

Novel questionnaire to enhance brace wear adherence in patients with adolescent idiopathic scoliosis and the relationship of the quality of life

Thamrong Lertudomphonwanit,
Nachapan Pengrung, Chaiwat
Kriwattanapong, Chanika
Angsanuntsukh, Pittavat Leelapattana,
Pongsthorn Chanplakorn

Department of Orthopedics, Faculty of
Medicine Ramathibodi Hospital,
Mahidol University, Bangkok, Thailand

Abstract

Bracing is an effective non-operative treatment, in patients with adolescent idiopathic scoliosis (AIS). The relationship between patients' quality of life (QOL) and brace wear adherence has been reported. This study aims to determine brace wear adherence for AIS patients with novel questionnaire. A nested case-control study was conducted, included patient age 10-18 years, coronal Cobb angle 20-50°, and Risser grade 0-3. Correlation between patients' QOL and the average hours of daily brace-wear were determined. Patients were divided into 3 groups based on brace wear adherence and were compared. QOL domains associated with the incompleteness of brace-wearing were determined by Cox proportional-hazards regression. Mean age of patients was 13.3 years (range 11-17.3 years) with initial Cobb angle of 33.5° (range 20-48°). There were significant negative correlations between total QOL scores and brace wearing time. Increased social domain scores was significantly associated with less brace wearing time (HR 1.5, 95% CI 1.12-2.04). Significant correlations between patients' QOL and the average hours per day of brace wear. Poor social QOL have a significant impact on brace wear adherence.

Introduction

Adolescent idiopathic scoliosis (AIS) is a complex 3-dimensional deformity of the spine affecting 2-2.5% of children after age 10 years but before skeletal maturity.¹ The primary objective of conservative treatment of AIS are prevention of curve progression, improve of pulmonary function, alleviate back pain and improve aesthetics.^{2,3} Bracing is the most common non-operative treat-

ment option for AIS patients indicated for a coronal curve, determined by Cobb's method, greater than 20 degrees.⁴ However, effectiveness of brace treatment for scoliosis which a curve more than 40 degrees have been reported.⁵⁻⁷ The likelihood of successful treatment by bracing may be influenced by several factors including age, gender, skeletal maturity, curve magnitude and the average hours of daily brace wear.^{3,8-10}

Recent evidences revealed the effectiveness of brace treatment, including a significant association between average hours of daily brace wear and a successful outcome, in preventing curve progression to the threshold for surgery.^{3,8,9} A recently published study revealed that the average hours of brace wear of 18.31 hours were associated with success rates of 88%.⁹ However, wearing plastic brace for long period especially during daytime may impact patient's quality of life (QOL) including physical, emotional and social well-being.¹¹⁻¹³ Furthermore, intervention during brace treatment to improve psychosocial well-being can improve compliance with bracing has been reported.^{14,15}

As aforementioned, the daily brace wear time is a key for successful conservative management of AIS with bracing. Therefore, patients' QOL that may affect brace-wearing time should be identified and optimized throughout brace treatment to improve the daily brace compliance.^{14,15} To the best of our knowledge, there are limited data regarding the relationship between patients' QOL and brace wear adherence.^{16,17} Thus, the aims of this study were 1) to assess the relationship between novel QOL questionnaire and the brace-wearing time and 2) to determine the QOL domain that would be associated with brace-wearing time in AIS patients undergoing brace treatment.

Materials and Methods

This prospective nested case-control study was conducted with institutional review board approval (certificate of approval no. MURA2015/458, Protocol number 08-58-03). Patients diagnosed with AIS at our institution and met indications for brace treatment between June 2015 and March 2017 were eligible for this study. Inclusion criteria were patient age 10-18 years, major curves between 20-50 degrees, no previous treatment (brace or surgery) and radiographic Risser grade 0-3. Patients who were not able to understand or respond to questionnaires and declined to participate in the study were excluded. Written informed consent was obtained from all

Correspondence: Pongsthorn Chanplakorn, Department of Orthopedics, Faculty of Medicine Ramathibodi Hospital, Mahidol University, 270, Rama VI Road, Ratchathewi, Bangkok, 10400, Thailand.
Tel.: +662.2011589 - Fax: +662.2011599.
E-mail: Pongsthornc@yahoo.com

Key words: Adolescent idiopathic scoliosis; brace adherence; quality of life; questionnaire; psychosocial well-being.

Acknowledgements: The authors would like to thank Department of Rehabilitation, Faculty of Medicine Ramathibodi Hospital, Mahidol University for all kindly helps and carry out the study. The authors wish to thank Alvin C. Jones, MD, Dayton Children's Hospital, Dayton, Ohio, United States of America for editing the manuscript.

Contributions: All authors conceptualized and designed the study. PC and TL analyzed the data, drafted and revised the manuscript. NP was responsible for collection, analysis and revised manuscript. CK, CA and PL provided their patients for research participation. PC helped to draft and revise the manuscript. All authors read and approved the final manuscript.

Competing interests: The authors declare that they have no competing interests

Funding: No external funding was obtained for this study.

Ethics approval and consent to participate: This study was approved by Institutional Review Boards of Faculty of Medicine Ramathibodi hospital, Mahidol University (certificate of approval no. MURA2015/458, Protocol number 08-58-03).

Consent for publication: Written, informed consent was obtained from the patient for published images of this article. A copy of the written consent is available for review by the Editor of this journal.

Availability of data and materials: The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Received for publication: 13 August 2020.
Revision received: 10 September 2020.
Accepted for publication: 24 October 2020.

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Orthopedic Reviews 2021;13:8840
doi:10.4081/or.2021.8840

patients and their parents before enrollment. All included subjects were prescribed a Boston-type thoracolumbosacral orthosis to be worn as much as tolerable but encourage them wearing a brace for at least 18 hours per day.⁹ The brace was built from polypropylene and customized for each individual.¹⁸ Subjects were asked to record daily brace wear duration in their logbooks. Brace treatment was prescribed for at least 6 months before the average hours of daily brace wear was evaluated using their participation logs. Subjects were encouraged to record the actual number of hours wearing the brace each day in their logbook, close checked by their parents and were reviewed by N.P. at every follow-up visit in order to maximize the accuracy of brace-wearing time. The subjects were followed at 3-month interval in clinic and reported their daily brace wear duration. Each subject's QOL was evaluated at the end of treatment using a Thai language questionnaire which was adapted from Brace Questionnaire (BrQ) proposed by Vasilidis *et al.*¹⁹ The BrQ use Likert scales (ie five rating scale) which might be difficult for children to understand and answer.²⁰ On the contrary, our questionnaire required only yes/no answers which is easy for children to understand and respond by themselves. The questionnaire was administered at clinic during patient visit with the clinician available

throughout for any clarification required by the subjects and it takes 15-20 minutes to complete. The questionnaire consisted of 21 questions divided into 3 domains, including physical, psychological and social, which was adjusted from 8 domains documented in BrQ questionnaire. Our questionnaire consists of 7 questions for the physical domain (Question no. 1-7), 7 questions for the psychological domain (Question no. 8-14) and 7 questions for the social domain (Question no. 15-21) (Table 1). Each question is scored equal 1 point. Each domain scores are calculated as well as a total score. A theoretical possible minimum total score is 0 and a maximum score is 21. A higher score indicates a worse QOL. Recent evidences reported that brace wear averaging at least 12-18 hours was associated with success rates of 88% to 93% (3, 9). On the basis of these findings, this study categorized the subjects into three groups according to the average hours of daily brace wear reported in their logbooks: group 1 (the least-adherent group) <12 hours per day, group 2 (the moderate-adherent group) 12-18 hours per day, and group 3 (the most-adherent group) ≥18 hours per day.

Radiological parameters (Cobb angle and Risser grading) were measured using the Picture Archiving and Communication System (PACS) at our hospital. The measurements were performed by a single spine-

trained surgeon blinded to the compliance metrics of each subject. The coronal Cobb angle is the angle formed by the intersection of two lines, one perpendicular to the top of the most tilted vertebra above the apex and the other perpendicular to the bottom of the most tilted vertebra below the apex. Radiographic analysis included the initial Cobb angle at the beginning of treatment and the final Cobb angle at the end of brace treatment. The maturity of each subject was assessed using Risser index at the beginning of treatment including 6 grades.

Statistical analyses were performed using STATA14 software (Stata Statistical Software: Release 14, 2015; StataCorp LP, College Station, TX). Categorical variables were analyzed using a Chi-squared test. Continuous variables were analyzed using one-way analysis of variance (ANOVA) or the Kruskal-Wallis test with post hoc analysis when needed. The association between QOL score domains, the total score and brace-wearing time was measured using Pearson correlation coefficient (*r*). The differences in QOL scores between 3 groups were analyzed using ANOVA test with post hoc analysis. The receiver operating characteristic (ROC) curve was used to determine the criterion value of the QOL score determining the incompleteness of brace-wearing time i.e. brace wearing time less than 18 hours and QOL domains associated with the

Table 1. Brace Questionnaire.

Please check (✓) the statement that match with you	Yes	No
1. During brace-wearing, you cannot eat.		
2. During brace-wearing, you cannot do sport activity.		
3. During brace-wearing, you cannot sleep.		
4. During brace-wearing, you cannot learn.		
5. During brace-wearing, you feel pain.		
6. During brace-wearing, you feel hot.		
7. During brace-wearing, you feel discomfort.		
8. During brace-wearing, you feel sad.		
9. During brace-wearing, you feel stress.		
10. During brace-wearing, you feel sick.		
11. During brace-wearing, you feel angry.		
12. During brace-wearing, you feel shame.		
13. During brace-wearing, you feel scared.		
14. During brace-wearing, you want to do nothing.		
15. During brace-wearing, you are bullied.		
16. During brace-wearing, you conflict to your family.		
17. During brace-wearing, you lose your body image.		
18. During brace-wearing, you cannot hangout with friends.		
19. During brace-wearing, you feel homesick.		
20. During brace-wearing, you need special clothes.		
21. You do not like to visit this hospital.		

incompleteness of brace-wearing were determined using Cox proportional-hazards regression. A P-value of less than 0.05 was considered statistically significant.

Results

There were 35 (87.5%) female patients and 5 (12.5%) male patients enrolled in this study. The mean age was 13.3 years (range 11-17.3 years). The average duration of follow-up was 30 months (range 6-67 months). The overall mean time for brace treatment was 19.7 months (range 6-48 months). Baseline characteristics (age, sex, body mass index (BMI), grade point average (GPA), caregivers, parents' income, air condition status and Risser grade) were displayed in Table 2. There were no significant differences in baseline characteristics except for the mean initial Cobb angle (39°, 30° and 32°, $P=0.009$). The average hours of brace wear per day of the least-adherent group, the moderate-adherent group and the most-adherent group were 7.7 hours, 13.4 hours and 20.6 hours, respectively ($P<0.0001$). As of last follow up, the least-adherent group had greater curve progression than the moderate-adherent and the most-adherent group (10°, 3° and 3°, respectively; $P=0.085$).

The relationships between quality of life scores and brace wearing time were shown in Figure 1. There were significant negative correlations between Total QOL scores ($r = -0.57$, $P=0.0001$), social domains scores ($r = -0.60$, $P<0.0001$) and physical domains scores ($r = -0.40$, $P=0.01$) and

brace wearing time. However, there were no significant correlations between psychological domain and brace wearing time ($r = -0.288$, $P=0.071$).

One-way analysis of variance (ANOVA) revealed that there were significant differences of social domain scores (4.3 vs. 1.4, $P<0.001$), physical domain

scores (4.0 VS 2.9, $P=0.042$) and total QOL scores (10.9 vs. 5.9, $P<0.001$) between group 1 and group 3. There were no significant differences of any domains and total score between those of group 2 and group 3 (Table 3). Cox proportional hazard model revealed that increased social domain scores (poorer QOL) was significantly asso-

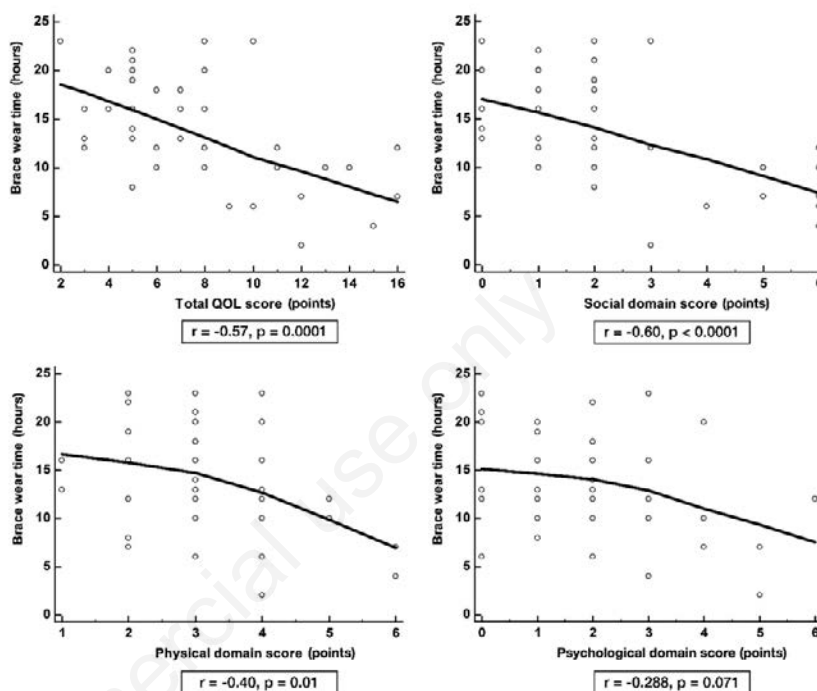


Figure 1. Correlation analysis between quality of life scores and brace wearing time. There were significant negative correlations between Total QOL scores, social domains scores and physical domains scores and brace wearing time per day.

Table 2. Baseline patient characteristics.

	Overall (n=40)	Group 1 (<12 hrs; n=13)	Group 2 (12-18 hrs; n=16)	Group 3 (>18 hrs; n=11)	P-value
Age, years	13.3±1.3	13.5±1.3	13.4±1.5	13.0±1.1	0.731
Female	35 (87.5%)	13 (100%)	12 (75%)	10 (91%)	0.119
BMI, kg/m ²	18.0±2.4	19.2±1.8	17.3±1.4	17.7±3.6	0.05
GPA3.4±0.5	3.3±0.5	3.5±0.5	3.3±0.6	0.880	
Parental caregiver	34 (85%)	12 (92.3%)	14 (87.5%)	8 (72.7%)	0.382
Income*, USD	871.8 (145.3-2906.1)	871.8 (145.3-2,324.9)	944.5 (435.9-2,906.1)	871.8 (581.2-2906.1)	0.869
Air conditioner at home	29 (72.5%)	9 (69.2%)	11 (68.8%)	9 (81.8%)	0.718
Air conditioner at school	18 (45%)	7 (53.8%)	6 (37.5%)	5 (45.4%)	0.679
Initial Cobb angle, degree	33±8.4	39±8	30±8	32±10	0.009
Final Cobb angle, degree	40±14	49±13	33±9	39±14	0.003
Curve progression*	4.5 (-1, 12)	10 (5, 19)	3 (-4, 8)	3 (-1, 12)	0.085
Risser, n (%)					
0, 1	19 (47.5)	4 (30.8)	8 (50)	7 (63.6)	0.227
2, 3	21 (52.5)	9 (69.2)	8 (50)	4 (36.4)	
Brace wear time (hours/day)	12.7±5.5	7.7±2.7	13.4±1.4	20.6±1.9	<0.0001

*median (range), USD: United States Dollar- 1 USD = 34.41 Thai baht (March, 2017.), BMI: body mass index, kg/m²: kilogram/square meter, GPA: grade point average. P-value < 0.05 was considered to be statistical significance.

Table 3. Comparison of quality of life score between the groups.

	QOL Score	Group 1 (<12 hrs; n=13)	Group 2 (12-18 hrs; n=16)	Group 3 (>18 hrs; n=11)	P-value
Social domain	4.3±1.8	1.3±1.5	1.4±0.9	<0.001	
Physical domain	4.0±1.3	3.1±1.2	2.9±0.7	0.042	
Psychological domain	2.6±1.6	1.9±1.4	1.6±1.4	0.232	
Total scores	10.9±3.3	6.4±3.4	5.9±2.2	<0.001	

QOL: quality of life, hrs: hours. P-value <0.05 was considered to be statistical significance.

ciated with less amount of brace wear per day (hazard ratio [HR] 1.5, 95% confidence interval [CI] 1.12–2.04) (Table 4). ROC curve analysis revealed the sum of QOL score more than 8 point was criterion for prediction of incompleteness of brace-wearing time with sensitivity 41.38% (95% CI 23.5–61.1), specificity 90.9% (95% CI 58.7–99.8) with positive likelihood ratio of 4.55 (P=0.042, area under the curve [AUC] 0.674).

Discussion

There is conflict information regarding the impact of psycho-social well-being on brace wear adherence.^{13,16,17-21} The purpose of this study was to determine whether poor Quality of life, especially for psychosocial well-being, had negatively impacted brace wear adherence. The results from this study revealed that there were significant negative correlations between Total QOL scores ($r = -0.57$, $P=0.0001$), social domains scores ($r = -0.60$, $P<0.0001$) and physical domains scores ($r = -0.40$, $P=0.01$) and the average hours per day of brace wear. This indicates poorer QOL (higher scores) is significantly correlated with poorer brace-adherence. Furthermore, we found that poorer social QOL was significantly associated with less amount of brace wear per day (HR 1.5, 95% CI 1.12–2.04).

Results from this study showed significant correlation between patients' QOL and the average hours of brace wear per day. When looking at the differences of total QOL scores between the least-adherent group (group 1) and the most-adherent group (group 3), findings from this study support the evidence that poor QOL negatively impacts brace wear adherence. Results from this study are consistence with prior reports.^{13,16,22} Rivett *et al.* studied the relationship between quality of life and brace compliance, and they found that poor compliance patients, wearing brace <20 hours/day, was associated with poorer QOL.¹³ Chan *et al.* explored the correlation between in-brace correction, compliance to brace and QOL of AIS patients and they

Table 4. QOL domains associated with the incompleteness of brace-wearing.

QOL Factors	HR (95% CI for HR)	P-value
Social factors	1.51 (1.12-2.04)	0.007
Physical factors	1.11 (0.70-1.77)	0.651
Psychological factors	0.95 (0.72-1.25)	0.694

QOL: quality of life, hrs: hours. P-value <0.05 was considered to be statistical significance.

revealed a positive relationship between patients brace wear compliance and their QOL as the poor compliance would cause a lower QOL.¹⁶ Piantoni *et al.* reported a negative impact of bracing on QOL in terms of psychological function, physical function, social function and school environment aspect.²² On the other hand, Schwieger *et al.* reported that QOL and body image did not have a significant impact on brace wear adherence for females with AIS.¹⁷ However, their study categorized patients into 2 groups, brace-wearing 0 to 6 hrs/day and brace wearing >12 hrs/day, which is different from our study. We believe that QOL may correlate with wearing brace for longer time up to 18 hrs/day.¹⁶ In addition, the differences of the results between the two cohorts may be partially explained by ethnic variation, Caucasian and Asian, in appearance concerns.²³

The findings of this study highlight the effects of social factors on brace treatment. There were significant negative correlations between social domains scores ($r = -0.60$, $P<0.0001$) and the average hours per day of brace wear. Furthermore, Cox proportional-hazards regression revealed that social domain was the only significant QOL factor for less amount of brace wear per day (HR 1.5, 95% CI 1.12–2.04). The results from patients' logs also identified the brace wearing pattern. The patients in least-adherent group most often wore brace only at nighttime. These patients stated that they refrained from brace at school because they did not want their peers to know that they need to wear brace. This indicated psychosocial effects as reflected by the poorer QOL score (Table 3). On the other hand, the patients in moderate-adherent group and most-adherent group also wore brace at nighttime, at home and at school. The

results of this study agree with prior reports. MacLean *et al.* reported that half of patients undergoing brace treatment had difficulties of social function in term of school activities and sport participation.²⁴ Piantoni *et al.* revealed that the majority of the patients (75%) in their cohort concerned about their social function during brace treatment and half of them had difficulties at school.²² Donnelly *et al.* found that braced patients often had conflict with their parents over brace wearing and they thought that their classmates treated them differently. Some patients reported that when teachers taught about AIS in their class, it made their friends more open-minded and sympathy toward patients with AIS.²⁵ A multidisciplinary team approach at the early stage of bracing might be needed to help the patients cope with the possible psychosocial effects of bracing.^{14,15,26,27} This study revealed that sum of QOL score more than 8 points was criterion for prediction of brace-wearing time less than 18 hours and we believe that this threshold might help for trigger the team to give intervention before the patients refrained from bracing.

This study revealed that physical QOL factors may affect brace compliance, which is consistent with prior reports. Rivett *et al.* studied the difference between good and poor brace compliance. They found that physical function, emotional function, self-esteem and aesthetics, vitality, school activity and social function were associated with brace wear compliance.¹³ Another study from the same author group revealed that the good compliance group also had higher quality of life scores.²⁸ Chan *et al.* studied the association of in-brace correction, compliance, and quality of life. They found that poor compliance was associated with poor quality of life, especially general health per-

ception, physical function, emotional function and bodily pain.¹⁶ Although not reach statistical significance, this study found that there was a tendency of correlation between psychological function and brace wearing time ($r = -0.288$, $P = 0.071$). This may be due to small sample size of this study which might not be able to detect this correlation.

There are some limitations to this study. First, the relatively small sample size of this study makes some comparisons and correlations lack statistical power and does limit the generalizability of our results. Larger-scale studies are necessary to address such confounding factors. Second, the status of brace wear adherence was not monitored by a device attached to the brace. Previous studies revealed that self-reports through patients' logs regarding brace wear adherence is associated with a higher risk of overestimation.²⁹ However, since such a device was not available in our country at the time of this study was conducted. To compensate for this limitation, we encouraged the patients to record the daily brace wear time in their logbooks. The logbooks were daily close checked by their parents and were reviewed by one investigator at every follow-up visit. Finally, a Thai language brace questionnaire was developed to evaluate the subjects' quality of life. Unfortunately, this questionnaire has not been previously validated.

Conclusions

This study shows significant correlations between QOL scores, especially for social domains, and the average hours per day of brace wear. The results from this study indicates that QOL of AIS patients undergoing brace treatment should be assessed in every follow-up visit throughout the treatment. When poor QOL are detected, efforts should be made to identify and correct the underlying problems. An interdisciplinary approach at early stage of bracing may help the patients to cope with the possible psychosocial impact on brace wearing.

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