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An analysis from the SILCARD Database

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Short title: Temporal trends in in-hospital mortality of cardiogenic shock

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INTRODUCTION

Cardiogenic shock (CS) is a low-cardiac-output state characterized by life-threatening end-organ hypoperfusion and hypoxia. Myocardial infarction (MI) with left ventricular failure remains one of the most frequent causes of CS [1]. The widespread implementation of early revascularization has decreased mortality from the previous 70%–80% to 40%–50% [2, 3]. Despite significant advances in percutaneous coronary interventions (PCI) and mechanical circulatory support (MCS) techniques, outcomes for patients with MI complicated by CS (MI-CS) remain unsatisfactory. Although some data suggest that treatment outcomes in this population have improved in recent years [4, 5], many authors highlight that in-hospital mortality of CS complicating MI has remained unchanged [2, 3]. Moreover, some recent registries have even shown an increase in mortality rate, which may be a consequence of the aging patient population and increasing risk profiles of CS patients [6, 7]. There is a paucity of comprehensive data concerning changes in treatment strategies and outcomes for all-comer MI-CS patients in recent years.

Therefore, we aimed to analyze the recent trends in the mortality of patients hospitalized with a diagnosis of MI-CS, as recorded in the Silesian Cardiovascular Database (SILCARD).

MATERIAL AND METHODS

General information on the SILCARD database (ClinicalTrials.gov identifier, NCT02743533) was described previously [8]. In brief, the SILCARD database was created under an agreement between the Silesian Center for Heart Diseases in Zabrze and the Silesian branch of the National Health Fund (NHF), the only health provider in Poland supplying data on patients with cardiovascular diseases. It contains records from all hospitals (n = 310) in the Silesian Province, a highly industrialized administrative region in Poland with a population of 4.4 million (11.6% of Poland's total population).

The Silesian Province provides a well-developed hospital network with two tertiary cardiology hospitals, three cardiac surgery departments, and 20 catheterization laboratories. The NHF has supplied all data to the database since 2006. The inclusion criteria were as follows: each hospitalization in the departments of cardiology, cardiac surgery, vascular surgery, or diabetology, and hospitalization with a cardiovascular diagnosis in the department of intensive care or internal medicine. The exclusion criteria were hospitalizations of patients younger than 18 years at admission or patients living outside of the Silesian Province.

The analysis included all patients from the SILCARD database hospitalized with a principal diagnosis of CS (R57.0 code according to the International Classification of Diseases, 10th Revision [ICD-10] and a diagnosis of MI [I21–I22 code according to ICD-10]) between 2006 and 2021. Medical procedures were defined by the ICD-9 classification. The diseases diagnoses involved in the table were based on data submitted to the NHF. It should be assumed that heart failure included patients diagnosed both before and during hospitalization without differentiating into types (reduced, mildly reduced or preserved ejection fraction).

The clinical characteristics, management, in-hospital, and one-year mortality were analyzed as trends across the years. Both all-cause mortality data and medical procedures during 1-year follow-up were obtained from the NHF records. Vital status at 12 months after MI-CS was available for all patients.

Statistical analysis

Continuous variables were presented as mean with standard deviation or median with interquartile range and categorical variables as counts and percentages. The significance of the time trends in the studied years was calculated using ANOVA with linear trend contrasts set for age, Jonckheere–Terpstra trend test for in-hospital stay and the Cochran–Armitage test for categorical variables. The significance of the difference between the two groups was assessed using the t-test

or the χ^2 test, depending on the type of data. TIBCO Software Inc. (2017) Statistica (data analysis software system), version 13.3, was used for all calculations.

RESULTS AND DISCUSSION

The analysis involved 7628 residents of the Silesian Province hospitalized with a diagnosis of CS from January 1, 2006, to December 31, 2021. Trends in patient characteristics, in-hospital, and 12-month outcomes are presented in **Table 1**. There was a significant decrease in the percentage of patients with CS complicating ST-segment elevation MI ($P < 0.001$) and the use of MCS with intra-aortic balloon pump ($P < 0.001$) over the years 2006–2021. Despite the increase in the frequency of coronary angiography and percutaneous revascularization, there were no significant changes in in-hospital and 1-year mortality trends. At the same time, there were increasing trends in occurrences of hypertension, diabetes, co-existing comorbidities, and previous revascularization procedures. Although a significant trend was found in the increasing percentage of patients undergoing rehabilitation after MI-CS ($P < 0.001$), the rate remains relatively low.

Our analysis found no significant changes in in-hospital mortality trends in MI-CS patients treated in the Silesian Province from 2006 to 2021. Although such results may seem disappointing, it is necessary to emphasize the increasing trends in the incidence of co-existing comorbidities in MI-CS patients, including heart failure, diabetes, previous MIs, strokes, and renal failure. Theoretically, these factors should lead to an increased mortality rate in the analyzed period. The growing availability of PCI procedures and advancements in CS treatment have likely prevented an increase in the mortality rate.

There are few data assessing trends in in-hospital mortality in the population of CS patients in recent years [4, 5]. Osman et al. [4] showed a reduction in in-hospital mortality in MI-CS American patients from 44% in 2004 to 35% in 2018 (P trend < 0.001). In the analysis of 441 696 patients with CS treated in Germany between 2005 and 2017, the in-hospital mortality rate remained around 60%. There was a trend towards lower mortality in patients with MI-CS without clear improvements in patients without MI [5]. Generally, the unsatisfactory outcomes of MI-CS treatment have not substantially changed in the past 25 years [1–3, 6, 9, 10].

The only available method of treatment in this group of patients with proven clinical efficacy is early revascularization [9]. We showed a trend in the increase in the frequency of PCI procedures with a much lower and stable percentage of patients undergoing coronary artery bypass grafting. This may be surprising if we assume that a certain proportion of patients may have had multivessel coronary artery disease. In another study from the SILCARD database, MI-CS patients undergoing coronary artery bypass grafting had lower in-hospital mortality than those

undergoing PCI [11]. In our analysis, the trend in the use of intra-aortic balloon pump decreased significantly over the years and the use of extracorporeal membrane oxygenation remained marginal. In the mentioned German analysis, the more frequent use of extracorporeal membrane oxygenation and other percutaneous MCS techniques did not significantly improve treatment results [5].

The treatment of patients with MI complicated by CS remains a problem requiring not only therapeutic but also logistical solutions. One of them might be the direct transfer of patients to specialized centers called Cardiac Shock Centers. These centers should provide access not only to a catheterization laboratory but also to the highest level of specialized care and cardiothoracic surgery [11–13]. A network of such centers seems necessary in Poland [11, 12].

It should be noted that this study has some limitations. First, the analyses included all-cause mortality. Second, an impossibility to establish a causal relationship due to lack of multivariate analyses.

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Table 1. Trends in patients characteristics, in-hospital and 12 months outcomes

Patients characteristic	Total n = 7628	2006 n = 523	2007 n = 466	2008 n = 422	2009 n = 432	2010 n = 455	2011 n = 523	2012 n = 549	2013 n = 499	2014 n = 493	2015 n = 469	2016 n = 446	2017 n = 511	2018 n = 494	2019 n = 477	2020 n = 456	2021 n = 413	Trend tests, P-value	
Age, years, mean (SD)	70.2 (11.3)	69.0 (11.5)	69.4 (11.8)	70.0 (12.4)	69.1 (11.3)	69.3 (11.3)	69.9 (11.5)	70.3 (11.6)	69.9 (10.8)	69.8 (11.7)	70.5 (11.3)	70.7 (11.3)	71.3 (10.4)	71.1 (10.6)	71.0 (11.3)	70.5 (11.0)	70.5 (11.3)	<0.001	
In-hospital stay, days, median (IQR)	4 (2–9)	3 (2–8)	3 (1–9)	4 (2–8)	4 (2–10)	5 (2–10)	5 (2–9)	4 (2–9)	4 (2–10)	4 (1–9)	4 (1–9)	4 (2–10)	4 (2–10)	5 (2–11)	5 (2–11)	5 (2–11)	5 (2–11)	4 (1–10)	<0.001
Female sex, n (%)	3192 (41.8)	232 (44.4)	209 (44.8)	192 (45.5)	180 (41.7)	192 (42.2)	218 (41.7)	228 (41.5)	206 (41.3)	191 (38.7)	196 (41.8)	178 (39.9)	221 (43.2)	194 (39.3)	195 (40.9)	182 (39.9)	178 (43.1)	0.028	
STEMI, n (%)	4976 (65.2)	385 (73.6)	340 (73.0)	311 (73.7)	314 (72.7)	309 (67.9)	352 (67.3)	346 (63.0)	300 (60.1)	323 (65.5)	280 (59.7)	276 (61.9)	308 (60.3)	301 (60.9)	279 (58.5)	278 (61.0)	274 (66.3)	<0.001	
NSTEMI, n (%)	2485 (32.6)	98 (18.7)	102 (21.9)	105 (24.9)	110 (25.5)	133 (29.2)	160 (30.6)	189 (34.4)	192 (38.5)	166 (33.7)	182 (38.8)	163 (36.5)	194 (38.0)	184 (37.2)	197 (41.3)	177 (38.8)	133 (32.2)	<0.001	
Non-identified MI, n (%)	167 (2.2)	40 (7.6)	24 (5.2)	6 (1.4)	8 (1.9)	13 (2.9)	11 (2.1)	14 (2.6)	7 (1.4)	4 (0.8)	7 (1.5)	7 (1.6)	9 (1.8)	9 (1.8)	1 (0.2)	1 (0.2)	6 (1.5)	0.003	
Hypertension,	5442	172	247	250	277	323	394	412	363	379	367	354	405	387	393	375	344	<0.001	

n (%)	(71.3)	(32.9)	(53.0)	(59.2)	(64.1)	(71.0)	(75.3)	(75.0)	(72.7)	(76.9)	(78.3)	(79.4)	(79.3)	(78.3)	(82.4)	(82.2)	(83.3)	1
Diabetes, n (%)	2667 (35.0)	95 (18.2)	119 (25.5)	126 (29.9)	129 (29.9)	131 (28.8)	183 (35.0)	200 (36.4)	183 (36.7)	172 (34.9)	173 (36.9)	183 (41.0)	204 (39.9)	203 (41.1)	196 (41.1)	213 (46.7)	157 (38.0)	<0.001
Atrial fibrillation, n (%)	826 (10.8)	15 (2.9)	35 (7.5)	22 (5.2)	31 (7.2)	38 (8.4)	61 (11.7)	68 (12.4)	53 (10.6)	47 (9.5)	57 (12.2)	64 (14.3)	62 (12.1)	64 (13.0)	71 (14.9)	72 (15.8)	66 (16.0)	<0.001
Heart failure, n (%)	518 (33.0)	108 (20.7)	111 (23.8)	116 (27.5)	127 (29.4)	151 (33.2)	174 (33.3)	193 (35.2)	179 (35.9)	181 (36.7)	147 (31.3)	161 (36.1)	189 (37.0)	164 (33.2)	186 (39.0)	179 (39.3)	152 (36.8)	<0.001
Renal failure, n (%)	592 (7.8)	9 (1.7)	11 (2.4)	20 (4.7)	28 (6.5)	29 (6.4)	37 (7.1)	34 (6.2)	43 (8.6)	34 (6.9)	43 (9.2)	44 (9.9)	54 (10.6)	53 (10.7)	60 (12.6)	53 (11.6)	40 (9.7)	<0.001
PVD, n (%)	3237 (42.8)	106 (20.3)	151 (32.4)	134 (31.8)	168 (38.9)	175 (38.5)	223 (42.6)	241 (43.9)	217 (43.5)	217 (44.0)	239 (51.0)	212 (47.5)	247 (48.3)	229 (46.4)	233 (48.8)	241 (52.9)	204 (49.4)	<0.001
Previous MI, n (%)	1114 (14.6)	27 (5.2)	39 (8.4)	35 (8.3)	57 (13.2)	58 (12.7)	76 (14.5)	99 (18.0)	74 (14.8)	77 (15.6)	74 (15.8)	74 (16.6)	86 (16.8)	84 (17.0)	91 (19.1)	83 (18.2)	80 (19.4)	<0.001
Previous PCI, n (%)	1161 (15.2)	13 (2.5)	18 (3.9)	27 (6.4)	46 (10.6)	68 (14.9)	64 (12.2)	86 (15.7)	79 (15.8)	74 (15.0)	81 (17.3)	84 (18.8)	107 (20.9)	110 (22.3)	111 (23.3)	99 (21.7)	94 (22.8)	<0.001
Previous CABG, n (%)	166 (2.2)	0 (0.0)	1 (0.2)	2 (0.5)	4 (0.9)	5 (1.1)	6 (1.1)	10 (1.8)	10 (2.0)	13 (2.6)	21 (4.5)	14 (3.1)	9 (1.8)	16 (3.2)	18 (3.8)	20 (4.4)	17 (4.1)	<0.001

Rehabilitation , n (%)	929 (12.2)	56 (10.7)	48 (10.3)	45 (10.7)	44 (10.2)	40 (8.8)	58 (11.1)	61 (11.1)	69 (13.8)	52 (10.5)	61 (13.0)	44 (9.9)	73 (14.3)	86 (17.4)	84 (17.6)	61 (13.4)	47 (11.4)	<0.00 1
1-year mortality, n (%)	5513 (72.3)	373 (71.3)	351 (75.3)	313 (74.2)	301 (69.7)	335 (73.6)	359 (68.6)	388 (70.7)	353 (70.7)	367 (74.4)	327 (69.7)	343 (76.9)	371 (72.6)	350 (70.9)	346 (72.5)	338 (74.1)	298 (72.2)	0.36

Abbreviations: CABG, coronary artery bypass grafting; decr., decreasing; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; incr., increasing; IQR, interquartile range; MI, myocardial infarction; NSTEMI, non-ST elevation myocardial infarction; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease; SD, standard deviation; STEMI, ST-segment elevation myocardial infarction