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ORIGINAL ARTICLE

Medical therapy versus transurethral resection of the prostate (TURP) for the treatment of symptomatic benign prostatic enlargement (BPE): a cost minimisation analysis

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Abstract

Purpose A cost minimisation analysis compares the costs of different interventions' to ascertain the least expensive over time. We compared different prostate targeted drug treatments with TURP to identify the optimal cost saving duration of a medical therapy for symptomatic benign prostatic enlargement (BPE).

Methods The *Evolution* registry is a prospective, multicentre registry, conducted by the European Association of Urology Research Foundation (EAUrf) for 24 months in 5 European countries. *Evolution* was designed to register the management of symptomatic BPE in clinical practice settings in 5 European countries. Direct cost evaluation associated with prostate targeted medical therapies and TURP was also recorded and analysed.

Results In total, 1838 men were enrolled with 1246 evaluable at 24 months. Medical therapies were more cost saving than TURP for treatment durations ranging from 2.9 to 70.4 years. Cost saving depended on both medication class and individual country assessed. Daily tamsulosin monotherapy was more cost saving than TURP for ≤ 13.9 years in Germany compared to ≤ 32.7 years in Italy. Daily finasteride monotherapy was more cost saving for ≤ 5.9 years in France compared to ≤ 36.9 years in Spain. Combination therapy was more cost saving for ≤ 5.9 years for Italian patients versus ≤ 13.8 years in Germany.

Conclusions BPE medical management was more cost saving than TURP for different specific treatment durations. Information from this study will allow clinicians to convey medical and surgical costs over time, to both patients and payors alike, when considering BPE treatment.

Keywords Benign prostatic enlargement · BPE · Benign prostatic hyperplasia · BPH · Cost minimisation analysis

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Abbreviations

BPE	Benign prostatic enlargement
CC	Comorbidities
TURP	Transurethral resection of the prostate

Introduction

Pharmacotherapy options for male patients with symptomatic benign prostatic enlargement (BPE) are α-adrenoceptor antagonists (α-AAs), 5α-reductase inhibitors (5ARIs) or a combination (CMT) of these pharmacological agents [1, 2]. Selecting tailored pharmacological agents for BPE can facilitate an individualised patient approach. Usually, α-AAs and 5ARIs are used as first-line management in isolation or in CMT to treat BPE, when fluid intake and lifestyle modifications fail [3]. The indications for and incidence of transurethral resection of the prostate (TURP) surgical

intervention for BPE have changed during the last 30 years due to the increasing prevalence of medical therapies. The most common contemporary indication for TURP is moderate to severe LUTS secondary to BPE that is refractory to medical therapy.

A cost minimisation analysis compares the cost of two interventions to determine which is less expensive over time [4]. The aim of this study was to perform a comparative economic evaluation of 3 BPE medical therapy strategies versus conventional TURP from a prospectively designed European registry (*Evolution*). The hypothesis that managing BPE with medical therapy(ies) was more cost saving than TURP for specific treatment durations was tested.

Methods

Overview of study design

The *Evolution* registry was a prospective, multicentre, international, industry sponsored (GlaxoSmithKline© [GSK]) registry, independently designed, implemented, conducted and analysed, by the European Association of Urology Research Foundation (EAURf). *Evolution*'s aim was to collect real life data to understand the unmet needs of pharmacological treatment of BPE in primary and secondary care centres in five European countries (France, Germany, Italy, Spain and United Kingdom [UK]) for 24 months. The *Evolution* protocol was designed in accordance with the Helsinki declaration and approved by the Ethics Committees according to the regulations of each participating country/hospital/practice. The study protocol was registered at the Dutch trial register (http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=2013). Direct cost evaluation associated with BPE outcomes and progression during the registry period was measured. The primary aim in the present study was to determine the duration for which it was more cost saving to manage BPE with medical therapy compared to TURP. Secondary outcomes were to compare the costs of medical therapies and TURP for BPE between different European countries.

Cost calculation of medical therapies

Evaluation of healthcare utilisation associated with the management of BPE focused on patients in the 3 main medication categories (i.e. α-AAs, 5ARIs or CMT). Medication costs were determined as an average daily cost for each different medication and were calculated per country based on the tariffs provided by pharmaceutical companies. Price to Patient (PTP) amount and Price to Hospital (PTH) amount were calculated when available based on average daily medication doses.

Cost evaluation of TURP

Participating countries' TURP tariffs were provided by the *Evolution* registry national coordinators in 2014. Tariffs were recorded as the amounts from the national health systems based on diagnosis-related group (DRG). DRG is a statistical system of classifying any inpatient stay into groups for the purposes of payment and reimbursement. For UK, Spain and Germany, separate tariffs were identified for patients with/without minor comorbidity and for patients with major comorbidities. A predicted number of hospitalisation days was also included in national tariffs. Therefore, no additional costs for extra hospital days were added. In Germany, in cases where patients were privately insured, an amount for doctor charges was added [5]. It was assumed that half of the German patients were privately insured and an average sum of €1350 was added for TURP patients [5]. The amount in France included DRG public rate, procedure reimbursement and anaesthesia reimbursement. When applicable, calculations were performed twice; firstly, assuming all patients were low risk (i.e. without major comorbidities) and secondly, assuming all patients were high risk (i.e. with major comorbidities). For our models, calculations were performed with lowest possible and highest possible cost variations in each country. Outpatient costs, post-operative complication costs, and re-admission costs were not available and were not included in the costing models.

Results

Patient demographics

In total, 1838 BPE patients were enrolled into the *Evolution* registry of which 1246 were evaluable at 24 months. Table 1 demonstrates the number of patients that were enrolled during the 2-year registry period for each participating country. Median patient age was 67 (range 50–89) years. Median prostate size estimated by digital rectal examination (DRE) at baseline was 42cc (range 20–200cc) and median

Table 1 *Evolution* European registry of sBPE patient numbers registered per country

Country	*N* (%)
France	299 (16.3)
Germany	617 (33.6)
Italy	338 (18.4)
Spain	265 (14.4)
United Kingdom	319 (17.4)
Total	1838 (100)

prostate volume measured by transrectal ultrasound (TRUS) at baseline was 47cc (range 15–190cc). Median maximum urinary flow rate (Q_{max}) was 12 ml/s at baseline and median post-void residual (PVR) measurement, measured by transabdominal ultrasound, was 45 ml. Median PSA at baseline was 2.3 (range 0.1–58.7) ng/ml and median creatinine at baseline was 87 (range 9–591) µmol/l.

Cost of medical therapies

Table 2 summarises the average daily drug cost for all available α-AAs, 5ARIs and CMT's, among the participating countries. Drug costs for individual medications in each category varied widely between each country. Overall, terazosin was the cheapest medication for managing BPE with cost ranging from €0.23 in the UK (where £ to € conversion rate was defined at the time of analysis and £0.80 equated to €1) to €0.48 in France per day. Combodart©/Duodart© (CMT) was the most expensive medication for managing BPE, with costs ranging from €0.83 in the UK to €1.25 in Spain per day. The 5ARI cost varied from €0.32 in Spain to €1.37 in France per day for finasteride to €0.70 in UK to €1.287 in Germany for dutasteride (Table 2).

Cost of TURP

Table 3 summarises the variations in average cost of TURP for BPE surgical management amongst the 5 participating European countries. It was cheapest in the UK at €2138.07 for patients without major comorbidities, and most expensive in Germany at €5644.28 in patients with major comorbidities. This cost increased to €6944.28 in patients with private health insurance (Table 3). The cost of TURP in

Table 2 Average daily drug cost per day for α-adrenoceptor antagonists, 5α-reductase inhibitors and combination therapy for the 5 recruiting European countries

Medication	Dose studied (Once daily dose)	DE (€)	FR (€)	ES (€)	IT (€)	UK* (€)**
Alfuzosin XR	1 OD 10 mg	1.014	0.449	0.378	0.725	0.79
Doxazosin	1 OD 4 mg	0.536	0.350	0.282	0.328	0.13
Silodosin	1 OD 8 mg	0.557	0.483	0.893	0.467	NA
Tamsulosin	1 OD 0.4 mg	0.608	0.263	0.365	0.222	0.73
Terazosin	1 OD 5 mg	0.439	0.486	0.259	0.261	0.23
Dutasteride	1 OD 0.5 mg	1.287	0.803	1.074	0.891	0.70
Finasteride	1 OD 5 mg	0.808	1.377	0.313	0.999	0.34
Tamsulosin/ Dutasteride (CMT)	1 OD (0.4 mg/0.5 mg)	1.119	1.027	1.252	1.212	0.83

The cost of each medication was calculated per country based on average daily recommended doses and tariffs provided by the pharmaceutical company/companies. Price-to-Patient (PTP) amount was available for Germany, France, Spain and Italy. Cost of office visits were not taken into account

Supplementary data: The tariffs provided are from the Evolution report (pages 591–599) and originate from June 2014. Medication prices were provided by GSK©. http://uroweb.org/evolution-luts-bph-registry-from-the-eau-rf/

OD once daily, *DE* Germany, *FR* France, *ES* Spain, *IT* Italy, *UK* United Kingdom, *NA* not available

*Price-to-Hospital (PTH) was only available for the UK

**£ to € conversion rate was defined at the time of analysis and £0.80 equated to €1

Table 3 Mean costs (in euros [pounds sterling for UK]) of TURP (lowest tariff) in each European country assessed

TURP category	DE (€)	FR (€)	ES (€)	IT (€)	UK (€)*
TURP		2971.31		2650.00	
TURP without/with minor comorbidities	3085.29		2954.00		2138.07
TURP with major comorbidities	5644.28		4210.00		3339.40
Doctor charges (DE) if private insured	1350.00				

In Germany, an additional amount of €1350 was added for doctor charges in patients with private health insurance (5). This additional tariff increased the mean cost of TURP to €4435.29 for patients undergoing mTURP without major comorbidities and to €6944.28 for patients with major comorbidities in Germany

Supplementary data: The tariffs provided are from the Evolution report (pages 591–599) and originated from June 2014 http://uroweb.org/evolution-luts-bph-registry-from-the-eau-rf/

DE Germany, *FR* France, *ES* Spain, *IT* Italy, *UK* United Kingdom

*£ to € conversion rate was defined at the time of analysis and £0.80 equated to €1

Table 4 Time-point (years) when TURP becomes more cost effective in sBPE patients compared to continued medical management in each recruiting European country

Medication	DE (years)	DE + cc (years)	DE + private* (years)	FR (years)	ES (years)	ES + cc (years)	IT (years)	UK (years)	UK + cc (years)
Alfuzosin XR	8.3	15.2	3.6	18.1	21.4	30.5	10	7.4	11.6
Doxazosin	15.8	28.8	6.9	23.3	28.7	40.9	22.1	45.1	70.4
Silodosin	15.2	27.8	6.6	16.9	9	12.9	15.5	NA	NA
Tamsulosin	13.9	25.4	6	30.9	22.2	31.6	32.7	8	12.5
Terazosin	19.3	35.2	8.4	16.7	31.2	44.5	27.8	25.5	39.8
Dutasteride	6.6	12	2.9	10.1	7.5	10.7	8.1	8.4	13.1
Finasteride	10.5	19.1	4.6	5.9	25.9	36.9	7.3	17.2	26.9
Tamsulosin/ Dustasteride (CMT)	7.6	13.8	3.3	7.9	6.5	9.2	5.9	7.1	11

The formula for performing the cost minimisation analysis was (4): Time interval (years) $= \frac{\text{Cost of TURP (€)}}{\text{Cost of medication per day (€)}} \div 365\,\text{(days)}$

For example, treatment of sBPE with finasteride in non-comorbid patients is more cost-effective for 10.5 + 4.6 = 15.1 years compared to mTURP in patients with private health insurance

CC major comorbidities, *DE* Germany, *FR* France, *ES* Spain, *IT* Italy, *UK* United Kingdom

*In Germany, an additional amount of €1350 was added for doctor charges in patients with private health insurance undergoing mTURP. This additional tariff may increase the medical therapy duration cost-effectiveness in sBPE patients

France and Italy (€2971.31 and €2650, respectively) and did not vary with patient co-morbidities.

Cost minimisation analysis

Table 4 demonstrates the cost minimisation analysis that determined the time interval at which it became more cost effective to manage BPE surgically with TURP compared to continued medical management in each of the 5 European participating countries. The time interval was calculated by the following formula [4]:

$$\text{Time interval (years)} = \frac{\text{Cost of TURP (€)}}{\text{Cost of medication per day (€)}} \div 365\,\text{(days)}.$$

The cost minimisation analysis showed varying intervals at which it was more cost saving to manage BPE with TURsP compared with continued medical therapy. Medical therapies were more cost saving than TURP for treatment durations ranging from 2.9 to 70.4 years (Table 4). Cost saving was dependent on the type of medication (i.e. α-AAs, 5ARIs and CMT), on individual drug cost within each drug category, median duration of use (based on efficacy and side effects), and on the individual country assessed. For example, sBPE management was more cost saving with daily tamsulosin, for ≤ 13.9 years for patients in Germany versus ≤ 32.7 years for patients in Italy. For daily finasteride, sBPE management was more cost saving for ≤ 5.9 years for patients in France compared to ≤ 36.9 years in Spain. For combination therapy, BPE management was more cost saving for ≤ 5.9 years for patients in Italy compared to ≤ 13.8 years in Germany.

Discussion

Research in the field of BPE therapy is continuously advancing and a variety of pharmacological agents alone as monotherapy, or in various combinations involving the entire lower urinary tract and targeting different tissues and receptors, are now available with proven symptomatic benefit. Despite the evolution of these medical therapies into daily clinical practice in successive decades, information from prospective studies on the management of BPE and patient outcomes across European countries is lacking. Furthermore, there is a complete absence of comparative data on the cost of such BPE medical therapy versus TURP. The main finding of this evaluation of *Evolution* study data was that BPE medical management was more cost saving than TURP for different specific treatment durations (Table 4). Cost saving was also dependent on the type of medical therapy prescribed, its median duration and on the individual country assessed.

Currently available α-AAs include terazosin, doxazosin, alfuzosin, tamsulosin and silodosin. All are effective for treating patients with mild, moderate, or severe LUTS, due to BPE (volume < 40 g) [6]. Although their side-effects and costs differ, all appear equally efficacious for sBPE [7]. Randomised controlled trials have demonstrated that

α-AAs reduced IPSS by 35–40%, increased bladder capacity, decreased detrusor overactivity and increased maximum urinary flow rate (Q_{max}) by 20–25% [8–10]. Alpha-adrenoceptor antagonists used as monotherapy act on the dynamic component of BPH by inhibiting alpha 1_A, alpha 1_B and alpha 1_D receptors. Newer α-AAs are more selective for prostate adrenoceptors and are associated with improved patient compliance due to their lower improved side-effect profiles. Based on the findings presented herein, α-AAs are more cost saving than TURP for treating uncomplicated BPE for durations ranging from 3.6 to 70.4 years in Germany and the UK, respectively (Table 4).

Steroid 5ARIs prevent the conversion of testosterone to DHT (Dihydrotestosterone) by inhibiting the enzyme 5-alpha reductase-2 [11]. Improvements in LUTS with 5ARIs are durable with a reduction in IPSS of 15–30%, decreased prostate volume by ≥ 30% and increased uroflowmetry Q_{max} by 2.0 ml/s after ≥ 2-years of treatment [12–15]. In contrast to α-AAs, 5-ARIs should be offered to men with moderate to severe LUTS and enlarged prostate volume (i.e. ≥ 40 g) detected by digital rectal examination and/or ultrasonography to reduce the risk of disease progression, AUR and surgery [16]. Our findings demonstrated that finasteride and dutasteride were more cost saving than TURP for treating uncomplicated BPE for ≤ 36.9 and ≤ 13.1 years in Spain and the UK, respectively.

The role of combining α-AAs with 5ARIs is established and recommended in all major guidelines for moderately/severely symptomatic men with LUTS due to BPE [16, 17]. The established role for combination therapy is based on large-scale randomised controlled trials (RCTs) such as the MTOPS and CombAT trials [18, 19]. These data further support the use of long-term combination therapy with α-blocker therapy and 5ARIs in patients that are at high risk for disease progression. Our results demonstrate that medical treatment of BPE with combination therapy was more cost saving than TURP for ≤ 13.8 years in Germany.

TURP has been the primary surgical treatment option for LUTS due to BPE for most of the last century and was, therefore, utilised as a surgical comparator in the present study [20]. Throughout the current innovative uro-pharmacological era, TURP has remained the standard reference point for improvement after treatment of BPE due to the availability of robust long-term data that describe efficacy and morbidity [21, 22]. Improved anaesthesia, advances in surgical technique and instrumentation development over the last 30 years have ensured that TURP remains the reference urological procedure for surgical management of BPE [23]. The chance of improvement in a patient's preceding voiding status after TURP ranges from 70 to 96%, with a symptom score reduction of 85% [24–26].

This analysis of the *Evolution* registry data has limitations and our findings should be interpreted with some caution. Costs of complications associated with medical therapies such as General Practitioner visits due to side effects Emergency Department (ED) presentations with urinary retention, haematuria and cystitis were not included. Similarly, costs of complications associated with TURP such as urosepsis, prolonged inpatient stay and clot retention were not considered in the cost minimisation analysis. These costs were documented in the registry database but were not included in this analysis as the aim herein was solely to provide a comparative cost guide of medical therapy and TURP. Additional accurate cost analyses from Evolution associated with complications from both treatment modalities are planned later for subsequent submission as a comparative cost-effectiveness publication model.

Conclusion

This cost minimisation analysis provides a comparative assessment of medical therapies and TURP costings for treating BPE in 5 major European countries. Medical therapies were more cost saving than TURP for treatment durations ranging from 2.9 to 70.4 years. Cost saving was dependent on the type of medical therapy prescribed, its median duration and on the individual country assessed. Information from this study will allow clinicians to convey medical and surgical costs over time, to both patients and payors alike, when considering BPE treatment.

Author contributions ND: Data collection, Data analysis, Manuscript writing; GJ: Data analysis, Manuscript writing; WW: Data collection, Manuscript editing; AB: Project development, Manuscript editing; CC: Data collection, Manuscript editing; AP: Data collection, Manuscript editing; AT: Data collection, Manuscript editing; DB: Project development, Manuscript editing; AT: Data analysis, Project development, Manuscript editing.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

Statement of human rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standard.

Informed consent Informed consent was obtained from all individual participants included in the study.

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