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## Quality of life and disability in primary chronic daily headaches

**Abstract** We assessed functional disability and health-related quality of life (HRQOL) in Italian patients suffering from chronic migraine and medication overuse (150 subjects) or chronic cluster headache (22 subjects). We used the validated Italian versions of the Migraine Disability Assessment Score (MIDAS) and of the Short Form 36 (SF-36). Patients with both conditions were characterised by significantly lower scores on most SF-36 scales than Italian normative data (Student's *t* test with Bonferroni correction). MIDAS scores revealed that patients had severe limitations in their ability to function, with high proportions forced to stop work and non-work activities, or experiencing significantly reduced productivity in all activity domains. These findings show that primary chronic headaches have a marked negative influence on patients' lives, compromising their sense of well being and their ability to function in different roles. We also found that MIDAS and SF-36 were sensitive to clinical changes in a group of 84 patients with chronic migraine and medication overuse who completed the both questionnaires before and after treatment.

**Key words** Disability • Health-related quality of life • Primary chronic headache • Chronic migraine • Chronic cluster headache • Migraine Disability Assessment Score (MIDAS) • Short Form 36 (SF-36)

### Introduction

The term chronic daily headache (CDH) has been introduced in recent years to refer to daily or almost daily headache, regardless of cause. Clinical experience suggests that it is possible to distinguish different forms of CDH. The classification of Silberstein and Lipton [1] distinguishes primary and secondary forms of CDH. Primary CDHs are divided into long-lasting (more than 4 hours) and short-lasting forms (less than 4 hours). The commonest long-lasting CDH forms are transformed or chronic migraine and chronic tension-type headache, while the typical short-lasting form is chronic cluster headache.

All chronic headaches are characterised by pain for more than 15 days per month and for this reason are intuitively likely to interfere with normal life and to have a negative effect on sense of well-being. Several studies published over the last decade have shown that patients with primary headaches report markedly impaired quality of life and decreased ability to function. However, most studies have focused on migraine (reviewed in [2]) and few studies on chronic headache disorders have been published [3–7]. We present data obtained studying Italian patients with two different forms of primary CDH, chronic migraine and chronic cluster headache.

### Disability and quality of life in chronic migraine as assessed by MIDAS and SF-36

We recruited 150 consecutive patients attending the Headache Centre of the C. Besta Neurological Institute, Milan, diagnosed with chronic migraine and medication overuse, according to the diagnostic criteria proposed by Silberstein and Lipton [1]. There were 125 women and 25 men of mean age 45.4 years (range, 19–72) and mean illness duration 25.6 years (range, 2–55 years). A mean of 53 (range, 20–200) symptomatic drugs were consumed per month.

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All patients completed the Migraine Disability Assessment Score (MIDAS) [8] in its validated Italian version [9] to assess headache-related disability. MIDAS is a brief and reliable headache-specific tool which captures headache-related disability. Five questions (MIDAS items) investigate the influence of headache on everyday activities over the preceding three months. Items 1 and 2 investigate paid work, enquiring as to the number of days off work due to headache and the number of days where productivity was reduced by half or more. Items 3 and 4 ask the same questions about household work. Item 5 enquires about missed days of recreational, social and family activities. The total score (MIDAS score) is obtained summing the individual scores (number of days affected) of the individual MIDAS items. From the score, one of four disability grades is assigned: *grade I*, minimal or infrequent disability corresponds to a MIDAS score of 0–5; *grade II*, mild or infrequent disability corresponds to a MIDAS score of 6–10; *grade III*, moderate disability corresponds to a MIDAS score of 11–20; and *grade IV*, severe disability corresponds to a MIDAS score of 21 or more.

We found that mean MIDAS score in the studied patients was quite high (79.2, SD=64.3). Fourteen patients (9.3%) had grade I disability; 5 (3.4%) had grade II; 11 (7.3%) had grade III disability and 120 (80.0%) had grade IV. Thus most (87.3%) patients had moderate or severe disability (grades III or IV). We also assessed the proportions of patients who reported total or partial disability in different activity domains as investigat-

ed by MIDAS items. As shown in Table 1, chronic migraine sufferers were impaired in all everyday duties and in most patients (69%–83%) domestic and social activities were significantly impaired. Workplace activities were also negatively influenced by headache attacks, in that more than 50% had a significant reduction in their work performance although they continued working when experiencing a migraine attack. Furthermore, 39% patients were forced to stop working.

Eighty-four of the patients with chronic migraine and medication overuse also completed the Short Form 36 (SF-36) [10, 11] in its validated Italian version [12], at their first visit at the Headache Centre.

The SF-36 is the most commonly used instrument to assess health-related quality of life (HRQOL). It is a generic instrument of 36 questions that assesses the influence of any disorder on a core set of eight domains of functioning and well-being: physical functioning (PF); role functioning, physical (RP); bodily pain (BP); general health (GH); vitality (VT); social functioning (SF); role functioning, emotional (RE); and mental health (MH). The scores for each domain are calculated from the replies to the questions.

The scores for the eight scales obtained in the patients were compared to those found in the Italian general population [12] by Student's *t* test with Bonferroni correction. We found that mean SF-36 scores were clinically (>5 point difference) and statistically ( $p < 0.001$ ) lower in these patients than in the general population on all scales (Table 2). Thus

**Table 1** Disability in each activity domain (as assessed by MIDAS items) among patients with chronic migraine and medication overuse, and among patients with chronic cluster headache

MIDAS item	Chronic migraine, n (%) (n=150)	Chronic CH, n (%) (n=22)
1. Work lost	58 (38.7)	8 (36.4)
2. Work reduced by 50% or more	79 (52.7)	11 (50.0)
3. Household work lost	103 (68.7)	5 (22.7)
4. Household work reduced by 50% or more	107 (71.3)	7 (31.8)
5. Family, social, leisure activities lost	124 (82.7)	13 (59.1)

CH, cluster headache

**Table 2** SF-36 scores in patients with chronic migraine and drug overuse and in patients with chronic cluster headache in comparison with Italian normative data (Student's *t* test with Bonferroni correction). Values are mean (SD)

SF-36 domains	Italian normative data	Chronic migraine (n=84)	<i>p</i>	Chronic CH (n=22)	<i>p</i>
PF	84.5 (23.2)	74.9 (19.5)	<0.001	80.7 (20.5)	NS
RP	78.2 (35.9)	18.3 (29.9)	<0.001	42.0 (37.3)	0.001
BP	73.7 (27.6)	22.9 (16.1)	<0.001	52.7 (10.3)	<0.001
GH	65.2 (22.2)	38.9 (18.1)	<0.001	51.5 (23.6)	0.05
VT	61.9 (20.7)	39.7 (18.5)	<0.001	59.3 (11.9)	NS
SF	77.4 (23.3)	42.4 (23.5)	<0.001	47.2 (22.8)	<0.001
RE	76.2 (37.2)	35.8 (38.6)	<0.001	40.9 (35.5)	0.001
MH	66.6 (20.9)	48.1 (18.9)	<0.001	50.4 (19.3)	0.003

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; NS, not significant

**Table 3** Characteristics of patients with chronic migraine and medication overuse, at baseline and after treatment intervention (Student's *t* test). Values are mean (SD)

	Baseline	Follow-up	<i>p</i>
Headache days, n/month	26.1 (4.0)	7.8 (7.3)	< 0.0001
Symptomatic drugs, n/month	48.9 (29.1)	8.1 (13.3)	< 0.0001
Midas score			
SF-36 scores	70.8 (59.3)	23.3 (28.1)	< 0.0001
PF	74.9 (19.5)	83.0 (17.7)	NS
RP	18.3 (29.9)	46.9 (42.7)	0.023
BP	22.9 (16.1)	41.7 (23.6)	0.003
GH	38.9 (18.1)	57.5 (25.6)	0.0008
VT	39.7 (18.5)	52.8 (21.7)	0.049
SF	42.4 (23.5)	61.4 (23.4)	0.010
RE	35.8 (38.6)	64.6 (39.7)	0.003
MH	48.1 (18.9)	61.5 (19.8)	0.003

NS, not significant

patients with chronic migraine with drug overuse have a significant reduction in their sense of well-being with evident limitations in all work and social activities due to their headache.

The 84 patients who completed both MIDAS and SF-36 questionnaires at their first visit were asked to come back six months later to return their diary cards and to compile the MIDAS questionnaire and SF-36 again. In the meantime they had undergone a treatment programme requiring admission to hospital with withdrawal of overused drugs, followed by prophylaxis (anti-migraine drugs, antidepressants or both). The differences between disability and quality of life scores before treatment and at the follow-up visit were assessed using Student's *t* test.

We found that treatment resulted in a major clinical change, associated with a significant reduction in the functional impact of the headache. Headache was present daily before therapy, while six months later the mean number of days with headache per month had reduced to  $7.8 \pm 7.3$  ( $p < 0.001$ ). Mean MIDAS score was  $70.8 \pm 59.3$  at baseline and  $23.3 \pm 28.1$  at six months, again significantly lower than before treatment intervention ( $p < 0.001$ ) (Table 3). For all the SF-36 scales, the mean scores after six months were higher than those at baseline, indicating improved quality of life. The difference was clinically significant (>5 point difference) for all domains; it was statistically significant ( $p < 0.05$ , Student's *t* test with Bonferroni correction) for all scales but one (PF). The difference was particularly clear for the scale evaluating intensity of pain and its influence on daily activities (BP), and for scales pertaining to the personal evaluation of health and to behavioural-emotional control (GH, MH, RE).

These findings indicate that both the MIDAS and SF-36 questionnaires are sensitive to clinical change following treatment intervention in patients with chronic migraine and medication overuse (Table 3).

#### Disability and quality of life in chronic cluster headache as assessed by MIDAS and SF-36

We administered the MIDAS questionnaire and SF-36 to 22 consecutive patients with chronic cluster headache. The inclusion criteria were: (a) diagnosis of chronic cluster headache according to International Headache Society criteria [13]; (b) had not started prophylactic treatment when recruited or had started but were still having daily headaches. There were 18 men and 4 women of mean age 46.2 years (SD=11); illness duration was 11.5 years (SD=9.9).

All patients completed the Italian versions of MIDAS [9] and SF-36 [12]. Student's *t* test with Bonferroni correction was used to compare scores for each SF-36 domain with those in healthy subjects [12]. The MIDAS results were analysed in terms of percentage of patients reporting disability for each activity investigated by the questionnaire.

As shown in Table 2, mean SF-36 scores were lower than in the general population for all scales. The difference was statistically significant for all scales but two (PF, VT). As expected, scores were particularly low for scales evaluating the extent to which pain and physical health interfere with work or other daily activities (BP, RP), but also for the

SF scale, which indicates the extent to which physical and emotional problems interfere with normal social activities. Patients also had poor scores on scales assessing the influence of the disorder on personal evaluation of mental and emotional components (MH, RE).

Analysis of the results obtained using MIDAS showed that over the previous three months about 60% of patients had missed family, social or leisure activities. With regard to paid work, 50% had their productivity reduced by more than 50% due to headache when they remained at work during days with cluster attacks, and 36% had not gone to work because of headache. Household work was also impaired (Table 1).

## Discussion

We assessed functional disability and HRQOL in Italian patients suffering from chronic migraine and chronic cluster headache – the primary CDHs most often diagnosed in tertiary care units.

Our findings on chronic migraine (a long-lasting CDH) are in agreement with those reported by other authors. Two studies found high disability scores when MIDAS [5] or the Headache Disability Inventory (HDI) [6] were administered to chronic migraine patients. CDH had a significant influence on most domains of HRQOL in three studies that employed the SF-36 on Spanish [3], American [5] and Chinese [4] patients. Our results confirm that chronic migraine causes significant changes in HRQOL particularly in regard to the extent to which physical health and emotional problems interfere with work and social activities, and also personal evaluation of health and well being.

This is the first study to focus on disability as well as HRQOL in chronic cluster headache – a particularly severe headache form, characterised by excruciatingly painful attacks occurring one to several times during the day or night, without headache-free periods or with remissions lasting less than 14 days [13]. The only previous study to assess quality of life in cluster headache is that published in 1994 by Solomon et al. [14]. They administered a standardized HRQOL instrument (SF-20) to 13 cluster headache patients, without specifying whether they suffered from the episodic or chronic forms. They reported that pain markedly influenced normal functioning, and that there were also limitations in social functioning. We found a more pervasive impact on quality of life in our series with a strongly negative influence on scales evaluating health perception. In conclusion, we found that primary chronic headaches have a strong negative influence on patients' lives: patients

with both conditions were characterised by a markedly lower HRQOL than normal, and by marked limitations in their ability to function in work and non-work activities.

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