

EDITORIAL COMMENT

To Size or Not to Size— There Is No Question

Balloon Sizing for Transcatheter Aortic Valve Replacement*

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When the association of paravalvular leak (PVL) and increased mortality was first described in 2012 at the 2-year PARTNER I presentation (1), the transcatheter aortic valve replacement (TAVR) community reacted with great concern that this promising technology was beginning to show signs of weakness. Since then, a great deal of data has been reported from multiple registries confirming this association. Despite this research, a causal relationship between PVL and mortality has not been proved, and the most effective method of preventing PVL is still unknown.

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The relationship of PVL and mortality is somewhat perplexing because even mild PVL has been associated with increased mortality. Although the majority of TAVR cases have some PVL post-implantation, it is important to note that the vast majority of these patients do well. As a result, most investigators have considered PVL that is “more-than-mild” as significant. The problem with these analyses is that the amount of PVL is based on qualitative echocardiographic observation. The pitfall of a qualitative echocardiographic approach is that the interobserver variability prevents true standardization. This variability likely has resulted in downgrading the amount of PVL actually present. Causal data have not yet been published regarding PVL and mortality, but anecdotal experience from high-volume operators has been reported at meetings, and moderate to severe PVL that is corrected by transcatheter repair resolves the symptoms of heart failure in TAVR patients. Newer indexes that quantify PVL, including aortic regurgitation (AR index), Pressure gradient between diastolic aortic pressure and left ventricular end-diastolic pressure ($\Delta P_{DAP-LVEDP}$), and ratio

of diastolic over systolic pressure time integral (DPTI:SPTI), may help clarify this issue. Our center routinely uses cardiac magnetic resonance imaging to measure the aortic regurgitant fraction after TAVR.

Although the degree of aortic calcification and correct placement of the transcatheter heart valve (THV) are important, the most important and modifiable cause of PVL is inappropriate sizing of the aortic annulus. Historically, the selection of the appropriate THV size has been based on 2-dimensional annular measurements using echocardiography. Due to the limitations inherent in 2-dimensional imaging, echocardiography was quickly surpassed by 3-dimensional computed tomography (CT) annular measurements, now considered the gold standard for valve sizing. Anecdotal data and registry data from high-volume centers suggested that optimal fit requires 10% to 15% oversizing of the annulus area by the balloon-expandable THV (2); however, this has not been validated in a prospective trial or a retrospective comparative trial. Comparing current with historical data (PARTNER I), more-than-mild PVL has been decreased from 12% using 2-dimensional echocardiography to 7.5% using CT (3) and <5% in other series. The selection of self-expanding valves has been largely based on CT scan circumference that also targets a 15% oversize. The risk of significantly oversizing is annular rupture, aortic hematoma, or heart block.

Although the CT revolution has been sweeping the TAVR community, there are a few investigators who have championed the idea that the balloon used during aortic valvuloplasty can be used as a valve sizer, similar to that used by a surgeon before surgical aortic valve replacement. The advantage of such a technique is that balloon valvuloplasty is part of most TAVR procedures and that the sizing can be directly determined rather than indirectly measured using only imaging. The idea was first described by our group using balloon pressure measurements (4,5), but gained popularity when balloon sizing with concomitant angiography was described by Alain Cribier and Helene Eltchaninoff, personal communication, 2010. This version of the technique was considerably simpler and thus disseminated successfully during proctoring of cases outside the United States and Canada. The idea was that a stop-flow diameter could be established and help differentiate annulus size in borderline cases. It also allowed on-table decisions and obviated the need for larger contrast loads that were prohibitive in patients with renal insufficiency (~20% of cases).

Patsalis et al. (6) from the West German Heart Center in Essen, Germany carefully describe their experience with balloon sizing and aortography, with a retrospective comparison with their earlier experience using conventional echocardiography sizing. The incidence of more-than-mild PVL was decreased from 14.4% to 7.8% without increasing the risk of stroke, transient ischemic attack, native aortic insufficiency, or

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annular damage. The decrease in PVL was associated with a significant decrease in mortality at 1 year, from 20% to 10.6%. For the first time, a technique used for the correct selection of THV was shown to affect both PVL and perhaps mortality, and the authors are to be commended.

So what are the technical caveats? First, the balloons need to be measured before they are used in order to be accurate. Second, aortography needs to be done close to the aortic valve commissures (the source of the leak). The pigtail catheter is placed in the noncoronary cusp or at the sinotubular junction. The diameter of the THV should be the same size as the balloon if contrast is power injected or the THV should be 1 mm larger than the balloon diameter if contrast is hand injected. Finally, even minimal leak around the balloon should identify insufficient size and indicate the choice of the larger THV in borderline cases.

So do the outcomes reported by Patsalis et al. reflect increasing experience or the incorporation of balloon sizing? Certainly there is some bias toward better outcomes with increasing experience; however, 39% of cases in the balloon-sizing group were considered borderline by an experienced operator. In this group, only 1 patient ended up with more-than-mild PVL, despite choosing the smaller THV size in 25% of patients. Importantly, there is little downside to balloon sizing, presumably because a more aggressive predilation with sizing decreased the need for post-dilation.

Does that mean balloon sizing, not CT, is the new gold standard for THV size selection? Certainly, the technique of balloon sizing and CT sizing are not adversarial but complementary. Most TAVR operators can agree that although the best method of sizing is not known, complementary techniques will corroborate the best THV size. In a time of cost containment and resource utilization, techniques such as balloon sizing and 3-dimensional echocardiography may fare better than cardiac CT.

TAVR devices continue to evolve rapidly, specifically for repositionable and retrievable attributes. Perhaps the

emphasis on valve sizing will become less intense as “1-shot” devices are replaced with those that can be dynamically sized and repositioned. The protocol for THV selection may also change as the new shapes of self-expanding and balloon-expandable devices with specialized skirts come to market. For now, balloon sizing using one of the oldest forms of imaging, cine-angiography, remains a worthy contributor to the new world of TAVR.

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