THESIS

OCCUPATIONAL RADIATION DOSE DURING THE TRANS-CATHETER AORTIC VALVE REPLACEMENT PROCEDURE

Submitted by

Omar Hani Shatila

Department of Environmental and Radiological Health Sciences

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Master's Committee:

Advisor: Thomas Johnson

Alexander Brandl
Charles Miller

ABSTRACT

OCCUPATIONAL RADIATION DOSE DURING THE TRANS-CATHETER AORTIC VALVE REPLACEMENT PROCEDURE

Fluoroscopy is an x-ray-imaging technique used during medical procedures such as trans-catheter aortic valve replacement (TAVR). The use of fluoroscopy exposes medical personnel to x-rays scattered from the patient. In this study, radiation dose to personnel at University of Colorado Hospital was measured using Phillips DoseAware dosimeters. The primary physician (0.106 mSv), secondary physician (0.035 mSv), perfusionist (0.027 mSv) received highest median doses of the operating room (OR) personnel. The physicians' relatively higher doses were expected because of their proximity to the isocenter of the x-ray beam. The perfusionist's position in the OR, however, is significantly further away from the isocenter than the physicians' position, suggesting the x-rays scatter unevenly and further away from the isocenter than previously expected. A linear relationship between fluoroscopic output and beam time was not found, however only 21 data points were collected. Factors other than fluoroscopy output can influence dose such as medical personnel movement, beam direction and scatter distribution. A dose map could relate dose to fluoroscopy output without the variability caused by these factors and be a better predictor of medical personnel doses. The dosimeters in this study were susceptible to radio-frequency interference (RF): future studies should consider dosimeters immune to RF.

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INTRODUCTION

Objective

Fluoroscopy is an x-ray-imaging technique used during medical procedures such as trans-catheter aortic valve replacement (TAVR). The use of fluoroscopy exposes both patient and medical personnel to ionizing radiation. The purpose of this project was to assess dose to medical personnel during the TAVR procedure and relate dose to fluoroscopy output/beam time.

Trans-Catheter Aortic Valve Replacement

Trans-catheter aortic valve replacement (TAVR) is used to treat valvular aortic stenosis. Fluoroscopy is used in the TAVR procedure to guide a catheter for replacing the aortic heart valve. TAVR is a minimally invasive procedure used in place of surgical arterial valve replacement. At this time, TAVR has only been approved by the FDA for high-risk patients that are not candidates for surgery or for patients enrolled in a clinical trial. Long-term success must be assessed before TAVR can become standard care for all patients [1]. The TAVR procedure is currently performed in the hybrid operating room (OR) at University of Colorado Hospital (UCH).

Due to the complexity of the TAVR procedure, a significant amount of fluoroscopic imaging is used, resulting in relatively high patient and staff radiation doses. Currently at UCH, approximately 20 medical personnel are present during each TAVR procedure. Previous studies have measured dose to medical personnel in interventional radiology and cardiac catheter suites. There are currently no occupational radiation dose data available in the literature estimating doses to individuals working in the hybrid OR setting or performing the TAVR procedure. Dose to personnel varies significantly between

procedures due to the complexity of the procedure and due to fluoroscopy machine settings. A complex procedure requires more patient exposure (more fluoroscopy output) and most likely higher medical personnel dose [2].

Ionizing Radiation in the Medical Field

Ionizing radiation from medical exposure is the source of over 90% of human exposure to anthropogenic radiation [3]. Ten percent of medical exposures are from fluoroscopic procedures [4]. Fluoroscopy is an imaging technique that uses x-rays to create real-time continuous images for diagnostic and therapeutic procedures. Progressively more complex medical procedures are performed using fluoroscopy without the need for invasive surgery, thereby increasing patient safety and reducing hospitalization time. The trade-off for using fluoroscopy is radiation dose delivered to the patient and also dose to medical personnel. The trade-offs should be justified by a net positive benefit to the patient [3].

Pantos et al have compiled 72 published studies from between 1986 and 2008 on non-pediatric fluoroscopy patient dose. The most common fluoroscopic procedures (FP) were coronary angiography, percutaneous coronary intervention, and radiofrequency ablation with a patient peak skin dose ranging from 3 to 3200 mGy. Pantos et al also showed that fluoroscopy time and dose area product have decreased on average for specific procedures over the same 1986 - 2008 time period, as shown in Table 1.

Table 1: Comparison of Fluoroscopy Time and Dose Area Product for Specific Procedures before and after year 2000

	Average Fluoroscopy Time (min)		Average Dose Area Product (mGy·cm^2)	
Time Scale	CA*	PCI*	CA*	PCI*
Before year 2000	6.2	21.3	52500	81700
After year 2000	3.7	12.2	31100	59200

***CA = Coronary Angiography, PCI = Percutaneous Coronary Intervention [4]**

Whereas doses for some procedures have decreased, medical doses are generally rising, contributing almost exclusively to the increase in annual global effective dose per capita. From United Nations Scientific Committee on the Effects of Atomic Radiation reports, the annual global effective dose per capita from medical procedures has increased from 0.3 mSv (1993 Report), to 0.4 mSv (2000 Report), reaching a value of 0.64 mSv (2008 report) [3]. Effective dose per capita from medical procedures in the United States is 3.0 mSv based on NCRP Report 160 (2009) [5].

Fluoroscopy System and System Output Values

A fluoroscopy system consists of an x-ray tube pointed at a digital image receptor. These two components are held aligned to each other using a C-arm, which allows the user to adjust the position and angle of the system. Electrons in the x-ray tube are accelerated from a filament to a target metal at a voltage potential up to 150 kV. X-rays are emitted upon electron impact on the target metal. Most x-rays produced are within the photoelectric effect energy range (~0 - 100 keV) with an energy of up to 150 keV. Photons in the energy range of 0 – 100 keV have a higher probability of interaction with high-Z elements like calcium in bones than muscle. Photoelectric effect dependence on Z is the basis for contrast in radiology imaging. Higher energy photons interact with bone and

tissue via Compton scattering and therefore are not effective for imaging [6]. Aluminum and copper filters reduce the number of low-energy photons that would be absorbed by the patient and do not contribute to imaging; filtration of low-energy photons reduces patient dose without detriment to image clarity and increases mean photon energy of the beam [7] [8]. Radio-opaque contrast agents based on iodine or barium may also be used to enhance image contrast.

Some patients are exposed to high levels of radiation during FPs, leading to concern of radiation-induced harm such as erythema (at 2 Gy) or increased cancer risk [4] [6]. Several quantities have been reported in the literature for assessing patient radiation exposure during FPs. Pantos et al compiled data on these quantities from 72 published studies from between 1986 and 2008 tabulated in Table 2.

Table 2: Quantities Used in Assessing Patient Dose

Quantity	No. of studies assessed this quantity
Fluoroscopy time	60
Cine time	12
Cine frames	27
Dose Area Product	53
Effective dose	23
Skin dose	12
Coronary dose	2

Non-dosimetric quantities are frequently used for quality control. Typical non-dosimetric quantities include fluoroscopy time, cine frames, and cine time. Fluoroscopy time was often included in previous literature because older equipment would only report fluoroscopy time [4]. The other remaining quantities are dosimetric. Dose area product (DAP) is the product of the area of the cross-section of an x-ray beam and the air kerma

averaged over that cross-section (mGy·cm^2). DAP multiplied by a conversion factor is used to calculate effective dose to the patient.

Air kerma (AK) is the kinetic energy released by ionizing radiation per unit mass of air. AK is related to patient dose and can be used for assessing skin dose (to predict erythema appearance). AK does not incorporate the overall amount of mass irradiated, thus AK does not account for the overall energy deposited into the patient. Conversely, DAP factors both air kerma and area irradiated. A larger DAP implies more x-ray photons (more energy) were emitted by the x-ray tube either by an increase in air kerma and/or an increase in area irradiated. Fluoroscopy time (min), air kerma (mGy; mJ/kg), and DAP (mGy·cm^2) are the fluoroscopic quantities reported in this study.

Occupational Exposure

In addition to patient dose, AK, DAP, and fluoroscopy time (FT) are relevant to occupational radiation exposure: an increase in these quantities would be expected to increase occupational exposure [2]. The primary source of occupational dose is Compton scatter of the of the x-ray beam from the patient [9]. Occupational exposure can also occur directly from the x-ray beam if personnel place extremities into the beam's path.

The point in space through which the central ray of the x-ray beam passes is the isocenter. Personnel closer to the isocenter would be expected to encounter higher dose rates. Dose rate decreases, following closely, although not precisely, the one over-distance squared law, making distance a significant factor of occupational dose. Orientation with respect to the fluoroscopy equipment can also influence dose, as scatter is not evenly distributed around the fluoroscopy device [10]. C-arm angle and position alters the distribution of scatter, however these factors were not considered in this study.

Occupational dose may vary up to a factor of three between the head, torso, and extremities [11].

Distance and orientation from the isocenter depends on medical personnel role. For example, an operating physician (operator) stands closest to the patient and therefore generally receives the highest dose of the hybrid OR staff. Access point of the catheter dictates operator location. For example, catheter introduction from a radial artery or percutaneously requires the operator to stand closer to the isocenter as compared to operating through the femoral artery. Choice of catheter introduction location depends on the specific procedure and may depend on patient vascular anatomy. Femoral access would be preferential for radiation safety even if it may increase procedure time [12]. Distance, especially for an operator, could be a more significant factor than time near the patient because dose rate decreases non-linearly. Anesthesiologist dose is also important to consider as they stand near the patient's head, thus near the isocenter. In addition to distance, adherence to other radiation safety principles and work techniques also influence radiation exposure.

Assisting operators, nurses, and technicians are likely to receive lower doses than primary operators because their roles generally have them further away from the patient/isocenter [13]. A circulating nurse may change positions during the procedure, thus encountering a variety of dose rates. A scrub nurse/technician will stand behind the operating physician, receiving a consistent, but lower dose rate. The variability of physical position of medical personnel creates uncertainty in dose assessment.

The upper extremities of some medical personnel, especially operators, are usually in the highest radiation dose areas (arms forward near the patient/isocenter). If necessary,

a physician's hands may enter the x-ray beam directly (a violation of good radiation safety practices). Dose to an operator's wrist was reported in a 2011 study as to be high as 5.23 mSv per procedure [14]. Extremities are, however, assigned a higher occupational dose limit of 500 mSv [15]. A finger dosimeter on the hand nearest to the x-ray tube is recommended for measuring hand dose to medical personnel who frequently places his or hand in the beam [12]. Extremity dose is not evaluated in this study.

Patient size affects scatter intensity. In Vano et al, a larger phantom was shown to scatter 31 times more radiation than a smaller phantom. A larger patient will result in increased dose to personnel. For this study, dose was not normalized to patient size.

Radiation Effects and Dose Limits

Radiation effects are classified either as stochastic or deterministic. A stochastic effect is an increased probability of an occurrence already present in a population (i.e. cancer). The probability of cancer occurrence increases with increased radiation exposed without an increase in severity. A baseline cancer rate exists in a population without any known anthropogenic radiation exposure. Radiation exposure is expected to increase the incidence of cancer in the population without increasing the severity of the cancer. The probability of stochastic effects at low-dose exposures (<100 mGy) is low. However, because DNA mutation is theorized to be dose-dependent, public safety policy follows the linear no threshold model for dose effects. All DNA damage caused by man-made radiation is assumed to increase risk of cancer [16]. When setting safety standards that ensure public protection, the theoretically safest dose is considered to be no dose.

Human exposure above naturally existing radiation levels will occur because societal benefits from the use of radiation, such as with fluoroscopy. Policy makers must set

occupational radiation dose limits that correspond to acceptable risk of stochastic effects [6]. No regulatory dose limits exists for patients from medical exposure. The benefit of a medical procedure should outweigh the risk from radiation exposure. Unjustified and overuse of medical imaging is a concern globally and is currently being discussed and addressed by organizations such as the IAEA or by governments such as in the European Union [3].

Occupational dose limits to personnel are well below deterministic effect thresholds with the possible exception of cataracts. Cumulative dose to the eye lens over time will result in cataract formation. Severity of cataract and length of latency period are correlated to dose [17]. In one retrospective analysis performed in Malaysia, cumulative dose to the lens ranged from 0.01 Gy to 43 Gy to interventional cardiologists, finding a strong dose–response relationship between occupational radiation exposure and the incidence of posterior lens changes [17].

Opacification of the lens is classified based on three anatomical locations: nuclear, cortical, and posterior subcapsular (PSC). Opacity increase in the PSC region is associated with radiation exposure. Opacity increase in the PSC has been found in interventional cardiologists, assisting nurses, and technicians [17]. Although age-related opacities occur in the PSC, they are the least common of the three regions. Cataracts in the nuclear region of the lens are generally age related and cataracts in the cortical region are commonly found in diabetic patients. A five Gy threshold is reported for detectable opacities in ICRP 103 from highly fractionated or protracted exposures. Studies after ICRP 103 have reported lower thresholds for cataracts and that cataracts appearance is more accurately described by a linear no-threshold model [17] [18]. The ICRP currently suggests am annual dose limit

to the lens of 20 mSv averaged over 5 years. Dose should not exceed 50 mSv in a single year [19] .

Radiation Safety

The dose limitation system recommended by ICRP in publications 26, 60 & 103 consists of justification, optimization, and limitation [6] [20]. Dose from fluoroscopy procedures to personnel are justified in our society because of the benefits received by the patient. Optimization consists of keeping doses as low as reasonably achievable (ALARA) such as following the radiation safety guidelines mentioned previously. The final component of the system, limitation, is setting an enforceable dose limit. No worker should exceed this limit, even after optimization.

Lack of adherence to proper radiation safety techniques unnecessarily increases personnel radiation exposure. Following basic radiation protection guidelines, time, distance, and shielding are one part of radiation safety. Collimation, the narrowing of an x-ray beam to target only the area of interest will reduce overall x-ray output: this technique decreases dose to both the patient and personnel. Use of mobile floor and ceiling mounted shields can reduce exposure. The operator should not place hands directly in the beam unless necessary for the procedure. The beam is already a high dose rate area and the fluoroscopy system will further increase kVp to compensate for the "darkening" caused by the operator's hands resulting in increased hand, patient dose and overall dose from scatter. Keeping to the bed-side area nearest to the detector exposes an operator to less scatter than the side nearest the x-ray tube as shown in Figure 1 [21].

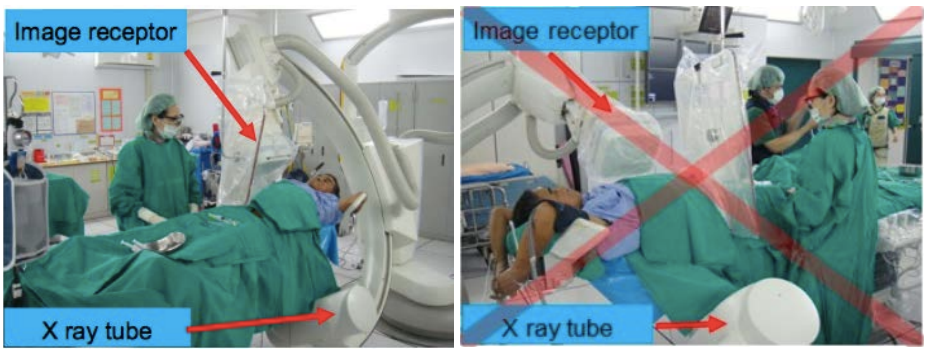

Figure 1: In the left photo, the operator is standing on the side near the image receptor, reducing her dose from scatter as compared to her position in the right photo. (Figure reproduced from the IAEA with permission.) [21]

In the United States, the construction of fluoroscopy and other radiation generating machines is regulated by the FDA, but OSHA, or individual states regulate the use of radiation generating machines. Specific requirements vary from state to state, but are generally similar and based on recommendations of the Conference of Radiation Control Program Directors (CRCPD). Colorado has an occupational dose limit of 50 mSv per year. No staff member at UCH exceeds the 50 mSv limit at this time.

Colorado law mandates a protective apron or barrier of 0.25 mm lead equivalent for personnel within 2 m of the tube head (6 CCR 1007-1 6.3.3.7). The protective apron must span from the lower thigh up to the shoulder covering about 83% of bone marrow [11]. A leaded thyroid cover may be used for further protection. Staff members who do not don protective clothing must maintain a distance of 2 m from the isocenter. Maeder et al found that a leaded apron with a thyroid cover reduced interventional cardiologists average annual dose from 46.2 mSv to 1.7 mSv [22]. Lead glasses, shields, and curtains can be used to further reduce dose.

Dosimetry

Absorbed dose is energy deposited per unit of mass (e.g. Gy = J/kg) and is used for assessing deterministic effects and overall exposure. Stochastic effects are measured using

effective dose which is calculated using absorbed dose multiplied by the corresponding radiation and tissue weighting factors.

A dosimeter for effective whole body dose is used under the assumption that radiation exposure to the body is uniform. Exposure is not uniform to personnel because lead-equivalent protective clothing does not cover the entire body. Effective dose to personnel with protective clothing must be assessed differently, such as using one of two of the following configurations developed by Landauer: EDE-1: one dosimeter at the collar and another below a lead apron at the waist; EDE-2: one dosimeter at the collar, above a lead apron. Deep dose equivalent (DDE) is assigned using one of the following respective equations [23]:

- EDE-1: 1.5 (Waist DDE) + 0.04 (Collar DDE)
- EDE-2: 0.30 (Collar DDE)

Relevant operational dose quantities for hybrid OR monitoring are deep dose, skin dose, and lens dose as adopted by the ICRP [20]. Each of these quantities is measured at specific tissue depth (Table 3). This depth is simulated using an appropriate filter over the dose-sensitive portion of the dosimeter. In this study, one dosimeter per person was used, measuring at a depth of 10 mm (deep dose).

Table 3: Tissue Depth for Dose Measurement [20]

Deep Dose	10 mm
Lens Dose	3 mm
Skin Dose	0.07 mm

A dosimeter must be calibrated to the energy levels of the x-rays from a fluoroscopy system to properly record dose. The x-ray tube voltage potential will vary, up to 150 kV. With added metal filter, the photon spectrum will have an average energy roughly one-half

of the maximum voltage potential. [8] Intensity of scatter radiation is less than beam intensity; however both have a similar mean energy at about one-half kVp. Data from Marshall et al's study have been compiled into Figure 2 below, relating voltage potential to mean scatter photon energy at the head and neck region of a worker. Mean scattered photon energy increases as kVp increases [8]. For the purposes of this study, scatter refers to Compton scattered photons from x-ray beam by the patient's mass to personnel.

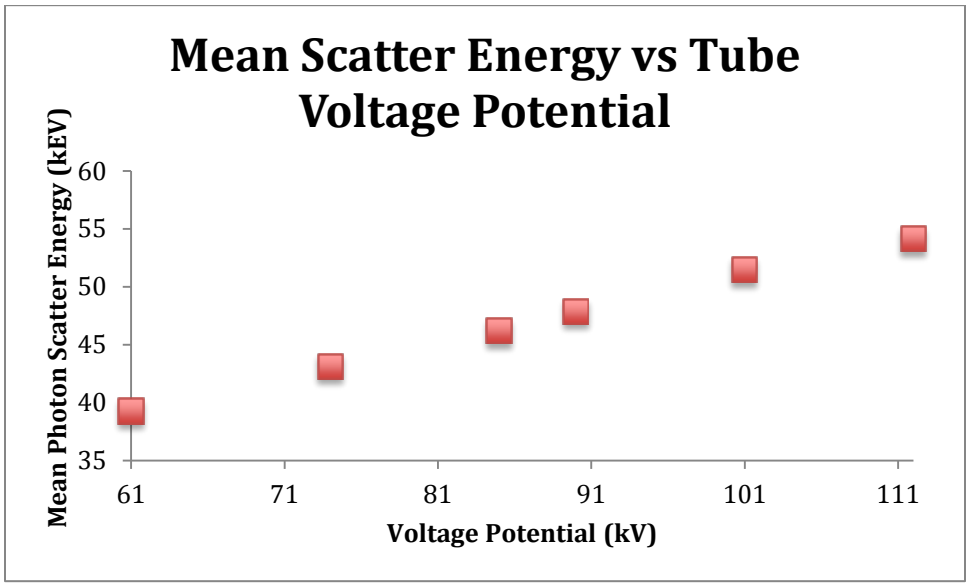

Figure 2: Mean Scatter Photon Energy as a Function of Tube Voltage Potential. (Undercouch Configuration, 0.5 m from the Patient [8])

METHODS AND MATERIALS

The Institutional Review Board (IRB) at Colorado State University (CSU) gave permission for the use of human subjects on 12/28/2014 until 12/27/2015; Protocol Number: 14-5436H. The IRB at UCH ceded to CSU's IRB, Protocol Number: COMIRB #15-0228. The Research Support Services at UCH gave permission for Hybrid OR facility use for this study on 2/5/2015. See Appendix B for approval letter. Radiation dose to TAVR medical personnel were measured at University of Colorado Hospital (UCH) in the hybrid OR (OR 7) per role per procedure. Doses could not be recorded per specific person to maintain subject confidentiality.

One to four TAVR procedures are regularly performed every Wednesday. On two occasions, the TAVR was also performed in an interventional radiology suite with a similar room and equipment arrangement as in the hybrid OR. The two types of TAVR procedures performed at UCH are trans-femoral and trans-apical. Personnel arrangement of the room is identical for both types of TAVRs except that the primary operator stands on side of detector during the trans-apical procedure versus near the x-ray tube during a trans-femoral procedure (see Figure 1). Figure 3 is a photo during TAVR preparation at UCH.

The fluoroscopy system in the hybrid OR was Philips Allura Xper FD20: Serial Number 1982, Mfg Date 06/2011 with Tube Model 989000080071: Mfg Date 01/2012.

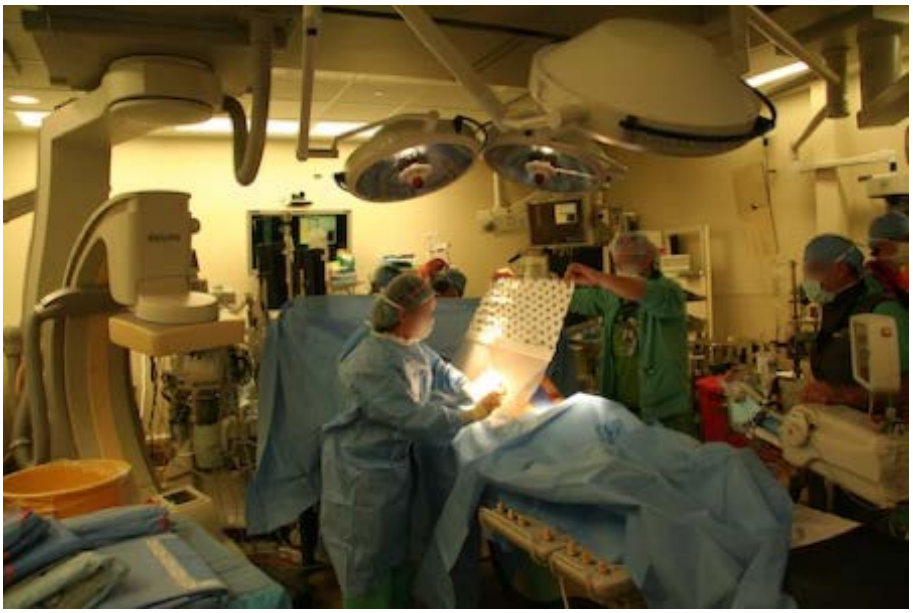

Figure 3: Hybrid OR at UCH During Patient Preparation

UCH distributes optically-stimulated luminescent dosimeters (OSLDs) to hospital staff exposed to ionization radiation such as in the hybrid OR. These dosimeters record quarterly dose. OSLD use was not practical for this study because of unreliability of dose recorded below 10 μSv and inability to rapidly record results from specific procedures. [24] The Phillips DoseAware Personal Dosimeter, an electronic personal dosimeter (EPD), can be easily read after each medical procedure and be ready for reuse. Registered dose is reliable down to 1 μSv [25]. An EPD utilizes a solid-state semiconductor for its detection medium [6]. See Table 4 for dosimeter specification.

Phillips DoseAware EPDs were clipped over leaded clothing in the chest and neck area (usually on the chest pocket or the bottom of the thyroid collar shield as shown in Figure 4 & Figure 5). Dosimeters were read after each individual procedure. The dosimeters were influenced by cell-phone radiofrequency signals with dose rates registering as high as 1000 mSv/h. Dose data suspected to be affected by cell-phone interference were omitted from the results.

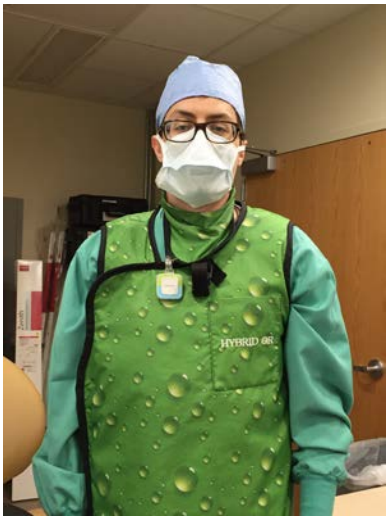

Figure 4: Dosimeter Clipped to Thyroid Shield Leaded Vest

Figure 5: Dosimeter Clipped to Chest Pocket of Leaded Vest

Table 4: Phillips Dose Aware Dosimeter Specifications [25]

Mass	30 grams (1.06 ounces)
Operational Dose Quantity	$H_P(10)$
Dose Range	1 µSv – 10 Sv
Dose Resolution	1 µSv
Energy Range	33 keV – 101 keV

Dose from the EPDs was recorded for each specific procedure and specific role with the fluoroscopy output values of the procedure: air kerma (AK), dose area product (DAP), and fluoroscopy time (FT). Roles, duties, and number per role are shown in Table 5. The

role referred to as operators in this study are the physicians who perform the TAVR procedure on the patient. The primary and secondary operators also operate the fluoroscopy system.

Table 5: Roles, Duties, and Number of Personnel Per TAVR Procedure

Role	Duties	Number Present Per Procedure
Primary Physician/Operator	Performs Procedure and Operates Fluoroscopy System	1
Secondary and Tertiary Physician/Operator	Assists Primary Physician/Operator	2-3
Bed-Side Scrub Nurse	Hands Sterile Operating Tools to Physicians	1
Desk Scrub Nurse	Prepares Artificial Valve	1
Cath-Lab RN	Assists Physicians and Handles Equipment	1
Room Circulating Nurse	Hands Equipment to Hybrid OR Personnel	1-2
Anesthesiologist (Includes primary, fellows, and assistants)	Administers Anesthesia to the Patient	1-2
Echocardiologist (Includes primary, fellows, and assistants)	Captures and Interprets Electrocardiogram of the Heart	1-2
Perfusionist	On Stand-By with Heart-Lung machine for Cardiopulmonary Bypass	1
Observer/Representative	Student, Company Representative, or Administrator Observing/Assisting	1-3

The hybrid OR is a dynamic environment during the TAVR: staff members' positions vary during the span of the procedure. At UCH, an anesthesiologist and echocardiologist may use a portable lead shield to reduce exposure. Figure 6 and Figure 7 are photos showing the positions personnel during the TAVR procedure at UCH. Figure 8 below is a diagram of the hybrid OR with the most common position for a specific role.

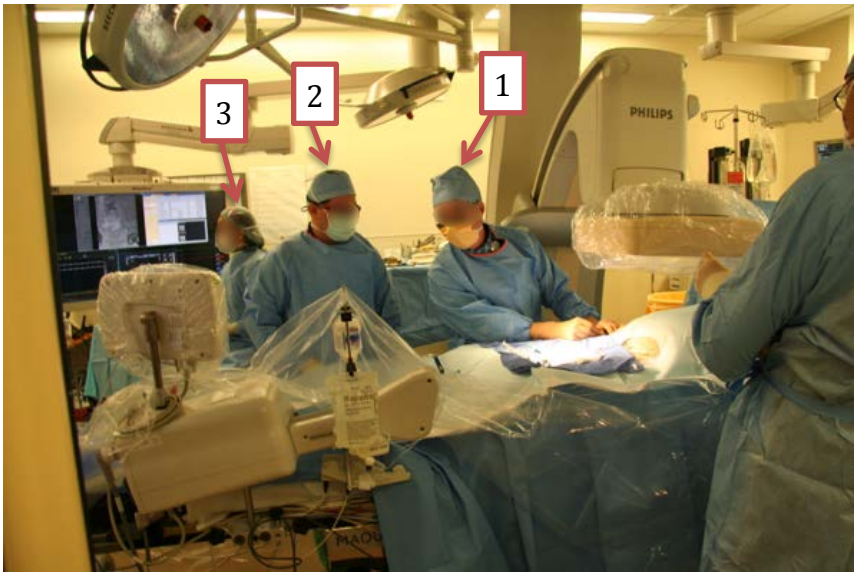

Figure 6: Photo During a TAVR Procedure: 1: Primary Operator, 2: Secondary Operator, 3: Bedside Scrub Nurse

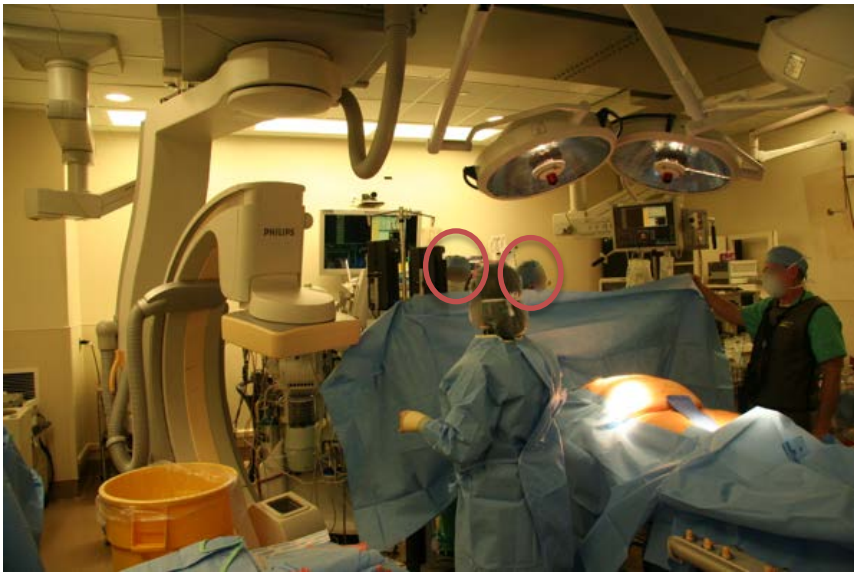

Figure 7: Photo During a TAVR Procedure Set-Up. The red circles highlight the position of the anesthesiologist and echocardiologist. Note the C-arm has not been for positioned for use yet

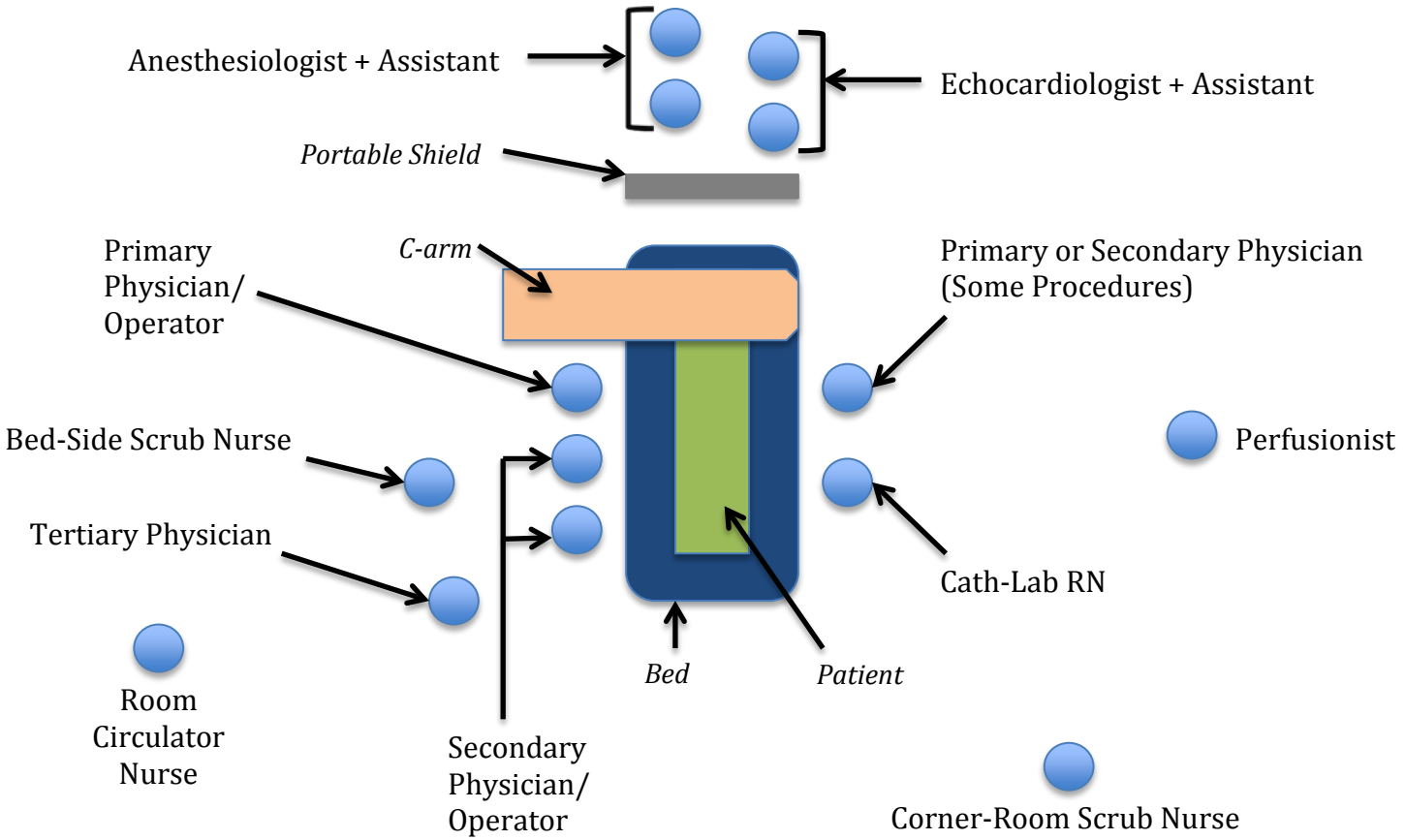

Figure 8: Diagram of Personnel Position and Room Arrangement During the TAVR Procedure

RESULTS

Figure 9 presents the median, mean, maximum and minimum doses for every role of the TAVR for a total of 21 procedures. Dose distribution was non-normal and was positively skewed as illustrated in Figure 9. Note that doses are reported from outside of protective clothing. If taken into consideration, protective clothing would reduce effective dose.

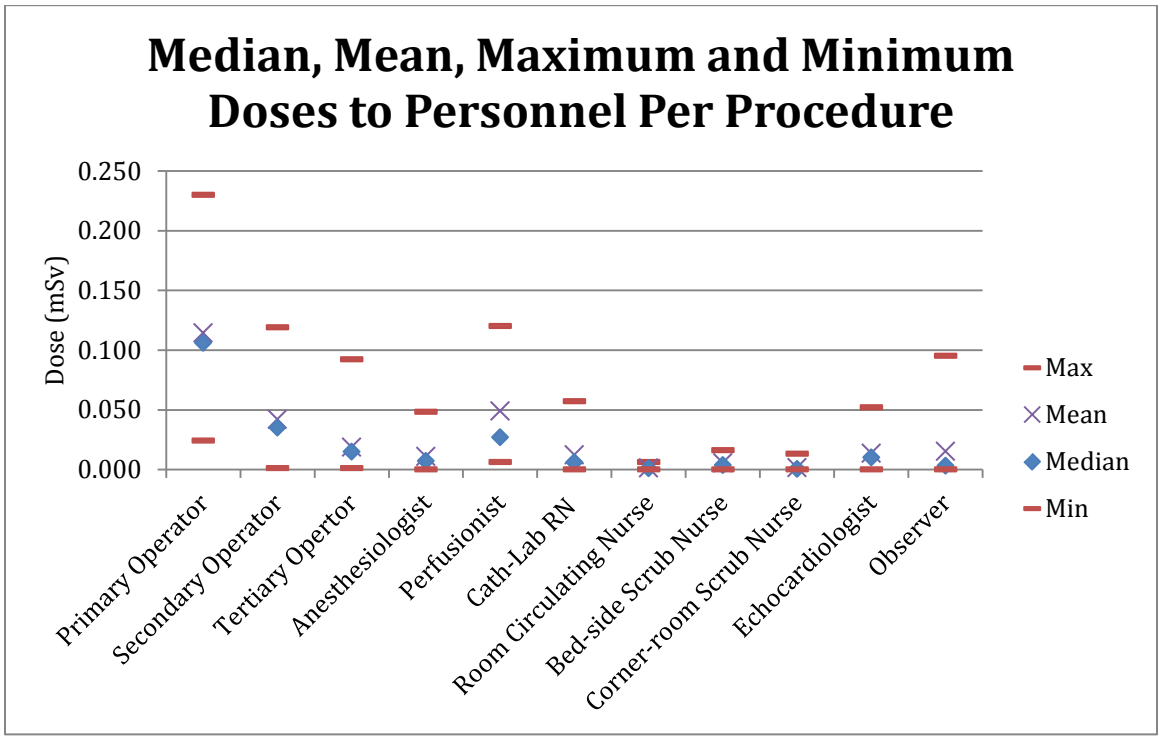

Figure 9: Dose to personnel per procedure. Bars represent maximum and minimum doses respectively. Data was collected from 21 procedures.

Dose to personnel during the TAVR was measured and matched to the three fluoroscopy system values: air kerma, DAP, fluoroscopy time. A comparison of fluoroscopy system outputs was performed using linear regression on Excel (Microsoft Corp, Seattle WA). The dosimeters used in this study where especially susceptible to cell-phone radio-frequency (RF) interference, leading to false high readings. Any dose determined to be influenced by RF was omitted from the data below.

A comparison of the personnel groups using ANOVA could not be performed because of the difference in variances of each group as shown in Table 6.

Table 6: ANOVA analysis table

Anova: Single Factor

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Primary Operator	18	2.05	0.113889	0.004366
Secondary Operator	33	1.385	0.04197	0.0012
Tertiary Operator	19	0.356	0.018737	0.000438
Anesthesiologist	21	0.23	0.010952	0.000145
Perfusionist	9	0.44	0.048889	0.002309
Cath-Lab RN	20	0.243	0.01215	0.000209
Room Circulating Nurse	18	0.024	0.001333	3.18E-06
Bed-Side Scrub Nurse	18	0.1	0.005556	2.96E-05
Corner-Room Scrub Nurse	20	0.03	0.0015	9.42E-06
Echocardiologist	18	0.242	0.013444	0.000179
Observer	8	0.152	0.019	0.001041

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	0.195475	10	0.019548	23.79853	1.04E-28	1.880544
Within Groups	0.156883	191	0.000821			
Total	0.352358	201				

Three charts are presented (based on the role of each worker) contrasting the fluoroscopy system output values and the following: air kerma, DAP, fluoroscopy time. Each data point on these charts represents dose from one specific procedure. The R^2 values presented in the following charts continued to change up to the last data point added to the results.

Primary Operator/Physician

Primary operator dose correlates best with air kerma with an R^2 value of 0.3504, followed by air kerma then fluoroscopy time. Only trans-femoral TAVR procedures were included in the results for this role. A trans-apical procedure necessitates that the primary operator stand on the opposite bedside, reducing his or her dose and adding an additional variable. Two doses omitted from trans-apical procedures were at 0.03 mSv and 0.045 mSv because the primary operator stood the on opposite bedside. The primary physician would usually switch positions with the secondary operator for a portion of the procedure, potentially lowering the R^2 due to movement (*N = 18*).

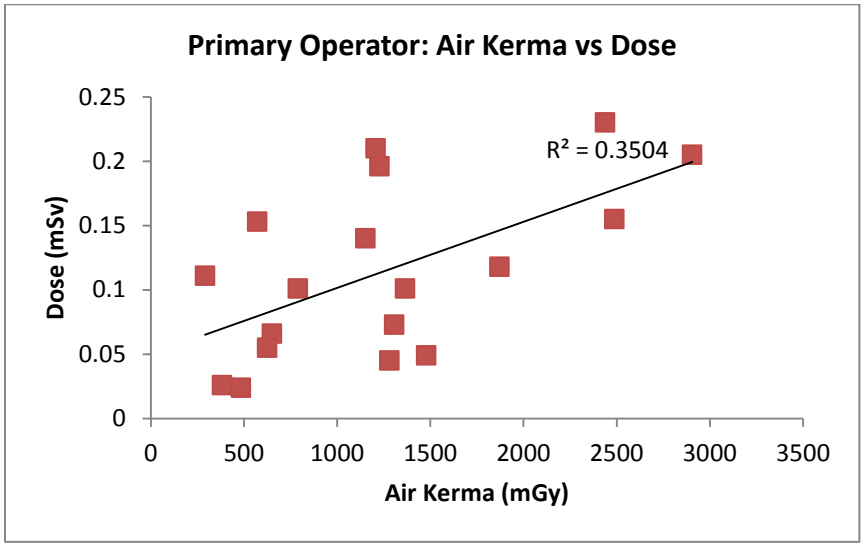

Figure 10: Primary Operator Dose as a Function of Air Kerma for Each Specific Procedure.

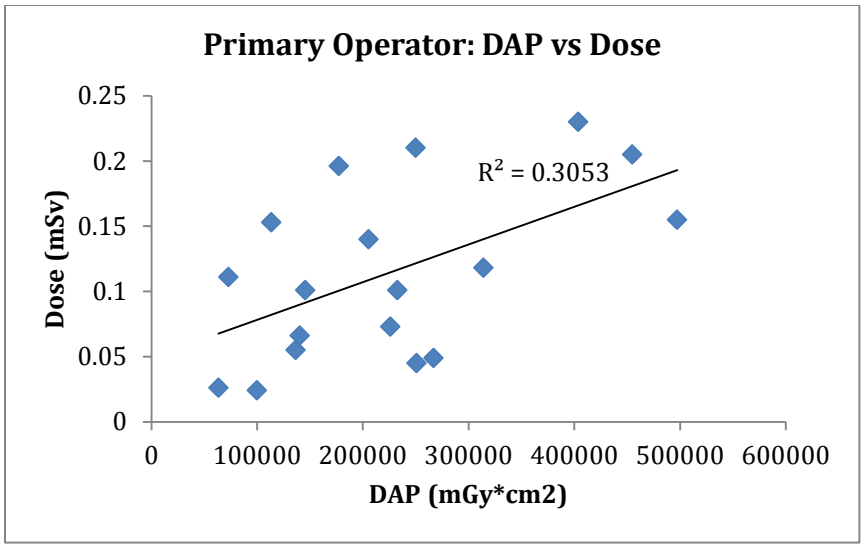

Figure 11: Primary Operator Dose as a Function of DAP for Each Specific Procedure.

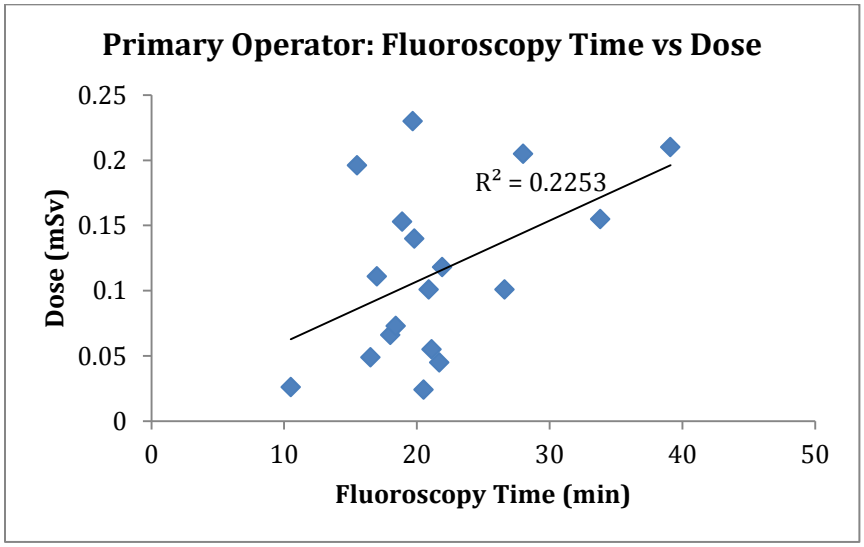

Figure 12: Primary Operator Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Secondary Operator/Physician

Air kerma and DAP have nearly identical R^2 values as apparent in these charts. Two secondary operators were usually present per procedure, each obviously in a different position. Both are secondary operators from a medical standpoint, but each stands at a different distance from the isocenter. This role had the most recorded data points at $N = 33$.

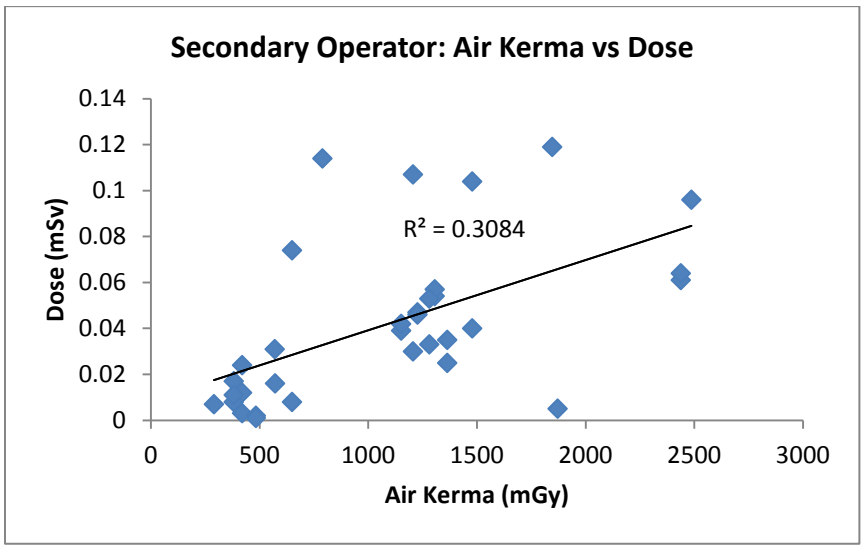

Figure 13: Secondary Operator Dose as a Function of Air Kerma for Each Specific Procedure.

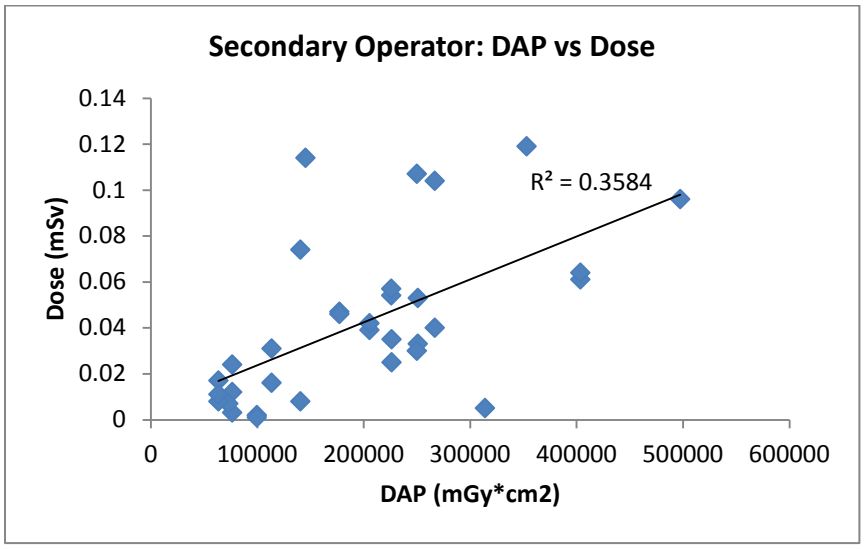

Figure 14: Secondary Operator Dose as a Function of DAP for Each Specific Procedure.

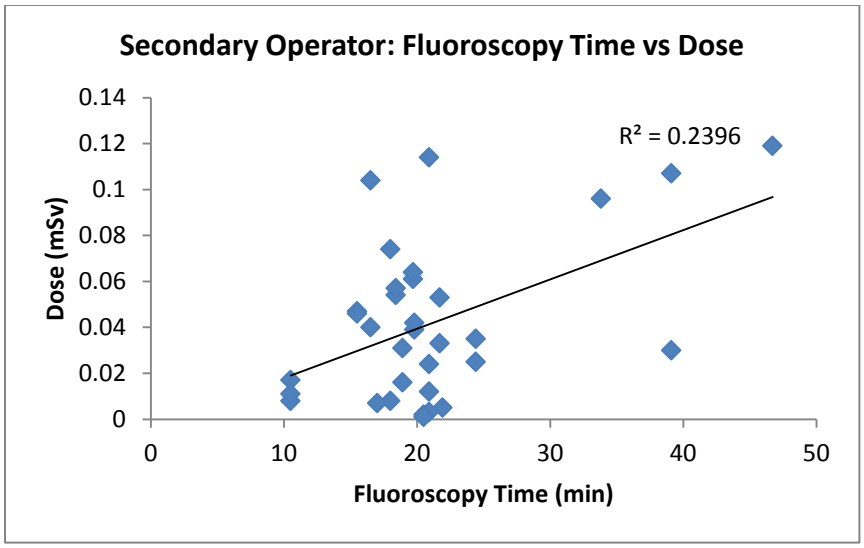

Figure 15: Secondary Operator Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Tertiary Physician

Overall, tertiary physician dose has a low R^2 with fluoroscopy outputs. The tertiary physician was an axillary role during the TAVR procedure contributing indirectly only when needed; therefore there was no required position with respect to the patient/isocenter. The tertiary physician could be standing behind the primary and secondary operators, or on the opposite bedside (N = 17).

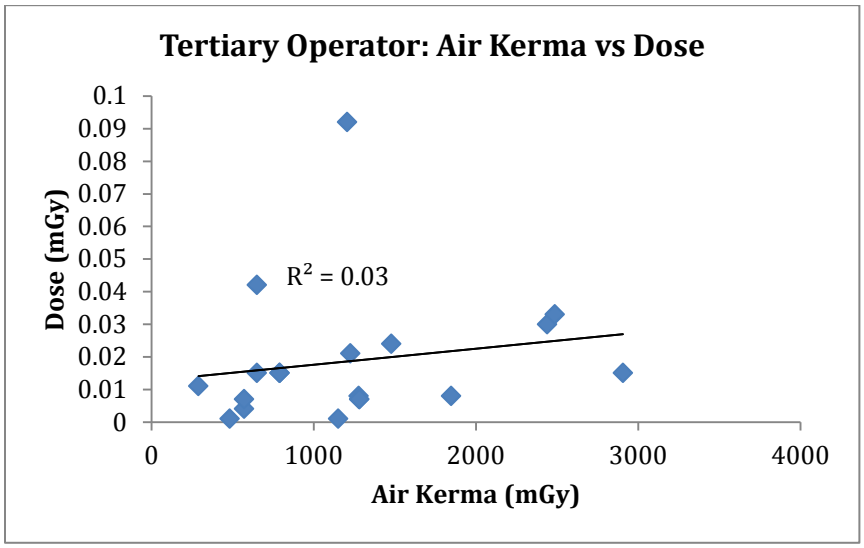

Figure 16: Tertairy Operator Dose as a Function of Air Kerma for Each Specific Procedure.

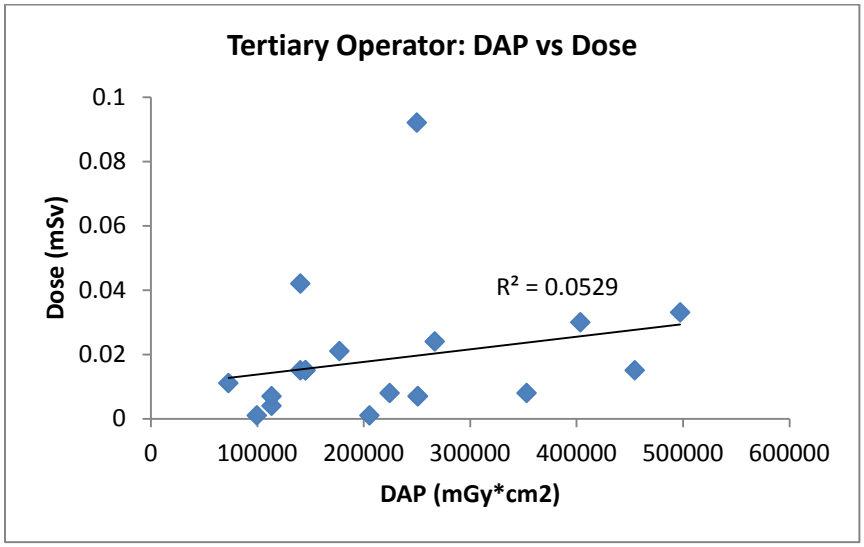

Figure 17: Tertairy Operator Dose as a Function of DAP for Each Specific Procedure.

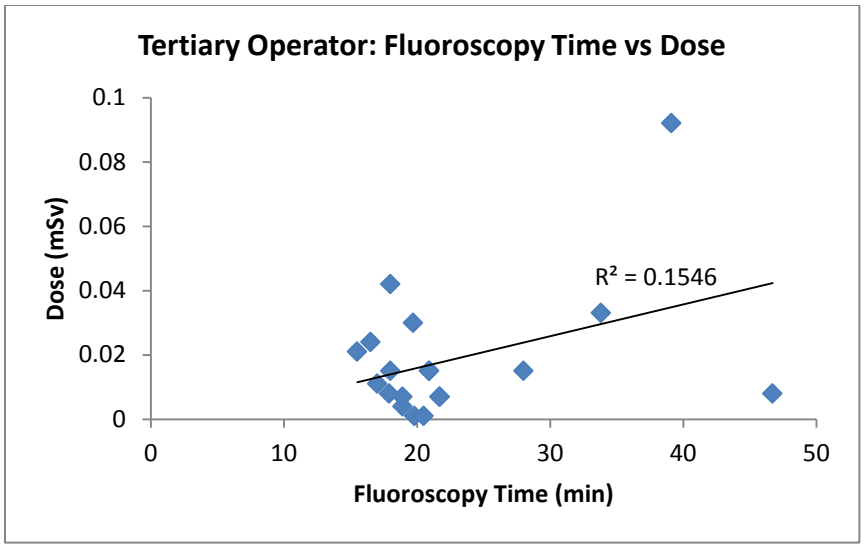

Figure 18: Tertairy Operator Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Anesthesiologist

Anesthesiologists, anesthesiologist fellows, and anesthesiologist assistants are grouped together because of their similar proximity from the isocenter and similar role (*N* = 21). For simplicity, they will all be referenced as an anesthesiologist. Air kerma and DAP R^2 values were both low and negative. The anesthesiologist would leave the room during the TAVR procedure at times as his or her responsibilities where mainly during the beginning and end of the procedure.

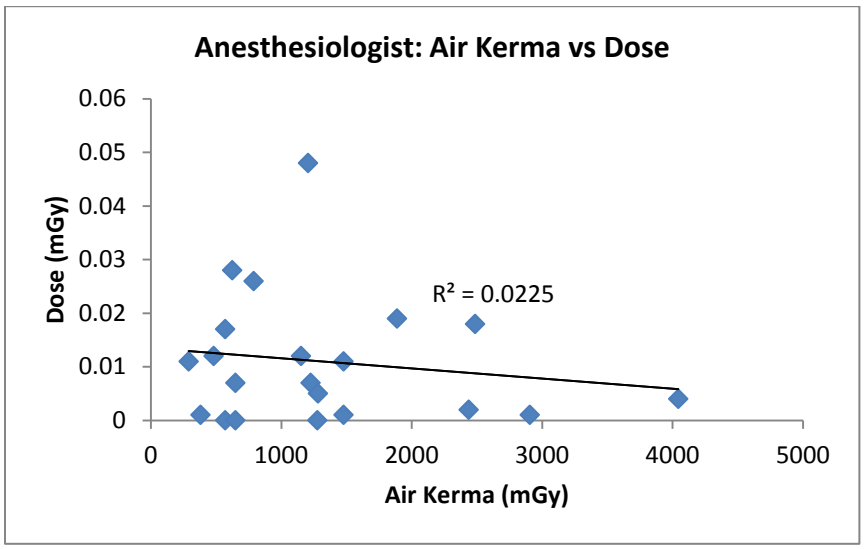

Figure 19: Anesthesiologist Dose as a Function of Air Kerma for Each Specific Procedure.

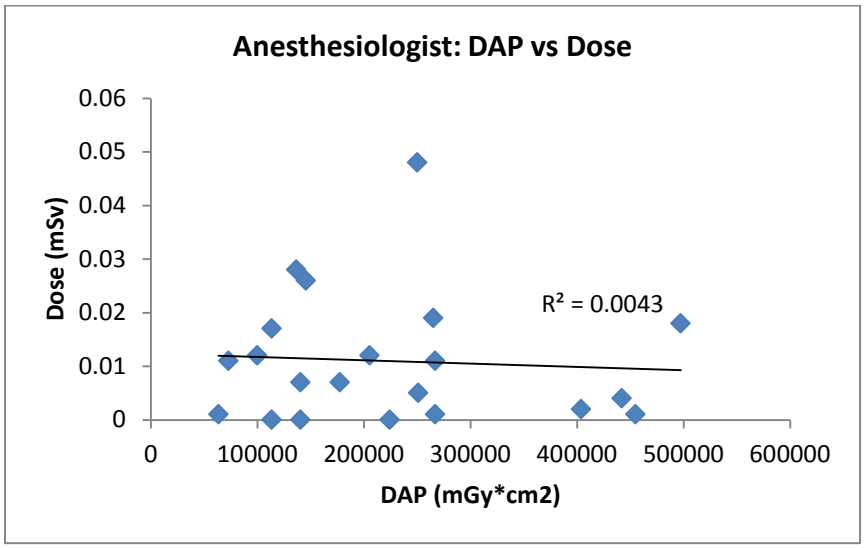

Figure 20: Anesthesiologist Dose as a Function of DAP for Each Specific Procedure.

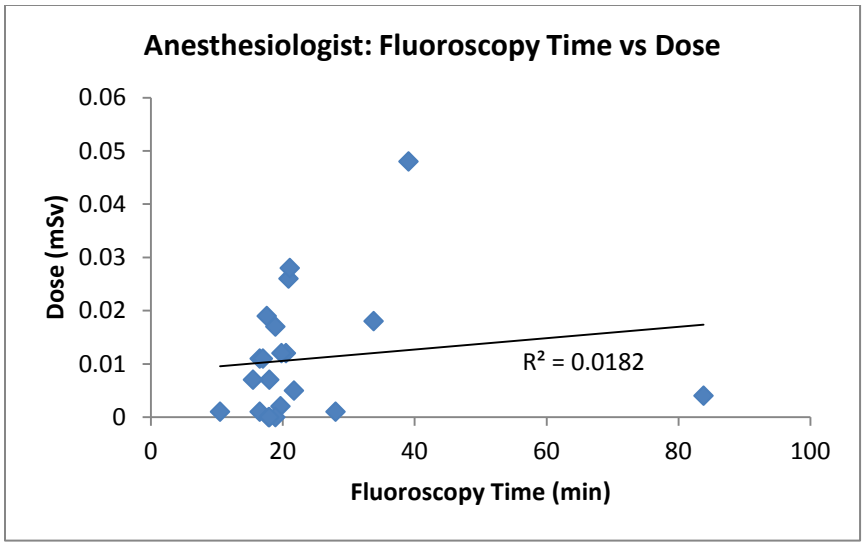

Figure 21: Anesthesiologist Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Perfusionist

Fluoroscopy output values have large R^2 with perfusionist dose, however the least number of data points were collected for this role at $N = 9$. Many data points were omitted because of suspected cell-phone interference. A perfusionist is present during the TAVR only in the case of an incident requiring the use of a bypass machine. During the TAVR cases of this study, the perfusionist was used for back-up in case of an incident (i.e. cardiac arrest).

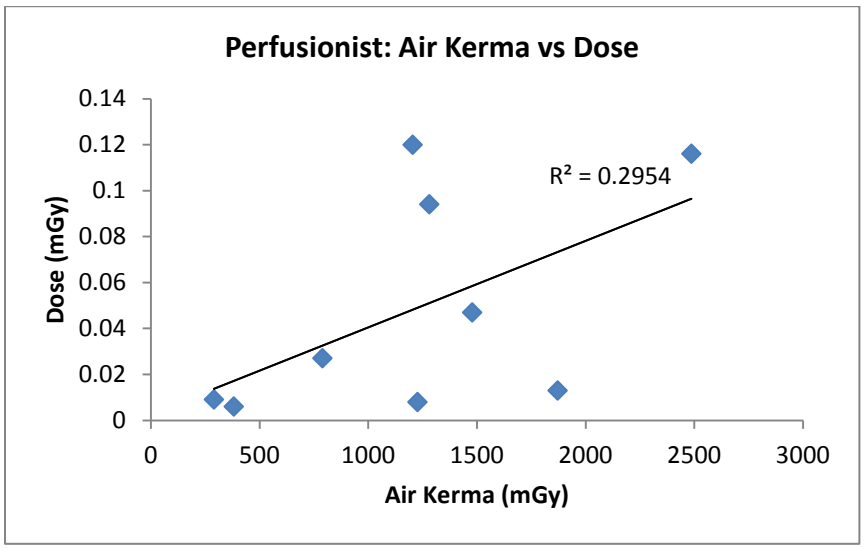

Figure 22: Perfusionist Dose as a Function of Air Kerma for Each Specific Procedure.

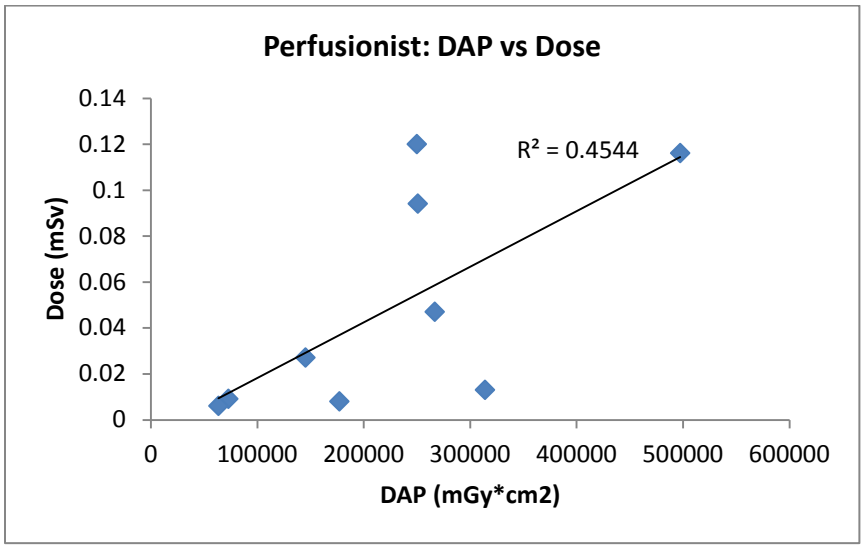

Figure 23: Perfusionist Dose as a Function of DAP for Each Specific Procedure.

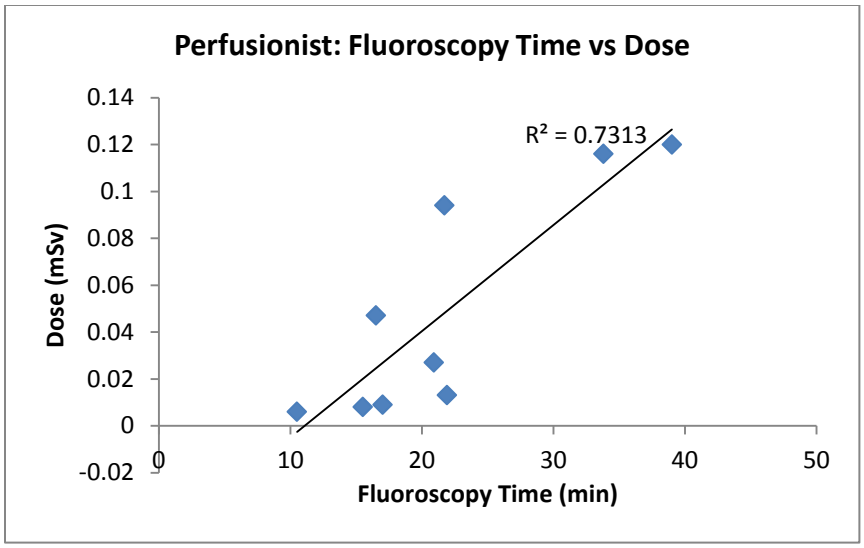

Figure 24: Perfusionist Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Cath-Lab RN

The cath-lab RN would stand near the patient side to assist operators and would also leave the patient table to retrieve tools and supplies for the procedure (N = 20). Data for fluoroscopy time aggregates in one area region of the chart with one far out data point as shown in Figure 27. This data point increases the R^2 value significantly, even with no apparent correlation.

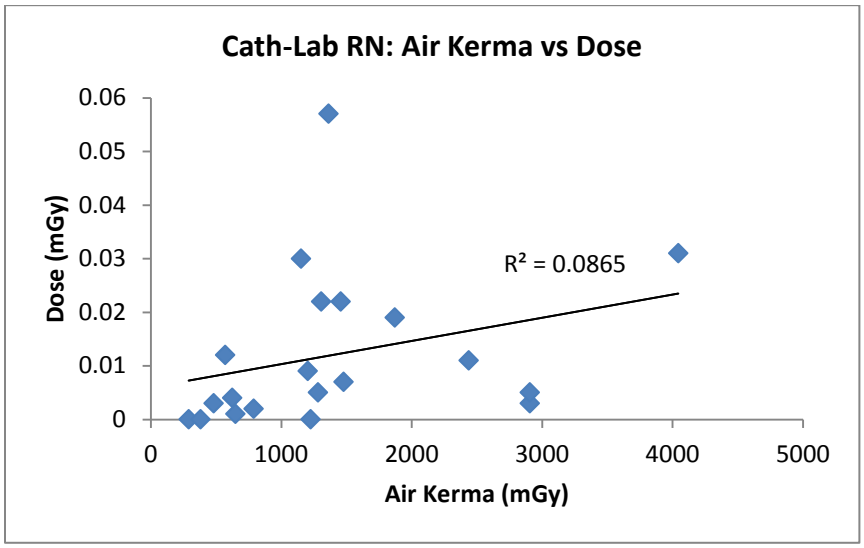

Figure 25: Cath-Lab RN Dose as a Function of Air Kerma for Each Specific Procedure.

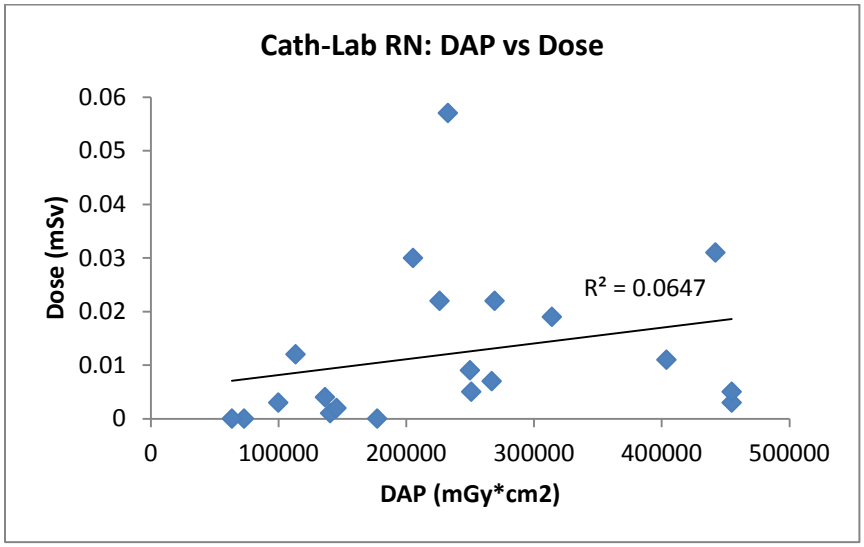

Figure 26: Cath-Lab RN Dose as a Function of DAP for Each Specific Procedure.

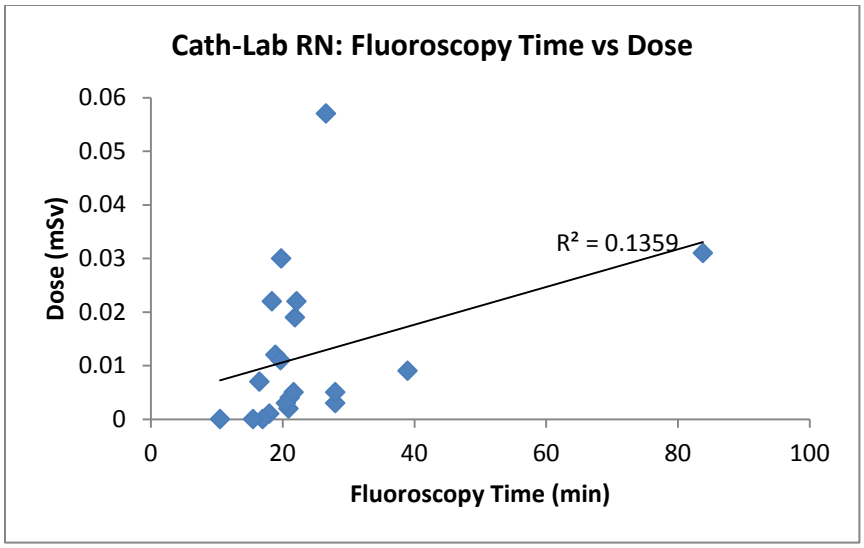

Figure 27: Cath-Lab RN Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Room Circulating Nurse

Fluoroscopy time correlates most with room circulating nurse dose, followed by air kerma then DAP. Similarly to the cath-lab RN data, fluoroscopy time data points aggregate in one region of the chart with an outlier that increases the R^2 value as shown in Figure 30 (N = 18).

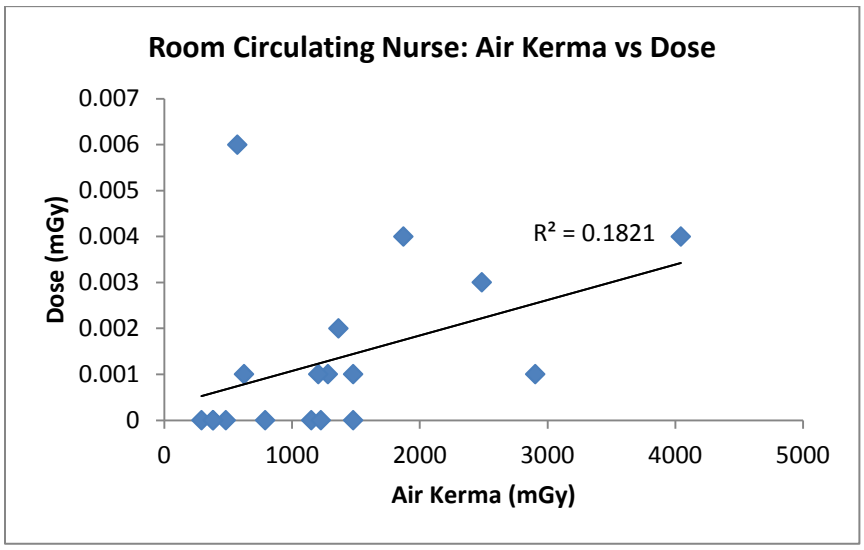

Figure 28: Room Circulating Nurse Dose as a Function of Air Kerma for Each Specific Procedure.

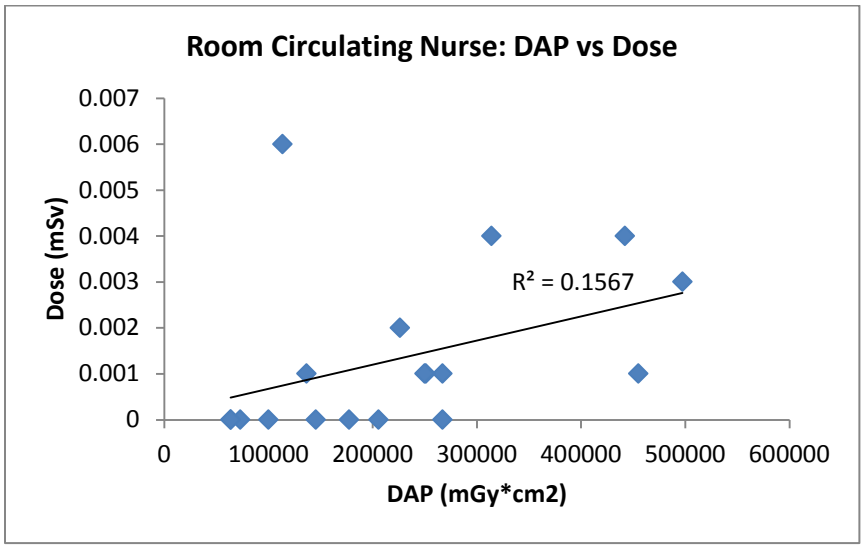

Figure 29: Room Circulating Nurse Dose as a Function of DAP for Each Specific Procedure.

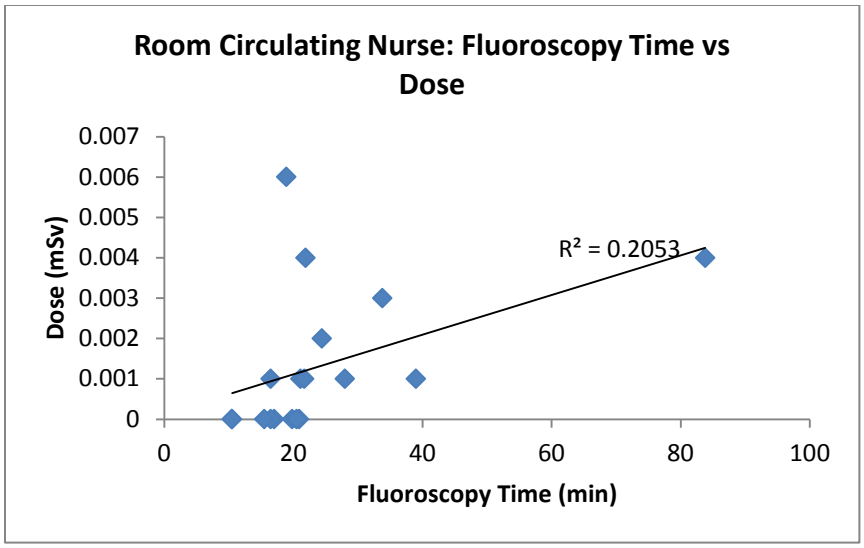

Figure 30: Room Circulating Nurse Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Bed-side Scrub Nurse

This role is unique in that human shielding could influence dose. The primary and secondary operator may act as shielding due to their position, reducing dose to the scrub nurse (N = 18).

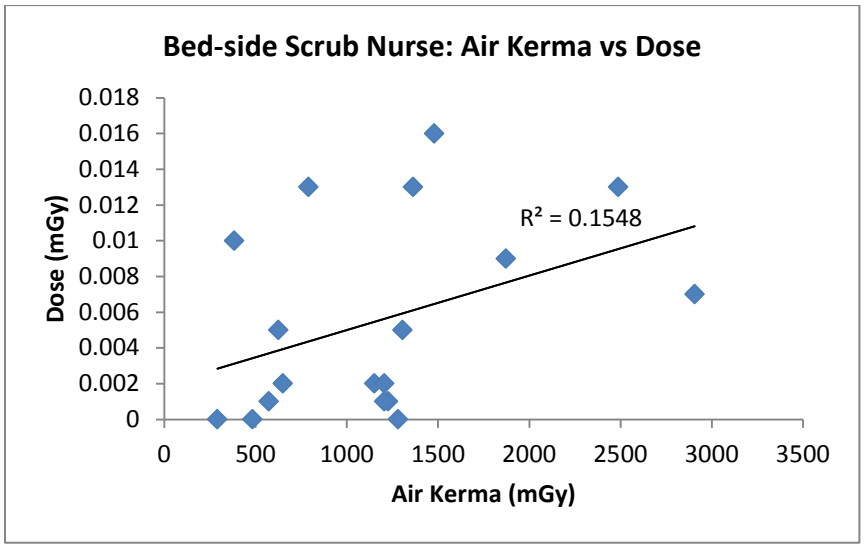

Figure 31: Bedside Scrub Nurse Dose as a Function of Air Kerma for Each Specific Procedure.

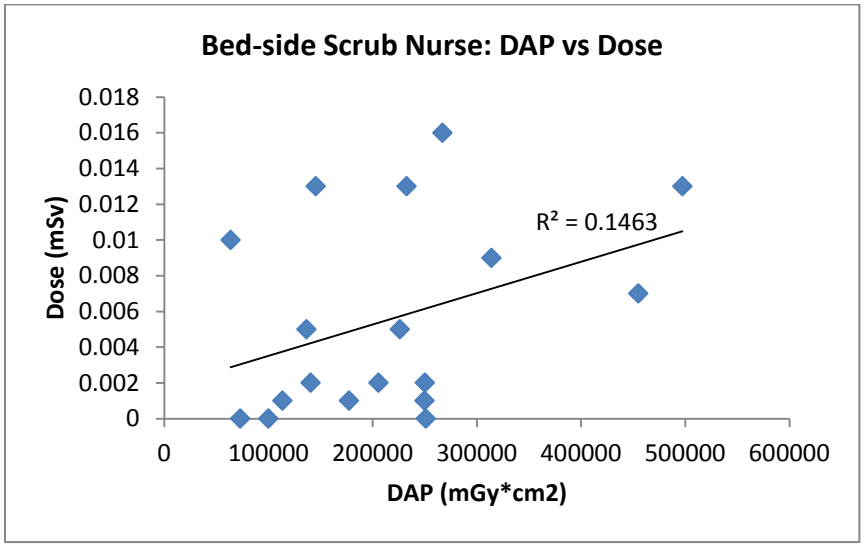

Figure 32: Bedside Scrub Nurse Dose as a Function of DAP for Each Specific Procedure.

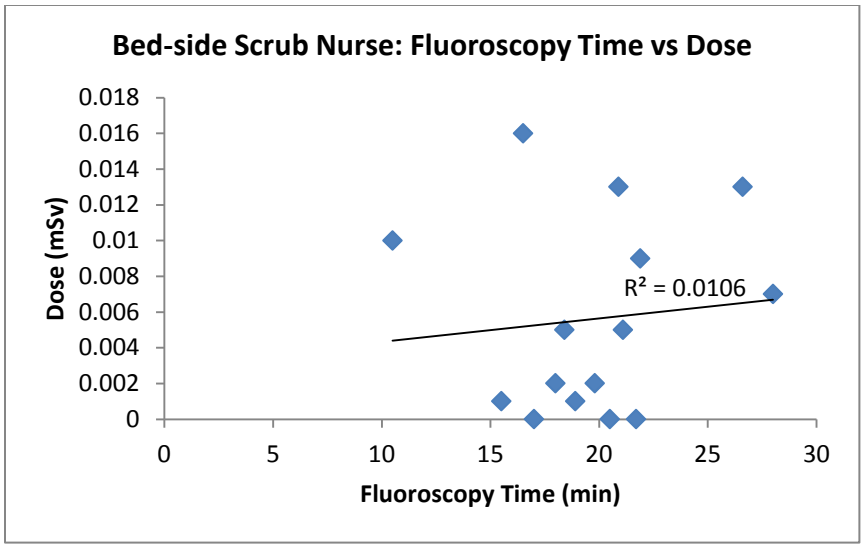

Figure 33: Bedside Scrub Nurse Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Corner-Room Scrub Nurse

None of the fluoroscopy output values have an R^2 greater than 0.02 in relations to this role's dose. This role was the farthest from the isocenter center, thus explaining the many low and zero doses (N = 20).

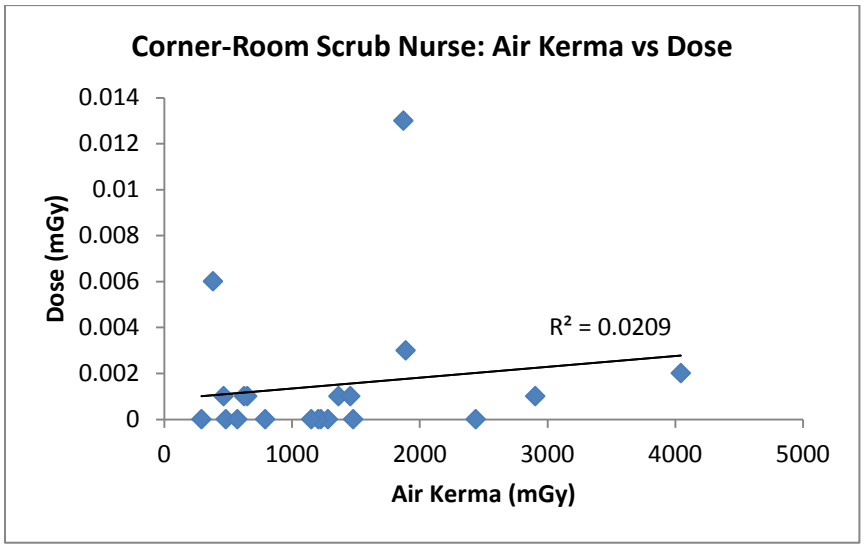

Figure 34: Corner-Room Scrub Nurse Dose as a Function of Air Kerma for Each Specific Procedure.

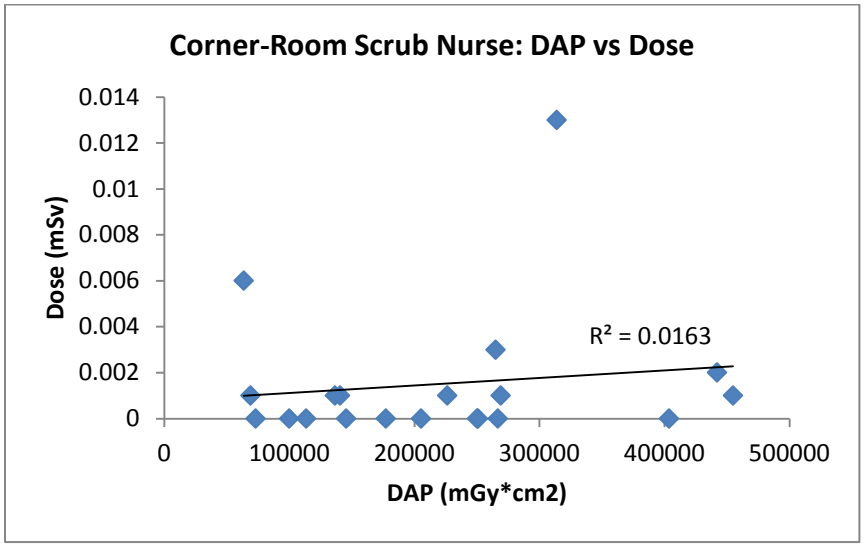

Figure 35: Corner-Room Scrub Nurse Dose as a Function of DAP for Each Specific Procedure.

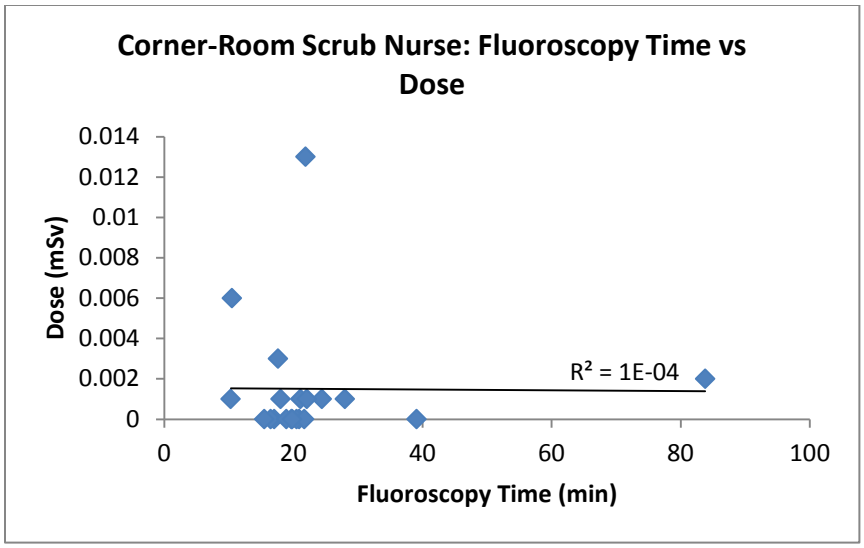

Figure 36: Corner-Room Scrub Nurse Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Echocardiologist

The echocardiologist, fellow, and assistant are grouped together because of their similar proximity from the isocenter and all will be referred to as an echocardiologist. The echocardiologist would at times use a portable shield. The echocardiologist's dosimeter read a dose of 0.32 mSv in one procedure. This dose is unusually high, reaching a dose higher than the primary operator maximum dose of 0.21 mSv. The echocardiologist's assistant dosimeter read a lower dose (< 0.040 mSv) from doses of all TAVR procedure combined from that day. The cause of this high reading is unclear, although the dose rate graph displayed no signs of RF interference the high dose was omitted from the results (*N* = 18).

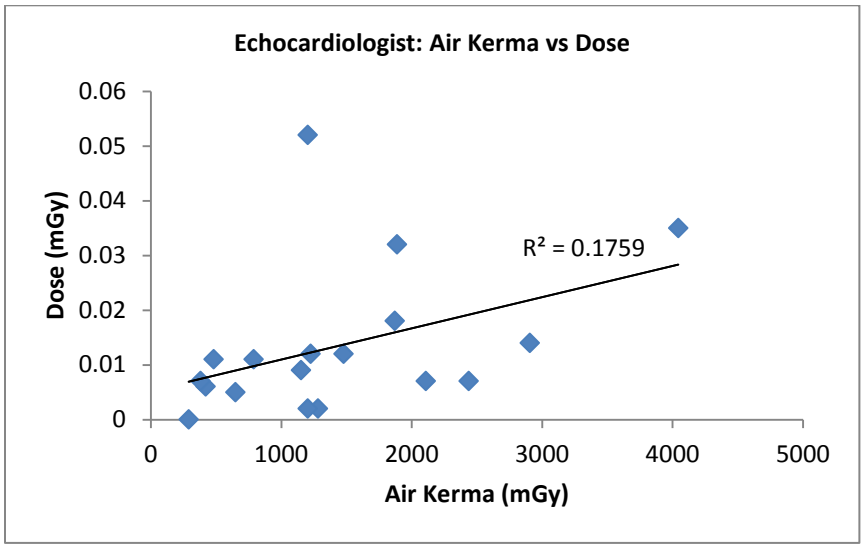

Figure 37: Echocardiologist Dose as a Function of Air Kerma for Each Specific Procedure.

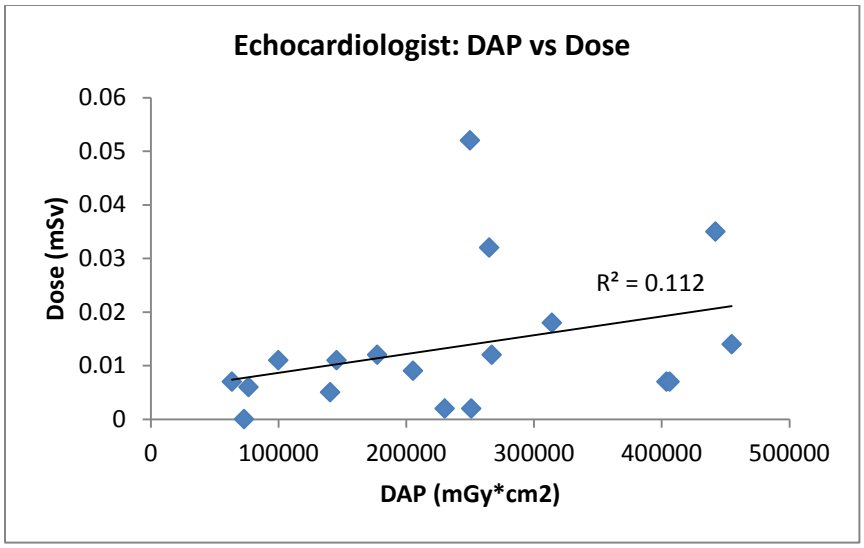

Figure 38: Echocardiologist Dose as a Function of DAP for Each Specific Procedure.

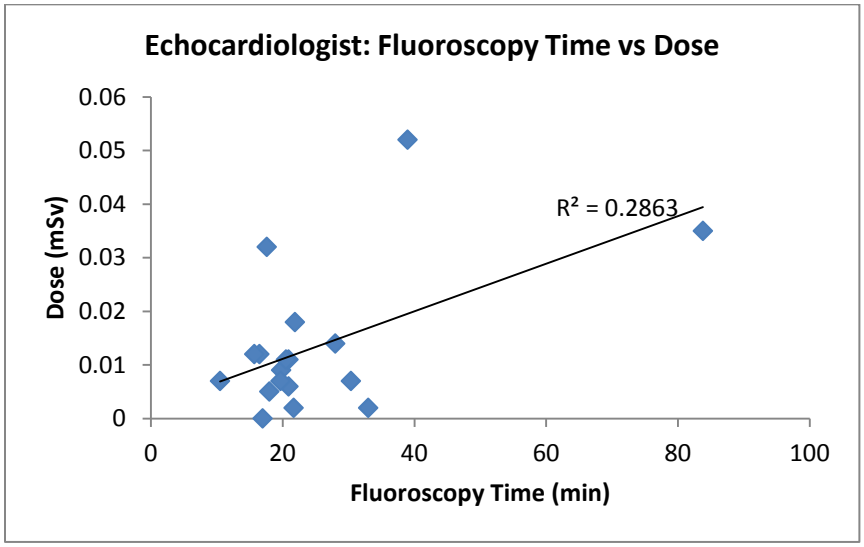

Figure 39: Echocardiologist Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

Observer

An observer has no specified position and therefore no correlation would be expected. Any correlation present is negative (N = 10).

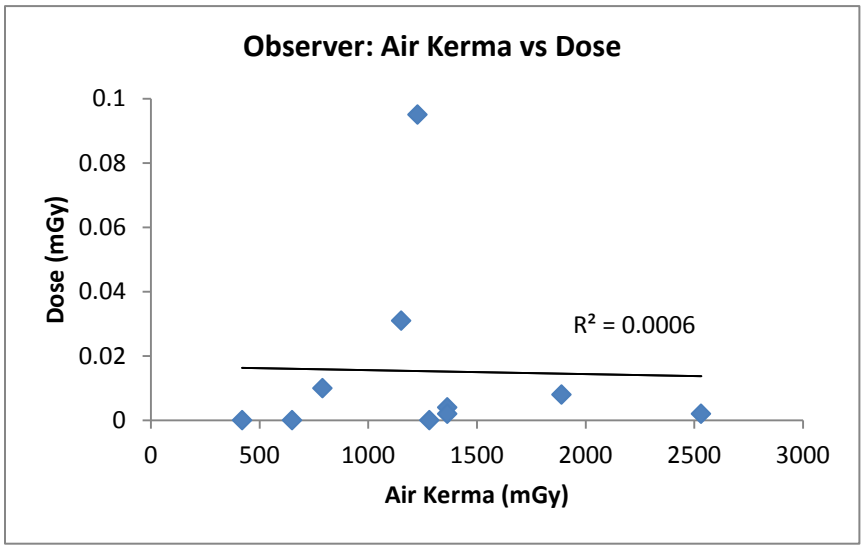

Figure 40: Observer Dose as a Function of Air Kerma for Each Specific Procedure.

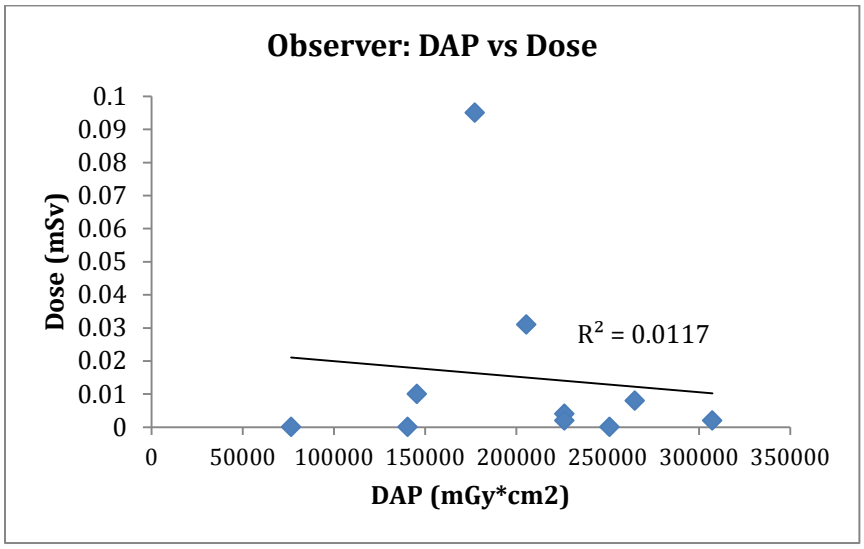

Figure 41: Observer Dose as a Function of DAP for Each Specific Procedure.

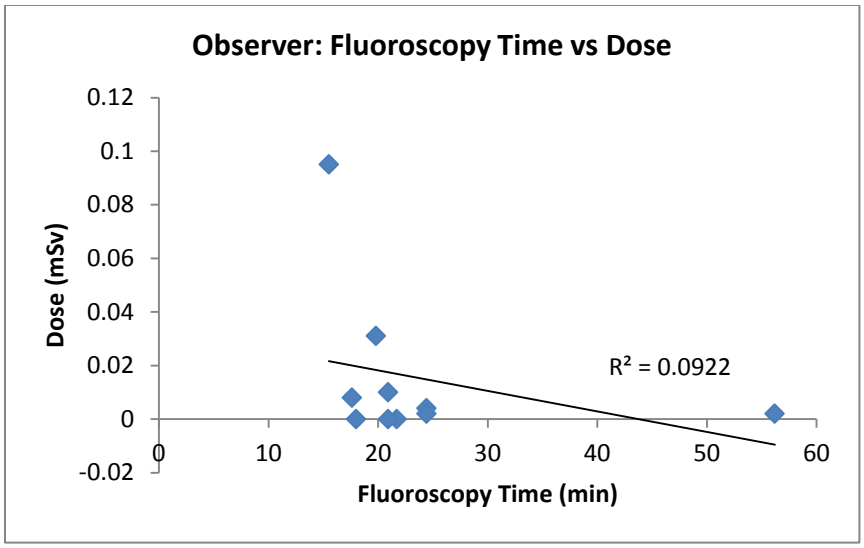

Figure 42: Observer Dose as a Function of Fluoroscopy Time for Each Specific Procedure.

DISCUSSION

Dose per Procedure

The primary operators received the highest median dose at 0.101 mSv followed by the secondary operators at 0.033 mSv. Both of these roles had the closest proximity to the isocenter, suggesting significance of distance as a factor of dose. The primary and secondary physician also stood on the bedside nearest to the x-ray tube (the side which receives more scatter), further increasing dose of these two roles (Figure 1). The primary operator would switch positions with the secondary operator for a portion of the procedure, positioning the secondary operator closer to the isocenter.

The perfusionists received the third highest median dose, however, only a few data points were collected due to cell-phone interference. A high median perfusionist dose would not be expected because their distance from the isocenter. Scatter appears to extend strongly in the direction towards the perfusionist's location. The bed-side scrub nurse was at a comparable distance from the isocenter, but did not receive as high of a median dose per procedure as the perfusionist. Non-uniform scatter distribution is expected to be the cause of these high doses and can vary based on C-arm angle and location. Creating a dose map of the room using area dosimeters would show how scatter is distributed around the room.

Median dose to the anesthesiologist and echocardiologist was unexpectedly low considering their proximity to the isocenter. A portable shield was used to reduce dose at times, however its use was not consistent and depended on the personal choice of the present staff members. The non-uniform radiation field may not have extended strongly in direction away from the top of a patient's head, towards the anesthesiologist and

echocardiologist. A dose map would explain the scatter distribution towards these two roles.

Dose Relationship to Fluoroscopy Output

An attempt was made to relate fluoroscopic output and beam time to worker dose. Air kerma versus dose to the primary physician role had one of the highest R^2 values of this study at 0.3504. The R^2 value can be interpreted that 35.04% of primary physician dose variation is accounted for by air kerma. There remains 65% of dose unaccounted for by air kerma. The low R^2 values for the primary physician role and all roles of this study suggest other factors influence dose than simply fluoroscopy output.

Movement, direction, patient size, and C-arm angle could all influence dose correlation to fluoroscopy output. The echocardiologist, for example, was a relatively static role in that his tasks are performed in one position in the hybrid OR. If the echocardiologist, however, was facing away from the isocenter, the dosimeter would have had a lower reading (shielded by the body of the echocardiologist) even though the radiation exposure would have been identical. Natural movement and job function could sporadically shift the direction of echocardiologist, potentially impacting the dosimeter reading. The direction of the staff member can potentially influence dose readings for all roles of the TAVR.

One factor that may have also lowered R^2 values to the secondary operators is that two are usually present during a single procedure, each obviously in a different position (side-by-side, see Figure 8). Both are secondary operators by name; however, each stood at a different position from the isocenter. Dose for each of the two positions of the secondary operators were not recorded separately, possibly influencing the R^2 values.

The anesthesiologist, like the echocardiologist, has a relatively static role if he or she were to stay in the hybrid OR for the entire span of the procedure. Dose correlation to fluoroscopy output is not only low but also negative. The anesthesiologist may leave the room during the procedure as his or her responsibilities are mainly during the beginning and end of a procedure. During a longer procedure, an anesthesiologist may be more inclined to leave the hybrid OR, therefore receiving less dose even with the greater fluoroscopy output of a longer procedure. Adding further variability, the anesthesiologist and echocardiologist may have been protected using a portable shield depending on the choice of the present OR staff members during a procedure.

The fewest number of data points were collected for the perfusionist role. The perfusionist had a relatively static position facing the isocenter. The R^2 values are the perfusionist are the highest of this study, however, because of the few data points, dose correlation of the perfusionist is not considered conclusive.

DAP was expected to have a stronger correlation to dose because it takes into account air kerma and the size of the area irradiated. A possible explanation is that the R^2 values are prone to significant change due to a single data point, and with more collected data DAP R^2 could change. Further testing of R^2 values can be done by using area dosimeters, placed in the positions of the staff members without the added variability of movement. All other roles not mentioned in this section, moved significantly during the TAVR procedure with corresponding low R^2 values (< 0.20).

Data Collecting and Cell-Phone Interference

The number of available procedures was a limiting factor in collecting data. The TAVR was performed on only one day of the week, with one to four procedures that day.

Even if more procedures were available, the current dosimeter reading method is a time consuming process. Each individual dosimeter is read one-by-one. More data points would increase the strength of the results, however a more automated approach to collecting data is recommended.

One of the largest causes of data corruption in this study was determining if a dosimeter had a false high reading caused by cell-phone interference. When interference was determined to be a significant issue during the study, personnel were asked to keep cell-phones away from the dosimeter. Unfortunately, in practice, some staff members would continue using their phones out of habit. The chest pocket where the dosimeter usually clipped on was also a convenient location to hold a cell-phone. Dosimeters were distanced from the chest pocket by clipping them to the thyroid cover (Figure 4) or the apron edge opposite to the chest pocket.

The extent of cell-phone interference was tested directly: six dosimeters were placed on an iPhone 6 near the top, middle, and bottom; front and back. A phone call was made for a duration of 60 seconds with the Wi-Fi feature switched off. The experiment is imprecise, though conveys the significant potential of cell-phone interference on dosimeter readings as shown in Table 7.

Table 7: Highest Dose Rate Caused By Cell-phone Inference in 60 seconds. *

		Top (mSv/h)	Middle (mSv/h)	Bottom (mSv/h)
Trial 1	Front	85	1800	2000
	Back	1100	480	1800
Trial 2	Front	2	100	750
	Back	625	270	60
Trial 3	Front	14.5	150	800
	Back	725	350	100

***Dose rates are a rough reading from dose rate graph.**

Anti-static plastic covering was used over each dosimeter; however, the plastic did not attenuate the RF interference as reported in a previous study (possibly the wrong type of anti-static covering) [26]. Area dosimeters placed in the hybrid OR during the procedure for comparison purposes. An area dosimeter is assumed to be far from any cell-phone and therefore can be used as a standard for dose, producing a dose graph (Figure 43) free of interference. Dose rate graphs from the staff dosimeters were compared to graphs from the area dosimeters for similar dose rate distribution. If a peak or shape present on the personnel dose graph did not appear on area dosimeter dose graph, the dose reading was considered to be affected by RF. Analyzing the dose graphs was a time consuming process that was necessary for data integrity.

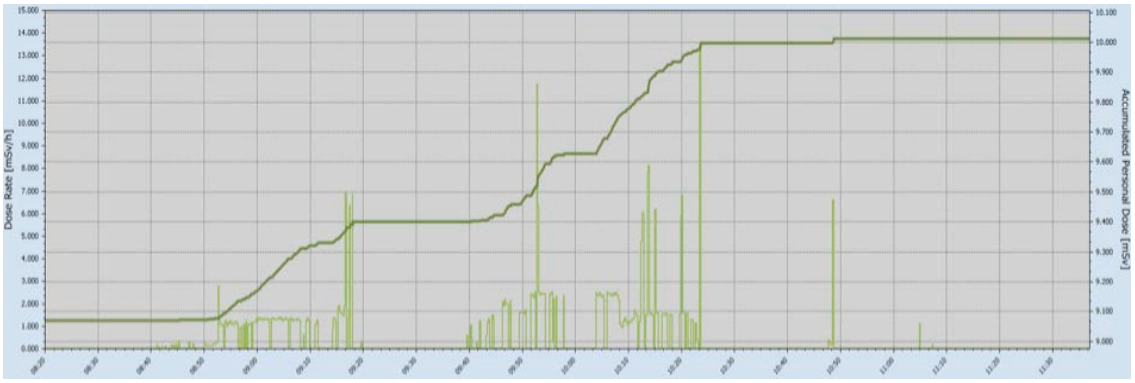

Figure 43: The above figure is an example of a dose graph from a single procedure. The green horizontal line represents accumulated dose. The green vertical lines represent the dose rate at a given time.

CONCLUSION

Median dose per procedure was highest to the personnel closest to the isocenter except for the perfusionist. The highest median dose was to the primary physician at 0.101 mSv with a maximum dose of 0.23 mSv outside of protective clothing. At a 50-mSv occupational dose limit in the United States, the median and maximum dose would limit a primary operator to 495 and 217 procedures per year respectively [15].

Dose mapping the radiation field in the hybrid OR is essential to future studies. A dose map would relate dose to fluoroscopy output without variability caused by movement, direction, or C-arm angle. The dose map can also be used to determine the distribution of the non-uniform radiation field and would be insightful as to why the perfusionist median dose was higher than expected considering the position.

A relationship between fluoroscopic output and beam time did not appear in this study because of the many other factors that could influence dose. The worker must remain stationary with no changes in scatter distribution from C-arm movement. Practically, no role is 100% static and changes in the C-arm angle and location vary through the procedure. The low correlation may also be due to the influence of a single large or small measurement on the R^2 value as the number of data points is small. DAP was expected to have the strongest correlation based on past studies [2] [27]. Continued data collection in this study could increase R^2 values for all variables and possibly demonstrate DAP has the highest correlation with personnel dose. Fluoroscopy time R^2 values were relatively large (> 0.30) for some roles; however the data did not demonstrate a correlation. More data collection is needed before considering R^2 conclusively.

A consideration for future studies is that dose should be recorded based on position, not the role. In this study, the two secondary operators were not distinguishable based on their position. Had the distinction been made, R^2 for both may have been larger. Future studies should also consider dosimeters immune from RF interference and a more automated way of measuring dose for each specific procedure. Manual dosimeter reading was a time-consuming process, especially in search of RF interference.

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APPEDNIX A: RAW DATA

If a field in the omitted column has text, that data point was omitted from the results of this study.

KEY

- ci = cell-phone interference
- ta = trans-apical (see primary operator section in results for more detail)
- kerma = air kerma was not properly recorded

Table 8: Primary Operator

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
1	0.153	571.57	113375	18.9	
2	0.066	650	140473	18	
3	0.14	1151.33	205443	19.8	
4	0.101	1364.02	232636	26.6	
5	0.03	1888.93	264942	17.6	ta
6	0.625	1178.09	353081	46.7	ci
7	0.055	624.86	136453	21.1	
8	0.101	790	145516	20.9	
9	0.045	3415.73	382869	77.7	ta
10	0.026	382.04	63518	10.5	
11	0.024	482.95	99782	20.5	
12	0.118	1872.02	314010	21.9	
13	0.111	290.65	72928	17	
14	0.23	2438.57	403726	19.7	
15	0.205	2905.8	454857	28	
16	0.049	1478.36	266880	16.5	
17	0.073	1306	226012	18.4	
18	0.196	1226.5	177245	15.5	
19	0.045	1281.07	251001	21.7	
20	0.155	2487	497320	33.8	
21	0.21	1205.82	250136	39.1	

Table 9: Secondary Operator

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
1	0.016	571.57	113375	18.9	
1	0.031	571	113375	18.9	
2	0.008	650	140473	18	
2	0.074	650	140473	18	
3	0.039	1151.33	205433	19.8	
3	0.042	1151.33	205443	19.8	
4	1.64	1396.49	232636	26.6	ci
4	0.025	1364.02	226266	24.4	
4	0.035	1364.02	226266	24.4	
5	0.013	1888.93	264942	17.6	ta
5	0.13	2889.29	409414	19.7	ta
6	0.15	1847.37	353081	46.7	ci+kerma
6	0.119	1204.47	230160	33	ci+kerma
6	0.008	1847.37	353081	46.7	ci+kerma
6	0.119	1847.37	353081	46.7	
7	0.003	420.08	76544	20.9	
7	0.012	420.08	76544	20.9	
7	0.024	420.08	76544	20.9	
8	0.114	790	145516	20.9	
9	0.484	4043.86	442016	83.8	ci
9	0.446	4043.86	442016	83.8	ci
10	0.008	382.04	63518	10.5	
10	0.017	382.04	63518	10.5	
10	0.011	382.04	63518	10.5	
11	0.002	482.95	99782	20.5	
11	0.001	482.95	99782	20.5	
11	0.167	482.95	99782	20.5	ci
12	0.005	1872.02	314010	21.9	
13	0.007	290.65	72928	17	
14	0.061	2438.57	403726	19.7	
14	0.064	2438.57	403726	19.7	
16	0.104	1478.36	266880	16.5	
16	0.04	1478.36	266880	16.5	
17	0.054	1306	226012	18.4	
17	0.057	1306	226012	18.4	
18	0.047	1226.5	177245	15.5	
18	0.046	1226.5	177245	15.5	
19	0.033	1281.07	251001	21.7	
19	0.053	1281.07	251001	21.7	
20	0.096	2487	497320	33.8	

21	0.03	1205.82	250136	39.1
21	0.107	1205.82	250136	39.1

Table 10: Tertiary Operator

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
1	0.004	571.57	113375	18.9	
1	0.007	571.57	113375	18.9	
2	0.015	650	140473	18	
2	0.042	650	140473	18	
3	0.001	1151.33	205443	19.8	
6	0.008	1847.37	353081	46.7	
8	0.015	790	145516	20.9	
8	0.015	790	145516	20.9	
9	0.432	4043.86	442016	83.8	ci
11	0.001	482.95	99782	20.5	
13	0.011	290.65	72928	17	
14	0.03	2438.57	403726	19.7	
15	0.015	2905.8	454857	28	
16	0.024	1478.36	266880	16.5	
17	0.008	1277	224332	17.9	
18	0.021	1226.5	177245	15.5	
19	0.007	1281.07	251001	21.7	
19	0.007	1281.07	251001	21.7	
20	0.033	2487	497320	33.8	
21	0.092	1205.82	250136	39.1	

Table 11: Anesthesiologist

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
1	0.017	571.57	113375	18.9	
1	0	571.57	113375	18.9	
1	15.9	571.57	113375	18.9	ci
2	0.007	650	140473	18	
2	1.99	650	140473	18	ci
2	0	650	140473	18	
3	0.012	1151.33	205443	19.8	
3	0.05	1151.33	205433	19.8	ci
3	1.79	1151.33	205433	19.8	ci
4	0.436	24.4	226266	1364.02	ci
5	0.019	1888.93	264942	17.6	
6	0.119	1847.37	353081	46.7	ci
7	0.028	624.86	136453	21.1	
7	12	420.08	76544	20.9	ci
8	0.026	790	145516	20.9	
9	0.067	4043.86	442016	83.8	ci
9	0.004	4043.86	442016	83.8	
10	0.001	382.04	63518	10.5	
11	0.012	482.95	99782	20.5	
13	0.011	290.65	72928	17	
14	0.002	2438.57	403726	19.7	
15	0.001	2905.8	454857	28	
15	0.027	2905.8	454857	28	
16	0.001	1478.36	266880	16.5	
16	0.011	1478.36	266880	16.5	
17	0	1277	224332	17.9	
18	0.007	1226.5	177245	15.5	
19	0.005	1281.07	251001	21.7	
20	0.018	2487	497320	33.8	
21	0.048	1205.82	250136	39.1	

Table 12: Perfusionist

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
1	21	571.57	113375	18.9	ci
2	0.064	650	140473	18	ci
3	0.114	1151.33	205433	19.8	ci
4	0.117	24.4	226266	1364.02	ci
5	0.562	2889.29	409414	19.7	ci
6	0.156	1847.37	353081	46.7	ci
7	0.066	624.86	136453	21.1	ci
8	0.027	790	145516	20.9	
9	0.109	4043.86	442016	83.8	ci
10	0.006	382.04	63518	10.5	
12	0.013	1872.02	314010	21.9	
13	0.009	290.65	72928	17	
14	0.09	2438.57	403726	19.7	ci
15	0.036	2905.8	454857	28	ci
16	0.047	1478.36	266880	16.5	
17	0.075	1306	226012	18.4	ci
18	0.008	1226.5	177245	15.5	
19	0.094	1281.07	251001	21.7	
20	0.116	2487	497320	33.8	
21	0.12	1204.69	249901	39	

Table 13: Cath-Lab RN

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
1	0.012	571.57	113375	18.9	
2	0.001	650	140473	18	
3	0.03	1151.33	205443	19.8	
4	0.057	1364.02	232636	26.6	
6	0.02	1847.37	353081	46.7	ci+kerma
7	0.004	624.86	136453	21.1	
8	0.002	790	145516	20.9	
9	0.031	4043.86	442016	83.8	
10	0	382.04	63518	10.5	
11	0.003	482.95	99782	20.5	
12	0.019	1872.02	314010	21.9	
13	0	290.65	72928	17	
14	0.011	2438.57	403726	19.7	
15	0.003	2905.8	454857	28	
15	0.005	2905.8	454857	28	
16	0.007	1478.36	266880	16.5	
17	0.022	1306	226012	18.4	
18	0	1226.5	177245	15.5	
19	0.005	1281.07	251001	21.7	
20	0.022	1456	269120	22.1	
21	0.009	1204.69	249901	39	

Table 14: Room Circulating Nurse

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP (mGy*cm^2)	Fluoroscopy Time (min)	Omitted
1	0.006	571.57	113375	18.9	
2	11.4	650	140473	18	ci
3	0	1151.33	205443	19.8	
4	0.002	1364.02	226266	24.4	
6	0.001	1847.37	353081	46.7	kerma
7	0.001	624.86	136453	21.1	
8	0	790	145516	20.9	
9	0.004	4043.86	442016	83.8	
10	0	382.04	63518	10.5	
10	0	382.04	63518	10.5	
11	0	482.95	99782	20.5	
12	0.004	1872.02	314010	21.9	
13	0	290.65	72928	17	
15	0.001	2905.8	454857	28	
16	0.001	1478.36	266880	16.5	
16	0	1478.36	266880	16.5	
18	0	1226.5	177245	15.5	
19	0.001	1281.07	251001	21.7	
20	0.003	2487	497320	33.8	
21	0.001	1204.69	249901	39	

Table 15: Bed-side Scrub Nurse

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
1	0.001	571.57	113375	18.9	
2	0.002	650	140473	18	
3	0.002	1151.33	205443	19.8	
4	0.013	1364.02	232636	26.6	
6	0.003	1847.37	353081	46.7	kerma
7	0.005	624.86	136453	21.1	
8	0.013	790	145516	20.9	
10	0.01	382.04	63518	10.5	
11	0	482.95	99782	20.5	
12	0.009	1872.02	314010	21.9	
13	0	290.65	72928	17	
15	0.007	2905.8	454857	28	
16	0.016	1478.36	266880	16.5	
17	0.005	1306	226012	18.4	
18	0.001	1226.5	177245	15.5	
19	0	1281.07	251001	21.7	
20	0.013	2487	497320	33.8	
21	0.002	1205.82	250136	39.1	
21	0.001	1204.69	249901	39	

Table 16: Corner-room Circulating Nurse

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
1	0	571.57	113375	18.9	
2	0.001	650	140473	18	
3	0	1151.33	205443	19.8	
4	0.001	1364.02	226266	24.4	
5	0.003	1888.93	264942	17.6	
6	0	1847.37	353081	46.7	kerma
7	0.001	624.86	136453	21.1	
8	0	790	145516	20.9	
9	0.002	4043.86	442016	83.8	
10	0.006	382.04	63518	10.5	
11	0	482.95	99782	20.5	
12	0.013	1872.02	314010	21.9	
13	0	290.65	72928	17	
14	0	2438.57	403726	19.7	
15	0.001	2905.8	454857	28	
16	0	1478.36	266880	16.5	
17	0.001	465	68856	10.3	
18	0	1226.5	177245	15.5	
19	0	1281.07	251001	21.7	
20	0.001	1456	269120	22.1	
21	0	1205.82	250136	39.1	

Table 17: Echocardiologist

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
2	0.005	650	140473	18	
3	0.009	1151.33	205443	19.8	
5	0.032	1888.93	264942	17.6	
6	0.002	1204.47	230160	33	
7	0.006	420.08	76544	20.9	
8	0.011	790	145516	20.9	
9	0.035	4043.86	442016	83.8	
10	0.007	382.04	63518	10.5	
11	0.011	482.95	99782	20.5	
12	0.018	1872.02	314010	21.9	
13	0	290.65	72928	17	
14	0.007	2438.57	403726	19.7	
15	0.014	2905.8	454857	28	
16	0.012	1478.36	266880	16.5	
17	0.369	1306	226012	18.4	See results section
18	0.012	1226.5	177245	15.7	
19	0.002	1281.07	251001	21.7	
20	0.007	2108.76	406315	30.4	
21	0.052	1204.69	249901	39	

Table 18: Observer

Procedure	Dose (mSv)	Air Kerma (mGy)	DAP ($mGy \cdot cm^2$)	Fluoroscopy Time (min)	Omitted
1	1.42	571.57	113375	18.9	ci
2	0	650	140473	18	
3	0.031	1151.33	205443	19.8	
4	0.004	1364.02	226266	24.4	
4	0.002	1364.02	226266	24.4	
5	0.008	1888.93	264942	17.6	
5	0.032	2889.29	409414	19.7	ci
6	0.053	1847.37	353081	46.7	ci
6	0.028	1847.37	353081	46.7	ci
7	0.007	420.08	76544	20.9	ci
7	0	420.08	76544	20.9	
8	0.01	790	145516	20.9	
9	0.002	2531.88	307360	56.2	
18	0.095	1226.5	177245	15.5	
19	0	1281.07	251001	21.7	

APPENDIX B: IRB APPROVAL LETTER

Colorado State University
Knowledge to Go Places

Research Integrity & Compliance Review Office
Office of the Vice President for Research
321 General Services Building - Campus Delivery 2011 Fort Collins, CO
TEL: (970) 491-1553
FAX: (970) 491-2293

NOTICE OF APPROVAL FOR HUMAN RESEARCH

DATE:	February 05, 2015
TO:	Johnson, Thomas Nickoloff, Jac, Shatila, Omar
FROM:	Swiss, Evelyn, Coordinator, CSU IRB 1
PROTOCOL TITLE:	Occupational Radiation Doses during Fluoroscopically Guided Procedures in a Hybrid Operating Room
FUNDING SOURCE:	NONE
PROTOCOL NUMBER:	14-5436H
APPROVAL PERIOD:	Approval Date: February 05, 2015 Expiration Date: December 27, 2015

The CSU Institutional Review Board (IRB) for the protection of human subjects has reviewed the protocol entitled: Occupational Radiation Doses during Fluoroscopically Guided Procedures in a Hybrid Operating Room. The project has been approved for the procedures and subjects described in the protocol. This protocol must be reviewed for renewal on a yearly basis for as long as the research remains active. Should the protocol not be renewed before expiration, all activities must cease until the protocol has been re-reviewed.

If approval did not accompany a proposal when it was submitted to a sponsor, it is the PI's responsibility to provide the sponsor with the approval notice.

This approval is issued under Colorado State University's Federal Wide Assurance 00000647 with the Office for Human Research Protections (OHRP). If you have any questions regarding your obligations under CSU's Assurance, please do not hesitate to contact us.

Please direct any questions about the IRB's actions on this project to:

IRB Office - (970) 491-1553; RICRO_IRB@mail.Colostate.edu
Evelyn Swiss, IRB Coordinator - (970) 491-1381; Evelyn.Swiss@Colostate.edu

Evelyn Swiss

Swiss, Evelyn

Administrative approval of addition of Deirdre Elder from University of Colorado Health as co-PI. COMIRB is currently ceding IRB approval to CSU.

Approval Period:	February 05, 2015 through December 27, 2015
Review Type:	EXPEDITED
IRB Number:	00000202