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The Cancion® CRS™ System

A novel percutaneous device for patients with decompensated heart failure.

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Heart failure affects nearly 5 million Americans, with more than 500,000 new cases diagnosed each year.[1] Despite recent advances in percutaneous interventions for coronary artery disease, the prevalence of heart failure continues to increase. More concerning is that 44% of the 1 million annual hospitalizations in the US for heart failure result in readmission within 6 months.[2] Recent advances in medical therapy for chronic heart failure due to systolic dysfunction have resulted in improved long-term outcomes. Unfortunately, however, therapy for patients with decompensated heart failure has been limited.

Medical therapy, including inotropes, diuretics, and natriuretic peptides, often results in acute clinical improvement, but enthusiasm is hampered due to lack of long-term benefit on morbidity and mortality. Various mechanical circulatory support devices have been studied for this patient population. Left ventricular assist devices have been studied as either a bridge to transplant or destination therapy, and results have been promising.[3,4] Unfortunately, implantation currently requires open heart surgery, is limited to a few medical centers, and long-term use is complicated by infection and device malfunction. Therefore, there is much interest in a less-invasive device that could improve hemodynamics and potentially result in improved clinical outcomes in patients with decompensated heart failure refractory to medical therapy.

THE CANCION CRS SYSTEM

The Cancion CRS cardiac recovery system (Orqis Medical Corporation, Lake Forest, CA) has demonstrated promise in treating the needs of this population. Based on the hypothesis that reduced aortic flow results in adverse downstream vascular signals, this percutaneously implanted device works as an extracorporeal pump that augments aortic flow continuously through the cardiac cycle. In animal models of heart failure, addition of continuous flow onto pulsatile aortic flow within the descending aorta resulted in ventricular unloading and improved hemodynamics.[5] Using the device resulted in immediate reduction in the filling pressures, increased forward cardiac output, and resulted in smaller left ventricular cavity dimensions when the pump was turned on. We report our experience with this novel device used to treat patients with decompensated heart failure in our institution.

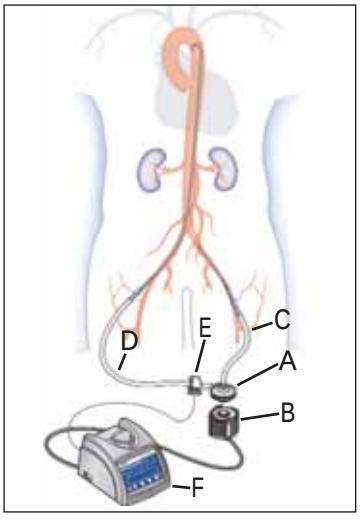

Figure 1. Cancion CRS cardiac recovery system. The centrifugal pump (A), driven by a bearingless electromagnetic motor (B), draws blood from the percutaneously placed inflow catheter (C) positioned in the left iliac artery and returns it to the descending thoracic aorta via the pigtail outflow catheter (D), which is percutaneously placed via the right femoral artery. Flow is monitored by a flow sensor (E) positioned on the outflow tubing and is regulated by the controller (F).

POPULATION

To date, a total of nine patients have been treated at the Henry Ford Hospital with this device. All patients were hospitalized due to acute exacerbation of chronic heart failure manifesting increasing dyspnea, and/or fatigue, and/or exercise intolerance; need for hemodynamic monitoring; treatment with intravenous diuretics and inotropic and/or vasodilator therapy, with inadequate response, or recurrence of signs and symptoms upon weaning attempt; elevated pulmonary capillary wedge pressure (≥18 mm Hg); stable drug doses (>6 hours); reduced left ventricular ejection fraction (≤30%), abnormal renal function or high diuretic requirement (serum creatinine >1.2 mg/dL, estimated creatinine clearance ≤60 mL/min, or intravenous furosemide ≥120 mg over 24 hours). Patients with systolic blood pressure <80 mm Hg, or clinical cardiogenic shock, recent Q-wave myocardial infarction are not candidates for this device.

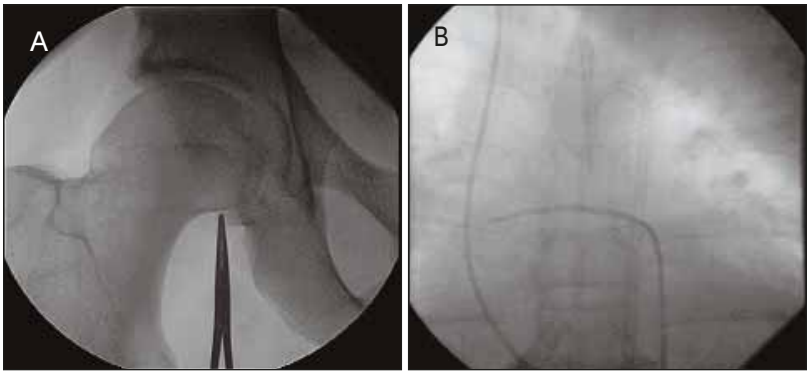

Figure 2. Fluoroscopy of femoral head to guide access (A). Fluoroscopy of the 12-F pigtail outflow catheter in the upper descending aorta (B).

PROCEDURE

Implantation

The Cancion system consists of a pump, tubing, and arterial access catheters that are designed to recirculate blood from the iliac artery to the upper descending aorta in a continuous, nonpulsatile fashion (Figure 1). The 12-F catheters (approximately 4 mm in diameter) need to be placed accurately in the common femoral artery to avoid complications. Therefore, we use fluoroscopy to identify the common femoral artery accurately using a hemostat placed in the inferior border of the femoral head to guide access (Figure 2A). Initially, an 8-F sheath is placed into the left femoral artery, and a 12-F sheath is placed into the right femoral artery using single front-wall punctures and serial dilations using the 6-F and 8-F dilators. Heparin is then administered to achieve an activated clotting time of >300 seconds. The 8-F sheath in the left femoral artery is then exchanged for the 12-F inflow catheter. The outflow from the pump is via a 70-cm-long, 12-F pigtail catheter inserted through the percutaneously placed right femoral artery sheath and positioned under fluoroscopy in the thoracic aorta just above the level of the tracheal carina (Figure 2B). The 12-F outflow pigtail catheter is inserted through the existing 12-F right femoral sheath using a .038-inch J wire and a dilator (Figure 3A). Inflow to the pump is via the 19-cm-long, 12-F catheter through the left femoral artery (Figure 3B). The inflow and outflow catheters are connected via polyvinylchloride tubing to a bearingless, magnetically levitated centrifugal pump designed to minimize hemolysis and thrombosis.

Maintenance

The blood capacity of the entire system is approximately 108 mL, including 32-mL pump priming volume. A bearingless, electromagnetic motor drives the pump, connected to a controller, with pump speeds of 3,000 rpm to 5,000 rpm to achieve flow rates of 1.1 L/min to 1.5 L/min (Figure 4). This additional nonpulsatile flow is superimposed on pulsatile cardiac output within the descending aorta. Anticoagulation with continuous unfractionated heparin is employed throughout the duration of circulatory support (up to 5 days) to maintain an activated partial thromboplastin time between 65 and 85 seconds. After implantation in the cardiac catheterization laboratory, the patient is transferred to an intensive care unit for the duration of device treatment, and remains there for an additional 24 hours of hemodynamic monitoring. Baseline hemodynamic measurements are performed using a pulmonary artery catheter in duplicate and were averaged, starting 24 hours prior to device implantation and continued through 24 hours after explantation at predefined intervals. The patient is on bed rest with head elevation up to 30º to 45º while the device is in place. This is usually ensured with a comfortable mattress, 24-hour nursing help, and liberal sedation of the patient. The insertion sites are inspected for bleeding, and the distal pulses are documented at regular intervals.

Explantation

At the end of the treatment period, the device is easily removed from the patient under fluoroscopy. In the cardiac catheterization laboratory, the pump is turned off without any immediate hemodynamic consequences. The polyvinylchloride tubing from the inflow and the outflow are each clamped with two clamps and cut between the

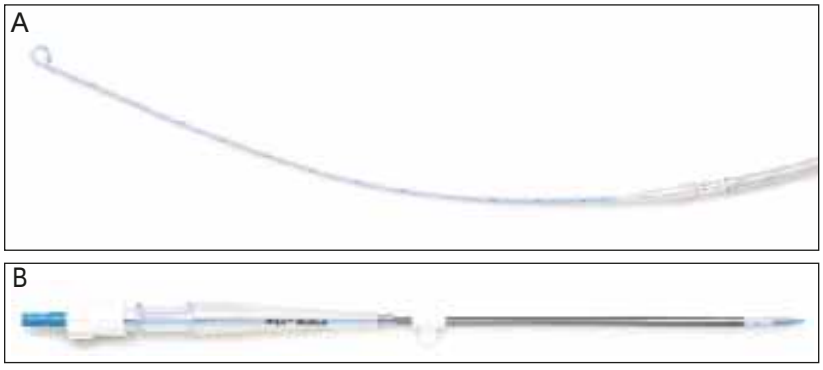

Figure 3. Cancion CRS system pigtail outflow catheter with attached tubing (A). Cancion CRS system inflow catheter with dilator, hemostasis cap, and suture wing (B).

clamps to disconnect the pump. The 12-F pigtail outflow catheter is straightened and withdrawn out of the 12-F sheath using a dilator. The existing 12-F sheath is then exchanged for a new 12-F sheath using an exchange wire. The patient is transferred to a holding area, and the 12-F inflow catheter in the left femoral artery and the 12-F sheath in the right femoral artery are removed when the anticoagulation wears off (activated clotting time <180). Manual pressure is maintained for approximately 20 to 30 minutes to achieve hemostasis.

Figure 4. The Cancion CRS system motor and pump.

DISCUSSION

In our experience, the device has been relatively easy to implant, monitor, and explant. The implantations and explantations in the cardiac catheterization laboratory have usually taken <30 minutes to perform. With diligence in obtaining access in the common femoral arteries, appropriate case selections, and careful hemostasis, we have avoided any major complications. The results of a feasibility study using this device conducted in nine centers in Europe and four centers in the US are currently being analyzed.

There are limited options for patients with decompensated heart failure and persistent hemodynamic derangement. We have observed that flow augmentation, using the Cancion system, markedly improved pulmonary capillary wedge pressure, pulmonary artery pressure, cardiac index, and systemic vascular resistance. This improvement was sustained after discontinuation of flow augmentation. In addition, serum creatinine decreased during treatment. The device does not assume or directly augment cardiac output, and hence differs from other forms of circulatory support.

The device, because of flow momentum preservation, results in reduced work for the left ventricular myocardium in generating the cardiac output. The mechanism of hemodynamic improvement is possibly due to cardiac unloading through conserving forward flow throughout the cardiac cycle. In a previous report of an *in vitro* model of the central arterial circulation, it was observed that low flow states result in reversal of blood flow along the aortic borders during diastole.[6] The device appears to favorably alter this blood flow pattern by maintaining continuous antegrade flow resulting in improved cardiac output. In addition, the augmentation of forward flow may stimulate vasodilatation within downstream resistance arterial beds. It has been demonstrated that flow-mediated endothelial release of vasoactive mediators, such as nitric oxide, results in vasodilatation.[7] This beneficial effect may be manifested by the reduction of the systemic vascular resistance, as well as a reduction in serum creatinine, which may be due to increased flow to the renal arteries and improved glomerular filtration due to vasodilatation. Thus, superimposing continuous flow on pulsatile aortic flow may result in significant left ventricular unloading and immediate improvement in hemodynamics. Long-term clinical benefits are possible via improvements in neurohormones, renal function, and ventricular remodeling. The device is a promising intervention to treat patients with decompensated heart failure refractory to conventional measures by breaking a vicious cycle characterized by reduced cardiac output and aortic flow, worsening peripheral vasoconstriction, and increased filling pressures.

The Cancion system is an investigational device, only available in the US through clinical trial; the ongoing Multicenter Trial of the Orqis Medical Cancion System for the Enhanced Treatment of Heart Failure Unresponsive to Medical Therapy (MOMENTUM) is a randomized, controlled trial evaluating the effects of the device added to medical therapy, versus medical therapy alone, on both hemodynamic and clinical outcomes. ■

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