Echocardiographic evaluation of patients receiving a new left ventricular assist device: the Impella® recover 100

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Abstract The aim of this study was to suggest a protocol for serial echocardiographic evaluations in patients undergoing circulatory support by a new miniaturized electric axial pump, the Impella® recover 100 (IR 100). IR 100 is implanted through the ascending aorta into the left ventricle drawing blood from the left ventricle to the aorta.

Methods and results This protocol has been applied in eight patients receiving twelve IR 100 implants. Before implantation echocardiography was useful to rule out anatomic contraindications. During and after implantation echocardiography provided informations for correct positioning and evaluation of left ventricular filling necessary to optimize pump performance. During assistance it gave important informations to assess left and right ventricular function.

Conclusion Echocardiography has pivotal role in IR 100 management before, during and after implantation.

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KEYWORDS Impella; Ventricular assist device (VAD); End stage cardiac failure; Transoesophageal echocardiography (TEE); Transthoracic echocardiography (TTE)

Introduction

Echocardiography has an increasing role in ensuring successful implantation of left ventricular assist devices (LVADs) nowadays more extensively employed in patients unresponsive to conventional haemodynamics support. Images of the heart, assessment and quantification of its function together with evaluation and optimization of LVAD's performance are proven issues in this setting.1–6

We describe the contribution of echocardiography in the use of a new LVAD: the miniaturized electric axial pump Impella® recover 100 (IR 100) (Impella Cardiotechnik AG, Germany). Currently a trial to evaluate its clinical role is in progress.7–9
Materials and methods

The device

IR 100 is an axial endovascular pump powered by external batteries and driven by a software placed in an external console. This device is positioned in the left ventricle through the ascending aorta (Fig. 1). The pump draws blood from the left ventricle to the ascending aorta and can deliver, at nine levels of performance, a non-pulsatile flow up to 5 l/min.10,11

The device is equipped by a pressure transducer to detect differential pressure between aorta and left ventricle (Fig. 2).

IR 100 can be inserted directly into the femoral artery by means of a J guidewire or through a small vascular prosthesis stitched on the ascending aorta at least 7 cm above the valve plane. The tip of the device must lie 4 cm under the aortic valve plane.

Main anatomic contraindications to IR 100 are:
- aortic valve stenosis/incompetence
- mixomatous mitral valve
- hypertrophic cardiomyopathy.

Its operating time is suggested not to exceed seven days. After that time the pump has to be removed.

Patients

From September 2002 to September 2003 we performed twelve IR 100 implants in eight patients (Table 1).

All patients showed left ventricle failure with preserved right ventricle function despite adequate haemodynamic conventional support.

The indications for IR 100 included: bridge to heart transplant (4 patients), recovery from acute myocarditis (2 patients) and recovery from postcardiotomy cardiogenic shock (2 patients).

Echocardiographic protocol

A protocol for perioperative echocardiographic evaluations before, during and after IR 100 implantation was developed (Table 2).

TEE mid-esophageal long axis view at 100–120° for:
- qualitative and quantitative assessment of aortic root, ascending aorta, Valsalva sinuses, aortic and mitral valves and left ventricular outflow evaluation;

- assessment of intra-aortic and intraventricular position of the cannula.

TEE four chambers view for:
- right to left atrial shunting exclusion by saline solution injection with Valsalva maneuver;
- qualitative assessment of right ventricular (RV) function;
- quantitative assessment of RV function by calculation of RV fractional area change (RVFAC) with the following equation:
RVFAC

\[
RVFAC = \frac{\text{end diastolic area} - \text{end systolic area}}{\text{end diastolic area}} \times 100
\]

- left ventricular end diastolic diameter (LVEDD) and volume (LVEDV) measurement;
- quantitative assessment of LV function by calculation of ejection fraction (EF) using Simpson method.

TEE short axis view at papillary muscle level for:
- assessment of RV inferior, free wall and ventricular septal motion.

Figure 2  Top: Impella® recover 100. Bottom on left: pressure transducer (sensor) integrated into the pump to detect differential pressure between aorta (P aorta) and left ventricle (P ventricle). Bottom on right: the differential pressure curve signal on IR 100 displays when the device is properly positioned.

Color Doppler for:
- mitral and tricuspidal regurgitation evaluation
- patency assessment of the cannula.

Post-operative controls were performed by TTE or by TEE whenever inadequate transthoracic windows were obtained.

Controls were performed daily to assess:
- position and patency of the cannula
- loading and function of right and left ventricles
- mitral and tricuspidal valve competence.

Controls were moreover performed every time IR 100 malfunction was suspected.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Age (years)</th>
<th>Cardiac disease</th>
<th>Indication</th>
<th>Length of support (days)</th>
<th>Number of implanted devices</th>
<th>Site of insertion</th>
<th>Outcome</th>
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<tr>
<td>1</td>
<td>f</td>
<td>55</td>
<td>IC</td>
<td>B</td>
<td>3</td>
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<td>B</td>
<td>10</td>
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<td>tr/dsc</td>
</tr>
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<td>30</td>
<td>AM</td>
<td>R</td>
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<td>R</td>
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<td>VC</td>
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<td>Unsuccessful</td>
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</tbody>
</table>

m, male; f, female; IC, ischaemic cardiomyopathy; PDC, primary dilated cardiomyopathy; VC, valvular cardiomyopathy; AM, acute myocarditis; IMI, intraoperative myocardial infarction; B, Bridge to heart transplant; R, recovery; PR, postcardiotomy recovery; tr, transplanted; rcv, recovered; dsc, discharged.
Results

In six patients IR 100 was implanted through the ascending aorta in the operating room under general anaesthesia. In two patients IR 100 was implanted through the femoral artery under local anaesthesia. In four patients IR 100 was replaced with another one due to prolonged assistance exceeding eight days.

Qualitative and quantitative assessment of left and right ventricle and ascending aorta by TEE are described in Table 3.

Echocardiographic assessment before implantation

Our patients did not show any anatomic contraindications to IR 100 positioning. Mitral regurgitation (++) or higher) and tricuspid regurgitation (++) or higher) were present in all patients. EF ranged from 10% to 25% and RVFAC was 22% or higher. Dilated left ventricle (>120 ml) was present in four patients.

Echocardiographic assessment during implantation

IR 100 is very echogenic: the cannula appears as two parallel segments with a round tip. During implantation the adequate position and direction of the cannula were achieved by several attempts (at least four) and by repeated TEE controls due to wedging of IR 100 tip into Valsalva sinuses (Fig. 3, top). After overcoming the aortic valve, the tip of the cannula (inlet) was easily positioned at the apex of the anterior leaflet of mitral valve 3.5–4.5 cm under the aortic valve plane (Fig. 3, bottom). Pump outlet was located 1.5 cm above the coronary ostia and pump outflow did not trouble

Table 3  Echocardiographic data before (pre) and after (post) VAD implantation

<table>
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<tr>
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<td>38</td>
<td>33</td>
<td>35</td>
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<td>uc</td>
<td>21</td>
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<td>ST junction (mm)</td>
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</tr>
</tbody>
</table>

AV, aortic valve; ST, sinus tubular; AR, aortic regurgitation; LVEDD, left ventricular end-diastolic diameter; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; TR: tricuspidal regurgitation; RVFAC, right ventricular fractional area change; ++++ = severe; +++ = moderate-severe; ++ = moderate; + = mild; uc, unchanged.
coronary inflow. IR 100 outflow positioning was documented by color Doppler (Fig. 4).

**Echocardiographic assessment after implantation**

Though ventilated patients usually show very poor transthoracic windows TTE supplied satisfying images in seven of eight patients (Fig. 5).

Abnormal position and consequent malfunction was observed in the two patients having IR 100 inserted through femoral artery (six and four episodes, respectively).

Two patients with LVEDV <120 ml showed episodes of IR 100 malfunction due to contact of inlet area with left ventricular free wall. IR 100 malfunction never occurred in those patients with dilated left ventricle (LVEDV >120 ml) even at the highest level of pump performance.

All patients showed reduction of mitral and tricuspid regurgitation and unchanged or improved RVFAC.

We found post-operative change of LVEF only in two patients showing an increase from 10% to 55% and from 20% to 40%, respectively, after 19 and 15 days of assistance (Table 3). Both of them were successfully weaned from IR 100. Two patients successfully underwent early heart transplant.

**Figure 3** Top: the cannula of IR 100 during positioning; IR 100 into ascending aorta (left) and IR 100 malplaced into Valsalva sinuses (right). Bottom: mid-esophageal longitudinal view at 118°. The tip of the cannula is at the apex of the anterior leaflet of mitral valve 3.5 cm under the aortic valve plane. AO, aorta; AV, aortic valve; LA, left atrium; LAM, mitral anterior leaflet; LV, left ventricle.
Four patients died because of multiorgan system failure.

Discussion

Echocardiographic assessment before implantation

Anatomic contraindications
Aortic regurgitation is a contraindication because the persistent retrograde aorta-to-left ventricle flow reduces the effective pump flow to the aorta.

Redundant mixomatous mitral valve (billowing valve) is a contraindication because inlet pump flow can be reduced by contact with anterior mitral leaflet.

Right ventricular function assessment
Qualitative and quantitative assessments of RV function and tricuspid regurgitation are predictive of RV failure during any LVAD implantation.

In Scalia’s experience patients with an RV FAC less than 20% evidenced right ventricular failure when on LVAD.

Our patients showed RV FAC more than 22% without post-operative RV failure.

Left ventricular function assessment
Three parameters are to be underlined: left ventricle volume (LVV), left ventricle ejection fraction (LVEF) and mitral regurgitation.

When left ventricle is severely dilated, IR 100 can work at the highest levels of performance without risk of malfunction due to contact with LV wall. In our experience it was not possible to gain the highest level of IR 100 performance in patients with normal or not massively dilated left ventricle. In these patients it was necessary to check frequently the position of the pump and to optimize LV loading. In patients showing LVEDV > 120 ml no problems related to pump position and LV loading were observed.

Pre-operative LVEF is of important concern for recovery and weaning.

Figure 4  Mid-esophageal off-axis view at 105°; color Doppler shows blood flow through IR 100 cannula; inflow area is near the interventricular tip, the outflow area is located where intra-aortic turbulence appears.

Figure 5  Left: TTE parasternal long axis view shows the correct position of the cannula. Right: color Doppler shows the flow into the cannula and the turbulent outflow. LA, left atrium; LV, left ventricle; RV, right ventricle.
Evaluation of pre-operative mitral regurgitation and its post-operative changes is essential to assess the effective contribution of IR 100 on haemodynamics.

**Echocardiographic assessment during implantation**

Echocardiography is the unique tool to guide the surgeon during positioning of IR 100.

- Continuous control of the procedure
- Check of correct positioning
- Check of blood flow through the cannula and correct pump functioning.

**Echocardiographic assessment after implantation**

In the intensive care management of patients with IR 100, echocardiography is an invaluable tool to assess the patency and the position of the cannula, the adequate left ventricular loading and the adequate ventricular function.

In patients having IR 100 inserted through the femoral artery, an abnormal position may frequently occur due to the length of the intra-aortic catheter. Echo-guided repositioning of the device is quick and easy (Fig. 6).

Even in cases of correct positioning, inlet obstruction due to contact with ventricular wall may occur. This event, well documented by TTE or TEE, is more frequent in patients with a nondilated left ventricle (LVEDV < 120 ml) and when the pump is working at the highest level of performance. Reducing the level of performance of the pump and increasing the preload of left ventricle were effective in counteracting this event.

RV function evaluation and management are determinant in post-operative course of patients on LVAD. Adequate LVAD function depends on normal or high left ventricle filling pressure which in turn depends on RV output. Echocardiographic qualitative and quantitative assessment of RV function was crucial in optimizing volume replacement therapy and titrating pharmacological support.

Echocardiography has also an irreplaceable role in evaluating heart function recovery during mechanical circulatory support.

In our experience the only two patients showing significant improvement of LVEF together with reduction of mitral and tricuspidal regurgitations were successfully weaned from IR 100.

**Conclusions**

In this clinical report we focused the role of echocardiography in patients receiving a new LVAD (Impella® recover 100).

TTE and TEE provided adequate information concerning anatomic contraindications for implantation. Moreover echocardiography was pivotal for correct positioning of the device, evaluation of adequacy of left ventricular filling and right ventricular function.

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Figure 6  Left: the TTE parasternal longitudinal axis view documents an abnormal position of the cannula in a patient having IR 100 inserted through the femoral artery. Right: the device has been replaced. Ao, aorta; LA, left atrium; LV, left ventricle; RV, right ventricle.
ventricular function and documenting improvement of left ventricle performance.

References