Does Updated Compared to Older Fluoroscopic Imaging Technology Reduce Radiation Dose During Interventional Spine Procedures? A Pragmatic Cohort Study

Aaron Conger DO, Taylor Burnham DO, Daniel M. Cushman MD, Shellie Cunningham BS, Masaru Teramoto PhD MPH, Richard Kendall DO, Zachary L. McCormick MD

Abstract
Objectives
Determine if an updated model compared to an older model of a common fluoroscope reduces radiation dose during interventional spine procedures.

Methods
Retrospective cohort study containing patients who underwent fluoroscopically-guided spine procedures between April 2016-December 2016. Multivariate regression analysis performed to examine the mean radiation dose during various interventional spine procedures using a GE OEC 9800 and GE OEC 9900 machine. Age, sex, BMI, spinal level, trainee presence, and fluoroscopy time was used as covariates in order to control for possible confounding variations in patient demographics and procedure characteristics before and after implementation of the new fluoroscope.

Results
Total of 271 injection encounters (male=43.9%, age=58.6 [13.4] years, BMI=29.0 [6.8] kg/m2) were analyzed. There was no significant difference in radiation dose per procedure between the machines (2779 [3158] mGycm2 vs. 2626 [3147] mGycm2, p=0.689). The mean fluoroscopy dose per procedure was significantly higher for lumbar compared to cervical injections (3778 [3736] mGycm2 vs. 1267 [968] mGycm2, p<0.001). These results did not change after adjusting for covariates (p>0.05). Higher BMI and longer fluoroscopy time were significantly associated with greater radiation dose (p<0.001).

Conclusions
Radiation dose exposure during fluoroscopically-guided interventional spine/pain procedures was not significantly different when comparing an older- and newer-generation fluoroscope; this remained true after controlling for possible confounding variables.

Keywords:
fluoroscopy; radiation exposure; radiation dose; cervical interventional procedures; lumbar interventional procedures

INTRODUCTION
Fluoroscopy is the standard of care for localizing anatomic structures and for needle guidance during interventional spine procedures (1-5). However, use of this technology is associated with radiation exposure to both patients and providers (6). Exposure to higher doses of radiation carries a risk of malignancy and tissue damage (7). In addition to the well-established risks of cancer induction, tissue reactions such as radiation-induced cataracts have received attention recently. One study of interventional radiologist providers demonstrated an 8% prevalence of radiation-induced cataracts and a 37% prevalence of posterior subcapsular opacities (PSOs), three times that of controls (12%) (8,9). Additional risks include radiation dermatitis, skin necrosis, infertility, and radiation arthritis (10,11). As such, efforts dependent on the provider and/or fluoroscopy-technician can and should be implemented in order to reduce radiation exposure to both patients and providers (12,13).

Newer-generation fluoroscopes are purported to reduce radiation exposure through advancements in X-ray beam spectral shaping filters, automatic exposure control (AEC) algorithms, electronic image magnification, and flat-panel detector technology (7). The OEC 9900 is advertised to include “high definition monitors, SmartMetal distortion control, and patented DRM technology” which provides “superb image quality” ensuring “no need for retakes and repeated exposures.” (14) However, there is minimal published medical literature that has described the quantitative reductions that result from these technology improvements. One study measured radiation exposure with newer versus older fluoroscopes associated with anterior-posterior and lateral images of each region of the

1 University of Utah, Division of Physical Medicine and Rehabilitation, Salt Lake City, UT
Conflicts of interest: None to declare
Corresponding author: Zachary L. McCormick, Department of Physical Medicine and Rehabilitation, University of Utah School of Medicine, 590 Wakara Way, Salt Lake City, UT 84103 Phone: 801 587 5458 Fax: 801 587 7111 Email: Zachary.McCormick@hsc.utah.edu

56
spine; a newer C-arm machine was found to decrease radiation exposure compared to older machines (15). However, this study was performed in a controlled setting using a cadaver, simple radiographic views without the intent of needle guidance relevant to interventional spine procedures, and no live fluoroscopic imaging according to the standard of care during epidural steroid injections (1,5,16). As such, the aim of the present study was to determine if an updated model compared to an older model of a common, commercially available fluoroscope reduces radiation dose during interventional spine procedures in a realistic clinical setting.

METHODS

This was a retrospective cohort study conducted at a tertiary, academic spine center. Local Institutional Review Board approval was obtained. The electronic medical record was queried between April, 2016 and December, 2016 in order to identify consecutive fluoroscopically-guided interventional spine procedures performed by a single provider (RK). All procedures during this period were included unless they fulfilled any of the following exclusion criteria: (1) missing fluoroscopy dose or (2) missing fluoroscopy time. At our institution, an OEC 9800 C-arm fluoroscope (GE Healthcare, Waukesha, WI) was used for all procedures performed between April, 2016 and September, 2016; this machine was replaced with an OEC 9900 C-arm fluoroscope (GE Healthcare, Waukesha, WI) in September, 2016, which was used for all subsequent procedures.

Data Collection

Collected data included age, sex, body mass index (BMI), laterality of the procedure (unilateral or bilateral), spinal level of the procedure (cervical or lumbosacral), procedure type, trainee involvement with the procedure (defined as a resident or fellow being present for the procedure), fluoroscopy time (in seconds), and fluoroscopy dose (mGy-cm²). Fluoroscopy time and radiation dose data were recorded by the fluoroscopy system and transcribed into the clinical database immediately following each procedure. In order to measure this dose, the radiation dose emitted from the C-arm is indirectly estimated from a dose-area product (DAP) meter. DAP is a product of the surface area of the patient that is exposed to radiation at the skin entrance (in square centimeters or square meters) multiplied by the radiation dose at this surface (in gray) (17). The DAP meter uses a transmission type ionization chamber mounted on the face of the x-ray collimator, which integrates exposure over the entire image field, often reported as mGy-cm² (11) BMI was calculated using the recorded height and weight within three months of the injection.

Procedures

All procedures were performed by a single provider (RK), board certified in both Physical Medicine and Rehabilitation, as well as Pain Medicine, with over 15 years of experience performing fluoroscopically-guided interventional spine procedures. The techniques used during these procedures are consistent with those described in clinical practice guidelines (5).

Statistical Analysis

Descriptive statistics were calculated for patient demographics and radiation dose stratified by fluoroscopy machine. χ² tests and independent t-tests were used to compare these variables. Radiation dose, stratified by machine and by body region, was examined using an independent t-test. Further, the number of procedures and the mean radiation dose per procedure were summarized separately for both fluoroscopy machines. Multivariate regression analysis with robust variance estimates was performed in order to examine radiation dose per procedure, specific to each machine, while using body
region, age, sex, BMI, trainee presence, and fluoroscopy time as covariates. Lastly, Pearson’s correlation

RESULTS

Of the total of 279 procedures, only 5 and 1 of them were done at the thoracic and multiple sites. Additionally, there were 2 cases of pars injection and facet/TFESI injections. Because of the small sample sizes, these procedures were excluded from the data analysis. As a result, a total of 271 procedure encounters were analyzed; 136 procedures on patient demographic characteristics and procedure details, 135 on the OEC 9800 and 135 on the OEC 9900. Table 1 shows the patient demographic characteristics and procedure details, stratified by fluoroscopy machine. There were no significant differences in demographic characteristics stratified by machine, except that a higher percentage of trainees participated in procedures after the acquisition of the OEC 9900 C-arm (23.7% vs. 9.6%, p = 0.002). There was a significant trend towards longer fluoroscopy time per procedure with the OEC 9800 compared to the OEC 9900 (50.1 [29.3] sec vs. 44.6 [24.3] sec, p = 0.092).

The mean radiation dose to the patient was not significantly different between machines when analyzed per-procedure (2779 [3158] mGy-cm² vs. 2626 [3147] mGy-cm², p = 0.689, respectively) (Figure 1). The Mean radiation dose was significantly higher for lumbar compared to cervical procedures (3778 [3736] mGy-cm² vs. 1267 [968] mGy-cm², p < 0.001). Table 2 shows the number of procedures and mean radiation dose stratified by procedure type and body region (cervical vs. lumbar), separately for both machines. Multivariate regression analysis showed that these results did not change after adjusting for covariates, including age, sex, BMI, machine type, procedure level, presence of a trainee during the procedure, and fluoroscopy time (Table 3). Higher BMI and longer fluoroscopy time were significantly associated with greater radiation dose (r = 0.424 and 0.660, p < 0.001).

DISCUSSION

The results of this study demonstrate no significant difference in radiation dose to patients (as measured by DAP) between an older and a newer generation fluoroscope when used in a realistic procedural setting. To the authors’ knowledge, this is the first pragmatic, comparative investigation of radiation dose between various of C-arm fluoroscopes. While a prior study demonstrated a difference in radiation dose of up to 30% among various fluoroscopes and a significant difference between older and newer generation fluoroscopes, this study used only simple, static radiographic views that are inadequate for the standard of care during interventional spinal procedures, and further, this investigation was conducted in a controlled environment that was not reflective of clinical practice (15). Given that the present study investigated use in live patients during actual spinal procedures with the intention of safe and effective diagnosis and/or treatment and also controlled for age, sex, BMI, procedure level, procedure type, and fluoroscopy time, among other potential confounding variables, the results of this study more generalizable and allow for more accurate estimates of the true radiation doses in clinical practice.

Consistent with prior studies (6,18–20), the present data demonstrated that higher BMI was associated with increased radiation dose; this finding was independent of age, sex machine type, body region of the procedure, trainee presence, and fluoroscopy time. Increased tissue mass requires higher fluoroscope energy output to produce adequate image quality, and this has been found to independently predict increased fluoroscopy time in other studies (20). Due to the greater amount of energy required to penetrate the greater tissue mass, spinal procedures may require up to a 12-fold increase in radiation dose compared to non-spinal musculoskeletal procedures (21). High BMI is strongly associated with increasing fluoroscopy radiation doses during lumbar TFESIs, sacroiliac joint injections, and increased fluoroscopy time in intraarticular hip injections (6,18–20).

Figure 1. Mean radiation dose exposure per procedure stratified by OEC 9900 e vs. 9800 fluoroscopy machines. No significant difference was observed. Whiskers show the 95% confidence intervals.

After adjusting for other co-variates that were independent predictors of dose, the present data suggested that trainee presence may be associated with lower radiation dose. Other studies have found that trainee presence is associated with shorter fluoroscopy time (22). This finding may be explained by institutional and provider preferences regarding trainees. Challenging cases are often performed completely by the attending physicians, while trainees at our institution tend to participate in less
complicated procedures, which may require less use of fluoroscopy and are less likely to require the use of digital subtraction imaging (23) (DSI), a technology that increases radiation dose compared to live fluoroscopy alone (24).

Higher radiation dose and longer fluoroscopy time were observed during lumbar procedures compared with cervical procedures, consistent with prior published literature (20,22,25). The mean fluoroscopy time of procedures in the present study was 50.1 seconds and 44.6 seconds (OEC 9800 cs 9900), which is marginally higher than prior estimations in a university setting (6,20,26). Wide ranges of fluoroscopy times and doses are reported in the literature, depending on setting (private vs. university) and even amongst individual providers within the same institution (12,26), suggesting a significant difference in fluoroscopy utilization patterns. Zhou et al noted average radiation doses as low as 158.0 mRem (1.58mSv) for other operators when performing a variety of different lumbar sacral pain procedures (26).

The effective dose is obtained by multiplying the radiation dose delivered (DAP for fluoroscopy) to each organ by its tissue weighting factor (to account for the carcinogenic sensitivity of each organ) and then by adding those values to get the sum which is expressed in mGycm² for lumbar spine lateral radiograph, or 35,000-48,000 mGycm² for head CT (17).

Limitations of this investigation must be acknowledged. Low energy modes such as pulsed imaging (11) or higher output settings such as DSI are available but are not separately recorded/quantified by the fluoroscope and therefore may represent unmeasured variables that could affect the data set. True radiation dose differences between the OEC 9800 and 9900 machines could have been masked, for example, if pulsed imaging or DSI had been used more frequently in with one machine compared to the other. However, this is unlikely given the performance of all procedures by a single provider during mid to late-career practice. Alternatively, investigator of only one provider’s procedure data limits the generalizability of the present findings to other experienced interventionalists in academic practice. An additional limitation is that only two C-arm models were compared from only one manufacturer; the present findings may differ from comparisons amongst various models from other manufacturers. Finally, because this study analyzed a wide spectrum of spinal procedures, the variability in fluoroscopy dose per procedure (reflected by standard deviations) is large. Larger studies could potentially reveal significant difference in radiation dose exposure. However, even if such were the case, it is unlikely that the difference would be clinically significant on a per-procedure basis. The differences of an entire standard deviation of the mean radiation dose exposures observed in the present cohort amount to little more than a lumbar spine x-ray (15). Furthermore, it is estimated that background radiation in the United States reaches about 3.0 mSv per year (roughly two lumbar spine x-rays). However, small differences may be clinically meaningful to operators and fluoroscopy suite staff, as there is evidence to suggest harm after high-dose exposures and lifetime doses greater than 100mSv (including occupational and environmental exposures) (28). Further investigation in the context of provider exposure and occupational hazard is warranted.

CONCLUSIONS
In this pragmatic study, comparing radiation dose exposure associated with various cervical and lumbar sacral fluoroscopically-guided interventional spine/pain procedures, no significant differences were observed between an older- and newer-generation machine; this remained true after controlling for age, sex BMI, procedure level, procedure type, trainee involvement, and fluoroscopy time.

REFERENCES
14. OEC 9900 Elite | GE Healthcare.

ACKNOWLEDGMENTS
None to declare.