



Primary PCI: Outcomes and Quality Assessment

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John S. Douglas

23.1 Introduction

ST-segment elevation myocardial infarction (STEMI) and patients with equivalent findings (true posterior MI, hyper-acute T-wave changes, anterior ST depression with ST elevation in lead aVR, and new left bundle branch block with Sgarbossa concordance criteria or hemodynamic instability) account for 30–50% of myocardial infarctions (MI) and are associated with substantial short- and long-term morbidity and mortality [1, 2]. Reperfusion of ischemic myocardium is the primary therapeutic goal and can be accomplished by primary angioplasty with stent implantation or intravenous fibrinolytic therapy. Timely PCI (≤ 90 min from first medical contact) is the preferred approach in PCI-capable hospitals (ACC/AHA class I recommendation, level of evidence A) resulting in more complete reperfusion and lower rates of early death, reinfarction, and bleeding, including intracranial hemorrhage, compared to fibrinolysis.

When hospital transfer for primary PCI involves a delay of more than 120 min, fibrinolytic therapy, if not contraindicated, is an ACC/AHA class I recommendation, level of evidence A. Following fibrinolytic therapy, subsequent transfer to a PCI-capable hospital is recommended. This reperfusion strategy (Fig. 23.1) has resulted in reductions in in-hospital mortality from over 20% to less than 5% in patients treated without significant delays due to need for non-cardiac diagnostic testing or other nonsystem delays. Evaluation of the care received by the STEMI patient requires an assessment of events extending from initial symptom onset to reperfusion to hospital discharge and return home [3]. Outcome data must be

J. S. Douglas

Department of Medicine, Emory University Hospital, Atlanta, GA, USA

Interventional Cardiology Fellowship Program, Emory University School of Medicine,
Emory University Hospital, Atlanta, GA, USA

e-mail: jdoug01@emory.edu

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T. J. Watson et al. (eds.), *Primary Angioplasty*,
https://doi.org/10.1007/978-981-13-1114-7_23

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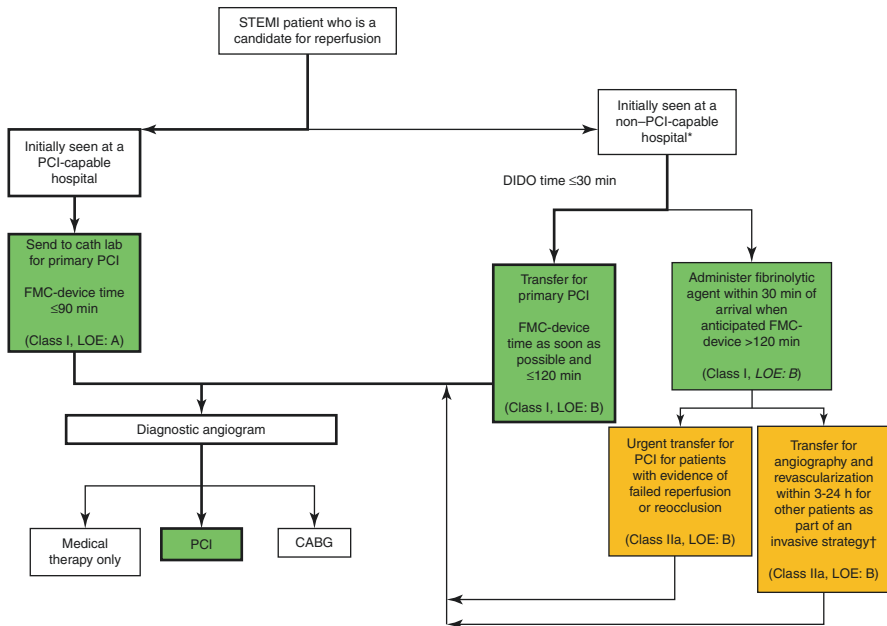


Fig. 23.1 Reperfusion therapy for patients with STEMI. The bold arrows and boxes are the preferred strategies. Performance of PCI is dictated by an anatomically appropriate culprit stenosis. *Patients with cardiogenic shock or severe heart failure initially seen in a non-PCI-capable hospital should be transported for cardiac catheterization and revascularization as soon as possible, DIDO, door-in-door-out. Source: O’Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2013; 61(4):e78-e140

risk-stratified as complications of death, acute kidney injury, and bleeding are highly influenced by baseline patient characteristics as well as subsequent clinical events. ACC/AHA STEMI guidelines give a class I recommendation for an active quality assessment and improvement program which is judged to be essential to optimize application of evidence-based reperfusion strategies and improve outcomes in all STEMI patients irrespective of gender, age, race, education, insurance status, and income.

23.2 Quality Assessment

Three components of quality assessment (QA) in healthcare have been conceptualized: (1) structure, (2) processes of care, and (3) outcomes (Table 23.1). In the STEMI patient, *structural components* include prehospital emergency medical services (EMS), emergency rooms, cardiac catheterization laboratories, inpatient

Table 23.1 Quality domains in primary angioplasty

<i>Structural components</i>
STEMI/cath lab QA committee: chairman and staff, regular meeting
Analysis of times to treatment including EMS, emergency department, and cath lab
Monthly-quarterly-annual reporting
Credentialing
Standardized forms and order sets
<i>Process domain</i>
Patient care issues
Procedural indications
Complication management
Medications
Infection control
Radiation safety
<i>Outcomes</i>
Mortality, risk adjusted
Procedural success
Complications
Radiation exposure
Length of stay
Hospital- and physician-specific data
NCDR and AHA registries, comparative results

hospital facilities, and medical personnel. Cath lab QA committees perform surveillance of times to treatment and initiate improvement activities needed to provide optimal STEMI care. *Process measures* include those actions performed by providers in the delivery of care to STEMI patients ideally using proven diagnostic and therapeutic strategies advocated by clinical guideline statements and appropriate use criteria. Writing committees of the ACC/AHA have established specific measures that assess essential aspects of care in STEMI patients [4, 5]. The AHA/ACC Task Force on Performance Measures was charged with updating performance and quality measures in patients hospitalized with STEMI in order to benchmark and improve the care of these patients. In 2017, this committee published a comprehensive measure set that included 22 total measures related to STEMI patients (Table 23.2). Seventeen were performance measures (those with the strongest supporting evidence such as administration of aspirin) and five quality measures (strong but less robust supporting evidence such as inappropriate in-hospital use of nonsteroidal anti-inflammatory drugs). The chair of the writing committee stated, “Implementation of this measure set by health care providers, physician practices and hospital systems will enhance the quality of care and likely improve *outcomes* of patients hospitalized with a heart attack.” Important in-hospital outcomes of patients with STEMI are substantially less favorable than with non-STEMI (Fig. 23.2) and include procedural success and complications, death, reinfarction, heart failure, shock, and stroke (Table 23.3).

Table 23.2 2017 AHA/ACC STEMI clinical performance and quality measures

Measure title	Measure region
<i>Performance measures</i>	
Aspirin at arrival	Effective clinical care
Aspirin prescribed at discharge	Effective clinical care
Beta blocker prescribed at discharge	Effective clinical care
High-intensity statin prescribed at discharge	Effective clinical care
Evaluation of LVEF	Effective clinical care
ACEI or ARB prescribed for LVSD	Effective clinical care
Time to fibrinolytic therapy	Communication and care coordination
Time to primary PCI	Communication and care coordination
Reperfusion therapy	Effective clinical care
Time from ED arrival at STEMI referral facility to ED discharge from STEMI referral facility in patients transferred for primary PCI	Communication and care coordination
Time from FMC (at or before ED arrival at STEMI referral facility) to primary PCI at STEMI receiving facility among transferred patients	Communication and care coordination
Cardiac rehabilitation patient referral from an inpatient setting	Communication and care coordination
P2Y12 receptor inhibitor prescribed at discharge	Effective clinical care
Immediate angiography for resuscitated out-of-hospital cardiac arrest in STEMI patients	Effective clinical care
Noninvasive stress testing before discharge in conservatively treated patients	Efficiency and cost reduction
Early cardiac troponin measurement (within 6 h of arrival)	Efficiency and cost reduction
Participation in ≥ 1 regional or national registries that include Patients with Acute Myocardial Infarction Registry	Community, population, and public health
<i>Quality measures</i>	
Therapeutic hypothermia for comatose STEMI patients with out-of-hospital cardiac arrest	Effective clinical care
Aldosterone antagonist prescribed at discharge	Effective clinical care
Inappropriate in-hospital use of NSAIDs	Patient safety
Inappropriate prescription of prasugrel at discharge in patients with history of prior stroke or TIA	Patient safety
Inappropriate prescription of high-dose aspirin with ticagrelor at discharge	Patient safety

Abbreviations: ACC American College of Cardiology, ACEI angiotensin-converting enzyme inhibitor, AHA American Heart Association, ARB angiotensin receptor blocker, ED emergency department, FMC first medical contact, LVEF left ventricular ejection fraction, NSAIDs nonsteroidal anti-inflammatory drugs, PCI percutaneous coronary intervention, PM performance measures, QM quality measures, LVSD left ventricular systolic dysfunction, STEMI ST-elevation myocardial infarction, TIA transient ischemic attack

Source: adapted from Jneid et al. [4]

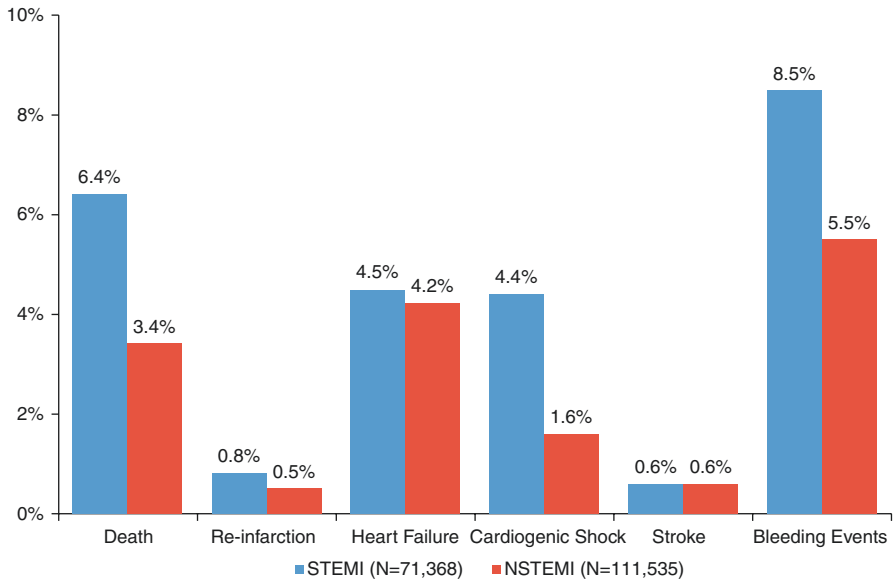


Fig. 23.2 In-hospital outcomes of the ACTION-GWTG Program 2014. Rates of death, reinfarction, heart failure, cardiogenic shock, stroke, or bleeding during hospitalization for patients with STEMI and NSTEMI. Source: Masoudi MD, Ponirakis A, de Lemos JA et al. Trends of US Cardiovascular Care. J Am Coll Cardiol 2017; 69:1427–50

Table 23.3 Characteristics and in-hospital outcomes of 10,730 patients with STEMI transported by EMS to 132 PCI-capable hospitals in 2015–2017

Median age	62 years
Male	70%
Prior MI	20%
Prior PCI	17%
Prior CABG	5%
Diabetes	27%
Symptoms to FMC	50 min
ED dwell time	30 min
Shock presentation	10%
Cardiac arrest	11%
Heart failure	9%
Primary PCI	90%
FMC to device ≤90 min	54%
In-hospital death	8.3%
Stroke	1%
Major bleeding	5.1%
Reinfarction	1%

Source: Data from Jollis et al. [3]

23.3 Risk Assessment and Adjustment

The risk associated with STEMI is highly dependent on demographic features such as age, acuity of presentation, baseline comorbidities (diabetes, peripheral vascular and chronic lung disease), left ventricular function, and findings at coronary angiography. High-risk angiographic findings include large culprit vessel size and distribution (left main, LAD). A number of risk scores have been developed to estimate the threat to life that STEMI poses to the individual patient. Although the majority of high-risk patients survive primary PCI without a complication, risk assessment models such as the NCDR CathPCI Registry Bedside Risk Scoring System (Table 23.4) allow the physician to estimate the risk of primary PCI, counsel the patient and family, and correlate clinical features and in-hospital mortality. In addition to the risk of ischemic complications, bleeding risk can be estimated. Bleeding risk has a different temporal pattern than ischemic risk (Fig. 23.3). Among patients presenting with STEMI to US hospitals and captured in the NCDR ACTION Registry between 2007 and 2009, the CRUSADE bleeding risk score predicted a fivefold difference in the risk of bleeding based on eight criteria (hematocrit, creatinine, heart rate, sex, heart failure, systolic blood pressure, prior vascular disease, and diabetes) (Fig. 23.4). Although the bleeding risk associated with the use of bivalirudin is lower than unfractionated heparin, fewer stent thromboses and lower costs favored the frequent use of unfractionated heparin which is documented in this figure and supported by the VALIDATE-SWEDEHEART randomized comparison of these two agents in 25 Swedish PCI centers and reported in 2017. The most important bleeding avoidance strategy, the use of radial artery access, is described below.

Among the highest risk patients are those experiencing out-of-hospital cardiac arrest. Only a small minority survive to reach the hospital. Those reaching the hospital have a significant risk of failure to recover neurologically. In a study of out-of-hospital cardiac arrest in North Carolina during 2012–2014, among 1507 patients with prehospital return of circulation, survival to discharge was approximately threefold higher in those transported to a PCI center even if the transport time exceeded 30 min [6]. However, survival to discharge in both groups was quite low (33% and 14.6%, respectively).

Cardiogenic shock is the most common cause of in-hospital death in patients with STEMI, and, disappointingly, mortality rates still approach 50% and are not decreasing in spite of early invasive strategies, better technology, and the availability of improved mechanical circulatory support devices [7, 8]. Risk scores have been proposed which allow early risk stratification (Fig. 23.5). In an adequately powered randomized trial, the use of intra-aortic balloon pump (IABP) compared to control showed no benefit with respect to mortality or hemodynamic parameters [9]. These findings led to downgrading of recommendations for the use of IABP in guideline statements (class III in the European STEMI guidelines) [10]. In three small randomized trials, the Impella 2.5 hemodynamic

Table 23.4 NCDR CathPCI Registry Bedside Risk Scoring System

Scoring response categories		Yes				Total points	Risk of inpatient mortality (%)
STEMI	No					0	0
	0	6				5	0
Age	<60		70-80	≥80		10	0.1
	0	4	9	15		15	0.1
						20	0.2
BMI	<20		30-40	≥40		25	0.3
	5	1	0	3		30	0.6
						35	0.9
CVD	No					40	1.4
		Yes				45	2.3
	0	2				50	3.7
PAD	No					55	5.9
		Yes				60	9.2
	0	3				65	14.2
Chronic lung disease	No					70	21.2
		Yes				75	30.4
	0	3				80	41.5
Prior PCI	No					85	53.6
		Yes				90	65.2
	3	0				95	75.3
					100	83.2	

(continued)

Table 23.4 (continued)

Scoring response categories		Insulin	Nominsulin	Insulin	Total points	Risk of inpatient mortality (%)
Diabetes mellitus	No				105	88.9
	0	3	2		110	92.9
GFR	Renal failure	45-60	30-45	60-90	115	95.5
	16	7	11	≥90	120	97.2
				0	125	98.2
EF	<30	40-50	30-40	≥50	130	98.9
	9	2	4	0	135	99.3
Cardiogenic shock/PCI status	Sustained shock and salvage	Transient shock but not salvage	Sustained shock alone or salvage alone	Emergency PCI without shock/salvage	Urgent PCI without shock/salvage	Elective PCI without shock/salvage
	54	37	43	22	11	0
NYHA class within 2 weeks	NYHA class IV	No HF	NYHA class <IV			
	7	0	3			
Cardiac arrest within 24 h	No	Yes				
	0	13				

Source: From Brennan JM, Curtis JP, Dai D et al. Enhanced mortality risk prediction with a focus on high-risk percutaneous coronary intervention. *J Am Coll Cardiol Interv* 2013; 6: 790-9

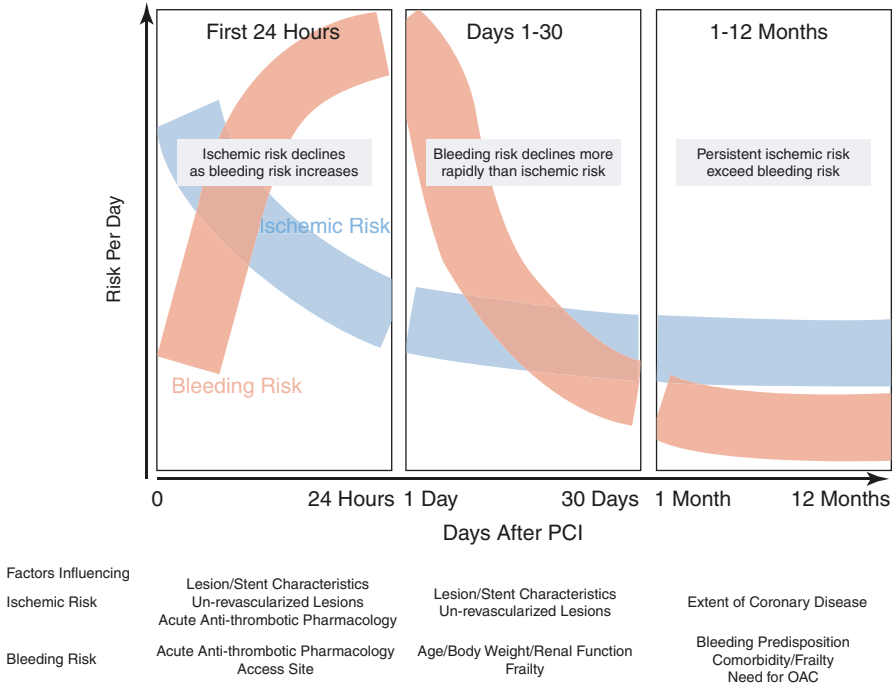


Fig. 23.3 Conceptualizing the temporal risk of ischemic and bleeding risk of PCI in STEMI. Ischemic risk is influenced by culprit and non-culprit lesion characteristics, antithrombotic therapy, and extent of coronary disease. Bleeding risk is affected by bleeding risk of the patient, access site, antithrombotic pharmacology, duration of antithrombotic therapy, and need for anticoagulation with warfarin. Source: Chew DP and Bhatt DL. *J Am Coll Cardiol* 2017; 70:1858–60

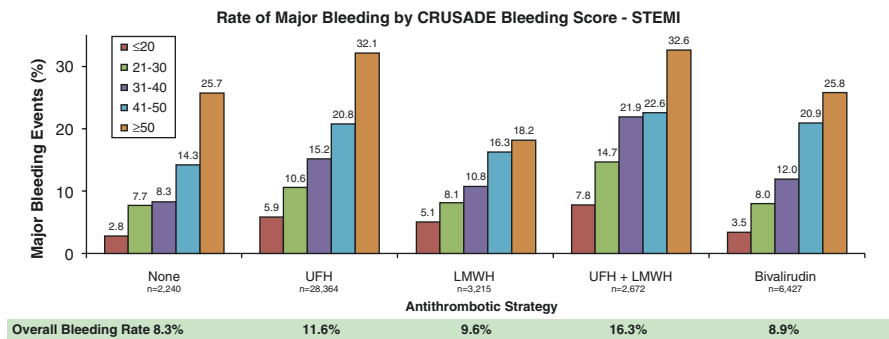


Fig. 23.4 Rates of major bleeding according to anticoagulation regimen and the CRUSADE BLEEDING RISK SCORE in patients with STEMI. Source: Kadakia MB, Desai NR, Alexander KP et al. Use of anticoagulant agents and risk of bleeding among patients admitted with myocardial infarction *J Am Coll Cardiol* 2010; 3:1166–77

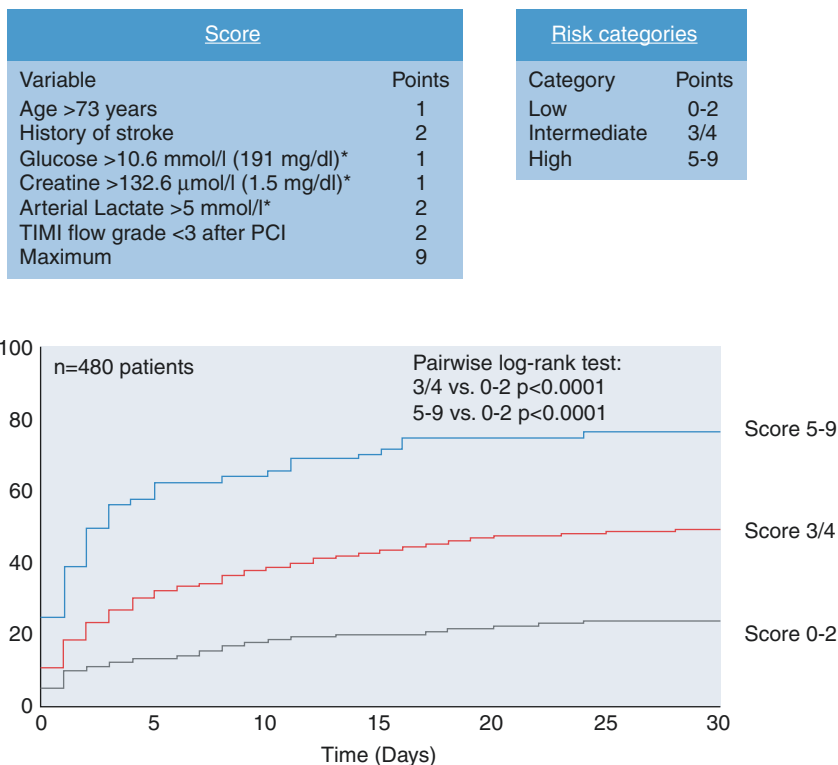


Fig. 23.5 Cardiogenic shock complicating acute myocardial infarction: IABP-SHOCK II RISK SCORE. The scoring system attributed one or two points per variable. Source: Pöss J, Köster J, Fuervan G, et al. *J Am Coll Cardiol* 2017; 69:1913–20

support device compared to IABP improved hemodynamics but was associated with more complications, and there was no difference in mortality. In a recently published randomized comparison of the Impella CP left ventricular support device (maximum output of about 3.7 L/min) and IABP in 48 STEMI patients with cardiogenic shock, there was no difference in mortality at 30 days or in serum lactate [11]. This study was underpowered but there was no signal, suggesting benefit with Impella CP use. It has been estimated that a trial of approximately 2500 cardiogenic shock patients would be required to confirm a significant mortality benefit of 4% with a strategy such as left ventricular support. In a randomized trial of patients with cardiogenic shock due to acute myocardial infarction and multivessel disease [7], the guideline-supported strategy of progressing to PCI of non-culprit arteries in patients with persisting shock resulted in worse outcomes than culprit-only PCI, suggesting that a change in the guideline statement may be needed. A recent AHA scientific statement reviewed efforts to study this thorny and resistant clinical problem [8].

23.4 Procedural Outcomes

In patients undergoing primary PCI for treatment of STEMI, complete reperfusion with development of TIMI 3 flow is achieved in over 90% of patients compared to 50–60% of patients treated with fibrinolytic therapy. Patients who achieve less than TIMI 3 flow with PCI are frequently late presenters, have large thrombus burden, and have poorer outcomes. No reflow due to microcirculation injury and/or distal embolization is a particularly unfavorable prognostic finding. With the advent of intracoronary stents, the need for emergency coronary bypass surgery has plummeted to 6% of STEMI patients according to the NCDR CathPCI Registry, but surgery may be required in advanced triple vessel or left main coronary artery disease that does not appear treatable with PCI. Surgery may be needed as the initial emergency revascularization (3% of STEMI patients) or at a later time after percutaneous treatment of the culprit coronary artery lesion (2% of STEMI patients).

There is an ongoing controversy regarding whether non-culprit coronary artery stenoses should be treated at the time of primary PCI in the absence of ongoing ischemia (ACC/AHA class IIb indication, level of evidence B). Although the presence of multivessel disease in the STEMI patient is an independent risk factor associated with a threefold increase in MACE on follow-up, recent studies indicate that immediate multivessel PCI is not necessary and favor staged PCI of non-culprit lesions (more in-depth discussion in Chap. 13). Also, routine manual thrombus aspiration which was supported by early studies was not shown to be beneficial in recent reports and was associated with a small increase in the risk of stroke (more in-depth discussion in Chap. 10). However, thrombus aspiration may be indicated in patients with large thrombus burden or thrombotic complications. Bleeding complications, most commonly access site bleeding, occur in 5–10% of patients and are a major source of morbidity and occasionally mortality. Increased use of radial artery access has occurred, especially in Europe (Fig. 23.6), and the use of fibrinolytic therapy has diminished dramatically both in Europe and the United States. Randomized trials have demonstrated that compared to femoral access, the use of radial artery access in STEMI patients leads to lower rates of bleeding, major adverse cardiac events, and in-hospital mortality (more in-depth discussion in Chap. 7). Recent studies indicate that, in experienced hands, radial artery access does not result in the use of more contrast media or increased radiation exposure of patients or operators. In spite of these advantages, the use of radial artery access in the United States remained less than 50% in early 2017 as reported by the NCDR CathPCI Registry. The failure to use radial artery access in higher-risk patients (e.g., elderly female patients) has been described as a “risk-treatment paradox.” Although the 2013 ACCF/AHA guideline statement supports implantation of either drug-eluting or bare-metal stents in patients with STEMI, the 2017 European guideline statement endorses the use of drug-eluting stents (more in-depth discussion in Chap. 11). The use of second-generation drug-eluting stents has become the standard practice in most US centers. The critical role of antithrombotic therapy in treatment of STEMI

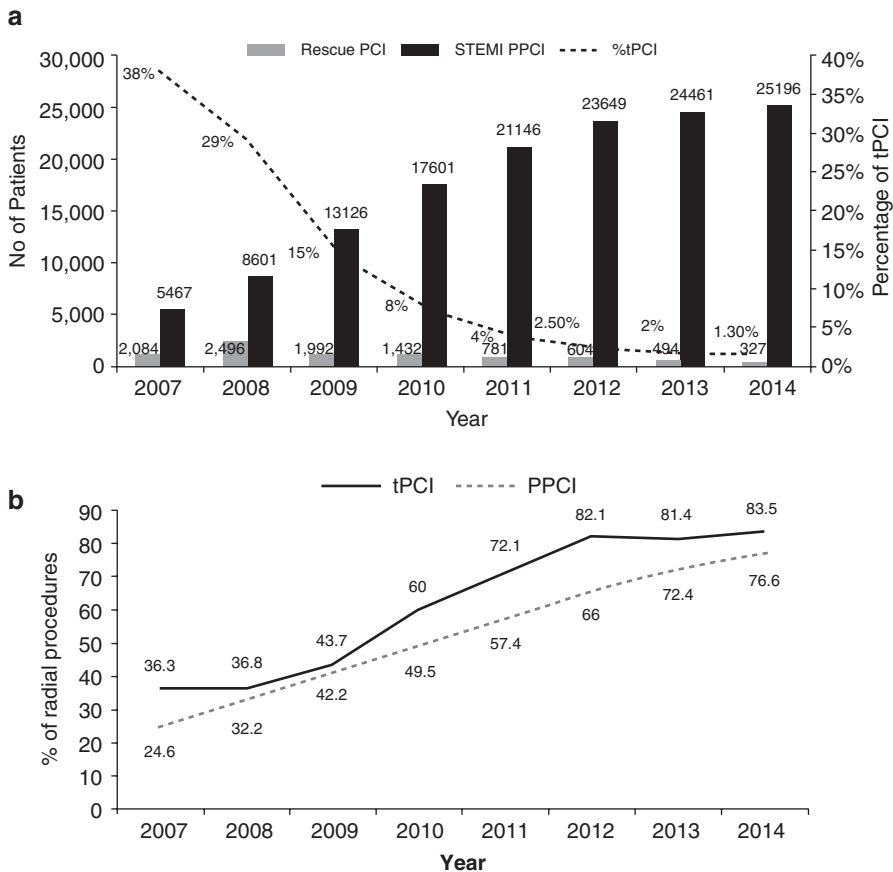


Fig. 23.6 Temporal trends in the thrombolytic and PCI activity and the use of radial access in STEMI in the United Kingdom. (a) Decrease in the use of fibrinolytic therapy and increase in radial artery access. (b) The use of radial access from 2007 to 2014. Source: Rashid et al. *J Am Coll Cardiol Interv* 2017; 22:2258–65

has been recognized. In addition to aspirin, an oral P2Y₁₂ inhibitor (clopidogrel, prasugrel, or ticagrelor) is recommended pre-procedure and to be taken for 1 year (more in-depth discussion in Chap. 8). Ticagrelor and prasugrel are more effective antiplatelet agents than clopidogrel but are associated with more bleeding necessitating a risk-benefit analysis and are more expensive, which becomes a factor in the uninsured patient. Glycoprotein IIb/IIIa platelet receptor inhibitors currently have a limited role in primary PCI being primarily reserved for treatment of thrombotic complications. Following primary PCI, STEMI patients have an increased risk of thrombotic events such as deep vein thrombosis and/or pulmonary embolism. Although anticoagulation with unfractionated heparin has been frequently used for several days post-PCI, data from HORIZONS-AMI and EUROMAX trials indicate that this practice is associated with more bleeding with no reduction in ischemic or

thrombotic events (more in-depth discussion in Chap. 9). Consequently, routine post-PCI anticoagulation should be avoided unless there is a clear indication for its use. With early reperfusion and better techniques, the results of primary PCI have improved substantially. In stented patients with early reperfusion and preserved left ventricular function, hospitalizations as short as 3 days are possible. In less fortunate patients, more prolonged hospitalizations are required to allow recovery of left ventricular function and monitor for complications and for titration of medical therapy. Treatment of heart failure symptoms may be required in large myocardial infarctions. Warfarin anticoagulation is needed when left ventricular aneurysms or mural thrombus is detected. Importantly, in all STEMI patients, education is provided regarding risk factor modification, activity, smoking cessation, medications, and follow-up planning, and referral to cardiac rehabilitation is accomplished.

23.5 Audit

There is a wide variation in treatment of patients with STEMI around the world. To improve quality of care, the US and European STEMI guideline statements indicate that measurable quality indicators be established (see Table 23.2), that routine data collection be carried out, and that routine audits be performed. The American College of Cardiology and American Heart Association have established registries, the NCDR CathPCI and ACTION Registries by the ACC, and the Mission: Lifeline program by the AHA. These registries provide parallel opportunities for collection of the important data relating to the STEMI patient and quarterly update on the performance of healthcare providers and systems aimed at reducing time to reperfusion and improving outcomes. In an analysis of quarterly AHA Mission: Lifeline reports in over 10,000 patients [3], it was shown that enhanced regional efforts can significantly reduce time to reperfusion and lead to a significant reduction in in-hospital mortality. Inpatient death was reduced from 4.4 to 2.3% ($p = 0.001$), a remarkable and encouraging outcome.

23.6 Conclusion

Primary PCI is the preferred reperfusion strategy in STEMI. Timely delivery of this strategy requires well-honed local and regional networks of dedicated professionals and institutions aimed at achieving the earliest possible reperfusion which has been shown to save lives in a significant number of patients presenting with STEMI.

23.7 Case Presentation

A 62-year-old female with a history of hypertension developed crushing chest pain and called emergency medical services. About 15 min before the ambulance reached the emergency room (ER), ventricular fibrillation occurred that was effectively

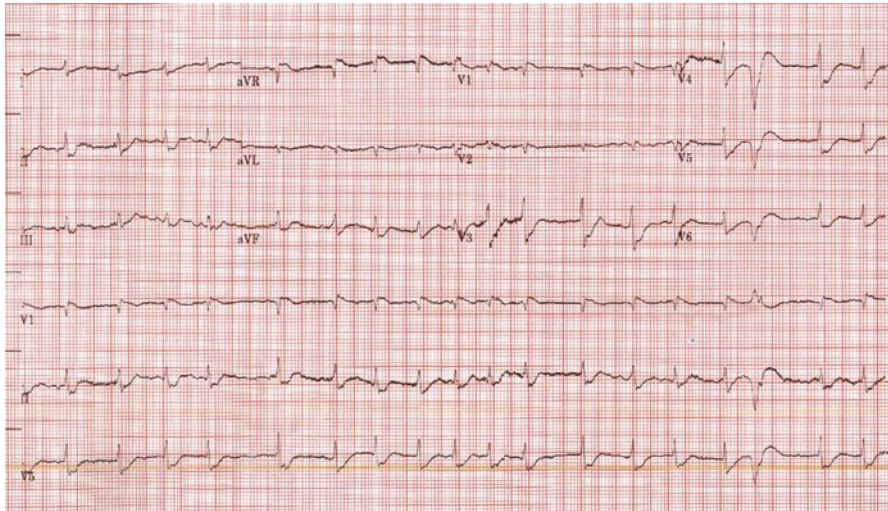


Fig. 23.7 Electrocardiogram following multiple cardioversions suggests diffuse subendocardial ischemia with ST-segment elevation in lead aVR and ST-segment depression in anterior leads

terminated with a shock. As the ambulance was nearing the hospital, ventricular fibrillation recurred which did not immediately respond to cardioversion, and the patient entered the ER with ongoing cardiopulmonary resuscitation (CPR). Tracheal intubation was performed and CPR continued. Amiodarone bolus plus infusion was initiated, but ventricular fibrillation recurred repetitively requiring over 20 shocks. Abnormal lab results included arterial blood pH 6.91 and serum lactate 18.9 mmol/L. Blood pressure was 70–80/30–40 mm Hg in spite of norepinephrine infusion. The ECG is shown (Fig. 23.7).

After 90 min of CPR, the rhythm stabilized long enough to rush the patient to the cardiac catheterization laboratory where ventricular fibrillation recurred twice. An intra-aortic balloon pump was inserted. Coronary angiography revealed moderate diffuse left coronary artery disease (Fig. 23.8a) and total occlusion of the proximal right coronary artery (Fig. 23.8b). Following placement of two drug-eluting stents in the right coronary artery, flow was restored (Fig. 23.8c). Cardiac rhythm stabilized and blood pressure increased to 100/60 mm Hg. The patient was treated with hypothermia and mechanical ventilation for 48 h and made a complete recovery.

Although the presence of refractory ventricular fibrillation, shock, and markedly elevated serum lactate are poor prognostic signs, observed cardiac arrest and even prolonged resuscitation can result in complete recovery. While the use of the intra-aortic balloon pump has not been shown to improve outcomes, its use is not contraindicated in ACCF/AHA guidelines, is thought by some experienced operators to provide assistance, and can be performed in a few minutes. Mechanical left ventricular assist devices provide more hemodynamic support but require longer times to insert and also have not been shown to save lives in randomized studies of shock in patients with STEMI [11].

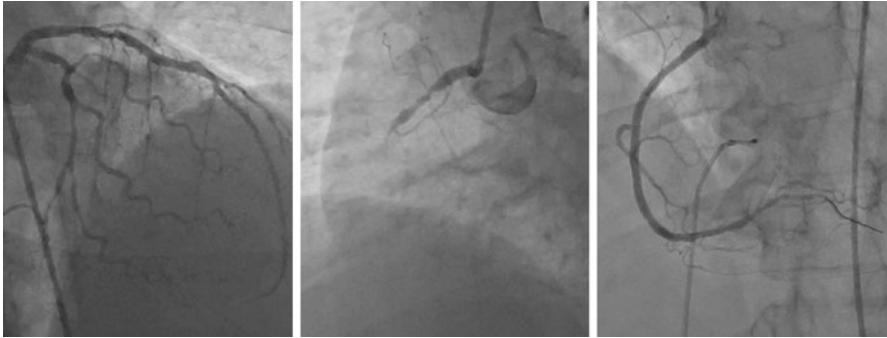


Fig. 23.8 Left coronary angiogram in the right anterior oblique view (a). Right coronary artery angiogram showing total occlusion (b). Right coronary angiogram after implantation of two drug-eluting stents and restoration of TIMI 3 flow (c)

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