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ORIGINAL ARTICLE

In-hospital outcomes in nonagenarian patients undergoing primary percutaneous coronary intervention

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ABSTRACT

BACKGROUND: The aim of the present analysis was to evaluate the incidence and predictors of in-hospital adverse outcomes in nonagenarian patients undergoing primary percutaneous coronary intervention (pPCI) for ST-segment elevation myocardial infarction (STEMI).

METHODS: Consecutive nonagenarian patients undergoing pPCI for STEMI from 2009 to 2019 were retrospectively included in an international multicenter registry. In-hospital all-cause death was the primary outcome.

RESULTS: A total of 308 patients were included (mean age 92.5±2.5 years, 65.6% female). Mean systolic blood pressure (SBP) at hospital admission was 130.7±33.5 mmHg, 46 (17%) patients presented with a Killip class III-IV, mean left ventricle ejection fraction (LVEF) was 40.0±11.5% and 147 (58%) patients were independent in everyday activities. In-hospital death occurred in 99 patients (32%). After multivariate adjustment, lower LVEF (OR per unit reduction 1.08, 95% CI: 1.03-1.11, P value <0.001), lower SBP (OR 1.02 per mmHg reduction, 95% CI: 1.01-1.03, P value 0.001) and being not independent at home (OR 2.56, 95% CI: 1.25-5.26, P value 0.01) resulted independent predictors of in-hospital mortality. A sensitivity analysis performed in final TIMI 3 flow population confirmed the prognostic role of LVEF and independency on in-hospital mortality.

CONCLUSIONS: Nonagenarian patients presenting with STEMI and undergoing pPCI have high in-hospital mortality. Independency in everyday life is a strong independent predictor of survival to hospital discharge.

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KEY WORDS: ST elevation myocardial infarction; Percutaneous coronary intervention; Aged, 80 and over; Frail elderly.

Life expectancy is progressively increasing in Western countries and ischemic heart disease is one of the leading causes of morbidity and mortality in this aging population.^{1, 2} Patients aged >75 years represent about one third of those with ST-segment elevation myocardial infarction (STEMI) referred for primary percutaneous coronary intervention (pPCI), which is regarded as the standard of care for patients suffering from acute myocardial infarction (AMI).³ Notwithstanding, the older old are often managed conservatively, even though this strategy has been associated with poorer short- and long-term outcomes.^{4, 5}

Advanced age is by itself one of the strongest predictors of worse outcomes among acute coronary syndrome cohorts, as atypical symptoms, delayed presentation, multiple comorbidities and treatment side effects occur frequently in this population.^{6, 7} However, very elderly STEMI patients are often excluded from randomized clinical trials (RCTs) and limited data are available to support clinical decisions in this subgroup of patients.

Accordingly, the aim of the present analysis was to evaluate the incidence and predictors of in-hospital adverse outcomes and the rate of successful PCI in nonagenarian patients undergoing pPCI for STEMI among the SENEX (primary percutaneous coronary intervention for ST-segment Elevation myocardial infarction in Nonagenarian patients: an international multicenter EXperience) Registry population.

Materials and methods

The SENEX Registry is an international multicenter retrospective registry including 10 cardiovascular Centers in Italy and Poland; participating Centers are reported in the Supplementary Digital Material 1 (Supplementary Text File 1). Consecutive patients aged ≥ 90 years-old undergoing pPCI for STEMI from January 2009 to December 2019 were included.

Data on demographics, cardiovascular risk factors, laboratory values, medications, electrocardiographic and echocardiographic parameters, angiographic data and in-hospital outcomes were collected on prespecified datasets through

the revision of clinical charts and electronic medical records. AMI and STEMI were defined according to the definitions available at the time of patients' hospital admission.⁸ Patients were considered independent if they did not rely on a third person for self-care and mobility. The SENEX Registry was conducted in accordance with the principles of the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice guidelines. Written informed consent was not requested given the retrospective nature of the Registry and the use of de-identified data sets. Patients were not involved in the design, conduct or reporting of our research.

Study outcomes

The primary outcome was the incidence of in-hospital all-cause death. Co-primarily, we investigated the predictors of in-hospital mortality. Additionally, the incidence of successful pPCI, mechanical complications, life-threatening arrhythmias, re-AMI, ischemic stroke, contrast-induced acute kidney injury (CI-AKI), need for non-invasive ventilation (NIV), and need for blood transfusions were also analyzed. pPCI success was defined as postprocedural Thrombolysis In Myocardial Infarction (TIMI) 3 flow of the culprit lesion.⁹ Mechanical complications encompassed free wall rupture, ventricular septal rupture and acute ischemic mitral regurgitation. Life-threatening arrhythmias included sustained ventricular tachycardia (VT) and ventricular fibrillation (VF). CI-AKI was defined as an increase by 1.5 times or more or by at least 0.3 mg/dL in plasma creatinine over baseline within 48 hours after exposure to contrast medium, according to the definition proposed by the KDIGO working group.¹⁰ The decision to perform PCI, along with the strategy of revascularization, arterial access and the choice of periprocedural drugs (i.e. dual antiplatelet therapy, heparin/bivalirudin and GpIIb/IIIa inhibitors) were at the operator's discretion.

Statistical analysis

Continuous data were reported as mean and standard deviations (SD) or median and interquartile range (IQR); categorical variables as absolute

numbers or percentages. Baseline characteristics of patients were compared by means of one-way ANOVA for normally distributed continuous variables, Kruskal-Wallis Test for non-normally distributed continuous variables and chi-squared test or Fisher's exact test for categorical variables. A multivariate logistic regression analysis was performed to evaluate independent predictors of in-hospital mortality. Variables with a univariate P value <0.10 were entered into the model. Results are reported as odds ratios (ORs) with 95% confidence intervals (CIs). To further characterize the association between patient characteristics and the probability of in-hospital death a spline curve was fitted. As sensitivity analyses, the outcomes of the main analysis were analyzed stratified by pPCI success, intended as the achievement of postprocedural TIMI 3 flow of the culprit lesion.

A two-sided P value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS version 26.0 (SPSS, Chicago, IL, USA) and in R environment (version 4.0.3, R Foundation for Statistical Computing, Vienna, Austria).

Results

Study population

Between January 2009 and December 2019, 321 nonagenarian patients with STEMI were admitted at the participating Centers and underwent pPCI. The number of nonagenarian patients undergoing pPCI for STEMI per year increased from 16 (5%) in 2009 to 41 (13%) in 2019 (Figure 1); the comparison between the first 5-year period (2009-2013) with the last 5-year period (2015-2019) showed a 2.1-fold increase in the number of procedures (89 vs. 181). Incomplete or unreliable data on study outcomes were present in 13 patients (4%), who were excluded from the present analysis, leaving a study population of 308 patients (Figure 2). Mean age was 92.5 ± 2.5 years and 202 (66%) patients were female. Two-hundred and forty (80%) patients had history of hypertension, 70 (24%) diabetes and 60 (21%) hypercholesterolemia. Overall, 147 (58%) patients were independent at home. On admission systolic blood pressure (SBP) was ≤ 90 mmHg in

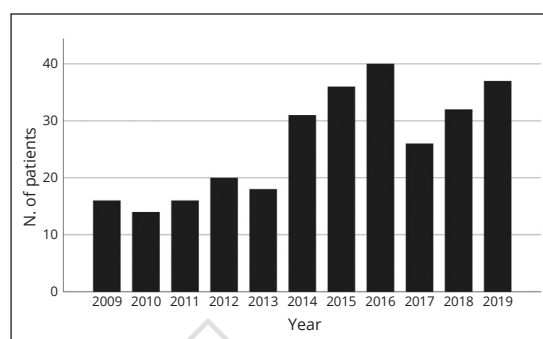


Figure 1.—Temporal trend of nonagenarians referred for primary PCI.

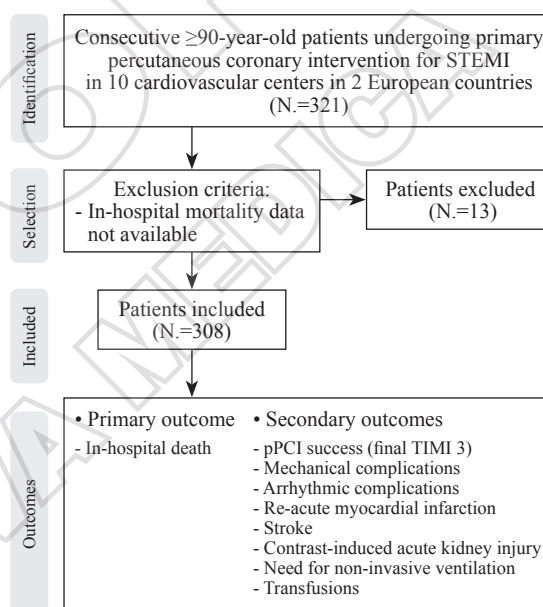


Figure 2.—Study flow diagram.

14.1% of patients (mean 130.7 ± 33.5 mmHg), 46 (17%) patients presented with Killip class III-IV, and mean left ventricle ejection fraction (LVEF) was $40.0 \pm 11.5\%$. At coronary angiography, the left anterior descending artery was the most common culprit vessel (55%), and 100 (53%) patients had multivessel disease; the intra-aortic balloon pump was positioned in 12 (5.8%) patients (Table I).

Outcomes

In-hospital death occurred in 99 patients (32%) after a median of 4.0 days (interquartile range 1.0 to 12.0 days) from admission (Table II). For the

TABLE I.—Baseline characteristics of the study population.

	Overall population N=308 (%)	In-hospital survivors N=209 (%)	In-hospital death N=99 (%)	P value
Age (years)	92.5±2.5	92.5±2.5	92.3±2.4	0.428
Female sex	202/308 (65.6)	134/209 (64.1)	68/99 (68.7)	0.430
Independent	147/254 (57.9)	112/168 (66.7)	35/86 (40.7)	<0.001*
BMI	23.8±4.0	24.0±4.0	23.2±3.6	0.310
Familiarity	23/227 (10.1)	20/163 (12.3)	3/64 (4.7)	0.088
History of hypertension	240/301 (79.7)	170/205 (82.9)	70/96 (72.9)	0.044*
Hypercholesterolemia	60/289 (20.8)	46/196 (23.5)	14/93 (15.1)	0.099
Diabetes	70/289 (24.2)	46/194 (23.7)	24/95 (25.3)	0.772
Smoke	40/238 (16.8)	29/169 (17.2)	11/69 (15.9)	0.820
History of HF	68/219 (31.1)	41/143 (28.7)	27/76 (35.5)	0.297
Atrial fibrillation	76/289 (26.3)	53/194 (27.3)	23/95 (24.2)	0.573
CAD	116/294 (39.5)	74/200 (37.0)	42/94 (44.7)	0.209
Prior AMI	62/287 (21.6)	38/193 (19.7)	24/94 (25.5)	0.259
Prior PCI	41/286 (14.3)	32/192 (16.7)	9/94 (9.6)	0.108
Prior CABG	13/286 (4.5)	9/192 (4.7)	4/94 (4.3)	0.869
PAD	80/280 (28.6)	51/188 (27.1)	29/92 (31.5)	0.445
COPD	36/285 (12.6)	21/190 (11.1)	15/95 (15.8)	0.256
CKD	117/306 (38.2)	82/209 (39.2)	35/97 (36.1)	0.598
Medications at baseline				
Aspirin	130/261 (49.8)	96/190 (50.5)	34/71 (47.9)	0.704
Clopidogrel	19/231 (8.2)	11/161 (6.8)	8/80 (11.4)	0.243
ACE-inhibitors	94/256 (36.7)	72/187 (38.5)	22/69 (31.9)	0.330
ARB	41/248 (16.5)	32/179 (17.9)	9/69 (13.0)	0.358
Beta-blockers	106/252 (42.1)	73/179 (40.8)	33/73 (45.2)	0.519
Statins	54/253 (21.3)	38/179 (21.2)	16/74 (21.6)	0.945
Oral anticoagulants	22/245 (9.0)	16/173 (9.3)	6/72 (8.3)	0.819
Clinical presentation				
Cardiogenic shock	35/304 (11.5)	9/206 (4.4)	26/98 (26.5)	< 0.001*
Killip class III-IV	46/268 (17.2)	21/187 (11.2)	25/81 (30.9)	< 0.001*
SBP (mmHg)	130.7±33.5	135.6±32.2	119.6±33.9	< 0.001*
SBP<90 mmHg	39/277 (14.1)	15/192 (7.8)	24/85 (28.2)	< 0.001*
DBP (mmHg)	71.7±17.0	73.6±16.6	67.3±17.3	0.004*
LVEF (%)	40.0±11.5	42.7±10.2	33.6±12.0	< 0.001*
Advanced AV block	30/276 (10.9)	20/189 (10.6)	10/87 (11.5)	0.821
Cardiac arrest	5/285 (1.8)	2/190 (1.1)	3/95 (3.2)	0.337
Hemoglobin (g/dL)	12.2±2.0	12.2±2.0	12.1±1.9	0.792
eGFR (mL/min)	45.3±18.7	46.8±18.1	42.0±19.9	0.041*
Procedural features				
Left-main culprit	5/155 (3.2)	4/102 (3.9)	1/53 (1.9)	0.661
LAD culprit	93/169 (55.0)	59/113 (52.2)	34/56 (60.7)	0.296
Multivessel	100/188 (53.2)	66/128 (51.6)	34/60 (56.7)	0.513
GPIIb/IIIa inhibitors	12/183 (6.6)	8/123 (6.5)	4/60 (6.7)	0.967
Radial access	77/169 (45.6)	63/117 (53.8)	14/52 (26.9)	0.001*
IABP	12/207 (5.8)	5/144 (3.5)	7/63 (11.1)	0.030*

ACE: angiotensin-converting enzyme; AMI: acute myocardial infarction; ARB: angiotensin II receptor blockers; AV: atrioventricular; BMI: body mass index; CABG: coronary artery bypass graft surgery; CAD: coronary artery disease; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; DBP: diastolic blood pressure; eGFR: estimated glomerular filtration rate (estimated by Cockcroft-Gault equation); GPIIb/IIIa: glycoprotein IIb/IIIa; HF: heart failure; IABP: intra-aortic balloon pump; LAD: left anterior descending artery; LVEF: left ventricular ejection fraction; PAD: peripheral artery disease; PCI: percutaneous coronary intervention; SBP: systolic blood pressure.

*Significant P values.

remaining 209 patients the median length of hospitalization was 10 days (interquartile range 6 to 13 days). Patients who died in-hospital were less likely to be independent at home (41% vs. 67%), showed worse hemodynamic profile at admis-

sion with lower SBP (mean SBP difference -16.0 mmHg), lower LVEF (mean LVEF difference -9.1%) and worse Killip class as compared to patients discharged alive (Killip III-IV 31% vs. 11%). Among patients who died in-hospital, rates

TABLE II.—*In-hospital outcomes.*

	Overall population N.=308 (%)	In-hospital survivors N.=209 (%)	In-hospital death N.=99 (%)	P value
Successful PCI (final TIMI 3)	99/153 (64.7)	74/104 (71.2)	25/49 (51.0)	0.015*
Mechanical complications	13/279 (4.7)	4/191 (2.1)	9/88 (10.2)	0.005*
Free wall rupture	6/279 (2.2)	0/191 (0.0)	6/88 (6.8)	0.001*
Ventricular septal rupture	2/255 (0.8)	0/173 (0.0)	2/82 (2.4)	0.103
Ischemic mitral regurgitation	5/277 (1.8)	4/191 (2.1)	1/86 (1.2)	1.000
Arrhythmic complications	12/273 (4.4)	4/190 (2.1)	8/83 (9.6)	0.013*
Ventricular tachycardia	10/273 (3.7)	3/190 (1.6)	7/83 (8.4)	<0.001*
Ventricular fibrillation	2/273 (0.7)	1/190 (0.5)	1/83 (1.2)	0.868
Re-AMI	2/277 (0.7)	0/191 (0.0)	2/86 (2.3)	0.096
Stroke	2/255 (0.8)	2/173 (1.2)	0/82 (0.0)	1.000
Contrast induced AKI	24/257 (9.3)	17/175 (9.7)	7/82 (8.5)	0.823
Need for NIV	28/273 (10.3)	14/187 (7.5)	14/86 (16.3)	0.026*
Transfusions	34/278 (12.2)	25/192 (13.0)	9/86 (10.5)	0.548

In-hospital death: N.=99 (32.1%); time to death in days: 4.¹⁻¹²

AMI: acute myocardial infarction; AKI: acute kidney injury; NIV: non-invasive ventilation; PCI: percutaneous coronary intervention; TIMI: thrombolysis in myocardial infarction.

*Significant P values.

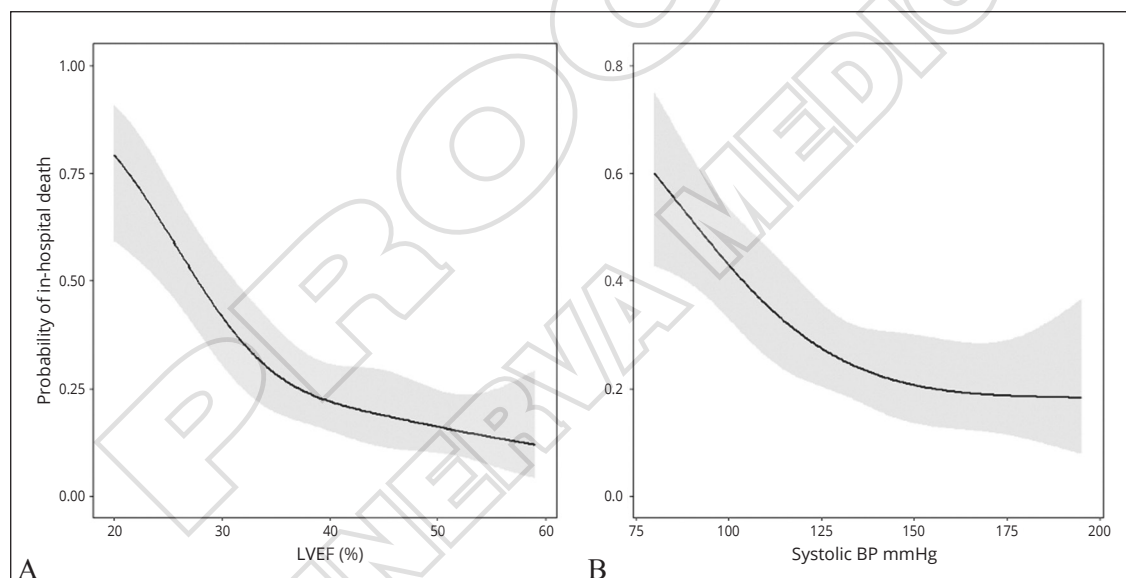


Figure 3.—Spline curves for in-hospital mortality and left ventricular ejection fraction (A) or systolic blood pressure (B).

of successful PCI of the culprit vessel were lower compared to patients discharged alive from hospital (51% vs. 71%, respectively). A spline curve analysis was performed to further characterized the association between patient characteristics at admission and in-hospital mortality. Figure 3 demonstrates that lower values of LVEF and SBP were associated with a higher probability of in-hospital death.

After multivariate adjustment (Table III), lower LVEF (OR per unit reduction 1.08, 95% CI:

1.03-1.11, P value <0.001), lower SBP (OR 1.02 per mmHg reduction, 95% CI: 1.01-1.03, P value 0.001) and being not independent at home (OR 2.56, 95% CI: 1.25-5.26, P value 0.010) resulted independent predictors of in-hospital mortality, as resumed in Supplementary Digital Material 2 (Supplementary Figure 1).

Secondary outcomes are reported in Table II; overall, mechanical complications (10.2% vs. 2.1%), arrhythmic complications (9.6% vs. 2.1%) and need for NIV (16.3% vs. 7.5%)

TABLE III.—*Multivariate logistic regression for in-hospital mortality.*

	Wald	OR	95% CI	P value
LVEF (per unit reduction)	16.22	1.08	1.03-1.11	<0.001*
SBP (per unit reduction)	10.65	1.02	1.01-1.03	0.001*
Not independent	6.64	2.56	1.25-5.26	0.010*
History of hypertension	1.10	0.62	0.26-1.52	0.295
eGFR at admission (per unit reduction)	0.19	1.01	0.98-1.02	0.667

CI: confidence interval; eGFR: estimated glomerular filtration rate (estimated by Cockcroft-Gault equation); LVEF: left ventricular ejection fraction; OR: odds ratio; SBP: systolic blood pressure.

*Significant P values.

were more frequent in nonagenarians who died in-hospital, whereas the remaining secondary endpoints were balanced between groups and in particular, re-AMI occurred in 0.7% of patients, stroke in 0.8%, CI-AKI in 9.3% and blood transfusions were needed in 12% of patients.

Sensitivity analysis

Data on postprocedural TIMI flow was available for 153 patients. Overall, a postprocedural TIMI 3 in the culprit vessel was achieved in 99/153 (65%) patients. Patient characteristics and procedural features of patients with postprocedural TIMI 3 flow are reported in Supplementary Digital Material 3 (Supplementary Table I). In-hospital mortality in this population was 25% and the median time to death was 3 days (interquartile range 1 to 14.5 days) (Supplementary Digital Material 4: Supplementary Table II). Results from univariate comparisons were consistent with the main analysis (Supplementary Table I). At logistic regression analysis, lower LVEF and being not independent at home were confirmed as predictors of in-hospital mortality in patients with successful pPCI (Supplementary Digital Material 5: Supplementary Table III). Secondary outcomes are reported in Supplementary Table II.

Discussion

The main findings of the present analysis, originating from a large international registry of nonagenarian patients undergoing pPCI for STEMI over a 11-year time frame, can be summarized as follows:

- the rate of nonagenarian patients undergoing pPCI for STEMI has more than doubled over the last five years compared to the first five years of our study period;

- pPCI in this population is feasible, but is characterized by a lower success rate as compared to the general population¹⁰ and by a high in-hospital mortality;

- both hemodynamic and social variables, such as higher systolic blood pressure and left ventricular ejection fraction and independency in daily living activities, entail a survival benefit among elderly patients undergoing pPCI for STEMI.

Despite being poorly represented in clinical trials, elderly STEMI patients are constantly incrementing and further expected to rise in clinical practice due to increased life expectancy;¹¹⁻¹⁴ our data confirm this upward trend from 2009 to 2019, as there was a two-fold increase in the number of nonagenarians undergoing pPCI for STEMI. These findings may also reflect increasing confidence in performing pPCI in the elderly combined with improved PCI devices and techniques.

Current STEMI guidelines recommend pPCI in all STEMI patients regardless of their age provided that symptoms onset is within 12 hours before the procedure or more than 12 hours with evidence of ongoing ischemia, as prompt revascularization can limit the infarct size and reduce the risk of mechanical complications.^{15, 16} Nevertheless, data supporting these recommendations lie on studies involving younger patients while older age itself has been recurrently acknowledged as an independent risk factor for short and long-term mortality in STEMI. The present analysis shows that pPCI is feasible in this high-risk population, though with lower success rate compared to younger cohorts with less than 65% of patients achieving TIMI 3 flow at the end of the procedure.⁹

In-hospital mortality after PCI has fallen for

all age groups in the last decades with the largest absolute reduction noted in older patients.¹⁷ Nevertheless, we found higher in-hospital all-cause mortality (32%) compared to previous studies (18-25%).¹⁸⁻²¹ This finding is likely connected to the overall higher baseline clinical risk with worse clinical presentation of our patients compared to prior reports, with a relevant proportion of the study subjects presenting with cardiogenic shock or Killip III-IV. The large prevalence of these well-known predictors of mortality might depend on the frequently atypical symptoms at presentation in elderly STEMI patients, which may lead to delayed presentation and treatment and consequent higher likelihood of death and mechanical complications.

Several studies investigated the predictors of clinical outcomes after pPCI in elderly patients, but only a few reports focused on nonagenarians. Cardiogenic shock and TIMI flow grade after revascularization were identified as main independent predictors of mortality in nonagenarians receiving pPCI.^{13, 18} A recently published analysis by Cepas-Guillén *et al.* comparing medical therapy vs. pPCI in STEMI nonagenarians showed a lower mortality in the pPCI group and identified Killip class III-IV, AMI mechanical complications and renal impairment at admission as independent predictors of all-cause mortality.¹⁹ Our results are in partial agreement with these findings, highlighting the crucial role of the hemodynamic status on admission in predicting short-term all-cause mortality, whereas no independent association was found between renal impairment and in-hospital mortality in our analysis. We found a lower rate of CI-AKI compared to a previous meta-analysis pooling data from over 6000 STEMI patients undergoing pPCI (9.3% vs. 13.3%)²² and disclosed similar rates of CI-AKI between patients who died in-hospital and those surviving.

Moreover, in the attempt to easily determine patients' frailty in an emergency setting such as STEMI, we evaluated their "independency" at home and found it to be associated with better in-hospital outcome. Along with age, frailty is becoming a critical element in the assessment of elderly patients with cardiovascular diseases and the relationship between frailty and in-hospital

mortality, 1-month mortality and prolonged hospital care is well established.²³ Despite the paramount role of frailty in the management of elderly patients undergoing PCI, frailty assessment is underused in clinical practice, likely due to the lack of standardized tools for frailty definition and quantification and the difficult assessment of risk tools in emergency settings.

Limitations of the study

This is an observational retrospective analysis and carries inherent limitations. Follow-up data are limited to the in-hospital stay and mid- to long-term follow-up was not available; however, we believe that the outcomes after hospital discharge might be strongly influenced by comorbidities in this elderly population and not directly mirror the results of pPCI itself. We only analyzed patients undergoing pPCI, whereas medically treated patients were not assessed. It is likely that STEMI associated with left bundle branch block and with paced rhythm which may confuse diagnosis, as well as with other critical medical conditions, which lower the likelihood of pPCI, were under-represented in the study. Due to the retrospective nature of the study some data could not be retrieved, and frailty was not quantified with a standardized scale. Lastly, the present analysis, ranging from 2009 to 2019, encompasses a wide range of technologies, different operators' skills and several PCI facilities being developed during this timeframe which could not be uniformly assessed. Strengths of our study included the real-world design, the multicenter nature and its relatively large sample size considering the lack of evidence on this peculiar population.

Conclusions

Nonagenarian patients presenting with STEMI represent a clinical and interventional challenge and should be considered a high-risk population with high mortality rates. Advanced age alone should not be considered an absolute contraindication for pPCI and frailty should be included in the overall assessment of the elderly being referred for such procedure, together with hemodynamic parameters. Further research is needed

to assess the appropriate rapid tools that can help physicians to effectively assess frailty of patients in emergency settings.

Key messages

- Elderly STEMI patients are increasing but underrepresented in clinical trials and predictors of outcomes after primary PCI are uncertain.
- Nonagenarian patients undergoing primary PCI have high in-hospital mortality; hemodynamic parameters and independency are strong predictors of outcome.
- Frailty assessment should be included in the overall evaluation of the elderly being referred for primary PCI, together with hemodynamic parameters and new risk tools to evaluate frailty also in emergency settings should be developed.

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