Original Research

Duration of Fluoroscopic-Guided Spine Interventions and Radiation Exposure Is Increased in Overweight Patients

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Background: The impact of patient body mass index (BMI) on image-guided spine interventions remains unknown. Higher BMI is known to complicate the acquisition of radiographic images. Therefore it can be hypothesized that the patient's body habitus can influence the delivery of a spinal injection.

Objective: To quantify the impact of patient BMI on the length of fluoroscopy and procedure times during spine interventions.

Design: Secondary analysis of 2 prospective observational studies.

Setting: All injections were performed in an outpatient university setting.

Participants: A total of 209 patients in whom spine injections were performed (99 women), with a mean age of 54.6 years.

Methods: The fluoroscopy times for 202 participants and total procedure times for 137 participants were recorded. Additional participant characteristics, including age, gender, BMI, and actual procedures performed, also were collected. Analysis of covariance and linear and nonlinear model analysis were performed to assess the effect of BMI on fluoroscopy and procedure times.

Main Outcome Measurements: Fluoroscopy time and procedure duration times. **Results:** Participants had a mean age of 54.6 years, 51% were men, and 77% (n = 155) were overweight (BMI \geq 25). Participants received the following interventions: 40 zygapophyseal joint injections, 33 medial branch nerve blocks, 113 transforaminal epidural injections, and 16 combined zygapophyseal joint injections and epidural injections. Gender, procedure number, and procedure type did not differ between groups. The overweight group demonstrated a 30% increase in mean fluoroscopy time and a 35% increase in mean procedure time. Controlling for other variables, we found that differences in fluoroscopy time and procedure time were significant (P = .032 and P = .031, respectively) between the 2 groups.

Conclusions: Significantly prolonged procedure time and fluoroscopy time in overweight patients increase the risks associated with spine interventions, not only to the patients but also to the operating room staff exposed to ionizing radiation.

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INTRODUCTION

Low back pain (LBP) plagues industrialized societies. Some researchers suggest that the incidence of LBP is increasing in part because of the growing obesity epidemic [1,2]. Although an association between obesity and LBP has not been found in all studies [2,3], in 2 independent studies, authors found that a body mass index (BMI) greater than 30 is associated with a 1.7-fold increased odds of developing back pain with disability [4,5]. Kaila-Kangas et al [6] found that a BMI within the overweight range (BMI >27.5 kg/m²) was associated with a 2.7-fold increase in the odds of back pain. Furthermore, weight reduction achieved via surgical means has been reported to significantly reduce or even resolve chronic LBP [7].

Recently published practice guidelines from the American College of Physicians and the American Pain Society recommend consideration of spine injections for treatment of certain lumbar spine conditions when patients do not respond to standard noninvasive therapies [8]. These interventions generally are performed under fluoroscopic guidance to improve their

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accuracy and safety. Higher BMI is known to compromise the acquisition of medical images, reduce image quality, and necessitate greater doses of radiation to obtain images of deep structures [9,10]. In addition, it complicates positioning and increases rates of postsurgical complications in spine surgery [11,12]. This study was initiated to investigate the impact of being overweight on percutaneous spine interventions. To our knowledge, this is a previously unexplored topic.

METHODS

This investigation was a secondary analysis of data obtained from 2 prospective observational studies, one in which the authors studied lumbar transforaminal epidural injections alone and another in which the authors studied multisite lumbar injections, including medial branch blocks, bilateral or multilevel zygapophyseal joint injections, or a combination of lumbar transforaminal epidural injections and zygapophyseal joint injections [13,14]. This analysis was approved by the University of Michigan institutional review board and was compliant with the Health Insurance Portability and Accountability Act.

During the data collection time frame between March 2006 and September 2008, all patients scheduled by their treating spine surgeon or physiatrist for a percutaneous spine intervention were considered as candidates for the index studies. Exclusion criteria were allergy to contrast, pregnancy, coagulopathy, systemic infection, mental disability, and inability to give informed consent. From the original study cohorts, all participants who received lumbar medial branch nerve blocks, lumbar zygapophyseal joint injections, and/or lumbosacral transforaminal epidural injections were included in the current study. All injections were performed by one experienced fellowshiptrained interventionalist (M.S.) and several fellows under his direct supervision in an outpatient university setting.

The patient data collected included age, gender, BMI (defined as weight in kilograms divided by height in meters squared), procedure level(s) and side(s), fluoroscopy time, and procedure time. For single injections, fluoroscopy time (in seconds) was automatically measured by the fluoroscope (GE OEC 9800, Salt Lake City, UT) and defined as the total fluoroscopy time recorded. Procedure time was measured with use of a stopwatch by a research assistant in the procedure room. The assistant started the stopwatch when the needle attached to the syringe containing local anesthetic first penetrated the patient's skin and stopped it when the treatment needle was removed from the patient.

In cases in which more than one level or side was injected, the time of the administration of fluoroscopy and of the procedure were recorded for the entire combination of injections and then converted to a per-injection format. Specifically, the total duration of fluoroscopy and the procedure was measured continuously from the first injection to the last injection. Then, to normalize the data on a per-injection basis, the total durations of

the fluoroscopy and procedure were divided by the number of injections performed for that participant.

Values used to define normal weight and overweight were determined by the World Health Organization BMI criteria: normal is 18.50-24.99, and overweight is \geq 25.00 (World Health Organization, 2004, http://www.who.int/mediacentre/factsheets/fs311/en/). To detect any pre-existing association between weight and age, gender, and type of procedure, χ^2 tests were performed to evaluate weight in terms of those characteristics.

To examine the distributional characteristics of fluoroscopy and procedure duration, we calculated the means, SDs, skewness, and kurtosis. The normality of each distribution was tested with the use of a one-sample Kolmogorow-Smirnov Goodness-of-Fit test. Data with significant Z values were normalized by log transformation. To account for the potential confounding effects of age, analysis of covariance was performed on the log-transformed fluoroscopy and procedure times, with weight group (normal versus overweight) and age as the covariates. Additional analyses that used generalized additive model were performed to account for the number of procedures, age, and gender and to assess nonlinearity of BMI's effect. All analyses were performed with the statistical analysis software (SAS) 8.2 software package (SAS Institute, Inc., Cary, NC), R (http://r-project.org), and STATA Statistics/Data Analysis 12.0 (StataCorp LP, College Station, TX).

RESULTS

In this study, we examined spine injections performed on 202 patients, 99 of whom were women, with a mean age of 54.6 years (SD 15.4). All participants were divided into normal-weight and overweight groups, with 47 (23.3%) and 155 (76.7%) in each group, respectively.

The distribution of interventions included 40 patients with zygapophyseal joint injections, 33 with medial branch nerve blocks, 113 with transforaminal epidural injections, and 16 with combined zygapophyseal joint injections and transforaminal epidural injections (Table 1). Because procedure times can vary on the basis of the number and type of injections, these factors were extensively analyzed. Most importantly, no statistical differences were found in the proportions of injection types or the average number of injections per patient in the 2 groups. Furthermore, no observable trends were noted between weight class and gender or types of procedure performed in our sample populations.

Overweight patients were younger than patients of normal weight (t = 1.84, P = .068), although this difference did not reach statistical significance. Regardless, age was examined as a covariate in the subsequent statistical tests in which we compared normal versus overweight subjects in terms of fluoroscopy and procedure times.

Average fluoroscopy time per procedure was 10.1 seconds (SD = 6.1) in the normal-weight group and 13.1 seconds (SD = 12.4) in the overweight group. Plotting the measured fluoroscopy time by weight class revealed a skewed distribution, with

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Table 1. Subject characteristics

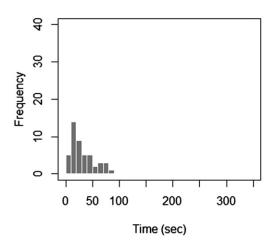
Variable	Normal Weight (n = 47)	Overweight (n = 155)	<i>P</i> Value	Total (n = 202)
Age, y (SD)	58.2 (17.5)	53.5 (14.6)	.068	54.6 (15.4)
Gender, n (%)				.= .= .
Male	22 (46.8)	81 (52.3)	.618	47 (51.0)
Female	25	74		99
Race				
White	17	56	.749*	73
Nonwhite	4	11		15
Unknown	26	88	.868 [†]	114
Procedure side [‡]				
Left	41	111	.234	152
Right	34	129		163
Procedure type				
z-joint only	10	30	.835	40
z-joint and epidural	1	15	.125	16
Medial branch Nerve blocks	10	23	.999	33
Epidural only	26	87	.999	113
Procedure level				
L1/L2	4	9	.314	13
L2/L3	13	32	.350	45
L4/L5	29	102	.796	131
L5/S1	33	118	.615	151
S1/S2	5	15	.586	20
Total	84	276		360

^{*}Compared with nonwhite known race.

the vast majority of fluoroscopy times falling in the 5-25 second range, and outlying fluoroscopy times, prolonged up to 110 seconds, exclusively found in overweight patients (Figure 1).

Because the length of the procedure was not recorded on the earliest-included participants in the index study, procedure time only was available for the final 137 of the 202 subjects. Following a trend similar to the fluoroscopy time, average procedure time was 88.5 seconds (SD = 52.4) in the normal-weight group and 119.5 seconds (SD = 92.2) in the overweight group. Time of procedure also was associated with a similarly skewed distribution, with the majority of procedure times in the 90-240 second range and outlying procedure times prolonged up to 585 seconds found exclusively in overweight patients (Figure 2). Overall, the fluoroscopy time in patients with a BMI \geq 25 was increased by 30% and the procedure time was increased by 35%. Because both the time of the fluoroscopy and procedure were found to be positively skewed (skewness = 4.6 and 2.6, respectively), the normality of each distribution was tested with a one-sample Kolmogorow-Smirnov Goodness-of-Fit test. For both the time of fluoroscopy and the procedure, the resulting Z value was statistically significant, indicating that the observed distributions significantly deviated from a standard normal distribution (Z = 2.65, P < .001; and Z = 2.31, P < .001, respectively). In an attempt to normalize the distributions, individual fluoroscopy and procedure times were log-transformed. When testing the log-transformed data, we found that the Z values were no longer significant, indicating that the transformations were successful in normalizing the distributions. The mean and SD of the fluoroscopy and procedure times for the raw and log-transformed data are presented in Table 2. Analysis of covariance conducted on the log-transformed fluoroscopy data indicated that there was a significant main effect of weight class when we controlled for age [F(1,134) = 4.76, P = .031]. A similar analysis conducted on log-transformed procedure times revealed a signif-

Fluoroscopy Time for BMI<25



Fluoroscopy Time for BMI>=25

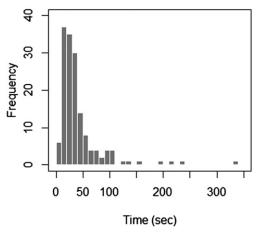


Figure 1. Stacked bar chart showing increased fluoroscopic times in overweight patients compared with normal-weight patients. BMI = body mass index.

[†]Compared with known race (either white or nonwhite).

^{*}Some individuals received both right and left procedures.

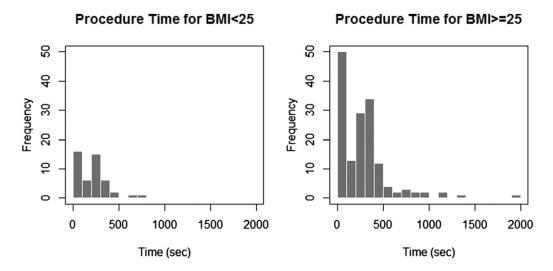


Figure 2. Stacked bar chart showing increased procedure times in overweight patients compared with normal-weight patients. BMI = body mass index.

icant main effect of weight class when we controlled for age [F(1,199) = 4.66, P = .032]. A generalized additive model in which we controlled for age, the number, and type of injections revealed that BMI is a linear predictor of fluoroscopy time in log scale.

DISCUSSION

Several authors have shown that obese patients are more likely to experience LBP [3-5]. Because the rate of obesity is anticipated to increase, the rate of LBP also may increase. Despite the increasing use of image-guided spine interventions for the treatment of LBP and the increasing rates of obesity, the impact of greater BMI on these procedures has remained unknown.

Spine injections without fluoroscopic guidance often are inaccurate. Needles are misplaced in 25%-36% of caudal epidural injections and in 7%-30% of lumbar interlaminar epidural injections without fluoroscopic guidance [15,16]. Studies have shown an even lower chance of correct needle placement without x-ray screening in obese patients [17]. Thus the use of fluoroscopy and iodinated contrast has become the standard of

Table 2. Means and SDs (in parentheses) for the raw and log-transformed fluoroscopy and procedure time for normal and overweight groups

Variable	Normal-Weight Patients	Overweight Patients	ANCOVA
Fluoroscopy time, s Log fluoroscopy time, s	10.1 (6.1) 2.14 (0.60)	13.1 (12.4) 2.34 (0.65)	P = .032
Procedure time, s Log procedure time, s	88.5 (52.4) 4.33 (0.54)	119.5 (92.2) 4.58 (0.60)	P = .031

ANCOVA = analysis of covariance.

care, leading to improved outcomes and reduced complications [18,19]. However, fluoroscopic-guided needle placement in overweight patients is complicated by difficulty in image acquisition and reduced image quality [20]. Given these difficulties, we hypothesized that overweight patients would necessitate increased procedure time and increased exposure to radiation during their procedures.

Indeed, our analysis showed that overweight patients often necessitated longer fluoroscopy and procedure times compared with patients of normal weight. Outliers (with fluoroscopy times up to 110 seconds and procedure times up to 585 seconds) were limited to the overweight patients. The increased distance from skin to target may account for some of the increased times measured in this study, but other factors are just as likely involved. In our opinion, difficulties in image acquisition and reduced image quality likely play a larger role. It is also possible that overweight patients had more degenerative spine disease, causing further difficulty with needle placement. However, in this study the overweight group was younger than the normal-weight group and thus less likely to have greater degeneration. Furthermore, the association between obesity and degenerative spine disease is not as clear as its association to LBP. Research has suggested that obesity may actually protect from common forms of spine degeneration; a study of Finnish twin patients showed that greater body mass actually was associated with less disk desiccation, contrary to current views [21,22].

Increased length of fluoroscopic time and procedure times are not benign findings. Prolonged procedure times are known to increase complication rates in procedures such as cordocentesis [23], cerebral angiography [24], and knee replacements, requiring the use of a tourniquet [25]. Increased time of fluoroscopy signifies increased exposure to radiation. Risks from ionizing radiation are

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cumulative over a lifetime and increase with dose [26,27]. Risks include increased chance of developing cataracts, leukemia, thyroid cancer, breast cancer, stomach cancer, colon cancer, ovarian cancer, and skin cancer [28-30].

The average yearly radiation exposure for an individual is approximately 360 mrem/yr, with 15% attributed to medical radiation exposure [26]. Schmid et al [31] found that 1-3 minutes of continuous fluoroscopy resulted in an effective dose of 43-125 mrem to the patient. In obese patients the radiation risk is even greater, because to maintain optimal imaging quality, the automatic brightness controls of most c-arm fluoroscopes automatically increase both the current and voltage of the x-ray beam [32]. Overweight patients also absorb more radiation from a beam than do thinner patients because of the increased length of beam penetration through the body, greater radiation scatter, and subsequent increased absorption of the scattered radiation [33]. Therefore overweight patients are not only exposed to the increased time of radiation exposure determined here but also receive a greater amount of radiation per second of exposure, which compounds the risk of added fluoroscopy time in these patients.

Increased time of fluoroscopy also poses hazards to the physician and procedure room staff. Scatter radiation from the patient dissipates at the inverse square of the distance from the source, placing the physician in the room at the greatest risk as the result of proximity. While assessing radiation exposure to the spine surgeon during fluoroscopically assisted thoracolumbar pedicle screw placement, Rampersaud et al [34] found that the mean dose rate to the neck was 8.3 mrem/min, the dose rate to the torso when the surgeon was positioned ipsilateral to the beam source was 53.3 mrem/ min, and the average hand dose rate was 58.2 mrem/min. The prolonged procedural time in overweight patients would subject the interventionalist to additional radiation. In addition, the increased procedural time subjects the interventionalist to the extra rigors of wearing heavy lead aprons and remaining in static postures for the prolonged time of the procedure. Therefore it is important for interventionalists and their staff to be aware of these risks and take care to optimize all controllable variables during procedures.

Time of fluoroscopy was used as a surrogate for radiation exposure but does not directly measure the effective dose. On the basis of the radiation dose estimations provided by Schmid et al [31], a small 10-second increase in fluoroscopy time translates to a 7.2-mrem increase in radiation exposure to the patient, or nearly 2% of the average individual's annual radiation dose. This study revealed an average 3-second increase in the time of the fluoroscopy procedure for overweight patients, translating to a 2.1-mrem increase in radiation exposure per patient. With adequate distance and proper shielding, the estimated radiation dose to the operator during fluoroscopic procedures is generally 0.1% of that to the patient [35]. Thus a crude estimate of the impact on the treating physician is possible. Hypothetically speaking, a

busy interventionalist performing a single spine injection during 1000 patient encounters per year, with the national average of 2 of 3 patients overweight, can expect to be exposed to a 1.4-mrem increase in radiation annually (1000 patients/yr \times 2/3 overweight patients \times 2.1 mrem average increase dose per overweight patient \times 0.1% estimated physician dose = 1.4 mrem/yr). Although this amount is a fraction of the annual occupational dose limit, radiation risk is cumulative over a lifetime. In addition, for reasons listed in the aforementioned paragraphs, these calculations likely underestimate the true radiation dose increases to the patient and physician. A prospective study can be designed to provide more accurate estimates of obesity's impact on radiation dose during spine interventions.

This study has several limitations. First, the injections were performed by a single physician. Injection styles and results may differ with alternate providers. Second, the interventionalist was not blinded to the weight of the patient. Third, procedure time was not available for approximately the earliest third of the recruited subjects. However, in this regard, the analysis provided statistically significant results, suggesting that a larger sample size was not necessary. Because the data from this study were collected for purposes of another investigation, we were not able to control several other factors. For instance, we were not able to evaluate the procedures to determine the potential sources of increased fluoroscopy and procedure time in overweight patients. Evaluating procedure time for patients who receive a single uniform type of injection would have been a simpler and purer approach to the questions asked in this study. However, when we controlled for multiple injections in our data analysis and evaluated the number and type of injections received by patients in the 2 groups, we found no statistically significant differences. Furthermore, we believe these data more closely represent a real-world practice in which some patients receive a single injection and some receive multiple injections. Thus we believe that these results are more representative of and applicable to general practice.

CONCLUSION

Given the findings of our study, we recommend that the concept of "as low as reasonably achievable" be rigorously implemented while performing fluoroscopy-guided procedures on overweight patients. Similarly, the use of protective shielding should be considered to reduce scattered radiation exposure [17,34]. Finally, because overweight patients may be technically more challenging, as suggested by the increased time fluoroscopic and procedure times, care must be taken to manage these patients to maximize safety for all parties involved.

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CME Question

What effect does Body Mass Index (BMI) have on fluoroscopically guided low back pain procedures?

- a. Patients with a BMI greater than 25 undergoing a fluoroscopic procedure for back pain may be exposed to higher levels of ionizing radiation and prolonged procedure times.
- b. A BMI of greater than 20 increases the likelihood of undergoing a fluoroscopic procedure.
- c. A BMI of less than 25 increases the risk of radiation exposure to the physician performing these procedures over time.
- d. The BMI of a patient has no impact on radiation and procedure times for interventional treatment of low back pain.

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