

## EDITORIAL COMMENT

# Endovascular Aneurysm Repair With the AneuRx Stent-Graft Is Safe, But Is it Effective?\*

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In this issue of the *Journal*, Howell et al. (1) present some truly remarkable results. Working in an interventional cardiology suite, they were able to implant the Medtronic AneuRx stent graft in all but one of 215 patients. Most of these patients had major comorbidity with an American Society of Anesthesiologists grade of IV or higher in 58.6% of patients. All these sick patients underwent stent-graft implantation under general anesthesia, yet only one patient suffered a non-Q-wave myocardial infarction, none died in the perioperative period, and most went home the next day.

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One notable aspect of the technique described by Howell et al. (1) is the use of the Prostar XL device to facilitate percutaneous arterial closure. The 16F contralateral access site was closed this way in 174 of 188 attempts, and the 22F ipsilateral access site was closed in 26 of 27 attempts. Few centers have achieved such a high rate of success with percutaneous arterial insertion of large-bore sheaths. Indeed, one wonders, given their results, why Howell et al. (1) did not attempt totally percutaneous repair in more cases.

Based on these results, one can certainly say endovascular aneurysm repair with the AneuRx device was safe, but one cannot say it was effective. The efficacy of endovascular aneurysm repair is usually assessed by the number of endoleaks (types 1 and 3), the rate of diameter change, and the incidence of rupture.

In the report by Howell et al. (1), the data on early endoleak are marred by a reliance on intraoperative angiography. Most of the patients in their study (1) had contrast-enhanced computed tomography (CT) prior to discharge from the hospital and again one month later, yet these data are not presented. Nevertheless, the rate of endoleak is close to the rate seen in multicenter studies of the AneuRx device. For example, the core laboratory data for the Food and Drug Administration (FDA) study (2) show an early endoleak rate of 50%. Most of these leaks are designated type IV based on their diffuse appearance. This type of endoleak, through tiny holes in the fabric, is often assumed to be self-limited and of no significance, an assumption that may

be ill founded. Holes in the fabric can transmit pressure to the aneurysm, even when they are small and plugged with thrombus. In my opinion, the porosity of the AneuRx graft accounts for the lower rate of aneurysm shrinkage relative to the rate seen with less porous stent grafts, such as the Guidant Ancure device (3).

The high rate of late rupture following endovascular aneurysm repair with the AneuRx device is a particular cause for concern (4,5). If one excludes the cases of perioperative rupture, the mean time to rupture of published cases was almost two years (4). Howell et al. (1) are not in the position to assess this aspect of device performance, because only 22 of their 214 patients were followed longer than two years. According to a recent health care advisory, the FDA has information on 25 cases of late rupture. This is a small number relative to the total number of devices inserted, but more worrisome when considered as a proportion of the small number of long-term implants.

The AneuRx device is not the only one associated with a high incidence of late rupture. Worldwide, even more cases of rupture followed repair with the Vanguard device. It is instructive to remember that the Vanguard, and its precursor the Stentor, looked very promising in the short-to-medium term (6), and by the time that problems became apparent, many patients had been treated. Other devices are less prone to late aneurysm rupture. For example, not a single case of late rupture has been reported following treatment with an Ancure bifurcated stent graft.

Reports of fabric tears, stent fractures, component separation, and migration are also worrisome. A recent study from Italy (7) showed migration of 10 mm or more in approximately 27% of AneuRx cases at three years. The corresponding incidence for the Ancure device was 0.5% (8).

In conclusion, every aspect of stent-graft function is device specific. Some devices are stable and effective, but others are not. The excellent results reported by Howell et al. (1) show that the AneuRx device can be safely implanted in an interventional suite. In two more years they will have the data to show whether or not this operation provided durable protection from aneurysm rupture.

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