Qual Life Res (2014) 23:1273–1277
DOI 10.1007/s11136-013-0556-9

BRIEF COMMUNICATION

Validating the Migraine-Specific Quality of Life Questionnaire v2.1 (MSQ) in Italian inpatients with chronic migraine with a history of medication overuse

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Accepted: 4 October 2013 / Published online: 16 October 2013
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Abstract
Purpose The purpose of the study is to assess validity, reliability and factor structure of the Italian version of Migraine-Specific Quality of Life Questionnaire v2.1 (MSQ) in patients suffering from chronic migraine (CM) with a history of medication overuse (MO).
Methods Patients were enroled at hospital admission for withdrawal from MO. Factor analysis was used to confirm the latent structure of the MSQ. Reliability was measured with Cronbach's alpha coefficient, item-total correlation and inter-item correlation. Construct validity was assessed with Pearson's coefficient and known-group analysis.
Results The three-factor structure is basically confirmed. Cronbach's alpha varied between 0.85 and 0.92; item-total correlations were on average higher than 0.70; average inter-item correlation ranged between 0.63 and 0.65. Correlations were all significant; known-group analysis shows that MSQ score was lower consistently with disease severity.
Conclusions Our findings confirm the factor structure, reliability and validity of the MSQ and expand results of previous validation studies to the Italian language and to a group of patients with severe CM requiring withdrawal treatment for MO.

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Keywords MSQ · Chronic migraine · Health-related quality of life · Psychometric properties · Validity

Introduction

Migraine is a common disease: its lifetime prevalence in European countries is 18.5 % [1], and its impact on individuals and societies in terms of disease cost and burden is relevant [2]. Chronic migraine (CM) is an unfavourable outcome of the migraine course, which seems to be mediated by lifestyle, comorbid conditions, genetic terrain and medication overuse (MO) [3, 4]: approximately 2 % of general population suffers from CM [5, 6], and 2.5 % of migraineurs progress to CM each year [7]. Compared with episodic migraineurs, CM patients show increased disability and reduced mood [8], in particular if they have a history of MO [9], reduced productivity and more missed days of work, housework, or leisure activities [10], and therefore, the cost of CM is threefold than that of episodic migraine (3561 vs. 1222€/year) [2].

However, the impact of CM cannot be assessed only by evaluating the features of migraine (e.g. the presence of aura or frequency of attacks), pain severity or the impact of the disease on work-related activities. Therefore, patient-reported outcome measures (PROMs) are used to evaluate the consequence of CM on patients' daily lives. PROMs enable to assess the benefits of treatments and provide evidence on changes in health status, health-related quality of life (HRQoL) or disability [11, 12]. In headache disorder research, the use of disease-specific PROMs is recommended by international guidelines to quantify the potential benefits of treatments [13, 14].

The Migraine-Specific Quality of Life Questionnaire v2.1 (MSQ) is one of the most used headache-specific PROM to assess HRQoL [15–17]. It is composed of 14 items that constitute three scales—Role Restriction (RR), Role Prevention (RP) and Emotional Function (EF)—that assess the impact of migraine on patients' HRQoL. Each scale has a 0-100 score: low scores indicate poor HRQoL. It has been mostly used in patients with episodic migraine, and two recent papers showed its validity in CM patients [18, 19]; however, there is no validation study in the Italian population. Aim of this study is to evaluate MSQ factor structure, reliability and validity in a sample of Italian CM inpatients admitted for withdrawal from MO.

Methods

Patients suffering from CM with a history of MO according to Silberstein's criteria [20] were consecutively enroled at admission for inpatient withdrawal treatment, in the period between June 2011 and December 2012. They completed the MSQ [15] to evaluate HRQoL, the WHO Disability Assessment Schedule-2 (WHO-DAS-2) [21] to evaluate disability and the Beck Depression Inventory-2 (BDI-2) [22] to evaluate mood state. The Migraine Disability Assessment (MIDAS) [23] was used as a proxy of disease activity. All patients filled in the whole protocol: the questionnaires were provided by psychologists on the second or third day of hospitalisation. Two are the reasons for this: first, to enable physicians to evaluate patients' eligibility; second, to make it more likely that patients were headache-free during administration of the protocol. In any case, they were allowed to postpone the completion of questionnaires if they had a headache. Each patient signed an informed consent form prior to data collection.

Data analysis

A confirmatory factor analysis was used to test the three-factor structure of MSQ. Promax rotation was applied, and factor loadings were calculated. We preferred an oblique rotation method as it is expected that the three MSQ factors are correlated each other with correlation values >.30.

Internal consistency was assessed using Cronbach's alpha coefficient, item-total correlation after correcting for overlap (i.e. after removing the item from the total score) and the average inter-item correlation. Scale was considered to have good reliability if Cronbach's alpha >.70 and if item-total correlation and inter-item correlation >.40.

Construct validity was assessed with Pearson's correlation coefficient: correlation was evaluated between each MSQ scale and MIDAS and WHO-DAS-2 and BDI-2 total scores. It was hypothesised that BDI-2 scores were more strongly correlated with MSQ-EF than with RR and RP and that MIDAS and WHO-DAS-2 scores were more strongly correlated with MSQ-RR and RP than with EF. All correlations were expected to be significant, but not strong (i.e. below .70) as the four measures are deemed to measure different constructs.

Known-group analysis was carried out by dividing patients according to the quartiles of MIDAS scores. We relied on this measure as the usual MIDAS grades (i.e. 0–5, 6–10, 11–20 and 21+) are not adequate to represent disease activity in samples of CM patients that, in the previous 3 months, should have had at least 45 headache days. ANOVA with Bonferroni post hoc test was used to assess group differences.

Data were analysed with SPSS, and all statistics were considered significant at $P < .05$ level.

Table 1 Sample description

Sociodemographic features	
Age, mean (SD)	43.8 (11.9)
Gender, *N* (%)	
Male	33 (18.1)
Female	149 (81.9)
Years of education, mean (SD)	12.9 (3.9)
Education level, *N* (%)	
Primary	8 (4.4)
Secondary	55 (30.2)
High	82 (45.1)
Academic	37 (20.3)
Marital status	
Never married	32 (17.6 %)
Married/cohabitating	134 (73.6 %)
Separated/divorced/widowed	16 (8.8 %)
Employment status	
Employed/student	135 (74.2 %)
Not employed	47 (25.8 %)
PROMs	
MIDAS score, mean (SD)	90.6 (70.2)
MIDAS quartiles (min–max)	
First quartile	(0–38)
Second quartile	(39–71)
Third quartile	(72–128)
Fourth quartile	(129–370)
WHO-DAS-2 score, mean (SD)	31.3 (13.7)
BDI-2 score, mean (SD)	17.2 (10.2)
MSQ	
Role restriction	33.2 (18.0)
Role prevention	48.2 (22.6)
Emotional function	42.5 (25.3)

Results

A total of 182 patients were enroled. Table 1 reports main demographic- and PROM-derived information: most patients were female, with a high or academic education level, employed and in a relationship; average length of stay was 6.4 days. MIDAS was considerably high, as 90.1 % of the sample reported a score >21.

The factor structure of MSQ is reported in Table 2: factor loadings showed that the three-factor structure is basically confirmed, with loadings to each factor being higher than 0.70. Item 4 (How frequently did migraines keep you from getting as much done at work or at home?) was the only one that loaded almost equally into factors 1 and 2.

Reliability analysis is shown in Table 2. Cronbach's alpha values varied between 0.85 (EF) and 0.92 (RR). The magnitude of change in Cronbach's alpha, in case of item removal, showed that each item provides relevant contribution to internal consistency. The only exception was with EF scale, where removal of item 12 (How frequently have you felt fed up or frustrated because of your migraines?) resulted in a small increase in alpha value. Item-total correlations were on average higher than 0.70: the only exception to this was with item 12, where correlation was 0.56. Finally, average inter-item correlation ranged between 0.63 (RR) and 0.65 (RP).

Construct validity and known-group analysis are reported in Table 3. Spearman's correlation coefficients were all significant at $P < .001$ level, and as hypothesised, MSQ-

Table 2 Item distribution characteristics, factor structure and internal consistency data of MSQ in Italian Chronic Migraine patients

	Mean (SD)	Factor loadings			Alpha if item deleted	Item-total correlation
		F1	F2	F3		
MSQ-Role Restriction (Cronbach's α .92; Inter-Item Correlation .63)						
1) How frequently have migraines interfered with how well you dealt with family, friends and others who are close to you?	4.36 (1.30)	.711	.666	.577	.91	.70
2) How frequently have migraines interfered with your leisure time activities, such as reading or exercising?	4.59 (1.06)	.824	.585	.487	.91	.76
3) How frequently have you had difficulty in performing work or daily activities because of migraine symptoms?	4.27 (1.07)	.808	.679	.393	.91	.78
4) How frequently did migraines keep you from getting as much done at work or at home?	4.02 (1.19)	.767	.771	.421	.91	.76
5) How frequently did migraines limit your ability to concentrate on work or daily activities?	4.28 (1.07)	.851	.642	.394	.90	.81
6) How frequently have migraines left you too tired to do work or daily activities?	4.30 (1.10)	.844	.548	.390	.91	.75
7) How frequently have migraines limited the number of days you have felt energetic?	4.55 (1.03)	.860	.457	.465	.91	.73
MSQ-Role Prevention (Cronbach's α .88; Inter-Item Correlation .65)						
8) How frequently have you had to cancel work or daily activities because you had a migraine?	3.58 (1.30)	.605	.853	.421	.84	.74
9) How frequently did you need help in handling routine tasks such as every day household chores, doing necessary business, shopping, or caring for others, when you had a migraine?	3.29 (1.41)	.490	.851	.453	.85	.73
10) How frequently did you have to stop work or daily activities to deal with migraine symptoms?	3.70 (1.22)	.563	.854	.391	.83	.77
11) How frequently were you not able to go to social activities such as parties, dinner with friends, because you had a migraine?	3.79 (1.34)	.655	.797	.515	.85	.71
MSQ-Emotional Function (Cronbach's α .85; Inter-Item Correlation .64)						
12) How frequently have you felt fed up or frustrated because of your migraines?	4.45 (1.24)	.529	.267	.774	.91	.56
13) How frequently have you felt like you were a burden on others because of your migraines?	3.60 (1.54)	.422	.553	.916	.68	.81
14) How frequently have you been afraid of letting others down because of your migraines?	3.59 (1.54)	.445	.522	.911	.69	.80

Reported factor loadings were rotated with Promax rotation and Kaiser normalisation

Table 3 Construct validity and known-group analysis

	RR	RP	EF
Pearson's correlation			
MIDAS	−.558	−.548	−.283
WHO-DAS-2	−.499	−.536	−.459
BDI-Total	−.335	−.276	−.470
One-way ANOVA			
MIDAS Q1	44.9 (39.1–50.7)	61.0 (53.5–68.5)	50.1 (42.1–58.0)
MIDAS Q2	37.5 (33.3–41.7)	55.6 (50.5–60.7)	47.4 (40.7–54.2)
MIDAS Q3	30.2 (26.1–34.3)	43.9 (38.0–49.8)	38.8 (31.6–45.9)
MIDAS Q4	19.9 (15.5–24.3)	31.9 (28.0–36.7)	33.4 (25.9–40.9)
F (P value)	21.0 ($P < .001$)	19.5 ($P < .001$)	4.5 ($P = .005$)
Bonferroni post hoc test	a, d, e	a, b, c, d, e	b, d

All correlations are significant at $P < .001$. For One-way ANOVA, mean (95 % CI) is reported. Bonferroni post hoc test: a) difference is significant between Q1 and Q3; b) difference is significant between Q1 and Q4; c) difference is significant between Q2 and Q3; d) difference is significant between Q2 and Q4; e) difference is significant between Q3 and Q4

Q1, first quartile; Q2, second quartile; Q3, third quartile; Q4, fourth quartile; RR, role restriction; RP, role prevention; EF, emotional function

RR and RP were more strongly correlated than EF with MIDAS and WHO-DAS-2, while BDI-2 correlated better with MSQ-EF than with RR and RP. These results were further on confirmed by known-group analysis: MSQ score tended to decrease in subjects with higher disease activity as measured by the MIDAS.

Discussion

The findings of this study confirmed the conceptual model of the MSQ in Italian CM patients admitted for withdrawal from MO. The reliability of MSQ scales was excellent, and item-level reliability statistics indicated good performance, with only one item reporting lower, though adequate, item-total correlation.

There are two previous papers addressing the validity and reliability of MSQ in CM. The first [18] was based on a wide sample of subjects participating to the International Burden of Migraine Study (IBMS): patients were identified as having episodic or chronic migraine using a set of screening questions based on the International Classification of Headache Disorders, second version, that explicitly excludes the presence of MO [24]. The second study was a clinical trial of onabotulinumtoxinA as headache prophylaxis, in which only 60 % of patients had a history of MO [19]. Therefore, those samples are different from our sample, which was composed only of patients with CM and a history of MO admitted for withdrawal treatment, who are reasonably deemed to suffer from a more severe form of headache: in fact, our patients reported RR scores that were 10.1–11.4 lower, RP scores that were 12.4–14.0 lower and EF scores that were 5.8–17.2 lower than those reported in the two previous studies [18, 19].

There are, however, some elements of convergence. The pattern of association between MSQ and MIDAS was similar to that observed in the IBMS study [18], i.e. lower correlations with MSQ-EF than with RR and RP. Similar to Rendas-Baum's findings [19], we found relatively weak psychometric properties in item 12: deleting it would make the internal consistency of MSQ-EF scale a little higher, but would reduce the comparability of data from Italian CM patients with those from patients enroled in different countries or settings.

A previous experience of use of MSQ in Italy was described by Cevoli et al. [25], who based their analysis on a sample of 953 migraineurs patients attending a headache centre for the first time. In that sample, only 2.5 % of patients had CM with a history of MO, and the overall mean scores were 50.8 (RR), 65.4 (RP) and 62.9 (EF), indicating a better HRQoL than that of our sample. The trend is, however, similar: the lowest scores were observed for RR, the highest for RP and EF scores were in between.

Some limitations need to be considered. Our sample is relatively small compared with those by Bagley [18] and Rendas-Baum [19]; however, it is surely closer to what is found in daily clinical practice with CM patients, who often present a history of MO and require withdrawal. Second, the cross-sectional design did not allow to assess test–retest validity.

In conclusion, our findings confirm those reported in previous validation studies on CM patients, and expand them to the Italian language and to a group of patients with a more severe form of CM.

Acknowledgments This study was and independent examination on disability and quality of life associated with chronic migraine (DIS.CHRONIC), sponsored by the Neurological Institute C. Besta IRCCS Foundation.

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