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EDITORIAL COMMENT

Overstepping the Boundaries of Percutaneous Pulmonary Valve Placement Guidelines

Renegade or Renaissance?*

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There is a famous quotation that goes like this: "If you are not the lead dog, the scenery never changes." Such is the case with routine interventions that are per protocol and as mandated in the Instructions For Use (IFU) for any device or valve procedure. So, I would like to add to the quotation by stating that "redundancy is boring." Performing a percutaneous valve procedure within the confines of IFU may not only become routine but excludes several patients who may fall very close to the parameters of inclusion criteria set in IFU, yet outside the limits of the IFU inclusion criteria. In general, inclusion/exclusion criteria defined by the manufacturer are conservative, overprotective, and based on the protocols that are set when Food and Drug Administration-approved trials are completed. Naturally there are several physicians who would like to test the boundaries set by the company. We may ask ourselves, can we do better, can we help more people, and can we be among the first ones to break the mold by overstepping the boundary? The instinctive response to this question in any profession is, "yes we can." But when the question is addressed to medical professionals, especially interventionalists, we should also ask, will the change be safe and will it simplify the future care of the patient? It is this attitude that prevents us from becoming renegades.

In the elegant study by Shahanavaz et al. (1) in this issue of *JACC: Cardiovascular Interventions*, several highly experienced contributors to the study tested the boundaries set by Melody (Medtronic Inc., Minneapolis, Minnesota) by placing percutaneous pulmonary valves in patients whose conduit size was smaller than recommended in the IFU. Although this is not a new concept in any form, and in essence this publication is an extension of previous publications where the valve was placed in conduits measuring 16 mm or less (2), the authors were able to collect enough data from several institutions for analysis and scientifically reached a conclusion that in most instances, this practice is safe and effective.

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Placing a percutaneous pulmonary valve in a previously placed 16-mm conduit (conduit size at the time of placement) is within the confines of the IFU, although the number of patients who underwent valve placement in a 16-mm conduit in previous studies was low and <10% (3). Median diameter of the conduit in the study by Shahanavaz et al. (1) was 15 mm and hence one-half of the patients who had successful placement of the valve were treated per IFU protocol. So, results and complication rate in patients who underwent the procedure per protocol should be comparable with complications published previously (3,4). Nevertheless, overall outcomes were optimal.

The most important complication to consider in cases where the conduit has to be dilated before a valve can be placed is conduit tear. In this study, there were 22 patients who had conduit tear and 1 who had conduit rupture; 19 tears were experienced in patients who received the valve and 4 (including rupture) in patients who did not receive the valve. This brings the rate of conduit tear to 16% (tear rate similar in implanted and nonimplanted group except

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for 1 rupture). This rate is high when compared with the Armstrong et al. (4) study and similar to other studies where the procedure was performed in patients where the conduit diameter was <16 mm (2). This rate is high especially when considering that 50% of the patients had implanted conduit diameter of 16 mm or close to it. Hence the complication rate is much higher in the subset where the valve was indeed <15 mm.

Regardless of the increase risk of complications, this study is a step forward and helpful to the cardiologist as to which patients may be better suited for percutaneous pulmonary valve placement despite small conduit size. As the authors stated, "these patients would be whose pre-intervention gradient is mild, they have pulmonary insufficiency predominantly, and the conduit diameter is at least more than 9 mm."

Future studies on this subject ideally should have prospective design to help further understand what type and what diameter conduit valves are safe to dilate and to what extent. What are the markers that increase the risk of conduit tear and of course, evaluate the longevity of the valve/conduit where multiple stents and valve have been placed? The largest diameter of the conduit in the future study should be 15 mm or less because this diameter certainly falls below the IFU recommended conduit diameter.

Some of the reasons percutaneous valve technologies are appealing is that it decreases the numbers of sternotomies that are required for valve replacement, avoids cardiopulmonary bypass, and decreases overall hospital stay. Can these patients be helped using hybrid techniques using mini-sternotomies? The hybrid techniques have been used electively with acceptable results in complex subset of patients (5).

Our aim should be to identify and study factors that will decrease the number of cardiac interventions and complications associated with it. An even more important factor is to determine if the results are sustainable over time. If we are to overstep the boundaries set by the IFU, we should do it for one purpose only: to improve the patient's quality of life with minimal interference. It is our patient care attitude that will qualify our actions as Renaissance interventionalists (Renaissance is an old French word meaning a period of new growth or activity) and not as renegade interventionalists.

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