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ORIGINAL RESEARCH

Same Day Discharge during the COVID-19 Pandemic in Highly Selected Transcatheter Aortic Valve Replacement Patients

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ABSTRACT

Background: Transcatheter aortic valve replacement (TAVR) with a standardized clinical pathway allows most patients to achieve safe next-day discharge. This approach has been successfully implemented across global centers as part of the Benchmark Program. Considering restricted hospital resources resulting from the COVID-19 pandemic, a modified same day discharge (SDD) clinical pathway was implemented for selected TAVR patients at a single Benchmark site.

Methods: All patients accepted for TAVR were assessed for the SDD clinical pathway. Eligibility criteria included adequate social support and accessibility to the TAVR program post-discharge. Patients with preexisting conduction disease were excluded. The clinical pathway comprised of mobilization, bloodwork and electrocardiogram 4 hours post-TAVR and discharge ≥8 hours following groin hemostasis.

Results: From June to December 2020, 142 patients underwent TAVR at a single community Benchmark site. Of those, 29 highly selected patients were successfully discharged the same day using the SDD clinical pathway. There were no vascular access complications, permanent pacemaker (PPM) implantation, or mortality in the SDD group during index admission or at 30-day follow-up. When compared to a standard therapy group, there was no statistically significant difference in 30-day cardiovascular readmission.

Conclusions: This study demonstrates the safety and feasibility of same day discharge post-TAVR in a highly selected cohort of patients, with no observable difference in safety outcomes when compared to patients who were discharged according to standard institutional practice.

Abbreviations: AS: aortic stenosis; ACT: Activated clotting time; AV: atrioventricular; AVB: atrioventricular block; BBB: bundle branch block; CAIC: Canadian Society for Cardiovascular Angiography; CCL: cardiac catheterization laboratory; CT: Computed topography; CV: cardiovascular; IQR: Interquartile Range; IVCD: intraventricular conduction delay; LBBB: left bundle branch block; LOS: length of stay; NDD: next day discharge; PPM: permanent pacemaker; RBBB: right bundle branch block; SCAI: Society for Cardiovascular Angiography and Intervention; SD: standard deviation; SDD: same day discharge; ST: standard therapy; STS PROM: society of thoracic surgeons predicted risk of mortality; TAVR: transcatheter aortic valve replacement; TF: transfemoral; THV: transcatheter heart valve; TTE: transthoracic echocardiogram; VARC: Valve Academic Research Consortium

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Introduction

Transcatheter aortic valve replacement (TAVR) has been established as an alternative to surgical aortic valve replacement in intermediate and high-risk patients.[1] Post-TAVR care has shifted to early discharge home with the advent of studies demonstrating the safety and efficacy of a standardized pre-, peri- and post-procedural clinical pathway to facilitate rapid reconditioning, avoidance of in-hospital complications and safe next-day discharge (NDD).[2,3] These pathways decreased the need for prolonged critical care monitoring with excellent safety outcomes.[2,3] This approach has been successfully implemented across global centers as part of the Edwards Benchmark Program, a mentored team-based quality improvement initiative aimed at facilitating the adoption of best practices across patients' journey of care from admission to discharge.

The COVID-19 pandemic has placed significant stress on healthcare systems worldwide and has put a spotlight on the importance of appropriate and stringent resource allocation.[4] In order to comply with public health guidelines and preserve essential resources, many cardiovascular (CV) procedures have been delayed with guidance provided by the Canadian Association of Interventional Cardiology (CAIC) and the Society for Cardiovascular Angiography and Intervention (SCAI).[4–6] Given the high morbidity and mortality associated with untreated severe symptomatic aortic stenosis (AS), timely

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access to intervention is vital.[7] While next-day discharge has been shown to be safe and efficacious, consideration during these unprecedented times is given to the development of an even more streamlined approach to TAVR. Same day discharge (SDD) post-TAVR may be one way, in highly selected patients, to provide this essential service while preserving resources. There is limited data on the safety of SDD post-TAVR, however, small retrospective studies have demonstrated that it is feasible in highly selected patients.[8–10]

The aim of this observational study was to assess the safety and feasibility of SDD post-TAVR in highly selected patients at a single site using a multidisciplinary standardized clinical pathway in order to improve timely access to care during the COVID-19 pandemic.

Material and methods

Study design and patient population

This was a single center observational study of patients treated at a community Benchmark site during the COVID-19 pandemic. Between June 2020 and December 2020, all patients undergoing TAVR were evaluated by a virtual multidisciplinary heart team to determine their eligibility for SDD. Elective outpatients who had a TAVR with a balloon expandable Sapien 3 transcatheter heart valve (THV) (Edwards Lifesciences, Irvine, California, USA) with adequate social support and accessibility to the TAVR program, either virtually or in person, in case of readmission were eligible for SDD (Figure 1). Adequate social support was defined as having a family member or caregiver present at the time of TAVR and discharge who would spend the first night post-discharge with the patient and subsequently maintain close contact. Patients with a preexisting pacemaker were eligible for SDD with a self-expanding valve. Patients with preexisting conduction disease including a bundle branch block (BBB), atrioventricular (AV) block or perioperative complications were excluded. All cases during this time period were considered for NDD as per usual institutional practice, but were eligible for SDD if they were agreeable and met the above criteria in order to minimize resource utilization during the COVID-19 pandemic. This study was approved by the Institutional Review Board.

Same day discharge clinical care pathway

The SDD clinical care pathway was developed using a virtual multidisciplinary team including interventional cardiology, cardio-thoracic surgery, nursing and social work (Figure 1). A validated care pathway to facilitate NDD post-TAVR has been implemented globally, across Edwards Benchmark sites (15 countries, 60 sites).[3,11,12] This pathway outlines a streamlined pre-, peri- and post-procedural approach to transfemoral TAVR.[2,3] Modifications to the pathway were made in order to facilitate SDD during the COVID-19 pandemic.

Peri-procedure

Patients were admitted to hospital on the day of their procedure. TAVR took place in the cardiac catheterization laboratory (CCL) or hybrid operating room. All cases deemed eligible for SDD based on criteria outlined above were completed before 11:00 AM. Local anesthesia (2% lidocaine) and light conscious sedation (midazolam 1–2 mg, fentanyl 25–50 mcg, or dexmedetomidine) were used with the support of anesthesia. A 4-French radial arterial line was used for hemodynamic monitoring. Additional central access was avoided in most cases. Ultrasound guidance was used for all vascular

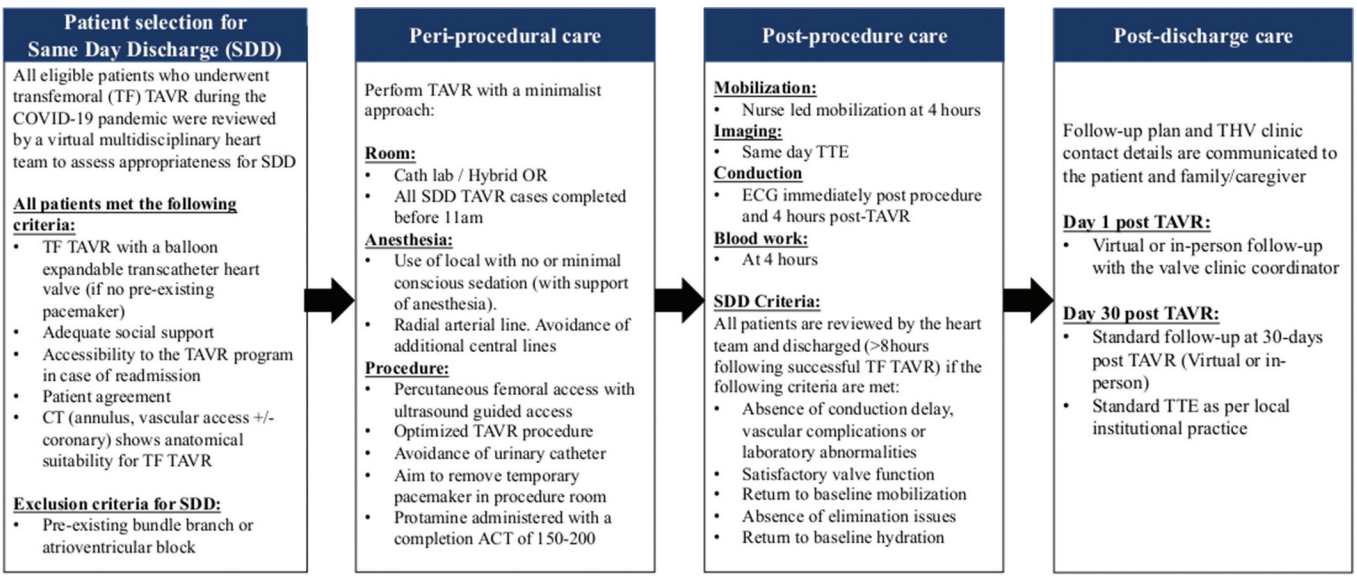

Figure 1. Same day discharge clinical care pathway.

This figure outlines the standardized clinical pathway, including eligibility criteria, peri-procedural, post-procedural and post-discharge care used in this study.
SDD: same day discharge; ACT: Activated clotting time; CT: computed tomography; ECG: electrocardiogram; TAVR: transcatheter aortic valve replacement; TTE: transthoracic echocardiogram

access. Femoral punctures were routinely pre-closed using two Perclose ProGlide devices (Abbott Vascular, Chicago, IL, USA). Contrast was minimized by using only two 15 mL injections for verification of the coplanar view and for valve deployment. In most cases, rapid ventricular pacing was achieved using the left ventricular wire in order to avoid an additional femoral puncture. If present, patients' own permanent pacemaker (PPM) or defibrillator was used. In patients with high risk features for post-operative conduction abnormalities such as a preexisting BBB, intraventricular conduction delay (IVCD) or high-grade AV block, a contralateral 5-French femoral venous pacemaker was inserted for temporary pacing. The transvenous pacer was removed in the procedure room unless high-grade AV block occurred after THV implantation. Following valve deployment, a limited on-table transthoracic echocardiogram (TTE) was obtained to assess left ventricular function, perivalvular leak, gradient across the THV and pericardial effusion. Protamine was administered upon completion for a post-procedure activated clotting time of 150–200. A posteroanterior "single shot" fluoroscopy was obtained on-table post-procedure, replacing the post-procedure chest X-ray. Manual compression to the femoral arterial access site was applied for 15 minutes. A limited neurologic exam and lower extremity arterial pulse checks were performed before procedure completion.

Post-procedure

Patients were admitted to the CCL recovery unit thereby bypassing the critical care unit. Patients were mobilized with the assistance of a registered nurse 4 hours post-procedure. TAVR physicians and the THV clinic coordinator were available at any time if any complications arose. All SDD patients and the majority of standard therapy (ST) patients had a complete TTE the same day, in order to assess post-implantation gradient, presence of perivalvular aortic insufficiency and pericardial effusion. Patients had an ECG immediately post-procedure and at 4 hours in order to assess for conduction abnormalities such as new IVCD, BBB or AV block. A complete blood count, creatinine and electrolytes were done 4 hours post-procedure. All SDD patients were reviewed by the heart team and discharged the same day (>8 hours following successful groin hemostasis) if they met post-procedure criteria for SDD. Requirements notably included the absence of any conduction issue including new IVCD, BBB or AV block and the absence of vascular access complications (Figure 1).

Post-discharge

The follow-up plan and THV clinic contact details were communicated to both the patients and family or caregiver. Patients had a virtual or in person follow-up appointment with the THV clinic coordinator, a specialized nurse practitioner the day following their procedure to assess for post-procedural complications including vascular access complications, new neurologic symptoms to suggest stroke or transient ischemic attack and symptomatic bradycardia. A standard follow-up with the physician-attended THV clinic and TTE were done at 30 days post-TAVR either in person or virtually, depending on patient and family preference. Patients were instructed to call the THV clinic if any non-urgent issues arose post-discharge. If there were any urgent issues, they were instructed to return to the emergency department.

Endpoints

The primary endpoint of this study was the safety of same day discharge, defined by mortality, vascular access site complications, new PPM implantation and cardiovascular readmission at 30 days. Vascular access site complications were defined as per the Valve Academic Research Consortium (VARC) criteria.[13]

Statistical analysis

Considering the feasibility nature of this study, we did not perform a formal sample size calculation. A target sample size of 25 SDD patients was selected on a basis of practical consideration of available resources and was believed to be large enough to provide reasonable evaluation for feasibility and safety of SDD strategy during the COVID-19 pandemic.

Patient baseline, procedural and outcome data were presented as mean and standard deviation (SD) for normally distributed variables, median and interquartile range (IQR) for non-normally distributed variables and frequency and proportion for categorical variables. The comparisons between SDD and ST patients were made with use of two-sample t-test for normally distributed variables, Wilcoxon Rank-Sum test for non-normally distributed variables and fisher's exact test or Chi-square test for categorical variables, depending on the expected cell counts. A two-sided alpha level of 0.05 was considered statistically significant with no adjustment of multiple testing given the exploratory nature of the study. All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, North Carolina, USA).

Results

Between June and December 2020, a total of 142 patients underwent TAVR at a single community Benchmark center. Of these, 29 patients were excluded from this analysis; 20 patients required urgent inpatient TAVR, 5 patients required alternate access, 2 patients had a Lotus valve implanted (Boston Scientific, Marlborough, MA, USA), 2 patients had a Bioprosthetic Aortic Scallop Intentional Laceration Coronary Artery Obstruction (BASILICA) procedure (Figure 2). Of the remaining 113 patients, 39% (n = 44 patients) met the baseline clinical and social criteria for SDD. Of these, 15 patients were ineligible based on peri- and post-procedural criteria and 29 patients were discharged the same day using the SDD clinical pathway (Figure 2). Patients excluded from SDD were discharged the next day or later, using standard institutional protocol. Reasons for exclusion from SDD are outlined in Table 1.

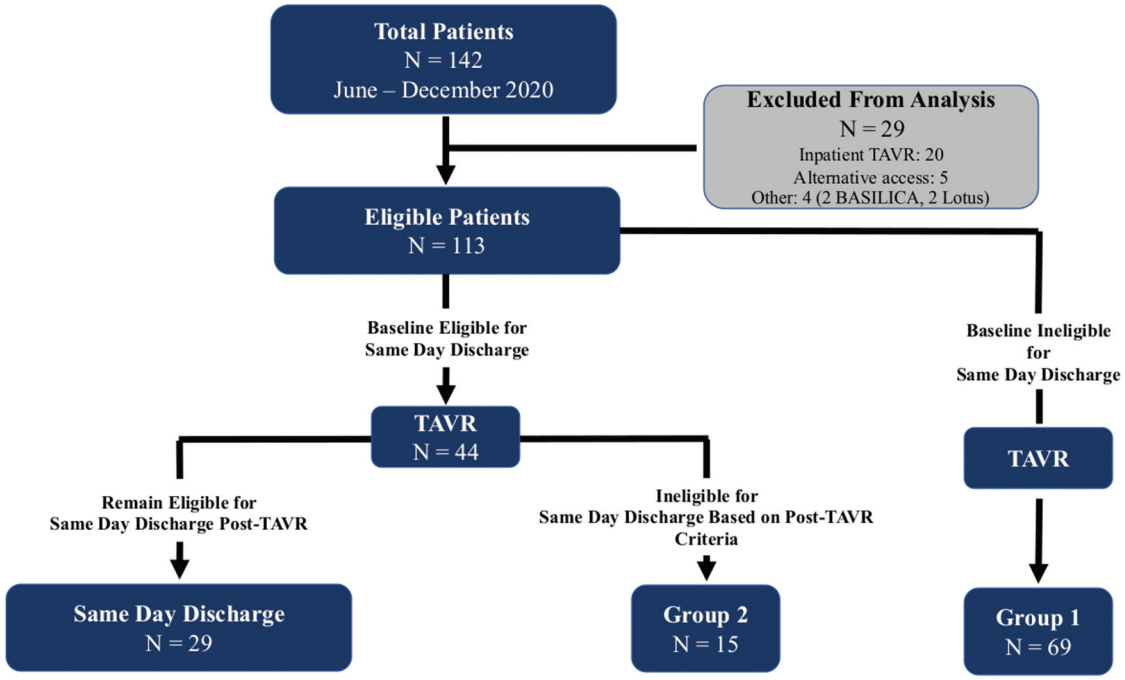

Figure 2. TAVR during the COVID-19 pandemic at a single community site.
outlines the selection of patients for same day discharge post-TAVR.
TAVR: transcatheter aortic valve replacement; BASILICA: Bioprosthetic Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery Obstruction

Baseline characteristics

Baseline characteristics are summarized in Table 2. The average age of the SDD group was 74 ± 9.4 years and 79% of the patients were male. When compared to the ST group, SDD patients were more likely to be younger (p = .037). Surgical risk trended lower, but not significant in SDD group (society of thoracic surgeons predicted risk of mortality (STS PROM) 1.8 vs 2.6, p = .08). 38% of SDD patients (n = 11) had a preexisting PPM.

Procedural data

Procedural data is summarized in Table 3. The majority of cases were done using a combination of local anesthesia and conscious sedation. Total procedural time was numerically lower (although not significant) in the SDD group compared to the ST group (p = .08). Contrast use in both groups was low, with a median of 15 mL in the SDD group and 17 mL in the ST group (p = .28). One patient with a preexisting PPM had a self-expandable THV implanted in SDD group. All patients in the SDD group had a TTE prior to discharge.

Patient outcomes

All patients in the SDD group were successfully discharged the same day, >8 hours following successful groin hemostasis. In the ST group, 92% of patients were discharged the next day. Of the seven patients who were not discharged the next day, two required PPM implantation, one required observation for a new left bundle branch block (LBBB), two had strokes, one of which required thrombolysis, one suffered a root rupture and one had a complicated post-operative stay due to frailty. There were no immediate or post-discharge vascular access complications, PPM implantation or mortality in the SDD group during the index admission or at 30-day follow up (Table 4). There were no cases of new BBB or high-grade AV block in the SDD group (Table 4). In the ST group,

Table 1. Exclusion from same day discharge.

Reason for exclusion*	Number
Pre-TAVR (n = 69)	
Patient/family preference	7
Frailty†	12
IVCD	2
RBBB	11
LBBB	2
First degree AV block	16
Long travel distance from implanting site	12
Heart failure	3
Procedural aspects‡	2
Post-TAVR (n = 15)	
New LBBB	10
New IVCD	2
New first degree AV block	4
New second degree AV block	1
New third degree AV block requiring PPM	3
Vascular access complications	4
Stroke	1
New onset atrial fibrillation	1

*Certain patients had more than one reason for exclusion
†Frailty was assessed using grip strength, 5 minute walk test and albumin.
‡Procedural aspects for exclusion included valve cracking and low coronary ostia.
AV, atrioventricular; IVCD, intraventricular conduction delay; LBBB, left bundle branch block; PPM, permanent pacemaker; RBBB, right bundle branch block; TAVR, transcatheter aortic valve replacement.

Table 2. Baseline characteristics.

	SDD (N = 29)	ST (N = 84)	*p* Value*
Age (years), mean±SD	74.0 ± 9.4	78.3 ± 8.4	.037
Sex (Female), n(%)	6 (20.7)	39 (46.4)	.015
CKD (eGFR <60), n(%)	12 (41.4)	35 (41.7)	.98
Diabetes, n(%)	9 (31.0)	25 (29.8)	.90
Hypertension, n(%)	19 (65.5)	73 (86.9)	.011
BMI, mean±SD	30.2 ± 4.9	31.4 ± 7.2	.35
Smoker			
Former, n(%)	6 (20.7)	28 (33.3)	.20
Current, n(%)	2 (6.9)	2 (2.4)	.27
Prior stroke/TIA, n(%)	1 (3.4)	7 (8.3)	.68
Peripheral arterial disease, n(%)	4 (13.8)	17 (20.2)	.44
Coronary artery disease, n(%)	6 (20.7)	20 (23.8)	.73
Atrial fibrillation, n(%)	9 (31.0)	24 (28.6)	.80
Prior PCI, n(%)	8 (27.6)	28 (33.3)	.57
Prior CABG, n(%)	5 (17.2)	7 (8.3)	.18
Prior AVR, n(%)	0 (0.0)	1 (1.2)	>.99
STS PROM, median(IQR)	1.8 (1.1–2.9)	2.6 (1.7–4.0)	.08
TAVR in hospital mortality risk, median(IQR)	1.8 (1.4–2.8)	2.3 (1.8–3.1)	.10
NYHA>II, n(%)	8 (27.6)	28 (33.3)	.57
CCS>II, n(%)	0 (0.0)	0 (0.0)	-
Pacemaker at baseline, n(%)	11 (37.9)	6 (7.1)	<.001
Complete RBBB, n/N(%)	2/26 (7.7)	12/84 (14.3)	.51
Complete LBBB, n/N(%)	0/25 (0.0)	3/83 (3.6)	>.99
High grade AVB (2nd degree type II and above), n/N(%)	0/21 (0.0)	1/83 (1.2)	>.99
Albumin, mean±SD	3.9 ± 0.4	3.9 ± 0.3	.68
Pre-TAVR EF, median(IQR)	55.0 (55.0–60.0)	55.0 (55.0–60.0)	.44
AV Calcium Score, median(IQR)	2073 (1478–2777)	2112 (1420–3030)	.96
Bicuspid Valve, n(%)	8 (27.6)	5 (6.0)	.004
Mean AV gradient, median(IQR)	42.0 (34.0–51.0)	40.0 (33.5–45.5)	.27
AVA, mean±SD	0.7 ± 0.1	0.8 ± 0.2	.012
AR > moderate, n(%)	0 (0.0)	1 (1.2)	>.99

AR, aortic regurgitation; AV, aortic valve; AVA, aortic valve gradient; AVB, atrioventricular block; AVR, aortic valve replacement; BMI, body mass index; CABG, coronary artery bypass graft; CCS, Canadian Cardiovascular Society; CKD, chronic kidney disease; EF, ejection fraction; eGFR, estimated glomerular filtration rate; IQR, interquartile range; LBBB, left bundle branch block; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RBBB, right bundle branch block; SD, Standard deviation; SDD, same day discharge; ST, standard therapy; STS PROM, Society of Thoracic Surgeons predicted risk of mortality; TAVR, transcatheter aortic valve replacement; TIA, transient ischemic attack; TTE, transthoracic echocardiogram.

* *p* value is from Fisher's exact test or Chi-square test for categorical variables, depending on the expected cell counts, and two-sample t-test for normally distributed variables and Wilcoxon Rank-Sum test for non-normally distributed variables.

Table 3. Procedural characteristics.

	SDD (N = 29)	ST (N = 84)	*p* Value†
Conscious sedation, n(%)	29 (100)	82 (97.6)	>.99
Pacing Through the LV Wire, n(%)	21 (72.4)	64 (76.2)	.68
Contrast Dye used (mL)*, median(IQR)	15.0 (15.0–21.5)	17.0 (15.0–30.0)	.28
Total procedural time (mins), median(IQR)	35.0 (32.0–46.0)	41.0 (33.0–56.0)	.08
Total radiation dose (cGy), median(IQR)	354.0 (194.0–538.0)	385.0 (241.0–676.0)	.19
Fluoroscopy time (mins), median(IQR)	10.0 (7.8–12.3)	9.8 (8.0–13.8)	.71
Same day TTE, n(%)	29 (100)	61 (72.6)	.002
AV mean gradient on TTE, median(IQR)	9.0 (6.0–12.0)	9.0 (7.0–13.0)	.72
Type of valve			
Balloon expandable, n(%)	28 (96.6)	82 (97.6)	>.99
Self expandable, n(%)	1 (3.4)	2 (2.4)	>.99

AV, aortic valve; IQR, interquartile range; LV, left ventricle; SDD, same day discharge; ST, standard therapy; TTE, transthoracic echocardiogram.

* In general, only 2 images are taken (15 mL/sec × 1 sec, 50% dye/saline mixture): baseline root aortogram for AV anatomy/angle confirmation AND deployment angiogram.

† *p* value is from Fisher's exact test or Chi-square test for categorical variables, depending on the expected cell counts, and Wilcoxon Rank-Sum test for non-normally distributed variables.

Table 4. Patient outcomes.

	SDD (N = 29)	ST (N = 84)	*p* Value*
Periprocedural outcomes (index admission)			
Procedural success, n(%)	29 (100)	83 (98.8)	>.99
Post-TAVR LOS (nights), median(IQR)	0.0 (0.0–0.0)	1.0 (1.0–1.0)	<.001
Post-TAVR ICU LOS (hours), median(IQR)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	.14
Death, n(%)	0 (0.0)	1 (1.2)	>.99
Stroke/TIA, n(%)	0 (0.0)	3 (3.6)	.57
New PPM implantation, n(%)	0 (0.0)	4 (4.8)	.57
Major vascular complications, n(%)	0 (0.0)	3 (3.6)	.57
Next day discharge, n/N(%)	0/29 (0.0)	76/83 (91.6)	<.001
New complete LBBB, n/N(%)	0/29 (0.0)	8/83 (9.6)	.11
New complete RBBB, n/N(%)	0/29 (0.0)	2/83 (2.4)	>.99
New high grade AVB (2nd degree type II and above), n/N(%)	0/29 (0.0)	1/83 (1.2)	>.99
30-day outcomes			
Death, n(%)	0 (0.0)	2 (2.4)	>.99
Stroke/TIA, n/N(%)	1/29 (3.4)	0/83 (0.0)	.26
Cardiovascular readmission, n/N(%)	1/29 (3.4)	6/83 (7.2)	.67
Major vascular complications, n/N(%)	0/29 (0.0)	0/83 (0.0)	-
PPM, n/N(%)	0/29 (0.0)	3/83 (3.6)	.57

AVB, atrioventricular block; ICU, intensive care unit; IQR, interquartile range; LBBB, left bundle branch block; LOS, length of stay; PPM, permanent pacemaker; RBBB, right bundle branch block; SDD, same day discharge; ST, standard therapy; TAVR, transcatheter aortic valve replacement; TIA, transient ischemic attack.
* *p* value is from Fisher's exact test or Chi-square test for categorical variables, depending on the expected cell counts, and Wilcoxon Rank-Sum test for non-normally distributed variables.

Table 5. Patient outcomes based on timing of exclusion from same day discharge.

	SDD (N = 29)	Pre-TAVR* (N = 69)	Post-TAVR† (N = 15)
Periprocedural outcomes (index admission)			
Death, n (%)	0 (0.0)	1 (1.4)	0 (0.0)
Stroke/TIA, n (%)	0 (0.0)	3 (4.3)	0 (0.0)
New PPM implantation, n (%)	0 (0.0)	4 (5.8)	0 (0.0)
Major vascular complications, n (%)	0 (0.0)	2 (2.9)	1 (6.7)
30-day outcomes			
Death, n (%)	0 (0.0)	1 (1.4)	0 (0.0)
Stroke/TIA, n/N (%)	1/29 (3.4)	0/68 (0.0)	0/15 (0.0)
New PPM implantation, n/N (%)	0/29 (0.0)	3/68 (4.4)	0/15 (0.0)
Major vascular complications, n/N (%)	0/29 (0.0)	0/68 (0.0)	0/15 (0.0)
Cardiovascular readmission, n/N (%)	1/29 (3.4)	7/68 (10.3)	0/15 (0.0)

PPM, permanent pacemaker; SDD, same day discharge; TAVR, transcatheter aortic valve replacement; TIA, transient ischemic attack.
*: Pre-TAVR group represents patients excluded from SDD based on baseline clinical and social characteristics.
†: Post-TAVR group represents patients excluded from SDD based on peri- and post-procedural criteria.

10 patients had a new BBB and one patient developed high-grade atrioventricular block (AVB) post-TAVR. Four of those patients required PPM implantation at the time of index hospitalization and three others required PPM implantation at 30-day follow-up (Table 4). One patient in the SDD group was readmitted to hospital with new neurologic symptoms with spontaneous recovery and less than 24-hour hospital stay within 30-day follow-up (Table 4). When compared to the ST group, there was no statistically significant difference in rates of cardiovascular readmission (p = .67) or post-procedural neurologic events (p = .26) at 30 days. There were no deaths in the SDD group and two deaths in the ST group at 30 days (Table 4). No patients in either the SDD or ST group contracted COVID-19 during their index hospitalization or at 30-day follow-up. When analyzed based on timing of exclusion from SDD (pre- or post-TAVR), the majority of complications both during the index admission and at 30 days occurred in patients excluded based on baseline clinical and social characteristics (Table 5).

Post-discharge follow-up

All patients in the SDD group were assessed by virtual or in person follow-up the day after discharge by the THV clinic coordinator (Table 6). They also had a routine 30-day virtual or in-person follow-up with TTE. Median post-TAVR echocardiographic

Table 6. Post-discharge follow-up.

	SDD (N = 29)	ST (N = 84)	*p* Value*
Time to follow up (days), median(IQR)	1.0 (1.0–1.0)	10.0 (6.0–33.0)	<.001
NYHA >II (%), n/N(%)	1/29 (3.4)	1/81 (1.2)	.46
CCS >II (%), n/N(%)	0/29 (0.0)	1/81 (1.2)	>.99
Post-TAVR EF, median(IQR)	57.5 (57.5–57.5)	57.5 (55.0–62.5)	.27
AV mean gradient on TTE, median(IQR)	14.0 (10.0–17.0)	12.0 (9.3–15.0)	.40
Presence of > mild paravalvular leak, n/N(%)	1/28 (3.6)	3/78 (3.8)	>.99

AV, aortic valve; CCS, Canadian Cardiovascular Society; EF, ejection fraction; IQR, interquartile range; NYHA, New York Heart Association; SDD, same day discharge; ST, standard therapy; TAVR, transcatheter aortic valve replacement; TTE, transthoracic echocardiogram.
* *p* value is from Fisher's exact test or Chi-square test for categorical variables, depending on the expected cell counts, and Wilcoxon Rank-Sum test for non-normally distributed variables.

aortic valve mean gradient was 14 mmHg in the SDD group and only one patient had greater than mild paravalvular leak.

Discussion

This community-based, single center study demonstrates the safety and feasibility of SDD post-TAVR during the COVID-19 pandemic in highly selected patients using a standardized clinical pathway (Figure 3). All patients were discharged safely the same day, with no 30-day mortality, vascular access complications or PPM insertion. There was one readmission to hospital with new neurologic symptoms with spontaneous recovery and less than 24-hour hospital stay. There was no observable difference in 30-day mortality, vascular access complications, post-procedure neurologic events or cardiovascular readmission between the SDD and ST groups. There was a higher incidence of conduction abnormalities and PPM implantation in the ST group. No patients contracted COVID-19 during their index hospitalization or at 30-day follow-up.

The COVID-19 pandemic has led to significant resource constraints and delays in essential CV procedures in order to comply with public health guidelines and minimize spread of the virus.[4] SCAI and CAIC have provided a framework for management of CV procedures during the different phases of the pandemic.[5,6] As COVID-19 cases continue to increase throughout the United States, many centers have had to defer diagnostic testing and invasive CV procedures given scarcity of hospital beds and critical care resources. There continues to be uncertainty around the duration of these restrictions, due to the unpredictability of the pandemic. Given the high morbidity and mortality associated with delaying essential TAVRs for patients with severe symptomatic aortic stenosis (AS), it is important to consider a temporary shift in management of patients post-TAVR in order to

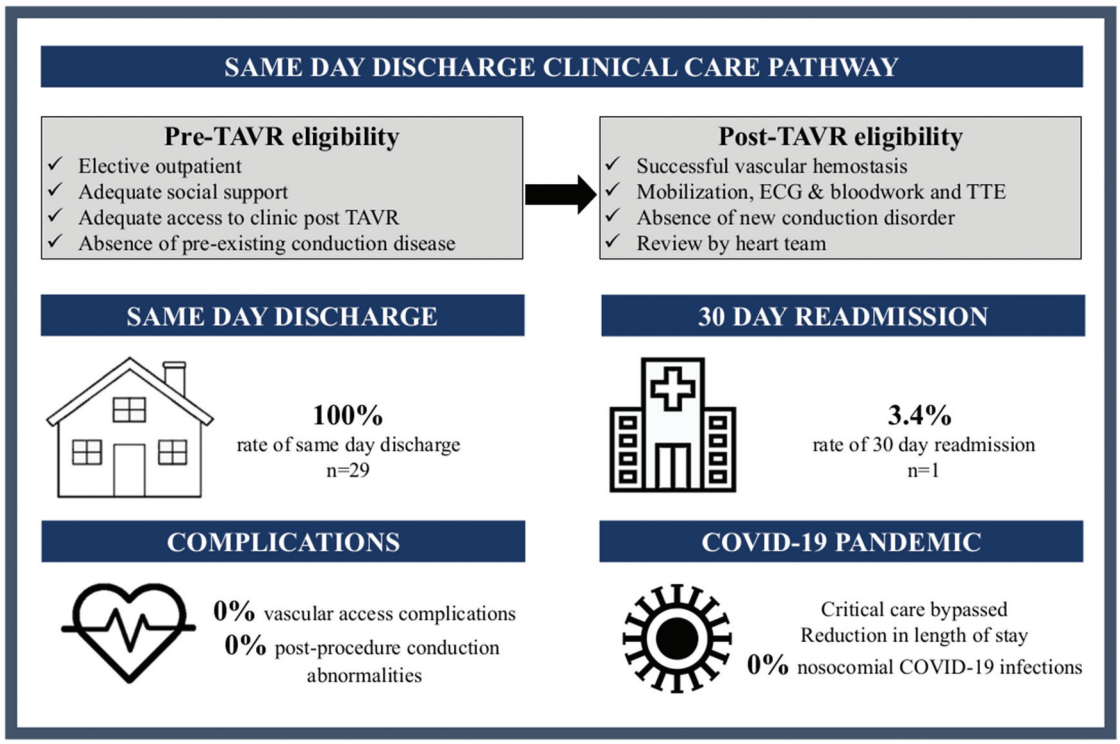

Figure 3. Same day discharge post-TAVR.
This figure highlights key eligibility criteria for same day discharge and key outcomes from the study.

minimize resource use but continue to provide care for these patients.[7] By bypassing critical care for the vast majority of patients and by reducing length of stay, the Benchmark approach has provided the framework to allow for continuation of minimalist TAVR, while conserving essential resources.[3]

SDD post-TAVR has been considered in small retrospective studies as a feasible option in highly selected patients during the COVID-19 pandemic.[8–10] To date, only large tertiary care centers have attempted SDD.[8–10] While there are no large-scale studies to support SDD post-TAVR, this study demonstrates the safety and feasibility of this approach in a community hospital in highly selected patients. A multidisciplinary pathway was designed in order to facilitate this process and ensure consistent, safe practice. All patients who required TAVR during the study time period were considered for the SDD clinical pathway. The presence of preexisting conduction disease was our primary exclusion criteria from the SDD clinical pathway. Conduction disease post-TAVR, including new high-grade AV block, IVCD or BBB, remains a significant cause of morbidity.[14] While there were no new conduction abnormalities observed in the SDD group, 37.9% of these patients had a preexisting pacemaker. There remains concern regarding delayed conduction abnormalities 1 to 2 weeks post-TAVR. Balloon expandable valves have been shown to have a lower incidence of PPM implantation when compared to self-expandable valves.[14,15] Therefore, only the Sapien valve (Edwards Lifesciences, Irvine, California, USA) was used in this study in order to facilitate safe SDD in patients without a preexisting PPM. As virtual care is adopted more widely as the pandemic progresses, event monitors or implantable loop recorders may be of use in patients at high risk for conduction abnormalities post-procedure to avoid prolonged admission to hospital.

Anesthesiologists play an important role in the SDD multidisciplinary team. The transition from using general anesthesia to conscious sedation and local anesthesia is desirable in the elderly TAVR population. By avoiding heavy sedation, it allows for patients to rapidly return to their baseline function and mobility and reduces the risk of peri-operative delirium.[16–18] Patient and family engagement, and adequate social support and accessibility to the TAVR program is critical for successful SDD. Many patients do not live in close proximity to a TAVR center, therefore patient and family education by a multidisciplinary team on appropriate monitoring for vascular complications, signs of conduction abnormality and indications to seek medical attention is critical and has allowed for safe discharge in many patients.

The outcomes of this single center study are similar to those reported in two small retrospective studies, also conducted during the COVID-19 pandemic. In a retrospective observational study, Perdoncin *et al.* demonstrated that SDD following uncomplicated TAVR was safe and feasible when compared to a cohort of next-day discharge patients.[8] In our study, we sought to provide a comprehensive clinical pathway to facilitate SDD with specific exclusion criteria in order to ensure safety. When compared to a cohort who were discharged according to standard institutional practice, primarily the next day, there was no signal for harm. Interestingly, in the standard therapy cohort, most complications arose in patients who were excluded based on baseline clinical and social characteristics, highlighting the importance of thorough multidisciplinary evaluation and careful patient selection. This overall shows promising feasibility of SDD using a standardized clinical pathway in highly selected patients during the COVID-19 pandemic.

Limitations

There are several limitations to this study. It was a small, single center study and therefore may not reflect current practice at other institutions. Patients in this study were deemed low risk for vascular complications and conduction abnormalities and were highly selected by a multidisciplinary heart team in order to ensure appropriate candidacy for SDD. The majority of cases were performed using a Sapien valve (Edwards Lifesciences, Irvine, California, USA), therefore these results cannot be generalized to other THV platforms without a preexisting PPM. A high proportion of patients in the SDD group had a preexisting pacemaker when compared to the standard therapy group, which decreased the incidence of conduction abnormalities post-TAVR and limits generalizability to an all-comer population. Further investigation with a large, multicenter study, the PROTECT-TAVR study, is underway in order to demonstrate the generalizability of SDD post-TAVR.

Conclusion

Overall, this study demonstrates that same day discharge post-TAVR in a highly selected group of patients at low risk of early vascular complications or conduction abnormalities is safe and feasible, with no observable difference in safety outcomes when compared to a cohort of patients who were discharged based on standard institutional practice. This strategy may be used in order to allocate resources in a time of crisis such as the COVID-19 pandemic.

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Disclosure statement

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Data availability statement

The data that support the findings of this study are available from the corresponding author, AMP, upon reasonable request.

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