Submitted: 27 September, 2025 Accepted: 11 October, 2025 Published: 08 December, 2025 DOI:10.22514/sv.2025.189

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Signa Vitae

EDITORIAL

Too soon to deflate? Rethinking IABP in the era of Altshock-2

Maks Mihalj[1], Charles Wanna[1], Sriram Nathan[1], Harish Devineni[1], Alessandro Belletti[2], Anna Mara Scandroglio[2], Igor D. Gregoric[1], Angelo Nascimbene[1,*], Biswajit Kar[1]

[1]Department of Advanced Cardiopulmonary Therapies and Transplantation, McGovern Medical School, University of Texas Health Science Center at Houston (UTHealth), Houston, TX 77030, USA
[2]Department of Anesthesia and Intensive Care, IRCCS San Raffaele Scientific Institute, 20132 Milan, Italy

***Correspondence**
angelo.nascimbene@uth.tmc.edu
(Angelo Nascimbene)

Abstract

Mechanical circulatory support (MCS) is frequently used in patients with cardiogenic shock to restore adequate organ perfusion, improve hemodynamic, reduce catecholamine-related adverse events, and prevent development of organ failure. Intra-aortic balloon pump (IABP) is usually the first line device used among currently available MCS systems, it is easily inserted at bedside, and associated with low complications rate. Despite its widespread use, a recent small, randomized study suggested that early implantation of IABP does not improve short-term outcomes in patients with Society of Cardiovascular Angiography Class B to D heart-failure related cardiogenic shock. In this article, we discuss possible limitations of recent studies on IABP, as well as updated evidence on effects on outcome and optimal patient selection for IABP support in patients with heart-failure related cardiogenic shock.

Keywords

Cardiogenic shock; Mechanical circulatory support; Intra-aortic balloon pump; Micro-axial flow pump; Adverse events

Intra-aortic balloon pump (IABP) is a mechanical circulatory support (MCS) device frequently used to provide hemodynamic support to patients with cardiogenic shock. Advantages of IABP include ease of insertion (including the possibility to be implanted at bedside), relatively simple management, and low complication rate [1]. Accordingly, IABP is frequently the first-line MCS device used in patients with cardiogenic shock, while micro-axial flow pumps (*e.g.*, Impella®) and extracorporeal membrane oxygenation are considered for more severe cases, or as second-line devices for patients deteriorating while on support [2].

Intra-aortic balloon pump provides several hemodynamic effects, including small improvements in cardiac output, improvement in coronary perfusion pressure, and decrease in myocardial workload by left ventricle (LV) unloading [3, 4]. The hemodynamic effects of IABP are generally accompanied by improvement in organ perfusion parameters and reduction in inotropic score. Notably, randomized controlled trials (RCTs) showed better improvement in organ perfusion parameters with IABP as compared with inotropes [5]. However, despite being widely used in clinical practice, the efficacy of IABP in terms of major clinical outcomes improvement remains a matter of debate and subject for ongoing investigations [6, 7].

In the most recent study published on the topic, AltShock-2 trial by Morici *et al.* [8], the Authors present results of a RCT enrolling patients with early (Society of Cardiovascular Angiography and Intervention (SCAI) stage B, C or D [9, 10]) heart failure-related cardiogenic shock (HF-CS) [11]. Patients were randomized to receive IABP on top of standard of care (SoC) (including inotropes) or SoC alone. The authors concluded that early IABP support did not improve survival or successful bridging to advanced therapies in patients presenting with cardiogenic shock. An accompanying editorial by Delmas *et al.* [12] titled "Bursting the Balloon" goes even further, asserting that "Based on the Altshock-2 results, there is probably no place for IABP as a bridge to heart replacement therapies (HRT)".

While the Altshock-2 trial failed to demonstrate a statistically significant difference between standard medical therapy and early IABP use, patient selection may have prevented the authors from ascertaining the current role and benefits of IABP in our current practice. Specifically, the observed survival rate was higher than expected in the SoC arm, possibly due to the inclusion of patients categorized as SCAI B shock (28%). Including patients at an early shock stage may have diluted the measurable benefit of IABP therapy, since these patients would generally not be prime candidates for mechanical circulatory support. To further support this notion, the majority of patients in both the IABP and SoC arms had arterial lactate levels $\leq$2.0 mmol/L (55% and 58%, respectively); therefore, this study cohort included patients who had borderline cardiac function but were not in classic shock [9–11]. The limited use of pulmonary artery catheters (PAC) (46%) may also have limited correct patient identification and response to IAPB *vs.* SoC, as

exemplified by a several crossovers in the control group. In particular, recent studies suggested that the patient most likely to benefit from IABP has an afterload-sensitive dilated LV, high filling pressures, and systemic vasoconstriction, a clinical picture frequently observed in patients with HF-CS [1, 13]. However, in the study by Morici *et al.* [8] the limited use of the PAC may have led to inclusion of patients less likely to benefit from IABP. Finally, the overall event mortality rate in the study by Morici *et al*. [8] was 22%, highlighting the relatively low risk of this population. Accordingly, the study is likely underpowered to detect significant differences in outcome.

Aside from the points mentioned above, the most significant limitation of the current trial is the assertion that IAPB seems equally ineffective across B, C, D SCAI Shock categories. Shock is a dynamic clinical entity, and while this study effectively proves that routine use of IABP in SCAI B may be futile, we believe it fails to represent IABP's ability to transiently and quickly improve/reverse end-organ perfusion, in appropriately selected patients [14] and escalate to larger devices based on individual hemodynamic response [15].

Indeed, a recently published meta-analysis investigating the tole of IABP in patients with HF-CS found that use of IABP was associated with improvement in a composite outcome of survival and bridge to HRT in the subgroup of patients in C or D SCAI shock class, while the effect was lost when including also SCAI B category [16]. Notably, only two studies with an overall pooled sample size of 133 patients were included, and the Authors underlined the need for additional trials with adequately selected patients before drawing definitive conclusions on the impact of IABP on outcome in HF-CS.

In addition, several studies suggested that improvement in organ function before HRT is associated with better long-term outcomes [17–21]. IABP may help stabilize and improve pre-HRT organ function (*e.g.*, renal function) indirectly improving long-term outcomes. This may not be captured by short- and mid-term follow-up of available studies.

Last, IABP still may have a role as a temporizing solution that is easily deployable at the bedside as a bridge to a micro-axial pump [22], for example by stabilizing patients while waiting transfer from a spoke to a hub center.

As temporary mechanical support has been widely adopted based on its ability to improve hemodynamics in the absence of a clear survival benefit, with one specific exception [23], so IABP have consistently shown to provide hemodynamic benefit without that benefit necessarily translates into a survival benefit due to the dynamic and multistage phases of care patient with marginal hemodynamic have to overcome to survive index hospitalization ultimately.

Given these considerations, we feel it would be premature and potentially harmful to dismiss IABP use on these limited results, and ultimately, findings of the Altshock-2 trial could lead to inappropriate withdrawal of IABP use from the heart failure toolbox.

AVAILABILITY OF DATA AND MATERIALS

Not applicable—No original data used for this article.

AUTHOR CONTRIBUTIONS

MM, CW, AN, AB, AMS—Performed the research. AN, AB—Formal Analysis. AMS, IDG, AN, BK—Investigation. AN, MM, CW—Data Curation. SN, HD, AB, AMS, IDG, AN, BK—Wrote the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

ACKNOWLEDGMENT

Not applicable.

FUNDING

This research received no external funding.

CONFLICT OF INTEREST

The authors declare no conflict of interest. Alessandro Belletti is serving as one of the Editorial Board members of this journal. We declare that Alessandro Belletti had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to FG.

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How to cite this article: Maks Mihalj, Charles Wanna, Sriram Nathan, Harish Devineni, Alessandro Belletti, Anna Mara Scandroglio, *et al*. Too soon to deflate? Rethinking IABP in the era of Altshock-2. Signa Vitae. 2025; 21(12): 1-3. doi: 10.22514/sv.2025.189.