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RESEARCH

Geographic, personal and clinical determinants of brace-wearing time in adolescents with idiopathic scoliosis

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Abstract

Purpose Adherence to brace treatment is crucial for its effectiveness in AIS. The study aimed to verify the impact of geographic, personal and clinical variables on adherence to brace wear.

Methods Design: retrospective cross-sectional study of consecutively collected participants at a tertiary referral institute. Inclusion criteria: AIS, one-year of follow-up after bracing, and use of a thermal sensor. The outcome was adherence and tested predictors were age, gender, ATR, TRACE, Cobb, curve type, Risser, and back pain at baseline, brace type and prescription time, income, living in the North, Centre, or South of Italy, city of residence size, distance from the sea, and height above sea level. The chi 2 test was used to investigate the association between the categories and adherence. The logistic regression model tested the predictors. STATA 17.0 MP was used.

Results We included 1904 adolescents, age 13.8 ± 1.6 (1597 females), worse scoliosis curve 35 ± 11° Cobb. The prevalence of good compliers, with more than 75% of the prescribed dosage, was 90.8%. Factors associated with higher adherence were living in the North of Italy ($p = 0.003$), prescription > 20 h per day ($p = 0.008$), female gender ($p = 0.008$), younger age and lower Risser sign (age 10 to 13: $p = 0.000$; Risser 0–1: $p = 0.013$). The regression model explained 4% of the variability.

Conclusion Living in the North of Italy, longer hours of brace prescription, female gender, younger age, and lower Risser sign increased adherence to brace wear. Nevertheless, there are other unknown factors that contribute to the explanation of adherence in this highly compliant population.

Keywords Adolescent idiopathic scoliosis · Brace · Adherence · Predictors

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Introduction

Idiopathic scoliosis is a three-dimensional deformity of the spine and trunk that develops in all ages of life. Idiopathic Scoliosis in Adolescents AIS is diagnosed after the age of 10 and progresses with growth, especially during puberty until growth is complete, with a prevalence of around 3%. Scoliosis progression is associated with trunk deformities leading to aesthetic impact, pain, and a decreased quality of life [1]. The impact of scoliosis depends on severity of the curve and on risk of progression. The treatment options range from observation in very mild cases to scoliosis-specific exercises (PSSE) in low to moderate cases and brace therapy in moderate to severe ones. In case of very high-degree curves, surgery (spinal fusion) may be recommended. Due to the limitations associated with arthrodesis, the absolute goal of conservative treatment for AIS is therefore to prevent the need for surgical intervention [1].

Bracing is an effective therapy that can prevent scoliosis progression when the severity of the curve is moderate to severe [1]. One of the key factors in the success of bracing therapy is the brace dosage [2]. Its accurate monitoring is crucial. New technologies, such as thermal and pressure sensors, enhance adherence tracking more precisely than self-reported dosage, since patients tend to overestimate their compliance [3]. Some factors showed an influence on adherence to brace therapy, such as age [4], early adherence to the prescribed brace wear time [5], and psychosocial factors [6, 7]. Other environmental factors, like those linked to climate and regional differences, have still to be explored.

The Italian peninsula is long almost 1300 km, extending from North to South, and consists of diverse orographic regions, ranging from alpine areas (with altitudes above 4000 m) to Mediterranean islands with significant climate differences. Italy also exhibits a great diversity in population distribution, with many villages in the countryside and some big cities.

Among the main issues for patients with bracing there is heat, especially during summer [8]. Another issue can be connected to the lifestyle, with people living along the seaside being used to spend the whole day on the beach, thus possibly affecting a fulltime brace prescription.

As far as we know, no study ever evaluated if geographical variables influence brace therapy adherence. Italian country is an ideal setting for such investigation. Therefore, the aim of this study was to investigate, in a large AIS population living in different areas, whether not only personal characteristics but also those linked to geographical location (North-Central-South Italy, altitude, distance from the sea and city size) influence adherence to brace therapy monitored with a thermal sensor.

Materials and methods

This is a cross-sectional study on adherence to brace wear in a cohort of consecutive patients. The setting was a tertiary referral outpatient institute specialising in the conservative treatment of spinal disorders in Italy. The local Ethics Committee approved this study (approval number 466_2021) on 29 April 2021. Written informed consent was obtained from all participants.

Participants

We enrolled patients who started brace treatment between January 2010 and October 2022. Inclusion criteria were: AIS diagnosis; brace treatment according to the Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) Guidelines [1]; one-year systematic quantitative recording of brace hours usage through a thermal sensor application; age between 10 and 18 years at the start of treatment.

Exclusion criteria were: secondary scoliosis; neuromotor disorders; missing radiographic or clinical data on the investigated variables. We excluded also participants with ≥2weeks of missing sensor data, who declared they had removed the sensor to swim with the brace on, or due to serious health issues, and participants starting brace wearing during the summer in June, July or August. In this case in fact, when clinically possible, doctors may ask patients to wear the brace only at night until September and then start the full-time wearing. This is a verbal counselling not reported in clinical reports, and it is consequently impossible to correctly judge sensors‘ recordings on adherence in these cases.

Intervention

In the clinic where the study was carried out, we use different braces according to the SOSORT Guidelines. We followed an already described step-by-step approach in treatment choice based on risk factors and shared decision-making with patients and families [9].

We applied one of the following braces [10]: (1) anterior closure, three-dimensional push-up TLSOs (Thoraco-Lumbo-Sacral Orthosis), either monocot rigid (Sibilla) or bivalve highly-rigid (Sforzesco) [11]; (2) for thoracolumbar and lumbar curves, either the short version (LSO - Lumbo-Sacral Orthosis) of the Sibilla brace or a ventral closure frontal & transverse plane detorsion monocot rigid LSO (PASB– Progressive Action Short Brace) [12]; Brace prescription was above 18 h per day (usually 20 to 24) at the first clinical consultation according to the curve’s magnitude and risk of progression. The dosage was subsequently reduced by a maximum of 2 h at every medical

follow-up according to the results obtained. The brace was never reduced below 18 h per day until the patient reaches the Risser 3. All patients were also prescribed PSSEs following the SEAS School [9]. We provided targeted support for brace adherence through cognitive behavioural interventions for patients and parents [9].

Variables

The tested dependent variables were: age in years, gender, Angle of Trunk Rotation (ATR) The Trunk Aesthetic Clinical Evaluation (TRACE) index using the recently developed Rasch compatible version, the worst curve's Cobb angle, single or double/triple curve, the bone age according to European Risser and back pain at baseline, the Body Mass Index (BMI), brace type (TLSO or LSO) and brace prescription time in hours per day, living in the North, Centre, or South of Italy, city of residence size (number of inhabitants), distance of living town from the sea (in kilometers) and its height above sea level (in meters), and income. Privacy issues prohibit to ask for the income of patients, but in our facility we offer discounts according to the family income as declared by the Italian States (ISEE declaration): this allowed to differentiated people for income In terms of regions, we considered Northern Italy Aosta Valley, Piedmont, Lombardy, Liguria, Veneto, Friuli Venezia Giulia, Trentino-South Tyrol, Emilia-Romagna; Central Italy: Tuscany, Umbria, Marche, Lazio; Southern Italy: Abruzzo, Molise, Campania, Apulia, Basilicata, Calabria, Sicily, Sardinia.

Outcome measure

The outcome was adherence, as a percentage of the hours per day prescription. Actual adherence was measured through a thermal sensor (ibutton) we use since 2010 as a standard of care [13]. We analysed the first year of therapy which is the period with the highest number of brace hours prescription.

Statistical analysis

The analysis was run with STATA 17.0 MP. For description, mean with standard deviation and proportions have been used according to the variable type. First, we checked the association between the dependent and independents variables with correlation coefficients and chi2 and Fisher exact test depending on the type of the variables. Alpha level set below 0.05 to show statistical significance.

We ran a series of regression models to test the role of these influencing factors. The histogram and q norm plot of the residuals have been used to test the linearity of the assumptions. The forward stepwise regression allowed automatic selection of the variables to be included in all models. To check model performance, we compared observed probabilities and expected probabilities, we then test calibration and discrimination of the developed clinical prediction rule.

1. A multivariate linear regression model with adherence as continuous outcome. To address skewness towards positive values, a logarithmic transformation have been applied.
2. A binary multivariate logistic regression model with adherence as a binary outcome (we arbitrary defined good adherence as >75% of the prescription in hours in brace per day).
3. A binary multivariate logistic regression model with adherence as a binary outcome and categorical independent variables to allow easier interpretation.

Results

2244 patients met the inclusion criteria. 31 participants were excluded since they had≥2weeks of missing sensor data and declared they had removed the sensor to swim with the brace on, or due to serious health issues. 309 were excluded because they started brace wearing during the summer. We finally included 1,904 patients, 1597 females (84%), age 13.7 ± 1.6, and curve 35 ± 11° Cobb.

Table 1 describes baseline characteristics of the sample. The difference in the mean age was statistically but not clinically significant: 13.7 years in the high adherence group and 14.3 years in the low adherence group. The distribution across Risser subgroups was significantly different for Risser 0 (31.2% in the high adherence group vs. 21.7% in the low adherence group, $p=0.009$) and Risser 5 (1.3% in the high adherence group vs. 3.4% in the low adherence group, $p=0.023$). The mean prescribed brace-wearing time (hours per day) was 21.6 overall, with a statistical but not clinical difference of 21.6 h in the high adherence group and 21.2 h in the low adherence group ($p=0.003$). Regarding geographic distribution, we found a difference for patients coming from northern Italy: 52.1% in the high adherence group and 4.2% in the low adherence group, $p=0.001$.

Most adherent patients had a prescription≥20 h/d ($p=0.001$), were females ($p=0.008$) and younger (age 10–13 $p=0.000$, Risser 0–2 $p=0.013$). Moreover, children from the North or Center adhered more than those from the South ($p=0.003$), while distance from the seaside did not influence adherence ($p=0.303$). All the other studied variables showed no association with adherence.

The stepwise forward multivariable linear regression performed to evaluate the relationship between

Table 1 Provides a description of the entire sample, and compares the baseline characteristics of the good compliers (>75% adherence), and bad compliers (<75%). For age, cobb, ATR, BMI; TRACE, time in brace prescription; distance from the sea, height above the sea, city inhabitants, mean and standard deviation described the sample. For the other variables (emale, Risser score, LSO, single curves, back pain, low income, living in the North, Center or South of Italy) percentages of the total sample are provided. ATR= Angle of Trunk Rotation, BMI = Body Mass Index, TRACE= Trunk Aesthetic Clinical Evaluation, LSO = Lumbar-sacral Orthosis

	All (n=1904)	Subgroups		P value
		>75% compliance (n=1729)	<75% compliance (n=175)	
Age (ys)	13.75(1.6)	13.7(1.6)	14.3(1.6)	0.000*
Female (n)	1597(84%)	1464(91%)	133(76%)	0.003*
Risser 0	30.4%	31.2%	21.7%	0.009*
Risser 1	15.0%	15.0%	14.9%	0.965
Risser 2	19.0%	18.8%	19.4%	0.918
Risser 3	25.6%	25.3%	28%	0.430
Risser 4	9.0%	8.3%	12.6%	0.057
Risser 5	1.6%	1.3%	3.4%	0.023*
LSO (n)	202 (11%)	191(95%)	11(5%)	0.051*
Cobb (°)	35.4(10.9)	35.4(11.0)	35.7(10.4)	0.735
Single curve	34.3%	34.3%	34.3%	0.997
ATR (°)	10.4(3.9)	10.4(3.9)	10.4(3.9)	0.878
BMI	19.4(3.03)	19.3(3.0)	19.7(3.1)	0.147
TRACE (%)	51.6(14.6)	51.5(14.8)	52.5(13.1)	0.369
Back pain	15.3%	15.1%	18.3%	0.265
Low income	4.0%	4.0%	2.9%	0.440
Prescription time in brace (hs/24)	21.6(1.8)	21.6(1.8)	21.2(2.0)	0.003*
Distance from the sea (km)	65.1(65.1)	65.4(65.1)	62.1(64.4)	0.516
Height over seas (metres)	178.0(190.1)	177.1(187.7)	186.9(212.5)	0.515
City inhabitants (n)	207,958(53871)	205,849(532307)	228,906(599896)	0.5906
North Italy	56.3%	52.1%	4.2%	0.001*
Center Italy	17.5%	15.9%	1.5%	
South Italy	26.2%	22.7%	3.5%	

Table 2 Results of the Stepwise forward multivariable linear regression and of the binary logistic multivariate regression performed to evaluate the relationship between all independent variables and adherence

	Stepwise forward multivariable linear regression			Binary logistic multivariate regression			
	β	SE	P<	OR	SE	p <	CI95%
Age	-1.005	0.18	0.000	0.8	0.04	0.000	0.73–0.90
LSO	2.9	0.92	0.002	1.74	0.56	0.09	0.92–3.28
Male Gender	-2.5	0.8	0.002	071	0.14	0.098	0.48–1.06
Living in the south of Italy	2.9	0.6	0.000	-0.52	0.09	0.000	0.37–0.72
Prescription	0.4	0.2	0.000				

all independent variables and adherence as a continuous outcome produced the following equation: *Compliance = 96.87+(− 1.005×Age)+(2.9×LSO)+(-2.9×South living)+(-2.5xmale gender)+(0.4xtime prescribed)* (Table 2). The model was statistically significant but explained only 4% of the variation. The histogram and the norm plot showed an abnormal distribution of the residuals. A logarithmic transformation mildly improved the model performance.

A stepwise forward logistic regression examined the relationship between the independent variables and the two subgroups. The model confirmed the same predictors, with the exclusion of the hours of prescription, and confirmed a moderate to low model fit (pseudo-R^2=0.03). The Area under the ROC curve was 0.64, meaning that the model has a moderate ability to distinguish between good and bad compliers (Fig. 1).

This final binary logistic multivariate regression model with categorical predictors highlighted that younger subjects with a full-time prescription living in the north of Italy had 71% higher odds of wearing the brace with good compliance (Table 3).

Discussion

Our study examined factors influencing adherence to brace treatment in 1,904 consecutive patients with AIS, with most patients demonstrating high adherence. The setting was a specialized referral center where treatment routinely includes cognitive-behavioral interventions to enhance adherence. We identified several predictive factors, including age, male gender, and living in the southern part of Italy, as well as some positive predictive factors, such as increased prescription hours and shorter braces (LSO). Nevertheless,

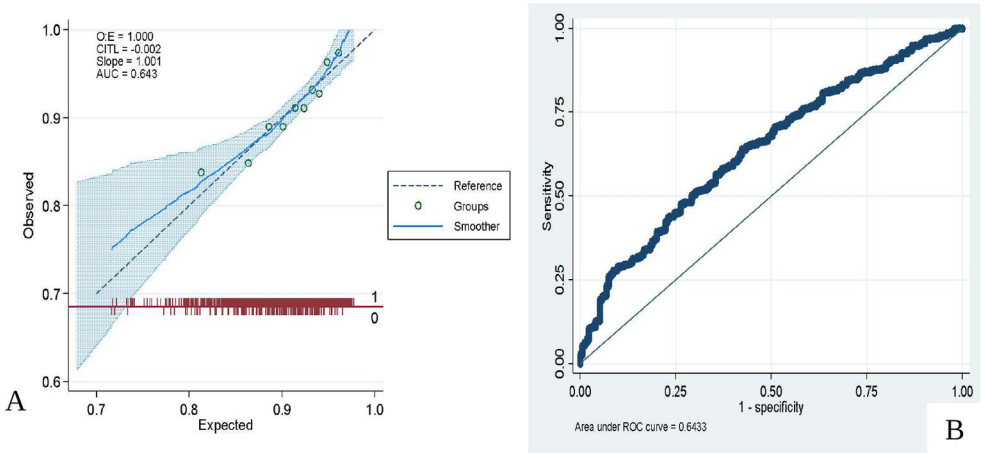

Fig. 1 Graphical representations of the results of the stepwise forward logistic regression model. **A**. Calibration plot: shows discrimination and calibration in the large of the developed clinical prediction rule. There is a trend toward underprediction in the extreme values, and there is too narrow a spread, showing that almost all patients reach high compliance. **B**. The ROC curve shows that discrimination of the model is not that high

Table 3 Binary logistic model to predict compliance>75%. The adjusted OR column presents the factors of a formula to calculate the probability of being a good complier (>75%) in this population (e.g. a female patient aged 11, with a 23 h/d prescription, living in Milan (North of Italy), with a 35° curve, and a TRACE of 8, will have a predicted 93% probability of being good compliant according to the formula (5.69)+ 1.71*1+ 1.93*1+ 1.57*1+ 0.72*0+ 0.70*1+ 1.66*0+ 0.67*1= 12.27, which restitutes a probability of 12.27/(1+12.27)= 0.93)

	Adjusted OR	CI95%	*P* value
Age 10 to 13	1.71	1.25–2.35	0.001 *
>20 h/day prescription	1.93	1.39–2.68	0.000*
North of Italy	1.57	1.15–2.13	0.004 *
Male	0.72	0.49–1.05	0.089
Cobb 30 to 44	0.70	0.51–0.96	0.029*
LSO	1.66	0.93–2.97	0.087
TRACE>8	0.67	0.42–1.05	0.086
Intercept	5.69	3.64–8.90	0.000*

the models predicted only partial adherence (4% for the stepwise forward multivariable linear regression), indicating that, at least in this highly compliant population, other factors play a much larger role.

In a previous study, we had a first exam on the factors influencing adherence to bracing in a cohort of 514 adolescents diagnosed with AIS [14]. Crucial determinants were age, gender, time-in-brace prescription. In this study with a larger population, we confirmed the influence of age, gender and time-in-brace prescription over compliance. Participants under 14 years of age showed higher adherence rates. The same result was found by Takemitsu et al. [4] and Hasler et al. [15]. With regard to gender, females exhibited significantly higher adherence rates than males, in accordance with Karol's and Yrjonen's results [16, 17], who both found that males tend to have poor adherence. On the contrary, Takemitsu et al. [4] didn't find a significant association between compliance and gender. The prescribed daily dosage had an influence on adherence, with higher prescription resulting in higher compliance, in contrast with the study by Takemitus at al. [4] that failed to find a clear relationship between prescription and adherence. Finally, wearing a LSO brace instead of a TLSO was associated with higher compliance, as previously reported by Aulisa et al. [18].

The specialized tertiary referral setting where the study was conducted consists of several clinics located across Italy. The Italian peninsula shows differences in climate, culture, tradition, and lifestyle between the North, Center, and South of the Country [19]. The North is more industrialized, with a "faster-paced" lifestyle, while the South is more agricultural, "slower-paced", and centred around family. Italy boasts a geographical diversity, ranging from alpine areas to Mediterranean islands like Sicily and Sardinia. As a result, temperatures and weather conditions vary significantly across Italy. Southern and coastal cities enjoy a temperate climate, characterized by milder winters and moderate summers. In contrast, northern and alpine areas experience colder temperatures in winter and remain cooler during the summer months (Fig. 2) [20].

One of the major complaints with brace treatment is the discomfort during warm seasons, as the plastic of the brace makes patients feel hot and sweaty, also potentially worsening possible skin complications [21]. Beyond the physical discomfort due to brace materials and design, reluctance caused by the brace's visual appearance and passive patient participation during the treatment process are among the main barriers to adherence [22] These previous findings suggest that there are some other factors (cultural, social) beyond temperature itself that may explain our results showing that living in the North or Centre of Italy is associated to higher compliance.

We further investigated the role of living near the seaside upon adherence. We guessed that patients who live by the sea are tempted to leave the brace home and spend the day at the beach, from April to October. Surprisingly, we did not find a significant role of the variable. Further, we verified if patients living in big or small towns had a different adherence to the treatment. In small villages, individuals tend to know one another, which fosters a sense of familiarity and

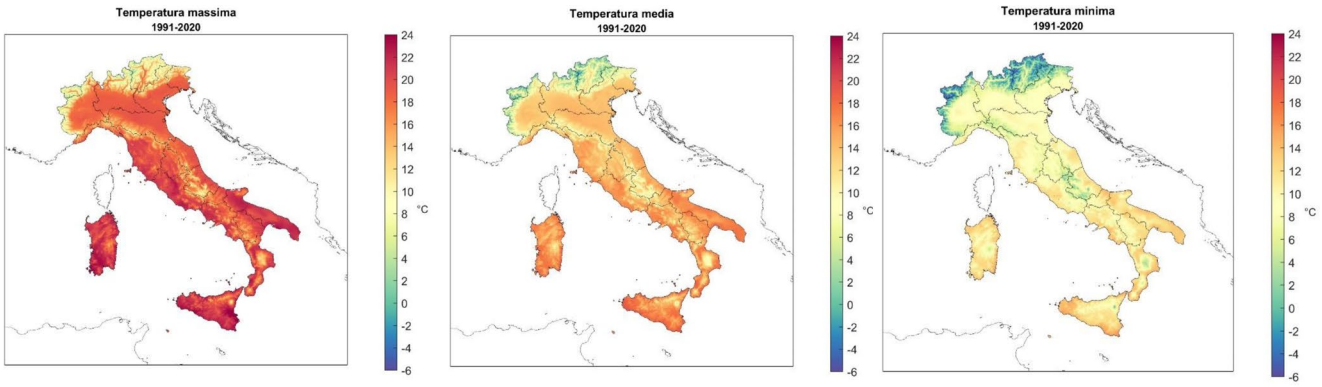

Fig. 2 Maps of yearly normal values of temperatures. Top: maximum; centre: average; bottom: minimum

mutual recognition. This interconnectedness can lead to more robust interpersonal relationships. In contrast, larger cities typically exhibit a different social dynamic characterized by greater anonymity. However, this variable too did not influence adherence to brace wear.

Thus, we hypothesize that individual differences in coping mechanisms, motivation, and social support networks may influence adherence behaviour [6, 23]. Younger patients may be more influenced by their care-givers, thus more adherent. As proposed by Lindeman and Behm, scoliosis girls may benefit from social contacts [6], but this may not be true for scoliosis boys. Moreover, It's been previously documented that patients with high self-esteem, above average peer relationships and poor brace-specific attitudes had lower brace compliance, although patients with increased loneliness and parental religiousness had higher compliance [7].

An additional "hidden" factor may be doctors' attitude during the first visit, emphasizing the possibility of improvement or expressing greater concern in the event of risk of progression and thus motivating the patient. This possibility may also be interpreted as a potential bias.

As far as we know, this is the first study about role of geographical and personal variables over compliance to brace treatment. A strength of our work is the sample size, that is bigger than in previous studies [4, 14]. The study also has some limitations, such as the exclusion of patients with missing data and the reliance on information available in medical records, which may not cover all determinants of adherence. Our study focused only on the variables at the start of treatment to understand the best approach to patients at the first consultation, and did not assess other potentially relevant variables intervening at a later stage, like immediate in-brace correction and the first out-of-brace radiograph results, explored in other studies [24].

In conclusion, the study highlights the importance of tailoring interventions to specific patient needs. Future research should focus on targeted strategies to improve adherence, in order to intervene and support patients who have characteristics that are more likely to lead to difficulties in wearing the brace.

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Author contributions AN, SN, and GF conceived the study. SD, FZ, MR and SN collected the data and reviewed the manuscript. GF and AN controlled the data. SD performed the statistical analysis and reviewed the manuscript. GR collected the data, drafted and reviewed the manuscript. All authors contributed to the interpretation of the data and critically revised it for important intellectual content. All authors reviewed, edited, and approved the final manuscript. All the authors have read and agreed to the published version of the manuscript.

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Data availability The data that support the findings of this study are openly available in Zenodo at https://doi.org/10.5281/zenodo.15125065.

Declarations

Ethics committee approval and trial registration The study was approved by the local Ethics Committee (Comitato Etico Milano Area 2; approval number 466_2021), and it has been registered at ClinicalTrials.gov (NCT04904627).

Patient involvement statement The study participants were not involved in the design, conduct, interpretation, or translation of the current research.

Competing interests SN, AN, and MR own shares of ISICO. The other authors have no conflicts of interest to declare.

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