Clinical results to date have been outstanding. Four patients have been implanted with the device. They were all men (average age, 74 years) with class IV+ heart failure. All were receiving maximal intravenous inotropes (cardiac index <1.6 L/min/M²), had a systemic blood pressure mean of less than 65 mmHg, and pulmonary artery diastolic pressures greater than 25 mmHg. The patients had lost an average of 25 lb due to heart failure. The average serum creatinine level was 2.5 mg/dL. Despite how sick the patients were, they all survived the surgery. One patient succumbed to pulmonary dysfunction, which was present preoperatively. The others weaned off inotropes, recovered renal function, and were fully ambulatory. One patient turns the device on at night and is device-free for 8 hours during the day — giving him an almost normal quality of life.

CardioVAD technology is exciting and brings hope to patients with severe CHF. If you would like to refer a patient, please call Dr. Jeevanandam at (773) 702-2500.

It is now estimated that more than 700,000 cardiac interventional procedures are performed each year in the United States.1 The success of these procedures is largely owing to significant improvements in technique and advancements in equipment, which allow percutaneous coronary interventions to be performed in 60 percent to 70 percent of patients who need coronary revascularization. However, these procedures still have a number of limitations.

Previously, acute complications, although infrequent, led to significant mortality and morbidity. The development and rapid growth of the use of stents has significantly reduced the number of acute complications of angioplasty procedures, so that the combined rates of death, myocardial infarction, and emergency bypass now are less than 5 percent, with an overall success rate of more than 95 percent, as recently reported by the National Heart, Lung, and Blood Institute PTCA (Percutaneous Transluminal Coronary Angioplasty) Dynamic Registry.2 Currently, more than 70 percent of coronary procedures involve the placement of a stent.2 A large number of studies also have shown that stents combined with platelet glycoprotein IIb/IIIa antagonists, such as abciximab (ReoPro, Eli Lilly and Company, Indianapolis,
tirofiban hydrochloride (Aggrastat, Merck & Co., Inc., Whitehouse Station, NJ) or eptifibatide (Integrilin, Schering-Plough, Kenilworth, NJ), can significantly reduce acute complications. The greatest benefit appears to occur in high-risk patients, such as those with non–ST segment elevation myocardial infarctions, high-risk unstable angina, acute myocardial infarction, or diabetes.

While the use of stents in coronary procedures now is remarkably successful and effective, two other major limitations continue to plague the technique. The most important of these is restenosis, which results in the need for another procedure within 6 months in approximately 20 percent to 30 percent of patients. Although stents have decreased the rate of restenosis to 15 percent in selected patients, the increased complexity of lesions currently treated has counterbalanced this reduction. Complex lesions treated with stents have a restenosis rate of 30 percent to 40 percent. Thus, the overall incidence of restenosis has not changed significantly.

In addition, when restenosis does occur within a stent, repeat angioplasty is not effective in preventing its recurrence and instant restenosis occurs in 30 percent to 60 percent of patients. This problem is growing as more stents are being used. Nearly all mechanical or drug treatments to prevent this problem have not been proven to be of clinical use.

The most exciting new advance in angioplasty has been the development of intravascular radiation, which involves the use of small radioactive wires or seeds with either a beta or gamma source. Low-dose, local radiation is then delivered to the site of vascular injury and stent placement. Five randomized clinical trials have shown that intravascular radiation can reduce restenosis by an average of 50 percent. The technique recently has been approved by the US Food and Drug Administration, and both gamma and beta sources are now available for use. The technique is still in its infancy, but optimal placement of the radioactive source and proper dosing now are recognized to be critically important to success.

At the University of Chicago, we have participated in a beta radiation trial and soon will be starting a new trial using gamma radiation for in-stent radiation. While the technique seems effective for instant restenosis, it is not clear whether it is effective when a stent is not placed. It is also unclear whether beta and gamma radiation are equally effective. We plan to address both issues in future randomized clinical trials.

In addition to radiation, very preliminary studies suggest that drug-eluding stents also may offer promise, and preliminary studies suggest that stents containing the antiproliferative agents paclitaxel (Taxol) or rapamycin may be able to significantly reduce restenosis. We anticipate starting clinical trials at the University of Chicago with one or both of these new agents in the near future. The advantage of the new stents that contain antiproliferative agents is that they likely will be used on all patients initially and not just restricted to those who already have developed restenosis. It seems likely that with these techniques, the problem of restenosis finally will be under control.

The other significant problem that confronts interventional techniques is the inability to perform them in patients with unfavorable coronary anatomy. As many as 30 percent to 40 percent of patients are not candidates for angioplasty, largely owing to chronic total occlusions, and a significant portion of these
patients (15 percent) also are not candidates for bypass surgery. Options to treat these patients currently are limited. However, a number of new, alternative revascularization strategies are under development.

Techniques such as angiogenesis (in which new collateral blood vessels are grown), transmural myocardial revascularization (TMR), or percutaneous myocardial revascularization (PMR) currently are under investigation in clinical trials. Current evidence suggests that TMR is effective in relieving angina and improving exercise tolerance; however, PMR has not been successful in recent studies. In addition, spinal cord stimulation has been used widely in Europe for many years and is known to reduce angina and improve coronary hemodynamics. Preliminary studies in the United States now are under way, and at the University of Chicago, TMR and spinal cord stimulators now are available.

Finally, one intriguing experimental study at Massachusetts General Hospital, Boston, suggests that stents may be used to bypass chronic total occlusions percutaneously. The stents create a shunt into an adjacent coronary vein and exit back into the coronary artery distal to the total occlusion. We anticipate clinical application in the near future.

Advances in interventional cardiology continue to occur at an occurrence of restenosis decreases and the use of new techniques is expanded to patients who are not currently revascularized, we expect continued and significant growth in the use of angioplasty.

REFERENCES