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Validation of a patient reported outcome questionnaire for assessing success of endoscopic prostatectomy

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Purpose: Several international committees involved in establishing standards of care have recommended that patients undergoing surgery for bladder outlet obstruction should be assessed with patient reported outcomes (PRO). The Patient Global Impression of Improvement (PGI-I) is an instrument designed to measure a patients interpretation of symptom changes following intervention. The objective of this study was to validate the PGI-I as a PRO assessment following surgery for bladder outflow obstruction (BOO) in men with benign prostatic hyperplasia (BPH).

Methods: Men undergoing photoselective vaporisation of the prostate were followed prospectively. Pre- and postoperative International Prostate Symptom Score (IPSS), Quality of life (QoL) index, peak urinary flow (Qmax), and postvoid residual (PVR) assessments were done. The PGI-I was conducted and correlated at 3 months postoperatively to changes in IPSS, QoL, Qmax, and PVR.

Results: One hundred and sixty-six consecutive patients were included. Following surgery, IPSS and QoL improved by 11 and 2.4 points ($P<0.0001$). PGI-I was found to correlate with postoperative changes in IPSS and QoL (Pearson correlation, 0.47 and 0.58, respectively; $P<0.0001$).

Conclusions: This is the first study to validate the PGI-I as a PRO measure to surgery for BOO. This suggests a potential for the PGI-I to be used to assess surgical therapies for BPH and may be a valuable addition for measuring outcomes in clinical trials evaluating surgical interventions for BPH.

Keywords: Patient outcome assessment, Lower urinary tract symptoms, Prostatic hyperplasia, Prostatectomy, Transurethral resection of prostate

INTRODUCTION

Lower urinary tract symptoms (LUTS) is a common condition in men with a prevalence of bothersome symptoms reported in 30%–50% [1,2]. LUTS suggestive of benign prostatic hypertrophy (BPH) is associated with a lower level of overall health related quality of life (HRQL) [3-5]. HRQL decreases as severity of LUTS increase [4,5]. Currently treatment success for this condition is limited to comparing symptoms scores and isolated quality of life (QoL) indexes. Several international committees in charge of establishing standards for measuring outcomes following intervention for LUTS however have recommended documenting the patients, self-reported, impact of treatment [6,7]. A patient's perspective of clinical impact and treatment benefits can be recorded in questionnaires called patient reported outcomes (PROs).

Currently, there are a range of validated questionnaires assessing symptoms and QoL for men with LUTS, the most recognised of which is the International Prostate Symptom Score (IPSS) also called the American Urological Association

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Table 1. Patient Global Impression of Improvement

Check the one number that best describes how your urinary tract condition is now compared with how it was before your operation	
1	Very much better
2	Much better
3	A little better
4	No change
5	A little worse
6	Much worse
7	Very much worse

(AUA) BPH symptom score questionnaire. This questionnaire includes five questions on voiding symptoms (nocturia, frequency, etc.) and a single question on QoL. These questionnaires are aimed at assessing a patient's symptoms at a particular point in time. Changes in scores overtime are used to assess outcomes following intervention but they are not designed to assess the patient's perception of changes in symptoms postintervention.

PRO assessments are designed specifically to assess a patient's perception of changes following treatment. A global index is a PRO assessment, which ranks patients change in symptom following intervention, in a way that is easy to use, compared and interpret. A global scale gives an overall appraisal of a patient's perception of change following intervention. Currently, no global assessment instrument has been validated for assessing outcomes in the management of LUTS. The Patient Global Impression of Improvement (PGI-I) index is a possible candidate for this role. The PGI-I scale was originally modelled after psycho-pharmacological scales described in 1976 (Clinical Global Impression) [8]. The Clinical Global Impression-Improvement (CGI-I) scale is a 7-point scale that requires the clinician to assess how much the patient's illness has improved or worsened relative baseline. The PGI-I scale used is the same but is completed by the patient (Table 1). It has been validated for use in female patients following intervention for both urinary incontinence and prolapse [9,10]. It has also been demonstrated to have excellent test-retest reliability [10]. Yalcin and Bump [9] altered the stem of the questionnaire for their patients with stress urinary incontinence but maintaining the response options. This study used their version of the PGI-I.

The aim of this study was to validate the use of the PGI-I in men following surgical treatment of LUTS by correlating it with other outcome assessment measures.

MATERIALS AND METHODS

This project was part of a prospective, longitudinal, observational study which recruited men with significant LUTS whom underwent photoselective vaporization of the prostate (PVP), using the 120 W Greenlight laser (American Medical Systems, Minnetonka, MN, USA).

The indications for surgery were consistent with those described by both the European Association of Urology and AUA guidelines [11,12]. Once identified as candidates for surgery, the men had their flow rate (Qmax) and postvoid residuals (PVRs) measured by uroflowmetry and bladder scanner. Their preoperative IPSS and QoL scores were also recorded at this time. Preoperatively, prostate size was determined by transrectal ultrasound (TRUS) assessment using the ellipsoid method.

The men subsequently underwent greenlight laser prostatectomy using the 120 W lithium triborate laser.

Men were reviewed at both 6 weeks and 3 months. It was at the 3 month review, that the men were reassessed with the same measures but with the addition of the PGI-I. Three months was chosen as the best assessment point for two reasons. Firstly, it is at 3 months when postoperative, healing symptoms would have settled for the vast majority of men (dysuria, urgency, frequency, etc.), and men can be regarded as having reached treatment baseline. Secondly it is close enough for most men to maintain reasonable recall of their preoperative symptoms and more accurately assess how their symptoms have changed with treatment.

The IPSS, QoL, Qmax, and PVR results were compared from baseline to the 3-month follow-up using paired *t*-test and Wilcoxon signed rank test. The validity of the PGI-I was assessed by correlating the PGI-I response to changes in the other assessment tools. Pearson coefficient was used for correlations. Statistical significance was concluded when $P \leq 0.05$. Statistical analysis was performed with SPSS Statstics GradPac ver. 18 (IBM Co., Amonk, NY, USA).

RESULTS

One hundred sixty-six consecutive patients who underwent PVP were included. Thirty-two patients were excluded due to incomplete follow-up. Incomplete follow-up occurred in 19 patients because the PGI-I score was not recorded (reasons unclear), in a further 12 patients because they did not attend follow-up and one died prior to follow-up.

Twenty-four patients were in acute retention preoperative, with 19 having an indwelling catheter and 5 doing intermittent self-catheterisation. When presenting changes in flow rate and PVR and when correlating these results with PGI-I, patients in acute retention were excluded.

Mean age at surgery was 67 years (Table 2). Mean TRUS