

The importance of quality-of-life assessment in the management of patients with multiple sclerosis

Recommendations from the Middle East MS Advisory Group

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ABSTRACT

يؤثر مرض التصلب المتعدد سلباً على نوعية الحياة لدى المرضى المصابين به. وقد قامت اللجنة الاستشارية لمرضى التصلب المتعدد في منطقة الشرق الأوسط بدراسة هذا الموضوع وخرجت بمجموعة من التوصيات. توصي المجموعة بأهمية تقييم نوعية الحياة لدى المرضى على الأقل مرة واحدة سنوياً وذلك باستخدام الاستبيان الدولي لتقييم تأثير التصلب المتعدد على نوعية الحياة والمتوفر باللغة العربية. وأوصت أن لا يُجرى هذا التقييم في فترة انتكاس المرض وذلك حتى يخلو من العوامل المربكة والمخيرة للمريض. أما في خلال الزيارات العادية للمرضى فيوصى إضافةً للفحص الجسدي الروتيني بمراقبة نوعية الحياة لديهم وذلك بتوجيه مجموعة من الأسئلة المباشرة والمتعلقة بمدى تأثير المرض على نوعية حياة المرضى. إن استخدام مثل هذه الأساليب سيسمح بمراقبة المظاهر الأساسية للمرض والمرتبطة بصحة المريض، كما سيساعد أيضاً في عملية اتخاذ القرارات المتعلقة بكيفية علاج المرضى وصراف العقاقير المناسبة لحالتهم.

Multiple sclerosis (MS) has a major negative impact on patients' health-related quality of life (QoL). A group of MS experts in the Middle East met to develop recommendations for the routine assessment of QoL in patients with MS. The group recommended that patients need to be assessed once a year using the multiple sclerosis international QoL questionnaire (MusiQoL), which is available in Arabic. Assessments should be made when patients are relapse-free to avoid confounding factors. At other clinic visits, patients' QoL should also be monitored, alongside their physical assessment, using open and structured questions on disease features that are likely to affect their QoL. This approach should allow long-term monitoring of key features of MS that are important to patients' well being, and aid decision-making regarding their management, including the use of disease-modifying drugs.

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Multiple sclerosis (MS) is a chronic neurological disorder that usually affects young adults, often producing profound effects on patients' physical, cognitive, and psychological well being. Assessment of quality of life (QoL) is by far one of the most important tools used to measure these effects of the disease. At the same time, QoL assessment also helps to monitor both the positive and negative effects of available treatments. The role of QoL in patients with MS was discussed

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QoL and health-related QoL. In 1993, the WHO put forward the following definition of QoL: the perception by individuals of their position in life, in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.¹ The QoL is therefore, a wide-ranging concept that is affected not only by people's health status, but also by their social setting, psychological state, level of independence, and their relationship to the environment in which they live. In studies on QoL in patients, this concept is often restricted to health-related QoL (HRQoL) that is, aspects of QoL that are directly affected by the disease and its consequent treatment, as perceived by the patient.

The burden of MS on patients' QoL. Studies comparing QoL in MS patients with that in the healthy population have demonstrated clear worsening of HRQoL.^{2,3} For example, deficits have been reported in measures of ambulation, dexterity, and pain,² as well as all of the physical domain scores of the Short Form-36 (SF-36) scale.³ Despite the high prevalence of mental-health problems in MS, effects on SF-36 scores for mental health were less clear-cut, because this scale tends to under-estimate the impact of MS on mental health and is less responsive to this measure than MS-specific scales.^{3,4} However, when the RAND-36 scale (which uses the same items but a different method of score analysis) was used in the same study, both physical and mental summary scores were markedly reduced.³ Furthermore, MS is associated with poorer QoL measurements than those found in patients with other chronic conditions.⁵

Key challenges to HRQoL in MS. Apart from the physical status, the Advisory Group discussed a list of other important factors that may affect a patients' QoL, and are known to be overlooked in a

busy clinic. These included the patient's psychological state, sexual dysfunction, pain, vitality, or fatigue, employment difficulties, access to medical care or living arrangements, social support versus isolation, financial problems, and the perception of MS within their community. Assessment of MS patients is usually confined to their physical status and mobility, usually utilizing the Expanded Disability Status Scale (EDSS),⁶ which does not reflect common patient problems in other areas, such as pain, vitality, and fatigue,⁷ and appears to be relatively unresponsive to clinical change.⁸ Therefore, it is not surprising that patient's disability measurement on the EDSS has been shown to correlate only poorly with the overall measures of patients' QoL, although it does predict scores on physical domains of QoL.⁹⁻¹¹ Fatigue, pain, sexual dysfunction, psychological distress, and impairment of cognitive function are also key predictors of worsening QoL in MS patients; even in those with early disease and little physical disability.^{2,12-18} A recent study reported that impairment of mental function was the most important predictor of patients' QoL.¹³ Loss of cognitive function and depression (a common symptom in patients with MS)¹⁹ are likely to affect patients' social functioning and employment status, both of which were identified by MS patients as key QoL dimensions.²⁰⁻²³ These studies demonstrate very well the fact that patients with MS often consider these symptoms to be more important than their physical/mobility impairments, in terms of their general well being.^{11,24-26}

The importance of measuring QoL in patients with MS. The fact that patients and physicians tend to evaluate the impact of a disease differently is well recognized. A meta-analysis of data on QoL assessments by physicians and patients across several diseases showed that patients' and physicians' perceptions of the patients' well-being often diverged, particularly when assessing more subjective, compared with objective, domains of QoL.²⁷ In MS, both patients and physicians assessed the physical disability similarly; however, clinicians tended to prioritize patients' physical dysfunction and were significantly less concerned than the patient with their mental health and emotional role limitations.²⁶ It is important to note that in this study, none of the physical disability measures correlated with patients' overall HRQoL, thus, it has become clear that several aspects of MS that are considered by patients to be at least as important as physical functioning have been relatively overlooked by conventional assessments methods, and that measurement of QoL is essential in the evaluation of patients with MS.²⁸ Furthermore, QoL assessment was found to correlate well with the burden of the disease, reflected by white matter lesions and atrophy on MRI.²⁹

Measuring QoL in patients with MS.

The SF-36 is a commonly used generic (non-disease-specific) QoL scale. It was designed to provide a broad assessment of QoL and allows comparison of QoL in MS with that in the general population, and across diseases.^{3,30} In addition, it was shown to collect significant information not provided by use of the EDSS scale.³¹ Testing of the SF-36 in MS patients has, however, demonstrated some shortcomings, which can only be overcome by supplementing it with an MS-specific scale that can capture additional information unique to patients with MS, such as the MSQoL-54.³² This scale was developed by combining the SF-36 with an additional 18 items in the areas of health distress (4 items), sexual function (4), satisfaction with sexual function (one), overall QoL (2), cognitive function (4), energy (one), pain (one), and social function (one). The final scale comprises 52 items in 12 subscales and 2 individual items, and, like the SF-36, has 2 underlying dimensions of physical and mental health.³³ The MS QoL Inventory (MSQLI) was also developed by addition of disease-specific measures to the generic SF-36 (the 9 symptom-specific measures cover fatigue, pain, bladder function, bowel function, emotional status, cognitive function, visual function, sexual satisfaction, and social relationships).³⁴ The reliability and construct validity of this scale has been well demonstrated in MS patients.³⁴ Scales not based on the SF-36 include the MS Impact Scale (MSIS-29),³⁵ the Functional Assessment of MS (FAMS) QoL scale,³⁶ and the Leeds MS QoL scale,³⁷ which were all developed from patient interviews and expert opinion to produce relevant questionnaire items. The MSIS-29 has been validated in samples of patients both in the community and in hospital, and results have indicated that its psychometric properties are consistent across these populations.³⁸ The FAMS mobility subscale was found to correlate with results from the EDSS, and to correlate well with results from the MSQOL-54.^{6,36} Recently, the MS International QoL Questionnaire (MusiQoL) has been developed (again, from interviews with patients) simultaneously in a number of countries and was validated alongside the SF-36 in patients with MS.³⁹

The effect of treatment on QoL in patients with MS. Data on the effects of disease modifying drugs (DMDs) on patients' QoL in MS has until recently been relatively sparse, and somewhat inconsistent.⁴⁰⁻⁴³ One possible explanation for these results is the burden that currently available DMDs place on patients, particularly at the start of treatment. Most require frequent self-injection, and are associated with common side-effects, such as injection-site

reactions and flu-like symptoms, which necessitate the use of an additional medication such as a non-steroidal anti-inflammatory drug or paracetamol. Their benefits, on the other hand (in terms of relapse prevention) are not immediately obvious to patients. A recent survey showed that patients were most commonly non-adherent to MS therapies for injection-related reasons, and that non-adherent patients also reported worse QoL.⁴⁴ In this context, it is expected that the addition of newer injection devices that can minimize pain of injection, and oral therapies such as cladribine are likely to be associated with better patient QoL. The use of Natalizumab, which does not require frequent self-injection and promotes more frequent contact between the patient and healthcare provider, is reported to be associated with improvements in QoL in both short and long-term assessments.^{44,45}

Measuring QoL in routine clinical practice.

The consensus among the Advisory Group members was that measuring QoL in patients with MS is not routinely carried out in any formal way, and that rating scales were rarely used. Neurologists spend time talking to patients regarding their perception of their current health status, and can form an impression about their QoL, however, HRQoL can only be properly assessed by the patient him/herself.⁴⁰ Thus, patient-completed scales provide a reliable way to obtain information on certain disease aspects that would otherwise go unrecognized.⁴⁶ In addition, the use of a structured form of questioning is likely to provide consistent and more comprehensive data from patients, and improve communication between the physician and patient, as it brings out issues that might not be otherwise discussed.⁴⁰ These data provide feedback for both the physician and patient on the benefits and/or disadvantages of their treatment decisions.⁴⁷ Evidence of benefits may aid patient adherence to the current regimen, whereas reductions in patients' HRQoL may prompt a change of treatment. Key issues for neurologists in this context are how to fit this assessment into a busy clinic schedule and which scale of QoL to use. The challenge of time in the clinic is paramount, especially for neurologists not working from an MS clinic with specialist nursing and proper administrative support. Thus, the time required to administer and complete the QoL questionnaire is an important consideration, as is the number of specific questions on QoL that it is possible to ask a patient during the course of a short clinical interview. Finally, the availability of QoL questionnaires in the local language, and its local reliability and validity are important in the selection of the best scale.

Table 1 - Summary of recommendations of the MS Advisory Group.

- Use the local-language version of the multiple sclerosis international quality of life (MusiQoL) questionnaire to assess patient QoL every 12 months
- This assessment should be made when the patient is relapse-free
- The local-language version of the SF-36 can be used to supplement this measure, if required
- At other clinic visits, ask structured and open questions on patient QoL and disease features that are likely to affect QoL (see Table 2)
- These assessments are to be made alongside the usual, routine monitoring of patients' physical and psychological functioning

Recommendations of the Advisory Group (Table 1). The Advisory Group recommended that patients should be formally assessed, using a validated QoL scale, not more than once each year to avoid artifactual answers as a result of repetition. These formal assessments should be conducted when patients are relapse-free, to avoid confounding effects of relapses,^{12,48} and provide consistent results over time. The Group recommended that routine QoL assessments are made using the MusiQoL, and the SF-36 can be used in addition if supplementary information that can be compared with a normal population is required (for neurologists in the Middle East, both the SF-36 and MusiQoL are available in Arabic.) The MusiQoL is short, consisting of 31 items scored on a consistent 5-point scale, and is patient-administered, so can easily fit into the clinic schedule. The Group also recommended that patients' QoL should be assessed at regular clinic visits, using a set of structured questions (Table 2). Open, but structured questioning will guarantee collection of important information on symptoms that are most problematic for patients, and guard against missing any of them, as patients may not provide such information voluntarily. Thus, it will help to optimize treatment decisions, for the present and the future. It is worth stressing that QoL assessments do not replace, but supplement, the use of conventional measures such as the EDSS.

In conclusion, the HRQoL measurements allow assessment of the impact of a disease on the patient's well being, from their own perspective, which often differs from that of the physician. Multiple sclerosis is a disorder in which both its symptoms and its treatment side-effects may have detrimental effects on patients' QoL. Thus, assessment of their QoL is paramount in planning the management of their disorder. The advisory group recommends that patients should be assessed yearly utilizing the MusiQoL questionnaire,

Table 2 - Key symptoms and features of MS likely to affect patients quality of life, which could be assessed routinely at clinic visits.

- Presence of depression
- Cognitive problems
- Fatigue
- Pain
- Sexual problems
- Problems with/changes in bladder function
- Change in patients' social situation
- Change in patients' employment
- Treatment side-effects

and regularly during routine visits utilizing structured questions on QoL-relevant key symptoms and features.

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