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Editor's Choice

Can benign prostatic hyperplasia be identified in the primary care setting using only simple tests? Results of the Diagnosis IMprovement in PrimAry Care Trial

J. Carballido,[1] R. Fourcade,[2] A. Pagliarulo,[3] F. Brenes,[4] A. Boye,[5] A. Sessa,[6] M. Gilson,[7] R. Castro[8]

SUMMARY

Aims: Diagnosis IMprovement in PrimAry Care Trial (D-IMPACT) was a prospective, multicentre epidemiological study in three European countries to identify the optimal subset of simple tests applied in primary care to diagnose benign prostatic hyperplasia (BPH) in men who spontaneously present with lower urinary tract symptoms (LUTS). **Methods:** Consecutive male patients aged ≥ 50 years who spontaneously attended their regular general practitioner (GP) office with LUTS were eligible for inclusion if they had not previously undergone BPH diagnostic tests or received treatment for BPH. Patients were assessed on three occasions, twice by their regular GP (visits 1 and 2) and once by a urologist (visit 3). The diagnostic accuracy of each variable was determined using the urologists' final BPH diagnosis (at visit 3) as gold-standard. Independent variables analysed were as follows: age; BPH diagnosis performed by GP in visit 1 (yes/no); probability of BPH diagnosis assessed by GP in visit 1; urinalysis (normal/abnormal); prostate-specific antigen (PSA); International Prostate Symptom Score (IPSS); diagnosis of BPH performed by GP in visit 2 (yes/no); and probability of BPH diagnosis assessed by GP in visit 2. Statistically significant variables ($p < 0.1$) were included in a logistic regression model to identify the best algorithm and describe each test contribution. **Results:** The most frequent spontaneously reported LUTS were nocturia and weak urinary stream. BPH study prevalence was 66.0% (95%CI: 62.3–69.5) and 32% of patients were at risk of BPH progression (PSA > 1.5 ng/ml and prostate volume ≥ 30 cm^3). Among the independent variables analysed, only age, IPSS and PSA showed a statistically significant relationship with BPH diagnosis. In a logistic regression model including age, IPSS, PSA and probability of BPH (based on physical examination and symptoms), positive predictive value (PPV) was 77.1%. Exclusion of BPH probability resulted in a PPV of 75.7%. **Conclusions:** A diagnostic algorithm including only objective variables (age, IPSS and PSA), easily implemented in any GP office, allows GPs to accurately diagnose BPH in approximately three-quarters of patients spontaneously reporting LUTS.

What's known

Available evidence suggests that procedures employed by primary care physicians to diagnose BPH vary widely across Europe. Expected increases in BPH prevalence accompanying the gradual aging of the population further highlight the importance of developing effective strategies for accurate diagnosis.

What's new

D-IMPACT has shown that BPH can be accurately diagnosed using a set of simple tests or variables (age, IPSS, PSA level) that can be easily implemented in the primary care setting.

[1]Hospital Universitario 'Puerta de Hierro-Majadahonda', Madrid, Spain
[2]Centre Hospitalier d'Auxerre, Service de Chirugie Urologique Auxerre, France
[3]Università degli Studi di Bari, Dipartimento Emergenza e Trapianti d'Organo, Sezione di Urologia Bari, Italy
[4]Centro de Atención Primaria Llefià Badalona, Spain
[5]Clin Ouest, Nantes, France
[6]Italian College of General Practitioners, Florence, Italy
[7]GlaxoSmithKline, Clinical Operations, Harlow, UK
[8]GlaxoSmithKline, Clinical Development, Oncology R&D, Philadelphia, PA, USA

Correspondence to:
Joaquin Carballido,
Urology Service, Hospital Universitario 'Puerta de Hierro-Majadahonda', c/Manuel de Falla no1. Majadahonda, Madrid 28222, Spain
Tel.: + 34 911916292
Email: j.carballido@terra.es

Disclosures

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Introduction

Benign prostatic hyperplasia (BPH) is a complex disease that is progressive in a large proportion of older men. BPH may be associated with bothersome lower urinary tract symptoms (LUTS), which can negatively impact quality of life (QOL); BPH can also progress to serious complications such as acute urinary retention and BPH-related surgery (1). Accurate diagnosis of BPH may allow treatment of appropriate patients to improve LUTS and QOL and to reduce the risk of complications.

The increasing prevalence of symptomatic BPH combined with greater medical intervention is likely to give general practitioners (GPs)/primary care providers (PCPs) an increasingly important role in the diagnosis, management and follow up of BPH. A simplified treatment approach for men with BPH/LUTS for use in the primary care setting has recently been proposed (2), in recognition of the

time constraints placed on PCPs. A similar, simplified approach to the diagnosis of BPH in primary care also has the potential to improve the management of men with BPH/LUTS. Diagnosis of BPH in primary care is often based on an assessment of symptoms. However, standardised assessment is performed in less than half of men who present with LUTS, although this is recommended in European guidelines (3,4). In addition, there can be considerable differences between countries with regard to local guidelines and diagnostic strategies (5).

The validity of simple BPH diagnostic tools used in a primary care setting has been assessed in a pilot study in 20 specialist urology clinics across Spain (6). The study showed a high correlation between BPH diagnosed by four simple tests [medical history, International Prostate Symptom Score (IPSS), digital rectal examination (DRE) and serum prostate-specific antigen (PSA)] and by a full battery of tests including ultrasonography and uroflowmetry. Diagnosis IMprovement in PrimAry Care Trial (D-IMPACT) investigated the accuracy of similar, simple diagnostic tests applied in a primary care setting in three European countries. By virtue of less selective inclusion criteria, D-IMPACT aims to expand on the pilot study and translate it to a wider, more heterogeneous population. D-IMPACT also aims to provide a non-subjective diagnostic algorithm that is reproducible in the primary care setting and to estimate the prevalence of BPH in patients spontaneously attending GP clinics with LUTS.

Methods

This was a prospective, epidemiological, multicentre study to evaluate the accuracy of simple tests used to diagnose symptomatic BPH in a primary care setting when compared with gold-standard diagnosis by a urologist. The trial involved 143 GPs and 38 urologists from France, Italy and Spain.

Consecutive male patients aged ≥ 50 years who spontaneously attended their regular GP office with LUTS were eligible for inclusion if they had not previously undergone BPH diagnostic tests or received treatment for BPH. Patients were excluded if they had a history of prostate cancer, had undergone previous invasive treatment for urinary flow obstruction or pelvic surgery involving the bladder, prostate or urethra, had any endocrine, neurological, inflammatory or infectious disease for which BPH tests had been performed, or had previously been treated with an alpha-blocker, 5-alpha reductase inhibitor or phytotherapies typically used in the treatment of symptomatic BPH.

Relevant Independent Ethics Committees approved the protocol and the trial was conducted in accordance with the Declaration of Helsinki, ICH Good Clinical Practice and any applicable local regulations. All patients provided written informed consent.

Study design

The rationale and design of the study have been described previously (7). Briefly, patients with LUTS were assessed on three occasions, twice by their regular GP (visits 1 and 2) and once by a urologist (visit 3) (Figure 1). At visit 1, patients were asked about their medical history and their initial symptoms, after which the GP recorded their BPH diagnosis. The patient was subsequently asked to fill in the IPSS and Bother Score Questionnaires (BSQ). Dipstick urinalysis was performed and, if required, a urinary sediment test was requested by the GP. PSA analysis was also requested. The second visit took place at the GP clinic when the results of the urinalysis and PSA tests had been received. The GP performed a DRE and recorded their BPH diagnosis. The final visit (visit 3) took place at the reference urologist surgery within 3 months of visit 2. The urologist reviewed the patient's symptoms and past medical history, performed a physical examination (including a DRE), reviewed the previous tests carried out by the GP and performed additional BPH diagnostic tests of abdominal ultrasound (with postvoid residual volume and prostate size estimation) and uroflowmetry. The urologist confirmed or refuted the previous diagnosis of BPH by the GP.

Study objectives

The primary objectives were to evaluate the diagnostic performance of a set of GP-performed simple tests in the diagnosis of BPH compared with gold-standard diagnosis by a urologist and to evaluate the prevalence of BPH in a population spontaneously attending GP clinics with LUTS.

Statistics

The sample size calculation was based on expected BPH prevalence. The prevalence of BPH in men referred to urology clinics with suspected BPH was estimated to be approximately 80%. To estimate this prevalence by means of an asymptotic confidence interval with a maximum imprecision of 3% at a 95% confidence level, a minimum of 683 patients were required. Assuming a 10% dropout rate, it was necessary to recruit 760 patients.

The diagnostic accuracy of each individual variable (including diagnostic tests and BPH diagnosis assessed by the GP in visits 1 and 2) was determined using the urologist's final BPH diagnosis as gold-

standard. Independent variables analysed were as follows: age; diagnosis of BPH performed by GP in visit 1 (yes/no); probability of BPH diagnosis assessed by GP in visit 1 (scale 0–100%); urinalysis (normal/abnormal); PSA; IPSS; diagnosis of BPH performed by GP in visit 2 (yes/no); and probability of BPH diagnosis assessed by GP in visit 2 (scale 0–100%).

The diagnostic accuracy of each independent variable was analysed using logistic regression and sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were determined. Statistically significant variables ($p < 0.1$) were included in a logistic regression model to identify the best algorithm and describe each test contribution. Different models were developed including only objective tests generally available in a primary care setting. BPH probability assessed by the GP in the second visit, based also on IPSS, urinalysis, PSA and DRE, was not included in the models because it was considered a secondary or intermediate variable that could be influenced by the results of those additional diagnostic tests evaluated at the same visit. PPV was considered the first indicator to select the best algorithm to be used in primary care to identify patients with BPH. It corresponds to the percentage of patients identified by the GP with a higher probability of a BPH diagnosis and who were finally diagnosed with BPH.

The per-protocol (PP) population was the primary population for analyses and included all patients who met the study selection criteria and who attended all three assessment visits.

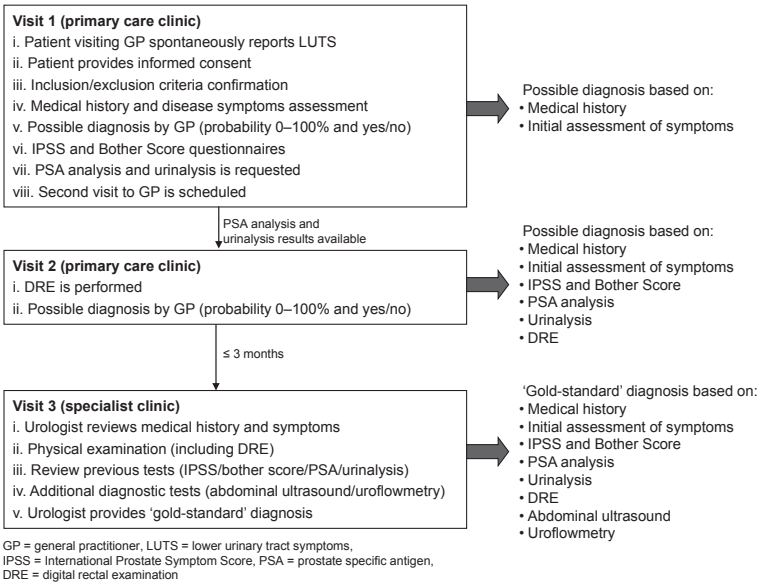

Figure 1 Study design (7)

Results

Study population

A total of 768 patients were recruited into the study, 666 of whom were included in the PP population. Reasons for exclusion from PP analysis were loss to follow up ($n = 55$), patient withdrawal from study ($n = 19$), final BPH diagnosis not assessed ($n = 6$) or other ($n = 22$). Baseline demographics are reported in Table 1. The overall study population had a mean ± SD age of 60.9 ± 7.9 years, with one-quarter of patients aged > 65 years. Almost half were overweight (49.1%) and 23.6% were obese [body mass index (BMI) > 30 kg/m^2]. Nearly three-quarters (74.5%) reported at least one comorbidity during the baseline visit, with high cholesterol and/or high triglyceride levels, diabetes and chronic obstructive pulmonary disease being the most frequently reported.

Minor but statistically significant differences between countries were observed in terms of age ($p = 0.039$), height ($p < 0.001$) and BMI ($p < 0.001$). The Spanish population was slightly older (mean age 61.8 years), with lower height (mean 168.6 cm) and higher BMI (mean 28.3 kg/m^2). The maximum differences between countries (France and Spain) were 1.9 years of age, 4.3 cm of height and 1.8 kg/m^2 in BMI.

No statistically significant differences were observed between countries in terms of family medical history related to any genitourinary system disorder and previous urological surgery. Some differences were observed, however, in terms of concomitant diseases. High cholesterol and/or high levels of triglycerides were reported more frequently by patients from Spain and France than those from Italy (34.4% and 33.6% vs. 19.6%; $p < 0.001$), as well as metabolic, endocrine or nutritional disease (9.1% and 4.6% vs. 0.9%; $p < 0.001$). Diabetes was more frequently reported by Spanish patients (16.1%) than those from France (8.3%) or Italy (8.7%) ($p = 0.012$). COPD was also more frequently reported by Spanish patients (12.2%), followed by Italian (7.3%) and French patients (2.8%) ($p < 0.001$).

Figure 2 shows a description of LUTS spontaneously reported in the inclusion visit and those reported by patients following GP questions in the baseline study visit. The most frequently reported LUTS were nocturia and weak urinary stream; these symptoms were reported spontaneously by more than half of patients. Baseline clinical characteristics are shown in Table 2. Mean baseline IPSS was 12.4 ± 6.9; 26.7% of patients had mild symptoms, 57.4% moderate symptoms and 15.9% severe symptoms. Fifty-two per cent of men were dissatisfied

Table 1 Demographics and baseline characteristics

	Per-protocol population (n = 666)
Age (years)	60.9 ± 7.9 (50–98)
Age category, *n* (%):	
≤ 65 years	500 (75.1)
> 65 years	166 (24.9)
Height (cm)	170.6 ± 6.9 (151–208)
Weight (kg)	80.1 ± 11.4 (47–124)
BMI (kg/m^2)	27.5 ± 3.7 (18.1–44.1)
BMI category, *n* (%):	
< 20 kg/m^2	8 (1.2)
20–25 kg/m^2	174 (26.1)
25–30 kg/m^2	327 (49.1)
> 30 kg/m^2	157 (23.6)
Race, *n* (%):	
Caucasian	447 (67.1)
Other	2 (0.3)
Not known*	217 (32.6)

*not recorded in France. BMI, body mass index. All data mean ± SD (range) unless otherwise stated.

with their BPH-related QoL. PSA values were > 1.5 ng/ml in 42.5% of patients and prostate size (measured by abdominal ultrasound) was medium (30–60 cm^3) or large (> 60 cm^3) in 66.2% of patients. Combining both measures, 32% of study patients were at risk of BPH progression, as defined by a PSA > 1.5 ng/ml and prostate volume ≥ 30 cm^3.

Symptoms reported by patients during the baseline study visit showed differences across countries. Weak urinary stream and prolonged voiding were more frequently reported by Italian patients (67.1% and 55.7%), followed by Spanish patients (64.8% and 43.9%) and French patients (52.5% and 36.4%) ($p < 0.01$). Incomplete bladder emptying was also more frequently reported by Italian patients (52.1%), followed by French patients (41.0%) and Spanish patients (34.4%) ($p < 0.001$). Difficulty in starting urine flow was more frequently reported by Spanish patients (37.0%), followed by those from France (31.8%) and Italy (15.5%) ($p < 0.001$). French patients reported less severe symptoms (mean IPSS 10.1) than Italian (mean IPSS 12.9) and Spanish (mean IPSS 14.1) patients ($p < 0.001$). The percentage of patients with moderate-to-severe symptoms was 58.1% in France, 79.6% in Spain and 81.7% in Italy ($p < 0.001$). The proportion of patients with prostate size ≥ 30 cm^3 was 54.4% in France, 78.7% in Spain and 86.8% in Italy ($p < 0.001$). However, there were no significant differences between countries in the proportion of patients with PSA > 1.5 ng/ml or in the proportion of patients at risk of BPH progression.

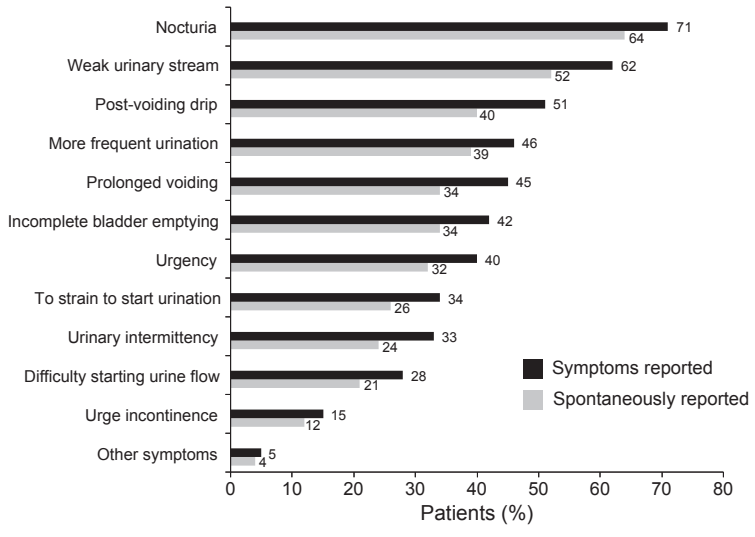

Figure 2 LUTS spontaneously reported by patients in the inclusion visit and those reported by patients following general practitioner questions in the baseline study visit

Impact of BPH symptoms on QOL

Patients with BPH confirmed by a urologist reported a significantly worse health-related QOL (HRQOL) than those without BPH ($p = 0.003$). HRQOL showed a statistically significant relationship with symptom severity; mean (SD) BSQ score was 2.12 (1.53) in patients with mild symptoms, 3.44 (1.24) in patients with moderate symptoms, and 4.57 (1.00) in those with severe symptoms ($p < 0.001$). The impact of symptoms on HRQOL was significantly greater in Italy and Spain than in France ($p < 0.001$).

Prevalence of BPH confirmed by urologist

Overall BPH study prevalence was estimated to be 66.0% (95%CI: 62.3–69.5) of patients spontaneously presenting with LUTS. No statistically significant differences were observed in BPH prevalence between the different countries (France, 65.0%; Italy, 63.9%; and Spain, 69.1%).

Diagnostic accuracy of tests

BPH diagnosis based on physical examination and symptoms (visit 1) had a PPV of 69.8% (Table 3). From the initial visit (visit 1) to the intermediate visit (visit 2), there was an increase in the specificity of GPs' diagnosis (from 29.2% to 42%; Table 3), suggesting that patients diagnosed as not having BPH by the urologist were more likely to be identified correctly by the GP at visit 2 than at visit 1.

Among the independent variables analysed (age, IPSS, PSA, BPH probability assessed by GP at visit 1, prostate size by DRE and abnormal urinalysis) only age, IPSS and PSA showed a statistically significant relationship with BPH diagnosis (Table 4).

In a logistic regression model including age, IPSS, PSA and probability of BPH (based on physical examination and symptoms), PPV was 77.1% and NPV was 46.8%. Exclusion of BPH probability resulted in a PPV of 75.7% and a NPV of 44.1%. Diagnostic accuracy of other models based on objective tests (age and IPSS, age alone, IPSS alone) is shown in Table 5.

Correlation between prostate volume assessed by DRE (GP or urologist) and ultrasound

There was no correlation between GPs and urologists DREs for prostate volume assessment [κ 0.284 (95% CI 0.22–0.35)] nor between GP-assessed and ultrasound-measured prostate volume [κ 0.171 (95% CI 0.11–0.24)]. However, there was substantial correlation between urologist-assessed and ultrasound-measured prostate volume [κ 0.624 (95% CI 0.57–0.68)].

Table 2 Baseline clinical characteristics

	Per-protocol population (*n* = 666)
IPSS score	12.4 ± 6.9 (0–33)
IPSS category, *n* (%):	
Mild symptoms (0–7)	178 (26.7)
Moderate symptoms (8–19)	382 (57.4)
Severe symptoms (20–35)	106 (15.9)
Bother score, *n* (%):	
Delighted	31 (4.7)
Very satisfied	70 (10.5)
More satisfied	99 (14.9)
Neither satisfied nor dissatisfied	120 (18.0)
More dissatisfied	219 (32.9)
Very dissatisfied	90 (13.5)
Terrible	37 (5.6)
PSA (ng/ml)	2.14 ± 2.41 (0.10–20)
PSA category, *n* (%):	
≤ 1.5 ng/ml	383 (57.5)
> 1.5 ng/ml	283 (42.5)
Prostate size by DRE performed by GP, *n* (%):	
Small (< 30 cm^3)	177 (26.6)
Medium (30–60 cm^3)	445 (66.8)
Large (> 60 cm^3)	44 (6.6)
Prostate size by abdominal ultrasound (cm^3)	38.0 ± 18.4 (2.7–142.8)
Prostate size category by abdominal ultrasound, *n* (%):	
Small (< 30 cm^3)	225 (33.8)
Medium (30–60 cm^3)	374 (56.2)
Large (> 60 cm^3)	66 (9.9)
Residual volume (cm^3)	41.1 ± 55.1 (0–300)
At risk of BPH progression (yes/no*), *n* (%)	213 (32)/453 (68)

*defined as a PSA > 1.5 ng/ml and medium or large prostate size (≥ 30 cm^3). BPH, benign prostatic hyperplasia; DRE, digital rectal examination; IPSS, International Prostate Symptom Score; PSA, prostate-specific antigen. All data mean ± SD (range) unless otherwise stated.

Discussion

The D-IMPACT study has shown that an algorithm based on a set of simple tests, which are recommended in European guidelines and can be implemented by a GP, has acceptable diagnostic accuracy for BPH in men presenting with LUTS. D-IMPACT expands the findings from the previous pilot study (6), conducted among urologists, to the GP/PCP setting making the findings applicable to a wider, more heterogeneous patient population.

The overall prevalence of BPH in this study was 66.0%. Small differences in BPH prevalence were observed across participating countries, ranging from 63.9% in Italy to 69.1% in Spain. These prevalence rates are consistent with those in previous reports of patients attending GP clinics with LUTS (8). The profile of the study population (e.g. age, severity of LUTS, PSA levels and prostate size) was also comparable with other studies of patients presenting with LUTS (5,6,9). Patients with BPH confirmed by a urologist reported worse HRQOL than those without BPH and the degree of impairment was related to symptom severity; again, these findings are consistent with those of other studies of men with symptomatic BPH (5,9).

All the objective study diagnostic tests, as well as factors known to be associated with a BPH diagnosis such as age, prostate size and PSA levels (10,11), were initially analysed individually and then combined in a number of different models to evaluate the diagnostic accuracy. Of all the analysed factors, only age, IPSS, PSA and BPH probability (based on medical history and symptoms) showed a statistically significant relationship with BPH diagnosis. Age, IPSS and PSA showed similar diagnostic accuracy, with PPV values ranging from 72.5% to 74.2%. The accuracy of different diagnostic models including these variables together with the probability of BPH as per GP assessment at the first visit was evaluated. The complete model, including age, IPSS, PSA and the initial BPH probability (based on medical history and symptoms) showed a good diagnostic accuracy with a PPV of 77.1%.

Diagnoses based on medical history and symptoms can result in very subjective estimations of BPH probability, so models were developed without this factor. Exclusion of BPH probability from the model resulted in non-significant reductions in sensitivity,

Table 3 Sensitivity, specificity, PPV, NPV and accuracy of initial BPH diagnosis (in a yes/no format) performed by GP in visit 1 and visit 2

	Visit 1		Visit 2	
	Rate	95% Confidence intervals (Exact binomial)	Rate	95% Confidence intervals (Exact binomial)
Sensitivity	84.1%	80.3–87.4%	80.0%	75.9–83.6%
Specificity	29.2%	23.4–35.6%	42.0%	35.5–48.8%
PPV	69.8%	65.7–73.7%	72.9%	68.7–76.8%
NPV	48.5%	39.9–57.3%	51.9%	44.4–59.3%

PPV, positive predictive value; NPV, negative predictive value; BPH, benign prostatic hyperplasia; GP, general practitioner.

PPV and NPV compared with the complete model. When both BPH probability and PSA were excluded from the model, further non-significant reductions in diagnostic accuracy were observed compared with the complete model, with regard to sensitivity, PPV and NPV.

Two models (age + IPSS + PSA and age + IPSS) were considered the best to define an optimal and objective BPH diagnostic algorithm. Both models had acceptable diagnostic accuracy and could be implemented in a standard GP practice. The model excluding PSA was considered as PSA determination may not be available in all GP practices and, even if accessible, will involve additional costs. PSA may also be recommended for prostate cancer screening in the patient population included in this study. Dependent on the specific local circumstances, either model (age and IPSS with or without PSA) could be used to provide acceptable diagnostic accuracy and thereby facilitate the approach to BPH diagnosis and management among GPs with different backgrounds and knowledge in the disease area. Although universal and fully validated, many GPs are reluctant to use the IPSS, perhaps because it is perceived as impractical and too time-consuming in a busy primary care setting (12,13). However, our results confirm its

Table 4 Statistical relationship (p-value) and accuracy of clinical variables and individual diagnostic tests performed by GP with final BPH diagnosis

	p-value	Sensitivity	Specificity	PPV	NPV
Age	< 0.001	51.6%	65.0%	74.2%	40.8%
Initial BPH probability	< 0.001	69.3%	56.2%	75.5%	48.5%
Initial BPH (yes/no)	< 0.001	84.1%	29.2%	69.8%	48.5%
IPSS	< 0.001	58.0%	59.3%	73.5%	42.0%
PSA	< 0.001	55.2%	59.3%	72.5%	40.5%
Prostate size (estimated by DRE)	0.123	–	–	–	–
Urinalysis	0.483	–	–	–	–

BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; PPV, positive predictive value; NPV, negative predictive value; PSA, prostate-specific antigen; DRE, digital rectal examination.

Table 5 Diagnostic accuracy of models based on objective tests

Parameters	PPV	NPV	Sensitivity	Specificity
Age + IPSS + PSA + BPH probability	77.1%	46.8%	62.7%	63.7%
Age + IPSS + PSA	75.7%	44.1%	58.9%	63.3%
Age + IPSS	75.5%	43.3%	56.8%	64.2%
Age	74.2%	40.8%	51.6%	65.0%
IPSS	73.5%	42.0%	58.0%	59.3%

IPSS, International Prostate Symptom Score; PSA, prostate-specific antigen; BPH, benign prostatic hyperplasia; PPV, positive predictive value; NPV, negative predictive value.

value with regard to accurate diagnosis of BPH in men with LUTS

There was an increase in the specificity of GPs' diagnosis from visit 1 to visit 2, suggesting that patients diagnosed as not having BPH by the urologist were more likely to be identified correctly by the GP at visit 2 than at visit 1. This is consistent with the fact that the GP was armed with additional information at visit 2 compared with visit 1 (e.g. urinalysis, PSA), and therefore better able to diagnose or exclude the diagnosis of BPH.

We did not observe a significant correlation between GP assessment of prostate volume and BPH diagnosis. There was also a low level of agreement between prostate volume assessed by GP DRE and abdominal ultrasound. Although DRE was not useful for BPH diagnosis in this study, it cannot be concluded that DRE is not useful in the evaluation of BPH or other prostatic disease. It is probable that the low agreement between DRE measurement performed by GPs and other evaluations of BPH is attributed to variable and/or insufficient experience of DRE on the part of some participating GPs. It might therefore be advisable for GPs who lack sufficient experience to avoid this invasive examination if they are planning a referral to a urologist based on other indicators (and to seek additional specific training in performing this examination), or to use PSA levels (if this test is available) as a surrogate for prostate volume, bearing in mind the limitations of applying the correlation between PSA and prostate volume at an individual rather than population level (14).

There are some limitations to this study. First, we did not collect information on the number and characteristics of the study screening failures (those patients who attended the GP office but were not included in the study). As a result, our BPH prevalence rate could be an overestimation of the real disease prevalence, although it is consistent with previously reported prevalence rates (8).

Another limitation relates to the lack of standardisation of the gold-standard diagnosis conducted by urologists. The study protocol did not include any definition of what would constitute a positive BPH diagnosis. The absence of standardised criteria to define a positive BPH diagnosis introduces the possibility of potential bias related to variability in urologist assessment. However, the study was specifically designed to reflect usual clinical practice and the similarities in urologist diagnosis between countries may suggest an overall consistent approach.

Some logistical problems between GPs and urologists in certain centres made it impossible for some patients to complete the final study visit. However, the exclusion of patients for logistical or administrative reasons does not, in principle, correlate with a patient's health and therefore should not introduce any bias to the study or significantly affect the conclusions. In addition, the final proportion of patients excluded from the PP population (13%) was close to the 10% dropout assumed in the calculation of the sample size.

In conclusion, a BPH diagnostic algorithm including only objective variables (age, IPSS and PSA) allows GPs to accurately diagnose BPH in approximately three-quarters of patients spontaneously reporting LUTS. These variables are widely accessible and easily implemented in any GP office and offer the prospect of improved diagnosis and initial management of this prevalent disease by GPs irrespective of their background and experience in this area. Such improvements in diagnosis could result in fewer but more appropriate patient referrals to a urologist and overall improved patient care.

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Spain *Urologists*: JM Aranda Lassa, J Bachiller Burgos, J Soler Martinez, J Ramon Bordalba, J Carballido Rodriguez, JM Cozar Olmo, C Garcia Freire, M Padilla Leon, C Marchal Escalona, M Unda Urzaiz, B Minana, L Parra Muntaner, V Ramos Gutierrez, FJ Torrubia Romero, JU Gonzalez-Tova *GPs*: M Aranaz Villarte, MP Blazquez Giron, C Jaques Sanchez, M Hernandez Serrano, JF Moraga Jimenez, S Orillan Verdugo, B Lopez Fernandez, FR Serrano Galan, A Baca Osorio, JC Villalobos Martin, A Hormigo Pozo, SC Sarriegui Doninguez, MA De La Fuente Martinez, C Plaza Nohales, MC Fouz Lopez, A Ruiz Sanchez, F Padilla Ruiz, JM Campos Navarro, V Conerjo Garcia, MJ Perez Villalba, C Cebreiro Suarez, JM Dios Diz, JJ Branas Rodriguez, S Gotor Montoro, EJ Guerrero Abellan, V Guirao Guijarro, FA Padilla Leon, M Paez Ruiz, JA Bermudez Martin, RA Lopez Garcia, IE Martinez Merida, AJ Alayo Arrugaeta, JA Castano Gabaldon, A Larrazabal Bilbao, A Pinero Marin, J Jimenez Guillen, J Boladeras I Sabater, SB Siquier Ramis, JA Coll Mari, M Puigserver Colom, J Dominguez Velazquez, S Viota Lima, B Cejas-Fuentes Padron, S Orribo Rodriguez, F Arias Silgo, PP Perez Alvarez, EJ Gamero De Luna, F Brenes Bermudez, C Lleal Barriga.

Italy *Urologists*: A Zezza, A Decata, F Mengoni, G Ragusa, B Sonni, AM Marconi *GPs*: L Giacci, M Caruso, G Ianiro, G Salvio, G Rauzino, E Cantoro, G Caracciolo, AA De Cristofaro, V Pisante, MR Presutto, V Puntonio, AM Scarlato, A Salvetti, C Pacella, M Demurtas, R Garofalo, S Golia, C Russo, A Taviani, A Metrucci, A Bianco, M Congedo, A De Maria, E De Maria, C Mariano, F Vernaleone, G Tommasielli, G Bernardi, S Buonocompagni, E Garaffa, B Guillaro, G Piccinocchi, A Volpe, A Sessa, M Calzolari, V Colombo, G Corgatelli, L Felloni, A Guerroni, O Rinaldi, M Zucarelli, A Tozzoli, M Passamonti, M Pigni, E Testolini.

France *Urologists*: R Fourcade, P Allard, AR Azzouzi, J Benchetrit, P Costa, A De La Taille, J-P Hurel, H Ibrahim, S Mallick, B Marc, B Rabut, C Saussine, JP Mignard, H Monsaint, Y Bermond, JF Hetet, P Bondil *GPs*: G Deffressigne, F Kolovratek, C Ranguet, H Saint-Amand, M Sanchez, R Charrau, J Nuel, A Castela, S Laymond, M Peytavin, M-C Rossignol, C Baghdadi, C Prade, C Salcion, A Spassova, L Guerrin, D Edet, D Teisseire, M L Hirondel, F Michel, J-P Goulon, K Mekki, P Boisson, C Rousselet, H Puymartin, M Moutel, T Gicquel, A Selles, J-J Tanguy, P Allanore, Y Bermond, P Caillibotte, M-P Eveno, J-A Fardel, C Lemoine, Y Marzin, J Robert, P-Y Treguer, P Algaba, J-M Aboun, A Boye, D Mahot, P Perrot, R Thibault, N Tournemine, F Lacoin, P Michellier, JP Cohen-Bacry, G Rouviere.

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