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IMPACT OF LOWER URINARY TRACT SYMPTOMS ON QUALITY OF LIFE USING THE FACT-G SCALE

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ABSTRACT

OBJECTIVES

To assess the impact of lower urinary tract symptoms (LUTS) on general quality-of-life (QoL) measures in an outpatient setting.

METHODS

1546 male patients aged 51 and older and scoring above 11 in the International Prostate Symptom Score (IPSS) completed the general version of the Functional Assessment Cancer Therapy (FACT-G), the Benign Prostatic Hyperplasia Impact Index (BII), and additional questions. Previous prostatic surgery and neuro-urologic conditions were exclusion criteria, whereas urologic medication was not.

RESULTS

LUTS and QoL were significantly related with age, older patients presented more symptoms and worse QoL. In addition, the results showed negative correlations between LUTS and QoL.

The division of severity groups according to IPSS showed that patients from the severe group reported significantly worse QoL compared to the moderate group. 32% of variance of FACT-G was explained by the IPSS items, controlling

for age. Nocturia combined with incomplete bladder emptying were the strongest predictors of QoL.

CONCLUSIONS

LUTS produce a considerable impact on the general wellbeing of the patient. Combined with age, they can explain up to 30% of variance in QoL. Nocturia and incomplete emptying are the most troublesome symptoms.

Keywords

- Lower urinary tract symptoms
- Quality of life measurement
- Benign Prostatic Hyperplasia

INTRODUCTION

The relationship between symptoms related to benign prostatic obstruction (BPO) and quality-of-life (QoL) has been shown with disease-specific scales[1] and general QoL measures.[2-4] Initially designed to compare cancer treatments, the FACT-G scale has been adopted in other health areas providing a reliable tool to evaluate and to compare QoL under different conditions.[5-6] The FACT-G scale has been shown to be reliable in urologic patients,[7-8] but has not been studied in symptomatic BPO patients. The aim of the present study was to assess the impact of BPO symptoms in the QoL of a large ambulatory population. Additionally, FACT-G reliability was studied for this specific sample.

MATERIAL AND METHODS

Males aged over 50 attending 350 outpatient Urological Units for LUTS throughout Spain were offered to participate in the present study. Prior to inclusion, patients were informed about the risks and benefits of participation and provided verbal consent. Those unable to understand the questionnaires, with previous prostatic surgery, or with neurological disease known to affect bladder function or insulin-dependent diabetes were excluded. Current treatment with drugs for LUTS was not an exclusion criterion. After filling in the IPSS, those patients with scores > 11 were asked to complete the rest of the scales. Clinical variables and inclusion criteria were recorded by clinicians. 1871 patients were recruited during a 3 month period. The questionnaires returned

incomplete were not considered (n = 325; 17.3%) resulting in a final sample of 1546 patients aged 51-90 years (mean 66.80 ± 7.34).

Each participant completed a booklet with the Spanish versions of the following questionnaires (Table I): the IPSS;[9] the Bother Score due to urinary Symptoms (BS) included after the IPSS items; the BII;[10] and the FACT-G,[5-6,11,12] an instrument measuring multidimensional QoL (physical, social/family, emotional, and functional well-being). In the FACT-G, each item is scored on a five-point scale from 0 (not at all) to 4 (very much) and subscales are added to obtain the general score (FACT-G). An additional question about the administration procedure (patient without help, patient with nurse's help, and nurse with patient's indications) was added.

A review of the questionnaires and double checking database introduction were carried out for avoiding errors. Analyses were performed by the Statistical Package for Social Sciences (SPSS), version 12.0. Internal consistency reliability of the FACT-G, IPSS and BII was analysed (Cronbach's alpha(α)). Differences in administration procedure according to age were compared using one-way ANOVA and post hoc Duncan's test. Spearman's rank correlations were performed to assess bivariate relationships between age, QoL and LUTS. Influence of the LUTS severity was analysed by pairwise Student *t*-test comparing two IPSS severity groups (12-19 moderate; 20-35 severe). Since one of the inclusion criteria was an IPSS score above 11, our categorization of the "moderate" group was slightly different to the commonly used[13]. Finally, the relationship between QoL and LUTS was analysing using separate stepwise linear regression analyses, adjusting for age which correlated significantly with the

criterion.

RESULTS

Patients not receiving any current treatment accounted for 24.2% of the sample, whereas 48.1% were being treated with an alpha blocker, 19.9% with plant extract therapy, 7.4% with 5-alpha reductase inhibitors, and 0.3% with anticholinergics. Regarding the administration procedure, 32.% of patients answered without help, 36.5% with nurse's help, and 31.6% of questionnaires were filled by nurses with patients' indications. Statistically significant differences were observed among the administration groups in terms of age (65.19 ± 6.96; 67.02 ± 7.29; and 68.18 ± 7.50 respectively). Duncan's post hoc test showed differences between the groups (P <0.001). Table I represents a summary of the descriptive statistics and reliability of the scales. Patients reported higher scores of weak stream, frequency and nocturia, and all the scales were internally consistent.

Spearman's rank correlations indicated that older age was significantly related to higher IPSS and BII scores, and less favourable scores on QoL indexes. As expected, bivariate correlations between LUTS and QoL were negative and significant (Table II).

As shown in Table III, significant differences between severity groups were found in the QoL indexes and BII. The severe group scored worse QoL and more BPO impact compared to the moderate group.

Stepwise linear regression indicated that nocturia and incomplete bladder emptying were the strongest predictors of QoL. Furthermore, urgency, hesitancy, intermittency, and frequency of urination remained significant predictors of QoL. Weak flow didn't appear as significant predictor (Table IV).

COMMENT

Our data confirm good reliability for all the LUTS and QoL related measures; all the subscales showed α over 0.70. Consequently, these instruments can be useful for research and assessment of those aspects in outpatient units. Regarding the descriptive statistics of the IPSS, all respondents reported relatively higher scores on weak stream, frequency and nocturia symptoms. Our results were similar to those reported by Badia[14] and Yoshimura.[15]

In our study, age was significantly associated with all the LUTS and QoL measures. Some other studies have found that older patients reported more voiding symptoms.[4,16] It is interesting to note the difference in these findings compared with those reported by Dapueto.[14] Their study indicated a trend toward higher scores in the social family well-being (WB) for aged patients. It is possible that characteristics of the sample, patients with cancer who ranged in age from 18 to 75 years old, may have had an effect on subject response.

Taken together, these results confirm the relationship between LUTS and QoL, suggesting worse QoL in patients suffering from more frequency of LUTS.

Division of patients according to the severity of symptoms proved to be an important factor: there were statistically significant differences between moderate and severe groups in all the QoL subscales. According to the regression analyses, these differences were mainly explained by nocturia and incomplete emptying. However, despite not having the higher mean scores, nocturia was the symptom that most influenced variance in the FACT-G (general QoL score) and in most of the QoL subscales, excepting for functional WB. Several authors have shown the relationship between LUTS and QoL-disease specific measures.[1] Similar correlations were found using general measures: the SF-36, [2] the SF 12, [4] and EuroQoL[3]. Our population showed a higher percentage of "symptom explained variance on QoL" compared to that reported by Haltbakk et al. [17] using the WHO–QoL scale, probably due to the fact that they included mildly symptomatic patients and they had an overall mean IPSS lower than ours.

An important finding in this study was that patients with severe LUTS had worse QoL scores than patients presenting organ-confined prostate cancer. [8] This difference is particularly more evident comparing severe LUTS patients and advanced (T3) prostate cancer patients or those from a cancer heterogeneous sample mainly with advance disease (Table V). [11,12] Socio-family WB and functional WB were the domains more affected, and it is noted that patients with moderate LUTS reported a decrease in SWB scores similar to advanced cancer patient's scores. Future research should examine further the difference between LUTS symptoms and cancer prostate patients in order to consider the role of QoL in clinical treatments.

Consistent results across LUTS related scales were obtained, indicating that they assess a quite homogeneous symptom complex or “constructa”, and the IPSS enables to study the degree of bother of each particular symptom. In the case of QoL measures, we also found a high relationship among them, but although they shared an important amount of variance, the FACT-G subscales provided us more specific details evaluating multiple WB areas.

CONCLUSIONS

FACT-G scale is a feasible instrument for the assessment of QoL on outpatient “BPH” patients. With these measures, the impact of LUTS on QoL appears to be higher than previously described with other instruments.

TABLE I. ***No of items, score range, means, standard deviations, and reliability of IPSS, BS, BII and FACT-G scales***

Measure	No of items	Score range		Mean ± SD	α
		Theoretical	Real		
IPSS †	7	0 – 35	12 – 35	20.00 ± 5.40	0.74
Emptying	1	0 – 5	0 – 5	2.64 ± 1.24	
Frequency	1	0 – 5	0 – 5	2.89 ± 1.16	
Intermittency	1	0 – 5	0 – 5	2.60 ± 1.29	
Urgency	1	0 – 5	0 – 5	2.79 ± 1.26	
Weak stream	1	0 – 5	0 – 5	3.48 ± 1.26	
Hesitancy	1	0 – 5	0 – 5	2.77 ± 1.34	
Nocturia	1	0 – 5	0 – 5	2.82 ± 1.03	
BS ‡	1	0 – 6	0 – 6	3.14 ± 1.39	
BII †	4	0 – 13	0 – 12	10.17 ± 3.02	0.88
FACT–G ‡	27	0 – 108	13 – 107	69.61 ± 16.28	0.93
Physical	7	0 – 28	2 – 28	22.19 ± 4.85	0.81
Emotional	7	0 – 28	0 – 24	14.87 ± 4.49	0.77
Social	7	0 – 28	0 – 28	17.80 ± 5.25	0.86
Functional	6	0 – 24	0 – 28	15.23 ± 5.62	0.88

KEY: IPSS = International Prostate Symptom Scale;
BS = Bother score;
BII = Benign Prostatic Hyperplasia Impact Index;
FACT-G = Functional Assessment Cancer Therapy, general version.
α= Cronhbach´s alpha
† Higher score indicates more symptoms.
‡ Higher score indicates better QoL.

TABLE II. ***Spearman's rank correlations across age and all scales***

	Age	IPSS	BS	BII	FACT-G	PWB	EWB	SWB	FWB
Age	1.00	0.21***	0.07**	0.21***	-0.34***	-0.33***	-0.21***	-0.25***	-0.33***
IPSS		1.00	0.56***	0.56***	-0.48***	-0.44***	-0.44***	-0.27***	-0.43***
BS			1.00	0.55***	-0.45***	-0.39***	-0.45***	-0.25***	-0.40***
BII				1.00	-0.62***	-0.59***	-0.61***	-0.36***	-0.53***
FACT-G					1.00	0.83***	0.81***	0.74***	0.88***
PWB						1.00	0.64***	0.45***	0.66***
EWB							1.00	0.43***	0.62***
SWB								1.00	0.58***
FWB									1.00

KEY: PWB = physical well-being; EWB = emotional well-being; SWB = social well-being; FWB = functional well-being. Other abbreviations as in Table I.
****p<0.001; **p<0.01.*

TABLE III. ***Student's t-test between LUTS severity groups***

	LUTS Severity			
	Moderate (n = 742) (IPSS= 15.42 ± 2.26)	**Severe (n = 778) (IPSS = 24.37 ± 3.60)**		
Measure	**Mean ± SD**	**Mean ± SD**	***t***	***P* Value**
BS	2.51 ± 1.28	3.76 ± 1.19	-19.77	<0.001
BII total score	4.45 ± 2.54	7.33 ± 2.76	-21.24	<0.001
FACT-G	76.17 ± 14.80	63.41 ± 15.15	16.64	<0.001
PWB	23.94 ± 3.90	20.51 ± 5.07	14.96	<0.001
EWB	16.51 ± 4.03	13.31 ± 4.35	14.98	<0.001
SWB	18.96 ± 5.18	16.69 ± 5.08	8.67	<0.001
FWB	17.37 ± 5.12	13.18 ± 5.30	15.74	<0.001

Abbreviations as in Table I and II.

TABLE IV. ***Summary of stepwise multiple regression equation predicting FACT-G using the IPSS items***

Dependent measure/predictors	β	R^2 **change**	R^2 **model**
Age	-0.35	0.13***	
Nocturia	-0.32	0.10***	
Emptying	-0.24	0.05***	
Urgency	-0.16	0.02***	0.32
Hesitancy	-0.14	0.02***	
Intermittency	-0.10	0.01***	
Frequency	-0.07	0.01*	

****p<0.001; *p<0.05*

Table V- ***Comparative scores on IPSS and FACT-G scales in "BPH" and prostate cancer patients. Average values and (standard deviation).***

Patient group	Moderate LUTS (pres series)	Severe LUTS (pres series)	Cotrols (Batista 2003)	*T1-T2a prostate ca* (8)	*T3-T4 prostate ca (11)*	*Cancer (80% advanced) (12)*
Number	756	790	21	60	51	309
Mean age	65.4 (7.0)	68.2 (7.4)	64.3 (6.5)	61 (5.9)	n.s.	56.7 (12)
IPSS	15.42 (2.26)	24.37 (3.6)	6.2 (1,1)	10.9 (9,1)	n.s.	n.s
BS	2.51 (1.28)	3.76 (1.19)	2.3 (1,1)	2.2 (1,7)	n.s.	n.s
FACT-G total	76.17 (14.80)	63.41 (15.15)	90.7 (7,6)	84.85 (11,3)	81,8 (13,8)	63.7
Physical WB	23.9 (3.9)	20.5 (5.07)	26.5 (4,6)	25.2 (3,9)	21.5 (5,2)	15.7
Emotional WB	16.51 (4.03)	13.31 (4.35)	20.4(3,5)	15.1(4,4)	14,4 (4,7)	13.5
Social WB	18.96 (5.18)	16.69 (5.08)	25.7(4,5)	22.7 (5,4)	22,1 (4,8)	18.6
Functional WB	17.37 (5.12)	13.18 (5.30)	20.4 (3,9)	20.5(4,7)	16,4 (6,2)	16

N.s. Not specified.

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