



GET IT DONE WITH ONE

DIAMONDBACK 360®
CORONARY ORBITAL ATHERECTOMY SYSTEM



SANDS INTIMAL



FRACTURES MEDIAL

TREATS SEVERELY CALCIFIED LESIONS FOR OPTIMAL STENTING.

[SEE HOW IT WORKS](#)

CSI. | CARDIOVASCULAR
SYSTEMS, INC.

Indication: The Diamondback 360® Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to de novo, severely calcified coronary artery lesions. **Contraindications:** The OAS is contraindicated when the ViperWire Advance® Coronary Guide Wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children. **Warnings/Precautions:** Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS was only evaluated in severely calcified lesions; A temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25% has not been evaluated. See the instructions for use before performing Diamondback 360 coronary orbital atherectomy procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. **Caution:** Federal law (USA) restricts this device to sale by, or on the order of, a physician.

Medical simulation in interventional cardiology: “More research is needed”

Peter Tajti, MD^{1,2}  |

Emmanouil S. Brilakis, MD, PhD¹ 

¹Minneapolis Heart Institute, Abbott Northwestern Hospital, Minneapolis, Minnesota

²Division of Invasive Cardiology, Second Department of Internal Medicine and Cardiology Center, University of Szeged, Szeged, Hungary

Correspondence

Emmanouil S. Brilakis, MD, PhD, Minneapolis Heart Institute, 920 E 28th Street #300, Minneapolis, MN 55407.
Email: esbrilakis@gmail.com

Key Points

- Medical simulation is being used for training fellows to perform coronary angiography.
- Medical simulation training was associated with 2 min less fluoroscopy time per case after adjustment.
- Whether medical simulation really works needs to be evaluated in additional, well-designed and executed clinical studies.

Training cardiology fellows to perform coronary angiography has traditionally been performed by observing cases and gradually performing the clinical tasks involved (obtaining arterial access, engaging the coronary arteries, injecting contrast and obtaining appropriate views, and achieving hemostasis). Training usually takes place during the first year of fellowship, with the advanced fellows often teaching younger fellows later during the course of fellowship (“see one, do one, teach one” concept). This training process is not perfect (there is risk for complications, the quality of education varies depending on the instructors and trainees, and it may be lengthy), but it works. Medical simulation can replicate some of the tasks required during cardiac catheterization and, as a result, allow teaching and practice without exposing patients to risk for complications and being flexible to accommodate each person’s

learning pace. Several simulators have been developed for coronary angiography and percutaneous coronary (as well as peripheral and structural) interventions, but there is limited data on whether and to what extent they are beneficial [1].

In this issue of the journal, Prenner et al. report their experience with use of the Procedicus VIST@-C endovascular system (Mentice, Gothenburg, Sweden). The system was used for 6 months (January to June 2013) at the Northwestern Memorial Hospital to train 12 fellows, whose procedural metrics were compared with 20 fellows who were trained between 2011 and 2015 without use of simulation [2]. Analysis was challenging due to growing use of radial access during the study period, but after adjustment fluoroscopy time was shorter by 2 min in fellows who had simulation training as compared with those who did not. There was minimal or no difference in fluoroscopy time among cases performed via femoral access, with the differences being concentrated in radial access cases.

What are the lessons from the study? First, the learning curve for cardiac catheterization via radial access is steeper than via femoral access. Approximately 30–50 cases are needed to achieve initial competence for procedures performed through the radial artery [3]. Second, simulation training can shorten (although slightly) this curve. Third, the time used for simulation training in the present study (3 hr) was small. The study has several weaknesses: non-randomized, design, controls from various time periods antedating and postdating the simulation training, combined didactic and simulation training during the same training session, change of access site patterns during the study, no data on complications, and no data on the quality of angiography. Improved simulators and simulations are also needed: the system used in the present study provides training on catheter engagement but does not include an X-ray gantry or real-time feedback on using optimal angulations, or avoiding using X-ray when not looking at the screen. It also does not provide training on how to obtain arterial access. Even though it appears improbable that simulation would teach the fellows harmful habits and adversely impact their developing skills, in a prior study in Sweden simulation training was associated with longer fluoroscopy time (360 [IQR 245–557] min vs. 289 [IQR 179–468] min, $P < 0.001$) and higher rate of complications (4.33% vs. 1.86%, $P < 0.001$), particularly when femoral access was used (6.25% vs. 2.53%, $P < 0.001$) [4]. Even if simulation training reduces fluoroscopy time for each trainee, this reduction will likely be limited to the initial training phase, since growing clinical experience would probably efface any differences in procedural efficiency gained by simulation over the long run.

Should simulation training be universally implemented for training in cardiac catheterization? The answer in our opinion is “not quite yet,” as it is unclear at present that the anticipated benefits exceed the associated risks and costs. Anticipated benefits include lower radiation

dose [5], potential avoidance of complications, and less stressful learning experience for the trainees. However, the supporting data is limited and weak. Moreover, there is a risk that the simulator may provide sub-optimal or non-realistic training resulting in trainee over-confidence and worse clinical outcomes. The simulator cost is currently approximately \$90,000, which is a steep price tag for many institutions to cover in this era of declining reimbursements and for an essentially unproven intervention. However, cost could decrease, for example by sharing a simulation among multiple institutions or leasing it for a few days every year, given fellow rotation. Also, preventing even a few complications could quickly recover the cost of the device.

“More research” may sound cliché, but is what the field of simulation in interventional cardiology truly needs. While the authors should be congratulated for providing data in this rapidly evolving field, additional high-quality studies are important to guide further development and implementation of medical simulation.

CONFLICT OF INTEREST

Peter Tajti, MD: none; Emmanouil S. Brilakis, MD, PhD: consulting/speaker honoraria from Abbott Vascular, ACIST, Amgen, Asahi, CSI, Elsevier, GE Healthcare, Medicare, Medtronic, and Nitiloop; research support from Boston Scientific and Osprey. Board of Directors: Cardiovascular Innovations Foundation. Board of Trustees: Society of Cardiovascular Angiography and Interventions.

ORCID

Peter Tajti MD  <http://orcid.org/0000-0002-3449-7604>

Emmanouil S. Brilakis MD, PhD  <http://orcid.org/0000-0001-9416-9701>

REFERENCES

- [1] Jacobs AK, Babb JD, Hirshfeld JW Jr, Holmes DR Jr; Society for Cardiovascular Angiography and Interventions. Task force 3: Training in diagnostic and interventional cardiac catheterization endorsed by the Society for Cardiovascular Angiography and Interventions. *J Am Coll Cardiol* 2008;51:355–361.
- [2] Prenner SB, Wayne DB, Sweis RN, Cohen ER, Feinglass JM, Schimmel DR. Simulation-based education leads to decreased use of fluoroscopy in diagnostic coronary angiography. *Catheter Cardiovasc Interv* 2018;91:1054–1059.
- [3] Hess CN, Peterson ED, Neely ML, Dai D, Hillegass WB, Krucoff MW, Kutcher MA, Messenger JC, Pancholy S, Piana RN, Rao SV. The learning curve for transradial percutaneous coronary intervention among operators in the United States: A study from the National Cardiovascular Data Registry. *Circulation* 2014;129:2277–2286.
- [4] Jensen UJ, Jensen J, Olivecrona G, Ahlberg G, Lagerquist B, Tornvall P. The role of a simulator-based course in coronary angiography on performance in real life cath lab. *BMC Med Educ* 2014;14:49.
- [5] Christopoulos G, Makke L, Christakopoulos G, Kotsia A, Rangan BV, Roesle M, Haagen D, Kumbhani DJ, Chambers CE, Kapadia S, Mahmud E, Banerjee S, Brilakis ES. Optimizing radiation safety in the cardiac catheterization laboratory: A practical approach. *Catheter Cardiovasc Interv* 2016;87:291–301.