Randomized Trial

Reducing Radiation Exposure in Lumbar Transforaminal Epidural Steroid Injections with Pulsed Fluoroscopy: A Randomized, Double-blind, Controlled Clinical Trial

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Background: Fluoroscopy-guided lumbar transforaminal epidural steroid injections (L-TFESI) result in radiation exposure that carries risks to patients, physicians, and procedural staff.

Objective: We aim to evaluate the feasibility of using pulsed fluoroscopy to safely reduce radiation exposure during L-TFESI.

Study Design: This is a prospective, double-blind, randomized controlled trial.

Setting: This study took place in a single-center, academic, outpatient interventional pain management clinic.

Methods: Patients undergoing L-TFESI were randomly assigned to either continuous mode fluoroscopy (high-dose), pulsed fluoroscopy with 8 pulses per second (medium-dose), or pulsed fluoroscopy with one pulse per second (low-dose). Data on radiation doses and other clinical and demographic factors were also collected.

Results: In total, 231 cases were analyzed in the high-dose group (n = 81), medium-dose group (n = 72), and low-dose group (n = 78). Mean radiation effective dose (μSv) was 121 in the high-dose group, 57.9 in the medium-dose group, and 34.8 in the low-dose group ($P < 0.001$). The incidence of inadequate image quality in the pulsed groups was 6% (9/150). The body mass index (BMI, mean ± SD) was significantly higher in patients with inadequate image quality (37.3 ± 7.2) than with adequate quality (30.5 ± 7.2, $P = 0.005$).

Limitations: Radiation doses were measured using the meter on C-arm fluoroscopes rather than by direct measurement.

Conclusions: The use of pulsed fluoroscopy during L-TFESI resulted in radiation dose reduction of up to 72.1% without causing any significant adverse events. Pulsed fluoroscopy should be considered as an initial fluoroscopic setting for L-TFESI to reduce radiation exposure.

Key words: Radiation, epidural, fluoroscopy, injection, exposure, pulse

Radiation exposure during fluoroscopy-guided lumbar transforaminal epidural steroid injections (L-TFESI) is typically minimal (1). However, cumulative exposure still increases the risk of stochastic injury to patients, physicians, and procedural staff and should not be ignored (2,3), especially considering that research surrounding chronic and cumulative low-dose radiation exposure has not produced conclusive results (4,5). Exposure to radiation should be limited and kept to as low of doses as possible to achieve a required

task – a principle commonly referred to as ALARA (as low as reasonably achievable). Strategies to adhere to the ALARA principle include the use of protective lead clothing and maximization of the distance from the x-ray beam in order to reduce radiation exposure among procedural staff. In addition to these strategies, there are several features of the fluoroscope that can also be used to reduce radiation such as minimizing magnification, low-dose copper filtration, collimation, intermittent fluoroscopy, and pulsed fluoroscopy.

L-TFESIs are widely used to treat patients with lumbar radicular pain (6,7), with the use of these injections increasing 609% from 2000–2014 per 100,000 people in the Medicare population (6). In addition to increased utilization, L-TFESIs have been effective in the management of a multitude of chronic spinal pain conditions, including long-term improvements in both managing lumbar disc herniation and the treatment of lumbar central spinal stenosis (8-12). While some argue that transforaminal, caudal, and interlaminar epidural steroid injections have all been equally effective in reducing pain scores, others state that transforaminal epidural steroid injections were significantly more effective than the caudal and interlaminar routes at both 6 months and 1 year (13-15). Serious complications are rare (16), but there are several reports of spinal cord infarction related to direct vascular injury or vascular uptake of particulate steroid (17,18). The use of fluoroscopy is recommended and routinely used to optimize accurate anatomical location of needle placement, thereby improving the efficacy and reducing the risk of intravascular injections (19,20).

Pulsed fluoroscopy is a fluoroscopic mode that delivers short pulses of x-ray beams at an adjustable rate of pulses per second as opposed to a continuous x-ray beam. Aufrichtig et al (21) demonstrated an average radiation dose savings of 49% when pulsed mode was used at 7.5 pulses per second versus continuous fluoroscopy in experimental models. Goodman et al (22) reported similar results, demonstrating an average exposure time reduction of 56.7% for a variety of interventional spine procedures when a protocol was initiated that included pulsed fluoroscopy and use of a low-dose filter. However, pulsed mode may result in decreased image quality due to a grainier image and slower frame rate when compared to continuous fluoroscopy. A previous study demonstrated that the use of digital pulsed fluoroscopy at a rate of 6.25 pulses per second in conjunction with a low-dose filter resulted in a greater than 50% reduction in dose area product (23).

Image quality in L-TFESI performed under low-dose pulsed fluoroscopy has not been studied.

The purpose of this study was to assess whether pulsed mode fluoroscopy is a feasible method of reducing radiation exposure while maintaining adequate image quality during L-TFESI, without negatively affecting the accuracy of needle placement and patient safety.

METHODS

This study was a prospective, randomized, double-blind, and controlled clinical trial conducted at a single multidisciplinary pain clinic within an urban tertiary academic center. This study was approved by the University of Kansas Medical Center Institutional Review Board prior to patient enrollment.

Simple randomization was used via a computer-generated list of random numbers to randomly assign patients undergoing L-TFESIs to 1 of 3 groups: continuous fluoroscopy without low-dose mode (high dose), pulsed fluoroscopy at 8 pulses per second with low-dose mode (medium dose), or pulsed fluoroscopy at one pulse per second with low-dose mode (low dose). Low-dose mode is a feature of the GE OEC 9900 fluoroscope (GE Healthcare, Amersham, UK) that reduces milliamperage by up to 50%. Patients and physicians were blinded to the group assignments, with only the radiology technician aware of a patient's treatment group. If at any point in the procedure the physician felt the image quality was inadequate to safely and accurately complete the procedure, he or she could request that the fluoroscopy mode be converted to the high-dose settings for the remainder of the procedure. Patients who required mode conversion were analyzed with their initial group assignment as part of an intention-to-treat analysis.

Participants

Eligible patients included those ages 18 or above who were scheduled to undergo L-TFESI for treatment of low back pain with radicular lower extremity pain at our single, high-volume, academic interventional pain management clinic during a 90-day period from October 2015 to January 2016. Patients excluded were those who were pregnant, allergic to iodine or contrast dye, or diagnosed with a psychiatric disorder that would interfere with obtaining informed consent. All patients provided written informed consent.

Data Collection

All L-TFESI procedures were performed using an

OEC 9900 Elite C-arm fluoroscope (GE Healthcare, Amersham, UK). The fluoroscope determined the tube current and beam energy using automatic exposure control. One of 5 interventional pain medicine physicians performed each procedure. Of these physicians, 4 were at the attending level and one was at the fellow level under direct supervision of an attending physician.

L-TFESI procedures were performed with the patient placed in the prone position in the procedure room. The lumbar region was then sterilized, and a drape was placed. An ipsilateral oblique view was used to guide a 22- or 25-gauge spinal needle toward the target neural foramen or foramina. Once adequate depth was obtained, the physician adjusted the view to verify transforaminal location of the needle tip using anterior-posterior, contralateral oblique, or lateral views. The needle was aspirated to ensure the absence of blood or cerebrospinal fluid, and iodinated contrast was injected to rule out intravascular, intrathecal, or soft tissue spread. A steroid-containing solution was injected after an epidurogram was obtained. The solution was at the discretion of the physician and contained particulate or nonparticulate steroid, with or without local anesthetic or preservative-free normal saline.

The following data were collected for each procedure: group assignment, performing physician, number of target injection sites, patient age, patient height, patient weight, patient body mass index (BMI), the requirement for unanticipated additional needle insertions, and whether the physician requested to convert to high-dose settings due to inadequate image quality. Outcome data of interest included: the total fluoroscopy time, cumulative radiation dose (mGy), and the dose area product (mGy·cm^2) for each procedure which was recorded from the radiation meter permanently installed on each fluoroscope. The dose area product was then converted to effective dose (μSv) using the lumbar spine coefficient of 0.21 (24). Finally, the mean effective dose per needle was calculated to allow comparison of results despite a varying number of target injection sites during each procedure. After trial commencement, there were no changes to the methods or outcomes and no interim analysis was performed.

Sample Size

A total of 215 patients were enrolled. Of the 215 patients enrolled, 16 had repeat procedures during the study's timeframe leading to a total of 231 procedures included in the analysis. No patients met exclusion criteria during the 90-day study period.

Statistical Analyses

All analyses were performed using SPSS Version 24.0 (IBM Corporation, Armonk, NY). Univariate differences were evaluated between the treatment groups for demographic and patient characteristic variables using t-tests and chi-square tests. A one-way ANOVA with pairwise tests adjusted for multiple comparisons (Tukey's method) was used to examine various responses for outcome variables across providers and treatment delivery modes. Unless otherwise indicated, the mean ± standard deviation (SD) was reported as the measure of central tendency. A type I error level of 0.05 was used to denote statistical significance.

Results

A total of 231 L-TFESI procedures were performed on 215 patients, with 16 patients having repeat procedures over the course of the study. All 231 cases were randomized and assigned to one of 3 groups: conventional fluoroscopy (high-dose, n = 81), pulse mode set at 8 pulses per second (medium-dose, n = 72), and pulse mode set at one pulse per second (low-dose, n = 78). All randomized cases were included in the analysis. Figure 1 displays the Consolidated Standards of Reporting Trials (CONSORT) flow diagram demonstrating patient progress through the study.

Demographic data are displayed in Table 1 by group assignment and Table 2 by physician performing the procedure. Demographic data were similar across each fluoroscopy mode assignment group (Table 1). The demographic characteristics of patients analyzed by treating physician also did not significantly differ (Table 2).

The results of the study outcome measures are summarized in Table 3. There was a significant difference in effective dose (mean [95% CI]) in the low-dose group (34.8 μSv [22.2-47.4]), medium-dose group (57.9 μSv [43.2-72.5]), and high-dose group (121 μSv [95.1-147]; P < 0.001) (Fig. 2). Five patients in the low-dose group and 4 patients in the medium-dose group required conversion to high-dose fluoroscopy due to poor image quality. One patient in the low-dose group had an unanticipated additional needle insertion due to inadequate image quality. No serious complications or adverse events occurred as a result of this study. Table 4 examines the characteristics of patients who required conversion to high-dose fluoroscopy. BMI was significantly higher in those who required conversion (37.3 ± 7.2) than those who did not (30.5 ± 7.2, P = 0.005).
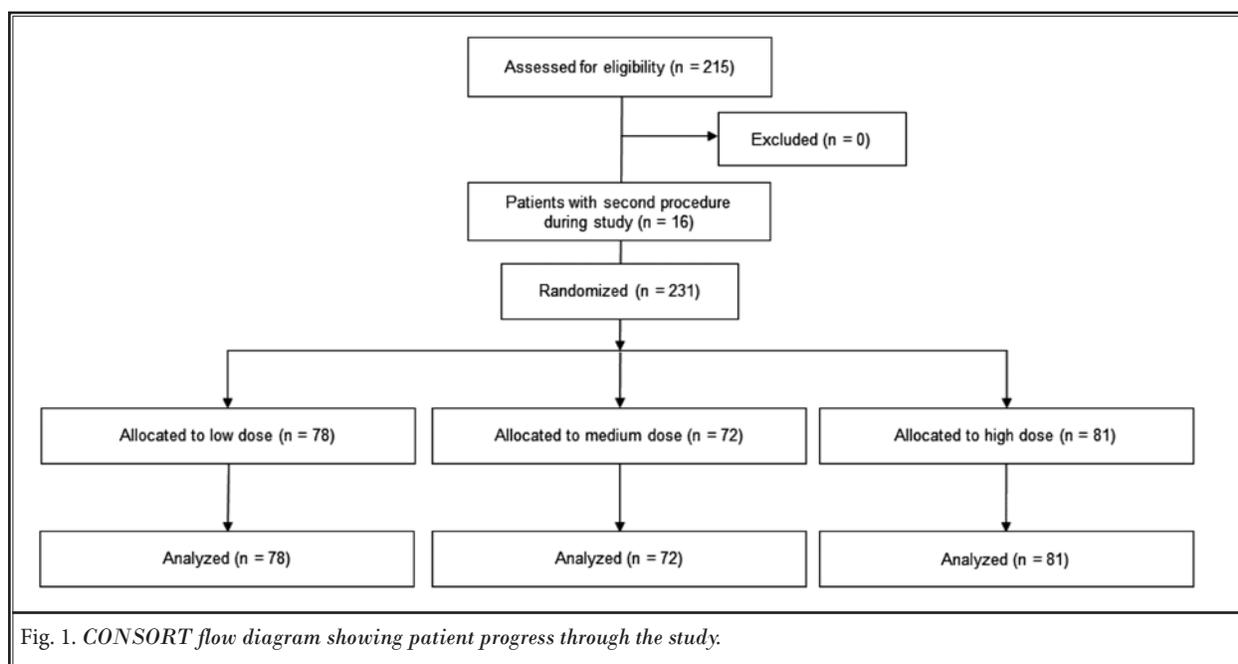
Fig. 1. *CONSORT flow diagram showing patient progress through the study.*

Table 1. *Patient characteristics by study group.*

	Low-Dose (n = 73)	Medium-Dose (n = 68)	High-Dose (n = 81)	*P*
Gender (male/female), %	45.2/54.8	45.6/54.4	55.6/44.4	-
Age, mean ± SD, y	61.2 ± 14.7	62.2 ± 11.9	61.9 ± 14.2	0.910
BMI, mean ± SD, kg/m²	29.0 ± 6.6	31.3 ± 7.8	31.1 ± 7.0	0.103

BMI = body mass index; low-dose = fluoroscopy at 1 pulse per second; medium-dose = 8 pulses per second; high-dose = continuous fluoroscopy

An interaction plot of the physicians performing procedures (Fig. 3) revealed interactions for providers 4 and 5. For provider 4, the interaction is attributed to a single patient in the low-dose group who required a conversion to high-dose mode and an extra needle insertion. These modifications resulted in an abnormally high radiation dose for the case (479 µSv). For provider number 5, the interaction was attributed to the low number of cases performed (n = 11). There were no other clear interactions interfering with the main effect.

Discussion

The main result of this study was a significantly lower radiation dose during L-TFESI while using pulsed mode fluoroscopy. Use of low-dose and medium-dose fluoroscopy resulted in 72.1% and 52.3% reductions in effective dose per needle insertion, respectively, when compared to the high-dose group. Previous studies have found dose reductions of 49% while using 7.5 pulses per second (21) and exposure reduction of 56.7% with unreported pulses per second (22). However, the significant differences in design and radiation measurement in these studies complicate direct comparison of results.

Six percent of patients in the pulsed mode groups required conversion to high-dose mode due to image quality that was inadequate to identify key anatomic landmarks. In each of the instances that required mode conversion, the cases were successfully and safely completed. There were no serious complications related to reduced image quality in this study, suggesting that low-dose fluoroscopy can be successfully and safely used in these procedures while adhering to the ALARA (as low as reasonably achievable) principle. Image quality on low-dose mode was adequate in a majority of patients, and in those cases requiring enhanced image quality, the conversion to medium- or high-dose fluoroscopy was safely completed.

Severe complications from L-TFESI are extremely rare, as there are only 14 documented cases of thoracolumbar spinal cord infarction following L-TFESI (25,26). An extremely large sample size would be required to detect a significant increase in complication rates with low- and medium-dose fluoroscopy, and it was not practical to power our study for this.

In the present study, higher BMI was associated with poorer image quality while using pulsed mode radiation, which is consistent with previous studies showing a correlation between BMI and required radiation dose (27). This occurs because x-ray penetration is reduced by the combination of increased adipose tissue and decreased radiation dose with pulsed fluoroscopy. Although pulsed mode imaging may be inadequate in obese patients, this study did not identify any significant risk to using pulsed mode for initial imaging since it can be converted to continuous fluoroscopy if needed.

Scattered radiation is the main contributor to radiation exposure of procedural staff and was not measured in this study. In addition to the radiation dose itself, scatter is also affected by the patient's distance from the detector and the angle of the x-ray beam. These factors were not controlled in this study and were at the discretion of the performing physician. Two of the 5 physicians in the study routinely used lateral fluoroscopic views, which greatly increase radiation dose and scatter. Interestingly, a 2015 study of interventional pain procedures found that scatter was reduced by 46.4% simply by real-time coaching on ideal physician and C-arm positioning, without any adjustment of radiation dose settings (28).

Particulate steroid resulting in spinal cord injury is an extremely rare catastrophic event that has been reported following cervical and L-TFESI. High-dose fluoroscopy using digital subtraction has been shown to nearly double the detection rate of intravascular injection in cervical transforaminal injections (29). Spinal cord infarc-

Table 2. Patient characteristics by performing physician.

	1	**2**	**3**	**4**	**5**	**P**
Patients, #	144	30	28	18	11	-
Gender (male/female), %	51.4/48.6	33.3/66.7	53.6/46.4	38.9/61.1	83.3/16.7	-
Age, mean ± SD, y	60.0 ± 14.1	67.1 ± 11.7	63.6 ± 11.9	61.4 ± 13.6	66.1 ± 14.9	0.076
BMI, mean ± SD, kg/m²	31.0 ± 7.4	31.9 ± 8.4	30.6 ± 5.8	29.4 ± 7.4	26.8 ± 5.4	0.321

BMI = body mass index

Table 3. *Results.*

Outcome	**Low-Dose (n = 78)**	**Medium-Dose (n = 72)**	**High-Dose (n = 81)**	**P**
ED per needle (mean, 95% CI), μSv	34.8 (22.2-47.4)	57.9 (43.2-72.5)	121 (95.1-147)	< 0.001
Fluoroscopy time (mean, 95% CI), s	6.10 (5.21-7.00)	8.66 (7.38-9.94)	17.8 (16.3-19.3)	< 0.001
Mode conversions, #	5	4	N/A	-
Extra needle insertions, #	1	0	0	-

ED = effective dose; low-dose = fluoroscopy at 1 pulse per second; medium-dose = 8 pulses per second; high-dose = continuous fluoroscopy; mode conversion = a change in mode from low or medium dose to high dose due to inadequate image quality

tion during L-TFESI continues to be reported despite negative aspiration of blood and the use of continuous digital subtraction fluoroscopy (30). The use of digital subtraction live fluoroscopy exposes staff and patients to exponentially higher doses of radiation than any of the modes used in this study. To date, the use of a nonparticulate steroid as opposed to a particulate steroid is the only strategy that has never been associated with spinal cord infarction during L-TFESI (31), and perhaps would be a better means of completely avoiding spinal cord injury.

Furthermore, it is well-known that cumulative radiation exposure increases the risk of adverse health effects such as genetic effects, cataracts, circulatory diseases, and sometimes cancer (32,33). As utilization of L-TFESI increases, more procedures are being performed on more patients who can then receive repeated L-TFESIs in the future (6). Thus, cumulative radiation doses should be monitored and taken into account for physicians and procedural staff present during these procedures (1). Although some have argued that exposure to low-dose radiation is not harmful and may even have beneficial effects (34), current epidemiological evidence has not shown exposure to low-dose radiation to be completely free of risk (3). This debate highlights an important consideration for physicians concerning risks versus benefits of abiding by the ALARA principle when using pulsed fluoroscopy in L-TFESI. As even the most sensitive high-dose fluoroscopy does not reliably prevent rare serious complications but does result in significant radiation exposure, it may be justified to use pulsed fluoroscopy in L-TFESI to minimize cumulative radiation exposure for patients, physicians, and procedural staff.
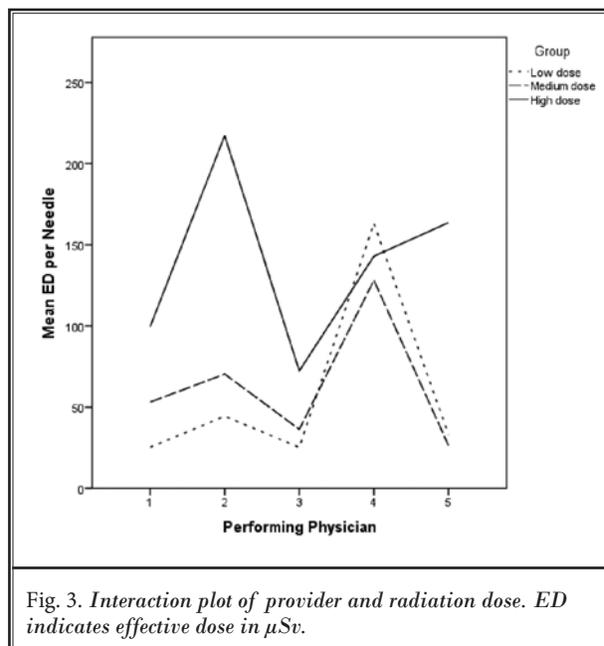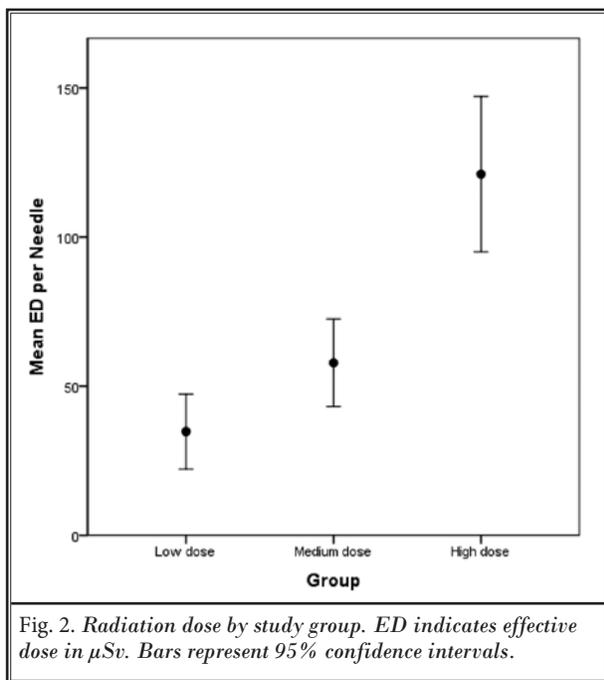
Fig. 2. *Radiation dose by study group. ED indicates effective dose in μSv. Bars represent 95% confidence intervals.*

Fig. 3. *Interaction plot of provider and radiation dose. ED indicates effective dose in μSv.*

Table 4. *Characteristics of patients requiring mode conversion.*

	Converted (n = 9)	Not Converted (n = 222)	P
Gender (male/female), %	22.2/77.8	49.1/50.9	-
Age, mean ± SD, y	61.4 ± 15.6	61.8 ± 13.7	0.942
BMI, mean ± SD, kg/m²	37.3 ± 7.2	30.5 ± 7.2	0.005

BMI = body mass index; converted = a change in mode from low or medium dose to high dose due to inadequate image quality

A limitation of this study is that radiation exposure was measured by the meter permanently installed on the fluoroscope as opposed to direct measurement by radiation detectors on patients and procedural staff. The advantage of this method was simplicity and standardization of radiation monitoring, as all fluoroscopes used in the study were identical. Although direct measurement may be more accurate, most fluoroscope radiation meters typically maintain precision of ± 15% of the actual dose received by the patient (35). Furthermore, consistency in direct measurement would be difficult as the angle of the fluoroscope beam varies from procedure to procedure. An additional limitation includes the widely varying degrees of experience of the pain physicians who performed the procedures.

Transforaminal epidural steroid injections did not result in a high radiation dose even in the conventional mode setting during our study. However, as this is a very commonly performed procedure, even small dose reductions can result in a significantly reduced cumulative dose – a benefit to both patients and physicians. Future research is needed to determine the viability and safety of pulsed fluoroscopy during other interventional pain procedures. Additionally, further research could investigate whether pulsed fluoroscopy reduces scattered radiation received by the performing physician and procedural staff.

Conclusion

In the present study, the use of low-dose pulsed fluoroscopy in conjunction with a low-dose filter dramatically reduced radiation dose during L-TFESI. In most cases, the lowest dose settings also provided adequate imaging to safely and adequately perform the procedure. These results suggest that the use of pulsed mode as the initial fluoroscopic setting may be beneficial when performing L-TFESI in order to keep radiation exposure as low as reasonably achievable, while still maintaining adequate image quality in most cases.

Acknowledgment

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