

JOHN STULAK: Hello. My name is John Stulak, and I'm a heart surgeon at the Mayo Clinic in Rochester, Minnesota. I have a special interest in the surgical treatment of advanced heart failure, including ventricular assist devices and heart transplantation.

Ventricular assist device therapy has proven to significantly improve survival and quality of life in select patients with advanced heart failure compared with medical therapy. Significant progress has been made in pump technology innovation, refinement in the timing of therapy and patient selection, implantation techniques, along with post-operative care and the prevention and management of device-related complications.

Currently, the majority of patients who are referred for LVAD implantation have end stage heart failure with critical shock or those who are experiencing a progressive decline and require intravenous medications to improve their heart function. It has been demonstrated that how sick a patient is at the time of LVAD implantation directly affects their surgical risk and long-term survival. So targeting a population of patients who are less sick could potentially improve survival and reduce complications and adverse events. Achieving these improvements and outcomes could potentially translate into reduced resource utilization and strain on the health care system in general and subsequently improve the cost effectiveness of this therapy.

Attempting to define how sick a patient is from their heart failure can be quite a challenge for practitioners. Currently, the most consistent way health care providers identify patients who are generally acceptable candidates for LVAD therapy are dependency on intravenous medications to assist heart function. However, even when a patient progresses to this point, survival may already be compromised compared to that if an LVAD was considered earlier. The classification systems currently used are just not adequate to discriminate severity of illness in a patient with less advanced heart failure. And no studies have rigorously evaluated LVAD therapy in patients who are not hospitalized and who are not dependent on intravenous heart medications.

Currently, thousands of patients who are treated for heart failure meet the current criteria and may benefit from LVAD therapy, but few are actually referred for this treatment. There is a perception that these patients are just too well for an LVAD until they progress to the point that I discussed before. And it is in these less sick patients that the efficacy of LVAD therapy has not been rigorously studied. There is concern that, because we have improved the outcomes of LVAD therapy to such a great extent over the last decade, that there would only be a marginal benefit from earlier adoption of this therapy.

In order to address these questions, research is focusing on just this very issue. At the Mayo Clinic, we are taking part in the ROADMAP clinical trial, which is an observational study comparing LVAD therapy with medical treatment in patients with significant heart failure, but who have not yet required multiple hospital admissions or intravenous medications to support their heart function. Through this study, patients choose which treatment course they want to take. And after enrollment, we observe them for clinical outcomes. Through this, we are hopeful to answer the question whether or not the adoption of LVAD therapy in less sick patients provides a benefit, both for survival and for quality of life. Ultimately, this study will help guide future practices in patient selection for the appropriate management given the severity of their heart failure.

Mayo Clinic has one of the largest, most integrated heart programs in the world, with over 300 heart specialists working together to treat more than 120 heart conditions and diseases. We have experienced striking growth in our program for the treatment of advanced heart failure, surpassing 200 LVAD implants within just the last five years. We have a very unique advanced heart failure program, and we treat high volumes of complex and rare heart conditions every day. We are currently following over 100 patients on LVAD support. And numerous different professionals collaborate behind the scenes to help find answers for our patients, including surgeons, cardiologists, physician assistants, nurse practitioners, anesthesiologists, and social workers, just to name a few.

For more information on LVAD therapy for patients with advanced heart failure or to schedule an appointment, please call the phone number on your screen or visit our website at www.MayoClinic.org. Thank you very much.