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ORIGINAL RESEARCH

The Effect of Concomitant Spinal Cord Injury on Postoperative Health-related Quality of Life After Traumatic Subaxial Cervical Spine Injuries: A Nationwide Registry Study

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Abstract

Objective: To evaluate the effect of spinal cord injury (SCI) on the health-related quality of life (HRQoL) in patients surgically treated for traumatic subaxial cervical spine injuries and investigate the agreement between objective neurologic outcomes and patient reported outcome measures (PROMs) in that context.

Study Design: Observational study on prospectively collected multi-institutional registry data.

Setting: Sweden.

Participants: Patients with traumatic subaxial spine injuries identified in the Swedish Spine Registry (Swespine) between 2006 and 2016.

Interventions: Anterior, posterior, or anteroposterior cervical fixation surgery.

Main Outcomes: Patient-reported outcome measures (PROMs) consisting of EQ-5D-3L$_{index}$ and Neck Disability Index (NDI).

Results: Among the 418 identified patients, 93 (22%) had a concomitant SCI. In this group, 30 (32%) had a complete SCI (Frankel A), and the remainder had incomplete SCIs (17%) Frankel B; 25 (27%) Frankel C; 22 (24%) Frankel D. PROMs significantly correlated with the Frankel grade (P<.001). However, post hoc analysis revealed that the differences between adjacent Frankel grades failed to reach both statistical and clinical significance. On univariable linear regression, the Frankel grade was a significant predictor of a specific index derived from the EQ-5D-3L questionnaire (EQ-5D-3L$_{index}$) at 1, 2, and 5 years postoperatively as well as the NDI at 1 and 2 years postoperatively (P<.001). Changes of PROMs over time from 1, to 2, and 5 years postoperatively did not reach statistical significance, regardless of the presence and degree of SCI (P>.05).

Conclusion: Overall, the Frankel grade significantly correlated with the EQ-5D-3L$_{index}$ and NDI and was a significant predictor of PROMs at 1, 2, and 5 years. PROMs were stable beyond 1 year postoperatively regardless of the severity of the SCI.

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Disclosures: The authors have no conflicts of interest.

Ethical Considerations: Swespine uses the opt-out method, meaning that patient consent is not needed to be part of the quality registry, but answering the questionnaires is voluntary. The Regional Ethical Review Board in Stockholm has authorized the study and the use of the data collection (Dnr 2016/897–31/1).

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Table 1 Frankel SCI grading scheme

Frankel Grade	Description
A	Complete SCI. Neither motor nor sensory function preserved below the level of the lesion.
B	Incomplete SCI. Sensory, but not motor function preserved below the level of the lesion.
C	Incomplete SCI. Motor function preserved below the neurologic level, without practical application.
D	Incomplete SCI. Useful motor function below the level of the lesion.
E	No SCI. Sensory and motor function normal.

The agreement between objective neurologic outcomes and health-related quality of life (HRQoL) or disability measures has yet to be investigated in the context of traumatic subaxial cervical spine injuries. A recent systematic review found that patient-reported outcome measures (PROMs) were to a lesser extent used in studies assessing surgical treatment of cervical spine injuries.[1] This discrepancy in the reporting of PROMs may be due to the lack of standardized metrics and the complex nature of these questionnaires, complicating their collection in a consistent and reproducible manner over long follow-up periods.[2-4] PROMs are also typically harder to interpret and their changes more difficult to perceive when compared with other variables,[5] traditionally viewed as estimates of the success or failure of a surgical intervention, such as neurologic function, need for reoperation, and death. The reporting of PROMs is also less frequent in studies including patients with spinal cord injury (SCI).[1] As a result, the evidence is scarce and contradictory.[6] It is well established that patients with traumatic SCI are susceptible to a poor HRQoL, owing to the interaction between multiple factors such as the disability itself, increased risk of secondary comorbidities, and decreased community integration or participation.[7-11] However, the relation between the severity of SCI and PROMs is poorly characterized.[6,12] While some studies indicate significant correlations between SCI severity and PROMs,[13-15] others do not.[16-19] Similarly, there is a paucity of studies pertaining to the evolution of PROMs with time in patients living with SCI.[6,20] A recent study evaluating PROMs for up to 5 years after surgery for subaxial cervical spine fractures found that PROMS improved during the first year after surgery, but then remain stable.[21]

The aim of this study was to investigate the effect of SCI on PROMs and their evolution 1, 2, and 5 years after surgery for subaxial spine fractures.

Methods

Study design

This observational study was performed in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines. Prospectively collected data from 2006 to 2016 were obtained from the Swedish Spine Registry (Swespine) (supplemental file S1). The first part of the study addresses the effect of SCI on PROMs, while the second part evaluates the effect of SCI on the evolution of PROMs during the follow-up period.

Sources and type of data

In 2016, Swespine had a coverage of 98% (46 of 47 spinal clinics), the completeness was approximately 75%, and the 1-year follow-up was performed in approximately 75%, covering all types of spine surgery.[22] Surgical approach, fracture type, preoperative neurologic status (Frankel grade; table 1), operated levels, perioperative complications (including thromboembolisms, urinary tract infections, bleeding/hematomas, wound infections, iatrogenic dural tears, implant related events, and vascular injuries), and reoperations are registered in Swespine by the treating physician. Patients are then asked to fill out questionnaires at 1, 2, 5, and 10 years postoperatively, answering questions relating to satisfaction, use of analgesic medication, ambulatory function, and postoperative (90 days) complications. Additionally, patients also receive Neck Disability Index (NDI),[23] and a specific index derived from the EQ-5D-3L questionnaire (EQ-5D-3L$_{index}$) surveys,[24] to cover disability and HRQoL aspects. The NDI ranges from 0 to 100, where 0 indicates no disability and 100 maximal disability. The NDI evaluates neck-related disability experienced by subjects in their everyday life. For the EQ-5D-3L$_{index}$, respondents are asked to rate 5 different health-related dimensions that include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression based on 3 severity levels: no, moderate, or severe problems.[25] Based on the UK Time Trade-Off (tariff for EQ-5D-3L) tariff, the answers are then translated to an index that ranges from -0.56 (worst imaginable health) to 1.00 (best imaginable health).

Study population and eligibility criteria

Patients surgically treated for a subaxial cervical spine fracture between 2006 and 2016 were identified using the Swespine. All patients with a minimum of 1 year of postoperative follow-up and with available PROMs were eligible for inclusion. In the first part of the study, all identified patients were included. In the second part, only patients with both 1 and 2 years PROMs were included (fig 1).

Statistical analysis

The descriptive data are presented as numbers with percentages for categorical variables and medians (interquartile range) for continuous variables. The Chi-squared, and when appropriate, the Fisher exact tests were used to compare proportions across groups. The Mann-Whitney U test or the Kruskal-Wallis test was used for group comparisons of continuous data. Post hoc analysis using the Bonferroni correction of P values was used to perform pairwise comparisons between groups when statistical significance was reached on the Kruskal-Wallis test. The Spearman's correlation coefficient Rho (ρ) was determined to assess the degree of correlation between continuous variables. The correlation was said to be strong when the absolute value of ρ lied between 0.50 and 1, moderate between 0.30 and 0.49, then weak when the absolute value of ρ fell below 0.29.

The Friedman's 2-way analysis of variance by ranks was used for comparison of continuous variables across several paired

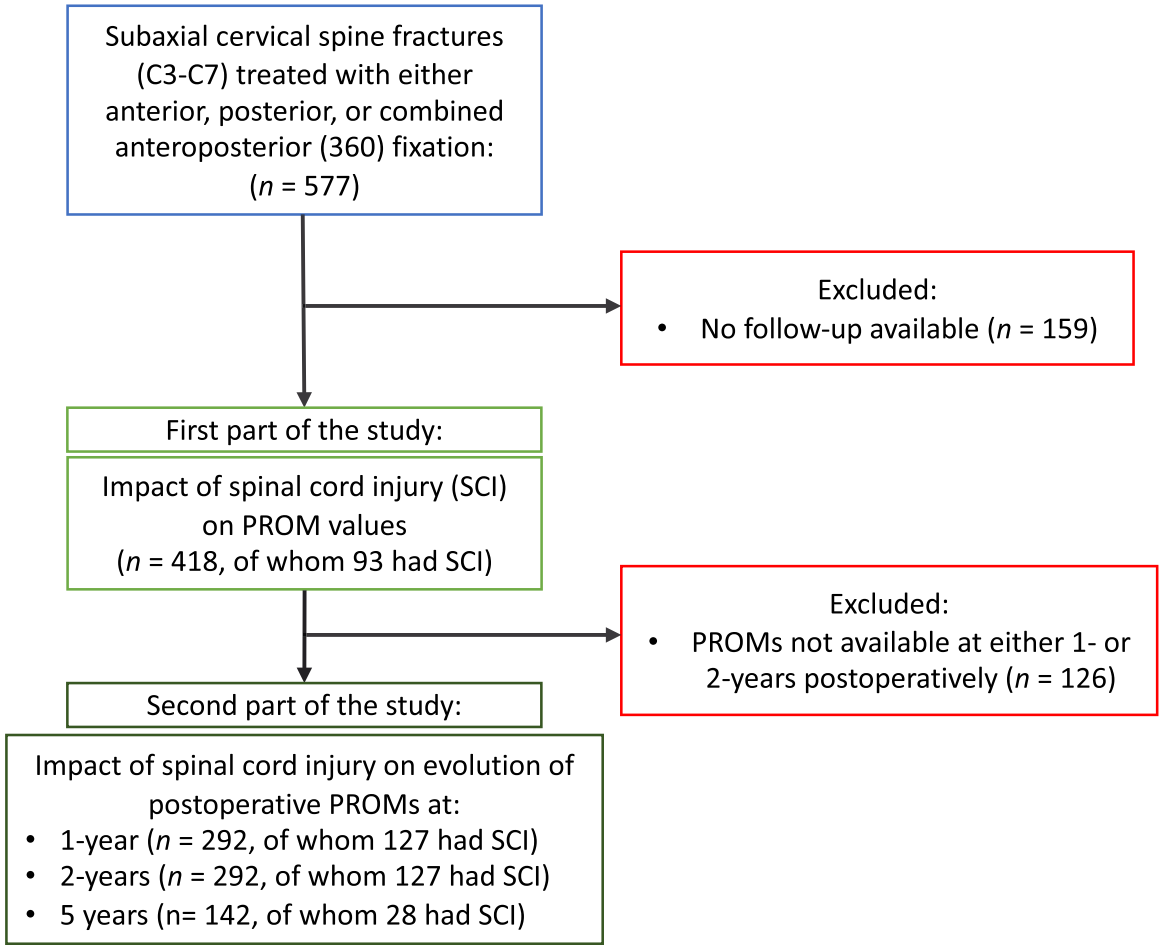

Fig 1 Flowchart.

samples. All statistical analyses were performed in the Statistical Package for the Social Science statistics software, version 26, and *P* values of <.05 were considered significant.

Clinical significance of the findings

Aside from testing the statistical significance when comparing PROMs, clinical significance and relevance of the findings was evaluated. Based on previous publications, the minimal clinically important differences (MCID) for NDI and EQ-5D $3L_{index}$ were 7.5 and 0.15, respectively.[5,26-28]

Ethical considerations

This study was approved by the Regional Ethical Review Board of Stockholm (Dnr 2016/897−31/1). Swespine uses the opt-out method, meaning that patient consent is not needed to be part of the registry, but answering the questionnaires is voluntary.

Results

A total of 418 patients with traumatic subaxial cervical spine fractures were included in the first part of this study. Among them, 93 (22%) presented with concomitant SCI with Frankel A (n=30, 32%), Frankel B (n=16, 17%), Frankel C (n=25, 27%), and Frankel D (n=22, 24%). The remaining 325 patients had no SCI and were Frankel E.

Part 1: effect of SCI and the injury severity on PROMs values

Baseline characteristics

Most patients were men (74%) and the median age was 60 (28), without any significant differences between the SCI and non-SCI groups (table 2).

The median number of injured vertebrae was 2 (0) and did not differ between the groups (*P*=.126). There was an uneven distribution of surgical approaches between patients with and without SCI (*P*=.03, table 2). The greatest difference was seen for the anteroposterior approach, more commonly performed in patients with SCI. The median number of anteriorly fixated levels was 1 (0) with a significantly higher number of segments being fixated in the SCI group compared to the non-SCI group (*P*=.005). The median number of posteriorly fixated segments was 4 (4) and did not significantly differ between the groups (*P*=.89). While the proportion of perioperative complications was similar between groups at around 10% (*P*=.58), patients presenting with concomitant SCI had longer initial hospital stays (4 vs 3 days; *P*<.001). Notably, this hospital stay only concerns the surgical unit and does not include subsequent stay at a rehabilitation clinic. At 1, 2, and 5 years postoperatively, the PROMs response rate did not

Table 2 Baseline characteristics

	Entire Cohort (n=418)	Non-SCI Group (n=325)	SCI Group (n=93)	*P* Value
Age	60 (28)	59 (29)	62 (23)	.25
Men sex	311 (74%)	241 (74%)	70 (75%)	.83
Type of vertebral fracture				.64
Compression	59 (14%)	46 (14%)	13 (14%)	
Burst	227 (54%)	180 (55%)	47 (51%)	
Distraction/translation/rotation	132 (32%)	99 (31%)	33 (36%)	
Admission Frankel grade				-
A	30 (7%)	-	30 (32%)	
B	16 (4%)	-	16 (17%)	
C	25 (6%)	-	25 (27%)	
D	22 (5%)	-	22 (24%)	
E	325 (78%)	325 (100%)	-	
Number of vertebrae injured (45 missing)	2 (0)	2 (0)	2 (0)	.13
Surgical approach				**.030**
Anterior	171 (41%)	136 (42%)	35 (38%)	
Posterior	202 (48%)	161 (50%)	41 (44%)	
Anteroposterior	45 (11%)	28 (9%)	17 (18%)	
Number of anterior segments fixated (5 missing)	1 (1)	1 (0)	1 (1)	**.005**
Number of posterior segments fixated (6 missing)	4 (4)	4 (5)	4 (4)	.89
Perioperative complications	43 (10%)	32 (10%)	11 (12%)	.58
Length of hospital stay in days (9 missing)	3 (3)	3 (2)	4 (7)	**<.001**
Postoperative PROMs available at:				
1-year	377 (90%)	296 (91%)	81 (87%)	.26
2-years	321 (77%)	250 (77%)	71 (76%)	.91
5-years	174 (42%)	140 (43%)	34 (37%)	.26

NOTE. Categorical variables are presented as number (%) and continuous variables are presented as median (interquartile range). Bold represents significant *P* values.

significantly differ between groups (*P*=.26; *P*=.91; *P*=.26, respectively) and were independent of the SCI status.

Effect of SCI on PROMS

There was no significant difference between EQ-5D-3L$_{index}$ at 1, 2, and 5 years for any Frankel grade. Similarly, there was no significant difference between NDI at 1, 2, and 5 years for any Frankel grade. However, when comparing Frankel grades, significantly lower values for EQ-5D-3L$_{index}$ were found in the more extensive spinal cord injuries. A similar pattern was seen for NDI but was not statistically significant at 5 years follow-up (table 3).

On post hoc analysis using the Bonferroni correction, the differences in PROMs scores between 2 adjacent Frankel grades, at 1, 2, and 5 years postoperatively, failed to reach statistical significance (*P*<.05; supplemental Fig S2, fig A). Furthermore, these differences also failed to reach clinical significance, as the MCID was not achieved. There was no difference between patients with Frankel D injury and those with no SCI (Frankel E), indicating that patients with mild SCI after a cervical fracture had similar HRQoL as patients with no SCI.

On the other hand, differences in median EQ-5D-3L$_{index}$, at 1, 2, and 5 years postoperatively, reached both statistical (*P*<.05) and clinical significance when comparing patients with and without SCI (Frankel A-D vs E) or those with complete and incomplete SCI (Frankel A vs B-D). Similar trends were seen for NDI at 1 and 2 years. However, the differences failed to reach statistical significance at 5 years postoperatively.

Correlation statistics and linear regression

Both the EQ5D-3L$_{index}$ and NDI scores significantly correlated with the Frankel grade, with more severe SCI resulting in lower EQ5D-3L$_{index}$ and higher NDI. At 1 and 2 years postoperatively,

Table 3 Comparison of PROMs based on the degree of spinal cord injury (in Frankel Grade)

Frankel Grade	E	D	C	B	A	*P* Value
EQ-5D-3L$_{index}$						
1 year (n=377)	0.760 (0.15)	0.726 (0.68)	0.620 (0.41)	0.260 (0.61)	0.002 (0.33)	**<.001**
2 years (n=321)	0.796 (0.19)	0.725 (0.37)	0.638 (0.23)	0.620 (0.66)	-0.027 (0.61)	**<.001**
5 years (n=174)	0.744 (0.19)	0.796 (0.37)	0.587 (0.14)	0.466 (0.83)	-0.095 (0.38)	**.003**
NDI						
1 year (n=377)	18 (30)	16 (30)	28 (21)	22 (32)	46 (12)	**<.001**
2 years (n=321)	18 (30)	22 (25)	27 (27)	38 (42)	46 (29)	**.033**
5 years (n=174)	22 (30)	7 (30)	20 (30)	30 (48)	46 (33)	.22

NOTE. Continuous variables are presented as median (interquartile range). Bold indicates significant *P* values (*P*≤.05).

Table 4 Correlation statistics and linear regression for the prediction of PROMs using the Frankel grade

	PROMs	EQ-5D-3L$_{index}$			NDI		
	Postop. FU	1 Year	2 Years	5 Years	1 Year	2 Years	5 Years
Frankel grade	Sample size (n)	377	321	174	370	317	173
	Spearman's Rho (ρ)	-0.33	-0.35	-0.21	0.18	0.16	0.08
	P value	**<.001**	**<.001**	**.005**	**<.001**	**.005**	.32
	Unstandardized beta coefficient (B)	0.122	0.119	0.113	-3.538	-3.039	-
	P value	**<.001**	**<.001**	**<.001**	**<.001**	**.001**	-

NOTE. Bold indicates significant *P* values ($P \leq .05$).
Abbreviation: FU, follow-up.

the EQ-5D-3L$_{index}$ moderately correlated with the Frankel grade (ρ=- 0.33, P<.001; ρ=-0.35, P<.001, respectively), while at 5 years only a weak correlation remained (ρ=0.21, P=.005). For the NDI, a weak but significant correlation with the degree of SCI was detected at 1 and 2 years postoperatively (ρ=0.184, P<.001; ρ=0.16, P<.001, respectively). There was however no correlation between the Frankel grade and the NDI at 5 years postoperatively (P=.315). On univariable linear regression, the Frankel grade significantly predicted EQ5D-3L$_{index}$ at 1, 2, and 5 years and the NDI at 1 and 2 years postoperatively (table 4).

Part 2: differences in the evolution of PROMs based on the Frankel grade

In the second part of this study, the changes in PROMs at different follow-up times were analyzed. Only patients with available PROMs at both 1 and 2 years postoperatively were considered (n=292). Almost half of these patients (n=142) had reported 5-year PROMs. Although a slight tendency toward long-term improvement of PROMs was seen in patients with incomplete SCI, the changes did not reach statistical significance (EQ-5D-3L$_{index}$: P=.29; NDI: P=.99). Similarly, patients with complete SCI experienced gradual worsening of PROMs, however this change did not reach statistical significance (EQ5D-3L$_{index}$: P=.58; NDI: P=.72). PROMs were stable during the follow-up period for patients without SCI. Overall there the PROMs did not change significantly at 1-, to 2-, and 5-years postoperatively regardless of Frankel grade (P>.05; fig 2).

Discussion

The findings of this study indicate that patients with SCI report lower PROMs the more severe the SCI. The 1-year PROMs remained stable during the follow-up period of 5 years. The degree of SCI, measured as Frankel grade, was a significant predictor of PROMs at 1, 2, and 5 years.

As expected, patients with SCI scored worse on both the EQ5D-3L$_{index}$ and NDI compared to those without SCI (Frankel E). Additionally, at all follow-up timepoints, a statistically significant difference in the median PROMs was found between groups with different Frankel grades. Parallels may be drawn to research on traumatic brain injury (TBI), where a recent study demonstrated significant correlations between both presence and severity of TBI and HRQoL, where an increased severity of TBI was associated with worse HRQoL outcomes.[29] The Frankel grade correlated with, and was a significant predictor of, the PROMs at 1, 2, and 5 years postoperatively, except for the NDI at 5 years (probably due to the small sample size). On post hoc pairwise analysis, the PROMs differences were nonsignificant for adjacent Frankel grades, but were significant when comparing Frankel grades A to E, or A to D. This was also the case when looking at the clinical relevance of the differences in median PROM values. Patients with no SCI (Frankel E) were neither statistically nor clinically different from patients with mild SCI (Frankel D), in terms of postoperative 1-, 2-, and 5-year PROMs. Contrarily, both statistical (P<.05) and clinical significance (surpassing the determined MCID) were achieved when comparing patients with and without SCI (Frankel A-D vs E) or those with complete and incomplete SCI (Frankel A vs B-D). Importantly, regardless of Frankel grade, even in the absence of SCI and neurologic deficits, all patients with subaxial cervical spine injury scored worse than the general population on EQ5D-3L$_{index}$ (0.825) and NDI (7%-10%), at all of the follow-up times.[30-32] In patients with SCI, this may be due to functional limitations related to the injury. The lower PROMs, compared with the general Swedish population, witnessed among patients without SCI may stem from residual pain after the trauma and surgery or restriction of normal neck movements as a result of the surgical fixation. Notably, a previous study on the same registry discovered that 44% of patients with subaxial cervical spine injuries received pain medications at last follow-up.

A recent study demonstrated that PROMs stabilize beyond 1 year in patients operated for traumatic subaxial injuries.[21] However, few studies have addressed this question in patients with concomitant SCI.[6,20] Extensive rehabilitation of patients with SCI may result in a certain degree of improvement in HRQoL beyond 1 year; however, the effect of time since injury on PROMs is still a matter of debate.[6] Certain studies have indicated a tendency of PROMs to improve with time,[17,33] whereas others have found PROMs to be more stable,[15,34] with a possibility of decline later over the years.[18] In this study, irrespective of presence or severity of SCI, the PROMs remained stable beyond 1 year. Part of the explanation may be that although patients with SCI do experience certain long-term improvements related to rehabilitation, they still suffer from the physical and social limitations resulting from the injury, that may negatively affect their overall HRQoL.[9,35-38] In our setting, extensive rehabilitation at specialized centers is common practice after SCI. The stabilization of PROMs beyond 1 year could hence indicate the role of rehabilitation in preventing progressive deterioration after the injury. Our findings lend support to studies demonstrating minimal changes in HRQoL scores over time in individuals with SCI.[7,9,10,15,34]

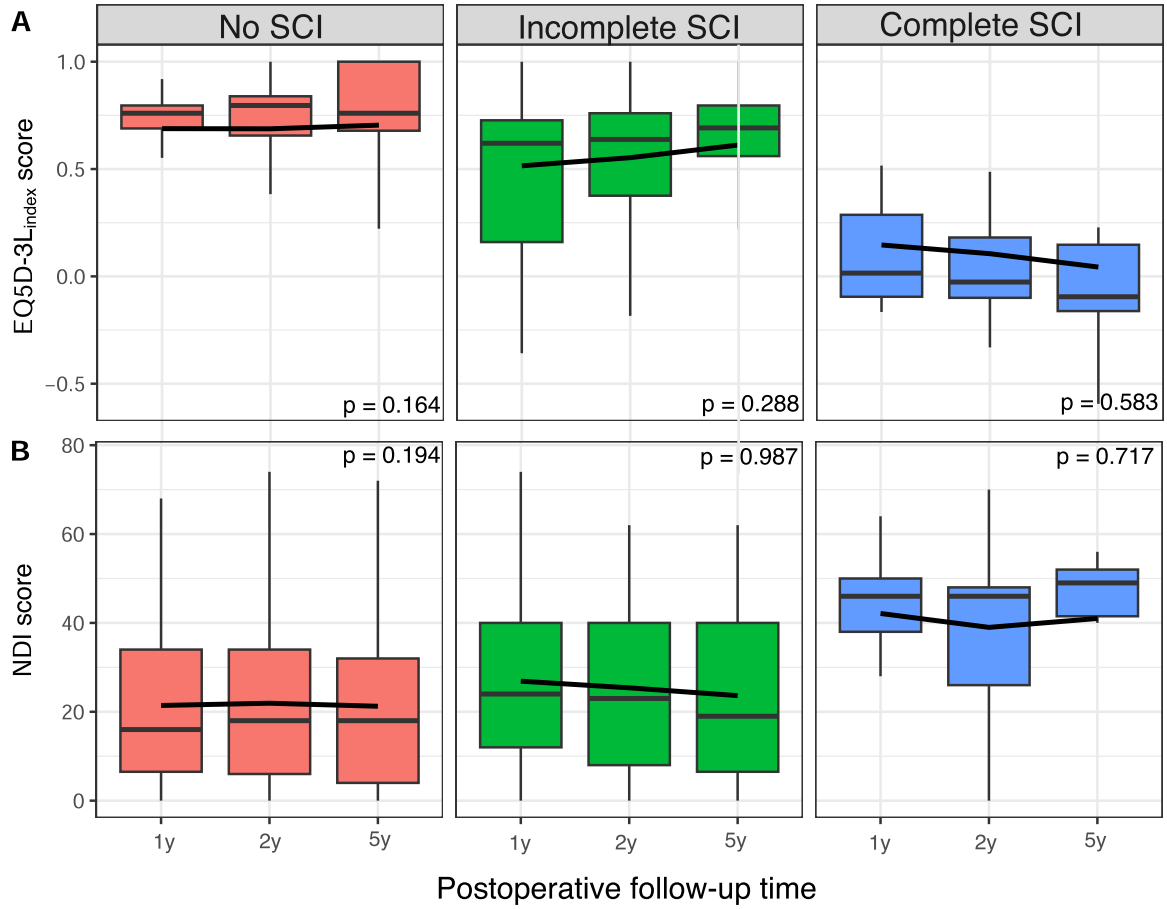

Fig 2 Longitudinal analysis of EQ-5D-3L$_{index}$ (A) and NDI (B) based on the degree of SCI. No SCI=Frankel E; incomplete SCI=Frankel D, C, and B; and complete SCI=Frankel A. The black line passes through the means, the boxes cover the interquartile range (IQR), the vertical lines extend from the minimal to the maximal value, and the lines dividing the boxes in 2 parts represent the median value. *P* values reflect the significance of the changes in PROMs across time.

Strengths and limitations

The strength of this study is its nationwide, population-based nature and availability of PROMs for up to 5 years. However, registry-based studies are hampered by the amount and granularity of the data in the underlying registry. Furthermore, there are limitations inherent to patient-reported data originating from voluntary questionnaires, where certain differences may be present between those who respond compared with those who opt out creating a selection bias. The results may also be affected by the loss to follow-up at 1, 2, and especially 5 years. Moreover, Frankel is the only neurologic function scale available in the Swespine registry. It has been replaced by the American Spinal Injury Association (ASIA) Impairment Scale due to certain limitations.[39] Swespine only reports preoperative Frankel grade and possible postoperative improvements could not be assessed. Additionally, several baseline variables, including racial, social determinants, and other potential confounders such as BMI or smoking status were missing in the Swespine registry, which prevented us from accordingly conducting adjusted analyses. Finally, the EQ5D-3L$_{index}$ sub scores for each domain including mobility, self-care, usual activities, pain/discomfort, anxiety/depression could not be retrieved.

Conclusion

In patients surgically treated for subaxial cervical spine injuries, both EQ5D-3L$_{index}$ and NDI were negatively affected by the presence and severity of SCI. The Frankel grade significantly correlated with the EQ5D-3L$_{index}$ and NDI and was a significant predictor of PROMs at 1, 2, and 5 years. Furthermore, the PROMs were stable beyond 1 year postoperatively regardless of the severity of the SCI.

Keywords

Patient-reported Outcome Measures; Rehabilitation; Surgical approach; Traumatic subaxial cervical spine injury

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