The introduction of new technology into the clinical arena mandates a careful balance between the need for prompt, universal access to promising interventions and the recognition that further refinements could still be necessary because the assessment of clinical performance may be incomplete even after initial experimental trials have been concluded. This is the case for devices that have received a seal of approval from the Food and Drug Administration (FDA) or, for that matter, for new procedures that have gained a sufficient degree of legitimacy in the academic literature to drive their adoption by the medical community at large. It has been a little more than 2 years since the first two systems for the endovascular repair of abdominal aortic aneurysms were approved for commercial use by the FDA on the basis of 1-year follow-up data. During the intervening 2 years, more than 20,000 of these devices have been implanted in the United States, despite the fact that implant data exceeding 3 years of follow-up are available for only a few hundred of each of the two proprietary systems. Late complications are now being recognized with increasing frequency, but the extent of these problems and their relationship to device malfunction and deployment, patient selection, or inadequate postoperative surveillance have yet to be fully defined.

In this issue of the Journal of Vascular Surgery, Bernhard et al\(^1\) provide a detailed accounting of the reported cases of aneurysm rupture after endovascular repair with one of the two systems that have received FDA approval. In a careful review of 686 patients treated with Guidant/EVT endografts (Indianapolis, Ind) under FDA protocols, five instances of aneurysm rupture were identified, all of which were associated with first generation tube grafts. Two additional cases of rupture have been documented among a larger cohort of patients in whom Guidant/EVT endografts were implanted after FDA market approval was granted on September 28, 1999. In both cases, the aneurysm was treated with a tube graft, albeit a second generation device in which hook fracture was not a contributing factor. Notably, the authors' analysis of the varying etiologies underlying the clinical failure of endovascular repair is discussed in the context of 40 additional ruptures after implantation of AneuRx, MinTec-Stentor, Talent, Vanguard, or other off-label devices that have been reported in the literature since 1995. As one might expect, most failures were caused by device failure, aneurysm remodeling, and inappropriate patient selection or device deployment, with an overall rupture-associated mortality rate of 50% in the entire collected series. Although aneurysm rupture was most often associated with a type I or type III endoleak, this catastrophic event also occurred among patients who had no discernable endoleak or aneurysm expansion. Thus, in the context of the ongoing debate surrounding endograft efficacy, it is certainly appropriate to question whether, in a large population of treated patients, overall rupture risk can ever be reduced to zero after endografting, even in the framework of a close surveillance program. In certain patient subgroups, such as younger patients who are at low risk for surgical intervention, the mere reduction of the risk for aneurysm rupture in the absence of complete protection may not sufficiently compensate for the acknowledged limitations of open surgical repair.

The article by Bernhard and his colleagues clearly illustrates that the potential for a catastrophe exists after placement of an endovascular graft. Of greater concern, however, is the absence of a true measure of the magnitude of this problem within the larger clinical community. Strictly speaking, it would be premature to conclude that clinical failure of any commercial endograft device has been an infrequent event after its market approval. To date, published estimates of the incidence of aneurysm rupture and open surgical conversion after endograft repair have been largely confined to reports that have originated from FDA-regulated clinical trials or, otherwise, from highly motivated groups of dedicated investigators. In these series, the treating endovascular surgeons have been uniformly well trained and supervised in device deployment, patient selection, and postoperative surveillance. In many cases the clinical sites were subjected to outside monitoring, the collected data were carefully scrutinized, and the reporting of adverse events was mandated. With these conditions, it has been reassuring to note that the annual reported incidence rate of aneurysm rupture generally has been less than 1%.\(^2\)\(^-\)\(^4\) Ultimately, however, the measured impact of device-
related technology is determined by the ease with which it can be safely adopted by a larger set of users in settings that extend well beyond the initial group of clinical investigators.

Postmarket surveillance of adverse events after the adoption of any new technology by the broader clinical community is far less rigorous than in a clinical trial, and the potential for underreporting device-related or procedure-related complications remains a substantial problem. This may be attributed to a number of reasons, such as concerns over medical liability, personal embarrassment regarding an adverse outcome, and perhaps in no small measure, the burden of appropriately collecting and reporting the requisite data. Nonetheless, the recognition and timely determination of the prevalence of adverse events—whether aneurysm rupture, elective conversion, or the necessity for a secondary intervention—provide the primary mechanisms for both the medical community and industry to rapidly address correctable device-related and procedure-related problems and, if necessary, to remove truly poor devices from the marketplace.

Problems with coronary stents, heart valves, artificial hips, and antiarrhythmia devices existed long before the introduction of endovascular grafts, so the need to monitor existing and newly released devices in the clinical community has been recognized for some time. In the United States, manufacturers and healthcare facilities are required to report all known device-related complications to the FDA; however, physicians are under no such obligation, and all of their reporting is voluntary. In an attempt to encourage the submission of relevant data, the FDA has created a safety information and adverse event-reporting program for drugs and devices known as MedWatch (www.fda.gov/medwatch), which is available to capture device-related or procedure-related problems. In this context, recent efforts by the Lifeline Registry of Endovascular Aneurysm Repair to initiate a pilot program for online collecting of postmarket data should be applauded, and efforts to expand and coordinate this program with the FDA should be encouraged. There is an obvious need for a universal registry to collect surveillance data to improve patient management through rapid access to postmarketing outcomes and to identify the inappropriate use of off-label devices. Moreover, the development of this kind of clinical registry potentially could shorten the review period of an investigational device by providing additional information concerning the community-based performance of similar or previous versions of the device and by persuading the FDA that there is a mechanism for vigilance once such a product enters the marketplace. In the absence of a system to ensure accurate and complete reporting that extends beyond a few academic medical centers, the potential exists that clinical recommendations will be based, at least in part, on the principles of “hear no evil, see no evil, and speak no evil.” As vascular surgeons, we must ensure that all blinders are removed as we continue to drive along the endovascular highway, for by having the clearest view of the road ahead will we provide the greatest service to our patients.

REFERENCES


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Please see the related article by Dr Victor M. Bernhard et al on pages 1155-62.