NCPD 2 HOURS
Nursing Continuing Professional Development

Guideline-Directed Cardiac Devices for Patients with Heart Failure

A review of current options, post-op care, and potential complications.

ABSTRACT: Heart failure affects over 6.2 million adults in the United States and is expected to affect over 8 million by 2030. The U.S. one-year mortality rate is almost 30% among Medicare beneficiaries. Technological advances have produced several new cardiac devices that are available for therapy and symptom management. This article reviews current device therapies for heart failure and uses a composite case to demonstrate how bedside nurses can help patients understand treatment options related to their disease process and care for them through this experience.

Keywords: arrhythmia, cardiac resynchronization therapy, ejection fraction, heart failure, implantable cardioverter–defibrillator, patient education

Over the past six months, Sam Martin, age 76, has been to the ED four times with shortness of breath. (This case is a composite based on my experience.) Each time, he was admitted for three days with a diagnosis of acute decompensated heart failure, given oxygen and diuretics, and his guideline-directed medical therapy was readjusted. Today Mr. Martin is admitted for insertion of an implantable cardioverter–defibrillator with cardiac resynchronization therapy (ICD/CRT, also called a CRT-D, cardiac resynchronization therapy–defibrillator, or a biventricular defibrillator). Although Mr. Martin had a myocardial infarction (MI) two years ago, there is no mention of cardiac arrhythmias in his history. Why is he getting this particular device? And why now?

Heart failure is a common reason for hospitalization and continues to be the most frequent diagnosis for 30-day hospital readmission.[1,2] It currently affects over 6.2 million American adults and is expected to affect more than 8 million by 2030.[2] The one-year mortality rate for heart failure among Medicare beneficiaries is almost 30%.[2] For a primer on heart failure, see *Heart Failure 101*.[3,4]

WHY AN ICD/CRT?

First-line treatment for patients like Mr. Martin is typically medication, but if that isn't enough to prevent shortness of breath, fatigue, and edema, the next step is a device to help the heart function more efficiently. The choice for Mr. Martin—an ICD/CRT—is based on the American College of Cardiology and American Heart Association guidelines for patients with heart failure.[5]

Today, after admission, Mr. Martin's vital signs are taken and are the following: heart rate is 85 beats per minute and blood pressure is 110/60 mmHg. His

respiratory rate is 22 breaths per minute, and oxygen saturation level is 94% on oxygen via nasal cannula at a rate of 2L per minute, but he is still dyspneic with any activity, such as using the bedside commode. These activity limitations classify his heart failure as New York Heart Association (NYHA) class III.[6] Mr. Martin's echocardiogram reveals a left ventricular ejection fraction (LVEF) of 28%, indicating heart failure with reduced ejection fraction (HFrEF). His 12-lead electrocardiogram (ECG) demonstrates sinus rhythm with a wide QRS complex and left bundle branch block. These diagnostic assessments, as well as the prior MI, are indications for ICD/CRT (see *Class I Indications for ICD or CRT*[7]), which Mr. Martin's electrophysiologist has recommended.

An ICD/CRT is a battery-powered generator implanted subcutaneously in the chest with leads that enter the heart through venous access (see Figure 1). An ICD may be placed to monitor a fast or life-threatening heart rhythm or stop it by delivering an electrical shock.[3] An ICD can also function as a pacemaker for a too-slow heart rate. A CRT device paces both ventricles simultaneously (biventricular) and resynchronizes the heart's pumping function, which improves cardiac output.[8]

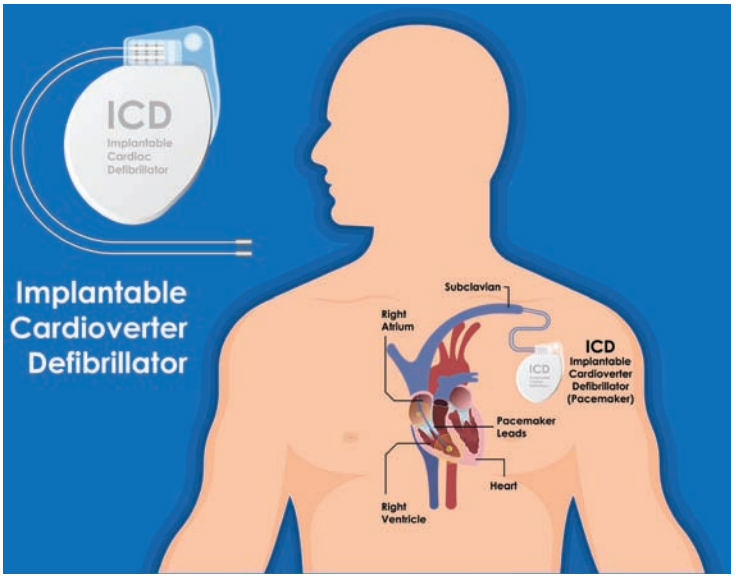
ICDs are implanted for either primary or secondary prevention. Some patients with heart failure who are at greater risk for arrhythmias may need an ICD to prevent a first event, as Mr. Martin did. A recent randomized clinical trial has demonstrated that ICD implantation for primary prevention was associated with reduced mortality in patients with heart failure who were at greater risk for sudden death.[9]

Patients may also receive an ICD for secondary prevention, meaning they have already had at least one life-threatening ventricular arrhythmia, and the ICD is intended to prevent a second event. These patients may or may not have heart failure.

Patients receiving an ICD should have an expected "meaningful survival" of more than one year.[10] This estimates factors in both the risks of surgery and the cost of the device (which can be upward of $30,000[11]). If the patient is likely to die within a year, the device is not a good choice. This isn't a consideration for a patient like Mr. Martin, a reasonably active man who is unlikely to die anytime soon. In patients who meet the class I indications (clear benefit),[7] CRT improves quality of life and reduces heart failure–related mortality and hospitalizations.[8, 12]

It's important to note that, before recommending an ICD or ICD/CRT, a patient should have maintained target doses of guideline-directed medications for at least three to six months, followed by a reassessment of symptoms and ejection fraction.[5] Mr.

Figure 1. ICD with Lead Wire in Right Ventricle



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Martin's medications include furosemide, spironolactone, metoprolol, sacubitril–valsartan, empagliflozin, and ivabradine, in line with all guideline-directed heart failure medical therapy (see Table 1[5]). He's been on target doses for four months.

SHARED DECISION-MAKING

It is essential for clinicians to communicate the risks and benefits of any ICD device to the patient and

Heart Failure 101

Heart failure is a structural problem in which the heart is unable to pump enough blood to meet metabolic requirements. Patients with heart failure are classified by their ejection fraction, which is the percentage of blood the left ventricle pumps with each contraction. Patients with a low ejection fraction (< 40%) are classified as having systolic heart failure or heart failure with reduced ejection fraction.[3] Patients with an ejection fraction of 40% to 49% are classified as having heart failure with midrange ejection fraction.[3] Patients with a normal ejection fraction (≥ 50%) are classified as having diastolic heart failure or heart failure with preserved ejection fraction.[3] All types of heart failure result in pulmonary congestion and edema, with symptoms of dyspnea, fluid retention, and decreased exercise tolerance.[4]

family. The patient's goals of care, preferences, and values, along with evidence-based recommendations, should all be considered.

To help Mr. Martin make the decision to add a cardiac device, his electrophysiologist went over the pros and cons with him during a recent office visit. First, she explained that because of his previous MI, his heart wasn't pumping enough blood and oxygen, placing him at higher risk for cardiac arrest and sudden death from a cardiac arrhythmia. (Survival of an out-of-hospital cardiac arrest can be less than 10%.[2]) She pointed out that an ICD would monitor his heart rate and rhythm, and if it detected a fast arrhythmia, would pace his heart faster to break (interrupt) the rhythm. "And if that doesn't work," she added, "the ICD will deliver an internal shock to break the rhythm." She cautioned Mr. Martin that this shock might be painful—some patients have described it as a jolt, a thump, or "being kicked or punched in the chest."[13] But many patients never receive a shock; the device just paces their heart and monitors its rate and rhythm. The ICD is there in case of emergency, like wearing a life preserver at sea.

When Mr. Martin asked about the ICD implantation itself, the provider told him that the surgical procedure carries a low risk of bleeding or infection and a rare risk of pneumothorax or cardiac perforation.[14] He will have an incision in his left upper chest just under his collarbone, and when it heals, the shape of the device will be visible under his skin.

Patients who are concerned about the cosmetic appearance of the ICD may have the device placed submuscularly. This is a more extensive procedure, and the patient may be in more postoperative pain. Some providers may choose to place the device in the axillary fossa, especially if the patient has very thin skin or has experienced previous device discomfort or tissue erosion in the chest.[15]

Although Mr. Martin need not worry about the device failing, they do wear out, the provider tells him, the battery lasting five to six years.[16] The provider will monitor the battery life wirelessly and when it gets too low, Mr. Martin will need surgery to remove the old device and implant a new one. This replacement surgery is simpler than the original implantation, as the leads will remain, and a new generator will be attached to them. Mr. Martin will have an incision but can go home the same day.

The provider explains cardiac resynchronization and tells Mr. Martin it should help his heart to beat more efficiently, relieve his shortness of breath, and improve his quality of life.[7]

Mr. Martin's goals of care include being more active, as he is an avid boater and fisherman. "I've got a lot of good years left and want to live my life to the fullest," he says. After consulting with his daughter, he agrees to the procedure.

Class I Indications for ICD or CRT[7,a]

ICD for Primary Prevention

- LVEF ≤ 35% due to previous MI (at least 40 days post-MI); NYHA class II or III
- LVEF ≤ 35% due to NIDCM; NYHA class II or III
- LVEF ≤ 30% due to previous MI (at least 40 days post-MI); NYHA class I

CRT

- LVEF ≤ 35%, sinus rhythm, LBBB (QRS ≥ 150 ms); NYHA class II or III, or ambulatory class IV symptoms on guideline-directed medical therapy

CRT = cardiac resynchronization therapy; ICD = implantable cardioverter–defibrillator; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NIDCM = nonischemic dilated cardiomyopathy; NYHA = New York Heart Association.

[a] Class I (procedure should be performed) is an American College of Cardiology Foundation/American Heart Association Class of Recommendation.

PATIENT EDUCATION: THE PICTURE TELLS A STORY

That morning in the hospital, while his nurse, Ms. Lewis, is doing his pre-op teaching, Mr. Martin says he's still a little confused: "Can you explain how 'resynchronization' will help me breathe better?"

A moment like this is a good time for a visual aid, which can be an effective strategy when explaining clinical concepts. Many people find it easier to understand something when they see it, as opposed to hearing it described.

Ms. Lewis draws a rough picture of the heart with its four chambers. "Mr. Martin," she says, "your previous heart attacks left some damaged areas here in the left ventricle, which is one of the lower chambers of the heart. We can tell from your ECG that your right and left ventricles are not beating in time with each other. This means the amount of blood and oxygen your heart can pump is reduced."

She then draws the CRT generator device at the left shoulder, a pacing and shock lead entering through the right atrium into the right ventricle and a pacing lead through the coronary sinus vein to the outside of the left ventricle (see Figure 2). "When these leads are connected to the ICD/CRT device, both ventricles will be paced at the same time—synchronously—which means your heart can pump more blood," she explains. "And because blood carries oxygen to your lungs, with improved cardiac output, you should breathe easier and be able to tolerate increased activity." Using the drawing, the nurse asks Mr. Martin to "teach it back" to assess his understanding of CRT.

The device will also remotely monitor intrathoracic impedance, which is an assessment of fluid volume. Impedance (resistance) to the flow of electrical current through the chest cavity is measured from the generator to the right ventricular shock lead. Decreased impedance indicates there is increased fluid in the thoracic area, which may mean there is fluid in the lungs.[17] Ms. Lewis explains that this is an added benefit of this device—that it senses if there is too much fluid in the chest, which may indicate heart failure is worsening, even before there are symptoms. That information will be sent wirelessly to the provider's office. If needed, they can call to see how the patient is feeling. "Think of this as an 'early warning' feature," she says.

POST-OP CARE AND POTENTIAL COMPLICATIONS

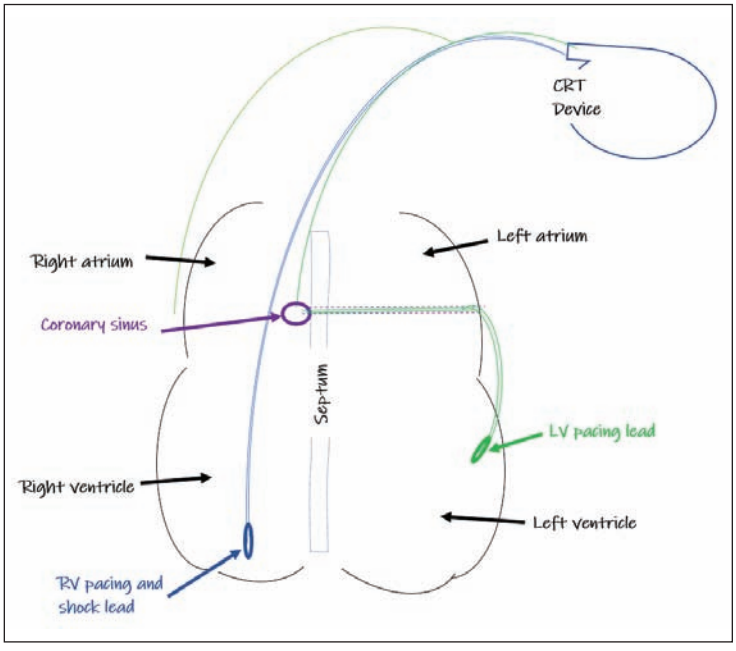
ICD/CRT implantations are very safe. Complications are reported to occur in less than 2% of procedures,[14] still patients must be monitored for them, especially in the immediate post-op period. The main complications of cardiac device insertion are lead dislodgment, bleeding, infection, pneumothorax, and cardiac perforation.[7,14] Mr. Martin's nurse tells him that, immediately after the procedure, they will take an anterior-posterior view chest X-ray to document lead placement and rule out pneumothorax. Another X-ray will be taken the following morning before he is discharged.

Ms. Lewis explains that the arm on the side of the chest where the device is placed (usually left) will be immobilized overnight so that it stays close to his chest. "This is to prevent arm movement that might dislodge the lead," she tells him. For the next two to four weeks, he will need to limit range of motion of that arm. More strenuous activities like golf or swimming can be resumed after six weeks.

Pre- and post-op prophylactic antibiotics will be ordered. The nurse will observe the incision site for bleeding or hematoma, as well as for signs of reduced cardiac output, such as tachycardia, dyspnea, and hypotension. The rare complication of cardiac perforation may cause bleeding into the pericardial sac and result in pericardial tamponade.

Mr. Martin's ECG will be monitored with telemetry. If the pacing function of the device is required (as it is in CRT), a ventricular pacing spike should occur with each beat, followed by a QRS complex. A ventricular pacing spike without a QRS may signal a dislodged lead (see Figure 3). The nurse should obtain a 12-lead ECG and notify the surgeon, who can order a chest X-ray and have the device company representative or other provider interrogate the device. This is done with a special computer called a programmer that is placed over the device and can adjust the electrical output through the skin. If the lead has indeed been dislodged, the patient must return to surgery to have it repositioned.

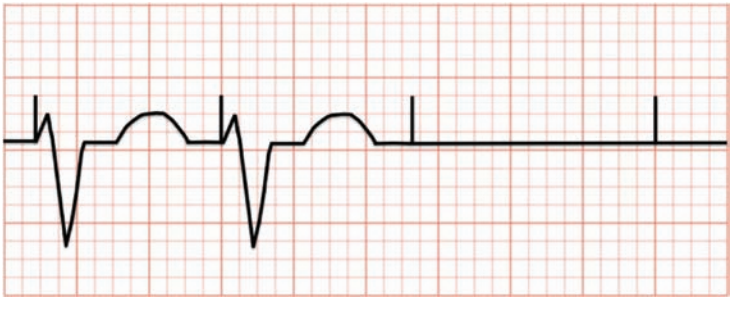
Figure 2. Patient Education ICD/CRT Diagram



Another possible complication of CRT device implantation is diaphragmatic pacing from phrenic nerve stimulation. One of the pacing leads may be close to the phrenic nerve. In this case, the patient will experience a pulsation over the upper abdomen that will likely be visible and palpable. It may be continuous or positional, especially when the patient is in a left-lateral position.[18] Because it can be uncomfortable, the nurse can change the patient's position to attempt to relieve the symptoms. The surgeon should be notified and can order the company representative to noninvasively reprogram the device.[18]

Once he leaves the hospital, Mr. Martin may be seen by a home health nurse. He'll have Steri-strips over the incision, which should stay in place until they fall off, and he may have shower restrictions for up to a week; these instructions are provider-

Figure 3. Ventricular Pacing Spike Not Followed by a QRS Complex



specific. Mr. Martin should observe the incision site for redness and swelling and notify the surgeon if this occurs. He may be given oral opioids for 24 hours for pain; after that, acetaminophen is usually adequate.

If Mr. Martin has any future surgical procedures, the tachyarrhythmia therapy or shock function should be disabled for the duration of the surgery, as the ICD may interpret surgical electrocautery as a ventricular arrhythmia and deliver a shock.

increasing myocardial oxygen consumption, thus improving LVEF.[20] In 2019, the FDA approved CCM for patients with NYHA Class III heart failure, who had LVEF of 25% to 45%, normal sinus rhythm, and no indication for CRT therapy.[22]

The CCM pulse generator is implanted subcutaneously in the upper chest and attached to two pacemaker leads inserted through the subclavian vein.[22] The leads are fixed to the right ventricular septum and electrical impulses are delivered to the septum at regular intervals throughout the day.

Before recommending an ICD or ICD/CRT, a patient should have maintained target doses of guideline-directed medications for at least three to six months, followed by a reassessment of symptoms and ejection fraction.

ICDs are designed to be sensitive to magnets. External magnets are used to disable the tachyarrhythmia therapy of an ICD (as in surgical procedures), but the pacing function remains intact. Therefore, the nurse tells Mr. Martin that he needs to be careful around common magnets, such as those in newer-generation smartphone chargers, which may interfere with the defibrillator or pacing function when in close contact with the device. He should avoid carrying his phone anywhere near the device, such as in a breast pocket, and should consult with his electrophysiologist about his specific device and smartphone interactions.[19] He's also given a device identification card to keep with him in the event he is asked to go through a metal detector.

OTHER DEVICES

Mr. Martin's case was ideal for an ICD/CRT. But what if the patient needs a different intervention? Here's a rundown of some of the other guideline-directed options approved by the Food and Drug Administration (FDA).

Cardiac contractility modulation. Not everyone with HFrEF, such as patients who don't have a wide QRS left bundle branch block on ECG,[20] will qualify for or benefit from CRT. Moreover, approximately 30% of those who do receive CRT and are on guideline-directed medical therapy do not respond with an improved LVEF, for a variety of reasons.[21]

These patients may benefit from cardiac contractility modulation (CCM), which modulates the strength of the heart muscle's contraction. The device delivers electrical current to the right ventricular septum, improving contractility without

These patients may also have an ICD with a shock lead in the right ventricle, meaning that three lead wires cross the tricuspid valve from the right atrium to the right ventricle. Although there was initial concern about three leads crossing the valve and influencing tricuspid function, this has not been an issue.[22]

Patients must be monitored for potential implant complications, such as lead dislodgment, bleeding, infection, pneumothorax, and myocardial perforation.[23] The CCM device is powered by a battery that lasts 10 years and must be recharged weekly for one hour with a transcutaneous external device.[22]

Subcutaneous ICD. Patients with heart failure who do not need CRT or pacing and only need a defibrillator for primary prevention may opt for a subcutaneous ICD (S-ICD), which was approved by the FDA in 2012.[24] This device does not have transvenous leads in the heart, so it cannot pace; its only function is to sense heart rate and rhythm and to shock lethal arrhythmias.[24] The system is implanted in the chest with a generator on the left side next to the rib cage and a lead just under the skin parallel to the sternum. Electrodes on each end of the lead sense the patient's heart rate and rhythm, and the shock coil is located between them.[25] If the electrodes detect a lethal arrhythmia, the shock coil will deliver a shock to the heart.[25] Patients are prescreened to ensure the device can detect their heart rhythm.

Since there are no transvenous leads in the heart, there is no risk of lead dislodgment, pneumothorax, or cardiac perforation.[26] Patients may spend one night in the hospital or go home the same day. There are no limitations on arm range of motion. As with other devices, the wound must be observed for signs

of bleeding or hematoma. The S-ICD has demonstrated high safety and efficacy in converting tachyarrhythmias in patients with HFrEF, even in those with several other comorbidities.[27]

Baroreflex activation therapy, which was given FDA premarket approval in 2019,[28] is indicated in patients with HFrEF who continue to have symptoms despite optimum guideline-directed medical therapy.[29] Patients who don't meet the indications for ICD/CRT (such as those who have a QRS duration of less than 150 ms) may be recommended for baroreflex activation therapy.

A generator is implanted under the clavicle with a 2-mm disc electrode placed on the carotid sinus nerve.[28] The purpose is to inhibit the sympathetic "fight or flight" response that constricts blood vessels and makes the heart work harder. The electrical stimulation of baroreceptors in the carotid sinus can reduce sympathetic activity by up to 30%[30] and augment parasympathetic activity, which lowers the heart rate.[28]

This action is significant, because in heart failure decreased cardiac output is sensed by baroreceptors in the aortic arch and carotid sinus and relayed to the brain stem. The sympathetic nervous system responds by secreting epinephrine and norepinephrine. These catecholamines boost heart rate, increase myocardial contractility, and increase peripheral vasoconstriction, which raises blood pressure and systemic vascular resistance. All these processes increase afterload, which is the pressure the left ventricle must pump against. By inhibiting the sympathetic response and increasing the parasympathetic response, baroreflex activation therapy reduces peripheral resistance and relieves afterload on the left ventricle.[28]

Implantation is considered minimally invasive surgery; most patients go home the same day. As with other implanted devices, the baroreflex activation stimulator has potential complications of infection or bleeding. Additionally, because of parasympathetic stimulation, patients may experience hypotension and/or syncope, although these effects have been reported rarely.[31]

Percutaneously inserted pulmonary artery pressure monitor. Approved by the FDA in 2014,[32] this heart failure device recently seen in clinical practice is not used for therapy, but for remote diagnostic monitoring. Introduced percutaneously into the pulmonary artery, it monitors changes in left ventricular filling pressures[33] and relays the data wirelessly to the health care provider. Monitoring pulmonary artery pressure in

Table 1. Guideline-Directed Medical Therapy for Heart Failure[5]

Medication Class	Examples	Purpose
Angiotensin-converting enzyme inhibitor	Captopril, enalapril, lisinopril, ramipril	Reduce vasoconstriction and blood pressure, reverse cardiac remodeling
Angiotensin receptor blocker	Candesartan, losartan, valsartan	
Angiotensin receptor–neprilysin inhibitor (ARNI)	Sacubitril–valsartan	
β-blocker	Bisoprolol, carvedilol, metoprolol succinate	Reduce mortality and improve clinical status
Diuretic	Bumetanide, furosemide, torsemide	Reduce fluid overload
Aldosterone antagonist	Eplerenone, spironolactone	Prevent salt and fluid buildup; reduce blood pressure and prevent fluid overload
Sodium–glucose cotransporter-2 inhibitor (SGLT2i)	Dapagliflozin, empagliflozin	Decrease heart failure hospitalization and mortality; improve renal function
Hyperpolarization-activated cyclic nucleotide-gated channel blocker	Ivabradine	Reduce resting heart rate in patients with stable heart failure with reduced ejection fraction on maximum tolerated β-blocker dose
Vasodilator	Hydralazine–isosorbide dinitrate	Improve clinical status in African American patients who are taking an ARNI, a β-blocker, an aldosterone antagonist, and a SGLT2i, and who have persistent symptoms

this way can alert the provider that fluid may be accumulating in the lungs and an extra dose of diuretic may be needed. This can prevent the patient's symptoms worsening to clinical congestion,[33] leading to hospitalization.

The device is costly, though—nearly $20,000—and not without risk.[34] In the first three years after FDA approval, 5,500 devices were implanted and 155 reports (2.8%) of 177 unique adverse events involving sensor failure, malfunction, or migration and 22 deaths (0.4%) were received.[32]

Ventricular assist devices. Patients who have end-stage heart failure may receive a mechanical circulatory support device called a ventricular assist device (VAD). VADs are pumps that can be implanted into the right ventricle (RVAD), left ventricle (LVAD), or both ventricles (BIVAD). The LVAD (the most common) diverts blood from a failing left ventricle and sends it to the ascending aorta.[35] It is powered by an external battery connected to driveline wires inserted through the skin. Patients who are awaiting a heart transplant may receive an LVAD as a bridge-to-transplant until a heart becomes available.[35]

However, patients with end-organ medical conditions may not be candidates for heart transplant. For them, an LVAD is destination therapy.[35] That is, the LVAD is their completed goal of care, and they will use it for the remainder of their life.[35] About half of the LVADs implanted in the United States are for destination therapy.[2]

Patients with LVADs must have a full-time caregiver, but the care requires a specific skill set and education. For instance, because of the continuous flow of the pump, auscultation will reveal a constant hum, decreasing S1 and S2 heart sounds, and peripheral pulses will be difficult to palpate. Systolic and diastolic blood pressures may not be obtainable, but the mean arterial pressure reading should be between 60 and 90 mmHg.[36] Family members or caregivers would need extensive training and support.

SENDING THE PATIENT HOME

Thanks to his ICD/CRT device, Mr. Martin's heart is now in a 100% biventricular paced rhythm, and he has had no postoperative complications. Before he's discharged on the day following implantation, his nurse discusses with Mr. Martin and his daughter home care for his incision and what to do if he experiences a shock.

Ms. Lewis reminds Mr. Martin that he needs to check his weight daily and notify his provider if he has gained more than two pounds in one day or five pounds in one week, as this may indicate fluid gain and the need for an extra diuretic. She gives him diet instructions with sodium restriction and shows him how to read a food label. She also teaches him how to recognize worsening symptoms, such as difficulty breathing, increased feet or ankle swelling, increased fatigue, or frequent coughing[37]—and to call his provider if he experiences any of these.

The nurse also completes medication reconciliation and reviews the drugs with Mr. Martin, asking him to teach them back. He's taking quite a few, and some are expensive, but fortunately case management has provided information on free or reduced-cost medications.

Now he's good to go, armed with the device in place and the information he needs. Patients like Mr. Martin face many challenges in managing their heart failure, but with detailed discussion and thoughtful preparation, they will be well equipped. The nurse at the bedside is perfectly positioned to help patients like Mr. Martin feel confident in their self-care. ▼

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