Quality of Life: an Outcome of Care Measure. The Case of Multiple Sclerosis

Outcomes of medical care are changes in health status attributable to antecedent medical intervention. They are usually measured in terms of morbidity, disability, and mortality (1). Chronic diseases impose significant medical, social, psychological, and economic burden on individuals, families, and society. To obtain a more comprehensive understanding of their care and impact, health status measures should be supplemented with information on physical, psychological, and social functioning, i.e., with an assessment of the quality of life (QoL). The World Health Organization defines the quality of life as “the individuals’ perception of their position in life in the context of the culture and value system in which they live and in relationship to their goals, expectations, standards, and concern” (2). There are two approaches to the assessment of QoL: objective and subjective. The objective approach refers to the dimensions of life that all people value or require, such as food, shelter, mobility, and adequate health. If QoL evaluation is to be of value distinct from that of health status assessment, it must be understood from the patient’s perspective, i.e., according to the subjective approach. The subjective QoL, or its synonym “subjective well-being”, is the degree to which people have a positive appraisal and feeling about their life. The use of the terms “appraisal” and “feeling” indicates that subjective well-being has both cognitive and affective features (3). People with disability report a different level of subjective well-being than people without disability: 33% of adults with disability are satisfied with their life in general, compared to 61% of adults without disability (4).

An alternative, more specific term is health-related quality of life (HRQoL), which is the perception of an individual of her or his degree of physical, psychological, and social well being and the effect of illness, disability, and treatment on daily life (5). The 36-item Short Form Health Survey (SF-36) is the commonly used generic assessment tool of health-related quality of life (6). The questionnaire has been translated, adapted to a relevant culture, and validated in 40 different languages; it is the most frequently used measure for assessing health-related quality of life in persons with disability (7); it was useful in QoL studies following amputation of lower limbs (8,9) and in spinal cord injuries (10).

Multiple sclerosis is an acquired, inflammatory, demyelinating neurological illness. It is a chronic progressive condition that affects young adults: its incidence is highest during the third and fourth decade of life, declining thereafter with only less than 5% of cases occurring after the age of 40 (11). It affects 30 to 80 persons per 100,000 population and is the most common non-traumatic central nervous system disease of young individuals. There are three main illness courses: primary progressive, secondary progressive, and relapsing-remitting. Early phases of the disease are often characterized by the relapsing-remitting rather than progressive course and new treatment can modify the course of the disease by keeping diseased individuals in the early stages longer (12). Life expectancy of individuals with the disease has been prolonged (13,14): multivariate analysis of 695 veterans of World War II with service-connected multiple sclerosis showed a median survival from the year of onset to be 33 years for men and 42 years for women (15). Outcome measures for multiple sclerosis were based on neurological examination confined to signs and symptoms, and limitation in everyday activities, particularly ambulation. The Expanded Disability Status Scale (EDSS, ref. 16) is the most widely used instrument in this context. However, since the disease often results in severe neurological disability over the years, in view of the relatively normal life expectancy of persons with the condition, one of the main goals of its medical care is to optimize the patient’s QoL. Moreover, health care costs and quality of care are at the forefront of current debates concerning rapidly expanding new therapeutic means in multiple sclerosis, and stimulate an interest in QoL as an outcome measure. Despite its personal and socioeconomic importance, assessment of QoL in multiple sclerosis has become an area of study only during the last decade (17-20). Eventually, health-related quality of life has received increasing attention by researchers investigating multiple sclerosis (21), is recognized an important outcome in clinical research, and is assessed in many trials of medications for the treatment of multi-
ple sclerosis (22-24). Studies of health-related quality of life in patients with multiple sclerosis consider an individual's own assessment of how medical treatment affects his or her performance of customary and desired roles and activities, including physical, social, and role functioning in addition to general and mental health (25,26). Several researchers have compared the QoL of people suffering from multiple sclerosis with other populations with disability, and all found that patients with multiple sclerosis were significantly less satisfied with their QoL than others, probably because multiple sclerosis produces multiple, distinct problems. Moreover, cognitive dysfunction affects 43-59% of patients with multiple sclerosis and has a negative influence on QoL (27). Patients with multiple sclerosis and accompanying cognitive impairments have been shown less professionally active, more dependent, less socially engaged, and reporting more sexual dysfunctions than those without cognitive problems (28). Also, depression and anxiety are present in 16-48% of patients with multiple sclerosis and adversely affect patients' perception of their disability and their QoL (29,30). Vitality and general and mental health are more important to these patients than physical disability (31). Scores of health-related quality of life in multiple sclerosis in all scales were shown to be lower than in cardiac rehabilitation patients and spinal cord injured (31) and the impact of multiple sclerosis on QoL was greater than that of other illnesses (17,19,31).

The generic SF-36 was used in many studies of QoL of patients with multiple sclerosis (25,26); it compares the relative burden of disease for people with different illnesses. Generic measures are designed to be applicable to anyone and can be compared because they address the same items. Disease-specific measures are designed to be applicable and relevant to a particular illness. Targeted measures are directed at some attribute of a group of people and have the potential advantage of being more relevant and sensitive to small but important differences. It is generally recommended to supplement generic measures with a specific measure whenever possible (7). In some studies, SF-36 was supplemented with health-related quality of life items particularly relevant to patients with multiple sclerosis to produce the disease-specific multiple sclerosis quality of life (MSQoL)-54, the SF 54 (31), allowing generic comparisons, as well as producing detailed multiple sclerosis specific information (31,32). A disease-specific tool may provide additional information regarding QoL in multiple sclerosis sufferers and assist caregivers to gain better insight into the lives of their patients, thereby leading to improved treatment and patient care. Functional Assessment of Multiple Sclerosis (FAMS) sufferers is such specific QoL measure, consisting of four subscales from 0 (poor) to 28 (high) and a thinking and fatigue subscale from 0 to 36 scores (18). The Functional Assessment of Multiple Sclerosis is adapted from the Functional Assessment of Cancer Therapy, with additional items specific for multiple sclerosis. However, it is not well validated and lacks norms (31,33).

Two studies were recently conducted to construct and validate a disease-specific tool for assessment of QoL in patients with multiple sclerosis, one in Israel (34) and the other in England (35). The Israeli "RAYS" scale has 3 subscales (physical, psychological, and social-familial), each consisting of 15 self-report items scored from 1 (best) to 4 (worse), which focus on the week preceding the report. It was found to be a sensitive tool that differentiates patients with multiple sclerosis from healthy subjects and has good internal consistency in all subscales indicating a homogeneity of questions. It is valid and has significant correlations between the Expanded Disability Status Scale and all subscales, thus further supporting its specificity for multiple sclerosis. Thus RAYS provides precise and detailed information concerning the impact of multiple sclerosis on a variety of daily activities. It seems to be a suitable disease-specific tool for measuring QoL in patients with multiple sclerosis (34). The Leeds Multiple Sclerosis scale (35) is targeted at the concept of well being with 8 items representing aspects of the disease that impact most on the well being of the person with multiple sclerosis. It is brief, easy to complete and to administer in clinics or as a postal questionnaire, and was found to be a reliable and valid tool to assess QoL in patients with multiple sclerosis (35).

In addition, assessment of QoL may lead to additional benefits. It may bring to light problems that are amenable to corrective intervention and, relating to the mode and place of treatment or other factors, may result in change of policy and care.

Including one of these disease-specific assessment tools as a measure in both clinical and pharmacological trials and in ongoing evaluations of comprehensive care in multiple sclerosis may assist in defining outcomes in terms of real-life issues. The tools are a construct distinct from the health status and provide an important adjunct to outcome measurement in multiple sclerosis. Self-perceived quality of life is a very significant outcome of care in chronic diseases and its measurement should be of great concern.

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References
7 Hays RD, Hahn H, Marshall G. Use of the SF-36 and other health-related quality of life measures to assess