A New International Questionnaire To Assess Health-Related Quality Of Life (HRQL) Specific To Viral Hepatitis C: PROQOL-HCV

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Objectives

This study aims at validating a new international questionnaire to assess Health-Related Quality of Life (HRQL) in patients living with HCV. The international PROQOL-HCV questionnaire has been developed to overcome current limitations of existing measurement instruments specific of HCV disease, especially the assessment of treatment impact. It is composed of 38 items describing 7 facets, and it demonstrates good validity and reliability properties.

Methods

In this cross-sectional study 660 HCV mono-infected and HCV/HIV co-infected patients, in three countries (France [59%], Brazil [30%], and Australia [11%]), completed paper or internet-based versions of: two existing HRQL questionnaires, and the PROQOL-HCV pilot. Information concerning symptoms, sociodemographic and clinical status were also collected. Psychometric item analysis and factor analysis (CFA) reduced the pilot 72-item PROQOL-HCV questionnaire. Next, reliability (Cronbach´s alpha), convergent validity (EQ-5D, SF-12, symptoms), and clinical validity (biological markers) were assessed using correlation and two-group comparison at a fixed 5% level. Statistical analysis were carried out using the R and Mplus software.

Results

The sample comprised 57% men and 43% women, aged on average 52 years, 80% vocational level and higher, 35% lived alone, 35% were co-infected with HIV (95% treated); 85% receiving anti-viral treatment: 25% interferon, 35% ribavirin, 43% Direct-Acting Antivirals (35% interferon-free); 27% depressive (71% treated). [Table 1]

Table 1: Characteristics of study participants.

	N	AUS N=70	BRA N=200	FRA N=103	FRH $N = 287$	Combined N=660	Test Statistic
Sexe : Men	609	67% (47)	48% (94)	33% (18)	65% (187)	57% (346)	$\chi^2_6 = 39,\ P < 0.001^1$
Women		31% (22)	52% (102)	64% (35)	35% (100)	43% (259)	
Age (years)	588	37 48 55	42 51 58	48 55 58	50 54 62	46 53 59	$F_{3,584} = 13,\ P < 0.001^2$
Weight (kg)	593	68 74 84	61 70 80	58 62 73	60 69 79	60 70 80	$F_{3,589} = 7,\ P < 0.001^2$
BMI (kg/m^2)	587	22 25 28	22 25 29	20 22 25	21 23 26	21 24 27	$F_{3,583} = 11,\ P < 0.001^2$
Familial status : Married	609	44% (31)	51% (101)	33% (18)	41% (118)	44% (268)	$\chi^2_9 = 14,\ P = 0.1^1$
Widowed		4% (3)	7% (14)	4% (2)	7% (19)	6% (38)	
Divorced		19% (13)	10% (19)	24% (13)	16% (47)	15% (92)	
Single		33% (23)	32% (63)	40% (22)	36% (103)	35% (211)	
Education level : No school	605	1% (1)	0% (0)	2% (1)	1% (3)	1% (5)	$\chi^2_9 = 74,\ P < 0.001^1$
Primary school		14% (10)	35% (69)	0% (0)	13% (37)	19% (116)	
Secondary school		70% (49)	38% (74)	53% (29)	61% (174)	54% (326)	
University		14% (10)	27% (54)	45% (25)	24% (69)	26% (158)	
Professional activity : Full-time	601	24% (17)	51% (100)	38% (21)	29% (82)	37% (220)	$\chi^2_{15} = 76,\ P < 0.001^1$
Part-time		16% (11)	7% (14)	9% (5)	9% (24)	9% (54)	
Looking for a job		30% (21)	11% (21)	15% (8)	9% (25)	12% (75)	
Student		1% (1)	0% (0)	0% (0)	0% (1)	0% (2)	
Retired		6% (4)	20% (40)	9% (5)	27% (74)	20% (123)	
Invalidity		23% (16)	11% (22)	29% (16)	26% (73)	21% (127)	

$a\ b\ c$ represent the lower quartile a, the median b, and the upper quartile c for continuous variables.
N is the number of non–missing values. Numbers after percents are frequencies. Tests used: [1]Pearson test; [2]Kruskal-Wallis test

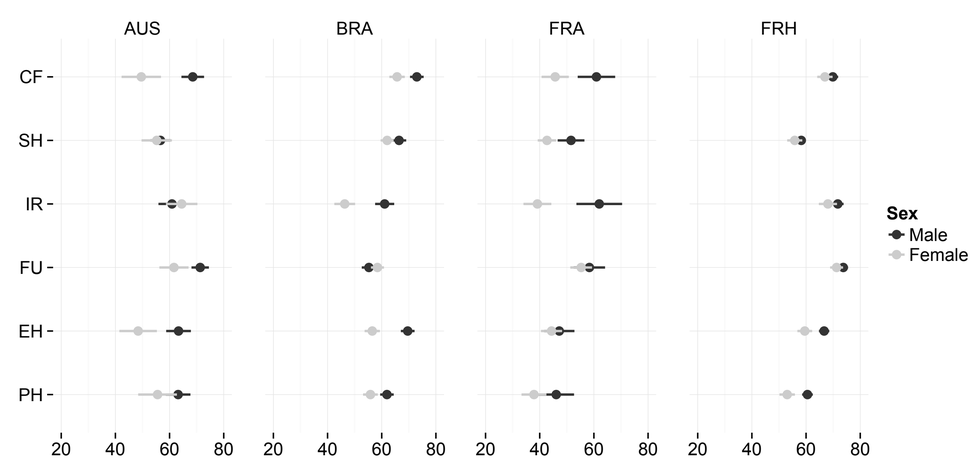
Table 2: Psychometric properties of the PROQOL-HCV questionnaire.

Dimension	Cronbach alpha	Average item correlation	Scaling success (%)	SF12 PHS	SF12 MHS	EQ-5D VAS
Physical Health (PH, 6 items)	0.900	0.609	100 (100)	0.608 (0.618)	0.542 (0.549)	0.487 (0.486)
Emotional Health (EH, 9 items)	0.929	0.599	100 (98.1)	0.326 (0.350)	0.542 (0.669)	0.411 (0.412)
Future Uncertainty (FU, 6 items)	0.793	0.390	86.1 (86.1)	0.209 (0.227)	0.431 (0.443)	0.399 (0.407)
Intimate Relationships (IR, 3 items)	0.856	0.662	100 (100)	0.207 (0.215)	0.390 (0.416)	0.206 (0.214)
Social Health (SH, 3 items)	0.470	0.235	33.3 (22.2)	0.358 (0.373)	0.494 (0.517)	0.436 (0.431)
Cognitive Functioning (CF, 3 items)	0.802	0.574	88.9 (77.8)	0.386 (0.391)	0.565 (0.578)	0.450 (0.447)
Treatment Impact (TI, 8 items)	0.605	0.171	97.9 (93.8)			

The PROQOL-HCV questionnaire was reduced to 38 items spanning 7 dimensions scored on a 100-point scale: Physical Health (PH, 6 items, Cronbach's α=0.90), Emotional Health (EH, 9 items, α=0.93), Future Uncertainty (FU, 6 items, α=0.79), Intimate Relationships (IR, 3 items, α=0.86), Social Health (SH, 3 items, α=0.47), Cognitive Functioning (CF, 3 items, α=0.80), and Treatment Impact (TI, 8 items, α=0.61). [Table 2] Results from CFAs suggested adequate fit to the data (RMSEA = 0.090, 90% CI [0.086;0.094]; CFI = 0.936; WRMR = 1.866).

Pearson correlations of PROQOL-HCV dimensions with the EQ5-D (general health), SF-12 mental and physical summary scores were in the acceptable range. [Table 2] PH dimension was negatively correlated with frequency of bothersome symptoms (p < 0.001).

Figure 1: Distribution of scale scores (mean ± 1 SE) across countries.



CF: Cognitive Functioning, SH: Social Health, IR: Intimate relationships, FU: Future Uncertainty, EH: Emotional Health, PH: Physical Health

Lower HRQL (PH, EH, CF) was reported by women (p < 0.01) [Figure 1], depressive patients (p < 0.001), patients on interferon (p < 0.01, except CF), and untreated patients (p < 0.01).

Conclusion

The PROQOL-HCV questionnaire demonstrates validity and encompasses new dimensions of Intimate Relationships, Social Health and Treatment Impact.