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EDITORIAL COMMENT

Did the COVID-19 Pandemic Just Turn TAVR Into an Outpatient Procedure?*

Jay Giri, MD, MPH,[a,b] Paul N. Fiorilli, MD[a,b]

Transcatheter aortic valve replacement (TAVR) has rapidly become a mainstay of treatment for patients with severe aortic stenosis at all levels of risk, and TAVR utilization in younger, low-risk populations has continued to expand.[1,2] Concomitantly, the principles of a "minimalist" TAVR procedure have broadly been accepted and implemented. The minimalist approach to TAVR is generally characterized by 3 central tenets: 1) utilization of percutaneous transfemoral arterial access; 2) utilization of intraprocedural conscious sedation (as opposed to intubation with general anesthesia); and 3) avoidance of unnecessary indwelling lines such as urinary/pulmonary artery catheters with early patient mobilization ideally outside of an intensive care unit setting.[3,4] Adoption of the minimalist approach has led to significantly shorter hospital stays, and in many centers has led to the standard of next-day discharge after TAVR. The established feasibility and safety of next-day discharge has relied upon the standardization of clinical care pathways to streamline and expedite post-procedural care among groups of patients at low risk of late-presenting complications.[5-7] Although same-day discharge (SDD) has been formally investigated in percutaneous coronary intervention (PCI), this issue has not yet been broached in the TAVR arena.

Enter the COVID-19 pandemic and the substantial strain that it has placed on health care systems and hospital-based resources. This strain, especially at times of peak viral surges, has jeopardized the ability of many centers to expeditiously offer life-prolonging procedures such as TAVR and has forced many to reconsider strategies of how to safely and effectively deliver these treatments. The arrival of COVID-19-associated hospital bed and resource shortages, coupled with the recent implementation of shorter hospital stays post-TAVR, created the perfect environment for a concept that would have seemed outlandish only a few short years ago: SDD post-TAVR.

SDD has been studied and incorporated extensively in the PCI space. A recent American College of Cardiology Expert Consensus statement outlines the key considerations for expedited discharge after PCI, including baseline patient characteristics, procedural considerations, and post-discharge follow-up planning.[8] Although the specific components of these 3 areas vary between PCI and TAVR, the general concepts remain the same. For TAVR, ideal preprocedure patient selection for SDD would include patients with planned percutaneous transfemoral procedures, adequate social support systems, and no pre-existing conduction system disease. Ideal periprocedural patient selection would include patients without significant periprocedural complications including vascular access site complications requiring surgical intervention and the development of new or progressive conduction system issues. Ideal post-procedure patient selection would include procedures finishing earlier in the day, those with stable rhythms, those without postprocedure bleeding, those demonstrating a return to baseline mobilization status, and those with the support to attend postprocedure follow-up appointments.

In this issue of *JACC: Cardiovascular Interventions*, 2 separate investigations aim to provide a durable

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From the [a]Department of Cardiovascular Medicine, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania, USA; and the [b]Center for Cardiovascular Outcomes, Quality, and Evaluative Research, University of Pennsylvania, Philadelphia, Pennsylvania, USA.

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framework for both patient selection and implementation of SDD post-TAVR. Collectively, these are 2 well-executed studies that provide an initial evidence base for expedited post-TAVR discharge and have substantial implications for hospital resource utilization and procedure-related cost.[9,10]

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Krishnaswamy et al[9] retrospectively analyzed patients undergoing minimalist transfemoral TAVR in 2019-2020 at a single U.S. center. They used predefined criteria for selection of patients for SDD and compared in-hospital and 30-day outcomes of patients with SDD and next-day discharge. The selection criteria for SDD included patients undergoing percutaneous transfemoral TAVR under conscious sedation, 6-hour post-TAVR bedrest with monitoring, no major complications observed or need for further monitoring, stable hemodynamics and electrocardiogram, comfortable post-procedure ambulation, and adequate post-discharge social support. A total of 114 patients were included who met this selection criteria. As compared with patients with next-day discharge (the standard of care at this site), the SDD cohort was younger (median age 77.5 vs 79.0 years for next day), predominantly male (75.4% vs 59.4% for next day), and of lower surgical risk (median Society of Thoracic Surgeons [STS] score 2.8% vs 4.3% for next day). A balloon-expandable valve was placed in 91.2% of the SDD cohort. In-hospital and 30-day outcomes were not significantly different between the groups. There were no deaths at 30 days in the SDD group, and only 1 patient (0.9%) required a permanent pacemaker (PPM) over the 30-day follow-up period. Procedure end time was identified as the strongest predictor of SDD in the cohort, an unsurprising finding given the requirement for 6 hours of post-TAVR bedrest in SDD patients. Based on these results, the investigators concluded that SDD is safe and feasible, and may serve as a strategy to improve bed utilization and minimize hospital resource utilization for TAVR patients.

The current issue also features the PROTECT TAVR study from Barker et. al,[10] which examined SDD after TAVR in a prospective, multicenter cohort. A total of 124 patients who underwent planned elective transfemoral TAVR at 7 international sites from March 2020 to August 2021 were included. The population had a mean age of 78.9 years, was predominantly male (71%), and were of low surgical risk with a median STS score of 2.4 (IQR: 1.4-4.2). Importantly, 32.3% of subjects had a pre-existing PPM. In this cohort, 96.8% of patients received a balloon-expandable valve (120/124), all patients had transfemoral procedures, no patients underwent general anesthesia, and all procedures were completed before noon. None of the 124 patients discharged the same day required a PPM at 30-day follow up. The overall composite endpoint of cardiovascular death, stroke, myocardial infarction, all-cause readmission, major vascular complications and new PPM at 30 days was low at 5.7%. Based on these results, the investigators concluded that SDD post-TAVR is safe and feasible in carefully selected patients.

The investigators are to be commended on these excellent studies, which were both fueled by and performed under the added layer of complexity imposed by the COVID-19 pandemic. The concordant results between the 2 studies highlight the similarities in patient selection that were prespecified by the 2 independent research groups. Both studies featured cohorts that were remarkably similar in age, sex, STS risk score, bioprosthesis choice, procedure completion time, and conduction system status. The selection criteria implemented in both studies aimed to account for and minimize the most significant concerns with early discharge of a post-TAVR patient (including vascular access site complications, development of bradyarrhythmias, and adequate access to social support). The low incidence of the primary outcomes provides initial support for the concept of SDD in patients with similar baseline and procedural characteristics at other experienced TAVR centers. The selection criteria of patients included, and the practices employed in these studies lay a roadmap for the broader implementation of an SDD strategy after TAVR.

There are, however, some caveats that must be considered before the broader uptake of SDD post-TAVR. First, all centers included in these 2 trials had extensive experience with minimalist TAVR and had already developed clinical care pathways that minimize critical care monitoring and promote early ambulation and reconditioning. Although a major trend toward conscious sedation over general anesthesia for TAVR has occurred in the last decade, only 64% of TAVR procedures performed in the United States in 2019 used a conscious sedation strategy.[11] In these 2 studies, only those patients receiving conscious sedation were offered SDD. Second, the vast majority of patients included in both of these trials underwent implantation of a balloon-expandable valve (91.2% in Krishnaswamy et al,[9] and 96.8% in Barker et al[10]). This is likely explained by both site-specific valve preferences and physician-specific valve selection based on differences in PPM rates between balloon-expandable and self-

expanding valves. Although employment of techniques to achieve higher annular positioning of self-expanding valves may reduce PPM rates below those reported in clinical trials, the differences in PPM rates in the most recent low-risk randomized trials were far lower with balloon-expandable valves[1,2] Given the low numbers of self-expanding valves included in the present analyses, strong conclusions regarding the safety and feasibility of SDD in these patients cannot be made. Third, neither trial is adequately powered to examine the endpoint of periprocedural stroke and its influence on differences in outcomes related to same-day discharge. Prior research has indicated that the risk of stroke remains elevated for 48 hours post-procedure, and it is possible that opportunities for optimal intervention in these cases may be delayed or missed altogether in patients being discharged on the same day.[12]

So, what is next for SDD after TAVR? Although these studies lay the foundation for future investigations, many specific questions will need to be rigorously addressed by the TAVR community. First and foremost, what is the true incidence of major complications occurring in the first 48 hours after TAVR that the medical team would miss an opportunity to intervene on by employing more widespread SDD? Although randomized trials are very valuable in many circumstances and would be welcomed to further clarify the efficacy of SDD, the aforementioned question regarding the safety of this practice might be best answered through careful appraisal of a largescale prospective registry, perhaps with administrative linkage. Investigators would ideally assess at proper scale for specific complications of major bleeding, stroke, PPM, and sudden death in the early postdischarge period. This would provide the TAVR community information on the true rates of these complications in a real-world, low-risk population treated with SDD. This would allow us all to judge whether the move toward SDD is justified from a population health perspective. Secondly, the technology exists and is rapidly improving to monitor patients out of the hospital for each of these feared complications, both with wearable and implantable devices. But well-designed implementation research is necessary to clarify the appropriate method of extending our reach to the patient's home for monitoring in the postdischarge period.

Finally, although there are significant potential benefits to alleviating bed strain and hospital resource utilization post-TAVR and decreasing overall hospital-associated costs with the procedure, we must also proactively account for any potential unintended financial consequences of a move toward more broad use of SDD for TAVR in the United States. Currently, all TAVR are billed at a hospital level through TAVR-specific inpatient diagnosis-related group codes. Under the current structure, many U.S. hospitals incur losses on their annual TAVR procedures as a whole. This is primarily due to the high pricing of current TAVR bioprostheses that are a result of a duopoly in this market. Prior research has estimated that nearly three-quarters of hospital costs associated with a TAVR procedure are attributable to the costs of the bioprosthesis.[13] Many of the improvements in TAVR efficiency have been successful at chipping away at the remaining hospital costs allowing efficient hospitals adopting these practices to realize a modest contribution margin from their TAVR programs.[14] However, if outpatient coding that reimburses significantly lower than current inpatient diagnosis-related group codes were to emerge for TAVR, this would actually be counterproductive to hospital finances despite the perceived efficiencies created by SDD. This could well exacerbate the already existing inequities in access to TAVR faced by rural, minority, and socioeconomically disadvantaged populations.[15,16]

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ADDRESS FOR CORRESPONDENCE: Dr Jay Giri, Cardiovascular Medicine Division, 11th Floor, South Pavilion, Perelman Center for Advanced Medicine, University of Pennsylvania Medical Center, 3400 Civic Center Boulevard, Philadelphia, Pennsylvania 19104, USA. E-mail: jay.giri@pennmedicine.upenn.edu.

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