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ORIGINAL ARTICLE

Influence of preoperative leg pain and radiculopathy on outcomes in mono-segmental lumbar total disc replacement: results from a nationwide registry

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Abstract
Purpose Currently, many pre-conditions are regarded as relative or absolute contraindications for lumbar total disc replacement (TDR). Radiculopathy is one among them. In Switzerland it is left to the surgeon's discretion when to operate if he adheres to a list of pre-defined indications. Contraindications, however, are less clearly specified. We hypothesized that, the extent of pre-operative radiculopathy results in different benefits for patients treated with mono-segmental lumbar TDR. We used patient perceived leg pain and its correlation with physician recorded radiculopathy for creating the patient groups to be compared.
Methods The present study is based on the dataset of SWISSspine, a government mandated health technology assessment registry. Between March 2005 and April 2009, 577 patients underwent either mono- or bi-segmental lumbar TDR, which was documented in a prospective observational multicenter mode. A total of 416 cases with a mono-segmental procedure were included in the study. The data collection consisted of pre-operative and follow-up data (physician based) and clinical outcomes (NASS form, EQ-5D). A receiver operating characteristic (ROC) analysis was conducted with patients' self-indicated leg pain and the surgeon-based diagnosis "radiculopathy", as marked on the case report forms. As a result, patients were divided into two groups according to the severity of leg pain. The two groups were compared with regard to the pre-operative patient characteristics and pre- and post-operative pain on Visual Analogue Scale (VAS) and quality of life using general linear modeling.
Results The optimal ROC model revealed a leg pain threshold of $40 \leq \text{VAS} > 40$ for the absence or the presence of "radiculopathy". Demographics in the resulting two groups were well comparable. Applying this threshold, the mean pre-operative leg pain level was 16.5 points in group 1 and 68.1 points in group 2 ($p < 0.001$). Back pain levels differed less with 63.6 points in group 1 and 72.6 in group 2 ($p < 0.001$). Pre-operative quality of life showed considerable differences with an 0.44 EQ-5D score in group 1 and 0.29 in group 2 ($p < 0.001$, possible score range -0.6 to 1). At a mean follow-up time of 8 months, group 1 showed a mean leg pain improvement of 3.6 points and group 2 of 41.1 points ($p < 0.001$). Back pain relief was 35.6 and 39.1 points, respectively ($p = 0.27$). EQ-5D score improvement was 0.27 in group 1 and 0.41 in group 2 ($p = 0.11$).
Conclusions Patients labeled as having radiculopathy (group 2) do mostly have pre-operative leg pain levels ≥ 40. Applying this threshold, the patients with pre-operative leg pain do also have more severe back pain and a considerably lower quality of life. Their net benefit from the lumbar TDR is higher and they do have similar post-operative back and leg pain levels as well as the quality of life as patients without pre-operative leg pain. Although randomized controlled trials are required to confirm these findings, they put leg pain and radiculopathy into perspective as absolute contraindications for TDR.

Keywords Lumbar spine · Leg pain · Radiculopathy · Total disc replacement · Registry · SWISSspine

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Introduction

Because of the reported long convalescence periods after spinal fusion and a presumed risk of adjacent segment degeneration, patients increasingly consider the opportunity of total disc replacement (TDR). Disc herniation (DH) is the widely accepted cause of leg pain. Looking at the published results for the classic posterior procedures such as conventional discectomy, microdiscectomy and percutaneous measures for treating DH, we observed heterogeneous results. Reported re-operation rates range between 0 and 18% [1, 2] and back or leg pain persist in 6–43% [1] of cases, emphasizing the necessity for clear-cut indications. These results show that an appreciable population is unsatisfied or re-operated. The aforementioned facts outline the demands for a single staged solution with sustainable long-term results for which the success rates of only 75 –80% for the classic posterior procedure (lumbar discectomy) should not be the goal [3].

In contrast to the European administrations, the Food and Drug Administration (FDA) approved the first TDR for the lumbar spine very late. It was the SB Charité/DePuy Spine in October 2004 [4, 5] followed by the approval of the Synthes ProDisc-L in August 2006 [6]. Considering the publications by TDR pioneers [7, 8] and studies leading to FDA approval, indications and contraindications for TDR were defined [4, 9, 10].

The generally accepted indications are:

Single-level degenerative disc disease (DDD) between L4-S1 confirmed by magnetic resonance imaging (MRI), computed tomography (CT) and/or CT myelography;

discogenic low back pain (LBP) at the segment to be operated concordant with the pain during the provocative discography;

back and/or leg pain without neural compression;

age between 18 and 60 years;

unsuccessful conservative therapy of at least 6 months duration.

Contraindications are determined as follows:

DH with neural compression, spondylolisthesis and spondylolysis,

central or lateral recess stenosis,

facet joint degeneration,

scoliosis and

osteopenia.

There are about 50 other contraindications according to the work of Wong et al. [11].

However, the current literature presents only a few studies dealing with the prevalence of indications and contraindications for TDR.

This suggests the need for randomized controlled trials (RCTs) comparing the fusion techniques or posterior techniques with motion preserving procedures, but their implementation remains difficult because of its various limitations [6, 12–14].

In the history of TDR development, many biomechanical concepts were brought up and drawbacks were seen [15, 16]. One widely noticed article raising concerns [17] led the Swiss Federal Office of Public Health to temporarily link the reimbursement of TDR to mandatory participation in a HTA registry. Following the governmental request for close monitoring of all TDR procedures, a nationwide registry was implemented according to the principle of "coverage with evidence development" [18, 19].

As a nationwide data collection project, the SWISSspine registry opened opportunities for investigations with a potentially high external validity. Amongst the most interesting topics were the indications and contraindications for lumbar TDR. In the framework of the registry and in the day-to-day routine clinical practice it was left to the surgeon's discretion to operate on patients with leg pain or radiculopathy. Taking into account the potentially wide range of cases and symptoms we hypothesized that preoperative presence or absence of leg pain or radiculopathy results in different benefits for patients treated with monosegmental lumbar TDR. Therefore, the aim of current study was to compare the outcome of TDA in patients with different levels of radiculopathy, using patient perceived leg pain and its correlation with physician recorded radiculopathy for creating the patient groups to be compared.

Materials and methods

Between March 2005 and April 2009, 577 patients with lumbar TDR were documented. The following implants were used:

ActiveL, Braun/Aesculap, Tuttlingen, Germany;

Dynardi, Zimmer, Warsaw, IN, USA;

Maverick, Medtronic Sofamor Danek, Memphis, TN, USA;

ProDisc II, Spine Solutions/Synthes, Paoli, PA, USA;

SB Charité, DePuy Spine, Raynham, MA, USA.

A total of 416 patients with a mono-segmental intervention and complete datasets were included in this study. 43% were male and 57% female with a mean age of 43.3 years (range 19.5–64.7 years) and 41.2 years (range 18.5–64.6 years), respectively. In total 967 lumbar TDR follow-up records with a follow-up time from 24 days to 4.2 years were completed and stored in the MEMdoc database at the University of Bern. Furthermore, 1,397 EuroQol-5D (EQ-5D) forms, 416 perioperative physician based records, 984 physician documented follow-ups and 1,373 NASS outcome forms were gathered. Mean follow-up time using the latest available patient based assessment during the first year was 8 months (range 33–399 days).

In this study, we compared two patient groups with regard to the presence or absence of leg pain or radiculopathy. Radiculopathy was based on pre-operative examination as indicated by the surgeon on the case report form. Leg pain was independently indicated by the patients using the VAS on the NASS form.

Patient based assessment

Pain was assessed using two separate VAS for back and leg pain, both located on the NASS form. General quality of life was assessed using EQ-5D. In this cost-utility based instrument values range from −0.6 (quality of life worse than death) via 0 (quality of life equals death) to 1 (best possible quality of life).

Statistical analysis

The receiver operating characteristic (ROC) curve based on the univariate logistic regression was used to discriminate the best cut-off leg pain score for distinguishing between the physician diagnosed "radiculopathy" and "no radiculopathy".

Descriptive statistics for patient characteristics were calculated for each group. Comparisons between the groups regarding patient characteristics were performed using chi-square and Wilcoxon rank-sum tests where applicable. Pre- and post-operative values, as well as pre- to post-operative differences of the two groups were compared using general linear modeling. Thereby Bonferroni–Holm adjustments were set to account for multiple testing between the groups. Correction factors of gender, age, medication, and level of the intervention were applied for all the outcome variables.

All statistical analyses were conducted using SAS 9.2 (SAS Institute Inc, Cary, NC) and statistical significance was accepted at the $p < 0.05$ level.

Results

ROC analysis

The analysis resulted in 40 VAS points as the best cut-off value for patients with or without physician diagnosed radiculopathy. Applying this cut-off sensitivity for the presence or absence of leg pain in diagnosing radiculopathy was 73%, the specificity 45%.

Two groups

Based on the cut-off value two study groups were defined. Group 1 consisted of 111 (26.2%) patients with pre-operative leg pain levels below 40. The remaining 313 patients with leg pain above 40 were allocated in group 2.

There were no significant differences between the two groups with respect to mean age, gender distribution, types of work, and work ability or pre-operative medication and distribution of operated levels (Table 1).

VAS back pain

The average pre-operative back pain was 63.6 points in group 1 and 72.6 points in group 2 ($p < 0.001$). Post-operative back pain was 28 points in group 1 and 33.5 points in group 2 ($p = 0.10$). The average back pain alleviation in group 1 was 35.6 points and in group 2 was 39.1 points ($p = 0.27$). 72% of patients reached the minimum clinically relevant pain improvement (MCRPI) of 20 points for back pain in group 1 and 75% in group 2 ($p = 0.55$) (Fig. 1; Table 2).

VAS leg pain

The average pre-operative leg pain was 16.5 points in group 1 and 68.1 points in group 2 ($p < 0.001$). Post-operative leg pain was 12.9 points in group 1 and 27 points in group 2 ($p < 0.001$). The average leg pain alleviation in group 1 was 3.6 points and in group 2 it was 41.1 points ($p < 0.001$) (Fig. 2; Table 2).

Quality of Life (EQ-5D)

The average pre-operative EQ-5D score was 0.44 points in group 1 and 0.29 points in group 2 ($p < 0.001$). The post-operative score was 0.78 points in group 1 and 0.71 points in group 2 ($p = 0.049$). The average EQ-5D score improvement in group 1 was 0.27 points and in group 2 it was 0.41 points ($p = 0.11$). 53% of patients in group 1 reached at least 0.25 points of EQ-5D score improvement and 59% in group 2 (p = 0.26) (Fig. 3).

Discussion

Based on several studies the FDA approved lumbar TDR with some exclusion criteria and many authors consider radiculopathy and leg pain as non-favourable preconditions [20]. Others, however, like Zigler et al. [13] described TDR as an option in these patients. In general, indications and contraindications have never been consequently adapted to newer results and a worldwide uncertainty still remains.

With data based on widely used and validated outcome instruments (EQ-5D, NASS–VAS) and on information recorded by the surgeons pre- and post-operatively we can

Table 1 Patient characteristics at baseline

	Group 1 $n = 110$ (leg pain <40 VAS)	Group 2 $n = 313$ (leg pain ≥40 VAS)	Group comparison (p value)
Mean age (years)	41.3	42.5	NS
Age range (years)	21–64	19–65	NS
Females (%)	61.8	58.2	NS
Occupat. sedentary work (%)	31.6	27	NS
Occupat. physical work (%)	57.9	51.4	
Occupat. housewife (%)	9.5	15.2	
Occupat. retired (%)	–	2	
Occupat. unemployed (%)	1	4.4	
Ability to work 90–100% (%)	65	52.4	NS
Ability to work 50–90% (%)	11.2	16.6	
Ability to work 0-50% (%)	7.5	6.1	
Unable to work (%)	16.3	24.9	
No pre-operative medication (%)	3.6	2.2	NS
Pre-operative NSAIDs (%)	88.2	81.5	NS
Pre-operative opioids (%)	35.5	37.4	NS
L2/3 (%)	1	0.7	NS
L3/4 (%)	7.8	4.3	
L4/5 (%)	42.7	44.6	
L5/S1 (%)	48.5	50.4	

NS not significant

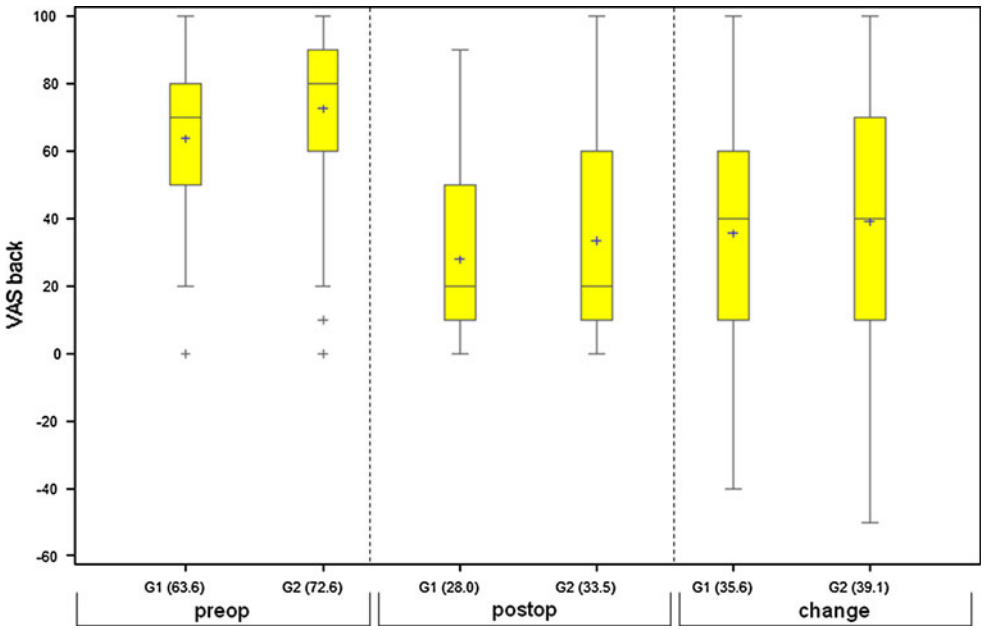

Fig. 1 Pre- and post-operative back pain levels and pre- to post-operative back pain alleviation of the two groups of patients

draw an image of the impact of TDR-surgery on patient's quality of life.

This study hypothesized that there are differences in outcome between the two patient groups defined by the presence or absence of radiculopathy and the extent of leg pain.

We found no differences in back pain relief and, similarly, post-operative leg pain levels were not significantly different either. Relative leg pain relief, however, differed between the two groups. The fact that patients with different pre-operative leg pain levels had similarly low

Table 2 Outcomes

Outcome	Group 1 ($n = 111$)			Group 2 ($n = 313$)		
	Pre-operative	Post-operative	Change	Pre-operative	Post-operative	Change
VAS back	63.6	28	35.6	72.6	33.5	39.1
VAS leg	16.5	12.9	3.6	68.1	27	41.1
EQ-5D	0.440	0.776	0.335	0.290	0.706	0.419

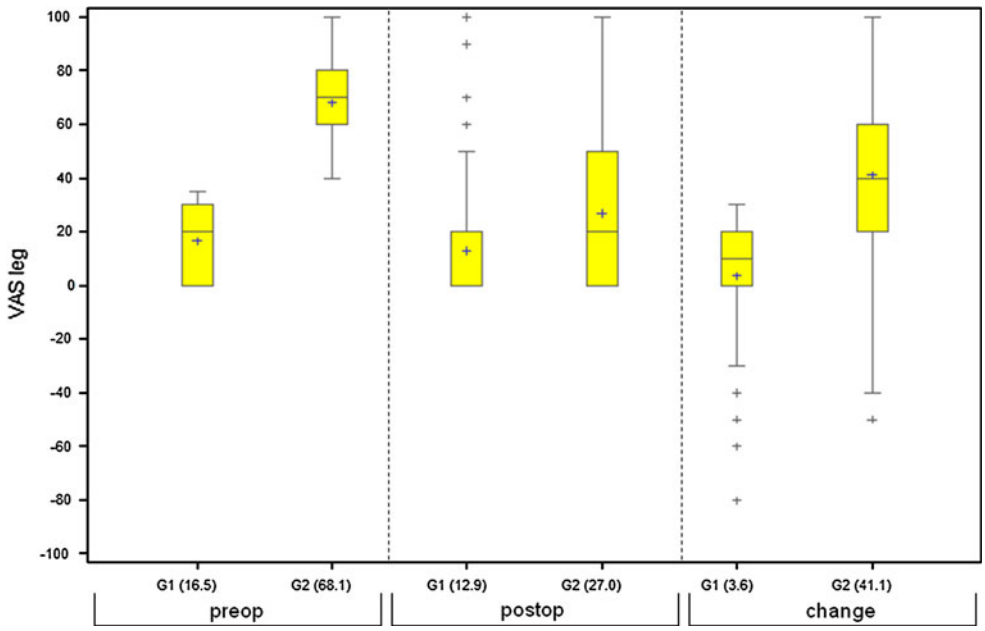

Fig. 2 Pre- and post-operative leg pain levels and pre- to post-operative leg pain alleviation of the two groups of patients

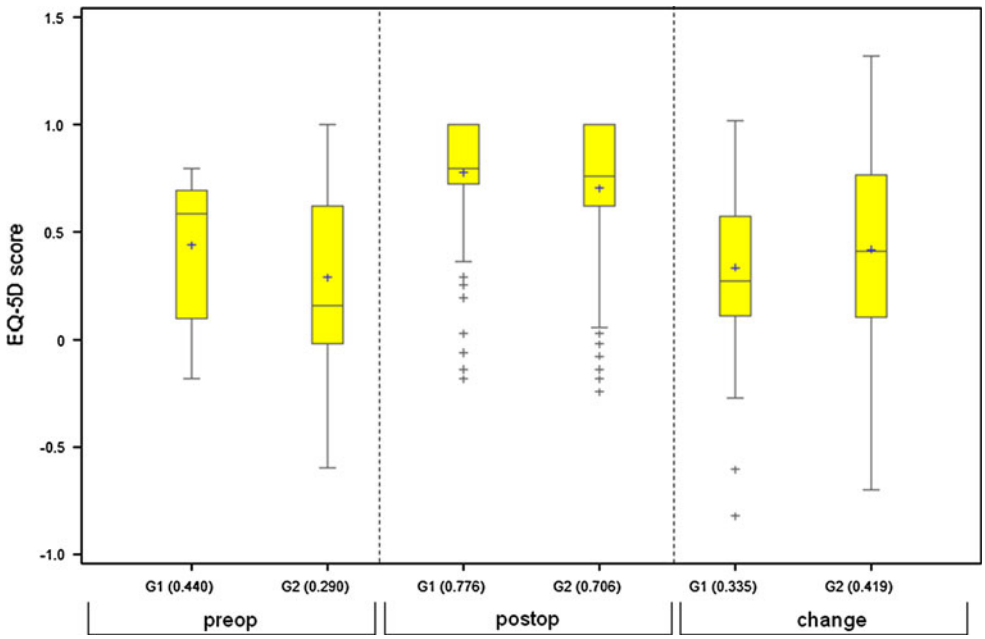

Fig. 3 Pre- and post-operative quality of life (EQ-5D) and pre- to post-operative quality of life improvement of the two groups of patients

post-operative pain levels shows that those with higher pre-operative leg pain had a higher benefit from the procedure. These findings challenge some of the previous limitations for TDR.

Leg pain and its relief have an obviously large impact on the patient's quality of life. Despite significantly different pre- and also post-operative EQ-5D scores, the absolute score differences between the groups were halfened, from 0.15 EQ-5D score points before to 0.07 points after surgery.

Recent publications focus on TDR as a sound twenty first century approach. Hopes and appraisals but even more polemics can be found [21, 22]. Ross et al. [23] evaluated 226 SB Charité III TDRs in 160 patients concluding that "These poor results indicate that the further use of this implant is not justified". In contrast, Mayer et al. and Siepe et al. [24] described the good results for the ProDisc II by even applying less invasive approaches. Since the alarming results of the Acroflex-Disc study [25] and the ongoing US court cases concerning the SB Charité [26], the Swiss health care authorities were reluctant to accept TDR as a safe and efficacious therapy. Therefore, a nationwide registry was mandated to closely monitor TDR in the less controlled clinical settings [19, 27]. Mirza [28] commented on important issues like polyethylene wear, loosening, as well as infection, and concluded that the hopes for a cure of back pain and a marketing bonanza must be held in check by the principles of fairness and responsibility and by long-term results.

Published reports like that of Chin et al. [10] suggested that 95% of patients undergoing lumbar spinal surgery had at least one contraindication for TDR. These conclusions do, however, depend upon the definitions of indications and contraindications of lumbar TDR.

According to the current literature patients having pathomorphological changes, such as DH or recess stenosis with consequent leg pain should not undergo lumbar TDR. Hence, patients presented in this study as group 2 are not accepted as ideal candidates to date [13].

Indications and contraindications will continue to evolve with the improved understanding of this procedure. Changing them might allow conceivably more patients or better selected patients to be considered for lumbar TDR [29]. Is this desirable? For sure, the optimized indication has highest priority for long-term outcomes of the procedure. The immediate perceived success obtained with the BAK cage for symptomatic DDD created an environment in which the indications were loosely modified and sub-optimal surgical candidates were stabilized with accordingly poorer results.

SWISSspine is a prospective observational study of a large cohort of TDR recipients. Using the latest available follow-up record of each patient in the first year we found no outcome differences between the patients with and without leg pain or radiculopathy. Although German and Foley [30] compared the literature concerning both TDR and stand-alone ALIF trying to identify the parallels, they concluded that the given obstacles are difficult to overcome.

To date ALIF seems to be the only comparator for TDR but it is a weak one, especially regarding to biomechanics. The hurdles to overcome when creating and running RCTs comparing TDR to ALIF are high, but it was done by Geisler, Guyer, Blumenthal or McAfee [12, 13, 31]. Their results showed a similar patient satisfaction and a slight superiority for TDR in several socio-economic areas such as work status and duration of hospitalization.

Our study has several limitations. The follow-up time is rather short when compared to other studies [7, 24] and it is based on registry data. Therefore, the limitations have to be considered in the analysis and interpretation of such data. Invalid conclusions can result when insufficient attention is paid to issues such as missing data, sources of bias and data quality. The interpretation of the symptom "radiculopathy" is widespread and examiners' subjectivity has influence on that variable. SWISSspine the surgeon determines if a radiculopathy is present or not and in some cases a false radiculopathy with pain above the knees may have been labelled as a true one, which is defined as pain that follows a dermatomal pattern radiating below the knee and into the foot and/or toes [32, 33]. In the current study, however, both the groups are comprised of more than 90% L4/L5 and L5/S1 pathologies. Clinical experience tells us that radicular pain caused by these nerve roots is less prone to misinterpretation.

In addition, a previous analysis revealed a very stable course of post-operative back pain and even an ongoing further improvement of leg pain until 400 days after surgery [19].

In the literature there is little information on this issue but we have to be aware that in high percentages of patients there is a clear and substantial reason for leg pain.

On the other hand, data collection in SWISSspine is multicentric and due to its setting the registry reaches a very high level of representativeness, i.e. external validity since the likelihood of a systematic selection bias of patients is low.

Conclusion

Our study revealed a relatively higher benefit from lumbar TDR procedures in patients that actually carry widely accepted relative contraindications like leg pain. Despite leg pain or pre-operative radiculopathy short-term outcomes were similar to patients without these pathologies.

Consequently, the current agreements on indications and contraindications for lumbar TDA are challenged and our findings should be confirmed in trials with higher evidence levels.

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Conflict of interest None.

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