Myocardial infarction with ST-segment-elevation: the acute management of myocardial infarction with ST-segment-elevation

NICE guideline
Draft for consultation, February 2013

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.
Contents

Introduction ..................................................................................................................................... 3
Patient-centred care......................................................................................................................... 5
Strength of recommendations ......................................................................................................... 6
Key priorities for implementation .................................................................................................... 8
1 Recommendations ....................................................................................................................... 10
2 Research recommendations ......................................................................................................... 15
3 Other information ......................................................................................................................... 18
  3.1 Scope and how this guideline was developed ........................................................................... 18
  3.2 Related NICE guidance ............................................................................................................. 19
4 The Guideline Development Group, National Collaborating Centre and NICE project team ................................................................. 21
Introduction

ST-segment elevation myocardial infarction (STEMI) occurs when a coronary artery becomes blocked by a blood clot, causing the heart muscle supplied by the artery to die. It belongs to a group of heart conditions known as acute coronary syndromes.

The incidence of STEMI has been declining over the past 20 years. It varies between regions and averages around 500 hospitalised episodes per million people each year in the UK. The London Ambulance Service attended 9657 cardiac arrests in 2011–12 for a population of around 8.2 million people (1177 per million people). Most of these will have been attributed to acute coronary syndromes, so the overall population prevalence of STEMI is likely to be in the region of 750–1250 per million people. Over the past 30 years, in-hospital mortality after acute coronary syndromes has fallen from around 20% to nearer 5%. This has been attributed to various factors, including improved drug therapy and speed of access to effective treatments.

Nearly half of potentially salvageable myocardium is lost within 1 hour of the coronary artery being occluded, and two-thirds are lost within 3 hours. Apart from resuscitation from any cardiac arrest, the highest priority in managing STEMI is to restore an adequate coronary blood flow as quickly as possible. In the 1980s and 1990s, the best way to restore flow was to administer a fibrinolytic drug.

The UK introduced a comprehensive system for delivering fibrinolysis after publication of the Department of Health's National Service Framework for Coronary Heart Disease. However, fibrinolysis was not suitable for use in some people because of bleeding complications. In around 20–30% of people, fibrinolysis failed to result in coronary reperfusion, and in a few (1.0%) it caused haemorrhagic stroke. To improve outcomes, attention turned to mechanical techniques to restore coronary flow (for example, coronary angioplasty, thrombus extraction catheters and stenting), which are grouped under the overarching term primary percutaneous coronary intervention (primary PCI).
The National Infarct Angioplasty Project concluded that primary PCI is both feasible and cost effective, and that it should become the treatment of choice for STEMI, provided it could be delivered ‘in a timely fashion’.

Primary PCI ‘timeliness’ is a key part of this guideline. This is addressed in detail, so commissioners and professionals delivering services for people with STEMI can plan their configuration in such a way that outcomes are optimal. This guideline also covers procedural primary PCI issues, the use of antiplatelet and antithrombin agents, and improving outcomes for the minority of people still receiving fibrinolysis.

The guideline will assume that prescribers will use a drug’s summary of product characteristics to inform decisions made with individual patients.
Patient-centred care

This guideline offers best practice advice on the care of adults (18 years or older) with spontaneous onset of myocardial infarction with ST-segment elevation (STEMI).

Patients and healthcare professionals have rights and responsibilities as set out in the NHS Constitution for England – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If someone does not have the capacity to make decisions, healthcare professionals should follow the Department of Health’s advice on consent, the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in Patient experience in adult NHS services.
Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also ‘Patient-centred care’).

Interventions that must (or must not) be used

We usually use ‘must’ or ‘must not’ only if there is a legal duty to apply the recommendation. Occasionally we use ‘must’ (or ‘must not’) if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions that should (or should not) be used – a ‘strong’ recommendation

We use ‘offer’ (and similar words such as ‘refer’ or ‘advise’) when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, ‘Do not offer…) when we are confident that an intervention will not be of benefit for most patients.

Interventions that could be used

We use ‘consider’ when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient’s values...
and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.
Key priorities for implementation

The following recommendations have been identified as priorities for implementation:

- Immediately assess eligibility (irrespective of age, ethnicity or sex) for coronary reperfusion therapy (either primary percutaneous coronary intervention [PCI] or fibrinolysis) in people with acute ST-elevation myocardial infarction (STEMI). [1.1.1]
- Do not use level of consciousness after cardiac arrest caused by suspected acute STEMI to determine whether a person is eligible for coronary angiography (with follow-on primary PCI if indicated). [1.1.2]
- Deliver coronary reperfusion therapy (either primary PCI or fibrinolysis) as quickly as possible for eligible people with acute STEMI. [1.1.3]
- Offer coronary angiography, with follow-on primary PCI if indicated, as the preferred coronary reperfusion strategy for people with acute STEMI if:
  - presentation is within 12 hours of onset of symptoms and
  - primary PCI can be delivered within 120 minutes of the time when fibrinolysis could have been given. [1.1.4]
- Offer fibrinolysis to people with acute STEMI presenting within 12 hours of onset of symptoms if primary PCI cannot be delivered within 120 minutes of the time when fibrinolysis could have been given. [1.1.5]
- Consider coronary angiography, with follow-on primary PCI if indicated, for people with acute STEMI presenting more than 12 hours after the onset of symptoms if there is evidence of continuing myocardial ischaemia. [1.1.8]
- Offer coronary angiography, with follow-on primary PCI if indicated, to people with acute STEMI and cardiogenic shock who present within 12 hours of the onset of symptoms of STEMI. [1.1.10]
- Offer an electrocardiogram to people treated with fibrinolysis, 60–90 minutes after administration. For those who have residual ST-segment elevation suggesting failed coronary reperfusion:
  - offer immediate coronary angiography, with follow-on PCI if indicated
  - do not repeat fibrinolytic therapy. [1.1.16]
DRAFT FOR CONSULTATION

- If a person has recurrent myocardial ischaemia after fibrinolysis, seek immediate specialist cardiological advice and, if appropriate, offer coronary angiography, with follow-on PCI if indicated. [1.1.17]

- When commissioning primary PCI services for people with acute STEMI, be aware that outcomes are strongly related to how quickly primary PCI is delivered, and that they can be influenced by the number of procedures carried out by the primary PCI centre. [1.1.19]
1 Recommendations

The following guidance is based on the best available evidence. The full guideline [hyperlink to be added for final publication] gives details of the methods and the evidence used to develop the guidance.

1.1 Recommendations

1.1.1 Immediately assess eligibility (irrespective of age, ethnicity or sex) for coronary reperfusion therapy (either primary percutaneous coronary intervention [PCI] or fibrinolysis) in people with acute ST-elevation myocardial infarction (STEMI).

1.1.2 Do not use level of consciousness after cardiac arrest caused by suspected acute STEMI to determine whether a person is eligible for coronary angiography (with follow-on primary PCI if indicated).

1.1.3 Deliver coronary reperfusion therapy (either primary PCI or fibrinolysis) as quickly as possible for eligible people with acute STEMI.

1.1.4 Offer coronary angiography, with follow-on primary PCI if indicated, as the preferred coronary reperfusion strategy for people with acute STEMI if:

- presentation is within 12 hours of onset of symptoms and
- primary PCI can be delivered within 120 minutes of the time when fibrinolysis could have been given.

1.1.5 Offer fibrinolysis to people with acute STEMI presenting within 12 hours of onset of symptoms if primary PCI cannot be delivered within 120 minutes of the time when fibrinolysis could have been given.

1.1.6 When treating people with fibrinolysis, give an antithrombin at the same time.
1.1.7 Offer medical therapy to people with acute STEMI who are ineligible for reperfusion therapy.

1.1.8 Consider coronary angiography, with follow-on primary PCI if indicated, for people with acute STEMI presenting more than 12 hours after the onset of symptoms if there is evidence of continuing myocardial ischaemia.

1.1.9 Do not offer routine glycoprotein IIb/IIIa inhibitors or fibrinolytic drugs before arrival at the catheter laboratory to people with acute STEMI for whom primary PCI is planned.

1.1.10 Offer coronary angiography, with follow-on primary PCI if indicated, to people with acute STEMI and cardiogenic shock who present within 12 hours of the onset of symptoms of STEMI.

1.1.11 Consider coronary angiography, with a view to coronary revascularisation if indicated, for people with acute STEMI who present more than 12 hours after the onset of symptoms and who have cardiogenic shock or go on to develop it.

1.1.12 Offer unfractionated heparin or low molecular weight heparin to people with acute STEMI who are undergoing primary PCI and have been treated with prasugrel or ticagrelor.

1.1.13 Consider thrombus aspiration during primary PCI for people with acute STEMI.

1.1.14 Do not routinely use mechanical thrombus extraction during primary PCI.

1.1.15 Consider radial (in preference to femoral) arterial access for people undergoing coronary angiography (with follow-on primary PCI if indicated).
1.1.16 Offer an electrocardiogram to people treated with fibrinolysis, 60–90 minutes after administration. For those who have residual ST-segment elevation suggesting failed coronary reperfusion:

- offer immediate coronary angiography, with follow-on PCI if indicated
- do not repeat fibrinolytic therapy.

1.1.17 If a person has recurrent myocardial ischaemia after fibrinolysis, seek immediate specialist cardiological advice and, if appropriate, offer coronary angiography, with follow-on PCI if indicated.

1.1.18 Consider coronary angiography during the same hospital admission for people who are clinically stable after successful fibrinolysis.

1.1.19 When commissioning primary PCI services for people with acute STEMI, be aware that outcomes are strongly related to how quickly primary PCI is delivered, and that they can be influenced by the number of procedures carried out by the primary PCI centre.

1.1.20 Offer people with acute STEMI written and oral information, advice, support and treatment on the topics in table A (where relevant) in line with published NICE guidance.

Table A Related NICE guidance for people with acute STEMI

<table>
<thead>
<tr>
<th>Topic</th>
<th>NICE guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking cessation</td>
<td>Smoking cessation services</td>
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<td></td>
<td>Brief interventions and referral for smoking cessation</td>
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<tr>
<td>Diet, weight management and exercise</td>
<td>Four commonly used methods to increase physical activity</td>
</tr>
<tr>
<td>Lipid modification and statin therapy</td>
<td>Identification and management of familial hypercholesterolaemia</td>
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<td></td>
<td>Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and</td>
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<tr>
<td>Secondary prevention of cardiovascular disease</td>
<td>Type 2 diabetes: the management of type 2 diabetes</td>
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<tr>
<td>Statins for the prevention of cardiovascular events</td>
<td>Type 1 diabetes: diagnosis and management of type 1 diabetes in children, young people and adults</td>
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<tr>
<td>Prevention, diagnosis and management of diabetes</td>
<td>Prevention, diagnosis and management of high blood pressure</td>
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<tr>
<td>Hypertension: clinical management of primary hypertension in adults</td>
<td>Hypertension: clinical management of primary hypertension in adults</td>
</tr>
<tr>
<td>Hyperglycaemia management in acute coronary syndromes</td>
<td>Hyperglycaemia in acute coronary syndromes: management of hyperglycaemia in acute coronary syndromes</td>
</tr>
<tr>
<td>MI secondary prevention</td>
<td>MI – secondary prevention: secondary prevention in primary and secondary care for patients following a myocardial infarction</td>
</tr>
<tr>
<td>Early management of unstable angina and NSTEMI</td>
<td>Unstable angina and NSTEMI: the early management of unstable angina and non-ST-segment-elevation myocardial infarction</td>
</tr>
<tr>
<td>Patient experience</td>
<td>Patient experience in adult NHS services: improving the experience of care for people using adult NHS services</td>
</tr>
<tr>
<td>Medicines adherence</td>
<td>Medicines adherence: involving patients in decisions about prescribed</td>
</tr>
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</table>
1.2  Recommendations incorporated from NICE technology appraisal guidance

This guideline incorporates NICE technology appraisal guidance 236 (TA236) on ticagrelor for the treatment of acute coronary syndromes and TA230 on bivalirudin for the treatment of STEMI.

1.2.1  Ticagrelor in combination with low-dose aspirin is recommended for up to 12 months as a treatment option in people with STEMI – defined as ST elevation or new left bundle branch block on electrocardiogram – that cardiologists intend to treat with primary PCI. [This recommendation is adapted from Ticagrelor for the treatment of acute coronary syndromes (NICE technology appraisal guidance 236).]

1.2.2  Bivalirudin in combination with aspirin and clopidogrel is recommended for the treatment of adults with STEMI undergoing primary PCI.¹ [This recommendation is from Bivalirudin for the treatment of ST-segment-elevation myocardial infarction (NICE technology appraisal guidance 230).]

¹ The use of bivalirudin in combination with prasugrel or ticagrelor is outside the marketing authorisation for bivalirudin.
2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

2.1 Primary PCI and fibrinolysis in people with acute STEMI who present very early

If a person with acute STEMI presents within 1 hour of the onset of symptoms, is it better for that person to be given fibrinolysis with a short call to needle time rather than be transferred to a centre that carries out primary PCI for primary PCI with a delay of up to 120 minutes?

Why this is important

Fibrinolytic drugs are administered intravenously and can be given out of hospital by an ambulance crew or in the emergency department of a hospital. Benefit from fibrinolysis declines significantly with time from onset of symptoms. Primary PCI, on the other hand, requires transfer to an interventional cardiology service, which inevitably delays the start of reperfusion treatment. Regardless of the reperfusion method used, delays to treatment are associated with an increased risk of impaired left ventricular systolic function and death.

It is unclear whether people with acute STEMI with a very short presentation delay would benefit more from immediate fibrinolysis (usually pre-hospital for people who do not self-present to hospital emergency departments) compared with transfer to a centre that carries out primary PCI.

To answer this question, a randomised controlled trial of pre-hospital fibrinolysis versus primary PCI in people with acute STEMI who have a short presentation delay of 1 hour or less is needed. Primary endpoints would include cardiovascular and all-cause mortality and other major adverse cardiovascular events. The STREAM study has recruited people who present early (less than 3 hours from onset of symptoms) and those presenting very early (less than 1 hour) could be analysed as a subgroup. However, it is not
known whether this cohort will be big enough to allow a statistically significant conclusion to be drawn.

2.2 Primary PCI and fibrinolysis in people with acute STEMI who have a long anticipated transfer time for primary PCI

In people with acute STEMI who present more than 1 hour after the onset of symptoms, is a primary PCI-related delay of 120–180 minutes associated with outcomes similar to, better or worse than pre-hospital administered fibrinolysis?

Why this is important

Primary PCI is the preferred coronary reperfusion therapy provided it can be delivered ‘in a timely fashion’. It is suggested that primary PCI is the preferred reperfusion strategy for primary PCI-related delays of at least up to 2 hours. However, there is inadequate evidence to conclude whether primary PCI is still preferable at primary PCI-related time delays of more than 2 hours.

No specifically designed randomised controlled trial or observational study has addressed the issue of the extent to which primary PCI-related time delay (and other factors such as presentation delay and a person’s risk profile) diminishes the advantages of primary PCI over fibrinolysis. For example, in more geographically remote areas, a short presentation delay together with an anticipated long primary PCI-related delay could favour a strategy of pre-hospital fibrinolysis.

To answer this question, a randomised controlled trial of pre-hospital fibrinolysis versus primary PCI in people with acute STEMI who have a primary PCI-related delay of 2 hours or more is needed. Primary endpoints would include cardiovascular and all-cause mortality and other major adverse cardiovascular events.
2.3 Radial arterial access primary PCI versus femoral arterial access primary PCI

What is the clinical and cost effectiveness of radial arterial access compared with femoral arterial access for coronary angiography or primary PCI in people with acute STEMI managed by primary PCI?

Why this is important
There is no current evidence that demonstrates if there is a mortality difference between radial arterial access primary PCI compared with femoral arterial access primary PCI. It is unclear if operator experience has influenced current evidence. Operators may need additional training if 1 approach was shown to be superior. A randomised controlled trial comparing the 2 interventions for longer-term outcomes of all-cause mortality and major adverse cardiovascular events would answer the question. The trial would need to address the impact of operator expertise on the clinical outcomes. In addition, the need for operator training could be informed by an observational study that looked at the effectiveness and impact on clinical outcomes of experienced radial operators primarily using the radial approach versus experienced femoral operators primarily using the femoral approach including closure devices. The study would need a sufficient number of participants to enable differences in outcomes to be detected.

2.4 Culprit vessel primary PCI versus multivessel PCI

Does multivessel PCI, at the time of presentation of people with acute STEMI, confer an advantage over a strategy of ‘culprit vessel only’ primary PCI, followed by further elective revascularisation driven by symptoms and evidence of ischaemia?

Why this is important
One-third of people presenting with STEMI have multivessel coronary artery disease at the time of presentation. Currently, there is uncertainty about whether to initially treat only the vessel likely to have caused the presentation or whether to treat all significant lesions. Most of the current evidence that examines ‘culprit vessel only’ primary PCI versus multivessel PCI in these
people comes from studies that are underpowered or non-randomised. Answering this question would clarify the appropriate revascularisation strategy for this patient group. A randomised controlled trial powered to examine all-cause mortality and major adverse cardiovascular events with a 5-year follow-up would be the optimum design.

2.5 **Relationship between volume of procedures and clinical outcomes**

What is the relationship between hospital volume of primary PCI procedures and optimal outcomes in people with acute STEMI?

**Why this is important**

There is a suggestion that outcomes may be better in larger-volume primary PCI units, and some retrospective registries have reported data to support this. However, the quality of the data is poor and still leaves the question open. In the UK, primary PCI is provided by units that vary greatly in the number of cases per year. The development of services has been ad hoc and not designed specifically around the provision of primary PCI. If it was possible to conclusively show that people were or were not better off being treated in larger volume units, then it would have important implications for the national provision of primary PCI.

3 **Other information**

3.1 **Scope and how this guideline was developed**

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover.
How this guideline was developed

NICE commissioned the National Clinical Guideline Centre to develop this guideline. The Centre established a Guideline Development Group (see section 4), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in The guidelines manual.

3.2 Related NICE guidance

Details are correct at the time of consultation on the guideline (February 2013). Further information is available on the NICE website.

Published

General

- Patient experience in adult NHS services. NICE clinical guidance 138 (2012).

Condition-specific

- Stable angina. NICE clinical guideline 126 (2011).
- **Chest pain of recent onset.** NICE clinical guideline 95 (2010).
- **Unstable angina and NSTEMI.** NICE clinical guideline 94 (2010).
- **Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events.** NICE technology appraisal guidance 210 (2010).
- **Cardiac resynchronisation therapy for the treatment of heart failure.** NICE technology appraisal guidance 120 (2010).
- **Smoking cessation services.** NICE public health guidance 10 (2008).
- **Familial hypercholesterolaemia.** NICE clinical guideline 71 (2008).
- **Implantable cardioverter defibrillators (ICDs) for arrhythmias.** NICE technology appraisal guidance 95 (2006).
- **Statins for the prevention of cardiovascular events.** NICE technology appraisal guidance 94 (2006).
- **Brief interventions and referral for smoking cessation in primary care and other settings.** NICE public health guidance 1 (2006).
- **Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction.** NICE technology appraisal guidance 73 (2003).
Under development

NICE is developing the following guidance (details available from the NICE website):


- **Lipid modification (update)**. NICE clinical guideline. Publication date to be confirmed.

4 The Guideline Development Group, National Collaborating Centre and NICE project team

4.1 Guideline Development Group

**Sotiris Antoniou**  
Consultant Pharmacist, Barts Health NHS Trust

**Charles Deakin**  
Consultant in Cardiac Anaesthesia and Intensive Care, University Hospital Southampton

**Huon Gray (Chair)**  
Consultant Cardiologist, Wessex Cardiac Unit, University of Southampton Hospital NHS Foundation Trust

**Rob Henderson (Deputy Chair)**  
Consultant Cardiologist, Nottingham University Hospitals NHS Trust

**Jason Kendall**  
Consultant in Emergency Medicine, Frenchay Hospital, North Bristol NHS Trust

**Hugh McIntyre**  
Consultant Physician, East Sussex Hospitals Trust
Jim McLenachan  
Consultant Cadiologist, Leeds General Infirmary

Francesco Palma  
Patient and carer member

Gerald Robinson  
Patient and carer member

Fiona Sayers  
Head of Nursing, Cardiology and Acute Services, Frimley Park Hospital

Dave Smith  
Consultant Interventional Cardiologist, Regional Cardiac Centre, Morriston Hospital

David Smith  
Consultant Cardiologist, Royal Devon and Exeter NHS Hospital Trust

Mark Vaughan  
GP, Lanelli

Mark Whitbread  
Senior Paramedic, London Ambulance Service, Essex

4.2 National Clinical Guideline Centre

Daria Bilan  
Information Scientist (until February 2012)

Serena Carville  
Senior Research Fellow/Project Manager (from October 2012)

Angela Cooper  
Senior Research Fellow (from December 2011)

Martin Harker  
Health Economist (from April 2012)
Taryn Krause  
Senior Project Manager/Research Fellow (until October 2012)

Kate Lovibond  
Senior Health Economist (until August 2012)

Jill Parnham  
Operations Director

Carlos Sharpin  
Information Science Lead (from February 2012)

David Wonderling  
Senior Health Economist (from August 2012)

4.3  
**NICE project team**

Phil Alderson  
Associate Director

Claire Turner  
Guideline Commissioning Manager

Andrew Gyton until Nov 2012; Carl Dawood from Nov 2012  
Guideline Coordinator

Toni Tan  
Technical Lead

Prashanth Kandaswamy  
Health Economist

Annette Mead  
Editor