

Massachusetts Department of Public Health
Special Project: Primary Angioplasty

Protocol/Revised (10/24/01)

Effective 9 AM, 10/24/01

VII. Protocol

A. Clinical Protocol

1. Clinical selection criteria

The following criteria must be met for the selection of patients for the performance of primary angioplasty:

a. The patient is 18 or more years of age

b. The patient presents with:

1. > 30 minute ongoing ischemic cardiac pain

and

2. > 0.1 mv ST-segment elevation in 2 or more contiguous ECG leads

or

new or suspected new LBB (ST- segment elevation infarction group)

or

>0.1 mv ST-segment depression in V1 and V2 consistent with true posterior infarction

c. The patient:

1. arrives in the ER < 12 hours after symptom onset.

and

2. can have a primary angioplasty procedure performed (“balloon inflation”) within 90 ± 30 minutes of ED arrival (“ED door”). If angioplasty cannot be performed within this time frame, then the patient should receive appropriate medical therapy.

2. Clinical exclusion criteria

Patients will be excluded from primary angioplasty procedures at a Special Project hospital if any of the following conditions apply:

a. The patient’s symptoms of myocardial infarction began > 12 hours prior to presentation at the Special Project hospital’s Emergency Department.

b. The patient has a sensitivity to contrast dyes which cannot be adequately pretreated with diphenhydramine and/or steroids.

c. The patient has severe peripheral vascular disease with inability of the operator to obtain vascular access.

3. For patients treated “unsuccessfully” with thrombolytics:

a. Within the 1.5 to 6 (> 1.5 and <6) hours after the initiation of the administration of a thrombolytic agent if the syndrome of chest pain and ST-segment elevation (>1mm in 2 or more adjacent leads) *continues*; and coronary angiography shows both severe stenosis (> 80%) and slow flow (TIMI grade 2 or less flow) in the infarct related artery, “rescue angioplasty” may be performed.

- b. In the absence of severe stenosis (>80%), slow flow (TIMI grade 2 or less flow), and persistent ST-segment elevation, however, chest pain alone ***is not*** a sufficient indication for the performance of “rescue angioplasty” after thrombolytic therapy, and ***is not*** permitted under the Special Project.
Note: If coronary angiography shows TIMI grade 3 flow in the infarct related artery of a patient who has been treated with thrombolytics, angioplasty ***is not permitted*** under the Special Project.
- 4. For patients in cardiogenic shock:
 - a. Cardiogenic shock is defined by clinical and/or hemodynamic criteria as follows:
 - 1. hypotension (systolic pressure less than 90mmHg for 30 minutes or blood pressure requiring pressor support to keep the systolic blood pressure greater than 90mmHg) and/or
 - 2. end organ hypoperfusion manifested by cool extremities and/or urine output less than 30cc per hour and/or
 - 3. hemodynamics required for a diagnosis of primary left ventricular failure are heart rate > 60 beats per minute, cardiac index $\leq 2.2\text{L}/\text{min}/\text{M}^2$, pulmonary capillary wedge pressure > 15mmHg
 - b. Physicians may choose to either perform angioplasty on site, at the participating hospital, or to emergently transfer the patient to a tertiary hospital with on-site open-heart surgery.
- 5. TIMI grade 3 flow
 In general if there is TIMI grade 3 flow in the infarct related artery primary angioplasty should not be performed at hospitals without on-site open-heart surgery. However, for those patients who are brought to the cath lab urgently with ST-segment elevation acute myocardial infarction, and are found to have a patent (TIMI grade 3 flow) but a stenotic infarct related artery (e.g.>80%) the treating physician may perform primary angioplasty if s/he decides the risk of abrupt reocclusion is high and the delay in transfer of the patient to a tertiary hospital is too great.
- 6. Primary angioplasty should not be performed if:
 - a. the infarct related artery cannot be identified
 - b. there is severe triple vessel disease best treated with CABG
 - c. there is > 50% stenosis of the left main coronary artery.
 - d. the lesions are extremely long or angulated infarct-related lesions with TIMI grade 3 flow.
 - e. the lesion is complex and TIMI grade 3 flow is present (without ongoing ischemia),
or
 - f. the infarct related lesions are of small or secondary vessels.
- 7. See Attachment D for suggested “Guidelines for Clinical Care”.