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Int J Spine Surg 2023, 17 (5) 708-714
doi: https://doi.org/10.14444/8535
https://www.ijssurgery.com/content/17/5/708

The International Journal of Spine Surgery
2397 Waterbury Circle, Suite 1,
Aurora, IL 60504, Phone: +1-630-375-1432

International Journal of Spine Surgery, Vol. 17, No. 5, 2023, pp. 708–714
https://doi.org/10.14444/8535

Do Diabetic Patients Have Poorer Clinical and Radiological Outcomes Following Minimally Invasive Transforaminal Lumbar Interbody Fusion?

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ABSTRACT

Background: The number of patients with diabetes mellitus (DM) seeking treatment for degenerative spondylolisthesis is expected to increase. However, there is a paucity of studies examining the patient-reported outcomes (PROs) and subjective measures in patients with DM following minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF). The present study aimed to compare PROs, satisfaction, and radiological fusion between DM and non-DM patients following MIS-TLIF.

Methods: The authors identified 30 patients with DM who underwent primary, single-level MIS-TLIF for degenerative spondylolisthesis from a spine registry. Each patient was matched 1:1 with 30 controls without DM using propensity scores to adjust for age, sex, body mass index, American Society of Anesthesiologists class, and baseline PROs. Visual analog scale leg pain, back pain, Oswestry Disability Index (ODI), SF-36 physical component score and mental component scores were compared at 1, 3, 6, and 24 months. Patients also completed a satisfaction questionnaire during these visits. Radiographic fusion was analyzed according to Bridwell grades.

Results: There was no difference in PROs between non-DM and DM patients at 2 years. However, a higher proportion of non-DM patients attained minimal clinically important difference for ODI (90.0% vs 66.7% $P = 0.028$) and SF-36 physical component score (90.0% vs 53.3% $P = 0.002$) at 3 months and ODI (96.7% vs 80.0%) at 6 months. A similar proportion of patients in each group were satisfied and had expectations fulfilled. A higher proportion of non-DM patients attained a grade 1 or 2 fusion (93.3%), as compared with DM patients (80.0%), although this did not reach statistical significance ($P = 0.129$).

Conclusions: DM patients have poorer initial PROs, which reach comparable levels to those in non-DM patients in the longer-term. Fusion rates of DM patients were poorer compared with non-DM patients.

Level of Evidence: 3.

Lumbar Spine

Keywords: diabetes, lumbar fusion, minimally invasive, transforaminal lumbar interbody fusion, fusion rates, outcomes, satisfaction, quality of life

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease that arises due to insufficient insulin production or decreased sensitivity of cells to insulin.[1] By the year 2030, the global prevalence of DM is expected to increase from to 439 million from 285 million in 2010.[2] Age is one of the main risk factors for DM.[3] Consequently, surgeons will encounter an increase in DM patients with degenerative conditions of the lumbar spine as the population ages.

DM patients incur higher costs of medical care[4] and have increased morbidity[5] following orthopedic procedures. Many studies have also concluded that DM is an independent risk factor for poor clinical outcomes as well as postoperative complications such as infection, prolonged hospitalization, and longer hospital stay after spine surgery.[6–8] Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) is a well-established modality for treating symptomatic degenerative lumbar spine diseases, with clinical outcomes comparable to open TLIF surgery,[9–11] as well as the added benefits of less intraoperative blood loss,[12] shorter hospital stays,[13] and lower complication rates.[14,15] In light of these advantages, it is likely that a higher number of patients with DM may opt to undergo MIS-TLIF in the coming years.

Various studies in the existing literature have reported that DM patients have poorer outcomes following lumbar spinal surgery, which include greater morbidity and lower fusion rates.[16–18] However, despite this, there is a paucity of data examining the patient-reported outcomes (PROs) of DM patients following MIS-TLIF specifically.

The aim of our study was to compare (1) self-reported pain, disability, and quality of life and (2) radiological fusion rates between DM patients and non-DM controls undergoing MIS-TLIF for degenerative spondylolisthesis.

METHODS

Study Design

This study was carried out after obtaining approval from a Centralized Institutional Review Board (CIRB 2018/2356). A retrospective review of prospectively collected data was performed for patients who underwent single-level MIS-TLIF for degenerative spondylolisthesis at an academic center between 2012 and 2014. The indications for surgery were grade 1 or 2 degenerative spondylolisthesis with symptoms of nerve compression such as radicular pain, paresthesia, or neurogenic claudication. A total of 218 patients underwent surgery during the defined time period, 30 of whom had DM.

Surgical Indications and Surgical Technique

Diabetic patients were assessed preoperatively by surgeons and anesthetists in the outpatient setting. Optimization of patients' medical comorbidities, with a HbA1c cut-off of 8.0, was utilized before commencing surgery. Patients were kept fasted and placed earlier on the surgical list, with postoperative glucose monitoring in place. All procedures were performed by the senior authors using a previously described technique, employing a similar preoperative protocol and management of our patients.[19] First, the operative level was confirmed using mobile C-arm x-ray imaging. A surgical incision was then made 3 to 5 cm parallel to the midline on the symptomatic side. Tissue dilators were inserted down to the facet complex. Facetectomy was performed to visualize the posterolateral part of the intervertebral disc, after which discectomy was performed and endplates were prepared. Intradiscal spreaders were used to distract the disc space, and allograft bone was placed anterior and contralateral to the annulotomy together with a polyetheretherketone interbody cage filled with autogenous bone graft. The positioning of the cage was then confirmed using fluoroscopy. To ensure decompression, the remainder of the ipsilateral facet and lamina was resected, and the lateral margin of the ligamentum flavum was removed to expose the ipsilateral exiting and transversing nerve roots. If there was bilateral disease, the patient was tilted and the tubular retractor was angled medially to visualize the contralateral side, followed by over-the-top decompression where indicated. After decompression, a percutaneous pedicle screw and rod were inserted via the same incision, and a second construct was inserted via a contralateral incision. Compression was applied, then the construct was tightened to restore lordosis. Hemostasis and wound irrigation were performed before closure.

Assessment of Clinical Outcomes

Preoperative data, including age, sex, body mass index, duration of procedure, length of stay, American Society of Anesthesiologists class, smoking status, and medical comorbidities, were collected. The operative time and length of stay were also recorded. Preoperative and postoperative clinical outcomes were assessed, including the visual analog scale (VAS) for back pain and leg pain, Oswestry Disability Index (ODI), and Short Form-36 (SF-36). The medical outcome study approach proposed by McHorney and Ware[20] was used to derive the higher-order summary scores for the SF-36, namely the physical component score (SF-36 PCS) and mental component score (SF-36 MCS). Clinical improvement in these scores was defined using the minimal clinically important difference (MCID). Published threshold scores for the ODI (12.8), SF-36 PCS (4.9), VAS back pain (1.2), and VAS leg pain (1.6)[21] were used to determine whether MCID was achieved. These variables were compared at 1 month, 3 months, 6 months, and 2 years postoperatively, together with an assessment of patient satisfaction and expectation fulfillment with the treatment results using the North American Spine Surgery questionnaire.[22]

Assessment of Radiological Outcomes

To compare radiological outcomes between the DM and non-DM patients, fusion rates were assessed according to the grading system described by Bridwell et al at 2 years.[23] Computed tomography was performed to assess contentious cases in greater detail.

Statistical Analysis

A power analysis was conducted with type I error set at 0.05 ($\alpha < 0.05$) and the type II error at 0.20 (80% power). A minimum sample size of 28 patients was required to detect a difference in ODI to met the MCID of 12.8 based on a 2-sided test hypothesis. Propensity-score matching was used to select a non-DM control group of 30 patients with adjustment for potential confounding variables such as age, sex, body mass index, American Society of Anesthesiologists classification,

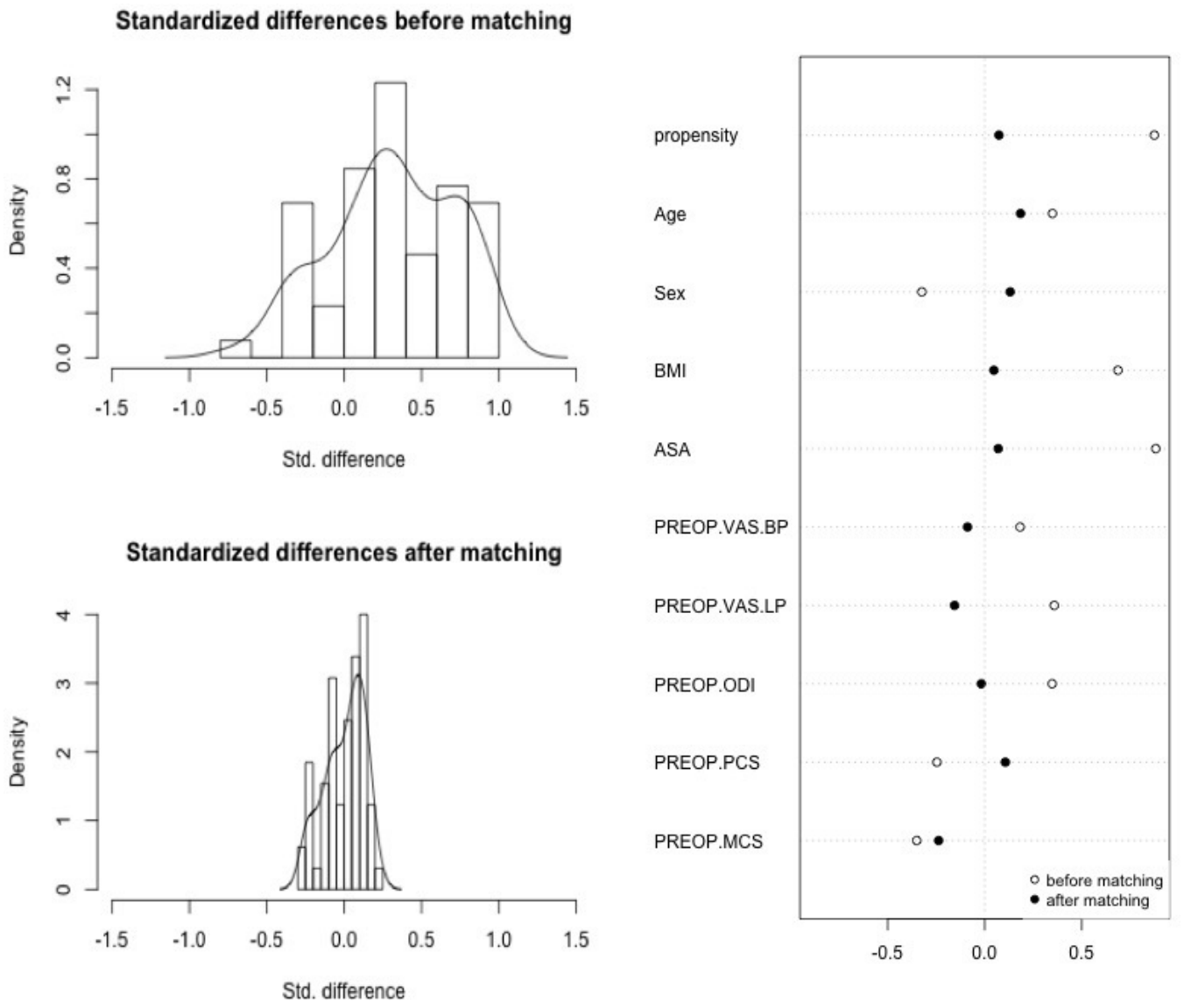

Figure. Absolute standardized difference for each variable before and after propensity-score matching. Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; BP, back pain; MCS, mental component score; ODI, Oswestry Disability Index; PCS, physical component score; LP, leg pain; Std, standard; VAS, visual analog scale.

and baseline clinical scores (VAS back pain, leg pain, ODI, SF-36 PCS, and SF-36 MCS). This enabled us to control for selection bias and maintain covariate balance by matching the DM patients with a subset of non-DM patients. This method has been well described in observational studies.[24] To measure covariate balance in the 2 groups, we computed the standardized difference for each variable before and after propensity-score matching (Figure). Baseline patient characteristics, clinical outcomes, and radiological parameters were compared between the groups using student's *t* test and χ^2 test to compare parametric and proportion-based outcomes, respectively. Statistical analyses were performed using the SPSS software package, version 23.0 (SPSS Inc., Chicago, IL, USA). We defined statistical significance at the 5% level ($P < 0.05$).

RESULTS

The mean age of non-DM patients was 61.7 ± 10.9 years and of DM patients was 63.3 ± 8.6 years. Approximately 43% and 50% of non-DM and DM patients were men, respectively. DM patients had more comorbidities such as hypercholesterolemia ($P = 0.032$; Table 1).

In terms of PROs (Table 2), there was no significant difference in VAS for leg pain or back pain, ODI, SF-36 PCS, or SF-36 MCS between DM and non-DM patients at all time points. However, a higher proportion of patients in

Table 1. Patient demographics and preoperative clinical outcomes.

Characteristics	Nondiabetics (n = 30)	Diabetics (n = 30)	P[a]
Age, y	61.7 ± 10.9	63.3 ± 8.6	0.533
Sex			
Women	17 (56.7%)	15 (50.0%)	0.605
Men	13 (43.3%)	15 (50.0%)	
Body mass index	28.0 ± 4.7	28.2 ± 4.3	0.863
ASA classification	2.3 ± 0.5	2.3 ± 0.5	0.786
Smoking	9 (30.0%)	5 (16.7%)	0.222
Comorbidities			
Hypertension	19 (63.3%)	22 (73.3%)	0.405
Hypercholesterolemia	15 (50.0%)	23 (76.7%)	**0.032**
Ischemic heart disease	3 (10.0%)	7 (23.3%)	0.166
Stroke	1 (3.3%)	0 (0.0%)	0.313
Asthma	1 (3.3%)	3 (10.0%)	0.301
Operative time, min	155.2 ± 44.3	155.3 ± 31.9	0.998
Length of stay, d	4.1 ± 1.9	4.5 ± 3.0	0.658
Preoperative outcomes			
VAS back pain	6.8 ± 2.8	6.5 ± 2.6	0.740
VAS leg pain	7.1 ± 3.0	6.7 ± 3.0	0.552
Oswestry Disability Index	52.9 ± 17.7	52.6 ± 17.9	0.945
SF-36 PCS	28.6 ± 8.2	29.7 ± 9.7	0.658
SF-36 MCS	47.6 ± 11.0	44.8 ± 12.0	0.341

Abbreviations: ASA, American Society of Anesthesiologists; MCS, mental component score; PCS, physical component score; SF-36, Short Form-36; VAS, visual analog scale.
Note: Data presented as n (%) or mean ± SD. **Boldface** values indicate statistical significance ($P < 0.05$).
[a]P value was calculated for each category using χ^2 analysis (categorical) or student's t test (continuous).

Table 2. Comparison of clinical outcomes at different postoperative intervals.

Comparison at 1 Mo	Nondiabetics (n = 30)	Diabetics (n = 30)	P[a]
VAS back pain	1.1 ± 2.3	0.4 ± 1.2	0.142
VAS leg pain	1.2 ± 2.2	0.7 ± 2.0	0.301
ODI	30.4 ± 15.4	31.1 ± 16.6	0.871
SF-36 PCS	28.9 ± 9.7	32.5 ± 12.2	0.211
SF-36 MCS	50.9 ± 11.7	48.6 ± 12.8	0.479
MCID attainment			
SF-36 PCS (4.9)	14 (46.7%)	13 (43.3%)	0.795
ODI (12.8)	19 (63.3%)	18 (60.0%)	0.791
VAS back pain (1.2)	24 (80.0%)	26 (86.7%)	0.488
VAS leg pain (1.6)	24 (80.0%)	25 (83.3%)	0.739
Comparison at 3 Mo	**Nondiabetics (n = 30)**	**Diabetics (n = 30)**	**P[a]**
VAS back pain	0.8 ± 2.4	1.0 ± 2.0	0.686
VAS leg pain	0.5 ± 1.9	1.0 ± 2.4	0.412
ODI	21.0 ± 18.2	23.8 ± 17.0	0.553
SF-36 PCS	44.3 ± 9.7	40.4 ± 11.5	0.168
SF-36 MCS	55.1 ± 8.3	53.9 ± 12.1	0.670
MCID Attainment			
SF-36 PCS (4.9)	27 (90.0%)	16 (53.3%)	**0.002**
ODI (12.8)	27 (90.0%)	20 (66.7%)	**0.028**
VAS back pain (1.2)	25 (83.3%)	24 (80.0%)	0.739
VAS leg pain (1.6)	24 (80.0%)	25 (83.3%)	0.739
Comparison at 6 Mo	**Nondiabetics (n = 30)**	**Diabetics (n = 30)**	**P[a]**
VAS back pain	0.7 ± 1.8	1.1 ± 2.3	0.539
VAS leg pain	0.5 ± 1.4	1.1 ± 2.5	0.282
ODI	13.6 ± 14.5	19.0 ± 15.5	0.169
SF-36 PCS	45.9 ± 9.9	43.3 ± 11.1	0.348
SF-36 MCS	54.9 ± 9.1	52.0 ± 10.2	0.248
MCID attainment			
SF-36 PCS (4.9)	26 (86.7%)	20 (66.7%)	0.067
ODI (12.8)	29 (96.7%)	24 (80.0%)	**0.044**
VAS back pain (1.2)	25 (83.3%)	22 (73.3%)	0.347
VAS leg pain (1.6)	26 (86.7%)	23 (76.7%)	0.317
Comparison at 2 Y	**Nondiabetics (n = 30)**	**Diabetics (n = 30)**	**P[a]**
VAS back pain	1.1 ± 2.5	0.8 ± 1.9	0.650
VAS leg pain	0.4 ± 1.7	0.8 ± 2.2	0.469
ODI	12.2 ± 17.9	15.1 ± 15.3	0.512
SF-36 PCS	45.7 ± 10.5	44.7 ± 10.9	0.704
SF-36 MCS	55.8 ± 10.7	50.5 ± 12.4	0.079
MCID attainment			
SF-36 PCS (4.9)	25 (83.3%)	22 (73.3%)	0.347
ODI (12.8)	29 (96.7%)	25 (83.3%)	0.085
VAS back pain (1.2)	25 (83.3%)	27 (90.0%)	0.448
VAS leg pain (1.6)	25 (83.3%)	25 (83.3%)	1.000

Abbreviations: MCID, minimal clinically important difference; MCS, mental component score; ODI, Oswestry Disability Index; PCS, physical component score; VAS, visual analog scale.
Note: Data presented as n (%) or mean ± SD. **Boldface** values indicate statistical significance ($P < 0.05$).
[a]P value was calculated for each category using χ^2 analysis (categorical) or student's t test (continuous).

the non-DM group compared with the DM group attained MCID for ODI (90.0% vs 66.7%, $P = 0.028$) and SF-36 PCS (90.0% vs 53.3%, $P = 0.002$) at 3 months. Similar findings were observed at 6-month follow-up, wherein a higher proportion of patients in the non-DM group attained MCID for ODI as compared with the DM group (96.7% vs 80.0%, $P = 0.044$). There was also a trend toward a higher proportion of patients in the non-DM group attaining MCID for SF-36 PCS, but this was not statistically significant (86.7% vs 66.7%, $P = 0.067$).

There were no statistically significant differences in patient satisfaction and expectation fulfillment postoperatively. At 2 years, 80.0% of patients were satisfied in the DM group compared with 93.3% in the non-DM group ($P = 0.129$), while 90.0% had expectations fulfilled in the DM group compared with 96.7% in the non-DM group ($P = 0.306$).

In terms of radiological outcomes, there was a higher proportion of non-DM patients who attained a grade 1 or 2 fusion (93.3%) as compared with DM patients (80.0%), but this did not reach statistical significance ($P = 0.129$).

The most common complication postoperatively was chronic low back pain, which was similar between the 2 groups (95% CI 0.270–8.34). There was 1 patient in the DM group who continued having postoperative numbness, and 1 DM patient who had screw loosening and cage collapse postoperatively. There were no cases of postoperative infections.

DISCUSSION

With the incidence of DM expected to rise in the future, MIS-TLIF could be an increasingly popular option for lumbar fusion for these patients due to its potential benefits. Recent studies have shown that DM is an independent risk factor for postoperative complications such as urinary retention, pseudarthrosis,

and altered mental status after MIS-TLIF.[25] However, there is a paucity of studies comparing PROs and radiological fusion between DM patients and non-DM patients.

In this study, a lower proportion of DM patients attained MCID for ODI and SF-36 PCS as compared with non-DM patients at 3 and 6 months postoperatively. Interestingly, this was not seen at the 2-year comparison. It is plausible that DM patients undergoing MIS-TLIF for degenerative spondylolisthesis had poorer initial postoperative outcomes as compared with non-DM patients, but in the long run, their outcomes reach the same endpoint. A study by Armaghani et al[26] also found that DM patients had worse patient-reported outcomes such as SF-12 PCS and ODI as compared with non-DM patients. Similarly, a study carried out by Moazzeni et al[27] showed that DM patients had poorer VAS scores. We postulate that pre-existing impaired wound healing[28] and lower immunity[29] due to the altered physiology in DM patients could result in poorer early postoperative outcomes.

In terms of patient satisfaction and expectation fulfillment, we found that DM did not lead to lower rates among patients undergoing MIS-TLIF. On the contrary, a study by Arinzon et al[30] found that DM patients had lower satisfaction rates as compared with non-DM patients after lumbar decompression surgery. However, unlike the prior study that utilized a generic Likert scale, we used the validated North American Spine Surgery questionnaire to grade patient satisfaction. In addition, this study focused specifically on MIS-TLIF to reduce heterogeneity. As improvement of pain and disability are major determinants of patient satisfaction after spine surgery, this could account for the concordant findings of comparable satisfaction rates and functional outcomes at 2-year follow-up. This was further supported by a study by Licina et al[31] of patients who underwent single-level spine surgery for degenerative lumbar spine conditions. To our knowledge, this is the first study to examine how DM affects patient satisfaction following MIS-TLIF specifically.

This study also found that a higher proportion of non-DM patients achieved a good fusion grade compared with DM patients at 2 years. This finding was shared by other studies in the literature, as Glassman et al[32] reported that DM patients undergoing lumbar fusion also had greater nonunion rates. The pathophysiology of DM may explain these differences, as patients with DM have impaired osteoclast and osteoblast function[33–35] coupled with underlying microangiopathy that could hinder bone graft revascularization, bone formation, and remodeling.[36] As this conclusion did not reach statistical significance, future studies with a larger sample size are needed to investigate this association.

Several limitations must be acknowledged. First, despite having sufficient statistical power for clinical outcome comparison, the relatively small sample size may limit the conclusions that can be drawn from this study. Second, this study was a nonrandomized, comparative study. However, data were prospectively collected according to an established protocol and stored in an institutional spine registry. We also attempted to adjust for potential confounders by performing propensity score matching so as to achieve a degree of homogeneity. Last, due to the small number of patients, we were not able to subcategorize DM patients into insulin-dependent and noninsulin-dependent DM patients or stratify the cohort according to HbA1c levels. A study by Takahashi et al showed that patients who were insulin-dependent with HbA1c levels of >6.5% had poorer surgical outcomes.[37] Larger prospective studies are necessary to address these limitations.

CONCLUSION

In conclusion, while DM patients had poorer clinical improvement in disability and quality of life in the short-term, they were still able to achieve equivalent PROs 2 years after MIS-TLIF. However, these patients may be at risk of lower fusion rates postoperatively. DM patients with degenerative spondylolisthesis should therefore be informed that undergoing surgery can potentially alleviate their pain and improve their clinical status, but their postoperative recovery may be slower compared with their non-DM counterparts.

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Funding: The authors received no financial support for the research, authorship, and/or publication of this article.

Declaration of Conflicting Interests: The authors report no conflicts of interest in this work.

Ethics approval: Centralized institutional review board (IRB) approval (CIRB 2018/2356) was obtained for this study.

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Published 18 October 2023