

Iatrogenic Radiation Exposure to Patients With Early Onset Spine and Chest Wall Deformities

Derek Khorsand, BS,* Kit M. Song, MD, MHA,‡ Jonathan Swanson, MD,§ Adam Alessio, PhD,† Gregory Redding, MD,¶ and John Waldhausen, MD||

Study Design. Retrospective cohort series.

Objective. Characterize average iatrogenic radiation dose to a cohort of children with thoracic insufficiency syndrome (TIS) during assessment and treatment at a single center with vertically expandable prosthetic titanium rib.

Summary of Background Data. Children with TIS undergo extensive evaluations to characterize their deformity. No standardized radiographical evaluation exists, but all reports use extensive imaging. The source and level of radiation these patients receive is not currently known.

Methods. We evaluated a retrospective consecutive cohort of 62 children who had surgical treatment of TIS at our center from 2001–2011. Typical care included obtaining serial radiographs, spine and chest computed tomographic (CT) scans, ventilation/perfusion scans, and magnetic resonance images. Epochs of treatment were divided into time of initial evaluation to the end of initial vertically expandable prosthetic titanium rib implantation with each subsequent epoch delineated by the next surgical intervention. The effective dose for each examination was estimated within millisieverts (mSv). Plain radiographs were calculated from references. Effective dose was directly estimated for CT scans since 2007 and an average of effective dose from 2007–2011 was used for scans before 2007. Effective dose from fluoroscopy was directly estimated. All doses were reported in mSv.

Results. A cohort of 62 children had a total of 447 procedures. There were a total of 290 CT scans, 4293 radiographs, 147 magnetic resonance images, and 134 ventilation/perfusion scans. The average accumulated effective dose was 59.6 mSv for children who had

completed all treatment, 13.0 mSv up to initial surgery, and 3.2 mSv for each subsequent epoch of treatment. CT scans accounted for 74% of total radiation dose.

Conclusion. Children managed for TIS using a consistent protocol received iatrogenic radiation doses that were on average 4 times the estimated average US background radiation exposure of 3 mSv/yr. CT scans comprised 74% of the total dose.

Key words: early onset scoliosis, thoracic insufficiency syndrome, radiation, imaging, CT scan, cancer risk, morbidity, children, pediatric.

Level of Evidence: 3

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The risk to patients of radiation exposure has been the subject of recent studies and public concerns.^{1–9} Medical radiography has been implicated as a significant contributor of radiation exposure for patients receiving treatment of adolescent idiopathic scoliosis.^{1–4} Adverse reproductive events in females exposed to multiple radiographs for scoliosis management and an increased incidence of cancer have been observed in adolescent idiopathic scoliosis cohorts undergoing regular radiographical studies.^{1,2,5,6}

Children with thoracic insufficiency syndrome (TIS) may receive implantable devices designed to preserve growth and stabilize structural deformities to preserve respiratory growth and function.^{7–9} The evaluation of these children prior to and during treatment can be intense and extend over many years. No standard protocols exist for the evaluation and management of these children. Imaging studies are done to assess spinal cord involvement, regional lung function, and to characterize changes in structure of the spine and chest wall before and after surgical treatment. Assessments include magnetic resonance images (MRI), computed tomographic (CT) scans of the chest and spine, plain radiography, ventilation and lung perfusion scans (V/Q), and intraoperative fluoroscopy during implantation and expansion procedures.¹⁰ All these tests, with the exception of MRI studies, expose the patient to ionizing radiation. The cumulative amount of radiation these children receive, which diagnostic examinations contribute most to the overall radiation exposure, and how the intensity of imaging and radiation exposure varies over the cycle of treatment of TIS are currently unknown. The purpose of this report is

From the Departments of *Orthopedic Surgery and †Radiology, University of Washington School of Medicine, Seattle, WA; ‡Shriners' Hospital for Children, Los Angeles, CA; and §Department of Radiology, ¶Division of Pulmonary Medicine, Department of Pediatrics, and ||Division of General and Thoracic Surgery, Department of Surgery, Seattle Children's Hospital, Seattle, WA.

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Address correspondence and reprint requests to Kit M. Song, MD, MHA, Shriners' Hospital for Children—Los Angeles, 3160 Geneva St, Los Angeles, CA 90020; E-mail: kmsong@shrinersnet.org

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to characterize the average radiation exposure to a cohort of children managed for TIS in a single center using a standard protocol.

MATERIALS AND METHODS

Patient Population and Clinical Management

This is an institutional review board approved retrospective cohort review of all patients surgically treated for TIS at our facility from October 2001 to June 2011. All children had placement of a growth sparing construct using vertical expandable prosthetic titanium rib (VEPTR) devices (Synthes Corp, West Chester, PA). Of the 75 treated patients, 6 were excluded from this study because they had chest wall reconstruction for major tumor resection. Six additional patients were excluded because their initial VEPTR implantation was performed at another institution. One patient was excluded who was managed by another surgeon at Seattle Children's Hospital who did not use the same evaluation protocol. The remaining 62 patients underwent treatment by a consistent team comprised of a single orthopedic surgeon, a general/thoracic surgeon, and a single pulmonologist.

For each case, the goal of treatment was to reach the age of more than 10 years using nonsurgical or surgical growth sparing techniques. Decisions for continuation of expansion surgery, final device removal, and/or spinal fusion were taken on a case-by-case basis as children reached 10 years of age.

All children had an evaluation phase prior to their primary device insertion and further evaluations for subsequent device expansions or revisions. The evaluation phase (first epoch) of care included obtaining a chest and spine CT scan, V/Q scans on most children, spinal MR image, and plain radiographs of the spine. Patients were observed using radiographs at 4- to 6-month intervals to follow the rate of progression of the deformity. Monitoring included upright PA radiographs until the Cobb angle measured 50° , at which time a supine anterior-posterior radiograph of the spine with traction was added. Surgical intervention was recommended to patient families for increasing lung V/Q asymmetry, worsening clinical respiratory status or lung functions, or the rigid Cobb angle on the traction radiograph exceeding 50° . At the time of VEPTR implantation, intraoperative fluoroscopy was used for pedicle screw placement and to confirm appropriate positioning of the device.

For expansion procedures, intraoperative fluoroscopy images were taken to confirm expansion and retention of the upper and lower anchors. Upright postoperative PA and lateral radiographs were obtained on postoperative day 3, at 4 to 6 weeks after initial implantation, and prior to expansion or revision at 6- to 9-month intervals. For the initial 17 patients, chest CT scans were scheduled at 6-month intervals as a part of the FDA requirements for an investigational device exemption (IDE) application. After completion of the IDE process, patients had a chest CT and V/Q scans at an average of 2 years and spine or chest CT scans if there was a concern about anchor position from the plain radiographs.

Radiation Calculations

We reviewed patient charts and radiology files of our institution to find the total number of radiographs, CT scans, and V/Q scans that they received related to the evaluation and/or treatment of TIS. The dates of primary VEPTR implantation, expansion, revision, and final spinal fusion procedures were noted. Imaging studies were assigned to each epoch of management, that is, period through first implantation and each subsequent period of expansion or replacement of the device. The end point of each time period was the day of each surgical procedure and included the intraoperative fluoroscopy.

We estimated radiation dosimetry using an average radiation exposure and the relative contribution of each procedure across this cohort of patients. We derived estimates for radiation exposure from published methods to ascertain average imparted doses. We chose to estimate effective dose, which is a construct for comparing different imaging studies. Effective dose is intended to describe the mean absorbed dose from a uniform whole body irradiation that would result in the same radiation detriment as a nonuniform, partial body irradiation.¹¹ Our in-house radiology database includes 4 variables for CT scans performed after 2006, which can be used to calculate the radiation that the patient received during the scan. These are the dose length product (DLP in mGy·cm), DLP phantom (16 or 32 cm), kilovoltage peak (kVp), and age at time of study. These 4 variables are specific to each study and were entered into a Web-based estimating tool for pediatric CT scans designed by Alessio and Phillips, 2010.¹² The resultant estimated radiation dose is described in units of millisieverts (mSv). Seventy spine CT scans, 12 chest CT scans, and 7 pelvis CT scans performed after 2006 had data sufficient to calculate the radiation dose the patient received from each scan. For 2002–2007, the CT protocols were based on work described by Paterson *et al.*¹³ This protocol has been automated since 2007. Our CT scanners were: 2002–2004 Toshiba Aquilion 4 slice scanner, 2004–2007 Toshiba Aquilion 16 slice scanner, 2007–current GE Lightspeed, and Discovery 64 slice scanner (Toshiba America, Irvine, CA). Our current protocols use recommendations established by Singh *et al.*¹⁴ and Strauss *et al.*¹⁵

The average values derived from these studies were then applied to 137 CT scans (56 spine, 78 chest, and 3 pelvis CTs) for which there was no data available by which to estimate radiation dose. A reference value of 2 mSv per V/Q scan was used to determine the radiation exposure the patient received from these studies.¹⁶ Radiation dose from fluoroscopy was calculated by collecting procedure specific values for the dose area product from a radiology database. The fluoroscopy dose area product was collected from 32 VEPTR implantation procedures (average $1.04 \text{ Gy}\cdot\text{cm}^2$ [$104.42 \text{ rad}\cdot\text{cm}^2$] per procedure) and from 95 expansion procedures, (average value $0.14 \text{ Gy}\cdot\text{cm}^2$ [$14.12 \text{ rad}\cdot\text{cm}^2$] per procedure). A conversion coefficient of 0.2 mSv per $\text{Gy}\cdot\text{cm}^2$ from Petoussi-Henss *et al.*¹⁷ was then applied to the average dose area product values for both procedure types, giving an average effective dose of 0.2 mSv for implantation and fusion procedures and 0.03 mSv for expansion procedures. These values were applied to all

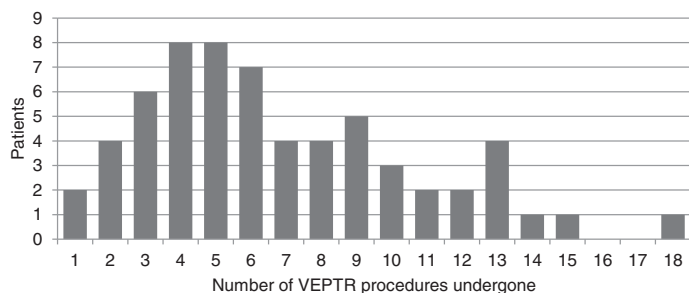


Figure 1. Histogram of number of surgical procedures per patient: procedures include VEPTR implantation, expansions, revisions, and removals. VEPTR indicates vertically expandable prosthetic titanium rib.

fluoroscopy radiation exposures for every implantation and expansion procedure. Reference values of 0.02 mSv for anterior-posterior chest radiographs, 0.08 mSv for lateral chest radiographs, and 0.6 mSv for pelvis radiographs were taken from Mettler *et al.*¹⁸ Values of 0.1 mSv for anterior-posterior whole spine radiographs and 0.15 mSv for lateral

spine radiographs from Lee *et al* were used.¹⁹ We recorded the number of MR image for scoliosis-related VEPTR management in each epoch of care. The total radiation from each of the 4 imaging studies using ionizing radiation (CT scans, radiographs, V/Q scans, and fluoroscopy) was tabulated for each patient.

The total number of radiographs, CT scans, and MR images ordered by physicians other than our VEPTR team for assessment of comorbidities were also recorded. The relative contribution of radiation exposure due to TIS compared with the exposure not for VEPTR related care was not evaluated.

The total radiation dose to the patient in the time period leading up to and including the date of the first procedure was tabulated as Epoch 1. The sum of effective dose from CT, X-rays, V/Q, and fluoroscopy for the remaining procedures was calculated, and divided by the total number of procedures minus 1 to reflect the average radiation dose per procedure for each time period or epoch of care after the initial implantation.

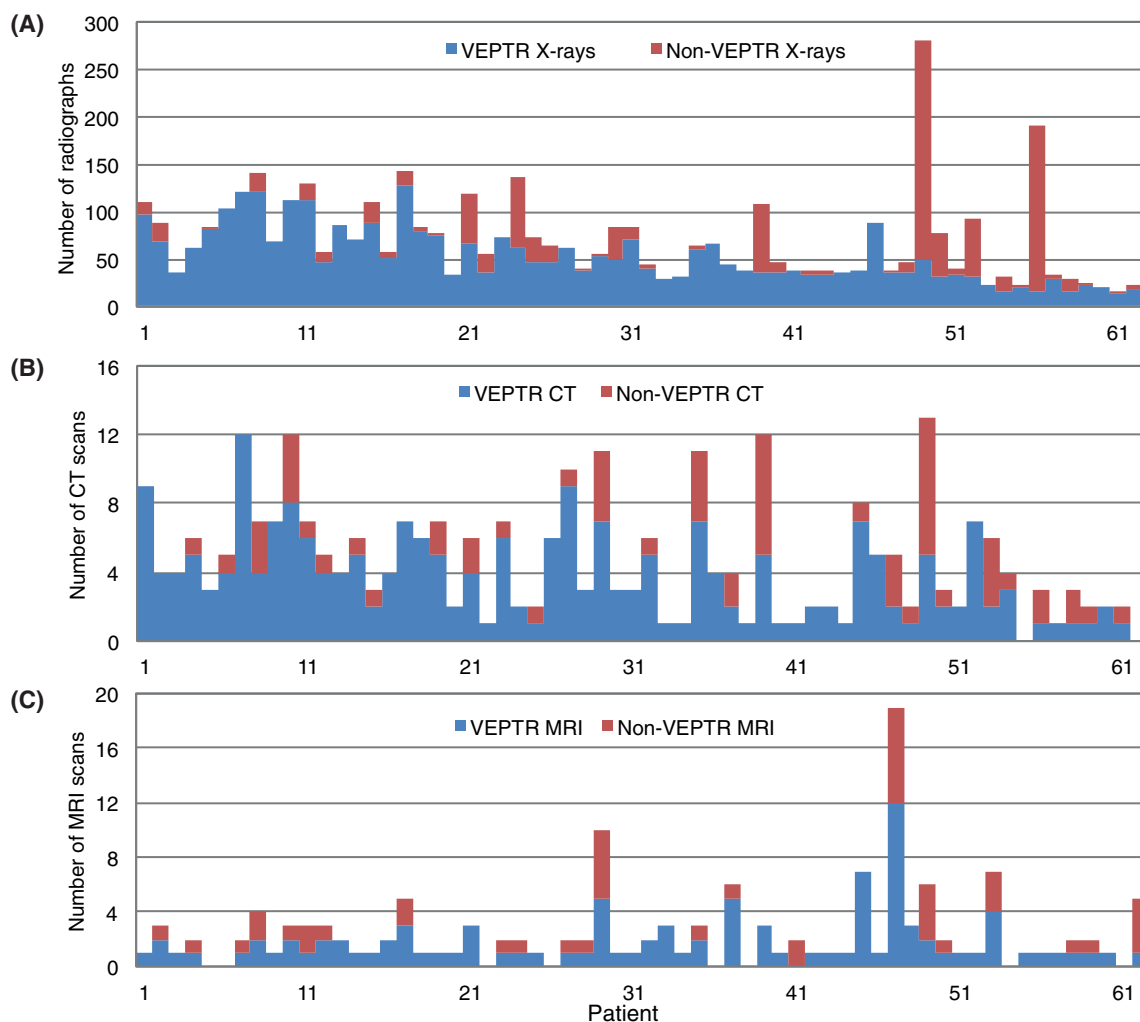


Figure 2. Summary of imaging studies by patient comparing TIS *versus* non-TIS reasons for radiographs (A), CT scans (B), and MR images (C). VEPTR indicates vertically expandable prosthetic titanium rib; TIS, thoracic insufficiency syndrome; MR, magnetic resonance; CT, computed tomography.

RESULTS

There were 447 surgical procedures (epochs) for 62 patients with TIS. There were 28 males and 34 females with a mean age of 5 and 6.9 (range, 1–18) years, respectively, at the time of initial surgical treatment. The average number of TIS related radiographs, MR images, CT scans, and V/Q scans per patient for epoch 1 was 17 (± 3), 1.5 (± 1.6), 1.6 (± 1), and 1 (± 0.7), respectively. The reference value used for V/Q scans was 2 mSv and our calculated average for chest CT scans was 3.3 mSv for each scan. The average time from initial visit to our clinic to time of first surgery (epoch 1) was 11 months (3–37 mo). The average number of TIS related radiographs, MR images, CT scans, and V/Q scans per subsequent epoch of care was 5 (± 2), 0.02 (± 0.03), 0.35 (± 0.26), and 0.14 (± 0.14), respectively. The number of patients and their number of procedures is shown in Figure 1. Nine patients had reached 10 years of age and undergone VEPTR removal and spinal fusion after an average of 10 procedures per patient spread over an average of 5.4 years (3.6–6.6). Figure 2 shows the number and proportion of radiographs, CT scans, and MR images associated with TIS management compared with the total number of studies for other reasons received during the same time period as their TIS management. All studies except for 4 CT scans were performed at our center.

The average value for spine, chest, and pelvis CT scans was calculated and is noted in Table 1. The first 17 patients were enrolled in an institutional review board approved FDA IDE protocol. The average number of CT scans for this cohort was 0.78 per epoch of treatment *versus* 0.55 scans per epoch for the remaining patients. Sixteen patients had revision of a proximal anchor during their treatment and all had CT scans of proximal anchor points with protocol chest CTs for lung volume. In 3 of these cases, the migration was not discernable by plain radiographs. The incidence of proximal anchor migration decreased dramatically after the introduction of VEPTR II. One subject had a CT scan of the lumbar spine due to migration of the distal hook into the canal. The average cumulative effective dose for our 62 patients in the time up to the first procedure (epoch 1) was 13.0 mSv (± 7.9). The average effective dose per procedure per patient for each subsequent epoch after the initial implantation was 3.2 mSv (± 3.6) (Table 2). The distribution of average radiation exposure by epoch of care is shown in Figure 3. Epoch 16 shows a significantly higher level of average radiation relative to adjacent epochs due to a patient who had a high exposure due to erroneous exposure.

TABLE 1. Average Calculated Doses for Spine, Chest, and Pelvis CT Scans

CT Type	Average Dose (mSv)	Number of CT	Standard Deviation
Spine	7.91	70	6.29
Chest	3.34	12	1.92
Pelvis	2.27	7	0.49

CT indicates computed tomography.

Table 3 shows the radiation exposures for the first epoch in row 1 and all subsequent epochs of treatment by study type for the 9 patients who have completed treatment in row 2. The average total amount of radiation per patient, combining implantations and expansion is shown in row 3 and was 59.6 mSv. CT scans accounted for the majority (74%) of ionizing radiation that these patients received.

The total radiation exposure for all 62 patients broken down by type of imaging and dose is shown in Figure 4. Patient 7 had a halo in place with weight adjustments and a simultaneous head and spine CT were performed with the higher dose head protocol extended down to the spine. Patient 27 had a total of 9 CT scans and was obese. Scan sequences using a lower noise technique (higher dose) had been used in early scans. Subsequent scans were done using lower doses. The percentile radiation exposure for all patients, all imaging studies, through all the recorded epochs of treatment is shown in Figure 5.

DISCUSSION

This article is the experience of one center that treats a high volume of patients with TIS by a single team using consistent protocols for evaluation and decision making for treatment. We do not claim that our protocol is the ideal one for children with TIS, but present the iatrogenic radiation exposure associated with its use. We found using a standard protocol that included CT scans of the spine and chest that children with TIS had an average exposure of 13.01 mSv during their initial investigation including the initial implantation of a VEPTR growth-sparing device (epoch 1). Many of the 62 patients in our series are still undergoing care. For this reason, we looked at the average radiation exposure during subsequent expansions and exchanges defining each of these as an epoch of

TABLE 2. Average Radiation Per Epoch for Each Study Type for All 62 Patients

	Avg. CT Rad/Ep.	Avg. XR Rad/Ep.	Avg. V/Q Rad/Ep.	Avg. FL Rad/Ep.	Avg. Total Rad/E.
First epoch avg.	8.91 mSv \pm 6.9 (68.5%)	1.87 mSv \pm 0.9 (13.7%)	2.03 mSv \pm 1.4 (15.6%)	0.29 mSv NA (2.2%)	13.01 mSv \pm 3.6
Other epochs avg. exposure per epoch	2.17 mSv \pm 2.0 (68.7%)	0.66 mSv \pm 0.3 (20.9%)	0.30 mSv \pm 0.3 (9.5%)	0.04 mSv \pm 0.03 (1.3%)	3.16 mSv \pm 3.6

CT indicates computed tomography; Avg, average; V/Q, ventilation and lung perfusion; FL, fluoroscopy.

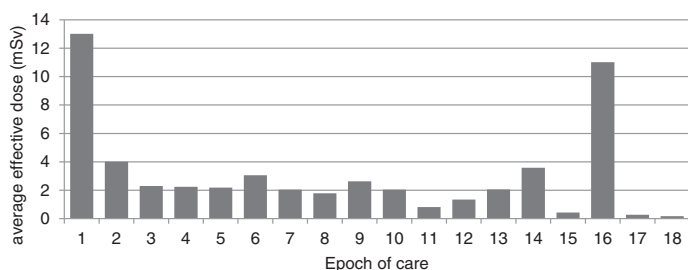


Figure 3. Average effective dose per epoch of care.

care. The exposure averaged 3.16 mSv/epoch of care for all of our patients. Yearly average background radiation in the United States is estimated to be 3.0 mSv per year.²⁰

The high relative contribution of CT scans to the overall radiation exposure of patients with VEPTR is of concern. CT has been implicated as a major source of ionizing radiation within medical imaging, particularly in pediatric radiology.^{21,22} Several published series emphasize the use of chest CTs for the assessment of lung volumes and a large number of imaging modalities in the assessment of this group of patients.^{10,23–26} These are done in an effort to understand the progression of their structural deformities, response to treatment, natural progression of disease, consequences of complications, and the impact of structural features to pulmonary function. The first 17 patients in our series were a part of the FDA IDE review of the VEPTR device. The protocol called for chest CT scans at 6-month intervals to assess lung volume. We rapidly moved away from this protocol upon completion of the IDE study. Subsequent patients had chest CT scans at 2-year intervals with the substitution of radionuclide V/Q scans as an alternative method of assessing lung function. This led to fewer scans per epoch of treatment. The need for CT scans to define anchor migration has declined over the time of the study with the introduction of VEPTR II leading to a marked decline in proximal anchor failures. Efforts to reduce radiation exposure due to CT scans are highly institution dependent at this time. The use of pediatric protocols that take into account the smaller body surface area have been popular since 2002¹² and implementation of these along with the “image gently” recommendations^{13,14} led to reductions in radiation dose. Technical improvements using wider array detectors

and automatic exposure controls have also helped to decrease doses received by pediatric patients. We may be underestimating the dose of radiation received in children who had imaging from 2001–2006, but the results reported in this article still lead us to conclude that CT scans are the source of greatest dose exposure in patients with TIS using current evaluation protocols. The introduction of 3D dynamic MRI may offer an option into the future for the assessment of both spine and lung development of function.^{27,28}

Nine patients in our series have completed treatment. For these 9 patients the average total radiation exposure beginning with VEPTR implantation and ending with fusion was approximately 59.6 mSv over 5.4 years. This level of radiation corresponds to approximately 20 years worth of background radiation in the US. We estimated the increased risk of detriment based on the very limited knowledge of risk from low levels of radiation. Using tables from the BEIR VII Phase 2, and an average age at time of initial procedure for males of 5.0 years, and for females of 6.9 years, the approximate increased lifetime attributable risk of any type of cancer from a 59.6 mSv exposure is 1.0% for males and 1.8% for females.²⁹ The increased risk of cancer mortality from this level of exposure in males and females of the same ages is 0.5% and 0.8%, respectively. These increased risks are coarse, but demonstrate that there is some risk associated with these examinations. It is worth noting that the background risk of cancer (in the absence of this additional radiation) far exceeds these increased risks (risk of incidence in males is 45.9% and females is 41.3%).²⁹

We think that future studies should focus on how to reduce radiation exposure to this group of patients by better defining the role of imaging in decision-making and management, implementing consistent dose reduction strategies, and refining the hardware and imaging algorithms to minimize exposure.

Limitations of this study are the retrospective nature of the review and a lack of a uniformly enforceable schedule of tests and evaluations. Additionally, radiation dosing for studies that were performed before we had direct dose measurements from our radiology database required an averaging of studies where we had dose measurements and applying these to studies where we were unable to calculate dose. The heterogeneity of the patients being seen necessitated variation in the

TABLE 3. Average of Epoch 1 Compared With All Other Epochs for 9 Patients Who Had Completed Treatment and Undergone Spinal Fusion

	Avg. CT Rad	Avg. XR Rad	Avg. V/Q Rad	Avg. FL Rad	Avg. Total Rad
First epoch avg.	7.24 mSv ± 5.8 (62.3%)	1.97 mSv ± 0.7 (16.9%)	2.2 mSv ± 1.2 (18.9%)	0.21 mSv NA (1.8%)	11.62 mSv ± 6.4 (19.5%)
Avg. of sum of all other epochs/% of total	37.02 mSv ± 26 (77.2%)	6.84 mSv ± 1.84 (14.3%)	3.56 mSv ± 1.89 (7.4%)	0.52 mSv ± 0.11 (1.1%)	47.94 mSv ± 16.9 (80.5%)
Avg. total radiation for entire course of treatment	44.26 mSv ± 21.3 (74%)	8.81 mSv ± 1.5 (14.8%)	5.76 mSv ± 3.0 (9.7%)	0.73 mSv 0.1 (1.2%)	59.56 mSv ± 23.5

CT indicates computed tomography; Avg, average; V/Q, ventilation and lung perfusion; FL, fluoroscopy; Rad, radiation.

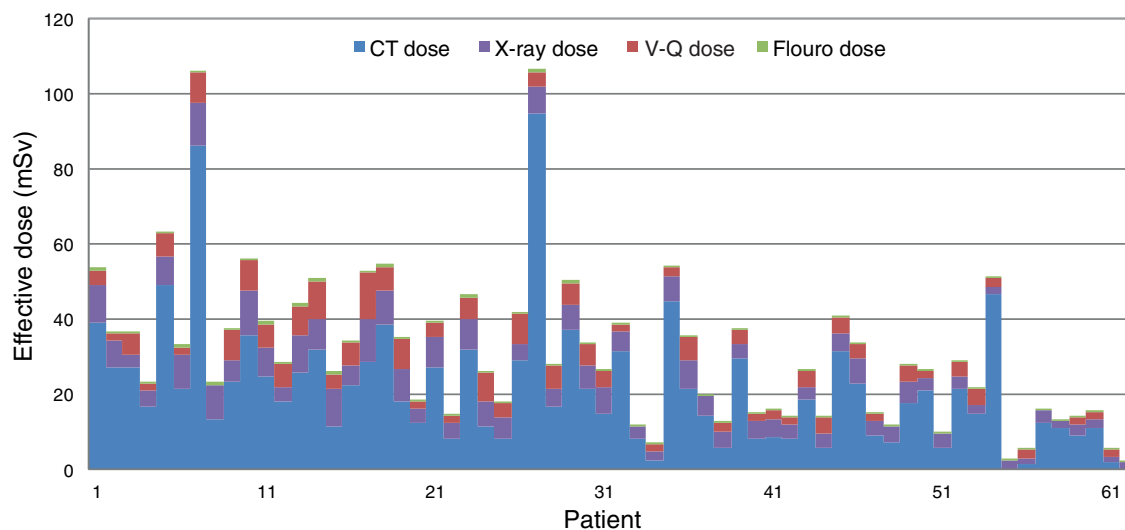


Figure 4. Total effective dose per patient with breakdown of dose per imaging type. CT indicates computed tomography; V/Q, ventilation/perfusion.

intensity of the evaluations due to varying degrees of deformity severity at presentation and variable comorbidities. It is notable that many of these children had additional radiation exposure as a result of evaluation of other organs independent of their TIS evaluation and treatment.

CONCLUSION

Children undergoing evaluation and treatment of TIS using current imaging protocols are exposed to levels of radiation 4 times their yearly exposure as compared with natural background levels of radiation. The lifetime increase in cancer risk as a result of this radiation exposure seems to be low, but is unknown. The majority of this exposure is during initial evaluation prior to initial surgery. CT scans account for 74% of total radiation exposure. Decreasing these studies would have the greatest impact in decreasing overall radiation exposure. The value of radiographical studies currently used for the assessment and management of these children is as yet unproven. Many of these are used as surrogates for pulmonary function. Development of more direct testing of lung

function may help diminish the intensity of imaging. Optimal imaging strategies for preoperative planning and tracking the progression of deformity may, in the future, also help diminish radiation exposure.

➤ Key Points

- ❑ Radiographical imaging for patients with TIS is intense during assessment and treatment.
- ❑ Average radiation exposure for a cohort of patients treated by a single center using a consistent protocol for TIS was 4 times natural background radiation over the same time.
- ❑ CT scans accounted for 69% of the total radiation exposure.

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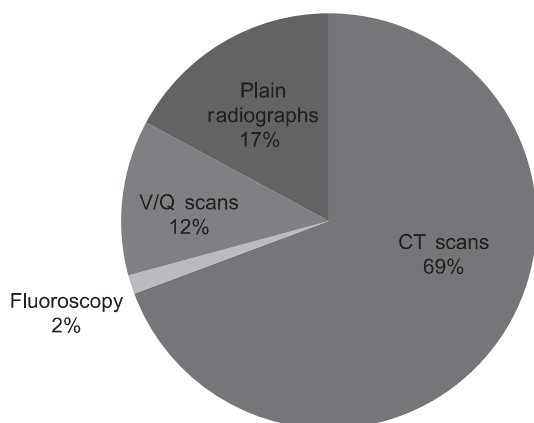


Figure 5. Breakdown of average total radiation by study type for all patients and all epochs. V/Q indicates ventilation/perfusion.

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