Adolescent Idiopathic Scoliosis and Adverse Events: A Canadian Perspective

by

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A thesis submitted in conformity with the requirements
for the degree of Doctor of Philosophy

Department of Health Policy, Management and Evaluation
University of Toronto

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ISBN: 978-0-494-97713-2

Our file Notre référence
ISBN: 978-0-494-97713-2

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Abstract

Background: Adolescent idiopathic scoliosis (AIS) surgery is the most common reason for elective pediatric orthopaedic surgery. Minimization of adverse events is an important goal. Institute of Medicine (IOM) outlined 6 facets of healthcare quality improvement within the acronym STEEEP. Two of these facets, Safety and Timeliness for AIS surgery in Canada, are examined in this thesis.

Methods: A three - part study, using clinical records at the largest Canadian pediatric hospital and CIHI national administrative data, determined i) the relationship between surgical wait times and rates of adverse events, along with determination of an empirically derived access target, ii) accuracy of ICD-10 coding of surgical AIS cases along with an optimal search strategy to identify surgical AIS cases, and iii) the volume – outcome relationships for scoliosis surgery using hierarchical and conventional single level multi-variate regression analysis.

Results: Access target of 3 months minimized the adverse events related to waiting. Optimal search strategy for AIS surgical cases using ICD-10 coding required combination of codes as each code in isolation was inaccurate due to limitations in coding definitions. There was no significant volume – outcome relationship using appropriate modeling strategies.

Conclusions: Ensuring timeliness of surgical treatment of less than 3 months is important in surgical cases of AIS given the potential for curve progression in higher risk individuals who are skeletally immature with large magnitude curves at time of surgical consent. At the administrative database level, knowledge of coding accuracy and optimal search strategies are needed to capture a complete cohort for analysis. In AIS, several ICD-10 codes need to be combined. AIS surgery cases captured through this optimal search strategy, revealed no significant volume-outcome relationships with appropriate modeling. Based on these results, minimum volume thresholds and regionalization of care for AIS surgery does not appear to be justified. However, a larger sample size was needed to determine whether there was a clinically significant difference in wound infection and blood transfusion rates. Furthermore, clinical variables, not part of an administrative database such as curve pattern were not included.

Acknowledgments

This thesis would not have been possible without the assistance and support of a number of people.

To my family, Gloria and our two children, Taylor and Cole – for having the patience and understanding so that I could complete this research. I could not have done this endeavor without their unending support.

To my supervisor, Dr. James Wright, for his insight, wisdom, mentorship, support and guidance; an exemplary role model.

To my Thesis Committee (Drs. Dorcas Beaton, Nizar Mahomed and Hans Kreder) for their input and guidance and taking their time to be a part of the committee amidst their busy schedules;

To my numerous Chiefs: Dr Ori Rotstein, Dr Richard Reznick, Dr Ben Alman and Dr Emil Schemitsch, who provided me with the invaluable opportunity to pursue this goal;

To the Surgeons in the Division of Orthopaedic Surgery at St Michael's Hospital, for their commitment to my academic endeavors;

To the Child Health Evaluative Sciences (CHES) Program at the Hospital for Sick Children for providing an environment that fosters academic success;

To my reviewers, who have taken the time off from their busy clinical and research work, to assess and review this work; thank you for being part of this defense.

To members of the Clinical Epidemiology program, Department of Health Policy, Management and Evaluation, (Dr. Ahmed Bayoumi, Amber Gertzbein, Jennifer James and Zarine Ahmed), for their administrative support and guidance on thesis related issues;

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List of Abbreviations

AIS Adolescent idiopathic scoliosis

CIHI Canadian Institute for Health Information

CIHI-DAD Canadian Institute for Health Information Discharge Abstract Database

ICD International Classification of Diseases

IOM Institute of Medicine

LR Likelihood ratio

MAWT Maximal Acceptable Wait Time

NPV Negative predictive value

NS No statistical significance

OR Odds ratio

PPV Positive predictive value

ROC Receiver operator curve

SN Sensitivity

SP Specificity

STEEEP Safety, Timeliness, Efficient, Equitable, Effective, and Patient Centered

Chapter 1

1 Introduction

1.1 Adverse Events and Adolescent Idiopathic Scoliosis

The Institute of Medicine (IOM) in the United States identified healthcare quality improvement (QI) as a critical goal for the 21st century through its 2001 report on "Crossing the Chasm" (1). The IOM identified six components of quality care reflected in their acronym 'STEEEP' – Safety, Timely, Efficient, Equitable, Effective and Patient Centered. The IOM felt that all six areas were important but this thesis focuses on adverse events and reduced waits and harmful delays for patients(1). Adverse events in the treatment of medical and surgical disorders are a significant health care issue (2-9). Adverse events are associated with increased costs (10;11); increased morbidity and mortality (3-6;8;9;12-14); and increased stress among family members and patients (2;15). Strategies to reduce adverse events have the potential to substantially improve surgical care and represent an important aspect of healthcare quality improvement (QI).

Most studies of adverse events have focused on adult patients. Although children represent over one-fourth of the Canadian population(16) few studies have examined adverse events in children(17). While adults compared to children are more likely to have adverse events based on a retrospective random sampling of all in-patient admissions in Colorado and Utah state hospitals during the year 1992 (11;17;17), the rates and types are likely different amongst pediatric of different ages. Thus programs focused on adverse event reduction, need to be tailored, based on evidence, to the specific needs of the target population.

Adolescent idiopathic scoliosis is the commonest reason for elective pediatric surgery with over 80% of scoliosis operations for AIS(18). The Scoliosis Research Society defines AIS as a lateral

curvature of the spine greater than or equal to 10º with rotation, of unknown etiology occurring in patients aged 10-18 years old. Progressive deformity of sufficient magnitude warrants surgical correction with instrumentation through a posterior, anterior or combined approach. Each of these approaches exposes patients to potential risks.

Rates for adverse events with AIS surgery including both local and systemic adverse events such as spinal cord injury and pulmonary embolism vary depending upon the reported series (19-22). These reported rates are based on American studies where the adverse event rates may differ between private and publicly funded Medicare hospitals, even within the same geographic region (23). Canada is an ideal site to determine adverse events because of publicly funded universal health coverage with no readily available access to private care. Waits for surgery are a frequent byproduct of publicly funded care. Access to care and reduction of adverse events, having prompted many health policy concerns, are the focus of this thesis. The remainder of this introductory chapter includes a review of problems associated with prolonged pediatric surgical wait times, an overview of potential methods of setting access targets, and discussion about the role for regionalization of surgical care to reduce adverse events. An overview of the thesis with description of the problems and specific study objectives of the three thesis papers then completes the introductory chapter.

1.2 Is There An Impact of Prolonged Surgical Wait Times on Adverse Events?

Prolonged waits for treatment are commonplace in universal health care systems such as Canada with imbalances between the influx of new surgical patients and the rates at which they are

treated (Figure 1.1-1.3) (24-28). Similar to adults, children must also wait for treatment(16;29). As a response to prolonged wait times, the Canadian Pediatric Wait Times Initiative has provided access targets for a number of different surgical procedures with the aim of improving quality of care(29).

Prolonged waiting lists can have many detrimental effects on quality of care for pediatric patients and their families including prolonged suffering and anxiety(30-32), increased utilization of health resources, irreversible developmental changes if certain conditions are not treated in a timely fashion (33) or progression of disease (28;34;35). An example where prolonged waits can lead to disease progression specific to children and not adults, are inguinal hernias particularly in children less than 1 year old. Incarcerated inguinal hernias, an adverse event as a result of disease progression, occurs at a rate of 5.2% in patients with a wait time of up to 14 days, as compared with 10.1% in patients with a wait time of up to 35 days (median wait time to surgery) ($p < 0.001$)(35). In contrast, adult hernias do not typically progress to incarceration.

The impact of waiting times on AIS is unknown. No study has examined the impact of prolonged surgical waiting on adverse events for AIS. However, AIS can be a progressive spinal deformity in growing adolescents despite bracing (36-39). As patients wait for surgery, curves can worsen in severity. The specific surgical intervention depends on curve magnitude and flexibility. Although surgical approaches vary from one center to another, larger stiffer curves are more difficult to correct compared to smaller flexible curves. Smaller magnitude curves are often treated with a posterior approach, with instrumentation and curve correction. In contrast, larger curves will likely require more extensive surgery which can include an anterior surgical release, followed by a posterior approach with instrumentation and fusion. More extensive surgery, probably increases surgical morbidity and potential for adverse events. Hypothetically,

while waiting, curve magnitude may progress sufficiently enough to require more extensive surgery compared to when consent was obtained for surgery. However, no study has assessed the impact of wait times, a common problem in the Canadian healthcare system, on the potential for adverse events in AIS surgery.

1.3 Methods of Determining an Access Target

The methodological process of setting a surgical access target has been poorly studied with few research papers outlining empirically or evidence based strategies. The most common empirically based method is setting the access target to minimize adverse events and then refining that target by reviewing the impact of that wait time on adverse events (40-45). Other studies examining patient's perspectives (46-48), has shown that patients are intolerant of waiting, due to considerable anxiety and stress (32;46-48). In an international study assessing patient perspectives on wait times for cataract surgery, patients identified that a wait over 6 months was "excessive" and that a 3 month wait list or less was "ideal", with a correlation between visual acuity loss and shorter ideal wait times(49). To date, patient perspectives have not been incorporated into setting an access target(49;50). Access targets have been predominantly determined by consensus of expert opinion or set by government bodies such the New Zealand target of 6 months for all surgical disorders (49-54). In certain countries, such as the United Kingdom, failures to meet access targets have specific enforcement strategies including tighter access targets (55). Unfortunately access targets have been defined differently from one country to another (56;57) including a maximal acceptable wait time, 90th percentile wait time, and median wait time. The fundamental issue is that outside of life threatening

disorders such as cancer surgery and for cardiovascular surgery (43), the actual process of setting access targets has been poorly researched.

1.4 The Evidence for Regionalization of Healthcare

Prior research suggests that high - volume hospitals obtain better clinical results with less adverse events compared to low-volume centers for certain surgical procedures(7-9;13;58-66). Inverse volume – outcome relationships have been the strongest for surgical procedures that are particularly high risk and performed relatively infrequently such as esophagectomy, hepatic resection and pancreatic resection where low end hospitals may perform only a few cases each year (9;63;64;67). In contrast to these higher risk procedures, the reported volume – outcome relationships for some general surgery and orthopaedic procedures has been inconsistent and not as substantial (68-70). In addition most of these studies have been predominantly focused on adult surgical care and in US hospitals with a mixture of private and publicly funded Medicare/Medicaid/VA patients. Little research has examined volume – outcome relationships for pediatric surgery, especially in a universal health care system such as Canada(22;71-75). In a recent systematic review, only 8 studies on volume – outcome relationships were identified in Canada and the United Kingdom compared to 124 studies in the United States(68). Furthermore, no study has assessed volume – outcome relationships for AIS correction in any universal health care systems including Canada.

The explanation for the improved outcomes for high – volume compared to low – volume centers is not well understood (68;76). While volume, in of itself cannot directly lead to increased or decreased rates of adverse events, volume may be a proxy for improved hospital proficiency and improved processes of hospital care.

Specific processes of care may be more likely to be used at high volume centers, which in turn may improve outcome include 1) increased usage of effective therapies such as use of aspirin and beta blockers following myocardial infarction(77) and use of adjuvant radiation therapy following rectal cancer resection(78), and 2) improved clinical judgment and technical proficiencies for the operation as a result of "practice makes perfect"(76). However in attempting to explain these findings, differences in pre-surgical processes of care such as more extensive forms of pre-operative testing and oncology assessments at high volume centers has not been shown to explain the volume related mortality differences(76). Post-surgically, there is evidence that high volume adult hospitals have better processes to "rescue patients" from adverse events through improved identification of complications, along with more intensive care unit facilities more proficient at managing ill patients compared to low volume centers(69). This ability to "rescue" patients, rather than potential differences in complication rates, may be a potential benefit of regionalization, especially for operations where there may be no difference or only a mild to moderate benefit in terms of adverse event rate differences.

The potential benefits of regionalized care to "rescue patients" found in the adult literature, may also extend to pediatric surgical procedures(75). Utilization of a pediatric ICU may help reduce the impact of complications following AIS surgery. Volume – outcome studies in pediatric intensive care units have affirmed lower severity - adjusted mortality rates and lengths of stay in higher volume pediatric ICUs compared to lower volume ICUs (79;80). Adult intensive care units, which may look after pediatric patients in low volume centers, are poorly equipped to look after pediatric patients (81;82).

These volume – outcome studies have lead to calls for regionalization of care. A potential draw – back of regionalization is the patient and family travel(73). When services are regionalized,

families may no longer be able to receive care at a local hospital and need to travel several hours or longer to obtain appropriate care due to "down-scaling" of local hospital services. In addition to the inconvenience, the distance may serve as a barrier to care. While research would suggest some families willing to accept increasing travel distances to reach a regional center in the hope of improvement in outcome(75), whether this is feasible in Canada is a geographically large nation where most hospitals are concentrated in few urban centers is uncertain.

1.5 Overview of the Thesis

The overall purpose of this thesis was to examine adverse events related to AIS surgery in Canada. This thesis directly addressed this question by 1) examining the impact of current waiting times, a common feature in Canada, on adverse events for AIS surgery by determining an optimal access target for AIS surgery, 2) determining rates of adverse events on a national basis, and 3) assessing for the presence of volume – outcome relationships for AIS surgery. The thesis is structured in the following chapters (with a brief synopsis of the problem and the specific chapter objectives).

Chapter 2.

PAPER 1. Evidence-Based Maximal Acceptable Wait Time: Adolescent Idiopathic Scoliosis Wait Times Cohort

Description of the Problem

Prolonged waits for treatment are commonplace in universal health care systems such as Canada (24-28). Similar to adults, children must also wait for treatment(16;29). Patient prioritization

using evidence-based maximal acceptable wait times (MAWT) is needed to ensure high quality care. While waiting for surgery, adolescent scoliosis can worsen, increasing risk of adverse events. The National Canadian Pediatric Wait Times Initiative has set a consensus based access target of 6 months.

Objective

To determine an evidence-based access target for scoliosis surgery used to reduce risk of adverse events and then to compare results to consensus based access targets.

Chapter 3.

PAPER 2. *ICD-10 Coding Accuracy for Adolescent Idiopathic Scoliosis*

And Determination of An Optimal Search Strategy For Large Administrative Databases

Description of the Problem

Adolescent idiopathic scoliosis (AIS) is the most common procedure performed in pediatric orthopaedics. Administrative databases such as the Canadian Institute of Health Information Discharge Abstract Database are frequently used in health services research to assess regional variations in care and to assess morbidity and mortality of treatments(9;83-85). Accuracy of administrative data is vital to ensure appropriate decisions. This accuracy is unknown for AIS.

Objective

1) To assess coding accuracy for surgically treated adolescent idiopathic scoliosis and 2) to determine an optimal method of ascertaining cases with a diagnosis of AIS from an administrative database using ICD-10 coding.

Chapter 4.

PAPER 3. *The Impact of Surgical Volume on Adverse Events For the Treatment of Adolescent Idiopathic Scoliosis. A National Canadian Perspective*

Description of the Problem

Strategies to reduce adverse events have the potential to substantially improve surgical care. Several studies have demonstrated a relationship between volume and outcome of surgical procedures, predominantly for adult surgical procedures. However, there are no Canadian studies assessing this for AIS surgery.

Objective

To determine: 1) what type and rate of adverse events occur with surgical treatment of AIS, and 2) if there were lower rates of adverse events in centers performing higher volumes of AIS correction surgery.

Chapter 5. Discussion and Conclusion

Overall conclusions from the three papers, the implications for the research findings, and directions for future research are described in this chapter.

Chapter 6. Appendix

Search strategy utilized for systematic review of the literature on methods of setting access targets and search strategy results.

Figure 1.1 Conceptual "bathtub" figure of wait time

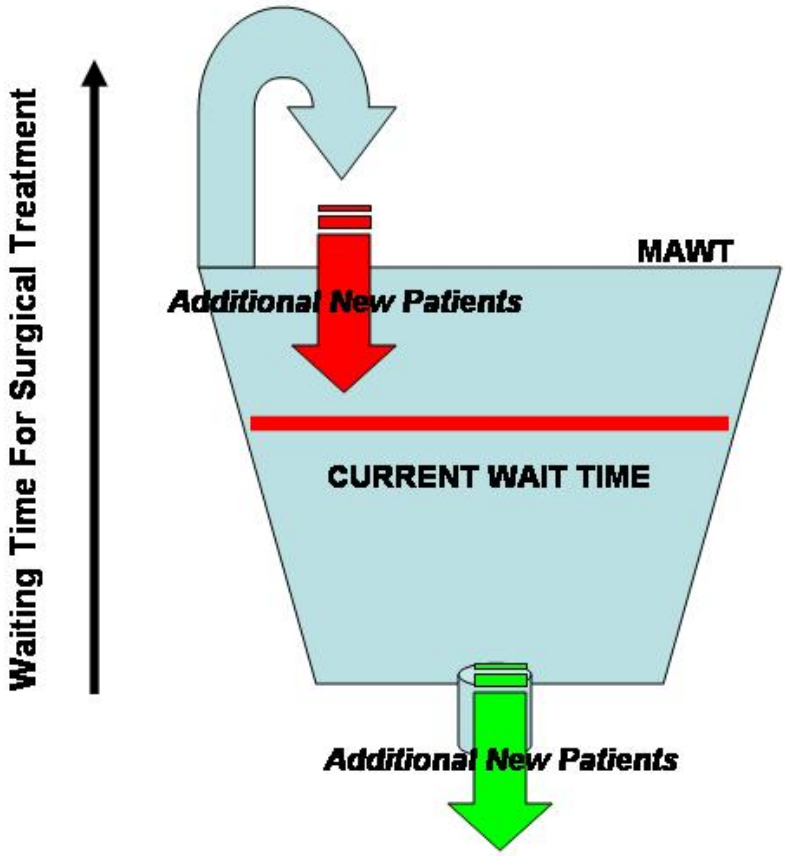

Figure 1.1 Conceptual "bathtub figure" for surgical wait time. This is dependant on the incidence rate of new surgical patients (the inflow into the tub) and the rate of treatment for patients (the drainage from the tub). Wait times will be stable when the two rates are similar. The top of the tub represents the MAWT.

Figure 1.2 Conceptual figure of wait time with fewer resources

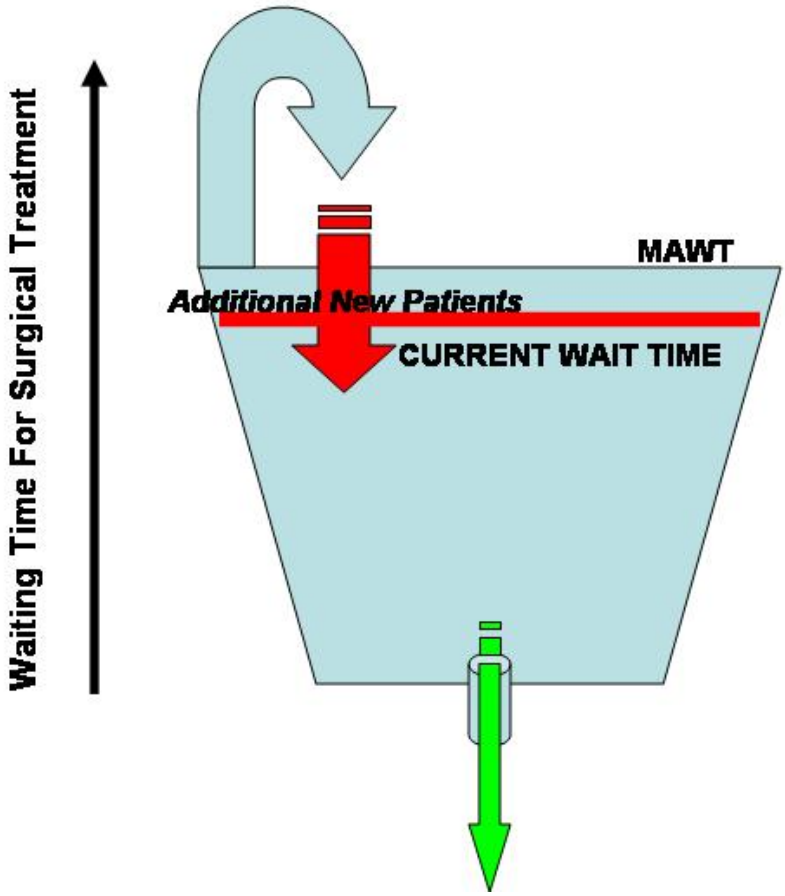

Figure 1.2 Figure showing the impact of reduced treatment rates for patients relative to a stable incidence rate of new surgical patients, leading to increased wait times. This imbalance in rates can lead to exceeding the MAWT (overflow from the tub).

Figure 1.3 Conceptual figure of wait time with greater resources

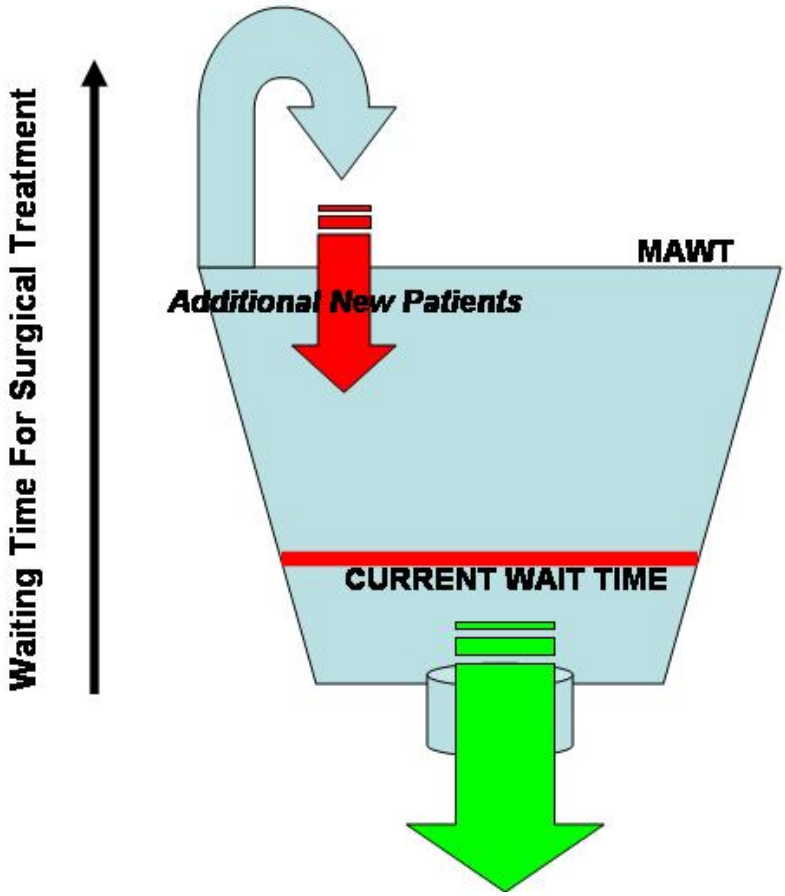

Figure 1.3 When treatment rates increases relative to a stable incidence rate of new surgical patients, wait times go down.

Chapter 2

2 Empirically Derived Maximal Acceptable Wait Time for Surgery to Treat Adolescent Idiopathic Scoliosis

Empirically Derived Maximal Acceptable Wait Time for Surgery to Treat Adolescent Idiopathic Scoliosis

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2.1 Abstract

Background

Patient prioritization using empirically derived access targets are needed to ensure high quality care. While waiting, adolescent scoliosis can worsen, increasing the risk of adverse events. Our objective was to determine an empirically derived access target for scoliosis surgery and compare this with consensus based targets

Methods

216 sequential patients receiving surgery for adolescent idiopathic scoliosis were included. Main outcome was need for additional surgery. Surgical wait time was related to need for additional surgery and a priori defined adverse events. Chi – square analysis and logistical regression modeling was performed.

Results

14.9% (13/87) who waited over 6 months needed additional surgery due to curve progression versus 1.6% who waited under 6 months (p=0.0001). Patients who waited over 6 months had increased curve progression, duration of surgery and hospital stay with less surgical correction(p=0.005). However, all cases requiring additional surgery occurred after 3 months. Receiver operator curve also suggested three month duration as an access target. Adjusted odds ratio for an adverse event for each additional 90 days of waiting from time of consent was 1.81, 95% Confidence Interval [1.34, 2.44], increasing with skeletal immaturity and larger magnitude curves at time of consent.

Interpretation

Prolonged surgical wait increased risk of additional surgical procedures and other adverse events. An empirically derived access target of 3 months for adolescent idiopathic scoliosis surgery could potentially eliminate the need for additional surgery by reducing curve progression. This is a shorter access target than the 6 months determined by expert consensus.

2.2 Background

Adolescent idiopathic scoliosis effects just over 2% of females aged 12-14 years of age(86-88). Although only 10% require surgery, spinal instrumentation and fusion for adolescent idiopathic scoliosis is the commonest procedure performed in paediatric orthopaedics(89). Patients waiting too long for scoliosis surgery potentially may require additional surgery such as anterior release to achieve satisfactory curve correction and maybe at increased risk of complications (36;90-98) such as increased blood loss, operative time, neurologic deficits, or inadequate curve correction. Furthermore, as seen in other wait list studies, patients and families undergo anxiety and prolonged suffering while waiting, negatively impacting quality of care(30;31;99-101). Programs such as the Canadian Pediatric Surgical Wait Times Initiative have determined a Maximal Acceptable Wait Time for adolescent scoliosis through expert consensus similar to other surgical wait time targets (29). Surprisingly, there has been little or no attention to developing evidence-based access targets or maximally acceptable waits for virtually all treatments(102). The purpose of this study was to determine the Maximal Acceptable Wait Time for surgical correction of adolescent idiopathic scoliosis using an empirically – based approach to minimize the possibility of adverse events related to curve progression.

2.3 Methods

Population

The study utilized a sequential retrospective cohort of all two hundred sixteen (176 females, 40 males) patients with adolescent idiopathic scoliosis receiving surgery at the Hospital for Sick Children in Toronto, Canada (November, 1997 to August, 2005). Patients were identified from

CIHI – DAD (Canadian Institute for Health Information Discharge Abstract Database) and hospital surgical procedure registry. The following patients were included: 1) diagnosis of adolescent idiopathic scoliosis and 2) 11 to 17 years of age. Patients with the following diagnoses were excluded: neuromuscular, congenital, syndromic, juvenile or infantile idiopathic scoliosis. Ethics approval was obtained from the Research Ethics Board prior to initiation of this study.

Patients received segmental spinal fixation posteriorly with hooks, and/or pedicle screws, or anteriorly using screws and rod construct (Universal Spine System, Synthes, USA) (Moss Miami, Depuy Spine, USA). Surgery was performed by four spinal surgeons using a standardized surgical technique. All patients had curve magnitudes measured by the Cobb angle of at least forty degrees. The Cobb angle measures the angle in degrees between the top and bottom vertebrae of a spinal curvature on the antero-posterior spine x-ray. During the study period, curves with a Cobb angle of 40-70 received either a posterior or anterior approach based on the curve pattern; curves with a Cobb angle of 70-90 degrees received an anterior release followed by a posterior approach staged 1-2 weeks apart; curves over 90 degrees, were similarly staged, but halo-femoral traction with weights was applied during the two week interval.
The surgical wait period, defined by the Ontario Ministry of Health as the interval between the day that both surgeon and patient agreed to surgical treatment and the day of surgery(103), was determined from the clinic and operative records. When the surgery was staged, the wait time was calculated relative to the first operation.

All patients had 3-foot standing AP/lateral radiographs routinely just prior to the decision to proceed with surgery. Another set of x-rays were obtained immediately just prior to surgery.

After surgery, a 3 - foot standing AP/lateral radiograph was obtained to assess curve correction. X-ray measurements were performed independent of chart abstraction.

The primary study outcome was the need for additional surgery. Need for additional surgery was based on comparison between what was planned at the time of the mutual decision to proceed with surgery and the actual surgery received. Secondary study outcomes were other adverse events defined *a priori* as follows: 1) more then 10 degrees of curve progression(37) (defined as the difference in the Cobb angles between the x-ray taken at the time of surgical booking and the x-ray just prior to surgery), 2) less than 50% curve correction (defined as the percent improvement in the Cobb angle from the post-operative x-ray and the x-ray just prior to surgery), 3) need for blood transfusion, 4) prolonged surgical time (defined as the highest 10^{th} percentile in duration between the start and stop of surgery, excluding aenesthesia time), and 5) peri-operative neurologic injury.

Statistical Analysis

SAS (SAS Institute Inc., Cary, N.C., U.S.A.) was used for statistical analyses. For the primary analysis of need for "additional surgery", a Chi – square analysis was performed with using a two tailed test with a p – level of 0.05. For the purpose of statistical analyses, we chose six months, based on expert consensus, as the hypothesized Maximal Acceptable Wait Time (29). This hypothetical Maximal Acceptable Wait Time was determined by a group of experts outside of this study as part of a Canadian Pediatric Wait Times Project(29) (manuscript in press Canadian Journal of Surgery). Sample size calculation showed that 75 patients were needed in each group, using an alpha of 0.05, beta of 0.80 to detect a 10 percent difference in rate of additional surgery between the two groups.

A logistical regression model was used to evaluate the relationship between surgical wait times (independent continuous variable) and "any adverse events" as defined above (outcome) controlling for the following potential confounders. 1) curve magnitude at time of consent, 2) Risser scale (a radiographic marker of skeletal maturity based upon the degree of lateral excursion of the iliac apophysis scored from 0 to 5, with 5 representing full maturity), and 3) age (38;93-97;104). The Hosmer-Lemeshow Goodness of Fit Test confirmed a good model fit by failing to reject the null hypothesis with an alpha of 0.05 threshold ($p=0.10$). The odds of an adverse event occurring was converted into a probability using the following equation: Probability = odds ratio / [1 + odds ratio].

2.4 Results

Description of Overall Cohort

From November 1997 to August 2005, 216 sequential patients (176 females, 40 males) received surgery for adolescent idiopathic scoliosis. Patients who waited 1) more or 2) less than six months had comparable baseline characteristics (see Table 2.1). Furthermore, regression revealed no relationship between waiting time and baseline characteristics including age, Risser scale, curve magnitude and gender.

Primary Outcome

In 15 cases, additional surgery was required; 13.3% (2/15) occurred in patients waiting less than 6 months, whereas the remaining 86.7% (13/15) of cases occurred in patients waiting more then 6 months ($p<0.0001$). 2.27% (2/88) of patients waiting less than 6 months required additional surgery compared to 10.2% (13/128) in patients waiting more than 6 months ($p=0.025$). The 2

cases receiving surgery within 6 months, both with curves less than 70 degrees at the time of surgical booking, received their surgery at 97 and 180 days. The 13 cases in the 6 month or greater surgical wait time group had a surgical wait time between 204 and 544 days.

In 86.7% of cases (13/15), a posterior - only approach was *initially* chosen. Due to curve progression, both an anterior and posterior approach was received because the curve progressed to greater than 70 degrees. In 13.3% (2/15) of cases, curves were between 70 and 90 degrees at the time of decision to proceed, but received traction after the initial anterior release because the curve had progressed to more than 90 degrees.

Secondary Outcomes

The odds of any adverse event for those waiting more than 6 months (calculated as 182 days) was 3.32, 95% CI [1.80, 6.2] (Table 2.3). Significant confounders were curve magnitude ($p=0.007$) and the Risser score ($p=0.007$) at time of booking (Table 2.3). Increased curve magnitude at time of booking and lower Risser score increased the odds of an adverse event occurring (OR 1.04, 95% CI [1.011, 1.072]) and (OR 0.76, 95% CI [0.64, 0.91]), respectively (Table 2.3). The probability of an adverse event increased with prolonged waits in those patients with larger curve magnitudes, and decreasing skeletal maturity (decreasing Risser values). For long duration waits, however, the probabilities approached similar values. The effect of a large curve at time of consent such as 100 degrees raised the risk level significantly even for short waits whereas the effect of skeletal immaturity at time of consent was more moderate.

A receiver – operator curve was also used to graphically assess the impact of various access targets as cut offs, increased incrementally from 1 to 365 days, on the potential prevention of

adverse events in patients that truly did have an adverse event (True Positives) versus prevention of adverse events in patients that did not have an adverse event (False Positives) (Figure 2.1). On the ROC plot, two operating points are marked; the left hand point, based upon visual appearance, was closest to being a potential inflection point, representing a 4 month access target (TP = 76%, FP = 46%) whereas the right hand point represented a 3 month access target (TP=84%, FP=64%) with an increased true positive rate and false positive rate compared to the 4 month access target cutoff. The three month access target was the shortest duration of waiting (97 days) that led to additional surgery due to curve progression. The adjusted odds ratio at this three month mark of any adverse event occurring and per additional 90 days of waiting is 1.81, 95% Confidence Interval [1.34, 2.44].

2.5 Interpretation

Main Findings

Determination of empirically derived maximally acceptable wait times provides important information for clinicians and health funders. In this study we have shown that prolonged waits increased the risks for patients receiving surgery for adolescent idiopathic scoliosis. Patients who waited over 6 months were more likely to receive additional surgery with increased odds of an adverse event. These differences reflect worsening curve magnitudes and increasing curve stiffness with prolonged wait times. In terms of secondary outcomes, there were a significantly higher percentage of patients with greater than ten degrees of curve progression and higher percentage of patients with prolonged surgery and less curve correction.

Comparison with Other Studies

Empirically derived Maximal Acceptable Wait Times have been determined for few surgical procedures. The Canadian Pediatric Surgical Wait Times project has developed consensus based access targets for more than 800 diagnoses in 11 surgical disciplines. For example, the consensus access target for infants with hernia was 21 days for infants under 1 year(29). A subsequent empirically-based target found that a waiting time longer than 14 days in young children, was associated with a significant increase in the rate of incarceration(105). In this study for the purposes of statistical analyses, we used 6 months based on expert consensus from the Canadian Pediatric Surgical Wait Times Project as the access target. Analysis of data revealed that 3 months (97 days) was the shortest duration of time associated with sufficient curve progression that resulted in additional surgery. Thus, a 3 month Maximal Acceptable Wait Time would have eliminated the need for additional surgery. An alternative approach as used in this study was to use the Receiver Operating Curve associated with adverse events. This approach suggested 3 or 4 months as potential access targets. However, there is no potential gain and no cost savings of prolonging wait times to reduce false positives such as using the 4 month working target compared to the 3 month target (Figure 2.1). Alternatively, arguments could be made that having no wait is optimal. However, there are trade offs to extremely short times including patients need time to bank blood and decide and ponder their decision regarding surgery. Furthermore, increased operating room resources would be probably necessary to provide the capacity to meet shorter access targets, leading to potential idle operating room time. In summary, an access target of 3 months has the potential to eliminate additional surgery, reduce the risk of adverse events and provide sufficient time for surgical preparation. This is a second example of where the empirically derived Maximally Acceptable Wait Time is less than the consensus target(35).

Limitations

This study has several potential limitations. First, this study was carried out retrospectively. Biases in chart and radiographic abstraction can occur. A prospective study would more likely minimize bias. However, prospective studies would pose practical and ethical issues because patients who become educated about the hypothetical risk of wait times could reasonably demand earlier surgery. In this study, biases in chart abstraction and radiographic abstraction were minimized by abstracting patient chart details separately and obtaining radiographic data blind to the duration of surgical wait. Furthermore, alternative analysis techniques may have been beneficial in reducing bias. Propensity score analysis reduces the bias of measured covariates in observational studies through the use of a propensity score. The propensity score of each subject has a range of 0 to 1 and is the probability of treatment given observed covariates. The propensity score is used to reduce imbalance in the measured covariates between two groups through propensity score matching of individuals, quintile stratification, weighting of subjects or usage as a covariate in regression analysis. A second potential weakness was that the study was performed at a single institution. However, the Hospital for Sick Children is the largest children's hospital in Canada and the only pediatric hospital in Toronto. All sequential cases over a seven year period received similar care and were treated with similar surgical techniques using segmental instrumentation were utilized. Because each patient who was seen and consented for surgery was operated on by the same surgeon, this eliminated surgeon bias as a potential reason for a patient to require additional surgery. A third potential limitation was that the need for additional surgery may be reduced by newer alternative techniques of scoliosis correction using only pedicle screws. However, wait greater than 6 months resulted in increased risk of other adverse events including curve progression and irrespective of the type of instrumentation, may still adversely affect the outcome of surgery as larger curves are more

difficult to correct. A fourth limitation is that the reasons for waiting were not entirely clear in many cases. Generally, the wait lists were full with new patients added to the end of the list and when a spot became available, patients had surgery. However, there are other potential reasons for prolonged waits involving surgeon factors such as time away from hospital, patient factors such as attempting to time surgery with school holidays, and system factors such as inadequate resources such as lack of beds leading to delays.

Treating Patients within the MAWT

Given the frequent resource limitations in a public health care system, obtaining timely access for *everyone* within the MAWT may not be realistic. Delays in treatment can be associated with increased costs related to adverse events associated with exceeding the MAWT such as additional surgery that was not initially planned for at the time of surgical consent. At a practical level, implementation of a system that prioritizes surgical patients based upon disease severity may reduce overall costs by reducing adverse events related to disease progression, by ensuring that patients most likely to progress are treated first. Wait time prioritization strategies exist for other disorders such as for cardiac surgery (106-108) that ensure that patients with the worst disease severity are treated first, given that these patients have the highest mortality rates while on a waiting list. It would be difficult to ensure that all cardiac patients are treated within a certain MAWT given the volume of patients relative to the available healthcare resources. In adolescent idiopathic scoliosis, prioritization would require assessing skeletal maturity and assessing the maximal curve magnitude. Patients with a low Risser score and higher curve magnitudes should have their surgery earlier.

Although not directly addressed by this study, waiting to see the spinal specialist after referral from the family physician also involves a wait that may add further delay to surgical treatment for patients. For these patients who may already need surgery, adding an additional

wait time to see the surgeon may negate any benefit of surgical prioritization to minimize surgical wait time. Therefore, referrals should be prioritized and accompanied by measurement of the Cobb angles to help identify patients who are already surgical candidates.

2.6 Conclusion

In conclusion, prolonged wait times increases the probability of adverse events for the surgical treatment of adolescent idiopathic scoliosis. A Maximal Acceptable Wait Time based on minimization of risk of additional surgery due to curve progression was 3 months, which is considerably less than the time frame originally determined by consensus opinion. The highest risks of adverse events due to prolonged waits occurred in patients who were skeletally immature and had larger curves. Patients with these risks should be prioritized and monitored for curve progression while waiting for surgery. Being able to meet a 3 month access targets, on a national level, has resource implications(102) and requires the provision of sufficient operating room time and personnel, intensive care unit beds, and funding for spinal hardware. Waiting to see the spinal specialist after referral from the family physician also involves a wait that may add further delay. Therefore, referrals should be prioritized and accompanied by Cobb angle measurements to help identify patients who are already surgical candidates. A Maximal Acceptable Wait Time that leads to a reduction in curve progression also has the potential to reduce healthcare resources by decreasing the need for further surgery.

Table 2.1 Baseline characteristics

Baseline characteristics and surgical data for the overall study population and the two surgical wait time groups.

	Overall Group	<6 month Surgical Wait Time	>=6 month Surgical Wait Time	Statistical Significance
N	216	128	88	
Gender	176 Females (81%) 40 Males (19%)	104 Females (81%) 24 Males (19%)	72 Females (82%) 16 Males (18%)	p=0.92
Median Age at First Consultation (years)	13.2 years IQR [12.2,14.5]	13.5 years IQR [12.4,14.6]	13.1 years IQR [11.8,14.4]	p=0.98
Median Age of Menarche (years)	12 years IQR[12,13]	12 years IQR [12,13]	12 years IQR [12,13]	p=0.66
Median Wait Time For Consultation (W1 Time days)	75 days IQR [47,111]	81 days IQR [47, 109]	66 days IQR [47, 114]	p=0.19
Median Maximal Cobb Angle at First Consultation (degrees)	55 degrees IQR [46,62]	54 degrees IQR [46, 62]	55 degrees IQR [47, 72]	p=0.13
Median Wait Time For Surgery (W2 Time days)	149 days IQR [92, 228]	103 days IQR [69,142]	247 days IQR [217, 308]	
Median Age of Patients at Surgery (years)	14.5 years IQR [13.4, 15.9]	14.3 years IQR [13.3, 15.8]	14.7 years IQR [13.4,16.1]	p=0.98
Median Risser Score at Surgical Booking	2 IQR [0,3]	2 IQR [0,3]	2 IQR [0,3]	p=0.18
Median Maximal Cobb Angle At Surgical Booking (Degrees)	60 degrees IQR [53,65]	58 degrees IQR [52, 65]	60 degrees IQR [54,66]	p=0.79

Table 2.1 continued

Median Maximal Cobb Angle At Time of Surgery (Degrees)	63 degrees IQR[55,70]	60 degrees IQR[53,67]	68 degrees IQR [57,78]	p=0.07
Median Curve Progression From Time of Surgical Booking To Time of Surgery (Degrees)	3 degrees IQR[0,10]	1 degree IQR[0,5]	9 degrees IQR[2,15]	**p<0.001**
Median BMI	20.5 IQR[18,21.6]	19.8 IQR[17.3, 21.8]	20.6 IQR [18.0,21.6]	p=0.72

Table 2.2 Clinical and surgical outcomes

Clinical and surgical outcomes in the overall study population and the two surgical wait time groups utilizing Wilcoxon testing with a 0.05 level of significance. Statistically significant results are bolded.

	Overall Group	<6 month Surgical Wait Time	>=6 month Surgical Wait Time	Statistical Significance
N	216	128	88	
Proportion with any Adverse Events	58.8%(127/216)	48.4% (62/128)	73.9% (65/88)	**p=0.002**
Percent of Patients with Curve Progression>10 degrees while waiting	25% (54/216)	13.3% (17/128)	42%(37/88)	**p=0.001**
Median Number of Levels Fused	11 levels IQR [9,12]	10 levels IQR [9,12]	11 levels IQR [10,13]	**p=0.003**
Surgical Approach	41 anterior+post 15 anterior only 160 posterior only	20 anterior+post 8 anterior only 100 posterior only	21 anterior+post 7 anterior only 60 posterior only	p=0.67
Percent of Cases Needing Thoracoplasty	22.7% (49/216)	22.7% (29/128)	22.7% (20/88)	p=0.99
Median Blood Loss (cc's)	1000 cc's IQR[700,1500]	1001 cc's IQR [700,1500]	1000 cc's IQR[700,1500]	p=0.41
Percent of Patients Needing Blood Transfusion	9.3% (20/216)	10.9% (14/128)	6.8% (6/88)	p=0.30
Median OR Time (minutes)	462 minutes IQR [390, 540]	432 minutes IQR [375,535]	480 minutes IQR [420,570]	**p=0.0011**
Percent of Patients With Prolonged Surgical Time (top 10th percentile)	11% (24/216)	7.8% (10/128)	15.9% (14/88)	p=0.06

Table 2.2 continued

Percent of Cases with Somatosensory Evoked Potentials changes	6.94% (15/216)	4.7% (6/128)	10.2% (9/88)	p=0.11
Median Length of Stay After Surgery (days)	8 days IQR [6,10]	7 days IQR [6,8]	9 days IQR [7,11]	**p=0.0302**
Median Curve Magnitude After Surgery (degrees)	23 IQR [18, 30]	22 degrees IQR [18,28]	27 degrees IQR [19, 33]	**p=0.003**
Percent of Cases With Less than 50% Curve Correction	29.2% (63/216)	22.7% (29/128)	38.6% (34/88)	**p=0.011**

Table 2.3 Unadjusted and adjusted odds ratios for variables

Unadjusted and adjusted odd ratios for variables included in the logistical regression model for the occurrence of any adverse event. Adverse events included one or more of: additional surgery compared to that planned at time of consent, more than 10 degrees of curve progression while waiting, less than 50% curve correction, need for blood transfusion, prolonged surgical time, and peri-operative neurologic injury.

	Unadjusted Odds Ratio	P value	95% Confidence Interval	Adjusted Odds Ratio	P Value	95% Confidence Interval
Wait Time (per additional 90 days)	1.73	0.0001	[1.30, 2.30]	1.81	0.0001	[1.34, 2.44]
Risser Scale	0.84	0.0305	[0.72,0.98]	0.76	0.007	[0.64, 0.91]
Curve Magnitude At Time of Consent	1.04	0.0050	[1.01,1.07]	1.04	0.007	[1.01, 1.07]
Age at Time of Consent	0.96	0.50	[0.86, 1.08]	0.99	0.89	[0.86, 1.14]

Figure 2.1 Receiver Operator Curve

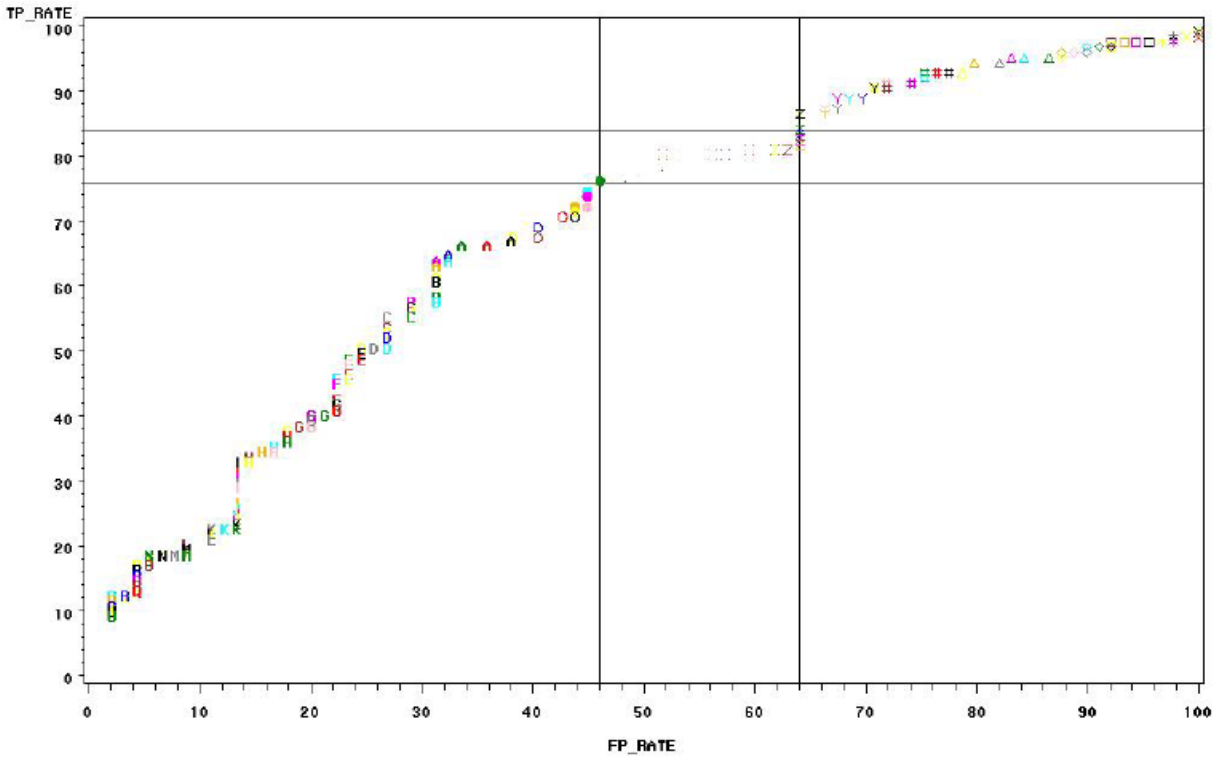

Figure 2.1 Receiver-operator characteristic (ROC) curve for adverse events related to surgical wait times with each symbol representing a different cut off wait time ranging from 1 day to 365 days. The large number of cut off wait times makes a legend impractical for the reader. True positives reflect cases with actual adverse events that may be prevented at a given cutoff. False Positives reflect cases with no adverse events that were thought to have been prevented at a given cutoff. There is no clear inflection point on the ROC curve. Two operating points are marked. The left operating point reflects a cutoff of 4 months (TP = 76%, FP=46%) and the right point is the 3 month cutoff point (TP=84%, FP=64%).

Chapter 3

3 ICD-10 Coding Accuracy for Adolescent Idiopathic Scoliosis And Determination of an Optimal Search Strategy For Large Administrative Databases

ICD-10 Coding Accuracy for Adolescent Idiopathic Scoliosis And Determination of an Optimal Search Strategy For Large Administrative Databases

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3.1 Abstract

Background

Adolescent idiopathic scoliosis (AIS) is the most common procedure performed in pediatric orthopaedics. Administrative databases such as the Canadian Institute of Health Information Discharge Abstract Database (DAD) are frequently used in health services research to assess regional variations in care and to assess morbidity and mortality of treatment. The purpose of this study was to determine the accuracy of diagnostic coding for AIS using ICD-10 codes in an administrative database.

Methods

All 384 spinal surgery cases performed between June 2003- June 2007, at the Hospital for Sick Children were identified through a surgical registry database. Diagnosis obtained via health record review was used as the gold standard. We calculated for sensitivity, specificity, positive likelihood ratio, and positive predictive value of CIHI-DAD coding compared with the health record.

Results

From 2003-2007, of the 384 spine cases, 223 cases were for AIS. Sensitivity of the individual codes, M41.1 and M41.2 were low, 60% and 32.7% respectively. Combining the two codes and only including patients over the age of 10, improved sensitivity to 93.6% with specificity of 70%, positive predictive value of 81% and positive likelihood ratio of 4.29.

Interpretation/Conclusion

Ambiguity in AIS coding definitions of M41.1 and M41.2 cases result in significant miscoding. Combination of M41.1 and M41.2 was the optimal search strategy for AIS cases. Clarification in the definition of M41.1 and M41.2 can potentially improve the reliability of AIS coding.

Key Words: Administrative database, ICD-10, adolescent idiopathic scoliosis, coding accuracy

3.2 Background

Administrative databases have been used to assess regional variations in care, determine morbidity and mortality related to procedures and disease states, and provide data for performance evaluations of hospitals (9;83-85). Accuracy of administrative data is vital to ensure appropriate decisions.

The Canadian Institute of Health Information Discharge Abstract Database (CIHI-DAD) is an example of a national database that captures diagnostic information during hospital admissions using the International Classification of Diseases (ICD-10-CA) for diagnostic coding. Previous CIHI-DAD data quality studies have shown high diagnostic and procedural coding accuracy rates. However, these are generalized studies, involving random sampling of hospital admissions across the country. Given the reasons for hospital admission and treatment are quite diverse; spectrum bias needs to be considered when evaluating coding practises. Spectrum bias can influence the statistical characteristics and properties such as sensitivity and specificity resulting in differing results for the overall group compared to the sub-groups (109-112).

Scoliosis is a common spinal diagnosis in pediatric patients of which the most common type is adolescent idiopathic scoliosis (AIS). Scoliosis surgery is the commonest procedure performed in paediatric orthopaedics(18;86-88). Over 80% of all pediatric scoliosis surgeries are performed for adolescent idiopathic scoliosis.

ICD-10 diagnostic coding accuracy for adolescent idiopathic scoliosis, treated surgically, has not been assessed. In other diseases such as spinal cord injury and rheumatology ICD coding has been shown to be inaccurate especially when there are many sub-types such as in the case of scoliosis (85;113-115). The purpose of this study was 1) to assess coding accuracy for surgically

treated adolescent idiopathic scoliosis and 2) to determine an optimal method of ascertaining cases with a diagnosis of AIS admitted for scoliosis surgery from an administrative database using ICD-10 coding. This study did not address non – surgically managed outpatient AIS cases such as those seen in the office, as these would not be coded within the CIHI-DAD database, a discharge administrative database of patients who were admitted to hospital.

3.3 Methods

Diagnostic codes are one element found in administrative databases. The ICD-10 or International Classification of Diseases was endorsed by the 43rd World Health Assembly in May 1990 and then endorsed by the World Health Organization in 1994 as the international standard to classify diseases and health problems, enabling the storage and then retrieval of diagnostic information for epidemiologic and quality purposes(85;114;116;117). In Canada, a variant of the ICD-10 (ICD-10-CA Canadian Enhancement) has gradually been implemented across the provinces since 2001, with most provinces using ICD-10-CA coding by 2004 except for the province of Quebec which recently implemented its use in 2006/2007.

Creating an administrative database requires in addition to a standardized diagnostic coding system, infrastructure to collect data and a central repository. In Canada, all hospital admissions including acute patient admissions, chronic long term admissions, rehabilitation admissions and day surgical procedures are submitted to the Canadian Institute of Health Information (CIHI) with the Discharge Abstract Database (DAD) using ICD-10-CA coding for the disease states, assigned by trained coders at each hospital, after reviewing the clinical records. This central

repository, which is publicly accessible, facilitates national and regional studies such as comparison of rates of adverse events.

Adolescent idiopathic scoliosis in this study was defined according to the Scoliosis Research Society as a "lateral curvature of the spine greater than or equal to 10 degrees with rotation of unknown etiology", occurring in children between the ages of 10 to 18 years of age. A hospital surgical registry database was used to obtain 384 sequential patients who received spine surgery between the dates of July 1, 2003 to June 30, 2007 at the Hospital for Sick Children, a regional pediatric quaternary care center in the largest urban centre in Canada. The Hospital for Sick Children treats the largest volume of surgical scoliosis cases in Canada. This strategy was chosen to capture a diverse group of spinal etiologies. Patients who had multiple surgical procedures in the same admission were assessed only once with respect to analysis of diagnostic coding. The health record review was used as the gold standard for AIS surgery. The diagnosis was obtained by reviewing the operative dictation, clinic notes before and after surgery, and radiological reports. In all cases, the clinical diagnosis was available and there were no conflicting diagnoses within the medical records.

The diagnosis obtained from the health record (gold standard) was compared to the diagnostic ICD-10-CA coding from the Canadian Institute of Health Information Discharge Abstract Database (CIHI-DAD). Coding is performed by trained individuals in the Hospital Health Record Department after each in-patient admission and each patient's CIHI-DAD is then submitted electronically by the Hospital for Sick Children to CIHI. The CIHI coding manual and charts uses 2 codes for AIS: 'M41.1 Juvenile idiopathic scoliosis (adolescent scoliosis)' and 'M41.2 Idiopathic scoliosis'. The remaining scoliosis codes (including 'M41.0 Infantile scoliosis', 'M41.3 Thoracogenic scoliosis', 'M41.4 Neuromuscular scoliosis', 'M41.5 Other

secondary scoliosis', 'M41.8 Other scoliosis', 'M41.9 Scoliosis unspecified') were incorrect for AIS. In addition, Canadian Classification of Health Interventions (CCI) used for procedural coding in the CIHI-DAD was compared to the surgical dictation as a second separate analysis. This separate analysis reviewed coding for anterior scoliosis correction and fusion 1.75.LL, combined anterior and posterior correction and fusion 1.75.LN, and posterior correction and fusion 1.75.PF. Research ethics board approval was obtained prior to initiation of the study.

Statistical analyses were performed to determine which codes were being utilized for adolescent idiopathic scoliosis and the other spinal etiologies. Sensitivity (SN), specificity (SP), positive likelihood ratio (LR+), and positive predictive value (PPV) was determined for M41.1 and M41.2 (the two codes used for adolescent idiopathic scoliosis). Sensitivity was defined as the proportion of AIS cases treated surgically that were correctly identified. Specificity was defined as the proportion of scoliosis cases that were not AIS that were correctly identified. All of these scoliosis cases, AIS and non-AIS, were obtained from the surgical registry and had surgical correction. The positive predictive value is the proportion of patients with a positive test result for AIS that was correctly diagnosed. The likelihood ratio of a positive result is the ratio of the probability of having AIS coding in the patients who actually have AIS compared to the probability of having AIS coding in patients who do not actually have AIS. The likelihood ratio of a positive test result is equal to SENSITIVITY/(1-SPECIFICITY). The statistical properties of the various codes and combination of codes were then assessed and the optimal method of ascertaining AIS cases from a large database using ICD-10 codes was then determined.

3.4 Results

Of the 384 spine cases, 223 (58%) had adolescent idiopathic scoliosis as confirmed by health record review (gold standard). The remaining 161 cases (42%) were due to other etiologies of scoliosis with the most common being neuromuscular (40%), juvenile idiopathic scoliosis (13.7%), congenital scoliosis (7%), and muscular dystrophy (7%).

The 223 AIS cases were coded as follows (Table 3.1): 1) M41.1 Juvenile scoliosis 59.6% (133/223), 2) M41.2 Other idiopathic 32.7% (73/223), 3) M41.9 Scoliosis Unspecified 7.2% (16/223) and 4) M 41.8 Other forms 0.01% (1/223). The great majority of AIS cases were coded as either M41.1 or M41.2, with the combination representing 92.3% of all AIS cases.

CIHI-DAD coding for the 161 non-AIS cases were also assessed. Non-AIS cases were coded as follows (Table 3.2): 1) M41.1 Juvenile scoliosis 26.1%(42/161), 2) M41.2 Other idiopathic 3.7% (6/161), 3) M41.9 Scoliosis Unspecified 22.9% (37/161), 4) M41.4 Neuromuscular 29.8% (48/161), 5) M41.8 Other forms 5.6% (9/161), 6) Q67.5 Congenital scoliosis 4.9% (8/161), 7) M41.0 Infantile idiopathic scoliosis 3.1% (5/161), 8) M41.5 Other Secondary 3.1% (5/161), and 9) M43 0.62% (1/161). The great majority of non-AIS cases were coded as either M41.4 or M41.1, representing 56% (90/161) of cases.

Sensitivity of M41.1 was 60%, specificity was 74%, positive predictive value was 76% and the positive likelihood ratio was 3.2 (Table 3.3, 3.9). Sensitivity of M41.2 was 32.7%, specificity was 96.2%, positive predictive value was 92.4%, and the positive likelihood ration was 12.2 (Table 3.5, 3.9). By combining both M41.1 and M41.2 to identify AIS cases, the sensitivity was 92.3%, specificity was 70.1%, positive predictive value was 81.1% and the positive likelihood ratio was 4.29 (Table 3.7, 3.9).

A significant proportion of false positives (19/42) were a result of juvenile idiopathic scoliosis patients being coded as M41.1. Juvenile idiopathic scoliosis occurs in children aged 4 to 10, whereas adolescent idiopathic scoliosis occurs in children aged 10 to 18. Utilizing age restriction, statistical analysis was repeated, with elimination of patients aged 10 and under – i.e. including patients only 11 to 18 years of age. For code M41.1, there was improvement in specificity to 78% (from 74%), positive predictive value 83.1% (from 76%), and positive likelihood ratio 4.92 (from 3.2) while sensitivity was maintained at 60% (Table 3.4). For M41.2, statistical values were similar for specificity 96.8% (versus 96.3%), sensitivity 32.7% (versus 32.7%), and positive predictive value 94.8% (versus 92.4%) with improvement for the likelihood ratio, 18.25 (versus 12.2) (Table 3.6). When the two codes M41.1 and M41.2 were combined with age restriction, sensitivity remained similar at 92.3% while there was improvement of specificity 75.4% (from 70.1%), positive predictive value 86.9% (from 81.1%), and positive likelihood ration 6.6 (from 4.3) (Table 3.8). Age restriction led to improved statistical values due to elimination of the false positive juvenile idiopathic scoliosis cases.

Surgical approach from the operative report (gold standard) was also compared against CCI coding from the CIHI-DAD database. The Canadian Institute of Health Intervention codes were 1.75.LL for anterior deformity correction and fusion for scoliosis, 1.75.PF for posterior deformity correction and fusion for scoliosis, and 1.75.LN for both an anterior and posterior approach for correction and fusion. Each of these codes were 100% sensitive and 100% positive with 100% positive predictive value. There were 19 anterior cases (1.75.LL), 304 posterior cases (1.75.PF), and 61 anterior/posterior cases (1.75.LN).

Table 3.1 Coding of AIS cases

Table outlining how AIS cases, determined by chart review as the gold standard, were coded with ICD-10 diagnostic codes. 92.3% of all AIS cases (206/223) were coded as either M41.1 or M41.2.

Coding	**Percentage of Cases**
M41.1 Juvenile Scoliosis Includes Adolescent Scoliosis	59.6% (133/223)
M41.2 Idiopathic scoliosis	32.7% (73/223)
M41.8 Other forms	0.01% (2/223)
M41.9 Scoliosis unspecified	7.2% (16/223)

Table 3.2 Coding of non-AIS cases

Table outlining how non-AIS cases, determined by chart review as the gold standard, were coded with ICD-10 diagnostic codes. 56% of all non-AIS cases (90/161) were coded as either M41.4 or M41.1.

Coding	**Percentage of Cases**
M41.1 Juvenile Scoliosis Includes Adolescent Scoliosis	26.1% (42/161)
M41.2 Idiopathic scoliosis	3.7% (6/161)
M41.4 Neuromuscular scoliosis	29.8% (48/161)
M41.5 Other secondary	3.1% (5/161)
M41.8 Other forms	5.6% (9/161)
M41.9 Scoliosis unspecified	22.9% (37/161)

Table 3.3 M41.1 coding for AIS cases

M41.1 coding for AIS cases – sensitivity (SN) 60% (133/223), specificity 74% (119/161), positive predictive value (PPV) 76% (133/175), and positive likelihood ratio (LR+) 3.17. Sensitivity of M41.1 is poor at 60% only.

M41.1	**Coded As AIS**	**Not Coded As AIS**
AIS Cases	133 (True Positive)	90 (False Negative)
Non-AIS Cases	42 (False Positive)	119 (True Negative)

Table 3.4 M41.1 coding with age requirement>10 years of age

M41.1 coding for AIS cases, with age requirement >10 years of age – sensitivity (SN) 60% (133/223), specificity 78% (99/126), positive predictive value (PPV) 76% (133/160), and positive likelihood ratio (LR+) 4.9. Restricting the age to identify patients over the age of 10, led to reduction in false positive and increase in specificity and positive predictive value, along with LR+.

M41.1 (age>10 years)	**Coded As AIS**	**Not Coded As AIS**
AIS Cases	133 (True Positive)	90 (False Negative)
Non-AIS Cases	27 (False Positive)	99 (True Negative)

Table 3.5 M41.2 coding for AIS cases

M41.2 coding for AIS cases– sensitivity (SN) 32.7% (73/223), specificity 96.2% (155/161), positive predictive value (PPV) 92% (73/79), and positive likelihood ratio (LR+) 12.16.

M41.2	**Coded As AIS**	**Not Coded As AIS**
AIS Cases	73 (True Positive)	150 (False Negative)
Non-AIS Cases	6 (False Positive)	155 (True Negative)

Table 3.6 M41.2 coding for AIS cases with age restricted > 10 years old

M41.2 coding for AIS cases– sensitivity (SN) 32.7% (73/223), specificity 96.8% (122/126), positive predictive value (PPV) 95% (73/77), and positive likelihood ratio (LR+) 18.3. Restricting the age to identify patients over the age of 10, led to reduction in false positive and increase in specificity and positive predictive value, along with LR+.

M41.2 (age>10 years)	**Coded As AIS**	**Not Coded As AIS**
AIS Cases	73 (True Positive)	150 (False Negative)
Non-AIS Cases	4 (False Positive)	122 (True Negative)

Table 3.7 M41.1 and M41.2 combined coding

M41.1 and M41.2 combined coding – sensitivity (SN) 92.3%, specificity 70.2%, positive predictive value (PPV) 81%, and positive likelihood ratio (LR+) 4.3.

M41.1 and M41.2	**Coded As AIS**	**Not Coded As AIS**
AIS Cases	206 (True Positive)	17 (False Negative)
Non-AIS Cases	48 (False Positive)	113 (True Negative)

Table 3.8 M41.1 and M41.2 combined coding with age restricted > 10 years old

M41.1 and M41.2 combined coding – sensitivity (SN) 92.3%, specificity 75.4%, positive predictive value (PPV) 87%, and positive likelihood ratio (LR+) 6.6. Restricting the age to identify patients over the age of 10, led to increased specificity, along with positive predictive value, along with LR+.

M41.1 and M41.2(age>10)	**Coded As AIS**	**Not Coded As AIS**
AIS Cases	206 (True Positive)	17 (False Negative)
Non-AIS Cases	31 (False Positive)	95 (True Negative)

Table 3.9 Statistical accuracy of individual and combination of codes

Table outlining statistical accuracy of the individual codes M41.1 and M41.2 and then the combination of both codes to identify AIS surgical cases.

Age>10	**SN**	**SP**	**PPV**	**LR+**
M41.1	60%	78%	83%	4.9
M41.2	32.7%	96.8%	95%	18.3
M41.1 or M41.2	92.3%	75.4%	87%	6.6

3.5 Discussion

It is vitally important to understand the quality of the data within an administrative database. Administrative databases are utilized by hospital administrators for reimbursement claims based upon coding of co - morbidities and underlying diagnoses, along with utilization by researchers comparing adverse event rates between institutions, and comparing geographic variations in care (22;118-120). Quality of the decisions based on research performed on administrative databases is determined by the accuracy of the recorded data. Analysis of inaccurate administrative data can lead to faulty decision making.

A significant issue with ICD-10 coded databases is the ambiguity in its coding definitions that allows for a given diagnosis to be coded under different categories. This does not represent a coder error as the chosen category is not wrong. Instead, the issue is with having several potential choices to code a particular diagnosis – namely due to ambiguous definitions that allow for overlap of categories. This is well described in the ICD-10 coding process for spinal cord injury and with heart failure where coders can select from a diverse range of codes(113;121). In AIS, one coder may validly select M41.1 whereas another coder may also validly select M41.2.

The ICD-10 classification system is significantly more detailed than the previous ICD-9 system, with 12420 codes versus 6969 codes. The ICD-10-CA coding manual defines M41.1 as "Juvenile scoliosis includes adolescent scoliosis". M41.2 is defined as "Other Idiopathic Scoliosis". Sensitivities of the codes in isolation were low as there were two potential categories to choose from – with M41.1 as 60% and M42.2 as 32%. In contrast, the combination of the two codes with a Boolean "OR" function, M41.1 or M41.2, improved sensitivity dramatically to 92%. Combining codes to increase sensitivity of searches has been previously described for other

diagnoses such as for spinal cord injury and heart failure due to having more than one code to select from when coding a diagnosis (113;121).

Furthermore, cases other than the diagnosis may be included (i.e. false positives) due to imprecise definitions. M41.1, "Juvenile scoliosis includes adolescent scoliosis" can be potentially be misleading, as this implies a different form of scoliosis occurring in younger children aged between 3 and 10 years rather than in the adolescent years of 10-18 years. As a result, 15 out of the 42 false-positives for M41.1 were juvenile idiopathic scoliosis patients rather than adolescent idiopathic scoliosis cases. Furthermore, M41.1 does not include the formal term "idiopathic". 133 out of 223 (60%) of AIS cases were coded as M41.1. The alternative code M41.2, is defined in the ICD-10-CA coding guideline as "Other idiopathic scoliosis". As a result of the term *idiopathic,* 73 of 223 cases of AIS (32.7%) were coded as M41.2. Furthermore, lack of precision in the definitions lead to significant numbers, 90 of 161 (56%) of non-AIS cases, as being coded as M41.1 or M41.2.

.Another potential source of error, coded mis-specification error(122), occurs when the primary diagnosis is not aligned with the medical evidence in the health record and this can occur when the chart review is not in-depth enough to obtain the actual diagnosis needed for coding(122). Large amounts of clinical information are reviewed to appropriately code the diagnoses for a discharge abstract. If the information is not readily dictated, prolonged chart review may be required to obtain the necessary information by the coder. If further information is not obtained due to lack of experience or lack of perseverance, misspecification error can occur. Mis-specification can be minimized through a clear and precise documentation of the diagnosis within the clinical records such as during clinic visits and within the operative dictation. In this study of reviewing surgical AIS cases, the cases were clearly defined through their clinic visits,

operative note and follow up notes in the clinic. Only 17 of 223 (7.7%) of AIS cases were not coded appropriately as M41.1 or M41.2. In contrast, the non-AIS cases did not have an accurate diagnosis in the surgical report, and actually required review of clinical dictation reports. This is reflected in the coding of 51 of 161 (31.1%) non-AIS cases as 'M41.9 Scoliosis unspecified' or 'M41.8 Other forms' or 'M41.5 Other secondary'.

Other sources of potential error at the coder level include up-coding by assigning codes that provide higher reimbursement value over codes with lesser reimbursement value. However, in this study period, there was no higher reimbursement provided for the various forms of scoliosis codes. Another similar type of coding error is unbundling where coders assign codes for all the separate parts of a diagnosis instead of assigning a code for the overall diagnosis in order to obtain higher reimbursement. Again, in the situation for AIS, there are no separate parts of a diagnosis such as in a medical syndrome and again there were no reimbursement issues during this study period with the different scoliosis diagnoses.

This study identified a potential solution to overcome limitations of administrative data due to ambiguity in diagnostic coding definitions. Combination of the two AIS codes, led to improved sensitivity and positive predictive value while maintaining specificity by capturing more AIS cases (True positives). Juvenile idiopathic scoliosis cases were also coded as M41.1 (False Positives). Elimination of juvenile idiopathic scoliosis patients through age exclusion reduced a large proportion of false positives, improving specificity and positive predictive value. Combination of codes using a Boolean "OR" function, to identify AIS cases occurs due to lack of clarity in ICD-10 definitions, leading to coders appropriately utilizing different codes for AIS (113;121).

The ICD-10 coding process can be further improved through refining the definitions for the various scoliosis categories and training of coders. For example, the code "M41.1" can be clarified through refining its description to "Adolescent Idiopathic Scoliosis", thereby excluding other potential diagnoses and reducing false positive cases (raising the positive predictive value and specificity). A specific separate classification for Juvenile Idiopathic Scoliosis should be created thereby leaving a single choice for AIS cases and potentially increasing the sensitivity through increasing the true positive cases. However, given the already high sensitivity of 92.3% using the combination of codes, the potential benefit from re-labeling the ICD-10 definitions, would be to mainly improve the specificity and positive predictive value, along with simplifying the coding process by creating tighter definitions. Further training of individual coders can also optimize coding accuracy (116;117). However, there will always be variability in the knowledge and quality of coders across different institutions. Accurate coding descriptions will likely be the most effective method of increasing accuracy of the diagnostic codes.

In contrast to diagnostic coding problems, procedural coding for AIS was accurate, similar to accuracy found in other procedural coding studies(84;114). This is likely due to clarity in the surgical dictation combined with clarity in the definition of the procedural categories for CCI coding(114).

This study has several potential limitations. First this study assessed accuracy at a high volume pediatric center. There is a wide variability in AIS surgical volumes with the majority of centers in Canada performing under 10 cases a year. Accuracy of diagnostic coding may differ at low volume centers as coders would have less experience.

Second, the statistical properties of the diagnostic codes vary depending on the heterogeneity of the assessed population of patients. Features such as the specificity and positive likelihood ratio

can vary depending on the diversity of patient diagnoses similar to the spectrum effect or spectrum bias found with diagnostic tests (109-112). For example, if all cases admitted to the hospital during the same study period were included for AIS coding accuracy, the number of patients *without* AIS would increase dramatically (i.e. true negatives). It would be unlikely that other diagnoses such as "Pneumonia" would be coded as M41.1 or M41.2. As a result, the number of false positives would not rise relative to the dramatic increase in true negative cases, leading to a significant increase in the specificity of the diagnostic code, and hence the likelihood ratio as 1-Specificity would decrease relative to a stable sensitivity. However, in this study, only surgical spine cases were analyzed to minimize potential spectrum effects of non-spinal diagnoses in enhancing specificity and positive likelihood ratios(109-112).

3.6 Conclusion

In conclusion, the combined diagnostic codes of M41.1 or M41.2, with age exclusion criteria provides a relatively accurate method of capturing surgical AIS cases with high sensitivity, specificity and with a strong positive predictive value. This data would not be valid to non – surgical cases of AIS such as those managed in an outpatient clinic given that this study only examined surgical cases of AIS. Using the codes in isolation is inadequate and will underestimate the cases treated as a result of ambiguity in group definitions. This study has provided a better understanding of the weaknesses in coding accuracy for surgical cases of AIS, the most common reason for elective pediatric spine surgery. In terms of future research, a multi-center accuracy coding study can be performed across the country with incorporation of low volume and higher volume centers utilizing improved category definitions.

Chapter 4

4 The Impact of Surgical Volume on Adverse Events For the Treatment of Adolescent Idiopathic Scoliosis. A National Canadian Perspective

The Impact of Surgical Volume on Adverse Events For the Treatment of Adolescent Idiopathic Scoliosis. A National Canadian Perspective

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4.1 Abstract

Background

Several studies have demonstrated a relationship between volume and outcome of surgical procedures leading to calls for centralization or regionalization of care. The objective of this study was to determine the relationship between hospital surgical volume and adverse events for adolescent idiopathic scoliosis.

Methods

The Canadian Health Information Institute Discharge Abstract Database was used to identify 1225 patients aged 11 to 17 with adolescent idiopathic scoliosis (AIS), receiving surgery from 2003-2007 in 29 institutions across Canada. Univariate, single - layer regression and the more appropriate statistical hierarchical modeling with random effects was used to assess the relationship between hospital volume of AIS surgery and length of stay, adverse events, surgical site infection or need for transfusion.

Results

Of 29 centers across Canada, 22 performed less than 10 cases per year. Overall adverse events affected 12.6% of all patients, similar to other reports in the literature. While significant with single - layer multi-variate regression, hierarchical modeling did not demonstrate a volume - outcome relationship. Only intensive care unit length of stay had a significant inverse relationship with hospital volume ($p=0.018$).

Interpretation

With appropriate statistical analyses, there was no volume outcome relationship for adolescent idiopathic scoliosis for overall adverse events. However, this study was limited by sample size with respect to assessing the need for transfusion and wound infection. Higher volume centers may be superior in "rescuing patients" following a complication. Although the results of this administrative based study would suggest regionalization will not lead to a reduction in adverse events, this study did not account for clinical level variables such as curve type and flexibility.

Key Words: Volume outcome relationship, hierarchical modeling, adolescent idiopathic scoliosis, administrative database

4.2 Background

Surgical correction of adolescent idiopathic scoliosis (AIS) is the commonest procedure performed in pediatric orthopedics(18). Prior research has demonstrated that rates and types of complications with deformity correction vary by center (19-22;123;124). One potential explanation for the reported variation is that the rates of adverse events maybe due to variable skills and expertise of the surgeons and centers (68;125-127).

Regionalization of treatment was first proposed by Luft et al. in 1979 after demonstrating relationships between increasing volumes and lower mortality rates for 12 surgical procedures including open-heart surgery, vascular surgery, prostate surgery and coronary bypass(128). Those hospitals performing 200 or more cases had per year, compared to hospitals with lower volumes, had a 25 to 41 percent lower mortality. Several studies have examined the relationship between surgical volume and outcome of orthopaedic procedures in adults. Katz in the Medicare population(129) and Kreder in the state of Washington(130) reported increasing mortality, infection rates and re-operations in hospital centers with low surgical volumes. Taylor et al. also reported lower mortality rates in higher volume hospitals for surgery of the hip, knee, spine and femur performed (123).

The majority of volume-outcome relationship studies in orthopaedic surgery have been for total hip arthroplasty with relatively little attention to spine(22;124). Vitale et al. examined the volume – outcome relationship using single level multi-variate regression analysis for all types of scoliosis surgery correction in Medicaid patients in California aged 0 -25 years old (124). The results of this study are difficult to extrapolate to AIS because the rates and types of adverse

events depend so heavily on the etiology of scoliosis (22;124;131). Furthermore, the results are generalizable only to that subset of patients in California receiving Medicaid. Patil also reviewed volume – outcome relationships for complications following surgery for idiopathic scoliosis in the United States, but his analyses included patients aged 1 to 44 years old(22). Finally, both the models by Patel and Vitale, treated all patients as independent observations, and did not account for clustering (or correlation) of patients who are nested within hospitals. Patients are not randomly allocated to different hospitals, but instead go to hospitals due to similar reasons such as place of residence and hospital reputation. Patients being treated within a hospital are also further correlated (or clustered) as they might be more likely to experience similar outcomes than patients treated by another hospital with the same volume due to differences in technique, skill, or supportive care. This correlation (or clustering) of patients, nested within hospitals, violates the basic premise of traditional regression analysis and needs to be accounted for during analysis. Ignoring this correlation can potentially lead to overestimation of the relationship between surgical volume and outcome.

Canada provides an ideal location to perform volume-outcome studies. In Canada, through the Canadian Health Act of 1984, the entire population is provided universal health care coverage with no option for private medical care. Thus, lack of insurance does not serve as a barrier to care. Furthermore, all hospitalized patients generate a discharge abstract collected by the Canadian Institute of Health Information (CIHI). The Discharge Abstract Database (DAD) of CIHI provides the opportunity to investigate volume outcome relationships comprehensively at a national level. The purpose of this study was to determine 1) the type and rate of adverse events occuring with surgical treatment of AIS, and 2) if there were lower rates of adverse events in centers performing higher volumes of AIS correction surgery.

4.3 Methods

The CIHI-DAD is a publicly accessible national database comprising all acute patient admissions, chronic long term admissions, rehabilitation admissions and day surgical procedures performed across Canada. Discharge diagnoses and adverse events (up to 25) are coded using the International Classification of Diseases – 10 – CA (ICD-10-CA Canadian Enhancement). Each discharge abstract has 19 groups of information, each with multiple fields, providing information on demographics, procedures performed (up to 21 per admission), co-morbidities, complications, length of stay, discharge disposition, and other aspects of care. The CIHI – DAD database has been validated with ongoing data validity checks(84). Furthermore, a separate study previously evaluated AIS coding accuracy (Ahn et al. IMAST/NASS-JSS 2009).

The CIHI – DAD database was used to identify all AIS (M41.1, M41.2) deformity correction fusions (1SC75PF posterior or 1SC75LL anterior or 1SC75LN combined anterior and posterior) across Canada except Quebec (which has only recently converted to ICD-10-CA coding) from 2003 until 2007-2008 fiscal year for patients between 11-17 years old. Procedures in the CIHI-DAD are coded according to the Canadian Classification of Health Interventions (CCI) rather than ICD-10 procedural codes. All neuromuscular scoliosis cases were excluded (M41.4).

Annual hospital volume was calculated for the 29 institutions performing at least one scoliosis surgery in patients 11-17 years based upon unique de-identified codes assigned by the CIHI for the purpose of this research. Average annual volumes were then calculated for each institution over the 5 fiscal years and each institution was assigned to a different quintile of volume

numbered 0 to 4 representing low to high volume centers; up to a mean of 10 cases per year, 11 to 22 cases per year, 23 to 36 cases per year, 37 to 65 cases, and 66 or more cases per year.

Outcomes included in – patient mortality, length of stay in the hospital, percentage of patients admitted to an intensive care post-operatively, need for blood products, and rates of adverse events. Adverse events included local complications (neurologic injury, wound infection, hematoma, and hardware failure) and systemic adverse events (pneumonia, gastrointestinal obstruction, heart failure and arrhythmia, urinary tract infections, pulmonary embolism and deep venous thrombosis).

Descriptive statistics and univariate, single level multi-variate regression analysis was performed along with hierarchical modeling using random effects. Analysis was performed with SAS Version 9.1.3 Service Pack 4 (Cary, NC, USA) using maximum likelihood explanation for the single level multi-variate regression analysis. Hierarchical modeling accounts for potential clustering effects of adverse events (68;132). As noted above, failure to account for clustering can lead to overestimation of the "treatment" effect (68;132). Analyses were controlled for *a priori* determined hospital level (quintile of surgical volume) and patient level (age, gender, and number of co-morbidities) variables with Proc Glimmix using Dual Newton Quasi Optimization technique. The hierarchical models had the same general form as the single level models, but included a random intercept term representing hospital-specific random effect. Based upon the requirements of hierarchical modeling, we assumed that the hospital-specific random effects were normally distributed and independent of each other (132;133). It was also assumed that the random error between hospital had a mean of zero(132;133). These assumptions have been carried out in previous studies(132;133). We specified a hierarchy of patients nested within hospitals.

The form of the single level multi-variate regression analysis for adverse events is:

$$\text{Adverse event} \sim \text{Binomial}\ (p_{ij})$$

$$\text{Log}\ p_{ij} / (1 - p_{ij}) = \text{logit}\ (p_{ij}) =$$

$$\alpha_0 + \beta_1 \text{Age} + \beta_2 \text{Gender} + \beta_3 \text{Approach} + \beta_4 \text{Comorbidities} + \beta_5 \text{Quintile of Surgical Volume}$$

where p_{ij} is the probability of the occurrence of an adverse event for the *i*th patient at the *j*th hospital.

The form of the hierarchical model for adverse events is:

$$\text{Adverse event} \sim \text{Binomial}\ (p_{ij})$$

$$\text{Log}\ p_{ij} / (1 - p_{ij}) = \text{logit}\ (p_{ij}) =$$

$$\tau_j + \alpha_0 + \beta_1 \text{Age} + \beta_2 \text{Gender} + \beta_3 \text{Approach} + \beta_4 \text{Comorbidities} + \beta_5 \text{Quintile of Surgical Volume}$$

with $\tau_j \sim N(0, \sigma^2)$ where p_{ij} is the probability of the occurrence of an adverse event for the *i*th patient at the *j*th hospital and where τ_j is a hospital specific random effect with a mean of 0 and variance σ^2.

4.4 Results

DESCRIPTIVE STATISTICS

From years 2003/4 until 2007/8, 1225 AIS corrections were performed in patients aged 11-17 years old in 29 centers in Canada (excluding Quebec). Of the 1225 patients, 1009 (82.3%) were female; 1032 (84.3%) were posterior correction and fusion; 118 (9.7%) were anterior correction and fusion; 73 (6%) were combined anterior/posterior correction (Table 4.1).

The mean number of AIS cases operated on per year ranged from 1 up to 66 cases per year, with an overall mean number of 9.0 cases done per year +/- 14. Of the 29 centers, 22 (76%) performed the lowest quintile in terms of mean annual volume of surgery (Figure 4.1). Four (13%) of 29 centers performed mean annual volumes of over 18 cases per year (top three quintiles) comprising 61% of the AIS correction cases during the study period.

Table 4.1 Demographics of patients

Demographics of patients operated on for adolescent idiopathic scoliosis in Canada between 2003-2008. Local adverse events occurred in 5.2% of patients who had AIS surgery in Canada between 2003-2008.

Number of Cases	1225	
Gender	1009/1225 Female (82.3%)	216 Male (17.7%)
Surgical Approach		
Anterior	199/1225 (9.7%)	
Posterior	1033/1225 (84.3%)	
Both	73/1225 (6%)	
Local adverse events		
Neurologic Injury	0.001% (1/1225)	
Wound Infection	1.5% (18/1225)	
Hematoma	1.9% (23/1225)	
Hardware failure	1.4% (13/1225)	

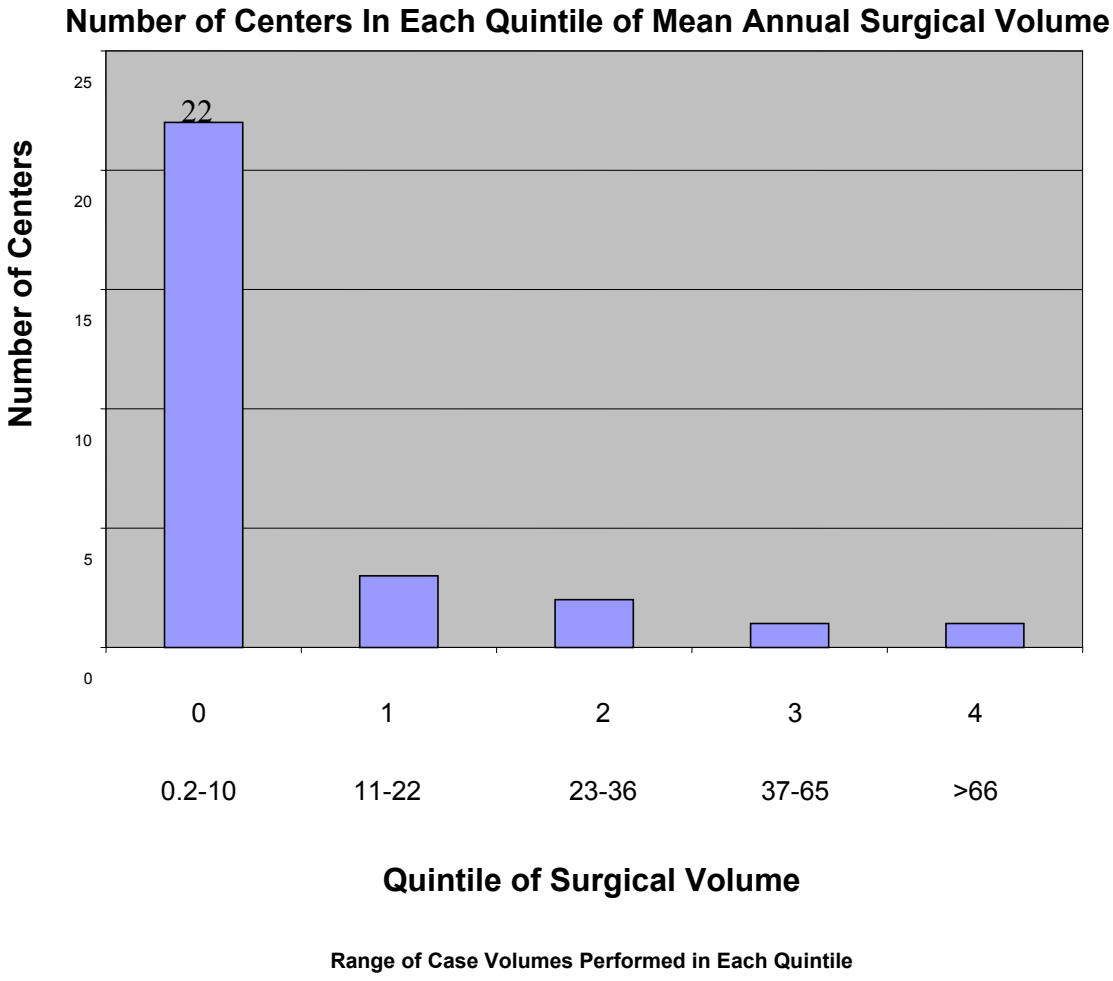


Figure 4.1 Number of centers in each quintile.

Number of centers in each quintile of mean annual surgical volume for AIS correction surgery; 22 out of 29 centers performed the lowest quintile of surgical volume, performing 0.2 to 10 AIS cases on average per year. Remaining quintiles had 3, 2, 1 and 1 centers respectively.

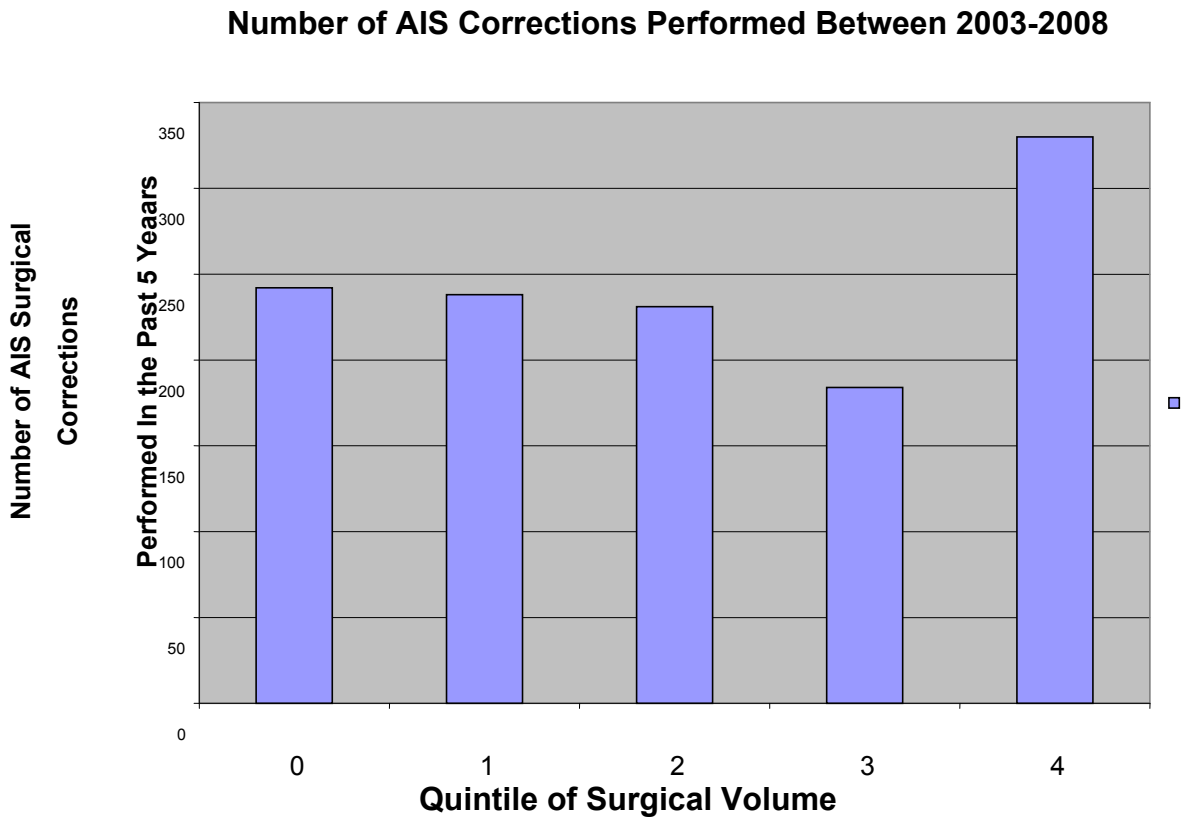


Figure 4.2 Number of AIS surgical corrections performed

Number of AIS surgical corrections performed over the past 5 years based on the quintiles of surgical volume; 39% of the total AIS corrections in the past 5 years were performed by the lowest volume centers (lowest 2 quintiles).

In this five years, there was no in - hospital mortality. Mean length of hospital stay was 8.0 +/- 8 days; 53.6% (48/1225) were in the ICU or Step Down Unit post-operatively; 3.9% (4/1225) required 2 visits to the ICU during their admission. The average admission to the ICU or Step Down Unit was 1.7 +/- 3.6 days with the vast majority of patients 98.5% discharged home (1207/1255) and 1.5% (18/1255) to rehabilitation.

During surgery 41.5% (508/1225) received some type of blood product of which 78.5% (399/508) was homologous red blood cells; plasma 15% (76/508); platelets 6.5% (33/508); albumin 8.3% (102/1225). Of the 399 patients that received homologous red blood cells, 299 patients or 75% had autologous blood also given. Of all AIS cases, 25% (301/1225) had autologous blood given during or after surgery.

Overall 12.3% (151/1225) had some adverse event occur during admission; 10.2% of patients (125/1225) had 1 adverse event. 1.8 % had 2 adverse events; 0.24% had 3 adverse events and 0.08% had 5 adverse events. Of the 1225 patients, 5.2% of all patients had a local complication (Table 4.1). Neurologic injury was rare at 0.001% (1/1225). Wound infection occurred in 1.5% (18/1225) of patients, hematomas occurred in 1.9% (23/1225), and hardware failure in 1.4% (13/1225). Systemic adverse events occurred in 5% of all patients (Table 4.2); 0.33% (4/1225) developed post-operative pneumonia; 4.5%(56/1225) had a pulmonary effusion post-operatively; 3.1% (38/1225) had gastrointestinal adverse events including superior mesenteric artery syndrome; no cases of heart failure and 0.16% (2/1225) had an arrhythmia; urinary tract infections occurred in 0.82% of cases (10/1225); no pulmonary embolisms and only 0.08% (1/1225) developed a DVT.

As noted in the methods we used two multivariate methods with the following outcomes; univariate analyses assessing post – operative adverse events and length of stay are shown in Table 4.3. In single level multi-variate linear regression analysis, increasing volume of AIS correction surgery ($p=0.03$) and increasing age ($p=0.0052$) were associated with decreased length of stay (Table 4.4). In contrast, increasing comorbidity ($p<0.0001$), combined anterior-posterior or anterior surgical approach ($p<0.0001$), and post-operative complication ($p<0.0001$) were associated with increased length of stay. Analyses were also performed using the same co-variates with random effects hierarchical modeling. With this analyses, surgical volume was not related to length of stay ($p=0.52$) although the remaining covariates remained statistically significant as with similar magnitudes with the single level regression analysis. Decreased length of stay in the intensive care unit post-operatively, was associated with increasing quintiles of surgery ($p=0.018$); a posterior only approach ($p=0.0156$); and decreased pre-admission comorbidities ($p<0.0001$) with hierarchical modeling and single level multi-variate analysis (Table 4.5). Estimates for these significant covariates did not change significantly between the two models.

Table 4.2 Systemic adverse events

Systemic adverse events occurred in 5% of patients. Breakdown of the various systemic events are shown in the table. Respiratory and gastrointestinal adverse events made up the majority of systemic adverse events.

Systemic adverse events	**Percentage of Cases**
Respiratory	
Pneumonia	0.33% (4/1225)
Pulmonary effusion	4.5% (56/1225)
Gastrointestinal	3.1% (38/1225)
Cardiac	
Arrythmia	0.16% (2/1225)
Heart failure	0%
Urinary tract Infection	0.82% (10/1225)
Deep venous thrombosis	0.0001% (1/1225)

Table 4.3 Univariate analysis

Univariate analysis of gender, approach, comorbidity index, and quantile of mean surgical volume on length of stay and number of adverse events.

	Length of Stay (days)	**Occurrence of Any Adverse Event**	**Statistical test**
Gender	7.91 Female (N.S) 8.15 Male	124/1009 (12.3%) (NS) Female 27/216 (12.5%) Male	t-test unequal variance
Approach	10.16 Anterior/Both 7.57 Posterior	27/192 (14.1%) (NS) Anterior/Both 124/1033 (12%) Posterior	t-test unequal variance **(p=0.0022)**
Comorbidity Index 0 1 2 3 4	 7.17 10.1 12.8 20.6 38.9 **(p<0.0001) for all comparisons except group 1+2**	 58/1087 (5.33%) 41/72 (56.94%) 27/33 (81.82%) 20/25 (80%) 5/8 (62.5%) **(p=0.006) between groups 0+1,0+2,0+3,0+4,1+3, 1+2, 3+0**	Analysis of variance
Quintile of Mean Surgical Volume 1 2 3 4 5	 8.0 6.8 * 7.3 ** 6.9 *** 9.8 *, **, *** **(p<0.0001) between quintiles 2+5 (*), 3+5 (**), 4+5 (***)**	 35/242 (14.46%) * 15/238 (6.30%) *, ** 22/231 (9.52%) 23/184 (12.5%) 56/330 (16.9%) ** **(p=0.0017) between quintiles 1+4 (**), 1+0 (*)**	Analysis of variance

Table 4.4 Overall Length of Stay (significant values highlighted in yellow)

TABLE 4.4
OVERALL LENGTH OF STAY

VARIABLE NAME	LEVEL	SINGLE LEVEL ESTIMATE	SE	P VALUE	MULTI LEVEL ESTIMATE	SE	P VALUE
Quantile of mean surgical volume	Hospital	-0.31	0.14	0.029	-0.15	0.23	0.52
Age	Patient	-0.33	0.11	0.0052	-0.34	0.12	0.0042
Gender	Patient	0.37	0.56	0.51	0.31	0.56	0.59
Combined approach	Patient	2.84	0.58	<0.0001	3.25	0.59	<0.0001
Number of preadmission comorbidities	Patient	2.99	0.28	<0.0001	2.99	0.29	<0.0001
Post operative cx	Patient	4.78	0.47	<0.0001	4.67	0.47	<0.0001

Table 4.5 SCU Length of Stay (significant values highlighted in yellow)

TABLE 4.5
SCU LENGTH OF STAY

VARIABLE NAME	LEVEL	SINGLE LEVEL ESTIMATE	SE	P VALUE	MULTI LEVEL ESTIMATE	SE	P VALUE
Quantile of mean surgical volume	Hospital	-0.34	0.095	0.0004	-0.34	0.14	0.018
Age	Patient	-0.13	0.074	0.0819	-0.12	0.075	0.11
Gender	Patient	0.11	0.36	0.74	0.06	0.36	0.88
Posterior only approach	Patient	-0.71	0.27	0.011	-0.69	0.28	0.0156
Number of preadmission comorbidities	Patient	1.05	0.16	<0.0001	1.01	0.17	<0.0001

Consistent with above results, using single –level multivariate logistical regression, the odds of having an adverse event was associated with lower quintiles of surgical volume, OR 0.87 95% CI [0.77, 0.99], that was not significant OR 1.01 95%CI[0.99,1.03] (p=0.10) using hierarchical modeling with random effects. Only presence of a pre-operative co-morbidity increased the odds of adverse events, OR 1.51[1.46, 1.56]. With hierarchical modeling, this remained a significant covariate with similar OR 1.51 [1.46, 1.55] (Table 4.6).

Table 4.6 Occurrence of adverse event (significant values highlighted in yellow)

TABLE 4.6
OCCURRENCE OF ADVERSE EVENT

VARIABLE NAME	LEVEL	SINGLE LEVEL OR	95% CI	MULTI LEVEL OR	95% CI
Quantile of mean surgical volume	Hospital	0.87	0.77,0.99	1.01	0.99, 1.03
Age	Patient	1.00	0.95,1.21	1.00	0.99, 1.01
Gender	Patient	0.95	0.40,1.30	0.95	0.90, 1.01
Combined approach	Patient	1.04	0.66,1.97	1.04	0.98, 1.09
Number of preadmission comorbidities	Patient	1.51	1.46,1.56	**1.51**	1.46,1.55
C stastitic		0.81			

Patients receiving transfusion or receiving blood products, using multivariate logistical regression analysis were more likely at centers performing lower quintiles of surgical volume, OR 0.83 95% C.I. [0.76, 0.90], younger OR 0.91 95% C.I. [0.85, 0.98], and had a posterior or a combined approach OR 1.62 95% C.I. [1.22, 2.14] (Table 4.7). Although posterior or combined approach OR 2.08 95% C.I. [1.53, 2.84] increased the odds of transfusion compared to anterior approach alone, with hierarchical modeling with random effects, surgical volume as a hospital level variable was not significant OR 0.76 95% C.I. [0.46, 1.27].

Table 4.7 Receiving a blood transfusion (significant values highlighted in yellow)

TABLE 4.7
RECEIVING A TRANSFUSION

VARIABLE NAME	LEVEL	SINGLE LEVEL OR	95% CI	MULTI LEVEL OR	95% CI
Quantile of mean surgical volume	Hospital	0.83	0.76,0.90	0.76	0.46,1.27
Age	Patient	0.91	0.85,0.98	0.93	0.86,1.00
Gender	Patient	1.07	0.77,1.49	1.20	0.84,1.70
Combined approach or Posterior	Patient	1.62	1.22,2.14	**2.08**	1.53,2.84
C stastitic		0.712			

Finally, odds for developing a wound infection were associated with lower quintiles of surgical volumes, OR 0.53 95% C.I. [0.35, 0.80] using single level multivariate logistic regression analysis, but not with hierarchical modeling OR 0.68 95% C.I. [0.34, 1.33] (Table 4.8).

Table 4.8 Developing a Wound Infection (significant values highlighted in yellow)

TABLE 4.8
WOUND INFECTION

VARIABLE NAME	LEVEL	SINGLE LEVEL OR	SINGLE LEVEL 95% CI	MULTI LEVEL OR	MULTI LEVEL 95% CI
Quantile of mean surgical volume	Hospital	0.53	0.35,0.80	0.68	0.34,1.33
Age	Patient	1.28	0.97,1.68	1.28	0.97,1.68
Gender	Patient	1.38	0.36,5.04	1.37	0.37,5.02
Combined approach or Posterior	Patient	0.85	0.24,3.01	0.62	0.16,2.33
Number of preadmission comorbidities	Patient	1.65	0.52,5.21	1.67	0.53,5.24
C statistic		0.754			

4.5 Discussion

Volume – outcome relationships in surgery, if true, have the potential to lead to better outcomes. While the exact mechanisms are unknown, volume – outcome relationships are presumed to occur because those centers and/or surgeons performing more procedures have greater experience and skill including a reduction in practice variation, improved adherence to best practices, and a greater concentration of resources(134;135;135). The association of higher case volumes and improved outcomes is frequently attributed to the principle of "practice makes perfect" where skills and processes are optimized by repetition(136). Significant volume - outcome relationships almost certainly exist for some rare and / or complex surgeries such as esophageal resection and pancreatic tumor surgery where there is a 12-13% median difference in mortality rates between the highest volume centers and lowest volume centers. In fact, the

Leapfrog Group promotes regionalization of procedures by making the broad encouragement for patients to seek care at high-volume centers (60).

However, volume – outcome relationships are controversial and do not always necessarily exist for more common and less complex surgery(69). In Canada, using a single payer system, volume outcome data has been conflicting in areas such cardiac procedures (137;138). In addition, other studies have found decreasing mortality in cardiac bypass surgery despite decreasing volumes of surgery (139).

One important issue is the correct statistical techniques must be used for analyses. The assumption that patients nested within a given hospital are independent observations is not true due to similarity in care received and similarity in reasons leading to their treatment at that particular hospital. Standard modeling techniques do not address the potential variation between higher level units such as hospitals; the individual patient is the unit of analysis (140;141). Failure to address the variation between hospitals separately (i.e. a separate error estimation term), leads to attributing more information of a higher level hospital variable such as surgical volume on patient level characteristics, and as result, the apparent effect of the volume-outcome relationship, can be inflated or determined to be present when there is no relationship (132). Simulation studies' techniques for hierarchical modeling, compared to the standard single level regression analysis technique, often leads to different statistical conclusions about the absence or presence of a volume-outcome relationship (142-144).

While two prior scoliosis studies have found a volume – outcome relationship (124;126;127;145) this study failed to show a volume – outcome relationship using appropriate analyses with hierarchical modeling. For all analyses performed there was an apparent inverse volume - outcome relationship for adolescent idiopathic scoliosis surgical correction when using

conventional single level multivariate regression analysis, with increasing risk of adverse events, wound infection and need for transfusion in lower compared to higher volume centers that was not present when using hierarchical modeling.

Another important issue is that even if analyses are correct, the association of higher volumes and improved outcomes maybe due to confounding. In the United States, patients may be selectively referred to institutions with better outcomes and as a result, high volumes are a result of patients selecting institutions with good care, and good outcomes are not causally related to high volumes (136).

The rationale for regionalization is based on the presumption of improved clinical outcomes in centers performing higher volumes of surgery compared to lower volume centers(136;146;147). Regionalization of resource intensive services may also lead to cost savings through a reduction of duplication of infrastructure and greater resource concentration that may increase efficiency of care delivery and allow for savings through economies of scale(148-150). However, implementation of regionalization may also have negative consequences (61;151;152). Removing patients from their local centers of treatment can add emotional stress endured by families and a sense of depersonalization of being transferred to large high volume hospitals as well as creating geographic obstacles to longitudinal care following surgery(151). Furthermore, many patients and families have expressed a desire to be treated at their local hospital rather than traveling despite knowing that being treated at a higher volume center may lead to reduction of adverse events (73;153).

This study adds additional evidence, using national administrative data, that regionalization does not necessarily improve clinical outcomes, at least, in this case of AIS surgery. Volume of cases is not necessarily a predictor of outcome with mortality rates for

cardiac procedures declining even with declining surgical volumes (137;139). In the case of AIS surgery, standards of care provided in both low and high volume centers are likely similar to have led to a lack of difference in adverse event rates. Spinal surgery has become more common place, especially with complex instrumentations over time, and these skill sets, both for surgeon and for the nursing staff, are likely transferable to other complex spinal procedures such as AIS surgery(137;139;154-156).

This study has several potential limitations. First, this study was based upon administrative data, which does not provide information on curve severity as measured by the Cobb angle, curve flexibility, and the pattern of the curve (Lenke 1 through 6). Larger stiffer curves are more difficult to correct compared to flexible small magnitude curves. More difficult curves are maybe more likely to be sent to higher volume centers. However, we have no reason to suspect that occurs to the extent to completely negate a true volume outcome relationship. Secondly, ascertainment of post-operative complications may not be accurately documented in administrative databases (69). However, the data in this database has undergone validity testing and there is no reason to suspect coding differs by centers to account for lack of volume – outcome relationship(84). Thirdly the sample size is relatively small to determine an effect for all outcomes. Adequacy of sample sizes for the outcomes in this study is related to the minimal clinically important difference for each outcome. For example, in terms of adverse events, we suggest a 25% reduction or greater in the event rate from 12.3% to at least 9%, or an odds ratio of 0.72 or less, would represent a clinically important difference. In our study, an odds ratio of 0.72 was excluded by the 95% confidence interval [0.99, 1.03] and as a result, there was adequate sample size for total adverse events. In contrast, in the analysis for wound infection and blood transfusion, again using a 25% reduction or greater, the required respective odds ratios representing a clinically important difference of 0.49 and 0.64, are within the 95% confidence

intervals of our study as was point estimates for wound infection was 0.67 with a 95% CI [0.34, 1.33]; the point estimate for blood transfusion was 0.76 with a 95% CI [0.46, 1.27]. In summary, our study was sufficiently powered to determine a volume – outcome relationship for overall adverse events especially the most important outcomes. However, a larger sample size is needed for identifying a clinically important difference for wound infection and blood transfusion. Fourthly, surgeon volume was not assessed in this study as surgeon specific data was not available. However, surgeon volume can impact volume outcome relationships (78;126;129;130;157;158).

Despite having no differences in complications rates, there may be other benefits of high volume centers, including the ability to "rescue patients" following a complication(69). Higher volume centers may have better skilled personnel to recognize and treat the complication in better facilities compared to lower volume centers. This ability to "rescue patients" may be reflected in this study's shorter intensive care unit stays in busier centers. This was the only volume – outcome relationship which was significant with hierarchical modeling suggesting this maybe a benefit of higher volume hospitals.

4.6 Summary

In summary, this study failed to show a volume-outcome relationship for adverse events, need for blood transfusion, total length of stay, and wound infection. Appropriate analysis that accounts for clustering of outcomes was used to avoid overestimation of the volume-outcome relationship. Further research is needed to determine if controlling for curve characteristics such as magnitude, affects the volume outcome analysis. Based on this study's results, regionalization of care appears unlikely to lower complication rates for AIS surgery. However, this study

utilized administrative data and did not analyze clinical variables such as curve pattern and rigidity.

Chapter 5
Discussion & Conclusion

5 Review of Thesis Objectives

This thesis investigated adverse events associated with adolescent idiopathic scoliosis surgery in Canada. The first paper assessed the impact of wait times on adverse events related to AIS surgery and used this information to determine an empirically based access target to minimize the risk of adverse events. The second paper examined the ICD-10-CA coding accuracy for surgically treated adolescent idiopathic scoliosis (a common health services approach to determining adverse events at a population level) and determined an optimal method of ascertaining cases with a diagnosis of AIS from an administrative database. The third paper assessed at a national level, the type and incidence of adverse events that occur with surgical treatment of AIS and determined if there were lower rates of adverse events in centers performing higher volumes of AIS surgery.

The discussion consists of four sections. The first section describes the contributions to the literature for each of the three papers. The second section, based on the evidence from the three studies comprising the thesis and the current literature, makes recommendations to reduce overall adverse events for AIS surgery. The third section proposes future healthcare quality improvement research for AIS surgery. The final section summarizes the results of this thesis.

5.1 Contributions to the Literature

PAPER 1: *Evidence-Based Maximal Acceptable Wait Time: Adolescent Idiopathic Scoliosis Wait Times Cohort*

Objective

To determine an empirically-based access target for AIS surgery to reduce risk of adverse events and then to compare results to consensus based access targets.

Contribution

This is the first study to determine an empirically based access target for AIS surgery. Currently most access targets, including those for AIS surgery, are based upon expert opinion. Through this study, an empirically based access target of 3 months was determined through two methods: 1) reduction of adverse events with the primary outcome of need for additional surgery due to curve progression while waiting, and 2) the novel use of a receiver operator curve. This is the first paper in the literature that describes the use of an ROC curve to help determine an access target(40). These methods have the potential to be utilized to determine maximal acceptable wait times for other procedures and diagnoses. This is also the first paper describing the type and incidence of adverse events related to prolonged waits for AIS surgery(40). This paper was published in the CMAJ June 14, 2011 (impact factor 9.0 2010).

PAPER 2: *ICD-10 Coding Accuracy for Adolescent Idiopathic Scoliosis*

And Determination of An Optimal Search Strategy For Large Administrative Databases

Objective

1) To assess coding accuracy for surgically treated adolescent idiopathic scoliosis and 2) to determine an optimal method of ascertaining cases with a diagnosis of AIS from an administrative database using ICD-10 coding.

Contribution

This is the first paper to assess coding accuracy for surgically treated adolescent idiopathic scoliosis with ICD-10 codes. ICD-10 codes, the standard method of hospital coding in Canada, is also being implemented by the American Centers of Medicare and Medicaid Services in 2013 (159). The ICD-10 classification system has been touted as being more comprehensive with a significant increase in the number of diagnostic classification codes compared to ICD-9. However, this paper provided insight into the limitations of ICD-10 coding definitions for AIS coding and provided an optimal search strategy, by combining codes, to maximize the capture of surgical AIS cases in administrative databases. Understanding and maximizing coding accuracy is important in capturing surgical AIS cases from administrative databases. This paper provides direct evidence on the importance of combining diagnostic codes using Boolean "OR" functions when performing ICD-10 searches when there is more than 1 valid diagnostic code such as in the case of AIS.

PAPER 3. *The Impact of Surgical Volume on Adverse Events For the Treatment of Adolescent Idiopathic Scoliosis. A National Canadian Perspective*

Objective

To determine: 1) what type and rate of adverse events occur with surgical treatment of AIS, and 2) if there were lower rates of adverse events in centers performing higher volumes of AIS correction surgery.

Contribution

This is the first paper to provide national Canadian data on adverse event rates for AIS surgery. Canada with universal health coverage and no option for private treatment, is an ideal setting to comprehensively capture all patients having surgery for AIS. Furthermore, most literature on adverse event rates focused on adult patients. The limited research on volume – outcome studies on pediatric AIS surgery had utilized data obtained either through a self report registry in the United State, through regional administrative databases such as the State of California discharge database that includes both publicly and privately funded patients of many etiologies, or through national data that includes adult scoliosis surgery (19;19;22;124). In addition, most prior studies on AIS surgery and adverse outcomes, many of which reported inverse volume - outcome relationships, used single level multi-regression analysis. While prior studies (focusing on ICU, cardiac and general surgery patients) have stressed the importance of appropriate analyses(132;133;160-166), conventional single level multi-variate regression analysis, appears to overestimate the treatment benefit of hospital volume on outcome(132;133). Hierarchical modeling takes into account the nesting of patients within hospitals. This is the first paper to examine volume outcome relationships in AIS surgery using both single level multi-regression

analysis and hierarchical modeling thereby highlighting the differences between hierarchical modeling versus conventional single level modeling.

5.2 Healthcare Quality Improvement for AIS Surgery Using the Principles of "Crossing the Chasm"

Safety

The Institute of Medicine (IOM), in their publication, "Crossing the Chasm" recognized the tremendous gap or chasm between the reality of healthcare provided and what was desired. The paper outlined the importance of healthcare quality improvement (QI) for the 21st century and emphasized 6 elements using the acronym STEEEP – 1) **S**afety, 2) **T**imely, 3) **E**fficient, 4) **E**quitable, 5) **E**ffective and **P**atient Centered. This thesis focused on the first two items. Safety refers to avoidance of injury to patients from the care that is intended to help them. Timeliness refers to reduction of waits and harmful delays.

The first component, "Safety", is an ongoing concern for health care providers. Health policy changes have the potential to improve safety at a national or provincial level. In this thesis, the impact of volume – outcome relationships for adverse events was examined. Conventional methods of analysis demonstrated a significant inverse volume – outcome relationship for adverse events, wound infections and needing a transfusion. If valid, this conclusion would have provided a rationale for regionalization of care or volume recommendation rules. Many organizations have recommended having surgeries performed at high volume centers specifically centers meeting some minimum volume thresholds. After using appropriate analyses, no volume – outcome relations was demonstrated. This emphasizes the importance of performing an appropriate statistical analysis.

While there was no volume – outcome relationship for most outcomes, one statistically significant difference was that volume was related to length of ICU stay. Intensive care unit literature has demonstrated significant inverse volume outcome relationships and it has been suggested that higher volume centers are better at "rescuing patients" should they experience a complication following surgery (69;70;167). In fact, it is hypothesized, that the inverse volume – outcome relationships found in high risk general surgical procedures, is predominantly due to differences in care from the ICU. In this study, whereby patients treated at higher volume centers experienced shorter stays in the intensive care unit compared to lower volume centers possibly due to better "rescue". However, it becomes even more complicated because the type of ICU may also effect outcome. While not examined in this thesis, other studies have reported that pediatric patients looked after within adult ICUs may have worse outcomes relative to pediatric patients treated in pediatric specific ICUs (75;80). Furthermore, in other specialties, adult patients "boarded" or placed in a non – ideal specialty ICU, have poorer outcomes including increased mortality and longer lengths of stay; such as a patient with an acute myocardial infarction being "boarded" in a neurosurgical intensive care unit (168). Based upon this thesis and evidence from other studies, it can be tentatively recommended that AIS patients should have access to pediatric ICUs postoperatively.

A limitation of this study is that the data used was administrative and thus no clinical risk adjustment was performed. In the ICU literature, Kahn et al. showed differences in volume – outcome relationships based upon appropriate risk adjustments with administrative data (no significant relationship) versus administrative data combined with clinical risk adjustment in non-surgical mechanically ventilated patients (169). In the case of AIS surgery, degree of curve magnitude, curve stiffness and type of curve pattern was not adjusted for. Hypothetically, more difficult curves are maybe more likely to be sent to higher volume centers. However, we have no

reason to suspect that occurs to the extent to completely negate a true volume - outcome relationship.

Another potential limitation of this study is that volume – outcome relationships may not be linear. For example, the relationship may initially start with an increasing upslope for low volumes followed by a plateau after a certain volume. If our study was performed on volumes after the plateau occurs, no volume outcome relationship would have been found. However, we analyzed a wide range of volumes in our analysis ranging from over 66 cases per year to under 10 in the lowest quintile.

When considering policy there are potential negative consequences when considering regionalization while not explored in this thesis, possible consequences including strain placed on families when patients are treated away from the local hospital at a distant regional center(73;153). Parents have been shown to be more willing to travel, if there were significant differences in outcomes such as mortality between the regional center and the local hospital (i.e. 9.7% versus 18%)(73). However, if outcomes were similar, 82.5% of parents wanted treatment at their local hospital. Parents were also less willing to travel when travel time increased from 2 hours to 4 hours. Lack of immediate access to care has the potential to adversely affect care. Furthermore, regionalization may result in down scaling of services at the peripheral centers to bring resources to the regional hospital. This may then result in harming of patients at the down scaled center that may have benefited from the additional local resources(75).

Timeliness

"Timeliness" is a significant issue in Canada with its waiting lists for surgery including children (170). This study, performed at the Hospital for Sick Children, with significant surgical

volumes, was an optimal location to assess the impact of waiting on outcomes. The first study showed that waiting too long for AIS surgery can have detrimental effects, especially in younger patients who are skeletally immature with larger baseline magnitude curves due to curve progression. The empiric determination of an access target of three months, to potentially reduce adverse events is superior to a consensus based approach. Improving timeliness for AIS surgery can also impact the safety of AIS surgery, the first dimension of the STEEEP guidelines.

This empirically based access target, however, did not incorporate patient desires. It is unknown what parents and patients desire in terms of the longest potential wait or their opinion of the maximal acceptable wait time. Access targets set with some patient feedback and incorporation of their opinions would enhance patient centeredness, another dimension of the IOM guidelines. A potential study is discussed in the future research section.

5.3 Future Research

Given that there are only 7 centers in the top four quintiles for AIS surgical volume, a prospective national registry could be established for AIS surgery or pediatric deformity surgery. This registry would ideally include number of cases, radiographs, and clinical data such as skeletal immaturity, curve magnitudes, curve type, and curve flexibility or stiffness. Along with clinical data, the registry can also contain the CIHI-DAD submission sent by the hospital's health records department to CIHI. The Rick Hansen Spinal Cord Injury Database is an example of a national Canadian database that is prospectively capturing clinical information of spinal cord injured patients in all major trauma centers in Canada, combined with their CIHI-DAD fields.

With more complete clinical data, the volume – outcome relationship for AIS surgery can be better assessed including clinical risk adjustment - such as curve type, magnitude, and curve

flexibility/stiffness. As noted above, modeling should be performed both using single level multi - variate analysis and hierarchical modeling. Further research also needs to be performed to optimize strategies to reduce wait times. As discussed by Wright et al (171), a multifaceted approach is needed to reduce wait times. Wright et al. describes five aspects of care needed to reduce wait times. Firstly, an effective referral management must be in place involving the family physician or pediatrician identifying the diagnosis to the referral being made and then having the patient being assessed by the specialist. Currently, the wait time periods prior to surgery (W1 time in Ontario) and the impediments to timely referral are unknown. Secondly, a wait list monitoring system for both W1 time and W2 time is needed with appropriate data quality. It is not known how wait times vary regionally across Canada. Accurate data will allow for identification of these regional differences and changes associated with new health policies implemented over time. Thirdly, wait time information needs to be shared amongst physicians, institutions and patients. Additional research can be performed on impact of sharing wait time information (W1 time and W2 time) on physician referral patterns. Does knowledge of a prolonged wait time at an institution influence where physicians refer patients to? Will physicians tend to refer patients to centers with lower wait times when they have an accurate knowledge of wait lists? Will patients demand referrals to shorter wait list centers? And fourthly, Wright et al. discussed the importance of identifying resources available for surgery along with optimizing efficient usage. For AIS, a national survey would be beneficial in providing an overview of the number of ICU beds, physicians, type of ICU (pediatric ICU or shared with adult patients), presence of a multidisciplinary care teams, care pathways for post operative recovery, geographical region treated and intra-operative tools such as neuro-monitoring and availability of cell saver during surgery. Furthermore, this information can provide an overview in the variability of resources across the country and help with additional

funding of centers with low resources – reducing variability in care. Similar healthcare should be obtainable in Canada, regardless of geographic location, given the Canada Health Act prohibiting patient access to private care.

Additionally, studies can be carried out to assess patient and family perspectives on access targets for AIS surgery. The study can be both qualitative but also incorporate a quantitative aspect, where patient and/or parents are offered a hypothetical choice between quicker access to surgery with a higher risk for an adverse event, versus a substantially longer wait along with a lower risk for an adverse event. Wait times can the be shifted systematically, until the patient abandons their first choice, providing a patient's perspective on a maximal acceptable wait time. This study would provide the diverse range of patient acceptable access targets, but also the median time.

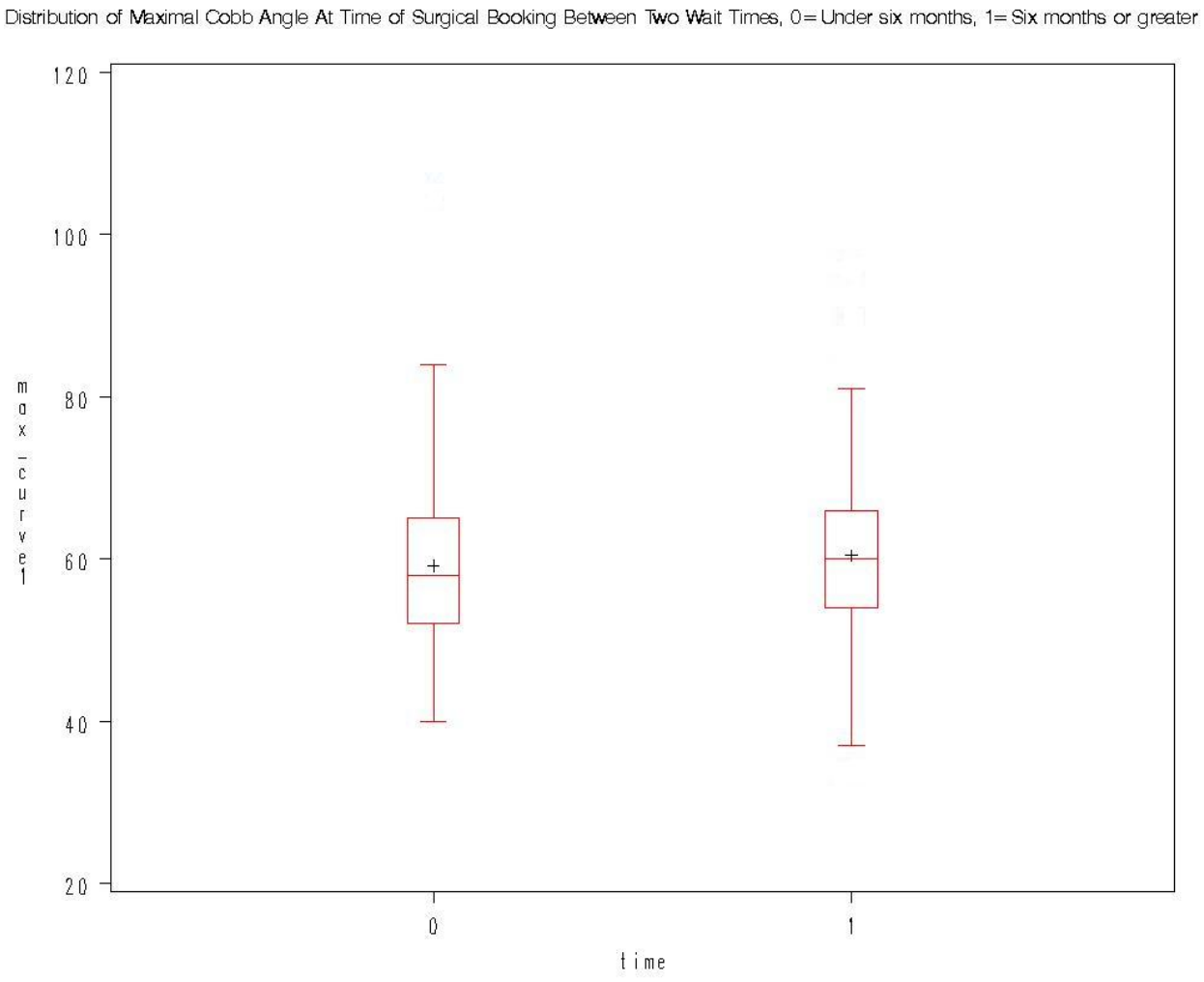
Lastly, there is no formal method of prioritizing patients for AIS surgery in Canada. As a result, a clinical severity score, utilizing clinical factors such as skeletal immaturity, magnitude, gender, etc that are risk factors for progression, combined with the patient/parent perspective on wait, can be created. Patients would then be placed onto the waiting list with a clinical severity score. Ideally, the goal would be to treat patients with the highest risk to progress as early as possible rather than treating patients on a first in – first out basis which is likely occurring currently.

5.4 Conclusion

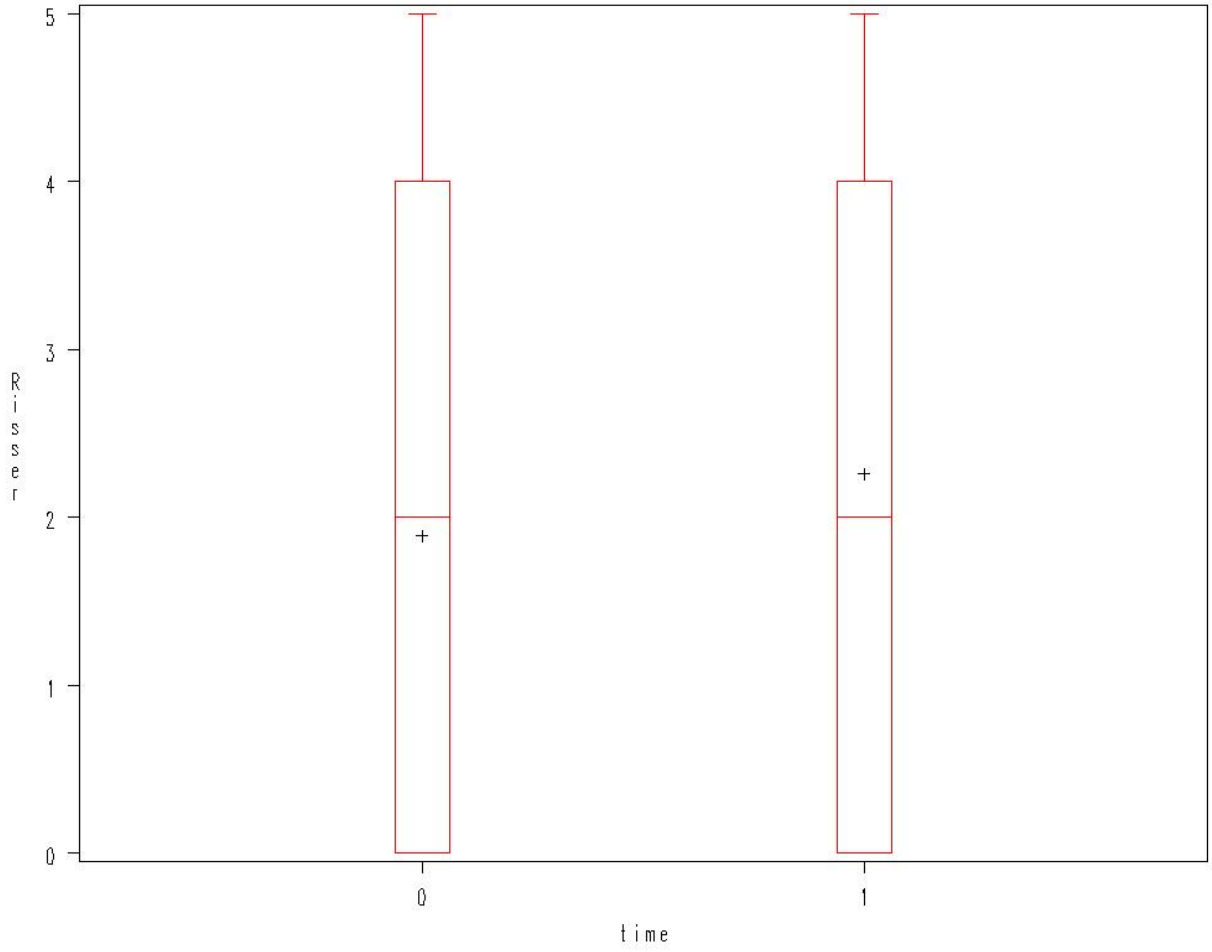
Overall, further steps can be taken to help improve the quality of care for AIS surgery through the implementation of the IOM's dimensions of care reflected in their STEEEP acronym. Based upon this thesis, "Timeliness" has been shown to be an important factor with increased adverse events associated with prolonged surgical wait times for AIS surgery. Adverse events may be reduced by ensuring patients meet the empirically based access target of three months. AIS is a progressive disorder during adolescence and timely access may prevent curve progression that requires additional surgery. Timely surgical access can be encouraged with incentives to the hospital and surgeon(57;172). Using administrative databases to identify all surgical AIS cases to examine adverse events, requires a combination of AIS codes with a Boolean "OR" function, due to the lack of clear ICD-10 definitions. Additionally, based upon this thesis, "Safety" would probably not be improved with having AIS surgery in higher volume centers compared to lower volume centers. Based upon the thesis results, formal health policies dictating regionalization of care or minimum volume thresholds for AIS surgery cannot be advocated.

Appendices

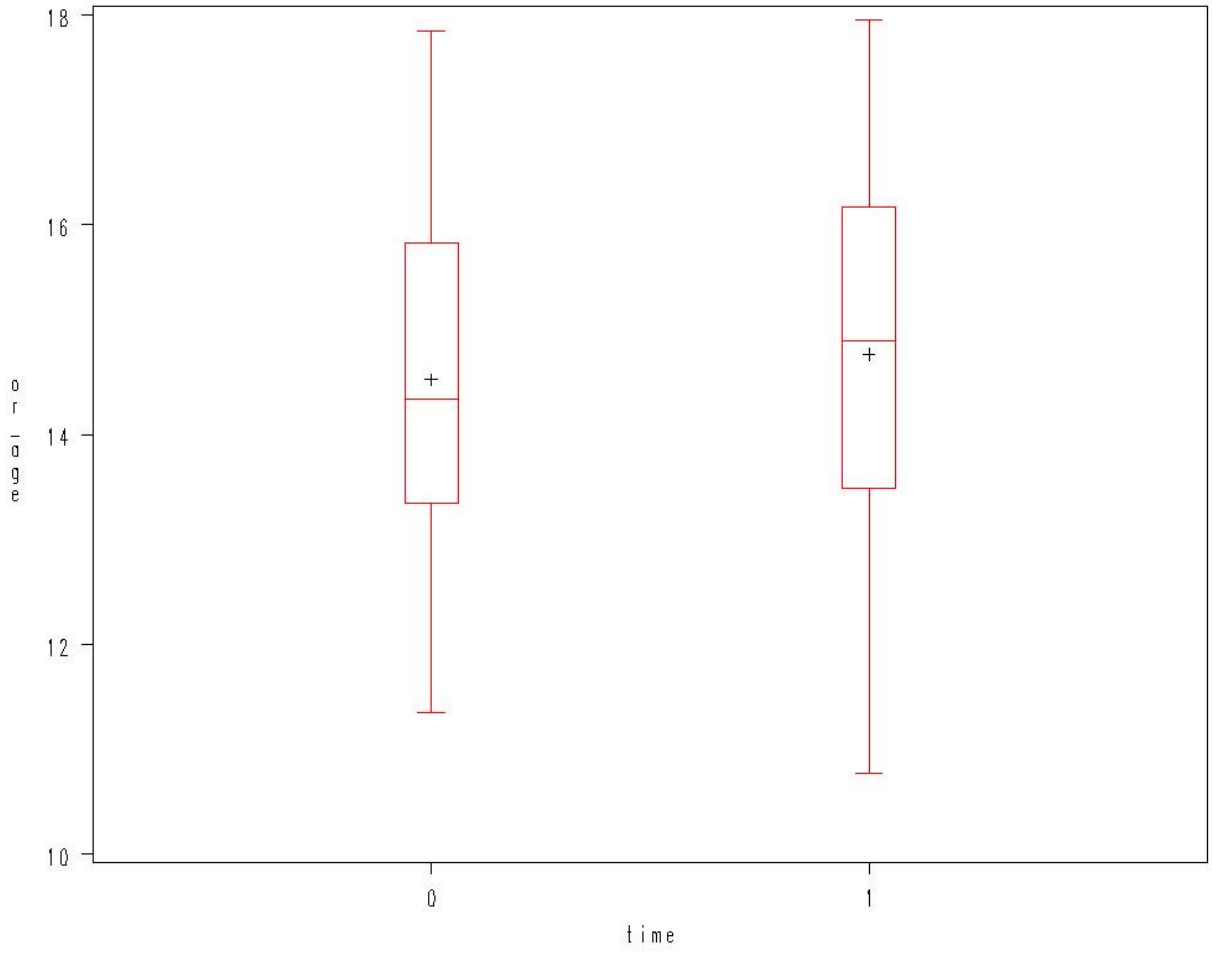
Appendix 1 Boxplots of variables from Project 1 (chapter 2) showing similar distribution.



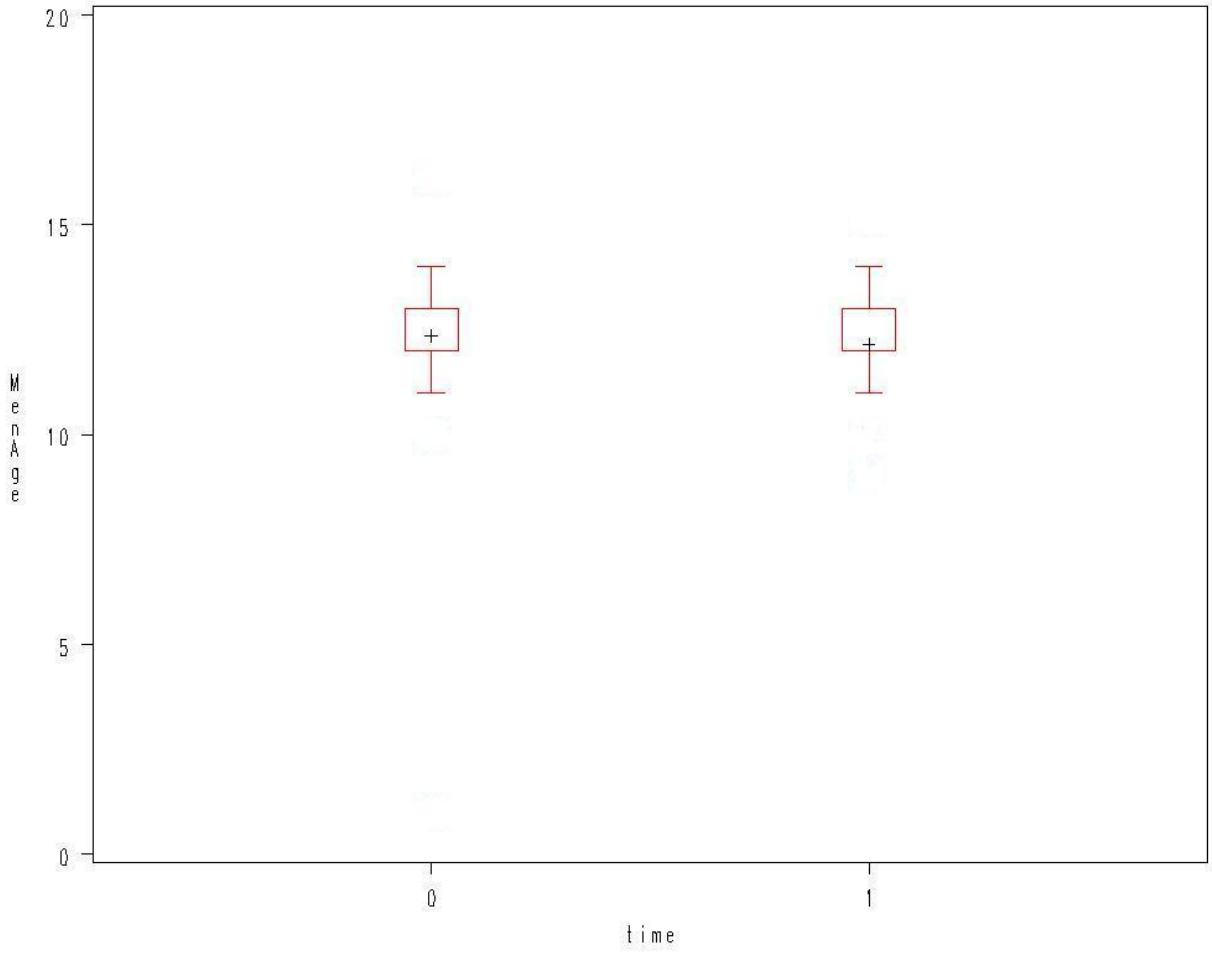
Distribution of Risser Score Between Two Wait Times, 0= Under six months, 1= Six months or greater



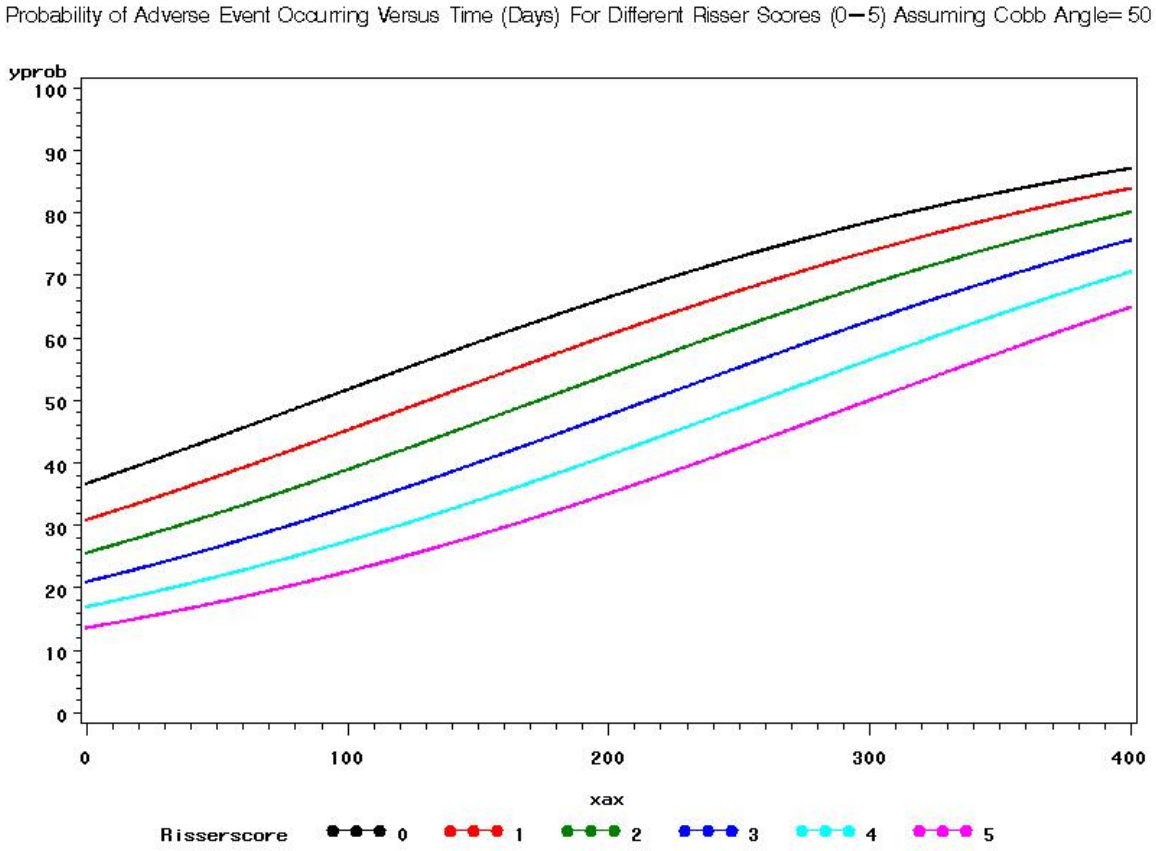
Distribution of Age At Consent Between Two Wait Times, 0= Under six months, 1= Six months or greater



Distribution of Menarchal Age Between Two Wait Times, 0= Under six months, 1= Six months or greater

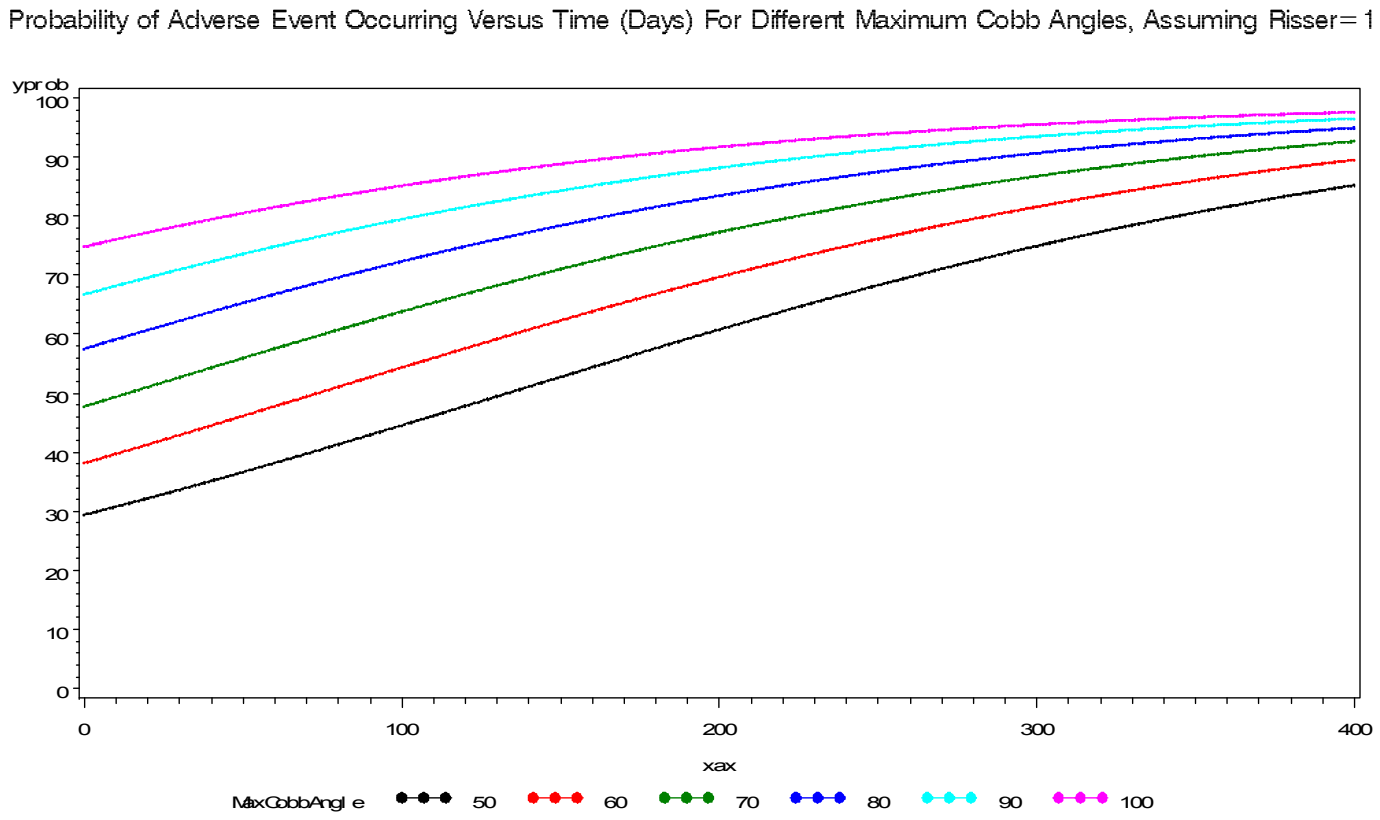


Appendix 2 Probability of adverse event occurring for different risser scores



The theoretical probability (based on the logistical regression analysis) of an overall adverse event (yprob) plotted against increasing surgical wait times (xax), assuming the Cobb angle at time of surgical consent was 50 degrees, for various Risser scores (as shown by the different colored lines). For a given waiting time, the lower the Risser score which reflects skeletal immaturity, the higher the probability of an adverse event occurring. The adverse events included additional surgery, more then 10 degrees of curve progression, less than 50% curve correction, need for blood transfusion, prolonged surgical time, and peri-operative neurologic injury.

Appendix 3 Probability of an adverse event for different maximum cobb angles



The probability of any adverse event was plotted against a clinically relevant range of curve magnitudes across increasing surgical wait times for patients with a Risser score of 1. For a given surgical wait time, the larger the Cobb angle when consent was obtained (as shown by the different colored lines), the larger the risk of an adverse event (yprob). The adverse events included additional surgery, more then 10 degrees of curve progression, less than 50% curve correction, need for blood transfusion, prolonged surgical time, and peri-operative neurologic injury.

Copyright Acknowledgements

None.

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