Devices to protect against embolization during primary angioplasty for ST-segment elevation myocardial infarction: the good, the bad and the ugly

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This editorial refers to ‘Role of adjunctive thrombectomy and embolic protection devices in acute myocardial infarction: a comprehensive meta-analysis of randomized trials’† by A.A. Bavry et al., on page 2989

Primary angioplasty is the established treatment for recanalization of coronary arteries during acute ST-segment elevation myocardial infarction (STEMI). However, due to the large thrombus burden encountered during the procedure, there is a high frequency of distal embolization, which contributes to no-reflow, and reduces the benefit of timely reperfusion. In the past, there have been many attempts to solve this problem by using adjunctive devices to angioplasty and stenting, either thrombus aspiration devices or filters and thrombus retrieval devices. While many clinical trials testing these devices have been performed, they have yielded conflicting results, and most have focused on surrogate endpoints such as electrocardiographic ST-segment resolution, or measurements of various angiographic indices of coronary flow and myocardial perfusion. Bavry et al. have presented a meta-analysis of all randomized trials testing devices to protect against embolization during primary percutaneous coronary intervention (PCI) for STEMI within the first 12 h of symptom onset. They report that the impact of these devices on mortality will vary according to the type of device: while thrombus aspiration devices are associated with an improved mortality [with an NNT (number needed to treat) of 59 to save one life], mechanical thrombectomy devices are associated with a borderline increase in mortality [relative risk (RR) 1.93, 95% confidence interval (CI) 1.00–3.72] at a weighted mean follow-up of 4.6 months, with an NNH (number needed to harm) of 38 patients. Finally, embolic protection devices (occlusive balloons or filters) appear to have neutral effects on mortality. Because this is a moving field, in which many of the trials are of small size, the potential for publication bias is high. The authors performed careful analyses to ensure that their results are not influenced by publication bias, and provided useful sensitivity analyses comparing studies published in full and those only presented in abstract format.

Despite a consistent improvement in surrogate markers of reperfusion, and even though they had recognized the clinical heterogeneity of the adjunctive devices used in primary PCI to prevent distal embolisation, previous meta-analyses on the same topic had not shown a reduction in mortality with protection devices in STEMI.‡ The results of Bavry et al. with adjunctive thrombectomy are consistent with another recent meta-analysis dealing specifically with manual thrombectomy and showing a survival benefit. This is an important finding, because mortality reduction remains the metric by which therapies are judged in STEMI.

Is another trial warranted?
The main difference between the two recent meta-analyses and prior studies is the inclusion of the TAPAS trial. TAPAS is a large single-centre trial which compared a composite of two interventions in primary PCI: thrombus aspiration combined with direct stenting vs pre-dilatation and no thrombus aspiration. Because direct stenting in itself has been reported to improve outcomes, it is important to clarify the role of thrombus aspiration per se. In addition, the total number of patients randomized in all of the trials of thrombus aspiration combined is only 3026. Because the implications for practice are far-ranging, a confirmatory trial is in order, particularly given that an apparent reduction in total mortality of >30% was achieved by use of these devices. While this would require a larger trial than TAPAS, it would still remain much smaller than trials which have been performed to test

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rather minute refinements of the adjunctive pharmacological armamentarium of PCI, with a modest impact on clinical outcomes. Because STEMI is frequent and deadly, any intervention which reduces mortality by >15% is likely to have major public health implications and should be thoroughly tested. Another implication from this analysis will be the need to monitor closely stroke occurrences in patients undergoing primary PCI with or without thrombus aspiration.

In conclusion, Bavry et al. are to be commended for performing this important analysis, which has identified a clinical heterogeneity between devices and strongly suggests that thrombus aspiration systems are (and are so far the only ones) associated with reduced mortality. These observations are credible and have clinical implications: while a confirmatory clinical trial powered for mortality would be welcome (if only to assuage concerns regarding a hypothetically increased risk of stroke), this analysis provides support for the use of these devices in primary PCI and argues against continued use of mechanical retrieval devices. Some emerging devices also deserve further study, such as those combining proximal occlusion with thrombus retrieval, which have shown promising results in angioplasty of saphenous vein grafts and are currently being tested in primary PCI.

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References