Interventional Therapies for Heart Failure in Older Adults

Dhaval Kolte, MD, PhD[a], Jinnette Dawn Abbott, MD[a], Herbert D. Aronow, MD, MPH[b,*]

KEYWORDS

• Heart failure • Elderly • Percutaneous coronary intervention • Mechanical circulatory support • Transcatheter aortic valve replacement • MitraClip • Transcatheter valve therapies • Implantable hemodynamic monitors

KEY POINTS

- Several transcatheter and interventional therapies have evolved over the past decade for the treatment of heart failure (HF) in older adults.
- Percutaneous coronary intervention with newer drug-eluting stents, percutaneous mechanical circulatory support devices, transcatheter aortic valve replacement, and percutaneous mitral valve repair with MitraClip have emerged as safe and effective alternatives to surgery in older patients with HF.
- Careful selection of the appropriate patient population, including the elderly, and end points in future clinical trials will be crucial to show the potential efficacy of novel interventional HF therapies.

INTRODUCTION

Heart failure (HF) remains a global epidemic with an estimated prevalence of 40 million individuals worldwide.[1] In the United States, approximately 5.7 million people have HF, with an incidence of 870,000 new cases per year.[2] Epidemiologic data suggest that HF increasingly represents a disease of the elderly. The prevalence of HF is less than 1% in individuals less than 40 years of age and is greater than 10% in those greater than 80 years of age.[3] HF is the leading cause of hospitalization in patients more than 65 years of age, and more than half of patients hospitalized for HF are more than 75 years of age. Despite advances in guideline-directed medical therapy (GDMT), 5-year survival for HF is approximately 50%, and advanced age remains a strong predictor of poor outcomes.[3] The use of GDMT in the elderly is often complicated by the presence of comorbid conditions (eg, renal dysfunction) and polypharmacy, which increase the risk of drug-related adverse effects. Older adults with HF are often considered poor candidates for surgical therapies, such as coronary artery bypass grafting (CABG), valve replacement, or heart transplant, because of multiple comorbidities and frailty, and this has led to an unmet need for novel therapeutic approaches for the treatment of HF, particularly in older adults. As a result, several transcatheter and interventional HF therapies have evolved over the past decade as alternatives to surgery in the elderly. This article summarizes data on interventional HF therapies that are currently approved or under investigation.

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[a] Division of Cardiovascular Medicine, Brown University, 593 Eddy Street, Providence, RI 02903, USA; [b] Division of Cardiovascular Medicine, The Warren Alpert Medical School of Brown University, 593 Eddy Street, RIH APC 730, Providence, RI 02903, USA
* Corresponding author.
E-mail address: herbert.aronow@lifespan.org

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INTERVENTIONAL THERAPIES FOR HEART FAILURE

Revascularization for Ischemic Cardiomyopathy

Coronary artery disease (CAD) is the most common cause of left ventricular dysfunction (LVD) and the underlying cause of HF with reduced ejection fraction (HFrEF) in 65% of patients.[4] In patients undergoing percutaneous coronary intervention (PCI) for a spectrum of indications, worsening LVD is an independent predictor of short-term and long-term mortality across all ages.[5,6] Nonetheless, revascularization has the potential to improve symptoms and also survival in this high-risk population. Recent data from the Surgical Treatment for Ischemic Heart Failure Extension Study (STICHES) showed that, at 10 years, the rates of all-cause death, cardiovascular death, and all-cause death or cardiovascular hospitalization were significantly lower with CABG plus medical therapy compared with medical therapy alone.[7] For a detailed discussion, see Sahil Khera and Julio A. Panza's article, "Surgical Revascularization in the Older Adult with Ischemic Cardiomyopathy," in this issue. This article reviews the current data and recommendations on PCI and the potential role of hybrid coronary revascularization (HCR) in patients with HF caused by ischemic cardiomyopathy.

Percutaneous coronary intervention

In contrast with CABG, data on PCI in patients with ischemic cardiomyopathy are scarce and the benefits less clear. In the past, most randomized controlled trials (RCTs) comparing PCI with medical therapy alone or with CABG have excluded patients with HFrEF. Three trials that included patients with left ventricle (LV) systolic dysfunction were BARI (Bypass Angioplasty Revascularization Investigation), AWESOME (Angina With Extremely Serious Operative Mortality Evaluation), and HEART (The Heart Failure Revascularisation Trial) (**Table 1**).[8–10] These studies showed no difference in long-term survival with PCI versus CABG. However, combined, these trials involve fewer than 500 patients with LV systolic dysfunction and include percutaneous transluminal coronary angioplasty or PCI with bare metal stents. The more contemporary trials comparing PCI versus CABG are also limited by the small number of patients with LV systolic dysfunction. Only 2% of patients enrolled in the SYNTAX (Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) trial had left ventricular ejection fraction (LVEF) less than 30%.[11] The FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease) trial reported similar outcomes with PCI with drug-eluting stents and CABG in patients with LVEF less than 40%, but only 32 patients (2.5%) were in this prespecified subgroup.[12]

In a systematic review and meta-analysis of 19 observational studies that included 4766 patients with LVEF less than or equal to 40%, among the 2981 who underwent PCI (mean age, 65 years; 95% confidence interval [CI], 62–68), in-hospital mortality was 1.8% (95% CI, 1.0%–2.9%) and 2-year mortality was 15.6% (95% CI, 11.0%–20.7%). Five studies compared PCI versus CABG and showed no difference in long-term mortality (relative risk, 0.98; 95% CI, 0.8–1.2; $P = .83$).[13] Recently, Bangalore and colleagues[14] compared outcomes of PCI with everolimus-eluting stents (EES) versus CABG in a propensity-matched cohort of 2126 patients with multivessel CAD and LVEF less than or equal to 35% included in the New York State PCI Reporting System and the Cardiac Surgery Reporting System registries (see **Table 1**). At a median follow-up of 2.9 years, PCI with EES had similar survival to CABG (hazard ratio [HR], 1.01; 95% CI, 0.81–1.28; $P = .91$) (**Fig. 1**). PCI was associated with a higher risk of myocardial infarction (in patients with incomplete revascularization) and repeat revascularization, and a lower risk of stroke compared with CABG. Although propensity analysis cannot be a substitute for RCT, this study represents the most contemporary evidence, suggesting that PCI with newer-generation drug-eluting stents may be an acceptable alternative to CABG in selected patients with LV dysfunction in whom complete revascularization is possible.

The 2014 European Society of Cardiology and the European Association of Cardio-Thoracic Surgery guidelines on myocardial revascularization give a class I recommendation for CABG and a class IIb recommendation for PCI in patients with chronic HF and LVEF less than or equal to 35%.[15] However, the American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) stable ischemic heart disease guidelines give a class IIb recommendation for CABG for improving survival in patients with severe LV systolic dysfunction (LVEF <35%) with no recommendations for PCI.[16] The ACCF/AHA guideline state that, "the choice of revascularization in patients with CAD and LV systolic dysfunction is best based on clinical variables (eg, coronary anatomy, presence of diabetes mellitus, presence of CKD), magnitude of LV systolic dysfunction, patient preferences, clinical judgment, and consultation between the interventional cardiologist and the cardiac surgeon."[16]