REVIEW ARTICLE

Treatment of bracing for adolescent idiopathic scoliosis patients: a meta-analysis

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Abstract

Purpose A meta-analysis was conducted to compare the efficacy and safety of bracing and other treatments in adolescent idiopathic scoliosis (AIS) patients.
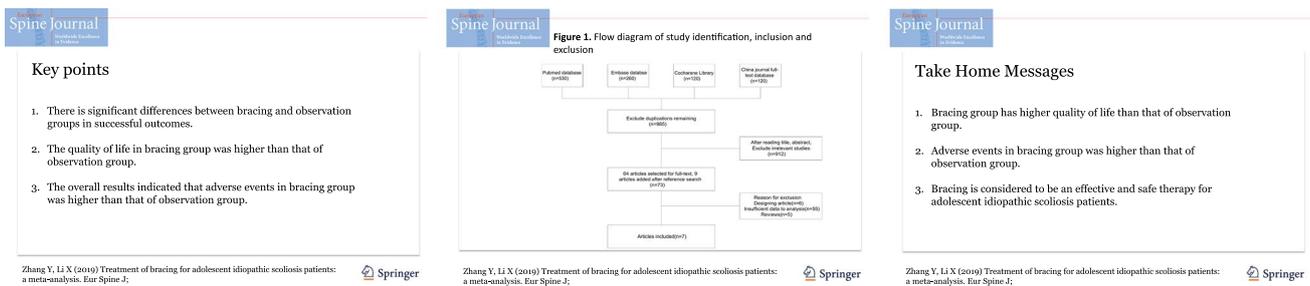
Methods PubMed, Embase, and Cochrane Central Register of Controlled Trials were searched for randomized controlled trials that investigated bracing and other treatments for AIS. The Mantel–Haenszel method with fixed-effects or random-effects model was used to calculate the relative risks and 95% confidence intervals (CIs). The results of heterogeneity, sensitivity analysis, and publication bias were analyzed.

Results Seven studies that met the eligibility criteria with 791 participants were included. The results of meta-analysis suggested significant differences between bracing and observation groups in successful outcomes [OR 3.58, 95% CI (1.92, 6.68), $P < 0.0001$; P for heterogeneity $= 0.008$, $I^2 = 65\%$], quality of life [MD $= 2.13$, 95% CI (0.51, 3.75), $P = 0.01$; P for heterogeneity $= 0.89$, $I^2 = 0\%$], and adverse events [OR 5.31, 95% CI (2.42, 11.66), $P < 0.0001$; P for heterogeneity $= 0.78$, $I^2 = 0\%$].

Conclusion The findings of this meta-analysis suggested that bracing is efficient and safe for the treatment of AIS.

Graphic abstract

These slides can be retrieved under Electronic Supplementary Material.

Keywords Bracing · Adolescent idiopathic scoliosis · Efficacy · Safety · Meta-analysis

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Background

Adolescent idiopathic scoliosis (AIS) is a common spinal deformity that occurs and develops during puberty and accounts for 74.7% of all scoliosis patients. This may often be worse in some patients, leading to serious thoracic deformity, and impairment of cardiopulmonary function, endangering the lives of patients [1–3].

The key steps for treating AIS include early detection, early diagnosis, and early intervention, avoiding the

occurrence of progressive changes in scoliosis. The evidence from the previous studies regarding the effectiveness of non-surgical treatment of AIS is insufficient [4, 5]. Some researchers even pointed out that AIS is a clinical syndrome that is related to body disorder, and the human body has certain compensatory abilities. Clinically, the deformities that do not affect the quality of life of patients need not be dealt, but external deformities have a negative impact on the physical and mental health of adolescents. Therefore, early non-surgical treatment is necessary. Generally, the patients with Cobb angle < 45 degrees can be treated by non-surgical treatment. Also, the degrees of progression of Cobb angle per year, whether the main bend is a structural bend, and Lenke classification of AIS are considered as the factors for deciding suitable treatment for AIS [6]. Currently, the non-surgical treatments mainly include exercise therapy, brace therapy, electrical stimulation therapy, massage, traction therapy, gypsum therapy, and so on.

Brace therapy for AIS has a long history and aims at the correction of scoliosis and vertebral rotation by physical methods. Bracing is characterized by lightness, comfort, and high efficiency. By correcting the curvature and rotation of the spine, especially the thoracic spine, the thoracic deformity caused by the spinal deformity can be prevented, the compression of the thoracic viscera can be reduced, and the cardiopulmonary dysfunction can be avoided [7, 8]. However, the use of braces has a disadvantage of growth restriction of patients' thorax, which subsequently affects the development of heart and lung in thoracic cavity [9].

There are several articles that reported the use of braces for AIS patients, in which there are several kinds of research designs, enrollment, exclusion criteria, and measurements. There are limited studies that reported the comprehensive evaluation of bracing for AIS. Hence, a meta-analysis was conducted to evaluate the clinical efficacy and complications of bracing comprehensively in AIS patients.

Methods

Search strategy

The PubMed, Embase, and Cochrane Central Register of Controlled Trials databases were searched for studies reporting the effect of bracing in the treatment of AIS. Publications from January 2001 to October 2018 were considered for review.

Two members of our team searched the articles independently using the following keywords: (1) bracing; (2) Adolescent Idiopathic Scoliosis OR AIS. Two independent investigators carried out the initial search, deleted the duplicate records, screened the titles and abstracts of relevance, and identified the publications by excluding or requiring

further assessment. Then, we reviewed the full-text articles for inclusion. The references of the retrieved articles and previous reviews were manually checked to identify additional eligible studies.

Selection of research studies

Two other researchers conducted initial screening and then collected the articles. The titles and abstracts of these articles are independent and carefully screened. The full texts of relevant articles were then obtained.

The articles were screened for the presence of the following inclusion criteria:

1. A randomized control trial or a controlled clinical trial;
2. Comparison between bracing and no specific treatment;
3. Availability of full text.

The researches were excluded if:

1. Not a randomized study;
2. Studies on treatments other than bracing;
3. Studies lacking outcome measures or comparable results.

There were no language restrictions for study selection. The bibliography of all selected articles was hand-searched to identify additional articles that met our inclusion criteria. In cases where multiple publications were available with more number of patients or longer follow-up for the same group, data from the most recent article was used for statistical analysis. The indicators include successful outcomes in the treatment of AIS, quality of life, and adverse events.

Data extraction

Two authors independently reviewed the formal published versions of all eligible studies for content and screened them according to the specified eligibility criteria using a data extraction form based on the Cochrane Consumers and Communication Review Group's data extraction template. Disagreements between the two review authors were resolved by discussion, and if no agreement could be reached, then a third author would decide. The following information was extracted in this study, which included the first author's name, publication year, years of onset, sample size, age range of patients, and outcome parameters. Quality evaluation was assessed by the risk of bias table in the software. Seven criteria were used in the evaluation: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias.

Statistical analysis

Meta-analysis was performed by Review Manager 5.0 (Cochrane Collaboration 2011) to assess the differences in clinical efficacy between bracing and observation to assess the publication bias. A Chi-squared based Q-test was performed to check between-study heterogeneity. An I^2 value of higher than 50 indicated moderate heterogeneity between the studies, and the effect size for each study was calculated by random-effects model (DerSimonian–Laird approach). If the I^2 value was less than 50, then a fixed-effects model was used. PedsQL scores [10] were analyzed for quality of life regarding the results of heterogeneity. Besides, funnel plot was presented to estimate the possible publication bias.

Results

Search results and characteristics of included studies

The initial search produced 1030 studies. Of these, 985 were selected after excluding the duplicates. After detailed evaluation, 7 studies fulfilled the eligibility criteria of our study. The studies were excluded as 6 studies did not meet the study design, 55 papers have insufficient data, and 5 articles are reviews. Figure 1 presents a flowchart of identification, inclusion, and exclusion criteria of studies.

All these articles were published from 2001 to 2018, and the sample size ranged between 13 and 242. The study included 329 patients in the bracing group and 422 in the observation group. Table 1 presents the list of first author name, year, sample size, and outcome parameters for each study.
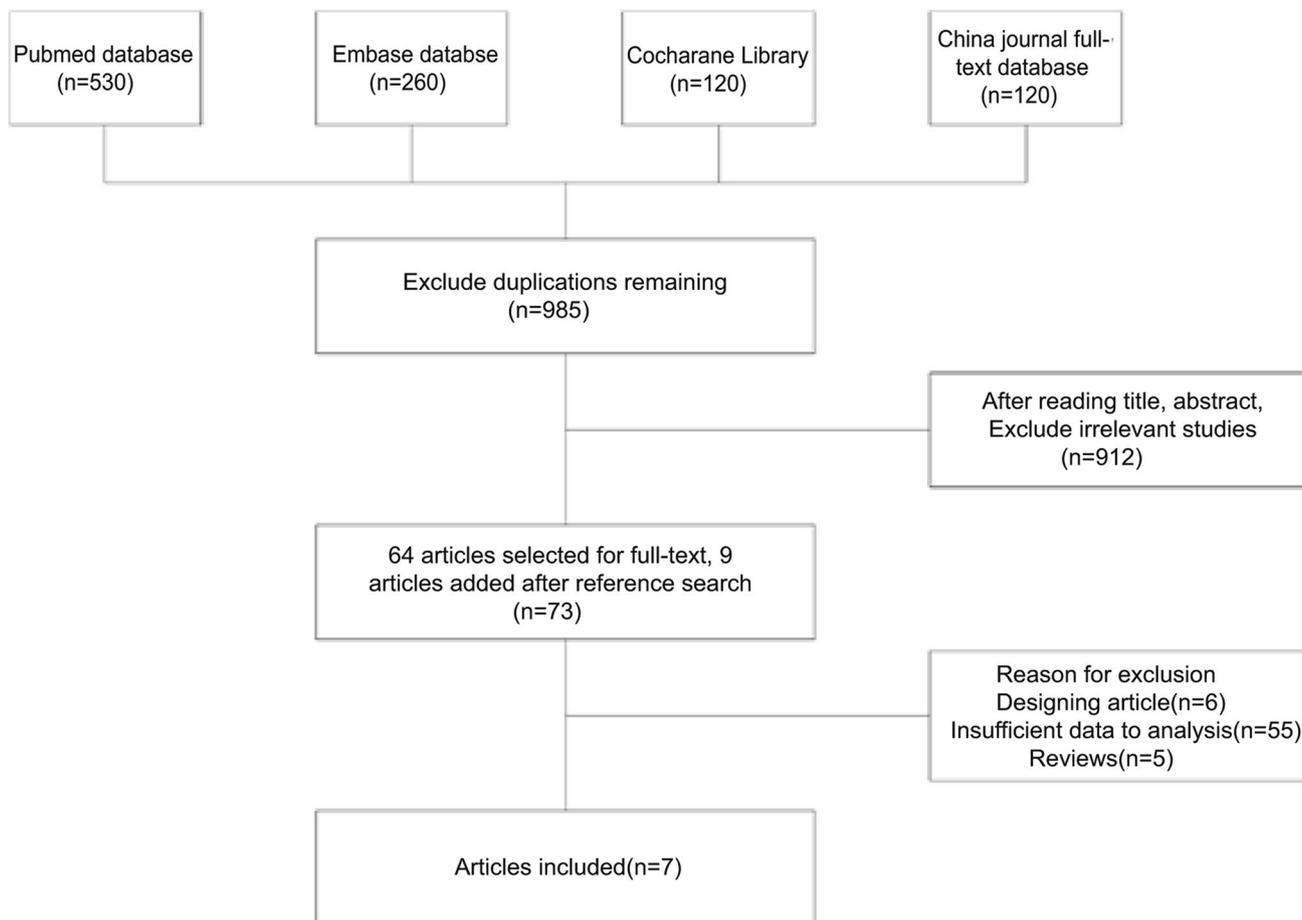

Fig. 1 Flow diagram of study identification, inclusion, and exclusion

Table 1 Characteristics of included studies

References	Language	Country	Age range (mean)	Gender (female/male)	Groups	n	Years of onset
Goldberg [11]	English	Ireland	15.58 ± 3.4	142/11	Bracing	43	December 1990–July 2000
					Observation	110	
Gur [12]	English	Turkey	14 ± 2.4	10/3	Bracing	7	January 2009–October 2014
					Observation	6	
Mak [5]	English	Canada	13.7 ± 1.1	17/3	Bracing	10	October 2002–June 2006
					Observation	10	
Piantoni [13]	English	Argentina	14.1 ± 1.1	43/0	Bracing	23	January 2010–January 2016
					Observation	20	
Sha [14]	English	China	9.3 ± 1.7	30/36	Bracing	22	January 1998–January 2008
					Observation	44	
Ugwonali [15]	English	America	13.8 ± 1.3	172/42	Bracing	78	August 2000–February 2013
					Observation	136	
Weinstein [16]	English	America	12.7 ± 1.1	221/21	Bracing	146	March 2007–February 2011
					Observation	96	

Quality assessment

The Cochrane Collaboration's "Risk of bias" tool was used for quality assessment [17]. The risk of bias in this study is presented in Fig. 2. Participants and respondents had low risk between bracing group and observation group. Figure 3 shows the details about bias among each of the included articles.

Results of meta-analysis

1. Successful outcomes

All included studies demonstrated successful outcomes. Figure 4 shows a stand map of the successful outcomes of the bracing and observation groups. All seven studies showed statistically significant differences in the outcomes of bracing and observation groups. These results suggested that bracing group had better successful outcomes

than observation group [OR 3.58, 95% CI (1.92, 6.68), $P < 0.0001$; P for heterogeneity = 0.008, $I^2 = 65\%$].

2. Quality of life

Forest plot for quality of life (PedsQL scores) is presented in Fig. 5. The results demonstrated that the quality of life in the bracing group was higher than that of the observation group [MD = 2.13, 95% CI (0.51, 3.75), $P = 0.01$; P for heterogeneity = 0.89, $I^2 = 0\%$].

3. Adverse events

The information regarding the adverse events is shown in Fig. 6. The overall results indicated that adverse events in the bracing group were higher than those of the observation group [OR 5.31, 95% CI (2.42, 11.66), $P < 0.0001$; P for heterogeneity = 0.78, $I^2 = 0\%$].

Fig. 2 Assessment of quality of included studies: low risk of bias (green hexagons), unclear risk of bias (white hexagons), and high risk of bias (red hexagons)
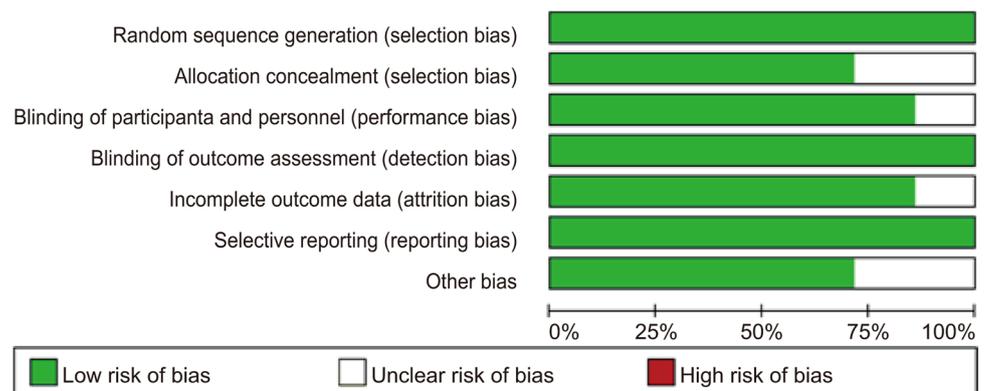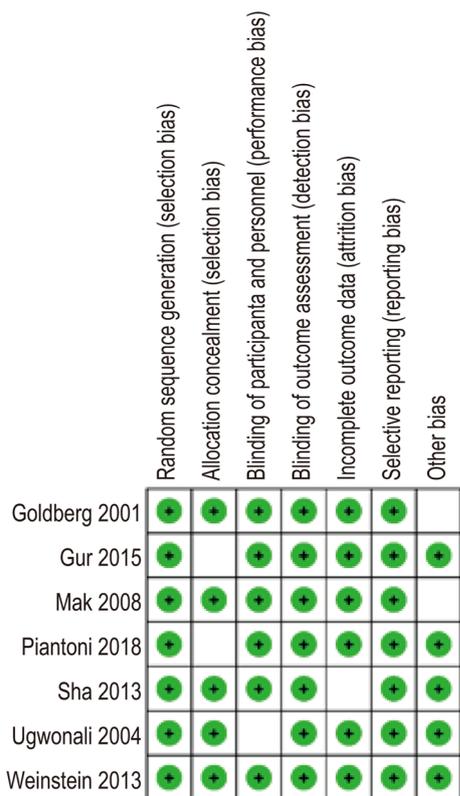
Fig. 3 Quality assessment of included studies

Sensitivity analysis

The results of heterogeneity of successful outcomes were high ($I^2 = 65\%$). As shown in Fig. 7, high heterogeneity of operation time may be attributed to the different results of each study. When the article of Ugwonali conducted in 2004 was excluded, the I^2 was changed to 61%, demonstrating the robustness of the results in this research.

Bias analysis

Funnel plots of successful outcomes in bracing and observation groups were presented. All studies are included in the plot. The results showed that the funnel plot had limited symmetry and some publication bias (Fig. 8). The results of Begg's and Egger's test suggested no significant evidence of potential publication bias ($z = 1.35$, $P = 0.176$ and $t = 1.14$, $P = 0.307$).

Discussion

AIS is a common deformity of the spine, with no definite cause. The spine in AIS is abnormally bent and rotated on the coronal plane and accompanied by the rotation of the vertebral body, making the spine of the patient in a radian state [18]. The right thoracic curve is one of the most common clinical features of AIS. Scoliosis most commonly occurs in women and shows more obvious curves. On average, women are seven times more likely to have scoliosis than men. AIS occurs in children aged more than 10, and 80% of them are girls [19].

For younger patients with AIS, the development of the disease is often very rapid and causes irreversible consequences if no timely intervention is provided. Hence, the treatment of adolescent AIS has become a hot issue currently [20]. Few studies [1–3] showed that early detection and treatment of AIS in adolescents can effectively reduce its complications, delay or prevent deformities in spinal morphology, correct the biomechanical imbalance on both sides of the spine in time, and improve the function and quality of life. Some negative effects of brace included pain, skin irritation, lung, and kidney dysfunction.

In our research, the difference in successful outcomes between bracing and observation groups was significant.
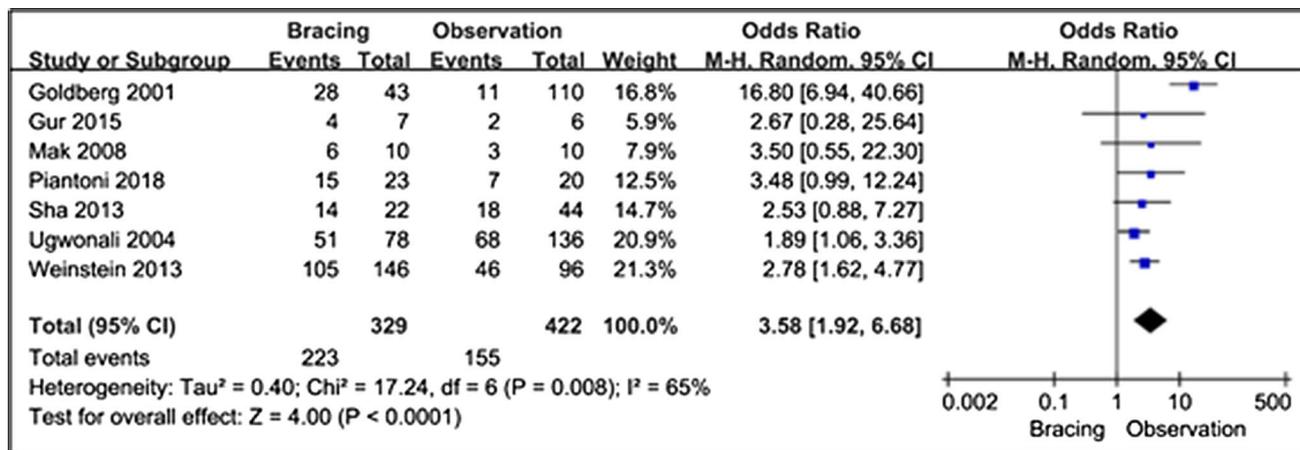

Fig. 4 A forest plot for successful outcome in bracing and observation groups
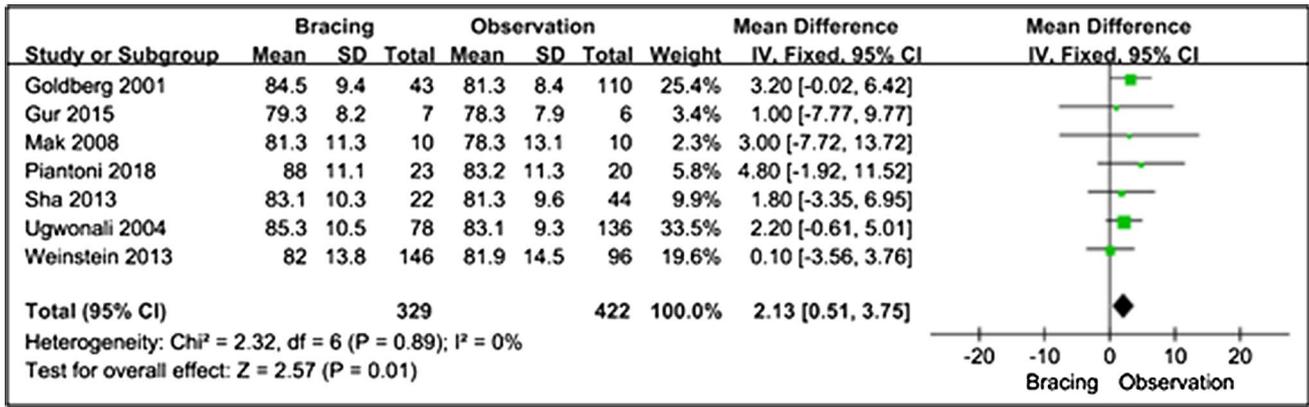
Study or Subgroup	Bracing			Observation			Weight	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Goldberg 2001	84.5	9.4	43	81.3	8.4	110	25.4%	3.20 [-0.02, 6.42]	
Gur 2015	79.3	8.2	7	78.3	7.9	6	3.4%	1.00 [-7.77, 9.77]	
Mak 2008	81.3	11.3	10	78.3	13.1	10	2.3%	3.00 [-7.72, 13.72]	
Piantoni 2018	88	11.1	23	83.2	11.3	20	5.8%	4.80 [-1.92, 11.52]	
Sha 2013	83.1	10.3	22	81.3	9.6	44	9.9%	1.80 [-3.35, 6.95]	
Ugwonali 2004	85.3	10.5	78	83.1	9.3	136	33.5%	2.20 [-0.61, 5.01]	
Weinstein 2013	82	13.8	146	81.9	14.5	96	19.6%	0.10 [-3.56, 3.76]	
Total (95% CI)			329			422	100.0%	2.13 [0.51, 3.75]	
Heterogeneity: Chi² = 2.32, df = 6 (P = 0.89); I² = 0%									
Test for overall effect: Z = 2.57 (P = 0.01)									

Fig. 5 A forest plot for quality of life in bracing and observation groups

Study or Subgroup	Bracing		Observation		Weight	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
	Events	Total	Events	Total			
Goldberg 2001	3	43	0	110	4.0%	19.10 [0.97, 377.89]	
Gur 2015	2	7	1	6	11.8%	2.00 [0.13, 29.81]	
Mak 2008	2	10	1	10	12.3%	2.25 [0.17, 29.77]	
Piantoni 2018	5	23	2	20	25.7%	2.50 [0.43, 14.61]	
Sha 2013	4	22	2	44	16.8%	4.67 [0.78, 27.81]	
Ugwonali 2004	5	78	2	136	21.0%	4.59 [0.87, 24.24]	
Weinstein 2013	13	146	0	96	8.4%	19.52 [1.15, 332.31]	
Total (95% CI)		329		422	100.0%	5.31 [2.42, 11.66]	
Total events	34		8				
Heterogeneity: Chi² = 3.19, df = 6 (P = 0.78); I² = 0%							
Test for overall effect: Z = 4.16 (P < 0.0001)							

Fig. 6 A forest plot for adverse events in bracing and observation groups

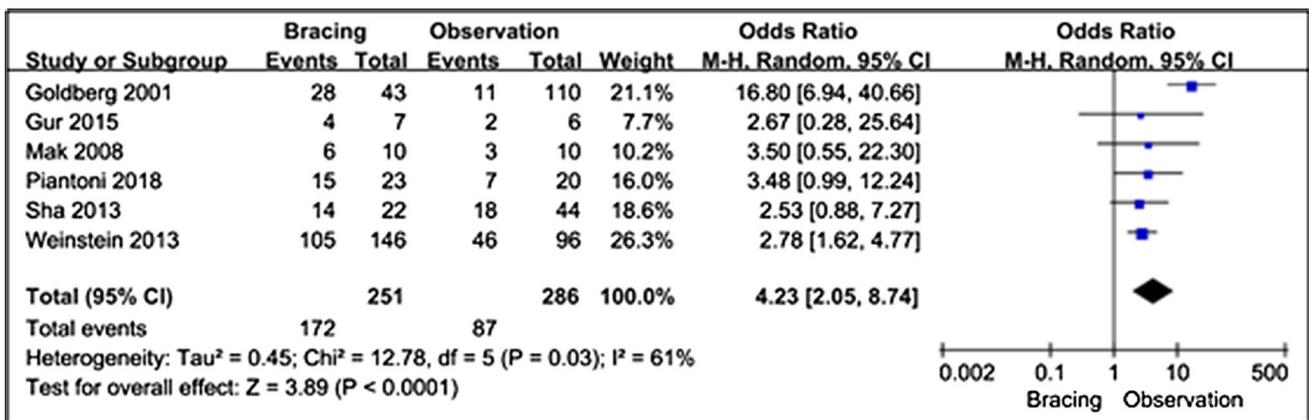| Study or Subgroup	Bracing		Observation		Weight	Odds Ratio M-H, Random, 95% CI	Odds Ratio M-H, Random, 95% CI
	Events	Total	Events	Total			
Goldberg 2001	28	43	11	110	21.1%	16.80 [6.94, 40.66]	
Gur 2015	4	7	2	6	7.7%	2.67 [0.28, 25.64]	
Mak 2008	6	10	3	10	10.2%	3.50 [0.55, 22.30]	
Piantoni 2018	15	23	7	20	16.0%	3.48 [0.99, 12.24]	
Sha 2013	14	22	18	44	18.6%	2.53 [0.88, 7.27]	
Weinstein 2013	105	146	46	96	26.3%	2.78 [1.62, 4.77]	
Total (95% CI)		251		286	100.0%	4.23 [2.05, 8.74]	
Total events	172		87				
Heterogeneity: Tau² = 0.45; Chi² = 12.78, df = 5 (P = 0.03); I² = 61%							
Test for overall effect: Z = 3.89 (P < 0.0001)							

Fig. 7 A forest plot for the sensitivity analysis of successful outcome in bracing and observation groups

Fig. 8 Funnel plot of publication bias
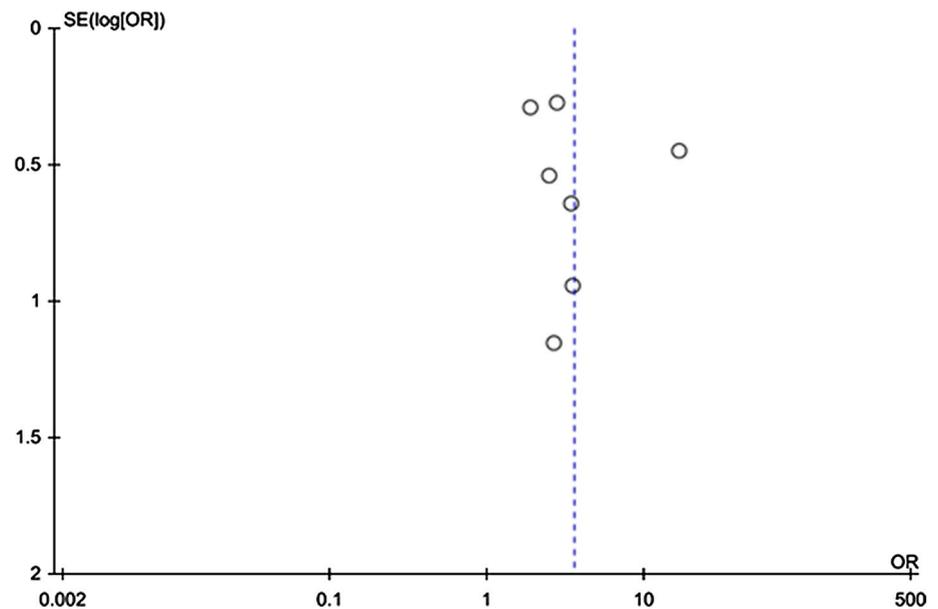
Similarly, the indicator of life quality (*P*edsQL scores) in bracing and observation groups was also significant. These results demonstrated that bracing was an effective treatment for AIS. These results were in line with Chalmers's research on the clinical effects of bracing in AIS patients [21].

The patients in the bracing group had higher complications than those in the observation group. This showed that although bracing improves AIS patients' health and life quality, it might lead to some adverse events. Lou stated that bracing might lead to complications, and this was consistent with our study results [22].

This study provided suggestions in the treatment of AIS patients, and our research was strengthened by inclusion of high-quality studies.

However, there are several limitations in this research. Firstly, the data of follow-up for AIS patients were not collected and are very little. Secondly, more details about adverse events could be investigated. These should be collected further and analyzed in future research studies.

In this study, low heterogeneities of meta-analyses were observed, and according to the funnel plots, limited publication bias was observed, supporting our results better.

In conclusion, bracing is considered to be an effective and safe therapy for AIS patients, and these results are coincident with several published researches.

Compliance with ethical standards

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