Early and delayed rupture after endovascular abdominal aortic aneurysm repair in a 10-year multicenter registry

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Objective: **Rupture after abdominal endovascular aortic aneurysm repair (EVAR) is a function of graft maintenance of the seal and fixation. We describe our 10-year experience with rupture after EVAR.**

Methods: **From 2000 to 2010, 1736 patients with abdominal aortic aneurysm (AAA) from 17 medical centers underwent EVAR in a large, regional integrated health care system. Preoperative demographic and clinical data of interest were collected and stored in our registry. We retrospectively identified patients with postoperative rupture, characterized as "early" and "delayed" rupture (≤30 days and >30 days after the initial EVAR, respectively), and identified predictors associated with delayed rupture.**

Results: **The overall follow-up rate was 92%, and the median follow-up was 2.7 years (interquartile range, 1.2-4.4 years) in these 1736 EVAR patients. We identified 20 patients with ruptures; 70% were male, the mean age was 79 years, and mean AAA size at the initial EVAR was 6.3 cm. Six patients underwent initial EVAR for rupture (n = 2) or symptomatic presentation (n = 4). Of the 20 post-EVAR ruptures, 25% (five of 20) were early, all occurring within 2 days after the initial EVAR. Of these five patients, four had intraoperative adverse events leading directly to rupture, with one type I and one type III endoleak. Of the five early ruptures, four patients underwent endovascular repair and one received repair with open surgery, resulting in two perioperative deaths. Among the remaining 15 patients, the median time from initial EVAR to rupture was 31.1 months (interquartile range, 13.8-57.3 months). Most of these delayed ruptures (10 of 15) were preceded by AAA sac increases, including three patients with known endoleaks who underwent reintervention. At the time of delayed rupture, nine of 15 patients had new endoleaks. Among all 20 patients, six patients did not undergo repair (all delayed patients) and died, nine underwent repeated EVAR, and five had open repair. For patients who underwent repair for delayed rupture, mortality at 30 days and 1 year were 44.4% and 66.7%, respectively. Multivariable Cox regression analysis identified age 80 to 89 (hazard ratio, 3.3; 95% confidence interval, 1.1-9.4; $P = .03$), and symptomatic or ruptured initial indication for EVAR (hazard ratio, 7.4; 95% confidence interval, 2.2-24.8; $P < .01$) as significant predictors of delayed rupture.**

Conclusions: **Rupture after EVAR is a rare but devastating event, and mortality after repair exceeds 60% at 1 year. Most delayed cases showed late AAA expansion, thereby implicating late loss of seal and increased endoleaks as the cause of rupture in these patients and mandating vigilant surveillance. (J Vasc Surg 2014;60:1146-53.)**

Endovascular aortic aneurysm repair (EVAR) was first described[1] in 1991 and has since become the standard of care for treatment of abdominal aortic aneurysm (AAA). Multiple trials have shown excellent short-term outcomes of EVAR compared with traditional open AAA repair,[2-7] but the superiority of long-term results has yet to be determined. Graft durability remains a chief concern, and lifelong radiographic surveillance has been considered mandatory to detect treatable complications such as endoleak, device migration, and aneurysm expansion.

AAA rupture is a dreaded but known complication after EVAR that can occur in the immediate perioperative period or after a delay. Aneurysm rupture after EVAR might occur because of technical error or the inability of devices to accommodate changes in anatomy over time, or might be due to graft material fatigue leading to failure. Although rare, the incidence of aneurysm rupture does not appear to have changed significantly since EVAR was introduced, and AAA rupture after EVAR continues to carry substantial associated morbidity and mortality.[8-13]

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We have previously described our experience with EVAR based on a large, multicenter registry over a 10-year period.[14] The purpose of the current study was to characterize early and delayed rupture after EVAR and to identify factors associated with delayed rupture after EVAR in the community setting.

METHODS

Kaiser Permanente Northern California (KPNC) is a large, integrated health care delivery system caring for more than 3 million people who are broadly representative of the local and statewide population. The KPNC Institutional Review Board approved a retrospective review of 1736 EVARs performed by clinicians from 17 KPNC medical centers from 2000 to 2010 with waiver of consent. Relevant clinical data were prospectively collected by trained research nurses, with December 31, 2010, as the last follow-up date. Baseline preoperative demographic and clinical characteristic data including sex, age, race and/or ethnicity, AAA sac size (hereafter termed aneurysm size), comorbidities, smoking status, and statin history were collected from digitized health records. Device type and operative details were collected from the operative report and device entry forms. Decisions regarding indications for surgery, suitability for endovascular repair, device type, and need for secondary intervention were made at the discretion of the operating surgeon. Data from the follow-up period such as rupture, aneurysm size, endoleak, reintervention, and mortality were also recorded in our registry.

Postoperative surveillance varied across medical centers (no standardized post-EVAR protocol existed during the study period); however, patients generally received a computed tomography (CT) scan 1 month postoperatively and then at regular intervals (usually every 6 to 12 months depending on the clinical scenario). EVAR in patients who presented with ruptured or symptomatic aneurysms at the preoperative CT scan was characterized as "urgent." All other EVAR was categorized as "elective." Detailed medical record review was conducted by the study investigators to confirm the patients who had a rupture event after the initial EVAR and their clinical characteristics of interest, including history of endoleak, aneurysm size, intervention before rupture, types of repair for rupture, and complications (eg, cardiac, pulmonary, renal, gastrointestinal, infectious) after rupture.[15]

Our primary outcome measures were the incidence and timing of rupture after the initial EVAR. Rupture after initial EVAR was categorized into two groups: early and delayed. Early ruptures were those that occurred in the immediate perioperative period (within 30 days) after initial EVAR; other ruptures were categorized as delayed. Secondary outcomes included change in aneurysm size over time, presence and type of endoleak, and the need for additional intervention.

Statistical methods. Differences in age and aneurysm size at the initial EVAR were compared between the early and delayed rupture groups using the *t*-test. Comparisons of demographic and clinical variables including sex, treatment of rupture, aneurysm size expansion at the time of rupture, and overall mortality at 30 days and 1 year between the early and delayed rupture groups were evaluated using χ^2 tests or Fisher exact tests. Before determining the potential risk factors associated with delayed rupture, we performed a bivariate analysis comparing the delayed rupture group and patients without rupture (henceforth called "no rupture group") using χ^2 tests or Fisher exact tests for categorical variables (demographic: sex; at the initial EVAR: age groups, urgent vs elective initial EVAR, comorbidities, history of statin treatment, and smoking status; intraoperative: bifurcated graft, adjunctive maneuver, and endoleak) and nonparametric Wilcoxon Mann-Whitney tests for nonnormally distributed continuous variables (age and aneurysm size at the initial EVAR). Because of the small number of patients with delayed rupture, a stepwise Cox proportional hazards model was used to identify risk factors of delayed rupture in 15 patients compared with 1716 with no rupture. The significance level to enter and remain in the model was set at $P < .05$. All analyses were performed using SAS 9.3 (SAS Institute Inc, Cary, NC) with the threshold of significance set at $P < .05$.

RESULTS

During the study period, 1736 EVARs were performed. The overall follow-up rate was 92%, and the median follow-up was 2.7 years (interquartile range [IQR], 1.2-4.4 years). Twenty cases of rupture after EVAR (1.2%) were identified, including 5 that occurred within 30 days ("early" rupture) and 15 cases occurring after 30 days ("delayed" rupture).

Seventy percent of ruptures occurred in male patients. In patients with ruptures, mean age and aneurysm size at the time of initial EVAR were 79 ± 9.1 years and 6.3 ± 0.7 cm, respectively (Table I). Six patients underwent initial EVAR for urgent repair, including two for ruptured AAA and four for symptomatic AAA; the remaining 14 patients had elective repair (Table I).

Demographic characteristics and complications of patients with early ruptures. Three of the five patients with early rupture were male, the mean age of patients was 78.2 ± 10.8 years, and the mean aneurysm size was 6.0 ± 0.6 cm at the time of initial EVAR (Table I). All five cases were performed in the second half of the study period (2006-2010). All of the ruptures occurred within 2 days of the initial EVAR. Two of these patients were noted to have intraoperative endoleaks (one type I and one type III; Table II), which were successfully treated during the initial EVAR with additional angioplasty and cuff placement, respectively. Two patients died within 30 days of rupture, of which one patient had a known ruptured AAA at the time of EVAR repair; the other was taken back to the operating room on the day of EVAR and found to have a large type I endoleak which was treated with angioplasty. All five patients experienced significant postoperative complications (Table III).