

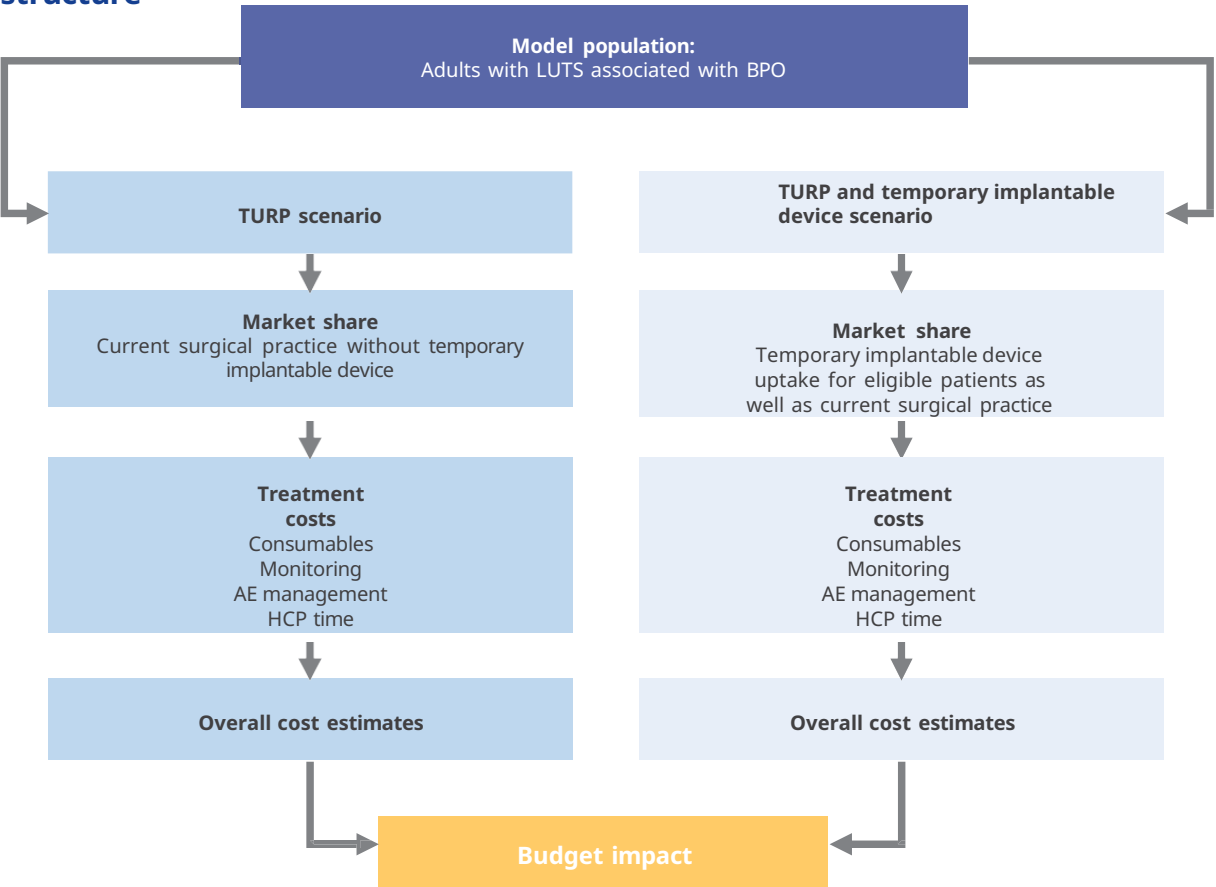
Budget Impact of a Minimally Invasive Surgical Treatment for Benign Prostatic Obstruction in Italian Healthcare Service

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Background

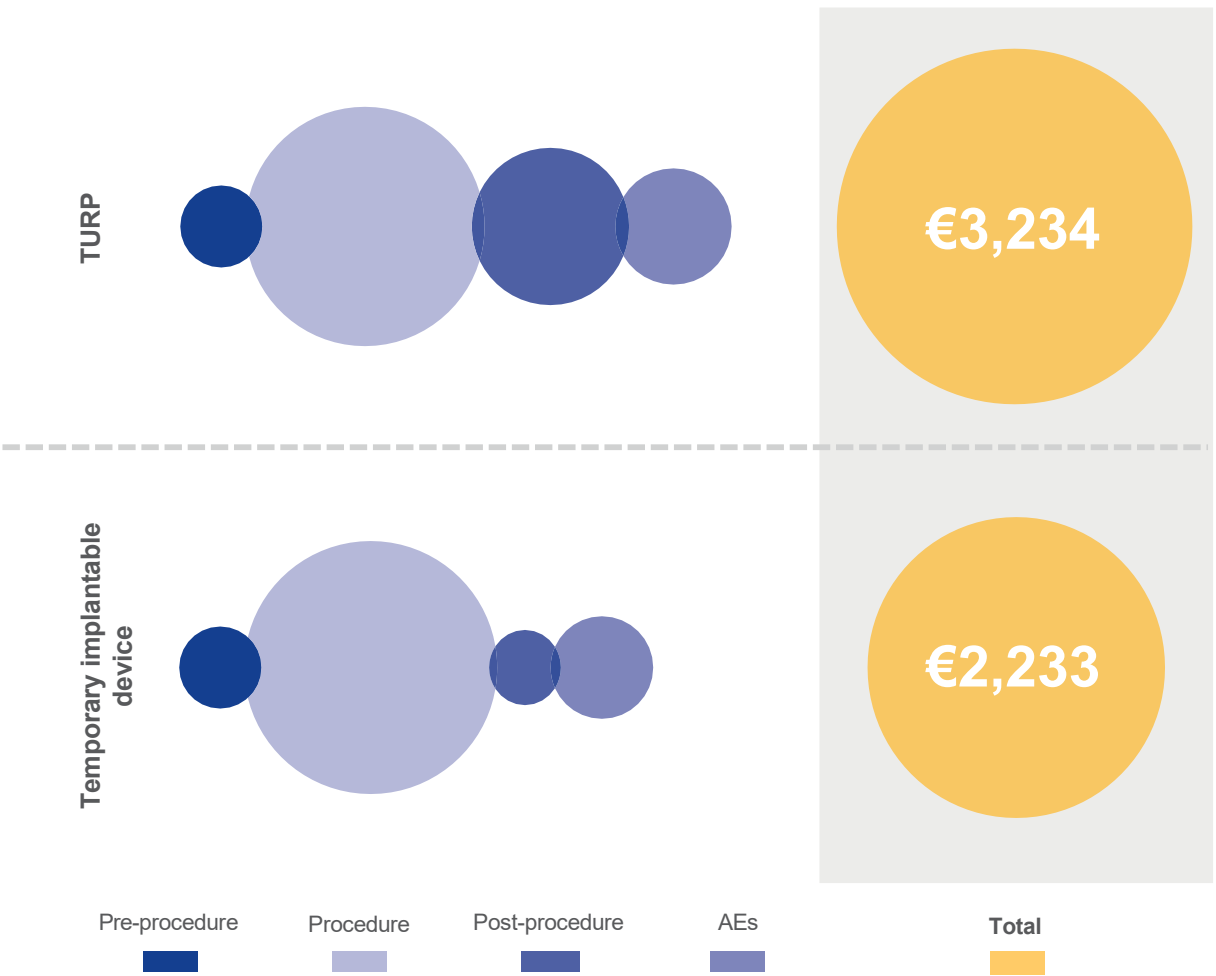
- Benign prostatic obstruction (BPO) is a progressive, non-malignant enlargement of the prostate common in men over 50.¹
- BPH may cause lower urinary tract symptoms (LUTS) which can have a major negative impact on quality of life.²
- Despite the advancement of minimally invasive surgical therapies (MISTs), transurethral resection of the prostate (TURP) remains the gold standard for the surgical management of LUTS for patients either failing or refusing medical therapy.³
- The temporary implanted nitinol device, which is placed into the prostatic urethra with the aim of reshaping the tissue of the prostatic urethra and the bladder neck, is a minimally invasive treatment option to deliver rapid and effective symptomatic relief from BPO symptoms.^{4,5}
- Within the context of an increasingly ageing population as well as backlogs and delays in elective urological procedures caused by the coronavirus disease 2019 pandemic, healthcare systems and societies face a considerable and growing burden associated with managing the condition.^{1,6}

Figure 1. Budget impact model structure



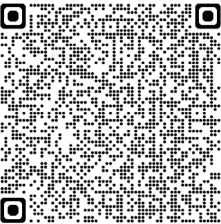
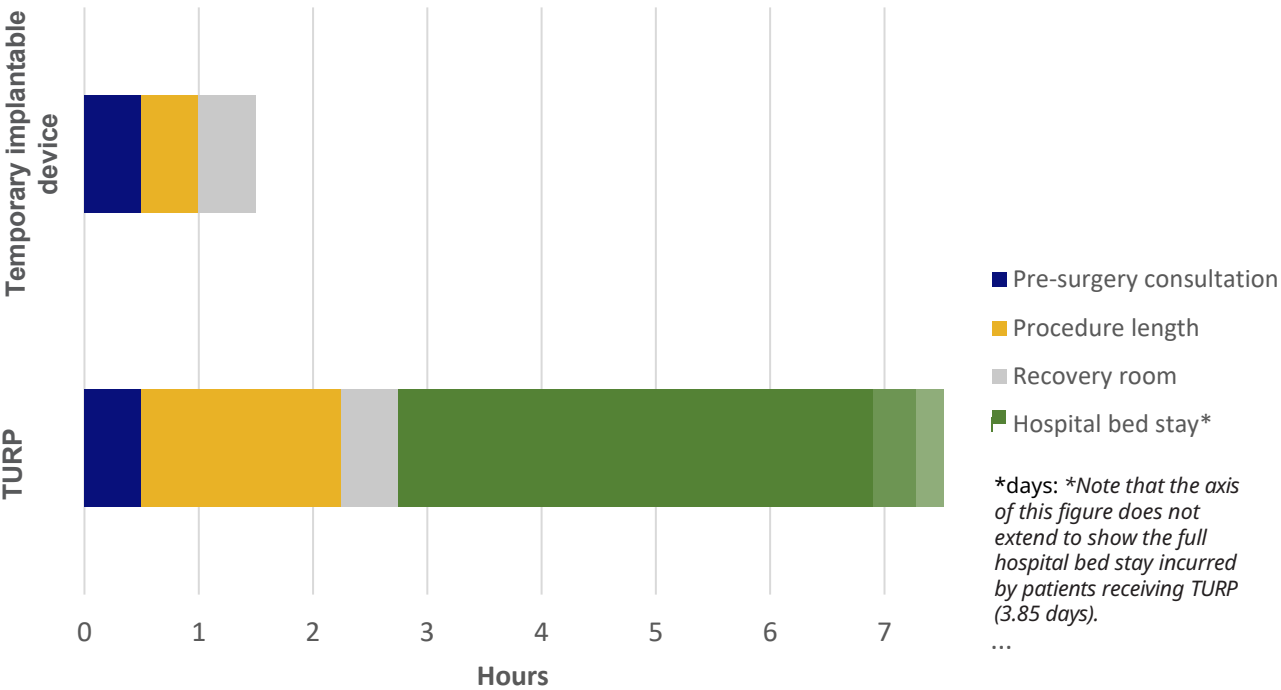
AE: adverse event; BPO: benign prostatic hyperplasia; HCP: healthcare professional; LUTS: lower urinary tract symptoms; TURP: transurethral resection of the prostate.

Figure 2. Disaggregated cost per procedure



AE: adverse event; TURP: transurethral resection of the prostate.
Note that the relative size of each bubble proportionally reflects the cost of each disaggregated cost element. Pre-procedure components include pathology costs and healthcare professional time required ahead of the procedure. Procedure cost components include consumables, and HCP and facility costs for. Post-procedure cost components reflect only HCP and facility time required following the procedure. AE components represent the average cost of managing complications associated with each procedure.

Figure 4. Disaggregated resource utilization: Patient time required per procedure



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Objective

- To estimate the cost and resource impact of the temporary implantable device as a minimally invasive treatment alternative to TURP for the treatment of LUTS associated with BPO in Italy.

Methods

Model Structure

- An Excel-based budget impact model was developed to estimate the economic impact of introducing the temporary implantable device in the Italian National Health System (NHS) setting.
- The model compared two scenarios; a reference case where all patients received either bipolar or monopolar TURP, and a scenario where a proportion of patients received the temporary implantable device rather than TURP (**Figure 1**).
- Reference case data were based on an estimate of 2023 BPO patients with LUTS who received a TURP within the NHS.

Market Dynamics

- In the TURP scenario, all patients received either bipolar (30%) or monopolar (70%) TURP.
- In the TURP and temporary implantable device scenario, 9% of patients received the temporary implantable device rather than TURP and this came from bipolar and monopolar procedures proportionally.
- Market dynamics inputs were based on Italian expert opinion.

Resource Use Inputs

- Modeled costs included the per procedure cost of consumables, pathology, healthcare professional (HCP) time, facility costs, and managing adverse events (AEs).
- Where available, pathology, HCP time, facility costs, and AE management costs were identified from Italian cost and tariffs, based on Italian ICD-9-CM codes and Italian DRG values
- Consumables, HCP time, and AE management costs were extracted from relevant scientific literature following a pragmatic literature search and inflation adjusted to 2024 values.

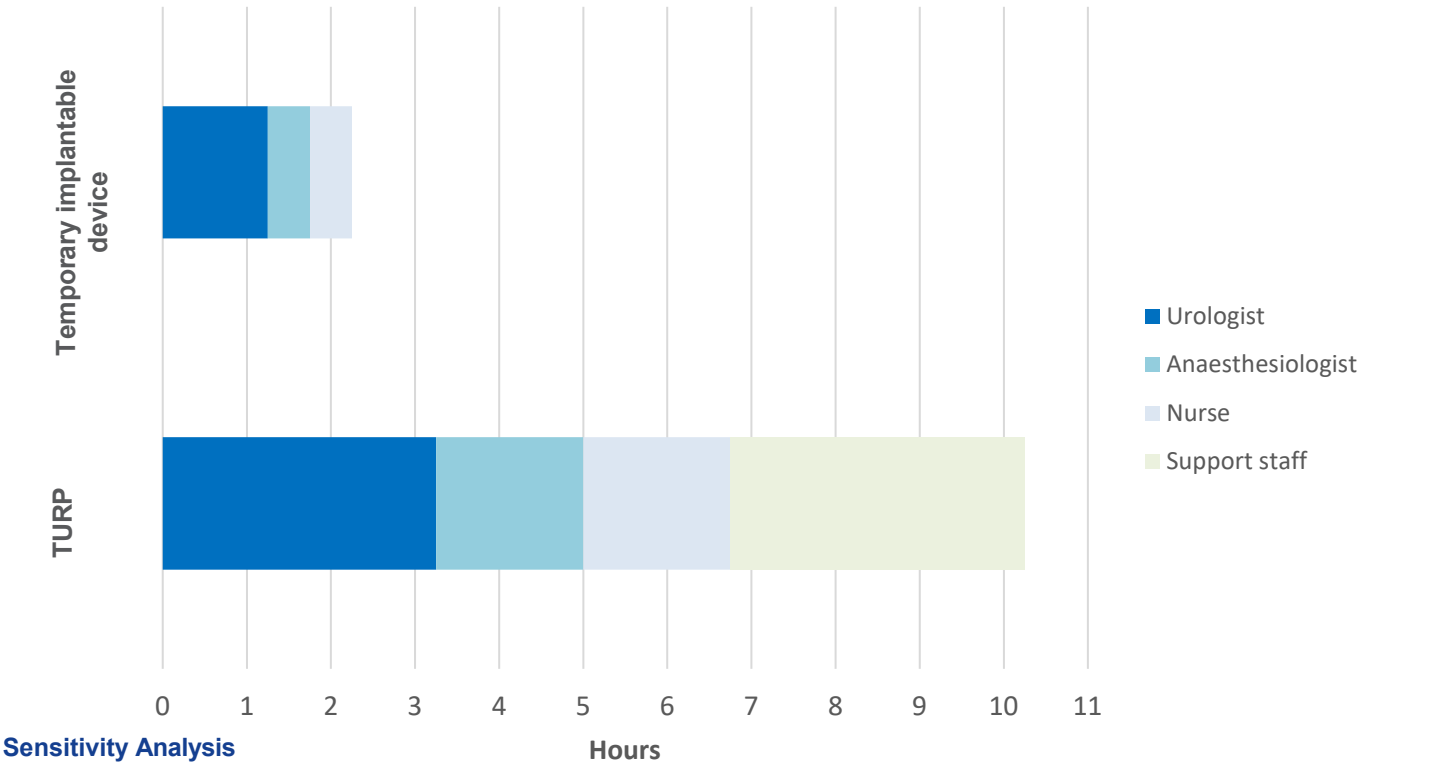
Outputs

- The primary model output was the total budget impact.
- Secondary model outputs included budget impact per person, average total and disaggregated per procedure costs, and per procedure resource utilization.

Budget Impact Results

- The total calculated costs of TURP and the temporary implantable device procedures in Italy were 3,234 EUR and 2,233 EUR, respectively (**Figure 2**; disaggregated per procedure costs also shown).
- Total budget impact of treating 9% (66,400) of patients with the temporary implantable device rather than TURP was -5,981,419 EUR (a 2.8% reduction in the total cost of care).
- Average budget impact per person was -90.1 EUR.
- In terms of resource utilization (**Figure 3 and 4**), 7,470 hours of operating room time, 47,808 hours of healthcare professional (urologists, anesthesiologists, nurses, and support staff) time, and 23,904 post-operative hospital bed days were saved in the scenario with the temporary implantable device (6.4%, 7%, and 9% reductions, respectively).

Figure 3. Disaggregated resource utilization: healthcare professional time required per procedure



Sensitivity Analysis

- The total budget impact was most sensitive to changes in the price of the temporary implantable device, followed by the operating cost of hospital resources (operating room and hospital bed costs), and AE management (surgical retreatment rate and the cost of managing clot retention).

Limitations

- The model retrospectively analyzed a static cohort of patients who received a TURP procedure, underestimating the burden of LUTS associated with BPO in Italy which could be managed with the temporary implantable device.
- Other patient groups (e.g., patients receiving medical therapy) that would benefit from a temporary implantable device procedure were excluded from this analysis.
- The model assumes that the temporary implantable device procedure was performed in an inpatient setting, but given there is no requirement for general anesthesia, the temporary implantable device procedure could be performed in an office setting.^{4,5}
- The model utilized inputs and assumptions to estimate the budget impact from a Italian NHS perspective, but the generalizability to specific hospitals with different costs or treatment options (e.g., no bipolar TURP or alternative MISTs offered) may differ.

Conclusions

- Adopting the temporary implantable device in clinical practice for eligible patients is a cost- and resource-saving approach to managing LUTS associated with BPO.

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