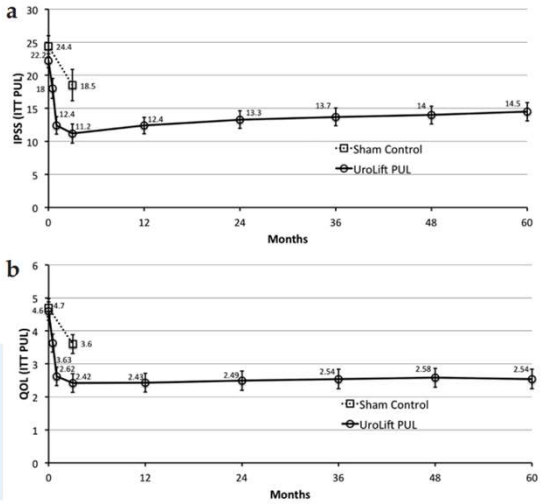
Five-year results of the prospective randomized controlled prostatic urethral L.I.F.T. study

Claus G Roehrborn [1], Jack Barkin, Steven N Gange, Neal D Shore, Jonathan L Giddens, Damien M Bolton, Barrett E Cowan, Anthony L Cantwell, Kevin T McVary, Alexis E Te, Shahram S Gholami, William G Moseley, Peter T Chin, William T Dowling, Sheldon J Freedman, Peter F Incze, K Scott Coffield, Sean Herron, Prem Rashid, Daniel B Rukstalis

- LUTS and QOL improved significantly within 2 weeks, with a return to preoperative physical activity in an average of 8.6 days
- Improvements in IPSS, QOL, and Qmax were sustained over 5 years, showing increases of 36%, 50%, and 44%, respectively
- The rate of surgical retreatment was 13.6% over the 5-year period



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L.I.F.T. Study Erectile Function

- 0% de novo sustained ejaculatory dysfunction
- Intensity and volume improved by 20% (p<0.01)
- Bother score improved by 30% (p<0.01)

	1 Month	3 Month	6 Month	12 Month
Question 1 [Frequency]: How often have you been able to ejaculate or "cum" when having sexual activity?				
n (paired)	77	80	84	75
Baseline	4.08±1.06	4.04±1.05	4.02±1.11	4.05±1.06
Follow-Up	4.25±1.07	4.38±1.01	4.35±0.95	4.23±1.03
Change [95%CI]	0.17 [-0.06 – 0.39]	0.34 [0.15 – 0.52]	0.33 [0.11 – 0.54]	0.18 [-0.05 – 0.40]
p-value	0.109	<0.001	<0.001	0.038
Question 2 [Intensity]: How would you rate the strength or force of your ejaculation?				
n (paired)	77	80	84	75
Baseline	2.57±1.22	2.56±1.22	2.58±1.21	2.59±1.21
Follow-Up	3.56±1.34	3.45±1.29	3.30±1.32	3.18±1.31
Change [95%CI]	0.99 [0.70 – 1.29]	0.89 [0.62 – 1.15]	0.72 [0.48 – 0.95]	0.59 [0.33 – 0.84]
p-value	<0.001	<0.001	<0.001	<0.001
Question 3 [Volume]: How would you rate the amount or volume of semen or fluid when you ejaculate?				
n (paired)	77	80	84	75
Baseline	2.49±1.32	2.47±1.35	2.54±1.37	2.56±1.37
Follow-Up	3.48±1.35	3.40±1.38	3.30±1.43	3.12±1.27
Change [95%CI]	0.99 [0.67 – 1.30]	0.93 [0.67 – 1.18]	0.76 [0.50 – 1.02]	0.56 [0.30 – 0.82]
p-value	<0.001	<0.001	<0.001	<0.001
Question 4 [Bother]: If you have had any ejaculation difficulties or have been unable to ejaculate, have you been bothered by this?				
n (paired)	77	80	84	75
Baseline	2.0±1.6	2.0±1.6	2.1±1.6	2.0±1.7
Follow-Up	1.3±1.4	1.0±1.3	1.1±1.1	1.2±1.3
Change [95%CI]	-0.7 [-1.0 - -0.4]	-1.0 [-1.3 - -0.7]	-1.0 [-1.3 - -0.7]	-0.8 [-1.1 - -0.4]
p-value	<0.001	<0.001	<0.001	<0.001

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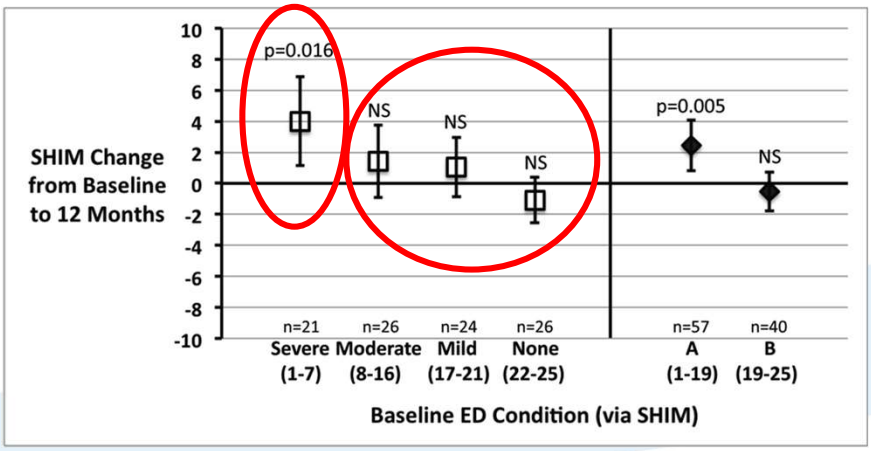
L.I.F.T. Study Erectile Function



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McVary K et al. J Sex Med 2014;11:279–287

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Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study

Christian Gratzke*, Neil Barber†, Mark J. Speakman‡, Richard Berges§, Ulrich Wetterauer¶, Damien Greene**, Karl-Dietrich Sievert††, Christopher R. Chapple‡‡, Jacob M. Patterson‡‡, Lasse Fahrenkrug§§, Martin Schoenthaler¶ and Jens Sonksen§§

- 2-year prospective multi-center RCT
- Non-validated BPH6 scores
- Better urinary outcomes with TURP
- Better ejaculatory function with PUL
- 100% vs. 66%
- No differences in ejaculatory bother

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Gratzke C. BJUI. 2016

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Water Vapor Thermal Therapy

WVTT should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g. (*Moderate Recommendation; Evidence Level: Grade C*)

WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (*Conditional Recommendation; Evidence Level: Grade C*)

Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

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Water Vapor Thermal Therapy (REZUM)

WVTT should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g. (*Moderate Recommendation; Evidence Level: Grade C*)

WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (*Conditional Recommendation; Evidence Level: Grade C*)

Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

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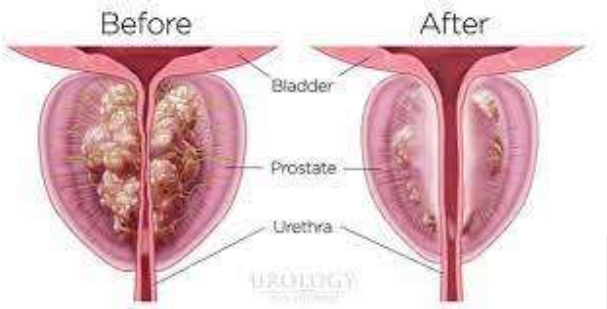
REZUM



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Rezūm Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study

Kevin T. McVary [a], Tyson Rogers [b], Claus G. Roehrborn [c]

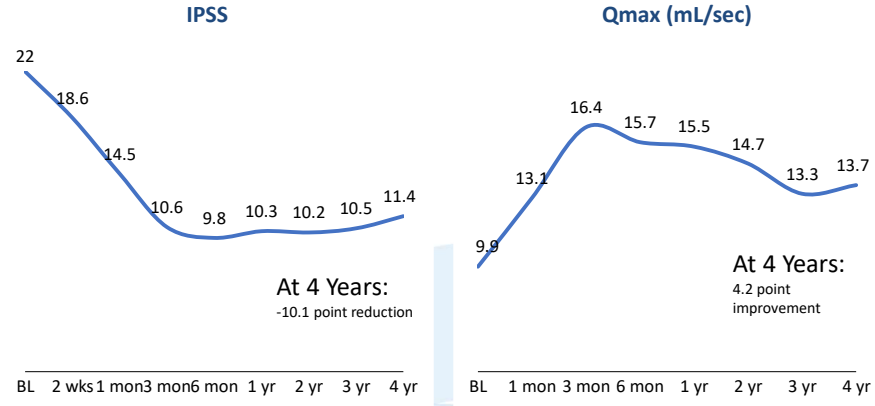

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Figure adapted from results of McVary K, Rogers T, Roehrborn C. Rezūm water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. *Urology*. 2018. ***In Press***

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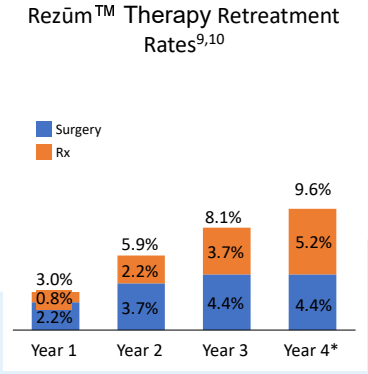
REZUM Retreatment Rates

- 4 & 5 year Surgical retreatment rates of 4.4% are consistent with 3-year results
- At 4 years, two additional patients started BPH medication for a total of 5.2% returning to medication



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McVary K, Rogers T, Roehrborn C. Rezūm water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. *Urology*. 2018. ***In Press.***

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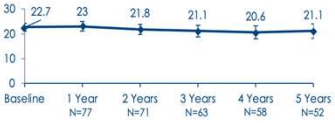
Sexual Function in Rezūm II Pivotal Study

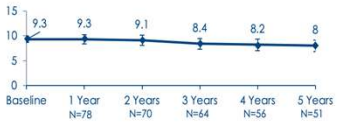
Treatment Arm Subjects – Improved Quality of Life - No Change Erectile Function

Mean Score

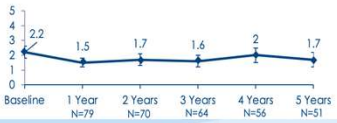
IIEF†
Erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction



MSHQ Function†
Frequency, strength and volume of ejaculation



MSHQ Bother°
Bother/satisfaction with ability to ejaculate



Key Points

1) **No de novo erectile dysfunction & limited impact on sexual function**

2) **Patients had sexual function issues at baseline**
   - 90 of 135 men were sexually active
   - 53% had history of ED
   - 25% had EjD

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McVary KT, et al. J Urol April 2021

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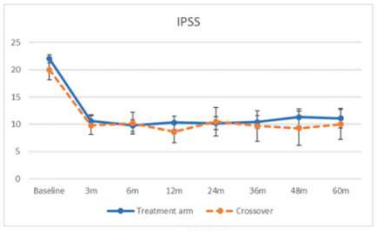
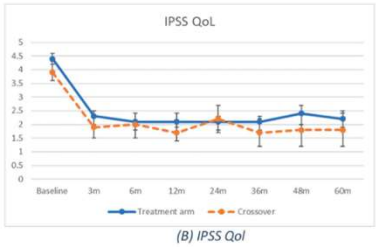
Sexual Function in Rezūm II Pivotal Study

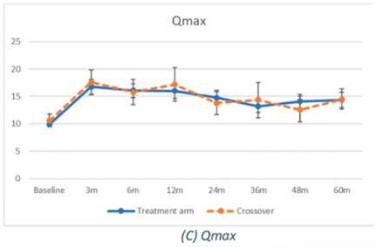
Treatment Arm Subjects – Improved Quality of Life - No Change Erectile Function



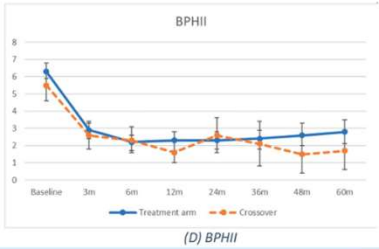
(A) IPSS



(B) IPSS QoI



(C) Qmax



(D) BPHII

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McVary KT, et al. J Urol April 2021

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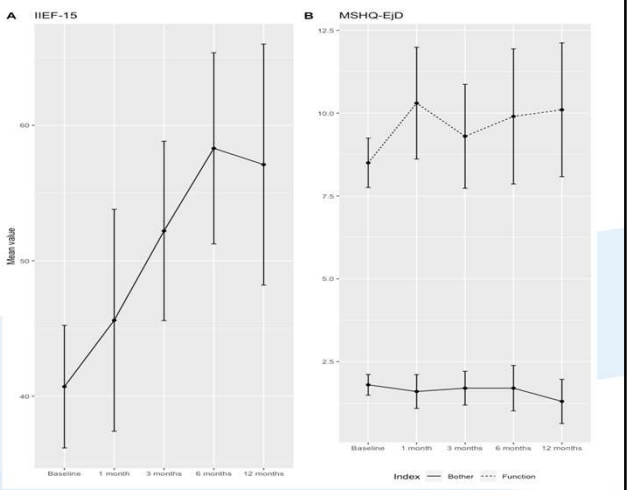
Rezūm water vapor therapy for large volume (≥80 mL) benign prostatic enlargement: Large, multi-center cohort

- IIEF showed no significant change from 52 at baseline to 57 at 12 months.
- Similarly, no changes in MSHQ function (10.3 to 10.1 at 12 months) or bother (1.4 to 1.3 at 12 months).



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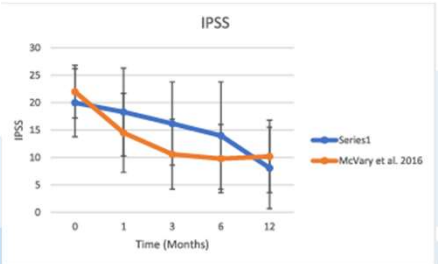
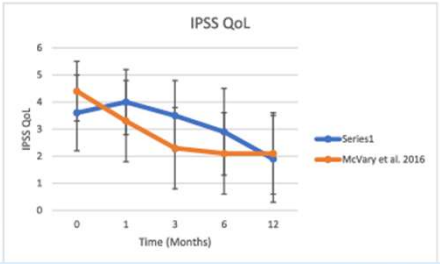
Pilot Study of "Less is More" Rezum for Treatment of BPH

Oluwatobi Aladesuru [1], Koby Amankwah [1], Dean Elterman [2], Kevin C Zorn [3], Naeem Bhojani [3], Alexis Te [1], Bilal Chughtai [4]

- The "less is more" treatment approach led to significant improvements in IPSS, IPSS QoL, and QMax at 3, 6, and 12 months.
- IPSS scores decreased by an average of 4 points (-20.7%) at the 3-month follow-up, with sustained results at 12 months.
- Patient-reported quality of life improved, with IPSS QoL scores reducing by 1.7 (-47.2%) at 12 months.





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Feasibility assessment of catheter–free water vapor thermal therapy for treatment of benign prostatic hyperplasia

Vi Nguyen [1], Joshua Winograd [2], Alia J Codelia-Anjum [2], Kevin C Zorn [3], Dean Elterman [4], Naeem Bhojani [3], Seth K Bechis [5], Bilal Chughtai [6]

- The study assessed the feasibility and safety of catheter-free water vapor thermal therapy (WVTT) for men with benign prostatic hyperplasia (BPH).
- Patients received 2–3 injections based on presence of bilobar versus trilobar hyperplasia
- Significant improvements in voiding parameters (voided volume, Qmax) and symptom scores (IPSS, OAB-SF) were observed at 3 days, 1, 3, and 6 months postoperatively.

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Feasibility assessment of catheter–free water vapor thermal therapy for treatment of benign prostatic hyperplasia

Vi Nguyen [1], Joshua Winograd [2], Alia J Codelia-Anjum [2], Kevin C Zorn [3], Dean Elterman [4], Naeem Bhojani [3], Seth K Bechis [5], Bilal Chughtai [6]

- Catheter-free WVTT is feasible for well-selected BPH patients and enhances both voiding and symptom scores.
- There were no notable changes in sexual function, infectious complications, or readmission rates.
- Only 1 patient (5%) required postoperative catheterization within the first 30 days.

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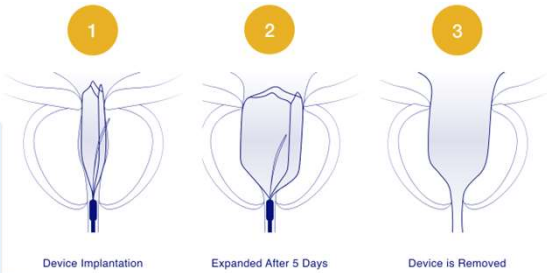
Temporarily Implanted Prostatic Devices (TIPD)

TIPD may be offered as a treatment option for patients with LUTS/BPH provided prostate volume is between 25 and 75 cc and lack of obstructive median lobe. (Expert Opinion)

- Treatment options for patients with LUTS/BPH
- Prostate volume between 25 to 75
- Lack of obstructive median lobe



Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

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Temporarily Implanted Nitinol Device (iTIND)

- Temporarily placed device exerts radial pressure
- Pressure necrosis and incisions into bladder neck and prostatic urethra
- Removed after 5-7 days
- FDA de novo approval March 2020
- Acquired by Olympus March 2021
- True MIST – no special equipment required

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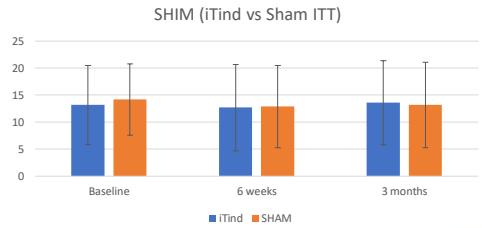
Preservation of sexual function in the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia in men treated with the iTind Temporarily Implanted Nitinol Device

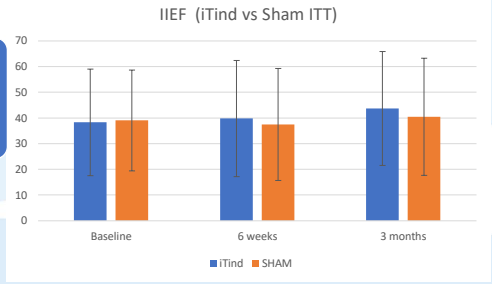
iTind does not cause sexual and ejaculatory dysfunction in men, regardless of age, prostate volume, or baseline ED status

There were no patient reported ejaculatory adverse events (vs. Rezum, who had 2.9% anejaculation compared to sham)[6]

iTind improved sexual function in:

- **Younger men, aged 45-60**
- **No baseline ED (SHIM >21)**





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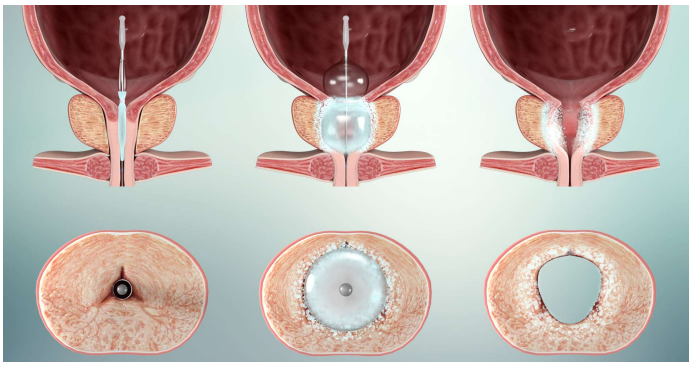
Optilume System

Optilume BPH is a minimally invasive surgical therapy that **combines mechanical dilation with concurrent localized delivery of paclitaxel** for treating BPH-induced lower urinary tract symptoms.



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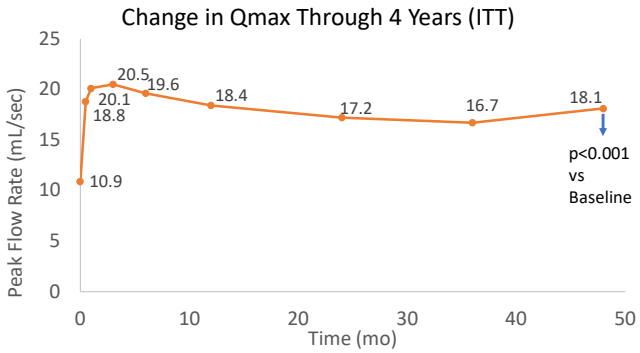
EVEREST Study 4 Year Data

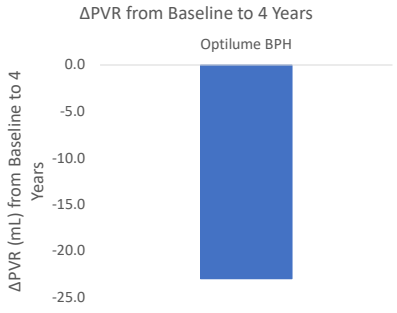
Peak Urinary Flow Rate (Qmax)

Significant immediate increase in Qmax observed immediately post treatment and sustained through 4 year follow-up.



Post-Void Residual Urine (PVR)

PVR improvement after treatment with the Optilume BPH device has been maintained through 4 years.



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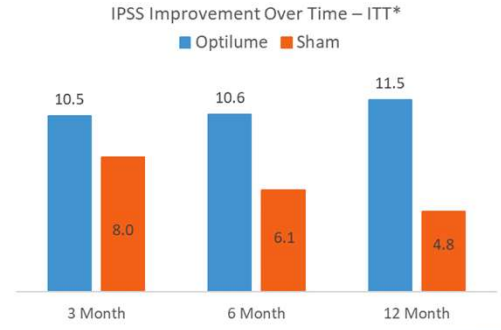
PINNACLE Study Outcomes



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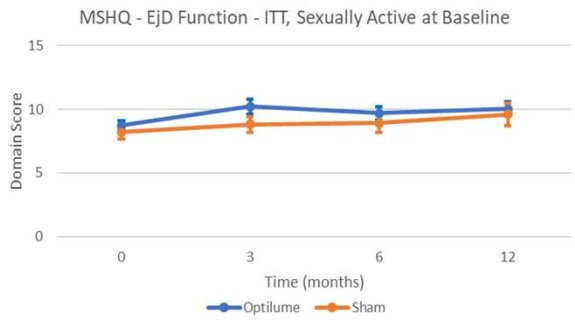
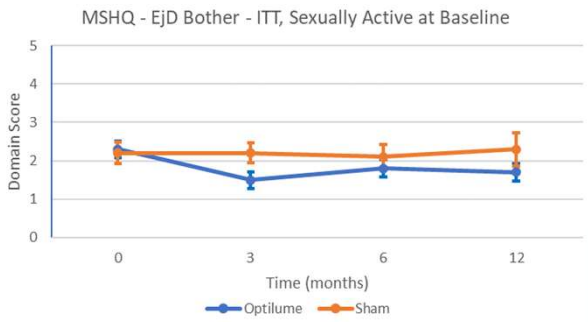
PINNACLE Study – Ejaculatory Function





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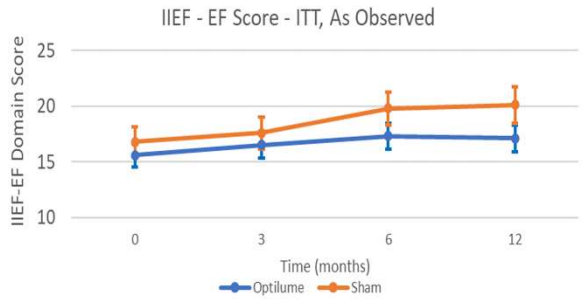
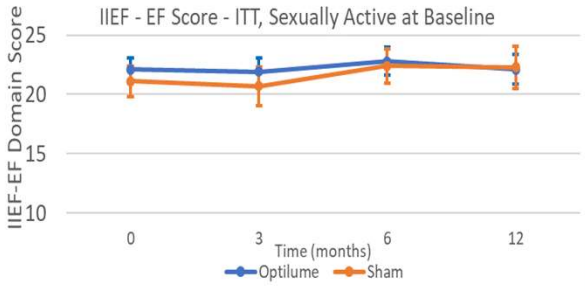
PINNACLE Study – Erectile Function





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PINNACLE Study Sexual Function Preservation

Arm (ITT, As Observed)	Measure	Baseline	3 Months	6 Months	12 Months
Optilume BPH	IIEF - EF	15.6 ± 10.3 (97)	16.5 ± 10.8 (92)	17.3 ± 11.0 (91)	17.1 ± 11.1 (87)
	MSHQ - EjD Function	7.5 ± 3.9 (98)	8.5 ± 4.8 (86)	8.3 ± 4.5 (87)	8.4 ± 4.6 (87)
	MSHQ - EjD Bother	2.5 ± 1.7 (98)	1.9 ± 1.6 (86)	2.1 ± 1.7 (87)	2.0 ± 1.7 (87)
Sham	IIEF - EF	16.8 ± 9.3 (48)	17.6 ± 9.8 (47)	19.8 ± 8.7 (35)	20.1 ± 8.4 (26)
	MSHQ - EjD Function	8.0 ± 3.4 (47)	8.8 ± 3.9 (47)	9.1 ± 3.4 (35)	9.9 ± 3.5 (26)
	MSHQ - EjD Bother	2.2 ± 1.7 (47)	2.0 ± 1.5 (47)	2.1 ± 1.6 (35)	2.0 ± 1.8 (26)

Subjects were evaluated for **perceived changes to sexual function** utilizing the IIEF and MSHQ-EjD Short Form questionnaires. **There were no changes in perceived sexual or ejaculatory function**, with each arm showing a slight improvement in scores from baseline to 1 year.

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Traditional Surgical Therapy

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Transurethral Resection of the Prostate

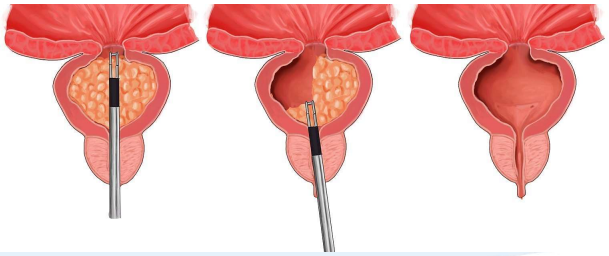
- TURP should be offered as a treatment option for patients with LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade
- Clinicians may use a monopolar or bipolar approach to TURP as a treatment option, depending on their expertise with these techniques. (Expert Opinion)

Monopolar or bipolar approach

Risks:

- bleeding, ED (5%)
- retrograde ejaculation (48%),
- incontinence [1]

Retreatment Rate: 2%



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Pavone C et al Arch Ital Urol Androl 2015 Mar 31;87(1):8-13

https://www.healthtravellersworldwide.com/treatments/transurethral-resection-of-the-prostate-turp/

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Long-Term Followup after Electrocautery Transurethral Resection of the Prostate for Benign Prostatic Hyperplasia

F. Kallenberg, T. A. Hossack, H. H. Woo

- The study included 72 men with a mean follow-up of 70 months, revealing significant long-term improvements in voiding symptoms.
- Participants experienced a 67% reduction in the International Prostate Symptom Score (IPSS) and a 63% improvement in quality of life (QOL), along with a 187% increase in peak urinary flow rate (Qmax) and an 80% decrease in postvoid residual (PVR).
- 14% of participants experienced urethral strictures

Table 3: Overall long-term outcome results post-TURP.

Parameter	Initial	Followup	Difference	% Improvement
IPSS	21	7	14	67%
QoL	4	1.5	2.5	63%
PGI-I		0.9		
Q_{max}	8	22	14	175%
VV	247	424	177	72%
PVR	205	65	140	68%

Table 4: Paired long-term outcome results post-TURP.

Parameter	n	Initial	Followup	Difference (%)	P
IPSS	39	21	7	14 (67%)	<0.001
QoL	39	4	1.5	2.5 (63%)	<0.001
Q_{max}	27	8	23	15 (187%)	<0.001
VV	27	249	421	172 (69%)	<0.001
PVR	25	220	45	175 (80%)	<0.001

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Ejaculatory Preserving Middle Lobe Onl-Transurethral Resection and Vaporization of the Prostate: 12-Year Experience

Zeynep Gul, Bilal Chughtai, Alexis E. Te, Dominique Thomas, and Steven A. Kaplan

- 312 men (mean age 61.3) w/LUTS (n = 147) or retention (n = 175), IPP>10mm treated with MLO-TURP from 2005 to 2017
- Mean baseline P.Vol.= 79.8 g (30−178 g)
- Mean baseline intravesical-prostatic protrusion = 13.6mm
- No difference in outcomes mono- vs bipolar
- Incidence of **ejaculatory dysfunction was 2.6%** (N = 8), there was 1 case of new onset ED (0.3%)
- No difference in outcomes <100 vs. >100mL

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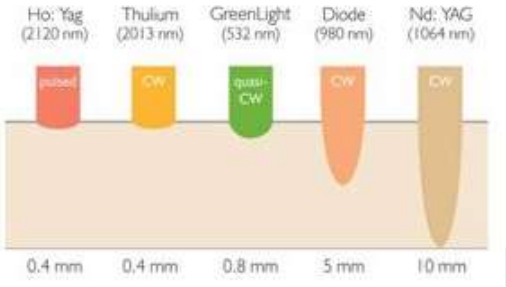
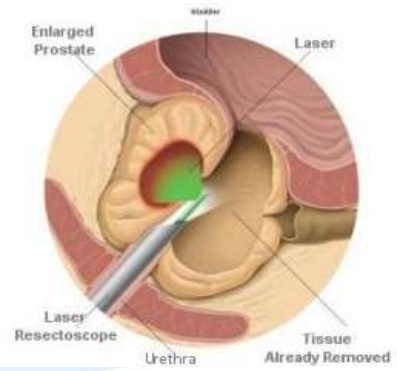
Photoselective Vaporization of the Prostate (PVP)

PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH. (*Moderate Recommendation; Evidence Level: Grade B)*





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https://www.londonurologypartnership.co.uk/web/pvp.html
Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

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Greenlight PVP Outcomes 5 Year Follow Up

Table 2 Long-term GL-PVP functional outcomes at up to 5-year follow-up

Functional outcomes									
Outcome	Baseline	Months							*p* value*
		3	6	12	24	36	48	60	
PSA ng/mL									*p* < 0.001
Mean (SD)	6.5 (22.9)		3.5 (28.4)	2.2 (2.4)	3.1 (5.6)	3.01 (5.32)	2.9 (3.44)	2.8 (3.4)	
Median (IQR)	3.3(1.7–6)		1.7 (0.8–3.1)	1.5 (0.7–2.8)	1.7 (0.7–3.7)	1.7 (0.7–3.6)	1.7 (0.7–3.6)	1.5 (0.6–3.5)	
PSA change	–		43.9%	45.0%	51.7%	45.8%	46.7%	46.4%	
No. pts	*n* = 3432		*n* = 1652	*n* = 162	*n* = 500	*n* = 364	*n* = 254	*n* = 136	
IPSS									*p* < 0.001
Mean (SD)	22.8 (6.7)	7.1 (4.4)	6.6 (4.3)	5.2 (4.2)	5.3 (4.3)	5.3 (4.0)	5.3 (4.2)	6.1 (5.4)	
Median (IQR)	22 (19–27)	6 (4–9)	5 (4–9)	4 (2–7)	4 (3–7)	4 (3–7)	4 (3–7)	5 (3–8)	
No. pts	*n* = 2482	*n* = 1013	*n* = 1906	*n* = 1587	*n* = 512	*n* = 374	*n* = 251	*n* = 176	
QoL									*p* < 0.001
Mean (SD)	4.1 (2.5)	1.4 (1.2)	1.0 (1.1)	0.9 (1.1)	0.9 (1.1)	0.9 (0.9)	0.9 (1.0)	1.2 (1.4)	
Median (IQR)	4 (3–5)	1 (1–2)	1.0 (1.1)	1 (0–1)	1 (0–1)	1 (0–1)	1 (0–1)	1 (0–2)	
No. pts	*n* = 1011	*n* = 53	*n* = 439	*n* = 433	*N* = 364	*n* = 249	*n* = 170	*n* = 148	
Qmax (mL/s)									*p* < 0.001
Mean (SD)	7.5 (10.8)	19.4 (6.6)	18.7 (6.8)	18.9 (6.8)	19.0 (7.1)	25.1 (113.2)	17.8 (6.1)	20.1 (25.5)	
Median (IQR)	6.3 (4–9)	19 (16–22)	18 (15–22)	18 (15–22)	19 (15–23)	18 (15–22)	17 (14–22)	17 (14–21)	
No. pts	*n* = 1441	*n* = 1008	*n* = 1004	*n* = 854	*n* = 444	*n* = 312	*n* = 229	*n* = 123	
PVR (mL)									*p* < 0.001
Mean (SD)	220.5 (341.6)	38.7 (60/8)	30.3 (54.3)	32.8 (61.4)	33.9 (69.1)	37.4 (73.1)	40.4 (94.7)	46.6 (91.2)	
Median (IQR)	122 (32–291)	17 (0–50.0)	15 (0–36.3)	15 (0–40)	10 (0–34)	10 (0–40)	13 (0–50.0)	46.6 (91.2)	
No. pts	*n* = 2129	*n* = 1051	*n* = 1062	*n* = 938	*n* = 514	*n* = 338	*n* = 239	*n* = 129	

*p value obtained using Kruskal–Wallis test

-46% DROP

Rapid and sustained improvements
Across all parameters

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Global Greenlight Group: largest international Greenlight experience for benign prostatic hyperplasia to assess efficacy and safety

Kyle W. Law[1] · Côme Tholomier[2] · David-Dan Nguyen[1] · Iman Sadri[1] · Félix Couture[3] · Ahmed S. Zakaria[4] · David Bouhadana[1] · Franck Bruyère[5] · Hannes Cash[6,7,8] · Maximilian Reimann[6] · Luca Cindolo[9] · Giovanni Ferrari[9] · Carlos Vasquez-Lastra[10] · Tiago J. Borelli-Bovo[11] · Edgardo F. Becher[12] · Vincent Misrai[13] · Dean Elterman[14] · Naeem Bhojani[4] · Kevin C. Zorn[4]

Dataset from **3627 men** treated with GL-PVP between 2011-2019 (performed by 1 of 8 expert surgeons)

Baseline

Mean age: 70 yrs (IQR 64-77)

Mean PV: 64cc. (IQR 47-90)

Mean PSA: 3.1

Mean IPSS: 22 → 35% Foley retention preop

➔ Operative time, hospital length of stay (LOS), duration of catheter, and Clavien–Dindo complications were collected. IPSS, QoL, Qmax, PVR, and PSA were collected at 3, 6, 12, 24, 36, 48, and 60 months

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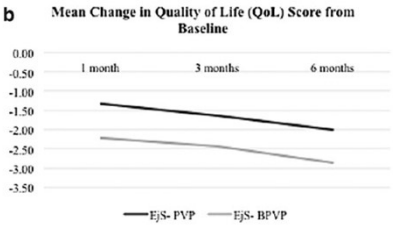
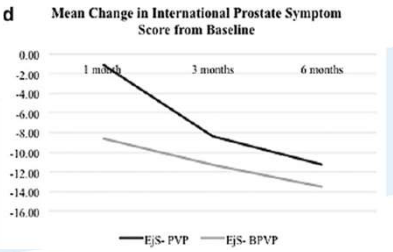
Ejaculatory Hood-Sparing Photoselective Vaporization of the Prostate *vs* Bipolar Button Plasma Vaporization of the Prostate in the Surgical Management of Benign Prostatic Hyperplasia

Mitali Kini, BS,[1] Alexis E. Te, MD,[1] James A. Kashanian, MD,[1] Steven Kaplan, MD,[2] and Bilal Chughtai, MD[1]

- Improvements in IPSS, QoL, Qmax, and PVR were sustained throughout the study for both groups.
- No significant difference in outcomes was observed between the two groups.
- The 6-month ejaculatory preservation rate was 85% in the EjS-PVP group and 78% in the EjS-BPVP group.
- No change in ejaculatory function was seen with EjS-BPVP, regardless of whether 180 W EjS-PVP or bipolar energy was used.





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Ejaculatory Hood-Sparing Photoselective Vaporization of the Prostate *vs* Bipolar Button Plasma Vaporization of the Prostate in the Surgical Management of Benign Prostatic Hyperplasia

Mitali Kini, BS,[1] Alexis E. Te, MD,[1] James A. Kashanian, MD,[1] Steven Kaplan, MD,[2] and Bilal Chughtai, MD[1]

TABLE 2. BASELINE AND POSTOPERATIVE MEAN VALUES OF LOWER URINARY TRACT SYMPTOMS

	Preoperative baseline		*Postoperative scores*		*3-Month scores*		*6-Month scores*		
	EjS-PVP (n=13) Mean±SD	*EjS-BPVP (n=14) Mean±SD*	*EjS-PVP Mean±SD*	*EjS-BPVP Mean±SD*	*EjS-PVP Mean±SD*	*EjS-BPVP Mean±SD*	*EjS-PVP Mean±SD*	*EjS-BPVP Mean±SD*	p[a]
PVR	87.8±161.4	71.0±95.9	18.4±33.5	31.4±42.4	17.8±32.3	29.4±32.5	38.7±33.7	31.4±24.7	0.591
Qmax	13.5±13.4	8.8±2.9	10.0±5.9	10.9±8.3	13.4±7.1	14.2±8.5	11.7±4.2	12.4±10.6	0.871
IPSS	18.5±7.7	18.9±6.5	17.3±11.1	12.0±9.1	10.2±9.9	7.6±5.0	8.5±5.9	8.4±5.8	0.970
QoL	3.9±0.86	3.9±1.2	2.8±1.9	2.1±1.8	2.3±1.6	1.4±0.85	2.3±1.7	1.6±1.0	0.255
SF-12 total	50.2±23.3	35.7±23.8	51.3±20.3	45.4±22.2	52.6±24.4	59.4±17.8	42.6±29.7	36.3±32.7	0.603
OAB-SF total	79.1±44.7	65.8±38.0	90.9±54.9	63.2±36.4	52.4±45.9	43.8±15.8	35.0±29.3	28.6±27.7	0.568

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Ejaculatory Hood-Sparing Photoselective Vaporization of the Prostate *vs* Bipolar Button Plasma Vaporization of the Prostate in the Surgical Management of Benign Prostatic Hyperplasia

Mitali Kini, BS,[1] Alexis E. Te, MD,[1] James A. Kashanian, MD,[1] Steven Kaplan, MD,[2] and Bilal Chughtai, MD[1]

TABLE 5. POSTOPERATIVE CHANGE IN SEXUAL FUNCTION PARAMETERS FROM BASELINE

	Postoperative		*3 Months*		*6 Months*		
	EjS-PVP Mean change (Δ)	*EjS-BPVP Mean change (Δ)*	*EjS-PVP Mean change (Δ)*	*EjS-BPVP Mean change (Δ)*	*EjS-PVP Mean change (Δ)*	*EjS-BPVP Mean change (Δ)*	p[a]
Total MSHQ	0.92	−18.0	12.0	6.50	−3.54	−19.6	0.347
Erection scale	−0.69	−0.93	1.54	0.93	−1.07	−2.29	0.601
Ejaculation scale	−1.23	−7.21	3.0	3.57	−2.15	−5.36	0.465

[a]Student's *t*-test.

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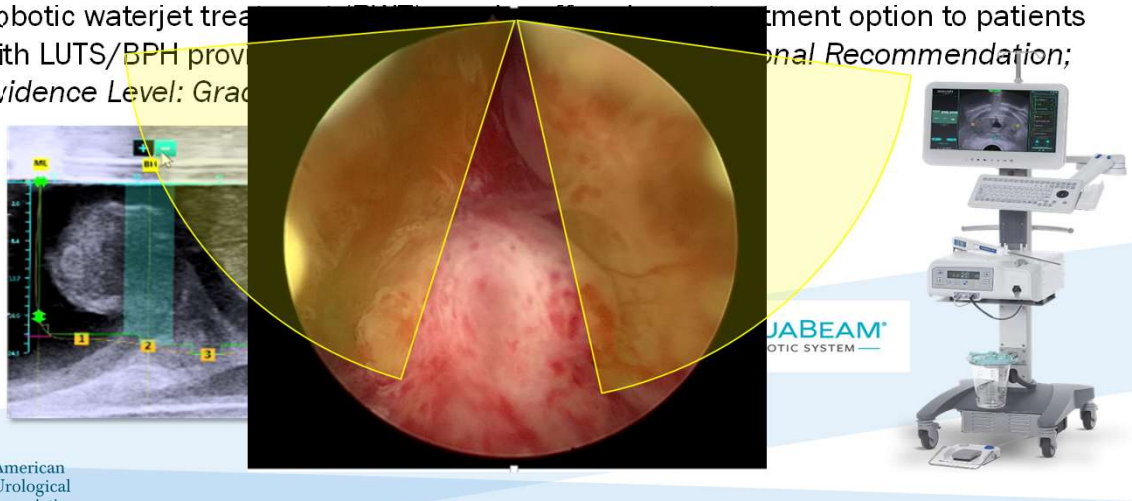
Water Jet Ablation of the Prostate (Aquablation)

Robotic waterjet trea tment option to patients with LUTS/BPH prov nal Recommendation; *Evidence Level: Grad*



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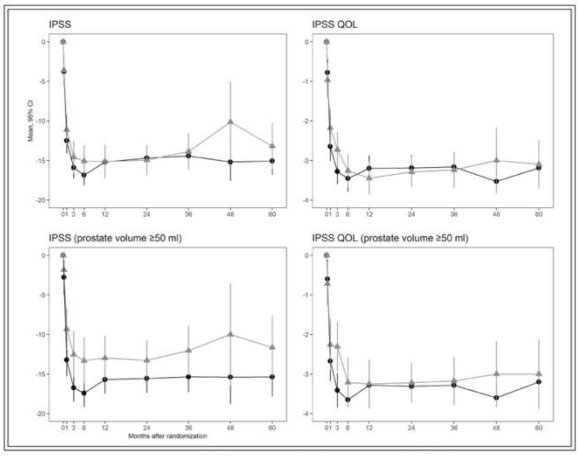
Five-year outcomes for Aquablation therapy compared to TURP: results from a double-blind, randomized trial in men with LUTS due to BPH



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AQUABLATION

30 – 80 mL
51% obstructive median lobe

17 Sites

4 Countries

			TURP
DURABILITY at 5 years	Surgical & Medical Retreatment	6%	12%
EFFICACY improvement over baseline at 5 years	Symptom Improvement (IPSS)	69% Δ15.1 pts	61% Δ13.2 pts
	Quality of Life Improvement (IPSS QoL)	67% Δ 3.2 pts	65% Δ 3.2 pts
	Peak Urinary Flow Rate Improvement (Qmax)	125% Δ 8.7 mL/sec	89% Δ6.3 mL/sec
SAFETY procedure related	Ejaculatory Dysfunction	7%	25%
	Erectile Dysfunction	0%	0%
	Incontinence	0%	0%

Gilling PJ et al. Can J Urol. 2022 Feb;29(1):10960-10968.

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AQUABLATION

30 – 80 mL
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Gilling PJ et al. Can J Urol. 2022 Feb;29(1):10960-10968.

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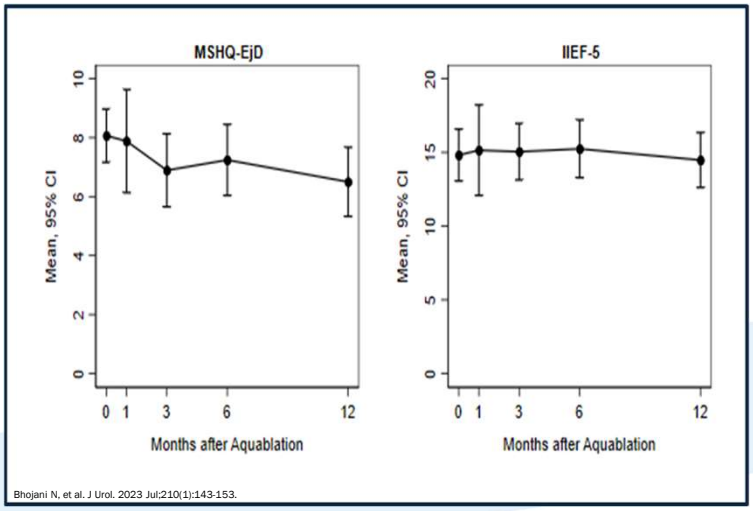
WATER II TRIAL (80-150 CC PROSTATES)



Bhojani N, et al. J Urol. 2023 Jul;210(1):143-153.

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AQUABLATION META-ANALYSIS

IPSS IMPROVEMENT	16 points
URINARY PEAK FLOW RATE	20.5 mL/sec
QUALITY OF LIFE IMPROVEMENT	3.3 points
POST VOID RESIDUAL IMPROVEMENT	62 mL
EJACULATORY DYSFUNCTION	10.8%
ERECTILE DYSFUNCTION	0%
INCONTINENCE	0.5%

- 4 clinical studies with 425 patients
- Prostate volumes 20 – 150cc
- 1 year follow–up
- Greatest risk of anejaculation with >5mm cut depth below veru

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Elterman D, et al. BMJ Surg Interv Health Technol. 2021 Jun 23;3(1):e000090.

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Is it time to offer True Minimally Invasive Treatments (TMIST) for BPH? – A review of office-based therapies and introduction of a new technology category

Dean S. Elterman, MD,[1] Kevin C. Zorn, MD,[2] Bilal Chughtai, MD,[3] Naeem Bhojani, MD[2]

A recent review of current literature assessing available MISTS

- Rezum and UroLift had significant improvement in symptoms and QoL, maintenance of erectile and ejaculatory function
- Urolift had quicker recovery
- Rezum had lower re-treatment rate
- iTIND shows promising results but requires long-term follow up

Competitive landscape

RIVER MARK

Allium Medical

Butterfly Medical

zenflow

ProArc medical

FloStent™ System

Urocross™

ProVerum

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Knowledge Check

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Q1: The following that is a risk factor for developing POD is:

A. Low serum bicarbonate

B. Small PVR

C. High serum creatinine

D. High serum sodium

E. Slow decompression of the residual urine

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MCQ 2

A 67 year old man with bothersome urinary symptoms brings a voiding diary to his office appointment that shows 13 voids, every 1-2 hours, in a 24 hour period. Void volumes range from 30 – 140 mL, with one episode of incontinence and nocturia x4. Uroflow shows a flattened curve with a peak flow of 5 mL/sec and a PVR is 60 mL. His symptoms are best described as:

A. Benign Prostatic Obstruction
B. Detrusor Overactivity
C. LUTS
D. Detrusor Underactivity
E. BPH

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MCQ 3

A 63 year old man has a weak urinary stream and urinary frequency with urgency. He is being evaluated for renal transplantation. DRE reveals a 30-gram prostate and he is taking an alpha blocker. 24-hour voiding diary shows voided volume of 50-60mL per void and total voided volume of 50-60mL per void and total voided volume of 450 mL. Urodynamics is notable for a maximum flow rate of 8mL/sec with Pdet Qmax 80cm H2O and PVR 5 mL. The next step is:

A. TURP
B. Anticholinergic medication
C. Finasteride
D. Evaluate bladder symptoms after transplant

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MCQ 4

A 69 year old man has a weak urinary nocturia x4, and urinary urgency has an IPSS of 18 and a PVR of 225 mL. The PVR result is:

A. An indication of surgical therapy
B. Of limited clinical value
C. Highly correlated with degree of LUTS
D. Predictive of renal injury
E. Associated with recurrent pyelonephritis

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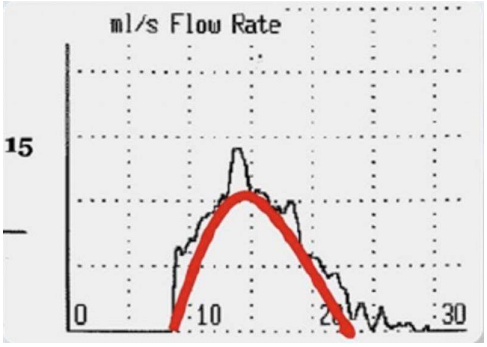
MCQ 5

A 65 year old man with bothersome weak stream and double voiding undergoes a non-invasive uroflow, results of which are shown below. He has a PVR of 125 mL and voided volume of 75cc.

Based on these results:

A. The study should be repeated until the voided volume is greater than 150 mL
B. He has obstruction
C. His AUASS is likely greater than 15
D. The etiology of his symptoms cannot be differentiated between obstruction and detrusor underactivity
E. He would have a poorer outcome after laser prostatectomy compared to a patient with a peak flow rate greater than 15 mL/sec



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Questions to consider...

- How do you manage patients whose primary issue is nocturia. For example, 68-year-old male c AUA 26/5, PVR 80cc c 4-5x nocturia. PMH DM. Started on Tamsulosin. Returns with AUA of 18/4, PVR 90cc with 3-5x nocturia. Will surgery help nocturia?

- How do you incorporate frequency volume charts into practice? If referred new patient for LUTS, do you have them do frequency vol chart prior to initial visit?

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Questions to consider...

- How do you incorporate Uroflow into assessment? Prior to office apt drink fluids and hold it -> uroflow in office? Or do you do it post cystoscopy? Do you use urocuff? Do you get paid for cysto/uroflow or cysto/urocuff at the same setting?

- How to you handle TOV (TWOC?). New patient urinary retention…How long to you keep catheter? How long do you wait after initiation of alpha blockers? Is volume of retention more important predictor of TWOC?

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Questions to consider...

- How do you council patients on delaying medical / surgical therapy for symptomatic BPH with regards to outcomes?
- Should urodynamics be performed in men with probable detrusor underactivity or acontractile bladder prior to TURP, PVP, Robotic Waterjet Treatment, TUIP, Water Vapor Thermal Therapy, PUL, temporary implanted prostatic devices?
- Should urodynamics be performed in men with probable detrusor underactivity or acontractile bladder prior to HoLEP or ThuLEP or GreenLEP?
- What % of patients who present with BPH in your clinic move on to surgery?

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Thank you!

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Associate Professor of Urology,

Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

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