

The real problem here is that we would like to know whether a patient fares better with one treatment instead of the other in terms of hard clinical endpoints, whereas all of these angiographic endpoints are just surrogates. Besides, minimal lumen diameter is far from being a perfect endpoint. In a given segment, what is important is to know how many stenoses are there, not just the narrowest one, because the impact on distal flow and its turbulence is determined by all of them. In this regard, recent developments suggest using different endpoints to have more reliable substitutes of clinical endpoints: 1) intravascular imaging to depict more detailed and comprehensive anatomic information and to inform on the best treatment strategy; and 2) physiology-derived data, including new noninvasive tools such as quantitative flow ratio, to provide more reliable information (functional significance) on the vessel flow distal to the lesion(s).

In the end, we believe that dogmas in interventional cardiology should not exist: any endpoint is the son of its period, and the endpoint of tomorrow is always a better one.

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TO THE EDITOR

Transcatheter Pulmonary Valve Replacement With 32-mm Balloon-Expandable Prosthesis



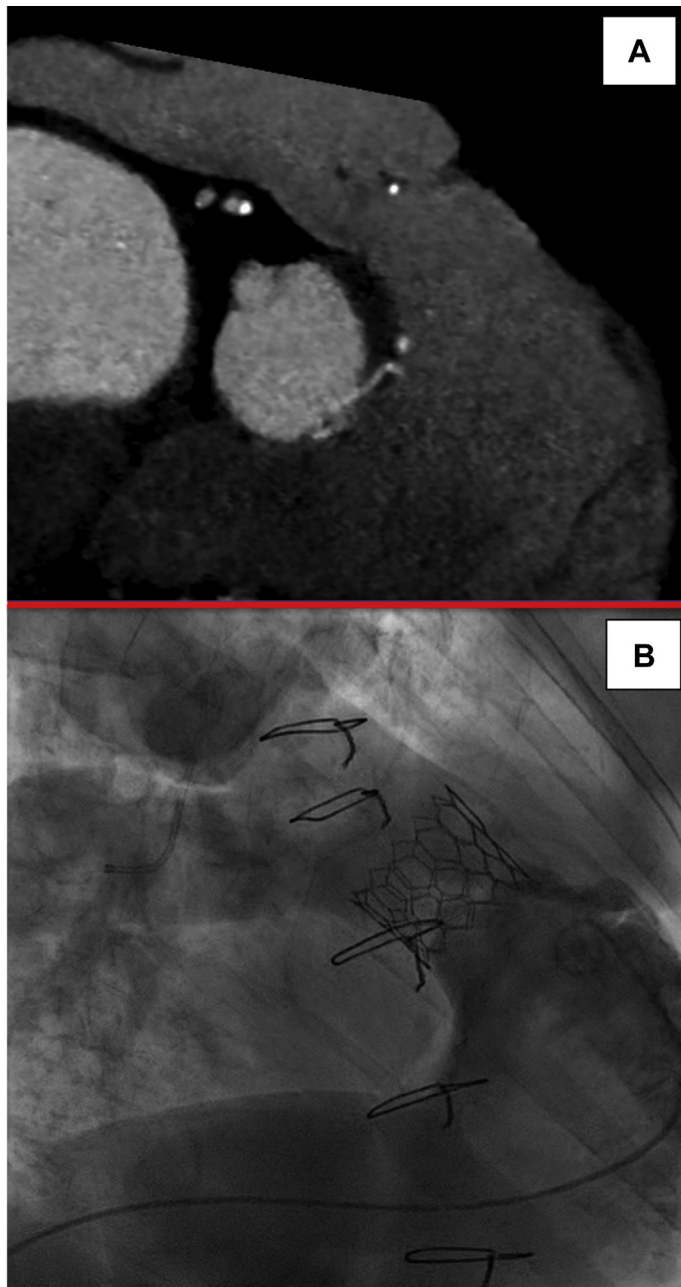
Another Strategy in Mildly Dilated RVOT

Congenital and acquired pulmonary valve disease has been shown to be suitable for transcatheter pulmonary valve replacement. However, right ventricular outflow tract (RVOT) morphology and dimension may limit implantation of currently available devices. Kamioka et al. (1) recently showed how downsizing the RVOT using commercially available endografts could allow implantation of a 29-mm Sapien-3 valve (Edwards Lifesciences, Irvine, California) even in severely dilated RVOT. We would like to suggest another possibility to treat mildly dilated RVOT: oversizing of a large balloon-expandable prosthesis.

A patient recently presented with severe pulmonary regurgitation, severe right ventricle overload, and effort dyspnea 41 years after surgical Fallot correction. Computed tomography revealed an RVOT landing zone diameter of 27.8 mm (area 604 mm²). Without landing zone calcification (Figure 1), a 20% area oversizing was considered necessary for balloon-expandable prosthesis anchoring, thus achieving an area of 725 mm². A 29-mm balloon expandable valve was deemed too small to fit in this anatomy.

Myval (Meril Life Sciences, Gujarat, India) is a balloon-expandable prosthesis that recently gained CE approval for larger sizes (30.5 mm and 32 mm) in the aortic position. The 32-mm Myval fits virtual basal ring ranging from 700 to 840 mm² and was deemed suitable for this RVOT anatomy. A Lunderquist wire (Cook Medical, Bloomington, Indiana) was advanced over a multipurpose catheter in the right pulmonary artery. The prosthesis was then implanted easily in the RVOT landing zone, achieving ideal anchoring with no paravalvular leak (Figure 1). Post-procedural course was uneventful. Follow-up echocardiography showed normal transprosthetic gradient (mean gradient 8 mm Hg) and no paravalvular leak.

This case highlights how significant oversizing (up to 20%) of balloon-expandable prosthesis may be a valuable option for transcatheter pulmonary valve replacement with mildly dilated RVOT, thus avoiding endograft implantation.

FIGURE 1 Pre-Procedural CT Scan and Prosthesis Implantation

(A) CT showing RVOT landing zone area with no calcification. (B) Prosthesis implanted with no pulmonary regurgitation. CT = computed tomography; RVOT = right ventricular outflow tract.

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REPLY: Transcatheter Pulmonary Valve Replacement With 32-mm Balloon-Expandable Prosthesis



Another Strategy in Mildly Dilated RVOT

We appreciate the comments by Dr. Ancona and colleagues regarding our recent work (1). The anatomic complexities of a large right ventricular outflow tract (RVOT) in palliated congenital heart disease patients brings both challenges and opportunities to transcatheter pulmonary valve implantation. As congenital heart disease patients become older, their candidacies for open surgical procedures may become more limited, making the possibility of transcatheter options more appealing, and in some cases the only option. Modifications of existing transcatheter technologies have long been embedded in the ethos of congenital interventions, whose patron saint may very well be MacGyver from the 1980s television series.

The Melody transcatheter pulmonary valve (Medtronic, Minneapolis, Minnesota) has a recommended maximal expansion of 22 mm internally but has been shown to have no significant increase in pulmonary regurgitation at an internal diameter of 24 mm (2). Similarly, the SAPIEN 3 transcatheter heart valve (Edwards Lifesciences, Irvine, California) also has additional expansion capacity of the 29-mm valve to 31 mm (3). The authors highlight the use of a CE (Conformité Européenne)-approved 32-mm Myval balloon-expandable aortic prosthesis in an RVOT landing zone diameter of 27.8 mm, which adds to the range of implantable RVOT diameters using commercial valve technologies. This transcatheter valve bears resemblance to the Edwards SAPIEN series.