IMPACT OF TEMPORARILY IMPLANTED NITINOL DEVICE IN THE TREATMENT OF URINARY SYMPTOMS IN PATIENTS WITH BENIGN PROSTATIC OBSTRUCTION IN SPAIN

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Background

- Benign prostatic obstruction (BPO) is a prevalent condition that often leads to lower urinary tract symptoms (LUTS), significantly affecting patients' daily lives. [1-2]
- Conventional treatment options typically include pharmacological therapy or invasive surgical procedures. Although these approaches can be effective in relieving symptoms, they are frequently associated with adverse events (AEs), postoperative complications, and a negative impact on both patients' quality of life (QoL) and the healthcare system's resources.[3]
- In recent years, minimally invasive surgical therapies (MISTs) have emerged as promising alternatives aimed at reducing these limitations. By offering effective symptom relief with fewer complications and faster recovery times, MISTs may represent a more balanced approach to managing BPO.

Figure 1. Budget impact model structure

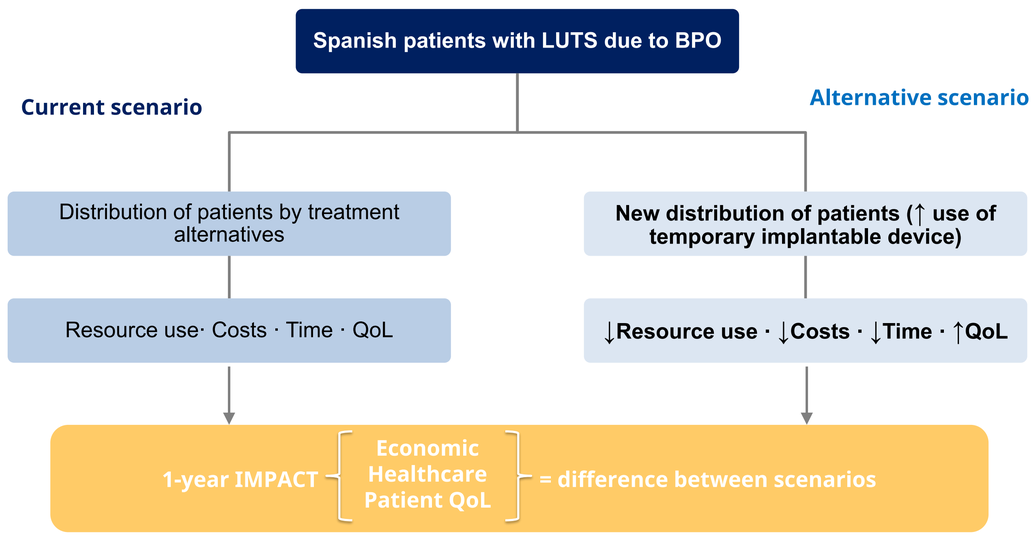


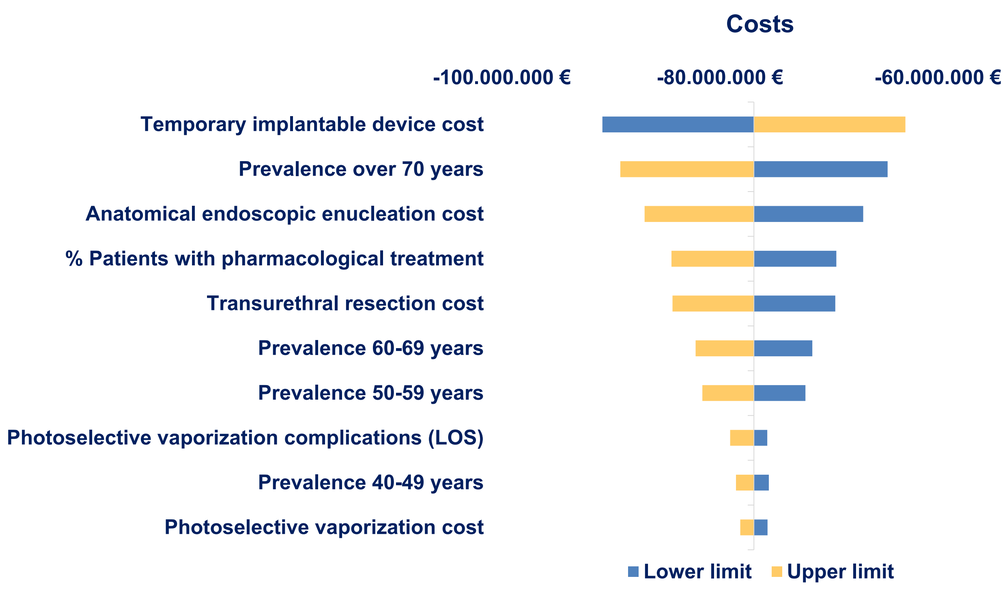
Table 1. Distribution of patients in current scenario

Pharmacological treatment	Monotherapy	60.5%	α-Adrenoceptor Blockers	90.8%
			5-α Reductase Inhibitors	8.2%
			Phosphodiesterase-5 Inhibitors	1.0%
	Combinations	39.5%	α-Adrenoceptor Blockers + 5-α Reductase Inhibitors	74.1%
			α-Adrenoceptor Blockers + Antimuscarinics	25.9%
Surgery	Highly invasive	8.4%	Open simple prostatectomy	8.4%
	Invasive	71.4%	Anatomical endoscopic enucleation	40.9%
			Transurethral resection	30.4%
			Laparoscopic simple prostatectomy	0.1%
	Minimally invasive	20.2%	Photoselective vaporization	10.9%
			Water vapor thermal therapy	7.0%
			Other	2.2%
			Transurethral incision	1.0%
			Bipolar plasma kinetic prostate vaporization	0.5%
			Prostatic urethral lift	0.4%
			Temporary implantable device	0.3%

Table 2. Results of scenario comparison

	Current scenario	Current vs scenario1	Current vs scenario2	Current vs scenario3
Pharmacological treatment	119.621.508 €	0 €	-657.464 €	-1.314.929 €
Follow-up (pharm)	75.508.080 €	0 €	-415.008 €	-830.016 €
AEs	21.905.366 €	0 €	-120.396 €	-240.793 €
Surgery	412.808.235 €	-84.854.916 €	-61.933.651 €	-39.012.386 €
Follow-up (surgery)	24.147.108 €	0 €	1.260.816 €	2.521.632 €
Complications	39.610.301 €	-16.766.613 €	-15.016.147 €	-13.265.682 €
Total costs	**693.600.597 €**	**-101.621.529 €**	**-76.881.851 €**	**-52.142.173 €**
Bed occupancy	136.725 days	-63.170 days	-56.667 days	-50.164 days
QALYs	809.476	220	540	859

Figure 2. Tornado diagram of costs results (current vs scenario 2)



LOS: length of stay (in days)

Objective

- This study assessed the impact of a temporarily implanted nitinol device for the treatment of BPO within the context of the Spanish National Health System (SNHS), emphasizing both healthcare outcomes and patient perspectives.

Methods

Model Structure

- An Excel-based model was developed to estimate the 1-year impact of increasing the use of temporary implantable device within the SNHS setting.
- The model compared two scenarios: current and alternative (Figure 1).
- Current scenario allocated patients between pharmacological treatment (57%) and surgery (6%), including invasive and MISTs using data from Spanish real-world studies (Table 1) [4-5].
- In the alternative scenario, the use of temporary implantable device has been increased to 5%. Three scenarios were defined based on the treatment shift of the new patients receiving temporary implantable device:
  - Scenario 1: 100% of new patients shifted from other surgical procedures.
  - Scenario 2: 90% of new patients shifted from other surgical procedures, and 10% from pharmacological treatment.
  - Scenario 3: 80% of new patients shifted from other surgical procedures, and 20% from pharmacological treatment.

Inputs

- Spanish patients with LUTS due to BPO were estimated from demographic and epidemiological data[6-7].
- Healthcare resource use costs for pharmacological treatment and its follow-up were estimated from dosages included in SmPC, scientific publications and official price lists [8-11]. AEs costs were calculated with incidence data and unit costs[4,11-17].
- Surgery costs were estimated using scientific publications, official tariffs and expert opinion[10-11,18-19]. Healthcare burden of each surgery was also estimated in terms of hospital bed occupancy. Costs of surgery-related complications were calculated based on their incidence and hospital length of stay[5,11].
- Utilities used to estimate the QoL of patients with LUTS due to BPO, as well as disutility values to assess the impact of AEs and complications, were obtained from scientific publications[10,12,20-23].

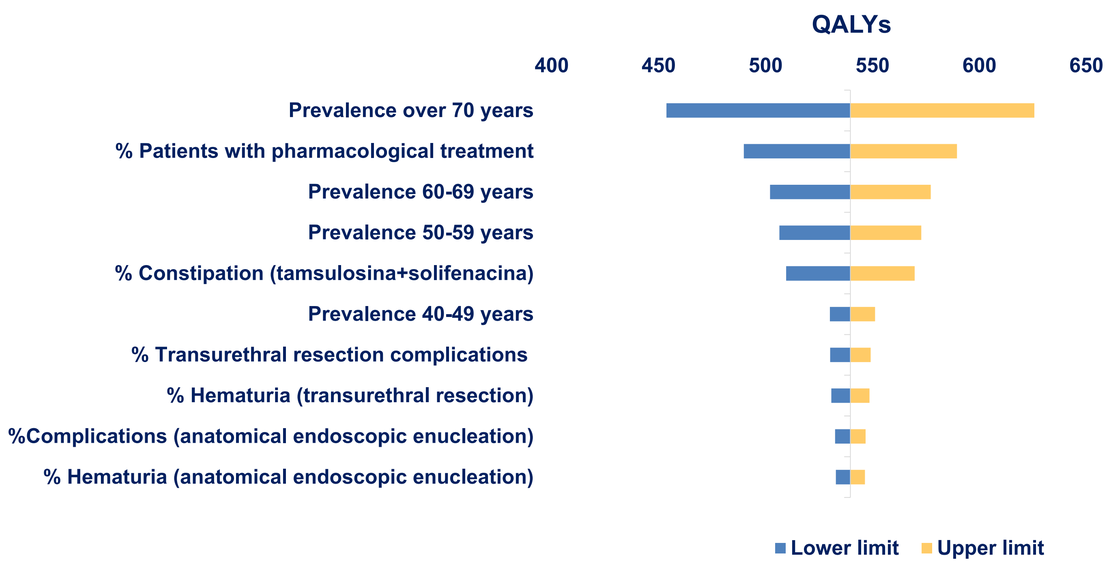
Outputs

- In each scenario, costs related to pharmacological treatment, AEs, surgeries, and complications (€, 2025), healthcare burden and quality-adjusted life years (QALYs) were assessed.
- Results were reported as differences between the current and alternative scenario.
- A one-way sensitivity analysis was conducted by varying each input by ±10% to identify the variables with the greatest impact on the current scenario.

Results

- A population of 1,032,124 patients with LUTS due to BPO was estimated.
- In the current scenario, total costs were €693,600,597 (30% due to pharmacological treatment, its follow-up, and AEs; 70% due to surgery, follow-up and complications); hospital bed occupancy was 136,725 days; and 809,796 QALYs (Table 1).
- Increasing the temporarily implanted nitinol device use by shifting 0-20% of patients from pharmacological treatment, could reduce total costs by 14% to 7%, avoid 63,170 to 50,164 hospital bed-days, and increase QALYs by 220 to 859, respectively (Table 1).
- The one-way sensitivity analysis confirmed result robustness, showing consistent cost savings and QALY gains despite parameter variations. (Figure2-3).

Figure 3. Tornado diagram of QALYs results (current vs scenario 2)



Limitations

- The model employed specific inputs and assumptions to estimate the budget impact from the SNHS perspective; however, its representativeness for individual hospitals with differing cost structures or treatment strategies may be limited.

Conclusions

- Temporary implantable device is an alternative treatment option for patients with LUTS due to BPO. Its increased use could generate cost savings for the SNHS, reduce hospital bed occupancy, and enhance patients' QoL.

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