Bending Radiograph as Predictive Factor of In-Brace Correction (IBC) in Adolescent Idiopathic Scoliosis (AIS)

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การถ่ายภาพเอ็กซเรย์ท่าเอียงลำตัวเพื่อเป็นปัจจัยพยากรณ์การแก้ไขโรคกระดูกสันหลังคดงอชนิด
ไม่ทรบสาเหตุในวัยรุ่นโดยกายอุปกรณ์ดามกระดูกสันหลังคด

นายราเดน อาค์มาด คานดรา พูตรา

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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ราเดน อาค์มาด คานดรา พูตรา : การถ่ายภาพเอ็กซเรย์ท่าเอียงลำตัวเพื่อเป็นปัจจัยพยากรณ์การแก้ไขโรคกระดูกสันหลังคดงอชนิดไม่ทรบสาเหตุในวัยรุ่นโดยกายอุปกรณ์ดามกระดูกสันหลังคด. (Bending Radiograph as Predictive Factor of In-Brace Correction (IBC) in Adolescent Idiopathic Scoliosis (AIS)) อ.ที่ปรึกษาหลัก : ศ. นพ.สมศักดิ์ คุปต์นิรัติศัยกุล

บทนำ: การแก้ไขโรคกระดูกสันหลังคดงอ (IBC) เป็นหนึ่งในปัจจัยสำคัญมากที่สุดในการรักษาโรคกระดูกสันหลังคดงอโดยไม่ทราบสาเหตุในวัยรุ่น (AIS) มีหลายปัจจัยที่มีผลกระทบต่อความสำเร็จของการรักษา IBC และพบว่าความยืดหยุ่นความโค้งมีความสัมพันธ์กับ IBC ในการประเมินความยืดหยุ่นความโค้งนั้น วิธีการหนึ่งที่ใช้กันอย่างแพร่หลายเพื่อพยากรณ์การรักษาทางศัลยกรรมของ AIS คือการถ่ายภาพเอ็กซเรย์ท่าเอียงลำตัว (side bending radiograph) อย่างไรก็ตาม ยังไม่มีข้อมูลที่ชัดเจนในภาคปฏิบัติด้านกายอุปกรณ์เสริมเกี่ยวกับการถ่ายภาพเอ็กซเรย์ท่าเอียงลำตัวเพื่อพยากรณ์การดามกายอุปกรณ์ IBC แบบเต็มเวลา วัตถุประสงค์ของการศึกษาครั้งนี้คือการประเมินความยืดหยุ่นที่วัดจากการถ่ายภาพเอ็กซเรย์ท่าเอียงลำตัวเพื่อเป็นปัจจัยพยากรณ์การแก้ไขกระดูกสันหลังคดงอชนิดไม่ทราบสาเหตุในวัยรุ่นโดยกายอุปกรณ์ดามกระดูกสันหลังคด

วิธีวิจัย: การศึกษาตามรุ่นย้อนหลังครั้งนี้ ประกอบด้วยผู้ป่วย AIS แบบต่อเนื่องจำนวน 82 รายที่ได้รับการรักษาด้วยการดามอุปกรณ์แบบเต็มเวลา (full-time bracing treatment) ที่โรงพยาบาลจุฬาลงกรณ์ สภากาชาดไทย (KCMH) ระหว่างเดือนมกราคม 2560 - ธันวาคม 2564 การเก็บข้อมูลยึดตามบันทึกเวชระเบียนของผู้ป่วย AIS เพื่อทำการตรวจสอบทบทวนข้อมูลประชากรและการถ่ายภาพเอ็กซเรย์ [ท่ายืน (standing posteroanterior) ก่อนการดามอุปกรณ์ ท่าเอียงลำตัว (side bending) และท่าดามอุปกรณ์ (in-brace)] สำหรับการพิจารณาความสัมพันธ์ระหว่าง IBC กับปัจจัยพยากรณ์นั้นใช้การวิเคราะห์สหสัมพันธ์และการวิเคราะห์ถดถอยเชิงเส้นแบบง่าย จากนั้นทำการวิเคราะห์ถดถอยเชิงเส้นแบบหลายตัวเพื่อสร้างโมเดลพยากรณ์ IBC

ผลการวิจัย: ค่าเฉลี่ยมุม Cobb angle เท่ากับ 32.9±8.7° ค่าเฉลี่ยมุม Cobb angle ในการถ่ายภาพเอ็กซเรย์ท่าเอียงลำตัวและท่าดามอุปกรณ์เท่ากับ 17.9±12.7° และ 22.5±11.8° ตามลำดับ ความยืดหยุ่นความโค้งมีความสัมพันธ์เชิงเส้นเป็นค่าบวกอย่างแข็งแรงกับ IBC (r = 0.732), P<0.001) ในการวิเคราะห์ตัวแปรเดียว ไม่พบความสัมพันธ์ระหว่าง IBC กับอายุ เพศ ส่วนสูง น้ำหนัก Risser sign และประเภทของความโค้งงอ โมเดลถดถอยที่สร้างขึ้นเพื่อพยากรณ์ IBC เท่ากับ (IBC = 60.42 + 0.51 (ความยืดหยุ่น) – 0.42 (มุม cobb angle เริ่มต้น) – 1.96 (BMI))

บทสรุป: ค่า IBC แบบดามอุปกรณ์เต็มเวลา กำหนดได้โดยใช้ค่าความยืดหยุ่นของกระดูกสันหลังที่วัดจากการถ่ายภาพเอ็กซเรย์ท่าเอียงลำตัว ปัจจัยที่มีอิทธิพลมากที่สุดใน IBC คือความยืดหยุ่นของกระดูกสันหลัง รองลงมาคือ ดัชนีมวลกาย (BMI) และมุม cobb angle เริ่มต้น

สาขาวิชา	เวชศาสตร์คลินิก	ลายมือชื่อนิสิต	....
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KEYWORD: Adolescent Idiopathic Scoliosis, spine flexibility, side bending radiograph, in-brace correction

Raden Achmad Candra Putra : Bending Radiograph as Predictive Factor of In-Brace Correction (IBC) in Adolescent Idiopathic Scoliosis (AIS). Advisor: Prof. SOMSAK KUPTNIRATSAIKUL, M.D.

Introductions: In-brace correction (IBC) is one of the most important factors in bracing treatment for Adolescent Idiopathic Scoliosis (AIS). Several factors influenced IBC achievement. The curve flexibility found to be associated with the IBC. One of the most common methods for assessing curve flexibility is to take a side bending radiograph. It has been widely used as a predictor of surgical correction in AIS. However, bending radiograph to predict the amount of fulltime IBC is not cleared in orthotics practice. The purpose of this study was to evaluate flexibility as measured by a side bending radiograph as a predictive factor of in-brace correction in AIS.

Methods: A retrospective cohort study. This study included 82 consecutive patients with AIS who received full-time bracing treatment at King Chulalongkorn Memorial Hospital (KCMH) from January 2017 to December 2021. Data collection was based on the medical record of AIS patients. Demographic data and radiographic imaging (standing posteroanterior before brace, side bending, and in-brace) were reviewed. The association between IBC and its associated predictive factors was determined using correlation analysis and simple linear regression. A multivariable linear regression was performed to establish the IBC prediction model.

Results: The mean Cobb angle was 32.9±8.7º. The mean Cobb angle in a side bending radiograph and in-brace were 17.9±12.7º and 22.5±11.8º, respectively. Curve flexibility had a strong positive linear relationship with IBC (r=0.732, P<0.001). Univariate analysis revealed no relationship between IBC with age, sex, height, weight, Risser sign, and curve types. The established regression model to predict IBC was ((IBC= 60.42 + 0.51(flexibility) – 0.42 (initial cobb angle) -1.96 (BMI)).

Conclusions: The amount of IBC in a full-time brace could be estimated using the flexibility of the spine measured by a side bending radiograph. The most influential factor

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Chapter 1. Introduction

Scoliosis is simply defined as a lateral curvature of the spine greater than 10 degrees observed from the coronal view [1]. In another definition, scoliosis describes a more complex deformity in three planes of the spine that includes coronal lateral curvature, sagittal hypokyphosis and/or lumbar hyperlordosis, and transverse vertebral rotation [2]. Idiopathic scoliosis (IS) is structural lateral spinal curvature with unclear cause (unknown). IS has been further classified according to the onset of the scoliotic curve developed: infantile idiopathic scoliosis (IIS) at age 0-3 years, juvenile idiopathic scoliosis (JIS) at age 4-9 years, and adolescent idiopathic scoliosis (AIS) at age 10 -18 years old [3]. Twenty percent of IIS and JIS cases are associated with neurological problems in which the curvature develops over time if left untreated, even after the patient has reached skeletal maturity. Therefore, natural history of AIS is quite different with IIS and JIS [4].

Seventy percent of idiopathic scoliosis cases are AIS. In children aged 10 to 18, the prevalence of AIS ranges from 2%-6% [5, 6]. In Surabaya, Indonesia, the prevalence of AIS was 2.93% [7]. In Thailand, the prevalence of AIS among children aged 11 to 13 years is estimated to be 4.46% [8]. The incidence of scoliosis with Cobb angle curve of 10º was equal in boys and girls. However, the incidence in girls was rising 10 times than the boys in the Cobb angle curve >30º [9].

The treatment of AIS can be either conservative or surgical. The primary aim of conservative treatment in AIS was to stop scoliosis curve being develop during the growth period [2]. The conservative treatment in AIS consist of observation, physiotherapy, and bracing. Bracing is a main conservative treatment for AIS for mild to moderate curve magnitude [10]. However, large curve magnitude more than 40° with remaining growth period will be most likely to be beneficial in treated with surgical treatment.

The benefit of brace to stop curve progression in AIS has been a debate among the clinicians and researchers for many years [6]. Several previous studies evaluated the effect of brace treatment in AIS with various types of braces. When compared to observation, the majority of studies revealed that the brace was beneficial in preventing curve progression [11, 12]. However, in the review study by Negrini et al.[13] found that most of published studies were low quality evidence, thus difficult to generalization.

Scoliosis Research Society (SRS) developed criteria for scoliosis brace study which aimed to make a researcher of brace in AIS to compare their findings with other researchers in similar baseline characteristics. After a brace trial study by Weinstein et al. in 2013, the evidence of brace effectiveness was increasing [6]. The success rate of brace group was much higher than observational group in this trial investigation. Literature review and meta-analysis study by Zhang and Li [14] strengthened the evidence of bracing for AIS in preventing curve progression by including RCTs in the meta-analysis.

The clinical observation by investigator at clinic orthotic in King Chulalongkorn Memorial Hospital revealed that the demands of scoliosis brace about 3 to 5 scoliosis braces per month. Most of the patients were AIS. Brace prescription mostly with full-time brace with Boston principle. There are several factors that might contribute to the result of brace treatment .The factors might include IBC, compliance, initial cobb angle, curve type, skeletal maturity, BMI , brace type, and other prognostic factor [15].

In-brace correction (IBC) is a percent of immediate curve correction after brace were applied. Ideally, IBC should achieve around 50% of correction from the initial curve [16]. However, there were many different cut points of IBC in the literature suggested for bracing to be successful [11, 17-23]. No conclusion of cut points of IBC can be made at this point for successful treatment. However, all studies suggested, higher IBC increased the likelihood of successful of bracing.

Good initial correction provided by brace is an important indicator for successful brace treatment in the long term outcome [24]. In current clinical orthotics practice, there are no clear methods for orthotist to understand whether the brace that have been fitted to patients provided maximum correction or not. Consequently, under-correction or over-correction, which make uncomfortable due to too much pressure which may lead to patient in less compliance for wearing a brace.

Spinal flexibility has been used widely in predicting the surgical correction [25]. There are several methods in measuring spinal flexibility which consist of traction, active or passive bending radiograph in supine, standing, sitting, or prone position, and push radiograph in prone position. However, there is no consensus on what technique is more superior than others [26]. The active bending radiograph is the most common method use for flexibility test prior to surgical treatment [27], where it can be done either in supine or standing position without giving any significant different result [28].

Spinal flexibility is one of important factor to achieve better IBC. The more flexible the spine, the more IBC will be increased [24, 29]. There are some studies use different techniques of spinal flexibility as a predictive factor for IBC. Traction with hanging method radiograph was used to estimate the initial correction[30]. However, the study was limited to only Osaka Medical Collage (OMC) brace type. Current study, using supine bending radiograph for flexibility could provide good estimation for IBC in specific providence brace with mean difference 0.2° [31].

The scoliosis curvature is commonly assessed with Cobb angle technique [32] which consider as the gold standard. It is originally measured with the manual procedure with direct measurement onto the radiographic film. Currently, it has been developed using computer-assisted measurement by integrated software program [33, 34]. However, the readers still must place the landmark of vertebrae manually and the angle will be automatically calculated. Therefore, the reliability analysis in Cobb angle measurement is suggested to minimize a measurement bias.

The use of bending radiograph to predict IBC in full-time bracing is still not cleared in orthotics practice. The evaluation on how bending brace used in predicting IBC will be useful for practician to forecast the benefit of bracing in AIS patients and evaluate whether the correction by the brace has provided maximum result or not, so that it is not either under-correction or over-correction. The goal of this study was to evaluate flexibility measured with bending radiograph predicted in-brace correction (IBC) for full-time bracing at King Chulalongkorn Memorial Hospital (KCMH).

Chapter 2. Literature Review

2.1 Cobb Angle Measurement Reliability in AIS

The Cobb angle method has been commonly used in measuring coronal curve of scoliosis to determine the most appropriate treatment, evaluate the curve progression, and evaluate the effectiveness of treatment in AIS [35, 36]. Although Cobb angle method was considered as an objective measurement, The error during determining the upper and lower end plates between observers could not be avoided. As a result, intra and inter-observer reliability of Cobb angle measurement is required prior to the analysis of studies in which Cobb angle is the primary variable of interest.

The measurement of Cobb angle can be done either manually by printed imaging or digitally with computer aid. Study by Gstottner et al. [37] conducted reliability analysis of these both methods. The study evaluated intra and inter-observer reliability to 48 posterior-anterior full spine radiographs. It found inter-observer ICC with digital and manual measurement were 0.93 and 0.97, respectively. Intra-observer ICC with digital ad manual measurement were 0.97 and 0.97, respectively. This study shown that the digital Cobb angle measurement did not improve the accuracy of measurement as both methods are still based on the 2D picture regardless the quality of the imaging.

Study by Wu et al [33] conducted the reliability analysis of Cobb angle measurement between conventional and computer assisted with SurgimapSpine software. For the analysis, 68 whole spine postero-anterior radiographs were used in the study. In measuring Cobb angle, there was no significant difference in inter and intra-observer reliability between manual and SurgimapSpine because both methods provide excellent reliability. Therefore, this study suggested that the use SurgimapSpine software could be served as one of more accurate method in measuring Cobb angle due to its features in digitalization, allowing contrast adjustment, zoom in and out, ang color enhancement for better visualization, thus increasing the accuracy in measurement.

Prestigiacomo et al. [38],in a recent study, examined the inter and intra-observer reliability in Cobb angle measurement using a digital method in different level of medical specialty and experience. It discovered that the intra and inter-observer reliability were both excellent, with ICCs ranging from 0.86 to 0.98 for interobserver reliability and ICC of 0.95 for interobserver reliability. In Cobb angle measurement, there was no significant difference between level of experience and specialty.

2.2 Cut-off Points of IBC

IBC is essential to successful brace treatment in AIS. However, there is no agreement on how much minimum IBC is required to achieve a successful result of bracing at the skeletal maturity [24]. Currently, many studies published that vary on the minimum cut-off point for successful brace treatment.

Two significant findings were made in the study of Castro et al. 2013 [17].

First, flexible spinal curvature responded better to correction by brace application than rigid curvature. Second, brace application was recommended for those who could achieve at least a 20% initial brace correction. However, this study did not examine the compliance of participants while wearing a brace.

Compliance, along with IBC, is often considered to be the most important factors in the analysis of brace outcome in AIS at skeletal maturity. The study of [11] aimed to find the predictive outcome based on clinical observations in AIS treated with Boston brace. It found that AIS patients with double curves who had at least 25% of initial brace correction and wore the brace for at least 18 hours/day showed significant success with the brace. However, this study was limited to the double curve group only. In another study by [20], it was found that a group of AIS patients with an IBC of at least 40% and high compliance during the weaning phase had better correction of up to 7 degrees than a group with lower IBC and lower compliance.

There are some studies where the cut-off point was set prior to the analysis of the brace outcome. The study by [19] set the cut-off point for a good IBC group at 45%. This study found that patients who had good IBC and wore the brace >12 hours/day increased successful rate at the end of treatment. The other study by Xu et al. [23] which set the optimal cut-off point for good IBC at 10% based on receiving operating characteristics (ROC) curve, concluded that high risk of brace failure was found in the group of patients who had a lower IBC of 10%

with skeletally immature patients.

2.3 The Relationship between Spinal Curve Flexibility and IBC

Curve flexibility is a crucial aspect that determines clinical decisions in AIS treatment. There are several methods to test the curve flexibility, including traction, active or passive bending radiograph in supine, standing, sitting, or prone position, and push radiograph in prone position. However, there was no consensus to which method is better [26].

Kuroki et al. [30] evaluated the flexibility by hanging method to estimate in-brace correction (IBC) by using Osaka Medical College (OMC) brace in idiopathic scoliosis patients. Mean of flexibility measured with hanging radiograph and IBC were 21.1% and 20.3%, respectively. They came to the conclusion that the hanging total spine radiograph might be used as tool estimate IBC in OMC brace. This hanging method produces longitudinal direction force that is not the same as the corrective force in the brace.

He et al. [39] conducted research to see which flexibility assessments may reliably predict in-brace correction (IBC). Supine, prone, sitting with lateral bending, and prone with lateral bending were all used in the study. To prevent x-ray radiation exposure, they used an ultrasound to measure Cobb angle. They concluded that of the four methods for predicting the IBC, the prone posture is the most accurate. However, because the transducer did not fit into the brace design in this investigation, the IBC was tested using an x-ray rather than ultrasound, which these different methods may have resulted in measurement bias.

Supine lateral bending radiograph (SLBR) is standard method in assessing the curve flexibility before surgical treatment [40]. Study by Nissen et al. [31] retrospectively investigated the use of SLBR in predicting IBC in AIS who underwent bracing with providence brace. They found that the mean difference between IBC and SLBR were 0.2 degrees in thoracic curves, 0.9 degrees for thoracolumbar/lumbar curves, and 0.4 degrees in double major curves. They concluded that SLBR serve as a good predictor for IBC before bracing. However, this study was limited to only providence brace type.

Study by Cheung et al. [41] investigated the use of supine radiograph (SR) in predicting IBC. The radiographic analysis of 105 patients underwent bracing. They reported a significant association between SR and IBC ($r=0.740$), with an established regression model of IBC of 0.809 x SR. The study concluded that SR can be a good method to determine the IBC. This study strengthened by Cheung et al. in 2020 [42] where they following the patient until the skeletal maturity has reached. The group of patients who has FR less than 28% was increasing the likelihood of curve progression. They concluded that SR was not only served as a good predictor of IBC but also the likelihood of the curve progression.

The standing side bending radiograph is one of method to assess the curve flexibility. This method is mostly applied in King Chulalongkorn Memorial

Hospital (KCMH) as a curve spinal flexibility. Until now, there was no study to assess the use of standing bending radiograph in predicting IBC. The supine lateral bending radiograph (SLBR) was found as a good predictor for IBC in previous study [31]. Moreover, there was one study by Hirsch et al. [28] who compared the spinal curve flexibility between supine and standing side bending. They assessed 50 AIS who underwent preoperative assessment. The result showed no significant difference of curve flexibility between supine and standing side bending to all of type curves. Based on this result, the use of standing side for assess flexibility served as a potential predictor for IBC.

2.4 The Association between BMI and IBC

A retrospective study by Goodbody et al [19] evaluated brace effectiveness based on BMI. They divided BMI of 182 patients into 3 groups; low (<20th percentile), mid (20th -85th percentile) and high (>85th percentile). After 2 years follow-up, there were significant brace failure in the group of patients with high and low BMI. Less in-brace correction and compliance were observed in high BMI group patient. According to the findings of this study, lower in-brace correction was associated to brace failure.

Study by O'Neill et al. [43] evaluated the difference scoliosis brace effect in patient with overweight and non-overweight. The study examined back at 276 patients with AIS who had been treated with a scoliosis brace. The curve progression in overweight patient found to be higher than in non-overweight patient. The percentange of patients with curve progression □45 in the overweight and non-overweight groups were 45 and 28 percent, respectively. It discovered that overweight patients had 3.1 times the risk of brace failure as non-overweight patients.

In contrast, study by Zaina et al. 2017 [44] found no significant difference in brace failure between overweight and normal weight. They reviewed 351 AIS patients who were treated with full-time bracing. The study found that 3% in overweight and 7% in normal weight got curve worsened. This result could probably cause by high compliance reported subjectively in overweight patients which might compensate the less in-brace correction in this group of patients. similarly to literature review study by Van den Boggart [21] found limited evidence of BMI with brace failure. Therefore, further study is needed to confirmed this factor.

Chapter 3. Methodology

3.1 Research Question

3.1.1 Primary

Is flexibility measured with bending radiograph a predictive factor of in-brace correction in AIS?

3.1.2 Secondary

1. How is the reliability of Cobb angle with digital measurement in KCMH?
2. Is the Cobb angle in AIS be reduced after the brace were applied?
3. Is there any association between curve flexibility and IBC?

3.2 Research Objectives

3.2.1 Primary

To evaluate the use of bending radiograph for curve flexibility measurement as a predictive factor for in-brace correction.

3.2.2 Secondary

1. To assess reliability of Cobb angle with digital measurement
2. To evaluate Cobb angle reduction before and after the brace were applied
3. To evaluate the association between curve flexibility and IBC

3.3 Hypothesis

There is a strong association between flexibility rate by measured by bending radiograph and IBC.

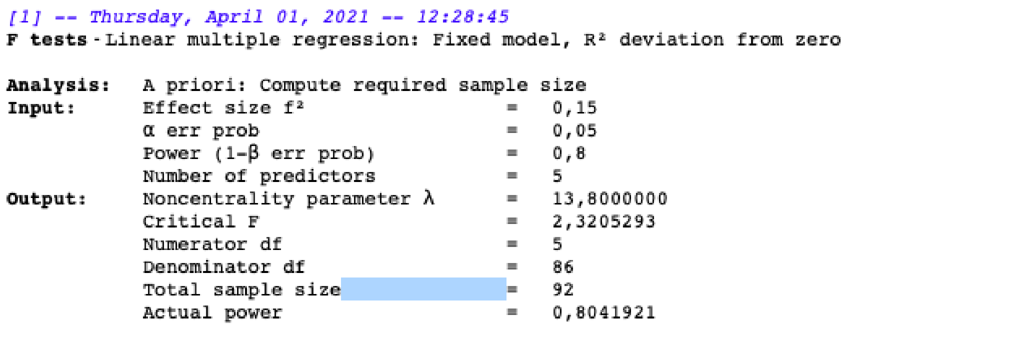
3.4 Research Design

Retrospective cohort study design.

3.5 Population and Sample

Population in this present study was patients with AIS who had been receiving full-time brace at Orthotics clinic, King Chulalongkorn Memorial Hospital (KCMH). The observation was done by investigator which found that the cases of scoliosis in King Chulalongkorn Memorial Hospital was around 3-5 cases per month.

The sample in present study is AIS patients who were treated with full time scoliosis brace from KCMH from 1st January 2017 to 28 February 2022 who met inclusion criteria of the study. The minimum sample size according to a priori power analysis (**Error! Reference source not found.**) for regression analysis is 92 samples with medium effect size based on cohen convention and 5 predictors (BMI, curve magnitude, Riser sign, curve type, and flexibility).



```
[1] -- Thursday, April 01, 2021 -- 12:28:45
F tests - Linear multiple regression: Fixed model, R² deviation from zero

Analysis:   A priori: Compute required sample size
Input:      Effect size f²                    =   0,15
            α err prob                        =   0,05
            Power (1-β err prob)              =   0,8
            Number of predictors              =   5
Output:     Noncentrality parameter λ         =   13,8000000
            Critical F                        =   2,3205293
            Numerator df                      =   5
            Denominator df                    =   86
            Total sample size                 =   92
            Actual power                      =   0,8041921
```

Figure 1. A sample size calculation using G*Power

3.6 Inclusion Criteria

The following characteristics of subjects were obtained from their medical records as inclusion criteria in this study:

1. Age in the range of 10 -18 years
2. Initial Cobb angle was equal or greater than 20º
3. The Risser sign was recorded at initial brace treatment
4. Complete radiographs data: Postero-anterior standing radiograph, side bending radiograph in supine or standing position, and in-brace radiograph
5. Never had any previous treatment

3.7 Exclusion Criteria

The following characteristics of subjects were obtained from their medical records as exclusion criteria in this study:

1. Other secondary diseases
2. Poor quality of radiographs

3.8 Instruments

1. Patient's medical record including digital radiographs
2. The case record form (Appendix 1).

3.9 Study Procedures

1. The proposal of study was reviewed by IRB and KCMH.
2. After all approval were obtained, principal investigator will initiate data collection by involving research assistant and clinical observers from the orthotic clinic in KCMH

3. Data were collected retrospectively from the medical record of KCMH
4. Medical record and radiographs of patients were screened according to the criteria
5. All data will be recorded in the case record form
6. Data analysis with the statistician
7. Make a final report and findings

3.10 Data Collection

1. The data collection began after the approval from IRB and issued permit letter from KCMH
2. Research assistant in Orthotic and Prosthetic clinic, Deparment of Rehabilitation collected the patient's hospital number of the AIS patients who underwent brace treatment
3. Screened medical records according to inclusion criteria in the study
4. Baseline characteristic of patient (age, gender, height, weight, BMI, curve type, and Risser sign) were recorded in case record form.
5. Two observers who has been experience in clinical setting and treat scoliosis will independently measure Cobb angle of postero-anterior standing before the initiation of brace treatment, side bending, and in-brace radiographs [45].
6. One observer will repeat the Cobb angle measurement randomly without knowing the result of the first measurement.
7. Age defined as chronological age during the brace has prescribed
8. Sex was a binary data consist of boys and girls.

9. The Risser sign was recorded according to the percent ossification of iliac crest
10. Curve pattern variable classification is according to the location of the apical curve [32]:
    a. T2-T11 – Thoracic curve
    b. T12-L1 – Thoracolumbar curve
    c. L2-L4 – Lumbar curve
11. According to WHO-2013, body mass index (BMI) was calculated by dividing the mass of body weight in kilograms by the square of height in meters.
12. In-brace correction (IBC) is a percentage of immediate curve correction after brace application calculated using the formula:

$$\square\square\square\ (\%) = \frac{\square\square\square - \square\square\square\square}{\square\square\square\square}\ \square\ 100\%$$

Note:

 - ICA: initial Cobb angle
 - IBCA: immediately after brace applied

13. Flexibility is defined as the percentage of Cobb angle correction from the standing radiograph and side bending calculated using a following formula:

$$\square\square\square\square\square\square\square\square\square\square\square\ (\%) = \frac{\square\square\square - \square\square\square\square}{\square\square\square\square}\ \square\ 100\%$$

Note: BRCA: Cobb angle in bending radiograph

1. 1 Ethical Consideration

The study was using a secondary data from medical records, there was no direct interaction between researchers and participants. Data was accessed in a private room at the clinic. Principle investigators ensuring that only observers and investigators were in the room during the data collection.

Data recorded in the case record form (as attached). Data was collected using the code instead of the sample's name and personal information without including the date, month, and year of birth and initial letter of the first name and the last name to respect the privacy of the samples. The document be kept in a locked cabinet, accessible only to the researchers involved in the study, for three years after the study is completed. There is no conflict of interest in this study.

This research was reviewed and approved by Institutional Review Board, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, with Certificate of Approval number 1060/2021.

3.11 Frame Work

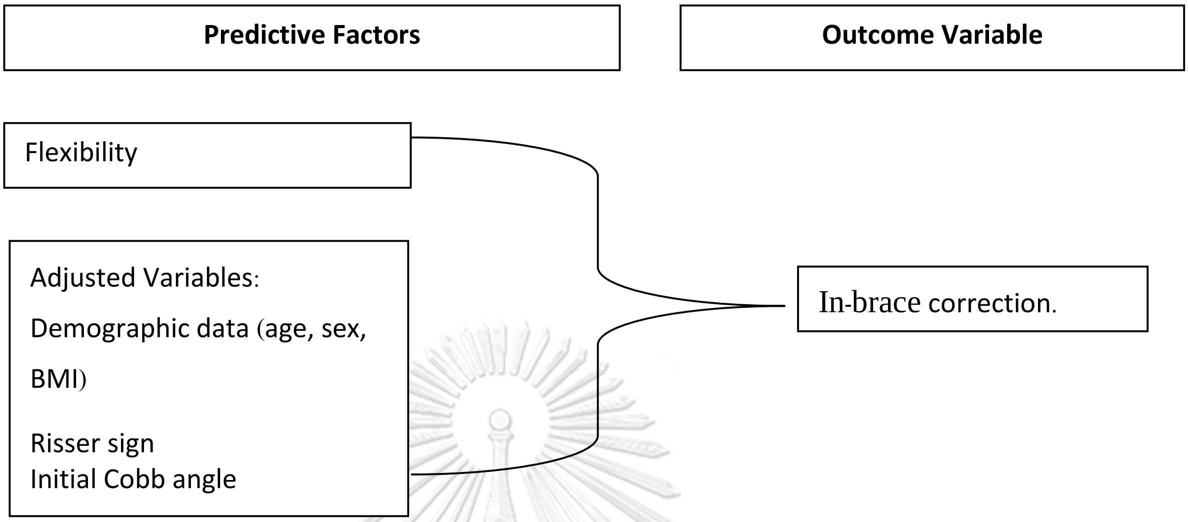


Figure 2. Frame work

3.12 Data Analysis

1. Descriptive analysis, Mean ± SD was used to describe continuous data (age, initial Cobb angle, flexibility, in-brace) and Number (proportions) for categorical data (gender, riser sign, curve pattern)

2. Inter and Intra observer's reliability was assessed by interclass correlation (ICC) as the data is continuous;

    - Radiographs was measured by two independent observers (k=2)_who were experienced in clinical practice for measuring cobb angle. Two-way mixed effect model with type of absolute agreement to calculate ICC estimates and 95% confident intervals

    - A single observer repeated the measurement one month after initial measurement without seeing the 1st result. Two-way mixed effect model with type of absolute agreement to calculate ICC estimates and 95% confident intervals.

3. A regression model was developed using a purposeful selection of covariates strategy;
    - Bivariate associations and include all whose p-value <0.20. Pearson correlation to see the correlation between continuous variables and IBC and Simple linear regression to see the association between categorical data and IBC
    - Run the model from the previous step to build the multivariable model 1- exclude all variables not statistically significant (p>0.05)
    - Re-introduce each excluded variable in previous model and assess the statistically significant and confounders (beta coefficient changes by 15%)
    - Re-introduce the excluded variable from bivariate analysis at first step which p value > 0.20
    - Evaluate the final model and the model fit through the percent of R^2 and adjusted R^2.

3.13 Expected Benefit

1. The study's findings can be used to improve the standard of care for AIS brace treatment by assessing flexibility with a bending radiograph.
2. The expected benefit of flexibility assessment by bending radiograph can be used to estimate the IBC to assist in fabrication of the brace.

3. The result of the study can also be used to evaluate the brace during the initial fitting. This can be done by evaluating the percentage IBC so that the brace can be adjusted by adding a corrective pad to increase the correction if there is still potential for correction by the brace based on flexibility.

Chapter 4. Results

4.1 Patients Recruitment

In present study, there were 125 patients who underwent brace treatment from January 2017 – December 2021. Of these 125 patients, A total of 43 patients were excluded for our study because of congenital scoliosis (3 patients), juvenile idiopathic scoliosis (5 patients), Risser sign more than 2 during initial brace treatment (13 patients), have another secondary diseases (4 patients), incomplete radiograph imaging (18 patients). Finally, we included 82 patients for our data analysis. The flow chart is of this recruitment is described in the **Error! Reference source not found.**.

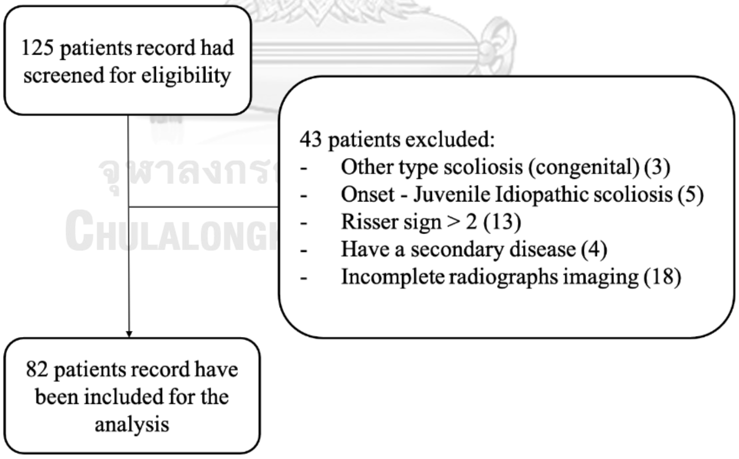


Figure 3. Flow chart of included patients

4.2 Reliability of Cobb Angle Measurement

A total of 50 postero-anterior of spine pre-brace, side bending, and in-brace radiographs of patient with AIS were randomly selected to determine the reliability of the Cobb angle measurement as described in **Error! Reference source not found.**. The inter-observer ICC for the pre-brace Cobb angle was 0.995 (95% CI=0.991 to 0.997), the side bending Cobb angle was 0.997 (95% CI=0.995 to 0.998), and the IBC Cobb angle was 0.995 (95% CI=0.990 to 0.997). In addition, intra-observer ICC for pre-brace Cobb angle, side bending and IBC Cobb angle were found to be excellent being 0.975 (95% CI=0.957 to 0.986), 0.991 (95% CI=0.985 to 0.995), and 0.987 (95% CI = 0.978 to 0.993), respectively. Therefore, the average measurement of Cobb angle was reliable and could be used for further regression analysis to predict IBC in this study.

Table 1. Reliability of Cobb Angle measurement

	Radiograph	ICC	95% CI	p	r
Inter-rater	Pre brace	0.995	0.991 – 0.997	< 0.001	0.99
	Side bending	0.997	0.995 – 0.998	< 0.001	0.99
	IBC	0.995	0.990 – 0.997	< 0.001	0.99
Intra-rater	Pre brace	0.975	0.957 – 0.986	< 0.001	0.97
	Side bending	0.991	0.985 – 0.995	< 0.001	0.99
	IBC	0.987	0.978 – 0.993	< 0.001	0.98

4.3 Study Characteristics

The baseline characteristics of the samples in this study are presented in **Error! Reference source not found.**. A total of 82 samples, including 6 (7.30%) boys and 76 (92.70%) girls with AIS, were included in the study. The mean of age was 12.98 ± 1.20 years. The mean of weight was 46.55 ± 7.77 kg, and height was 157 ± 7.68 cm. The mean BMI of patients at the initial brace treatment was 18.82 ± 8.82 kg/m^2. Twelve (14.63%) had Risser sign 0, 30 (36.59%) had Risser sign 1, and 40 (48.78%) had Risser sign 2. Of the 82 samples, 37 (42.12%) had thoracic, 25 (30.49%) thoracolumbar, and 20 (24.39%) had lumbar curves.

Table 2. Baseline characteristics of sample in the study

Variable	Sample (n=82)
Age (years)	12.98 ± 1.20
Sex (%)	
Male	7 (7.30)
Female	75 (92.70)
Weight (kg)	46.55 ± 7.77
Height (cm)	157 ± 7.68
BMI (kg/m^2)	18.82 ± 8.82
Risser sign (%)	
0	12 (14.63)
1	30 (36.59)
2	40 (48.78)
Curve type (%)	
Thoracic	37 (45.12)
Thoracolumbar	25 (30.49)
Lumbar	20 (24.39)

Data are presented as mean ± SD or numbers (%).

4.4 Cobb Angle, Flexibility and In-brace based Across Curve Type

Error! Reference source not found. shows the distribution of the mean Cobb angle before starting to wear braces, side-bending, and in-brace radiographs. The overall mean of Cobb angle before brace treatment was 32.9 ± 8.7. There was no significant difference in the Cobb angle at baseline between the thoracic, thoracolumbar, and lumbar curves.

The overall mean Cobb angle in side-bending during brace treatment was

17.9 ± 12.7. This study shows a significant difference in the mean Cobb angle between thoracic, thoracolumbar, and lumbar (P = 0.043). Post hoc analysis using Tukey's method in **Error! Reference source not found.** shows no significant difference in mean of Cobb angle between thoracic with thoracolumbar, thoracic with lumbar, and thoracolumbar with lumbar.

Table 3. Cobb angle, flexibility, and in-brace correction rate based on curve type

	Pre-Brace (°)	Side Bending (°)	In-Brace (°)	Flexibility (%)	In-brace Correction (%)
All curve (82)	32.9 ± 8.7	17.9 ± 12.7	22.5 ± 11.8	49.0 ± 29.8	34.4 ± 23.4
Thoracic (37)	33.2 ± 9.6	21.7 ± 12.1	23.8 ± 11.7	37.1 ± 24.5	31.0 ± 19.6
Thoracolumbar (25)	33.1 ± 6.6	14.8 ± 11.0	22.4 ± 10.2	57.6 ± 28.0	34.2 ± 22.0
Lumbar (20)	32.0 ± 9.4	14.5 ± 14.5	20.4 ± 14.0	60.0 ± 34.0	41.0 ± 30.3
P	0.086	*0.043	0.594	*0.003	0.309

Data are presented as mean ± SD

One-way ANOVA

*P<0.05

Patients underwent another spine PA radiograph with using brace in range of 2-4 weeks after the brace was fitted by a clinical orthotist and got approval for delivery from a physician. The overall mean of Cobb angle with bracing was 22.5 ± 11.8. There was no significant difference between the different types of curvatures.

The overall mean flexibility rate was 49.0 ± 29.8, and there was a significant mean difference in flexibility rate between thoracic, thoracolumbar, and lumbar (P=0.003). Post hoc analysis using Tukey's method in **Error!**

Reference source not found. showed a statistical mean difference between thoracic with thoracolumbar (P=0.017) and thoracic with lumbar (P=0.012). The overall mean of IBC was 34.4 ± 23.4, and the mean difference between flexibility and IBC was 14.6. There was no significant mean of IBC difference between thoracic, thoracolumbar, and lumbar.

Table 4. Tukey's method analysis

Variable	Group		Mean difference (°)	P
Side-Bending	Thoracic	Thoracolumbar	6.91	0.087
		Lumbar	7.22	0.098
	Thoracolumbar	Lumbar	0.31	0.996
Flexibility	Thoracic	Thoracolumbar	20.51	*0.017
		Lumbar	22.92	*0.012
	Thoracolumbar	Lumbar	2.40	0.956

4.5 Univariate analysis between IBC with Associated Factors

Error! Reference source not found. describes the relationship between IBC and all continuous independent variables that could contribute to the results of IBC. Pearson's correlation analysis revealed no significant relationships between IBC and age, height, sex, and Risser sign. A strong positive linear relationship was observed between IBC and flexibility (r=0.732, P<0.001). The fitted line of percent IBC in relation to flexibility is shown in **Error! Reference source not found.**. Small negative linear relationships were observed between IBC and initial Cobb angle (r= -0.489, P= <0.001) and weight (r= -0.322 P=0.003). A small negative relationship was observed between IBC and BMI (r= -0.272, P=0.013). No significant relationship with IBC was observed for age (r=-0.056, P=0.612), height (r=-0.171, P=0.123), and Risser sign (r=-0.029, P=0.793). However, high correlation was observed between weight and BMI (r =0.820) and between age and Risser sign (r= 0.720).

Table 5. Correlation analysis between IBC with associated factors

Variables	Correlation coefficient (r)	P
Age	-0.056	0.612
Height	-0.171	0.123
Weight	-0.322	*0.003
BMI	-0.272	*0.013
Risser	-0.029	0.793
Initial Cobb angle	-0.489	*<0.001
Flexibility	0.732	*<0.001

* Statistically significant p<0.05

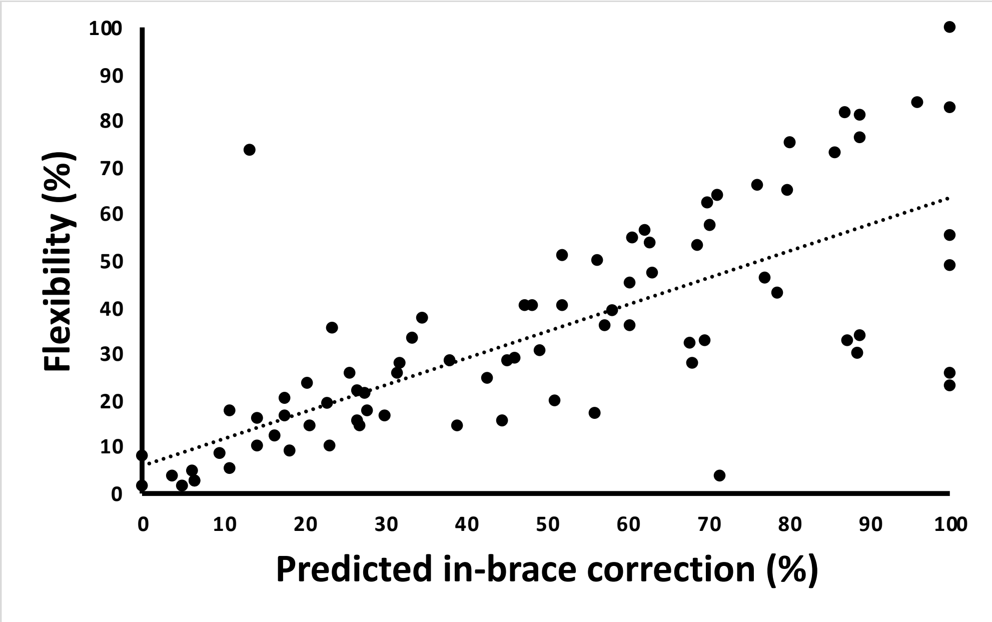


Figure 4. The association between IBC and flexibility with the fitted line in simple linear regression

Univariate linear regression was used to determine the relationship between the percent of IBC and all associated factors described in **Error! Reference source not found.**. A significant positive linear association with IBC was found for flexibility (β=0.57 95% CI: 0.45 to 0.69, P<0.001).

Table 6. Univariate analysis of IBC and associated factors

Variable	B (95% CI)	t	P
Flexibility	0.57 (0.45 to 0.69)	9.61	<0.001*
Age	-1.10 (-5.44 to 3.22)	-0.51	0.612
Sex			
Boy	Ref.		
Girl	-3.61 (-23.50 to 16.27)	-0.36	0.718
Height	-0.52 (-1.19 to 0.14)	-1.56	0.123
Weight	-0.97 (-1.60 to -0.33)	-3.05	0.003*
BMI	-2.55 (-4.55 to -0.55)	-2.54	0.013*
Risser sign			
0	Ref.		
1	6.78 (-9.16 to 22.74)	0.85	0.400
2	-0.52 (-15.90 to 14.84)	-0.07	0.946
Initial Cobb angle	-1.31 (-1.84 to -0.79)	-5.02	<0.001*
Curve Types			
Lumbar	Ref		
Thoracic	-10.01 (-22.93 - 2.90)	-1.54	0.127
Thoracolumbar	-6.80 (-20.77 - 7.15)	-0.97	0.335

*Statistically significant p<0.05

Significant negative linear association with IBC was found in weight (β=-0.97, 95% CI=-1.60 to -0.33, P=0.003), BMI (β=18.82, 95% CI =18.27 to 19.37, P<0.001), and initial Cobb angle (β= -1.31 95%CI=-1.84 to -0.79, P<0.001).

Univariate linear regression in this study also revealed no significant association between IBC and age, height, and Risser sign with P-values of 0.854, 0.123, and 0.794, respectively. Using the lumbar curve as a reference, no significant associations were found between IBC and thoracic (P=0.127) and thoracolumbar (P=0.335) curves. No significant difference in IBC was also found between boys and girls (P =0.718).

4.6 Creating the Multivariable Model to Predict IBC

To construct the multivariable model to predict percent of IBC, a purposeful selection covariates strategy was used. First of all, all variables with P<0.25 were included in the 1st model, as shown in **Error! Reference source not found.**.

Table 7. Multivariable analysis for predicting IBC-Model 1

Variable	B (95% CI)	t	P
Flexibility	0.51 (0.39 to 0.63)	8.25	*<0.001
Height	-1.59 (-5.93 to 2.74)	-0.73	0.467
Weight	2.72 (-4.84 to 10.28)	0.72	0.476
BMI	-8.65 (-27.30 to 9.99)	-0.92	0.358
Initial Cobb angle	-0.47 (-0.93 to -0.008)	-2.03	*0.046
Constant	311.35 (-372.65 - 995.38)	0.91	*<0.001
P=<0.001, Adjusted R^2=0.591, RMSE=14.98			

* Statistically significant p<0.05

The initial multivariable linear regression model described the overall statistical significance of the model including all independent variables (P<0.001). The adjusted R^2 of the model was 0.591, indicating that 59.1% of the variance in IBC was explained by height, weight, BMI, initial Cobb angle, and flexibility. However, there were no significant associations between IBC and height, weight, and BMI. IBC has a significant association with initial Cobb angle and flexibility with a P-value of 0.046 and <0.001, respectively.

Secondly, the model was developed by excluding all variables with no statistically significant P>0.05. The multivariable model 2 is shown in **Error! Reference source not found.**. The model was statistically significant in predicting IBC by initial Cobb angle and flexibility (P < 0.001). The adjusted R^2 of the model was 0.560, which means that 56% of the variance of IBC was explained by initial Cobb angle and flexibility. The model also shows that the relationship between IBC with initial Cobb angle and flexibility remains significant, with P-values of <0.001 and 0.012, respectively.

Table 8. Multivariable analysis for IBC- model 2

Variable	B (95% CI)	t	P
Flexibility	0.50 (0.39 to 0.63)	7.83	<0.001
Initial Cobb angle	-0.56 (-1.00 to -0.12)	-2.57	0.012
Constant	28.47 (10.09 – 46.86)	3.08	0.003
P<0.001, Adjusted R^2=0.560, RMSE=15.533			

* Statistically significant p<0.05

Thirdly, reintroduce each excluded variable one at a time from the previous step into the model. The purpose of this step was to determine whether any of the variables became statistically significant or were a confounding factor. For model 2 described in **Error! Reference source not found.**, the height factor was reintroduced into the model. It was found that the height was not statistically significant (P=0.869) and did not have any confounding effect on the other variables included. Therefore, the height was not included into the final model.

Table 9. Multivariable analysis for IBC- model 3

Variable	B (95% CI)	t	P
Flexibility	0.50 (0.37 to 0.63)	7.83	<0.001
Initial Cobb angle	-0.56 (-1.00 to -0.11)	-2.57	0.015
Height	-0.03 (-0.50 to 0.42)	-0.17	0.869
Constant	34.34 (-38.80 – 107.49)	0.93	0.353
P<0.001, Adjusted R^2=0.555, RMSE=15.63			

* Statistically significant p<0.05

Error! Reference source not found. shows the multivariable model 3 by adding BMI back into the model. It shows that β-coefficient of the initial cobb angle was changed by 33% from -0.56 to -0.42. BMI had a significant negative association with the percentage of IBC (P=0.005). The adjusted R^2 of the model was 0.598, which means that 59.8% of the variance in IBC was explained by flexibility, initial Cobb angle and BMI. Therefore, BMI was included in the final model.

Table 10. Multivariable analysis for IBC- model 4

Variable	B (95% CI)	t	P
Flexibility	0.51 (0.39 to 0.63)	7.83	<0.001
Initial Cobb angle	-0.42 (-0.85 to 0.0009)	-1.99	0.051
BMI	-1.96 (-3.31 to -0.62)	-2.91	0.005
Constant	60.42 (32.35 – 88.50)	0.93	<0.001
P<0.001, Adjusted R^2=0.598, RMSE=14.849			

* Statistically significant p<0.05

The final step in purposeful selection of covariates was to reintroduce the variables that were excluded in the univariate step. Sex and curve types were excluded because of the univariate P-value > 0.25. **Error! Reference source not found.** shows the model 4 with sex included in the model. There was no significant association between sex in predicting percentage of IBC (P=0.446). Therefore, sex remained excluded from the final model.

Table 11. Multivariable analysis for IBC- model 5

Variable	**B** (95% CI)	t	P
Flexibility	0.51 (0.39 to 0.63)	7.83	<0.001
Initial Cobb angle	-0.42 (-0.85 to 0.21)	-1.98	0.051
BMI	-2.01 (-3.36 to -0.65)	-2.95	0.004
Sex (female)	-4.85 (-17.47 to 7.77)	-0.77	0.446
Constant	65.80 (34.36 to 97.25)	4.14	<0.001
$P<0.001$, Adjusted R^2=0.596, RMSE=14.888			

* Statistically significant p<0.05

The reintroduction of curve types into the model was described in **Error! Reference source not found.** as a multivariable model 5. No significant association was found between curve types and IBC. Lumbar curve, which was set as the reference, no significant relationships were observed between IBC with thoracic (P=0.494) and thoracolumbar (P=408). Therefore, curve types were not included in the final model.

Table 12. Multivariable analysis for IBC- model 6

Variable	B (95% CI)	t	P
Flexibility	0.54 (0.41 to 0.68)	8.27	*<0.001
Initial Cobb angle	-0.38 (-0.81 to 0.44)	-1.78	0.078

BMI	-1.83 (-3.18 to -0.48)	-2.70	*0.009
Curve Types			
Lumbar	Ref		
Thoracic	2.98 (-5.66 - 11.63)	0.69	0.494
Thoracolumbar	-3.71 (-12.60 - 5.17)	-0.89	0.408
Constant	54.60 (24.99 – 84.22)	3.67	<0.001
P<0.001, Adjusted R^2=0.6022, RMSE=14.784			

* Statistically significant $p<0.05$

The final model for predicting IBC was described in **Error! Reference source not found.**. Due to the presence of heteroscedasticity in the final model, a robust standard errors regression was used. The final regression model was: IBC=60.42 + 0.51(flexibility) – 0.42 (initial cobb angle) -1.96 (BMI). The adjusted R^2 was 0.598, which means that 59.8% of the variance of IBC was explained by flexibility, initial Cobb angle, and BMI. Holding the other variables constant, one percent increase in flexibility would increase the percentage of IBC by 0.51 percent.

Table 13. Final multivariable analysis for IBC with robust standard errors

Variable	B (95% CI)	β	t	P
Flexibility	0.51 (0.39 to 0.63)	0.65	6.55	*<0.001
Initial Cobb angle	-0.42 (-0.85 to 0.0009)	-0.16	-2.36	*0.021
BMI	-1.96 (-3.31 to -0.62)	-0.20	-3.02	*0.003
Constant	60.42 (32.35 – 88.50)	-	3.79	*<0.001
P<0.001, Adjusted R^2=0.5987, RMSE=14.849				

* Statistically significant p<0.05

Chapter 5. Discussion

The effectiveness of using brace as a main conservative treatment for AIS was described in previous clinical trial study [6]. Proposed evaluation of effectiveness in bracing for AIS was described by SRS committee [1]. It should include the evaluation of curve progression 5º at skeletal maturity, number of patients progressed over 45º, two-years follow-up post skeletal maturity, and compliance measures during brace treatment. Current literature review by Karavidas [15] revealed the evidence of several factors that might contribute to the effectiveness of bracing in AIS such as types of prescribed brace, in-brace correction (IBC), compliance, BMI, curve magnitude, and the specific exercise for scoliosis. In addition, it found that in-brace correction as one of the most important factors for bracing in AIS to be successful besides compliance.

The accuracy of Cobb angle measurement for analysis IBC in this study is crucial. The digital measurement of Cobb angle has been becoming routine practice in KCMH. Therefore, the reliability measurement should be done before the main analysis was taken place. The Cobb angle variability mostly caused by determination of lower or upper endplates of vertebrae [37]. Previous literature showed the inter and intra observer calculation error was in the range of 4º to 8º [33, 36, 37]. Inter and intra observer reliability of Cobb angle before brace treatment, in side bending position, and in-brace radiograph. in this study were excellent to all types of radiographs. This result showed similar ICCs to study by Gstoettner et al. [37] with mean inter ICC of 0.93 and mean intra ICC of 0.96. Therefore, the Cobb angle measurements in our study were reliable for any further analysis.

In-brace correction (IBC) is the percent of correction in coronal scoliosis curvature by using a scoliosis brace. The cut-off points of IBC suggested to be ideally of 50% for successful brace treatment [16]. The mean of IBC in this study was 34.4% for all major curves; 31.4% for thoracic curve, 34% for lumbar curve, and 41% for thoracolumbar curve. No statistically significant difference IBC among curve types. The study by Katz, 2001 [11] described that a minimum of 25% of IBC showed high success rate with minimum of 18h/day of bracing. The study by Goodbody et al. [19] described a minimum of 45% of IBC increased the success rate at the end of treatment. Another study by Xu, et al [23] found the cut-off point for IBC was 10% for successful brace outcome. Although there were no clear described the cut-off point for IBC for successful brace treatment, it was generally stated that the greater the IBC, the higher success rate of scoliosis brace treatment [21]. This present study was the first evaluation of IBC at KCMH. Previous studies with Boston principle, IBC lied in the range of 35% - 50% [11, 46]. However, the IBC could be improved by a clinician orthotist by adding a correction pad if the curve still flexible and patient could tolerate with the pressure. Therefore, this study could be used as the initial evaluation to improve bracing treatment in AIS in KCMH.

The primary finding in this present study was the flexibility measured by side bending had strong positive relationship to IBC. The mean Cobb angle difference between side bending and in-brace was 4.6º. Similarly, Cheung et al. [41] showed mean difference of 3.6º between supine radiograph flexibility and IBC. Study by Nissen et al. [31] showed mean difference less than one degrees between supine lateral bending radiograph and IBC in night-time Providence brace (PB). The results in this study described that the flexibility measured by side bending radiograph also be used to full-time bracing with Boston type as a routine practice in KCMH.

The multivariable regression model in this study shown that flexibility, initial Cobb angle, and BMI were statistically significant with the percent of IBC. Previous literatures found significant association between high initial Cobb angle with the risk of curve progression [11, 47, 48]. In contrast, other studies found no significant association between initial Cobb angle with effectiveness of brace in AIS [23, 49]. Our study found that initial Cobb angle have negative correlation to IBC. One degree increases in Cobb angle, it decreases in-brace correction rate as much as 0.42%. Although the role of initial Cobb angle in brace effectiveness still in debate, our study found that higher initial Cobb angle was associated to lower IBC. As this IBC is one of the most important factor for success in brace treatment in AIS [15].

BMI was calculated from mass of body weight in kilogram divided by square of height in meter. The mean of BMI in present study was normal being 18.8. Our model found that significant association of BMI with IBC. One-point increases in BMI, it decreases the percent of IBC as much as 1.96%. This finding similar to study by O'Neill et al. [43] that stated overweight patient have higher risk of brace failure as much as 3.1 times than non-overweight. Patient with obese had associated with large initial Cobb angle due late scoliotic curve detection [50]. Study by Goodbody [19] found that the association between high BMI and less IBC. In addition, the less IBC could be caused by correction pad in bracing giving an effective correction force to the apical curve as surrounded by soft tissues.

The flexibility by side bending often considered as subjective measures due to it needs patient effort to actively bend the spine during radiograph procedures. However, this present study provides scientific description about its relationship with IBC. The multivariable regression model in this study showed significant association of flexibility rate measured by side bending radiograph and IBC. As one percent increases in flexibility, IBC increases by 0.51. Study by Cheung et al [41] showed superior result of regression model in predict IBC with Cobb angle in supine radiograph about 81%. Kuroki et al. [30] found that hanging radiograph Cobb angle could be used to predict IBC as mean Cobb angle difference was less than one degree. Similarly, a study by Nissen et al [31] found that flexibility measured by supine bending radiograph could serve as a tool to estimate IBC in night-time brace. Regardless the method of radiographs for flexibility assessment, it provides that a significant association with IBC implying that it can be used to estimate how much possible correction could be achieved.

The result of IBC could be affected by several factors such as the brace tightness, adequate correction pad, and patient tolerance to pressure where these factors were not assessed in the present study. At the moment, there is no clear guidance for clinical orthotist for pad adjustment in the brace if the curve correction is still inadequate based on in-brace radiograph. The utilization of side bending radiograph for brace treatment could be used as a guideline of prognostic curve correction while also consider the patient tolerance with the pressure.

There are some limitations in this present study. The nature of retrospective could not be avoided in inherent bias. The in-brace radiograph included in this study based on the first radiograph after brace was delivered. The brace might have some adjustments in terms of pad correction or placement by clinical orthotist and all patient did not have another Xray afterward until next follow-up in 6 months. It should be taken into account that this result only can apply to full time Boston brace principle as a main brace treatment in KCMH.

Chapter 6. Conclusion

This is the first study to evaluate brace treatment in KCMH and evaluate the role of side bending radiograph as a flexibility measurement to predict IBC. From the present study, we can conclude that reliability of Cobb angle with digital measurement in KCMH were excellent. The mean of in-brace correction from the cohort AIS patient was 34.4%. There was significant strong positive association between flexibility measured by bending radiograph and IBC. Our multivariable regression model found that flexibility, initial Cobb angle, and BMI are associated with the percent of IBC.

The utilization of side bending radiograph as flexibility measurement in routine practice could help physician and clinical orthotist to estimate the percent of IBC that might be achieved. Therefore, it could help an orthotist to decide how much correction could be applied during brace fabrication. Our study can also be used to evaluate the correction after in-brace radiograph is taken placed. If the correction in in-brace radiograph still not adequate, it can be a guideline for an orthotist to adjust correction pad while concerning on patient ability to tolerate with the pressure.

Further recommendation of study would be a prospective study include controlling brace tightness by orthotist during in-brace radiograph procedure, evaluate the curve progression by following the patients until their reaching the skeletal maturity, and follow-up 2 years after brace weaning, and compliance assessment. A prospective study including an x-ray after adjustment was warranted to confirm the effect of flexibility.

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The Case Record Form

1. No:…………………………………..……|………
2. Gender: Male ☐ Female ☐
3. Age during initial treatment:………years old
4. Weight:……………...……. kg Height :……………..cm
5. Risser Sign: 0- ☐ 1- ☐ 2- ☐ 3- ☐ 4- ☐ 5- ☐
6. Date of orthotic treatment …………/…………/……………….(DD/MM/YYYY)
7. **Curve Classification**: (According to apical cuvr)

   ☐ Thoracic

   ☐ Thoracolumbar

   ☐ Lumbar

   ☐ Double Major Thoracic

   ☐ Double Major Thoracolumbar/Lumbar

Cobb angle progression

Observer: I/II

Description	Date of X-ray	Cobb Angle	Note
Pre-brace A-P radiograph			
Side Bending Radiograph			
IBC			

COA No. 1060/2021

IRB No. 598/64

INSTITUTIONAL REVIEW BOARD

Faculty of Medicine, Chulalongkorn University

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Certificate of Approval

The Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, has approved the following study which is to be carried out in compliance with the International guidelines for human research protection as Declaration of Helsinki, The Belmont Report, CIOMS Guideline and International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Study Title : Bending Radiograph as Predictive Factor of In-Brace Correction (IBC) in Adolescent Idiopathic Scoliosis (AIS)

Study Code : -

Principal Investigator : Mr. Raden Achmad Candra Putra

Affiliation of PI : M.Sc. in Clinical Sciences (International Program), Graduate Affairs, Faculty of Medicine, Chulalongkorn University.

Review Method : Expedited

Continuing Report : At least once annually or submit the final report if finished.

Document Reviewed :

1. Research Proposal Version 1 Date 06/07/2021
2. Protocol Synopsis Version 1 Date 06/07/2021
3. Case Record Form Version 1 Date 20/07/2021
4. Curriculum Vitae and GCP Training
   - Mr. Raden Achmad Candra Putra
   - Prof. Somsak Kuptniratsaikul, M.D.

Approval granted is subject to the following conditions: (see back of this Certificate)

- Trai Promsang, M.D.

Signature .... Signature ....

(Emeritus Professor Tada Sueblinvong MD)
Chairperson
The Institutional Review Board

(Assistant Professor Thananya Thongtan, PhD)
Member and Secretary
The Institutional Review Board

Date of Approval : July 22, 2021

Approval Expire Date : July 21, 2022

Approval granted is subject to the following conditions: (see back of this Certificate)

โรงพยาบาลจุฬาลงกรณ์ **สภากาชาดไทย**

บันทึกข้อความ

งานสนับสนุนศูนย์ความเป็นเลิศและงานวิจัย ECC 251 / 2564 วันที่ ~~8~~ 14 ธันวาคม 2564

เรื่อง ยินดีให้ นาย ราเดน อาค์มาด คานดรา พูตรา เข้ามาเก็บข้อมูลการวิจัย

เรียน ประธานหลักสูตร วท.ม.สาขาวิชาเวชศาสตร์คลินิก (นานาชาติ)

อ้างถึง โครงการวิจัย เรื่อง การถ่ายภาพเอ็กซเรย์ท่าเอียงลำตัวเพื่อเป็นปัจจัยพยากรณ์การแก้ไขโรคกระดูกสันหลังคดงอชนิดไม่ทราบสาเหตุในวัยรุ่นโดยกายอุปกรณ์ดามกระดูกสันหลังคด

ตามโครงการวิจัยที่อ้างถึง แจ้งว่า นาย ราเดน อาค์มาด คานดรา พูตรา สังกัด นิสิตปริญญาโท ภาควิชาออร์โธปิดิกส์ คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ได้ขออนุมัติทำวิจัยในรพ.จุฬาลงกรณ์ เรื่อง การถ่ายภาพเอ็กซเรย์ท่าเอียงลำตัวเพื่อเป็นปัจจัยพยากรณ์การแก้ไขโรคกระดูกสันหลังคดงอชนิดไม่ทราบสาเหตุในวัยรุ่นโดยกายอุปกรณ์ดามกระดูกสันหลังคด ดังรายละเอียดแจ้งแล้วนั้น

รพ.จุฬาลงกรณ์พิจารณาแล้ว ไม่ขัดข้อง ยินดีให้ดำเนินการตามที่ขอมา โดยติดต่อประสานงานได้ที่ฝ่ายผู้ป่วยนอก โทรศัพท์ 02-256-5005, 02-256-5009 อนึ่ง สำหรับบุคลากรภายนอกรพ.จุฬาลงกรณ์ หรือคณะแพทยศาสตร์ ก่อนเข้าเก็บข้อมูลขอให้นำบัตรนิสิต/นักศึกษาหรือบัตรประชาชนพร้อมบันทึกข้อความฉบับนี้มาติดต่อขอรับบัตรประจำตัวผู้เก็บข้อมูล ณ กลุ่มธุรการประสานงาน ตึกรัตนวิทยาพัฒน์ ชั้น 4 โดยให้ติดบัตรประจำตัวผู้เก็บข้อมูลตลอดเวลาที่เข้ามาทำการเก็บข้อมูลภายในรพ.จุฬาลงกรณ์ กรณีเป็นบุคลากรของรพ.จุฬาลงกรณ์หรือคณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย โปรดคล้องบัตรประจำตัวเจ้าหน้าที่ตลอดเวลาที่ทำการเก็บข้อมูล

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