

State of the Art in Radiation Safety During Fenestrated EVAR

A discussion of radiation exposure during FEVAR.

BY MELISSA KIRKWOOD, MD; DAVID TIMARAN, MD; AND CARLOS TIMARAN, MD

Fluoroscopically guided interventions (FGIs) are increasing in number and complexity. Vascular surgeons who routinely perform FGIs, as well as their patients, are at risk of significant radiation exposure and the potential associated harmful deterministic and stochastic effects. Deterministic effects result from a predictable dose-related response with a threshold below which the effect is unlikely to occur, such as skin injury and cataract development. Stochastic effects (ie, cancer formation) have a probability of occurrence that increases with dose, but the severity is dose independent.¹

The Zenith Fenestrated (ZFEN) endovascular graft (Cook Medical) is available for implantation in abdominal aortic aneurysms with short infrarenal necks. This graft can be designed with three fenestrations/scallops at most, each with its own restrictions with respect to location and positioning in the proximal aspect of the graft. There is at least 1 month of manufacturing time required for the device. Multicenter studies have shown that it is a safe and effective tool with low morbidity and mortality in properly selected patients.² Because of the increased complexity of fenestrated endovascular aortic aneurysm repair (FEVAR) using the ZFEN device, the purpose of the study described in this article was to assess patient and operating room staff radiation exposure during FEVAR. Device design was also assessed in terms of radiation dose during FEVAR.

METHODS

In our most recent series, we evaluated 79 FEVARs, performed by a single surgeon on the Allura Xper FD20 fluoroscopy system equipped with AlluraClarity technology (Philips Healthcare). Radiation doses to the operating room staff were measured using a personal dosimetry system (DoseAware, Philips Healthcare) worn on the outside of the lead apron at the left upper chest position. Before each procedure, dosimeters were reset and the cumulative reading for each participant was immediately collected following the case from the in-room display monitor. Procedure type, patient body mass index (BMI), reference air kerma (RAK), and kerma area product (KAP) were recorded. RAK and KAP were corrected for BMI based on

an exponential fit of fluoroscopy dose rate and the dose per radiographic frame. Operator dose was corrected for BMI by the ratio of normalized to measured KAP. A one-sided Wilcoxon rank sum test was used to compare personnel radiation doses, RAKs, and KAPs between device design and level of fenestration. The statistical significance was $P \leq .05$.

RESULTS

ZFENs showed relatively low mean RAK (1,800 mGy), KAP (210 Gy-cm²), primary operator dose (220 μSv), assistant operator dose (60 μSv), circulating nurse dose (10 μSv), and scrub nurse dose (10 μSv). When compared to more complex investigational custom-made devices, ZFENs had significantly lower patient, primary and assistant operator, and operating room personnel dose. Two-vessel fenestration cases tended to have a lower RAK (1,600 mGy vs 2,670 mGy) and KAP (240 mGy-cm² vs 320 mGy-cm²) compared to three-vessel fenestrations, but this trend did not reach significance.

DISCUSSION

The appropriate use of operating factors, as well as the interventionalist's knowledge regarding best practice guidelines during fluoroscopy, greatly contributed to radiation dose. All endovascular surgeons should be properly trained in radiation safety and adhere to using radiation doses that are "as low as reasonably achievable" (ie, the ALARA principle).³ When these tenets are applied, surgeons are able to lower radiation dose during FGIs.⁴ However, even with ALARA compliance, procedure type and case complexity remain major factors in determining dose. We have shown that FEVAR is the highest-dose procedure performed by vascular surgeons in our practice.⁴ Furthermore, surgeon and trainee doses are significantly higher with FEVARs compared to other complex FGIs.⁵ Additional factors that affect dose during FEVAR include patient BMI, operator position around the angiographic table, the use of dose-lowering software and adjunctive lead shielding, as well as procedure-related factors including level of fenestration and device design.^{4,6}

Patient obesity is a risk factor for increased dose because higher radiation doses are needed to penetrate the body in larger patients; therefore, obese patients are exposed to higher levels of radiation for the same procedure compared to thinner patients.^{1,7} In terms of surgeon dose, we have found that standing at the left brachial artery position when the C-arm is on the left is the highest-dose position for FEVAR, followed by standing closest to the flat panel detector on the right side of the patient. Both of these positions result in roughly twice as much dose as the assistant operator who stands one position down from the patient on the right side.⁵ Routine use of the table-mounted lead skirt also significantly decreases surgeons' lower body dose.⁵

Advances in new image processing and noise-reduction software can also reduce radiation dose during FEVAR. We have shown that the addition of AlluraClarity technology reduces both the fluorography and fluoroscopy dose rates by about 50% for FEVAR.⁶ It is essential that endovascular surgeons stay current with new software developments that can minimize dose.

The greatest concern regarding radiation dose during FEVAR is the risk for patient skin injury. A threshold dose of 2 Gy has widely been reported.⁸ We have not had any events of skin injury in either our retrospective or prospective FEVAR study with mean RAK doses well above the threshold dose of 2 Gy.^{9,10} This demonstrates that FEVAR is safe for patients and operators; nevertheless, the risk of potential harm is real and every attempt must be made to mitigate the risks by limiting exposure. ■

1. Brown KR, Rzucidlo E. Acute and chronic radiation injury. *J Vasc Surg.* 2011;53(1 suppl):155-215.

2. Oderich GS, Greenberg RK, Farber M, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. *J Vasc Surg.* 2014;60:1420-1428 e1-5.

3. US Food and Drug Administration. Avoidance of serious x-ray-induced skin injuries to patients during fluoroscopically-guided procedures. <https://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm116677.pdf>. Published September 9, 1994. Accessed September 8, 2017.

4. Kirkwood ML, Arbique GM, Guild JB, et al. Surgeon education decreases radiation dose in complex endovascular procedures and improves patient safety. *J Vasc Surg.* 2013;58:715-721.

5. Kirkwood ML, Guild JB, Arbique GM, et al. Surgeon radiation dose during complex endovascular procedures. *J Vasc Surg.* 2015;62:457-463.

6. Kirkwood ML, Guild JB, Arbique GM, et al. New image-processing and noise-reduction software reduces radiation dose during complex endovascular procedures. *J Vasc Surg.* 2016;64:1357-1365.

7. Hymes SR, Strom EA, Fife C. Radiation dermatitis: clinical presentation, pathophysiology, and treatment 2006. *J Am Acad Dermatol.* 2006;54:28-46.

8. Balter S, Hopewell JW, Miller DL, et al. Fluoroscopically guided interventional procedures: a review of radiation effects on patients' skin and hair. *Radiology.* 2010;254:326-341.

9. Kirkwood ML, Arbique GM, Guild JB, et al. Radiation-induced skin injury after complex endovascular procedures. *J Vasc Surg.* 2014;60:742-748.

10. Kirkwood ML, Arbique GM, Guild JB, et al. Deterministic effects after fenestrated endovascular aortic aneurysm repair. *J Vasc Surg.* 2015;61:902-906.

Melissa Kirkwood, MD

Assistant Professor of Surgery
Division of Vascular and Endovascular Surgery
UT Southwestern Medical Center
Dallas, Texas
Disclosures: None.

David Timaran, MD

Postdoctoral Scholar
UT Southwestern Medical Center
Dallas, Texas
Disclosures: None.

Carlos Timaran, MD

Chief of Endovascular Surgery
G. Patrick Clagett Professor in Surgery
Division of Vascular and Endovascular Surgery
UT Southwestern Medical Center
Dallas, Texas
carlos.timaran@utsouthwestern.edu
Disclosures: Receives research support and consulting and proctoring fees from Cook Medical.