

Observational Report



Radiation Dose Practice Audit of 6,234 Fluoroscopically-Guided Spinal Injections

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Background: Fluoroscopic imaging guidance is frequently used in performing spinal interventional techniques. Reference level standards are a quality improvement tool to help reduce radiation dose and serve as benchmarks for physicians and their technologists to achieve reasonable radiation exposure while performing fluoroscopically-guided spinal procedures. There are limited data describing radiation dose for musculoskeletal injections - in particular, spinal injections without any published reference standards.

Objective: The purpose of this study is to perform a practice audit of radiation doses of fluoroscopically-guided spinal injections to establish preliminary reference levels as a quality improvement tool for potential use in future radiation reduction measures.

Study Design: Retrospective, observational study.

Settings: An academic-based subspecialty, high volume pain medicine practice.

Methods: A retrospective analysis of 6,234 spinal injections of 9 different types performed by experienced practitioners between January and December 2012 was conducted under an institutional review board's approval with HIPAA compliance and waiver of informed consent. Cumulative radiation dose (in mGy) and exposure time (in seconds) distributions (percentiles) as displayed on the C-arm were calculated per injection for each type of fluoroscopically-guided spinal injection. Confidence intervals for the dose distributions were determined by using bootstrap resampling and were used to determine preliminary reference levels.

Results: Proposed preliminary reference levels of cumulative radiation dose (in mGy) and exposure time (in seconds) for fluoroscopically-guided spinal interventional procedures are provided for lumbar transforaminal (13 mGy, 30 s), cervical transforaminal (6 mGy, 49 s), caudal epidural (12 mGy, 23s), cervical facet injection (3 mGy, 36 s), lumbar facet injection (9 mGy, 20s), interlaminar (13mGy, 39s), lumbar radiofrequency denervation (7 mGy, 17s), lumbar sympathetic block (21 mGy, 39s), cervical medial branch block (2 mGy, 25 s), lumbar medial branch block (4 mGy, 12s) and sacroiliac joint injections (18 mGy, 37s).

Limitations: Study performed at a single subspecialty institution using only one type of C-arm which limits generalizability.

Conclusions: Radiation doses and preliminary reference levels of fluoroscopically-guided interventional spine procedures performed by experienced practitioners are made available without correction for body habitus or field of view, magnification or subtraction techniques or continuous vs pulsed mode. A registry of radiation-dose data for fluoroscopically-guided interventional spine procedures would be the next step to refine this data.

Key Words: Spinal procedures, radiation dose, patient safety

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Medical radiation exposure has significantly increased over the past several years (1). Radiation exposure has associated potential risks to the physician, patient, and procedure room personnel. Concerns of radiation exposure are increased risk of radiation-induced cancer, cataracts, local skin erythema, epilation, and dermal necrosis (2). Reducing ionizing radiation and following the ALARA principle (As Low As Reasonably Achievable) is considered a mandatory task for all medical providers.

An increase in the number of fluoroscopically-guided interventional procedures is one source contributing to the identified increased radiation dosage (3). Fluoroscopic imaging guidance is frequently used in performing spinal interventional techniques. The major purposes of fluoroscopy are accurate needle placement, confirmed absence of intravascular uptake, and documented injectate spread in order to ensure target specificity and technically accurate delivery of the injected medication (4-13).

Reference level standards are a quality improvement tool to help reduce radiation dose (14) and serve as benchmarks for physicians and their technologists to achieve reasonable radiation exposure while performing fluoroscopically-guided spinal procedures. Reference levels have been suggested for interventional radiology (15), diagnostic fluoroscopy (16), and cardiology examinations (17).

Data is limited that describes radiation doses for musculoskeletal injections. In particular, spinal injections in prior studies reported only epidural injections and neither created reference standards nor reviewed other spinal procedures (18,19). Spinal injections vary from other interventional radiology procedures as radiation dose increases with the number of injections per procedure (i.e. number of spinal levels injected and bilateral versus unilateral injections).

The purpose of this study is to perform a practice audit of radiation dose per level for fluoroscopically-guided spinal injections performed by experienced practitioners and to provide preliminary reference doses for potential use in future dose reduction measures.

METHODS

This study was performed after approval of the Institutional review board with Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance. There was a waiver of informed consent. There was no industry support for this project.

Patients

This retrospective, observational study evaluated 7,184 consecutive spinal injections performed from January 2012 to December 2012 at an academic based subspecialty, high-volume pain medicine practice. Inclusion criteria were: nonpediatric patients of all ages who underwent a lumbar transforaminal, cervical transforaminal, caudal, lumbar facet injection, interlaminar (translaminar), cervical radiofrequency denervation, lumbar radiofrequency denervation, lumbar sympathetic block, cervical medial branch block, lumbar medial branch block or sacroiliac joint injection. These injections were chosen because they are the most commonly performed at our institution and yield at least 40 cases per procedure type. Thoracic injections were not included because only a small number were performed. Patients were excluded if they had more than one type of injection.

Procedures

All procedures were performed on 1 of 4 GE OEC 9900 Elite fluoroscopy units (General Electric Healthcare, Waukesha, WI) that each receive routine, quality control measures and calibration testing every 6 months. One unit was installed 2009, 2 units installed in 2011, and 1 unit installed in 2012. There were 18 different physicians consisting of 10 physiatrists and 8 anesthesia pain management physicians. There were 21 radiology technologists. All the studies were performed in the special procedures unit and were performed by experienced technologists who were specifically trained passed a competency checklist. With all procedures coning/collimation was used as good procedural practice.

Data collection

Cumulative total radiation dose (in mGy) and fluoroscopy time (in seconds) were obtained from the C-arm report of each procedure (Fig. 1). The radiation dose from the C-arm report accounts for all fluoroscopy time and radiation used during the procedure. The dose reported is entrance surface skin dose and is calculated on the basis of dose area product by the x-ray unit software. If more than one site was performed during a case, the cumulative reported radiation dose and fluoroscopy time was divided by the number of sites injected and mean dose per injection site. The mean fluoroscopy time per injection site was subsequently calculated. For example, if the bilateral L3/4 and right L4/5 facet injection dose was 2.74 mGy and time was

60.1 s, than the mean dose per injection site was 2.74 mGy / 3 sites = 0.91 mGy and the mean fluoroscopy time per injection site was 60.1 s / 3 sites = 20.03 s.

Statistical Analysis

Descriptive statistics were performed for frequency of injection type with mean and standard deviation of the reported dose expressed in mGy.

Density curves of reported dose per injection and time per injection for each procedure were created using kernel density estimation for determination of dose distribution. A Shapiro-Wilk test for normality was performed with P value cutoff 0.05, which showed radiation dose per injection and fluoroscopy time per injection were not normally distributed for each injection type. As such, a bootstrap, which is a nonparametric method for calculating confidence intervals, was performed for calculation of dose per injection and time per injection estimates of quartiles and confidence intervals. Basic bootstrap was performed with 10,000 bootstrap subsamples with replacement from the original data set. Preliminary reference levels were obtained by rounding approximately midway between the 75th percentile and the upper bound of the 75th percentile, similar to prior publications (20). Statistical analysis and graphing was performed with R, a language and environment for statistical computing version 3.2.3 (21).

RESULTS

After applying the inclusion and exclusion criteria, 6234 procedures were evaluated, including 3,590 transforaminal lumbar, 157 transforaminal cervical, 658 caudal epidural, 62 cervical facet joint, 410 lumbar facet joint, 446 interlaminar (translaminar), 318 radio-frequency denervation (lumbar), 296 lumbar sympathetic block, 41 cervical medial branch block, 169 lumbar medial branch block, and 87 sacroiliac joint injections. Single level procedures comprised 59%, 2 level procedures comprised 29%, and 3 or more levels comprised 12%. The mean number of levels was 1.6, the median 1, and the 75th percentile was 2.

Recorded dose distributions for the 9 procedure types were plotted and found to be from non-normal distributions. Table 1 lists the radiation dose and the fluoroscopy time with the 10th, 25th, 50th, and 75th percentile estimates for the 9 procedures.

Preliminary reference levels of cumulative reported radiation dose (in milliGray) and exposure time (in seconds) for the 11 fluoroscopically-guided interventional procedures are provided in Table 2.

Name		Date
Patient ID		Physician
Procedure		
Accession #		
Generator Mode	Time	Cumulative Dose
Fluoro	56.1 s	79.8 %
HLF/Dig. Spot/Subtr	4.0 s	20.2 %
Film	0.0 s	0.0 %
Totals	60.1 s	2.74 mGy
Field of View	Time	Cumulative Dose
Normal	4.1 s	5.1 %
Mag 1	25.2 s	30.3 %
Mag 2	30.8 s	64.5 %
Mode	Time	Cumulative Dose
Continuous	60.1 s	100.0 %
Pulsed	0.0 s	0.0 %
Dose Summary		

Fig. 1. Example of dose report. This patient had a cumulative exposure time of 60.1 s and cumulative dose of 2.74 mGy.

Lumbar sympathetic block had the highest dose per injection (21 mGy), whereas cervical medial branch block had the lowest dose per injection (2 mGy) for reference levels. Transforaminal cervical had the highest time per injection (49 sec) but nearly the lowest dose per injection (6mGy), while cervical medial branch block had the lowest dose (2 mGy) and a mid level time per injection (25 sec). Lumbar sympathetic block had the highest dose per injection and the second highest time per injection (39 sec).

DISCUSSION

Musculoskeletal disorders are a substantial cause of morbidity worldwide, with spine-related pain syndromes being particularly problematic. Spinal injections are minimally invasive, can supplement diagnostic testing and provide therapeutic benefit such that, in some cases, replace or delay the need for surgery (4-9). Proper needle placement using image guidance, most often with fluoroscopy, insures precision, maximizes treatment effect and minimizes complications (10-13). The number of spinal procedures performed has grown over 100% from 2000 through 2008 (3).

These now commonly performed spinal injections can be a substantial source of radiation exposure. The procedures often involve injecting multiple spinal levels/structures and are frequently repeated. Ionizing

Table 1. Dose (mGy) per injection and time (s) per injection by procedure.

Radiation Dose (mGy)								
Procedure	Number of studies	Mean dose	Standard deviation	10th percentile with 95% CI	25th percentile with 95% CI	50th percentile with 95% CI	75th percentile with 95% CI	95th percentile with 95% CI
Transforaminal Lumbar	3590	10.4	11.9	2.0 (1.9-2.2)	3.5 (3.3-3.6)	6.7 (6.5-7.0)	12.5 (11.9-13.1)	32.4 (30.6-34.2)
Transforaminal Cervical	157	5.6	6.5	1.0 (0.8-1.1)	1.8 (1.4-2.2)	3.3 (3.0-3.7)	5.7 (3.3-6.5)	21.8 (18.0-27.6)
Caudal epidural	658	10.0	12.4	1.6 (1.3-1.7)	3.1 (2.8-3.6)	6.0 (5.5-6.4)	11.0 (9.6-12.4)	32.8 (27.3-36.3)
Facet joint Cervical	62	2.6	2.8	0.5 (0.4-0.8)	0.7 (0.3-0.9)	1.5 (0.9-1.7)	3 (1.3-4)	8.4 (6.8-12.1)
Facet joint Lumbar	410	6.45	6.41	1.1 (0.7-1.2)	2.2 (2.1-2.5)	4.1 (3.3-4.5)	8.7 (7.9-10)	19 (15.2-22.1)
Interlaminar (translaminar)	446	11.2	14.7	1.4 (1.2-1.6)	2.7 (2.2-3.0)	6.4 (5.8-7.4)	12.4 (9.3-13.6)	42.2 (26.7-52.5)
Radiofrequency denervation (Lumbar)	318	4.7	6.6	0.5 (0.4-0.6)	1.3 (1.1-1.5)	2.7 (2.3-3.1)	6.3 (5.7-7.5)	15.8 (13.0-20.1)
Lumbar sympathetic block	296	15.4	16.2	2.5 (2.0-2.8)	4.5 (3.1-5.3)	9.9 (7.9-10.9)	19.2 (15.3-21.9)	49.9 (40.1-62.8)
Medial branch block cervical	41	2.2	2.1	0.4 (0.2-0.5)	0.7 (0.3-1)	1.7 (0.8-2.4)	2.8 (1.4-3.4)	6.4 (2.7-8.9)
Medial branch block lumbar	169	3.4	4.4	3.9 (3-4.1)	5.2 (4.6-5.5)	7.9 (6.8-8.5)	12.1 (10.6-13.8)	21.8 (14.8-25.7)
Sacroiliac joint	87	9.9	8.2	2.0 (1.4-2.5)	3.7 (1.9-4.9)	7.0 (5.9-7.7)	15.0 (11.8-21.3)	27.4 (22.6-33.9)
Procedure Time (s)								
Procedure	Number of studies	Mean time	Standard deviation	10th percentile with 95% CI	25th percentile with 95% CI	50th percentile with 95% CI	75th percentile with 95% CI	95th percentile with 95% CI
Transforaminal Lumbar	3590	24.3	15.4	10.4 (10.1-10.6)	14.3 (14.0-14.6)	20.3 (19.7-20.8)	29.9 (29.2-30.9)	52.7 (50.9-55.2)
Transforaminal Cervical	157	40.4	28.6	18.2 (17.3-20.5)	21.1 (18.6-22.6)	31.2 (27.0-35.7)	46.3 (37.7-52.0)	105.0 (84.5-122.6)
Caudal epidural	658	18.9	13.9	7.3 (6.7-7.9)	10.1 (9.6-10.5)	14.8 (13.8-15.6)	22.6 (20.7-23.8)	44.8 (34.9-49.4)
Facet joint cervical	62	27.0	18.5	11.2 (9.7-13.5)	13.6 (10.3-15)	22.1 (17.8-26.7)	35.2 (28.3-43.6)	52.3 (19.8-61.2)
Facet joint lumbar	410	16.5	9.1	7.3 (6.7-7.7)	10.3 (9.3-11.1)	14.4 (13.5-14.9)	20.5 (18.9-21.8)	33.5 (31.2-37.2)
Interlaminar (translaminar)	446	29.5	20.7	11.6 (10.8-12.1)	15.4 (14.3-16.5)	23.5 (20.9-25.4)	37.3 (34.9-40.1)	64.2 (54.7-70.3)
Radiofrequency denervation (Lumbar)	318	13.5	10.4	4.8 (3.7-5.5)	7.3 (6.6-8.0)	11.5 (10.9-12.4)	16.2 (14.8-17.8)	28.2 (21.4-30.6)
Lumbar sympathetic block	296	32.3	14.0	19.1 (17.8-20.6)	23.9 (22.9-24.7)	29.1 (27.2-30.5)	37.5 (35.8-39.7)	59.1 (48.9-67.8)
Medial branch block cervical	41	19.1	10.0	6.9 (1.8-8.4)	12.3 (9.4-16.6)	16.9 (11.3-19.6)	25.4 (21.1-29.6)	35 (18.4-41.4)
Medial branch block lumbar	169	9.8	7.3	3.9 (3-4.1)	5.2 (4.6-5.5)	7.9 (6.8-8.5)	12.1 (10.6-13.8)	21.8 (14.8-25.7)
Sacroiliac joint	87	28.6	14.5	13.3 (12.4-15.1)	16.6 (13.5-19.4)	27.8 (23.7-33.8)	36.1 (30.1-38.6)	54.7 (46.7-63.8)

radiation has risks to both providers and patients. Two programs introduced by the American College of Radiology (ACR) to decrease radiation dose or patient exposure for diagnostic imaging are “Image Wisely” and “Image Gently” (22,23). Techniques to reduce radiation dose during diagnostic and interventional procedures are known however, decreasing radiation dose during interventional procedures, can be more difficult (24). Decreasing the use of subtraction and magnification techniques, increasing use of collimation and use of pulsed fluoroscopy are recognized as contributing factors to controlling radiation exposure.

Reference level metrics are a quality assurance, and quality improvement tool for controlling radiation dose. National and international advisory bodies have supported the use of reference levels (25,26). This study builds upon prior research that established fluoroscopy reference doses for cardiology and interventional radiology procedures (15,17). There is minimal radiation dose data in the current literature for spinal injections, which has primarily focused on vertebroplasty was not part of our study. Spinal injections may need to be evaluated differently than the other types of percutaneous image-guided procedures, as the metric of dose per injection is more appropriate than total dose since spinal procedures are often performed at multiple levels. Two previous studies reported radiation dose for fluoroscopy guided epidural injections and compared them to CT guidance but did not create reference standards, did not look at other spinal procedures, and reported the mean dose per procedure as opposed to per level (18,19). Although fluoroscopy time per injection site was reported, radiation dose is a more important variable. For example, transforaminal, facet, and medial branch block cervical spinal injections have greater time compared to lumbar spinal injections but lower dose because the automatic exposure control sets a lower technique for the smaller/thinner neck tissue as compared to the lower back.

Our data provides an approximation of radiation dose for commonly performed spinal injections. Some of our reported radiation times and doses are low. The reason for low dose and radiation times is likely multifactorial. This is a practice audit of a subspecialty, high volume pain medicine practice consisting of very experienced physicians in these techniques and who perform them regularly. The majority of procedures are done by only the attending even when a trainee is involved. Also, the dose and times are presented per level, and many of the procedures are multi-level. We

Table 2. *Proposed fluoroscopy reference levels by procedure.*

Procedure	Reference Dose level (mGy)	Reference Time level (s)
Transforaminal Lumbar	13	30
Transforaminal Cervical	6	49
Caudal epidural	12	23
Facet joint Cervical	3	36
Facet joint Lumbar	9	20
Interlaminar (translaminar)	13	39
Radiofrequency denervation (Lumbar)	7	17
Lumbar sympathetic block	21	39
Medial branch block cervical	2	25
Medial Branch block lumbar	4	12
Sacroiliac joint	18	37

believe the fluoroscopic times reflect the efficiency and skill of these clinicians.

Limitations

There are several limitations to this study. A primary limitation is that there is no standard fluoroscopy technique used for the procedures. Procedures are performed with the general guiding principal of low dose technique, utilizing primarily pulsed, non-magnification techniques, except when the image is deemed inadequate by the physician. Additionally, coning/collimation was not recorded or tracked. Accuracy of needle placement was determined by each of the individual clinician operators. Further, it is not known if these are ideally conducted procedures; efficacy and safety of the procedure were not evaluated in this study and are not part of our hypothesis. This study was performed at a single subspecialty institution using only one type of C-arm, which potentially limits applicability across other devices. We also did not compare this with CT-guided injections. Patient weight and body habitus is not addressed as these data were not available but is a very important determinate of radiation dose and possibly time. Procedural difficulty or complex anatomy (e.g. postoperative, scoliosis) also was not taken into account. The use of magnification and/or digital subtraction techniques, which contribute significantly to the reported cumulative radiation dose / exposure or pulsed versus continuous fluoroscopy, were not independently analyzed for this study. These interventions are performed by a variety of providers with a majority consisting of pain medicine physician and

non-radiologists (e.g. physiatry), as these groups who perform most spinal injection procedures (27).

Since our results are based on a single institution's experience, the generalizability and extrapolation beyond similar circumstances may be problematic, however, given the substantial number of cases per individual procedure, we believe this can serve as a preliminary reference dose. Benchmarks can serve as target doses for physicians and technologists as a mechanism for self-assessment to establish radiation dose reduction strategies. It is important to add that lower radiation doses are not always representative of best practices as values far below a reference level (i.e. below the 10 percentile as recommended by the International

Atomic Energy Agency) may provide poor image quality with inadequate visualization of target structures and potentially impact therapeutic effect.

CONCLUSION

Radiation doses and preliminary reference radiation dose levels from a practice audit of fluoroscopically-guided spinal injections performed by experienced practitioners are provided without correction for body habitus or varied fluoroscopic techniques. A national radiation dose registry would be useful to refine these reference levels. Future research is needed to establish if using these benchmark values as goals will effectively decrease radiation dose.

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