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Risk Factors, Dynamics, and Clinical Consequences of Aortic Neck Dilatation after Standard Endovascular Aneurysm Repair

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WHAT THIS PAPER ADDS

Aortic neck dilatation occurs after endovascular aneurysm repair (EVAR) with self expanding stent grafts but may progress, ultimately exceeding the implanted endograft's diameter, placing patients at risk of abdominal aortic aneurysm rupture. This study suggests that aortic neck dilatation after EVAR is driven by endograft oversizing and radial force. Despite being greater during the first post-operative year, it decreases once the nominal endograft size is reached in most cases. Importantly, baseline aortic neck diameter and endograft characteristics were associated with an increased risk of neck dilatation beyond the nominal graft diameter. The importance of suprarenal stents remains uncertain as the studied suprarenal fixation endografts have greater radial force than their infrarenal counterparts. Additionally, patient selection differences may also have contributed to the reported findings. For patients at risk of excessive neck dilatation and with a long life expectancy, alternative repairs may be preferable for a durable result.

Objective: Aortic neck dilatation (AND) occurs after endovascular aneurysm repair (EVAR) with self expanding stent grafts (SESs). Whether it continues, ultimately exceeding the endograft diameter leading to abdominal aortic aneurysm (AAA) rupture, remains uncertain. Dynamics, risk factors, and clinical relevance of AND were investigated after EVAR with standard SESs.

Methods: All intact EVAR patients treated from 2000 to 2015 at a tertiary institution were included. Demographic, anatomical, and device related characteristics were investigated as risk factors for AND. Outer to outer diameters were measured at a single standardised aortic level on reconstructed computed tomography (CT) images.

Results: A total of 460 patients were included (median follow up 5.2 years, interquartile range [IQR] 3.0, 7.7 years; CT imaging follow up 3.3 years, IQR 1.3, 5.4). Baseline neck diameter was 24 mm (IQR 22, 26) and increased 11.1% (IQR 1.5%, 21.9%) at last CT imaging. Endograft oversizing was 20.0% (IQR 13.6, 28.0). AND was greater during the first year (5.2% [IQR 0, 11.7]) decreasing subsequently (two to four years to 1.4%/year [IQR 0.0, 4.5%], $p \leq .001$) and was associated with suprarenal fixation endografts (t value $= 7.9$, $p < .001$) and oversizing (t value $= 4.4$, $p < .001$). AND exceeding the endograft was 3.5% (95% CI 2.2% — 4.8%) and 14.4% (95% CI 11.0% — 17.8%) at five and eight years, respectively. Excessive AND was associated with baseline neck diameter (OR 1.2/mm, 95% CI 1.05 — 1.41) while the Excluder endograft had a protective effect (OR 0.15, 95% CI 0.04 — 0.58). Excessive AND was associated with type 1A endoleak (HR 3.3, 95% CI 1.1 — 9.7) and endograft migration $>$ 5 mm (HR 3.1, 95% CI 1.4 — 6.9).

Conclusion: AND after EVAR with SES is associated with endograft oversizing and radial force but decelerates after the first post-operative year. Baseline aortic neck diameter and suprarenal stent bearing endografts were associated with an increased risk of AND beyond nominal stent graft diameter. However, it remains unclear whether patient selection, differences in endograft radial force or the suprarenal stent are accountable for this difference.

Keywords: Aortic aneurysm, Abdominal (MeSH), Blood vessel prosthesis implantation (MeSH), Aortic neck dilatation, Retrospective studies
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INTRODUCTION

Abdominal aortic aneurysm (AAA) management has been revolutionised by endovascular aneurysm repair (EVAR) owing to its lower procedural morbidity and mortality than open repair.[1,2] However, the risk of complications following EVAR increases over time, making understanding of the mechanisms of EVAR failure crucial to improving clinical outcomes.[3] A durable proximal seal is vital to sustain clinical success. It is often described that the infrarenal sealing zone progressively dilates following EVAR when self expandable stent grafts (SESs) are used.[4–6] However, it is unknown whether this process stops when the SES radial force on the sealing zone diminishes, as the nominal diameter of the oversized endograft is reached, or if it continues jeopardising the proximal seal and putting the patient at risk of type 1A endoleak and AAA rupture.

The aim of this study was to assess the long term dynamics of the infrarenal aneurysm neck following EVAR with contemporary SES. Additionally, the risk factors and clinical implications of proximal neck dilatation were investigated.

MATERIALS AND METHODS

Design and population

A retrospective observational study was performed including EVAR patients treated at the Erasmus University Medical Centre (Rotterdam, The Netherlands) from January 2000 to December 2015. All imaging and clinical follow up performed until August 2019 was analysed. The study conformed with the Declaration of Helsinki in research ethics. Informed consent for this report was not required according to institutional policy on retrospective research. All patients treated electively by standard EVAR with SES primarily for a degenerative infrarenal AAA were included. Patients treated for pseudo-aneurysms, infected aneurysms, or isolated degenerative iliac aneurysms were excluded. Patients for whom a pre- or post-operative computerised tomography (CT) could not be retrieved were also excluded from analysis.

Measurements

All measurements were obtained on CT imaging by four investigators with experience in image analysis (N.O., F.B.G., J.P.P., R.F.) with access to dedicated image processing software (3mensio, Bilthoven, The Netherlands). Pre- and all post-operative CTs performed prior to any proximal neck related event (see definition below) were reconstructed using the vessel centre lumen line (CLL). With this methodology, the group has reported a high interobserver agreement for aneurysm diameter, neck diameter, neck length, and proximal seal length measurements.[7] All diameter determinations were performed outer to outer. Also, aneurysm volume and neck angulation were determined according to previously validated methodology.[8,9]

Definitions

The infrarenal outer to outer neck diameter was measured in two axes (anteroposterior and transverse) at a plane determined by the endograft first covered stent on the day 30 CT imaging (Fig. 1). The distance from the start of the proximal covered stent to the lowest renal artery was used as reference to determine the corresponding neck diameter measurement plane on pre- and subsequent post-operative imaging. A simple average of two diameter measurements was considered. Changes in this distance were registered as endograft migration. Endograft migration $>$ 5 mm was reported. Only neck diameters obtained prior to the development of any neck related adverse event (see definition below) were considered. Reported oversizing was calculated from dividing the device diameter by baseline neck diameter at the abovementioned aortic plane, and not relative to the pre-operative reference neck diameter used for EVAR sizing.

A normalised outer to outer aortic neck diameter was calculated by adding the implanted endograft's nominal diameter to the thickness of both aortic walls. The aortic wall thickness was determined in a sample of 50 patients. Mean wall thickness was 1.0 mm $\pm$ 0.4 for the anterior and posterior walls and 1.2 mm $\pm$ 0.6 for the transverse walls. The average mean aortic wall thickness was 1.1 mm $\pm$ 0.4 mm. The value of the upper bound standard deviation (1.5 mm) was used as the reference aortic wall thickness in the infrarenal neck to calculate the nominal aortic neck diameter. If the ratio between the measured outer to outer aortic diameter and the normalised aortic neck diameter was $>$ 1, excessive neck dilatation was considered to have occurred.

Neck configuration was classified according to Balm *et al.*[10] Aortic necks demonstrating progressive diameter increments $\geq$ 10% along their length were considered as inversed tapered neck (type II) configuration. Neck thrombus and calcification were classified into quartiles of circumferential involvement.

Patient comorbidities and aneurysm related outcomes are reported according to the Society for Vascular Surgery (SVS) reporting standards, with the exception of migration (5 mm was considered instead of the recommended 10 mm threshold).[11] Sac growth was defined as post-operative increase in aneurysm sac volume $>$ 5% or as $>$ 5 mm increase in sac diameter compared with the day 30 imaging.

Infrarenal neck related adverse events were defined as a composite of type 1A endoleak, endograft migration $>$ 5 mm, or secondary intervention related to the infrarenal neck (Palmaz stent, proximal cuff, other endovascular intervention or open conversion due to neck related complications).

AAA related adverse events included any type 1, type 3, or undetermined endoleak, post-operative aneurysm sac growth, device migration $>$ 10 mm, device integrity failure,

AAA related death, AAA rupture, or any AAA related secondary intervention. Secondary interventions were considered if performed to resolve or prevent a possible complication. These included endovascular procedures (proximal cuff and stent implant, distal extension implant, catheter based thrombolysis, iliac angioplasty, coil or glue embolisation of aortic branch vessels), as well as surgical procedures (balloon thrombectomy, femorofemoral crossover, conversion to open repair, open or laparoscopic ligation of collaterals).

Post-operative surveillance

A 30 day and yearly CT angiography follow up protocol has shifted towards a more liberal follow up regimen during the study period. Coloured duplex ultrasound (DUS) and non-contrast CTs were used in selected patients considered to be at a lower risk of complications according to the 30 day CT angiogram or if presenting with renal function impairment. For the purpose of this study, both contrast and non-contrast CTs were considered and imaging follow up was considered until the date of the last CT.

Endpoints

The primary endpoint was proximal neck dilatation. The association between morphological and device related characteristics with proximal neck dilatation was also evaluated. Finally, the occurrence of excessive neck dilatation and its association with neck related adverse outcomes was assessed.

Statistical analysis

Continuous variables with a normal distribution are described as mean and standard deviation. Continuous variables are presented as median and interquartile range (IQR) if skewed and were tested among groups using the Mann—Whitney U test for independent samples. Related variables were compared with the Wilcoxon signed rank test. Categorical variables are presented as count and percentage and compared using the Pearson chi squared test or the Fisher exact test in cases of low event numbers. For association between baseline characteristics and neck dilatation in each of the assessed time periods, a multivariable logistic regression model was created including variables with α value ≤ 0.10 on univariable analysis once any multicollinearity was excluded. Stepwise backward elimination of variables with $p > .050$ was also used during multivariable modelling. Time was included as a co-variate. Confidence intervals of 95% (95% CI) were used and statistical significance was considered for $\alpha < .050$. For the analysis of the infrarenal neck during the overall study time, a linear mixed model with subjects as random effects was constructed. Survival curves were obtained by Kaplan—Meier methods. For events solely detected by CT imaging, date of event was defined as the date the examination was performed. All statistical analyses were performed using

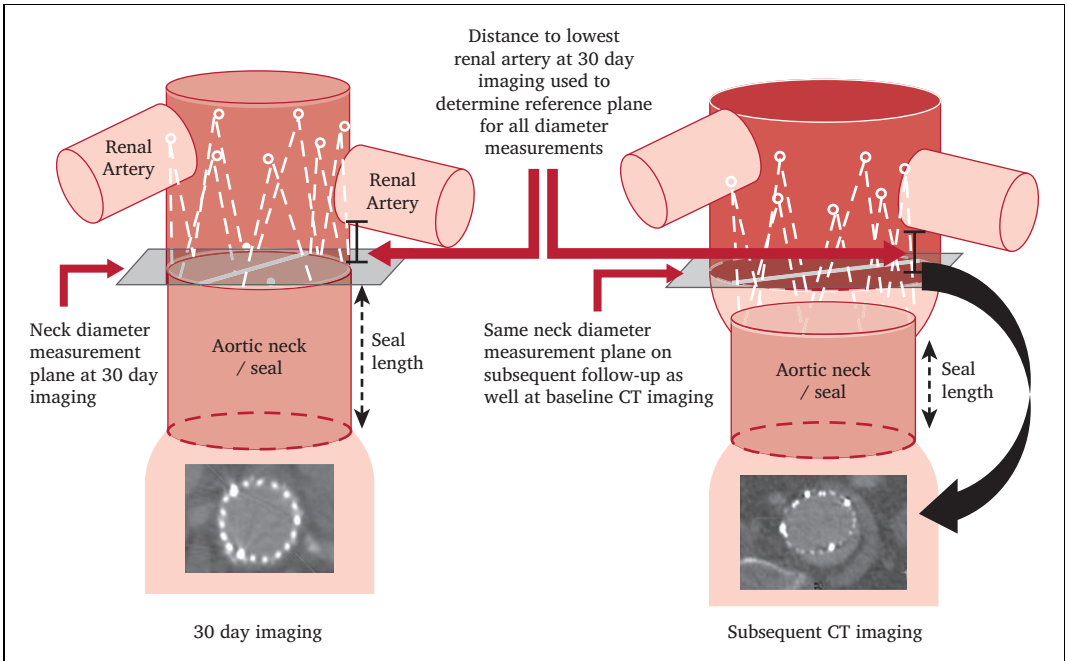

Figure 1. Neck diameter measurement methodology. The infrarenal outer to outer neck diameter was measured in two axes (anteroposterior and transverse) at a plane determined by the endografts' first covered stent on the 30 day computed tomography (CT) imaging. A normalised outer to outer aortic neck diameter was calculated by adding the implanted endografts' nominal diameter to the thickness of both aortic walls. If the ratio between the measured outer to outer aortic diameter and the normalised aortic neck diameter was >1, excessive neck dilatation was considered to have occurred.

Statistical Package for Social Sciences 21.0 (IBM Inc, Chicago, IL, USA) and the "R" Project for Statistical Programming (version 3.2.5, R Foundation for Statistical Computing, Institute for Statistics and Mathematics, Vienna, Austria).

RESULTS

From 2000 to 2015, 660 patients underwent EVAR at the centre. Among these, 33 pseudo-aneurysms, one traumatic aortic rupture, nine infected aneurysms, 21 isolated iliac aneurysms and 89 patients presenting with a ruptured AAA were excluded. From the remaining 507 patients, either pre- or post-operative CT imaging was not obtainable for 43 patients and four patients had a type 1A endoleak at 30 day imaging. After excluding these 47 patients (9.3%), a final study population of 460 standard EVAR patients with a median follow up of 5.2 years (IQR 3.0, 7.7; Fig. 2) was created. Baseline comorbidities and anatomical details are presented in Table 1. Median post-operative CT imaging follow up was 3.3 years (IQR 1.3, 5.4; maximum 13.9 years). Each patient had a median of three post-operative CTs available for assessment (IQR 2, 4). Patients who developed AAA related adverse events underwent a median of four post-operative CTs (IQR 2, 5) while the remainder had only three (IQR 2, 5; $p < .001$).

Infrarenal neck dilatation — dynamics and predictors

The median infrarenal neck diameter at baseline was 24.0 mm (IQR 22.0, 26.0) and endograft oversizing was 20.0% (IQR 13.6, 28.0). At the last available CT imaging, the infrarenal neck diameter had increased a median 11.1% (IQR 1.5%, 21.9%; Table 2) and neck dilatation > 10% and > 20% was found in 241 (52.4%) and in 131 (28.5%) patients, respectively. The annual rate at which the infrarenal neck enlarged was greater during the first post-operative year (median 5.2%; IQR 0, 11.7) than the subsequent two to four year period (median 1.4%/year; IQR 0, 4.5%, $p < .001$) or to the five to seven year period (median 1.5%/year; IQR 0.0, 3.3%, $p = .002$).

Baseline demographic, anatomical, and device related characteristics were tested for association with neck dilatation within defined time intervals. In multivariable analyses, endograft oversizing and suprarenal fixation were associated with > 10% neck dilatation throughout all time points (Table S1). Oversizing was associated with > 10% neck dilatation at 30 day imaging (odds ratio [OR] 1.05, 95% CI 1.01 — 1.08 per % of endograft oversizing), two to four year follow up (OR 1.09, 95% CI 1.07 — 1.12) and during the five or more year post-operative period (OR 1.06, 95% CI 1.01 — 1.12). Suprarenal fixation was associated with > 10% neck dilatation at one year (OR 4.23, 95% CI 1.83 — 9.76), at two to four year follow up (OR 7.09, 95% CI 3.82 — 13.2) and at five or more year CT imaging (OR 5.68, 95% CI 1.52 — 21.2). These findings persisted after linear mixed regression modelling using all neck diameter determinations (suprarenal fixation endografts $p < .001$ and endograft oversizing $p < .001$; Table S2, Fig. S1).

Subanalyses comparing the two most common endografts in the population (424 patients — 94.3% of the overall population) were performed (Tables S3 and S4). In multivariable analyses, the Endurant endograft was associated with > 10% neck dilatation at each of the assessed time intervals as well as at the last CT imaging (OR 5.12, 95% CI 2.98 — 8.80) while the Excluder endograft was not.

In subanalysis excluding those 57 patients who developed AAA related adverse events during the study period, endograft oversizing was associated with neck dilatation > 10% at 30 day imaging (OR 1.05 per %, 95% CI 1.02 — 1.09, $p = .002$), at one year (OR 1.03 per %, 95% CI 1.00 — 1.06, $p = .040$), at two to four years (OR 1.10, 95% CI 1.06 — 1.14, $p < .001$) and at the last available imaging (OR 1.07, 95% CI 1.04-1.10, $p < .001$, Table S5). Suprarenal fixation endografts were also associated with neck dilatation > 10% at one year (OR 3.05, 95% CI 1.46 — 6.38, $p = .003$), at two to four years (OR 6.38, 95% CI 3.1 — 12.9, $p < .001$), after five year follow up (OR 7.93, 95% CI 1.62 — 38.8, $p = .011$), and at the last available imaging (OR 4.75, 95% CI 2.70 — 8.37, $p < .001$).

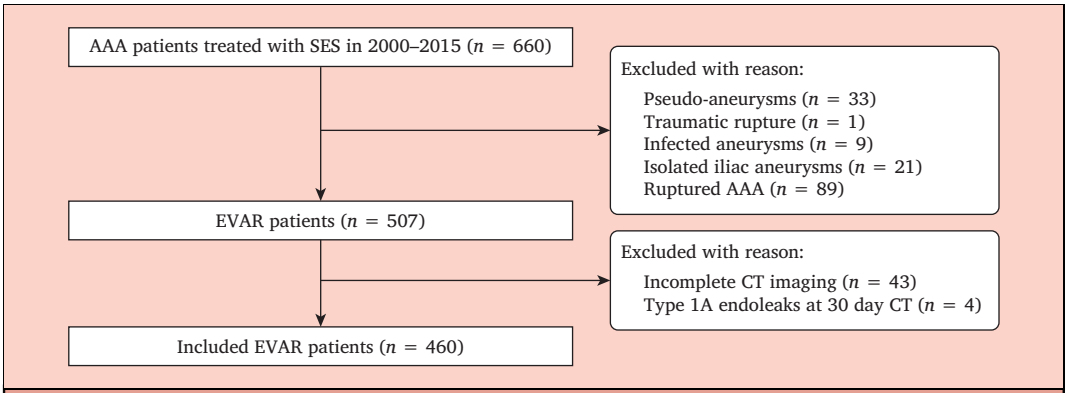

Figure 2. Population inclusion flowchart. All patients treated electively by standard endovascular aneurysm repair (EVAR) with self expanding stent grafts (SES) primarily for a degenerative infrarenal abdominal aortic aneurysm were included. Patients treated for pseudo-aneurysms, infected aneurysms or isolated degenerative iliac aneurysms were excluded. Patients for whom pre- or post-operative computerised tomography (CT) could not be retrieved were also excluded from analysis.

Table 1. Baseline clinical, anatomical and device related variables of 460 patients studied for aortic neck dilatation after endovascular aneurysm repair (EVAR)

	Patients (n = 460)
CT imaging follow up time − y	3.28 (1.28–5.41)
Age − y	73.1 (68.0–78.0)
Male gender	408 (88.7)
Hypertension	330 (71.8)
Diabetes mellitus	78 (17.0)
eGFR <60 mL/min/1.73 m^2 †	101 (22.0)
Continuous smoking at EVAR ‡	178 (38.7)
ASA class III/IV †	250 (54.4)
Cardiac status ≥2 *,‡	78 (17.0)
Peripheral arterial occlusive disease †	71 (15.4)
Cerebrovascular disease ‡	61 (13.3)
Pulmonary disease ‡	68 (14.8)
Antiplatelets †	282 (61.3)
Max AAA diameter − mm	59.0 (54.0–67.0)
AAA volume	179.0 (135.0–243.0)
Infrarenal neck diameter at seal site − mm	24.0 (22.0–26.0)
Infrarenal neck length − mm	28.0 (20.0–40.0)
Inverse tapered neck	104 (22.6)
Neck thrombus >25%	152 (33.0)
Neck calcification >25%	101 (22.0)
α Angle − degrees	21.0 (11.0–33.0)
β Angle − degrees	36.0 (24.0–52.0)
Oversizing − %	20.0 (13.6–28.0)
Aorto-uni-iliac configuration	15 (3.3)
Suprarenal fixation	278 (60.4)
Endografts	
Endurant	243 (52.8)
Excluder	181 (39.4)
Talent	13 (2.8)
Zenith	6 (1.3)
Others	17 (3.7)
Proximal seal length at 30 day CT imaging − mm	21.0 (14.0–27.0)
Distance from endograft to lowermost renal artery at 30 day imaging − mm	2.0 (0.0–4.0)

Data are presented as n (%) or median (interquartile range). AAA = abdominal aortic aneurysm; CT = computed tomography; ASA = American Society of Anesthesiologists classification system; eGFR = estimated glomerular filtration rate.

* According to the Society for Vascular Surgery/American Association for Vascular Surgery medical comorbidity grading system.

† Missing data for >2% <5%.

‡ Missing data for >5%.

Excessive neck dilatation

At the last available CT imaging, the endograft had not reached nominal diameter in 404 patients (87.8%, Fig. S2), while in 23 patients this threshold had been exceeded. Among them, seven patients no longer had an effective proximal seal (three presented with a type 1A endoleak): five patients underwent neck related secondary interventions (conversion, fenestrated cuff repair) while the other two patients refused treatment. For the remaining 13 patients who exceeded the normalised aortic diameter, the median proximal seal length was 21 mm (IQR 14.0, 29.0), which remained effective below the measured level.

Neck dilatation exceeding the normalised neck diameter was 3.5% at five years (95% CI 2.2% — 4.8%; Fig. 3) and 14.4% at eight years (95% CI 11.0% — 17.8%, Fig. S3). Among Excluder or Endurant implanted patients, the nominal aortic diameter was not reached until three years follow up had elapsed (Fig. S4). Freedom from dilatation beyond nominal aortic diameter among Excluders at five and eight years was 98.8% (95% CI 97.6% — 100%) and 96.7% (95% CI 94.3% — 99.1%) while among Endurant patients it was 95.7% (95% CI 93.6% — 97.8%) and 77.8% (95% CI 72.1 — 83.5) respectively, $p < .001$. In multivariable analysis, baseline neck diameter (OR 1.21, 95% CI 1.05 — 1.41) was associated with an increased risk of dilatation beyond the nominal aortic diameter while EVAR with an Excluder endograft conferred protection against excessive neck dilatation (OR 0.15, 95% CI 0.04 — 0.58, Table 3). A subanalysis was performed including only patients with neck diameters < 30 mm and neck length > 15 mm treated either with Excluders (n = 154) or Endurants (n = 175). Median stent graft oversizing at the predefined aortic plane was 16.7% (IQR 12.0, 21.7) among Excluder patients and 23.0% (IQR 16.7, 33.3%) among Endurant patients ($p < .001$). Median neck diameter at the assessed aortic plane was 23.0 mm in the Excluder patients (IQR 21.0, 25.0) and 24.0 mm (22.0 — 27.0) among Endurant patients, $p = .003$) while neck length was 31.0 mm (25.0 — 43.3) and 30.0 mm (25.0 — 37.0), $p = .31$. In this subgroup of patients, freedom from neck dilatation beyond nominal aortic diameter at five years at the predefined aortic plane was 100% for the Excluder patients (n = 58) and 96% for Endurant patients (standard error 0.023; n = 46, $p = .001$).

A subanalysis was performed including 132 patients (28.7%) who reached the 90% endograft expansion threshold during follow up (Table S6). The median annual neck diameter increase was 5.1% / year (IQR 2.5%, 9.7%) before reaching 90% endograft expansion threshold and decreased significantly thereafter (median 0.8%/year, IQR 0.0, 2.8%, $p < .001$). Among these 132 patients, the 21 patients (15.9%) with baseline neck diameters ≥ 30 mm reached the 90% endograft expansion threshold earlier (median 2.8 *vs.* 4.3 years, $p = .026$) and presented greater rates of neck dilatation after the 90% threshold (median yearly rate of 3.5% *vs.* 0.6%, $p = .041$) compared with the remaining subgroup.

Infrarenal neck dilatation and clinical consequences

Infrarenal neck dilatation was tested for association with the development of complications at several time points. Patients with neck dilatation distributed within the fourth highest quartile on 30 day CT imaging (> 4.2% neck dilatation) were not found to incur a greater risk of neck related adverse events during subsequent follow up (Table 4). For those patients presenting neck diameter increments within the fourth quartile at one year follow up (> 11.7% neck dilatation) only an increased risk of endograft migration > 5 mm at the last available imaging was detected (HR 2.8, 95% CI 1.2 — 6.2). On the last available CT imaging, excessive neck dilatation was associated with type 1A endoleaks (HR 3.3, 95% CI 1.1 — 9.7), endograft migration > 5 mm (HR 3.1,

Table 2. Aortic neck diameter dynamics in 460 patients treated by endovascular aneurysm repair (EVAR)

	Time after EVAR					
Clinical and DUS based follow up	**30 d (n = 460)**	**1 y (n = 428)**	**2–4 y (n = 309)**	**5–7 y (n = 197)**	**≥8 y (n = 93)**	**At last available CT imaging (n = 460)**
CT imaging follow up*	459 (99.8)	278 (65.0)	281 (90.9)	98 (49.8)	56 (60.2)	460 (100)
Time of last CT imaging within period – y	3 days (2.0–26.0)	1.0 (0.7–1.1)	3.9 (3.1–4.1)	6.7 (5.9–7.2)	9.3 (8.1–11.4)	3.3 (1.3–5.4)
Absolute, cumulative neck diameter change during follow up†						
Median (IQR) – mm	0.0 (0.0–1.0)	1.0 (0.0–3.0)	2.0 (0.0–5.0)	4.0 (2.0–6.2)	5.0 (3.0–7.0)	3.0 (0.4–5.0)
Median (IQR) – %	0.0 (0.0–4.2)	4.8 (0.0–10.9)	9.5 (0.0–20.8)	16.4 (7.9–25.8)	22.4 (12.3–30.4)	11.1 (1.5–21.9)
Relative neck diameter change per each time period†,‡						
Median (IQR) – mm	0.0 (0.0–1.0)	1.0 (0.0–3.0)	1.0 (0.0–3.0)	1.0 (0.0–2.0)	1.0 (0.0–2.2)	–
Median (IQR) – %	0.0 (0.0–4.2)	4.8 (0.0–10.8)	4.5 (0.0–13.0)	3.9 (0–0–9.0)	3.8 (0.0–10.3)	–
Neck diameter change per year†						
Median (IQR) – mm	–	1.1 (0.0–2.8)	0.3 (0.0–1.2)	0.3 (0.0–0.9)	0.3 (0.0–0.7)	–
Median (IQR) – %	–	5.2 (0.0–11.7)	1.4 (0.0–4.5)	1.5 (0.0–3.3)	1.4 (0.0–2.6)	–

Data are presented as n or n (%) unless stated otherwise. IQR = interquartile range; DUS = duplex ultrasound; CT = computed tomography.
* Number of patients varies, according to availability of CT imaging performed within time interval
† The infrarenal outer to outer neck diameter was measured in two axes (anteroposterior and transverse) at a plane determined by the endografts' first covered stent on the 30 day CT imaging (Fig. 1). The distance from the start of the proximal covered stent to the lowermost renal artery was used as reference to determine the corresponding neck diameter measurement plane on pre-operative imaging and subsequent post-operative imaging. The simple average of each of two diameter measurements was considered.
‡ Excludes neck diameter changes occurring in the preceding time periods.

95% CI 1.4 — 6.9), and neck related adverse events overall (HR 2.6, 95% CI 1.3 — 5.2) but not with AAA sac growth.

Although excessive neck dilatation occurred more frequently among Endurant implanted patients (see above), no differences between endografts were revealed up to eight years either regarding neck related adverse events overall (Excluder −19.6%, Endurant −20.6%, p = .89) or type 1A endoleaks in particular (Excluder −6.3%, Endurant −8.7%, p = .29).

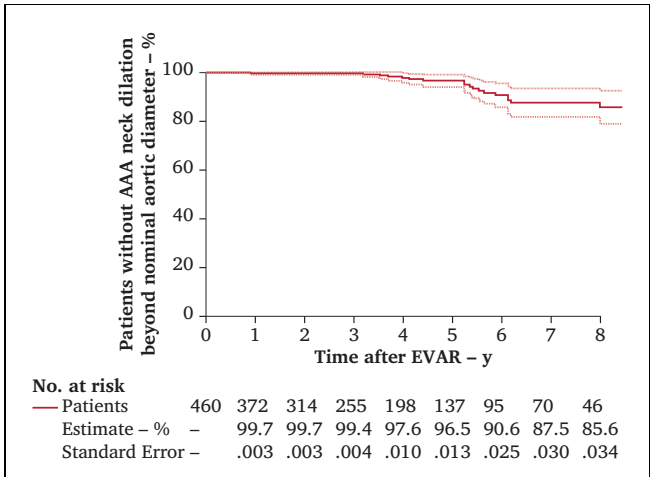

Figure 3. Cumulative Kaplan–Meier estimate for freedom from neck dilatation beyond nominal aortic diameter in 460 patients with abdominal aortic aneurysm (AAA) treated by endovascular repair (EVAR). A normalised outer to outer aortic neck diameter was calculated by adding the implanted endografts' nominal diameter to the thickness of both aortic walls. If the ratio between the measured outer to outer aortic diameter and the normalised aortic neck diameter was >1, excessive neck dilatation was considered to have occurred. Dashed lines represent upper and lower 95% confidence intervals.

DISCUSSION

Neck dilatation after EVAR was a frequent event in the study, with half of the study population presenting > 10% dilatation at the end of the study period. It was found that for most patients, the rate at which it developed progressively decreased over follow up until the oversized endograft approximated to its nominal diameter and the influence of endograft radial force on the aortic neck progressively reduced. The Excluder endograft was associated with a decreased risk of neck dilatation. However, when compared with the Endurant endograft, the occurrence of neck related adverse events or type 1A endoleaks was similar among devices, despite the contrasting neck anatomies treated in each cohort. Also, the study suggests that a baseline neck diameter ≥ 30 mm is also a relevant risk factor for excessive neck dilatation.

Although neck dilatation became more critical after EVAR, since treatment largely relies on effective seal zones, it was initially described following open repair in 13% — 20% of the cases, suggesting that multiple factors may share a role in its genesis.[5,12–15] Histological hallmarks of aneurysmal degeneration including elastic lamina destruction and upregulation of metalloproteinases have been identified in the aortic neck well before developing dilatation.[16]

Endograft related factors have a major role in the development of post-EVAR neck dilatation. Oversized SESs exert a chronic outward force on the aortic wall until its nominal diameter is reached. Additionally, it has been suggested that endografts may contribute to wall hypoxia which may promote neck degeneration.[17] Consequently, post-EVAR neck dilatation is a common event, with rates

Table 3. Predictors of neck dilatation beyond normalised aortic diameter at last available imaging (logistic regression) in 460 patients treated with endovascular aneurysm repair (EVAR)

Variables	Univariable analysis*		Final multivariable model*	
	OR (95% CI)	*p*	OR (95% CI)	*p*
Age per year	0.98 (0.92–1.04)	.51		
Male gender	1.32 (0.30–5.88)	.72		
Hypertension	0.60 (0.25–1.43)	.25		
Diabetes mellitus	0.67 (0.19–2.34)	.53		
eGFR <60 mL/min/1.73 m^2†	0.76 (0.21–2.73)	.67		
Continuous smoking at EVAR‡	2.12 (0.90–5.00)	.19		
ASA class III/IV†	0.57 (0.24–1.34)	.20		
Peripheral arterial occlusive disease†	0.23 (0.03–1.68)	.14		
Cerebrovascular disease‡	0.72 (0.16–3.21)	.67		
Pulmonary disease‡	2.47 (0.91–6.71)	.077	2.89 (0.94–8.88)	.064
Cardiac status ≥2‡,§	0.77 (0.22–2.70)	.68		
AAA diameter per mm	1.00 (0.96–1.03)	.86		
Proximal neck diameter per mm‖	1.30 (1.14–1.48)	<.001	1.21 (1.05–1.41)	.011
Proximal neck length per mm	0.98 (0.94–1.01)	.18		
Reversed tapered neck	0.57 (0.17–1.99)	.38		
Neck thrombus ≥25%	2.00 (0.85–4.71)	.11	–	–
Neck calcification ≥25%	0.55 (0.16–1.90)	.34		
α angle ≥45°	0.4 (0.05–3.16)	.39		
β angle ≥ 60°	1.85 (0.69–4.95)	.22		
Stent graft models				
Endurant¶	3.16 (1.16–8.61)	.024	–	–
Excluder	0.18 (0.05–0.58)	.005	0.15 (0.04–0.58)	.006
Talent¶	5.83 (1.43–23.89)	.014	–	–
Oversizing per %	0.96 (0.92–1.00)	.060	0.95 (0.90–1.00)	.062
Proximal seal <10 mm on 30 day CT imaging	1.21(0.34–4.29)	.77		
Distance >5 mm to lowermost renal artery on 30 day CT imaging	0.24 (0.03–1.81)	.17		

ASA = American Society of Anesthesiologists classification system; AAA = abdominal aortic aneurysm; CT = computed tomography; eGFR = estimated glomerular filtration rate.
* Time included as covariate in each model.
† Missing data for >5%.
‡ Missing data for >2% <5%
§ According to the Society for Vascular Surgery/American Association for Vascular Surgery medical comorbidity grading system.
‖ A normalised outer to outer aortic neck diameter was calculated by adding the implanted endografts' nominal diameter to the thickness of both aortic walls. For nominal aortic neck diameter calculation, an aortic wall thickness of 1.5 mm was considered. If the ratio between the measured outer to outer aortic diameter and the normalised aortic neck diameter was >1, excessive neck dilatation was considered to have occurred.
¶ Multivariable analysis did not include Endurant and Talent stent grafts due to multicollinearity.

reaching 33% as reported by Badran *et al.*[18] In the study, over 50% of the population had a > 10% neck diameter increase at a median of four years follow up. Sampaio *et al.*, in a study including two different endografts (Ancure and AneuRx), showed neck dilatation to occur in two phases, with both endograft oversizing and radial force being correlated with abrupt neck dilatation on 30 day imaging later followed by a slower oversizing driven dilatation phase.[19] A systematic review has further confirmed a positive correlation between oversizing and aortic neck dilatation.[20] The results suggest that this biphasic evolution is not as evident with later generation endografts, given the minimal changes observed at 30 day follow up. This may be due to reduced radial force compared with previous generations, leaving oversizing as the main endograft dependent factor extending neck dilatation into midterm follow up.[5,15,21–23] Furthermore, once the endograft's nominal diameter is reached, the aortic neck may not dilate beyond that point. This observation had been made by Monahan *et al.*[21] but the reduced population size in that study, with only 29 patients reaching two year follow up, limited their conclusions. In the present larger study, faster rates of neck dilatation were only noted at one year imaging and progressively decelerated subsequently as the nominal endograft diameter was approached. Importantly, when compared with their < 30 mm counterparts, neck dilatation was more accelerated among patients with neck diameters ≥ 30 mm and persisted even after full endograft expansion was approached, suggesting that these patients may be at greater risk of proximal seal complications. To mitigate this, longer proximal seal lengths are advised in these patients. For low risk patients with ≥ 30 mm neck diameters, open repair may be preferable. If otherwise high risk or unsuitable for complex EVAR, other alternatives such as fenestrations may be considered in order to prolong the proximal seal. Whether endo-anchors avoid neck dilatation beyond

Table 4. Neck dilatation and clinical consequences in 460 patients treated by endovascular aneurysm repair

	Patients −*n*	Type 1A endoleak	Migration > 5 mm at last available CT	Proximal neck related interventions	Neck related adverse events	Aneurysm sac growth
*Neck dilatation at 30 day CT**	459					
4th quartile (>4.2%)	108	4 (3.7)	8 (7.4)	5 (6.5)	12 (11.1)	10 (9.3)
Controls	351	19 (5.4)	36 (10.3)	29 (8.3)	51 (14.5)	44 (12.5)
HR (95% CI)		0.80 (0.27−2.36)	0.81 (0.37−1.76)	0.65 (0.25−1.67)	0.91 (0.48−1.72)	0.81 (0.41−1.62)
p value		.69	.59	.37	.77	.81
*Neck-dilatation at one year CT**	278					
4th quartile (Δ>11.7%)	77	3 (3.9)	11 (14.3)	3 (3.9)	10 (13.0)	5 (21.7)
Controls	201	9 (4.5)	14 (7.0)	13 (6.5)	22 (11.0)	47(10.8)
HR (95% CI)		1.04 (0.28−3.84)	2.75 (1.23−6.15)	0.69 (0.20−2.43)	2.55 (1.25−5.19)	1.44 (0.57−3.64)
p value		.96	.014	.57	.010	.44
*Neck dilatation beyond nominal neck diameter at last imaging**	460					
Dilatation beyond nominal neck diameter	23	4 (17.4)	5 (21.7)	5 (21.7)	9 (39.1)	5 (21.7)
Controls	437	18 (4.1)	37 (8.5)	29(6.6)	53 (12.1)	47(10.8)
HR (95% CI)		3.28 (1.10−9.74)	3.05 (1.35−6.90)	2.56 (0.99−6.65)	2.55 (1.25−5.19)	1.44 (0.57−3.64)
p value		.033	.008	.053	.010	.44

Data are presented as *n* (%), unless stated otherwise. CT = computed tomography; HR = hazard ratio; CI = confidence interval. At 30 days and one year, patients within the fourth quartile proximal neck diameter increases were compared with the remaining cohort. At the last available imaging, patients with neck dilatation beyond nominal neck diameter were compared with the remaining cohort. A normalised outer to outer aortic neck diameter was calculated by adding the implanted endograft's nominal diameter to the thickness of both aortic walls. For nominal aortic neck diameter calculation, an aortic wall thickness of 1.5 mm was considered. If the ratio between the measured outer to outer aortic diameter and the normalised aortic neck diameter was >1, excessive neck dilatation was considered to have occurred.
* Number of patients varies, according to availability of CT imaging performed within time interval.

the implanted endografts nominal diameter has not been demonstrated but may be pre-emptively considered to achieve better endograft fixation in high risk patients.

Interestingly, the results suggest an association between the included suprarenal fixating endografts and neck dilatation. Comparative bench testing has demonstrated that the suprarenal fixating SESs included in the present study actually have higher radial forces than their infrarenal counterparts, which may be the main explanation for the findings.[24] However, it remains unclear if chronic outward forces due to the presence of an additional suprarenal stent may also influence the findings. Additionally, differences in patient selection may not have been adequately captured and accounted for. In this study, the anatomy of those patients treated with suprarenal fixation devices was significantly different from their infrarenal counterparts. These patients had significantly larger neck diameters and shorter neck lengths, which reflects the tailored stent graft selection process involved in EVAR planning at the centre. This policy may help to explain why patients with more hostile neck characteristics achieve comparable results to their more favourable counterparts. Since there were no predefined criteria for endograft selection in individual patients, the issue cannot be explored further in this study. To minimise this selection bias, a subanalysis comparing only patients with neck diameters < 30 mm and neck length > 15 mm treated with either of the two most commonly implanted endografts (Excluder and Endurant) was added. Despite reducing differences in baseline proximal neck anatomy, they were not entirely eliminated. In this subanalysis, neck dilatation beyond nominal aortic diameter did not occur among the subgroup of patients treated with Excluders while it was identified among 4% of the Endurant patients, up to five year follow up.

Contradictory associations between baseline neck diameter and neck dilatation have been reported. Makaroun *et al.*[25] and others described greater rates of dilatation among neck diameters ≤19 mm.[26,27] This conflicting evidence was captured by a recent systematic review and may be caused by excessive oversizing in such small diameter necks.[28] Inversely, Cao *et al.* found that the risk of neck dilatation (defined as ≥3 mm increments) increased in wider necks (HR 1.2/mm, 95% CI 1.1−1.4).[13] A similar trend was reported previously by the group among neck diameters ≥30 mm.[29] Comparable findings are presented in the current study, where patients with baseline neck diameters ≥30 mm were at increased risk of excessive dilatation.

Continuing neck dilatation may exceed the implanted nominal endograft diameter, leading to device migration or type 1A endoleak and consequent risk of post-implant rupture. In the study, the influence of increased neck dilatation rates during early follow up was tested as a predictive factor for late proximal seal related complications but significant associations were not found. Only when neck dilatation exceeded the normalised aortic diameter was an increased risk of type 1A endoleaks, endograft migration > 5 mm and neck related adverse events overall identified.

This may have been due to the low number of events and to the fact that aortic neck dilatation was only determined at a single plane and not throughout the entire proximal seal zone. Consequently, caution is advised when interpreting the results in this respect.

Noteworthy, there are other relevant limitations to this study. The retrospective and single centre design inevitably introduces a bias in patient and graft selection that restricts the extrapolation of these results to all EVAR populations. Still, all reported patients were treated consecutively with contemporary endografts, which is clinically valuable. Secondly, the limited study population and the reduced number of post-operative CTs performed on each patient may have underpowered the results, limiting the possibility of revealing more subtle differences. However, current surveillance protocols preclude the use of annual CT imaging particularly in patients at low risk of developing complications at least during an early uneventful follow up.[30] Patients who developed AAA related complications had more neck diameter measurements available compared with those patients without incidents during their follow up, which also may have introduced bias into the results. Nevertheless, all CTs performed throughout the study period were measured, all neck diameter measurements were prospectively entered into the database, yearly dilatation rates calculated and subanalyses excluding those patients with AAA related adverse events provided to minimise this bias. Endograft oversizing data herein presented were calculated relatively to a reference aortic plane defined by the position where there the endograft was deployed initially (which was traced back to pre-operative imaging) and should not be considered as representative of the centre's policy on stent graft oversizing. In this respect, EVAR sizing takes into account a reference neck diameter (usually the largest diameter throughout the planned sealing zone) and follows a 10% — 20% range (with more aggressive oversizing being planned in more challenging anatomies, as reported elsewhere[31]). Furthermore, choice of outer to outer diameter measurements was based on the SVS reporting standards[11] but may limit comparison with studies where inner to inner measurements were used. Also, to calculate the nominal aortic diameter according to the implanted endograft, the aortic wall thickness had to be accounted for, which may also have introduced bias.

In conclusion, neck dilatation is frequent after EVAR with SES and is associated with endograft oversizing and radial force. This dilatation occurs in two phases, one faster during the first year and then slower until the nominal graft diameter is reached, almost stopping from then on in the majority of the cases. For most patients, neck dilatation is clinically irrelevant, for up to six years of follow up. Large baseline diameters (>30 mm) was associated with an increased risk of excessive proximal neck dilatation at the assessed aortic plane while treatment using the Excluder endograft seemed to confer a protective effect, for reasons still unclear. Distinct endograft radial force among the studied endografts and baseline differences in proximal neck anatomy (including diameter and neck length) may contribute significantly to the observed differences in AND. Separating these differences from the influence of the suprarenal fixating stent itself is not possible in the data but could be an interesting topic for future research. Despite this, proximal neck related complications were similar among patients treated either with an Excluder or an Endurant stent graft. The proportion of patients with excessive dilatation is small, but they experience more adverse clinical events.

Due to the risk of expansion beyond nominal graft diameter, lifelong image surveillance remains necessary, particularly for higher risk patients. Alternative repair methods providing longer proximal seal lengths or enhancing proximal fixation may be considered in these particular subgroups and balanced against the risks of open AAA repair.

CONFLICT OF INTEREST

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APPENDIX A. SUPPLEMENTARY DATA

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