



# Predictive model for major complications 2 years after corrective spine surgery for adult spinal deformity

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## Abstract

**Purpose** ASD surgery improves a patient's health-related quality of life, but it has a high complication rate. The aim of this study was to create a predictive model for complications after surgical treatment for adult spinal deformity (ASD), using spinal alignment, demographic data, and surgical invasiveness.

**Methods** This study included 195 surgically treated ASD patients who were > 50 years old and had 2-year follow-up from multicenter database. Variables which included age, gender, BMI, BMD, frailty, fusion level, UIV and LIV, primary or revision surgery, pedicle subtraction osteotomy, spinal alignment, Schwab-SRS type, surgical time, and blood loss were recorded and analyzed at least 2 years after surgery. Decision-making trees for 2-year postoperative complications were constructed and validated by a 7:3 data split for training and testing. External validation was performed for 25 ASD patients who had surgery at a different hospital.

**Results** Complications developed in 48% of the training samples. Almost half of the complications developed in late post-op period, and implant-related complications were the most common complication at 2 years after surgery. Univariate analyses showed that BMD, frailty, PSO, LIV, PI-LL, and EBL were risk factors for complications. Multivariate analysis showed that low BMD, PI-LL > 30°, and frailty were independent risk factors for complications. In the testing samples, our predictive model was 92% accurate with an area under the receiver operating characteristic curve of 0.963 and 84% accurate in the external validation.

**Conclusion** A successful model was developed for predicting surgical complications. Our model could inform physicians about the risk of complications in ASD patients in the 2-year postoperative period.

**Graphical abstract** These slides can be retrieved under Electronic Supplementary Material.

**Key points**

1. A successful model was developed for predicting surgical complications in the 2-year period after surgical treatment for adult spinal deformity (ASD), based on spinal alignment, patient demographic, and surgical invasiveness data.
2. Multivariate logistic regression analysis showed that low BMD (T-score < -1.5), PI-LL > 30deg., and frailty were independent risk factors for surgical complications (BMD: odds ratio 3.3 [95%CI: 1.4-7.3], PI-LL > 30° : odds ratio 2.8 [95%CI: 1.4-5.8], and frailty (mFI class): odds ratio 2.6 [95%CI: 1.5-4.4]).
3. Our predictive model was 92% accurate with an AUC of 0.963, and 84% accurate in the external validation sample, indicating excellent fit.

Variable	Odds ratio	P value	95% CI
BMD (T-score ≤ -1.5)	3.3	0.001*	1.4-7.3
PI-LL (> 30deg.)	2.8	0.002*	1.4-5.8
Frailty (mFI class)	2.6	0.008*	1.5-4.4

\*indicates statistically significant. CI: confidential interval

**Take Home Messages**

1. Among surgically treated ASD patients, complications developed in 48%. Almost half of the complications developed in late post-op period and implant-related complications were the most common complication at 2 years after surgery.
2. We developed a model for predicting 2-year surgical complications after surgery for adult spinal deformity (ASD) from spinal alignment, patient demographics, and surgical invasiveness.
3. Independent risk factors for complications were PI-LL, BMD, and frailty. Our model was 92% accurate in testing samples and 84% in the external validation, indicating excellent fit.

**Keywords** Adult spinal deformity · Complication · Surgery · Risk stratification · Predictive model

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Extended author information available on the last page of the article

## Introduction

Adult spinal deformity (ASD) is a heterogeneous and complex spinal disorder that often requires surgery [1–3]. Corrective spine surgery for ASD is invasive, but effective for most symptomatic ASD cases, while conservative treatment often fails [2, 4, 5]. A recent prospective study by Smith et al. [5] showed that surgery for ASD significantly improves the health-related quality of life (HRQoL) at the 2-year follow-up point, whereas conservative treatment does little to reduce pain and disability. Although ASD surgery provides favorable outcomes, it often requires large dissection, long-segment spinal fusion, osteotomy, blood transfusion, and extended hospitalization and thus has a substantial risk of major complications and poor outcomes in both the perioperative and long-term postoperative time periods [6–12].

The major complications of ASD surgery include neurological deficit, implant-related issues, surgical-site infection, other infection, excessive bleeding, delirium, and cardiopulmonary, gastrointestinal, and renal complications [13]. Reported risk factors for major complications after ASD surgery include advanced age, obesity, diabetes, smoking, mental status, low bone mineral density (BMD), lower instrumented vertebral (LIV) level, three-column osteotomy, and excessive bleeding [6–12]. Studies using multivariate analyses also revealed independent risk factors for major complications in ASD surgery [6–12, 14–18]. However, while multivariate analysis, i.e., logistic regression analysis, can provide independent risk factors for a complication and the odds ratio for each risk factor, it does not provide a specific prediction for the complication in a given patient [19]. For the physician, it is more important to be able to predict the development of major complications, when planning and performing a patient's treatment [15, 20–22].

A predictive model for perioperative (6-week) complications was reported by Scheer et al. [23] in 2017. To build their model, they used data from 409 surgically treated ASD patients who were older than 18 years from multiple centers. This model showed reasonable accuracy (87%) for predicting perioperative complications, but it focused on the perioperative time period and did not predict longer-term postoperative complications. Most postoperative complications (implant related, surgical-site infection, and pseudoarthrosis) develop more than 3 months after surgery and usually require revision surgery [5, 6, 9, 10]. In addition, the created model did not include patient frailty, a known risk factor for major complications and inferior clinical outcomes in ASD [18, 21]. Moreover, the subjects used to create it included young adults, who have a low risk of developing major complications. The purpose of our study was to develop a predictive model for all major complications occurring within 2 years after surgery in middle-aged to elderly ASD patients.

## Materials and methods

### Patient population

This study was approved by our institution's review board. We reviewed records from a multicenter database for 170 consecutive patients who underwent corrective spine surgery for ASD for model building and internal validation. Additionally, we reviewed records of 25 consecutive patients who underwent surgery at another hospital that was not included in the multicenter database and independent from those used for model building for external validation.

### Inclusion and exclusion criteria

The patients were older adults (age  $\geq 50$  years) at the index surgery, with ASD defined by a Cobb angle  $\geq 20^\circ$ , C7 sagittal vertical axis (C7SVA)  $\geq 50$  mm, or pelvic tilt (PT)  $\geq 25^\circ$ . The patients selected for analysis had a minimum of five fused vertebral levels, segmental pedicle screw fixation from the upper-instrumented vertebral (UIV) to the LIV level, and complete 2-year follow-up data. Patients were excluded if they lacked appropriate radiographs or had a syndromic, neuromuscular, or other pathological condition.

### Data collection and radiographic and HRQoL assessment

The demographic and clinical data collected included the patient's age, gender, body mass index (BMI), bone mineral density (BMD), and spine surgery history. Frailty and comorbidities were assessed by the modified frailty index (mFI) and Charlson comorbidity index (CCI) [20, 22].

The surgical data collected included the Schwab-SRS ASD classification and sub-category [1, 3], application of pedicle subtraction osteotomy (PSO), UIV and LIV levels, and number of posterior fused vertebrae. BMD was calculated from dual X-ray absorptiometry (DXA) scores of the right femoral neck. Full-length standing whole-spine radiographs obtained at baseline (pre-surgery) and at the 6-week and 2-year follow-up were analyzed. Radiographic data included the Cobb angle, C7SVA, T5-T12 thoracic kyphosis (TK), T12-sacrum lumbar lordosis (LL), sacral slope (SS), pelvic tilt (PT), pelvic incidence (PI), and spinopelvic alignment (PI-LL). As a surrogate for the HRQoL, the Oswestry Disability Index (ODI) and Scoliosis Research Society-22r questionnaire (SRS-22r) results were recorded at baseline and at 2 years post-operation.

Among the 179 patients used for model building and internal validation who reached the 2-year post-operation time point, 170 patients had complete demographic and radiographic data that could capture any postoperative

complications and thus were included in this study. Seven patients were lost during follow-up and two patients died during follow-up for reasons unrelated to the surgery (cancer and unknown reason) and therefore were excluded from the cohort. For the external validation, 25 of 27 patients had a complete data set and therefore were included (Fig. 1).

### Inclusion of major complications

Major complications included all postoperative complications recorded in the charts and found in the radiographs within the 2-year postoperative time period. Major complications were categorized as neurological, implant related (proximal and distal junctional kyphosis, rod breakage, pseudoarthrosis, implant dislodgement, screw breakage, and others), surgical-site infection, other infection (urinary tract infection and others), excessive bleeding (> 2000 mL), delirium, cardiopulmonary (hemodynamic instability, myocardial infarction, deep venous thrombosis, pulmonary embolisms, thoracic atelectasis, congestive heart failure, and others), gastrointestinal (ileus, cholecystitis), and renal (acute renal failure).

### Data preparation

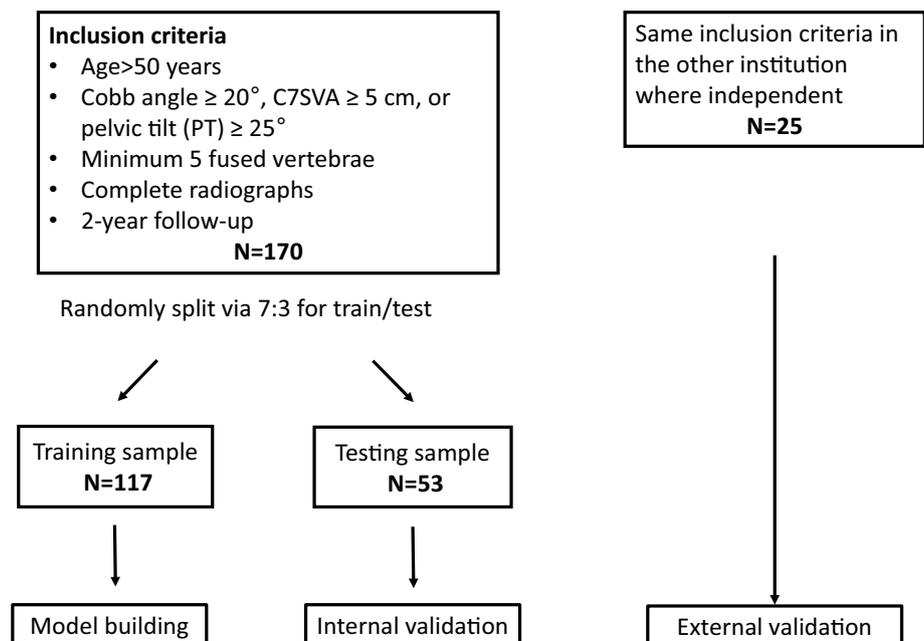
Patients were grouped according to whether or not they had developed at least one major surgical complication at any time during the 2-year postoperative time period. Relationships between patient demographics, spinal alignment, surgical factors, and the development of major

complications were investigated by univariate and multivariate logistic regression analyses using the data of the entire training group (117 patients). The outcomes of interest were: (1) age, (2) gender, (3) BMI, (4) BMD, (5) mFI, (6) CCI, (7) UIV and LIV level, (8) levels involved, (9) application of PSO, (10) C7SVA, (11) PI-LL, (12) baseline ODI, (13) baseline SRS22r total score, (14) baseline SRS22r pain domain score, (15) baseline SRS22r function domain score, (16) baseline SRS22r mental status score, (17) estimated blood loss (EBL), and (18) time of surgery (TOS). Categories were created as follows: age 50–75 years and  $\geq 75$  years; BMD  $T$  score  $\leq -1.5$  and  $> -1.5$ ; frailty robust (mFI=0), prefrail (mFI < 0.21), or frail (mFI  $\geq 0.21$ ); UIV T1–T6 (proximal thoracic: PT) and T9–T11 (lower thoracic: LT); LIV L5 and above, and pelvis; EBL < 1000 mL and  $\geq 1000$  mL; and TOS  $\geq 5$  h and < 5 h.

### Univariate risk analysis for major complication development in the testing samples

We calculated the overall summary statistics, including the means and standard deviations for continuous variables, and the frequencies and percentages for categorical variables. After the descriptive analysis, independent associations between potential risk factors and major complications were analyzed by univariate comparison. Univariate risk analyses were carried out with unpaired  $t$  tests and Tukey's honest significant difference (HSD) test or the Wilcoxon ranked test where appropriate [24].

**Fig. 1** Participant inclusion criteria and flow diagram for model building, internal validation, and external validation



## Multivariate risk analysis for major complication development in the testing samples

We then created a multivariate binary logistic regression model to evaluate the adjusted associations of each potential explanatory variable and to predict the likelihood of developing major complications. Clinically relevant variables and variables with a univariate significance level  $\leq 0.20$  were included in the multivariate logistic regression analysis.

## Building a predictive model for major complication development

After the risk analysis, we created decision-making trees with risk variables. We then compared the overall accuracy and area under the receiver operating characteristic curve (AUC) between model building samples and model testing samples. To build a decision-making tree, the patient samples were randomly split into training and testing samples with a 7:3 ratio (117 vs 53). The binary target variable of the decision trees was complication developed versus no complication developed during the 2-year post-operation period. An ensemble of decision-making trees was constructed using the C5.0 algorithm with five different bootstrapped models [24–26]. The final overall predictions from the models were combined and chosen by voting, with random selection for tied votes [24–26]. The variables included age ( $> 75$  years), gender, frailty, CCI, LIV level, application of PSO, PI-LL ( $> 30^\circ$ ), C7SVA, ( $> 95$  mm), and surgical time ( $> 5$  h) based on the risk analysis results. All analyses were performed using the Statistical Package for the Social Sciences (SPSS version 24.0. and modeler version 18.0. IBM Corp., Armonk, NY).

## Internal and external validation of the predictive model for major complication development

The predictive model was applied to randomly selected testing samples that were not used for the model development. The overall accuracy and area under the receiver operating characteristic curve (AUC) were calculated to internally evaluate the predictive model [24–26]. For the external validation, 25 consecutive ASD patients who met the inclusion criteria and had undergone surgery at an institution independent from those used to create the model were selected as external validation samples, and the accuracy was calculated.

## Results

### Patient characteristics in the training sample

Of the 170 patients, 117 were randomly categorized as training samples and 53 as testing samples. The patient

characteristics are shown in Table 1. The mean C7SVA and PI-LL indicated severe sagittal deformity. The major complication rate was 48% (81/170) within the 2-year postoperative period, and almost half of the complications (48 of 81) developed in the perioperative time period (30 days post-operation) and other developed between 30-day and 2-year postoperative period (43 of 81). The most common complication was implant related (50 cases; 30% of total), and the next most common complication was neurological (17 cases; 10% of total) within the 2-year postoperative period.

## Comparisons of clinical outcomes between the no-complication group and complication group

Patients developing major complications nevertheless experienced significant improvements in HRQoL, as measured by the ODI ( $P < 0.01$ ) and SRS22r total score at the 2-year postoperative time point ( $P < 0.01$ ). However, inferior SRS22 scores and a tendency toward inferior ODI were found for patients who had major complications compared with the no-complication group during the 2-year postoperative time period, while the baseline HRQoLs were similar between the two groups (Table 2).

## Univariate risk analysis for major complication development in the testing samples

Univariate analyses revealed that low BMD ( $T$  score  $\leq -1.5$ ), frailty (mFI  $> 0.21$ ), PI-LL  $> 30$  degrees LIV level (pelvis), application of PSO, and EBL ( $\geq 1000$  mL) were significant risk factors for major complication (Table 3).

## Multivariate risk analysis for major complication development in the testing samples

Multivariate analyses revealed that BMD ( $T$  score  $\leq -1.5$ ), spinopelvic alignment (PI-LL  $> 30^\circ$ ), and frailty (mFI class) were independent risk factors for major complication development after ASD surgery (Table 4).

## Building and validation of a predictive model for major complication development

Five decision-making trees were built for the predictive model (supplemental figure 1–5). The depth of the five built decision-making trees ranged from 8 layers to 11 layers, and each algorithm contained 12–20 nodes. The accuracy of each decision-making tree for the postoperative complications ranged from 77.2 to 90.3% (Table 5), and the overall accuracy of the predictive model was 92.3% in the training sample (true 108, false 9). The internal validation with the testing sample for our predictive model showed 92.5%

**Table 1** Characteristics of the patient cohort

Patient cohort	Training sample	Testing sample	Validation sample	<i>P</i> value
Number of patients	117	53	25	
Age (years)	64.6 ± 10.0	64.1 ± 11.9	68.1 ± 7.3	0.77
Gender (male/female)	7:110 (4%:96%)	4:49 (7%:93%)	4:21 (16%:84%)	0.70
BMI (kg/m <sup>2</sup> )	22.2 ± 3.7	21.9 ± 3.6	23.1 ± 3.7	0.77
BMD ( <i>T</i> score)	-1.2 ± 0.8	-1.1 ± 0.8	-1.1 ± 0.7	0.71
mFI	0.10 ± 0.12	0.08 ± 0.13	0.08 ± 0.08	0.59
CCI	2.03 ± 1.46	2.00 ± 1.66	1.96 ± 1.17	0.89
Number of levels fused	10.0 ± 2.2	10.9 ± 2.6	11.8 ± 2.1	0.81
Time of surgery (h)	4.9 ± 1.3	4.8 ± 1.2	5.0 ± 1.3	0.91
EBL (mL)	699 ± 496	719 ± 512	1010 ± 983	0.88
Application of PSO	18 (15%)	6 (11%)	5 (20%)	0.38
UIV (LT)	74(63%)	32(58%)	17 (68%)	0.37
LIV (pelvis)	66 (56%)	32 (56%)	18 (72%)	0.97
Revision surgery	13 (11%)	6 (11%)	5 (20%)	0.91
C7SVA (mm)	89.2 ± 62.4	86.2 ± 58.4	12.1 ± 72.4	0.91
PI-LL (°)	38.1 ± 22.3	38.0 ± 22.1	42.0 ± 23.5	0.67
PT (°)	29.1 ± 10.6	26.8 ± 13.1	35.4 ± 11.8	0.71
Number of complications	57 (49%)	23 (43%)	12 (48%)	0.25
Number of patients who developed complications	41 (35%)	18 (32%)	8 (32%)	0.65

Means and standard deviations. Percentages in parenthesis

*P* value indicates comparisons between the values from training samples and testing samples

accuracy with an AUC of 0.963 (true 49, false 4). The accuracy of the predictive model was 84% in the sample from an institution that was different and independent from those used for model creation and internal validation.

## Discussion

Due to the increasingly aging populations in advanced countries, more people are suffering from symptomatic spinal deformity and requiring surgical treatment [2, 17]. Although the surgery for ASD is very invasive, patients undergoing surgery show a significant improvement in HRQoL compared to those receiving conservative treatment [5]. However, a high surgical complication rate for ASD surgery is also reported [6–12]. The reported major complication rate for ASD surgery varies from 15 to 78% at 2 years post-operation [6–12]. Cho et al. [10] reported a 34% major complication rate in 166 surgically treated ASD patients. Simon et al. [11] reported a 20% perioperative complication rate and 45% late complication rate after surgery in elderly ASD patients. Simon et al. [11] also reported that most of the late complications were adjacent segmental failure and implant-related complications. Glassman et al. [27] demonstrated that major complications in ASD led to worse clinical outcomes, as indicated by lower Short Form-12 scores.

The present results confirmed that report. Almost half of the complications developed between 30-day and 2-year post-operation time period and vast majority of the late complications required revision surgery (30/41, 73%), although most of the perioperative complications could be successfully treated conservatively. Moreover, even though the post-operative HRQoLs were significantly improved in patients developing major complications, the HRQoLs at the 2-year follow-up in these patients were significantly worse than those in the no-complication group. Therefore, minimizing both perioperative and late complications is important for improving the overall surgical outcome for ASD patients.

Reported risk factors for major complications for ASD include age, gender, severe deformity, obesity, comorbidities, osteoporosis, and a history of diabetes, smoking, or depression [6–12]. The results of risk assessment in the present study were consistent with the previous reports. Here, we found that frailty, low BMD, LIV level (pelvis), PI-LL > 30°, application of PSO, and higher EBL (≥ 1000 mL) were significant risk factors for major complication. Our multivariate analysis revealed that BMD, spinopelvic alignment, and frailty were independent risk factors for major complication after ASD surgery. Using these values, we successfully developed a predictive model for major complication in surgically treated middle-aged to elderly ASD patients (median age 71 years). These patients

**Table 2** Comparison of HRQoL measures between patients with no complication and those with complications

HRQoLs	Baseline	<i>P</i> value	2 years	<i>P</i> value
<b>ODI (%)</b>				
No complication	52.5 ± 15.0	0.90	29.4 ± 10.4	0.14
Complication	52.1 ± 16.8		32.9 ± 15.2	
<b>SRS22</b>				
<b>Function</b>				
No complication	2.7 ± 0.6	0.18	3.7 ± 0.6	0.03*
Complication	2.9 ± 0.8		3.4 ± 0.8	
<b>Pain</b>				
No complication	2.8 ± 0.7	0.72	3.7 ± 0.7	0.01*
Complication	2.8 ± 0.8		3.4 ± 0.9	
<b>Self-image</b>				
No complication	2.4 ± 0.8	0.002*	3.8 ± 0.7	0.001*
Complication	2.8 ± 0.9		3.4 ± 1.0	
<b>Mental health</b>				
No complication	2.6 ± 0.8	0.25	3.9 ± 0.7	0.003*
Complication	2.8 ± 0.8		3.5 ± 1.0	
<b>Satisfaction</b>				
No complication	3.6 ± 0.5	0.37	4.0 ± 0.8	0.07
Complication	3.2 ± 0.8		3.7 ± 0.6	
<b>Total</b>				
No complication	2.8 ± 0.5	0.26	3.8 ± 0.5	0.008*
Complication	2.9 ± 0.5		3.5 ± 0.9	

Mean and standard deviation

\*indicates statistically significant

**Table 3** Univariate risk analysis for surgical complication development in the training sample

Variable	Odds ratio	<i>P</i> value	95% CI
Age (≥ 75 years)	2.3	0.18	0.7–6.8
Gender (male)	2.9	0.12	0.8–11.7
BMI (≥ 25 kg/m <sup>2</sup> )	1.3	0.53	0.8–3.3
BMD ( <i>T</i> score ≤ − 1.5)	3.2	< 0.001*	1.5–6.4
Frailty (mFI ≥ 0.21)	3.3	0.02*	1.5–5.9
CCI (> 4)	1.9	0.12	1.1–3.9
C7SVA (≥ 95 mm)	1.8	0.07	1.0–3.4
PI-LL (≥ 30°)	2.6	< 0.001*	1.4–5.0
Revision surgery	1.4	0.81	0.3–5.1
Level fused (≥ 12 levels)	0.6	0.80	0.3–0.8
UIV (LT)	1.4	0.45	0.6–2.9
LIV (pelvis)	2.4	0.009*	1.3–4.4
Application of PSO	2.9	0.03*	1.2–7.5
Surgical time (≥ 5 h)	1.8	0.10	1.0–3.5
EBL (≥ 1000 mL)	2.6	0.03*	1.1–6.1

LT lower thoracic (T9–T11), CI confidence interval

\*indicates statistically significant

**Table 4** Multivariate risk analysis for major complication in the training sample

Variable	Odds ratio	<i>P</i> value	95% CI
BMD ( <i>T</i> score ≤ − 1.5)	3.3	0.001*	1.4–7.3
PI-LL (≥ 30°)	2.8	0.002*	1.4–5.8
Frailty (mFI class)	2.6	0.008*	1.5–4.4

CI confidence interval

\*indicates statistically significant

**Table 5** Accuracy of each decision-making tree for major complication in the training sample

	Accuracy (estimate) (%)
Tree 1	90.2
Tree 2	79.6
Tree 3	86.3
Tree 4	88.4
Tree 5	77.3

have a higher risk of developing major complications in both perioperative and late operative periods after ASD surgery than young and middle-aged patients. Our predictive model was 92% accurate in the testing samples with an AUC of 0.963 and 84% accurate in the unrelated institution samples, indicating excellent fit.

Two prediction tools for postoperative complications in ASD were recently reported. Pellise and the European Spine Study Group reported that the Adult Deformity Surgery Complexity Index (ADSCI) is a valid tool for quantifying the complexity of ASD surgery and predicting postoperative complications [28]. The ADSCI was created based on expert consensus and validated for intraoperative bleeding and length of surgery. Although excellent predictive scores for blood loss and surgical time were reported, the AUC of the ADSCI for surgical complication was moderate, probably because the ADSCI was created based on surgical complexity and surgeon experience, but did not include the patient comorbidities and frailty. Buchlak et al. [29] used the Seattle spine score as a predictive tool for the 30-day complication risk after ASD surgery, based on data from 136 surgically treated ASD patients. Despite the good fit of their predictive model, that study had weaknesses: a wide range of patient ages (20–85 years old) and lack of external validation of the predictive model. Age is known to have a significant impact on surgical complication, with younger subjects having less risk of major complication [6–12]. In addition, both of these previous studies aimed to create a predictive tool for perioperative complications but not for 2-year complications, which include mostly implant-related complications. Therefore,

we only used subjects older than 50 years and included frailty as a potential risk factor for major complications, to improve the accuracy of our predictive model. Furthermore, we created a predictive model for 2-year total complications, because late complication is a common sequela of ASD surgery and often requires revision surgery to improve the patient's HRQoL. Indeed, 73% of late complications required revision surgery in our series.

Limitations of this study include a 5% loss of patients reaching the 2-year follow-up time due to incomplete data, and the relatively small sample size. However, our predictive model, which was generated using decision-making trees with bootstraps, provided highly accurate predictions in both the internal and external validations, with excellent AUCs. Another limitation is that our predictive model was based on data from ASD patients in an East Asian country, who were mostly Asian. Age, lifestyle, and ethnicity could have impacted the surgical outcomes and complications [29]. Therefore, it may be necessary to further validate the model in different patient populations.

Since complication is a multifactorial phenomenon, it can be difficult to acquire the numerous potential risk variables to develop a predictive model [6–12]. Nevertheless, our patient data from multiple centers included most of the reported potential risk factors for complications, including spinal alignment, demographic data, DXA score, comorbidities, LIV level, and PSO. We then performed logistic analysis to identify independent risk factors for major complication development, which enabled us to create an accurate predictive model.

Our predictive model should help alert physicians when an ASD patient is likely to develop a surgical complication after surgery. Prophylactic strategies addressing modifiable risk factors and surgical plans designed to prevent major complication should be applied for high-risk patients who undergo corrective spine surgery for ASD.

## Conclusion

A successful model was created for predicting surgical complications after ASD surgery that included patient demographic, radiographic, and surgical invasiveness data. Our predictive model could inform physicians about patients with a high risk of complication in the 2-year postoperative period. Further research on predicting complications of ASD surgery, including studies in other countries, will improve patient selection and safety when considering surgical treatment for ASD.

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## Compliance with ethical standards

**Conflict of interest** The authors report no conflict of interest.

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