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REVIEW ARTICLE

Establishing consensus on the best practice guidelines for the use of bracing in adolescent idiopathic scoliosis

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Abstract

Study design Survey.

Objectives Bracing is the mainstay of conservative treatment in Adolescent Idiopathic Scoliosis (AIS). The purpose of this study was to establish best practice guidelines (BPG) among a multidisciplinary group of international bracing experts including surgeons, physiatrists, physical therapists, and orthotists utilizing formal consensus building techniques.

Summary of background data Currently, there is significant variability in the practice of brace treatment for AIS and, therefore, there is a strong need to develop BPG for bracing in AIS.

Methods We utilized the Delphi process and the nominal group technique to establish consensus among a multidisciplinary group of bracing experts. Our previous work identified areas of variability in brace treatment that we targeted for consensus. Following a review of the literature, three iterative surveys were administered. Topics included bracing goals, indications for starting and discontinuing bracing, brace types, brace prescription, radiographs, physical activities, and physiotherapeutic scoliosis-specific exercises. A face-to-face meeting was then conducted that allowed participants to vote for or against inclusion of each item. Agreement of 80% throughout the surveys and face-to-face meeting was considered consensus. Items that did not reach consensus were discussed and revised and repeat voting for consensus was performed.

Results Of the 38 experts invited to participate, we received responses from 32, 35, and 34 for each survey, respectively. 11 surgeons, 4 physiatrists, 8 physical therapists, 3 orthotists, and 1 research scientist participated in the final face-to-face meeting. Experts reached consensus on 67 items across 10 domains of bracing which were consolidated into the final best practice recommendations.

Conclusions We believe that adherence to these BPG will lead to fewer sub-optimal outcomes in patients with AIS by reducing the variability in AIS bracing practices, and provide a framework future research.

Level of evidence Level IV.

Keywords Adolescent idiopathic scoliosis · Bracing · Best practice guideline

Introduction

The goal of non-operative treatment in adolescent idiopathic scoliosis (AIS) is to prevent curve progression and the need for future surgical correction [1]. Bracing has demonstrated efficacy in preventing curve progression [2–4] and is the mainstay of non-operative intervention for curves greater than 25° [5]. The recent milestone Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST) demonstrated 72% success in preventing curve progression to > 50° in patients with curves between 20° and 40° [6].

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Unfortunately, the scientific evidence supporting non-operative management of AIS is generally of lower quality, a fact which contributes to the significant variability in clinical practice [4, 6–9]. The Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) developed guidelines in 2016 using relevant evidence on observation, bracing and physiotherapy [8]. These guidelines, while helpful, are not comprehensive and several of the specific recommendations lack scientific support. Given the current uncertainty, there is a pressing need for additional evidence on a myriad of topics such as indications to start and discontinue bracing; methods to assess skeletal maturity; ideal frequency and method of imaging; impact of the brace type on curve progression; frequency and duration of PSSE treatment; and the impact of vitamin D/calcium supplementation on curve.

Given the well-established utility of non-operative management in reducing both curve progression and the need for surgery in patients with AIS, bracing has a key role in this population. However, there is insufficient evidence and agreement on the specific details of non-operative care for AIS. Thus, there is an immediate and urgent need to develop guidelines based on up-to-date evidence to optimize patient care. The purpose of this study is to create best practice guidelines (BPG) for non-operative care in AIS utilizing a multi-disciplinary consensus-based approach including clinical scientists and relevant providers such as orthopedic surgeons, physical therapists, and orthotists.

Methods

Literature review

A scoping review of the AIS bracing and PSSE literature was performed (M.E.S.). PubMed was utilized and searched using keywords such as spinal deformit*, adolescent*, adolescent idiopathic scoliosis, AIS, scoliosis, brace*, bracing, orthos*, scoliosis specific exercise*, physiotherapeutic scoliosis specific exercise*, PSSE, conservative care, non-operative care*, and non-operative management. Studies were limited to English and screened based on the title and abstract to identify relevant articles. Articles were excluded if the study population was not adolescents or patients with AIS. Review articles were also excluded. Articles were graded according to the Oxford Centre of Evidence-based Medicine-Levels of Evidence [10].

Previous work

In 2017–2018, our group explored variability in non-operative management of AIS via a survey of two separate cohorts. Our first survey included 55 expert physicians, nurse practitioners, researchers, physician assistants, orthotists, and physical therapists from the northeastern United States. Our second survey included 31 international pediatric orthopedic surgeons who were members of the International Pediatric Orthopaedic Think Tank. We found extensive variability within and between professions on most topics. For example, providers differed on how to best assess skeletal maturity, prescribed hours in brace, and indications for initiating bracing. Only a fraction of the surveyed items was endorsed by the majority of participants. The results of these surveys guided the iterative surveys used in the current project.

Consensus participants

Thirty-eight orthopedic surgeons, physiatrists, orthotists, physical therapists, and research scientists from seven countries (United States, Canada, France, Greece, Italy, Japan, and Spain) were selected based on their clinical and research expertise and approached about participation. Descriptive information was obtained for participants through a questionnaire administered after the iterative surveys and nominal process.

Delphi process

The Delphi technique is a well-recognized and validated method in the social and medical sciences for establishing group consensus [11–13]. This process has been used by the authors in the past to create best practice guidelines (BPG) for surgical site infections, intra-operative neuromonitoring, wrong level surgery in spinal deformity, and the use of halo gravity traction [14–17]. Experts are asked their opinion on topics via surveys in an anonymous, iterative process. Results from each successive survey are presented along with additional relevant information regarding the questions and/or answers. In each subsequent round, the original statements/questions are modified and new questions are added. Throughout the process, statements are revised based on participant feedback and collaborative discussion [18, 19]. Each iteration of the survey drives information gathering, understanding of current practices and establishment of variability in practice [20–22].

All questionnaires were created and distributed electronically through Qualtrics® (Qualtrics, Provo, UT), an online survey development and distribution platform. Responses were collected anonymously and stored on a secure database. The response distributions were coded as follows: consensus ($\geq 80\%$ agreement among respondents), near consensus (70–79% agreement), and equipoise (30–69% agreement).

Questionnaires 1–3 (January–March 2019)

Based on our previous survey of current practices in non-operative management of AIS and the results of our literature review, the primary authors (B.D.R, M.E.S) created iterative surveys covering aspects of brace treatment including indications for bracing, recommended brace hours, brace type, radiographic assessment, physical activities, discontinuing bracing, and PSSE combined with bracing. Most responses were formatted as a four-point Likert scale: strongly agree, agree, disagree, and strongly disagree. Items for which consensus was reached ($\geq 80\%$ agreement) were separated into a list of consensus items or were modified and re-asked to further expand on the topic in subsequent rounds. Those with near consensus (70–79%) were modified for clarity or to be interpreted more broadly and re-posed. Questions that had 30–69% agreement (equipoise items) that were deemed possible to gain consensus on with modifications were re-phrased and re-asked.

Nominal process (April 2019)

Using the nominal group process, the results of the scoping literature review, the consensus items, near consensus items, and equipoise items from the first three surveys were presented at a face-to-face meeting utilizing the nominal group process at the 14th annual SOSORT meeting in April 2019. The nominal group process is a well-established decision-making method that is particularly useful when there may be a diversity of opinions within the group, and when equal participation and buy-in is sought [21]. This technique includes a structured face-to-face discussion where the results from the surveys and the literature review findings relevant to each statement are presented by a moderator, discussed, and voted on to modify the statements and drive consensus building. Items with full consensus are considered those with 80% agreement or $<20\%$ agreement (80% disagreement). The Audience Response System (Turning Point Solutions) was used for anonymous voting. Near consensus and equipoise items from the preceding three surveys were discussed in depth and voted on.

Fourth questionnaire (May 2019)

During the meeting, the topic of defining high-risk versus low-risk AIS patients arose. Due to time constraints, creating and voting on questions to clarify this topic was not feasible. Therefore, it was decided that a fourth survey solely focusing on this topic should be created and distributed.

Results

Literature review

Eighty-eight articles were included (Online Appendix 1). Studies addressed numerous domains within bracing and PSSE treatment and varied in terms of study design and level of evidence (Level 1–Level 5). There was a distinct lack of randomized controlled trials and prospective cohort studies.

Table 1 Participant characteristics

	Survey 1	Survey 2	Survey 3	Nominal meeting	Survey 4
Number of participants	32	35	34	27	34
Years in practice [all, (mean ± SD)]	24.7 ± 8.8	24 ± 10	24.3 ± 10.3	24 ± 8.9	24.5 ± 10.4
Years of AIS bracing experience [surgeon, PM&R, orthotist, (mean ± SD)]	24.5 ± 9.8 [*N* = 23]	24.5 ± 9.9 [*N* = 23]	24.9 ± 9.9 [*N* = 24]	24.7 ± 8.7 [*N* = 18]	24.9 ± 10.1 [*N* = 23]
Years of PSSE experience [PT, (mean ± SD)]	12.6 ± 9.4 [*N* = 7]	11 ± 9 [*N* = 9]	10.5 ± 9.2 [*N* = 8]	8.7 ± 4.2 [*N* = 7]	12.9 ± 10.2 [*N* = 9]
Number of AIS patients seen per month [surgeon, PM&R, orthotist, PT, (mean ± SD)]	112.8 ± 53.2 [*N* = 29]	88.9 ± 115.5 [*N* = 31]	107.5 ± 114.2 [*N* = 32]	94.6 ± 51.1 [*N* = 25]	110 ± 115.2 [*N* = 31]
Braces prescribed per month [surgeon, PM&R, (mean ± SD)]	18.7 ± 35 [*N* = 20]	12 ± 27.8 [*N* = 20]	21.1 ± 27.2 [*N* = 21]	22 ± 26.8 [*N* = 15]	21.1 ± 27.2 [*N* = 21]
Braces built per month [orthotist, (mean ± SD)]	48.3 ± 27.5 [*N* = 3]	48.3 ± 24.8 [*N* = 3]	48.3 ± 27.5 [*N* = 3]	48.3 ± 26.8 [*N* = 3]	32.5 ± 3.5 [*N* = 2]
Braces checked per month [surgeon, PM&R, orthotist, (mean ± SD)]	31.5 ± 22.9 [*N* = 23]	32.6 ± 22.7 [*N* = 23]	32.4 ± 22.7 [*N* = 24]	33.6 ± 27.5 [*N* = 18]	32.5 ± 23.2 [*N* = 23]

Participants

Out of the 38 invited experts, 32, 35, 34, and 35 experts responded to each survey, respectively (Table 1). Nineteen orthopedic surgeons, 4 physical medicine and rehabilitation physicians, 3 orthotists, 10 physical therapists, and 1 research scientist participated in at least 1 stage of the BPG. Overall, physicians and orthotists had a mean of 24.6 years of bracing experience (standard deviation 9.8) and physical therapists had a mean of 12.9 years of PSSE experience (standard deviation 10.2). On average, physicians prescribed 20.3 braces per month (standard deviation 26.1) and checked 31.4 braces per month (standard deviation 20.7). On average, orthotists built 48.3 braces per month (standard deviation 27.5) and checked 48.3 braces per month (standard deviation 31.8).

Questionnaires 1–3

In total, consensus was reached for 49 items and near consensus was reached for 9 items after the first 3 surveys (Online Appendix 2). Thirteen items remained in equipoise following the third survey.

Nominal process

Twenty-seven participants attended the face-to-face meeting (11 orthopedic surgeons, 4 physiatrists, 8 physical therapists, 3 orthotists, and 1 research scientist). Twenty-two had completed all three preceding surveys. Overall, the group had a mean of 24.5 years in practice and a mean of 20.5 years of experience working with patients with scoliosis treated with bracing. Five different countries in North America (United States and Canada) and Europe (Greece, Italy, and Spain) were represented. The group reached consensus on 13 additional items (Online Appendix 3).

Fourth questionnaire

Thirty-four experts responded to the fourth questionnaire which was solely focused on defining which patients with AIS are at a high versus a low risk of progression. The respondents reached consensus on ten items with participants reaching near consensus on two additional items. Equipoise existed among the respondents for six statements in this survey.

All items which for which consensus was reached over the four surveys and the face-to-face meeting were consolidated into the final best practice guidelines (Table 2). Supporting literature and their levels of evidence according to the Oxford Centre of Evidence-based Medicine-Levels of Evidence was also compiled (Online Appendix 4) [10]. Overall, participants reached consensus on 67 items, near consensus on 6 items, and equipoise existed for 15 items. The 21 items for which participants failed to reach consensus (Online Appendix 5) were converted into equipoise questions for further research (Table 3).

Discussion

As a result of this multidisciplinary effort, we were able to establish 67 items of consensus across 10 domains of brace treatment in AIS. While we appreciate the extraordinary effort that resulted in the 2016 SOSORT guidelines [8], those guidelines did not specifically focus on AIS or bracing. This current effort contributes additional valuable recommendations to the practice of bracing in AIS to help guide practice and standardize care. Additionally, identifying items of true equipoise helps to highlight areas without consensus that need the attention of research. Other areas for further research that can further hone the recommendations from this BPG were compiled by the primary authors based on discussion (Table 4).

Tremendous variability in the non-operative care of patients with AIS exists in the literature and among experts. Variability implies that some patients are getting sub-optimal care. This variability is likely due to the lack of high-quality evidence for many aspects of non-operative treatment in general, and brace treatment specifically. However, waiting for research evidence to "catch up" prior to establishing recommendations takes considerable time and may be a disservice to our patients. Therefore, we saw an urgent need to establish consensus-based guidelines for bracing in AIS in the interim by seeking the expertise of an international cadre of multidisciplinary bracing experts. These guidelines may decrease variability in the current management of patients and guide future research. Additionally, we have demonstrated that equipoise exists for many aspects of non-surgical management of AIS which in turn opens the door for ethical, meaningful research to improve and further standardize treatment strategies. Figure 1 illustrates a potential clinical application of these BPG in the form of a practical clinical checklist consisting of 24 recommendations supported by this process. This checklist has clinical utility and can assist clinicians in the implementation of bracing in AIS.

Strengths of this effort include that the BPG were developed based on the consensus of internationally recognized bracing experts, many of whom participated in the creation of the 2016 SOSORT guidelines. We also had a high and consistent degree of participation in the surveys (84–92% participation across all four surveys) and at the meeting (71% of those invited).

However, there are several limitations inherent to generating and implementing BPGs. The need for BPGs is based on the lack of the high-quality literature from which to

Table 2 Final best practice guidelines for bracing in adolescent idiopathic scoliosis

Recommendation	Grade
Goals of therapy	
The primary goal of bracing therapy in adolescent patients with AIS is to prevent or limit curve progression (including progression to surgery) in the growing child	A
Indications	
Bracing should not be initiated for curves $\leq 15°$ or ≥ 60 degrees	C
A skeletally mature patient (Risser 5, Sanders 7 or 8, minimal to no growth in 1 year) is not a brace candidate	A
A patient's skeletal maturity should affect the indications for initiating bracing	A
Defining higher risk of progression	
Skeletal markers an increased risk of progression include Sanders stage ≤ 3, Risser 0, and open triradiate cartilage	A
A curve $\geq 30°$ should be considered a marker for a higher risk of progression	A
Defining lower risk of progression	
Skeletal markers of a decreased risk of progression include a Risser sign of ≥ 4 and a Sanders stage ≥ 6	A
Curves $\leq 15°$ should be considered a marker for a lower risk of progression	A
The online prognosis calculator from the University of Iowa Stead Family Children's Hospital (https://uichildrens.org/ais-prognosis-calculator-simplified) is a good way to stratify risk in AIS	C
Brace prescription	
High risk patients with AIS should be braced a minimum of 18 h per day	A
Initiating bracing for less than 6 h a day is not indicated in AIS	A
Brace type	
There is a difference in effectiveness between brace types	A
Rigid braces (e.g. Boston brace) are superior to non-rigid braces (e.g. SpineCor)	A
If a properly worn brace is unable to achieve meaningful curve correction you should modify or remake the brace	C
Radiographic assessment	
Sanders staging is the most accurate method to evaluate skeletal maturity	B
An in-brace X-ray should be obtained for a new brace after a break in period of 2–6 weeks	C
Low-dose biplanar radiography is preferable to plain radiographs to monitor patients	C
When obtaining the initial in-brace X-ray, PA and lateral films should be taken	C
Coronal Cobb angle correction and radiographic sagittal parameters should be measured in-brace	B
The in-brace coronal Cobb angle of the major curve should be measured on the biggest measurable residual curve (even if the end vertebrae are different from the pre-brace radiograph) instead of the same vertebral levels that were measured in the pre-brace radiograph	C
After the initial in-brace X-ray, all subsequent X-rays should be taken out of brace	C
If a patient has a leg length discrepancy, the pelvis should be made level when obtaining radiographs	C
Patients undergoing their rapid growth phase (Sanders 3 or 4) should have radiographs every 4–6 months	C
Patients outside of their rapid growth phase should have radiographs every 6–12 months	C
Physical activities	
Braces should be removed for physical activities	C
Sports or physical activities should be recommended and the specific activities are not important	B
Patients should not be restricted from specific physical activities	C
Discontinuing bracing	
Sanders stage, Risser stage, change in height, curve magnitude, and curve progression should be considered when discontinuing bracing	C
Once the decision to stop bracing has been made, there should be a weaning period of at least 6 months before fully discontinuing the brace	C
PSSE	
Consider prescribing PSSE along with bracing where available	A
PSSE is not a substitute for bracing in AIS when bracing is indicated	C
Other	
Brace compliance should be monitored using electronic sensors	A
A scoliometer should be used at diagnosis or initial presentation of AIS patients and at every subsequent follow-up visit	B
The height of patients treated with bracing should be routinely tracked at clinical visits	C
The patient's emotional/psychological health is a factor in making bracing decisions	C
When possible, a family centered team approach to bracing (e.g. physician, orthotist, PSSE therapist, etc.) is recommended	C

Table 3 Equipoise questions for further research

Can an in-brace physical therapy session help patients wear the brace more effectively?
Should a patient's skeletal maturity affect their PSSE treatment plan?
Should bracing be indicated in adolescent females who are 2 years post menarchal?
Should bracing be continued in a patient when the brace cannot achieve meaningful correction, despite remaking or modifying the brace multiple times?
If low-dose biplanar X-ray imaging is not available, should lateral radiographs be included at follow-up visits?
Should patients be specifically instructed not to perform exercises that incorporate forward bending and rotation?
Should menarchal status be routinely considered when discontinuing bracing?
Should body topography mapping be routinely used to manage patients treated with bracing?
Should CAD/CAM technology be used to make scoliosis braces?
Should a Risser sign of 1 be considered a marker of accelerated growth and, therefore, a higher risk of progression?
Should a Sanders stage of 4 be considered a marker of accelerated growth and therefore a higher risk of progression?
Should a 20-degree curve be considered a marker for a higher risk of progression?
Should a 25-degree curve be considered a marker for a higher risk of progression?
Should a Risser sign of 2 or 3 be considered a marker of slower growth and therefore a lower risk of progression?
Should a Sanders stage of 5 be considered a marker of slower growth and therefore a lower risk of progression?
Should a 20-degree curve be considered a marker for a lower risk of progression?

Table 4 Other areas for further research to further hone the BPG

What curve size is an indication for starting bracing?
What level of skeletally maturity is an indication for starting bracing?
What curve size is an indication for discontinuing bracing?
What level of skeletally maturity is an indication for discontinuing bracing?
What should be the frequency of clinical and radiographic follow up?
What is the impact of sagittal plane parameters on bracing success?
What is the impact of coronal curve correction on bracing success?
What are the ideal number of hours in-brace?

derive evidence-based recommendations. In other words, when high-level data simply do not exist, then BPGs represent the best available recommendations until the data can be developed. As such, many of these recommendations developed through the Delphi process have no available literature to support them and are solely based on expert opinion developed through decades of clinical experience. As such, BPG recommendations represent only level 5 evidence according to the Oxford Levels of evidence scheme [10]. Nonetheless, we anticipate that these guidelines together with our identifying areas where consensus is lacking will drive future high-quality research to support or reject the recommendations contained in these guidelines. We also acknowledge the potential lack of reliability in these recommendations due to the relatively small number of participants. However, we specifically chose experienced leaders in the field of AIS bracing across numerous disciplines, institutions and regions to maximize representativeness and relevance. Other limitations include the generic nature of the guidelines which do not account for legitimate practice variability based on individual patient characteristics and the possibility that certain guideline recommendations may not be feasible for some patients or in some contexts due to a lack of access to qualified providers or due to prohibitive cost. One possible outcome of disseminating this guideline may be to assist health teams treating patients with AIS in deciding which resources to make available consistent with the guidelines, and lobby to obtain the necessary resources.

In conclusion, we have established BPG for the use of bracing in AIS using validated formal consensus building techniques with an international group of multidisciplinary bracing experts. All meeting participants agreed to support the final BPG and to implement them into their daily care of patients with AIS undergoing bracing. The process of creating this BPG suggests several areas for future research to strengthen the evidence supporting bracing in AIS, and we believe its use will help maximize outcomes in patients with AIS.

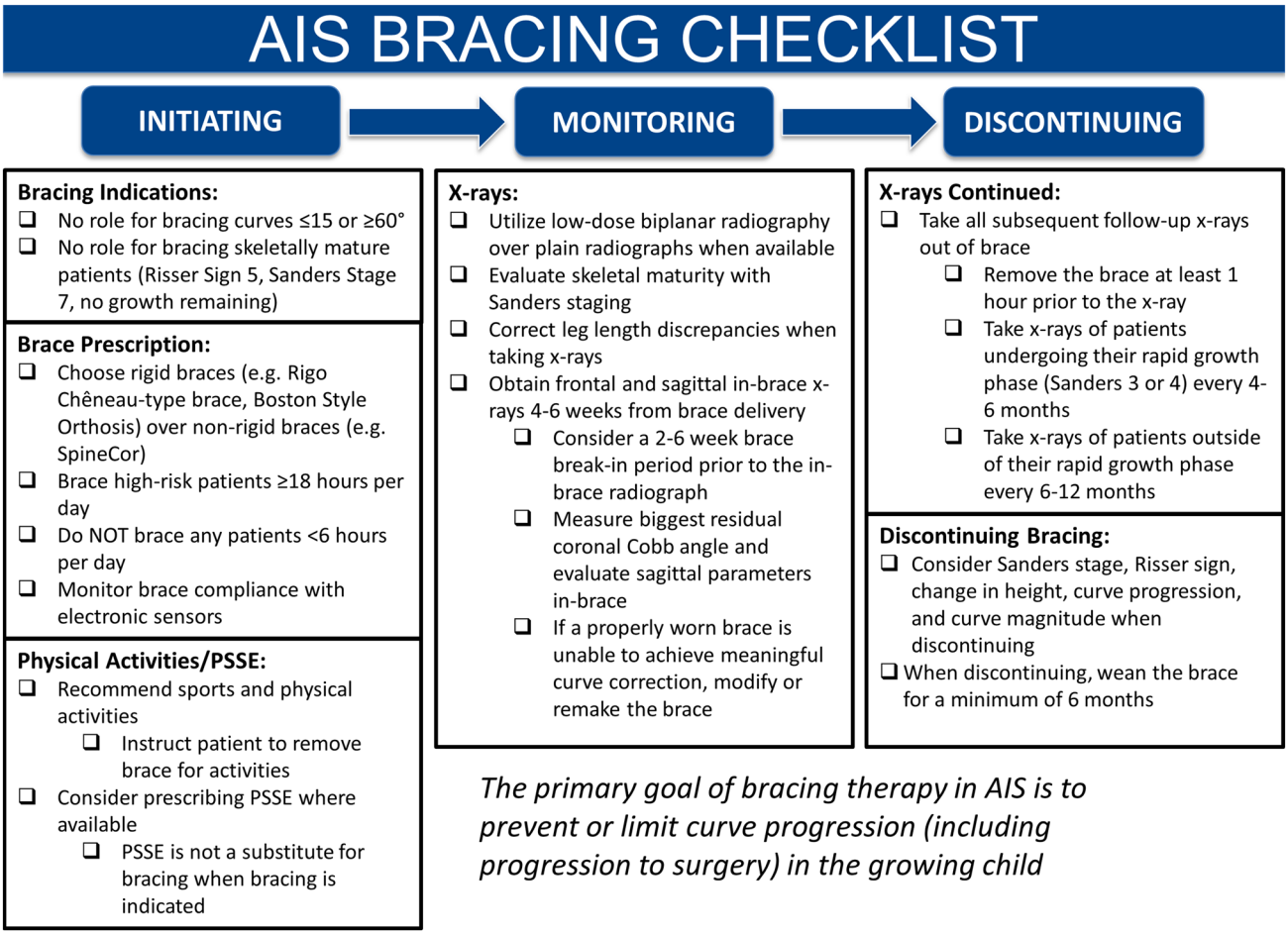

Fig. 1 Bracing in AIS clinical checklist

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Author contributions BDR: Conceptualization, data analysis, data interpretation, revising manuscript, final approval. MES: Data curation, Resources, Conception and design, data interpretation, visualization, original draft, revision, final approval. HM: Conception and design, supervision, final approval. PB, HB, LAD, KG, TBG, MTH, LAK, BSL, MM, SN, PON, ECP, MR, LS, JT, SLW, GW: Investigation, revision, final approval. MGV: Conception and design, supervision, final approval.

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Compliance with ethical standards

Copyright and patient information No copyrighted materials or patient information is included in this manuscript submission.

IRB approval/research ethics committee This work is approved by the Institutional Review Board at Columbia University (Protocol AAAR6403).

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