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Same Day Discharge After Structural Heart Disease Interventions in the Era of the Coronavirus-19 pandemic and Beyond.

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Abstract

With recent advancements in imaging modalities and techniques and increased recognition of the long-term impact of several structural heart disease interventions, the number of procedures has significantly increased. With the increase in procedures, also comes an increase in cost. In view of this, efficient and cost-effective methods to facilitate and manage structural heart disease interventions are a necessity. Same-day discharge (SDD) after invasive cardiac procedures improves resource utilization and patient satisfaction. SDD in appropriately selected patients has become the standard of care for some invasive cardiac procedures such as percutaneous coronary interventions. This is not the case for the majority of structural heart procedures. With the Coronavirus Disease 2019 (COVID-19) pandemic, safely reducing the duration of time spent within the hospital to prevent unnecessary exposure to pathogens has become a priority. In light of this, it is prudent to assess the feasibility of SDD in several structural heart procedures. In this review we highlight the feasibility of SDD in a carefully selected population, by reviewing and summarizing studies on SDD among patients undergoing left atrial appendage occlusion (LAAO), patent foramen ovale (PFO)/atrial septal defect (ASD) closure, Mitra-clip, and Trans-catheter aortic valve replacement (TAVR) procedures.

Key Words: Mitra-Clip; Transcatheter Aortic Valve Replacement; Same-Day Discharge; Atrial Septal Defect, Coronavirus.

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Core Tip: Same-Day Discharge can safely be done among a highly selected group of patients undergoing structural interventional cardiac procedures.

INTRODUCTION

Same-day discharge (SDD) following percutaneous coronary interventions (PCI) in certain patient groups has been shown to have no increased risk of death, re-hospitalization, and has been associated with increased patient satisfaction (1-4). According to the 2021 American College of Cardiology (ACC) SDD after PCI decision pathway, SDD is defined as a procedure that does not include supervised overnight monitoring in a facility or hospital after an elective procedure (5). Several prerequisites have been postulated and the ACC consensus pathway provides a checklist that can be used to determine eligibility for SDD in patients undergoing PCI, however, no consensus has been formulated yet for patients undergoing structural interventional heart procedures (5). Ideally, patients should be identified as candidates suitable for SDD before the procedure, have an uncomplicated procedure and recovery, be able to pick up required medications, be willing to depart on the same day, and have the means to care for themselves or have reliable caregivers to monitor them over the next 24 h. Most patients would be followed up on the same day *via* telephone-health and some are offered next day in-person visits to be assessed by the interventionalist (5,6). This has now become important especially due to the current COVID-19 pandemic, as initially all elective procedures were recommended to be postponed by several leading health care authorities to prevent unnecessary exposure to patients and health care workers and to conserve personal protective equipment and bed availability. Delays in timely intervention among patients with structural/valvular heart disease place these patients at increased risk for adverse cardiovascular outcomes, including death (7). A position statement from the ACC/Society for Cardiovascular Angiography and Interventions provides a framework to triage patients in need of structural heart interventions during the COVID-19 pandemic and discusses pre-procedural evaluation by a dedicated 'Heart Team' and procedural indications (7). In this manuscript, we aim to review and summarize the available literature on the safety of SDD among patients undergoing structural heart interventional procedures including, left atrial appendage occlusion (LAAO), patent foramen ovale (PFO)/atrial septal defect

(ASD) closure, Mitra-clip, and Trans-catheter aortic valve replacement (TAVR) procedures.

SEARCH STRATEGY

⁴ We performed an extensive search of electronic databases including PubMed/Medline, Google Scholar, and ClinicalTrials.gov from inception till October 1st, 2021. We included studies that included structural intervention procedures and included patients who were discharged on the same day of the procedure. Eligible studies were reviewed and information was summarized by all authors.

LEFT ATRIAL APPENDAGE OCCLUSION DEVICE PROCEDURE

It was estimated that in the year 2010 around 9 million residents of the European Union were living with Atrial Fibrillation (AF). AF significantly increases the risk of embolic strokes and the postulated primary source of thrombus formation is the left atrial appendage (8). Current ACC guidelines recommend the option of LAAO for patients with non-valvular AF at high risk for serious bleeding events or who have contraindications for long-term oral anticoagulation to reduce the risk of embolic stroke (9). Left atrial appendage occlusion can be achieved percutaneously by deploying the WATCHMAN device (Boston Scientific, Marlborough, MA, USA), at the left atrial appendage ostia *via* transseptal puncture using a 12 French sheath *via* trans-femoral venous access. In the PROTECT-AF and the PREVAIL trials, LAAO was found to be non-inferior to warfarin in the prevention of stroke, systemic embolization, and cardiovascular death (10,11). The EWOLUTION study concluded that LAAO led to reduced incidence of stroke and non-procedural bleeding(12).

Traditional practice is to admit patients and observe them overnight after LAAO device procedures and to discharge them after around 24 h. Complications following LAAO procedures typically occur during or within a few hours after the procedure (13), hence certain groups created a clinical pathway for safe SDD after LAAO procedures. There have been four recently published studies with data regarding the feasibility of SDD among patients that underwent LAAO, with the vast majority being with the WATCHMAN device (13-16). In a single-center, retrospective analysis of 190 successful

LAAO device implantation using the WATCHMAN device, Tan *et al* compared 7 and 45- day outcomes among SDD patients compared to non-SDD patients (14). In their study, 72 patients were discharged on the same day of the procedure compared to 118 patients that required at least one night of observation. In their study, pre-requisites for SDD were being able to ambulate two hours after the procedure to assess vascular integrity, anti-platelet and oral anticoagulant started or on hand, hemodynamic stability,

no vascular access site complications, and some patients underwent a trans-thoracic echocardiogram (TTE) before discharge. The primary outcome of the study was a composite of stroke, systemic embolism, bleeding requiring blood transfusion, vascular access site complication, and death. The 7-day and 45-day primary outcomes were met by (1.2% vs. 5.9% of SDD *vs* non-SDD patients) and (2.8% vs. 9.3% of SDD *vs* non-SDD patients), respectively, $P = 0.26$ and $P = 0.14$. There was also no difference in re-admission or 45-day peri-device flow >5mm between SDD and non-SDD patients (14).

Several other smaller single-center studies reported on the feasibility of SDD among patients undergoing LAAO procedures. In a study by Gilhofer *et al*, 24 out of 78 patients were discharged on the same day of the LAAO procedure (13). Pre-requisites to SDD in their study were lack of significant frailty determined by a local scoring system, good home support, a TTE performed after 5 h of step-down observation revealing no significant pericardial effusion, and agreement to come in again the next morning for a repeat TTE and outpatient evaluation. They reported no significant events in either the SDD or non-SDD group (13). In an effort to enhance SDD, Marmagkiolis *et al* performed all WATCHMAN procedures under conscious sedation and were able to discharge 112 of their 178 patients within six hours after the procedure. They also required a TTE before discharge without evidence of significant pericardial effusion and a next-day follow-up TTE. They reported no complications in the SDD group (15). In another retrospective analysis of 177 LAAO procedures in the United Kingdom using various LAAO devices, 78 patients were discharged on the same day. Half of the patients had LAAO with the Amplatzer Cardiac Plug, 41% with the Amulet Occluder, and 2.5% with

WATCHMAN. They reported **that** 1.7% of all their procedures suffered major in-hospital complications, hence were not suitable for SDD. They had required all patients to have a TTE on the day of the procedure without evidence of pericardial effusion, available transportation, and completion of the procedure before 4 pm to be considered eligible for SDD. In their study one patient from the SDD group was readmitted within 7 days, however, they concluded that it would have not been prevented by an overnight stay. Of note, all patients were discharged on DAPT for 28 days and then transitioned to SAPT thereafter, consistent with the European expert consensus statement (16,17).

MITRA-CLIP

Chronic systolic heart failure eventually leads to left ventricular dilatation and mitral regurgitation (MR) may develop secondary to ventricular remodeling and geometric dislocation of the mitral valve apparatus including the papillary muscles and chordae tendineae, impairing coaptation of the mitral leaflets (18). In a recent meta-analysis of 45,900 patients with secondary mitral regurgitation, secondary mitral regurgitation was associated with an increased risk of heart failure hospitalizations, cardiac mortality, and death (19). The MITRA-FR study showed no difference in the primary outcome of death from any cause or hospitalization for heart failure (HF) at one year, while the COAPT trial showed a significant reduction in HF hospitalizations and all-cause mortality within 2 years (20, 21). The main reason for the observed differences was attributed to the enrollment in the COAPT trial requiring all patients to be on maximally tolerated guideline-directed medical therapy (GDMT) before enrollment, as compared with the MITRAFR trial (22). The current 2021 ACC expert consensus HF guidelines recommend that GDMT should be optimized before percutaneous trans-catheter mitral valve repair based on evidence from previous randomized control trials (20,21,23). The main reason for overnight observation in Mitra-clip procedures is usually to monitor for vascular access complications, as it requires a 24 French sheath introduced *via* the femoral vein, raising concern over possible bleeding complications.

In a single-center retrospective study by Marmagkiolis *et al*, 95 patients underwent Trans-catheter mitral valve repair, of which 82 were discharged on the same day of the

procedure (24). In their study, 39 patients had primary MR and 43 had secondary/Functional MR due to heart failure. They included patients with a society of thoracic surgery (STS) score $>8\%$ and deemed unsuitable for surgical mitral valve repair/replacement. The mean age of participants was 80.2 ± 2.5 years, mean EF=45%, 20% with grade 3 MR, and 80% with grade 4 MR. They had a 100% procedure success rate and all procedures were performed under minimal conscious sedation or monitored anesthesia care and TEE guidance. All patients that had no intra-procedural complications and a stable course during observation for 6-8 h and were able to walk with no vascular access complications were considered for SDD. In their study, all patients underwent a figure of eight suture to the access site and only one patient had suffered from a minor bleeding event according to the valve academic research consortium-2 criteria (24).

In a case report by Chen *et al*, they describe an expedited Mitra-clip procedure for an 86-year-old patient with severe MR who was discharged on the same day during the COVID-19 pandemic. His STS risk score was 4.2%, with an EF of 40%, and NYHA III heart failure symptoms. Following the procedure, the patient was observed for four hours, a TTE showed no pericardial effusion, and confirmed the placement of the Mitraclips. The patient was sent home with a 7-day continuous rhythm-monitoring device without any documented arrhythmia and was seen on days 1 and 2 after the procedure *via* telephone-health calls (25). These prior studies indicate that SDD is reasonable and possible for selected patients undergoing the Mitra-clip procedure without procedural complications and with adequate follow-up.

TAVR

Aortic stenosis (AS) is the most common type of valvular heart disease in the United States and is typically caused by calcific degeneration of a tri-leaflet aortic valve or stenosis of a congenital bicuspid aortic valve (AV) (26). TAVR is an alternative to surgical aortic valve replacement for treating severe AS or Bio-prosthetic AV dysfunction in patients at high or intermediate surgical risk based on the STS score, frailty, and existing comorbidities (27). Recently, the five-year outcomes from the

PARTNER trial were published and showed no significant difference in the incidence of death or stroke in patients undergoing TAVR at intermediate surgical risk compared to SAVR (28). Despite TAVR being a commonly performed interventional procedure in the current era, it does not come without the potential for serious procedural and post-procedural complications. As with any interventional procedure, TAVR has been associated with vascular access complications especially due to the large sheath introduced mainly *via* the femoral artery. Other complications include pericardial effusions and tamponade, peri-procedural stroke, and new conduction abnormalities such as high-grade atrioventricular block (AV) and complete heart block requiring permanent pacemaker (PPM) implantation (28,29). Hence, the standard practice is to observe patients 24-48 h after the procedure for new or worsening conduction abnormalities (30). However, with the COVID-19 pandemic and the patient population undergoing TAVR usually being elderly with multiple co-morbidities placing them at higher risk of COVID-19 related complications, several studies sought and reported on SDD following TAVR (6,31,32).

In a case series, three elderly patients with AS underwent TAVR and were discharged home on the same day with 7 days of continuous rhythm monitoring (31). Authors hypothesized that SDD may be safe after TAVR in a pre-selected cohort of patients with AS and also help reduce the risk of unnecessary COVID-19 transmission, conserve hospital beds, and PPE. Since the authors recognized that the loss of a single patient secondary to preventable complications due to early discharge is a never event, they developed protocols and safety nets for their SDD protocol. They considered patients with no significant comorbidities such as end-stage kidney disease, hemoglobin <9 mg/dL, NYHA ≥ 3 symptoms, EF<30%, no significant pericardial effusion, new or worsening AV block, and no vascular access complications able to be discharged on the same day of the procedure after observation for 4-6 h. In order to minimize complications, they performed ultrasound-guided vascular access, performed a TTE immediately after device deployment and 4 h after deployment to detect complications, obtained serial electrocardiogram's to mainly assess QRS intervals,

ambulated patients after 4 h, and performed serial lower extremity pulse checks. In their case series, there were no new conduction abnormalities detected and all patients were followed up on days 1 and 2 post-procedure. They had no deaths or re-admissions within 24 days of the procedure (31).

Rai *et al* reported their experience of SDD based on 6 patients with severe symptomatic AS or bio-prosthetic valve dysfunction and proposed an SDD protocol (32). Since the major barrier to discharge patients after TAVR is related to new or worsening conduction abnormalities, they hypothesized that having a pre-procedure PPM or discharge with real-time continuous monitoring could allow for safe SDD. In their case series, they included patients that had predictors of next-day discharge after TAVR based on previous analyses (30). In a recent study, rapid atrial pacing using the temporary pacing wire used for ventricular standstill during TAVR deployment while in the right atrium, had a 99% negative predictive value for pacemaker implantation after TAVR if no Wenckebach phenomenon developed at a heart rate of 120 bpm (33). Rai *et al* utilized this method in one of their patients and proposed its use prior to SDD in all patients without chronic AF, pre-existing PPM, or pre-existing AV block. Additionally, all patients had pre-procedure and post-procedure ECGs performed and if there was a pre-existing right bundle branch block (RBBB) or new AV conduction disturbances, patients were admitted overnight for observation. Otherwise, if patients had a pre-procedure PPM, unchanged ECG from baseline, and no Wenckebach on rapid atrial pacing, they were considered for SDD after 4 h of observation given lack of vascular access site complications. Despite one of their patients developing Wenckebach at 110 bpm, he

was discharged on the same day due to a low positive predictive value of the finding and the lack of other conduction abnormalities noted. All six patients were followed with continuous rhythm monitoring for seven days and followed up in person the next day. Based on their experience, they recommend patients with a baseline RBBB not be considered for SDD, as it is one of the strongest predictors for pacemaker need following TAVR (34), additionally, patients who develop a new left bundle branch

block after TAVR should be kept overnight for monitoring. Of note, all 6 patients in their series underwent balloon-expandable valve replacements and these recommendations could not be generalized to patients undergoing TAVR utilizing a self-expandable system, as there has been evidence suggesting higher PPM implantation in these patients (35).

The largest study regarding SDD in TAVR was conducted by Perdoncin *et al*, in which they report on 29 consecutive SDD TAVR procedures at their center and compared outcomes to patients who underwent TAVR at their center that were non-SDD, who could have qualified for SDD based on their devised protocol (6). They considered patients with an EF>30%, hemoglobin >10, INR <2, those who received a contrast load <3 times the estimated Glomerular Filtration Rate (eGFR), without new or worsening conduction abnormalities, or hemodynamic instability for SDD. The primary outcome was to compare 30-day mortality, PPM implantation, stroke, and cardiovascular-related admissions in SDD patients and non-SDD patients. They compared 29 SDD patients to 128 patients that were non-SDD who currently met their protocol for SDD and were fairly similar with regards to baseline characteristics. Procedural characteristics were similar in both groups and all cases were performed *via* trans-femoral access under conscious sedation. Post-procedure, both groups had no in-hospital complications. At 30 days, there were no deaths, the rate of stroke was 0.6%, and delayed PPM implantation was also 0.6% in both groups combined. They noted a trend towards a higher rate of cardiovascular re-admissions in the non-SDD group compared to the SDD group. One patient in the non-SDD group was re-admitted for high-grade AV block requiring PPM implantation. Of note, both self-expanding and balloon expanding valves were used with a trend towards higher use of self-expanding valves in the SDD group. However, further studies are required to determine the feasibility of the use of self-expanding valves for SDD TAVR procedures given the potential concern of outward sub-annular radial force and risk of delayed conduction changes (36).

Overall, based on the prior studies the main concern for SDD in TAVR is related to new or worsening conduction abnormalities that could arise during or after the procedure.

All patients considered being candidates for SDD should be identified early during a 'heart team' multi-disciplinary discussion and deemed suitable based on pre-procedure pre-requisites. All patients with a baseline RBBB, new high-grade AV block after the procedure, new inter-ventricular conduction delay, or Wenckebach on right atrial pacing after valve deployment should be admitted overnight for inpatient observation. If considered for SDD, all patients must be willing to go home, have no vascular access complications after initial observation, have close follow-up arranged, and be sent home with a real-time rhythm monitor to detect arrhythmias. We present a proposed protocol for SDD following TAVR in Figure 1.

PFO/ASD CLOSURE

ASDs are one of the most common congenital heart defects found in the general population. Unrepaired ASDs can result in various cardiopulmonary adverse events such as arrhythmias, pulmonary hypertension, and paradoxical embolization. Current adult congenital heart disease guidelines recommend ASD closure in carefully selected patients with hemodynamic instability or clinical consequences resulting from their long-standing intra-cardiac shunting (37). Additionally, up to 50% of patients with a cryptogenic stroke have been found to have an associated PFO (38). The first three randomized controlled trials CLOSURE I, PC, and RESPECT failed to show any statistical significance in secondary stroke prevention (39-41). More recent studies, however, have demonstrated that in carefully selected patients, PFO closure is preferable to medical therapy for secondary stroke prevention of cryptogenic strokes in patients with PFO (42-43). In a review article published in the Journal of the American College of Cardiology, authors proposed a clinical pathway to aid in the appropriate selection of patients that should undergo PFO closure based on randomized trials showing benefit (38).

The PFO closure procedure is usually done as a day case procedure using one of only two FDA approved devices in the United States; ⁵ the Gore Cardioform Septal Occluder (W.L. Gore and Associates, Inc, Newark, DE) or the Amplatzer PFO Occluder (Abbott Structural, Santa Clara, CA). The procedure is done under fluoroscopic and

echocardiographic guidance in the form of TEE or intracardiac echocardiography (ICE) *via* femoral vein access.

In a single-center, retrospective study of 53 consecutive patients the safety and feasibility of SDD in PFO closure using ICE was evaluated (44). In this study, a 12 Fr sheath for the occluder device and an 11 Fr sheath for the ICE probe were inserted into the femoral vein using only local anesthetic and light sedation. In this study 5 of the 53 patients were found to not have PFO by ICE. The remaining 48 patients underwent successful PFO closure with the HELEX occluder (GORE, Flagstaff, AZ, $n = 47$) and the Amplatzer device (AGA medical corporation, Golden Valley, MN, $n = 1$). SDD candidates had to ambulate successfully following the procedure and undergo TTE prior to discharge to confirm appropriate device placement. Appropriate device positioning was confirmed on all 48 patients. Only 1 patient failed SDD due to groin hematoma requiring observation overnight and was discharged the following day. No other complications were reported. Patients were scheduled for a three-month TTE follow-up to assess for any residual shunting. At three months follow up, 45/48 (94%) had no residual shunt.

In a nonrandomized, retrospective, single-center observational study Barker *et al* analyzed peri-procedural outcomes of 467 patients undergoing PFO closure. All patients underwent closure with the Amplatzer PFO Occluder; 381 patients underwent fluoroscopy-only occlusion and 86 patients with ICE guidance. ICE guidance was used as a backup modality and limited to complex atrial septal anatomy as seen on TEE. There was no significant difference in periprocedural complications between the fluoroscopy-only and ICE group. SDD occurred in 97.6% of all patients; 98.2% and 95.3% in the fluoroscopy and ICE group respectively ($P = 0.246$). Complete closure was seen in 94.6% of patients at the three-month TTE follow-up. There was no significant difference in death, 30-day readmission, device thrombosis, and stroke/TIA between the fluoroscopy-only and ICE group (45). As of the writing of this article, the literature review reveals only one prospective case series proposing a SDD clinical pathway for patients undergoing ASD/PFO closure (46). Prerequisites for SDD following PFO

closure in their study includes hemodynamic stability and the ability to ambulate 2 h post- procedure. Patients are permitted to go home 1-hour post mobilization with a 6-month TEE follow-up and 6 mo of antithrombotic therapy based on the device placed. In their study of 187 patients that underwent PFO/ASD closure (PFO = 117, ASD = 70); SDD occurred in 99.4% of cases. There were no major complications, and a 6-month TEE revealed no residual shunt in 96% of patients (46).

FUTURE SCOPE

Adopting a standardized method for same-day discharges will help reduce adverse events. However, as most of the evidence available to date comes from case series and retrospective studies, there is a need for larger prospective studies to be undertaken to validate the safety of SDD across a greater cohort of patients undergoing structural intervention cardiac procedures, to be reflected in the guidelines, before it becomes the standard of care.

SEARCH STRATEGY

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placing them at higher risk of COVID-19 related complications, several studies sought and reported on SDD following TAVR (6,31,32).

In a case series, three elderly patients with AS underwent TAVR and were discharged home on the same day with 7 days of continuous rhythm monitoring (31). Authors hypothesized that SDD may be safe after TAVR in a pre-selected cohort of patients with AS and also help reduce the risk of unnecessary COVID-19 transmission, conserve hospital beds, and PPE. Since the authors recognized that the loss of a single patient secondary to preventable complications due to early discharge is a never event, they developed protocols and safety nets for their SDD protocol. They considered patients with no significant comorbidities such as end-stage kidney disease, hemoglobin <9 mg/dL, NYHA ≥ 3 symptoms, EF<30%, no significant pericardial effusion, new or worsening AV block, and no vascular access complications able to be discharged on the same day of the procedure after observation for 4-6 h. In order to minimize complications, they performed ultrasound-guided vascular access, performed a TTE immediately after device deployment and 4 h after deployment to detect complications, obtained serial electrocardiogram's to mainly assess QRS intervals, ambulated patients after 4 h, and performed serial lower extremity pulse checks. In their case series, there were no new conduction abnormalities detected and all patients were followed up on days 1 and 2 post-procedure. They had no deaths or re-admissions within 24 days of the procedure (31).

Rai *et al* reported their experience of SDD based on 6 patients with severe symptomatic AS or bio-prosthetic valve dysfunction and proposed an SDD protocol (32). Since the major barrier to discharge patients after TAVR is related to new or worsening conduction abnormalities, they hypothesized that having a pre-procedure PPM or discharge with real-time continuous monitoring could allow for safe SDD. In their case series, they included patients that had predictors of next-day discharge after TAVR based on previous analyses (30). In a recent study, rapid atrial pacing using the temporary pacing wire used for ventricular standstill during TAVR deployment while in the right atrium, had a 99% negative predictive value for pacemaker implantation

after TAVR if no Wenckebach phenomenon developed at a heart rate of 120 bpm (33). Rai *et al* utilized this method in one of their patients and proposed its use prior to SDD in all patients without chronic AF, pre-existing PPM, or pre-existing AV block. Additionally, all patients had pre-procedure and post-procedure ECGs performed and if there was a pre-existing right bundle branch block (RBBB) or new AV conduction disturbances, patients were admitted overnight for observation. Otherwise, if patients had a pre-procedure PPM, unchanged ECG from baseline, and no Wenckebach on rapid atrial pacing, they were considered for SDD after 4 h of observation given lack of vascular access site complications. Despite one of their patients developing Wenckebach at 110 bpm, he was discharged on the same day due to a low positive predictive value of the finding and the lack of other conduction abnormalities noted. All six patients were followed with continuous rhythm monitoring for seven days and followed up in person the next day. Based on their experience, they recommend patients with a baseline RBBB not be considered for SDD, as it is one of the strongest predictors for pacemaker need following TAVR (34), additionally, patients who develop a new left bundle branch block after TAVR should be kept overnight for monitoring. Of note, all 6 patients in their series underwent balloon-expandable valve replacements and these recommendations could not be generalized to patients undergoing TAVR utilizing a self-expandable system, as there has been evidence suggesting higher PPM implantation in these patients (35).

The largest study regarding SDD in TAVR was conducted by Perdoncin *et al*, in which they report on 29 consecutive SDD TAVR procedures at their center and compared outcomes to patients who underwent TAVR at their center that were non-SDD, who could have qualified for SDD based on their devised protocol (6). They considered patients with an EF>30%, hemoglobin >10, INR <2, those who received a contrast load <3 times the estimated Glomerular Filtration Rate (eGFR), without new or worsening conduction abnormalities, or hemodynamic instability for SDD. The primary outcome was to compare 30-day mortality, PPM implantation, stroke, and cardiovascular-related admissions in SDD patients and non-SDD patients. They compared 29 SDD patients to

128 patients that were non-SDD who currently met their protocol for SDD and were fairly similar with regards to baseline characteristics. Procedural characteristics were similar in both groups and all cases were performed *via* trans-femoral access under conscious sedation. Post-procedure, both groups had no in-hospital complications. At 30 days, there were no deaths, the rate of stroke was 0.6%, and delayed PPM implantation was also 0.6% in both groups combined. They noted a trend towards a higher rate of cardiovascular re-admissions in the non-SDD group compared to the SDD group. One patient in the non-SDD group was re-admitted for high-grade AV block requiring PPM implantation. Of note, both self-expanding and balloon expanding valves were used with a trend towards higher use of self-expanding valves in the SDD group. However, further studies are required to determine the feasibility of the use of self-expanding valves for SDD TAVR procedures given the potential concern of outward sub-annular radial force and risk of delayed conduction changes (36).

Overall, based on the prior studies the main concern for SDD in TAVR is related to new or worsening conduction abnormalities that could arise during or after the procedure. All patients considered being candidates for SDD should be identified early during a 'heart team' multi-disciplinary discussion and deemed suitable based on pre-procedure pre-requisites. All patients with a baseline RBBB, new high-grade AV block after the procedure, new inter-ventricular conduction delay, or Wenckebach on right atrial pacing after valve deployment should be admitted overnight for inpatient observation. If considered for SDD, all patients must be willing to go home, have no vascular access complications after initial observation, have close follow-up arranged, and be sent home with a real-time rhythm monitor to detect arrhythmias. We present a proposed protocol for SDD following TAVR in Figure 1.

PFO/ASD CLOSURE

ASDs are one of the most common congenital heart defects found in the general population. Unrepaired ASDs can result in various cardiopulmonary adverse events such as arrhythmias, pulmonary hypertension, and paradoxical embolization. Current

adult congenital heart disease guidelines recommend ASD closure in carefully selected patients with hemodynamic instability or clinical consequences resulting from their long- standing intra-cardiac shunting (37). Additionally, up to 50% of patients with a cryptogenic stroke have been found to have an associated PFO (38). The first three randomized controlled trials CLOSURE I, PC, and RESPECT failed to show any statistical significance in secondary stroke prevention (39-41). More recent studies, however, have demonstrated that in carefully selected patients, PFO closure is preferable to medical therapy for secondary stroke prevention of cryptogenic strokes in patients with PFO (42-43). In a review article published in the Journal of the American College of Cardiology, authors proposed a clinical pathway to aid in the appropriate selection of patients that should undergo PFO closure based on randomized trials showing benefit (38).

The PFO closure procedure is usually done as a day case procedure using one of only two FDA approved devices in the United States; ⁵ the Gore Cardioform Septal Occluder (W.L. Gore and Associates, Inc, Newark, DE) or the Amplatzer PFO Occluder (Abbott Structural, Santa Clara, CA). The procedure is done under fluoroscopic and echocardiographic guidance in the form of TEE or intracardiac echocardiography (ICE) *via* femoral vein access.

In a single-center, retrospective study of 53 consecutive patients the safety and feasibility of SDD in PFO closure using ICE was evaluated (44). In this study, ² a 12 Fr sheath for the occluder device and an 11 Fr sheath for the ICE probe were inserted into the femoral vein using only local anesthetic and light sedation. In this study 5 of the 53 patients were found to not have PFO by ICE. The remaining 48 patients underwent successful PFO closure with the ² HELEX occluder (GORE, Flagstaff, AZ, *n* = 47) and the Amplatzer device (AGA medical corporation, Golden Valley, MN, *n* = 1). SDD candidates had to ambulate successfully following the procedure and undergo TTE prior to discharge to confirm appropriate device placement. Appropriate device positioning was confirmed on all 48 patients. Only 1 patient failed SDD due to groin hematoma requiring observation overnight and was discharged the following day. No

other complications were reported. Patients were scheduled for a three-month TTE follow-up to assess for any residual shunting. At three months follow up, 45/48 (94%) had no residual shunt.

In a nonrandomized, retrospective, single-center observational study Barker *et al* analyzed peri-procedural outcomes of 467 patients undergoing PFO closure. All patients underwent closure with the Amplatzer PFO Occluder; 381 patients underwent fluoroscopy-only occlusion and 86 patients with ICE guidance. ICE guidance was used as a backup modality and limited to complex atrial septal anatomy as seen on TEE. There was no significant difference in periprocedural complications between the fluoroscopy-only and ICE group. SDD occurred in 97.6% of all patients; 98.2% and 95.3% in the fluoroscopy and ICE group respectively ($P = 0.246$). Complete closure was seen in 94.6% of patients at the three-month TTE follow-up. There was no significant difference in death, 30-day readmission, device thrombosis, and stroke/TIA between the fluoroscopy-only and ICE group (45). As of the writing of this article, the literature review reveals only one prospective case series proposing a SDD clinical pathway for patients undergoing ASD/PFO closure (46). Prerequisites for SDD following PFO closure in their study includes hemodynamic stability and the ability to ambulate 2 h post- procedure. Patients are permitted to go home 1-hour post mobilization with a 6-month TEE follow-up and 6 mo of antithrombotic therapy based on the device placed. In their study of 187 patients that underwent PFO/ASD closure (PFO = 117, ASD = 70); SDD occurred in 99.4% of cases. There were no major complications, and a 6-month TEE revealed no residual shunt in 96% of patients (46).

FUTURE SCOPE

Adopting a standardized method for same-day discharges will help reduce adverse events. However, as most of the evidence available to date comes from case series and retrospective studies, there is a need for larger prospective studies to be undertaken to validate the safety of SDD across a greater cohort of patients undergoing structural

intervention cardiac procedures, to be reflected in the guidelines, before it becomes the standard of care.

CONCLUSION

Same-day discharge appears to be feasible in appropriately selected patients undergoing TAVR, Mitra-clip, LAA, ASD/PFO closure. Safe same-day discharge ¹has the potential to not only reduce hospital costs but also improve patient satisfaction. The availability of a 'heart team' consisting of a multi-disciplinary group of providers to identify suitable patients for SDD is prudent. Additionally, only centers with significant volume and experience performing complex structural procedures should consider SDD in their pre-selected suitable patients. We propose an algorithm to facilitate SDD following structural intervention procedures based on the review of available literature (Figure 2, Central Figure). We also provide a framework checklist to consider when adopting a SDD approach at centers performing structural intervention procedures along with a summary of previous studies with SDD with structural heart procedures (Tables 1 and 2).

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