Timing of impella placement in PCI for acute myocardial infarction complicated by cardiogenic shock: An updated meta-analysis

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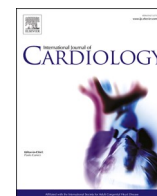
Review

Timing of impella placement in PCI for acute myocardial infarction complicated by cardiogenic shock: An updated meta-analysis

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ABSTRACT

Introduction: The timing of hemodynamic support in acute myocardial infarction complicated by cardiogenic shock (AMICS) has yet to be defined. The aim of this meta-analysis was to evaluate the impact of timing of Impella initiation on early and midterm mortality.
Methods: A systematic literature review and meta-analysis was conducted using PubMed and Cochrane databases. All studies reporting short-term mortality rates and timing of Impella placement in AMICS were included. Meta-regression analysis and sensitivity analysis were performed on the primary endpoint, short-term mortality ($\leq$30 days), and secondary endpoints (midterm mortality, device-related bleeding, and limb ischemia).
Results: Of 1289 studies identified, 13 studies (6810 patients; 2970 patients identified as receiving Impella pre-PCI and 3840 patients receiving Impella during/post-PCI) were included in this analysis. Median age was 63.8 years (IQR 63–65.7); 76% of patients were male, and a high prevalence of cardiovascular risk factors was noted across the entire population. Short-term mortality was significantly reduced in those receiving pre-PCI vs. during/post-PCI Impella support (37.2% vs 53.6%, RR 0.7; CI 0.56–0.88). Midterm mortality was also lower in the pre-PCI Impella group (47.9% vs 73%, RR 0.81; CI 0.68–0.97). The rate of device-related bleeding (RR 1.05; CI 0.47–2.33) and limb ischemia (RR 1.6; CI 0.63–2.15) were similar between the two groups.
Conclusion: This analysis suggests that Impella placement prior to PCI in AMICS may have a positive impact on short- and midterm mortality compared with post-PCI, with similar safety outcomes. Due to the observational nature of the included studies, further studies are needed to confirm this hypothesis (CRD42022300372).

1. Introduction

Cardiogenic shock (CS) is the leading cause of in-hospital mortality in acute myocardial infarctions (AMI), occurs in up to 10% of cases, and is increasing in frequency [1,2]. Primary percutaneous coronary intervention (pPCI) is the cornerstone of treatment for AMI complicated by CS (AMICS), and its routine use is associated with long-term survival benefit [3]. However, despite innovations in pharmacologic and device-based therapies and systems of care, in-hospital and 30-day mortality remain high (50 to 70%), especially in older patients [4].

To address this survival plateau, percutaneous mechanical circulatory support devices (pMCS) have been introduced in this clinical setting. The first device to be widely used was the intra-aortic balloon pump (IABP); however, due to its modest impact on cardiac output and left ventricle end diastolic pressure and following the result of the IABP-SHOCK II trial routine use of IABP in CS was downgraded to a class III recommendations in the most recent ESC guidelines and class IIa in the most recent US guidelines [4,5].

The Impella (Abiomed, Danvers, MA, USA) microaxial flow pump is a percutaneous left ventricular assist device (pLVAD) that actively pumps blood from the left ventricle (LV) into the aorta, augmenting cardiac output and unloading the LV. Despite the neutral effect of short-term

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survival benefit compared to IABP in the small ($n = 48$) IMPRESS in Severe Shock trial [6], and in the matched-pair analysis of 237 patients treated with Impella versus 237 patients treated with IABP from the IABP-SHOCK II trial [7], retrospective analysis from recent multicenter registries suggests an increased survival in CS [8]. These outcome differences may be related to significant differences in patient selection [44] Timing of MCS placement has also emerged as an important consideration in the management of CS to prevent the adverse metabolic consequences of prolonged myocardial ischemia and hypoperfusion [10].

The aim of the present meta-analysis is to compare the impact of Impella MCS placement prior versus post primary percutaneous coronary intervention (pPCI) in AMICS.

2. Methods

The present study was performed according to the Cochrane Collaboration and PRISMA statements [11–13]. The original study protocol was registered on the PROSPERO platform (CRD42022300372).

2.1. Search

We searched for clinical trials in MEDLINE/PubMed (last search September 2021). We restricted our searches to human studies, clinical trials, controlled trials or randomized trials and observational (prospective, retrospective and propensity matched) studies. There was no language restriction. We used the keywords and Medical Subject Headings "cardiogenic shock", "Impella", "percutaneous coronary intervention", "revascularization", "axial pump", "mechanical circulatory support", as well as additional text words (such as abbreviations) in combination with an established search strategy for MEDLINE/PubMed/ Cochrane database. We also hand-searched bibliographies of identified studies and recent meta-analyses. The search was concluded in November 2021.

2.2. Selection

Study selection was performed by three independent reviewers (MI, LF, GGB), with differences resolved by consensus. Citations were first scanned at the title/abstract level. Shortlisted studies were then retrieved in full text. They were considered suitable for inclusion if a) reporting on a randomized control trial or observational study in which Impella support was used, b) AMICS was the indication, c) subgroup analysis regarding the timing of Impella placement was reported and d) that reported mortality rates in both populations. Studies were excluded if a) they included fewer than 10 patients treated with Impella, b) indication was post-cardiotomy CS, c) a pediatric population was involved. Corresponding authors of each study were asked to provide additional study and publication data as needed.

2.3. Abstraction and appraisal

Data abstraction and study appraisal were performed by three independent reviewers, with differences resolved by consensus. Key study and patient characteristics were extracted, including age, gender, cardiovascular risk factors, comorbidities, timing of Impella placement, clinical presentation, ejection fraction and lactate levels.

2.4. Endpoints and definitions

The primary endpoint was short term mortality considered as in-hospital or in the first 30 days after the event. Midterm mortality (considered as death between 1 month and 1 year), device-related bleeding and limb ischemia were assessed as secondary outcomes.

2.5. Evaluation of study quality

The quality of included studies was independently appraised by 3 reviewers (MI, LF and GGB), with disagreements resolved by consensus. For each included paper, we evaluated the risk of bias (low, unclear, or high) for random-sequence generation, allocation concealment, blinding of patients and physicians, blinding during assessment of follow-up, incomplete outcome evaluation, and selective reporting, in keeping up with the Cochrane Collaboration approach.

2.6. Statistical analysis

Continuous variables are reported as mean (SD) or median (interquartile range). Categorical variables are expressed as n (%). Statistical pooling for incidence estimates was performed according to a fixed-effect or random-effect model with generic inverse-variance weighting depending on statistical homogeneity, computing risk estimates with 95% confidence intervals (CIs), using RevMan 5.2 (The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark). Small study bias was appraised by graphical inspection of funnel plots. Sensitivity analysis was performed according to whether placement of the Impella CP/ or 5.0 devices was >60% of total Impella devices used (as opposed to the 2.5). Meta-regression analysis was performed to assess the impact of baseline features on the primary endpoint and leave-one-out analysis to evaluate any single study effect with Comprehensive Meta-analysis software. Hypothesis testing for statistical homogeneity was set at the 2-tailed 0.10 level and based on the Cochran Q test, with I^2 values of 25%, 50%, and 75% representing mild, moderate, and severe heterogeneity, respectively.

3. Results

3.1. Selected studies and baseline characteristics

Of 1289 studies identified, 13 observational studies (6810 patients; 2970 patients identified as receiving Impella pre-PCI and 3840 patients receiving Impella during/post-PCI) were included in this analysis [6,8,14–24](see Supplementary Fig. 1 and Supplementary Table 1). Median age was 63.8 years (IQR 63–65.7), 76% (IQR 73–81.8%) of patients were male, and a high prevalence of cardiovascular risk factors was noted across the entire population (diabetes, 32.2%, IQR 23.5–40.2%; hypertension, 55.8%, IQR 39.6–72.2%;, chronic kidney disease, 26.2%, IQR 16.1–27.3%; see Table 1). The clinical presentation was ST elevation myocardial infarction in 83.4% (IQR 76.6–91.8%), with a high prevalence of out-of-hospital cardiac arrest (47.5%; IQR 28.4–59.2%) and elevated lactate values (6.7 mg/dL; IQR 6.2–7.5).

3.2. Primary end-point analysis

The mean short-term mortality in the overall population was 47.5% (IQR 41.6–45.8%), and was lower in the pre-PCI group (37.2%, IQR 29.1–41%) compared with post-PCI group (53.6%, IQR 48–53.8%) with a risk ratio (RR) of 0.7 associated with pre-PCI Impella (95% confidence interval [CI], 0.56–0.88, see Fig. 1). With sensitivity analysis, the benefit of pre-PCI Impella placement was consistent in both the Impella 2.5 (RR 0.72, 95% CI, 0.53–0.98) and Impella CP/5.0 group and (RR 0.68, 95% CI, 0.48–0.096, see Supplementary Fig. 2).

At meta-regression analysis, among baseline characteristics, only greater percentage of female gender (beta −0.04 95%CI -0.06 - -0.01 p < 0.01, see Supplementary Fig. 3 Panel a) and older age (beta −0.07 95%CI -0.12 - - 0.02 p < 0.01, see Supplementary Fig. 3 Panel b) were associated with the primary outcome significantly, while any procedural characteristics or Impella device used (beta 0.002, CI - 0.003-0.007, see Supplementary Fig. 3 Panel c and Supplementary Fig. 4) were not significant.

Table 1
Included studies baseline characteristics.

First Author	Age	Male Gender	Diabetes	CKD	Hypertension	COPD	PAD	Prior stroke	Prior MI	Prior CABG	Baseline Lactate	LVEF	OHCA	STEMI	Mechanical ventilation	Type of Impella	Timing of Impella placement in Post PCI group
Basir et al	63.4	77.2	39.5	15.7					21.5	6.6	5.4		20.5	77.6		Impella CP. 92%; Impella 2.5. 6%; Impella RP. 2%	27% intraprocedural 73% postprocedural
Boshara et al	64	61.3	48.4	29	80.6	16.1	16.1		22.6	16.1		20				Impella CP. 100%	Not specified
Chatzis et al	68.4	84	33.3	59.3	76.5	21	34.6	7.4	37	16	8.6	32.9	100.00	49.4	100.00	Impella 2.5. 100%	100% postprocedural
Hemradj et al	60.7	81.8	15.9		33.5		5.7	2.3	18.1		7.1		44.3	100.00	88.6	Impella CP. 51%; Impella 2.5. 40%; Impella 5.0. 9%	Not specified
Jensen et al	63	84	26.00		53.00	4.00	3.00		15		7.6	17	36.7	86.1	86.1	Impella CP. 92%; Impella 5.0. 9%. Impella RP. 3%	100% postprocedural
Joseph et al	65.7	73.2	44.8	25.6	72.3		17.7		34.1	11.3		25.7		71.7	77	Impella 2.5. 100%	Not specified
Loehn et al	68.9	72.6	38.4	21.9	72.6		12.3				6.3	29	24.7	65.8	75.3	Impella CP. 100%	Not specified
O'Neill et al	63.5	73														Impella CP. 61%; Impella 2.5. 33%: Impella 5.0. 5%	Not specified
Ouweneel et al	60.1	80.4	15.3		35.2		5.7	3.7	15.7		6.2		74.2		89.3	Impella CP. 46%; Impella 2.5. 36%; Impella 5.0. 18%	100% postprocedural
Ouweneel et al	58	75	9.00		20.00		9.00	0	5		7.5			100	100.00	Impella CP. 100%	100% postprocedural
Schafer et al	65	82.5	27.00	15.00	60.00					1.00	6.8	21		69.00		Impella CP. 77%; Impella 2.5. 23%	Not specified
Tarantini et al	66	73	35.00		54.00	11.00	14.00	5	36	5.00	4.7	25				Impella CP. 39%. Impella 2.5. 61% (All shock patients. Not specific to AMICS PCI)	Not specified
Wilkins et al	63.8	71.1	42.2	16.6			11.1	5.6	8.9	3.3		36.6	32.2	87.7	51.1	Impella CP. 18%; Impella 2.5. 82%	Not specified

CKD: Chronic Kidney Disease/Renal Insufficiency. PAD: Peripheral artery disease. MI: Myocardial Infarction. CABG: Coronary Artery Bypass Graft. OHCA: Out of Hospital Cardiac Arrest. STEMI: ST Elevation Myocardial Infarction.

Short term mortality

Study name	Statistics for each study					Risk ratio and 95% CI
	Risk ratio	Lower limit	Upper limit	Z-Value	p-Value	
Basir, M. B., et al. (2019)	1,302	0,709	2,393	0,851	0,395	
Boshara, A., et al. (2021)	1,238	0,679	2,256	0,698	0,485	
Chatzis, G., et al. (2021)	0,657	0,437	0,989	-2,014	0,044	
Hemradj, V. V., et al. (2020)	0,778	0,478	1,267	-1,009	0,313	
Jensen, P. B., et al. (2018)	0,409	0,134	1,246	-1,573	0,116	
Joseph, S. M., et al. (2016).	0,659	0,489	0,887	-2,746	0,006	
Loehn, T., et al. (2020).	0,510	0,309	0,841	-2,636	0,008	
O'Neill, W. W., et al. (2018).	0,855	0,805	0,907	-5,140	0,000	
Ouweneel, D. M., et al. (2019).	0,788	0,488	1,271	-0,977	0,329	
Ouweneel, D. M., et al. (2017).	0,380	0,063	2,309	-1,051	0,293	
Schäfer, A., et al. (2020).	0,264	0,172	0,405	-6,102	0,000	
Tarantini, G., et al. (2021)	0,558	0,353	0,880	-2,507	0,012	
Wilkins C. E., et al. (2019)	1,277	0,770	2,120	0,947	0,344	
	0,702	0,561	0,878	-3,093	0,002	

0,01   0,1   1   10   100
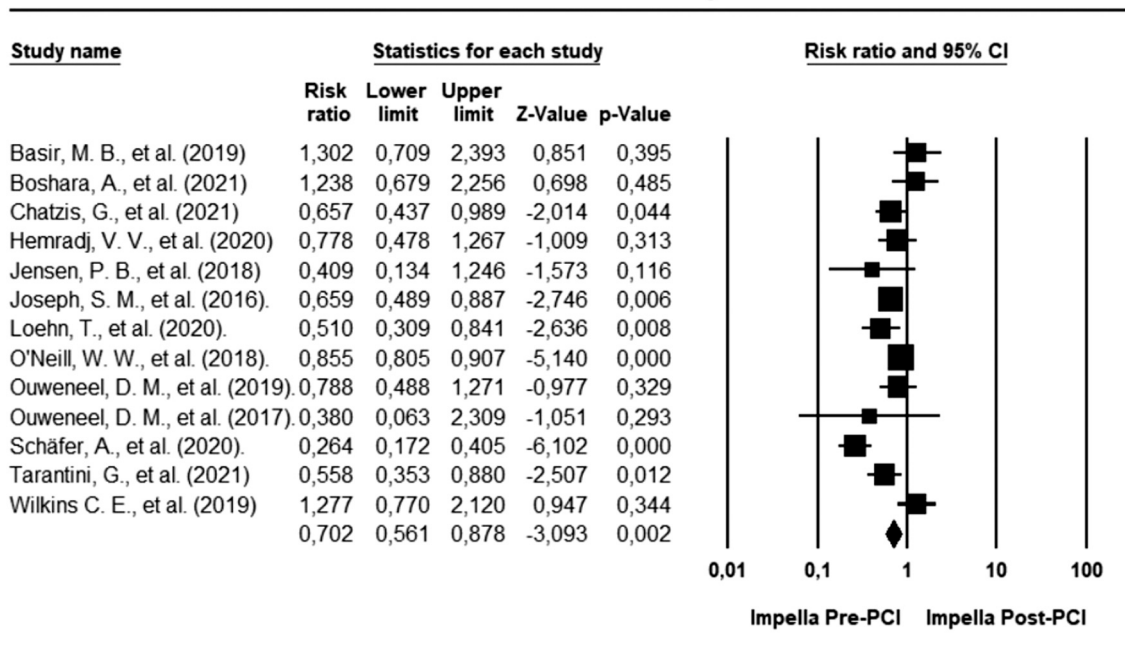
Impella Pre-PCI   Impella Post-PCI

Fig. 1. Forest Plot for short-term mortality in Impella placement pre vs post PCI.
CI: Confidence Interval; PCI: Percutaneous Coronary Intervention.

3.3. Secondary end-point analysis

Midterm mortality was reported in 6 studies, with a mean follow-up of 6.6 months (IQR 6–12 months). Midterm mortality was significantly lower in the pre-PCI group (47.9%, IQR 48.6–52.8%) compared with the post-PCI group (73%, IQR 71.7–76.9%) and was associated with a RR of 0.81 (95% CI, 0.68–0.97, see Fig. 2). On the other hand, the mean rates of device-related bleeding and limb ischemia were reported in 4 studies and there was no difference between the two groups for either outcome, with pre-PCI vs post-PCI device-related bleeding occurring in 18.1% (IQR 10.5–24.8%) and 18.6% (IQR 10–19.8%) of patients, respectively (RR, 0.81; 95% CI, 0.68–0.97). Limb ischemia occurred in 10% (IQR

7.8–11.2%) and 7% (IQR 2.2–9.5%) of pre-PCI and post-PCI group patients, respectively (RR, 1.05; CI, 0.47–2.33; see Fig. 3 Panels a and b).

3.4. Publication bias evaluation

Bias evaluation confirmed a moderate to high quality level for all studies included in this analysis (see Supplementary Table 2). Heterogeneity was generally mild to extensive: for the primary outcome of short-term mortality, the heterogeneity statistic I^2 was 78.9. For the secondary outcomes of midterm mortality, device-related bleeding, and limb ischemia, the I^2 statistics were 0; 63.3, and 0, respectively. Graphical inspection of funnel plots did not show significant

Medium term mortality

Study name	Statistics for each study					Risk ratio and 95% CI
	Risk ratio	Lower limit	Upper limit	Z-Value	p-Value	
Chatzis, G., et al. (2021)	0,677	0,460	0,996	-1,980	0,048	
Hemradj, V. V., et al. (2020)	0,816	0,523	1,274	-0,894	0,371	
Jensen, P. B., et al. (2018)	0,669	0,366	1,220	-1,311	0,190	
Loehn, T., et al. (2020).	0,650	0,446	0,948	-2,236	0,025	
Ouweneel, D. M., et al. (2019).	0,836	0,540	1,295	-0,801	0,423	
Tarantini, G., et al. (2021)	0,999	0,837	1,192	-0,011	0,991	
	0,814	0,682	0,971	-2,288	0,022	

0,01   0,1   1   10   100

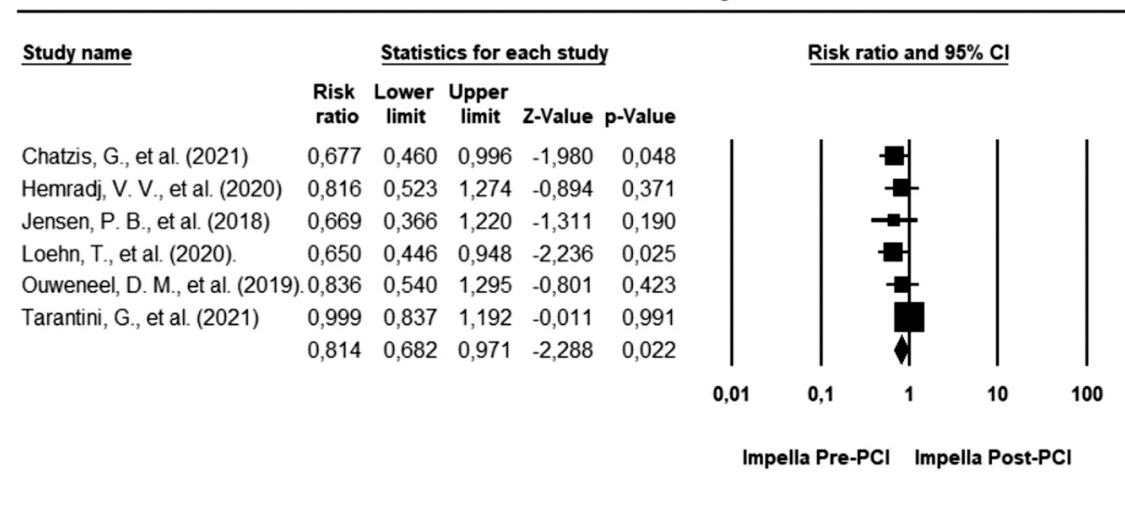Impella Pre-PCI   Impella Post-PCI

Fig. 2. Forest Plot for Mid term mortality in Impella placement pre vs post PCI.
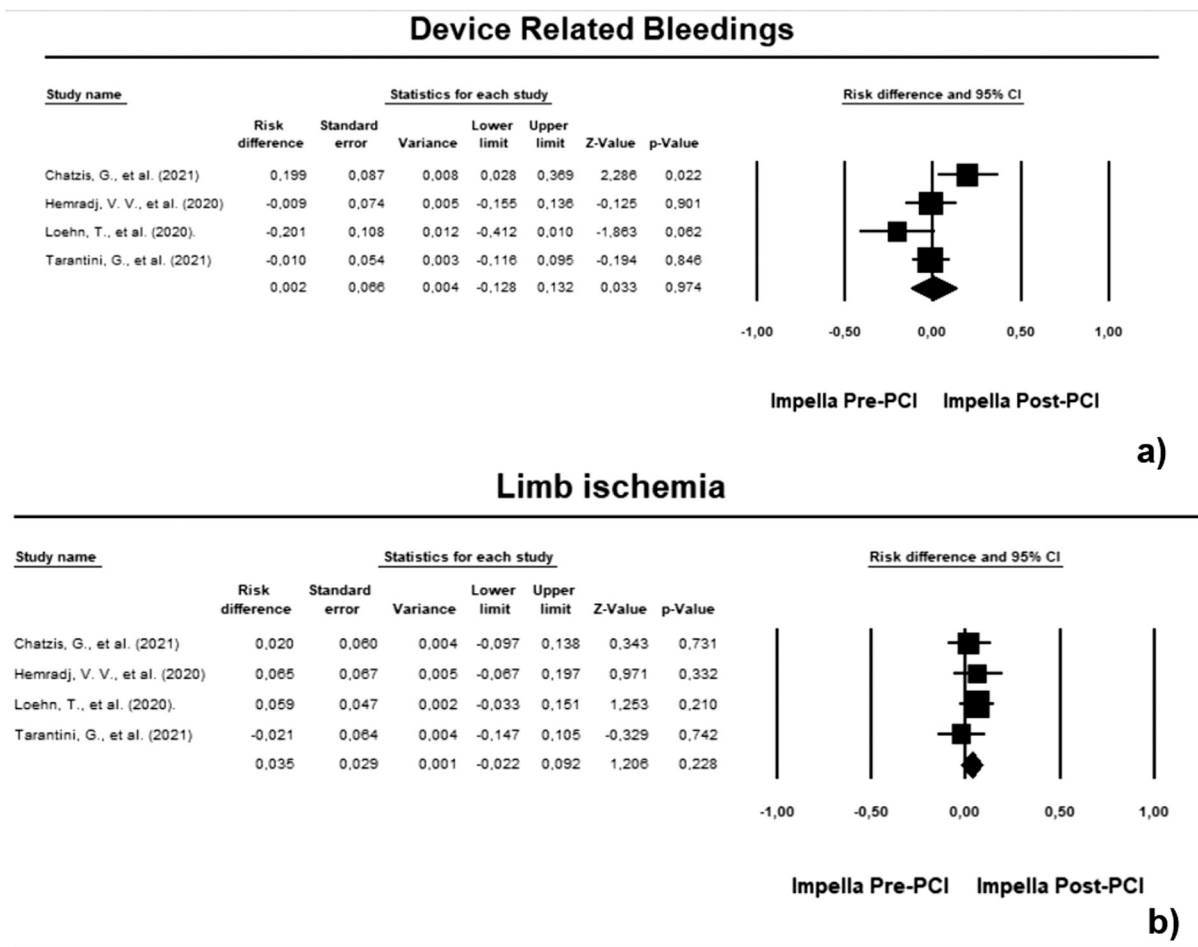CI: Confidence Interval; PCI: Percutaneous Coronary Intervention.

Device Related Bleedings

Study name	Statistics for each study							Risk difference and 95% CI
	Risk difference	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value	
Chatzis, G., et al. (2021)	0,199	0,087	0,008	0,028	0,369	2,286	0,022	
Hemradj, V. V., et al. (2020)	-0,009	0,074	0,005	-0,155	0,136	-0,125	0,901	
Loehn, T., et al. (2020).	-0,201	0,108	0,012	-0,412	0,010	-1,863	0,062	
Tarantini, G., et al. (2021)	-0,010	0,054	0,003	-0,116	0,095	-0,194	0,846	
	0,002	0,066	0,004	-0,128	0,132	0,033	0,974	

Impella Pre-PCI   Impella Post-PCI

a)

Limb ischemia

Study name	Statistics for each study							Risk difference and 95% CI
	Risk difference	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value	
Chatzis, G., et al. (2021)	0,020	0,060	0,004	-0,097	0,138	0,343	0,731	
Hemradj, V. V., et al. (2020)	0,065	0,067	0,005	-0,067	0,197	0,971	0,332	
Loehn, T., et al. (2020).	0,059	0,047	0,002	-0,033	0,151	1,253	0,210	
Tarantini, G., et al. (2021)	-0,021	0,064	0,004	-0,147	0,105	-0,329	0,742	
	0,035	0,029	0,001	-0,022	0,092	1,206	0,228	

Impella Pre-PCI   Impella Post-PCI

b)

Fig. 3. Forest Plot for Device related bleeding (Panel a) and Limb Ischemia (Panel b) in Impella placement pre vs post PCI.
Legend. CI: Confidence Interval; PCI: Percutaneous Coronary Intervention.

asymmetries confirmed by Egger's test for the primary or secondary endpoints in any of the analyses that were performed (see Supplementary Figs. 6 and 7). Leave-one-out analysis did not show any single study with a significant effect on the primary or secondary endpoints. In particular, even after removing the largest population reported by O'Neill et al. [8], the main result remained significant, with pre-PCI Impella associated with a 0.68 RR (95% CI, 0.52–0.89; see Supplementary Fig. 8).

4. Discussion

Despite early revascularization, AMICS management remains challenging, outcomes poor, and treatment decisions are often made on a case-by-case basis highly dependent on physician/center experience and organization [25]. The latest European Society of Cardiology guidelines give only class IIb recommendation (level of evidence C) for short-term MCS in AMICS, both in ST elevation (STE) and non-STE MI, without any preference for MCS type or timing due to scarcity of data in this setting [5,26]. The complexity of addressing this issue in an RCT is well known: AMICS management is multidisciplinary and whereas some interventions might be clearly ineffective, other factors such as study design, patient selection and barriers to informed consent and randomization in emergency settings may have possibly influenced the results of some trials. For this reason, a recent experts' position paper suggested that alternative study designs might provide valuable insights into treatment effects [27]. We performed a meta-analysis of nonrandomized observational studies exploring outcomes according to timing of Impella placement in AMICS. This is the largest meta-analysis

to date to address this issue, and the first providing meta-regression analysis. The main findings can be summarized as follows:

- Impella placement before PCI in AMICS is associated with a reduced risk of both short-term mortality (RR 0.7; CI 0.56–0.88) and midterm mortality (RR 0.81 CI 0.68–0.97) compared with the post-PCI group. This result was consistent, independent of the Impella device used.
- The meta-regression analysis suggested that male gender and age were associated with the primary outcome significantly.
- Complication rate was comparable between the two strategies as no difference was observed regarding device-related bleeding (RR 1.05; CI 0.47–2.33) and limb ischemia (RR 1.6; CI 0.63–2.15) between the two groups.

After the increased use of an early invasive strategy, the in-hospital and 30-day mortality of AMICS has decreased over the years [28–30]. Whereas "the earlier the better" paradigm is currently widespread for revascularization in this scenario, an equivalent consensus on early pMCS does not exist [31]. Timing of pMCS may be crucial, as the potential benefit of Impella may be reduced if the patient is already crashing in an unstoppable downward spiral with multisystem organ failure. Remarkably, the population of this meta-analysis represent a very high-risk cohort of severely ill patients, as demonstrated by the median lactate level of 7 mmol/L and by the relatively high proportion of OHCA (median of 34%). Moreover, median mortality across included studies was 45%, in line with previous data [32]. Nevertheless, we reported that an upfront Impella placement strategy prior to PCI in AMICS is associated with a decreased short- and midterm mortality compared

with post-PCI implantation, mostly independent from baseline characteristics as confirmed by the meta-regression analysis and sensitivity analysis. Accordingly, only age and female gender were associated with worse outcome in the present analysis at the univariate level. Although age is a well-known mortality risk factor for AMICS [33], gender is reported to be less important in predicting the outcome in cardiogenic shock after adjusting for other variables [34,35].

In summary, our data supports the recently proposed "door-to-support" concept [10,36]. Rapid pMCS placement even before primary PCI appears not only safe and feasible, but also effective in further reducing mortality in this setting. Timely Impella placement might have a dual beneficial effect: the unloading of the left ventricle, with consequent reduction of the ischemia-reperfusion injury [37], and the fast reversal of the shock state. The former is associated with infarct size reduction, due to both decreased myocardial oxygen consumption and to a shift in expression of protective genes associated with mitochondrial function [38]. The latter might also allow operators to obtain more complete revascularization, further translating into better midterm outcomes [16–18,21].

Interestingly, the primary outcome was not influenced in the meta-regression analysis nor in the sensitivity analysis by the type of Impella device used. Though it was not possible to have a direct comparison between the two strategies, the risk ratio in the Impella CP/5.0 subgroup was numerically lower than the 2.5 subgroup. These results are in line with a previously published, albeit smaller, meta-analysis [39], but in contrast with the largest report included in the present analysis, wherein Impella CP was associated with better survival compared with Impella 2.5, independent of timing [8]. However, it has to be highlighted that in the Impella CP/5.0 fewer than 10% of the patients were treated with the 5.0 device. Our findings might be explained by the fact that the possible device-specific positive effects might become less important compared to "door-to-support" time when analyzing larger sample sizes. As AMICS management is highly variable both within and between different hospitals and each site may have diverse criteria for pMCS patient selection and implant timing, the findings of O'Neill et al. may be more applicable to US centers. According to our study, timing of support implantation could have a larger impact on survival than specific device type.

In our analysis, there was no difference in the risk of device complications (specifically, device-related bleeding and limb ischemia) between the two strategies, further supporting the safety of providing hemodynamic support before proceeding to PCI in AMICS. Nonetheless, it must be acknowledged that Impella is associated with an increased risk of vascular complications and life-threatening bleeding compared to IABP in this setting, most likely due to its much larger French size [7]. Furthermore, a recent propensity-matched analysis of 3360 patients found that Impella was associated with an increased risk of in-hospital major bleeding and mortality regardless of the timing of device placement [40]. A potential explanation is that the increased bleeding is strongly associated with mortality as reported by previous studies [6,41,42]. Nevertheless, bailout Impella placement was associated with higher rates of vascular complications/bleeding and mortality, compared to pre- and post-procedural implantation in non-emergent patients undergoing high-risk PCI [43]. Unfortunately, a clear distinction between intraprocedural and post-procedural placement was not possible in our analysis; still, our data are reassuring on the safety and feasibility of an upfront implantation.

5. Limitations

There are some limitations to this analysis. Firstly, only observational studies could be included in the analysis, and most of them were retrospective. Each study carries inherent selection bias invariably associated with patients' characteristics and operators' preferences at the time of revascularization. Secondly, the timing of insertion of the Impella devices (whether pre- or post-PCI) was not standardized across included studies, and it was not possible to distinguish between intra-procedural/bailout and post-procedural placement. Third, the lack of standard insertion protocols (for example, micropuncture, ultrasound-guidance), or hemodynamic assessment criteria (Swan-Ganz data) may be source of bias. Moreover, systematic collection of door-to-support time was not possible. The wide variability in sample sizes across the studies is another limitation of the present work, even if the results were consistent at the leave-one-out analysis. Since the study results were derived from univariate analyses, the potential biases coming from this approach must be considered as well. Lastly, the results of the sensitivity analyses and the meta-regression results might have been affected by the small number of the included studies and unmeasured confounding factors and must be interpreted with caution.

6. Conclusion

This analysis suggests that Impella placement prior to PCI in AMICS may be associated with lower short- and midterm mortality compared with post-PCI placement, with similar safety between upstream and downstream Impella placement strategies regarding device-related bleeding and limb ischemia. Due to the observational nature of the included studies further studies are needed to confirm this hypothesis.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2022.05.011.

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