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ORIGINAL PAPER

Quick Prostate Test (QPT): Motion for a tool for the active contribution of the general pratictioner to the diagnosis and follow up of benign prostatic hyperplasia

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Summary *Introduction: Less than 40% of men with LUTS consult their doctor. Patients consider the LUTS as physiological and are resigned to endure them. It is necessary to foster awareness of the micturition disorders, to monitor their development and to assess the effectiveness of therapies. At present the only validated test is the IPSS-Q8, but in Italy it is used by only 4% of General Practitioners (GPs). Because the IPSS is complex and not easy to handle, we need a more simple test but nevertheless efficient. The Italian Society of Urology (SIU) and the Italian Society for Interdisciplinary Primary Care (SIICP) presented the "Quick Prostate Test" (QPT) in November 2012. We aimed to evaluate the efficiency of QPT versus the IPSS-Q8 and its suitability in primary care.*
Materials and Methods: The QPT is composed of 3 questions to be answered "yes" or "no." The answer "yes" just to one question makes "positive" the test. We enrolled 64 men, ≥ 50 years old, suffering from BPH, extracted from the database of five GPs. The patients were randomized into two arms: to the arm 1 only QPT was administered, to verify efficiency of the test; to the arm 2 both the QPT that the IPSS-Q8 were administered.
Results: Into the arm 1, the 96.4% has tested positive for QPT. Into the arm 2, the 89% of patients with one or two positive responses to the QPT showed a moderate IPSS-Q8 score; the 75% of the patients with three positive responses to the QPT had a serious IPSS-Q8 score. The GPs (80%) have expressed the highest level of satisfaction for the QPT for the "time of administration" and for the "simplicity" of the test.
Conclusions: The experience with the QPT has shown that the test is efficient and suitable in the primary care setting. We want to encourage the GPs to use the QPT for the monitoring of patients with lower urinary tract symptoms (LUTS) and to contribute to the validation of the test.

KEY WORDS: Benign Prostatic Hyperplasia; Lower Urinary Tract Symptoms; International Prostate Symptom Score.

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INTRODUCTION

The benign prostatic hyperplasia (BPH) is a chronic disease characterized by prostate alterations resulting in the lower urinary tract symptoms (LUTS), related to the phases of filling, emptying of the bladder and to the post-voiding period, that interfere with quality of life of male subjects (1). In clinical practice, only 30-40% of patients with overt BPH starts a diagnostic and therapeutic program, for a moderate-severe symptomatology, and about half of these for the appearance of more or less serious complications (infections, urinary retention). The 60% of men with BPH, for the slow onset of symptoms, lives together with them, thus favoring the deterioration of the bladder. They will contact their physicians when the detrusor alterations will be irreversible. As these aren't disorders that endanger life, BPH and LUTS are likely to be underestimated, regarded as disorders inexorably associated with aging. In fact they represent a real socio-economic problem because have an impact both on the quality of life of patients and on the health system that supports the costs of these disorders, characterized by their high prevalence and progression over time (1-3).
The progression of BPH is not identifiable only by an increase in the gland volume but also by a worsening of the uroflowmetry, of the clinical symptomatology and, consequently, of the quality of life (4, 5).
The symptoms related to BPH can be divided into three groups (1):

- *Symptoms of bladder emptying phase:* starting hesitancy, intermittency, weak urinary stream, use of abdominal pressure, spraying or bifid urinary stream, terminal drip;
- *Symptoms of bladder filling phase:* urgency, frequent urination, nocturia, urge incontinence, altered bladder sensation;
- *Symptoms of post micturition phase:* feeling of failure to empty the bladder, post-voiding dribbling.

The perception of his urinary disorders is fundamentally subjective. For their assessment, we need simple, easily repeatable and validated tools (reliable and reproducible), in order to quantify the severity of LUTS, their

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variation over time (also in relation to the various treatments) and the impact on quality of life. In this regard, the experts of the Consensus Conference on Guidelines for the Management of BPH recommended "*an increasing involvement of the general practitioner in the follow up of the patient in treatment for LUTS/BPH, so that clinical monitoring of these patients is more consistent and effective*" (1). The most used rating scale of the symptoms is the IPSS (*International Prostate Symptom Score*). The IPSS is recommended as a tool to measure the symptoms, to be used for the initial assessment of their severity in men with LUTS. To perform the test you have to answer 7 questions, each corresponding to a score from 0 to 5. The score obtained by the sum of all seven questions allows you to categorize urinary disorders in '*absent*', '*mild*', '*moderate*', '*severe*'. The IPSS finally provides an eighth question, which quantifies the quality of life (QoL = Q8) in relation to own urinary condition at the time and must not be added to the previous seven questions. Despite "*the symptom scores*" in general, and the IPSS-Q8 in particular, are recommended they are rarely used in Italy: only 3.5% of general practitioners uses the IPSS-Q8 and in addition, because of the poor handling of the test only 15% of urologists uses it (2).

Given the complexity, the poor handling of the IPSS questionnaire and the closer times of work in the primary care setting, the General Practitioner needs for a "*symptom questionnaire*" to be easier administered than IPSS, but at the same time efficient, both to put the suspected diagnosis and for the subsequent follow-up of patients with BPH and during medical therapy. For this reason, in November 2012, jointly by the SIU (*Italian Society of Urology*) and by the SIICP (*Italian Society for Interdisciplinary Primary Care*) the "*Quick Prostate Test*" (QPT) was presented as a quick and easy tool to put the suspicion of LUTS and to assess the development of the BPH and the effectiveness of the therapies, appropriate to the setting and the time of the "*basic medicine*". Waiting for cohort studies on large series are completed, since there is no data in the literature, we wanted to evaluate the efficiency of the QPT versus the IPSS-Q8, in the patient with LUTS/BPH and during pharmacological treatment and its suitability in primary care.

Materials and Methods

IPSS-Q8

The *International Prostate Symptom Score* (IPSS) is recommended as a tool for measurement of the symptoms to be used for baseline assessment of their severity on men with LUTS (6, 7). The IPSS also incorporates a question that assesses the overall impact of LUTS on the quality of life (QoL = Q8). To perform the test you have to answer 7 questions each corresponding to a score from 0 to 5. The sum of the scores of the seven questions allows you to classify urinary disorders in:

- *Absent or Mild urinary disorders* if the sum is between 0 and 7
- *Moderate urinary disorders* if the sum is between 8 and 19
- *Severe urinary disorders* if the sum is between 20 and 35.

Finally, the IPSS includes an eighth question, which quantifies the quality of life in relation to own urinary condition at the time and must not be added to the scores of the previous seven questions.

Quick Prostate Test (QPT)

The QPT test consists of 3 questions that the patient must answer "*yes*" or "*not*". It is a quick and simple test that can help to optimize the management of the health status of the patient with BPH, facilitating doctor-patient dialogue in the first visit and on subsequent visits for follow-up. It allows you to monitor the well-being of patients with BPH with or without ongoing treatments. It consists of three questions related to LUTS, but it is not associated with a rating/score. The composition of the test takes into account the following aspects: it evaluates the most prevalent and troublesome symptoms; the severity of symptoms is proportional to the discomfort; the severity of the symptoms and discomfort is proportional to the risk of progression.

Two questions investigate irritative or "*filling*" symptoms, one question investigates the obstructive or "*emptying*" symptoms, for a total of only three questions (Table 1). The affirmative answer to one of the three questions indicates that the test is positive.

Table 1.
Quick Prostate Test:
Yes to one question indicates positive test.

Quick Prostate Test	
1.	In the last month, did you get up at least twice from bed by night to urinate (from when you go to sleep in the evening until you wake up in the morning?
2.	In the last month, had you difficulties several times to delay the urination?
3.	In the last month, had you ever the feeling of not to be able to completely empty your bladder?

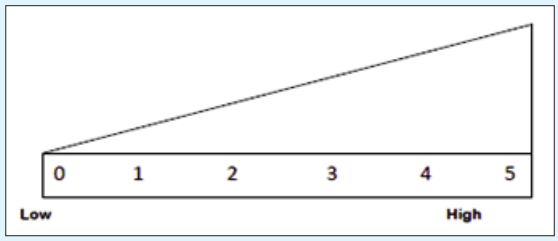
Study design

The study lasted five months, from 1 May 2012 to 30 September 2012. In the first phase of recruitment we have obtained the lists of patients to be included in the study by extrapolating data from GPs softwares and using the following search criteria (keywords): the diagnosis of BPH or drugs used in the medical treatment of BPH: α-blockers (alfuzosin, doxazosin, terazosin, tamsulosin, silodosin), or 5-α-reductase inhibitors (5ARI) (dutasteride, finasteride). The inclusion criteria were: ≥ 50 years old men; BPH diagnosed; therapy with α-blockers for at least a month and with inhibitors of 5-alpha reductase (5ARI) for at least three months or in combined therapy.

Some of the extracted patients were invited to a phone interview for medical history and for each of them has been agreed on a date. Other patients were subjected to the test in an "*opportunistic*" way: on the occasion of their visit to the general practitioner, that occurred for other reasons.

Patients were randomized into two arms: "*the arm 1*" has been subjected to administration of the interview only

Figure 1.
Level of satisfaction of the general practitioner displaying the QPT.



Dear colleague, on the basis of your level of satisfaction in the completion of the QPT-BPH test, please cross a number from zero (lower level of satisfaction) to five (highest level of satisfaction), considering the parameters "time" and "simplicity" of application.

with QPT, to verify efficiency of the test in relation to the ongoing therapy (α-blockers, 5ARI, α-blockers + 5ARI); "*the arm 2*" has been subjected to interview with administration of both the QPT and the IPSS-Q8 to evaluate efficiency of QPT compared to the validated test (IPSS-Q8).
A total of 64 patients were interviewed. At 28 patients (arm 1) it was administered the QPT (Quick Prostate Test) and at 25 patients (arm 2) they were administered both the QPT and the IPSS-Q8. Age, pharmacological treatments, associated diseases and treatment for BPH were recorded for each enrolled patient. At the end of the study, the general practitioners who participated in the data collection were invited to express their level of satisfaction after using the QPT taking into account two parameters: "*time used for administration of the QPT*" and "*simplicity of the questions*". A linear scale was made to assess the acceptance of the QPT by physician: it quantifies the level of satisfaction of each general practitioner (Figure 1). The satisfaction level is represented on a line that brings numeric values from 0 to 5 in ascending order (useful to display the wedge drawn on the line that represents numeric values in increasing order). The zero indicates dissatisfaction while 5 indicates the maximum satisfaction and approval.

Results

For administration of the test it was necessary a time varying from 5 to 20 minutes, with the variability associated with the type of questionnaire (Time for QPT < Time for IPSS-Q8). The choice to not participate to the study was made for the following reasons: patients no longer in therapy, which in most cases has been voluntarily suspended without inform their doctor; patients who had undergone prostate surgery (not reported in the software of general practitioners), and therefore not eligible in our study; lack of real willingness on the part of some physicians "*for time problem*"; patients who did not come to the appointment set. Sixty-four patients were interviewed: 9 patients had discontinued therapy, and therefore the QPT had not been administered to them (group of patients excluded); 2 patients, despite having already undergone TURP, were excluded from the study, but were also submitted to the QPT for follow-up after the surgery. The mean age of patients was 69 years. The prevalence of the most important comorbidities calculated on the total sample (64 patients) are: 62.5% hypertension; 21.87% diabetes mellitus; 12.5% dyslipidemia; 6.25% chronic obstructive pulmonary disease; 4.68% gastro-esophageal reflux; 4.68% arthrosis.
The effectiveness and/or appropriateness of ongoing therapy has been evaluated on the 28 patients of QPT group. Twenty-five patients in medical therapy for BPH were submitted to both QPT and IPSS (QPT-IPSS group) with the aim to evaluate the efficacy of the ongoing therapy and to get results able to demonstrate the efficiency of the QPT, performing a comparison with its validated predecessor (IPSS). Results obtained in the "QPT-IPSS group" (arm 2) are summarized in Table 2.

Table 2.
Level of satisfaction of the general practitioner displaying the QPT.

	QPT0	QPT1	QPT2	QPT3
IPSS slight (1-7)	xxx	x	x	
IPSS moderate (8-19)		xxxxxxxxx	xxxxx	x
IPSS severe (20-35)				xxx

QPT 0 = all "negative to QPT" patients had a mild IPSS score (< 8);
QPT 1 = the majority of the patients with only one positive response to the QPT obtained a moderate IPSS score (8-19);
QPT 2 = the majority of the patients with two positive responses to the QPT obtained a moderate IPSS score (8-15);
QPT 3 = the majority of the patients with three positive responses to the QPT obtained a severe IPSS score (> 19).
The two patients who had undergone TURP were both positive to QPT test, index of disease progression, and were sent to the attention of their general practitioners.
Four out of five GPs expressed a level of satisfaction equal to 5 (highest level of satisfaction), and one expressed a level of satisfaction equal to 4.

Discussion

The QPT has helped to assess the effectiveness and/or appropriateness of ongoing medical therapy for patients with BPH. The use of QPT allows to analyze in a short time the prostatic symptoms in their main aspects. The arm 2 (patients underwent both QPT and IPSS) revealed a close correlation between the positivity to the QPT and the increasing of the IPSS score. From the comparison of the two tests it results that the majority of patients who got one or two affirmative answers to QPT had a medium IPSS score, therefore between 8 and 19. A significant correlation has also emerged among patients who have given three affirmative answers to the QPT, in fact they have shown an IPPS score between 20 and 35, expression of severe urinary disorders. These surprising data form the basis for the validation of the QPT and for the applicability as a more simple substitute for the IPSS, test

that has not reached the so expected widespread diffusion due to the complexity of the eight questions and answers that compose it.
From the data obtained by comparing the two tests you can think of the QPT as a suitable replacement for the IPSS, perfect for the work of the general practitioner which is subject to the "*time*" factor. In fact it is evident as the time required for the administration of the two tests is very much in favor of QPT, simple test and easy to handle, which analyzes with only three questions the urinary problems associated with benign prostatic hyperplasia (2). Furthermore, given its simplicity, the QPT could be conceived as a test of self-administration unlike the IPSS, more specialised test, which requires the aid of a qualified personnel. Data in the literature show that the IPSS is used only by 3.5% of general practitioners and 15% of urologists. Therefore the low level of use even among specialists demonstrates its poor practicality in terms of ease of administration and of time needed for administration. The study has also allowed us to make an assessment of the "*satisfaction*" of the 5 general practitioners who participated in the enrollment of patients, based on "*time required*" and "*simplicity of the questions*" of the QPT. Eighty percent of the GPs expressed a level of satisfaction equal to 5 (the highest level of satisfaction), and the remaining 20% expressed a satisfaction level of 4. These data show the suitability of the QPT, relatively to the time spent on administration and to the simplicity of the three questions that comprise it, in the general practice setting. The QPT can be an "*opportunistic*" test, that can evaluate the progress of the urinary disease during a normal office visit for reasons of other nature, and to assess from the outset the need for diagnostic procedures and/or of any adjustment in course of therapy.
The general practitioner needs a tool that is fast in administration and efficient for the evaluation of patients with BPH. By our study, although conducted on a small sample of patients (64), it was found that the Quick Prostate Test could effectively replace the IPSS for the monitoring of the patient with BPH in the setting of general practice. In fact the experts of the Consensus Conference on Guidelines for the management of BPH recommend "*an increasing involvement of the general practitioner in the follow up of the patient in treatment for LUTS/BPH, so that the clinical surveillance of these patients is more constant and effective*" (1).

Conclusions

Based on the data we collected in our experience with the QPT, despite the small number of patients enrolled in the study, we verified the possible efficiency of the test and the sure suitability for the setting of primary care, taking into account the simplicity and rapid time of administration. While we await trials on a much larger number of patients and therefore statistically validating, we want to encourage general practitioners to use the QPT in the setting of general practice to monitor the patient with LUTS, with the opportunity to contribute with the number of their patients in the validation of the test.

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