# Maximal aortic diameter affects outcome after endovascular repair of abdominal aortic aneurysms

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#### **ABSTRACT**

**Objective:** The purpose of this study was to evaluate whether maximal aortic diameter affects outcome after endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm (AAA).

**Methods:** Clinical data of patients undergoing EVAR between 1997 and 2011 for nonruptured asymptomatic AAAs in a tertiary center were reviewed. Patients were classified according to diameter of AAA: group 1, <5.0 cm; group 2, 5.0 to 5.4 cm; group 3, 5.5 to 5.9 cm; and group 4, ≥6.0 cm. The primary end point was all-cause mortality; secondary end points were complications, reinterventions, and ruptures.

**Results:** There were 874 patients studied (female, 108 [12%]; group 1, 119; group 2, 246; group 3, 243; group 4, 266); mean age was 76  $\pm$  7.2 years. The 30-day mortality rate was 1.0%, not significantly different between groups (P < .05). Five-year survival was 68%; freedom from complications and reinterventions was 65% and 74%, respectively; rupture rate was 0.5%. Multivariate analysis revealed that factors associated with all-cause mortality included maximal aortic diameter, age, gender, surgical risk, cancer history, and endograft type (P < .05). Group 4 had increased risks of mortality (hazard ratio [HR], 2.0; 95% confidence interval [CI], 1.38-2.85; P = .002) and complications (HR, 1.6; 95% CI, 1.2-2.7; P = .009) relative to group 1. Reinterventions were more frequent for aneurysms  $\ge$ 6.0 cm (HR, 2.0; 95% CI, 1.2-3.3; P = .01). Late rupture rate after EVAR was not different between groups.

**Conclusions:** Maximal aortic diameter is associated with long-term outcomes after elective EVAR. Patients with large AAAs (≥6.0 cm) have higher all-cause mortality, complication, and reintervention rates after EVAR than those with smaller aneurysms. We continue to recommend that AAAs be repaired when they reach 5.5 cm as recommended by the guidelines of the Society for Vascular Surgery. On the basis of our data, EVAR should be considered even in high-risk patients with a maximal aortic diameter between 5.5 and 6.0 cm because surgical risk with aneurysm size above 6.0 cm will increase significantly. (J Vasc Surg 2016; 1-10.)

Abdominal aortic aneurysm (AAA) is the most common aneurysm, and rupture continues to be the most frequent and lethal complication. To prevent AAA rupture, open repair (OR) used to be the "gold standard"; however, with the advent of endovascular aneurysm repair (EVAR)<sup>1</sup> and development of endovascular

technology, the use of EVAR in the United States has increased from 5.2% in 2000 to 74% in 2010.<sup>2</sup> At our institution, the proportion of EVAR for asymptomatic AAA has been >70%.<sup>3</sup>

In a recent publication on outcome of EVAR patients, we observed that clinical presentation predicted early mortality and complications and advanced age predicted all-cause mortality.<sup>4</sup> When we compared outcome after EVAR vs OR using propensity score modeling, maximal aortic diameter increase per 1 cm was a risk factor predicting late all-cause mortality.<sup>3</sup>

The current size threshold to recommend OR for asymptomatic AAAs in men has been established at 5.5 cm.<sup>5-9</sup> On the basis of two randomized controlled trials and evidence from single-institutional data,<sup>10</sup> this size has also been accepted as a threshold for EVAR. A report from the European Collaborators on Stent/graft Techniques for aortic Aneurysm Repair (EUROSTAR) registry, published in 2004, first called attention to the size of AAA as a factor predicting late outcome after EVAR. In this international registry of 4392 patients, the patients with large AAAs (≥6.5 cm) after EVAR had the highest

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rate of all-cause and aneurysm-related death and late aneurysm rupture. Outcome of patients with small (<5.5 cm) AAAs was excellent, similar to data reported by us and others. A review of long-term results of a prospective multicenter investigational device exemption clinical trial of EVAR found that patients with large AAAs ( $\geq$ 6.0 cm) had a shorter life expectancy and a higher risk of rupture, surgical conversion, and aneurysm-related death compared with patients with smaller AAAs (<5.0 cm). Others found that size of the aneurysm ( $\leq$ 5.4 cm vs  $\geq$ 5.5 cm) had no association with outcome after EVAR.

The association of AAA size and outcome after EVAR in early through recent experience has not been well established. The purpose of this study was to evaluate whether maximal aortic diameter is associated with outcome after EVAR performed for asymptomatic nonruptured AAA at a tertiary medical center.

#### **METHODS**

Study population. Clinical data of consecutive patients who underwent EVAR for nonruptured asymptomatic infrarenal AAA between January 1, 1997, and December 31, 2011, at Mayo Clinic, Rochester, Minnesota, were retrospectively reviewed. Patients with maximum external diameter of AAA measured by computed tomography (CT) or CT angiography (CTA), according to reporting standards for EVAR,<sup>16</sup> were included. Patients who received physician-modified, research trial, or branched or fenestrated endografts during the study period were excluded. Demographic data, comorbidities, diagnostic and laboratory results, interventional records, mortalities, complications, reinterventions, and ruptures were abstracted from the Mayo Clinic Aortic Registry. The primary end point was all-cause mortality; secondary end points were complications, reinterventions, and ruptures. Adverse events that occurred within 30 days after the index procedure were defined as early or 30-day results; those that occurred after 30 days were defined as late results. Informed consent of the patients was obtained for the study; this study was approved by the Mayo Foundation Institutional Review Board.

Indications for EVAR included asymptomatic, nonruptured infrarenal AAA patients with a maximal aortic diameter ≥5.5 cm in diameter in men and ≥5.0 cm in women as recommended by the Society for Vascular Surgery (SVS) guidelines.<sup>17</sup> Those with smaller aneurysms included rapid growth (>0.5 cm/y); overly anxious patients, especially those with a family history of AAA; and smaller AAAs with large (>3.5 cm) or rapidly growing associated iliac artery aneurysm. EVAR was performed on patients with eligible aortoiliac artery anatomy confirmed by preoperative CTA.<sup>3.4</sup> Patients were classified into four groups based on the diameter of AAA: group 1, diameter < 5.0 cm; group 2, 5.0 cm ≤ diameter < 5.5 cm; group 3, 5.5 cm ≤ diameter < 6.0 cm; group 4,

#### **ARTICLE HIGHLIGHTS**

- **Significance:** The study investigated whether large abdominal aortic aneurysms (AAAs) treated with endovascular aneurysm repair (EVAR) are associated with worse outcomes.
- Type of Research: Retrospective cohort study
- Take Home Message: This retrospective study of 874 patients found that those with AAAs ≥6.0 cm had higher mortality, complication, and reintervention rates after EVAR than those with smaller AAAs.
- **Recommendation**: The authors suggest elective EVAR for AAAs < 6.0 cm in diameter.
- Strength of Recommendation: 2. Weak
- · Level of Evidence: B. Medium

diameter  $\geq$  6.0 cm. SVS comorbidity scores were used to stratify patients into low/normal-risk (score  $\leq$  10) or high-risk category (score > 10).<sup>18</sup>

Procedure. The procedure of EVAR was described previously. 3.4 Briefly, EVAR was performed using aortobi-iliac endografts. Aortouni-iliac endograft was used in patients with contralateral iliac artery occlusive disease followed by femoral-femoral bypass grafting. Straight endograft placement was performed on selected patients with AAA confined to abdominal aorta with sufficient landing zone to the bifurcation, usually early in the experience. Staged or simultaneous embolization of the internal iliac artery was performed on patients with iliac artery aneurysms or when stent graft extension beyond the iliac bifurcation was required.

Follow-up. Patients were asked to return at 1 to 3 months after EVAR for physical examination and imaging studies including CT scanning and duplex ultrasound and every 6 months afterward. Follow-up information including reinterventions was obtained from the medical records and mailing questionnaires. The patient's vital status was established from charts, mailing questionnaire, death certificate, or autopsy report.

Definitions. Technical success was defined as successful deployment of the device without complication or conversion surgery. Complications were identified using the criteria of the SVS Vascular Quality Initiative.<sup>19</sup> Procedure-related and device-related complications were defined according to SVS reporting standards.<sup>20</sup> Types of endoleak were defined as described in SVS practice guidelines.<sup>17</sup> Reinterventions were defined as any open or endovascular new procedures because of vascular causes, including endograft limb and lower extremity artery thrombosis, or nonvascular complications, including wound infection and lymph leak requiring surgery. Reinterventions due to procedure- or device-related complications or endoleak were

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