### **EVOLVING TECHNOLOGY/BASIC SCIENCE**

## Intra-aortic balloon pump inserted through the subclavian artery: A minimally invasive approach to mechanical support in the ambulatory end-stage heart failure patient

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**Objective:** Intra-aortic balloon pumps are traditionally inserted through the femoral artery, limiting the patient's mobility. We used alternate approaches of intra-aortic balloon pump insertion to provide temporary and minimally invasive support for patients with decompensating, end-stage heart failure. The present study describes the outcomes with closed-chest, transthoracic intra-aortic balloon pumps by way of the subclavian artery.

**Methods:** During a 3-year period, 20 patients underwent subclavian artery–intra-aortic balloon pump in the setting of end-stage heart failure. The balloon was inserted through a polytetrafluoroethylene graft sutured to the right subclavian artery in 19 patients (95%) and to the left subclavian artery in 1 patient (5%). The goal of support was to bridge to transplantation in 17 patients (85%) and bridge to recovery in 3 patients (15%). The primary outcome measure was death during subclavian artery–intra-aortic balloon pump support. The secondary outcomes included survival to the intended endpoint of bridge to transplantation/bridge to recovery, complications during subclavian artery–intra-aortic balloon pump support (eg, stroke, limb ischemia, brachial plexus injury, dissection, bleeding requiring reoperation, and device-related infection), emergent surgery for worsening heart failure, and ambulation during intra-aortic balloon pump support.

**Results:** The duration of balloon support ranged from 3 to 48 days (mean,  $17.3 \pm 13.1$  days). No patients died during subclavian artery–intra-aortic balloon pump support. Of the 20 patients, 14 (70%) were successfully bridged to transplant or left ventricular-assist device. Two patients (10%) required emergent left ventricular-assist device for worsening heart failure.

**Conclusions:** An intra-aortic balloon pump inserted through the subclavian artery is a simple, minimally invasive approach to mechanical support and is associated with limited morbidity and facilitates ambulation in patients with end-stage heart failure. (J Thorac Cardiovasc Surg 2012;144:951-5)

The intra-aortic balloon pump (IABP) was first used successfully by Kantrowitz and colleagues<sup>1</sup> in 1968 for patients with cardiogenic shock. Annually, tens of thousands of patients benefit from the use of IABPs for indications including refractory angina pectoris, post-cardiopulmonary bypass shock, temporizing complications of percutaneous coronary intervention, and complications of myocardial infarction refractory to pharmacologic therapy.<sup>2</sup>

Conventionally, IABPs are placed using femoral artery access. However, this approach is associated with a number of important limitations. Most significantly, it requires bed

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rest—precluding ambulation. Second, there is a significant risk of leg ischemia, with a reported incidence of 5% to 19%.<sup>2</sup>

Given these limitations, alternative approaches, including by way of the subclavian artery (SCA), have been explored. Although technically more demanding and more time consuming, the SCA approach overcomes important limitations of femoral placement, because the SCA is generally free of atherosclerosis, even in patients with significant peripheral arterial disease. Furthermore, it allows patients to ambulate early. SCA placement of IABPs was described by Mayer<sup>3</sup> in 1978. McBride and colleagues<sup>4</sup> described ambulatory use of the balloon pump, and Cochran and colleagues<sup>5</sup> reported their ambulatory technique in 4 patients awaiting transplantation.

In the present series, we report a 3-year experience with SCA-IABP at a single institution. This is the largest experience with SCA-IABPs published to date. The approach we describe includes important technical modifications we have developed during our growing experience.

#### METHODS Data Collection

#### Data Collection

The present study was in accordance with the University of Chicago's institutional review board. The patient data, including preprocedure

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#### **Abbreviations and Acronyms**

CABG = coronary artery bypass grafting IABP = intra-aortic balloon pump LVAD = left ventricular assist device SCA = subclavian artery

characteristics and outcomes, were obtained from our institutional cardiac surgery outcomes database. Among the 20 patients receiving SCA-IABP support, 15 (75%) were men and 5 (25%) were women. Their age ranged from 20 to 70 years (mean, 57.8  $\pm$  13.0 years).

#### **Study Population**

The analysis included 20 consecutive patients who underwent SCA-IABP principally to support heart failure while awaiting cardiac transplantation. Other indications included deteriorating hemodynamics in patients who were not transplant or ventricular assist device candidates and in 1 instance with concomitant coronary artery bypass grafting (CABG) when it was anticipated that the balloon might be necessary for an extended period.

#### **Statistical Analysis**

The patients were followed up from the date of SCA-IABP insertion to the date of device removal, transplant, insertion of a ventricular assist device, or death. The date of the last known follow-up examination was September 28, 2011.

#### **Operative Technique**

In each instance, either the right (17 patients) or, less frequently, the left SCA (3 patients)-when access through the right was not possible-was isolated through a small incision in the infraclavicular region. After 5,000 U of heparin, a side-biting clamp was applied to the SCA. A 4 by 7-mm, tapered polytetrafluoroethylene graft (Gore-Tex, W. L. Gore & Associates, Inc, Flagstaff, Ariz) was used. An incision was made 8 cm from the most narrow portion and another 1.5 cm from the proximal end. This was to ensure that the 1-way stopper slid over the distal portion and was at the level of the skin without stretching or kinking. This was then anastomosed to the artery using 6-0 polypropolene suture on a small needle. As previously described,<sup>6</sup> and as shown in Figure 1, the 1-way valve was obtained from the 8F introducer sheath in our standard Maquet IABP catheter kit (the sheath was cut at the hub, the side hole was cut off, the inner metal coil was removed to prevent balloon rupture), and the 1-way valve was placed on the graft and secured with three 2-0 silk ties. Under fluoroscopic guidance, the glide wire was then inserted through the needle into the graft and then through the SCA into the aorta.

Occasionally, the wire will pass directly into the descending aorta. On other occasions, the wire will head preferentially into the ascending aorta. The following procedure can be useful in redirecting the catheter:

- Place a right coronary artery Amplatz catheter (AGA Medical, Plymouth, Minn) in the ascending aorta and work the catheter leftward and upward, toward the arch.
- 2. Use an Omniflush (AngioDynamics, Latham, NY) catheter (reverse angle catheter) and non-stiff glide wire. Once the wire is pointed in the appropriate direction, switch out the Omniflush for a glide catheter or quick-cross catheter; and direct the wire into descending aorta.
- If a type 1 or 2 arch is present and access is from the right, using a directional hydrophilic (eg, angled glide wire) and simple curved catheter (eg, Kumpe [Cook, Bloomington, Ind] or Bernstein [AngioDynamics]), advance the catheter into the arch and direct the catheter down the arch.
- 4. If a type 3 arch is present and access is from the right, a complex curved catheter (eg, Simmons 1 [Cook]) can be advanced down the ascending aorta and then pulled back to engage the tip on the greater curve.

5. As a last resort, the catheter can be placed in the left ventricle; then, using the inferior wall to support the catheter, a stiff wire can be inserted upward back through the aortic valve into the ascending aorta. The wire then typically goes into the arch and then into the descending aorta.

Next, the balloon is placed over the wire to a point 2 cm below the left SCA. The distal end should be placed just distal to the left subclavian. This can typically be confirmed by both transesophageal endocardiography and fluoroscopy. The wound over the polytetrafluoroethylene graft (Gore-Tex, W. L. Gore & Associates) is closed in layers. Therefore, the only foreign material that traverses the skin is the balloon catheter, which does so through a separate puncture site below the incision.

#### Outcomes

The primary outcome of interest was death during SCA-IABP support. The secondary endpoints included survival to transplantation or recovery without the need for additional mechanical support (eg, ventricular assist device), interval to ambulation, stroke, bleeding requiring reoperation, limb ischemia, other vascular complications, and device failure.

#### RESULTS

#### **Study Population and Indications**

The intent of the IABP was as a bridge to transplantation in 17 patients, and 3 (patients 3, 9, and 17) had a non-bridge to transplantation indication. The intent was to either achieve recovery or temporize pending decisions about more definitive therapy. One of these patients (patient 3) was a 66-year-old patient who had undergone CABG and repair of a postinfarct ventricular septal defect, who was readmitted with a leak from the ventricular septal defect patch and sepsis. An IABP in the subclavian position was a bridge to recovery because he was not a candidate for either a ventricular assist device or transplantation because of the sepsis. A second patient (patient 9) was a 65-year-old man who presented with cardiogenic shock after acute anterior wall infarction. After percutaneous transluminal coronary angioplasty, a femoral IABP and a tandem heart were placed for support. A SCA-IABP was later placed for long-term support in exchange for the femorally placed devices. Because of a history of Alzheimer's disease, he was not a candidate for ventricular assist device or transplantation. The third patient (patient 17) was a 57-year-old man with triple vessel disease and an ejection fraction of 15%. He underwent subclavian IABP with concomitant CABG.

#### **Patient Management**

Of the 20 patients, 9 (45%) underwent the procedure under local anesthesia and 11 (55%) required general anesthesia. Of the 20 patients, 6 (30%) received no anticoagulation or only prophylactic subcutaneous heparin doses postoperatively, and 14 (70%) received anticoagulation with intravenous heparin, low-molecular-weight heparin, or warfarin.

#### **Primary Outcomes**

As summarized in Table 1, the duration of balloon support ranged from 3 to 48 days (mean,  $17.3 \pm 13.1$  days). No patients died during SCA-IABP support.

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