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OPINION

Safety and Feasibility of Same Day Discharge after Transcatheter Aortic Valve Replacement Post COVID-19

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Transcatheter Aortic Valve Replacement (TAVR) remains a complex procedure with the potential for life-threatening complications including heart block, bleeding from vascular access sites, and pericardial tamponade. Nevertheless, in the face of this complexity, it has been shown that TAVR can be safely performed across a large spectrum of centers.[1] Further, the safety of next-day discharge (NDD) after TAVR is now well established[2] and has become the standard at many centers including our own, with more than 70% of patients discharged home on post-procedure day 1.

During the Coronavirus (COVID) pandemic, numerous changes to inpatient surgical care generated discussion within the Structural Heart community regarding the possibility of same day discharge (SDD) after TAVR. Considering the impact of the COVID surge on our region, our heart team weighed the risks and benefits of SDD and implemented a strategy to offer SDD to well-selected patients. In this report, we describe a series of three patients who safely underwent SDD after transfemoral (TF) TAVR at our institution on a single day.

New realities of care of TAVR patients during the COVID surge

Given our center's location in New Jersey, our patients and program faced a significant challenge during the surge. For a period of nearly 6 weeks, treatment at our center was limited to the highest acuity patients. The cumulative effects of the surge in our region were measurable. It is estimated that during the COVID surge in NJ (mid-March to early May), 800 more people died of heart disease than were expected based on death rates during the same timeframe in previous years.[3] This occurred because patients were either unwilling or unable to obtain needed cardiovascular care.

As we reopened our program to less acute patients, significant concerns remained. Even after the height of the surge, many areas of our hospital where TAVR patients are typically managed had been repurposed to manage COVID patients and remained at high capacity or were fully unavailable for alternative use. Furthermore, the population of patients undergoing TAVR are predominantly advanced in age with a high prevalence of hypertension and diabetes and therefore are at extremely high risk for adverse outcomes if infected with the severe acute respiratory syndrome coronavirus −2 (SARS-CoV-2). Moreover, to protect patients, families, and staff, visitors were not allowed in the hospitl; thus, all hospitalized patients remained separated from their loved ones for the duration of their inpatient stay.

Given limitations in hospital beds and other essential resources, concerns for in-hospital transmission of COVID, and hesitancy of patients to seek care, we sought ways to minimize resource utilization, limit the inpatient footprint, and reduce length of stay. As each patient-provider encounter and room-to-room transfer presents an independent risk of transmission and consumes already scarce personal protective equipment (PPE), we hypothesized that the strategy of same day discharge in well-selected patients would decrease the risk of inpatient transmission, conserve hospital beds and PPE, and encourage patients to pursue needed treatment.

Patients, procedures, and outcomes

Three patients with aortic stenosis (AS) who had tested negative for the SARS-CoV-2 infection were scheduled for TAVR on a single day. Demographic, clinical characteristics, and outcomes of patients are given in Table 1. There were two males and one female who were 67, 85, and 74 years old, respectively.

As is standard at our institution, all cases were performed in the hybrid operating room (OR) under conscious sedation via a transfemoral approach. The Sapien 3 transcatheter heart valve (Edwards Lifesciences) of sizes 23, 23, and 26 were used in patients 1, 2, and 3, respectively. There was no evidence of paravalvular or valvular aortic regurgitation, pericardial effusion, or vascular access site complication in any of the patients. Post-operatively,

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Table 1. Baseline demographic, clinical/procedural characteristics, and outcomes.

Variable	Patient 1	Patient 2	Patient 3
Age	67	74	85
Sex	M	F	M
Race/Ethnicity	Caucasian	Asian	Caucasian
BMI (kg/m^2)	28.1	18.9	22.5
NYHA class	III	III	IV
STS risk score (%)	1.3	3.1	1.4
Frailty (EFT)	3/5	3/5	1/5
ECG features			
PR interval (ms)	152	156	200
QRS duration (ms)	166	94	90
RBBB/LBBB	RBBB	None	None
Rhythm	NSR	NSR	NSR
Co-morbid conditions			
Hypertension	Yes	Yes	Yes
HLD	Yes	Yes	Yes
CAD	Yes	No	Yes
CKD	No	No	No
DM	Yes	Yes	No
Atrial fibrillation	No	Yes	Yes
COVID-19	Negative	Negative	Negative
Indication for TAVR	Frailty, advanced stage cancer	Surgical Risk based on STS, frailty, and cachexia	Advanced age
Pre-procedure echocardiographic parameters			
AVA (cm^2)	0.89	0.45	0.91
LVEF (%)	60	66	60
MR	Mild	Mild	Mild
AR	Mild	Mild	Moderate
Mean gradient (mmHg)	48	76	33
Procedural characteristics			
Approach	Transfemoral	Transfemoral	Transfemoral
Valve type	S3	S3	S3
Valve size	23	23	26
Device side vascular closure	Proglide x 2 + BO x 5 m	Proglide x 2	Proglide x 2
Diagnostic vascular closure	Angioseal	Angioseal	Angioseal
BLE pulse exam	Unchanged	Unchanged	Unchanged
Pericardial effusion	None	None	None
Cardiac function	Grossly unchanged	Grossly unchanged	Grossly unchanged
PVL	None	None	None
Post-procedure assessment (>4 h)			
Pericardial effusion	None	None	None
AVA (cm^2)	1.7	1.8	2
LVEF (%)	60–65	55–60	55–60
MR	Trace	None	Mild
PVL	None	None	None
Mean gradient (mmHg)	8	7	6
Peak velocity (m/s)	2.18	1.83	1.71
PR interval (ms)	158	154	196
QRS duration (ms)	174	90	96
RBBB/LBBB	RBBB	None	None
Rhythm	NSR	NSR	NSR
BLE pulse exam	Unchanged	Unchanged	Unchanged
PPM	No	No	No
Vascular comp	No	No	No
PVL	None	None	None
Stroke	No	No	No
Procedural success	Yes	Yes	Yes
Valve-in-valve	No	No	No
In-hospital mortality	No	No	No
Re-admission (24 days)	No	No	No

Notes. BMI, body mass index; NYHA, New York Heart Association; STS, Society of Thoracic Surgery; LHC, left heart catheterization; EKG, electrocardiogram; RBBB, right bundle branch block; LBBB, left bundle branch block; HTN, hypertension; HLD, hyperlipidemia; CAD, coronary artery disease; CKD, chronic kidney disease; AVA, aortic valve area; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; AR, aortic regurgitation; NSR, normal sinus rhythm. BLE, bilateral lower extremity; PVL, paravalvular leak.

patients were transferred to the post-operative care unit and monitored over a duration of two to four hours. Patients underwent continuous telemetry, O2 saturation, heart rate, and blood pressure (BP) monitoring. Serial EKGs were recorded immediately post-procedure and prior to discharge. All patients were clinically stable in normal sinus rhythm or baseline AF without evidence of new or deteriorating conduction abnormality. Patients were discharged home on the same day within 5 hours post-procedure.

Technical concerns and preventive measures

The loss of even a single patient due to complications resulting from premature discharge should be a never event. Therefore, meticulous procedural technique and implementation of safety nets are required for any rapid discharge protocol. Important technical and management issues include:

(1) Vascular access. Appropriate arterial access was obtained with ultrasound and micro puncture at the mid-femoral head and confirmed with a limited angiogram in each of the three cases. This was done on both the device and diagnostic catheter side. After valve deployment and removal of the delivery sheath, two Proglides (Perclose Proglide, Abbott vascular) were deployed on the device side. A completion angiogram with runoff was then performed to confirm artery patency and hemostasis. It is our practice that if more than a small leak persists, the vessel is large, and the vessel is without obvious injury, a third proglide is deployed. Alternatively, as was required in 1 of the cases, if there is more than a slight leak from the vessel and/or the vessel is compromised, we cross over from the diagnostic side to the device side and perform balloon occlusion at the access site with an appropriate sized Mustang balloon (Mustang Balloon dilation catheter, Boston Scientific), typically for 5 minutes. After hemostasis was confirmed on the device side, an angio-seal (Angio-seal closure device, Abbott vascular) was used

to achieve hemostasis on the diagnostic side. At the completion of the case, bilateral lower extremity (BLE) pulse checks were performed to ensure pulses were unchanged compared to baseline.

(2) Post-deployment cardiac assessment. To confirm valve position and assess PVL, cardiac function, and hemodynamic result, as well as to rule out pericardial effusion and/or tamponade, a TTE was performed immediately after valve deployment in each of the three patients. In each case, the valve position was as expected, PVL was trace to none, cardiac function was unchanged, and there was no evidence of tamponade.

(3) Conduction. Consideration for SDD should be limited to patients with short PR and narrow QRS intervals or those with a preexisting PPM. Any changes in conduction post-procedurally should serve as a contraindication to the SDD. This is determined by continuous EKG monitoring throughout the procedure.

In each of the three patients, our standard rapid discharge protocol was applied. The patients were transferred from the hybrid OR to the PACU, and in-hospital post-procedure evaluation included the following:

(1) Serial EKGs. Each patient had a 12-lead EKG upon arrival to the PACU and at 4 hours post-procedure to confirm new changes in conduction related to PR and QRS intervals as well as new LBBB or RBBB. In each case, PR and QRS intervals were unchanged compared to baseline, and there was no evidence of new EKG changes.

(2) Repeat TTE at ≥ 4 hrs. Each patient underwent a bedside TTE to rule out change in cardiac function, valve migration, or evidence of new pericardial effusion. None of these complications were observed.

(3) Ambulation at 4 hours. Each patient was ambulated at 4 hours post-procedure.

(4) BLE Pulse exams. No changes were noted.

Telehealth follow-up

After SDD, each of the three patients were followed for 7 days with remote home monitoring with continuous EKG using the Zio system (Zio AT iRhythm, San Francisco, CA). This system functions to alert the patient and provider to conduction changes in real time. At our center, this is standard follow-up for all patients discharged within 5 days of catheter-based or open surgical valve replacement. In these 3 patients, there were no events of advanced AV block or bradycardia (HR <40 BPM) detected by the Zio system. In addition, each patient had a virtual follow-up visit on post-procedure days 1 and 2. After a follow-up duration of 24 days, there were no reports of death or re-hospitalization.

Discussion

The strategy of rapid discharge with real-time home monitoring may play an important role in the post-surge period as well as throughout seasonal pandemic fluctuations. Criteria for SDD should take into consideration baseline clinical

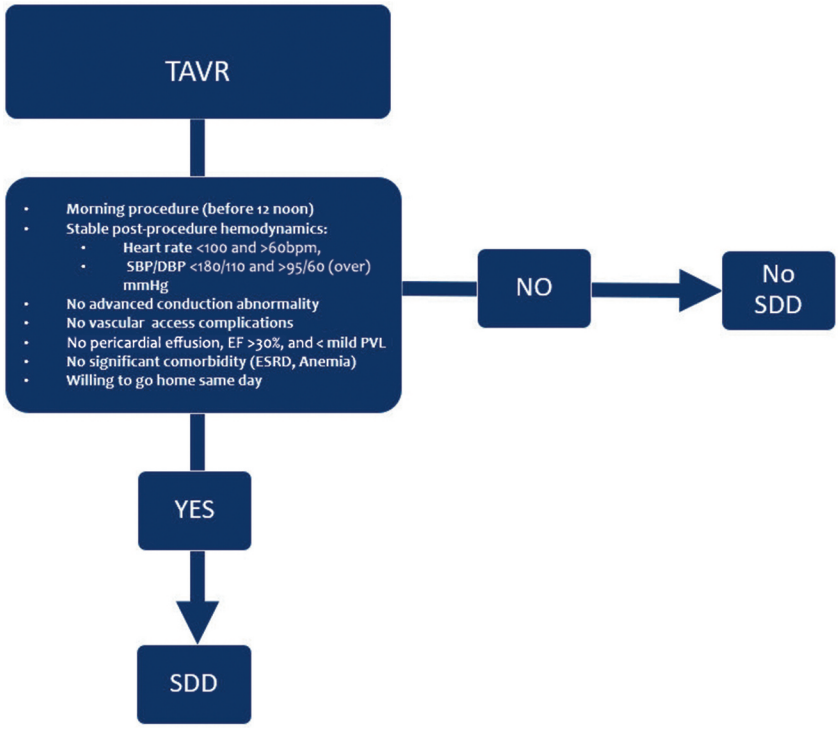

Figure 1. Flow chart representation of proposed protocol for patients who may be suitable for same day discharge (SDD) after TAVR in the era of COVID-19 pandemic. SBP, systolic blood pressure; DBP, diastolic blood pressure; EF, ejection fraction; PVL, paravalvular leak; ESRD, end-stage renal disease.

characteristics imaging features and post-procedure related outcomes. For this unique cohort, only patients without significant comorbidities including but not limited to end-stage renal disease and anemia (Hemoglobin <9 mg/dl) without poor functional status (New York Heart Association Class ≥ III) should be considered. Same day discharge can be considered in patients with LVEF > 30%. Post-procedure, there should be no advanced conduction abnormalities or vascular access issues such as bleeding, and the patient should be willing to go home on the same day [Figure 1].

In conclusion, we describe a series of three patients who underwent TAVR and were discharged uneventfully on the same day. More data is needed to assess the safety and benefits of SDD. Treatment-related metrics should encompass morbidity/mortality, including COVID conversion. Utilization metrics should comprise provider encounters, length of stay, and proportion of same day or next day discharges. To better define optimal imaging protocols, workflow, and the role of telehealth in this population, it will be imperative to assess patients' willingness to schedule telemedicine consults; rates of successful consult completion; need for in-person consult with same provider; significance of tele monitoring parameters; and the ability of home monitoring systems to alert providers to late adverse events.

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Consent

All patients consented to the publication of these cases.

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