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with DES when using systematic implantation technique and imaging guidance, Biscaglia and Campo reference their published registry of 162 patients treated with BVS matched with DES control subjects (UNDERDOGS) (3), but they should note that in that study, the mean scaffold length was on average 30 mm shorter than in our group of lesions with scaffold length ≥60 mm (54 ± 15 mm vs. 85.9 ± 7.2 mm, respectively), preventing any meaningful comparison. Conversely, consistent with the UNDERDOGS study, overlapping BVS did not appear to have an impact on clinical outcomes of GHOST-EU patients compared with no-overlapping bioresorbable scaffolds (4), and the rate of TLF in patients with scaffold lengths between 30 and 60 mm was more reassuring (4.5%). Accordingly, we reiterate our conclusion that "treatment of very long coronary lesions (scaffold length ≥60 mm) with BVS was associated with a high TLF rate" (1). Whether this is the consequence of issues related to patient selection, implantation technique, or the device itself cannot be addressed by our or the UNDERDOGS study and is open to future investigations.

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Permanent Pacemaker Implantation Following Transcatheter Aortic Valve Replacement

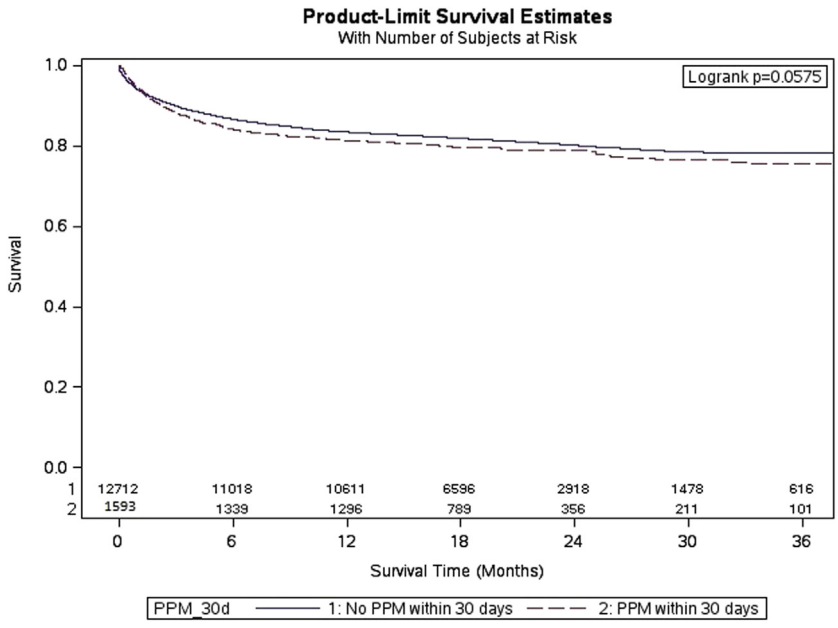
The introduction of transcatheter aortic valve replacement (TAVR) as an alternative to open surgery in high-risk patients has been increasing steadily across the United States since the Food and Drug Administration approval of the Edwards Lifesciences SAPIEN device (Edwards Lifesciences, Irvine, California) for inoperable patients in 2011 (1). As the use of this technology continues to expand, interest in the use of TAVR for treatment of intermediate- and low-risk patients with aortic stenosis has also grown. However, several complications associated with TAVR, such as the need for permanent pacemakers (PPMs), have not been fully evaluated and their long-term clinical consequences remain unclear.

The recent publication by Fadahunsi et al. (2) used a novel approach to answer this question by using the STS/ACC TVT (U.S. Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy) registry to identify 9,785 TAVR patients and the Centers for Medicare & Medicaid Services (CMS) database to follow patients through 1-year post-implantation. Their results indicate that PPM placement within 30 days post-TAVR is found in 6.7% of patients undergoing either balloon-expanding Edwards SAPIEN valve or self-expanding Edwards SAPIEN valve, and is associated with increased mortality and hospitalizations. This study also sought to understand the impact of PPMs in TAVR patients using CMS Medicare claims.

This study contains 14,305 TAVR patients whose index hospitalization occurred between January 2011 and December 2013. TAVR patients were identified using Common Procedural Terminology (CPT) codes, and PPMs were identified using previously validated International Classification of Diseases-9th Revision- Clinical Modification (ICD-9-CM) procedure codes present within 30 days post-TAVR. Using MEDPAR (Medicare Provider Analysis and Review) files, patient follow-up was recorded through December 2014. Similar to Fadahunsi et al. (2), patients with previous PPMs were excluded from this study.

The results of Fadahunsi et al. (2) indicate that 6.7% of all TAVR patients received PPMs within

FIGURE 1 Kaplan-Meier Survival Model of 3-Year Mortality in U.S. Medicare TAVR Patients



Kaplan-Meier survival estimates of transcatheter aortic valve replacement patients in the U.S. Medicare population stratified by permanent pacemaker implantation within 30 days of surgery. PPM = permanent pacemaker; TAVR = transcatheter aortic valve replacement.

30 days post-TAVR. We found that 11% (1,593) of all TAVR patients required PPM within 30 days post-TAVR. This large discrepancy between the prevalence of PPM patients may be due to the difference in registry collection methods, or in the exclusion criteria used because Fadahunsi et al. (2) excluded any TAVR provider that performed ≤30 TAVRs. In this study, a total of 16% (2,296) of patients' TAVRs were performed at centers with ≤30 TAVRs. We chose not to exclude these patients from this study because they represent a large proportion of the population and provide more validity to our results. A study by Urena et al. (3) found a PPM rate of 15.4% and used similar exclusion criteria to this study, although other studies have found lower rates of PPM 30 days post-TAVR (4).

When reviewing the clinical outcomes of Fadahunsi et al. (2), we noted several significant similarities and differences between the results of their study and ours. First, it is important to note that in-hospital and 30-day outcomes were similar between the 2 studies. Using multivariable models to identify predictors of PPM placement, we also found age to be a positive predictor of PPM within 30 days (hazard ratio [HR]: 1.02 [95% confidence interval (CI): 1.01 to 1.02]; $p < 0.01$). This is notable considering Fadahunsi et al. (2) was only the second publication ever to find age to be a predictor of PPM placement.

Although this study did report several similar findings to Fadahunsi et al. (2), there were also significant differences seen in long-term outcomes. Most notably, we found that PPM placement did not have a significant impact on long-term mortality in either unadjusted or adjusted survival models. Our results indicate that survival out past 3 years post-TAVR is not significantly associated with PPM within 30 days of TAVR (**Figure 1**), and PPM placement is not a predictor of long-term mortality in a multivariate cox proportional hazard model (HR: 1.06 [95% CI: 0.94 to 1.18]; $p = 0.33$). Although this study did find a trend toward increased composite mortality or heart failure readmissions in PPM patients versus non-PPM patients in an unadjusted comparison (26% vs. 23%; $p = 0.02$), a multivariable model did not find PPM to be a predictor of composite mortality or heart failure readmissions (HR: 1.07 [95% CI: 0.97 to 1.19]; $p = 0.20$). Because the size of this study cohort is significantly larger and our follow-up period extends 2 years later than Fadahunsi et al. (2), the differences seen between studies may be due to the increased power and longer follow-up of this study.

It is important to note that the findings of Fadahunsi et al. (2) represent one of the largest and most

comprehensive cohorts used to examine PPM post-TAVR. However, the differences seen in PPM prevalence and long-term outcomes between studies produce conflicting conclusions. Differences in study populations and time periods, as well as the power of the size of this study compared with Fadahunsi et al. (2) may explain these differences. Similar to previous studies focusing on the long-term outcomes of PPM placement in TAVR patients, the results of our long-term study do not find any association between mortality or heart failure readmission and PPM (3,5). Although Fadahunsi et al. (2) provides great insight into the factors affected by PPM placement in TAVR patients within the first-year post-implant, an expansion of this cohort and follow-up period indicates that PPM placement is not associated with significant adverse events.

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REPLY: Permanent Pacemaker Implantation Following Transcatheter Aortic Valve Replacement

We thank Dr. Savino and colleagues for their interest in our publication (1). A direct comparison between datasets is challenging as we do not have access to the detailed methodology by Dr. Savino and colleagues. In addition, our study used the Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) TVT registry, whereas Dr. Savino and colleagues used an administrative database. Both data sources are important and complementary. However, unlike administrative data, registries provide detailed demographic, clinical, and procedural data that are rigorously collected and systematically audited, and therefore may be better suited to answer clinical questions with greater granularity (2).

Dr. Savino and colleagues found a higher 30-day permanent pacemaker (PPM) rate of 11% compared with 6.7% in our study. Inclusion of centers that had performed ≤30 transcatheter aortic valve replacement (TAVR) procedures did not change our findings (PPM implantation rate of 7%). We excluded these centers on the basis of studies demonstrating that proficiency plateaus after 30 cases, and centers with smaller numbers of patients tend to add statistical noise to the data (3). Self-expanding valves (SEV) have a higher risk for needing PPM compared with balloon-expanding valves. A total of 11.2% of our population had a SEV compared with 44.9% in Urena et al. (4) (15.4% PPM rate). The proportion of SEV in the Dr. Savino and colleagues cohort was not reported, and is a critical data point that may be challenging to obtain from their dataset that may significantly confound the interpretation of their results. Unlike our study, Dr. Savino and colleagues found no association between PPM insertion post-TAVR and long-term mortality, but do not describe the indications for TAVR in their population or how deaths and patients lost to follow-up were ascertained. A clear understanding of the patient population and detailed outcomes data are necessary facets of this research before any useful interpretations of their work can be made.

In conclusion, PPM rates post-TAVR remain high despite the introduction of newer valve designs.