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*Int J Spine Surg* 2018, 12 (4) 528-532 doi: https://doi.org/10.14444/5064 https://www.ijssurgery.com/content/12/4/528

This information is current as of May 17, 2025.

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SPINE SURGERY

## Comparison of Surgical Outcome Between Diabetic Versus Nondiabetic Patients After Lumbar Fusion

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#### ABSTRACT

**Background:** The prevalence of diabetes mellitus (DM) is increasing worldwide. Thereby, an increasing rate of patients with DM are subjecting to spine surgery. Reviewing the literature, a higher rate of surgery-related complications is reported in DM patients. There is no prospective study comparing the outcomes of lumbar fusion surgery in patients with and without DM. We aimed to investigate whether DM is associated with worse patient-reported outcomes, lower fusion rate, and higher complication rate in subjects undergoing spinal lumbar fusion surgery.

**Methods:** Forty-eight subjects with DM (DM group) and 48 controls (control group) were recruited. Data regarding age, duration of diabetes, comorbidities, fasting blood sugar, HbA1c, insulin dependence, duration of operation and the volume of bleeding, and the number of infused packed cell were recorded for all patients. Pain and functional status of the patients using the visual analogue scale (VAS) and Oswestry Disability Index (ODI) were measured before operation and 2 weeks, 6 months, and 1 year after lumbar spinal fusion surgery. Using lumbar computed tomography scan and anteroposterior and lateral x-ray 1 year after the surgery, fusion was assessed.

**Results:** Fusion rate after 1 year was 78% in the control group and 53% in the DM group (P = .02). Patients with DM had higher VAS scores comparing to controls 1 year after the operation, but the difference was not significant (P = .07). However, comparing the functional status of the subjects, significantly higher ODI scores were found among DM patients comparing to controls (P = .002).

**Conclusion:** Rate of fusion among diabetic patients who undergo lumbar spinal fusion surgery is lower than healthy controls. Spine surgeons should consider this to provide the best possible facilities during the surgery to increase the fusion rate in these patients.

Lumbar Spine

Keywords: lumbar, fusion, diabetes

#### INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease that occurs when the human body produces insufficient insulin or because cells do not respond to the produced insulin.<sup>1</sup> Diabetes mellitus is a significant contributor to morbidity and mortality worldwide.<sup>2</sup> The number of people with DM is increasing due to population growth, aging, urbanization, increasing prevalence of obesity, and physical inactivity. The global prevalence of DM among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014, and it is estimated that, in 2040, 1 in 10 adults will suffer from DM.<sup>3</sup> As the prevalence of degenerative lumbar diseases is also increasing, a higher number of patients with concomitant DM and degenerative lumbar disease

would refer to spine surgeons for lumbar spine decompression and fusion in future.

Previous studies on patients with degenerative lumbar disease have shown lower pain improvement and higher incidence of postoperative complications in patients with DM comparing to non-DM subjects.<sup>4–6</sup> As the possible explanation, irreversible nerve damage due to microvascular changes in DM patients has been reported in the literature.<sup>7,8</sup> Therefore, it is suggested that decompression in DM patients may not have the same effect as in those who are not diabetic.<sup>9</sup> In addition, a higher rate of postoperative complications and substantial morbidity and mortality is reported in DM patients who underwent spine surgery.<sup>10</sup> All these make the spine surgery of DM patients with lumbar degenerative disease challenging. Determining the risk factors for spine surgery complications in DM patients could help with educational purposes and would result in new preventive policies at clinical and surgical guidelines.

To our knowledge, there is no prospective study comparing the outcomes of lumbar fusion surgery in patients with and without DM. The aim of this study was to assess whether the presence of diabetes in patients undergoing lumbar fusion surgery is associated with worse patient-reported outcomes, lower fusion rate, and more complications.

#### MATERIAL AND METHODS

This prospective study was conducted in Shariati Hospital (an academic and educational hospital affiliated with Tehran University of Medical Sciences) between March 2014 and March 2015. Two groups of patients who were candidates for spine instrumentation and fusion were enrolled. Group 1 consisted of patients with diabetes. All patients with a fasting blood glucose screen exceeding 126 mg/dL or with HbA1C higher than 6.5% were considered diabetic, even in the absence of a known history of treated or untreated diabetes (based upon the World Health Organization diagnostic criteria for diabetes), including both insulin-dependent and independent patients.<sup>11</sup> All patients who entered into this group had history of diabetes, and all of them were on medication. Group 2 consisted of patients without diabetes who were age- and sex-matched with Group 1. Inclusion criteria were as follows: the need for spine instrumentation and fusion because of canal stenosis, disc herniation with instability, and degenerative spondylolisthesis. Data regarding age, duration of diabetes, comorbidities, fasting blood sugar (FBS), HbA1c, polyneuropathy, insulin dependence, duration of operation and the amount of bleeding, the number of infused packed cell, and duration of hospitalization were recorded for all patients. All patients with DM underwent electrodiagnostic studies (EMG-NCV).

Decompression and 1-level posterolateral fusion was performed using pedicle screws and a local bone graft. Great care was taken to ensure adequate decortication of the transverse processes and lateral facet surfaces. Bilateral facet fusion was performed in all patients. Local bone was generated from the decompression site lamina. No additional biologic materials were used for spinal fusion. All participants were examined by a neurosurgeon before the surgery, and 2 weeks, 6 months, and 1 year after

Table 1.	Baseline	patient and	operative	characteristics.
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	Diabetic (n = 48)	Nondiabetic (n = 48)	P Value
Age (y)	59.5 ± 8.4	56.1 ± 7.7	.04
Sex			
Male	20 (41.7%)	16 (34%)	.4
Female	28 (58.3%)	32 (66%)	
Duration of operation (h)	$3.8 \pm 0.9$	$3.4 \pm 0.8$	.02
Duration of hospitalization (d)	$5.5 \pm 3.4$	$4.6 \pm 1.7$	.09
Comorbidity			
HTN	27 (56.2%)	10 (20.8%)	.01
IHD	7 (14.5%)	3 (6.2%)	
RA	2 (4%)	1 (2%)	
Hypothyroidism	0	1 (2%)	
Polyneuropathy	29 (60.4%)	ŇA	
Insulin dependent	18 (37.5%)	NA	

Abbreviation: NA, not available.

that, and isometric muscle force of lower extremities were recorded before and 1 year after the surgery. We also asked our patients to fill out a valid and reliable Persian version of the Oswestry Disability Index (ODI)<sup>12</sup> and rate their pain by means of the visual analogue scale (VAS) before the operation, 2 weeks, 6 months, and 1 year postoperation. Lumbar computed tomography scan and lateral and anteroposterior x-ray were obtained 1 year after the surgery to evaluate fusion. Bone fusion was defined as bridging bone remodeling across the transverse processes between the adjacent vertebrae.

All data were analyzed using SPSS software (version 20; SPSS Inc, Chicago, Illinois). Data were presented as mean  $\pm$  SD for continuous or frequencies for categorical variables. Independent sample *t* test was used for comparison of continuous variables. Logistic regression by considering fusion as independent variable and patient group, age, bleeding volume, duration of hospitalization, preoperative ODI, and perioperative VAS as independent variables were done. A *P* value less than .05 was considered as significant.

#### RESULTS

Forty-eight cases in the diabetic group and 48 in the control group were recruited. Basic patient information is presented in Table 1. Among the subjects of the diabetic group, the mean duration of diabetic disease, FBS, and Hb1Ac were  $9.2 \pm 5.8$  years,  $143.7 \pm 19.9$  mg/dL, and  $7.5 \pm 0.7$ , respectively.

After 1-year follow up, fusion rate was 53% in the DM group and 78% in the control group (P = .02). Our data showed no significant relationship between the fusion rate and the FBS level of diabetic

Table 2. Comparison of different VAS and ODI scores between the 2 groups.

	Diabetic	Nondiabetic	P Value
Pre-operation ODI	$67.6 \pm 10.4$	55.1 ± 15.7	<.001
Pre-operation VAS	$7.8 \pm 0.9$	$7.1 \pm 1.1$	.002
ODI 2 wk postoperation	$54.3 \pm 12.9$	$40.8 \pm 13.4$	<.001
VAS 2 wk postoperation	$5.4 \pm 1.5$	$4.4 \pm 1.6$	.003
ODI 6 mo postoperation	$45.5 \pm 13.7$	$34.7 \pm 12.8$	<.001
VAS 6 mo postoperation	$4.2 \pm 1.8$	$3.6 \pm 1.5$	.08
ODI 1 y postoperation	$40.7 \pm 15.4$	$31.5 \pm 12.5$	.002
VAS 1 y postoperation	$3.5 \pm 2$	$2.9 \pm 1.3$	.07
Lumbar fusion	28 (58.3%)	38 (79.1%)	.02
Pre-operation force/5		· · · · ·	
3-4	1 (2.1%)		.2
3	2 (4.2%)		
4	6 (12.5%)		
Intact	39 (81.3%)		
Force of lower limbs at 1 y			
postsurgery			
Improved	4 (8.3%)	3 (6.2%)	.08
Unchanged	41 (85.4%)	44 (91.6%)	
Deteriorated	3 (6.2%)	1 (2%)	

Abbreviations: ODI, Oswestry Disability Index; VAS, visual analogue scale.

patients who underwent fusion surgery (142.5  $\pm$  19.5 versus 145.3  $\pm$  20.9, P = .6).

Comparing the outcome measurements of the study, we found that, except VAS scores at 6 months and 1 year after surgery, all other scores were significantly different between the 2 groups. Patients in the DM group had higher ODI scores comparing to controls (Table 2). Complications were not significantly different between the 2 groups (Table 3). Bleeding was significantly higher in the diabetic group. After 1 year of follow up, ODI and VAS were not significantly different postoperation between diabetic patients with or without polyneuropathy (P = .1 and .1, respectively). As it is shown in Table 4 of the study, there was no difference between the ODI and VAS of DM patients with or without dependency to insulin, after 1-year follow up. Table 5 shows the complication rate of insulindependent and nondependent patients who underwent surgery.

 Table 3.
 Comparison of complications between diabetic and nondiabetic patients.

	Diabetic	Nondiabetic	P Value
Bleeding (mL)	556.2 ± 255	428.1 ± 182.7	.006
Infused packed cell	$1.1 \pm 0.4$	$1 \pm 0.2$	.6
Root damage	0	2 (4%)	.5
Cerebral vascular accident	1 (2%)	0	
Pelvic pain	0	1 (2%)	
Decrease of isometric motor force	1 (2%)	0	
Need for reoperation	1 (2%)	0	
Wound infection	7 (14.5%)	5 (10.4%)	
Dural tear	4 (8%)	3 (6.2%)	
Postoperation hematoma	0	1 (2%)	
Thromboembolism	0	1 (2%)	

Table 4. Comparison between insulin-dependent and nondependent groups.

	Insulin Dependent (N = 18)	Insulin Independent (N = 30)	P Value
FBS	149.2 ± 16	$140.3 \pm 21.5$	.1
HbA1C	$7.9 \pm 0.8$	$7.3 \pm 0.6$	.006
Duration of hospitalization	$6 \pm 2.6$	$5.3 \pm 3.8$	.4
Pre-operation ODI	$72.1 \pm 8.7$	$65 \pm 10.5$	.02
Pre-operation VAS	$8.1 \pm 0.9$	$7.6 \pm 0.9$	.1
ODI 2 wk postoperation	$58.6 \pm 12.1$	$51.8 \pm 12.9$	.07
VAS 2 wk postoperation	$5.8 \pm 1.5$	$5.1 \pm 1.5$	.1
ODI 6 mo postoperation	$50.8 \pm 12.3$	$42.3 \pm 13.6$	.03
VAS 6 mo postoperation	$4.8 \pm 1.6$	$3.9 \pm 1.8$	.06
ODI 1 yr postoperation	$45 \pm 14.1$	$38.1 \pm 15.8$	.1
VAS 1 yr postoperation	$3.9 \pm 1.8$	$3.3 \pm 2$	.3
Lumbar fusion	10 (55.5%)	18 (60%)	.7

Abbreviations: FBS, fasting blood sugar; ODI, Oswestry Disability Index; VAS, visual analogue scale.

#### DISCUSSION

According to this study, the fusion rate was significantly higher in nondiabetic cases than in diabetic ones (79 versus 58%, P = .02). Oswestry Disability Index scores were also significantly higher in diabetic patients; however, it was only different in the pre-operation period and 6 months after the operation. In agreement with our results, Guzman et al reported the fusion rates in controlled diabetics, noncontrolled diabetics, and nondiabetic patients as 55, 47, and 54%, respectively.<sup>13</sup> They also found a significantly greater rate of fusion revisions in uncontrolled diabetic cases than in controlled diabetics or nondiabetics.<sup>13</sup> In another study. Glassman et al evaluated 94 diabetics (51 noninsulin-dependent, and 43 insulin-dependent patients) with 43 controls who were matched for demographic characteristics. Nonunion rates were higher in insulin-dependent diabetes (26%) than in noninsulin-dependent diabetes (22%) and controls (5%).<sup>14</sup> Also, Armaghani et al compared 434 diabetics and 571 nondiabetics who underwent

 Table 5.
 Comparison of complications between insulin-dependent and nondependent cases.

	Insulin Dependent (N = 18)	Insulin Independent (N = 30)
Root damage	1 (2%)	1 (2%)
CVA	0	1 (2%)
Pelvic pain	NA	ŇA
Decrease of motor force	0	1 (2%)
Need for reoperation	1 (2%)	0
Wound infection	3 (6%)	4 (8%)
Dura rupture	2 (4%)	2 (4%)
Postoperation hematoma	NA	ŇA
Thromboembolism	NA	NA

Abbreviation: NA, not available.

elective spine surgery. They reported higher ODI and Numeric Rating Scale for pain in diabetic patients.<sup>15</sup>

In the current study, the mean VAS was significantly higher in diabetic patients before operation and 2 weeks after operation. These findings show that diabetic patients who undergo spine fusion surgeries will suffer from nonunion, pain, and disability more than non-DM ones.

Diabetes mellitus is a multi-organ disease with a prevalence of near 300 million adults in 2010, which is estimated to reach 439 million adults in 2030.<sup>16</sup> Diabetes-related complications may cause multiorgan system failures, and consequently, adverse surgery outcomes.<sup>16</sup> Previous studies reported higher rates of surgical site infections, nonunion, and extended length of stay in patients with diabetes who underwent spine surgery.<sup>1,17–20</sup> The rate of complications in the current study was 29% in diabetic patients. Bendo et al evaluated 32 diabetic cases who underwent spine surgery and reported the complication rate as 31%.<sup>21</sup> Glassman et al found complications in 53% of patients with noninsulindependent diabetes and 56% of patients with insulin-dependent DM, while this rate was 21% in control group.<sup>14</sup> Evaluating 23 adults with noninsulin-dependent diabetes. Cho et al reported that diabetes was not a significant risk factor for perioperative complications in spine surgery.<sup>22</sup> Similarly, in another study on patients undergoing lumbar spine decompression, the outcome and improvement in symptoms were similar in diabetic and nondiabetic patients.<sup>23</sup> Thus, there are controversies regarding the role of diabetes in developing perioperative complications. Insulin dependence is also a challenging issue in this area. Reviewing the literature, insulin dependence is considered to increase the risk of postoperative complications, ie, length of hospital stay and readmission.<sup>24</sup> In the current study, the rate of wound infection was similar in noninsulin-dependent DM and insulindependent DM groups. Furthermore, the rate of complications between insulin-dependent and nondependent cases were not significantly different in the current study, while according to other studies, insulin-dependent DM patients had 1.9 times higher risk of wound infection than noninsulin-dependent DM patients.1,17,18,25,26

Diabetes is considered to be related to longer duration of surgery and hospitalization. Previous studies confirmed that diabetes led to increase of the length of stay in lumbar fusion patients.<sup>12,15</sup> Golinvaux et al reported long hospitalization (more than 5 days) following elective lumbar fusion in 14.9% of nondiabetic, 20.1% of insulin-independent, and 26% of insulin-dependent patients.<sup>24</sup> In our study, the duration of hospitalization was neither significantly different between diabetic and nondiabetic patients nor between insulin-dependent and independent ones. These controversies could be due to different sample sizes, heterogeneous inclusion and exclusion criteria, and different treatment protocols. As another possible complication, higher rate and volume of blood transfusion is reported in diabetic cases, although our data showed no significant difference between diabetic and nondiabetic patients.

A list of limitations regarding the methodology and interpretation of the data of this study could be mentioned. First, it was conducted in a tertiary referral hospital, and our patients could not be representative of the whole society. Second, the sample size was relatively small, with different surgical indications and comorbidities. This could affect the outcome of the study. Third, more assessment time points and longer follow-up period are required to clarify the accurate surgical outcome and define the surgical cautions in diabetic patients who undergo spinal fusion surgery.

#### CONCLUSIONS

Rate of fusion among diabetic patients who undergo lumbar spinal fusion surgery is lower than healthy controls. This could be considered by spine surgeons to provide the best possible facilities during the surgery to increase the fusion rate in these patients.

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**Disclosures and COI:** The authors received no funding for this study and report no conflicts of interest.

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#### Published 31 August 2018

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