Cost-Utility Analysis of Smart Litho Plus versus Standard Electromagnetic Extracorporeal Shock Wave Lithotripsy for Renal Calculi Treatment in Thailand

Supoj Ratchanon, MD[1], Nonthana Assawawitoontip, MD[2], Swiss Suharitdumrong, MD[2], Apirak Santingamkun, MD[1]

[1] Division of Urology, Department of Surgery, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand; [2] Division of Urology, Department of Surgery, King Chulalongkorn Memorial Hospital, Bangkok, Thailand

Abstract

Background: Urolithiasis is common in Thailand, particularly in the northeast. Extracorporeal shock wave lithotripsy (ESWL) is a widely used non-invasive treatment for renal calculi. Smart Litho Plus, a Thai-manufactured electromagnetic lithotripter, was developed as a lower-cost alternative to imported systems, but its cost-effectiveness has not been formally evaluated.

Objective: To compare the cost-utility of Smart Litho Plus with a standard imported electromagnetic ESWL system for renal calculi in Thailand, from healthcare provider and societal perspectives.

Materials and Methods: A model-based cost-utility analysis was conducted using head-to-head effectiveness data from a 121-patient multicenter retrospective cohort. The base case used a 10-year decision-analytic cohort model, extended to a lifetime Markov model. Costs and outcomes were discounted at 3% annually, following Thai HITAP guidance. The willingness-to-pay threshold was 160,000 THB per quality-adjusted life year (QALY). Uncertainty was assessed using deterministic sensitivity analysis, threshold analyses, two-way analysis, and probabilistic sensitivity analysis with 10,000 Monte Carlo simulations. Reporting followed CHEERS 2022.

Results: In the base case, Standard ESWL dominated Smart Litho Plus under both perspectives, being less costly and more effective. From the provider perspective, total costs were 124.4 million THB for Standard ESWL and 140.3 million THB for Smart Litho Plus, while Standard ESWL gained 6.15 additional QALYs. Cost per case was 70,786 THB versus 79,839 THB. In probabilistic analysis, Standard ESWL had a 76.8% probability of strict dominance and an 81.0% probability of being cost-effective. Smart Litho Plus became cost-effective only if its stone-free rate increased from 44% to approximately 53%.

Conclusion: Despite its lower purchase price, Smart Litho Plus was dominated by Standard ESWL because lower effectiveness led to higher downstream salvage costs.

Keywords: Cost-utility analysis; Cost-effectiveness; ESWL; Lithotripsy; Kidney stones; Urolithiasis; Thailand; Health technology assessment

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Urolithiasis is one of the most common urological conditions worldwide, and northeastern Thailand reports a particularly high incidence[1]. The disease places a heavy burden on patients and on the health system[2]: it causes severe pain, often leads to emergency visits or hospital admission, and carries a high lifetime risk of recurrence[3,4].

When it was introduced in the early 1980s, extracorporeal shock wave lithotripsy (ESWL) transformed the treatment of urinary calculi by offering

Correspondence to:

Santingamkun A.

Division of Urology, Department of Surgery, Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand.

Phone: +66-81-5525925

Email: Apirak.S@chula.ac.th

ORCID: 0000-0002-8665-7200

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What is already known about this topic?

ESWL is a common first-line treatment for renal calculi, and the Thai-manufactured Smart Litho Plus system offers a lower-cost alternative to imported lithotripters but achieves a lower stone-free rate than the standard imported system (44% vs. 64%). Whether this lower acquisition cost represents better value, once the downstream costs of treatment failure are taken into account, had not been formally evaluated.

What does this study add?

In this CUA, standard imported ESWL dominated Smart Litho Plus from both the healthcare provider and societal perspectives—being both less costly and more effective—because the lower stone-free rate of the domestic device generated higher downstream salvage costs; Smart Litho Plus would become cost-effective only if its stone-free rate improved from 44% to approximately 53%. These findings indicate that procurement decisions for medical devices should be based on clinical effectiveness and the downstream costs of treatment failure, not on acquisition price alone.

a non-invasive alternative to open or endoscopic surgery[5]. A modern ESWL device has four core parts: a shock wave generator, a focusing system, a coupling mechanism, and an imaging or localization unit[6]. European Association of Urology (EAU) guidelines list ESWL as a first-line option for renal stones under 2 cm in most calyces and for lower-pole stones under 1 cm[7]. Reported stone-free rates vary widely, from roughly 35% to 89%, depending on stone characteristics, patient factors, and the device used[8,9].

Imported ESWL technology imposes a substantial and ongoing financial burden on Thailand's public healthcare system. In the Thai market, a standard imported electromagnetic lithotripter represents a major capital investment, with annual maintenance and service contracts adding considerably to the total cost of ownership. Furthermore, because many of these expenditures are denominated in foreign currencies, the healthcare system remains vulnerable to exchange-rate fluctuations and disruptions in the global supply chain.

Developing medical devices domestically has therefore become a national priority in Thailand, driven by the goals of containing costs, reducing reliance on imports, and supporting local industry. Smart Litho Plus, a Thai-manufactured electromagnetic lithotripter, is one product of this effort. Three of the four core ESWL components—the shock wave generator, the focusing system, and the coupling mechanism—are made domestically, while the imaging and localization unit is still imported. This brings the purchase price down to about half that of the imported alternative[8].

In a recent multicenter retrospective cohort, Ratchanon et al. compared Smart Litho Plus with a standard imported electromagnetic system in 121 patients across three Thai tertiary hospitals (Sunpasitthiprasong, Chulalongkorn, and Thammasat)[8]. At four weeks, the stone-free rate was 44.0% for Smart Litho Plus and 64.0% for the standard system ($p=0.048$), and the two devices had comparable safety profiles. The Thai device reached its lower stone-free rate while delivering fewer shock waves per session, but the 20-percentage-point gap raises an obvious question: does the lower purchase price come at the cost of more downstream treatment failure—repeat ESWL, salvage ureteroscopy (URS) or percutaneous nephrolithotomy (PCNL), and management of complications[10,11]?

Answering that question requires a formal economic evaluation. If a cheaper device performs poorly enough, it can end up raising total costs once salvage procedures, repeat treatments, and indirect societal costs are counted[10,11]. No cost-effectiveness or cost-utility analysis (CUA) has yet compared Smart Litho Plus with the standard imported system in the Thai setting.

We therefore carried out a model-based CUA comparing Smart Litho Plus with the standard electromagnetic ESWL system for renal calculi in Thailand. The analysis took both the healthcare provider and societal perspectives and followed the methodological guidelines of the Thai Health Intervention and Technology Assessment Program (HITAP)[12]. A 10-year decision-analytic cohort model served as the base case, and a lifetime Markov state-transition model captured stone recurrence and the long-run depreciation of capital equipment(3,4). Reporting followed the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 statement[13].

Materials and Methods

Study Design and Reporting Standards

We performed a model-based CUA comparing Smart Litho Plus, a Thai-manufactured electromagnetic ESWL system, with a standard imported electromagnetic system for treating renal calculi in adults. Reporting followed the CHEERS 2022 checklist[13], and the modeling assumptions and parameter values were guided by the Thai HTA methodological guidelines from HITAP[12]. The study followed an a priori protocol (research proposal and protocol synopsis) approved by the Institutional Review Board (COA No. 0623/2024, IRB No. 0195/67); a separate, standalone health economic analysis plan was not published.

Population and Setting

The target population was adults aged ≥18 years with a single opaque renal calculus less than 2 cm in greatest diameter (or less than 1 cm in the lower calyx) and none of the following: prior lithotripsy, active urinary tract infection, uncorrected coagulopathy, distal ureteral obstruction, body mass index ≥30 kg/m^2, previous kidney transplant, abnormal renal anatomy, renal impairment, pregnancy, or orthopedic/spinal deformity. These criteria match those of the underlying effectiveness study[8]. The setting was the Thai public health system, and the effectiveness data came from a multicenter retrospective cohort at three tertiary hospitals[8].

Interventions

Two strategies were compared:

1. Standard ESWL: an imported electromagnetic shock wave lithotripsy system used in two tertiary

hospitals in the source cohort[8].

2. Smart Litho Plus: a Thai-manufactured electromagnetic shock wave lithotripsy system using a locally produced shock wave generator, focusing system, and coupling mechanism, with an imported imaging unit[8].

Patients who were not stone-free after ESWL were assumed to undergo salvage URS, followed by PCNL if URS also failed[10].

Perspective, Time Horizon, and Discount Rate

Following HITAP guidelines[12], we used two perspectives: (i) the healthcare provider perspective, which captures direct medical costs, and (ii) the societal perspective, which also includes patient travel costs and productivity losses. The base-case horizon was 10 years for the cohort model and lifetime (to age 100) for the Markov extension, reflecting the chronic, recurrent nature of urolithiasis[3,4]. Costs and outcomes were discounted at 3% per year as HITAP recommends[12], with sensitivity analyses at 0% and 6%.

Health Outcomes and Effectiveness Measure

The primary outcome was the quality-adjusted life year (QALY). Four-week stone-free rates came from the source cohort[8]: 64.0% (43/67) for Standard ESWL and 44.0% (24/54) for Smart Litho Plus. Adverse-event rates were taken from the same cohort[8]: sepsis in 1.5% (Standard) versus 0% (Smart Litho), and stone street in 1.5% versus 5.6%. We assumed a URS salvage success rate of 90% and a further PCNL salvage success of 95%.

Measurement and Valuation of Health-Related Quality of Life

Health-state utilities were drawn from published studies of stone-disease populations. We set the stone-free utility at 0.92 and the residual-stone utility at 0.81, in line with the EQ-5D values that Polotti et al. reported for kidney stone patients and matched healthy controls[14] and with the earlier SF-36 findings of Bensalah et al.[15]. Each complication (sepsis or stone street) was given a one-time disutility of 0.05 QALY. For any future primary data collection in this population, the Thai EQ-5D-5L value set[16] would be the instrument of choice.

Resource Use and Cost Estimation

Costs were measured in 2024 Thai Baht (THB). Direct medical costs comprised:

- Capital costs of the lithotripter, amortized over a 7-year equipment lifespan (assumed equal across both technologies)
- Annual maintenance and service contract costs
- Per-session operating costs (drugs, staff time, room costs, and baseline imaging), with an additional cost per shock wave reflecting electrode wear
- Salvage URS cost (base case 80,000 THB, sensitivity range 40,000-150,000 THB)
- Salvage PCNL cost (base case 150,000 THB)
- Sepsis admission cost (base case 60,000 THB)
- Stone street treatment cost including double-J stent insertion (base case 30,000 THB)

Where standard Thai unit-cost tables existed, we drew parameter values from published cost-list data[17]. Where no direct measurement was available, values were estimated and then stress-tested in extensive sensitivity analyses. For the societal perspective, indirect costs added the estimated travel cost per visit and productivity losses (patient ± caregiver) per ESWL session and per URS visit, valued at the Thai minimum wage. We modeled the number of ESWL sessions per case as 1 when the initial procedure achieved stone-free status and 2 when re-treatment was needed before salvage.

Choice of Model

We constructed a deterministic decision-analytic cohort model in Microsoft Excel for the base-case 10-year analysis, capturing initial ESWL treatment, salvage pathways, and complications. The decision-tree structure is shown in Figure 1. The root decision node represents the choice of ESWL device; each device pathway proceeds through a chance node representing initial treatment success or failure, then — for failures — through a salvage cascade of URS and, if URS fails, PCNL. Complications (sepsis and stone street) are applied as independent side outcomes at each pathway.

To extend the analysis to a lifetime horizon and incorporate stone recurrence[3,4], we built a Markov state-transition model with the structure shown in Figure 2. The model comprises three health states: Stone-free, Residual stone, and Death (absorbing), with 1-year cycles. Cohort members enter the Stone-Free or Residual Stone state based on the outcome of the initial ESWL cascade (Figure 1); recurrence events cause a proportion of stone-free patients to be re-treated with the same modality; and age-specific all-cause mortality applies to both non-absorbing states.

The cohort was initialized at age 57 (mean age from the source cohort)[8]. All-cause mortality was estimated from Thai life tables. The annual stone recurrence rate was set at 7% per year for the first five

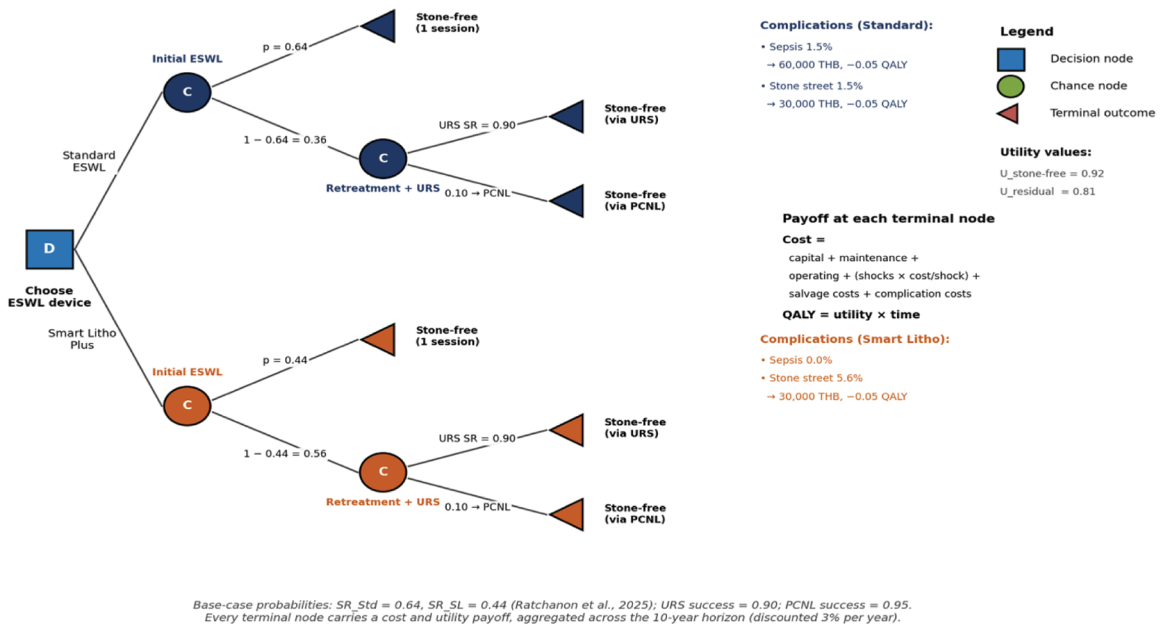

Figure 1. Decision tree structure for the 10-year cohort model. Base-case probabilities: SR_Std=0.64, SR_SL=0.44 (Ratchanon et al., 2025) (8), URS success=0.90, PCNL success=0.95. Each terminal node aggregates costs (capital, maintenance, operating, shocks, salvage, complications) and QALYs over the 10-year horizon with 3% annual discounting.

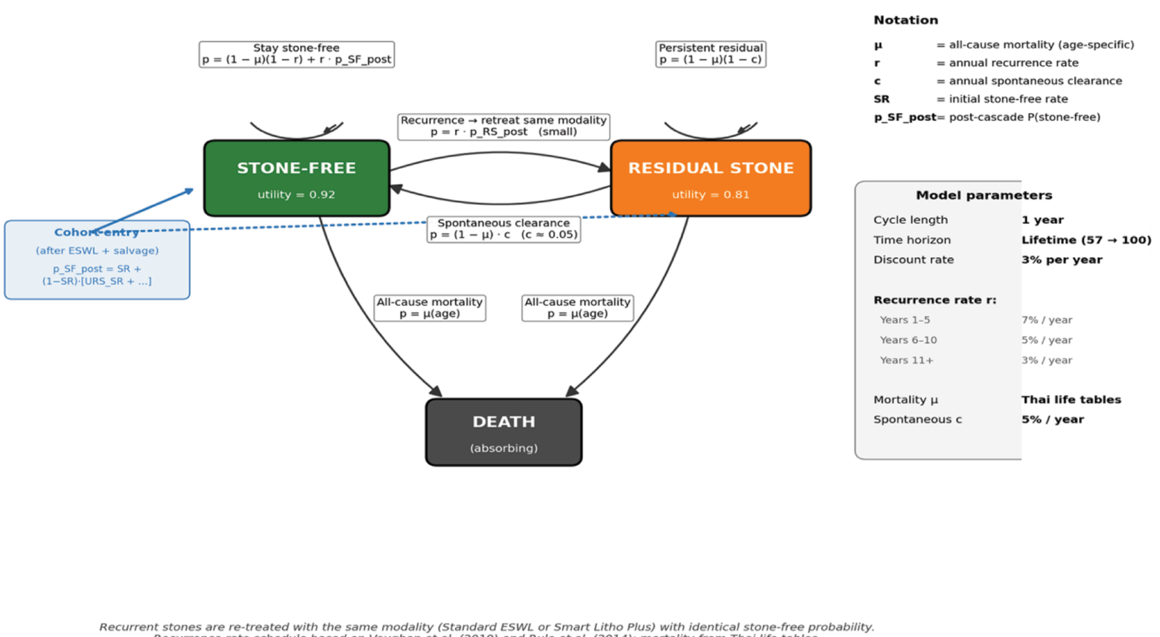

Figure 2. Markov state-transition model for lifetime extension. Three states (Stone-free, Residual stone, Death), annual cycle length. Transition probabilities depend on annual recurrence rate r, spontaneous clearance rate c, and age-specific mortality μ. Recurrent stones are re-treated with the same modality with identical stone-free probability.

years post-treatment, declining to 5% in years 6-10 and 3% thereafter, based on longitudinal stone-recurrence cohort data from Vaughan et al.[3] and Rule et al[4]. Recurrent stones were assumed to be treated with the same modality as the original treatment. A half-cycle correction was applied to the utility accumulation.

Transition probabilities per cycle are summarized as follows: Stone-Free → Stone-Free with probability $(1 - \mu)(1 - r) + r \cdot p\_SF\_post$; Stone-Free → Residual Stone with $r \cdot p\_RS\_post$; Stone-Free → Death with μ; Residual Stone → Stone-Free with $(1 - \mu) \cdot c$; Residual Stone → Residual Stone with $(1 - \mu)(1 - c)$; and Residual Stone → Death with μ. Here, p_SF_post denotes the post-cascade probability of stone-free status derived from the initial ESWL treatment plus salvage pathway (Figure 1), and c denotes the annual spontaneous clearance rate for the residual stone state (5%).

Assumptions

Key model assumptions included:

- Equal eligibility for both technologies (no patient-level differential routing)
- All ESWL failures proceed to URS salvage (sensitivity-tested)
- Operating cost per session is independent of stone-free status
- Recurrent stones are managed identically to incident stones
- No technology learning curve effect on stone-free rate over time
- Adverse events are independent across cycles
- Annual case volume of 200 cases per device

The complete set of model inputs — base-case values, the ranges explored in deterministic sensitivity analysis, the probability distributions used in the probabilistic analysis, and data sources — is provided in Table 1.

Statistical Analysis

Base-case analysis: The incremental cost-effectiveness ratio (ICER) was the difference in mean discounted costs divided by the difference in mean discounted QALYs between Standard ESWL and Smart Litho Plus. A strategy was strictly dominant when it was both less costly and more effective. The willingness-to-pay (WTP) threshold was 160,000 THB per QALY, equal to one time Thai GDP per capita as recommended by HITAP[12]. We also computed the incremental net monetary benefit (INMB): INMB = (WTP × ΔQALY) – ΔCost, where a positive value indicates cost-effectiveness.

Sensitivity analyses: For the one-way analyses, we varied each parameter in turn across a plausible range and displayed the results as a tornado diagram ranked by effect on INMB. Threshold analysis found the URS salvage cost at which the decision reversed. A two-way analysis varied URS salvage cost (20,000-150,000 THB) together with the Smart Litho Plus stone-free rate (35% to 80%). The probabilistic sensitivity analysis (PSA) used Monte Carlo simulation with 10,000 iterations: probabilities were drawn from Beta distributions based on sample-size-derived standard errors from the source cohort[8], costs from Gamma distributions with coefficients of variation of 10% to 30%, and utilities from Beta distributions. We summarized the joint uncertainty with cost-effectiveness planes and a cost-effectiveness acceptability curve (CEAC) spanning WTP thresholds from 0 to 500,000 THB/QALY.

Software: We ran the deterministic base case in Microsoft Excel (Microsoft Corp., Redmond, WA) and the Markov model and probabilistic analyses in Python (NumPy, pandas, Matplotlib). A generative AI assistant (Claude, Anthropic) was used to support the construction of the decision-analytic and Markov models, to implement the deterministic and probabilistic sensitivity analyses, and to generate the figures and tables. The model structure, all input parameters, and all assumptions were defined by the authors; the authors independently verified the model logic, calculations, and outputs and take full responsibility.

Model validation: The model was validated using standard good-practice checks. Face validity of the model structure and of the input parameters was reviewed by the clinical and health-economic investigators. Technical (internal) validity was verified by independently reproducing the deterministic cohort calculations and by confirming that extreme and null parameter values produced the expected directional changes in costs and QALYs. Cross-validation was performed by comparing the 10-year deterministic cohort model with the lifetime Markov model; both produced consistent conclusions (Standard ESWL dominant). External validation against an independent model was not possible, as no previous CUA comparing these devices exists.

Subgroup, equity, and patient-engagement considerations: Because effectiveness estimates were available only at the aggregate cohort level, no subgroup (heterogeneity) analyses — for example by stone size, location, or composition — were undertaken. No distributional or equity-focused analysis was performed. No patients, members of the public, or other external stakeholders were involved in the design, conduct, or interpretation of this model-based evaluation.

Ethical Approval

This CUA was reviewed and approved by the Institutional Review Board of the Faculty of Medicine,

Table 1. Model input parameters, ranges, distributions, and sources

Parameter	Base-case	Range (DSA)	Distribution (PSA)	Source
Clinical effectiveness				
Stone-free rate: Standard ESWL (Std) (%)	64.0	50.0-80.0	Beta (43, 24)	Ratchanon 2025[8]
Stone-free rate: Smart Litho Plus (SL) (%)	44.0	35.0-60.0	Beta (24, 30)	Ratchanon 2025[8]
URS salvage success (%)	90.0	80.0-95.0	Beta	Assumption (literature-informed)
PCNL salvage success (%)	95.0	90.0-99.0	Beta	Assumption
Sepsis rate: Std/SL (%)	1.5/0.0	0-5	Beta	Ratchanon 2025[8]
Stone-street rate: Std/SL (%)	1.5/5.6	0-10	Beta	Ratchanon 2025[8]
Shock waves/session: Std/SL	4,613/3,731	±20%	Fixed	Ratchanon 2025[8]
ESWL sessions/case (success/failure)	1.0/2.0	Fail 1.5-2.5	Fixed (scenario)	Assumption (chart review)
Annual stone recurrence (year 1-5/6-10/≥11) (%)	7/5/3	Year 1-5: 5-10	Beta	Vaughan 2019[3], Rule 2014[4]
Health-state utilities				
Utility: stone-free	0.92	0.85-0.95	Beta	Polotti 2020[14], Bensalah 2008[15]
Utility: residual stone	0.81	0.70-0.85	Beta	Polotti 2020[14], Bensalah 2008[15]
Disutility per complication event (QALY)	0.05	0.025-0.10	Beta	Assumption (Thai EQ-5D-5L value set[16] for future primary data)
Costs: capital and operating (2024 THB)				
Capital cost: Standard ESWL (Std)	16,822,430	12M-20M	Gamma (CV 10%)	Procurement data (institutional)
Capital cost: Smart Litho Plus (SL)	8,300,000	6M-11M	Gamma (CV 10%)	Procurement data (institutional)
Equipment lifespan (years)	7	5-10	Fixed	Assumption
Annual maintenance: Std/SL	1,401,869/500,000	±50%	Gamma (CV 20%)	Service-contract estimate/assumption
Operating cost per session	5,000	3,000-8,000	Gamma (CV 30%)	Hospital estimate/assumption
Cost per shock wave	1.5	±50%	Gamma	Assumption
Costs: salvage and complications (2024 THB)				
Salvage URS	80,000	40,000-150,000	Gamma (CV 30%)	Thai cost data[17]/assumption
Salvage PCNL	150,000	100,000-300,000	Gamma (CV 30%)	Thai cost data[17]/assumption
Sepsis admission	60,000	30,000-120,000	Gamma (CV 30%)	Hospital estimate/assumption
Stone-street treatment (including stent)	30,000	15,000-60,000	Gamma (CV 30%)	Hospital estimate/assumption
Societal (indirect) inputs				
Travel cost per visit	500	±50%	Gamma	Assumption
Productivity loss per session/visit (days)	2	1-3	Fixed	Assumption
Daily wage (productivity valuation)	400	±25%	Gamma	Assumption (Thai minimum wage basis)
Model settings				
Annual case volume per device	200	100-400	Fixed in PSA	Assumption
Discount rate (costs and outcomes)	3%	0% to 6%	Fixed (scenario)	HITAP guideline[12]
Base-case time horizon (years)	10	5-20	Fixed (scenario)	Assumption (lifetime in Markov)
WTP threshold (THB/QALY)	160,000	-	Fixed	1× Thai GDP per capita, HITAP[12]

DSA=deterministic sensitivity analysis; PSA=probabilistic sensitivity analysis; THB=Thai Baht; ESWL=extracorporeal shock wave lithotripsy; QALY=quality-adjusted life-year; URS=ureteroscopy; PCNL=percutaneous nephrolithotomy; WTP=willingness-to-pay; CV=coefficient of variation; M=million.

Beta distributions were assigned to probabilities and utilities and Gamma distributions to costs. Beta parameters for stone-free rates reflect the source-cohort numerators and denominators (Standard 43/67; Smart Litho Plus 24/54). Parameters labelled "Assumption" were not derived from a specific published source and were varied across the stated range in sensitivity analysis; "±" denotes the fraction by which the base case was varied. All costs are expressed in 2024 THB and were not inflation-adjusted across years; no cross-currency conversion was applied.

Chulalongkorn University (COA No. 0623/2024, IRB No. 0195/67) under an expedited review procedure (approved 29 April 2024). The analysis used aggregated cohort data and published parameter values; no individual patient-level data were re-analyzed. The underlying clinical effectiveness estimates were obtained from a previously published multicenter retrospective cohort study, which had separately been approved by the same Institutional Review Board (IRB No. 0194/67) with a waiver of informed consent for its retrospective design[8].

Results

Base-Case Cost-Effectiveness (10-year horizon)

In the base case (10-year horizon, 200 patients per device per year), Standard ESWL strictly dominated

Table 2. Base-case cost-utility results (10-year horizon, 200 cases per device per year)

Outcome	Standard ESWL (Std)	Smart Litho Plus (SL)	Difference (Std – SL)
Provider perspective			
PV total cost (THB)	124,386,503	140,295,026	–15,908,523
PV total QALYs	1,607.05	1,600.90	+6.15
Cost per case (THB)	70,786	79,839	–9,053
ICER (THB/QALY)	-	-	Standard ESWL dominant
INMB at WTP 160,000 (THB)	-	-	+16,892,523
Societal perspective			
PV total cost (THB)	128,201,210	144,996,874	–16,795,664
PV total QALYs	1,607.05	1,600.90	+6.15
ICER (THB/QALY)	-	-	Standard ESWL dominant
INMB at WTP 160,000 (THB)	-	-	+17,779,664

ESWL=extracorporeal shock wave lithotripsy; THB=Thai Baht; PV=present value; QALY=quality-adjusted life-year; ICER=incremental cost-effectiveness ratio; INMB=incremental net monetary benefit; WTP=willingness-to-pay

"Dominant" indicates the strategy is simultaneously less costly and more effective. Costs and QALYs were discounted at 3% per year. INMB = (WTP × ΔQALY) – ΔCost at WTP=160,000 THB/QALY. Probabilistic analysis (10,000 iterations) gave a 76.8% probability that Standard ESWL was dominant and an 81.0% probability that it was cost-effective at the WTP threshold (provider perspective).

Smart Litho Plus under both the provider and the societal perspective: it was less costly and produced more QALYs at the same time.

From the provider perspective, the present value (PV) of total costs over 10 years was 124.4 million THB for Standard ESWL and 140.3 million THB for Smart Litho Plus, a difference of –15.9 million THB in favor of Standard ESWL. The PV of QALYs was 1,607.05 versus 1,600.90, favoring Standard ESWL by 6.15 QALYs. Mean cost per case was 70,786 THB for Standard ESWL and 79,839 THB for Smart Litho Plus, a gap of about 9,053 THB.

Under the societal perspective, which adds patient travel costs and productivity losses, the cost difference widened to –16.8 million THB while the QALY gain stayed at 6.15; Standard ESWL again strictly dominated Smart Litho Plus.

The reason is straightforward. The lower capital cost of Smart Litho Plus saved about 6,000 THB per case in fixed costs, but that saving was too small to cover the extra downstream costs created by its lower stone-free rate (44% vs. 64%)[8]. Because more patients in the Smart Litho Plus arm failed treatment, they needed more salvage URS procedures and more repeat ESWL sessions, and the cost of these outweighed the savings on equipment.

The base-case cost-utility results from both the provider and societal perspectives are summarized in Table 2.

One-Way Deterministic Sensitivity Analysis

In the one-way analysis, we varied each parameter across a plausible range and recomputed the INMB at the WTP threshold of 160,000 THB per QALY(12). The base-case INMB was +16.9 million THB in favor of Standard ESWL. The tornado diagram (Figure 3) ranks the parameters by their effect on this value. Only three could reverse the decision: the Standard ESWL stone-free rate (50% to 80%), the annual case volume (100-400), and the Smart Litho Plus stone-free rate (35% to 60%). URS salvage cost (40,000-150,000 THB) and the time horizon (5-20 years) moved the result substantially but never flipped it within plausible limits. Utilities, operating cost per session, and the discount rate mattered little.

Threshold Analysis: URS Salvage Cost

Threshold analysis pinpointed the URS salvage costs at which the conclusion changed. From the provider perspective, Standard ESWL strictly dominated Smart Litho Plus at any URS cost of 34,734 THB or more. Below that, dominance was lost, and once URS cost fell below 31,934 THB, the ICER crossed the Thai WTP threshold[12], making Smart Litho Plus the cost-effective option. The corresponding societal-perspective thresholds were lower, at 32,605 and 29,749 THB.

Reported URS costs in the Thai public sector and the wider region typically exceed 40,000 THB—well above these thresholds—so the finding that Standard ESWL dominates Smart Litho Plus appears robust to realistic variation in URS pricing.

Two-Way Sensitivity: URS Cost × Smart Litho Plus Stone-Free Rate

We also examined the joint influence of URS

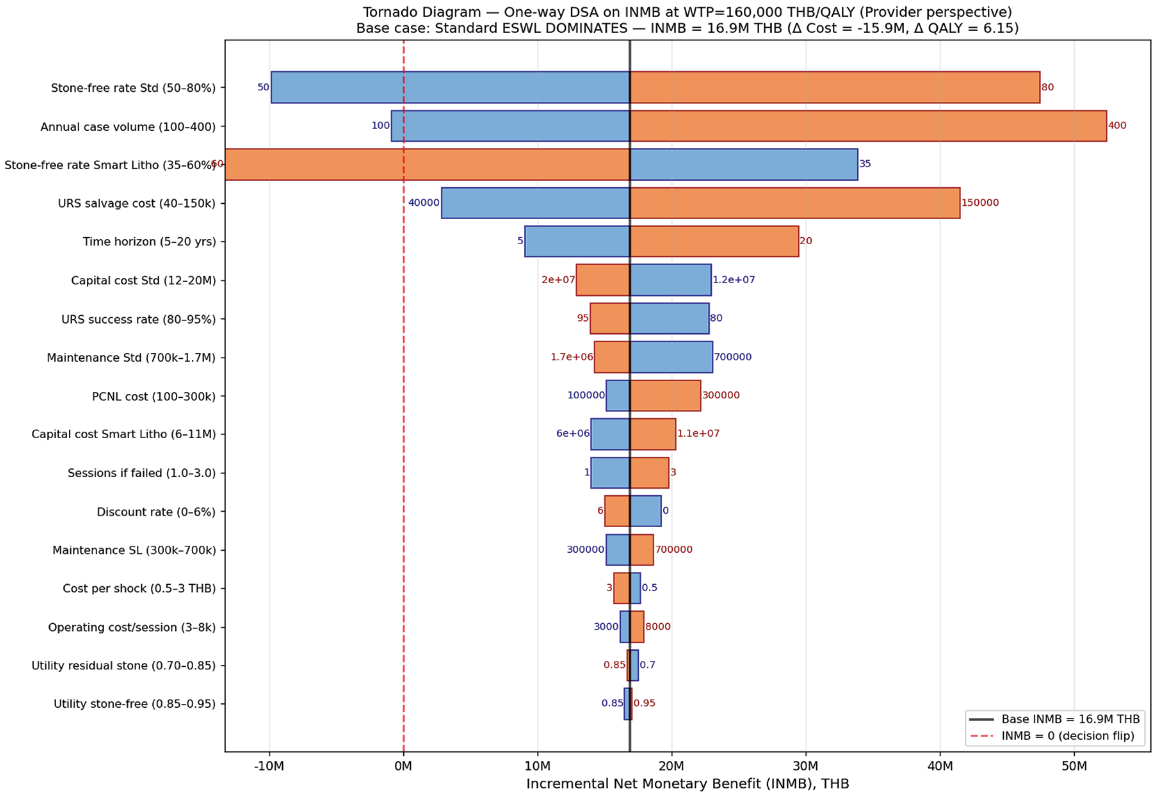

Figure 3. Tornado diagram of one-way deterministic sensitivity analysis on incremental net monetary benefit (INMB) at WTP=160,000 THB/QALY (provider perspective). Vertical solid line=base-case INMB; dashed red line=INMB=0 (decision threshold).

salvage cost (20,000-150,000 THB) and the Smart Litho Plus stone-free rate (35% to 80%) on the decision. At the current stone-free rate of 44%[8] and a URS cost of 80,000 THB, the base case fell well within the region where Standard ESWL is preferred.

To become cost-effective at the base-case URS cost of 80,000 THB, Smart Litho Plus would need to raise its stone-free rate to about 53.0%. At URS costs of 60,000 and 40,000 THB, the required rates fall to 50.4% and 46.4%. If the device matched the Standard ESWL stone-free rate of 64%, it would dominate at every URS cost we examined.

Probabilistic Sensitivity Analysis

The PSA ran 10,000 Monte Carlo iterations, with distributions assigned to every uncertain parameter. From the provider perspective, the mean ΔCost (Standard – Smart Litho Plus) was –16.4 million THB (95% credible interval –60.1M to +18.1M) and the mean ΔQALY was +6.44 (95% CI –2.0 to +16.6). Standard ESWL was strictly dominant in 76.8% of iterations and cost-effective at the Thai WTP threshold of 160,000 THB/QALY in 81.0%[12]. On the cost-effectiveness plane, most simulations lay in the quadrant where Standard ESWL was both less costly and more effective (Figure 4). The societal-perspective figures were similar (77.6% and 81.8%).

The CEAC (Figure 5) plots each strategy's probability of being cost-effective across WTP thresholds from 0 to 500,000 THB/QALY. Standard ESWL stayed near 80% across the whole range, rising only slightly as WTP increased—evidence that the conclusion holds across plausible threshold values.

Lifetime Markov Model Extension

To capture the chronic, recurrent nature of urolithiasis[3,4] and the long service life of the equipment, we extended the analysis to a lifetime horizon with a Markov state-transition model using annual cycles, running from the cohort mean age of 57 years to age 100. The Markov results matched the base case: Standard ESWL strictly dominated Smart Litho Plus over a lifetime. From the provider perspective, lifetime PV cost was 23.6 million THB for Standard ESWL versus 26.6 million THB for Smart Litho Plus (Δ=–3.0 million THB), with Standard

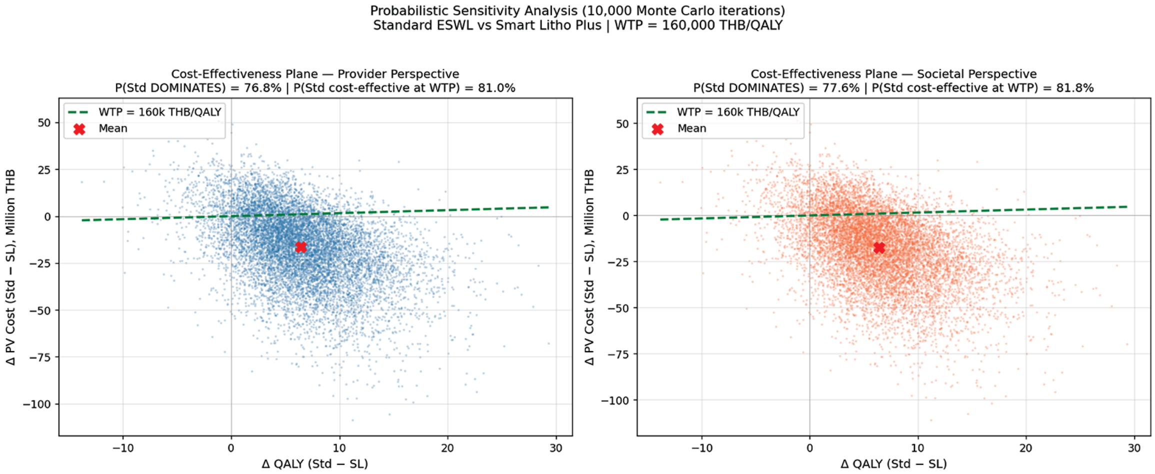

Figure 4. Cost-effectiveness plane from probabilistic sensitivity analysis (10,000 Monte Carlo iterations). Each dot=one simulation; red X=mean. Most simulations cluster in the lower-right quadrant, indicating Standard ESWL is both less costly and more effective. Dashed green line=Thai WTP threshold (160,000 THB/QALY).

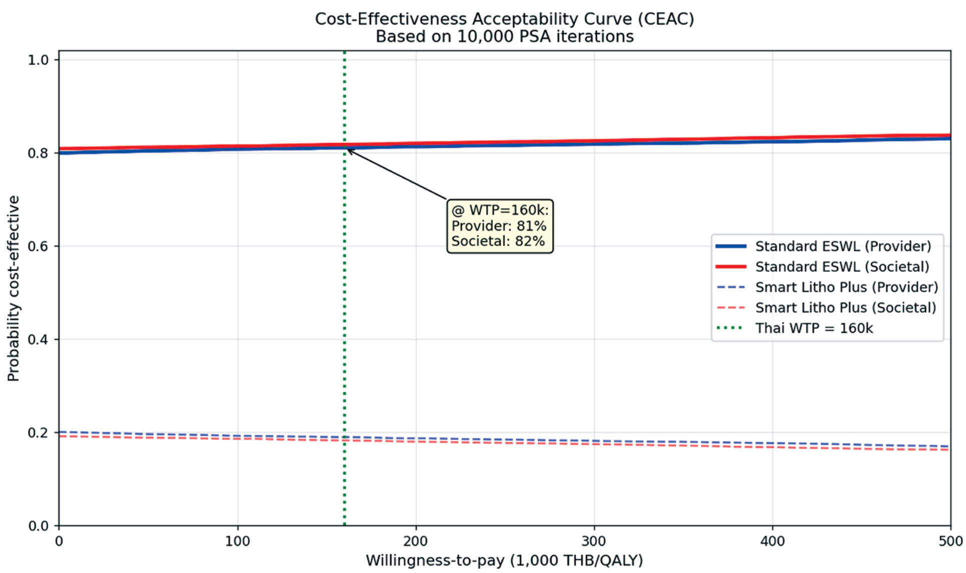

Figure 5. Cost-effectiveness acceptability curve. Standard ESWL maintains approximately 80% probability of cost-effectiveness across the entire range of WTP thresholds. Vertical dotted green line=Thai WTP threshold (160,000 THB/QALY).

ESWL gaining 0.33 QALYs (INMB=+3.06 million THB at WTP=160,000 THB/QALY[12]). The societal perspective pointed in the same way (Δ Cost=–3.2 million THB; INMB=+3.23 million THB).

Discussion

Principal Findings

In this CUA comparing the Thai-manufactured Smart Litho Plus with an imported standard lithotripter for renal calculi in Thailand, Standard ESWL strictly dominated Smart Litho Plus under both perspectives and across every method we used: the 10-year deterministic model, the lifetime Markov model, and the PSA with 10,000 iterations.

What drove this result was the large stone-free-rate difference (64% vs. 44%) in the underlying cohort[8]. That 20-percentage-point gap meant many more Smart Litho Plus patients needed salvage URS and repeat ESWL, and these cost more than cancelled out the device's lower purchase price.

The two-way analysis gives a clear performance target: at the base-case URS cost of 80,000 THB, Smart

Litho Plus would need to lift its stone-free rate from 44% to about 53% to become the cost-effective choice. Reaching this may be possible through a better shock-wave generator, improved coupling, or more careful patient selection[6].

Comparison with Existing Literature

These findings add to the economic literature on lithotripsy, which has mostly compared treatment modalities (ESWL vs. URS vs. PCNL) rather than competing ESWL devices. In a systematic review and meta-analysis, Geraghty et al. found URS more cost-effective than ESWL on average, though with wide variation in costs and outcomes across health systems[10]. The recent PUrE RCT 1, in the UK NHS, pointed the other way: ESWL was more cost-effective than flexible ureterorenoscopy for lower-pole stones ≤10 mm, with a high probability of cost-effectiveness at the £20,000 per QALY threshold even though its stone-free rate was lower[11].

As far as we know, this is the first formal CUA comparing a domestically made lithotripter with an imported standard in a middle-income health system. The finding that the cheaper local device is dominated by the imported one challenges a common assumption: that a lower purchase price automatically makes a locally produced device better value. It fits, however, with the international pattern in which downstream effectiveness and retreatment costs, rather than purchase price, tend to drive the economics of lithotripsy[10,11].

Strength

This analysis has several strengths. It draws on head-to-head effectiveness data from a multicenter Thai cohort[8], so the stone-free and adverse-event rates of the two devices are directly comparable in the local population. It reports both the provider and societal perspectives, as HITAP recommends[12]. It includes a wide range of sensitivity analyses—one-way, threshold, two-way, and a 10,000-iteration PSA. It extends to a lifetime Markov model that accounts for stone recurrence and competing all-cause mortality, drawing on longitudinal recurrence data[3,4]. It follows the CHEERS 2022 reporting standards[13].

Limitation

The study also has limitations. First, the effectiveness data come from a non-randomized retrospective cohort in which the treatment arm depended on the site[8]. Such a design is open to selection bias and to unmeasured confounding by stone composition, operator experience, and imaging quality; a randomized trial of the two devices would give stronger evidence.

Second, several cost parameters were estimated rather than measured directly. We used Thai standard unit-cost lists[17] where they existed, but primary micro-costing at the three hospitals would strengthen the cost side of the analysis. Where no verifiable source existed, we flagged the value as an estimate and tested it in sensitivity analyses.

Third, the number of ESWL sessions per case—modeled as 1 for successes and 2 for failures—is a structural assumption we could not verify directly from the cohort[8]; a chart review of the 121 patients would help confirm it.

Fourth, the health-state utilities came from international studies of stone patients[14,15] rather than from EQ-5D-5L data collected in Thai patients; the Thai EQ-5D-5L value set[16] offers a ready instrument for such primary collection in the future.

Fifth, the model assumes no learning-curve effect on the Smart Litho Plus stone-free rate. If that rate improves as operators gain experience with the device, its long-run cost-effectiveness could shift in its favor. Finally, the model does not account for stone composition, which is known to affect ESWL success[6]; the source cohort[8] lacked dual-energy computed tomography (CT) data, so subgroup analysis by composition was not possible.

Implications for Policy and Practice

The main policy message is that a lower purchase price alone does not make a piece of equipment good value. When Thai public hospitals choose a lithotripter, they should weigh the device's own stone-free rate and the downstream cost of treatment failure, as the principles of health technology assessment require[10,12,13]. At its current performance, rolling out Smart Litho Plus in place of the standard imported system would use public resources inefficiently from both perspectives.

None of this argues against investing in Thailand's medical-device industry, which remains important for self-reliance, supply-chain resilience, and economic growth. The point is rather that domestic devices should face the same evidence requirements as imported ones—including head-to-head comparative effectiveness and explicit cost-effectiveness analysis.

Future Research Directions

Several priorities emerge for future research:

- A randomized controlled trial of Smart Litho

Plus versus standard ESWL would provide higher-quality effectiveness evidence and allow stratified analysis by stone characteristics.

- Primary collection of EQ-5D-5L data in Thai stone patients across treatment, residual, and recurrence states, using the Thai value set[16].
- Hospital micro-costing studies at the three participating sites would replace estimated operating, URS, PCNL, and complication costs with directly measured values, building on the Thai standard cost list framework[17].
- Engineering research to improve Smart Litho Plus stone-free rate should be a priority for the manufacturer.

Conclusion

Drawing on head-to-head effectiveness data from a multicenter Thai cohort[8], this CUA found that the standard imported electromagnetic ESWL strictly dominated the Thai-made Smart Litho Plus for renal calculi treatment under both the provider and societal perspectives. The result held up across one-way, threshold, and two-way sensitivity analyses, the PSA (76.8% probability of dominance and 81.0% probability of cost-effectiveness at the Thai WTP threshold[12]), and the lifetime Markov model.

Its lower purchase price could not make up for the extra downstream costs caused by its lower stone-free rate (44% vs 64%)[8]. At the URS salvage cost currently seen in Thai public hospitals, Smart Litho Plus would need a stone-free rate of about 53% to become cost-effective.

The broader lesson is that buying decisions for major medical equipment must weigh clinical effectiveness and the cost of treatment failure, not just the purchase price. For Smart Litho Plus, becoming cost-effective would take continued engineering work to raise its stone-free rate, together with lower salvage URS costs.

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Authors Contributions

SR: Conceptualization, methodology, formal analysis, investigation, writing-original draft, writing-review & editing, and supervision. NA: Data curation, investigation, writing-review & editing. SS: Data curation, investigation, and writing-review & editing. AS: Methodology, formal analysis, validation, and writing-review & editing. All authors read and approved the final manuscript.

Clinical Trial Registration

Not applicable. This study is a model-based health economic evaluation using aggregated data from a previously published cohort and does not constitute a clinical trial; therefore, clinical trial registration was not required.

Conflicts of Interest

The authors declare no conflicts of interest. None of the authors has any financial relationship with the manufacturers of either lithotripter system.

Data Availability Statement

All model parameters, formulas, and outputs are provided in the supplementary Excel workbook and analysis scripts. Aggregated clinical data from the underlying cohort are available in the published report of Ratchanon et al.[8].

Ethics Approval and Consent to Participate

This CUA was reviewed and approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University (COA No. 0623/2024; IRB No. 0195/67), under an expedited review procedure (approved 29 April 2024). The analysis used aggregated cohort data and published parameter values; no individual patient-level data were re-analyzed, and no participants were recruited or contacted for this study, so individual informed consent was not applicable. The underlying clinical effectiveness estimates were obtained from a previously published multicenter retrospective cohort study, separately approved by the same Institutional Review Board (IRB No. 0194/67) with a waiver of informed consent for its retrospective design.

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Use of Artificial Intelligence

During the preparation of this work, the authors used Claude (Anthropic) to assist with drafting and language editing and, as described in the Methods, with building the health economic model, conducting the sensitivity analyses, and preparing the figures and tables. After using this tool, the authors reviewed and edited all content, independently verified all data, calculations, and references, and take full responsibility. The tool was not used as a substitute for the authors' scientific judgement and is not listed as an author.

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