

COMMENTS

The limits of endovascular aortic aneurysm repair

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Open surgical repair is highly successful in preventing aneurysm rupture but is associated with a significant morbidity and mortality rate. Endovascular aneurysm repair can greatly reduce perioperative morbidity and quickly return patients to normal function. However, the efficacy of endovascular aneurysm repair in altering the natural history of aneurysms and in preventing death from aneurysm rupture is not yet known. The case reported in this issue of the *Journal of Vascular Surgery*¹ highlights a number of important issues and provides some important lessons related to endovascular aneurysm repair.

COMMENTS REGARDING THE CASE REPORT

The patient had an asymptomatic 7-cm aortic aneurysm and was considered to be at high risk for aneurysm rupture on the basis of the size of the aneurysm. He was a suitable candidate for endovascular aneurysm repair, and this was successfully accomplished with a bifurcated endovascular graft. The aneurysm was completely excluded from the circulation, and there was no evidence of perigraft flow in the aneurysm sac at 2 days, 1 month, 3 months, and 6 months after the procedure. This initial excellent result, however, was not maintained because after 9 months an endoleak was discovered for the first time on helical computed tomographic angiography and color duplex ultrasound scan. There was no change in aneurysm size, and the patient was asymptomatic. Given this situation, the authors prudently decided to perform an angiogram to evaluate the new endoleak. Unfortunately, they

focused their efforts on investigating the lumbar arteries by selective angiography of the internal iliac arteries in hopes of coil embolization rather than specifically evaluating the stent graft itself and its attachment sites to the aorta and iliac arteries.

Three months later, 1 year after endovascular repair, the endoleak was considerably larger and the aneurysm had enlarged to 8 cm. Angiographic results at this time revealed a 9-mm tear in the polyester graft caused by erosion of the graft fabric by a moving, angulated stent strut. In retrospect, graft erosion surely was present, albeit smaller, 3 months earlier when the new onset endoleak was discovered. The fact that the aneurysm had enlarged 1 cm in a 3-month period and now measured 8 cm in diameter placed the patient at a particularly high risk for rupture. At this point, open surgical repair of the aneurysm was indicated, in my view, particularly because there was evidence of disruption of the integrity of the stent graft, the patient had no prohibitive medical risk, and the aneurysm was large and enlarging.

Nonetheless, it was decided to persist with endovascular strategies, thus testing the limits of this approach. A second endovascular stent graft (tube graft) of the same design was inserted within the body of the previously placed bifurcated stent graft. This reduced the size of the endoleak but did not eliminate it. Further efforts at coil embolization of lumbar arteries 1 month later similarly were not successful in sealing the endoleak. Systemic pressure and blood flow continued in the aneurysm sac, which continued to enlarge and did eventually rupture.

That endovascular efforts to secondarily treat the new onset endoleak failed is not surprising. The Vanguard (Boston Scientific, Natick, Mass) bifurcated endovascular aortic graft used in this patient consists of a self-expanding nitinol stent framework within a synthetic polyester graft. The individual nitinol stent bodies are joined together end to end with numerous separate polypropylene sutures, but the stent framework is not attached to the polyester graft except at the ends of the stent graft. If the sutures break, the stent bodies can move in relation to one another within the polyester graft. The stents are on the inside of

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the graft, so it is highly unlikely that placement of a new endograft within the disrupted device could be effective because freely moving stent bodies would occupy the space between the new polyester graft and the perforation in the original polyester graft, thus preventing a seal. Indeed, in this patient, the new stent graft served to reduce the size of the endoleak but was not effective in sealing it.

Persistence in applying secondary and tertiary endovascular treatments after an unsuccessful endovascular aneurysm repair often is the result of a common misperception regarding the end point of endovascular aneurysm repair. The misconception here is that the objective or end point of endovascular repair is to prevent or correct endoleak. Rather, the primary objective is to prevent enlargement and rupture of the aneurysm. The presence or absence of an endoleak is a poor predictor of subsequent events, as is well demonstrated by this case. Efforts at coil embolization in this patient may have diverted attention from the clear fact that the aneurysm was large and enlarging and that there was a hole in the polyester graft. Reduction in the demonstrated size of the endoleak may have led to a false sense of security, which allowed the aneurysm to continue to enlarge and ultimately rupture.

The natural history of aneurysm repair is to enlarge and rupture with the risk for rupture increasing greatly with increasing size. It is remarkable that this patient did not rupture his aneurysm for 11 months after it was discovered that a new endoleak had developed. During that period of time, the aneurysm increased from 7 to 10 cm. There was ample time to electively repair the aneurysm before rupture. Furthermore, when the aneurysm ruptured, the leak was small and the patient's condition was hemodynamically stable, which allowed successful surgical repair. This may be caused by the fact that the stent graft being in place in the aorta may have prevented a large exsanguinating hole in the aorta, allowing flow only through a small endoleak or inadequate seal. Thus, although the endograft did not ultimately prevent aneurysm rupture, perhaps, at least in this case, it served to prevent death from rupture and allowed time for surgical repair.

GENERAL COMMENTS

Endovascular stent grafts are new devices of various designs, and all potential failure modes are not yet known. Suture breakage in the Vanguard graft has been noted in the past, and graft erosion, such as was seen in this case, has been reported in six patients with the Vanguard stent graft.¹

This problem may be specific to this particular device and may not apply to other stent grafts with different structures and designs. A not dissimilar technical problem occurred in the clinical investigation of the Endovascular Technologies endograft when fractures of metallic struts were discovered.² This problem was corrected by the manufacturer, and no further strut fractures have been reported. One might anticipate that modification of device design of the Vanguard graft will eliminate the potential for suture breakage that could lead to graft erosion. The technical difficulties of some endograft device designs do not negate the overall value of endovascular aneurysm repair. The clinical benefit of a significant reduction in the morbidity rate associated with aneurysm repair will stimulate refinement of manufactured devices and eliminate or minimize technical failures. This case, however, serves as a warning that patients who undergo endovascular aneurysm repair should be followed closely and should undergo treatment according to normal surgical standards, with evaluation of risk of rupture compared with the risk of operation. Device manufacturers must evaluate and reevaluate structure and design of their products to ensure device integrity.

The availability of endovascular stent grafts will enhance our ability to treat patients with aortic aneurysms with improved safety and broader applicability to elderly patients with significant medical comorbidities. However, endovascular stent grafts should not be viewed as the only treatment strategy and should not cloud good surgical judgement. Although "conversion" to open surgical repair is reported as a primary indicator of failure of endovascular aneurysm repair, it should be remembered that the primary end point in the treatment of aneurysms is to prevent rupture. Misguided efforts aimed at avoiding surgical conversion, deferring needed open repair, or reserving surgical repair to only those patients with aneurysm rupture will have an adverse impact on patient care.

A number of lessons can be learned from this experience and other experiences. First, the absence of an endoleak after successful endovascular aneurysm repair does not guarantee continued long-term success. All patients who have undergone endovascular repair should undergo continued close follow-up and aortic imaging. Second, the development of a new endoleak, months after successful repair, should be suspected to have a significant problem that needs further investigation. The structure and design of the endograft should be well understood, and secondary treatments should be made on the basis of correcting

the problem, not eliminating radiographic evidence of endoleak. Finally, the limits of endovascular aneurysm repair must be guided by good judgement, not by the technical capabilities of administering catheter-based treatments. This judgment must be made on the basis of an understanding of the natural history and risk of rupture of aneurysms, surgical experience, and clinical wisdom. The endovascular device failure in this case is an issue for the manufacturer. The patient treatment failure and aneurysm rupture is an issue for the treating physicians.

REFERENCES

1. Krohg-Sørensen K, Brekke M, Drolsum A, Kvernebo K. Periprosthetic leak and rupture after endovascular repair of abdominal aortic aneurysm: the significance of device design for long-term results. *J Vasc Surg* 1999;29:1152-8.
2. Moore WS, Rutherford RB. Transfemoral endovascular repair of abdominal aortic aneurysm: results of the North American EVT phase 1 trial. *J Vasc Surg* 1996;23:543-53.

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