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Predictors and Clinical Importance of Postoperative Coronal Malalignment After Surgery to Correct Adult Spinal Deformity

（成人脊柱変形手術における術後冠状面アライメント不良の予測因子および臨床成績）

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Predictors and Clinical Importance of Postoperative Coronal Malalignment After Surgery to Correct Adult Spinal Deformity

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Study Design: A retrospective observational study of a cohort of consecutive patients.

Objective: The objective of this study was to determine the correlations between clinical outcomes of spinal surgery to correct adult spinal deformity (ASD) including mechanical complications and coronal malalignment and clarify the risk factors for postoperative coronal malalignment.

Summary of Background Data: Despite the coronal malalignment seen regularly in adult patients who have undergone spinal surgery to correct spinal deformity, the associations between coronal malalignment, and clinical outcomes including mechanical complications after the surgery have remained unclear until now. To understand the associations between coronal malalignment and outcomes of surgery to correct ASD, and risk factors for postoperative coronal malalignment has substantial clinical importance.

Materials and Methods: We included data from 121 consecutive patients who had undergone spinal surgery to correct ASD and were followed up for a minimum of 2 years. Iliac screws were used for pelvic fixation in all cases. The coronal balance was defined as the horizontal distance between the midpoint of C7 and the center of the sacrum on the coronal plane, and coronal malalignment was defined as when the absolute coronal balance was >20 mm. Preoperative radiographic parameters, surgical features, and clinical outcomes including mechanical complications were compared between groups of patients with coronal balance and those with malalignment. Univariate and multivariate regression analysis were used to clarify risk factors for postoperative coronal malalignment.

Results: Postoperative coronal malalignment had no significant association with the clinical outcome as evaluated by a Roland-Morris Disability Questionnaire and Oswestry Disability Index but had a significant association with the frequency of rod fracture. A large preoperative coronal imbalance (malalignment), L5 coronal tilt angle, and use of lateral lumbar interbody fusion were found as risk factors for postoperative coronal malalignment.

Conclusion: Postoperative coronal malalignment had no significant association with the clinical outcome as evaluated by the Oswestry Disability Index and Roland-Morris Disability Questionnaire but was significantly associated with the frequency of rod fracture.

Level of Evidence: Level III.

Key Words: adult spinal deformity, coronal malalignment, corrective spinal surgery, rod fracture, mechanical complication

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Achieving optimal spinopelvic alignment is a major goal of surgery to correct adult spinal deformity (ASD).[1–3] In particular, ideal sagittal global alignment after the surgery is believed to produce favorable outcomes and avoid mechanical complications. Therefore, numerous studies have investigated surgical strategy and health-related quality of life of patients with ASD focusing on sagittal malalignment.[4–6] The better sagittal and coronal spinopelvic correction has become possible after surgery to correct ASD because of advances in techniques including minimally invasive lateral lumbar interbody fusion (LLIF), 3-column osteotomy, and more powerful sacrum-pelvic fixation.[7–9] However, strategies to select the best procedures have not yet been established.

Despite the coronal malalignment (CM) seen regularly in patients who have undergone spinal surgery to correct ASD, the associations between CM on clinical outcomes including patient satisfaction and mechanical complications after the surgery have remained unclear.[10–15] It is not unusual to observe poor outcomes or mechanical complications after the surgery, even after what is considered an ideal sagittal correction. Therefore, understanding the associations between CM and clinical outcomes of surgery to correct ASD, and risk factors for postoperative CM has substantial clinical importance.

The present study aimed to determine the correlations between clinical outcomes of spinal surgery to correct ASD including mechanical complications and CM.

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MATERIALS AND METHODS

Patients and Surgical Techniques

After approval by our institutional review board (application no. 1183), we conducted a retrospective observational study of a cohort of consecutive patients with a diagnosis of ASD who underwent spinal surgery to correct the deformity. Patients were considered candidates for thoracolumbar correction if fusion was indicated because of ASD and a full course of conservative care had been exhausted. The inclusion criteria were age older than 60 years and a radiographic diagnosis of ASD defined by at least one of the following parameters: a coronal Cobb angle > 30 degrees; a C7 sagittal vertical axis, which is the distance between the C7 plumb line and the posterosuperior edge of S1, > 5 cm; and/or a > 30 degrees pelvic tilt, which is the orientation of the pelvis with respect to the femurs and the rest of the body. Patients were excluded if they had ankylosing spondylitis, a rounded back because of Parkinson disease, had undergone surgery without the use of iliac screws, or they had not been followed up for at least 1 year.

We included data from 121 consecutive patients who underwent corrective spinal surgery between April 2012 and March 2016 as performed by 2 board-certified spinal surgeons at a single institution and were followed up for a minimum of 2 years. Basic demographic and surgical data including age, sex, bone mineral density, type of procedure, and area of fusion were recorded (Table 1).

Surgical Procedures

The surgeons used an anterior approach to lateral interbody fusion from L1–L2 or L2–L3 to the level of the L4–L5 disk to obtain adequate coronal and sagittal global spine alignment in patients with ASD.[7] Subsequently the patient was placed in a prone position to undergo a posterior lumbar interbody fusion at the level of the L5–S1 disk and spinal kyphosis was corrected using a cantilever force with bilateral S1 screws and bilateral single or dual iliac screws. Where flexibility of spinal motion was lost, we added a suitable osteotomy, which was classified as grade 1–6 by Scoliosis Research Society-Schwab criteria[8] (Table 1). Allogenic and local autogenous bone grafts were used. Bone morphogenetic protein was not used.

TABLE 1. Patient Characteristics Preoperatively

Variables	N = 121 [n (%)]
Age at surgery (y)	71.7 ± 7.1
Female/male (n)	107/14
BMD (% young adult mean)	74.2 ± 15.1
Location of UIV	
T3	2 (1.7)
T4	9 (7.4)
T5	6 (5.0)
T6	2 (1.7)
T8	7 (5.8)
T9	29 (24.0)
T10	61 (50.4)
T11	3 (2.5)
L1	2 (1.7)
SRS osteotomy classification	
Grade 1	52 (43.0)
Grade 2	21 (17.4)
Grade 3	35 (28.9)
Grade 4	8 (6.6)
Grade 5	5 (4.1)
Use of LLIF	53/121 (43.8)

Interval and ratio values represent the mean ± SD.

LLIF indicates lateral lumbar interbody fusion; SRS, Scoliosis Research Society; UIV, upper instrumented vertebra.

Radiographic Measurements

Radiographic data consisted of full-length lateral radiographs obtained preoperatively, 4–6 weeks postoperatively, and at 2 years postoperatively, with the patient in a freestanding posture and their fingers placed on their clavicles. On preoperative and postoperative coronal radiographs, the following 3 parameters were measured: (1) Cobb angle (the angle between the superior endplate of the most tilted vertebra cranially and the inferior endplate of the most tilted vertebra caudally), left scoliosis was defined as negative (–) and scoliosis on the right side as positive (+). (2) Coronal balance was defined as the horizontal distance between the midpoint of C7 and the center of the sacrum on coronal plane; if the C7 plumb line was located at left side of the center of the pelvis the coronal balance was defined as negative (–), and if located on the right side the balance was defined as positive (+). CM was defined as when the absolute coronal balance was > 30 mm. (3) L1, L2, L3, L4, L5, and sacral tilt angles were measured between the superior endplate and the horizontal. The following radiographic parameters were measured preoperatively and postoperatively using a lateral view: T5−T12 thoracic kyphosis; T12−S1 lumbar lordosis angles; pelvic incidence; pelvic tilt; sacral slope; sagittal vertical axis; T1 pelvic angle, which is the angle between the line from the center of femoral heads to the center of S1 and the line from the femoral head to the center of T1 vertebra[9]; and global tilt, which is the angle formed by the intersection of 2 lines, the first line drawn from the center of C7 to the center of the sacral endplate and the second line drawn from the center of the femoral heads to the center of the sacral endplate.[16] Kyphosis was expressed as a positive value and lordosis as a negative value. The proximal junctional angle (PJA) was measured as the angle between the caudal endplate of the upper instrumented vertebra to the cephalad endplate of 2 proximal vertebrae. Increased PJA was calculated as the increased angle between the PJA obtained on postoperative radiographs and the PJA obtained 2 years postoperatively. Radiographic measurements were made by 2 board-certified spine surgeons (T.O. and H.O.) to determine the interobserver error. We applied the mean values of these measurements to the analyses that followed. The intraclass coefficient was 0.880, indicating that the inter-rater reliability was almost ideal. These authors had > 10 years of experience in spinal surgery and were blinded to patient data before the measurements were made.

Clinical Outcomes

Postoperative baseline patient health status was measured (for lumbar pain-related factors) using a Roland-Morris

Disability Questionnaire (RDQ) and Oswestry Disability Index (ODI), where 0% indicates no disability and 100% indicates extremely debilitating disability[17] at 2 years after surgery.

Statistical Analyses

We report mean ± SD for continuous variables or number (%) for categorical variables. We performed the Student *t* or Fisher exact test when we compared means between 2 groups statistically, assuming normal distributions for continuous variables. We determined the relationship between postoperative CM and preoperative coronal radiographic parameters (coronal balance, main Cobb angle, L1-sacral tilt angle) using Pearson correlation coefficients, considering multiple comparisons. We used Prism (version 6.0; GraphPad Software, La Jolla, CA) to calculate summary statistics and perform the *t* tests, R statistical software (version 3.2.3) to calculate odds ratios and determine correlation coefficients, and Statistical Analysis System software (SAS Institute, Cary, NC) to calculate other values. Asterisks indicate statistical significance ($P<0.05$). We adopted Bonferroni post hoc correction of significance levels when there were multiple comparisons.

RESULTS

Patient Population

The overall mean age of the eligible patients was 71.7 ± 7.1 years, mean bone mineral density (% young adult mean) was 74.2 ± 15.1% and 90% were women (Table 1). Postoperatively, the spinopelvic alignment of the patients improved significantly. The mean preoperative and postoperative alignments are summarized in Table 2. Postoperatively, all sagittal spinopelvic parameters and the main Cobb angle were improved significantly. By contrast, no significant improvement of coronal balance was observed.

Comparison of the Coronally Balanced and Malaligned Groups

On the basis of absolute postoperative coronal balance, 96 patients were grouped into a coronal balanced group and 25 patients were grouped into a CM group. As shown in Table 3, there were no significant differences in age, sex, number of fused levels, or frequency of osteotomy. By contrast, the frequency of LLIF was significantly higher in the group with CM than it was in the group with coronal balance (31% vs. 92%; $P<0.0001$) (Table 3, Fig. 1A).

TABLE 2. Preoperative and Postoperative Spinopelvic Parameters

Variables	Preoperative	Postoperative	*P*
Pelvic tilt (deg.)	37.1 ± 10.1	21.5 ± 9.2	< 0.0001**
Sacral slope (deg.)	15.2 ± 13.2	28.9 ± 8.6	< 0.0001**
LL (deg.)	9.0 ± 21.1	50.0 ± 11.2	< 0.0001**
PI-LL (deg.)	42.0 ± 21.3	0.8 ± 13.1	< 0.0001**
Sagittal vertical axis (mm)	124.4 ± 69.1	26.3 ± 39.2	< 0.0001**
Global tilt (deg.)	53.1 ± 17.2	22.1 ± 11.2	< 0.0001**
T1 pelvic angle (deg.	41.4 ± 14.4	17.0 ± 10.5	< 0.0001**
Main Cobb angle (deg.)	23.3 ± 16.2	10.4 ± 7.1	< 0.0001**
Coronal balance (mm)	−10.9 ± 31.8	−9.0 ± 22.5	NS
Absolute coronal balance (mm)	24.8 ± 22.5	19.5 ± 14.7	< 0.05*

Interval and ratio values are presented as the mean ± SD.
LL indicates lumbar lordosis; NS, not significant; PI, pelvic incidence.
*$P<0.05$ in comparison with preoperative value.
**$P<0.0001$ in the comparison with preoperative value.

TABLE 3. Comparison of Patient Characteristics Preoperatively, Surgical Features, Complications, and Clinical Outcomes 2 Years Postoperatively Between Coronally Malaligned and Balanced Groups

Variables	Coronal Balance (N = 96)	Coronal Malalignment (N = 25)	*P*
Patient characteristics preoperatively			
Age (y)	71.5 ± 7.5	71.1 ± 5.9	NS
Sex (female:male)	85:11	21:4	NS
No. fused levels	9.2 ± 2.1	9.1 ± 2.2	NS
Use of LLIF [n (%)]	**30/96 (31)**	**23/25 (92)**	**< 0.0001****
SRS osteotomy classification			
Grade 1	42	15	NS
Grade 2	18	3	NS
Grade 3	28	5	NS
Grade 4	7	1	NS
Grade 5	4	1	NS
Complication			
Increased PJA (deg.)	8.9 ± 9.7	11.7 ± 10.1	NS
Rod fracture [n (%)]	**16/96 (17)**	**9/25 (36)**	**< 0.05***
Clinical outcome			
2 y ODI (%)	28.9 ± 14.2	20.3 ± 14.6	NS
2 y RDQ	10.2 ± 5.8	6.9 ± 5.5	NS

Bold values indicate significant difference.
Interval and ratio values are presented as the mean ± SD.
NS indicates not significant; ODI, Oswestry Disability Index; PJA, proximal junctional angle; RDQ, Roland-Morris Disability Questionnaire; SRS, Scoliosis Research Society.
*$P<0.05$ in comparison with preoperative value.
**$P<0.0001$ in the comparison with preoperative value.

Association Between Postoperative CM and Clinical Outcomes Including Mechanical Complications

There was no significant difference in increased PJA, ODI, and RDQ between the groups.

By contrast, the frequency of rod fracture was significantly higher in the group with CM than it was in the group with coronal balance (36% vs. 17%; $P<0.05$) (Table 3, Fig. 1C). The postoperative absolute coronal balance was significantly larger in patients with rod fracture than it was in those without (Fig. 1B).

Correlation Between Postoperative Coronal Balance and Preoperative Radiographic Coronal Parameters

Univariate regression analysis showed significant positive correlation between preoperative coronal balance and postoperative coronal balance. In addition, significant negative correlation was shown between L3, L4, L5, sacral coronal tilt angle, and postoperative coronal balance (Fig. 2). Therefore, we used multivariate regression analysis using coronal parameters predictive for large postoperative coronal imbalance (malalignment), which

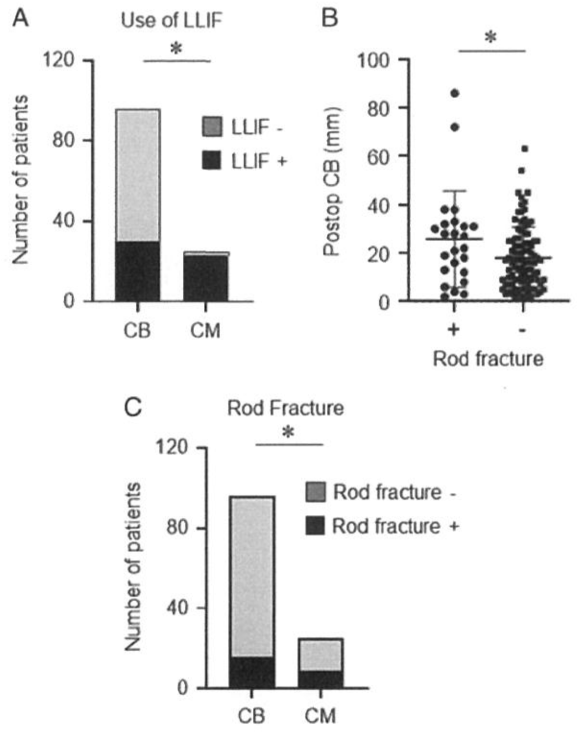

FIGURE 1. A, Comparison of the frequency of lateral lumbar interbody fusion (LLIF) use between the group with coronal balance (CB) and the group with coronal malalignment (CM). B, Comparison of postoperative CB between groups with (–) and without (+) rod fracture. C, Comparison of the frequency of rod fracture between the group with CB and the group with CM. *$P<0.05$.

included preoperative coronal balance, L3, L4, L5, and sacral coronal tilt angle. Multivariate regression analysis indicated potential preoperative risk factors for postoperative CM are large preoperative coronal balance and L5 tilt angle (Table 4, Fig. 2).

DISCUSSION

The present study showed postoperative CM had no significant association with the clinical outcome as evaluated by ODI and RDQ but was significantly associated with the frequency of rod fracture. The incidence of rod fracture after surgery to correct ASD is reported as ranging from 9% to 41%.[16–19] The risk factors for rod fracture have been reported as a use of 3-column osteotomy, sagittal rod contour > 60 degrees, baseline sagittal imbalance, and greater sagittal imbalance correction.[16,17] To our knowledge, the association between postoperative coronal alignment and rod fracture has not been described until now. Therefore, this is the first study to indicate that to avoid rod fracture attention should be paid, not only to sagittal alignment but also to coronal alignment.

A recent study has indicated a significant correlation between preoperative coronal balance and postoperative coronal balance.[20] In addition, we found that among preoperative coronal radiographic parameters, an L5

TABLE 4. Univariate and Multivariate Regression Analysis of Risk Factors for Postoperative Coronal Malalignment

Parameter	*r*	*P*
Univariate		
Preoperative coronal balance (mm)	0.247*	**< 0.05**
Main Cobb angle (deg.)	0.173	NS
L1 tilt (deg.)	0.171	NS
L2 tilt (deg.)	–0.01	NS
L3 tilt (deg.)	–0.23*	**< 0.05**
L4 tilt (deg.)	–0.43**	**< 0.0001**
L5 tilt (deg.)	–0.47**	**< 0.0001**
Sacral tilt (deg.)	–0.23*	**< 0.05**

Parameter	Regression Coefficient	95% CI	*P*
Multivariate			
Intercept	–5.194	–8.915 to –1.473	**< 0.05**
Preoperative coronal balance (mm)	0.3136**	0.1901–0.4372	**< 0.0001**
L3 tilt (deg.)	0.1388	0.388–0.2377	NS
L4 tilt (deg.)	–0.5866	–1.295 to 0.1213	NS
L5 tilt (deg.)	–1.118*	–2.013 to –0.2234	**< 0.05**
Sacral tilt (deg.)	0.8182	–0.8407 to 1.374	NS

Bold values indicate significant difference.
CI indicates confidence interval; NS, not significant.
*$P<0.05$.
**$P<0.0001$.

coronal tilt angle was significantly correlated with CM postoperatively. Our data also clearly showed that the frequency of LLIF use was significantly higher in the group with CM than it was in the group with coronal balance, despite the substantial coronal corrective force effected by LLIF.[8] Indeed, significant improvement of Cobb angle, but not the improvement of coronal balance was shown by the present study. Because lateral anterior lumbar fusion (ALIF) has not been demonstrated at L5/S1 level (OLIF51) yet in the present study, the correction of L5 coronal tilt angle was less than other lumbar levels, which are corrected with LLIF. Strong correction of the lumbar curve using

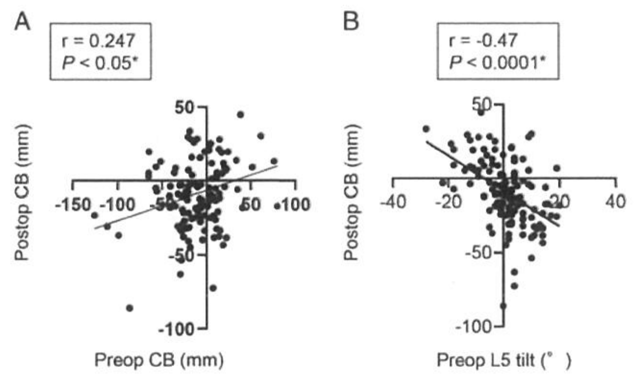

FIGURE 2. A, Correlation between preoperative and postoperative coronal balance (CB); *$P<0.05$. B, Correlation between preoperative coronal L5 tilt angle and postoperative CB; *$P<0.0001$.

LLIF with L5 coronal tilt angle is still remained, might result in the formation of a straight spine on an oblique foundation, which is typically called "oblique take-off." Oblique take-off should be one of the main causes of postoperative CM. The present study indicates the importance of avoiding postoperative CM to decrease the risk of rod fracture. Surgical techniques to avoid postoperative CM such as 3-column osteotomy and asymmetric pedicle subtraction osteotomy have been proposed.[7,21–23] In particular, when ASD patients have a large L5 coronal tilt angle, the surgical technique to correct L5 coronal tilt angle should be preferred, such as ALIF and/or lateral ALIF at L5/S1, 3-column osteotomy, TLIF and/or compression/distraction at the lumbosacral fractional curve and asymmetric pedicle subtraction osteotomy. Otherwise, LLIF at the upper lumbar spine should not performed with the L5 coronal tilt angle is remained.

This retrospective study is limited in that the strategy to choose surgical procedures such as LLIF, osteotomy, and select the spinal level for the upper instrumented vertebra was dependent on the surgeon. In addition, further study with an increasing number should be demonstrated. For example, if we remove 2 outliers of rod fracture group from statistical analysis in Figure 1B, there was no significant difference of postoperative coronal balance between groups.

However, to our knowledge, this is the first study indicated postoperative CM had no significant association with the clinical outcome as evaluated but was significantly associated with the frequency of rod fracture. Further study is warranted to establish how preoperative evaluations may be used to guide the choice of surgical techniques.

CONCLUSION

Postoperative CM had no significant association with the clinical outcome as evaluated by ODI and RDQ but was significantly associated with the frequency of rod fracture.

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