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Safety and feasibility of elective high-risk percutaneous coronary intervention procedures with Left ventricular support of the Impella Recover LP 2.5

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Abstract

Currently, the most used left ventricular support device is an intra-aortic balloon counterpulsation. The percutaneous implantable Impella Recover LP 2.5 system is a novel left ventricular (unloading) assist device. We studied the feasibility and safety of left ventricular support with the percutaneous implantable Impella Recover LP 2.5 system in 19 consecutive high-risk percutaneous coronary intervention patients. Procedural success using the device and PCI procedures was achieved in all 19 patients, who were very poor candidates for surgery. The patients were elderly (84% were >60 years of age), 74% had previous myocardial infarction, 63% had left ventricular ejection fractions of ≤25%, and all had left ventricular ejection fractions of ≤40%. There were no procedural deaths and 2 device-unrelated in-hospital late deaths. Mean decrease in hemoglobin level was 0.7±0.4 mmol/L. The device did not induce or increase aortic valve regurgitation. There were no important device related adverse events during left ventricular support with the Impella Recover LP 2.5 system. However, these encouraging findings must be confirmed by larger studies, longer assist times, and in other patient categories.
Introduction

Currently, the most used left ventricular (LV) support device is an intra aortic balloon counter pulsation (IABP). It reduces afterload, increases coronary perfusion and improves cardiac output. However, in acute ST-segment elevation myocardial infarction (STEMI) patients, it does not reduce infarct size or improve clinical outcome, even in high-risk patients,\(^1,2\) although it may recruit the stunned myocardium more quickly.\(^3\) A recent study comparing an implantable left ventricular assist device (LVAD) with IABP after PCI for STEMI patients in shock demonstrated some short term (hours to days) hemodynamic benefit, but this LVAD device resulted in severe complications rendering it a not usable device.\(^4\) Routine periprocedural implantation of an IABP may reduce adverse events in elective high-risk PCI.\(^5\) Therefore, routine periprocedural left ventricular support with a more potent left ventricular assist like device may offer even more benefit and may be feasible.\(^6\) The Impella technique is basically a micro-axial rotary blood pump that expels blood from the left ventricle into the ascending aorta, unloading the left ventricle much like an assist device. There are two CE marked Impella Recover systems for femoral introduction. The larger Impella Recover LP 5.0 system needs femoral surgery for placement due its 21 Fr size and its LD version has been mainly used for patients after cardiac surgery.\(^7-10\) The other Impella Recover LP 2.5 system device can be introduced through a femoral percutaneous approach (12 Fr) and can deliver an output of up to 2.5L/minute. For comparison, an IABP only delivers an output of 0.5L/minute. There is only one human case report described with the Impella Recover LP 2.5 system device.\(^11\) We report safety and feasibility using the Impella Recover LP 2.5 device in 19 elective high-risk PCI cases.

Methods

From October 2004 through August 2005 we have used the Impella Recover LP 2.5 system device (Impella 2.5 LP device) in 19 high-risk PCI patients. These patients were selected after a joint meeting with our cardiothoracic surgeons. All patients were very poor candidates for surgery, as shown in table 1. To assess feasibility and safety we recorded the following items: accessibility through the contra lateral (other than the PCI catheter) femoral artery, successful positioning of the Impella 2.5 LP device into the left ventricle, successful engaging the guiding PCI catheters into the left or right coronary artery, stability of either the guiding catheter and the Impella 2.5 LP device. We also assessed subjective pain of the patient during the procedure in the limb distal to the access site (leg) of the Impella 2.5 LP device. We recorded device related periprocedural femoral bleedings, hemoglobin levels and need for blood transfusion. Echocardiograms were performed in all patients before implantation of the Impella 2.5 LP device to exclude left ventricular structures, such as thrombus, especially considering...
the patients that were selected. Echocardiograms were also performed to monitor the effect of the Impella 2.5 LP device through the aortic valve on aortic valve regurgitation. In all patients, except for one, the Impella 2.5 LP device was removed after the procedure. Therefore, maximum left ventricular support time was 120 minutes.

For femoral closure, we used manual compression in the first 4 cases. In all other cases we used the double Perclose device technique to close the accompanying 13 Fr sheath access of the “Impella-femoral artery”. We first introduced a 6 or 7 Fr sheath to check LV accessibility through the femoral artery. If so, the 13 Fr sheath was placed after positioning both sets of Perclose sutures with a 90° angle for hemostatic control after extraction of the Impella 2.5 LP device. For the 6 Fr guiding access we used a single Perclose device.

Results

Patients who were treated with the assistance of the Impella 2.5 LP device constituted a high-risk patient group. The majority was older than 60 years (84%) and had a previous myocardial infarction (74%). Fifty three percent of the patients had diabetes mellitus. All patients had a left ventricular ejection fraction (EF) ≤40% and 12 patients (63%) had an EF ≤ 25%. In 10 (53%) patients, we performed a PCI of the left main coronary artery or of the last remaining vessel. Multivessel PCI was performed in 7 (37%) patients and in 7 (37%) patients more than 1 intracoronary stent was implanted. Successful passage through the femoral artery and implantation into the left ventricle of the Impella 2.5 LP device was achieved in all 19 patients. Furthermore, in all patients the guiding catheter was successfully engaged and remained stable during the procedure. No patient experienced limb pain during Impella 2.5 LP device operation. In short, no patients experienced important device related complications associated with the implantation and operation of the Impella 2.5 LP device. Only one patient had a large haematoma after the procedure, with a significant decrease in haemoglobin levels and the need for blood transfusion; local compression resolved the bleeding. One other patient required manual compression after an unsuccessful Perclose closure. All other 14 patients in which we used the double Perclose closing technique had quick and uneventful hemostasis. Hemoglobin levels were assessed before and after the procedure in 15 patients. In the other 4 patients there were no haematomas and or evidence of blood loss; all had an event free recovery. Mean periprocedural hemoglobin level drop was 0.7± 0.4 mmol/L (range 0.3 - 1.9 mmol/L). A hemoglobin level drop ≥ 1 mmol/L was recorded in 4 patients and one patient required a blood transfusion after the procedure. From all 19 patients, 17 had elective PCI procedures. Two deplorable patients had urgent Impella 2.5 LP implantation and died after 1 day later. In one patient after long and complicated cardiac surgery that could not be weaned from bypass, we implanted the Impella 2.5 LP device as a last resort therapy. The patient died 1 day later. During the period of assist (30 hours) there were no device related complications, as mentioned above and there were no malfunctions of the
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device. In another 79 year old patient in cardiogenic shock with imminent multi organ failure, we performed a last remaining vessel PCI procedure with Impella 2.5 LP device support. The patient died 1 day after the procedure due to full blown multi organ failure. We experienced some difficulty in one patient with an extreme tortuous peripheral arterial trajectory, but we could pass the Impella 2.5 LP device catheter using the Back-up Meier 0.035 inch wire, as a with buddy wire, through the 13 Fr sheath. In one patient screened for Impella 2.5 LP device support, the pre-procedural echocardiogram revealed an intracavitary thrombus and therefore disqualifying the patient for this kind of LV support.

A total of 12 patients had evaluation of aortic valve regurgitation during Impella 2.5 LP device operation, 11 with echocardiograms and one with an ascending aorta angiogram. We found no important increase or new presence of aortic regurgitation in all patients with pre- and per-procedural assessment of aortic valve regurgitation (Table 2).

Discussion

This preliminary experience showed that periprocedural left ventricular support using the Impella 2.5 LP device is safe and feasible. In fact, until now we have not experienced any serious complication using this CE marked device in elective high-risk PCI cases. Before accepting the abovementioned statement, two important questions need to be answered. First, is the patient population really a high-risk patient group? Secondly, are there no drawbacks using the Impella 2.5 LP device? We believe that our patient population was truly a high-risk group. All patients were poor or no candidates for surgery. Most patients were old, had diabetes mellitus and previous myocardial infarcts with very poor left ventricular function and underwent unprotected left main or last remaining vessel PCI procedures.

Although implantation of the Impella 2.5 LP device appears feasible and safe, its implantation requires more care, time and effort when compared with an IABP catheter implantation. The Impella 2.5 LP device, which is rather soft with a pig-tail at its end, surprisingly, encounters little problems in passing through the most complex peripheral arterial tortuous trajectories. After LV insertion of the guide wire, necessary for LV introduction of the Impella 2.5 LP device, careful handling is warranted for the guide wire not to be pulled from the LV. If this occurs, reintroduction of the rather flexible 0.014 inch guide wire, without the use of another (usually JR4) catheter, is seldom successful and this leads to a longer implantation time.

After successful placement of the Impella 2.5 LP device in the LV, no important complications have occurred in our experience. The PCI procedures were then performed successfully without any additional delays. We did not compare the Impella 2.5 LP device with (or stand-by) IABP in this setting, which was common practice in these procedures. However, it is our experience that we were able to perform these high-risk procedures
with more time and less discomfort for the patient during balloon inflations in these patients with very poor LV function. In fact, we have incorporated the Impella Recover 2.5 LP device in our clinical practice, at least as an alternative to the IABP, especially in those patients with very poor left ventricular function (EF <25%) and complex unprotected left main coronary artery or last remaining vessel PCI procedure. There was only one significant post-procedural femoral bleeding, resolved by manual compression, with a hemoglobin level decrease of 1.9 mmol/L and need for blood transfusion. We used the double Perclose technique in almost all patients and encountered no problems in achieving hemostasis, except for one patient needing additional manual compression. However, some training with a single Perclose is advisable before using this double technique.

Another important point is the pre-procedural echocardiogram. From all patients whom we planned for Impella 2.5 LP device supported PCI, only one had an intracavitary thrombus. This may therefore seem not important but we believe that a pre procedural echocardiogram is a prerequisite before Impella 2.5 LP device usage, especially since those patients who may qualify for this kind of support are more prone to have intracavitary thrombus.

Although this technology appears to be promising, and is feasible and safe to be used in elective high-risk patients, the question remains: is 2.5L/minute enough for patients that are in deplorable hemodynamic states. Retrospectively, it may not have been enough for the post cardiac surgery patient in cardiogenic shock. Also, the high-risk PCI patient in imminent cardiogenic shock that died due to multi organ failure might have had benefit from the support of 2.5L/min if we had left the device in place for an additional longer period rather than only during the procedure.

Therefore these encouraging findings, concerning the safety and feasibility of the Impella recover LP 2.5 system as an assist device in elective high-risk PCI procedures, must be confirmed by larger studies, longer assist times and in other patient categories.

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References


