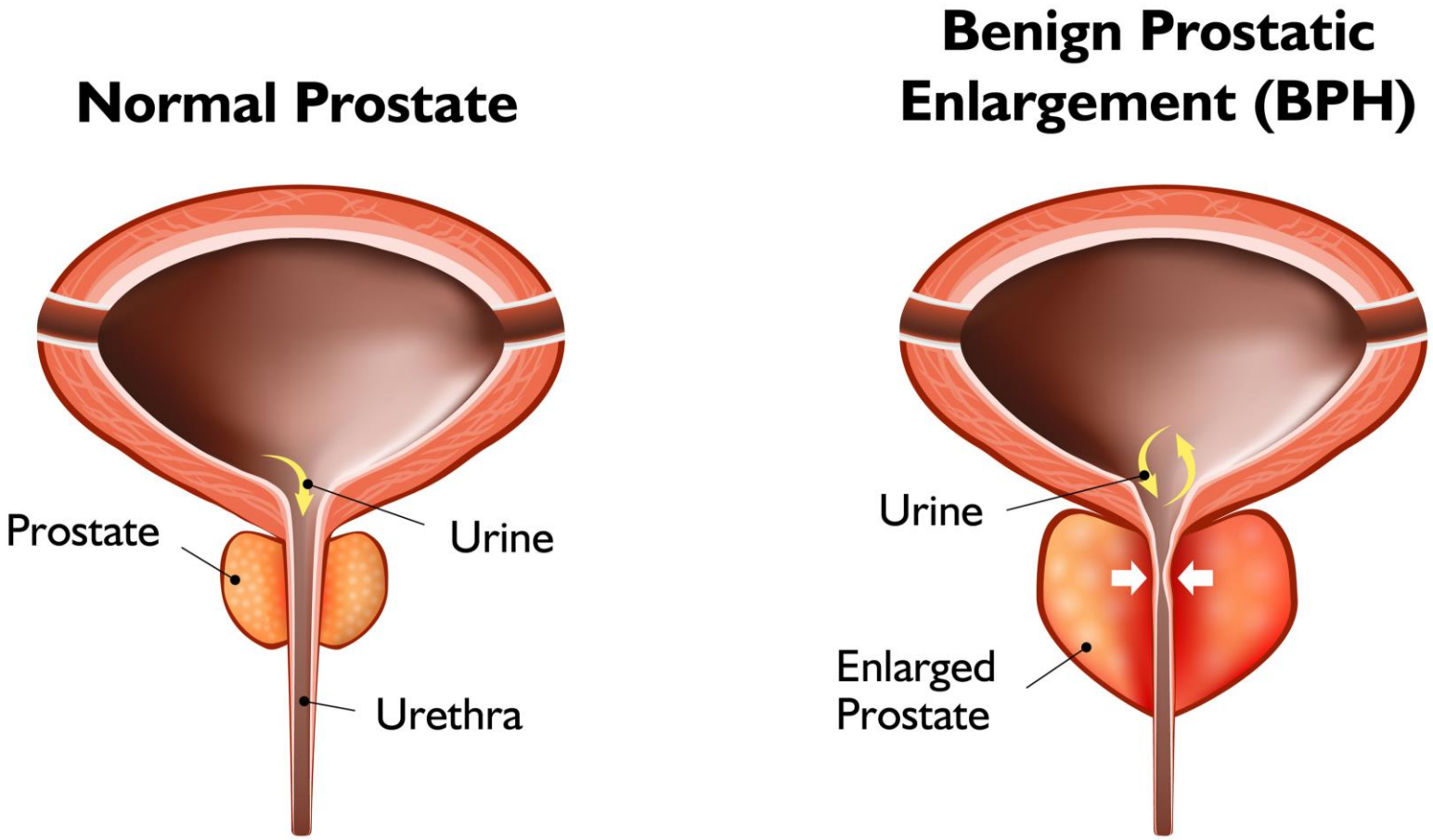
Benign Prostatic Hyperplasia

2021 NWOOA CONFERENCE
DR SALVADOR PERON
NOVEMBER 13TH, 2021

Prostate Anatomy



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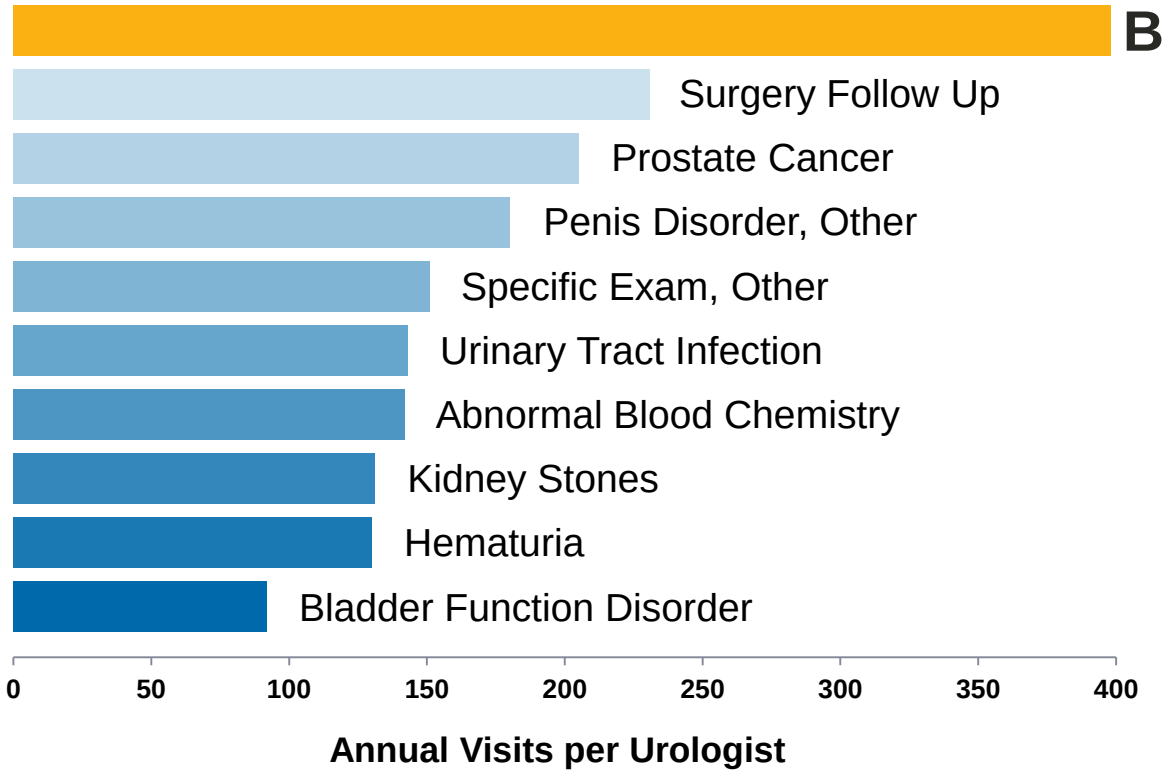
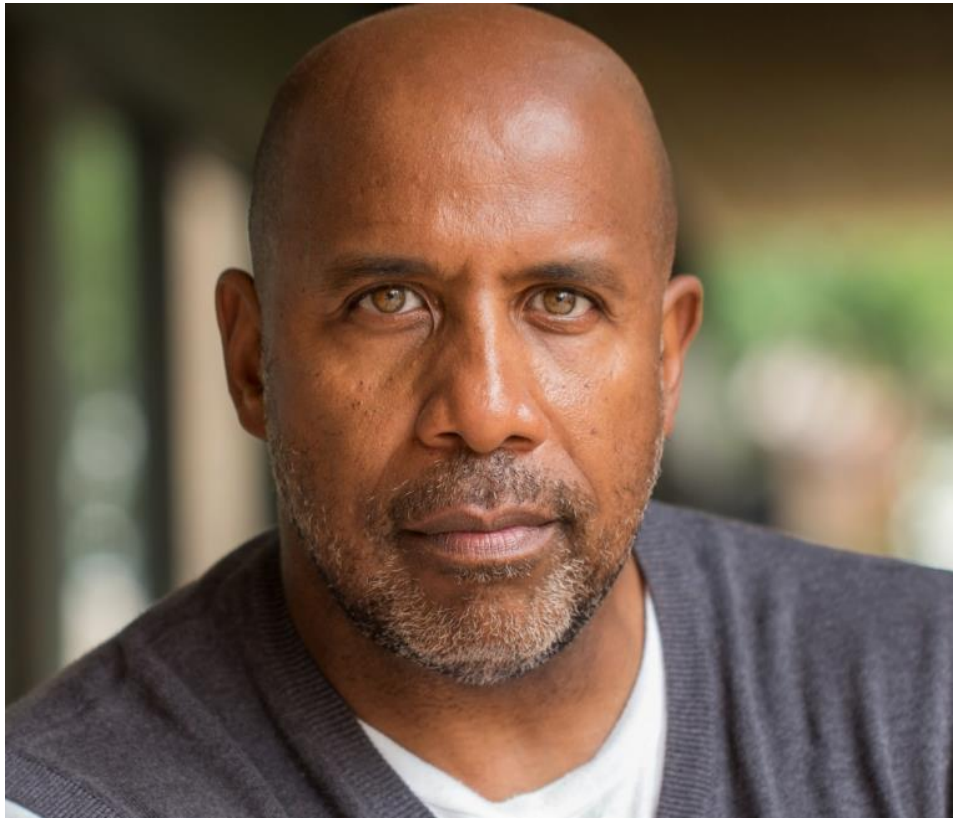
The Current State of Urology

Top 10 Reasons for Visits to Urologists[1]

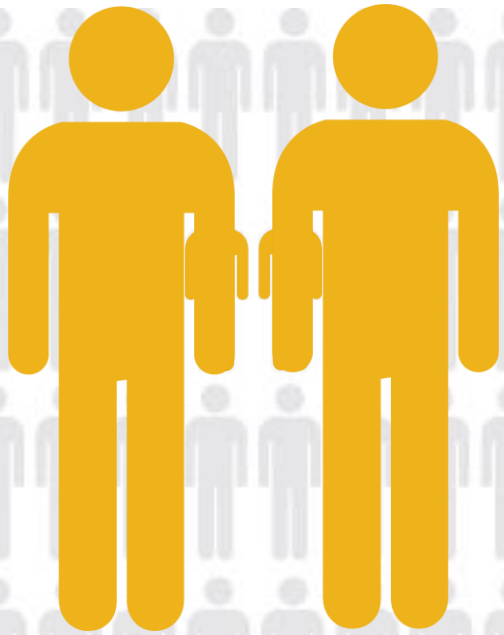




1. IMS Health NDTI Urology Specialty Profile, July 2012 - June 2013

BPH Can Be Frustrating for Both Urologists and Patients

2%[1]



1. 2% of men get an advanced BPH procedure. Data on file. NeoTract US Market Model estimates for 2019 based on IQVIA Health Drug and Procedure data.

Patient Populations

Watchful Waiting

34%

4.3 Million
Patients

Medical Therapy

64%

7.9 Million
Patients

Surgery/Procedure

2%

248,000
Patients

Each year, **26%** of BPH drug patients discontinue taking medication and are managed with watchful waiting
(inadequate relief, side effects, etc.)

NeoTract US Market Model estimates for 2020 based on IQVIA Health Drug and Procedure data

THE BPH PARADIGM

2018 Patient Population Breakdown

40.9 Million
Men with BPH Pathology[1] (Age ≥ 30)

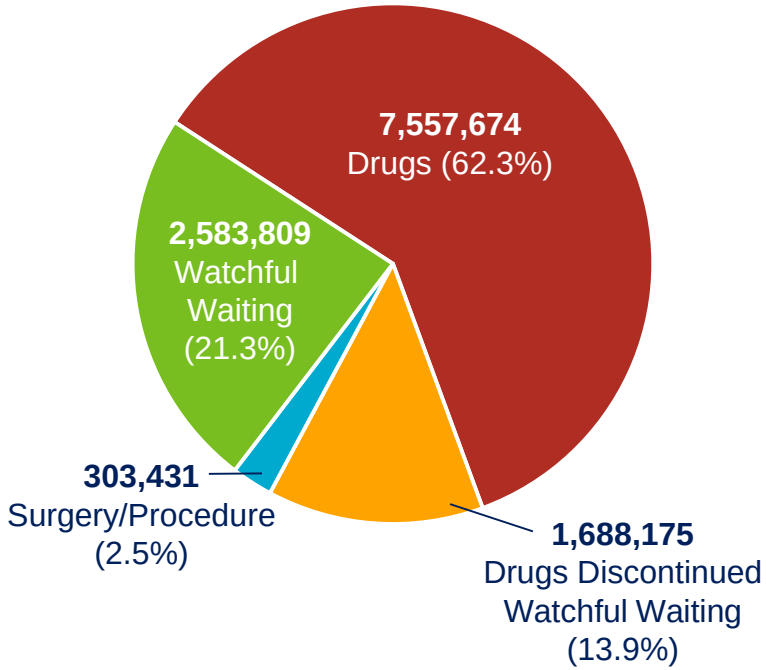
22.4 Million
with IPSS > 7 (Age 40-79)[2]

13.8 Million
that have Consulted Physician for BPH[3]

12.1 Million
Actively Managed for BPH/LUTS[4]

Therapy Breakdown

12.1 Million
patients actively managed each year



1 Based on Berry, et al., J Urol 1984; 132: 474-479 and US Census population estimates; 2 Based on Wei, et al., Urologic Diseases in America, NIH publication 07-5512: 43-67 and US Census population estimates; 3 IMS Health data and Based on Roehrborn, Prostate Cancer and Prost Dis 2006; 9: 30-34 and US Census population estimates; 4 U.S. Market Model 2016-18 for Investors

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Many Men Who See a Urologist...

- Experience LUTS secondary to BPH[1]
- Do not proactively seek care[2]
- Are not compliant on medication[3]
- Will not elect surgery such as TURP, PVP, etc.[4]

Undertreatment

1. Madersbacher S, Sampson N, Culig Z: Pathophysiology of Benign Prostatic Hyperplasia and Benign Prostatic Enlargement: A Mini-Review. Gerontology 2019;65:458-464. doi: 10.1159/000496289; 2. Cindolo et al. BMC Urology 2015; 3. Gannon K, Glover L, O'Neill M, Emberton M. Men and chronic illness: a qualitative study of LUTS. J Health Psychol. 2004 May;9(3):411-20. doi: 10.1177/1359105304042350. PMID: 15117540.; 4. NeoTract US Market Model estimates for 2020 based on IQVIA data, data on file

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Common Side Effects of BPH Drugs

	Long-Known Potential Side Effects[1]	Recently Discovered Potential Side Effects
ALPHA Blockers 	• Lightheadedness • Headaches • Fatigue • Ejaculatory dysfunction • Insomnia • Nasal congestion	• Intraoperative floppy iris syndrome first described 8 years after tamsulosin introduction[2] • Increased risk of stroke[3] • Increased risk of dementia[4]
5-ARI 	• Diminished ejaculate • Erectile dysfunction • Decreased libido • Gynecomastia	• Depression and self-harm[5] • Increased risk of metabolic syndromes[6,7] • Increased risk of dementia[8] • PFS (Post-Finasteride Syndrome)[9]

1. AUA Guideline, 2003, 2010, 2. Chang DF, Campbell JR, J Cataract Refract Surg. 2005 Apr; 31(4): 664-673, 3. Lai et al, CMAJ. 2016 Mar 01; 188(4): 255-260, 4. Duan et al, Pharmacoepidemiol Drug Saf. 2018 Mar; 27(3): 340-348, 5. Welk et al, JAMA Intern Med. 2017 May 1; 177(5): 683-691, 6. Traish et al, Horm Mol Biol Clin Investig. 2017 Jun 21; 30(3): 1-16, 7. Wei et al, BMJ. 2019 Apr 10; 365:I12049 8. Welk et al, J Neurol Sci. 2017 Aug 15; 379: 109-111, 9. S. Diviccaro, et al. Neurobiology of Stress 12 2020

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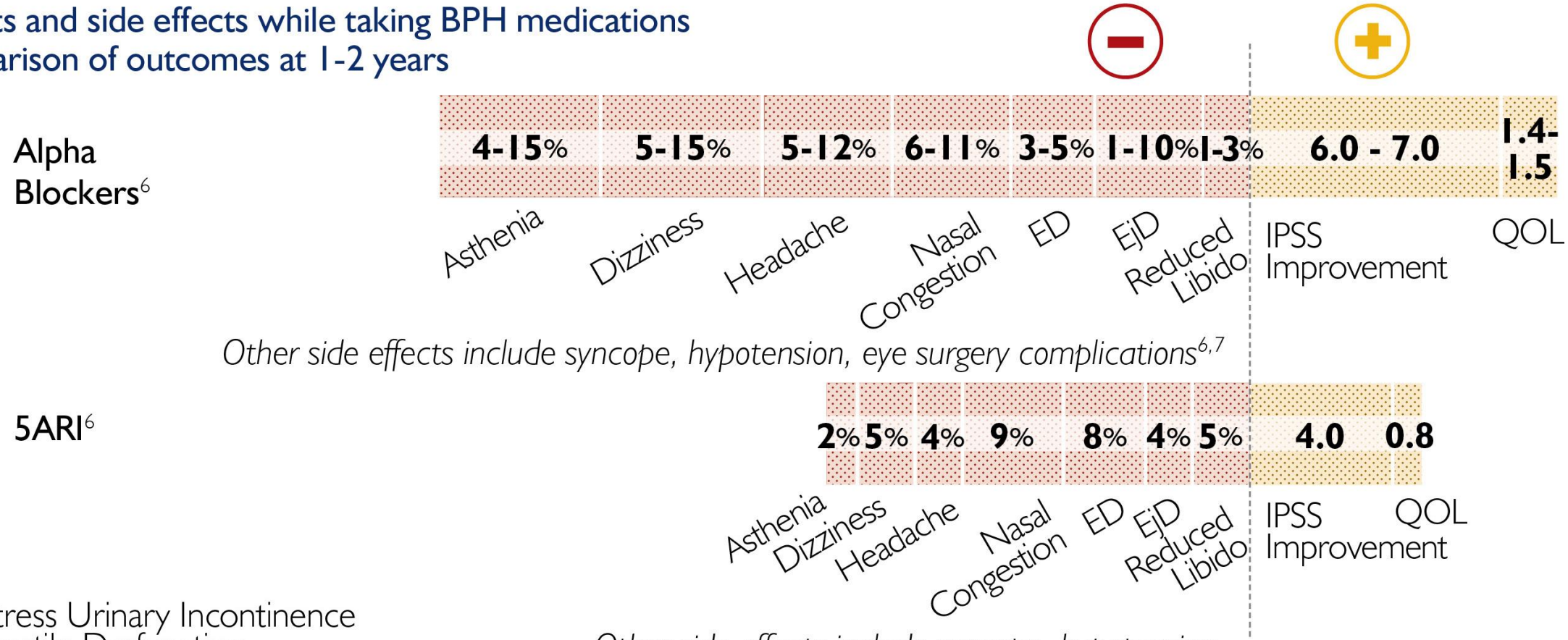
Patients Have Faced Hard Choices…Until Now

Benefits and side effects while taking BPH medications
Comparison of outcomes at 1-2 years



SUI – Stress Urinary Incontinence
ED – Erectile Dysfunction
EjD – Ejaculatory Dysfunction

1. Roehrborn, J Urol 2013; There was no occurrence of new onset, sustained erectile or ejaculatory function in the L.I.F.T. study. Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate and resolved within two to four weeks after the procedure. 2. Roehrborn, Urol Practice 2015 3. Sonksen, Eur Urol 2015 4. Montorsi, J Urol 2008 5. Naspro, Eur Urol 2009 6. AUA BPH Guidelines 2003, 2010 7. Jan Teper, Cent Eur J Urol 2011 8. Traish, J Sex Med 2011

Marginal Improvement with Drug Therapy for BPH

MTOPS (Medical Therapy of Prostatic Symptoms) Study

3,047 patients ≥ 50 years old with average follow-up of 4.5 years,
double-blind, placebo-controlled, randomized, multicenter (17) study


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 18, 2003 VOL. 349 NO. 25

The Long-Term Effect of Doxazosin, Finasteride, and Combination Therapy on the Clinical Progression of Benign Prostatic Hyperplasia

Independently conducted by the US National Institutes of Health (NIH) to determine whether long-term medical therapy with finasteride, the alpha-blocker doxazosin, or their combination would prevent or delay the clinical progression of BPH

Median Change in AUA Symptom Score* at 4 Years

Placebo	Doxazosin	Finasteride	Combination Therapy
-4.0	-6.0	-5.0	-7.0

*AUA Symptom Scores can range from 0 (no symptoms) to 35 (severe symptoms)

McConnell et.al N Engl J Med 2003

Watchful Waiting is Not Without Consequences

The VA Study

556 patients evaluated up to 60 months after randomization between watchful waiting and TURP

Original Articles

5-YEAR OUTCOME OF SURGICAL RESECTION AND WATCHFUL WAITING FOR MEN WITH MODERATELY SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA: A DEPARTMENT OF VETERANS AFFAIRS COOPERATIVE STUDY

ROBERT C. FLANIGAN, DOMENIC J. REDA, JOHN H. WASSON,* ROBERT J. ANDERSON, MAZEN ABDELLATIF AND REGINALD C. BRUSKEWITZ

ABSTRACT

Purpose: We determine outcomes after 5 years of followup for men who were randomized to receive transurethral resection or watchful waiting for moderate symptoms of benign prostatic hyperplasia.

Materials and Methods: A total of 556 patients were evaluated up to 60 months after randomization providing 966 patient-years of followup for transurethral prostatic resection and 960 for watchful waiting. Patients randomized to watchful waiting were evaluated according to whether they remained on treatment or crossed over to surgery. Outcomes included treatment failure, a genitourinary symptom score, peak flow rate, post-void residual urine volume and the degree of bother from genitourinary symptoms.

Results: All outcomes were significantly better for transurethral prostatic resection than for watchful waiting. Treatment failure rates were 10% for transurethral prostatic resection versus 21% for watchful waiting ($p = 0.0004$). The crossover rate at 5 years was 36% and was positively associated with the degree of bother. Men with low pretreatment peak flow rates who were randomized to transurethral prostatic resection had 85% greater improvement in peak flow rate than comparable men who were randomized to watchful waiting and eventually crossed over to resection. However, after crossover, bother from genitourinary symptoms was similar to that of the resection group.

Conclusions: For men with moderate symptoms of benign prostatic hyperplasia transurethral prostatic resection has more favorable outcomes up to 5 years of followup compared to watchful waiting. While many men do well on watchful waiting, those who undergo transurethral prostatic resection after a trial of watchful waiting have less improvement in measures of bladder function than men randomized to resection, although there is no difference in serious adverse outcomes or bother from genitourinary symptoms.

KEY WORDS: prostatic hypertrophy, treatment outcome

Between 1986 and 1992 investigators at 9 Veterans Affairs Hospitals conducted a multicenter trial comparing watchful waiting to transurethral resection of the prostate in men with moderate symptoms of benign prostatic hyperplasia (BPH).[1] Results reported after 3 years of followup demonstrated that men assigned to transurethral prostatic resection experienced significantly fewer treatment failures, less bother from genitourinary symptoms and better improvement in activities of daily living than the watchful waiting group. Surgery did not cause impotence or incontinence. Overall 90% of patients treated with resection improved compared to 39% of the watchful waiting group. Men achieving the greatest benefit from transurethral prostatic resection were those who were most bothered initially. However, the symptoms of many watchful waiting patients with moderate symptoms stabilized or regressed without treatment. We examine the outcomes of transurethral prostatic resection and watchful waiting for up to 5 years after randomization to explore whether the previously reported patterns through 3 years continue during a longer followup.

MATERIALS AND METHODS

Patients and measurements. From July 1986 to July 1989 consecutive men referred to 9 Veterans Affairs urology clinics because of symptoms of BPH who had no contraindication to surgery were asked to participate in a trial of transurethral prostatic resection compared to watchful waiting. A total of 280 moderately symptomatic men were randomized to transurethral prostatic resection and 276 to watchful waiting after stratification according to participating hospital and severity

5-Year Outcome of Surgical Resection and Watchful Waiting for Men with Moderately Symptomatic Benign Prostatic Hyperplasia: A Department of Veterans Affairs Cooperative Study

"…for some men delay of transurethral prostatic resection may have some deleterious effects on symptom resolution, peak flow rates and residual urinary volume.[1]"

1. Flannigan, et al. J Urol 1998

New Study Shows Medications for Enlarged Prostate Are Linked to Heart Failure Risk

10-year retrospective population-based study
conducted in Ontario, Canada with 175,201 men with BPH

Men treated with 5-alpha reductase inhibitor and a-blocker, alone or in combination, ***had a statistically increased risk of being diagnosed with cardiac failure compared to no medication use****."*

Cardiac failure risk was:

- Highest for **a-blockers alone**
- Intermediate for **combination a-blockers/5-alpha reductase inhibitors**
- Lowest for **5-alpha reductase inhibitors alone**

Nonselective a-blocker had a higher risk of cardiac failure than selective a-blockers.


ARTICLE IN PRESS

THE JOURNAL of UROLOGY

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

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

Abbreviations and Acronyms

Key Words: prostatic hyperplasia, heart failure, 5-alpha reductase inhibitors, adrenergic alpha-antagonists, lower urinary tract symptoms

Lusty et al. (2020). Cardiac Failure Associated with Medical Therapy of Benign Prostatic Hyperplasia: A Population Based Study. The Journal of Urology.

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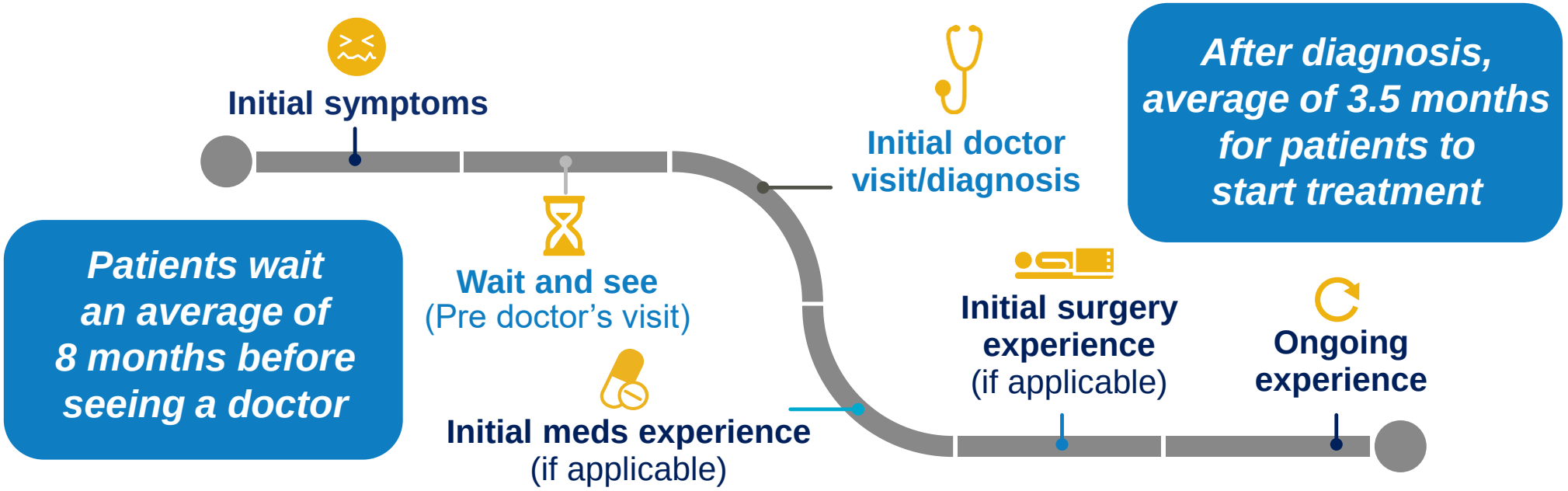
BPH Patient Journey Research Shows Patients Wait an Average of 8 Months Before a Doctor Visit

Blinded research with 250 patients; conducted in-depth interviews and online surveys.



Available resources

Patient education materials, co-marketing opportunities

There is a critical need to educate patients and raise awareness on bladder health and BPH

Primary market research with patients in the US conducted by Lieberman Research Worldwide, February 10-27, 2021, n=250

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Research Identifies Symptom Impact as the Biggest Driver of Action by Patients

Urinary frequency

Urinary urgency

Most common bothersome BPH symptoms experienced by patients

Patient consults their doctor

If treatment prescribed by doctor doesn't work, **patients lose trust.**

Nearly ¼ of men surveyed* who take medication to treat their BPH symptoms are unsatisfied with the effectiveness of their medication

*Content based on survey of 1,000 US men and 1,000 US women conducted by Teleflex l NeoTract in 2020. Sample size may vary depending on qualifying questions.
Primary market research with patients in the US conducted by Lieberman Research Worldwide, February 10-27, 2021, n=250

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Men are Bothered by LUTS, Even When on Rx Therapy

1 in 3

men are satisfied with the

65%

of men age > 50 seeing a urologist are interested in an alternative to medication for BPH[1]

82% OF MEN

over 50 wake up at least 1x per night to urinate on a regular basis

Content based on a survey of 2,000 US men and women conducted by NeoTract in 2017

1. Prostate Research Study, Harris Interactive Group 2007

Annual 2021 Men's Health Survey Suggests Men With Urinary Symptoms Often Anticipate Bathroom Needs and Avoid Events/Activities They Enjoy

Infographics Available for Download
Patient Education Portal

*Content based on survey of approximately 1,000 US men, aged 45+, who have experienced at least one urinary symptom commonly associated with an enlarged prostate (also known as benign prostatic hyperplasia or BPH) conducted by NeoTract | Teleflex in 2021. Urinary symptoms may have multiple causes and should only be diagnosed by a doctor. Sample sizes in this survey may vary depending on qualifying questions.

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Research Highlights the Need to Proactively Communicate Expectations and Share a Plan With Patients

Four topics to proactively discuss with your BPH patients:

Bladder health

IPSS scores

Diagnostic exams
Ex. Cystoscopy

Treatment options

Primary market research with patients in the US conducted by Lieberman Research Worldwide, February 10-27, 2021, n=250

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AUA Guidelines

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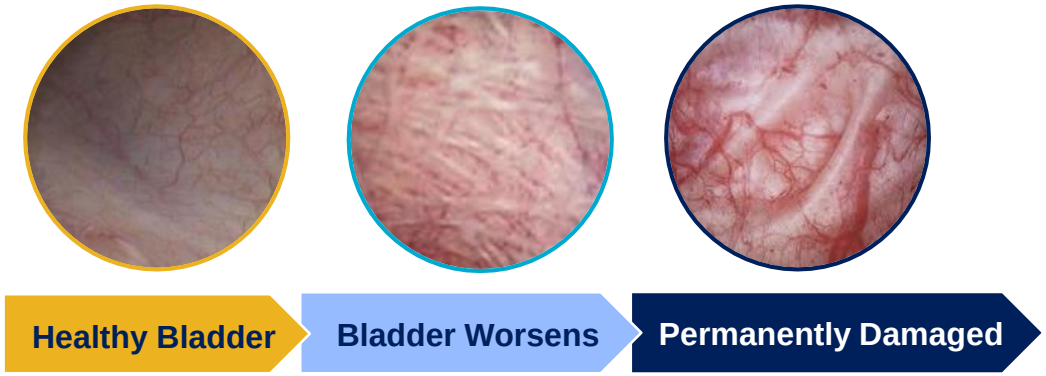
AUA BPH Guidelines Recognize the Need for Intervention

From healthy bladder to permanent damage



> ***"Since many men discontinue medical therapy, yet proportionately few seek surgery, there is a large clinical need for an effective treatment that is less invasive than surgery.*** *With this treatment class, perhaps a significant portion of men with BOO who have stopped medical therapy can be treated prior to impending bladder dysfunction."*

American Urological Association

AUA Guidelines Emphasize the Value of Cystoscopy

"…the approach to the **differential diagnosis and the differentiated treatment of male LUTS/BPH has become substantially more sophisticated with prostate size and morphology** playing an important role in the decision-making process."

"The importance of prostate imaging and, specifically, the presence of an intravesical or obstructing lobe in determining natural history and treatment responses are of great clinical importance to make the best therapeutic decisions…**Clinicians should consider assessment of prostate size and shape via abdominal or transrectal ultrasound, or cystoscopy…prior to surgical intervention for LUTS attributed to BPH."**

AUA Guidelines 2020

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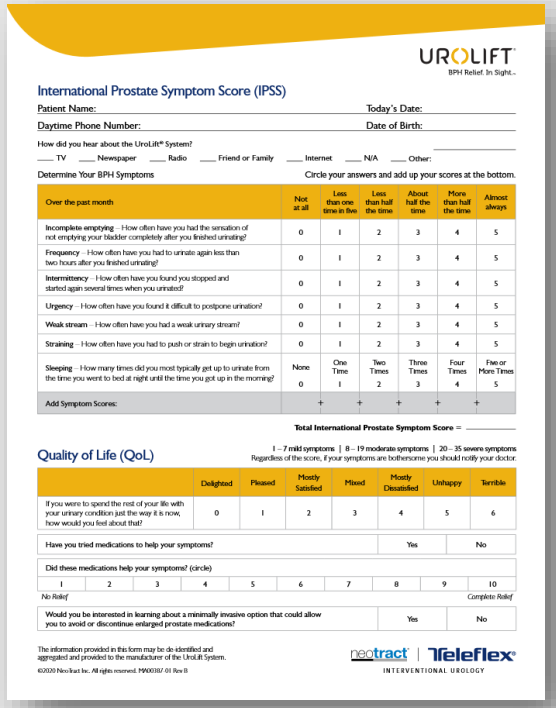
IPSS Is Recommended by the AUA Guidelines for Initial Evaluation of Patients and as a Tool for Shared Decision-Making

"In the initial evaluation of patients presenting with bothersome LUTS possibly attributed to BPH, clinicians should take a medical history, conduct a physical examination, ***utilize the AUA Symptom Index (AUA-SI),*** *and perform a urinalysis. (Clinical Principle)*

The AUA-SI, a validated self-administered questionnaire, can ***provide clinicians with information regarding the symptom burden patients are experiencing…***

… *Following initial evaluation,* ***clinicians and patients should utilize a shared decision-making approach to determine the need for and type of therapy****. This decision will guide the need for further evaluation should the patient desire treatment."*



UROLIFT
BPH Relief In Sight.

International Prostate Symptom Score (IPSS)

Patient Name: Today's Date:

Daytime Phone Number: Date of Birth:

How did you hear about the UroLift® System?

___ TV ___ Newspaper ___ Radio ___ Friend or Family ___ Internet ___ N/A ___ Other:

Determine Your BPH Symptoms — Circle your answers and add up your scores at the bottom.

Over the past month	Not at all	Less than one time in five	Less than half the time	About half the time	More than half the time	Almost always
Incomplete emptying – How often have you had the sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
Frequency – How often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
Intermittency – How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
Urgency – How often have you found it difficult to postpone urination?	0	1	2	3	4	5
Weak stream – How often have you had a weak urinary stream?	0	1	2	3	4	5
Straining – How often have you had to push or strain to begin urination?	0	1	2	3	4	5
Sleeping – How many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	None 0	One Time 1	Two Times 2	Three Times 3	Four Times 4	Five or More Times 5
Add Symptom Scores:		+	+	+	+	+

Total International Prostate Symptom Score = _____

Quality of Life (QoL)

1 – 7 mild symptoms | 8 – 19 moderate symptoms | 20 – 35 severe symptoms
Regardless of the score, if your symptoms are bothersome you should notify your doctor.

	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6

Have you tried medications to help your symptoms?	Yes	No

Did these medications help your symptoms? (circle)

1	2	3	4	5	6	7	8	9	10
No Relief									*Complete Relief*

Would you be interested in learning about a minimally invasive option that could allow you to avoid or discontinue enlarged prostate medications?	Yes	No

The information provided in this form may be de-identified and aggregated and provided to the manufacturer of the UroLift System.

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Cystoscopy/TRUS Now Recommended

2003, 2010 Guidelines

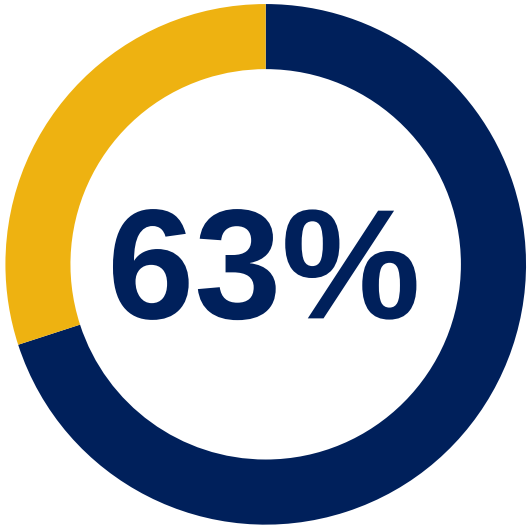
Endoscopy of Lower Urinary Tract

Endoscopic evaluation of the lower urinary tract is not recommended in an otherwise healthy patient with an initial evaluation consistent with BOO, although it has certain indications as previously described for imaging. There are treatment alternatives in which success or failure depends on the anatomical

2018 Guidelines

Clinicians **should consider assessment of prostate size and shape via abdominal or transrectal ultrasound, or cystoscopy**, or by preexisting cross-sectional imaging (i.e. magnetic resonance imaging [MRI]/ computed tomography [CT]) prior to surgical intervention for LUTS attributed to BPH. (Clinical Principle)

Majority of Men Are Unaware of Cystoscopy; Several Patient Education Tools Available



of men surveyed had never heard of cystoscopy[6]

Cystoscopy Patient Education Materials:

- ✓ Bladder Health and Cystoscopy Patient Education Flyer
- ✓ Before-and-After Educational Aid for Cystoscopy Suite
- ✓ Meet Mike Video

Source: NeoTract online study of patient awareness and attitudes in May 2020, N=500; men age 50+ with BPH symptoms; either watchful waiting or on BPH medication; no prior BPH surgery/procedure

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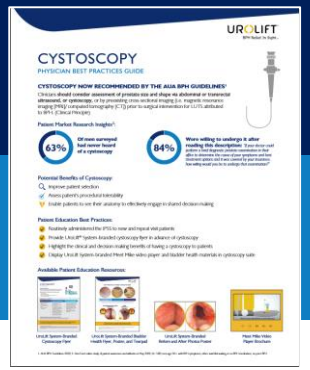
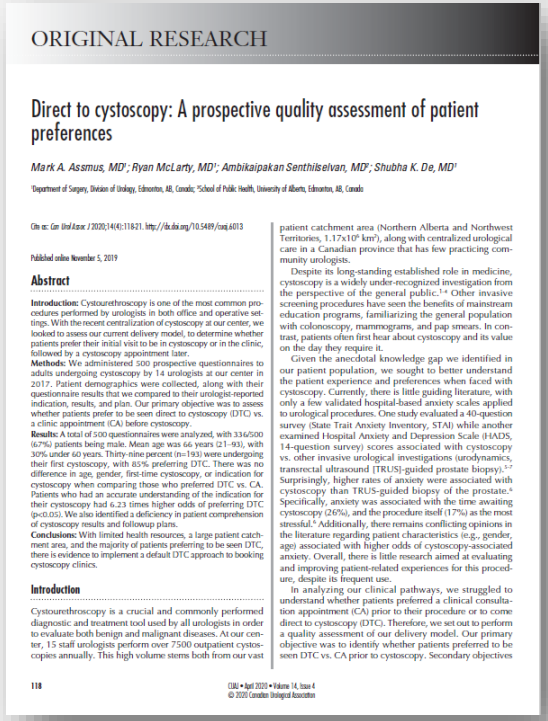
Study Shows Direct-to-Cystoscopy Appointments Are Acceptable to Patients

- **“85% of patients** who responded to the question of whether they would prefer a direct-to-cystoscopy approach vs. a clinic appointment before cystoscopy **said they would prefer the direct-to-cystoscopy approach.”**
- **Effective patient education** may help reduce anxiety and improve experience.

Available resource:
Cystoscopy Patient Education Toolkit




ORIGINAL RESEARCH

Direct to cystoscopy: A prospective quality assessment of patient preferences

Mark A. Assmus, MD[1]; Ryan McLarty, MD[1]; Ambikaipakan Senthilselvan, MD[2]; Shubha K. De, MD[1]

[1]Department of Surgery, Division of Urology, Edmonton, AB, Canada; [2]School of Public Health, University of Alberta, Edmonton, AB, Canada

Cite as: *Can Urol Assoc J* 2020;14(4):118-21. http://dx.doi.org/10.5489/cuaj.6013

Published online November 5, 2019

Abstract

Introduction: Cystourethroscopy is one of the most common procedures performed by urologists in both office and operative settings. With the recent centralization of cystoscopy at our center, we looked to assess our current delivery model, to determine whether patients prefer their initial visit to be in cystoscopy or in the clinic, followed by a cystoscopy appointment later.

Methods: We administered 500 prospective questionnaires to adults undergoing cystoscopy by 14 urologists at our center in 2017. Patient demographics were collected, along with their questionnaire results that we compared to their urologist-reported indication, results, and plan. Our primary objective was to assess whether patients prefer to be seen direct to cystoscopy (DTC) vs. a clinic appointment (CA) before cystoscopy.

Results: A total of 500 questionnaires were analyzed, with 336/500 (67%) patients being male. Mean age was 66 years (21–93), with 30% under 60 years. Thirty-nine percent (n=193) were undergoing their first cystoscopy, with 85% preferring DTC. There was no difference in age, gender, first-time cystoscopy, or indication for cystoscopy when comparing those who preferred DTC vs. CA. Patients who had an accurate understanding of the indication for their cystoscopy had 6.23 times higher odds of preferring DTC ($p<0.05$). We also identified a deficiency in patient comprehension of cystoscopy results and followup plans.

Conclusions: With limited health resources, a large patient catchment area, and the majority of patients preferring to be seen DTC, there is evidence to implement a default DTC approach to booking cystoscopy clinics.

Introduction

Cystourethroscopy is a crucial and commonly performed diagnostic and treatment tool used by all urologists in order to evaluate both benign and malignant diseases. At our center, 15 staff urologists perform over 7500 outpatient cystoscopies annually. This high volume stems both from our vast patient catchment area (Northern Alberta and Northwest Territories, 1.17x10^6 km^2), along with centralized urological care in a Canadian province that has few practicing community urologists.

Despite its long-standing established role in medicine, cystoscopy is a widely under-recognized investigation from the perspective of the general public.[1-4] Other invasive screening procedures have seen the benefits of mainstream education programs, familiarizing the general population with colonoscopy, mammograms, and pap smears. In contrast, patients often first hear about cystoscopy and its value on the day they require it.

Given the anecdotal knowledge gap we identified in our patient population, we sought to better understand the patient experience and preferences when faced with cystoscopy. Currently, there is little guiding literature, with only a few validated hospital-based anxiety scales applied to urological procedures. One study evaluated a 40-question survey (State Trait Anxiety Inventory, STAI) while another examined Hospital Anxiety and Depression Scale (HADS, 14-question survey) scores associated with cystoscopy vs. other invasive urological investigations (urodynamics, transrectal ultrasound [TRUS]-guided prostate biopsy).[2,3] Surprisingly, higher rates of anxiety were associated with cystoscopy than TRUS-guided biopsy of the prostate.[4] Specifically, anxiety was associated with the time awaiting cystoscopy (26%), and the procedure itself (17%) as the most stressful.[4] Additionally, there remains conflicting opinions in the literature regarding patient characteristics (e.g., gender, age) associated with higher odds of cystoscopy-associated anxiety. Overall, there is little research aimed at evaluating and improving patient-related experiences for this procedure, despite its frequent use.

In analyzing our clinical pathways, we struggled to understand whether patients preferred a clinical consultation appointment (CA) prior to their procedure or to come direct to cystoscopy (DTC). Therefore, we set out to perform a quality assessment of our delivery model. Our primary objective was to identify whether patients preferred to be seen DTC vs. CA prior to cystoscopy. Secondary objectives

Assmus, M. A., McLarty, R., Senthilselvan, A., & De, S. K. (2020). Direct to cystoscopy: A prospective quality assessment of patient preferences. *Canadian Urological Association journal = Journal de l'Association des urologues du Canada*, *14*(4), 118–121. https://doi.org/10.5489/cuaj.6013

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Shared Decision-Making Is Important, Particularly With Respect to Patient's Sexual Function and Overall Satisfaction

2020 AUA Guidelines:

"Given the strong observed relationship between ED and LUTS/BPH, this group of men is at high risk for sexual dysfunction.

In all instances, **patients should be provided with the risk/benefit profile for all treatment options** in light of their circumstances to allow them to make informed decisions regarding their treatment plans."

AUA Guidelines 2020
This statement was first noted in the 2018 AUA Guidelines Update.

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Concluding Paragraph from AUA Guidelines

Traditionally, the primary goal of treatment has been to alleviate bothersome LUTS that result from BOO.

While a MIST may not alleviate symptoms to the same degree or durability as more invasive surgical options, a more favorable risk profile and reduced anesthetic risk would make such a treatment attractive to many patients and providers.

Since many men discontinue medical therapy, yet proportionately few seek surgery, there is a large clinical need for an effective treatment that is less invasive than surgery.

With this treatment class, perhaps a significant portion of men with BOO who have stopped medical therapy can be treated prior to impending bladder dysfunction.

The guidelines are available on the AUA website at the link below:
https://www.auanet.org/guidelines/surgical-management-of-lower-urinary-tract-symptoms-attributed-to-benign-prostatic-hyperplasia-(2018)

Why Aren't PCP's Referring BPH Patients to a Specialist?

Patient doesn't want surgery
"It is an extra cost to the patient if they are not going to consider the options that will be presented."

PCP can prescribe meds
"Most don't need referrals. Meds are effective 95% of the time."

Concern about wasting patient's/urologist's time
"…if I refer early and the urologist doesn't do anything, the patient will be hesitant to go back…"

Other reasons
- Extra co-pay
- Time off work
- Distance to travel

Blinded PCP Qualitative Research conducted by NeoTract, 2019 (n=20)

Surgery is a Big Step for Patients

- General anesthesia with operative risks
  - Transfusion, significant hematuria[1]
- Catheterization for days[2]
- 4-6 weeks irritative voiding symptoms[1,3]
- Up to 6 week recovery[4,5]
- Risk of permanent complications[1]
  - Urinary incontinence
  - Ejaculatory dysfunction
  - Erectile dysfunction
  - Urethral stricture

Only 0.3M (2.5%) elect surgery

1 AUA Guidelines 2003; 2 Bachmann, Eur Urol 2014 May; 65(5): 931-42; 3 Miano, Med Sci Mont 2008; 14(7): RA94-102;
4 Wasson, Perspectives in Nursing 2000; Vol 1, No 3; 5 NIH U.S. National Library of Medicine – TURP patient instructions
U.S. Market Model 2016-18 for Investors

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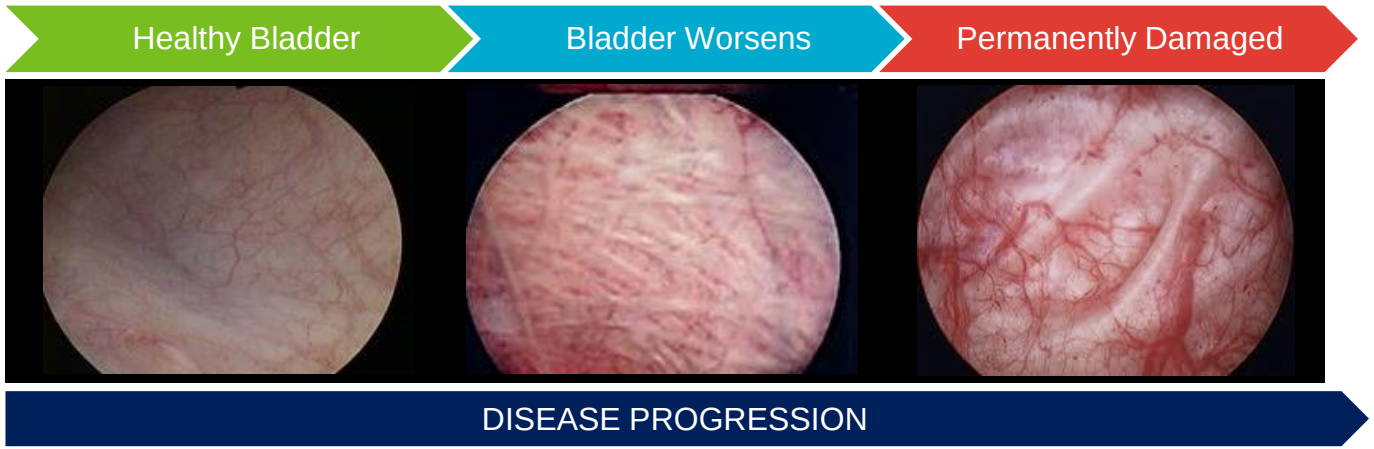
INTERVENTIONAL UROLOGY

Why A Truly Minimally Invasive Approach is Needed

- Approximately 7.5 million US men on BPH meds in 2018[1]
- Up to 70% reported not compliant in first year[2], yet don't want TURP
- By the time they elect TURP/laser, bladder can be weakened or permanently damaged[3]



We need to address obstruction earlier in the disease.
The solution? Safer, better, easier patient experience.

1 NeoTract US Market Model estimates for 2018 based on IMS Health Drug and Procedure data,2 Cindolo, et al. Eur Urol 2015; 3 Flannigan, et al. J Urol 1998; 4 Lukacs, et al. Eur Urol 2013; Strope. Urology 2015

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International Prostate Symptom Score (IPSS)

Patient Name: Today's Date:

Determine Your BPH Symptoms Circle your answers and add up your scores at the bottom.

Over the past month	Not at all	Less than one time in five	Less than half the time	About half the time	More than half the time	Almost always
Incomplete emptying – How often have you had the sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
Frequency – How often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
Intermittency – How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
Urgency – How often have you found it difficult to postpone urination?	0	1	2	3	4	5
Weak stream – How often have you had a weak urinary stream?	0	1	2	3	4	5
Straining – How often have you had to push or strain to begin urination?	0	1	2	3	4	5
Sleeping – How many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	None 0	One Time 1	Two Times 2	Three Times 3	Four Times 4	Five or More Times 5
Add Symptom Scores:	+	+	+	+	+	

Total International Prostate Symptom Score = _____

1 – 7 mild symptoms | 8 – 19 moderate symptoms | 20 – 35 severe symptoms

Regardless of the score, if your symptoms are bothersome you should notify your doctor.

Quality of Life (QoL)

	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6

Have you tried medications to help your symptoms?	Yes	No

Did these medications help your symptoms? (circle)										
1	2	3	4	5	6	7	8	9	10

No Relief *Complete Relief*

Would you be interested in learning about a minimally invasive option that could allow you to discontinue your BPH medications?	✓ Yes	No

Consider using this condensed IPSS for every man over 45, every time

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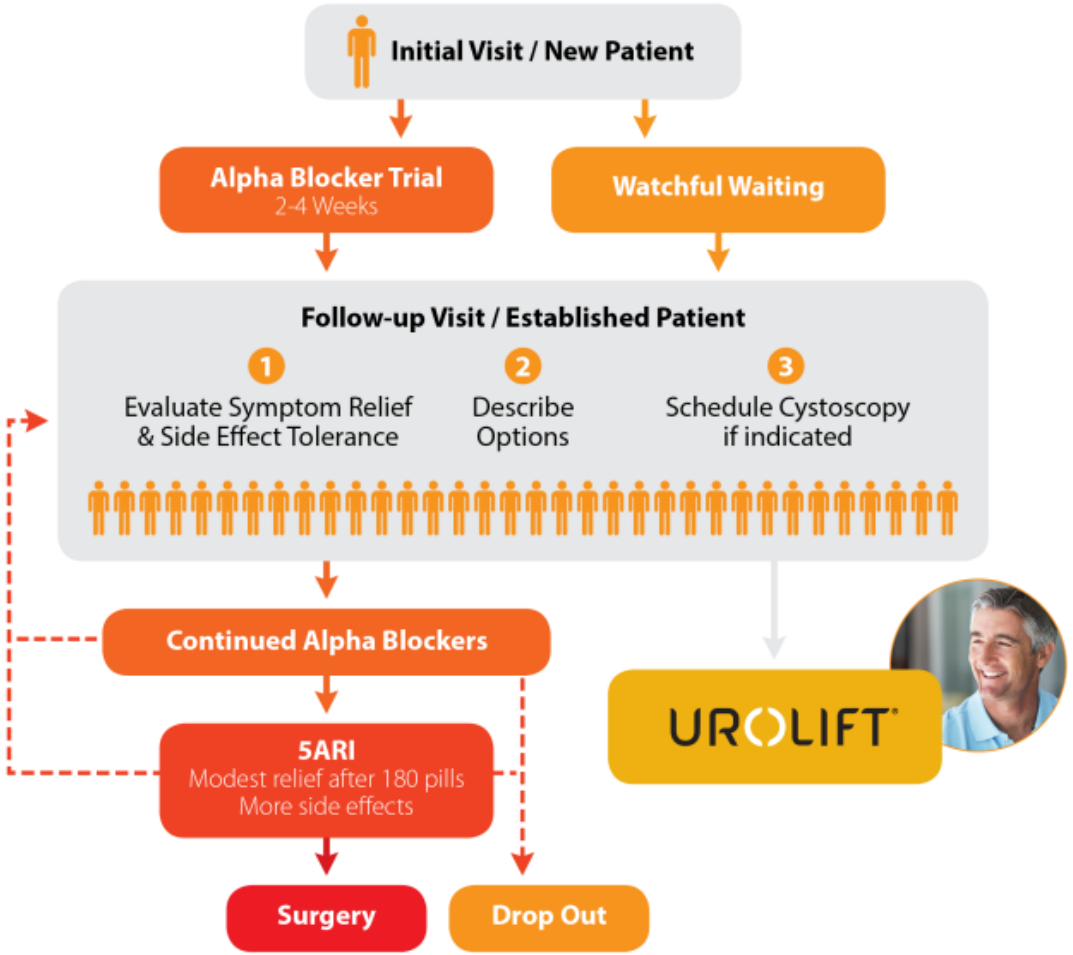
My Workup

- Establish the need: patient preference, supported by IPSS/QoL/PVR
- Trial α-blocker (2-4+ weeks); schedule follow-up IPSS reassessment and possible cystoscopy
- Provide ample patient education materials and web info at the first visit, then answer questions and complete counseling at the follow-up appointment
- Workup can typically be completed in 2 visits
- +/- TRUS or abd US; uroflow; UDS
  - *the use of some evaluation tools are dictated by insurers*

Sample Care Pathway



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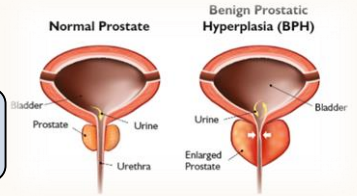
BPH Care Pathway



Primary Care Provider

Symptom Assessment
Irritative, Voiding IPSS: _____

If >=8, refer to Urology

Diagnostic Testing: *PSA*
Refer to Urology

If patient selects to learn more about alternatives to medications or refuses medical management, refer to Urology

Medical Management
Alfuzosin, Tamsulosin

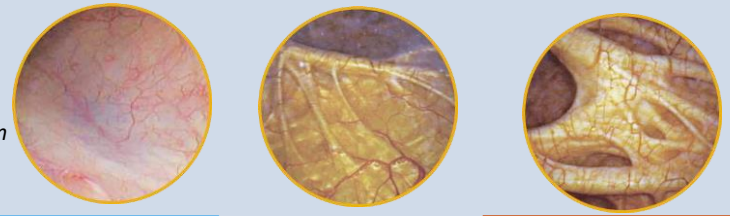
If symptoms don't improve within **4-6 weeks** or side effects are bothersome, refer to Urology

Urologist

Diagnostic Testing

- ***Cystoscopy:***

Optional
- *PVR/Bladder Scan*

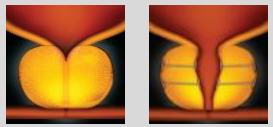


Healthy Bladder → Bladder Worsens → Permanently Damaged

Advanced Treatment

Minimally Invasive → Surgery

UroLift™
- No cutting, Quick Recovery, No sexual side effects, No tissue destruction



Rezum™
- Steam application to the prostate
- Catheter for 1-5 days
- Risk of Ejaculatory dysfunction

TURP
- Removes tissue
- Catheter for 2-5 days
- Risk of ED, Ejaculatory dysfunction

Patient Screening

Both Flexible Cystoscopy & Ultrasound are recommended

Flexible Cystoscopy allows for Assessment of:

- Lateral Lobe hypertrophy
- Intravesicular structures, including Intravesicular Prostatic Protrusions (IPP)
- Median Lobe Classification
- Tolerance for In-Office Treatment

Ultrasound (TRUS or Transabdominal)

- Provides shape detail not available during DRE and/or Cysto
- May allow for more accurate Prostate sizing ≤ 100cc