Late abdominal aortic aneurysm rupture after AneuRx repair: A report of three cases

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Rupture due to device failure and/or endoleak is the most feared complication of endoluminal grafting for exclusion of abdominal aortic aneurysm. We present three previously unreported cases of abdominal aortic aneurysm rupture 23 months after AneuRx "repair" and describe the mechanisms of failure and discuss instructive technical aspects of their management. (J Vasc Surg 2000;31:599-606.)

Prevention of rupture of abdominal aortic aneurysm (AAA), with its attendant morbidity and mortality, is the primary driving force behind elective aneurysm repair. Since the first report of endovascular repair of AAA by Dr Juan Parodi and Dr Julio Palmaz, there has been a steadily escalating interest in endoluminal grafting for exclusion of aneurysms. In spite of improved results with open AAA repair and an overall mortality close to 3% in elective cases, the potential for lower morbidity and mortality, shorter hospital stays, lower costs, and an earlier return to normal activity has resulted in endoluminal repair being pursued with increasing enthusiasm. This approach has gained significant acceptance in the academic community despite relatively short follow-up data from clinical trials. Recently, the Ancure (Guidant Corporation, Menlo Park, Calif) and AneuRx (Medtronic, Sunnyvale, Calif) devices received approval by the Food and Drug Administration (FDA). In 405 cases of successful implantation, two cases of rupture, one on day 1 and one at 14 months, were reported at recent FDA hearings leading to the approval of the AneuRx device. We report three new cases of AAA rupture in patients previously treated with the AneuRx device. All aneurysm ruptures occurred essentially two years after implantation.

CASE REPORT

Patient 1. M. O. H. was an 87-year-old man with a positive history of coronary disease, congestive heart failure, cerebrovascular accident, and hypertension; at 85 years of age, he was referred for endoluminal repair because of an asymptomatic 8.5-cm AAA. The aneurysm was repaired at the Arizona Heart Institute in Phoenix through the deployment of a 28 × 15-mm AneuRx device with a 14-mm contralateral limb. The procedure was complicated by left iliac dissection requiring deployment of a Symphony stent (Boston Scientific Corporation, Watertown, Mass) to maintain limb patency. No endoleak was observed on a completion angiogram. Seven months postoperatively, the patient had a follow-up duplex scan and contrast computed tomography (CT) that demonstrated no endoleak and an aneurysm shrinkage from 8.5 to 6.5 cm. The details of follow-up studies between 7 and 23 months are unknown to us. The patient was seen at Seton Northwest Medical Center 23 months after endograft repair with abdominal and back pain. On admission, blood pressure was 87/60 mm Hg. A noncontrast CT scan demonstrated a large retroperitoneal hematoma with an 8-cm AAA (Fig 1). Contrast was not given because of a creatinine level greater than 2.0 mg/100 mL. The patient was taken promptly to the operating room for repair of an obviously ruptured aneurysm. The operation was technically difficult and resulted in 6 L of blood loss. The abdomen was opened through a long midline incision. A small amount of free peritoneal blood and a large retroperitoneal hematoma were encountered. The iliac arteries were dissected and clamped. A Crawford clamp was positioned at the supraceliac aorta. The retroperitoneum was opened, the aorta was isolated, and an infrarenal aortic clamp was placed. The aneurysm had ruptured anteriorly near the site of the modular junction. When the aneurysm was opened longitudinally, the main body of the endograft was encased by firm, organized, intraluminal thrombus; however, there was fresh thrombus overlying the modular junction. Beneath this fresh thrombus was the left...
teric artery (IMA), or other collateral vessels were incorporated and secure. No patent lumbar, inferior mesenteric artery; therefore, supraceliac crossclamping was readily obtained because of a low, large superior mesenteric surface. A separate length of a Dacron graft with a fluorofluoroprene felt covering the entire anterior and lateral surfaces. A separate length of a Dacron graft with a 6-mm diameter was interposed between the bifurcation limb and the left hypogastric artery to provide pelvic outflow, because a long iliac stent trapped its orifice. At the completion of the procedure, the hemodynamics were improved with a systolic blood pressure in the range of 120 mm Hg; there was adequate urine output and no evidence of coagulopathy. The operative time was 4 hours. Use of the cell-saver allowed return of 2500 cc of the patient’s red blood cells.

Postoperative evaluation of plain abdominal radiographs shows angulation of the graft in the lateral view (Fig 3). The anteroposterior (AP) view shows that the limb markers have migrated out of the main body, and a small area now lacks fabric overlap, signaling Type III endoleak (Fig 4). The degree of endograft angulation and the significance of the limb markers were not appreciated until comparison was made with the ex vivo specimen. Subsequent ex vivo dissection of the graft from the aortic thrombus confirmed graft limb migration and lack of fabric overlap (Fig 2, B). The patient developed acute renal and pulmonary insufficiency on day 2 and died 10 days after operation of multisystem organ failure.

**Patient 2** R. S. is a 72-year-old man with a medical history reflecting no serious comorbidities who underwent treatment of a 5-cm asymptomatic aneurysm with an AneuRx device at St Vincent’s Hospital in Indianapolis in April 1997 (Fig 5, A). The operative note of that procedure did not indicate the size of the device implanted. A proximal aortic extender, as well as two distal iliac extenders into the external iliac arteries, was required for complete obliteration of all endoleaks. Extenders are modular stent graft components. The patient’s 1-year follow-up CT scan showed the device to be positioned properly without the presence of endoleaks. There appeared to be no decrease in the size of the aneurysm (Fig 5, B). Eleven months later (23 months after implantation), the patient was seen at Bloomington Hospital in Bloomington, Ind, with a ruptured AAA. His vital signs on presentation to the emergency department were stable (blood pressure, 125/76 mm Hg; heart rate, 88 beats per minute [bpm]). A preoperative CT scan demonstrated a large retroperitoneal rupture in addition to an increase in the size of the aneurysm to 7.5 cm (Fig 5, C). The patient became unstable. His blood pressure dropped to 80/30 mm Hg, and his heart rate rose to 122 bpm. He was taken immediately to the operating room.

The aneurysm was approached through a midline incision. There was blood in the peritoneal cavity and a large retroperitoneal hematoma. Finger dissection in the vicinity of the renal arteries allowed palpation of the device. This served as a guide to the renal arteries and helped avoid injury to the left renal vein. A clamp was placed immediately distal to the renal arteries, a few millimeters above the proximal aortic extender. The patient remained hypotensive, and Fogarty clamps were placed on both common iliac arteries to obtain rapid distal control, even though they contained the stented limbs of the graft. The patient’s hemodynamics improved with proximal and distal vascular control and volume resuscitation. The aneurysm was opened, and the main body appeared to have become separated from the aortic extender. This extender was itself well incorporated into the aortic wall. This separation and a resultant endoleak are presumed to have resulted in the aneurysm rupture. The site of rupture was on the left posterolateral aortic wall, immediately above the bifurcation. The extender was secured with a hemostat, and torque was applied circumferentially before pulling caudal. The proximal extender was removed without resultant injury to the aortic wall. In fact, the aortic cuff used for constructing the proximal anastomosis incor-
incorporated 3 to 4 mm of aortic tissue previously covered by the proximal stent graft.

Both limbs of the stent graft were exposed intraluminally and transected with wire cutters. Care was taken not to fray the fabric. After removal of the distal vascular clamps, a no. 4 Fogarty balloon catheter was passed distally through the transected stent into the left iliac artery. There was no resistance to passage of the balloon as it traversed the metal stent, which had impressively restored its luminal configuration despite the previous application of a Fogarty clamp. After bilateral lower extremity thrombectomy through each iliac stent graft, a bifurcated Dacron graft, measuring 20 × 10 mm, was used for aortic reconstruction. The graft was anastomosed to the infrarenal aorta and to both limbs of the transected stent graft, which appeared well incorporated and secure in the iliac vessels. The distal anastomoses incorporated the iliac arterial walls as well as the stent graft, with its external support left intact. This choice of graft size resulted in the best size match to the iliac stent grafts and proximal neck. The operative time was 1 hour and 55 minutes. The use of the cell-saver allowed return of 750 cc of the patient’s red blood cells.

Postoperatively, the patient had atrial fibrillation requiring intravenous antiarrhythmic agents and eventual conversion to oral medications. He was discharged home in 12 days with palpable pedal pulses. He continues to do well, walking without claudication at 6-month follow-up. A CT scan shows an intact aneurysm repair without evidence of leakage or angulation at the distal anastomotic sites that incorporate residual segments of the stent graft (Fig 5, D).

**Fig 2.** Explanted AneuRx device with ex vivo dissection. **A,** Penmarks indicate anatomic endograft orientation. White paper insert demonstrates disengaged left iliac limb. **B,** Enlarged view of disengaged limb shows lack of fabric overlap of graft components. Note the acute fresh thrombus overlying the graft separation zone. This is the site of acquired Type III endoleak. White paper insert contrasts the stent graft fabric and surrounding thrombus.
Patient 3. H. G. was an 83-year-old man with a past medical history significant for chronic obstructive pulmonary disease, hypertension, hypothyroidism, and alcohol abuse who underwent AneuRx repair of his AAA at Harbor-UCLA in Torrance, Calif, approximately 23 months before the present admission. The repair was complicated by postoperative Type II endoleak from an accessory left renal artery. Follow-up studies showed persistence of this leak with outflow provided by a patent right lumbar artery (R. A. White, verbal communication, October 1999). A laparoscopic approach to ligation of the accessory renal artery was considered and offered to the patient; however, he refused further surgical or radiologic attempts to treat his endoleak. The patient went to the emergency department of South Austin Hospital with severe abdominal and back pain and a systolic blood pressure of 76 mm Hg. A CT scan of the abdomen was obtained while the vascular surgeon was en route. This scan demonstrated a large AAA whose precise dimensions were obscured by the extensive retroperitoneal hematoma and contrast extravasation into the abdomen (Fig 6). He was taken immediately to the operating room and explored through a midline incision. There was a small amount of free blood within the peritoneal cavity, and a large retroperitoneal hematoma was encountered. The aorta was clamped at the supraceliac level, and the iliac arteries were clamped distal to the easily palpable endograft. The site of aneurysm rupture appeared to be on the anterior surface. The aneurysm sac was opened and very loose; poorly organized thrombus was found and removed. Although the endograft components were appropriately coupled, manipulation of the device within the aneurysm sac produced separation of the contralateral limb from the body of the graft. The body of the graft, including stent and fabric, was incised vertically with Mayo scissors to the renal arteries. The entire stent graft was
removed easily, although it was well incorporated proximally and distally. A large right inferior lumbar artery showed significant backbleeding and was suture ligated. An identifiable accessory renal artery was not found, but incorporation of a small collateral vessel into the proximal anastomosis cannot be excluded or verified with certainty. A bifurcated 14 × 7-mm Dacron graft was anastomosed proximally to the aorta at the renal artery level and to the common iliac arteries distally. A strip of polytetrafluoroethylene felt was used to reinforce the anterior wall of the proximal anastomosis. The patient bled diffusely as a result of multifactorial coagulopathy characterized by hypothermia, thrombocytopenia, and simple dilution of coagulation factors from severe blood loss and large volume transfusion. He required more than 25 units of blood and blood products intraoperatively, including 15 units of packed red blood cells, 10 units of fresh frozen plasma, platelets, and cryoprecipitate. This combination returned his coagulation status to normal levels within the parameters of prothrombin time, partial thromboplastin time, platelet count, and fibrinogen level. The use of the cell-saver allowed the return of 2100 cc of the patient’s red blood cells. The operative time was 2 hours and 45 minutes. The patient also required large volumes of intravenous fluids postoperatively, but he eventually stabilized at 36 hours. On day 3, he became hypotensive and hypoxic and became increasingly difficult to oxygenate despite appropriate mechanical ventilation. The refractory hypoxemia was suggestive of a right-to-left shunt, and an echocardiogram confirmed an atrioseptal defect. Arterial blood gases showed hypoxemia without carbon dioxide retention or acidosis. The patient was also leukopenic and thrombocytopenic. In spite of heightened intensive care, he deteriorated steadily and died within 2 hours of respiratory failure. In addition to adult respiratory distress syndrome, pulmonary embolus, pneumonia, and sepsis were considered as possible causes for his abrupt deterioration. Permission to perform an autopsy was declined.
DISCUSSION

The current debate over open surgical versus endoluminal treatment of AAA is beyond the scope of these case reports. There is considerable controversy over whether the latter approach will truly reduce morbidity and mortality or whether shorter hospital stays and a quicker return to normal activity are the only advantages of this technique. The literature is replete with reports documenting the equivalency of endograft therapy to the standard approach. However, long-term outcome data are lacking, and durability has not yet been demonstrated.\(^5\) May et al\(^6\) reported a 3-year success rate of only 70% as defined by continuing graft function without endoleak or conversion to open repair, and Walker et al\(^7\) reported a disappointing 11.3% 30-day mortality rate for aortic endografting in 221 patients. Investigators are currently debating the importance of device design, attachment stability in the face of aortic wall evolution and remodeling, endoleaks and their potential for calamity or closure, associated costs, and many other issues that would only serve to detract from the clinical focus of this paper if discussed here. This report is intended to contribute to the awareness of late aneurysm rupture after implantation of the AneuRx device, its possible mechanisms, and the lessons learned in management of this disastrous complication.

Incidence of AAA rupture after AneuRx endograft placement. The initial report of the phase II US AneuRx trial mentioned no ruptures.\(^8\) This position was held until April 1999.\(^9\) However, in June 1999, FDA hearing transcripts indicate that two ruptures were reported and discussed.\(^4\) One occurred at 24 hours and was believed to represent delayed recognition of an operative catheter injury. The second one occurred at 14 months after a 12-month follow-up duplex scan showed resolution of a persistent endoleak seen on a 6-month CT scan. The 0.5% incidence (2/ 405) was considered low when compared with the natural history of the disease. We now report three other late ruptures occurring in a relatively short period. All ruptures were beyond 23 months, but none had reached the 24-month mark after implantation. All have been reported to the manufacturer. At a recent meeting, Dr Zarins disclosed that nine ruptures are now known to have occurred.\(^10\) These data have not yet been published. We presume this number includes these three cases because all of the implanting physicians were notified of the ruptures and each was an investigator in the clinical trials. Also, all devices were returned to the company for evaluation. Again, an incidence of 0.5% was projected and not considered high when viewed against the natural history of the disease, not the natural history of standard surgical repair. However, this number of ruptures surfacing in only 6 months (June-November) is worrisome, particularly because the ruptures are occurring late. Patients 1 and 2 reported here had follow-up radiologic studies that showed no evidence of endoleak and showed either AAA size reduction or no enlargement. Rupture, in spite of such encouraging follow-up, has been reported by other authors.\(^11\) Late rupture clearly argues for routine radiologic surveillance well past 2 years, if not indefinitely, to ensure that late endoleak or aneurysm enlargement has not occurred. The late fate of aortic endografts is still a critical issue, and there are numerous reports of late ruptures to add doubt to the long-term success of present devices.\(^6,7,11-18\)

The mechanism of failure. The mechanism of failure appears to be different, although possibly related, in the three cases reported here. The AneuRx endograft combines a self-expanding Nitinol stent structure with a thin Dacron prosthesis and is deployed over a guidewire. It has a modular (component) design, consisting of a main aortouniliac body and a contralateral iliac limb that fit together to function as a single unit to exclude aortic blood flow from the aneurysm.\(^8\) In cases where endoleaks are apparent at completion of the deployment of the main body and contralateral limb, graft extenders can be used either proximally or distally to create a seal. Endoleaks can occur at the proximal or distal attachment sites (Type I), or at the modular junctions due
to separation of components (Type III). The latter was the cause of failure in Patient 1, and the former was the cause of failure in Patient 2. Thus, component separation was involved in producing late endoleaks and rupture in two of the three cases reported here. In Patient 1, the contralateral limb appears to have become disengaged from the main body because of forces incurred during angulation and shortening of the aneurysm sac over time. In Patient 2, the proximal aortic extender became separated from the main body of the graft, leading to similar consequences. Patient 3 demonstrates a third mechanism of failure that may or may not be related to the particular endograft design. This patient had a Type II endoleak, (ie, perigraft flow originating from open collaterals communicating with the aneurysm sac). This was present from the early postoperative period to the time of rupture. Follow-up studies demonstrated that the open collateral vessels were an accessory renal artery and a lumbar artery. Three-dimensional reconstruction of the raw CT data was performed after rupture of the aneurysm in Patient 3. This was compared serially with previous three-dimensional reconstructions and demonstrated an increase in the lumbar-to-accessory renal artery flow and an increase in aneurysm volume. The images also showed the modular components to be appropriately overlapped (R. A. White, personal communication, November 1999). It is presumed that the aneurysm rupture was a result of an increase in aneurysm volume resulting from Type II endoleak from the patent collateral vessels. It might be held that the AneurX design increases the risk of this type of endoleak in that the “protected” inner fabric may be less likely to incorporate into the aneurysm wall than an internally stented endograft. However, this is speculation. The importance of persistent Type II endoleaks after endoluminal repair has been widely debated. A policy of close observation has been recommended, but if there is aneurysm expansion or persistence of the endoleak for an extended period of time, it seems reasonable to consider these leaks dangerous and in need of standard repair. The outcome of our third patient, who is said to have refused intervention, clearly reinforces that point.

Management of AAA rupture associated with endograft repair. Operative conversion to the open procedure after endografting is not a simple endeavor. As reported by May et al, there is considerable mortality for patients with multiple severe comorbidities. They reported a 43% mortality for open conversion in that population, and only one case was for aortic perforation at the time of device placement. Walker et al, from the United Kingdom, reported a 100% mortality for five patients requiring conversion to the open procedure; all patients had immediate conversion. Clearly, conversion in the face of aneurysm rupture adds greater hazards to the patient than the technical difficulty of repair without an indwelling endoluminal device. The difficulties encountered in obtaining vascular control and in dealing with an aorta that has lost much of its integrity during the process of removing the endograft makes surgical repair much more difficult than in the setting of a “simple” ruptured AAA. Some consider that the endograft might provide a partial barrier to extravasation in the face of aneurysm rupture and the patient is more likely to survive until operative repair can be undertaken. This may be true of some small endoleaks, but getting the patient to the operating room and completing an open repair does not guarantee a successful outcome, as reflected by our experience. Two of our three patients died, and all were in shock. Including the other two cases reported to the FDA, four of the five patients we have knowledge of with this complication have died within 4 months of technically successful conversion. Nevertheless, certain observations and technical maneuvers in these three cases may contribute to future management of this complication: aortic wall changes produced by the endograft, gaining proximal and distal control, the management of concomitant stents and extenders, and preserving elements of the device to simplify emergency operation.

The operation to explant the endograft and repair the AAA in Patient 1 was quite difficult. With endograft placement close to the level of the renal arteries, removal of the graft resulted in removal of the subjacent layers of the aortic wall, much like an endarterectomy. This left the aortic wall dangerously thin and necessitated suprarenal and then supraceliac aortic crossclamping, and the use of an extensive Teflon strip to bolster the anastomosis. We presume that this difficulty would not arise in the patient requiring immediate or early conversion because the graft will not have had time to incorporate, thereby making its removal less likely to destroy the aortic wall. Obtaining proximal control quickly and securely is critical in any ruptured aneurysm. Recommended juxtarenal placement of these devices and the difficulties in extracting them add to the challenge of vascular control. Supraceliac clamping was required in two of our cases and may be preferable in most.

Adjunctive stenting, at the time of the original procedure or subsequently, may introduce additional difficulties. In this same patient (1), the left iliac sys-
tem had required long segment stenting for dissection at the time of the original procedure. This left the hypogastric artery covered by an intraluminal stent. Because the IMA was occluded at the time of original repair and the right hypogastric artery was badly diseased, it was necessary to completely excise the iliac artery with the stent to construct the distal anastomosis. An interposition graft from the bifurcated Dacron graft to the left hypogastric artery was constructed to preserve pelvic and colonic blood flow.

The presence of stent extenders may create difficulties. The presence of a proximal and two long distal (external iliac) extenders made the operation in Patient 2 technically challenging. On the other hand, this successful case demonstrates that less than complete explantation of the endograft is a worthwhile option in some cases. Extraction of the entire device, with all of its components, might have led to the need for an aortobifemoral bypass, which would have prolonged operative time and probably increased postoperative morbidity. The decision to retain part of the endograft will depend on whether the attachment is stable and whether clamping the stented ends to gain control has damaged their integrity. The ability of the Nitinol structure to preserve pelvic and colonic blood flow.

In conclusion, we present three new cases of late rupture of AAA after AneuRx repair. These late failures, especially the two AAAs thought to be successfully repaired, suggest the need for indefinite radiologic surveillance at no more than 6-month intervals, until the long-term performance of this device is better defined.

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REFERENCES


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