European best practice: a step forward to optimize Impella-protected percutaneous coronary intervention to improve outcome after high-risk coronary interventions

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Percutaneous mechanical circulatory support (MCS) with the Impella system is being increasingly used in patients who are at high surgical risk and have hostile coronary artery disease which is unsuitable for coronary artery bypass graft surgery. Medical therapy and elective or semi-elective high-risk percutaneous coronary interventions (PCIs) are often the only treatment option for these patients. The concept of protected, high-risk PCI is currently supported by one randomized trial, registry data, and consensus documents with conflicting results. However, in daily clinical routine, the use of Impella MCS is widely adopted due to the haemodynamic support which allows the operator to concentrate on coronary intervention in complex disease with concomitant complete revascularization. When taking a deep dive into literature, data, and personal expert opinions, it becomes apparent that operators can be divided into MCS believers or non-believers. Believers mainly argue with constant and reliable haemodynamics throughout the procedure with the possibility of achieving complete revascularization and concomitant renal protection while non-believers mainly argue with a lack of hard outcome data and increased bleeding and vascular complication rates. Interestingly, the overall goal for all operators is to achieve optimal lesion preparation, have minimal complication rates, and achieve an excellent outcome for the patient. The route to this goal, however, is different and the ongoing PROTECT IV study, a randomized trial of high-risk surgical turn-down patients that are randomized to receive either Impella support or none/IABP support will finally answer these questions.

However, due to the broad clinical usage of the Impella system, a standardized approach for patient selection, device insertion, monitoring, and its post-procedural management is urgently needed, since these factors have a huge impact on complication rate and outcomes. Since MCS is only a supportive device, e.g. allowing for stable haemodynamics throughout a procedure, handling of the device and device-associated complication rates need to be as low as possible. In this context, it is important to mention that MCS itself cannot solve interventional problems of unexperienced operators but can make problems even larger: If the operator is not familiar with large bore access or skilled enough to master the complexity of an intervention, MCS support per se cannot help to achieve a favourable PCI result. Access-site complications can be devastating and life-threatening and coronary complications such as acute vessel occlusion and perforation cannot be solved with an MCS device.

Interestingly, a variety of different techniques and approaches to prevent complications and improve outcomes have been developed in recent years in various centres worldwide. A non-representative survey of various operators showed intra- and inter-individual, operator- as well as centre-based deviations in major aspects of the procedure. The learning curve over years has transferred in lower complication rates as seen recent registry data (e.g. PROTECT III). When focusing on standards and safety measures, centre-specific complication rates can be as low as 0%.
In order to overcome the individual learning curve and the typical ups and downs when first using a novel device in interventional cardiology a number of experienced centres shared their optimal treatment strategies with the Impella system. Here, we present the results of the key essentials, regarded as best practice in Europe (Figure 1).

We will focus on aspects of optimized patient selection addressing the pivotal question of choosing the right patient of MCS support in non-emergent conditions. Guidelines and study results lead our decision-making process but still an individual assessment may be necessary according to the patient-specific clinical situation as
well as the operator- and site-specific conditions. When
deciding for a protected procedure, the optimal
pre-procedural clinical work-up will pave the road for
a successful outcome. Knowing the patient’s individual
problems is often the solution for a successful treat-
ment. Therefore, aspects of pre-, peri-, and post-
procedural anticoagulation will be discussed and
standards provided for patients with PCI and micro-
axial flow pump support. Handling the patient in the
cath lab and achieving optimal or complete revascular-
ization is the centrepiece of all and the key point during
a protected PCI procedure. A vast number of studies
have addressed these issues and still we are debating
about the degree of revascularization and how to
achieve it. One of these articles will debate these as-
pects and provide clinical standards. Finally, as men-
tioned, the device is in place to achieve optimal
results and should not be the source of complications.
Bail-out and complication management strategies are
therefore of pivotal importance in order to achieve
the best possible result if problems occur. With current
techniques and materials, most complications can be
resolved if standards are in place, materials are avail-
able and operators are firm in applying bail-out techni-
quies if needed. Best practices try to help solve clinical
problems—the case vignettes give practical insights
and help to establish the proposed best practice in
the individual mind and cath lab.

We hope that this series of articles on best practice,
written by several experts throughout Europe, will be
of interest to the readers of the European Heart Journal.

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Data availability
All research data is available through the corresponding
author and can be used for future research.