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Stand-alone ALIF versus TLIF in patients with low back pain – A propensity-matched cohort study with two-year follow-up

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A R T I C L E I N F O

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A B S T R A C T

Introduction: Instrumented lumbar fusion by either the anterior or transforaminal approach has different advantages and disadvantages. Few studies have compared PatientReported Outcomes Measures (PROMs) between stand-alone anterior lumbar interbody fusion (SA-ALIF) and transforaminal lumbar interbody fusion (TLIF).

Research question: This is a register-based dual-center study on patients with severe disc degeneration (DD) and low back pain (LBP) undergoing single-level SA-ALIF or TLIF. Comparing PROMs, including disability, quality of life, back- and leg-pain and patient satisfaction two years after SA-ALIF or TLIF, respectively.

Material and methods: Data were collected preoperatively and at one and two-year follow-up. The primary outcome was Oswestry Disability Index (ODI). The secondary outcomes were patient satisfaction, walking ability, visual analog scale (VAS) scores for back and leg pain, and quality of life (QoL) measured by the European Quality of Life-5 Dimensions (EQ-5D) index score. To reduce baseline differences between groups, propensity-score matching was employed in a 1:1 fashion.

Results: 92 patients were matched, 46 S A-ALIF and 46 TLIF. They were comparable preoperatively, with no significant difference in demographic data or PROMs ($P > 0.10$). Both groups obtained statistically significant improvement in the ODI, QoL and VAS-score ($P < 0.01$), but no significant difference was observed ($P = 0.14$). No statistically significant differences in EQ-5D index scores ($P = 0.25$), VAS score for leg pain ($P = 0.88$) and back pain ($P = 0.37$) at two years follow-up.

Conclusion: Significant improvements in ODI, VAS-scores for back and leg pain, and EQ-5D index score were registered after two-year follow-up with both SA-ALIF and TLIF. No significant differences in improvement.

1. Introduction

Back pain is a leading cause of disability globally (Hoy et al., 2012; Wu et al., 2020). In patients with debilitating low back pain (LBP), spine surgery with instrumented lumbar fusion aims to reduce segmental instability and pain. A posterior approach and transforaminal lumbar interbody fusion (TLIF) or an anterior approach by stand-alone anterior lumbar interbody fusion (SA-ALIF) is commonly performed, but the optimal surgical technique remains controversial. Both surgical procedures aim to obtain fusion, decompress neurological structures and restore optimal anatomical alignment (Goyal et al., 2009; Hackenberg et al., 2005). Surgically this is obtained by removing the disc and exposing the adjacent endplates, followed by inserting an interbody implant to facilitate interbody arthrodesis.

A TLIF technique comprises a posterior approach with complete unilateral facetectomy, discectomy, and endplate preparation allowing for the insertion of a cage (Mobbs et al., 2015; Spiker et al., 2019). The technique can be associated with postoperative lower back pain due to extensive muscle dissection and retraction and the risk of damaging the nearby nerve root when inserting the TLIF (Reisener et al., 2020).

The anterior approach to the spine used in SA-ALIF grants access to the entire disc, making a nearly complete discectomy possible. This allows inserting a larger cage with improved restoration of the local disc angle, lumbar lordosis (Hsieh et al., 2007; Lightsey et al., 2022) and improved sagittal balance compared to TLIF (Mobbs et al., 2015). SA-ALIF is also possibly advantageous in terms of muscle and nerve root damage, less perioperative blood loss, reduced surgical time, and shorter length of stay (Strube et al., 2012; Szadkowski et al., 2020). On the other

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hand, the risks of an anterior approach include serious visceral and vascular injuries (Szadkowski et al., 2020; Mobbs et al., 2013), damage to the sympathetic plexus, and retrograde ejaculation (Christensen et al., 1997; Wood et al., 2010; Kain et al., 1993; Phan et al., 2017). Another potential complication is post-operative subsidence and subsequent loss of disc height. However, subsidence rates following SA-ALIF, are generally very low and turn out not to impact clinical outcomes or fusion significantly (Rao et al., 2017).

Only a few studies offer insight in terms of differences in long-term patient-reported outcome measures (PROMs), which we consider critical for patient counseling (Bassani et al., 2020; Kuang et al., 2017; Adogwa et al., 2016). Specifically, for the L5/S1 level, there is only one single surgeon experience utilizing a mini-open ALIF approach (Bassani et al., 2020).

The aim of our study is to compare two-year follow-up with PROMs in a cohort of patients who underwent single-level lumbar fusion at L5-S1 with either SA-ALIF or TLIF.

2. Materials and methods

Data from the Danish national surgical spine database DaneSpine (Danespine) were extracted for this dual-center register-based study. Pre- and postoperative questionnaires, surgical data, and baseline demographics were retrieved.

Adult patients (age>18) who had undergone one-level SA-ALIF or TLIF at L5-S1 between January 1st' 2010 and December 31st' 2018 at the Spine Center of Southern Denmark or Zealand University Hospital were included. Exclusion criteria were incomplete ODI-scores pre-operatively or at two-year follow-up.

Baseline data included patient age, sex, body mass index (BMI), smoking status, use of analgesics, duration of symptoms, and previous spine surgery. The primary outcome was the Oswestry Disability Index (ODI), which ranges from 0 (no disability) to 100 (maximal disability) (Comins et al., 2020; Fairbank et al., 2000), and an improvement of at least 12.8 points was considered to be the minimal clinically important difference (MCID) (Copay et al., 2008). The secondary outcomes were patient satisfaction, walking ability, visual analog scale (VAS) scores for back and leg pain (Briggs et al., 1999), Euro-Qol-5D (EQ-5D) ranging from −0.596 to 1, with higher scores indicating better quality of life (Brooks, 1996; Dolan, 1997).

2.1. Statistical analysis

Data analysis was performed in R version 4.2.1. TLIF cases were matched to SA-ALIF cases using closest neighbor propensity-score matching on age, sex, smoking status, body mass index (BMI), baseline ODI, VAS, and EQ5D scores. Categorical data are presented with frequencies (%) and compared using the Pearson Chi test. Continuous data are reported as a mean ± standard deviation (SD). Pre- and postoperative continuous data differences are compared using paired *t*-test with Welch correction, whereas differences between groups are compared using unpaired tests. The significance level was set at 0.05.

3. Results

317 patients with single-level SA-ALIF (132) or TLIF (185) at L5/S1 were identified. Baseline data and two-year follow-up were available for 143 patients. Finally, 92 patients (46 S A-ALIF and 46 TLIF) were propensity matched. Baseline data were comparable. Only previous spine surgery was more frequent in the TLIF group (Table 1).

Both groups showed statistically significant improvement in ODI at two years −15 (95%CI -20; −10) for SA-ALIF and −10 (95%CI -16; −5) for TLIF groups, respectively. We found lower ODI scores for SA-ALIF, but no significant difference between the groups after two years −6 (95%CI -15; 2, p = 0.14) (Fig. 1). In addition, we observed no significant group differences in EQ-5D scores or VAS scores for leg or back pain.

Table 1
Baseline demographics.

	SA-ALIF (n = 46)	TLIF (n = 46)
Age, year, Mean (SD)	46 (12)	42 (9)
Females, N (%)	27 (59%)	25 (54%)
BMI, kg/m^2, Mean (SD)	26 (4)	26 (4)
Smoker, N (%)	11 (24%)	12 (26%)
History of spine surgery, N (%)		
Yes	14 (30%)	22 (48%)
Unknown	1	0
Duration of back pain, N (%)		
>24 months	30 (65%)	30 (65%)
12–24 months	8 (17%)	10 (22%)
3–12 months	7 (15%)	5 (11%)
<3 months	1 (2%)	1 (2%)
Duration of leg pain, N (%)		
>24 months	20 (43%)	20 (44%)
12–24 months	10 (22%)	16 (35%)
3–12 months	9 (20%)	6 (13%)
<3 months	2 (4%)	2 (4%)
No	5 (11%)	2 (4%)
Use of analgesics, N (%)		
Yes	42 (91%)	43 (94%)
Unknown	1	0
Frequency of analgesics, N (%)		
Regularly	31 (74%)	29 (67%)
Sometimes	11 (26%)	14 (33%)
≤unknown	4	3
Walking distance, N (%)		
<100 m	10 (22%)	12 (26%)
100–500 m	16 (35%)	10 (22%)
0.5–1 km	5 (11%)	12 (26%)
>1 km	15 (33%)	12 (26%)

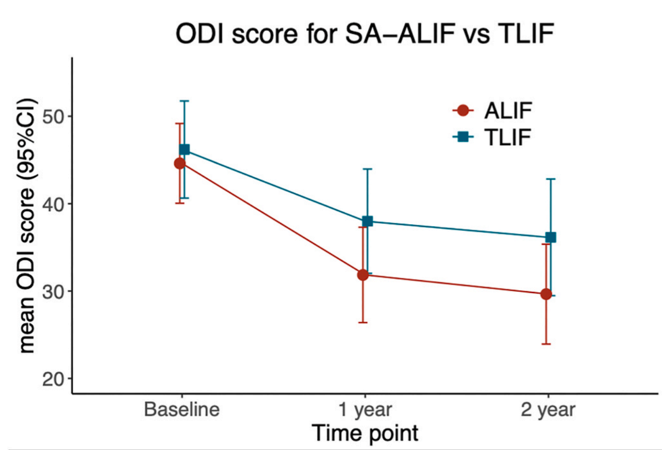

Fig. 1. The mean Oswestry disability index (ODI) score with 95%CI of Stand-alone Anterior lumbar interbody fusion (SA-ALIF) vs Transforaminal lumbar interbody fusion (TLIF) in Baseline, 1 year, and 2 years. Both groups showed statistically significant improvement in ODI at one and two years, but no significant difference between them was observed.

PROMs are presented in Table 2.

Although previous spine surgery status was associated with a worse preoperative ODI score of 52 vs. 41, p < 0.01, we found no significant association with ODI change or two-year follow-up scores (p = 0.13 and p = 0.23, respectively).

Patient satisfaction at two-year follow-up was also not significantly different, with 26 satisfied patients (58%) in the SA-ALIF group and 22 patients (49%) in the TLIF group. 8 patients (18%) and 12 patients (27%), respectively, were dissatisfied and 11 patients (24%) in each group were undecided. The rate of satisfied patients corresponded to the proportion of patients exceeding MCID for ODI, with 59% in the SA-ALIF and 48% in the TLIF group. For back pain, 72% of SA-ALIF and 67% of TLIF patients reported at least some improvement at two years, whereas

Table 2
Patient reported outcome measures at two years.

	SA-ALIF			TLIF				
	Baseline	2 years	Change	Base-line	2 years	Change	Difference at 2 years	P-value
ODI index (0–100)	45 (15)	30 (19)	−15 (−20;-10)	46 (19)	36 (23)	−10 (−16;-5)	−6 (−15; 2)	0.14
EQ5D index (up to 1)	0.48 (0.20)	0.65 (0.30)	0.17 (0.09; 0.25)	0.42 (0.30)	0.59 (0.26)	0.17 (0.08; 0.26)	0.05 (−0.04; 0.17)	0.25
VAS LP (0–100)	55 (30)	40 (31)	−15 (−25;-5)	58 (28)	39 (33)	−18 (−28;-8)	2 (−12; 14)	0.88
VAS BP (0–100)	66 (19)	45 (31)	−22 (−31;-12)	65 (23)	50 (28)	−16 (−25;-6)	−6 (−18; 7)	0.37

*Data are means (SD) or (95%CI).
*higher ODI index and VAS scores indicate more disability and pain.
*lower EQ5D index indicates lower Health Related Quality of Life.
*difference test using *t*-test with Welch correction for unequal variance.

53% and 64% reported at least some improvement for leg pain, respectively. Functional outcomes other than PROMs are presented in Table 3.

4. Discussion

From our propensity-matched analyses, we found statistically significant improvement in ODI, EQ-5D, and VAS back and leg pain at two years. Although they favored SA-ALIF, the differences were relatively small and statistically non-significant. Two-thirds of the patients in each group reported at least some improvement in back pain and about half reached an improvement in ODI exceeding MCID of 12.8 points.

These results indicate no superiority of either technique concerning functional outcomes after two years. This is in line with the few previous studies reporting ODI outcomes for TLIF vs. SA-ALIF (Bassani et al., 2020; Kuang et al., 2017; Adogwa et al., 2016; Rathbone et al., 2023). However, two of these report considerably larger ODI improvements in both groups: From 50 to 25 for SA-ALIF and 52 to 24 for TLIF (Kuang et al., 2017) and 65 to 15 and 78 to 21, respectively (Bassani et al., 2020). Their study design differs considerably from the present since they are both single surgeon retrospective reports and their cohorts are more selective, with the exclusion of patients with BMI >28 or 30, previous surgery (Kuang et al., 2017) and diabetes (Bassani et al., 2020). The results are thus less generalizable. The multi-institutional register study by Adogwa et al. (2016) is more comparable, although previous spine surgery was exclusion criteria and surgery was not exclusively at the L5/S1 level. They found a decrease in ODI scores much comparable to our results, with 47 to 32 in both groups. Despite these comparable scores, they report that 70% and 79% of patients, respectively, improve to a level that meets the patients' expectations at one year. Our study marked a difference between 58% and 49%, respectively, highlighting the importance of managing patients' expectations and that the difference in the wording of the follow-up questions can impact the results.

The strength of the current study is the registry-based propensity-matched cohort that allows us to identify substantial PROM-data with two-year follow-up from patients undergoing fusion at the L5/S1 level specifically. Although, as a register-based study, there is an inherent risk of selection bias regarding which patients are registered and who are willing or able to respond to questionnaires. Here complete data were available for 45% of eligible patients. However, this was not related to surgical procedure, as completion was 42% in the SA-ALIF vs. 48% in the TLIF group, $p = 0.30$.

For statistically non-significant results, type-2 errors must be considered. In our case, we compared groups of 46 patients, which was insufficient to show the statistical significance of a mean difference in ODI at two-year follow-up of 6 points. However, since 6 points are less than half the specified MCID for the ODI, we consider the difference not clinically important.

Furthermore, observational studies have an increased risk of residual confounding compared to randomized trials. Propensity score matching, utilized in this study, is an attempt to reduce confounding by mimicking randomization, but it is not a perfect tool. A profound disadvantage is that it is only possible to match potential confounders, which are accounted for. We matched on important potential confounders previously shown to be associated with outcomes after spine surgery, i.e. age, sex, smoking status, BMI, as well as baseline ODI, VAS, and EQ5D scores (Fairbank et al., 2000; Briggs et al., 1999; Brooks, 1996). Despite this matching, 18% more patients in the TLIF group had undergone previous spine surgery compared to the ALIF group, but we found no indication of confounding from previous surgery status with regard to ODI change or follow-up scores ($p > 0.10$).

It is important to note the clinical symptoms before surgery. LBP with radiculopathy and MRI-verified spinal stenosis were undoubtedly significant factors influencing the decision to proceed with surgery. Our results indicate that patients, who are considered candidates for either technique by the treating surgeons, could have similar long-term functional outcomes independent of the chosen approach. However, since we were unable to account for the reasoning behind each surgeon's choice of approach for each specific patient, this could have led to an unrecognized difference in prognosis between the groups called confounding by indication. Thus, we encourage confirmation from randomized controlled trials.

Table 3
Functional outcomes at two-years.

	SA-ALIF (n = 46)	TLIF (n = 46)	P-value
Self-reported walking distance			
<100 m	2 (4%)	7 (15%)	
100–500 m	11 (24%)	6 (13%)	
0,5-1 km	2 (4%)	6 (13%)	
>1 km	30 (67%)	27 (59%)	0.09
Self-reported leg pain			
no pain before	2 (4%)	2 (4%)	
complete relief	7 (15%)	7 (16%)	
much better	13 (28%)	11 (24%)	
somewhat better	11 (24%)	11 (24%)	
no change	8 (17%)	7 (16%)	
Worse	5 (11%)	7 (16%)	0.99
Self-reported back pain			
no pain before	1 (2%)	0 (0%)	
complete relief	4 (9%)	1 (2%)	
much better	13 (28%)	12 (26%)	
somewhat better	16 (35%)	18 (39%)	
no change	7 (15%)	8 (17%)	
Worse	5 (11%)	7 (15%)	0.65
Treatment satisfaction			
Satisfied	26 (58%)	22 (49%)	
in doubt	11 (24%)	11 (24%)	
Dissatisfied	8 (18%)	12 (27%)	0.57

*Data are numbers (%).
SA-ALIF indicates Stand Alone Anterior lumbar interbody fusion; TLIF, transforaminal lumbar interbody fusion.

5. Conclusion

In this dual-center propensity score-matched registry-based study on prospectively collected data, we found significant improvement in ODI, EQ5D and VAS for back and leg pain at two-year follow-up for SA-ALIF and TLIF at L5/S1 with no significant differences between the groups. It is, however, important to inform patients of possible suboptimal outcomes that may be associated with each of the two types of surgery.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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