

Ventricular Assist Device Therapy: A ROUNDTABLE DISCUSSION

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Within the last decade, treatment with mechanical circulatory support (MCS) has become an accepted standard of care for patients with advanced heart failure who have failed medical management. In this roundtable discussion between leading physicians in the fields of cardiology and thoracic surgery, the participants share their expertise in using ventricular assist devices (VADs), particularly the HeartMate II® Left Ventricular Assist

System (Thoratec Corporation, Pleasanton, CA) to save and support individuals with failing hearts.

ANTICIPATED TIME HORIZON FOR VAD SUPPORT

DR O'CONNELL: Heart failure is one of the most important cardiovascular problems seen in the United States, with a wealth of data illustrating this point. There are 5.1 million American adults who are afflicted by this condition—a figure that is projected to increase by 25% by the year 2030. In individuals over the age of 45, the incidence of heart failure has reached 670,000 new cases each year, with more than 56,000 annual deaths due to heart failure. The total cost of treating heart failure in 2012 reached almost \$31 billion—a tally anticipated to climb to almost \$70 billion by 2030, given the projected 8 million individuals who will suffer from this condition (**FIGURE 1**).

When MCS first emerged in the 1980s in an effort to keep patients with postcardiotomy heart failure alive long enough

Disclosures

Dr O'Connell discloses that at the time of the roundtable discussion he was a paid consultant for Thoratec Corporation. As of September 30, 2013, he is a full-time employee of Thoratec Corporation. Dr O'Connell also discloses that he is on the Data and Safety Monitoring Committee for Auvon Therapeutics.

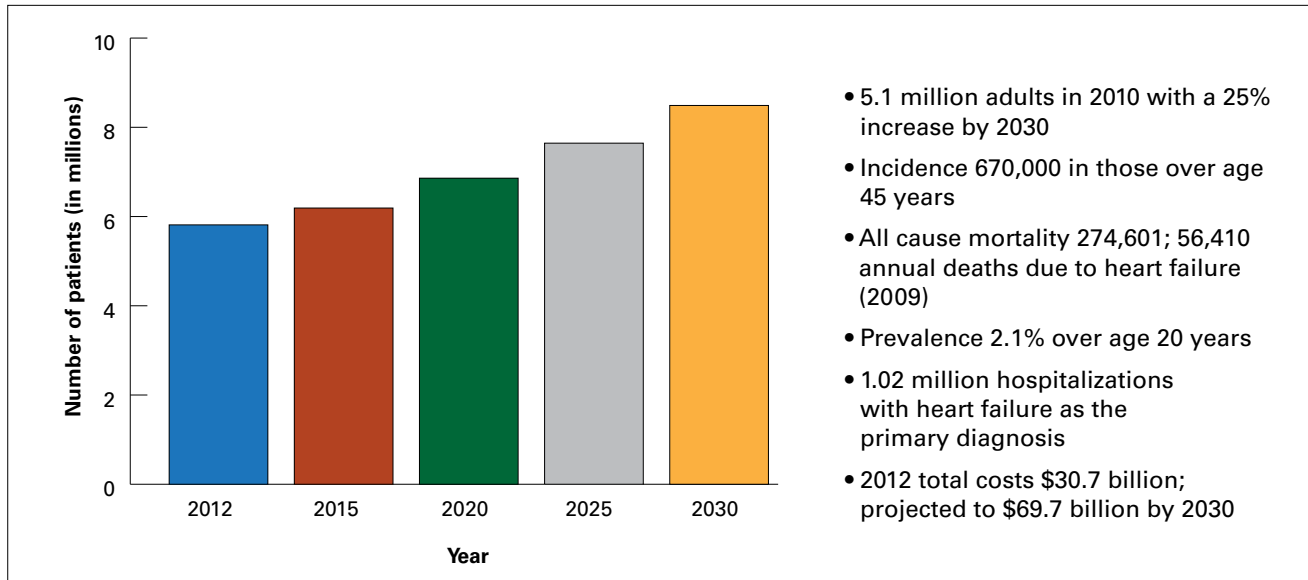
Dr Dembitsky discloses that he is a paid consultant and lecturer for, and has received research grants from, Thoratec Corporation.

Dr John discloses that he is a paid consultant for, and has received research grants from, Thoratec Corporation.

Dr Lahpor discloses that he is a paid consultant and speaker for Thoratec Corporation.

Dr Rich discloses that he has received honoraria in the past from Thoratec Corporation.

FIGURE 1
Heart failure growth in the United States, 2012 – 2030



Sources:
Heidenreich PA, Albert NM, Allen LA, et al; American Heart Association Advocacy Coordinating Committee; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; Council on Clinical Cardiology; Council on Epidemiology and Prevention; Stroke Council. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. *Circ Heart Fail.* 2013;6(3):606-619.
Go AS, Mozaffarian D, Roger VL, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2013 update: a report from the American Heart Association [published corrections appear in *Circulation.* 2013;127(23):e841; *Circulation.* 2013;127:doi: 10.1161/CIR.0b013e31828124ad]. *Circulation.* 2013;127(1):e6-e245.

to obtain a donor organ for transplantation, expected survival amounted to days. However, survival with these devices has increased dramatically over time, reaching weeks by the 1990s and months by 2000. By 2012, VAD clinical trials were measuring endpoints of 2-year survival, which may increase further still to 5-year survival by 2015.

The experience with the HeartMate II Left Ventricular Assist System has grown exponentially over the last 5 years. More than 15,000 patients worldwide have now been implanted with the device, 6,000 of whom are still living with ongoing support. In fact, approximately 300 patients with the HeartMate II device are currently alive with ongoing support for more than 5 years.

When evaluating a patient for VAD therapy, what is the time horizon for support that you have in mind?

DR DEMBITSKY: At my institution in San Diego, we face a shortage of timely donor organs. As a result, we fully anticipate long-term implantation of a VAD in at-need patients with heart failure, with expected time horizons of 5 to 10 years. In fact, we have a patient who has been using VAD devices now for 11 years and who refuses transplantation.

DR JOHN: I agree. The University of Minnesota, where I practice, also suffers from a shortage of adequate donor

hearts. Any time we implant a patient with a VAD, we anticipate a survival period at least in excess of 3 years.

DR O’CONNELL: The data from clinical trials now appear to support this concept of long-term support. Dr Rich, would you please explain these data?

DR RICH: That is correct. Anecdotal experiences suggest that patients are living longer on these devices and now emerging data support these observations as well. When the bridge to transplant (BTT) trial of the HeartMate II device was completed, there was interest in determining the real-world, postapproval experience with the device. As such, the first 169 consecutive HeartMate II patients enrolled in the national Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) were prospectively followed for at least 1 year after implant and then compared with patients in the pivotal BTT clinical trial. At 12 months after device implantation, those patients who received the HeartMate II in the postapproval era exceeded the survival of patients in the clinical trial (1-year survival: 85% vs 70%). This was somewhat unexpected, given that patients in clinical trials often attain better outcomes than patients in real-world practice given the strict entry criteria and rigorous follow-up in such trials.

After BTT trial completion and approval of HeartMate II, the next step, of course, became evaluating the device as destination therapy (DT) and getting it approved for that indication. The HeartMate II DT study was a success, and as a result, the device is approved for both BTT and DT indications. I think that the success of the DT study of HeartMate II really puts into perspective just how much the VAD field has evolved over the past 10 to 15 years.

The most recent American College of Cardiology Foundation/American Heart Association heart failure guidelines reflect the data that I just mentioned in that, in patients with Stage D refractory heart failure, consideration should be given to the entire armamentarium of therapies currently available. For example, some patients are not eligible for transplantation and should be considered for MCS or perhaps even palliative inotropes. Other patients who are eligible for transplantation may need a VAD first as a bridge. The key point is that the guidelines do not dictate a specific sequence of therapy; it is both reasonable and appropriate to consider advanced options such as a VAD or transplant before a patient's heart failure progresses to a terminal, irreversible state with multi-organ failure.

The harsh reality is that the number of suitable donors for heart transplantation in this country, and frankly worldwide, has remained relatively static. And yet the epidemic of heart failure is growing at an astronomic pace. This means we are in need of therapies that can either support our patients while they wait for longer times on the transplant list or that can be used as DT in patients who are not suitable transplant candidates. Such therapies are becoming available and we have data to support this. In a recent study, among patients implanted with a VAD with the intention of bridging them to transplantation, at 1 year only approximately 42% of these patients have actually received a transplant, whereas nearly the same percentage are still alive and doing well while waiting for an organ to become available.

DR O'CONNELL: Survival isn't the only important aspect of VADs. In order for these devices to be highly effective in this sick patient population, VADs need to improve quality of life and produce sufficiently low rates of adverse events to minimize the costs of readmission and supportive care.

DR JOHN: I would like to focus on the objective data that support the validity of the HeartMate II device in not only improving survival, but in also markedly reducing adverse events and lowering morbidity as compared to an earlier generation of VADs.

The adverse events that cause tremendous disadvantage to patients on VAD therapy—events such as bleeding, infection (sepsis, local infection, and device-related infection), cardiac arrhythmias, and hemorrhagic stroke—

all significantly decreased in the DT mid trial period (2007-2009) versus the early trial period (2005-2007) with greater HeartMate II experience. One of the most feared complications with VAD therapy is stroke, which can present as hemorrhagic, ischemic, or mixed. Based on published data over the last 10 years, the stroke rates observed in patients with the HeartMate II device are the lowest reported in a VAD population, without exception.*

We should discuss a very important outcome that we all desire for our patients: quality of life. As a surgeon involved in treating patients with heart failure, I want these individuals to be active members of society and to be able to participate in family events. Many patients who present with advanced heart failure can barely walk at all; a large proportion are so disabled by heart failure that they are bedbound. Objective data demonstrate that at 6 months postimplant, patients receiving the HeartMate II device are able to walk an average of 377 yards—the length of almost 4 football fields—in a period of 6 minutes.

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DR O'CONNELL: Aside from the excellent survival seen with the HeartMate II device, the improvement in quality of life has been extremely impressive to me. As a heart failure cardiologist, I remember being excited about approval of the cardiac resynchronization therapy (CRT) system, which improved the 6-minute walk distance by 46 meters. We are now witnessing improvements of 150 meters or more with VADs. Many of us never thought we would see advanced heart failure patients who led a bed-to-bathroom existence be able to get up and walk the kind of distances we see now. It is truly impressive.

Based on the recent advances in VAD therapy, are we getting to a point of equipoise between a VAD and transplantation as options for patients with heart

*This is based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables. Please refer to the HeartMate II Instructions for Use about indications, contraindications, adverse events, warnings, and precautions (<http://www.thoratec.com/medical-professionals/resource-library/ifus-manuals/heartmate-ii-lvad.aspx>).

failure? Can we call VAD therapy a standard of care in the management of advanced heart failure patients?

DR LAHPOR: I am absolutely convinced that we are closing in on that moment, and perhaps we have already reached that point. Heart transplantation is still regarded as the gold-standard treatment for heart failure patients. However, in Europe, as in the United States, a donor heart is becoming a very rare asset and patients who want to be considered for transplant have to be in superb condition, so to speak. Using VADs as a standard of care provides highly effective treatment to a greater pool of patients who are not in excellent condition—that is, those with renal insufficiency or other comorbidities like a recent malignancy.

DR JOHN: I completely agree that heart transplantation is the gold standard for patients with advanced heart failure. However, the overall impact of this treatment on the epidemiology of heart failure is just a drop in the ocean. VADs constitute an effective FDA-approved therapy with acceptable short- and mid-term outcomes. Although there is room for improvement in regard to adverse events, over the last 10 to 15 years we have made tremendous strides in the success with VADs for patients with heart failure. I truly believe VADs are a standard of care for these patients. There is a definite role for heart transplantation and there always will be. But I think VADs need to be placed on the same level as a treatment of choice for these patients.

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DR O'CONNELL: When comparing transplant with VADs, I cannot help but think of a couple important points. First, no patient with Stage D heart failure improves on medical management. They continue to deteriorate, which makes them poor transplant candidates. Second, when a patient is ready for a VAD, we pull it off the shelf. When they are ready for transplant, we wait 2 years. It seems as though we need to look to the immediately available options to best help our patients.

DR DEMBITSKY: I fully agree. The fact is that there are many more candidates for VAD therapy than those who actually receive it. As such, there is a huge gap between what we know works and what could work. Although the efficacy of these devices has been proven beyond a doubt, this gap is based on public perception of mortality, morbidity, and cost. This all pertains to socialization of the devices. However, experience with these devices is growing and VADs are being increasingly used in the United States and abroad. Thus, whereas VADs are on the trajectory of being implanted more and more, transplantation, on the other hand, has remained static.

DR RICH: I also agree. The fact that more of these devices are being implanted suggests that we are starting to make a small dent in this very big epidemic of advanced heart failure. I think most cardiologists would still agree that the gold-standard treatment for an eligible younger person would be heart transplantation to achieve the best long-term outcomes. However, the reality is that patients on the transplant list may have to wait a very long time for an organ to become available. In other instances, patients may need a VAD simply to become a suitable transplant candidate, such as in the setting of worsening heart failure or severe pulmonary hypertension. Thus, we are often needing to support our patients with a VAD to stabilize their heart failure and then to ultimately bridge them to transplant when an organ becomes available.

DR LAHPOR: I foresee a different role for heart transplantation in the future. I believe that we should start to treat all patients with end-stage heart failure with a VAD before proceeding to transplant. In this way, transplantation can be reserved to extend the lives of patients with devices or to provide an alternative therapy if there are safety problems with the devices.

INCORPORATING VAD IMPLANTATION EARLIER IN HEART FAILURE PROGRESSION

DR O'CONNELL: Given that patients are being supported on VADs for longer periods of time, it begs the question of whether we should begin to expand the patient population and investigate the use of these devices earlier in the heart failure continuum before patients develop multi-organ failure. In that light, I would like to ask Dr Dembitsky to talk about patient selection, particularly with regard to patient age and size.

DR DEMBITSKY: When we looked at our population of patients at Sharp Memorial Hospital in San Diego that had received VADs around the time these devices were approved for treatment of terminal heart failure, we identified a considerable number of patients over the age of 70 years. We performed an analysis evaluating outcomes

FIGURE 2

**HeartMate II experience in small patients
(body surface area <1.5 m²)**

United States experience^a

• **Patients**

- n=74 patients (BSA <1.5m²)
- 44 BTT
- 30 DT
- Smallest patient = BSA 1.29 m²
- 89% female
- 1/3 of the DT patients were ≥70 years of age

• **Outcomes**

- ~79% 2-year survival (for both BTT and DT)
- Low adverse event rates
 - Total stroke rate = 0.08 and 0.06 EPPY (BTT and DT respectively)
 - No thrombus
- Significant improvement in QOL (6-minute walk test)
 - 70% were unable to walk at baseline
 - ~900 ft average walk distance at 1 year

Outside the United States experience^b

- Smallest patient in Europe = BSA 1.1m²
- As of June, ~50% of Japanese HeartMate II patients, posttrial, had BSA ≤1.5m²

^aINTERMACS Data on File as of December 2012.

^bData on File as of June 2013

Abbreviations: BSA, body surface area; BTT, bridge to transplantation; DT, destination therapy; EPPY, events per patient year; QOL, quality of life.

in patients older than age 70 years and published that experience in 2011. Among our small group of patients (N = 55), those aged 70 years and older showed exactly the same outcomes with regard to survival, morbidity, and adverse events as patients aged younger than 70 years. We subsequently analyzed a larger group of patients and found the same results. We also analyzed outcomes in patients over the age of 80 years, and the results are superimposable with those of younger patients. Growing experience suggests that chronologic age cannot be used as a discriminator for selecting patients for VAD implantation.

Size has always been a concern when implanting VADs. This was an early problem with the total artificial hearts and the HeartMate I was also a very large device. The emphasis has been to try to develop smaller devices, although there are, of course, practical limits to how small the device can be. The HeartMate II is a smaller device and has been implanted in quite a few patients—close to 100 patients now—with body surface area less than 1.5 m². Given the increasing Asian experience with the HeartMate II, this figure is bound to increase dramatically. In general, the outcomes with the HeartMate II have been superb in these smaller patients (FIGURE 2).

DR O'CONNELL: I would like to move on to discuss the optimal time during the course of the illness for patients to be referred for an implant.

DR RICH: We have learned a lot from the INTERMACS scoring system in terms of how we approach patients in need of VAD therapy. I believe that as cardiologists we should think of heart failure in terms of a therapeutic window. At the very beginning when a patient is first diagnosed with heart failure, achieving optimal medical therapy is the cornerstone of treatment. Unfortunately, however, heart failure is a progressive disorder and over time, medications alone often become insufficient and there is a need to offer patients advanced therapies. If we wait too long to initiate the evaluation process—for example, when there is already significant multi-organ dysfunction—patients tend to have poorer outcomes following VAD implantation. On the other hand, we certainly do not want to put a VAD in a patient who is thriving with medical management. As a result, it becomes very important to begin to consider the need for advanced therapies when a patient begins to slide—by that I mean examples such as admissions to the hospital for heart failure exacerbations, the need to lower the doses of heart failure medications due to low blood pressure or intolerance, worsening appetite and/or weight loss, or other signs of increasing frailty in general. These are all patients who we should start considering for advanced therapies before it becomes too late to intervene.

If we wait too long to initiate the evaluation process—for example, when there is already significant multi-organ dysfunction—patients tend to have poorer outcomes following VAD implantation.

DR LAHPOR: I believe heart failure patients should be referred to a cardiac surgeon the moment that the cardiologist begins to talk about the possibility of heart transplantation, even if the patient has not yet reached end-stage heart failure. The moment that the patient is in the situation of possibly needing a transplant, while they are still ambulatory and still at home, this is also the moment that the cardiologist should talk about the possibility of a VAD. These patients should be referred to a cardiothoracic surgeon to talk about both the advantages and the risks of an implanted device.

DR O'CONNELL: The multidisciplinary team should be involved in every step along the way. In many programs, there are no longer VAD team meetings but more general advanced heart failure team meetings in an effort to get all physicians engaged early in the process.

Interestingly, Thoratec® held a meeting of 365 VAD recipients and their caregivers and found that one of the principal reasons that they were reticent to accept a VAD is that they did not feel they had enough time to adequately consider this treatment option. In fact, fewer than half had at least 30 days to make their decision and one-third had only 1 week to make their decision, yet on average, these individuals had a 9-year history of heart failure. This suggests that it is important to educate patients early in the game about their condition and their options down the road.

Dr Rich, you are a heart failure cardiologist, as I am. We tend to pride ourselves on the fact that we can tell when a patient is getting sicker. When do you want to see the patient?

We need to increase the level of health care support in the community by taking away the myth that dealing with patients with a VAD is burdensome.

DR RICH: I certainly agree with what Dr Lahpor said, but I would even go one step further. I would like to see these patients even earlier in their heart failure illness. There are subtle markers of disease progression that are not always as obviously apparent as are swollen legs or other metrics. For example, it is very important to recognize malnutrition and subtle evidence of liver dysfunction as being markers of heart failure progression. By the time a patient actually has overt biventricular failure with liver dysfunction, renal dysfunction, and/or weight loss, the patient becomes much more challenging to manage. This is not to say that we cannot help these patients, but we may not be able to provide VAD therapy with optimal outcomes.

DR O'CONNELL: Dr Dembitsky, you have been quoted as saying that you would rather put a VAD in a patient 5 months too early rather than 5 minutes too late. Is that because your population is so old?

DR DEMBITSKY: No, I think that paradigm applies to all patients: the earlier the better. Like Dr Rich was saying, trying to recognize when patients are starting to decline is very

difficult. This is hard to accomplish with laboratory tests. Such tests can measure a few things, such as C-reactive protein and albumin levels, that indicate when patients start to enter that terminal phase of dying that we are now collectively calling frailty. However, we would like to be able to intervene much earlier in these patients. Sometimes one needs to actually see patients, identify changes in family dynamics, and recognize when patients' appetites are decreasing and when their strength is fading, to be able to identify declining health status earlier on.

DR O'CONNELL: Dr John, at what point would you like to see patients referred to you for care?

DR JOHN: There are data supporting numerous objective markers for patient referral: the inability to walk 1 block, increasing intolerance to beta-blockers, decreasing sodium, increasing creatinine, and increasing diuretic requirements, to name a few. There are also some more subtle, more subjective markers that should trigger referral for a VAD. Unfortunately, there is no 1 objective criterion to say, "Now is the time."

SUPPORT STRUCTURE FOR VAD PROGRAM SUCCESS

DR O'CONNELL: As increasingly more patients with VADs are supported for longer periods of time, what types of additional support structure will be required?

DR DEMBITSKY: Over time we have developed a large community-based infrastructure that helps support our implanted patients. We have developed home health care programs for patients and through these efforts we have been able to reduce our readmission rates. For example, one of the things we have done is use care extenders in the community. These are usually individuals with a low level of medical sophistication but who can help manage driveline infections and assist patients moving about the community. Using extenders is one way to bring overall outpatient costs down since the services provided by these individuals are relatively inexpensive and they help to prevent patient readmission.

DR JOHN: Many of our patients in the Midwest live hundreds of miles away from our facility where they had their VAD implanted. Having these patients come back to the tertiary or quaternary care center for all of their health care needs not only imposes an additional burden on hospital logistics, but more importantly, we are doing a huge disservice to patients and their families by asking them to regularly drive to these centers for routine care. Thus, we need to increase the level of health care support in the community by taking away the myth that dealing with patients with a VAD is burdensome.

Toward that end, I'll share an example of what has succeeded for us. We have to send many of our patients with VADs to rehabilitation facilities. Initially, the personnel at the rehabilitation facilities were very concerned about caring for such patients based on lack of experience and a high level of discomfort in dealing with VADs. We went out and provided training in basic VAD management at those rehabilitation centers. Now everyone feels very comfortable having our patients sent to these rehabilitation centers and our patients have done quite well.

The reality is that the field continues to move forward. The number of devices being implanted is growing, and patients are living longer. We need to embrace this reality. From a patient perspective, particularly for those who end up receiving a VAD as DT, although survival remains incredibly important, quality of life on the device is perhaps of equal importance.

DR O'CONNELL: Dr John, once you have demystified the complexity of VADs with the cardiologists you work with, how do you integrate these physicians into your VAD program? What rules do you establish in terms of the care delivered at the implanting center and the care delivered locally in the community?

DR JOHN: Although such relationships can sometimes be delicate, it is vital to strongly encourage and welcome other health care professionals. We frequently invite cardiologists to spend a week with the heart failure team and observe a VAD being implanted in an effort to demystify their thoughts and feelings about VADs. Importantly, when the community-based cardiologists are seeing local patients with a VAD, we send VAD coordinators to help them get used to caring for such individuals.

Thoratec has recently undertaken a large Shared Care™ initiative, which I think provides tremendous benefits to all members of the VAD team. This is a partnership program between the implant centers and community clinicians for co-managing patients with HeartMate II devices. The most important stakeholder in this program is the patient. The program adds to their quality of life by enabling them to resume their pre-implant lifestyle. The patient benefits from reduced travel time and increased convenience for routine monitoring appointments and importantly, the program provides patients with the ability to maintain a close relationship with their home-based hospitals and cardiologists who have often cared for these patients for years. For the implant centers, the program reduces the logistical burden of ongoing patient care and enables deeper relationships with community cardiologists. Finally, for the community clinicians, Shared Care provides a huge opportunity for hands-on involvement in the care of their patients, along with greater familiarity with the benefits of VAD treatment and improvements

in quality of life. The program also broadens and differentiates the practice of these community clinicians, which could potentially increase the number of new advanced heart failure patients seeking evaluation at the community sites.

DR O'CONNELL: In order for community hospitals to become a Shared Care site, they first need to purchase the equipment used to monitor the VAD, the cost of which is about \$2,000. These facilities can then bill a VAD interrogation code for the time spent with the patient, in addition to an evaluation and management code.

DR JOHN: Although you alluded to the financial part of Shared Care, one cannot put a price on quality of life and the satisfaction that patients and their families receive from being managed by physicians who have known them for 10 to 20 years.

DR O'CONNELL: Dr Rich, would you discuss some of the things that physicians can take advantage of when managing patients with a VAD in the community?

From a patient perspective, particularly for those who end up receiving a VAD as destination therapy, although survival remains incredibly important, quality of life on the device is perhaps of equal importance.

DR RICH: Certainly. The overarching theme is that, moving forward, there is going to need to be an emphasis placed on increasing our collaborative efforts to make long-term, durable VAD support both attractive and highly successful for everyone involved. This entails collaboration between the cardiothoracic surgeons implanting the devices, the community cardiologists referring patients for implant, the patients and their families, and our industry colleagues who have the resources to help train and develop the community facilities into durable and capable VAD care centers, even if they're not implanting VADs themselves. Our industry colleagues, such as those from Thoratec, have several very highly trained, capable clinical representatives who can help with training and the collaborative process in general.

DR O'CONNELL: I think that Thoratec has recognized that to ensure the success of its MCS program, support

is needed at multiple levels in terms of community education, community programmatic growth, and active networking. Initially, they support growth of VAD therapy through fellowships training and education, economic summits that help hospitals optimize their financial position when starting VAD programs, clinical work groups, and research. In fact, Thoratec has supported more than 250 refereed publications and multiple scientific-meeting presentations. The company then sought to expand VAD program support, which it does through the Shared Care network and through community and regional cardiologist and nurse practitioner training programs that are offered multiple times each year.

Thoratec also seeks to promote VAD program excellence. To do so, the company provides support through programs that aid in the management of patients and the equipment. For example, Thoratec recently acquired a company that helps with the long-term management of the peripherals that are necessary to support patients with the HeartMate II device. These comprehensive efforts comprise the Thoratec 360 program, which is relatively unique in that the VAD company is really supporting development of the field. ■

Suggested Reading

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J228-0913