First Canadian experience with high-risk percutaneous coronary intervention with assistance of a percutaneously deployed left ventricular assist device

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Mechanical assist devices play an increasing role in high-risk percutaneous coronary intervention (PCI) in highly complex and critically ill patients. The Impella Recover LP 2.5 is a minimally invasive left ventricular assist device that is inserted percutaneously via a 13 Fr sheath. The device is engineered to provide a significant increase in cardiac output in patients with severe left ventricular impairment as well as in patients undergoing high-risk coronary intervention, and may provide substantive circulatory support when severe hemodynamic compromise occurs. It can potentially be maintained *in situ* for five to seven days. Canada's first implantations of an Impella device providing circulatory support in patients undergoing complex, high-risk PCI are reported. Larger studies will be required to identify whether a survival benefit or improvement in left ventricular function can be achieved when using the Impella device to support patients undergoing high-risk PCI or those in cardiogenic shock.

Key Words: High risk; Impella; Left ventricular assist device; Percutaneous coronary intervention

Critically ill patients with severely impaired left ventricular function and patients undergoing high-risk percutaneous coronary intervention (PCI) often require mechanical cardiac support. Intra-aortic balloon pump (IABP) counterpulsation, the most commonly used technique, has shown its efficacy for reducing intraprocedural major adverse cardiac and cerebral events, and is associated with relatively low rates of complications (1). However, IABP support only modestly augments cardiac output and coronary blood flow, and may provide inadequate circulatory support when hemodynamic collapse occurs (2). The Impella Recover LP 2.5 (Abiomed, Germany) device is minimally invasive and is currently the most compact left ventricular assist device (LVAD). It is inserted percutaneously via a 13 Fr sheath (Figures 1 and 2). The device is capable of providing blood flow of up to 2.5 L/min, which leads to a significant increase in cardiac output in patients with severe left ventricular impairment as well as in patients undergoing high-risk PCI. It can be maintained *in situ* for five to seven days, although in Canada, it is currently approved only for up to 24 h of use. A more powerful version of the device, the Impella Recover LP 5.0 (Abiomed), can in fact be used as a temporary replacement pump device, with blood flow of up to 5 L/min, but requires a 22 Fr femoral sheath and formal surgical cut-down on the groin.

Another potential use is in the setting of cardiogenic shock. Currently, there are no data on the use of the Impella Recover LP 2.5 in this setting; however, a multicentre trial is being planned. The

Une première expérience canadienne d'interventions coronaires percutanées à haut risque avec l'aide d'un dispositif d'assistance ventriculaire gauche à déploiement percutané

Les dispositifs d'assistance mécanique jouent un rôle croissant dans les interventions coronaires percutanées (ICP) à haut risque dans des cas très complexes en phase critique. Le dispositif Impella Recover LP 2.5 est un dispositif d'assistance ventriculaire gauche très peu effractif inséré par voie percutanée au moyen d'une gaine Fr 13. Il est conçu pour accroître le débit cardiaque de manière significative chez les patients atteints d'une grave défaillance ventriculaire gauche ou qui subissent une intervention coronaire à haut risque, et il peut fournir un soutien circulatoire important en cas d'atteinte hémodynamique. Il est possible de le maintenir *in situ* de cinq à sept jours. On rend compte des premières implantations canadiennes de dispositifs Impella pour assurer un soutien circulatoire chez des patients subissant des ICP complexes et à haut risque. Il faudra mener des études plus vastes afin d'établir si le recours au dispositif Impella pour soutenir les patients qui subissent une ICP à haut risque ou qui sont en choc cardiogène s'associe à des bienfaits sur la survie ou à une amélioration de la fonction ventriculaire gauche.

LVAD does not function in the setting of right ventricular dysfunction; however, a percutaneously deployed right ventricular assist device is currently being developed.

Implantation of the Impella Recover LP 2.5 device does not require complex manoeuvres such as transseptal punctures, a technique that is needed to deploy another percutaneously deployed LVAD in clinical use (TandemHeart device [CardiacAssist Inc, USA]). Transseptal puncture is commonly performed by operators who treat patients with congenital heart disease, but not by the majority of interventional cardiologists. Although at somewhat higher risk for vascular complications than an IABP because of the need for a 13 Fr sheath, the Impella Recover LP 2.5 is less likely to cause these complications than other LVADs or circulatory bypass devices requiring much larger sheaths (larger than 20 Fr). We report Canada's first Impella device implantations providing circulatory support in patients undergoing complex, high-risk PCI.

CASE PRESENTATIONS

Case 1

A 52-year old woman with recent-onset diabetes, hypertension, hypercholesterolemia, a family history of ischemic heart disease and an extensive smoking history presented with a six-month history of exertional dyspnea. She was found to be in heart failure (Canadian Cardiovascular Society class II) and echocardiography suggested poor

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Figure 1) The Impella Recover LP 2.5 (Abiomed, Germany) left ventricular assist device. Picture courtesy of Abiomed

left ventricular function with an estimated ejection fraction of less than 35%. Coronary angiography revealed a 40% left mainstem lesion. The circumflex artery had an ostial 50% stenosis followed by a chronic total mid-vessel occlusion. The second diagonal artery had a 70% ostial lesion and the left anterior descending artery (LAD) was diffusely diseased with no flow-limiting lesion. The large, dominant right coronary artery (RCA) was tortuous, with a 60% ostial lesion followed by a 90% mid-vessel stenosis and a further 80% plaque in a more distal segment. She was scheduled for PCI of the RCA. Because of the large territory of myocardium at risk, in combination with the chronic total occlusion of the circumflex artery and poor left ventricular function, circulatory support was chosen. Following written informed consent, the Impella Recover LP 2.5 LVAD was used.

Both groins were prepared for vascular access. After local anesthesia, a 7 Fr sheath and a 6 Fr sheath were inserted in the right femoral vein and artery, respectively. A contrast study of the aorta and both iliac arteries confirmed the suitability of using the assist device. A Swan-Ganz catheter was placed in the right pulmonary artery to monitor and assure adequate filling pressures, required to achieve optimal performance with the Impella device. The left femoral artery was then cannulated and sutures of a Perclose device (Abbott Vascular Devices, USA) were inserted to facilitate hemostasis at the end of the procedure. Heparin was administered intravenously to achieve an activated clotting time of 325 s, and an intravenous bolus and infusion of eptifibatide were initiated. The 13 Fr sheath was then inserted over the wire. A 7 Fr sheath was inserted into the 13 Fr sheath in the left femoral artery to reduce leakage from the hemostatic valve. Through

Figure 2) The position of the Impella Recover LP 2.5 device (Abiomed, Germany) in the left ventricle. Picture courtesy of Abiomed

this sheath, a JR4 diagnostic catheter was advanced over a standard 0.035 in wire into the left ventricle. The guidewire was removed and replaced by the Impella 0.014 Platinum guidewire. After removal of the JR4 catheter, the Impella device was passed over the Platinum guidewire into the left ventricle. Guided by pressure curves, the position of the Impella device was adjusted to ensure blood flow through the pump across the aortic valve (Figure 3). The pump was started at performance level (P) 7, providing approximately 2.0 L of circulating blood per minute.

PCI was then performed, choosing a JR4 5 Fr guide catheter to reduce pressure damping and allow deep-seating in the RCA for better support. A Prowater guidewire (Asahi Intecc Co, Japan) was manoeuvred into the distal vessel and multiple predilation inflations were performed using a 2.5 mm × 15 mm Sprinter balloon (Medtronic Inc, USA) at 16 atm to 20 atm. With every balloon dilation, the systolic pressure dropped, but the diastolic pressure remained stable at 75 mmHg, supported by the Impella device. A Balance Middle Weight buddy wire (Abbott Corporation, USA) was required to pass a 2.5 mm × 18 mm Cypher Select Plus drug-eluting stent (Cordis Corporation, USA) covering the distal lesion. Further predilation with a 2.75 mm × 20 mm Sprinter balloon was needed before an overlapping and more proximal 2.5 mm × 28 mm Cypher Select Plus stent could be placed. After further predilation of the proximal and ostial RCA, the vessel dissected and flow down the RCA ceased. The performance level of the Impella device was increased to P9, providing a maximum flow of 2.5 L/min. The patient remained hemodynamically stable, with the diastolic pressure remaining firmly at 75 mmHg. This allowed the completion of this complex procedure in a controlled environment. The final, proximal and overlapping 2.75 mm × 33 mm Cypher Select Plus stent was deployed at 24 atm to cover the ostial lesion. This achieved an excellent angiographic result in a well-tolerated procedure (Figure 4). The Impella device was withdrawn and the sheath was

Figure 3) Case 1. The Impella Recover LP 2.5 device (Abiomed, Germany) positioned in the left ventricle

Figure 4) Case 1. Right coronary artery before (A) and after (B) stent deployment

removed at the end of the procedure. Vascular closure was achieved with the Perclose device. The patient was transferred to the coronary care unit (CCU) overnight and was discharged the next day. After seven months, she remained symptom-free.

Case 2

An 81-year-old man presented to the emergency department of a community hospital with new-onset atrial fibrillation complicated by congestive heart failure. His relevant medical history included mild to moderate dementia secondary to both Alzheimer's disease and multi-infarct dementia. His cardiac risk factors included hypertension and hyperlipidemia. On presentation to the emergency room, his electrocardiogram was found to have marked anterolateral ST segment depression involving leads V1 to V5. Cardiac biomarkers were positive. He was diagnosed with a non-ST segment elevation myocardial infarction and treated with enoxaparin in addition to acetylsalicylic acid and Plavix (sanofi-aventis Canada Inc). He was diuresed judiciously with low-dose diuretics. The patient stabilized on medical therapy and was referred for cardiac investigations. Transthoracic echocardiography revealed a left ventricular ejection fraction of 45%, with evidence of mild global hypokinesis. There was evidence of moderate to severe mitral regurgitation, which was thought to be of ischemic etiology.

Figure 5) Case 2. Left main artery before (A) and after (B) stent deployment

Coronary angiography revealed a very distal 95% left main stenosis extending into both the ostial circumflex and ostial LAD. The circumflex and LAD vessels both had 95% stenoses at their origins. The first diagonal artery had an ostial 80% stenosis. There were no other flow-limiting stenoses in the LAD, circumflex or the dominant RCA.

The patient was referred for coronary artery bypass graft surgery, but was turned down because of his cognitive dysfunction. He was subsequently referred and accepted for PCI. Because of the high-risk nature of the anatomy in addition to left ventricular dysfunction and severe mitral regurgitation, circulatory support was chosen. Following written informed consent, the Impella Recover LP 2.5 LVAD was used.

Both groins were prepared for vascular access. After local anesthesia, a 7 Fr venous line and a 7 Fr arterial line were inserted in the right groin. The LVAD was inserted as described above and was started at P6, providing approximately 2.0 L of circulating blood per minute. A Voda Left 3.5 mm guide catheter was used to cannulate the left main artery. Heparin 5000 IU was administered to achieve an activated clotting time of 312 s. A Pilot guidewire (Guidant Corporation, USA) was advanced down the circumflex vessel. A Prowater guidewire was then advanced down the LAD. At this point, the patient became hypotensive, and the performance level was increased to P8 (2.4 L/min). Dopamine infusion was started at 10 µg/kg/min. It was difficult to cross the severe left main-LAD stenosis, even with a 1.5 mm balloon. It was finally possible to cross and predilate the lesion with a Schwager 1.1 mm × 12 mm balloon (SIS Medical, Switzerland) up to 20 atm, then predilate further with a Sprinter 1.5 mm × 15 mm balloon up to 20 atm, and a Sprinter 2.5 mm × 15 mm balloon up to 18 atm. The circumflex lesion was subsequently dilated with a Sprinter 2.5 mm × 15 mm balloon up to 13 atm. At this point, the blood pressure improved and the LVAD performance level was turned down to P6 (2.1 L/min). A Taxus 3.0 mm × 16 mm drug-eluting stent (Boston Scientific Corporation, USA) was then placed in the LAD and a Taxus 2.75 mm × 16 mm stent was placed in the circumflex vessel; both stents extended into the distal left main artery. The simultaneous kissing stent technique was used to deploy the two stents at 20 atm and 16 atm, respectively (Figure 5). Following stent insertion, the LVAD flow rate was

decreased to P2 (1.3 L/min). The dopamine infusion was decreased to 2.5 µg/kg/min. Intravascular ultrasound was performed to ensure adequate stent deployment. The Impella device and sheath were withdrawn at the end of the procedure. Vascular closure was achieved with the Perclose device. The patient was brought to the CCU for observation and was transferred back to the referring hospital 48 h later with no complications. He was doing well and was free of chest pain or dyspnea at six months.

DISCUSSION

We have reported the first Canadian experience of PCI in very high-risk patients with support of the Impella Recover LP 2.5 LVAD. Case selection was particularly important. In both cases, although PCI was a high-risk procedure, it was believed to be the better revascularization option. Coronary anatomy and comorbidity in both patients suggested that transient ischemia might lead to disastrous hemodynamic compromise. We therefore decided that a device providing continuous flow even in the event of hemodynamic collapse would be preferable. While IABP counterpulsation may be of value in patients with left ventricular dysfunction undergoing PCI, we believed that transient occlusion of the culprit vessel during PCI, a likely event in these cases, might compromise left ventricular contractility to such an extent that the capability of the IABP to provide adequate support could be overwhelmed. We therefore opted for the Impella Recover LP 2.5 LVAD, a device that ensures flow from the left ventricle across the aortic valve up to 2.5 L/min, even in the absence of left ventricular contractility, which might occur in a very high-risk patient during a complicated PCI procedure.

Published experience with the Impella device is limited. The safety and feasibility of performing elective high-risk PCI procedures with mechanical left ventricular support of the Impella Recover LP 2.5 device was recently assessed in a small series of 19 patients (3). The device was successfully placed in all patients without procedural deaths; two in-hospital deaths were unrelated to device insertion. Device placement did not cause aortic valve regurgitation and there were no device-related complications during the period of left ventricular support. In a study (4) of 11 patients with compromised left ventricular function undergoing high-risk PCI, the device increased aortic and intracoronary pressure, hyperemic flow velocity and coronary flow velocity reserve, and decreased coronary microvascular resistance. The Impella-induced increase in coronary flow likely resulted from both an increased perfusion pressure and a decreased left ventricular volume-related intramyocardial resistance. Valgimigli et al (5) reported a patient with severe left ventricular impairment who underwent high-risk PCI with the use of the Impella Recover LP 2.5 device. The effects on global cardiac output were determined by thermodilution and left ventricular pressure-volume loops obtained by conductance catheter. The rapid and sustained unloading effect of the left ventricle with the Impella device was observed and the continuous expulsion of blood into the ascending aorta throughout the cardiac cycle resulted in an increase in overall cardiac output (5).

Both cases described in the present report required hemodynamic support. In the first patient, Thrombolysis In Myocardial Infarction (TIMI) grade 0 flow in a large, dominant RCA due to dissection following balloon dilation was well-tolerated in spite of marked pre-existing left ventricular dysfunction and a second occluded artery, and the procedure was successfully completed, achieving an excellent angiographic result and successful outcome. In the second procedure, the high-risk anatomy, more than severe left ventricular impairment, was the reason to choose an Impella device. Cardiac output dropped as soon as the guidewire was passed through the critically stenosed distal left main stem lesions. However, a small dose of dopamine in addition to the Impella device ameliorated his temporary hypotension and the patient remained stable until the end of the procedure. In our assessment, IABP

counterpulsation would not have given us the level of support needed to overcome the anticipated hemodynamic compromise.

Careful angiographic assessment of the femoral and iliac arteries to ensure the suitability of vascular access and preclosure with the Perclose device will also likely reduce the risk of vascular and ischemic complications. The Impella device can easily be removed immediately after the procedure. Also, the device can be left in situ for five to seven days, although current Health Canada approval is for deployment up to only 24 h. There were no issues with device migration after placement or peripheral vascular problems in either case. Both patients were well at six and seven months follow-up, respectively.

Although the Impella LP 2.5 device is not difficult to deploy, the setup and control of the device console does require specialized expertise. The device is not likely to be used more than a few times per month in any catheterization laboratory. Therefore, we have partnered with our cardiovascular surgical colleagues as well as the perfusionists in the implementation of this program. In this partnership, we are able to maintain two Impella consoles in our hospital – one in the cardiac catheterization laboratory and the other in the perfusion department that supports the cardiovascular surgery program. Each device can be used by either program in the case of failure of one of the devices. The console also serves the Impella 5.0, which is generally implanted surgically. Perfusionists are in an ideal position to support this program because they are already familiar with and support surgically implanted LVADs. In addition, we arranged for extensive in-service training of nurses in the cardiac catheterization laboratory and the CCU to aid in running and troubleshooting problems with the device during the operation.

While the Impella device has primarily been used in patients undergoing high-risk PCI, it can also offer support in acute severe cardiomyopathy or postcardiotomy low-output syndrome. To a certain degree, the Impella 2.5, but particularly the higher capacity Impella LP 5.0 device, can be used as a bridge to transplantation or an implantable LVAD. Larger studies will be required to identify whether a survival benefit or improvement in left ventricular function can be achieved when using the Impella device to support patients undergoing high-risk PCI or those in cardiogenic shock.

SUMMARY

We report the first Canadian experience of using the Impella Recover LP 2.5 LVAD in patients undergoing high-risk PCI. The Impella Recover LP 2.5 is an effective, minimally invasive and versatile LVAD that can support the circulation in acute and subacute low-output states. It is another useful tool in the armamentarium of interventional cardiologists in treating critically ill patients with severe left ventricular dysfunction undergoing high-risk PCI.

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