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Early revascularization is associated with improved survival in elderly patients with acute myocardial infarction complicated by cardiogenic shock: a report from the SHOCK Trial Registry

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Aims The SHould we emergently revascularize Occluded Coronaries in cardiogenic shocK (SHOCK) Trial showed no benefit of early revascularization in patients aged ≥75 years with acute myocardial infarction and cardiogenic shock. We examined the effect of age on treatment and outcomes of patients with cardiogenic shock in the SHOCK Trial Registry.
Methods and results We compared clinical and treatment factors in patients in the SHOCK Trial Registry with shock due to pump failure aged <75 years (n=588) and ≥75 years (n=277), and 30-day mortality of patients treated with early revascularization

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Abbreviations:
CK(-MB), creatine kinase (-MB);
ECG, electrocardiogram, electrocardiography;
GUSTO-I, Global Utilization of Streptokinase and TPA (alteplase) for Occluded coronary arteries;
IABP, intra-aortic balloon pump;
MI, myocardial infarction;
PCI, percutaneous coronary intervention;
SHOCK, SHould we emergently revascularize Occluded Coronaries in cardiogenic shocK?;
TIMI, Thrombolysis In Myocardial Infarction.

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<18 hours since onset of shock and those undergoing a later or no revascularization procedure. After excluding early deaths covariate-adjusted relative risk and 95% confidence intervals were calculated to compare the revascularization strategies within the two age groups. Older patients more often had prior myocardial infarction, congestive heart failure, renal insufficiency, other comorbidities, and severe coronary anatomy. In-hospital mortality in the early vs. late or no revascularization groups was 45 vs. 61% for patients aged <75 years ($p=0.002$) and 48 vs. 81% for those aged ≥75 years ($p=0.0003$). After exclusion of 65 early deaths and covariate adjustment, therelative risk was 0.76 (0.59, 0.99; $p=0.045$) in patients aged <75 years and 0.46 (0.28, 0.75; $p=0.002$) in patients aged ≥75 years.

Conclusions Elderly patients with myocardial infarction complicated by cardiogenic shock are less likely to be treated with invasive therapies than younger patients with shock. Covariate-adjusted modeling reveals that elderly patients selected for early revascularization have a lower mortality rate than those receiving a revascularization procedure later or never.

Introduction

Though complicating fewer than 10% of all cases, cardiogenic shock is the most common cause of death in patients hospitalized with acute myocardial infarction.[1–3] Mortality arising from cardiogenic shock treated with conservative measures is between 70 and 80%.[4,5] Conversely, case series have shown in-hospital mortality rates as low as 26% with early, successful percutaneous coronary intervention.[6–9] The SHould we emergently revascularize Occluded Coronaries in cardiogenic shocK (SHOCK) Trial, a randomized trial of early revascularization vs. initial medical stabilization, reported a nonsignificant group difference in 30-day mortality but significantly lower 6- and 12-month mortality in the group randomized to early revascularization.[10,11] However, in a prespecified age subgroup analysis, the elderly aged ≥75 years derived no apparent treatment benefit from early revascularization. Although the elderly group consisted of just 56 patients, based on this result, the recently updated ACC/AHA Guidelines for the Treatment of Patients with Acute Myocardial Infarction included only those under 75 years of age in their Class I recommendations for emergent revascularization.[12]

The SHOCK Trial Registry is a large, prospective, multicenter registry of patients with cardiogenic shock who were not enrolled in the SHOCK Trial. In contrast to the very limited sample of 56 patients aged ≥75 years in the trial, the registry included 277 patients in this age group among the 865 patients registered who had shock on the basis of pump failure prior to any revascularization procedure. The purposes of this analysis were to: (1) compare the use of invasive procedures and outcomes between age groups in the SHOCK Registry patients with shock on the basis of pump failure; (2) study the association between early revascularization and mortality after exclusion of early deaths, and (3) compare the outcome for the elderly undergoing early revascularization and those undergoing late or no revascularization in the Registry with patients aged ≥75 years managed with these two strategies in the randomized SHOCK Trial.

Methods

Thirty-six centers prospectively registered 1189 patients with suspected cardiogenic shock complicating acute myocardial infarction, regardless of trial eligibility.

Patients

Medical history, patient characteristics, therapeutic interventions, and vital status at hospital discharge were recorded for all Registry patients. Compliance with registration was monitored with site audits. Complete capture was obtained by retrospectively registering missing patients. Registration continued from April 1993 through August 1997. The 24 US centers registered 729 patients (61%); five Canadian centers registered 256 patients (22%); four Belgian centers registered 76 patients (6%), and centers in Australia, New Zealand, and Brazil registered the other 128 patients (11%). This report is based on the 865 patients who had either predominant left ventricular failure or isolated right ventricular shock and who had no revascularization attempt prior to shock onset.

Data collection

The SHOCK study coordinators extracted data from medical records, after central training to complete standard report forms. Patient and myocardial infarction characteristics, hemodynamics, procedure use, and vital status at discharge were recorded, as were reasons for trial ineligibility (and thus enrollment in the Registry): failure to meet all inclusion criteria, presence of an exclusion criterion, presentation outside the specified time windows, and inability to obtain or refusal of consent.

The Clinical Coordinating Center abstracted data from angiography and angioplasty reports and recorded these on standard data forms. Right-heart catheterization was performed in 548 patients, with pulmonary capillary wedge pressure (PCWP) recorded in 516 and cardiac index values in 397. Ejection fraction was measured during hospitalization by contrast angiography, echocardiography, or gated blood-pool scanning in 318 patients. The following variables were recorded only on revised study forms and are available on approximately two-thirds of patients: medication usage, left ventricular ejection fraction, and history of elevated lipids and peripheral vascular disease.

Definitions

Predominant left ventricular failure was designated as the etiology of shock when none of the following was indicated: isolated right ventricular shock, mechanical etiology (acute severe mitral regurgitation or ventricular septal rupture), tamponade or cardiac rupture, prior severe valvular heart disease, excessive beta or calcium-channel blockade, or shock resulting from complication of cardiac catheterization. Location of infarction as indicated by the electrocardiogram was defined according to the Global Utilization of Streptokinase and TPA (alteplase) for Occluded coronary arteries (GUSTO-I) criteria: anterior, leads V1 to V4; inferior, leads II, III, or AVF; apical, leads V5 to V6; lateral, leads I or AVL; and posterior, leads V1 to V4. Highest creatine kinase (CK) values are presented, based on at least three samples for 71% of patients.

The early revascularization group was defined as those patients undergoing a revascularization procedure within 18 h of onset of shock, to allow for a comparison with the SHOCK Trial in which patients were all enrolled within 12 h of onset of shock, and where patients assigned to the early revascularization group were to have a revascularization procedure within 6 h of randomization.

Statistical methods

Patients were divided into two age groups for analysis: <75 years old (68%), and ≥75 years old (32%). Secondary analyses then divided each age group into those undergoing early revascularization and those undergoing later or no revascularization procedure. Groups were compared using Fisher's exact test for categorical variables, the Wilcoxon rank-sum test for ordinal and non-normally distributed continuous variables, and Student's *t*-test for normally distributed continuous variables. Survival by age group and revascularization status was estimated by the Kaplan–Meier method and compared using the log–rank test. In-hospital mortality by age group was analyzed using Cox proportional hazards regression. Cox regression was also used to obtain covariate-adjusted hazard ratios for death by treatment group for Registry and Trial patients. All analyses were conducted using SAS® and S-PLUS for Windows.

Early death exclusion

It is possible that the difference in mortality between patients undergoing an early revascularization procedure and those receiving such a procedure later or never may have been exaggerated by the fact that the most critically ill patients, especially the elderly, died before they could be treated with a revascularization procedure. This would have rendered the group undergoing revascularization at lower risk and less likely to die irrespective of therapy administered. In order to correct for this source of bias, we performed a secondary analysis of survival by excluding those who died within 3 h of presentation to the SHOCK center. This broad 3-h window should have excluded any patient not being revascularized because of any delay in the ability of a participating center in any healthcare system to assemble the team necessary to perform an emergency percutaneous or surgical revascularization procedure.

Results

Baseline clinical characteristics

A total of 865 of the 1189 patients (73%) in the Registry fulfilled the criteria for this analysis. Of these, 826 patients had shock on the basis of predominant left ventricular failure while 39 had isolated right ventricular shock. Table 1 shows that older patients were significantly more likely to be

Table 1 Clinical characteristics of SHOCK Registry patients with pump failure

	Age <75	Age ≥75	*p*-Value
N	588	277	
Age (years)	62.4±9.6	81.1±4.7	<0.001
Female sex (%)	32.3	46.6	<0.001
History of hypertension (%)	50.6	53.7	0.453
Diabetes mellitus (%)	34.7	30.7	0.273
Prior myocardial infarction (%)	35.8	48.1	<0.001
Dilated cardiomyopathy (%)	4.3	4.7	0.859
Prior angioplasty (%)	7.0	4.6	0.218
Prior bypass surgery (%)	9.5	9.6	1.00
Severe systemic illness (%)	6.5	9.8	0.097
History of congestive heart failure (%)	16.3	28.0	<0.001
History of renal insufficiency (%)	8.7	15.4	0.006
Median time from MI to shock (h)	4.9	7.1	0.129
Anterior index MI (%)	55.8	54.4	0.754
Non-Q-wave infarct or old LBBB (%)	18.6	23.6	0.102
Systolic blood pressure (mmHg)	88.7±24.1	86.4±21.1	0.189
Diastolic blood pressure (mmHg)	53.6±17.1	49.7±17.4	0.007
Heart rate (bpm)	94.7±26.0	93.4±25.5	0.500
Cardiac index (l/min/m^2) (*n*=286, 101)[a]	2.11±0.77	1.78±0.62	<0.001
PCWP (mmHg) (*n*=377 for age <75, 139 for age ≥75)[a]	24.1±8.8	22.9±8.8	0.311
Median-adjusted CK (highest/upper limit of normal)	10.4	5.6	<0.001
In-hospital left ventricular ejection fraction (%) (*n*=241 for age <75, 77 for age ≥75)	31.0±12.8	29.0±13.4	0.191

[a]On support measures.

Table 2 Use of interventions and in-hospital mortality in SHOCK Registry patients with pump failure

	Age <75	Age ≥75	*p*-Value
N	588	277	
Vasopressors (%) (*n*=422, 194)	95.7	95.9	1.00
Thrombolytic therapy			
Streptokinase (%)	24.4	29.1	0.454
Alteplase (%)	72.4	62.0	0.089
Swan–Ganz catheterization (%)	68.5	52.4	<0.001
Intra-aortic balloon pump (%)	61.4	28.9	<0.001
Angiography (%)	70.4	37.2	<0.001
Angioplasty (%)	36.2	16.3	<0.001
Bypass surgery (%)	19.1	6.1	<0.001
Angioplasty or bypass surgery (%)	51.7	22.4	<0.001
In-hospital mortality (%)			
All patients (%)	55.1	75.8	<0.001
Angioplasty or bypass surgery (%)	38.5	45.2	0.393
No angioplasty or bypass surgery (%)	72.9	84.7	0.002

female, and have a history of prior myocardial infarction, congestive heart failure, and renal insufficiency. Older patients also were significantly more likely to have a lower mean diastolic blood pressure, adjusted CK level and cardiac index.

Invasive strategies and survival

Table 2 summarizes the use of pharmacological and procedural interventions. Utilization rates of Swan–Ganz catheters, intra-aortic balloon pump support, pulmonary artery catheter use, coronary angiography, percutaneous coronary intervention, and coronary artery bypass grafting surgery were all significantly lower in the elderly. In-hospital mortality was 55% in patients aged <75 years vs. 76% in those aged ≥75 years (p<0.001). The trends in in-hospital mortality over time up to 60 days in the patients treated by early revascularization and those revascularized later or never are illustrated in the Kaplan–Meier plot in Fig. 1a. In-hospital survivors were censored out at the time of discharge. Overall, in-hospital mortality in the early vs. late or no revascularization groups was 45 vs.

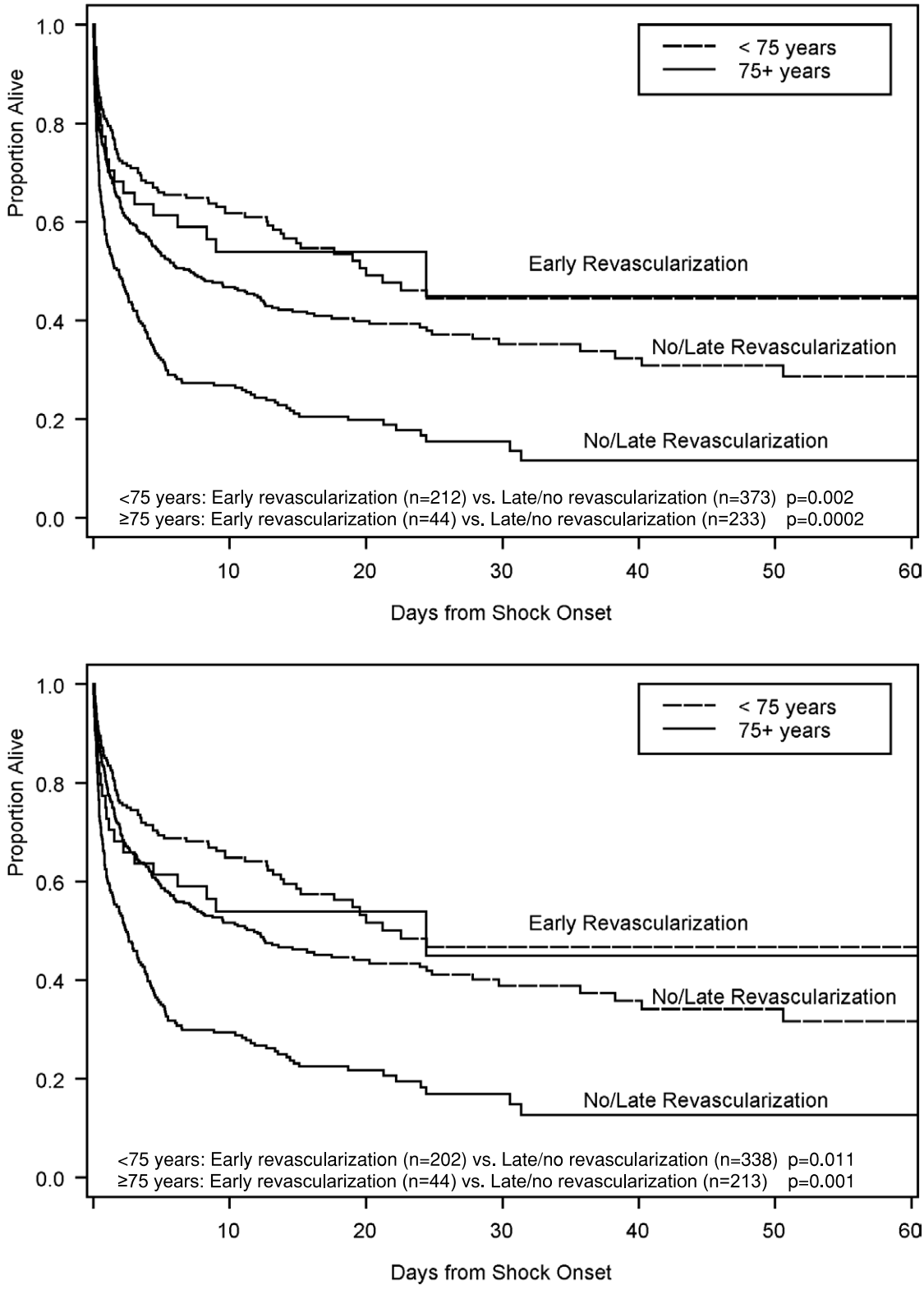


Fig. 1 (a) Kaplan–Meier survival estimates of in-hospital survival by age category and use of an early revascularization procedure (<18 h after shock onset), and (b) similar estimates but with exclusion of patients with early death <3 h from presentation to the SHOCK hospital. Estimates past 60 days following admission are not shown but include two deaths in the early revascularization group aged <75 years and one death in the no/late revascularization group aged ≥75 years.

Table 3 Angiographic characteristics and procedural outcome of SHOCK Registry patients with pump failure by age group (%)[a]

	Age <75	Age ≥75	*p*-Value
Number undergoing angiography	414	103	
Number of diseased vessels	(*n*=390)	(*n*=97)	0.002
0	1.0%	1.0%	
1	23.1%	12.4%	
2	22.8%	14.4%	
3	53.1%	72.2%	
Left-main disease ≥50% diameter stenosis[b]	(*n*=390)	(*n*=97)	
	16.2%	27.8%	
Number undergoing angioplasty	213	45	
Final TIMI grade 2 or 3 flow[b]	(*n*=134)	(*n*=22)	1.00
	80.6%	81.8%	
Postprocedural stenosis <50%[b]	(*n*=174)	(*n*=35)	
	84.5%	85.7%	

[a]Angiographic data were extracted at the Coordinating Center from procedure reports and were only available for the numbers of patients indicated.
[b]In the culprit vessel.

61% for patients aged <75 years (relative risk 0.68; 95% confidence interval 0.54, 0.87; $p=0.002$), and 48 vs. 81% for those aged ≥75 years (relative risk 0.43; 95% confidence interval 0.28, 0.68; $p=0.0002$). Of the patients aged <75 years who were revascularized early, the 178 who underwent a percutaneous coronary intervention had an in-hospital mortality rate of 47%. Eighteen went on to have a subsequent coronary artery bypass grafting procedure. The 52 patients in this age group who underwent early bypass surgery had an in-hospital mortality of 42%. In the group aged ≥75 years, 39 patients underwent an early percutaneous coronary intervention procedure with a mortality of 49%, while four of five patients (80%) who underwent early bypass surgery survived to hospital discharge. No patient in the elderly age group treated with percutaneous coronary intervention subsequently went on to bypass surgery.

Coronary anatomy and angioplasty results

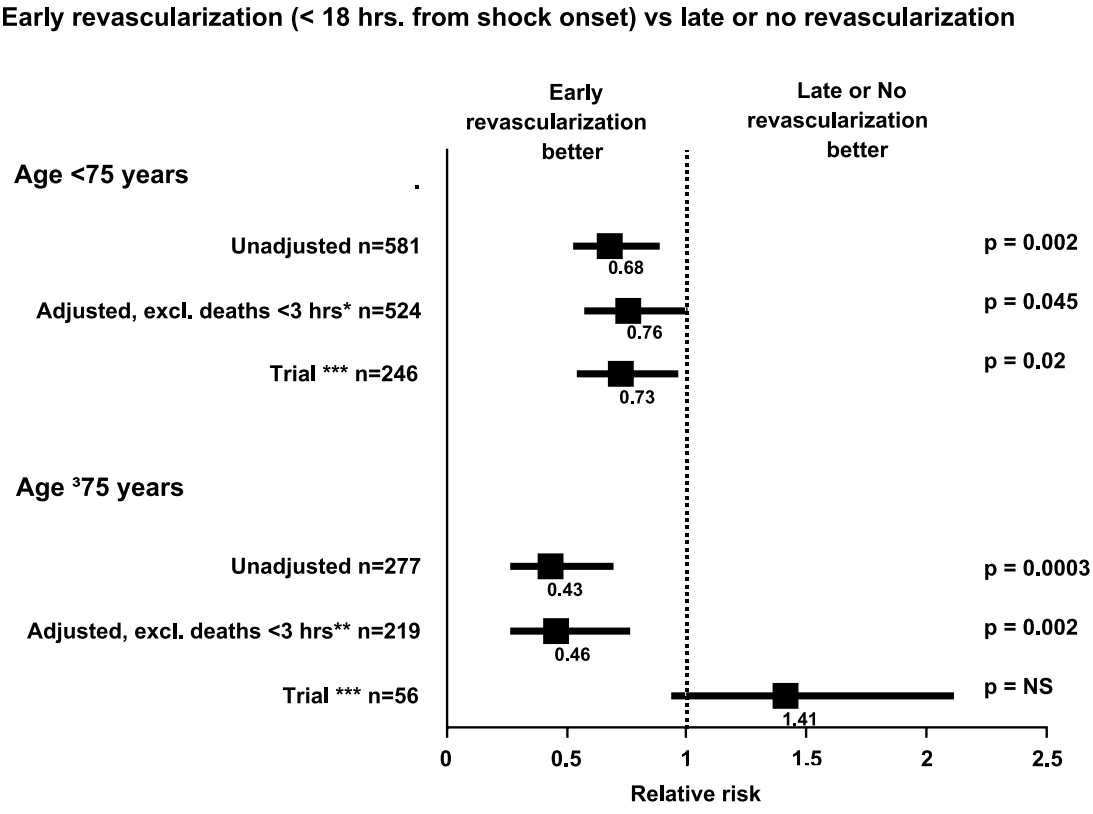
Descriptive angiographic reports were available for 487 patients (Table 3). Three-vessel and left-main disease occurred more frequently in the elderly. Percutaneous coronary intervention success rates (defined as re-establishing flow with achievement of Thrombolysis In Myocardial Infarction [TIMI] grades 2 and 3 flow) were similar in the two age groups, occurring in 80.6 and 81.8% of patients aged <75 and ≥75 years, respectively.

Early death and relationship between early revascularization and mortality

In the elderly group aged ≥75 years, 20 patients (7%) died within 3 h of presentation. In-hospital mortality in the remaining 257 elderly patients was 79% in the 213 patients without early revascularization and 48% in the 44 patients with an early revascularization procedure (relative risk 0.45; 95% confidence interval 0.28, 0.72; $p=0.001$). These findings were similar for the 536 patients aged <75 years who survived at least 3 h after presentation to the SHOCK center [45 early deaths (8%) were excluded], with 84 of 200 (42%) of those revascularized early having in-hospital mortality, compared with 192 of 336 (57%) revascularized later or never (relative risk 0.69; 95% confidence interval 0.53, 0.90; $p=0.011$).

It is likely that baseline characteristics and comorbid conditions played a role in the selection for revascularization, especially in the elderly, and that patients who were less sick and more likely to survive in any case were selected for revascularization. We thus performed a Cox-modeling approach to determine if the benefit from early revascularization persisted after adjustment for possible confounders.

Patients in the Registry aged ≥75 years who underwent early revascularization differed from those with later or no revascularization in a number of respects. Elderly patients with early revascularization had a higher CK, and were more likely to be transferred from another hospital, to have had a prior percutaneous coronary intervention, and a history of hypertension (all $p<0.05$). As well, they tended to have a higher heart rate and were more likely to have an inferior MI ($0.05<p<0.20$). Patients aged <75 years who were revascularized early also had a higher peak CK and had earlier time from myocardial infarction to shock. They were also more likely to have chest pain, ST elevation in ≥2



* 45 patients with death <3 hours from admission and 12 patients with missing baseline data excluded. Adjusted for diabetes (p=0.047) and prior CABG (p=0.017)

** 20 patients with death <3 hours from admission and 28 patients with missing baseline data excluded Adjusted for transfer status (p=0.002) and inferior MI location (p=0.089)

*** See Reference 10

Fig. 2 Covariate relative risk and 95% confidence intervals for in-hospital mortality of SHOCK Registry patients who underwent early revascularization (<18 h after shock onset) vs. late or no revascularization, stratified by age group.

leads, and a history of congestive heart failure, diabetes, dilated cardiomyopathy, severe systemic illness, a new left bundle branch block, and a trial-qualifying myocardial infarction presentation than those revascularized late or never (all $p<0.05$). In addition, they tended to a higher PCWP, a greater likelihood of a Q-wave myocardial infarction, an inferior myocardial infarction, and a lower likelihood of peripheral vascular disease, hypertension, renal insufficiency, prior myocardial infarction, and prior coronary artery bypass surgery ($0.05<p<0.20$). These variables were entered into a multivariate model and factors that remained significant were then retained as covariates to produce covariate-adjusted relative risks and estimates as illustrated in Fig. 2. As this covariate-adjusted analysis reveals, early revascularization in patients aged ≥75 years is associated with improved survival (relative risk 0.46; 95% confidence intervals 0.28, 0.75; $p=0.002$), in contrast to the trial in which the elderly are seen to have no benefit or trend toward benefit from the early revascularization strategy. Covariate-adjusted modeling in the group aged <75 years similarly reveals early revascularization to be associated with better survival compared to later or no revascularization (relative risk 0.76; 95% confidence intervals 0.59, 0.99; $p=0.045$).

Discussion

This SHOCK Trial Registry study examined clinical and treatment characteristics of the elderly compared with younger patients. Invasive procedures were used less frequently in elderly patients. Early revascularization in the elderly was associated with better in-hospital survival. Significant differences existed between the elderly and younger patients in important clinical characteristics, which could have affected their ability to survive cardiogenic shock. Of note, significantly more patients in the older group had a history of MI, congestive heart

failure, severe systemic illness, and renal insufficiency. Although we did not have data on left ventricular function for all Registry patients, these patients likely had a reduced ejection fraction due to dysfunction in zones remote from the index myocardial infarction.[13] These factors may have influenced physician decisions to pursue aggressive treatment measures.

Early revascularization and survival in the elderly

In the current, large, prospective multicenter series, patients aged ≥75 years who underwent early revascularization procedure had a significantly higher in-hospital survival rate than those revascularized late or never. This experience contrasts with that of the randomized SHOCK Trial as well as the University of Alberta observational study in which the very elderly with cardiogenic shock (>75 years old) did poorly, irrespective of revascularization status.[9]

Our results confirm, however, the results of a regional study of trends in treatment and outcome in cohorts of patients with shock aged ≥65 years in 1986–1991 and 1993–1997 in Worcester, MA.[14] In this analysis, Dauerman et al. reported a significant decrease in mortality in the second period, and found early revascularization to be the most powerful predictor of survival. The magnitude of reduction in mortality from the initial to the later period appeared similar in patients aged 65–74 and those aged ≥75 years, although the number of patients in the older group is not clear.

Although other studies have suggested significantly better survival in patients in cardiogenic shock successfully revascularized compared with those with unsuccessful angioplasty or those treated conservatively,[6–8,15,16] none has specifically examined the effect of revascularization on outcome of elderly shock patients. Some authors failed to identify age as a possible predictor of survival.[13] Hibbard et al.[7] reported 74% in-hospital survival in cardiogenic shock patients aged <70 years vs. 14% in those aged ≥70 years in a series of 45 patients, concluding that age is a critical variable in interpreting survival data and in selecting appropriate therapy for patients with cardiogenic shock. Similarly, age <65 years was the only clinical variable found to predict improved survival by Gacioch et al.[6] Hochman et al. found shock patients undergoing angiography to be significantly younger than those not selected for this procedure, the critical step toward revascularization (64.0±11.2 vs. 70.2±11.7 years, $p<0.001$).[17] The mortality rate of patients with angiography was lower than that of patients without angiography (51.3 vs. 85.2%).

In all of these reports, mortality continues to be high despite the use of revascularization. In part this may reflect a decreased efficacy of angioplasty in this setting, which may be limited by no-reflow and higher re-occlusion rates. The high prevalence of total occlusions observed in these patients[18] may be a key factor in promoting early and late procedural failure, due to an increased local burden of thrombus, a systemic thrombogenic milieu, and a greater propensity for dissection.[19] The use of stents, recently studied in the setting of non-acute coronary occlusions,[20,21] has been shown to be associated with favorable outcomes in cardiogenic shock in a small series[22] as well as a large international registry.[23] Use of new platelet inhibitors such as abciximab also may be beneficial in the management of patients in cardiogenic shock.[24] Application of these new strategies may further enhance any potential benefit of early revascularization in all patients with cardiogenic shock, particularly the elderly, who may have a lower success rate from angioplasty in this setting.[9] Coronary artery bypass surgery is an alternative for appropriate candidates. In the SHOCK Trial the small number[5] of elderly patients that surgeons selected for early bypass surgery had a high survival rate.

Comparison with the randomized SHOCK Trial

An association has been found between early revascularization and reduced mortality rates in patients aged ≥75 years in the Registry. This is in contrast to patients in the prespecified subgroup aged ≥75 years in the SHOCK Trial, who were found to have no benefit from early revascularization. The reason for this difference in outcome is not entirely clear, but likely reflects careful and appropriate case-selection in the Registry of patients with more favorable clinical and angiographic characteristics, who are more likely to benefit from early revascularization. Certainly a selection bias was observed in the Bypass and Angioplasty Revascularization Investigation (BARI) Registry in which patients selected for percutaneous revascularization had a more favorable outcome than those randomized in the BARI Trial, but they also had more favorable angiographic characteristics, specifically, a lower likelihood of type C lesions.[25]

Nevertheless, despite an almost certain selection bias, the low mortality rate associated with

early revascularization in the elderly is encouraging. These data suggest that the elderly should not be categorically denied aggressive care, nor should aggressive care be applied to all routinely. The decision regarding intervention should be individualized.

Study limitations

Conclusions about the benefits of urgent intervention and other invasive measures in elderly patients are hampered by what is likely appropriate selection by experienced physicians of those most likely to benefit from intervention in this nonrandomized, observational study. Prior functional status is an important variable that was not recorded. As has been shown, significant selection of patients for angiography and revascularization is based on a complex set of clinical factors as well as patient and physician preferences. It is impossible to completely account for all variables, measured and unmeasured, that come into play in the management of this complex patient group.

Conclusions

Compared with younger patients, the elderly presenting with cardiogenic shock due to pump failure are less likely to be managed with angiography, intra-aortic balloon counterpulsation, and revascularization. In contrast to the SHOCK randomized trial, the elderly selected for early revascularization in the Registry have improved survival compared to those treated conservatively. Elderly patients not selected for early revascularization also have a far worse outcome than those revascularized early, but they also appear to have a greater burden of pre-existing disease. Based on these data, elderly patients presenting with acute myocardial infarction complicated by cardiogenic shock on the basis of pump failure should be considered for early revascularization. When appropriately selected, they may be expected to have a survival benefit similar to younger patients presenting with this grave complication.

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