

Clinical Study

Surgical risk stratification based on preoperative risk factors in adult spinal deformity

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Abstract

BACKGROUND CONTEXT: Corrective surgery for adult spinal deformity (ASD) improves health-related quality of life but has high complication rates. Predicting a patient's risk of perioperative and late postoperative complications is difficult, although several potential risk factors have been reported.

PURPOSE: To establish an accurate, ASD-specific model for predicting the risk of postoperative complications, based on baseline demographic, radiographic, and surgical invasiveness data in a retrospective case series.

STUDY DESIGN/SETTING: Multicentered retrospective review and the surgical risk stratification.

PATIENT SAMPLE: One hundred fifty-one surgically treated ASD at our hospital for risk analysis and model building and 89 surgically treated ASD at 2 other our hospitals for model validation.

OUTCOME MEASURES: HRQoL measures and surgical complications.

METHODS: We analyzed demographic and medical data, including complications, for 151 adults with ASD who underwent surgery at our hospital and were followed for at least 2 years. Each surgical risk factor identified by univariate analyses was assigned a value based on its odds ratio, and the values of all risk factors were summed to obtain a surgical risk score (range 0–20). We stratified risk scores into grades (A–D) and analyzed their correlations with complications. We validated the model using data from 89 patients who underwent ASD surgery at two other hospitals.

RESULTS: Complications developed in 48% of the patients in the model-building cohort. Univariate analyses identified 10 demographic, physical, and surgical risk indicators, with odds ratios from 5.4 to 1.4, for complications. Our risk-grading system showed good calibration and discrimination

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in the validation cohort. The complication rate increased with and correlated well with the risk grade using receiver operating characteristic curves.

CONCLUSIONS: This simple, ASD-specific model uses readily accessible indicators to predict a patient's risk of perioperative and postoperative complications and can help surgeons adjust treatment strategies for best outcomes in high-risk patients. © 2018 Elsevier Inc. All rights reserved.

Keywords: Adult spinal deformity; Complication; Predictive model; Risk stratification; Scoliosis; Corrective spine surgery

Introduction

Surgery to correct major deformities in adult spinal deformity (ASD) is technically demanding [1–5]. Although ASD surgery provides favorable outcomes, it often requires extensive dissection, osteotomy, blood transfusion, and extended hospitalization, and thus has a substantial risk of major complications and poor outcomes in both the perioperative and late postoperative periods [1–10].

Surgical outcomes and complications do not depend solely on the surgeon's abilities, and studies have attempted to define risk factors for postoperative complications. Potential risk factors for surgical complications include advanced age, obesity, malnutrition, anemia, comorbidities, a large sagittal malalignment, a large degree of correction, three-column osteotomy, low bone mineral density (BMD), previous spine surgery, more levels of fusion, and a lower lowest instrumented vertebra (LIV) level [1–12]. Preventing late complications is especially important, because they usually require revision surgery [10].

To minimize complications and optimize outcomes, surgeons need ways to stratify surgical risk and identify cases that are likely to develop postoperative complications, especially when planning treatment strategies. The POSSUM audit system (Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity) is designed for easy and rapid use, is widely recognized in both elective and emergency settings, and is applicable in a heterogeneous population [11–13]. However, there are few studies of quantitative risk scoring for complications based on ASD-specific risk variables. This study aimed to analyze surgical complications in an ASD cohort and to establish a simple, accurate, ASD-specific grading system that stratifies the risk of postoperative complications after surgery for ASD.

Materials and methods

This study was approved by the review board at our institution, and all subjects were consented and agreed with its inclusion. This study used STROBE statement to assess observational data. No funding was received for this study.

Patient population

This study was approved by our institution's review board. We retrospectively reviewed charts and radiographs for 240 consecutive patients who underwent surgery for ASD in 3 academic hospitals between 2010 and 2015. This

number includes 151 consecutive patients treated at our hospital whose data were used to build the model, and 89 consecutive patients from 2 unrelated hospitals whose data were used to validate the model.

Inclusion and exclusion criteria

Subjects were at least 21 years old at the index surgery and had a spinal deformity defined by a Cobb angle $\geq 20^\circ$, a C7 sagittal vertical axis (C7SVA) ≥ 5 cm, or pelvic tilt (PT) $\geq 25^\circ$. We included patients with at least five fused vertebral levels, segmental pedicle-screw fixation from the upper-instrumented vertebra (UIV) to the LIV, and complete 2-year follow-up data. Patients were excluded if they lacked appropriate radiographs or had a syndromic, neuromuscular, or other pathologic condition.

Collection of radiographic, health-related quality of life (HRQoL), and other data

We collected demographic and clinical data for each patient, including age, gender, body mass index (BMI), BMD, and any history of spine surgery. We also assessed comorbidities, including a history of diabetes mellitus, cancer, congestive heart failure, hypertension requiring medication, cerebrovascular accident with or without neurologic deficit, chronic obstructive pulmonary disease or other chronic pulmonary disease, conjunctive tissue disease, percutaneous coronary intervention, prior cardiac surgery, angina, transient ischemic attack, myocardial infarction, peripheral vascular disease, impaired sensorium, dementia, kidney disease, leukemia, lymphoma, liver disease, immune deficiency virus infection, or acquired immunodeficiency syndrome. Frailty and comorbidities were assessed using the modified frailty index (mFI) and the Charlson comorbidity index (CCI) [14,15].

We collected the following surgical data: the Schwab-SRS ASD classification and subcategory [16], application of pedicle subtraction osteotomy (PSO), UIV and LIV levels, and number of fused vertebrae. BMD was calculated from dual-X ray absorptiometry scores of the right femoral neck. Radiographic data, assessed from full-length standing whole-spine radiographs obtained at baseline and at the 6-week and 2-year follow-up examinations, included the following: Cobb angle, C7SVA, T4–T12 thoracic kyphosis, T12–sacrum lumbar lordosis (LL), sacral slope, pelvic tilt (PT), pelvic incidence (PI), T1 pelvic angle, and spinopelvic alignment (PI–LL). As a surrogate for HRQoL, we

used the Oswestry Disability Index (ODI) and Scoliosis Research Society-22r questionnaire (SRS-22r) results at baseline and at the 2-year follow-up.

Of 249 candidates, 240 subjects had complete demographic and radiographic data sufficient to capture any postoperative complications, and thus were included in the study cohort. The remaining nine candidates were lost during follow-up, including two who died for reasons unrelated to the surgery (cancer and unknown reason), and were excluded from the cohort.

Inclusion of complications

We included all intraoperative and postoperative complications, whether recorded in patients' charts or found in radiographs, that developed within 2 years of the operation. Complications were categorized as neurologic, implant-related (including proximal and distal junctional kyphosis, rod breakage, pseudoarthrosis, implant dislodgement, and screw breakage), surgical-site infection, other infection (urinary tract and others), excessive bleeding (>2,000 mL), delirium, cardiopulmonary (hemodynamic instability, myocardial infarction, deep venous thrombosis, pulmonary embolism, thoracic atelectasis, congestive heart failure, and others), gastrointestinal (ileus, cholecystitis), and renal (acute renal failure), based on categories used in previous studies [3,17]. The severity of the complication was categorized by Clavien–Dindo classification [18].

Data preparation

Subjects were categorized according to whether they had any surgical complication within 2 years of the operation, or were free of complications. We investigated relationships between patient demographics, spinal alignment, surgical factors, and the development of complications by univariate logistic regression analysis using the data of the model-building cohort. The predictor variables were age, gender, BMI, BMD, mFI, CCI, history of diabetes mellitus, UIV and LIV levels, number of levels involved, use of PSO, C7SVA, PI–LL, and Cobb angle. We created categories based on clinical importance and on the results of unpaired *t* tests and Tukey's honest significant difference test or the Wilcoxon ranked test where appropriate, as follows: age ≤ 70 years or > 70 years; BMD T-score ≤ -1.5 or > -1.5; mFI = 0 (robust), mFI < 0.21 (pre-frail), or mFI > 0.21 (frail); UIV T1–T6 (proximal thoracic) or T9–T11 (lower thoracic, LT); LIV L5 and above or pelvis; Cobb angle < 70° or > 70°; C7SVA < 95 mm, 95–149 mm, or > 150 mm; and PT < 20 or ≥ 20.

Analysis of risks for major complications in the model-building cohort

We calculated overall summary statistics including means and standard deviations for continuous variables, and frequencies and percentages for categorical variables. After descriptive analysis, we analyzed associations

between potential risk factors and major complications by univariate comparison. Potential risk variables were categorized and analyzed by univariate logistic regression.

Building and validation of a model for predicting major complications

Based on the predictors obtained from univariate analysis, we designed a risk-stratification score as a simplified algorithm, to predict the incidence of 2-year surgical complication. When there are two variables with a correlation of 0.5 or more, one variable should be omitted to avoid multicollinearity [19]. Thus, although we identified 10 risk indicators, we included 9 in our risk-stratification model. We first established values for each risk indicator by rounding the OR obtained in the univariate analysis to the nearest whole integer (range 0–5). Next, the values for all applicable risk indicators were added together to establish the surgical risk-stratification score (range 0–20). We first evaluated the discriminative ability of this risk-stratification score for model-building based on the area under the receiver operating characteristic (ROC) curve (AUROC), and then assessed the risk-stratification score in our validation cohort [20]. The risk score was used to stratify risk into risk grade A (risk score 0–1), B (risk score 2–6), C (risk score 7–11), and D (risk score > 12), which had the highest risk. We analyzed correlations between the risk grade and complication rate and validated the model with 89 patients treated surgically for ASD at 2 hospitals unrelated to our institution.

Statistical analysis

Differences between the complications group and complication-free group were compared by unpaired *t* test, chi-square test, Tukey's honest significant difference test, and Fisher's exact test as appropriate. Changes between baseline and postoperative values were analyzed by paired *t* test. Potential risk variables were analyzed by univariate logistic regression. A smooth nonparametric calibration line of the distribution of the observed complication rate for each risk-stratification score was created with the quadratic slope algorithm that best fit the data points with a 95% confidence interval (CI). The regression was computed using the least squares method and a constant [20,21].

A *p* value less than .05 with a CI of 95% was considered statistically significant, and an AUROC ≥ 0.750 was considered a good predictive accuracy. All analyses were performed using the Statistical Package for the Social Sciences (SPSS statistics version 25.0, SPSS modeler version 17, IBM Corp., Armonk, NY).

Results

Patient characteristics in the model-building, validation, and total cohorts

Patient characteristics are shown in Table 1. The mean C7SVA and PI–LL indicated severe sagittal deformity in both

Table 1
Patient characteristics

| Variables | Total | Building sample | Validation sample |
|---------------------------------------|-------------|-----------------|-------------------|
| Number of patients | 240 | 151 | 89 |
| Age (y) ^a | 58.4 ± 16.7 | 54.1 ± 18.5 | 65.7 ± 9.6 |
| Female (no. [%]) | 220 (92) | 136 (90) | 84 (94) |
| BMI (kg/m ²) [*] | 21.6 ± 3.6 | 21.4 ± 3.6 | 22.0 ± 3.7 |
| Diabetes (no. [%]) | 22 (9%) | 11 (7%) | 11 (13%) |
| BMD (T-score) [*] | -1.0 ± 0.9 | -0.9 ± 1.0 | -1.0 ± 0.8 |
| Frailty (no. [%]) | | | |
| Robust | 141 (59) | 99 (66) | 42 (47) |
| Pre frail | 79 (33) | 42 (28) | 37 (42) |
| Frail | 20 (8) | 10 (7) | 10 (11) |
| Number of levels fused [*] | 9.6 ± 2.8 | 9.0 ± 2.7 | 10.6 ± 2.7 |
| PSO (no. [%]) | 30 (13) | 15 (10) | 15 (17) |
| Revision (no. [%]) | 16 (7) | 8 (5) | 8 (9) |
| Schwab-SRS classification (no. [%]) | | | |
| Type T | 31 (13) | 29 (19) | 2 (2) |
| Type D | 74 (31) | 40 (27) | 34 (38) |
| Type L | 69 (29) | 43 (29) | 26 (29) |
| Type N | 66 (28) | 39 (26) | 27 (30) |
| Spinal alignment [*] | | | |
| C7SVA (cm) | 8.9 ± 6.4 | 8.0 ± 6.3 | 10.0 ± 6.2 |
| PI-LL (°) | 38.2 ± 22.9 | 37.9 ± 23.3 | 38.6 ± 22.6 |
| PT (°) | 32.5 ± 12.1 | 33.1 ± 12.3 | 31.8 ± 12.0 |
| TPA (°) | 29.2 ± 15.4 | 28.4 ± 15.7 | 30.4 ± 15.1 |

BMI, body mass index; BMD, bone mineral density; mFI, modified frailty index; PSO, pedicle subtraction osteotomy; C7SVA, C7 sagittal vertical axis; PI-LL, spinopelvic alignment; PT, pelvic tilt; TPA, T1 pelvic angle.

Percentage in bracket.
* Mean ± standard deviation.

the model-building and validation cohort. Of 151 patients in the model-building cohort, 72 (48%) developed complications within 2 years of the operation. By Clavien–Dindo grade, the complications were grade 1 in 37 patients (51%), grade 2 in

Table 2
Clavien–Dindo classification of ASD surgical complications

| Grade | Total | Building sample | Validation sample |
|-------|------------------|-----------------|-------------------|
| 1 | 57 (53% [24%]) | 37 (51% [25%]) | 20 (59% [23%]) |
| 2 | 11 (11% [5%]) | 8 (11% [5%]) | 3 (9% [3%]) |
| 3a | 6 (6% [3%]) | 5 (7% [3%]) | 1 (3% [1%]) |
| 3b | 24 (22% [10%]) | 15 (21% [10%]) | 9 (26% [10%]) |
| 4a | 8 (7% [3%]) | 7 (10% [4%]) | 1 (3% [1%]) |
| 4b | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 |
| Total | 106 (100% [44%]) | 72 (100% [48%]) | 34 (100% [38%]) |

Complication values are given as numbers and percentages.

8 (11%), grade 3 in 20 (28%), and grade 4a in 7 (10%; Table 2). A similar distribution of surgical complications was observed in the validation cohort. Neither the model-building nor validation cohorts included any mortality or grade 4b complications (life-threatening complications, including central nervous system (CNS) complications, with multiorgan dysfunction requiring IC/ICU management) [18]. Implant-related complications were the most common, affecting 43 patients (28% of the total cohort) and including 26 cases of proximal junction kyphosis (PJK) and 15 with rod breakage, followed by neurologic complications, affecting 20 patients (13% of the total cohort) and including 12 with partial motor deficits and 8 with sensory deficits.

Clinical outcomes in the complication and complication-free groups in the model-building cohort

Patients who developed complications nevertheless experienced significant improvements in HRQoL, as measured by the ODI (p<.01) and SRS22r (total score and all subdomains; p<.01) at the 2-year follow-up (Table 3). However, their 2-year SRS22 scores were worse than those

Table 3
HRQoL in patients with and without postoperative complications

| | Group | Baseline | p Value | 2-Year follow-up | p Value | Δ Value | p Value |
|----------------|-------|-------------|---------|------------------|---------|-------------|---------|
| ODI, % | NC | 51.6 ± 16.1 | .90 | 27.9 ± 11.4 | .24 | 23.4 ± 13.0 | .79 |
| | C | 51.2 ± 16.3 | | 30.7 ± 15.4 | | 22.7 ± 13.8 | |
| SRS22 Function | NC | 3.2 ± 0.9 | .01* | 3.9 ± 0.6 | <.001* | 0.6 ± 0.7 | .79 |
| | C | 2.9 ± 0.9 | | 3.5 ± 0.8 | | 0.5 ± 0.7 | |
| Pain | N | 3.2 ± 0.9 | .05 | 4.0 ± 0.7 | <.001* | 0.9 ± 0.7 | .45 |
| | C | 2.9 ± 0.9 | | 3.6 ± 0.9 | | 0.7 ± 0.9 | |
| Self-image | NC | 2.3 ± 0.7 | .44 | 3.8 ± 0.7 | <.001* | 1.5 ± 0.7 | .05* |
| | C | 2.2 ± 0.7 | | 3.5 ± 0.8 | | 1.2 ± 0.9 | |
| Mental health | NC | 2.9 ± 0.9 | .16 | 3.9 ± 0.7 | .003* | 1.1 ± 1.0 | .05* |
| | C | 2.7 ± 0.8 | | 3.6 ± 0.9 | | 0.8 ± 1.0 | |
| Satisfaction | NC | | | 4.0 ± 0.8 | .003* | | |
| | C | | | 3.7 ± 0.6 | | | |
| Subtotal | NC | 2.9 ± 0.7 | .05 | 3.9 ± 0.6 | <.001* | 1.1 ± 0.7 | .06 |
| | C | 2.7 ± 0.6 | | 3.5 ± 0.7 | | 0.8 ± 0.7 | |

NC, no complications; C, complications.
Δ, Values from 2-year follow-up minus baseline values.
Values are mean ± standard deviation.
p Values are for the comparison between NC and C groups.
* Statistically significant.

of complication-free patients despite similar baseline HRQoLs in the two groups (Table 3). Significantly lower delta value (change from baseline) of SRS22 self-image, mental health and tendency for lower delta value for SRS22 subtotal score was found in C group though not statistically significant (Table 3).

Risk analysis for major complications in the model-building cohort

Comparisons of demographics and radiographic data between the complications and complication-free groups using a parallel coordination model indicated different distributions of age, frailty, CCI, C7SVA, and PI–LL (Fig. 1A). These variables also deteriorated with the Clavien–Dindo grade (Fig. 1B). Univariate analyses revealed the following significant risk factors for major complications, in the order of the odds ratio (OR): frailty (OR 5.4),

BMD (3.2), PSO (2.4), C7SVA (2.4), LIV at pelvis (2.3), Cobb angle (1.7), PI–LL (1.6), age (1.5), diabetes (1.4), and male gender (1.4; Table 4).

Building of a model to predict surgical complications

We created a surgical risk grading system with 9 of the 10 risk variables identified in the univariate analysis, namely frailty, BMD, history of diabetes, gender (male), PSO, LIV (pelvis), age, C7SVA, and Cobb angle. The 10th risk variable, PI–LL, was omitted due to significant multicollinearity between PI–LL and C7SVA or PSO ($r=0.688$ and 0.597 , respectively). Each risk variable was weighted from 0 to 5 based on its OR determined by univariate analysis, as described in Materials and Methods section, and the surgical risk score was determined as the sum (range 0–20) of the values of the risk variables. The quadratic slope algorithm that

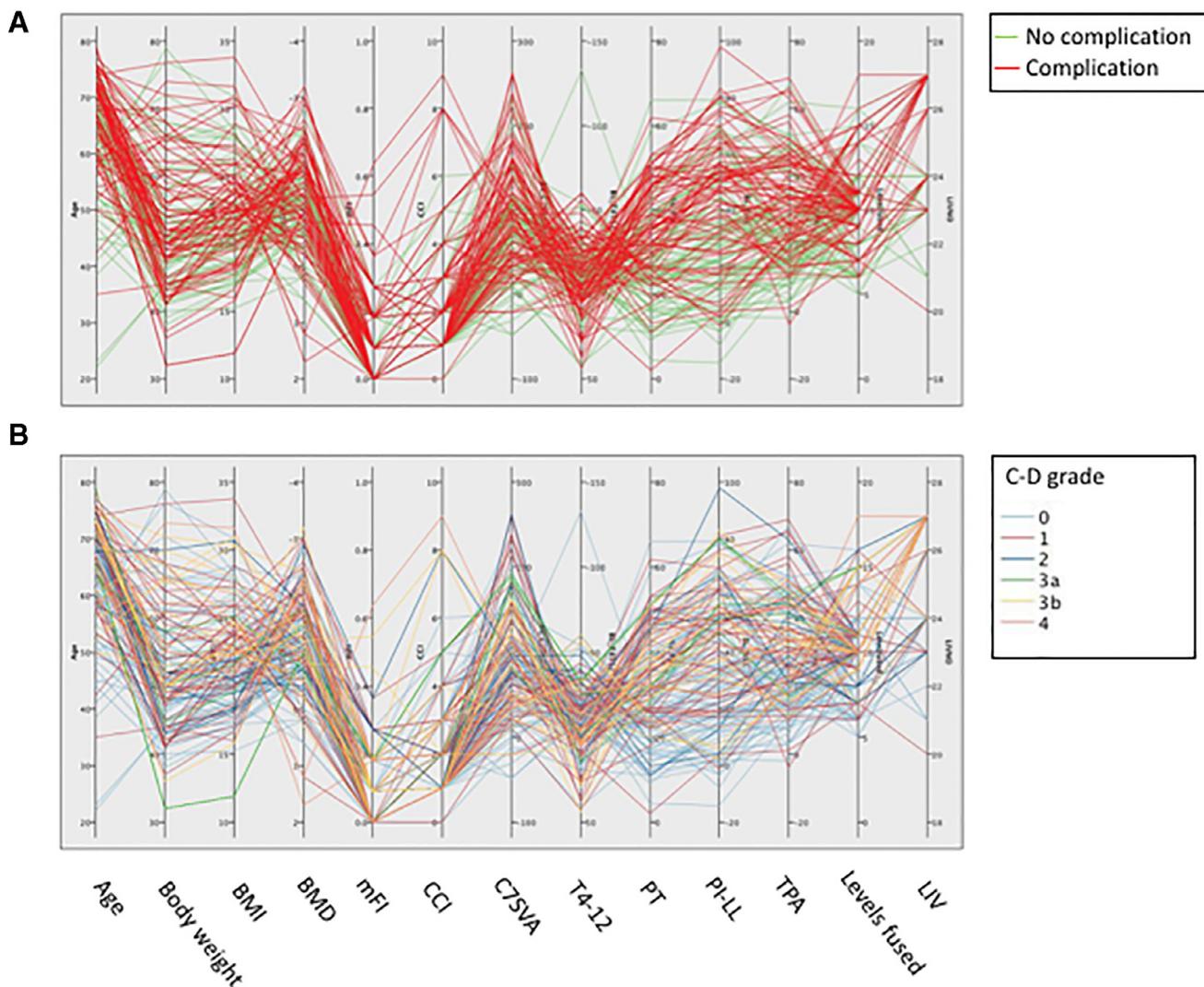


Fig. 1. Distributions of demographic and radiographic variables in the model-building cohort using parallel coordination (A) for the presence (red line) or absence (green line) of surgical complications, and (B) stratified by Clavien–Dindo classification in the model-building cohort. BMI, body mass index; BMD, bone mineral density, mFI, modified frailty index; CCI, Charlson comorbidity index; C7SVA, C7 sagittal vertical axis; T4–T12, thoracic kyphosis; PT, pelvic tilt, PI–LL, spinopelvic alignment; TPA, T1 pelvic angle; LIV, lowest instrumented vertebra.

Table 4
Univariate logistic regression analysis of postoperative complications in the model-building cohort

| Variable | Odds ratio | p Value | 95% CI |
|----------------------------------------------|------------|---------|----------|
| Age | | | |
| ≤70 years | Reference | | |
| >70 years | 1.5 | .18 | 0.8–2.9 |
| Gender | | | |
| Female | Reference | | |
| Male | 1.4 | .12 | 0.8–2.9 |
| BMI | | | |
| <18.5 kg/m ² | 1.1 | .86 | 0.7–32.5 |
| 18.5–24.9 kg/m ² | Reference | | |
| >25 kg/m ² | 1.5 | .27 | 0.8–3.3 |
| BMD | | | |
| T-score>−1.5 | Reference | | |
| T-score≤−1.5 | 3.2 | .01* | 1.6–6.4 |
| History of diabetes mellitus | | | |
| No | Reference | | |
| Yes | 1.4 | .04* | 1.0–4.7 |
| Frailty | | | |
| Robust | Reference | | |
| Pre frail | 2.4 | .01* | 1.5–5.8 |
| Frail | 5.4 | .01* | 2.7–22.3 |
| Comorbidities | | | |
| CCI=0, 1 | Reference | | |
| CCI=2, 3 | 1.6 | .16 | 0.8–3.1 |
| CCI>4 | 2.5 | .11 | 0.9–6.6 |
| Sagittal alignment | | | |
| C7SVA<95 mm | Reference | | |
| C7SVA=95–149 mm | 1.4 | .01* | 1.0–1.9 |
| C7SVA≥150 mm | 2.4 | .01* | 1.4–4.9 |
| PT<20° | reference | | |
| PT=20–30° | 1.1 | .33 | 0.6–1.9 |
| PT>30° | 1.7 | .29 | 0.8–4.1 |
| PI–LL<10° | Reference | | |
| PI–LL=10–20° | 1.3 | .39 | 0.7–2.7 |
| PI–LL>20° | 1.6 | .04* | 1.0–7.9 |
| Magnitude of major curve | | | |
| Cobb angle≤70° | Reference | | |
| Cobb angle>70° | 1.7 | .04* | 1.0–3.9 |
| Type of surgery | | | |
| Primary surgery | Reference | | |
| Revision surgery | 1.3 | .83 | 0.4–5.0 |
| Level fused | | | |
| ≤10 levels | Reference | | |
| >10 levels | 1.8 | .48 | 0.4–3.5 |
| UIV level | | | |
| UT | Reference | | |
| LT | 1.4 | .43 | 0.6–2.8 |
| LIV level | | | |
| L5 and above | reference | | |
| Pelvis | 2.3 | .01* | 1.2–4.3 |
| Application of pedicle subtraction osteotomy | | | |
| No | Reference | | |
| Yes | 2.4 | .02* | 1.2–7.5 |

BMI, body mass index; BMD, bone mineral density; mFI, modified frailty index; CCI, Charlson comorbidity index; C7SVA, C7 sagittal vertical axis; PT, pelvic tilt; PI–LL, spinopelvic alignment; UIV, upper instrumented vertebra; UT, upper thoracic; LT, lower thoracic; LIV, lowest instrumented vertebra.

* Statistically significant.

best fit the data points with a 95% CI showed excellent correlation between the surgical risk-stratification score and the actual development of surgical complications,

using the following regression model: $y=10.29 + 7.94x - 0.13x^2$ and $r^2=0.941$ (Fig. 2A). This surgical risk-stratification score also correlated well with complications with a Clavien–Dindo grade greater than 2 in the model-building cohort, using the following regression model: $y=6.77 + 0.57x + 0.32x^2$, and $r^2=0.824$ (Fig. 2B). The risk for postoperative complications was stratified into grades based on surgical risk scores (Table 5); of the model-building cohort, 28% of the patients were classified as grade A, 44% as grade B, 25% as grade C, and 3% as grade D. The distribution was similar in the validation cohort (18% grade A, 38% grade B, 38% grade C, and 4% grade D; $p=.14$). Surgical complications increased exponentially as the risk grade worsened, and correlation coefficient analysis confirmed that there was an excellent correlation between the risk grade and the incidence of complications ($r^2=0.969$) or the incidence of complications with a Clavien–Dindo grade greater than 2 ($r^2=0.949$; Fig. 3A and B). The risk-stratification score and risk grade had good accuracy for predicting the incidence of surgical complications, with an AUROC of 0.815 (95% CI 0.722–0.907) for the risk-stratification score and 0.767 (95% CI 0.667–0.867) for the risk grade (Fig. 3C). In the model-building cohort, the AUROC of the risk-stratification score and the risk grade for surgical complications with a severity greater than Clavien–Dindo grade 2 showed acceptable model fit, with an AUROC of 0.709 (95% CI 0.577–0.840) for the risk-stratification score, and an AUROC of 0.724 (95% CI 0.583–0.863) for the risk grade (Fig. 3D).

Validation of our model for predicting surgical complications

We assessed our grading system for surgical risk using an 89-patient validation cohort from hospitals not associated with our institution. The surgical risk grade showed excellent correlation with the incidence of surgical complications ($r^2=0.971$) in the validation cohort (Fig. 4A). The surgical risk score and grade showed good accuracy for predicting the incidence of overall surgical complications, with an AUROC of 0.751 (95% CI 0.665–0.821) and 0.756 (95% CI 0.669–0.824), respectively (Fig. 4B). In addition, the surgical risk grade showed excellent correlation with the incidence of complications with a Clavien–Dindo grade greater than 2 ($r^2=0.903$) or greater than 3 ($r^2=0.938$) in the validation cohort (Fig. 4C and D).

Discussion

As populations in developed countries continue to age, the number of people with symptomatic spinal deformities requiring reconstructive spine surgery will increase [22]. Clinical outcomes improve significantly for ASD patients treated surgically, but not for those treated

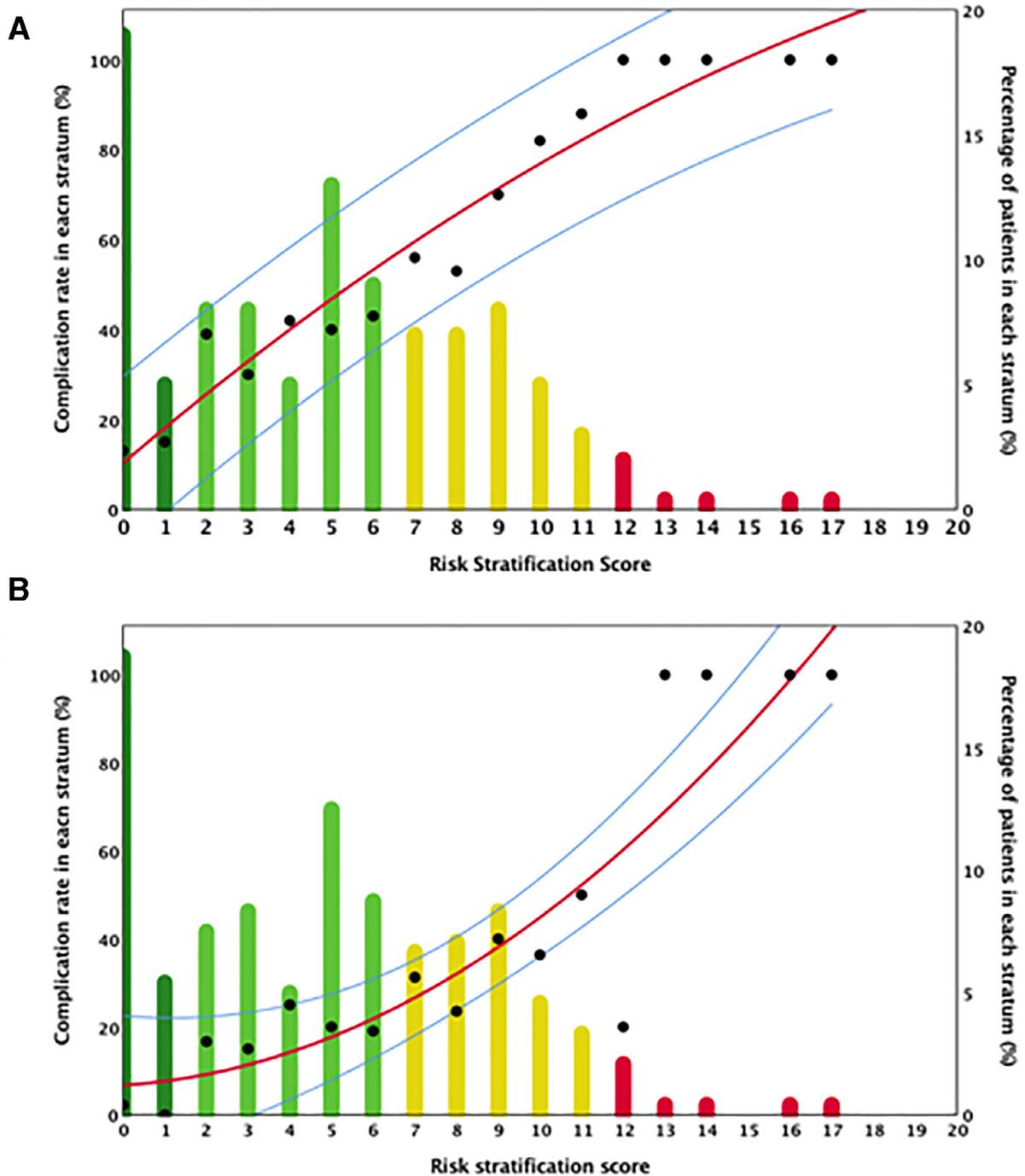


Fig. 2. Distribution of risk-stratification scores in the model-building cohort (bars) relative to the observed complication rate for each score. The smoothed line was created using the quadratic slope algorithm that best fit the data points with a 95% confidence interval (red line). (A) Distribution of surgical complications in the model-building cohort, stratified by risk-stratification score. Regression model: $y=10.29 + 7.94x - 0.13x^2$ and $r^2=0.941$. (B) Distribution of surgical complications with a Clavien–Dindo grade greater than 2 in the model-building cohort, stratified by risk-stratification score. Regression model: $y=6.77 + 0.57x + 0.32x^2$ and $r^2=0.824$.

conservatively [23]. The rate of major complications within 2 years of ASD surgery is reported to be 15–78% [1–11]. In the present study, 44% of surgically treated ASD patients developed complications. Simon et al. reported a 20% rate for perioperative complications and 45% rate for late complications (occurring at least

30 days after surgery) in elderly de novo scoliosis patients [4]; most late postoperative complications were implant-related (such as PJK) and required revision surgery due to deteriorating clinical outcomes [4]. Glassman et al. described an adverse effect of major surgical complications on ASD outcomes, as evidenced by

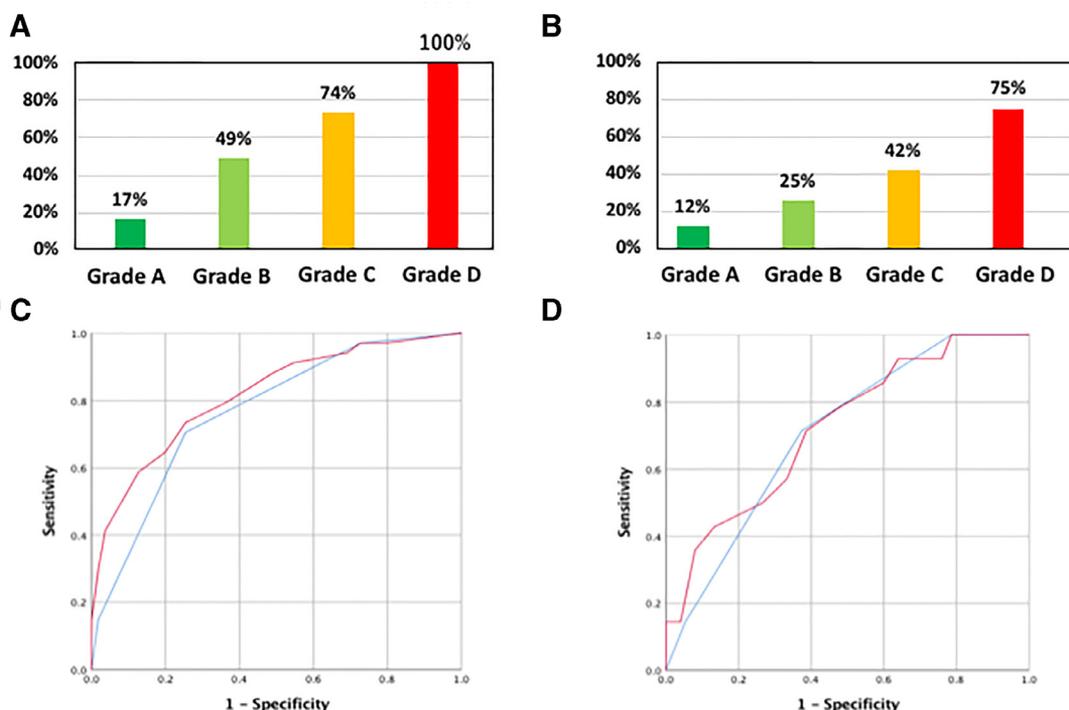


Fig. 3. Distribution of surgical complications in the model-building cohort. (A) All surgical complications stratified by risk grade (grades A–D); $r^2=0.969$; and (B) complications with a Clavien–Dindo grade greater than 2, stratified by risk grade (grades A–D); $r^2=0.949$. (C) Receiver operating characteristic (ROC) curve for all surgical complications, for the risk-stratification score (solid line) and grade (dotted line), with an area under the curve (AUROC) of 0.815 (95% CI 0.7220–0.907) for the risk-stratification score and an AUROC of 0.767 (95% CI 0.6670–0.867) for the risk grade. (D) ROC curve for complications with a Clavien–Dindo grade greater than 2, for the risk-stratification score (solid line) and grade (dotted line), with an AUROC of 0.709 (95% CI 0.5770–0.840) for the risk-stratification score and an AUROC of 0.724 (95% CI 0.5830–0.863) for the risk grade.

deteriorating SF-12 scores [24]. These reports align with our findings. Although the postoperative HRQoLs improved significantly even for patients who developed complications, HRQoLs at the 2-year follow-up were significantly better for the complication-free patients (Table 3). Therefore, minimizing the surgical complications improves the overall surgical outcomes for ASD.

Several predictive models have recently been reported for ASD [5,8,25,26]. Buchlak et al. established the Seattle Spine Score as a tool for predicting the 30-day complication risk after ASD surgery, based on data from 136 surgically treated ASD patients [25]. This predictive model had an acceptable model fit (AUROC 0.712) in an internal validation cohort but was based on surgical results from a single facility, in which case the patients may have received similar surgical and postoperative care, perhaps from a single surgeon. This model still requires external validation to confirm its versatility. Sheer et al. recently described a model for predicting perioperative complications in ASD surgery; this model uses a decision-making tree [26] and showed reasonable accuracy (87%) for predicting perioperative complications. Although both models focus on the perioperative period, the complications most likely to require revision surgery tend to occur later, after discharge [25,26]. Another model described by Yagi et al. uses a decision-making tree to predict proximal junction failure after

Table 5
Risk-grading system for surgical complications in ASD

| Risk indicator | | Score* | Risk grade |
|----------------|--------------|--------|---------------------------|
| Age | <70 years | 0 | Total score: 0, 1 Grade A |
| | 70–75 years | 1 | |
| | >75 years | 2 | |
| Gender | Female | 0 | |
| | Male | 1 | |
| BMD | T-score>−1.5 | 0 | Total score: 2-6 Grade B |
| | T-score<−1.5 | 3 | |
| Diabetes | No | 0 | |
| | Yes | 1 | |
| Frailty | Robust | 0 | Total score: 7-11 Grade C |
| | Pre frail | 2 | |
| | Frail | 5 | |
| C7SVA | <95 mm | 0 | |
| | 95–149 mm | 1 | |
| | ≥150 mm | 2 | |
| Cobb angle | ≤70° | 0 | Total score: >12 Grade D |
| | >70° | 2 | |
| LIV | L5 and above | 0 | |
| | Pelvis | 2 | |
| 3-CO | No | 0 | |
| | Yes | 2 | |

BMD, bone mineral density; mFI, Modified Frailty Index; C7SVA, C7 sagittal vertical axis; LIV, lower instrumented vertebra.

* Risk score is determined by adding the values for all applicable risk indicators (center column).

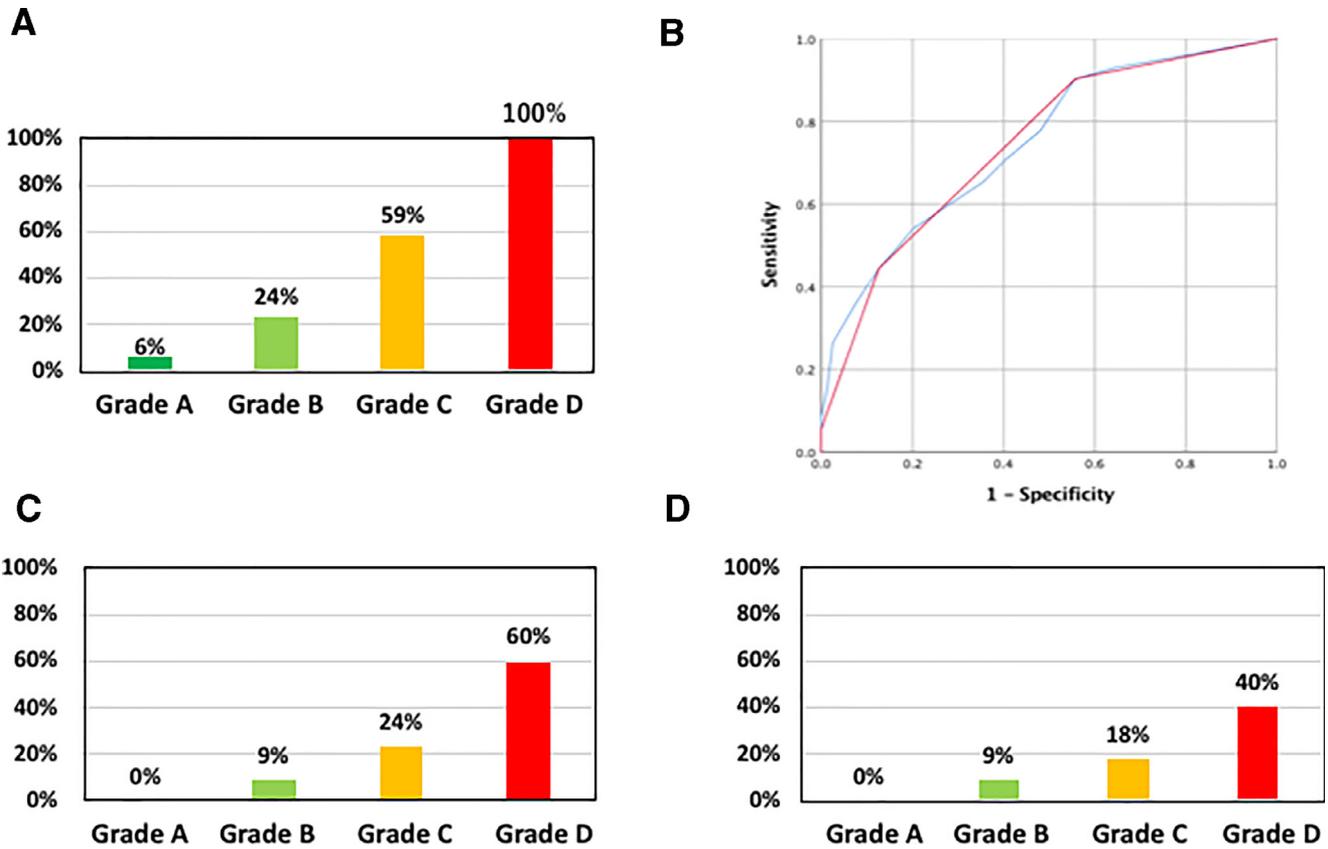


Fig. 4. Distribution of complications and risk scores and grade in the validation cohort. (A) Distribution of surgical complications in the model validation cohort, stratified by risk grade (grades A–D); $r^2=0.971$. (B) Receiver operating characteristic (ROC) curve of surgical complications for the risk-stratification score (solid line) and grade (dotted line) in the model validation cohort. The area under the ROC curve (AUROC) was 0.751 for the risk-stratification score (95% CI 0.6650–0.821) and 0.756 (95% CI 0.6690–0.824) for the risk grade. (C) Distribution of surgical complications with a Clavien–Dindo grade greater than 2, in the model validation cohort stratified by risk grade (grade A–D); $r^2=0.903$. (D) Distribution of surgical complications with a Clavien–Dindo grade greater than 3 in the model validation cohort stratified by risk grade (grade A–D); $r^2=0.938$.

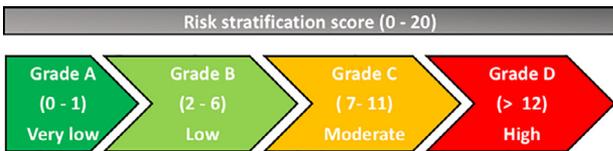


Fig. 5. Diagram showing the surgical risk stratification based on our risk-grading model.

surgery for ASD [27] and has an accuracy of 98% with an AUROC of 1.0 in external validation samples [27]. Although all models have acceptable accuracy, they require specific data sets and programs, which may limit their application in routine clinical practice.

Almost half of the surgical complications (implant-related, surgical-site infection, and pseudoarthrosis) are likely to develop more than 3 months after ASD surgery. Most of these later complications require revision surgery [28], underscoring the importance of predicting both perioperative and late postoperative complications. We here report a simple, easy-to-read risk-grading system with good model fit for predicting the risk of complications within

2 years of ASD surgery. This system demonstrated a significant correlation with surgical complications (Table 5; Fig. 5). Our risk-grading system has a strong advantage in that it uses risk factors that are routinely assessed in most practices prior to spinal surgery, namely, frailty, BMD, PSO, C7SVA, LIV, Cobb angle, PI–LL, age, diabetes, and gender.

ASD is heterogeneous in terms of age, curve types, and clinical outcomes [16]. Although various risk factors have been identified, our data analysis indicated that these potential risk factors are predictive for postoperative complications only when assessed together. Surgical complications increased exponentially with increases in surgical risk grade, in both our model-building and external validation cohorts. Our newly established risk-grading system showed good model fit in an external validation cohort, with an AUROC of 0.756 (95% CI 0.669–0.824) and $r^2=0.971$.

Limitations of this study include a 2% loss of patients reaching the 2-year follow-up due to incomplete data, and a relatively small sample size. However, our risk-grading system provided accurate predictions in both internal and external validation, with excellent correlation and good

AUROC values. In addition, our predictive model was built using a cohort almost entirely of one ethnic group, and it is widely recognized that demographic variables, including ethnicity and race, can impact surgical outcomes and complications [2,31]. Thus, this model should be further validated in diverse populations. Finally, our sample size was relatively small (n=240). However, our patient data were obtained from three independent hospitals and included multiple potential risk factors for complications, such as spinal alignment, demographic data, BMD, frailty, comorbidities, and surgical invasiveness. Even when using nationwide or other large databases, it may be difficult to find records with enough potential risk variables to develop an accurate predictive model, or to detect records with mis-coded diagnoses or procedures [29]. Databases often include only perioperative complications and lack data for spinal alignment, BMD, and other important predictive factors [30]. In contrast, our institution's database is well designed and carefully maintained, with rigorous built-in quality controls, and information from this database is likely to be more accurate than that from a larger but less thorough or less rigorously maintained database.

Our risk-stratification model can help clinicians inform individuals of their specific surgical risk factors and consider strategies for treating modifiable risk factors, such as bone quality, frailty, and comorbidities, as part of the surgical-treatment planning. The aggregate calculation is especially important for patients with multiple comorbidities and other complex issues that render a single risk factor inadequate for predicting surgical outcomes. The ability to predict risk levels can help staff prepare for staging or other strategic changes to mitigate complications, and can guide surgeons in selecting less complex procedures, especially in preference to less familiar and technically challenging techniques, for patients at high risk of complications.

Conclusion

Our risk-stratification scoring model successfully predicted complications after ASD surgery using patient demographics and radiographic parameters that would normally be collected routinely when considering surgical treatment for a patient with ASD. This simple, easy-to-read predictive model can help physicians identify patients with a high risk of postoperative complications, treat modifiable risk variables, and plan appropriate surgical strategies.

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