Functional outcome in operated patients of multilevel lumbar canal stenosis and use of HRQoL role in depicting the anxiety and its correlation with the pain

Ajay Kumar Singh, Prashant Raj Singh*, Tarun Kumar Pandey, Ankur Kumar and Abhay Kumar Agarwal

Abstract

Background: Lumbar canal stenosis (LCS) is a degenerative spinal disease of elderly people, and it not only impairs the mechanical activity but also alters the economic and mental status of the patients indirectly. This is single-center observational prospective study conducted for 2 years and included 30 consecutive operated patients of multilevel LCS patients and excluded the patients with single-level LCS, with primary LCS or with grade II subluxation. We analyzed the various measurement indices used for the surgical outcome assessment as ED-5D 5L and OLBPDI (Oswestry low back pain disability index). Statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical Analysis Software. The independent t test, post hoc analysis, Wilcoxon signed rank statistic test and RM-ANOVA test were also applied.

Result: Most patients have improvement in pain and all the components of HRQoL (health-related quality of life) after surgery, which was further improved in mean follow-up of 1 year. Our study also suggested that the patients with higher anxiety/depression have higher pain intensity and low HRQoL, which was persistent in postoperative period (p < .001).

Conclusion: ED-5D 5L and OLBPDI are good indices to assess all the components of quality of life and give valuable information overall. Anxiety has shown important correlation with the pain component in both preoperative and postoperative phase.

Keywords: Lumbar canal stenosis, HRQoL, OLBPDI, Lumbar fusion

Background

Lumbar canal stenosis (LCS) was defined by the North American Spine Society as “a clinical syndrome of buttock or lower extremity pain, which may occur with or without back pain, associated with diminished space available for the neural and perivascular elements in the lumbar spine” [1]. Most consistent feature associated with LCS is neurogenic claudication (pseudo-claudication) while leg pain, buttock or back pain may be present [1, 2]. MRI (spine) is helpful to establish the clinical diagnosis and findings as dural cross-sectional area and mean canal diameter had been studied as a prognostic factor in the surgical outcome in many studies [3–6]. Patients with persistent symptoms and failed conservative management of at least 6 months are recommended to undergo surgical treatment and good to excellent results have been reported after surgery in approximately 64% of the cases [4].

During the past decade, there have been emerging studies employing health-related quality of life (HRQoL)
using SF-36 (36-item Short Form Health Survey) or EQ-5D (Euro Qol-5D) [7–9]. The interesting aspect of EQ-5D 5L is that it measures both functional and socioeconomic status of the patients and it also includes the psychological factor (anxiety/depression) as a domain which was not used in most of other scales [10]. Another useful index, the Oswestry low back pain disability index (OLBPDI), not only calculates the pain intensity but also reacts to changes in the functional status of the patient and is closely correlated with the degree of patient’s satisfaction after surgery [10, 11].

Since evidences are still lacking in Indian subcontinent population, we performed this prospective study to evaluate functional outcome using HRQoL (EQ-5D 5L) and OLBPDI, in surgically treated patients with multilevel LCS at 1-year follow-up, and also tried to establish role of psychological factor in reduction of pain and outcome measures in operated patients of LCS.

**Methods**

This prospective observational study was done in our tertiary institution for 2 years (2016–2018), including 30 consecutive patients of multilevel degenerative lumbar canal stenosis with or without grade I degenerative spondylolisthesis, based on the inclusion criteria. Patients with single-level lumbar canal stenosis were excluded from the study. The ethical clearance for the study has been approved by VPIMS ethical committee (ECR/1514/inst/UP/2021).

**Inclusion criteria**

Patients included in the study should have 2 or more than 2 level of degenerative lumbar canal stenosis, claudication distance less than 100 m and failure of trial of adequate conservative treatment for 6 months.

**Exclusion criteria**

Patients with primary LCS, with spondylolisthesis (>grade II), and one-level LCS were excluded from the study. The patients who are unfit for general anesthesia due to associated comorbidities, osteoarthritis of the knee or hip joint, those who had prior lumbar or lower extremity surgery, patients with major depressive disorder, polynuropathy or peripheral arterial disease were excluded from the study.

**Methodology**

Patients fulfilling the inclusion criteria were admitted in our department and detailed analysis was done in terms of clinical symptoms and signs. Radiological studies including X-ray (dynamic lumbar spine) and MRI (lumbar spine) were done and assessed by the radiologist and senior spine surgeon.

Clinical assessment using OLBPDI and EQ-5D 5L was done preoperatively and in follow-up period up to 1 year. EQ-5DL questionnaire has 5 components (mobility, self-care, usual activity, pain and disability, anxiety–depression) and each has 1–5 levels (level 1—no problem, 2—mild, 3—moderate, 4—severe, 5—unable to perform).

OLBPDI has 10 components (PI—pain intensity, PC—personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, travel) and each has score from 0 to 5 (10 × 5 = 50-maximum score) [11]. The level of disability is calculated by the percentage disability—score (X) 50 × 100; for 0–20% percentage disability—level 1 (minimal) disability, for 21–40%—level 2 (moderate), 41–60%—level 3 (severe), 61–80%—level 4 (crippled), 81–100%—level 5 (disabled).

**Surgical intervention and follow-up**

Surgical management included laminectomy of the decided level with or without discectomy in all the patients while in 9 patients with spondylolisthesis (grade I) patients, laminectomy with pedicle screw fixation at the involved level with interbody fusion was done using titanium posterior lumbar interbody fusion (PLIF) implant. Patient was mobilized after 4–5 h of surgery and was allowed to walk and sit with minimal help. No orthosis was provided to the patient except in patients with spinal instrumentation. Patient was usually got discharged in 4–10 days after surgery and asked to start the physiotherapy after 6 weeks with certain precautions. Our team has a group of physiotherapist which starts the physiotherapy routinely in patients during preoperative period and continues it in postoperative period during the admission. Patients with neurological deficits were followed more diligently during the follow-up visits. Follow-up was done at 3 months and 12 months postoperatively. Complete neurological examination, claudication distance and questionnaires of functional outcome asked and noted at each follow-up. Psychological counseling of patients was done by the senior consultant of the department in preoperative phase and in each follow-up postoperatively. Radiological assessment was done in follow-up with X-ray and CT scan (computer tomography) to look for the solid fusion.

**Outcome analysis**

1. To study and evaluate the functional outcome of surgically managed multilevel lumbar canal stenosis using EQ-5D 5L and OLBPDI questionnaire.

2. To evaluate the psychological factors as anxiety/depression for predicting the surgical outcome in patients of multilevel lumbar canal stenosis.
Statistical analysis
The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical Analysis Software. The values were represented in number (%) and mean ± SD. The Wilcoxon signed rank statistic \( W^+ \) is computed along with the \( p \) value for the assessment of all the variables of HRQoL and OLBPDI in pre- and postoperative period and post hoc analysis was also done to compare these variables in preoperative period to the follow-up period of 3, 6 and 12 months. Independent t test was applied to analyze the anxiety level to the pain intensity, while RM-ANOVA was applied to compare the outcome in patients with and without spondylolisthesis.

Results
The demographic and clinical characteristics are summarized in Table 1.

Preoperative consideration
Assessment of health-related quality of life (EQ-5D 5L) at the time of admission is given in Table 1 and Fig. 1. It was observed that majority of the patients had moderate to severe level of problems for mobility (80.0%), self-care (66.7%), usual activities (66.7%) and pain and discomfort (83.3%). Majority of the patients had level 1 (6.7%) and level 2 (63.3%) of problem in anxiety/depression component; while 9 (30%) patients had level 3 and level 4 (moderate to severe level) of anxiety/depression in the preoperative period. We have also analyzed the OLBPDI and found that before surgical intervention, none of the patient had minimal disability (Table 1, Fig. 2). Majority of the patients 23 (76.7%) were either crippled or disabled (40.0 and 36.7%, respectively), while 6 (20.0%) had severe level of disability and only 1 (3.3%) patient had moderate level of disability (Table 1).

Functional outcome
At 3 months post-surgery, majority of patients had level-1 and level-2 quality of life (ED-5QL) for mobility (90.0%), self-care (90.0%), usual activities (90.0%), discomfort and pain (96.7%) and anxiety/depression (93.3%). Surprisingly, at 3-month follow-up, 80% of patients moved to level 1 and 13.3% to level 2 in anxiety/depression component, while only 2 patients (6.7%) were in level 3. Statistically significant changes in all the components (mobility, self-care, usual activities, discomfort and pain and anxiety/depression) were observed at 3 months post-surgery (Z score—4.66–4.75, \( p \) value < 0.001), shown in Table 2 and Fig. 1. At 12-month follow-up (Table 2 and Fig. 1), majority of patients had level-1 and level-2 quality of life for mobility (95.8%), self-care (95.8%), usual activities (100.0%), discomfort and pain (100.0%) and anxiety/depression (100.0%).

Table 1 Characteristics of the study population

| Variables                  | n—30(%) |
|----------------------------|---------|
| Age                        | Mean ± SD 57.03 ± 9.42 years |
| Range                      | 35–72 years |
| Gender                     | Male 21 (70%) |
|                             | Female 7(30%) |
| Symptoms                   | 1—Sensory paresthesia 29 (96.7%) |
|                             | 2—Motor weakness 8 (26.7%) |
|                             | 3—Bladder bowel involvement 6 (20%) |
| Imaging features           | 1—Level of stenosis a—L3-4/L4-5 20 (66.7%) |
|                             | b—L4-5/L5-S1 7 (23.3%) |
|                             | 2—Spondylolisthesis |
| Present                    | 9 (30%) |
| Absent                     | 21 (70%) |
| Preoperative EQ-5D 5L      | 1—Mobility a—Level 1 and 2 3 (10%) |
|                             | b—Level 3–5 27 (90%) |
|                             | 2—Self-care a—Level 1 and 2 8 (26.7%) |
|                             | b—Level 3–5 22 (73.3%) |
|                             | 3—Usual activities a—Level 1 and 2 7 (23.3%) |
|                             | b—Level 3–5 23 (76.7%) |
|                             | 4—Pain and discomfort a—Level 1 and 2 3 (10%) |
|                             | b—Level 3–5 27 (90%) |
|                             | 5—Anxiety and depression a—Level 1 and 2 21 (70%) |
|                             | b—Level 3–5 9 (30%) |
| Preoperative OLBPDI        | 1—Minimal disability 0 |
|                             | 2—Moderate disability 1 (3.3%) |
|                             | 3—Severe disability 6 (20%) |
|                             | 4—Crippled 12 (40%) |
|                             | 5—Disabled 11 (36.7%) |

After 3 months of surgery, out of 23 (76.7%) patients who were completely disabled or crippled improved to moderate or severe levels of disability; while at 12-month follow-up, 19 out of 24 (79.1%) patients were improved to minimal disability level from crippled condition. Statistically significant has also been noted for the all the aspects of the life (OLBPDI) in preoperative disability level among all the 30 patients at 3 months.
(Z score—4.28–4.82, \( p \) value < 0.001) (Fig. 2). Post hoc comparison analysis has shown statistically significant outcome in all the components of the OLBPD score (Table 3).

**Correlation of anxiety and pain**

There was strong correlation between anxiety (on HRQoL score) and pain (OLBPD score), which was statistically significant (\( p < 0.001 \)) (Fig. 3) and we also found
that higher anxiety level directly affects the pain intensity level even in postoperative period ($p < 0.001$) (Fig. 4).

In 30% of the all the patients, there was associated grade I spondylolisthesis. The higher proportion of spondylolisthesis can be explained by the long-standing progressive degenerative process in the multilevel canal stenosis. All the patients with fixation had significant improvement in functional outcome and there was no significant difference in functional outcome and pain intensity in both the groups of with and without fixation.

**Table 2** Changes in mean score of five components of HRQoL over time

| Component of HRQoL | Mobility | Self-care | Usual activities | Discomfort and pain | Anxiety/ depression | Overall score |
|--------------------|----------|-----------|------------------|---------------------|---------------------|--------------|
| Mean               | SD       | Mean      | SD               | Mean                | SD                  | Mean         | SD          |
| Pre-op             | 3.56     | 0.81      | 3.13             | 0.97                | 3.16                | 0.91         | 3.46        | 0.77       | 2.36       | 0.80       | 15.70       | 3.47       |
| 3 months           | 2.03     | 0.66      | 1.73             | 0.82                | 1.70                | 0.74         | 1.76        | 0.50       | 1.30       | 0.70       | 8.53        | 2.78       |
| 6 months           | 1.56     | 0.81      | 1.46             | 0.81                | 1.33                | 0.66         | 1.20        | 0.40       | 1.30       | 0.53       | 6.86        | 2.51       |
| 12 months          | 1.53     | 0.62      | 1.33             | 0.60                | 1.36                | 0.61         | 1.26        | 0.44       | 1.30       | 0.59       | 6.80        | 2.36       |
| $p$ value          | $<0.001$ | $<0.001$  | $<0.001$         | $<0.001$            | $<0.001$            | $<0.001$     | $<0.001$    | $<0.001$   | $<0.001$   | $<0.001$   | $<0.001$    |

**Table 3** Changes in mean OLBPD score at different time intervals

| OLBPD   | Mean | SD  | Post hoc        |
|---------|------|-----|-----------------|
| Pre-op  | 73.82| 14.82| Pre-op versus 3 months $< 0.001$ |
| 3 months| 43.86| 8.87| Pre-op versus 6 months $< 0.001$ |
| 6 months| 35.48| 10.29| 3 months versus 6 months $< 0.001$ |
| 12 months| 32.034| 9.68| 3 months versus 12 months $< 0.001$ |
| $p$ value | $<0.001$ | $<0.001$ | 6 months versus 12 months $0.001$ |

**Fig. 3** Bar diagram showing the changes in mean value of anxiety and depression score of HRQoL and pain intensity in preoperative period and depicted the strong relationship between both the variables.
Most probable explanation for this would be that spondylolisthesis alone is not responsible for functional disability and involve multiple variables in degenerative lumbar disease.

**Complications**

Two patients developed urinary straining in immediate postoperative period which improved in 3-month follow-up while one patient had superficial wound site infection.

**Fig. 5** Line diagram depicting the HRQoL in patients of multilevel lumbar canal stenosis with and without subluxation and showed the similar improvement in both the group in the postoperative period.
for which antibiotics are given for 6 weeks and responded well to it. Eight patients (26%) presented with weakness/foot drop in either unilateral or bilateral foot. Seven patients (87.5%) improved in motor power in postoperative period but only one patient (12.5%) still needs foot drop splints for ambulation at 1 year. Six patients (20%) presented with BBI in preoperative period, four (66.6%) of them were improved clinically, but only two (33.3%) still have BBI at 1-year follow-up.

Discussion

Our study has also established the fact that once the adequate management has been provided to the multilevel LCS patient with the focus on the psychological component. Majority of the patients have significant improvement in all the components of HRQoL and OLBPd at 1-year follow-up, irrespective of spondylolisthesis in a subset of the patient. We have also observed in our study that there are higher percentages of significant preoperative neurological deficits as foot drop and bladder bowel involvement and this can be explained by the long-standing multilevel canal stenosis and ignorance of health-related issues in the Indian population. The ideal time for surgery in multilevel LCS is always a matter of debate and but the good surgical outcome was achieved for 3–4 years after surgery and maximum for 10 years, which was supported by many randomized control trial (including the largest one-SPORT—Spine Patient Outcomes Research Trial) [12–18]. While considering the patient for surgery, detailed evaluation and risk benefit ratio should always be calibrated as few meta-analyses have shown that the one-fourth of the surgical patients may come for re-operation [17, 19]. The role of conservative treatment as drug therapy including the epidural injection, bed rest at initial treatment, “back school,” use of orthosis, physiotherapy before and after surgery, and early rehabilitation is the important component of multidirectional approach [12, 15, 16].

Various preoperative factors have been analyzed in the past to predict the surgical outcome and a systemic review has suggested that psychological factors as depression, physical parameters as higher BMI (body mass index), lesser walking capacity, associated comorbidities, higher socioeconomic status and preoperative scoliosis have a direct negative effect on the outcome while younger age group, male gender and pronounced central stenosis have positive impact on the outcome [4, 7, 17, 20, 21]. A detailed study correlating the type of stenosis in MRI (magnetic resonance imaging) with the LCS has shown no statistically significant relationship, although the degenerative scoliosis was considered significant in these patients, therefore it is very crucial to delineate all the factors before suggesting the surgical treatment [6, 22].

We found that the age and gender have no effect on the clinical outcome after the surgery at 1-year follow-up similar to many studies[7, 15, 21]; while few studies have concluded that patients with age more than 65 years were less satisfied than younger group at 1-year follow-up and also demonstrated that the age of the patient was significantly associated with the late postoperative deterioration of symptoms especially back pain than of neuroischemic symptoms. Few articles noted more recurrent back pain in elderly, which was explained by the continued degenerative process in the elderly,[9, 23], while Ulrich et al. have shown that both young and elderly have no difference in clinical outcome in all the aspect except in the “anxiety” domain at 1-year follow-up [24].

The role of psychological aspect is critical in patient with LCS as pain component and reduced working capacity may precipitate depressive features or the preexisting depression may worsen the pain and disinterest in physical activities may indirectly affect the surgical outcome; hence anxiety/depression domain of EQ-5D 5L is studied and elaborated in many studies [4, 20]. We also found direct correlation in the anxiety and pain component and their effect in the postoperative period. Hence, we want to stress on the psychological counseling in both preoperative and postoperative follow-up period. We have not used any drug therapy for combating depressive features during the treatment, even in the postoperative period. There is no consensus in the literature regarding the use of antidepressant drug in the spinal surgery patient and few risk factors as decreased platelet aggregation, chances of bleeding and poor bony fusion has been reported in the previous articles but more extensive randomized control trial are needed to prove the benefits and risk factors [25, 26]. Many studies have shown that about 20–40% of the LCS patients have clinically significant depressive symptoms.[7]; and psychological factors importance can also be understandable by the fact that the unrealistic preoperative expectations regarding pain, low optimism and lesser interest in physical activity have poor postoperative clinical outcome [4, 7, 27, 28]. Few studies have also stressed on cognitive-behavioral patient education and role of psychotherapist in improving the clinical as well as quality of life in LCS patients and surgery can be delayed in patients with moderate LCS [7, 29].

Similar to our results, many studies have also shown that no fixation and fixation group have no significant differences in functional outcome except the longer hospital stay and lower physical factor (PF) score [19, 21]. Similar outcome in both groups may be explained by the same degenerative process causing the spinal
compression and symptoms relieve by the decompression itself in both the groups. The role of fixation is to slow or stop the degenerative process but clinical improvement may present very late or subtle and may need longer follow-up to comment upon.

The limitations of the study are the small cohort of the patients because of the inclusion of only two or more than two-level lumbar canal stenosis, lack of use of certain scales of anxiety and depression and only 1 year of follow-up of the patients.

Conclusion

HRQoL using ED-5L 5D and OLBPDI score is very useful functional outcome assessment scales in the operated patient of multilevel LCS patients. The positives of the study are the evaluation of the psychological factor in determining the functional outcome and also inclusion of only multilevel lumbar canal stenosis patients in the study cohort. Our study wants to stress on the impact of psychological component on the outcome and counseling may play a vital role in predicting the final outcome in early postoperative period.

Abbreviations

LCS: Lumbar canal stenosis; HRQoL: Health-related quality of life; OLBPDI: Oswestry low back pain disability index.

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Authors’ contributions

AS, TP and PS contributed to conceptualization. PS and TP contributed to methodology. AS, PS, AK and AA contributed to formal analysis and investigation. AS, PS, TP, AK and AA contributed to writing and editing. PS and TP contributed to supervision. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval and consent to participate

This study was approved by the ethics committee of Vivekananda Polyclinic and Institute of Medical Sciences, Lucknow, UP, India, with approval number (ECR/1514/inst/UP/2021).

Consent of publication

Not applicable.

Competing interest

None.

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AS, TP and PS contributed to conceptualization. PS and TP contributed to methodology. AS, PS, AK and AA contributed to formal analysis and investigation. AS, PS, TP, AK and AA contributed to writing and editing. PS and TP contributed to supervision. All authors read and approved the final manuscript.

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