NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA47 Glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes

This guidance was issued in September, 2002

The review date for this guidance: A review of glycoproteins was considered during July 2007. It was decided (after consultation) that the existing guidance should be updated within the NICE clinical guideline on unstable angina and non-ST-segment-elevation myocardial infarction (NSTEMI). However, only part of the current guidance has been updated by NICE clinical guideline 94 'Unstable angina and NSTEMI' (sections 1.1 - 1.6). This review covers sections 1.7 and 1.8 of the guidance.

Recommendation

• A review of the guidance should be transferred to the static list. That we consult on the proposal.

Consideration of options for recommendation:

Options	Comment
A review of the guidance should be planned into	No new evidence
the appraisal work programme.	
The decision to review the guidance should be	No significant evidence has emerged
deferred	
A review of the guidance should be combined	No related technology appraisal
with a review of a related technology and	
conducted at the scheduled time for the review	
of the related technology.	

A review of the guidance should be combined with a new appraisal that has recently been referred to the Institute.	No relevant guidance
A review of the guidance should be incorporated	No relevant clinical guideline for sections 1.7 - 1.8
into an on-going clinical guideline.	
A review of the guidance should be updated into	No relevant clinical guideline for sections 1.7 - 1.8
an on-going clinical guideline.	
A review of the guidance should be	No new evidence has emerged. The guidance should be transferred to
transferred to the 'static guidance list'.	the 'static guidance list'.

Original remit(s)

Glycoproteins was a 2nd wave topic with no remit.

Current guidance

Sections 1.1 – 1.6 have been updated by NICE clinical guideline 94 on unstable angina and NSTEMI (Unstable angina and NSTEMI: the early management of unstable angina and non-ST segment elevation myocardial infarction) issued in March 2010.

1.7. It is recommended that a GP IIb/IIIa inhibitor is considered as an adjunct to PCI for all patients with diabetes undergoing elective PCI, and for those patients undergoing complex procedures (for example, multi-vessel PCI, insertion of multiple stents, vein graft PCI or PCI for bifurcation lesions); currently only abciximab is licensed as an adjunct to PCI. In procedurally uncomplicated, elective PCI, where the risk of adverse sequelae is low, use of a GP IIb/IIIa inhibitor is not recommended unless unexpected immediate complications occur.

1.8. GP IIb/IIIa inhibitors are not currently licensed in the UK for use as an adjunct to thrombolytic therapy in ST-segment-elevation MI.

Relevant Institute work

Secondary prevention in primary and secondary care for patients following a myocardial infarction. Clinical guideline CG48. Issued May 2007, review date May 2010.

Unstable angina and NSTEMI: the management of unstable angina and non-ST segment elevation myocardial infarction. Clinical guideline CG94.Issued March 2010, review date to be confirmed.

Chest pain of recent onset: assessment and diagnosis of recent onset chest pain/discomfort of suspected cardiac origin. Clinical guideline CG95. Issued in March 2010, review date to be confirmed.

Prasugrel for the treatment of acute coronary syndromes with percutaneous coronary intervention. Technology appraisal TA182. Issued October 2009, review date August 2010.

Clopidogrel in the treatment of non-ST-segment-elevation acute coronary syndrome. Technology appraisal TA80. Issued July 2004, review date March 2010.

Coronary imaging: Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. Technology appraisal TA73. Issued November 2003, reviewed in December 2009 when it was proposed the guidance should be updated in the on-going clinical guideline on the 'Assessment and investigation of recent onset chest pain of discomfort of suspected cardiac origin' which is currently due to be published in March 2010.

Ticagrelor for the treatment of acute coronary syndromes (ACS). Technology appraisal due to be issued July 2011.

Guidance on the prevention of cardiovascular disease at the population level. Public health guidance due to be issued in April 2010.

On-going trials

Trial name and contact	Details
The INFUSE - anterior myocardial infarction (AMI) study (NCT00976521)	The primary objective of the study is to demonstrate that among subjects undergoing primary PCI for anterior STEMI treated with a bivalirudin monotherapy anticoagulation strategy, the intracoronary infusion of an abciximab bolus with or without thrombus aspiration prior to stent implantation, compared to no infusion with or without thrombus aspiration (standard of care), results in 1) reduced infarct size measured by cardiac MRI at 30 days (range -7 days/+14 days; i.e., between 23 and 44 days), 2) reduce microvascular obstruction (MVO) by cardiac MRI at 5 + 2 days (i.e., between 3 and 7 days), 3) enhanced ST-segment resolution, 4) improved myocardial perfusion, 5) reduced thrombus burden and angiographic complications, and 6) no increase in major and minor bleeding. Estimated enrolment: 452. Estimated Study Completion Date: May 2012

New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline(R) In-Process and Embase. References from 2007 onwards were reviewed.

Implementation

A submission from Implementation is attached at the end of this paper.

Equality and diversity issues

No equality and diversity issues were identified.

Appraisals comment:

The literature search of this review indentified an ongoing trial that examines different ways of administration of abciximab (if intracoronary bolus administration is superior to intravenous bolus administration). However, the population in this study (CICERO) does not match the population being considered in recommendation 1.7 of the current guidance, and is not considered relevant. Therefore, no significant new data appear to be available that indicate the need for a review of sections 1.7 and 1.8 of the current guidance at this time. No changes have been made to the marketing authorisations for these drugs in this population and no new indications or licence extensions are expected.

Since no new evidence base has emerged, no changes have been made to the marketing authorisations and no new indications or licence extensions are anticipated, it would be appropriate that recommendations 1.7 and 1.8 of the technology appraisal 47 Glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes be transferred to the 'static guidance list'.

Summary

It would be appropriate that recommendations 1.7 and 1.8 of the technology appraisal 47 Glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes be transferred to the 'static guidance list'.

GE paper sign off:

Frances Sutcliffe 11/03/10

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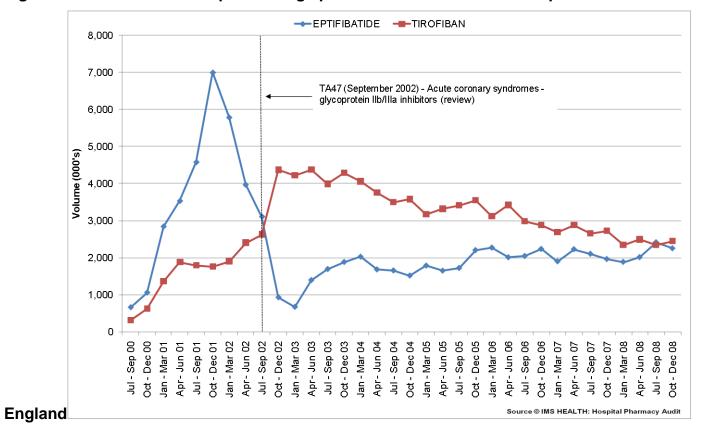
IMPLEMENTATION DIRECTORATE

Guidance Executive Review

Technology appraisal 47: Glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes

1. National Prescribing

1.1 Data showing trends in prescribing costs and volume are presented below. Unfortunately this data does not link to diagnosis so needs to be treated cautiously in relation to the specific recommendations of the guidance. Estimated costs are also calculated by IMS using the drug tariff and other standard price lists. Many hospitals receive discounts from suppliers and this is not reflected in the estimated cost.



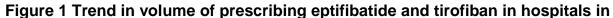
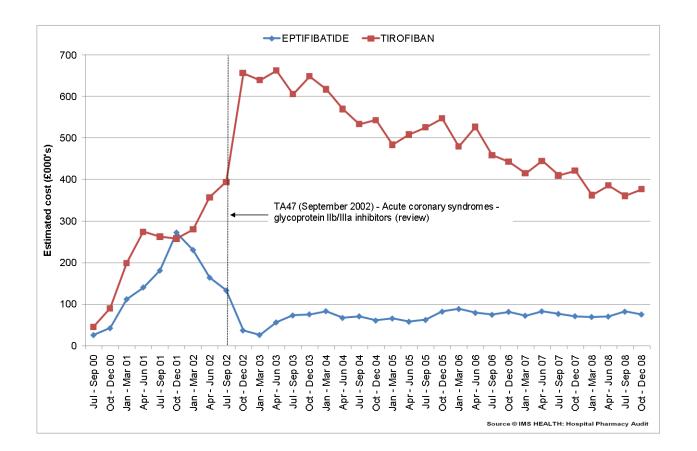


Figure 2 Trend in cost of prescribing eptifibatide and tirofiban in hospitals in England



2. External literature

2.1 ERNIE

The Healthcare Commission (2007) <u>The best medicine: the management of medicines in acute and specialist trusts</u> London: Healthcare Commission

Description: A national review of medicines management in 173 acute and specialist NHS trusts in England. Data from a trust questionnaire as part of this review found that for technology appraisal 47, 92% of organisations treat some patients according to guidance and 69% treat all patients according to the guidance. 89% of trusts have an agreement about funding in place with commissioners and 56% of organisations reported having an audit completed or in progress.

2.1.2 The Information Centre for Health and Social Care (2009) Hospital Prescribing, 2008: England

http://www.ic.nhs.uk/webfiles/publications/Primary%20Care/Prescriptions/hospre08/Hospital_prescribing_2008_report2.pdf

Cost (£000s)	Primary care	% growth primary	FP10HP*	% growth	Hospital	% growth hospital	Total	% grow th total
Eptifibatide	-	-	-	-	296.7	-2.0	296.7	-
Tirofiban	-	-	-	-	1,506.9	-10.9	1,506.9	-10.9

*FP10HP = prescriptions written in hospitals but dispensed in the community

The data shows that all prescribing for Eptifibatide and Tirofiban is carried out in a hospital setting.

2.1.3 Viswanathan G, et al (2009) <u>Guidelines to practice gap in the use of glycoprotein IIB/IIIA inhibitors from ISAR-react to overreact</u> *Journal of Interventional Cardiology* Volume 22, Number 2, April 2009, pp. 163-168(6)

Description: Authors audited use of GPI against NICE guidance. Data was collected from 1,685 patients between Sept-Nov in 2002,2003,2004,2007. In 2007, 44.5% of patients did not receive a GPI as NICE guidelines recommend. The study found a decline in compliance to NICE guidelines on GPI usage