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ORIGINAL ARTICLE



Real-world data and treatment patterns of patients with lower urinary tract symptoms due to benign prostatic hyperplasia in Germany: an observational study using health insurance claims data

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Abstract

Purpose Benign prostatic hyperplasia (BPH) is associated with lower urinary tract symptoms (LUTS), representing one of the most common urological conditions. However, insights into the actual healthcare of this patient cohort in Germany are scarce. We aimed to retrospectively analyse management patterns of patients with LUTS in Germany using health insurance claims databases.

Methods A retrospective, longitudinal cohort analysis was conducted obtaining claims data from the German InGef health insurance database containing approximately five million member-records from over 60 nationwide statutory health insurances. First, a cross-sectional prevalence analysis was performed on all individuals with a diagnosis on LUTS (ICD-10 GM N40) in 2018. Second, a longitudinal analysis of individuals with either a newly started BPH medication or initial BPH surgery who were indexed in 2014 and followed-up for 4 years.

Results In 2018, 132,386 (6.7%) prevalent BPH patients were identified from 1,979,916 continuously insured males. A potential overcoding bias could not be assessed which may influence the outpatient sector estimation. 10,361 (0.7%) patients were identified with incident BPH medication and 1768 (0.1%) patients with incident BPH surgery out of 1,575,604 males (2013–2018). Alpha-blockers were the drug of choice (95.6%) in the first year. Half of patients received specific BPH medications four years after index, while almost 98% of initial BPH surgeries were performed within the inpatient setting. TURP was the most frequent surgical intervention (76%).

Conclusions A widespread diffusion of alternative individualized minimally invasive approaches in the outpatient sector might address pharmacotherapy discontinuation and patient-access barriers to other treatments.

Keywords Prostatic hyperplasia [MeSH] \cdot BPH \cdot Drug therapy [MeSH] \cdot Minimally invasive surgical procedures [MeSH] \cdot Health insurance [MeSH] \cdot Delivery of health care [MeSH]

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Introduction

BPH is one of the most common male diseases with significant socio-economic implications [1]. The choice of BPH therapy depends on the severity of symptoms and the risk of progression. Patients' adherence to pharmacotherapy has been shown to be low and varies depending on drug class. A recent study showed that < 10% of patients take the prescribed combination therapy after 12 months, compared to 35% for alpha-blockers and 18% for 5-ARI monotherapy [2]. Transurethral resection of the prostate (TURP) has been considered the standard operative therapy for men with LUTS due to BPH. Nevertheless, it has a 30-day postoperative mortality between 0.1 and 0.4% and an overall morbidity of > 10% [3]. Therefore, its shortcomings have given rise to the emergence of minimally invasive alternatives, emphasizing unfulfilled medical needs [4]. Despite the clinical, epidemiological, and economic disease burden of BPH [5, 6], research on the treatment patterns and the actual healthcare situation in Germany is lacking. Further real-world data are required to compare TURP and open prostatectomy with more recent surgical approaches in terms of safety and efficacy.

This is the first study to describe and analyse the medical and surgical management of BPH/LUTS patients in Germany by employing statutory health insurance (SHI) claims data. The study's aim was to investigate real-world BPH treatment pathways in Germany through health care insurance data.

Patients and methods

Study design and participants

SHI claims data study

The analysis was conducted using German SHI claims data from a research database (InGef) containing approximately five million member-records from over 60 nationwide SHIs. Claims data were available from 2013 to 2018. The sample is representative of the German population (age- and sexadjusted) with an overall good accordance of the database to the German population in terms of morbidity, mortality, and drug usage measures [7]. Projections to the German population can be made by multiplying by a factor of 19.34 (2014) or 19.78 (2018) based on the ratio between the number of individuals in the database and the German population, respectively.

First, a cross-sectional analysis was performed of all individuals with BPH in Germany (prevalent setting). Second, a longitudinal analysis of individuals with either a newly started BPH medication or initial BPH surgery. Within the cross-sectional setting, individuals were identified in 2018 upon BPH diagnosis (ICD-10 GM N40) as a confirmed outpatient or inpatient (main or secondary) diagnosis. The M2Q criterion was used, meaning that individuals must have had one inpatient diagnosis or at least two secured outpatient diagnosis in different vearly quarters. Within the longitudinal setting, individuals were indexed in 2014 and observed at baseline one year before indexing and subsequently during a four-year follow-up (FU) after the FU1 index. Individuals must have had a main or secondary BPH diagnosis confirmed in outpatient or inpatient care within the index quarter. For those first managed with BPH medication, indexing was upon the first BPH medication prescription in 2014. Alternatively, for patients first treated with BPH surgery, indexing was upon the first BPH surgery in 2014. Individuals prescribed with beta 3 agonists or anticholinergics, BPH surgery at baseline, not continuously insured, and those with cancer diagnoses were excluded from the analyses to ensure a newly treated study cohort.

Outcomes

The baseline characteristics and outcomes measured were: age, BPH medication, surgeries, surgery setting, length of hospital stay, acute events, speciality of diagnosing physician and medication prescriber. Office-based physicians were classified according to the German physician speciality codes. The included BPH medications based on the anatomical-therapeutic-chemical classification system (ATC) were: alpha-blockers (G04CA:-01,-02,-03,-04,-05,-51,-52,-53), 5-ARI (G04CB:-01,-02), anthroposophical drugs (G04CH:-01,-20), herbal drugs (G04CP:-02,-03,-05,-06,-07,-30,-50,-52,-55,-56) and other drugs (G04CX:-03,-04,-54). BPH surgery procedures (OPS): transurethral destruction/excision of prostatic tissue (5-601*), transurethral incision of the prostate (TUIP) (5-600.0), non-transurethral excision (5-603:-0,-00,-01,-1,-10,-11), dilation/stent insertion (5-609:-3,-4), stent change/removal (5-609:-5,-6), stent revision (5-609.7) and other procedures (5-601:-a,-x,-y).

Ethical approval and data protection

The analyses did not involve decisions regarding interventions or the omission of interventions, therefore, institutional review board/ethical approval and patient informed consent was waived. All individual patient data are de-identified in the InGef database to comply with German federal data protection regulations. Due to data protection regulations, patient numbers below five cannot be displayed. For data storage and processing, Microsoft Office Excel[®] 2010 and R (Open 3.5.0) were used.

Results

Prevalent outline (cross-sectional setting)

In 2018, there were 132,386 (6.7%) prevalent BPH patients out of 1,979,916 continuously insured males in the database. The mean age was 72 ± 10.6 years (Table 1). The main point of contact in the outpatient sector was GPs (58.1%), followed by urologists (46.1%). In terms of treatment pathways, the majority of BPH patients received neither medication nor surgery (55%), 44.4% received medication only, and 1.6% underwent surgical treatment. Specifically, alpha-blockers

Table 1 Key	characteristics of	f patients in t	he prevalent	BPH outline
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Prevalent BPH			
Total, <i>n</i> (%)	132,386 (100%)		
Age [years] mean \pm SD	71.2 ± 10.6		
Physicians visited (speciality) at index quarter*			
General practitioner (outpatient)	76,862 (58.1%)		
Urologist (outpatient)	61,005 (46.1%)		
Total (outpatient)	127,863 (96.6%)		
Inpatient	4523 (3.4%)		
Treatment pathways			
Medication therapy* ²	58,806 (44.4%)		
Alpha-blockers	55,320 (94.1%)		
5-ARI	9552 (16.2%)		
Surgical therapy* ³	2175 (1.6%)		
Transurethral destruction or excision of pros-	2003 (92.1%)		
tatic			
tissue (OPS 5-601*)	1654 (00 60)		
TURP (OPS 5-601.0/.1)	1654 (82.6%)		
Laser (OPS 5-601.4/.7)	411 (20.5%)		
Excision non-transurethral (OPS 5-603.0)	165 (7.6%)		
TUIP (established technique) (OPS 5-600.0)	13 (0.6%)		
Dilation/stent insertion (OPS 5-609.3/.4)	7 (0.3%)		
No surgery, no medication	72,802 (55%)		
Potential high-risk patients			
Age above 80 years	26,903 (20.3%)		
Contraindications for surgery ^{*4}	110,896 (83.8%)		
Cardiovascular diseases	108,694 (98%)		
Anticoagulation intake	24,131 (21.8%)		
Catheterisation	6222 (5.6%)		
Age above 80 years	25,638 (23.1%)		

*Patients may receive multiple diagnoses within one quarter by different physicians

*²Double count possible for patients with different prescriptions

*³Double count possible for patients with different surgeries

*⁴Double count possible for patients with different contraindications

(94.1%) were the medication of choice, 82.6% of procedures involved transurethral destruction/excision, with TURP accounting for 76% of all surgical procedures.

110,896 patients (83.8%) had a potentially high risk for surgery hallmarked by contraindications including anticoagulation intake and cardiovascular diseases. Alternatively, 16.2% (n=21,490) of BPH patients did not present any of the defined critical diagnoses or prescriptions potentially leading to a higher surgical risk. Of those with contraindications or prescriptions indicating a potentially higher risk, 23.1% (n=25,638) were ≥ 80 years.

First BPH medication outline

The first BPH medication outline depicts the health care situation of BPH patients after initial BPH drug prescription (Table 2). 10,361 (0.7%) patients were identified in the database with incident BPH medication out of 1,575,604 (2013–2018). Their mean age was 68 ± 10.7 years. The urologist was the main BPH medication prescriber accounting for 75%, while every fifth patient received the prescription from a GP. Subsequent BPH medications were prescribed mainly by the urologist (83.1%). The drug of choice was alpha-blockers (95.6% in FU1) with tamsulosin (86.7%) being prescribed the most. 5-ARIs were prescribed less frequently (9.5%), with finasteride being the most prominent one (98.8%).

Half of patients initially managed with BPH medication continued to receive BPH-specific drugs four years after index (Table 2). Continuous BPH medication prescriptions halved during follow-up, ~ 10% of patients switched medication each year. With respect to treatment pathways, 8% of patients underwent subsequent BPH surgery after initial BPH medication. Thereof, 16.2% received another BPH medication after surgery. Patients under medication showed morbidity that may be attributed to side effects of drug intake at index, including sexual dysfunction (12.9%), dizziness and giddiness (10.2%) and chronic sinusitis (4.4%). In addition, BPH patients showed a high burden of urologic diseases in FU1, for instance, UTI 16%, incontinence (incl. stress incontinence) 15%, and prostatitis 7%. Acute events such as UTI or prostatitis increased in FU1 compared to baseline and declined within follow-up, while urinary incontinence remained high at 13.2-15.5% during follow-up.

First BPH surgery outline

The first BPH surgery outline depicts the health care situation of BPH patients after initial BPH surgery (Table 3). 1768 (0.1%) patients with incident BPH surgery out of 1,575,604 (2013–2018) were identified in the database. The mean age was 71 ± 8.7 years. Almost 98% of BPH surgeries were performed within the inpatient setting; therefore, the outpatient sector currently does not seem to play a significant role (2.4%). Considering treatment pathways, every fifth patient underwent a second surgery (21%). Of those, 57% had a second BPH surgery within 30 days while 43% > 30 days after the first surgery. Nearly 19% received BPH medication after their first BPH surgery. The surgery of choice was TURP in 87.1%. In comparison, laser-based interventions seem not to be widespread (16%) and nontransurethral excisions, i.e. open prostatectomy were performed in 7.5%.

Almost 25% of patients with transurethral prostate destruction/excision were readmitted within 90 days of the

Table 2 Key characteristics of patients in the first BPH medication outline

First BPH Medication

	FU-1	FU1 incl. Index	FU2	FU3	FU4
Total, <i>n</i> (%)	10,361 (100%)	10,361 (100%)	10,055 (100%)	9783 (100%)	9502 (100%)
Deceased, n (%)	0	306 (3.0%)	272 (2.6%)	281 (2.7%)	250 (2.4%)
Age [years] at index quarter, mean \pm SD	67.6 ± 10.7				
Prescribing physician (speciality)—initial					
General practitioner	2313 (22.3%)				
Urologist	7767 (75.0%)				
Prescribing physician (speciality)—following					
General practitioner	4875 (47.1%)				
Urologist	8613 (83.1%)				
Specific treatment pathways in FU total					
First BPH medication at index, subsequent BPH surgery (combination)	831 (8.0%)				
First BPH medication at index, subsequent BPH surgery and BPH medication thereafter	135 (16.2%)				
Continuous BPH prescriptions					
At least one prescription in each quarter of the year	0	2987 (28.8%)	1552 (15.4%)	1400 (14.3%)	1448 (15.2%)
At least one prescription in two quarters of the year	0	6334 (61.1%)	4316 (42.9%)	4135 (42.3%)	4008 (42.2%)
At least one prescription per year	0	10,361 (100%)	5420 (53.9%)	5039 (55.4%)	4839 (50.9%)
Patients with more than one BPH medication (switch)	0	1096 (10.6%)	561 (5.6%)	481 (4.9%)	533 (5.6%)
Medication therapy* ²					
Alpha-blockers (ATC G04CA)	0	9908 (95.6%)	5067 (50.4%)	4706 (48.1%)	4528 (47.7%)
Alfuzosin	0	643 (6.2%)	325 (6.4%)	306 (6.5%)	308 (6.8%)
Tamsulosin	0	8994 (86.8%)	4468 (88.2%)	4066 (86.4%)	3900 (86.1%)
Terazosin	0	143 (1.4%)	53 (1.0%)	59 (1.3%)	56 (1.2%)
Silodosin	0	265 (2.6%)	159 (3.1%)	158 (3.4%)	136 (3.0%)
Doxazosin	0	36 (0.3%)	13 (0.3%)	6 (0.1%)	11 (0.2%)
Tamsulosin and Dutasteride	0	452 (4.4%)	268 (5.3%)	264 (5.6%)	282 6.2%)
5-ARI (ATC G04CB)	0	987 (9.5%)	748 (7.4%)	682 (6.7%)	706 (7.4%)
Finasteride	0	975 (98.8%)	740 (98.9%)	677 (99.3%)	697 (98.7%)
Dutasteride	0	15 (1.5%)	12 (1.6%)	6 (0.9%)	10 (1.4%)
Side effects					
Sexual dysfunctions, not caused by an organic disorder or illness (ICD F52)	1074 (10.4%)	1338 (12.9%)	1147 (11.4%)	1114 (11.4%)	1149 (12.1%)
Dizziness and giddiness (ICD R42)	991 (9.6%)	1061 (10.2%)	1059 (10.5%)	1109 (11.3%)	1094 (11.5%)
Chronic sinusitis (ICD J32)	405 (3.9%)	453 (4.4%)	426 (4.2%)	436 (4.5%)	406 (4.3%)
Acute events					
Urinary tract infection* ³	1410 (13.6%)	1666 (16.1%)	1041 (10.4%)	1009 (10.3%)	958 (10.1%)
Urinary incontinence ^{*4}	1091 (10.5%)	1604 (15.5%)	1331 (13.2%)	1369 (14.0%)	1384 (14.6%)
Prostatitis (N41)	605 (5.8%)	769 (7.4%)	518 (5.2%)	484 (4.9%)	481 (5.1%)

*Patients may receive multiple diagnoses within one quarter by different physicians

*2Double count possible for patients with different prescriptions

*³UTI including acute/unspecified/interstitial (chronic)/other chronic cystitis; other urethritis, urinary tract infection, localization unspecified (N30.0, N30.1, N30.2, N30.9, N34.1, N34.2, N37.0, N39.0)

*⁴Urinary Incontinence including: neuromuscular dysfunction of the bladder, stress incontinence, reflex incontinence, urge incontinence, overflow incontinence, recurrent incontinence and unspecified incontinence (N31, N39.3 N39.40, N39.41, N39.42, N39.47!, N39.48, R32)

initial surgery. BPH patients showed a high urologic disease burden in FU1: urinary tract infection (UTI) 41%, incontinence (incl. stress incontinence) 32%, and prostatitis 11%. Acute events such as UTI or urinary incontinence were already high at baseline and peaked in FU1 but declined thereafter, whereas prostatitis peaked already at baseline.

Table 3 Key characteristics of patients in the first surgery outline

First surgery					
	FU-1	FU1 incl. Index	FU2	FU3	FU4
Total, <i>n</i> (%)	1768 (100%)	1768 (100%)	1717 (100%)	1668 (100%)	1626 (100%)
Deceased, n (%)	0	51 (2.9%)	49 (2.8%)	42 (2.4%)	44 (2.5%)
Age [years] at index quarter, mean \pm SD	70.5 ± 8.7				
Surgery setting in FU total*2					
Inpatient incl. contracted physician service in hospital	1960 (97.6%)				
Ambulatory surgery in hospital	<5				
Outpatient	48 (2.4%)				
Specific treatment pathways in FU total					
First BPH surgery at index, second BPH surgery	368 (20.8%)				
Second BPH surgery after TURP within $> = 30$ days	209 (56.8%)				
Second BPH surgery after TURP within > 30 days	159 (43.2%)				
First BPH surgery at index, subsequent BPH medication (combi- nation)	332 (18.8%)				
Surgery therapy* ²					
Transurethral destruction or excision of prostatic tissue (OPS 5-601)	0	1632 (92.3%)	30 (1.7%)	20 (1.2%)	9 (0.6%)
Classic TURP (OPS 5-601.0/.1)	0	1422 (87.1%)	29 (96.7%)	20 (100%)	9 (100%)
Laser (OPS 5-601.4/.7)	0	262 (16.1%)	<5 (3.3%)	<5 (5.0%)	0
Hospital readmission after transurethral destruction or excision within 30 days		240 (14.7%)			
Hospital readmission after transurethral destruction or excision within 90 days		376 (23.0%)			
Excision non-transurethral (OPS 5-603.0)	0	133 (7.5%)	<5 (0.06%)	0	<5 (0.06%)
TUIP (established technique) (OPS 5-600.0)	0	13 (0.7%)	0	0	0
Dilation/stent insertion (OPS 5-609.3/.4)	0	8 (0.5%)	< 5 (0.06%)	0	0
Acute events					
Urinary tract infection* ³	681 (38.5%)	726 (41.1%)	247 (14.4%)	194 (11.6%)	198 (12.2%)
Incontinence*4	464 (26.2%)	564 (31.9%)	394 (22.9%)	351 (21.0%)	359 (22.1%)
Prostatitis (N41)	304 (17.2%)	199 (11.3%)	84 (4.9%)	71 (4.3%)	74 (4.6%)
Renal failure (N17-N19)	302 (17.1%)	313 (17.7%)	270 (15.7%)	302 (18.1%)	303 (18.6%)

*Patients may receive multiple diagnoses within one quarter by different physicians

*2Double count possible for patients with multiple surgeries

*³UTI including acute/unspecified/interstitial (chronic)/ other chronic cystitis; other urethritis, urinary tract infection, localization unspecified (N30.0, N30.1, N30.2, N30.9, N34.1, N34.2, N37.0, N39.0)

*⁴Urinary Incontinence including: neuromuscular dysfunction of the bladder, stress incontinence, reflex incontinence, urge incontinence, overflow incontinence, recurrent incontinence, and unspecified incontinence (N31, N39.3 N39.40, N39.41, N39.42, N39.47!, N39.48, R32)

Discussion

The findings emphasise that BPH is prevalent among elderly German men. In 2018, approximately 132,000 patients were identified, which corresponds to roughly 2,600,000 individuals when extrapolated to the German population. This figure supports previous BPH prevalence estimates [8].

We found that 72,802 patients (55%) neither received disease-related medication nor surgery, indicating either incorrect coding or a lack of individualized therapeutic options. Some patients may have been diagnosed with BPH based on radiological/ultrasonographic findings without any symptoms to substantiate the diagnosis. Alternatively, premature BPH coding may have occurred in patients presenting with LUTS in whom the underlying cause; however, may not be BPH-related [9, 10].

A high number of patients (50.9–53.9%) discontinued drug treatment (defined as less than one prescription per year), even though only few patients received surgery (n = 1768). It is possible that there was disease progression, medication non-compliance or abandonment due to pharmacological side effects causing patients to reconsider their medication uptake. Hence, medication appeared not to be favoured by patients, lending support to previous findings in the literature about low adherence to BPH pharmacological therapy [11]. This may be the underlying cause as to why surgically treated patients showed a high disease burden at baseline and index year. It is possible that patients unsatisfied with pharmacotherapy may have interrupted their treatment despite disease progression and, therefore, presented with a higher disease burden at a later point in time when surgery was needed.

Most patients that underwent surgery for BPH received inpatient TURP (FU1 n = 1422; 87.1%) whereas laser procedures (16%) and new technologies did not play a significant role. In contrast to our findings, using data of the German local healthcare funds (AOK), Gilfrich et al. showed that the proportion of TURP significantly decreased from 83.4% in 2008 to 78.7% in 2018 due to the increasing adoption of laser procedures [3]. The higher rates observed in our study may be due to the persistence of multiple codes per case or for the condition of a concurrent BPH diagnosis. Similarly, surgical outcomes assessment showed that there was a notable decrease in UTIs after surgery (FU1: 41.1%, FU2: 14.4%; FU3: 11.6%; FU4:12.2%) which was not reflected in the number of incontinence diagnoses possibly due to ongoing coding independent of symptoms or continued incontinence after surgery. Concurrently, data from the United States showed that between 2000 and 2008 there was a gradual increase in outpatient TURP, from 17 to 31.9%, while in 2008 outpatient procedures constituted 53.9% of all laser procedures [12]. Jeon et al. demonstrated that although the number of TURPs performed in South Korea did not change between 2010 and 2017, the number of holmium laser enucleation procedures dramatically increased by 1268% [13].

Moreover, 38% of surgically treated patients were readmitted to the hospital and 12% underwent a further intervention within 30 days after TURP, representing higher rates than previously published findings. Gilfrich et al. reported a 30-day reintervention rate of 7.26% and a one-year complication rate of 18.8%. A reason for these deviations may be the higher number of TURP procedures in our cohort, since the authors also demonstrated that laser-based procedures carried a lower risk for 30-day transfusions and reinterventions than TURP [3]. Interestingly, a large number of patients (n = 332; 18.8%) continued to take medication after surgery possibly due to detrusor instability and voiding dysfunction following TURP (Table 3) [14]. Han et al. found that 55.1% of patients continued medical therapy > 3 months after TURP and showed that age > 70 years, a history of diabetes, history of a cerebrovascular event, previous LUTS/ BPH medication use, and antimuscarinic drug use were significantly associated with symptom persistency and continuing medical therapy [15]. Surgically treated patients might still be confronted with ongoing symptoms, potentially leading to continued coding and inadequate postoperative disease monitoring and treatment. Enhanced cooperation between hospitals, established urologists, and GPs could constitute a measure to address this issue.

The number of patients that underwent surgery was much lower than the number of patients who discontinued their medication treatment (10,361 vs. 1768). Thus, there is a large number of patients (prevalent setting n = 72,802) who received no further management. This finding demonstrates a gap in health care and reinforces the importance of providing patients with individualized treatment pathways [16]. There is a high potential for minimally invasive treatment options in the outpatient sector as shown in several studies [3, 12, 13, 17, 18], considering that nearly all surgeries were performed inpatient. Inpatient procedures are related to higher health care expenses, giving rise to more widespread outpatient solutions [19]. Lastly, 23% of patients had indicators for a potential "high-risk" group who showed contraindications for surgery or were > 80 years. This patient group might profit from minimally invasive alternatives.

Strengths and limitations

The study's major strength is the large sample size. This highly representative German population sample [7] provides valuable insights into the reality of BPH patients' health care. In addition, the two-pronged approach allows for analyses of prevalent and incident patient cohorts.

Claims data are limited in that their analyses depend on the specificity and differentiability of the underlying coding system and on the quality of the coding in everyday clinical practice. The coding practice in the outpatient sector could account for a possible overestimation of BPH cases in Germany. Patients might be coded with BPH anticipatively within the context of the prostate cancer screening programme, or as an incidental radiologic finding without symptoms to corroborate the diagnosis [20, 21].

Conclusion

Despite its considerable risks and complications, TURP remains the standard of care for BPH patients whereas new technologies have not played a notable role. The high number of patients who discontinue their medication, but are not subjected to surgery, might be unsatisfied with the therapeutic pathway offered or are unwilling to undergo TURP, thus leaving them with no viable individualized therapeutic options. Therefore, a more widespread diffusion of alternative therapeutic options needs to be considered in the outpatient sector. Although surgical treatment is still an inpatient issue, new solutions should also target the outpatient sector since it is considered to be more cost-effective and to have lower access barriers. Author contributions AM: protocol/project development; data analysis, manuscript writing/editing; JF: data analysis, manuscript writing/ editing; BL: protocol/project development; data analysis, data collection or management, manuscript writing/editing; IK: data analysis, manuscript writing/editing; VM: data analysis, manuscript writing/ editing; DM: data collection or management, data analysis, manuscript writing/editing; MM: protocol/project development; data collection or management, data analysis; CG: protocol/project development; data analysis; RS: protocol/project development; data analysis, manuscript writing/editing.

Declarations

Conflict of interest Prof. Dr. med. Christian Gratzke is advisor for Astellas Pharma GmbH, DE, Ipsen Pharma GmbH, DE, Steba Biotech S.A., LUX, Bayer Pharma, DE, Olympus Winter & Ibe GmbH, DE, Medi-Tate Ltd., IL, MSD, DE, Astra-Zeneca, UK and Roche, CH. He receives speaker fees from Amgen, USA, Astellas Pharma GmbH, DE, Ipsen Pharma GmbH, DE, Janssen-Cilag GmbH, BEL, Bayer Pharma, DE, Takeda Pharmaceuticals, JPN and medac GmbH, DE. Prof. Dr. med. Arkadiusz Miernik has received research funding from the Federal Ministry of Education and Research (BMBF), DE, coverage of travel expenses from the German Association of Urology (DGU), DE, European Association of Urology (EAU), NL; he is advisor for KLS Martin GmbH, DE, Dornier MedTech Europe GmbH, Richard-Wolf GmbH, DE, KarlStorz SE & Co. KG, DE, Lisa laser OHG, DE, Boston Scientific, USA, Dornier MedTech Europe GmbH, DE, Medi-Tate Ltd., IL and reviewer for Ludwig Boltzmann Gesellschaft, A; he has royalties from Walter de Gruyter, DE, Springer Science + Business Media, DE. Dr. med. Jonas Fritzsche has no conflict of interest to declare. At the time to conduction of this study Berit Libutzki, Melanie May and Damon Mohebbi were employees of HGC Healthcare Consultants GmbH, which received funding from Medi-Tate Ltd. to conduct this study. Vanessa Malka and Ido Kilemnik are employed at Medi-Tate Ltd. Dr. med. Rodrigo Suarez has no conflicts of interests to declare.

Human participants and/or animals This analysis is based on retrospective claims data of individuals insured within the German statutory health insurance. All individual patient data were de-identified to comply with German federal data protection regulations. Due to data protection regulations, patient numbers below five were not displayed.

Informed consent The analysis did not involve decisions regarding interventions or the omission of interventions, therefore, institutional review board/ethical approval and patient informed consent was not needed.

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