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The Adolescent Idiopathic Scoliosis International Disease Severity Study: Do Operative Curve Magnitude and Complications Vary by Country?

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Abstract

Background: The prevalence of adolescent idiopathic scoliosis (AIS) in diverse regions of the world has been studied. Access to care varies widely, and differences in disease severity and operative treatment outcomes are not well understood. This study aimed to determine variation in disease presentation and operative complications for AIS patients from an international cohort.

Methods: This is a retrospective study carried out at seven surgical centers in the United States (Manhattan and Miami), Ghana, Pakistan, Spain, Egypt, and China. A total of 541 consecutive patients with AIS were evaluated. Preoperative major curve magnitude, operative parameters, and complications were compared among sites using analysis of variance with post hoc tests and Pearson correlation coefficients. Univariate and multivariate forward stepwise binary logistic regressions determined the variables most predictive of complications.

Results: Countries with lowest-access to care (Ghana, Egypt, and Pakistan) displayed larger curves, more levels fused, longer operative time (OT), and greater estimated blood loss (EBL) than the other countries ($p \leqslant .001$). Increasing curve magnitude was correlated with greater levels fused, longer OT, and greater EBL in all groups ($p = .01$). In the univariate regression analysis, Cobb magnitude, levels fused, EBL, and OT were associated with complication occurrence. Only OT remained significantly associated with complication occurrence after adjusting for Cobb magnitude, levels fused, and site (odds ratio [OR] = 1.005, 95% confidence interval 1.001-1.007, $p = .003$). Complications were greatest in Pakistan and Ghana (21.7% and 13.5%, respectively) and lowest in Miami (6.5%).

Conclusions: Larger curve magnitudes in the least-access countries correlated with more levels fused, longer OT, and greater EBL, indicating that increased curve magnitude at surgery could explain the difference in operative morbidity between low- and high-access countries. With OT as the prevailing predictive factor of complications, we suggest that increased curve magnitude leads to longer OTs and more complications. A lack of access to orthopedic care may be the largest contributor to the postponement of treatment.

Level of Evidence: Level II.

Keywords: Disease severity; Adolescent idiopathic scoliosis; Operative treatment outcomes; International; Operative complications

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Introduction

Adolescent idiopathic scoliosis (AIS) is the most common pediatric spinal deformity confronting orthopedic surgeons worldwide [1]. Early detection of the disease allows for timely nonoperative intervention or observation and is impacted by health care infrastructure and treatment norms.

A wide range of studies have documented the varied scoliosis prevalence globally [2-9]. A meta-analysis indicated that scoliosis prevalence increases in the northern geographic latitudes and decreases when approaching the equator, ranging from 0.93% to 12% [10]. These variations may be due to differences in clinical examination methods and age group selected; however, they may reflect real differences in geographical prevalence [10]. Variations in access to routine health care, scoliosis screening, and treatment differences, especially bracing, also exist internationally [11-13].

Surgical treatment availability for scoliosis ranges from readily available private and public insurer funding and access to multiple experienced surgeons to little or no funding and no access to adequately trained surgeons. Differences may exist in surgical cost and length of stay (LOS) even within different regions of the same country, despite relatively uniform surgical approach and techniques [14]. These barriers are further compounded by the high cost of scoliosis surgery [15,16].

Therefore, a global, multicenter study of surgical AIS patients from seven spine centers in the United States, Spain, China, Pakistan, Ghana, Egypt, and China was conducted. The study aimed to compare preoperative major curve magnitude, operative variables, and complications among an international cohort. This is an effort to explore disease severity and operative characteristics of AIS surgery in various countries, the influence of these factors on outcomes, and the role of access to care. We propose that variability in disease severity will have an influence on outcomes.

Materials and Methods

This is a retrospective study carried out at seven surgical centers in Manhattan (New York), Miami (Florida), Accra (Ghana), Karachi (Pakistan), Barcelona (Spain), Cairo (Egypt), and Nanjing (China). All operations were carried out between 2005 and 2008, with some from 2013 to 2014 for the China site only. A total of 541 consecutive patients were evaluated: New York, 94; Miami, 84; Ghana, 88; Pakistan, 25; Spain, 43; Egypt, 59; and China, 149. IRB approval was obtained at each institution. The indication for surgery in all cases was AIS, age 10–21 years, which was progressive or of curve magnitude greater than 45° at presentation.

Standard demographic, operative, radiographic data and early complications occurring within the period of hospitalization or within the first three months postoperatively were collected for each patient. Operative time (OT), LOS, and estimated blood loss (EBL) data were not available from Ghana. Approach to surgery included posterior only, anterior only, and combined approaches. Types of instrumentation used included all–pedicle screws constructs, pedicle screw-hook, and sublaminar wire hybrids. Complications were reported as one "major complication" umbrella variable that included surgical site infections, implant issues (reoperation required), neurologic complications, and other major complications.

Descriptive statistics were performed with an analysis of variance with post hoc tests (Bonferroni). Pearson correlation coefficients were calculated to determine the relationship between all continuous variables; Spearman correlation coefficients were calculated for the categorical variable of "approach" ($p < .05$). The impact of Cobb magnitude, levels fused, OT, EBL, surgical approach, and geographic site on the occurrence of complications was evaluated; first using a univariate binary logistic regression, followed by entering significant predictors into a multivariate forward stepwise binary logistic regression. Alpha was set at $p \leqslant .05$ to declare significance.

Results

We found significant differences ($p \leqslant .001$) between age, gender, approach, levels fused, percentage pedicle screw constructs used, osteotomies, OT, EBL, and LOS among the six groups (Table 1). Those patients at the Ghana site were the oldest (16.9 years old) and had the largest mean preoperative curve magnitude (72°) ($p \leqslant .001$). All sites reported more than 60% female patients. The smallest curve magnitudes were from New York and China (52.1°, 54.5°).

All groups differed significantly on surgical approach ($p \leqslant .001$) (Table 1). New York and Egypt had significantly more anterior cases (20.4%) than other sites, including 2.3% in Spain and 0% to 1% at all other sites. Egypt had significantly more combined procedures (56%) than all other groups (all <11%). Spain, Pakistan, Miami, and China had greater than 95% posterior cases; 81.8% of all cases among the groups were posterior only.

Table 1
Demographic and surgical data, by country.

	Egypt	Ghana	Miami	New York	Pakistan	Spain	China	Significance (p)
N	59	88 (82)	84	93	25	43	150	n/a
Age	13.8	16.9	14.3	15.2	13.2	15.1	14.8	⩽.001
% female	—	72	82	64	60	93	84	⩽.001
Curve magnitude (°)	63.1	71.5	56.7	52.1	64.7	61.2	54.5	⩽.001
Approach								
Posterior (%)	44.1	92.1	100	68.6	100	95.3	99.3	⩽.001
Anterior (%)	20.4	0	0	20.4	0	2.3	0.7	⩽.001
Combined (%)	10.8	7.9	0	10.8	0	2.3	0	⩽.001
Levels fused	10.6	10.7	9.6	8.7	13	9.7	10.6	⩽.001
Operative time (min)	302.9	—	189.4	216.6	473.9	262.3	255.4	⩽.001
EBL (mL)	1,188.8	—	617.4	1,029.4	1,402	1,837.4	880.8	⩽.001
Constructs used (% all pedicle screw/hybrid)	53/47	25/75	100	100	40/60	44/56	100	⩽.001
Osteotomies (%)	—	0	71.4	43.3	0	6.9	4.7	⩽.001
LOS (days; range)	—	—	5.8 (5-8)	5.2 (3-19)	11.6 (8-14)	10.4 (5-37)	28.7 (13-167)	⩽.001

EBL, estimated blood loss; LOS, length of stay; n/a, not available.

Levels fused also varied between sites; Pakistan fused the most levels [13], followed by Ghana (10.7; p ⩽ .001). Pakistan fused approximately four more levels than the least levels fused—8.7 in New York. Pakistan had the second largest curve magnitude, the longest OT and a higher EBL than most sites (473.9 minutes; 1402 mL). New York had the smallest curve magnitudes, shorter OT and lower EBL than most sites (216.6 minutes, 1,029.4 mL). Ghana used the most hybrid constructs and the US sites and China used exclusively pedicle screw constructs.

There was wide variation in LOS data between the sites (unavailable for two sites). LOS was longest in China (28.7 days) where most patients travel long distances for their surgery and therefore often live in the hospital for weeks before the operation. This time before surgery could not be separated from the postoperative LOS in this retrospective assessment, however, as it contributes to cost and possible outcomes; regardless, we included the variable.

Correlation coefficients are reported for curve magnitude, EBL, levels fused, OT, and LOS (Table 2). Increasing curve magnitude was significantly correlated with greater levels fused, longer OT, greater EBL, and a longer LOS. The combined approach was not well correlated with increased EBL and OT. Increased OT was correlated with more levels fused, greater EBL, and a longer LOS. Increased EBL was also correlated with more levels fused and a longer LOS. Missing data from the Ghana site prevented calculation of certain relationships. Pakistan was the only country that did not follow any of the trends noted above.

Complications were greatest in Pakistan and Ghana (21.7% and 13.5%) and lowest in New York and Miami (7.1% and 6.5%); however, these values were not significantly different (p = .21) (Table 3). It should be noted that one postoperative tracheostomy (Cobb: 98°), one case of excessive bleeding and hemodynamic instability requiring cessation of surgery and subsequent reoperation, and one intraoperative anoxic brain injury due to excessive blood loss (Cobb: 70°) were recorded in Ghana, which had the highest rate of ''other'' major complications (9.46%).

In the univariate regression analysis of predictors of complications, Cobb magnitude (odds ratio [OR] = 1.02, p = .02), levels fused (OR = 1.26, p = .008), and OT

Table 2
Correlations between surgical variables, by site (reported *R* values).

Variables correlated	Egypt	Ghana	Miami	New York	Pakistan	Spain	China
Cobb–approach	NC	NC	NC	NC	NC	−0.310**	NC
Cobb–levels fused	0.544*	0.425*	0.513*	0.438*	NC	0.402*	0.326**
Cobb–operative time	0.734*	—	0.423*	0.612*	NC	0.425*	0.451**
Cobb–EBL	NC	—	0.424*	0471*	NC	0.489*	0.333**
Approach–levels fused	NC	NC	NC	NC	NC	NC	NC
Approach–operative time	NC	—	NC	NC	NC	NC	NC
Approach–EBL	NC	—	NC	NC	NC	NC	NC
Levels fused–operative time	0.586*	—	0.524*	0.466*	NC	0.471*	0.436**
Levels fused–EBL	NC	—	0.467*	0.477*	NC	0.459*	0.457**
Operative time–EBL	NC	—	0.490*	0.631*	NC	0.452*	0.416**

EBL, estimated blood loss; NC, variables not correlated.
All correlations involving the ''Approach'' variable were Spearman correlations. All other correlations are Pearson correlations.
*p = .01; **p = .05

Table 3
Complications.

	Egypt	Ghana	Miami	New York	Pakistan	Spain	China
% complications (total)	8.6	13.5	6.5	7.5	21.7	12.2	8.7
Neurologic complications, n (%)	0	1 (1.35)	0	0	1 (4.34)	0	1 (0.7)
Infections, n (%)	3 (5.17)	1 (1.35)	0	3 (3.22)	2 (8.69)	2 (4.76)	0
Implants, n (%)	1 (1.72)	1 (1.35)	4 (4.76)	0	2 (8.69)	2 (4.76)	10 (6.7)
Other major complications,* n (%)	1 (1.72)	7 (9.46)	2 (2.38)	3 (3.22)	0	2 (4.76)	2 (1.3)

* "Other major complications" included pleural spillage, transient femoral nerve affection, hematoma with drainage, hemothorax, superior mesenteric artery syndrome, dural tear, paraspinal drainage, proximal jejunal kyphosis, retained item, tracheostomy, hemodynamic instability, and brain anoxia.

Table 4
Summary of findings from univariate binary logistic regression evaluating individual predictors of complication occurrence.

	Odds ratio	p value
Major Cobb magnitude	1.02	**.02**
Levels fused	1.26	**.008**
Operative time	1.004	**.006**
Estimated blood loss	1	.08
Approach	0.85	.685
Site 3: NY (indicator)	*	.221
Site 1: Spain	2.42	.148
Site 2: Egypt	1.37	.619
Site 4: Miami	1.12	.855
Site 5: Pakistan	**4.03**	**.034**
Site 6: Ghana	2.27	.131
Site 7: China	1.26	.650

The bold p values are statistically significant as they are below .05
* Not calculated for indicator variable.

(OR = 1.004, p = .006) were individually significant predictors of complication occurrence (Table 4). EBL did not reach significance. Each site was entered into a univariate binary logistic regression, with the site with the lowest complication rate (Miami) as the indicator variable. Pakistan had a significantly greater odds of a complication compared with Miami (OR = 4.03, p = .034); however, none of the other sites had significantly greater odds of complication. When site, Cobb magnitude, levels fused, and OT were entered into the multivariate regression, only OT remained a significant predictor of complication occurrence (OR = 1.00, 95% confidence interval 1.001-1.007, p = .00; Table 5).

Table 5
Summary of findings from multivariate forward stepwise logistic regression identifying remaining significant predictor of complication occurrence.

	Odds ratio	p value
Major Cobb magnitude	1.01	.39
Levels fused	1.09	.40
Operative time	1.00	**.00**
Site 3: NY (indicator)	—*	.84
Site 1: Spain	2.14	.24
Site 2: Egypt	0.95	.94
Site 4: Miami	1.37	.63
Site 5: Pakistan	1.23	.84
Site 6: Ghana	n/a†	n/a†
Site 7: China	1.16	.80

The bold p values are statistically significant as they are below .05
* Not calculated for indicator variable.
† This site was dropped from the multivariate analysis because of missing operative time.

Discussion

Disease severity for AIS as represented by curve magnitude at presentation for surgical treatment and postoperative complications has implications regarding the nature of a country or region's health care infrastructure, treatment strategies, and the potential morbidity associated with surgical intervention. Little research has been performed on geographic variations in scoliosis from a global perspective. Only one international comparison study identified differences in preoperative AIS health-related quality of life between Japanese and American adolescents with similar curve magnitudes [17]. We sought to take a first look at differences in AIS disease severity in seven spine centers around the world.

In this study, Ghana, Pakistan, and Egypt had significantly larger preoperative curves (71.5°, 64.7°, and 63.1°, respectively) than the other countries represented; this could be attributed to increased curve progression because of poor access to care, delayed referral to specialists, and a reliance on homeopathic medicine. It is well established that patients from developing countries have difficulty accessing surgical care, either due to a lack of available trained surgeons, climates that make bracing impractical, financial barriers, or cultural norms discouraging certain treatments [18]. Access to care is often assessed by proxy variables of number of hospital beds per 10,000 people and number of doctors per 1,000 people, as reported by the World Health Organization (WHO). The lowest numbers are found in Africa and the Middle East (<1 bed, 0.25 doctors). In contrast, Europe has 64 beds and 3.3 doctors: Americas 25 beds and 2.0 doctors [18-20]. Luboga et al. showed the impact of such impediments to care: the overall disease burden associated with surgical conditions in sub-Saharan Africa is estimated at 38 disability-adjusted life years (DALYs; years of life lost due to disability, poor health, or early death due to disease) lost per 1,000 people, the highest in the world [18,21]. Surgical conditions have been suggested to be the next so-called neglected disease in developing countries now that HIV infection, tuberculosis (TB), and malaria are being spotlighted [22,23].

Table 6
Access to health care: variables of interest in comparing health care access among different countries.

	Egypt	Ghana	United States	Pakistan	Spain	China
Largest provider in health care system	Public	Public	Mixed	Private	Public	Mixed
No. of doctors/1,000 people	2.4	1	˜2.7	<1	4	1.9
Health expenditure as % GDP	6%	5%	15%	0.7%	8.5%	5.6%

GDP, gross domestic product.

Reports on access to care in the countries included in this study paint a complex and diverse picture of health care standards. Low-access countries tend to display a large gap in access depending on income, compounded by a relative lack of operative resources [18,23]. Surgical care is often neglected in low-access countries because of shortfalls in infrastructure, supplies, and procedures undertaken, despite being cost-effective [24]. Countries spending the least money (US$100 per capita) on health care perform approximately 295 major surgical procedures per 100,000 people each year, whereas countries spending the most (>$1,000 per capita) have a surgical rate of 11,110/100,000 [25]. Research shows that spending on basic surgical care compares favorably (USD$11–33/DALY averted) with vaccinations (USD$5/DALY averted) and is more cost-effective than antiretroviral therapy (USD$300–500/DALY averted), even assuming high HIV prevalence [22]. The nature of the health care system and expenditures in each country in this study are described in Table 6.

Cultural reasons may also contribute to the postponement of surgical treatment. Body-covering cultural dress in largely Muslim countries (such as Egypt and Pakistan) may lead to delayed identification [26]. Traditional beliefs about medicine, social stigmas, poverty, and illiteracy also impact access to health care in rural Ghana [27]. As a greater proportion of AIS patients are female, gender discrimination in access to health care in some countries may compound the aforementioned factors [28,29].

No clear trend was noticed in terms of age at operation and country of origin. The youngest patients were from Pakistan and Egypt: we had expected the youngest patients to come from the United States where children are regularly examined by their pediatrician, scoliosis screening exists, and bracing is widely practiced [30-33]. Despite criticisms against the efficacy and usefulness of screening, the use of screening methods to offset differences in early access to speciality care internationally should be investigated.

A clear impact of country of origin on operative parameters and complications was noted in this study, although the differences in complication rates did not reach statistical significance probably because of inadequate sample size. However, the nature of the complications tended to be graver in developing nations with, for example, a report of postoperative tracheostomy and anoxic brain injury in two patients in the Ghana site. Countries in the low-access category (Egypt, Pakistan, and Ghana) tended to fare worse on multiple parameters when compared with those higher-access countries (China, Spain, United States).

Approach was not statistically related to any operative parameters, likely as a result of an overwhelming preference for the posterior approach. The relationship between OT and approach was inconsistent. Egypt took 302 minutes/case, but 44% of their surgeries were combined; in contrast, Pakistan performed no combined cases and had the highest OTs. Hee et al. compared posterior and anterior approaches and found that OT was significantly shorter in the posterior group [34]. Combined procedures are known to have longer OTs than single approaches, ranging from 420–720 minutes in one series; therefore, our results were unexpected [35-37]. Surgeon experience and technique may account for the inconsistent OT differences based on approach.

Levels fused was found to be correlated with curve magnitude at all sites, except Pakistan, which was surprising given the greater number of levels fused and large preoperative curve magnitude compared with the other sites. A much greater number of levels fused at that site, 13 compared with the second greatest of 10.7 levels in Ghana and 10.6 in Egypt, was noted. Longer fusions to a more stable level to avoid junctional progression and because of concern that patients would not return for follow-up as a result of limited health care resources, a concern also reported for cancer patients in India [38].

Although centers outside the United States used more hybrid constructs, the data were collected over a time period in which the superior curve correction and lower revision rates afforded by pedicle screws was accepted in high-access countries [39]. Also, pedicle screws were initially too expensive for some countries with later availability of ‘‘generic,’’ low-cost implants or pricing differentials of branded implants. In Ghana, all implants were donated; therefore, there was some rationing of the more expensive screws and more use of the less-expensive wires and hooks, explaining the 75% hybrid construct rate.

OT was significantly longer in Pakistan and Egypt than in Spain and the United States. Surgeon experience has been shown to be a crucial factor in reducing OT, EBL, and outcomes [40,41]. Lonner et al. reported the learning curve associated with thoracoscopic spine surgery and thoracic pedicle screw placement [39,40]. Lower OTs in the United States and Spain could be attributed to a greater number of surgeons with a subspecialization within spine.

EBL in the United States was significantly lower than in Spain and Pakistan; this difference could be attributed to

increased emphasis on blood conservation. These procedures included extensive use of electrocautery, antifibrinolytics, hypotensive anesthesia, and topical thrombin, all of which may account for EBL variability [42]. EBL was greatest in countries with the most combined approach cases, which are known to have greater EBL [43]. Greater EBL was correlated with increased curve magnitude, more levels fused, longer OT, and increased LOS, suggesting that disease severity is a likely factor in EBL variability across groups. Greater curve magnitude, increased EBL, and longer OT were associated with increased LOS, indicating that the more severe cases required a longer hospital recovery.

Percentage complications ranged from 6.5% to 21.7% (Miami and Pakistan, respectively). The category of ''other major complications'' was the most common, varying from 0% to 9.46% (Pakistan and Ghana, respectively). This category included life-threatening complications, with the most severe cases occurring in Ghana. Infections (ranging from 0% in China to 8.7% in Pakistan) and implant problems requiring reoperation (ranging from 0% in New York to 8.69% in Pakistan) were the next most common. The SRS Morbidity and Mortality Committee reported a complication rate of 5.2% in anterior spinal fusion and in 5.1% posterior spinal fusion cases in the AIS population and ~10% in combined approach cases, which is consistent with our US-reported data [44].

The univariate analysis indicated that the major Cobb angle, levels fused, and OT were individual, significant predictors of complications at all sites; however, when the factors were compared with one another in the multivariate regression analysis, only OT was statistically predictive of complications. It is most likely that these three variables are highly interrelated and that OT is simply the variable with the narrowest, most reliable confidence intervals and predictive power of complications. It should be noted that the consistency of the reporting of complications data is not known, and therefore the conclusions drawn should be considered a preliminary evaluation. It is reasonable to conclude that milder curves at the time of surgery may be associated with lower major complication rates given this data.

This study provides a preliminary glimpse of disparities in the severity of disease and, by implication, health care infrastructure and access to care for surgical management of AIS globally. There are a number of weaknesses of our study that could inform future research. First, not all regions of the world were represented, as only a few countries were evaluated. A more in-depth, broad study of country-wise approaches to AIS care, including medical/interventional treatment, would be informative to determine best practices from the standpoint of cost-effective, efficacious, and safe care. There were also differences in sample size as the numbers of patients evaluated per country differed. Also, the data presented is relatively dated (largely 2005–2008) with little contemporary data. Further study of more recent trends would be useful. In addition, because of the retrospective nature of this study, one cannot ascertain the completeness of data, particularly reporting on complications. Further studies should include information on the type of setting the patient came from, that is, rural, urban, or suburban, as well as other socioeconomic data (educational background, household income compared with national norms, insurance type). Finally, prior nonoperative treatment received by the patient as well as the method of detection of their scoliosis would be valuable.

Conclusion

The larger curve magnitudes in the low-access countries were correlated with more levels fused, longer OTs, greater EBL, and a longer LOS, indicating that increased curve magnitude at surgery could explain the difference in surgical variables between low- and high-access countries. With OT as the prevailing predictive factor of complications in this study, we can suggest that increased curve magnitude leads to longer OTs and more complications. These results indicate that outcomes in AIS surgery are impacted by the severity of disease at the time of surgery and may be influenced by the infrastructure and health care system of a nation.

An overall lack of access to health care, particularly specialty care in orthopedics, may be the largest contributor to treatment postponement. Though the realities of access to care and outcomes varied between the regions, by and large scoliosis surgery can be carried out relatively safely in different countries.

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