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Radiation Dose Incurred in the Exclusion of Vascular Filling in Transforaminal Epidural Steroid Injections: Fluoroscopy, Digital Subtraction Angiography, and CT/Fluoroscopy

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Conflicts of interest: Dr. Maus is a Board Member of the International Spine Intervention Society. Dr. Schueler is on the Executive Committee of the American Association of Physicists in Medicine.

Abstract

Objective. This study seeks to measure the radiation dose incurred in the evaluation of vascular filling during transforaminal epidural steroid injections (TFESI) using conventional fluoroscopy (CF), digital subtraction angiography (DSA), and multislice, pulsed computed tomography fluoroscopy (CT/F).

Methods. Three portable C-arms and a fixed multipurpose C-arm were evaluated. The radiation dose rate was measured using an anthropomorphic phantom during CF and DSA in anterior–posterior positions for cervical and lumbar TFESIs. Effective doses were calculated for 5-second exposures. The effective doses incurred in the cervical and lumbar spine during two CT/F exposures were calculated based on the reported volume CT dose index and dose length product.

Results. DSA imaging increased the effective dose incurred over CF with portable C-arms (medium dose rate) by 2.5–4.3 fold for cervical TFESI and 2.3–4.2 fold for lumbar TFESI. The incremental dose incurred with DSA ranged from 4.0 to 7.7 μSv in the cervical region and from 22–38 μSv in the lumbar spine. CT/F increased the incurred dose 19-fold in the cervical region and 8.0-fold in the lumbar region (incremental doses 49 μSv and 140 μSv, respectively) relative to CF.

Conclusion. The use of DSA imaging to exclude vascular uptake during TFESI increases radiation dose over CF. CT/F incurs additional dose beyond most DSA. Minimizing radiation dose by limiting DSA and CT/F use to spine segments or clinical situations involving higher risk may be desirable. However, the incremental radiation doses incurred by DSA or CT/F are of such low magnitude that health risks cannot currently be estimated.

Key Words. Epidural (Injection Space); Fluoroscopy; Radiculopathy; Safety; Steroids

Introduction

Transforaminal epidural steroid injections (TFESI) have been shown to be clinically effective [1] in the lumbar spine; the evidence is less robust in the cervical spine [2]. Rare catastrophic embolic events have occurred, more commonly complicating cervical than lumbar TFESIs [3]. Contrast injection to exclude arterial filling has appropriately become a keystone of risk mitigation strategies [4]. Digital subtraction angiography (DSA) has been shown to detect vascular filling at a higher rate than conventional fluoroscopic (CF) observation and has been advanced as enhancing the safety of TFESIs [5]. The US Food and Drug Administration is in the process of developing guidelines for rendering epidural injections as safe as possible, and early drafts of these guidelines refer to DSA as the optimal measure to detect arterial uptake.

The routine use of DSA to exclude arterial uptake in TFESIs may be advocated to promote safety, but this does not consider the radiation dose incurred. It is conceivable that the theoretical reduction of risk of intra-arterial injection may be outweighed by the potential risk of radiation exposure.

This risk/benefit calculation becomes more significant with the use of nonparticulate steroids for TFESI; embolic complications have not been reported with nonparticulate steroids, and the benefit associated with DSA may be reduced. TFESI may also be performed under multislice pulsed computed tomography fluoroscopic (CT/F) guidance; the use of CT/F in exclusion of vascular filling has been previously described [6]. Use of this modality bears the same burden of exclusion of arterial uptake to insure safety.

A literature search revealed no valid data that might address the relative radiation dose incurred with CF, DSA, or CT/F specifically in the exclusion of vascular filling in cervical and lumbar TFESIs. This study was undertaken to provide data to allow an objective assessment of concerns regarding radiation dose present with these guidance modalities in the performance of TFESIs.

Methods

Five-second CF and DSA exposures were chosen as the maximum likely exposure used in clinical practice for exclusion of vascular uptake by these modalities. The raw data were obtained as dose rates, which were linear over time; doses for lesser exposure times could be easily extrapolated. For the CT/F measurements, two acquisitions were the unit of measurement, as acquisitions during and immediately after cessation of contrast injection have been described as a means of exclusion of vascular filling [6]. Incremental dose for DSA or CT/F was defined as the additional dose for that modality above that incurred by CF (either medium or high-dose rate).

CF and DSA Methods

Two different anthropomorphic phantoms were used to simulate CF and DSA TFESI procedures. Both phantoms included a human skeleton (either a cervical spine or lumbar spine section) cast inside a urethane material radiologically equivalent to soft tissue (The Phantom Laboratory, Salem, NY, USA). Entrance skin doses were measured with four types of fluoroscopic units, including three mobile C-arms and one multipurpose fixed C-arm system: the OEC 9900 Elite (General Electric Medical Systems, Salt Lake City, UT, USA; designated Mobile 1), ARCADIS Avantic (Siemens Healthcare, Forchheim, Germany; designated Mobile 2), BV Pulsera (Philips Medical System, Best, The Netherlands; designated Mobile 3), and Multi-Diagnostic Eleva (Philips Medical Systems, designated fixed C-arm).

For each fluoroscopy system, the phantoms were placed on a fluoroscopic table with pad, and a clinical imaging configuration was replicated. The field of view closest to 15 cm was selected for the cervical spine phantom and 23 cm for the lumbar spine phantom and with collimation of the X-ray beam to the spine. Entrance skin dose rate was measured under automatic dose rate control with an ionization chamber (10X5–6, Model 9015, calibrated to ±5% accuracy, Radcal, Monrovia, CA, USA) positioned in contact with the phantom in the center of the exposure field. Measurements were obtained using all available fluoroscopic and DSA acquisition dose modes for each system. X-ray beam filtration and kilovoltage was recorded for each exposure configuration. Effective dose was calculated using Monte Carlo technique (PCXMC, STUK, Radiation and Nuclear Safety Authority, Helsinki, Finland). An average adult human model was selected, and organ doses were estimated using the corresponding X-ray beam energies from each exposure configuration. Effective dose was calculated using the definition provided in International Commission on Radiological Protection Report 103 [7].

CT/F Methods

Radiation dose measurements for CT/F were obtained on two common scanner models: a 64-slice scanner (Siemens Sensation 64, designated CT/F1, Siemens Healthcare) and a 128-slice CT scanner (CT/F2, Definition Flash, Siemens Healthcare). The imaging parameters on the 64-slice scanner included: 12×0.6 mm collimation that provided three images with 2.4 mm slice thickness, 120 kV, 80 mAs, and 0.5-second rotation time. Computed tomography dose index-volume ($CTDI_{vol}$) and dose length product (DLP) values recorded by the CT scanner were 7.17 mGy and 5.17 mGy cm. The imaging parameters on the 128-slice scanner included: 12×1.2 mm collimation that provided six images with 2.4 mm slice thickness, 120 kV, 80 mAs, and 0.5-second rotation time. The reported $CTDI_{vol}$ and DLP values were 6.33 mGy and 9.11 mGy cm. The same imaging techniques were used for cervical and lumbar spine injections.

The effective dose was calculated using the k-factor method, in which the DLP was multiplied by a conversion factor (k factor) [8,9]. The conversion factors were calculated using Monte Carlo simulations for different body regions. A recent study also reported conversion factors as a function of voltage, region, and age [10]. Based on this study, the conversion factors for an adult patient and 120 kV beam were 0.0051 mSv/mGy cm for the neck (cervical spine) and 0.0153 for the abdomen (lumbar spine). Effective dose was then calculated by multiplying these conversion factors with the DLP for each scan region and scanner type.

Results

The entrance surface radiation doses for the several fluoroscopic devices tested using a 5-second CF or DSA run are presented in Table 1. The results of the subsequent calculations to generate effective radiation doses for CF, DSA, and CT/F are seen in Table 2. To allow better comparison among the devices and modalities, Table 2 also provides ratios of effective dose of DSA (medium dose setting) vs CF (medium dose) for 5-second exposures. DSA imaging increased the effective dose incurred in detecting vascular uptake for portable C-arms (medium dose rate) by 2.5–4.3 fold for cervical TFESI and by 2.2–4.2 fold for lumbar TFESI. The fixed C-arm, using

Table 1 Entrance surface dose (mGy) for 5-second exposures

Anatomic Segment	Acquisition Mode	Dose Mode	Mobile 1	Mobile 2	Mobile 3	Fixed C-arm
Cervical	CF	Low	0.19	0.21	0.14	0.090
		Medium	0.70	0.33	0.22	0.19
		High	1.6	0.37	0.50	0.26
	DSA	Low				0.85
		Medium	2.1	0.9	0.75	3.3
		High				6.0
Lumbar	CF	Low	0.41	0.7	0.47	0.39
		Medium	1.5	1.1	0.7	0.8
		High	3.1	1.3	1.5	1.1
	DSA	Low				4.1
		Medium	3.9	1.8	2.1	16
		High				22

Portable C-arms limited to 1 DSA dose mode.
Fixed C-arm: DSA frame rates for low/ medium/high = 0.5/2/4 frames per second.

2/second frame rate DSA, increased the effective dose by 25-fold in both the cervical and lumbar region over 7.5 pulse/second CF. CT/F, using the more widely available CT/F1 scanner, increased the incurred dose 19-fold in the cervical region and 8 fold in the lumbar region over CF.

The incremental effective doses incurred by DSA vs CF, and for CT/F vs the mean CF doses for portable C-arms, are seen in Table 3.

The incremental dose incurred with DSA ranged from 4.0 to 7.7 μSv for the cervical region and from 22 to 38 μSv in the lumbar spine (medium CF dose rate). CT/F, using the more widely available CT/F1 scanner, increased the incremental dose 49 μSv in the cervical region and 140 μSv in the lumbar region relative to medium dose rate CF.

Discussion

Image guidance for TFESI may be divided into phases: 1) establishing the working vector and siting the point of skin entry; 2) needle manipulation to target; 3) contrast injection to exclude vascular filling and assess epidural flow to target; 4) washout, proving medication reaches the target. This study focused solely on the dose incurred with exclusion of vascular filling during contrast injection. DSA is more dose intensive than CF in this phase of image guidance. CT/F incurs additional dose above most DSA.

Considering the three portable C-arms, the most common imaging device used in interventional pain procedures, DSA delivered approximately 2–4 fold more dose during a 5-second exposure in comparison with CF in both the

Table 2 Effective radiation doses (μSv) in exclusion of vascular uptake using 5-second exposures for fluoroscopy and DSA, two CT acquisitions

		Cervical				Lumbar			
Modality	Device	CF Med Dose	CF High Dose	DSA	CT	CF Med Dose	CF High Dose	DSA	CT
Fluoro	Mobile 1	5.0	12	13 (2.5)		31	61	69 (2.2)	
	Mobile 2	1.8	2.0	6.1 (3.3)		18	22	40 (2.3)	
	Mobile 3	1.2	2.8	5.2 (4.3)		11	25	48 (4.2)	
	Fixed C-arm^	1.2	1.6	28 (25)		14	19	360 (25)	
Mean values mobile C-arms		2.7	5.5	8.0		20	36	52	
CT	CT/F 1 (3 images)				52 (19)				160 (8.0)
	CT/F 2 (6 images)				92 (34)				280 (14)

^ CF pulse rate of 7.5 pulse/second, 2 frames per second DSA.
() ratio of DSA or CT/F dose to CF medium dose; CT/F was compared with the mean of the medium CF doses.

Table 3 Incremental effective dose delivered (μSv) for DSA and CT/F relative to medium or high dose CF

Device	Incremental Dose DSA vs CF (Medium Dose) μSv	Incremental Dose DSA vs CF (High Dose) μSv	Incremental Dose CT/F vs CF (Med Dose) μSv	Incremental Dose CT/F vs CF (High Dose) μSv
Cervical				
Mobile 1	7.7	0.93		
Mobile 2	4.2	4.0		
Mobile 3	4.0	2.4		
Fixed C-arm	27	27		
CT/F1			49	46
Lumbar				
Mobile 1	38	7.5		
Mobile 2	22	18		
Mobile 3	37	23		
Fixed C-arm	350	340		
CT/F1			140	124

cervical and lumbar regions. There are significant differences in the dose rates for both DSA and CF among vendors, emphasizing the importance of the practitioner knowing the dose delivered by their device, preferably measured directly by medical physicists.

The safety advantage ascribed to DSA imaging depends on its greater sensitivity to the detection of intravascular contrast [5]. Intravenous contrast opacification may render the injection ineffective, as there will be no or diminished deposition of corticosteroid agent into the target ventral epidural space. Intra-arterial opacification, with filling of a radiculomedullary or medullary artery supplying the spinal cord in the lumbar region, or the vertebral artery or reinforcing contributors to the anterior spinal artery in the cervical region, may be a harbinger of a catastrophic complication with embolic injury to the spinal cord or posterior fossa if a particulate steroid were injected.

For several years, interventional pain physicians performing TFESIs were forced to consider a perceived choice between the accepted greater safety of the nonparticulate steroid dexamethasone vs presumed greater efficacy with particulate steroids. Recent evidence suggests this is a false choice; both a randomized, double-blinded, pragmatic trial [11] and a large observational study (N = 3,645) with a noninferiority analysis [12] have shown no difference in the efficacy or clinical effectiveness of dexamethasone vs particulate steroids in lumbar TFESIs.

The nonparticulate steroid dexamethasone carries no embolic risk. In two animal models, direct injection of dexamethasone into the neuraxial arterial circulation via the carotid artery in rats [13] or the vertebral artery in pigs [14] produced no clinical or pathological deleterious effects. No catastrophic neuraxial complications have been reported with the use of dexamethasone in TFESI. The absolute urgency to exclude arterial opacification during TFESI on safety grounds has diminished with the use of nonparticulate steroids. The risk/benefit analysis of the radiation dose incurred with DSA imaging must be viewed in a new context.

Radiation dose management in medical procedures is governed by the principle of keeping the incurred dose as low as reasonably achievable (ALARA). Given the diminished or nonexistent embolic risk associated with the use of dexamethasone in TFESI, and the measurable increases in radiation dose associated with the use of DSA, it may be prudent to limit advocacy of the use of DSA in the lower lumbar region, where the complications have been rare [3], to problematic circumstances where CF is impaired, such as when gadolinium contrast agents are used out of necessity, where CF visualization is poor due to body habitus, or where the spinal canal is obscured by postoperative change or anatomic anomaly. It may be reasonable to consider more aggressive use of DSA at L3 and above, where the observed frequency of a medullary artery is greater [15], or in postoperative foramina where arterial anastomoses may be present [16]. Complications have been more frequently reported during cervical TFESI, and it may be reasonable to advocate for the more liberal use of cervical DSA in any circumstance that CF is nonideal [3,4].

It must be noted, however, that DSA is no panacea for exclusion of arterial uptake. DSA must be of excellent quality to be useful, with suspended respiration and no patient motion, including swallowing in cervical procedures. If the patient is noncompliant, DSA may be doubly harmful, as misregistration artifact may conceal arterial uptake while additional radiation dose is delivered.

Use of CT/F to exclude vascular uptake has been described [6,17], but rates of vascular uptake detected with CT/F have not been reported. It remains unproven if CT/F is as sensitive to the detection of vascular uptake as

DSA or even CF. The present study demonstrates that in comparison with portable C-arms, CT/F acquisitions to exclude vascular uptake incurred more dose than CF and incrementally more than DSA in both the cervical and lumbar TFESI positions. In the cervical region, neurologic catastrophes have occurred prior to injection of corticosteroid, due to transgression of the vertebral artery and arterial dissection [4]. Theoretically, CT/F guidance could allow access to the cervical neural foramen without the possibility of vertebral artery transgression, as the vessel can be visualized during the course of needle advancement, which is not true for CF [6]. Operator error always may intervene. CT/F may also provide unique guidance advantages in challenging anatomy in the lumbar spine, and in avoidance of vulnerable structures in the cervical spine, but any perceived benefit must be weighed against greater radiation dose.

While the ALARA principle provides guidance in radiation use during medical procedures, it contains the implicit assumption that all detectable radiation is harmful. The incremental doses under consideration are small. For comparison, the average annual natural background exposure to a person in the United States is approximately 3 mSv (range 1–10 mSv) [18]; the incremental effective dose incurred by DSA over CF (Table 3) ranges from 0.1–0.2% (cervical) to 0.7–1.2% (lumbar) of the annual background dose. The incremental dose from CT/F over CF is 1.6% (cervical) to 4.7% (lumbar) of the annual background dose. Health affects at these dose levels cannot be readily assigned. The American Association of Physicists in Medicine position statement on radiation risks in medical imaging notes: "Risks of medical imaging at effective doses below 50 mSv for single procedures or 100 mSv for multiple procedures over short time periods are too low to be detectable and may be nonexistent" [19]. Similarly, the Health Physics Society states that at radiation doses below 50–100 mSv "estimation of adverse health effect remains speculative" [20]. The incremental doses incurred by CT/F or DSA over CF are 2.5 to 4 orders of magnitude below the 50 mSv effective dose where radiation may have detectable causality in deleterious health effects. However, the inability to measure negative health effects does not imply that prudence should be abandoned. Although not directly measured in this study, the increased patient doses with DSA and CT/F may be reflected in a minimal increased dose to the operator, which may accumulate over time; this speaks as well to prudence in the use of these techniques.

The study has weaknesses. The use of DSA occurs as a clinical decision during a TFESI guided by fluoroscopy; this study identifies the incremental radiation dose associated with that decision. It does not identify how this incremental dose compares to the overall dose incurred by the entire procedure. The comparison of CT/F incremental doses to CF observation applies only to one phase of the procedure. The study also does not identify dose differences for an entire TFESI procedure guided by CT/F vs CF.

Conclusion

The use of DSA with portable C-arms in the exclusion of vascular uptake increases the radiation dose by 2.5–4.3 fold (4.0–7.7 μSv incremental effective dose) for cervical TFESI and by 2.2–4.2 fold (22–38 μSv incremental effective dose) for lumbar TFESI relative to CF observation. CT/F doses for exclusion of vascular uptake are incrementally higher than DSA. When the risk of embolic catastrophe during TFESIs is reduced by the use of nonparticulate steroids, prudent radiation dose management may suggest that DSA imaging to exclude vascular filling be used selectively in higher risk situations, rather than universally. The incremental radiation dose incurred by DSA or CT/F, however, falls below the level at which negative health effects can currently be measured.

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Editor's Note

During 2013, the Food and Drug Administration (FDA) completed deliberations with representatives of several Societies involved with the use of epidural injections of steroids. Those deliberations resulted in the formulation of certain recommendations designed to promote the safe conduct of these interventions. Amongst the recommendations was the use of digital subtraction imaging (DSI) to check for vascular uptake of injectates. Concerns were raised by representatives of the International Spine Intervention Society about the increased radiation that DSI imposed, but at the time of compensation of the FDA recommendations no data were available. These concerns and the lack of data prompted the present study by Maus et al. Ironically, that study was undertaken and completed before the FDA recommendations had been published. A paper reporting the FDA recommendations is being prepared. Under those conditions, Maus et al could not provide a formal citation for the recommendations that prompted their study.

NIKOLAI BOGDUK, Spine Section Editor