

Domenico D'Amico
Alessandra Ferraris
Licia Grazzi
Susanna Usai
Massimo Leone
Gennaro Bussone

An Italian pilot study on the use of the migraine disability assessment questionnaire

Received: 21 January 2000
Accepted in revised form: 15 February 2000

D. D'Amico • A. Ferraris • L. Grazzi
S. Usai • M. Leone • G. Bussone (✉)
Regional Centre for the Diagnosis
and Treatment of Headaches
and Craniofacial Pain,
Neurological Institute C. Besta,
Via Celoria 11, I-20133 Milan, Italy
Tel.: +39-02-2394264
Fax: +39-02-70638067

Abstract The migraine disability assessment questionnaire (MIDAS) is a recently developed, validated questionnaire for assessing the impact of migraine on individual patients. We carried out a pilot study to assess the stability and reliability of a preliminary Italian version of MIDAS, based on the original 6-item version. One hundred four patients with migraine without aura completed the MIDAS form during a session with a neurologist and again 21 days later. Eighty-six patients (83%) returned the second form. Pearson's ($r = 0.8$) and Spearman's

($r = 0.7$) tests showed a good test-retest reliability for the scores obtained at first and second compilations. In the majority of patients, the disability grade was stable after 21 days (Wilcoxon signed rank test $p > 0.05$). Our preliminary adaptation of the MIDAS questionnaire is satisfactorily stable and highly reliable, preparing the way for a definitive Italian version.

Key words Migraine • Disability • Migraine disability assessment questionnaire • MIDAS • Italian version • Reliability

Introduction

Migraine is a primary headache form characterised by recurring intense headaches associated with autonomic symptoms (nausea, vomiting, photophobia and phonophobia) [1]. The condition is heterogeneous in that the frequency and severity of the attacks may vary [2]; however, for many patients the severity is such that normal activity must be curtailed or becomes impossible. Several studies have shown that migraine has a negative influence on daily living activities, affecting work and scholastic performance and participation in social and leisure activities [3–6].

The impact of migraine on an individual patient can be measured in terms of disability, defined as the consequences of illness on the ability to work and function in other roles [7]. The group of Lipton and Stewart recently developed the migraine disability assessment question-

naire (MIDAS), based on experience with previous instruments [8–10]. The main characteristic of MIDAS is that it is simple to compile by patients who only have to reply to a few questions about their headaches during the previous 3-month period.

The grade of disability is assigned on a one-to-four scale based on the sum of the scores to few questions (six in the earlier version and five in the latest) which cover three domains of activity, i.e. school or paid work, household work, family-leisure activities. Population-based studies in the USA and UK have validated MIDAS in migraine sufferers, showing in particular that it has good internal consistency and test-retest reliability [11, 12].

MIDAS is therefore a reliable and simple-to-use instrument for assessing the impact of migraine on individual patients [13], and it would be useful to have an Italian version for assessing disability in Italian-speaking patients.

We carried out the present pilot study to assess the stability and the test-retest reliability of a preliminary Italian version of the MIDAS questionnaire. The study involved compilation of the questionnaire by a group of migraine patients on two separate occasions. The correspondence between migraine-dependent disability, determined from the questionnaire on the two occasions, was then analysed. The results of this analysis will assist in the formulation of a definitive Italian version of MIDAS.

Materials and methods

The only inclusion criterion for this study was diagnosis of migraine without aura according to International Headache Society criteria [1]. One hundred four consecutive patients of both sexes were enrolled during May and June 1998 from among the outpatients presenting at the Regional Headache Centre, C. Besta Neurological Institute, Milan. There were 81 women and 23 men of average age 39.9 years (SD, 11.1); mean disease duration was 18.2 years (SD, 10.6).

The patients first completed the MIDAS form during a session with an examining neurologist after full explanation. A second copy of the MIDAS form was given to the patients with instructions to complete it 21 days later and post it back to the Headache Centre. The questionnaire was translated by Headache Centre staff from the six-item version of MIDAS, as that was then the only version available when the study started. This translation is shown in Fig. 1.

No change in ongoing therapy (symptomatic or prophylactic) was prescribed to patients during the course of the study.

The six-item questionnaire has not been fully utilised in clinical practice, while the five-item MIDAS is well reported [12]. Apart from some differences in the level of instruction given to patients, the most important change in the five-item form is the exclusion of one question. For these reasons our data were analysed in two different phases: first considering all the original six items and then considering only the definitive five items (i.e. excluding the question asking about the 'number of days in which ability to do family, social or leisure activities was reduced by half or more', item 2 in the Italian translation in Fig. 1).

We analysed both MIDAS scores and disability grades. MIDAS scores have been obtained summing the scores of individual questions about different activities, and thus they refer to the total number of days lost because of headaches. Disability grades relate to the range of scores within which an individual patient's score lies, according to four progressive levels of impairment in activities. The different grades and the corresponding MIDAS scores are shown in Table 1.

Pearson's and Spearman's tests were used to evaluate the test-retest reliability between the scores reported by each patient at the first and second compilations. The stability of disability grades was evaluated, comparing the distribution of different grades at the first and second compilations in the studied population using Wilcoxon signed rank sum test. The percentages of patients who changed disability grade were also investigated.

ISTRUZIONI: rispondi alle seguenti domande considerando tutti gli episodi di cefalea negli ultimi 3 mesi (conta ogni parte di giornata come 1 giorno). Segna la risposta nello spazio accanto ad ogni domanda; scrivi zero (0) se non hai svolto le attività in questione durante gli ultimi tre mesi.

A. Quanti giorni negli ultimi 3 mesi hai avuto cefalea?
_____ giorni

B. Considerando una scala da 0 a 10, quale era l'intensità media di questi episodi di cefalea?

1. In quanti giorni negli ultimi 3 mesi hai dovuto rinunciare ad attività familiari, sociali o di svago a causa della cefalea?
_____ giorni

2. Nelle occasioni in cui eri ancora in grado di partecipare alle attività familiari, sociali o di svago, in quanti giorni la tua capacità di partecipare era ridotta della metà o più?
_____ giorni

3. In quanti giorni non hai potuto svolgere i lavori di casa a causa della cefalea?
_____ giorni

4. Nelle occasioni in cui eri ancora in grado di svolgere i lavori di casa in quanti giorni il tuo rendimento era ridotto della metà o più?
_____ giorni

5. In quanti giorni ti sei assentato da scuola o dal lavoro a causa della cefalea?
_____ giorni

6. Nelle occasioni in cui eri ancora in grado di lavorare o di andare a scuola, in quanti giorni il tuo rendimento era ridotto della metà o più?
_____ giorni

Somma dei punteggi dalla domanda 1 alla domanda 6
Punteggio totale _____

Copyright Innovative Medical Research, 1997.

VERSIONE ITALIANA A CURA DEL CENTRO REGIONALE PER LA DIAGNOSI E CURA DELLE CEFALEE, ISTITUTO NAZIONALE NEUROLOGICO "C. BESTA", MILANO.

Fig. 1 MIDAS questionnaire, Italian version

Table 1 MIDAS disability grades corresponding to different scores

MIDAS grades	MIDAS scores ^a	Disability
Grade I	0–5	Low pain without disability
Grade II	6–10	Moderate-high pain with minimal disability
Grade III	11–20	Moderately limiting disability
Grade IV	> 20	Severely limiting disability

^a Sum of scores to questions 1–6

Results

Of the 104 patients enrolled, 86 (83%) completed both the first and second MIDAS forms, while 18 (17%) did not return the second form.

Analysis of the test-retest reliability showed good correlation between MIDAS scores as obtained by the first and second compilations of the questionnaire, both when all six items and when only the definitive five items were used to obtain MIDAS scores. Pearson's correlation coefficient was 0.84 when the six-item based scores were considered, and 0.82 when the five-item based scores were used. Spearman's correlation coefficient was 0.76 (six-item scores) and 0.72 (five-item scores).

The distributions of disability grades determined at the first and second compilations of the 6-item MIDAS questionnaire are shown in Table 2. In 56.98% of patients the disability grade was IV, in 22.09% it was III, in 13.95% it was II and in 6.98% the disability grade was I. At the second assessment, the distribution of disability grades was not statistically different (Wilcoxon signed rank sum test, $p = 0.5$). When we compared the first and second determinations of disability grade for individual patients, we found that 67.5% of patients had the same grade, while 32.5% had changed disability grade (Table 3).

When the 5-item MIDAS questionnaire was considered, 47.7% of patients had grade IV, 23.2% grade III, 17.4% had grade II and 11.7% had grade I disability at the first compilation (Table 4). Also in this case, the distribution of disability grades at the second assessment was not statistically different (Wilcoxon signed rank sum test, $p = 0.1$). Comparison of the first and second determinations of disability grade for individual patients revealed that 59.3% of patients had the same grade, and that the disability grade had changed in 40.7% (Table 5).

The distribution of patients who changed disability grade from the first to the second questionnaire compilations was not homogeneous. The lowest rate of patients who changed was observed among those who were most disabled (grade IV) at the first testing, when data were analysed according to both the six-item and the five-item MIDAS questionnaires (Tables 3 and 5)

Table 2 Distribution of disability grades determined using the six-item MIDAS questionnaire according to first and second compilations. Only the 86 patients who completed both questionnaires are considered

Disability grade	Patients, n (%)				
	I	II	III	IV	Total
First compilation	6 (6.98)	12 (13.95)	19 (22.09)	49 (56.98)	86 (100)
Second compilation	5 (5.81)	13 (15.12)	24 (27.91)	44 (51.17)	86 (100)

Table 3 Changes in disability grades from first to second compilation of the 6-item MIDAS questionnaire. Of the 86 patients who compiled both questionnaires, a total of 28 (32.5%) changed disability

Disability at second test	Disability at first test			
	I n = 6	II n = 12	III n = 19	IV n = 49
I	3	1	0	1
II	1	4	6	3
III	1	7	11	5
IV	1	0	2	40
Patients who changed, n (%)	3 (50.0)	8 (66.7)	8 (42.1)	9 (18.4)

Table 4 Distribution of disability grades determined using only the definitive five items of the MIDAS questionnaire, at first and second compilations. Only the 86 patients who completed both questionnaires are considered

Disability grade	Patients, n (%)				Total
	I	II	III	IV	
First compilation	10 (11.7)	15 (17.4)	20 (23.2)	41 (47.7)	86 (100)
Second compilation	11 (12.8)	18 (20.9)	25 (29.1)	32 (37.2)	86 (100)

Table 5 Changes in disability grades from first to second compilation of the 5-item MIDAS questionnaire. Of the 86 patients who compiled both questionnaires, a total of 35 (40.7%) changed disability

Disability at second test	Disability at first test			
	I n = 10	II n = 15	III n = 20	IV n = 41
I	5	2	2	2
II	4	7	7	0
III	1	6	9	9
IV	0	0	2	30
Patients who changed, n (%)	5 (50.0)	8 (53.3)	11 (55.0)	11 (26.9)

Discussion

The present pilot study has assessed a preliminary Italian version of MIDAS based on the older six-item English version. The results indicate that this instrument may be valid for quantifying disability in Italian migraine patients.

Statistical analysis showed good test-retest reliability of the scores as obtained in the first and second compilations, with Pearson's and Spearman's correlation coefficients similar to those reported for the original English version of MIDAS [13]. Furthermore, in the majority of patients disability grade was stable over the 21 days between the first and second assessments.

The fact that some patients changed disability grade between the first and second compilations could be partly due to the intrinsic variability of migraine severity. The three-week interval between compilations was chosen to be the same as that in studies that validated the original version of MIDAS.

No important difference was noted in the distribution of MIDAS disability grades in the studied population between analyses based on the six-item and the five-item questionnaires. Furthermore, in both cases the lowest percentage of patients changing disability grade was found among those initially found to be most disabled (Tables 3 and 5). The majority of patients with a different disability at second compilation (22 of 28, 78.6% when six items were considered; 30 of 35, 85.7% when five items were considered) had only a one-grade change.

On the other hand the test-retest reliability of MIDAS scores was similar both when all original six items and when only the definitive five items were used to obtain MIDAS scores (0.8 at Pearson's test and 0.7 at Spearman's test, in both cases).

It is noteworthy that the majority of patients who returned the second questionnaire (about 90% with the six-item form, about 70% using the five-item form) had moderate or high grade disability (III–IV) as determined by MIDAS, indicating that migraineurs who present at a Headache Centre suffer from considerable compromise in their daily lives.

Of the 104 patients who started the study, 17% did not return the second questionnaire. Similar drop-out rates were reported in validation studies on English-speaking migraineurs [13]. The distribution of MIDAS grades among the drop-outs was similar to that of the patients who completed the study (data not shown).

In conclusion, the results of this pilot study are encouraging and indicate that this preliminary Italian adaptation of the MIDAS questionnaire is satisfactorily stable and highly reliable. The process of preparing a definitive five-item version of the questionnaire for Italian patients, employing techniques used for culturally adapting quality of life instruments [14, 15], is already underway.

Acknowledgements The authors thank Dr. Richard Lipton for his thoughtful contribution.

References

1. Headache Classification Committee of the International Headache Society (1988) Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain. *Cephalalgia* 8[Suppl 7]:1–96
2. Stewart WF, Schechter A, Lipton RB (1994) Migraine heterogeneity. Disability, pain intensity, and attack frequency and duration. *Neurology* 44[Suppl 4]:24–39
3. Clarke CE, MacMillan L, Sondhi S, Wells NE (1995) Economic and social impact of migraine. *QJM* 89:77–84
4. Stewart WF, Lipton RB, Simon D (1996) Work-related disability: from the American migraine study. *Cephalalgia* 16:231–238
5. Smith R (1996) Impact of migraine on the family. *Headache* 36:278 (abstract)
6. Pryse-Phillips W, Findlay H, Tugwell P, Edmeads J, Murray TJ, Nelson RF (1992) Canadian population survey on the clinical, epidemiologic and societal impact of migraine and tension-type headache. *Can J Neurol Sci* 19:333–339
7. National Academy of Sciences/Institute of Medicine (1991) *Disability in America: toward a national agenda for prevention*. National Academy of Sciences, Washington DC
8. Von Korff M, Ormel J, Keefe FJ, Dworkin SF (1992) Grading the severity of chronic pain. *Pain* 50:133–149
9. Von Korff MR, Stewart WF, Lipton RB (1994) Assessing headache severity. New directions. *Neurology* 44[Suppl 4]:S40–S46
10. Stewart WF, Lipton RB, Simon D, Von Korff M, Liberman J (1998) Reliability of an illness severity measure for headache in a population sample of migraine sufferers. *Cephalalgia* 18:44–51
11. Stewart WF, Lipton RB, Sawyer J (1998) A multi-national study to assess the reliability of the migraine disability assessment (MIDAS) score. In: 40th Annual Meeting of the AASH, San Francisco, 26–28 June 1998, pp 160–161 (abstract)
12. Stewart WF, Lipton RB, Kolodner K, Liberman J, Sawyer J (1999) Reliability of the migraine disability assessment score in a population-based sample of headache sufferers. *Cephalalgia* 19:1–96
13. Sawyer J, Edmeads J, Lipton RB, Stewart WF (1998) Clinical utility of a new instrument assessing migraine disability: the migraine disability assessment (MIDAS) questionnaire. *Neurology* 50:A433–434 (abstract)
14. Ware JE Jr, Keller SD, Gandek B, Brazier JE, Sullivan M, and the IQOLA Project Group (1995) Evaluating translations of health status questionnaires: methods from the IQOLA Project. *Int J Technol Assess in Health Care* 11(3):525–551
15. Apolone G, Mosconi P (1998) The Italian SF-36 Health Survey: translation, validation and norming. *J Clin Epidemiol* 51(11):1025–1036