Quality of life of patients with spinal cord injury in Italy: preliminary evaluation

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Abstract. Quality of life is a complex concept, entailing the person's physical health and level of independence, as well as psychological well-being, social participation and the relationship with specific and relevant aspects of the environment. The World Health Organization encourages the integration of a comprehensive definition of health when examining patient-related outcomes after injury or disease. This study aims at evaluating the quality of life of 130 Italian patients with spinal cord injury, focusing on the associations among functional status and health dimensions elicited by SF-36 questionnaire. The subscale scores that revealed a stronger impact of the lesion were those related to the physical domains, especially for the physical functioning and physical role functioning. Physical functioning scores were significantly different in the acute phase with respect to chronic phase, in inpatients with respect to outpatients and in patients with lower functional impairment versus patients with higher functional impairment. Moreover, the functional impairment influenced significantly physical role, bodily pain and vitality scales. Disease phases also showed significantly different scores for general health. No differences were highlighted between tetraplegic and paraplegic patients.

Keywords. Spinal cord injury, quality of life, SF-36

Introduction

Faced with the ever increasing demands for health services, national health systems have become interested in the effectiveness and cost-effectiveness of health care interventions. Patient-perceived health has become an important outcome of health care, and therefore a measure of effectiveness. An important consequence has been the development and promotion of generic profile measures of health status.

Health status measures are being used extensively in clinical trials, but they have a number of weaknesses for use in economic evaluations [1]. The main approach in health economics and, more in general, in medical decision making, is to value a health status in a single unit of measure known as "quality adjusted life years" (QALYs) [2,3], which reflects both life expectancy and quality of life.

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Actually, the World Health Organization's International Classification of Functioning, Disability and Health encourages the integration of a comprehensive definition of health when examining patient-related outcomes after injury or disease [4]. One of the most relevant disabilities is caused by spinal cord injury (SCI). Typical causes of spinal cord damage are trauma (such as a traffic collision, diving into shallow water, a fall, a sports injury), disease (such as transverse myelitis, multiple sclerosis or polio), or congenital disorders (such as spina bipida). Tetraplegia, also known as quadriplegia, is a paralysis caused by illness or injury that results in the partial or total loss of use of all limbs and torso; paraplegia is similar but does not affect the arms. The loss is usually sensory and motor, which means that both sensation and control are lost [5]. The rehabilitation process following a spinal cord injury typically begins in the acute care setting. Physical therapists, occupational therapists, social workers, psychologists and other healthcare professionals typically work as a team under the coordination of a physiatrist to decide on goals with the patient and develop a plan of discharge that is appropriate for the patient's condition. A primary goal of rehabilitation is to restore, to the greatest possible extent, the physical functioning of an individual after illness or injury.

The aim of this study is twofold: 1) to evaluate the quality of life (QoL) of patients with SCI, focusing on the associations among functional status and health dimensions and 2) to provide a synthetic quality of life index to be used in cost-utility analyses involving SCI patients.

1. Methods

To date, a specific, validated tool for assessing quality of life in patients with SCI is not available to our knowledge. A recent meta-analysis [6] identified the SF-36 questionnaire as the most commonly used QoL instrument in the SCI literature. It has been widely promoted by the International Quality Of Life Assessment project [7] and translations have been developed and validated for more than 60 countries. Anyway, only few studies have evaluated the quality of life of SCI patients through this questionnaire in Italy and these studies involved a limited number of patients [8, 9].

The SF-36 is a 36-item self-administered survey that measures 8 health domains: physical functioning (PF), social functioning (SF), role limitations due to physical health (RP), role limitations due to mental health (MH), general health (GH), emotional well-being (RE), vitality (VT), and bodily pain (BP) [10]. The health domains described in the SF-36 range in score from 0 to 100, with higher scores representing higher levels of functioning or better health. From these scores, two further synthetic indexes may be calculated: physical (PSI) and mental (MSI).

The SF-36 questionnaire was not originally conceived to provide a utility coefficient (U), i.e. a single value that can be directly used to calculate QALYs. However, as for other similar scales, a number of mapping functions have been developed to convert its scores into a utility value. For this study we applied the algorithm developed by Brazier and colleagues [11].

The SF-36 questionnaire has been administered to 130 SCI patients treated at the Spinal Unit of Maugeri IRCCS Foundation. Patients were recruited consecutively from January 2013 to January 2014. Spinal cord injuries were classified as complete and incomplete by the American Spinal Injury Association (ASIA) classification [12]. The ASIA scale grades patients based on their functional impairment as a result of the

injury, grading a patient from A to E where: A = Complete: no motor or sensory function is preserved in the sacral segments S4-S5; B = Incomplete: sensory but not motor function is preserved below the neurological level, including the sacral segments S4-S5; C = Incomplete: motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3; D = Incomplete: motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more; E = Normal: motor and sensory functions are normal.

A Microsoft Access database has been developed to collect patients' personal data (age, gender, disease phase – acute/chronic, ASIA grade – A or B/C or D, paralysis type – tetraplegia/paraplegia, patient status – inpatient/outpatient, cause of the lesion – traumatic/not traumatic). A user-friendly interface has been designed to input all the questionnaire responses and to implement the conversion algorithm that calculates for each questionnaire the scores of the 8 SF-36 scales plus two synthetic indexes, physical and mental (Figure 1). For the utility coefficients calculation an Excel file delivered by Brazier and colleagues was utilized.

Figure 1. User-friendly interface for data input (A) and data elaboration (B)

Respondents' quality of life was evaluated comparing the distributions of all the scales in different groups of patients (Mann-Whitney test) related to gender, disease phase, ASIA grade, paralysis type and patient status.

2. Results

At the time of the questionnaire administration, 82 out of 130 patients were hospitalised while the remaining 48 were outpatients. Sixty-six patients presented a traumatic spinal cord injury and sixty-four non-traumatic injuries/illnesses. Median age was 54 years in men and 60 years in women. Patients in acute phase of disease were 36. Patients distribution between ASIA categories was well balanced (75 patients were ASIA A or B).

Values for the ten SF-36 health domains ranged from 0 to 100 except for MH that ranged from 4 to 100. Utility coefficients ranged from 0.319 to 0.965. Table 1 reports mean values and standard deviations (SD) of the health dimensions for the whole population and for the considered subgroups. The subscale scores that revealed a stronger impact of SCI were those related to the physical domains, especially for the physical functioning and physical role functioning subscales and these results are consistent with those reported in [8]. Statistically significant differences were shown for PF scores in the two disease phases (p=0.01) and the two patient status (inpatient or outpatient) (p=0.005), for GH in the two disease phases (p=0.04), for VT in males

versus females (p=0.048), and for PSI in the patient's status (p=0.032). PF (p=0.033), RP (p=0.008), BP (p=0.032) and VT (p=0.01) scales reported statistically significant differences between two groups with different functional impairment (ASIA A or B versus ASIA C or D). No differences were highlighted between tetraplegic and paraplegic patients as reported in [13]. No correlation was found between the values of the health dimensions and the elapsed time from the spinal cord lesion for the entire group of patients. ASIA C or D subgroup showed a significant inverse correlation between GH score and the elapsed time from the spinal cord lesion (p=0.034). This finding is likely related to the poor prognosis of motor and functional recovery and therefore of personal autonomy.

   With respect to general Italian population [14] (Figure 2), SCI patients show, as expected, very low values concerning PF, RP and BP scales.

Table 1. Dimension mean values (SD) for all the patients and for the considered subgroups

Variable	All patients	Acute phase	Chronic phase	ASIA A or B	ASIA C or D	Outpatients	Inpatients
PF	19.04 (24.54)	13.06 (23.88)	21.33 (24.52)	15 (21.01)	24.55 (27.93)	27.81 (28.64)	13.9 (20.26)
RP	47.5 (44.01)	41.67 (41.4)	49.73 (44.98)	56.33 (43.71)	35.45 (41.86)	55.73 (43.83)	42.68 (43.65)
BP	50.69 (30.66)	45.39 (29.96)	52.72 (30.85)	55.81 (30.8)	43.71 (29.32)	54.9 (27.17)	48.23 (32.44)
GH	56.37 (24.46)	63.5 (21.69)	53.63 (25.01)	56.57 (24.31)	56.08 (24.89)	56.1 (26.05)	56.52 (23.65)
VT	55.85 (24.45)	53.19 (24.76)	56.86 (24.38)	60.67 (22.87)	49.27 (25.19)	56.77 (23.6)	55.3 (25.06)
SF	70.1 (30.12)	62.85 (34)	72.87 (28.2)	71.33 (29.48)	68.41 (31.17)	73.7 (29.2)	67.99 (30.62)
RE	66.15 (42.53)	64.81 (41.36)	66.67 (43.17)	71.11 (40.02)	59.39 (45.22)	70.83 (42.73)	63.41 (42.43)
MH	66.12 (23.24)	64.78 (22.58)	66.64 (23.58)	67.73 (22.85)	63.93 (23.8)	69 (22.35)	64.44 (23.72)
PSI	30.99 (9.95)	29.67 (8.44)	31.49 (10.47)	31.45 (9.41)	30.36 (10.69)	33.38 (10.82)	29.59 (9.18)
MSI	52.4 (13.59)	51.67 (12.55)	52.68 (14.02)	54.05 (13.7)	50.16 (13.23)	52.98 (13.55)	52.07 (13.68)
U	0.62 (0.14)	0.59 (0.15)	0.63 (0.14)	0.63 (0.15)	0.6 (0.13)	0.65 (0.14)	0.6 (0.14)
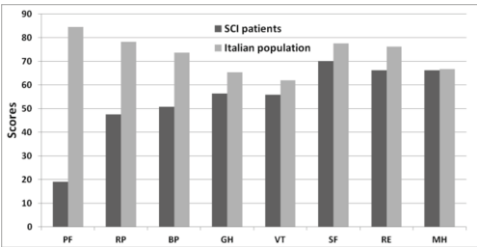
Figure 2. Scales mean scores for SCI patients and for Italian general population

3. Discussion

Achieving an adequate quality of life is considered the final goal of the rehabilitation process following a SCI and the need for outcome measures assessing health and

quality of life following rehabilitation is therefore becoming increasingly important. Since improved quality of life is indicative of the success of treatment programs, it should be routinely measured among SCI patients. The present study develops reflections on the perceived quality of life of 130 SCI Italian patients and, even if the sample size is quite small, the reported results are consistent with the ones already published.

Although in rehabilitation medicine the SF-36 questionnaire has been widely used for patients with SCI, these current measures could be insufficient to represent their serious disability because many items were developed for use in the general population. An example can be related to PF subscale which includes 3 questions referring to walking and 2 others that are related to climbing stairs. The questions posed in these terms may lead to an underestimation of the subscale scores regarding the physical functionalities. To overcome this issue, a modified version of the SF-36 questionnaire can be implemented as proposed in [15] where concepts like "climbing stairs" and "walking" are replaced with the word "going". Further researches are needed in this direction to develop valid and reliable instruments to assess the health status in people with SCI.

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