Editorial

Preventive percutaneous coronary intervention and aspiration thrombectomy—updates in the management of ST-elevation myocardial infarction

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Introduction

The management of patients with acute ST-elevation myocardial infarction (STEMI) has undergone change in recent years with associated reductions in mortality (1). The short-term goal of treatment is to restore blood flow to the occluded infarct artery. Prompt percutaneous coronary intervention (PCI) and stenting of the stenosis causing the occlusion reduces the risk of cardiac death and recurrent infarction (2). Recently, the American College of Cardiology and American Heart Association (ACC/AHA) recommended preventive PCI and to stop using aspiration thrombectomy (3).

Preventive PCI

In about half of patients with STEMI, stenoses are identified in non-infarct arteries at the time of PCI (4). In 2013, the ACC/AHA advised that PCI be limited to the infarct artery (5), because of concern that the hazards of PCI in non-infarct arteries may outweigh the benefits. In 2015 this was revised with advice that multivessel (preventive) PCI, be considered either at the time of performing the PCI to the infarct artery or as a planned staged procedure (3)—the same advice that the European Society of Cardiology had given a year before (6).

The 2013 ACC/AHA recommendation was based on non-randomised studies, that are susceptible to selection bias, but the 2015 recommendation was based on randomised trial evidence, that avoids this bias. *Figure 1* is a meta-analysis plot (7) that summarises the non-randomised studies (upper part of *Figure 1*) and the published randomised trials (lower part of *Figure 1*), in which the outcome (death or myocardial infarction) of patients with STEMI and multivessel disease who received preventive PCI was compared with the outcome of patients treated by infarct artery PCI alone. The difference between the non-randomised and randomised summary estimates of effect is striking, indicating the extent of the selection bias affecting the non-randomised studies and demonstrating how such studies can give the wrong answer. The randomised trials published to date (8-12) (two others are in progress) (13,14), show a benefit of preventive PCI; a statistically significant 48% reduction in the risk of cardiac death or myocardial infarction (7). The magnitude of the effect and its consistency across studies suggests the ACC/AHA revision from class III (harm) to IIb (benefit ≥ risk) did not go far enough. Nonetheless, the new ACC/AHA recommendation is a step forward, which if followed, will substantially improve the outcome of patients with this disorder.

Aspiration thrombectomy

STEMI results primarily from sudden-onset coronary artery plaque rupture and occlusion by adherent thrombus (15). Removing thrombus to restore flow and prevent the thrombus from embolising down the coronary artery makes intuitive sense, and several aspiration thrombectomy devices have been developed for this purpose. In 2013, the ACC/AHA recommended that aspiration thrombectomy be performed before balloon/stent insertion, classifying the treatment as class IIa (benefit >> risk) (5), but in 2015 this was downgraded to class III (no benefit) (3). Unlike preventive PCI, the 2013 recommendation was based on

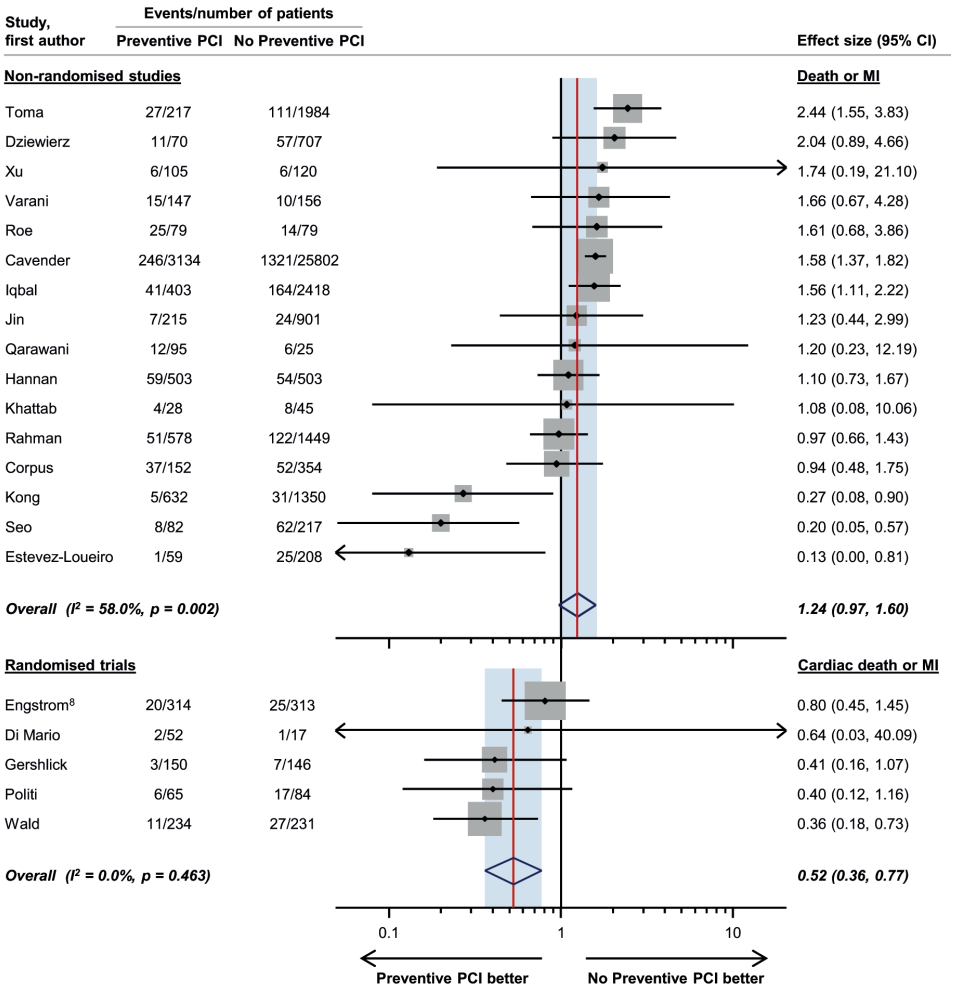

Figure 1 Preventive percutaneous coronary intervention (PCI) versus infarct artery-only PCI—outcomes in non-randomised studies (all-cause death or myocardial infarction) and in randomised trials (cardiac death or myocardial infarction). Meta-analysis based on Wald *et al.* (7), updated to include Engstrom *et al.* (8).

randomized trial evidence, interpreted as showing benefit. The 2015 revision followed two more randomized trials, (16,17) which, taken together with the earlier trials, were interpreted as showing harm. *Figure 2*, shows the randomized trials of aspiration thrombectomy versus no aspiration thrombectomy in patients with STEMI, ranked by the size of effects on death (cardiac death used when available) or myocardial infarction (upper part of *Figure 2*) (16-29). The confidence intervals for every trial except one (25), cross the line of unity, indicating no clear evidence of benefit or harm. The summary estimate [0.88 (0.78–1.00)] is consistent with a borderline significant 12% improvement in outcome from aspiration thrombectomy. However, largely on account of one trial published in 2015 (16), which showed an unexpected increase in the risk of stroke (lower part of *Figure 2*), this modest possible benefit was given little weight because of concerns of harm, and led the ACC/AHA to conclude that "*routine aspiration thrombectomy is not useful*" (3). The word "routine" leaves open the possibility, that in some patients, for example in those with a large thrombus burden and failure to achieve arterial reperfusion with balloon treatment alone, aspiration thrombectomy may still have a clinical role.

With the two recommendations relating to preventive PCI and aspiration thrombectomy, there is an opportunity, to learn from past experience. For preventive PCI, the mistake was to draw a conclusion of harm based on non-randomised studies of treatment, when the potential for

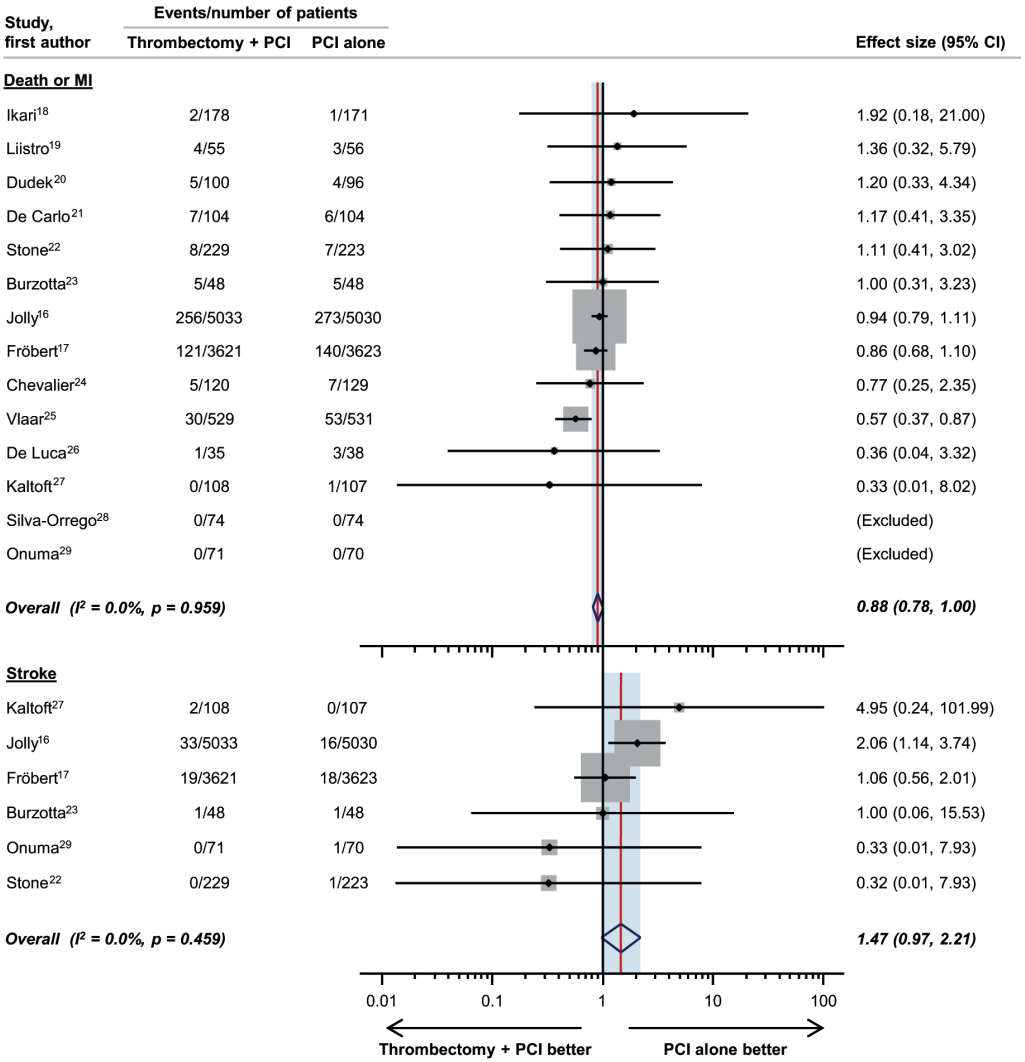

Figure 2 Aspiration thrombectomy versus no aspiration thrombectomy—outcomes in randomized trials (death or cardiac death when reported) or myocardial infarction and stroke.

selection bias made neither a conclusion of benefit nor harm secure. Randomised trials were needed and their primacy exposes the danger of using non-randomised studies to guide practice (7). For aspiration thrombectomy, the randomized trial evidence was available but was inconclusive, showing no clear evidence of benefit or harm, so the practice remains uncertain.

The current ACC/AHA classification system recommending treatments (30) suffers from two limitations. First, it gives similar weight to evidence as consensus, when the latter is a discussion point. Second is the lack of an "uncertain" category, which forces a recommendation of benefit, no benefit or harm when the true position may be unknown. Introducing an uncertain category would avoid this and help focus attention on areas of clinical practice most in need of research.

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Footnote

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Comment on: Levine GN, Bates ER, Blankenship JC, *et al*. 2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. J Am Coll Cardiol 2016;67:1235-50.

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