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Original article

JOA Back Pain Evaluation Questionnaire: initial report

The Clinical Outcomes Committee of the Japanese Orthopaedic Association, The Subcommittee on Evaluation of Back Pain and Cervical Myelopathy

The Subcommittee on Low Back Pain and Cervical Myelopathy Evaluation of the Clinical Outcome Committe of the Japanese Orthopaedic Association

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Abstract

Background. There is no widely accepted objective evaluation for lumbar spine disorders. New outcome measures should be patient-oriented and should measure symptoms and self-reported functional status in multiple dimensions. The aim of this study was to identify items to be included in the disease-specific quality of life (QOL) questionnaire for the assessments of patients with lumbar spine disorders.

Methods. The draft of the QOL questionnaire that consisted of a total of 60 items, including 24 items derived from the Japanese version of the Roland Morris Disability Questionnaire (RDQ) and 36 items derived from the Japanese version of Short Form 36 (SF-36), were administered to patients and controls. After obtaining written informed consent, the following data were collected from the patient group (n = 328) and the control group (n = 213): (1) background characteristics, including age, diagnosis, Japanese Orthopaedic Association (JOA) score, and finger to floor distance; (2) responses to the questionnaire; (3) the identification rate by discrimination analysis to select the candidates for adoption and by adopting explanatory variables. The items to be excluded were determined by examining the explanatory variables, which were selected after the discrimination analysis, by setting the candidate to-be-excluded items as an objective variable.

Results. Based on the distribution of the responses, two items, RDQ-15 and RDQ-19, were excluded. From the results of the correlation coefficient calculation for each question in the patient group, 33 items were excluded and 27 candidate items were adopted. Based on the adoption explanatory variable used in the discrimination analysis, 25 of the 27 candidate items for adoption were accepted.

Conclusions. This study identified the 25 specific questionnaire items that should be included in the questionnaire to evaluate QOL of patients with various lumbar spine disorders.

Introduction

The assessments of lumbar spine disorders have been based on biological, physiological, and anatomical outcomes, such as measurements of the range of spinal motion, laboratory tests, and imaging studies.[1] However, these indicators have little meaning for the patient and the society. On the other hand, alleviation of symptoms, such as pain intensity, and an improved quality of life

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(QOL) have more significance for the patients and the society. It has been reported that patient self-rated measures of symptom intensity and QOL are as reproducible as many physiological measurements and are acceptable with respect to objectivity and stability.[2] Thus, patient-based outcomes involving patient self-assessment of symptom intensity and QOL should be used in clinical research.

Conventionally, surgery is evaluated based on a simple four-grade scale: excellent, good, fair, and poor. This approach has limitations due to its subjectivity and the lack of clear definitions for each grade. Therefore, the evaluation of treatment results depends on individual researchers and is not fully comparable. Furthermore, the four-grade scale is not sufficient to measure pain intensity, activities of daily living, or the ability to work. For example, a patient might not be able to return to work despite a decrease in pain, or there may be no alleviation of pain intensity despite an improvement in activities of daily living. Given such circumstances, an improvement in one dimension does not necessarily mean an improvement in other dimensions; thus, the evaluation of medical treatments must be multidimensional and include patient-based outcomes. Given these perspectives, the Assessment Standards Committee prepared this report dealing with the new standards for evaluating the results of treatments for lumbar spine disorders.

Materials and methods

Selection of lumbar spine disorders evaluation items

The aim of this study was to establish a multidimensional method for evaluating treatment results for lumbar spine disorders that was centered on patient-based outcomes and that could be used internationally. Pain intensity can be measured using a visual analogue scale (VAS) and the NASS questionnaire.[3,4] The Roland-Morris disability questionnaire (RDQ) and the Oswestry disability questionnaire are low back pain-specific QOL questionnaires.[5,6] With respect to the RDQ, the Japanese version of the RDQ has been developed that conforms to the psychometric standards in the areas of reliability, validity, and responsiveness.[7] Both alleviation of patients' symptoms and its impact on their activities of daily living can be measured using the RDQ. Widely used international measures for general well-being include the SF36, SF12, and the Euro QOL; Japanese versions of the SF36 and the Euro QOL have been developed.[8–11] Thus, it would be desirable to use the VAS for measuring the intensity of low back pain, the RDQ for measuring low back pain-specific QOL, and the SF-36 for assessing general well-being. However, the evaluation of all of these items in daily practice is impractical owing to the large number of items. The approximate time to complete the RDQ is 5 min, and it takes 10 min to complete the SF36.[1] To reduce the number of items necessary to evaluate the efficacy of treatments for lumbar spine disorders, the usefulness of various evaluation criteria to differentiate patients with lumbar spine disorders from normal subjects was studied.

Examination of the evaluation rating score (true value) in the lumbar spine disorders group

Eight institutions (including affiliated institutions) were asked to recruit at least 40 subjects during the period from February to May 2002. The questionnaire consisted of a total of 60 items: 24 items derived from the Japanese version of the RDQ and 36 items derived from the Japanese version of the SF-36. Lumbar disc herniation and lumbar canal stenosis were the two main targets. Subjects who had other orthopedic disorders and those with impaired ability to understand the questions, such as patients with dementia, were excluded. Normal subjects were defined as adults with no orthopedic disorders. Adults living independently and not requiring nursing care but who were undergoing alternative treatments (e.g., acupuncture, moxibustion, massage, and chiropractic treatments) were included in the control group. Health care professionals were excluded.

Prior to conducting the investigations, subjects in the patient group and the control group gave their written informed consent.

Background characteristics of the patient group

The distribution of subjects' background characteristics, such as age, diagnosis, Japanese Orthopaedic Association (JOA) score, and finger to floor distance, was analyzed to verify that the group represents the general population of patients with spine disorders.

Examination of removable candidate QOL items

A QOL item could be removed if it satisfied any of the following criteria: (1) items to which most subjects gave the same answer; (2) items the answers for which were highly correlated with the answers to other questions; (3) items that could be explained by several questions; (4) items whose score distributions did not show any statistically significant differences between the patient and control groups.

To test for the above conditions, the distribution of responses for the RDQ and SF36 were compared between the two groups. The correlation coefficient for each question in the patient group was analyzed using the Spearman correlation coefficient.

Table 1. Demogrphics of pateints and controls

	Patients			Controls		
	Male	Female	Total	Male	Female	Total
	187	159	346	96	120	216
Age group (years)						
10–19	1	2	3			
20–29	19	16	35	15	33	48
30–39	23	13	36	18	22	40
40–49	18	19	37	20	16	36
50–59	30	29	59	15	21	36
60–69	39	40	79	12	15	27
70–79	47	32	79	12	12	24
80–89	9	8	17	4	1	5
≥90	1		1			
Diagnosis						
Lumbar disc herniation (LDH)			160			
Lumbar spinal canal stenosis (LCS)			183			
LDH + LCS			3			
Other orthopedic disorders						
Present			18			3
Absent			328			213

Examination of the identification rate by discrimination analysis of candidate items

After using the above-described criteria to identify the candidate items to be included in the final questionnaire, discrimination analysis was done to eliminate further the number of items. By setting one of the candidate items for adoption as the objective variable, the rest of the items were examined as explanatory variables; the discrimination rate was then analyzed, and items with a minimum discrimination rate ≥70% were considered to be items that could be excluded. The final items that were excluded were determined by examining the explanatory variables, which were selected after discrimination analysis, setting the candidate to-be-excluded items as the objective variable.

Results

Background characteristics of the patient group

Table 1 shows the age, sex, and diagnosis of 328 subjects in the patient group and 213 subjects in the control group. There was significant difference in sex and age distribution between the two groups ($P = 0.03$, Fisher's exact test). In the patient group, the straight leg raising (SLR) test was positive in approximately 40%, sensory disturbance was present in 60%, muscle weakness was seen in 40%, and bladder dysfunction was impaired in approximately 10% of the subjects (Table 2). The distribution of the finger to floor distance revealed that the

Table 2. Clinical findings

Parameter	Patients	Control
	328	213
SLR		
Normal	201	211
30°–70°	110	1
<30°	17	1
Sensory		
Normal	124	210
Mild disturbance	150	2
Obvious disturbance	54	1
Motor		
Normal	191	212
Mild muscle weakness	107	0
Obvious muscle weakness	30	1
Bladder function		
Normal	293	207
Mild dysuria	33	6
Severe dysuria	2	0
Finger-to-floor distance		
– –15	1	6
–14 – –5	3	10
–4 – 4	95	108
5 – 14	68	54
15 – 24	54	30
25 – 34	51	5
35 – 44	17	0
45 – 54	24	0
55 – 64	8	0
65 – 74	1	0
75 – 84	2	0
Measurement not possible	4	0

SLR, straight-leg raising

mobility of the lumbar spine in the patient group was significantly restricted compared to that of the control group. Although we cannot make any conclusions, given the above results we considered that the patient group represented the general population of the patients with lumbar spine disorders.

RDQ

The nonresponse rate for the RDQ was less than 5% for all questions; no questions were difficult to answer. As expected, more than 95% of the normal subjects answered "no" to all questions. In the patient group,

Table 3. Results of the RDQ (Roland-Morris Disability Questionnaire)

	Patients (n = 328)			Controls		
Question item	Yes	No	No response	Yes	No	No response
RDQ-1	174	148	6	1	212	
	53.0%	45.1%	1.8%	0.5%	99.5%	
RDQ-2	232	92	4	20	193	
	70.7%	28.0%	1.2%	9.4%	90.6%	
RDQ-3	253	69	6	7	204	2
	77.1%	21.0%	1.8%	3.3%	95.8%	0.9%
RDQ-4	110	210	8	2	211	
	33.5%	64.0%	2.4%	0.9%	99.1%	
RDQ-5	183	135	10	4	209	
	55.8%	41.2%	3.0%	1.9%	98.1%	
RDQ-6	215	109	4	3	208	2
	65.5%	33.2%	1.2%	1.4%	97.7%	0.9%
RDQ-7	119	204	5	3	210	
	36.3%	62.2%	1.5%	1.4%	98.6%	
RDQ-8	185	139	4	4	209	
	56.4%	42.4%	1.2%	1.9%	98.1%	
RDQ-9	152	170	6	2	211	
	46.3%	51.8%	1.8%	0.9%	99.1%	
RDQ-10	193	129	6	4	209	
	58.8%	39.3%	1.8%	1.9%	98.1%	
RDQ-11	166	156	6	6	207	
	50.6%	47.6%	1.8%	2.8%	97.2%	
RDQ-12	86	237	5	1	211	1
	26.2%	72.3%	1.5%	0.5%	99.1%	0.5%
RDQ-13	128	195	5	11	202	
	39.0%	59.5%	1.5%	5.2%	94.8%	
RDQ-14	162	159	7	2	211	
	49.4%	48.5%	2.1%	0.9%	99.1%	
RDQ-15	53	270	5		212	1
	16.2%	82.3%	1.5%		99.5%	0.5%
RDQ-16	166	157	5	3	209	1
	50.6%	47.9%	1.5%	1.4%	98.1%	0.5%
RDQ-17	222	100	6	6	206	1
	67.7%	30.5%	1.8%	2.8%	96.7%	0.5%
RDQ-18	114	210	4	2	210	1
	34.8%	64.0%	1.2%	0.9%	98.6%	0.5%
RDQ-19	28	296	4		213	
	8.5%	90.2%	1.2%		100.0%	
RDQ-20	109	211	8	1	212	
	33.2%	64.3%	2.4%	0.5%	99.5%	
RDQ-21	263	58	7	7	206	
	80.2%	17.7%	2.1%	3.3%	96.7%	
RDQ-22	105	219	4	4	209	
	32.0%	66.8%	1.2%	1.9%	98.1%	
RDQ-23	257	65	6	10	203	
	78.4%	19.8%	1.8%	4.7%	95.3%	
RDQ-24	82	242	4		213	
	25.0%	73.8%	1.2%		100.0%	

Table 4. Exclusion and adoption of items (first level)

Excluded items	Reason	Items adopted
RDQ-3	RDQ-17, 23 Correlation	RDQ-1
RDQ-7	RDQ-12 Correlation	RDQ-2
RDQ-9	RDQ-16 Correlation	RDQ-4
RDQ-10	RDQ-1, 17 Correlation	RDQ-5
RDQ-15	Answers concentrated on ⌈NO⌋	RDQ-6
RDQ-19	Answers concentrated on ⌈NO⌋	RDQ-8
RDQ-21	RDQ-17, 23 Correlation	RDQ-11
RDQ-24	RDQ-4 Correlation	RDQ-12
QOL-2	QOL-1 Correlation	RDQ-13
QOL-3a	QOL-3g Correlation	RDQ-14
QOL-3b	QOL-3g Correlation	RDQ-16
QOL-3c	QOL-3e Correlation	RDQ-17
QOL-3d	QOL-3e, 3g Correlation	RDQ-18
QOL-3h	QOL-3e, 3g Correlation	RDQ-20
QOL-3i	QOL-3e, 3g Correlation	RDQ-22
QOL-3j	QOL-3e Correlation	RDQ-23
QOL-4a	QOL-8 Correlation	QOL-1
QOL-4c	QOL-8 Correlation	QOL-3e
QOL-4d	QOL-8 Correlation	QOL-3f
QOL-5a	QOL-8 Correlation	QOL-3g
QOL-5b	QOL-8, 9f Correlation	QOL-4b
QOL-5c	QOL-8, 9f Correlation	QOL-8
QOL-6	QOL-8 Correlation	QOL-9f
QOL-7	QOL-8 Correlation	QOL-9g
QOL-9a	QOL-9h Correlation	QOL-9h
QOL-9b	QOL-9f Correlation	QOL-11b
QOL-9c	QOL-9f Correlation	QOL-11c
QOL-9d	QOL-9f, 9h Correlation	
QOL-9e	QOL-9h Correlation	
QOL-9i	QOL-9g Correlation	
QOL-10	QOL-8 Correlation	
QOL-11a	QOL-11b Correlation	
QOL-11d	QOL-1, 11b Correlation	

more than 80% of respondents chose the same answers for items 15, 19, and 21; and approximately 80% chose the same answer for items 3 and 23. In particular, for items 15 and 19, more than 80% of the patient group chose the same answer (no) as the normal healthy subjects (Table 3). Therefore, based on these results, RDQ-15 and RDQ-19 were listed as candidates to be excluded.

SF-36

The nonresponse rate for the SF-36 was less than 5% for all questions, and none of the questions was difficult to answer. There was a statistically significant difference in the distribution of responses between the patient group and the control group ($P < 0.05$, by χ^2). Furthermore, there were no questions for which the answers were predominantly concentrated on one choice in the patient group.

Correlation coefficient for each question in the patient group

For the 24 RDQ items, there were mutual correlations between two groups of item s: RDQ-1, 3, 10, 17, 21, and 23 (six items); and RDQ-4, 7, 9, 12, 16, and 24 (six items). For the SF-36 items, there were mutual correlations among four groups: QOL-1,2,11a,11b, and 11d (5 items); QOL-3a–3j (10 items); QOL-4a–4d, 5a–5c, 6, 7, 8, and 10 (11 items); QOL-9a–9i (9 items). Thus, 33 items were excluded, and 27 remained as candidates for adoption. The reasons for exclusion are shown in Table 4.

Discrimination analysis

The discrimination rate of the answer for each item, based on the discrimination analysis, was determined for the 27 candidates for adoption. To arrive at the discrimination rate, one item was set as the objective variable, and the other items were set as explanatory variables; the item with a high minimum value for the

Table 5. Results of discrimination analysis

Question item	Minimal ratio of discrimination for each choice	Ratio of discrimination through all choices	κ
RDQ-1	75.2%[a]	77.3%[a]	0.54
RDQ-2	60.5%	81.5%[a]	0.53
RDQ-4	66.7%	81.0%[a]	0.57
RDQ-5	74.8%[a]	80.1%[a]	0.59
RDQ-6	62.1%	80.5%[a]	0.55
RDQ-8	69.2%	76.7%[a]	0.52
RDQ-11	69.0%	72.7%[a]	0.45
RDQ-12	69.6%	87.0%[a]	0.65
RDQ-13	55.0%	68.8%	0.34
RDQ-14	70.6%[a]	74.5%[a]	0.49
RDQ-16	76.6%[a]	78.3%[a]	0.57
RDQ-17	64.2%	83.4%[a]	0.59
RDQ-18	60.0%	77.2%[a]	0.48
RDQ-20	61.0%	77.0%[a]	0.47
RDQ-22	44.4%	72.6%[a]	0.33
RDQ-23	57.1%	84.3%[a]	0.50
QOL-1	30.0%	56.2%	0.31
QOL-3e	52.8%	68.8%	0.45
QOL-3f	46.3%	61.5%	0.38
QOL-3g	50.0%	69.7%	0.50
QOL-4b	48.1%	58.2%	0.46
QOL-8	46.0%	55.9%	0.41
QOL-9f	36.7%	56.6%	0.41
QOL-9g	28.6%	47.1%	0.28
QOL-9h	14.3%	48.5%	0.28
QOL-11b	21.1%	48.3%	0.27
QOL-11c	5.6%	58.7%	0.23

[a] Discrimination rate >70%

discrimination rate was excluded from adoption. The minimum value for the discrimination rate was > 70% in four items (RDQ-1, 5, 14, and 16) (Table 5). The discrimination rate calculated the ratio that the answers of patients group accorded with the estimated answers by classification rule. To compute the κ value, we made a contingency table using the answers of patients group and by the estimated answers.

Adoption of the explanatory variables in discrimination analysis

To verify whether it would be appropriate to exclude RDQ-1, 5, 14, and 16, the explanatory variable chosen for each objective variable in discrimination analysis was determined (Table 6). Consequently, it was found that if RDQ-1 and 5 were excluded RDQ-14 and 16 could not be excluded because RDQ-1 and 5 would be necessary. Given these results, 25 of the 27 candidate items for adoption were adopted; RDQ-1 and 5 were excluded.

Discussion

Several issues must be considered when creating a new evaluation method for medical treatments. First, the evaluation should be structured so the effect of medical intervention is accurately reflected. If medical treatment results are mainly determined by genetic or environmental factors, the quality of the treatment cannot be evaluated. Second, the evaluation of medical treatment results must contain a framework that accurately and reliably captures changes in the patient's health condition. Finally, to evaluate the medical treatment results accurately, the treatment evaluation period should be the same as the time period during which information is obtained about the patients' complications and social background that can affect the medical treatment outcomes.

Evaluation of medical treatment outcomes used to be a subject of concern for health care professionals only. Recently, however, the evaluation of medical treatment outcomes is becoming more of a concern to patients and governments who pay the medical costs. Evaluating medical treatment results is key to assessing cost effectiveness and to validating treatments themselves. Thus,

Table 6. Explanatory variable chosen for every objective variable on discrimination analysis

		Objective variable			
		RDQ-1	RDQ-5	RDQ-14	RDQ-16
Minimum value of discrimination rate for every choice		75.2%	74.8%	70.6%	76.6%
All choices by discrimination rate		77.3%	80.1%	74.5%	78.3%
κ		0.54	0.59	0.49	0.57
Variable	Explanation				
RDQ-1	I stay at home most of the time because of my back.	–		○	○
RDQ-2	I change position frequently to try to get my back comfortable.			○	○
RDQ-4	Because of my back, I am not doing any of the jobs that I usually do around the house.	○	○	○	
RDQ-5	Because of my back, I use a handrail to get upstairs.		–		○
RDQ-6	Because of my back, I lie down to rest more often.	○			○
RDQ-8	Because of my back, I try to get other people to do things for me.	○			○
RDQ-11	Because of my back, I try not to bend or kneel down.	○		○	○
RDQ-12	I found it difficult to get out of a chair because of my back.		○	○	○
RDQ-13	My back is painful almost all the time.		○	○	
RDQ-14	I find it difficult to turn over in bed because of my back.	○		–	○
RDQ-16	I have trouble putting on my socks (or stockings) because of the pain in my back.	○		○	–
RDQ-17	I only walk short distances because of my back.	○	○	○	
RDQ-18	I sleep less well because of my back.		○	○	
RDQ-20	I sit down for most of the day because of my back.	○	○		○
RDQ-22	Because of my back pain, I am more irritable and bad tempered with people than usual.	○			○
RDQ-23	Because of my back, I go upstairs more slowly than usual.	○	○		○
QOL-1	In general, would you say your health is:				
QOL-3e	Does your health now limit you in climbing one flight of stairs?		○		
QOL-3f	Does your health now limit you in bending, kneeling, or stooping?		○		○
QOL-3g	Does your health now limit you in walking more than a mile?		○		○
QOL-4b	Any problems as a result of your physical health: accomplished less than you would like?				
QOL-8	How much did pain interfere with your normal work?	○			
QOL-9f	Have you felt downhearted and blue?				
QOL-9g	Did you feel worn out?				
QOL-9h	Have you been a happy person?	○			○
QOL-11b	I am as healthy as anybody I know.	○		○	○
QOL-11c	I expect my health to get worse.	○			

criteria used for the evaluations should be objective and structured in such a way that the patients' perspective is respected. In this way, the results can be understood not only by health care professionals but also by patients and third parties. Evaluation of medical treatment based on the creation of standards can be used to document and improve the performance of the medical system and health care technology.

This study has several limitations. There was a significant difference in sex and age between the patients group and the normal group. Hence, there is a possibility that this difference affects the results of our study. For many research purposes, it may be optimal to include both disease-specific (RDQ) and generic functional status measures (SF-36). However, an instrument that includes both disease-specific and general functional status measures has not been established. Although it may not be ideal to combine items from two different instruments, our final goal was to find the disease-specific daily functions, physical function, role function, pain, vitality, mental health, and health perception. However, only the Japanese version of the RDQ as the disease-specific and the Japanese version of the SF-36 as the generic functional status measure were available. Therefore, we combined items from the two instruments to find the disease-specific functional status that included many dimensions.

We were able to identify 25 specific questions that would elucidate the QOL of patients with various lumbar spine disorders. The next step is to assess the validity and responsiveness of the questionnaire that includes the selected 25 questions by measuring the

outcome of patients with lumbar spinal disorders. Also, we have to complete cross-cultural adaptation of the BPEQ so it can be used internationally.

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