**Table VIs - Studies of secondary literature (HTA Report, Systematic Reviews and Meta-analysis)**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **N°** | **FIRST  AUTHOR** | **TITLE** | **YEAR** | **JOURNAL/****INSTITUTION** | **STUDY TYPE** | **N° of considered STUDIES** | **INTERVENTION** | **CONTROL** | **OUTCOME** | **RESULTS** | **CONCLUSION** |
| **1**  | **Batsides [18]** | Outcomes of Impella 5.0 in Cardiogenic Shock. A Systematic Review and Meta-analysis  | 2018  | Innovations   | Systematic Review and Meta-analysis  | 6  | Impella 5.0  | nd   | Survival to discharge  | The use of Impella 5.0 was associated with a survival to next therapy rate of 73.5% in patients supported for acute on chronic decompensated heart failure and a 30-day survival rate of 68.6%.  | Impella 5.0/LD is associated with very favourable survival outcomes and a high rate of myocardial recovery in CS patients.   |
| **2**  | **Den Uil [19]** | Short-term mechanical circulatory support as a bridge to durable left ventricular assist device implantation in refractory cardiogenic shock: a systematic review and meta-analysis  | 2017  | European Journal of Cardio-Thoracic Surgery  |  Systematic Review and Meta-analysis   | 39   | MCS (IABP, Impella 5.0, TandemHearth, ECMO, CentriMaag)  | Other MCS  | All available outcome  |   | Thirty-nine studies, mainly registries of heterogeneous patient populations (n = 4151 patients), were identified. Bridge to durable LVAD was most frequently performed in patients with end-stage cardiomyopathy. The study concludes that temporary MCS can be used to bridge patients with cardiogenic shock towards durable LVAD.   |
| **3**  | **Schultz [20]** | Meta-Analysis of Outcomes of Axillary and Subclavian Implanted Impella 5.0 for Cardiogenic Shock  | 2019  | Journal of Cardiac Failure  | Meta-analysis  | 10  | Impella 5.0  | nd  | Survival Adverse effect  |   | Ten studies included in the final analysis (n=125 patients) evaluated 30-day survival and adverse events. In conclusion the axillary or subclavian Impella 5.0 has a relatively low adverse event rate and can be used for longer periods of time than others temporary support devices.  |
| **4**  | **Health Evidence Review Commission  (HERC) [21]** | Temporary Percutaneous Mechanical Circulatory Support with Impella Devices  | 2018  | Health Evidence Review Commission (HERC) (Draft for public Consultation)  | Systematic Review  | 7   | Impella 5.0  | IABP, Impella 2,5/CP, TandemHeart  | Survival, Major adverse effect,  |   | Based on a small number of comparative studies, Impella 5.0 does not appear to improve clinical outcomes for both indications (cardiogenic shock and percutaneous coronary angioplasty with high risk) and, in cardiogenic shock, appears to be associated with a greater number of adverse events as compared to IABP. Thus, HERC does not recommend the reimbursement of Impella 5.0 for either of the two indications.  |
|  **5**  | **Esfandiari [22]** | The Impella® Percutaneous Ventricular Assist Device  | 2009  | Report HTA of the McGill University Health Centre  | HTA Report  | 45   | Impella 5.0/2.5/CP  |   | Survival to sicharge, 30-day survival, hemodynamic stability  |   | The Impella 5.0 device is clearly more clinically effective than IABP or ECMO. It is also less traumatic and less expensive than other available ventricular assist devices. •  the use of Impella 5.0 can be cost saving. • Case selection is critical. Used too early is unproductive and expensive. Used too late, when pump failure, end-organ failure or brain death are irreversible its use is wasteful. • Review of current use of this technology at the McGill University Health Centre indicates that utilisation is restrained and appropriate.  |
|  **6**  | **Lee [23]** | Percutaneous Ventricular Assist Devices: A Health Technology Assessment  | 2017  | Report HTA - Health Quality Ontario  | HTA Report  | 18  | Impella 5.0 / 2.5  | nd  | Mortality, hemodynamic stability, major adverse events, bleeding complications, vascuolar complications,  | No randomized controlled trials or prospective observational studies with a control group have studied Impella CP and Impella 5.0 (other models of the device) in patients undergoing high-risk PCI or patients with cardiogenic shock.   | On the basis of evidence of low to very low quality, Impella 2.5 devices were associated with improved hemodynamic stability, but had mortality rates and safety profile similar to IABPs in high-risk PCI and cardiogenic shock. Our cost-effectiveness analysis indicated that Impella 2.5 is likely associated with greater costs and fewer quality-adjusted life years than IABP.  Their budget impact analysis revealed that, in the first 4 years, publicly funding Impella 2.5 and Impella 5.0 could result in incremental spending for high-risk PCI ($1.3–$5.3 million per year) and cardiogenic shock ($1.6–$6.3 million per year)  |
|  **7**  | **Emergency Care Research Institute  (ECRI) [24]** | Impella 5.0/LD (Abiomed, Inc.) for Treating Left Ventricular Heart Failure  | 2017  | ECRI Institute  | HTA Report  | 6   | Impella 5.0  | ECMO, Impella 2,5  |   |   | Available evidence is insufficient to draw conclusions about the comparative safety and effectiveness of the Impella 5.0 compared to other temporary circulatory support devices for treating left ventricular heart failure.   |

*Legend:*

LV (left ventricle), ECMO (extracorporeal membrane oxygenation), ECRI (Emergency Care Research Institute) LVAD (left ventricular assist device), MCS (mechanical circulatory support), CS (cardiogenic shock), HTA (Health Technology Assessment), IABP (Intra-aortic balloon pump), HERC (health evidence review commission), PCI (percutaneous coronary interventions), GRADE (Grading of Recommendations Assessment, Development, and Evaluation),