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Review

Interventional heart failure therapy: A new concept fighting against heart failure

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ABSTRACT

Heart failure is a progressive disease that is associated with repeated exacerbations and hospitalizations. The rapid increase in the number of heart failure patients is a global health problem known as the 'heart failure pandemic'. To control the pandemic, multifaceted approaches are essential, ranging from prevention of onset to long-term disease management. Especially in patients with moderate to severe heart failure (stages C and D), surgical and catheter-based interventions are prerequisites for saving lives, preserving cardiac function, improving quality of life (QOL), and prognosis. In addition, various new medical technologies for these interventions have been clinically applied and have been shown to be effective against symptoms and improve the QOL and prognosis of patients with heart failure. Furthermore, the concept of interventional heart failure (IHF) therapy, which considers heart recovery and prevention of worsening of heart failure via multidisciplinary treatment using surgical, catheter interventions, and mechanical circulatory support devices, has been proposed worldwide. This review discusses the importance of IHF therapy in heart failure management, recent changes in interventional technologies and strategies for patients with heart failure, and worldwide education attempts for IHF specialists.

Introduction

The rapid increase in heart failure patients is a global health problem and is referred to as the 'heart failure pandemic'. There are > 6.2 million patients with heart failure in the United States, and the number is expected to reach 8 million by 2030 [1]. The prevalence of heart failure increases with age. Bleumink et al. reported that 17.4% of people aged > 85 years suffer from heart failure [2]. Furthermore, in the Chronic Heart Failure Analysis and Registry in the Tohoku District (CHART-2) study, 68% of those with heart failure were ≥ 65 years [3]. Thus, the super-aging society in developed countries has accelerated the heart failure pandemic.

Heart failure is a progressive condition, and the prognosis worsens markedly with repeated exacerbations as the disease progresses [4]. Multifaceted approaches, ranging from prevention to post-onset management, are essential for controlling the heart failure pandemic. Especially in patients with moderate to severe heart failure (stages C and D), surgical, and catheter-based interventions are prerequisites for saving lives, preserving cardiac function, and improving quality of life (QOL) and prognosis [5].

There are three major phases when surgical and catheter-based interventions are important in stage C and D heart failure (Fig. 1). The first is a life-saving intervention in the acute phase. In life-threatening acute diseases, such as cardiogenic shock due to acute myocardial infarction, the treatment goal is to save lives and allow patients to return to society as soon as possible by supporting hemodynamics while minimizing myocardial and systemic damage. The second is an intervention for the etiology of heart failure. In the Japanese Cardiac Registry of Heart Failure in Cardiology (JCARE-CARD) [6] and the CHART-2 study [3], ischemic heart disease (IHD) was the most common cause of heart failure in Japan, followed by valvular disease and hypertension. Surgical and catheter-based interventions are prerequisites for the curative treatment of many causes of heart failure, and appropriate treatment of the causative cardiovascular disease prevents the progression of heart failure in the future. The third is bridge therapy, mainly with hemodynamic support, for patients with end-stage heart failure who are transitioning to an implantable left

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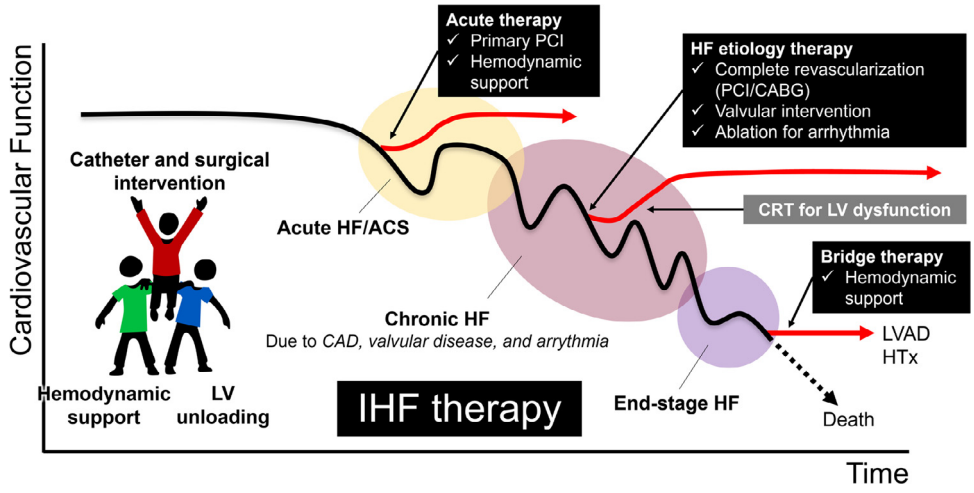

Fig. 1. Concept of interventional heart failure (IHF) therapy
IHF therapy is a multidisciplinary treatment strategy for preventing the occurrence and worsening of heart failure using surgical and catheter interventions with optimal circulatory support. ACS, acute coronary syndrome; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CRT, cardiac resynchronization therapy; HF, heart failure; HTx, heart transplantation; LV, left ventricular; LVAD, left ventricular assist device; PCI, percutaneous coronary intervention

ventricular assist device (LVAD) or waiting for cardiac transplantation. In this phase, surgical and catheter-based interventions play a life-bridging role.

Surgical and catheter-based interventions can improve the prognosis of patients with stage C or D heart failure. In addition, the potential of these interventions is expanding with the advancement of technology. It also means that the medical team must determine the appropriate IHF strategy by combining multiple interventions. In extremely heterogeneous heart failure conditions, it is very difficult to implement sophisticated and complex intervention strategies for individual patients. In addition, individual physician experience and device-specific clinical evidence are not sufficient for optimization. Considering these unmet needs in interventional strategies for heart failure, the concept of interventional heart failure (IHF) therapy, which is a multidisciplinary treatment strategy for preventing the occurrence and worsening of heart failure using surgical or catheter interventions and mechanical circulatory support (MCS) devices, has been proposed worldwide [7–9].

This review explains the importance of surgical and catheter-based interventional therapy in managing stage C or D heart failure and the recent changes in IHF therapy technology. We also discuss attempts that have been made around the world to train interventionalist heart failure therapy specialists who can integrate these interventions and discuss the need for this field in Japan.

MCS devices for IHF therapy

MCSs, such as intra-aortic balloon pumping (IABP), veno–arterial extracorporeal membrane oxygenation (VA-ECMO), and LVAD contribute to IHF therapy via hemodynamic stabilization and left ventricular (LV) unloading. The addition of MCS to the interventional strategy can stabilize the procedures and improve its impact on heart failure prevention [5].

The LVAD is a powerful assistive device that mechanically depresses the left ventricle and increases total blood flow; it is widely used in both the acute and chronic phases of heart failure [10]. Recently, percutaneous LVADs, such as TandemHeart® (LivaNova, PLC., London, UK and Impella (Abiomed Inc., MA, USA) have revolutionized the field of LVADs and MCSs in clinical settings [11]. **Fig. 2** compares the MCSs for acute and transient use that are currently available in Japan. IABP can be established in a short time and is easy to manage after insertion, while the f hemodynamic support level and LV unloading are limited [12]. V-A→VA ECMO has a strong hemodynamic supportive effect but requires specialized staff and facilities for management [13]. In addition, the increased blood flow (independent of native cardiac output) due to V-A→VA ECMO worsens LV afterload [14]. Impella offers a variety of hemodynamic support effects and LV unloading [11]. However, the risk of thrombosis and bleeding is greater than that of IABP [15,16]. Thus, the risk-benefit and cost-benefit for an individual patient must be fully considered to initiate Impella [17].

IHF therapy in several stages of heart failure

Acute therapy

Appropriate IHF therapy is directly related to lifesaving and cardiac prognosis in conditions where myocardial damage and hemodynamic deterioration progress acutely, such as acute heart failure, cardiogenic shock, and myocardial infarction.

Acute heart failure or cardiogenic shock

Acute heart failure is a circulatory failure caused by impaired cardiac pumping function. Hypoxia, acidosis, and increased capillary permeability have progressed under shock conditions. The mortality rate of cardiogenic shock remains high at 30–50% [18]. Although inotropes and vasoconstrictors are often forced to prevent severe hypotension, the increased use of these drugs worsens the prognosis of patients with cardiogenic shock [19]. Thus, the negative spiral of acute heart failure and cardiogenic shock needs to be terminated by early recognition and appropriate correction of systemic perfusion using MCS devices and treatment of the causative cardiovascular disease [20]. IHF therapy providers should understand the differences between MCS devices (Fig. 2) and take early action for adequate hemodynamic management. In addition, if cardiac recovery is not expected, the treatment strategy should be shifted to the use of durable ventricular support or palliative care for patients with no indication of durable ventricular support [4,10].

Acute myocardial infarction (AMI)

Advances in the emergency medical system and the establishment of early reperfusion therapy have reduced the mortality rate of patients with ST-segment elevation myocardial infarction (STEMI) from > 20% in the 1980s to approximately 5% [21]. However, it has also been reported that approximately 30% of patients

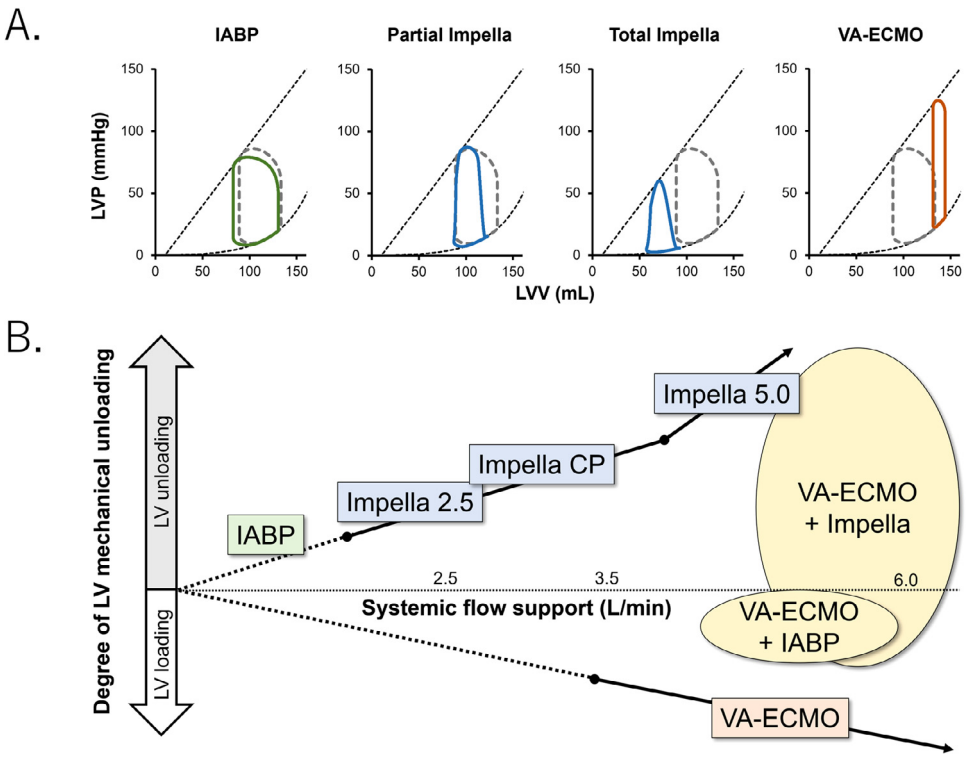

Fig. 2. Differences between IABP, Impella, and VA-ECMO in terms of the PV loop and hemodynamics
(A) Differences between IABP, Impella, and VA-ECMO in terms of the PV loop. The dotted line represents the baseline PV loop. Impella shifts the PV loop lower and left compared with IABP, indicating a high LV unloading effect. In terms of total Impella support, Impella markedly lowers the LV pressure and makes the PV loop small. VA-ECMO increases the LV pressure and shifts the PV loop higher to the right, indicating an increase in LV load.
(B) Relationship between the degree of LV mechanical unloading and the hemodynamic support effect in various mechanical circulatory supports (MCS). The combination of Impella with VA-ECMO is called ECPELLA. Impella unloads the VA-ECMO loaded LV and further increases the systemic flow.
IABP, intra-aortic balloon pumping; LV, left ventricular; LVP, left ventricular pressure; LVV, left ventricular volume; VA-ECMO, veno–arterial extracorporeal membrane oxygenation

with AMI develop heart failure [22]. In addition, myocardial damage in AMI determines the prognosis of heart failure [23]. Thus, primary percutaneous coronary intervention (PCI) for AMI is the most critical IHF therapy to prevent heart failure.

Since the impact of the acceleration of reperfusion on the subsequent prognosis has reached the limit [24], we need to develop another approach to reduce myocardial damage beyond reperfusion. Recently, acute LV unloading with percutaneous LVAD in the acute phase of AMI has attracted considerable attention as a new option for AMI therapy. Meyns et al. reported that acute LV unloading suppressed infarct size in a sheep model of ischemia-reperfusion [25]. Moreover, Kapur et al. reported the suppression of reperfusion injury by acute LV unloading prior to reperfusion in a porcine ischemia-reperfusion model [26]. We also reported that acute LV unloading before reperfusion in a mongrel dog ischemia-reperfusion model prevented subsequent heart failure, depending on the degree of LV unloading [27]. The timing of acute LV unloading is an issue in clinical practice because the percutaneous LVAD introduction before ischemia-reperfusion may delay the timing of reperfusion therapy. Previous data suggest that acute LV unloading before reperfusion and not after reperfusion could improve clinical outcomes [28]. Based on these findings, the concept of "door to unload" in which acute LV unloading is performed before reperfusion therapy has been proposed [29] and is currently being evaluated in the United States in the STEMI-DTU trials (NCT03947619).

Heart failure etiology therapy

The ultimate goal of IHF therapy is to improve long-term clinical outcomes by addressing the etiology of heart failure. Advances in various catheter technologies have allowed catheter interventions in patients without indication for surgery. Moreover, the MCS development has contributed to the success of catheter and surgical interventions for the causative diseases of heart failure.

Ischemic heart disease

Complete revascularization via coronary artery bypass grafting (CABG) in patients with IHD with low cardiac function reduces cardiovascular events and improves prognosis [30]. Although there is no evidence suggesting that PCI improves the long-term outcomes of patients with IHD compared to CABG [31,32], advances in coronary stents dramatically change the PCI impact on multivessel in patients with IHD and low cardiac function if complete revascularization is possible [33]. In an aging society, many patients cannot undergo CABG because of the high surgical risk [34]. Therefore, it is crucial that heart teams providing IHF therapy have a risk-benefit discussion about the revascularization strategy, with careful consideration of the patient's condition, coronary lesions, revascularization strategy, myocardial viability, and risk of complications.

The MCS plays an essential role in IHF treatment strategies. The prophylactic use of IABP in patients with high-risk PCI with low LV function has been reported to reduce mortality and major complications compared with the IABP use as a bailout option in cardiogenic shock [35,36]. In the PROTECT II trial, which compared Impella with IABP for high-risk PCI, there was no significant difference in 30-day mortality between the two groups, but there was a trend toward lower 90-day adverse events in the Impella group [37]. In patients with high-risk PCI, Impella use leads to complete revascularization and postoperative improvement in LV ejection fraction [38]. Therefore, MCS-supported PCI stabilizes the

PCI procedure and has the potential to improve the quality of IHF therapy.

Valvular disease

Surgical intervention has become a common curative treatment strategy for valvular diseases. Several risk scores exist to estimate the mortality and complication rates of each disease and procedure, such as the STS score proposed by the Society of Thoracic Surgeons (STS), the Euro score by the European Association for Cardio-Thoracic Surgery (EACTS), and the JAPAN score calculated from the Japanese Cardiovascular Surgery Database [39–41]. According to the latest guidelines of the Japanese Circulation Society (JCS), a predicted risk of a mortality rate of $\geq$ 8% is considered high-risk [42]. The number of inoperative older patients with valvular disease considering surgical risk scores is increasing in Japan.

In the past, catheter interventions for valvular disease were limited to temporary and palliative uses, such as balloon dilation for aortic or mitral stenosis and mitral commissurotomy (PTMC). Starting with the clinical application of transcatheter aortic valve implantation (TAVI) for aortic stenosis, interventional technologies for valvular diseases have developed rapidly as curative treatments. The term “IHF therapy” is sometimes used to refer to new interventions for valvular disease [7].

Aortic stenosis (AS) is the most common valvular disease, and its incidence increases rapidly with age, ranging from 2.5% to 8.1% in the older population of $>$ 75 years old [43,44]. The prognosis of symptomatic severe AS is poor, with an average survival time of 2–3 years [45]. Therefore, AS is one of the most severe causes of heart failure in Japan. Surgical aortic valve replacement (SAVR) has been used to treat symptomatic severe aortic stenosis, but approximately 30% of older patients with aortic stenosis are highly likely to undergo open-heart surgery [45]. TAVI, a catheter-based aortic valve implantation technique based on the idea of Dr. Alain Cribier, was first performed in 2002 on a 52-year-old man who was unable to undergo surgical treatment due to cardiogenic shock [46]. Initially, the technique was attempted in patients with inoperable thoracic surgery and STS-PROM (predictor risk of mortality) scores of 10 or higher. The Placement of Aortic Transcatheter Valves (PARTNER) 1 trial was a multicenter, randomized clinical trial comparing TAVI (The SAPIEN^{TM} heart-valve system, Edwards Lifesciences Corp., CA, USA) with standard therapy in high-risk patients with severe aortic stenosis, including a prespecified cohort of patients who were not considered suitable candidates for surgery [47]. This trial demonstrated the superiority of TAVI compared to no treatment. In addition, the PARTNER 3 trial, published in 2019, showed that TAVI had a lower incidence in the combined endpoint of death, stroke, and rehospitalization at 1 year compared with SAVR in a group of patients at low risk (STS-PROM scores of $\leq$ 3) [48]. Similar results were also reported using the CoreValve^{TM} series (Medtronic, Inc., MN, USA) [49]. Based on the results of these clinical trials, TAVI is now recommended in the US and European guidelines as a class I procedure for patients with AS who are not at high risk for SAVR. In addition, TAVI is expected to be considered as a first-line treatment for patients at lower surgical risk [50,51].

Functional mitral regurgitation (FMR) is also a common valvular heart disease in patients with heart failure, accounting for approximately 25% of patients with ischemic or dilated cardiomyopathy [52]. Although the presence of FMR is a prognostic factor for patients with heart failure, the impact of surgical mitral valve repair is limited for FMR [53]. Furthermore, as with severe AS patients, approximately 50% of the patients with FMR are classified in the inoperative group due to aging, frailty, or severe heart failure [44]. MitraClip® (Abbott Vascular, IL, USA) is a catheterization procedure that aims to imitate a surgical procedure called "edge-to-edge repair [54]". The MitraClip® system received a CE mark in Europe in 2008 and FDA approval in 2013. The Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy (COAPT) trial reported that MitraClip® significantly reduced mortality and hospitalization for heart failure compared with standard therapy in patients with inoperable FMR [55]. However, in a different patient population, the MITRA-FR study found no significant difference in death or rehospitalization related to worsening heart failure with Mitraclip® versus optimal medical therapy in patients with inoperative FMR [56]. Although single clinical evidence could not optimize the strategy of MitraClip® for FMR regulation in patients with heart failure, additional catheter intervention for those with inoperable FMR may lead to attenuation of heart failure exacerbation.

The progression of valve intervention has not only enabled the treatment of inoperative patients but has also markedly broadened the range of therapeutic indications. Some cases are recommended for catheter intervention rather than surgery considering long-term heart failure management, despite having a low surgical risk [57]. Combined catheter interventions for multiple valvular diseases or interventions with MCS have revolutionized the treatment strategy for patients with valvular disease and heart failure. Heart team discussions are essential for optimizing this strategy.

Arrhythmia

The incidence of supraventricular and ventricular arrhythmias is increased in heart failure and is a risk factor for hemodynamic compromise and sudden death, especially in patients with stage C or D heart failure [58]. Atrial fibrillation (AF) is the most common arrhythmia associated with the occurrence and worsening of heart failure [59]. The Framingham study reported that the incidence of heart failure in patients with AF is 33 per 1,000 per year, and the incidence of AF in patients with heart failure is 54 per 1,000 per year. In addition, the incidence of heart failure in patients with AF and AF in patients with heart failure is associated with increased mortality [60]. Hsu et al. reported that sinus rhythm maintenance via catheter ablation improved the LVEF in patients with low cardiac function [61]. The CASTLE-AF study also showed that rhythm control for AF via catheter ablation was superior to drug therapy in maintaining sinus rhythm, improving cardiac function, and survival in patients with LVEF $\leq$ 35% and NYHA II or higher [62].

In recent years, there has been an increasing number of reports on high-risk catheter ablation using MCS [63,64]. Impella is useful in high-risk ablation strategies because it is less invasive than ECMO→VA-ECMO and more powerful in maintaining hemodynamics than IABP. **Fig. 3** shows the simulation of ventricular tachycardia (VT) induction, which sometimes occurs during catheter ablation, using our previously reported simulator [65]. During VT with collapsed hemodynamics, Impella maintains minimal blood flow and thereby blood pressure by shifting to total support.

An implantable cardioverter defibrillator (ICD) should always be considered in patients with stage C or D heart failure with low cardiac function. According to the JCS guidelines [66], ICD implantation for primary prevention is recommended as class I for patients with low LV function (EF $\leq$ 35%) with NYHA II or higher and non-sustained VT, regardless of whether it is ischemic or non-ischemic. In addition, ICD is recommended as secondary prevention for patients with low LV function (EF $\leq$ 35%) with episodes of ventricular fibrillation, non-sustained VT, and out-of-hospital cardiopulmonary arrest requiring defibrillation.

CRT for severe LV dysfunction

Intraventricular conduction defects in patients with chronic heart failure are known to induce contractile dyssynchrony in the LV, leading to decreased contractility, functional mitral regurgitation, and an increased risk of sudden death [67]. Cardiac resynchronization therapy (CRT) can improve exercise tolerance, cardiac

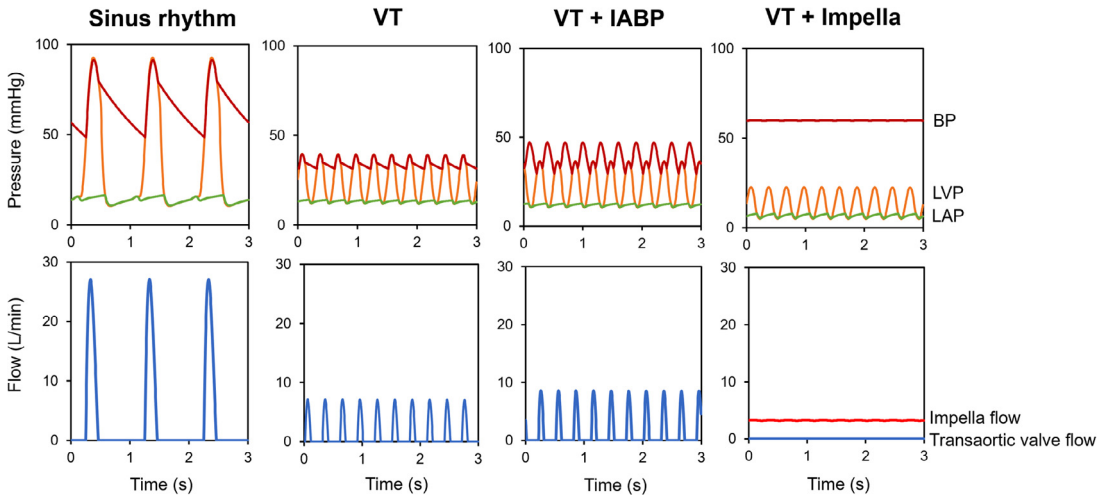

Fig. 3. High-risk catheter ablation under hemodynamic support with IABP and Impella The induction of ventricular tachycardia (VT) during catheter ablation leads to hemodynamic collapse during heart failure. With collapsed hemodynamics, IABP cannot generate systemic flow, while Impella maintains blood pressure by shifting the total support condition. We modelled impaired cardiac function by adjusting end-systolic elastance (E_{es}) of right and left ventricle at 0.3 and 0.8 mmHg/mL, respectively. To simulate VT, we decreased E_{es} of right and left ventricle to 0.12 and 0.3 mmHg/mL and increased heart rate from 60 to 200 bpm.
BP, blood pressure; IABP, intra-aortic balloon pumping; LAP, left atrial pressure; LVP, left ventricular pressure

remodeling, and prognosis in several stages of heart failure [68]. In Japan, CRT is recommended as class I for patients with heart failure symptoms of NYHA III or higher, LVEF ≤ 35%, a left bundle branch block waveform of 120 ms ≥ QRS and sinus rhythm, and those with heart failure symptoms of NYHA II, LVEF ≤ 30%, a left bundle branch block waveform of 150 ms ≥ QRS and sinus rhythm [66]. CRT control of ventricular dyssynchrony is an important treatment option for IHF therapy that should be considered in conjunction with other interventions.

Bridge therapy in end-stage heart failure

As severe heart failure progresses, LVAD placement or heart transplantation should be considered. The intervention plays a vital role in the stable introduction of LVADs in patients who are unlikely to recover their cardiac function. The JCS guideline (JCS/JSCVS/JATS/JSVS 2021 Guideline on Implantable Left Ventricular Assist Device for Patients with Advanced Heart Failure) recommends using MCS, such as IABP or Impella, when the patient presents with organ failure and is refractory to maximal medical therapy [69]. In addition, the guidelines recommend the combined use of pharmacotherapy, renal replacement therapy, and MCS to improve right heart failure [70]. The percutaneous LVAD development has made temporary roles previously played by LVAD with surgical insertion. Impella can be used as a bridge to decision (BTD) and bridge to recovery (BTR) in some INTERMACS profile 1 or 2 situations, such as acute decompensation of advanced heart failure [15,71,72]. It is also expected to be effective for patients on perioperative stabilization of end-stage heart failure transitioning to an implantable LVAD or waiting for cardiac transplantation [73,74].

In IHF therapy, the heart team needs to decide the indications for LVAD and heart transplantation, considering the advantages and disadvantages of these therapies. For the decision, the patient's condition, social background, and wishes, various treatment options, and the team's capabilities are also important.

New interventional technology

The regulatory environment for heart failure devices is rapidly changing in the United States. The FDA issued guidance for early feasibility and first-in-human trials in 2013 and the Breakthrough Devices Program for promoting device innovation in 2016 [75]. **Tables 1 and 2** show some of the next-generation IHF therapy devices that have not been approved in Japan. Regarding devices for hemodynamic intervention, pumps that provide hemodynamic support, renal blood flow maintenance, and LV unloading have been developed [76–78]. Devices that regulate venous flow by placing a pump catheter in the inferior vena cava or balloon occlusion system in the superior vena cava have also been developed [78]. In addition, the left atrial decompression by shunting devices has attracted much attention as a new therapeutic strategy for the treatment of symptomatic heart failure [79–82] **(Table 1).**

Following TAVI and MitraClip®, many structural intervention devices that correct the structure of the heart and valves have been developed and prepared for clinical application [75,83–85]. Cardiac contractility modulation (CCM), which intervenes in the cardiac stimulation conduction system, has shown clinical benefits for patients with heart failure [86]. Based on the accumulation of knowledge in many basic research fields, autonomic interventions have recently made remarkable progress toward clinical application [75,87–89] **(Table 2).**

The treatment of heart failure is a field where unmet needs remain, despite the optimized IHF therapies. It is necessary to constantly discuss how to incorporate new device medicines into IHF therapy.

The need for a training system for IHF therapy specialists

IHF therapy is a framework based on general cardiology, advanced hemodynamic understanding, and device technology. The heart team approach consisting of interventional cardiology, heart failure, cardiovascular intensive care, and cardiac surgery is required for the provider. The need for such an integrated framework has also been recognized in the field of cardiovascular intensive care. Recently, the position of critical care cardiologists and the field of interventional critical care have been established [90,91].

In the complicated heart failure treatment strategy, the IHF therapy tailored to the individual patient's situation is an issue directly related to the prognosis of patients with heart failure, and the training of IHF providers is a prerequisite. In addition,

Table 1
Development of hemodynamic intervention of devices.

Category	Method	Device (Company)	Concept
Hemodynamic Intervention	**Mechanical circulatory support**	**HeartMate PHP (Abbott Inc.)**	A second-generation transcatheter axial flow circulatory support system. The collapsible catheter pump is inserted through a 14 Fr. sheath, deployed across the aortic valve expanding to 24 Fr., and can deliver up to 5 L/min blood flow.
		iVAC 2L (PulseCath BV)	A percutaneous and pulsatile pump design consists of an extracorporeal membrane pump connected to a large-bore catheter inserted across the aortic valve retrogradely into the left ventricle. An IABP console drives the pulsatile pump.
		Retain Catheter pump (Cardiobridge GmbH.)	A catheter-mounted pump-head with a foldable propeller and surrounding cage. The pump in the descending aorta creates a pressure gradient, reducing the afterload and enhancing organ perfusion.
		Aortix™ (Procyion Inc.)	A novel percutaneous mechanical circulatory support device implanted in the descending aorta via the transfemoral approach delivers up to 5.0 L/min of flow.
		Second heard assist (Second heard assist Inc.)	A pump placed immediately above the renal arteries supports flow up to 4 L/min and improves kidney function. The chronic wireless device is also being developed for Class III HF.
		CorInnova (CorInnova Inc.)	A minimally invasive, non-blood contacting cardiac assist device for acute heart failure. The device conforms to the heart's surface and gently compresses the heart to increase cardiac output using an external pneumatic driver that operates in synchrony with the heartbeat.
		Synergy® (CircuLite Inc.)	A miniature partial circulatory support device. The Synergy® is implanted through a right, mini-thoracotomy procedure. Therefore, the inflow cannula is placed in the left atrium, and the outflow graft is attached to the subclavian artery.
	Venous flow control	**preCARDIA (Abiomed, Inc.)**	Reduces central venous pressure through intermittent superior vena cava occlusion via a balloon control system.
		TRVD™ (Magenta Medical Ltd.)	An axial-flow pump-head is positioned in the inferior vena cava (IVC) to treat hospitalized patients with acutely decompensated heart failure by reducing the renal venous pressure and decompressing the kidneys.
		Doraya catheter (Revamp Medical Ltd.)	The catheter is positioned in the inferior vena cava below the renal veins and intermittently leads to partial and adjustable obstruction of venous flow with decreasing renal venous pressure.
	Left atrial decompression by shunting	**Corvia Atrial Shunt System: IASD® (Corvia Medical, Inc.)**	A passage is created between the left and right atria. This passage allows blood to flow from the high-pressure left atrium to the lower pressure right atrium, reducing left atrial pressure.
		V-Wave Ventura® (V-Wave Ltd.)	An hourglass-shaped implantable device for the shunting of blood across the interatrial septum.
		AFR (Occlutech Holding AG)	A self-expandable nitinol mesh braided into two flat discs is used to create permanent interatrial communication with a predetermined diameter. The device is designed to allow for interatrial bidirectional flow.
		Transcatheter atrial shunt system (Edwards Lifesciences corp.)	A novel approach for LA access via the coronary sinus (CS), used to deliver a shunt device for LA decompression in patients with symptomatic HF.

HF, heart failure; IABP, intra-aortic balloon pumping; LA, left atrium

physicians who have received interdisciplinary training for IHF therapy can further develop the clinical and academic fields of cardiovascular care. Various medical institutions in the United States are implementing dedicated hybrid training programs for IHF therapy following the completion of a general cardiology fellowship program (Fig. 4) [9,92]. At present, fellowship programs for cardiologists in Japan are institution-specific. Many cardiologists start training in their specialty after acquiring knowledge, skills, and case experience to become board-certified members of the Japanese Circulation Society. Since the aim of IHF therapy education is not to master a particular intervention technique, it may be desirable to have experience after general cardiologist training.

Vallabhajosyula et al. introduced the disadvantages of hybrid training for cardiologists [93]. They pointed out issues, such as the limited number of training sites, reduction of experience in each technique during the IHF training period, delay of the fellow period, differences in appropriate training periods among the treatments, and employment issues from the perspective of medical institutions. The inability to dedicate all clinical and research efforts to develop a specific subspecialty can be a disadvantage for both the individual physician and the employed medical institution. The optimal IHF therapy training program is yet to be discussed.

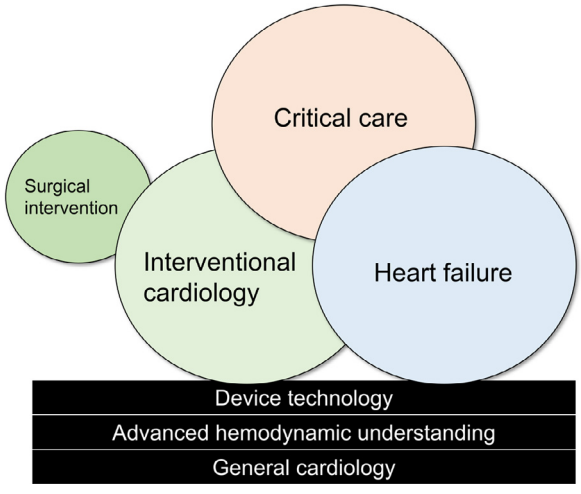

Fig. 4. Need for a training system for interventional heart failure (IHF) therapy specialists IHF therapy is a framework based on the general cardiology, advanced hemodynamic understanding, and device technology. The heart team approach consisting of interventional cardiology, heart failure, cardiovascular intensive care, and cardiac surgery is required for the provider.

Table 2
Development of structural, electrical, and autonomic intervention of devices

Category	Method	Device (Company)	Concept
Structural intervention	**LV expander**	**CORolla™TAA (CorAssist Inc.)**	A cone-like LV expander composed of three elastic arms for implantation on the endocardial wall. The device is anchored to the apex through a fixation suture. The device makes it available to augment diastolic performance for diastolic heart failure.
	Left ventricle reshaping	**Revivent TC™ (BioVentrix, Inc.)**	A device approach for volume reduction through micro-anchors designed to exclude left ventricular scarred myocardial tissue by the percutaneously inserted wire from LV to RV.
		AccuCinch® (Ancora Heart, Inc.)	A direct, device-based, catheter-delivered basilar ventriculoplasty system that involves the anchors' implantation under the posterior mitral annulus, thus reducing the septal free wall dimension, approximation of the papillary muscles and the mitral leaflets, and reducing LV volume.
	Mitral valve implantation	**Intrepid™ (Medtronic, Inc.)**	A self-expanding prosthesis valve is compressed inside a hollow delivery catheter, and implantation is completed through trans-apical access.
		Tendyne™ (Abbot, Inc.)	A self-expandable, tri-leaflet bioprosthetic valve customized to fit individual patient anatomies.
		Sapien M3 (Edwards lifesciences corp.)	Transcatheter mitral valve implantation via the LV apex or vein through a transseptal puncture with a balloon-expandable valve (e.g., Sapien3 transcatheter aortic valve implantation).
	Mitral valve repair	**Pascal™ (Edwards lifesciences corp.)**	An edge-to-edge mitral plastic device with two paddle-shaped grasping arms that are independently closable (clasps) and a central spacer intended to fill the regurgitant jet area.
		Cardioband™ (Edwards lifesciences corp.)	Mitral regurgitation is treated by inserting a catheter through the coronary sinus and suturing the mitral annulus to control mitral regurgitation.
	Tricuspid valve repair	**TriClip™ (Abbot,Inc.)**	A transcatheter edge-to-edge valve repair system designed for a tricuspid valve using technology similar to the MitraClip®.
	Tricuspid valve implantation	**EVOQUE (Edwards lifesciences corp.)**	Transcatheter tricuspid bioprosthetic valve implantation.
		Interpid™ TTVR (Medtronic, Inc.)	Transcatheter tricuspid valve implantation using a self-expanding bio-prosthesis valve.
Electrical intervention	**Cardiac contractility modulation**	**Optimizer® (Impuls Dynamics, Inc.)**	Electrical stimulation during the absolute refractory period of the ventricle via non-exciatatory impulses to change intracellular Ca handling and increase contractility for patients with moderate to severe heart failure.
Autonomic intervention	**Vagal nerve stimulation**	**VITARIA® (LivaNova, Inc.)**	The Vitaria System is designed to deliver autonomic regulation therapy through vagal nerve stimulation for patients with heart failure.
	Splanchnic nerve blockade	**Satera™ (Axon therapies, Inc.)**	A catheter system for splanchnic nerve blockade to manage intravascular fluid distribution in patients with HFpEF.
	Barorecepter stimulation	**BAROSTIM NEO™ (CVRx, inc.)**	BAROSTIM NEO aims to stimulate both the afferent and efferent pathways of the autonomic nervous system by activating baroreceptors in the wall of the carotid artery.

HFpEF, heart failure with preserved ejection fraction.

Conclusion

Surgical and catheter-based interventions can significantly improve cardiac function and prognosis in patients with stage C and D heart failure. In addition, advances in IHF therapy technology have expanded its potential; thus, it is a crucial countermeasure to the heart failure pandemic. However, the appropriate IHF therapy development requires not only advances in technology and techniques but also the organization of the heart team, focusing on heart recovery and education of IHF providers.

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