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Review

Impella ventricular support in clinical practice: Collaborative viewpoint from a European expert user group

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ABSTRACT

Mechanical circulatory support represents an evolving field of clinical research and practice. Currently, several cardiac assist devices have been developed but, among different institutions and countries, a large variation in indications for use and device selection exists. The Impella platform is an easy to use percutaneous circulatory support device which is increasingly used worldwide.

During 2014, we established a working group of European physicians who have collected considerable experience with the Impella device in recent years. By critically comparing the individual experiences and the operative protocols, this working group attempted to establish the best clinical practice with the technology. The present paper reviews the main theoretical principles of Impella and provides an up-to-date summary of the best practical aspects of device use which may help others gain the maximal advantage with Impella technology in a variety of clinical settings.

1. Background

The use of percutaneous mechanical support has increased over the last decade. Given the recent data on the questionable value of intra-aortic balloon pump (IABP) particularly in acute post-infarction shock [1–4], leading to a downgrade in the ESC guidelines for routine use (class III A), an expectation of the possible clinical value of newer devices which afford greater circulatory support has increased. Among the most common of these are the extracorporeal systems, either left atrium to aorta (TandemHeart) or right atrium to aorta (Extracorporeal Membrane Oxygenation (ECMO)) and the Impella transaortic intraventricular pump. The Impella device was approved in Europe (2005), Canada (2006), Latin and South America (2008) and recently in China (2013) for a variety of indications including high risk percutaneous coronary intervention (PCI) and cardiogenic shock. It is estimated that in the last eight years, over 8000 patients have been supported outside the United States of America (US). In the US, the device has been used since 2006 in the Protect I FDA trial for high risk PCI and was granted 510(k) clearance in 2008 [5]. Currently, more than 800 US hospitals have supported over 20,000 patients.

Although first introduced in Europe, there is remarkable variation in indications for use and type of devices used among different countries (Fig. 1). The reasons for such disparity may be partially due to different reimbursement conditions across the region but also uncertainty on best applications for the various devices in different clinical scenarios. This working group, whose members jointly represent an experience of over 1000 European Impella implants, aims to give a state-of-the-art overview, enabling better understanding of the basic fundamentals of the Impella technology and application.

2. Impella technical data

Impella technology is based upon a miniaturized axial pump built on a 9 F catheter. The inlet cage allows for blood to be aspirated from the

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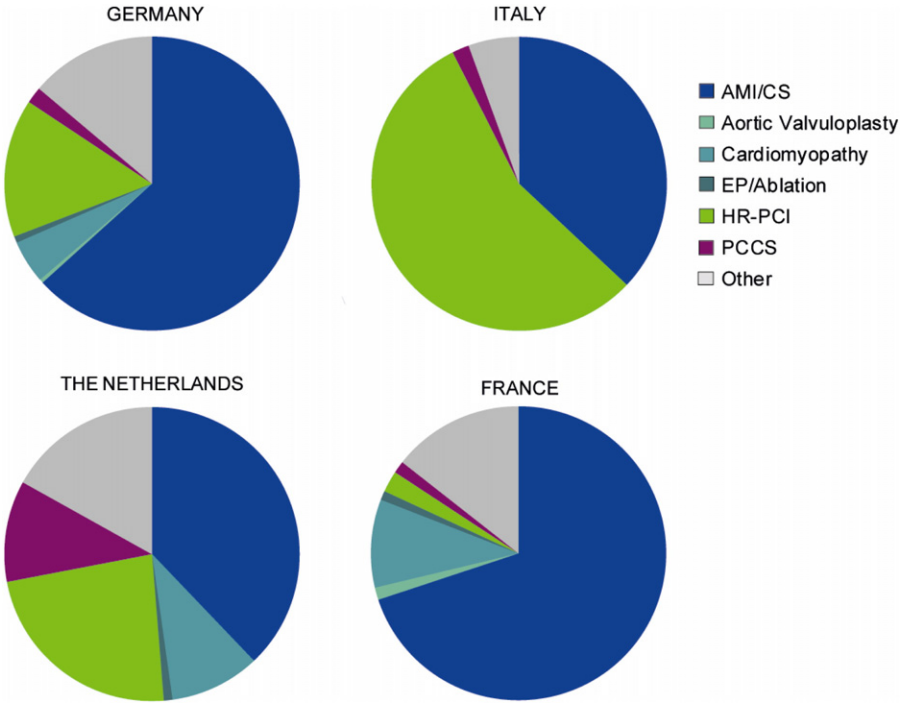

Fig. 1. Geographic distribution of Impella per indication comparing Germany, France, The Netherlands and Italy.

left ventricle (LV) into the cannula portion of the pump and then expelled above the aortic valve into the ascending aorta. The power connections for the pump motor and sensors are contained in the 9 F guiding catheter. The end of the catheter is connected to an external console which consists of an integrated controller for the pump and purge system (Fig. 2) The different Impella catheter models vary in size, insertion technique and maximum flow capabilities. These pump characteristics are listed in Table 1.

3. Physiology of Impella support

There are three key physiologic effects of left sided Impella support. First and foremost, the Impella unloads the left ventricle, reducing LV end diastolic pressure and LV wall tension and, consequently, decreasing LV work and myocardial oxygen demand [4]. The characteristic change of the left ventricular pressure volume curve predicted by computational physiology is shown in Fig. 3 and corresponds well to physiologic observations.

Secondly, Impella operation results in an increase in mean arterial pressure, diastolic pressure, cardiac output and thus cardiac power output, leading to improved systemic perfusion and increased coronary flow. Impella support has been found to improve coronary perfusion through the combined mechanism of increased aortic pressure working synergistically with LV unloading and decreased wall tension [4,6].

Third, Impella leads to a decrease in pulmonary capillary pressure and a secondary reduction in right ventricular afterload.

4. Impella support and therapeutic effect

Impella technology is load dependent but not rhythm dependent which leads to a number of physiologic implications. Pump flow is afterload sensitive in that forward flow through the pump decreases with increasing ventriculo-aortic pressure gradient. This sensitivity accounts for the characteristic phasic motor current fluctuations during the cardiac cycle with highest pump flow and motor current achieved during systole when the gradient between LV and aorta is minimal.

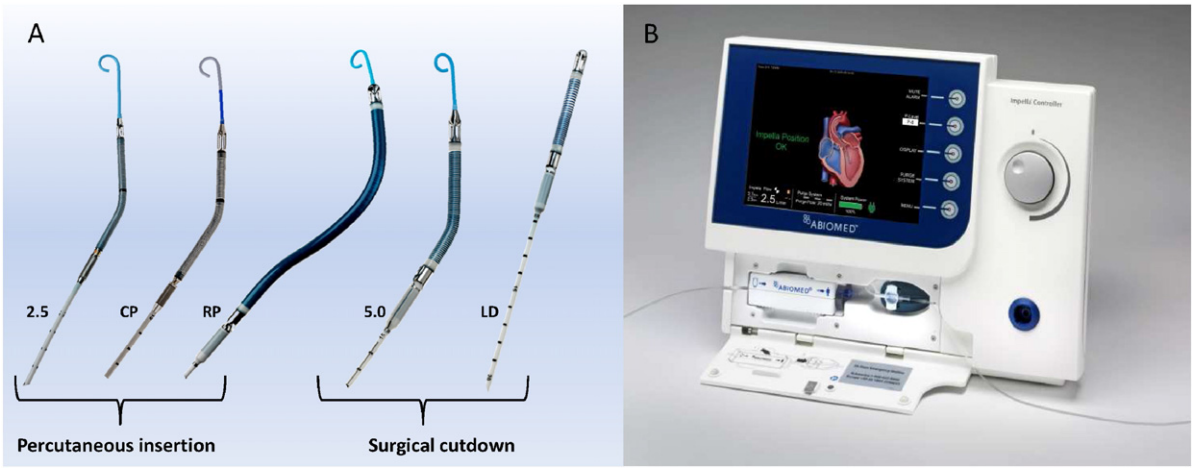

Fig. 2. The Impella (a) Catheter pumps and (b) Automated Impella Controller.