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## Disability in migraine patients: Italian experience

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**Abstract** Migraine is associated with functional impairment. The migraine disability assessment (MIDAS) scale is a scientific instrument which captures headache-related disability. The Italian version of MIDAS was developed through a multi-step standardized methodology. Studies on Italian clinical samples showed that migraine patients were disabled in all activity domains. Non-work activities were more affected than work activities. Among patients in paid work, most continued working with a headache attack, although productivity was significantly reduced. The Italian MIDAS was used also in patients with transformed migraine

and drug overuse. These patients were markedly disabled. MIDAS scores were higher than those found in migraine patients. When disability was assessed after 6 months from withdrawal therapy, MIDAS scores were significantly lower than at baseline. Our results confirmed the negative impact of the lives of headache patients, and suggest the use of MIDAS as a sensitive outcome measure for monitoring patients' progress.

**Key words** Migraine • Disability • Transformed migraine • Migraine disability assessment (MIDAS) • Outcome measure

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### Introduction

Migraine usually results in functional impairment during attacks [1, 2]; the condition is therefore a cause of disability. The WHO definition of disability [3] is any restriction or lack of ability to perform an activity in the manner or within the range considered normal for a human being. The migraine disability assessment (MIDAS) questionnaire has been developed to assess headache-related disability, and has been shown to be a valid instrument for this purpose in English-speaking migraine patients [4, 5].

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### Italian version of MIDAS

We carried out a programme to adapt the MIDAS questionnaire into Italian. After a pilot study which produced a preliminary translation based on the older six-item version of the

questionnaire [6], the definitive Italian MIDAS instrument was compiled by our group in collaboration with the Mario Negri Institute (Milan) and the University of Bari [7]. 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 [8], involving forward translations, back translations, evaluation for simple correct language, assessment of equivalence to the original, and production of the definitive Italian version. The Italian MIDAS then underwent scientific validation with 109 migraine patients, 86 of whom completed the form a second time 21 days later. The study [7] showed that the Italian MIDAS had good internal consistency (Cronbach's alpha, 0.7) with highly stable overall score (Spearman's correlation coefficient, 0.7). The stability of the responses to the five questions about disability in various activities was good (correlation coefficients ranged from 0.5 to 0.81). Thus, the Italian MIDAS was shown to be a valid instrument for clinical use and research on Italian-speaking migraine patients.

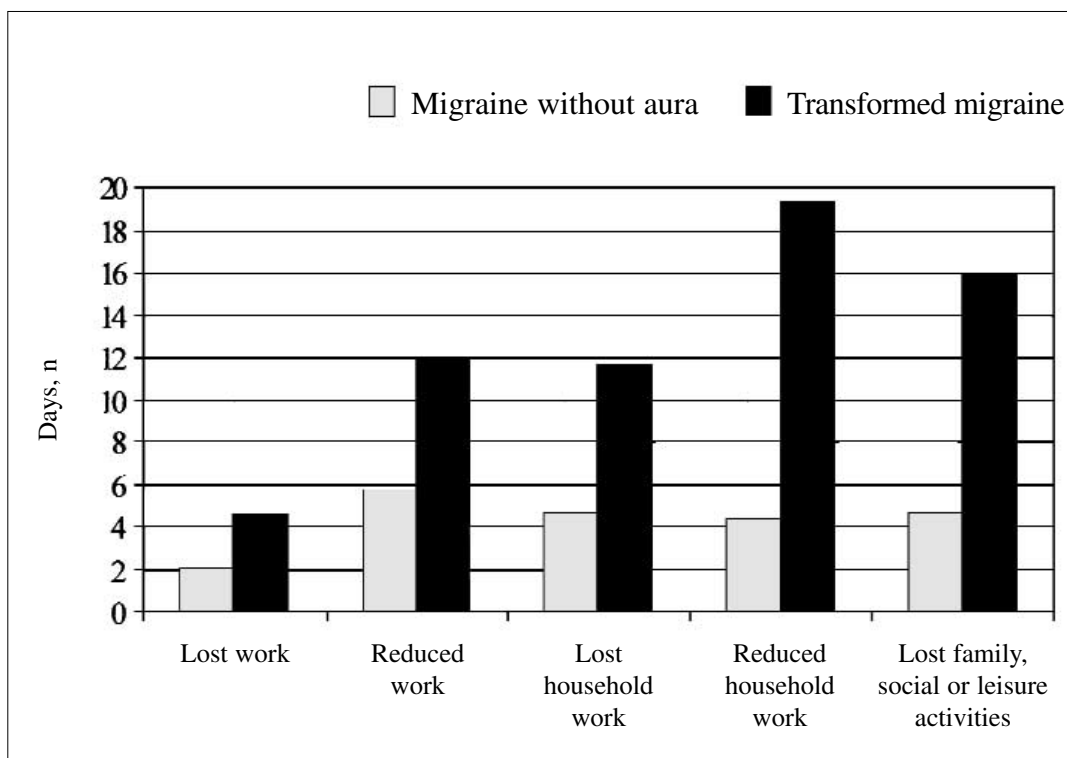
The study also indicated that patients attending a Headache Centre are on average more impaired than migraineurs in the general population. Among the studied patients, 35% had MIDAS grades I-II, and 65% had grades III-IV, while population-based studies report that around 43% of subjects have grades I-II disability, and 57% have grades III-IV [4, 5].

### MIDAS in migraine patients

Following validation, we used the Italian MIDAS in clinical studies. We assessed disability in 225 consecutive migraine patients [8]. Most reported severe disability (mean MIDAS score 20). Analysis by activity domains showed that non-work activities were more affected than work activities, in terms of missed days (missed days in household, 4.6+missed days in family-social-leisure activities, 4.6=total 9.2; missed days of paid work=2) (Fig. 1). Among patients in paid work, most continued working with a headache attack, although their productivity was significantly impaired. Patients had more days in which productivity was reduced by more than 50% than days lost due to headache (6.6 vs. 2.1).

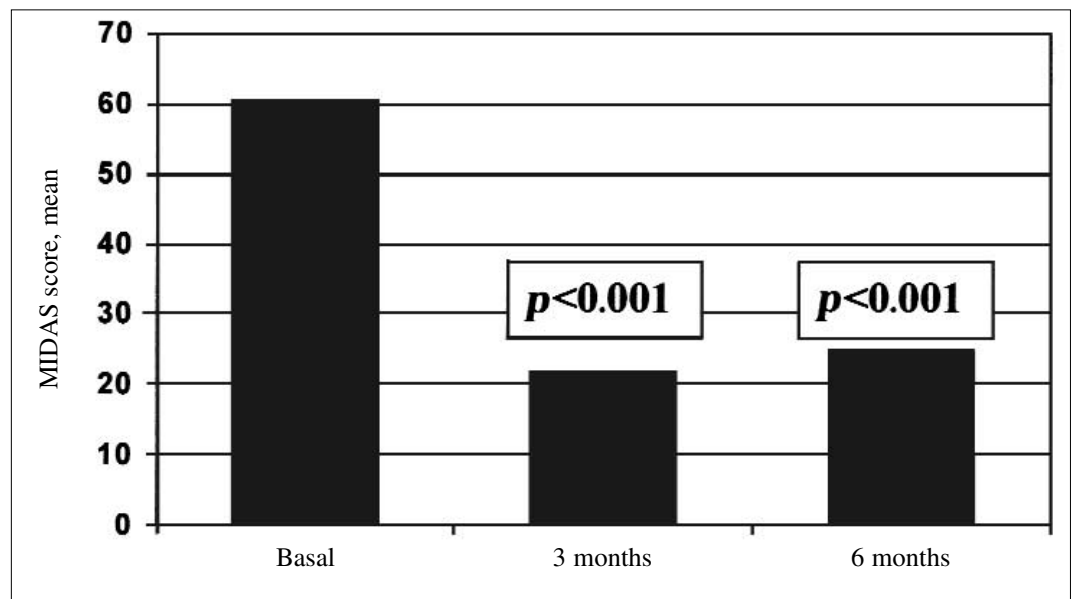
### MIDAS in transformed migraine

We also used MIDAS to assess patients with transformed migraine (TM) [9], the form characterised by daily or near-daily headaches that had once been migraine. Sixty-two patients with TM and drug overuse (diagnosed according to the criteria proposed by Silberstein et al. [10]) completed the MIDAS questionnaire before they underwent in-patient treatment consisting of abrupt withdrawal of the overused drug, detoxification, and prophylaxis with antimigraine drugs or antidepressants. After discharge, these patients were given a diary card to record headache frequency and drug consumption, and were asked to come back after three and six months. Mean baseline MIDAS score (all patients) was high (64.8), and all activity domains were compromised. Forty-nine patients completed the study. At the six-month assessment both frequency and analgesic consumption were markedly reduced in those who completed the study (mean days with headache per month, from 30 to 8.3; mean drugs per month, from 44.4 to 12.6). Mean MIDAS score was 60.2 in these patients at first compilation and 24.8 six months from withdrawal ( $p<0.0001$ , Student's *t* test) (Fig. 2). These findings show that most TM patients with drug overuse are highly disabled and that appropriate management can improve their ability to function, as shown by the change in MIDAS score.



**Fig. 1** Disability in different activity domains assessed using MIDAS questionnaire, in patients with migraine without aura (n=225) and in patients with transformed migraine (n=62). Values are means

**Fig. 2** MIDAS score in patients with transformed migraine and drug overuse: mean baseline score vs. mean score after 3 and 6 months from withdrawal therapy (statistical analysis, Student's *t* test)



## Conclusions

Migraine has a negative impact on the lives of those who suffer from it. The MIDAS questionnaire is a simple instrument for evaluating disability in all activity domains. Studies conducted at our centre on Italian migraine patients show that the Italian MIDAS retains the simplicity and reliability of the original questionnaire. Our subsequent studies showed that MIDAS is a useful tool for follow-up and for outcome assess-

ment in migraine patients. MIDAS allows the evaluation of functional impairment in headache patients, and the comparison of disability grades in different patient groups (e.g. those from the general population vs. tertiary care patients) and for different headache types (episodic vs. chronic headache). Our experience with patients with transformed migraine and drug overuse demonstrates that MIDAS is sensitive to clinical change after intervention, suggesting the use of the instrument as an outcome measure for monitoring patients' progress in everyday practice and in clinical trials.

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