Cost-Effectiveness of Convective Water Vapor Energy Therapy Compared to Prostatic Urethral Lift for Treatment of Benign Prostatic Hyperplasia

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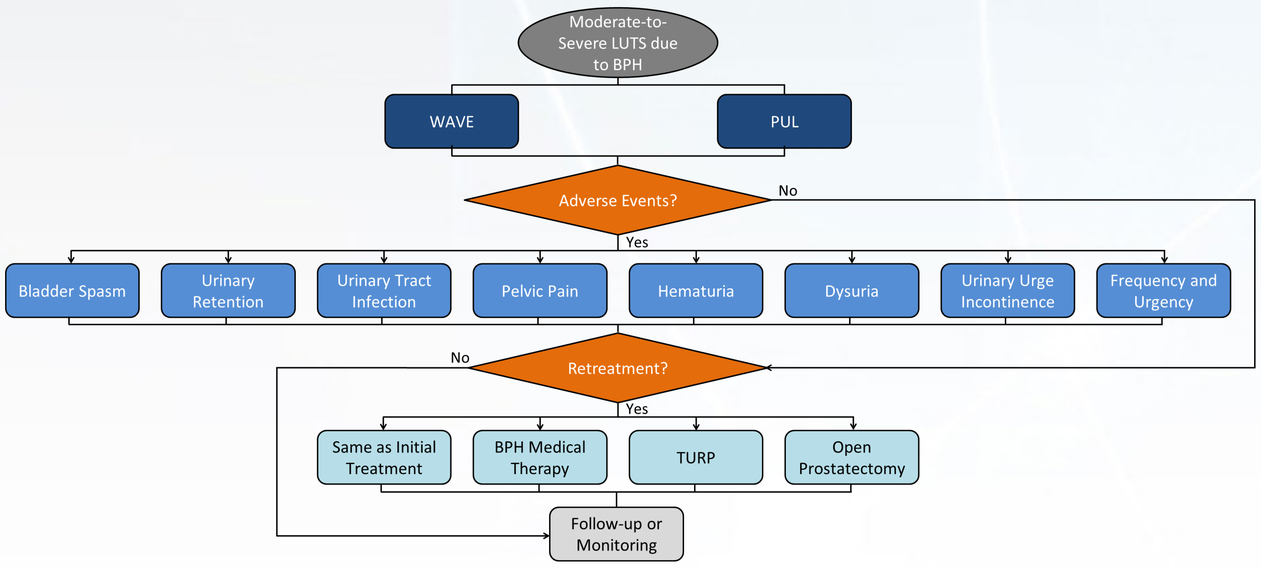
OBJECTIVE

- Benign prostatic hyperplasia (BPH) is a highly prevalent and costly health condition among men ≥50 years old in the United States.[1]
- Men with moderate-to-severe lower urinary tract symptoms (LUTS) often begin with pharmacotherapy; however, 6-month adherence to pharmacotherapy is relatively low (~32%).[2]
- Convective water vapor energy therapy (WAVE: Rezum™ System) and prostatic urethral lift (PUL: Urolift™ System) are safe and effective minimally invasive surgical treatment options for men with BPH experiencing moderate-to-severe LUTS.
- We sought to estimate the cost-effectiveness of WAVE compared to PUL in the U.S. using long-term clinical trial data.

METHODS

- An Excel-based Markov model was developed to evaluate the cost-effectiveness of WAVE versus PUL from a U.S. Medicare perspective (**Figure 1**).
- The model was constructed with a 4-year time horizon and a 3-month cycle length in the first year and a 1-year cycle length from years 2 through 4.
- The model was populated with males with a mean age of 63 and an average International Prostate Symptom Score (IPSS) of 22.[3]
- Cost-effectiveness was evaluated using a willingness to pay threshold of $50,000 per quality-adjusted life year (QALY) gained and presented as an incremental cost-effectiveness ratio (ICER).

Figure 1. Model Schematic



- Clinical inputs for WAVE and PUL were obtained from the Rezum II[3,4] and LIFT[5,6] randomized controlled trials and are presented in **Table 1**.
- 73% of initial treatments occurred in an office setting and 27% in an ambulatory surgical center.[7]
- Clinical measures included IPSS, LUTS-related adverse events (AEs) and retreatment rates.
- AEs for WAVE[3] and PUL[5] were reported at 0-3 and 4-12 months; 4-12 month rates were evenly distributed across the corresponding 3-month cycles. No AEs were assumed to occur after 12 months.
- Retreatment rates were calculated from the Rezum II and LIFT CONSORT diagrams[4,6] using life-table survival analysis.

Table 1. Clinical and Utility Inputs

	WAVE		PUL		
	0-3 Months	4-12 Months	0-3 Months	4-12 Months	Utility
Mean IPSS*	22.0[3]	10.3[3]	22.2[5]	11.5[6]	0.79/0.90[8]
Adverse Events					
Bladder Spasm	N/A	N/A	3.6%[5]	0.7%[5]	-0.06[9]
Urinary Retention	3.7%[3]	0.0%[3]	0.7%[5]	0.7%[5]	-0.18[9]
Urinary Tract Infection	3.7%[3]	0.0%[3]	2.9%[5]	0.0%[5]	-0.07[9]
Pelvic Pain	2.9%[3]	0.0%[3]	17.9%[5]	1.4%[5]	-0.03[†]
Hematuria	11.8%[3]	0.0%[3]	25.7%[5]	0.7%[5]	-0.26[10]
Dysuria	16.9%[3]	0.7%[3]	34.3%[5]	0.7%[5]	-0.03[9]
Urinary Urge Incontinence	N/A	N/A	3.6%[5]	0.7%[5]	-0.20[9]
Frequency and Urgency	5.9%[3]	0.0%[3]	7.1%[5]	2.1%[5]	-0.03[†]
Catheterization	90.4%[3]		51.4%[5]		-0.05[11]
Retreatment Type					
WAVE	15.4%[4]		N/A		N/A
PUL	N/A		21.9%[6]		N/A
BPH Medical Therapy	53.8%[4]		40.6%[6]		-0.03[9]
TURP[‡]	23.1%[4]		37.5%[6]		-0.14[12]
Open Prostatectomy	7.7%[4]		0.0%[6]		-0.16[13]

*Baseline and 12 months; [†]Assumption; [‡]TURP, Transurethral Resection of the Prostate

- Follow-up, monitoring and AE care was assumed to occur in a physician office visit.
- Utility values for BPH health states and disutility values associated with catheterization, AEs, and retreatments were retrieved from published literature (**Table 1**).[8-13]
- Utility decrements for AEs were applied for a finite period of time using the mean time to recovery retrieved from Rezum II.[7]
- Procedural and AE-related costs were based on 2019 Medicare national reimbursement rates (**Table 2**).[14]
- BPH medical therapy costs for retreatment were based on the average spending per dosage unit using 2017 Medicare Part D Drug Spending[15] and inflated to 2019 USD.[16]
- One-way sensitivity analysis (OWSA) and probabilistic sensitivity analysis (PSA) were conducted to assess the impact of parameter uncertainty on model results. For OWSA, all model inputs were varied by ± 10%.

Table 2. Cost Inputs

	Costs	Codes
Initial Treatment		
WAVE	$1,689	CPT 53854
PUL	$5,617	CPT 52441, 52442; HCPCS C9740
Office Visit	$75	CPT 99213
Catheterization	$75	CPT 99213
Retreatment Type		
WAVE	$1,689	CPT 53854
PUL	$5,617	CPT 52441, 52442; HCPCS C9740
BPH Medical Therapy	$415	Tamsulosin HCL once daily
TURP	$4,793	CPT 52601; DRG 714
Open Prostatectomy	$7,511	CPT 55821; DRG 667

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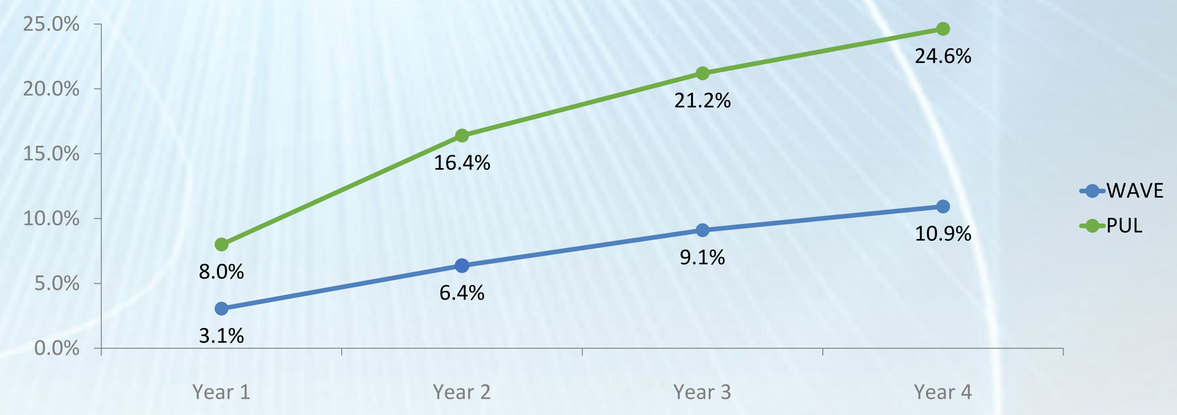
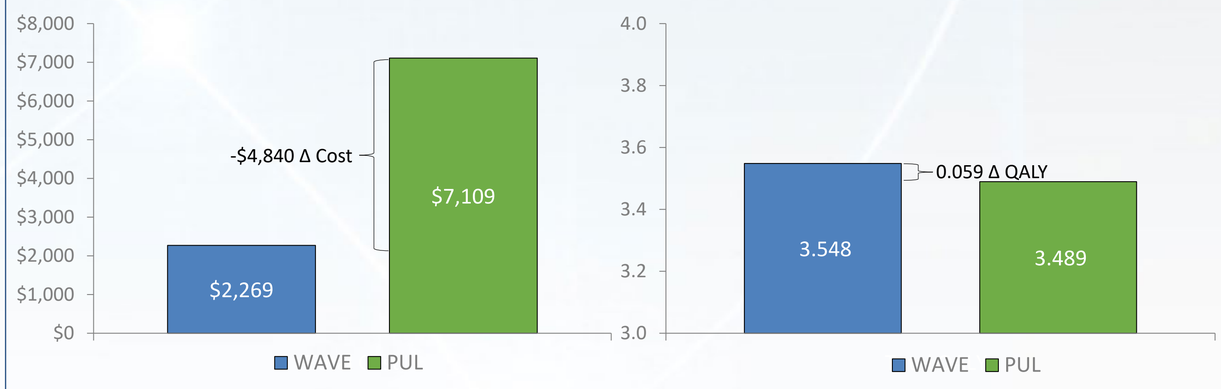
RESULTS

Figure 2. Retreatment Rates at 4 Years



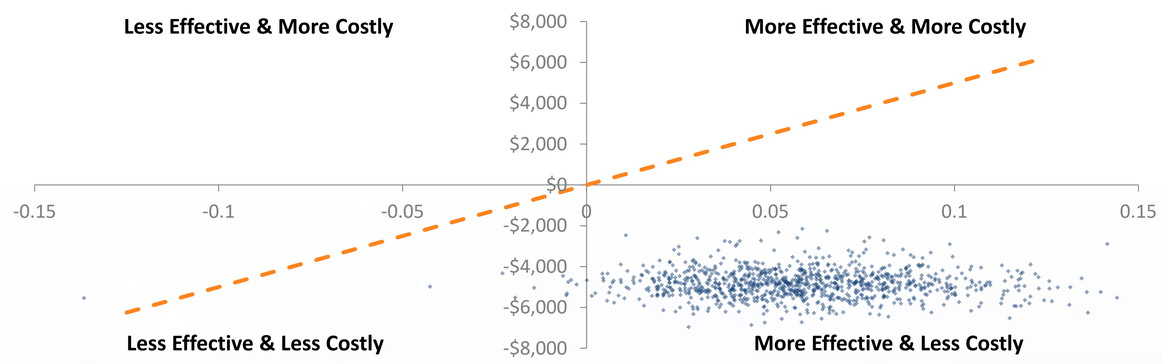
- The retreatment rate at 4 years was 10.9% for WAVE compared to 24.6% for PUL (**Figure 2**).
- At 4 years, WAVE was associated with 73% lower retreatment costs than PUL ($247 vs $923) and 68% lower total costs ($2,269 vs $7,109).
- WAVE was associated with greater QALYs than PUL (3.548 vs 3.489).

Figure 3. Total Costs and QALYs at 4 Years



- WAVE was more effective and less costly than PUL, making it the dominant treatment.
- OWSA demonstrated that among the clinical and cost parameters, the initial treatment costs of PUL and WAVE and the retreatment cost of PUL had the most considerable impact on model results.
- PSA showed that WAVE was less costly than PUL 100% of the time and associated with higher QALYs 95% of the time (**Figure 4**).

Figure 4. Scatter Plot of Incremental Costs and QALYs at 4 Years



LIMITATIONS

- This cost-effectiveness analysis was based on an indirect comparison of the Rezum II and LIFT trials as no randomized controlled trial has directly compared WAVE to PUL.
- Further research is needed to understand the cost effectiveness of WAVE relative to other BPH treatment options.

CONCLUSIONS

- WAVE had a lower retreatment rate and was cost saving compared to PUL for the minimally invasive treatment of moderate-to-severe LUTS associated with BPH.
- Given the robustness of these findings, it is highly likely that WAVE would also be cost saving from a commercial payer perspective.

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Disclosures

Drs. Bilal Chughtai and Neal Shore are clinical consultants to Boston Scientific. Kurt Neeser, Vanessa Appah-Gyamenah, Dmitry Gultyaev, and Michael Minshall are paid consultants to Boston Scientific. Sirikan Rojanasarot and Stacey Amorosi are full-time employees of Boston Scientific.