The Spine Journal 14 (2014) 1984–1990

Clinical Study

Management decisions for adolescent idiopathic scoliosis significantly affect patient radiation exposure

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Received 25 October 2012; revised 9 October 2013; accepted 26 November 2013

Abstract

BACKGROUND CONTEXT: Adolescent idiopathic scoliosis (AIS) patients treated before the 1990s have a 1% to 2% increased lifetime risk of developing breast and thyroid cancer as a result of ionizing radiation from plain radiographs. Although present plain radiographic techniques have been able to reduce some of the radiation exposure, modern treatment algorithms for scoliosis often include computed tomography (CT) and intraoperative fluoroscopy. The exact magnitude of exposure to ionizing radiation in adolescents during modern scoliosis treatment is therefore unclear.

PURPOSE: To determine the difference in radiation exposures in patients undergoing various forms of treatment for AIS.

STUDY DESIGN: Retrospective cohort.

PATIENT SAMPLE: Patients aged 9 to 18 years with a diagnosis of AIS, followed and/or treated with nonoperative or operative management for a minimum of 2 years.

OUTCOME MEASURES: Number of radiographs and total radiation exposure calculated.

METHODS: The charts and radiographs of patients managed for AIS at a single institution between September 2007 and January 2012 were reviewed. Patients were divided into three groups: operative group, braced group, and observation group. Patient demographics, Cobb angles, and curve types were recorded. The number of radiographs per year that each patient received and the total radiation dose were recorded. The plain radiographic radiation exposure was then combined with the direct exposure recording from ancillary tests, such as fluoroscopy and CT, and a radiation exposure rate was calculated (mrad/y). A single-factor analysis of variance (α=0.01) with a Tukey honest significant difference post hoc analysis was used to test significance between groups.

RESULTS: Two hundred sixty-seven patients were evaluated: 86 operative, 80 brace, and 101 observation. All groups had similar demographics and curve type distribution. The mean initial Cobb angle at presentation was significantly different between the groups: operative (57°±11°), brace (24°±7.9°), and observation (18°±9.4°) (p<.01). There was a significant difference among the groups in terms of the mean number of radiographs received per year; operative group, 12.2 (95% confidence interval [CI]: 10.8–13.5; p<.001); braced group, 5.7 (95% CI: 5.2–6.2; p<.001), and observed group, 3.5 (95% CI: 3.160–3.864; p<.001). The operative group received 1,400 mrad per year (95% CI: 1,350–1,844; p<.001), braced group received 700 mrad per year (95% CI: 598–716; p<.001), and observed group received 400 mrad per year (95% CI: 363–444; p<.001). Importantly, 78% of radiation in the operative group was attributable to the operative fluoroscopy exposure.

CONCLUSIONS: Significant differences exist in the total radiation exposure in scoliosis patients with different treatment regimens, with operative patients receiving approximately 8 to 14 times more radiation than braced patients or those undergoing observation alone, respectively. Operative

FDA device/drug status: Not applicable.

Author disclosures: ***SMP:*** Nothing to disclose. ***TK:*** Nothing to disclose. ***ML:*** Nothing to disclose.

The author (SMP) verifies that he had full access to all the data in the study and takes responsibility for the integrity of the data, the accuracy of data analysis, and the decision to submit for publication.

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http://dx.doi.org/10.1016/j.spinee.2013.11.055

patients also receive more than twice the radiation per year than braced or observed patients. Almost 78% of the annual radiation exposure for operative patients occurs intraoperatively. Because children are notably more sensitive to the carcinogenic effects of ionizing radiation, judicious use of present imaging methods and a search for newer imaging methods with limited ionizing radiation should be undertaken.

Keywords: Adolescent idiopathic scoliosis; Radiation exposure; Fluoroscopy; Absorbed radiation dose; Treatment algorithm; Brace treatment

Introduction

Adolescent idiopathic scoliosis (AIS) has a reported incidence of 25 adolescents per 1,000 in a population aged 10 to 18 years [1]. Full spinal radiographs in both posteroanterior (PA) and lateral projections remain central to the diagnosis and management of patients with scoliosis. Depending on the age, the initial curve magnitude, and any associated bracing or surgical interventions, patients may require repeated studies in intervals of 3 to 12 months. It has been estimated that the typical patient with scoliosis will have approximately 22 plain radiographic examinations over a 3-year treatment period [2]. As many as 618 plain films in a single patient have been reported [3,4].

Multiple major scientific committee reports have shown that children are more sensitive to radiation than adults because they have more time to express a cancer and have more dividing cells on which the radiation acts [5,6]. There is particular concern about the risk of breast cancer because progressive scoliosis is seen most commonly in the female population and the breast tissue of teenage girls is particularly sensitive to radiation [3,6]. Nash et al. [7] reported a 110% increase in breast cancer risk after routine radiographic follow-up for AIS. Bone et al. repeated the study by Nash et al. almost 20 years later and found a 4.2% increased lifetime risk of developing breast cancer with a 3% increased risk of birth defects [8].

The magnitude of radiation exposure in the modern treatment of scoliosis is unclear. Although modern plain radiographic techniques have been able to reduce a patient's exposure, new diagnostic imaging technologies and surgical techniques such as intraoperative fluoroscopy, computed tomography (CT), and pedicle screw instrumentation necessarily increase a patient's exposure. The purpose of this study is to determine the average radiation exposure for a child undergoing management of AIS over a minimum duration of 2 years in the modern era.

Methods

In this institutional review board approved study, a comprehensive review of a single institution's medical records between September 2007 and January 2012 was performed. Patients were included if the patient was diagnosed and treated for AIS, were 9 to 18 years of age at the time of first evaluation, were managed with either nonoperative or operative means for their AIS, and were followed for a minimum of 2 years. Patients were excluded if they were diagnosed with neuromuscular scoliosis, congenital scoliosis, or any condition that required additional serial radiation exposure during that time period, such as malignancy.

The included patients were divided into three study groups. The first group was surgically treated with a posterior spinal fusion, either with a hybrid construct of hooks, wires, and pedicle screws or a pure pedicle screw construct. The second group comprised those treated nonoperatively with brace management alone. The third group consisted of the patients managed with observation only. Lumbar and thoracic pedicle screws in the operative group were placed using standard anatomic landmarks with a freehand technique using a curved probe. A ball-tip sounding probe was used to test the integrity of the pedicle path. If the pedicle path was felt to be intact, a pedicle screw of appropriate diameter and length was inserted, and the screw position was verified with orthogonal fluoroscopic views once all the fixation points for the construct had been placed. If the integrity of the pedicle path was suspected, a guide wire or a ball-tip probe was placed in the pedicle tract and its position was examined under biplanar fluoroscopy to direct repositioning. No three-dimensional navigation techniques were used for placement of the screws. Pedicle screw position was further verified with triggered electromyography, using 8 mA as a threshold. All surgeries were performed by one of two fellowship-trained pediatric orthopedic spine surgeons.

Patient demographic data was gathered from the charts: age at presentation, age at treatment completion, gender, and total months followed. Curve characteristics were determined from the initial radiographs. Cobb angles at the time of diagnosis were determined from plain radiographs using the standard method. A modified Lenke classification was used to describe the curve patterns without the use of bending films or the requirement that curves should be of operative magnitude. The curves were grouped 1 through 6, according to the standard Lenke classification, by considering the curve with the largest Cobb measure structural and the other curves structural only if measuring greater than 25° [9]. The number of radiographs (PA, lateral, bending) that each patient received throughout the time course of the study was also recorded. Because of large variation in the time of follow-up among patients, radiation exposures were standardized between groups by calculating

EVIDENCE & METHODS

Context

The negative health effects of long-term exposure to ionizing radiation are well known. Patients with adolescent idiopathic scoliosis (AIS) have been shown to be at elevated risk of breast and thyroid cancer in the past. The impact of modern treatment algorithms, in terms of radiation exposure, remains unclear at present.

Contribution

The authors retrospectively evaluated 267 patients treated nonoperatively, as well as surgically for AIS. They determined that patients treated surgically for AIS received as much as 14 times the radiation dose of individuals managed through nonoperative methods. Seventy-eight percent of radiation exposure in the operative group was due to fluoroscopy used at the time of surgery. The authors anticipate that the extent of radiation exposure in patients with AIS may elevate the lifetime risk of solid cancers to between 1.4% and 2.4%.

Implications

Although this was a retrospective cohort study, the findings are important from both a surgical, as well as a health policy perspective. In light of the topic, as well as the population under consideration, findings such as these may represent best available evidence. The authors correctly advocate that surgeons treating AIS patients need to be cognizant of cumulative radiation does at a minimum and carefully evaluate the strategic necessity of radiographs and computed tomography. The authors' calls for broader approaches at the societal level and changes to postoperative surveillance algorithms are also laudable.

—*The Editors*

rates, specifically number of radiographs per year and total radiation exposure (mrad) per year.

A computed radiology system (Toshiba OEC, Tustin, CA, USA; Konica CR 9900, Ramsey, NJ, USA) was used for all plain radiographs. For most radiographic techniques, there is a difference between the radiation emitted by the machine (emitted radiation) and the radiation absorbed by the patient (absorbed radiation). When feasible in this study, absorbed radiation doses were recorded because it is more clinically relevant. To calculate an average absorbed radiation dose (mrad) for a specific plain radiographic technique, a commercial optical stimulated luminescence (OSL; Landauer, Glenwood, IL, USA) dosimetry system was used for both PA and lateral radiographs separately [10,11]. The OSL dosimetry badge was placed in the center of the radiation field for 10 patients undergoing routine scoliosis follow-up radiographs at our institution, with one badge used for the full-length PA films and the other for the lateral film.

The radiation exposure received by patients in the operating room (OR) via fluoroscopy (OEC; GE, Fairfield, CT, USA) or CT scan (Somatom Definition AS 2010; Siemens, Washington, DC, USA) was directly reported by the calibrated machine. In contrast to the radiographs from follow-up where absorbed radiation was directly measured, the emitted radiation dose recorded by the fluoroscopy machine was assumed to be identical to the actual amount of absorbed radiation seen by the patient. For CT scans, however, Monte Carlo simulations were used to calculate absorbed radiation dose to the soft tissues using the ImPACT Patient Dosimetry Calculator (Version 1.0; August 28, 2009, http://www.impactscan.org) that has been developed and validated [12] to calculate tissue-specific absorbed doses from CT. All the variables required for the dosimetry calculation were obtained from subject medical records as recorded by the machine. A postoperative CT scan was performed only when the surgeon felt it was prudent to check if any of the placed pedicle screws had breached into the spinal canal. If a CT scan was performed, it encompassed the entire length of the construct and was a standard thoracolumbar CT. No intraoperative O-arm was used.

To calculate the risk of developing cancer later in life from the radiation exposure found in this study, the total radiation absorbed by patients was multiplied by cancer-induction rates based on the latest report from the European Nuclear Society's committee on the Biological Effects of Ionizing Radiation (BEIR) [5]. The BEIR VII report compiled data on cancer incidence in several cohorts to develop a model for estimating risk based on radiation dose received. This was broken down into the percentage increase in risk of lifetime cancer for follow-up radiographs for the three study groups and the percentage increase with the addition of either intraoperative fluoroscopy or CT scan.

A single-factor analysis of variance test (α=0.01) was used to test differences between groups. A Tukey honest significant difference post hoc analysis was performed to determine the significance between individual groups. A subanalysis was also performed using regression analysis to determine if there was a difference in radiation exposure based on the number of vertebral levels fused and the total number of pedicle screws used.

Results

Statistical significance was noted between groups with regard to the mean age at initial presentation ($p<.001$), the mean age at treatment completion ($p<.001$), the gender distribution among groups ($p<.001$), and the total number of months that each group was followed ($p<.001$) (Table 1). In the operative group, the average length of time that a patient was followed before surgery was 13.1±11.6 months, with an average of 3.9±2.8 office visits.

Table 1
The demographic data of the three treatment groups is shown

Demographics	Surgery	Braced	Observation	p
N	86	80	101	
Age at presentation (y)	13±2.1	12±1.5	12±1.5	<.001
Age at end point (y)	16±2	14±1.6	15±1.6	<.001
Females (%)	62 (72)	70 (88)	78 (72)	<.001
Months followed (mo)	35±1.2	31±8.1	29±8.1	<.001
Initial Cobb (°)	57±11	24±7.9	18±9.4	<.001

Postoperatively, patients averaged 21.6±12.0 months follow-up or about 6.3±4.3 office visits.

No significant differences existed for the modified Lenke curve type between groups, with the most common modified Lenke curve type as a Type 1 (ie, main thoracic). The mean Cobb angle at initial presentation for the three groups was 57°±11° for the operative group, 24°±7.9° for the patients who were braced, and 18°±9.4° for the observation-only group ($p<.001$).

A statistically significant difference was identified for the number of plain radiographs received between groups (Table 2). The operative group received 12.2 radiographs per year (95% confidence interval [CI]: 10.8–13.5; $p<.001$), the braced group received 5.7 per year (95% CI: 5.2–6.2; $p<.001$), and the observed group received 3.5 per year (95% CI: 3.160–3.864; $p<.001$).

The average doses of absorbed radiation for PA and lateral films based on dosimeter calculations were 115.1 and 461.1 mrad, respectively. The ratio of PA to lateral films was about 2:1 among all groups and throughout the treatment course. The radiation dose for each group based on plain radiographs alone was also statistically different and paralleled the differences noted in the number of radiographs obtained. The operative group received 1,400 mrad per year (95% CI: 1,350–1844; $p<.001$), the braced group received 700 mrad per year (95% CI: 598–716; $p<.001$), and the observed group received 400 mrad per year (95% CI: 363–444; $p<.001$).

This significant difference in radiation between the groups was further magnified when the radiation exposure from both the intraoperative fluoroscopy and postoperative CT scans ($n=4$ patients) in the surgical group were taken into account. The amount of intraoperative radiation emitted from biplanar fluoroscopy alone averaged 13,900 mrad per patient per case or 5,200 mrad per year when normalized for duration of follow-up. The average amount of active fluoroscopy time per case was 31.3±12.9 seconds. The average amount of absorbed radiation per postoperative CT scan, as calculated by the Monte Carlo simulations, was 4,200±300 mrad.

The total absorbed radiation dose that patients in our surgically treated group received from all sources over their entire course of treatment averaged 17,700 mrad, which is 8 to 14 times more than the braced or observed groups, respectively (Table 2). Of importance, 78% of the average annual radiation exposure in the operative group was from intraoperative fluoroscopy alone, even though the index surgery represents only one point in time.

Using regression analysis, it was determined that neither the number of vertebral levels fused nor the total number of pedicle screws used per fusion construct contributed significantly to radiation exposure in the operative group. The coefficients of determination (R^2) for the number of levels fused is 0.0195 (Fig. 1) and for the number of pedicle screws per construct is 0.1269 (Fig. 2). Of note, there are apparent outliers noted in both Figs. 1 and 2, where only four or five levels were fused and only five to seven pedicle screws were used. The cases of four or five level fusions were all for idiopathic Lenke 5C curves. As for the cases where only five to seven pedicle screws were used, all of these constructs also had sublaminar wires to provide additional points of fixation.

Using the latest estimates from BEIR VII, the percentage increase in risk of developing cancer later in life was calculated for each of the study groups by sex (Table 3). The lifetime cancer risks for following patients with routine follow-up radiographs in the office for the observation group were 0.032% and 0.052% for men and women, respectively. For those patients being treated with braces, the increased risks for men and women from follow-up radiographs were 0.056% and 0.091%, respectively. Undergoing posterior spinal fusion for AIS conferred the largest increased risk of developing cancer. From follow-up radiographs alone, the surgical group had a 0.112% increase for men and a 0.182% for women. The radiation from intraoperative fluoroscopy contributed an increased lifetime cancer risk of 1.112% for men and 1.807% for women. The decision to perform a postoperative CT scan conferred an increased risk of 0.32% and 0.52% for men and women, respectively.

Table 2
The large variation in the number of radiographs per year and therefore, radiation exposure among all three treatment groups is shown

	Surgery	Braced	Observation	p
No. of plain radiographs per year (95% CI)	12.2 (10.8–13.5)	5.7 (5.2–6.2)	3.5 (3.2–3.9)	<.001
Average annual radiation exposure (mrad/y) from follow-up radiographs alone (95% CI)	1,400 (1,350–1,844)	700 (598–716)	400 (363–444)	<.001
Average annual radiation exposure (mrad/y) from all studies	1,820	855	525	<.001
Total radiation dose (mrad)	17,700	2,193	1,275	<.001

CI, confidence interval; CT, computed tomography.

Note: Adding in the radiation from both fluoroscopy and CT scans (total radiation dose) to the operative group further magnifies the difference.

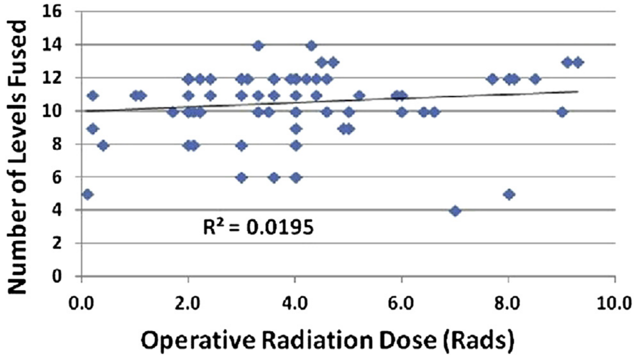

Fig. 1. The number of levels fused is plotted against the total fluoroscopic radiation dose (rads). A regression analysis is shown along with the coefficient of determination (R^2). There is no statistical relationship between the two variables.

Discussion

The present study demonstrates that in the modern era of AIS treatment, pediatric patients continue to be subjected to a potentially hazardous amount of radiation. Most alarming are the differences in annual radiation exposure between treatment groups, with the operative group receiving upwards of 14 times the radiation dose of patients treated with nonoperative modalities. To put things into perspective, the standard background radiation exposure in North America is thought to be about 100 mrad per year [13]. A patient with AIS who undergoes operative treatment receives approximately 9 to 10 times more exposure than the background radiation dose.

In addition, children are particularly susceptible to the deleterious effects of radiation. Theoretically, children provide a longer latency period after initial radiation exposure during which malignancy may develop and, by the nature of their smaller size and surrounding soft tissues, see a greater effective dose on the tissues for a given amount of radiation emitted from an X-ray source. The National Academy of Sciences' latest report on radiation risk, called the BEIR VII, concluded that the risk of cancer increases in a linear fashion and the smallest dose has the potential to cause a small increase in malignancy risk to humans [5]. This linear risk differs from the threshold phenomenon that had been previously thought. The report also estimated that the lifetime solid cancer incidence increases at a rate of 0.80% for males and 1.30% for females for every 10 rad of exposure as an adult. Using the amount of total radiation that our patients were exposed to, this would translate into an appreciable increase in solid cancer risk of approximately 1.4% and 2.4% for men and women, respectively. This estimated rate from the BEIR VII, again based on adults, would presumably be even higher for pediatric patients. The Food and Drug Administration has been aware of these data and in May 2012 announced a proposal encouraging manufacturers to consider the safety of children in the design of new X-ray imaging devices.

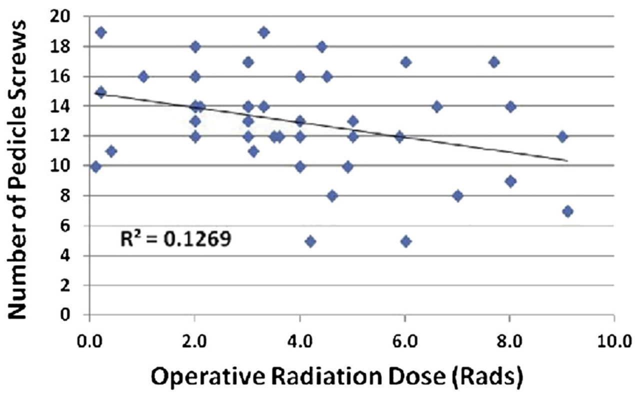

Fig. 2. The number of pedicle screws used in the posterior spinal construct is plotted against the total fluoroscopic radiation dose (rads). A regression analysis is shown along with the coefficient of determination (R^2). There is no statistical relationship between the two variables.

Table 3
Using the BEIR VII results, the lifetime increase in cancer risk is given for each year of follow-up for each of the three study groups and every additional CT scan and surgery

	Risk for men (%)	Risk for women (%)
Per year of observation	0.032	0.052
Per year of follow-up (braced group)	0.056	0.091
Per year of follow-up (surgical group)	0.112	0.182
Per CT scan	0.32	0.52
Per operation (fluoroscopy)	1.112	1.807

CT, computed tomography.

One notable result from the present study is that 78% of the total cumulative radiation exposure received by the operative group came from intraoperative radiation during fluoroscopic examination. This percentage is more striking when one considers the sheer numbers of plain films obtained for the pre- and postoperative evaluations, with some operative patients in this study receiving upwards of 78 radiographs throughout their treatment. This finding focuses attention on one of the little recognized drawbacks of pedicle screw constructs for the correction of AIS. Although more powerful deformity correction is possible with pedicle screws, patient radiation exposure is seemingly higher during surgery when using this technique, and as such, potentially poses harmful long-term clinical consequences for pediatric patients. This is particularly interesting with the recent advances in minimally invasive spine surgery and the potential for greater reliance on fluoroscopic imaging to help guide the placement of pedicle screws, not to mention the emergence of the three-dimensional navigation techniques to confirm screw placement. Although we recognize that there is a large variation in surgeon preference in regard to the amount of reliance on fluoroscopic imaging during pedicle screw placement, our two surgeons in this study practice moderate use (on average 31 seconds), making the results fairly generalizable. Interestingly, our data showed that the amount of radiation that our patients were exposed to from intraoperative sources was not affected by either the number of pedicle screws placed or the number of levels fused.

An additional and important note is the safety of the OR staff, including the surgeons themselves. Certainly the patients themselves would be subjected to the highest radiation exposures because they are closest to the radiation source and the OR staff typically separates themselves with either distance or shielding, but the cumulative effects of performing multiple cases in a week or month should also be taken into consideration.

The study also finds that there is an almost twofold increase in radiation exposure for patients undergoing brace treatment when compared with the observation group. This is likely related to the additional in-brace films for brace application and a pattern of more frequent follow-ups for the patients being braced. As bracing remains the most accepted modality for nonoperative control of curve progression in North America, this increased radiation exposure and the potential long-term consequences are worthy of discussion with parents when deciding on treatment options. In this study, our female patients treated with bracing alone have approximately 0.1% increased rate of developing cancer in their lifetime.

The present data emphasizes the need for the pediatric spine surgeon to make judicious choices when ordering radiographs. The surgeon must balance the diagnostic information afforded by a radiograph, CT scan, or fluoroscopic image against the risk of future malignancy. Particularly in the surgical candidate with AIS, the surgeon must be cognizant of the cumulative radiation doses these patients are exposed to as a result of both radiographic study types and entrenched practice algorithms of lengthy, serial follow-up radiographs. The Nuclear Regulatory Commission's proposed upper limit of 50 mSv (approximately 5 rad) per year of exposure for workers, elaborated in the ALARA principle (As Low As Reasonably Achievable), is currently the best reference for balancing the risk versus benefit of a radiologic examination and is in turn used by radiologists as an upper limit for safe patient exposure [14]. The number may serve as a starting point for discussions on acceptable ranges of radiation exposure for the evaluation and treatment of scoliosis in pediatric patients.

Clearly, more research is needed in this area. First, a better understanding of a pediatric patient's total exposure to radiation, inclusive of all tests performed in 1 year, is required. This may be facilitated by the emergence of comprehensive electronic health records. In addition, the Scoliosis Research Society may take the lead in this assessment by making radiation exposure a component of the members' annual Morbidity and Mortality submission set, with each surgeon submitting the cumulative emitted fluoroscopy doses for all their cases. Second, the utility of each examination in clinical decision-making needs to be critically assessed. What is a reasonable interval for scoliosis follow-up and what radiographic views should be ordered at each visit? Finally, additional research is needed to derive new low dose or no dose radiation formats by which scoliosis may be tracked. Such options that are beginning to be investigated for these purposes include rapid, low cost magnetic resonance imaging and spinal topography systems [15,16].

To minimize overall radiation exposure, we would recommend that the routine follow-up interval for observed or braced patients be 6 months, as our anecdotal experience suggests radiographic or clinical findings over shorter intervals rarely impact clinical decision-making. Postoperative patients are routinely evaluated at a higher frequency in the first 6 months after surgery, but we have found no utility to subsequent follow-up intervals shorter than a year. A PA projection is recommended for every initial and follow-up evaluations. A lateral radiograph, which again has four times the radiation of a PA radiograph, should also be obtained for curve atypia, marked clinical kyphosis, neurologic abnormality, and routine pre- and post-operative evaluations.

The strengths of the present study include the large number of patients, the uniform equipment and standardized radiographic methods used for execution of radiographs, and the use of a sensitive radiation detection badge (ODL) to improve the accuracy of calculated radiation doses from plain films.

Some limitations to the present study are also noted. First, statistically significant differences were noted between groups with regard to age at initial presentation, age at treatment completion, gender distribution among groups, and the total number of months that each group was followed. However, these differences are recognized as intrinsic to the group categories and of little clinical significance in terms of study parameters. Second, it is assumed that the operative patients receive the total emitted dose of radiation as reported by the calibrated fluoroscopy machines in the OR. However, there is a recognized difference between the emitted dose and the absorbed dose. The actual absorbed dose depends on a variety of variables including the amount of radiation scatter. For this study, we assumed that this relationship was 1:1, but it is possible that the reported number may be either an over- or underestimate. Third, the reported radiation exposures outside the OR may have been underestimated because it was not possible to determine in a retrospective nature the number of radiographs that were repeated because of technical error, as these erroneous radiographs are not recorded in our electronic radiography systems. Similarly, we could not take into account the number of studies obtained outside of the study institution before or during the follow-up period.

In summary, there is a significant difference in annual and total radiation exposure in our study for AIS patients treated with observation, bracing, or surgery. Bracing and surgical patients received significantly greater radiation than patients treated with simple observation on an annual basis. Total radiation exposure for surgically treated patients over the course of treatment was 8 to 14 times greater than braced or observed groups. The study highlights the need to consider the radiation exposures imparted to growing children during the evaluation and treatment of AIS and underscores the need for additional research efforts into low radiation methods for evaluation of the spine, both in the office and in the OR.

Conclusion

Surgically treated patients received significantly greater average annual radiation doses than braced or observed AIS patients. Braced patients received significantly more annual radiation exposure than patients who were simply observed. The vast majority (78%) of the average annual radiation exposure to the operative patient is derived from intraoperative sources. Surgeons should, therefore, be aware of the impact of intraoperative imaging for treatment of spinal deformity on the long-term health of the child and use such technology judiciously until a safer alternative is available.

Acknowledgments

Special thanks to Matt Solomito for all of his hard work and dedication to orthopedic research.

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