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OPTIMIZING POPULATION HEALTH AND ECONOMIC OUTCOMES: INNOVATIVE TREATMENT FOR BENIGN PROSTATIC HYPERPLASIA (BPH)

Transcribed and adapted for publication by Janice L. Clarke, RN, BBA

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Acknowledgment

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Optimizing Population Health and Economic Outcomes: Innovative Treatment for BPH

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Editorial

David B. Nash, MD, MBA

On first meeting Ted Lamson, PhD, I was struck by his obvious intellectual curiosity, his creativity, and, importantly, his wholehearted commitment to improving treatment and outcomes for the burgeoning population of American men with benign prostatic hyperplasia (BPH).

An inventor by nature and profession, Lamson's interest in BPH was brought about by 2 personal experiences involving his father and an uncle. Both men, in their 80s, suffered from the disease yet had no satisfactory treatment option. Both had symptoms that could not be managed sufficiently with medications and, because of comorbidities, neither was a candidate for surgical alternatives. Both wished for a better option before catheterization became necessary.

Focusing on the clinical issues associated with BPH rather than on a specific invention, Lamson shadowed surgeons and spoke with numerous men who had undergone different therapies. Without visualizing a device or procedure, he formulated certain specifications, such as the ability to perform the procedure in any venue, under local anesthesia, with rapid relief of symptoms and a minimal need for postoperative catheterization.

In 2005, Lamson cofounded NeoTract, Inc., a medical device company headquartered in Pleasanton, California, to focus on developing and implementing a minimally invasive solution for BPH. The company pioneered a new technology intended to fill a serious gap in traditional treatment options. The UroLift® System was launched and subsequently studied internationally and later in the United States. It received Food and Drug Administration approval for US market release in September 2013.

Because transparency is a company priority, outcomes for every clinical study patient treated with the procedure have been published. Having read these articles, there is little doubt in my mind that UroLift® is likely to emerge as a "disruptive" innovation. Originally coined by Harvard Business School professor Clayton M. Christensen, the term refers to a new

technology or innovation that unexpectedly displaces an established one. It follows that a disruptive innovation in health care is one that creates a whole new approach to a condition affecting a large population, thereby changing the value proposition and disrupting the existing treatment paradigm.

I suspect that the UroLift® System will change the existing paradigm for BPH treatment because it is a simple, elegant procedure that:

- Can be performed in a physician's office or acute surgery center setting under local anesthesia.
- Produces rapid relief of lower urinary tract symptoms with minimal side effects.
- Preserves full sexual function.
- Is durable and potentially cost-effective.

There has been an unusually high degree of enthusiasm about this new technology among my colleagues, and I look forward to feedback from our readers.

Introduction

Prior to Food and Drug Administration approval and the US launch of the UroLift® System in late 2013, NeoTract, Inc., sought expert feedback from across the stakeholder continuum regarding the clinical evidence, physician education and training, reimbursement and cost-benefit models, and patient information and engagement.

On June 11, 2013, the Jefferson School of Population Health convened an expert stakeholder panel (Panel) to describe and discuss this novel approach to treating benign prostatic hyperplasia (BPH) by addressing the anatomical defects underlying its symptoms. Facilitated by David B. Nash, MD, MBA (Dean, Jefferson School of Population Health), the meeting was organized around a series of presentations, followed by interactions among the presenters and panelists.

In addition to *Ted Lamson, PhD* (Cofounder and Chief Technical Officer, NeoTract, Inc.) and *Dave Amerson, MBA* (President and Chief Executive Officer, NeoTract, Inc.), who described the UroLift® System, presenters on the Panel included:

- **Steven N. Gange, MD, FACS** (Western Urological Clinic, Salt Lake City, UT) – *Clinical Best Practices in the Treatment of BPH*, an overview of BPH and current forms of treatment.
- **Daniel B. Rukstalis, MD** (Professor, Surgical Sciences-Urology, Wake Forest Baptist Health, Winston-Salem, NC) – *The BPH Continuum of Care*, the evolution of BPH over time and its impact on bladder health.
- **Mike McClure, MBA** (Senior Director, Health Economics and Strategic Reimbursement, NeoTract, Inc.) – *The New Value Proposition*, a discussion of the likely costs and benefits of the UroLift® System compared with existing treatment modalities.
- **Ronald E. Myers, PhD, DSW** (Director of the Division of Population Health Science, Department of Medical Oncology, Thomas Jefferson University, Philadelphia, PA). – *Patient Perspective: Informed Choice and Shared Decision Making*, an in-depth discussion from a patient-centered viewpoint.

Other panelists were:

Paul Bleicher, MD, PhD (Chief Executive Officer, Optum Labs, Cambridge, MA)

Matthew R. Cooperberg, MD, MPH (Assistant Professor, Urology, Epidemiology, Biostatistics, University of California, San Francisco, CA)

Joseph P. Fuhr, PhD (Professor of Economics, Widener University, Chester, PA)

Steven Goldberg, MD, MBA (Chief Medical Officer, WellCare, Tampa, FL)

Lawrence S. Hakim, MD (Chairman, Department of Urology, Cleveland Clinic, Weston, FL)

Thomas James, III, MD (Corporate Medical Director, Clinical Policy, AmeriHealth Caritas, Philadelphia, PA)

Steven Peskin, MD, MBA, FACP (Senior Medical Director of Clinical Innovations and Pilot Lead, Horizon Blue Cross/Blue Shield of New Jersey, Newark, NJ)

Paul Radensky, MD, JD (Partner, McDermott Will & Emery LLP, Washington, DC)

Brian Silverstein, MD (President, HC Wisdom, Owings Mills, MD)

Benign Prostatic Hyperplasia

Overview

The prostate is a mixture of stromal (fibromuscular) tissue and glandular epithelial (semen and PSA-producing) tissue. BPH is a noncancerous enlargement of the prostate that occurs as men age. The enlarged prostate presses on the urethra, causing bothersome lower urinary tract symptoms (LUTS) such as frequent urination, urgency, and incontinence. Figure 1 depicts a normal, healthy bladder on the left and a hypertrophic bladder (the result of nonintervention for BPH) on the right.

Histologic BPH leads to bladder outlet obstruction resulting in LUTS. Left untreated, the clinical consequences of BPH include urinary tract infection, bleeding, stones, acute and chronic urinary retention, overflow incontinence, diverticuli, hydronephrosis, and renal failure – all of which compromise daily activities and sexual function.¹⁻³

Chronic LUTS often lead to loss of sleep, social isolation, and depression, thus having a significant impact on a pa-

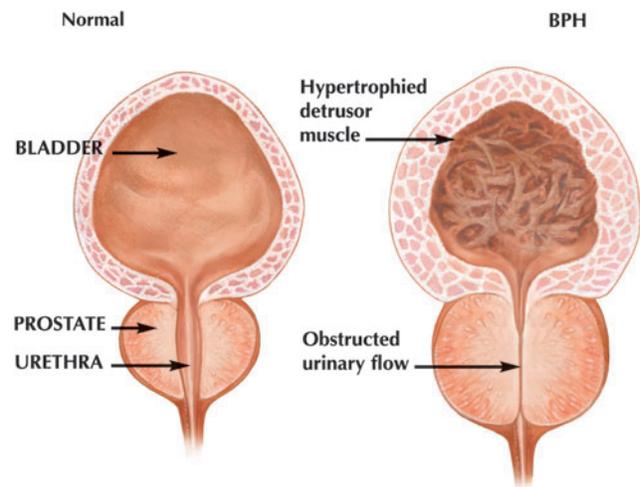


FIG. 1. Anatomy of BPH. BPH, benign prostatic hyperplasia. A color version of this figure is available in the online supplement at www.liebertonline.pub/pop.

tient’s quality of life.⁴ An estimated 50% of men have histologic evidence of BPH by age 50, and 75% by age 80. In 40%–50% of these men, BPH becomes clinically significant. Multiple studies show that the prevalence of histologic BPH increases steeply with age, beginning as early as age 15 in some men, and reaches 100% by age 80.⁵ In the general elderly population, indwelling urinary catheter (related to BPH and other causes) is the second leading reason for placement in institutional care and the primary reason for nonacceptance by assisted living facilities.⁶

Today, “enlarged prostate” ranks number 4 (13.5%) among the top 10 diagnosed diseases in men aged 50 years and older, surpassed only by coronary artery disease/hyperlipidemia, hypertension, and type 2 diabetes mellitus.⁷ Although generally overlooked as such, BPH is – and will continue to be – a population health issue.

Symptoms and Diagnosis. Early manifestations of BPH include the following symptoms:

- Storage/irritative symptoms (ie, daytime frequency, nocturia, urgency, urinary incontinence),
- Voiding/obstructive symptoms (ie, slow stream, “spraying,” intermittent stream, hesitancy, staining, terminal dribble), and
- Post-voiding symptoms (ie, feeling of incomplete emptying, post-micturition dribble).⁸

Diagnosis of BPH can be made using the American Urological Association’s (AUA) Symptom Score (Figure 2), a tool whereby a patient responds to 7 questions pertaining to LUTS symptoms using a rating scale of 0=*not at all* to 5=*almost always*. A score of 18–35 indicates severe BPH. In general, patients with a score of ≥ 7 should be referred to a urologist for evaluation.

As LUTS symptoms increase, sexual function decreases. Studies reveal that, although 65% of men report being sexually active at age 70–79, sexual activity declines with increasing severity of LUTS independent of age.⁹ Not surprisingly, men desire BPH therapy that enhances their

	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	
1. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5	
2. 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	
3. Over the past month, how often have you found you stopped and started again several times after urinating?	0	1	2	3	4	5	
4. Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5. Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
6. 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 or more times	
7. Over the past month, 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?	0	1	2	3	4	5	
Total Symptom Score							

FIG. 2. American Urological Association Symptom Score. Adapted from Barry M, Fowler FJ Jr, O’Leary MP, et al. The American Urological Association symptom index for benign prostatic hyperplasia. The measurement committee of the American Urological Association. *J Urol.* 1992;148:1549–1557.

quality of life by relieving urinary symptoms and reducing interference with daily activities, while preserving sexual function and continence.

Initial diagnosis and medical treatment of BPH generally occur in the primary care physician’s (PCP) office; in fact, the majority of prostate medications are ordered by PCPs. Because the condition is progressive, it is essential that changes in symptoms and quality of life be tracked over time (eg, administering the AUA Symptom Score annually). Ideally, patients whose symptoms are not well managed on a medical regimen or who are suffering from side effects should be referred to urologists for more comprehensive evaluation and alternate interventions.

Current BPH treatment paradigm

As early as 1000 BC, the Indian surgical text, *Sushruta Samhita*, described using bronze, silver, and wooden tubes “anointed” with oil, butter, or egg white to catheterize men to relieve LUTS.¹⁰ By the late 1800s, Sir Peter Freyer had performed the first open prostatectomy, and by the mid-1930s the transurethral resection of the prostate (TURP) was quickly becoming the gold standard of surgical procedures for treatment of BPH. In 1935 Frederick Foley introduced the modern catheter.

In the United States today, over 8.8 million men are being treated for BPH – 40% with active surveillance (“watchful

waiting”), 58% with medications, and 2% with surgery or thermotherapy.¹¹

Active surveillance. An appropriate option for patients with mild symptoms – as well as for some with moderate-to-severe symptoms – active surveillance implies that the patient is followed annually but receives no active intervention for symptom relief.¹ The patient is advised to watch his weight and diet (eg, avoid alcohol and spicy foods) and to exercise regularly. Many men treated with active surveillance experiment with homeopathic remedies; although a huge placebo effect has been reported for some, none of these remedies is proven.

Pharmaceutical treatments. α_1 -adrenergic blockers are the mainstay drug class for treatment of BPH. These drugs deliver rapid but modest improvement in LUTS and flow, sexual dysfunction (primarily ejaculatory disturbances), dizziness, fatigue, asthenia. Unfortunately, none of these agents alter urodynamic parameters or prostate volume; none delay the natural progression of the disease; none prevent acute urinary retention; and none eliminate the eventual need for surgery.

Although 5-alpha-reductase inhibitors have been shown to reduce prostate size when taken for 3–6 months, thereby improving symptoms and altering the disease progression,

the side effects are consequential (eg, reduced libido, erectile and ejaculatory dysfunction, loss of libido, gynecomastia). Additive outcomes produced by combination therapy are both positive (eg, rapid acting/size reducing) and negative (eg, limited to large prostates, combined side effects, additive costs, modest improvement vs. surgery).^{12,13}

Phosphodiesterase type 5 inhibitor therapy relaxes smooth muscle and avoids the adverse events associated with the other drug classes; however, symptom response is less than optimal, there is no improvement in flow rate, and the cost is approximately \$1600 per year (May 2013 rates).

Irrespective of the drug class, medications are not effective for all patients. Approximately 30% of men on medications for BPH discontinue therapy because the perceived benefit is insufficient to offset the side effects.⁵ Succinctly stated, medications can manage the problem but do not correct it.

BPH surgical procedures.

- **Transurethral Resection of Prostate (TURP)** – The gold standard surgery for BPH, TURP is analogous to coring an apple. It is an hour-long, inpatient surgical procedure under general anesthesia with a 4- to 6-week recovery/ follow-on period. TURP results in strong, durable symptom improvement (14.9 point American Urological Association Symptom Index [AUASI] improvement at year 1 and 8% re-treatment over 10 years) with a low mortality rate (0.2%). Side effects include ejaculatory dysfunction (65%), erectile dysfunction (10%), urethral stricture (7%), and permanent urinary incontinence (3%).¹ Risks and limitations include general/spinal anesthesia, a 1- to 4-day hospitalization, postoperative urinary catheterization for 1–3 days, and a 4- to 6-week recovery period. The reoperation rate (eg, for bladder neck contracture, stricture related to scarring, insufficient tissue removal) is 25%, and up to 25% of patients who undergo TURP do not have satisfactory results.¹⁴ In addition, the procedure is contraindicated for patients older than 80 years of age and patients with coagulopathy.¹⁵ A somewhat less invasive surgery – the transurethral incision of prostate (TUIP) – is an appropriate option for men with very small prostates. Similar in nature to TURP, TUIP involves creating 2 deep channels through a prostate rather than removal of the entire adenoma. It shares the same list of complications but at lower rates in general.
- **Photoselective Vaporization of the Prostate (PVP) and Other Laser Procedures** – These procedures produce a TURP-like response with an average 13.4 point AUASI improvement at 1 year. There is less bleeding compared with the TURP, and laser procedures can be performed on patients taking anticoagulants; however, the average operation time is significantly longer than the TURP procedure.¹⁶ Side effects include ejaculatory dysfunction (42%), erectile dysfunction (7%), urethral stricture (3%), and permanent urinary incontinence (3%). Risks and limitations include general/spinal anesthesia, potential 1 day of hospitalization, up to 3 days of catheterization, and a 4- to 6-week recovery period.^{1,17}

Minimally invasive therapies. Currently available procedures include transurethral microwave thermotherapy

(TUMT) and transurethral needle ablation. Theoretically, these procedures can be performed in physician offices. In general, they provide greater symptom relief than medications and result in fewer complications than TURP and laser procedures. Side effects such as prolonged catheterization because of swelling, 4 to 5 weeks of voiding symptoms, and a 20%–25% risk of acute urinary retention result in less than optimal patient satisfaction for 1–2 months post procedure. Additionally, re-treatment rates have been shown to be as high as 50%, calling into question the durability of treatment.^{18–23}

BPH Continuum of Care: Bladder Health

Because prostate growth begins to progress when men are in their 30s, the bladder is obstructed to some degree by the time they reach their 50s. BPH was not as widespread a problem in the early twentieth century because average life expectancy for a man was age 50.

Scientific investigation has taught us over the years that BPH is not solely a disease of the prostate. It is a condition that, left untreated, severely compromises bladder health. Continued obstruction over time results in bladder wall thickening and detrusor muscle hypertrophy, forcing the bladder to work progressively harder until, eventually, the bladder decompensates.

Randomized studies have demonstrated that patients with BPH who opted for active surveillance and later received a TURP had poorer outcomes than those who opted for earlier surgery (eg, urinary peak flow rates 85% less).²⁴

The current BPH treatment paradigm imposes serious barriers to bladder health. As bladder health declines, present-focused men deal reflexively with symptoms by making lifestyle changes (eg, habit changes with respect to caffeine and alcohol intake). They opt for symptomatic relief with medications, many of which interact adversely with other drugs (eg, antihypertensive agents). Both the patient and PCP consider the treatment successful if symptoms are alleviated. However, as noted, although BPH medications treat LUTS symptoms they do not reduce the obstruction; consequently, bladder health worsens. As a result, men undergo surgery much later in the disease process and, because the bladder has remained obstructed, there is less recovery.

The imminent launch of an alternative to early medication and late surgery makes a new paradigm possible – one that lowers the barrier to bladder health for a substantial population of American men.

New Treatment Option for BPH

By definition, prostate tissue affected by BPH is *benign*. Existing surgical therapies have been designed to attack this benign tissue and, although they effectively address the obstruction caused by prostatic encroachment on the urethra, they are associated with serious complications and side effects because of surgical removal of and/or injury to healthy tissue. The creators of UroLift[®] took a different approach. Rather than focus on removing nonmalignant tissue, they sought to address the chief clinical issue (ie, LUTS caused by obstruction) while retaining the prostate's function – in effect, de-linking LUTS from BPH.

The UroLift[®] System treatment is a minimally invasive cystoscopic procedure that mechanically opens the prostatic



FIG. 3. UroLift[®] system device and implant. Image ©NeoTract, Inc. Reprinted with permission. A color version of this figure is available in the online supplement at www.liebertonline.pub/pop.

urethra with small implants that effectively separate encroaching prostatic lobes, like opening window curtains. The procedure is accomplished by means of a precisely designed instrument (Figure 3) equipped with a scope for visualization and a spring-loaded 19 gauge needle that delivers small implants, each sized in situ to the prostate lobe at that location.

The UroLift[®] System

As with TURP, the surgeon assesses the degree of obstruction. Rather than resecting the obstructing tissue as in TURP, the urologist uses the UroLift[®] System to deploy permanent transprostatic implants to reshape the prostate at the points of obstruction (Figure 4). Under endoscopic guidance, the physician determines the precise location to compress the obstructing prostatic lobe(s) and delivers the permanent transprostatic implant(s) via a needle. The needle is passed through the prostate and, upon retraction, it delivers one end of the implant to the outer capsule of the prostate. The implant's central filament is automatically tensioned and a urethral end piece is affixed while simultaneously trimming the filament and releasing the implant. This process is repeated, typically at 4 locations, until a

continuous channel is observed through the prostatic fossa. Because the prostate glandular tissue is compressible and the outer capsule is fibromuscular, implant compression opens the urethral surface out toward the capsule, thus reducing obstruction.

The efficacy of the UroLift[®] System has been demonstrated in numerous studies, including a randomized double-blind study conducted primarily in the United States, a European retrospective registry, and open label studies conducted in the United Kingdom, Germany, the Netherlands, Spain, Italy, France, and Australia.^{25–29} Improvement in urinary symptoms, indicated by reduction in AUASI, has been consistent across the various studies, showing rapid relief within 2 weeks and sustained effect to 2 years (Figure 5). Over 450 patient-years of data have been presented in peer-reviewed publications to date.

In addition to reducing LUTS, the UroLift[®] System has a significant positive impact on peak urinary flow rate (Q_{max}) (ie, improving the rate 4.0 to 6.3 mL/sec at, $P < 0.01$).^{30,31} Quality of life also improved significantly, with the International Prostate Symptom Score (IPSS) Quality of Life and BPH Impact Index improving 43% and 47%, respectively, $P < 0.01$.^{30,31} Re-treatment rates remain low for a BPH procedure, with 5%–6% re-treatment at 1 year and 8% at 2 years.^{25,30,31} No additional surgical intervention has been required for complications typically associated with other BPH procedures, such as bladder neck contracture, stricture, transfusion, or incontinence. Complication-related reoperation rates of 14%–25% have been reported for TURP, the standard surgery for BPH.^{1, 32–35}

The achievable treatment outcomes with the UroLift[®] System surpass those attainable with drug therapy in terms of symptom relief and improvement in urinary flow/bladder health (Figure 6). Although TURP and laser therapies offer, on average, 3–4 points greater IPSS reduction, these come at an increased risk of several significant complications. A striking advantage of the UroLift[®] System treatment, compared to all other conservative therapies and operative procedures, is the preservation of sexual function.^{36–38}

The UroLift[®] System has consistently demonstrated an excellent safety profile. Typically, the procedure requires lighter anesthesia (ie, intravenous conscious sedation and

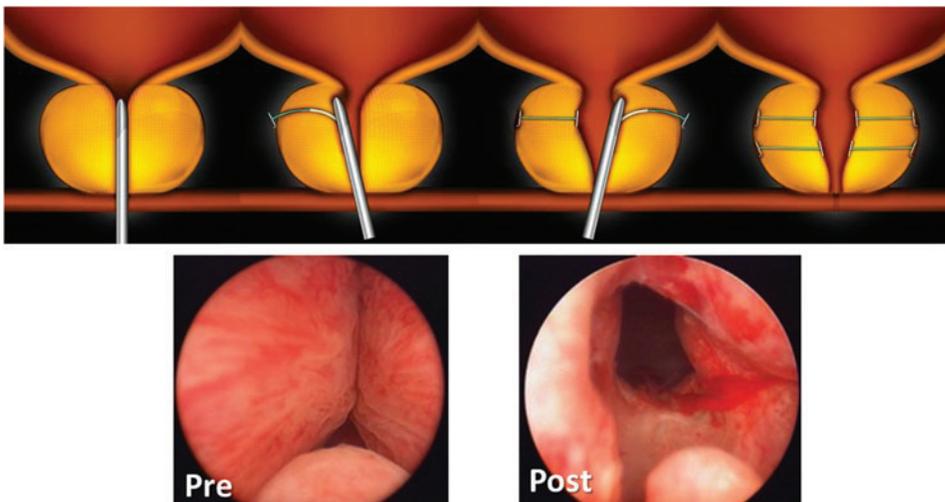


FIG. 4. The UroLift[®] system implant procedure. Image ©NeoTract, Inc. Reprinted with permission. A color version of this figure is available in the online supplement at www.liebertonline.pub/pop.

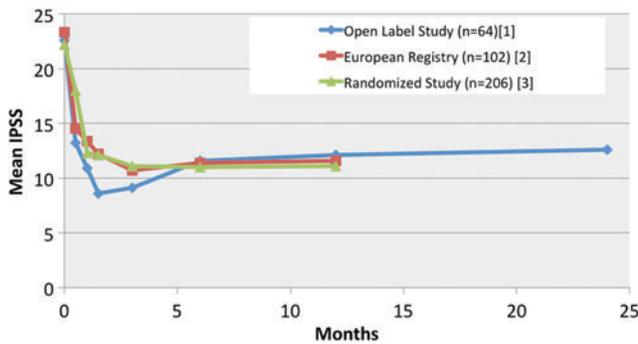


FIG. 5. International Prostate Symptom Score (IPSS) reduction as a result of UroLift® System treatment in three major studies.^{25, 30, 31} A color version of this figure is available in the online supplement at www.liebertonline.pub/pop.

local anesthetic) than TURP or laser (ie, general anesthesia). Compared with TURP, there is less bleeding, with a 0% transfusion rate to date for UroLift® vs. 5%–7% for TURP. Postoperative catheterization rates for UroLift® have ranged from 30%–35% (100% for TURP) with a mean duration of 0.9 days (1–5 days for TURP).^{1, 25, 30–35}

In general, UroLift® System treatment is associated with mild-to-moderate transurethral side effects (eg, dysuria, hematuria, pelvic discomfort, urgency) that typically resolve within 2 weeks. In a randomized study, the occurrence of urinary tract infection and retention were not statistically different from the cystoscopy control group (3% vs 2% for UroLift®, and 2% vs 2% for control).³⁰ There has been no incidence of transfusion, bladder neck contracture, stricture, or permanent incontinence reported in any study of the UroLift® system.^{25,30,31}

Preservation of sexual function is a unique feature of treatment with the UroLift® System. There has been 0% incidence of anejaculation/retrograde ejaculation in any of the published studies, a favorable comparison with the pub-

lished 40%–80% rates for TURP and laser procedures and the 10%–28% rates published for alpha-blockers.^{1,32–33,36–38} Erectile function has been preserved, with no incidence of erectile dysfunction (ED), compared to the widely published 10% rate associated with TURP and laser.^{1,32–33} Moreover, Woo et al demonstrated that, in addition to maintaining erectile function for men entering the study with no or mild ED, erectile function improved for men who entered the study with severe ED.²⁷

Building on the substantial evidence to date, additional studies are being undertaken. A second European randomized study is currently enrolling patients, a randomized study is planned in France, and open label studies are under way in several countries.

Positioning of UroLift® in BPH Treatment Paradigm

There is an obvious gap in current treatment options along the BPH continuum of care. Active surveillance and medications are appropriate in the early, mild-to-moderate stages of the disease, but many men discontinue medical therapy because the adverse side effects of medication outweigh the mild symptomatic relief it offers. Several surgical treatment options are available; however, the risks associated with these procedures are such that men often choose to wait until the condition becomes severe and symptomatic relief is not achievable.

The gap lies in the broad, moderate-to-severe stage of the disease. With demonstrated rapid symptom relief, durable results, and excellent safety profile devoid of the major complications of surgical options, UroLift® affords patients with moderate-to-severe disease another option – one that may offer access to a surgical level of symptom relief earlier in the disease process.

Expert Panel Discussion: Clinical Perspective

- There was consensus among panel members regarding the clinical value of the innovation and general agree-

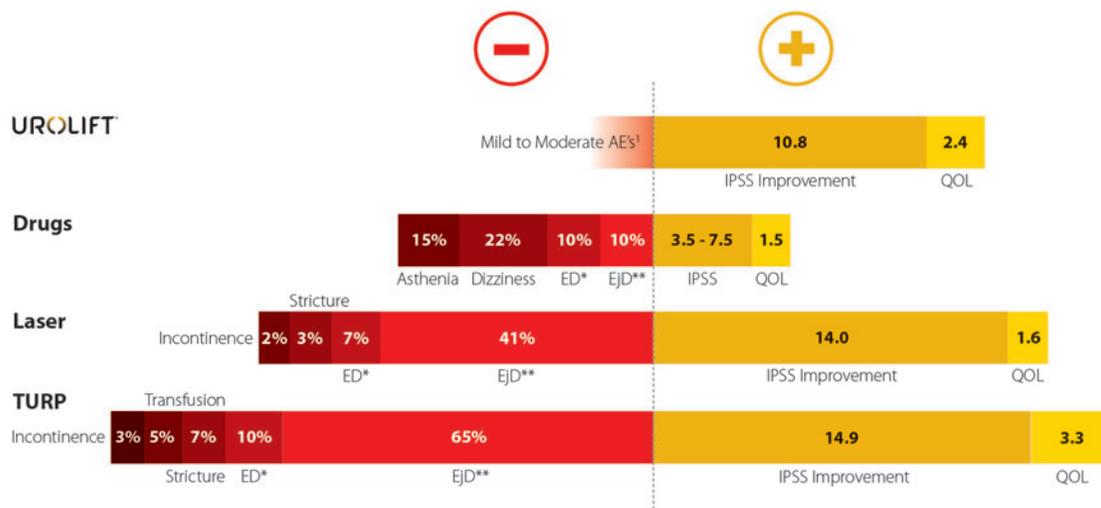


FIG. 6. Graphic summary of risk/benefit comparison of UroLift® System treatment as compared to transurethral resection of the prostate (TURP), laser vaporization, and drug treatments for BPH.^{25, 30–33} AE, adverse event; ED, erectile dysfunction; EjD, ejaculatory dysfunction; IPSS, International Prostate Symptom Score; QOL, quality of life. A color version of this figure is available in the online supplement at www.liebertonline.pub/pop.

ment that physician awareness, education, and training would be a top priority in assuring the inclusion of this therapy in the standard of care. Because diagnosis, treatment, and referral for BPH occur in the primary care setting, PCP awareness and education – particularly with respect to earlier intervention to preserve bladder health – are essential.

- Careful consideration must be given to assuring that physician and facility reimbursement for the UroLift® implant procedure is appropriate and aligned with reimbursement for comparable outpatient surgical procedures. Although there is obvious excitement about this game-changing technology, it is paramount that novel technologies be studied from the standpoint of resource requirements for the procedure so that reimbursement accurately reflects these.
- Suprapubic ultrasound, a bladder health screening tool in use outside the United States, should be considered to assess the condition of the prostate and bladder and to help identify patients for whom the procedure would be beneficial. This tool could be useful in demonstrating the utility of securing bladder health earlier in the disease process.
- Although the clinical studies conducted to date are thorough and comprehensive, it is very important to monitor the therapeutic effect in the “real world” setting. A BPH registry that includes treatment with the UroLift® system as well as the current treatment options would help physicians provide patient-centered, accountable care.

New Value Proposition

In today’s environment, a new technology must not only present a better clinical option to patients but also offer benefit to the provider, the payer, and, ideally, to society as a whole. In addition to its patient-centered clinical benefits, the UroLift® System appears to have the potential to achieve this additional “trifecta.”

Provider perspective. Multiple studies have shown that the procedure can be performed efficiently with predictable outcomes. Skilled surgeons performing the UroLift® implantation procedure under endoscopic visualization can assess the result in real time by observing the degree of expanded opening of the prostate. Without the typical side effects of prostate surgery, the patient’s progress through the provider system can be efficient and predictable.

Payer perspective. UroLift® dovetails with the general trend of shifting care away from high-cost inpatient settings and toward ambulatory surgery center (ASC) and practitioner office settings. Because the procedure offers the opportunity to treat a progressive condition earlier in the disease process, cost savings are achievable in terms of fewer office visits (for monitoring) and a lower incidence of complications and/or insufficient response to a surgical procedure performed late in the disease process.

Societal perspective. The availability of this technology may effect a change in the way men behave with regard to preserving their bladder health and quality of life. An aver-

age return to normal activity within a week of the UroLift® procedure, rather than 1–2 months for other surgical options, has positive implications for patients, their employers, and their caregivers. With symptom relief 2–3 times greater than what is achievable with medications, men can become more productive over a longer period of time. Because the procedure is more tolerable than other surgical options – and without the ubiquitous threat to sexual function – men may become more future-focused, addressing prostate obstruction earlier and breaking the cycle of steady decline in bladder health that is evident in the current treatment paradigm.

Addressing bladder health: Breaking the cycle

Younger men suffer under the illusion of immortality – mature men grapple with the reality of mortality. The introduction of a completely new approach to BPH treatment affords an opportunity to realign the value proposition. Offering a treatment that is more easily tolerated and is associated with fewer risks than current surgical techniques may be attractive both to present-focused men who want a “quick fix” and future-focused men who realize that an earlier intervention will preserve their health in the long run.

TURP and TURP-like procedures (eg, laser) are effective for reducing the prostate obstruction; however, they are generally not effective for men in their 80s and often introduce new problems for patients and payers. Five percent of patients require reoperation at 8 years,^{1,17} and each operation is associated with:

- 3–5 days in the hospital
- A 4- to 6-week recovery period
- Catheterization for 1–2 weeks postoperatively
- A 65% risk of ejaculation dysfunction¹
- A 10% risk of impotence¹

The potential for positive impact of treatment is highest at the early stages of BPH because the bladder is healthy. This potential diminishes as palliative BPH medications yield modest, diminishing symptom relief, with bothersome side effects, and the disease progresses to the point of surgery. The inherent value of an earlier, more effective (compared with medical management) and durable solution lies in the fact that a less invasive procedure may encourage men to be more future-focused (ie, to relieve their bladder obstruction earlier in the disease process). Patients treated early may be less likely to progress to surgery or medical bladder dysfunction. If surgery is required in the future, the bladder is more likely to respond with fewer complications and less follow-on care.

Cost benefit analysis: The big picture

Episode of care savings. Any discussion of costs associated with BPH must include: (1) the substantial indirect costs (eg, compromised quality of life and work productivity for both the patient and his spouse/life partner), (2) the direct costs (eg, medications, repeated visits for medical management) of managing an escalating condition until surgery is the only option, and (3) the substantial cost of treating adverse events associated with current indexed BPH treatment alternatives. Currently available surgical approaches are associated with risks of general anesthesia, nosocomial infection

related to overnight or extended inpatient hospitalization, complications (eg, hemorrhage, sexual dysfunction, urinary tract infection secondary to catheterization, urinary retention, incontinence), follow-on care, and re-treatment.

Over the last decade, the practice of urology has undergone a major shift away from the hospital setting – from 2% of total procedures done in the practitioner office or ASC setting in 2001 to 39% of total procedures done in the office or ASC setting in 2012. (Linear regression [based on 2004–2009 Thomson-Reuters Database procedure volume and site of service data] used to project to 2010–2012.) Given the current economic landscape and continued increases in the cost of health care, the prospect of a new technology that safely lowers the barrier to earlier care for patients with a chronic condition – and is performed in a reduced-cost setting – is an attractive one that offers value to patients, health care providers, and payers alike.

Patients, providers, and payers desire solutions that are cost-effective in the short term as well as the long term. As shown in Figure 7, the reduced costs associated with an outpatient venue, fewer personnel requirements, less anesthesia and operative time, and shorter postoperative management period lead to substantial cost savings with UroLift® versus TURP. UroLift® also avoids costs associated with alternative surgeries’ 20% perioperative complication rates.

The foregoing does not imply that UroLift® System treatment is a replacement for alternative surgical procedures; in fact, for many men, it is not. An apt analogy for UroLift® versus TURP might be cardiac stenting/angioplasty versus coronary artery bypass graft (CABG) surgery. The availability of a more tolerable yet durable treatment for angina (angioplasty) has led to earlier treatment in the progression of heart disease without replacing CABG. The introduction of UroLift® may precipitate a similar shift in the treatment of bladder disease. Ultimately, the clinical goal is to promote an appropriate therapeutic choice for each unique patient. This is best accomplished by means of

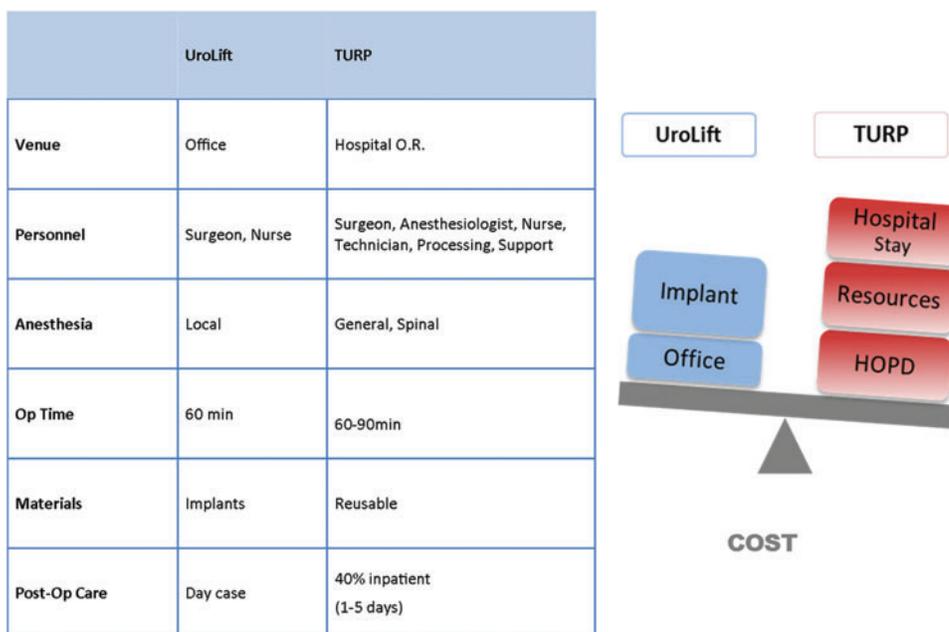
physician-patient discussions regarding risks and benefits within the context of the disease’s progression, and by frank appraisals of the medical, social, and economic costs of delayed or nontreatment of a chronic condition.

Longitudinal savings. Although AUA guidelines and other meta-analyses offer insight into complication rates associated with BPH treatments, these are based on tightly controlled clinical studies. Often, further understanding is gained by analyzing the “real world” data available from health care systems. To that end, NeoTract and Medical Technology Partners conducted an extensive study of the Medicare Standard Analytical Files (SAF) to methodologically analyze how cost and outcomes differ by BPH patient treatment choice. The SAF represents a random sample of 5% of Medicare claims and has been shown to be a statistically valid representation of Medicare trends.

The study population consisted of approximately 67,000 male Medicare recipients who filed a claim associated with LUTS as a diagnosis in 2009. Three BPH diagnoses accounted for nearly 80% of obstructive BPH diagnoses (Diagnosis-Related Groups 600.01, 600.21, 600.91). Of these, 4044 patients received TURP, PVP or TUMT as a primary treatment (no index procedure in the previous year). Costs, charges, and procedure counts were tracked from the original treatment in 6-month intervals up to 2 years. Drug costs are not included in the SAF file. An additional 58,000 men had LUTS-related claims but did not receive interventional procedures.

Several important findings illuminate the true cost of BPH treatment choices; in particular, the costs associated with re-treatment and the often hidden cost of treating complications. Of equal interest was the finding that men suffering from BPH who do not receive interventional treatment represent a significant cost to the health care system. For the 58,000 men studied, the average charges over a 2-year period were \$1129 with an average Medicare payment of \$359. Considering that this group represents only 5% of Medicare claims, the national cost estimate would be \$415 million

FIG. 7. Considering the entire cost of an episode of care. HOPD, hospital outpatient department; OR, operating room; TURP, transurethral resection of the prostate. A color version of this figure is available in the online supplement at www.liebertonline.com/pub/pop.



excluding the cost of BPH medications (ie, \$800–\$2000 per patient per year.)

Re-treatment rates for BPH procedures were somewhat higher than those observed in controlled clinical studies. Over 2 years, re-treatment after TURP, PVP and TUMT were 4.3%, 7.7%, and 13.7%, respectively. Costs associated with repeat procedures and follow-up were significant, with an average charge per original patient of \$2744 and Medicare payments of \$847 per patient over 2 years. The charges for re-treatment of TURP and PVP were \$1087 and \$1417 with Medicare payments of \$353 and \$439, respectively.

Treatment related to complications is perhaps the most interesting finding in this study. In general, patients who underwent a BPH procedure were 2–3 times more likely to have an emergency room visit than those with no procedure (TURP and control encounters per person were 0.216 and 0.097, respectively). One of every 2 men receiving TURP or PVP required a cystoscopy during the following 2 years (0.52 cystoscopies per patient). A major complication of both TURP and PVP in the study population was the 3% rate of iatrogenic permanent incontinence.¹ TURP and PVP were associated with 0.11% and 0.09% rates, respectively, for high-cost artificial urinary sphincter implantations; the rate for untreated patients was 0.01%.

BPH surgery's greatest "hidden cost" was revealed when tracking only genitourinary procedures. TURP and PVP were associated with charges of \$7203 and \$7156, respectively, for genitourinary procedures excluding retreatment for BPH. (Medicare paid \$2160 and \$2277, respectively.)

This Medicare claims database analysis suggests that the actual 2-year cost of the "standard of care" TURP procedure far exceeds the listed \$2739 payment; rather, it amounts to a total of \$8524 per patient over 2 years. The total is derived from a 60:40 blend of payments for inpatient:outpatient procedures (\$6011) plus an additional \$2513 in re-treatment and treatment of iatrogenic complications over the following 24 months.

Key Findings from Medicare Study

- Standard of care procedures (TURP, PVP) resulted in over \$2000 per patient in additional genitourinary procedure payments over 2 years post index procedure.
- Less invasive TUMT microwave treatment was associated with a much higher rate of repeat prostate procedures (including repeat TUMT) as well as conversion to TURP and PVP.
- Two-year longitudinal costs of current BPH procedures are 42% to 93% higher than the simple cost of the episode of care.

Although UroLift[®] is not yet in the Medicare database, it will be important to track this technology once it is adopted. When evaluating how this novel therapy translates to cost-effective advantages, it will be important to compare it to the longitudinal reality of the standard of care. Treatment with the UroLift[®] system is associated with a low 5%–6% re-treatment rate at 2 years, similar to TURP and PVP; importantly, UroLift[®] has not been associated with any of the typical major complications of the standard surgical procedures. Clearly, UroLift[®] represents the potential for substantial longitudinal savings.

Expert Panel Discussion: Value Perspective

- *Focus on Return on Investment* – As mentioned, it is important to show near-term and longer-term cost benefit. With an implant system that could be more expensive than some of the other therapies as an episode of care cost, it will be important to model the costs avoided by using UroLift[®] (eg, nursing home placement for patients needing catheterization, operative morbidity/mortality).
- *Focus on Commercial Payers* – Although Medicare processes must be pursued, a compelling value proposition such as that of UroLift[®] may resonate and be more rapidly covered by cost conscious commercial insurers.
- *Approach Employers* – Inform large employers and/or business coalitions on health (eg, National Business Coalition on Health) of the benefits and potential cost savings of early intervention. Self-insured employers have a vested interest in covering health care services that improve worker productivity.
- *Develop Cost Models with Claims Databases* – The longitudinal BPH study conducted with Medicare SAF database lays an excellent foundation and, as UroLift[®] is adopted, it will be important to use both Medicare and individual payers' real-world cost data to model costs.

Patient and Family Engagement

As described by the Institute of Medicine in 2001, patient-centered care is care that is respectful of, and responsive to, individual patient preferences, needs, and values. Ultimately, it ensures that the patient's values guide all clinical decisions: "...the most important attribute of patient-centered care is the active engagement of patients when fateful health care decisions must be made – when an individual patient arrives at a crossroads of medical options, where the diverging paths have different and important consequences with lasting implications."³⁹

Tools for facilitating informed choice and providing decision support

Decision aids. Decision aids to promote patient-centered care include such things as pamphlets, brochures, and booklets; oral, scripted presentations; audiovisual or digital recordings; and computer or Web-based software applications. Although the literature is clear that decision aids increase patient knowledge, decrease decisional conflict, increase satisfaction, and decrease the use of aggressive care, the communication is 1-way and unmediated.

Results of a population-based survey mailed to 878 physicians (surgeons, medical oncologists, and radiation oncologists) revealed that only 46% of respondents were aware of decision aids related to their areas of practice and, of these, only 24% reported using decision aids in the context of routine care. The main barriers to the use of decision aids in practice appear to be a lack of awareness and limited time and resources.⁴⁰

Decision-support interventions. In contrast to decision aids, decision-support interventions help people think about the choices they face, describe where and why choice exists, and provide information about options including, where reasonable, the option of taking no action. Decision-support

interventions can be used for 1-way delivery of information to patients (unmediated) or in the context of a 2-way interaction between a patient and a health care provider (mediated).⁴¹ The mediator may be a nurse or other health care professional, or a family member.

Decision counseling. Mediated decision making is an essential component of decision counseling. A decision counselor initiates a dialogue with the patient to provide information about the decision to be made. To help the patient clarify his or her preferences, the counselor reviews information, identifies and ranks the factors influencing the patient's decisions, determines the relative importance of each factor for the patient, computes and interprets a patient preference score, and verifies the patient's preference. Results of decision counseling sessions are useful in physician-patient shared decision making.

A study was conducted comparing the relative effectiveness of (1-way, unmediated) decision aids with (2-way, mediated) in-office counseling in communicating information about the prostate gland, common prostate problems in the general population, screening tests, and what related issues can be addressed in the PCP's office. Decision aids were mailed to the study population (asymptomatic male patients, age 50–69 years, who were eligible for prostate cancer screening and had a scheduled appointment for non-acute care at one of 2 urban primary care practices) and prostate screening prompts were added to all charts. The control group completed an in-office satisfaction survey, and the study group received an in-office counseling session wherein a nurse reviewed the information and verified patient understanding. Results showed statistically significant positive changes, both in patient knowledge and informed decision making, in the intervention group.

Informed choice and decision support for prostate care

The Prostate Cancer Intervention Versus Observation Trial compared and contrasted active surveillance versus active treatment among men with early-stage, low-risk prostate cancer. From 1994 through 2002, 731 men with localized prostate cancer were randomized to radical prostatectomy or observation and were followed through 2012. At 10 years, all-cause and prostate cancer mortality did not differ significantly between men who underwent a radical prostatectomy and those who were observed.⁴² Researchers concluded that active surveillance is a reasonable treatment option for men with early-stage, low-risk prostate cancer.

Prostate and bladder health are vital to the well-being of the mature male population; however, the risks and benefits associated with treatment options for BPH make choices difficult for many patients. What can physicians do to help patients understand their conditions and to make decisions in the face of counterintuitive, sometimes controversial, evidence?

In an ongoing study of patients with low-risk prostate cancer – the Decision Counseling about Active Surveillance and Active Treatment Study – the goal is helping the patient understand the value proposition. After participating in a counseling session, a summary report is sent to the patient and shared with the clinical team. A follow-up call is made to the patient 5 days after the appointment, and an end point

chart audit is completed after 90 days. Used by nurses, physicians, and other health care professionals, the online decision counseling program contains an options grid with frequently asked questions and active surveillance/active treatment options (eg, prostatectomy, radiation). The 30-minute process is focused on helping the patient clarify what he wants to do.

The measure of success for the study is the movement away from uncertainty rather than the specific decision made. The current small sample suggests a positive change both in knowledge and clarity about treatment choices, and a reduction of decisional conflict.

Ideally, patients make rational decisions based on the data, but this is not necessarily the case. Many patient decisions are driven by impressions of the data (eg, How likely is it that I'll be around to see my grandkids?). Informational points can change the decision.

It is important to recognize that BPH is a couples' disease and involvement of the patient's spouse or partner in decision making is key. Women, the primary purchasers of health care services, often come to counseling sessions with men, and the counselor shares information with and listens to both parties.

Expert Panel Discussion: Patient Perspective

- The patient can make a good decision only if all durable treatment options are included in the counseling. Involving knowledgeable people in explaining the options is essential.
- For counseling to be effective and unbiased, patients must be reassured that they have made the best decisions they are able to make.
- In real-world settings, all patients are initially placed under active surveillance. With capitation rates of less than \$40 per month, there is little incentive to "actively" follow patients.
- Learn about engaging patients from the disease management industry. To a large extent, engagement depends upon who makes calls and who presents the material.
- Electronic medical record vendors may be able to elicit information on patient preferences and integrate patient feedback from a population perspective.
- Develop educational information for patients and spouses that discusses treatment options from the standpoint of long-term benefits with aging as well as short-term preventive benefits.
- Many men seek health information outside of the physician office setting. Men for whom drugs are ineffective and men who want to avoid TURP use the Internet and communicate online. Create an awareness campaign to educate and engage patients.

Summary

With the aging of the population, BPH is becoming better recognized as a chronic health issue for most American men. When the bladder is obstructed by an enlarged prostate over time, bladder health is seriously compromised. Existing treatment options include active surveillance, medications for symptom relief in mild cases (with poorly tolerated side

effects for many patients), and surgical removal in severe cases (associated with high costs and serious postoperative complications).

The UroLift® System is a minimally invasive procedure that addresses bladder outflow obstruction caused by the prostate, thus relieving symptoms and allowing for continued bladder health. It is often performed under local anesthesia in an outpatient setting and produces rapid symptom relief while preserving sexual function. The procedure can be performed earlier in the course of the disease, thereby promoting bladder health and avoiding secondary complications of BPH. Having published American and international clinical studies and built cost-effectiveness models, NeoTract, Inc., plans a US launch of the technology in late 2013.

Although new to the US market, this technology has been well studied and has already been incorporated into standard practice in some countries. A health economic analysis conducted with the Medicare claims database indicates significant opportunity to address patient needs while also reducing short- and long-term costs for public payers and health care systems.

There is a fundamental opportunity to reframe BPH as a disease that involves the health of the bladder as well as the prostate. The UroLift® System is a potentially disruptive innovation – one that leads to what David E. O’Ryan, President and Cofounder of Advanced Technology and Marketing Group, LLC, would term the “constructive integration of existing, new and forward thinking innovations” that can improve economic benefits to the entire health care system.

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