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ORIGINAL ARTICLE

The *intelligent* Impella: Future perspectives of artificial intelligence in the setting of Impella support

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Abstract

Aims Artificial intelligence (AI) has emerged as a potential useful tool to support clinical treatment of heart failure, including the setting of mechanical circulatory support (MCS). Modern Impella pumps are equipped with advanced technology (SmartAssist), enabling real-time acquisition and display of data related to both pump performance and the patient's haemodynamic status. These data emerge as an 'ideal' source for data-driven AI applications to predict the clinical course of an ongoing therapeutic protocol. Yet, no evidence of effective application of AI tools in the setting of Impella support is available. On this background, we aimed at identifying possible future applications of AI-based tools in the setting of temporary MCS with an Impella device.
Methods We explored the state of research and development at the intersection of AI and Impella support and derived future potential applications of AI in routine Impella clinical management.
Results We identified different areas where the future implementation of AI tools may contribute to addressing important clinical challenges in the setting of Impella support, including (i) early identification of the best suited pathway of care according to patients' conditions at presentation and intention to treat, (ii) prediction of therapy outcomes according to different possible therapeutic actions, (iii) optimization of device implantation procedures and evaluation of proper pump position over the whole course of support and (iv) prevention and/or rationale management of haemocompatibility-related adverse events. For each of those areas, we discuss the potential advantages, challenges and implications of harnessing AI-driven insights in the setting of MCS with an Impella device.
Conclusions Temporary MCS with an Impella device has great potential to benefit from the integration of AI-based tools. Such tools may indeed translate into groundbreaking innovation supporting clinical decision-making and therapy regulation, in particular in complex scenarios such as the multidevice MCS strategy.

Keywords artificial intelligence; cardiogenic shock; Impella; machine learning; temporary mechanical circulatory support

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Introduction

Modern Impella technology (Abiomed, Danvers, MA, USA) comprises different pumps for temporary mechanical circulatory support (tMCS) of both the left and right ventricles.[1] Current evidence suggests the efficacy of Impella tMCS to protect the myocardium during high-risk percutaneous coronary interventions and/or promote myocardial recovery following acute heart failure/cardiogenic shock.[1–5]

Since the introduction of the first Impella device in clinical practice, both the pump and the external control unit have undergone great technological innovation. In particular, over the years, we have seen the introduction of progressively more sophisticated pumps as well as interactive user interfaces, allowing not only to set the device operating parameters but also to monitor in real time the system performance.

Specifically, the new Automated Impella Controller (AIC) is equipped with advanced software able to automatically recognize different features of pump malfunction and communicate specific automated alarms. In addition, all Impella pumps come with SmartAssist technology, enabling a real-time display of pump metrics, device placement and the patient's haemodynamic status.[6] These include feedback on pump motor current and pressure difference between the pump inlet and outlet, as well as left ventricular (LV) systolic and end-diastolic pressure, cardiac output and cardiac power output, and pulmonary artery, central venous pressures and the pulmonary artery pulsatility index, in the left- and right-sided Impella, respectively. Those tools provide clinicians the chance for immediate and, importantly, *rationale* intervention to restore correct pump support, as well as evaluation of correct positioning, management and, eventually, weaning of the device.[7,8]

Nevertheless, although modern Impella integrated technology gives clinicians a great deal of technical and clinically relevant data, there are still enormous challenges with tMCS, from device selection and definition of optimized therapeutic approaches (escalation/de-escalation strategies, multidevice support, etc.) to the prediction of outcomes in the different possible scenarios. This is basically due to the intrinsic complexity of the clinical setting, the multitude of concomitant therapeutic efforts and the dynamic patient-response and pump-patient interplay, which continuously change over the course of support, especially in the case of multidevice support therapy.

In recent years, with the exponential growth of artificial intelligence (AI) research applied to medicine, a wide range of AI-powered applications have been developed in various fields of heart failure, including MCS.[9] In particular, machine learning (ML) algorithms have been proposed for candidate selection, patient-risk stratification and the prediction of complications and outcomes.[10,11]

Given the peculiar features and capabilities of ML and the evidence that in the field of tMCS, there is a constant need for dynamic risk assessment and adaptive decision-making, AI-based tools hold the potential to introduce true, groundbreaking advancements in the clinical management of Impella-supported patients. Indeed, the huge set of data continuously provided by the Impella device emerges as an 'ideal' source for data-driven ML applications able to automatically adapt their performance to evolving data points and continuously refine risk stratification/prediction models to the current scenario.[11] Nevertheless, the potential role of Impella integrated technology to give substance to AI-powered tools that may better shape the indications and management of tMCS with Impella remains poorly explored.

In this work, we aimed at identifying possible future applications at the intersection of Impella devices and AI and analysing the potential advantages, challenges and implications of harnessing AI-driven insights into the complex and delicate scenario of tMCS.

AI-predictive model of Impella therapy outcomes

With the SmartAssist technology, several device-related and patient's haemodynamic parameters are displayed by the AIC with the aim of assisting the patient's management. Whether these parameters might replace invasive haemodynamics in Impella patients (which are currently recommended in acute MCS patients)[12] is still not clear. Indeed, the specific contribution to the total cardiac output of the left native heart, in adjunct to pump flow, remains difficult to estimate. Assessing native heart function on tMCS is not straightforward, and echocardiography[13] is also very important for clinical practice, as it might give direct feedback on the effectiveness of tMCS therapy and guide decisions on the next step of care.

Introducing new algorithms to achieve accurate estimation of the patient's cardiac output seems, from preliminary data, theoretically possible thanks to ML technology. The paper by Rüschen *et al*. presents indeed an approach for estimating total cardiac output from the signals provided by the optical pressure sensors mounted on the inlet and outlet of Impella CP.[14] In their paper, Rüschen *et al*. describe that in in vivo tests (pre-clinical animal model of induced acute cardiogenic shock and Impella support), the comparison of the estimated cardiac output with an ultrasonic flow measurement in the pulmonary artery (i.e., the gold standard for invasive blood flow diagnostics in research) showed 95% limits of agreement.[14]

When focusing on the Impella device and its intrinsic unique technology, a further important aspect is that by monitoring pump metrics, as displayed by the AIC, it is possible to derive data related to current patient status and, in turn, predict the trajectory of the adopted therapeutic protocol. Indeed, Unoki *et al*. were able to demonstrate that the motor current of the Impella pump mirrors the degree of unloading of the assisted LV, and this applies both to single-device tMCS with Impella and in the case of multidevice support strategies, such as extracorporeal membrane oxygenation (ECMO) + Impella (ECPELLA).[15] According to this finding, the authors suggested that their proposed method opens the perspective for the development of new algorithms for automated control of Impella support, where the cardiac output is first estimated from device operation data recorded by the AIC and then used as the control variable for automatic closed-loop setting of pump operation (i.e., pump speed, level of support, etc.).[15]

In view of that evidence, we therefore envision a true possibility of introducing AI in the setting of Impella support, as AI applications receiving real-time data from the device console might contribute to (i) determining the contribution of the native heart to the total cardiac output, thus accurately estimating the degree of LV unloading and heart recovery, (ii) automatically setting the best suited level of support to optimize the therapeutic effort and (iii) facilitating clinical decision-making in critical steps of tMCS, such as the identification of optimal timing for de-scalation and weaning. In particular, the finding of a direct relationship between motor current amplitude and the degree of unloading at every P-level during Impella support[15] is very intriguing, as it highlights that the degree of unloading (i.e., a clinical target) can be immediately estimated (and possibly predicted) from Impella operation data (i.e., motor current) or even device console data (P-level). When looking at the literature, the degree of unloading in Impella patients is dictated by clinical needs[16] and escalation/de-escalation algorithms.[17,18] However, the effectiveness and degree of unloading may vary from patient to patient according to the haemodynamic condition, which is, by definition, dynamic, making careful titration of tMCS and frequent re-assessments needed in clinical practice. The possibility of implementing AI algorithms to perform (at least part of) these complex tasks might therefore enhance the definition of optimized—personalized—therapeutic approaches.

Further supporting this future possible application of AI in the setting of Impella support, it should be acknowledged that the device manufacturer (Abiomed Inc., USA) is developing an AI-based algorithm for estimating future evolution and trends of patients' haemodynamic parameters based on the prior 5 min of console data (Impella predictive AI).[19] Target data include, indeed, arterial pressure, stroke volume, LV pressure and cardiac output. Furthermore, Abiomed is studying AI to predict the probability that a patient will recover native heart function and to assist medical providers in determining if an alternative course of action is needed.[19] However, performance data for those tools, either partial or preliminary, have yet to be made available. In our perspective, the combined use of data from the SmartAssist technology together with those recorded by the intensive care unit (ICU) patient's monitor might further enhance the reliability of those algorithms, that is, further expand the number of input variables in the AI-based decision model.

AI-driven Impella digital twin

The development of a 'digital twin' derived from AI systems is emerging as a promising concept to assist clinical decision-making in the setting of cardiovascular disease.[20] A digital twin is a virtual replica (the digital twin) of a real-life patient (the real-life twin) receiving real-time updates of a range of data variables associated with the patient's status and ongoing treatments and personalizing the prognosis according to AI predictions.[19] Specifically, a digital twin is a computational platform running analytical algorithms that extracts and integrates data acquired from multiple sources and analyses these metrics in real time to detect abnormalities, predict trends and patterns and diagnose complications.[20] A digital twin can also be used to virtually test the efficacy of possible alternative treatments and overall optimize the performance of the real-life asset.[20]

Accordingly, a further envisioned possible application of AI in the setting of Impella support is related to the generation of a digital twin platform to virtually test the efficacy of possible different therapeutic scenarios and identify a priori the best suited tMCS strategy according to patients' conditions at presentation and intention to treat. This might be particularly useful in the case of multidevice support strategies [e.g., ECPELLA or Impella + intra-aortic balloon pump (IABP)], where a great need for properly assessing and calibrating LV unloading exists. In our perspective, a computer simulation platform of the MCS-assisted patient's cardiovascular system (the digital twin) might therefore provide important inputs for an AI-based predictive algorithm of optimized directed interventions.

Supporting our perspective, previous papers in the setting of tMCS with the Impella device suggest that available AIC data, eventually combined with data from computer simulation models, can indeed be used to provide predictions of outcomes in Impella-supported patients.

Jelenc and colleagues[21] analysed different LV venting options and atrial septostomy with a simulation computer model developed in Matlab (The MathWorks Inc., Natick, MA, USA). The study compared two different circulatory support devices: (i) the centrifugal CentriMag pump (Thoratec, Pleasanton, CA, USA) and (ii) the Impella 2.5. The main result of the study was the finding of an inverse linear relationship between left atrial pressure and venting. Specifically, while atrial septostomy reduced left atrial pressure but induced stasis in the LV, direct LV venting with Impella avoided blood stasis.[21]

Similar data were provided in the simulation study by Di Molfetta *et al*.,[22] who developed a lumped-parameter model of the cardiovascular system to simulate and compare the haemodynamic scenario of veno-arterial ECMO (VA-ECMO), atrial septal defect and Impella CP. The cardiogenic shock condition of the simulated patient was modelled according to haemodynamic and echocardiographic data. The authors documented better performance by the Impella pump at unloading the LV compared with atrial septostomy, according to an increment in mean arterial pressure up to 67%, a reduction in mean pulmonary arterial pressure up to 8% and a reduction in LV end-systolic volume up to 11% with a reduction of up to 97% of LV cardiac output. Conversely, atrial septal defects reduced left atrial pressure (19%), increased right atrial pressure (22%), increased mean arterial pressure (18%), decreased LV end-systolic volume (11%), increased right ventricular volume (33%) and decreased LV cardiac output (55%).[22]

Two other simulation studies implemented numeric cardiovascular models to compare the unloading effect of the

Impella device compared with the VA-ECMO or IABP. Donker *et al*.[23] implemented a computer simulation of the cardiovascular model of an adult patient with severe, predominant LV systolic heart failure. Simulation results showed that VA-ECMO increased LV loading. When an IABP was used in adjunct to VA-ECMO support, an increase of 5%–10% in pulsatility and LV stroke volume was documented due to a reduction of the afterload, yet pulmonary capillary wedge pressure and LV end-diastolic volume remained unchanged.[23] On the other hand, the Impella device enhanced LV unloading and reduced left atrial pressure (23% decrease of end-diastolic volume and 41% decrease of pulmonary capillary wedge pressure, respectively).[23] In parallel, other interventions of left atrial/ventricular venting were tested, which also led to substantial unloading, though not comparable to Impella.[23] The authors abstained from suggesting clinical recommendations based on their findings but rather stressed the remarkable role of real-time computer simulations to provide quantitative patient-specific clinical measures of LV overload, depending on the degree and type of MCS support.[23]

Consistent findings were also provided by De Lazzari *et al*.,[24] who analysed the LV unloading efficacy of IABP versus Impella as a single device with the CARDIOSIM© software simulator (https://cardiosim.dsb.cnr.it/) in a virtual patient with cardiogenic shock. In line with previous papers, Impella 2.5 led to significant unloading of the LV with a greater reduction in left atrial pressures, LV end-systolic and end-diastolic volumes, LV external work and left atrial pressure–volume loop area compared with IABP.[24] At the same time, the authors underline that the level of improvement driven by IABP and Impella 2.5 was strongly dependent on the simulated pathological haemodynamic scenario, stressing the importance of developing clinically relevant simulation settings that specifically address different patients' conditions.[24]

Of note, consistent advancements towards the development of a reliable computational platform to study the effects of tMCS on cardiac unloading in cardiogenic shock have been recently reported.[25] Also, different works on how to translate numerical tools towards clinical decision support systems in tMCS with ECMO have been reported.[26]

In this regard, we acknowledge that computer model simulations may present limitations, as important pathophysiological elements that play a relevant haemodynamic role in clinical practice are difficult to take into account on a simulated virtual platform (e.g., septal ventricular interaction, changes in right heart function, the effects of positive pressure ventilation, the dynamic effects mediated by vasoactive drugs, etc.), yet we highlight that informative data guiding clinical decision-making can be anticipated by computer models fed with parameters derived from the real-world scenario.

AI-driven evaluation of optimal Impella position

A further technology gap in current Impella technology was prominently highlighted by Baldetti *et al*.[27] Despite the existence of position alarms in the AIC (with SmartAssist technology also providing support for device re-positioning), Baldetti and colleagues reported that some 'types' of Impella malpositioning are not detected by the device software or via standard imaging techniques, that is, fluoroscopy.[27] The authors reviewed data on 109 cardiogenic shock patients supported with an Impella 2.5 or CP and were able to define a specific pattern of Impella malposition ('malrotation') not associated with overt device malfunction or abnormal Impella console tracings (pressure or motor current waveforms as displayed on the Impella AIC) but resulted in suboptimal haemodynamic support and, in some cases, a higher rate of haemocompatibility-related adverse events.[27] Conversely, Baldetti and colleagues demonstrated that Impella malrotation can be identified by echocardiographic evaluation, further supporting evidence accumulated in recent years on the importance of regular echocardiographic monitoring of Impella pump position, starting from the time of implantation.[28,29]

The issue of optimal Impella positioning thus emerges as a suitable situation for ML: Training a model to account for the combination of multiple source data (i.e., AIC data together with data from different imaging modalities) in order to recognize optimal positioning versus pump malrotation might facilitate not only pump implantation but also assessment of proper Impella positioning over the whole course of Impella support.

The 'intelligent' Impella: What else?

Besides the above-cited 'more immediate' areas of possible future application of AI in the setting of Impella support, we identified two further features of tMCS that have great potential to benefit from AI, which are (i) the prevention—or rational management—of haemocompatibility-related adverse events (haemolysis and thromboembolic and haemorrhagic complications) and (ii) the early stratification of patients according to the chance of native heart recovery to promptly identify the best suited pathway of care.

Adverse events related to haemocompatibility negatively impact the outcomes of tMCS. This issue has fuelled great efforts to define and share algorithms and protocols to improve and standardize clinical management in the case of complications.[30] However, addressing haemocompatibility issues in patients with MCS remains very complex, mainly due to the multitude of variables that synergistically concur to the development of adverse events (e.g., patient characteristics, type of mechanical support, blood laboratory values, concurrent medical therapies, etc.) coupled with the great clinical inter-individual variability (e.g., aetiology and degree of shock, patient comorbidities and susceptibility to adverse events, etc.). Consequently, the timing and types of treatment in response to acute adverse events may vary according to institutional practice. In this regard, Van Edom *et al*.[30] collected evidence and experience on the management of haemolysis and bleeding in patients supported with Impella devices and implemented great efforts to provide suggestions and define new, simple algorithms for standardizing the therapeutic response to adverse events.

As a direct consequence of this approach, we envision a potential for AI-powered algorithms to further improve (and standardize) the prevention and management of haemocompatibility-related adverse events, which may result in tangible and valuable inputs for clinical practice. Those algorithms may provide, for example, predictive models for

Table 1 Summary of current evidence in the literature supporting the future application of AI in the setting of Impella support.

Manuscript	Study domain	Key finding
AI-predictive model of Impella therapy outcomes		
Rüschen *et al*. 2019[14]	Pre-clinical animal model of induced CS and Impella support	• The total cardiac output can be readily estimated from the signals provided by the optical pressure sensors of the Impella pump • Online, reliable estimation of the total cardiac output can offer immediate and physiologically relevant feedback regarding optimal pump setting, enhancing positive therapeutic outcomes (e.g., pump speed, P-level, etc.)
Unoki *et al*. 2022[15]	Clinical study on ECPELLA support	• Existence of a direct relationship between the motor current of the Impella pump and the degree of LV unloading at every P-level, also in the case of multidevice support strategies (e.g., ECPELLA) • Potential for the development of new algorithms for automated control of Impella operation (i.e., pump speed, P-level, etc.) based on data recorded by the AIC
https://www.abiomed.com/about-us/news-and-media/press-releases/fda-approves-data-streaming-impella-console-setting-stage-artificial-intelligence[19]	Clinical data retrieved from the Impella console	• AI-based algorithm for estimating future evolution and trends of patients' haemodynamic parameters based on the prior 5 min of Impella console data
AI-driven Impella digital twin		
Jelenc *et al*. 2022[21] Di Molfetta *et al*. 2020[22]	Simulation/computer model	• Combining available AIC data with data from computer simulation models can provide predictions of outcomes in Impella-supported patients
Donker *et al*. 2019[23] De Lazzari *et al*. 2023[24]	Simulation/computer model	• Real-time computer simulations can provide quantitative and patient-specific clinical measures of LV overload • The model is sensitive to the degree and type of MCS support (IABP, Impella, VA-ECMO, IABP + VA-ECMO vs. left atrial/ventricular venting)
Contarino *et al*. 2022[25]	Simulation/computer model	• Computer simulation of the cardiovascular system in patients with CS and Impella support can provide reliable data for clinical decision-making (e.g., predicting the outcome of different possible therapeutic approaches in a patient-specific environment)
Pladet *et al*. 2023[26]	Simulation/computer model	• Computational simulations provide accurate predictive assessments of MCS-related risks and benefits, thus improving complex clinical decisions surrounding MCS allocation and management
AI-driven evaluation of optimal Impella position		
Baldetti *et al*. 2023[27]	Clinical study on Impella-supported patients	• The optimal Impella position can be evaluated by integrating data from the AIC with those from multimodal imaging techniques
Prevention/rational management of haemocompatibility-related adverse events		
Van Edom *et al*. 2023[30]	Clinical study on Impella-supported patients	• Development of a rationale algorithm to standardize anticoagulation management in the case of adverse events (haemolysis, bleeding) while on Impella support
Early stratification of patients according to the chance of native heart recovery		
Luo *et al*. 2022[31] Gutman *et al*. 2022[32] Sardar *et al*. 2019[33] Manlhiot *et al*. 2022[34]	Clinical study on patients with HF/review article	• Integration of AI and clinical data to classify patients according to predicted different outcomes and guide individualized clinical decisions
Kapur 2023[35]	Clinical study on patients with CS	• Mortality in CS patients can be predicted by AI-based models

Abbreviations: AI, artificial intelligence; AIC, Automated Impella Controller; CS, cardiogenic shock; ECPELLA, extracorporeal membrane oxygenation + Impella therapy; HF, heart failure; IABP, intra-aortic balloon pump; LV, left ventricular; VA-ECMO, veno-arterial extracorporeal membrane oxygenation.

haemolysis or bleeding/thromboembolic complications in response to different protocols to titrate the antithrombotic therapy to a single patient-specific profile or ‘quantify’ the patient-specific risk for complications according to the phase of the tMCS and patient-risk profile.

A further unmet need in clinical practice is the inability to accurately categorize patients who receive tMCS for cardiogenic shock with respect to the probability of native heart recovery. Patients on tMCS ultimately go through different pathways of care, depending on whether native heart recovery is achieved or whether they require bridging to heart replacement therapies (i.e., a heart transplant or a durable ventricular assist device). A predictive AI model might represent a breakthrough in the field, enhancing the early identification of such patients’ trajectory according to their clinical characteristics at presentation and/or trends over the early stage of support to ensure each patient’s most beneficial outcome. Of note, supporting our perspective on the clinical implementation of such a tool, different deep learning (DL) models that can successfully integrate clinical data, classify patients according to predicted outcomes and guide individualized clinical decisions have been successfully tested in medical practice, including heart failure.[31–34] Similarly, ML-prediction models of mortality in cardiogenic shock patients have also been developed.[35]

Challenges for the ‘intelligent’ Impella

Despite the growing number of successful reports of AI applied in medical care, the potential of AI in tMCS scenarios has not been demonstrated yet. Several challenges exist indeed to design, implement and finally translate AI into routine clinical practice. Most of those challenges are common to other medical fields (logistical barriers for implementation, the need for strategic investments, the crucial role of the quality of input data to train the models, the implementation of multidisciplinary taskforces, etc.),[11] but there is one that is intrinsic and peculiar to tMCS. Indeed, predictive models in the setting of tMCS should be able to constantly and indiscriminately (especially in the case of a model that receives inputs from multiple data sources) adapt and re-set themselves to the actions implemented by clinicians. The scenario predicted by the model may indeed quickly and consistently change following clinical actions, which are very frequent given that tMCS is a very dynamic scenario.

In particular, when applied to individualized patient stratification, the ability of AI models to provide reliable predictions based not only on the representations of the current clinical state of the patient and available history but also according to physician actions is critical. In their paper, Beaulieu-Jones *et al*. well described how, following examination, the clinician’s beliefs regarding potential outcomes may trigger information on which actions might or might not be implemented. These actions, in turn, influence the patient’s resulting state, and the cycle repeats iteratively.[36] To summarize, the concept of integrating ‘clinician-initiated’ and ‘non-clinician-initiated’ data is essential for effective implementation of AI tools for Impella tMCs.[36]

To date, AI models potentially able to manage the complexity typical of the real clinical world have not yet been validated in the healthcare scenario, and further relevant technological advancements (generative AI) are needed before such a model will be made available at bedside.

Accordingly, we acknowledge that the content of this work is far from providing any recommendation for the use of AI algorithms for clinical application, yet it is intended to trace a possible roadmap for the future implementation and clinical translation of AI in the setting of Impella support.

Conclusions

With the lack of current concrete applications of AI in the clinical practice of Impella tMCS, some major areas of immediate possible application of AI-based tools have been identified and others argued. In detail, according to available data in the literature, we envision a true chance to develop data-driven AI-based solutions that might support clinical decision-making in every step of the tMCS journey (identification of the best suited pathway of care, device implant and management, calibration of LV unloading, especially in cases of multidevice support, patient-risk stratification to prevent complications, etc.). A summary of current evidence in the literature supporting the future application of AI in the setting of Impella support is reported in Table 1. Such tools might benefit from integrating data continuously retrieved from the Impella AIC, multimodal imaging techniques and computational models. Of note, according to the reported existence of a correlation between console data (P-level) and the degree of LV unloading, we also envision the future development of closed-loop AI-driven models to automatically evaluate patients’ haemodynamic status and set (or suggest) optimal Impella settings. Although several challenges exist that must be overcome—including technological challenges to implement reliable models able to continuously adapt their predictive power to the dynamic evolution of the clinical state of tMCS patients—the integration of AI in a complex scenario such as that of tMCS may represent a breakthrough with extraordinary impact on the real clinical world.

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Conflict of interest statement

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