


Are sagittal spinopelvic radiographic parameters significantly associated with quality of life of adult spinal deformity patients? Multivariate linear regression analyses for pre-operative and short-term post-operative health-related quality of life

Mitsuru Takemoto^{1,2}  · Louis Boissière¹ · Jean-Marc Vital¹ · Ferran Pellisé³ · Francisco Javier Sanchez Perez-Grueso⁴ · Frank Kleinstück⁵ · Emre R. Acaroglu⁶ · Ahmet Alanay⁷ · Ibrahim Obeid¹

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Abstract

Purpose To evaluate the association in ASD patients between spinopelvic sagittal parameters and health-related quality of life (HRQL), adjusted for demographic and surgical variables.

Methods We constructed multiple linear regression models to investigate pre-operative (PreOp) and 6-month post-operative (PostOp) HRQL as assessed by the Oswestry Disability Index (ODI), with sagittal parameters as independent variables adjusted for potential confounders, such as age, sex, body mass index, past spine surgery, types of surgical treatment, and complications.

Results A total of 204 patients (164 women, 40 men, mean age 53.1 years) were included in this study. In multivariate models for PreOp ODI, no significant association was observed between PreOp HRQL and sagittal parameters when adjusted for covariates. Interestingly, age, sex, American Society of Anesthesiologists score, and body mass index were still significantly associated with PreOp HRQL. In contrast to PreOp analysis, there was a significant association between PostOp worse HRQL (higher ODI) and positive T1 sagittal tilt (T1ST: the angle between a line drawn from the center of the femoral head axis to the midpoint of the T1 vertebral body and a vertical line). Sagittal vertical axis had a weaker association with HRQL than T1ST. PostOp ASD patients lose flexibility in the fused spinal segment, and might be predisposed to symptoms related to spinal sagittal malalignment due to limited compensatory ability to maintain a balanced standing posture. Interestingly, in patients with sagittal imbalance, low pelvic tilt (PT) of <20 was significantly associated with PostOp worse HRQL; this suggests that lack of pelvic compensatory ability can cause significant disability after ASD surgery.

Conclusions Pre-operatively, the impact of sagittal parameters on HRQL was not as strong as reported in the previous studies that used univariate analysis. Not only sagittal parameters, but also the pre-operative patient's general condition should be carefully reviewed when considering indication for ASD surgery. In contrast, although this is a short-term follow-up study, PostOp HRQL was significantly associated with sagittal parameters. When ASD surgery has been indicated, restoration of spinal sagittal alignment is certainly important for PostOp HRQL.

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✉ Mitsuru Takemoto
m.take@mac.com

- ¹ Spine Unit 1, Bordeaux University Hospital, Bordeaux, France
- ² Department of Orthopaedic Surgery, Kyoto City Hospital, Nakagyo-ku, Mibu-Higashi-Takada-cho 1-2, Kyoto 604-8845, Japan
- ³ Spine Surgery Unit, Hospital Vall d'Hebron, Barcelona, Spain
- ⁴ Spine Surgery Unit, Hospital Universitario La Paz, Madrid, Spain
- ⁵ Department of Orthopedics and Neurosurgery, Spine Center, Schulthess Clinic, Zurich, Switzerland
- ⁶ Spine Surgery Unit, Ankara Acibadem ARTES Spine Center, Ankara, Turkey
- ⁷ Spine Surgery Unit, Acibadem University, Istanbul, Turkey

Keywords Adult spinal deformity · Sagittal vertical axis · T1 sagittal tilt · Pelvic tilt · Pelvic incidence

Introduction

In adult spinal deformity (ASD) surgery, it is currently one of the basic concepts to maintain spinal sagittal alignment to achieve a better clinical result. This concept was developed based on several studies using univariate analyses that demonstrated positive correlation between spinal sagittal parameters and health-related quality of life (HRQL) of ASD patients [1–6]. On the other hand, the previous studies have also suggested the existence of various confounding factors in clinical and radiologic presentations of ASD patients. Those include age [1, 2, 5, 7–10], sex [11, 12], body mass index (BMI) [12–15], American Society of Anesthesiologists (ASA) score [16], coronal curve types (SRS-Schwab ASD classification [17]) [16, 18, 19], history of prior spine surgery [5, 11, 20, 21], and surgical treatment and complications [21–23]. To evaluate true association of the spinopelvic alignment with HRQL adjusted for confounding factors, multivariate analyses are necessary but still lacking.

In this study, we conducted multiple regression analyses with these potential cofounders as covariates for discreet evaluation into how sagittal parameters are associated with pre- and post-operative HRQL.

Materials and methods

Patient cohort and analyzed variables

This study analyzed prospectively collected data from a multicentric database on ASD patients [16]. Inclusion criteria were age 18 years or over, and having at least one of the following: a spinal coronal Cobb angle of $\geq 20^\circ$, SVA ≥ 5 cm, PT $\geq 25^\circ$, or thoracic kyphosis $\geq 60^\circ$. At the time of study initiation (September 2014), the database contained a total of 1093 patients (408 surgical candidates and 685 non-surgical candidates). We excluded non-surgical candidates and cases with congenital deformity, post-traumatic deformity, neuromuscular disease, and Scheuermann disease. In addition, patients who had not yet finished 6 months of follow-up were also excluded (Fig. 1). Owing to the limitation of short follow-up period of the database, we evaluated post-operative clinical and radiographic data 6 months after surgery. All subjects had full-length standing coronal and sagittal spinal radiographs taken in free-standing position with fists overlaying ipsilateral clavicles [24].

Analyzed demographic independent variables were age, sex, BMI, ASA score, and history of prior spine surgery (past surgery). Pre-operative (PreOp) and post-operative (PostOp)

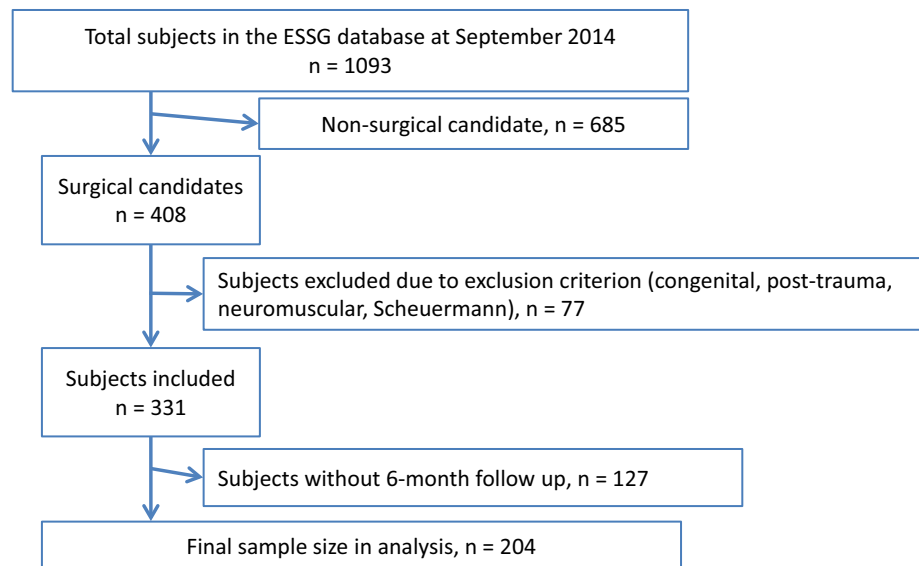
radiographic parameters, including coronal curve types (SRS-Schwab ASD classification [17]), SVA, T1 sagittal tilt (T1ST: the angle between a line drawn from the center of the femoral head axis to the midpoint of the T1 vertebral body and a vertical line) [4, 25, 26], PT, PI minus lumbar lordosis (PIminusLL) were also analyzed as independent variables. Variables related to the surgical treatment (surgical variables) were: fusion length (number of fused vertebra); lumbosacral fusion (yes/no); decompression procedure (yes/no); posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF) procedure (yes/no); and osteotomy procedure, including at least one Smith–Petersen osteotomy, pedicle subtraction osteotomy, or vertebral column resection (yes/no). Complications related to the surgical treatment were classified as major or minor based on the previous literature [23]. Major complication and reoperation are reported to positively impact the surgical results [22, 23]. Therefore, patients were stratified as having no major complication (no), major complication requiring no reoperation, and major complication requiring reoperation. Major complications included spinal cord injury, nerve root injury, deep infection, paralysis, pulmonary embolism, sepsis, cardiac infarction, renal failure, and instrumentation or junction failure. Dependent variables were PreOp and PostOp Oswestry Disability Index (ODI) scores, which were analyzed separately.

Statistical analyses

Statistical analyses were performed using the JMP11 software (SAS Institute, Cary, NC, USA), STATA14 (StataCorp, College Station, TX, USA). Statistical significance was set at $P < 0.05$. BMI was classified into three groups according to the World Health Organization [13, 15], and defined as BMI < 25 (normal to underweight), BMI ≥ 25 but < 30 (overweight), and BMI ≥ 30 (obesity). SVA, PT, and PIminusLL were classified into three grades, respectively, according to the SRS-Schwab ASD classification [17, 18]. T1ST classification was developed based on the previous literature [4, 25, 27], and defined as T1ST $< 0^\circ$ (non-pathologic), T1ST $\geq 0^\circ$ but $< 5^\circ$ (moderate deformity), or T1ST $\geq 5^\circ$ (marked deformity). PreOp and PostOp differences in ODI and radiographic variables were assessed with Student's *t* tests for continuous variables, or Pearson Chi-square tests for categorical variables.

Univariate and multivariate linear regression analyses for PreOp and PostOp ODI

Univariate and multivariate linear regressions were fitted separately for the PreOp and PostOp ODI score with robust standard error. Owing to a strong correlation observed among radiographic sagittal parameters, three separate

Fig. 1 Flow of patients in study cohort

models were tested: one including SVA and PT (model 1), a second including T1ST and PT (model 2), and a third including P_lminusLL (model 3). Variance inflation factor was calculated for each independent variable and used to check that no multi-collinearity existed. In each model, we also checked the assumptions of normality, linearity, homoscedasticity, and independence of the residuals.

In the multivariate analysis with PreOp ODI as a dependent variable, all possible independent variables (age, sex, BMI, ASA score, past surgery, and PreOp radiographic variable) were entered together.

In the multivariate analysis with PostOp ODI as a dependent variable, a three-step approach was applied. First, a reference model was defined comprised of a set of demographic variables (age, sex, BMI, ASA score, past surgery, and hospital) and PreOp ODI score. The second model was constructed by sequentially adding two blocks of predictors, and removed using a backward elimination method (removal criteria of $P > 0.1$): (1) the PreOp radiographic variables (PreOp SVA, PreOp T1ST, PreOp PT, and PreOp P_lminusLL); and (2) surgical variables (fusion length, lumbosacral fusion, decompression, PLIF/TLIF, osteotomy, and complication). Finally, three sets of PostOp radiographic variables (model 1, 2, and 3) were force-entered separately into the final regression model.

To explore age variation, interaction terms of radiographic sagittal parameters by age were forward-selected after its main effects were entered; however, no significant interaction was detected. Separate interaction analysis investigated potential modification of effect on SVA/T1ST by PT. Interaction terms of SVA/T1ST by PT were forward-selected after its main effects were entered. As a significant interaction was found between T1ST and PT for PostOp ODI, we performed subsequent stratification

analysis and compared the least-squared means for each stratified group adjusted for covariates.

Results

Demographics, surgical treatments, and complications (Table 1)

A total of 204 patients (164 women, 40 men) were included in this study. The mean age was 53.1 years, and 47% of the patients were more than 60 years old. The median number of fused vertebra was nine, and 88 patients (43%) received lumbosacral fusion. A total of 39 patients (19%) experienced at least one major complication, such as deep infection and/or instrumentation failure, and 22 patients (11%) received reoperation before 6 months post-operatively.

PreOp and PostOp radiographic variables and surgical results

All sagittal parameters except PT improved post-operatively, with a significant decrease in the percentage of patients with moderate or marked deformity (Table 2). The mean ODI score significantly decreased post-operatively from 42.0 [95% confidence interval (CI) 39.1–44.8] to 32.4 (95% CI 29.8–35.1, $P = 0.000$).

Univariate and multivariate linear regression analyses for PreOp ODI score

In the univariate linear regression analysis for PreOp ODI, the factors significantly associated with higher ODI (worse HRQL) were higher age, higher BMI, higher ASA score,

Table 1 Demographic, surgical variables, and major complications of the study population

	<i>N</i>		<i>%</i>	
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
Demographic variables				
Age (years)				
Age <40	58		28	
40 ≤ age < 60	51		25	
Age ≥60	95		47	
Sex				
Female	164		80	
Male	40		20	
BMI				
BMI < 25	99		49	
25 ≤ BMI < 30	68		33	
BMI ≥ 30	35		17	
ASA score				
Grade I	79		9	
Grade II	106		52	
Grade III	19		39	
Past surgery	62		30	
Spine center				
Ankara	27		13	
Barcelona	34		17	
Bordeaux	61		30	
Istanbul	35		17	
Madrid	36		18	
Zurich	11		5	
Surgical variables				
Fusion length, number of fused vertebra				
Median (IQR)	9 (7–13)		–	
Fusion to sacrum	88		43	
Decompression	74		36	
TLIF/PLIF	65		32	
Osteotomy^a	92		45	
Major complications				
	Total		Reoperation required	
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
Intraoperative				
Spinal cord injury	1	0	–	
Nerve root injury	3	1	–	
Post-operative				
Deep infection	10	5	7	3
Paralysis	8	4	1	0
Pulmonary embolism	2	1	0	0
Sepsis	1	0	0	0
Cardiac infarction	2	1	0	0
Renal failure	1	0	0	0
Follow-up				
Instrumentation failure	18	9	11	5
Junction failure	9	4	4	2

Table 1 continued

Major complications	Total		Reoperation required	
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
At least one complication	39	19	22	11

ASA American Society of Anesthesiologists, BMI body mass index, IQR Interquartile range, TLIF transforaminal lumbar interbody fusion, PLIF posterior lumbar interbody fusion

^a Osteotomy includes at least one Smith–Petersen osteotomy, pedicle subtraction osteotomy, or vertebral column resection

Table 2 Pre- and post-operative radiographic variables

Radiographic variables	Pre-operative		Post-operative		<i>P</i>
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	
Coronal curve (Schwab classification)					
N	90	44			
T	12	6			
L	57	28			
D	45	22			
Sagittal vertical axis (mm)					
SVA <40	109	53	128	63	0.001*
40 ≤ SVA ≤ 95	48	24	35	17	
SVA >95	40	20	14	7	
T1 sagittal tilt (°)					
T1ST <0	122	60	143	70	0.001*
0 ≤ T1ST < 5	50	25	25	12	
T1ST ≥5	23	11	9	4	
Pelvic tilt (°)					
PT < 20	74	36	72	35	0.796*
20 ≤ PT ≤ 30	71	35	66	32	
PT > 30	55	27	45	22	
PI minus LL (°)					
PI-LL <10	89	44	116	57	0.000*
10 ≤ PI-LL ≤ 20	33	16	36	18	
PI-LL >20	77	38	31	15	

SVA sagittal vertical axis, T1ST T1 sagittal tilt, PT pelvic tilt, PI pelvic incidence, LL lumbar lordosis

* Pearson Chi-square tests

history of past surgery, higher SVA, higher T1ST, higher PT, and higher PIminusLL (Table 3). In multivariate models for PreOp ODI, no significant association was observed between ODI and sagittal parameters when adjusted for covariates (Table 4).

Univariate and multivariate linear regression analyses for PostOp ODI score

In the univariate linear regression analysis for PostOp ODI, the factors significantly associated with a higher PostOp

ODI were higher age, sex (female), higher ASA score, history of past surgery, higher PreOp ODI, higher Pre/PostOp SVA, higher Pre/PostOp T1ST, lumbosacral fusion, and major complication requiring reoperation. (see Supplemental Digital Content, Table Supple).

The backward stepwise multiple regression analysis yielded combined models consisting of the covariates (age, sex, BMI, ASA score, past surgery, PreOp ODI, major complication, and spine center) and force-entered PostOp radiographic sagittal parameters (Table 5). Among the radiographic sagittal parameters, PT in model 1, and T1ST and PT in model 2 were found to be significantly associated with PostOp ODI. Higher PostOp T1ST and lower PT were significantly associated with higher PostOp ODI (worse HRQL).

A significant interaction was detected between T1ST and PT in model 2 (degree of freedom = 4, $F = 3.14$, $P = 0.016$). We decomposed the interaction as follows: balanced (T1ST <0) with low PT (PT < 20), balanced with high PT (PT ≥ 20), imbalanced (T1ST ≥ 0) with low PT, and imbalanced with high PT (Fig. 2). In patients with a balanced spine (T1ST <0), there was no significant difference in ODI between groups with low and high PT (least-square mean ± standard error for low PT vs. high PT: 33.3 ± 2.0 vs. 29.0 ± 1.8 , $P = 0.098$). However, in patients with an imbalanced spine (T1ST ≥ 0), there was a significant difference in ODI between groups with low and high PT (62.0 ± 7.05 vs. 36.3 ± 3.4 , $P = 0.001$).

Discussion

In this study, we analyzed the association between the HRQL of ASD patients and sagittal parameters unadjusted and adjusted for covariates. The results for univariate analysis were consistent with the previous studies [1–6], with a significant association between PreOp and PostOp disability and sagittal parameters. However, for multivariate models, PreOp sagittal parameters were no longer significantly associated with HRQL. In contrast, PostOp sagittal parameters (T1ST and PT) were significantly associated with PostOp ODI even after adjustment for covariates. Interestingly, in patients with sagittal imbalance, low PT (PT < 20) had a significant association with worse HRQL.

Pre-operative HRQL of ASD patients

Contrary to the previous studies reporting a positive correlation between sagittal malalignment and PreOp HRQL [1, 2, 5, 10], a significant association was not observed in multivariate analysis in this study. Contrarily, age, sex, ASA score, and BMI (model 3) were still significantly

Table 3 Univariate linear regression for pre-operative Oswestry Disability Index

Pre-operative ODI (univariate regression)			
	Coef.	Std. err.	<i>P</i>
Control variables			
Age 0.000			
Age <40 (base)	0.0		
40 ≤ Age < 60	21.0	3.4	0.000
Age ≥60	29.2	3.0	0.000
Sex 0.101			
Female (base)	0.0		
Male	−5.8	3.5	0.101
Body mass index 0.000			
BMI <25 (base)	0.0		
25 ≤ BMI < 30	13.6	3.0	0.000
BMI ≥30	14.9	3.6	0.000
ASA score 0.000			
Grade I (base)	0.0		
Grade II	16.0	2.7	0.000
Grade III	32.3	3.6	0.000
Past surgery 0.000			
No (base)	0.0		
Yes	11.5	2.7	0.000
Radiographic variables			
Coronal Schwab classification 0.000			
N (base)	0.0		
T	−17.8	5.6	0.002
L	−5.3	3.0	0.076
D	−22.3	3.6	0.000
Pre-operative SVA 0.000			
SVA <40 (base)	0.0		
40 ≤ SVA ≤ 95	9.2	3.1	0.003
SVA >95	14.3	3.7	0.000
Pre-operative T1ST 0.000			
T1ST <0 (base)	0.0		
0 ≤ T1ST < 5	10.1	3.0	0.001
T1ST ≥5	15.5	4.1	0.000
Pre-operative PT 0.000			
PT < 20 (base)	0.0		
20 ≤ PT ≤ 30	17.5	3.2	0.000
PT > 30	17.1	3.4	0.000
Pre-operative PI minus LL 0.000			
PI-LL <10 (base)	0.0		
10 ≤ PI-LL ≤ 20	15.2	4.2	0.000
PI-LL >20	15.1	3.0	0.000

Each model was statistically adjusted for spine center

Bold values correspond to the *p*-value determined by the *F*-test for each variable

Coef. regression coefficient, *Std. err.* robust standard error, *BMI* body mass index, *ASA* American Society of Anesthesiologists, *SVA* sagittal vertical axis, *T1ST* T1 sagittal tilt, *PT* pelvic tilt, *PI* pelvic incidence, *LL* lumbar lordosis

Table 4 Multivariate linear regression for pre-operative Oswestry Disability Index

Pre-operative ODI (multivariate regression)									
	Model 1 $R^2 = 0.568, n = 193$			Model 2 $R^2 = 0.563, n = 193$			Model 3 $R^2 = 0.576, n = 197$		
	Coef.	Std. err.	<i>P</i>	Coef.	Std. err.	<i>P</i>	Coef.	Std. err.	<i>P</i>
Control variables									
(Constant)	38.4	4.3	0.000	39.1	4.0	0.000	38.9	3.9	0.000
Age			0.000			0.000			0.000
Age <40 (base)	0.0			0.0			0.0		
40 ≤ Age < 60	13.1	3.7	0.001	13.3	3.6	0.000	13.1	3.5	0.000
Age ≥60	16.2	4.1	0.000	16.3	4.1	0.000	16.5	3.9	0.000
Sex			0.007			0.002			0.008
Female (base)	0.0			0.0			0.0		
Male	-7.9	2.9	0.007	-8.7	2.7	0.002	-7.3	2.7	0.008
BMI			0.073			0.054			0.039
BMI <25 (base)	0.0			0.0			0.0		
25 ≤ BMI < 30	6.0	2.6	0.022	6.3	2.6	0.016	6.4	2.5	0.011
BMI ≥30	3.8	3.3	0.258	3.9	3.2	0.227	4.1	3.2	0.204
ASA score			0.001			0.002			0.000
Grade I (base)	0.0			0.0			0.0		
Grade II	3.8	2.8	0.174	2.6	2.8	0.348	2.5	2.7	0.353
Grade III	16.9	4.5	0.000	15.3	4.5	0.001	16.5	4.1	0.000
Past surgery			0.565			0.338			0.267
No (base)	0.0			0.0			0.0		
Yes	1.5	2.6	0.565	2.4	2.5	0.338	2.7	2.4	0.267
Radiographic variables									
Coronal Schwab classification			0.013			0.028			0.250
N (base)	0.0			0.0			0.0		
T	-7.6	4.9	0.128	-7.4	4.9	0.134	-6.9	4.9	0.166
L	-3.2	2.7	0.243	-2.6	2.6	0.321	-3.0	2.6	0.254
D	-11.5	3.5	0.001	-10.6	3.6	0.003	-10.3	3.4	0.003
Pre-operative SVA			0.582						
SVA <40 (base)	0.0			-	-	-			
40 ≤ SVA ≤ 95	2.6	2.5	0.301	-	-	-			
SVA >95	1.1	3.7	0.774	-	-	-			
Pre-operative T1ST						0.528			
T1ST <0 (base)	-	-	-	0.0					
0 ≤ T1ST < 5	-	-	-	1.0	2.8	0.735			
T1ST ≥5	-	-	-	4.3	3.8	0.259			
Pre-operative PT			0.320			0.305			
PT < 20 (base)	0.0			0.0					
20 ≤ PT ≤ 30	3.8	3.0	0.212	4.0	2.9	0.175			
PT > 30	0.6	3.6	0.875	1.0	3.2	0.751			
Pre-operative PI minus LL									0.114
PI-LL <10 (base)	-	-	-	-	-	-	0.0		
10 ≤ PI-LL ≤ 20	-	-	-	-	-	-	6.2	3.1	0.049
PI-LL >20	-	-	-	-	-	-	4.5	2.7	0.099

Each model was statistically adjusted for spine center

Bold values correspond to the *p*-value determined by the *F*-test for each variable

Coef. Regression coefficient, *Std. err.* robust standard error, *df* degrees of freedom, *F* *F* value, *BMI* body mass index, *ASA* American Society of Anesthesiologists, *SVA* sagittal vertical axis, *T1ST* T1 sagittal tilt, *PT* pelvic tilt, *PI* pelvic incidence, *LL* lumbar lordosis

Table 5 Multivariate linear regression for post-operative Oswestry Disability Index

Post-operative ODI score									
	Model 1 $R^2 = 0.346, n = 168$			Model 2 $R^2 = 0.417, n = 174$			Model 3 $R^2 = 0.357, n = 181$		
Control variables	Coef.	Std. err.	<i>P</i>	Coef.	Std. err.	<i>P</i>	Coef.	Std. err.	<i>P</i>
(Constant)	25.3	4.8	0.000	25.8	4.4	0.000	25.0	4.7	0.000
Age			0.230			0.213			0.067
Age <40 (base)	0.0			0.0			0.0		
40 ≤ Age < 60	-6.2	4.4	0.160	-6.6	3.9	0.092	-8.6	4.0	0.033
Age ≥60	-2.8	5.6	0.620	-4.5	5.1	0.383	-5.4	5.4	0.321
Sex			0.044			0.019			0.060
Female (base)	0.0			0.0			0.0		
Male	-7.7	3.8	0.044	-7.8	3.3	0.019	-6.2	3.3	0.060
Pre-operative ODI			0.001			0.001			0.000
Score per 10 points	3.4	0.1	0.001	3.4	0.1	0.001	3.5	0.1	0.000
Complications			0.016			0.015			0.002
No (base)	0.0			0.0			0.0		
Without reoperation	7.2	3.8	0.064	7.2	3.9	0.065	6.9	3.6	0.055
Requires reoperation	11.0	4.5	0.015	10.5	4.3	0.016	13.8	4.1	0.001
Other covariates	<i>df</i>	<i>F</i>	<i>P</i>	<i>df</i>	<i>F</i>	<i>P</i>	<i>df</i>	<i>F</i>	<i>P</i>
BMI	2	0.16	0.856	2	0.19	0.831	2	0.15	0.858
ASA score	2	0.67	0.511	2	1.52	0.222	2	0.76	0.471
Past surgery	1	2.22	0.138	1	3.45	0.065	1	3.33	0.070
Spine center	5	1.13	0.350	5	1.65	0.150	5	1.87	0.102
Sagittal parameters	Coef.	Std. err.	<i>P</i>	Coef.	Std. err.	<i>P</i>	Coef.	Std. err.	<i>P</i>
Post-operative SVA			0.145						
SVA <40 (base)	0.0								
40 ≤ SVA ≤ 95	2.3	3.9	0.557						
SVA >95	11.0	5.6	0.050						
Post-operative T1ST						0.009			
T1ST <0 (base)				0.0					
0 ≤ T1ST < 5				12.4	4.5	0.006			
T1ST ≥5				14.0	6.9	0.045			
Post-operative PT			0.035			0.027			
PT < 20 (base)	0.0			0.0					
20 ≤ PT ≤ 30	-7.6	3.1	0.014	-7.2	2.8	0.012			
PT > 30	-8.8	4.4	0.047	-6.9	3.5	0.053			
Post-operative PI minus LL									0.839
PI-LL <10 (base)							0.0		
10 ≤ PI-LL ≤ 20							-1.9	3.2	0.555
PI-LL >20							-0.4	3.3	0.910

Bold values correspond to the *p*-value determined by the *F*-test for each variable

Coef. regression coefficient, *Std. err.* robust standard error, *Df* degrees of freedom, *F* *F* value, *ODI* Oswestry Disability Index, *BMI* body mass index, *ASA* American Society of Anesthesiologists, *SVA* sagittal vertical axis, *T1ST* T1 sagittal tilt, *PT* pelvic tilt, *PI* pelvic incidence, *LL* lumbar lordosis

associated with PreOp HRQL. As reported in many previous studies, these covariates correlate with both radiographic sagittal parameters and ODI. [1, 5, 7–16, 28, 29] When adjusted for these covariates in multiple regression models, the coefficients of the radiographic sagittal parameters may decrease and lose statistical significance. These results suggest that the impact of sagittal parameters on PreOp HRQL is not as strong as reported in the previous studies that used univariate analysis. Not only sagittal parameters, but also the pre-operative patient's general condition, such as age, sex, ASA score, and BMI should be carefully reviewed when considering indication for ASD surgery.

To our knowledge, only four studies have used multivariate analysis to evaluate the impacts of spinal sagittal malalignment on the HRQL of ASD patients [1, 2, 10, 12]. Three of these studies reported a positive correlation between spinal sagittal malalignment and HRQL. However, it is difficult to compare our results with these studies; one study included only subjects with positive sagittal balance [2], and the others adjusted only for age [1, 10]. One general population-based study by Araújo et al. found that SVA had no significant impact on HRQL in sex-stratified subjects when adjusted by age, education, and BMI [12]; however, this study also had some limitations owing to its general population-based nature and the limited number of pathological subjects.

While the results of this study were negative, we cannot yet reject the hypothesis of a possible association between PreOp spinal sagittal malalignment and HRQL of ASD patients. Like other patient population-based studies, all the subjects included in this study were ASD patients who had sagittal or coronal deformity; therefore, the impact of radiographic parameters on HRQL could be biased and

might include type 2 errors. Further studies including a larger sample size could have decreased the possibility of type 2 errors, which is one of our ongoing projects.

Short-term post-operative HRQL of ASD patients

In contrast to PreOp analysis, we identified a significant association between PostOp sagittal parameters and HRQL, although this is a short-term follow-up study. After ASD surgical treatment, which can be done using a long construct with lumbosacral fusion, patients lose most of their spinal compensatory mechanisms [30, 31]. The PostOp ASD patients have a limited surplus capacity to maintain a balanced standing posture, because they have to depend on the remaining compensatory mechanisms below the pelvis (e.g., hips and knees). This may lead to a predisposition of PostOp ASD patients to symptoms related to spinal sagittal malalignment. In addition, PostOp patients have received proper decompression surgery, and their HRQL could be affected more by sagittal malalignment than neurological symptoms. These results indicate that, when ASD surgery have been indicated, restoration of spinal sagittal alignment is certainly important for PostOp HRQL.

Impact of positive sagittal balance on post-operative HRQL

PostOp sagittal imbalance ($T1ST \geq 0$) was significantly associated with worse HRQL. As already discussed extensively in the literature, patients with sagittal malalignment have to use compensatory mechanisms to keep the center of gravity (COG) of the trunk on the

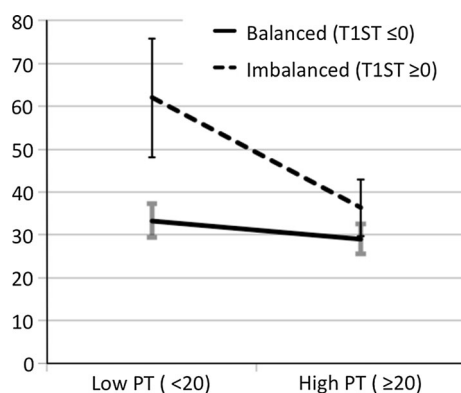


Fig. 2 Least-square means of ODI of low PT and high PT patients adjusted for covariates, stratified by groups of patients with sagittally balanced (a solid line, $T1ST < 0$) and imbalanced (a dotted line, $T1ST \geq 0$) spine. In the imbalanced group, low PT patients showed significantly higher ODI (worse QOL) than high PT patients. ($P = 0.001$) Error bars standard errors

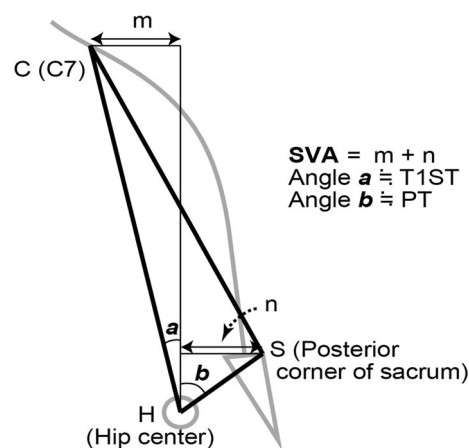


Fig. 3 Mathematical decomposition of SVA. Note that angle a is nearly equal to T1ST (T1 sagittal tilt: the angle between a line drawn from the center of the femoral head axis to the midpoint of the T1 vertebral body and the vertical line), angle b is almost identical to PT (pelvic tilt). SVA is sum of m ($HC \times \sin a$) and n ($HS \times \sin b$). When C7 is behind the hip center, m and angle a is presented by minus

femoral head [4]. Duval-Beaupère et al. suggested that compensation for sagittal malalignment requires patients to make uneconomical efforts [32–34]. Positive sagittal balance ($T1ST \geq 0$) indicates decompensated anterior shift of COG of trunk [4] and may cause significant disability.

Role of PT in post-operative HRQL

In general, higher PT is considered a reflection of a compensatory retroversion of the pelvis in response to spinal sagittal malalignment, and has an association with worse HRQL [3–6]. However, our multivariate linear regression analysis for PostOp ODI demonstrated a significant association between low PT and worse HRQL in ASD patients with sagittal imbalance ($T1ST \geq 0$). This suggests that the lack of pelvic compensatory ability can cause significant disability after ASD surgery. For such patients, we have to pay attention to the possibility of underlying pathomechanisms of low PT despite a global sagittal malalignment [35], such as hip flexion contracture secondary to hip pathologies [36], neuromuscular disease causing predominant flexor muscle activity [36], and posterior muscle exhaustion in extremely severe cases.

Lafage et al. described similar findings when patients were stratified into four groups by high and low PT and high and low SVA [4]. They found that the group with high SVA and low PT had the worst ODI. Other recent studies have also mentioned this paradoxical phenomenon [6, 36], and these authors began to reconsider the role of PT in ASD patients [35, 36]. Lamartina et al. proposed in their radiographic classification a new category of “pelvic kyphosis” characterized by increased SVA without signs of pelvic compensation. Ferrero et al. compared the clinical and radiographic findings between ASD patients with sagittal malalignment and low PT and those with normal to high PT, and reported high disability in both groups [35].

SVA and T1ST as indicators of sagittal imbalance

SVA had a weaker association with HRQL than T1ST. SVA was originally reported by Jackson et al. [37], and is now the most commonly used measurement of spinal sagittal balance. In this study, T1ST [21, 38], which is also reported as T1 sagittal offset [25] or T1 spinopelvic inclination (T1SPi) [4, 6, 27, 35], was also adopted as an indicator of spinal sagittal balance. As shown in Fig. 3, SVA implies information of both T1ST and PT. As the impacts of T1ST and PT on HRQL are opposite to each other, SVA has a weaker association with HRQL than T1ST.

Other significant predictors of post-operative HRQL

Other covariates with a significant regression coefficient were sex, PreOp ODI, and major complication requiring reoperation. These results are consistent with the previous studies [11, 12, 21–23].

Limitations of this study

Limitations of our study include short-term follow-up periods after surgery and the lack of analysis for HRQL of mental status. At least 12-month follow-up seems desirable to discuss the results of surgical treatment for ASD, because it is reported that the first significant improvement and fluctuation of HRQL after surgical treatment of ASD patients occurs between 6 weeks and 1 year post-operatively [19, 21, 22]. We have tried to adjust this bias by adding the PreOp HRQL scores as a covariate in multivariate regression models. For the assessment of HRQL of mental status, we have analyzed SRS-22 mental domain and SF-36 mental component score using the same statistical methodology; however, the number of the subjects for multivariate analysis was not enough to make definite conclusions.

In general, after longer follow-up, it would be more difficult to detect a significant association between variables (i.e., more type 2 errors), since both radiographic parameters and HRQL could be affected by time and other confounders, such as adjacent segment degeneration, proximal junctional kyphosis, and implant failure. However, as we can expect continuous progress in sample size and longer follow-up for subjects in our database, these limitations will be corrected in future studies.

Conclusions

Pre-operative multivariate analyses revealed that the impact of sagittal parameters on HRQL was not as strong as reported in the previous studies that used univariate analysis. Interestingly, age, sex, ASA score, and BMI were still significantly associated with PreOp HRQL even after adjustment for covariates. Not only sagittal parameters, but also the pre-operative patient’s general condition should be carefully reviewed when considering indication for ASD surgery. Contrary to PreOp analysis, although this is a short-term follow-up study, PostOp HRQL was significantly associated with sagittal parameters even in multivariate analyses. When ASD surgery have been indicated, restoration of spinal sagittal alignment is certainly important for PostOp HRQL.”

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Compliance with ethical standards

Conflict of interest None.

Ethical approval Protocol for ESSG database has been approved by the local ethical committee.

Informed consent Informed consent was obtained from each patient.

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