Radiographic Classification of Complications of Instrumentation in Adolescent Idiopathic Scoliosis

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Abstract In spinal deformity surgery, techniques and implants must be assessed for their safety and efficacy. Regulatory bodies, third-party payors, and patients will increasingly scrutinize treatment methods based on the frequency of adverse events. We therefore developed a classification of adverse hardware-related events using plain radiographic criteria. We analyzed the adverse events in 466 patients surgically treated for adolescent idiopathic scoliosis for a Type 1 (Lenke et al.) curve. We used plain

radiographic films to define complications as either serious radiographic adverse events or radiographic adverse events in four technique groups: posterior spinal fusion with hooks and/or hybrid systems, posterior spinal fusion using mostly pedicle screws, open anterior spinal fusion, and thoracoscopic anterior spinal fusion. We defined serious radiographic adverse events as those requiring subsequent surgery. The minimum followup was 2 years. We found a reoperation rate ranging from 4.5% (open anterior spinal fusion) to 8.8% (posterior spinal fusion with hooks); we found no difference in the incidence of serious radiographic adverse events between surgical techniques. Among serious radiographic adverse events, the most common problems were revision for lumbar progression, rod breakage, and proximal screw pullout in the anterior spinal fusions and instrumentation removal for pain and infection in the posterior spinal fusions. We propose a new radiographic system of adverse hardware-related events for patients with Type 1 adolescent idiopathic scoliosis.

Level of Evidence: Level III, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained. This work was performed at The Children's Hospital of Philadelphia and the Shriners Hospital for Children Philadelphia.

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Introduction

Over the last three decades, the surgical management of adolescent idiopathic scoliosis has changed dramatically as techniques and implants have become more sophisticated. Meanwhile, surgeons, patients, payors, and regulatory agencies increasingly demand methods to evaluate the safety of these rapidly changing techniques and implants. A comprehensive classification of adverse events would include clinical, radiographic, and outcome information. While these are valuable, they might include perioperative

complications, such as urinary tract infections or rashes, that should not be related directly to surgical techniques and implants. In addition, these comprehensive complication classifications would require information that must be gleaned retrospectively from patient charts and other sources. However, adverse event data from charts or payor information might be incomplete and subjective. If an objective, widely generalizable radiographic classification of adverse events can be adopted by scoliosis surgeons and regulatory bodies, techniques and implants can be compared and the value or danger of new methods or implants can be recognized in a more efficient manner and therefore allow for quick assessment.

We therefore developed a classification of adverse events based on objective plain radiographic data that would be available on every patient who had surgery for their adolescent idiopathic scoliosis.

Patients and Methods

This project involved two separate phases: (1) defining and categorizing different types of radiographic adverse events and (2) testing these categories on a relatively uniform group of healthy children with adolescent idiopathic scoliosis treated by different methods. We retrospectively reviewed data on 466 patients enrolled in an adolescent idiopathic scoliosis database who had treatment of a Type 1 curve as classified by the system of Lenke et al. [7]. We reviewed the entire radiographic record of each patient. All patients were followed for a minimum of 2 years after their index surgery. No patients were lost to followup; none were seen in review specifically for this chart and radiographic study.

We defined complications as either serious radiographic adverse events or radiographic adverse events. All were identifiable from the patient's radiographic record. In the case of unplanned trips to the operating room, perioperative images would signal the event and the operative note was then evaluated to identify the cause and treatment. Radiographic adverse events were defined as (1) asymptomatic loss of correction in the coronal or sagittal plane greater than 10°; (2) asymptomatic progression above or below instrumentation greater than 10°; (3) asymptomatic loss of fixation; and (4) symptomatic implant failure. Serious radiographic adverse events were defined as (1) an unplanned return trip to the operating room; (2) postoperative curve progression beyond the initial deformity magnitude (either the coronal or sagittal plane); and (3) pain, prominent implants, progressive deformity, or potential neurologic symptoms from a radiographically identifiable problem (for example, a dislodged hook or a broken rod or screw, indicating a likely pseudarthrosis).

We tested our categorization of serious radiographic adverse events and radiographic adverse events on a relatively uniform population of 466 healthy adolescents who had treatment of a Type 1 curve as classified by the system of Lenke et al. [7]. In this system, there are six types of adolescent idiopathic scoliosis, and curve type (1–6) is based on the location of the major curve and structural characteristics of the minor curves. In this study, we used patients who had a major curve in the main thoracic spine with minor nonstructural proximal thoracic and thoracolumbar/lumbar curves (Type 1).

We treated the 466 patients with four different general methods: (1) posterior instrumented spinal fusion with an anchor system utilizing hooks or hooks, wires, and screws (hybrid systems); (2) posterior instrumented spinal fusion with an anchor system utilizing a majority of pedicle screws; (3) open anterior instrumented spinal fusion; or (4) thoracoscopic anterior instrumented spinal fusion. One hundred seventy-two patients were treated with an anterior instrumented spinal fusion (either open or thoracoscopic), and 194 patients were treated with a posterior instrumented spinal fusion (all anchor types).

The frequency of the serious radiographic adverse events and radiographic adverse events for each of the four treatment groups was determined by a study group of more than 20 experienced spine surgeons. In patients with more than one radiographic adverse event identifiable on their postoperative radiographs, the most serious radiographic adverse event was assigned by the study group after being presented with the radiographic data. Multiple variables, including anchor types and surgical approaches, were analyzed for the frequency of adverse events.

Statistical analysis of our data included an overall chi square test for all four treatment groups for the existence of a serious radiographic adverse event and a radiographic adverse event. Analysis was performed using SPSS® Version 12.0.01 (SPSS Inc, Chicago, IL).

Results

We identified no difference in radiographic adverse events rates among the four techniques (Table 1). Each of the serious radiographic adverse events was for surgical revision, with a reoperation rate ranging from 4.5% (open anterior instrumented spinal fusion) to 8.8% (posterior instrumented spinal fusion with an anchor system utilizing hooks or hybrid systems) (Table 2). Among serious radiographic adverse events, the most common problems in adolescents who had an anterior spinal fusion (either open or thoracoscopic) were revision for lumbar progression, rod breakage, and proximal screw pullout (Fig. 1). Serious radiographic adverse events in adolescents who had a

Table 1. Differences in the number of complications between each type of surgical treatment

Type of event	Compared treatment groups	P values*
Serious radiographic adverse event	OASF to TASF	0.77
	PSFH to PSFS	0.38
	OASF to PSFH	0.12
	OASF to PSFS	0.73
	TASF to PSFH	0.32
	TASF to PSFS	0.97
	Overall	0.427
Radiographic adverse event	OASF to TASF	0.47
	PSFH to PSFS	0.78
	OASF to PSFH	0.51
	OASF to PSFS	0.77
	TASF to PSFH	0.91
	TASF to PSFS	0.72
	Overall	0.88

* P values were calculated using an overall chi square test for all treatment groups for existence of a serious radiographic adverse event ($p = 0.427$) or a radiographic adverse event ($p = 0.88$); no significant difference was found between the different surgical treatments; OASF = open anterior instrumented spinal fusion; TASF = thoracoscopic anterior instrumented spinal fusion; PSFH = posterior instrumented spinal fusion with an anchor system that utilized hooks or hooks, wires, and screws (hybrid systems); PSFS = posterior instrumented spinal fusion with an anchor system that utilized a majority of pedicle screws.

posterior instrumented spinal fusion (hooks, hybrid, or screws) were implant removal for postoperative pain or unplanned reoperation for infection.

Discussion

Many studies have analyzed complications or adverse outcomes in scoliosis surgery, but none describes a radiographic classification of adverse events for adolescent idiopathic scoliosis. Previous studies have been comprehensive surgeon-reported complication rates [1]; descriptions of particular complications, such as infections

Fig. 1 The anteroposterior radiograph demonstrates an example of a serious radiographic adverse event based on our classification scheme. The white arrow indicates a broken rod at the T10–T11 disc in a patient who was treated for adolescent idiopathic scoliosis using open anterior instrumented spinal fusion. This was defined as a serious radiographic adverse event, as it was a failure of an implant indicating a likely pseudarthrosis.

[11], superior mesenteric artery syndrome [4, 13], etc; complications related to a certain technique, such as thoracoscopic treatment [8, 10]; or complications compared between different techniques, such as hooks versus screws [5, 6, 12]. Our aim was to define a radiographic system of

Table 2. Frequency of radiographic serious adverse events and adverse events

Type of event	Treatment group			
	OASF (n = 178)	TASF (n = 94)	PSFH (n = 136)	PSFS (n = 58)
Serious radiographic adverse event	8 (4.5%)	5 (5.3%)	12 (8.8%)	3 (5.2%)
Radiographic adverse event	11 (6.2%)	8 (8.5%)	11 (8.1%)	4 (6.8%)

OASF = open anterior instrumented fusion; TASF = thoracoscopic anterior instrumented fusion; PSFH = posterior instrumented spinal fusion with an anchor system that utilized hooks or hooks, wires, and screws (hybrid systems); PSFS = posterior instrumented spinal fusion with an anchor system that utilized a majority of pedicle screws.

adverse events and then test the system in 466 patients with Lenke Type 1 adolescent idiopathic scoliosis.

As with many descriptive studies, there are possible limitations to our study. First, the goal of our study was not to address all complications but only to classify complications visible on radiography. As a result, we did not include neurologic complications, wound problems, pain, and other symptoms that would not be visible on a radiograph. Second, we recognize some of these complications identifiable on radiographs require supplemental clinical material that can be evaluated after the complication is identified. As stated before, this study was not meant to try to establish a classification system based on radiographs that would predict whether a complication would happen. Our study was meant to describe postoperative complications seen on radiographs. Third, we focused on only patients with Type 1 curves so we could observe a cohesive subject population for this study. While this gave small numbers for statistical analysis, the overall goal of this study was to simply establish a classification scheme for surgical complications that can be further researched. Fourth, the criteria established for our classification was developed by a study group of more than 20 experienced spine surgeons and therefore is essentially based on expert opinion. However, there is no standard in the literature with which we can compare our criteria. The research presented here is important to further evaluate rates of postoperative complications among different surgical techniques and implants used during treatment for adolescent idiopathic scoliosis.

Several recent studies report complications related to the surgical treatment of scoliosis, some of which report a relatively high complication rate. An extensive review of the English language literature was recently published, focusing on 287 published scoliosis studies in which “rate of complication” was among the keywords [14]. The authors included studies related to all different underlying diagnoses and found a complication rate from 0% to 89%. While comprehensive, this literature review does not offer the sort of specific adverse event data necessary to vet different technique options. One recent study exclusively evaluated inpatient complications in the United States between 1993 and 2002, using the National Inpatient Sample administrative database [9]. Of the 51,911 patients

who underwent surgery for idiopathic scoliosis over this 10-year period, the inpatient complication rate for “pediatric patients” was 14.9%, while the inpatient complication rate for adult patients was 25.1%. Pulmonary and postoperative bleeding were the most common complications in this series. Like the recently published literature review mentioned above, this study gives general complication rates (in this case just during hospital stay) but does not compare treatment methods or new technologies. Another recent study reported a 0.69% rate of neurologic complications in 1301 children undergoing spinal fusion and instrumentation for adolescent idiopathic scoliosis [3]. In a study of nonneurologic complications in a cohort of 702 patients who underwent surgical correction of adolescent idiopathic scoliosis, it was concluded the complication rate was 15.4% [1]. There were 10 respiratory complications (1.42%), six cases of excessive bleeding (0.85%), five wound infections (0.71%), and five cases of wound hematoma, seroma, or dehiscence (0.71%). Five patients, two with an early infection and three with late failure of the implant, required reoperation. The Scoliosis Research Society published a society-wide evaluation of complications in 2006 [2]. The study reported, of the 1164 patients who underwent anterior fusion and instrumentation, 5.2% had complications; of the 4369 who underwent posterior instrumentation and fusion, 5.1% had complications; and of the 801 who underwent combined instrumentation and fusion, 10.2% had complications (Table 3). There were two patients (0.03%) who died of their complications. The populations are quite large in these studies compared with our sample population, and therefore, their percentages of complications are smaller.

Regulatory bodies, third-party payors, and patients will increasingly scrutinize treatment methods based on the frequency of adverse events. We developed a simple, radiographic classification that can be applied objectively to any patient who has had surgical treatment of adolescent idiopathic scoliosis and who has had postoperative plain radiographs. Patient records are needed only in the case of unplanned trips to the operating room; in this scenario, perioperative images would signal the event, and then the operative note can be evaluated to identify the cause and treatment.

Table 3. Comparison of presented complication data with cited literature

Study	ASF patients		PSF patients		Total % complication rate
	Number	% with complications	Number	% with complications	
Carreon et al. [1]	NA		NA		15.4
Coe et al. [2]	1164	5.2	4369	5.1	NA
Flynn et al. [current study]	272	11.7	194	15.4	13.3

ASF = anterior instrumented spinal fusion; PSF = posterior instrumented spinal fusion; NA = not applicable.

Of the four different treatment methods analyzed for this particular study of 466 healthy adolescents, none appeared inherently safer, although the complications did vary among the different treatment methods used. A prospective evaluation of our radiographic classification and others is underway, further enhancing its utility by surgeons, patients, payors, and regulatory bodies.

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