Absence of Gender Differences in Clinical Outcomes in Patients With Cardiogenic Shock Complicating Acute Myocardial Infarction

A Report From the SHOCK Trial Registry

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OBJECTIVES

The aim of this study was to assess the impact of gender on clinical course and in-hospital mortality in patients with cardiogenic shock (CS) complicating acute myocardial infarction (AMI).

BACKGROUND

Previous studies have demonstrated higher mortality for women compared with men with ST elevation myocardial infarctions and higher rates of CS after AMI. The influence of gender and its interaction with various treatment strategies on clinical outcomes once CS develops is unclear.

METHODS

Using the SHould we emergently revascularize Occluded Coronaries for cardiogenic shocK? (SHOCK) Registry database of 1,190 patients with suspected CS in the setting of AMI, we examined shock etiologies by gender. Among the 884 patients with predominant left ventricular (LV) failure, we compared the patient demographics, angiographic and hemodynamic findings, treatment approaches as well as the clinical outcomes of women versus men. This study had a 97% power to detect a 10% absolute difference in mortality by gender.

RESULTS

Left ventricular failure was the most frequent cause of CS for both gender groups. Women in the SHOCK Registry had a significantly higher incidence of mechanical complications including ventricular septal rupture and acute severe mitral regurgitation. Among patients with predominant LV failure, women were, on average, 4.6 years older, had a higher incidence of hypertension, diabetes and a lower cardiac index. The overall mortality rate for the entire cohort was high (61%). After adjustment for differences in patient demographics and treatment approaches, there was no significant difference in in-hospital mortality between the two gender groups (odds ratio 1.03, 95% confidence interval of 0.73 to 1.43, p = 0.88).

Mortality was also similar for women and men who were selected for revascularization (44% vs. 38%, p = 0.244).

CONCLUSIONS

Women with CS complicating AMI had more frequent adverse clinical characteristics and mechanical complications. Women derived the same benefit as men from revascularization, and gender was not independently associated with in-hospital mortality in the SHOCK Registry. (J Am Coll Cardiol 2001;38:1395–401) © 2001 by the American College of Cardiology

Myocardial infarction (MI) strikes close to one million Americans annually (1) and accounted for one of every 4.8 deaths in 1995 (2,3). With the establishment of coronary care units, advances made in early detection and treatment of obstructive coronary artery disease and the application of thrombolytic treatment strategies in acute MI (AMI), the mortality rate in patients admitted to hospitals with MI has declined in recent years (2,3). Despite these advances, mortality associated with cardiogenic shock (CS) complicating MI remains unacceptably high (4,5). Conventional treatment with intravenous thrombolytic therapy has had limited impact on 30-day mortality in patients with MI after pump failure is diagnosed (6). Importantly, women may have a higher incidence of CS and mortality, complicating acute ST elevation MI, than that seen in men (4,7–20). However, whether there are gender differences in treatment approaches and clinical outcomes in patients with CS is less clear.

The SHould we emergently revascularize Occluded Coronaries for cardiogenic ShocK (SHOCK) trial was a National Heart, Lung, and Blood Institute-sponsored multicenter study designed to assess the impact of a direct invasive strategy including emergent coronary angiography and revascularization on 30-day mortality in patients with AMI complicated by CS. In an effort to ensure that all potentially eligible patients were screened for the study, patients with any clinical or hemodynamic evidence of CS complicating an AMI who were not enrolled in the ran-
domized trial were entered in the SHOCK Registry. The purpose of this analysis was to ascertain if there were differences in procedural utilization and clinical outcomes between men and women enrolled in the SHOCK Registry.

METHODS

Patients. From April 1993 to August 1997, a total of 1,190 consecutive patients (709 men and 481 women) with suspected CS complicating AMI, whether meeting all enrollment criteria for the SHOCK trial or not, were enrolled in the SHOCK Registry. Reasons for trial ineligibility (and subsequent enrollment in the SHOCK Registry) have been previously published (5) and included failure to meet all clinical and hemodynamic inclusion criteria, failure to adhere to specified time windows, presence of any clinical exclusion criterion and inability to obtain informed consent. Patients were enrolled at 36 international clinical sites including 24 U.S. centers (730 patients), five Canadian centers (256 patients), four Belgian centers (76 patients) and one center each in Australia, New Zealand and Brazil (128 patients). All enrolled patients with a local discharge diagnosis of AMI with CS (diagnosis related groups [DRGs] 410, 410.1 to 410.9 or combined with 785.51) or a suspected diagnosis of CS complicating AMI, regardless of the final discharge diagnosis, were entered into the Registry. Cardiogenic shock due to predominant left ventricular (LV) failure (see definitions in the following text) was noted in 74% (n = 884) of the 1,190 registered patients. Shock etiologies were examined by gender using the entire Registry cohort. However, in view of significant differences in the incidence of various etiologies of CS for men and women, subsequent comparisons of patient characteristics, clinical findings, hemodynamics and angiographic data by gender, including multivariate analyses for treatment strategies and mortality models, were based on the subset of 884 patients (562 men and 322 women) with predominant LV failure.

Data collection. Patient demographics, MI characteristics, vascular hemodynamics, procedure utilization and vital status at hospital discharge were recorded in standardized case report forms by centrally trained SHOCK study coordinators and sent to the data coordinating center. Cardiac catheterization and angioplasty reports were also forwarded to the clinical coordinating center for abstraction and centralized completion of a standardized form. Reinfarction, vasopressor use, history of or elevated lipids and peripheral vascular disease, cardiac output and pulmonary artery pressures were recorded on revised data collection forms only and available for two-thirds of patients. A total of 568 patients with predominant LV failure underwent right heart catheterization, with pulmonary capillary wedge pressure obtained in 533 and cardiac index in 407. Left ventricular ejection fraction at or after shock development was measured in 300 patients—36% by left ventriculography at any time during the hospitalization; 59% of patients underwent echocardiogram, and gated blood pool scan was obtained in 5%.

Definitions. Patients were categorized as having predominant LV failure as the contributing etiology of their CS when other major causes of CS were absent. These causes included isolated right ventricular shock, a mechanical cause (acute severe mitral regurgitation or ventricular septal rupture), tamponade/LV rupture, prior severe valvular heart disease, dilated cardiomyopathy, excess beta or calcium channel blockade, shock due to cath lab complications or other non-cardiac causes of shock.

Global Use of Strategies to Open Occluded Coronary Arteries (GUSTO) I criteria were used for electrocardiogram locations of MI: V1 to V4, anterior; II, III, AVF inferior; I, AVL, lateral; V1 to V2, posterior and V5 to V6 apical. Creatine kinase (CK) values analyzed were the highest recorded (based on three or more measurements for 71% of patients).

Reinfarction was defined as: 1) recurrent chest pain or ischemic symptoms ≥30 min and recurrent ST segment elevation, new Q waves or new left bundle branch block, 2) total CPK at least twice the upper limit of normal and >25% or 200 U/ml over the previous value with an elevated CK-isoenzyme (MB) level or 3) a rise in CK-MB above the upper limit of normal after it had reverted to the normal range.

Statistical methods. Groups were compared using 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. In-hospital mortality and selection for angiography and revascularization by gender were analyzed using logistic regression. In order to determine if gender was an independent predictor of outcome, a multivariate model was constructed by including all variables with a univariate p value for gender comparison of 0.20 or less. All variables with a final p value of 0.05 or less were retained in the model. This study had 97% power to detect a 10% absolute
Table 1. Etiologies of Cardiogenic Shock by Gender

<table>
<thead>
<tr>
<th></th>
<th>Men (n = 709)</th>
<th>Women (n = 481)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predominant left ventricular failure (%)</td>
<td>79.3</td>
<td>66.9</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Severe mitral regurgitation (%)</td>
<td>7.1</td>
<td>11.4</td>
<td>0.014</td>
</tr>
<tr>
<td>Ventricular septal rupture (%)</td>
<td>3.5</td>
<td>7.7</td>
<td>0.003</td>
</tr>
<tr>
<td>Isolated right ventricular shock (%)</td>
<td>2.8</td>
<td>4.2</td>
<td>0.251</td>
</tr>
<tr>
<td>Tamponade (%)</td>
<td>1.1</td>
<td>2.5</td>
<td>0.105</td>
</tr>
<tr>
<td>Shock due to cath lab complications (%)</td>
<td>1.8</td>
<td>2.5</td>
<td>0.520</td>
</tr>
<tr>
<td>Active bleeding (%)</td>
<td>4.4</td>
<td>4.4</td>
<td>1.00</td>
</tr>
<tr>
<td>Other causes of shock (%)</td>
<td>3.4</td>
<td>4.6</td>
<td>0.288</td>
</tr>
</tbody>
</table>

Table 2. Baseline Characteristics in Patients With Predominant LV Failure

<table>
<thead>
<tr>
<th></th>
<th>Men (n = 562)</th>
<th>Women (n = 322)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>66.8 ± 12.3</td>
<td>71.4 ± 11.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hx MI (%)</td>
<td>44.7</td>
<td>32.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hx hypertension (%)</td>
<td>45.6</td>
<td>62.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>28.3</td>
<td>40.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hx smoking (%)</td>
<td>57.5</td>
<td>40.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hx CABG (%)</td>
<td>12.1</td>
<td>6.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hx PTCA</td>
<td>7.6</td>
<td>5.1</td>
<td>0.200</td>
</tr>
<tr>
<td>Hx congestive heart failure (%)</td>
<td>20.1</td>
<td>19.2</td>
<td>0.788</td>
</tr>
<tr>
<td>Hx renal insufficiency (%)</td>
<td>11.4</td>
<td>9.5</td>
<td>0.419</td>
</tr>
<tr>
<td>Hx PVD (%) (n = 560)</td>
<td>18.6</td>
<td>19.0</td>
<td>0.910</td>
</tr>
<tr>
<td>Hx elevated ligids (%) (n = 443)</td>
<td>40.6</td>
<td>39.5</td>
<td>0.841</td>
</tr>
</tbody>
</table>

CABG = coronary artery bypass graft surgery; Hx = history of; LV = left ventricular; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; PVD = peripheral vascular disease.

difference in mortality by gender, assuming a significance level of 0.05 and a mortality rate in men of 59%. All analyses were conducted using the Statistical Analysis System (SAS Institute, Cary, North Carolina) and S-PLUS for Windows (Statistical Sciences Inc., Seattle, Washington).

RESULTS

Etiologies of CS. Predominant LV failure after MI was the most common (74.3%) cause of CS for both men and women (Table 1). It was more frequently a cause of CS in men than it was in women (79.3% vs. 66.9%, p < 0.001), in part due to the higher incidence of mechanical complications in women including development of severe mitral regurgitation due to papillary muscle dysfunction (11.4% in women vs. 7.1% in men, p = 0.014) and ventricular septal rupture (7.7% in women vs. 3.5% in men, p = 0.003).

Patient characteristics. Of 884 patients with AMI complicated by CS due to predominant LV failure, 322 (36.4%) were women (Table 2). Female patients were, on average, 4.6 years older and had a higher prevalence of hypertension (62.1% vs. 45.6%) and diabetes (40.8% vs. 28.3%), while male patients were more likely to have a history of smoking (57.5% vs. 40.7%), prior MI (44.7% vs. 32.0%) and previous bypass surgery (12.1% vs. 6.7%; all p < 0.001).

Clinical and hemodynamic findings. Patients enrolled in the SHOCK Registry were critically ill; 96% of patients with predominant LV failure received vasopressors, and 75% of patients were intubated, with similar rates for women and men. Infarct locations were also comparable between the two gender groups with the majority of infarcts involving the anterior wall (Tables 3 and 4). Both male and female patients with LV failure had a relatively large myocardial infarct size with median highest CK of 1,869 IU/ml for men and 1,965 IU/ml for women. The median time from onset of MI symptoms to diagnosis of CS was 6.2 h and was similar for women and men. Hemodynamics did not differ by gender, except that cardiac index, largely measured on inotropic support, was significantly lower in women than it was in men (1.8 ± 0.6 l/min/M² vs. 2.2 ± 0.8 l/min/M², p < 0.001).

Angiographic findings. Coronary angiography was performed at the same rate in women and men (62%), and the majority (57%) of patients had three-vessel disease (Table 5). There were no significant differences in the extent of coronary artery disease by gender. The distribution of infarct-related vessel location was similar for the two groups. Specifically, the left main coronary artery was classified as the culprit vessel in 7% of patients, with similar frequency observed in women and men.

Treatment strategies. The rates of thrombolytic treatment were similar for men and women (32% for women vs. 36% for men, p = 0.304) (Table 5). However, intra-aortic balloon pump (IABP) use was less common in women than it was in men (48% in women vs. 55% in men, p = 0.050), despite a lower cardiac index demonstrated in women. Women were more likely to receive blood transfusions (47% for women vs. 35% for men, p = 0.001).

Although the overall frequency of coronary angiography was similar (62%) for women and men with predominant LV failure (p = 1.00), after adjusting for the older age and greater prevalence of diabetes in women and higher rates of prior percutaneous transluminal coronary angioplasty (PTCA), previous coronary artery bypass grafting (CABG), dilated cardiomyopathy and severe systemic illness in men, women were more likely to undergo angiography than men (odds ratio [OR] = 1.8, 95% confidence interval [CI] = 1.01 to 1.95, p = 0.042).

The rate of percutaneous or surgical revascularization was similar for the two gender groups. In patients with predominant LV failure, 35% of women and 31% of men underwent PTCA (p = 0.234). In the angiography cohort (in which 57% of women and 50% of men underwent PTCA), after adjustment for differences in age, left main disease, bypass surgery and dilated cardiomyopathy, the frequency of PTCA remained gender neutral (n = 453; OR = 1.12, 95% CI = 0.71 to 1.78, p = 0.624). Similarly, although there was a higher incidence (17.3% vs. 12.1%, p = 0.042) of male patients undergoing coronary bypass surgery, this gender
difference dissipated after adjusting for the age difference between the two groups (OR = 0.76, 95% CI = 0.50 to 1.14, p = 0.190). Furthermore, selection of patients for revascularization (either PTCA or bypass surgery) did not differ significantly between women and men after adjustment for differences in patient characteristics including age, dilated cardiomyopathy, diabetes, prior CABG and prior PTCA (OR = 1.27, 95% CI = 0.96 to 1.67, p = 0.140).

In-hospital mortality. Despite differences in patient characteristics including age, history of diabetes and prior CABG between women and men, there was no significant gender difference in in-hospital mortality associated with MI complicated by CS due to predominant LV failure (women 63.4% vs. men 59.3%, OR = 1.16, 95% CI = 0.87 to 1.55, p = 0.252) (Fig. 1). This gender neutrality was maintained even after adjustment for differences in patient demographics (age, diabetes and prior CABG) as well as for treatment approaches (CABG and transfection) between the two groups (OR = 1.03, 95% CI = 0.73 to 1.43, p = 0.88).

In the subset of patients who underwent right heart catheterization, in-hospital mortality adjusted for differences in cardiac index as well as other patient and treatment factors was similar between women and men (OR = 0.77, 95% CI = 0.47 to 1.28, p = 0.313).

Mortality rates by gender and intervention approaches are displayed in Figure 1. No differences were found in in-hospital mortality by gender for patients who underwent revascularization (44% for women vs. 38% for men, p = 0.244) or for those with no revascularization attempt (79% for women vs. 78% for men, p = 0.818). Mortality rates after PTCA and CABG were also similar for men and women (Fig. 1).

**DISCUSSION**

In the SHOCK Registry, women more often had mechanical etiologies of CS complicating AMI. In addition, women had a higher risk profile than men, including advanced age and lower cardiac index. Women and men underwent revascularization at similar rates. Furthermore, women derived as much benefit from revascularization as men.

**Gender and MI.** The impact of gender on the prognosis after AMI remains unclear. Previous studies have suggested that the female gender may carry a worse prognosis after MI in both the pre- and post-thrombolytic era (7–20). The conclusions reached by these investigations were often limited by the sample size and lack of adjustment for other confounding variables (7,8). On the other hand, there are other well-designed retrospective studies documenting female patients who have fared as well as their male counterparts (21–31).

### Table 3. Myocardial Infarction Characteristics in Patients With Predominant LV Failure

<table>
<thead>
<tr>
<th>MI Location</th>
<th>Men (n = 562)</th>
<th>Women (n = 322)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior (%)</td>
<td>58.8</td>
<td>58.8</td>
<td>1.00</td>
</tr>
<tr>
<td>Inferior (%)</td>
<td>43.0</td>
<td>44.0</td>
<td>0.824</td>
</tr>
<tr>
<td>Posterior (%)</td>
<td>17.9</td>
<td>16.4</td>
<td>0.627</td>
</tr>
<tr>
<td>Lateral (%)</td>
<td>31.7</td>
<td>32.3</td>
<td>0.825</td>
</tr>
<tr>
<td>Apical (%)</td>
<td>8.8</td>
<td>10.9</td>
<td>0.382</td>
</tr>
<tr>
<td>Highest total CK (IU/ml) Median</td>
<td>1,869 (622, 4,193)*</td>
<td>1,965 (652, 3,960)*</td>
<td>0.703</td>
</tr>
<tr>
<td>Highest CK/normal limit Median</td>
<td>8.4 (2.7, 19.0)*</td>
<td>10.3 (3.1, 20.2)*</td>
<td>0.122</td>
</tr>
<tr>
<td>MI to shock (h) Median</td>
<td>5.8 (1.7, 20.3)*</td>
<td>7.5 (2.0, 19.5)*</td>
<td>0.458</td>
</tr>
</tbody>
</table>

*Numbers in parentheses denote 25th and 75th percentiles.

CK = creatine kinase; LV = left ventricular; MI = myocardial infarction.

### Table 4. Hemodynamic Findings in Patients With Predominant LV Failure

<table>
<thead>
<tr>
<th>Metric</th>
<th>Men</th>
<th>Women</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate (beats/min)</td>
<td>832</td>
<td>94.9 ± 26.3</td>
<td>95.5 ± 24.8</td>
</tr>
<tr>
<td>Systolic blood pressure (mm Hg)</td>
<td>833</td>
<td>87.9 ± 22.2</td>
<td>89.2 ± 24.2</td>
</tr>
<tr>
<td>Diastolic blood pressure (mm Hg)</td>
<td>729</td>
<td>53.4 ± 17.2</td>
<td>51.7 ± 17.1</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>300</td>
<td>29.1 ± 12.0</td>
<td>31.4 ± 13.4</td>
</tr>
<tr>
<td>Right heart catheterization</td>
<td>568</td>
<td>63.0%</td>
<td>66.5%</td>
</tr>
<tr>
<td>PCWP (mm Hg)</td>
<td>533</td>
<td>24.1 ± 8.9</td>
<td>23.0 ± 8.0</td>
</tr>
<tr>
<td>PA systolic (mm Hg)</td>
<td>239</td>
<td>42.1 ± 14.0</td>
<td>39.7 ± 10.7</td>
</tr>
<tr>
<td>Cardiac output (l/min)</td>
<td>281</td>
<td>4.3 ± 1.7</td>
<td>3.2 ± 1.1</td>
</tr>
<tr>
<td>Cardiac index (l/min/M²)</td>
<td>407</td>
<td>2.2 ± 0.8</td>
<td>1.8 ± 0.6</td>
</tr>
</tbody>
</table>

Values obtained close to shock onset and often on support measures.

LVEF = left ventricular ejection fraction same day as or after shock; PA = pulmonary artery. PCWP = pulmonary capillary wedge pressure.
The apparent increase in mortality in AMI in women might be attributed to a variety of other confounding variables including delayed presentation to the hospital for treatment. Once in the hospital, women seemed to be less likely to receive thrombolysis, undergo catheterization, angioplasty or bypass surgery (16–18). An extensive review by Vaccarino et al. (32) based on 27 published reports from 1966 through 1994 reported no difference in early mortality between women and men after MI. Stone et al. (33), using the Primary Angioplasty in MI database, were able to demonstrate that gender was not an independent predictor for in-hospital mortality. Indeed, female gender treated with PTCA was independently associated with improved in-hospital survival. Malacrida et al. (34), using the Third International Study of Infarct Survival database, evaluated early (35-day) mortality in 9,600 women and 26,480 men with suspected MI and noted that the female gender had a small independent adverse effect on early mortality and morbidity with an OR of 1.14 (95% CI = 1.05 to 1.23).

More in-depth evaluation of the TIMI 2 and 3 as well as GUSTO 2 studies revealed that the higher mortality in women was seen with ST elevation MI only; similar clinical outcomes were reported for men and women with non-ST elevation MI (35–37). Hochman et al. (37) proposed that perhaps reduced collateral flow in women may account for more prevalent angina with less severe coronary artery obstructions and more frequent complications, including a higher incidence of CS and mechanical complications (ventricular septal rupture and severe mitral regurgitation), in women with AMI compared with men.

Interestingly, a recent analysis using the National Registry of MI 2 database involving more than 384,000 patients,
Vaccarino et al. (38) concluded that in-hospital mortality after AMI was higher in younger but not older (≥75 years old) women compared with men. This difference in clinical outcome may be, in part, due to differences in the pathoanatomy of coronary lesions (plaque erosion vs. rupture) or pathophysiology (a higher incidence of coronary spasm and higher platelet activity or reduced collateral flow) of younger versus older women (39).

**Present study.** Consistent with the findings of the Worcester CS Heart Attack study showing that women developed CS more often than men (4), the SHOCK Registry had a high prevalence (40%) of women in-patients with CS complicating AMI when compared with the 25% to 30% of female gender in large MI series (39–41). In the SHOCK Registry, women were more likely to receive transfusions than men during their hospital stay. This may reflect more frequent bleeding complications associated with invasive procedures in older female patients (42). In addition to more frequent bleeding complications, the overall smaller artery size in female patients may contribute to the lower IABP utilization in women than it did in men in the Registry. Other patient demographics, including older age and a higher prevalence of hypertension and diabetes in the female patients in the SHOCK Registry, were similar to other AMI series. Importantly, our Registry demonstrated that there was no difference in the treatment approaches between the two gender groups. Indeed, the SHOCK Registry data demonstrated that women underwent catheterization more frequently than men. Moreover, the clinical outcomes after PTCA and CABG were similar for men and women. These differences in treatment approaches and the resulting clinical outcomes may be due to changes in practice pattern over time. Alternatively, the profound acuity of the disease state that was present in the majority of patients with CS may neutralize any potential gender differences in pathoanatomy, treatment strategies or clinical outcomes that have been reported in other AMI series and in studies involving patients in more elective settings.

**Study limitations.** We cannot rule out that a disproportionate number of men or women with shock died before presentation to the hospitals; therefore, the relative mortality rates only reflect those of patients who reach the hospital.

Given that the database is a registry of patients who either failed to meet all the enrollment criteria or refused to participate in the multicenter randomized SHOCK trial, there are inherent biases that might have contributed to some of the differences observed in the clinical findings or treatment approaches used in Registry versus trial patients. Furthermore, although the Registry data were prospectively collected, they are observational only, and, therefore, hemodynamic and angiographic findings are based on only those patients who were selected to undergo right and left heart catheterization.

**Conclusions.** Despite more frequent adverse clinical characteristics and associated mechanical complications in women with CS, gender was not an independent predictor of in-hospital mortality in the SHOCK Registry patients with predominant LV failure. After adjusting for differences in patient characteristics between men and women, there was no gender bias in patient selection for revascularization in the SHOCK Registry. Furthermore, the apparent benefit derived from PTCA and CABG was similarly observed for both men and women.

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