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Cost-effectiveness analysis of minimally invasive surgical treatments for benign prostatic hyperplasia: implications for Japan's public healthcare system

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ABSTRACT

Aims: Benign prostatic hyperplasia (BPH) represents a significant public health issue in Japan. This study evaluated the lifetime cost-effectiveness of water vapor energy therapy (WAVE) versus prostatic urethral lift (PUL) for men with moderate-to-severe BPH from a public healthcare payer's perspective in Japan.

Materials and methods: A decision analytic model compared WAVE to PUL among males in Japan. Clinical effectiveness and adverse event (AE) inputs were obtained from a systematic literature review. Resource utilization and cost inputs were derived from the Medical Data Vision database and medical service fee national data in Japan. Experts reviewed and validated model input parameters. One-way and probabilistic sensitivity analyses were conducted to determine how changes in the values of uncertain parameters affect the model results.

Results: Throughout patients' lifetimes, WAVE was associated with higher quality-adjusted life years (0.920 vs. 0.911 year 1; 15.564 vs. 15.388 lifetime) and lower total costs (¥734,134 vs. ¥888,110 year 1; ¥961,595 vs. ¥1,429,458 lifetime) compared to PUL, indicating that WAVE is a more effective and less costly (i.e. dominant) treatment strategy across all time horizons. Lifetime cost-savings for the Japanese healthcare system per patient treated with WAVE instead of PUL were ¥467,863. The 32.7% cost difference between WAVE and PUL was predominantly driven by lower WAVE surgical retreatment rates (4.9% vs. 19.2% for WAVE vs PUL, respectively, at 5 years) and AE rates (hematuria 11.8% vs. 25.7%, dysuria 16.9% vs. 34.3%, pelvic pain 2.9% vs. 17.9%, and urinary incontinence 0.4% vs. 1.3% for WAVE vs PUL, respectively, at 3 months). Model findings were robust to changes in parameter input values.

Limitations: The model represents a simplification of complex factors involved in resource allocation decision-making.

Conclusions: Driven by lower retreatment and AE rates, WAVE was a cost-effective and cost-saving treatment for moderate-to-severe BPH in Japan compared to PUL, providing better outcomes at lower costs to the healthcare system.

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PLAIN LANGUAGE SUMMARY

Benign prostatic hyperplasia (BPH) is an important public health issue in Japan, given its high prevalence and potential morbidity in a rapidly aging population. This study compared the clinical and economic outcomes of two minimally invasive surgical treatments for BPH (water vapor energy therapy [WAVE] vs. prostatic urethral lift [PUL]) for patients in Japan. Clinical effectiveness and adverse event (AE) information from published medical literature, and real-world health services and cost data from Japan, were used to estimate the impact of the two treatments. Compared to PUL, WAVE was found to provide better clinical outcomes and quality-of-life for patients whilst costing less to the Japanese healthcare system. Patients treated with WAVE had higher lifetime quality-adjusted life years vs. patients treated with PUL (15.564 vs. 15.388). Lifetime cost-savings for the Japanese healthcare system per patient treated with WAVE instead of PUL were estimated to be ¥467,863. The 32.7% cost difference between WAVE and PUL was predominantly driven by lower retreatment rates for WAVE (surgical retreatment rate was 4.9% vs. 19.2% for WAVE vs. PUL, respectively, at 5 years) and AE rates (AE rates at 3 months for WAVE vs. PUL, respectively, were: hematuria 11.8% vs. 25.7%, dysuria 16.9% vs. 34.3%, pelvic pain 2.9% vs. 17.9%, and urinary incontinence 0.4% vs. 1.3%). These findings provide evidence-based insights for clinicians, payers, and health policymakers to further define the role of WAVE for BPH in Japan.

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Introduction

Benign prostatic hyperplasia (BPH) is an important public health issue in Japan, given its high prevalence and potential morbidity in a rapidly aging population[1–3]. BPH affects over 56 million men in Asia[4], with close to 200,000 men over the age of 60 estimated to suffer from symptomatic BPH in Japan each year[5,6]. It is estimated that half of men aged 51–60 have histological BPH and $\geq$25% have moderate-to-severe lower urinary tract symptoms (LUTS)[7]. By age 70, approximately 70% of men have histological BPH and the prevalence is approximately 90% by age 85[7]. Since 27.7% of the population in Japan was 65 years of age or older in 2017, and this proportion is expected to grow to 38.4% by 2065, the number of men with BPH requiring treatment will continue to rise[7].

BPH is associated with progressive LUTS[8], which affects patients, their partners, their caregivers, and society. BPH negatively affects patient quality-of-life[1,9], and chronic LUTS due to BPH are associated with serious medical morbidities and can result in sleep loss, increased risk of falls, reduced productivity, impaired sexual life, social isolation, and clinical depression[1,9–11]. Men in the general population diagnosed with BPH are approximately 1.5–2-times more likely than other men of the same age to rate their current health as only fair or poor[12]. Men with moderate-to-severe BPH reported that their condition caused problems in their marriage, including lack of physical intimacy, avoidance or withdrawal, a feeling of isolation or distance, anger or conflict, and lack of communication[9]. Further, untreated BPH may result in serious complications, including acute and chronic urinary retention, hematuria, urinary tract infection, bladder stones, bladder wall damage, renal dysfunction, incontinence, and erectile dysfunction (ED)[13,14].

The goals of BPH treatments are to (1) improve LUTS; and (2) prevent disease progression that would diminish health and result in the need for invasive surgical procedures[15]. Medication therapy has been considered the dominant first-line treatment of BPH, but long-term clinical utility may be limited since many patients discontinue treatment due to medication intolerance, side-effects, or inadequate symptom relief[16,17]. Surgical treatment is an option for men with clinically significant LUTS attributable to BPH for whom the side-effects of medical treatment are intolerable or where medical treatment has not provided adequate symptom relief. Transurethral resection of the prostate (TURP) is considered the standard method for the surgical treatment of BPH[18]. The key benefits of TURP, however, may be offset by the need for general anesthesia and longer hospitalization, increased risk in older patients with comorbidities, and post-operative adverse events (AEs) and sexual dysfunction[17].

Minimally invasive surgical therapy (MIST) for BPH is an alternative to more invasive surgery and is intended to deliver an effective treatment, reduce lifetime complications and morbidity, and improve the overall patient experience[18–21]. Novel MIST techniques, including Rezūm[i] Water Vapor Therapy and the UroLift[ii] System, have been gaining favor as contemporary therapies that do not require general anesthesia and that preserve sexual function[22,23]. Evidence from clinical trials, real-world data analyses, and systematic reviews demonstrates the transformative clinical and patient-centered benefits of MISTs for BPH[24]. Managing men with symptomatic BPH requires consideration of patient and surgeon preferences, patient-specific factors, and the economic impact that different BPH therapies confer[25,26].

To date, much of the health economic research evaluating MIST treatments for BPH has been conducted in the United States. Cost-effectiveness and budget impact models have previously been developed from a US Medicare perspective to compare water vapor energy therapy (WAVE) to prostatic urethral lift (PUL) over 4- and 5-year time horizons[27,28]. However, it is known that the clinical and economic implications and cost-effectiveness of new technologies differs by the patient populations evaluated and by the country of analysis. To our knowledge, data regarding the real-world clinical and economic implications and cost-effectiveness outcomes associated with WAVE and PUL in Japan is absent. Against the backdrop of a rapidly aging population and healthcare budget considerations, cost-effectiveness is an increasingly important factor in funding decision-making and product adoption in Japan. Treatment strategies that improve BPH outcomes, whilst reducing healthcare expenditure, can provide significant benefit to Japanese patients and the healthcare system. The objective of this study was to evaluate the lifetime cost-effectiveness of WAVE versus PUL for men with moderate-to-severe BPH from a public healthcare payer's perspective in Japan.

Methods

Study design and model structure

A Markov model evaluated the cost-effectiveness of WAVE relative to PUL from a Japan public healthcare payer perspective. Clinical inputs in the model were derived from both global and local sources; healthcare resource use and cost inputs in the model were derived from local sources. The model time horizon was the patients' lifetime given the chronicity of BPH and the relevance of this time horizon for a public healthcare system. Patients treated with WAVE or PUL could experience BPH improvement, stabilization, or worsening (assessed with International Prostate Symptom Score [IPSS] relative to baseline), and could experience adverse events (AEs), retreatment, or die from other causes in each model cycle. Patients entering the model started at age 63.0 with an IPSS score of 22.0, similar to the baseline characteristics of patients in the MIST pivotal randomized controlled trials (RCTs)[29,30]. The inclusion criteria for patients in the WAVE pivotal trial includes having had no prior invasive prostate intervention or surgery of the prostate and the requirement to undergo a washout period for a number of medications[29]. The inclusion criteria in the PUL pivotal trial includes having had no prior surgical treatment for BPH and the requirement to undergo washouts of selected medications[30]. Three-month cycles (quarterly) were utilized for the first year, followed by annual cycles for subsequent years. AE and retreatment rates were considered over the first 5 years and mortality was considered over the entire simulation

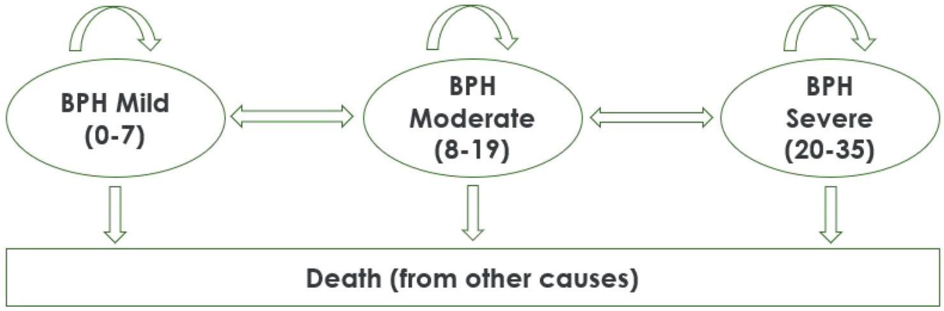


Figure 1. Markov state transition.

time. The Markov state transition diagram, which represents each health state, is depicted in Figure 1. A comprehensive patient pathway, encompassing common adverse events and retreatment options, was previously published in Chughtai et al.[27,28].

Model input parameters

Clinical inputs – effectiveness and health state utilities

The model inputs were derived using published literature and real-world health services data from Japan, and model input and validation was attained from local clinical and health economic experts. Safety and efficacy data were extracted from the Rezum II[22,29,31,32] and LIFT[23,33] RCTs identified from a previous systematic literature review of WAVE and PUL[34]. The trials compared WAVE or PUL to either an active or sham surgery control in subjects with symptomatic benign prostatic obstruction.

A random-effects network meta-analysis (NMA), based on the controlled indirect treatment comparison approach used by Bucher et al.[35], was carried out to obtain adjusted IPSS changes for each treatment[27,28]. This was combined with an aggregate regression model to conduct the indirect comparison. Baseline age and IPSS were used to account for the heterogeneity between trials and the difference in the distribution of baseline characteristics between comparators. At 1 year, results showed that patients with a mean age of 63 years and a baseline IPSS score of 22 who were treated with WAVE had a greater 1-year IPSS improvement (−Δ11.7) compared to those treated with PUL (Table 1). The IPSS improvements of WAVE and PUL were mostly sustained throughout the 5-year time period (Table 1).

AEs and recurrence were modeled as a risk of experiencing the event in each model cycle. Table 2 presents the AE rates utilized in the model[22,23,29–31,33]. Since the RCTs of WAVE and PUL contain AE rates for both short- and long-term durations, the reported rates were utilized in the analysis without pooling AEs from multiple data sources. For AEs directly related to the surgical procedure, three-month data is presented as these AEs are most likely to occur within the immediate postoperative period. The durability of therapeutic outcomes was evaluated through the proportion of cases requiring surgical retreatment, from 3 months to 5 years (Table 3). The reintervention rate for WAVE is based on the surgical retreatment rates reported for the 1–5-year postoperative period[22]. The cumulative retreatment rate for PUL is derived from the surgical retreatment events reported over a 5-year postoperative period[36]. This timeframe is most appropriate for evaluating the durability of treatment effects. The same proportion of retreatment was applied to patients who were lost to follow-up. Age-dependent general mortality (mortality due to other causes) was addressed using an abridged life table sourced from Japan's 2019 data[37].

Table 1. IPSS change from baseline to year 5 from the random-effects NMA model[27,28].

	Baseline	3 months	6 months	1 year	2 years	3 years	4 years	5 years
WAVE	22.0	10.6	9.8	10.3	10.2	10.5	11.4	11.1
± SD	4.8	6.4	6.2	6.7	6.2	6.1	7.4	7.8
PUL	22.0	10.9	10.5	11.6	11.5	11.8	12.7	12.4
± SD	4.8	6.4	6.2	7.0	6.5	6.4	7.7	8.1

Abbreviations. IPSS, International Prostate Symptom Score; NMA, network meta-analysis; PUL, prostatic urethral lift; WAVE, water vapor energy therapy.

Utility and disutility were used in the model to capture changes in quality-of-life as a consequence of treatment (Table 4). The utility decrement of each periprocedural and short-term AE was applied for a finite time period corresponding to the condition. The utility values were summed over the model time horizon to obtain overall quality-adjusted life years (QALYs). Utility inputs were derived from published evidence and were verified by clinical experts.

Economic inputs – healthcare resource utilization and unit costs

The model evaluated all relevant costs to the Japanese public healthcare system including procedural costs, hospital costs, follow-up costs, and AE costs. In the Japanese setting, the procedures in this study are undertaken in hospital. Following the initial procedure, it was assumed that patients would need four office visits within the first year. In subsequent years, a single visit annually was assumed for patients with mild-to-moderate LUTS, while those with severe LUTS were assumed to require two clinic visits per year. Regardless of the index surgery type, it was assumed that all patients would require catheterization. In Japan, patients are typically discharged after catheter removal, thus the model does not account for any follow-up visits for catheter removal. Patients requiring retreatment could undergo either the same initial treatment or TURP. With respect to retreatment, it was assumed that 61.0% of patients who underwent WAVE were retreated with TURP, while 39.0% were retreated with a

Table 2. AE rates.

WAVE AEs						PUL AEs					
Periprocedural AEs	0–3 months	4–6 months	7–9 months	10–12 months	13–60 months	Periprocedural AEs	0–3 months	4–6 months	7–9 months	10–12 months	13–60 months
Immediate acute urinary retention[29]	3.7%	NA	NA	NA	NA	Immediate acute urinary retention[23,30]	0.7%	NA	NA	NA	NA
Short-term AEs	0–3 months	4–6 months	7–9 months	10–12 months	13–60 months	Short-term AEs	0–3 months	4–6 months	7–9 months	10–12 months	13–60 months
Bladder spasm* [n/a]	0.0%	0.0%	0.0%	0.0%	0.0%	Bladder spasm[30]	3.6%	0.2%	0.2%	0.2%	0.0%
Urinary retention[29]	3.7%	0.0%	0.0%	0.0%	0.0%	Urinary retention[30]	0.7%	0.2%	0.2%	0.2%	0.0%
Urinary tract infection[29]	3.7%	0.0%	0.0%	0.0%	0.0%	Urinary tract infection[30]	2.9%	0.0%	0.0%	0.0%	0.0%
Pelvic pain[29]	2.9%	0.0%	0.0%	0.0%	0.0%	Pelvic pain[30]	17.9%	0.5%	0.5%	0.5%	0.0%
Hematuria[29]	11.8%	0.0%	0.0%	0.0%	0.0%	Hematuria[30]	25.7%	0.2%	0.2%	0.2%	0.0%
Dysuria[29]	16.9%	0.2%	0.2%	0.2%	0.0%	Dysuria[30]	34.3%	0.2%	0.2%	0.2%	0.0%
Urinary urge incontinence[29]	0.0%	0.0%	0.0%	0.0%	0.0%	Urinary urge incontinence[30]	3.6%	0.2%	0.2%	0.2%	0.0%
Frequency and urgency[29]	5.9%	0.0%	0.0%	0.0%	0.0%	Frequency and urgency[30]	7.1%	0.7%	0.7%	0.7%	0.0%
Encrusted implants [n/a]	0.0%	0.0%	0.0%	0.0%	0.0%	Encrusted implants[30]	1.8%	1.8%	1.8%	1.8%	0.0%
Long-term AEs	0–3 months	4–6 months	7–9 months	10–12 months	13–60 months	Long-term AEs	0–3 months	4–6 months	7–9 months	10–12 months	13–60 months
Urinary incontinence[31]	0.4%	0.4%	0.4%	0.4%	0.0%*	Urinary incontinence[33]	1.3%	1.3%	1.3%	1.3%	1.3%

Abbreviations. AE, adverse event; PUL, prostatic urethral lift; WAVE, water vapor energy therapy.
*No AE was identified from published literature; 0.0% was assumed.

repeat WAVE procedure. It was assumed that, of those patients who initially underwent PUL and required retreatment, 63.2% pursued TURP for retreatment, while 36.8% opted for PUL. Retreatment type proportions were approximations informed by the current clinical landscape and expert consensus. All assumptions regarding healthcare resource use were reviewed and validated by experts based on the clinical practice in Japan.

WAVE and PUL procedure cost inputs and AE cost inputs are presented in Tables 5 and 6, respectively. Model cost inputs were obtained from actual costs available from Japanese real-world data (Medical Data Vision [MDV] database) or national lists of Medical Fee Points in Japan. The MDV database is a large-scale database containing claims data from over 460 hospitals in Japan, with insights on over 40 million patients ≥18 years, with more than 1 million cases each month. It covers 26% of acute care hospitals. Technical and material fees for WAVE were based on the approved reimbursement fee (September 2022) and the technical and material fees for PUL were based on the approved reimbursement fee per implant (December 2021) and the assumption of 4.9 implants per procedure[23]. The drug fee was validated by clinical experts. The anesthesia fee for WAVE was estimated by using the ratio of each anesthesia in the Rezum II trial and actual costs in the MDV database. The anesthesia fee for PUL was estimated using the ratio of each anesthesia in the PUL Japan regulatory report[44] and actual costs in the MDV database. The capital costs were not included as the Japanese Ministry of Health, Labour and Welfare (MHLW) does not reimburse capital systems separately. Hospital costs for WAVE and PUL were based on estimated length of hospital stay for both procedures. Estimated length of hospital stay was obtained from clinical experts whilst the specific costs were obtained from national lists of Medical Fee Points in Japan. Hospital costs for TURP as a retreatment were obtained from the MDV database. Follow-up and AE costs were based on follow-up care and AE treatment type. Follow-up care and AE treatment type were obtained from clinical experts and the specific costs for these inputs were derived from the national lists of Medical Fee Points in Japan. Costs are reported in 2021 Japanese Yen.

Analyses

Clinical and economic outcomes were presented in a simple, disaggregated form to provide decision-makers with as broad a view as possible of the outcomes of the two interventions. Clinical effectiveness was presented as retreatment rates, AE rates, and the number of quality-adjusted life years (QALYs) for each treatment arm. Disaggregated costs for the two treatment arms included all medical costs to the healthcare system. Cost-effectiveness was evaluated as the incremental cost per QALY (as appropriate). A willingness to pay threshold of ¥5 million/QALY was utilized as this is the accepted threshold in Japan[45]. Incremental costs and outcomes were evaluated at years 1, 5, and over the lifetime. A 2% annual discount rate was applied to both costs and QALYs, as recommended by experts in Japan.

Table 3. Durability of treatment rates (proportions of patients without surgical retreatment)[22,36].

Proportion of patients without surgical retreatment	3 months	6 months	9 months	1 year	2 years	3 years	4 years	5 years
WAVE	98.7%	98.2%	97.9%	97.6%	96.7%	96.1%	95.5%	95.1%
PUL	98.4%	97.1%	96.0%	94.9%	91.0%	87.4%	84.0%	80.8%

Abbreviations. PUL, prostatic urethral lift; WAVE, water vapor energy therapy.

Table 4. Health state utilities.

	Source	Utility	Assumption
Treatment			
WAVE	Assumption; Ackerman[38]	−0.03	The disutility of transurethral microwave thermotherapy was applied
PUL	Assumption; Ackerman[38]	−0.03	The disutility of transurethral microwave thermotherapy was applied
TURP	Bjerklund[39]; Cher[40]	−0.05	Apply the disutility score for 30 days
Catheterization	Chen[41]	−0.05	The disutility value was derived from utility for improved urinary incontinence (0.92–0.87)
Health States			
BPH Mild	Baladi[42]	0.99	NA
BPH Moderate	Baladi[42]	0.90	NA
BPH Severe	Baladi[42]	0.79	NA
Death	NA	0	
Periprocedural AEs			
Immediate acute urinary retention	Ackerman[38]	−0.18	NA
Short-term AEs			
Bladder spasm	Ackerman[38]	−0.06	NA
Urinary retention	Ackerman[38]	−0.18	NA
Urinary tract infection	Ackerman[38]	−0.07	NA
Pelvic pain	Assumption; Ackerman[38]	−0.03	The disutility value of dysuria was used.
Hematuria	Assumption; Rognoni[43]	−0.20	The disutility value of urinary urge incontinence was used.
Dysuria	Ackerman[38]	−0.03	NA
Urinary urge incontinence	Ackerman[38]	−0.20	NA
Frequency and urgency	Assumption; Ackerman[38]	−0.03	The disutility value of dysuria was used
Encrusted implants	Assumption; Ackerman[38]	−0.03	The disutility of transurethral microwave thermotherapy was applied
Long-term AEs			
Urinary incontinence	Ackerman[38]	−0.20	NA

Abbreviations. AE, adverse event; BPH, benign prostatic hyperplasia; PUL, prostatic urethral lift; TURP, transurethral resection of the prostate; WAVE, water vapor energy therapy.

Table 5. WAVE vs. PUL cost inputs for one procedure (in Japanese Yen).

Fee category	Description of specific fees	WAVE	PUL with 4.9[23] implants
Technical fee	Technical fee	123,000	123,000
	Material fee used in a surgical operation	390,378	482,378
	Drug fee used in a surgical operation	1,301	1,301
	Sum of technical fee	514,679	606,679
Anesthesia fee	General anesthesia	829	14,580
	Epidural anesthesia	–	–
	Spinal anesthesia	1,751	–
	IV anesthesia	396	–
	Local anesthesia	5,225	5,527
	General + epidural anesthesia	–	–
	Sum of anesthesia fee	8,201	20,107
Hospital fee	Hospital fee (DPC fee)	142,474	142,474
Total fee	Total treatment fee	665,354	769,260

Abbreviations. DPC, diagnosis procedure combination; IV, intravenous; PUL, prostatic urethral lift; WAVE, water vapor energy therapy.

Sensitivity analyses were conducted to determine how changes in the values of uncertain parameters affected the results of the model. One-way sensitivity analyses (OWSAs) were conducted to assess the impact of individual parameters on the cost-effectiveness results by varying model inputs associated with the two technologies by ±25%. Probabilistic sensitivity analysis (PSA) was likewise reported at intervals of 1 year, 5 years, and the lifetime horizon, presuming a normal distribution of values. In the absence of an available standard deviation, ±25% values of the mean were employed as a surrogate standard deviation.

Both scatter plots and cost-effectiveness acceptability curves (CEACs) were included to represent PSA results. The CEAC is a graphical representation that is used to show the probability of a health intervention being cost-effective at various willingness-to-pay (WTP) thresholds ranging from ¥0 to ¥20 million. This graph is based on the joint distribution of incremental costs and effects, summarizing the uncertainty in cost-effectiveness estimates. The CEAC is constructed by plotting the proportion of cost-effect pairs deemed cost-effective against each WTP threshold value. This is done using the results from a probabilistic sensitivity analysis (PSA) conducted over two different simulation periods, such as 5 years and lifetime. The Y-axis shows the probability of WAVE and PUL being cost-effective and the X-axis shows the WTP thresholds. The lower and upper confidence intervals

Table 6. AE treatment cost inputs (in Japanese Yen) [Source: National lists of Medical Fee Points in Japan].

AE category	AE list	Costs	Codes or descriptions
Periprocedural AEs	Immediate acute urinary retention	¥76,110	DPC (110200xx02xxxx), extended length of stay 3 days
Short-term AEs	Bladder spasm	¥22,491	Tamsulosin tablets 0.2 mg 2 times/day for 5 days, Mirabegron tablets 25 mg once per day for 5 days 2 times office visit, 2 times checkup/diagnosis service, one prescription/dispensing service
	Urinary retention	¥21,800	Urethral dilatation (J066) 2 times office visit, 2 times checkup/diagnosis service
	Urinary tract infection	¥23,026	Clarithromycin antibiotic tablets 200 mg 2 times/day for 14 days 2 times office visit, 2 times checkup/diagnosis service, one prescription/dispensing service
	Pelvic pain	¥22,742	Paracetamol tablets 400 mg 3 times/day for 14 days 2 times office visit, 2 times checkup/diagnosis service, one prescription/dispensing service
	Hematuria	¥19,640	2 times office visit, 2 times checkup/diagnosis service
	Dysuria	¥22,206	Tamsulosin tablets 0.2 mg 2 times/day for 10 days 2 times office visit, 2 times checkup/diagnosis service, one prescription/dispensing service
	Urinary urge incontinence	¥23,843	Mirabegron tablets 25 mg once per day for 14 days 2 times office visit, 2 times checkup/diagnosis service, one prescription/dispensing service
	Frequency and urgency	¥23,843	Mirabegron tablets 25 mg once per day for 14 days 2 times office visit, 2 times checkup/diagnosis service, one prescription/dispensing service
	Encrusted implants	¥230,240	DPC (11013xxx97xxxx), length of stay 4 days Removal of debris in posterior urethra (K8152), Anesthesia (L0085)
Long-term AEs	Urinary incontinence	¥112,062	Solifenacin tablets 5 mg once per day for 365 days or Mirabegron tablets 25 mg once per day for 365 days According to expert assumption, solifenacin for urgency urinary incontinence: mirabegron for stress urinary incontinence = 2:1

Abbreviation. AE, adverse event.

(5% and 95% CIs) of the CEAC are estimated using bootstrapping. This method involves resampling from the simulated cost and effectiveness distributions of WAVE and PUL to quantify the uncertainty in the probability that an intervention is cost-effective at different WTP thresholds. A specific number of 100 resampling iterations are performed, which has been found to provide sufficient information about the bounds. From these iterations, a distribution of cost-effectiveness probabilities for each WTP threshold is produced, from which the 5% and 95% CIs are derived. These intervals are then represented as colored dots around the CEAC, offering a visual depiction of the uncertainty. By incorporating confidence intervals, the CEAC offers decision-makers a visual understanding of the certainty in the cost-effectiveness of an intervention across various WTP thresholds. This aids in making informed decisions about healthcare investments.

Results

Base case

WAVE was associated with lower retreatment rates at 5 years (4.9% vs. 19.2%) and lower rates for most AEs commonly reported across the two technologies at 3 months, including hematuria (11.8% vs. 25.7%), dysuria (16.9% vs. 34.3%), pelvic pain (2.9% vs. 17.9%), and urinary incontinence (0.4% vs. 1.3%). At year 1, WAVE was associated with higher QALYs (0.920 vs. 0.911) and lower total costs (¥734,134 vs. ¥888,110) compared to PUL (Table 7). The same trend continued through 5 years (4.335 vs. 4.287; ¥791,069 vs. ¥1,022,448) and the lifetime horizon (15.564 vs. 15.388; ¥961,595 vs. ¥1,429,458), making WAVE the more effective and least costly strategy across the short- and long-term (Table 7).

Sensitivity analyses

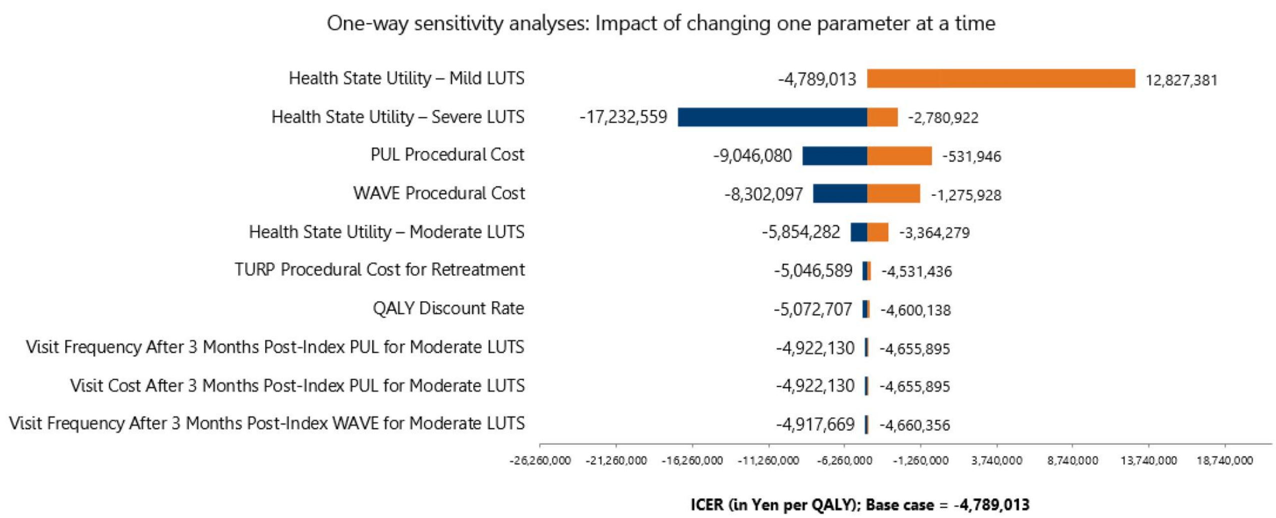
Tornado diagrams illustrating the 10 most impactful model input parameters on model results at 5 years and lifetime in descending order of influence are depicted in Figure 2. The OWSAs demonstrated that health state utilities and procedural costs for WAVE and PUL had the most impact on model results at both the 5-year and lifetime time horizons. The PSA demonstrated that, at 5 years, WAVE was less costly than PUL 99% of the time and was associated with higher QALYs 80% of the time (Figure 3a). Over the lifetime time horizon, WAVE was less costly than PUL 100% of the time and was associated with higher QALYs 78% of the time (Figure 3b). The results of the Cost-Effectiveness Acceptability Curves (CEAC) for 5 year (Figure 4a) and lifetime (Figure 4b) simulation periods are depicted for WAVE and PUL, along with their respective 5% and 95% confidence intervals (5% CI and 95% CI). The CEACs are shown as dark blue (WAVE) and orange (PUL) lines, indicating the probability that the health interventions are cost-effective across a range of willingness-to-pay (WTP) thresholds. The 95% confidence intervals are represented by the dotted lines flanking the CEAC, illustrating the degree of uncertainty in these probabilities. The dashed red line marks a specific WTP threshold, allowing for

Table 7. Base case results.

	Total Costs, ¥	Incremental Costs, ¥	Total QALYs	Incremental QALYs	ICER WAVE vs. PUL
1 Year					
PUL	888,110	–	0.911	–	–
WAVE	734,134	−153,976	0.920	0.009	Dominant
2 Years					
PUL	926,265	–	1.797	–	–
WAVE	750,874	−175,391	1.816	0.019	Dominant
3 Years					
PUL	960,777	–	2.658	–	–
WAVE	765,397	−195,380	2.687	0.029	Dominant
4 Years					
PUL	992,463	–	3.488	–	–
WAVE	778,515	−213,948	3.527	0.039	Dominant
5 Years					
PUL	1,022,448	–	4.287	–	–
WAVE	791,069	−231,379	4.335	0.048	Dominant
Lifetime					
PUL	1,429,458	–	15.388	–	–
WAVE	961,595	−467,864	15.564	0.176	Dominant

Abbreviations. ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; PUL, prostatic urethral lift; WAVE, water vapor energy therapy.

a) 5-year time horizon results



b) Lifetime time horizon results

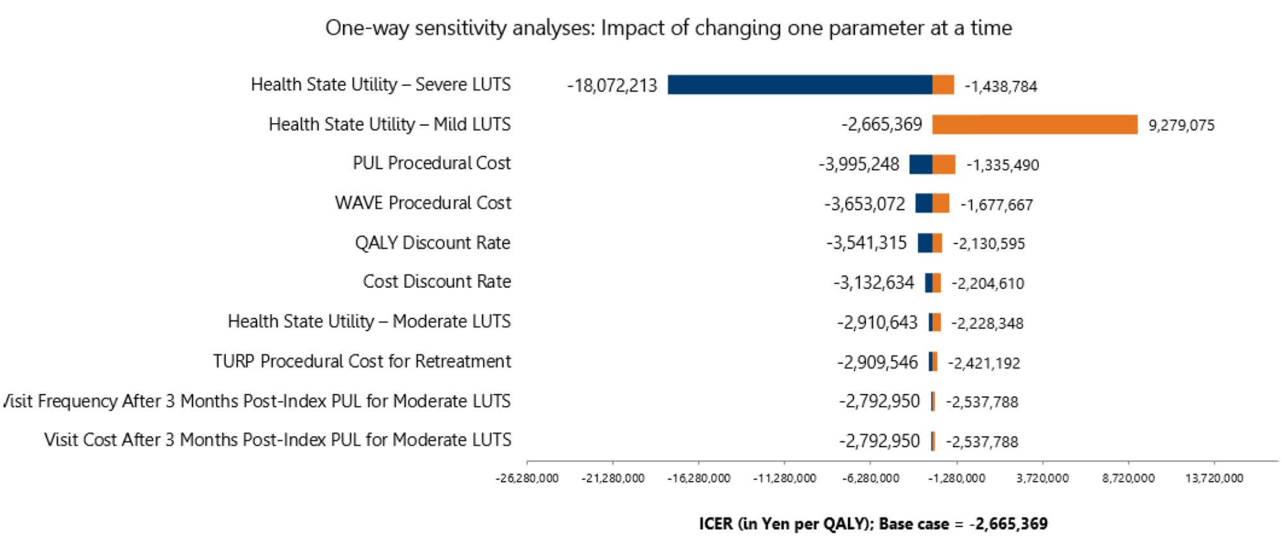


Figure 2. One-way sensitivity analyses (OWSAs).
Abbreviations. ICER, incremental cost-effectiveness ratio; LUTS, lower urinary tract symptoms; OWSA, one-way sensitivity analysis; PUL, prostatic urethral lift; QALY, quality-adjusted life year; TURP, transurethral resection of the prostate; WAVE, water vapor energy therapy.

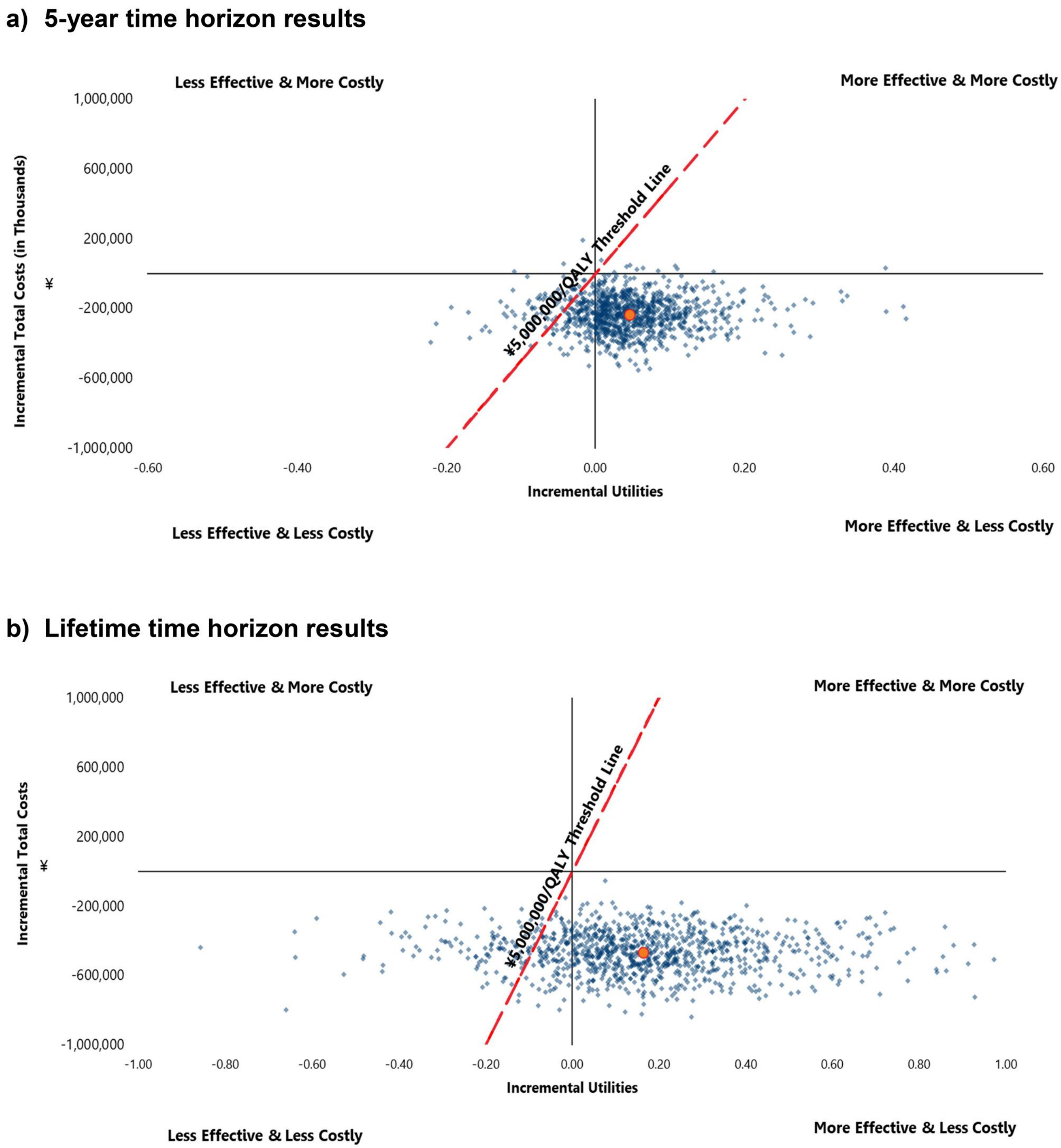


Figure 3. Probabilistic sensitivity analyses (PSAs) scatter plots comparing WAVE versus PUL at 5-year and lifetime horizons.
Abbreviations. QALY, quality-adjusted life year; PSA, probabilistic sensitivity analysis; PUL, prostatic urethral lift, WAVE, water vapor energy therapy.

a visual assessment of the probability of cost-effectiveness at that point. The analysis of the graphs reveals that, as the willingness-to-pay (WTP) threshold rises, the likelihood that intervention with WAVE is cost-effective tends to decline, whereas the likelihood that PUL is cost-effective tends to increase. This trend is accompanied by an expansion of the confidence intervals, signaling a slightly increased uncertainty at elevated WTP levels. With a WTP threshold of ¥5,000,000, the probability of WAVE being cost-effective in the 5-year simulation is 93.5% (95% CI = 92.5–94.5%) and for PUL 6.5% (95% CI = 5.5–7.5%). For the lifetime simulation, the probability of being cost-effective is for WAVE 89.1% (95% CI = 87.9–90.4%) and for PUL 10.9% (95% CI = 9.6–12.1%).

Discussion

Asia is home to 60% of the world's population, with rapidly aging societies in many countries including Japan[46]. These demographic features put increasing pressure on healthcare budgets and systems. Despite having a relatively healthy population and low-cost healthcare relative to that of the US

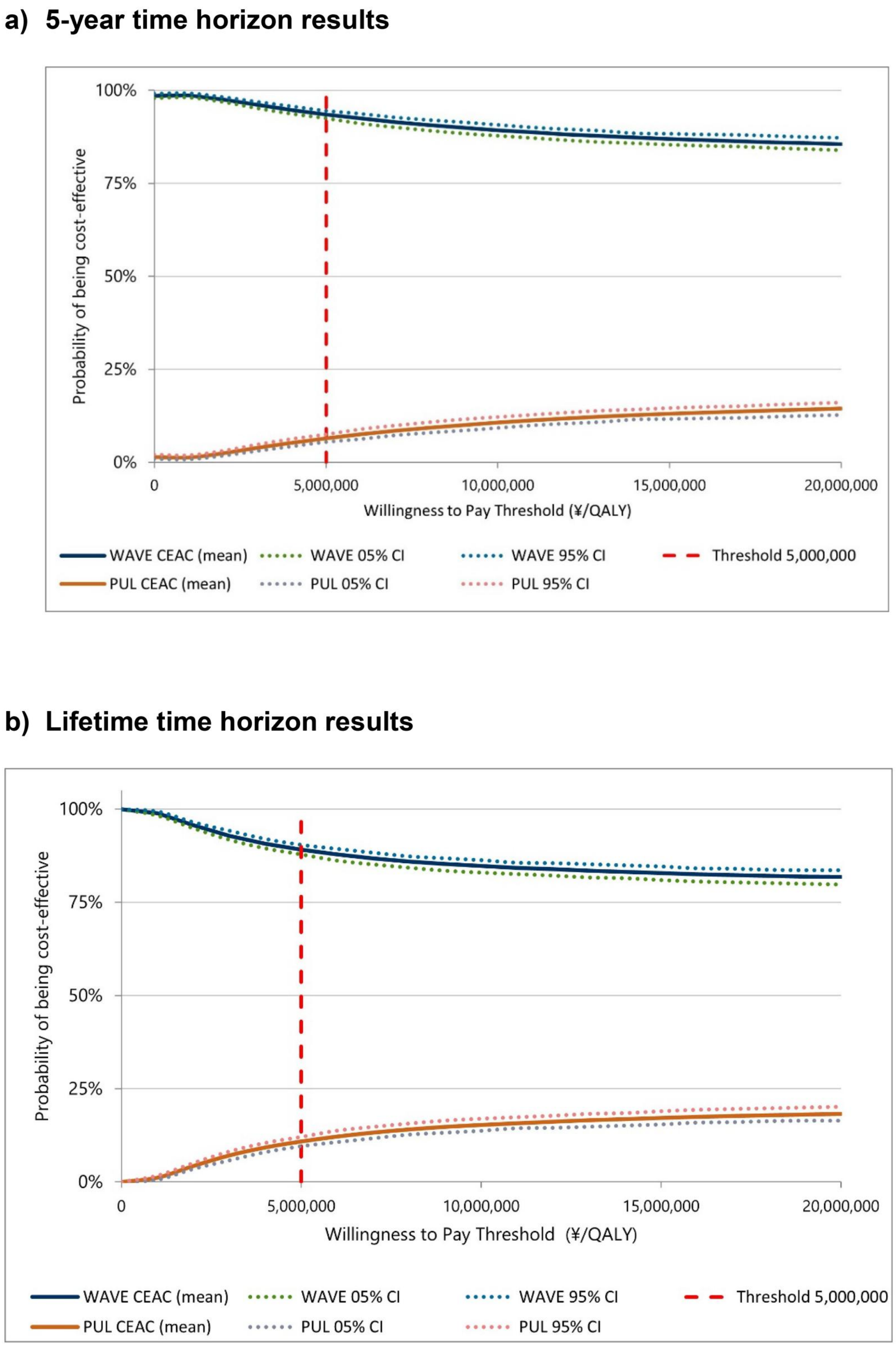


Figure 4. Cost-effectiveness acceptability curves (CEACs) at different time horizons.
Abbreviations. CEAC, cost-effectiveness acceptability curve; CI, confidence interval; PUL, prostatic urethral lift; QALY, quality-adjusted life year; WAVE, water vapor energy therapy.

and other Organization for Economic Cooperation and Development (OECD) member countries[47], concerns remain about the potential inflation of national healthcare costs in Japan[48]. The challenge to healthcare payers and providers is to maximize the net benefits obtained from healthcare expenditures. The intent of health economic research is to help identify cost-effective medical treatments and, in turn, achieve better value for money for prevalent illnesses such as BPH. This change is to be achieved, in part, through the selection of therapies that have been proven effective while providing value for money.

The findings from this health economic evaluation of MIST technologies provide insights into quality-of-life impact to patients and the long-term cost impact to the

Central Social Insurance Medical Council (CSIMC) of Japan. Results are presented from 1 year post-treatment through to lifetime. This captures the long-term economic impact of the treatments whilst aligning with the time points at which the most relevant clinical data were available. Research has shown that avoiding further retreatment is important for men with BPH when selecting a treatment option[49]. Retreatment rates at 5 years were nearly four times greater with PUL compared to WAVE (19.2% vs. 4.9%). The rates of most AEs were also greater with PUL compared to WAVE at 3 months, including hematuria (25.7% vs. 11.8%), dysuria (34.3% vs. 16.9%), pelvic pain (17.9% vs. 2.9%), and urinary incontinence (1.3% vs. 0.4%). The improved clinical outcomes translated into higher QALYs with WAVE through 1 year, (0.920 vs. 0.911), 5 years (4.335 vs. 4.287), and the lifetime time horizon (15.564 vs. 15.388). The economic component of our analysis found that WAVE resulted in cost-savings for the Japanese healthcare system of ¥467,863 per BPH patient treated with WAVE instead of PUL over the lifetime horizon. Hence, WAVE was found to be a more effective and less costly treatment strategy (i.e. dominant across the short- and long-term). A more effective, cost-saving, and durable procedure for this age-related condition has the potential to result in significant savings for constrained healthcare systems in Asia, while simultaneously improving patient quality-of-life. Model findings were also shown to be robust in response to changes in parameter input values.

Other comparative effectiveness evidence demonstrates the transformative clinical and patient-centered benefits of MISTs for BPH based on clinical trials, real-world data analyses, and systematic reviews[24]. Recent guidelines have elevated interventional treatment for LUTS attributable to BPH to first-line therapy for select patients, including those who want to avoid taking a daily medication, have failed medical therapy, or who have certain conditions that require more intensive intervention[25,26]. Advantages that have been demonstrated include favorable efficacy, effectiveness, and safety, low retreatment rates, and low rates of erectile and ejaculatory dysfunction[24]. Increased evidence in recent years highlights the distinct advantages of WAVE and PUL including that they can be performed in-office, do not require general anesthesia and may better preserve ejaculatory function[21]. WAVE utilizes convective radiofrequency to create stored thermal energy in the form of steam, which is delivered transurethrally into the transition zone of the prostate to ablate tissue[17]. In a WAVE procedure, there is no permanent metallic hardware left in the body, therefore eliminating risks seen with mechanical technologies such as mechanical device failure, device infection, or implant migration[17].

Evidence has shown that BPH impacts health-related quality-of-life, work productivity, and healthcare use of men in Japan, with greater impact among undiagnosed men experiencing LUTS and frequent nocturia[1]. Patients with diagnosed and undiagnosed BPH in Japan have reduced health-related quality-of-life, including declines in mental component (mean $\geq$3.1 points) and physical component (mean $\geq$2.0 points) summary scores, as well as health utility scores (mean $\geq$0.05) (all $p < 0.001$)[1]. An impact on work and non-work activity is also seen in patients with diagnosed and undiagnosed BPH, with mean absenteeism, work and non-work activity impairment $\geq$1.4-fold greater in this group ($p < 0.01$)[1]. Healthcare utilization is also significantly higher amongst diagnosed and undiagnosed BPH patients, with more frequent healthcare provider visits and hospitalizations[1].

The findings from this study are consistent with US cost-effectiveness and budget impact models comparing WAVE to PUL from a Medicare perspective over 4- and 5-year time horizons[27,28]. At 4 years, PUL was associated with higher retreatment rates (24.6% vs. 10.9%), lower QALYs (3.490 vs. 3.548), and higher total costs ($7,393 vs. $2,233) compared with WAVE[27]. The 70% total cost difference of PUL and WAVE was predominantly driven by higher PUL procedural ($5,617 vs. $1,689) and retreatment ($976 vs. $257) costs[27]. The 5-year analysis compared WAVE and PUL, in addition to generic combination therapy (CT), photoselective vaporization of the prostate (PVP), and TURP for the treatment of BPH[28]. At 5 years, WAVE, PVP, and TURP were shown to have higher QALYs than CT and PUL. Total Medicare costs at 5 years were lowest for WAVE ($2,655) and highest for PUL ($9,580)[28]. Again, the key cost drivers for PUL were higher procedural and retreatment costs ($7,258 and $1,168, respectively). Further, recent evidence from Singapore shows the cost-effectiveness of WAVE as a first-line treatment for moderate or severe BPH patients in Singapore[50].

To our knowledge, this study is the first cost-effectiveness evaluation of MIST BPH procedures in the Japanese setting. Additional strengths of this study are its use of a long-term (lifetime) time horizon, the use of QALYs as the clinical effectiveness outcome (which incorporates both the clinical impact and patients' quality-of-life), and the use of local real-world data from Japan. Limitations of this study are mostly those inherent to all decision analytic modeling studies. Economic models represent a simplification of the complex factors associated with the clinical and economic outcomes of BPH patients and summarize only a subset of the information needed for resource allocation decision-making. Models do, however, provide more explicit details regarding the potential implications of alternate decisions and therefore can be a valuable input for the decision-making process. In designing the decision model, we sought to achieve a balance between determining reasonable clinical treatment pathways and creating a transparent model based on published evidence. Nonetheless, the model was built by combining data from multiple sources to identify inputs for effectiveness, resource utilization, and costs. The process involved a variety of assumptions regarding the disease state, treatment patterns, and costs, and these assumptions may not be generalizable to all patients. Where primary data were not available for a Japanese population, inputs were extrapolated from international sources. We recognize that AEs and utilities may differ across geographies, particularly in response to differing demographics, aging populations, and life expectancies. We performed a number of sensitivity analyses and engaged local clinical and economic experts in an effort to validate the model assumptions and inputs. There is a need for future research to consider factors such as the complex pathologies and functional declines prevalent in older populations that may be more common in certain geographies, particularly in the context of evaluating treatment safety.

Conclusions

Cost-effectiveness is an increasingly important factor in healthcare decision-making and technology adoption in Japan. This health economic evaluation found that, compared to PUL, WAVE was a cost-effective and cost-saving MIST for moderate-to-severe BPH, providing better outcomes at lower costs to the healthcare system in Japan. WAVE was associated with lower retreatment rates and fewer short- and long-term AEs compared to PUL. These findings provide evidence-based insights for clinicians, payers, and health policymakers to further define the role of WAVE for BPH in Japan.

Notes

i. Rezūm Water Vapor Therapy, Boston Scientific Corporation, Marlborough, MA, USA.
ii. UroLift System, Teleflex Incorporated, Pleasanton, CA, USA.

Transparency

Declaration of funding

This work was supported by Boston Scientific.

Declaration of financial/other relationships

HA and FE were a paid clinical consultant to Boston Scientific and compensated for their participation in this study. GS, KT, and SR are full-time employees of Boston Scientific.

Author contributions

All authors contributed to the study design, manuscript development, and critical manuscript revision and have read and approved the final manuscript and agree to be accountable for all aspects of the work. All authors had full access to the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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A reviewer on this manuscript has disclosed that they have previously carried out economic analyses for the sponsor of this article (Boston Scientific), although not for this specific technology or indication, or within the context of the Japanese market. Peer reviewers on this manuscript have no other relevant financial relationships or otherwise to disclose.

Previous presentations

Findings from this paper have been presented at the 37th Annual Meeting of the Japanese Society of Urological Endoscopy and Robotics (JSER).

IRB information

Since this study does not involve human participants, neither institutional review board approval nor participant consent was required.

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References

[1] Yoshida M, Flores NM, Vietri J, et al. Burden of benign prostatic hyperplasia among men in Japan: patient-reported outcomes among those diagnosed and experiencing symptoms. Int J Urol. 2015;22(10):949–955. doi: 10.1111/iju.12849.
[2] Homma Y, Gotoh M, Yokoyama O, et al. JUA clinical guidelines for benign prostatic hyperplasia. Int J Urol. 2011;18(11):e1–e33. doi: 10.1111/j.1442-2042.2011.02861.x.
[3] Homma Y, Gotoh M, Kawauchi A, et al. Clinical guidelines for male lower urinary tract symptoms and benign prostatic hyperplasia. Int J Urol. 2017;24(10):716–729. doi: 10.1111/iju.13401.
[4] Institute for Health Metrics and Evaluation (IHME). Global Burden of Disease (GBD) Study 2019. Available from: https://vizhub.healthdata.org/gbd-results/
[5] Statistics Bureau of Japan. 2021 July Survey. 2021. Available from: https://www.stat.go.jp/english/
[6] The Japanese Urological Association (JUA). Clinical guidelines for male lower urinary tract symptoms and benign prostatic hyperplasia. Tokyo (Japan): RichHill Medical; 2017.
[7] Government of Japan Cabinet Office. The ageing society: current situation and implementation measures FY 2017. 2018. Available from: https://www8.cao.go.jp/kourei/english/annualreport/2018/pdf/c1-1.pdf
[8] Wei JT, Calhoun E, Jacobsen SJ. Urologic diseases in America project: benign prostatic hyperplasia. J Urol. 2005;173(4):1256–1261. doi: 10.1097/01.ju.0000155709.37840.fe.
[9] Zhang AY, Xu X. Prevalence, burden, and treatment of lower urinary tract symptoms in men aged 50 and older: a systematic review of the literature. SAGE Open Nurs. 2018;4:2377960818811773.
[10] McVary KT. BPH: epidemiology and comorbidities. Am J Manag Care. 2006;12(5 Suppl):S122–S128.
[11] Soliman Y, Meyer R, Baum N. Falls in the elderly secondary to urinary symptoms. Rev Urol. 2016;18(1):28–32.
[12] Roehrborn CG, Marks L, Harkaway R. Enlarged prostate: a landmark national survey of its prevalence and impact on US men and their partners. Prostate Cancer Prostatic Dis. 2006;9(1):30–34. doi: 10.1038/sj.pcan.4500841.
[13] Beckman TJ, Mynderse LA. Evaluation and medical management of benign prostatic hyperplasia. Mayo Clin Proc. 2005;80(10):1356–1362. doi: 10.4065/80.10.1356.
[14] Emberton M, Cornel EB, Bassi PF, et al. Benign prostatic hyperplasia as a progressive disease: a guide to the risk factors and options for medical management. Int J Clin Pract. 2008;62(7):1076–1086. doi: 10.1111/j.1742-1241.2008.01785.x.
[15] Lerner LB, McVary KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia:

AUA GUIDELINE PART I, initial work-up and medical management. J Urol. 2021;206:806–817.
[16] Cindolo L, Pirozzi L, Fanizza C, et al. Drug adherence and clinical outcomes for patients under pharmacological therapy for lower urinary tract symptoms related to benign prostatic hyperplasia: population-based cohort study. Eur Urol. 2015;68(3):418–425. doi: 10.1016/j.eururo.2014.11.006.
[17] McVary KT, Chughtai B, Miller LE, et al. Putting patients ahead by leaving nothing behind: an emerging treatment paradigm in minimally invasive surgical therapy for benign prostatic hyperplasia. Med Devices (Auckl). 2021;14:59–64. doi: 10.2147/MDER.S265237.
[18] Chung ASJ, Woo HH. Update on minimally invasive surgery and benign prostatic hyperplasia. Asian J Urol. 2018;5(1):22–27. doi: 10.1016/j.ajur.2017.06.001.
[19] Dahm P, MacDonald R, McKenzie L, et al. Newer minimally invasive treatment modalities to treat lower urinary tract symptoms attributed to benign prostatic hyperplasia. Eur Urol Open Sci. 2021;26:72–82. doi: 10.1016/j.euros.2021.02.001.
[20] Harkaway RC, Issa MM. Medical and minimally invasive therapies for the treatment of benign prostatic hyperplasia. Prostate Cancer Prostatic Dis. 2006;9(3):204–214. doi: 10.1038/sj.pcan.4500869.
[21] Bortnick E, Brown C, Simma-Chiang V, et al. Modern best practice in the management of benign prostatic hyperplasia in the elderly. Ther Adv Urol. 2020;12:1756287220929486. doi: 10.1177/1756287220929486.
[22] McVary KT, Gittelman MC, Goldberg KA, et al. Final 5-year outcomes of the multicenter randomized Sham-controlled trial of a water vapor thermal therapy for treatment of moderate to severe lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Urol. 2021;206(3):715–724. doi: 10.1097/JU.0000000000001778.
[23] Roehrborn CG, Barkin J, Gange SN, et al. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. Can J Urol. 2017;24(3):8802–8813.
[24] Tzeng M, Basourakos SP, Lewicki PJ, et al. New endoscopic in-office surgical therapies for benign prostatic hyperplasia: a systematic review. Eur Urol Focus. 2021;8(2):522–531. doi: 10.1016/j.euf.2021.02.013.
[25] Foster HE, Barry MJ, Dahm P, et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline. J Urol. 2018;200(3):612–619. doi: 10.1016/j.juro.2018.05.048.
[26] Parsons JK, Dahm P, Köhler TS, et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline amendment 2020. J Urol. 2020;204(4):799–804. doi: 10.1097/JU.0000000000001298.
[27] Chughtai B, Rojanasarot S, Neeser K, et al. Cost-effectiveness and budget impact of emerging minimally invasive surgical treatments for benign prostatic hyperplasia. J Health Econ Outcomes Res. 2021;8(1):42–50. doi: 10.36469/jheor.2021.22256.
[28] Chughtai B, Rojanasarot S, Neeser K, et al. A comprehensive analysis of clinical, quality of life, and cost-effectiveness outcomes of key treatment options for benign prostatic hyperplasia. PLoS One. 2022;17(4):e0266824. doi: 10.1371/journal.pone.0266824.
[29] McVary KT, Gange SN, Gittelman MC, et al. Minimally invasive prostate convective water vapor energy ablation: a multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Urol. 2016;195(5):1529–1538. doi: 10.1016/j.juro.2015.10.181.
[30] Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. Study. J Urol. 2013;190(6):2161–2167. doi: 10.1016/j.juro.2013.05.116.
[31] Dixon CM, Cedano ER, Pacik D, et al. Two-year results after convective radiofrequency water vapor thermal therapy of symptomatic benign prostatic hyperplasia. Res Rep Urol. 2016;8:207–216. doi: 10.2147/RRU.S119596.
[32] Boston Scientific Corporation. Safety and efficacy study for the treatment of BPH (Enlarged Prostate) (REZUM): ClinicalTrials.gov Identifier: NCT01912339, 2020. 2023.
[33] National Institute for Health and Care Excellence (NICE). Lower urinary tract symptoms in men: management – Clinical guideline [CG97] 2015 [cited 2023 Aug 9]. Available from: https://www.nice.org.uk/guidance/cg97
[34] Tallman CT, Zantek PF, Hernandez N, et al. Effectiveness of convective water vapor energy therapy versus prostatic urethral lift for symptomatic benign prostatic hyperplasia: a systematic review and indirect comparison. World J Urol. 2021;39(9):3207–3215. doi: 10.1007/s00345-021-03595-8.
[35] Bucher HC, Guyatt GH, Griffith LE, et al. The results of direct and indirect treatment comparisons in meta-analysis of randomized controlled trials. J Clin Epidemiol. 1997;50(6):683–691. doi: 10.1016/s0895-4356(97)00049-8.
[36] 新医療機器の承認に関する情報. 新医療機器の承認に関する情報 2023.
[37] Ministry of Health, Labour and Welfare of Japan. Abridged life table. 2019. Available from: https://www.mhlw.go.jp/toukei/saikin/hw/life/life19/xlsx/life19-12.xlsx
[38] Ackerman SJ, Rein AL, Blute M, et al. Cost effectiveness of microwave thermotherapy in patients with benign prostatic hyperplasia: part I-methods. Urology. 2000;56(6):972–980. doi: 10.1016/s0090-4295(00)00828-1.
[39] Bjerklund Johansen TE, Baker TM, Black LK. Cost-effectiveness of combination therapy for treatment of benign prostatic hyperplasia: a model based on the findings of the combination of avodart and tamsulosin trial. BJU Int. 2012;109(5):731–738. doi: 10.1111/j.1464-410X.2011.10511.x.
[40] Cher DJ, Miyamoto J, Lenert LA. Incorporating risk attitude into Markov-process decision models: importance for individual decision making. Med Decis Making. 1997;17(3):340–350. doi: 10.1177/0272989X9701700311.
[41] Chen HW, Bercik RS, Werner EF, et al. Cost-effectiveness of percutaneous tibial nerve stimulation versus extended release tolterodine for overactive bladder. J Urol. 2012;187(1):178–184. doi: 10.1016/j.juro.2011.09.052.
[42] Baladi J-F, Menon D, Otten N. An economic evaluation of finasteride for treatment of benign prostatic hyperplasia. Pharmacoeconomics. 1996;9(5):443–454. doi: 10.2165/00019053-199609050-00007.
[43] Rognoni C, Tarricone R. Healthcare resource consumption for intermittent urinary catheterization: cost-effectivness of hydrophilic catheters and budget impact analysis. BMJ Open. 2017;7(1):e012360. doi: 10.1136/bmjopen-2016-012360.
[44] Neotract I. Urolift system review report, PDMA 2018 [cited 2023 Aug 9]. Available from: https://www.pmda.go.jp/medical_devices/2018/M20181108001/index.html
[45] Japan Ministry of Health L, and Welfare. Health economic evaluation discount rate 2023. Available from: https://www.mhlw.go.jp/index.html
[46] Nakamura K. A “super-aged” society and the “locomotive syndrome”. J Orthop Sci. 2008;13(1):1–2. doi: 10.1007/s00776-007-1202-6.
[47] Akiyama N, Shiroiwa T, Fukuda T, et al. Healthcare costs for the elderly in Japan: analysis of medical care and long-term care claim records. PLoS One. 2018;13(5):e0190392. doi: 10.1371/journal.pone.0190392.
[48] Ogura H, Komoto S, Shiroiwa T, et al. Exploring the application of cost-effectiveness evaluation in the Japanese National Health Insurance System. Int J Technol Assess Health Care. 2019;35(6):452–460. doi: 10.1017/S0266462319000060.
[49] Rojanasarot S, Cutone B, Durand K, et al. Patients’ perspectives on attributes while choosing minimally invasive surgery for benign prostatic hyperplasia procedures: experience from men undergoing water vapor thermal therapy. J Endourol. 2023;37(5):575–580. doi: 10.1089/end.2022.0607.
[50] Chay J, Tung JYM, Su RJ, et al. Cost-effectiveness of alternative first- and second-line treatments for benign prostatic hyperplasia in Singapore. J Med Econ. 2023;26(1):1269–1277. doi: 10.1080/13696998.2023.2266958.