Disability may influence patient willingness to participate in decision making on first-line therapy in multiple sclerosis

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Summary

Patient autonomy is a concept that implies variable degrees of patient participation in different aspects of health and healthcare, including the choice of therapy. This study, conducted in patients with multiple sclerosis (MS), examined several factors in relation to the patient's role in the therapeutic decision-making process.
One hundred newly diagnosed patients with MS attending their first ever specialist consultation at the MS center of Catania, Italy, were consecutively enrolled in a single-center, open, observational study. Clinical and demographic data were collected as part of this routine first consultation. Through administration of the Control Preferences Scale, we ascertained the patients' willingness to participate in the decision-making process on their first-line treatment, classifying them, on the basis of their attitude, as passive, collaborative or active.
Of 100 patients with MS, 40 had a passive attitude, while 35 were willing to collaborate and 25 wanted to play an active role in the decision-making process. The patients showing an active attitude had a significantly higher Expanded Disability Status Scale score and a significantly higher number of relapses ($p<0.5$ for both) than those who showed other attitudes.
Persons with MS prefer to know the benefits and risks related to the first-line treatment. Those with higher disability prefer to be active in the decision-making process.

KEY WORDS: first ever consultation, multiple sclerosis, multiple sclerosis therapy, shared decision-making process

Introduction

Patient-centered care is a complex approach within the healthcare system that focuses on the provision of care that is respectful of and responsive to individual patient preferences, needs and values, and which seeks to ensure that patient values guide all clinical decisions (Wilson et al., 2014). Shared decision making (SDM) is a cornerstone of patient-centered care: health decisions should be made jointly by the health professional and the patient, and they should be based on the best available evidence and on patient values (Charles et al., 1997). In recent years, increasing evidence has shown that patient-centered care and SDM are associated with increased patient satisfaction and empowerment, less decisional conflict, less treatment non-compliance, less medical litigation, and a stronger patient-physician alliance (Heesen et al., 2007).
Multiple sclerosis (MS), a chronic disease of the central nervous system that typically occurs in young adults, and affects women two to three times more frequently than men, is a paradigmatic disease for the study of patient-centered care and SDM, because patients with MS are highly aware of their disease (Wilson et al., 2014; Heesen et al., 2013).
We assessed the willingness of newly diagnosed patients with MS to participate in the treatment decision-making process.

Materials and methods

From January 2013 to February 2014, a total of 115 patients with MS were consecutively admitted to the tertiary MS center of Catania, Italy, for a first ever MS consultation. At the time of the consultation, all the patients were naive to any licensed therapy for MS (Wingerchuk and Carter, 2014). MS was diagnosed according to the 2005 McDonald criteria (Polman et al., 2005). Patients eligible for inclusion in this study were aged 18 years or older and able to understand and give informed consent.
As part of the first consultation, clinical and demographic data, including details of education and employment status, were collected. Participating patients were administered the Control Preferences Scale (CPS). The CPS was developed to evaluate the

preference of an individual regarding his/her involvement in healthcare decisions (Degner et al., 1997). It consists of five cards, each illustrating, through a cartoon and a short descriptive statement, a different role in decision making: the examiner asks the subject to choose his/her preferred card, which is then covered up; the examiner then asks the subject to choose his/her preferred card from the remaining four cards. The procedure continues (for a total of four choices) until one card is left. If the second preference is incongruent with the first (non-adjacent pairing, such as card A with card C), then the test is explained again, and re-administered. In the event of further incongruences the test is abandoned. The test has six possible results, based on the person's two most preferred roles. These results are collapsed to: "active'' (active-active or active-collaborative), "collaborative" (collaborative-active or collaborative-passive), or "passive" (passive-collaborative or passive-passive). We used the Italian version of the CPS (Giordano et al., 2008). Disability was assessed using the Expanded Disability Status Scale (EDSS) (Kurtzke, 1983), administered by a trained neurologist, and the number of relapses since clinical onset was recorded.

All the patients in the study sample gave their written consent to participate. The protocol was approved by the local ethics committee.

Statistical analysis

The Shapiro-Wilk test was used to verify the normal distribution of the continuous variables. Descriptive statistics were calculated in the total sample of patients with MS and in the sample divided into two subgroups on the basis of preferred level of participation in the decision-making process on the first-line MS treatment (passive and collaborative-active). Demographic (gender, age, education, marital status, employment status) and clinical characteristics (age at onset, age at diagnosis, disease duration, MS phenotype, EDSS score, number of relapses) were compared between the two subgroups using the chi-square test or the Mann-Whitney U test as appropriate. The main results were reported by means of frequency distribution graphs. Statistical analyses were performed in SPSS Statistics, Version 22. Significance was accepted as $\alpha \leq 0.05$.

Results

Of the 115 patients approached, 15 refused to participate in the study. Lack of time was the most frequent reason given for refusal. Table I shows the demographic and clinical characteristics of the whole group of participating patients, and of the patients divided into three subgroups (passive, collaborative, active) on the basis of their preferred level of participation in the decision-making process prior to the start of the first-line MS treatment. Demographic characteristics were similar across the three subgroups (Table I).

Forty of the 100 patients with MS preferred to be passive in the decision-making process regarding the first-line treatment, 35 preferred to share in the process ("co-participation"), while the remaining 25 expressed a willingness to have an active role. The subgroup analysis of the passive, collaborative and active groups showed that the active group had a higher median EDSS score and a higher mean number of relapses than the other groups (Table I).

Discussion

Patients with MS should be regarded as partners in medical decision making. Our study investigated the patients' willingness, at the first specialist consultation, to participate in the therapeutic decision-making process. Interestingly, factors such as years of education and employment status did not seem to influence willingness to receive health information (another aspect investigated by the CPS). A higher EDSS score and higher mean number of relapses influenced the taking of an active role in SMD. Clinicians know that patients with more "active MS" appear more worried about their disease, possibly because they are more fearful regarding its evolution; this may lead them to show more engagement in their own healthcare. More studies seeking to shed light on the issues that influence patient engagement in MS are needed.

Previously, a collaborative role was found to be preferred by Italian MS patients (who varied in clinical and general characteristics) (Giordano et al., 2008). The patients' cognitive styles and personality traits were not routinely investigated in depth. However, no patient suffered from psychiatric symptoms or cognitive decline or showed limitations in daily social functioning. In advanced stages of MS, when patients may present cognitive deficits and/or altered decision-making abilities and emotional reactivity or psychiatric symptoms, patient participation in decision making may seem impossible. Further studies are needed to clarify the impact of decision-making abilities and emotional reactivity on MS treatment decisions.

These interesting data need to be confirmed in prospective studies that could evaluate the importance of worsening disability (and its management) and relapses (in terms of frequency and severity) as modulators of MS patients' willingness to be involved in SDM.

Patient autonomy has been stressed as the ideal concept for medical decision making. MS could represent a prototypical condition for studying this approach, both because the disease affects young people who are highly disease aware, and also because the available treatments can have side effects (particularly in second- and third-level therapy) (Utz et al., 2014).

In recent years several studies have outlined communication and information deficits in the care of patients with MS (Wilson et al., 2014). Tools such as question-

Table I - Demographic and clinical characteristics of participants by total group (A) and decision-making subgroups (B).

	Total group	Decision-making subgroups			p-value
	n=100	Passive (n=40)	Collaborative (n=35)	Active (n=25)	
Sex M/F	40/60	18/22	14/21	8/17	n.s.
Age (yrs)	33.4±10.3	33±9	33±10	34±12	n.s.
Age at onset (yrs)	29.7±9	30±8	30±7	29±10	n.s.
Age at diagnosis (yrs)	32.9±10.2	33±9	33±8	33±12	n.s.
Disease duration (yrs)	4.8±3.9	4±3	4±4	4±5	n.s.
Education(yrs)	11.9±4.3	11±4	11±5	12±5	
Years of education, n					
≤ 8	38	18	10	10	n.s.
8-13	39	16	13	10	
> 13	23	6	12	5	
Marital status, n					
Single	47	18	15	14	n.s.
Married	53	22	20	11	
Employment status					
Unemployed	41	18	13	10	n.s.
Working	59	22	22	15	
Type of MS, n					
RMS	89	36	30	23	
PMS	11	4	5	2	n.s.
Relapses	3.4±2.5	2.8±1.6	2.3±1.8	4.1±3.0	p<.05
Median EDSS score	1.7	1.2	1.4	2.1	p<.05
EDSS score subgroups, n					
< 4.0	90	30	25	18	n.s.
≥ 4.0	10	10	10	7	

Abbreviations: M=male; F=female; n=number; yrs=years; MS=multiple sclerosis; RMS= relapsing MS; PMS= progressive MS; EDSS= Expanded Disability Status Scale. Data are frequencies or mean ± SD.

naires designed to assess knowledge of the disease and the feeling of involvement and participation in medical processes have been developed for MS patients (Wilson et al., 2014). Clinical trials have been performed to validate batteries of tools designed to analyze different steps in SDM in MS in order to help to benchmark knowledge and compare the decision-making process in different healthcare settings or different countries and cultures. The SIMS-Trial was performed in five Italian centers and it showed that information in newly diagnosed MS patients improves disease knowledge and satisfaction with the patient-physician relationship (Borreani et al., 2014).

However, it is not entirely clear whether patients really want to participate, whether they really do share decisions, or whether they just want to feel that they are involved. We also do not yet know which other clinical factors (related to the MS itself) influence the decision-making process. Our findings may be helpful in addressing prospective randomized clinical trials in order to better study DSM in patients with MS.

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