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Observational Study

Benefits of Inferential Statistical Methods in Radiation Exposure Studies: Another Look at Percutaneous Spinal Cord Stimulation Mapping [Trialing] Procedures

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Background: Two studies, each consisting of large sample sets, were recently published on radiation exposure in percutaneous spinal cord stimulation (SCS) trialing procedures. A more rigorous use of statistical methods in the second study more accurately defined benchmark reference levels. Principally, one physician implanter—considered an advanced interventional pain physician—performed all such procedures to nullify inter-physician variability. However, the literature is sparse in articles comparing exposure levels of radiation in pain procedures conducted by novice and advanced interventionally trained physicians, and inferential statistical analysis is seldom included in radiation exposure studies.

Objective: The aim of this study was to compare fluoroscopy times between novice and expert physician implanters performing SCS trialing procedures, and to the benchmarked reference level, using inferential statistical methods. As a secondary objective, the importance of statistical concepts in interpretive-imaging and image guidance studies for interventional pain procedures will be outlined.

Design: An observational study.

Setting: A non-university outpatient Interventional Pain Management practice in the United States.

Methods: Fluoroscopy time (in seconds) was retrospectively studied in 18 SCS trialing procedures (with dual lead placement in the low thoracic spine) performed over a 3-month period. The procedures were categorized by physician experience: one novice physician implanter with n = 5 cases and one expert physician implanter with n = 13 cases. All procedures were conducted with the same fluoroscope operator and the same mobile C-arm fluoroscopy system. A two-tailed t-test was used to compare mean fluoroscopy times between physician categories. Left-tailed t-tests were used to compare mean fluoroscopy times for each physician category separately to the benchmark level (μ = 71.7 seconds). Incident air kerma (KERMA) was assessed by nonsimplistic modeling.

Results: No statistical difference was found in mean fluoroscopy times for SCS trialing procedures between the novice- and expert-implanter, $\bar{\chi}_{novice}$ = 63.5 seconds and $\bar{\chi}_{expert}$ = 53.9 seconds. In the case of the novice implanter, although mean fluoroscopy time was lower than the benchmark reference level, $\bar{\chi}_{novice}$ = 63.5 seconds compared to μ = 71.7 seconds, this was not significantly relevant. In the case of the expert implanter, a statistically relevant reduction in mean fluoroscopy time was observed compared to the benchmark level, $\bar{\chi}_{expert}$ = 53.9 seconds versus μ = 71.7 seconds. KERMA ranged from 5.3 mGy to 9.1 mGy with a mean and standard deviation of 6.5 mGy and 1.5 mGy, respectively, in the novice implanter sample set. KERMA ranged from 2.6 mGy to 13.1 mGy with a mean and standard deviation of 5.8 mGy and 3.2 mGy, respectively, in the expert implanter sample set.

Limitations: Given that reference levels for radiation exposure in SCS trialing procedures are established, combined with comparisons in fluoroscopy times based on physician experience, expanding the physician database will assist in data validation.

Conclusion: Radiation exposure levels in SCS trialing procedures remain negligible. While no differences in fluoroscopy times for such procedures were detected based on physician experience, the expert implanter demonstrated the ability to use less fluoroscopy time than that of the benchmark reference level.

Key words: Neuromodulation, radiation safety, fluoroscopy, dosimetry, dose reduction, health physics

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Subsequent to our first report on radiation exposure in percutaneous spinal cord stimulation (SCS) mapping procedures, published in *Pain Physician* in 2010 (1), a new sample population was studied, prospectively, under the same imaging and procedural methodology but with 2 additional parameters: 1) patient size and 2) source-to-skin distance (SSD). With respect to the original report (a retrospective observational study), the use of simplistic modeling methods to estimate radiation exposure rendered these 2 parameters computationally unnecessary, and thus that information was not collected. Nevertheless, both factors are important to consider in more sophisticated radiation exposure models.

Using a more sophisticated model, analysis of the new data set was featured in the chapter on interventional pain medicine in the textbook *Pain Management - Current Issues and Opinions* (published in 2012 and edited by Drs. Racz and Noe) (2). Notably, descriptive statistical methods were used to compare/contrast the original data and the new data. Moreover, with respect to both data sets, neither inter-physician nor intra-physician variability was a concern since the same physician (as well as the same fluoroscope operator) performed all SCS trialing procedures, n = 106 and n = 110, the new and original sets, respectively. Due to the large sample sizes, these 2 studies, when combined, provide the framework to help benchmark fluoroscopy times and radiation doses associated with SCS trialing procedures. However, to definitively benchmark a reference level (population mean) with respect to fluoroscopy time, results from the second study (i.e., the new data set) should take precedence due to the more rigorous statistical analysis employed for that study (2). In doing so, the mean fluoroscopy time for SCS trialing procedures is $\mu = 71.7$ seconds and a standard deviation $\sigma = 34.9$ seconds.

As noted in the original report, no data is available to compare fluoroscopy times between novice and expert physician implanters (with respect to trialing procedures). To the knowledge of this author, Zhou et al (3) provide the only radiation exposure themed report for interventional pain procedures that addresses these 2 physician categories. Thus, as a final installment in our investigation of radiation exposure in percutaneous SCS mapping [trialing] procedures, it is the aim of this paper to perform inferential statistical analysis to compare fluoroscopy times between novice and expert physician implanters in the private practice setting (as well as compare each category to the benchmark level). The null hypotheses are 1) no difference in mean fluoroscopy times will be detected between physician categories, and 2) neither physician category will show reduced fluoroscopy time compared to the benchmark (population mean). Moreover, while this paper showcases the benefits of inferential statistical methods for quality assurance protocols in radiation safety programs, a broader view of statistical analysis relative to the field of interpretive-imaging and image-guidance appears as a special collection, the "Statistical Concepts Series," from 2002 to 2004 in the journal *Radiology* (4). On this point, an overview of the importance of such concepts will be explicitly outlined for interventional pain medicine applications.

Methods

Twenty-seven SCS trialing procedures using dual parallel lead alignments with multiple independent current controlled SCS systems (Boston Scientific Neuromodulaiton, Valencia, CA, USA) in the non-university, outpatient setting from April 2011 to June 2011 were studied retrospectively. Case inclusion was based on epidural lead placement in the low thoracic spine to treat intractable low back and/or lower extremity pain related to post-laminectomy syndrome. Thus, 8 procedural cases were excluded: 6 cases due to cervical epidural lead placement only; one case due to both cervical and low thoracic epidural lead placements; and one case due to placement of lumbosacral subcutaneous leads. Of the remaining 19 procedural cases, a statistical outlier (defined to be greater than the absolute value of 2 standard deviations of the mean) with respect to fluoroscopy time was present in the data set for the novice implanter. These inclusion/exclusion and statistical criteria produced sampling data sets with n = 5 cases for the novice physician implanter and n = 13 cases for the expert physician implanter.

The designation of "novice" or "expert" physician implanter was based on 1) time spent in the private practice setting following dedicated training through an interventional pain fellowship and 2) the number of SCS trialing procedures performed in that period. For the novice implanter, this was defined as less than 1-year and 13 procedures, respectively. For the expert implanter, this was defined as greater than 5-years and more than 400 procedures, respectively. Moreover, the expert implanter was also the same physician who performed the 216 cases compiled from the first 2 studies

(representing a 2-year period) (1,2).

Imaging methodology has been previously described in detail (1). The same radiologic technologist who operated the C-arm during the 2-year period that covered the first 2 reports (1,2) also operated the C-arm for this study. The fluoroscopy system (OEC 9800 Super-C with HX class multifield image intensifier, GE Healthcare, Salt Lake City, UT, USA) automatically tabulated total fluoroscopy time (in seconds) per case, and partitioned the absolute time and the percentage of time allocated to pulsed and continuous-mode imaging in the "Dose Summary" (Fig. 1). The fluoroscope was deemed to be in compliance with all state rules/regulations, as well as manufacturer calibrations and annual physics acceptance testing. High dose fluoroscopy, or "boost" mode, was not used. The fluoroscopy table was a standard 6-way adjustable radiolucent table with a standard .5 mm lead equivalent table skirt.

For the dose model, radiation output was measured with a dosimeter/ion chamber (Radiation meter – Model 1515 with converter model 1050U and ion chamber model 10X6-6M, Radcal Co., Monrovia, CA, USA) located 30 cm from the image intensifier, along the central axis of an anteroposterior projected beam. Entrance skin exposure was estimated based on the following equation, where ESE_{pat} and ESE_{pha} are skin exposure to the patient and phantom (3.8 cm of aluminum); O_{pha} and O_{pat} are radiation output for phantom- and patient-exposure (in Röentgens); SSD_{pat} and SSD_{pha} are the distances from the x-ray source to the skin for the patient and phantom; and t_{flu} is fluoro-time (converted to minutes).

$$ESE_{pat} = ESE_{pha} \bullet \left[\frac{O_{pha}}{O_{pat}} \bullet \left(\frac{SSD_{pat}}{SSD_{pha}}\right)^2\right] \bullet t_{flu}$$

The name of the quantity which corresponds to entrance skin exposure and which is recognized by the International Commission on Radiation Units

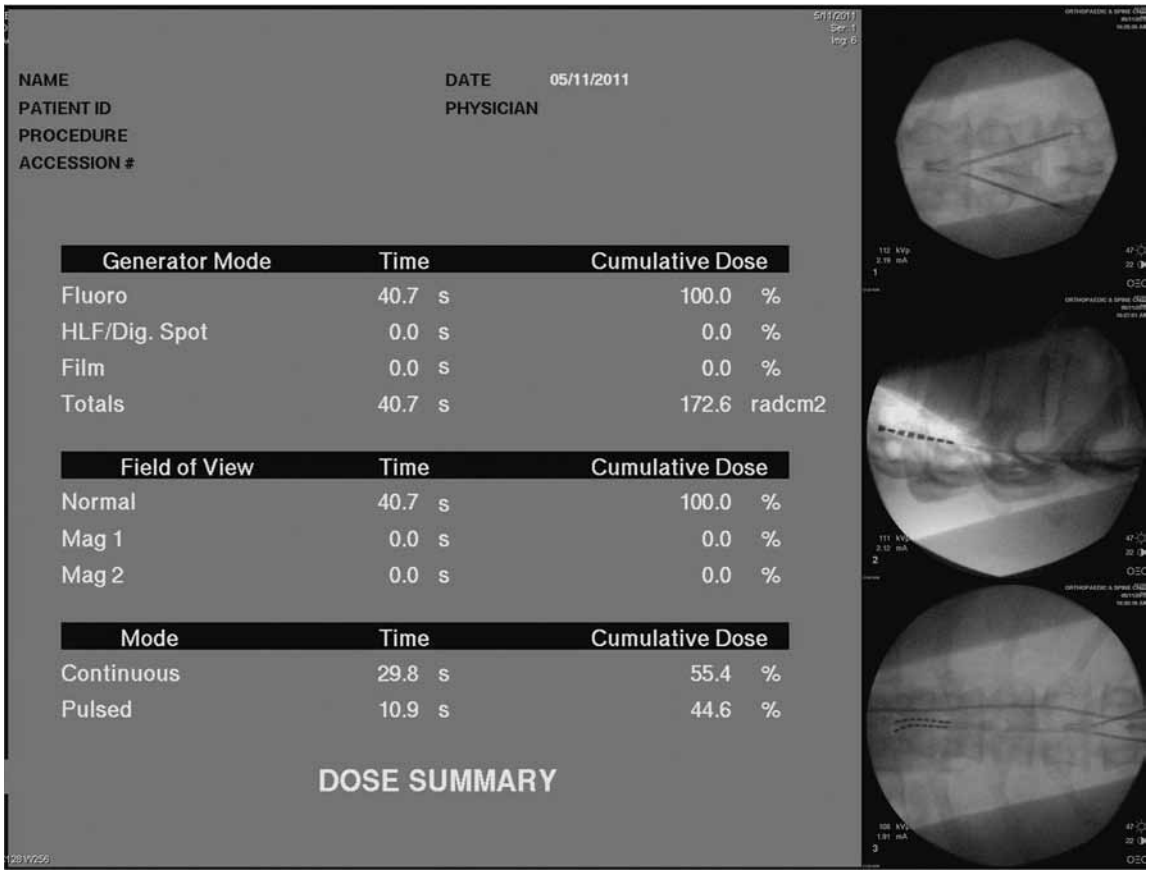

Fig. 1. *Dose Summary from case 9 of the n = 13 data set. The SCS trial was initiated to treat intractable post-laminectomy pain, with a radiating component into each leg. Note: Placement of the electrode arrays compare favorably with dermatomal representations of the spinal cord as detailed by Feirabend et al (5).*

and Measurements is incident air kerma (6), and the unit of measurement is milligray (mGy). Incident air kerma is converted from ESE_{pat} by applying a factor of 8.76 mGy to 1 Röentgen. The above formula and conversion factor subsequently allowed estimates of incident air kerma, including stratified values according to SSD and low dose mode (engaged or disengaged).

Statistical Methods

Calculations for the summary statistics were performed using Microsoft Office Excel 2007 (Microsoft Co., Seattle, WA) (Table 1). Reference levels for fluoroscopy time and incident air kerma were obtained from Wininger (2), in which the reported number of SCS procedural cases n = 106 (now considered the population for purposes of this study) was normally distributed with a mean fluoroscopy time μ = 71.7 seconds and a standard deviation σ = 34.9 seconds. Comparison between the mean fluoroscopy times of the sample sets (i.e., expert physician implanter compared to novice physician implanter) was conducted using a 2-tailed t-test. The alpha-level was .05 (and thus, .025 with respect to the 2-tailed test), with degrees of freedom equal to 16. Comparison between the mean fluoroscopy times from each sample set to the mean fluoroscopy time associated with the population (i.e., the benchmark) was conducted using left-tailed t-tests. The alpha-level was .05 for each of these tests, while the degrees of freedom depended on the comparison being conducted. For the novice implanter sample set, 4 degrees of freedom were used, and for the expert implanter sample set, 12 degrees of freedom were used. Finally, each sample mean was assessed using a 90% confidence interval.

Calculations of all t-tests and confidence intervals were made using a TI-84 Plus handheld calculator (Texas Instruments, Dallas, TX, USA).

Date	Case	Fluoro-Time Total	rad cm2	kVp	mA	Continuous Fluoro		Pulsed Fluoro	
						Time	% Dose	Time	% Dose
Expert Implanter									
4/6/2011	1	34.3	140.4	105	1.66	27.2	65.0	7.1	35.0
4/6/2011	2	33.3	66.6	95	1.34	24.9	56.1	8.5	43.9
4/13/2011	3	114.8	300.6	102	1.57	109.3	88.7	5.6	11.3
4/13/2011	4	25.3	67.2	102	1.57	19.3	62.7	6.0	37.3
4/14/2011	5	59.2	212.2	104	1.66	44.9	68.6	14.3	31.4
4/27/2011	6	33.4	54.4	98	1.42	24.6	59.0	8.8	41.0
4/27/2011	7	98.4	567.8	105	4.83	90.2	77.4	8.2	22.6
5/11/2011	8	40.7	172.6	108	1.91	29.8	55.4	10.9	44.6
5/11/2011	9	57.5	238.7	111	2.12	56.2	97.9	1.3	2.1
5/19/2011	10	53.4	158.4	106	1.76	48.5	84.0	4.9	16.0
5/26/2011	11	71.4	254.5	111	2.14	66.6	91.1	4.7	8.9
6/9/2011	12	40.0	127.9	103	1.68	29.9	55.2	10.1	44.8
6/22/2011	13	39.6	104.1	103	1.63	28.8	57.2	10.8	42.8
	mean	53.9							
	std dev.	26.9							
	minimum	25.3							
	maximum	114.8							
Novice Implanter									
4/8/2011	1	48.9	207.3	101	1.52	42.7	69.4	6.2	30.6
4/15/2011	2	87.1	301.1	103	1.64	69.1	58.2	18.0	41.8
4/29/2011	3	65.8	106.7	94	1.31	42.5	58.7	23.2	41.3
5/13/2011	4	58.7	221.2	111	2.05	44.9	63.7	13.9	36.3
6/3/2011	5	56.9	180.4	96	1.39	39.9	52.0	17.0	48.0
	mean	63.5							
	std dev.	14.5							
	minimum	48.9							
	maximum	87.1							

Table 1. *Summary statistics.*

Results

Table 2 summarizes inferential statistical testing results.

No statistical difference was found (insufficient evidence in the data to reject the null hypothesis) in the mean fluoroscopy times for SCS trialing procedures between the novice and expert implanters, $\bar{\chi}_{novice}$ = 63.5 seconds (standard deviation, 14.5 seconds) and $\bar{\chi}_{expert}$ = 53.9 seconds (standard deviation, 26.9 seconds), respectively.

No reduction was found (insufficient statistical evidence in the data to reject the null hypothesis) in the mean fluoroscopy time for the novice implanter versus the benchmark reference level, $\bar{\chi}_{novice}$ = 63.5 (standard deviation, 14.5 seconds) seconds compared to μ = 71.7 seconds (standard deviation, 34.9 seconds). The 90% confidence interval was (49.7 seconds < $\bar{\chi}_{novice}$ < 77.3 seconds.

There was a reduction (sufficient statistical evidence in the data to reject the null hypothesis) in the mean fluoroscopy time for SCS trialing procedures performed by the expert implanter compared to the benchmark reference level, $\bar{\chi}_{expert}$ = 53.9 seconds (standard deviation, 26.9 seconds) versus μ = 71.7 seconds (standard deviation, 34.9 seconds). The 90% confidence interval was 40.6 seconds < $\bar{\chi}_{expert}$ < 67.2 seconds.

Figure 2 shows regression analysis (i.e., "goodness of fit") per sample concerning the raw data. In the expert implanter sample set, approximately 71% of the variation in the response variable (rad cm^2) can be explained by the predictor variable (fluoroscopy time). Whereas this was found to be a much smaller percentage, approximately 26%, in the novice implanter sample set. There were moderate positive and weak positive correlations between fluoroscopy time and rad cm^2 in the expert and novice sample sets, respectively.

Figure 3 shows regression analysis (i.e., "goodness of fit") per sample concerning the skin dose model. In the expert implanter sample set, 99.64% of the variation in the response variable (incident air kerma, in mGy) can be explained by the predictor variable (fluoroscopy time). Similarly, in the novice implanter sample set, the percentage was 96.0%. There were strong positive correlations between fluoroscopy time and incident air kerma estimates in both the expert and the novice sample sets.

Incident air kerma ranged from 5.3 mGy to 9.1 mGy with a mean and standard deviation of 6.5 mGy and 1.5 mGy, respectively, in the novice implanter sample set. For the expert implanter sample set, incident air kerma ranged from 2.6 mGy to 13.1 mGy with a mean and standard deviation of 5.8 mGy and 3.2 mGy, respectively.

Table 2. *Results of inferential statistical testing.*

Hypotheses (H)	Test Parameters	Test Results	Decision
H_0: $\bar{\chi}_{novice} = \bar{\chi}_{expert}$ H_1: $\bar{\chi}_{novice} \neq \bar{\chi}_{expert}$ 63.5 = $\bar{\chi}_{novice}$ 14.5 = s_{novice} 53.9 = $\bar{\chi}_{expert}$ 26.9 = s_{expert}	DF = 16, α = .05, α/2 = .025 Two-tailed t-test: $t_{16, .025}$ Critical value: ± 2.120 = t_{cv} Reject H_0 if $\|t\| > \|t_{cv}\|$ Reject H_0 if $P < .05$	t = .748 P = .4655	Do not reject H_0: .748 $\not>$ 2.120 Do not reject H_0: .4655 $\not<$ .05
H_0: $\bar{\chi}_{novice} \geq \mu$ H_1: $\bar{\chi}_{novice} < \mu$ 63.5 = $\bar{\chi}_{novice}$ 14.5 = s_{novice} 71.7 = μ, 34.9 = σ	DF = 4, α = .05 Left-tailed t-test: $t_{4, .05}$ Critical value: -2.132 = t_{cv} Reject H_0 if $\|t\| > \|t_{cv}\|$ Reject H_0 if $P < .05$	t = -1.265 P = .1373	Do not reject H_0: $\|-1.265\| \not> \|-2.132\|$ Do not reject H_0: .1373 $\not<$ .05
H_0: $\bar{\chi}_{expert} \geq \mu$ H_1: $\bar{\chi}_{expert} < \mu$ 53.9 = $\bar{\chi}_{expert}$ 26.9 = σ_{expert} 71.7 = μ, 34.9 = σ	DF = 12, α = .05 Left-tailed t-test: $t_{12, .05}$ Critical value: -1.782 = t_{cv} Reject H_0 if $\|t\| > \|t_{cv}\|$ Reject H_0 if $P < .05$	t = -2.386 P = .0172	Reject H_0: $\|-2.386\| > \|-1.782\|$ Reject H_0: .0172 < .05

Key: H_0 = null hypothesis, H_1 = experimental hypothesis, s = standard deviation of the sample, μ = population mean, σ = standard deviation of the population, DF = degrees of freedom, α = alpha level, t = t-test statistic, and P = probability value.

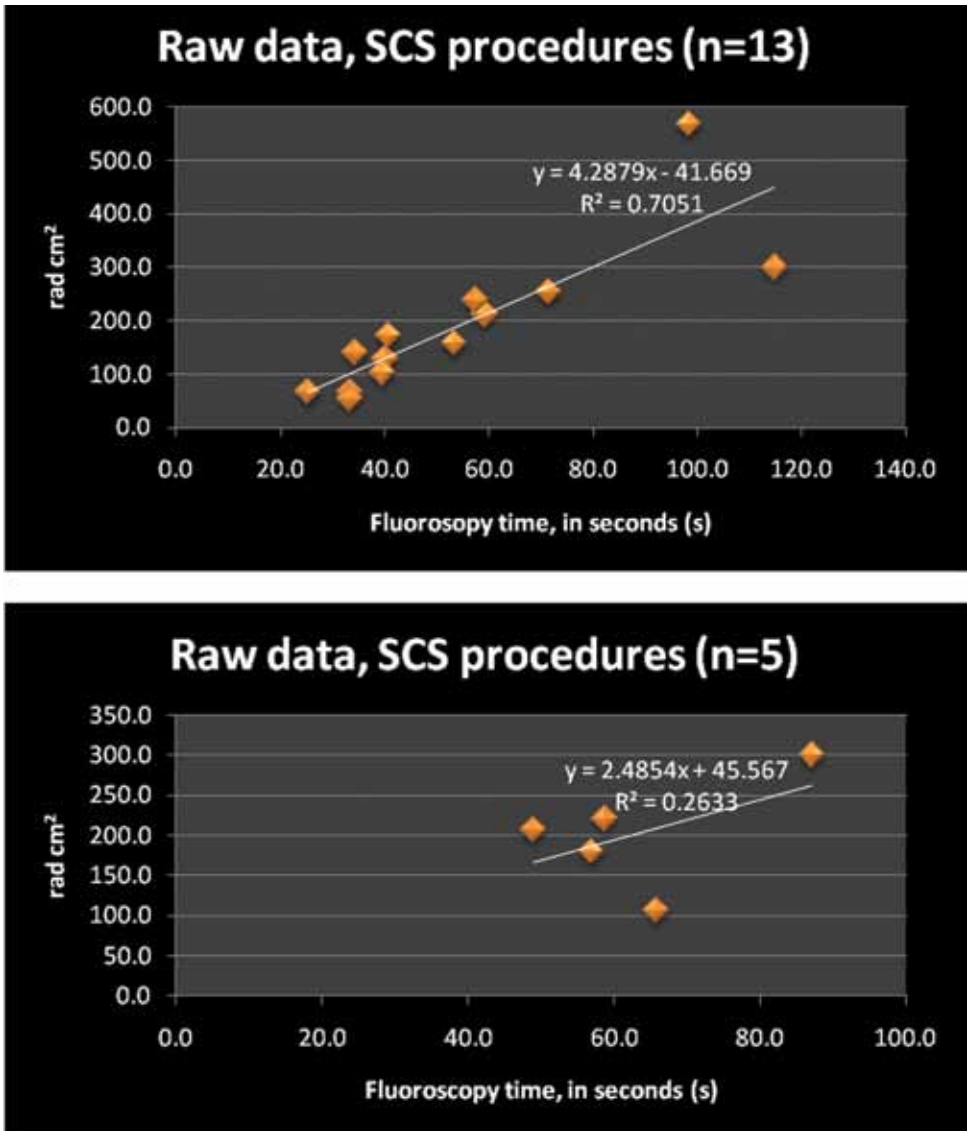

Fig. 2. *Scatter plots with trendlines for raw data from each set (n = 13 and n = 5). Note: Rad is the unit of [radiation] absorbed dose, while the Système International unit is the gray (Gy), with 1 rad = 1 cGy and 100 rad = 1 cGy. The horizontal axis is fluoroscopy time in seconds (s), whereas the vertical axis is rad cm2 (which is the absorbed dose per square centimeter of tissue).*

Discussion

Fluoroscopy time remains the traditional metric used for clinical radiation management (7). The value in collecting data on this acquisition parameter serves to benchmark performance, and such practice is inherent to optimization strategies in health physics (8). However, apart from Zhou et al (3) and Botwin et al (9), the literature is sparse with discussion on the amount of fluoroscopy time for pain procedures between beginner/novice and advance/expert interventionally trained physicians.

Interestingly, the results presented here show that for SCS trialing procedures performed by novice and expert implanters (each of whom underwent an interventional pain fellowship) there was no statistical difference in the mean fluoroscopy times. This result may reflect a comparatively high level of training imparted

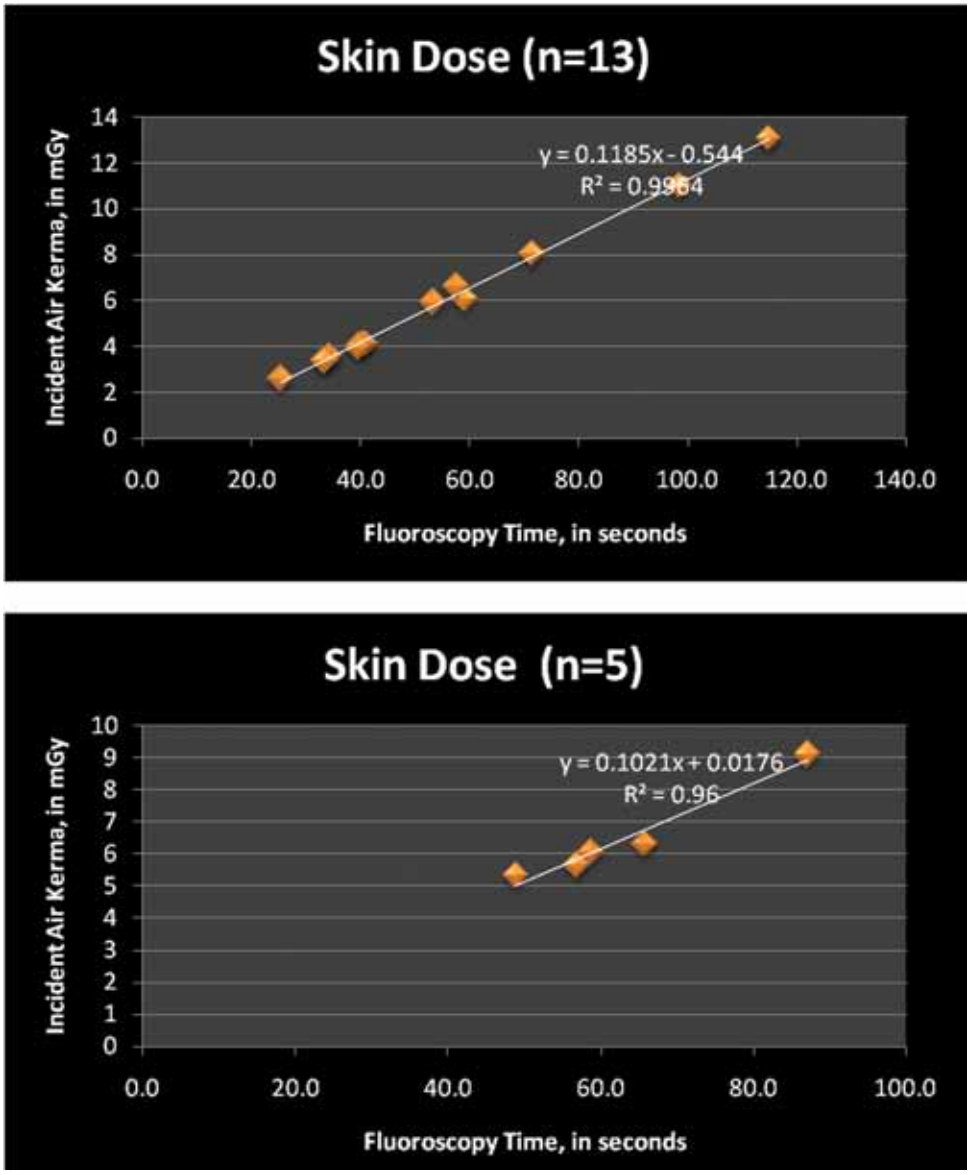

Fig. 3. *As derived from the R2 values (i.e., "coefficient of determination"), strong positive correlations exists, nearly 1.0 for each set, between fluoroscopy time and incident air kerma based on the skin dose model.*

on the 2 physicians during fellowship, and in particular, the novice or neophyte physician, including emphasis on radiation risk management.

Concerning mean fluoroscopy times per each sample set to the benchmark (population mean), there was no statistically relevant reduction compared to the population mean with respect to the novice implanter sample set. On the other hand, the expert implanter produced a lower sample mean that was statistically relevant compared to the benchmark (population mean). It is speculated that this outcome reflects the ability of the expert implanter to recall past experiences in order to make proficient changes in the techniques employed to gain epidural access and/or thread leads to the desired location, which in turn saves time both fluoroscopically and procedurally.

As discussed by Wininger et al (1), 5 factors are considered to have general clinical relevance on the

variance found in fluoroscopy time in SCS trialing procedures.

- Differences in neural tract arrangement and epidural space geometry
- Aberrant bony/spinal alignment
- Proper introducer needle angle/placement
- Intra-epidural tissue obstructions and/or epidural scarring
- Attenuation physics/image quality

It is noteworthy to mention that Zhou et al (3) emphasized image quality as a variance factor relative to fluoroscopy times for beginner and advanced interventional pain physicians. To this end, the reader is directed to the work by Wininger (1,2) for a comprehensive review on attenuation physics and image quality relative to interventional pain management.

Radiation Risk Management and Incident Air Kerma

In recent years the assessment of radiation dose has received increased scrutiny; notably, the evaluation of deterministic effects, for which the severity of effects will vary according to the dose received and for which dose thresholds usually exist (e.g., 2.0 Gy for radiation induced skin injuries) (1,10). Moreover, dose assessment has seemingly evolved from an academic enterprise to a clinical endeavour. Direct influence on clinical practice is appreciated by The Joint Commission's recent decision to add unexpectedly prolonged fluoroscopic exposure to its list of reviewable sentinel events, as well as their suggestion to follow-up qualifying events with a period of over 6 months to one year to monitor cumulative skin dose (11). Further, it is known that fluoroscopy time alone provides inadequate skin dose estimates (1). Furthermore, this statement is well-demonstrated in the values of the coefficient of determination R^2 for the raw data, as seen in Fig. 2, which illustrates a relatively poor to moderate goodness of fit between rad cm2 and fluoroscopy time in each sample set (R^2 = .71 with a moderately positive correlation and R^2 = .26 with a weak positive correlation for the expert and novice sample sets, respectively).

Alternatively, the dose model showed high valuations in the goodness of fit between skin exposure (incident air kerma) and fluoroscopy time (i.e., each R2 value is nearly equal to 1.0 with strong positive correlations), as illustrated in Fig. 3. Notably, the skin dose model accounted for the amount of total fluoroscopy time per procedure dedicated to continuous and pulsed fluoroscopy. Finally, to serve as a reference chart, Fig. 4

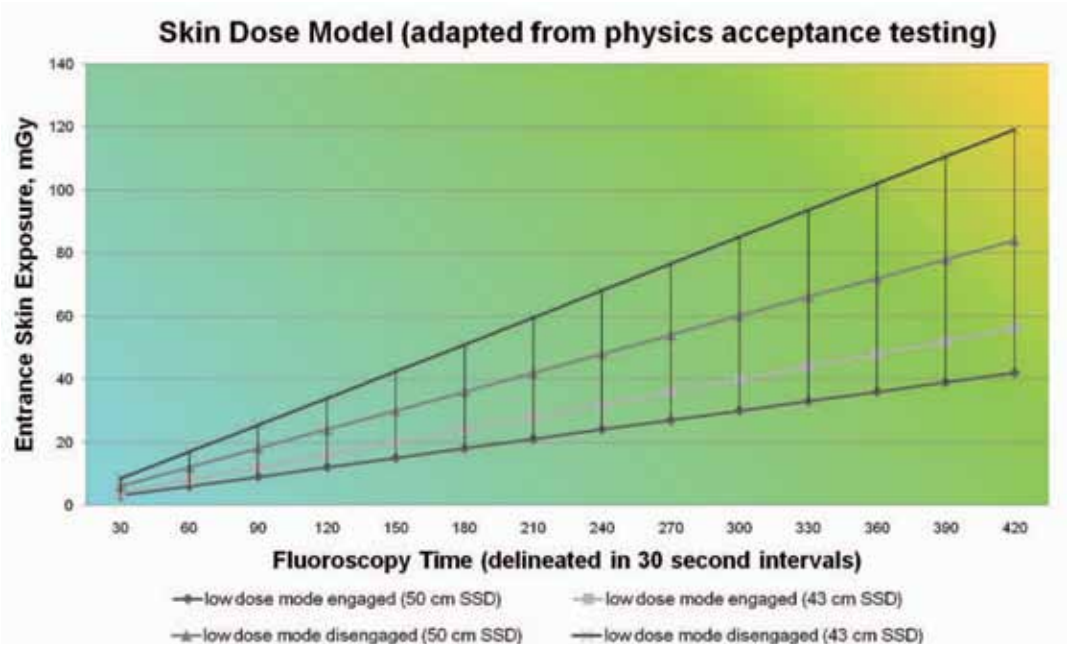

Fig. 4. *Skin dose model reference chart. ESEpat to anterior chest: 50 kg. adult patient accounting for one dose reduction feature, i.e., the low dose mode, either "on" or "off" for stratified SSDs (either 43 cm or 50 cm) in percutaneous spinal cord stimulation mapping [trialing] procedures. (Note: Valuations represent continuous-mode imaging, no beam collimation.)*

shows estimates of skin exposure stratified according to different SSDs (43 cm and 50 cm) and with low dose mode engaged or disengaged based on the model and physics acceptance testing.

As shown here, the use of radiation for image guidance in SCS trialing procedures is negligible, and the evidence suggests that expert implanters have the capability to lower the amount of fluoroscopy time used for image guidance. As shown by the skin dose reference chart, linearity is present (12,13), and hence all interventional pain physicians and fluoroscopic operators should strive to ensure the amount of radiation is as low as reasonable achievable (1,2).

Statistical Concepts

In today's environment of evidence-based medicine, statistical literacy can be encouraged in a 4-fold manner for the interventional pain armamentarium (4,14).

1. Education of statistical methods emphasizing the applications of medical statistics—particularly interpretive-imaging and image-guidance studies specific to pain management.
2. Support of continued development of consensus guidelines on the proper reporting of scientific research, such as those cited by the editors of *Pain Physician* (15). This includes the Consolidated Standards on Reporting Trials statement for randomized trials; the Strengthening of the Reporting of Observational Studies in Epidemiology statement on observational studies; the Studies of Accuracy of Diagnostic Tests with respect to interpretative aspects of results; and the Quality of Reporting of Meta-analyses statement for meta-analyses and systematic reviews.
3. Encourage the learning of critical thinking skills and research methodology.
4. Promote the value of scientifically rigorous reports, relative to that of less scientific ones, at professional meetings.

Study Limitations

The t-test is the appropriate statistical construct in the analysis of small sample sizes (where n is less than 30). Moreover, such sample sizes may be pragmatically useful to allow individuals responsible for radiation protection to sample radiation exposure compared to benchmark levels (as was performed here) for quality assurance protocols. However, it is recognized that larger sample sizes ($n \geq 30$) will render improved accuracy in data analysis, including the calculations of confidence intervals for sampling means. Hence, in light of the more definitive benchmark level with respect to mean fluoroscopy time in SCS trialing procedures, and an established protocol employing inferential statistical methods, expanding the physician database will assist in validating the results reported here between novice and expert physician implanters.

Conclusion

As the final installment to our work on this subject matter, this paper sheds light on exposure levels of radiation in percutaneous SCS mapping [trialing] procedures associated with novice and expert implanter physicians. Moreover, this was accomplished via inferential statistical methods. There was insufficient evidence in the data to reject the null hypothesis concerning differences in fluoroscopy times between novice and expert implanters (i.e., there was no statistical difference in the mean values from the sample sets). Interestingly, while there was statistically little difference in the mean fluoroscopy time associated with the novice implanter to the population mean (the benchmark), it was statistically shown that the mean fluoroscopy time for the expert implanter was lower. It is speculated that the skill level of the expert implanter permitted necessary adjustments to the techniques needed to gain epidural access and/or thread the leads to the desired location, and thus contributed to this reduction.

While fluoroscopy time alone produces inadequate skin dose estimates, the skin dose model suggests reliable estimates are obtainable (as evidenced by the resulting coefficients of determination and strong correlations). To the end, it may be stated that exposure levels of radiation in SCS trialing procedures remain negligible. Moreover, the skin dose model reference chart provides a comparative means to help interventional pain physicians maintain radiation doses as low as reasonably achievable for such procedures.

Lastly, statistical concepts provide an integral part of interpretive-medicine and image-guidance studies specific to pain management, and the importance of their encouragement was outlined.

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