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REAL-WORLD EFFECTIVENESS OF BRACE TREATMENT OF ADOLESCENTS WITH IDIOPATHIC SCOLIOSIS

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Background

The Bracing Adolescent Idiopathic Scoliosis (AIS) Trial (BrAIST) demonstrated the efficacy of bracing for AIS, but a comparison with everyday clinical real-world settings showed that it included only about 2% of patients. The BrAIST-Calc and IS-GROWTH provided reliable predictive models for AIS. The availability of these predictive models enables planning for real-world effectiveness studies.

Study Design

Secondary analysis of a retrospective study on prospectively collected data, comparing results at bone maturity to the expected individual natural history.

Objective (s)

To check the effectiveness of bracing in a very large population.

Methods

Setting: a tertiary-level institute specialised in the rehabilitation of patients with spinal disorders. We included all AIS patients observed until bone maturity (EU Risser 3, corresponding to US Risser 4) between 2003 and 2017, as in the previous study: age 10 or above, Risser 0-2, Cobb angle 11-45, and any treatment. Using IS-GROWTH, we calculated the risk for each individual of reaching two significant adult thresholds: 30° and 50° Cobb. Additionally, within the total and braced 20-40° Cobb populations, we calculated the risk of reaching the 45° threshold with BrAIST-Calc and IS-GROWTH. We then compared post-treatment results with those expected from the prognostic models, computing the Standardised Incidence Ratio (SIR) with 95% confidence intervals and Poisson statistics, the Absolute Risk Reduction (ARR), the Number Needed to Treat (NNT), and the Relative Risk Reduction (RRR) for all considered populations.

Results

We studied 1,302 consecutive patients (age 12.9±1.4 years, 25°±9° Cobb at start), of whom 820 (12.8±1.3 years, 28°±6° at start) met the BrAIST inclusion criteria, and 710 were treated with braces. Compared with the IS-GROWTH natural history, treating 2.5 and 4.7 patients in the total population prevents one patient from reaching clinically significant thresholds of 30° and 50° (NNT), with ARR of 41% and 21%, respectively. In the 20°-40° population, considering the threshold of 45°, NNT were 3.0 and 2.6 for IS-GROWTH and BrAIST-Calc, respectively. Even though highly correlated (0.849; r²=0.721), the BrAIST-Calc predictions over 45° were slightly higher: 42% vs 37%, mean difference 13±10%.

	Total		20-40°		20-40° braced		
Number	1302		820		701		
Females	82%		84%		84%		
	<i>Av</i>	<i>SD</i>	<i>Av</i>	<i>SD</i>	<i>Av</i>	<i>SD</i>	
Start Age	12,9	1,4	13,0	1,4	13,0	1,4	
Start Weight	47,3	9,2	47,9	9,2	48,1	9,2	
Start Height	158,3	9,2	158,6	9,1	158,6	8,8	
Start BMI	18,8	2,7	18,0	2,8	19,0	2,9	
Start Risser	0,8	0,9	0,9	0,9	0,8	0,9	
Start Cobb	25	9	28	6	29	6	
End Risser	3,7	0,9	3,9	0,8	3,9	0,8	
End Cobb	24	10	26	9	26	9	
Expected above 45° - Braist-Clac	NA		344	42%	313	45%	
Expected above 45° - IS-GROWTH	393	30%	300	37%	280	40%	
Final result above 45°	40	3%	23	3%	22	3%	
	IG30	IG50	IG45	BC45	IG45	BC45	
Absolute Risk Reduction ARR	41%	21%	34%	39%	37%	35%	
Number Needed to Treat NNT	2,5	4,7	3,0	2,6	2,7	2,9	
Standardized Incidence Ratio SIR	0,35	0,07	0,08	0,07	0,08	0,07	
Ratio	95CI	0,31	0,04	0,05	0,04	0,05	0,04
	95CI	0,40	0,11	0,12	0,10	0,12	0,11
	P (Poisson)	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000
RR Reduction RRR	284%	1407%	1303%	1492%	1271%	1214%	

IG30: IS-GROWTH prediction at 30°; **IG50:** IS-GROWTH prediction at 50°; **IG45:** IS-GROWTH prediction at 45°; **BC45:** BraIST-Calc prediction at 45°; **NA:** Not

Conclusion(s)

This study shows the effectiveness in everyday clinical practice of braces confirming the efficacy shown in RCTs. However, results from a single institute (even if multicenter with over 30 physicians) limit generalizability and require further confirmation.

Clinical significance

Valid predictive models allow effectiveness studies, which are crucial for showing the real-world relevance of RCTs' results. RCTs focus on internal validity in controlled environments, while effectiveness studies like this evaluate benefits in routine practice, offering a better view of public health impact.