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**Editor’s Note**

**High-Risk Medical Devices**

**Why Do We Not Better Understand Effectiveness and Safety?**

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**The intra-aortic balloon pump** (IABP), a mechanical device designed to increase both myocardial perfusion and cardiac output, was pioneered in the 1960s to treat patients in cardiogenic shock. An innovation at the time, the device was made available for use prior to passage of the 1976 Medical Device Amendments, which gave the US Food and Drug Administration (FDA) authority to require evidence of effectiveness and safety for high-risk medical devices before granting market clearance. It is likely that no clinical data were submitted for FDA review prior to market clearance of the IABP. More than 70 000 IABPs are inserted annually in the United States for a broad array of indications including acute coronary syndromes, cardiac surgery, complications of heart failure, and cardiogenic shock. Some estimate that half of all patients hospitalized for acute myocardial infarction (AMI) complicated by cardiogenic shock receive IABP therapy.

The evidence to support IABP therapy has never been as strong as the enthusiasm for its use. In this issue of JAMA Internal Medicine, Ahmad and colleagues systematically reviewed and meta-analyzed the published evidence examining...
ing IABP therapy for AMI treatment and found disappointing results: randomized clinical trials demonstrate no summary evidence of benefit on 30-day mortality risk, regardless of whether the patients have cardiogenic shock. Summarized observational studies similarly demonstrated no benefit.\(^1\)

Another study in this issue by Khera and colleagues\(^2\) suggests that physicians are growing increasingly aware of the limited evidence to support IABP therapy. They analyzed nationally representative administrative claims data from hospitals and found declining use of IABP therapy from 2007 through 2012, particularly among patients hospitalized for AMI with or without cardiogenic shock.\(^3\) Whereas this trend is reassuring, a related trend is disturbing: a 30-fold increase in use of percutaneous ventricular assist devices (PVADs), a mechanical device that provides ventricular support in a manner similar to an IABP.\(^2\)

Although PVADs are designated as a high-risk device that would traditionally require market clearance through the FDA's Premarket Approval pathway, requiring clinical evidence of effectiveness and safety, they received market clearance through the FDA's 510(k) pathway, which does not require clinical evidence of device safety or effectiveness. Instead, manufacturers need only demonstrate that the device is substantially equivalent in materials, purpose, and mechanism of action to another "predicate" device already on the market. The predicate for the PVAD was likely the IABP, as FDA documents can be traced back to the 1978 510(k) clearance of a vascular pump that was considered substantially equivalent to a device already on the market.\(^3\) Whereas some clinical studies have found the hemodynamic parameters of patients receiving PVAD therapy to be superior to those receiving IABP therapy, no benefit has been shown for clinical outcomes such as deaths, AMIs, or strokes.

Both IABP and PVAD therapy are used for critically ill patients with a poor prognosis. Nonetheless, these are expensive, invasive devices that require substantial clinical care and monitoring because of the associated serious safety risks. Despite limited clinical evidence to support their use, these high-risk medical devices have been rapidly adopted into clinical practice. Food and Drug Administration market clearance should require clinical evidence of device safety and effectiveness for all high-risk medical devices to better inform patient and physician decisions before devices are widely adopted. Otherwise, the best we may be able to offer our patients are substantially equivalent treatments of uncertain benefit.

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