

TITLE

Operator Radiation Exposure for Right vs Left trans-radial catheterization. **Hyper Adduction of Right Radial Artery/Arm vs left arm drag over technique, HARRA study.**

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INTRODUCTION, BACKGROUND AND SIGNIFICANCE:

Several studies have evaluated operator and (patient) exposure comparing left and right transradial approaches. The TALENT study by Schiabasi et al concludes left radial approach for coronary diagnostic procedures is associated with lower fluoroscopy time and radiation dose adsorbed by patients compared with the RRA, particularly in older patients and for operators in training. This study laid the foundation examining different radiation doses comparing left and right transradial approaches. Subsequent studies (OPERA, RAD-MATRIX) examined operator dose favoring LRA procedures. However the primary access point for interventional cardiologist is the RRA due to catheterizations laboratories historically set up for the operator to work from the right side of the fluoroscopic table which makes it a more ergonomic procedure. In light of new data elucidating that an adducted right arm yields lower amounts of operator exposure compared with an abducted arm we seek to determine if this technique will yield similar operator radiation exposure comparing an adducted right radial artery approach to a left radial artery approach.

STUDY OBJECTIVES

- Studying the difference between radiation exposure to primary operator for diagnostic coronary angiography procedure with right transradial access in HARRA position versus standard left transradial access.
- Evaluating the radiation exposure difference between right and left eye of the primary operator
- Studying the total fluoroscopic time and patient's radiation exposure during the diagnostic coronary angiogram and its relationship to presence of subclavian artery tortuosity

HYPOTHESIS

Several studies have shown that operator exposure via left transradial catheterization has yielded less operator exposure compared to standard right transradial procedure. However, in light of new data, we hypothesize a hyperadducted right arm during right transradial cardiac catheterization will yield comparable, or the same operator radiation exposure.

STUDY DESIGN

Randomized, non-blinded prospective study

Subjects: Explain who potential subjects are, where they will be recruited, etc.:

- **All the Cardiac Catheterization Laboratory (CCL) physician operators who consent to participate in the study are the primary study subjects**
- **7-10 CCL physician operators will participate in the study as the primary study subjects**
- **Patients undergoing the procedure will be secondary study subjects only**
- **Sample size for secondary study subjects: 534 patients of any sex and gender and Age > 18 years old**

- **Patients seen at Maimonides Medical Center, who meet the inclusion criteria**

Eligibility Criteria: Include inclusion and exclusion criteria.

Inclusion Criteria:

- All the Cardiac catheterization laboratory physician operators who consent to participate in the study
- Patients of any sex and gender.
- Age > 18 years old.
- Patients undergoing diagnostic coronary angiogram from in-patient and out-patient settings

Exclusion Criteria:

- History of prior CABG (Coronary Artery Bypass Surgery). CABG patients will be excluded due to inherent increased fluoroscopic time (finding grafts).
- Patients undergoing elective PCI (Percutaneous Coronary Intervention)
- Patients that have cognitive dysfunction

Data Collection Procedures:

Variables to be collected include:

Operator variables

- Primary operator's radiation exposure at the end of a case at four sites: right and left eye, thorax and abdomen
- Primary operator's normalized radiation dose exposure, measured by dividing cumulative dose by dose area product (CD/DAP)
- Primary operator's height, weight and body surface area

Patient variables

- medical record number
- dose area product (cGy.cm²) [radiation to patient]
- fluoroscopy time (minutes)
- amount of contrast delivered in cc's
- Milligray [radiation to patient]
- number of cineangiograms taken
- number of diagnostic catheters used for the exam
- age
- sex (female, male)
- race/ethnicity (white, black, Hispanic, East Asian (Chinese etc.), South Asian (India, Pakistan & surrounding areas), other
- height measured in centimeters
- weight measured in kilograms
- body mass index

- body surface area
- hypertension
- diabetes
- smoker
- previous coronary angiography
- chronic kidney disease
- distal radial approach used
- Presence of subclavian artery tortuosity

Statistical analysis:

Sample size:

- **Number of CCL physician operators as the primary study subjects: 10**
- Estimated number of participants to be screened as secondary study subjects: 1500
- Eligible participants to be included as the secondary study subjects in the study: 534
- Calculation for power analysis: Sample size was calculated using data from a previous study (Dominici et al., 2013). Left radial artery values were M=33, SD=37 μ Sv and right radial artery values were M=44, SD=32 uSV. Calculations were performed for a Mann Whitney test due to skewed data with alpha=0.05, power=0.90, a balanced study design, with a two tailed test, and adding 10% to each group for sample size for people who start the procedure but due to difficulty in catheter placement then cannot continue the procedure and need to use a different access site. This results in 267 participants for each of the left radial artery and right radial artery groups for a total of 534 participants.

Data Analysis:

- Biostatistician will be analyzing de-identified data and will guide statistical interpretation
- Descriptive statistics of mean and standard deviation will be used for the continuous variables. Frequency and percentage will be used for the categorical variables. Inferential statistics of the Mann Whitney test will be used to compare μ Sv values in operators between the left radial artery and right radial artery groups.

Expected Outcomes: Explain what you hope the study will determine.

We expect to find that using hyperadduction technique of the right arm can make operators radiation exposure from the hyperadducted right radial approach is less. The objective of this study is superiority with a power value of 80%.

References:

1.

Am Heart J. 2011 Jan; 161(1):172-9. doi: 10.1016/j.ahj.2010.10.003.
Transradial approach (left vs right) and procedural times during percutaneous coronary procedures: TALENT study.
Sciahbasi A¹, Romagnoli E, Burzotta F, Trani C, Sarandrea A, Summaria F, Pendenza G, Tommasino A, Patrizi R, Mazzari M, Mongiardo R, Lioy E.

2.

Operator exposure to x-ray in left and right radial access during percutaneous coronary procedures: OPERA randomised study.
Randomized controlled trial
Dominici M, et al. Heart. 2013.
Dominici M¹, Diletti R, Milici C, Bock C, Placanica A, D'Alessandro G, Arrivi A, Italiani M, Buono E, Boschetti E.

3.

JACC Cardiovasc Interv. 2014 Jul;7(7):810-6. doi: 10.1016/j.jcin.2013.11.026. Epub 2014 Jun 18.
Operator radiation exposure and physical discomfort during a right versus left radial approach for coronary interventions: a randomized evaluation.
Kado H¹, Patel AM¹, Suryadevara S¹, Zenni MM¹, Box LC¹, Angiolillo DJ¹, Bass TA¹, Guzman LA².

Eur Heart J 2008;29:63-70 Introduction RADIANT study

4.

Am Heart J. 2018 Feb;196:113-118. doi: 10.1016/j.ahj.2017.10.014. Epub 2017 Oct 28.
Determinants of radiation dose during right transradial access: Insights from the RAD-MATRIX study.
Sciahbasi A¹, Frigoli E², Sarandrea A³, Calabr [HYPERLINK](#)
"https://www.ncbi.nlm.nih.gov/pubmed/?term=Calabr%C3%B2%20P%5BAuthor%5D&cauthor=true&cauthor_uid=29421003" [d HYPERLINK](#)
"https://www.ncbi.nlm.nih.gov/pubmed/?term=Calabr%C3%B2%20P%5BAuthor%5D&cauthor=true&cauthor_uid=29421003" P⁴, Rubartelli P⁵, Cortese B⁶, Tomassini F⁷, Zavalloni D⁸, Tebaldi M⁹, Calabria P¹⁰, Rigattieri S¹¹, Zingarelli A¹², Sardella G¹³, Lupi A¹⁴, Rothenb [HYPERLINK](#)
"https://www.ncbi.nlm.nih.gov/pubmed/?term=Rothenb%C3%BCbler%20M%5BAuthor%5D&cauthor=true&cauthor_uid=29421003" [u HYPERLINK](#)
"https://www.ncbi.nlm.nih.gov/pubmed/?term=Rothenb%C3%BCbler%20M%5BAuthor%5D&cauthor=true&cauthor_uid=29421003" hler M¹⁵, Heg D¹⁵, Valgimigli M¹⁶.
Journal of the American College of Cardiology
Volume 69, Issue 20, May 2017 DOI: 10.1016/j.jacc.2017.03.018
PDF Article

5.

Radiation Exposure and Vascular Access in Acute Coronary Syndromes
The RAD-Matrix Trial

[Int J Cardiol.](#) 2014 Jan 15;171(1):66-72. doi: 10.1016/j.ijcard.2013.11.046. Epub 2013 Nov 23.

6.

Left radial access for percutaneous coronary procedures: from neglected to performer? A meta-analysis of 14 studies including 7,603 procedures.

[De Rosa S¹, Torella D¹, Caiazzo G¹, Giamp HYPERLINK](#)

["https://www.ncbi.nlm.nih.gov/pubmed/?term=Giamp%C3%A0%20S%5BAuthor%5D&cauthor=true&author_uid=24331866"](https://www.ncbi.nlm.nih.gov/pubmed/?term=Giamp%C3%A0%20S%5BAuthor%5D&cauthor=true&author_uid=24331866)à [HYPERLINK](#)

["https://www.ncbi.nlm.nih.gov/pubmed/?term=Giamp%C3%A0%20S%5BAuthor%5D&cauthor=true&author_uid=24331866"](https://www.ncbi.nlm.nih.gov/pubmed/?term=Giamp%C3%A0%20S%5BAuthor%5D&cauthor=true&author_uid=24331866) S¹, Indolfi C².

7.

[Braz J Med Biol Res.](#) 2015 Aug; 48(8): 743–750.

Published online 2015 Jun 23. doi: [10.1590/1414-431X20154571](#)

PMCID: PMC4541695

[Comparative efficacy and safety of the left versus right radial approach for percutaneous coronary procedures: a meta-analysis including 6870 patients](#)

[S.L. Xia, X.B. Zhang, J.S. Zhou, and X. Gao](#)

8.

[JACC Cardiovasc Interv.](#) 2015 Aug 17;8(9):1189-1196. doi: 10.1016/j.jcin.2015.03.026.

Epub 2015 Jul 22.

[Effect of Vascular Access Site Choice on Radiation Exposure During Coronary Angiography: The REVERE Trial \(Randomized Evaluation of Vascular Entry Site and Radiation Exposure\).](#)

[Pancholy SB¹, Joshi P², Shah S³, Rao SV⁴, Bertrand OF⁵, Patel TM⁶.](#)

9.

[Clin Interv Aging.](#) 2015; 10: 1003–1008.

Published online 2015 Jun 24. doi: [10.2147/CIA.S81568](#)

PMCID: PMC4484656

10.

[Randomized comparative study of left versus right radial approach in the setting of primary percutaneous coronary intervention for ST-elevation myocardial infarction](#)

[Qiang Fu, Hongyu Hu, Dezhao Wang, Wei Chen, Zhixu Tan, Qun Li, and Buxing Chen](#)