the aneurysm wall to remain intact, and so the absence of rupture in EVAR patients, particularly those with small aneurysms, does not necessarily reflect graft durability or effectiveness. Reports of loss of the survival advantage conferred by EVAR when compared with open repair after 1 year of follow-up,4 as well as the present study’s finding that preoperative aneurysm size was predictive of rupture after EVAR, do not equate with graft durability. Indeed, stent fractures have been reported in 71% of for-cause explanted grafts and in 31% of incidentally explanted grafts.5

Although the need for secondary intervention in 18.28% of EVAR patients reflects on the effectiveness of the grafts, as well as on the skill required for their successful deployment, late secondary intervention in 2.7% of EVAR patients must be assumed to relate to stent graft failure over time, unless the authors state otherwise. This is at least as relevant a measure of graft durability as freedom from rupture. Eighteen aneurysm ruptures were reported in the EVAR group, and 8 aneurysm-related deaths were reported between years 1 and 6. A total of 34% of the EVAR group died during 5 years of follow-up, and further information on causes of death would be of interest. Classification of cause of death as verified, probable, or indeterminate, as recommended by reporting standards for aortic EVAR,6 is not provided.

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REFERENCES

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Reply

Dr Manning takes issue with our conclusion that endovascular aneurysm repair (EVAR) is an effective and durable treatment of infrarenal aortic aneurysms because the conclusion is based on a low aneurysm rupture and aneurysm-related death rate and a low surgical conversion rate. However, prevention of aneurysm rupture and death from rupture is precisely why aortic aneurysms are treated. Therefore, the effectiveness and durability of EVAR in achieving these objectives must be viewed as the primary outcome measures. The Lifeline Registry data show that EVAR was effective in preventing aneurysm rupture in 99% of patients over a 6-year follow-up period. Similarly, EVAR was effective in preventing aneurysm-related death in 98% of patients, with no diminution of effectiveness over the 6-year follow-up period. Although avoiding “surgical conversion”—or open surgical repair—is not a primary objective of aneurysm treatment per se, it is an objective of EVAR. Thus, the low surgical conversion rate reported by the Lifeline Registry must be viewed as evidence of the effectiveness and durability of EVAR in achieving the objective of avoiding open surgical repair. In this regard, it should be noted that the surveillance strategy for small aneurysms to which Dr Manning refers was not entirely effective in preventing aneurysm rupture and death, because 1% of small aneurysms ruptured each year despite close surveillance and early treatment, if needed. Furthermore, the mortality rate for rupture was very high (90%): 11% of all deaths in the surveillance group were due to aneurysm rupture. Surveillance also was not a durable strategy in the UK small aneurysm trial, because 74% of patients in the surveillance group were treated with open surgery over an 8-year follow-up period.

With regard to reports of a loss of EVAR’s early survival advantage over open surgery after 1 year, no information on graft durability was provided.5 Indeed, the use of all-cause mortality as the primary endpoint in these trials may obscure information related to the long-term durability of each aneurysm treatment strategy, because most deaths were due to non–aneurysm-related causes. In the prospective, randomized EVAR-1 trial, the reduction in the aneurysm-related death rate after EVAR (4%) remained lower than that after open surgery (7%) at 4 years (P = .04).4 Similarly, there was a persistent low aneurysm-related death rate after EVAR in the Lifeline Registry (2% at 6 years). The threefold reduction in perioperative mortality which was demonstrated in the prospective randomized trials,2-3 along with the reduced morbidity and more rapid recovery after EVAR, is a significant advantage to the patient despite subsequent late death from unrelated causes.

The Lifeline Registry report was focused on the primary outcome measures of EVAR as a treatment strategy and not on the specifics of individual device durability. As Dr Manning indicates, adverse events and endograft device failures can occur after EVAR. After 5 years, 22% of patients in the Lifeline Registry had undergone a secondary interventional procedure, and 5% had undergone surgical conversion. Nonetheless, the long-term primary outcome measures remained stable, with no suggestion of an increasing aneurysm rupture or aneurysm-related death rate over time, and open surgical repair had been avoided in 95% of patients. Thus, EVAR can be viewed as an effective and durable treatment strategy, within the 6-year time frame of the study, provided that patients are monitored and secondary treatments are performed when needed.

Christopher K. Zarins, MD, on behalf of the Lifeline Registry of EVAR Publications Committee

REFERENCES