Reliability of the Thai Version of SF-36 Questionnaire for an Evaluation of Quality of Life in Multiple Sclerosis Patients in Multiple Sclerosis Clinic at Siriraj Hospital

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Background: *To study the application, validity and reliability of a Thai version of SF-36 questionnaires in Thai multiple sclerosis (MS) patients.*
Material and Method: *An evaluation of quality of life using a Thai version of SF-36 was performed in 70 MS or clinical isolated syndrome (CIS) patients.*
Statistical analysis: *Measurement of internal consistency was done by Cronbach's alpha coefficient and inter-item correlation; measurement of The test-retest reliability assessing consistency of the measure was done by Pearson correlation.*
Results: *There were 55 clinical definite MS patients, 12 laboratory-supported definite MS patients and 3 clinical-probable MS patients, according to Poser criteria. MS types were classified as PP-primary progressive MS (2), RR-relapsing remitting MS (59), SP-secondary progressive MS (3) and CIS (6). Internal consistency measured by Cronbach's Alpha exceeded 0.7 except social functions, which was 0.69. The item correlation coefficient ranged from 0.47-0.88. Reliability of test-retest all items determined by Pearson correlation was significant, ranging from 0.84-0.94.*
Conclusion: *Thai version SF-36 questionnaire is reliable for the assessment of quality of life in Thai multiple sclerosis patients.*

Keywords: *Thai, SF-36, Multiple sclerosis, Quality of life*

J Med Assoc Thai 2011; 94 (Suppl. 1): S84-S88
Full text. e-Journal: *http://www.mat.or.th/journal*

Multiple sclerosis (MS) is an inflammatory demyelinating disease of the central nervous system resulting in impairment, disability and handicap in physical activity, social life, as well as mental health.

In 1973, there were only 5 articles listed when searching for publications in the Medline database using "quality of life" as a keyword; during the subsequent five-year intervals, there were 195, 273, 490, and 1,252 of such articles, respectively. In the growing fields of research assessing outcome and health-technology[1], quality of life measurements were incorporated to the evaluation of the efficacy, cost effectiveness and net benefit of new therapeutic strategies in order to determine whether the associated increases in expenditures for health care are justified[2].

Many questionnaires have been developed to fit with patients' conditions in order to accurately evaluating their illnesses. In contrast, SF-36 which is a 36-item questionnaire widely used to and proved to be sensitive in measuring health status by assessing quality of life in various patients groups[3-5]. It is used to measure quality of life in numerous clinical trials[6]. Reference values for this instrument are available from USA and UK population[7].

SF-36 can capture broad effects of MS, showing that patients were also bothered frequently with health problems such as bodily pain and low vitality. These problems, not reflected in the widely used standard scoring system for the disability in MS patients (Expanded Disability Status Scale:-EDSS), should receive more attention when treating patients and when evaluating the interventions[8].

The 36 items of the questionnaire cover 8 aspects of quality of life namely, physical functioning,

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role limitations due to physical problems, social functioning, role limitations due to emotional problems, bodily pain, general mental health, vitality and general health perceptions.

A Thai version of the SF-36 questionnaire version 2 had been validated[9,10]. Therefore, application of SF-36 questionnaire is tested for validity and reliability in Thai MS patients.

This study is part of the MS quality of life questionnaire validation and reliability study which was approved by Siriraj Institutional Review Board (Protocol number 154/2006).

Material and Method

Seventy patients with MS or CIS attending MS Clinic at Siriraj Hospital were studied. The exclusion criteria were possible MS, opticospinal MS, recurrent optic neuritis, recurrent myelitis and neuromyelitis optica (Devic's syndrome). Recruitment period was between June and October 2006. An informed consent was obtained from each patient.

The first evaluation was done during a visit to MS Clinic. The self-administered questionnaire was completed within that day. All patients were advised to revisit within 21 ± 7 days. If the second visit was not possible for the scheduled period, each patient would be given the retest questionnaire in a stamp-prefixed envelope to be mailed back. If the patient did not reply within the planned period, a telephone interview by a clinician would be done.

Table 1. Demographic characteristics

Characteristics	Data
Sex, n (%)	
Male	16 (22.9)
Female	54 (77.1)
Age at examination, mean ± SD years	37.5 ± 12.8
Age at onset, mean ± SD years	31.5 ± 11.7
Duration of the disease, mean ± SD years	6.0 ± 5.5
Family status, n (%)	
Single	37 (52.9)
Couple	29 (41.4)
Live with relative or family	4 (5.7)
Education, n (%)	
Primary	9 (12.9)
Secondary	32 (45.7)
Tertiary	29 (41.4)
EDSS, median (range)	2.5 (0-9)
Medical history unrelated to MS, n (%)	13 (18.6)
Treatment, n (%)	
IFNβ1a	19 (27.1)
IFNβ1b	8 (11.4)
Immunosuppressive drug	19 (27.1)
Mitoxantrone	1 (1.4)*

* The patient was treated by IFNβ1 then switched to mitoxantrone

Statistical analysis

Reliability, an extent to which similar measurements on the same person are similar in different setting, was assessed through internal consistency and test-retest measure.

The SF-36 questionnaire would be internally consistent if the responses to items or questions that contribute to the same scale correlate well with each other. The internal consistency of the SF-36 questionnaire was assessed by 2 techniques: Cronbach's alpha coefficient and inter-item correlation. Reliability is considered acceptable when Cronbach's alpha exceed 0.7 and inter-item correlation exceed 0.4.

The test-retest reliability assessed consistency of the measure from first time to 2-4 weeks later by Pearson correlation is good when exceeding 0.75.

SPSS version 12 was used for statistical analysis.

Results

There were 55 clinical definite MS patients, 12 laboratory-supported definite MS patients and 3 clinical probable MS patients, according to Poser criteria. There were 2 primary progressive MS patients, 59 relapsing remitting MS patients, 3 secondary progressive MS patients and 6 clinically isolated syndrome patients. The demographic characteristics were shown in Table 1.

All 70 patients completed the self-administered questionnaire at the first visit. For the re-assessment, 25 patients completed the questionnaire when they attended the MS Clinic within 21 ± 7 days, 35 patients completed the questionnaire and submitted by mail, and 10 patients had phone call interviews.

Internal consistency measured by Cronbach's Alpha exceeded 0.7, except for social functions, which was 0.69; thus all but one category satisfied the criteria for reliability (Table 2). The inter-item correlation coefficient for 8 aspects ranged from 0.47-0.88, which also satisfied the criteria for reliability.

Reliability of test-retest assessment in all items was good by Pearson correlation, ranging from 0.84-0.94 (Table 3).

Table 2. Internal consistency of SF-36 health profile in MS patients

SF-36 scales	No. of items	Internal consistency (Cronbach's alpha)
1. Functional status		
a) Physical functioning	10	0.95
b) Social functioning	2	0.69
c) Role limitations attributed to physical problems	4	0.88
d) Role limitations attributed to emotional problems	3	0.75
2. Well-being		
a) Mental health	5	0.88
b) Vitality	4	0.84
c) Bodily pain	2	0.89
3. Overall evaluation of health		
a) General health perception	5	0.79

Table 3. Test-retest reliability

SF-36 scales	Pearson correlation	p-value
1. Functional status		< 0.001
a) Physical functioning	0.94	
b) Social functioning	0.92	< 0.001
c) Role limitations attributed to physical problems	0.85	< 0.001
d) Role limitations attributed to emotional problems	0.92	< 0.001
2. Well being		< 0.001
a) Mental health	0.89	< 0.001
b) Vitality	0.88	< 0.001
c) Bodily pain	0.94	< 0.001
d) Role limitations attributed to emotional problems		
3. Overall evaluation of health	0.89	< 0.001
a) General health perception		

Discussion

An information system to assess the relation between medical intervention and health outcomes is necessary in order to achieve a goal of efficient and quality care[11].

Thai version of SF-36 had reliability, as shown by the internal consistency and the test-retest reliability of items in all 8 aspects of quality of life in MS patients. SF-36 Thai version had previously been tested for reliability in patients with cardiac disease[12], arthroplasty[13], osteoarthritis[14], low back pain[10], as well as in general non-clinical population[9,15]. Internal consistency measured by Cronbach's alpha coefficient showed reliability exceeding 0.7 in most studies. Items with lower correlations included mental health[13], bodily pain[14], role limitation due to physical problems[14], social function[15], and vitality[13,15].

Previous study on quality of life (SF-36 Health Survey) at baseline in relapsing-remitting MS patients significantly predicted change in disability measured by EDSS 1 year later. Low scores on the SF-36 mental health scale were significantly correlated with increased (worsened) EDSS scores 1 year later[16]. Application of SF-36 Thai version to evaluate for quality of life would enhance a better care for Thai MS patients, and whether increases in disability could be predicted should be investigated.

Conclusion

Thai version SF-36 questionnaire is reliable for the assessment of quality of life in Thai multiple sclerosis patients.

Potential conflicts of interest

None.

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ความน่าเชื่อถือของแบบสอบถามทางสุขภาพ (SF-36) ฉบับภาษาไทยในการประเมินผู้ป่วยไทยที่เป็นโรคมัลติเพิล สเคลอโรสิส

นเรศสักดิ์ เหล่าแสงอเนก, ทัดดาว วิโรจน์อุไรเรือง, สสิธร ศิริโท, นาราพร ประยูรวิวัฒน์

ภูมิหลัง: เพื่อศึกษาถึงการนำแบบสอบถามทางสุขภาพ (SF-36) ฉบับภาษาไทยมาใช้ประเมินผู้ป่วยไทยที่เป็นโรคมัลติเพิล สเคอโรสิส (เอ็มเอส)

วัสดุและวิธีการ: ใช้แบบวัดคุณภาพชีวิตผู้ป่วยโรคเรื้อรัง (SF-36) ฉบับภาษาไทยเพื่อประเมินคุณภาพชีวิตของผู้ป่วยเอ็มเอสหรือผู้ป่วย clinically isolated syndrome (ซีไอเอส) จำนวน 70 ราย

การวิเคราะห์ทางสถิติ: การวัดความเที่ยงภายใน (internal consistency) โดยการคำนวณค่าสัมประสิทธิ์ Cronbach's alpha และค่าสถิติสหสัมพันธ์ระหว่างคำถาม (inter-item correlation) การวัดความน่าเชื่อถือของการทดสอบและทดสอบซ้ำ (test-retest reliability) ใช้ค่าสถิติสหสัมพันธ์เพียร์สัน (Pearson correlation)

ผลการศึกษา: ผู้ป่วยโรคเอ็มเอสที่วินิจฉัยเอ็มเอสจากอาการทางคลินิก 55 ราย, ผู้ป่วยเอ็มเอสที่วินิจฉัยโรคเอ็มเอสจากอาการทางคลินิกและผลทางห้องปฏิบัติการ 12 ราย, น่าจะเป็นโรคเอ็มเอสจากอาการทางคลินิก 3 ราย ตามเกณฑ์การวินิจฉัย Poser ชนิดของโรคเอ็มเอสพบว่าเป็นโรคเอ็มเอสชนิดดำเนินโรครุดหน้าตั้งแต่แรก 2 ราย, เอ็มเอสชนิดกำเริบสลับทุเลา 59 ราย, เอ็มเอสชนิดโรครุดหน้าในระยะหลัง 3 ราย ซีไอเอส 6 ราย ผลการวัดความเที่ยงภายในโดยค่าสัมประสิทธิ์ Cronbach's alpha พบว่าค่าโดยรวมมีค่ามากกว่า 0.7 ยกเว้นข้อคำถามในเรื่องการเข้าสังคมซึ่งมีค่า 0.69 ความน่าเชื่อถือของความสัมพันธ์ระหว่างคำถามแต่ละหัวข้ออยู่ที่ 0.47-0.88 ความน่าเชื่อถือของการทดสอบและทดสอบซ้ำโดยค่าสถิติสหสัมพันธ์เพียร์สันอยู่ที่ 0.84-0.94

สรุป: แบบสอบถาม SF-36 มีความน่าเชื่อถือในการใช้ประเมินคุณภาพชีวิตของผู้ป่วยไทยที่เป็นโรคเอ็มเอส