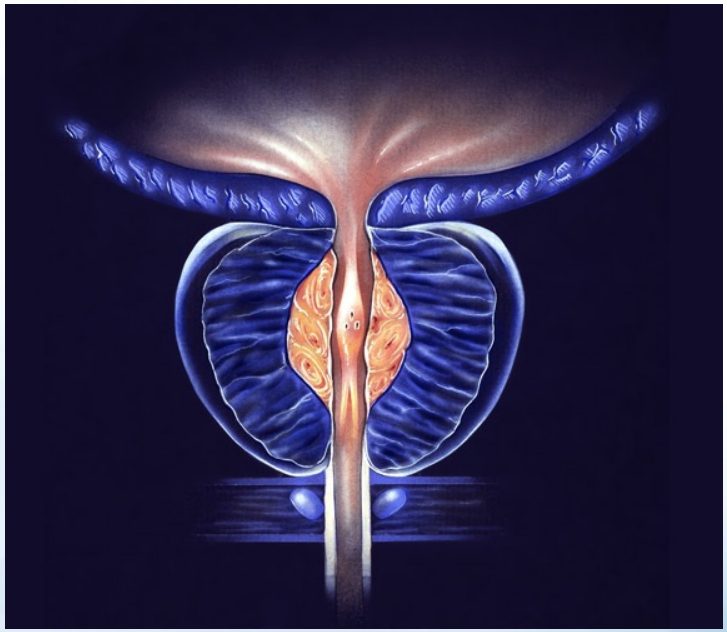
Should MIST be First Line for BPH?



Credit: Judith Glick - stock.adobe.com

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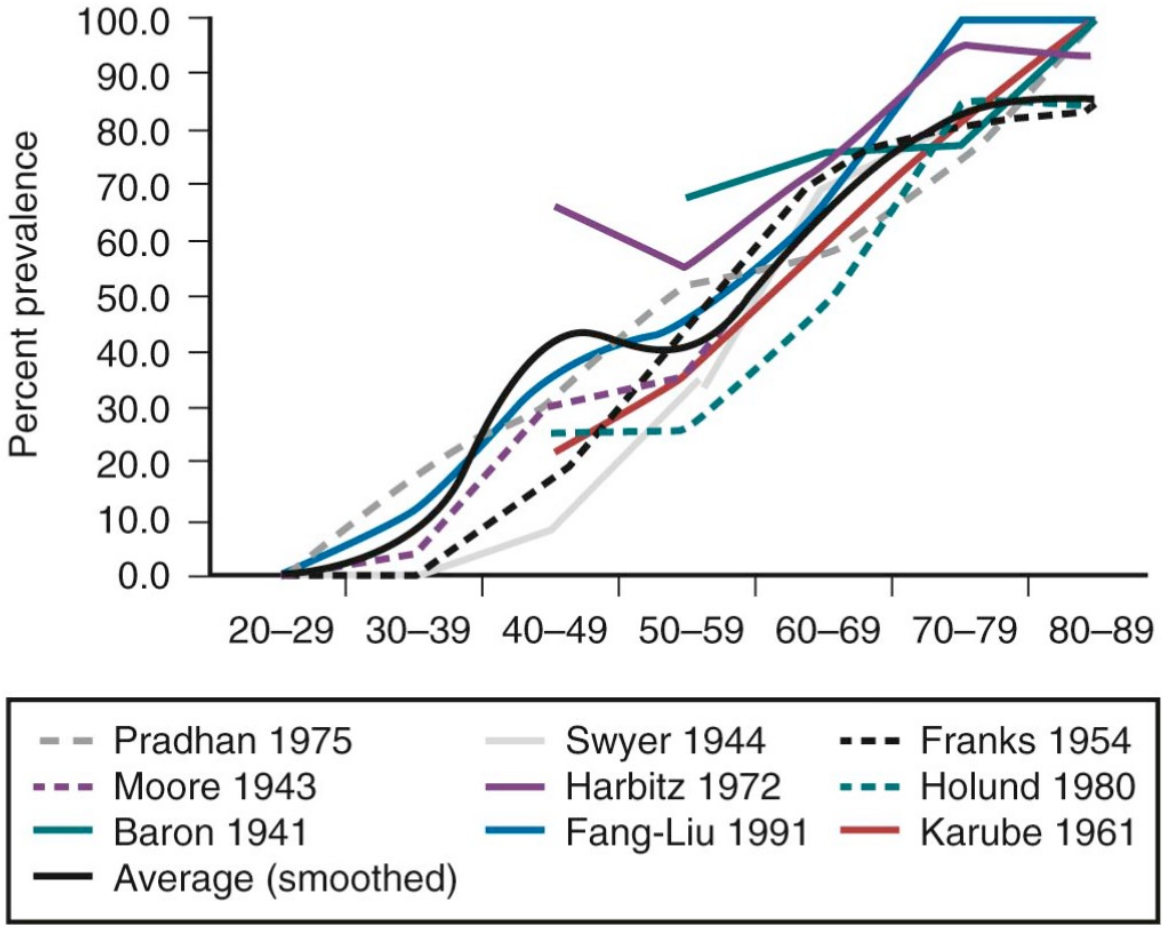
Disclosures: Seth Bechis

- Consultant
  - Ambu
  - Auris
  - Boston Scientific
  - BD
  - Calyxo
  - Dornier
  - Olympus
- Speaker
  - Cook Medical
  - Karl Storz Endoscopy

BPH prevalence increases with age



Age 60-69: 70%

Age >80: 80%

Age-stratified autopsy prevalence of histologic BPH

Berry SJ, Coffey DS, Walsh PC, et al. J Urol 1984;132:474-9.

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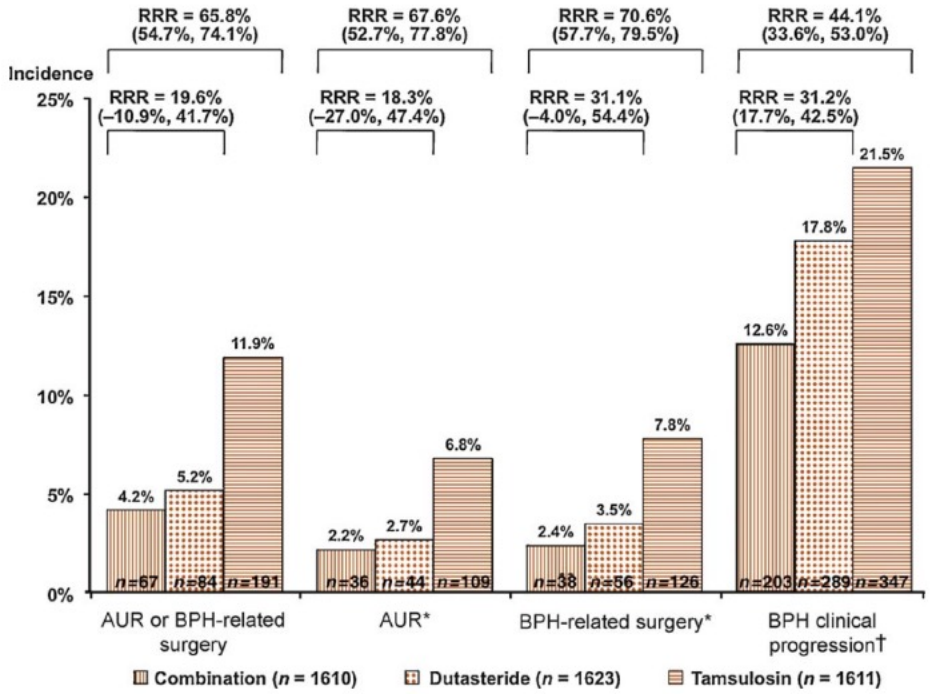
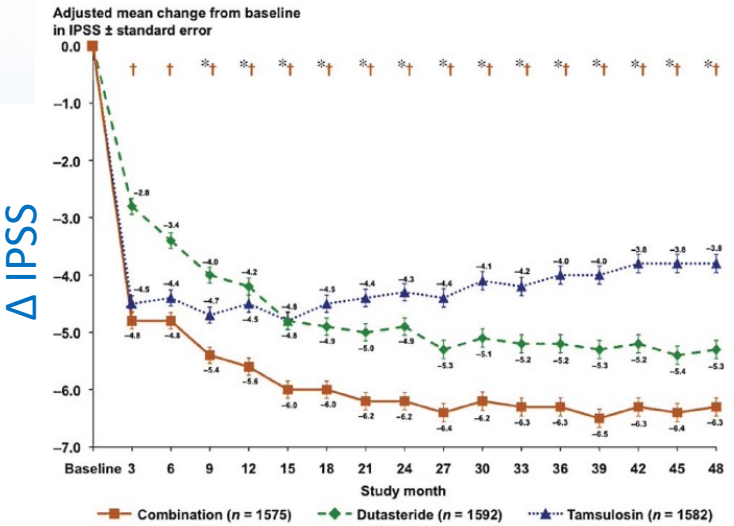
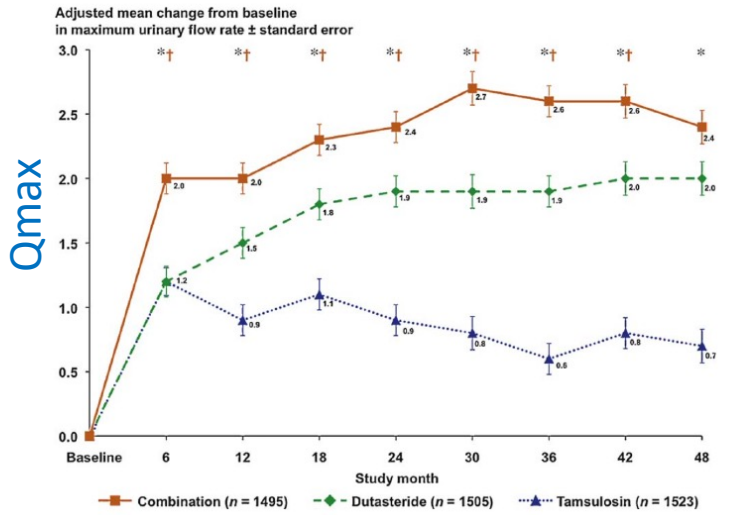
BPH Medication, Especially Combo, is Effective

- Medical therapy superior to WW
- Combo therapy superior to individual meds
- CombAT Study, MTOPS







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Roehrborn CG et al. Eur Urol 57 (2010): 123-131.

BPH Medication Is Not Without Long-Term Risk

- Alpha blockers: cardiac, cognitive
- 5ARIs: psychological
- Sexual Function
- Poor Patient Compliance
  - 60-80% stop taking after 1 year

- 4.7-16% of patients on medication have worsening LUTS (IPSS>3)
- 0.5-1.6% develop acute retention

- Patient outcomes were worse when surgery was delayed until after failure of medical therapy

Nichol et al. J Urol 181. 2009.
Cindolo et al. Eur Urol 68. 2015.

BPH Medication Therapy Affects Sexual Function

- Alpha blockers
  - ↓IPSS by 30-40%, ↑Qmax by 16-25%
  - 33% of men experience no symptom improvement
  - Ejaculatory Dysfunction

Table 1 Double-blind randomized placebo-controlled studies involving ABs. Open trial data not included. Adapted from Wiser and Kohler [22]

Treatment	Patients (Drug/Placebo)	Erectile Dysfunction (Drug/Placebo)	Decreased Libido (Drug/Placebo)	Ejaculatory Dysfunction (Drug/Placebo)
Alfuzosin 10 mg Qday [21]	143/154	0 %/0.7 %	0 %/0.7 %	0 %/0 %
Alfuzosin 2.5 mg TID [21]	150/154	0 %/0.7 %	0.7 %/0.7 %	0 %/0 %
Doxazosin [18]	275/269	5.8 %/3.3 %	3.6 %/1.9 %	3.6 %/1.9 %
Doxazosin [23]	3652/3489	3.56 %/3.32 %	1.56 %/1.4 %	1.1 %/0.83 %
Silodosin [13]	466/457	-/-	-/-	28 %/0.9 %
Silodosin [24]	176/89	-/-	-/-	22 %/0 %
Tamsulosin 0.4 mg [15]	244/239	-/-	-/-	11 %/<1 %
Tamsulosin 0.8 mg [15]	248/239	-/-	-/-	18 %/<1 %
Tamsulosin [14]	381/193	0.8 %/1.6 %	1 %/0 %	4.5 %/1 %
Terazosin [19]	305/305	6 %/5 %	3 %/1 %	0.3 %/1 %

BPH Medication Therapy Affects Sexual Function

- 5-ARIs
  - ↓IPSS 0.8-4.5 points, ↑Qmax by 1.9 mL/s
  - ED, Decreased Libido, Ejaculatory Dysfunction

Table 2 Double-blind randomized placebo-controlled studies involving 5ARIs. Open trial data not included. Adapted from Traish et al. [52]

Treatment	Patients (Drug/Placebo)	Erectile Dysfunction (Drug/Placebo)	Decreased Libido (Drug/Placebo)	Ejaculatory Dysfunction (Drug/Placebo)
Dutasteride [53]	126/127	0 %/1 %	2 %/0 %	-/-
Dutasteride [54]	60/59	11 %/3 %	4 %/2 %	-/-
Dutasteride [55]	2,166/2,158	1.7 %/1.2 %	0.6 %/0.3 %	0.5 %/0.1 %
Dutasteride [56]	4,105/4,126	9 %/5.7 %	3.3 %/1.6 %	1.4 %/0.2 %
Dutasteride 1 year [35]	1510/1441	6 %/3 %	3.7 %/1.9 %	1.8 %/0.7 %
Dutasteride 2 years [35]	1510/1441	1.7 %/1.2 %	0.6 %/0.3 %	0.5 %/0.1 %
Finasteride [57]	1,577/1,591	6.6 %/4.7 %	4 %/2.8 %	2.1 %/0.6 %
Finasteride (1 mg) [58]	779/774	1.4 %/0.9 %	1.9 %/1.3 %	1 %/0.4 %
Finasteride (1 mg) [59]	133/123	0.75 %/0 %	1.5 %/1.6 %	0 %/0.8 %
Finasteride (1 mg) [60]	286/138	3.8 %/0.7 %	4.9 %/4.4 %	2.8 %/0.7 %
Finasteride [61]	1,759/583	5.6 %/2.2 %	2.9 %/1 %	2.1 %/0.5 %
Finasteride [54]	55/59	11 %/3 %	13 %/2 %	-/-
Finasteride [62]	547/558	4.8 %/1.8 %	3.8 %/2.3 %	3.1 %/1.1 %
Finasteride [23]	768/737	4.5 %/3.3 %	2.4 %/1.4 %	1.8 %/0.8 %
Finasteride [63]	1,736/579	8.1 %/3.8 %	5.4 %/3.3 %	4.0 %/0.9 %
Finasteride [64]	9,423/9,457	67.4 %/61.5 %	65.4 %/59.6 %	67.4 %/61.5 %
Finasteride [34]	1,524/1,516	5.1 %/5.1 %	2.6 %/2.6 %	0.2 %/0.1 %
Finasteride [32]	297/300	3.4 %/1.7 %	4.7 %/1.3 %	4.4 %/1.7 %
Finasteride [65]	310/303	15.8 %/6.3 %	10 %/6.3 %	7.7 %/1.7 %

5-ARIs Affect Sexual Function

- Post-finasteride syndrome
  - 11,909 men: duration of finasteride exposure was associated with persistent ED for median 1348 days[1]
- MTOPS: 2783 men completed BMSFI @1 and 4 yrs
  - Finasteride or combo → worsening of ejaculatory and sexual function[2]
- Meta-analysis: 24,463 men on 5-ARI and 22,270 on placebo
  - Mean follow up 99 weeks
  - 5-ARI use → hypoactive sexual desire [OR 1.54] and ED [OR 1.47][3]
- Meta-analysis: 11,392 5-ARI, 12,003 placebo
  - 5-ARI → decreased libido [OR 1.7], ejaculatory disorder [OR 2.94], gynecomastia (4.5% vs 2.8%)[OR 2.32], impotence [OR 1.74][4]

1 Kiguradze T et al. PeerJ 5. 2017.
2 Fwu CW et al. J Urol 191. 2014.
3 Corona G et al. Andrology 5. 2017.
4 Kim JH et al. Plos One 13. 2018.

THE JOURNAL of UROLOGY®

Cardiac Failure Associated with Medical Therapy of Benign Prostatic Hyperplasia: A Population Based Study

Vol. 205, 1-8, May 2021

Avril Lusty, D. Robert Siemens,* Mina Tohidi, Marlo Whitehead, Joan Tranmer and J. Curtis Nickel

From the Department of Urology (AL, DRS, JCN), Queen's University, Kingston, Ontario, Canada, Department of Oncology (DRS), Queen's University, Kingston, Ontario, Canada, Division of Cancer Care and Epidemiology (DRS), Queen's University Cancer Research Institute, Queen's University, Kingston, Ontario, Canada, Department of Surgery (MT), Queen's University, Kingston, Ontario, Canada, ICES-Queen's (MW, JT), Queen's University, Kingston, Ontario, Canada

- Population study in Ontario: 175,201 men >66 yrs with BPH from 2005-2015
  - Exposure to meds: none, alpha blocker (AB), 5ARI, AB+5ARI combo
  - Selective AB: silodosin, tamsulosin
  - Nonselective AB: terazosin, doxazosin, alfuzosin
- Primary outcome: new diagnosis of cardiac failure

THE JOURNAL of UROLOGY®

Cardiac Failure Associated with Medical Therapy of Benign Prostatic Hyperplasia: A Population Based Study

Table 2. *Subdistributional hazard ratios for new cardiac failure diagnosis*

	Adjusted Model		
	Rate	Hazards Ratio (95% CI)	p Value
Exposure group:			
5-ARI exposure	11.01	1.09 (1.02–1.17)	< 0.001
α-Blocker	12.08	1.22 (1.18–1.26)	
Both 5-ARI + α-blocker	11.92	1.16 (1.12–1.21)	
No medications	9.41	Reference	

- Longer AB drug exposure >420 days: ↑ risk of cardiac failure (14-16%)

- AB > AB+5ARI > 5ARI associated with new cardiac failure
- Nonselective AB higher risk than selective

Table 3. *Subdistributional hazard ratios for new cardiac failure diagnosis in men initiating medical therapy*

		Adjusted Model	
Drug Exposure	Rate	Hazard Ratio (95% CI)	p-value
5-ARI exposure	9.81	Reference	0.02
α-Blocker	10.59	1.10 (1.02–1.18)	
Both 5-ARI + α-blocker	11.27	1.05 (1.00–1.14)	
Nonselective α-blocker	12.15	1.08 (1.00–1.117)	0.04
Selective α-blocker	9.81	Reference	

Adjusted for age, dyslipidemia, atherosclerosis, hypertension, diabetes, chronic ischemic heart disease, myocardial infarction in a Cox Proportional Hazards Model. Time starts from first drug exposure.

ORIGINAL REPORT

Tamsulosin and the risk of dementia in older men with benign prostatic hyperplasia

Yinghui Duan[1,2] | James J. Grady[1,2] | Peter C. Albertsen[3] | Z. Helen Wu[2,4]

340 | Copyright © 2018 John Wiley & Sons, Ltd. wileyonlinelibrary.com/journal/pds *Pharmacoepidemiol Drug Saf.* 2018;27:340–348.

- Suppression of α1A receptors in mice brain →poor cognitive ability
- Dementia patients: decreased expression of α1A in prefrontal cortex

- Retrospective, propensity-score-matched cohort study of Medicare beneficiaries diagnosed with BPH from 2006-2012
  - ≥1 inpatient or ≥2 outpatient claims containing BPH diagnostic code
  - Cohort: use of tamsulosin (253,136 patients)
  - Comparison cohorts: other ABs (not α1A selective), 5ARIs, no meds
- Study endpoint: incident dementia

ORIGINAL REPORT

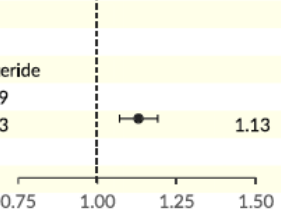
Tamsulosin and the risk of dementia in older men with benign prostatic hyperplasia

TABLE 1 Crude incidence of dementia before propensity-score matching

	Tamsulosin	No BPH- medication	Doxazosin	Terazosin	Alfuzosin	Dutasteride	Finasteride
No. of patients	253 136	180 926	28 581	23 858	17 934	34 027	38 767
No. of cases	18 199	10 135	1 525	1 470	959.0	1 791	2 474
Person-years	468 912	420 255	55 543	44 960	33 837	67 672	75 521
Incidence[a]	38.8	24.1	27.5	32.7	28.3	26.5	32.8

[a]In 1000 person-years.

Matched Cohort-pairs ‡			HR (95% CI)	*p-value*
	Tamsulosin *vs*	No BPH-medication		
No. of patients	161,729	161,729		
Person-years	301,987	380,420	1.17 (1.14 - 1.21)	*<0.001*
No. of cases	9,442	9,847		
Incidence †	31.3	25.9		
	Tamsulosin *vs*	Doxazosin		
No. of patients	28,575	28,575		
Person-years	60,451	55,530	1.20 (1.12 - 1.28)	*<0.001*
No. of cases	1,976	1,525		
Incidence †	32.7	27.5		
	Tamsulosin *vs*	Terazosin		
No. of patients	23,856	23,856		
Person-years	49,457	44,956	1.11 (1.04 - 1.19)	*0.002*
No. of cases	1,833	1,469		
Incidence †	37.1	32.7		
	Tamsulosin *vs*	Alfuzosin		
No. of patients	17,926	17,926		
Person-years	41,624	33,816	1.12 (1.03 - 1.22)	*0.010*
No. of cases	1,266	959		
Incidence †	30.4	28.4		
	Tamsulosin *vs*	Dutasteride		
No. of patients	34,009	34,009		
Person-years	76,698	67,635	1.26 (1.19 - 1.34)	*<0.001*
No. of cases	2,509	1,790		
Incidence †	32.7	26.5		
	Tamsulosin *vs*	Finasteride		
No. of patients	38,739	38,739		
Person-years	74,966	75,473	1.13 (1.07 - 1.19)	*<0.001*
No. of cases	2,764	2,473		
Incidence	36.9	32.8		



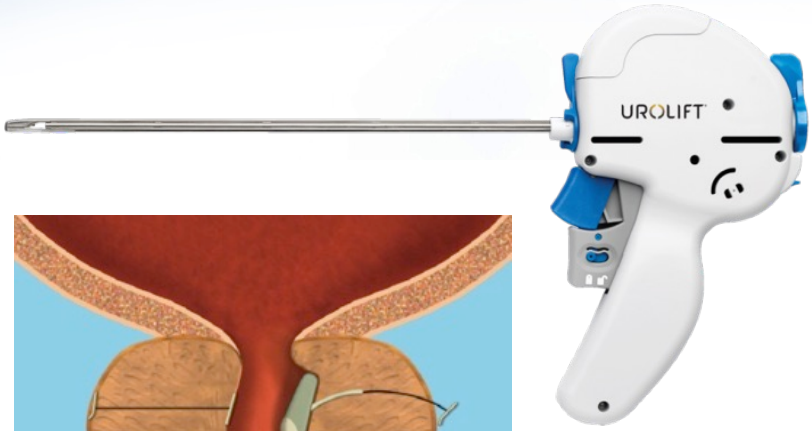
- Tamsulosin use showed increased risk of dementia compared to any other cohort of meds or no BPH meds
  - 31.3 vs 25.9 per 1000 person-yrs
  - Higher for higher dose levels

5-ARIs linked to depression

- Poland: 4,035 men with BPH: 22.4% depressed (1.6% mod/severe)
  - Associated w LUTS severity, ED, 5-ARIs, CKD, CHF[1]
- PCPT: 13,935 men over 7 yrs:
  - Finasteride→10% increased risk of new Medicare claims for depression[2]
- Ontario: 93,197 men matched cohort study
  - ↑ incident depression for 18 months after starting 5-ARI (HR 1.94, 1.73-2.16), then slightly lower to (HR 1.22, 1.08-1.37)[3]

1 Pietrzyk B et al. Int Urol Nephrol 47;3. 2015.
2 Unger J et al. J Natl Cancer Inst 108;12. 2016.
3 Welk B et al. JAMA Intern Med 177;5. 2017.

MIST procedures offer an alternative to meds



Urolift

Rezum

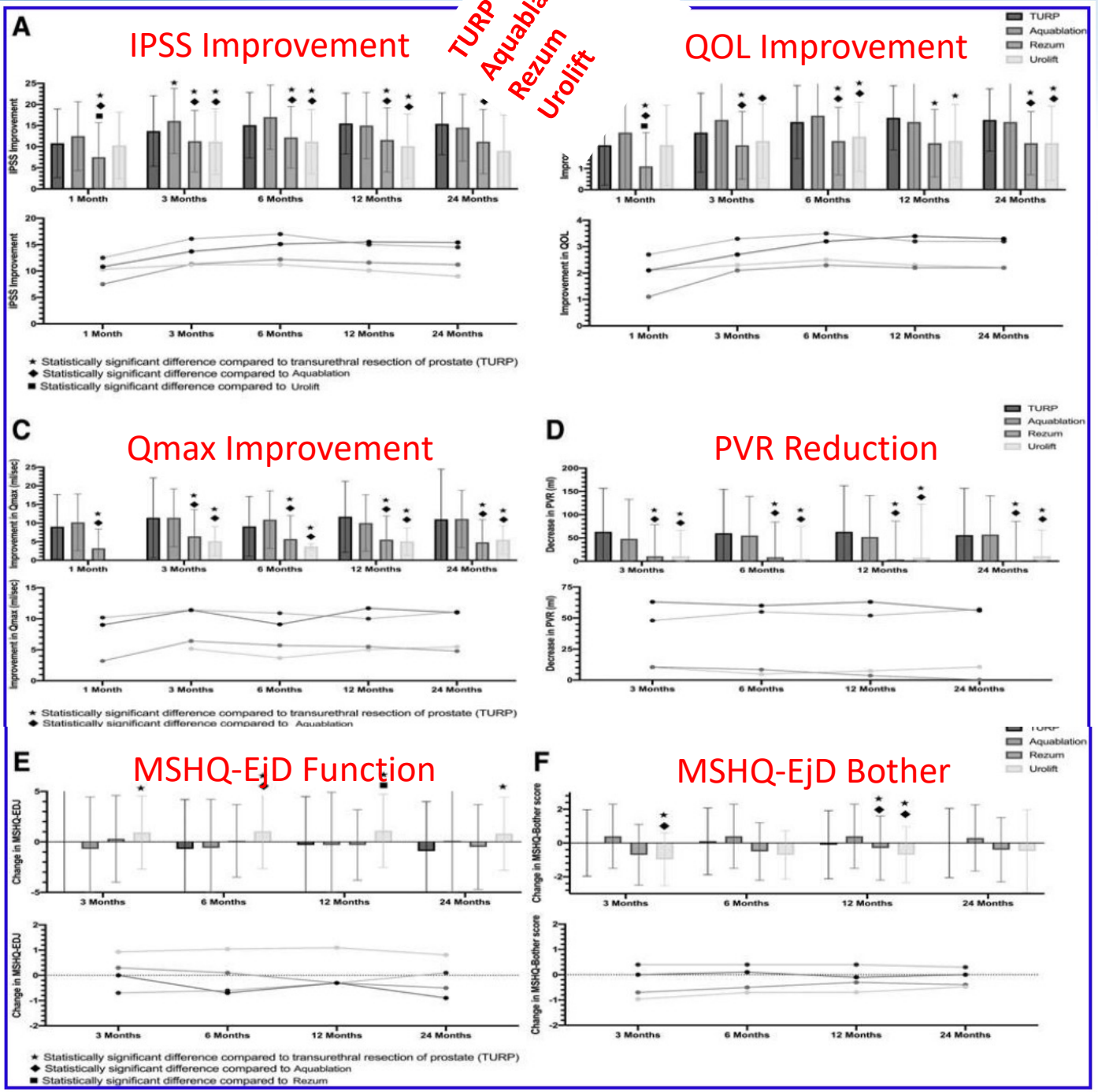
iTind

EARLY DATA

OptiLume

MIST procedures are durable for at least 3-5 years

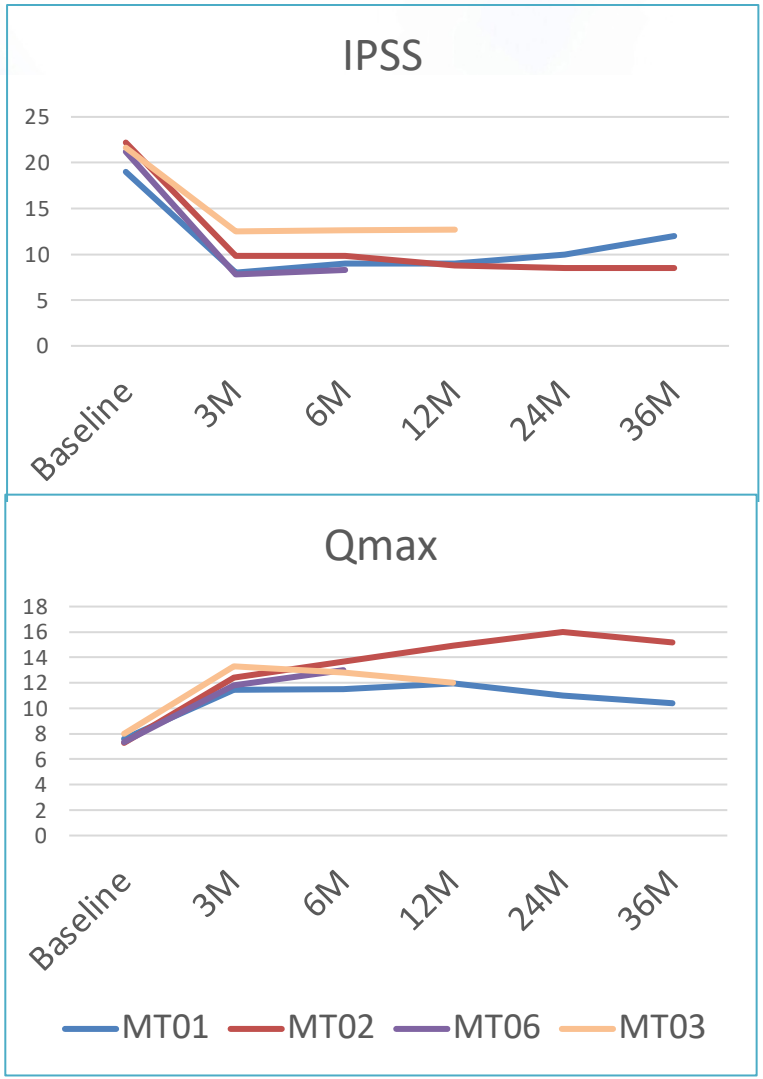
- Appropriately selected patients: prostate size and shape (ie median lobe)



Network Meta-Analysis Model of MISTs
Tanneru K et al. J Endo 35:4 (2021): 409-416.

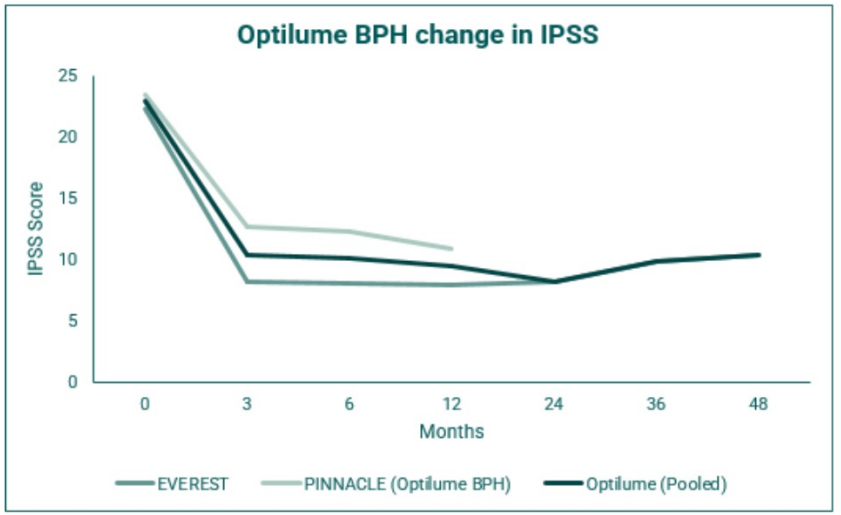
iTind and Optilume show promise

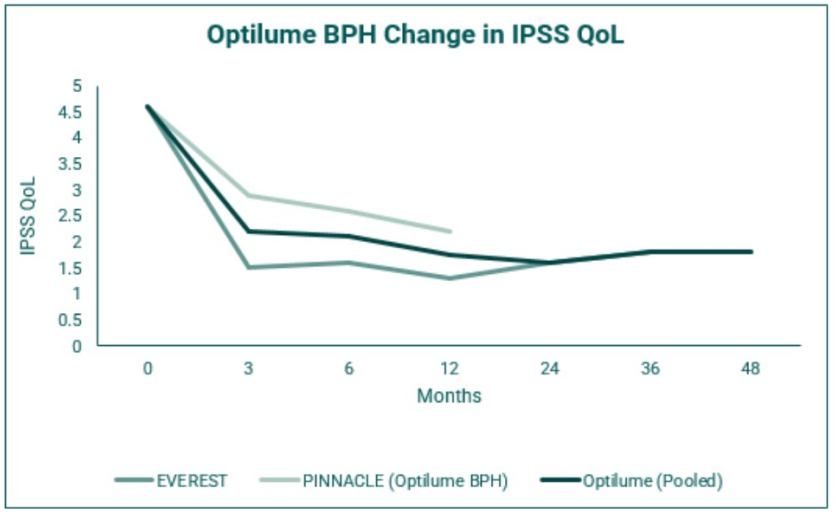
iTIND



Amparore et al. Prostate Cancer and Prostatic Diseases 24;2021.

Optilume





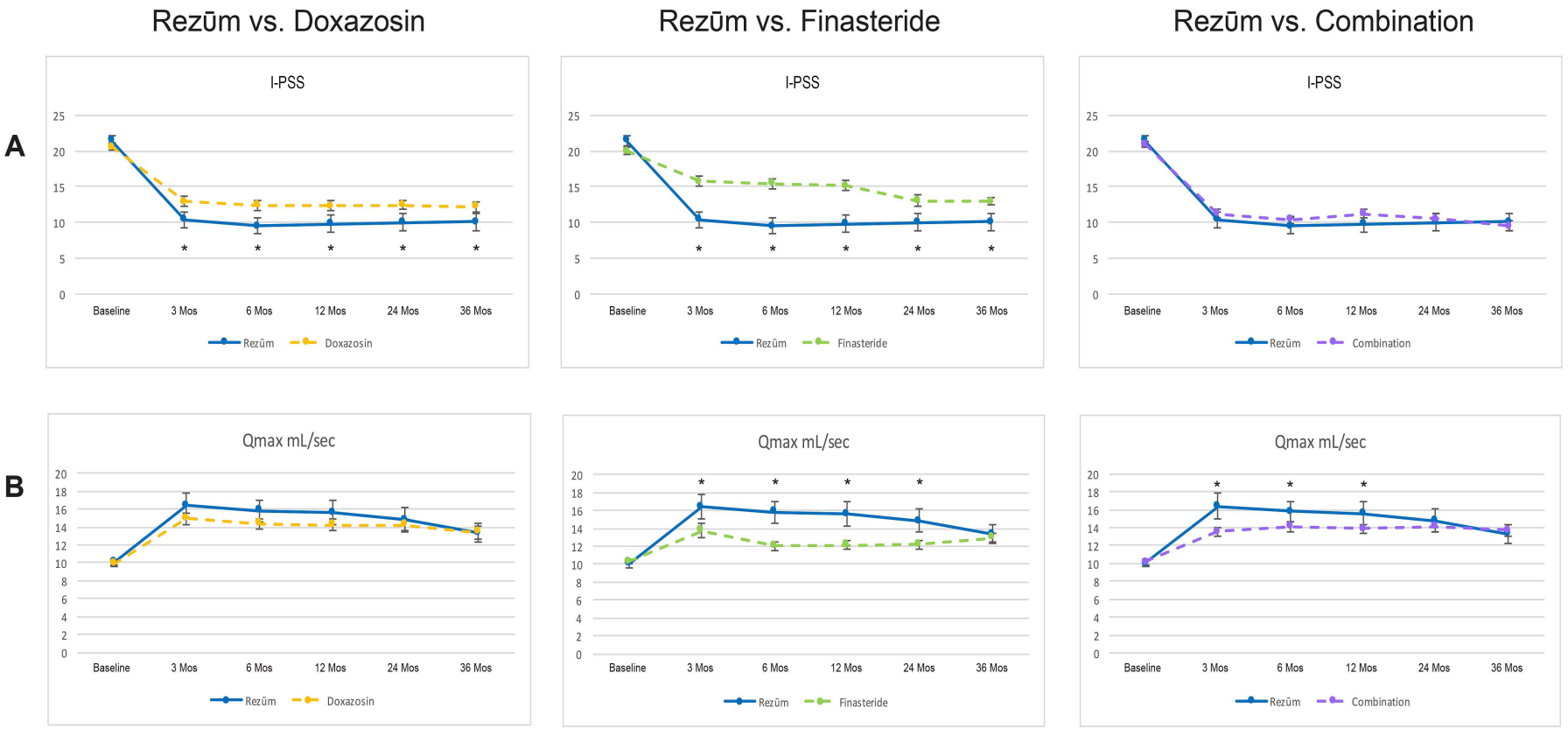
Kaplan S et al. J Urol 210;2023. Kaplan S et al. AUA 2023 MP 76-02

Three-Year Treatment Outcomes of Water Vapor Thermal Therapy Compared to Doxazosin, Finasteride and Combination Drug Therapy in Men with Benign Prostatic Hyperplasia: Cohort Data from the MTOPS Trial

Nikhil Gupta,* Tyson Rogers, Bradley Holland, Sevann Helo, Danuta Dynda and Kevin T. McVary†,‡

THE JOURNAL OF UROLOGY™ Vol. 200, 405-413, August 2018

- Single Rezum treatment similar to daily combo med therapy over 3 yrs



*p<0.05

THE JOURNAL OF
SEXUAL MEDICINE

EPIDEMIOLOGY

ORIGINAL RESEARCH

Is Sexual Function Better Preserved After Water Vapor Thermal Therapy or Medical Therapy for Lower Urinary Tract Symptoms due to Benign Prostatic Hyperplasia?

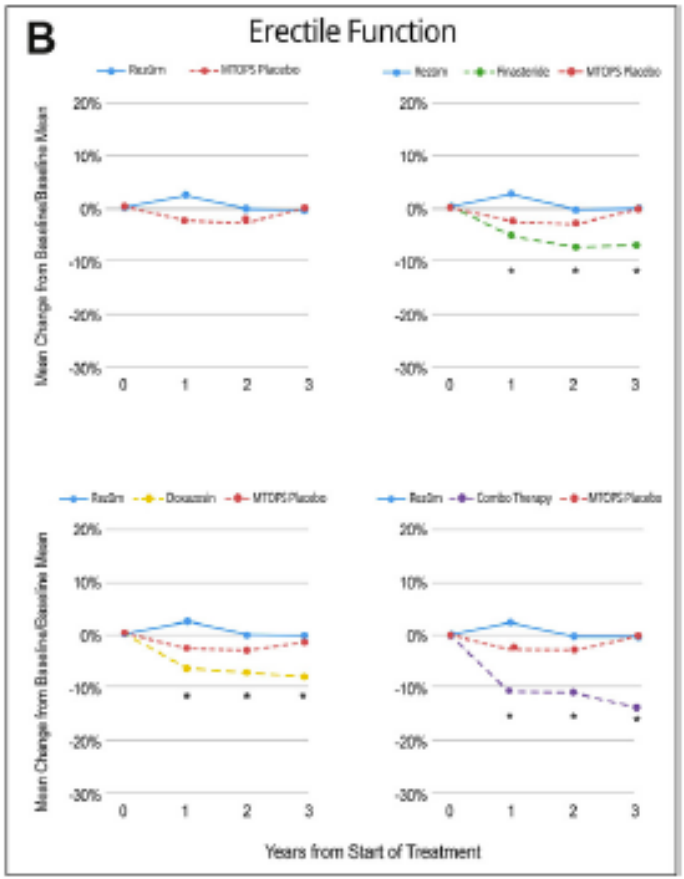
Kevin T. McVary, MD,[1] Tyson Rogers, MS,[2] Joseph Mahon, MD,[1] and Nikhil K. Gupta, MD[3]

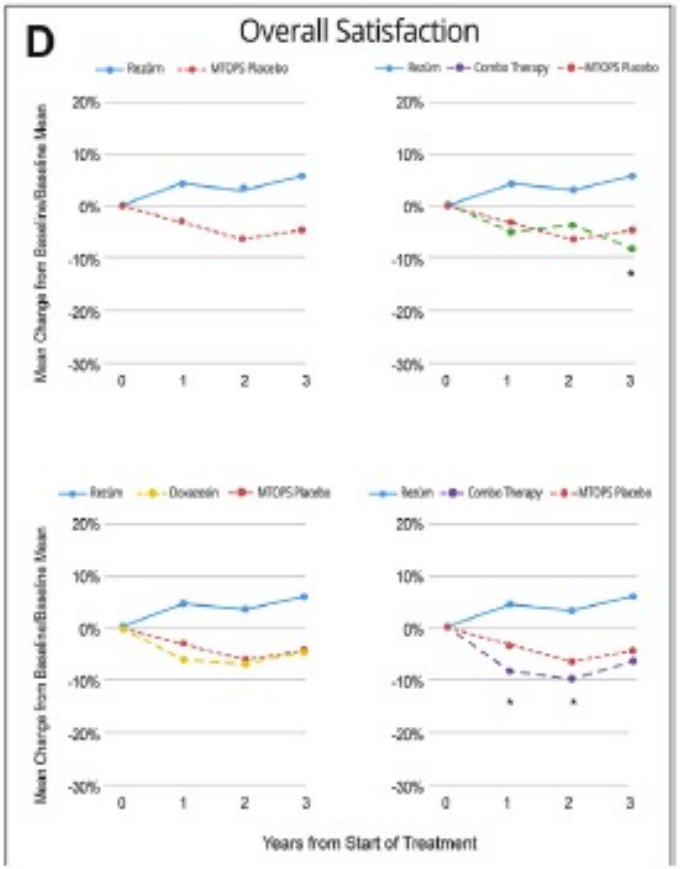
Vol. 200, 405-413, August 2018

J Sex Med 2018;15:1728–1738.

Rezum vs MTOPS

- Long-term daily meds (single or combo) led to worsening sexual function, whereas no significant changes with Rezum over 3 years

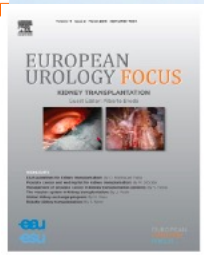




goHealth

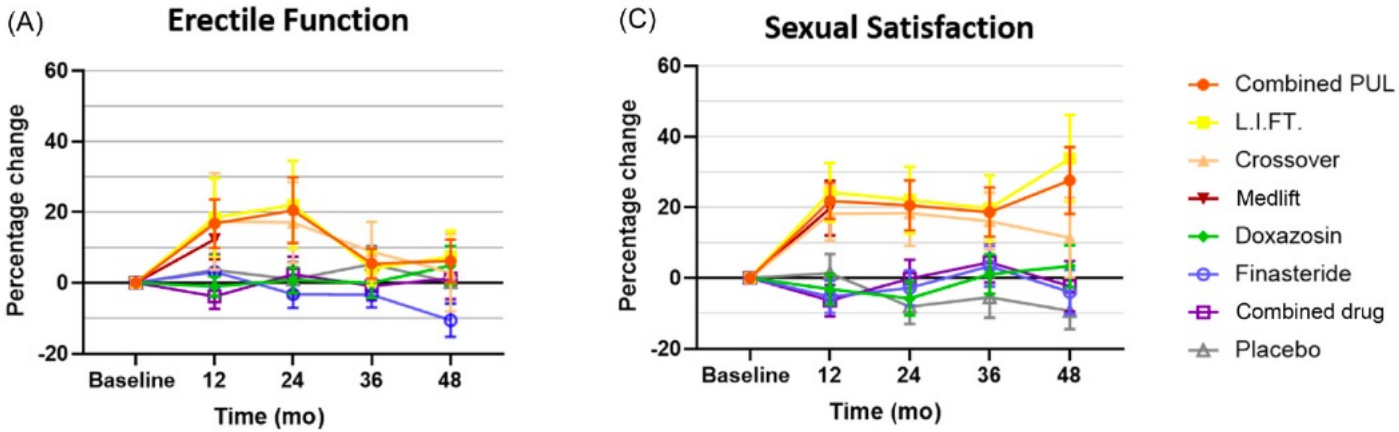
Prostatic Urethral Lift Versus Medical Therapy: Examining the Impact on Sexual Function in Men with Benign Prostatic Hyperplasia

Claus G. Roehrborn [a,*], *Daniel B. Rukstalis* [b]



Urolift (3 studies) vs MTOPS

- Long-term daily meds (single or combo) led to worsening sexual function, whereas Urolift showed no worsening changes and even short term improvement



What about cost?

Current Urology Reports (2018) 19: 72
https://doi.org/10.1007/s11934-018-0822-z

BENIGN PROSTATIC HYPERPLASIA (K MCVARY, SECTION EDITOR)

Costs of Managing Benign Prostatic Hyperplasia in the Office and Operating Room

Bradley C. Gill[1,2,3] · James C. Ulchaker[1,2]

- Simplified cost model from payer perspective (Medicare)
  - Alpha Blocker: $46-$299 per month, 5ARI: $92-$166 per month
  - Per year: $552-$3588 (monotherapy), $1656-$5580 (combo)

Intervention type	Intervention	Treatment cost (US dollars)	Equivalence time (years)
Office-based	Water vapor ablation	$1742.00	1.05
	Prostatic urethral lift	$2721.00	1.64
Outpatient	TURP	$1667.00	1.01
	Button vaporization	$2046.00	1.24
	Laser vaporization	$2127.00	1.28
Inpatient	TURP	$4367.00	2.64
	Button vaporization	$5661.00	3.42
	Laser vaporization	$6828.00	4.12
	Simple prostatectomy	$2884.00	1.74
Medication	Medical therapy (1 year)	$1656.00	1.00

Current Urology Reports (2018) 19: 72
https://doi.org/10.1007/s11934-018-0822-z

BENIGN PROSTATIC HYPERPLASIA (K MCVARY, SECTION EDITOR)

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Medication	Medical therapy (1 year)	$1656.00	1.00

ClinicoEconomics and Outcomes Research

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ORIGINAL RESEARCH

Cost-effectiveness analysis of six therapies for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia

ClinicoEconomics and Outcomes Research 2018:10 29–43

- Markov model and probabilistic sensitivity analysis
- 40 publications (2000-2017) to determine average IPSS improvement and cost effectiveness over 2 years
  - [avg treatment cost / IPSS improvement]

Simulated patients receive a therapy, follow-up and possible adverse event (AE) with re-treatment in 6-month cycles

- AEs: incontinence, new ED, stress/urge incontinence, stricture, UTI

Table 1 Estimates of effectiveness of treatment (IPSS improvements), durability of effects, and transition probabilities[a] for occurrence of early and late AEs

Number of subjects included in effectiveness and safety assessments				Change in IPSS compared with baseline[a]				Return of LUTS (% patients)	
	Baseline	Year 1	Year 2		Year 1	Year 2	Reference	Per 6-month cycle	Reference
ComboRx	2,524	2,403	1,575	ComboRx	−1.70	−6.20	22,23	0.70	23
Rezūm®	189	165	109	Rezūm	−11.65	−11.80	24–26	0.60	24–26
UroLift®	420	331	136	UroLift	−10.65	−9.47	27–33	4.92	27–29
Prostiva®	626	346	139	Prostiva	−11.24	−11.06	34–40	0.93	34,37,38,41
Greenlight® PVP	2,478	1,185	432	Greenlight PVP	−15.08	−13.62	42–50	0.93	42–46,48,49,51–54
TURP	539	429	302	TURP	−16.79	−13.06	33,35,36,44–46,49,54–58	0.31	44–46,49,58

AEs (% patients) per 6-month cycle

	Incontinence			De novo erectile dysfunction		Stricture, contracture, or stenosis			Acute urinary retention		Urinary tract infection		
Therapy	Early[b]	Late[c]	Ref.	Early	Ref.	Early	Late	Ref.	Through Year 2	Ref.	Early	Late	Ref.
ComboRx	0.07	0.02	22	5.38	59	0.01[d]	0.01[d]	NA	0.07	22	0.07	0.02	22
Rezūm	0.01[d]	0.01[d]	24–26	0.01[d]	24–26	1.13	0.42	24–26	0.27	24–26	1.99	0.43	24–26
UroLift	1.05	0.97	27–33	0.01[d]	27–33	0.01[d]	0.01[d]	33	1.31	26–33	2.17	0.64	27–33
Prostiva	0.01[d]	0.26	39	0.46	36,39	0.01[d]	0.11	36–39	0.01[d]	NA	4.77	1.59	39
Greenlight PVP	4.75	0.01[d]	42,43,45,46,52	0.01[d]	43,45,46,60	1.51	0.61	43–51,53,54	1.30	43,50,51,53,54	19.90*	1.11	44,46,50,51,53,54
TURP	2.06	0.78	50,51,54,58,61	1.05	33,46	4.66	0.62	46,49–51,54,58,61	1.76	33,50,51,54	12.23*	2.09	33,46,50,51,54,61

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ORIGINAL RESEARCH

Cost-effectiveness analysis of six therapies for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia

James C Ulchaker[1]
Melissa S Martinson[2]

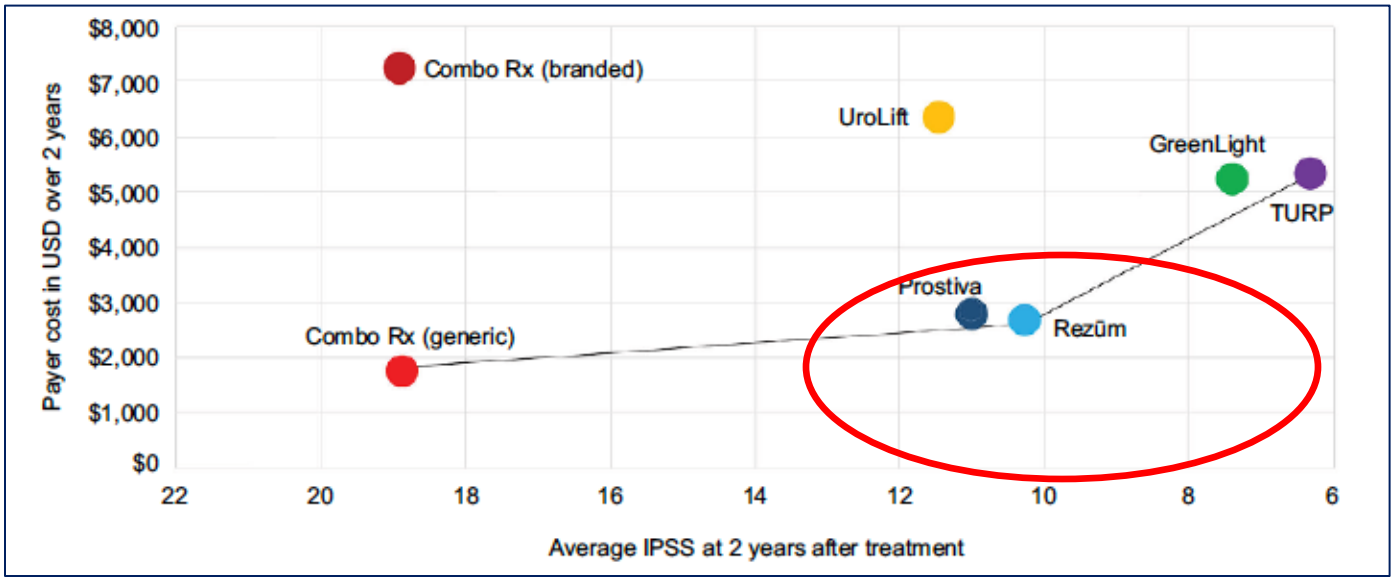
ClinicoEconomics and Outcomes Research 2018:10 29–43

Current Urology Reports (2019) 20: 29
https://doi.org/10.1007/s11934-019-0896-2
BENIGN PROSTATIC HYPERPLASIA (K MCVARY, SECTION EDITOR)

Comparing Outcomes of Medical Management and Minimally Invasive Surgical Techniques for Lower Urinary Tract Symptoms due to BPH

Joshua Sterling[1] · Nicholas Farber[1] · Nikhil K. Gupta[1]

- Combo Rx is variable in cost but least effective over 2 yrs
  - Less cost-effective due to smaller IPSS changes and prolonged use
- TURP, Greenlight more expensive due to anesthesia and postop AEs
- MISTs warrant consideration as first-line



Prostate Cancer and Prostatic Diseases
Clinical Research
Published online: 10 June 2022

Pharmacotherapy vs. minimally invasive therapies as initial therapy for moderate-to-severe benign prostatic hyperplasia: a cost-effectiveness study

Yeva Sahakyan[1], Aysegul Erman[1], Naeem Bhojani[2], Bilal Chughtai[3], Kevin C. Zorn[2], Beate Sander[1,4,5] and Dean S. Elterman[6]

- Initial WVTT is most cost-effective for moderate to severe BPH over longterm
  - Higher QALYs at lower costs
  - $5,000 savings
  - Lower costs vs PhTx over many years

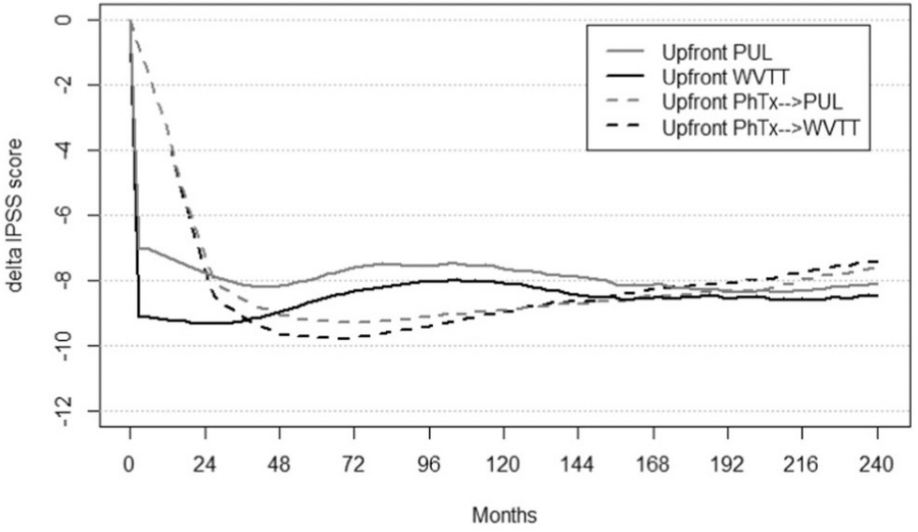


Table 2. Discounted (3%) lifetime costs (in 2020 USD) and QALYs per patient and cost-utility analysis.

Strategy	Costs	QALYs	Incremental costs	Incremental QALYs	ICUR
WVTT → repeat WVTT or PhTx or TURP → TURP	$15,461	13.05	–	–	–
PhTx → WVTT → TURP or PhTx	$20,280	12.92	$4819	−0.13	Dominated
PUL → repeat PUL or PhTx or TURP → TURP	$20,930	12.86	$650	−0.06	Dominated
PhTx → PUL → TURP or PhTx	$22,424	12.87	$1494	0.01	Dominated

There is a MIST For Everyone!

- Young
- Elderly
- Multiple comorbidities (avoid general anesthesia)
- Don’t want medications
- Interested in preserving sexual function
- ?Prophylaxis for future symptom progression

- Prostate size, shape help guide the optimal procedure
  - Ie, presence of median lobe

Summary

- Medications have side effects
  - cardiac, cognitive, psychological, sexual
  - Poor patient compliance
- MISTs are lower risk than surgery
  - Durable
  - Preserve sexual function
  - Same or greater symptom improvements than medication
- WVVT has favorable cost profiles
- One size does not fit all: need personalized approach

Thank you!

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Benign Prostatic Diseases

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