

How to establish a successful destination therapy ventricular assist device program

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Introduction

Heart failure is one of the most important cardiovascular problems in the United States with 5.7 million adults afflicted in 2015 (1). This number is projected to increase to eight million (one out of every 33 adults) by the year 2030 (2,3). Overall treatment costs in 2012 were almost \$31 billion and are anticipated to reach almost \$70 billion by 2030 (2). Currently, approximately 5,000 to 6,000 patients are treated annually with left ventricular assist devices (LVADs). However, projections range from 35,000 to 150,000 annual cases (4,5).

LVAD implantation in patients with congestive heart failure has excellent outcomes when compared to medical therapy (6-8) and has become an important option for the treatment of patients with advanced heart failure (9-12). Nowadays, the number of LVAD implantations exceeds the number of annual heart transplantations worldwide (12). LVADs are used as a bridge to recovery, a bridge to transplant (BTT), a bridge to decision, and as destination therapy (DT). The indications of using LVAD as BTT include patients who have class IV symptoms for at least 60 days under optimal heart failure therapy, or need inotropic support for heart failure treatment or IV inotrope-dependent for 14 days; or have been balloon pump-dependent for 7 days, display a left ventricular ejection fraction (LVEF) under 25%; have a peak oxygen consumption of <12–14 mL/kg/min; or show a documented inability to be weaned off intravenous inotropic therapy (13).

Patients selected for DT usually are LVAD candidates but have contraindications for heart transplantation, such as age >70 years, malignancy within the past 5 years,

comorbidities such as insulin-dependent diabetes mellitus with end-organ damage, chronic renal failure, drug abuse, severe obesity or fixed pulmonary hypertension with a trans pulmonary gradient of above 15 mmHg and vascular resistance >6 Wood units (14)

As LVAD becomes a more accepted technology in the armamentarium of heart failure treatments, patients are increasingly undergoing LVAD as destination therapy (DT LVAD), and the number of transplant centers establishing DT LVAD programs is rising. As of July 2016, Centers for Medicare and Medicaid Services reported 151 VAD destination centers in the United States (15). This article provides information on how to establish a successful DT LVAD program? We carefully considered various factors which are important in implantation this technology a number of recommendations have particular relevance to the American situation, but it could be used as a road map or a guidance for different health systems too.

Step 1: identify the need for a DT LVAD program

Perform a thorough evaluation of the potential number of LVAD implantations you might be able to perform. Note that the program might not be cost effective in the beginning due to capital investments to establish the infrastructure. However, on top of direct revenues, the DT LVAD program will create a “halo effect” for the medical center by increasing upstream and downstream activities. Among the heart failure patients referred for LVAD assessment, many will not receive LVAD implantations but will undergo percutaneous interventions, surgery, or an

electrophysiology procedure at the center (vital points for persuading hospital leadership to adopt the project).

Step 2: identify the physician leadership team

The physician leadership team needs to be willing to give sufficient time and effort to proceed with this labor-intensive endeavor. It should comprise of a qualified cardiothoracic surgeon with training and experience in mechanical circulatory support and a qualified heart failure cardiologist. They are the project champions and will continuously oversee the program, periodically reassess and manage patient selection and ensure high quality outcomes. They also need to critically analyze policies, training, annual competencies and recommend restructuring when indicated.

Step 3: sell the idea to hospital leadership

It is essential to have full administration support for this capital investment. Hospital administration should be convinced about the program and be willing to invest and continue supporting the project all the times as returns on investments will not be immediate. You will need to perform a cost analysis for the impact of the DT LAVD program on patient flow in your center. The analysis should also include marketing, program infrastructure, capital, and commitment to create formal alignment of care providers throughout the region. As a selling point, focus on the importance of having a DT LVAD program and on the halo effect and hospital visibility along with what has been mentioned above. These are some tips for engaging leaders in your project (16,17):

- (I) Understand your leader's style: knowing the personality of the person to whom you are trying to "sell" the idea or program is critical. You need to find out what convinces the leader. Is he open to new ideas?
- (II) Find the best access to hospital administration: try to build a cross-disciplinary team (guiding coalition) of other department leaders, hospital frontline staff, patients and families who support the work. Secure the help from individuals within this group who are perceived as credible (16). Having diverse voices of support will build leverage for getting leadership buy-in;
- (III) Be sure to establish a clear, ambitious vision that can inspire: use evidence and experts to make your

case; providing excellence can only be done by using evidence-based practices. Leaders want to know that you have done your homework before committing resources to a new project;

- (IV) Align with external priorities: leadership is more likely to support a project that is in alignment with the future of their field. Appeal to your leaders by aligning your initiative with national priorities, especially those that are cutting edge;
- (V) Communicate: communicate by using all channels (meetings, emails, one on one conversations). Getting administration buy-in is only half the battle. They still need the go-ahead from leadership to fund the project. Once leaders are onboard, it is important to frequently share information to help transitioning them from a supportive to a committed role (18).

Step 4: identify your clinical team, then establish your staffing and training model

The key to success is having a coordinated team of professionals (the core team) who are ready to dedicate a significant portion of their time caring for LVAD recipients. This team will usually include at least two surgeons trained in implantation and management, at least one cardiologist, plus perfusionists, an intensive care physician, and anesthesiologists, these are also expert in managing patients on extracorporeal membrane oxygenator in case of need for support, a nutritionist, physical therapist, rehabilitation therapist, outpatient nurses, infectious disease physician, psychologist, nephrologist, social workers, financial manager, and nurses who will help take care of these patients. Because device malfunctions and complications can happen at any time, the program will also need at least two LVAD coordinators (usually nurses, nurse-practitioners, or physician's assistants) to oversee all aspects of the patients' care. The number of team members need to increase as patient numbers increase. These employees will become staff level champions.

Once these components and individuals are in place, start team education. This should include a structured competency model of mock loops of wet lab LVAD implantation to become familiar with the technique (for this, it is imperative to receive institutional review board and Institutional Animal Care and Use Committee approval from your institution). It is essential to arrange for team members to assist in real life implantation in other hospitals

where they can also learn about the procedure and patient management before and after surgery. You should also anticipate and address staff resistance and culture change; continuous education is a key point for success. Remember, engaging diverse staff throughout the planning, design, and implementation of program improvement strategies is critical for facilitating successful and lasting change.

Step 5: identify a nearby heart transplant program

While building your team, identify and develop a collaborative relationship with a nearby heart transplant program. A good relationship will be vital for patients who have LVAD as bridge to decision and for patients whose LVAD implantation condition might change from destination LVAD to BTT LVAD.

Step 6: implant your first LVAD/apply for accreditation to the Joint Commission for Accreditation of Hospital Organizations (JACHO) and CMS

The multidisciplinary LVAD team needs to select the perfect candidate to be the first patient receiving an LVAD, as the JACHO approval is depending on procedure and outcome of the first LVAD implantation. Hospital administration needs to decide whether to cover costs or to wait for a candidate with sufficient insurance, if the first patient does not have the optimal reimbursement plan. Most hospital administrators prefer to cover all costs instead of delaying the start of the program.

Submit your application to JACHO after discharge of the first patient. It might take at least 4 months before the JACHO visit; it is vital to continue team education and the mock training loops during this time to keep standards high. When approved, the hospital can get reimbursed by Medicare. Medicare reimbursement is the lifeblood of the LVAD program, and hospital billing staff must understand the complexities of Medicare coding regarding patient care and all equipment, supplies, and services associated with LVAD implantation. When patient numbers increase, it might be beneficial to consider hiring dedicated billing staff that works only for the LVAD program.

Step 7: keep a successful, profitable LVAD program

Excellent outcomes are important. The hospital will not

make profit without good results, as the program will not get referrals from cardiologists resulting in less revenue for the program. Careful selection of patients eligible to receive LVAD is vital for success. It is key that implantation candidates should be approved by all members of the multidisciplinary LVAD team; marginal candidates should not be selected.

Conclusions

LVAD becomes a more accepted technology in the armamentarium of heart failure management. DT LVAD is no longer the “future”, it is here. Professionals interested in establishing the program need to realize that the process is time consuming, and a lot of effort is required before it becomes profitable. The key to any successful DT LVAD program is a coordinated team of professionals who dedicates all or at least a significant portion of their time to caring for LVAD patients. Sufficient institutional support and staffing is also essential. Once established, it is imperative that ongoing training and proficiency methods are in place in order to assure optimal results.

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Footnote

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