

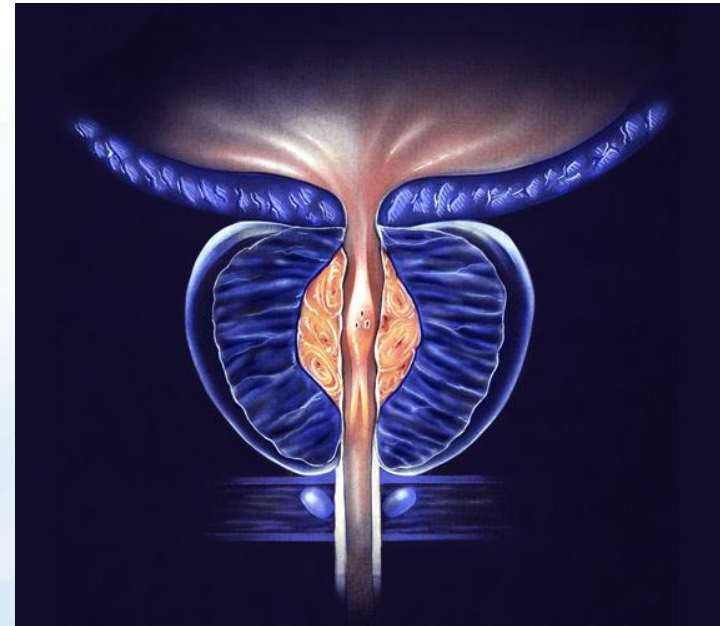
# Hot Topics in Medicine: BPH Updates

## Medical, Surgical and Minimally Invasive Options

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 @BechisUrology



Credit: Judith Glick - stock.adobe.com

UC San Diego Health

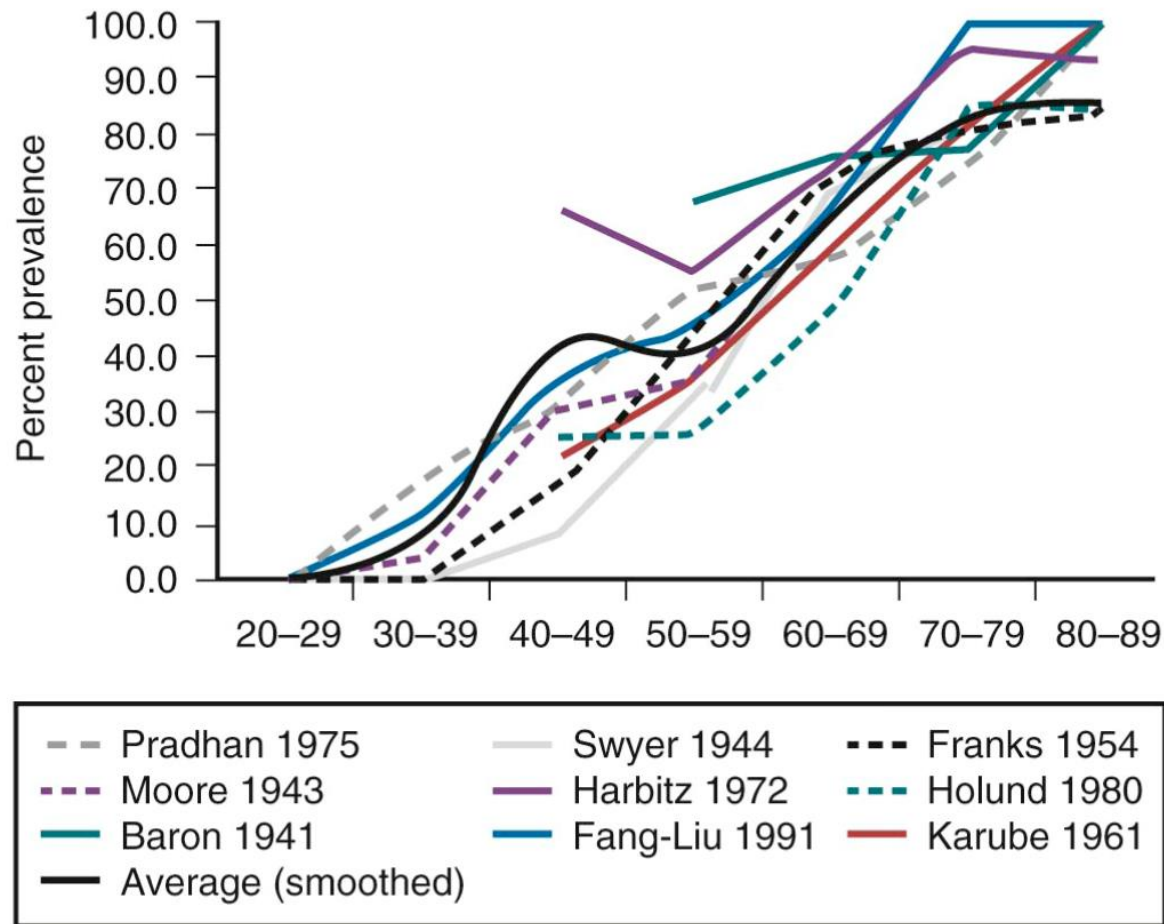
# Disclosures: Seth Bechis

- Consultant
    - Boston Scientific
    - Dornier
    - Ambu Medical
    - Calyxo
    - BD
  - Speaker
    - Karl Storz Endoscopy
- 
- Acknowledgments: Marcelino Rivera, Naeem Bhojani, Bilal Chughtai

# Goals of this Talk

- Optimize how to evaluate the patient with BPH
- Understand medical treatment options
- Highlight differences between BPH procedures
  - Minimally Invasive Surgical Therapies (MISTs)
  - Understand when each procedure might be useful
- Recognize when to involve the Urologist

# Epidemiology: BPH prevalence increases with age



Age 60-69: 70%

Age >80: 80%

Risk factors:

- Family Hx
- Diabetes
- Obesity
- ↓ physical activity

Age-stratified autopsy prevalence of histologic BPH

# Worldwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction

Debra E. Irwin, Zoe S. Kopp\*, Barnabie Agatep\*, Ian Milsom<sup>†</sup> and Paul Abrams<sup>‡</sup>

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<sup>‡</sup>Southmead Hospital, Bristol Urological Institute, Bristol, UK

Accepted for publication 14 September 2010

Study Type –  
(prospecti  
Level of Evid

## OBJECTIVE

- To estimate regional prevalence of lower urinary tract symptoms (LUTS) and urinary incontinence (UI) in the current International Symptom Definition years.

## PATIENTS AND

- Numbers are affected by each with an estimate stratified by study along with worldwide prevalence estimates from International [

## INTRODUCTION

Lower urinary tract overactive bladder incontinence (UI) and bladder outlet obstruction (BOO) are prevalent conditions that impair the quality of life of individuals [3–5]. These conditions are stigmatized [6] and are associated with a substantial economic and human burden [7–9]. According to current (2002)

## RESULTS

- An estimated 45.2%, 10.7%, 8.2% and 21.5% of the 2008 worldwide population (4.3 billion) was affected by at least one LUTS, OAB, UI and LUTS/BOO, respectively. By 2018, an estimated 2.3 billion individuals will be affected by at least one LUTS (18.4% increase), 546 million by OAB (20.1%), 423 million by UI (21.6%) and **1.1 billion by LUTS/BOO (18.5%)**.
- The regional burden of these conditions is estimated to be greatest in Asia, with numbers of affected individuals expected to increase most in the developing regions of Africa (30.1–31.1% increase across conditions, 2008–2018), South America (20.5–24.7%) and Asia (19.7–24.4%).

The prevalence of LUTS, OAB, UI and LUTS/BOO increases with advancing age [1,11–13],

add?

ins and to our knowledge reported LUTS symptoms. One and future worldwide estimates that LUTS are highly time.

uggests that LUTS, OAB, UI are highly prevalent worldwide. Numbers of affected individuals are expected to increase with the fastest increase in burden in developing regions. Important worldwide public health management implications over the next decade to identify and manage these

urinary tract symptoms, overactive bladder, urinary incontinence, and bladder outlet obstruction

Prevalence is expected to increase with the predicted aging of the population [14]. There are, however, inconsistencies across studies in reported prevalence; for example, reported prevalence for male and female ranges from 13% [15] to 67% [16] for LUTS, 4% to 26% [18] for OAB and 4% to 26% [18] for UI. These inconsistencies

have been attributed to differences between studies in the questions used for symptom assessment, mode of questionnaire

**COSTS in U.S. per year:**

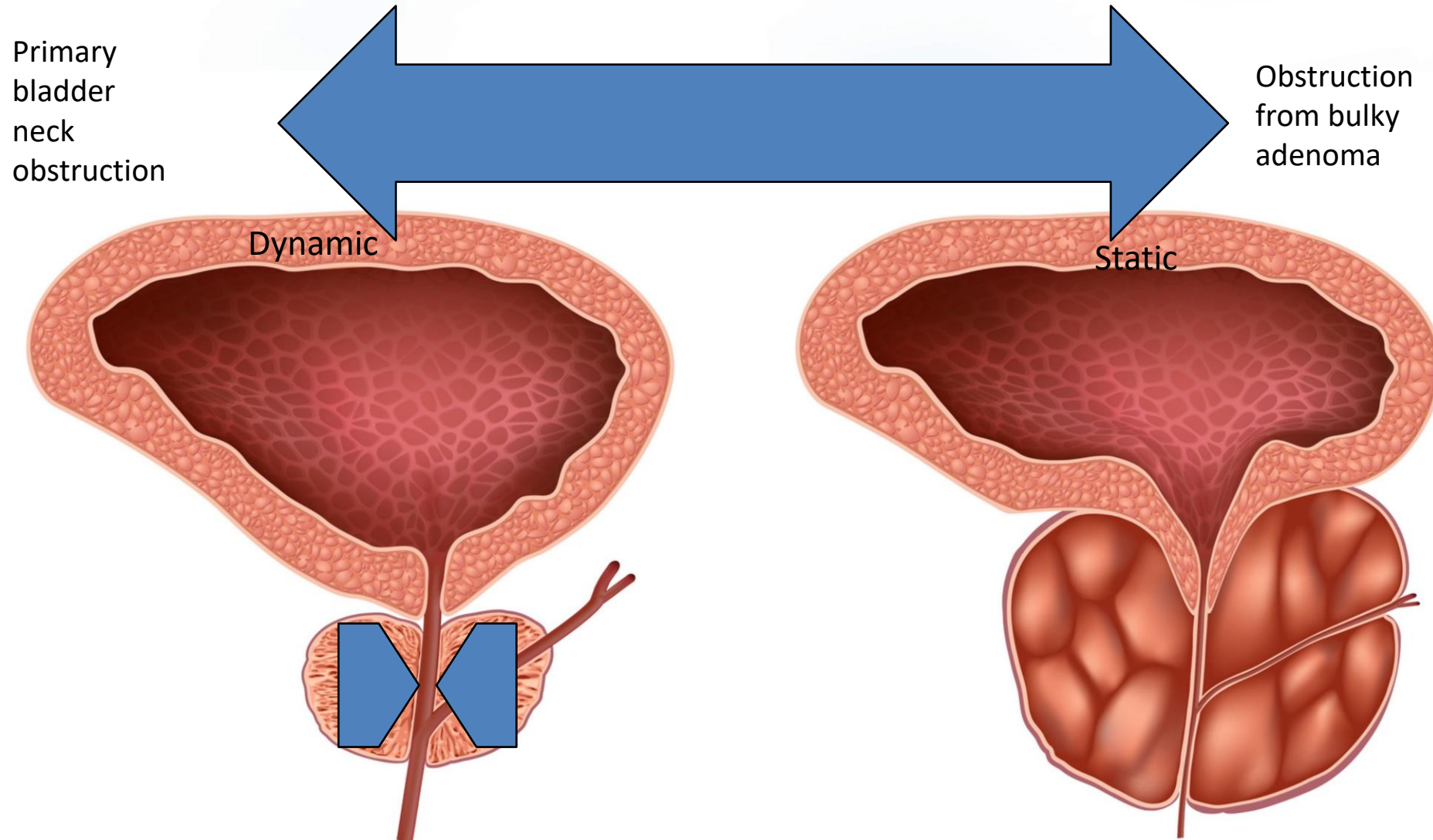
**Rx for BPH-related LUTS: \$194 million**

**Incremental annual burden of a BPH dx: \$1500**

**Overall: \$4 billion**

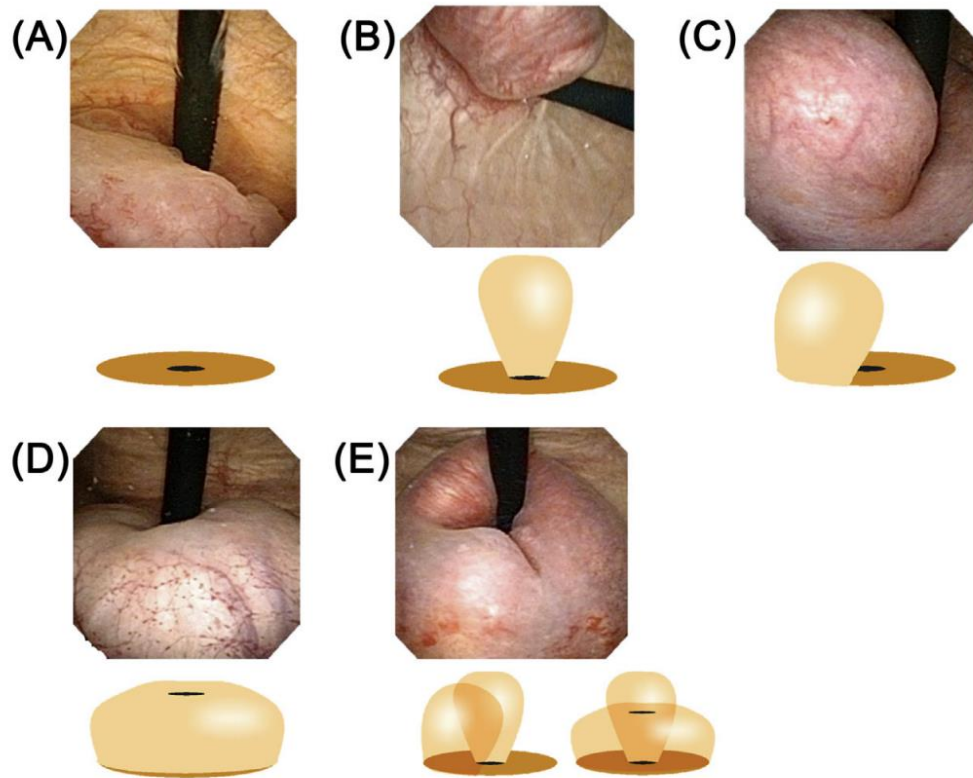


# Each Prostate is Unique: Spectrum of Outlet Disease

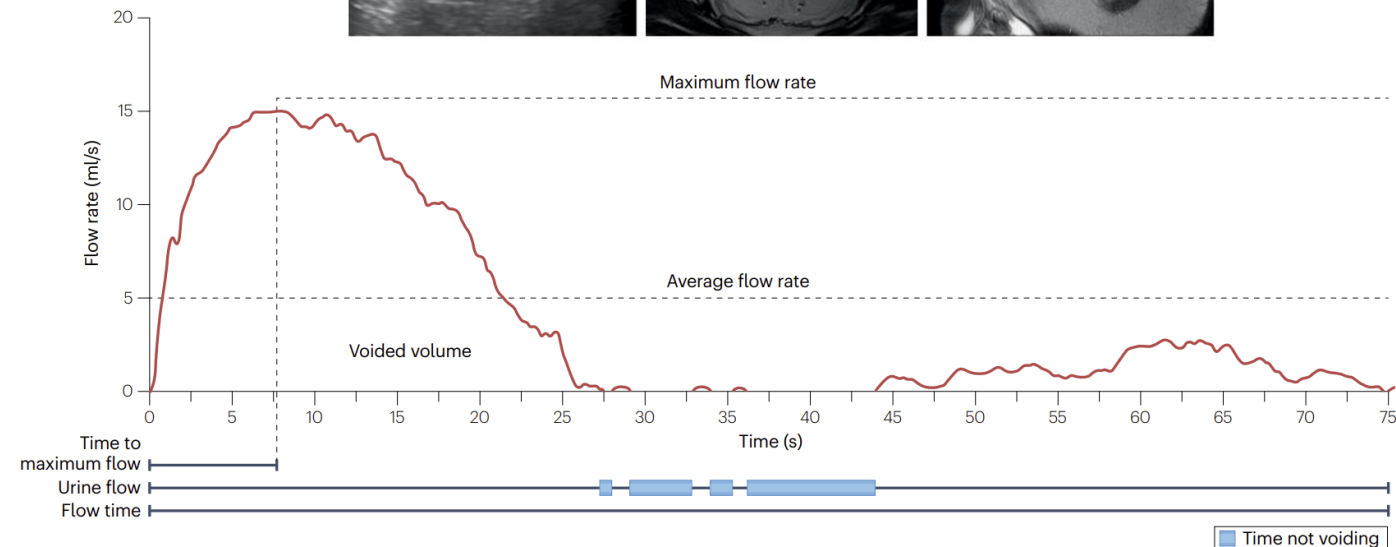
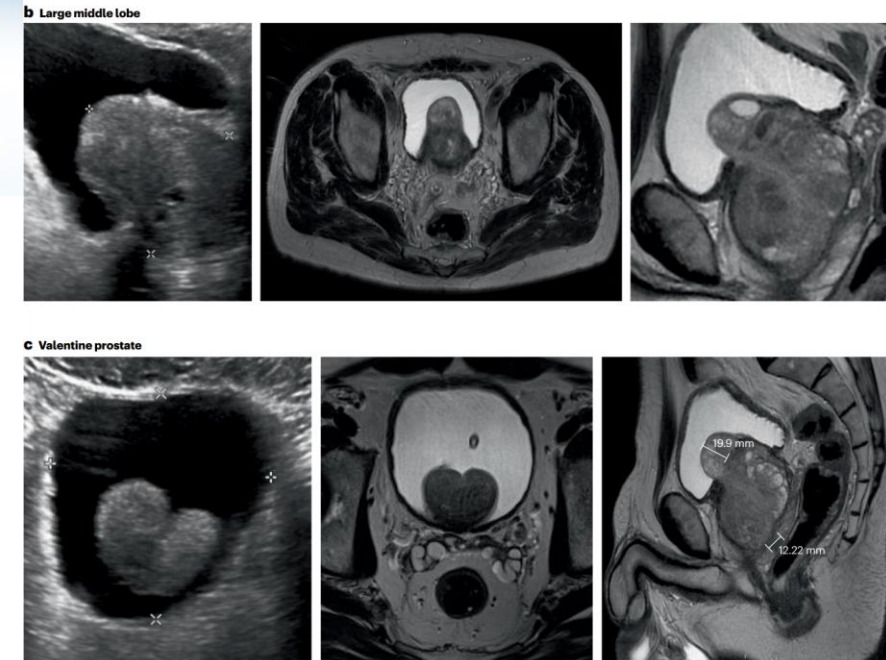


# Median Lobe Variants Cause Obstruction

## *Intravesical Prostatic Protrusion*



Gharbieh, S., et al. *Nat Rev Uro* **20**, 11 (2023)  
 Topazio, L., et al. *BMC Urology* **18**, 6 (2018)  
 Hirayama, K.M., et al. *Urology* **86**, 565-569 (2015)  
 Ito, K. *Neurourology and Urodynamics* **37**, 2160-2166 (2018)



**Fig. 2 | Classic uroflowmetry pattern in a patient with middle lobe enlargement.** Misleading initial reasonable flow with prolonged terminal dribbling (voided 306 ml, maximum flow rate 15 ml/s, post-void residual 230 ml).

# Two Categories of LUTS

1

## ABILITY TO HOLD URINE

**Urgency:** the need to urinate immediately or urgently

**Frequency:** the need to urinate more often than normal

**Nocturia:** the need to urinate frequently while sleeping

**Incontinence:** complete loss of the ability to hold urine

2

## EMPTYING THE BLADDER

**Straining:** the need to push to start or complete urinating

**Dysuria:** pain or stinging while urinating

**Hesitancy:** difficulty starting to urinate

**Weak Stream:** gentle instead of a strong stream of urine

**Intermittency:** a urine stream that starts and stops

**Retention:** complete loss of the ability to empty the bladder



# AUA Guidelines Basic Management of LUTS

## 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)

Sandhu JS, et al. AUA Guideline amendment 2023. *J Urol*. **211**, 2024

# Subjective Scoring (IPSS)

## AUA Symptom Score:

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

## AUA symptom score expected improvement

- Placebo (1-2)
- Alpha-Blocker (1-5)
- Combination therapy (2-9)
- PDE-5 inhibitor (1-5)

### International Prostate Symptom Score (IPSS)

Name:

Date:

	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always	Your score
<b>Incomplete emptying</b> 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	
<b>Frequency</b> 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	
<b>Intermittency</b> 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	
<b>Urgency</b> Over the last month, how difficult have you found it to postpone urination?	0	1	2	3	4	5	
<b>Weak stream</b> Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
<b>Straining</b> 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
<b>Nocturia</b> 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.

# AUA Guidelines Basic Management of LUTS

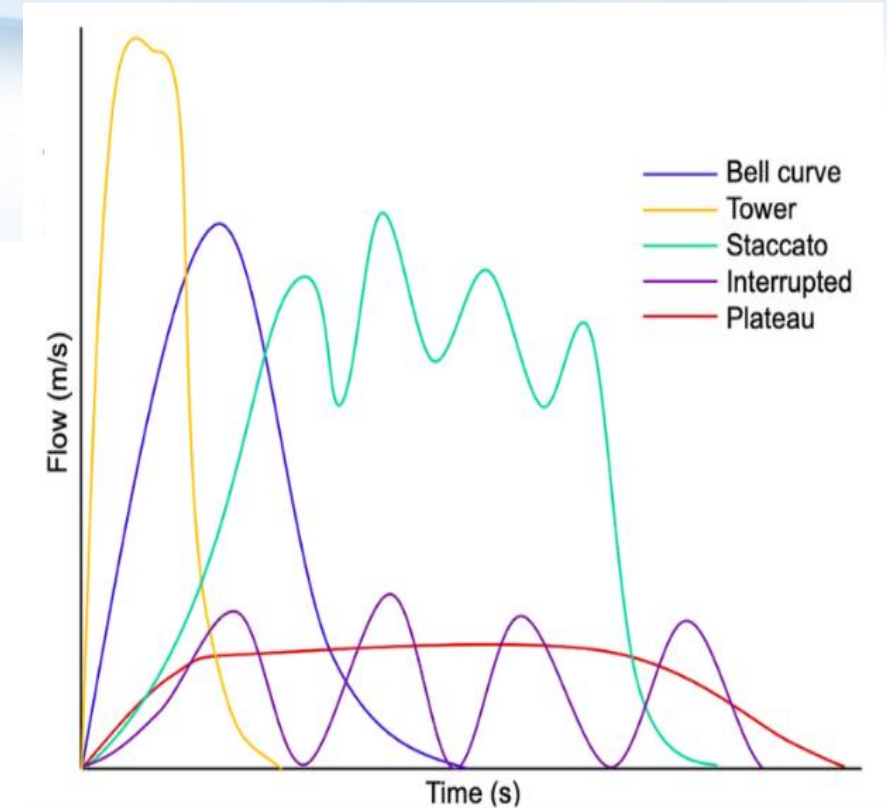
## Follow-up Evaluation

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. Reevaluation 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)

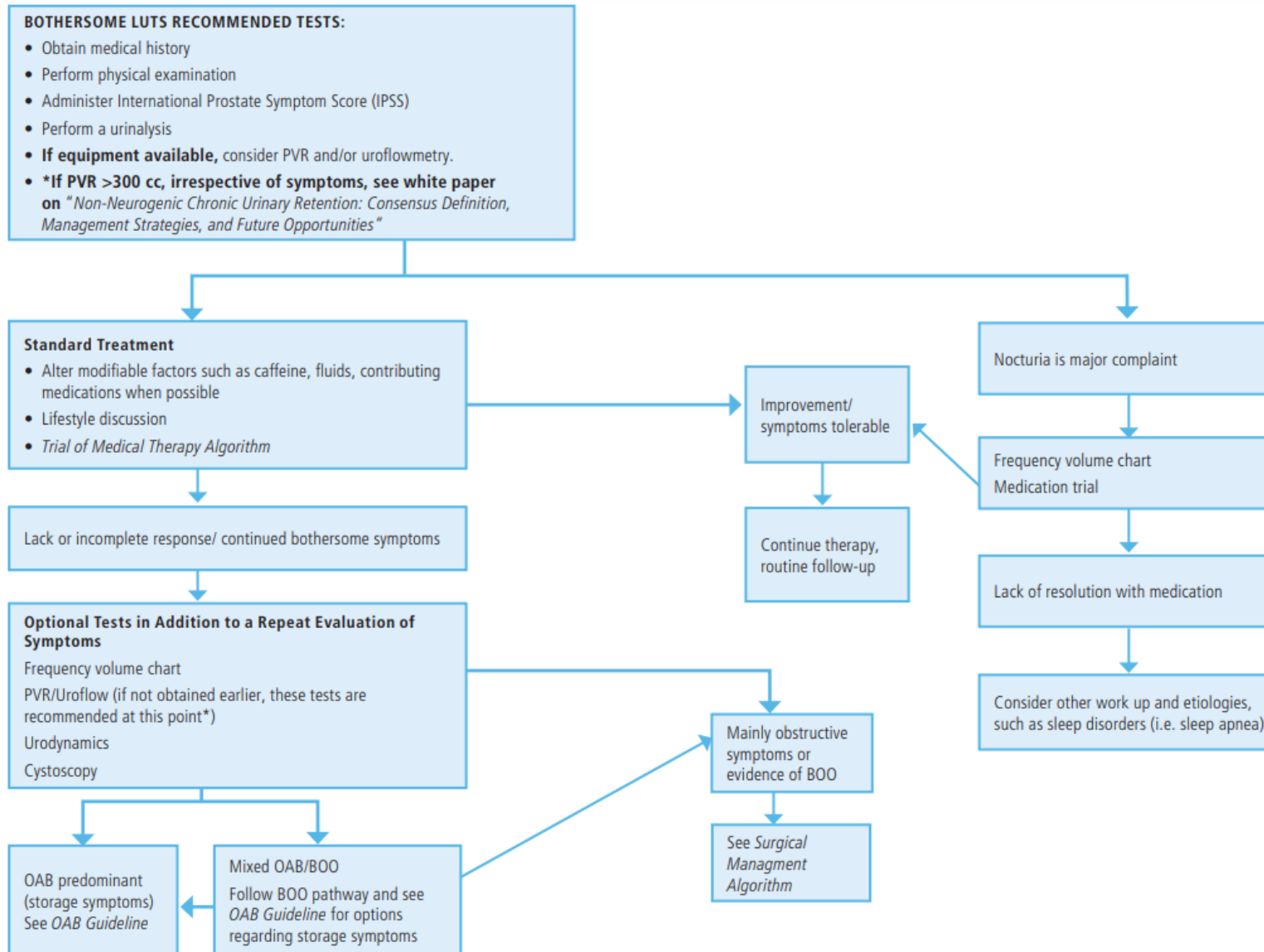
Sandhu JS, et al. AUA Guideline amendment 2023. *J Urol.* **211**, 2024

# Objective Scoring

- Includes **flow rate (Qmax)** and **post-void residual (PVR)**
- **Cystoscopy:** not routinely recommended in patients with initial presentation consistent with BOO
  - Offers a visual inspection of the urethra, prostate, & bladder when considering treatments where success may depend on anatomic configuration
- **Urodynamics: optional prior to intervention**
  - Can be useful to quantify the degree of bladder outlet obstruction (BOO) and/or detrusor under- or overactivity in the context of mixed lower urinary tract symptoms.



# AUA Guidelines Basic Management of LUTS

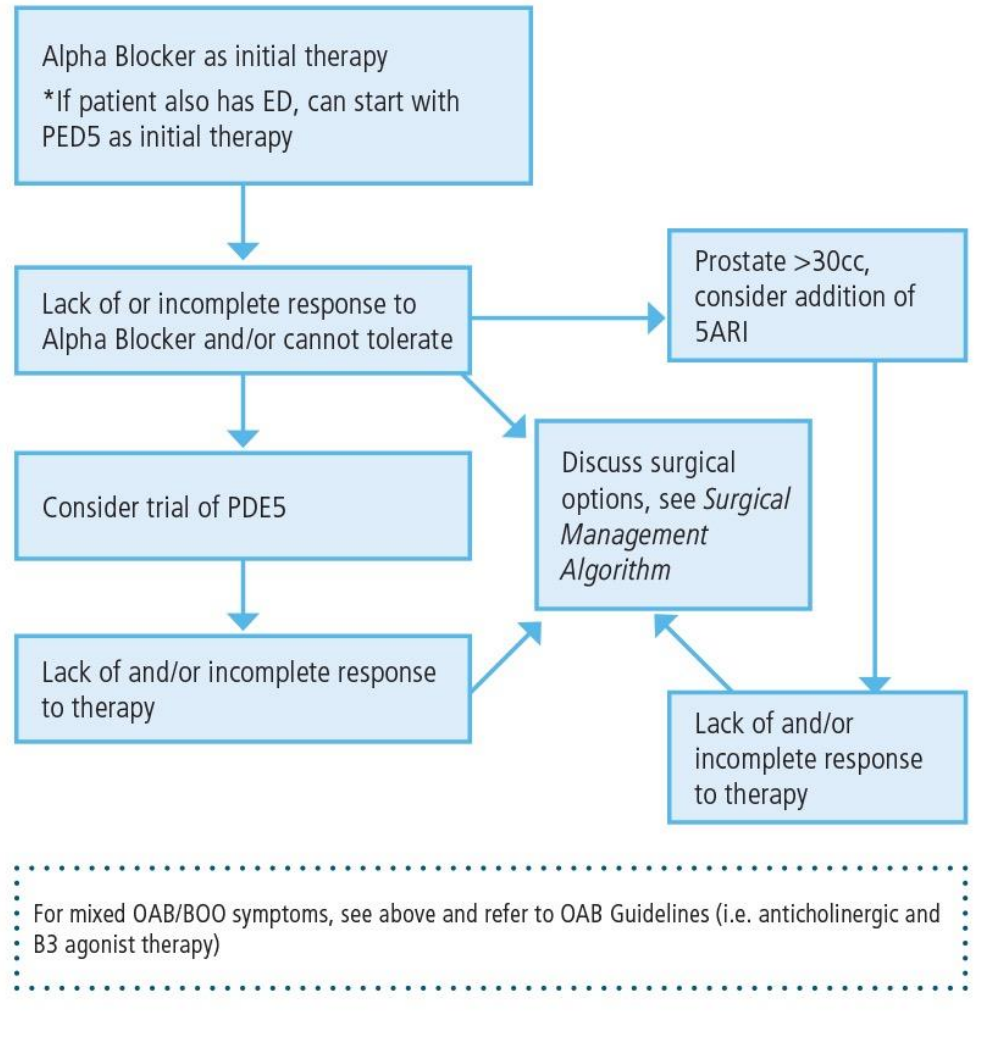




# MEDICAL MANAGEMENT

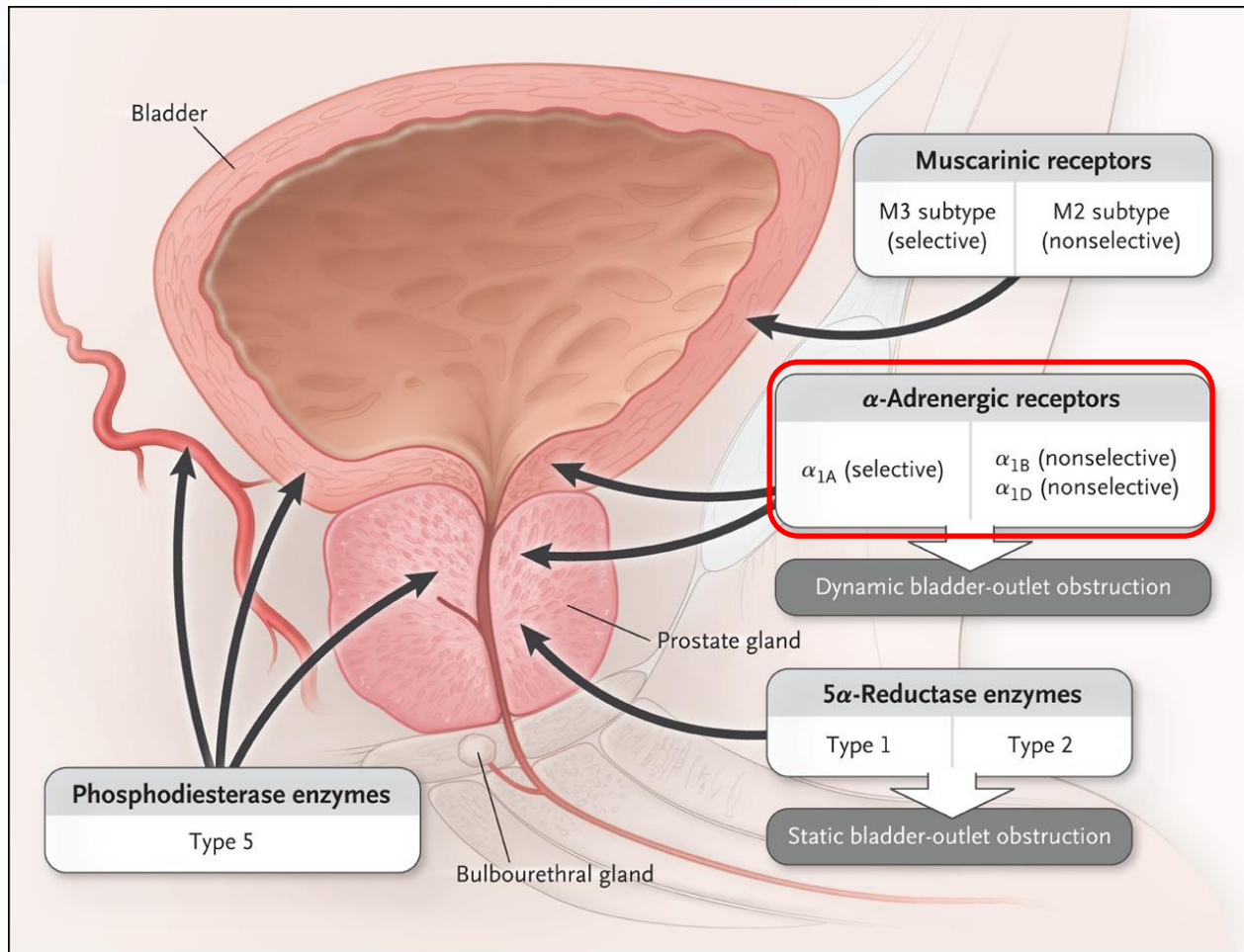
# Medical Management

## Trial of Medical Therapy Algorithm



- After behavioral and dietary interventions
- Consider comorbidities and side effects of therapy
- Dizziness, headache, asthenia, postural hypotension, rhinitis, sexual dysfunction, retrograde ejaculation, floppy iris syndrome, nasal congestion

# Medical Management: alpha blockers



N Engl J Med 2012; 367:248-257

## alpha1-adrenoceptor blockers

### Non-Selective

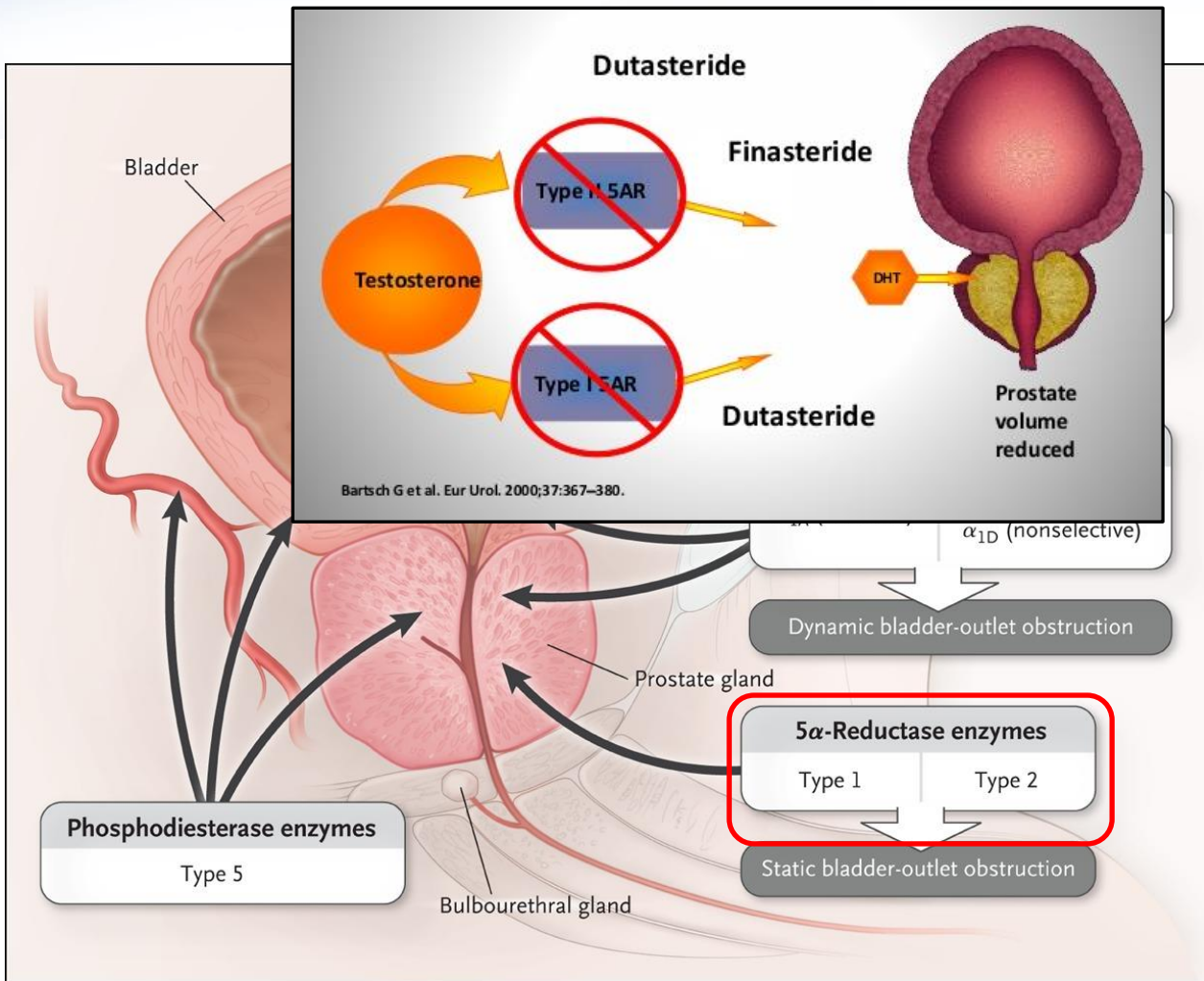
Doxazosin	1-8mg	alpha <sub>1A</sub> -, alpha <sub>1B</sub> -, and alpha <sub>1D</sub>
Terazosin	1-20mg	alpha <sub>1A</sub> -, alpha <sub>1B</sub> -, and alpha <sub>1D</sub>
Alfuzosin	10mg	alpha <sub>1A</sub> -, alpha <sub>1B</sub> -, and alpha <sub>1D</sub>

### Selective

Tamsulosin	0.4-0.8mg	alpha <sub>1A</sub> > alpha <sub>1B</sub>
Silodosin	4-8mg	alpha <sub>1A</sub> >> alpha <sub>1B</sub>

- Orthostatic hypotension (nonselective)
- Retrograde/Anejaculation (selective)
- Floppy Iris Syndrome
- Nasal congestion

# Medical Management: 5-alpha reductase inhibitors



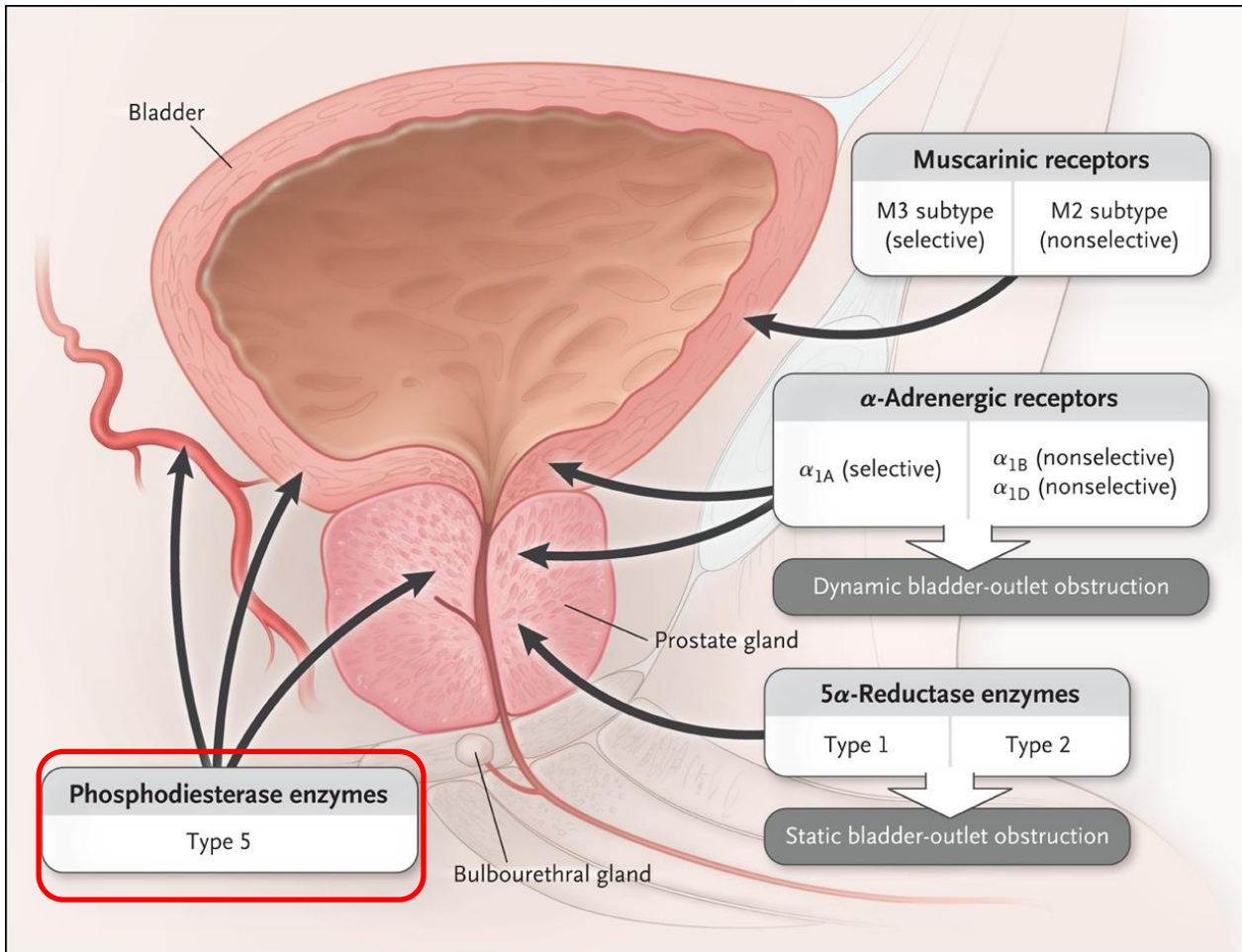
Drug Name	Mechanism	Dose	Adverse effects
Finasteride	Inhibits type II isozyme	5mg qd	decreased libido, impotence, decreased ejaculate, ejaculation disorder, breast enlargement, breast tenderness, and rash
Dutasteride	Inhibits type I and type II isozyme	0.5mg qd	impotence, decreased libido, gynecomastia, and ejaculation disorder

- 57-79% ↓risk urinary retention
- 48-69% ↓risk need for surgery
- Prostate volume: 15-32% decrease
  - Effect maximal at 6 months
- Useful for prostate volume >40cc
- ED (8%), ↓libido (6%), gynecomastia (0.5%)

N Engl J Med 2012; 367:248-257



# Medical Management: PDE-5 inhibitors

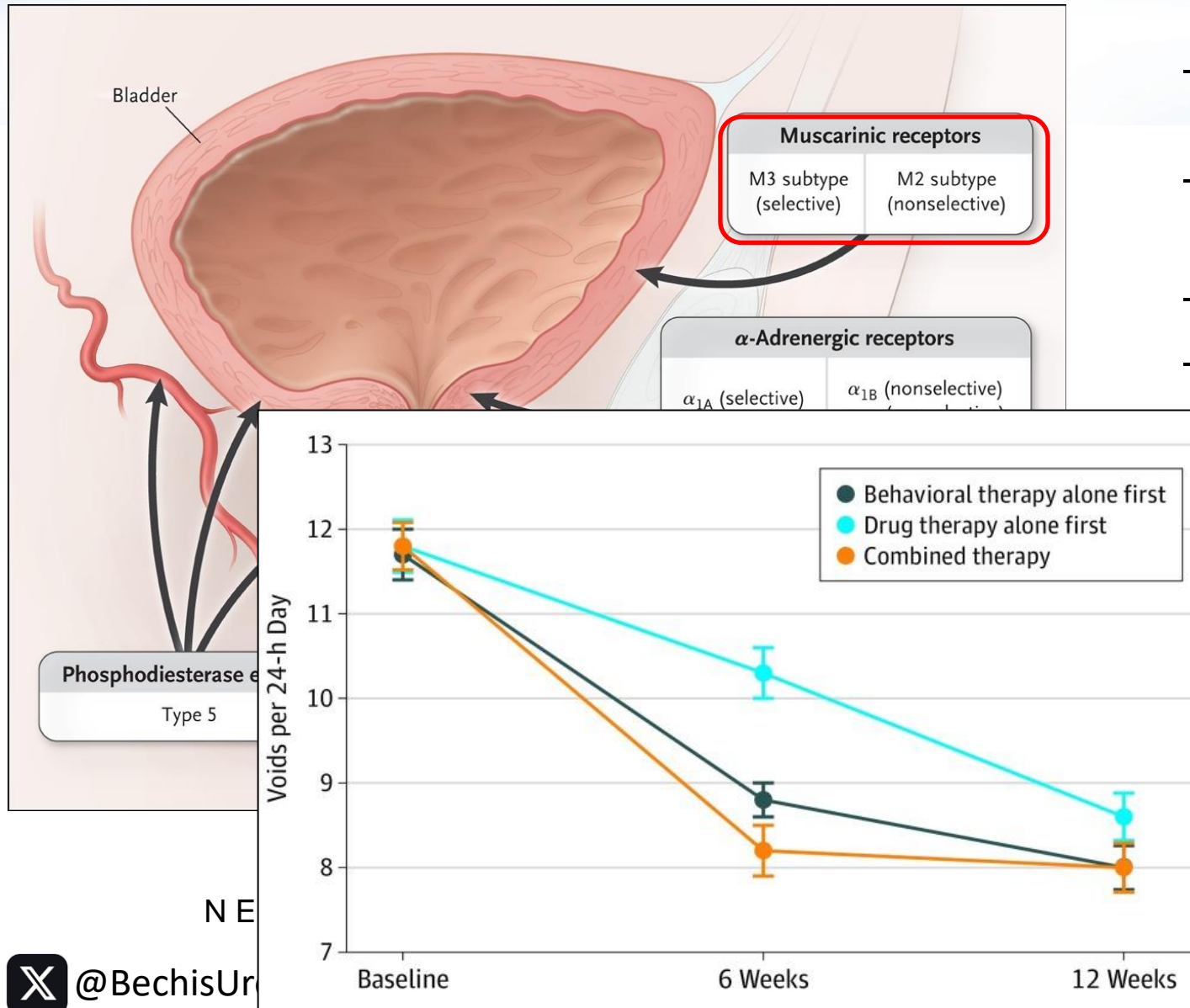


- Significant improvements in I-PSS and QoL
- No major changes in PVR or Qmax
- 50% response at 1 week, 70% at 4 weeks
- Headache (10-20%), back pain (3%), dyspepsia (4-10%)
- All agents lead to improvements in LUTS
- Greater satisfaction compared to alpha blockers

N Engl J Med 2012; 367:248-257



# Medical Management: OAB and BPH

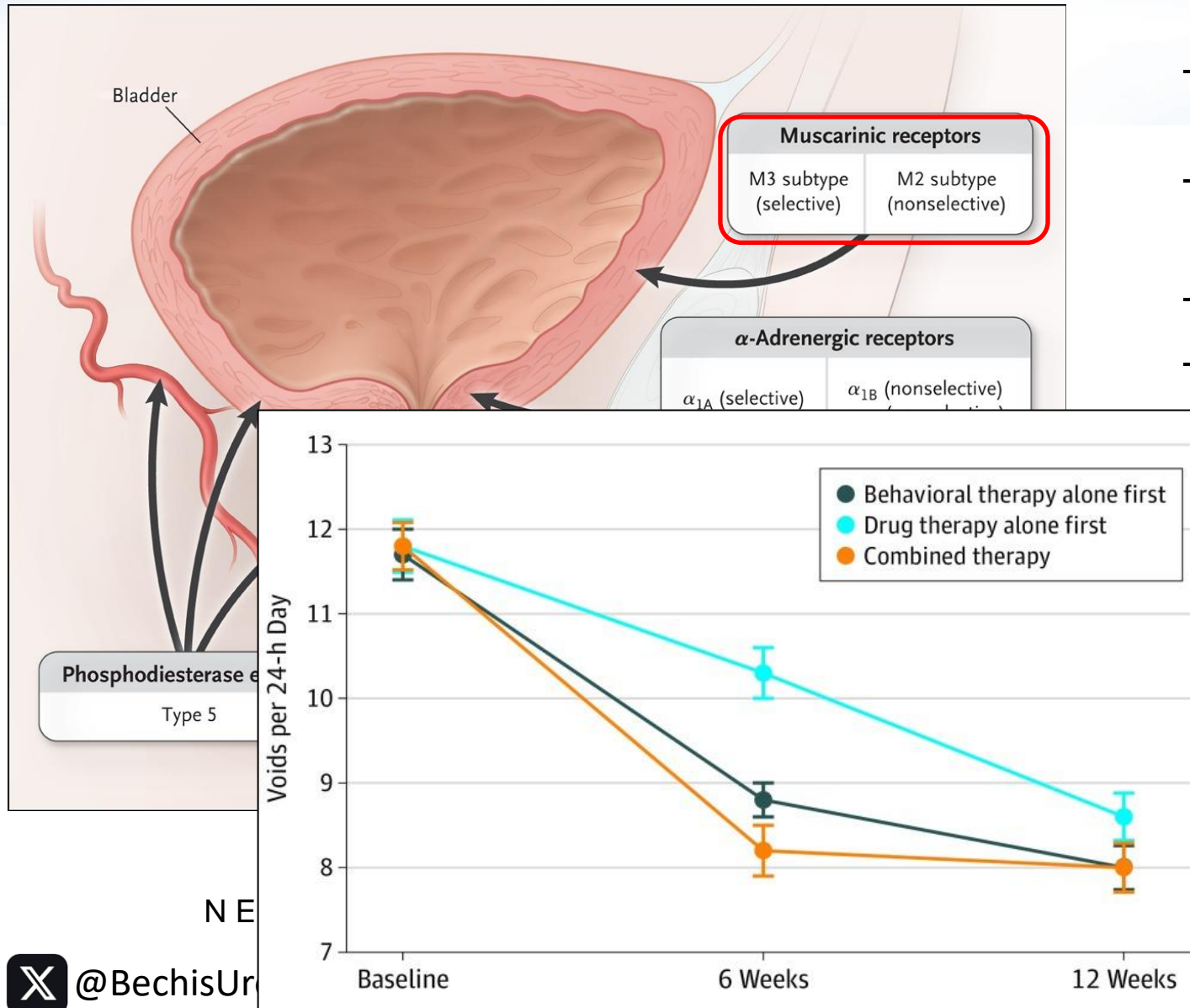


- OAB is secondary due to BPH
  - often with median lobes
- Treatment of the BPH will improve OAB in up to 70% of men
- Behavioral therapy
- Combination of alpha blocker and anticholinergic / beta3 agonist
  - reduce AUA-SS 6-8.5

Side effects: Dry mouth (20-40%), Constipation (10-20%), Retention (1-6%)

JAMA Intern Med. 2020 Mar; 180(3): 411–419

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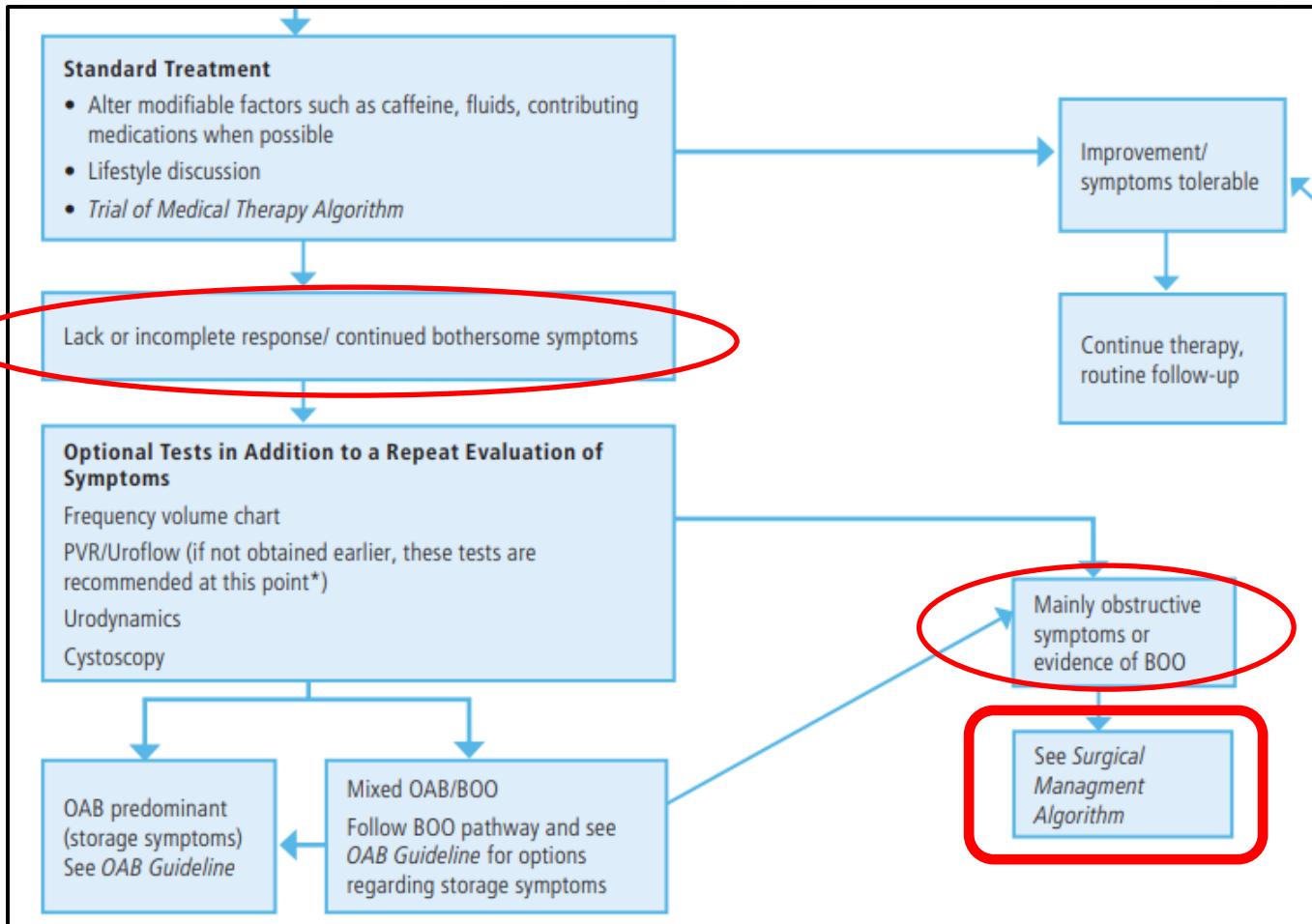
JAMA Intern Med. 2020 Mar; 180(3): 411–419

# Medications are not without long term risk

- Alpha blockers: cardiac failure, cognitive (dementia)
- 5ARIs: psychological depression, suicidality
- Sexual dysfunction
- Poor patient compliance
- **One size does not fit all: need personalized approach**

# SURGICAL MANAGEMENT

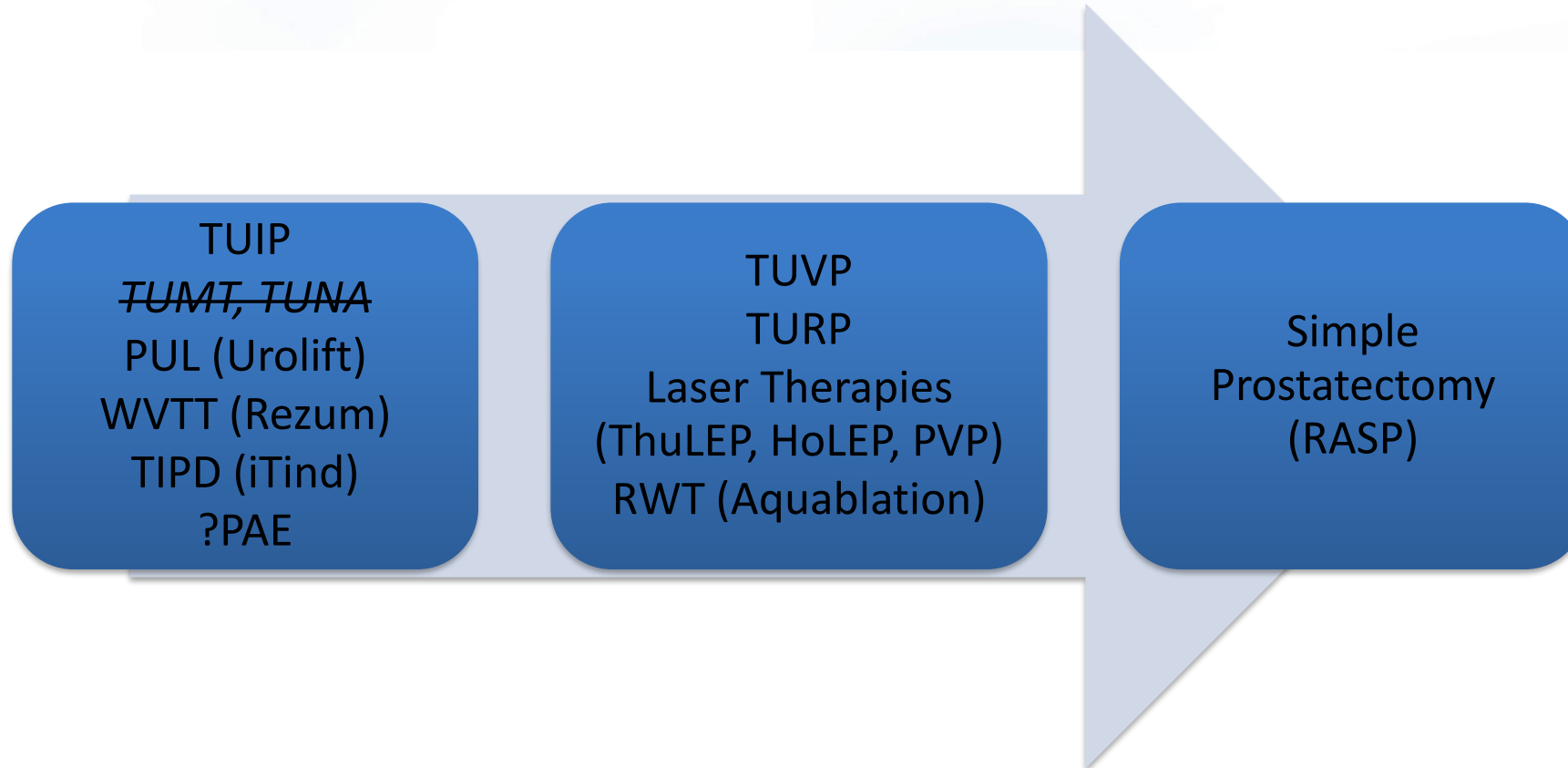
# When to refer to a Urologist for BPH surgery



- Failure/intolerance of medical therapy
- Recurrent UTIs
- Refractory urinary retention
- Refractory gross hematuria
- Recurrent bladder stones
- Renal insufficiency due to outlet obstruction

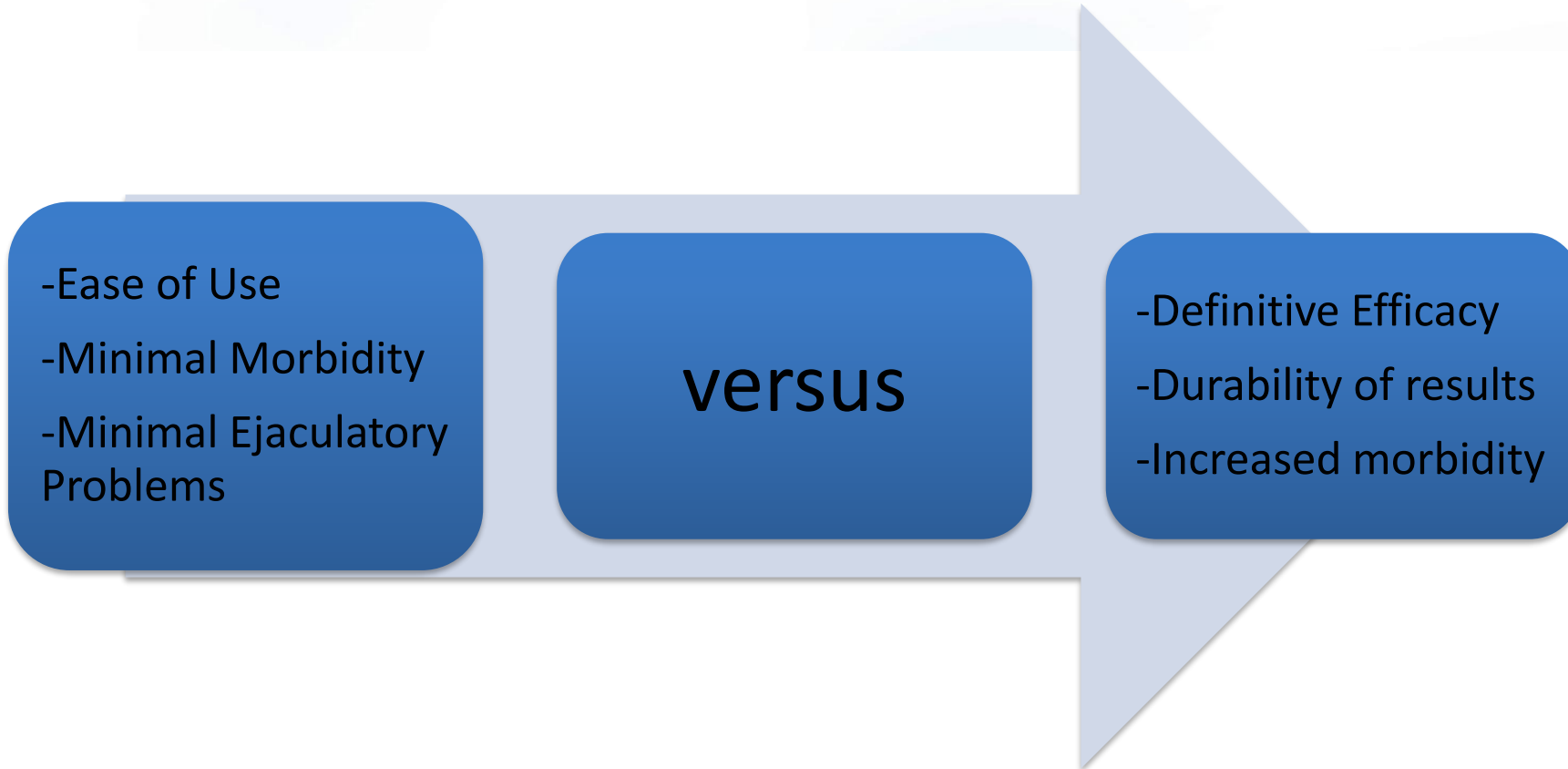


# BPH: MIST and Surgical Therapies



Invasiveness

# BPH: MIST and Surgical Therapies



Invasiveness

# *What is the patient most bothered by?*

## *What are their goals for treatment?*

- Storage vs. Voiding Symptoms
  - May need medication for persistent urgency
- Patient preferences
  - No catheter
  - Preserve ejaculatory function
  - Fast return to normal activity
  - Avoid postop symptoms
  - Low retreatment rate
- Patient and anatomic factors
  - Comorbidities, bleeding risk, poor anesthesia candidate
  - Prostate size, shape (ie, median lobe)



# AUA Guideline on Surgical Management of BPH 2023

## Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia

### SURGICAL THERAPY

Assessment of Prostate Size via imaging or cystoscopy

Large Prostate (>80-150cc) or  
Very Large Prostate (>150cc)

- Simple Prostatectomy (Open, Laparoscopic, Robotic)
- HoLEP
- ThuLEP

Average Prostate (30-80 cc)

- RWT<sup>1</sup>
- HoLEP
- PVP
- PUL<sup>2</sup>
- ThuLEP
- TIPD<sup>5</sup>
- TURP
- TUV
- WVTT<sup>3</sup>

Small Prostate (<30cc)

- HoLEP
- PVP
- ThuLEP
- TIPD<sup>5</sup>
- TUIP<sup>4</sup>
- TURP
- TUV

~~TUNA~~  
~~TUMT~~

Patients concerned with preservation of erectile and ejaculatory function may be offered PUL or WVTT as data indicate that both therapies provide a greater likelihood of preservation of sexual function.

RWT: Aquablation

PUL: Urolift

WVTT: Rezum

TIPD: iTind

### MEDICALLY COMPLICATED PATIENTS

In patients who are at higher risk of bleeding, such as those on anticoagulation drugs, therapies with a lower need for blood transfusion, such as HoLEP, PVP, and ThuLEP, should be considered. For additional information on the use of anticoagulation and antiplatelet therapy in surgical patients, refer to the ICUD/ AUA review on Anticoagulation and Antiplatelet Therapy in Urologic Practice.

Based on the evidence reports of the current guidelines, the following criteria are recommended when utilizing these approaches:

<sup>1</sup> RWT: prostate volume 30-80cc.

<sup>2</sup> PUL: absence of obstructing midline prostate tissue and prostate volume 30-80cc.

<sup>3</sup> WVTT: prostate volume 30-80cc.

<sup>4</sup> TUIP: prostate volume ≤30cc.

<sup>5</sup> TIPD: prostate volume 25-75cc and absence of obstructive middle lobe

# AUA Guideline on Surgical Management of BPH 2023

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- HoLEP
- PVP
- PUL<sup>2</sup>
- ThuLEP
- TIPD<sup>5</sup>
- TURP
- TUVp
- WVT<sup>3</sup>

Small Prostate (<30cc)

- HoLEP
- PVP
- ThuLEP
- TIPD<sup>5</sup>
- TUIP<sup>4</sup>
- TURP
- TUVp

~~TUNA~~  
~~TUMT~~

Patients concerned with preservation of erectile and ejaculatory function may be offered PUL or WVT as data indicate that both therapies provide a greater likelihood of preservation of sexual function.

### Considerations:

Size

Median lobe

Ejaculation Preferences

RWT: Aquablation

PUL: Urolift

WVT: Rezum

TIPD: iTind

### MEDICALLY COMPLICATED PATIENTS

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<sup>2</sup> PUL: absence of obstructing midline prostate tissue and prostate volume 30-80cc.

<sup>3</sup> WVT: prostate volume 30-80cc.

<sup>4</sup> TUIP: prostate volume ≤30cc.

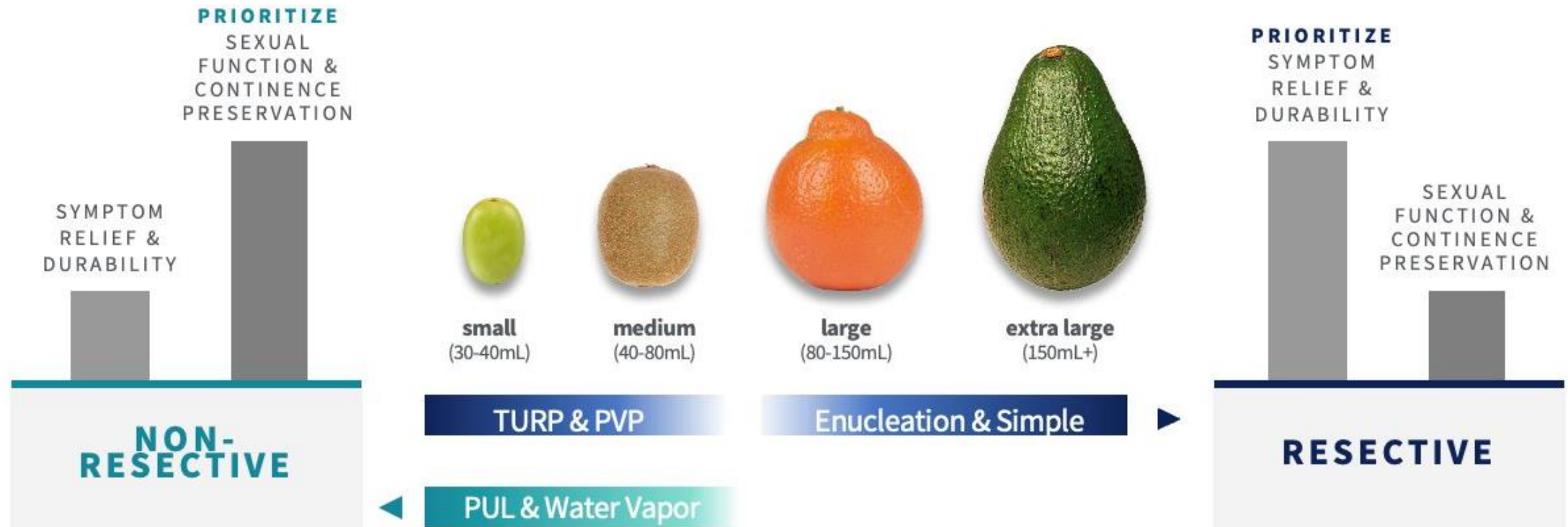
<sup>5</sup> TIPD: prostate volume 25-75cc and absence of obstructive middle lobe





# Most Procedures Require A Prioritization of Desired Outcomes

## THE IMPOSSIBLE COMPROMISE



# **MIST THERAPY**

## **MINIMALLY INVASIVE SURGICAL THERAPY**

# \*Prostatic Urethral Lift (Urolift)

- Permanent implants retract lateral lobes
- Rapid relief, minimal catheter need, preserve ejaculatory and erectile function

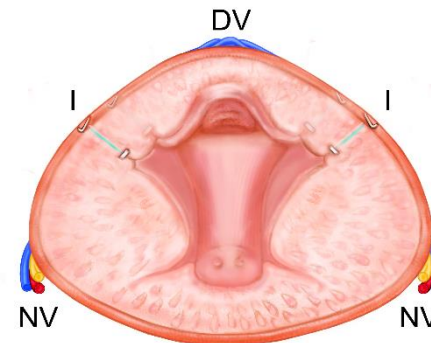
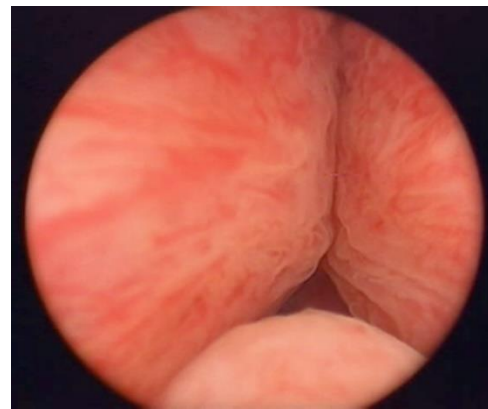
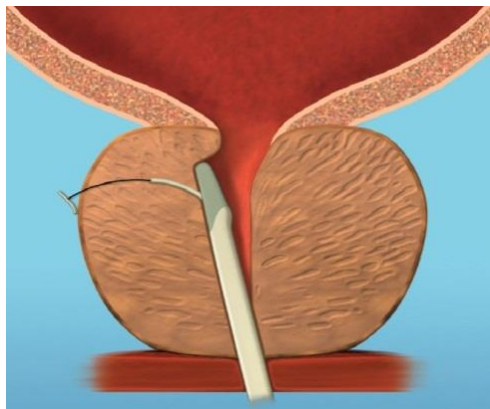
## PROSTATIC URETHRAL LIFT (PUL)

### GUIDELINE STATEMENT 34

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*)

### GUIDELINE STATEMENT 35

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*)

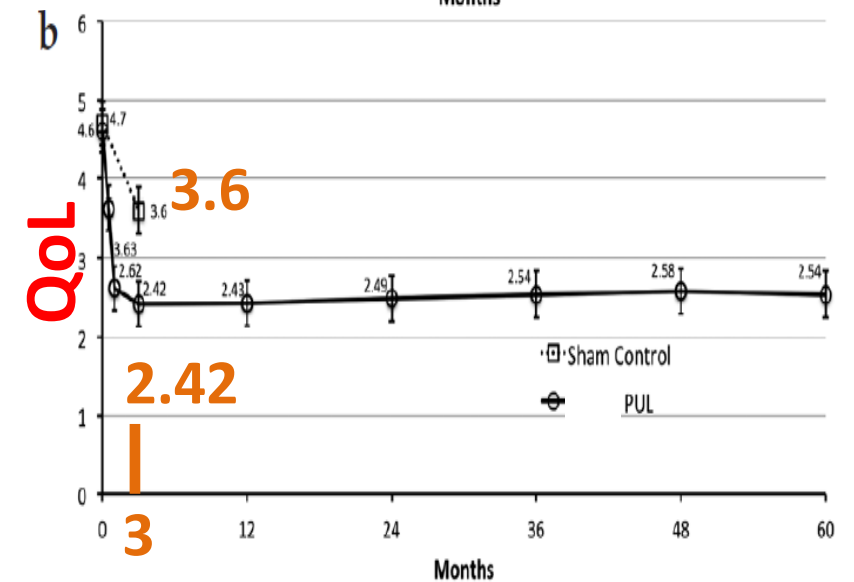
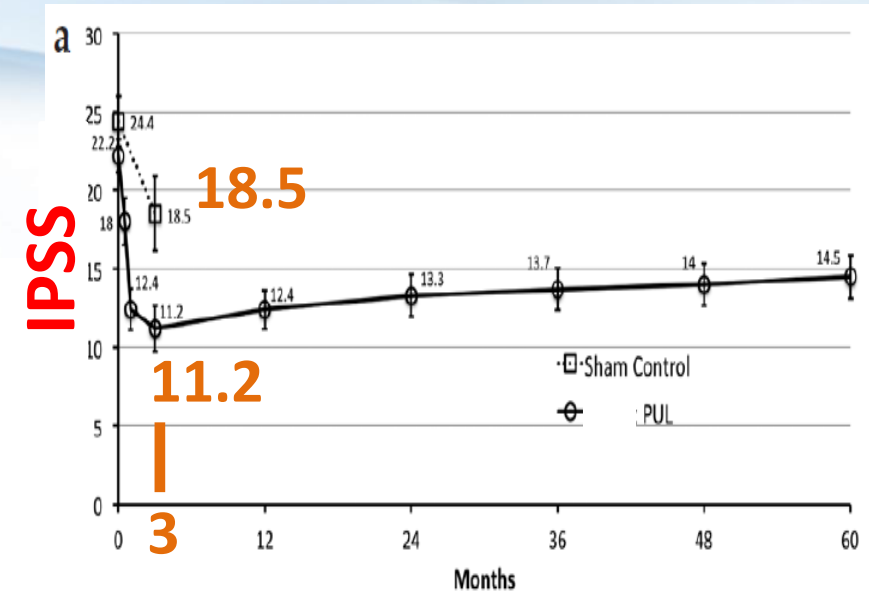
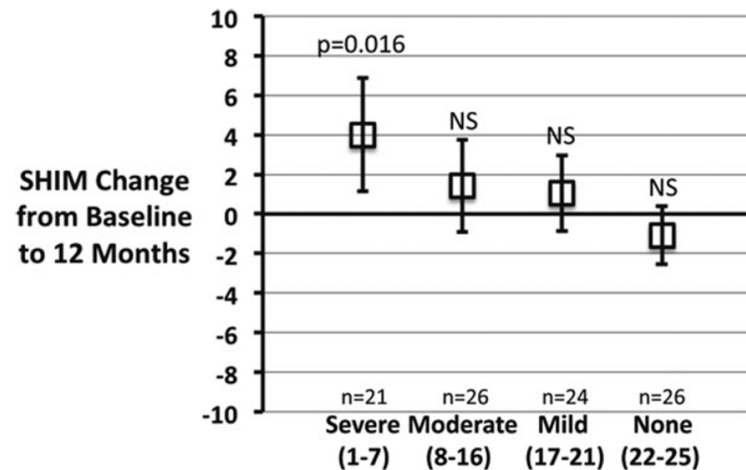


# PUL: L.I.F.T. Study

- 206 patients, 30-80g prostate, average 4.9 implants
- RCT (144 Urolift vs 66 SHAM)  
Excluded median lobe
- 32% failed void trial → catheter for avg 0.9 days
- Return to normal activity by 8.6 ± 7.5 days
- 1 month: IPSS 22.3 → 12.3 (88% better than sham)

No new onset sustained sexual dysfunction (EjD or ED)

MSHQ-EjD bother and function stable up to 5 yrs



Mild-mod adverse effects usually resolve within 2-3 weeks

No new onset sustained sexual dysfunction (EjD or ED)

5 yrs: 13.6% surgical retreatment, 10.7% use of BPH meds

May reduce quality of prostate MRIs for elevated PSA workup\*

Prostate Cancer and Prostatic Diseases (2019) 22:411–419  
<https://doi.org/10.1038/s41391-018-0118-x>

## ARTICLE

Clinical Research

## Prostatic Urethral Lift (PUL) for obstructive median lobes: 12 month results of the MedLift Study

Daniel Rukstalis<sup>1</sup> • Douglas Grier<sup>2</sup> • Sean P. Stroup<sup>3</sup> • Ronald Tutrone<sup>4</sup> • Euclid deSouza<sup>5</sup> • Sheldon Freedman<sup>6</sup> • Richard David<sup>7</sup> • Jed Kamientsky<sup>8</sup> • Gregg Eure<sup>9</sup>

TABLE 1. Adverse events over 5 year course of study

Time period [months]	0-3	4-12
Total available subjects	140	139
Total subject-months (SM)	413.6	1210.3
Related adverse events [total events]	162	15
Related adverse events [subjects]	100	12
% SM with adverse event per total SM:		
Abdominal pain	0.3%	
Bladder spasm	0.3%	0.09%
Chills (rigors)		
Diarrhea	0.2%	
Dizziness	0.2%	
Fever (pyrexia)	0.06%	
Vomiting	0.02%	
Hypotension	0.04%	
Orchitis/epididymo-orchitis	0.3%	
Painful erection	0.2%	
Urinary retention	0.4%	
Urethral stenosis (stricture)	< 0.01%	< 0.01%
Prostatitis	0.4%	< 0.01%
Urinary tract infection	0.1%	0.03%
Pelvic pain	6%	1%
Hematuria	4%	0.2%
Dysuria	9%	1%
Urinary urge incontinence	3%	3%
Other	4%	3%

*Observational cohort study (45 pts)  
 Improved Qmax, IPSS, EjD function  
 Not in AUA Guidelines*



# \*Water Vapor Thermal Therapy (Rezüm)

- Convective water therapy → ablates prostate contained within the capsule

## WATER VAPOR THERMAL THERAPY (WVTT)

### GUIDELINE STATEMENT 36

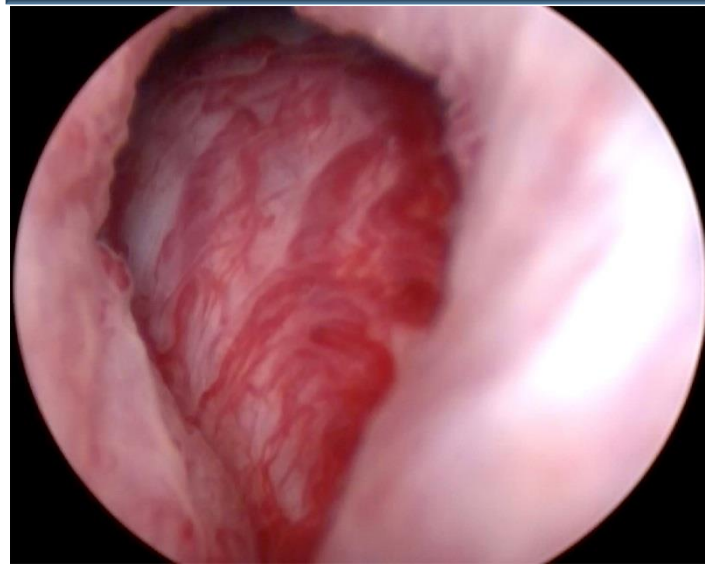
**WVTT should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g. (Moderate Recommendation; Evidence Level: Grade C)**

### GUIDELINE STATEMENT 37

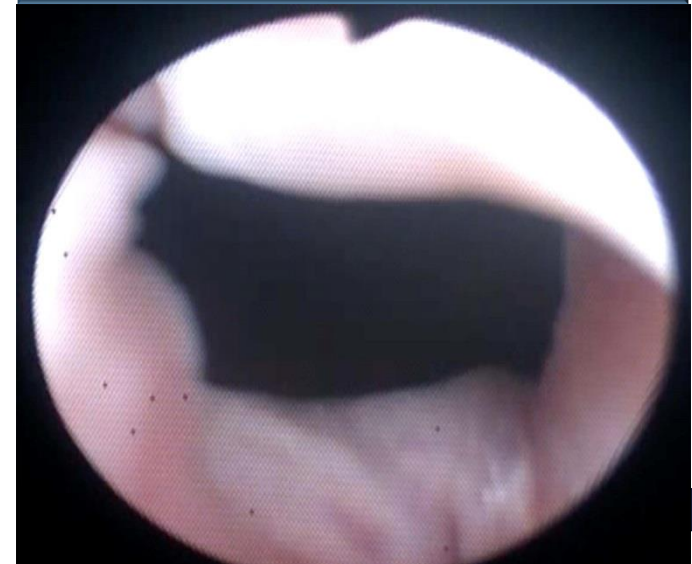
**WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)**



Pre-Treatment



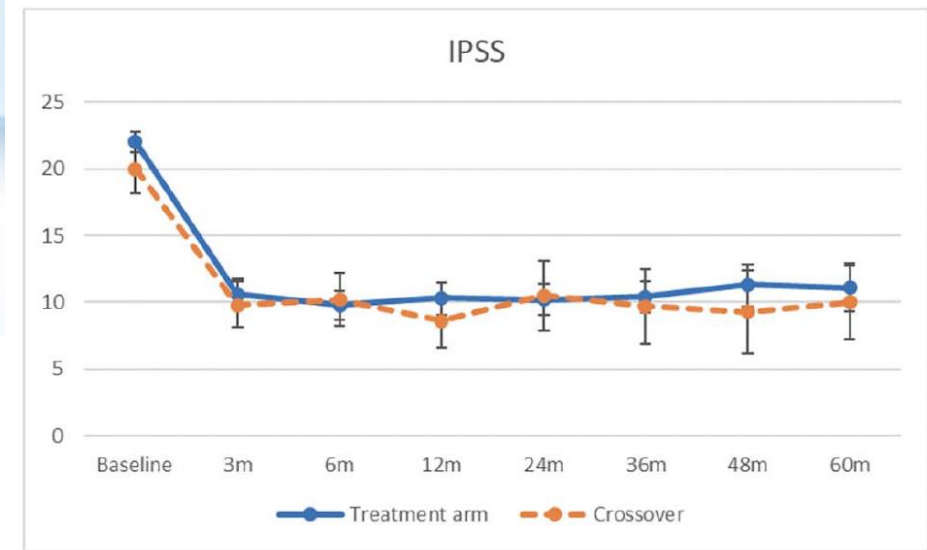
6-Month



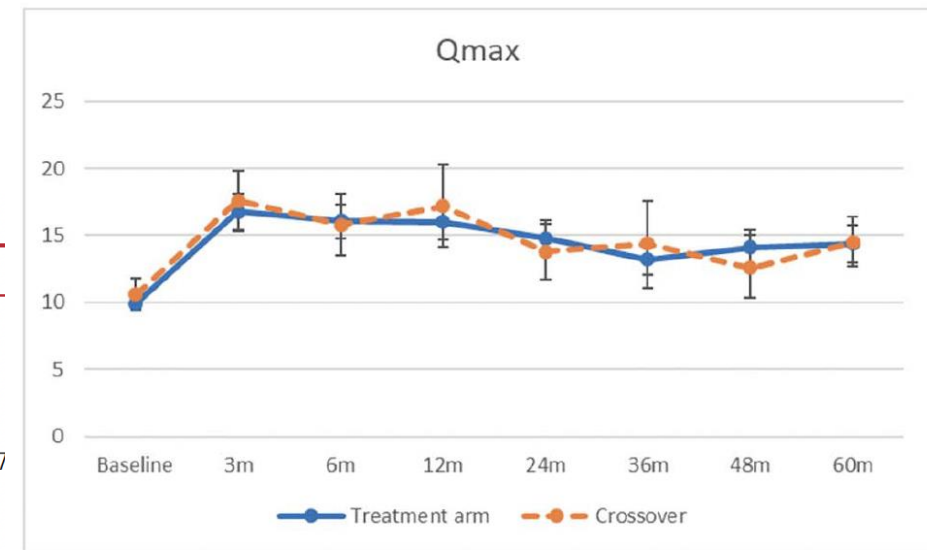


# WVTT: Rezum Study

- 197 patients, 30-80g prostate size, 4.5 median injections
  - 31% had median lobe (additional 1.6 treatments)
- RCT (135 Rezum vs 61 SHAM)
- 90.4% required catheter for mean 3.4 days
- Return to normal activity by median 4 days
- Improvement as early as 2 weeks, maximum at 3-6 months



(A) IPSS



(C) Qmax

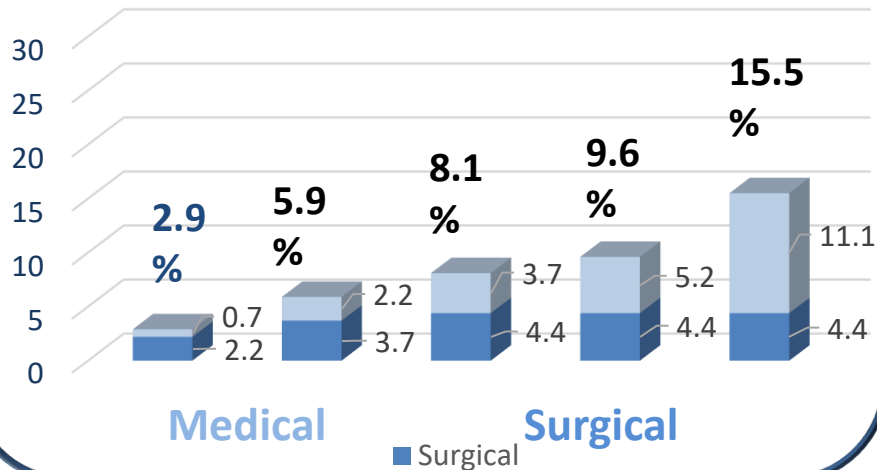
**Table 4.** Changes in outcomes in thermal treatment group from baseline through 12 months

	2 Wks	1 Mo	3 Mos	6 Mos	12 Mos
<b>I-PSS:</b>					
No. (paired values)	130	132	134	129	120
Mean $\pm$ SD baseline	21.9 $\pm$ 4.8	21.8 $\pm$ 4.7	22.0 $\pm$ 4.8	22.0 $\pm$ 4.8	21.8 $\pm$ 4.8
Mean $\pm$ SD followup	18.6 $\pm$ 7.1	14.5 $\pm$ 7.2	10.6 $\pm$ 6.4	9.8 $\pm$ 6.2	10.2 $\pm$ 6.6
Change $\pm$ SD	-3.2 $\pm$ 7.8	-7.4 $\pm$ 8.1	-11.3 $\pm$ 7.6	-12.2 $\pm$ 7.6	-11.7 $\pm$ 7.2
% Change (95% CI)	-12 (-18, -5)	-31 (-37, -25)	-50 (-55, -44)	-54 (-59, -49)	-53 (-58, -47)
p Value	0.0006	<0.0001	<0.0001	<0.0001	<0.0001
<b>Qmax:</b>					
No. (paired values)		133	133	125	117
Mean $\pm$ SD baseline		9.9 $\pm$ 2.3	9.9 $\pm$ 2.3	9.9 $\pm$ 2.2	9.8 $\pm$ 2.2
Mean $\pm$ SD followup		13.1 $\pm$ 5.5	16.1 $\pm$ 7.3	15.4 $\pm$ 6.5	14.9 $\pm$ 6.8
Change $\pm$ SD		3.2 $\pm$ 5.2	6.2 $\pm$ 7.1	5.5 $\pm$ 6.3	5.1 $\pm$ 6.3
% Change (95% CI)		36 (26, 46)	67 (53, 80)	61 (48, 73)	54 (42, 66)
p Value		<0.0001	<0.0001	<0.0001	<0.0001

# WVTT: Rezum Study

- Dysuria (17%), hematuria (12%), hematospermia (7%), urgency (6%), retention (4%), decreased Ej volume (3%), anejaculation (3%) resolve within 3 weeks
- After 3 months: Dysuria (0.7%), decreased Ej vol (1.5%)
- No impact on erectile or ejaculatory function

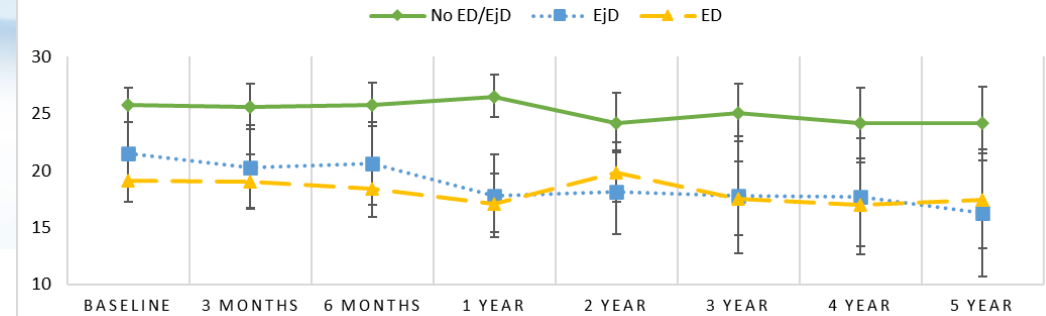
## Retreatment Rates through 5yrs



5 yrs:  
4.4% surgical  
retreatment  
11.1% BPH meds

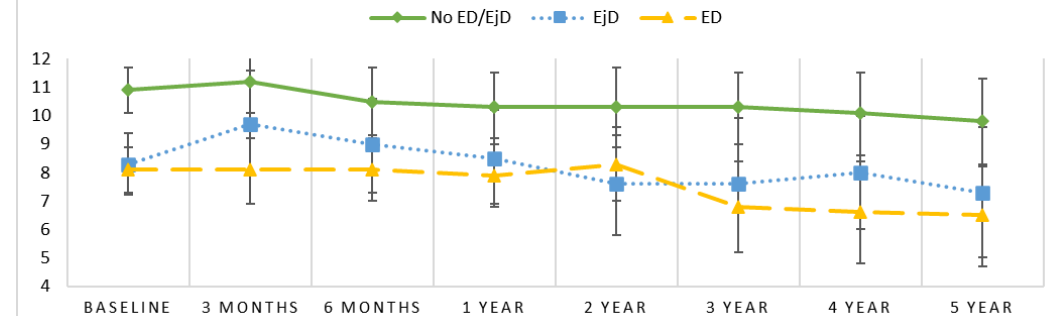
## IIIEF-EF SCORE

ERROR BAR IS 95% CI



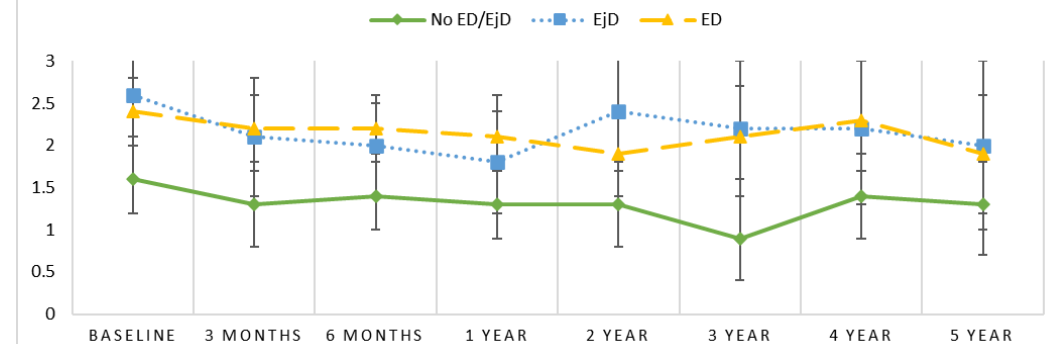
## MSHQ-EJD FUNCTION

ERROR BAR IS 95% CI



## MSHQ-EJD BOTHER

ERROR BAR IS 95% CI



McVary KT, Roehrborn CG et al. Sex Medicine 2021.

# Prostatic Diseases and Male Voiding Dysfunction

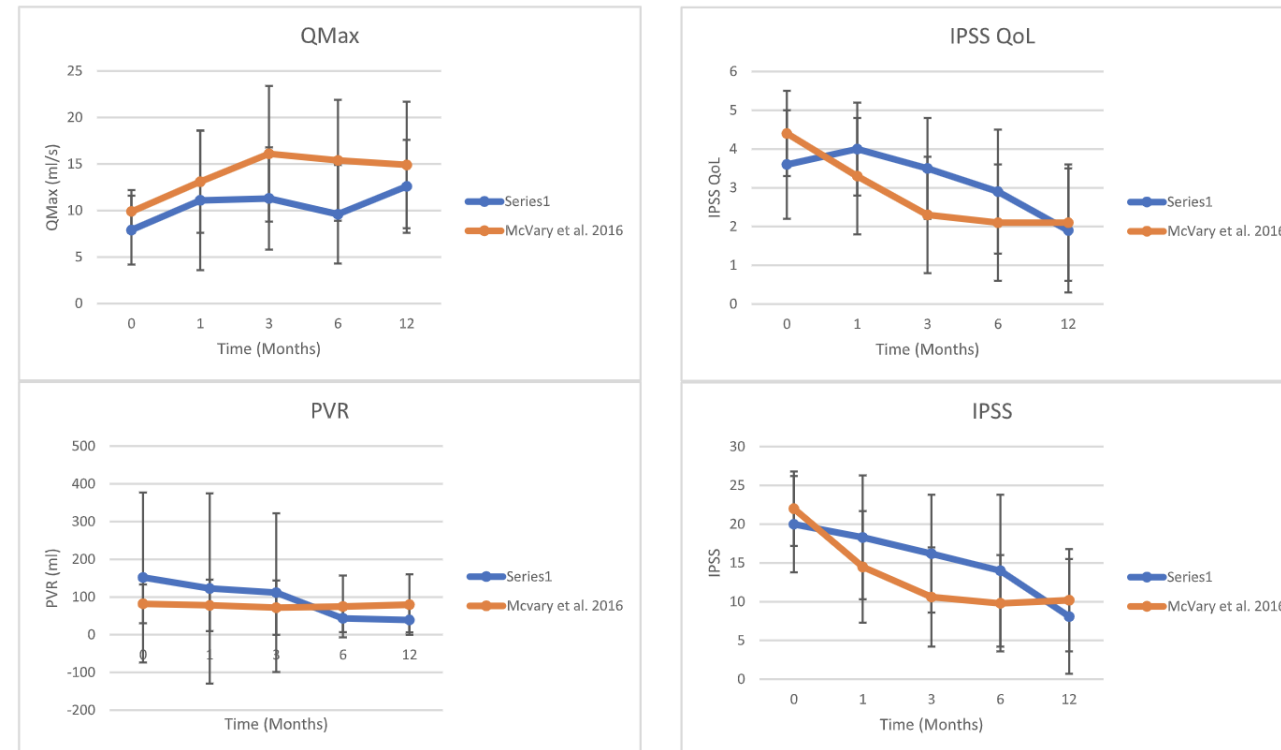
## Pilot Study of “Less is More” Rezum for Treatment of BPH



Oluwatobi Aladesuru, Koby Amankwah, Dean Elterman, Kevin C. Zorn, Naeem Bhojani, Alexis Te, and Bilal Chughtai

UROLOGY 165: 256–260, 2022.

- 1 treatment per lobe is comparable to standard therapy
- May take longer to achieve maximum results, but less irritation along the way
- 12.5% vs 43.4% AEs



# Prostatic Diseases and Male Voiding Dysfunction

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- 1 treatment per lobe is comparable to standard therapy
- May take longer to achieve maximum results, but less irritation along the way
- **12.5% vs 43.4% AEs**

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

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

- Catheter-free WVT is feasible in well selected patients and enhances both voiding and symptom scores

# \*Temporarily Implanted Prostatic Devices (iTind)

- Deep, bloodless incisions created through ischemic pressure and subsequent necrosis → permanently remodel the prostatic urethra and bladder neck

## TEMPORARY IMPLANTED PROSTATIC DEVICES (TIPD)

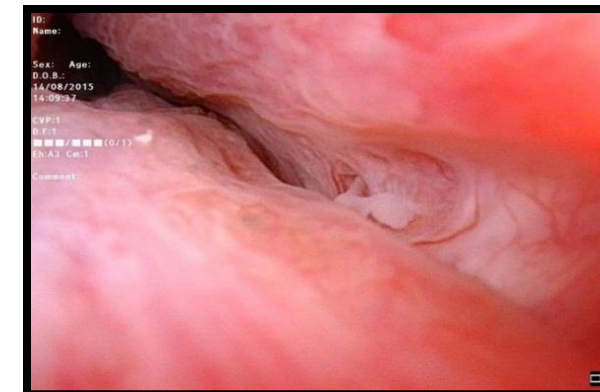
### GUIDELINE STATEMENT 41

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

Ischemic incisions immediately after device removal (5-7 days)



12 months after removal





# TIPD: iTind

- 185 patients, 25-75g prostate size
- RCT (118 iTIND vs 57 SHAM)
  - Excluded median lobe, PVR>250, Qmax>12, IPSS<10
- 78.6% vs 60% IPSS improvement @3 mos (21.6→12.7)
- Qmax improved @12 mos (8.4→11.9 ml/s)
- No change in IIEF or SHIM @12 mos
  
- Sustained at 4 years

No sexual or ejaculatory dysfunction, regardless of age, prostate size, or baseline ED status

## Prostatic Diseases and Male Voiding Dysfunction

### The iTind Temporarily Implanted Nitinol Device for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Multicenter, Randomized, Controlled Trial

Bilal Chughtai\*, Dean Elterman\*, Neal Shore, Marc Gittleman, Jay Motola, Sheldon Pike, Craig Hermann, William Terrens, Alfred Kohan, Ricardo R. Gonzalez, Aaron Katz, Jeffery Schiff, Evan Goldfischer, Ivan Grunberger, Le Mai Tu, Mark N. Alshak, and Jed Kaminetzky

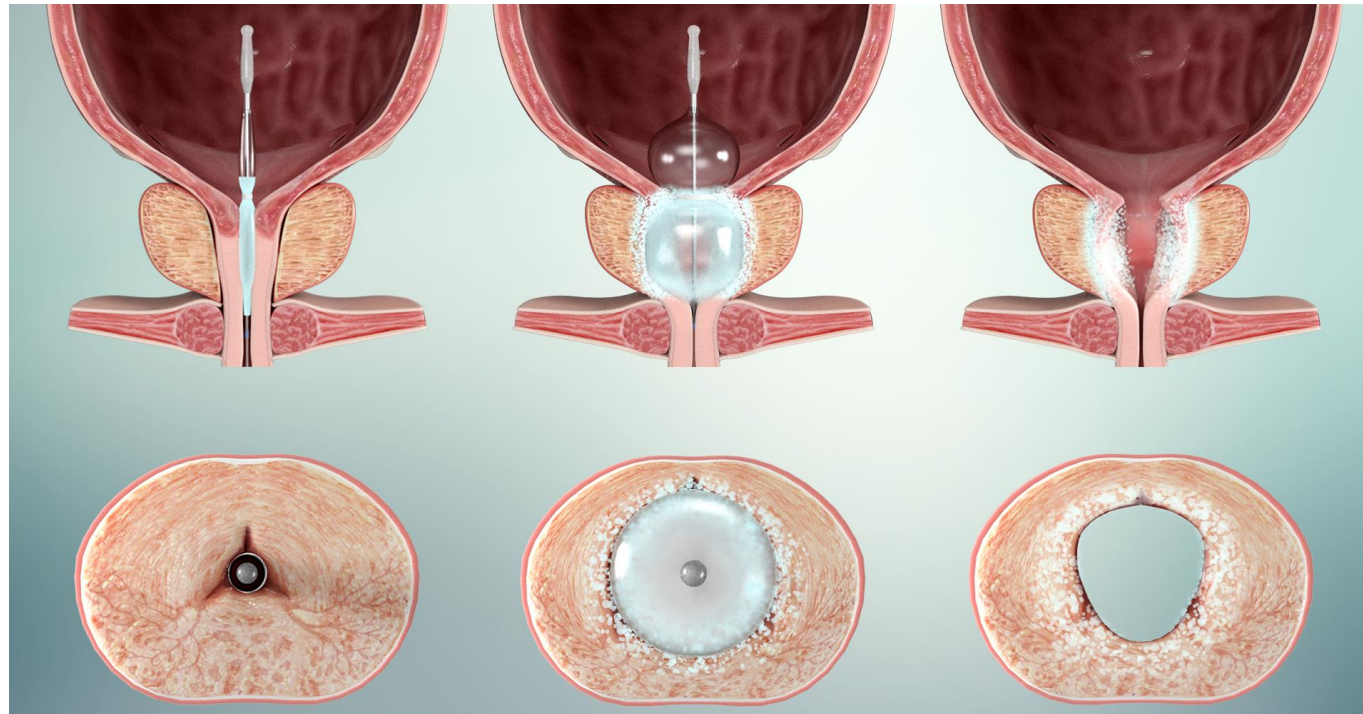
Table 3. Overview of adjudicated adverse events

	iTind Group 0-30 days			Sham Group 0-30 days			iTind Group 1-3 months			iTind Group 3-12 months		
	Events (n)	Subjects (n)	Subjects (%)	Events (n)	Subjects (n)	Subjects (%)	Events (n)	Subjects (n)	Subjects (%)	Events (n)	Subjects (n)	Subjects (%)
Serious AEs	16	10	7.8	2	2	3.5						
Related serious	5	3	2.3									
All AEs	109	45	38.1	19	10	17.5						
Related AEs	81	39	33.1	4	4	7	2	2	1.6	1	1	0.8
Dysuria		27	22.9		5	8.8						
Hematuria		16	13.6									
Micturition urgency		6	5.1		1	1.8						
Pollakiuria		8	6.8		1	1.8						
Urinary retention		7	5.9				1	1	0.8			
Urinary tract infection		2	1.7				1	1	0.8		1	0.8
Sepsis		1	0.8									
Pain		1	0.8									



## \*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. **NOT YET IN AUA GUIDELINES**

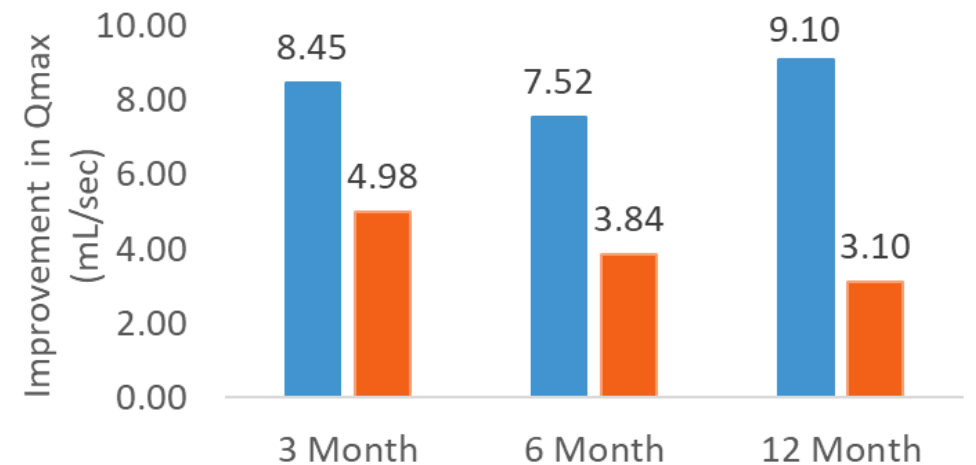
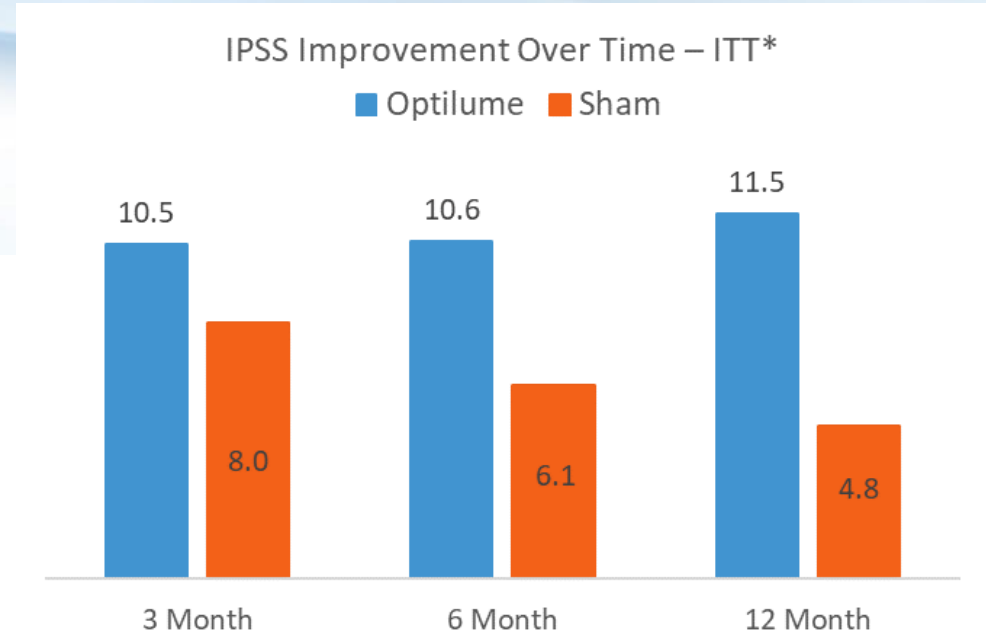


Optilume BPH is a minimally invasive surgical therapy that combines mechanical dilation with concurrent localized delivery of paclitaxel for treating BPH-induced lower urinary tract symptoms.

# Optilume

- **PINNACLE TRIAL:**
- Significant immediate increase in Qmax observed immediately post treatment and sustained through 4 year follow-up.
- PVR improvement after treatment with the Optilume BPH device has been maintained through 4 years

No sexual or ejaculatory dysfunction, regardless of age, prostate size, or baseline ED status



# TRADITIONAL SURGICAL THERAPY

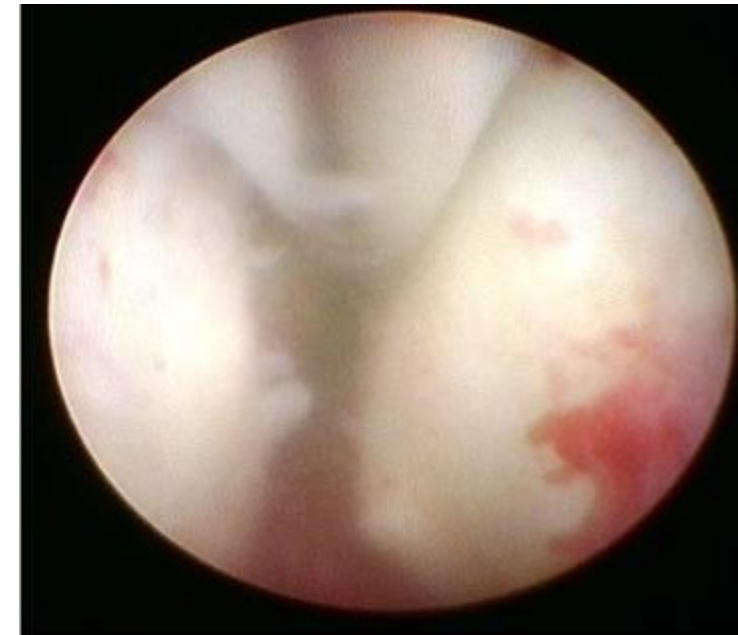
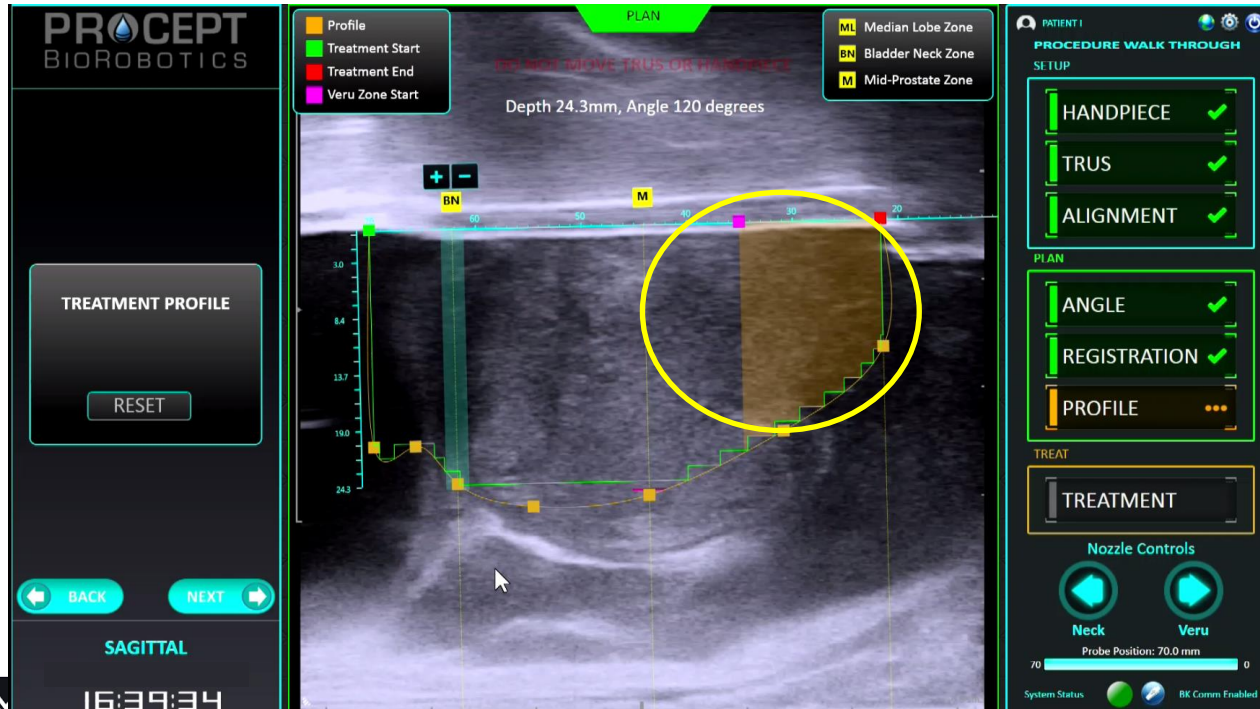
# \*Robotic Waterjet Treatment (Aquablation)

- Ultrasound guided water jet resects tissue, then TURP for hemostasis

## ROBOTIC WATERJET TREATMENT (RWT)

### GUIDELINE STATEMENT 39

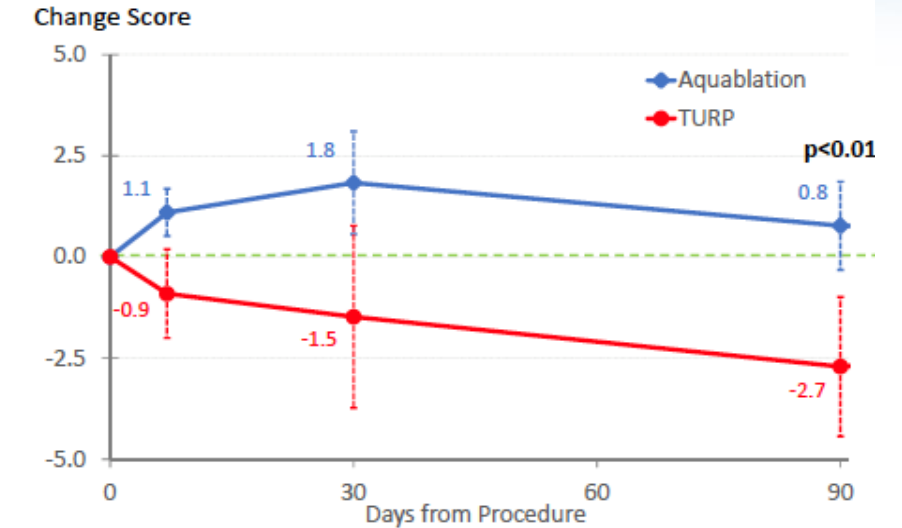
Robotic waterjet treatment (RWT) may be offered as a treatment option to patients with LUTS/BPH provided prostate volume 30-80g. (*Conditional Recommendation; Evidence Level: Grade C*)



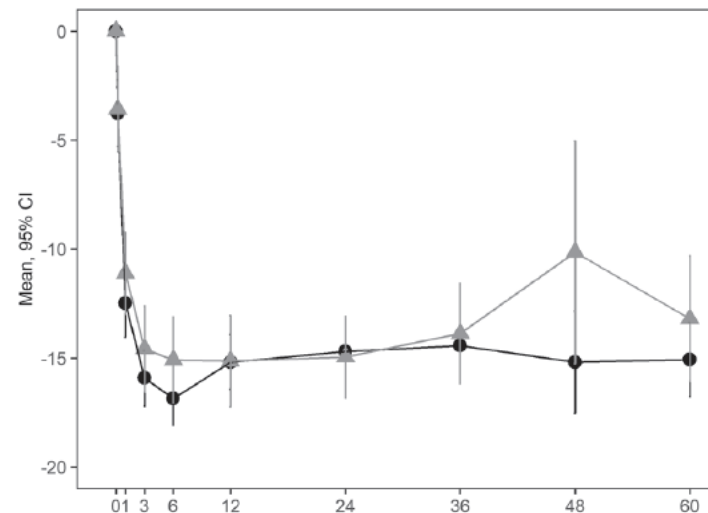
# RWT: Water Study

- 181 patients, 30-80g prostate size
  - 50% had median lobe
- RCT (116 Aquablation vs 65 TURP)
- 10% vs 36% anejaculation @3yrs
- 6% retreatment @5 yrs (12% TURP)

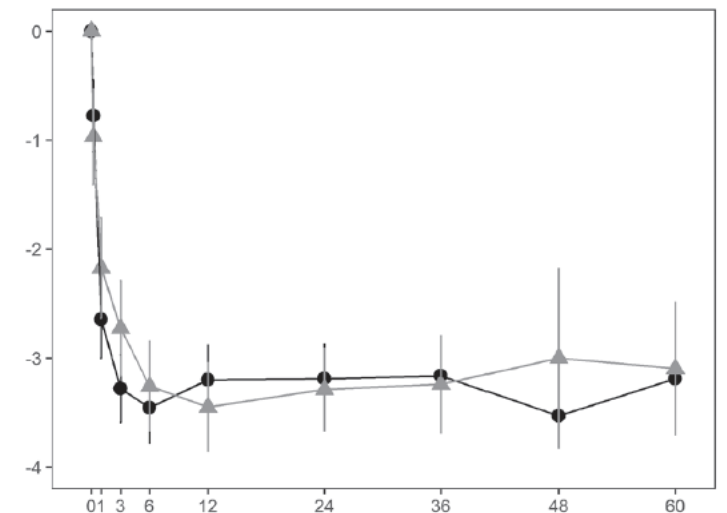
## Ejaculatory Function (MSHQ-EjD)



## IPSS



## IPSS QOL

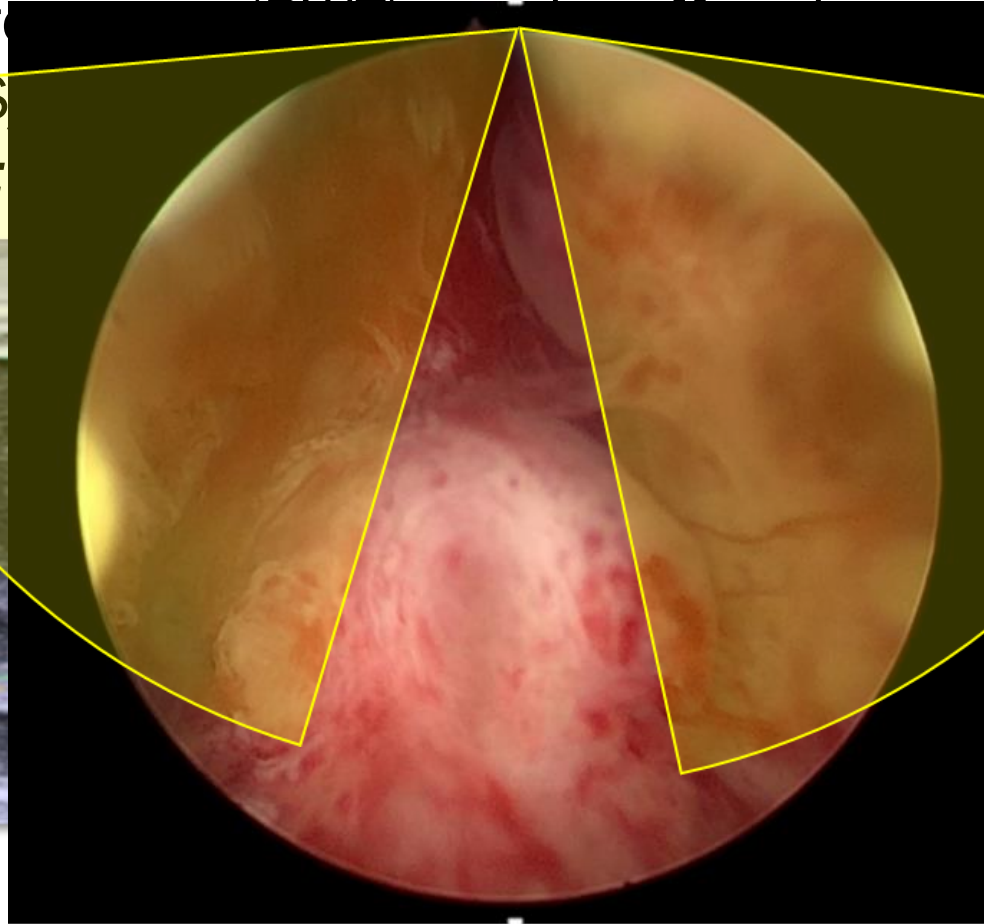
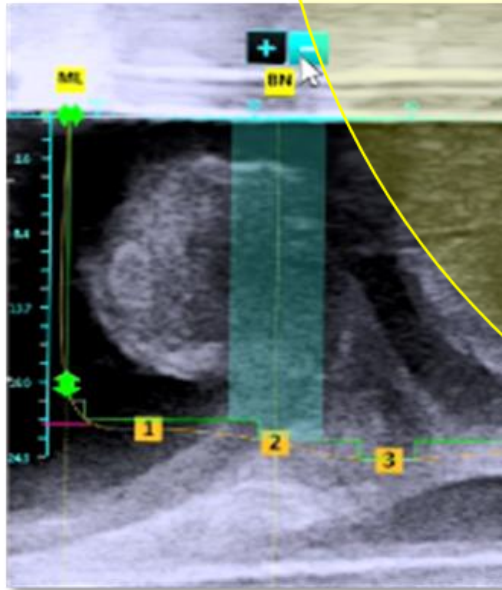




# WATER JET ABLATION OF PROSTATE (AQUABLATION)

Robotic waterjet treatment option to patients with LUTS  
*Recommendation;*

treatment option to  
Og. (Conditional



AQUABEAM®  
ROBOTIC SYSTEM



# AQUABLATION



30 – 80 mL  
51% obstructive median lobe



17 Sites

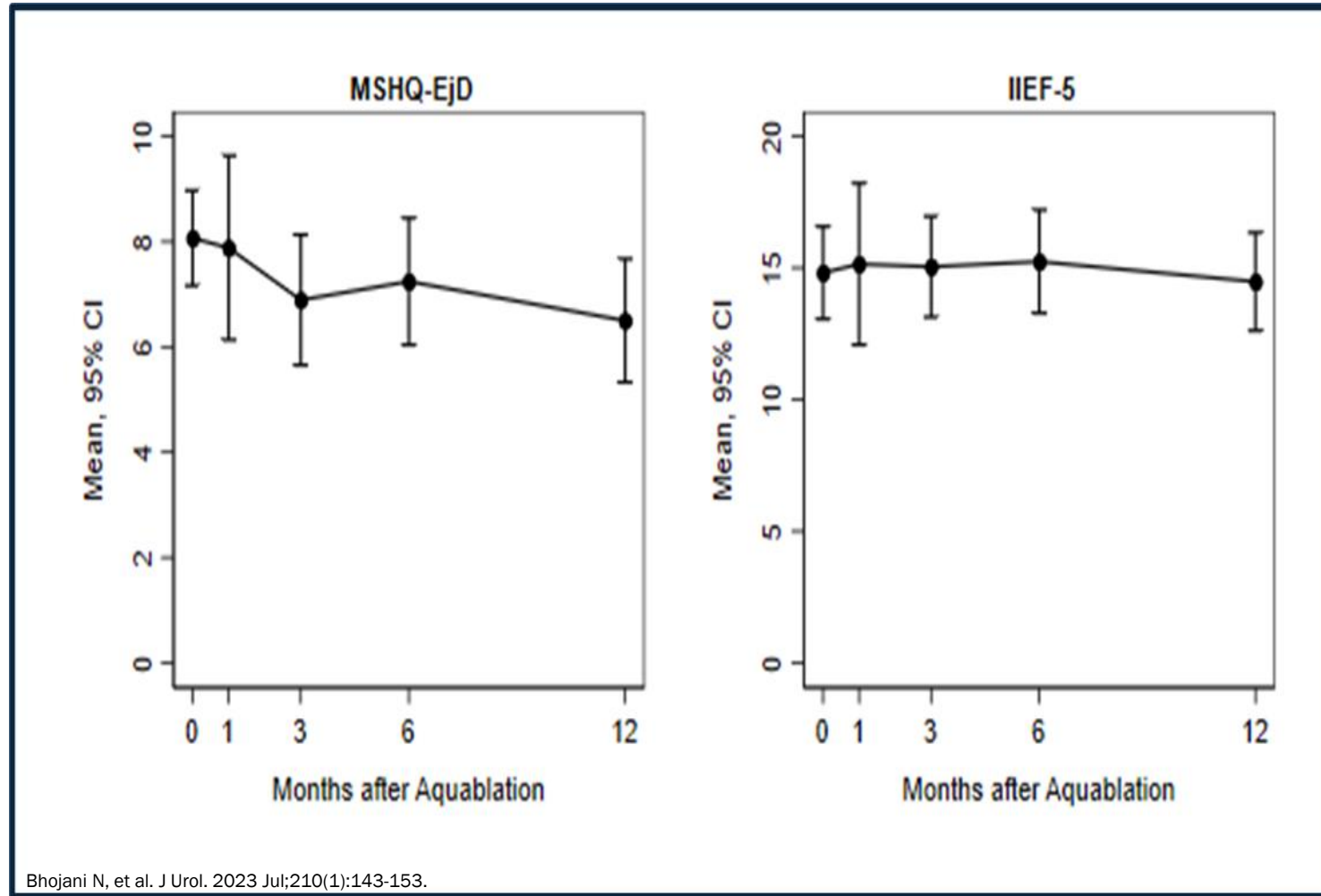


4 Countries

<b>DURABILITY</b> at 5 years			<b>TURP</b>
<b>EFFICACY</b> improvement over baseline at 5 years	Surgical & Medical Retreatment	6%	12%
	Symptom Improvement (IPSS)	69% $\Delta$ 15.1 pts	61% $\Delta$ 13.2 pts
	Quality of Life Improvement (IPSS QoL)	67% $\Delta$ 3.2 pts	65% $\Delta$ 3.2 pts
	Peak Urinary Flow Rate Improvement (Qmax)	125% $\Delta$ 8.7 mL/sec	89% $\Delta$ 6.3 mL/sec
<b>SAFETY</b> 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.

# WATER II TRIAL (80-150 CC PROSTATES)



# 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

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

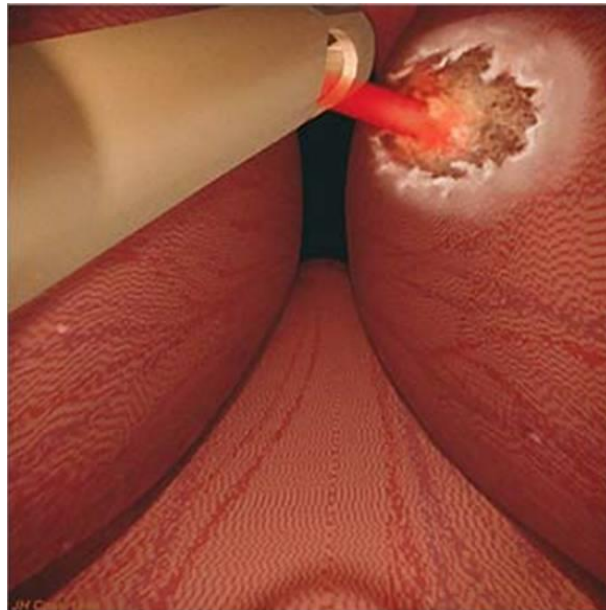
# \*Photoselective Vaporization of the Prostate

- 532nm greenlight laser
- Tissue ablation/vaporization with a thin layer of underlying coagulation

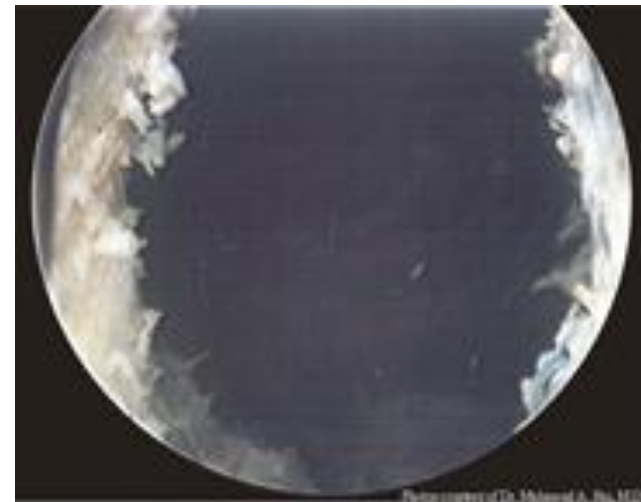
## PHOTOSELECTIVE VAPORIZATION OF THE PROSTATE (PVP)

### GUIDELINE STATEMENT 33

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



Pre-PVP Procedure

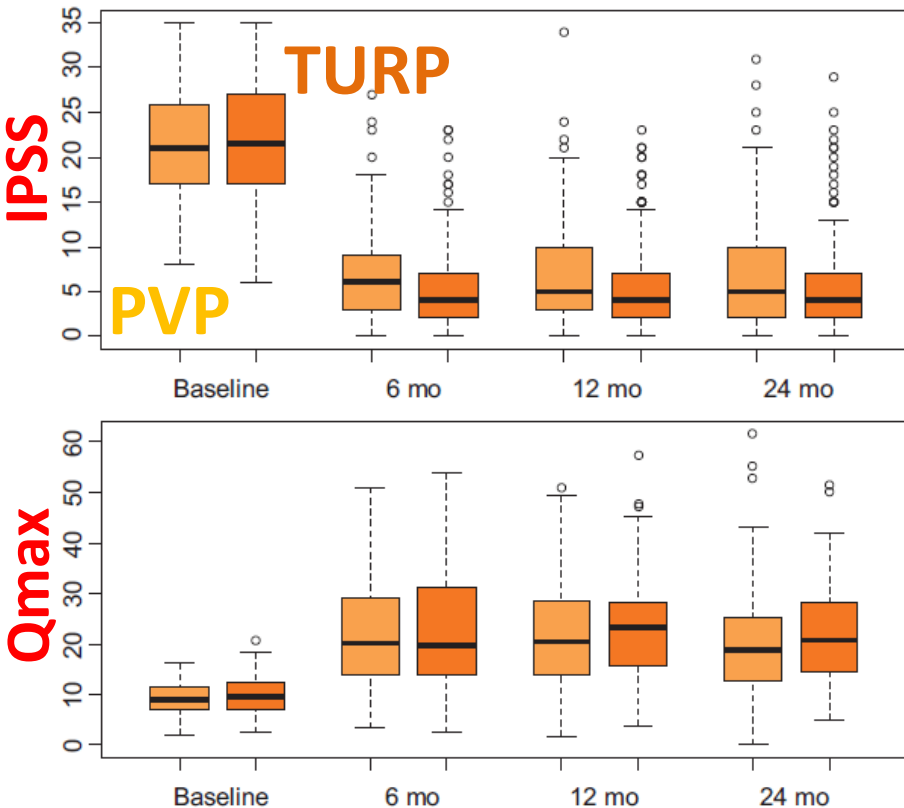


Immediate Post PVP



# PVP: At least as good as TURP

- GOLIATH: PVP is noninferior to TURP at 2 yrs
  - 269 patients, 46g avg prostate size



- 2011-2019, 3,627 patients
- Mean 64g, IPSS 22
- 60 months follow up
- 2.8% LUTS @6mos
- 0.7% Incontinence @6mos
- 1.5% Retreatment @5yrs
- 10-15% retreatment at 10 yrs

World Journal of Urology (2021) 39:4389–4395  
<https://doi.org/10.1007/s00345-021-03688-4>

## ORIGINAL ARTICLE



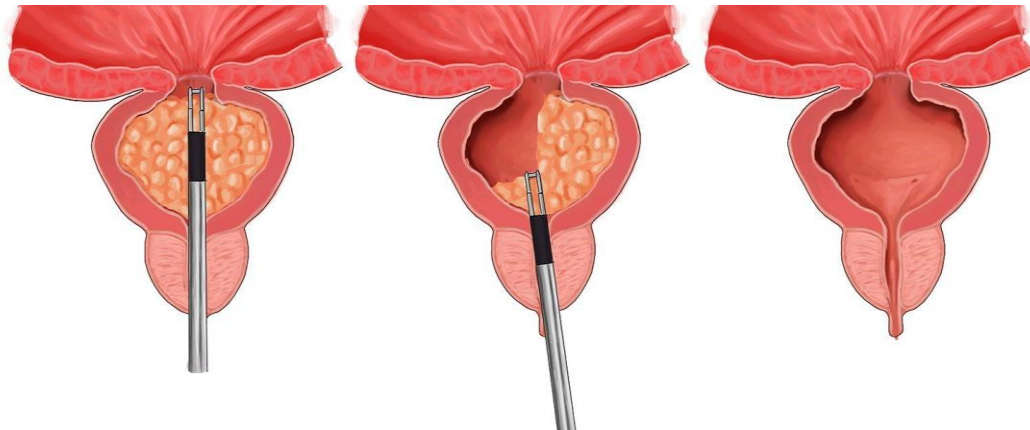
### Global Greenlight Group: largest international Greenlight experience for benign prostatic hyperplasia to assess efficacy and safety

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

Complication	Clavien–Dindo grade	Number of patients (%)
<b>Perioperative</b>		
Prostatic capsule perforation	IIIa	21 (1.4%)
Conversion to TURP	IIIa	47 (2.8%)
<b>Early postoperative (&lt; 30 days)</b>		
30-day readmission	–	192 (13.3%)
# On anti-coagulants	–	58 (30%)
Fever	I	62 (4.0%)
UTI	I	118 (5.3%)
LUTS*	I	500 (22.6%)
OAB	I	6 (1.1%)
Incontinence	I	232 (10.5%)
Retention	I	164 (7.4%)
Hematuria	I	219 (9.9%)
Paraphimosis	I	1 (0.2%)
Hematuria	II	32 (4.3%)
Osteitis pubis	II	1 (0.2%)
Urosepsis	II	8 (0.5%)
Stenosis (urethra, meatus, bladder neck)	IIIb	1 (0.1%)
Arrhythmia	IVa	6 (0.4%)
Major cardiac event**	IVb	12 (0.8%)
Respiratory distress (desaturation)	IVb	3 (0.2%)
Death	V	4 (0.3%)
<b>Long term at 5-year follow-up</b>		
Bladder neck contracture	IIIb	11 (1.93%)
Urethral stricture	IIIb	5 (0.89%)
BPH recurrence requiring medical reintervention	II	19 (3.34%)
BPH recurrence requiring surgical reintervention	IIIb	10 (1.5%)

# \*Transurethral Resection of the Prostate (TURP)

- Monopolar or bipolar approach
- **Risks:**
  - bleeding, ED (5%)
  - retrograde ejaculation (48%),
  - incontinence (10%)
- **Retreatment Rate:** 15% at 10 years



# \*Holmium Laser Enucleation of the Prostate (HoLEP)

- The only size independent procedure for BPH
- Consider for patients at increased risk of bleeding

## LASER ENUCLEATION

### GUIDELINE STATEMENT 38

Holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP) should be considered as an option, depending on the clinician's expertise with these techniques, as prostate size-independent options for the treatment of LUTS/BPH. (*Moderate Recommendation; Evidence Level: Grade B*)

The HoLEP surgery "hollowing out" process



Developed by: Northwestern Memorial Hospital Department of Urology ©June 2022 Northwestern Memorial HealthCare 900427 (6/22) Holmium Laser Enucleation of the Prostate Surgery

# HoLEP

- Pros:
  - Lowest reoperation rate 1.4% (0-4% @7 years) [1][2]
  - No effect on erectile function at 3 yrs [3]
- Downsides:
  - Retrograde ejaculation (92.5% of patients) [4]
  - Transient urinary leakage (15% at 1 month, 3% > 6 months) [5]
  - Learning curve – need 50 cases [6]



1. Elkoushy MA et al J Endourol. 2015
2. Gilling PJ et al. European Urol 2008
3. Klett DE et al. Urology 2014
4. Gild P et al. Andrology 2020
5. Hout M et al. World Journal of Urology 2022
6. Schaeffer Urology 2007

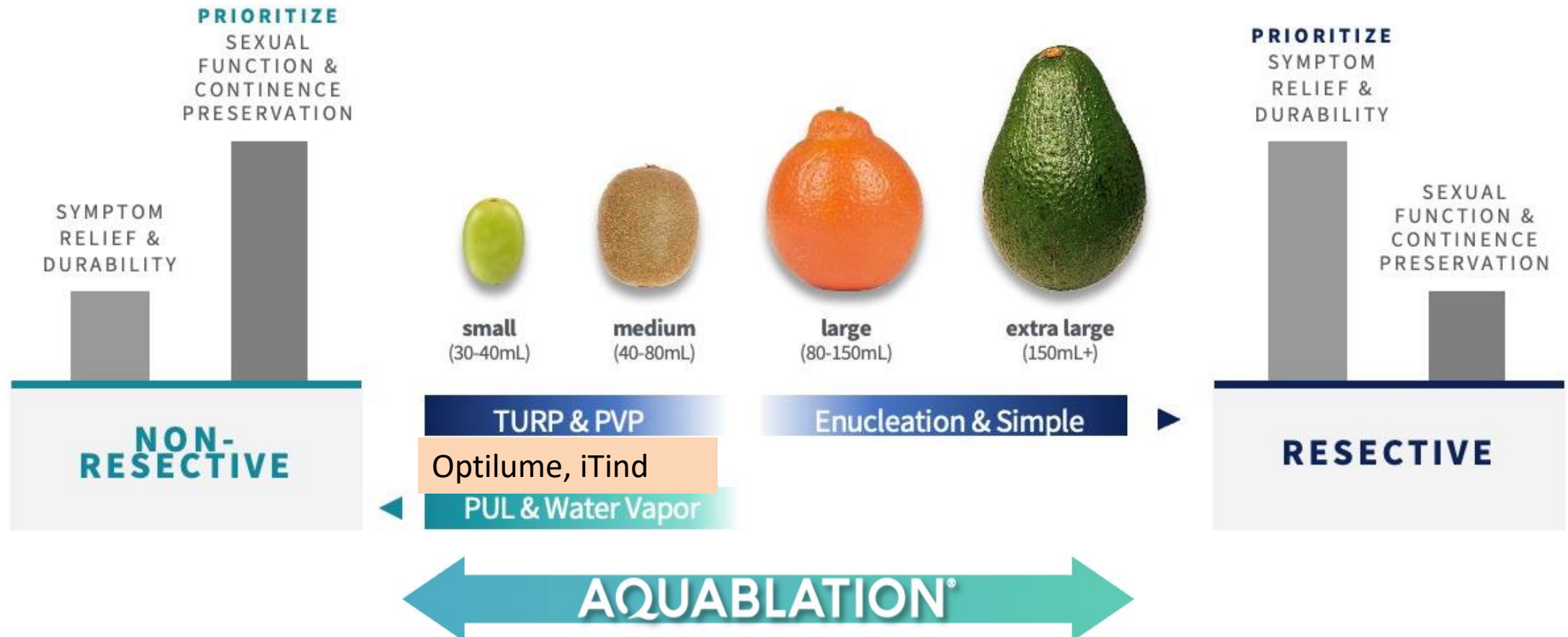


To Summarize...



# Summary of Procedures

PROSTATES COME IN ALL SIZES & SHAPES



To Summarize...

# My Practice: How I Counsel Patients

- Review the data together: bladder health, prostate size, etc.
  - Review cystoscopy
  - Uroflow
- Shared decision making – manage patient expectations
  - “I want you to have the best result and recovery possible so let’s make sure you understand your choices and what will happen.”
- Anticipate recovery pathways and postop hurdles
  - Postop LUTS, catheter, etc.

# Thank you!

Seth Bechis, MD, MS  
Professor of Urology  
**Endourology**  
**Benign Prostatic Diseases**

[sbechis@health.ucsd.edu](mailto:sbechis@health.ucsd.edu)

