2013 STEMI Guideline Data Supplements

Data Supplement 1. ECG Criteria for Diagnosis of STEMI in the Setting of LBBB

Odds Ratios and Scores for Independent Electrocardiographic Criteria		
Criterion	Odds Ratio (95% CI)	Score
ST-elevation ≥1 mm and concordant with QRS complex	25.2 (11.6 - 54.7)	5
ST-segment depression ≥1 mm in lead V_1, V_2, or V_3	6.0 (1.9 - 19.3)	3
ST-elevation ≥5 mm and discordant with QRS complex	4.3 (1.8 - 10.6)	2

CI indicates confidence interval.
Reprinted from Sgarbossa et al. (2). 8559200

In the NRMI-2 registry, 6.7% of MI patients had left bundle branch block (LBBB) and 6.2% had right bundle branch block (RBBB) on initial ECG (1). ECG diagnosis of STEMI in the setting of RBBB and left anterior and posterior fascicular blocks does not require special diagnostic criteria. However, interpreting the ST-segments is more difficult in patients with LBBB. Criteria for the ECG diagnosis of STEMI in the setting of LBBB have been developed and may help identify patients presenting with chest pain and LBBB who are more likely to be experiencing an MI. Sgarbossa identified 3 criteria used in a 10-point scale that improved the specificity of the diagnosis of STEMI in patients with LBBB: ST-elevation of at least 1 mm that was concordant with the QRS complex (5 points), ST-segment depression of at least 1 mm in lead V_1, V_2, or V_3 (3 points), and ST-elevation of at least 5 mm that was discordant with the QRS complex (2 points) (2). A meta-analysis of studies exploring the utility of the Sgarbossa criteria demonstrated that a score or ≥3 had a specificity of 98% for acute myocardial infarction, but a score of 0 did not rule out STEMI (3) 18342992.

Data Supplement 2. PCI for Cardiac Arrest Evidence												
Study Name	Aim of study	Study Type	Study Size	Patient Population/ Inclusion & Exclusion Criteria		Endpoint		Statistical Analysis Reported	P-Values & 95% CI	OR: HR: RR:	Study Summary	Study Limitations
				Inclusion Criteria	*Exclusion Criteria*	*Primary Endpoint*	*Secondary Endpoint*					
Primary coronary angioplasty for AMI complicated by OOH-CA. Kahn at al., 1995 (4) 7747692	First report of PPCI in OOH-CA pts	Case series	11	Clinical judgment of cardiologist. No prespecified criteria used.	Clinical judgment of cardiologist. No prespecified criteria used.	Survival to hospital discharge	Neurological outcome	None			11 pt OOH-CA pts brought to PPCI. 6/11 survived, 4/11 with full neurologic recovery.	Single institution, Selection bias
Immediate coronary angiography in survivors of OOH-CA. Spaulding at al., 1997 (5) 9171064	Determine impact of PPCI on OOH-CA survivors	Consecutive case series	84	OOH-CA, 30-75 y, <6 h onset of symptoms in pts previously leading a normal life, no obvious noncardiac etiology.	None	Survival to hospital discharge	Prevalence of CAD on angiography	Multivariate logistic regression showed successful PPCI was an independent predictor of survival.	p=0.04; 95% CI: 1.1- 24.5	OR: 5.2	84 pt OOH-CA consecutive pts brought to cath/PPCI. 48% had acute coronary occlusion. Presence of chest pain, ECG ST-elevation poor predictors. Successful PCI independent predictor of survival.	Selection bias
Early direct coronary angioplasty in survivors of OOH-CA. Keelan et al., (6) 12804734	Determine impact of PPCI on OOH-CA VF survivors	Case series	15	OOH-CA, VF initial rhythm	Initial rhythm not VF	Survival to hospital discharge		None			15 pts with OOH-CA due to VF treated with PPCI, 11/14 survived.	Selection bias
Impact of PCI or CABG on outcome after nonfatal CA outside the hospital. Borger van der Burg et al., 2003 (7) 12667561	Determine impact of revascularization on outcome from OOH-CA	Case series	142	OOH-CA, VF/pVT as initial rhythm	VF/pVT in the setting of an AMI	2 y recurrence-free survival	Survival to hospital discharge	Kaplan-Meier	p<0.001		142 non-AMI, OOH-CA pts. Revascularized pts had a better recurrence-free survival.	Nonrandomized case series, selection bias

Long-term prognosis after OOH-CA and PPCI. Bendz et al., 2004 (8) 15451586	Assess outcome in OOH-CA STEMI pts treated with PPCI	Case series	40	OOH-CA, STEMI	Interval from CA onset to start of CPR >10 min	Survival to hospital discharge		Kaplan-Meier comparison of 36 mo survival in OOH-CA STEMI pts receiving PPCI (n=40) vs nonarrest STEMI pts receiving PPCI n=325	p=NS between groups after discharge from hospital		Found no significant difference in 36 mo survival in OOH-CA STEMI pts receiving PPCI (n=40) vs nonarrest STEMI pts receiving PPCI (n=325).	Nonrandomized case series, selection bias
Treatment and outcome in post-resuscitation care after OOH-CA when a modern therapeutic approach was introduced. Werling et al., 2007 (9) 17241730	Assess factors associated with outcome in OOH-CA pts undergoing early coronary angiography	Case series	85	OOH-CA		Survival to hospital discharge		Fisher's exact test	Factors associated with survival: initial VF p=0.002; coronary angiography p<0.0001; PCI p=0.003; CABG p=0.03; PCI or CABG p<0.0001	Factors associated with survival OR: 1. Initial VF OR: 5.7; 95% CI: 2.0-16.5 Coronary angiography OR: 9.1; 95% CI: 3.6-21.5 PCI OR: 6.8; 95% CI: 1.9-24.6; CABG OR 9.9; 95% CI: 1.1-93.5; PCI or CABG OR: 9.8; 95% CI: 3.0-32.3	85 pt case series, factors associated with increased survival: initial VF; coronary angiography; PCI; CABG, PCI or CABG.	Selection bias
Six-month outcome of emergency PCI in resuscitated pts after CA complicating STEMI. Garot at al., 2007 (10) 17353440	Determine impact of revascularization on outcome from OOH-CA	Case series	186	OOH-CA, STEMI, referred for PCI		Survival to 6 mo after hospital discharge		Multiple stepwise regression		Factors associated with 6 mo survival in pts receiving PPCI: absence of shock 12.7%; 95% CI: 3.4-47.6; absence of diabetes 7.3%; 95% CI: 1.6-29.4; absence of prior PCI 11.0%; 95% CI: 1.7-71.4	186 pts resuscitated from OOH-CA complicating acute MI; factors associated with 6 mo survival in pts receiving PPCI: absence of shock; absence of diabetes; absence of prior PCI.	Selection bias

PPCI after OOH-CA: pts and outcomes. Markusohn et al., 2007 (11) 17491217	To define the demographic, clinical and angiographic characteristics, and the prognosis of STEMI pts undergoing primary PCI after OOH-CA	Case series	25	OOH-CA, STEMI		1 y survival	1 y survival without severe disability				25 OOH-CA, STEMI pts receiving PPCI. 1 y survival 72%; 1 y survival without severe disability 64%.	Selection bias
Acute STEMI after successful CPR. Gorjup et al., 2007 (12) 17161902	To define the demographic, clinical and angiographic characteristics, and the prognosis of STEMI pts undergoing primary PCI after OOH-CA	Case series	135	CA, STEMI		Survival to hospital discharge with CPC 1 or 2		Ordinal logistic regression	Smoking p<0.001; inhospital arrest p=0.002; shockable rhythm p=0.005; motor response to pain p=0.007; corneal reflexes p<0.001; pupil light response p<0.001; breathing p<0.001; seizures p=0.02; PPCI p=0.02	Predictors of hospital survival with CPC 1 or 2 smoking OR: 0.57; 95% CI: 0.36-0.89; inhospital arrest OR: 0.31; 95% CI: 0.18-0.54; shockable rhythm OR: 0.66; 95% CI: 0.53-0.81; motor response to pain OR: 0.32; 95% CI: 0.19-0.57; corneal reflexes OR: 0.10; 95% CI: 0.01-0.64; pupil light response. OR: 0.06; 95% CI: 0.01- 0.64; breathing OR: 0.29; 95% CI: 0.16-0.52; seizures OR: 1.39; 95% CI: 1.08-1.77; PPCI OR: 0.69, 95% CI: 0.56-0.84	135 pts with STEMI, CA; predictors of survival included smoking, inhospital CA, shockable rhythm, neurological status on admission, PPCI	Selection bias

Thrombolytic therapy vs PPCI after VF CA due to STEMI and its effect on outcome. Richling et al., 2007 (13) 17543659	Assess outcome in OOH-CA STEMI pts treated with thrombolysis vs PPCI.	Case series	147 (thrombolysis, n=101; PPCI, n=46)	Witnessed OOH-CA, STEMI, VF initial rhythm, ROSC, treated with either thrombolysis or PPCI.		Best neurological outcome at 6 mo	6 mo mortality	Kaplan-Meier	CPC 1 or 2 at 6 mo comparing thrombolysis with PPCI p=0.58; survival at 6 mo p=0.17	CPC 1 or 2 at 6 mo comparing thrombolysis with PPCI aOR:1.24 95% CI: 0.48-2.62; survival at 6 mo aOR: 1.74 95% CI: 0.80-3.80	147 pt nonrandomized case series found no difference in 6 mo neurologically intact survival in OOH-CA, VF, STEMI pts treated with thrombolysis vs PPCI	Selection bias
Survival and neurologic recovery in pts with STEMI resuscitated from CA. Hosmane et al., 2009 (14) 19179198	Assess outcome in CA STEMI pts and predictors of survival	Case series	98	OOH-CA, STEMI	Refused permission for cath, died prior to cath, received thrombolytic therapy.	Survival to hospital discharge, neurological outcome		Multivariable logistic regression	Inhospital mortality lower in revascularized compared to nonrevascularized pts 25% vs 76%; p<0.0001		98 STEMI, OOH-CA pt case series showing inhospital mortality lower in revascularized compared to nonrevascularized pts.	Selection bias
Coronary angiography predicts improved outcome following CA: propensity-adjusted analysis. Reynolds et al., 2009 (15) 19321536	Use propensity-adjusted analysis to assess importance of coronary angiography in predicting outcome from OOH-CA	Case series	241	CA	Early withdrawal of care, first GCS obscured by a sedative or paralytic agent, planned emergent surgical intervention or immediate rearrest.	Discharge to home or acute rehabilitation facility "good outcome".		Propensity-adjusted analysis	Propensity-adjusted analysis showed that cath vs no cath associated with a good outcome independently 54.2 % vs 24.8%; p<0.0001; Association between cath and good outcome p<0.02	Propensity adjusted logistic regression demonstrated an association between cath and good outcome OR: 2.16; 95% CI: 1.12-4.19	241 pt case series using propensity-adjusted analysis showing that cath vs no cath associated with a good outcome independently.	Not randomized

Acute coronary angiographic findings in survivors of OOH-CA. Anyfantakis et al., 2009 (16) 19185639	Assess the prevalence of coronary lesions in OOH-CA survivors	Case series	72	OOH-CA		Coronary angiographic findings	Survival to hospital discharge	Multivariable analysis	64% had angiographic CAD, 38% had an acute lesion; PCI attempted in 33% ROSC p=0.0004; need for inotropic support during angiography p=0.0009	Independent predictors of hospital death: prolonged interval from CA onset to ROSC OR: 14.6; 95% CI: 3.3-63.5; need for inotropic support during angiography OR: 11.2; 95% CI: 2.7-46.9	72 pt case series showing that 64% had angiographic CAD, 38% had an acute lesion; PCI attempted in 33%	Selection bias
Emergent PCI for resuscitated victims of OOH-CA. Kern et al., 2010 (17) 20049976	Assess the value of early angiography/ PCI and hypothermia in OOH-CA	Case series	5	OOH-CA		Coronary angiographic and ECG findings			Combining these therapies resulted in long-term survival rates of 70% with >80% of all such survivors neurologically functional		5 OOH-CA cases showing little correlation between ST-elevation on ECG and presence of an acute coronary lesion	Selection bias

AMI indicates acute myocardial infarction; CA, cardiac arrest; CABG, coronary artery bypass graft surgery; CAD, coronary artery disease; cath, catheterization; CI, confidence interval; CPC, circulating progenitor cell; CPR, cardio pulmonary resuscitation; CPT, current procedural terminology; ECG, electrocardiogram; EP, electrophysiology; GCS, Glasgow coma scale; n, number; NS, nonsignificant; OOH-CA, out-of-hospital cardiac arrest; PCI percutaneous coronary intervention; PPCI, primary percutaneous coronary intervention; pt, patient; pVT, paroxysmal ventricular tachycardia; ROSC, return of spontaneous circulation; STEMI, ST-elevation myocardial infarction; VF, ventricular fibrillation; and VT, ventricular tachycardia.

Data Supplement 3. Antithrombotic Therapy for Primary PCI									
Trial Name	Study Type	N	n [# of pts who had STEMI (%=n/N)]	Study Population (experimental and comparator/control)	Primary Efficacy Endpoint	Primary Safety Endpoint	Selected Prespecified Subgroups	Subgroup/Other Analyses	Comments
CURRENT-OASIS 7 (18) 20817281	RCT	25,087 pts with ACS	7327 (29%)	2 X 2 factorial design. Pts with ACS randomized to either double dose clopidogrel (600 mg LD, followed by 150 mg/d for 6 d, then 75 mg/d) or standard dose clopidogrel (300 mg LD followed by 75 mg/d) and to either higher dose ASA (300-325 mg/d) or lower dose ASA (75-100 mg/d)	Cardiovascular death, MI, and stroke at 30 d: double-dose clopidogrel 4.2% vs standard-dose clopidogrel 4.4%, HR: 0.94; 95% CI: 0.83-1.06; p=0.30; higher-dose ASA 4.2% vs lower-dose ASA 4.4%, HR 0.97, 95% CI: 0.86-1.09, p=0.61.	Major bleeding: double-dose clopidogrel 2.5% vs standard-dose clopidogrel 2.0%, HR: 1.24; 95% CI: 1.05-1.46; p=0.01; higher-dose ASA 2.3% vs lower dose ASA 2.3%, HR: 0.99; 95% CI 0.84-1.17; p=0.90.	Prespecified subgroup analyses (both clopidogrel and ASA dose comparisons included) qualifying condition (STEMI vs non-STEMI, age >65 or >75 y, body weight <60 kg, prior stroke/TIA) Additional prespecified subgroup analyses for the clopidogrel dose comparison included: ACS (STEMI) subjects undergoing PCI vs those not undergoing PCI	In the subgroup of pts who underwent PCI after randomization (69%, n=17263), double-dose clopidogrel was associated with a significant reduction in the rate of the prespecified secondary outcome of stent thrombosis (1.6% vs 2.3%; HR: 0.68; 95% CI: 0.55-0.85; p<0.001 and 0.7% vs 1.3% for *definite* stent thrombosis, HR: 0.54; 95% CI: 0.39-0.74; p=0.0001). There was also reduction of the prespecified outcome of probable or definite (by ARC criteria) stent thrombosis consistent across DES and non-DES subtypes. In addition, double-dose clopidogrel reduced the rate of the primary composite outcome in this subgroup (3.9% vs 4.5%, HR: 0.86; 95% CI: 0.74-0.99; p=0.039). Higher and lower dose ASA did not differ with respect to the primary composite outcome. Major bleeding occurred more frequently with double-dose clopidogrel (1.6% vs 1.1%, HR: 1.41; 95% CI: 1.09-1.83; p=0.009.)	Subgroup analyses of the pts who underwent PCI after randomization are hypothesis generating. In pts with ACS including STEMI referred for an invasive strategy, there was no significant difference between a 7 d double-dose clopidogrel regimen and the standard dose regimen, or between higher dose ASA and lower dose ASA, with respect to the primary outcome of cardiovascular death, MI or stroke.

TRITON-TIMI 38 trial (19) 19249633	RCT	13,608 pts with moderate to high risk ACS	3534 (26%)	Pts with moderate to high risk ACS undergoing planned invasive strategy randomized to prasugrel (60 mg LD and a 10 mg daily maintenance dose) or clopidogrel (300 mg LD and a 75 mg daily maintenance dose), for 6 to 15 mo.	Cardiovascualr death, nonfatal MI, or nonfatal stroke at 15 mo: prasugrel 9.9% vs clopdogrel 12.1%, HR: 0.81; 95% CI 0.73-0.90; p< 0.001. The HR for prasugrel, as compared with clopidogrel, for the primary efficacy endpoint at 30 d was HR: 0.77; 95% CI 0.67- 0.88; P<0.001 and at 90 d HR: 0.80; 95% CI 0.71- 0.90; p<0.001.The difference between the treatment groups with regard to the rate of the primary endpoint was largely related to a significant reduction in MI in the prasugrel group (9.7% in the clopidogrel group vs 7.4% in the prasugrel group; HR: 0.76; 95% CI 0.67- 0.85; p<0.001).	Major bleeding was observed in 2.4% of pts receiving prasugrel and in 1.8% of ptsreceiving clopidogrel (HR: 1.32; 95% CI 1.03-1.68; p=0.03). Also greater in the prasugrel group was the rate of life-threatening bleeding (1.4% vs 0.9%; p=0.01), including nonfatal bleeding (1.1% vs 0.9%; HR: 1.25; p=0.23) and fatal bleeding (0.4% vs 0.1%; p=0.002) and CABG related TIMI major bleeding (13.4% vs 3.2%; HR: 4.73; 95%CI 1.9 - 11.2; p=<.001).	UA or non-STEMI, STEMI, sex, age, diabetes mellitus, stent placement during index procedure, GP IIb/IIa,	A significant benefit of prasugrel was observed in the STEMI cohort alone (HR: 0.79; 95% CI, 0.65 - 0.97; P = 0.02). The benefit with prasugrel tended to be greateramong the 3146 pts with diabetes (17.0% of whom had the primary end point in the clopidogrelgroup, vs 12.2% in the prasugrel group; HR: 0.70; 95% CI 0.58-0.85; p<0.001) than among 10,462 pts without diabetes (10.6% of whom had the primary endpoint in the clopidogrel group, vs 9.2% in the prasugrel group; HR: 0.86; 95% CI: 0.76- 0.98; p= 0.02). The rate ofdefinite or probable stent thrombosis, as defined by the Academic Research Consortium, was significantlyreduced in the prasugrel group as compared with the clopidogrel group, with 68 pts (1.1%) and 142 pts (2.4%), respectively, having at least 1 occurrence (HR: 0.48; 95% CI 0.36 - 0.64; p<0.001). Pts who had a previous stroke or TIA had net harm from prasugrel (HR:1.54; 95% CI: 1.02-2.32; p=0.04), pts age ≥75 y had no net benefit from prasugrel (HR: 0.99; 95% CI: 0.81-1.21; P = 0.92), and pts weighing <60 kg had no net benefit from prasugrel (HR: 1.03; 95% CI: 0.69 -1.53; p=0.89)	In subgroup analyses those with prior stroke/TIA fared worse with prasugrel and no advantage was seen in those >75 y or <60 kg. Pts who presented with STEMI for primary PCI were allowed to receive prasugrel or clopidogrel before angiography or PCI. Pts who presented with STEMI after 12 h to 14 d were randomized to study drug only after the coronary anatomy was defined.

PLATO (20) 21060072	RCT	18,624 ACS pts	7026 (38%)	Pts with ACS with or without ST-elevation randomized to ticagrelor (180-mg LD, 90 mg twice daily thereafter) vs clopidogrel (300- or 600-mg LD, 75 mg daily thereafter)	Primary composite endpoint: death from vascular causes, MI, or stroke at 12 mo: 9.8% ticagrelor group vs 11.7% clopidogrel group, HR: 0.84; 95% CI: 0.77-0.92; p<0.001.	Major bleeding: There was no significant difference between ticagrelor and clopidogrel groups in the rates of major bleeding (691 [11.6%] vs 689 [11.2%], p=0.43).	Age, sex, weight, final diagnosis, time from index event to treatment, troponin I, diabetes mellitus, previous MI, previous CABG, ASA during first hospital admission, GP IIb/IIIa during first hospital admission, geographical region, OL clopidogrel before randomization, total clopidogrel (OL+IP) before randomization to 24 h after first dose IP	Composite primary endpoint in 7,544 pts with ST-elevation or LBBB undergoing primary PCI was reduced from 10.8% in the clopidogrel arm to 9.4% in the ticagrelor arm; HR 0.87; 95% CI: 0.75-1.10; p=0.07. Primary PCI subgroup. Definite Stent thrombosis HR: 0.66; p=0.03; MI HR: 0.80; p=0.03 The rate of death from any cause was also reduced with ticagrelor (4.5%, vs 5.9% with clopidogrel; p<0.001). In the ticagrelor group, there was a higher rate of non–CABG-related major bleeding (4.5% vs 3.8%, p=0.03). Episodes of intracranial bleeding (26 [0.3%] vs 14 [0.2%]; p=0.06), including fatal intracranial bleeding were more frequent with ticagrelor (11 [0.1%] vs 1 [0.01%]; p=0.02). There were fewer episodes of other types of fatal bleeding in the ticagrelor group (9 [0.1%], vs 21 [0.3%]; p=0.03).	An interaction between the treatment effect and geographic region (North America) raises the possibility that higher doses of ASA used in that region beyond 100 mg daily may have an adverse effect. This observation, however, may be due to the play of chance.
ARMYDA-6 MI (21) 21958886	RCT	201	201 (100%)	Pts undergoing primary PCI for STEMI randomized to a 600 mg (n=103) or 300 mg (n=98) clopidogrel LD before the procedure	Primary Endpoint: Infarct size determined as the AUC of cardiac biomarkers: 600 mg LD median CK-MB 2,070 ng/mL (IQR: 815 to 2,847 ng/mL) vs 300 mg LD 3,049 ng/mL (IQR: 1,050 to 7,031 ng/mL) in the 300-mg group, p=0.0001; 600 mg LD troponin-I 255 ng/mL (IQR: 130 to 461 ng/mL) vs 300 mg LD 380 ng/mL (IQR: 134 to 1,406 ng/mL), p<0.0001.	30 d bleeding and entry site complications. Major bleeding: 1.9% in 600 mg group vs 2.0% in 300 mg group. Entry site complications 2.9% vs 3.1%.	N/A	TIMI flow grade <3 after PCI 600 mg LD 5.8% vs 300 mg LD 16.3%, p=0.031; LVEF at discharge 600 mg LD 52.1 + 9.5% vs 300 mg LD 48.8 + 11.3%, p=0.026; 30-d MACE 600 mg LD 5.8% vs 300 mg LD 15%, p=0.049. No difference in bleeding or access site complications.	Surrogate endpoint trial underpowered for clinical events. Measurement of AUC less accurate than cardiac MRI for assessment of infarct size.

ARC indicates Academic Research Consortium; ASA, aspirin; AUC, area under the curve; ARMYDA-6 MI, Antiplatelet therapy for Reduction of Myocardial Damage during Angioplasty-Myocardial Infarction study; CABG, coronary artery bypass surgery; CURRENT–OASIS 7: Clopidogrel and ASA Optimal Dose Usage to Reduce Recurrent Events−Seventh Organization to Assess Strategies in Ischemic Syndromes; DES, drug-eluting stents; GRACE, Global Registry of Acute Coronary Events risk score; GUSTO, Global Use of Strategies To Open Occluded Coronary Arteries; IQR, interquartile range; IP, investigational product; LBBB, left bundle branch block; LD, loading dose; LVEF, left ventricular ejection fraction; MACE, major adverse cardiovascular events; MI, myocardial infarction; MRI, magnetic resonance imaging; PCI, percutaneous coronary intervention; PLATO, Platelet Inhibition and Patient Outcomes trial; pts, patients; OL, open label; STEMI, ST- elevation myocardial infarction; TIA, transient ischemic attack, and TIMI, Thrombolysis In Myocardial Infarction trial.

Data Supplement 4. Early Catheterization and Rescue PCI for Fibrinolytic Failure in the Stent Era							
Study Name	Study Type	Study Size	Inclusion Criteria	Endpoints	Findings	Limitations	Comments
MERLIN, 2004 (22) 15261920	Randomized multicenter study of rescue angioplasty compared with continued medical therapy for pts with acute STEMI and failed thrombolysis.	307	STEMI ≤10 h of onset of symptoms. CP >30 min ST-elevation ≥2 mm in ≥2 chest leads or 1 mm in ≥2 limb leads. Failure to respond to FT at 60 min.	All-cause mortality at 30 d. Secondary EP: Composite of death, re-MI, CVA, CHF and clinically driven subsequent revascularization within 30 d RWMI	Death: Conservative vs rescue = 11% vs 9.8%; p=0.7 RD: 1.2; 95% CI: -5.8- 8.3 Composite Secondary EP: 50% vs 37.3%; p=0.02; RD: 12.7%; 95% CI: 1.6-23.5 Strokes: 4.6% vs 0.6%; p=0.03 RWMI was not different.		Rescue PCI had no significant effect on total mortality, although the secondary composite clinical endpoint was lower with rescue PCI compared with conservative care. Stroke rates were significantly higher in the rescue PCI group.
REACT, 2005 (23) 16382062	Randomized multicenter study to determine the best treatment for failed fibrinolysis by comparing rescue PCI to repeat fibrinolysis to conservative therapy.	427	Age 21 to 85 y, with evidence of failure of fibrinolysis; Rescue PCI could be performed within 12 h of onset of CP.	Composite of death, re-MI, CVA or severe CHF at 6 mo.	Rescue PCI vs repeat FT vs Conservative: 15.3% vs 31% vs 29.8%; p=0.003 PCI vs conservative: HR: 0.47; 95% CI: 0.28-0.79; p=0.004 PCI vs Re-FT: HR: 0.43; 95% CI: 0.26-0.72; p=0.001 Re-FT vs conservative therapy: HR: 1.09; 95% CI: 0.71-1.67; p=0.69 Minor bleeding more frequent with PCI No significant difference in major bleeding		Rescue PCI demonstrated a benefit when compared with conservative care or repeat fibrinolysis, although minor bleeding was significantly higher. Repeat FT did not offer any clinical benefit to conservative care.
Collet et al., 2006 (24, 25) 17258087, 17010790	Meta-analysis of clinical trials of cath following fibrinolysis in various settings. This included Rescue PCI, Immediate PCI (within 24 h) and Facilitated PCI. Focus of this table is on data from rescue PCI.	920	Trials of pts with failed fibrinolysis randomized to rescue PCI or conservative care.	Mortality and Re-MI	Short term mortality: OR: 0.63; 95% CI: 0.39- 0.99; p=0.055 Long term mortality: OR: 0.69; 95% CI: 0.41-1.57; p=0.16 Short term mortality or Re-MI: OR: 0.60; 95% CI: 0.41-0.89; p=0.012 Long term mortality or Re-MI: OR: 0.60; 95% CI: 0.39- 0.92; p=0.019	Differences in study protocol, study endpoints and duration of follow-up.	Meta-analysis supported a strategy of rescue PCI for pts with clinical evidence of failure to reperfuse following fibrinolysis.

					Higher rate of major bleeding with rescue PCI		
Wijeysundera et al., 2007 (24) 17258087	Meta-analysis of the benefits of rescue PCI compared with either repeat fibrinolysis or conservative care.	1,177	Trials of pts with clinical or angiographic evidence of failed fibrinolysis randomized to rescue PCI, repeat fibrinolysis or conservative care.	Mortality and Re-MI, CHF, CVA, and bleeding	Rescue PCI vs Conservative: Mortality: RR: 0.69; 95% CI: 0.46-1.05; p=0.09 CHF: RR:0.73; 95% CI: 0.54-1.0; p=0.05 Re-MI: RR=0.58; 95% CI: 0.35-0.97; p=0.04 Composite of Death: re-MI and CHF RR: 0.72; 95% CI: 0.59-0.88; p=0.001 CVA: RR: 4.98, 95% CI: 1.1- 22.5; p=0.04 Minor bleeding: RR: 4.58; 95% CI: 2.46-8.55; p<0.001 Rescue PCI vs repeat FT: Mortality RR: 0.68; 95% CI: 0.41-1.14; p=0.14 Re-MI: RR:1.79; 95% CI: 0.92-3.48; p=0.09 Minor bleeding: RR: 1.84; 95% CI: 1.06-3.18; p=0.03 Major bleeding: RR: 1.54; 95% CI: 0.54-4.4; p=0.42	Differences in study protocol, study endpoints and duration of follow-up.	Meta-analysis supported rescue PCI compared with conservative care in pts with clinical or angiographic evidence of failure of FT at the expense of a higher incidence of CVA and bleeding complications.

Cath indicates catheterization; CHF, congestive heart failure; CI, confidence interval; CP, chest pain; CVA, cerebrovascular accident; FT, fibrinolytic therapy; MI, myocardial infarction; PCI, percutaneous coronary intervention; pts, patients; RD, risk difference; RWMI, regional wall-motion index; and STEMI, ST-elevation myocardial infarction.

Data Supplement 5. Early Catheterization and PCI Following Fibrinolysis in the Stent Era							
Study Name	Study Type	Study Size	Inclusion Criteria	Endpoints	Findings	Limitations	Comments
SIAM III, 2003 (26) 12932593	Randomized multicenter trial of immediate stenting within 6 h of fibrinolysis vs delayed stenting at 2 wk.	195	Age >18 y, symptoms of AMI <12 h, ST-elevation of >1 mm in ≥2 limb leads and ST-elevation >2 mm in precordial leads, or new LBBB; no contraindication to lytics.	Composite of death, re-MI, ischemic events and TLR at 6 mo.	Early stent vs delayed stent MACE: 25.6% vs 50.6%; p=0.001 No differences in bleeding complications.	Analysis limited to only those pts who had stents	Study demonstrated a benefit of immediate stenting performed within 6 h of FT as compared with a strategy of delayed stenting. This was primarily driven by reduction in ischemic events (by definition, a pt. in delayed stent arm who required cath before 2 wk was considered to have reached an ischemic endpoint.)
GRACIA, 2004 (27) 15380963	Randomized multicenter study of routine early cardiac cath (6 to 24 h) following fibrinolysis vs ischemia guided approach.	500	Pts ≥18 y with ST-elevation ≥1 mm in ≥2 contiguous leads, or a nondiagnostic ECG due to LBBB or paced rhythm; symptoms ≥30 min and ≤12 h unresponsive to NTG treated with a fibrin specific agent and consented 6 h after FT.	Composite of death, re-MI and ischemia induced revascularization at 1 y. Note: In-hospital ischemia induced revascularization not considered part of primary endpoint.	Early Cath vs Ischemia Guided RR: 0.44; 95% CI: 0.28- 0.70; p=0.0008 Endpoint of death or re-MI: HR: 0.58; 95% CI: 0.33-1.05; p=0.07 No difference in major bleeding	Pts randomized 6 h after FT	Study demonstrated a benefit of early routine cath compared with an ischemia driven approach. This was largely seen by a 70% reduction in ischemia driven revascularization in the invasive group compared with conservative group at 1 y.
Lepzig Prehospital Fibrinolysis Study, 2005 (28) 16061501	Randomized multicenter study of prehospital fibrinolysis with PCI vs prehospital fibrinolysis alone and standard care.	164	Symptoms for at least 30 min and <6 h, and ST-elevation >0.1 mV in ≥2 limb leads or >0.2 mV in ≥2 precordial leads.	Final infarct size by MRI.	Early Cath vs Standard Care Final infarct size on MRI : 5.2% (IQR: 1.3 to 11.2) vs 10.4% (3.4 to 16.3) p=0.001 Trend towards fewer clinical events.	Small study and surrogate endpoints	Immediate cath and PCI following fibrinolysis resulted in smaller infarct size on MRI compared with standard care.
CAPITAL AMI, 2005 (29) 16053952	Randomized multicenter study of fibrinolysis with immediate transfer for cath vs fibrinolysis alone and transfer for unstable symptoms.	170	Symptoms ≤6 h and ≥30 min; ST-elevation ≥1 mm in ≥2 leads or LBBB and 1 of the following: AWMI; Extensive nonanterior MI; Killip class 3; SBP (22) <100 mmHg	Composite of death, re-MI, re-UA or CVA at 6 mo.	Early Cath vs Ischemia-Guided Approach MACE: 11.6% vs 24.4%; p=0.04 RR: 0.48; 95% CI: 0.24- 0.96 Minor bleeding higher in the early cath group. No differences in major bleeding.	Small study, with mix of transfer pts or pts at centers with PCI capabilities. "Standard" care group was managed very conservatively.	Demonstrated a benefit to immediate cath compared with standard care (which was stress test at 30 d). This was primarily driven by less recurrent MI or UA in the PCI group within the 1st wk of care.
Di Pasquale et al., 2006 (30) 16622610	Randomized single-center study of immediate cath <2 h and PCI vs delayed PCI 12 to 24 h after fibrinolysis.	451	First STEMI ≤12 h from symptom onset, with ST-elevation >1 mm in peripheral leads, and or 2 mm in	Ischemic events (MI, abnormal stress test, restenosis, and death) at 6 mo.	Immediate Cath vs Delayed Cath Ischemic events 18.2% vs 9.7%; p=0.005 More minor bleeding in immediate PCI	Pts only included following successful reperfusion.	Study failed to show a benefit to immediate cath and PCI within 2 h, compared with early cath and PCI at 12 to 72 h among pts who have demonstrated evidence of successful

			precordial leads involving >1 lead, Killip class 1-2, acceptable echo window, and abnormal wall motion on echo. Baseline CPK and TRP normal. Successful reperfusion following lytic therapy. Age of >18 or <75 y.		group. No difference in major bleeding.	Pts treated with unapproved regimen of half dose lytic and GPI.	reperfusion following cath.
WEST, 2006 (31) 16757491	Randomized multicenter feasibility study of PCI vs fibrinolysis with early cath (within 24 h) vs fibrinolysis with standard care.	304	Nonpregnant, ≥18 y, symptoms at least 20 min and ECG with high-risk MI (ST-elevation ≥2 mm in 2 precordial leads or 2 limb leads, or ≥1 mm ST-elevation in limb leads with ≥1 mm ST depression in precordial leads, or presumed new LBBB.	Efficacy: 30 d composite of death, re-MI, reischemia, CHF, shock or major ventricular arrhythmias. Safety endpoints: ICH, CVA, major bleeding.	No difference in the primary efficacy or safety endpoints in the 3 groups.	Very small study	Feasibility study failed to show a difference in efficacy or safety endpoints for the 3 approaches. A subsequent analysis compared a strategy of primary PCI with fibrinolysis (with or without early cath) and showed a lower rate of 30-d death and MI in the primary PCI group (HR: 0.29; 90% CI: 0.11- 0.74); P-log rank=0.021)
Collet at al., 2006 (25) 17010790	Meta-analysis of clinical trial of cath following fibrinolysis in various settings. This included rescue PCI, immediate PCI (within 24 h) and facilitated PCI. Focus in this table on results from immediate cath.	1,508	Clinical trials of STEMI pts receiving fibrinolysis and randomized to immediate or early cath compared with ischemia driven cath (excluded trials that looked at early vs delayed cath).	Mortality and Death/MI	Early Cath vs Ischemia Driven Cath Death: All studies: OR: 0.83; 95% CI: 0.52-1.35; p=0.47 Stent era: OR: 0.56; 95% CI: 0.29-1.05; p=0.07 POBA: OR: 1.44; 95% CI: 0.69-3.06; p=0.33) Death and MI All studies: OR: 0.85; 95% CI: 0.47-1.55; p=0.42 Stent era: OR: 0.53; 95% CI: 0.33- 0.83; p=0.0067 POBA: OR: 1.76; 95% CI: 0.97- 3.21; p=0.064	Different regimens of medications and timing to cath and different time periods in which trials were performed. Investigators reviewed overall results of all studies, and then examined the results from studies performed in the stent era.	Study showed a benefit to systematic early cath compared with an ischemia driven approach from studies performed in the “stent era” but not for studies performed in the “balloon angioplasty era”.
Wijeysundera, 2008 (24) 17258087	A meta-analysis of trials examining fibrinolysis with immediate transfer for cath with	1,235	Clinical trials of STEMI pts receiving fibrinolysis and randomized to routine early	All-cause mortality, Recurrent MI	Immediate Cath vs Ischemia Driven Cath Mortality: OR: 0.55; 95% CI: 0.34- 0.90; p=0.02;	There was a variable definition of early cath for	Study showed a benefit to a routine invasive strategy of cath following fibrinolysis compared with an ischemia driven approach in the “stent

	fibrinolysis and an ischemia-guided approach.		invasive management compared with ischemia driven cath in the "stent era".		Re-MI: OR: 0.53; 95% CI: 0.33- 0.86; p=0.01 No difference in stroke or major bleeding	each trial, and different durations of follow-up.	era".
CARESS-AMI, 2008 (32) 18280326	Randomized multicenter trial of immediate transfer for PCI following FT in high risk patient compared with standard care and rescue PCI.	600	STEMI with symptoms ≤12 h, and ≥1 high-risk features: Cumulative ST-elevation of >15 mm, new onset LBBB, prior MI, Killip class ≥2, or LVEF ≤35%.	Composite of all-cause death, re-MI and refractory ischemia at 30 d.	Early Cath vs Standard Care MACE: HR: 0.4; 95% CI: 0.21- 0.76; log rank p=0.004 Minor or minimal bleeding was higher in the immediate cath group. There was a 47.8% higher major bleeding in immediate cath group (not statistically significant).	Used an unapproved regimen of half dose RPA.	Study demonstrated a benefit to immediate transfer of high-risk pts with STEMI following fibrinolysis compared with transfer for rescue PCI or standard care. The primary endpoint was driven largely by recurrent ischemia.
TRANSFER AMI, 2009 (33) 19553646	Randomized multicenter trial of FT followed by immediate transfer for cath compared with fibrinolysis and standard care (rescue cath/or cath 24 h to 2 wk).	1,059	Symptoms ≤12 h and ST-elevation ≥2 mm in anterior leads, or ST ≥1 mm in the inferior leads with: SBP <100, Killip class 2 or 3, ST-depression of ≥2 mm in the anterior leads, or ST-elevation of ≥1 mm in the right-sided leads.	Combined incidence of death, re-MI, recurrent ischemia, new or worsening CHF or shock at 30 d.	Early Cath vs Delayed Cath MACE: 11.0% vs 17.2%; RR: 0.64; 0.47-0.87; p=0.004 Significantly more mild GUSTO bleeding in the immediate cath group.		Study demonstrated a benefit to immediate transfer of high-risk pts with STEMI following fibrinolysis compared with transfer for rescue PCI or early cath (24 h-2 wk).
NORDSTEMI, 2010 (34) 19747792	Multicenter randomized study of FT and immediate transfer for PCI compared with FT and standard care.	276	Age 18 to 75 y, symptoms <6 h; ST-elevation of ≥2 mm ST in 2 precordial leads, or ≥1 in 2 inferior leads or new LBBB; expected time delay for PCI over 90 min.	Death, Re-MI, CVA or new ischemia at 12 mo.	Early Cath vs Routine Care Primary Endpoint: 21% vs 27% HR: 0.72; 95% CI: 0.44-1.18; p=0.19 Death, CVA or re-MI: 6% vs 16% HR: 0.36; 95% CI: 0.16- 0.81; p=0.01 No differences in bleeding complications.		Study failed to demonstrate a benefit of immediate cath following fibrinolytic therapy in achieving the primary endpoint of death, re-MI, CVA or ischemia at 12 mo. However, immediate cath resulted in a significant reduction in the 2nd endpoint when compared with standard care (rescue PCI/ ischemia guided PCI or routine cath done 2 to 4 wk) following fibrinolysis.
Borgia et al., 2010 (35) 20601393	A meta-analysis of trials examining fibrinolysis with immediate transfer for cath with fibrinolysis alone and standard care.	2,961	Included all trials of STEMI pts treated with fibrin-specific agents and randomized to immediate PCI or standard care.	Death, re-MI or combined endpoint of death, re-MI and re-ischemia and revascularization at 30 d or longer. Safety endpoint was major bleeding a	Early Cath vs Delayed Cath or Ischemia Driven Cath 30 d Death 3.3% vs 3.8%; OR: 0.87; 95% CI: 0.59-1.30; p=0.51 30 d Re-MI 2.6 vs 4.7%; OR: 0.55; 95% CI: 0.36- 0.82;	Different endpoint definitions which the investigators attempted to resolve by reevaluating some of the endpoints of the individual trials.	Meta-analysis demonstrated a benefit to a routine strategy of early cath following lytic therapy compared with standard care by reducing the combined endpoint of death and re-MI at 30 d, without a significant increase in adverse events including bleeding or stroke. A meta-regression analysis looking at baseline risk of the pts for each study demonstrated a

				stroke.	p=0.003 <u>30 d Death/Re-MI</u> 5.6 vs 8.3%; OR: 0.65; 95% CI: 0.49-0.88; p=0.004 <u>30 d Recurrent ischemia</u> 1.9 vs 7.1%; OR: 0.25; 95% CI: 0.13- 0.49; p<0.001 <u>6 to 12 Mo Death</u> 4.8 vs 5.4%; OR: 0.88; 95% CI: 0.62-1.25; p=0.48 <u>6 to 12 Mo Re-MI</u> 3.9 vs 6%; OR: 0.64; 95% CI: 0.40-0.98; p=0.01 <u>6 to 12 Mo Death/Re-MI</u> 8.6 vs 11.2%; OR: 0.71; 95% CI: 0.52-0.97; p=0.03 No difference in Major bleeding. No difference in stroke.	Time from FT to PCI varied from 84 min to 16.7 h.	greater benefit to this approach among the higher risk group of pts.

AMI indicates acute myocardial infarction; AWMI, anterior wall myocardial infarction; cath, catheterization; CHF, congestive heart failure; CI, confidence interval; CPK, creatine phosphokinase; CVA, cerebrovascular accident; EP, electrophysiology; FT, fibrinolytic therapy; GPI, glycoprotein inhibitor; GUSTO, Global Utilization of Streptokinase and t-PA for Occluded Coronary Arteries; ICH, intracranial hemorrhage; LBBB, left bundle-branch block; LVEF, left ventricular ejection fraction; MACE, major adverse cardiac events; MI, myocardial infarction; PCI, percutaneous coronary intervention; POBA, plain old balloon angioplasty; pts, patients; RD, risk difference; RPA, reteplase; RWMI, regional wall motion index; SBP, systolic blood pressure; STEMI, ST-elevation myocardial infarction; TLR, transmyocardial laser revascularization; TRP, thrombosis risk panel; and UA, unstable angina.

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