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Tablesides Skirt Modification of the SAPIEN 3 Valve to Reduce Paravalvular Leak During Transcatheter Mitral Valve Replacement

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The external fabric skirt incorporated into the balloon-expandable SAPIEN 3 valve (Edwards Lifesciences, Irvine, California) (Figure 1A) significantly reduced paravalvular leak (PVL) during transcatheter aortic valve replacement (1). Fabric outside rather than inside the valve frame appears important for annular sealing. PVL nevertheless limits transseptal transcatheter mitral valve replacement (TMVR) using the SAPIEN 3 in both surgical rings (valve in ring [VIR]) and mitral annular calcification (valve in mitral annular calcification [VIM]) (2). The short “landing zone” afforded by the 7- to 8-mm SAPIEN 3 external skirt, compounded by valve malalignment decreasing the “effective” skirt height and imperfect implantation depths characteristic of TMVR using available delivery systems, commonly results in leakage around the transcatheter valve skirt (3). The SAPIEN 3 Ultra lengthens the external skirt by 2 to 3 mm (Figure 1B), further improving annular sealing (4). Unfortunately, the 29-mm SAPIEN 3 Ultra, required for most VIR and VIM TMVRs, is not commercially available.

We aimed to reduce PVL by lengthening the 29-mm SAPIEN 3 landing zone, particularly in cases in which complete coaxiality cannot be achieved and/or when more atrial valve deployment is desired to reduce left ventricular outflow tract (LVOT) obstruction. We lengthened the landing zone during tablesides modification of the valve to suture a low-profile skirt composed of high-molecular weight fabric onto a SAPIEN 3 to resemble Ultra (SCHM-Ultra), still allowing transcatheter delivery.

We sewed a $0.4 \times 9 \times 90$ mm expanded polytetrafluoroethylene cardiovascular patch (W.L. Gore, Newark, Delaware) abutting the external SAPIEN 3 skirt using running 8–0 polypropylene suture, and along the lower aspect of the upper cell frame using running 7–0 polypropylene (Figure 1C, Video 1). The valve was crimped directly onto a 29-mm Commander delivery balloon (Edwards Lifesciences) for convenient direct transfemoral

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

delivery using a 26-F DrySeal Flex introducer (W.L. Gore). All other procedural aspects were standard for transseptal TMVR at our institution.

With Institutional Review Board approval, we retrospectively analyzed post-implantation geometry and PVL after consecutive VIR and VIM TMVR at our institution using the SCHM-Ultra in 6 patients (VIR, n = 2; VIM, n = 4) compared with 8 otherwise similar immediately consecutive procedures (VIR, n = 1; VIM, n = 7) using standard 29-mm SAPIEN 3 devices. Valve heights above the annular plane on transesophageal imaging (n = 13) and/or fluoroscopy (n = 1) were used to determine percentage ventricular or atrial deployment and to calculate valve coaxiality (canting angles, 0° being ideal). PVL severity was determined on pre-discharge and 30-day transthoracic echocardiography interpreted by a blinded reader.

Baseline mean intercommissural and maximal mitral annular diameters were similar (19.7 mm vs. 20.3 mm and 29.4 mm vs. 29.0 mm, respectively). We used similar rates of adjunctive percutaneous transthoracic left ventricular wire externalization to achieve more coaxial alignment (5/8 vs. 5/6) and laceration of the anterior mitral leaflet to prevent outflow obstruction (7/8 vs. 4/6). Valves were deployed with similar additional balloon inflation volumes (2.1 ± 3.9 ml vs. 1.5 ± 2.4 ml), with no postdilatation.

Valve canting was unaffected by SCHM-Ultra (1.4° vs. 1.5°, respectively). “Effective” skirt height was increased from 8.1 mm (8.0 to 8.1 mm) to 11.5 mm (11.4 to 11.6 mm) by SCHM-Ultra. Despite significantly greater valve heights above the annular plane and more atrial deployment (31% vs. 14%; $p < 0.01$) (Figure 1H), the incidence of mild or greater PVL due to valve malalignment was reduced from 75% using the SAPIEN 3 to 0% using the SCHM-Ultra ($p = 0.001$) (Figure 1I). No patient had an increase in mean LVOT gradient >10 mm Hg. There was no central regurgitation or stenosis in any case to suggest interference with transcatheter heart valve leaflet function from the added skirt. There were no other complications (embolization, hemolysis, etc.) attributable to the modified skirt. Event-free 30-day survival was 88% after SAPIEN 3 implantation and 83% after SCHM-Ultra implantation.

PVL, even mild, with resultant hemolysis has been associated with poor outcomes and remains a limitation of VIR and VIM SAPIEN 3 TMVR. Saddle-shaped and inhomogeneous landing zones and noncoaxial and variable-depth implantation contribute to PVL. SCHM-Ultra increased the skirt height and effective landing zone length by about 3.5 mm and eliminated all PVL without increasing LVOT obstruction, embolization, or other adverse consequences. Similar results were reported after sewing a felt strip onto SAPIEN-family valves during open transatrial implantation, but with attendant surgical morbidity (5).

We cautiously conclude from this preliminary series that SCHM-Ultra modification reduces PVL and may enhance TMVR outcomes pending commercial availability of the 29-mm SAPIEN 3 Ultra or equivalent.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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FIGURE 1. Skirt-Modified SAPIEN 3 During TMVR

(A) SAPIEN 3 (S3), (B) SAPIEN 3 Ultra, and (C) tableside-modified 29-mm SCHM-Ultra (skirt composed of high-molecular weight fabric onto a SAPIEN 3 to resemble Ultra).

(D,E) Representative case of valve-in-mitral annular calcification (VIM) transcatheter mitral valve replacement (TMVR) with standard 29-mm SAPIEN 3 valve external skirt length (blue dotted lines), annular landing zone (yellow arrows), and resultant moderate paravalvular leak (PVL) (red arrows). (F,G) Representative case of VIM TMVR with graft-modified 29-mm SAPIEN 3 valve external skirt length (green dotted lines), annular landing zone (yellow arrows), and resultant trivial PVL (red arrow).

(H) Final valve implant characteristics. (I) PVL severity before and after adoption. See Video 1.