8-5-2021

Preoperative HbA1c > 8% Is Associated With Poor Outcomes in Lumbar Spine Surgery: A Michigan Spine Surgery Improvement Collaborative Study

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Recommended Citation

Lim S, Yeh HH, Macki M, Mansour T, Schultz L, Telemi E, Haider S, Nerenz DR, Schwalb JM, Abdulhak M, Park P, Aleem I, Easton R, Khalil J, Perez-Cruet M, and Chang V. Preoperative HbA1c > 8% Is Associated With Poor Outcomes in Lumbar Spine Surgery: A Michigan Spine Surgery Improvement Collaborative Study. Neurosurgery 2021.

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Received, December 8, 2020.
Accepted, June 7, 2021.

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BACKGROUND: Preoperative hemoglobin A1c (HbA1c) is a useful screening tool since a significant portion of diabetic patients in the United States are undiagnosed and the prevalence of diabetes continues to increase. However, there is a paucity of literature analyzing comprehensive association between HbA1c and postoperative outcome in lumbar spine surgery.

OBJECTIVE: To assess the prognostic value of preoperative HbA1c > 8% in patients undergoing elective lumbar spine surgery.

METHODS: The Michigan Spine Surgery Improvement Collaborative (MSSIC) database was queried to track all elective lumbar spine surgeries between January 2018 and December 2019. Cases were divided into 2 cohorts based on preoperative HbA1c level (≤8% and >8%). Measured outcomes include any complication, surgical site infection (SSI), readmission (RA) within 30 d (30RA) and 90 d (90RA) of index operation, patient satisfaction, and the percentage of patients who achieved minimum clinically important difference (MCID) using Patient-Reported Outcomes Measurement Information System.

RESULTS: We captured 4778 patients in this study. Our multivariate analysis demonstrated that patients with HbA1c > 8% were more likely to experience postoperative complication (odds ratio [OR] 1.81, 95% CI 1.20-2.73; $P = .005$) and be readmitted within 90 d of index surgery (OR 1.66, 95% CI 1.08-2.54; $P = .021$). They also had longer hospital stay (OR 1.12, 95% CI 1.03-1.23; $P = .009$) and were less likely to achieve functional improvement after surgery (OR 0.64, 95% CI 0.44-0.92; $P = .016$).

CONCLUSION: HbA1c > 8% is a reliable predictor of poor outcome in elective lumbar spine surgery. Clinicians should consider specialty consultation to optimize patients' glycemic control prior to surgery.

KEY WORDS: Diabetes, HbA1c, Lumbar spine surgery, MSSIC, Outcome

Neurosurgery 0:1–9, 2021 https://doi.org/10.1093/neuros/nyab294 www.neurosurgery-online.com

Diabetes mellitus (DM) is a metabolic dysregulation of blood glucose level that can cause systemic microvascular disease and neuropathy.[1] It is a prevalent condition in the United States, believed to affect approximately 25.8 million people as of 2010.[2] The condition is also known to be correlated with progression of lumbar degenerative disease and poor surgical outcome.[3]

Patients with diabetes are at risk for increased odds of infection, cardiac complications, venous thromboembolism, and inpatient mortality.[4]

ABBREVIATIONS: aOR, adjusted odds ratio; **CAD,** coronary artery disease; **COPD,** chronic obstructive pulmonary disease; **DM,** diabetes mellitus; **GED,** general education development; **GEE,** generalized estimating equation; **HbA1c,** hemoglobin A1c; **ICD,** International Classification of Diseases; **MCID,** minimum clinically important difference; **MSSIC,** Michigan Spine Surgery Improvement Collaborative; **PROMIS,** Patient-Reported Outcomes Measurement Information System; **PROMIS-PF,** Patient-Reported Outcomes Measurement Information System Physical Function; **RA,** readmission; **SSI,** surgical site infection

Supplemental digital content is available for this article at www.neurosurgery-online.com.

Specifically, surgical site infection (SSI) is one of the most frequently cited complication related to DM. Diabetic patients are also likely to experience diminished improvement in patient-reported outcomes after spine surgery.[5] Thus, aggressive glucose management is crucial in optimizing surgical patients.

Glycated hemoglobin (hemoglobin A1c, HbA1c) indicates a mean glucose level over a 2 to 3 mo period formed by glycation of hemoglobin molecule. It is a good proxy of average glycemia and chronic DM management.[6,7] Obtaining preoperative HbA1c is also extremely useful in risk stratification since a significant number of diabetic patients in the United States are undiagnosed, and the HbA1c test adds little additional burden to standard preoperative laboratory studies.[8]

The prognostic value of a preoperative HbA1c value >8% on postoperative outcomes has been investigated across various surgical subspecialties.[9-11] However, it is difficult to establish a comprehensive association between HbA1c > 8% and postoperative outcome in lumbar spine surgery based on the existing literature.

This study was designed to assess the prognostic value of preoperative HbA1c and whether patients should be adequately optimized prior to undergoing surgery. We hypothesize that patients with HbA1c > 8% will have a greater incidence of postoperative complications, longer hospital stays, and lower patient satisfaction following lumbar spine surgery.

METHODS

Study Design

The Michigan Spine Surgery Improvement Collaborative (MSSIC) database was queried to track patients who underwent elective lumbar spine surgeries. The details of this database have been described previously.[12] Briefly, MSSIC prospectively collects data on patients who undergo elective spine surgeries at hospitals across the state of Michigan including tertiary academic centers, smaller community hospitals, and private practice clinics. MSSIC involves 29 hospitals and 185 orthopedic spine surgeons and neurosurgeons. Participating hospitals perform at least 200 annual spine surgeries with participation from both neurosurgeons and orthopedic surgeons. They are obligated to hire dedicated health information technicians as data abstractors and clinical reviewers to ensure database quality.

The MSSIC database was queried between January 2018 and December 2019 to identify all elective lumbar spine surgery patients who had a preoperative HbA1c level recorded. Cases were divided into 2 cohorts based on HbA1c level (≤8% and >8%). HbA1c level of 8% was chosen as a benchmark as the specific cut-off value has been shown to correlate with poor postoperative outcome. Emergent cases (ie, trauma, acute cauda equina) and patients with incomplete charting outcomes are not included in this study.

For all cases, we captured both preoperative and intraoperative variables for analysis. We included patient age, body mass index (BMI), gender, race, educational status, history of depression, coronary artery disease (CAD), smoking status, chronic obstructive pulmonary disease (COPD), deep venous thrombosis (DVT), and stroke. Patients' preoperative ambulatory status, opioid use prior to surgery, prior spine surgery, and American Society of Anesthesiologists (ASA) class were included as well. In addition, we included operative details including the number of levels operated on, fusion procedures, and operative durations.

The primary outcome was any complication following lumbar spine surgery. This included mortality, SSI, readmission (RA), urinary retention, stroke, claudication, ileus, myelopathy, wound dehiscence, cerebrospinal fluid leak, myocardial infarction, pulmonary embolism, urinary tract infection, DVT, unplanned reoperation during admission, and return to the odds ratio (OR) after discharge. Secondary outcome measures include SSI, RA within 30 d (30RA) and 90 d (90RA) of index operation, patient satisfaction, and the percentage of patients who achieved minimum clinically important difference (MCID) using Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function (PROMIS-PF) 4-item Short Form after 90 d from index surgery. Patients who had an increase in PROMIS-PF ≥ 4.5 points were considered as patients who achieved MCID.[13]

The North American Spine Society patient satisfaction index, scored from 1 to 4, was used to measure patient satisfaction at 90 d after the surgery.[14] Scores of 1 (the treatment met my expectations) and 2 (I did not improve as much as I hoped, but I would undergo the same treatment for the same outcome) were categorized as "satisfied." Scores of 3 (I did not improve as much as I had hoped, and I would not undergo the same treatment for the same outcome) and 4 (I am the same or worse than before treatment") were categorized as "unsatisfied."

Statistical Analysis

We used Pearson's χ^2 test or Fischer's exact test for categorical variables and student Mann-Whitney *U*-test or *t*-test for continuous variables. Univariate analysis was performed for comparison between the 2 cohorts. Multivariate generalized estimating equation (GEE) models with a logit link were performed to investigate the association of preoperative HbA1c level with surgical outcomes and account for potential differences in all variables listed in Table 1, including demographic and past medical history information, as well as the operative variables of fusion status, level of surgery, and operative duration. The correlation between patients who underwent surgery in the same hospital was taken into account by these GEE models. All analyses were performed using SAS 9.4 (SAS Institute Inc, Cary, North Carolina).

Ethical Consideration

Approval was obtained from our Institutional Review Board (IRB# 10581). Patient consent is not required for the MSSIC registry because the project has been deemed exempt as a quality improvement initiative.

RESULTS

Univariate Analysis

We identified a total of 4778 patients in this study. Patients were divided into 2 cohorts based on a preoperative HbA1c value of 8%. A total of 4359 (91.3%) patients were included in the control cohort (HbA1c ≤ 8) while 419 (8.7%) patients had preoperative HbA1c > 8% (Figure).

Our univariate analysis demonstrated that patients in the control cohort had lower BMI and were more likely Caucasian. They were also less likely to have a CAD, stroke history, or assigned advanced ASA greater than 2, and were more likely to

TABLE 1. Univariate Comparison of Comorbidities and Operative Details

	HbA1c ≤ 8% n = 4359	HbA1c > 8% n = 419	*P*-value
Age (yr; mean ± SD)	61.5 ± 13.4	62.0 ± 11.9	.386
BMI (mean ± SD)[a]	32.5 ± 6.6	34.0 ± 6.2	<.001
Gender			.081
Male	2285 (52.6%)	239 (57.0%)	
Female	2060 (47.4%)	180 (42.9%)	
Race[a]			.025
White	2409 (55.3%)	185 (4.2%)	
Black/African American	242 (5.6)	25 (6.0%)	
Others	123 (2.8%)	18 (4.3%)	
Not documented	1585 (36.4%)	191 (45.6%)	
Education			.144
Less than high school	173 (4.0%)	16 (3.8%)	
High school diploma or GED	1401 (32.1%)	129 (30.8%)	
Two-year college degree	600 (13.8%)	37 (8.8%)	
Four-year college degree	335 (7.7%)	23 (5.5%)	
Postcollege	268 (6.2%)	16 (3.8%)	
Not documented	1582 (36.3%)	198 (47.4%)	
Depression	1576 (36.1%)	150 (35.8%)	.885
CAD[a]	812 (18.6%)	123 (29.3%)	<.001
Current smoker	394 (9.0%)	36 (8.5%)	.760
COPD	568 (13.0%)	66 (15.7%)	.117
Stroke[a]	213 (4.9%)	34 (8.1%)	.004
Ambulatory preop[a]	3306 (75.8%)	280 (66.8%)	<.001
Taking opioids daily to control pain	1170 (43.2%)	100 (45.2%)	.559
DVT	40 (0.9%)	4 (0.9%)	.921
History of spine surgery	4171 (95.6%)	397 (94.7%)	.371
ASA > 2[a]	2739 (62.8%)	354 (84.4%)	<.001
Number of levels operated[a]			.005
1	1951 (45.2%)	188 (45.8%)	
2	1210 (28.0%)	139 (33.9%)	
3+	1152 (26.7%)	83 (20.2%)	
Fusion[a]	2568 (59.0%)	214 (51.0%)	.002
Duration of surgery (min; mean ± SD)	136.7 ± 89.7	135.0 ± 108.3	.752

SD, standard deviation; GED, general education development; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; DVT, deep venous thrombosis; ASA, American Society of Anesthesiology.
[a]Denotes statistical significance, $P < .05$.

be ambulatory prior to surgery. Patients in the control cohort underwent spine surgeries that required more levels and had a higher proportion of fusion surgery (Table 1).

In univariate analyses, we observed that patients with HbA1c > 8% experienced more postoperative complications. They were also more likely to be readmitted within 30 and 90 d of index surgery and have a longer hospital stay. Patients with HbA1c > 8% were also less likely to be satisfied with their surgery and less likely to achieve a MCID on PROMIS-PF at 90 d of surgery (Table 2).

Multivariate Analysis

Our regression analysis continued to demonstrate significant differences in outcomes between the 2 groups (Table 3). Patients with HbA1c > 8% were more likely to experience postoperative complications (adjusted odds ratio [aOR] 1.40, 95% CI 1.01-1.94; $P = .0406$) and be readmitted within 30 d (aOR 1.55, 95% CI 1.14-2.09; $P = .0048$) and 90 d (aOR 1.51, 95% CI 1.11-2.06; $P = .0093$) of index surgery (**Supplemental Digital Content**, **Table**). They also were more likely to have a hospital stay >3 d (aOR 1.39, 95% CI 1.11-1.74; $P = .0047$) and were less likely to achieve PROMIS-PF MCID within 90 d of surgery (aOR 0.70, 95% CI 0.52-0.94; $P = .0193$). Patients with HbA1c > 8% were also less likely to be satisfied after surgery although statistical significance was not reached (aOR 0.81, 95% CI 0.58-1.12; $P = .1967$). Interestingly, HbA1c > 8% was not significantly associated with higher SSI rate (aOR 0.69, 95% CI 0.26-1.86; $P = .4668$).

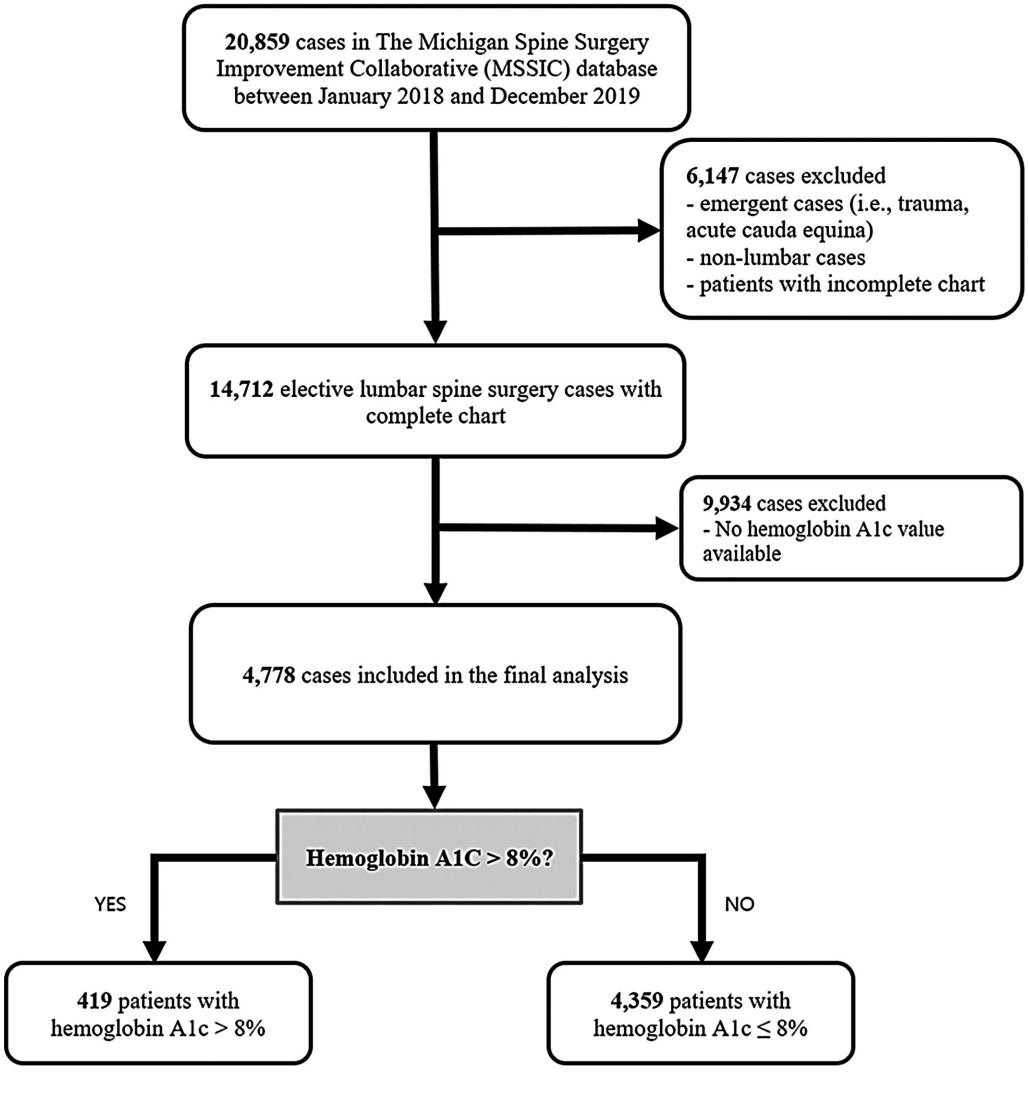

FIGURE. *Patient flow diagram.*

DISCUSSION

Key Results

Our study demonstrated that patients with HbA1c > 8% were much more likely to have 1 or more complications than control cohort (25.3% vs 18.0%). This difference persisted when baseline difference was adjusted using our multivariate model (aOR 1.4, 95% CI 1.01-1.94; $P = .0406$). The HbA1c > 8% cohort also had significantly higher rate of hospital stays over 3 d (aOR 1.39, 95% CI 1.11-1.74; $P = .0047$) and higher RA rate within 30 d (aOR 1.55, 95% CI 1.14-2.09; $P = .0048$) and 90 d (aOR 1.51, 95% CI 1.11-2.06; $P = .0093$) of index surgery. We also observed that surgery was less likely to show improvement in self-reported physical function. The proportion of patients who achieved MCID on PROMIS was significantly lower in the HbA1c > 8% cohort compared to control group (aOR 0.70, 95% CI 0.52-0.94; $P = .0193$). Patients with HbA1c > 8% were less satisfied with surgery outcome, but this difference did not reach statistical significance (aOR 0.81, 95% CI 0.58-1.12; $P = .1967$). We also demonstrated an interesting result that an HbA1c > 8% was not predictive of increased SSI rate (aOR 0.69, 95% CI 0.26-1.86; $P = .4668$).

TABLE 2. Univariate Comparison of Outcomes

Outcomes	HbA1c ≤ 8% n = 4359	HbA1c > 8% n = 419	*P*-value
Any complication[a]	334 (7.6%)	59 (14.0%)	<.001
SSI	112 (2.6%)	9 (2.2%)	.133
RA within 30 d[a]	181 (4.1%)	30 (7.1%)	.004
RA within 90 d[a]	326 (7.5%)	51 (12.1%)	<.001
Satisfaction[a]	1939 (83.2%)	165 (77.8%)	.047
MCID on PROMIS at 90 d[a]	916 (57.3%)	69 (47.5%)	.023
Length of stay (d; mean ± SD)	2.67 ± 2.44	3.03 ± 2.55	.113

SSI, surgical site infection; MCID, minimum clinically important difference; PROMIS, Patient-Reported Outcomes Measurement Information System; SD, standard deviation.
[a]Denotes statistical significance, $P < .05$.

TABLE 3. Multivariate Analysis of Outcomes

Outcomes	aOR (95% CI)	*P*-value
Any complication[a]	1.70 (1.26, 2.29)	.001
SSI	0.72 (0.28, 1.89)	.510
RA within 30 d	1.63 (1.19, 2.24)	.002
RA within 90 d[a]	1.56 (1.17, 2.08)	.0038
Satisfaction	0.79 (0.57, 1.09)	.149
MCID on PROMIS at 90 d[a]	0.72 (0.53, 0.98)	.034
Length of stay[a]	1.36 (1.08, 1.71)	.008

aOR, adjusted odds ratio; SSI, surgical site infection; MCID, minimum clinically important difference; PROMIS, Patient-Reported Outcomes Measurement Information System; SD, standard deviation.
[a]Denotes statistical significance, $P < .05$.

This is the first multicenter study using detailed clinical data from a nonadministrative surgical registry to demonstrate negative associations with elevated HbA1c and lumbar surgery outcomes.

Interpretation

DM has become a common medical condition in the United States with its prevalence increasing from 5.5% in 1988 to 1994 to 10.8% in 2011 to 2014; nearly doubling over 2 decades.[2,8] Uncontrolled DM is also one of the most frequently cited medical comorbidities associated with perioperative complication across various surgical subspecialties.[4,10,15-19] However, this association is not always consistent depending on how one defines "poorly controlled DM." To illustrate, Merchant et al[20] demonstrated that uncontrolled DM had a positive correlation with poor postoperative outcome following total joint arthroplasty. On the other hand, analysis done in the study by Adams et al[21] did not reveal any significant association between postoperative complication and poor glycemic control. Adams et al used HbA1c > 7% to categorize uncontrolled DM while Merchant et al used International Classification of Diseases (ICD)-9 diagnosis.

HbA1c value is useful in both diagnosing DM and monitoring glycemic control. Preoperative HbA1c value may also assist with identifying undiagnosed DM patients and appropriate risk stratification. The role of preoperative HbA1c has been emphasized by Ali et al.[22] The authors recommended that all patients with preoperative HbA1c > 8% undergo specialist consultation to achieve tighter glucose control prior to spine surgery in their proposed enhanced recovery after surgery (ERAS) protocol.[22] This recommendation was tested by Kallio et al[23] who demonstrated that optimizing patients with preoperative HbA1c > 8% before total joint arthroplasty resulted in significant reduction of complication rate and shorter hospital stay.

We postulated whether lower HbA1c threshold should be considered (ie, 7%) instead of 8%. However, review of current literature suggests that surgical complications are more consistently associated with HbA1c > 8%.[9-11,21,23,24] Therefore, we selected patients that can potentially benefit from aggressive optimization at the cost of delaying surgery if needed. Furthermore, excessive glycemic control in relatively well-managed diabetic patients can cause iatrogenic hypoglycemia and increase perioperative morbidity.[25,26]

In this study, we demonstrated that HbA1c > 8% was associated with higher postoperative complication rate, which is similar to other reports in different surgical disciplines. Underwood et al reviewed the NSQIP database, which demonstrated preoperative HbA1c above 8% correlated with longer hospital stay and higher complication rates for patients undergoing noncardiac procedures.[10] Han and Kang[9] also reported that a preoperative HbA1c level greater than 8% was an independent risk factor for wound complications in patients with diabetes undergoing total knee arthroplasty. Similar findings have been reported in spine surgery as well. Guzman et al[4] reviewed over 2 million lumbar spine surgeries from a national database and demonstrated that diabetic patients are at increased risk of acute complications such as cerebrovascular accidents, venous thromboembolism, postoperative hemorrhage, or shock. Given the implications of uncontrolled DM, some surgeons have recommended that patients with known diabetes and HbA1c > 8%

should undergo specialty consultation with an endocrinologist prior to spinal surgery, and this recommendation appear to be appropriate based on our study findings.[22]

In addition to complication, our analyses also elucidate the negative correlation between HbA1c > 8% and important quality measures including MCID on PROMIS-PF at 90 d, length of stay, and RA rates. These findings corroborate the results from previous studies. To illustrate, Armaghani et al[5] reported uncontrolled DM is a significant risk factor for diminished improvement in patient-reported outcomes including Short Form 12, EuroQol-5D, Oswestry Disability Index, Neck Disability Index, and Numeric Rating Scale pain scores after elective spine surgery. Additionally, diabetic patients are likely to have longer hospital stay after spine surgery due to prolonged recovery and perioperative complications.[27-29] Walid et al[27,30,31] also discussed compromised quality measures including length of stay for patients with elevated preoperative HbA1c in spine surgery and insisted on using HbA1c as a screening tool for identification and optimization of high-risk patients. Also, studies done by Epstein and Sivaganesan et al demonstrate that uncontrolled DM is a risk factor for RA of spine surgery patients.[32,33]

However, this study did not find a significant association between HbA1 > 8% and diminished patient satisfaction although previous studies have reported that patients with uncontrolled DM were less likely to be satisfied with surgical outcome. Arinzon et al[34] reviewed 257 elderly patients who underwent lumbar decompression surgery and found diabetic patients were not as satisfied with surgical outcome compared to nondiabetic cohort. Menendez et al[35] also conducted a systemic review and found diabetes is a risk factor for nonsatisfactory outcome. This conflicting finding may be from different patient selection criteria (ie, ICD-9 diagnosis vs HbA1c > 8%) or outcome measurements, and warrants further study.

Also, our analysis provided an interesting result that HbA1c > 8% was not significantly associated with higher SSI rate (2.6% vs 2.2%; $P = .4668$). SSI is one of the most well-documented complications from DM in surgical patients, and it is associated with increased morbidity, mortality, length of stay, and financial burden after spine surgery.[15-17,36-40] Our results were even more unexpected considering the baseline difference between the 2 cohorts in that patients with HbA1c > 8% were more likely to have cardiac condition or stroke history, have advanced ASA class, and were less likely to be ambulatory prior to surgery. However, it should be noted that the overall SSI rate is low. The small sample size in the group of HbA1c > 8% with SSI reduces the power to detect differences. For example, to have 80% power to detect a difference in proportions of 1% (2% vs 1%), a sample size of at least 2300 patients in each group would be needed.

While our results reiterate previous study findings, our analyses offer significant practical value to clinicians that HbA1c > 8% is a reliable indicator of poor outcomes, higher RA rates, and diminished improvement after surgery. Our findings suggest that preoperative HbA1c value can be a simple but powerful screening tool for identifying and optimizing high-risk patients.

Limitations and Generalizability

There are a few inherent limitations to the study design and registry data. Our analysis results were subject to both known and unknown confounders, and unmeasured variables could not be addressed via multivariate regression analysis. Moreover, given that collecting HbA1c was not mandatory in MSSIC, there could be a potential sampling bias for the patients where the data were available. In addition, as MSSIC is a statewide registry, there may be certain demographic features unique to the state of Michigan that may not be universally applicable in all settings. However, given that MSSIC currently encompasses 29 hospitals (ie, community hospital to quaternary academic institutions) across a wide range of practice environments with both orthopedic spine and neurosurgeons, we believe that the findings in this study are widely generalizable to most surgical practices.

CONCLUSION

We demonstrated that preoperative HbA1c > 8% was associated with postoperative complications and patient-reported outcomes. Our analysis suggests that spine surgeons, when feasible, may seek to optimize high-risk patients with poor glycemic control who are undergoing elective lumbar spine surgery in an effort to minimize potential morbidity.

Funding

This study did not receive any funding or financial support.

Disclosures

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article. Dr Chang receives research funding from Medtronic, who was not involved in this project specifically. He is a consultant for Globus Medical, K2M, and SpineGuard. Dr Schwalb receives research funding from Medtronic, StimWave, and Neuros. He is a consultant for BlueRock and Guidant. None of these relationships are related to this project specifically. He receives some salary support from BCBSM for his role as a codirector of MSSIC. Miguelangelo Perez-Cruet has stock ownership in Thompson MIS and speaker Bureau for Orthofix. Although Blue Cross Blue Shield of Michigan and MSSIC work collaboratively, the opinions, beliefs, and viewpoints expressed by the authors do not necessarily reflect the opinions, beliefs, and viewpoints of BCBSM or any of its employees. Support for MSSIC is provided by Blue Cross and Blue Shield of Michigan and Blue Care Network as part of the BCBSM Value Partnerships program.

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Supplemental Digital Content. Table. Type of complications. This table summarizes all adverse events collected by MSSIC and the incidence of each for both cohorts.

COMMENT

Lumbar spine operations can often be scheduled electively, weeks in advance, presenting an opportunity to patients and their health care team to optimize health status before the significant physiological stress of surgery and recovery. We applaud the authors for exploring this concept in the context of diabetes, a large and growing public health threat in the United States. This quality improvement collaborative study adds perspective to the literature on deleterious effects of inadequate blood glucose regulation. Yet, constraints of conducting this study retrospectively, and with an abstracted data set, limit the reader's ability to determine the magnitude of effects seen in patients classified

by a single pre-operative hemoglobin A1c. There is an inherent selection bias of patients for whom someone decided to order an A1c; the authors acknowledge this but nonetheless excluded two-thirds of lumbar spine surgery patients on this basis. Is the remaining one-third representative of the whole? It is also not reported whether the A1c value was from its valid period of 3 mo before surgery, whether blood glucose was measured or controlled in the post-operative setting, and what if any diabetes medications the studied patients were taking, including insulin. Thus, we urge the reader to use this study as a starting point in the discussion of pre-habilitation or optimization for scheduled procedures, and as a signal of the unmet need for prospective, clinical studies on the impact of improved glycemic control on lumbar spine surgical patient outcomes.

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