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Original Article

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Transperineal prostate biopsy under local vs general anaesthesia: a cost-effectiveness analysis

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Objectives

To estimate the cost effectiveness of local anaesthetic (LA) transperineal prostate biopsy (TPB) compared to general anaesthetic (GA) TPB, considering both hospital/health system and societal perspectives.

Patients and Methods

Individual-patient data from a prospective pilot study of 80 patients who underwent LA (n = 40) or GA (n = 40) TPB according to patient preference was used. A cost-effectiveness analysis was conducted using a decision tree model considering cancer detection rates, perioperative and return to work considerations between LA and GA TPB. The economic model included costs associated with consumables, device (capital, maintenance) and personnel for each approach. Cost-effectiveness was evaluated in terms of the incremental cost/quality-adjusted life-years (QALYs) and incremental net monetary benefit. Probabilistic and one-way sensitivity analyses were performed.

Results

Clinical parameters were generally similar between groups, including overall (55%) and significant (35% vs 23%; P = 0.32) cancer detection and procedure-specific duration (20 vs 21 min; P = 0.53). Total procedure and recovery durations were longer in the GA group by 8 min (P < 0.001) and 32.5 min (P < 0.001), respectively. Participants in the LA group returned to work earlier than the GA group (2 vs 4 days; P = 0.046). There was a marginal gain in QALYs between the LA and GA groups (0.82385 vs 0.82383), but LA TPB had lower costs (Australian dollars [AU$]715.80 vs AU$1673.58), with an estimated average cost savings of ~AU$959. From the societal perspective, driven by the reduction in productivity loss, the average cost savings with LA TPB were ~AU$1639. Sensitivity analyses showed the probability of LA being cost effective was 100%, while utilisation of operating theatre for GA TPB was the main driver of cost difference.

Conclusion

Performing TPB via the LA approach would be cost-saving from both hospital and societal perspectives without reducing the accuracy of the biopsy.

Keywords

cancer detection, complications, local anaesthesia, prostate cancer, transperineal biopsy, cost-effectiveness analysis, economic evaluation

Introduction

Prostate cancer is the most commonly diagnosed malignancy in males [1], usually via prostate biopsy after PSA testing, examination (DRE) and imaging (MRI). Traditionally prostate biopsy was performed transrectally under TRUS guidance and was the standard of care for many years and still is in some jurisdictions [1]. TRUS-guided biopsy can be performed under sedation or local anaesthetic (LA) in the outpatient setting, but despite antibiotic use, the infection

risk can be up to 5–7%, with a 2–4% risk of hospital re-admission [2,3].

The transperineal prostate biopsy (TPB) approach has been increasingly used due to simultaneous reduction in risk of urinary tract sepsis, addressing concerns for antimicrobial resistance, and improving anterior and apical prostate sampling [2-6] with less discordance with radical prostatectomy histology [7]. Traditionally, TPB is performed using TRUS guidance with a brachytherapy stepper and grid template usually under a general anaesthetic (GA) or spinal anaesthetic. Despite improvements in health care use due to post-biopsy infection, use of TPB under GA increases operating theatre use and healthcare costs [8], by up to 153% (or 2.5 times) [9], limiting availability of this method of biopsy at some hospitals. Costs can be reduced with increasing use of TPB under GA due to reduced need for inpatient admission, potentially as a result of reduced biopsy cores taken, as well as incorporation of multiparametric MRI for biopsy triage [8]. In the UK, the TPB approach has been reported to be cost effective compared to the transrectal route for a given device cost [10], which is driven by differences in consumables cost, reduced cost of treating infections, and quality-adjusted life years (QALYs) gains associated with reduced infections [11].

Advances in TPB device development have led to implementation of probe-mounted biopsy guides to enable TPB to be performed freehand in the office setting under LA. Overall, LA TPB has been demonstrated to be a safe and well tolerated method of prostate sampling, with a very low incidence of urinary tract sepsis (0.16%) and acute urinary retention (AUR; 1.6%) with satisfactory cancer detection rates [12-14]. Prospective comparative studies between LA and GA approaches are limited; however, a pilot cohort study of 80 patients (GA TPB $n = 40$; LA TPB $n = 40$) using the PrecisionPoint™ (BXTAccelyon Ltd, Burnham, Slough, UK) device reported cancer detection and side effects to be equivalent between the groups [15]. Additionally, formal cost analysis is yet to be conducted, considering hospital and societal aspects, which is critical given the ageing population and the expected doubling in prostate cancer cases by 2040 [16].

Therefore, the aim of this study was to estimate the cost effectiveness of LA TPB compared to GA TPB, considering perspective of both hospital/health service and society.

Patients and Methods

Design and Patient Population

The study used de-identified, individual-patient data from the prospective pilot study conducted by Hogan et al. [15] and is reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 statement (Table S1) [17].

Patients who underwent TPB between February 2020 and September 2020 and elected to undergo LA vs GA according to their preference following usual procedural informed consent discussions. The study was designed as a pilot and recruited 40 consecutive patients into each of the LA and GA arms (total sample size $n = 80$). The primary outcome of the published study was patient tolerability, according to pain scores, while secondary outcomes included cancer detection, complication rates, and theatre utilisation. Pain scores were assessed at many time points perioperatively and postoperatively using a 0–10 numeric rating scale (NRS). Additional patient-reported outcome measures that were collected included: IPSS, International Index of Erectile Function (IIEF), EuroQoL five Dimensions five Levels (EQ-5D-5L), time away from work, presence of any complications, overall satisfaction, and willingness for repeat procedure. Appropriate clinicopathological data were collected, including age, serum PSA, DRE findings, Prostate Imaging-Reporting And Data System (PI-RADS) score and prostate volume, as outlined in the original report [15], which received ethical approval from the Monash Human Research Ethics Committee and all participants provided informed written consent.

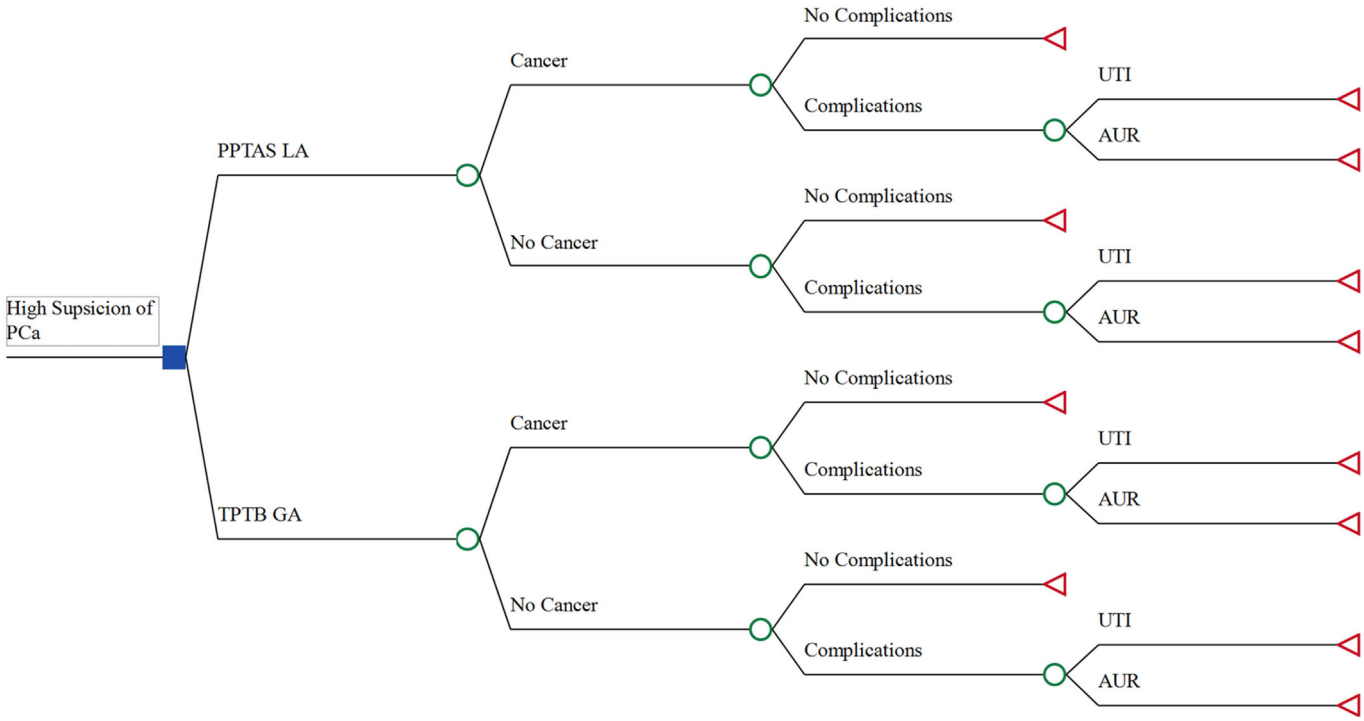
Prostate Biopsy Approaches

Full details of the LA and GA TPB approaches are provided in the original report [15]. TPB performed under LA used the PrecisionPoint Transperineal Access System device, while TPB under GA was performed using a brachytherapy 5-mm grid/stepper unit. All participants received the same peri-procedural medications, prophylactic antibiotics, scrotal fixation, transperineal probe and postoperative care instructions. Key differences between the groups included the use of LA to the skin (10 mL 1% lignocaine with adrenaline) followed by periprostatic block (15 mL 1% lignocaine without adrenaline) in the LA group, while pudendal nerve block (20 mL 0.75% ropivacaine) was performed according to surgeon preference in the GA group. Additionally, two of 42 patients (4.8%) in the LA group were converted to GA as the LA procedure was not tolerated and were not included in the data analysis.

Cost-Effectiveness Analysis

A cost-effectiveness analysis was computed as incremental net monetary benefit (INMB) for improvements in QALYs as well as other measurement of effectiveness, such as difference in the postoperative pain scores, using both the hospital and societal perspectives. For LA TPB to be considered cost-effective, the cost-effectiveness analysis should yield a positive INMB value. A decision tree model was developed to portray the two biopsy strategies: LA TPB and GA TPB, along with their associated complications (Fig. 1). Discount rates were not applied, given

Fig. 1 Decision tree model. PCa, prostate cancer; PPTAS, PrecisionPoint™ Transperineal Access System; TPTB, transperineal template biopsy.



the rapid resolution of complications associated with TPB. In addition, a one-way sensitivity analysis and a probabilistic sensitivity analysis were performed using Monte Carlo microsimulation with 5000 iterations to account for uncertainty in model parameter values. All analyses were performed using TreeAge Pro (Version.2023 R1.0; TreeAge Software, LLC, Williamstown, MA, USA).

The majority of the clinical parameters used in the model (Table 1) [15,18,19,20], such as cancer detection rate, probability of AUR and UTI, NRS score of 0–10 for postoperative pain (leaving recovery), were derived from the aforementioned study [15]. The disutility associated with UTI and AUR were extracted from published literature [18,19].

Patient-level data included costs associated with devices, consumables, medicines, and anaesthesia, and were utilised to estimate the costs in the economic model. For LA TPB, the cost of performing a biopsy was calculated by multiplying procedure-specific time (including anaesthesia) for each patient by the average hourly wage of the urologist and nurse. In contrast, the procedure-specific time was multiplied by the average cost/h of theatre utilisation for GA TPB. These calculations were based on the assumption that LA TPB is performed in an outpatient setting by a urologist and a nurse, while GA TPB is performed in an operating theatre. Indirect treatment costs, limited to productivity loss due to absenteeism, were estimated using the human capital approach. Productivity loss was calculated using the 'lost wages method', multiplying the total number of workdays lost by the median daily earnings in Australia (Australian dollars [AU$]284.56/day for full-time work (7.25 h) or AU$39.50/h) as reported by the

Table 1 Clinical parameters used in the model.

Variable	PPTAS under LA	TPTB under GA	Distribution	Source
Cancer detection rate, %	55	55	Beta	Hogan et al. [15]
Probability of AUR	0.025	0.05	Beta	Hogan et al. [15]
Probability of UTI	0.05	0.0	Beta	Hogan et al. [15]
Probability of no complication	0.925	0.95	Beta	Defined as 1-sum (AUR, UTI)
NRS pain score, mean (SD)	1.1 (1.48)	1.87 (2.04)	NA	Hogan et al. [15]
Baseline utility	0.824	Gamma		Ngo et al. [20]
Disutility due to AUR	0.18	Gamma		Chugtai et al. [18] Ackerman et al. [19]
Disutility due to UTI	0.07	Gamma		Chugtai et al. [18] Ackerman et al. [19]

NA, not applicable; PPTAS, PrecisionPoint™ Transperineal Access System; TPTB, transperineal template biopsy.

Table 2 Cost data.

Costs categories	PPTAS LA, AU$	TPTB GA, AU $	Source
Devices and consumables, mean (SD)			
PrecisionPoint	350.00 (0)	NA	Hogan et al. [15]
Template biopsy device (stabiliser and stepper)	NA	28.43 (0)	$38 240/unit; assuming 269 biopsies/year at Western Health and average lifespan of 5 years
Transducer cost	46.94 (0)	46.94 (0)	AU$37 880/unit; assuming 269 biopsies/year at Western Health and lifetime of 3 years
Ultrasound	44.10 (0)	44.10 (0)	AU$119 470/unit; assuming 269 biopsies/year at Western Health and lifetime of 10 years
Consumables	99.87 (27.19)	222.47 (0)	Cost data reports from the Western Health
Anaesthetics	NA	59.06 (7.32)	Cost data reports from Western Health
Medication	31.46 (26.50)	14.15 (5.45)	
Personnel costs			
Preoperative cost, mean (SD)	11.08 (4.31)	22.06 (7.43)	Cost data reports from Western Health
Urologist, mean (SD)	122.05 (38.40)	NA	AU$197.46/h; average pay of specialist Year 5–9 (fractional doctors), 17.6 + h/week in Victoria
Nurse, mean (SD)		NA	AU$52.22/h; average pay of Registered Nurse Grade 5 based on Nurse Award by Fair Work Ombudsman
Theatre utilisation, mean (SD)	NA	1226.81 (315.26)	The average cost/h was AU$1822 or ~AU$30/min[†][22] ; adjusted for inflation using GDP implicit price deflator and procedure specific time as reported in Hogan et al. [15]
Total costs (95% CI)	**705.50 (692.59 –718.41)**	**1664.02 (1561.23 –1766.81)**	Note: gamma distribution was applied to the total mean cost in the model
Cost of complications			
Cost UTI	110.22		GP visit (AU$89.99), 7-day trimethoprim (PBS Item 2922 T), urine analysis (MBS Item 73 805)
Cost AUR	191.29		Two registered nurse visit (AU$46.24), bladder scan (MBS Item 55 085), catheter placement (MBS Item 36 800), 7-day catheter equipment cost (AU$31.95)[‡]

GDP, gross domestic product; MBS, Medicare Benefits Schedule; NA, not applicable; PBS, Pharmaceutical Benefits Scheme; PPTAS, PrecisionPoint™ Transperineal Access System; TPTB, transperineal template biopsy. †The cost/h includes costs directly recorded by health services as occurring in theatres—salary costs for surgeons, anaesthetists, nurses and technicians, and sterilising services. ‡Cost of catheter equipment = catheter + sterile leg drainage bags + anchoring device + overnight drainage system × 7 + catheter valves. This was based on costing information as reported by Illawarra Shoalhaven Local Health District [23]

Australia Bureau of Statistics [21]. All costs were adjusted to 2023 AU$. A summary of cost data used in the model is presented in Table 2 [15].

Results

Patient Characteristics

From 80 participants (LA n = 40, GA n = 40), most baseline clinical characteristics were similar between the groups. The LA group had a higher median PI-RADS score compared to the GA group (4 vs 3; P = 0.032). Pain scores were similar during and after the procedure but were higher at baseline in the LA group. Participants in the LA group returned to work earlier than the GA group (2 vs 4 days; P = 0.046).

Cancer detection rates were similar between the groups overall (55% vs 55%, P = 1) and for clinically significant cancer (35% vs 23%; P = 0.32), with a higher median number of cores taken in the LA group than the GA group (33 vs 27; P = 0.008). Complication rates were similar between the groups (LA vs GA) for AUR (2.5% vs 5%; P = 1) and re-admission (2.5% vs 5%; P = 0.49).

Despite similar procedure specific times (20 vs 21 min; P = 0.53), total procedure time (30.5 vs 39 min; P < 0.001), recovery time (18.5 vs 51 min; P < 0.001) and total time (54 vs 93 min; P < 0.001) was shorter for the LA group than GA group, respectively.

Cost-Effectiveness Analysis

The base case from a hospital perspective is presented in Table 3. There was no significant difference in the QALYs between the LA and GA groups (0.82385 vs 0.82383). However, the cost of LA TPB was AU$715.80 (95% CI 715.06–717.26), which was lower compared to GA TPB (AU $1673.58, 95% CI 1661.88–1679.65). At a willingness-to-pay threshold of AU$50 000/QALY, a well-accepted threshold, the INMB was AU$958.75.

Sensitivity Analyses

A one-way sensitivity analysis was conducted to assess the impact of individual parameters on the cost-effectiveness results. As shown in Fig. S1, the tornado diagram indicates that the parameter with the greatest influence on INMB was the cost

Table 3 Results of the cost-effectiveness analysis.

Strategy	Costs, AU$ (95% CI)	Incremental cost, AU$	Effectiveness, QALY (95% CI)	Incremental effectiveness, QALY	NMB, AU$ (95% CI)	INMB, AU$
PPTAS LA	715.80 (715.06–717.26)	−957.79	0.82385 (0.81288–0.83597)	0.00002	40 476.53 (29 927.99–41 082.22)	958.75
TPTB GA	1673.58 (1661.88–1679.65)		0.82383 (0.81286–0.83594)		39 517.79 (38 972.15–40 126.63)	

NMB, net monetary benefit; PPTAS, PrecisionPoint Transperineal Access System; TPTB, transperineal template biopsy.

of GA biopsy. The main driver of the cost for GA biopsy was the utilisation of operating theatre to perform the biopsy.

A probabilistic sensitivity analysis was also undertaken to assess uncertainty surrounding the model parameters, involving 5000 randomly drawn simulations of parameter values. The probabilistic sensitivity analysis with 5000 iterations of all distributions as presented in Fig. S2, resulted in a mean INMB of AU$955.71. From a hospital perspective, at a willingness-to-pay of AU$50 000/QALY, LA was the cost-effective strategy in 100% of the iterations.

Societal Perspective

From a societal perspective, at a willingness-to-pay threshold of AU$50 000/QALY, the INMB of the LA approach (compared to GA) was AU$1638.89. Of note, the number of employed patients was imbalanced between the two arms (employed higher in GA arm). Among the employed patients, those in the GA arm returned to work in an average of 5.5 days, while those in the LA arm returned in only 2.6 days on average.

Cost-Effectiveness of Using Other Measurement of Effectiveness

As there was no statistically significant difference between the two groups when assessing overall cancer detection rate, cost-effectiveness of LA was compared to GA TPB using mean postoperative pain score reported by patients (on a scale of 0–10) as the clinical outcome. The mean postoperative pain score was 1.1 (95% CI 0.63–1.57) in the LA group compared to 1.875 (95% CI 1.22–2.52) in the GA group, resulting in a difference of 0.775 (95% CI −0.19 to 1.57).

Exploratory analyses based on difference in the mean postoperative pain score (in favour of LA) showed that the LA TPB was the dominant strategy, i.e., less costly and more effective in terms of pain score reduction.

Discussion

The desire to deliver best clinical practice in a cost-effective manner underpins health service sustainability, particularly for prostate cancer where diagnoses and biopsies are expected to double by 2040 due to increased use of screening and population growth [16]. While TPB serves to reduce infection-related morbidity and antimicrobial resistance, wider implementation has partly been hampered by cost limitations. This analysis has shown that LA TPB using a probe-mounted device provides a positive INMB for hospitals and health systems (AU$955.71/patient) and society (AU$1638.89/patient). These findings are important for wider implementation of LA TPB approach for the following reasons.

First, this study is the first cost-effectiveness analysis comparing LA and GA TPB approaches and showed LA TPB to be cost-effective, primarily driven by avoided costs generated by operating theatre utilisation and less time away from the workplace. Costing of operating theatre costs is complex and multifactorial, estimated to be AU$33–42/min (AU$2004–2500/h) [22,24], similar to United States dollars (US$)37/min in the USA [25], while incorporation of training in all aspects (medical, nursing etc.) also increases costs [26]. Performing procedures in an office-like environment intuitively uses less resources and has been shown to be less costly for bladder [27] and skin cancer management [28]. A single-centre study in the USA of LA TPB vs LA TPB with additional intravenous sedation reported that use of additional sedation was associated with less pain (score 3/10 vs 0/10, $P < 0.01$) for an increase in activity-based costs (US $961.64 vs US$2208.16 ($P < 0.01$) [29]. However, a randomised phase III trial comparing inhaled methoxyflurane to placebo for analgesia during transrectal biopsy reported no difference in pain scores at 15 min [30], but inhaled methoxyflurane reduced patient-reported discomfort, overall experience and willingness to undergo repeat biopsies. Furthermore, despite higher baseline pain scores, the LA TPB approach in this study was able to reduce time off work leading to further benefits from a societal perspective. This was conservative, considering that more patients were employed in the GA TPB arm compared to the LA TPB arm. Therefore, the whole patient-perspective in this study showed further cost-benefits considering quality of life.

Second, in addition to the patient journey, we considered costs relating to both consumables and maintenance of capital equipment (brachytherapy stepper) in the analysis. Ongoing maintenance costs of the reusable equipment (fixed table 'arm' and 'stepper'), in addition to variable requirement for formal sterilisation of the 'stepper' between cases in some hospitals increases costs of this method further. Use of the brachytherapy stepper is also expected to be very difficult with a LA approach due to patient movement against the fixed probe, limiting visualisation and accurate biopsy targeting, and wider skin

puncture area. While use of the PrecisionPoint™ device was shown to be cost-effective at AU$350/patient, other probe-mounted devices are available. Furthermore, given costs were largely dependent on time in operating theatre, hospitals should consider which device will be equally effective and time efficient for the attending surgeons. However, implementation of LA TPB poses a challenge to surgeons and health services, as some reports indicate a learning curve for surgeons [31] in addition to requisite training of support staff. Our experience is that the learning curve for surgeons who are already performing TPB under GA is acceptable (10–15 cases). We recommend surgeons start by performing cases under GA to be familiar with the TPB approach and the device, then followed by supervised cases when performing the procedure under LA. Therefore, the cost benefit of LA TPB will need to be weighed up against the logistical challenges of introduction of a new service and its training requirements. Additionally, health system reimbursement will remain a challenge depending on the specific scenario, with limited motivations to convert to a LA TPB approach in Australia currently, particularly in the private sector.

Despite the strengths of the study, including cost-analysis of prospectively collected data from multiple surgeons on both LA and GA approaches, consideration of the limitations is important for translation to clinical practice. First, the study was limited by single-centre data collection and non-randomised allocation, which could introduce a selection bias for patients more (chose LA) and less (chose GA) likely to tolerate the LA TPB approach, respectively. Patients in the LA TPB group who required conversion to GA (two of 42 [4.8%]) were excluded from the study and, therefore, from the cost-analysis. However, conversions from LA to GA TPB may slightly increase the costs of the LA TPB approach. Second, the analysis was conducted from an Australian health system and society perspective, which may not be absolutely reflective of expected benefits in other countries and health systems. For health systems considering the implementation of LA TPB, potential variation in staffing or other factors, such as post-recovery and hospital length of stay, should be carefully evaluated, as these can impact the overall costs. Assuming that LA TPB was performed in an outpatient setting with a urologist and two nurses, the INMB decreased by 3%. However, when incorporating statistically significant differences in recovery times between the LA and GA groups, using nurse wages as a proxy for recovery costs, the INMB increased by 3%.

In conclusion, performing TPB via the LA approach (using the PrecisionPoint™ device) would be cost-saving from both hospital and societal perspectives without reducing the accuracy of the biopsy. Furthermore, the LA approach may be more cost-effective considering postoperative pain reduction. Further validation in prospective studies conducted in other health systems is encouraged, as are assessments of additional benefits of the LA approach for health systems (additional operating theatre time, surgical wait list impacts).

Author Contributions

Matthew J. Roberts, Henry Yao and Haitham Tuffaha contributed to the study conception and design. Material preparation and data collection were performed by Donnacha Hogan, Brendan Dias, David Wetherwell, Homayoun Zargar. Data analysis was performed by Shiksha Arora and Haitham Tuffaha. The first draft of the manuscript was written by Matthew J. Roberts and Shiksha Arora and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Disclosure of Interests

Matthew J. Roberts serves as a consultant for BXTAccelyon and receives payment to provide training to surgeons. BXTAccelyon had no role in the conception, design, interpretation or writing of this study, nor funding provided for the research. The remaining authors have no relevant financial or non-financial interests to disclose.

Ethics Approval

The study was performed in line with the principles of the Declaration of Helsinki. Ethical approval was granted by the Monash Human Research Ethics Committee.

Data Availability Statement

The datasets generated during and/or analysed during the present study are available from the corresponding author on reasonable request.

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Abbreviations: AU$, Australian dollars; AUR, acute urinary retention; GA, general anaesthesia; INMB, incremental net monetary benefit; LA, local anaesthesia; NRS, numeric rating scale; PI-RADS, Prostate Imaging-Reporting And Data System; QALY, quality-adjusted life-year; TPB, transperineal prostate biopsy; US$, United States dollars.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 statement.

Fig. S1. One-way sensitivity analysis (Tornado diagram).

Fig. S2. Probabilistic sensitivity analysis from a hospital perspective.

