The impact of obesity on the outcome of decompression surgery in degenerative lumbar spinal canal stenosis: analysis of the lumbar spinal outcome study (LSOS)- a swiss prospective multicenter cohort study

Burgstaller, Jakob M; Held, Ulrike; Brunner, Florian; Porchet, François; Farshad, Mazda; Steurer, Johann; Ulrich, Nils H

Abstract: STUDY DESIGN Prospective, multicenter cohort study including 8 medical centers of the Cantons Zurich, Lucerne, and Thurgau, Switzerland. OBJECTIVE The aim of the study was to assess whether obese patients benefit after decompression surgery for degenerative lumbar spinal stenosis (DLSS). SUMMARY AND BACKGROUND DATA Lumbar decompression surgery has been shown to improve quality of life in patients with DLSS. In the existing literature, the efficacy of lumbar decompression in the obese population remains controversial. METHODS Baseline patient characteristics and outcomes were analyzed at 6 and 12 months follow-up with the Spinal Stenosis Measure (SSM), the Numeric Rating Scale (NRS), Feeling Thermometer (FT), the EQ-5D-EL, and the Roland and Morris Disability Questionnaire (RMDQ). Body mass index (BMI) was classified into 3 categories according to the WHO. Minimal clinically important differences (MCIDs) in SSM for different BMI categories were considered as main outcome. RESULTS Of the 656 patients in the Lumbar Spinal Outcome Study database as of end of October 2014, 166 patients met the inclusion criteria. Fifty (30.1%) had a BMI less than 25 (underweight and normal weight group), 72 (43.4%) had a BMI between 25 and less than 30 (preobesity group), and 44 (26.5%) patients had a BMI at least 30 (obese group). We found for the main outcome that in obese patients 36% reached MCID at 6 months, and 48% at 12 months. The estimated odds ratios for MCID in the obese group were 0.78 (0.34-1.82) at 6 months and 0.99 (0.44-2.23) at 12 months in a logistic regression model adjusting for levels of laminectomy. In the additional outcomes, SSM, NRS, FT, and RMDQ showed statistically significant mean improvements in the 6 and 12 months follow-up. CONCLUSION Obese patients can expect clinical improvement after lumbar decompression for DLSS, but the percentage of patients with a meaningful improvement is lower than in the group of patients with underweight, normal weight, and preobese weight at 6 and 12 months.

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The Impact of Obesity on the Outcome of Decompression Surgery in Degenerative Lumbar Spinal Canal Stenosis: Analysis of the Lumbar Spinal Outcome Study (LSOS): A Swiss Prospective, Multicenter Cohort Study

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Study Design. A prospective, multicenter cohort study including 8 medical centers of the Cantons Zurich, Lucerne, and Thurgau, Switzerland.

Objective. The aim of this study was to assess whether obese patients benefit after decompression surgery for degenerative lumbar spinal stenosis (DLSS).

Summary of Background Data. Lumbar decompression surgery has been shown to improve quality of life in patients with DLSS. In the existing literature, the efficacy of lumbar decompression in the obese population remains controversial.

Methods. Baseline patient characteristics and outcomes were analyzed at 6 and 12 months follow-up with the Spinal Stenosis Measure (SSM), the Numeric Rating Scale (NRS), Feeling Thermometer (FT), the EQ-5D-EL, and the Roland and Morris Disability Scale (RMDS). Body mass index (BMI) was classified into 3 categories according to the World Health Organization (WHO). Minimal clinically important improvement (MCID) in SSM for different BMI categories was considered as the main outcome.

Results. Of the 656 patients in the LSOS-database as of end of October 2014, 166 patients met the inclusion criteria. Fifty (30.1%) had a BMI less than 25 (underweight and normal weight group), 72 (43.4%) had a BMI between 25 and less than 30 (pre-obesity group), and 44 (26.5%) patients had a BMI at least 30 (obese group). We found for the main outcome that in obese patients, 36% reached MCID at 6 months and 48% at 12 months. The estimated odds ratios for MCID in the obese group were 0.78 (0.34–1.82) at 6 months and 0.99 (0.44–2.23) at 12 months in a logistic regression model adjusting for levels of laminectomy. In the additional outcomes, SSM, NRS, FT, and RMDQ showed statistically significant mean improvements in the 6 and 12 months follow-up.

Conclusion. Obese patients can expect clinical improvement after lumbar decompression for DLSS, but the percentage of patients with a meaningful improvement is lower than in the group of patients with under-, normal, and pre-obese weight at 6 and 12 months.

Key words: body mass index, clinical outcomes, decompression, degenerative, laminectomy, laminotomy, lumbar spinal canal stenosis, lumbar spine, obesity, satisfaction.

Level of Evidence: 3

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Spine surgeons are increasingly confronted with a wide variety of degenerative changes of the lumbar spine in obese patients. Obesity affects one-third of the adult U.S. population and is associated with numerous clinical problems.1–3 On the basis of the latest estimation of the World Health Organization (WHO) in European countries, overweight affects 30% to 70% and obesity affects 10% to 30% of the adults.4 The impact of obesity on musculoskeletal, degenerative spinal disease, quality of life, and back pain has been well documented.5–13 Obesity and
musculoskeletal disease may lead to degenerative lumbar spinal stenosis (DLSS).

DLSS is a major factor in the development of back pain for millions of people in the U.S. and worldwide. DLSS may compress the spinal cord and nerve roots causing back and leg pain making it difficult to maintain an exercise regimen. The inability to exercise, in turn, can limit the ability to maintain a healthy weight.

Failure of conservative treatment permits the indication for surgery. The aim of surgery is to decompress the spinal canal and dural sac from degenerative bony and ligamentous overgrowth. For instance, in the metropolitan area of Zurich with around 1.3 million inhabitants, over 970 lumbar decompressions without fusions are done every year.15

Owing to the lack of relevance that obesity might play in patients after decompression with DLSS, we used data from the Lumbar Stenosis Outcome Study (LSOS)16 to further explore this issue. In some patients, postsurgical improvement is not satisfactory and obesity may be associated with less favorable outcome8,17; therefore we test the hypothesis18 that obese patients have less clinical improvement after surgery for symptomatic DLSS in comparison to nonobese patients.

MATERIALS AND METHODS

Patient Selection

Patients were recruited from outpatient clinics at all participating centers. The study population consists of patients with a history of neurogenic claudication. Patients had no evidence of stenosis caused by tumor, fracture, infection, or significant deformity (>15 degrees lumbar scoliosis). Magnetic resonance imaging (MRI) verified lumbar spinal canal stenosis. None of the patients had prior lumbar spine surgery. Furthermore, patients had no clinical peripheral artery occlusive disease (confirmed by a vascular specialist in patients without palpable pulses in the lower limb). We also excluded patients with a diagnosis of diabetes mellitus.

Surgical Procedure

Surgery consisted of a standard open posterior lumbar laminectomy or laminotomy at the affected level or levels without instrumentation. Decompression of the lateral recess and foramina was performed when necessary to decompress the local nerve roots. The use of loops or the microscope was at the preference of the spinal surgeon but was not recorded as part of the LSOS study.

Data Collection and Follow-up

Parts of the basic data sheet were interview-administered and recorded by a study coordinator. All other questionnaires were self-administered and filled in by the patients themselves. All data were collected at baseline and at 6 months. Long-term outcome data were gathered after 1 year.

Questionnaires

Spinal Stenosis Measure (SSM)

The SSM, an instrument specifically developed for spinal stenosis patients by Stucki et al,19 targets to measure severity of symptoms and quantifies disability of the lumbar spinal stenosis population. It is recommended by the North American Spine Society (NASS) and used in different studies on lumbar spinal stenosis.20–23 It consists of 3 different subscales: the symptom severity subscale, the physical function subscale, and the satisfaction subscale. The symptom severity scale can be divided into a pain domain (severity, frequency, and back pain) and a neuroischemic domain (leg pain, weakness, numbness, and balance disturbance). Score range is from 1 to 5 and 1 to 4 (best–worst).

Feeling Thermometer (FT) and Numeric Rating Scale (NRS)

General assessment of lumbar spinal stenosis symptoms such as lower extremity pain and discomfort were measured. Score range is from 0 to 100 and 0 to 10 (best–worst).

EQ-5D-3L

The EQ-5D-3L is an assessment tool to measure health-related quality of life. It measures general nondisease-specific health-related quality of life, including physical, mental, and social dimensions.24 The health status measures 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), which can be calculated as a sum score (score range 0–100, worst–best). The second part of the questionnaire estimates patient’s actual health status (score range 0–100, worst–best).

Roland and Morris Disability Questionnaire (RMDQ)

The Roland and Morris Disability Questionnaire is a back pain specific, self-rated physical disability questionnaire developed by Roland and Morris in 1983.25 Disability is measured with respect to the following categories: physical function activities and activities of daily living including eating and sleeping. Score range is from 0 to 24 (best–worst).

Cumulative Illness Rating Scale (CIRS)

Comorbidity was measured using CIRS26 that rates the presence and severity of comorbid diseases in 14 organ systems (according to modified version by Miller et al26). Score range was from 0 to 56 (best-worst).

Minimal Clinically Important Difference (MCID)

The minimal clinically important difference (MCID) is defined as “the smallest difference in a score that is considered to be worthwhile or important.”27 Thus, the MCID is threshold for a relevant change in an outcome measure. Patients who reached or even exceed this threshold consider a change as meaningful and worthwhile. According to Stucki et al,19 MCID for SSM is reached when “symptom severity scale” improve at least 0.48 points and “Physical Function scale” at least 0.52 points at the 6-month follow-up.
**Outcomes**
The main outcome of this study was clinically meaningful improvement in SSM, which is denoted as MCID, after 6 and 12 months. Additional outcomes of interest were changes in SSM, NRS, FT, EQ-5D-EL sum score and actual health status, and RMDQ within BMI categories from baseline to 6 months.

**Ethics**
This cohort study was conducted in compliance with all international laws and regulations as well as any applicable guidelines. The study was approved by the independent Ethics Committee of the Canton Zurich (KEK-ZH-NR: 2010-0395/0).

**Statistical Analyses**
Analysis of data consisted of descriptive statistics of patient demographics and outcomes. Continuous variables were shown as median and interquartile ranges and categorical variables were shown as numbers and percentages of total. For each patient, we evaluated whether MCID was reached at 6 and 12 months from baseline (within categories of BMI). In a multiple logistic regression model, we assessed whether BMI categories had a significant influence on reaching MCID, and we quantified the impact of BMI categories with MCID as outcome variable and adjustment for number of levels of laminectomy. In addition to Wald tests for single categories of BMI, we also used the global F-test to assess the importance of all 3 BMI categories as a whole. For the additional outcomes, we calculated changes from baseline at 6 months. To assess whether these changes differed significantly from zero, we used paired Wilcoxon tests. For graphical representations of the changes within BMI categories over time, box plots were used.

**RESULTS**

**Patient Characteristics**
At baseline, a total of 166 patients met the inclusion criteria. In our patient population, the median age was 74 years (interquartile range, IQR 12) and 80 (48%) were female patients. The median CIRS total score was 8, IQR 4.8 at baseline. Sixty-two (37.3%) patients had a 1-level laminectomy and 104 (62.7%) had a laminectomy on 2 or more levels. Of the study population, 110 (66.3%) patients hold higher education degree (no university) and 23 (13.9%) hold a university degree (Table 1). In the BMI category less than 25, there were 50 patients with a median CIRS score or value of 8, IQR 3. Seventy-two patients were pre-obese and had a median CIRS of 8, IQR 5. Forty-four patients were obese and had a median CIRS of 9, IQR 4. Further patient’s characteristics are summarized in Table 1.

**Main Outcome: MCID in the SSM**

**BMI <25 Category (Underweight and Normal-Weight Group)**
Twenty-one patients (42%) showed MCID at the 6 months follow-up. At the 12 months follow-up, 24 patients (48%) showed MCID (Table 2A).

**BMI 25 to <30 Category (Pre-Obesity Group)**
Forty-one patients (56.9%) showed MCID at the 6 months follow-up. At the 12 months follow-up, 44 patients (61.1%) showed MCID (Table 2A).

**BMI ≥30 Category (Obese Group)**
Sixteen patients (36.4%) showed MCID at the 6 months follow-up. At the 12 months follow-up, 21 patients (47.7%) showed MCID (Table 2A).

**Odds Ratio for Meaningful Improvement**
We fitted a multiple logistic regression model to MCID depending on BMI category and levels of laminectomy. The estimated odds ratio (OR) for reaching MCID in BMI 25 to less than 30 category versus the BMI less than 25 category was 1.82 (0.87–3.8; P = 0.11) at the 6 months follow-up. At the 12 months follow-up, the estimated OR was 1.69.

**TABLE 1. Patients Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Total Population</th>
<th>BMI &lt;25</th>
<th>BMI 25 to &lt;30</th>
<th>BMI ≥30</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>166</td>
<td>50</td>
<td>72</td>
<td>44</td>
</tr>
<tr>
<td>Age at time of surgery, median (IQR)</td>
<td>74 (12)</td>
<td>74 (11.5)</td>
<td>74.5 (12)</td>
<td>73.5 (12.5)</td>
</tr>
<tr>
<td>Sex, female (%)</td>
<td>80 (48.2)</td>
<td>31 (62)</td>
<td>29 (40.3)</td>
<td>20 (45.5)</td>
</tr>
<tr>
<td>CIRS, median (IQR)</td>
<td>8 (4.8)</td>
<td>8 (3)</td>
<td>8 (5)</td>
<td>9 (4)</td>
</tr>
<tr>
<td>Levels of laminectomy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Level (%)</td>
<td>62 (37.3)</td>
<td>18 (36)</td>
<td>28 (38.9)</td>
<td>16 (36.4)</td>
</tr>
<tr>
<td>&gt;1 Level (%)</td>
<td>104 (62.7)</td>
<td>32 (64)</td>
<td>44 (61.1)</td>
<td>28 (63.6)</td>
</tr>
<tr>
<td>Level of education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compulsory education (1–9 yrs) (%)</td>
<td>33 (19.9)</td>
<td>9 (18)</td>
<td>14 (19.4)</td>
<td>10 (22.7)</td>
</tr>
<tr>
<td>Higher education/vocational training (no university) (10–12 yrs) (%)</td>
<td>110 (66.3)</td>
<td>27 (54)</td>
<td>54 (75)</td>
<td>29 (65.9)</td>
</tr>
<tr>
<td>University degree (%)</td>
<td>23 (13.9)</td>
<td>14 (28)</td>
<td>4 (5.6)</td>
<td>5 (11.4)</td>
</tr>
</tbody>
</table>

BMI indicates body mass index; CIRS, Cumulative Illness Rating Scale; IQR, interquartile range.
(0.81–3.52; \( P = 0.16 \)). In the category of at least 30 BMI \textit{versus} category of less than 25 BMI, we estimated an OR of 0.78 (0.34–1.82; \( P = 0.57 \)) at the 6 months follow-up. At the 12 months follow-up, we estimated an OR of 0.99 (0.44–2.23; \( P = 0.98 \)). None of the single ORs for MCID was significantly different from 1. When the global F-test was used to assess the importance of the variable BMI with all 3 categories at once, the resulting \( P \) values were \( P = 0.067 \) at the 6 months follow-up and \( P = 0.236 \) at the 12 months follow-up. All results are summarized in Table 2B.

**Additional Outcome at Baseline, 6 Months, and 12 Months Follow-Up**

In Supplement Table 1, http://links.lww.com/BRS/B44, descriptive statistics are summarized for the SSM and subdomains, NRS, FT, EQ-5D-EL sum score and actual health status, and RMDQ within BMI categories and over time. Figure 1 shows the changes with BMI categories over time in SSM and subdomains with box plots. Each box plot contains a notch that displays a confidence interval around the median. If the notches of 2 box plots do not overlap, there is ‘strong evidence’ that the 2 medians differ significantly.20 The corresponding box plots for the other scales can be found in Figure 2.

**Changes in Additional Outcomes From Baseline to 6 Months in the 3 BMI Categories**

We found statistically significant median improvements in all additional outcomes over all BMI categories (Table 3). These improvements varied between 0.6 and 1 for the SSM subdomains. In the obese patients, there was a non-significant worsening in the outcome EQ-5D-EL actual health status.

**DISCUSSION**

This study investigated 166 consecutive patients treated with lumbar decompression due to symptomatic lumbar spinal stenosis. Of these, 44 (27%) were obese according to the WHO classification by having a BMI at least 30. The percentage of patients in the obese group with a minimal clinically important improvement was 36% six months after baseline and even 48% twelve months after baseline. With respect to changes in the SSM over time, median score values significantly improved in the obese patients from baseline to 6 months. Our study provided further evidence that simple decompression without fusion was an effective treatment for some patients with DLSS even with a BMI at least 30. Forty-eight percent of the patients in the underweight and normal-weight group, 61% in the pre-obese group, and 48% in the obese group reached MCID. Thus, our results do not support the hypothesis that obesity is associated with worse outcome after decompression surgery in DLSS-patients compared with nonobese.

Two studies have shown a strong relationship between obesity and increased incidence of operative complications.18,20 In addition, those authors concluded that patients with a higher BMI sustained increased transfusion requirements and may rise the prevalence of perioperative complications. Further, Ou et al10 presented their results of the impact of BMI on adjacent segment disease after lumbar fusion for degenerative spine disease. The authors concluded in their retrospective study of 190 patients that BMI is a risk factor for adjacent segment disease. Other studies of spinal surgery found no influence of obesity on clinical outcome.18,31 In a retrospective subgroup analysis, Rihn et al8 concluded that obesity does not affect the clinical outcome of operative treatment for lumbar spinal canal stenosis. Gepstein et al14 evaluated the effect of lumbar decompression in the aged obese patients and showed similar reduction in pain and overall improvement in obese and nonobese patients.31 Furthermore, Djurasovic et al12 showed in a retrospective analysis of obese and nonobese patients undergoing lumbar fusion nonsignificant differences in back and leg-pain as well as in ODI-score at 2-year follow-up. Rosen et al33 showed no significant differences between body habitus and outcome after lumbar spine fusion surgery in terms of self-reported outcome measures, operative time, and length of hospital stay.

<table>
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<tr>
<th>Table 2b. Estimated Odds Ratios for Meaningful Improvement From a Multiple Logistic Regression Model Including BMI Category and Levels of Laminectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI</strong></td>
</tr>
<tr>
<td><strong>Odds Ratio (95% CI)</strong></td>
</tr>
<tr>
<td>25 to &lt;30 vs. &lt;25</td>
</tr>
<tr>
<td>( \geq 30 ) vs. &lt;25</td>
</tr>
<tr>
<td><strong>Levels of laminectomy</strong></td>
</tr>
<tr>
<td>( &gt;1 ) vs. 1</td>
</tr>
</tbody>
</table>

MCID indicates minimal clinically important differences, CI, confidence interval, BMI, body mass index.

Global \( F \) test \( P = 0.0675 \) and \( 0.236 \).
Whether type of surgery is a predictor for outcome remains controversial and was not part of our study. We used a standard open posterior lumbar laminectomy or laminotomy at the affected level or levels without fusion. The decompression of the lateral recessus and foramina was performed when necessary. We included the number of levels of laminectomy in our multiple logistic model to obtain adjusted effects of BMI categories.

Our obese patient population had a slightly worse comorbidity score (CIRS) than the nonobese population reflecting some differences at baseline and in the perioperative situation. A prospective study by Andreshak et al., comparing perioperative findings between obese and nonobese patients undergoing lumbar spine surgery demonstrated no differences in operative time, blood loss, or hospital stay. BMI categories could also be associated with higher blood loss, longer hospital stay, higher reoperation rate, or higher postoperative infection rate. This was not part of our study and should be included in future studies with the LSOS-data base. In addition, patients with higher risk factors (eg, higher CIRS than in our cohort) may not have been recommended for surgery and were not included in our study.

Our study provides evidence that obesity is no contraindication for decompression surgery in DLSS-patients. BMI is clinically objective and modifiable. The control of body weight before and after operation may provide opportunities to reduce the rate of DLSS and could improve the outcome of decompression surgery.

There are 2 limitations to our study. First, different distributions of prognostic indicators, including gender, level of education, and income between the 3 groups of

Figure 1. SSM and subdomains in categories of BMI at baseline, 6 months, and 12 months.
patients, may have an impact on the results. Second, we did not reassess BMI at specific postoperative time points. The reassessment of BMI at specific time-points would improve the understanding of the effect whether pain from a spine etiology restricts the ability of obese patients to lose weight.

As part of the lumbar spinal outcome study (LSOS; www.lumbalstenose.ch), we will present our 2- and 3-year results in the future. A follow-up period of 2 years would strengthen our study to evaluate the continued effect of MCID. A longer follow-up period would evaluate and...
compare our results with other long-term studies, such as the Main Lumbar Spine Study, or the Spine Patient Outcomes Trial (SPORT). Our results do not support the hypothesis that obesity is associated with worse outcome after decompression surgery in DLSS-patients compared with nonobese. At the 6 months follow-up evaluation, the obese and nonobese patient population showed significant mean improvements in all additional outcome categories. The only exception was the EQ-5D-EL (actual health status) that showed no significant improvement in the obese population. To our knowledge, our study is the first one about the evaluation of decompression surgery in obesity to consider MCID in SSM. These MCID reflects changes after clinical interventions that are meaningful for the patient and reveal worthwhile changes in the outcome measures.

Our study shows that even obese patients benefit from surgical treatment. Obese patients can expect meaningful clinical improvement after lumbar decompression for symptomatic DLSS, but the percentage is smaller than in the group of pre-obese, normal-weight, and underweight patients.

Acknowledgments
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Key Points
- Obesity is assumed to be associated with less favorable outcome following decompressive surgery of DLSS.
- In the main outcome, 16 obese patients (36%) showed a MCID at the 6 months follow-up and 21 patients (48%) showed a MCID at the 12 months follow-up.
- In the additional outcomes, Spinal Stenosis Measure scores, Numeric Rating Scale, Feeling Thermometer, EQ-5D-EL sum score, and Roland and Morris Disability Questionnaire showed statistically significant \( P < 0.001 \) changes between baseline and 6 months follow-up.

Obese patients can expect meaningful clinical improvement after lumbar decompression for symptomatic DLSS, but the percentage is smaller than in the group of pre-obese, normal-weight, and underweight patients.

Supplemental digital content is available for this article. Direct URL citations appearing in the printed text are provided in the HTML and PDF version of this article on the journal’s Web site (www.spinejournal.com).

References

TABLE 3. Change in Secondary Outcomes From Baseline to 6 Months in the 3 BMI Categories

<table>
<thead>
<tr>
<th></th>
<th>BMI &lt;25</th>
<th>P</th>
<th>BMI 25 to &lt;30</th>
<th>P</th>
<th>BMI ≥30</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>△ SSM symptoms 0–6</td>
<td>0.7 (0.9)</td>
<td>&lt;0.001</td>
<td>1 (0.8)</td>
<td>&lt;0.001</td>
<td>0.8 (0.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>△ SSM function 0–6</td>
<td>0.6 (0.7)</td>
<td>&lt;0.001</td>
<td>0.7 (0.8)</td>
<td>&lt;0.001</td>
<td>0.7 (0.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>△ NRS 0–6</td>
<td>3.1 (2.8)</td>
<td>&lt;0.001</td>
<td>3.9 (2.8)</td>
<td>&lt;0.001</td>
<td>2.7 (2.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>△ Feeling Thermometer 0–6</td>
<td>30.4 (30.4)</td>
<td>&lt;0.001</td>
<td>35.9 (28.5)</td>
<td>&lt;0.001</td>
<td>29.9 (29.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>△ EQ-5D-EL sum score 0–6</td>
<td>−15.3 (16.7)</td>
<td>&lt;0.001</td>
<td>−16.1 (19.4)</td>
<td>&lt;0.001</td>
<td>−12.3 (18.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>△ EQ-5D-EL abs 0–6</td>
<td>−13.9 (28)</td>
<td>&lt;0.001</td>
<td>−19.3 (29.9)</td>
<td>&lt;0.001</td>
<td>2.1 (29.7)</td>
<td>0.9731</td>
</tr>
<tr>
<td>△ RMDQ 0–6</td>
<td>4.2 (5.8)</td>
<td>&lt;0.001</td>
<td>4.7 (4.8)</td>
<td>&lt;0.001</td>
<td>4.8 (5.5)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

0–6 indicates baseline to 6 months; NRS, Numeric Rating Scale; abs, actual health status; RMDQ, Roland and Morris Disability; BMI, body mass index, SD, standard deviation.


