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ESC guidelines for percutaneous coronary interventions

The guidelines on primary percutaneous coronary intervention (PCI) published in the April issue of the European Heart Journal recommend early PCI for most of the clinical spectrum of acute coronary syndromes (ACSs).¹

In a recent editorial, the issue of thrombolysis vs. primary PCI for ST-elevation myocardial infarction is raised again by Townsend and Doshi.² They suggest adopting a strategy of early, pre-hospital thrombolysis, followed by early PCI.

The merits of early PCI are deemed to be established and are incorporated in recent guidelines from the European Society of Cardiology as well as the American College of Cardiology and the American Heart Association.³⁻⁵

These recommendations are based on meta-analysis of randomized controlled trials and do not incorporate the results from registries reflecting what happens in the 'real world'. Van de Werf *et al.*⁶ reported for the GRACE Investigators on this subject recently. This registry of 28 825 in 14, mostly developed, countries showed that the risk of death at 6 months, and bleeding complications and stroke in hospital, was higher among patients who were admitted first to hospitals with facilities for angioplasty. Although part of the excess risk may be procedure related, the excess mortality at 6 months suggests that other mechanisms may be involved, including under-reported peri-procedural infarcts, which will adversely affect longer term outcome. In their report, they refer to concordant results from other investigators.

Moreover, guidelines recommend that skilled support staff should be available for all such angioplasties.¹ This usually means an experienced cardiac surgeon, cardiac anaesthesiologist, perfusionist, theatre nurses, and other support staff on site, with a theatre available and ready. In the 'real world', this probably does not happen.

Recent reviews of guidelines have not incorporated information from registries reflecting what actually happens when these guidelines are implemented. This information should perhaps influence the revision of guidelines as much as, if not more than, meta-analysis of randomized trials.

CVD will be the leading cause of death worldwide by the year 2020. In the 1999 World Health Report, the then Director General, Gro Harlem Brundtland, states that 'we are halfway through a two century

transition in which CVD will dominate as the major cause of death and disease'.⁷

In the UK, the British Cardiac Society studied the number of PCI procedures needed per million population based on current evidence. The estimate is 2000-3000 procedures per million.⁸

Implementing a strategy of early PCI will carry enormous costs worldwide for decades.

Uncertainties about the consequences of implementing this approach in the real world should be addressed before embarking on such a policy.

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ESC guidelines for percutaneous coronary interventions: reply

The members of the ESC-PCI Guidelines Task Force¹ greatly appreciate the thoughtful comments by Dr Dieker *et al.* and Dr Kholeif.

We are pleased that Dr Dieker agrees with us regarding the comparison between primary PCI and thrombolysis. We also agree that we have to wait for ASSENT-IV, OAT, and APRICOT-3 for further insights into the changing field of optimal STEMI treatment. However, regarding a 'selective' invasive strategy, i.e. in the case of recurrent ischaemia and/or haemodynamic instability, we do not think we differ with the last year's AHA/ACC STEMI guidelines² because we still recommend this strategy at evidence level IB (Table 7, p. 817¹). Our alternative recommendation of a routine coronary angiography after thrombolysis and PCI, if applicable, is not primarily based on 'observational data from registries and subgroup analyses' but rather on four randomized trials (Table 6, p. 817¹). At this point, it is important to emphasize that we followed a general consensus demanding randomized trials with a primary clinical endpoint, adequately powered and reaching its primary endpoint to obtain levels of evidence A or B. As there are two randomized trials (SIAM-III and GRACIA-1) with a primary clinical endpoint adequately powered and with positive results comparing the benefit of early post-thrombolysis PCI vs. a conservative strategy, the level of evidence resulted in an 'A'. For the 'elective' strategy of pre-discharge inducible ischaemia in patients with STEMI after thrombolysis, there is only a single randomized study (DANAMI-1), thus resulting in a level B. The critique of 'clustering' the four studies in Table 6 with a total of 1031 patients is well taken. However, Dr Dieker might consider that DANAMI-1 randomized 1008 patients, a number similar to the one he criticized. Predominantly, on the basis of GRACIA-1, we strongly believe that a routine invasive strategy after thrombolysis implementation in daily clinical practice comes at an adequate point in time and not too early as Dr Dieker suggests.

The other question raised by Dr Dieker requires more clarification. A routine invasive strategy after thrombolysis strategy consists in the use of a routine coronary angiography the next day (within 24 h) with elective (not primary) PCI, even in asymptomatic patients without demonstrable

ischaemia, who received thrombolysis <12 h of STEMI. Therefore, the strategy we recommended differs from the concept of facilitated angioplasty. Facilitated angioplasty is defined as a planned intervention within 12 h after the onset of symptoms, soon after clot dissolving medication to bridge the delay between first medical contact and primary PCI. Our guidelines are indeed the first ones to make the point that thrombolysis is not the final treatment.

Dr Kholeif raises the important question of pre-hospital thrombolysis. The primary task of guidelines is to analyse the existing data, to draw practically oriented conclusions from these trials. Regarding the pre-hospital thrombolysis vs. primary PCI, however, there is only one single randomized trial with a primary clinical endpoint (CAPTIM), with no significant difference between both strategies. Therefore, on the basis of evidence, we could not recommend pre-hospital thrombolysis when primary PCI is available.

We agree that the interpretation of the registries presents a problem. Of course, registries reflect the 'real world' with a large number of patients. However, patients in registries are not randomized and the reported results may reflect the substantial bias of physicians. For example, if the sicker patients were referred for primary PCI and the more stable patients underwent thrombolysis, then the results would be as indicated. Regarding our assertion 'In patients with STEMI, primary PCI

should be the treatment of choice in patients presenting in a hospital with PCI facility and an experienced team' there is a misunderstanding; we did not mean to recommend the presence of an on-site surgery.

Finally, Dr Kholeif raised the old but still important question whether guidelines should fit the available health care system or should the health care system follow the evidence. We are strong advocates of the latter option. For example, we all know the benefit of treatment with beta-blockers in patients with heart failure. However, in clinical practice, beta-blockers are given to only 58% of the patients.³ Does this mean we have to look for another alternative treatment for patients not receiving beta-blockers or is it better to enforce the implementation of guidelines in clinical practice? We assume that primary PCI is not available for all patients in all countries, and we do not doubt that the reperfusion strategy in a patient with non-PCI facilities should be fibrinolysis. However, we must remember that these guidelines are PCI guidelines, and we should insist that nowadays primary PCI is the gold standard of reperfusion in patients with STEMI. So, although we are aware that implementing a strategy of early PCI will carry enormous costs, the consequences of this approach will save lives worldwide. Practical recommendations of how to implement modern STEMI guidelines will be given soon.⁴

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