ARTICLE IN PRESS

Journal of Cardiothoracic and Vascular Anesthesia ■ (■■■) ■■■-■■



Contents lists available at ScienceDirect

Journal of Cardiothoracic and Vascular Anesthesia

journal homepage: www.jcvaonline.com



Case Conference

Can I Go Home With That Balloon Pump?

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Key Words: intra-aortic balloon pump; intra-Vascular Assist System; heart transplantation

INTRA-AORTIC BALLOON PUMP (IABP) counterpulsation is the most commonly used mechanical circulatory support (MCS) device, especially for the following 3 subsets of medical conditions: cardiogenic shock, acute myocardial infarction, and high-risk percutaneous coronary intervention (PCI). The advantages of an IABP are improved coronary perfusion and decreased afterload; the drawbacks are potential limb ischemia and limited ambulation. Recently, new counterpulsation techniques and devices have been developed to address some of the disadvantages. In this case conference, the novel investigational counterpulsation device, the intra-Vascular Assist System (iVAS; NuPulseCV Raleigh, NC), is presented. The iVAS is an air-filled counterpulsation device implanted through either subclavian artery (left or right) and connected to permanent subcutaneous electrodes and a portable device unit during patient ambulation.

Case Presentation*

A 52-year-old male (height 188 cm, weight 110 kg) with a history of hypertrophic cardiomyopathy resulting in heart failure presented to the authors institution for iVAS placement.

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His medical history was significant for chronic kidney disease (stage 3) from immunoglobulin A nephropathy, chronic systolic and diastolic heart failure, atrial fibrillation and flutter, hypothyroidism, pulmonary hypertension, gout, and obesity. His surgical history was significant for insertion of a biventricular implantable pacemaker/defibrillator and 2 arrhythmia ablations. Pertinent medications included carvedilol, levothyroxine, milrinone, and prednisone.

He was diagnosed with hypertrophic cardiomyopathy in the 1980s, subsequently placed on beta-blockers, and then monitored with serial echocardiographic examinations. The patient had experienced functional decline in the previous 6 months, with intermittent chest pain on exertion, before presentation. Preoperative echocardiography showed abnormal diastolic performance, left ventricular ejection fraction of 40%, inferior wall hypokinesis, and no significant valvular disease. He then underwent a right heart catheterization, which revealed a low cardiac index that improved with milrinone. The milrinone was continued upon his transfer to the intensive care unit (ICU). In the ICU, the patient reported persistent dizziness and chest tightness on ambulation. He underwent transplantation evaluation and fulfilled the criteria for listing, except for a history of illicit drug use. The patient qualified for iVAS placement as a bridge to transplantation while awaiting 2 months to be listed.

The patient arrived at the operating room hemodynamically stable, with intravenous access and an infusion of milrinone 0.25 µg/kg/min. After placement of a right radial arterial line,

https://doi.org/10.1053/j.jvca.2018.01.021 1053-0770/© 2018 Published by Elsevier Ltd.

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anesthesia was induced intravenously with 5 mg midazolam, 300 μg fentanyl, 50 mg propofol, and 100 mg rocuronium. His airway subsequently was intubated with a single-lumen 8.0 endotracheal tube, and inhaled sevoflurane was started for maintenance. After placement of a transesophageal echocardiography (TEE) probe, a 9 Fr double-lumen introducer sheath was placed in the right internal jugular vein. A continuous cardiac output pulmonary artery catheter (PAC) was inserted through the introducer sheath and positioned in the pulmonary artery.

After antibiotic administration, an incision inferior to the left clavicle was made. The left subclavian artery was isolated by careful dissection, and heparin was administered intravenously. Subsequent to clamping the artery, the end of an iVAS graft was anastomosed to the side of the subclavian artery via suture. After clamp removal, the device was inserted through the graft and properly positioned in the descending aorta under fluoroscopy. A subcutaneous pocket 2.5 cm deep and 8 cm wide was created in the left upper quadrant of the abdomen for the skin interface device (SID). Lateral, medial, and right-sided subcutaneous electrodes were implanted and connected to the driveline (Fig 1). After activation of the iVAS, the milrinone infusion was discontinued, protamine was administered, and hemostasis was achieved. On completion of the procedure, glycopyrrolate and neostigmine were administered to reverse any residual muscle relaxation. The TEE probe then was removed, the patient's airway was extubated easily, and he was transferred to the ICU in stable condition.

On postoperative day (POD) 1, with the help of physical therapy, the patient ambulated and was started on 5 mg warfarin with a goal international normalized ratio (INR) of 1.5. He was transferred to the floor on POD 4 and discharged home on POD 12. The postoperative course was complicated by a hypertensive emergency associated with headache, which required readmission on POD 41. He underwent an orthotopic heart and kidney transplantation on POD 90. During the heart transplantation, the iVAS was explanted before the recipient cardiectomy. The patient experienced an uneventful post-transplantation course and was discharged home 33 days later.

NuPulse intra-Vascular Assist System (iVAS)

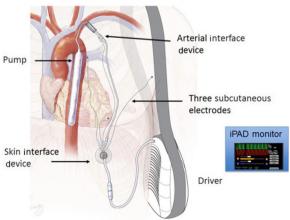


Fig 1. iVAS superimposed on thorax.

Table 1 iVAS Cases at University of Chicago Medical Center from July 2016 to June 2017

Patient	Received Heart Transplantation	POD of Initial Ambulation
1	Yes	2
2	Yes	4
3	Yes	2
4	Yes	2
5	Yes	1
6	Yes	2
7	Yes	1
8	Yes	1
9	Yes	1
10	Yes	1
11	No	2
12	No	1
13	Yes	1
14	Yes	1
15	No	1

Abbreviations: iVAS, intravascular assist system; POD, postoperative day.

At the authors' institution, the iVAS was implanted in 15 patients from July 2016 to June 2017. All were able to ambulate within 4 days of surgery, and only 3 of the 15 have not undergone heart transplantation (Table 1). Two of the transplantation patients were able to go home with the iVAS before undergoing transplantation and reported no device malfunction. Every patient received a general endotracheal anesthetic, all but 2 were extubated at the end of the case in the operating room, and none had any apparent anesthetic complications. Three patients experienced problems with electrode malfunction that required revision in the operating room but no thrombosis, air embolism, limb ischemia, vascular injury, or major bleeding developed.

Discussion

IABPs function by synchronized counterpulsation, resulting in augmented arterial diastolic pressure and a reduction in systolic pressure. The balloon inflates during diastole to displace blood into the proximal aorta and increase coronary blood flow. An increase in aortic diastolic pressure improves myocardial oxygen supply by increasing coronary perfusion pressure. Rapid deflation at end-diastole, before systolic ejection, reduces myocardial oxygen demand by decreasing afterload. Figure 2 shows the IABP arterial waveform tracing demonstrating assisted and unassisted systolic and diastolic pressures.

The IABP is optimally positioned in the proximal descending aorta just distal to the left subclavian artery. Positioning is assessed using fluoroscopy or TEE (Fig 3), especially if placement is in the operating room. Positioning too proximal can obstruct aortic arch vessels, particularly the left subclavian artery; improper distal positioning can obstruct vessels supplying gastrointestinal organs or the kidneys. Historically, access to the proximal descending thoracic aorta is through the femoral artery. The femoral artery is preferred because of ease

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