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Outcome following Surgery and Percutaneous Intervention for Cardiogenic Shock and Left Main Disease

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Abstract

Background—The ideal revascularization strategy (bypass surgery vs. percutaneous coronary intervention [PCI]) for patients with cardiogenic shock in the setting of left main coronary artery (LMCA) disease is unknown.

Methods—The Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock Trial and Registry included 164 patients with LMCA disease who underwent revascularization. Although the standard of care at the time and the trial protocol recommended bypass surgery for patients with LMCA disease, the revascularization strategy (79 bypass surgery and 85 PCI) was individualized for each patient by site investigators.

Results—The median time from myocardial infarction to revascularization was 24.3 hours (interquartile range, 8.7 to 82.5 hours) in the surgical group and 7.4 hours (interquartile range, 3.7 to 19.5 hours) in the PCI group ($p < 0.05$). Overall 30-day survival with surgery in this setting was 569% (95% confidence interval (0.43, 0.69) and was significantly superior to the 21% (95% confidence interval (0.09, 0.35) in the PCI group ($p < 0.01$). When the LMCA was the infarct-related artery, the 30-day survival rate was 40% in the surgical group ($n=6$) and 16% in the PCI group ($n=15$) ($p=0.03$). Bypass surgery [hazard ratio 0.41, 95% confidence interval (0.22, 0.77), $p=0.006$] and age [per 10 years, hazard ratio 1.04, 95% confidence interval (1.01-1.08); $p=0.02$] were independently associated with 30-day survival.

Conclusions—Bypass surgery appeared to provide a survival advantage over PCI at 30-day follow up in patients with LMCA disease. The impact of current PCI strategies on this subgroup is undetermined.

Keywords

Coronary artery bypass grafts; Myocardial infarction

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Cardiogenic shock occurs in approximately 5 to 10% of patients with ST elevation myocardial infarction and is the leading cause of death in these patients (1-3). Early revascularization improved survival compared with initial medical stabilization and delayed revascularization in patients with myocardial infarction complicated by cardiogenic shock (4-6). Similar survival rates were observed in patients treated with coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) (6,7).

Left main coronary artery (LMCA) disease represents a significant independent predictor of mortality in patients with myocardial infarction complicated by cardiogenic shock (8). The revised American College of Cardiology/American Heart Association guidelines indicate that PCI as a class IA indication for the management of myocardial infarction complicated by cardiogenic shock as well as a class IA indication for CABG if there is suitable coronary anatomy (9). The standard of care for patients with LMCA disease is CABG (10). However, PCI has been shown to be a viable alternative in patients with LMCA disease, including high-risk patients (11,12).

The purpose of this study was to evaluate the 30-day survival with CABG and PCI in patients with LMCA disease to identify the ideal revascularization strategy in patients with myocardial infarction complicated by cardiogenic shock and LMCA disease.

METHODS

Study population

The Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) Trial and Registry enrolled patients from 36 multinational centers starting from April 1993 and to November 1998 for the trial, and to August 1997 for the registry. The registry required a clinical diagnosis of shock and the trial inclusion and exclusion criteria have been previously defined (13). The clinical criteria for cardiogenic shock included hypotension (a systolic blood pressure of <90 mm Hg for 30 minutes or the need for inotropic agents or an intra-aortic balloon pump to maintain a systolic blood pressure of 90 mm Hg) and hypoperfusion of end organs (cool extremities or a urine output of <30 ml/hour, and a heart rate of 60 beats/minute). The hemodynamic criteria for cardiogenic shock included a cardiac index of no more than 2.2 liters/minute/square meter of body-surface area and a pulmonary-capillary wedge pressure 15 mm Hg (4). The prospective, multicenter registry included patients who did not meet all the inclusion criteria for randomization and those who met criteria but were not enrolled in the randomized trial, were outside the specific time windows, were unable or refused to sign consent, or had an exclusion criterion (14). Of the 302 patients in the trial and 1190 patients in the registry, the study population included 164 patients who had LMCA stenosis 50% who underwent emergent revascularization (CABG 79 and PCI 85). The use of intra-aortic balloon pump counterpulsation was protocol recommended for patients in the trial. There were no recommendations for the management of registry patients. There were protocol recommendations in the trial regarding the choice of revascularization, but the decision was by site investigators, made on an individual basis.

The SHOCK clinical coordinating center at New York University has Institutional Review Board (IRB) approval to continue to do analyses and publish. Regarding the first author (M.S.L.) the UCLA IRB determined that the research does not involve human subjects as defined in the federal regulations since no individual level data was obtained or accessed.

Randomized trial protocol recommendations for revascularization

Emergency PCI of the infarct-related artery was recommended if patients had single- or double-vessel coronary artery disease, in patients with single-, double-, or triple-vessel disease where the stenoses in 2 non-infarct-related arteries were <90% or were located in arteries supplying small branch vessels (7).

Emergency CABG was recommended for patients with LMCA stenosis 50%, 2 total or subtotal occlusions, stenoses of >90% in 2 non-infarct-related major arteries, disease unsuitable for PCI, or unsuccessful PCI (7). If PCI was successfully performed only on the infarct-related artery in patients with triple-vessel disease, evaluation for subsequent CABG was recommended during the same hospitalization.

Angiographic core laboratory

All angiograms obtained in the trial were analyzed by the Angiographic and Echocardiographic Core Laboratories by two independent, blinded readers. A third reader resolved any discrepancies. In contrast, angiograms obtained in the registry were not analyzed in a core laboratory but rather during central completion of standardized report forms based on local laboratory reports.

Definitions

Complete revascularization with CABG was judged by the surgeon at the time of CABG (4).

Statistical Analysis

Continuous variables were summarized as mean $\pm$ standard deviation and were compared using Student's t test. Categorical variables were compared by the Fisher exact test. Thirty-day survival curves were generated by the Kaplan-Meier method, and group differences were assessed by the log-rank test. A multiple Cox regression model with left truncation was used to identify risk factors for 30-day mortality and attempt to correct for the bias that would be attributable to the differential time to revascularization. All statistical tests were 2-tailed, and a significance level of 0.05 was used throughout. Statistical analysis was conducted using SPSS version 14.0 (SPSS Inc, Chicago, IL).

RESULTS

Baseline demographic and angiographic characteristics

The study population was comprised of 164 patients with myocardial infarction complicated by cardiogenic shock and LMCA disease who underwent emergent revascularization (CABG 79 and PCI 85). The CABG group had a higher prevalence of triple-vessel disease compared with the PCI group (72.9% vs. 87.0%; $p=0.02$; Table 1). The LMCA was the infarct-related artery in 24.5% who underwent CABG and 24.4% who underwent PCI. The

mean peak creatine kinase level was 2502 ± 2593 U/l in the CABG group and 4203 ± 5364 U/l in the PCI group ($p=0.011$).

Timing and baseline hemodynamic data

The median time from myocardial infarction to revascularization was 24.3 hours (interquartile range, 8.7 to 82.5 hours) in the CABG group and 7.4 hours (interquartile, 3.7 to 19.5 hours) in the PCI group ($p < 0.01$) (Table 2). The median time from the onset of shock to revascularization was 11.3 hours (interquartile range, 3.9 to 77.8 hours) in the CABG group compared with 3.8 hours (1.9 to 7.6 hours) in the PCI group ($p < 0.01$). The median time from myocardial infarction to revascularization was 33.2 hours (interquartile, 8.6 to 113.0 hours) in the CABG registry group compared with 7.1 hours (4.5 to 14.8 hours) in the PCI registry group ($p < 0.01$). The median time from the onset of shock to revascularization was 18.1 hours (interquartile range, 2.2 to 100.3 hours) in the CABG registry group compared with 4.8 hours (2.4 to 9.9 hours) in the PCI registry group ($p < 0.01$).

There were no significant differences in hemodynamic data including systolic blood pressure, cardiac index, wedge pressure, and cardiac power index between the two groups (Table 3).

CABG procedure

Complete revascularization was achieved in 75 patients (94.8%) (Table 4). The mean number of grafts per patient was 3.0 ± 0.2 , and 29.0% of patients received a left internal mammary artery conduit to the left anterior descending artery. Intra-aortic balloon counterpulsation was used in 92.4%.

PCI procedure

Multivessel PCI was performed in 11.1% (Table 5). Stents were implanted in 26 patients (28.4%). Over the course of the study, the rate of stenting increased from 6.7% in 1993-1994 to 53.9% in 1997-1998 ($p < 0.01$). Glycoprotein IIb/IIIa antagonists were used in 6.8%. The rate of glycoprotein IIb/IIIa antagonists increased from 0% in 1993-1994 to 23.1% in 1997-1998 ($p < 0.01$). Intra-aortic balloon counterpulsation was used in 87.1%. Bypass surgery was performed in 13 patients (15.3 %) after initial PCI.

30-day survival

The estimated 30-day survival is presented in Figure 1. The survival rate in the CABG group was 54% compared with 14% in PCI group ($p < 0.001$). The survival rate was similar in the trial and registry patients who underwent CABG (58% vs. 55%, $p = \text{NS}$). When the LMCA was the infarct-related artery, the survival rate was 40% in the CABG group and 16% in the PCI group ($p = 0.03$). No statistically significant association between survival and the use of stents and glycoprotein IIb/IIIa antagonists were found in this small number of patients over the 2-year time intervals due to small strata ($p = 0.15$).

Correlates for survival

The following variables were entered into a stepwise multivariable Cox proportional hazard model for 30-day survival: age, sex, prior myocardial infarction, hypertension, diabetes,

congestive heart failure, renal failure, smoking, prior CABG, prior PCI, multivessel disease, CABG (vs. PCI), cardiac index, cardiac power index, systolic blood pressure, and heart rate. Bypass surgery [hazard ratio 0.41, 95% confidence interval (0.22, 0.77), $p=0.006$] and age [per 10 years, hazard ratio 1.04, 95% confidence interval (1.01-1.08); $p=0.02$] were significantly associated with 30-day survival.

COMMENT

The most important finding in this analysis was that patients with myocardial infarction complicated by cardiogenic shock and LMCA disease treated with CABG had a higher 30-day survival compared with patients treated with PCI. This finding supports current recommendations for the use of CABG as the preferred modality for patients with LMCA disease. However, very few patients undergo CABG for cardiogenic shock complicating myocardial infarction (15). Acute occlusion of the LMCA can result in severe circulatory decompensation within minutes and often manifests with fatal consequences (16-19).

Wong et al. reported that the mortality was particularly high when the LMCA was the infarct-related artery (78.6%) (20). Quigley et al. reported that 8 of 9 patients died who presented with myocardial infarction and LMCA disease complicated by cardiogenic shock and underwent PCI or CABG (21). In a multi-center registry of 40 patients with myocardial infarction who underwent unprotected LMCA PCI, 93% had cardiogenic shock, and the in-hospital survival rate was 45% (22).

Despite the trial protocol recommending CABG in patients with LMCA disease, nearly half of these patients underwent PCI. This suggests that surgeons may have deemed these patients unsuitable for surgery (e.g. patients had poor distal vessels that were not amenable to CABG) and led to an attempt at PCI. Also, it is possible that more stable patients were referred for CABG and unstable patients underwent PCI as it could be performed more expeditiously. Therefore, unmeasured confounders likely amplified the apparent survival benefit of surgery, even in the adjusted analysis. Despite the similar baseline hemodynamic data in the CABG and PCI patients, the longer time from myocardial infarction and cardiogenic shock to revascularization suggests that surgeons selected patients who survived the early, highest risk period potentially further favoring outcomes in the CABG group. In the PCI group, 11/85 (13%) patients were trial patients and 22/79 (28%) of the CABG patients were trial patients which may suggest that CABG patients were more stable and perhaps more likely to be randomized. Those who underwent CABG days after shock onset likely had resolution of shock prior to surgery and despite use of statistical adjustment, this bias cannot be completely accounted for. On the other hand, there was a higher prevalence of triple-vessel disease in the CABG group, which was adjusted for in the model. Another possible explanation of the improved survival observed in those who underwent CABG may be due to a high proportion of complete revascularization (89%) achieved with CABG. Therefore, CABG may be preferred when LMCA disease with or without severe triple-vessel disease is present or when unsatisfactory and less complete revascularization with PCI is likely (23-26). Other possible advantages with CABG may be due to protection of ischemic myocardium with cardioplegia, and unloading of the ventricle during cardiopulmonary bypass (7). The increased mortality observed in the PCI group may have

also been due to larger infarcts compared with the CABG group. The LMCA was more frequently the infarct-related artery compared with the CABG group. The highest mortality in patients with myocardial infarction complicated by cardiogenic shock was observed in whom the LMCA was the infarct-related artery (8).

Most PCI patients underwent single-vessel intervention (82%), perhaps because the standard of care was performing PCI only on the infarct-related artery, even though 73% had multivessel coronary disease. Because of the high prevalence of multivessel coronary disease and the possible deleterious effect of ischemia in non-infarct related territories on left ventricular function during the peri-infarction period, particularly in LMCA disease, a strategy to provide more complete revascularization with acute PCI of both the infarct-related artery and non-infarct related stenoses may be beneficial in hemodynamically unstable patients since the LMCA perfuses a large amount of jeopardized myocardium (10,23,27,28).

Zeymer et al. reported that mortality was strongly related to the procedural success of PCI in patients with myocardial infarction complicated by cardiogenic shock, with the lowest mortality in patients with Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow (8). Similarly, the SHOCK registry reported that the presence of TIMI grade 3 flow was associated with improved survival (20). Although stenting did not result in higher TIMI grade 3 flow rates in 2 randomized trials of myocardial infarction (29,30), stenting with adjunctive abciximab increased the likelihood of TIMI grade 3 flow in patients with cardiogenic shock (31). There was a trend towards lower in-hospital mortality after stenting compared with balloon angioplasty (35% vs. 70%; $p=0.1$) in patients with myocardial infarction who underwent unprotected LMCA PCI (22). Although stents and glycoprotein IIb/IIIa antagonists were used increasingly over time in this analysis, the overall rate was not high enough to draw any conclusions regarding survival. It is unknown if increased use of stents and glycoprotein IIb/IIIa antagonists might have increased survival in the PCI-treated patients.

Limitations

This analysis was limited due to a small number of patients and the short duration of follow up. Although protocol recommendations for the trial were available to help investigators select the mode of revascularization for the trial, patient selection bias may have played a role. The decision for CABG versus PCI may have been based upon acuity, severity, and technical feasibility. Data was not available on how the investigator's decision corresponded with the protocol recommendations in the trial. The potential impact of better hemodynamic support from percutaneous circulatory assist devices during PCI is unclear and is currently being studied. Data on collateral flow were not available. Data on complete revascularization was not available in all patients in the PCI group.

Conclusions

Despite having more extensive coronary disease CABG appeared to provide a survival advantage over PCI at 30-day follow up in patients with LMCA disease. Independent correlates of 30-day survival were performance of CABG and age. Only a randomized

clinical trial comparing CABG versus PCI with stents and glycoprotein IIb/IIIa antagonists and possibly left ventricular assist devices can definitely assess the optimal revascularization strategy in the current era of improved surgical and interventional techniques. Until the results of such a trial is available, it is reasonable to recommend CABG for these patients, especially if multi-vessel disease is present or when complete revascularization with PCI is unlikely to be achieved.

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Figure 1.
Kaplan-Meier 30-day survival estimates in the CABG and PCI groups.

Table 1
Baseline Demographic and Angiographic Characteristics

	CABG n=79	PCI n=85	p value
Age (yrs $\pm$ SD)	68.1 $\pm$ 10.8	67.6 $\pm$ 9.8	0.34
Men (%)	70.9	67.1	0.60
Hypertension (%)	54.7	49.4	0.51
Diabetes mellitus (%)	25.3	23.8	0.82
Renal insufficiency (%)	11.7	10.3	0.78
Previous myocardial infarction (%)	34.6	33.3	0.87
Previous CABG (%)	6.4	14.6	0.12
Previous PCI (%)	4.0	12.4	0.08
Triple-vessel disease (%)	87.3	72.9	0.02
Infarct-related artery			0.81
Left main (%)	24.5	24.4	
Left anterior descending artery (%)	33.9	32.1	
Left circumflex artery (%)	13.2	15.4	
Right coronary artery (%)	28.3	25.6	
Saphenous vein graft (%)	0.0	2.6	
Peak creatinine kinase (U/L $\pm$ SD)	2502 $\pm$ 2593	4203 $\pm$ 5364	0.011

CABG = coronary artery bypass graft surgery; PCI = percutaneous coronary intervention; SD = standard deviation

Table 2
Timing Data

	CABG (n=79 patients)	PCI (n=85 patients)	p value
Median time from AMI to revascularization (h) *	24.3 (8.7-82.5)	7.4 (3.7-19.5)	<0.01
Median time from shock to revascularization (h) *	11.3 (3.9-77.8)	3.8 (1.9-7.6)	<0.01
	(n=22 trial patients)	(n=11 trial patients)	
Median time from AMI to revascularization (h) *	19.1 (10.4-31.0)	7.1 (4.5-14.8)	0.02
Median time from shock to revascularization (h) *	10.7 (6.2-16.0)	4.8 (2.4-9.9)	0.02
	(n=57 registry patients)	(n=74 registry patients)	
Median time from AMI to revascularization (h) *	33.2 (8.6-113.0)	7.1 (4.5-14.8)	0.001
Median time from shock to revascularization (h) *	18.1 (2.2-100.3)	4.8 (2.4-9.9)	0.002

AMI = myocardial infarction

* Median (interquartile)

Table 3
Hemodynamic Data

	CABG (n=79)	PCI (n=85)	p value
Hemodynamics *			
Heart rate (beats/min)	100.1 ± 21.8	95.5 ± 23.1	0.19
Systolic blood pressure (mm Hg)	85.3 ± 19.2	84.9 ± 25.8	0.89
Ejection fraction (%)	26.9 ± 9.9	37.4 ± 11.0	0.91
Cardiac index (L/min/m ²)	2.0 ± 0.6	1.9 ± 0.8	0.60
Wedge pressure (mm Hg)	23.3 ± 7.2	24.5 ± 9.5	0.43
Cardiac power index	132.5 ± 49.8	133.6 ± 78.8	0.78

* Measurement often obtained while patients were receiving support mean ± standard deviation

Table 4
Procedural details of CABG

Complete revascularization * (%)	94.8%
Number of grafts	3.0 ± 0.19
Internal mammary artery graft-to-left anterior descending graft (%)	29.0
Hemodynamic support with intra-aortic balloon pump (%)	92.4

CABG = coronary artery bypass grafting,

* was judged by the surgeon at the time of CABG.

Table 5**Procedural details of PCI**

Multiple vessels treated initially (%)	11.1
Stenting (%)	28.4
Glycoprotein IIb/IIIa antagonists (%)	6.8
Hemodynamic support with intra-aortic balloon pump (%)	87.1
Subsequent bypass surgery (%)	15.3

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