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 questionnaire (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.

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
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.

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**Fig. 1 MIDAS questionnaire, Italian version**
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).

Table 1 MIDAS disability grades corresponding to different scores

| MIDAS grades | MIDAS scores* | 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 |

* Sum of scores to questions 1–6

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 | 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 first test | I | II | III | IV |
|--------------------------|---|----|-----|----|
| n = 6                    | 3 | 1  | 0   | 1  |
| n = 12                   | 1 | 4  | 6   | 3  |
| n = 19                   | 1 | 7  | 11  | 5  |
| n = 49                   | 1 | 0  | 2   | 40 |

| Patients who changed, n (%) | 3 (50.0) | 8 (66.7) | 8 (42.1) | 9 (18.4) |
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.

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.

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