Prostatic urethral lift: a novel approach for managing symptomatic BPH in the aging man

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Introduction: *Benign prostatic hyperplasia (BPH) is an obligate disorder of the aging male prostate with close associations to other metabolic conditions of aging including obesity. Clinical manifestations of this chronic disorder increase as men age suggesting that a growing number of older men will require intervention for progressive voiding symptoms or bladder dysfunction.*
Materials and methods: *The Prostatic Urethral Lift (PUL) procedure represents a new endoscopic approach in which small permanent intraprostatic implants are positioned to correct bladder outlet obstruction without tissue destruction. An overview of the treatment modality, review of recent literature, and analysis of data in the context of cost considerations is presented.*
Results: *The mean symptom score improvement of the prospective, sham controlled, pivotal trial was 11 points, 88% greater than sham controls. Multiple studies have confirmed symptom score improvement of at least 52%. Durability has been established out to 3 years. A randomized comparison between PUL and transurethral resection of the prostate (TURP) established PUL as superior to TURP in terms of a composite BPH6 endpoint which incorporated symptom relief, quality of recovery, erectile function preservation, ejaculatory function preservation, continence preservation, and safety. The National Institute for Health and Care Excellence of the United Kingdom conducted an analysis that found PUL is less costly than TURP. Earlier management with PUL may even reduce overall cost for those patients managed with medication.*
Conclusion: *Current reports have demonstrated rapid voiding symptom improvement with a low risk of adverse events suggesting that this procedure represents a safe and cost effective new paradigm for the early therapy for BPH/LUTS.*

Key Words: aging male, disease progression, prostatic urethral lift, safety

Introduction

Benign prostatic hyperplasia (BPH) is an obligate disorder of the aging male prostate that is associated with alterations in both the stromal and glandular components of this gland. The underlying pathophysiology likely involves an autosomal dominant inheritance pattern, inflammation within the stromal compartment that stimulates glandular epithelial proliferation and contributions from alterations in nuclear steroid hormone receptor function. Additionally, metabolic factors such as hyperinsulinemia and dietary lipids may stimulate glandular hyperplasia, as BPH is more common in men with Type 2 diabetes mellitus and obesity.

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The number of older men in whom clinical BPH may be a relevant health concern is increasing. One examination of decennial life tables in the US population has found that the life expectancy for a man has increased by 26.5 years between 1900 and 2000.[1] The successful extension in length of life in the United States has also been associated with an increase in the number of chronic disorders suffered by elderly individuals. These disorders may represent as much as 50% of the US health burden with all the attendant costs of care. An analysis of the Canadian population suggests that the number of men older than 50 years of age will increase by 39.5% between 2005 and 2018 with a prediction of a 41% increase in the number of individuals with BPH/LUTS.[2]

The histologic manifestations of BPH begin as early as the second decade in a man's life and appear to precede the clinical enlargement of the prostate gland by approximately 10 years.[3] Autopsy series have demonstrated that approximately 10% of men younger than 30 years of age have histologic BPH with the incidence increasing to 42% by age 60 and 88% for men in the 8th decade of life.[4] While histologic BPH is almost ubiquitous in the prostate glands of aging men, clinically significant enlargement that results in lower urinary tract voiding symptoms (LUTS) and bladder outlet obstruction develops in approximately one half of these men.[5]

Medical management of BPH/LUTS with alpha adrenergic receptor blocking agents and 5-alpha reductase inhibitors has been codified into national guideline documents.[6] Agents such as finasteride, either alone or in combination with an alpha blocking agent, have been shown to reduce the progression of BPH related complications or surgical intervention.[7] However, the available clinical information suggests successful management of symptoms for only as long as 4 years. Furthermore, urodynamic evaluation of men receiving medical management with agents such as doxazosin has found that the therapy does not correct the underlying bladder outlet obstruction even as the LUTS improve significantly.[8,9] Therefore, it remains likely that a sizeable minority of men will still require a surgical intervention in an effort to achieve better symptom control or to prevent deterioration in bladder related events such as urinary retention.[5] Roehrborn has estimated this minority to be as high as 30% of the men initially managed with medical therapy.[10]

It is likely that the need for intervention will escalate, as healthy men grow even older. Information from the Baltimore Aging Study demonstrated that in 1057 men followed for 30 years the group aged 40-49 with voiding symptoms had a 13% probability of receiving prostate surgery for BPH while an older group aged 50-59 had a 39% likelihood of receiving bladder outlet related surgery.[11]

BPH and associated LUTS represents a chronic condition for which more safe and cost effective interventions would be valuable, particularly since this phase of life is already associated with the highest health care expense. Any significant improvement in the management of such a chronic condition would likely result in an overall reduction in the functional limitations experienced by older men. The improvement that could follow from a renewed focus on the resolution of bladder outlet obstruction with surgical intervention, rather than palliation of associated symptoms with the current pharmacologic agents, could result in quality of life improvements for older men equivalent to new advancements in the management of coronary artery disease.[12]

The Prostatic Urethral Lift (PUL) procedure is a novel endoscopic therapy for resolving prostate related bladder outlet obstruction through the creation of an open urethral channel from the bladder neck to the prostatic apex. By significantly reducing the toxicity associated with surgical treatment of bladder outlet obstruction, PUL may offer a positive shift in the treatment paradigm, allowing for improved preservation of bladder function in a large minority of men seeking treatment for LUTS associated with BPH.

Surgical intervention choice and candidate selection

Since extirpative procedures such as transurethral resection of the prostate (TURP) and open simple prostatectomy have demonstrated effective and sustained improvement in voiding symptoms over at least 10 years of follow up, it is important to understand the change in the paradigm for the choice and timing of surgical intervention.[13] Malaeb and co-workers evaluated the 100% Medicare carrier file from 2000-2008 and found that there was an overall decline in all BPH interventions by 15% during this time period. The number of hospital based TURP procedures declined while laser vaporization, outpatient procedures and office based procedures increased by approximately 51% during this time period.[14] Importantly, the decline in surgical procedures for BPH/LUTS is occurring at the same time that the number of men with clinically significant BPH is growing larger.

The explanation for changes in surgical selection has not been established but may be secondary to toxicity and cost considerations. Established adverse events following monopolar TURP include the need for transfusion, TUR syndrome from absorption of hypotonic irrigation fluid, capsular perforation, urethral stricture and incontinence. These outcomes may be mitigated to some degree with a change to bipolar resection or with laser resection techniques.[15,16] There appears to be a 0%-16% incidence of erectile dysfunction with a wide variety of medical and surgical treatments for BPH.[17] Additionally, men may be dissuaded by the risk of ejaculatory dysfunction reported to occur in approximately 67% of surgically treated patients.[18,19] Finally, cost savings of laser vaporization techniques relative to TURP may be of influence.[20] Despite potential cost reduction, the overall per patient expenditures appear to have increased suggesting that optimizing candidate selection and reducing adverse events continue to be warranted.[21]

Traditional indications for surgical intervention in men with BPH/LUTS include the development of urinary retention, recurrent urinary tract infections, bladder calculus and renal insufficiency. These outcomes likely represent the final stages of bladder dysfunction and may not resolve adequately after delayed surgical therapy. Surgical extirpation is also recommended for LUTS that are incompletely responsive to medical therapy. This indication requires monitoring of voiding symptoms with regular completion of validated patient questionnaires.[22] Importantly, the information obtained from these questionnaires may be inadequate for the prediction of BPH progression. Therefore, the early diagnosis of BPH related bladder outlet obstruction that is likely to progress to medically deleterious bladder dysfunction remains a clinical goal for physicians.

Disease progression is a transition from one health state to a more deleterious state, and it follows that there could be baseline characteristics or measureable factors during initial management that predict this transition. Roehrborn has reviewed the data from several prospective placebo controlled trials of the medical management of BPH and identified advancing age (more acute urinary retention episodes in men between 70-79 compared to 40-49 years of age), initial symptom severity (moderate to severe versus mild) and initial serum prostate-specific antigen (PSA) level as associated with symptom progression, acute urinary retention or need for a prostatic procedure.[23] A pelvic ultrasound may provide additional information for stratifying risk of disease progression. Pelvic ultrasound performed through a suprapubic window can measure bladder wall thickness as well as ultrasound estimated bladder weight. Both of these measurements have been linked to the presence of bladder outlet obstruction and provide some information about response to therapy and future progression of disease.[24-26] The ultrasound finding of intravesical prostate protrusion may be a more predictive metric with a close correlation to peak detrusor pressure on pressure flow urodynamic evaluation.[27,28] Additionally, prostatic anatomy as visualized directly with cystoscopy or by pelvic ultrasound can influence the likely efficacy of surgical interventions such as the prostatic urethral lift.

Prostatic urethral lift as a potential shift in BPH treatment paradigm

The advent of the PUL procedure may represent a promising opportunity to reduce BPH related bladder outlet obstruction in the largest cohort of men with prostate volumes below 80 cm^3 while addressing concerns regarding treatment associated toxicity. A rigid cystoscope is used to deliver small, permanent transprostatic UroLift implants, Figure 1, (Neotract, Inc., Pleasanton, California, USA) which are positioned in the anterior and lateral aspects of the prostatic urethral lumen. Once the prostate lobe is compressed with the cystoscope, the implant tethers the compressed tissue to the prostatic capsule, thereby holding the coapting prostatic tissue apart and establishing an open anterior lumen from the bladder neck to the veru montanum, Figure 2. A prospective, sham controlled double blind (patient and assessor) clinical trial enrolled 206 men in 19 centers and demonstrated a mean symptom score improvement of 11 points (88% greater than sham controls) with durability established out to 3 years.[29,30] The results of this trial supported the decision for FDA approval of the implant device in 2013. The efficacy of the procedure has been validated in several additional clinical reports further demonstrating an improved symptom score of at least 52% at 12 months following the intervention, Table 1a, b, c.[31-35] Importantly, a recent randomized comparison between the PUL and TURP established the new implant procedure as superior to the TURP in terms of a composite BPH6 endpoint that measures symptom

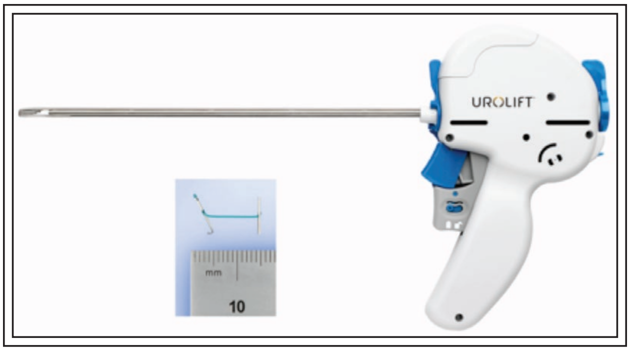

Figure 1. UroLift implant system. Courtesy of NeoTract, Inc.

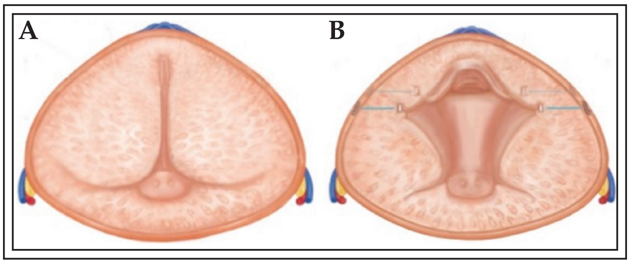

Figure 2. Prostatic urethral lift (PUL) procedure. **A)** Prior to treatment, lateral prostate lobes obstruct urethra; **B)** after PUL, small transprostatic implants hold compressed prostate lobes to surrounding capsule, thus opening an anterior channel through prostatic fossa.

TABLE 1a. **Summary of prostatic urethral lift clinical study results (2 weeks and 3 months)**

Study			**2 weeks**			**3 months**		
IPSS	**No.**	**Baseline**	**Follow up**	**Change**	**% Change**	**Follow up**	**Change**	**% Change**
Roehrborn 2015	140	22.1 (5.4)	18.0 (7.9)	-4.3 (7.6)	-17	11.0 (7.6)	-11.1 (7.7)	-50
Sonksen 2015	45	21.9 (5.7)	14.6 (7.7)	-7.3 (9.4)		10.5 (7.4)	-11.7 (8.5)	
Cantwell 2014	53	23.3 (5.5)	18.8 (8.2)	-4.5 (7.4)	-18	12.3 (7.9)	-11.1 (7.2)	-48
Shore 2014	51	21.5 (5.4)	15.8 (9.0)	-5.7 (9.6)	-24			
McNicholas 2013	102	22.7 (5.6)	14.5 (7.2)	-8.2	-36	10.7 (6.3)	-12.6	-54
Chin 2012	64	22.6 (5.4)	13.2 (6.3)	-9.4	-42	9.1 (5.1)	-13.6	-60
Abad 2013	20	26.7 (6.0)				16.6	-9.9	-37
QoL								
Roehrborn 2015	140	4.6 (1.1)	3.6 (1.6)	-1.0 (1.7)	-17	2.4 (1.7)	-2.2 (1.8)	-47
Sonksen 2015	45	4.7 (1.1)	3.0 (1.9)	-1.7 (2.3)		2.1 (1.5)	-2.6 (1.7)	
Cantwell 2014	53	4.5 (1.2)	3.4 (1.6)	-1.1 (1.7)	-20	2.2 (1.5)	-2.3 (1.7)	-49
Shore 2014	51	4.6 (1.0)	2.9 (2.1)	-1.7 (2.3)	-33			
McNicholas 2013	102	4.9 (0.9)	3.0 (1.6)	-1.9	-39	2.0 (1.4)	-2.8	-59
Chin 2012	64	4.9 (0.9)	2.7 (1.7)	-2.1	-44	2.1 (1.5)	-2.8	-58
BPH II								
Roehrborn 2015	140	6.8 (2.8)	7.0 (3.4)	0.2 (3.9)	30	2.9 (3.0)	-4.0 (3.2)	-56
Sonksen 2015	45	7.3 (2.5)	6.3 (3.3)	-1.0 (4.3)		2.6 (2.9)	-4.8 (3.6)	
Cantwell 2014	53	6.3 (3.0)	6.5 (3.2)	0.2 (2.5)	38	3.0 (2.9)	-3.3 (2.9)	-52
Shore 2014	51	6.7 (3.1)	5.7 (3.9)	-1.0 (4.1)	-3			
McNicholas 2013	102	7.3 (2.5)	5.5 (3.6)	-1.8	-24	3.3 (2.8)	-4.3	-57
Chin 2012	64	7.2 (2.9)	4.4 (3.1)	-2.8	-39	2.5 (2.7)	-4.6	-65
Abad 2013	20	8.4 (2.3)				5.3	-3.1	-37
Qmax								
Roehrborn 2015	140	8.1 (2.4)				12.4 (5.4)	4.2 (5.1)	64
Sonksen 2015	45	9.4 (3.5)				13.6 (5.3)	4.2 (5.0)	
Cantwell 2014	53	9.6 (4.2)				12.1 (6.0)	2.5 (5.3)	34
Shore 2014	51	8.2 (2.2)						
McNicholas 2013	102	9.6 (3.2)	13.3 (4.7)	3.7	38	12.9 (4.5)	4.3	50
Chin 2012	64	8.3 (2.2)	12.0 (7.6)	3.8	45	10.5 (4.1)	2.4	30
Abad 2013	20	8.6 (2.9)				13.5	4.8	55
SHIM								
McVary 2014	83	17.9 (5.9)				17.4 (7.6)	1.3 (4.7)	15
Sonksen 2015	38	20.3 (4.3)				19.7 (5.6)	-0.7 (5.2)	
Cantwell 2014	40	15.1 (7.4)				16.2 (8.1)	0.7 (9.2)	
Shore 2014	34	17.9 (6.4)						
Chin 2012	33	18.2 (4.9)				19.8 (5.3)	2.2	13
MSHQ-EjD function								
McVary 2014	84	9.2 (3.1)				11.0 (3.2)	2.3 (2.6)	36
Sonksen 2015	38	10.6 (2.6)				11.5 (3.5)	0.7 (3.9)	
Cantwell 2014	39	9.1 (3.1)				9.7 (3.6)	0.3 (4.6)	
Shore 2014	34	10.3 (2.6)						
Chin 2012	28	10.6 (2.1)				12.5 (2.6)	1.6	15
MSHQ-EjD Bother								
McVary 2014	84	2.0 (1.6)				1.1 (1.3)	-1.1 (1.4)	-48
Sonksen 2015	38	1.8 (1.8)				1.1 (1.4)	-0.7 (2.1)	
Cantwell 2014	38	2.7 (1.7)				2.2 (1.5)	-0.4 (2.3)	
Shore 2014	34	1.8 (1.4)						
Chin 2012	28	1.5 (1.4)				0.8 (1.2)	-0.7	-48

TABLE 1b. **Summary of prostatic urethral lift clinical study results (1 year and 2 years)**

Study				1 year			2 years	
IPSS	**No.**	**Baseline**	**Follow up**	**Change**	**% Change**	**Follow up**	**Change**	**% Change**
Roehrborn 2015	140	22.1 (5.4)	11.1 (7.0)	-10.6 (7.4)	-48	12.5 (7.8)	-9.2 (7.6)	-42
Sonksen 2015	45	21.9 (5.7)	10.7 (8.1)	-11.4 (8.4)				
Cantwell 2014	53	23.3 (5.5)	14.6 (7.7)	-8.7 (7.5)	-37			
Shore 2014	51	21.5 (5.4)						
McNicholas 2013	102	22.7 (5.6)	11.6 (5.6)	-12.3	-52			
Chin 2012	64	22.6 (5.4)	12.1 (7.1)	-10.4	-46	12.6 (7.2)	-9.2	-42
Abad 2013	20	26.7 (6.0)	15.3	-11	-42			
QoL								
Roehrborn 2015	140	4.6 (1.1)	2.2 (1.6)	-2.3 (1.6)	-51	2.3 (1.6)	-2.2 (1.7)	-48
Sonksen 2015	45	4.7 (1.1)	1.9 (1.6)	-2.8 (1.8)				
Cantwell 2014	53	4.5 (1.2)	2.6 (1.6)	-2.0 (1.7)	-41			
Shore 2014	51	4.6 (1.0)						
McNicholas 2013	102	4.9 (0.9)	2.3 (1.5)	-2.6	-53			
Chin 2012	64	4.9 (0.9)	2.5 (1.6)	-2.4	-49	2.5 (1.8)	-2.2	-48
BPH II								
Roehrborn 2015	140	6.8 (2.8)	2.7 (2.9)	-4.0 (3.3)	-58	2.7 (2.9)	-3.8 (3.4)	-56
Sonksen 2015	45	7.3 (2.5)	2.3 (2.8)	-5.0 (3.7)				
Cantwell 2014	53	6.3 (3.0)	3.4 (2.7)	-3.1 (3.1)	-44			
Shore 2014	51	6.7 (3.1)						
McNicholas 2013	102	7.3 (2.5)	2.9 (2.8)	-4.7	-62			
Chin 2012	64	7.2 (2.9)	3.0 (3.0)	-4.1	-58	2.8 (3.6)	-4.1	-60
Abad 2013	20	8.4 (2.3)	5.0	-3.4	-41			
Qmax								
Roehrborn 2015	140	8.1 (2.4)	12.1 (5.4)	4.0 (4.9)	58	12.4 (5.4)	4.2 (5.0)	58
Sonksen 2015	45	9.4 (3.5)	13.6 (5.5)	4.0 (4.8)				
Cantwell 2014	53	9.6 (4.2)	12.5 (5.3)	2.5 (5.0)	35			
Shore 2014	51	8.2 (2.2)						
McNicholas 2013	102	9.6 (3.2)	11.9 (3.5)	4.0	51	n/a		
Chin 2012	64	8.3 (2.2)	10.8 (3.7)	2.6	32	10.3 (4.1)	2.8	38
Abad 2013	20	8.6 (2.9)	12.8	4.2	48			
SHIM								
McVary 2014	83	17.9 (5.9)	16.7 (7.8)	0.7 (5.12)	19	16.7 (7.6)	1.1 (4.8)	22
Sonksen 2015	38	20.3 (4.3)	20.7 (5.2)	-0.1 (4.7)				
Cantwell 2014	40	15.1 (7.4)	16.8 (6.8)	0.9 (5.7)				
Shore 2014	34	17.9 (6.4)						
Chin 2012	33	18.2 (4.9)	19.7 (5.2)	1.8	10	17.6 (5.6)	1.1	7
MSHQ-EjD function								
McVary 2014	84	9.2 (3.1)	10.3 (3.2)	1.6 (2.7)	28	9.8 (3.3)	1.1 (2.5)	30
Sonksen 2015	38	10.6 (2.6)	11.9 (3.0)	1.3 (3.3)				
Cantwell 2014	39	9.1 (3.1)	10.1 (2.6)	0.8 (2.8)				
Shore 2014	34	10.3 (2.6)						
Chin 2012	28	10.6 (2.1)	11.1 (3.0)	0.2	2	9.3 (2.8)	-1.1	-11
MSHQ-EjD Bother								
McVary 2014	84	2.0 (1.6)	1.4 (1.4)	-0.8 (1.6)	-28	1.6 (1.5)	-0.6 (1.5)	-21
Sonksen 2015	38	1.8 (1.8)	1.2 (1.1)	-0.5 (2.2)				
Cantwell 2014	38	2.7 (1.7)	2.1 (1.3)	-0.4 (1.4)				
Shore 2014	34	1.8 (1.4)						
Chin 2012	28	1.5 (1.4)	0.8 (0.9)	-0.7	-48	1.6 (1.4)	0	0

TABLE 1c. **Summary of prostatic urethral lift clinical study results (3 years)**

Study	No.	Baseline	Follow up	3 years Change	% Change
IPSS					
Roehrborn 2015	140	22.1 (5.4)	12.7 (8.0)	-8.8 (7.4)	-41
Sonksen 2015	45	21.9 (5.7)			
Cantwell 2014	53	23.3 (5.5)			
Shore 2014	51	21.5 (5.4)			
McNicholas 2013	102	22.7 (5.6)			
Chin 2012	64	22.6 (5.4)			
Abad 2013	20	26.7 (6.0)			
QoL					
Roehrborn 2015	140	4.6 (1.1)	2.2 (1.6)	-2.3 (1.7)	-49
Sonksen 2015	45	4.7 (1.1)			
Cantwell 2014	53	4.5 (1.2)			
Shore 2014	51	4.6 (1.0)			
McNicholas 2013	102	4.9 (0.9)			
Chin 2012	64	4.9 (0.9)			
BPH II					
Roehrborn 2015	140	6.8 (2.8)	2.7 (2.8)	-3.8 (3.3)	-53
Sonksen 2015	45	7.3 (2.5)			
Cantwell 2014	53	6.3 (3.0)			
Shore 2014	51	6.7 (3.1)			
McNicholas 2013	102	7.3 (2.5)			
Chin 2012	64	7.2 (2.9)			
Abad 2013	20	8.4 (2.3)			
Qmax					
Roehrborn 2015	140	8.1 (2.4)	11.8 (4.8)	3.5 (5.0)	53
Sonksen 2015	45	9.4 (3.5)			
Cantwell 2014	53	9.6 (4.2)			
Shore 2014	51	8.2 (2.2)			
McNicholas 2013	102	9.6 (3.2)			
Chin 2012	64	8.3 (2.2)			
Abad 2013	20	8.6 (2.9)			
SHIM					
McVary 2014	83	17.9 (5.9)	17.0 (7.9)	0.5 (4.4)	4
Sonksen 2015	38	20.3 (4.3)			
Cantwell 2014	40	15.1 (7.4)			
Shore 2014	34	17.9 (6.4)			
Chin 2012	33	18.2 (4.9)			
MSHQ-EjD function					
McVary 2014	84	9.2 (3.1)	9.7 (3.5)	0.6 (2.5)	9
Sonksen 2015	38	10.6 (2.6)			
Cantwell 2014	39	9.1 (3.1)			
Shore 2014	34	10.3 (2.6)			
Chin 2012	28	10.6 (2.1)			
MSHQ-EjD Bother					
McVary 2014	84	2.0 (1.6)	1.6 (1.5)	-0.6 (1.5)	-27
Sonksen 2015	38	1.8 (1.8)			
Cantwell 2014	38	2.7 (1.7)			
Shore 2014	34	1.8 (1.4)			
Chin 2012	28	1.5 (1.4)			

relief, quality of recovery, erectile function preservation, ejaculatory function preservation, continence preservation and safety.[36] While, as anticipated, the symptomatic and flow improvements from TURP edged out PUL, when both effectiveness and toxicity are considered, the choice between therapies becomes considerably less formulaic.

If it is true that men and their physicians are concerned about surgically related toxicity and are therefore delaying more definitive intervention in lieu of palliative medication, then the PUL may provide a reason for earlier therapy in men at increased risk of disease progression. The PUL was superior to TURP in terms of preservation of ejaculation and quality of the postoperative recovery.[36] McVary and colleagues employed several validated questionnaires to assess preservation of erectile and ejaculatory function following the PUL and found no evidence of degradation in either aspect of sexual function. In fact, the overall ejaculatory bother score was actually improved by 40% over baseline while some men with the most severe erectile dysfunction experienced an improvement in erectile function after treatment.[37] Additionally, the accumulating clinical experience suggests that the associated adverse events with the PUL are limited to initial dysuria, hematuria, urgency, infrequent bacterial cystitis and rare urinary retention. In particular, the majority of men who receive the PUL do not require a urethral catheter or have a short dwell time of 0.9 days.[29,38]

Finally, cost considerations may influence the choice of BPH therapy in the future as discussed earlier in this review. The PUL may be performed in all available clinical environments from a physician office to the hospital outpatient operating room. The procedure has most commonly been performed under local anesthesia but may also involve intravenous sedation or anesthesia.[38] The National Institute for Health and Care Excellence (NICE) of the United Kingdom recently published a comprehensive health economic analysis that concludes that the PUL is less costly than TURP.[39] The primary health economic advantages of PUL resided in its reliable delivery on an outpatient basis, more efficient resource utilization as an operation, and reduced cost in retreatment (both retreatment for LUTS and treatment of complications are combined). This finding was supported by a similar analysis using a US Medicare database study.[40] Interestingly, in the randomized study, 1 year retreatment for LUTS was 7% and 6% for PUL and TURP, respectively; however when treatment for complications were added, total retreatment comparison was 7% versus 14%.[36] Although no specific cost assessment investigations have yet been performed to compare PUL to medication, rudimentary mathematics would support health economic parity by two to four years, depending on whether the medication is name brand or generic.[41,42] One cost analysis of pharmacologic therapy for BPH estimated a cost of $44,336 per quality adjusted life year for finasteride.[43] Although these cost estimates attempt to take efficacy of therapy into account and can not be directly compared to the cost of a PUL procedure this information certainly suggests an opportunity for cost reduction of earlier management with PUL relative to ongoing medical management in a large population of men.

Conclusion

The population of men over the age of 50 years who are likely to develop clinically significant BPH is growing. Although management with pharmacologic agents following initial evaluation is likely to remain the mainstay of therapy there will be a sizeable minority of men who will require surgical intervention to prevent permanent bladder dysfunction. The combination of age, serum PSA level, symptom severity and pelvic ultrasound may be able to identify these men earlier prior to progression. The Prostatic Urethral Lift procedure appears to be an effective surgical intervention for the relief of bladder outlet obstruction with a low risk of adverse events. If results from widespread adoption as a standard of care ultimately reflect the controlled clinical data showing effective resolution of bladder outlet obstruction with few adverse events and a low retreatment rate, then this procedure is likely to represent an important positive shift in the healthcare burden associated with BPH and LUTS. An example of a UroLift procedure video using local anesthesia can be found on *The Canadian Journal of Urology* web site (http://www.canjurol.com/how-i-do-it).[44]

Disclosure

Dr. Daniel B. Rukstalis served as a co-primary investigator for the FDA monitored randomized trial and currently serves as a consultant for Neotract, Inc. ☐

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