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Impact of robotics and a suspended lead suit on physician radiation exposure during percutaneous coronary intervention

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ABSTRACT

Background: Reports of left-sided brain malignancies among interventional cardiologists have heightened concerns regarding physician radiation exposure. This study evaluated the impact of a suspended lead suit and robotic system on physician radiation exposure during percutaneous coronary intervention (PCI).

Methods: Real-time radiation exposure data were prospectively collected from dosimeters worn by operating physicians at the head- and chest-level during consecutive PCI cases. Exposures were compared in three study groups: 1) manual PCI performed with traditional lead apparel; 2) manual PCI performed using suspended lead; and 3) robotic PCI performed in combination with suspended lead.

Results: Among 336 cases (86.6% manual, 13.4% robotic) performed over 30 weeks, use of suspended lead during manual PCI was associated with significantly less radiation exposure to the chest and head of operating physicians than traditional lead apparel (chest: 0.0 [0.1] μSv vs 0.4 [4.0] μSv, $p < 0.001$; head: 0.5 [1.9] μSv vs 14.9 [51.5] μSv, $p < 0.001$). Chest-level radiation exposure during robotic PCI performed in combination with suspended lead was 0.0 [0.0] μSv, which was significantly less chest exposure than manual PCI performed with traditional lead ($p < 0.001$) or suspended lead ($p = 0.046$). In robotic PCI the median head-level exposure was 0.1 [0.2] μSv, which was 99.3% less than manual PCI performed with traditional lead ($p < 0.001$) and 80.0% less than manual PCI performed with suspended lead ($p < 0.001$).

Conclusions: Utilization of suspended lead and robotics were observed to result in significantly less radiation exposure to the chest and head of operating physicians during PCI.

1. Introduction

In order to reduce potential occupational hazards related to radiation exposure in the catheterization laboratory [1–4], physicians performing percutaneous coronary intervention (PCI) traditionally wear lead apparel. This approach has several limitations, including suboptimal head-level protection and an increased risk of developing orthopedic injuries attributable to chronically bearing the weight of heavy lead garments [5–7]. A potential solution to these limitations is utilization of a lead suit that is suspended from above the operator [8]. Although use of a suspended lead suit was shown in a single prior study to reduce operator radiation exposure during interventional radiology procedures, its efficacy during PCI procedures has not been fully evaluated [8].

A robotic system for performing PCI has also been introduced as a novel means to protect operators from radiation [9–11]. Robotic PCI is performed by an operating physician seated within a lead-lined cockpit [11]. Dosimeters worn by operators in the cockpit have been shown to detect 95% less radiation than dosimeters at the operating table during robotic PCI [11]. However, physician radiation exposure in robotic PCI has not been directly compared to exposure in manual PCI, especially when manual PCI is performed using conventional bedside lead shields known to effectively attenuate 80% of scatter radiation [12]. Furthermore, the robotic system does not protect the operating physician from scatter radiation during diagnostic angiography, which is commonly performed as part of most PCI procedures. It remains unknown whether operator exposure can be further minimized by combining robotic PCI with use of a suspended lead suit, thus attempting to reduce exposure during all parts of the PCI procedure.

The present prospective observational study was undertaken to evaluate the impact of a suspended lead suit and a robotic system on physician radiation exposure during PCI. Accordingly, physician radiation exposure was measured at the chest- and head-level during consecutive PCI procedures and compared in three study groups: 1) manual PCI with the physician wearing traditional lead apparel; 2) manual PCI with the physician using a suspended lead suit; and 3) robotic PCI with the physician using a suspended lead suit.

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2. Material and methods

2.1. Study population

The Combining Robotic-Stenting and Proactive Shielding Techniques in the Catheterization Laboratory to Achieve Lowest Possible Radiation Exposure to Physicians and Staff (SHIELD) study was a single-center prospective observational study, designed to investigate the impact of both robotic PCI and proactive shielding techniques on radiation exposure to physicians and staff in the catheterization laboratory. The study was conceived, designed, and conducted by investigators of the Frederik Meijer Heart & Vascular Institute of Spectrum Health (Grand Rapids, Michigan). The protocol was approved by the local institutional review board and all participants provided informed consent. The study sponsor, which did not have access to the collected data and did not write the manuscript, did approve the final study protocol and had an opportunity to read the final manuscript prior to submission.

During the 30-week study period, data were prospectively collected during all cases conducted in two fluoroscopy suites having identical imaging systems (Allura Xper FD10 X-ray system, Philips, Amsterdam, The Netherlands). Consecutive cases having a start time between approximately 8 o'clock AM and 5 o'clock PM, Monday through Friday, were included in the study. The present pre-specified analysis of the SHIELD data evaluated physician radiation exposure during consecutive PCI cases. There were no PCI cases that were excluded from this analysis. Only cases that did not have a PCI performed were excluded.

2.2. Radiation monitoring

Real-time radiation exposure data were collected during each case using a commercially available dosimetry system (RaySafe i2, Unfors RaySafe, Billdal, Sweden). For each case during the study period, the operating physician wore two dosimeters. An outer dosimeter, worn on either the left anterior side of the glasses or on the left anterior side of the thyroid collar, was intended to provide an estimate of head-level radiation exposure. An inner badge, worn on the V-neck of the scrub shirt underneath any lead protection, was intended to measure chest-level radiation exposure. The dosimetry system utilized in this study contains a bedside monitor capable of displaying real-time exposure data during a case; however, physician operators and staff were blinded to both the monitor display and to the radiation data collected by the dosimeters for the duration of the study.

2.3. Radiation protection

For all cases, two ancillary lead shields were used per standard operating protocol at the study institution. These included a ceiling-mounted upper body lead shield with a patient contour cutout and a lower body lead shield attached to the side of the operating table, extending from the table to the floor [12]. A radiation-absorbing disposable pad (RadPad, Worldwide Innovations & Technologies, Kansas City, Missouri), which was available upon request for use in all cases, was utilized at the discretion of the operating physician and staff members.

For personal protection in each case, physician operators either wore traditional lead apparel, consisting of a lead skirt and apron, or used a suspended lead suit (Zero-Gravity, CFI Medical, Fenton, Michigan). The suspended lead suit consists of a lead apron extending from the neck to the distal calves and a lead shield that extends upward from the neck to protect the head [8]. The decision to use traditional lead apparel or the suspended lead suit was at the discretion of the physician operator, as both are available and considered part of standard operating procedure at the study institution.

2.4. Robotic PCI

PCI was performed either manually or using a robotic system (CorPath 200, Corindus Vascular Robotics, Waltham, Massachusetts) previously described [9–11]. The decision to perform robotic PCI was at the discretion of the operating physician. For robotic PCI procedures, the operating physician manually engaged a guide catheter into the target vessel. All subsequent advancements and retractions of guidewires, balloon catheters, and stent catheters were attempted robotically by the operating physician. For the purposes of this analysis, procedures attempted but not entirely completed robotically were included in the robotic PCI group and not the manual PCI group.

2.5. Outcome measures

Physician radiation exposure is reported at both the chest- and head-level as dose per case and maximum dose rate per case. In order to control for the amount of radiation used in each case, radiation exposure per case is also reported after normalizing to the dose area product (DAP) [13]. The DAP, which is automatically calculated in each case by the fluoroscopy imaging system, was recorded at the completion of all cases. The reported radiation exposure includes all radiation obtained during the case, including any radiation obtained during diagnostic angiography, if performed in the same setting. In this manner, the radiation exposures reported in the present study reflect the catheterization procedure in its entirety. Data were collected on procedure time, defined as the time from arterial sheath insertion to guide catheter removal.

2.6. Statistical analysis

Descriptive statistics were used to summarize baseline characteristics and outcome measures. Normally distributed continuous variables are shown as mean ± standard deviation. Non-normally distributed continuous variables are shown as median [interquartile range]. Categorical variables are shown as count (% frequency). P-values for comparison of continuous variables were derived from Wilcoxon rank sum tests. P-values for comparison of categorical variables were generated with Fisher's exact test. All p-values were adjusted within each variable for multiple comparisons using Holm's method. Regression modeling was performed to identify variables independently associated with radiation exposure. Use of the suspended lead suit, robotics, a disposable radiation-absorbing pad, radial access, performance of fractional flow reserve, number of lesions treated, and imaging of bypass grafts was included as variable in the regression model. Due to the large number of exposure values equal to zero in the data set, radiation exposure was treated as a semi-continuous response variable, and regression modeling was performed using a two-part model as described by Duan et al. [14] for head-level radiation exposure per case normalized to DAP. This approach involved a logistic regression to model the probability that a given observation will have zero radiation exposure and a linear regression to model the magnitude of the radiation exposure, conditional on the value being non-zero. To satisfy linear regression assumptions, the non-zero values of radiation exposure were log transformed prior to modeling. All statistical analyses were performed using the R statistical software environment version 3.2.3 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Study population

Between August 3, 2015 and February 26, 2016, the radiation exposure to operating physicians was measured in 1345 consecutive cases. Of these cases, 45 were excluded as no radiation was used and 964 were excluded as no PCI was performed. The remaining 336 (25.8%)

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