Dosimeter Location and Measured Effective Radiation Dose in Pain Management Physicians

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1. **Protocol Title:**

   Dosimeter Location and Measured Effective Radiation Dose in Pain Management Physicians

2. **Objectives**

   The primary objective is to determine if there is a significant difference in radiation readings between dosimeters worn on the chest versus the hand of interventional pain management physicians and elucidate which dosimeter had higher readings.

   The secondary objectives are to examine trends in radiation exposure in each group (chest only or chest plus hand) over the course of the study to understand if overall radiation exposure decreases over time due to changes in practice habits as a response to exposure reports. The last objective will be to track incidences of physician glove breaches in both groups to assess if wearing hand dosimeters is associated with an increased risk of the event.

3. **Background**

   Radiation producing imaging use is ubiquitous in medicine with a wide range of imaging modalities. Of these, computed tomography (CT) and fluoroscopy are the most commonly used and are associated with some of the highest radiation exposure for patients and operators.[1-2] This is particularly important in fields such as Interventional Pain Management where these modalities are essential to daily practice. The utilization of opioid-sparing minimally invasive techniques for low back pain and arthritis using CT and fluoroscopy has expanded over the years which has greatly increased radiation exposure among pain specialists.

   Current Occupational Safety & Health Administration (OSHA) guidelines for occupational dose limitations indicate that the total maximum effective dose to the head and trunk is 12.5 mSv per calendar quarter and 187.5 mSv per quarter for the hands and feet.[4] Complications of acute and chronic radiation exposure can include tissue reactions such as skin burns and cataracts or stochastic affects like cancer or hereditary derangements.[5]

   Spatial relationship to the imaging device, imaging type, and technical execution of the procedure all affect the amount of radiation physicians and patients are exposed to. In terms of equipment location, the highest levels of radiation in C-arm fluoroscopy is very close to the physician's waist and abdomen.[6] Discrepancy in exposure among imaging type is noted by Hoang et al who showed that CT guided techniques have approximately half the effective dose to physicians compared to conventional fluoroscopy techniques.[12] However this is not without a tradeoff, as procedures such as epidural steroid injections under CT guidance are associated with more than eight times the radiation dose to patients as compared to fluoroscopy guided.[13] Thankfully, techniques that incorporate the benefits of both such as ultralow-dose CT are being popularized, which actually has a lower does than traditional fluoroscopy to the patient.[22]

As one might imagine, this highly variable and multifaceted nature of radiation exposure can potentially lead to large effective doses at one time. Several studies from other specialties found that the radiation exposure to vulnerable body parts like the eyes, thyroid, and hands often meet acceptable levels but could be easily and significantly affected based on physician practices; particularly by the improper use of personal protective equipment, patient positioning, and work ergonomics.[16-19] Perhaps unsurprisingly, a review by Martin shows that, in radiologists and cardiologists, the hands are the part of the body most affected by work practice and positioning when it comes to radiation exposure and the author highly recommends the use of a hand dosimeter.[20] Stoeckelhuber et al. noted that interventionalists performing procedures under CT that expose their hand to the primary beam can receive an effective radiation dose of up to 0.6 mSv in procedures lasting only 20 seconds.[8] At this rate, if a physician were to use fluoroscopy in this manner for a two-minute procedure, they would only be able to safely preform a mere 52 procedures per calendar quarter to maintain OSHA safety standards.

The use of multiple protective measures such as long needle holders, protective gloves, and lead drapes is considered the gold standard in practice and have been shown to decrease dose rates by up to 99.6% overall.[8,14] Similarly, Hoffler et al found that, when compared to no protective measures, just the use of attenuating gloves and leaded eye protection can reduce the radiation exposure to the hands and eyes by 69.4% and 65.6% respectively.[21] However, in a survey of 708 interventional pain physicians, 93% stated they were concerned with radiation exposure but only 63% had formal safety training and there was low overall understanding of evidence-based radiation safety practices.[9] Therefore, better understanding of a physician's individual practices on effective radiation dose through a quality improvement study will help to close gaps in knowledge and understanding of exposure.

A dosimeter is a small device which measures the radiation the physician receives from their practice. There are several different kinds of dosimeters including the commonly worn chest monitor and others closer to the hands of the physician, such as wrist bands or rings. Carinou et al indicate that these devices are overall generally accurate at measuring the correct radiation dose but have their limitations depending on the manufacturer, scope of intended use, and material composition.[15] There are currently no studies comparing dosimeter location and radiation exposure readings in pain management physicians. The effective dose detected by a single chest monitor is likely not an accurate representation of the does received in other parts of the body in pain management physicians. There are also no published studies assessing the risk of wearing hand dosimeters in sterile procedures, such as increased frequency of glove breaches or procedure-related infections.

Of the various factors that influence radiation exposure risk, dosimeter location on a proceduralists body is of particular interest to interventional pain physicians. Yamashita et al. found a large discrepancy in dosimeter readings among spine surgeons using fluoroscopy between the dosimeters worn on the chest (125.6 mSv) and those worn on the thumb (368 mSv).[10] This discrepancy indicates that the hands of proceduralist may be exposed to radiation exceeding the acceptable safe limit despite a chest worn dosimeter measuring safe radiation levels. This has obvious and dangerous implications for individuals that only wear a chest dosimeter.

Our review of literature identifies a knowledge gap between dosimeter location and radiation risk among interventional pain physicians. This evidence supports the need of a quality improvement study to further assess radiation exposure in pain management physicians. In order to ensure physician safety, it is crucial to have adequate radiation exposure training and protective equipment as well as accurate measurements of effective radiation dose. This is particularly important with parts of the body such as the hands where effective radiation dose may be much higher than being recorded on chest dosimeters. This quality improvement study will be essential to providing valuable insight into radiation exposure and may help guide safety protocols in the future for OHSU physicians.

In sum, the variability in effective radiation dose based on procedure type, imaging modality, protective equipment and procedural approach requires further investigation into dosimeter location to accurately evaluate provider safety during radiation generating procedures.

4. Study Design

This is a prospective quality and safety improvement study designed to examine potential differences in radiation measurements depending on dosimeter location on an interventional pain medicine practitioner's body. The comparison will be made between a group wearing chest worn dosimeters (control) and chest plus hand worn dosimeters (experimental) between October 1, 2022 and April 21, 2023.

The study will be performed at the Comprehensive Pain Center at Oregon Health and Science University (OHSU) and involve attending physicians and fellow physicians who consent to participate. The physicians who consent will then be randomly assigned by a computer-generated program to either the control group (chest dosimeter) or experimental group (chest plus hand dosimeter).

The control group will be assigned a chest dosimeter to wear while the experimental group will be assigned a hand and chest dosimeter. The dosimeters will be collected according to standard processing protocol every three month(s) by the designated Comprehensive Pain Center dosimeter collector. The badges will then be submitted to the vendor, Mirion, who will process the dosimeters and return an electronic report available for viewing online and at the procedure area nursing station. All study participants will also be emailed a copy of the report.

The study team will assess physician compliance with wearing the dosimeter(s) by having the procedure nurses perform a daily written audit of chest and hand dosimeter presence or absence.

Radiation measurements and compliance logs will be recorded inOHSU Microsoft Teams

Excel. We are done collecting data. We are using Microsoft Excel in Teams to input and analyze the data. Data analysis will be performed by an OHSU statistician.

Consistent with the OHSU standards for wearing hand dosimeters for sterile procedures, for each procedure the physician wearing the hand dosimeter will be required to:

1) Wash the hand dosimeter with one pump (2 mL) of Avaguard
2) Place the hand dosimeter on a bare hand
3) Dispense one pump (2 ml) into the palm of one hand. Dip fingertips of the opposite hand into the hand prep and work under fingernails. Spread remaining hand prep over the hand and up to just above the elbow.
4) Dispense one pump (2 ml) and repeat procedure with opposite hand.
5) Dispense final pump (2 ml) of hand prep into either hand and reapply to all aspects of both hands up to the wrists. Allow to dry. Do not use towels to dry.
6) Double glove both hands using sterile gloves.

At the conclusion of each procedure, the physicians in both groups will be required to inspect their surgical gloves for any visible breaches. All breaches of one or both gloves on each hand that are recognized during or after the procedure must be reported to the study team. The physician will also indicate on which hand the hand dosimeter, if applicable, was worn.

5. Study Population

Inclusion and Exclusion Criteria

Inclusion criteria includes:

a. Physicians actively performing fluoroscopy procedures at the OHSU Comprehensive Pain Center.

Exclusion criteria includes:

a. Those that do not want to participate in the quality improvement project.

Number of Subjects

Of 6 attending physicians and 4 fellows that qualify for the study, we anticipate 8 participants in the study.

Vulnerable Populations

a. Vulnerable populations are not involved in this quality improvement study.

6. Setting

The study examines radiation exposure of OHSU physicians performing their routine medical practice at the OHSU Comprehensive Pain Center Procedure Rooms 1 and 2. Hand dosimeters are currently used at OHSU in other departments. All study activities will take place at OHSU or remotely using OHSU provided secure computers, by OHSU personnel.

7. Recruitment Methods

Volunteers will be recruited through OHSU email. Consent to participate will be collected prior to the start of the study.

8. Consent Process

Participants will be de-identified in OHSU Microsoft Teams Excel. Individual consents will be obtained from Comprehensive Pain Center physicians prior to the start of the data collection period. For all procedure patients, standard procedure informed consent will be obtained.

9. Procedures

The study team will directly input data collected from dosimeters and compliance reports into OHSU Microsoft Teams Excel.

The variables that will be recorded in OHSU Microsoft Teams Excel **for each participant** will include:

a. Group identifier – control or experimental
b. Chest dosimeter radiation exposure reading (Total Effective Dose Equivalent in rem) for each 3-month period
c. Hand dosimeter radiation exposure reading (Total Effective Dose Equivalent in rem) for each 3-month period
d. Dosimeter compliance for each 3-month period (%)
e. Report(s) and date(s) of glove breaches during the procedure

10. Data and Specimens

Handling of Data and Specimens

No specimens will be collected for this study. OHSU Microsoft Teams Excel will be used for data collection and storage. No identifiers will be collected that could link the participant to published data. Access to data is restricted to study personnel and access to data requires OHSU ID/password authentication.

11. Sharing of Results with Subjects

The study results will be published.

12. Data and Specimen Banking

Data will not be stored for future research. Data will be retained for up to 3 years or until the study is completed and results are published.

13. Data Analysis

For the statistical analysis, to perform hypothesis testing, the statistician will use a t-test between dosimeter type and effective radiation dose.

The statistician will perform an analysis using descriptive statistics, tables, and data visualization techniques. The statistics will include median (min, max) and mean (SD) with 95% confidence intervals for continuous variables and frequencies and proportions for binary and categorical variables. The statistician will use multiple imputation to address missing data if the missing rate is more than 10%. Multiple imputation by chained equations (MICE) is implemented assuming missing at random.

14. Privacy, Confidentiality and Data Security

Access to data during the study period is restricted to study personnel and access to data requires OHSU ID/password authentication.

Data for this project will be stored in Microsoft Teams Excel

The study team will not collect protected health information.

Standard institutional practices will be followed as described by the OHSU Information Security Directives at the following link: http://www.ohsu.edu/xd/about/services/integrity/policies/ipspolicies-info-sec-directiv.cfm#results to maintain the confidentiality and security of data collected in this study.

Study staff will be trained with regard to these policies. Electronic data will be stored on encrypted: computers, laptops, tablets, and iPads.

Electronic data is stored:
• On restricted drives on the OHSU network.

• OHSU Microsoft Teams Excel

Access to data is restricted to study personnel. Access to data requires OHSU ID/password authentication.

15. Risks and Benefits

a. Risk

There is a risk of breach of confidentiality. There is no increased risk of radiation exposure to participants as they will not be asked to modify their routine medical practice in any way. There is a risk of hand dosimeters being associated with a glove breach. To address this risk, all physicians wearing hand dosimeters will be required to double glove per OHSU standards. There is no evidence of dosimeters causing increased risk to patients and standard procedure consent will be obtained per routine medical practice as is consistent with OHSU departments using hand dosimeters.

b. Potential Benefits to Participants

Identifying a discrepancy in radiation exposure between chest dosimeters and hand dosimeters that could lead to changes in provider radiation safety.

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