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ORIGINAL RESEARCH ARTICLE

Health technology assessment (HTA) of prostatic urethral lift (PUL) for the treatment of benign prostatic hyperplasia (BPH) in the Italian context

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ABSTRACT

Background: Health technology assessment (HTA) is a process evaluating various aspects of healthcare technologies to support evidence-based decisions. Benign prostatic hyperplasia (BPH) is a common condition among aging men, significantly affecting QoL. Traditional treatments like transurethral resection of the prostate (TURP) and Holmium Laser Enucleation (HoLEP) are effective but often associated with complications and sexual dysfunction. The Prostatic Urethral Lift (PUL) system (UroLift) offers a minimally invasive alternative, preserving sexual function and ensuring faster recovery.

Methods: Using the EUnetHTA Core Model 3.0, UroLift was evaluated across nine domains, combining a systematic review of literature, expert consultation, and real-world evidence. A Budget Impact Model (BIM) simulated treatment pathways over five years, comparing UroLift with TURP and HoLEP.

Results: As the analysis shows, despite the higher initial acquisition cost, UroLift generates savings for the NHS in all the years considered within the analysis. Specifically, savings are derived from the lower incidence of adverse events and complications, both post-operative and in the long term, implying lower inpatient costs and less use of human resources. As anticipated, savings begin in the first year with a differential between the two scenarios considered at 57,747.40 and peak in the fifth year with savings of approximately €1.35 million, for a total estimated savings over the considered time horizon, considering the market shares, of €3,154,997.63.

Conclusions: UroLift demonstrates clinical efficacy, faster recovery, and sexual function preservation while generating cost savings, supporting its integration into BPH management pathways in Italy.

Keywords: Benign prostatic hyperplasia, Budget impact model, HTA, Urolift

Background

Health Technology Assessment (HTA) is a multidisciplinary process that synthesizes information on clinical, economic, social, and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, and robust manner (1). Its aim is to contribute to the identification of safe, effective, patient-centred, and best value healthcare policies. The term "health technology" refers not only to medical devices and drugs but also to diagnostic procedures, surgical interventions, and organizational models. Therefore, in a context of an increasing need for healthcare economic resources, since they are becoming more and more limited, and the rapid advancement of medical technologies, HTA was created to provide decision-makers with a complete and integrated picture of information in order to determine the value of a healthcare technology at different points in its life cycle, so as to make informed and sustainable decisions for the healthcare system (2). To this end, the HTA survey operates on multiple dimensions, referring to both clinical and non-clinical issues, resulting in nine different evaluation domains. Specifically, four of these deal with clinical issues, while the remaining five are divided between economic, organizational, social, ethical, and legal issues. Benign prostatic hyperplasia (BPH) is a common condition among aging men, associated with an enlargement of the prostate gland that often leads to mechanical obstruction of the urethra (3), resulting in lower urinary tract symptoms (LUTS) such as urgency, nocturia, weak urinary flow, and incomplete bladder emptying. The average prostate is commonly described to patients as the size of a walnut, with an average weight of 11 grams in younger adult men. The average range is between 25 and 30 grams (4). The average

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prostate volume doubling time is 32.6 years, with an average growth rate of about 2.2 percent per year (5). In Italy, there has been a 29% increase in prevalence between 2000 and 2019, with 1,540,000 and 1,990,000 cases, respectively (6). This absolute upward trend in the burden has been observed in most regions and many countries, reflecting the primary role of widespread demographic growth and aging in the substantial increase in cases of BPH. While demographic growth and aging are the two most significant factors, diverging trends in age-standardized rates suggest an influence from other risk factors for BPH, such as metabolic syndrome, obesity, diabetes, and acute and chronic prostatic inflammation (7-10). Management of BPH depends on the severity of symptoms and their impact on a patient's quality of life. Transurethral resection of the prostate (TURP) has long been considered the gold standard for BPH treatment, particularly for prostates between 30 and 80 grams, and Holmium laser enucleation of the prostate (HoLEP) has emerged as another effective surgical option (11). As the burden of BPH continues to grow globally, there is an increasing need for innovative treatment strategies that address both clinical efficacy and patient quality of life, ensuring fewer side effects and shorter recovery time. The UroLift system (PUL) represents a significant advancement in this area. This minimally invasive procedure uses small implants to lift and hold the obstructing prostate tissue away from the urethra, restoring normal urinary flow without cutting or removing prostate tissue. Unlike traditional surgeries, the PUL preserves sexual function, an important consideration for many patients.

The objective is to present the results of an HTA validated on an advisory board by members of the Italian Society of Urology (SIU), so as to detail the key points that emerged from the HTA in order to provide as transparent and clear an overview as possible of all dimensions concerning UroLift and to support evidence-based decisions in the management of BPH in the Italian context. The panel of experienced clinicians, through multiple focus groups, was relied upon to verify the relevance, accuracy, and consistency of the data and assumptions used in the model, with particular attention to clinical pathways and the feasibility of adoption in the Italian context.

Methods

This study was developed based on the HTA approach, ensuring a systematic and comprehensive evaluation of the technology under investigation, the new mini-invasive PUL, on a multidimensional level. The structure of the study follows the framework of the Core Model 3.0 (12) of the European Network for HTA (EUnetHTA), which organizes the assessment into the nine domains described above. For the development of this work, a detailed review of existing literature, clinical guidelines, and relevant regulatory documents was conducted. Data collection involved systematic searches in medical and scientific databases, expert consultations, and the analysis of real-world evidence where available. The research question was formulated using the PICO model, which includes the study population (P), the intervention evaluated (I), the comparator (C), and the outcome of interest (O). The population considered in this analysis includes male patients aged over 50 who suffer from lower urinary tract symptoms (LUTS) resulting from BPH. The intervention under review is the prostatic urethral lift (PUL), referred to, UroLift. This minimally invasive procedure has been compared against two standard surgical treatments: TURP, which remains the conventional reference treatment, and HoLEP, a more recent laser-based technique. The evaluation focuses on multiple outcome domains, including clinical safety and efficacy, as well as economic and organizational aspects. These dimensions have been selected to provide a comprehensive understanding of the intervention's value, both from a patient-centered and a health system perspective.

The search strategy identified a total of 52 records. According to the following inclusion criteria, a total of 5 records were excluded from the first evaluation, based on title and abstract assessment. The inclusion criteria selected were:

- Relevance to the technology under study
- Relevance to the condition under study
- Article in Italian or English
- Sufficient information on the aspects analyzed

In the second screening (full text analysis), applying the same criteria, were excluded a total of 7 records, for a total of 40 studies included in the review, which were divided into domains Health Problem and Current use of the Technology (CUR) (10), Description and Technical Characteristics of Technology (TEC) (13), Safety and Clinical Effectiveness (SAF/EFF) (31), Costs and Economic Evaluation (ECO) (6), Organizational aspects (ORG) (1), Ethical, Legal, Patient and Social aspects (ELSI) (4) (Fig. 1).

Specifically, in the economic section, to assess the economic impact on the NHS in Italy, a Budget Impact Model (BIM) (13) was developed. The analysis covers a 5-year time horizon and follows the perspective of the national healthcare system (NHS), so only health care costs directly attributable to the alternative under investigation are considered within the analysis. Two scenarios are compared: a scenario in which UroLift is implemented, and a counterfactual scenario, which considers the actual standard of care as a reference scenario, which is the current scenario, where the cost of the comparators currently in use is estimated. Each scenario considers population size, patient eligibility, speed of uptake, and market share of the intervention, as well as cost inputs and clinical outcomes. The economic analysis conducted was based on a decision tree (Fig. 2), and it starts with an initial decision node offering three treatment options: Urolift, TURP, or HoLEP. The model was structured to evaluate three distinct treatment strategies. In the first strategy, the initial intervention consisted of the UroLift procedure, followed by TURP as a second-line option in case of treatment failure. The second strategy involved the use of TURP as both first- and second-line therapy. The third strategy explored the sequential use of HoLEP as the initial treatment, with TURP serving as the fallback intervention. From each of these treatment options, several possibilities branch off depending on the outcome of the treatment. If the chosen treatment option is successful, the patient may go into remission, and there

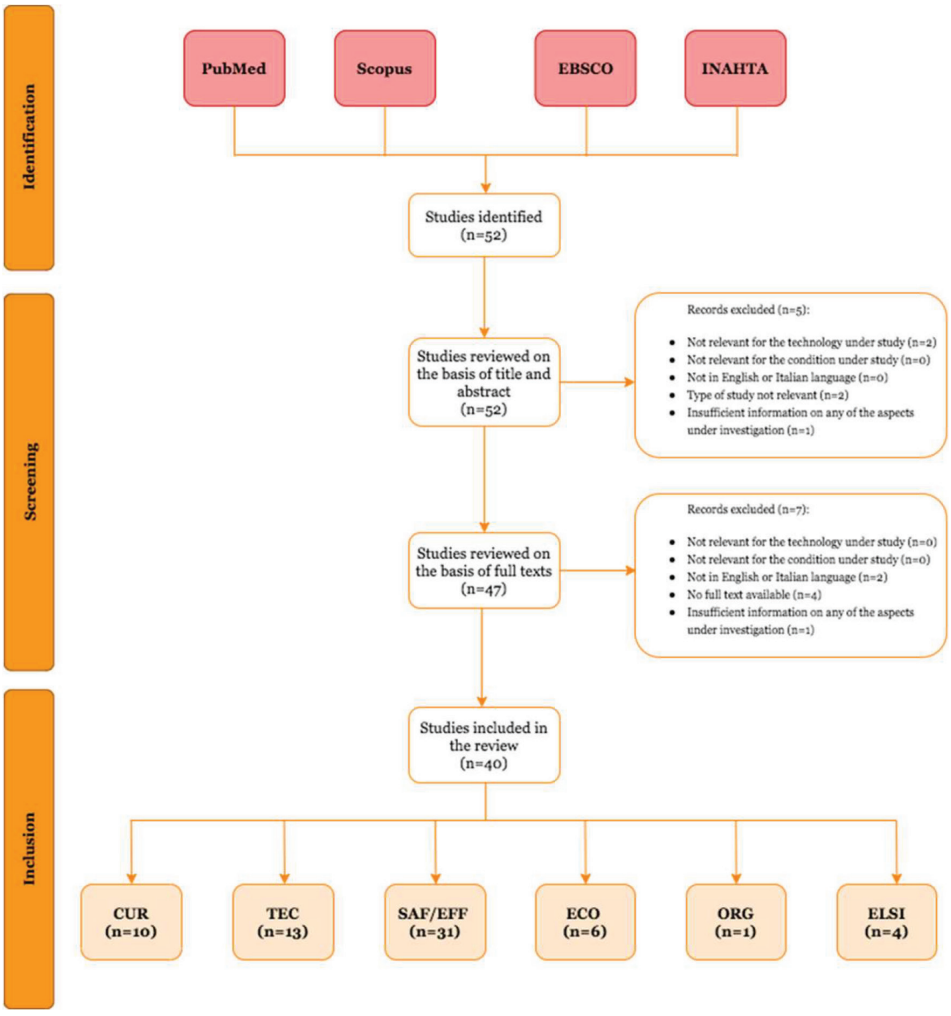
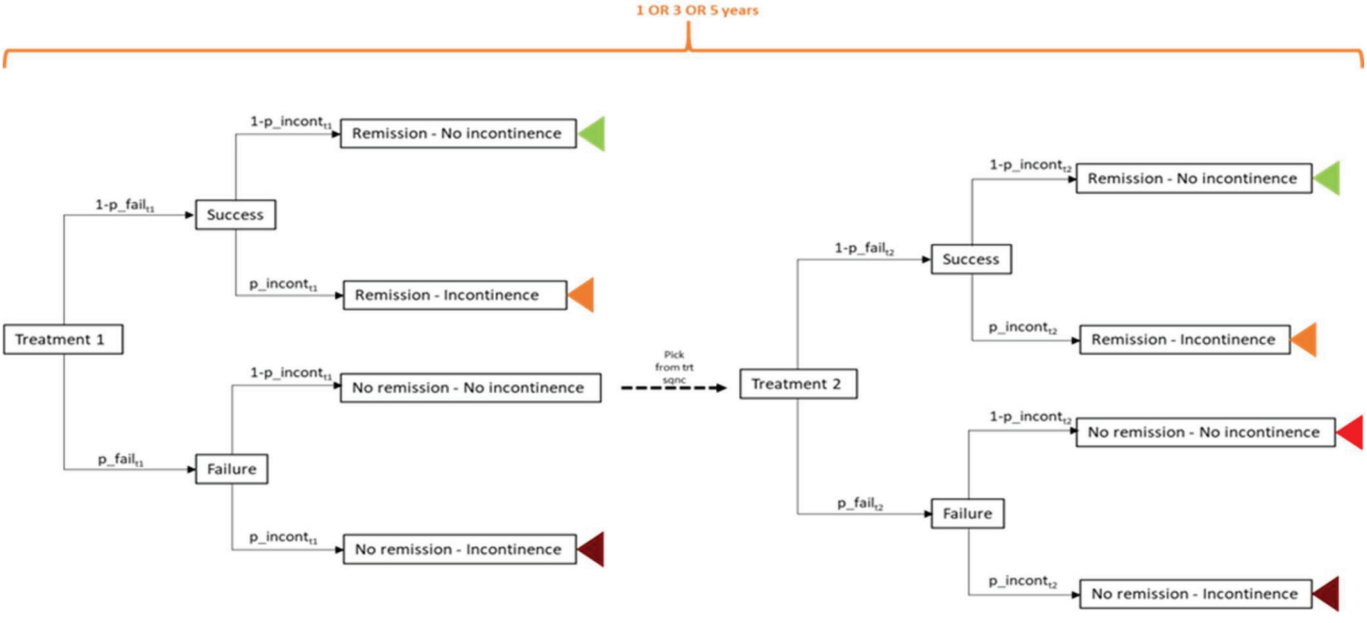


FIGURE 1 - Literature review results (PRISMA model).

FIGURE 2 - Decision tree.



are two different modalities of remission, with or without incontinence. In the first case, the treatment results in being successful, but the patient will report an adverse event to be treated. In the second case, the treatment results without complications. The tree branches into an end-of-decision node indicating treatment success. Conversely, if treatment fails, the patient may or may not experience urinary incontinence. If the patient remains incontinence-free, the tree branches into a decision-end node indicating treatment failure but no incontinence. On the other hand, if the patient experiences urinary incontinence following failed treatment, the tree offers two possible sequential treatment options: TURP or HoLEP. From each of these sequential treatment options, new possibilities for success or failure branch off, and the tree develops further depending on outcomes. The transition probabilities of the model are explained in detail in Table 1.

The target population for this analysis is Italian men over the age of 50 with BPH. The Italian general population and target population are referenced by ISTAT (National Institute of Statistics), while the prevalence of BPH was estimated based on a global study conducted by the Global Burden of Disease Study (6). The percentage of BPH patients requiring intervention was obtained from the 2019 SDO (Hospital Discharge Form) data, accounting for 47,096 individuals, representing the subpopulation of Italian men over the age of 50 with BPH who may need intervention to manage the condition. This patient cohort represents the population analyzed annually within the BIM, with the aim of capturing, for each year of the time horizon, the differences in outcomes among all patients potentially eligible for the three therapeutic alternatives under evaluation.

Within the analysis, inputs were considered that referred to the probability of treatment failure (expressed as the probability of failure at 1, 3, and 5 years) and the probability of post-operative complications (Table 1). The data inputs presented in Table 1 were calculated by determining the proportion of patients who experienced treatment failure relative to the total number of patients included in each study. Moreover, in the absence of follow-up data, fixed failure rates were applied across the relevant comparators. However, for the UroLift intervention, it was possible to model time-dependent variations in failure rates, thereby enhancing the robustness and granularity of the effectiveness estimates. Furthermore, failure rates used as efficacy inputs were subjected to sensitivity analysis to test the stability and reliability of the model's outcomes under varying assumptions.

In addition to identifying and assigning costs to specific activities performed within an organization, the method of time-driven activity-based costing (TD-ABC) was used. Specifically, the time required to perform the procedures at the object of this analysis was considered, both the cost per minute in the ward and the theatre. These were then multiplied by the cost per minute of the professionals involved in them, whose result is shown in Table SI. The inputs contained in the following Table were derived from the national collective labour agreement (CCNL) and from the opinions of the experts participating in the project's Advisory Board. Lastly, Table SI shows the costs of equipment and consumables for the three procedures investigated. For consumables, unit costs and the number of consumables used for each procedure are given. For UroLift, we report a cost of €500.00 for the device and an implant, with a total of 4 consumables used per procedure and a reusability of 1 time, for a total cost of €2,000.00. For TURP, a cost of €137.50 is reported for the loop electrode, with one consumable used per procedure and a reusability of 10 times, for a total cost of €13.75. For HoLEP, we report a cost of €400.00 for the molecular blade and €500.00 for the fibre, with one consumable used per procedure and a reusability of 20 times for both, for a total cost of €20.00 for the blade and €50.00 for the fibre. The data on consumables for TURP and HoLEP were obtained from the Piedmont Region's regional tender.

TABLE 1 - Effectiveness and post-operative complications

	TURP	UroLift	HoLEP
Effectiveness			
1-year failure probability (14)	6.00%	1.43%	4.08%
3-year failure probability (15)	6.00%	6.43%	4.08%
5-year failure probability (16)	6.00%	9.29%	4.08%
Post-operative complications			
Incontinence probability (16)	3.00%	3.00%	2.91%
Retention probability (16)	5.00%	0.40%	3.55%
Stricture probability (16)	7.00%	0.00%	5.88%
TUR syndrome probability (14,17)	3.00%	0.00%	0.93%
UT infections probability (16)	6.00%	0.10%	5.88%
Blood transfusion probability (14)	2.90%	0.00%	2.16%
Theatre time	45 minutes	20 minutes	60 minutes
Ward time (days)	3.03	0.50	1.98

The BIM incorporates market share data derived from the currently observed distribution of therapeutic alternatives, thereby representing the real-world utilization of the available treatment options (Scenario AS IS). Conversely, the TO BE scenario is designed to simulate a potential market evolution over a five-year time horizon, in response to the gradual adoption of the UroLift system, and to estimate the corresponding financial impact (Table 2). In the AS-IS scenario, market shares for the three urological procedures—UroLift, TURP, and HoLEP—are assumed to remain constant over the entire analysis period. In the TO BE scenario, market shares are modified to reflect a projected shift in procedural distribution, characterized by a progressive increase in UroLift adoption and a corresponding decline in TURP utilization. HoLEP shares, on the other hand, are held constant at 13.5%

based on expert opinion, which anticipates a stable trend in its clinical use over the coming years.

TABLE 2 - Market share

SCENARIO AS IS (Current market mix)					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
UroLift	2.9%	2.9%	2.9%	2.9%	2.9%
TURP	83.6%	83.6%	83.6%	83.6%	83.6%
HoLEP	13.5%	13.5%	13.5%	13.5%	13.5%
SCENARIO TO BE (Revised market mix)					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
UroLift	3.5%	5.5%	9.0%	14.5%	19.0%
TURP	83.0%	81.0%	77.5%	72.0%	67.5%
HoLEP	13.5%	13.5%	13.5%	13.5%	13.5%

Finally, a statistical analysis was conducted to ensure the robustness and reliability of the model outcomes. A deterministic sensitivity analysis (DSA) was performed to assess the impact of individual parameters on the results. In order to determine the degree of uncertainty of each parameter used in the model, these were subjected to sensitivity analysis, considering a parameter variance of ±25%. Tornado diagrams were used to identify the parameters with the greatest influence on cost differentials, and this is shown in Figure S1.

Results

To pursue the objective of this paper, the nine typical domains of the EUnetHTA core model, in relation to PUL technology, were analyzed and are described below, broken down by domain of interest. Starting from the first domain, "Current Use of Technology" (CUR), the current criticality of BPH emerged due to its increasing prevalence and impact on quality of life globally. In fact, in 2019, there were 94 million prevalent cases of BPH globally among men aged 40 and older, representing an important increase compared to 2000, when the prevalence cases were 51.1 million. Men aged 65-74 years had the highest absolute burden of BPH, accounting for 42% of the total prevalent cases (6). The rising burden of BPH worldwide can be attributed to population growth and ageing, with other risk factors such as metabolic syndrome, obesity, diabetes, and prostatic inflammation potentially playing a role. Addressing the burden of ageing-related diseases, including BPH, has become one of the top global health priorities. The recommended treatments vary according to the severity of the disease; lifestyle modifications are the initial management, followed by pharmacotherapy as the first line of treatment. Two drug classes are used: 5-alpha-reductase inhibitors, which aim to shrink the prostate, and alpha-adrenoceptor antagonists, which relax the smooth muscle of the prostate and bladder neck. Combination therapy with both drugs is highly effective (20). Surgical intervention is recommended for patients with moderate to severe lower urinary tract symptoms when pharmacotherapy has not been sufficient or appropriate (21). The most common form of surgery is TURP or HoLEP, (11) both of which are performed transurethrally under general anesthesia. Therefore, as a health priority, it emerged the need to overcome current treatments emerged, despite both TURP and HoLEP having demonstrated over the last decades to be safe procedures able to provide meaningful and durable improvement, but they are often associated with post-operative complications and erectile and ejaculatory dysfunction (22-24). In recent years, novel minimally invasive treatment options have emerged with the main goal of being equally effective to current standards but with a more favourable safety profile. The rapid and durable relief of LUTS with a short reconvalescence and the smooth return to normal activity are patients' preferences that need to be met. As sexual function is compromised after standard surgical procedures, a true minimally invasive technique is supposed to completely preserve it. Ideally, it can be performed under local anesthesia in an ambulatory setting. This is of particular interest to older patients with significant morbidities who are unfit for surgery, or for those patients who have the will to preserve their sexuality.

In the "Description and Technical Characteristics" (TEC) domain, PUL is an innovative and minimally invasive medical device designed to treat BPH, a condition where the prostate gland enlarges and obstructs the urethra, causing urinary symptoms. Unlike traditional surgical methods such as TURP or HoLEP, the PUL procedure does not involve cutting, removal, or ablation of prostate tissue, preserving the prostate's natural anatomy and function, and theoretically avoids damage to the primary neurovascular bundle and dorsal venous complex (25). The procedure is performed on an outpatient basis under local anesthesia, using a delivery device and small permanent implants made of Nitinol, a durable and biocompatible alloy. These implants lift and hold the obstructing prostate tissue, creating an open channel for urine flow. The implants are well-tolerated by the body, minimizing side effects and complications. The system's precision allows implants to be deployed uniformly, ensuring consistent and reliable results. One of the key advantages of the UroLift system is the immediate relief of BPH symptoms such as difficulty urinating, weak stream, frequent urination, and incomplete bladder emptying. Its rapid recovery time and tailored approach to individual anatomy make it a highly personalized treatment option. Between the benefits emerged the quick post-operative resolutions of LUTS and rapid return to normal living, as well as the absence of ejaculatory or erectile dysfunction (ED), the procedure does not affect the integrity of the bladder neck, therefore normal antegrade ejaculation is maintained and in the absence of thermal tissue damage, the risk of ED is minimal (26). Its simplicity, effectiveness, and ability to meet patient-specific needs position it as a revolutionary option for managing BPH.

Referring to the "safety and clinical effectiveness" (SAFEFF) domain, to provide recommendations, different outcomes were investigated for both efficacy and safety. In this section, the focus will be on the studies that performed a direct comparison between PUL and TURP. In the first study, by Sønksen et al. from 2015 (27), the PUL procedure not only met the study's primary endpoint of non-inferiority, but also demonstrated superiority over TURP regarding the

primary endpoint BPH6. Indeed, endpoint analysis of the BPH6 element showed that TURP was superior in reducing International Prostatic Symptoms Score (IPSS) (p=0.05), while PUL was superior for quality of recovery (p = 0.008) and preservation of ejaculatory function (p<0.0001). No significant differences were observed for erectile dysfunction, incontinence, or grade II+ adverse events. In Gratzke et al. in 2017 (28), both the PUL and TURP procedures offered significant improvement in symptoms, Qmax, and HRQoL. Erectile function was preserved in both arms, whereas ejaculatory function was superior for PUL compared with TURP. TURP has been found to significantly compromise continence function at 2 weeks and 3 months, whereas average continence scores among patients in the PUL arm were stable. For both treatment methods, most patients perceive LUTS improvement after their procedure. Unlike TURP, the PUL procedure has been found to offer significant improvement in the overall quality of sleep.

The "organizational impact" (ORG) of PUL compared to TURP and HoLEP can be significant. PUL can reduce the demand for hospital beds, reduce the need for general anesthesia, reduce the risk of complications, and offer similar long-term outcomes to traditional surgical treatments. These benefits can make PUL an attractive treatment option for healthcare providers, offering potential cost savings and improved patient outcomes. PUL has the potential to reduce indirect costs associated with BPH treatment compared to traditional surgical interventions like TURP and HoLEP. By avoiding hospitalization and post-operative complications and promoting a quicker recovery and return to work, PUL can have a positive impact on both patient outcomes and overall healthcare costs.

In the "patient and social aspects" (ELSI), focus has been made on the impact of BPH on patients' quality of life and social functioning, showing its significance, affecting their ability to perform daily activities, sleep, and engage in social interactions. Preserving ejaculatory function is becoming increasingly important as patients seek to preserve their quality of life. Sexual activity is important for many men, and ejaculatory dysfunction can have a negative impact on quality of life (29), causing decreased orgasmic intensity, anxiety, and depression. Modified endoscopic surgical techniques and mini-invasive non-ablative techniques are emerging to help preserve ejaculatory function. Studies have shown that these techniques can be effective, particularly for younger patients with small prostates, moderate symptoms, and a strong desire to preserve their sexuality (27,28,30). However, more research is needed to assess the impact of these treatments on ejaculation dysfunction. Patients should be informed of the risks and benefits of these therapies and select them accordingly. Additionally, it is essential to frame the adoption of the PUL procedure within its broader ethical and legal context, in line with national and European regulatory principles. From an ethical perspective, PUL contributes to the promotion of patient-centered care by offering a minimally invasive option that preserves sexual function and reduces the physical and emotional burden of treatment. These characteristics are particularly relevant in addressing the ethical principles of beneficence, non-maleficence, and respect for patient autonomy, as recognized in the Italian Code of Medical Ethics (Codice di Deontologia Medica), which calls for shared decision-making and the consideration of the patient's values and preferences in clinical choices (Art. 20, FNOMCeO, 2014). The ability to offer a less invasive procedure, often in an outpatient setting, also aligns with the ethical principle of equity, by potentially reducing waiting times and improving access to care for patients who are not ideal candidates for general anesthesia or inpatient surgery. From a legal and regulatory standpoint, the PUL system is a Class IIb medical device, duly CE-marked and authorized for use in the European Union under Regulation (EU) 2017/745 on medical devices (MDR). In Italy, the introduction of new health technologies must comply with the Law 833/1978, which established the Italian National Health Service and guarantees the right to health as a fundamental right of the individual, with the Legislative Decree 502/1992, as amended, which assigns the Regions the responsibility for health planning and delivery, including the introduction of innovative technologies and finally with the Legge 24/2017 (Legge Gelli-Bianco), which reinforces the principles of clinical appropriateness, patient safety, and risk management in healthcare settings. At the time of this assessment, no specific legal or ethical concerns have emerged regarding the use of PUL in the clinical literature or through expert consultation. Nevertheless, it is recommended that continuous monitoring, transparent communication with patients, and institutional validation be maintained to ensure the safe and appropriate integration of this technology into clinical pathways.

For the "Economic impact" (ECO), considering the probabilities associated with the decision tree and considering the three macro-categories of direct costs associated with the three procedures, the results are presented in Table 3, and will be presented in detail in the supplementary materials (Table SII) With regard to capital and consumable costs.

The following Table 4 presents the results for two scenarios, "AS IS" and "TO BE", where an incremental spread of PUL usage for BPH treatment in the Italian healthcare context is shown. To ensure methodological consistency and a comprehensive estimation of costs, a tiered costing approach was adopted within the budget impact analysis. Specifically, the 1-year treatment cost was applied to the first and second years of the model, the 3-year cost was applied to the third and fourth years, and the 5-year cost was applied to the fifth year. This choice reflects the fact that the target population is retained throughout the five-year time horizon, meaning that patients treated in earlier years continue to be considered in subsequent periods. Accordingly, the total cost per patient associated with each respective follow-up duration, including both procedural costs and the management of expected complications, was applied at each time point. This method ensured consistency between the treatment cost data reported in Table 3 and the cumulative cost estimates presented in Table 4, while also capturing the evolving resource use profile of each intervention. Importantly, this approach was selected to avoid underestimating the overall economic burden, which might otherwise occur if only incremental cost differences between follow-up intervals were considered. The average annual cost per patient, as detailed in Table 3,

TABLE 3 - Total direct healthcare cost at 1, 3, 5 years

	YEAR 1		
	Urolift	**TURP**	**HoLEP**
Capital and consumables costs	1,822.05 €	13.75 €	147.90 €
Procedure costs	485.46 €	2,421.13 €	1,780.01 €
Complications costs	49.09 €	361.37 €	268.84 €
Cost per sequential treatment (TURP)	252,99 €	163,47 €	111,26 €
Total costs per patient	**2,619.58 €**	**2,796.25 €**	**2,196.76 €**
	YEAR 3		
	Urolift	**TURP**	**HoLEP**
Capital and consumables costs	1,878.40 €	13.75 €	147.90 €
Procedure costs	651.22 €	2,421.13 €	1,780.01 €
Complications costs	178.43 €	466.85 €	368.97 €
Cost per sequential treatment (TURP)	264,75 €	171,07 €	116.43 €
Total costs per patient	**2,708.05 €**	**2,901.73 €**	**2,296.88 €**
	YEAR 5		
	Urolift	**TURP**	**HoLEP**
Capital and consumables costs	1,823.28 €	13.75 €	147.90 €
Procedure costs	703.54 €	2,421.13 €	1,780.01 €
Complications costs	302.05 €	572.34 €	469.09 €
Cost per sequential treatment (TURP)	276,50 €	178.66 €	121.60 €
Total costs per patient	**2,828.87 €**	**3,007.22 €**	**2,397.00 €**

served as the reference for each respective time frame in the BIM, supporting a more comprehensive and realistic estimation of the long-term economic impact.

As the analysis shows, despite the higher initial acquisition cost, UroLift generates savings for the NHS in all years considered within the analysis. Specifically, savings are derived from the lower incidence of adverse events and complications, both post-operative and in the long term, implying lower inpatient costs and less use of human resources. As anticipated, savings begin in the first year with a differential between the two scenarios considered of €57,747.40 and peak in the fifth year with savings of approximately €1.35 million, for a total estimated savings over the considered time horizon, considering the market shares, of €3,154,997.63.

The sensitivity analyses conducted offer a comprehensive assessment of the robustness of the economic evaluation concerning the introduction of UroLift as an alternative treatment for male patients over the age of 50 affected by LUTS due to BPH. To assess the degree of uncertainty associated with each parameter included in the model, a variation range of ±25% was applied. Figure S1 illustrates the impact of key parameters on the cost differential between the two scenarios—without and with the adoption of UroLift—highlighting the most critical cost-driving factors. Among these, the most influential parameter was identified as the "duration of operation" for the comparator procedure, TURP, which demonstrated a considerable variation in costs, ranging from approximately €4-2.3 million. Other significant parameters affecting the cost outcomes included the probabilities of urinary tract infections and TUR syndrome associated with TURP, both contributing to cost variations between €3.6 and €2.7 million.

Discussion

This manuscript provides a comprehensive evaluation of the PUL system in the treatment of BPH, integrating clinical, economic, organizational, and patient-centered perspectives

TABLE 4 - Budget impact results

	SCENARIO AS IS				
	Y1	**Y2**	**Y3**	**Y4**	**Y5**
UroLift	3,564,126 €	3,564,126 €	3,713,876 €	3,713,876 €	3,863,627 €
TURP	110,094,621 €	110,094,621 €	114,247,785 €	114,247,785 €	118,400,950 €
HoLEP	13,966,886 €	13,966,886 €	14,603,457 €	14,603,457 €	15,240,029 €
Total Scenario AS IS	**127,625,634 €**	**127,625,634 €**	**132,565,119 €**	**132,565,119 €**	**137,504,605 €**
	SCENARIO TO BE				
	Y1	**Y2**	**Y3**	**Y4**	**Y5**
UroLift	4,301,531 €	6,759,549 €	11,525,824 €	18,569,382 €	25,313,418 €
TURP	109,304,469 €	106,670,626 €	105,911,524 €	98,395,222 €	95,598,853 €
HoLEP	13,966,886 €	13,966,886 €	14,603,457 €	14,603,457 €	15,240,029 €
Total Scenario TO BE	**127,572,886 €**	**127,397,062 €**	**132,040,805 €**	**131,568,062 €**	**136,152,299 €**
Differential	**–52.747,40 €**	**–228.572,08 €**	**–524.314,78 €**	**–997.057,61 €**	**–1.352.305,77 €**

within the Italian healthcare context. Specifically, it aimed to compare treatment strategies with Urolift, TURP, and HoLEP. It emerged that the former strategy would seem to improve patients' quality of life, in the first instance, at the ejaculatory level. Indeed, Urolift, having the ability to preserve ejaculatory function, is becoming progressively more important and sought after among patients eager to maintain their sexuality. Second, it has been found to have better outcomes in terms of remission without incontinence, shorter operative time, and reduced peri- and post-operative complications. The latter potentially allows the patient to avoid having to undergo additional surgeries, in the short and medium term, generating substantial savings for the National Health Service. This is primarily due to reduced complications, shorter hospital stays, and quicker patient recovery. The deterministic sensitivity analysis confirmed the robustness of the model, indicating that the most influential parameters on cost variation—such as operative time and complication rates—still supported the cost-saving potential of UroLift. Organizationally, the minimally invasive nature of UroLift implies reduced resource utilization, including less demand for operating rooms, hospital beds, and post-operative care. Moreover, if to these costs are added the potential indirect costs, resulting from an increased quality of life and a faster recovery period, it is clear how the implementation of the Urolift device as a first-line treatment, in young patients, with a non-excessive prostate volume size, with moderate symptoms and, above all eager to preserve sexual function, is necessary.

Limitations

The most important lies in the fact that the model assumes a constant share over the next five years of the procedures performed with HoLEP. From the results of our analysis, HoLEP is the least expensive procedure compared to PUL and TURP. It was chosen to maintain a constant share based on expert opinion, which anticipates a stable trend in its clinical use over the coming years, and to "isolate" the savings in direct healthcare costs from the use of PUL compared to TURP. Moreover, the economic model applies fixed failure rates for TURP and HoLEP in the absence of longitudinal data, while instead guaranteeing progression for UroLift.

Conclusions

This study underscores the critical role of evaluating innovative treatment options like the UroLift system for BPH within the Italian healthcare context. By utilizing the HTA framework, the analysis provides a comprehensive understanding of the clinical, economic, and organizational implications associated with UroLift compared to traditional interventions such as TURP and HoLEP. The results demonstrate that UroLift offers a patient-centric approach, addressing key concerns such as rapid symptom relief, reduced post-operative complications, and the preservation of sexual function. These benefits are particularly significant for older patients or those with comorbidities who are not ideal candidates for invasive surgical procedures. From an economic perspective, the analysis highlights the potential for substantial cost savings for the Italian NHS over the time horizon. The lower incidence of adverse events and shorter recovery times associated with UroLift contribute to its cost-effectiveness, especially as its market share increases. Organizationally, UroLift's minimally invasive nature reduces the demand for hospital resources, including ward occupancy and surgical time, while ensuring comparable long-term outcomes to traditional surgeries. This efficiency is crucial in optimizing healthcare resource allocation and addressing the growing burden of BPH due to demographic changes and aging populations. Overall, the findings support the integration of UroLift into the standard care pathway for BPH in Italy. As healthcare systems evolve to prioritize patient-centered and cost-effective solutions, UroLift represents a significant step forward in meeting both clinical and economic goals. It is important to emphasize that the Urolift procedure is associated with a lower incidence of adverse events and could also have potential advantages in organizational terms due to the fact that patients seem to have shorter stays than with the other procedures.

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Conflict of interest: The authors declare that they have no conflicts of interest related to this work.

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