Background text technical press

Impella® heart pumps – effective support for the high-risk percutaneous coronary intervention (PCI)

Circulatory support pump systems, such as the Impella heart pump, may enhance the safety and efficacy of the percutaneous intervention (PCI) in high-risk patients. Impella systems may also be used during a PCI in patients with multi-vessel disease, hemodynamic impairments, comorbidities, or if they are considered inoperable.

Increasing life expectancy will lead to a rise in the number of elderly heart patients indicated for a PCI [1]. Comorbidities such as diabetes mellitus, renal function impairments and frailty are also on the rise. In addition, older coronary patients are frequently considered inoperable due to difficult anatomical situations, or an impaired left ventricular function. Even though high-risk patients may greatly benefit from an operation or coronary intervention (PCI), the associated risks often result in an intervention not being performed [2]. However, the prognosis of patients without intervention is considerably worse compared to those that have already been surgically treated [3]. With the help of the Impella heart pump it is possible to perform a so-called “Protected PCI” in high-risk patients thus reducing the risk of the procedure and improving the prognosis of the patient.

Protected PCI with Impella heart pumps

Some Impella heart pumps are indicated for use during high-risk percutaneous coronary interventions (PCI) as well as for left ventricular unloading following a percutaneous coronary intervention (Post-PCI). The Impella 2.5® heart pump is the smallest and least invasive percutaneous heart pump which supports the left ventricle. In Europe, the system has been certified since February 2004. In the US, the pump has been in use since the beginning of the PROTECT-I study in 2006 for the treatment of hemodynamically stable patients with severe coronary disease and reduced left ventricular ejection fraction who have undergone an elective or acute PCI.
How does the heart pump work?

The Impella 2.5® heart pump is percutaneously inserted through the femoral artery generally via a catheterization procedure. It is then advanced via the aorta and the aortic valve into the left ventricle. The heart pump delivers up to 2.5 l of blood per minute via a cannula from the left ventricle to the ascending aorta. This takes place continuously and independent of the heartbeat, so that blood is being pumped into the aorta even during the resting period between the contractions of the ventricle.

Left ventricular support has several favorable physiological effects:

- The end-diastolic volume and the end-diastolic pressure in the left ventricle as well as the pulmonary capillary pressure are reduced by the continuous function.
- There is a decrease in the cardiac workload due to reduced left ventricular wall tension, which in turn decreases the oxygen demand.
- The mean arterial pressure increases due to the continuous left ventricular support, thus improving coronary artery perfusion.

The Impella heart pump provides safety in several ways. It protects the patient from hemodynamic instability during the PCI, arising out of repeated reversible myocardial ischemias due to temporary coronary occlusions. In addition, it reduces the oxygen demand of the heart whilst simultaneously improving the oxygen supply. This will also protect the myocardium [4]. The heart can recover and its myocardial pump function can be restored as far as possible as a result of the reduced ventricular workload and the improved oxygen supply to the heart muscle. Last but not least, it provides the physician with the assurance of being able to perform the entire Impella-supported “Protected PCI” intervention with minimum risk and under safe conditions.
Facilitation of complete revascularisation

A further criterion for the use of the Impella® device is the goal of the treating physician to achieve an as complete revascularization as possible, thereby minimizing the myocardial infarct size and improving the patient’s quality of life [5].

The support with the Impella 2.5 also protects against acute renal failure during a high-risk PCI, even despite the presence of chronic kidney disease and a decrease in the pumping ability of the heart. [6]. A “Protected PCI” gives the treating physician enough time to completely open as many vessels as possible, thereby achieving complete revascularization [7].

Which patients benefit from Impella heart pumps?

Hemodynamic support during the PCI using an Impella heart pump (“Protected PCI”) should be particularly applied in patients with complex coronary diseases, e.g. multi-vessel disease, left ventricular dysfunction, instable angina and a high risk of temporary ischaeas. The use of an Impella catheter can also be favorable for patients at an advanced age, or patients with comorbidities such as diabetes mellitus, renal insufficiency, impaired lung function, cardiac insufficiency, overweight patients and frail patients [7]. The Impella heart pump can also be used to unload the left ventricle following a percutaneous coronary intervention (Post-PCI).

Studies demonstrate the advantages of Impella 2.5 heart pumps

Efficacy and safety of “Protected PCI” with the Impella 2.5 system has been demonstrated in various studies in more than 1600 patients. The first of these studies included the PROTECT-I study with 20 patients, demonstrating that the Impella heart pump is easy and safe to use, promoting excellent hemodynamic support [8].

The PROTECT-II study examined the left ventricular support with the Impella 2.5 heart pump in comparison with the intraaortic balloon pump (IABP) in 452 high-risk patients undergoing elective, complex PCI. Compared to the IAB group, the combined endpoints “Major Adverse Events”(MAE) and “Major Adverse Cardiovascular and Cerebral Events” (MACCE) were significantly lower in the Impella 2.5 group after 90 days. The MAE decreased from 51% to 40% (p=0.023), the MACCE from 31% to 22% (p=0.033), corresponding to a reduction of MACCE incidence of 29% [9]. The Impella 2.5 heart pump also lowered the risk of another revascularisation within 90 days by 52% compared to the IAB (6% vs. 13 %; p=0.024) and reduced hospitalisation by 2 days (7 vs. 9 days; p=0.008). 58% of the patients in the study improved their NYHA classification III and IV into a more favorable function class (p<0.001).
Proven under real word conditions
Data from the USpella Registry (which is now being continued as global cVAD Registry) also demonstrate the feasibility and safety of Impella 2.5 heart pumps under real world conditions, i.e. in clinical practice. Revascularization was successful in 99% of the patients, improving the ejection fraction from 31% to 36% (p < 0.0001). In 51% of the patients, the status improved by more than one NYHA class (p < 0.001). After 30 days, the MACCE rate was 8% and the survival rate 96% [10].

References

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