Table 1 continued

1) I have not been able to do them at all.

2) I have been unable to do them most of the time.

3) I have sometimes been unable to do them.

4) I have been able to do them most of the time.

5) I have always been able to do them.

Q5-3 Has your work routine been hindered because of the pain?

1) Greatly 2) Moderately 3) Slightly (somewhat)

4) Little (minimally) 5) Not at all

Q5-4 Have you been discouraged and depressed?

1) Always 2) Frequently 3) Sometimes 4) Rarely 5) Never

Q5-5 Do you feel exhausted?

1) Always 2) Frequently 3) Sometimes 4) Rarely 5) Never

Q5-6 Have you felt happy?

1) Never 2) Rarely 3) Sometimes 4) Almost always 5) Always

Q5-7 Do you think you are in decent health?

1) Not at all (my health is very poor)

2) Barely (my health is poor)

3) Not very much (my health is average health)

Table 1 continued

4) Fairly (my health is better than average)

5) Yes (I am healthy)

Q5-8 Do you feel your health will get worse?

1) Very much so 2) A little bit at a time

3) Sometimes yes and sometimes no 4) Not very much 5) Not at all

Regarding 0 as "no pain (numbness) at all" and 10 as "the most intense pain (numbness) imaginable," mark a point between 0 and 10 on the lines below to show the degree of your pain (numbness) when your symptom was at its worst during the last week.

If you feel pain or stiffness in your neck or shoulders, mark the degree

0 10

If you feel tightness in your chest, mark the degree

0 10

If you feel pain or numbness in your arms or hands, mark the degree (If there is pain in both limbs, then the worse of the two)

Table 1 continued

0 10

If you feel pain or numbness from chest to toe, mark the degree

0 10

0 : No pain (numbness) at all

10 : The worst state imaginable

Q4-2 × 5 + Q4-3 × 10 + Q4-4 × 5 − 30) × 100 ÷ 80; quality of life: (Q5-1 × 3 + Q5-2 × 2 + Q5-3 × 2 + Q5-4 × 5 + Q5-5 × 4 + Q5-6 × 3 + Q5-7 × 2 + Q5-8 × 3 − 24) × 100 ÷ 96. The score of each domain ranges from 0 to 100 points, which is proportional to the patients' clinical conditions [4–6].

The data of those over 90 years old were extracted from the study; then the answers of 1,629 volunteers were used for the analysis. Irrelevant data where subjects did not respond to all the questions or clearly inappropriate answers in which subjects did not follow instructions were excluded from the analyses for each domain. The Steel–Dwass test was used for multiple comparisons among different generations, and the Jonckheere-Terpstra test was used to determine age trends in each gender by domain. $P < 0.05$ was considered significant.

Table 2 Gender and age distribution of volunteers

Age groups (years)	Male	Female	Total
20–29	115	120	235
30–39	122	117	239
40–49	117	120	237
50–59	113	123	236
60–69	118	122	240
70–79	109	117	226
80–89	104	112	216
Total	798	831	1,629

Results

The volunteers comprised 798 men and 831 women. The gender and age distributions of the volunteers are shown in Table 2. The distribution of the scores for each domain in the JOACMEQ (from 10th to 90th percentile) are shown in Tables 3, 4, 5, 6, and 7. In the elderly healthy volunteers, the JOACMEQ scores decreased with age. The average score for cervical spine function was more than 90 points in the younger generation from the 20s to 60s, and in those in their 70s and 80s, the average score decreased to 80 points and 70 points, respectively (Table 3). There were significant differences in the average scores between the younger generation in their 20s to 60s and the elderly generation in their 80s in both genders. The average score for upper extremity function was more than 95 points in those in their 20s to 70s and decreased to 80 points for those in their 80s in both genders (Table 4). There were also significant differences in the average scores between the younger generations and elderly in their 80s in both genders. The average lower extremity function score was more than 95 points in those in their 20s to 60s in males and decreased to 70 points in their 80s. In females, the average score was more than 95 points in those in their 20s to 40s and decreased to <95 points in their 50s and 60s; in 70s and 80s, the average score further decreased to 80 points and 60 points, respectively (Table 5). There were significant differences in the average scores between the younger generation below 70 years of age and elderly generation above 70 in both genders. The average bladder function score was more than 90 points in the young generations in their 20s to

Table 3 Distribution of scores for domains in the JOACMEQ; cervical spine function

Cervical spine function	Male	20–29	30–39	40–49	50–59	60–69	70–79	80–89	Female	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Number	Valid	115	120	117	113	118	106	102	Valid	119	115	118	121	121	115	109
	Invalid	0	2	0	0	0	3	2	Invalid	1	2	2	2	1	2	3
Average		96.9	98.4	97.0	93.8	95.0	86.9	74.9*		98.1	97.6	97.1	94.9	93.1	87.4	79.7*
Median		100.0	100.0	100.0	100.0	100.0	100.0	85.0		100.0	100.0	100.0	100.0	100.0	100.0	90.0
Standard deviation		12.2	6.7	8.5	12.6	10.0	21.5	27.7		6.3	5.6	8.1	10.3	15.6	21.5	22.6
Percentile	10.0	90.0	100.0	85.0	80.0	75.0	57.0	31.5	10.0	90.0	88.0	85.0	80.0	75.0	58.0	40.0
	25.0	100.0	100.0	100.0	87.5	97.5	85.0	55.0	25.0	100.0	100.0	100.0	95.0	90.0	80.0	65.0
	50.0	100.0	100.0	100.0	100.0	100.0	100.0	85.0	50.0	100.0	100.0	100.0	100.0	100.0	100.0	90.0
	75.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	75.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	90.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	90.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

* $p < 0.05$; the average scores were significantly lower than those in the young generations in their 20s to 60s in both genders

Table 4 Distribution of scores for domains in the JOACMEQ; upper extremity function

Upper extremity function	Male	20–29	30–39	40–49	50–59	60–69	70–79	80–89	Female	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Number	Valid	115	121	116	113	117	107	103	Valid	120	114	120	122	122	117	109
	Invalid	0	1	1	0	1	2	1	Invalid	0	3	0	1	0	0	3
Average		99.0	99.7	99.6	99.2	99.0	96.9	88.4*		100.0	99.8	99.9	98.9	98.5	96.3	88.1*
Median		100.0	100.0	100.0	100.0	100.0	100.0	95.0		100.0	100.0	100.0	100.0	100.0	100.0	95.0
Standard deviation		6.3	1.6	1.7	2.6	3.9	9.2	16.4		0.5	1.6	0.6	3.1	5.3	10.6	16.0
Percentile	10.0	100.0	100.0	100.0	95.0	100.0	89.0	65.0	10.0	100.0	100.0	100.0	95.0	95.0	89.0	68.0
	25.0	100.0	100.0	100.0	100.0	100.0	100.0	84.0	25.0	100.0	100.0	100.0	100.0	100.0	95.0	81.5
	50.0	100.0	100.0	100.0	100.0	100.0	100.0	95.0	50.0	100.0	100.0	100.0	100.0	100.0	100.0	95.0
	75.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	75.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	90.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	90.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

* $p < 0.05$; the average scores were significantly lower than those in the young generations in their 20s to 70s in both genders

Table 5 Distribution of scores for domains in the JOACMEQ; lower extremity function

Lower extremity function	Male	20–29	30–39	40–49	50–59	60–69	70–79	80–89	Female	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Number	Valid	115	121	117	112	116	109	103	Valid	119	113	118	121	120	114	111
	Invalid	0	1	0	1	2	0	1	Invalid	1	4	2	2	2	3	1
Average		98.6	97.8	97.9	96.3	95.8	90.4*	73.2*		97.0	97.9	96.9	94.4	94.5	88.0*	63.7*
Median		100.0	100.0	100.0	100.0	100.0	100.0	77.0		100.0	100.0	100.0	100.0	100.0	95.0	68.0
Standard deviation		4.1	6.7	5.5	8.0	10.0	15.6	25.6		7.0	6.1	7.6	9.9	11.2	17.4	27.0
Percentile	10.0	95.0	95.0	91.0	83.2	80.5	68.0	27.0	10.0	86.0	92.6	82.0	77.0	77.0	66.0	23.0
	25.0	100.0	100.0	100.0	96.3	95.0	86.0	59.0	25.0	100.0	100.0	100.0	95.0	95.0	82.0	45.0
	50.0	100.0	100.0	100.0	100.0	100.0	100.0	77.0	50.0	100.0	100.0	100.0	100.0	100.0	95.0	68.0
	75.0	100.0	100.0	100.0	100.0	100.0	100.0	95.0	75.0	100.0	100.0	100.0	100.0	100.0	100.0	86.0
	90.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	90.0	100.0	100.0	100.0	100.0	100.0	100.0	99.0

* $p < 0.05$; the average scores were significantly lower than those in young generations in their 20s to 60s in both genders

Table 6 Distribution of scores for domains in the JOACMEQ; bladder function

Bladder function	Male	20–29	30–39	40–49	50–59	60–69	70–79	80–89	Female	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Number	Valid	113	120	114	112	117	108	102	Valid	118	116	120	120	120	113	106
	Invalid	2	2	3	1	1	1	2	Invalid	2	1	0	3	2	4	6
Average		97.1	94.9	94.1	90.1*	87.5*	83.2*	72.1*		97.5	97.5	95.2	91.2*	89.6*	84.2*	75.1*
Median		100.0	100.0	100.0	94.0	94.0	88.0	75.0		100.0	100.0	100.0	94.0	94.0	88.0	81.0
Standard deviation		6.5	8.0	9.2	10.3	12.9	15.5	22.2		6.7	5.3	6.8	9.4	10.2	13.8	20.0
Percentile	10.0	88.0	81.0	81.0	75.0	69.0	62.0	38.0	10.0	88.0	88.0	88.0	81.0	75.0	64.8	44.0
	25.0	100.0	88.0	94.0	82.8	81.0	75.0	62.0	25.0	100.0	100.0	88.0	88.0	81.0	81.0	62.0
	50.0	100.0	100.0	100.0	94.0	94.0	88.0	75.0	50.0	100.0	100.0	100.0	94.0	94.0	88.0	81.0
	75.0	100.0	100.0	100.0	100.0	97.0	94.0	94.0	75.0	100.0	100.0	100.0	100.0	100.0	94.0	94.0
	90.0	100.0	100.0	100.0	100.0	100.0	100.0	94.0	90.0	100.0	100.0	100.0	100.0	100.0	100.0	94.0

* $p < 0.05$; the average scores were significantly lower than those in young generations in their 20s to 40s in both genders

Table 7 Distribution of scores for domains in the JOACMEQ; quality of life

Quality of life	Male	20–29	30–39	40–49	50–59	60–69	70–79	80–89	Female	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Number	Valid	113	121	116	112	117	106	103	Valid	114	114	117	120	118	112	108
	Invalid	2	1	1	1	1	3	1	Invalid	6	3	3	3	4	5	4
Average		75.7	70.6	68.5	66.2	70.3	68.5	60.2*		73.0	70.5	65.7	64.2	67.5	64.3	58.9*
Median		77.0	70.0	69.5	65.5	72.0	72.0	61.0		73.5	69.0	64.0	65.0	67.5	63.0	57.0
Standard deviation		16.0	14.6	13.2	16.3	14.0	15.9	18.5		15.8	13.0	13.4	13.6	14.4	16.3	17.2
Percentile	10.0	51.4	53.0	52.0	46.0	49.8	46.7	38.4	10.0	54.0	55.0	49.0	49.1	48.0	45.0	38.9
	25.0	65.5	62.0	60.0	56.3	60.5	57.8	46.0	25.0	64.0	61.0	57.5	54.0	57.8	52.0	47.0
	50.0	77.0	70.0	69.5	65.5	72.0	72.0	61.0	50.0	73.5	69.0	64.0	65.0	67.5	63.0	57.0
	75.0	86.0	82.0	76.0	77.0	80.5	79.3	74.0	75.0	83.3	79.3	74.5	73.0	77.0	77.0	71.0
	90.0	97.0	88.8	84.0	88.7	89.0	89.3	83.0	90.0	95.5	89.0	83.2	80.9	88.0	85.7	82.0

* $p < 0.05$; the average scores were significantly lower than those in young generations in their 20s to 60s in both genders

50s in both genders; the average score decreased to 80 points in those in their 60s and 70s and to 70 points in their 80s in both genders (Table 6). There were significant differences in the average scores between the younger generations in their 20s to 40s and elderly generations in their 50s to 80s in both genders. The average quality of life score of each generation was approximately 70 points in the generations in their 20s to 60s in both genders and decreased to the 60–70 points in their 70s in males and at 70s and 80s in females (Table 7). There were significant differences in the average scores between the younger generations and elderly generation in their 80s in both genders. With regard to the age trend on the Jonckheere–Terpstra test, scores tended to decrease in the five domains as age increased in both genders.

The scores for each domain in the VAS for pain or stiffness in the neck or shoulders, tightness in the chest, pain or numbness in the arms or hands, and pain or numbness from the chest to toe are shown in Tables 8, 9, 10, and 11. The volunteers recorded the VAS scores as a mark on the bar scale as a value according to the instructions in the attached document. However, if both a mark on the bar scale and a numerical value on the sheet were present, the former was used for the analysis. The VAS scores for all domains increased with age; however, the score for pain or stiffness in the neck or shoulders in females tended to decrease with age (Table 8). The scores of the generation in their 40s and 50s for females were significantly higher than those of the elderly in their 70s and 80s. Tightness in the chest was not a frequent complaint in either gender (Table 9), and there were no significant differences in the scores among different generations in either gender. The VAS score for pain or numbness in the arms or hands was more frequent in males in those who were in their 60s and above and in their 50s and above in females, and it was a common complaint in the 80s in both genders (Table 10). There were significant differences in the scores between the younger generation and elderly in their 80s in both genders. Also, the score for pain or numbness from the chest to toe was more frequent in those over 60 years in males and over 50 years in females, with a particularly high incidence in those in their 80s in both genders (Table 11). In male volunteers, there were significant differences in the scores between the younger generations in their 20s to 50s and elderly generations in their 60s to 80s, and in females, there were significant differences in the scores between the younger generations in their 20s to 60s and elderly in their 70s and 80s. Regarding age trends among the VAS scores, the scores tended to increase with age in both genders across all domains, except neck stiffness in women, which showed a tendency to decrease with an increase in age.

Table 8 Distribution of scores in VAS scales for pain or stiffness in the neck or shoulders

Pain or stiffness in the neck or shoulders	Male	20–29	30–39	40–49	50–59	60–69	70–79	80–89	Female	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Number	Valid	106	119	111	106	106	101	91	Valid	118	113	115	117	114	105	109
	Invalid	9	3	6	7	12	8	13	Invalid	2	4	5	6	8	12	3
Average		17.2	23.4	28.5	27.2	20.1	21.5	29.2		28.1	33.0	36.1*	41.2*	31.0	22.2	24.6
Median		9.5	15.0	20.0	17.5	15.5	11.0	26.0		20.0	28.0	31.0	39.0	24.0	13.0	15.0
Standard deviation		21.6	25.3	27.8	27.0	22.0	26.4	28.3		28.0	27.8	25.1	30.6	26.2	24.9	27.5
Percentile	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.0	0.0	0.0	6.2	0.0	0.0	0.0	0.0
	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	25.0	3.8	11.0	15.0	13.5	9.5	0.0	0.0
	50.0	9.5	15.0	20.0	17.5	15.5	11.0	26.0	50.0	20.0	28.0	31.0	39.0	24.0	13.0	15.0
	75.0	25.0	35.0	50.0	49.3	31.3	35.5	49.0	75.0	49.3	50.0	57.0	68.0	51.0	41.5	44.0
	90.0	54.6	65.0	74.8	70.3	49.3	63.6	72.2	90.0	75.0	74.4	72.8	80.0	72.0	61.4	69.0

* $p < 0.05$; the average scores were significantly higher than those in the elderly in their 70s and 80s in females

Table 9 Distribution of scores in VAS scales for tightness in the chest

Tightness in the chest	Male	20–29	30–39	40–49	50–59	60–69	70–79	80–89	Female	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Number	Valid	108	120	114	107	105	101	94	Valid	120	115	119	117	111	106	110
	Invalid	7	2	3	6	13	8	10	Invalid	0	2	1	6	11	11	2
Average		3.7	3.1	5.9	5.1	2.4	4.9	8.1		2.4	3.1	2.9	3.9	3.8	3.2	7.9
Median		0.0	0.0	0.0	0.0	0.0	0.0	0.0		0.0	0.0	0.0	0.0	0.0	0.0	0.0
Standard deviation		8.6	10.7	14.8	10.2	7.2	12.6	17.1		9.4	10.0	9.8	12.5	11.9	11.0	16.8
Percentile	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	50.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	50.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	75.0	0.0	0.0	3.0	6.0	0.0	0.0	8.0	75.0	0.0	0.0	0.0	0.0	0.0	0.0	8.0
	90.0	18.0	7.9	19.0	21.0	8.0	19.8	36.0	90.0	8.0	10.0	10.0	11.6	12.6	5.3	28.5

Table 10 Distribution of scores in VAS scales for pain or numbness in the arms or hands

Pain or numbness in the arms or hands	Male	20–29	30–39	40–49	50–59	60–69	70–79	80–89	Female	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Number	Valid	106	121	112	106	102	102	92	Valid	118	116	120	121	112	108	108
	Invalid	9	1	5	7	16	7	12	Invalid	2	1	0	2	10	9	4
Average		3.5	4.3	6.6	6.8	9.9	12.7	20.4*		3.1	4.3	6.4	10.5	10.7	11.3	16.7*
Median		0.0	0.0	0.0	0.0	0.0	0.0	5.0		0.0	0.0	0.0	0.0	0.0	0.0	0.0
Standard deviation		10.8	12.0	17.8	13.3	17.7	22.3	29.0		8.2	12.9	13.6	18.8	18.6	23.0	25.7
Percentile	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	50.0	0.0	0.0	0.0	0.0	0.0	0.0	5.0	50.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	75.0	0.0	0.0	5.0	9.0	10.8	17.8	30.0	75.0	0.0	0.0	4.8	11.5	15.0	9.3	29.0
	90.0	11.0	17.4	19.4	26.0	39.0	46.0	68.8	90.0	12.1	12.6	26.6	44.4	38.5	53.1	50.1

* $p < 0.05$; the average scores were significantly larger than those in young generations in their 20s to 40s in both genders

Table 11 Distribution of scores in VAS scales for pain or numbness from chest to toe

Pain or numbness from chest to toe	Male	20–29	30–39	40–49	50–59	60–69	70–79	80–89	Female	20–29	30–39	40–49	50–59	60–69	70–79	80–89
Number	Valid	105	122	115	106	105	99	94	Valid	119	115	120	119	111	108	107
	Invalid	10	0	2	7	13	10	10	Invalid	1	2	0	4	11	9	5
Average		2.3	3.3	6.1	5.5	11.0*	11.9*	24.4*		1.9	3.6	4.7	10.2	9.8	14.0*	19.1*
Median		0.0	0.0	0.0	0.0	0.0	0.0	14.5		0.0	0.0	0.0	0.0	0.0	0.0	1.0
Standard deviation		9.5	10.0	16.9	13.9	19.7	21.2	29.1		9.0	10.6	14.1	19.3	18.9	25.2	25.3
Percentile	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	50.0	0.0	0.0	0.0	0.0	0.0	0.0	14.5	50.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0
	75.0	0.0	0.0	2.0	4.5	18.5	13.0	43.5	75.0	0.0	0.0	0.0	16.0	11.0	19.8	38.0
	90.0	4.0	11.7	20.4	17.0	34.2	46.0	74.5	90.0	0.0	14.0	17.9	50.0	33.6	64.3	56.2

* $p < 0.05$; the average scores were significantly larger than those in young generations in their 20s to 50s in males and in their 20s to 60s in females

Discussion

Spinal cord function related to cervical myelopathy was assessed by the JOA (Japanese Orthopaedic Association) score, which was established in 1975 [2] and revised in 1994 [3]. The original JOA score was used as a functional assessment for cervical myelopathy worldwide, and the high inter- and intraobserver reliability of the score was demonstrated [7]. Although the JOA score attaches importance to the physical function of the upper and lower extremities and bladder dysfunction, the score does not include cervical spine function, including neck pain, a stiff neck, patient satisfaction, disability, or QOL.

The JOACMEQ was developed as a new self-administered questionnaire to measure outcomes in patients with cervical myelopathy [1] to solve problems of the original JOA score. With this new score, specific outcome measures of patient satisfaction, disability, handicaps, and general health, which are necessary information to evaluate patients with cervical myelopathy, are obtained. However, the influence of age and gender on the score has not been examined, and concern exists that the age-related decline may influence the evaluation.

In the current study, 1,629 healthy volunteers were recruited in 23 institutions to establish the standard values of the JOACMEQ by age using data obtained from healthy volunteers in their 20s to 80s.

In the elderly healthy volunteers, the JOACMEQ scores decreased with age. As for upper and lower extremity function, there was a relatively weak influence of age and gender; however, there was a strong influence of aging on bladder function. The bladder function scores were retained only up to 40 years of age, then declined significantly after 50 years. Also in the QOL score, even in the younger volunteers, the average score did not reach the full score of 100.

The authors believe that the standard scores for cervical spine function, upper extremity function, and lower extremity function should be regarded as 95 points for relatively young patients under the age of 60, and for bladder function, the lower limits of the score for healthy subjects should be regarded as 80 points. The QOL scores may not be altered with age or gender, and the standard value should be regarded as over 70 points. There was a significant decrease in the JOACMEQ score in those in their 80s in the current study. These results indicate that persons older than 80 years of age might have accompanying age-related degeneration of the central and/or peripheral nervous systems, impairment of motor functions, and other general complications even if they look healthy.

As for the VAS, an influence of age was also found in the healthy volunteers. Most domains in the VAS were influenced by age-related degenerative diseases of the cervical spine. In the domain of pain or numbness in the arms or hands, the scores in the elderly generation were significantly higher than those in the younger generations. These results may be induced by peripheral arterial diseases or neuropathy that may exist in the elderly population. The VAS in most domains tended to increase with age; however, in females, the VAS for pain or stiffness in the neck or shoulders decreased with age. These findings suggest that pain or stiffness in the neck or shoulders may not be affected by age-related degenerative conditions of the cervical spine, but may be caused by muscular or posture distress related to office work or household work in relatively younger female generations.

The JOACMEQ was designed as a self-administered questionnaire to evaluate spinal functions in myelopathy patients and may be suitable for a relative evaluation in each case and may not be suitable for direct comparison with other patients. We can judge that a treatment is "effective" for a patient if: (1) the patient answers all questions necessary to calculate the score of a domain and an increase of $\geq$20 points is obtained for that score, or (2) the functional score after treatment is >90 points even if the answers for the unanswered questions were supposed to be the worst possible choice. The effectiveness of the treatment can be evaluated based only on the two above-mentioned conditions [8]. Although these criteria were chosen based on the extensive analysis of a considerable amount of data, which was obtained in a series of previous studies, by the statistics expert, a revision may be necessary for the elderly populations. According to our results, the average functional scores of most domains in normal healthy volunteers were <90 points in the elderly population in the 70s and 80s. In the JOACMEQ, exceptional attention to judgment about the treatment or relative evaluation in the assessment for elderly individuals over 70 years old might be needed.

As for limitations of this study, the detailed medical history and general health of the volunteers were not fully assessed; therefore, potentially unhealthy subjects might have been included in the study group, especially in the elderly generations. Also, the mental status was not investigated to exclude psychiatric diseases. These physical and mental conditions may have affected the score.

In conclusion, the standard values for the five domains of the JOACMEQ were established using healthy volunteers. Physicians should be aware that there are differences in the scores among different generations. Patients with cervical myelopathy should be evaluated with this new self-administered questionnaire, JOACMEQ, taking the standard value in each generation into account. This new self-administered questionnaire can be used to evaluate the outcomes in patients with cervical myelopathy more efficiently and will be helpful to identify the most appropriate

surgical and medical treatments, thereby improving medical skills.

Conflict of interest The authors declare that they have no conflict of interest.

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Validity and Reliability of the Japanese Version of the painDETECT Questionnaire: A Multicenter Observational Study

Yoshitaka Matsubayashi[1*], Katsushi Takeshita[1], Masahiko Sumitani[2], Yasushi Oshima[1], Juichi Tonosu[1], So Kato[1], Junichi Ohya[1], Takeshi Oichi[1], Naoki Okamoto[1], Sakae Tanaka[1]

1 Department of Orthopaedic Surgery, Faculty of Medicine, the University of Tokyo, Tokyo, Japan, **2** Department of Anesthesiology and Pain Relief Center, the University of Tokyo, Tokyo, Japan

Abstract

Objectives: The aim of this study was to evaluate the validity and reliability of the Japanese version of the painDETECT questionnaire (PDQ-J).

Materials and Methods: The translation of the original PDQ into Japanese was achieved according to the published guidelines. Subsequently, a multicenter observational study was performed to evaluate the validity and reliability of PDQ-J, including 113 Japanese patients suffering from pain.

Results: Factor analysis revealed that the main component of PDQ-J comprises two determinative factors, which account for 62% of the variance observed. Moreover, PDQ-J revealed statistically significant correlation with the intensity of pain (Numerical Rating Scale), Physical Component Score, and Mental Component Score of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The Cronbach alpha for the total score was 0.78 and for the main component was 0.80. In the analysis of test–retest method, the intraclass correlation coefficient between the two scores was 0.94.

Conclusions: We demonstrated the validity and reliability of PDQ-J. We encourage researchers and clinicians to use this tool for the assessment of patients who suffer suspected neuropathic pain.

Citation: Matsubayashi Y, Takeshita K, Sumitani M, Oshima Y, Tonosu J, et al. (2013) Validity and Reliability of the Japanese Version of the painDETECT Questionnaire: A Multicenter Observational Study. PLoS ONE 8(9): e68013. doi:10.1371/journal.pone.0068013

Editor: Kazutaka Ikeda, Tokyo Metropolitan Institute of Medical Science, Japan

Received April 8, 2013; **Accepted** May 24, 2013; **Published** September 30, 2013

Funding: This study received financial funds from the "Health and Labour Sciences Research Grant." The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: The authors have declared that no competing interests exist.

* E-mail: ymatsubayashi-tky@umin.ac.jp

Introduction

Neuropathic pain is defined as "pain caused by a lesion or disease of the somatosensory system" [1], and its prevalence reaches about 7%–8% in the European population [2,3]. A variety of diseases such as diabetic polyneuropathy, postherpetic neuralgia, spinal cord injury, and peripheral nerve compression cause neuropathic pain, and they generally follow a chronic course. Chronic pain in patients results in anxiety, depression, and interference with sleep, normal work, and social activities [4,5]. It has a strong negative impact on the quality of life [6] and has been estimated to result in an expense of more than $100 billion per year in direct medical costs and about $100 billion as indirect costs from absenteeism and decreased productivity at work in the United States [7]. Among chronic pain conditions, neuropathic pain impairs the quality of life profoundly, and patients with neuropathic pain are likely to generate more expenses compared with those with other pain conditions [8]. Although early and intense care of neuropathic pain is important, diagnosing neuropathic pain is a challenge because lesions of the somatosensory nervous system are not readily detectable. Unlike non-neuropathic pain conditions, neuropathic pain usually reveals characteristic symptoms such as "burning sensation," "prickling sensation," and/or a sensation of "electric shock [9]." On the basis of such characteristic descriptions, screening tools have been developed to identify the components of neuropathic pain from a patient's presentation of symptoms.

The painDETECT questionnaire (PDQ) is one of the screening tools of neuropathic pain, which was published by Freynhagen et al. from Germany [10,11]. They established the usefulness and validity of this brief, self-administered questionnaire in identifying neuropathic components of pain in patients with chronic lower back pain. PDQ has already been

Figure 1. The painDETECT Questionnaire–Japanese version (PDQ-J)

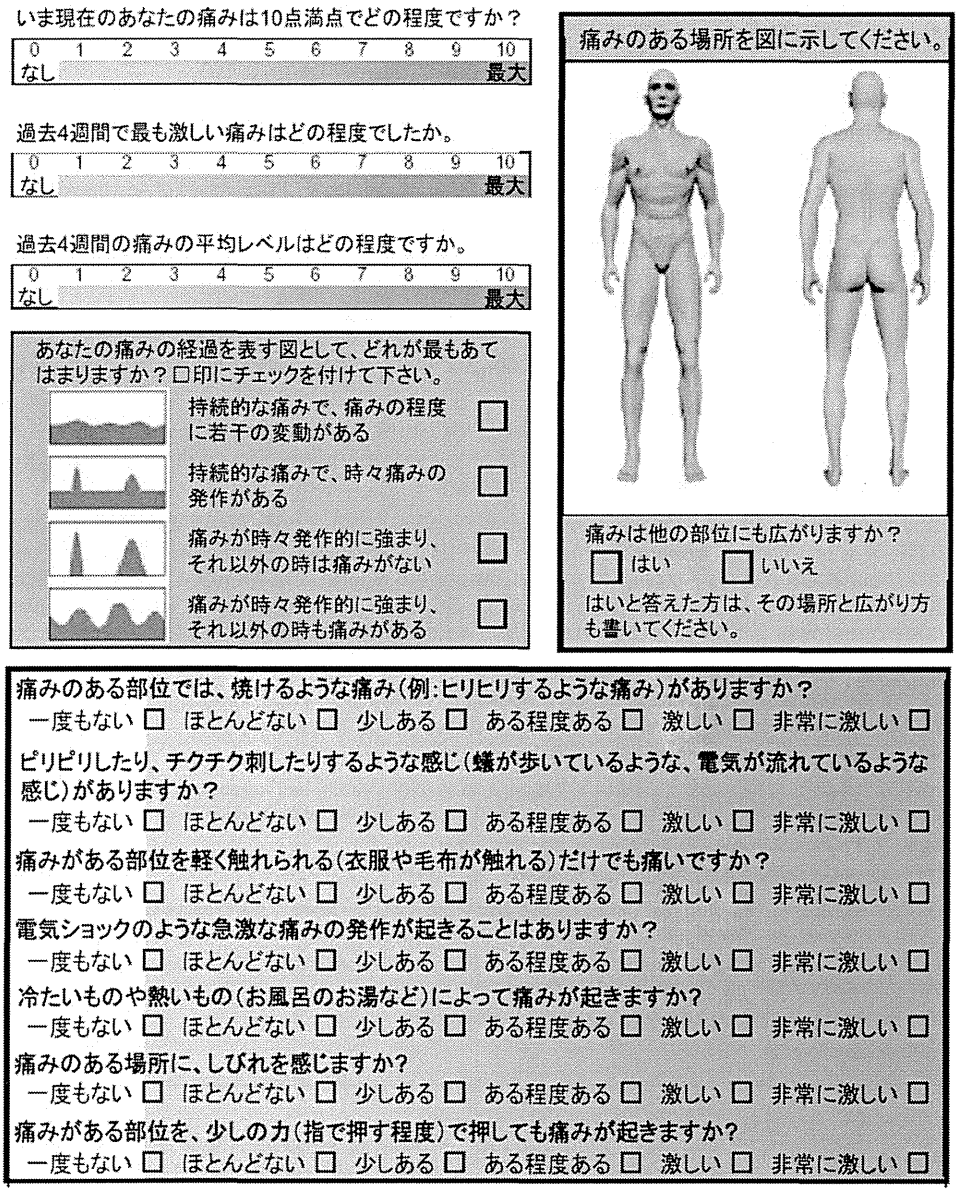

Figure 1. The painDETECT Questionnaire-Japanese version (PDQ-J).

doi: 10.1371/journal.pone.0068013.g001

translated into Spanish [12], Dutch [13], and Japanese [14]. The Japanese version of PDQ (PDQ-J) was translated and reported by one of the authors of the present study in 2007 (Figure 1). Translation and cross-cultural adaptation of PDQ-J was performed in accordance as per the established guidelines [15,16]. First, for forward translation, a professional native Japanese translator and a bilingual Japanese physician independently translated the original PDQ into Japanese. Second, an expert committee, including specialists in pain management, orthopedics, and methodology, conducted synthesis of the translation. Third, two native English translators, who were uninformed about the nature of the study, completed back translations of the translated PDQ; thereafter, back-translations were sent to the expert committee to detect any existing cultural bias, and the final version of PDQ-J was completed. Nevertheless, the validity of PDQ-J has not been confirmed yet; therefore, this study aimed to assess the validity and reliability of PDQ-J.

Materials and Methods

The study protocol was approved by the institutional review board of the Clinical Research Support Center of the University of Tokyo Hospital. Participants provided their written informed consent to participate in this study.

We conducted a multicenter observational study, and patients from two adult populations were enrolled. All the enrolled patients suffered from pain with an intensity of 3 or more out of 10 on an 11-point numerical rating scale (NRS). The first study group included patients with neuropathic pain (NeP group) diagnosed by a pain specialist in the pain center as per the guidelines established by the International Association for the Study of Pain (IASP) [17]. In the pain center, only neuropathic patients with stable disease condition and tolerable pain were selected; in addition, they were selected if it could be estimated that there would be little change in their pain during the study period. The second study group comprised patients suffering from acute nociceptive pain (NocP group) induced by trauma or orthopedic patients with a degenerative condition of the extremities. Moreover, patients with cultural or language barriers or with poor mental health status that prevented them from understanding or responding to proposed questions were excluded from this study. Informed consent was provided by selected patients from both the groups. In the first survey, all patients were asked to complete a set of questionnaires including PDQ-J, a three-type numeric rating scale (NRS) of pain (i.e., pain during the survey, a four-week average, and maximum pain experienced), and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The patients answered questions regarding their demographic data (e.g., age, sex, height, weight, occupation, smoking history, and education). Thereafter, the physicians reported the original diagnoses, comorbidities, and treatment options. The second survey questionnaire was administered only to the neuropathic patients 2–5 weeks after the first visit, and it included the same set of three questionnaires with one additional question regarding whether there was an increase, decrease, or no change in pain since the administration of the first survey.

PDQ comprises a main component along with two additional components. In the main component, termed as "gradation of pain," the patient is asked to identify the presence of seven pathological pain sensations: burning, tingling, or prickling sensations, tactile and thermal allodynia, electric shock-like sensations, numbness, and pressure-evoked pain sensation. The patient grades the presence of each type of pain as follows: 0 = never; 1 = hardly noticed; 2 = slightly; 3 = moderately; 4 = strongly; 5 = very strongly. This main component of PDQ yields scores from 0 to 35 points. A second component of PDQ, termed as "pain course pattern," is a multiple-choice questionnaire accompanied by four pain charts; the patient is asked to quantify the pattern of experienced pain as follows: persistent pain with slight fluctuations (0 points); persistent pain with pain attacks (−1 point); pain attacks without pain between them (1 point); pain attacks with pain between them (1 point). The third component of PDQ, termed "radiating pain," asks patients regarding radiation of pain to other regions of the body (2 points). A total score is calculated by adding the scores from the three components; a high score indicates that the pain is possibly neuropathic in nature.

The intensity of pain was assessed by a three-type NRS where the patient is asked to grade the actual pain level experienced, the maximum pain level experienced in the last four weeks, and the average pain level experienced in last four weeks on a scale of 0-10 (0 = no pain, 10 = worst pain imaginable).

The SF-36 consists of eight subscales, namely physical functioning, physical role functioning, bodily pain, general health perceptions, vitality, social role functioning, emotional role functioning, and mental health [18,19]. Each subscale is transformed to a score ranging from 0 to 100, with lower scores indicating poor health-related quality of life. For analysis, we used two summed scores: the Physical Component Score (PCS) and the Mental Component Score (MCS). Each score has the same mean and standard deviation (50 and 10, respectively) in a normal population.

Feasibility

We analyzed the number of unanswered questions to evaluate the feasibility of PDQ-J.

Validity

To establish construct validity, we performed an exploratory factor analysis with principal components extraction. The Kaiser criterion (eigenvalues > 1.0) and Scree plot were used to determine the number of factors. As for criterion-related validity, we calculated the Pearson correlation coefficient between PDQ-J, NRS, PCS (SF-36), and MCS (SF-36). Following are the generally accepted rankings for coefficients: 1.0–0.81 (excellent); 0.80–0.61 (very good); 0.60–0.41 (good); 0.40–0.21 (fair); and 0.20–0 (poor) [20].

Reliability

Internal consistency was measured with Cronbach's alpha. Alpha coefficients of a magnitude of ≥0.70 were considered useful as evidence of adequate scale reliability at the level of group comparisons [21]. Repeatability was assessed by a test–retest method. Retest was administered to neuropathic patients more than two weeks after first survey. Intraclass correlation coefficients (ICCs) between test and retest scores were calculated from the data from patients who responded with no change of symptoms between the two surveys; moreover, those with coefficients >0.80 were considered as having excellent reliability [22].

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS version 21.0) software.

Results

A total of 122 Japanese patients were recruited in this study. However, nine patients were excluded because of incomplete responses to the proposed questions; most (six of nine) of the blank responses were to the question regarding the radiation of pain. Following exclusions, a total of 113 patients were further evaluated: 60 patients were diagnosed as having neuropathic

Table 1. Demographic data of study patients.

	NeP (n=60) (SD)	NocP (n=53) (SD)	P value (t-test)
Age (mean)	59 (15)	57 (18)	n.s.
Male/Female	40/20	30/23	n.s.
Height (mean)	164 (10)	164 (11)	n.s.
Weight (mean)	64 (17)	62 (13)	n.s.
Duration (months)	63 (71)	2.3 (7.9)	<0.001

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t001

Table 2. Demographic data of study patients (education).

Education	NeP (n)	NocP (n)
Middle school	8	11
High school	24	14
Junior college	6	13
University	16	15
Graduate university	4	0

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t002

Table 3. Demographic data of study patients (occupation).

Occupation	NeP (n)	NocP (n)
Employee	15	18
Retired	19	12
Self-employed	11	9
Housewife	8	8
Part-time job	3	6
Student	1	0
Employer	1	0

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t003

pain, and 53 were categorized as having nociceptive pain. The demographic characteristics of these patients are presented in Tables 1, 2, and 3; in addition, it lists specific etiologies of pain in patients in the NeP group [brachial plexus injury (12 patients); radiculopathy (12 patients); herpes zoster (11 patients); spinal cord injury (10 patients); diabetic or alcoholic polyneuropathies (7 patients); phantom pain (5 patients); complex regional pain syndrome (CRPS; 2 patients); carpal tunnel syndrome (1 patient); and thalamic pain (1 patient)] and the NocP group [trauma in 47 patients (89%), and degenerative diseases in 6 patients (11%)] (Table 4). Specific etiologies included fractures (32 patients), contusion/sprains (10 patients), osteoarthritis (4 patients), muscle pain (3 patients), dislocations (2 patients), tenosynovitis (1 patient), and rotator cuff injury (1 patient).

Tables 5 and 6 presents the summary of patient responses of PDQ-J, and Table 7 presents the scores for each questionnaire in NeP and NocP group, respectively. On the

Table 4. Etiology of study patients.

Neuropathic Pain	Nociceptive Pain
Brachial Plexus Injury 12, Radiculopathy 12, Herpes zoster 11, Spinal cord injury 10, Neuropathy 7, Phantom pain 5, complex regional pain syndrome 2, Carpal Tunnel Syndrome 1, Thalamic pain 1	Fracture 32, Contusion/sprain 10, Osteoarthritis 4, Muscle pain 3, Dislocation 2, Tenosynovitis 1, Rotator cuff injury 1

doi: 10.1371/journal.pone.0068013.t004

Table 5. PainDETECT Questionnaire-Japanese version (PDQ-J): summary of patient responses (Q1-7).

n (NeP/NocP)	No	Hardly noticed	Slightly	Moderately	Strongly	Very strongly
Q1. Burning	14 (4/10)	25 (11/14)	30 (9/21)	21 (17/4)	18 (14/4)	5 (5/0)
Q2. Tingling	10 (0/10)	12 (6/6)	39 (13/26)	25 (17/8)	19 (18/1)	8 (6/2)
Q3. Pain by touch	17 (8/9)	30 (15/15)	24 (10/14)	21 (12/9)	15 (12/3)	6 (6/2)
Q4. Electric shock-like pain	28 (9/19)	34 (16/18)	18 (11/7)	18 (12/6)	9 (8/1)	6 (4/2)
Q5. Pain on cold/hot stimulation	33 (8/25)	40 (23/17)	19 (12/7)	15 (12/3)	2 (2/0)	4 (3/1)
Q6. Numbness	15 (1/14)	23 (5/18)	19 (7/12)	19 (13/6)	18 (17/1)	19 (17/2)
Q7. Pain by pressure	5 (3/2)	28 (18/10)	22 (8/14)	26 (14/12)	19 (10/9)	13 (7/6)

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t005

pain intensity scale, patients from the NeP group experienced pain that was significantly more severe compared with that in the NocP group. The PDQ-J and SF-36 scores revealed similar trends: patients in the NeP group revealed lower physical and mental functioning compared with that in patients in the NocP group.

Validity

The factor analysis by Promax rotation using the Kaiser criterion (eigenvalues ≥1.0) and a Scree plot revealed that the main component of PDQ-J consists of two determinative factors, and it explained 62% of the variance. One of these determinative factors can be termed as "spontaneous pain," and the other as "evoked pain." For criterion-related validity, the total score of PDQ-J revealed statistically significant correlations with pain intensity, PCS (SF-36), and MCS (SF-36; Table 8).

Table 6. PainDETECT Questionnaire-Japanese version (PDQ-J): summary of patient responses (Q8-9).

Q8. Pain course pattern	n (NeP/NocP)
Persistent pain with slight fluctuations	46 (22/24)
Persistent pain with pain attacks	21 (12/9)
Pain attacks without pain between them	18 (3/15)
Pain attacks with between them	28 (23/5)
Q9. Radiating pain	**n (NeP/NocP)**
Yes	74 (35/39)
No	34 (23/11)

NeP: Neuropathic Pain, NocP: Nociceptive Pain

doi: 10.1371/journal.pone.0068013.t006

Table 7. Scores of Pain Intensity, Neuropathic pain, and health-related outcomes.

Outcomes	NeP (SD)	NocP (SD)	P-value (t-test)
Pain Intensity-NRS (present)	6.5 (2.3)	4.3 (2.9)	< 0.001
Pain Intensity-NRS (average)	6.7 (2.0)	4.2 (2.3)	< 0.001
Pain Intensity-NRS (maximum)	8.3 (1.6)	6.6 (3.2)	< 0.001
painDETECT	18.6 (6.3)	11.8 (6.3)	< 0.001
PCS (SF-36)	26.6 (16.9)	34.3 (20.8)	< 0.05
MCS (SF-36)	41.6 (11.7)	52.7 (10.2)	< 0.001

NeP: Neuropathic Pain, NocP: Nociceptive Pain, NRS: Numerical Rating Scale, SF-36: Medical Outcomes Study 36-Item Short-Form Health Survey, PCS: Physical Component score, MCS: Mental Component Score

doi: 10.1371/journal.pone.0068013.t007

Table 8. Pearson correlation coefficient with PDQ-J.

	PDQ-J	P Value
Pain-Intensity (NRS)	0.44	< 0.01
PCS (SF-36)	−0.27	< 0.01
MCS (SF-36)	−0.34	< 0.01

NeP: Neuropathic Pain, NocP: Nociceptive Pain, NRS: Numerical Rating Scale, SF-36: Medical Outcomes Study 36-Item Short-Form Health Survey, PCS: Physical Component score, MCS: Mental Component Score

doi: 10.1371/journal.pone.0068013.t008

Reliability

The Cronbach alpha for the total score of PDQ-J was 0.78 and that of the main component of PDQ (i.e., "gradation of pain") was 0.80, which was comparable to 0.83 and 0.86 reported in the original and Spanish versions, respectively [11,12]. The score for each of the nine questions in PDQ-J revealed a statistically significant correlation with the total score of PDQ-J. We could recruit 16 patients with neuropathic pain for a test–retest study; of these, 11 patients reported no change in their symptoms, and the data for each these patients were evaluated. The average period between the two surveys was 23.1 days [standard deviation (SD): 8.3]. The mean score of the first and second survey was 20.4 (SD: 7.7) and 20.2 (SD: 7.2), respectively. Furthermore, ICC between the two scores was 0.94 despite the relatively long interval between the two surveys (Figure 2).

Figure 2.

Relationship between results of first and second PDQ-J scores in the retested patients

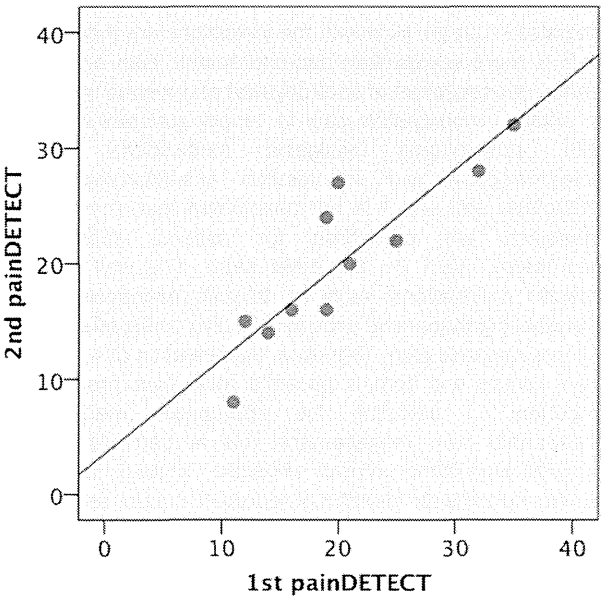

Figure 2. Relationship between results of first and second PDQ-J scores in the retested patients.

doi: 10.1371/journal.pone.0068013.g002

Discussion

This study demonstrated that PDQ-J has good validity and reliability. In addition, the results obtained in this study were comparable with those obtained in previous studies [11,12]. With regard to construct validity, the factor analysis revealed that the seven Likert items of PDQ-J consist of two determinative factors, which could be designated as "spontaneous pain" and "evoked pain." These factors are consistent with clinical characteristics of neuropathic pain. Further, with regard to criterion-related validity, the correlation between PDQ-J and NRS, MCS (SF-36), and PCS (SF-36) was moderate, indicating that PDQ-J can reflect pain intensity as well as impairments of mental status and physical status of individual patients. There is evidence from a previous study to support this, in which patients with more intense pain revealed higher total scores on PDQ [23]. Therefore, PDQ-J might be used as a score of pain severity, although another study should be conducted to validate this. In this study, we demonstrated fair to good criterion-related validity, excellent internal consistency, and high reliability with statistical significance, although the number of patients was limited, particularly in the

analysis of repeatability. As this study evaluated two distinct types of pain, neuropathic and acute nociceptive pain in the extremities, the methods and results obtained in this study might be useful in a wide patient population suffering from various types of pain.

Because the prevalence of patients with neuropathic pain is limited in general population [24], neuropathic pain has not been still recognized well in clinical settings all over the world and also in Japan. However, the indications are that this type of pain is more severe than non-neuropathic pain and results in profound impairment of both physical and mental quality of life. In addition, neuropathic pain is usually resistant to treatment with conventional analgesic medications such as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), and yet, it is not uncommon that such ineffective measures are prescribed for patients suffering from neuropathic pain. On the other hand, it is well known that specific medications such as tricyclic antidepressants and pregabalin/gabapentine provide effective analgesia in patients with neuropathic pain. Therefore, the detection of a neuropathic pain component from a patient's total pain presentation is important in selecting the appropriate medication for appropriate pain management; this is particularly true for general physicians without expertise in pain management. Screening tools for identifying neuropathic pain, such as PDQ, have revealed that a neuropathic pain component is underdiagnosed in a profound number of patients with pain, thereby suggesting that patients with neuropathic pain are not administered analgesics that are most effective in treating this type of pain. Similar circumstances are probably present in Japan as well. The results of the present study along with confirmed reliability and validity of PDQ-J provide the rationale to encourage extension of its use by general physicians in Japan to promote appropriate pain management in patients suffering with conditions involving chronic pain.

Conclusion

This study confirms that PDQ-J has good reliability and validity as a pain assessment tool. Thus, we encourage researchers and clinicians to use PDQ-J for the assessment of patients suffering from pain that is suspected to be neuropathic in origin.

Author Contributions

Conceived and designed the experiments: KT MS. Performed the experiments: YM KT MS YO SK JO TO NO ST JT. Analyzed the data: KT YM. Wrote the manuscript: YM KT MS.

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Mod Rheumatol
DOI 10.1007/s10165-013-0876-1

ORIGINAL ARTICLE

Prevalence of low back pain as the primary pain site and factors associated with low health-related quality of life in a large Japanese population: a pain-associated cross-sectional epidemiological survey

Koji Yamada · Ko Matsudaira · Katsushi Takeshita · Hiroyuki Oka · Nobuhiro Hara · Yasuo Takagi

Received: 27 December 2012 / Accepted: 25 March 2013

Abstract
Objectives This study aimed to estimate the prevalence, magnitude, and direction of the associations among disability, pain intensity, number of pain sites, and health-related quality of life (HRQoL) in patients reporting low back pain (LBP) as their primary pain.
Methods In January 2009, an Internet survey was performed for randomly selected adults aged 20–79 years who were registered as Internet research volunteers. Of 20 044 respondents, individuals with LBP as the primary pain were analyzed for associations among disability, number of pain sites, and HRQoL. Factors associated with low HRQoL were examined using multiple logistic regression modeling.
Results Of the 20 044 respondents, 25.2 % ($n = 5060$) reported LBP and 13.5 % ($n = 2696$) reported LBP as their primary pain. Among those with LBP as the primary pain, HRQoL decreased with increase in disability and number of pain sites. In multivariate analyses, disability [adjusted odds ratio (aOR), 2.93–4.58], number of pain sites (aOR, 1.42–6.12), pain intensity ≥ 7 (aOR, 1.88), and age ≥ 60 years (aOR, 1.55) were associated with low HRQoL.
Conclusions Approximately 13.5 % of patients reported LBP as their primary pain. Disability with absence from social activity and ≥ 7 pain sites were strongly associated with low HRQoL.

Keywords Disability · EQ-5D · Low back pain · Multisite pain · Sick leave

K. Yamada (✉) · K. Takeshita · N. Hara
Department of Orthopaedic Surgery, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
e-mail: forpatients2008@gmail.com

K. Matsudaira
Clinical Research Center for Occupational Musculoskeletal Disorders, Kanto Rosai Hospital, Kawasaki, Kanagawa, Japan

H. Oka
Department of Joint Disease Research, 22nd Century Medical and Research Center, The University of Tokyo, Tokyo, Japan

Y. Takagi
Graduate School of Health Management, Keio University, Fujisawa, Kanagawa, Japan

Introduction

Low back pain (LBP) is a common [1], costly [2], and, at times, disabling [3] condition that can lead to disability and sick leave from work or school. Pain at this site often fluctuates over time with frequent recurrences or exacerbations [4, 5]. The prevalence of LBP has been reported to range from 12–33 % [4] due to the methodologic heterogeneity across LBP prevalence studies [6, 7]. LBP is the most frequent and most expensive cause of work-related disability [8] and can affect health-related quality of life (HRQoL). LBP is a part of musculoskeletal pain [9, 10], but only one-sixth to one-third of individuals who suffer from LBP have LBP as their only pain source. Most LBP respondents also have pain at other sites [10]; this pain could be the primary reason for their disability. Moreover, a positive correlation was reported between the number of pain sites and functional problems in a large clinical study [9]. However, the prevalence and the impact of working disability and number of pain sites on HRQoL in those who have LBP as the primary pain have not been well examined.

Published online: 10 April 2013

Therefore, the aim of this study was to estimate the prevalence, magnitude, and direction of the associations among disability, pain intensity, number of pain sites, and HRQoL in those reporting LBP as their primary pain in the pain-associated cross-sectional epidemiological (PACE) survey, which covers a large Japanese population.

Materials and methods

Subjects

The PACE survey was a cross-sectional Internet survey designed to evaluate the prevalence and characteristics of musculoskeletal pain in a large Japanese population. The study was performed over 10–18 January, 2009. Respondents were recruited at random from 1 477 585 research volunteers who were registered with an Internet survey company (Rakuten Research Inc., Tokyo, Japan), consistent with the Japanese demographic composition [11]. An invitation to participate in the research was sent through an e-mail containing a link to the survey. Double registration was prevented by checking the e-mail address and disabling the link to the questionnaire once the responder completed the survey. Forms were configured to automatically reject incomplete questionnaires. An additional credit point for Internet shopping was given as a financial incentive to the responders. On 18 January, 2009, the survey was closed when the number of respondents reached 20 063; thus, the response rate is not relevant in this survey. Individuals whose reported age was <20 years or >79 years were excluded; thus, 20 044 participants were retained. This study was approved by Keio University's institutional review board.

Measures

The questionnaire included questions regarding musculoskeletal pain in the previous month and various individual factors. The respondents were asked about the characteristics of their musculoskeletal pain, such as the pain site(s), pain intensity at each site, site of the primary pain, duration of the primary pain, and disability due to the primary pain. Pain intensity was scored with a numeric rating scale (NRS) comprising 11 points (0 = no pain, 10 = worst pain imaginable). Disability was classified into three categories using a modified graded chronic pain scale (GCPS) [12], based on disability for social activity, such as work, school, and housework. Those with LBP and no disability were classified as modified GCPS grade 1, those with LBP and disability for social activity as modified GCPS grade 2, and those with LBP and disability leading to absence from social activity as modified GCPS grade 3. Respondents were asked about their demographic characteristics, including age, sex, occupational status, and HRQoL. HRQoL was measured using the Japanese EQ-5D instrument [13].

Definition of LBP

LBP was defined as pain experienced (over the previous month) below the costal margin and above the inferior gluteal folds, as described on the full-body manikin (Fig. 1, site 13), excluding those with pain around the anus (Fig. 1, site 21). Chronic LBP was defined as pain lasting ≥3 months.

EQ-5D

The EQ-5D instrument is a standardized general system for describing and valuing HRQoL [14]. It has good reliability and validity, and comprises five dimensions (mobility, self-care, usual activity, pain/discomfort, anxiety/depression) that are rated on three levels (1 = no problem, 2 = some problem, 3 = extreme problem); thus, it generates 243 theoretically possible health states (11111 = full health, 33333 = most extreme state).

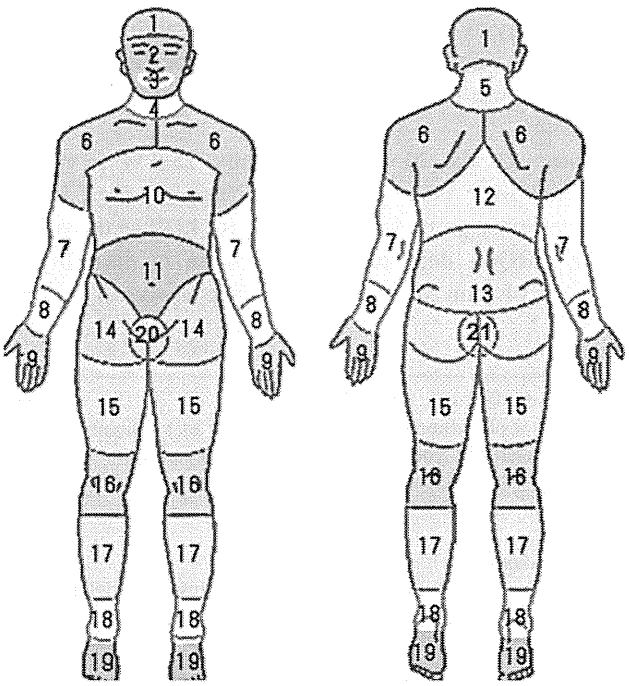

Fig. 1 The full-body manikin used in the pain-associated cross-sectional epidemiological (PACE) survey. Low back pain was defined as pain experienced below the costal margin and above the inferior gluteal folds, described as site number 13, excluding those with pain around the anus (site number 21)

Statistical analysis

First, the 1-month prevalence was calculated for those who had any LBP, LBP as the primary pain, and LBP as the only pain source (localized LBP). Further analyses were performed for those reporting LBP as their primary pain site using SPSS version 18 (IBM Corp., Armonk, N.Y., USA). Spearman's rho correlation coefficient was used to assess the correlations among HRQoL (EQ-5D score), disability, number of pain sites (other than LBP), and pain intensity (NRS score). For logistic regression analysis, the lowest 20 % of the EQ-5D scores in the total study population of the PACE survey was used as the dependent variable. A two-sided 5 % significance level was used in all statistical tests.

Results

LBP prevalence

Of the 20 044 respondents, 9746 (48.6 %) were men, and the overall mean score on the EQ-5D was 0.850 [standard error (SE), 0.001] with a ceiling effect of 45.7 % (9165 respondents; Table 1). The 1-month prevalence of LBP was 25.2 % (5060 respondents), of which only approximately half (2696 respondents; 13.5 % of all respondents) reported LBP as their primary pain and about one-seventh (706 respondents; 3.5 % of all respondents) reported LBP as their only pain source.

HRQoL in those with LBP as the primary pain

Further analyses were conducted for those with LBP as their primary pain. Of the 2696 respondents who reported LBP as the primary pain, 53.8 % ($n = 1{,}424$) were men, 78.1 % ($n = 2{,}106$) had chronic pain, 55.3 % ($n = 1{,}491$) reported LBP and no disability (modified GCPS grade 1), and 44.7 % ($n = 1{,}205$) reported disability for social activity with or without absence from social activity (Table 2). The mean EQ-5D score was 0.776 (SE, 0.003), which was significantly lower than that of the total study population (unpaired t test, $P < 0.01$).

Next, the associations among HRQoL, number of pain sites, and pain intensity according to disability were analyzed (Table 3). We found that HRQoL decreased (Spearman's rank correlation coefficient, −0.371; $P < 0.01$) while pain intensity increased (Spearman's rank correlation coefficient, 0.418; $P < 0.01$) with higher disability. An increase in the number of pain sites was seen only between grade 1 and grade 2 disabilities (Table 3). Based on further evaluation of HRQoL stratified by age, sex, and disability, mean EQ-5D scores generally were lower in those with higher age and higher disability, and in women (Table 4).

Table 1 Characteristics of the total study population ($n = 20{,}044$)

Characteristic	*n* (%)
Age group (years)	
20–29	1,981 (9.9)
30–39	3,903 (19.5)
40–49	3,923 (19.6)
50–59	4,328 (21.6)
60–69	4,126 (20.6)
70–79	1,783 (8.9)
Mean ± SD	49.0 ± 14.2
Sex	
Male	9,746 (48.6)
Occupational status	
Worker	10,597 (52.9)
Housework and/or retired	7,655 (38.2)
Other (including student)	1,792 (8.9)
LBP prevalence	
Any LBP[a]	5,060 (25.2)
LBP as primary pain[b]	2,696 (13.5)
Localized LBP[c]	706 (3.5)
EQ5D score, mean ± SE	0.850 ± 0.001
Ceiling effect	9,165 (45.7)

LBP Low back pain, *SE* standard error

[a] Prevalence of respondents with LBP

[b] Prevalence of respondents with LBP as the primary pain site

[c] Prevalence of respondents with LBP as the only pain source

Further analyses were conducted to evaluate the association among each variable stratified by the number of pain sites (Table 5). The number of respondents with LBP as a part of multisite pain was approximately 6.2 times larger than the number of those with localized LBP. In this analysis, HRQoL showed a negative correlation with the number of pain sites (Spearman's rank correlation coefficient, −0.256; $P < 0.01$). HRQoL was highest when the pain was localized, and lowest when the number of pain sites was ≥ 7. The proportion of those with disability for social activity (modified GCPS grades 2 and 3) and pain intensity also showed a positive correlation with the number of pain sites (Spearman's rank correlation coefficient, 0.184 and 0.359, respectively; both $P < 0.01$).

Factors associated with low HRQoL

In multivariate analyses adjusted by modified GCPS, number of pain sites, sex, age, and pain intensity, all the variables except sex were positively associated with low HRQoL (Table 6). The odds were higher as both disability and number of pain sites increased. Disability with absence