

LVAD – Who Needs It?

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Dr. Bell: Welcome again to another installment of our interview with the experts here at Mayo Clinic Rochester. My name is [Malcolm R. Bell, M.D.](#) I'm the vice chair of the Department of Cardiovascular Medicine. And I have pleasure in welcoming today my friend and colleague, [Andrew \(Drew\) N. Rosenbaum, M.D.](#) Drew works in our heart failure, mechanical circulatory support and cardiac transplantation services, and is here today to talk to us about LVADs. Welcome, Drew.

Dr. Rosenbaum: Thanks for having me, Dr. Bell. Appreciate it.

Dr. Bell: Yeah. So, really a fascinating and very new area in the last decade or so and something which is really important. But before really we get into some of the discussion here, I just wonder if you could perhaps just define for our audience here, what type of VADs are we talking about? These are durable VADs, I assume. But also are we talking about a destination therapy or a bridge to transplantation?

Dr. Rosenbaum: Right. Right, so we're talking about durable left ventricular assist devices, devices that are surgically implanted that provide blood flow from the left ventricle to the aorta. And because of recent trial data, their lines have been blurring between destination therapy and bridge to transplant, as there's been newer bridge to decision and bridge to recovery indications as well. So the lines are blurring in that field.

Dr. Bell: So Drew, in the United States today, how many patients do you think might benefit from an LVAD?

Dr. Rosenbaum: Sure. Yeah. The current estimates are about 6.5 million people over the age of 20 years old have heart failure and that projection is estimated to grow to about 8 million by 2030. And of those patients, about 300,000 or so have NYHA class 3 or 4 four symptoms and are in the age range that would potentially benefit from LVAD therapy. Now, among those patients with advanced heart failure, probably two-thirds to three-quarters of those would have comorbidities that would preclude benefit from LVAD therapy. So probably in the range of 75,000 to 100,000 patients in the United States would be potentially eligible for LVAD therapy.

Dr. Bell: That into context, how many patients would be transplant candidates?

Dr. Rosenbaum: A roughly similar number. Although there may be fewer, sort of, comorbidities that would prevent use of transplantation. And currently in the United States, approximately 4,000 to 5,000 patients are transplanted each year and a similar number of LVADs are implanted.

Dr. Bell: Yeah, but that still leaves a huge number of patients who are left unserved by either currently. So who are the patients that are going to really benefit from an LVAD placement?

Dr. Rosenbaum: Sure. And we can show the illustration, but the LVADs are indicated for AHA stage D heart failure patients with either an ischemic or nonischemic etiology and NYHA class 3B to 4 symptoms, who are failing traditional medical therapy and have impaired exertional capacity, or have developed cardiogenic shock. And one aspect I think that's overlooked with regard to LVAD therapy is that LVADs are thought, are beneficial by unloading the left ventricle and left atrium. But their true benefit is really improving low-output symptoms. And patients with low cardiac output syndromes who tend to get, tend not to get recurrent congestion and actually probably derive the most benefit from LVADs, whereas patients with recurrent congestion due to a low compliance phenotype, probably — but intact cardiac output — probably have the least benefit from LVAD therapy, broadly speaking.

Dr. Bell: So I hope our viewers can see the illustration there. But in the group of patients that you described, with groups of patients that you've described, are their age limits here in terms of, are you too young to get an LVAD? And maybe as you answer that you could perhaps just summarize, how long these are durable for and are their older age limits here? Are there specific cutoffs similar to what we have for transplantation?

Dr. Rosenbaum: Sure. So younger, there's no absolute age limit on the lower end. Patients as young as preteens can receive an LVAD therapy. It's a more of a size constraint thing. And obviously in the pediatric patient, the goal would be as a bridge to transplant. And we have performed LVAD implants and in young patients for that purpose. On the older end, again, same idea. There's no absolute age limit. People with advanced heart failure tend to become quite frail when the age gets up into the 80s and 90s, though. In appropriately selected patients, there could be octogenarians who would benefit from LVAD therapy, and we've implanted LVADs in folks over the age of 80. But it's a patient-specific decision.

Dr. Bell: Well I guess to my next question then, because, recognizing that not all septuagenarians or octogenarians are the same but, are there patients who clearly won't benefit from an LVAD. And obviously, you know, we see some very, very ill patients with chronic severe congestive heart failure. And presumably not all of those are going to be eligible for an LVAD. So could you just maybe outline how you and your colleagues assess these patients in terms of who would be considered not to be a candidate?

Dr. Rosenbaum: Sure. Sure. Yeah. As I mentioned, two-thirds or three-quarters of patients probably wouldn't benefit from LVAD implantation due to comorbidities. And the most important ones are those of advanced end-organ dysfunction. And those are the most significant contraindications often, which is specifically liver cirrhosis and end-stage renal disease. And outcomes are really quite poor at that. But even significant cerebrovascular disease, malignancy, severe psychiatric illness, very advanced age which we discussed, are significant. Frailty. Don't tend to fare well. One of the things that we focus on is right heart function pre-implant, because LVAD therapy offers no support to the right ventricle and in fact, may be detrimental in some. And so invasive indices are often relied upon to assess the right ventricle before implant. These include the pulmonary artery pulsatility index or PAPI, or the right ventricular stroke work index. And these are markers pre-implant to determine adequacy of RV function. Some of the less common cardiac contraindications to LVAD therapy include a restrictive cardiomyopathy

who don't tend to benefit as much, and refractory ventricular arrhythmias, which aren't really solved by all that. Conversely, patients who are NYKA class 3 without true signs or symptoms of progression to stage D heart failure really don't benefit because of the morbidity and mortality of LVAD implantation kind of outweighing its benefit.

Dr. Bell: Maybe I can just get your opinion here then, advice for dealing with patients who do have end-stage renal disease. And I'm thinking particularly of patients who are on chronic hemodialysis and, as we know, a very difficult population to take care of. But we also see patients who have maybe just recently gone on to dialysis, and then there's a question about if they went on to an LVAD we could perhaps reverse that and get them off dialysis, rather than — do see that in your practice? And how do you approach those patients?

Dr. Rosenbaum: Patients who have an acute presentation with cardiogenic shock who require continuous hemodialysis or intermittent hemodialysis, in the acute timeframe may have renal function that recovers. And in those patients we still consider them for LVAD and actually transplantation as well. But anyone who's sort of progressed through the chronic kidney disease stages sequentially, generally do not have enough renal function to tolerate LVAD therapy or transplant without concomitant kidney transplant as well. And so end-stage renal disease and, and the data suggests that people with end-stage renal disease do very poorly after LVAD. That the mortality is quite high and so it really does present an almost absolute contraindication.

Dr. Bell: Ok. Yeah, thanks for making that clear. The combination of advanced kidney disease and heart disease is really a bad one, isn't it, in so many respects? And then just in terms of your current experience in patients who do get durable VAD, how long would these be expected to last?

Dr. Rosenbaum: Good question. Yeah, thanks. So, you know, the data are constantly evolving. The newest generation of LVADs are the HeartMate 3 LVADs. And we don't actually have natural history data because the first HeartMate 3s were implanted in 2015. But people are, the two-year survival between, in their most recent trial with HeartMate 3 was actually similar to cardiac transplant. And so it's expected that the median survival could approach seven-eight years with these devices. And there's no serious mechanical reason why failure would occur at any point. And we have patients out over a decade on durable mechanical circulatory support. So there's no, unlike the old pulsatile devices, there's no sort of inherent life limitation from the device standpoint alone. And obviously there's an opportunity for device exchange, too, if there's failure for any reason.

Dr. Bell: And in the remaining minute, Drew, here, if we just focus on the outpatient population. I'm not talking about the acute presentation cardiogenic shock and the CICU, but the outpatient population. What advice would you give to physicians who are taking care of patients with chronic or recent onset heart failure, in terms of when they should be considered for referral to a center that would be able to offer assessment and implantation of an LVAD?

Dr. Rosenbaum: Sure, Sure. Well, if you look at the illustration again on the right side, there's kind of a nice mnemonic recently described a few years ago for when to refer to an LVAD center. And that's folks who are recently initiated on chronic home inotrope therapy, for patients,

any patient with an NYHA class 4 symptoms, or very high NT-proBNP. Patients with end-organ dysfunction in the setting of heart failure, left ventricular ejection fraction less than 20 percent, or recent defibrillator shocks. Patients with greater than one hospitalization in the last year for heart failure. Patients on escalating diuretic therapy with low blood pressures less than 90 millimeters mercury, or patients in whom medical therapy needs to be withdrawn, these are kind of, this makes up for the mnemonic "I need help" and that's a good, those are good things to think about with respect to referral to an LVAD center for consideration of implants.

Dr. Bell: Well Drew, thank you very much. That's all we have time for today, but I appreciate the fact that you could give us this really extraordinarily helpful insight into dealing with these critically ill patients and potentially providing them with lifesaving therapy. So thank you so much for your time today.

Dr. Rosenbaum: Thanks, Dr. Bell.

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