

Editorial



Sapien 3 versus Sapien XT Balloon-expanding Valve for Transcatheter Aortic Valve Replacement: Improved Immediate and Late Outcomes at the Expense of Smaller Effective Orifice Area

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Conflict of Interest

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Transcatheter aortic valve replacement (TAVR) has successfully demonstrated its efficacy and safety as an alternative therapy to surgical aortic valve replacement not only in high or intermediate risk patients but also in low risk patients with severe aortic valve stenosis.^{1,2)} However, TAVR is associated with morbidities such as paravalvular leak (PVL), conduction abnormalities, and vascular complications.^{2,3)} Sapien valve system (Edwards Lifesciences, Irvine, CA, USA) was the first commercially available TAVR prosthesis for clinical use.⁴⁾ Sapien 3 is the latest generation valve currently available in Korea. Whereas the previous generation Sapien XT used an introducer sheath of 16–18F diameter, Sapien 3 requires a lower profile sheath of 14–16F. In addition, Sapien 3 added an outer sealing skirt made of polyethylene terephthalate to minimize paravalvular leak.

In this issue of *Korean Circulation Journal*, Kook et al.⁵⁾ reported outcomes of Sapien 3 in TAVR in Korean patients compared with Sapien XT. In their study, Sapien 3 showed a higher device success rate and a lower incidence of moderate or severe PVL than Sapien XT. The 1-year cardiovascular mortality rate was also lower with Sapien 3. This study has limitations including retrospective study design, small sample size, inadequate adjustment of confounding factors, especially learning curve of procedure skills and difference experience levels among participating centers. Despite these limitations, the findings of the study are generally consistent with the previous reports.^{6,7)} A recent meta-analysis study demonstrated that Sapien 3 achieved higher rates of device success and lower rates of moderate or severe PVL, major vascular complications, major bleeding, stroke, and early mortality than Sapien XT.⁶⁾ Thus, the lower delivery system profile and the outer skirt of the Sapien 3 appear to successfully reduce procedure-related complications and significant PVL and to improve the device success. However, permanent pacemaker implantation rate was higher after implantation of Sapien 3 rather than Sapien XT. The outer skirt of Sapien 3 may be helpful to reduce PVL, however it seems to induce more atrioventricular conduction abnormality as a trade-off. However, in the present study, the pacemaker implantation rate was very low for both Sapien XT and Sapien 3 (2.1% vs. 1.1%, $p=0.621$). Whether operator techniques or patient ethnicity might contribute to the low permanent pacemaker implantation rate remains unknown.

Kook et al.⁵⁾ reported in this study that the effective orifice area of the implanted valve was smaller with Sapien 3 than Sapien XT and suggested that the outer skirt of Sapien 3 might cause a smaller effective orifice area. Similar findings have been also observed in the other studies. Abdelghani et al.⁸⁾ speculated lesser valve oversizing as another explanation for the smaller effective orifice area (EOA) with Sapien 3. They described that there was a significant decline of percentage oversizing of the balloon expanding valves from 11.4% with Sapien XT to 3.7% with Sapien 3 despite similar manufacturer's sizing recommendation. The authors explained that the data on annulus rupture by excessive oversizing in cases of Sapien XT might have contributed in part to more conservative approach in valve sizing since Sapien 3 is capable to reduce PVL with the outer sealing skirt. Thus, from the safety point of view, lesser oversizing of the Sapien 3 appears to be appropriate. However, smaller EOA is associated with a higher residual transvalvular pressure gradient and a higher incidence of patient-prosthesis mismatch (PPM) especially in cases of small valve sizes. Theron et al.⁹⁾ demonstrated that the risk of PPM is increased with 23 mm Sapien 3 in comparison with 23 mm Sapien XT. PPM has been shown to be associated with an increase in all-cause and cardiac-related mortality over long-term follow-up.¹⁰⁾ Therefore, Sapien valve system needs to find a solution to increase the EOA and thereby to reduce the risk of PPM especially in cases of small valve sizes.

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