Original Article

Comparing Generic and Disease-Specific Instruments in Assessing Health-Related Quality of Life in Chronic Obstructive Pulmonary Disease (COPD)

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Abstract

Introduction-Background: Chronic Obstructive Pulmonary Disease (COPD) is a widespread disease with negative impact on patients' quality of life (QoL)). It is mainly characterized by a progressive decline in lung function with frequent and unpredictable occurrence of symptomatic seizures that are potentially life-threatening. Since the clinical symptoms of COPD and its unpredictable seizures have an important impact on patients' life, it is therefore necessary that therapeutic interventions aim at a significant impact on improving patients' QoL.

Methods: This study explored the association between subjective perception of quality of life (QoL) and the objective laboratory data in patients with Chronic Obstructive Pulmonary Disease (COPD), investigating whether there are corresponding changes after six months with the appropriate therapeutic treatment. One hundred consecutive outpatients with COPD were classified into four groups based on their spirometric performance (FEV₁) at baseline visit. They were asked to complete the general health questionnaire SF-36 and the disease-specific St. George's Respiratory Questionnaire (SGRQ). After six months of specific treatment for each group, the patients returned for a new spirometry and recompleted the two questionnaires.

Results: Results revealed strong correlation between FEV_1 and SGRQ (Pearson *r*<-.9, *p*<.001) during both sessions. Similarly for SF-36 (*p*<.001), strong correlation was found between FEV_1 and the domains of General Health Perceptions and Vitality ($r \ge .7$), moderate correlation with Bodily Pain, Physical and Social Role functioning ($r \le .6$), and weak correlation with Physical and Emotional Role Functioning ($r \le .4$).

Conclusions: QoL in COPD patients, as measured by both SGRQ and SF-36, is consistent with objective findings that characterize its course and therefore healthcare professionals are encouraged to use both tools to gain a better insight into the effectiveness of their patients' treatment.

Keywords: Chronic Obstructive Pulmonary Disease, Quality of life, St. George's Respiratory Questionnaire, Health survey SF-36

Introduction-Background

Chronic Obstructive Pulmonary Disease (COPD) is a widespread disease with negative impact on patients' quality of life (QoL) (Moy et al. 2009; Ståhl et al. 2005). It is the fourth leading cause of death worldwide with an alarming upward trend towards the third position (Buistet et al. 2007; GOLD 2009). It is mainly characterized by a progressive decline in lung function with frequent and unpredictable occurrence of symptomatic seizures that are potentially lifethreatening. COPD includes a number of accompanying symptoms like shortness of breath, cough, confusion, headache, with consequent implications on patients' OoL (GOLD 2009). Since the clinical symptoms of COPD and its unpredictable seizures have an important impact on patients' life (Kaplan et al. 2005; Moy et al. 2009; Pereira et al. 2009; Peruzza et al. 2003), it is therefore necessary that therapeutic interventions aim at a significant impact on improving patients' QoL.

Several disease-specific tools for measuring QoL in patients with COPD have been previously presented in the literature (Jones et al. 1992; Katsura et al. 2003; Paddison et al. 2012; Polley et al. 2008; Van der Molen et al. 2003). The St. Georges Respiratory Questionnaire (SGRQ) is a reliable and valid disease-specific instrument that has been used in the most studies on the OoL in patients with COPD (Jones et al. 1992; Martin et al. 2016; Paap et al, 2015; Weatherall et al. 2009). Some of the previous studies that have compared disease-specific and generic health status questionnaires, suggested that both categories should be used in order to achieve the most holistic approach to the overall burden of COPD on patients' QoL (Engstrom et al. 2001; Malý & Vondra 2006), while others emphasized that disease-specific instruments are less influenced by co-morbidities (Wacker et al. 2016) and have greater ability to discriminate among different levels of severity stages of COPD compared to generic tools (Buss and Silva 2009; Pickard et al. 2011; Wilke et al.2012). However, there is a scarcity of longitudinal studies that evaluate the strength of associations among clinical and health-related QoL measuresboth disease specific and generic- in COPD, regardless of the disease' stage (Wilke et al.2012) and after the appropriate therapeutic intervention, investigating their responsiveness to

change.

The purpose of this study was to investigate whether objective laboratory data on COPD patients are consistent with their subjective perception of QoL and whether the expected changes in spirometric performance at a sixmonth follow up, after the appropriate therapeutic intervention can be reflected in patients' QoL. Furthermore, the study aimed in determining the correlation between the changes in the St. George's Respiratory Questionnaire (SGRQ) and the well-established generic tool, SF-36.

Methods

Participants: The study involved 100 consecutive patients diagnosed with COPD that have visited the outpatient clinic of an Academic Pulmonary Department in North Greece, in Papanikolaou General Hospital. They were examined twice, at their initial visit and after a six-month period. Between the two visits, patients followed physicians' instructions in terms of their medications, exercise and nutrition. Inclusion criteria for this study were: patients' informed consent to participate in the study and the diagnosis of COPD (according to their spirometric performance). Exclusion criteria included having a history of co-morbidities that hinder their daily activities (chronic heart failure. cancer, chronic kidney failure. psychiatric diseases, rheumatic diseases). Twelve patients with COPD were excluded from the study due to co-morbidities.

Evaluation of respiratory function: All subjects underwent testing of their respiratory function through spirometry. Two measures that were recorded were the volume-time curve (simple spirometry) and the flow-volume curve (which has greater sensitivity) (Nelson et al. 1990). The estimated Forced Expiratory Volume in 1 sec (FEV₁) was the main parameter used for the operational control of breathing (Nelson et al. 1990). Patients were divided in four study groups, as shown in Table 1, according to their spirometric performance (GOLD 2009).

Treatment approach according to the COPD stage by GOLD: At the baseline visit, the patients' pharmaceutical treatment was determined, according to the GOLD guidelines (GOLD, 2009). More specifically, it was recommended to Stage I patients (group 1) to stop smoking, use salbutamol on demand and maintain ideal body weight. In addition to these measures, it was recommended to Stage II patients (group 2) a variety of breathing exercises, physical therapy, proper hydration and use of anticholinergic medications. Stage III patients (group 3) were asked to add beta-2 agonists to their bronchodilator therapy. Finally, inhaled corticosteroids were added to the treatment of Stage IV patients (group 4). Instructions were given on diet, exercise and activities of daily living and the opinions of psychiatrists and cardiologists were sought for patients who indicated that they needed it.

Questionnaires: We used two questionnaires to measure quality of life, a disease-specific St. Georges Respiratory Questionnaire (SGRQ) and a well- established generic instrument, SF-36. The patients were requested to complete them both at baseline and follow up visits.

St. Georges Respiratory Questionnaire (**SGRQ**): SGRQ is a reliable and valid questionnaire especially designed for measuring QoL in COPD patients (Jones et al. 1992), while it's Greek version has been checked for its psychometric properties (Katsoulas et al. 2010). It consists of two parts comprising 55 items, distributed in three subscales: symptoms, activities and barriers. The score that a respondent can achieve ranges from 0 to 100. The closer to 0 the result is, the better the QoL is characterized.

Health survey SF-36: Health survey SF-36 is a well- established tool that relates to general health status that has been previously used in COPD patients (Mahler & Mackowiak 1995) and has been validated in the Greek language (Pappa 2005). This questionnaire has been structured based on the assumption that the two main dimensions of health, physical and psychosocial, can be viewed using the eight sections that have been constructed: 1. Physical Functioning, 2. Physical Role Functioning, 3. Bodily Pain, 4. General Health Perceptions, 5. Vitality, 6. Social functioning, Emotional Role 7. Role Functioning, and 8. Mental Health. The score ranges from 0 to 100 and the closer it is to 0, the poorer the QoL is considered.

Statistical Analysis: Continuous variables were summarized with mean and standard deviation (SD). Categorical variables were presented with frequencies and the corresponding percentages. The scores of SGRQ, SF-36 and the values of FEV₁ at baseline and at the six-month follow up were checked for statistical significant differences using the pair samples t-test. Pearson

correlation coefficient (r) was used for the estimation of the degree of possible correlation between FEV₁ and the scores of the QoL questionnaires, as well as between the scores of SGRQ and SF-36, both at baseline and at the sixmonth follow up. All analyses were performed with IBM/SPSS Statistics Version 21.0. P-values were two-tailed with a significance level of .05.

Results

The mean age of the participants was 60.4 (SD \pm 8.92) years old. The demographic characteristics of the patients and their distribution in the four groups per gender are shown in Table 1.

FEV1 Assessment: Although FEV_1 values increased in all patients' groups, as shown in Table 2, statistically significant increase after six months was observed only in groups 2 and 4 (p < .05).

Quality of Life questionnaires:

SGR: In Table 3, the mean values of SGRQ and its subscales at baseline and after six months are presented, as well as the p values of the paired sample t-test. Only in groups 2 and 4 statistical significant improvement in QoL was found in both total SGRQ and in all three subscales (p<.001).

SF-36: The mean values of the eight SF-36 domains at baseline and after six months and the p values of the paired sample t-test are presented in Table 4. Again, only in groups 2 and 4 statistical significant improvement in quality of life was found in all SF-36 subscales (p<.05).

Correlation between FEV₁ and the QoL questionnaires: Strong correlation was found between FEV₁ and SGRQ's total score and subscales. Specifically, the Pearson *r* coefficient for the correlation between FEV₁ and SGRQ's total score was r = -.963, FEV₁ and Symptoms subscale r= -.927, FEV₁ and Activities subscale r= -.944, while FEV₁ and Constraints subscale r= -.941 (p < .001).

Statistical significant correlations was also found between FEV₁ and all SF-36 domains (p<.001). Emotional Role Functioning showed the weaker correlation (Pearson r= .360), while General Health Perceptions the stronger (Pearson r= .730). The correlation coefficients between FEV₁ and both QoL questionnaires are presented in Table 5. **Correlation between SGRQ and SF-36:** Statistical significant correlation was found between the four sections of SGRQ with the eight sections of the questionnaire SF-36 (p < .001). The strongest correlation was observed between the total score of the SGRQ and general health domain of SF-36. The Pearson coefficients are presented in detail in Table 6.

Table 1: Patients' demographic characteristics and distribution in the four groups according to
their spirometric performance at baseline visit (<i>n</i> =100)

Characteristic	N (%)
Gender	
male	62 (62%)
Smoking habit	
Smokers	52 (52%)
Ex-smokers	48 (48%)
Educational level	
University degree	31 (31%)
High school graduates	46 (46%)
Primary school graduates	23 (23%)
Marital Status	
Married/ divorced/ windowed	88 (88%)
Single	12 (12%)
Group/ stage of COPD	N (male /female)
Group 1/ Stage I	22 (12/10)
Group 2/ Stage II	38 (24/14)
Group 3/ Stage III	27 (19/ 8)
Group 4/ Stage IV	13 (7/6)

Table 2: Mean values and standard deviation of FEV_1 % at Visit 1 and Visit 2 and p values of paired sample t-test

(Group FE'	V ₁ % FEV ₁ %	/o p value
	Vis	sit 1 Visit 2 (at six	months)
1	89.4 ± 4.1	91.5 ± 6.5	.229
2	60.9 ± 4.9	64.2 ± 7.0	.021
3	43.8 ± 3.5	45.9 ± 5.8	.342
4	26.2 ± 2.4	29.2 ± 4.8	.038

Table 3: Mean values of the three SGRQ subscales and total SGRQ at Visit 1 and Visit 2 and p
values of paired sample t-test.

Group	Sym	ptoms	Acti	ivities	Cons	traints	To	tal
	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2
1	21.27	20.14	11.86	11.02	28.73	27.59	22.23	21.18
2	38.76	28.95* *	37.24	30.16**	47.39	40.92**	42.75	35.50* *
3	58.93	58.33	62.22	61.59	66.85	65.59	64.03	63.08
4	87.77	76.46* *	84.31	74.77**	87.31	74.08**	86.47	74.71* *

** *p*<.001

Domain	Vi	oup 1 sit 1 sit 2	Gr Visit 1	oup 2 1 Visit 2	V	roup 3 isit 1 isit 2	Vis	oup 4 sit 1 sit 2
Physical	81.8	81.9	75.6	82.09*	65.7	66.33	46.15	63.22
Functioning	2	9	5		4			*
Physical Role	82.2	82.7	71.3	80.11*	59.2	60.41	42.30	56.85
Functioning	7	1	1		5			*
Bodily Pain	84.5	85.8	69.2	77.13*	54.8	56.87	40.76	48.39
	4	0	1		1			*
General Health	85.2	86.0	72.1	81.03*	50.9	52.66	44.23	54.98
Perceptions	2	0	0		2			*
Vitality	82.0	83.2	70.0	78.55	58.0	60.13	43.00	55.00
•	0	1	0	*	0			*
Social Role	88.0	88.4	77.4	86.19	60.8	61.12	47.73	61.32
functioning	7	4	4	*	3			*
Emotional Role	83.3	83.7	76.3	83.99*	56.7	57.09	46.15	58.99
Functioning	3	7	2		9			*
Mental Health	81.2	82.9	69.3	76.47	52.3	54.55	40.77	51.91
	7	7	6	*	7			*

Table 4: Mean values of the eight subscales of SF-36 at Visit 1 and Visit 2 and <i>p</i> values of paired
sample t-test.

Table 5: Correlation of $FEV_1\,\%$ with SGRQ $\,$ and SF-36 subscales in all groups.

Questionnaire	FEV ₁ % Pearson <i>r</i>	<i>p</i> value
SGRQ		
Symptoms	927	<.001
Activities	944	<.001
Constraints	941	<.001
Total	963	<.001
SF-36 domains		
Physical Functioning	.381	<.001
Physical Role Functioning	.503	<.001
Bodily Pain	.599	<.001
General Health Perceptions	.730	<.001
Vitality	.672	<.001
Social Role functioning	.568	<.001
Emotional Role Functioning	.360	<.001

-	~	~	SGRQ Total
Pearson r	Pearson r	Pearson r	Pearson r
421**	428**	381**	415**
515**	542**	554**	556**
603**	625**	606**	627**
739**	737**	716**	746**
674**	672**	705**	705**
612**	.594**	596**	613**
384**	.424**	387**	409
-0.708	-0.673**	-0.709	-0.714
	421** 515** 603** 739** 674** 612** 384**	Symptoms Pearson rActivities Pearson r421**428**515**542**603**625**739**737**674**672**612**.594**384**.424**	Symptoms Pearson rActivities Pearson rConstraints Pearson r421**428**381**515**542**554**603**625**606**739**737**716**674**672**705**612**.594**596**384**.424**387**

 Table 6: Pearson correlation coefficients between SGRQ subscales and total score and SF-36 subscales.

**p<.001

Discussion

This study provides evidence that the measurements of QoL in COPD patients, by both SGRQ and SF-36, are consistent with objective findings that characterize its course, regardless of the COPD stage. Therefore both questionnaires are reliable and appropriate to capture the changes accompany spirometric that performance, although the disease-specific SGRQ was more strongly correlated with the values of FEV1 compared to the generic instrument. As far as the effectiveness of the therapeutic intervention was concerned, only groups 2 and 4 patients have shown statistically significant improvement in both FEV₁ and QoL at six months, raising questions about the need to redefine the treatment strategy in groups 1 and 3.

The disease-specific questionnaire SGRQ was found a reliable tool in capturing accurately the changes in the QoL of patients with respiratory problems, being very strongly associated with FEV_1 (r <-.9). This finding reinforces the psychometric properties of this tool, being in line with previous studies (Buss and Silva 2009; Ferrer et al. 2002; Pickard et al. 2011; Wacker et al. 2016; Weatherall et al. 2009; Wilke et al.2012). Although SF-36 is a generic instrument appropriate to record the subjective image of the general health status that the respondents had, our findings indicate that its domains' scores correlated statistical significantly with the results of both spirometry and SGRQ questionnaire scores, for the totality of the examined patients. The calculated coefficients revealed weak correlation between FEV₁ and the domains of Physical Functioning and Emotional Role Functioning ($r \le .4$), a moderate correlation with Physical Role Functioning, Bodily Pain and Social Role functioning $(r \leq .6)$, and a strong correlation with General Health Perceptions and Vitality $(r \ge .7)$. Our findings provide further evidence that SF-36 is a reliable tool and could be therefore used as a supplementary tool in order to capture a wider range of the implications of COPD on the patients' QoL, reinforcing the findings of studies that were in support of using generic disease-specific both and tools ((Engstrom et al. 2001; Malý & Vondra 2006). As Guyatt et al. (1993) described, the reliability of a good tool for measuring QoL depends on whether or not there are significant correlations between the values of the various measurements.

The main strength of this study is its longitudinal design, since it has explored the correlation between the subjective perceptions of QoL with objective laboratory data of COPD patients in all stages of COPD, checking for the response to change after a six-month therapeutic intervention. One limitation of this study was that the size of all groups of participants was not equal, ranging from 13 to 38 participants each, since the first 100 consecutive patients enrolled. This could have affected the power of the study's sample to detect statistically significant changes. However, in order to achieve an effect size of 0.8, a power of 0.8 and a significance level of 0.05, it was estimated that 12 patients were required per group for the pair sample t-test that was employed. This explains why even in the group with the smaller number of participants, statistically significant changes in FEV₁ and both the two QoL questionnaires were detected after the six months period.

Conclusions: In conclusion, changes in FEV_1 were strongly correlated with the scores with all the sections of the SGRQ questionnaire and moderately to strongly correlated six out of the eight domains of the SF-36 questionnaire. This indicates the simultaneous change in the three parameters examined in this investigation and confirms the achievement of its original objective. Our findings encourage health care professionals to use disease-specific as well as generic instruments to gain a better insight into the effectiveness of the treatment on patients' QoL in all stages of the disease.

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