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Suspected multiple sclerosis – what to do? Evaluation of a patient information leaflet

C Heesen¹, N Schäffler¹, J Kasper^{1,2}, I Mühlhauser² and S Köpke^{1,2}

Background Parallel to the establishment of early treatments in multiple sclerosis (MS), new diagnostic criteria have made an earlier diagnosis possible. While there is ongoing discussion about possible benign courses and only partial effective treatments, there have been no attempts today to facilitate shared decision making on diagnostic testing between patients with suspected MS and their physicians.

Objective This study describes the development and validation process of a leaflet to be presented to people with suspected MS to engage them in a diagnostic decision-making process.

Methods After a qualitative study showing acceptability among five patients, the leaflet was presented to a retrospective cohort ($n = 87$ of which 70 replied) of patients being diagnosed within the last 2 years as well to a prospective cohort of $n = 51$ patients with symptoms suggestive of MS.

Results Approximately 70% of patients in the prospective as well as in the retrospective cohort wanted to be informed about a possible MS before testing, whereas 10% did not. The leaflet did not seem to elicit anxieties. The attitude to undergo diagnostic testing was not influenced by the leaflet, which can be explained by the nonexperimental design of the study.

Conclusion Taken together, our findings demonstrate that early information about possible MS is warranted by patients and does not show negative side effects. Further studies on evidence-based patient information in early MS seem necessary. *Multiple Sclerosis* 2009; 15: 1103–1112. <http://msj.sagepub.com>

Key words: anxieties; diagnostic tests; evidence based patient information; multiple sclerosis; shared decision making

Introduction

Patients with symptoms suggestive of multiple sclerosis (MS) and also physicians are increasingly confronted with MS management guidelines, claiming an early diagnostic workup in any symptom situation suggestive of MS. Recently, an international expert panel developed a new criteria for the diagnosis of MS, the so-called McDonald criteria [1,2]. Compared to the formerly used criteria, the new criteria allow diagnoses for very early MS, even as early as after a first clinical episode suggestive of MS. They classify definite and probable MS and strongly emphasize magnetic resonance imaging (MRI) patterns making the criterion of dissemination in time, independent of clinical symptoms through MRI

follow-up. The new diagnostic criteria have been inaugurated parallel to the development of disease-modifying agents in MS. Immunomodulatory agents have been shown to delay a second episode of the disease for about 12 months in 14% of patients treated with beta-interferons [3]. As a result, early diagnosis of symptoms suggestive of MS has been strongly emphasized to enable early immunomodulatory treatment. Presently, long-term effects of these very early interventions are not clear [3]. In fact, follow-up data of these studies comparing early and 2-year delayed treatment up to 5 years of follow-up do not allow for definite conclusions about the gain of very early treatment in all patients with possible MS [4,5]. At the same time, discussion is ongoing whether a benign variant of

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MS exists and if so, how large this cohort of patients might be [6]. Also, in the situation of a first clinical attack, there are no strong clinical or paraclinical prognostic markers for long-term disability development [7]. Against this background, obligatory early diagnostic testing in any symptom situation suggestive of MS is questionable. Also, any decision on early disease management depends on a subjective weighing of data and calls for enabling patients to make informed decisions in a shared decision making encounter with their physicians [8].

It has been claimed that it is not sufficient to judge the value of diagnostic tests on the basis of test accuracy and validity. More importantly, the value of diagnostic testing should be based on subsequent improvements in patient-relevant outcome parameters [9]. Studies on the accuracy of early diagnostic procedures in MS have so far failed to show satisfactory results [10]. In the largest multicenter study [11] with 532 patients, McDonald MRI criteria [1] had a sensitivity of 49% and a specificity of 79%. Furthermore, the efficacy of diagnostic tests in MS for patients' well-being is still unknown as impact of the tests on clinically relevant endpoints has never been investigated. Randomized controlled trials are warranted according to evidence-based methodological standards on the evaluation of diagnostic procedures [12,13].

Nevertheless, they have rarely been performed in the evaluation of new diagnostic tools in any disease. Ideally, a new diagnostic test would lead to prompt therapeutic measures that should positively influence relevant health outcomes and result in considerable improvement in mortality, morbidity, symptom control, or quality of life [9,12]. This view on the value of diagnostic tests might contradict patients' and clinicians' intuition that results of diagnostic tests are always valuable, particularly if the test is not painful and without directly tangible unwanted side effects.

Patients should be involved in all medical diagnostic and therapeutic decision-making processes, which has recently been underlined again by the British General Medical Council in 2008. Earlier studies in MS patients on decision making have shown considerable autonomy preferences [14,15]. Furthermore, recent work by our group has shown that patients are able to cope with evidence-based patient information without being troubled by the presentation of scientific uncertainty [16]. On the other hand, there are substantial information deficits on people with MS; especially in the situation of diagnosis disclosure [17]. As a major deficit, patients reported the lack of communication about a possible MS diagnosis at the stage of diagnostic testing.

Participation of patients in any medical decision making, which also includes decisions about diagnostic procedures, has been recommended [18,19].

However, in daily clinical practice, diagnostic procedures are often performed implicitly without discernible decision-making processes.

To allow patients to participate in decision making about MS diagnostic testing, we developed a short patient information leaflet. In particular, it was intended to raise patients' awareness to the fact that the diagnostic process is not an implicit automatism. We aimed at providing patients with information to support informed choice in the early stages of the diagnostic process. Therefore, the information had to be as concise as possible. While we considered criteria of evidence-based patient information such as balanced presentation, reference to the best current evidence, and readability [20], the information was not developed as comprehensive evidence-based patient information. We expected the information to emphasize that a decision, whether to undergo diagnostic tests or not, has to be made. We furthermore postulate that by outlining the pros and cons of early diagnostic tests, the intervention leaves the decision more difficult but without increasing worries and concerns. This corresponds to the concept of shared decision making, putatively making decisions more difficult with an increased knowledge of uncertainties and risks [21].

Methods

Development of the information leaflet (Appendix 1)

A leaflet "Suspected MS – what to do?" was developed for patients with symptoms suggestive of MS to be distributed before a decision about diagnostic testing was made. Considering the limited time-frame available to read the information, it had to be short and clearly laid out. Because the suspicion of MS is perceived as a shock by most patients, we also took into account that information processing might be limited due to the emotional involvement. An expert panel defined seven essential aspects to be communicated to patients in this situation: first, patients need to know that there might be a large percentage of benign courses of the MS. Second, few patients realize themselves as participating in a decision making, when treatment decisions are to be made [22]. As even fewer patients realize that there is a choice whether to perform diagnostic testing or not, it is important to emphasize that there is a decision to be made. Therefore, the leaflet needs to make explicit that a decision concerning diagnostic testing has to be made. Third, as a prerequisite of evidence-based patient information and patient decision aids, possible risks, and benefits of the measures in question

have to be characterized [20,23]. Obviously, it is easier to imagine advantages of an early diagnostic procedure than disadvantages, although these clearly exist, irrespective of the result of the diagnostic test. In the leaflet, it is emphasized that a MS diagnosis might have negative psychological impact especially if no obvious symptoms occur for years. On the other hand, existing symptoms might become explained and the additional life risk factor of an evolving disease could be helpful for further life planning. Fourth, the uncertainty of prognosis, which has to be faced and communicated: even if a MS diagnosis is made, any assumption about individual prognosis is very difficult. Fifth, accuracy of the diagnostic procedures at this stage of suspected MS must be tackled. Therefore, the leaflet emphasizes that diagnostic testing might not definitely rule out MS or a possible MS diagnosis in the future. Sixth, possible benefits and risks of early treatment are compared with delayed treatment initiation. Finally, components of diagnostic tests such as MRI and lumbar puncture are explained. Considering these aspects, a first draft of the leaflet was prepared by NS and JK. The draft was reviewed using the feedback of CH, IM, and SK. The second draft comprised 775 words.

Evaluation of the leaflet

The leaflet was evaluated in three steps. First, we performed in-depth interviews with patients currently in the diagnostic process in May 2007. Second, the leaflet feasibility was evaluated by a questionnaire that was mailed to all MS patients who had had a diagnosis of MS during the last 2 years and presented to our clinic in 2006 or 2007 (retrospective cohort). Patients not responding within 4 weeks were sent a reminder letter with a second questionnaire. Third, a slightly modified questionnaire was presented to consecutive patients presenting to our MS clinic between June 2007 and June 2008 with symptoms suggestive of a first manifestation of MS (prospective cohort). Patients received the information leaflet and the questionnaire during their first encounter to our clinic.

Interview study

Five in-depth interviews were performed by NS under supervision of JK. Interviews took 45–60 min. The interviews used the think aloud method [24]. The interviewer led the patient through the leaflet sentence by sentence, reading them aloud, and listened to the patient's thoughts and comments. First, we assessed readability and immediate processing. Apart from understandabil-

ity, we evaluated whether the leaflet increased concerns and anxiety. Furthermore, we assessed whether the leaflet increased the difficulty of decision making by making the option of diagnostic decision making explicit and emphasizing the potential negative impact of an early diagnosis of a possibly benign MS.

Questionnaire study

A questionnaire was designed to evaluate the patients' perception of the information by implying the results from the interview study. The questionnaire survey was conducted based on the assumption that few patients who enter the diagnostic process are explicitly informed and that a decision on diagnostic testing is pending. Also, we assumed that the patients to prefer information about a possible MS before diagnostic testing. We hypothesized that the leaflet would be considered a new, understandable, and relevant piece of information. Concerning the impact of the leaflet, we postulated that the instrument might increase the difficulty to make a decision on diagnostic testing, but on the other hand would not increase anxiety levels by stressing the possible benign courses. Finally, we believed that patients would recommend the flyer to other MS patients.

Two versions were prepared for a retrospective and a prospective cohort. Items covered demography and disease-related data. Patients' role preferences for medical decision making were assessed using the Control Preference Scale [14,25]. As an indicator of patients' cognitive coping style, their attribution of disease-specific risk was assessed by asking the patients to compare their estimated risk of becoming wheelchair bound within 2 years with fictive age and disease state matches. This approach was used by Janssens, *et al.* [26] in a study evaluating risk perception of MS patients. Estimating the own risk higher than that of a matching person indicates a problem-sensitive and pessimistic coping style. Downsizing the own risk indicates a more repressive coping style.

Direct emotional responses to the leaflet were assessed by visual analog scales (VAS) by applying a set of formerly used items [16,27]. Five dimensions were assumed relevant for emotional appraisal of evidence-based patient information: familiarity, understanding, relevance, emotional arousal, and certainty. These dimensions were presented by labeling the extreme poles with pairs of corresponding adjectives. Responses were ascertained as percentage scores, which represented the proportion of the distance between the two poles.

In contrast to the prospective cohort, in the retrospective cohort, we assessed the status of

diagnosis (definitive or probable MS) and actual emotional or physical burden of the disease. Patients' subjective reviews of their diagnostic process were investigated by assessing adequateness of timing, reports of delayed diagnostic procedures, and setting of diagnostic procedures. In the retrospective cohort, we did not evaluate the extent of increased worries and concerns or the perceived helpfulness of the leaflet for the decision-making process. Instead, patients were asked whether they would have liked similar information before diagnostic testing. Also we asked if they considered communication of uncertainties of the MS diagnostic procedure as important. Patients in both the cohorts were asked whether they would recommend the information to other patients, and in an open question, what they considered the most relevant information of the leaflet.

Statistical analyses

Data were documented and analyzed using SPSS 15.0 (SPSS Inc., Chicago, Illinois). Responses to the items presented by use of VAS were ascertained as percentage scores, which represented the proportion of the distance between the two poles. Scores were then projected on a minus 50 to plus 50 scale. Descriptive data were analyzed with mean and range values. Pearson correlation coefficients were calculated between risk attribution scores and emotional response scores from VAS.

Results

Interview study

Transcripts of the interviews were analyzed by NS and JK for statements with reference to the three domains uncertainty, information needs, and support provided by the leaflet. Excerpts were then discussed with CH and SK. On the basis of the results, no modification of the leaflet was considered necessary (for selected comments see Appendix 2).

General comment

All patients found the leaflet to be understandable and considered the extent of information as adequate.

Uncertainty

Patients appraised the openness of the leaflet addressing the many uncertainties.

Information needs

Patients liked the positive information that up to one-third of patients might have a benign course. In general, patients critically commented that previous encounters did not mention a possible MS or did not address patients' feelings or did not give information about the disease. It was positively remarked that the leaflet informed about diagnostic tests, as some patients reported considerable concerns and worries about MRI and lumbar puncture.

Support provided by the leaflet

As pros and cons of diagnostic testing are equally addressed in the leaflet, patients did not feel pressed to go into one direction.

Critique

One patient critically mentioned that the performance and value of evoked potentials are not addressed in the leaflet. Another patient pointed out that suggestion on how to handle negative test results is missing. Explanation of the McDonald diagnostic criteria was considered not clear enough by another patient. Nevertheless, we chose not to expand the leaflet as the relevance of evoked potentials is not high. Also, we decided not to expand the passage on negative findings as it is already pointed out that negative results cannot rule out MS in the future. As the McDonald criteria are closely linked to the option of very early treatment, we kept the explanation of those.

Questionnaire study

Prospective questionnaire study

A total of 51 patients were included (for demographic data, see Table 1). Patients who had visual disturbances were 25 (49%), sensory symptoms 7 (14%), presented with pareses 4 (8%), with gait and balance problems 3 (6%), had pain 4 (8%), and had vertigo 2 (4%). At the time of the appointment in the MS clinic, 23 patients (45%) had already undergone MRI, in 23 patients (45%) lumbar puncture had already been performed, and only 6 patients (12%) had not received any diagnostic test. A total of 45 patients (88%) had already been informed through extern or intern neurologists that MS might be a possible diagnosis and 40 (78%) were informed that a decision had to be made about further diagnostic tests. The high frequencies of diagnostic tests, especially lumbar puncture, and of

Table 1 Cohort data

	Prospective cohort (n = 51)	Retrospective cohort (n = 70)
Number of females (%)	34 (66)	56 (80)
Mean age (range)	37 (20–61)	36 (18–72)
Symptom duration before presentation in days (range)	14 (1 day–3 years)	28 (14 days–29 years)
Patients attitude to information about possible multiple sclerosis before testing		
Warranted (%)	35 (69)	46 (66)
Neutral (%)	8 (16)	12 (17)
Not desired (%)	6 (12)	10 (14)

information about a possible MS were due to the fact that in most cases the leaflet was handed out during the first encounter at the MS unit during which a decision about lumbar puncture had usually already been reached.

Most patients (69%) preferred being informed about a possible MS diagnosis before diagnostic testing (see Table 1). The comparative risk item was not answered by 18 patients. Patients who responded (n = 33) attributed themselves to a much lower risk compared to similar patients they were instructed to imagine (mean = 31.7%; range: risk much lower = -50%, risk much higher = +50%). Rating the information in the dimension of content, most patients considered the information understandable and relevant. It was considered relatively new and, in general, sufficient although there was a tendency for claiming more information (see Figure 1). No correlation was found between patients' ways to attribute their risk of further disease progress and the extent by which the leaflet was considered supportive in decision making (r = 0.29, P = 0.11) or reports of emotional arousal to the leaflet (r = 0.13, P = 0.47). Risk attribution was weakly correlated to

rating the information as new (r = 0.38, P = 0.03) and rating the information as too extensive (r = 0.34, P = 0.05).

The information was well-balanced between eliciting anxieties on the one hand and relieving on the other hand. There was no clear effect to judge it as helpful for the decision process (Figure 2). There was no effect on the decision about diagnostic testing, as only one patient decided not to undergo diagnostic tests after having read the leaflet.

Retrospective questionnaire survey

All 87 patients from the database were contacted by mail. Data of 70 patients (80%) who responded were analyzed. Regarding the actual physical burden of the disease, only 11 patients (16%) rated themselves as very impaired and 25 (36%) not impaired at all, whereas on the other hand 15 patients (21%) considered the emotional burden high and 20 (29%) did not feel emotionally impaired at all.

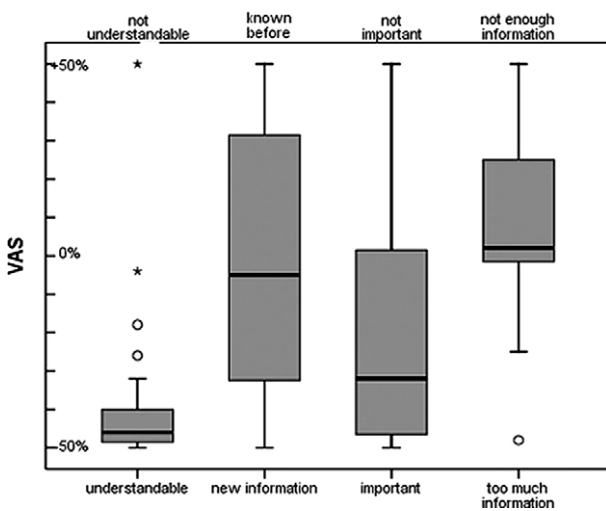


Figure 1 Appraisal of the information (prospective cohort, n = 51); VAS, visual analog scale value. Data in Box Whisker plots with mean values, 25th and 75th percentile, outliers and extreme values.

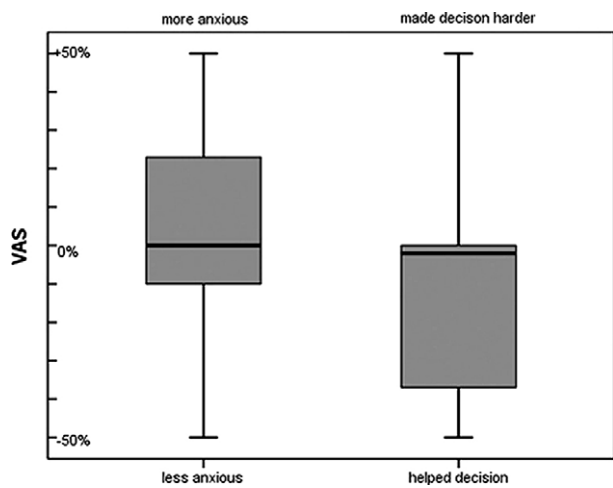


Figure 2 Emotional appraisal and impact on decision making (prospective cohort, n = 51); VAS, visual analog scale value. Data in Box Whisker plots with mean values, 25th and 75th percentiles.

In 62 patients (89%), a definitive MS diagnosis had been established when they received the questionnaire, 7 (10%) were considered probable MS, in 1 case MS had been excluded. Symptom duration before a diagnostic procedure was started showed a considerable variation between some days and 29 years (median = 28 days).

As shown in Table 2, only 60% of patients had been informed to some extent about a decision concerning diagnostic tests before these were performed, while the highest rates of giving information were obtained at the UMC. Asking explicitly for mentioning the differential diagnosis MS, 53 patients (76%) were not informed about the suspicion of MS before initial diagnostic procedures (see Table 2).

Similar to the prospective cohort, most of the patients (66%) would have liked information before diagnostic testing. A total of 12 patients previously had decided against a diagnostic test or had delayed diagnostic testing on MS at some occasion. This group of patients did not differ in their reported degree of having been informed.

Regarding the speed of diagnostic testing, 37 patients (53%) rated as adequate, 20 (28%) as quite slow, and 5 (7%) as much too slow, whereas 8 (11%) patients would have liked a more careful evolution of diagnostic tests.

A total of 63 patients (90%) rated the information of the leaflet as understandable or very understandable, whereas 6 patients (9%) rated it as difficult. In all, 63 patients (90%) considered communication of uncertainties to be important ($n = 37$; 53%) or very important ($n = 26$; 37%), only 3 patients (4%) were concerned about the communication of uncertainties.

Combined results

Autonomy preferences were comparable between groups (see Figure 3). Analyzing both the cohorts together ($n = 121$), 62 patients (51%) preferred a shared decision-making approach and 53 patients (44%) opted for an informed choice pattern. Only two patients (2%) preferred a professional as agent style and one patient (1%) a paternalistic interaction style.

In all, 88 patients (73%) would recommend the leaflet to other people with symptoms suggestive of MS, 26 (22%) of the supporters were strongly in favor of this approach, and 15 (12%) would not recommend the leaflet. There were no differences between the prospective and retrospective cohorts.

A total of 78 patients from both the cohorts answered the open question asking for the leaflet's most relevant information. Of these, 16 patients (21%) found the information about the chance of benign course as the most relevant and 12 (15%) rated the information about uncertainties concerning early treatment as most relevant. The description of symptoms and the disease was named by 12 patients and the descriptions of paraclinical examinations, the most important information, were named by 10 patients. Uncertainties in diagnosis and prognosis were named by 10 patients and 2 chose the fact that a decision can be made most relevant. Two patients considered contact data most important and seven patients considered the leaflet giving a good general overview.

Discussion

This is the first study on the feasibility of a partly standardized approach to inform patients about a possible MS diagnosis and the decision on diagnostic testing.

In general, the leaflet was considered understandable and relevant. Although it clearly addresses a possible MS diagnosis for patients with suggestive symptoms, it did not increase concerns. In the interview study, patients positively appraised the frank communication of uncertainties. Patients found the leaflet to provide balanced information about pros and cons of diagnostic testing without suggesting any specific direction. This is an important finding, stressing the approach of evidence-based patient information to provide balanced information about all treatment options including the option to refrain from therapeutic or diagnostic interventions. This kind of information gives patients the opportunity to evaluate the information and make an informed decision considering the evidence and his or her preferences and values [20]. The results certainly do not support the perspective that the information might be perceived

Table 2 Information before diagnostic testing in different settings

	Cohort	MS outpatient clinic UMC	Inpatient UMC	Other hospitals	Private practice
N	70	10 (14%)	18 (26%)	25 (36%)	17 (24%)
Information on decision about diagnostics before testing	43 (61%)	8 (80%)	12 (67%)	13 (52%)	10 (59%)
Information about possible MS before testing	17 (24%)	5 (50%)	5 (28%)	5 (20%)	2 (12%)

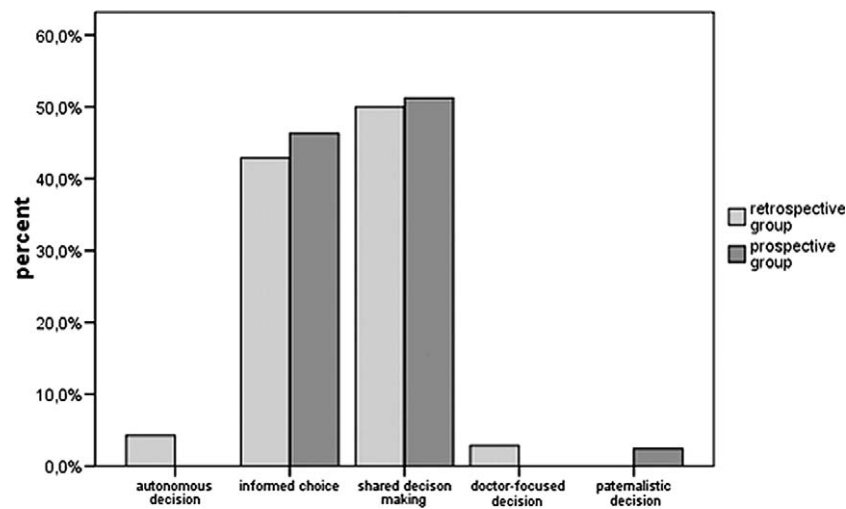


Figure 3 Autonomy preferences in medical decision making in a retrospective recently diagnosed cohort ($n = 51$) and in a prospective diagnostic cohort ($n = 78$); autonomy preferences according to the control preference scale ratings [25].

as advising against diagnostic procedures. This is reflected by the fact that only one patient decided not to undergo diagnostic tests after having read the information.

In the leaflet, the displayed estimated prevalence rate of benign courses seems to counterbalance the given risk of having MS. In contrast to findings of Janssens, *et al.* [28], patients in the current study attributed the 2-year risk of becoming wheelchair-dependent more optimistic although cohort characteristics were quite similar to the cohort of Janssens, *et al.* In both of our cohorts 81 (70%) patients agreed to the idea that a possible MS diagnosis and the consequences of a MS diagnosis should be discussed before diagnostic testing. This confirms findings of our earlier study [17].

For most patients, the option to refrain from diagnostic testing seems an unusual approach. Therefore, our hypothesis was that in the prospective cohort the leaflet would make decisions, on whether to undergo diagnostic testing or not, more difficult. Surprisingly, this could not be shown. Patients rated decision-making neither difficult nor easier after reading the leaflet. Why is this? As a limitation, this study did not control for the attitude of physicians, which might have counterbalanced the message of the leaflet. The leaflet was presented during a first encounter in our outpatient clinic, so any rating had already been influenced by the interaction with an MS physician. Especially in specialized centers with a scientific interest in diagnostic testing, for example, to further classify MS heterogeneity and prognostic markers, physicians usually want to obtain all possible information. On the other hand, the critical attitude toward diagnostic tests and interventions has been a matter of

research and clinical practice in the center since 2001, counterbalancing the attitude of sampling as much information as possible. Of course, this might also have influenced patients' perception of the leaflet, especially in the retrospective group. Furthermore, most patients had already been told that MS was considered a possible diagnosis and 50% of the patients had already undergone some diagnostic tests. Therefore, the leaflet did not meet decision-naïve patients. In fact, the retrospective study showed that even without an explicit information about decision making about diagnostic procedures, 12 (17%) patients had at some point delayed or even refrained from diagnostic tests presumably based on implicit decision-making processes.

As questionnaires in the prospective cohort were filled in anonymously, we have no data on possible differences in the perception of the early information in those who had normal test results in the following.

The patients in the retrospective cohort who thought that the timing of diagnostic steps was adequate were 50% and one-third found the process too slow, a rate similar to the study of Janssens, *et al.* [26]. Therefore, an easily accessible tool to guide the decision-making process on diagnostic tests might help to overcome this feeling of procrastination.

In more than two-thirds of the patients of the retrospective cohort, tests had been performed without information about possible MS. But, as well one-third of patients were not sure if information about a possible diagnosis should be made available to all patients. Further studies should elucidate reasons for this. Maybe for patients with high levels of

anxiety or for children, the concept of early disclosure is not feasible. Indeed, earlier studies have shown that there are high levels of distress and anxiety among MS patients and their relatives accompanied by feelings of isolation and abandonment in the first year after diagnosis [29,30]. To our knowledge, no studies have investigated supportive tools, for example, patient information programs and psychological counseling at this disease stage. By providing these, a more straightforward confrontation with a possible MS diagnosis and the offer of diagnostic testing might be justified.

In conclusion, this study shows that patients with suspected MS prefer standardized basic information addressing the suspected disease and also want decisions on diagnostic testing for MS to be made explicit. The study was designed to explore the ways open for information about a possible MS processed in the routine clinical setting framed by already performed diagnostic tests and clinical appointments. Therefore, we could not quantify the change of attitude toward testing through the leaflet. The results of this study show that the majority of patients should be engaged early in decisions about diagnostic testing and that the diagnostic process should be accelerated, which confirms previous findings in Greece [31]. We conclude that the leaflet could be a helpful tool to initially debrief patients with symptoms suggestive of MS to enable shared decision making about diagnostic testing. Such a tool used in an interactive approach with a two-way exchange of information between patient and physician, that is, a shared decision-making process, might help to tailor diagnostic procedures to individual needs. Combining this early information with a patient education module on diagnostic tests, prognostic markers and the scientific evidence in early treatment might help to enhance patient self-management competences. Supposedly, this approach will decrease anxiety and depression as well as loss of control for patients in the diagnostic process and in the first years of MS. Further research should use controlled trial settings to evaluate the effects and side effects of early information. This should include early individual counseling with evaluated evidence-based information tools in test-naïve patients who had received only a small amount of information earlier. The data presented here support such an approach. Such a study is in progress in a multicenter approach in Italy, the SIMS trial (Effectiveness of a Structured Information Interview in People with Newly-Diagnosed Multiple Sclerosis). Also, a randomized trial using a group education approach in recently diagnosed patients with possible or definite MS, studying effects on risk knowledge, risk perception, and decision making on early treatment (patient education on diagnosis, prognosis, and

early treatment in early MS, PEPADIP) has recently been started in five academic German centers.

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Appendix 1

Translation of the patient information leaflet

Suspected MS...What to do?

Your complaints could be symptoms of multiple sclerosis (MS). Especially, early MS can have many different “faces.” Therefore, one has to consider MS as the possible cause of a number of different com-

plaints. On the other hand, it also implies that your complaints can have other causes. Many people, who are told of the suspected MS, are shocked. First, you should know first that up to one-third of people with MS experience a benign course.

MS is a chronic, lifelong disease of the central nervous system (CNS), which includes the brain and spinal cord. Typically, initial complaints are impaired vision (diplopia, blurred vision), paresthesia (tingling or numbness of arms or legs), or impairment of gait and balance. These complaints are caused by inflammatory focuses and degeneration in certain areas of the brain.

Most commonly MS starts with a “relapsing–remitting” course, where complaints (or relapses) occur from time to time and can disappear again.

There is a decision to be made: do you want further diagnostic testing on MS to be carried out or not?

An early diagnosis gives the opportunity to consider different therapies at an early stage. Still, a MS diagnosis does not mean certainty about how the complaints will develop in future. Even without noticeable impairment, the diagnosis itself can mean a heavy burden. Whereas for others, the diagnosis may come as a relief, as nonspecific complaints can be now called a name and can be taken into account for future life planning. Yet, if diagnostic tests cannot confirm a suspected MS, MS cannot still be definitely ruled out.

A decision against further diagnostics does not have to be final. It can be reconsidered at any times, that is, if new complaints occur. As for now, you will be left without explanation for your complaints.

No one knows for sure, what MS is and what it is caused by. It might even be that all the different manifestations of MS are caused by different disease processes resulting in a similar appearance.

Nevertheless, scientists have agreed on how to establish a diagnosis. If certain criteria are met, the disease can be called MS. To establish a diagnosis of MS, findings of examinations have to be put together like a jigsaw puzzle.

At the moment, since 2001 the so-called McDonald criteria are used. Before, a diagnosis could only be established if a second relapse occurred.

Therefore, the condition of suspected MS sometimes prevailed a long time. By including results of MRI scans into the criteria, a final statement can now be made after only 4 weeks.

A MS diagnosis does not mean certainty about the future disease progression. Normal test results do not mean that MS will never develop.

Apart from a physical examination by a neurologist, further diagnostic tests usually include

MRI scan:

Magnetic resonance imaging pictures show slices of the brain and spinal cord. The examination takes place in a narrow tube and lasts about half an hour. On the MRI pictures, areas of inflammation (so-called lesions) might be detected. Enhancement of contrast agent in these lesions is a sign of active inflammation. Dissemination, number and size of lesions can be suggestive of MS or may indicate other diseases.

Lumbar puncture:

For this examination, cerebrospinal fluid (CSF) and blood have to be taken at the same time. A needle is inserted between the lumbar vertebrae to puncture the fluid-filled dural sack surrounding the spinal cord and let CSF drip out. The procedure itself is not much more straining than taking blood. But side effects, especially headaches might occur. In the laboratory, CSF and blood are analyzed together for MS-specific findings. With CSF analyses, some rare causes of the complaints can be ruled out, i.e. tick-bite disease (borreliosis).

What can you expect of an early therapy?

If a therapy would help is uncertain. There is some evidence for the effectiveness of immunotherapies in MS.

That means: In some patients the occurrence of relapses is delayed by the drugs. Immunotherapy is supposed to positively affect inflammation in the CNS. Not all disease courses of MS involve the same amount of inflammation.

A relapsing–remitting course and lesions on the MRI scan with enhancement of contrast agent indicate a high activity of inflammation. In that case, the benefit of a therapy is more likely.

We do not know whether immunotherapies can beneficially influence the long-term course of the disease. So far, studies could not show positive effects of immunotherapy on permanent impairment in the long term.

For further questions, further decision support, and information, please contact your attending doctor or our MS outpatient clinic.

Appendix 2

Selected patient's comments from the interviews

General comment

“For the introduction it is quite good. Why should I take more information now, if I don't even know yet, if I've got MS or not.”

Uncertainty

“This leaflet's starting point is not coming across with the bad news in the first place. And that everything is a little uncertain.”

“It is not really reassuring, but seems to be honest, what on the other hand I find very helpful.”

“Reassuring by all means, because information always is an advantage. And I am not that worried anymore.”

Support provided by the leaflet

“I find this very good: on the one hand this, on the other hand that. You know, what it is all about [...] and if I don't want to deal with it now, I can still come back to it another time.”