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Standard endovascular aneurysm repair in patients with wide infrarenal aneurysm necks is associated with increased risk of adverse events

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ABSTRACT

Objective: Endovascular aneurysm repair (EVAR) has progressively expanded to treat more challenging anatomies. Although EVAR in patients with wide infrarenal necks has been reported with acceptable results, there is still controversy regarding the longer-term outcomes. Our aim is to determine the impact of infrarenal neck diameter on midterm outcome following EVAR with a single endograft with suprarenal fixation.

Methods: A retrospective case-control study was designed using data from a prospective multicenter database. Patients who electively underwent standard EVAR with an Endurant stent graft (Medtronic Ave, Santa Rosa, Calif) for a degenerative abdominal aortic aneurysm from January 2008 to December 2012 in three high-volume centers in The Netherlands were included. All measurements were obtained using dedicated reconstruction software and center-lumen line reconstruction. Patients with an infrarenal neck diameter of ≥30 mm were compared with patients with a neck diameter of <30 mm. The primary end point was freedom from neck-related adverse events (a composite of type Ia endoleak, neck-related secondary intervention, and endograft migration). Secondary end points were primary clinical success, type Ia endoleak, neck-related reinterventions, endoleaks, and aneurysm-related secondary interventions.

Results: Four-hundred twenty-seven patients were included. Seventy-four patients (17.3%) with a neck diameter of ≥30 mm were compared with a control group of 353 patients. There were no significant differences at baseline between groups including demographics, comorbidities, baseline aneurysm diameter, infrarenal neck length, suprarenal angulation, or infrarenal neck angulation. Median stent graft oversizing was 12.5% (7.9-16.1) and 16.6% (12.0-23.1) in the ≥30-mm neck-diameter and control groups, respectively ($P < .001$). Median follow-up was 3.1 years (1.2-4.7) and 4.1 years (2.7-5.6) for the large neck and control groups, respectively ($P < .001$). Type Ia endoleaks occurred in 17 patients (4.0%) and were significantly more frequent in patients with ≥30-mm neck diameter (9.5% vs 2.8%; $P = .005$). Neck-related secondary interventions were performed in 20 patients (4.7%) and were also more common among patients with neck diameters of ≥30 mm (9.5% vs 3.7%; $P = .04$). The 4-year freedom from neck-related adverse events were 75% and 95% for the large neck and control groups, respectively ($P < .001$). On multivariable regression analysis, infrarenal neck diameter of ≥30 mm was an independent risk factor for neck-related adverse events (odds ratio [OR], 3.8; 95% confidence interval [CI], 1.6-9.1), type Ia endoleak (OR, 2.7; 95% CI, 1.0-8.3), and neck-related secondary interventions (OR, 3.2, 95% CI, 1.1-9.2).

Conclusions: EVAR in patients with large diameter necks is associated with an increased risk of neck-related adverse events in midterm follow-up. This may influence the clinical decision regarding choice of repair and toward a more intensive surveillance following EVAR in these patients in the long term. (J Vasc Surg 2016;■:1-9.)

Endovascular aneurysm repair (EVAR) is currently the preferred repair method for abdominal aortic aneurysms.[1] Endografts have progressively improved to cope with increasingly more complex anatomies, particularly at the infrarenal neck and together with increased physician proficiency have broadened the range of patients eligible for EVAR.

EVAR in patients with hostile aneurysm necks is associated with an increased risk of adverse events.[2] Although EVAR in patients with wide necks has been reported

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with acceptable results over short-term follow-up, long-term results conflict.[3,4] Moreover, most series include different endografts with distinct instructions for use, which greatly reflect the performance of the stent graft in challenging aortic necks. Consequently, the overall understanding of the outcomes of EVAR in these patients is not adequately supported by data. To expand the range of anatomically eligible patients, EVAR device industry has, among other innovations, increased the range of commercially available proximal graft diameters. This has led to generalization of implants in proximal attachment zones in diameter of ≥30 mm that per definition are already aneurysmal.

Therefore, our objective was to determine midterm outcomes following EVAR with a single endograft in patients with large diameter aneurysm necks. Our hypothesis is that EVAR in patients with an infrarenal neck diameter of ≥30 mm is associated with an increased risk of neck-related complications.

ARTICLE HIGHLIGHTS

- **Significance:** This study investigated neck-related adverse events after endovascular aneurysm repair using Endurant stent grafts.
- **Type of Research:** Retrospective multicenter case control study using data of a prospectively collected database.
- **Take Home Message:** Patients with an infrarenal neck of ≥30 mm had more type I endoleak than those with a neck of <30 mm (9.5% vs 2.8%; $P = .005$), and large neck was an independent risk factor for neck-related adverse events, secondary interventions, and type I endoleaks.
- **Recommendation:** The results suggest that patients with abdominal aortic aneurysm with neck diameters of ≥30 mm undergo complex endograft or open repair or if standard Endurant endografts were used, have rigorous computed tomography follow-up.
- **Strength of Recommendation:** 1. Strong
- **Level of Evidence:** B. Medium

METHODS

Design and population. A retrospective case-control study was designed based on a prospectively maintained database from three high-volume centers in The Netherlands (Erasmus University Medical Center, Rotterdam; St. Antonius Hospital, Nieuwegein; and University Medical Center, Utrecht). This study complies with the Declaration of Helsinki in research ethics. Informed consent was waived according to institutional policy on retrospective research. Consecutive patients undergoing an elective primary EVAR with an Endurant stent graft (Medtronic, Santa Rosa, Calif) between January 2008 and December 2012 for infrarenal abdominal aortic aneurysms were included. Anastomotic, infectious, or isolated iliac aneurysms were excluded. In addition, patients receiving adjunctive endoanchors during the primary repair, without preoperative computerized tomography (CT) or postoperative CT imaging available for analysis were also excluded.

Patients with a reference infrarenal neck diameter of ≥30 mm were included in the study group and the remaining population as controls.

Measurements. All measurements were performed by two observers trained in image analysis (N.O., F.B.G.), using dedicated postprocessing software (3Mensio Vascular, Bilthoven, The Netherlands). Preoperative, 30-day and last available CTs were analyzed following center-lumen line reconstruction. In previous reports, high rates of interobserver agreement regarding aneurysm diameter, neck diameter, neck length, and proximal seal length measurements have been demonstrated with this methodology by our group.[5,6] Aneurysm-volume and neck angulation were also measured according to previously validated methodology.[7,8] Intraobserver variability for neck diameter and aneurysm-sac volume was tested for 59 patients, with very good agreement (Pearson correlation coefficient: neck diameter, 0.994; $P < .001$; aneurysm volume, 0.992; $P < .001$; Fig 1).

Definitions. Neck diameters were measured in two perpendicular axes just distal to the lowermost renal artery ostium, and at every 5 mm distally along the first 15 mm of the infrarenal neck on center-lumen line reconstructed imaging. The reference neck diameter was considered as the average of the two largest neck measurements. In patients with a neck length of <15 mm, the average of the first two measurements was taken as the reference diameter. This reference neck diameter was used to select the study group (diameter ≥30 mm) and to calculate oversizing. For assessment of neck dilatation, neck diameter was measured on the 30-day CT angiography (CTA) at the top of the first covered stent of the endograft. The lowermost renal artery was used as landmark; the distance separating the start of the covered stent and the lowermost renal artery at 30-day imaging was used to determine the point of measurement on the preoperative imaging and at last CT, as well as to determine any endograft migration.

Neck configuration was classified according to published methodology.[9] Briefly, neck diameter variations of 10% along the neck length were considered as indicative of nonparallel aortic walls. Aortic necks demonstrating progressive diameter increments ≥10% along their length were considered as inversed tapered neck (type II) configuration. Neck thrombus and calcification were classified according to circumferential involvement of the neck within the proximal seal zone.