

**FACTORS INFLUENCING MAGNITUDE OF
CURVE CORRECTION IN PATIENTS WITH
ADOLESCENT IDIOPATHIC SCOLIOSIS
UNDERGOING POSTERIOR SPINAL
CORRECTION AND FUSION**

DR SUNDARESAN SOUNDARARAJAN

**DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENT FOR THE DEGREE OF MASTER
OF MEDICINE
(ORTHOPAEDICS)**



UNIVERSITI SAINS MALAYSIA

2022

**Factors Influencing Magnitude Of Curve
Correction In Patients With Adolescent
Idiopathic Scoliosis Undergoing Posterior
Spinal Correction and Fusion**

FROM THE YEAR 2004 TO 2020

STUDY VENUE: HOSPITAL UNIVERSITI SAINS MALAYSIA

ACKNOWLEDGEMENTS

The author would like to express deepest gratitude and thanks to the following individuals for their advice, guidance, comments and support during the preparation of this dissertation.

- Professor Dr Mohd Imran Yusof, supervisor of this study, lecturer of Orthopedics Department, HUSM for his guidance during the course of this study and completion of this paper.
- Associate Professor Dr Nor Azwany Yaacob, lecturer Epidemiology & Biostatistics Department of Community Medicine, HUSM for her guidance in medical statistic and data analysis.
- Dr Belzinder Pal Singh, Master of Medicine (Orthopaedics), Department of Orthopaedics, HUSM for his brilliant suggestions and assistance in the completion of this study
- To my family for their unwavering support during my time away to finish this study
- Colleagues and all staff in the Orthopedics Department, HUSM.

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ABSTRAK

Pengenalan

Magnitud pembetulan kelengkungan skoliosis adalah bacaan utama radiologi yang diukur pada pesakit yang menghidap penyakit Skoliosis Idiopathik Remaja (AIS) yang telah menjalani pembedahan pembetulan tulang belakang (PSCF). Walaubagaimanapun, faktor-faktor yang mempengaruhi bacaan ini belum dikaji dengan lebih mendalam. Kajian ini cuba mengenalpasti factor-faktor pra-operasi yang boleh mempengaruhi bacaan ini dengan tujuan memahami perhubungan antaranya untuk mempertingkatkan kejayaan pembedahan dan ekspektasi pesakit.

Kaedah Kajian

Semua pesakit dengan diagnosis AIS yang menjalani PSCF dari tahun 2004 hingga 2020 telah diambil untuk kajian ini. Pesakit dengan skoliosis bukan idiopatik atau yang telah menjalani pembedahan pembetulan tulang belakang secara berperingkat dikecualikan. Faktor-faktor pra-operasi mereka iaitu umur, jantina, darjah Cobb pra-operasi, fleksibiliti tulang belakang, klasifikasi Lenke, petanda Risser dan pengalaman pakar bedah yang melakukan pembedahan serta peratusan pembetulan lengkung dianalisis. Semua hasil bacaan diukur dan analisis statistik (IBM SPSS Statistics Version 27) dengan menggunakan *t-test* dan *korelasi Pearson* untuk mencari perhubungan antara mereka. Model regresi linear berbilang langkah kemudiannya dijalankan untuk menentukan faktor yang berkorelasi tinggi yang mampu meramalkan magnitud pembetulan lengkung. Analisis deskriptif dibentangkan sebagai min (sisihan piawai).

Keputusan

Terdapat sebanyak 41 pesakit untuk kajian ini. Purata umur kohort ialah 15.1 ± 2.1 dengan umur purata bagi lelaki 15.5 ± 1 tahun dan 15.2 ± 2.2 untuk perempuan. Purata darjah Cobb pra-operasi, darjah Cobb selepas operasi, fleksibiliti tulang belakang dan magnitud pembetulan lengkung (MCC) masing-masing ialah $63.05 \pm 23.3^\circ$, $29.45 \pm 20.5^\circ$, $32.3 \pm 13.7\%$ and $56.26 \pm 14.4\%$. *Korelasi Pearson* tidak menunjukkan korelasi yang signifikan antara klasifikasi Lenke dan petanda Risser dengan magnitud pembetulan lengkung. Regresi linear berbilang langkah pula menunjukkan darjah Cobb pra-operasi dan fleksibiliti tulang belakang sebagai peramal yang paling penting untuk menentukan magnitud pembetulan lengkung dengan nilai R^2 0.328 ($p < 0.001$). Umur, jantina dan pengalaman pakar bedah tidak mempunyai pengaruh terhadap jumlah pembetulan lengkung yang dicapai. MCC boleh diramal menggunakan formula: $46.06 + (-0.182 \times \text{Pre-op Cobb angle}) + (0.672 \times \text{Curve flexibility})$.

Kesimpulan

Darjah Cobb pra-operasi dan fleksibiliti tulang belakang adalah peramal yang paling penting dalam menentukan magnitud pembetulan lengkung pesakit dengan AIS yang menjalani PSCF.

Kata Kunci:

Skoliosi Idiopathik Remaja, tahap kelengkungan, klasifikasi Lenke, pembetulan lengkung, pembedahan dari belakang

ABSTRACT

Introduction

Curve correction magnitude is an important primary radiological outcome that is measured in patients with Adolescent Idiopathic Scoliosis (AIS) who have underwent posterior spinal correction and fusion (PSCF). However, factors that influence this outcome have not been extensively studied. We attempted to identify pre-operative factors that have significant influence on this outcome with the aim of better understanding the relationship between these variables and possibly improve the surgical outcomes and patient satisfaction.

Materials and methods

All patients with the diagnosis of AIS who underwent PSCF from the year 2004 to 2020 were recruited for this study. Patients with non-idiopathic causes of scoliosis or who had undergone anterior spinal release prior to surgical correction were excluded. Their pre-operative factors namely age, gender, pre-operative Cobb angle, curve flexibility, Lenke classification, Risser sign and experience of the surgeon performing the surgeries along with the percentage of curve correction were analyzed. All parameters were measured and statistical analysis (IBM SPSS Statistics Version 27) using *t* test and Pearson correlation was performed to look for correlation significance. A step-wise multiple linear regression model was then run to determine the independent factors that were highly correlated and predictive of the curve correction magnitude. Descriptive analysis of the numerical variable was presented as mean (standard deviation).

Results

A total of 41 patients was available for this study. The mean age of the cohort was 15.1 years old $\pm$ 2.1 with the mean age for males 15.5 $\pm$ 1 years old and 15.2 $\pm$ 2.2 for females. The mean pre-operative Cobb angle, post-operative Cobb angle, curve flexibility and magnitude of curve correction (MCC) was 63.05 $\pm$ 23.3°, 29.45 $\pm$ 20.5°, 32.3 $\pm$ 13.7% and 56.26 $\pm$ 14.4% respectively. Pearson correlation showed no significant correlation between Lenke classification and Risser signs with the magnitude of curve correction. A step-wise multiple linear regression showed pre-operative Cobb angle and curve flexibility to be the most important predictor of magnitude of curve correction, with R^2 value of 0.328 ($p < 0.001$). Age, gender and surgeon experience had no influence on the amount of curve correction achieved. MCC can be predicted using the formula: 46.06 + (-0.182 X Pre-op Cobb angle) + (0.672 X Curve flexibility).

Conclusion

Pre-operative Cobb angle and curve flexibility were the most important predictors of magnitude of curve correction in patients with AIS undergoing single stage PSCF.

Key Words:

Adolescent Idiopathic Scoliosis, Curve severity, Lenke classification, Curve correction, Posterior approach

CHAPTER 1: INTRODUCTION

1.1 INTRODUCTION

Adolescent Idiopathic Scoliosis (AIS) is a complex 3 dimensional deformity of the spine. It occurs between the age of 10 to 18 years old with no single identifiable cause. The prevalence reported in literature varies between 0.4% to 7% in Asian population while in Malaysia, the incidence is around 2.5% [1,2].

Options of treatment for patients with AIS varies from conservative, bracing to surgical intervention depending on the severity and progression of the disease. When subjected to surgical intervention, the goals of treatment are to achieve balanced correction of the deformity, to obtain fusion of the corrected segment, preventing progression/morbidity and last but not least, psychosocial and cosmetic appearance.

The outcomes that are commonly observed in scoliosis surgery are radiological changes, clinical condition and patient satisfaction. Radiological study in particular has been long studied in the never ending research of scoliosis surgery as it is one of the most objective and easily measurable outcomes.

Curve correction magnitude is one of the primary outcome measured in AIS deformity surgeries. In general, surgeons attempt to achieve the best and most correction that is possible for a given patient and their individual characteristics. However studies on the factors that influence this outcome are scarce. Identifying factors and its relationship with this outcome would be of significant benefit to the surgeon attempting the surgery as well as having a realistic goal of correction outcome that can be conveyed to the patient and their families.

This study attempts to find the correlation of pre-operative factors that have a significant correlation to curve correction magnitude that will be able to give a better understanding in the surgical management of AIS.

1.2 OBJECTIVE

General Objective:

To identify factors that influences the amount of curve correction in AIS patients undergoing posterior spinal fusion (PSF).

Specific Objective:

1. To explore the effects of age and gender on the magnitude of curve correction
2. To analyse the effects of type of scoliosis curve, pre-operative curve value and curve flexibility on the amount of curve correction
3. To explore the relationship between Risser sign and amount of curve correction
4. To study the factor of surgeon experience on the degree of curve correction achieved in scoliosis surgery
5. To generate an equation that can predict the magnitude of curve correction based on factors that highly correlated and significant

CHAPTER 2: STUDY PROTOCOL

DISSERTATION PROPOSAL

**TITLE: Factors Influencing Magnitude of
Curve Correction in Patients With
Adolescent Idiopathic Scoliosis Undergoing
Posterior Spinal Correction and Fusion**

NAME: DR SUNDARESAN SOUNDARARAJAN

MATRIK NO: P-UM 0189/18

MMC No: 58338

SUPERVISOR:

PROFESSOR DR MOHD IMRAN YUSOF

Introduction

Adolescent Idiopathic Scoliosis (AIS) is a complex 3 dimensional deformity of the spine. It occurs between the age of 10 to 18 years old with no single identifiable cause. The prevalence reported in literature varies between 0.4% to 7% in Asian population while in Malaysia, the incidence is around 2.5% [1,2].

Options of treatment for patients with AIS varies from conservative, bracing to surgical intervention depending on the severity and progression of the disease. When subjected to surgical intervention, the goals of treatment are to achieve balanced correction of the deformity, to obtain fusion of the corrected segment, preventing progression/morbidity and last but not least, psychosocial and cosmetic appearance.

The outcomes that are commonly observed in scoliosis surgery are radiological changes, clinical condition and patient satisfaction. Radiological study in particular has been long studied in the never ending research of scoliosis surgery as it is one of the most objective and easily measurable outcomes.

Curve correction magnitude or curve correction rate is one of the primary outcome measured in AIS deformity surgeries. In general, surgeons attempt to achieve the best and most correction that is possible for a given patient and their individual characteristics. However studies on the factors that influence this outcome are scarce. Identifying these factors and the relationship with this outcome would be of significant benefit to the surgeon attempting the surgery as well as having a realistic goal that can be conveyed to the patient and their families.

This study attempts to find the correlation of pre-operative factors that have a significant correlation to curve correction magnitude that will be able to give a better understanding in the surgical management of AIS.

Problem statement & Study rationale

Curve correction magnitude is a commonly measured outcome in scoliosis research [3-5]. This outcome has been shown to be closely related to clinical outcome and patient satisfaction [6]. There are various studies that has investigated the amount of curve correction and its association with these outcomes. However, to our knowledge, there is a paucity in studies that looked into factors that directly affect the amount of curve correction in scoliosis especially in our local setting.

By studying these factors and its relationship, we hope to have an insight and a new understanding towards the approach of scoliosis surgery and its management. This would be highly beneficial to the operating surgeon and to a certain extent, managing patient expectation and their subsequent outcomes.

Research Question(s)

1. Are there any factors that influences the amount of curve correction in scoliosis surgery?
2. Is the amount of curve correction dependant on multifactorial elements?

Objective

General Objective:

To identify factors that influences the amount of curve correction in AIS patients undergoing posterior spinal fusion (PSF).

Specific Objective:

6. To explore the effects of age and gender on the magnitude of curve correction
7. To analyse the effects of type of scoliosis curve, pre-operative curve value and curve flexibility on the amount of curve correction
8. To explore the relationship between Risser sign and amount of curve correction
9. To study the factor of surgeon experience on the degree of curve correction achieved in scoliosis surgery
10. To generate an equation that can predict the magnitude of curve correction based on factors that highly correlated and significant

Literature review

Based on literature search, there seems to be a paucity of studies looking at the influence of factors on the amount of curve correction achievable. Observational studies looking at the solitary factors and the amount of pre and post correction magnitude have also been scarce.

Looking at age and gender as a factor of influence, Marks et al found no difference in male and female curve correction magnitude or their age [6]. This findings was also demonstrated by Ameri et al who showed no difference in post-operative correction magnitude although males presented at an older age compared to females [7]. However Guidici et al showed age plays a role in the radiological outcome of scoliosis correction and age of above 17 years old was demonstrated to have increased risk of post operative correction loss by 2.5 times [8]. Cheong et al also found post-operative Cobb angle to be highly correlative with the age of the patient at the time of surgery [9].

Another factor that was looked into was the effect of the type of curve on the curve correction magnitude. Giudici et al showed that the type of curve had no significant difference in post-operative curve correction [8]. Lenke classification is a system for grouping AIS curve type and location (**Figure 1**). Luk et al however found that curve type of Lenke 1A and 1B had significant correlations between post-operative Cobb angles and preoperative parameters [9].

In a recent study by Mihara et al., they attempted to predict the magnitude of curve correction by studying pre-operative and peri-operative factors that are correlated to the outcome [10].

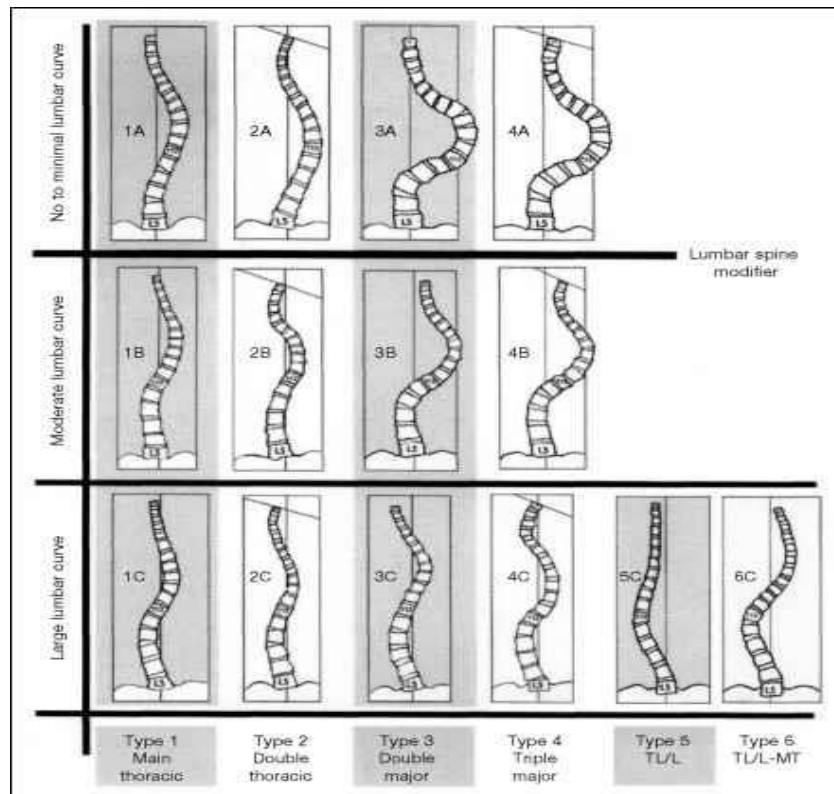


Figure 1 : Lenke classification for Adolescent Idiopathic Scoliosis

Surgeon experience has been widely studied of its relationship on curve correction magnitude. Cahill et al showed a direct effect on the outcome of correction magnitude with the experienced surgeons having a better correction percentage and improved functional outcomes when compared to junior surgeons [11,12].

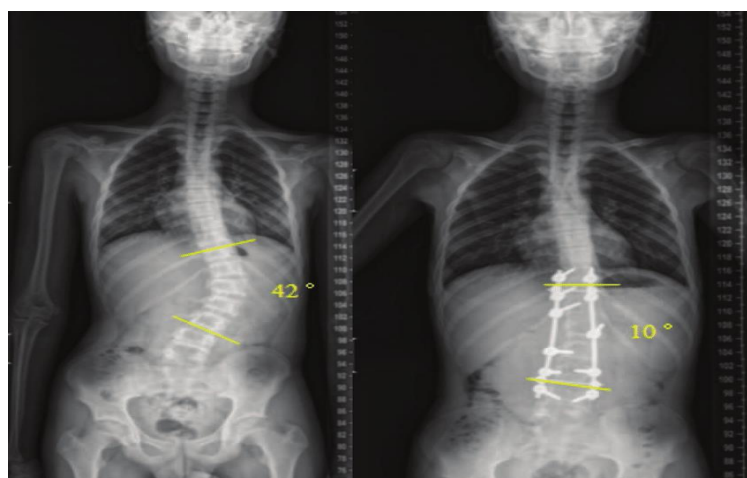
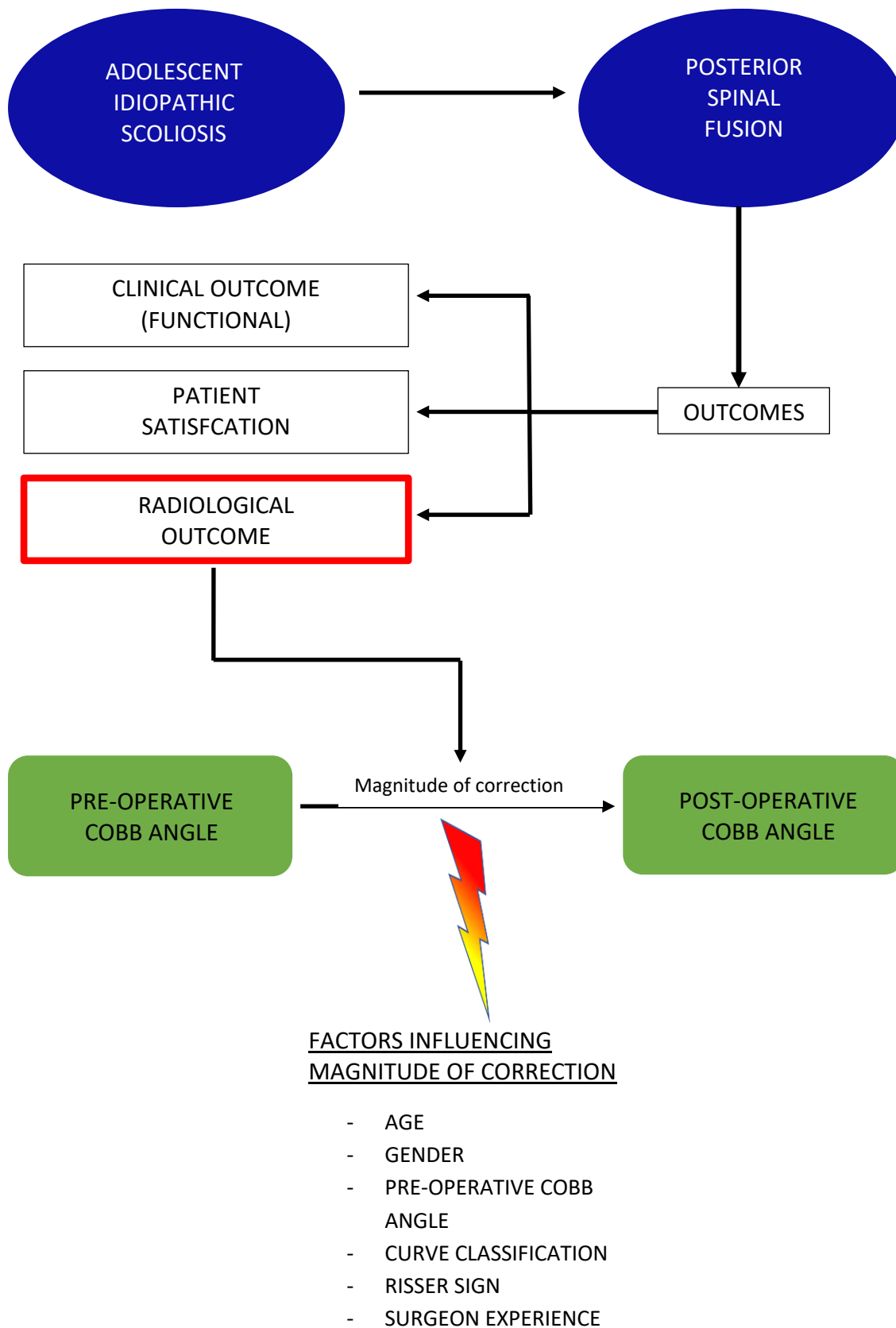


Figure 2 : A pre-operative and post-operative radiograph denoting the Cobb angle value respectively

Conceptual framework



Research design

This research uses a retrospective and a descriptive cohort design to identify the influence of factors on post-operative Cobb angle value in a population with Adolescent Idiopathic Scoliosis undergoing scoliosis corrective surgery.

Study area

The study will be conducted in Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan.

Study population

Reference population – Patients diagnosed with Adolescent Idiopathic Scoliosis

Target population- Patients with Adolescent Idiopathic Scoliosis undergoing Posterior Spinal Fusion

Source population / sampling pool – Patients with scoliosis who underwent PSF in HUSM from the year 2004 to 2020

Sampling frame – Operative record lists of patients with scoliosis undergoing PSF

Subject criteria

Inclusion criteria

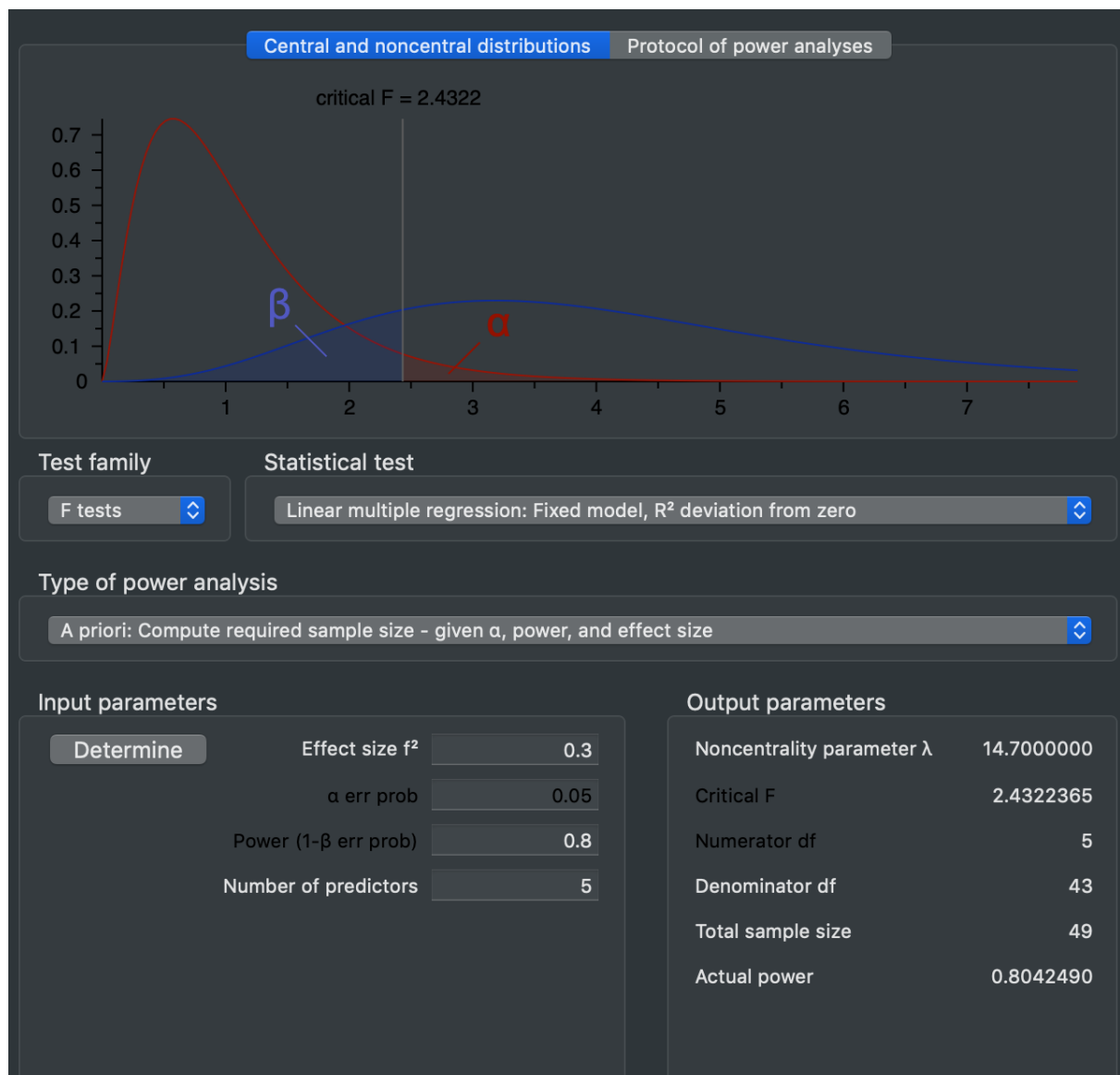
- *Age 10 to 19 years old*
- *Complete medical records (esp pre-op and post op radiographs)*
- *Single stage PSF*

Exclusion criteria

- *Non-idiopathic scoliosis*
- *Scoliosis which other causes have not been ruled out*
- *Underwent anterior release before/prior to spinal instrumentation*
- *PSF with osteotomies for severe curve magnitude*

Sample size estimation

Sample size was estimated using the G Power software ver 3.1. The statistical method used to evaluate was *Linear multiple regression : Fixed Model, R^2 deviation from zero* with 5 number of predictors.



With a power of 0.8 and 95% confidence interval, the estimated sample size needed for this study would be 49 participants.

With an estimated 20% dropout rate (incomplete medical records/ inaccessible), the total sample size needed would be $49 + 10 = 59$ participants.

Sampling method and subject recruitment

Sampling method will include reviewing the master list of operative procedure for scoliosis corrective surgery in HUSM Spine Clinic. All patients undergoing posterior instrumentation for scoliosis will be reviewed and subjects will be included and excluded according to the study criteria.

Research tool

Data needed for this study will be obtained via 2 research tools ie;

1. Medical record from HUSM

- Medical record of patients will be obtained from Patient Records Repository in the hospital.

2. Radiographic images from PACS HUSM

- Radiographs of subjects will be reviewed from the Centricity™ Universal Viewer Picture Archiving and Communication System (PACS) by GE Healthcare utilised in this hospital. (*Figure 3*)

-

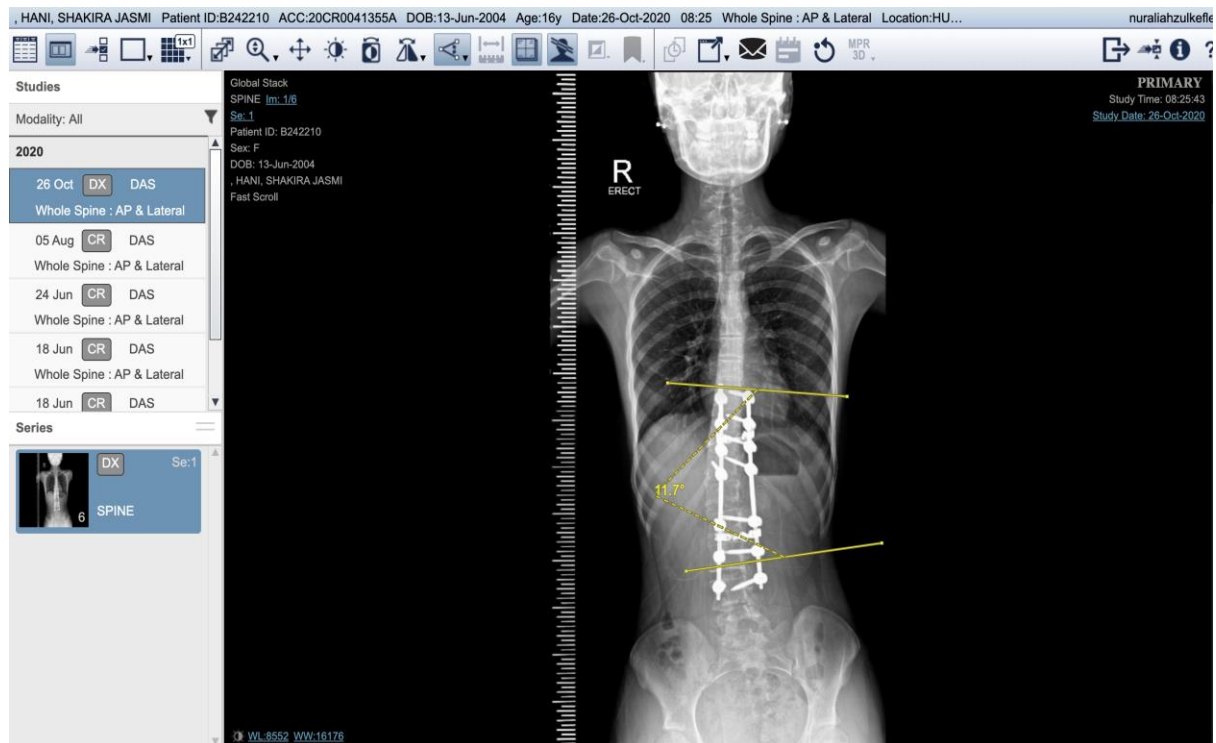


Figure 3 : A screenshot of the PACS system used for radiograph evaluation of the subjects

Operational definition

Adolescent Idiopathic Scoliosis – 3 dimensional deformity of the spine occurring in the adolescent age group with no identifiable cause.

Posterior Spinal Fusion – Surgery involving insertion of pedicle screws and rods to correct spinal deformity to achieve balanced correction and fusion .

Age – The age of patient calculated by date of birth and at the time of corrective surgery.

Gender – biological sex of female or male.

Curve classification – The type of scoliosis curve based on Lenke classification (primary classification system for scoliosis adopted globally). Ranges from Lenke 1 to Lenke 6

Pre-operative Cobb angle – The cobb angle of the primary curve measured prior to surgery

Curve flexibility – The percentage of reduction of the major curve's Cobb angle on a standing side bending view radiograph.

Risser sign – Classification of Risser based on pelvic radiograph assessed by appearance of apophysis ossification over iliac crest. Ranges from Risser 0 to Risser 5

Surgeon experience – Defined by number of cases performed at the time of surgery of the subject – less than 25 or more than 25 cases.

Data collection method

A retrospective review of clinical data from patient's clinical file traced from record office will be performed. Patient demographics, diagnosis and investigations/ operative notes will be analysed to ensure correct diagnosis was made. Radiographs from PACS system, HUSM will be reviewed to measure the Cobb's angle pre and post operatively, the type of curve classification and Risser sign.

Cobb angle – Cobb angle is a widely used tool to measure the magnitude of spinal deformities. It is measured by identifying the terminal vertebrae (the vertebrae at the end of the deformity). This is identified by using the vertebrae which has the end plate that is most tilted towards each other. A line is drawn along the end plates of these two vertebrae and a perpendicular line is drawn from these lines. The intersecting angle will be defined as the Cobb angle of the spine deformity. In the PACS system employed in this study, there is a dedicated tool to measure these angles without drawing these perpendicular lines. The Cobb angle of the major structural curve (primary curve) is identified and measured.

Formula for calculating Curve flexibility:

$$\text{Curve flexibility (\%)} = [(\text{pre Cobb} - \text{Cobb angle on side bending view}) / \text{pre Cobb}] \times 100$$

Formula for calculating Magnitude of curve correction (MCC):

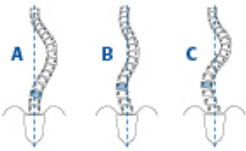
$$\text{Magnitude of curve correction (MCC) (\%)} = [(\text{pre Cobb} - \text{post Cobb}) / \text{pre Cobb}] \times 100$$

Lenke classification

The Lenke classification system for AIS				
Curve type	Proximal Thoracic	Main Thoracic	Thoracolumbar/Lumbar	Description
1	Nonstructural	Structural*	Nonstructural	Main Thoracic
2	Structural*	Structural*	Nonstructural	Double Thoracic
3	Nonstructural	Structural*	Structural*	Double Major
4	Structural*	Structural§	Structural§	Triple Major
5	Nonstructural	Nonstructural	Structural*	Thoracolumbar/Lumbar (TL/L)
6	Nonstructural	Structural*	Structural*	Thoracolumbar/Lumbar-Main Thoracic (TL/L-MT)

*Major curve: largest Cobb measurement, always structural; *Minor curve: remaining structural curves; §Type4 – MT or TL/L can be the major curve

Structural Criteria (Minor curves)		Location of Apex (SRS Definition)	
Proximal Thoracic	- Side Bending Cobb $\geq 25^\circ$ - T2-T5 Kyphosis $\geq +20^\circ$	Curve	Apex
Main Thoracic	- Side Bending Cobb $\geq 25^\circ$ - T10-L2 Kyphosis $\geq +20^\circ$	Thoracic	T2 to T11-12 Disc
Thoracolumbar/Lumbar	- Side Bending Cobb $\geq 25^\circ$ - T10-L2 Kyphosis $\geq +20^\circ$	Thoracolumbar	T12-L1
		Lumbar	L1-2 Disc to L4

Modifiers			Thoracic Sagittal Profile T5-T12	
Lumbar Spine Modifier	Center Sacral Vertical Line to Lumbar Apex		Modifier	Cobb Angle
A	Between pedicles		- (Hypo)	$< 10^\circ$
B	Touches apical body(ies)		N (Normal)	$10^\circ - 40^\circ$
C	Completely medial		+ (Hyper)	$> 40^\circ$

Curve Type (1-6) + Lumbar Spine Modifier (A, B, C) + Thoracic Sagittal Modifier (-, N, +) = Curve Classification (e.g. 1B+):

Classification of the Lenke system will be based on 6 TYPES OF CURVE + Lumbar spine modifiers + Thoracic sagittal modifier

Eg of final classification – Lenke 2AN or Lenke 4B-

The classification will also be assigned after discussion with investigating team to assign which classification best suits each of the subject studied.

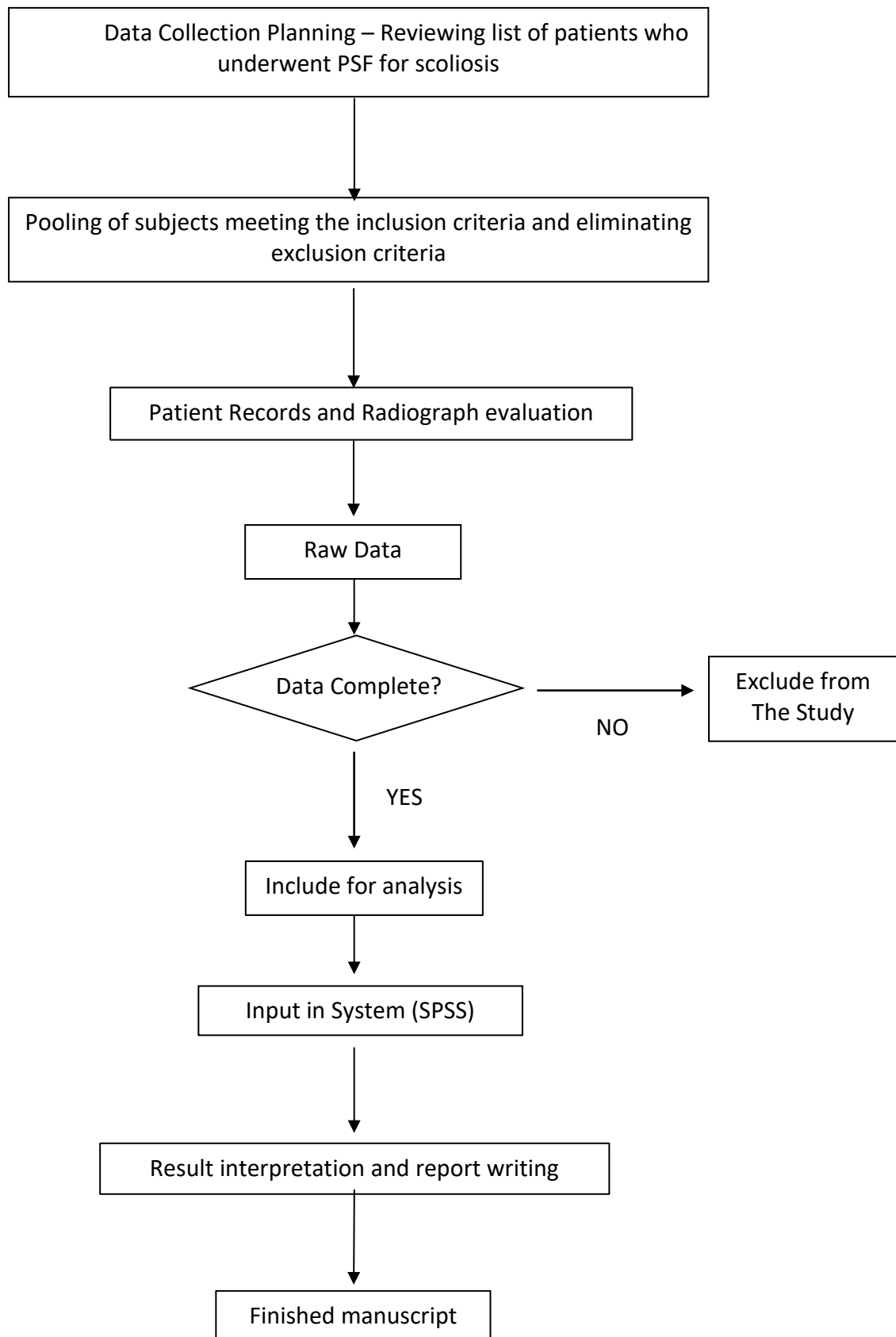
For practical purpose, we will classify the patients based on Lenke classification generally without including thoracic and lumbar modifiers in these study ie; Lenke 1 to Lenke 6.

Risser sign

Risser classification will be based on pelvic radiographs that visualized both iliac crest to determine the ossification of iliac apophysis. It will be grade either Risser 0, 1, 2, 3, 4 or 5.

Data obtained will be kept securely by principal investigator via personal computer accessible to only himself. Data will only be shared among the investigators involved in this study for further analysis and discussion. Patient confidentiality will always be prioritized.

Study flowchart



Data analysis

Data entry will be done using Microsoft Excel and the statistical analysis will be done using the program Statistical Package for the Social Sciences (SPSS, Chicago, IL, USA) version 27.

Simple linear regression was performed to identify variables that are correlated with MCC. The factors that are analyzed were age, gender, pre-operative Cobb angle, Lenke classification, Risser sign and surgeon experience. From there, a step-wise multiple linear regression was done to identify factors that were independent predictors of MCC by means of correlation coefficients. Statistical significance was defined with p value of <0.05 with 95% confidence interval. Pearson correlation was done to identify correlation between Lenke curves and Risser signs against MCC. Analysis of variance (ANOVA) with Tukey's post hoc test was ran to look for significant differences between these two categorical variables. For quantitative variables, independent and paired t test was performed. p value was taken as <0.05 for statistical significance.

Expected result(s)

Dummy table for data recording of patient demographics and curve correction magnitude and associated variables

No	Name	Age	Diagnosis	Curve type	Curve Location	Surgeon Experience	Pre- Cobb	Post-Cobb
1	Xx							
2	xy							
3	zz							
4	zy							
5	yx							

Dummy Table for statistical analysis of factors and relationship with magnitude of curve correction

Characteristics	Crude b (95% CI)	p value
Age		
Gender		
Male		
Female		
Curve type		
Lenke 1		
Lenke 2		
Lenke 3		
Surgeon Experience		
Less than 25 cases		
More than 25 cases		
Risser sign		
Risser 1		
Risser 2		
Risser 3		

Gantt chart & milestone

No.	Activity	2020		2021							
		Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug
Phase 1: Preparation											
1.	Proposal presentation to department										
2.	Proposal presentation to Ethics Committee										
Phase 2: Fieldwork											
1.	Data collection										
2.	Data entry										
Phase 3: Data Analysis											
1.	Data analysis										
2.	Write up										
3.	Presentation										
4.	Final report submission										

Budget proposal [If applicable]:

Not applicable

Ethical consideration(s) [if applicable]:

1. Subject vulnerability

No interaction with patient. Only retrospective data of patient will be used and in confidence among researchers

2. Declaration of absence of conflict of interest

No conflict of interest or monetary gain from this study

3. Privacy and confidentiality

All forms are anonymous and will be entered into SPSS software. Only research team members can access the data. Data will be presented as grouped data and will not identify the responders individually.

4. Community sensitivities and beliefs

No sensitivity or beliefs will be affected by this study or in the process of it.

Patient/Participant Information Sheet and Consent Form (PIS and CF) Assessment:

Not applicable

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