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The Cancion[®] System for Heart Failure

Procedural techniques for insertion and removal.

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Therapy for patients with heart failure remains complicated, particularly in patients with low cardiac output and severe volume overload. In those patients, inotropes and diuretics often fail to provide long-term benefit. Left ventricular assist devices, although they have improved significantly as a bridge to cardiac transplantation or as a destination (permanent) therapy, require a thoracotomy to implant and may lead to significant morbidity in the long term. These shortcomings suggest a need to develop novel therapies, both medical and mechanical, to aid in the treatment of heart failure in a safe, effective, and minimally invasive manner. We discuss our approach to insertion of the Cancion System (Orqis Medical Corporation, Lake Forest, CA) and its use during a randomized, controlled trial.

AN OVERVIEW OF THE CANCION SYSTEM

The Cancion System, currently CE Marked and available in select international markets, is a percutaneous cardiac assist device designed to improve hemodynamics by augmenting aortic flow in patients hospitalized with heart failure. The Cancion System works by superimposing a modest amount of continuous flow on pulsatile aortic blood flow, called *continuous aortic flow augmentation* (CAFA). Blood is circulated by a small, bearingless, magnetically levitated centrifugal pump connected to a controller. Two 12-F arterial access catheters placed via the femoral arteries circulate blood from the iliac artery to the descending thoracic aorta in a continuous, nonpulsatile manner (Figure 1). Insertion and removal are performed in the cardiac catheterization laboratory. CAFA has been found to reduce left heart filling pressures and volumes and to augment left ventricular stroke volume and ejection fraction in a canine heart failure model. It was observed that there was a progressive reduction in pulmonary capillary wedge pressure (PCWP), an increase in cardiac index, and evidence of a favorable shift in the Starling curve with CAFA treatment in a controlled series of patients with exacerbation of chronic heart failure.^{1,2}

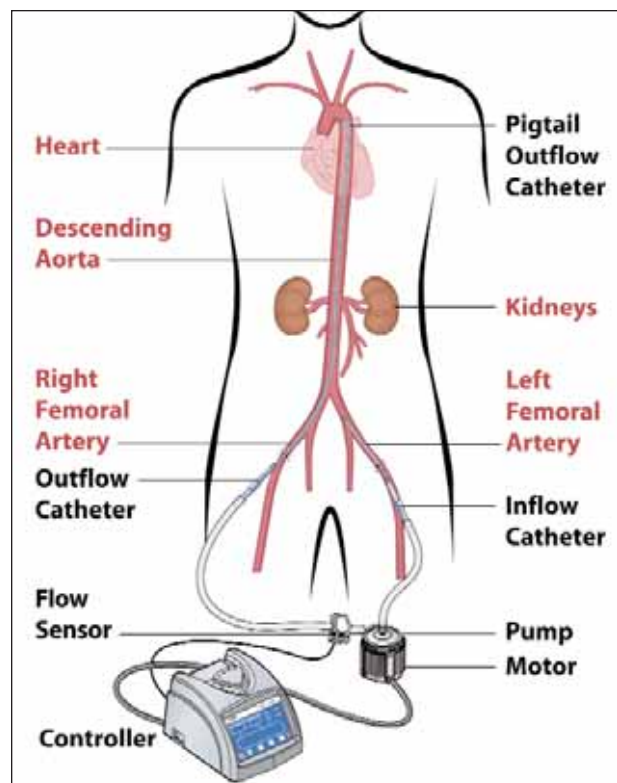


Figure 1. The Cancion System consists of inflow and outflow catheters, tubing, and a pump that creates a blood flow circuit and a motor, controller, and flow sensor to manage blood flow to provide CAFA to treat heart failure inadequately responsive to medical management.

POPULATION

To date, a total of six patients have been treated at California Pacific Medical Center with this device. Nine patients were enrolled into the recently concluded randomized Multicenter Trial of the Orqis Medical Cancion System for the Enhanced Treatment of Heart Failure Unresponsive to Medical Therapy (MOMENTUM) examining the effects of CAFA therapy added to medical ther-

apy versus medical therapy alone on both hemodynamics and clinical outcomes. Six patients were randomized to the device group, and three were randomized to the control group at our institution. Following IRB and FDA approval and before randomization, all patients signed informed consent and met strict criteria for randomization. All patients were hospitalized due to acute exacerbation of chronic heart failure manifesting as increasing dyspnea, and/or fatigue, and/or exercise intolerance; need for hemodynamic monitoring; treatment with intravenous diuretics and inotropic and/or vasodilator therapy; elevated PCWP ≥ 18 mm Hg; stable intravenous drug doses (>6 hours); reduced left ventricular ejection fraction ($\leq 35\%$); cardiac index < 2.4 L/min per m^2 ; and abnormal renal function or high diuretic requirement (serum creatinine > 1.2 mg/dL or intravenous furosemide ≥ 120 mg over 24 hours).

GENERAL CONSIDERATIONS

Patient selection is an important factor in successful outcomes. Caution should be exercised in patients who have been diagnosed with clinically significant peripheral vascular disease. Assessment for peripheral arterial disease should be conducted using physical assessment, Doppler flow studies, and if needed, angiography at the time of device insertion.

INSERTION PROCEDURE

Arterial Access

Fluoroscopy is used to identify the inferior border of the femoral heads bilaterally before attempting arterial access. Using the modified Seldinger technique, an 8-F sheath is placed in the left common femoral artery (CFA). Using a No. 11 blade scalpel, a small nick should be made over the Seldinger needle to accommodate a 12-F sheath that will be inserted into this artery later. If there is suspicion of aortoiliac atherosclerosis or aneurysm, a 5-F pigtail catheter can be inserted through the sheath to perform angiography of the abdominal aorta and bilateral iliac arteries. Again using the modified Seldinger technique, a 12-F sheath is then inserted into the right CFA and sewn into place. We recommend using the series of 8-, 10-, and 12-F dilators included in the Cacion System to accommodate insertion of the 12-F sheaths. After arterial access has been obtained, administration of a bolus dose of unfractionated heparin is delivered at 70 U/kg (not to exceed 7,000 U) to ensure sufficient anticoagulation before insertion of the catheters and initiation of the Cacion System.

Pump Assembly

The pump should be reverse flushed with a heparinized

normal saline solution from the outlet port through the inlet port three times before attaching the provided tubing. To fit the tubing to the patient, measure the distance from the puncture site to the proximal calf and cut the .25-inch portion of the tubing. It should be noted that both the inflow and outflow tubing taper from .375-inch (pump side) to .25-inch (catheter side). Cutting the .375-inch portion of the tubing will compromise the pump-tubing connection. The yellow-marked inflow tubing should be attached to the barbed connector on the inlet port of the pump, and the blue-marked outlet tubing should be attached to the barbed connector on the outlet port of the pump, ensuring that the tubing fully covers the second barb. The tubing can be moistened with sterile saline to allow smooth passage of the tubing over the barbs.

The pump with attached tubing should then be primed with heparinized saline using the provided priming set or a 60-mL syringe by filling through the outflow tubing, pump, and inflow tubing, in series. Extreme care must be taken to avoid trapping air bubbles in the system. During the initial prime, we hold the pump perpendicular to the floor and rotate it as it fills until it is parallel to the floor to minimize the entrapment of air bubbles. Once the system is completely primed with heparinized saline and free of air, the inflow and outflow lines are clamped, and the system is placed on the sterile table.

Inflow Catheter Preparation and Placement

The inflow catheter and dilator should be flushed and wiped in standard fashion in preparation for insertion into the left CFA. The white hemostasis cap should be placed over the barbed connector of the inflow catheter, and the dilator should be inserted until the hub is fully seated into the recessed pocket of the hemostasis cap. The 8-F sheath in the left CFA is then exchanged over the 150-cm guidewire provided in the kit: first, for a 10-F dilator, then for the inflow catheter itself. Careful attention must be paid to the angle of insertion during initial arterial cannulation because too steep an angle could lead to a kink in the circuit. The inflow catheter should then be inserted completely until the hub meets the skin line. After insertion, the dilator and wire should be carefully withdrawn, and a clamp should be placed on the opaque section of the inflow catheter, located approximately 5 to 10 cm distal to the hub.

Outflow Catheter Preparation and Placement

The outflow catheter and dilator should be flushed and wiped in the standard fashion in preparation for its insertion into the right CFA. The white hemostasis cap should be placed over the barbed connector of the outflow

(Courtesy of Sanjaya Khanal, MD.)

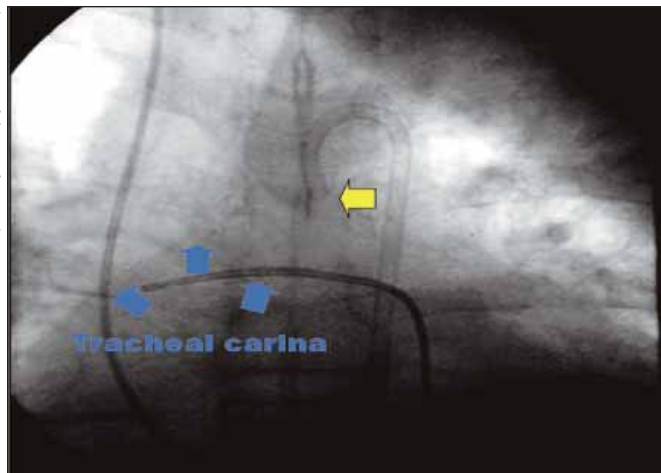


Figure 2. Fluoroscopy of the 12-F pigtail outflow catheter positioned at a level above the tracheal carina in the descending aorta.

catheter. The modified dilator should be inserted into the catheter until resistance is met. While firmly holding the dilator, gently pull back the outflow catheter to straighten the tip. The dilator is then completely inserted until the hub is fully seated into the recessed pocket of the hemostasis cap and backloaded with the 150-cm guidewire. Leading with the guidewire and under fluoroscopy, the outflow catheter should be advanced through the previously placed 12-F sheath in the right CFA to a level just superior to the level of the tracheal carina (Figure 2).

Under fluoroscopy, the guidewire and modified dilator should be slowly withdrawn until the catheter regains its pigtail shape. The distal tip of the catheter should be oriented medially and located approximately 3 cm superior to the tracheal carina, ensuring that it is distal to the aortic arch. Once catheter placement is confirmed, the wire and dilator are completely withdrawn, and the catheter should be clamped on the opaque portion located approximately 5 to 10 cm distal to the hub.

Connecting the Circuit

Once the catheters have been placed, a controlled back bleed of the inflow catheter should be performed to remove all air from the catheter hub. Next, a 60-mL catheter-tip syringe should be filled with heparinized saline, and a wet-to-wet connection should be made between the inflow catheter and the inflow tubing, ensuring that there is a fluid-to-fluid interface between the tubing and catheter while they are connected so as not to entrain air bubbles. If air is present, detach the connection and remake the wet-to-wet connection. If no air is present, advance the inflow tubing so that it covers the second barb on the inflow catheter. Perform the same procedure for the connection of the outflow

catheter to the outflow tubing. Upon completion, use fluoroscopy to confirm the position of the catheters and adjust as necessary. Inspect the system to confirm that all tubing connections are past the second barb, the circuit is free of air, and the tubing is arranged in a manner that will prevent kinks or restrictions of flow.

Securing the Pump Into the Motor

Construct an additional barrier from the sterile field around the pump and the tubing portion of the circuit, and pass the circuit to a nonsterile assistant. Match the grooves on the pump with the fittings on the motor, and rotate the pump counter-clockwise until it locks securely into place, then tighten the retention screw. Attach the flow sensor to the outflow tubing in the appropriately marked section, ensuring that the directional arrow on the flow sensor is aiming in the same direction as the arrows on the outflow tubing.

Before initiating therapy, one last screen for air in the system should be performed. If air bubbles are visualized, a clamp should be applied between the bubbles, and the proximal end of the catheter and the tubing should be cut circumferentially (the cutting portion of the tubing is labeled as such). Reconnect the tubing using the process described previously. Repeat this process until no air bubbles are seen.

Initiating Therapy

Before starting the pump, ensure that the motor and flow sensor are connected to the controller and inspect the system to confirm that all connections are over the second barb, the circuit is free of air, and the tubing is arranged in a manner that will prevent kinks or restrictions of flow. Once verified, remove the clamps in the following order: (1) inflow catheter, (2) inflow tubing, (3) outflow catheter, and (4) outflow tubing. Depress the "SET RPM" keypad on the controller and then the "INCREASE" arrow keypad to begin therapy. Increase the "RPM" setting until the desired flow rate has been achieved (approximately 1.5 L/min). Depress the "MENU" keypad once to display "SET MIN FLOW" and increase or decrease to set the desired minimum flow rate; confirm by depressing the "MENU" keypad. The clamps should then be kept at the bedside for use in the event of an unexpected cessation of flow or emergency.

After flow has been established and before transport out of the catheterization lab, the catheters should be secured into place with nonabsorbable sutures, and sterile dressings are applied to the access sites.

PATIENT MANAGEMENT

After implantation in the cardiac catheterization laboratory, the patient should be transferred to an intensive care unit for the duration of the device treatment. The patient should remain on bed rest on a comfortable mattress with 24-hour nursing support and liberal sedation.³ The insertion sites should be routinely inspected for bleeding, and the distal pulses should be documented at regular intervals. Systemic anticoagulation should be maintained with unfractionated heparin to keep the activated partial thromboplastin time between 65 to 85 seconds.

REMOVAL TECHNIQUE

At the end of the treatment period, we remove these devices in the catheterization lab. The Cancion System provides a removal kit, which includes a 12-F introducer sheath, as well as a modified dilator for the pigtail outflow catheter. The pump is turned off without any hemodynamic consequences,³ heparin is discontinued, and the dressings and sutures are removed. The hubs of both the inflow and outflow catheters and the inflow and outflow tubing are clamped with the provided tubing clamps approximately 12 inches from their respective connections. Both the inflow and outflow tubing between the tubing clamps are cut. To release the barbed connectors on the indwelling catheters, the remaining tubing is cut linearly with a scalpel and peeled back. Both groins are then prepped and draped in the standard sterile fashion, and the white hemostasis caps are placed over the barbed connections on both the inflow and outflow catheters.

Outflow Catheter Removal

The provided modified dilator is loaded with the 150-cm guidewire and inserted into the outflow catheter in the right CFA under fluoroscopic guidance. When the dilator reaches the curve of the outflow catheter proximal to its tip, the catheter itself is pulled back over the dilator until it straightens. The outflow catheter, dilator, and sheath are removed together over the wire and exchanged for a new 12-F sheath.

Inflow Catheter Removal

The 12-F inflow catheter in the left femoral artery is removed when the anticoagulation reaches an acceptable level for removal of an arterial sheath, after which manual or mechanical pressure should be applied for approximately 20 to 30 minutes to achieve hemostasis.³

CONCLUSIONS

In our experience with patients with severe exacerbations of heart failure and persistent hemodynamic

derangement, despite intravenous diuretic and inotropic and/or vasodilator therapy, we observed that CAFA with the Cancion System markedly improved PCWP, pulmonary artery pressure, and cardiac index in association with reduced systemic vascular resistance. We also noted that hemodynamic improvement was still present after discontinuation of therapy.

The Cancion System appears to improve cardiac performance favorably by altering blood-flow patterns in the aorta. In a previous report, it was observed that disturbances observed under conditions of low flow along the periphery of an *in vitro* arterial tree model of central arterial circulation may be normalized by CAFA,⁴ and such changes may influence the downstream production of vasoactive mediators, such as nitric oxide.⁵ The device appears to alter these abnormal blood-flow patterns favorably by maintaining continuous antegrade flow, resulting in improved cardiac output.² Thus, we find the device to be a promising intervention to treat patients with heart failure who are inadequately responding to medical management. ■

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The Cancion System is CE Marked and not available for sale in the US.

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