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Coronary Artery Disease (D Feldman and V Voudris, Section Editors)

Revascularization in Cardiogenic Shock and Advanced Heart Failure

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Abstract

Purpose of review Ischemic heart disease is the most common cause of heart failure with systolic dysfunction. The progressive course of heart failure characterized by increasing levels of care and worsening quality of life often indicates an advanced stage. Similarly, cardiogenic shock remains a major clinical problem with prohibitively high mortality rates despite major advances in clinical care. Here, we review the current treatment options and available data for revascularization in patients with ischemic cardiomyopathy, advanced heart failure, and cardiogenic shock. We also explore the emerging role of Interventional Heart Failure specialist within the Heart Team.

Recent findings Although guideline-directed medical therapy remains the cornerstone treatment strategy for patients with advanced heart failure, coronary revascularization is sometimes indicated. There is a relatively paucity of evidence regarding different revascularization strategies and the use of acute mechanical circulatory support in patients with advanced heart failure and in those presenting with cardiogenic shock. A deep understating of the physiologic and hemodynamic effects of different acute mechanical support platforms is of paramount importance in preparation for revascularization in these patients.

Summary The decision regarding revascularization in patients with coronary artery disease in the setting of left ventricular dysfunction remains challenging. Clinical decision-making in these cases requires interdisciplinary discussion and assessment of the potential long-term survival derived from surgical revascularization against its higher perioperative risk.

Introduction

Heart failure (HF) is a growing public health issue worldwide as the incidence and prevalence of HF continue to steadily increase over the last decades. This trend is in part due to improved survival of patients with cardiovascular diseases and an aging general population [1]. Coronary artery disease (CAD) represents the predominant etiology of HF and left ventricular (LV) dysfunction [2]. In fact, almost 60% of the patients enrolled in the Acute Decompensated Heart Failure National Registry had a history significant for CAD [3]. Moreover, ongoing ischemia is a common precipitant of acute decompensated HF [4]. While guideline-directed medical therapy remains the cornerstone treatment strategy for these patients, coronary revascularization is sometimes indicated in HF patients with CAD [5]. Although revascularization by coronary artery bypass grafting (CABG) and/or percutaneous coronary interventions (PCI) has been studied in different settings, there is relatively little evidence for such strategies in patients with HF and CAD, particularly in cases with advanced HF and cardiogenic shock (CS). Lastly, the use of acute mechanical circulatory devices (AMCS), durable mechanical circulatory devices, and bridge strategies must be considered in these patients undergoing revascularization by a multidisciplinary team. Here, we review the current treatment options and available data for revascularization in patients with ischemic cardiomyopathy (ICM), advanced HF, and CS.

The Heart Failure Association (HFA), American College of Cardiology/American Heart Association, and Heart Failure Society of America have used various criteria to define advanced HF [6, 7]. Furthermore, the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) has designated different clinical profiles dictating the need for advanced therapies [8•]. In 2018, the HFA of the European Society of Cardiology published a position statement with an updated definition of advanced HF (Table 1) to include patients with clinical features of HF with preserved ejection fraction and with unplanned outpatient visits for HF [10, 11]. An understanding of the severity, complexity, and diversity of the HF syndrome is needed for patients planned to undergo revascularization.

Revascularization strategies in heart failure with reduced ejection fraction secondary to coronary artery disease: CABG versus PCI

Left ventricular dysfunction and CAD frequently coexist with comorbidities that translate into higher risk for invasive or surgical procedures. Although new technologies and tools have been designed and introduced, revascularization strategies in the setting of LV dysfunction remain an area of interest and debate.

The Surgical Treatment for Ischemic Heart Failure (STICH) trial compared optimal medical therapy (OMT) plus CABG with OMT in 1212 patients with ICM and LV ejection fraction of ≤ 35% [12••]. Mortality within the first 30 days was significantly higher in the surgical group (4% vs. 1%; HR 3.12; 95% CI 1.33 to 7.32; $p = 0.009$). At a median of 4.6 years, OMT plus CABG did not result in a significant reduction in the primary outcome of all-cause mortality compared with those assigned to OMT alone (36% vs. 41%; HR 0.86; 95% CI 0.72 to 1.04; $p = 0.12$). More recently, however, the STICH Extension Study did find a significant extended effect of CABG on top of OMT in this cohort of patients. Here, after a median follow-up of 9.8 years, all-cause mortality was significantly reduced in the CABG group compared to that in OMT alone (59% vs. 66%; HR 0.84; 95% CI 0.73–0.97; $p = 0.02$) (Fig. 1). Moreover, the CABG group had significant reductions in the prespecified secondary outcomes of cardiovascular

Table 1. Updated HFA-ESC criteria for defining advanced heart failure

Updated HFA-ESC criteria for defining advanced heart failure
All the following criteria must be present despite optimal guideline directed treatment:
Severe and persistent symptoms of heart failure [NYHA class III (advanced) or IV].
Severe cardiac dysfunction defined by a reduced LVEF ≤ 30%, isolated RV failure (e.g., ARVC) or non-operable severe valve abnormalities or congenital abnormalities or persistently high (or increasing) BNP or NT-proBNP values and data of severe diastolic dysfunction or LV structural abnormalities according to the ESC definition of HFpEF and HFmrEF [9].
Episodes of pulmonary or systemic congestion requiring high-dose intravenous diuretics (or diuretic combinations) or episodes of low output requiring inotropes or vasoactive drugs or malignant arrhythmias causing > 1 unplanned visit or hospitalization in the last 12 months.
Severe impairment of exercise capacity with inability to exercise or low 6MWTD (< 300 m) or pVO_2 (< 12–14 mL/kg/min), estimated to be of cardiac origin.
In addition to the above, extracardiac organ dysfunction due to heart failure (e.g., cardiac cachexia, liver, or kidney dysfunction) or type 2 pulmonary hypertension may be present but are not required.
Criteria 1 and 4 can be met in patients who have cardiac dysfunction (as described in criterion #2), but who also have substantial limitation due to other conditions (e.g., severe pulmonary disease, non-cardiac cirrhosis, or most commonly by renal disease with mixed etiology). These patients still have limited quality of life and survival due to advanced disease and warrant the same intensity of evaluation as someone in whom the only disease is cardiac, but the therapeutic options for these patients are usually more limited.

ARVC, arrhythmogenic right ventricular cardiomyopathy; *BNP*, brain-type natriuretic peptide; *ESC*, European Society of Cardiology; *HFA*, Heart Failure Association; *HFmrEF*, heart failure with mid-range ejection fraction; *HFpEF*, heart failure with preserved ejection fraction; *LV*, left ventricular; *LVEF*, left ventricular ejection fraction; *NT-proBNP*, N-terminal pro-B-type natriuretic peptide; *NYHA*, New York Heart Association; *pVO_2*, peak exercise oxygen consumption; *RV*, right ventricular, *6MWTD*, 6-min walk test distance

mortality and the combination of all-cause mortality with cardiovascular hospitalization [13••].

Given the early mortality hazard associated with CABG, the advances made in PCI and mechanical circulatory support devices have led some to propose revascularization with PCI as an alternative to CABG for patients with ICM. Although numerous studies have compared surgical and percutaneous revascularization, most of these randomized trials focused on symptomatic coronary artery disease and excluded patients with congestive heart failure and/or reduced LV function. Available data directly comparing PCI and surgical revascularization in the setting of LV dysfunction is limited to observational studies. A recent analysis of the New York state registries used propensity score matching to compare PCI and CABG in 1063 matched pairs with multivessel disease (excluding significant left main disease) and left ventricular ejection fraction (LVEF) of ≤ 35% over a period of 4 years. At a median follow-up of 2.9 years, there was no significant difference in all-cause mortality between the two groups (HR 1.01; 95% CI 0.81–1.28). PCI was associated with fewer strokes but more myocardial infarctions and repeat revascularizations [14].

The Ischemic Cardiomyopathy Percutaneous Revascularization for Ischemic Ventricular Dysfunction (the REVIVED-BCIS2) is an ongoing prospective multicenter randomized controlled trial comparing percutaneous revascularization plus OMT with OMT alone in patients with LVEF of ≤ 35% and viable myocardium [9] (Fig. 2). Since August 2013, more than 400 patients have been randomized. Follow-up continues for at least 2 years following randomization. The primary outcome is a composite endpoint of all-cause death or

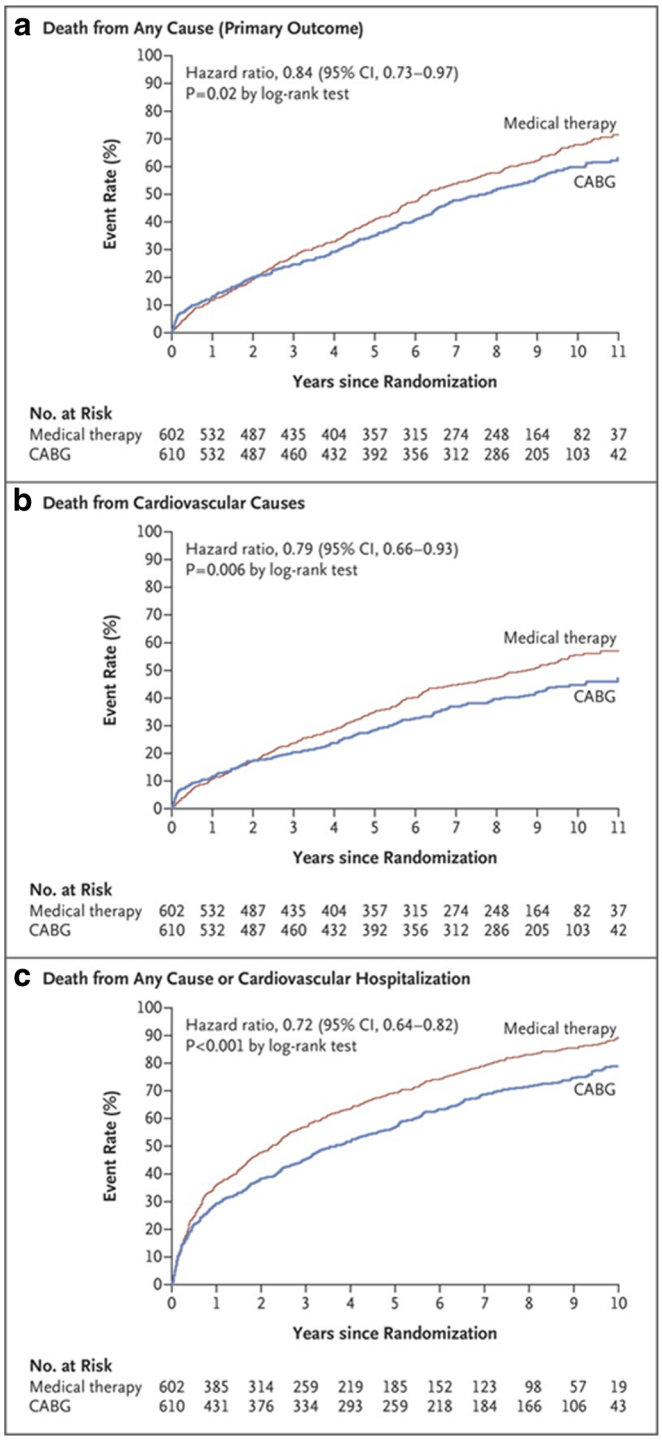

Fig. 1. Kaplan–Meier estimates of the primary and secondary outcomes of the STICHES trial. Panel **a** shows the rates of death from any cause; panel **b** shows the rate of death from cardiovascular causes; panel **c** shows the rate of death from any cause or hospitalization for cardiovascular causes.

hospitalization due to HF. Secondary outcomes include LVEF assessment at 6 and 12 months from randomization, quality of life scores, appropriate implantable cardioverter defibrillator therapy, and acute MI. Results are expected to be released in 2022.

Revascularization strategies in patients with cardiogenic shock: from door-to-balloon to door-to-support

Cardiogenic shock secondary to ICM results in hemodynamic disarray characterized by a loss of cardiac output leading to reduced end-organ perfusion and promoting pulmonary and venous congestion. When identified early, achieving several key hemodynamic objectives can reverse the shock state and prevent the onset of end-organ failure. One of these objectives is rapid restoration of coronary blood flow along with supporting systemic circulation and unloading the LV and/or right ventricle [4]. In acute myocardial infarction complicated by cardiogenic shock (AMI-CS), the landmark Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) trial identified that early revascularization improves long-term survival when compared to initial medical stabilization [15]. Revascularization was accomplished by either CABG or angioplasty. Since then, three decades have passed with little improvement in clinical outcomes for patients with CS. Patients with CS represent a minority of those undergoing CABG; yet, they have persistently high operative risks, accounting for 14% of deaths in CABG patients [16]. Recently, Thiele et al. showed that culprit-vessel-only revascularization as opposed to multivessel PCI during AMI-CS was associated with better clinical outcomes.

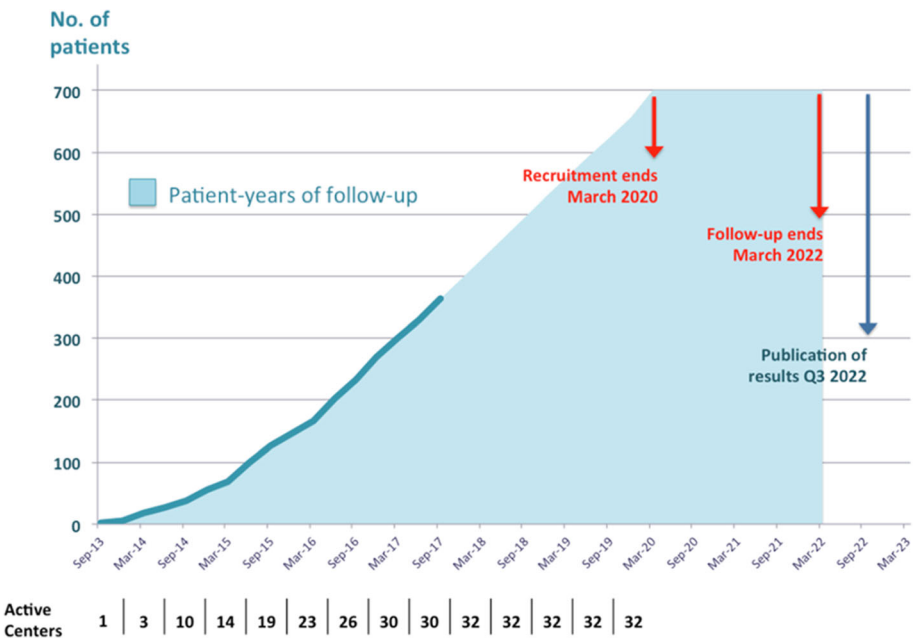

Fig. 2. Study timeline of the REVIVED-BCIS2 trial sowing approximately 400 patients with left ventricular dysfunction randomized since August 2013 with 1:1 allocation between the percutaneous coronary intervention and optimal medical treatment arms.

Here, investigators randomly assigned 706 patients who had multivessel disease, acute myocardial infarction, and CS to one of two initial revascularization strategies: either culprit-lesion-only PCI with the option of staged revascularization of non-culprit lesions or immediate multivessel PCI. The primary endpoint was a composite of death or renal failure leading to renal-replacement therapy within 30 days after randomization. Safety endpoints included bleeding and stroke. At 30 days, the composite primary endpoint occurred in 45.9% of subjects in the culprit-lesion-only PCI group and 55.4% in the multivessel PCI group (relative risk [RR], 0.83; 95% CI, 0.71 to 0.96; $p = 0.01$). The RR of death in the culprit-lesion-only PCI group as compared with the multivessel PCI group was 0.84 (95% CI, 0.72 to 0.98; $p = 0.03$) and for renal replacement therapy was 0.71 (95% CI, 0.49 to 1.03; $p = 0.07$) [17••]. Furthermore, data on 1-year follow-up were recently published by the same investigators, affirming the benefits of culprit-vessel-only PCI in patients presenting with AMI-CS. At 1 year, death had occurred in 50.0% of patients in the culprit-lesion-only PCI group compared to 56.9% in the multivessel PCI group (RR, 0.88; 95% CI, 0.76 to 1.01) (Fig. 3). The rate of recurrent infarction was 1.7% with culprit-lesion-only PCI and 2.1% with multivessel PCI (RR, 0.85; 95% CI, 0.29 to 2.50), and the rate of a composite of death or recurrent infarction was 50.9% and 58.4%, respectively (RR, 0.87; 95% CI, 0.76 to 1.00). Importantly, repeat revascularization occurred more frequently in patients initially randomized to culprit-lesion-only PCI than in patients with multivessel PCI (32.3% vs. 9.4%; RR, 3.44; 95% CI, 2.39 to 4.95), as did rehospitalization for heart failure (5.2% vs. 1.2%; RR, 4.46; 95% CI, 1.53 to 13.04) [18••].

With percutaneously delivered AMCS increasingly available, this paradigm may begin to change in patients with CS. Ventricular unloading and systemic circulatory support may be initiated by experienced operators even before achieving effective restoration of coronary flow. While the door-to-balloon time continues to be important for ST-elevation MI not complicated by CS, optimizing systemic circulation and organ perfusion in patients with CS appears to be as or more important than immediately opening an occluded vessel in order to avoid hemo-metabolic shock [19]. Timely initiation of AMCS, or the "door-to-unload time" (DTU), may be a key determinant of outcomes in patient presenting with CS [20]. Preliminary data from the Detroit Shock Initiative to treat AMI-CS has shown improving survival rates by up to 65%. Here, clinicians utilized a standardized protocol for patients presenting with AMI-CS, including but not limited to mechanical unloading using the Impella CP, a catheter-mounted trans-valvular axial flow pump, prior to primary PCI [21]. Although more appropriately powered and randomized data are required, our current level of knowledge seems to support prompt and proper initiation of AMCS in patients presenting with AMI-CS.

Revascularization in patients with advanced heart failure and patients on durable mechanical circulatory support devices

It is important to differentiate patients who are "crashing, burning, or sliding fast" (INTERMACS 1–2) as discussed above from patients with HF who are

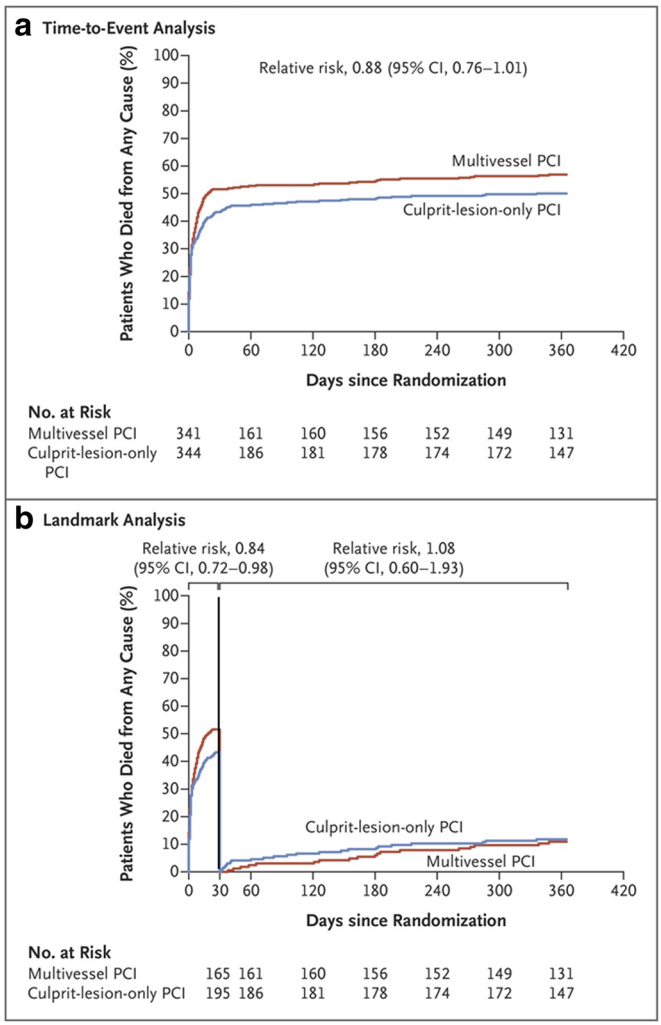

Fig. 3. Time-to-event and landmark analyses for death from any cause through 1 year of the CULPRIT-SHOCK trial. Panel **a** shows Kaplan–Meier estimates of the rate of death from any cause through 1 year. Panel **b** shows the rate of death from any cause through 30 days, as well as the rate between 30 days and 1 year.

relatively stable (INTERMACS 3–7) (Table 1) when planning for revascularization. Moreover, a deep understanding of temporary AMCS platforms is critical since they may be indicated in these cases. Devices that are used to provide hemodynamic support during revascularization include the intra-aortic balloon pump (IABP), trans-valvular axial flow pumps, and veno-arterial extracorporeal membrane oxygenator (VA-ECMO).

Although IABP augments coronary perfusion, overall reduction in myocardial ischemia is limited by the fact that this device provides little or no reduction in native LV work and thus myocardial oxygen demand [22]. IABP works by diastolic augmentation and volume displacement mainly driven by the native heart's pulsatility. In failing hearts, this effect is particularly modest because native pulsation is needed to achieve effective counterpulsation. For this and other reasons in patients with LV dysfunction undergoing IABP-assisted

revascularization, adjunct pharmacologic support with inotropes or vasopressors may be required which in fact can worsen myocardial ischemia. In cases of severe CAD with high "Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery" (SYNTAX) score, LV dysfunction and/or planned for surgical revascularization, timely initiation of IABP support prior to CABG has been associated with better outcomes including perioperative mortality and all-cause 30-day mortality [23].

The Impella is an axial flow catheter placed into the LV in retrograde fashion across the aortic valve. The Impella transfers kinetic energy from a circulating impeller to the blood stream, which results in continuous blood flow from the left ventricle to the ascending aorta. The PROTECT II trial randomized 452 patients referred for non-emergent high-risk PCI to insertion of an Impella 2.5 or IABP before PCI. High-risk PCI was defined as a LVEF ≤ 35% and unprotected left main or last patent coronary conduit or LVEF < 30% with three-vessel coronary disease. Heart failure severity was based on LVEF and functional class (NYHA class III/IV 67% of the Impella group and 64% of the IABP group). The Impella 2.5 demonstrated superior hemodynamic support compared to IABP therapy. No difference in the primary endpoint (composite rate of intra- or post-procedural major adverse events at discharge or 30-day follow-up) was observed between groups (35% vs. 40%, Impella 2.5 vs. IABP, $p = 0.227$). At 90-day follow-up, a trend towards reduced MACE was observed in the Impella arm but not in the IABP arm (40.6% vs. 49.3%, $p = 0.066$) in the intention-to-treat population and (40% vs. 51%, $p = 0.02$) in the per-protocol population [24]. Since the completion of that trial, newer generation axial flow pumps with higher performance power have been developed, namely, the Impella CP and Impella 5.0. Data on assisted revascularization with these platforms are limited to case series, but it has been shown to be a feasible concept in patients with severe LV dysfunction.

Lastly, VA-ECMO withdraws deoxygenated venous blood from the body and delivers it to a centrifugal pump. The pump then delivers this deoxygenated blood through an oxygenator and back into the arterial circulation. VA-ECMO can be initiated using central (surgical) or peripheral (percutaneous or surgical) access [25]. It provides circulatory support by displacing blood volume from the venous to the arterial circulation, which increases aortic systolic, diastolic, and mean arterial pressures. VA-ECMO, however, does not provide effective ventricular unloading. By pressurizing the arterial circulation, LV afterload is increased, and depending on native LV function, VA-ECMO may in fact be associated with increased LV end-diastolic pressures, potentially leading to or worsening pulmonary edema. To date, revascularization while on VA-ECMO has been reported in patients with LV dysfunction suffering from cardiopulmonary collapse or intractable arrhythmias.

The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Trial demonstrated that durable, surgically implanted left ventricular assist devices (LVADs) improved survival in patients with end-stage HF compared to medical therapy alone. Moreover, in 2009, continuous flow LVADs (CF-LVADs) showed significantly improved 2-year survival compared to pulsatile LVADS. Since then, the use of permanent CF-LVADs has grown exponentially to more than 2500 implants per year. In these patients, revascularization is practically an unknown topic given the paucity of available data. Chest pain on LVAD support is a complex

presentation that is most commonly due to non-cardiac causes. The true incidence of ischemic chest pain during LVAD support remains undefined, but ischemia may nevertheless be a possible cause of pain in these patients. Acute MI can occur in LVAD patients and may be due to coronary plaque rupture, paradoxical thromboembolism, LV or aortic root thromboembolism, and impaired myocardial perfusion due to elevated LV filling pressures secondary to LVAD failure. Left heart catheterization should be performed only after carefully weighing the risks and potential benefits and by operators with experience in durable mechanical support. Potential benefits of coronary intervention for patients with LVAD include symptom relief, prevention of arrhythmogenesis, reduction of ongoing myocardial damage, and support of RV function. Future studies are necessary to evaluate the benefit of revascularization in the setting of LVAD support, especially as the number of patients receiving LVADs as "bridge to decision" and "destination therapy" continue to grow. Whether coronary revascularization in LVAD patients with severely depressed LV systolic function who demonstrate myocardial viability impacts clinical outcomes remains unknown.

Heart-team approach in patients with advanced heart failure undergoing revascularization

Growth in three major cardiac device domains has helped to shape contemporary practice around advanced HF. A landmark study identified that the Heartmate II (Thoratec, Pleasanton, CA) rotary flow LVAD demonstrated superior clinical outcomes compared with pulsatile LVADs for patients with advanced HF, triggering immense growth in the use of LVADs amongst HF specialists and cardiac surgeons. Around the same time, AMCS device and newer generation stents used within the interventional cardiology community were growing mainly for high-risk percutaneous coronary intervention. Finally, there has been improvement in "off-pump" surgical techniques and increasing use of arterial conduits for CABG. Ever-expanding device development and improving surgical and percutaneous techniques have led to the creation of heart teams at tertiary medical centers. This unique collaboration should be applied universally to patients with advanced HF undergoing revascularization procedures. Communication and collaboration amongst a team consisting of HF and cardiac transplantation specialists, interventional cardiologists, cardiac surgeons, intensivists, and others are fundamental to optimizing clinical outcomes in this challenging patient population [26]. The interventionalist offers invasive hemodynamic assessment, coronary revascularization, and possibly AMCS for LV, RV, or biventricular failure. The cardiac surgeon manages post-MI mechanical complications and surgical coronary revascularization if PCI is not an option, to assist with initiation of AMCS or VA-ECMO and to provide input regarding candidacy for LVAD or orthotopic heart transplantation (OHTx). The advanced HF specialist also assists with evaluating a patient's candidacy for LVAD or OHTx in addition to optimizing hemodynamics, managing AMCS or VA-ECMO, and providing input regarding end-of-life decision-making, palliation, and medical futility. The cardiac intensivist further assists with hemodynamic optimization and AMCS device management and provides input on the

management of non-cardiac organ systems, the prevention and treatment of infectious complications, and the importance of nutrition, early mobilization, and prophylaxis against deep venous thrombosis, gastric ulcers, and cutaneous ulcers. Indeed, recent data suggests that incorporation of a cardiac intensivist into the team approach improves short- and long-term mortality in CS. In addition, laying out the end goal, exit plan, and bail-out strategies is a fundamental aspect when planning revascularization in HF patients. Moreover, defining medical futility is a critical part of the management of these patients. A team-based approach in these complex contexts may facilitate the decision-making process.

Conclusion

Given the complexity of the patient population in contemporary clinical practice, the decision regarding revascularization in patients with CAD in the setting of LV dysfunction remains challenging. Clinical decision-making in these cases requires interdisciplinary discussion and assessment of the potential long-term survival derived from CABG against its higher perioperative risk. In accordance with the available data, we believe that surgical revascularization offers improved survival, particularly in those with more extensive multivessel disease and the greatest degree of LV systolic dysfunction and remodeling. These patients, it must be noted, are also at the greatest short-term risk of mortality with CABG. When necessary, PCI is feasible and safe. Data from large randomized clinical trial testing newer generation stents and the use of mechanical circulatory support is needed to further aid these decisions. A heart-team approach including but not limited to a general cardiologist, heart failure specialist, interventional cardiologist, cardiothoracic surgeon, palliative care provider, and critical care specialist is of paramount importance. Indeed, interventional heart failure is an emerging field within cardiology. Trainees become proficient in interventional cardiology, advanced heart failure, and the use of MCS devices. This new breed of cardiologist may narrow the gap between these two important sub-specialties with an increasingly overlapping patient population with the goal of improving outcomes.

Compliance with Ethical Standards

Conflict of Interest
The authors declare that they have no conflicts of interest.

Human and Animal Rights and Informed Consent
This article does not contain any studies with human or animal subjects performed by any of the authors.

Publisher's Note

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