Journal of the American College of Cardiology
Vol. 36, No. 3, Suppl A
© 2000 by the American College of Cardiology
ISSN 0735-1097/00/$20.00
Published by Elsevier Science Inc.
PII S0735-1097(00)00875-5

Impact of Thrombolysis, Intra-aortic Balloon Pump Counterpulsation, and Their Combination in Cardiogenic Shock Complicating Acute Myocardial Infarction: A Report from the SHOCK Trial Registry

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OBJECTIVES We sought to investigate the potential benefit of thrombolytic therapy (TT) and intra-aortic balloon pump counterpulsation (IABP) on in-hospital mortality rates of patients enrolled in a prospective, multi-center Registry of acute myocardial infarction (MI) complicated by cardiogenic shock (CS).

BACKGROUND Retrospective studies suggest that patients suffering from CS due to MI have lower in-hospital mortality rates when IABP support is added to TT. This hypothesis has not heretofore been examined prospectively in a study devoted to CS.

METHODS Of 1,190 patients enrolled at 36 participating centers, 884 patients had CS due to predominant left ventricular (LV) failure. Excluding 26 patients with IABP placed prior to shock onset and 2 patients with incomplete data, 856 patients were evaluated regarding TT and IABP utilization. Treatments, selected by local physicians, fell into four categories: no TT, no IABP (33%; n = 285); IABP only (33%; n = 279); TT only (15%; n = 132); and TT and IABP (19%; n = 160).

RESULTS Patients in CS treated with TT had a lower in-hospital mortality than those who did not receive TT (54% vs. 64%, $p = 0.005$), and those selected for IABP had a lower in-hospital mortality than those who did not receive IABP (50% vs. 72%, $p < 0.0001$). Furthermore, there was a significant difference in in-hospital mortality among the four treatment groups: TT + IABP (47%), IABP only (52%), TT only (63%), no TT, no IABP (77%) ($p < 0.0001$). Patients receiving early IABP (≤6 h after thrombolytic therapy, n = 72) had in-hospital mortality similar to those with late IABP (53% vs. 41%, n = 64, respectively, $p = 0.172$). Revascularization rates differed among the four groups: no TT, no IABP (18%); IABP only (70%); TT only (20%); TT and IABP (68%, $p < 0.0001$); this influenced in-hospital mortality significantly (39% with revascularization vs. 78% without revascularization, $p < 0.0001$).

CONCLUSIONS Treatment of patients in cardiogenic shock due to predominant LV failure with TT, IABP and revascularization by PTCA/CABG was associated with lower in-hospital mortality rates than standard medical therapy in this Registry. For hospitals without revascularization capability, a strategy of early TT and IABP followed by immediate transfer for PTCA or CABG may be appropriate. However, selection bias is evident and further investigation is required. (J Am Coll Cardiol 2000;36:1123–9) © 2000 by the American College of Cardiology

Small retrospective studies of patients suffering from acute myocardial infarction (MI) complicated by cardiogenic shock (CS) suggest that the addition of intra-aortic balloon pump counterpulsation (IABP) to thrombolytic therapy (TT) reduces in-hospital mortality rates, compared with TT treatment alone (1–4). Furthermore, the large nonrandomized National Registry of Myocardial Infarction study reported lower mortality rates in patients treated with TT combined with IABP (49%) compared to TT alone (69%) (5). However, in the GUSTO (Global Utilization of Streptokinase and tPA for Occluded Coronary Arteries) thrombolytic trial, there was only a trend toward reduced in-hospital and 30-day mortality in a subset of patients presenting with CS who were treated with TT followed by early IABP (6). Theoretically, IABP should improve coro-

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Manuscript received February 16, 2000; revised manuscript received May 31, 2000, accepted June 7, 2000.

Abbreviations and Acronyms

CABG	= coronary artery bypass graft surgery
CK	= creatine phosphokinase
CS	= cardiogenic shock
IABP	= intra-aortic balloon pump
LV	= left ventricular, left ventricle
LVEF	= left ventricular ejection fraction
MI	= myocardial infarction
PTCA	= percutaneous transluminal coronary angioplasty
SHOCK	= SHould we emergently revascularize Occluded Coronaries for cardiogenic shocK?
TT	= thrombolytic therapy

nary flow and patency after TT by augmenting diastolic perfusion pressure and unloading the left ventricle (LV).

Nonrandomized studies also suggest that revascularization of patients in CS with percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft surgery (CABG) may also reduce mortality (7–21). Recently the multicenter randomized trial, SHould we emergently revascularize Occluded Coronaries for cardiogenic shocK? (SHOCK Trial), demonstrated that emergency early revascularization with PTCA or CABG improves six-month and one-year survival in patients with CS due to LV failure, compared with patients treated with initial medical stabilization (22–24). However, the smaller and non-significant mortality difference between the groups at hospital discharge and 30 days may have resulted partially from the relatively low 30-day mortality observed in the initial medical stabilization group, in which there was a high rate of IABP and TT use. The concurrent SHOCK Trial Registry of patients with suspected CS complicating acute MI who were not randomized affords the opportunity to assess the impact of IABP and TT on mortality in the broader CS population. This report describes the clinical, hemodynamic and angiographic characteristics, as well as the procedure utilization and in-hospital mortality rates, of patients receiving four different treatments used at either the primary or tertiary referral site: no TT, no IABP; IABP only; TT only; and TT and IABP.

METHODS

Patient population. Patients with suspected CS complicating acute MI, whether meeting strict trial criteria for CS or not, were prospectively registered at 36 SHOCK Trial Registry institutions after obtaining approval of the committee on human research at each center. The criteria for enrollment and the definitions used in the SHOCK Trial Registry are described in the report on the overall findings of the SHOCK Trial Registry (25). Of the 1,190 patients enrolled in the SHOCK Trial Registry, 884 (74%) had CS due to predominant LV failure. Predominant LV failure was designated as the etiology of CS when none of the following major shock categories was indicated: acute severe mitral regurgitation, ventricular septal rupture, isolated right ventricular failure, cardiac tamponade or rupture, prior severe valvular heart disease, excess beta or calcium channel blockade, dilated cardiomyopathy, CS associated with recent hemorrhage or resulting from a cardiac catheterization laboratory complication or shock due to other causes (e.g., sepsis, anaphylaxis). This analysis was based on 856 patients because of the exclusion of 26 patients with IABP placed prior to shock onset and 2 patients with incomplete TT and IABP data.

Data collection. Data were abstracted from the medical record by SHOCK study coordinators, who were centrally trained to complete standardized study report forms. Patient characteristics, MI location, hemodynamics, procedure utilization and vital status at hospital discharge were recorded. Cardiac catheterization and angioplasty reports were sent to the Clinical Coordinating Center for abstraction and centralized completion of a standardized form. The following variables were collected only on the revised study report forms and are available for a maximum of 615 patients: medication usage, left ventricular ejection fraction (LVEF), pulmonary artery pressures, pulmonary edema, history of elevated lipids and history of peripheral vascular disease.

Statistical methods. Groups were compared using the Fisher exact test for categorical variables, the Wilcoxon rank sum test for ordinal and non-normally distributed continuous variables, and Student *t*-test for normally distributed continuous variables. When four groups were being compared, continuous variables were evaluated using analysis of variance and the Kruskal-Wallis test. When a significant difference among the four groups was identified, a Bonferroni correction (significance level 0.017) was used to compare the TT-and-IABP group to each of the other three groups. In-hospital mortality for all patients and for revascularized and nonrevascularized patients was analyzed separately using logistic regression, with main effects for TT and IABP status and an interaction term of the two effects to evaluate whether the impact of TT was independent of IABP use. Multivariate modeling evaluated all variables that differed among the four groups with a p value of ≤ 0.20. All analyses were conducted using the Statistical Analysis System (SAS Institute, Cary, North Carolina).

RESULTS

Patient characteristics. The patient characteristics for the four treatment groups are summarized in Table 1. Patients treated with TT and IABP were significantly younger than patients in all other groups and less likely to have the risk factors of prior MI, congestive heart failure, renal insufficiency or peripheral vascular disease, compared with patients who received neither TT or IABP. Patients treated with IABP were almost twice as likely to be transferred to a SHOCK Trial tertiary medical center (55% vs. 30%, $p < 0.001$). There was no significant difference in the time from MI to shock in the patients receiving the different treat-

Table 1. Baseline Characteristics of Patients With CS Due to Predominant LV Failure

	No TT No IABP	IABP Only	TT Only	TT + IABP	p Value
n	285	279	132	160	—
Age	73 ± 11	66 ± 11	71 ± 12	63 ± 12*	0.0001
Male	59%	66%	62%	69%	0.138
History of hypertension	57%	47%	53%	45%	0.046
Diabetes	38%	33%	25%	28%	0.039
Smoking	50%	55%	43%	56%	0.126
History of elev. lipids (n = 427)	32%	45%	32%	47%	0.031
History of CHF	30%	16%	17%	12%*	< 0.0001
Transfer	28%	53%	33%	60%	< 0.0001
History of MI	49%	42%	36%	24%	< 0.0001
History of PTCA	6%	10%	8%	3%	0.050
History of CABG	12%	12%	5%	5%	0.015
History of renal insuf.	19%	7%	8%	6%	0.0001
History of PVD (n = 543)	29%	15%	14%	13%	0.0007

*p < 0.05 TT only vs. TT and IABP.
CABG = coronary artery bypass surgery; MI = myocardial infarction; PTCA = any percutaneous coronary intervention (balloon, stent, etc.); PVD = peripheral vascular disease.

ments. Patients who did not receive TT or IABP were less likely to have chest pain at presentation (76% vs. 87% with TT and/or IABP, $p < 0.001$) (Table 2). Patients receiving IABP support were more likely to be put on a ventilator or receive inotropic support ($p < 0.001$).

ECG characteristics and CK values. Ninety-five percent of the patients receiving thrombolytics had ST elevation in two or more leads, significantly more than the groups without thrombolytics (61%, $p < 0.0001$). However, only 45% of the patients with ST elevation received thrombolytics. The distribution of MI location, however, was similar among the four groups (Table 3). The median highest CK and its ratio to the upper limit of the local laboratory normal value were significantly higher in the group receiving TT and IABP support, compared to each of the other three groups ($p < 0.001$).

Hemodynamic and angiographic characteristics. Systolic and diastolic blood pressure, cardiac index, LVEF, and pulmonary arterial and wedge pressure were similar among the four treatment groups (Table 4). There was a significant, but not clinically relevant, difference in heart rate among patients who received the four treatments. Right heart catheterization was more likely to be performed if IABP support was chosen (80% vs. 47%, $p < 0.001$). Patients who were treated with IABP were also more likely to receive coronary angiography ($p < 0.001$) and were more likely to have left main disease (19% vs. 9%, $p = 0.021$). The number of diseased vessels (≥50% stenosis) was similar across all treatment groups.

In-hospital treatment and outcome. Thrombolytic therapy (with or without IABP) was associated with a lower in-hospital mortality rate than no TT (54% vs. 64%, odds ratio [OR] 0.66, $p = 0.005$) even after adjustment for age and revascularization status (OR 0.70, $p = 0.027$) (Table 5). Intra-aortic balloon pump use was also associated with a lower mortality rate than no IABP (50% vs. 72%, $p < 0.0001$) because of the higher rate of attempted revascularization in the IABP group (IABP vs. no IABP mortality, $p = 0.313$ after adjustment for revascularization). Among patients treated with IABP, those with early IABP support (≤6 h post-lytic, n = 72) had an in-hospital mortality rate similar to that of patients in whom an IABP was placed later (>6 h, n = 64): 53% vs. 41%, respectively ($p = 0.172$).

In-hospital mortality rates of the four TT/IABP groups differed significantly ($p < 0.0001$). In particular, patients in CS selected for combined TT and IABP treatment had a mortality rate of 47%, significantly lower than the 63% mortality of patients receiving TT only ($p = 0.007$).

Table 2. Clinical Characteristics and Management of Patients With CS Caused by Predominant LV Failure

Variable	No TT No IABP	IABP only	TT only	TT + IABP	p Value
n	285	279	132	160	—
MI to shock (median, h)	7.7	4.8	7.3	5.0	0.702
Chest pain	76%	85%	89%	88%	0.001
Pulmonary edema on X-ray, (n = 608)	53%	65%	61%	57%	0.126
Ventilator	72%	83%	55%	86%*	< 0.0001
Inotropes (n = 615)	63%	79%	62%	79%*	0.0004
Vasopressors (n = 615)	96%	94%	95%	100%*	0.030

*p < 0.05 TT only vs. TT + IABP.
MI = myocardial infarction.

Table 3. ECG Characteristics and CK Values of Patients With CS Caused by Predominant LV Failure

	No TT No IABP	IABP only	TT only	TT + IABP	p Value
n	285	279	132	160	—
ST elevation	56%	66%	94%	96%	< 0.0001
New LBBB	17%	10%	6%	4%	0.0002
MI location					
Anterior	55%	59%	63%	57%	0.458
Inferior	45%	43%	40%	48%	0.347
Posterior	17%	18%	15%	21%	0.663
Lateral	37%	32%	31%	28%	0.276
Apical	9%	8%	9%	13%	0.428
Multiple	50%	48%	45%	53%	0.593
Median highest CK	1,059	1,939	1,992	3,126*	0.0001
Median CK/Upper Normal limit	5.1	9.7	9.7	14.1*	0.0001

*$p < 0.05$ TT only vs. TT + IABP.
CK = creatine phosphokinase; LBBB = left bundle branch block; MI = myocardial infarction.

Differences among the four groups persisted even after adjustment for patient (but not treatment) differences among the four groups, including age, prior MI, transfer status and chest pain at presentation ($p = 0.002$). After adjustment for treatment (ventilator use and revascularization), there was no difference in mortality among the four groups ($p = 0.378$). However, when examining the impact of TT and IABP therapy on mortality separately for revascularized and nonrevascularized patients, patients selected to undergo PTCA or CABG had lower in-hospital mortality than patients who did not undergo revascularization (39% vs. 78%, $p < 0.0001$).

In patients undergoing revascularization (Fig. 1), TT was associated with the lowest mortality in the absence of IABP support (48% mortality for n = 52 with TT, 95% confidence interval [CI] 35% to 62%, vs. 19% mortality for n = 27 with no TT, 95% CI 4% to 33%). By contrast, mortality was similar for the TT and no-TT groups when IABP support was used: 41% mortality for n = 195 with TT versus 37% mortality for n = 109 with no TT (TT by IABP interaction $p = 0.048$). However, after adjusting for age, transfer status, and heart rate, there was no significant differential effect of IABP use on mortality (no TT:TT ORs for death = 1.74 without IABP and 1.07 with IABP, interaction $p = 0.128$). A subgroup analysis of patients undergoing PTCA was also conducted to examine the effect of unloading with IABP. There was no difference in in-hospital mortality for patients unloaded with IABP prior

Table 4. Hemodynamics and Coronary Anatomy of Patients With CS Caused by Predominant LV Failure

Variable	No TT No IABP	IABP only	TT only	TT + IABP	p Value
n	285	279	132	160	—
Systolic BP	88 ± 27	89 ± 21	85 ± 19	88 ± 21	0.116
Diastolic BP	53 ± 18	54 ± 18	52 ± 16	52 ± 16	0.755
Heart rate	94 ± 26	98 ± 26	88 ± 25	97 ± 24*	0.004
RH cath performed (n = 549)	47%	80%	47%	81%	< 0.0001
CI (n = 393)	1.9 ± 0.6	2.1 ± 0.8	2.1 ± 0.8	2.0 ± 0.8	0.264
PCWP (n = 516)	23 ± 9	24 ± 9	22 ± 7	24 ± 8	0.425
PA systolic (n = 328)	43 ± 12	42 ± 15	40 ± 10	38 ± 12	0.063
PA diastolic (n = 330)	24 ± 6	25 ± 9	23 ± 8	23 ± 8	0.321
LVEF (%) (n = 325)	32 ± 13	28 ± 12	32 ± 11	31 ± 14	0.086
Coronary angiography performed	29%	89%	36%	89%*	< 0.0001
(n)	79	242	41	136	
LM disease	11%	20%	7%	17%	0.104
Number of diseased vessels					0.203
0	1%	1%	2%	0%	
1	23%	16%	29%	29%	
2	22%	22%	17%	18%	
3	54%	60%	51%	53%	

*$p < 0.05$ TT only vs. TT + IABP. Hemodynamic variables were often recorded on support measures (mean ± SD).
BP = blood pressure; CI = cardiac index; LM = left main coronary artery; LVEF = left ventricular ejection fraction; PA = pulmonary artery; PCWP = pulmonary capillary wedge pressure; RH = right heart; VD = vessels diseased.

Table 5. In-hospital Treatment of Patients With CS Due to Predominant LV Failure

Variable	No TT No IABP	IABP only	TT only	TT + IABP	p Value
n	285	279	132	160	—
PTCA	15%	47%	16%	51%*	< 0.0001
CABG	4%	26%	5%	23%*	< 0.0001
PTCA or CABG	18%	70%	21%	68%*	< 0.0001

*p < 0.05 TT only vs. TT + IABP.

to PTCA (n = 98; 47% mortality) when compared with 1) those treated with IABP after PTCA (n = 95; 47% mortality) and 2) patients treated with PTCA without IABP (n = 56; 46% mortality).

In patients not undergoing revascularization (Fig. 1), TT was associated with lower mortality (72% with TT, compared with 81% without TT, p = 0.044); there was no evidence of an interaction of IABP and TT use (interaction p = 0.785).

DISCUSSION

Benefit of thrombolysis in CS. In this cohort of prospective, multicenter Registry patients with CS due to predominant LV failure, those treated with TT had lower in-hospital mortality than those who did not receive TT. This is a contrast to previous reports from large-scale thrombolytic trials. For example, in the GISSI-1 Trial (26), patients in Killip class IV had high in-hospital mortality with no difference between control patients and those treated with streptokinase (69.9% vs. 71.1%). However, in the Fibrinolytic Therapy Trialist overview (27), patients with pump failure as evidenced by both a systolic blood pressure below 100 mm Hg and a heart rate above 100 beats/min had 7 lives saved per 100 patients treated with TT. Because of the small sample size in that trial, the difference was not significant. In this study, the number of patients analyzed with CS due to predominant LV failure is larger (n = 856), and there was an absolute benefit of 10 percentage points. Overall, those patients treated with TT did better than those without TT, even after adjustment for age and revascularization status. The lowest mortality rate (19%) was observed with the treatment of TT alone followed by revascularization. Most likely, these were patients in CS who promptly reperfused and were then revascularized later in their hospitalizations.

Benefit of IABP. As in prior retrospective studies (1–5), this prospective Registry demonstrated that patients treated with the combination of IABP support and TT had the lowest observed in-hospital mortality. However, this was not significantly different from the mortality of patients treated with IABP alone. There was no significant interaction of IABP and TT in both revascularized and nonrevascularized subgroups of patients after adjustment for patient characteristics. In the largest of the prior studies, in which 21,178 patients were identified and 6,993 (32%) received IABP, the use of an IABP was associated with a lower in-hospital mortality rate in patients who received TT (49%), compared with those who did not receive TT (69%) (5). Thus, the observations of these two large registries support the theory that IABP improves survival after TT by augmenting diastolic perfusion pressure and unloading the LV. Experimental studies demonstrate that unloading the LV during ischemia and reperfusion resulted in greater infarct salvage, compared with reperfusion alone (28). The lack of difference in in-hospital mortality between IABP unloading prior to, versus after, PTCA revascularization may result from differences in patient selection. The higher CK level in the group receiving TT and IABP may have

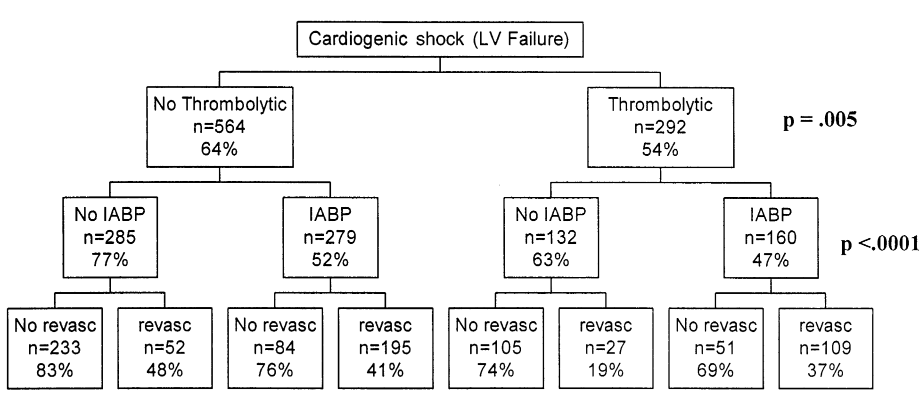

Figure 1. In-hospital mortality rates of SHOCK Trial Registry patients with predominant left ventricular failure. Patients receiving thrombolytic therapy had significantly lower mortality than those not receiving thrombolytic therapy in the overall cohort (p = 0.005), and this benefit was independent of IABP use (interaction p = 0.126). There was a significant difference in in-hospital mortality among the 4 subsets of patients treated with thrombolysis with IABP, thrombolysis without IABP, IABP alone or neither. Treatments were selected by local physicians. In each of these subsets, patients who underwent revascularization had lower mortality than those who were not revascularized (p < 0.0002).

resulted from "early washout" from a patent artery. Treatment with early IABP support (within 6 h after TT administration) was associated with an in-hospital mortality rate of 53%, compared with 41% in patients treated with later IABP support (>6 h); these rates were not significantly different. This observation may also represent a selection bias, because early IABP support may have been performed sooner if the patients were deteriorating hemodynamically and were at a greater imminent risk of death.

Benefit of revascularization. In the nonrandomized Registry portion of the SHOCK Trial, revascularization at any time during the hospitalization was associated with the largest difference in in-hospital mortality (39% revascularized vs. 78% nonrevascularized). It is possible that the less-than-expected reduction in the 30-day mortality rate by emergency revascularization (22) in the randomized SHOCK Trial may be partly explained by the relatively low 30-day mortality observed in the initial medical stabilization group; this, in turn, may have resulted from the high rate of IABP use (86%), TT use (63%) and delayed revascularization (25%).

Study limitations. Marked differences in patient characteristics certainly contributed to the selection of different treatments and the final clinical outcome. The differences noted in these clinical factors suggest that patients selected for IABP/TT were a lower-risk group who may have been pre-selected for a more favorable outcome by virtue of their younger age, less comorbid disease, lower likelihood of a prior MI and likely, other factors not explicitly measured in this study.

Implications. The randomized SHOCK Trial demonstrated that 6 and 12 month mortality was lower with a strategy of emergency early revascularization, compared with initial medical stabilization including IABP and TT. However, IABP and TT may be appropriate initial therapy at hospitals without revascularization facilities, if followed by prompt transfer to tertiary care centers. This remains to be demonstrated in a randomized trial.

Conclusions. This SHOCK Trial Registry of 856 patients represents the largest prospectively collected series of patients in CS due to predominant LV failure that examines the outcome of various treatments and combinations of therapeutic options. Revascularization by PTCA/CABG, IABP unloading and, to a lesser extent, TT was associated with lower in-hospital mortality rates than treatment with standard medical therapy.

Acknowledgment

The assistance of Colleen Whelan, BA, in the preparation of this manuscript is greatly appreciated.

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