CLINICAL REPORT

New approach to evaluation of clinical state in patients with multiple sclerosis

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Abstract

The authors used a new method of evaluating clinical disability — Multiple Sclerosis Functional Composite (MSFC). Three quantitative tests, for the upper, lower extremities and cognitive functions, were used in 90 multiple sclerosis (MS) patients. The correlation between these results and Expanded Disability Status (EDSS) has shown that in slightly disabled patients there was achieved relatively high correlation especially for the upper extremities function. Their function remains saved for comparatively a long time. During the gradual deterioration of clinical status high correlation between the severity of disability and lower extremities function was achieved. The lowest degree of correlation was observed in cognitive functions, which are monitored more senzitively by MSFC method than by EDSS. The best correlation was revealed in seriously disabled group, not in slight and moderate affections, because EDSS evaluates these functions only marginally and cannot catch discover the beginning of the cognitive deficit. ***(Tab. 1, Ref. 4.)***

Key words: multiple sclerosis, EDSS method, MSFC method, correlation MSFC and EDSS.

Expanded Disability Status Scale (EDSS) has been a traditional clinical rating scale of physical disability and has been used for the outcome measuring of the disease activity in multiple sclerosis (MS) (Cutter et al., 1999). However, the limitations of this scale have been identified for its insuficient evaluation criteria and, therefore, the results fluctuate.

That is why, Multiple Sclerosis Functional Composite (MSFC) has been recently recommended as a new clinical system of measurement for MS. It evaluates quantitatively not only the arm, hand and leg functions, but also cognitive functions. Simple measurements are used, and results have been defined in time units or in number of correct answers. The results are transformed into standardized Z-score values (Recommendations ..., 1997).

We have performed a study to validate the correlation between MSFC and EDSS, and correlation between individual components and EDSS as well.

Methods

In the Department of Neurology, Faculty Hospital, Brno-Bohunice, 90 patients (average age 37.9±7.8), 25 males (average age 37.8±7.5) and 65 females (average age 38.3±8.7) were analyzed during the year 2000. In 10 points disability status scale EDSS in these patients ranged from 1.0 to 9.0. Patients were divided into three groups according to the severity of the disease. The group with slight disability included 54 patients (EDSS 1.0—3.0), moderate disability 22 patients (EDSS 3.5—5.5) and serious disability 14 patients (EDSS 6.0—9.0).

MSFC involves three clinical dimensions and uses three standard tests.

1. Leg function is tested by the measurement of walking speed on a 25-feet long track (7.5 meter). The test is called 25-TWT (Timed 25-Foot Walk). A patient is directed to one end of a clearly marked 7.5 meter course, and he is instructed to walk as quickly as possible, but safely. Later on a walking speed back in the same distance is measured.
2. Arm/hand function is evaluated with 9-HPT (9-Hole Peg Test). It is a quantitative measuring of the upper extremity function — arm and hand. A patient is instructed to pick up nine pegs from a container and put them into holes as quickly as possib-

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le and then to remove the pegs and return them to the container. Both hands are tested twice, the dominant one as the first.

3. The third test is denoted PASAT-3 (Paced Auditory Serial Addition Test) and evaluates cognitive function. On the audiotape there are presented single digits in the intervals of 3 seconds, and the patient must add each new digit to that preceding. The test result is a number of correct sums out of 60 possible. The average values of TWT, 9-HPT and PASAT-3 are transformed into standardized values, Z-scores and MSFC is calculated from these values.
   The general formula for creating MSFC is:

$$MSFC = \frac{(Z\ arm - Z\ leg + Z\ cognitive)}{3}$$

Then the correlation between EDSS and MSFC was performed (Tab. 1).

Tab. 1. The correlation between EDSS and MSFC.

	MSFC	9-HTTP	TWT	PASAT-3
EDSS 1-9	-0.8339	-0.7070	-0.7727	-0.4247
EDSS 1-3	-0.4110	-0.4801	-0.2227	-0.1750
EDSS 3.5-5.5	-0.1118	-0.0179	-0.5466	-0.2302
EDSS 6-9	-0.9110	-0.2288	-0.8329	-0.5569

Results

a) The correlation between EDSS and MSFC is highly significant (r=-0.8339). After evaluating individual parameters, the best correlation was achieved for leg function 25-TWT (r=-0.7727), for arm/hand functions 9-HPT there was achieved a correlation (r=-0.7010) and only (r=-0.4247) for evaluating psychic functions PASAT-3. The correlation between MSFC and EDSS of the whole group is high, for the leg and arm functions it is lower, and for cognitive functions it is the lowest.

b) For slightly disabled group of 54 patients (EDSS 1.0—3.0) good correlation between EDSS and MSFC and hand function was achieved, whereas for leg and cognitive functions it was poor.

c) For moderately disabled group of 22 patients (EDSS 3.5—5.5) there was achieved low correlation between EDSS, 9-HPT, 25-TWT and MSFC. Good correlation was found only for leg functions.

d) For seriously disabled group of 14 patients (EDSS 6.0—9.0) there was achieved the highest correlation between EDSS and MSFC, leg and cognitive functions, but the correlation with arm/hand functions was low. The results of both methods EDSS and MSFC are very similar. The difference can be seen in tests of MSFC. The arm/hand function correlates best in slightly disabled group (r=-0.4801), leg function correlates in moderately and seriously disabled patients (r=-0.5466, e.c. -0.8329). Cognitive functions correlate best in seriously disabled group (r=-0.5569).

Discussion

The clinical expression of disability in MS patients fluctuates across patients and over time and, therefore, the evaluation is very difficult (Recommendations ..., 1997). Important funstional systems — motoric, senzitive, senzory, bowel, bladder, sexual and cognitive functions, are mostly affected. The primary clinical outcome measure for evaluating multiple sclerosis has been EDSS, which assesses cognitive functions only marginally. Therefore, the new clinical outcome measure MSFC was recommended. The MSFC consists of three objective quatitative tests of the arm and hand, leg and cognitive functions. The new method has been verified in the set of 5457 patients (Fisher et al.) and in comparison with EDSS it was shown to be more senzitive in patients in various course of the illness. The reliability is acceptable not only in repeated examinations but also if the examination is performed by two independent specialists. The correlation coefficient for intra and inter examination is 0.97 and 0.95 (Fisher et al., 1999). The new method also includes the test for cognitive functions. Its value was found out to remain stable for a long time in patients with various severity of motoric deterioration. The objective and quantitative assessments have promised perspective utilization especially for the evaluating of MS treatment.

The correlation between results of EDSS and MSFC has proved that MSFC is more exact, because it consists of three quantitative tests. Therefore, it is useful for exact evaluation of the upper, lower extremities and cognitive functions. The reached results promise perspective utilization for the evaluation of the clinical neurological status and also a potential outcome measure for future clinical trials.

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