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Disability and quality of life in headache: where we are now and where we are heading

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Abstract Headache disorders determine relevant personal and societal burden, and thus the use of patient-reported outcome measures (PROMs) investigating the level of disability and health-related quality of life (HRQoL) have been increasingly used in headache research. The aim of this review was to address the status of research on disability and HRQoL, by addressing results from recently published clinical trials as well as in longitudinal observational studies on headache patients. PubMed has been searched for papers in which measures of HRQoL and/or disability were used as primary or secondary outcome on adult subjects with primary headache, and published in 2010–2012. Among the 70 records retrieved, 12 papers were selected for narrative synthesis. They included data on 2,621 patients with episodic migraine with and without aura, chronic daily headache, and/or chronic migraine with and without medication overuse. The selected trials investigated the efficacy of different pharmacological prophylaxis, of some surgical approaches, of education programmes and osteopathic manipulative treatment; two studies reported longitudinal observations of patients currently under treatment. Overall, the results of our review showed that headache frequency as well as HRQoL and disability were positively impacted by treatment interventions; positive outcomes were less evident in two studies, and similar results were found in the two observational studies. Our findings confirmed that the most commonly used PROMs, including disease-specific tools to assess disability and HRQoL and SF-36, are sensitive to the beneficial effects occurring over time in functioning and quality of life domains in headache patients. They also suggest that the personal and societal costs of headache disorders are likely to be reduced when headache patients receive appropriate treatments and when continuity of care is offered. In terms of future directions, we note that the systematic use of appropriate PROMs should be encouraged both in the clinical practice and in the research field, as they offer a valid option to assess the global effect of treatments on patient-perceived sense of well-being and quality of performance.

Keywords Headache · Patient-reported outcome measures (PROMs) · Disability · Health related quality of life · Review

Introduction

Headache disorders determine relevant reductions in functioning and in quality of life. Recent reviews have been mostly focused on migraine and chronic daily headache (CDH). These reviews showed that migraine substantially impairs a person's functions in different activity domains during attacks and diminishes health-related quality of life (HRQoL) during and between attacks [1], determining difficulties in specific aspects such as vitality, social functioning, mental and physical health [2]. Similar results were found for CDH, which generally causes higher levels of burden and disability as well as more evident HRQoL reduction than episodic migraine, particularly in patients with medication overuse [3, 4].

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Given the relevance of the personal and social burden imposed by headache disorders, the use of patient-reported outcome measures (PROMs) investigating the level of disability and HRQoL have been increasingly used in headache research. Some generic and disease-specific instruments have been used as secondary outcome measures in several clinical trials evaluating the efficacy of both acute and prophylactic medications in headache patients [2–4].

Aim of this review was to address the status of research on disability and HRQoL, by addressing results from recently published clinical trials as well as in longitudinal observational studies on headache patients.

Methods

PubMed has been searched for papers published in 2010–2012 that systematically assessed disability and/or HRQoL in headache disorders. Selection criteria were the following: clinical trials or longitudinal observational papers in which measures of HRQoL and/or disability were used as primary or secondary outcome; studies on adult subjects. Papers were excluded if the primary focus of research was not on headache, if information on HRQoL and/or disability was analysed only with cross-sectional methods, if information was derived from population studies or cases studies.

To ensure quality and consistency of data, abstracts and 20 % of selected full-texts were double checked. Full-texts were analysed for their content and research results are presented with a narrative approach.

Results

In total, 70 records were retrieved, and 12 papers were selected for narrative synthesis. The flow of papers' selection is shown in Fig. 1 : these papers provided data from 2,621 patients with different diagnoses, i.e. episodic migraine with and without aura, CDH, and\or chronic migraine with and without medication overuse. Table 1 provides an overview of selected papers' features and of the main outcome.

There were one trial on onabotulium toxin A [5], three trials on prophylactic medications, one on levetiracetam [6] and two on β-blockers [7, 8]. Four studies described a surgical approach: two were procedures for deactivation of trigger sites [9, 10], one approach was the occipital nerve stimulation [11], and one approach was bariatric surgery for obese patients patients comorbid migraine [12]. Two studies reported short-term longitudinal observations of patients currently under treatment for migraine who were prescribed tailored medications including both acute and prophylactic ones [13, 14]. Two studies presented results of non-pharmacological treatments, the first was based on a

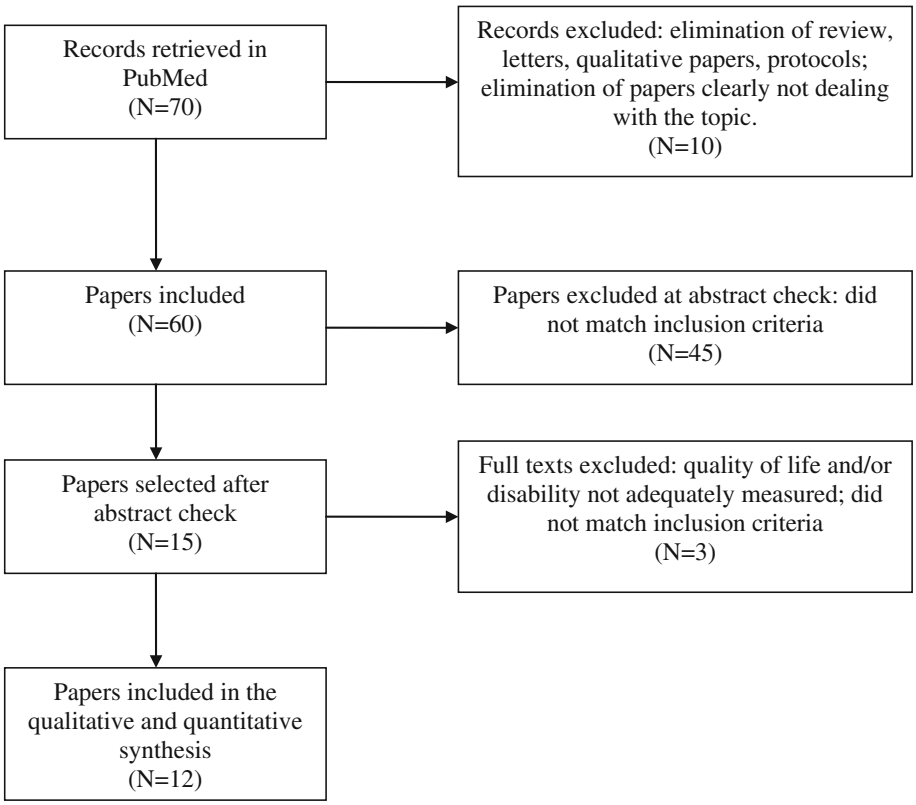

Fig. 1 Flowchart of paper selection

Table 1 Description of included papers

References	Sample description	Intervention	Outcome measures	Results
Dodick et al. [5]	1,384 pts with CM	OnabotuniumtoxinA vs. placebo	HIT-6; MSQ	OnabotuniumtoxinA was effective towards reduction of headache frequency and headache-related disability and improvement of QoL
Holroyd et al. [7]	232 pts with MA and MWA	β-blocker vs placebo vs BMM + placebo vs BMM + β-blocker	MSQ	The addition of BMM and β-blocker, but not of BMM or β-blocker alone, improves optimised migraine care in terms of reduced headache frequency and improved QoL
Smith et al. [15]	284 pts with migraine	Participation to MMMP	HIT-6; MSQ	Patients participating to MMMP reported reduction of headache frequency and disability, improvement in cognitive and emotional aspects of headache management and QoL
Beran and Spira [6]	96 pts with CHD	Levetiracetam vs placebo	SF-36	No significant reduction of headache frequency is shown; only mental health aspect of QoL is significantly improved
Guyuron et al. [9]	69 pts with MA and MWA	Surgical deactivation of trigger sites	MIDAS; MSQ; SF-36	5 years after surgery, patients showed reduced headache frequency, reduced disability and improved QoL
Novack et al. [12]	29 obese pts with migraine	Bariatric surgery	HIT-6; MIDAS	6 months after surgery, frequency of headache and headache-related disability were significantly reduced
Raggi et al. [13]	87 pts with MA and MWA	Standard treatment	SF-36; WHO-DAS-2	Changes over 3 months, in a sample of patients currently under treatment, in disability and QoL were small or negligible
Voigt et al. [16]	42 pts with MA and MWA	OMT group vs control group	SF-36; MIDAS	Although number of days with migraine was not significantly reduced over 6 months, there was a reduction in patients' disability and improvement in QoL
Faber et al. [10]	89 pts with MA and MWA	Surgical deactivation of trigger sites	MIDAS; MSQ	5 years after surgery, patients showed reduced headache frequency, reduced disability and improved QoL, which are accompanied by a relevant cost saving
Raggi et al. [2]	102 pts with MA and MWA	Standard treatment	SF-36; WHO-DAS-2	Headache frequency and severity was stable over 3 months, but small improvement in disability was observed
Seng et al. [8]	177 pts with MA and MWA	β-blocker; BMM; BMM + β-blocker	MSQ; HDI	Patients with comorbidity of anxiety or mood disorders showed larger reduction in headache frequency and improvement in QoL and disability
Serra et al. [11]	30 pts with CM and MOH	ONS	MIDAS; SF-36	After 12 months, patients with ONS device implantation showed a decreased headache frequency, reduced disability and improved QoL

MA migraine with aura; *MWA* migraine without aura; *CM* chronic migraine; *CHD* chronic daily headache; *MOH* medication overuse headache; *BMM* behavioural migraine management; *MMMP* mercy migraine management programme; *OMT* osteopathic manipulative treatment; *ONS* occipital nerve stimulation; *QoL* quality of life; *HIT-6* headache impact test; *MSQ* migraine specific quality of life questionnaire; *SF-36* 36-items short-form survey; *MIDAS* migraine disability assessment; *WHO-DAS II* WHO disability assessment schedule; *HDI* headache disability inventory

patient education programme [15] and the second on osteopathic manipulative treatment [16]. Finally, the two trials on β-blockers also included a behavioural management approach in migraine treatment [7, 8].

The results of these trials showed that headache frequency, patients' HRQoL and disability were positively impacted by preventive treatments with different compounds and surgical approaches as well as by behavioural or educational treatments. These positive outcomes were less evident in two studies: the double-blind, randomised placebo-controlled study on levetiracetam in CDH by Beran and Spira [6] and the randomized study on osteopathic manipulative treatment of female patients with migraine by Voigt et al. [16], In these reports, however, some changes towards improvement in QoL and in disability were observed. Similar results were found in the two observational studies by Raggi et al. [13, 14] in which small changes in QoL and disability were detected over a three-month follow-up period in samples of patients currently under treatment, although headache frequency was substantially stable.

Our review confirmed that the most commonly used PROMs were three disease-specific tools: the migraine disability assessment (MIDAS) [17] and the headache impact test questionnaire (HIT-6) [18], among those investigating disability and impact on daily activities, and

the migraine specific quality of life questionnaire (MSQ) [19] among those measuring the effects on HRQoL. In six studies a generic HRQoL tool, the 36-items short-form survey (SF-36) [20], was also used.

Discussion

This review reported the most recent developments in the field of headache as far as the use of PROMs measuring HRQoL and disability in clinical trials and longitudinal observational studies on headache patients.

Overall, the results of the published reports showed that several interventions aimed to reduce the frequency of headache are likely to have beneficial effects on the level of disability and also of HRQoL. This observation is consistent with the results of a recent literature review [2], focused on migraine, in which the most relevant determinants of improvement over time were the use of disease-specific treatments, in particular symptomatic and prophylactic medications as well as surgery, and the reduction of headache frequency. On the other hand, a trend towards improvement in patient's health status was evident, even in reports in which the frequency of headache was stable over different study periods—for reasons possibly including low efficacy of treatment as well as the fact of being already in treatment.

Some limitations need to be considered in the interpretation of our results, the most relevant being the limited span of period of the present literature research, and the fact that only PubMed has been searched. Furthermore, most of the papers included in our analyses were clinical trials, in which a strong control over study variables was performed. This approach is likely to reduce the ecological validity of our results, as subjects participating in clinical trials are exposed to a situation that is not the same commonly found in daily practice, where clinicians have to deal also with issues such as acceptance and adherence to treatments [21, 22].

Future directions

The results of this study confirm that some disability and HRQoL tools currently used in clinical research can be viewed as sensitive outcome measures in assessing the changes in the impact of headache disorders in patients under specific treatments, as well as in observational studies out of the setting of a formal clinical trial.

Overall our findings suggest that the personal and societal costs of headache disorders are likely to be reduced when headache patients receive appropriate treatments and when continuity of care is offered.

In terms of future directions, we note that the systematic use of PROMs should be encouraged both in the clinical practice and in the research field. The assessment of disability in different domains and of the limitations in quality of life domains may be particularly relevant when dealing with "difficult headache patients" (i.e. those with chronic headache forms and\or medication overuse) in whom classical endpoints, such as number of headache episodes or of headache days, may be not sufficient to offer a valid insight into longitudinal changes over follow-up periods.

This concepts were in fact included in the "Guidelines for controlled trials of prophylactic treatment of chronic migraine in adults" published in 2008 [23], and in a more detailed way in the recently published "Guidelines for controlled trials of drugs in migraine" proposed by the International Headache Society Clinical Trials Subcommittee [24]. In this paper it is stated that "endpoints currently used in migraine trials may not reflect all participants' values and are not appropriate to assess the global effect of treatments on patient-perceived sense of well-being and quality of performance in different roles and daily activities", and that consequently "The use of standardized, validated tools to assess the changes in ability to function and in HRQOL in clinical trials is recommended as secondary endpoints".

A widespread use of PROMs will also allow a better characterization of the information provided by the different tools in order to address the choice of the most appropriate instruments to be used in a particular clinical and research setting.

Conflict of interest The authors certify that there is no actual or potential conflict of interest in relation to this article.

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