

Reperfusion therapy for ST-elevation myocardial infarction complicated by cardiogenic shock: the European Society of Cardiology EurObservational programme acute cardiovascular care-European association of PCI ST-elevation myocardial infarction registry

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Aims

To determine the current state of the use of reperfusion and adjunctive therapies and in-hospital outcomes in European Society of Cardiology (ESC) member and affiliated countries for patients with ST-segment elevation myocardial infarction (STEMI) complicated by cardiogenic shock (CS).

Methods and results

ESC EurObservational Research Programme prospective international cohort study of admissions with STEMI within 24 h of symptom onset (196 centres; 26 ESC member and 3 affiliated countries). Of 11 462 patients enrolled, 448 (3.9%) had CS. Patients with compared to patients without CS, less frequently received primary percutaneous coronary intervention (PCI) (65.5% vs. 72.2%) and fibrinolysis (15.9% vs. 19.0), and more often had no reperfusion therapy (19.0% vs. 8.5%). Mechanical support devices (intraaortic balloon pump 11.2%, extracorporeal membrane oxygenation 0.7%, other 1.1%) were used infrequently in CS. Bleeding definition academic research consortium 2–5 bleeding complications (10.1% vs. 3.0%, $P < 0.01$) and stroke (4.2% vs. 0.9%, $P < 0.01$) occurred more frequently in patients with CS. In-hospital mortality was 10-fold higher (35.5% vs. 3.1%) in patients with CS. Mortality in patients with CS in the groups with PCI, fibrinolysis, and no reperfusion therapy were 27.4%, 36.6%, and 62.4%, respectively.

Conclusion

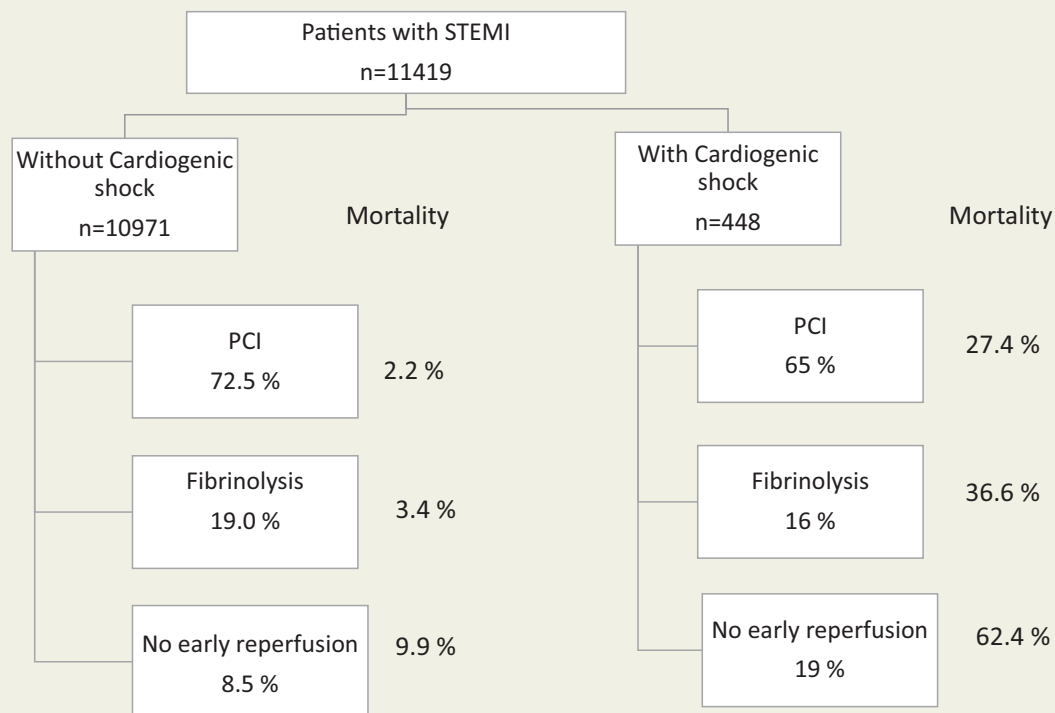
In this multi-national registry, patients with STEMI complicated by CS less frequently receive reperfusion therapy than patients with STEMI without CS. Early mortality in patients with CS not treated with primary PCI is very high. Therefore, strategies to improve clinical outcome in STEMI with CS are needed.

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[†] Listed in the [Supplementary material online, Appendix 1](#).

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Graphical Abstract



Acute reperfusion therapies and in-hospital mortality in patients with and without cardiogenic shock.

Keywords

Cardiogenic shock • ST-elevation myocardial infarction • Primary percutaneous coronary intervention • Registry • Reperfusion therapy

Introduction

The highest mortality in patients with acute ST-elevation myocardial infarction (STEMI) is observed in the subgroup of patients with cardiogenic shock (CS). Despite improvements in management, early mortality in patients with STEMI and CS approach 40%.¹ The European Society of Cardiology (ESC) has issued practice guidelines for patients with STEMI, the two latest versions published in 2012 and 2017,^{2,3} which recommend primary percutaneous coronary intervention (PCI) as preferred reperfusion therapy in CS. It has been shown that adherence to these guidelines improves outcomes.^{4,5} The 'Stent for life' initiative of the ESC has been created to increase the rate of patients treated with primary PCI within Europe and the Mediterranean basin.⁶ However, previous ACS-Surveys within the Euro Heart Survey Program performed in 2000, 2004, and 2008 and the snapshot registry in 2009 revealed gaps between recommendations by guidelines and their implementation into clinical practice.^{7–10} These gaps may have the greatest impact in the sickest patients, such as those with CS.¹ Here, we report the current status of reperfusion therapy and outcomes in patients with STEMI complicated by CS in an international prospective registry.

Methods

The design and methods of the registry have been published.^{11,12} This study describes the demographic, clinical, and biological characteristics of patients with STEMI admitted to cardiology centres in ESC-member and affiliated countries. Information on reperfusion therapies and the reasons why reperfusion therapy was not used were also evaluated. Details on technical aspects of PCI and adjunctive antithrombotic therapies as well as hospital events were collected.

Study organization

This registry is a joint initiative of the association of acute cardiovascular care and the European Association of PCI (EAPCI) under the umbrella of the EurObservational Research Programme (EORP). Centres with and without PCI facilities were invited to participate.

Patients

Between 1 January 2015 and 31 March 2018, patients aged > 18 years with an initial diagnosis of STEMI according to the ESC 2012 STEMI guidelines admitted within 24 h after symptom onset were identified on admission to the hospital, in the emergency room or directly in the catheterization laboratory and given a unique study number. For this

analysis, replicate counts of cases for STEMI occurring in the same patient were removed and only the earliest presentation included.

Data

Baseline data included demographic data, patient history, risk factors, and time intervals. Invasive coronary angiographic data and details of the revascularization procedures were collected. Medications given in the pre-hospital phase, during hospitalization and discharge were documented, as well as clinical events.

Definitions

CS was defined according to the ESC STEMI guidelines² and included hypotension <90 mmHg and/or the need of catecholamines, pulmonary congestion, and signs of end organ failure. Bleeding complications were classified according to the bleeding definition academic research consortium (BARC) definition.¹³

Statistics

Descriptive statistics are used to summarize frequency tabulations (*n*, %) and distributions (mean, SD). All the results are summarized with and without CS. For categorical data, frequency tabulations are presented (without missing values if applicable).

Results

Patients

A total of 11 462 patients from 196 centres in 29 countries were enrolled into the registry. From these, 448 patients (4.4%) presented

with CS. The baseline demographics of the patients with and without CS are given in [Table 1](#). Patients with CS were older and more often female. They had more co-morbidity, with more prior MI, prior stroke, history of atrial fibrillation, and also more frequently diabetic and cancer. While the rate of anterior AMI was around 50% in patients with and without CS, heart rate was higher and systolic blood pressure was lower in patients with CS ([Table 2](#)). The time-intervals between symptom onset, first medical contact and the start of primary PCI were not significantly different between patients with and without CS and about 60% of patients had primary PCI within 120 min after first medical contact in both groups ([Table 3](#)).

Reperfusion therapy

The intended treatment in patients with and without CS was PCI in the centre in 70.9% vs. 72.6%, transfer out for PCI at another hospital in 2.1% vs. 3.2%, fibrinolysis in 14.8% vs. 18.7%, no acute reperfusion therapy in 12.2% vs. 5.5%, and not determined in 3.5% vs. 5.8%, respectively. Treatment received with and without CS occurred for primary PCI in 65.2% vs. 72.5%, fibrinolysis in 15.9% vs. 19.0%, and without acute reperfusion therapy in 19.0 vs. 8.5%, respectively ([Figure 1](#)). Acute reperfusion therapies in seven predefined regions¹³ are shown in [Supplementary material online, Table S1](#). The reasons for not performing acute reperfusion therapy in the patients with and without CS were as follows: deemed clinically inappropriate (45.3% vs. 17.2%), contraindication to anticoagulation/antiplatelet therapy (13.2% vs. 4.6%), late presentation (28.3% vs. 40.4%), spontaneous reperfusion (0% vs. 16.9%), wrong diagnosis (0% vs. 4.0%),

Table 1 Baseline characteristics of the patients without and with cardiogenic shock

	Without CS	With CS	P-value
Patients (N)	10 971	448	
Age, years, mean ± SD	60.9 ± 12.7	65.2 ± 13.6	<0.001
Women	2485 (22.7%)	151 (33.7%)	<0.001
Prior myocardial infarction	1190/10 008 (11.9%)	74/398 (18.6%)	<0.001
Previous percutaneous coronary intervention	1093/10 910 (10.0%)	50/422 (11.9%)	0.221
Previous CABG surgery	188/10 937 (1.7%)	5/426 (1.2%)	0.393
Previous stroke/transient ischemic attack	560/10 915 (5.1%)	38/417 (9.1%)	<0.001
Peripheral artery disease	445/10 443 (4.3%)	23/397 (5.8%)	0.140
History of atrial fibrillation	414/10 872 (3.8%)	35/434 (8.1%)	<0.001
Diabetes mellitus	2855/10 741 (26.6%)	135/420 (32.1%)	0.012
Current smoker	4923/10 746 (45.8%)	182/415 (43.9%)	0.432
Hypercholesterolemia	3611/9410 (38.4%)	133/390 (39.2%)	0.749
Cancer or other life-limiting diseases	972/10 787 (9.0%)	54/408 (13.2%)	0.020

Table 2 ECG and clinical findings on admission in patients without and with cardiogenic shock

	Without CS	With CS	P-value
Anterior STEMI	5047/10 246 (49.2%)	209/431 (48.5%)	0.263
Other STEMI	5163/10 264 (50.3%)	217/431 (50.4%)	
Left bundle branch block	51/10 264 (0.5%)	5/431 (1.2%)	
Atrial fibrillation on qualifying ECG	511/10 966 (4.7%)	59/448 (13.2%)	<0.001
Heart rate (beats per minute) mean \pm SD	79.6 \pm 19.2	84.9 \pm 34.8	0.006
Systolic blood pressure (mmHg) mean \pm SD	134.8 \pm 26.7	93.1 \pm 30.6	<0.001
Out of hospital cardiac arrest	376/10 501 (3.5%)	112/442 (25.3%)	<0.001

Table 3 Mean time intervals (\pm SD) between symptom-onset, first medical contact (FMC) and percutaneous coronary intervention (PCI)

	Without CS	With CS	P-value
Symptom-onset to FMC (min)	(n = 10756) 220.6 \pm 461.4	(n = 440) 228.5 \pm 318.6	0.568
FMC to PCI (min)	(n = 7854) 195.3 \pm 1119.3	(n = 289) 152.6 \pm 173.0	
FMC to PCI <30 min	283/7854 (3.6%)	7/289 (2.4%)	
FMC to PCI <60 min	1646/7854 (21.0%)	40/289 (13.8%)	
FMC to PCI <120 min	4869/7854 (62.0%)	168/289 (58.1%)	

patient refusal (0% vs. 5.6%), and other (13.2% vs. 11.2%), respectively.

Invasive coronary findings and interventional features

Patients with CS more often had three-vessel disease and unprotected left main stem disease (Table 4). Before PCI, the culprit lesion was more often occluded in patients with CS vs. those without CS. Restoration of normal flow [thrombolysis in myocardial infarction (TIMI) 3 patency] in the infarct-related artery after PCI was observed less often in CS (81.1% vs. 89.9%, $P < 0.001$). Thrombectomy was used infrequently in both groups. Mechanical support devices [intraaortic balloon pump (IABP) 11.2%, extracorporeal membrane oxygenation (ECMO) 0.7%, other 1.1%] were used in about 14% in CS.

Pharmacotherapies

The acute antithrombotic therapies used according to reperfusion therapies are summarized in Table 5. The use of aspirin was over 91%, and the most widely used P2Y12 inhibitor was clopidogrel. Intravenous antiplatelet agents were given somewhat more often

in patients with CS (24.8% vs. 19.2%), with glycoprotein (GP) IIb/IIIa inhibitors as preferred choice. With respect to anticoagulation unfractionated heparin was most commonly used followed by low molecular weight heparins, while bivalirudin and fondaparinux were administered only rarely in both groups.

In-hospital procedures

Less than half of the patients with CS (44.2%) were mechanically ventilated during the hospital stay and 6.0% received therapeutic hypothermia. Emergency coronary artery bypass graft (CABG) surgery was performed in only 5 (1.1%) of the patients with CS. Additional revascularization procedures after Day 1 were performed in 11.9% of the patients with CS and are listed in Figure 2.

In-hospital outcomes

Median length of stay was 6.2 vs. 8.6 days in patients without and with CS. The in-hospital mortality was 3.1% without and 35.5% with CS. The association between different reperfusion strategies and the in-hospital mortality in patients with and without CS is given in Figure 3. There were 40 of 292 patients (13.8%) with primary PCI and immediate treatment of non-culprit lesions during the index PCI procedure. However, we do not know for sure if this was complete revascularization. The mortality of patients with immediate non-culprit PCI was 27.5% vs. 27.0% of those without immediate non-culprit PCI. Mechanical complications to myocardial infarction were reported in 19 (4.2%) patients with CS. Three had a ventricular septal defect, nine mitral insufficiency, and seven a cardiac tamponade. Definite or probable stent thrombosis and stroke occurred significantly more often patients with CS (Table 6). In addition, BARC bleeding complications were reported more often in patients with CS (Table 6). Left ventricular ejection fraction before discharge in patients with shock ($n = 386$) was 40 \pm 12% vs. 46.4 \pm 11% without shock ($n = 10312$).

Discussion

In this large international registry, including over 11 000 patients with STEMI from 29 countries, the incidence of recorded CS was about 5%.¹³ The main finding was that patients with CS less often received

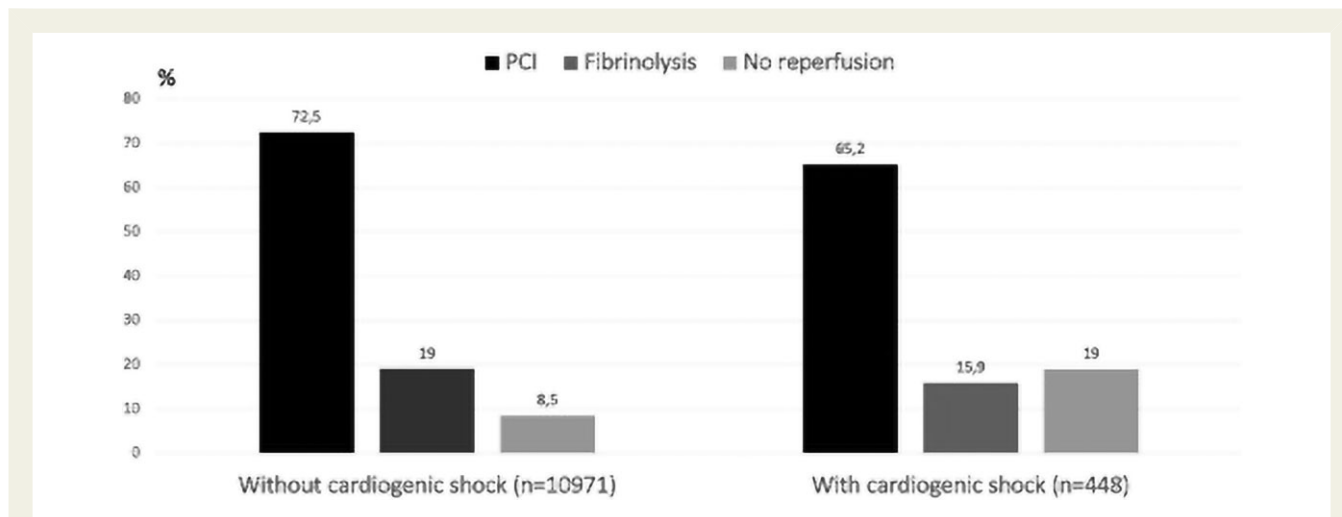


Figure 1 Rate of early reperfusion therapies performed in patients with and without cardiogenic shock. PCI, primary percutaneous coronary intervention.

Table 4 Angiographic findings and procedural features of PCI in patients with and without cardiogenic shock

	Without CS	With CS	P-value
N	8885	313	
Single vessel disease	4079 (45.7%)	122 (39.0%)	<0.001
Two-vessel disease	2755 (30.8%)	83 (26.5%)	
Three-vessel disease	1886 (21.1%)	103 (32.9%)	
Unprotected left main disease	745/8885 (8.4%)	56/317 (17.7%)	<0.001
Arterial access			
Femoral	3740/8993 (41.6%)	188/319 (58.9%)	<0.001
Radial	5147/8993 (57.2%)	122/319 (38.2%)	
Both	99/8993 (1.1%)	7/31 (2.2%)	
TIMI flow culprit vessel before PCI	N = 8401	N = 296	
0/1	6582 (78.5%)	258 (87.2%)	<0.001
2	936 (11.1%)	27 (9.1%)	
3	873 (10.4%)	11 (3.7%)	
TIMI flow culprit vessel after PCI	N = 8633	N = 302	
0/1	311 (3.6%)	28 (9.3%)	<0.001
2	558 (6.5%)	29 (9.6%)	
3	7764 (89.9%)	245 (81.1%)	
Thrombectomy	1686/8395 (20.1%)	72/303 (23.8%)	0.117
Non-culprit PCI during index PCI procedure	628/8911 (7.1%)	43/318 (13.5%)	<0.001
Non-culprit PCI during primary PCI procedure	557/7950 (7.0%)	40/292 (13.8%)	<0.001

primary PCI than patients without CS. CS is still the most important factor associated with mortality in patients with STEMI.¹ Early reperfusion therapy with PCI has been shown to improve outcome and is therefore recommended in ESC guidelines and position statements.¹⁻³

We found that less than two-third of patients with CS were treated with primary PCI. The in-hospital mortality of these patients was 27.4%, which is somewhat lower compared with the mortality of

patients in the two largest randomized trials in CS IABP-shock²¹⁵ and culprit-shock.¹⁶ This might be due to a selection bias, where for example patients dying very early might have been less likely to be included in our registry. However, our results underscore the clinical benefit of primary PCI in CS.

The data about the efficacy of fibrinolysis in CS are limited. In our analysis, 70 patients (16%) were given fibrinolysis and only 20 of the latter received subsequent revascularization with either PCI (n = 16)

or CABG ($n = 4$). Despite this low rate of revascularization therapy in-hospital mortality was only 36% compared to 62% without reperfusion therapy suggesting the possibility of a beneficial effect of fibrinolysis on outcome in STEMI with CS. However, it is not possible to use these observational data to infer cause and effect, so whether fibrinolysis was responsible for reduced mortality or simply associated, cannot be determined. In the STREAM study in patients with STEMI without CS fibrinolysis followed by early PCI within 6–24 h was not inferior to immediate primary PCI,¹⁷ thus it might be

speculated that a higher rate of secondary revascularization procedures after fibrinolysis might have led to improved outcomes.

As reported before^{18,19}, the mortality in patients with STEMI and CS not receiving early reperfusion therapy is extremely high, only one-third of these patients survived until discharge. There were multiple reasons given for not performing early reperfusion therapy, however, given the very high mortality these reasons should be evaluated in more depth. Attempts to reduce the high mortality in CS might include an increased rate of primary PCI in these patients and also the use of sophisticated left ventricular support. Such strategies need to be tested in randomized clinical trials.

In this cohort, the use of CABG surgery in CS was rare with only 5 patients receiving emergency CABG surgery, and 10 patients operated on a later timepoint during the initial hospital stay. Because of these low numbers the mortality of this approach cannot be properly evaluated in our data set.²⁰

The culprit-shock trial¹⁶ has shown that immediate multivessel PCI with PCI of non-culprit lesions is associated with an impaired prognosis in CS. In our registry, the overall rate of immediate non-culprit PCI was low, but performed two times more often in patients with CS. This might be due to the fact that the 2012 ESC STEMI Guidelines² (current at the time of recruitment into this registry) were more in favour of immediate multivessel PCI in CS, as these guidelines were published before the culprit-shock trial has been published. Procedural success defined as TIMI 3 flow of the culprit lesion was around 10% lower in patients with CS. However, the TIMI flow rate in CS was above 80%, suggesting that these patients can be treated with a high success rate in clinical practice in different countries and centres. These results are in line with earlier reports of the procedural success rates in CS.²¹

Mechanical support devices were used infrequently in CS. Despite the fact that the IABP is not recommended in the ESC guidelines for

Table 5 Antithrombotic therapy during the first 24 h according to the presence of cardiogenic shock (CS)

	Without CS	With CS
Aspirin	10701/10 959 (97.7%)	410/447 (91.7%)
Clopidogrel	7192/10 960 (65.6%)	287/448 (64.1%)
Prasugrel	1207/10 959 (11.0%)	28/448 (6.3%)
Ticagrelor	2582/10 960 (23.6%)	99/448 (22.1%)
Dual antiplatelet therapy	10559/10 958 (96.4%)	397/447 (88.8%)
GP IIb/IIIa inhibitors	1971/10 254 (19.2%)	107/431 (24.8%)
Cangrelor	5/10 254 (0.1%)	3/431 (0.7%)
Unfractionated heparin	6991/10 952 (63.8%)	300/447 (67.1%)
Low-molecular-weight heparin	4092/10 953 (37.4%)	146/448 (32.6%)
Bivalirudin	129/10 862 (1.2%)	4/446 (0.9%)
Fondaparinux	217/10 856 (2.0%)	5 (446) 1.1%

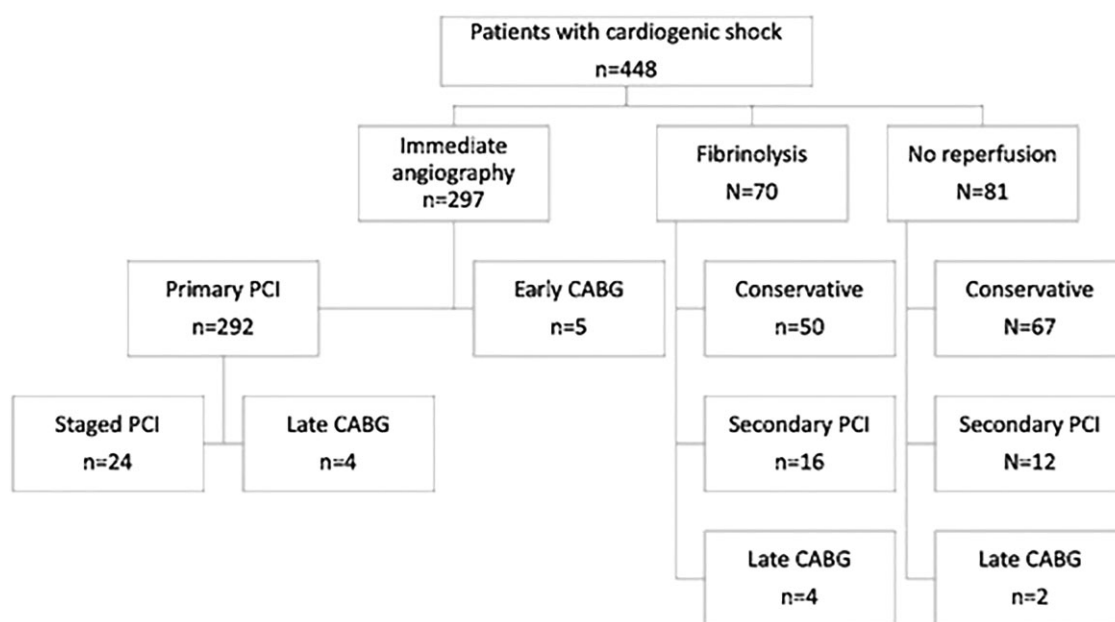


Figure 2 Flow diagram with the rate of initial reperfusion strategy and subsequent revascularization procedures in patients with cardiogenic shock. CABG, coronary artery bypass graft surgery; PCI, percutaneous coronary intervention.

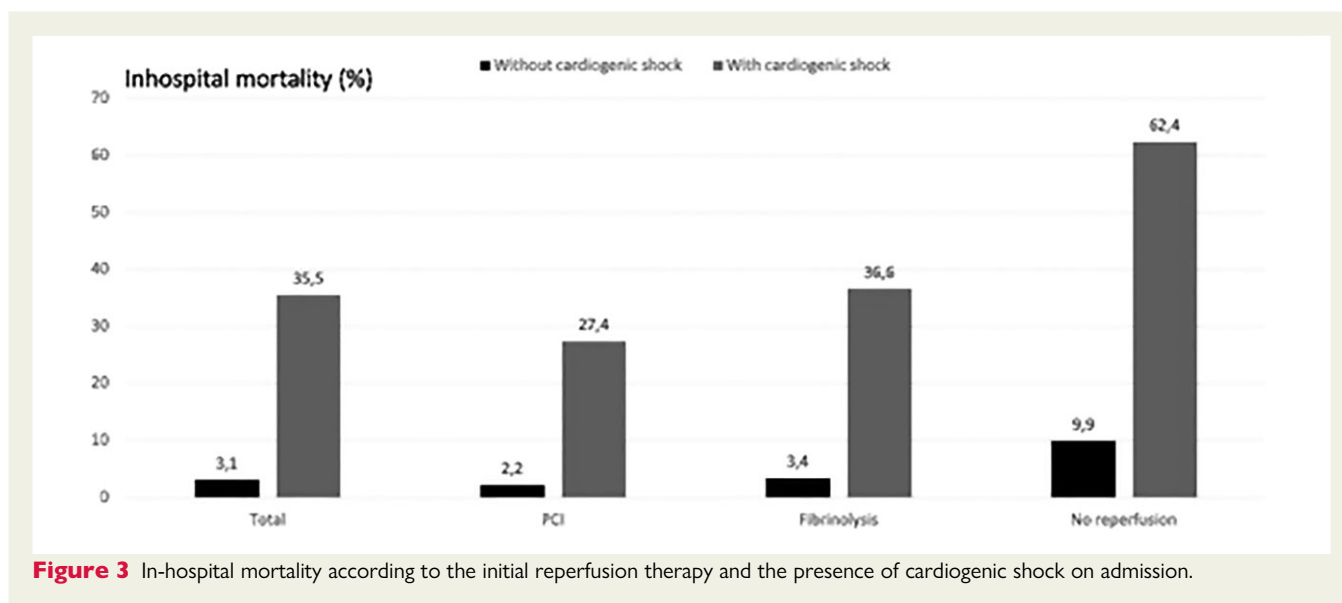


Figure 3 In-hospital mortality according to the initial reperfusion therapy and the presence of cardiogenic shock on admission.

Table 6 In hospital events in patients without and with cardiogenic shock

	Without CS	With CS
Re-infarction	113/10 969 (1.0%)	7/448 (1.6%)
Stent thrombosis		
All	138/10 927 (1.3%)	17/446 (3.8%)
Definite	97/10 927 (0.9%)	9/446 (2.0%)
Probable	28/10 927 (0.3%)	6/446 (1.4%)
Stroke	96/10 969 (0.9%)	19/448 (4.2%)
Total BARC bleeding complications	597/10 966 (5.4%)	70/447 (15.6%)
BARC 2–5 bleeding	327 (3.0%)	45/447 (10.0%)

routine use in CS about 11% were treated with an IABP, while only less than 2% received other mechanical support devices. While the IABP has been studied in a large-randomized trial, the evidence for the use of ECMO and Impella is limited,¹ which could be the reason for low usage in our registry.

Limitations

Despite the large number of patients included the representativeness of the patient population for the participating countries and Europe was limited. The rate of patients with CS was lower than 5%, which suggests selection bias, and limits the ability to extrapolate our findings to the wider population. Data about left ventricular ejection fraction were not available on admission and for the acute phase but only at discharge.

Conclusion

In our observational study, we observed a low use of primary PCI in patients with STEMI complicated by CS. Mortality in CS without reperfusion therapy is high and efforts should be made to try to

understand ways to improve this, which might include an increase in the rate of early revascularization.

Supplementary material

Supplementary material is available at *European Heart Journal: Acute Cardiovascular Care*.

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Data availability

The data belong to the EORP of the ESC and are not available.

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