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Use of Impella device in cardiogenic shock and its clinical outcomes: A systematic review and meta-analysis

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ABSTRACT

Introduction: Cardiogenic shock (CS) is a life-threatening condition and mechanical circulatory support (MCS) might exert a relevant impact on its clinical course. Among MCS devices, Impella is very promising. Yet, its usefulness is still debated. We performed a meta-analysis of all studies evaluating the clinical impact of Impella in CS.

Methods: All studies including patients with CS and treated with Impella were included. The primary endpoint was short-term mortality. Secondary endpoints were vascular access complications and major bleeding. Data synthesis was obtained using random-effects metanalysis.

Results: Thirty-three studies and 5204 patients were included. Short-term mortality was 47%. Meta-regression analysis showed that patients age ($p = 0.01$), higher support level ($p = 0.004$) and pre-PCI insertion ($p < 0.001$) were significant moderators for the primary endpoint. Vascular access complications were registered in 6.4% of cases, whereas age ($p = 0.05$) and diabetes ($p = 0.007$) were significant predictors. Major bleeding occurred in 16.4% of patients. Meta-analysis of the subgroup of studies comparing Impella to IABP showed no significant difference in short-term mortality ($RR = 1.08$, $p = 0.45$), while rates of vascular access complications ($p < 0.001$) or major bleeding ($p < 0.001$) were significantly higher with Impella. Subgroup and metaregression analyses showed that these results were influenced by lower adoption rates of higher degree of MCS support ($p = 0.003$), and by higher vascular complications rates ($p = 0.014$).

Conclusions: Our results suggest that the choice of adequate device size, careful patients selection and optimal timing of MCS initiation are key to clinical success with Impella in CS. Large prospective studies are mandatory to confirm these results deriving from retrospective studies.

1. Introduction

Cardiogenic shock (CS) is a life-threatening condition caused by severe impairment of cardiac function that results in diminished cardiac output, organ hypoperfusion and hypoxia [1]. CS is generally defined as a systolic blood pressure value <90 mmHg for ≥30 min or inotropic support required to maintain blood pressure upon this value. CS complicates 5–10% of acute myocardial infarction (MI) cases and is the leading cause of death after MI [2]. Despite optimization of early revascularization therapies and medical treatment, short-term mortality of this condition remains soberly high at 40–50% [3–6]. With the increase in the population average age and the consequential increase in related comorbidities, mortality rate of CS has further increased in recent times [7,8].

Mechanical circulatory support (MCS), such as intra-aortic balloon pump (IABP), TandemHeart™, Impella® (Abiomed, Danvers, MA, USA) and Extracorporeal membrane oxygenation (ECMO), have proved to be very useful tools in the management of CS. MCS is designed to provide blood flow to vital organs in patients with conditions that severely impair end-organ perfusion. One of the most used MCS devices is Impella, a percutaneous system that consist of a micro-axial pump to provide left ventricular unloading and reduction of left ventricle (LV) end diastolic pressure, lowering myocardial oxygen demand [9]. The Impella is a family of percutaneous cardiac pumps that can be placed

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into either the left ventricle or right ventricle and can provide up to 5.0 L of cardiac output. Very recently the Impella 5.5 has been introduced to further increase cardiac output [10]. The two most relevant clinical scenarios in which Impella is used are high-risk PCI and CS. The "Impella® System Therapy" is therefore a temporary ventricular support device intended for short term use and indicated for the treatment of ongoing CS that occurs immediately (<48 h) following AMI or open-heart surgery or in the setting of cardiomyopathies. The aim of Impella System Therapy is to increase cardiac output and to reduce end diastolic ventricle pressure [11]. Initial experience with the Impella device had shown an improvement in medium- to long-term outcomes in patients undergoing high-risk PCI [12], while there are fewer prospective randomized trials on the use of Impella in CS. In recent years, retrospective analyses from multicenter registries have suggested an increased survival with Impella in patients with CS, when adequate device selection, timing of implant, as well as invasive hemodynamic monitoring are provided [13]. In this context, the aim of this meta-analysis was to evaluate the efficacy and safety of MCS with Impella in CS as well as to compare clinical outcomes with Impella versus IABP.

2. Methods

The present meta-analysis was performed according to Cochrane Collaboration and PRISMA guidelines[14,15].

2.1. Research

Literature was systematically searched for studies reporting the use of Impella device in CS. Scientific literature was searched for on the following public databases: PubMed (https://pubmed.ncbi.nlm.nih.gov/) and Cochrane Library (https://www.cochranelibrary.com/) until December 31st 2021). We used the following keywords: "Impella", "Impella CP", "Impella 5.0" "Cardiogenic shock" and "Impella vs IABP".

2.2. Study selection with inclusion/esclusion criteria

Two investigators (GP, DT) independently screened search records to identify eligible trials. Divergencies were resolved though discussion on study methodology until consensus was reached. Studies were selected if they fulfilled all the pre-defined inclusion criteria reported. The criteria for study inclusion were: (a) any clinical study in which an Impella device was used; (b) the clinical setting in which Impella was used was CS; (c) short-term mortality was reported. Exclusion criteria were: case reports; editorials or systematic review or meta-analysis; mean age of study population <18 years; case series of <10 patients included; short-term mortality was not reported; use of Impella device in clinical settings different from CS (for example high risk PCI). Data extraction was performed by two independent reviewers (GP, DT), with divergences resolved by consensus. Baseline characteristics of the patients included were extracted to an excel worksheet, including age, gender, cardiovascular risk factors, cardiac arrest (CA) at admission, lactate serum levels and pre/post PCI Impella insertion, in addition to outcomes data (short-term mortality, major bleeding, vascular access complications). Based on the studies retrieved, we presented both descriptive results on the use of Impella and a comparison between Impella devices and IABP as the comparator.

2.3. Endpoints

Primary endpoint was considered as 30-day mortality or in hospital mortality. Secondary endpoints were vascular access complications (defined as ischemia requiring Impella removal or vascular surgical intervention) and/or trial defined major bleeding (defined as BARC > 2, TIMI Major or GUSTO severe bleeding).

2.4. Evaluation of study quality

For each study selected, quality of the study was discussed by 2 reviewers (GP, DT). Divergences were solved by consensus. For each included study, we evaluated the risk of bias (low, moderate, serious, critical) for confounding, selection of participants, classification of interventions, deviation from intended intervention, missing data, measurement outcomes, selection of the reported results in accord to ROBINS-I tool [16].

2.5. Statistical analysis

Continuous variables are reported as mean and standard deviation. Categorical variables are expressed as percentages. Cumulative incidence was calculated according to a random-effects model by Mantel-Haenszel. 95% CI were provided for every outcome rate, using OpenMetaAnalyst 10 (Brown University, Providence, Rhode Island) and RevMan 5.4 (The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark), as previously described [17]. Study bias was appraised by graphical inspection of funnel plots and by Egger's and Beggs tests. Meta-regression analysis was performed with Comprehensive Meta-Analysis software using the unrestricted maximum likelihood method (trial version) as described in more detail elsewhere [18]. Heterogeneity of studies was measured by means of the Inconsistency index (I^2) and tested for using the Cochran's Q test.

This meta-analysis and its protocol have been registered on the PROSPERO international prospective register of systematic reviews (https://www.crd.york.ac.uk/prospero/:306865).

3. Results for Impella insertion trials or observational studies

3.1. Study search and selection

As reported in Fig. 1, from the 755 studies retrieved from PubMed (n = 709) or the Cochrane library (n = 46), a total of 33 observational studies were finally selected according to the pre-specified criteria, including 5203 patients with CS treated with Impella insertion. Across the studies, 37% of patients received Impella 2.5, 50% were treated with Impella CP, while 13% were implanted with an Impella 5.0. Among these 33 studies, 7 studies provided a retrospective comparison between Impella and IABP use, reporting on clinical outcomes (Fig. 1). These 7 studies compared 2079 patients treated with Impella versus 2087 patients managed with IABP alone. Mean age was 62.7 ± 4.7 years. All patients were admitted for CS and most had an acute coronary syndrome as the underlying cause of CS. Patients had a high cardiovascular risk profile. The Impella CP and Impella 2.5 devices were mainly used, while Impella 5.0 was seldom used. Studies baseline characteristics are provided in supplementary Table 1 while detailed information on usage distribution of different formats for single studies are shown in the supplementary Table 2 (Supplementary data).

3.2. Clinical impact of Impella

3.2.1. Primary endpoint

Of the 5203 patients included, 2445 reached the primary endpoint. Short-term mortality of patients treated with Impella device was 47.0% (95% CI 43.6–50.4%, Fig. 2A). Meta-regression analysis showed that older age was associated with a negative impact on the outcome (p = 0.01, Fig. 3A). Specifically, the regression line of the impact exerted by Impella on mortality crossed the zero-effect line by the mean age of 67 years, suggesting no benefit for older age (Fig. 3). In addition, we found a significant interaction between the percentage of patients receiving higher MCS with Impella CP or Impella 5.0 and short-term mortality (p = 0.004, Fig. 3B), suggesting a larger benefit with higher MCS (Fig. 4). Specifically, the regression line of the impact exerted by Impella on mortality crossed the zero-effect line as the mean percentage of higher

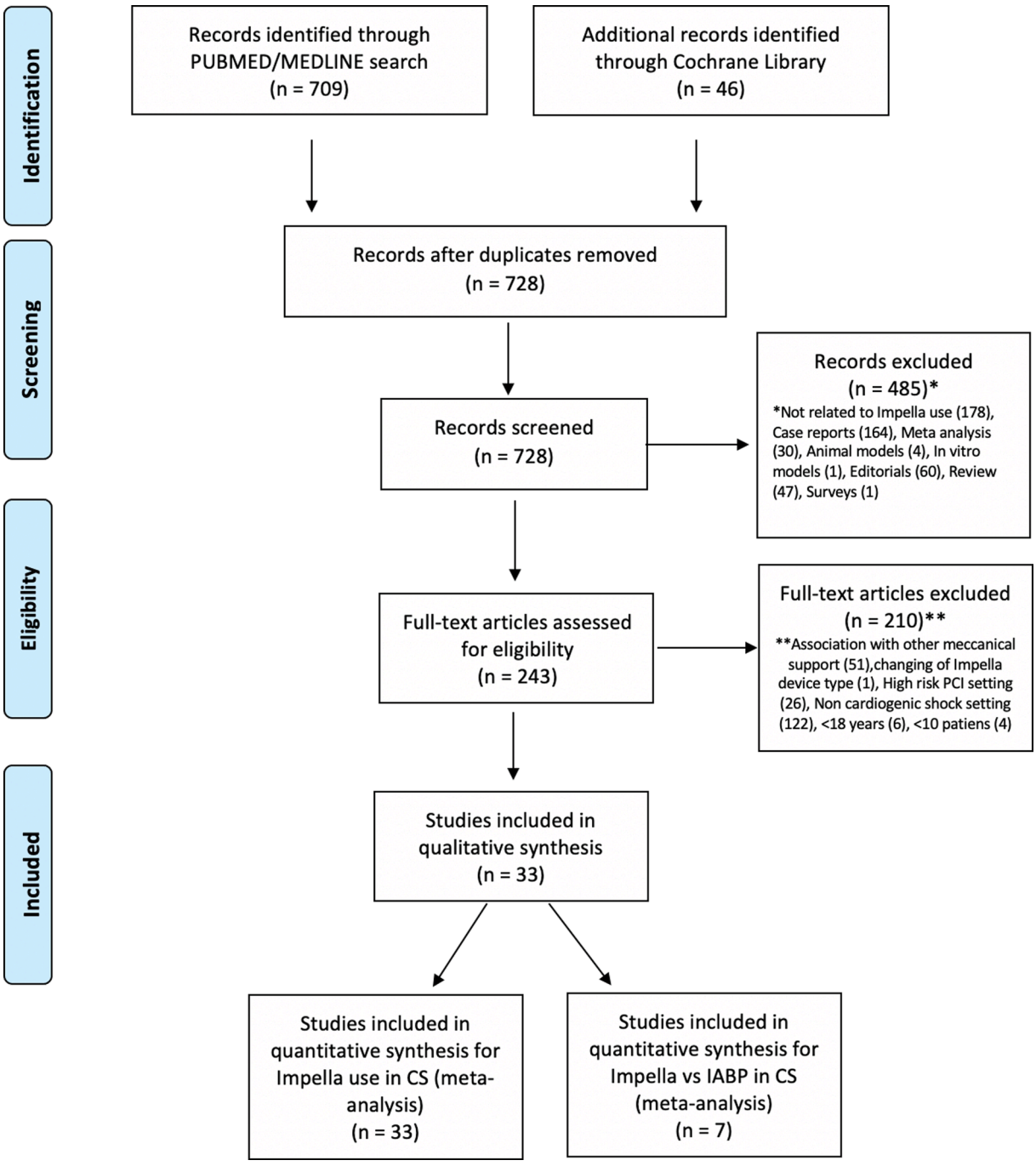

Fig. 1. Meta-Analysis Flow Chart Flow diagram demonstrating study selection for meta-analysis.

MCS reached the 50%, suggesting no benefit for lower adoption of higher MCS (Fig. 3B). Of note, no interaction was found between the percentage of higher MCS and the rate of vascular access complications ($p = 0.951$) (Supplementary Fig. 1).

Positioning of Impella before starting the percutaneous coronary intervention (pre-PCI) was associated with a lower mortality, as the percentage of patients put on Impella support pre-PCI was a significant moderator at meta-regression analysis ($p < 0.001$; Fig. 3C).

Finally, using the etiological diagnosis underlying CS as a moderator, meta-regression analysis showed a significant direct interaction between the proportion of ACS patients and short-term mortality rates ($R = 0.003$ 95%CI 0.001–0.004; $p < 0.001$) (Supplementary Fig. 2). Similarly, a significant inverse interaction was found between the proportion of patients with Myocarditis as the etiological diagnosis and short-term mortality ($R = -0.003$ 95% CI −0.004 to −0.001; $p < 0.001$) (Supplementary Fig. 3).

3.2.2. Secondary endpoints

Vascular access complications occurred in 6.4% (4.8–8.1%, Fig. 2B). At meta-regression analysis, older age ($p = 0.005$), diabetes ($p = 0.007$) and use of Impella 5.0 ($p = 0.04$) were significant predictors of vascular access complications. Finally, major bleeding was observed in 16.4% of cases (12.4– 20.5%).

3.3. Comparison of Impella with IABP

3.3.1. Primary endpoint

Of the 4166 patients included, 953 (45.8%) versus 769 (36.8%)

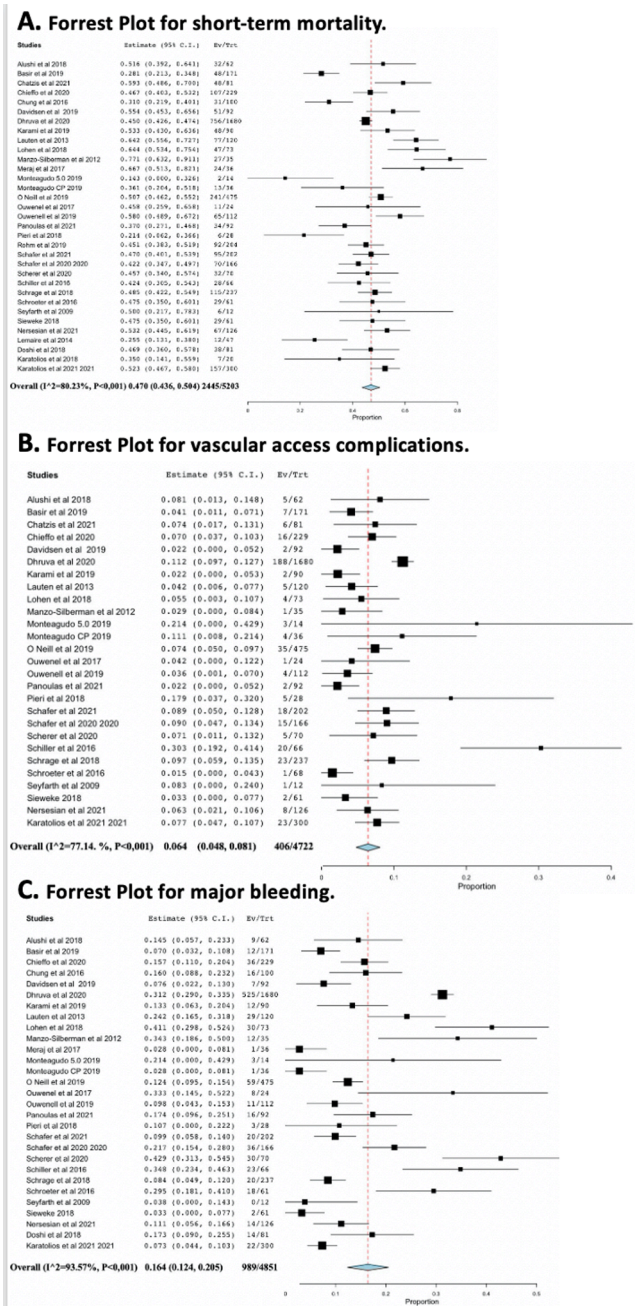

Fig. 2. Measures of Efficacy and Safety. Forest plots illustrating results of meta-analysis on the rate of short-term mortality (A) vascular access complications (B) and major bleeding (C).

reached the primary endpoint respectively in the Impella and IABP groups. At meta-analysis, Impella was not superior to IABP (RR = 1.08; 95% CI 0.89–1.31; p = 0.45; Fig. 4A). Overall heterogeneity was moderate. However, sensitivity analysis showed that most heterogeneity was related to the different percentage of use of higher MCS (using Impella 5.0 or Impella CP). In fact, when we stratified the studies into two subgroups based on the percentage of adoption of higher MCS, heterogeneity was low in both the low ($I^2 = 23\%$) and the high ($I^2 = 26\%$) MCS adoption rate subgroups. Subgroup analysis showed a significant difference in the primary endpoint between the subgroups (p = 0.003). While a nonsignificant trend towards a mortality benefit with Impella was observed in the subgroup of studies with a higher percentage of adoption of higher MCS (RR = 0.94; 95% CI 0.77–1.15; p = 0.529), short-term mortality was significantly lower with IABP in the subgroup of studies with lower adoption of a high MCS (RR = 1.26; 95% CI 1.08–1.48; p = 0.005) (Supplementary Fig. 4). At meta-regression analysis including multiple moderators, the rate of Impella-related vascular complications (p = 0.014) but not the proportion of adoption of higher MCS (p = 0.058), nor age (p = 0.067) was significantly associated with short-term mortality.

3.3.2. *Secondary endpoints*

The rate of vascular access complications was 10.7% in the Impella and the 3.1% in the IABP group (RR = 3.32; 95% CI 2.54–4.33; p < 0.001; Fig. 4B). Major bleeding occurred in 27.8% of cases in the Impella group versus 13.9% in the IABP group (RR = 1.99; 95% CI 1.75–2.25; p < 0.001; Fig. 4C).

3.4. *Study quality*

Evaluation of possible biases related to the included studies demonstrated a mild to moderate risk of bias (Supplementary Fig. 5). Heterogeneity was moderate to severe. Graphical evaluation of the funnel plots did not demonstrate severe asymmetries as confirmed by the Egger's and Beggs tests, except for vascular access complications (Supplementary Fig. 6). The leave-one-out analysis showed consistency of the results across the studies for both the primary and the secondary endpoints (Supplementary Fig. 7).

4. Discussion

Despite several innovations in the management of CS, its short-term mortality remains very high, as widely demonstrated in the literature [19]. Impella is an effective tool in the management of this clinical scenario. Nevertheless, mortality remains close to 50% [20]. The main finding of the present study is that use of higher MCS, e.g. with Impella 5.0 and Impella CP is associated with a lower short-term mortality in CS, as robustly shown by meta-regression analysis involving 33 observational studies and 5203 patients. In addition, despite no significant difference in short-term mortality versus use of IAPB was observed in the subgroup of studies comparing Impella with IABP, both subgroup and meta-regression analyses suggest that this result is mostly related to the lower adoption of higher MCS support Impella devices in those studies. Particularly, our results suggest that especially when the degree of support is not adequately high, the impact of vascular complications prevails, as also shown by the significantly higher proportion of vascular access complications and major bleeding rates with the Impella. Altogether, these results suggest that careful selection of adequate device size is key to clinical success, as the use of lower MCS e.g. with the Impella 2.5 might not be sufficient to counteract the hemodynamic impairment in CS. At the same time, complication rates are not negligible neither with the smaller Impella 2.5 cannulation, shifting the overall balance to a negative net clinical impact. In this regard, our results of meta-regression analyses are reassuring. In fact, while meta-regression analyses showed that use of larger support Impella formats (Impella CP or Impella 5.0) are significantly associated to lower short-term mortality rates (Fig. 3B), no such interaction (p = 0.950) was found for vascular complications (Supplementary Fig. 1), suggesting that the propensity to undergo vascular access complications is less influenced than short-term mortality by the use of larger Impella format.

Furthermore, our results suggest that older age and severe comorbidities such as diabetes may jeopardize the benefit derived from the use of MCS. These results are in line with the available literature, showing lower impact by MCS in patients with comorbidities such as diabetes or chronic renal failure [21]. Special considerations are to be discussed regarding age. In fact, as with other types of MCS devices, older age is significantly associated to both more adverse clinical course in CS and to higher complication rates, leaving a very narrow therapeutic range to physicians dealing with CS in older adults

Last but not least, our data also suggest that the appropriate choice of

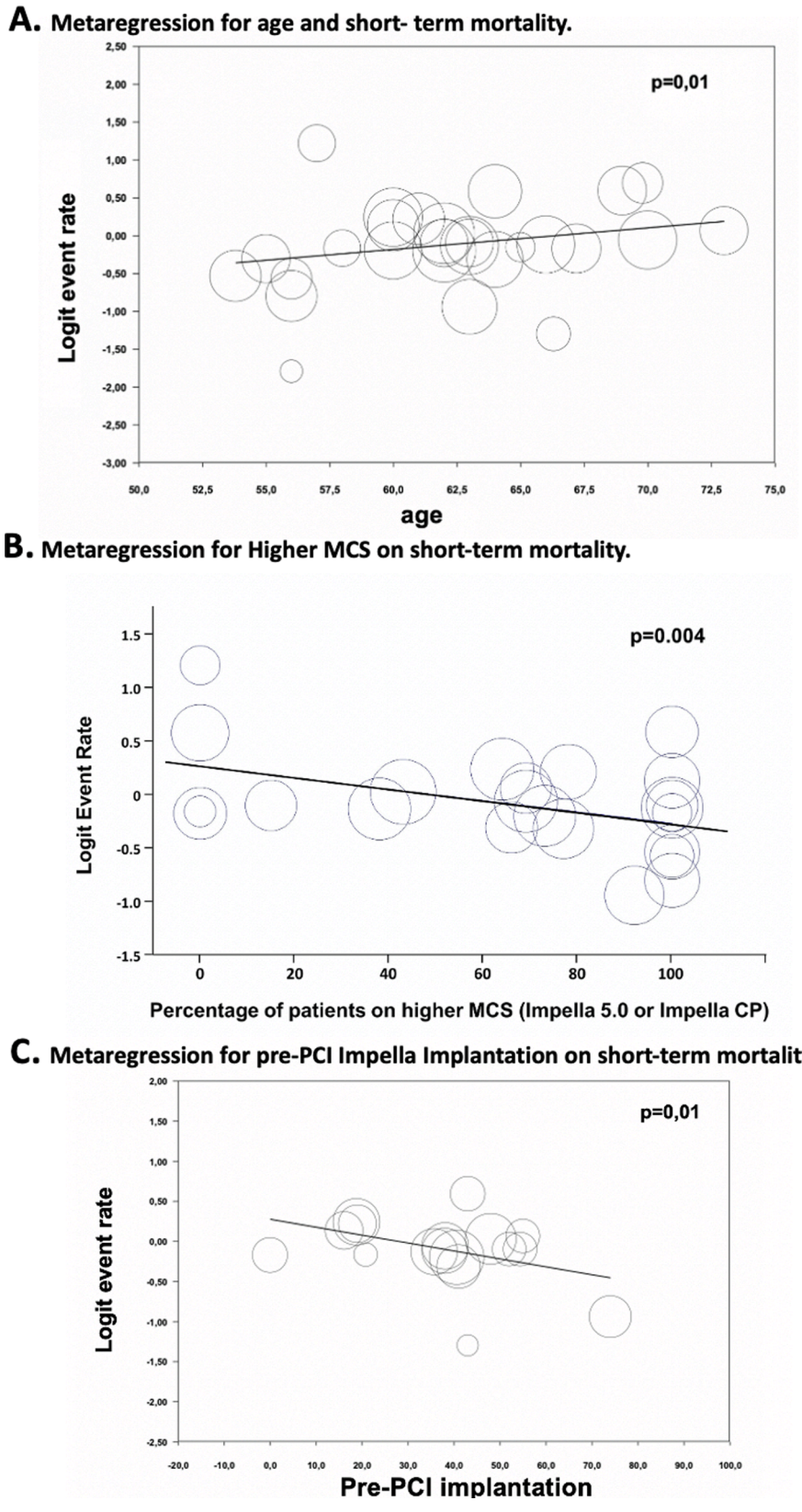

Fig. 3. Meta-Regression Analysis. Meta-regression analysis showing the interaction of event rate (short term mortality) with Age (A), higher MCS (B) and pre-PCI Impella implantation (C).

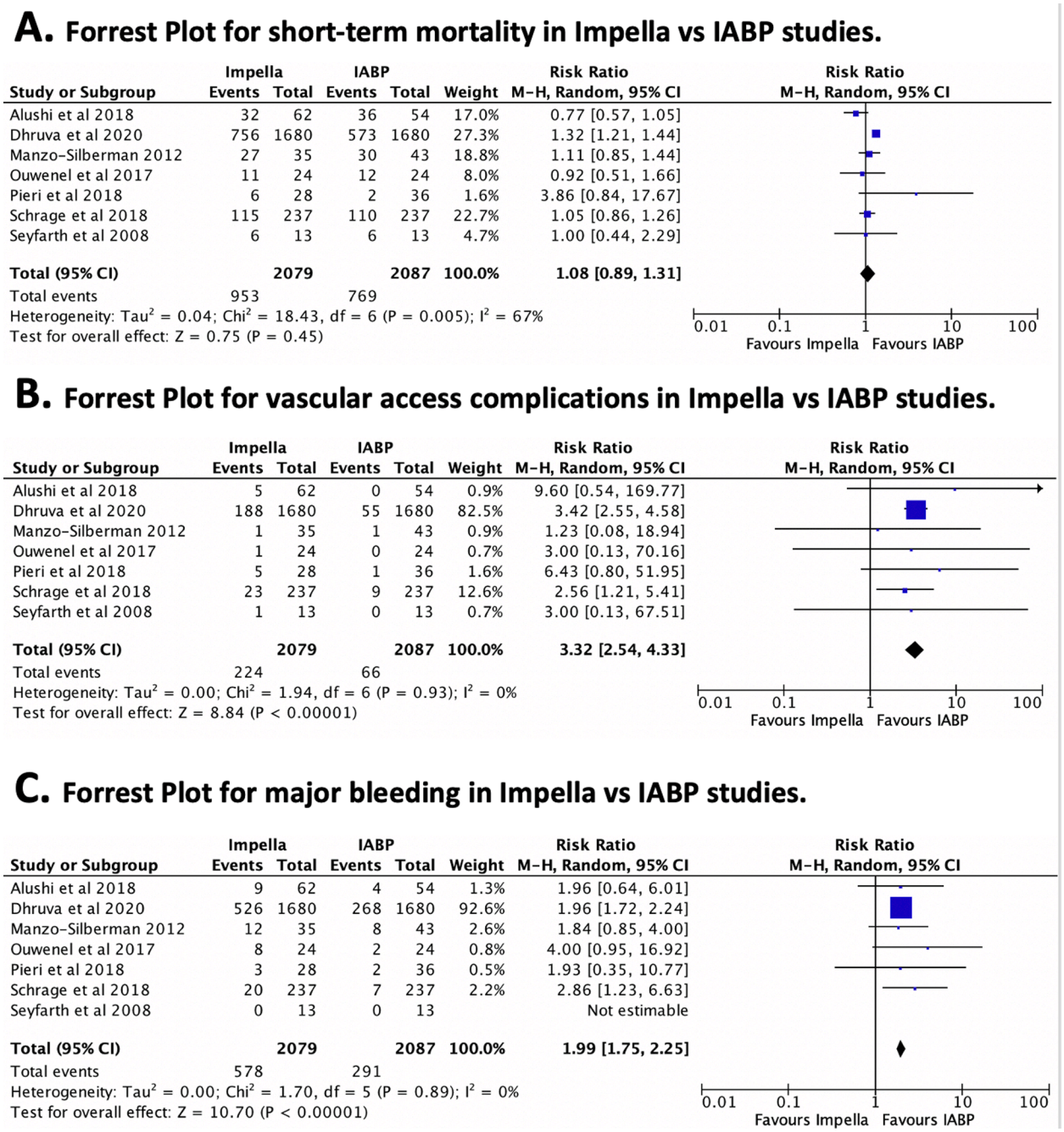

Fig. 4. Measures of Efficacy and Safety. Forest plots illustrating results of meta-analysis on the rate of short-term mortality (A) vascular access complications (B) and major bleeding (C) in Impella vs. IABP trials.

timing is key to clinical success. In fact, we found that pre-PCI insertion of Impella was significantly associated to better clinical outcomes. This is well in line with a robust literature evidence showing that the earlier we act in CS, the better outcomes are to be expected, be it a shorter time-to-unload or a shorter time-to-drug therapy [22,23].

Similar meta-analyses have recently addressed the issue of MCS in CS. Nevertheless, substantial differences should be noted compared with our work. In fact, they are either including patients treated with MCS for high-risk PCI, which represent a completely different clinical scenario [24,25] or they do not include an alternative device as direct comparison [26]. In contrast to previous meta-analyses, our study includes a larger number of studies and patients allowing adequately powered meta-regression analysis pointing to clinically relevant results regarding the general clinical impact of MCS with Impella and in comparison with the most widely used device, namely IABP.

4.1. *Limitations*

The limitations of this study derive, first of all, from the type of studies included in our analysis, which are all retrospective studies. Also, different selection criteria of the patients have been used among the studies included. Definition of bleeding in the different studies was heterogeneous in several cases. Finally, the duration of follow-up in some cases differed from one study to another as some studies reported mortality at 30 days while others reported in hospital mortality. Centers expertise is likely to have affected vascular complication rates. Furthermore, meta-analytical synthesis of secondary endpoints could not include all selected studies. In fact, among the studies included,

some did not report data on all pre-specified secondary endpoints. Specifically, the studies from Chung et al. and Rohm et al. were not included in the analysis of vascular complications and major bleeding because in the study from Chung et al Impella insertion was executed by trans axillary approach, and in the study from Rohm et al did not provide data on vascular access complication and major bleeding. In addition, the studies by Lemaire et al., Karatolios et al, and Chatzis et al. did not report any data not bleeding and were not included in that specific secondary analysis. Similarly, the studies by Meraj et al., Lemaire et al., Doshi et al., and Karatolios et al published in 2018 did not report data on vascular access complications and could not be included in this specific analysis. Furthermore, no data were provided regarding the timing of Impella insertion in the studies by Chung et al., Lauten et al., Manzo-Silberman et al., Monteagudo et al., Rohm et al., Schiller et al., Panoulas et al., Seyfarth et al., Lemaire et al., and Doshi et al., which could not be included in the pre/post PCI Impella insertion meta-regression analysis. Finally, as the study by Pieri et al did not distinguish between Impella CP or Impella 2.5, it could not be included in the meta-regression analysis regarding for impact of the level of hemodynamic support on short-term mortality. Similarly, longer-term clinical outcomes were not presented in most studies, and their relative follow-up lengths were heterogenous. The latter did not allow to perform additional analyses on longer-term clinical results.

4.2. Conclusions

Despite clinical evidence about MCS with Impella is still limited to small retrospective studies, our study shows that the use of higher degree of hemodynamic support, e.g. with Impella 5.0 or CP as compared to Impella 2.5, is associated with significant improvement in short-term mortality in CS. Despite large prospective clinical trials are needed to have a definitive picture of the actual clinical impact of MCS with Impella, the results of the present study provide a useful practical guide to optimize selection of patients, to the adoption of the most appropriate device size and to the choice of the optimal timing of MCS initiation in CS. At the same time, despite prospective clinical studies are very demanding in the setting of CS, our results should be useful to inform their design to maximize their clinical impact.

Declaration of Competing Interest

The authors report no relationships that could be construed as a conflict of interest.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2022.101007.

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