

# **Quality of life in adolescent patients with idiopathic scoliosis after brace treatment** A meta-analysis

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# Abstract

**Background:** Whether brace-treated adolescents with idiopathic scoliosis (AIS) have improved quality of life (QoL) is still unknown. Thus, we conducted a meta-analysis to compare the QoL of brace-treated AIS patients with untreated AIS patients. The pain, self-image/appearance, mental health, function/activity, satisfaction with management, total score without satisfaction, and total score of patients were used to measure the QoL after the intervention.

**Methods:** Multiple electronic databases including PubMed, Web of Science, and Embase were searched for all years up to June 30, 2016. Articles in English that used the Scoliosis Research Society-22 (SRS-22) or a modified version of the SRS-22 questionnaire to evaluate the QoL differences between brace-treated AIS patients and untreated AIS patients were included in the meta-analysis. The Newcastle–Ottawa Scale was used in the quality of literature evaluation. The pooled standardized mean difference (SMD) with its corresponding 95% confidence interval (CI) for each parameter was computed. Egger test and Begg test were used to test for publication bias.

**Results:** The SRS-22 or a modified SRS-22 questionnaire was used to evaluate the QoL after surgery. There was no significant difference in pain (SMD=0.123, 95% CI: -0.101 to 0.347, P=.282), self-image/appearance (SMD=0.108, 95% CI: -0.116 to 0.332, P=.334), mental health (SMD=0.031, 95% CI: -0.130 to 0.201, P=.365), function/activity (SMD=0.202, 95% CI: -0.022 to 0.425, P=.077), and total score without satisfaction (SMD=0.123, 95% CI: -0.232 to 0.478, P=.497) between the untreated (observation) and brace-treated AIS patients, whereas a significant difference was observed in satisfaction with management (SMD=0.393, 95% CI: 0.127-0.659, P=.004) and total score (SMD=0.312, 95% CI: 0.054-0.571, P=.018) between the 2 groups.

**Conclusion:** Our meta-analysis indicated that brace-treated AIS patients had a higher QoL. However, further analysis could not be performed because of insufficient data, such that we were unable to make subgroup analysis of QoL for different types of AIS and the therapeutic methods chosen by brace-treated AIS patients.

**Abbreviations:** AIS = adolescents with idiopathic scoliosis, CI = confidence interval, NOS = Newcastle–Ottawa Scale, QoL = quality of life, SF-36 = Short Form-36, SMD = standardized mean difference, SRS-22 = Scoliosis Research Society-22.

Keywords: AIS, brace, meta-analysis, QoL

# 1. Introduction

Unexplained adolescents with idiopathic scoliosis (AIS), a deformity of spine, presents as spinal scoliosis, vertebral rotation, and a flexible or rigid deformity of the spine in the frontal plane.<sup>[1,2]</sup> The most common form involves pediatric

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spinal deformity. It will be termed AIS if it happens to those who are between the ages of 10 and 18.<sup>[3]</sup> AIS is a common disease globally, affecting up to 3% of adolescents around the world.<sup>[4]</sup> The radiographic image of patients with AIS is characterized by a spinal curve of at least 10° (measured by the Cobb method) but no vertebral abnormalities.<sup>[5]</sup> The etiology of AIS remains obscure, but its gender prevalence in females is recognized with the ratio of female-to-male incidence ranging from 1.5:1 to 3:1.<sup>[6]</sup> AIS is usually asymptomatic, but it may progress and lead to back pain, respiratory problems, and changes in physical appearance, and thus can have unfavorable effects on the quality of life (QoL).<sup>[7]</sup>

Given that the main goals in patients with AIS are to correct the deformity and reduce the progression of spinal curvature, there are 3 approaches to their rehabilitation: observation with regular follow-up, bracing, and surgery.<sup>[8–10]</sup> Among these interventions, brace treatment (usually lasting for months or even years) is one of the most frequently used conservative options to prevent progression of spinal deformity.<sup>[11]</sup> Braces are designed to exert external forces on the spine that resist the forces producing curvature during the growth phase of the patients.<sup>[10]</sup> Brace treatments have been utilized clinically for more than 50 years, and various types of braces have been developed on the basis of

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differences in period of wear, fabrication, area of curve intervention, and protocols of use.<sup>[12]</sup>

For patients with AIS, attention has been paid to their QoL during brace treatment.<sup>[13]</sup> One prospective multicenter study that investigated the difference in the QoL in 2 groups of AIS patients undergoing observation versus brace treatment reported that the 2 groups had similar levels of QoL measured by both the Scoliosis Research Society-22 (SRS-22) and Short Form-36 (SF-36) questionnaires.<sup>[14]</sup> However, data from another 2 related articles published in 2009 and 2015 suggested that AIS patients receiving brace treatment had improved pain and self-image/ appearance, therefore having a better QoL.<sup>[15,16]</sup> Given these results, we conducted the current meta-analysis to appraise the difference in QoL between the untreated (observation) and bracetreated AIS patients. Pain, self-image/appearance, mental health, function/activity, satisfaction with management, total score without satisfaction, and total score of the patients after intervention were considered to be outcomes of interest.

# 2. Materials and methods

All pooled analyses are based on previously published studies, and thus no ethical approval and patient consent are required.

#### 2.1. Literature research

The literature was retrieved using multiple online databases including PubMed, Web of Science, and Embase for all years up to June 30, 2016. Terms selected in our search were "adolescent idiopathic scoliosis" AND (SRS-22r OR "Health related quality of life" OR SRS-22 OR "Scoliosis Research Society-22") AND brace. In addition, more studies were identified from the literature cited within these papers.

#### 2.2. Inclusion and exclusion criteria

The retrieved literature was screened by 2 independent investigators to evaluate eligibility, and any discrepancies were settled by discussion and consensus. The inclusion criteria were the study included AIS, brace-treated interventions, comparisons of observation or no treatment, and the QoL was assessed by SRS-22 or modified version of SRS-22 questionnaire; published in English; full text of all references were available; if overlapping subject populations were enrolled in different reports, the one of higher quality or with a larger sample size was selected for inclusion. Studies were excluded if the reports were in the form of letters, abstracts, reviews, or comments; it was impossible to extract relevant data; or the AIS patients were treated with surgery.

# 2.3. Data extraction

The following data were independently extracted by 2 authors: the name of first author, year of publication, study type, country, number of patients under observation and brace treatment, female ratio, age of patients, and the follow-up period. Information on outcomes of interest including pain level, selfimage/appearance, mental health, function/activity, satisfaction with management, total score without satisfaction, and total score of the patients was also collected and extracted. When relevant data had not been reported, we contacted the authors by email or in other ways to attempt to obtain the missing information.

#### 2.4. Quality assessment

The Newcastle–Ottawa Scale (NOS),<sup>[17]</sup> a tool to assess the quality of a case–control or cohort study, was used to judge the quality of each trial in the study. This scoring system evaluates the quality of an article based on 3 broad perspectives: the cohort selection (0–4 stars), comparability (0–2 stars), and assessment of outcomes (0–3 stars). The number of stars for each trial could range from 0 to 9. Those with calculated scores of 3 or less were regarded as poor quality; 4 to 6, moderate quality; and 7 or more, high quality. Any disagreement between the 2 investigators was resolved through discussion.

#### 2.5. Data synthesis and statistical analysis

The outcomes of interest were all continuous variables, so the standardized mean difference (SMD) with its corresponding 95% confidence interval (CI) for each parameter was computed in bracetreated versus untreated AIS patients. Statistical heterogeneity across included studies was examined by the Cochrane Q test and  $I^2$  statistic.<sup>[18]</sup> An  $I^2 > 50\%$  or P < .1 signified the possibility of statistical heterogeneity, and the random-effects model was chosen for the computation of SMD with its corresponding 95% CI. Otherwise, no obvious heterogeneity was considered to have occurred in the included studies, and the fixed-effects model was selected to generate the SMD with its corresponding 95% CI. The forest plot for each parameter was constructed to illustrate the weight ratio of each incorporated study. Subgroups were analyzed to determine the influence of different factors on the overall risk assessment to identify the sources of atypia. Funnel plots and Egger tests were used to evaluate the symmetrical characteristic of the references, whereas the P value of Begg test was used to evaluate the publication bias. In order to evaluate the sensibility of the metaanalysis, articles were excluded one by one and the differences of the combing effect before and after exclusion were compared. If the pooled outcomes reversed after exclusion, the outcomes may be unstable. All statistical analyses were carried out using the STATA 12 software (STATA Corp LP, College Station, Texas), and the significance threshold was a 2-sided P < .05.

The relevant data in untreated patients served as reference for the estimation of SMD with the corresponding 95% CI. An SMD > 1 indicates that the score of the parameter in patients receiving brace treatment is higher than that in untreated patients.

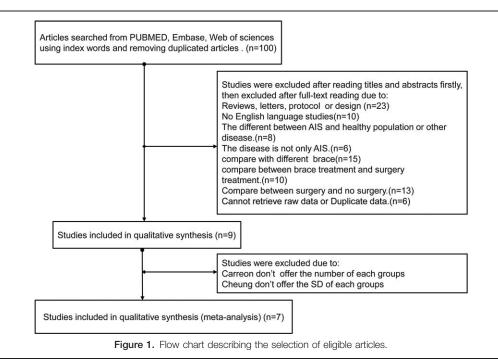
## 3. Results

# 3.1. Study selection and quality assessment

A total of 100 publications were retrieved after removing duplicate articles from the first literature search. We scanned the titles and abstracts of these 100 papers and excluded 85. The remaining 15 articles were screened by full-text reading, and 7 papers<sup>[14–16,19–22]</sup> met the above inclusion and exclusion criteria. Figure 1 presents the study selection process. Of the 7 qualifying articles (Table 1), 4 were prospective studies. The ratio of females in each of the 7 studies was not lower than 70%. According to the results of the NOS (Table 2), the studies of Parent et al<sup>[15]</sup> and Mousavi et al<sup>[22]</sup> rated 6 stars, indicating moderate quality, and the other 5 studies rated 7 or more stars, denoting high quality.

# 3.2. Difference in pain and self-image between the untreated and brace-treated AIS patients after intervention

There were 5 eligible studies for the analysis of pain and self-image, respectively. Significant heterogeneity ( $I^2 = 53.4\%$ , P = .073) was



#### Table 1

#### Special characteristics of included studies.

Reference		Country	Observation/brace	Female, %	Skeletal age, y	Follow-up, y
Danielsson et al <sup>[14]</sup>	Prospective	Sweden	40/37	100	10–15	11
Parent et al <sup>[15]</sup>	Prospective	Canada	107/32	100	18.6	-
Feise et al <sup>[21]</sup>	Prospective	Canada	24/30	83.30	10-18	-
Mousavi et al <sup>[22]</sup>		Iran	25/14	70	12-18	-
Fong et al <sup>[16]</sup>	Prospective	China	31/18	94	12-15	1
Lee et al <sup>[20]</sup>	_	China	68/3	81	14.2	-
Yu et al <sup>[19]</sup>	-	China	179/32	84	12–18	-

# Table 2

Quality assessment of individual study.

	Selection						Outcome		
Reference	Representativeness of exposed cohort	Selection of nonexposed cohort	Ascertainment of exposure	Outcome not present at start	Comparability	Assessment of outcome	Follow-up length	Follow-up adequacy	Score
Danielsson et al <sup>[14]</sup>	*	*	*	*	**	*	*	*	9
Parent et al <sup>[15]</sup>	*	*	*	*	*	*			6
Mousavi et al <sup>[22]</sup>	*	*	*	*	*	*			6
Lee et al <sup>[20]</sup>	*	*	*	*	**	*			7
Yu et al <sup>[19]</sup>	*	*	*	*	**	*			7
Fong et al <sup>[16]</sup>	*	*	*	*	**	*	*	*	9
Feise et al <sup>[21]</sup>	*	*	*	*	**	*			7

A study can be awarded a maximum of 1 star for each numbered item within the Selection and outcome categories. A maximum of 2 stars can be given for Comparability.

detected for pain, while no evidence of heterogeneity ( $I^2 = 29.3\%$ , P = .226) was observed for self-image. Therefore, the randomeffects model was used to calculate the SMD with its corresponding 95% CI for pain, whereas the fixed-effects model was applied for the self-image (Table 3). The value of the SMDs were 0.123 (95% CI: -0.101 to 0.347, P = .282, Fig. 2A) and 0.108 (95% CI: -0.116 to 0.332, P = .334, Fig. 2B) for pain and self-image, respectively, suggesting that there was no significant difference in pain and self-image between the untreated and brace-treated AIS patients after intervention.

# 3.3. Difference in function, mental health, and satisfaction with management between the untreated

## and brace-treated AIS patients after intervention

In terms of function and mental health, a total of 5 and 7 studies, respectively, were included for these analyses (Table 3).

Table 3

Study	SMD/WMD	Lower limit	Upper limit	<i>P</i> (OR)	f	P (Heterogeneity)	P (Begg test)	P (Egger test
Pain	0.123	-0.101	0.347	.282	53.40%	.073	.086	.015
Self-image/appearance	0.108	-0.116	0.332	.334	29.30%	.226	.806	.625
Function/activity	0.202	-0.022	0.425	.077	< 0.01%	.484	.806	.962
Mental health	0.089	-0.103	0.281	.365	3.90%	.392	.260	.171
Satisfaction with management	0.393	0.127	0.659	.004	22.20%	.277	1.000	.927
Total score without satisfaction	0.123	-0.232	0.478	.497	< 0.01%	.375	1.000	_
Total score	0.312	0.054	0.571	.018	< 0.01%	.968	.734	.930

OR = odds ratio, SMD = standardized mean difference, WMD = weighted mean difference.

There was no significant heterogeneity in the 2 other analyses (function:  $I^2 < 0.01\%$ , P = .484; mental health:  $I^2 = 7.50\%$ , P = .371). The fixed-effects model was adopted for the generation of SMDs with their corresponding 95% CIs for the 2 parameters. The values of SMDs were 0.202 (95% CI: -0.022 to 0.425, Fig. 3A) and 0.031 (95% CI: -0.130 to

0.201, Fig. 3B) for function and mental health, respectively, and the *P* values were not significant (function: P=.077; mental health: P=.365), which leads to the conclusion that the difference in the function and mental health between the untreated and brace-treated AIS patients was not significant after intervention.

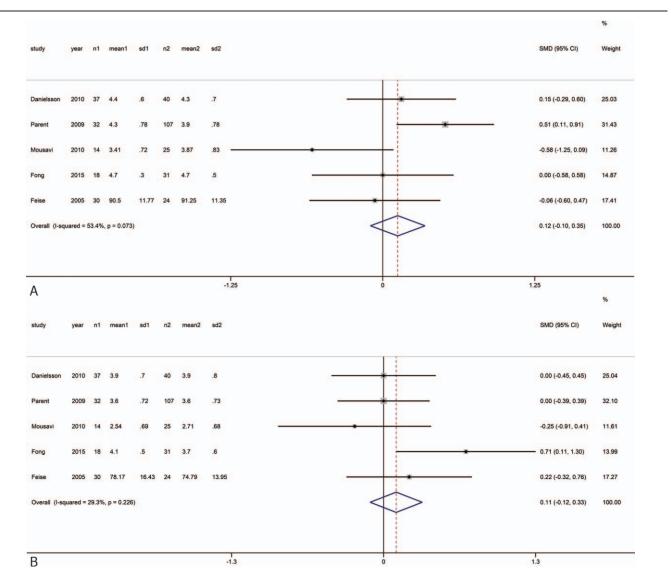


Figure 2. Forests plots of studies evaluating the difference in the pain (A) and self-image (B) between the untreated and brace-treated adolescents with idiopathic scoliosis patients after intervention.

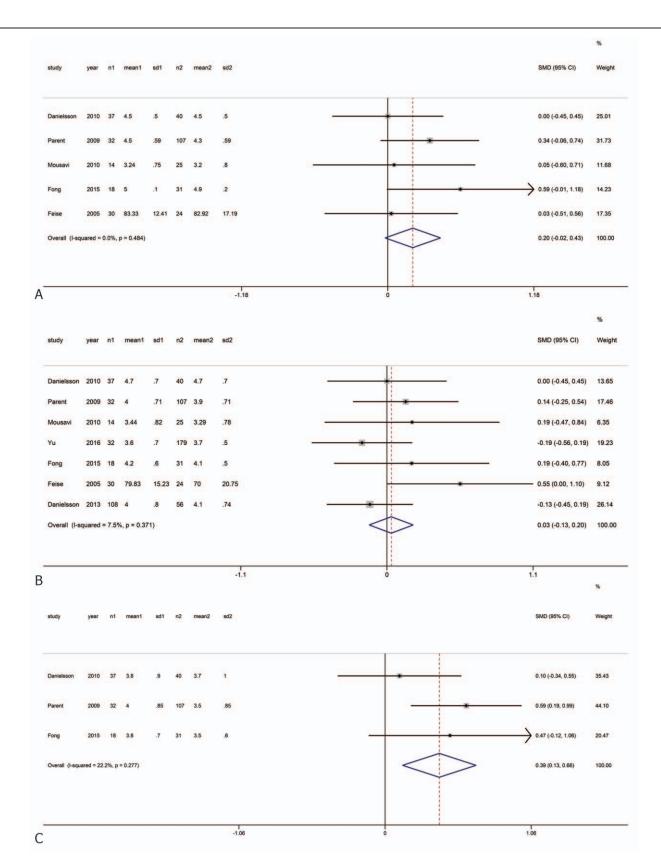
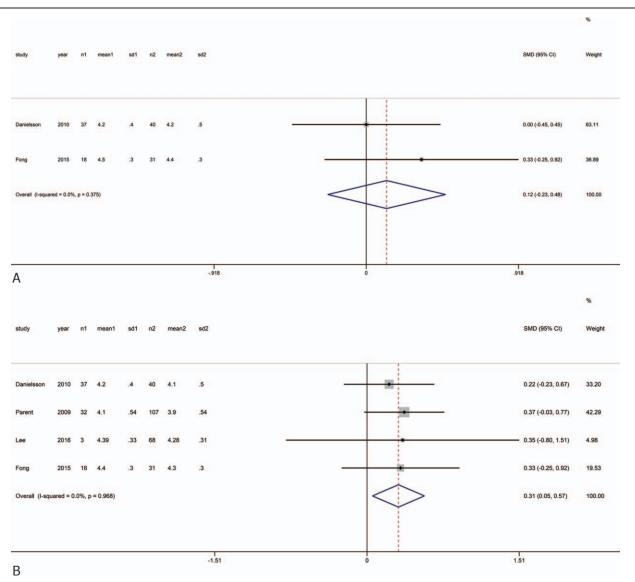
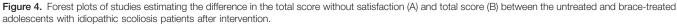


Figure 3. Forest plots of studies assessing the difference in the function (A), mental health (B), and satisfaction with management (C) between the untreated and brace-treated adolescents with idiopathic scoliosis patients after intervention.





Data from 3 studies were incorporated for the analysis of satisfaction with management (Table 3). The fixed-effects model was selected to construct a forest plot for the analysis because of the absence of statistical heterogeneity ( $I^2=22.2\%$ , P=.277). The value of SMD was 0.393 with a 95% CI range of 0.127 to 0.659 (Fig. 3C), and P=.004, which indicates that the satisfaction scores in braced-treated AIS patients after the intervention were significantly higher than those in untreated AIS patients.

# 3.4. Difference in total score without satisfaction and total score between the untreated and brace-treated AIS patients after intervention

With regard to the total score without satisfaction and total score, there were 2 and 4 studies eligible for these analyses, respectively (Table 3). A small degree of heterogeneity was found in the analyses (total score without satisfaction:  $I^2 < 0.01\%$ , P = .375; total score:  $I^2 < 0.01\%$ , P = .968), so the fixed-effects model was

selected for the construction of forest plots. The values of SMDs were 0.123 (95% CI: -0.232 to 0. 478, P=.497, Fig. 4A) and 0.312 (95% CI: 0.054-0.571, P=.018, Fig. 4B) for the total score without satisfaction and total score, respectively, indicating that no significant difference was detected in the total score without satisfaction between the untreated and brace-treated AIS patients, while there was significant difference in the total score between the 2 groups after intervention.

## 3.5. Publication bias

The Begg funnel plots for these analyses were constructed to estimate the publication bias (Figs. 5A–D and 6A–C). The shape of all 7 funnel plots was practically symmetric, which indicates that there was no significant publication bias in our meta-analysis. As for the results of Egger test (Table 3), considering the symmetric funnel plot for pain, it appears that no significant publication bias occurred during analyses of pain, even when P < .05; the values of P for the other 6 outcomes of

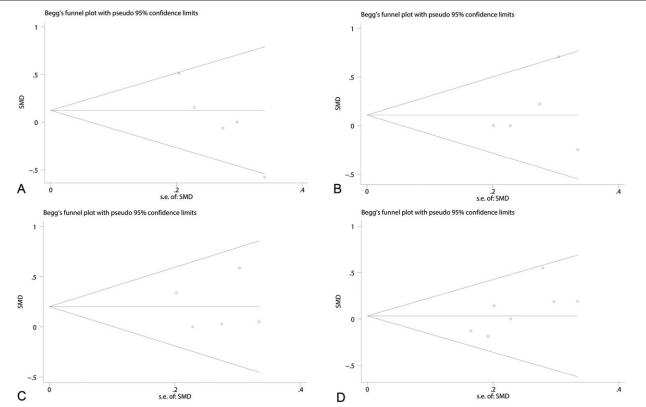


Figure 5. Funnel plots of studies appraising the difference in the pain (A), self-image (B), function (C), and mental health (D) between the untreated and brace-treated adolescents with idiopathic scoliosis patients after intervention.

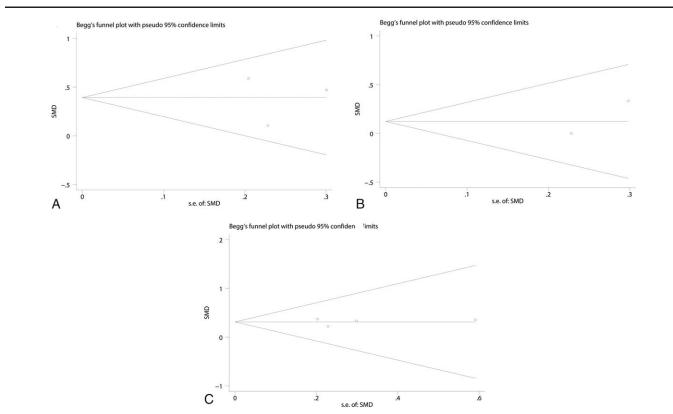


Figure 6. Funnel plots of studies assessing the difference in the satisfaction with management (A), total score without satisfaction (B), and total score (C) between the untreated and brace-treated adolescents with idiopathic scoliosis patients after intervention.

interest were all larger than .05, signifying no significant publication bias.

#### 3.6. Sensitivity analysis

After combining every parameter, we obtained the references one by one, and then combined these references again. From all these outcomes, we found that there were no significant differences between combined SMD and general SMD after exclusion, and the outcomes exhibited no changes. As the results were shown, all the outcomes we analyzed were more stable with low sensitivity.

# 4. Discussion

Our meta-analysis incorporated 7 eligible studies, and the results showed that the scores for pain, self-image/appearance, mental health, function/activity, and total score without satisfaction for untreated AIS patients were similar to those for brace-treated patients after intervention, while the score of satisfaction with management and total score for brace-treated AIS patients were significantly higher than those for the untreated-patients.

AIS, which occurs in children after the age of 10 or after puberty, is a frequent disease with 80% of the diagnoses occurring in girls.<sup>[4]</sup> Based on its definition, AIS is a lateral deviation of the spine, and a right-sided thoracic curve may be one of the most common clinical features for AIS cases.<sup>[23]</sup> Although several factors have been proposed to explain the pathogenesis of AIS including genetics; connective tissue abnormalities; and associated neurological, muscular, and skeletal disorders, its exact etiology is still unclear.<sup>[24]</sup> Adolescence is the phase of development during which establishment of self-respect and self-confidence occurs, so living with a chronic disease may make the process challenging and difficult.<sup>[25]</sup> It has been documented that AIS patients may tend to experience mental disorders or even commit suicide, even though AIS itself is not a life-threatening disease.<sup>[13,26,27]</sup>

For patients with AIS, brace treatment, which requires the active participation of the patient and their parents, is an effective therapy that eliminates the need for surgery.<sup>[28,29]</sup> Brace treatment has been developed and refined over several decades since it was first described by Blount et al,<sup>[30]</sup> and multiple types of this therapy have been proposed and tested including the Milwaukee brace, Wilmington brace, Boston brace, Dynamic Spine-Cor brace, Charleston brace, and Providence brace.<sup>[12,30]</sup> Data from a relevant study of 84 AIS patients, conducted by Mousavi et al<sup>[22]</sup>, concluded that AIS patients receiving brace treatment had similar QoL to those under observation. Our meta-analysis, with a larger sample size, indicated that AIS patients receiving brace treatment were more likely to have higher satisfaction scores and total scores than untreated patients, and thus, to have improved QoL.

It has been reported that the improved QoL flowing from in brace treatment is related to changes in pain, family relationships, and activity levels in the AIS patients.<sup>[31]</sup> A variety of surveys have been developed to evaluate the QoL in AIS patients by both scoliosis clinics and relevant service organizations, such as the Brace Questionnaire, the Bad Sobernheim Stress Questionnaire, the SRS-22 Questionnaire, and the SF-36 Survey.<sup>[14,32]</sup> In our study, to reduce bias and increase accuracy, we only included studies in which the QoL was assessed by SRS-22 or modified version of SRS-22 Questionnaire. The SRS-22 Questionnaire consists of 5 domains: pain, self-image/appearance, mental health, function/activity, and satisfaction with management with a total of 22 items.<sup>[20]</sup> Two indices (total score without satisfaction and total score) calculated as in previous studies<sup>[16,19]</sup> were also used as outcomes of interest to measure the QoL in our study, and these results demonstrated that brace-treated AIS patients were likely to have improved QoL compared with untreated patients.

Although explicit methods have been used for study inclusion, data extraction and synthesis, there is still a limitation in our meta-analysis. As a complex disease, AIS may be associated with a combination of genetic, environmental, and lifestyle factors.<sup>[5]</sup> However, a subgroup analysis stratified by ethnicity has not been performed due to the insufficient data, and if more relevant research becomes available, the subgroup analysis should be carried out.

In summary, our meta-analysis indicates that compared with untreated AIS patients, those treated with brace therapy have higher satisfaction scores and total scores, and thus, appear to have improved QoL relative to patients treated less aggressively. Thus, brace treatment should be recommended to AIS patients in hopes of achieving a more favorable QoL, and perhaps a decreased long term need for surgical intervention.

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