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EDITORIAL COMMENT

Percutaneous Aortic Valves and Imaging*

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Advances in management of complex health problems raise the expectations of consumers but also increase the cost of health care. Patients with severe aortic stenosis and multiple comorbidities not only want to get their aortic valve replaced with a minimally invasive approach but also want to accomplish this more safely than with conventional methods. The economic

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impact of such technologies challenges the providers who are asked to reduce health care costs. Commitment to safety while reducing cost makes this challenge particularly difficult to meet. In this issue of *iJACC*, Bagur et al. (1) propose the use of transesophageal echocardiography (TEE) as a primary imaging technique for transapical transcatheter aortic valve implantation (TAVI) to obviate the need for a hybrid operating room with state-of-the-art fluoroscopic imaging equipment.

The most critical factor with respect to inserting new percutaneous devices is accurate positioning, and this also holds true for mitral, tricuspid, and aortic valves, and endovascular aortic devices. Usually, radiography (fluoroscopy and angiography) is the primary imaging modality during device implantation. Echocardiography is frequently used as an adjunct imaging tool. Computed tomography (CT), which is critical in preparing for the procedure, is increasingly integrated with intraprocedural imaging. The fusion of images from various modalities is rapidly evolving with 3-dimensional (3D) visualization of anatomy and devices. Fluoroscopy has a large field of view and depicts 3D information on a 2-dimensional (2D) monitor, whereas echocardiography can show 2D or 3D information that limits field of view on mostly 2D monitors. Details of the devices are much better seen on radiographic imaging, whereas noncalcified tissues are better visualized by ultrasound. As with the cup/glass analogy, the observation of fullness can be differently determined depending on cup material, shape, and angle of viewing. For example, an opaque bone china cup examined from the side is better imaged by radiographic beam, but ultrasonic sound waves are fine for a paper cup and better if viewed or imaged from above. Similarly, the aortic valve hinge points, in a calcified aortic valve or porcelain root, are better imaged radiographically (either by pre-operative CT or intraoperatively by fluoroscopy), whereas in a noncalcified valve the imaging is better assessed with TEE unless more contrast is used for fluoroscopy. At present, most TAVI centers have adopted the technique of positioning the Edwards SAPIEN valve (Edwards Lifesciences, Inc., Irvine, California) at 50-50 (i.e., one-half the valve "aortic" in relation to the valve hinge points, and one-half "ventricular") (2–4). Therefore, for a heavily calcified valve the perception of "half empty" is best determined by fluoroscopy when examining the part of the valve above the aortic valve hinge points, whereas TEE is the better method for assessing the "half full" part of the ventricular side of the device in relation to the hinge points and the mitral valve anterior leaflet.

In our early experience with the transapical approach in animals, we found that TEE was more useful because of their lack of calcium (2). Similarly, we also tried intracardiac echocardiography, but the technology at that time was neither adequate nor advanced enough. Furthermore, we also found this approach was not useful in humans. However, once human studies commenced, the change occurred quite rapidly in imaging using C-arms to hybrid operating rooms, and we found that improved radiographic techniques proved to be more useful in many patients than TEE. Indeed, over time, be-

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cause of the poor visualization with C-arms, for the Partner Edwards SAPIEN valve trial, C-arms were disallowed, and patients had to have their imaging done in either a hybrid operating room or a catheterization lab operating room with adequate airflow standards (3–5). Intraprocedural TEE with 3D imaging provides critical information, such as delineating the location of the guidewire in the left ventricle to ensure that it is not entangled in the chordae. This was a potential problem in the early period of transapical procedures. Furthermore, the aortic and mitral valves can also be well-imaged, in addition to looking at the 3D images of the leaflets, and the axis of insertion can be carefully studied. Of note, Doppler signals are essential for assessing valve function and device leaflet function, whereas radiographic techniques are not as useful. A caveat, however, exists for TEE when the calcium load is high in the leaflets or the root is calcified or there is moderate-to-severe mitral annular calcification, particularly anteriorly, involving the anterior mitral valve leaflet or the left coronary or noncoronary sinus, because in these situations ultrasound visualization is suboptimal. By contrast, when there is little calcification of the aortic valve leaflets or annulus, then fluoroscopy might be inadequate for examining the aortic root unless repeated injections of contrast are used during the procedure. In this latter situation, injection of the aortic root with a pigtail catheter with contrast during the period of inflation is sometimes required to check for positioning during inflation of the device balloon. Although intraoperative 3D CT images can be obtained during rapid fluoroscopic rotation imaging with contrast injections of the root, such as with the Dyna CT (Siemens, Erlangen, Germany), these images are still not accurate enough when no calcium landmarks are available or registry points are present. Undoubtedly, the technology will improve over time and enable the generation of intraprocedural rotational CT-like images to help with placement. Use of fluoroscopy requires contrast dye, but intraoperative dose can be reduced considerably with proper planning by routinely pre-operatively obtaining the best angle of the aortic root and the nadir of the sinuses both during coronary catheterization and pre-operative root CT angiography with 3D reconstruction (6).

Is one better than the other in telling whether the cup is half full or half empty? Clearly, depending on the circumstances, one might be more useful than the other, and they should not be considered mutually exclusive but complementary, ensuring valve positioning is accurate. Will changes in device design influence the choice of imaging modality in the future? Better radiographic markers on the deployment balloon and the current stainless steel cage and new chromium carbide valves certainly would help, but so would having echocardiographic contrast media in the device or balloon or in the inflation liquid. Bubbles in the injection medium are seen during inflation on echocardiography during the balloon valvuloplasty, but this does not really help with positioning. Although we continue to use 3D imaging to look at the device in relation to the leaflets in the aortic root before deployment, we have not found this reliable enough, because of the leaflet thickness or calcium. Also, it is often difficult to visualize the crimped valve over the balloon, particularly in cases with heavy aortic root calcification. Clearly, the imaging techniques are complementary and increase the confidence in valve placement when used together. It is obvious that without fluoroscopy, the entire procedure is infeasible; in other words, the procedures have to be done in suites with proper radiographic equipment for the near future. TEE is helpful for accurate device placement, but more importantly it is also used to monitor, identify, prevent, and manage complications. In most cases, fluoroscopy with radiographic contrast is the leading technique, with the role of TEE being principally to assess residual aortic regurgitation and perivalvular leakage. Severe regurgitation is less common, and an argument can be made for not using TEE but rather intracardiac echocardiography or transthoracic echocardiography, and hence some centers in Europe forgo TEE, particularly when patients are only sedated for procedures.

In this issue of *iJACC*, Bagur et al. (1) present their experience by comparing radiographically placed valves with C-arms against TEE placement, and they advocate positioning by primarily TEE. Of note, the population that they deal with is somewhat different from the other TAVI populations. The patients are younger (79 years of age), have lower Society of Thoracic Surgeons score (8.5%) and European System for Cardiac Operative Risk Evaluation score (25.8%), and are smaller and therefore likely to have a smaller valve area with less calcium than a larger person. None are reported to have either a porcelain aorta or radiation heart disease or mitral annular calcification, which are associated more often with heavy calcification or porcelain aortas. Thus, for the population of the Quebec group, TEE imaging might have been more useful. Indeed, none of the submitted images show much calcium on the radiographic studies. The Quebec group C-arm imaging might also have been inadequate for positioning of devices. Better radio-

graphic imaging, including dedicated room fluoroscopic imaging, might have prevented the left main artery occlusion problems they experienced, and they could have better dealt with the other problems; for example, putting a wire in a coronary artery before deployment of the device can be used for coronary procedures. The obvious question is whether reliance on TEE affected outcome—particularly on malpositioning—and associated complications, which occurred in 12% of their patients in both groups (embolization, malposition, coronary occlusion, and the like). These malposition problems could likely have been reduced with proper radiographic imaging with state-of-the-art (biplane or robotic) systems in a hybrid procedure operating room or a catheterization lab. Hence, the call for use of only TEE is questionable, and similarly, the need for a randomized trial is not justified. The only potential benefit from using TEE alone is that of cost and possibly to avoid the complication of renal failure, although none occurred in their radiographic group and only 1 occurred in the TEE group. Clearly when newer procedures are a combination of both percutaneous coronary intervention and TAVI, then dye contrast load will become a greater issue, as likely will radiation dose. Currently this is not a problem. It is prudent to be extremely judicious about the use of radiographic contrast, but a small amount necessary for visualization of aortic root during implantation should be tolerated by most patients. Another peculiarity of the study group was that prevalence of mitral valve regurgitation was much more common in the TEE group. Whether this was related to the selection of patients or the increasing enrollment of patients with severe mitral valve regurgitation in their transapical group remains unclear. Nonetheless, in the Partner B study, those patients with severe mitral valve regurgitation had the most benefit out to 1 year as assessed by the relative risk analysis (3).

Ultimately, we have been strong advocates of the team approach for percutaneous valve insertion, and this applies also to imaging. We consider both TEE and radiographic techniques to be essential. Whether biplane is required or a robotic arm is better is still debatable. We believe diligent preparation with both pre-operative CT of the root and root aortography, intraoperative TEE, and fluoroscopic imaging in a hybrid operation room is essential for the best possible result. Indeed, in just under 100 transfemoral TAVI patients, we have had excellent results and no patient requiring dialysis, and for 40 transapical TAVI patients our operative mortality has been low, with 1 renal failure. We thus continue to believe that, as long as cost is not the issue, better results will be obtained by a combination of both sound waves and radiation beams. Undoubtedly with fusion of echocardiographic and radiographic imaging and newer devices that make positioning easier and more controlled, complications from malpositioned devices should decline. Furthermore, these modalities will continue to be complementary and additive for newer mitral valve devices, endovascular aortic procedures, and other procedures.

In summary, although it is provocative to rely on only 1 imaging modality (TEE in this case, and many other reports suggesting radiography as the only imaging modality), it does not make practical sense to close "one eye" to assess whether the cup is half full during the procedure in the environment where we are trying to perfect a new technique and potentially make it applicable for low-risk patients. It would be prudent to use all our imaging power to make the procedure as safe as possible for the current devices, particularly in centers that are commencing their use. With the advent of newer devices and more experience, more focus can be directed toward the cost of the procedure.

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