SAFETY AND EFFECTIVENESS OF THE IMPELLA CP PERCUTANEOUS CIRCULATORY SUPPORT IN CARDIOGENIC SHOCK

Spanish full text

Introducción: The mortality rate due to cardiogenic shock still remains very high (50-80%), despite early coronary revascularisation with currently available percutaneous mechanical circulatory support devices, such as the intra-aortic balloon pump and short-term mechanical ventricular assistance devices (Extracorporeal Membrane Oxygenation or Levitronix), whose main limitation is the low cardiac output they produce (<0.5 L/min). The Impella CP (Impella 4.0), an improved version of the Impella 2.5, is a ventricular assistance device equipped with a continuous flow pump, which can be implanted percutaneously (via the femoral vein), and which is capable of producing a cardiac output of up to 4 L/min. The Impella 4.0 device has been granted premarket approval by the FDA for continuous use (<4 days) in patients in cardiogenic shock in the 48 hours following an acute myocardial infarction, cardiac surgery resulting from left ventricular heart failure that does not respond to conventional medical treatment, acute myocarditis, or even as a bridge-to-transplantation. This device also received CE mark approval in April 2016 for use in periods of no more than 5 days.

Aim: To determine the safety and effectiveness of the Impella CP percutaneous circulatory support in cardiogenic shock.

Methods: A systematic review was carried out of the literature from different sources, such as medical literature databases including the Centre for Reviews and Dissemination (CRD), databases including HTA (Health Technology Assessment), DARE (Database of Abstracts of Reviews of Effectiveness), Cochrane Library Plus, Medline (PubMed), Embase (OVID) and the ISI Web of Science (Web of Knowledge), together with databases from research projects that are currently ongoing, such as ClinicalTrials.gov. The articles were selected by two researchers independently, based on a previously defined inclusion/exclusion criteria. Finally, the information was summarised in evidence tables, and the methodological quality of the studies was evaluated independently by two researchers using the checklist that was specifically designed for case series by the *Institute of Health Economics* (IHE).

Results: The literature search produced a total of 33 references. Based on the selection criteria, 11 primary studies were included, of which 5 were case series, and 6 were single case studies. The use of Impella CP ventricular assistance devices is associated with the appearance of different serious adverse events, such as haemolysis requiring transfusion, migration of the device, and intracraneal haemorrhage, amongst others. With regard to its effectiveness, the 30-day survival rate was around 36% in one study, while in another it was 65% and 60% at 60 and 90 days respectively. In the majority of the studies, the survival of patients was associated with carrying out a heart transplant after removing the Impella CP device.

Conclusions: The Impella CP ventricular assistance device could be useful for maintaining and/or recovering haemodynamic stability in patients with cardiogenic shock; however, due to the existence of adverse events associated with its use, the indication of these devices should be made in subgroups of selected patients.