

Letters to the Editor

Reliability, validity and acceptability of the WHOQOL-Bref in a sample of Italian psychiatric outpatients

Dear Editor:

The evaluation of Quality of life (Qol) is now considered as fundamental in psychiatry as in other branches of medicine (Katschnig, 1997); it has been recommended in routine practice (Orley *et al.*, 1998), and in evaluating mental health services (Barry & Zissi, 1997). Although a large number of instruments are currently available, in recent years considerable efforts have been made under the aegis of the World Health Organization to develop instruments to evaluate Qol in various areas of health care and different cultural settings (Saxena *et al.*, 2001). The need to have access to easy to administer instruments for use in routine practice, clinical trials and large epidemiological surveys has led to the development of WHOQOL-Bref, a 26 item self-report instrument derived from the original 100-item instrument, which had demonstrated clear validity and reliability in a large international field trial (Skevington *et al.*, 2004). The suitability of WHOQOL-Bref for use in different cultural settings has been also proven (Saxena *et al.*, 2001), and the instrument has been translated into many languages and validated in various countries including Italy (De Girolamo *et al.*, 2000). The reliability and validity of WHOQOL-Bref in psychiatric patients have been specifically assessed in a limited number of studies performed on subjects affected by depression (Berlim *et al.*, 2005; Naumann *et al.*, 2004), alcoholism (Da Silva Lima *et al.*, 2005) and chronic psychiatric disorders (Herrman *et al.*, 2002; van de Willige *et al.*, 2005); only one study evaluated reliability and validity of the instrument in a large population of Dutch psychiatric outpatients (Trompenaars *et al.*, 2005). Based on these premises the present study was performed to test reliability, validity and acceptability of the Italian version of WHOQOL-Bref in a sample of psychiatric outpatients.

METHODS

Subjects

The study was performed in two phases. In the first phase a sample of 229 consecutive psychiatric outpatients in the charge of a University Community Mental Health Centre was considered; in the second phase a control group made up of a randomly selected sample of 236 healthy subjects was examined. All subjects gave their informed consent to take part in the study.

Evaluation

Patients were all interviewed and diagnosed according to DSM-IV-TR criteria by a M.D. fellow in psychiatry; subsequently, patients were all re-submitted to clinical evaluation and diagnosis by the senior Authors (BC, MGC). The severity of illness was evaluated by means of Clinical Global Impression (CGI) scale. Patients affected by mental retardation, relevant cognitive deficits and/or severe psychotic states which significantly impaired "reality testing" were excluded. Moreover, subjects (both psychiatric patients and controls) affected by relevant, chronic or acute medical disorders were also excluded from the study.

In order to have a balanced number of "normal" controls (at least a 1:1 ratio), we divided patients according to sex and age groups (<20, 21-25; 26-30; 31-35; 36-40; 41-45; 46-50; 51-55; 56-60; 61-65; 66-70; > 71 yrs). Subsequently a control group was randomly drawn from the anagraphical records of the town, where the university community mental health centre is located. After stratification according to sex and the same age-groups indicated for patients, a total of 24 cells was obtained; a random sample was subsequently extracted (one in fifty) from each cell until a number of control subjects corresponding at least to the

number of patients present in each cell was obtained. Each control as contacted and invited to take part in the study. Those who accepted were asked to complete the Italian version of the *Self Reporting Questionnaire* (SRQ) (Carta *et al.*, 1993), a ten-item screening instrument originally developed for transcultural use by WHO, in order to exclude the presence of any clinically relevant mental disorder at the time of the study. On displaying a score equal to or higher than 8 to SRQ, subjects were interviewed by means of the Italian version of the MINI Interview, version 5.0.0 (Conti *et al.*, 1999). Patients obtaining a positive result for any psychiatric diagnosis after the MINI Interview were excluded. Following clinical evaluation and screening, patients and controls completed the Italian version of QOL-WHO-bref (WHOQOL Italian Collaborating Centre Group, 2001); when occurred, assistance was given to subjects in reading and choosing their answers.

Statistical analyses

Reliability was evaluated by means of test-retest method; for this purpose a subsample of 46 "stable" patients (i.e. no modification of Clinical Global Impression, CGI, severity score) was re-submitted to the questionnaire after 2-3 weeks; internal consistency was evaluated by means of Cronbach alfa; discriminant validity was evaluated comparing patients and controls with regard to mean values obtained at each single item and mean scores at each one of the four domains of WHOQOL-Bref (Physical Health, Psychological Health, Social Relationship, Environment); differences between samples' means and 95% confidence limits were calculated. Acceptability was evaluated by calculating number of subjects assisted in fulfilling WHOQOL-Bref, mean time required to complete the questionnaire, number of missing items. Statistical analyses were performed by means of SPSS statistical Package version 10.1; chi square test or Fisher's Exact Test were used to test for differences in proportions of categorical variables; Student's t test for independent samples and ANOVA-one way was used to evaluate differences between means in case of continuous variables. Significance was set at p value equal to or less than 0.01.

RESULTS

Demographic variables

Demographic characteristics of the groups are reported in table I. No significant differences in sex distribution, mean age and mean years of education were detected

between patients and controls. A significantly higher number of singles was detected among patients. No gender differences were detected either among controls or patients, with the exception of mean age which was significantly higher among females both in patients' (M= 37.6+/- 12.4 ; F= 41.4+/-13.5, t=-2.14, p=.03) and control groups (M=37.9+/-12.6 ; F= 40.8+/-13.5; t= -2.13, p= .034).

Tabella I. – Demographical characteristics of the sample.

	Patients	Controls
Gender °		
Males	100 (43.7%)	103 (43.6%)
Females	129 (56.3%)	133 (56.4%)
Mean age (yrs+/-s.d.)°	39.7+/-13.1	39.4+/-13.3
Education (mean yrs+/-s.d)°	11.0+/-4.5	12.2+/-3.8
Marital status*		
Married	92 (40.4%)	136 (57.6%)
Single	136 (59.6%)	100 (42.4%)

° no significant differences between groups

* chi square test = 13.16, df = 1, p<.001

Clinical characteristics

103 (45%) patients selected for the study were affected by one of the DSM-IV-TR Mood Disorders (Major Depression, Dysthymia, Depression NOS ,Bipolar Disorder), 70 (30.6%) by an Anxiety Disorder (General Anxiety Disorder, Panic Disorder, Any Phobic Disorder, Obsessive-Compulsive Disorder, Acute and Post-traumatic Stress Disorder, Anxiety Disorder NOS); 44 (19.2%) by Schizophrenia or other psychotic disorder (Schizophreniform, Schizoaffective, Delusional, Brief Psychotic Disorder), 12 (5.2%) by other disorders (Eating disorders, Adjustment disorders) .

Acceptability of WHOQOL-bref

WHOQOL-Bref was totally self-fulfilled by the majority of subjects; only 12 controls (5.1%) and 23 patients (10.0%) required assistance in completing the questionnaire; this difference was not statistically significant. No difference in mean time of administration was detected among the two groups (Patients: 11.4+/-4.4 min; Controls: 9.9+/- 3.7 min), whilst mean number of missing items was significantly higher among patients (Patients: 2.82+/- 0.98; controls: 0, t=-15.18, df=54, p<.001).

Influence of demographical variables on WHOQOL-Bref scores

No significant difference as to gender and marital status emerged from mean scores obtained at each WHO-

QOL-Bref domain either in patients or controls. Age resulted as being significantly and inversely correlated to WHOQOL-bref score only in reference to Physical health both in patients ($r = -0.218, p < .01$) and in controls ($r = -.303, p < .01$). Finally, no significant correlation was detected between education, expressed as number of years, and WHOQOL scores at each domain, both among patients and controls.

Reliability and Validity Measures of WHOQOL-Bref

At the test-retest evaluation, intraclass coefficients and 95% confidence intervals per each of the four domains were respectively: “Physical”: 0.92 (0.85-0.96);

“Psychological”: 0.94 (0.88-0.97); “Social Relationships”: 0.89 (0.80-0.93); “Environment”: 0.80 (0.75-0.85); all correlations were statistically significant ($p < 0.05$). Cronbach alfa for each dimension was: 0.82 (“Physical”), 0.81 (“Psychological”), 0.76 (“Environment”), 0.71 (“social relationships”).

As far as discriminant validity was concerned, the mean values (+/- s.d) for each of the four main dimensions of WHOQOL-Bref were significantly higher in controls respect to patients (table II); for mean scores rated at each single item of WHOQOL-Bref (table III) those obtained by controls were significantly higher than patients in all items, with the exception of items n.14 (leisure activities) and n.25 (public transports).

Tabella II. – WHOQOL-Bref domains: Mean scores (+/-s.d.) in patients and controls, differences between means and 95% Confidence Intervals.

WHOQOL Domain	Patients	Controls	t	p	Difference Between means (se)	IC (95%)
Physical Health	15.5 (2.0)	26.3 (12.7)	-11.541	<0.001	10.8 (0.84)	9.13-12.97
Psychological Health Relationships	13.2 (1.3)	24.0 (12.2)	-6.395	<0.001	10.8 (0.81)	9.20-12.39
	14.7 (2.3)	36 (12.1)	-8.754	<0.001	21.30 (0.81)	19.70-22.89
Environment	12.8 (2.1)	29 (11.9)	-3.317	<0.001	16.20 (0.79)	14.63-17.769

Tabella III. – WHOQOL-Bref: Items' Mean scores (+/-s.d) in patients and controls, differences between means and 95% Confidence Intervals.

WHOQOL Items	Patients	Controls	t	P	Difference Between means (s.e.)	I.C. (95%)
Qol 1	3.21 (.90)	3.79 (.57)	-8.29	<.001	0.58 (0.07)	0.443/0.717
Qol 2	2.85 (1.0)	3.80 (.72)	-11.7	<.001	0.95 (0.08)	0.791/1.109
Qol 3	1.72 (.79)	2.23 (1.1)	-5.72	<.001	0.51 (0.09)	0.334/0.686
Qol 4	1.32 (.60)	2.62 (1.2)	14.90	<.001	1.30 (0.09)	1.125/1.475
Qol 5	2.32 (.90)	2.93 (.73)	-7.98	<.001	0.610 (0.07)	0.461/0.759
Qol 6	3.10 (1.22)	3.81 (.89)	-7.16	<.001	0.710 (0.09)	0.515/0.905
Qol 7	2.65 (.90)	3.46 (.74)	-10.52	<.001	0.810 (0.07)	0.660/0.960
Qol 8	2.54 (.86)	3.20 (.76)	-8.73	<.001	0.660 (0.07)	0.512/0.808
Qol 9	2.88 (1.12)	3.27 (1.02)	-3.90	<.001	0.390 (0.10)	0.194/0.586
Qol 10	2.71 (1.02)	3.66 (.93)	-10.44	<.001	0.950 (0.09)	0.772/1.128
Qol 11	2.61 (1.04)	3.39 (.77)	-9.21	<.001	0.780 (0.08)	0.613/0.947
Qol 12	2.45 (1.19)	2.93 (1.03)	-4.63	<.001	0.480 (0.10)	0.277/0.683
Qol 13	2.92 (.98)	3.22 (.83)	-3.54	<.001	0.30 (0.08)	0.134/0.466
Qol 14	2.58 (1.14)	2.64 (.94)	-0.61	n.s.	0.06 (0.009)	-0.131/0.251

Tabella III. – segue

WHOQOL Items	Patients	Controls	t	P	Difference Between means (s.e.)	I.C. (95%)
Qol 15	2.94 (1.06)	3.42 (.90)	-5.23	<.001	0.480 (0.09)	0.301/0.659
Qol 16	3.07 (1.10)	3.73 (.88)	-7.13	<.001	0.660 (0.09)	0.478/0.842
Qol 17	2.95 (1.11)	3.71 (.75)	-8.62	<.001	0.760 (0.08)	0.588/0.932
Qol 18	2.96 (1.12)	3.74 (.76)	-8.72	<.001	0.780 (0.09)	0.606/0.954
Qol 19	2.89 (1.15)	3.87 (.79)	-10.69	<.001	0.98 (0.09)	0.800/1.160
Qol 20	3.14 (1.06)	3.77 (.73)	-7.42	<.001	0.630 (0.08)	0.464/0.796
Qol 21	2.67 (1.15)	3.78 (.88)	-11.63	<.001	1.11 (0.09)	0.923/1.297
Qol 22	3.05 (1.17)	3.50 (.77)	-4.87	<.001	0.450 (0.09)	0.270/0.630
Qol 23	3.37 (1.18)	3.93 (.83)	-5.93	<.001	0.560 (0.09)	0.374/0.746
Qol 24	2.85 (1.03)	3.30 (1.03)	-4.85	<.001	0.450 (0.09)	0.262/0.638
Qol 25	3.32 (1.06)	3.36 (1.04)	-0.47	n.s.	0.040 (0.01)	-0.152/0.232
Qol 26	3.14 (1.01)	2.25 (.65)	-11.30	<.001	0.890 (0.07)	0.734/1.046

DISCUSSION

The findings of this study should be considered whilst bearing in mind several methodological limitations, such as the fact that psychiatric diagnosis of patients was not assessed by means of standardized techniques of interview, the degree of diagnostic concordance between different evaluators was not calculated, and the heterogeneity of patients taken into account. This notwithstanding, the results seem to be worthy of interest. The samples considered in the present study were well matched according to sex and age, and may be considered homogeneous as far as demographical parameters are concerned. The time required to complete the questionnaire was relatively short both in patients and controls and no significant differences were detected. Although a significantly higher mean number of missing responses was found at each single item of WHOQOL-Bref among patients, in absolute terms this value was actually quite low (approx 2.8). Furthermore, only 10% of patients and 5% of normal controls required assistance in completing the questionnaire; this difference was not statistically significant. The results obtained, which probably reflect the fairly high level of education of both patients and controls, seem to indicate an adequate level of acceptability and comprehensibility of the WHOQOL-Bref. Demographic variables were seen to exert little influence over sub-

jective Qol evaluation; indeed, no significant differences in mean scores at each dimension of WHOQOL were found according to gender, marital status and education. These findings are consistent with those of Ruggeri *et al.* (1999), who generally found little or no influence of these variables on overall and dimensional quality of life scores in a large cohort of patients in the charge of a community mental health service in Northern Italy. In our study age exerted a limited influence, being inversely related to Qol measures only with regard to "Physical health" domain (i.e. a worse subjective Qol, as indicated by lower scores at WHOQOL, was related to higher age) both among patients and controls; this may reflect a higher probability of worsening of physical health with increasing age.

Data from test-retest show both a fairly good stability over time and internal consistency, taking into account that values higher than 0.70 are generally considered satisfactory (Bech *et al.*, 1993). As expected, mean scores at each of the four main dimensions of the questionnaire were invariably significantly higher among controls, indicating a better subjective quality of life respect to patients. Moreover, mean scores obtained at each of the 26 items of WHOQOL-Bref were all significantly higher among controls respect to patients (with the exception of item 14 assessing satisfaction with leisure and spare time activities and item 25 on satisfaction with public trans-

port). These results indicated the efficacy of the instrument in discriminating between healthy subjects and those affected by mental disorders. Overall these results tend to confirm the reliability and validity of the Italian version of WHOQOL-Bref, previously demonstrated in a large sample of subjects including only a very limited number of psychiatric outpatients (De Girolamo et al., 2000), and are substantially consistent with results reported in a recent, similar Dutch study, specifically concerning validity and reliability of WHOQOL-Bref in a large population of psychiatric outpatients (Trompenaars et al., 2005).

CONCLUSION

The findings obtained in this study demonstrate how the Italian version of WHOQOL-Bref is a valid and reliable instrument for evaluation of quality of life in psychiatric outpatients. The instrument is particularly indicated for use in patients who are clinically stable and devoid of any significant cognitive and reality testing impairment.

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