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Disability and migraine: recent outcomes using an Italian version of MIDAS

Abstract Migraine is associated with functional impairment. The migraine disability assessment (MIDAS) questionnaire is a scientific instrument which captures headache-related disability. The Italian version of MIDAS was developed through a multistep standardized methodology. Studies on Italian clinical samples confirmed that migraine patients are disabled in all activity domains. Migraine exhibits a peculiar disability pattern: non-work activities are more affected than work activities; among patients in paid work, most continue working with a headache attack. We also found that MIDAS disability grades

correlate with health-related quality of life scores at the SF-36 survey, namely with the extent to which physical health, emotional state and pain interfere with functioning in different roles. We conclude that MIDAS (also in its Italian version) is a reliable and useful instrument for assessing the impact of migraine on patients' daily activities, and that it can be used not only in clinical practice but also in clinical research.

Key words Migraine • Disability • Migraine disability assessment questionnaire (MIDAS) • Italian version • Disability pattern • Health-related quality of life

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Introduction

Migraine is a widespread neurological disorder which affects about 10%–15% of the general population [1]. It is characterized by recurrent pain attacks associated with autonomic symptoms [2]. The condition is a cause of disability in many sufferers, causing interruption or reduction of work and school performances [3–5] but also influencing participation in family and social activities [6, 7].

Migraine has a wide range of impacts [8] resulting in different grades of functional disability. Disability refers to the consequences of illness on the ability to work and function in various settings and roles [9]. In view of these variable consequences of migraine, it is important to have instruments that can accurately assess the impact of migraine on patient's lives.

Measuring headache-related disability: the MIDAS questionnaire

Several instruments have been developed in recent years to assess the functional consequences of migraine: the Henry Ford Hospital headache disability inventory (HDI) [10]; the chronic pain index (CPI) [11]; the headache impact questionnaire (HIQ) [12]; the migraine disability assessment (MIDAS) questionnaire [13]; and the HIT-6, a questionnaire derived from the headache impact test (HIT-DynHA) available on the Internet [14].

The MIDAS questionnaire is the most extensively-studied instrument [13, 15, 16]. MIDAS captures headache-related disability in all life domains over a 3-month period. It contains only seven questions and has simple and intuitive scoring rules. The first five questions investigate the influence of

headache on three domains: questions 1 and 2 investigate paid work, enquiring as to the number of days off work due to headache and the number of days in which productivity was reduced by half or more; questions 3 and 4 ask the same questions about household work; question 5 enquires about missed days of recreational, social and family activities. Two additional questions (A and B) concern headache frequency (number of days with headache in the previous three months) and headache intensity (average pain intensity of headache attacks); they are not scored to calculate disability, but were included to provide the physician with clinical information.

The overall MIDAS score is obtained by summing the scores (number of days affected) of the first five questions. Four disability grades are obtained expressing increasing impairment of activities: grade I, minimal or infrequent disability, when total score is 0–5; grade II, mild or infrequent disability, when total score is 6–10; grade III, moderate disability, when scores range from 11 to 20; and finally grade IV, severe disability, for patients with total scores of 21 or more.

Development of the Italian version of MIDAS

We carried out a programme to adapt the MIDAS questionnaire into Italian and to use it as a research tool in clinical studies on Italian headache sufferers.

After a pilot study which produced a preliminary translation based on the older six-item version of the questionnaire [17], the definitive Italian MIDAS instrument was compiled by our group in collaboration with the Mario Negri Institute (Milan) and the University of Bari [18]. The work was financially supported by the Italian Ministry of Health. A standardized translation methodology based on previous experience in adapting quality of life instruments was used [19], involving forward translations, back translations, assessment of equivalence to the original, and production of the definitive Italian version. The results [18] showed that the Italian MIDAS form had good internal consistency (Cronbach's alpha, 0.7) with a highly stable overall score

(Spearman's correlation coefficient, 0.7) and good correlation coefficients of all MIDAS questions. Thus, the Italian MIDAS was shown to be a valid instrument for use with Italian-speaking migraine patients.

Clinical studies using MIDAS in Italian patients

Following validation, we used the Italian MIDAS in clinical studies.

In the first study [20], disability was assessed in a population of migraine patients attending two Italian headache centres. A total of 190 consecutive out-patients with a diagnosis of migraine without aura (according to International Headache Society (IHS) criteria) attending the Headache Centres of Milan and Bari entered the study (137 women, 53 men). They were invited to complete the Italian MIDAS questionnaire, in order to evaluate the number of days with total or partial disability in different domains during the previous 3 months.

The overall MIDAS score was rather high (mean, 21.05; median, 16.5). Distribution of MIDAS disability grades showed that most patients were significantly disabled, as 69.5% patients were classified in MIDAS grades III-IV, corresponding to moderate or severe disability. This was the first study to assess disability in a large sample of Italian migraine sufferers.

Afterwards, we made a survey on a larger sample: 264 patients affected by migraine without aura who attended the Headache Center at the C. Besta National Neurological Institute in Milan. The aims of the study were to confirm previous results, and to investigate the pattern of functional disability from migraine in different activity domains.

The main characteristics of the patients were as follows: 197 women and 67 men; mean age, 37.6 years (SD=10.88 years; range, 17–69 years); mean illness duration, 18.8 years (SD=11.6 years; range, 1–50 years).

The distribution of disability grades was: grade I, 13.3%; grade II, 13.6%; grade III, 26.1%; and grade IV, 47%. The overall MIDAS score was 23.4 (SD=17.55; median, 19). The scores at individual MIDAS items are shown in Table 1.

Table 1 Scores at the MIDAS questionnaire (Italian translation) in 264 migraine patients

MIDAS item	Mean	Median
1. On how many days in the past 3 months did you miss work or school because of your headaches?	2.2	0.5
2. How many days in the past 3 months was your productivity at work or school reduced by half or more because of your headaches?	6.6	5.0
3. On how many days in the past 3 months did you not do household work because of your headaches?	4.3	3.0
4. How many days in the past 3 months was your productivity in household work reduced by half or more because of your headaches?	4.6	3.0
5. On how many days in the past 3 months did you miss family, social or leisure activities because of your headaches?	5.0	3.0
Overall score	23.4	19.0

Considering the mean number of days with disability in each MIDAS item, patients were more impaired in personal, familial and social aspects than in the work place: when considering household work missed and reduced plus impaired family, social and leisure activities, there were on average 14.5 days with disability; in contrast, for work activities missed and activities reduced, there were on average 8.8 days with disability.

We then performed another kind of analysis to better understand the pattern of headache-related disability in migraine patients, calculating the proportion of patients who reported disability in each activity domain. This analysis confirmed that migraine sufferers were impaired in all everyday duties and that, in the majority of subjects

(64%–79%), domestic and social activities were significantly impaired. On the other hand, workplace activities were also negatively influenced by headache attacks: 50% of subjects were forced to stop working and a higher proportion of them (73.5%) suffered from significant reduction of their performances, although they continued to work when experiencing a migraine attack (Fig. 1).

We continued to investigate the relationship between disability and quality of life in migraine. Health-related quality of life (HRQOL) is a multidimensional concept which encompasses an individual’s health status, functional status, and well-being. We chose a well known instrument, the Medical Outcomes Study short form (SF)-36, which is the most used generic HRQOL survey [21–23]. The main

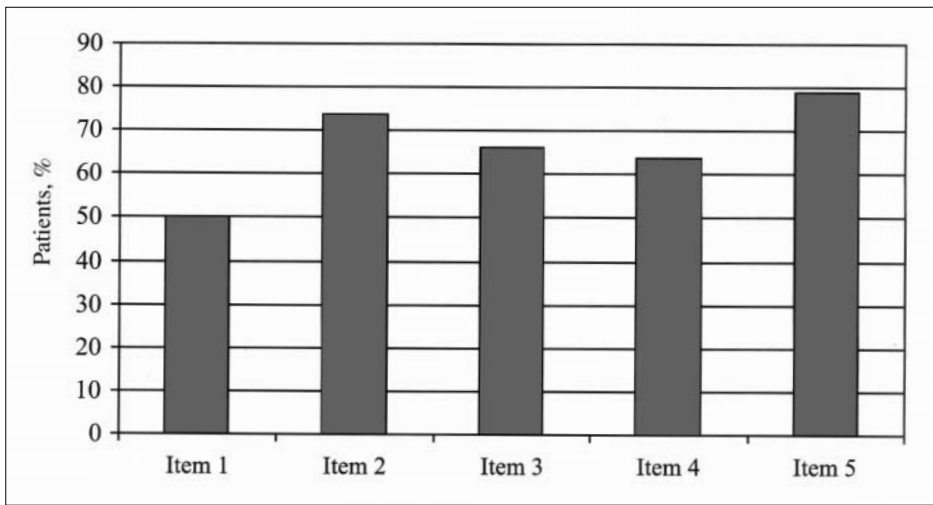


Fig. 1 Proportion of Italian migraine patients reporting disability in each activity domain (items 1–5) of the MIDAS questionnaire

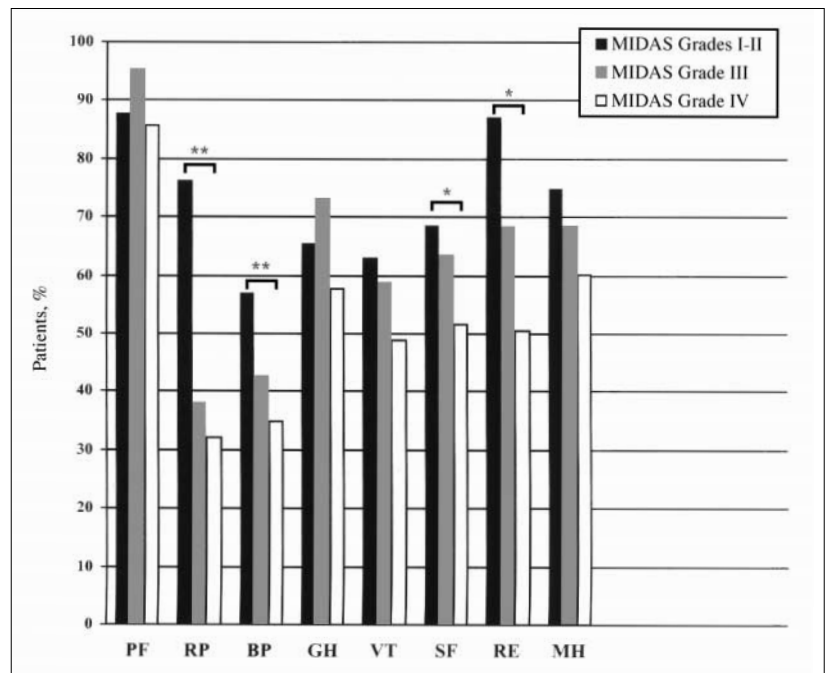


Fig. 2 Correlation between MIDAS disability grades and scores on individual SF-36 scales for 68 migraine patients (Kruskal-Wallis test with Bonferroni correction). *PF*, physical functioning; *RP*, role functioning, physical; *BP*, bodily pain; *GH*, general health; *VT*, vitality; *SF*, social functioning; *RE*, role functioning, emotional; *MH*, mental health. ** $p < 0.002$; * $p < 0.03$

aim of our study was to determine whether MIDAS disability grades correlated with HRQOL scores. A total of 68 patients with a diagnosis of migraine without aura (according to IHS criteria) were studied. They were 52 women and 16 men of mean age 38.52 years (range, 17–69 years); mean illness duration was 21.18 years (range, 1–50 years). Patients completed the SF-36 and MIDAS questionnaires during a consultation at the Headache Centre. The validated Italian versions of both questionnaires were used [18, 19]. Student's *t* test with Bonferroni correction was used to compare the patient's SF-36 scores with Italian normative data. The correlation between MIDAS disability grades and SF-36 scores was assessed on the Kruskal-Wallis test again with Bonferroni correction.

Migraine patients' mean SF-36 scores were numerically lower than those of the Italian general population for all components (scales) of the questionnaire, suggesting poorer HRQOL. Scores were significantly lower than normal for: role functioning, physical; bodily pain; social functioning ($p < 0.0001$); and role functioning, emotional ($p = 0.02$). The distribution of MIDAS disability grades was as follows: grades I-II: 19 patients (27.9%); grade III, 18 patients (26.5%); and grade IV, 31 patients (45.6%). A significant correlation between MIDAS disability grade and SF-36 score was found for the following SF-36 scales: role functioning, physical; bodily pain ($p = 0.002$); social functioning ($p = 0.03$); and role functioning, emotional ($p = 0.03$) (Fig. 2).

The statistical analysis showed that increasing disability (as reflected by higher MIDAS disability grade) correlated with decreased SF-36 scores on the scales that assess the extent to which physical health, emotional state and pain interfere with functioning in different domains (including impairment in workplace productivity, household duties and social activities).

Conclusions

Several studies showed that migraine has important functional consequences and is characterized by the inability to carry out normal tasks. We performed a multistep research programme to investigate headache-related disability in Italian migraine patients. The first step was the development

and validation of the Italian MIDAS questionnaire. MIDAS is a recently developed instrument which was designed to assess the functional consequences of migraine in all activity domains, and which proved to be a reliable tool when used in English-speaking migraineurs [13, 15, 16].

The Italian MIDAS form maintains the brevity and simplicity of the English version, and is characterized by test-retest reliability parameters similar to those of the original. It is therefore suitable as a clinical and research tool in Italian patients [18].

We performed a series of clinical studies to investigate functional impairment in samples of Italian migraine patients, paying attention to clarify the disability pattern of migraine. Our findings confirmed that migraine is a disabling disorder. Most migraine patients attending a headache centre reported a remarkable impact on their daily activities.

Migraine exhibited a peculiar disability pattern. Familial and social duties were heavily reduced, and patients were more likely to significantly reduce their work performances than miss work days.

On the basis of our experience, we conclude that MIDAS presents itself as a reliable and useful instrument for assessing the impact of migraine on patients' daily activities, and that it can be used not only in clinical practice but also in clinical research. Furthermore, we found that MIDAS is brief and simple-to-use, and that MIDAS disability grades correlated with quality of life scores, namely with the extent to which physical health, emotional state and pain interfere with functioning in different roles.

An ongoing study will assess the role of MIDAS as an outcome measure in migraine patients after treatment intervention. Patients with migraine who require prophylactic treatment have been recruited in a multicentre study, involving more than 10 headache centres of Lombardy (Northern Italy). All subjects completed the MIDAS and SF-36 questionnaires at the first consultation. Patients will be asked to complete the same disability and HRQOL instruments at follow-up visits 3 and 6 months after the start of preventive therapy. The main aims of the study are to assess the changes in functional disability and quality of life induced by prophylaxis and to investigate the roles of MIDAS and SF-36 questionnaires as outcome measures for use in future clinical trials.

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