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Age as a Predictor for Complications and Patient-reported Outcomes in Multilevel Transforaminal Lumbar Interbody Fusions

Analyses From the Michigan Spine Surgery Improvement Collaborative (MSSIC)

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Study Design. Retrospective review of a multi-institutional data registry.

Objective. The authors sought to determine the association between age and complications & patient-reported outcomes (PRO) in patients undergoing multilevel transforaminal interbody lumbar fusion (MTLIF).

Summary of Background Data. Elderly patients undergoing MTLIF are considered high risk. However, data on complications and PRO are lacking. Additionally, safety of multilevel lumbar fusion in the elderly remains uncertain.

Methods. Patients ≥50-year-old who underwent MTLIF for degenerative lumbar spine conditions were analyzed. Ninety-day complications and PROs (baseline, 90-d, 1-y, 2-y) were queried using the MSSIC database. PROs were measured by back & leg visual analog scale (VAS), Patient-reported Outcomes Measurement Information System (PROMIS), EuroQol-5D (EQ-5D), and North American Spine Society (NASS) Patient Satisfaction Index. Univariate analyses were used to compare among elderly and complication cohorts. Generalized estimating equation (GEE) was used to identify predictors of complications and PROs.

Results. A total of 3120 patients analyzed with 961 (31%) ≥ 70-y-o and 2159 (69%) between 50–69. A higher proportion of elderly experienced postoperative complications ($P = .003$) including urinary retention ($P = <.001$) and urinary tract infection ($P = .002$). Multivariate analysis demonstrated that age was not independently associated with complications. Number of operative levels was associated with any ($P = .001$) and minor ($P = .002$) complication. Incurring a complication was independently associated with worse leg VAS and PROMIS scores ($P = <.001$). Preoperative independent ambulation was independently associated with improved PROMIS, and EQ5D ($P = <.001$). Within the elderly, preoperative independent ambulation and lower BMI were associated with improved PROMIS ($P = <.001$). Complications had no significant effect on PROs in the elderly.

Conclusion. Age was not associated with complications nor predictive of functional outcomes in patients who underwent MTLIF. Age alone, therefore, may not be an appropriate surrogate for risk. Furthermore, baseline preoperative independent ambulation was associated with better clinical outcomes and should be considered during preoperative surgical counseling.

Key words: complications, elderly, lumbar fusion, Michigan spine surgery improvement collaborative, patient-reported outcome measures, spinal fusion.

Level of Evidence: 3

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As our population continues to age, the number of elderly requiring lumbar fusion (LF) will increase.[1] Posterior lumbar fusion techniques such as posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF) are two of the most common techniques used for LF.[2] The process of aging includes physiologic attributes not present in younger patients. These attributes may pose a higher risk or poorer tolerance to more extensive spinal surgeries requiring longer operative and anesthetic time, such as multilevel lumbar fusions (MLLF).[3,4] LF in the elderly has been associated with an increased risk of complications.[5–11] However, there remains a lack of consensus regarding the overall safety of MLLF in the elderly population.[5,6,10,12–18] Specifically, complication risk and patient-reported outcomes (PROs) in the elderly undergoing MLLF are not well known.[2] Small sample sizes, homogeneity, and lack of reported outcomes were some of the limitations of prior studies. Focus has turned more to the evaluation of frailty and comorbid burden as surrogates for risk, rather than chronologic age alone.[19–21] As the rate of LF in the elderly increases, the assessment of safety and PROs in this population have become increasingly more important for clinicians.[12] With that in mind, the Michigan Spine Surgery Improvement Collaborative (MSSIC), a large multi-institutional registry, was used to assess the effect of age on complications and PROs in patients who underwent multilevel TLIF. We sought to identify whether age is associated with complications and PROs. Secondarily, we sought to identify the predictors of complications in the elderly (≥70 y-o) and whether complication was associated with PROs in the elderly.

MATERIAL AND METHODS

Design, Setting, and Participants

The MSSIC is a multi-institutional quality-improvement collaborative, with 26 participating hospitals across Michigan established in 2013, funded and supported by Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). The detailed design, goals, and administration of MSSIC have been published previously.[22] Each institution individually collects and enters data into a centralized registry with a single coordinating center overseeing the administration, quality control, and abstractor training. MSSIC captures a wide variety of surgical settings, including small community hospitals and large tertiary care centers. Criteria for inclusion in the MSSIC include cervical and/or lumbar spine surgery for general degenerative conditions, such as spondylosis, intervertebral disc disease, and low grade (grade 1 or 2) spondylolisthesis. Exclusion criteria include complex diagnoses, such as patients less than 18 years-old, moderate (25°–50°) or severe (>50°) scoliosis, thoracic only procedures, tumor, meningitis, preexisting spinal infection, spinal deformity, high-grade spondylolisthesis, congenital anomalies of the nervous system, traumatic fracture, and spinal cord injury.

Variables, Data Sources, and Measurements

MSSIC's standardized data collection includes preoperative patient demographics, clinical presentation, surgical characteristics, inpatient details including adverse events, adverse events within 90-days, and PROs at 90-days, 1-year, and 2-years postoperatively. Only patients with degenerative spinal conditions were included in the MSSIC registry. Therefore, we sought to focus on those over 50 years-old in which spinal degeneration is the predominant diagnosis. Those less than 50 years-old could represent outliers and would eventually be removed in the multivariate analysis. By comparing the >50-<70 y-o age group with the ≥70 y-o, it would also help answer the commonest dilemma we face in a clinical setting, which is to determine the surgical risk of a "'young-elderly" *versus* an "old-elderly." Patients ≥, 50 years-old who underwent multilevel TLIF between 2014 and 2019 were queried for 90-day complications and PROs. Elderly was defined as ≥ 70 years old, similar to recent literature.[2,12,23,24] Complications were defined as major or minor as described by Carreon *et al*.[5] PROs were measured by back & leg visual analog scale (VAS), Patient-reported Outcomes Measurement Information System (PROMIS short form–physical function), EuroQol-5D (EQ-5D), and North American Spine Society (NASS) Patient Satisfaction Index.

Statistical Analysis

Comparability between groups (patients with complications *vs*. without complications & elderly *vs*. non-elderly) was evaluated by univariate analysis. Covariates with clinically and statistically significant differences were identified to be included in the multivariate analyses. Complications by age, PROs over time were analyzed using univariate analyses. $P < .05$ was considered significant.

Between 0% and 30% of the patient covariates and 30% of baseline PROs were missing. Missing pattern was identified. Due to the nonmonotone missingness, multiple imputations by chained equations were used to impute for both the covariates and the PRO outcome variables. Missing data were not imputed for complications because of the extremely low incidence of missing data (3/3120 among all cohorts and 0/961 among >70 y-o). Using multiple imputations, 30 complete datasets were created and pooled. When missing data accounted for >1% of the variable, sensitivity analyses using the imputed data were performed to test the Missing-at-random (MAR) assumption (refer to supplementary content, http://links.lww.com/BRS/B668). Outcomes that satisfied the MAR were analyzed using the generalized estimating equation (GEE) to account for potential cluster effects that vary between the sites and between subjects.

To identify predictors of complications (any, minor & major), separate GEE models were run while adjusted for age, smoking, preoperative ambulation, American Society of Anesthesiologists (ASA) grade >2, diabetes mellitus (DM), atrial fibrillation (A-fib), cerebrovascular accident (CVA), chronic obstructive pulmonary disorder (COPD), ≥ three comorbidities, preoperative anticoagulation use, number of operative levels, postoperative day-0 ambulation, estimated blood loss (EBL), and surgery duration. We then removed age as an independent variable from the list of independent variables and repeated the model for the elderly (>70 y-o) subgroup.

To identify predictors of PROs, separate GEE models were run for each PRO which satisfied the MAR assumptions while adjusted for age, baseline PROs (except satisfaction), body mass index (BMI), major complications, minor complications, smoking, preoperative ambulation, American Society of Anesthesiologists (ASA) grade >2, diabetes mellitus (DM), atrial fibrillation (A-fib), CVA, COPD, ≥ three comorbidities, preoperative anticoagulation use, number of operative levels, postoperative day-0 ambulation, EBL, and surgery duration. We then removed age as an independent variable from the list of independent variables and repeated the model for the elderly (>70 y-o) subgroup.

A logit-link function and binomial error distribution were specified for models with a dichotomous outcome. The log link function and Poisson error distribution were specified for models with PROs as the dependent variable. Bonferroni's correction was used for multivariate analyses, and a P value < .003 was considered significant.

RESULTS

Participants and Descriptive Data

A total of 3120 patients were included in the analysis, with 961 patients (31%) ≥70 years-old and 2159 (69%) between 50 and 69 years-old. There were statistically significant differences among the complications groups (Table 1). Important clinically and statistically significant differences between the complication group demonstrated that patients with complications were more likely to have nonprivate insurance, inability to ambulate preoperatively, ASA >2, more comorbidities, operative levels, longer operative times, hospital stay and fail to ambulate on postoperative day-0. Similarly, we observed several statistically significant differences in baseline characteristics & medical history between elderly and non-elderly patients (Table 2).

Complications and PROs

Nine hundred ninety-nine patients (32%) experienced a complication. There were a total of 1356 complications (minor 1177 and major 179). One hundred seventy-one patients (5.5%) experienced at least one major complication, 942 patients (30.2%) experienced at least one minor complication, and 999 patients (32%) experienced at least one of any complications. Two hundred sixty-two (8.4%) patients suffered more than one complication. The proportions of non-elderly suffering from any (30.3% *vs.* 35.8%, $P = .003$), or minor complications (28.4% *vs.* 34.1%, $P = .001$) were significantly lower compared to the elderly (Table 3). There was no significant difference between the elderly and non-elderly (5.4% *vs.* 5.7%, $P = .733$) regarding major complications (Table 3).

The most commonly occurring complications postoperatively were minor (30.2%) (Table 3). Radicular findings (15.1%), urinary retention (10.3%), and urinary tract infection (4.4%) were the most frequent minor complications, whereas surgical site infection (2.5%) and surgical site hematoma (1.3%) were the two most common major complications. Univariate analysis demonstrated a significantly higher proportion of non-elderly experiencing new postoperative radicular findings ($P = .047$) while the elderly experienced a higher proportion of urinary retention ($P = <.001$) and urinary tract infections ($P = .002$). There was no significant difference in the incidence of major complications. Overall, patients had significant improvement in all PROs over time ($P = <.001$) (Table 4).

Multivariable Analysis of Complications

Controlling for all other covariates, age was not independently associated with any, major or minor complications (Table 5). However, controlling for all other covariates and by one unit change of the independent variable, the OR of a patient having any complication changes for surgery duration (OR 1.002, 95% CI 1.001–1.003, $P = .001$) and the number of operative levels (OR 1.21, 95% CI 1.08–1.35, $P = .001$); similarly, surgery duration (OR 1.002, 95% CI 1.001–1.003, $P = .001$) and the number of operative levels (OR 1.20, 95% CI 1.07–1.34, $P = .002$) were independently associated with increasing the OR of a patient having a minor complication. No statistically significant associations with major complications were identified.

Multivariable Analysis of Complications in the Elderly

Among the elderly patients (≥70-y-o), our multivariable analyses did not demonstrate any statistically significant independent association with any, major, or minor complication (Table 6).

Multivariate Analysis of PRO Using MI-GEE

Only PROMIS and satisfaction satisfied the MAR assumption. All significant covariates and up to 4 nonsignificant covariates were reported (Table 7).

For PROMIS as repeated continuous measures during 90-day to 2-year postoperative, controlling for all other covariates, the mean value of PROMIS increases/decreases by a ratio of Exp(B) given one unit increase in the baseline PROMIS (exp(B) 1.01, 95% CI 1.01–1.1, $P < .001$) and BMI (exp(B) 1.00, 95% CI 0.99–1.01, $P < .001$). Similarly, the mean value of PROMIS increases/decreases by a ratio of Exp(B) if the patient has a history of COPD (exp(B) 0.95, 95% CI 0.92–0.98–1.1, $P = .002$), independent preoperative ambulation (exp(B) 0.95, 95% CI 0.93–0.98, $P < .001$), and minor complication (exp(B) 0.97, 95% CI 0.95–0.99, $P = .002$). There was no significant independent association between satisfaction and the adjusted covariates.

Multivariate Analysis of PRO in the Elderly Using MI-GEE

For PROMIS as repeated continuous measures during 90-day to 2-year postoperative, controlling for all other covariates, the mean value of PROMIS increases by a ratio of 1.01 (95%CI 1.-1.01, $P < .001$) given one unit increase in

TABLE 1. Demographics by Complication

N = 3120	No Complication (n = 2121)	Complication (n = 999)	*P*
Demographics			
Age	64.6 ± 8.2	65.5 ± 8.5	**.007**
BMI	31.2 ± 7.5	31.7 ± 6.3	.052
Sex			**<.001**
Male	1039 (49.0)	460 (46.0)	
Female	1082 (51.0)	539 (54.0)	
Current smoker	316 (14.8)	133 (13.3)	**<.001**
Private insurance	679 (32.0)	263 (26.3)	**<.001**
Independent preop ambulation	1564 (73.7)	710 (71.1)	**<.001**
ASA > 2	1256 (59.2)	668 (66.8)	**<.001**
Medical history			
Diabetes	521 (24.5)	319 (31.9)	**<.001**
Coronary artery disease	351 (16.5)	190 (19.0)	**<.001**
Hypertension	1466 (69.1)	737 (73.7)	**<.001**
Acute myocardial infarction	60 (2.8)	23 (2.3)	**<.001**
Atrial fibrillation	104 (4.9)	86 (8.6)	**<.001**
Congestive heart failure	60 (2.8)	42 (4.2)	**<.001**
Transient ischemic attack	89 (4.2)	48 (4.8)	**<.001**
Cerebrovascular accident	96 (4.5)	47 (4.7)	.150
COPD	260 (12.3)	142 (14.2)	**<.001**
Osteoporosis	251 (11.8)	145 (14.5)	**<.001**
Anxiety	544 (25.6)	263 (26.3)	.687
Depression	646 (30.4)	349 (34.9)	**<.001**
Preop anticoagulation use	236 (11.1)	171 (17.1)	**<.001**
History of blood clot	110 (5.2)	87 (8.7)	**<.001**
≥3 Comorbidities	806 (38.0)	481 (48.1)	**<.001**
Previous spine surgery	1172 (55.2)	557 (55.7)	.187
Surgical indication			
Disc herniation	1379 (65.0)	688 (68.9)	**.034**
Recurrent disc herniation	95 (4.5)	32 (3.2)	.092
Spinal stenosis	1966 (92.7)	928 (92.9)	.840
Spondylolisthesis	1385 (65.3)	662 (66.3)	.596
Adjacent segment disease	318 (15.0)	148 (14.8)	.896
Revision of hardware	256 (12.1)	120 (12.0)	.963
Other	119 (5.6)	55 (5.5)	.905
Perioperative characteristics			
Symptom duration			.226
< 3 months	123 (5.7)	63 (6.3)	
3 months–1 year	434 (20.4)	181 (18.1)	
> 1 year	1456 (68.6)	714 (71.4)	
Not documented	108 (5.1)	41 (4.1)	
Number of levels			**<.001**
2	1401 (66.1)	596 (59.6)	
3	547 (25.7)	266 (26.6)	
4 or more	173 (8.2	137 (13.7)	
Day 0 ambulation	1022 (48.1)	390 (39.0)	**<.001**
Estimated blood loss (mL)	394.5 ± 335.5	441.0 ± 393.5	**.001**
Length of hospital stay (d)	3.4 ± 1.7	4.5 ± 3.2	**<.001**
Surgery duration (min)	194.1 ± 86.5	213.7 ± 92.8	**<.001**

Continuous data are presented as mean ± SD; categorical data are presented as n (%). Boldface type indicates statistical significance.

P < .05 considered significant; ASA, American Society of Anesthesiologist physical status grade; BMI, body mass index; COPD, chronic obstructive pulmonary disease; d, days; min, minutes; mL, milliliters.

TABLE 2. Demographics by Age

N = 3120	Non-elderly (n = 2159)	Elderly (n = 961)	*P*
Demographics			
Age	60.5 ± 5.5	74.9 ± 4.0	**<.001**
BMI	32.0 ± 7.8	30.1 ± 5.4	**<.001**
Sex			.092
Male	1059 (49.1)	440 (45.8)	
Female	1100 (50.9)	521 (54.2)	
Current smoker	397 (18.4)	52 (5.4)	**<.001**
Private insurance	871 (40.3)	75 (7.8)	**<.001**
Independent preop ambulation	1641 (76.0)	633 (65.9)	**<.001**
ASA > 2	1262 (58.5)	662 (68.9)	**<.001**
Medical history			
Diabetes	535 (24.8)	305 (31.7)	**<.001**
Coronary artery disease	295 (13.7)	248 (25.8)	**<.001**
Hypertension	1444 (66.9)	758 (78.9)	**<.001**
Acute myocardial infarction	83 (3.8)	51 (5.3)	.063
Atrial fibrillation	97 (4.5)	103 (10.7)	**<.001**
Congestive heart failure	76 (3.5)	51 (5.3)	**.020**
Transient ischemic attack	78 (3.6)	71 (7.4)	**<.001**
Cerebrovascular accident	92 (4.3)	70 (7.3)	**<.001**
COPD	288 (13.3)	130 (13.5)	.887
Osteoporosis	214 (9.9)	183 (19.0)	**<.001**
Anxiety	618 (28.6)	191 (19.9)	**<.001**
Depression	778 (36.0)	219 (22.8)	**<.001**
Preop anticoagulation use	233 (10.8)	187 (19.5)	**<.001**
History of blood clot	139 (6.4)	58 (6.0)	.669
≥3 Comorbidities	663 (30.7)	341 (35.5)	**.008**
Previous spine surgery	1219 (56.5)	509 (53.0)	.070
Surgical indication			
Disc herniation	1433 (66.4)	634 (66.0)	**<.001**
Recurrent disc herniation	86 (4.0)	41 (4.3)	.712
Spinal stenosis	1975 (91.5)	919 (95.6)	**<.001**
Spondylolisthesis	1362 (63.1)	685 (71.3)	**<.001**
Adjacent segment disease	323 (15.0)	143 (14.9)	.954
Revision of hardware	274 (12.7)	102 (10.6)	.100
Other	119 (5.5)	55 (5.7)	.812
Perioperative characteristics			
Symptom duration			**.026**
< 3 months	124 (5.7)	62 (6.5)	
3 months–1 year	406 (18.8)	209 (21.7)	
> 1 year	1536 (71.1)	634 (66.0)	
Not documented	93 (4.3)	56 (5.8)	
Number of levels			**<.001**
2	1435 (66.5)	562 (58.5)	
3	512 (23.7)	301 (31.3)	
4 or more	212 (9.8)	98 (10.2)	
Day 0 ambulation	984 (45.6)	457 (47.6)	.306
Estimated blood loss (mL)	417.7 ± 361.1	390.9 ± 342.7	**.049**
Length of hospital stay (d)	3.7 ± 2.5	3.9 ± 2.1	**.005**
Surgery duration (min)	200.4 ± 92.4	200.4 ± 81.1	.978
Postoperative complication	655 (30.3)	344 (35.8)	**.003**
Major complication	116 (5.4)	55 (5.7)	.691
Minor complication	614 (28.4)	328 (34.1)	**.001**

Continuous data are presented as mean ± SD; categorical data are presented as n (%). Boldface type indicates statistical significance.

$P < .05$ considered significant; ASA, American Society of Anesthesiologist physical status grade; BMI, body mass index; COPD, chronic obstructive pulmonary disease; d, days; min, minutes; mL, milliliters.

TABLE 3. Complications by Age, Univariate Analysis

N = 3117*	Non-elderly (n = 2156)	Elderly (n = 961)	*P*
Any complication	655 (30.3)	344 (35.8)	**.003**
Major complication	116 (5.4)	55 (5.7)	.691
Surgical site infection	56 (2.6)	22 (2.3)	.611
Surgical site hematoma	27 (1.3)	12 (1.2)	.993
Pulmonary embolism	15 (0.7)	9 (0.9)	.478
Myocardial infarction	12 (0.6)	7 (0.7)	.569
New neurological deficit	8 (0.4)	2 (0.2)	.607
Any mortality	4 (0.2)	5 (0.5)	.108
Minor complication	614 (28.4)	328 (34.1)	**.001**
Radicular findings	345 (16.0)	127 (13.2)	**.047**
Urinary retention	171 (7.9)	150 (15.6)	**<.001**
Deep vein thrombosis	30 (1.4)	19 (2.0)	.225
Urinary tract infection	78 (3.6)	58 (6.0)	**.002**
Wound dehiscence	55 (2.6)	19 (2.0)	.331
Ileus	43 (2.0)	25 (2.6)	.284
CSF leak	40 (1.9)	17 (1.8)	.869

Categorical data are presented as n (%); complications within 90 days of surgery. Boldface type indicates statistical significance.
P < .05 considered significant, CSF, cerebrospinal fluid.
*Three non-elderly patients have missing complication data.

TABLE 4. Patient Reported Outcomes Over Time, Univariate Analysis

	Baseline	90 Day	1 Year	2 Year	MCID (%)	Δ	95% CI	*P*
Back pain (N = 94)	7.4 ± 2.3	3.6 ± 2.7	3.7 ± 2.9	3.9 ± 2.9	68.5	4.15 ± 3.05	4.00–4.30	**<.001**
Leg pain (N = 94)	6.8 ± 2.7	2.5 ± 3.0	2.7 ± 3.1	2.9 ± 3.2	73.3	4.55 ± 3.49	4.38–4.72	**<.001**
PROMIS (N = 94)	34.6 ± 5.1	40.2 ± 6.7	41.2 ± 7.6	40.7 ± 8.1	56.1	6.94 ± 7.08	6.61–7.28	**<.001**
EQ5D (N = 94)	.52 ± .21	.72 ± .20	.72 ± .21	.72 ± .21	50.9	.222 ± .244	.208–.235	**<.001**

Δ = difference between the best PRO-baseline over 2 years.
MCID = proportion of patients who reached an improvement from baseline >MCID over 2 years.
Data are presented as mean ± SD; P < .05 considered significant. Boldface type indicates statistical significance.
PROMIS, Patient Reported Outcomes Measurement Information System.
N represents number of patients who had complete PRO data for all time intervals.

TABLE 5. Multivariable Analysis for Complication

N = 3117*	OR	95% CI	*P*
Any complication			
Age	1.006	0.99–1.02	.262
Surgery duration (min)	1.002	1.001–1.003	**.001**
Number of levels	1.21	1.08–1.35	**.001**
>3 Comorbidities	1.24	1.03–1.51	.024
Major complication			
Age	1.003	0.98–1.03	.823
Surgery duration (min)	1.001	0.99–1.002	.258
Number of levels	0.99	0.78–1.25	.963
>3 Comorbidities	1.35	0.92–2.003	.122
Minor complication			
Age	1.006	0.99–1.02	.264
Surgery duration (min)	1.002	1.001–1.003	**.001**
Number of levels	1.20	1.07–1.34	**.002**
>3 Comorbidities	1.24	1.02–1.51	.031

P < .003 considered significant; CI, confidence interval; OR, odds ratio; min, minutes. Boldface type indicates statistical significance.
Adjusted independent variables: age, body mass index (BMI), smoking, preoperative ambulation, American Society of Anesthesiologists (ASA) grade >2, diabetes mellitus (DM), atrial fibrillation (A-fib), cerebrovascular accident (CVA), chronic obstructive pulmonary disorder (COPD), ≥ 3 comorbidities, preoperative anti-coagulation use, number of operative levels, postoperative day-0 ambulation, estimated blood loss (EBL), and surgery duration.
*Three non-elderly patients have missing complication data.

TABLE 6. Multivariable Analysis for Complication in the Elderly

N = 3117*	OR	95% CI	P
Any complication			
Surgery duration (min)	1.002	1.00–1.004	.020
Number of Levels	1.20	0.99–1.46	.062
>3 Comorbidities	1.07	0.76–1.52	.678
Major complication			
Surgery duration (min)	0.99	0.99–1.002	.505
Number of levels	1.08	0.71–1.66	.714
>3 Comorbidities	1.55	0.79–3.04	.201
Minor complication			
Surgery duration (min)	1.003	1.001–1.005	.005
Number of levels	1.17	0.96–1.42	.127
>3 Comorbidities	1.03	0.73–1.45	.881

P < .003 considered significant; CI, confidence interval; OR, odds ratio; min, minutes.

Adjusted independent variables: body mass index (BMI), smoking, preoperative ambulation, American Society of Anesthesiologists (ASA) grade >2, diabetes mellitus (DM), atrial fibrillation (A-fib), cerebrovascular accident (CVA), chronic obstructive pulmonary disorder (COPD), ≥ 3 comorbidities, preoperative anticoagulation use, number of operative levels, postoperative day-0 ambulation, estimated blood loss (EBL), and surgery duration.

**Three non-elderly patients have missing complication data.*

the baseline PROMIS (Table 8). Conversely, controlling for all other covariates, the mean value of PROMIS decreases by a ratio of 0.99 (95%CI 00.99–1, $P < .001$), given one unit increase in BMI. There was no significant independent association between satisfaction and the adjusted covariates (Table 8).

DISCUSSION

The number of elderly requiring treatment for lumbar degenerative conditions continues to increase. Elderly patients have historically been considered high risk with high rates of complications.[1,5–7,9,10] These patients tended to have increased comorbidity with longer hospital stays and were less tolerant of increased blood loss and anesthetic time compared to younger patients.[1,7,9] In patients 80 years and older, lumbar spine surgery was associated with an increase of in-hospital and cumulative mortality.[9] Some series reported complication rates as high as 80% in patients 60 years and older.[5,7] However, other series reported more acceptable complication rates in the elderly, such as 30%[18] and 40%.[14] With evolving medical knowledge, technology, and a general improvement in awareness of a healthy lifestyle, we sought to elucidate further the relationship between chronological age and surgical risk, as well as postoperative long-term functional outcomes in patients who undergo elective lumbar surgeries.

TABLE 7. Multivariate Analysis for PRO (MI-GEE)

N = 3120	Exp (B)/ OR	95% CI	P
PROMIS			
Baseline PROMIS	1.01	1.01–1.01	**<.001**
BMI	1.00	0.99–1.00	**<.001**
History of COPD	0.95	0.92–0.98	**.002**
Independent preop ambulation	0.95	0.93–0.98	**<.001**
Minor complication	0.97	0.95–0.99	**.002**
Satisfaction			
BMI	0.98	0.96–1.00	.014
History of COPD	0.62	0.42–0.91	.016
Smoking	0.63	0.45–0.89	.009
Independent preop ambulation	0.74	0.55–0.98	.038

P < .003 considered significant; BMI, body mass index; CI, confidence interval; OR, odds ratio; Exp (B), exponential beta coefficient; COPD, chronic obstructive pulmonary disease; PROMIS, Patient Reported Outcomes Measurement Information System; Satisfaction, NASS satisfaction scale. Boldface type indicates statistical significance.

MI-GEE—Multiple imputation of PRO in conjunction with Generalized estimating equation.

Adjusted independent variables: age, baseline PROs (except satisfaction), body mass index (BMI), major complications, minor complications, smoking, preoperative ambulation, American Society of Anesthesiologists (ASA) grade >2, diabetes mellitus (DM), atrial fibrillation (A-fib), cerebrovascular accident (CVA), chronic obstructive pulmonary disorder (COPD), ≥ 3 comorbidities, preoperative anticoagulation use, number of operative levels, postoperative day-0 ambulation, estimated blood loss (EBL), and surgery duration.

TABLE 8. Multivariate Analysis for PRO in the Elderly (MI-GEE)

N = 3,120	Exp (B)	95% CI	*P*
PROMIS			
Baseline PROMIS	1.01	1.00–1.01	**<.001**
BMI	0.99	0.99–1.00	**<.001**
Independent preop ambulation	0.95	0.92–0.98	.003
History of COPD	0.95	0.91–0.99	.009
Satisfaction			
Major complication	0.46	0.19–1.12	.086
BMI	0.97	0.93–1.01	.100
History of COPD	0.64	0.36–1.14	.129
Minor complication	0.73	0.47–1.14	.167

$P < .003$ considered significant; BMI, body mass index; CI, confidence interval; Exp (B), exponential beta coefficient; COPD, chronic obstructive pulmonary disease; PROMIS, Patient Reported Outcomes Measurement Information System; Satisfaction, NASS satisfaction scale.

MI-GEE—multiple imputation of PRO in conjunction with generalized estimating equation.

Adjusted independent variables: baseline PROs (except satisfaction), body mass index (BMI), major complications, minor complications, smoking, preoperative ambulation, American Society of Anesthesiologists (ASA) grade >2, diabetes mellitus (DM), atrial fibrillation (A-fib), cerebrovascular accident (CVA), chronic obstructive pulmonary disorder (COPD), ≥ 3 comorbidities, preoperative anticoagulation use, number of operative levels, postoperative day-0 ambulation, estimated blood loss (EBL), and surgery duration.

As the focus has turned to comorbidity rather than age as a predictor for complications, many of the previous articles described an increase in complications and mortality as the number of comorbidities increased.[9,14] In fact, Smith and Hanigan[25] reported that patients with three or more comorbidities had a higher rate of complications. Raffo *et al.*[10] also demonstrated that comorbidity rather than age alone was linked to occurrences of major complications. Thus, comorbidity and frailty or reduced physiologic reserve, found more commonly in older patients, were more closely associated with adverse outcomes than age alone.[26] Although specific to multilevel (≥2 levels) fusions, our series demonstrated similar findings. Due to a more stringent *P*-value, comorbidity was not found to be a significant predictor of complications despite evidence to suggest some association.

In our series, age alone was not independently associated with increased odds of having any complication in patients undergoing multilevel TLIF. Instead, the risk of observing a complication may be more a product of surgery duration and the number of operative levels, supporting our initial hypothesis regarding physiologic reserve required to tolerate more extensive surgeries with longer anesthetic times.

Our series is the first large study to specifically evaluate the relationship between complications and patients' subsequent reported outcomes when undergoing more extensive lumbar fusions for nondeformity conditions. Overall, patients experienced significant improvement in all PROs. However, incurring a complication was associated with worse PROMIS following surgery. Within the elderly subgroup, complications had no significant association with PROs as the number of complications in the elderly subgroup likely posed a sample size issue for the regression. Rather, preoperative characteristics (BMI, preoperative PRO) were independently associated with outcomes in the entire cohort and within the elderly subgroup. Preoperative independent ambulation status was independently associated with improved PROMIS in the whole cohort. We demonstrated that patients' preoperative function as measured by both preop ambulation status and preop baseline PRO was highly associated with their long-term PROs. The relationship between postoperative morbidity and frailty has been well established, with preoperative ambulation being a component in the frailty score.[27,28] Additionally, there is a growing body of evidence suggesting prolonged preoperative symptom duration was strongly correlated with worse outcomes and less improvement in pain and disability.[29,30] Prolonged preoperative symptom duration may be associated with worsening of ambulation and preoperative functional status. With our findings, we demonstrated that optimizing patients' preoperative ambulation and functional status may improve postoperative functional outcomes. Conversely, it begs the question whether prolonged preoperative symptom duration, which might lead to worsening ambulation and functional status, may lead to worse postoperative functional outcomes.

Our study highlights the continual evolution of chronologic age and its effect on spine surgery outcomes. Age alone was not independently associated with incurring a complication, nor was it associated with developing worse clinical outcomes. These findings underscore the importance of looking beyond age as an absolute number. Instead, age should be evaluated based on biologic, physiologic, and functional status. This also likely underscores the benefit of timely and early surgical intervention at a time when the patients are still maintaining a reasonable preoperative functional and ambulation status.

Limitations

These results drawn from a large, multicenter registry database have several limitations and thus should be interpreted with those limitations in mind.[31–33] As with all registry databases, we are limited to the data collected and recorded set forth by the MSSIC administers. Therefore, the lack of other potentially useful or confounding variables like minimally invasive *versus* open approach or uncollected emergency department visits may limit the granularity of our data. Although many of the data fields are prospectively collected with a predefined data dictionary, many aspects, including the analyses, were done retrospectively, thus subject to potential bias. Additionally, results of any singular registry study should be seen only as associations rather than causation and used as hypothesis-generating for future investigation with improved rigor.

With large sample sizes achieved using registry data, statistical significance can be attained easily without demonstrating clinical significance. We attempted to account for this bias by adhering to a more stringent *P* value threshold utilizing the Bonferroni correction. However, despite a more stringent *P* value, there remain predictors in our multivariate analyses, which demonstrated an increased odds ratio without a likely clinically meaningful risk.

As with most registry studies, ours, too, was subject to missing data. Missing covariate and outcome data were handled using multiple imputations with the MAR assumption.[34] Multiple imputations are commonly used and a valid means of controlling this type of data yet, still at risk for biased or falsely precise results.[35] PROs that failed the MAR assumption were not included in the GEE. Failing the MAR assumption means the probability of the missing data is related to the values of the missing data itself. In this study, patients with missing PROs may be more likely to have worse outcomes or better outcomes on average than patients without missing PROs. PROMIS and satisfaction are the only two PROs which satisfied the MAR assumption and used in the GEE. For the other PROs, missing outcome data could not be easily overcome by statistical methods. Rather, it is an inherent methodological limitation for registry studies.

CONCLUSION

This analysis of a large, prospective, multicenter registry demonstrated that older age was not independently associated with increased risk of complications or worsening clinical outcomes following multilevel transforaminal lumbar interbody fusion. Therefore, age alone may not be an appropriate surrogate for evaluating risk in patients undergoing a multilevel lumbar fusion. Furthermore, baseline independent ambulation and function were independently associated with better clinical outcomes and should be considered during the preoperative counseling of any surgical candidate.

Disclaimer Statement: Although Blue Cross Blue Shield of Michigan and MSSIC work collaboratively, the opinions, beliefs, and viewpoints expressed by the author do not necessarily reflect the opinions, beliefs, and viewpoints of BCBSM or any of its employees.

➢ Key Points

- ❑ This retrospective review of a prospectively maintained multi-institutional database was performed to evaluate and compare postoperative complications and patient-reported outcomes among the elderly (≥70-yo) who underwent multilevel transforaminal lumbar interbody fusion for degenerative spinal conditions.
- ❑ GEE was used to identify predictors of complications and PROs for the whole cohort and within the elderly cohort.
- ❑ Age was not a predictor of complications nor predictive of functional outcomes in patients who underwent multilevel TLIF. Chronologic age should not be a primary determining factor when determining selection for surgery.
- ❑ Age should not be a deterrent when discussing surgical options.
- ❑ Rather, attention should focus on a thorough evaluation and optimization of comorbidity as well as discussing the association of preoperative independent ambulation and baseline functional status and postoperative outcomes.

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