



A real-world evidence study of interhospital variability in the surgical treatment of patients with benign prostatic hyperplasia: the REVALURO study

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Abstract

Purpose Lower urinary tract symptoms associated with benign prostatic hyperplasia (LUTS/BPH) is a growing condition in males associated with a high clinical, economic and humanistic burden. Several surgical techniques are available for the treatment of LUTS/BPH; thus, the aim of this study was to describe and explore the variability in the use of surgical procedures among Spanish hospitals.

Methods The REVALURO was a retrospective, observational study conducted by collecting data from the clinical records of patients with LUTS/BPH aged ≥ 35 years, from 5 national reference hospitals, who were surgically treated between 2018 and 2022.

Results Among the 3038 patients who underwent 3084 surgeries, 66% were invasive (2018: 57.5%, 2022: 71.5%), 22% were minimally invasive (MISTs) (2018: 20.7%, 2022: 20.2%) and 12% were highly invasive (2018: 21.8%, 2022: 8.4%). A total of 22.4% of patients' complications, with a maximum incidence of 28.6% (open prostatectomy) and a minimum 0.8% (water vapor thermal therapy (WVTT)) ($p < 0.001$). The reintervention rate was 1.5% over the study period. The median length of hospital stay after surgery increased from 0 days (interquartile range [IQR]: 0) with WVTT to 5 days (IQR: 4–8) with open prostatectomy ($p < 0.001$).

Conclusion Trends in surgical treatment showed that the use of invasive techniques increased, while the use of highly invasive techniques decreased, and the use of MISTs remained constant. However, given the heterogeneity among hospitals, national clinical guidelines and recommendations are needed to guide the decision on which technique should be used and to homogenize the criteria.

Keywords Benign prostatic hyperplasia · Lower urinary tract symptoms · Real-world data · Real-world evidence · Surgical treatment

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Introduction

Benign prostatic hyperplasia (BPH) is an age-related male disease caused by the progressive nonmalignant proliferation of prostatic epithelial cells leading to the enlargement of the prostate [1]. Tissue growth near the urethra causes lower urinary tract symptoms (LUTSs) in almost half of patients [2], including obstructive symptoms such as urinary hesitancy or the sensation of incomplete bladder emptying; and irritative symptoms such as nocturia or urinary and incontinence urgency [3].

Given that life expectancy is increasing, the worldwide population is aging, and thus, the burden of LUTS attributed to BPH (LUTS/BPH) is predicted to increase among urological conditions [4]. In addition to their clinical and epidemiological impact, LUTS/BPH can negatively affect patients' health-related quality of life (HRQoL) [5] and have a considerable economic impact [6]. In this sense, the expenditures associated with nonmalignant urological diseases rely not only on health care systems, but also on indirect costs or out-of-pocket expenses [7], which might contribute to the deterioration of patients' well-being.

In any case, several therapeutic alternatives are available for the management of LUTS/BPH. Although pharmacological therapy is effective in treating mild-moderate symptoms, as disease severity worsens, patients might require surgical interventions [8]. Historically, surgical removal of the adenoma was performed by open prostatectomy [9]. In contrast to these highly invasive techniques, new procedures comprising invasive techniques, such as transurethral resection of the prostate (TURP) or anatomical endoscopic enucleation of the prostate (AEEP) and minimally invasive surgical treatments (MISTs), such as water vapor thermal therapy (WVTT) [Rezüm®, Boston Scientific®], photoselective vaporization of the prostate (PVP) [Greenlight®, Boston Scientific®], bipolar plasma kinetic vaporization of the prostate (BPKVP), temporary implantable nitinol device (TIND) [iTind®, Olympus®] prostatic urethral lift (PUL) [Urolift®, Teleflex®] or transurethral incision of the prostate (TUIP), have been developed [10, 11].

However, the incorporation of these novel surgical techniques in clinical practice remains uncertain in Spain. In this context, real-world evidence (RWE) studies are key to providing insights into the use of these surgical treatments in daily practice. Thus, the aim of the REVALURO study was to describe and explore the variability in the use of surgical techniques, health outcomes and clinical course of patients with BPH among five reference hospitals in Spain.

Methods

Study design and participants

The REVALURO project consisted of a multicentric, retrospective and observational RWE study including patients diagnosed with BPH aged 35 years or older. Five reference hospitals located in different regions of Spain were selected: University Hospital Virgen de las Nieves (Granada), University Polytechnic Hospital La Fe (Valencia), General University Hospital in Valencia, Clinic Hospital in Barcelona, and University Hospital Marqués de Valdecilla (Cantabria).

This study was approved by the Ethics Committee of the General University Hospital in Valencia (Reference: 46/2023) on 28th April 2023. The research was conducted according to the General Data Protection Regulation (GDPR) and the Declaration of Helsinki principles.

Data collection

Anonymized data from participants were extracted from the hospitals' medical records from May to June 2023. Information of interest was collected for patients with BPH who underwent surgery during the 5 years prior to the study (1st January 2018 – 31st December 2022) and were followed over this period.

Data on patients' demographic and clinical characteristics included age, date of surgery, prostate size (cm³), international prostate symptoms score (IPSS), maximum urinary flow determined by uroflowmetry (mL/sec), level of prostate-specific antigen (PSA) (ng/mL), glomerular filtration rate (GFR) (mL/min/1.73 m²) and presence of acute urinary retention (AUR). In relation to the surgical interventions, information was collected regarding the type of procedure (highly invasive, invasive and MIST), specific intervention among each type of procedure (highly invasive: open prostatectomy; invasive: laparoscopic prostatectomy, TURP and AEEP; MIST: WVTT, PVP, PUL, TIND, BPKVP and TUIP), incidence and type of complications, patients requiring reintervention and length of postsurgical hospital stay (days).

Statistical analyses

Analyses were performed for the pooled data from the five hospitals participating in REVALURO. Analyses were also conducted for hospital-specific data.

The results concerning qualitative variables were measured as relative and absolute frequencies. Quantitative variables were presented as the mean and standard deviation (SD) or the median and interquartile range (IQR). Although

the objective of the study was mainly descriptive, inference tests were conducted to explore the statistical significance of differences among hospitals in an exploratory analysis. The Shapiro–Wilk test was first performed to determine whether each variable was normally distributed or not. For normally distributed variables, ANOVA was used for inference analyses; otherwise, the Kruskal–Wallis test was used. The Chi-Squared test or Fisher’s Exact test were used for qualitative variables. One-sided analyses were conducted, and a p-Value of 0.05 indicated statistical significance. Sample size requirements were not estimated as the study aimed to include as much data as possible to provide a faithful reflection of clinical practice. Thus, statistical power was measured for each inference test according to the sample available. Statistical analyses were performed in Python 3.12.

Results

Participants’ demographics, clinical characteristics and treatment pathway

A total of 3038 patients with BPH who underwent surgical procedures were included in the study. The mean time after surgery was 2.4 years (SD: 1.5; median: 2.3; IQR: 2.5). Demographics and treatment pathways, both for the entire sample and specific to each hospital, are presented in Table 1. The clinical characteristics of patients who underwent the different surgical techniques are summarized in Supplementary Tables 1 and 2.

Over the study period, 3084 surgeries were reported due to reinterventions (Table 1), mainly involving invasive techniques (66.0%), followed by MISTs (22.0%) and highly invasive techniques such as open prostatectomy (12.0%).

The evolution in the use of surgical techniques over the follow-up period for the pooled and hospital-specific samples is presented in Fig. 1.

Postsurgical outcomes: complications, reinterventions and hospital stays

Data on post-surgical complications were available for 1148 patients. During the study period, 257 patients (22.4%) experienced any complications, including hematuria, bacteremia, fever, urinary tract infection (UTI) and other associated problems.

The incidence of complications and the proportion of each type of complication associated with the different surgical procedures are presented in Fig. 2A, B, respectively. Statistically significant differences were found for the incidence of complications among the techniques ($p < 0.001$).

Over the 5 year period, 46 patients required reinterventions (1.5%). Of those, 29 (63.0%) were first treated with TURP, 11 (23.9%) with AEEP, 4 (8.7%) with PVP, and 1 (2.2%) with PUL.

The length of hospital stay after each surgical procedure is summarized in Table 2. Overall, the shortest hospital stay was associated with the WVTT, with a mean length of 0.2 days (SD: 0; median: 0; IQR: 0). Significant differences were observed for the median days of stay after surgery ($p < 0.001$).

Discussion

RWE studies provide real-world data (RWD) concerning the effectiveness and safety of health interventions in daily clinical practice, the use of therapeutic alternatives, patient adherence, health care resource consumption, etc. These RWD are key to supporting decision-making on health care resource allocation, thus guaranteeing the sustainability of health care systems and, ultimately, improving patients’ health by improving the quality of health care [12].

In this context, despite the descriptive and exploratory objective of the study, the REVALURO study provides insight into the actual clinical practice concerning BPH surgical management in five reference hospitals in Spain. The most remarkable finding of this study was the high variability regarding the use of surgical procedures among centers. Overall, the use of invasive techniques has increased in recent years, reducing the use of highly invasive techniques. The MISTs remained constant over the time horizon. Among the invasive procedures, AEEP increased notably, while the use of TURP decreased over the follow-up time. In the case of MISTs, the use of different techniques has remained stable since 2019. However, although the WVTT is still the selected procedure in one-third of patients, the PVP showed a slight tendency to decrease, in favor of other MISTs, such as the PUL, TIND, BPKVP or TUIP.

The decreasing use of open prostatectomy and TURP can be explained by the incidence of post-surgical complications (28.6% and 29.8%, respectively) and the mean length of hospital stay (6.1 and 3.1 days, respectively) associated with both procedures. In this sense, surgical techniques that cause fewer complications and allow hospital discharge as soon as possible, have significant advantages from the perspective of patients and health care institutions. In addition, the reduction in the use of these more invasive techniques could be motivated by the latest clinical guidelines published by the European Association of Urology, which recommends the use of HoLEP instead of open prostatectomy or TURP as long as the prostate morphology allows its use [13].

In relation to the patients’ perspective, there is no standard surgical technique that fits every patient’s needs and

Table 1 Participants' demographics, clinical characteristics and treatment pathway

	Global	Results by hospitals					p-value
		Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	
Number of participants [N]	3084	383	324	565	1004	762	–
Percentage of participants (vs. Global) [%]	100%	12.4%	10.5%	18.3%	32.6%	24.7%	–
Patients' demographics							
Age (years)							
Mean (SD)	70.8 (9)	74.0 (9.3)	68.9 (9)	69.2 (9)	71.1 (8.8)	70.8 (8.8)	–
Median (IQR)	71 (65.0 – 77.0)	74 (68.0 – 80.0)	69 (63.0 – 76.0)	70 (63.0 – 75.9)	71 (65.0 – 77.0)	71 (65.1 – 76.0)	<0.001 ^A
Range (Min – Max)	35 – 99	49 – 97	43 – 89	38 – 96	41 – 99	35 – 99	–
Distribution by age: 35–64 [N (%)]	737 (24.3%)	53 (13.8%)	103 (31.8%)	173 (30.3%)	230 (22.9%)	178 (23.4%)	<0.001 ^B
Distribution by age: ≥ 65 [N (%)]	2,301 (75.7%)	330 (86.2%)	221 (68.2%)	392 (69.4%)	774 (77.1%)	584 (76.6%)	<0.001 ^B
Treatment pathway: overall use of surgical procedures (during the 5-years follow-up)							
Highly invasive techniques: [N (%)]	384 (12.5%)	43 (11.4%)	100 (30.3%)	95 (16.5%)	31 (3.0%)	113 (14.6%)	<0.001 ^B
Open prostatectomy [N (%)]	371 (96.6%)	45 (100%)	87 (87.0%)	95 (100%)	31 (100%)	113 (100%)	<0.001 ^B
Radical prostatectomy [N (%)]	13 (3.4%)	0 (0.0%)	13 (13.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	<0.001 ^B
Invasive techniques [%]	2034 (66.0%)	184 (48.5%)	201 (60.9%)	321 (55.8%)	946 (92.7%)	382 (49.4%)	<0.001 ^B
Laparoscopic prostatectomy [%]	17 (0.9%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	15 (3.9%)	<0.001 ^B
TURP [%]	1157 (56.9%)	147 (79.9%)	194 (96.5%)	185 (57.6%)	359 (38.0%)	272 (71.6%)	<0.001 ^B
AEEP [%]	860 (42.2%)	37 (20.1%)	7 (3.5%)	134 (41.8%)	587 (62.0%)	95 (24.5%)	<0.001 ^B
MISTs [%]	665 (21.6%)	152 (40.1%)	29 (8.8%)	159 (27.7%)	44 (4.3%)	280 (36.2%)	<0.001 ^B
WVTT [%]	194 (29.2%)	0 (0.0%)	0 (0.0%)	112 (70.4%)	44 (100%)	38 (13.6%)	<0.001 ^B
PVP [%]	423 (63.8%)	152 (100%)	29 (100%)	15 (9.4 %)	0 (0.0%)	227 (80.0%)	<0.001 ^B
PUL [%]	9 (1.4%)	0 (0.0%)	0 (0.0%)	9 (5.7%)	0 (0.0%)	0 (0.0%)	<0.001 ^B
TIND [%]	6 (0.2%)	0 (0.0%)	0 (0.0%)	6 (3.8%)	0 (0.0%)	0 (0.0%)	<0.001 ^B
BPKVP [%]	11 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (4.0%)	<0.001 ^B
TUIP [%]	21 (3.2%)	0 (0.0%)	0 (0.0%)	17 (10.7%)	0 (0.0%)	4 (1.4%)	<0.001 ^B

AEEP anatomical endoscopic enucleation of the prostate, BPKVP bipolar plasma kinetic vaporization of the prostate, IQR interquartile range, MIST minimally invasive surgical technique, PUL prostatic urethral lift, PVP photoselective vaporization of the prostate, SD standard deviation, TIND temporary implantable nitinol device, TUIP transurethral incision of the prostate, TURP transurethral resection of the prostate, WVTT water vapor thermal therapy

^AStatistical inference estimated by Kruskal-Wallis test

^BStatistical inference estimated by Chi-Squared or Fisher's Exact tests

preferences. First, the clinical features of the patients should be addressed. Most MISTs are indicated for prostates under 80 cc in size, while open or laparoscopic prostatectomy are preferred for large prostates. In addition, procedures such as PVP should be considered for patients at high risk of bleeding. Moreover, patients' preferences can also indicate which intervention is most adequate. For instance, patients aiming to preserve erectile and ejaculatory function should receive WVTT or PUL [13].

Incorporating the patient's perspective in health care practice is essential to move toward person-centered medicine.

Shared-decision making (SDM), which involves inviting patients and/or caregivers to cooperate on treatment decisions, is a key component of patient engagement [14]. The advantages of SDM, in terms of emotional, financial and patient-reported outcome benefits, have been widely studied [15–17]. In addition, the initiatives of SDM conducted in the field of urology [18–20], including patients with LUTS/BPH [21–23], highlighted the importance and feasibility of implementing this process in the daily practice of urologists, with the aim of improving patients' experience, well-being and quality of life.



Fig. 1 Evolution in the use of surgical procedures over the time. Other MISTs include: PUL, TIND, BPKVP and TUIP. AEEP anatomical endoscopic enucleation of the prostate, BPKVP bipolar plasma kinetic vaporization of the prostate, MIST minimally invasive

surgical technique, PUL prostatic urethral lift, PVP photoselective vaporization of the prostate, TIND temporary implantable nitinol device, TUIP transurethral incision of the prostate, TURP transurethral resection of the prostate, WVT water vapor thermal therapy

In addition to promoting SDM strategies, another aspect that should be encouraged in urological clinical practice is the use of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs). These questionnaires are designed and validated to measure subjective

aspects of the disease, such as symptoms, well-being or quality of life, in the case of PROMs; or aspects related to a patient's satisfaction with a health care process, in the case of PREMs [24]. Several questionnaires, including IPSS [25], International Index of Erectile Function (IIEF)

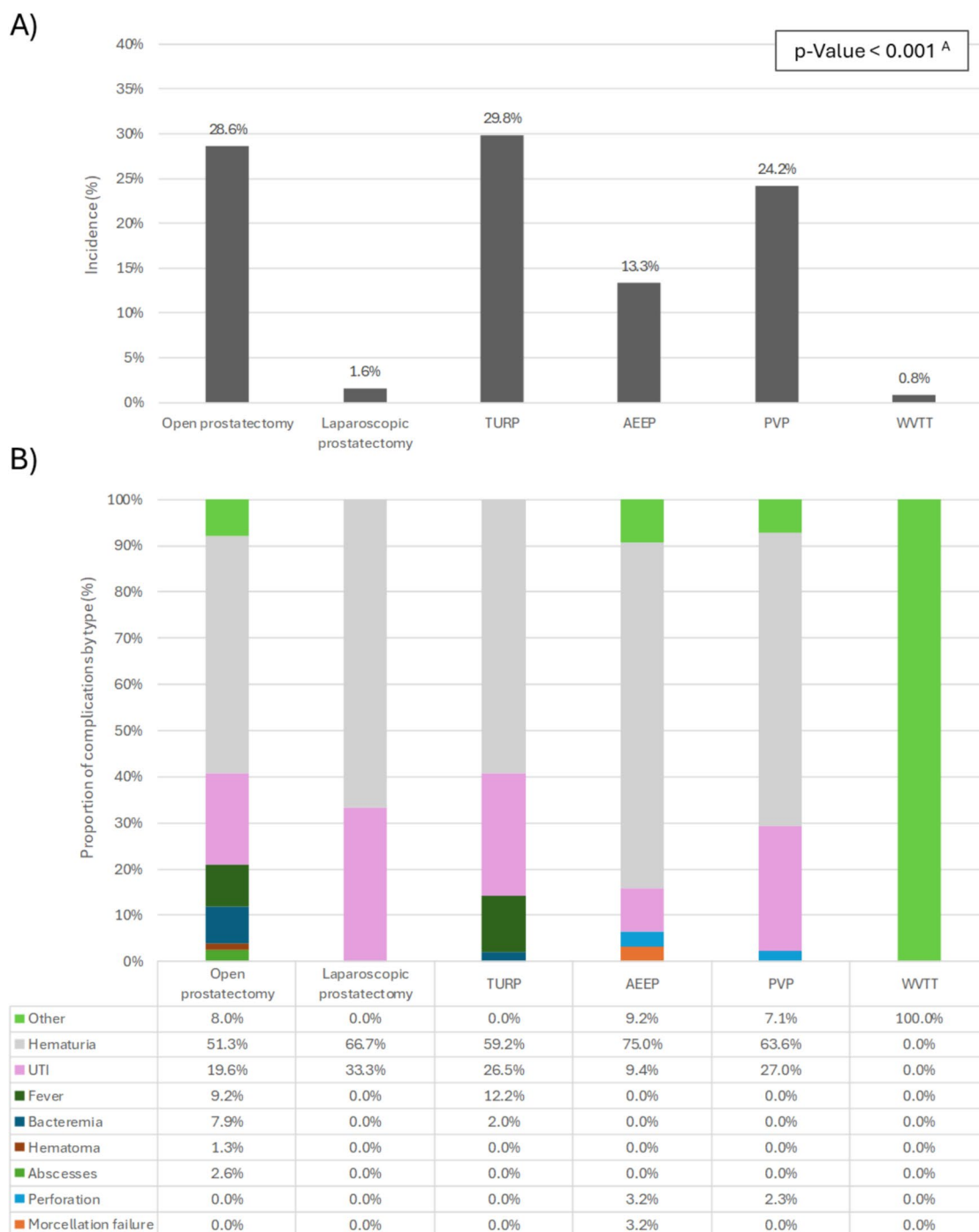


Fig. 2 Incidence and types of post-surgical complications among surgical techniques. *AEEP* anatomical endoscopic enucleation of the prostate, *TURP* transurethral resection of the prostate, *WVT* water vapor thermal therapy, *PVP* photoselective vaporization of the pros-

tate. ^AStatistical inference estimated by Chi-Squared or Fisher's Exact tests. The category "Other" include other adverse events such as vasovagal syncope

[26], Overactive Bladder Symptom Score (OABSS) [27] or Benign Prostatic Hypertrophy Health-Related Quality of Life Questionnaire [28], are available for assessing different issues of LUTS/BPH [29]. The use of these tools in combination with the evaluation of conventional clinical measures

should be generalized to achieve a more accurate assessment of the effectiveness of BPH treatments [30].

Beyond patients' needs and preferences, the treatment pathway for BPH has important implications for health care institutions. There is a lack of evidence regarding the

Table 2 Post-surgical hospital stay

Descriptive statistics and differences among hospitals							
		Results by hospitals					
		Global	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5 p-value ^a
Highly invasive techniques: open prostatectomy							
Mean (SD) [days]	6.5 (4.7)	8.0 (6.4)	3.8 (1.6)	4.2 (3.0)	4.9 (1.6)	9.3 (4.8)	–
Median (IQR) [days]	5 (4–8)	5 (4–8)	4 (3–4)	4 (3–5)	5 (4–6)	8 (7–9)	<0.001 ^A
Range [days]	0–43	2–43	2–11	0–19	2–9	5–43	–
Invasive techniques							
TURP							
Mean (SD) [days]	3.1 (2.9)	2.7 (2.3)	2.0 (1.0)	2.0 (1.6)	2.8 (2.9)	4.9 (3.5)	–
Median (IQR) [days]	3 (2–4)	2 (2–3)	2 (1–2)	2 (1–2)	2 (1–3)	4 (3–5)	<0.001 ^A
Range [days]	0–35	1–34	1–8	0–13	0–29	2–35	–
AEEP							
Mean (SD) [days]	2.9 (2.3)	2.4 (1.2)	– ^B	2.2 (1.4)	2.8 (2.2)	4.8 (2.8)	–
Median (IQR) [days]	2 (2–3)	2 (2–3)	– ^B	2 (1–3)	2 (2–3)	4 (3–6)	<0.001 ^A
Range [days]	0–33	1–6	– ^B	0–10	0–33	0–18	–
MISTs							
WVTT							
Mean (SD) [days]	0.2 (0.7)	– ^B	– ^B	0.5 (1.0)	0.0 (0.2)	0 (0)	–
Median (IQR) [days]	0 (0–0)	– ^B	– ^B	0 (0–0)	0 (0–0)	0 (0–0)	<0.001 ^A
Range [days]	0–4	– ^B	– ^B	0–4	0–1	0–0	–
PVP							
Mean (SD) [days]	1.4 (1.8)	2.1 (1.5)	1.2 (0.4)	1.6 (1.4)	– ^B	1.0 (1.9)	–
Median (IQR) [days]	1 (0–2)	2 (1–3)	1 (1–1.5)	1 (1–2)	– ^B	0 (0–2)	<0.001 ^A
Range [days]	0–13	1–13	1–2	0–6	– ^B	0–13	–
Differences among surgical techniques (global: all participants)							
	Open prostatectomy	TURP	Laser enucleation	WVTT	FVP	p-Value	
Mean (SD) [days]	6.5 (4.7)	3.1 (2.9)	2.9 (2.3)	0.2 (0.7)	1.4 (1.8)	–	
Median (IQR) [days]	5 (4–8)	3 (2–4)	2 (2–3)	0 (0–0)	1 (0–2)	<0.001 ^A	
Range [days]	0–43	0–35	0–33	0–4	0–13	–	

AEEP anatomical endoscopic enucleation of the prostate, IQR interquartile range, MIST minimally invasive surgical technique, PVP photoselective vaporization of the prostate, SD standard deviation, TURP transurethral resection of the prostate, WVTT water vapor thermal therapy

^AStatistical inference estimated by Kruskal-Wallis test

^BThe data for the intervention is unavailable or the surgical technique was not performed in the hospital during the study period

economic impact of BPH in Spain. A study conducted in 2004 revealed that the pharmacological treatment of this disease caused approximately 24% of the pharmaceutical expenditure [31]. Additionally, previous studies revealed that heterogeneity in clinical practice, which was also observed in the REVALURO study, led to important variability in health care resource consumption and costs [32]. In any case, several therapeutic strategies could decrease the cost associated with BPH management, including pharmacological [6, 33] and surgical interventions [34, 35]. Thus, this economic evidence should also be addressed to provide a solid basis for decision-making. However, further research

should be conducted to assess the gaps in the knowledge on this topic.

Despite these potential benefits from the perspective of both patients and health care institutions, the decision of which technique is performed is not aligned with the criteria previously described. In the present study, the WVTT was found to cause fewer complications (0.8%) and to lead to the shortest mean hospital stay after the intervention (0.2 days). However, trends in the use of surgical techniques revealed that WVTT, which was selected for the treatment of approximately 7% of patients overall, remained constant over time. In addition to the potential

reduction in costs associated with WVT [35], this technique could also fit the preferences of patients with BPH. According to a patient preference study, males with BPH value interventions that are effective, minimize the risks of complications and enhance the recovery process [36]. The results of the present RWE study suggested that the WVT is the intervention that best meets these patients' preferences. Additionally, 24.3% of the patients in the REVALURO cohort were aged 35 to 65 years, mainly corresponding to working age. These patients can especially benefit from the WVT, as the procedure is associated with short lengths of hospital stay. Given that erectile and ejaculatory dysfunction are rare after WVT [37], sexually active patients constitute another potential group that could benefit from WVT.

The decision of which surgical procedure should be performed for each patient with BPH could be guided by several criteria, including the patient clinical profile and preferences, risk of complications, length of hospital stay, associated costs, etc. In contrast, the REVALURO study revealed that the selection of the technique to be performed relies on the history of the hospital and the experience of the urologists in performing the different procedures. Patients and health care institutions could benefit from different surgical treatment pathways, thus, clinical practice guidelines and recommendations based on expert consensus are key to homogenizing health care regarding BPH. This would lead to an improvement in the patient's perceived benefit (PROM) and experience (PREM), enhancing equity in accessing to surgical treatments among patients and guaranteeing the sustainability of health care systems.

Although the REVALURO results are informative and useful for decision-making, this study is not exempt from limitations that should be assessed. First, the retrospective collection of RWD through medical records may have resulted in the loss of relevant information; however, this limitation is applicable to every study with retrospective design. Second, the study included 5 hospitals in the Spanish territory. Despite being 5 reference centers for BPH management in Spain, the representativeness of the results could be compromised. Nonetheless, the heterogeneity observed among hospitals in the study could be expected to be generalizable at the national level.

In contrast, the main strengths of the present study include the large sample size and real-world population. Thus, the findings of the REVALURO, combined with the results of previous RWE studies on BPH conducted in Spain, provide a wide vision of the clinical practice regarding BPH in Spain, including the evolution of patterns of health care [38], and an exhaustive clinical characterization of the patients [39, 40].

Conclusions

In recent years, invasive surgical techniques for the treatment of BPH have gained prominence in clinical practice, to the detriment of highly invasive techniques, while the use of MISTs has remained constant.

The surgical management of patients with BPH should be oriented by the patients' clinical profile, risk of complications and/or length of hospital stay associated with the procedures. However, in Spain the surgical treatment pathway seems to be based on the history of the hospital where the intervention is performed and the experience of the urologists. Thus, the development of clinical guidelines or recommendations based on expert consensus is key to guiding decision-making in the surgical management of BPH. In this sense, further research regarding clinical and economic data in this regard is needed to provide a solid basis for decision-making on the most appropriate surgical intervention for each BPH patient profile.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s11255-024-04239-7>.

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Author contributions PMI, DAM, SBA, and GHJ participated in the data collection and manuscript review. BAA, PCL, GBJL, VPFI, TME, BAP and LAE participated in study conceptualization and manuscript review. OAG participated in the data analyses, interpretation of the results and manuscript review. dIC-GA, G-BM and CMA participated in the interpretation of the results and manuscript drafting. All the authors have read the final version of this manuscript and agreed with its contents after being submitted to the journal.

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Data availability The data used to conduct this study cannot be shared openly in order to protect study participants privacy.

Declarations

Conflict of interest IPM is a proctorship of Boston Scientific. ABA is a proctorship of Boston Scientific and Olympus regarding the area of the BPH. JLGB has received fees for lectures and training courses for Boston Scientific, Medtronic and Astellas, and collaborated in clinical trials with Janssen. ETM and PBA are employees of Boston Scientific. GOA is an employee of HOPES. ACG, MGB and MAC are employees of Pharmacoeconomics & Outcomes Research Iberia (PORIB), a consulting firm specializing in economic evaluation and health outcomes research, which has received payment for interpretation of results and drafting of the manuscript. MDA, ASB, JGH, LPC, FJVP and ELA reported no conflicts of interest.

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