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Health-related quality of life in patients undergoing lumbar total disc replacement: A comparison with the general population

Pablo Clavel[a,1], Gheorghe Ungureanu[b,*,1], Ignasi Catalá[a], Guillermo Montes[a], Xavier Málaga[a], Moisés Ríos[a]

[a] Barcelona Spine Center, Pl. Alfonso Comín 5-7, Barcelona, Spain
[b] Department of Neurosurgery, Victor Babes, 43/7, 400191, Cluj-Napoca, Romania

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ABSTRACT

Objectives: In up to half of the cases, low back pain (LBP) is thought to be related to a degeneration of the lumbar disc. Lumbar total disc replacement (LTDR) emerged as an alternative to fusion, but its use and indications are still subject to debate. The purpose of this paper was to compare Health-related Quality of life (HRQOL) in patients undergoing LTDR for one or two-level degenerative disc disease (DDD) with the paired age and gender general population values and to assess functional disability and residual pain at one year after the surgical procedure.

Material and methods: A series of 51 patients operated on for a one or two level DDD, were evaluated at one year after the surgical procedure. HRQOL was compared to that of paired age and gender general population using the EQ-5D-5L questionnaire. Disability, back (BP) and leg pain (LP) were compared to the preoperative values.

Results: ODI showed a mean improvement of 31.78 ($p < 0.001$, 95% CI 27.39–36.17), BP-VAS of 5.29/10 (95% CI 4.56–6.02), LP-VAS of 4.03/10 (95% CI 3.15–4.92) at one year compared to the preoperative assessment. HRQOL had similar values to the general population in 32 patients and inferior in 19 patients. "Pain" was the HRQOL dimension in which most of the patients had inferior results compared to data from the general population. Patients with previous spinal surgery had lower improvements in HRQOL index, disability, and pain than those without previous surgery.

Conclusions: We found that the majority of patients improved their HQOL to values similar to those of the general population. Disability and pain are significantly reduced compared to preoperative evaluations. Larger scale studies are needed to identify the best candidates for LTDR.

1. Introduction

Low back pain (LBP) is one of the most common conditions found in the general adult population and the most common occupational disorder in working individuals, with a prevalence of 84% [1,2]. Chronic LBP, defined as the presence of constant back pain for more than 12 weeks, has a profound effect on people's quality of life (QOL), causing various degrees of disability [1]. Several studies investigating possible causes of LBP found that in up to 45% of cases an intervertebral degenerated disc is present [3].

The concept of lumbar degenerative disc disease (LDDD) is still controversial, but it usually refers to structural changes in the intervertebral disc leading to deterioration and remodeling of the disc, especially in the endplates and adjacent vertebral structures [1,4]. Surgical management is reserved for cases refractory to medical treatment. In the surgical armamentarium, total disc replacement (TDR) initially emerged as a viable option, as it theoretically allowed for the preservation of motion in the affected segment and thus a similar function to an intact disc [5]. This seems especially important in the young, working adults, in which disability caused by LDDD has a severe impact, and the consequences of fusion would be very high. TDR has been available for several years and is viewed by some as a method to deal with the shortcomings associated with fusion. Its utility is still under debate, as some surgeons and professional organizations advise against its use and this leads to limited evidence-based research related to LTDR, compared to other technologies used in spinal surgery [6].

Patient-reported outcome measures (PROMs) became one of the primary tools in analyzing the results of spinal surgery [7,8]. Health-related QOL (HRQOL) and LBP disability questionnaires evaluate different but interconnected aspects of a patient's quality of life.

* Corresponding author.
E-mail address: ungureanugeorge@gmail.com (G. Ungureanu).
[1] These authors contributed equally to this work.

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Although various studies reported postoperative outcomes after lumbar TDR (LTDR), there is a lack of data on how the QOL of these patients compares to that of the demographic-paired general population and if patients return to QOL states comparable to the general population after LTDR.

The purpose of this study was twofold: first, was to compare HRQOL outcome measures in patients with LTDR to the gender and age-paired general population; second, was to identify and gauge the impact of TDR on functional disability caused by chronic LBP.

2. Material and methods

A series of patients that underwent LTDR surgery in one Spanish institution was evaluated 12–14 months after the surgical intervention. Inclusion criteria were: LBP for more than 6 months; failure of conservative treatment; positive MRI criteria for LDDD, with or without disc displacement, accessible through an anterior approach; absence of any other structural anomaly (e.g. spondylolisthesis, facet joint disease, etc.), evaluated by MRI and CT/spinal radiography; T scores on Dexa scans > 15; lack of conditions that could alter bone function; intact mental and emotional state; absence of any prior extensive abdominal surgery; Spanish origin. We did not exclude those patients with a previous history of spinal surgery at other levels or persistent back pain after discectomies at the level of the DDD if they met the above criteria.

HRQOL was evaluated using the EQ-5D-5L (EQ-5D). This questionnaire is a standardized measure developed by the EuroQol Group to provide a generic measure of HRQOL. It uses a five dimension system to define QOL, each of which has five possible levels [9]. The combination of these dimensions offers an Index-based value (EQ-Index). Furthermore, it offers the EQ-VAS to record the respondent's self-rated health on a 20 cm vertical visual analog scale, with endpoints labeled as "the best health you can imagine" and "the worst health you can imagine" [10]. To evaluate disability caused by LBP, we used the Oswestry Disability Index (ODI). It consists of ten items, each with six possible statements scored from 0 to 5, with higher scores indicating greater disability [11]. Its scores offer five degrees of disability, ranging from minimal to bedbound [12]. Local and radiated pain were evaluated using the Back-Pain, and Leg-Pain Visual Analogue Scale (BP-VAS, LP-VAS, respectively) and another questionnaire analyzed return to work at one year and free-time sports activity.

HRQL among patients was compared to the general Spanish population by comparing the EQ-Index and EQ-VAS values in the study sample with age and sex-adjusted population norms provided in the literature [13]. EQ-5D population normative values were collected from 21,007 people representative of the Spanish population and are divided according to age group and gender [13]. From the population norms, we extracted the mean value of EQ-5D and EQ-VAS in the population, according to age and sex of each patient. EQ-5D index and EQ-VAS for each patient were compared to the mean value of individuals of the same sex and age group. To identify meaningful differences between patients and the general population, we used a difference of 0.074 for EQ-Index, which is the value cited in the literature as being the minimum clinically important difference (MCID) [14]. The frequency of each health state in the general population was determined as the mean of frequency in individuals of the same age group as that of patients. ODI, BP-VAS, LP-VAS were compared with preoperative scores. A change between preoperative and postoperative scores of 12.8 points in ODI, 1.2 for BP-VAS and 1.6 for LP-VAS were considered to be the MCID, as suggested by Ghogawala et all [15]. ODI scores were divided into five degrees of disability: minimal (0–20%), moderate (20–40%); severe (40–60%); crippled (60–80%); bedbound or exaggerating (80–100%). BP and LP-VAS scores were rated into four categories of pain: no pain (0-0.4); mild (0.5–44); moderate (4.5–7.4); severe (7.5–10) [16].

To determine the EQ-Index values, we used the EQ-5D-5L Crosswalk Index Calculator, provided by the EuroQol, which uses the methodology published by van Hout et al. [17]. The Statistical analysis was performed using SPSS Statistics, Version 20 (IBM Corp, Armonk. NY). In all cases, a p value of < 0.05 was considered statistically significant.

All the patients included in the study were operated using the same technique. The surgical approach was made in all cases through a midline incision, centered on the affected level(s). A left retroperitoneal dissection was performed, allowing for exposure of the affected intervertebral disc. Once the level was exposed, a total discectomy was performed. In the presence of disc displacement, the displaced part was also removed. A disc prosthesis, selected according to level and size of the endplates, was placed in the midline under radioscopic control. Any injury to the vascular structures was promptly addressed. After inspection of the integrity of anatomical structures wound closure was conducted. A draining tube was inserted and removed the next day when mobilization was initiated in all cases. Patients were discharged 3 or 4 days after surgery.

3. Results

Out of the 51 patients included in the study, 30 patients were males and 21 females. Thirty-four patients had one level TDR, and seventeen had two level TDR. Gender, age, and the number of levels are detailed in Table 1. Past medical history and demographics of the patients are found in Table 2.

All the parameters significantly improved at the postoperative evaluation versus the preoperative ($p < 0.05$ in all cases). EQ-Index showed a mean improvement of −0.37 (95% CI −0.49 to −0.24), EQ-VAS of −21.13 (95% CI −34.80 to −7.4), ODI of 31.78 ($p < 0.001$, 95% CI 27.39–36.17). BP-VAS of 5.29 (95% CI 4.56–6.02) and LP-VAS of 4.03 (95% CI 3.15–4.92). The improvement was greater than the MCID in 47 patients (92%) for ODI, in 46 patients (90%) for BP-VAS and 39 patients out of 45 (87%) for LP-VAS. Six patients had an initial score for LP-VAS of 1, lower than the 1.2 thresholds for MCID. At the preoperative evaluation, patients with previous spinal surgery reported higher disability, back, and leg pain, and reported lower scores of QOL, but the only significant statistical difference was in the BP-VAS (mean: $p < 0.05$, 95% CI: 0.65–2.60). Patients with a previous spinal surgery showed a much lower change than patients with no previous surgery in LP-VAS, BP-VAS, EQ-VAS and a slightly higher change in EQ-Index. In the four patients that did not reach MCID for ODI, all had previous surgery, and the seven that did not reach MCID for LP-VAS had previous surgery (Fig. 1).

At the preoperative evaluation, three patients (6%) had a minimal disability, 18 patients (36%) had a moderate disability, 30 patients (59%) had a severe or crippling disability. 44 (86%) had moderate or severe back pain, and 7 (33%) minimal back pain, 31 patients (60%) had moderate or severe leg pain, and 20 (40%) patients had minimal leg pain. Postoperatively, 33 patients (64%) reported no disability, 7 (13%) reported minimal disability, nine patients (17%) reported a moderate disability and two patients (4%) reported severe disability. For back pain, 21 patients (41%) reported none, 24 (47%) reported

Table 1
Cross tabulation by gender, age, and number of levels of TDR.

Number of levels		Age				Total
		18–29	30–39	40–49	50–59	
1 level	Female	1	6	9	1	17
	Male	0	8	7	2	17
2 levels	Female	1	1	2	0	4
	Male	2	3	7	1	13
Total	Female	2	7	11	1	21
	Male	2	11	14	3	30
	Total	4	18	25	4	51