Adjunctive Thrombectomy for Primary Percutaneous Coronary Intervention

What Would Dr Bayes Do?

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Prompt and expertly performed primary percutaneous coronary intervention (PCI) has emerged as the preferred therapy for ST-segment–elevation infarction (STEMI). Numerous procedural and technical innovations have contributed to improved results with primary PCI. These include potent adjunctive pharmacotherapy (glycoprotein IIb/IIIa receptor inhibitors, direct thrombin inhibitors, and new thienopyridines), new devices, such as drug-eluting stents and those for hemodynamic support, and new access sites (radial). Despite these innovations, numerous challenges remain, and room for improvement remains. Particularly challenging and frustrating to the operators has been the inability to prevent and treat the no-reflow phenomenon (defined as diminished or absent antegrade coronary flow despite the presence of a patent epicardial artery). Numerous factors can contribute to no reflow because acute myocardial infarction is the end result of complex epicardial, microcirculatory, and myocyte interactions. These factors include macro- or microembolization of thrombus, release of cytokines and vasoactive molecules, and intense microcirculatory spasm. Because thrombus is ubiquitous in STEMI, whether it can be visualized angiographically, numerous mechanical approaches for prevention of no reflow have been tried.

Since the publication of the seminal but negative Enhanced Myocardial Efficacy and Recovery by Aspiration of Liberated Debris trial,¹ interest has shifted to the use of mechanical aspiration devices. These devices, which are intuitively appealing and relatively low cost, are remarkably simple to use in the catheterization laboratory. Numerous randomized trials have been launched to assess the safety and efficacy of these devices, unfortunately, almost all of these have been vastly underpowered to draw clinically relevant conclusions. In this issue of Circulation: Cardiovascular Interventions, Mongeon et al² attempt to rectify this deficiency by performing a Bayesian meta-analysis of the available data. This review will attempt to answer what can be learned from this meta-analysis, how is it best placed in context, and what practical conclusions interventionalists can draw to inform day-to-day practice.

Interventionalists are by now quite familiar with the concept of meta-analysis. Meta-analysis has a number of advantages over the traditional narrative review, including objective combination and appraisal of results of trials meeting inclusion and exclusion criteria, enhancing statistical power to identify treatment effects should they exist, and providing a more precise estimate of these treatment effects (ie, tighter confidence intervals around a weighted average point estimate of effect).³ On the other hand, deciding which trials to include or exclude has an inescapable element of subjectivity and unless a collaborative network exists to access original patient level data, the assessment of end points is limited by what is published in the literature. Rather than the more commonly used frequentist models, Mongeon et al choose a Bayesian probabilistic approach to the combination of trial results. Bayesian probabilistic models have the advantage of incorporating previous knowledge in the form of a prior distribution, which is then modified by the data to form a posterior probability distribution. Results are expressed as a point estimate and 95% credible intervals. Probabilistic models allow for the possibility of estimating how likely one procedure or treatment is superior to another, rather than simply stating the likelihood the observed results occurred by chance. Bayesian credible intervals are usually wider than those of other models.

With that background, let us examine the results of Mongeon et al. The results of 21 individual trials (including 16 with simple aspiration catheters) representing a total of 4299 patients are combined. Although all trials included only STEMI patients, some variability between trials in inclusion and exclusion criteria exists, which is not unexpected. Low information prior probabilities were used, which means that the impact of previous knowledge was minimized—leading one to wonder why a Bayesian approach was selected. Efficacy assessment was limited to 30-day results, reflecting a significant inherent limitation of this type of analysis. Nonetheless, the results are important and significant: use of thrombectomy devices led to large and significant reductions in no-reflow, more ST segment resolution, and better myocardial perfusion. The clinical end points of death, recurrent myocardial infarction, and stroke were not reduced, which likely reflects low statistical power to detect any such differences. The overall number of end points is relatively low and is based on enrollment of relatively low-risk patients (mortality only 3.2% in the largest trial for example), and the very short follow-up period. Both points bear emphasis.
Interventionalists do not treat patients to prevent angiographic end points or to improve 30-day event rates. We treat patients to improve their chances of long-term event-free survival. To assess the effect of thrombectomy on these criteria, we need to look elsewhere.

Two other relevant meta-analyses have also been published recently. The first, by Bavry et al., used classical meta-analytic methods to combine results of 30 trials that enrolled 6415 STEMI patients randomly assigned to an adjunctive device (mechanical or aspiration thrombectomy or a distal protection device) versus no adjunctive device. During a weighted mean follow-up of 5 months, aspiration thrombectomy reduced mortality (2.7% versus 4.4%, \(P=0.018\)) but mechanical thrombectomy and distal protection did not. Mechanical thrombectomy actually seemed to increase mortality in this analysis. The second analysis, by Burzotta et al., was a collaborative effort between 10 principal investigators of 11 of 17 eligible trials who provided patient level abstracted data. The great advantage of this approach is reflected in the 99.6% complete 1-year clinical follow-up of 2686 enrolled patients. In this analysis, thrombectomy was associated with significantly lower mortality at 1 year (log rank \(P=0.049\)) and reduced the combined end point of any death, myocardial infarction, or target vessel revascularization (\(P=0.011\)). This analysis again suggested that the benefit was restricted to simple aspiration devices.

A single trial of 1071 patients, the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction study has reported significant results at 1 year. These experienced investigators from Groningen randomized patients to simple aspiration or none during primary PCI. Follow-up to at least 1 year was available in 99% and demonstrated significant reductions in cardiac death (3.6% versus 6.7%, \(P=0.020\)) as well as cardiac death or myocardial infarction (5.6% versus 9.9%, \(P=0.009\)).

These results allow us to place the observations of Mongeon et al into context. The available data point to certain key concepts—STEMI is an acute on chronic thrombotic disorder, simple aspiration thrombectomy improves short-term angiographic results, and very likely is associated with improvements in clinically important events after 1 year of follow-up. These facts, combined with the ease, rapidity, safety, and relatively low cost of aspiration thrombectomy favor its routine use during primary PCI. Therefore, if Rev Bayes was an interventional cardiologist, would he perform aspiration thrombectomy during primary PCI? My answer is, yes, in “all probability.”

**Disclosures**

None.

**References**


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