



Validating the preoperative Japanese Core Outcome Measures Index for the Neck and comparing quality of life in patients with cervical spondylotic myelopathy and ossification of the posterior longitudinal ligament by the patient-reported outcome measures

Yasuaki Mizoguchi^{1,2} · Kiyokazu Akasaka^{1,3} · Kenta Suzuki² · Fumihiko Kimura² · Toby Hall⁴ · Satoshi Ogihara⁵

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Abstract

Purpose This cross-sectional study serves two main purposes. Firstly, it aims to validate the preoperative Japanese Core Outcome Measures Index for the Neck (COMI-Neck) in patients with cervical spondylotic myelopathy (CSM) and ossification of the posterior longitudinal ligament (OPLL). Secondly, it seeks to elucidate differences in preoperative quality of life (QOL) between these two cervical pathologies using patient-reported outcome measures (PROMs).

Methods A total of 103 preoperative patients (86 with CSM and 17 with OPLL) scheduled for cervical spine surgery were included in the study. Validated PROMs, including the Japanese COMI-Neck, Neck Disability Index (NDI), EuroQol-5 Dimension-3 level (EQ-5D-3L), and SF-12v2, were used to assess QOL. Baseline demographic and clinical data were collected, and statistical analyses were performed to compare the PROMs between CSM and OPLL groups.

Results The Japanese COMI-Neck demonstrated good construct validity, with positive correlations with NDI and negative correlations with EQ-5D-3L and SF-12v2. Comparison of preoperative PROMs between CSM and OPLL groups revealed differences in age, body mass index, and EQ-5D-3L scores. The CSM group had higher NDI scores for concentration and lower EQ-5D-3L scores for self-care compared to the OPLL group.

Conclusions This study validated the preoperative Japanese COMI-Neck in CSM and OPLL patients and identified specific QOL issues associated with each condition. The findings highlight the importance of considering disease-specific QOL and tailoring treatment plans accordingly. Further research should include postoperative assessments and a more diverse population to enhance generalizability.

Keywords Cervical spondylotic myelopathy · Ossification of the posterior longitudinal ligament · Patient-reported outcome measures · Quality of life

Introduction

Cervical spine conditions that commonly require surgery include cervical spondylotic myelopathy (CSM), ossification of the posterior longitudinal ligament (OPLL), cervical disk herniation, osteoarthritis of the cervical spine, and cervical radiculopathy [1]. In particular, CSM and OPLL are spinal conditions that cause significant disability and reduced quality of life (QOL). CSM is known as a degenerative disease characterized by narrowing of the spinal canal due to age-related changes such as disk degeneration, osteophytes, and ligamentous hypertrophy [2]. These changes may manifest as motor weakness, sensory disturbance, and gait instability.

✉ Kiyokazu Akasaka
akasaka-smc@umin.ac.jp

¹ Saitama Medical University Graduate School of Medicine, 981 Kawakado, Moroyama, Iruma, Saitama, Japan

² Department of Rehabilitation, Kimura Orthopaedic Clinic, Saitama, Japan

³ School of Physical Therapy, Faculty of Health and Medical Care, Saitama Medical University, Saitama, Japan

⁴ Curtin School of Allied Health, Curtin University, Perth, Australia

⁵ Department of Orthopaedic Surgery, Saitama Medical Center, Saitama Medical University, Saitama, Japan

OPLL, on the other hand, is a pathological proliferation of bone along the posterior longitudinal ligament that causes clinical symptoms similar to CSM and has a high prevalence in the Japanese population [3, 4]. Although the clinical manifestations of CSM and OPLL are similar, the underlying mechanisms and pathophysiology are different. Consequently, these variations may contribute to distinct patterns of symptom severity, functional impairment, and ultimately QOL.

Several studies have focused on improving QOL in patients with CSM and OPLL with surgical intervention [5, 6]. However, studies comparing preoperative QOL between these two conditions are limited, and systematic reviews have shown a lack of preoperative data [7]. This article uses established patient-reported outcome measures (PROMs) such as the Japanese Core Outcome Measures Index for the Neck (COMI-Neck) [8, 9], Neck Disability Index (NDI) [10], EuroQol-5 Dimension-3 level (EQ-5D-3L) [11, 12], and SF-12v2 [13] to focus on various aspects of QOL. The COMI-Neck is a comprehensive patient-reported outcome measure specifically designed for assessing neck-related disability and QOL [8, 14]. It covers domains such as pain intensity, functional disability, work and social disability, and quality of sleep. The Japanese COMI-Neck has been validated based on pre- and postoperative values for patients with various cervical spine disorders [8]. The NDI is a condition-specific tool commonly utilized to measure disability related to neck pain [10]. The EQ-5D-3L is a generic instrument widely used to evaluate health-related QOL, considering five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [11], while the SF-12v2 assesses general health-related QOL across physical and mental health domains. Lubelski D et al. suggest that a combination of various QOL assessments should be used for preoperative and postoperative evaluation in patients with

CSM, and we decided to adopt this approach in this study [15].

In summary, the validation of the Japanese COMI-Neck and the comparison of preoperative PROMs between CSM and OPLL are inherently connected objectives in this study. The validation step ensures that the QOL assessments in both conditions are measured using a reliable instrument, while the comparison of preoperative PROMs provides valuable insights into the distinct QOL issues faced by patients with CSM and OPLL. Together, these objectives contribute to the overall goal of improving preoperative care and postoperative rehabilitation for patients with cervical spine disorders. By identifying specific QOL challenges associated with each condition, healthcare providers can develop tailored treatment plans, enhance patient satisfaction, and ultimately optimize the management of CSM and OPLL.

Methods

Study design and participants

This study was conducted with the approval of the Institutional Review Board of Saitama Medical Center, Saitama Medical University (No. 1969-III). This cross-sectional study aimed to compare the QOL of preoperative patients with CSM and OPLL and was conducted according to the STROBE statement. The study period spanned from April 2018 to June 2022. A total of 164 consecutive patients who were scheduled for cervical spine surgery were included in the study. Patients were selected based on their willingness to participate and their availability to complete the required PROMs. Among the 164 patients, 103 patients (86 with CSM and 17 with OPLL) completed the PROMs and were included in the final analysis (Table 1). Those patients with

Table 1 Descriptive statistics and group comparisons of patients in this study

	Total number (<i>n</i> = 103)	CSM (<i>n</i> = 86)	OPLL (<i>n</i> = 17)	<i>p</i>	Power (1- β)
Age (years)	66.8 ± 11.3	67.9 ± 11.2 (68.5)	61.3 ± 10.4 (62.0)	0.02*	0.60
Sex, <i>n</i> (male/female [%])	81 (78.6) / 22 (21.4)	65 (75.6) / 21 (24.4)	16 (94.1) / 1 (5.9)	0.08	0.99
BMI (kg/m ²)	24.5 ± 4.1	23.8 ± 3.4 (23.1)	28.1 ± 5.6 (27.3)	<0.001*	0.92
ASA classification (1/2/3 [%])	10 (9.7) / 79 (76.7) / 14 (13.6)	9 (10.5) / 67 (77.9) / 10 (11.6)	1 (5.9) / 12 (70.6) / 4 (23.5)	0.47	–
Smoke, <i>n</i> (%)	75 (72.8)	63 (73.3) / 23 (23.4)	12 (70.6) / 5 (29.4)	0.52	0.10
Diabetes mellitus, <i>n</i> (%)	21 (20.4)	17 (19.8) / 69 (80.2)	4 (23.5) / 13 (76.5)	0.47	0.16
Hypertension, <i>n</i> (%)	45 (43.7)	37 (43.0) / 49 (57.0)	8 (47.1) / 9 (52.9)	0.48	0.13
Hyperlipidemia, <i>n</i> (%)	10 (9.7)	9 (10.5) / 77 (89.5)	1 (5.9) / 16 (94.1)	0.48	0.33
Arrhythmia, <i>n</i> (%)	5 (4.9)	5 (5.8) / 81 (94.2)	0 (0.0) / 17 (100)	0.40	0.71

Mean ± SD; **P* value < 0.05; PROMs patients-reported outcome measures; CSM cervical spondylotic myelopathy; OPLL ossification of the posterior longitudinal ligament; BMI, body mass index; ASA American Society of Anesthesiologists

cervical disk herniation (six patients), tumors (five patients), and others (two patients) were excluded from the study.

Data collection

Baseline demographic and clinical characteristics of the participants were collected. These included age, sex, body mass index (BMI: kg/m²), ASA classification, smoking status, and history of diabetes, hypertension, hyperlipidemia, and arrhythmias. These variables were collected from the patients' medical records.

Patient-reported outcome measures

The following PROMs were used to assess QOL in the preoperative patients: Japanese COMI-Neck, NDI, EQ-5D-3L, and SF-12v2. These questionnaires were administered to the patients prior to their scheduled cervical spine surgery. The Japanese COMI-Neck questionnaire was used to assess the severity of neck pain [8]. This questionnaire includes domains such as pain, function, symptom-specific well-being (SSWB), general QOL, and disability. The COMI-Neck is given a score for each item ranging from 0 to 10, and the summary score is calculated as the average of each item, with higher scores indicating a worse outcome or a greater impact of spinal disease on the patient's life [9]. The NDI questionnaire evaluated the impact of neck disability on daily activities. The NDI consists of seven items related to activities of daily living, two items related to pain, and one item related to concentration [10]. Each item is rated on a six-point scale from 0 to 5, with higher total scores indicating greater impairment in daily living. The EQ-5D-3L is a questionnaire that comprehensively assesses health-related QOL in terms of five items: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each item is rated on a scale of 1 to 3, with higher scores indicating more problems with that item. A utility score is calculated from the five item scores [11, 12]. The SF-12v2 questionnaire measures a patient's overall physical and mental health status and is composed of eight health concepts: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Three summary scores can be calculated from these items: physical component score (PCS), mental component score (MCS), role component score (RCS), and national norm-based scoring [13].

Statistical analysis

Descriptive statistics were used to summarize the baseline characteristics of the study population. Spearman's correlation coefficient was employed to assess the correlation between the preoperative Japanese COMI-Neck scores and

the various PROMs. To compare the preoperative PROMs and basic information between the CSM and OPLL groups, the Mann–Whitney U-test and χ^2 -test were utilized for continuous and categorical variables, respectively. If any PROMs items showed significant differences in between-group comparisons, multiple regression analysis using the forced entry method with age and BMI as independent variables was performed to examine the effect of covariate variables on PROMs. All statistical analyses were conducted using IBM SPSS Statistics for Windows, version 29.0 (Armonk, NY: IBM Corp. Released 2021), and the significance level was set at $p=0.05$. Post hoc power analysis was calculated using the power analysis application G*Power 3.1.9.2 (<http://www.gpower.hhu.de/>).

Results

Validity of the Japanese COMI-Neck constructs

The correlation between Japanese COMI-Neck summary score and each PROM showed a positive correlation in NDI ($\rho=0.81$, $p<0.001$) and a negative correlation in EQ-5D-3L ($\rho=-0.46$, $p<0.001$) and SF-12v2 (PCS: $\rho=-0.236$, $p<0.05$; MCS: $\rho=-0.370$, $p<0.001$; RCS: $\rho=-0.323$, $p<0.001$). Correlations between the Japanese COMI-Neck subscales and various PROMs are shown in Table 2.

Comparison of preoperative PROMs between groups

The results of the comparison between the two groups are shown in Tables 1, 3, and 4. The CSM group was older (median-CSM: 68.5, OPLL: 62.0), BMI was lower (median-CSM: 23.1, OPLL: 27.3), and EQ-5D was lower (median-CSM: 0.53, OPLL: 0.59). In the NDI and EQ-5D sub-items, the CSM group scored higher on the concentration item of the NDI (median—CSM: 2, OPLL: 1) and lower on the self-care item of the EQ-5D (median—CSM: 2, OPLL: 3), indicating greater difficulty in each. No significant differences were found in the other parameters.

Both the CSM and OPLL groups had Japanese COMI-Neck summary scores and sub-item scores of 4 or higher. It was particularly high in SSWB (median: CSM and OPLL, 10 points), indicating a significant impairment in QOL related to the neck. The EQ-5D scores in both groups showed a decrease of approximately 60% compared to the mean QOL values of the respective age group. Similarly, the SF-12 PCS scores showed a decrease of 48% compared to the median national standard values. The NDI scores for pain intensity, lifting, work, and recreation were high in both groups, and there was a trend toward greater limitation in these items.

Table 2 The correlation between the Japanese COMI-Neck score and each PROM

COMI-Neck	PROMs	Spearman ρ	Power (1- β)
Summary score	NDI	0.81**	1.00
	EQ-5D	-0.46**	1.00
	SF-12_PCS	-0.24*	0.69
	SF-12_MCS	-0.37**	0.97
	SF-12_RCS	-0.32**	0.91
Pain	NDI	0.38**	0.98
	SF-12_MCS	-0.24*	0.69
Function	NDI	0.65**	1.00
	EQ-5D	-0.35**	0.96
	SF-12_MCS	-0.28*	0.82
	SF-12_RCS	-0.31*	0.90
SSWB	NDI	0.34**	0.95
General QOL	NDI	0.66**	1.00
	EQ-5D	-0.50**	1.00
	SF-12_PCS	-0.38**	0.98
	SF-12_MCS	-0.38**	0.98
	SF-12_RCS	-0.27*	0.80
Disability	NDI	0.72**	1.00
	EQ-5D	0.40**	0.99
	SF-12_PCS	-0.27*	0.80
	SF-12_MCS	-0.24*	0.69
	SF-12_RCS	-0.28	0.82

Values represent Spearman's rank correlation coefficients (ρ). * P value < 0.05; ** P value < 0.01; *COMI* Core Outcome Measures Index; *SSWB* symptom-specific well-being; *QOL* quality of life; *PROMs* patients-reported outcome measures; *NDI* Neck Disability Index; *EQ-5D* EuroQol-5 Dimension; *SF-12* Short Form-12; *PCS* physical component summary; *MCS* mental component summary; *RCS* role component summary

Ancillary analysis

We conducted multiple regression analyses with age and BMI as independent variables for PROMs items showing significant between-group differences. For the NDI-Concentration item, neither age ($\beta = -0.02$, $p = 0.87$) nor BMI ($\beta = -0.16$, $p = 0.18$) significantly influenced scores, as indicated by non-significant ANOVA ($p = 0.34$). The EQ-5D-3L Utility score's ANOVA was also non-significant ($p = 0.053$). Although age showed a non-significant negative trend ($\beta = -0.21$, $p = 0.07$), indicating a potential decrease with age, it did not reach statistical significance. BMI had no significant effect ($\beta = 0.05$, $p = 0.67$) on the EQ-5D-3L Utility score. The self-care item of the EQ-5D-3L showed a significant ANOVA result ($p = 0.01$). Age had a significant positive effect ($\beta = 0.26$, $p = 0.02$), suggesting increased self-care difficulties with age. BMI had no significant effect ($\beta = -0.07$, $p = 0.56$) on Self-care item scores.

Discussion

The purpose of this study was to validate the preoperative Japanese COMI-Neck in patients with CSM and OPLL, and to compare QOL from various perspectives between these two diseases based on preoperative PROMs. This study confirmed the validity of the Japanese COMI-Neck limited to patients with CSM and OPLL and revealed specific QOL issues associated with CSM and OPLL.

The correlation analysis of the Japanese COMI-Neck score with other PROMs indicates that the Japanese COMI-Neck captures specific elements of disease-specific QOL in the cervical spine and also partially reflects general QOL. These findings provide evidence for the construct validity of the Japanese COMI-Neck in patients with CSM and OPLL. The correlation coefficient between Japanese COMI-Neck and NDI shown in this study ($r = 0.81$) was slightly higher than that reported by Oshima et al. ($r = 0.78$), who first showed the effectiveness of the Japanese COMI-Neck [8]. This difference may be influenced by the exclusion of patients with cervical spine tumors, trauma, and infections in our study. It has been shown that patients with CSM have more severe cervical cord-derived disability, which has a greater impact on QOL compared to patients with tumors [16]. The average time from morbidity to surgery for CSM and OPLL is 2–3 years, which is expected to be longer than for other cervical spine diseases such as trauma, tumor, and infection [17, 18]. Consequently, the duration of various life problems caused by neck and extremity symptoms is also expected to be longer. Hence, since this study was limited to patients with CSM and OPLL, it is inferred that the correlation coefficient between Japanese COMI-Neck and NDI, which reflects more cervical symptoms, was higher.

Comparing the preoperative PROMs between the CSM and OPLL groups, several differences were observed. The CSM group, older and with lower BMI, showed lower EQ-5D-3L Utility scores than the OPLL group. Although the age of onset of both diseases is around 50 years [19, 20], obesity in OPLL patients has been reported at a younger age [21], consistent with the younger age and higher BMI of the OPLL group in this study. CSM group scored lower in EQ-5D-3L self-care items, potentially related to aging [22]. Ancillary analysis highlighted age's impact on self-care, while NDI-Concentration and EQ-5D-3L Utility remained unaffected by age and BMI. These findings emphasize age's role in self-care difficulties and its relevance for preoperative care and rehabilitation planning. Incorporating age and BMI as covariates in future analyses can enhance QOL understanding in this population. Long-term follow-ups with diverse cohorts can deepen insights into age and BMI effects on QOL post-surgery.

Table 3 Comparison of preoperative PROMs between CSM and OPLL groups (1)

	CSM (n=86)	OPLL (n=17)	p	Power (1-β)
<i>COMI-Neck</i>				
Summary score	6.4±2.0 (6.7)	6.3±1.9 (7.0)	0.93	0.05
Pain	4.2±3.0 (4.0)	4.5±2.1 (4.0)	0.65	0.07
Function	5.7±3.5 (7.5)	5.0±3.2 (5.0)	0.44	0.12
SSWB	9.0±2.2 (10.0)	9.3±1.5 (10.0)	0.91	0.09
General QOL	7.4±2.1 (7.5)	7.1±2.5 (7.5)	0.90	0.08
Disability	5.6±3.8 (5.0)	5.7±3.8 (5.0)	0.78	0.05
<i>NDI</i>				
NDI score	42.8±16.8 (42.0)	40.4±14.6 (36.0)	0.46	0.09
Pain intensity	2.8±1.1 (3.0)	2.7±1.1 (3.0)	0.69	0.06
Personal care	2.3±1.1 (2.0)	2.2±1.2 (2.0)	0.44	0.06
Lifting	2.9±1.3 (3.0)	2.6±1.3 (3.0)	0.29	0.13
Work	2.2±1.3 (3.0)	2.4±1.4 (2.0)	0.92	0.08
Headaches	0.5±1.0 (0.0)	0.2±0.6 (0.0)	0.23	0.26
Concentration	2.0±1.3 (2.0)	1.2±0.8 (1.0)	0.04*	0.77
Sleeping	2.3±1.5 (2.0)	2.1±1.7 (1.0)	0.51	0.07
Driving	2.0±1.5 (2.0)	2.3±1.4 (2.0)	0.56	0.12
Reading	1.2±1.4 (1.0)	1.5±1.4 (1.0)	0.32	0.12
Recreation	3.1±1.6 (3.0)	3.0±1.5 (3.0)	0.68	0.06

Mean ±SD (median); *P value <0.05; PROMs patients-reported outcome measures; CSM cervical spondy-
lotic myelopathy; OPLL ossification of the posterior longitudinal ligament; COMI Core Outcome Measures
Index; SSWB symptom-specific well-being; QOL quality of life; NDI Neck Disability Index

Table 4 Comparison of preoperative PROMs between CSM and OPLL groups (2)

	CSM (n=86)	OPLL (n=17)	p	Power (1-β)
<i>EQ-5D</i>				
Utility score	0.5±0.2 (0.5)	0.6±0.2 (0.6)	0.02*	0.44
Mobility	2.0±0.5 (2.0)	1.7±0.6 (2.0)	0.06	0.50
Self-care	1.9±0.6 (2.0)	1.5±0.6 (1.0)	0.03*	0.68
Usual activities	2.2±0.6 (2.0)	1.9±0.7 (2.0)	0.17	0.39
Pain/discomfort	2.2±0.6 (2.0)	2.1±0.4 (2.0)	0.31	0.11
Anxiety/depression	1.8±0.6 (2.0)	1.7±0.6 (2.0)	0.43	0.09
<i>SF-12v2</i>				
PCS	22.4±13.3 (21.3)	26.5±17.1 (28.4)	0.16	0.16
MCS	49.8±11.3 (48.6)	48.5±8.8 (47.9)	0.82	0.08
RCS	34.0±14.4 (33.8)	38.6±14.4 (37.1)	0.26	0.21
Physical functioning	21.1±16.4 (16.0)	28.5±19.6 (29.2)	0.14	0.32
Role physical	20.2±13.3 (17.5)	25.3±13.7 (23.8)	0.13	0.28
Bodily pain	29.3±13.3 (23.9)	28.5±13.1 (23.9)	0.78	0.06
General health	37.8±11.0 (35.7)	39.4±10.5 (35.7)	0.52	0.08
Vitality	40.5±10.5 (38.5)	42.2±9.7 (38.5)	0.45	0.09
Social function	36.1±15.5 (33.7)	39.1±14.1 (45.1)	0.47	0.11
Role emotional	32.5±15.5 (32.0)	36.6±12.6 (38.1)	0.28	0.19
Mental health	40.1±13.6 (39.8)	41.9±12.2 (39.8)	0.67	0.08

Mean ±SD (median); *P value <0.05; PROMs patients-reported outcome measures; CSM cervical spondy-
lotic myelopathy; OPLL ossification of the posterior longitudinal ligament; EQ-5D EuroQol-5 Dimension;
SF-12 Short Form-12; PCS physical component summary; MCS mental component summary; RCS role
component summary

Both CSM and OPLL groups had impaired neck-related QOL, decreased overall health-related QOL, compromised physical health, and limitations in pain intensity, lifting, work and recreation. These results confirm the negative impact of quadriplegia on the preoperative lives of patients with CSM and OPLL [23, 24].

There are several limitations that should be considered when interpreting the results of this study. Firstly, the study design was retrospective and comparative, which may introduce inherent biases. Additionally, we acknowledge that there is a disproportionate distribution of patients in the CSM and OPLL groups, with 86 patients in the CSM group compared to only 17 patients in the OPLL group. This imbalance in sample size may impact the statistical analysis and warrants cautious interpretation of the study findings. Secondly, the study focused solely on preoperative PROMs, and postoperative assessments were not included in the analysis. While many studies have shown that surgery can lead to an improvement in overall QOL scores [22, 25], this study does not provide insight into the specific items of each PROM that are improved following surgical intervention. To better understand the effectiveness of surgical interventions and their impact on QOL outcomes, future studies should incorporate long-term follow-up assessments that encompass both preoperative and postoperative data. Furthermore, it should be acknowledged that the study sample predominantly consisted of patients from a single institution. As such, the generalizability of the findings may be limited. To enhance the external validity of the results, future research should include a more diverse and larger population from multiple centers. Despite the valuable insights gained from this study, these limitations should be taken into account while interpreting the findings.

Conclusions

In conclusion, this study validated the preoperative Japanese COMI-Neck in patients with CSM and OPLL and compared QOL between the two conditions using PROMs. The findings confirmed the construct validity of the Japanese COMI-Neck and revealed specific QOL challenges associated with CSM and OPLL. Our results highlighted the impact of quadriplegic symptoms on preoperative QOL and emphasized the need for tailored interventions in these patient groups. Future research with larger and more diverse patient cohorts, along with long-term follow-up assessments, will be essential to build upon these findings and optimize preoperative care and postoperative rehabilitation for patients with CSM and OPLL.

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Data availability The manuscript has no associated data.

Declarations

Conflict of interest No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript. The manuscript submitted does not contain information about medical device (s)/drug (s).

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional review board of the Saitama Medical University Medical Center, Saitama Medical University (1969-III), and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent A disclosure statement was posted on the website, with contact information for refusal to use the data for research, and the data of eligible patients who were notified of the refusal would not be used.

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