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Changes in Aortoiliac Anatomy After Elective Treatment of Infrarenal Abdominal Aortic Aneurysms with a Sac Anchoring Endoprosthesis

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WHAT THIS PAPER ADDS

This study provides a more detailed review than has been published previously of changes in aortoiliac anatomy after endovascular aortic sealing of infrarenal abdominal aneurysms. The current study shows that filling of endobags inside the aneurysm to a pressure of 180 mmHg is associated with a low risk of peri-procedural complications. Results regarding changes in aortoiliac length and angulation may require revision of current pre-operative planning and sizing protocols for EVAS.

Objective: Endovascular aortic sealing (EVAS) with the Nellix endosystem (Endologix, Irvine, CA, USA) is a new concept to treat infrarenal abdominal aortic aneurysms (AAAs). By sealing the aneurysm, potential endoleaks may be avoided. Early results of EVAS are good, but no data have been published regarding peri-procedural changes in aortoiliac anatomy. In this study, 27 consecutive patients who underwent elective EVAS repair of an AAA were reviewed.
Method: Specific AAA (diameter, length from renal arteries to aortic bifurcation, supra- and infrarenal neck angulation, AAA volume, thrombus volume, and flow lumen volume), and iliac artery characteristics (length, angulation, location of most severe angulation with reference to the origin of the common iliac artery) were determined from pre- and post-procedural reconstructed computed tomography angiograms.
Results: No type I or II endoleaks were seen at 30 day follow up. Total AAA volume, suprarenal and infrarenal angulation, as well as aortic neck diameter did not change significantly post-EVAS. AAA flow lumen increased significantly (mean difference −4.4 mL, 95% CI 2.0 to −8.6 mL) and AAA thrombus volume decreased (mean difference 3.2 mL, 95% CI 2.0 to −1.1 mL). AAA length (125.7 mm vs. 123.1 mm), left common iliac artery length (57.6 mm vs. 55.3 mm), and right and left maximum iliac artery angulation (right 37.4° vs. 32.2°; left: 43.9° vs. 38.4°) were reduced significantly and the location of maximum angulation was further from the iliac artery origin post-EVAS, suggesting slight straightening of the aortoiliac anatomy.
Conclusion: Most aortoiliac anatomic characteristics remained unchanged post-EVAS. Filling of the endobags to a pressure of 180 mmHg may lead to lost thrombus volume in some patients, probably because liquid is squeezed into lumbar or the inferior mesenteric artery. The absolute differences in pre- and post-EVAS aortoiliac lengths were small, so pre-operative sizing is accurate for determining stent length.

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INTRODUCTION

Endovascular aortic sealing (EVAS) with the Nellix endosystem (Endologix, Irvine, CA, USA) is an innovative method to exclude infrarenal abdominal aortic aneurysms (AAAs).[1,2] The concept of EVAS is based on sealing of the aneurysm and both common iliac arteries by polymer filling of endobags that surround cobalt chromium balloon expandable covered stents. The stents provide flow lumens to both legs, and sealing of the aneurysm prevents both movement of the EVAS system and types I and II endoleaks.[3,4] According to the instructions for use, common iliac artery aneurysms, up to 35 mm, can be treated with EVAS.[5]

Filling of the endobags has to be performed with care and is based on pre-operative volume calculations. The volume of the flow lumen from the lowest renal artery to

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both expected landing zones in the common iliac arteries has to be calculated. During treatment, the endobags will be prefilled with non-heparinized saline until an intended fill pressure of 180 mmHg has been reached in both endobags. When digital subtraction angiography confirms a good position of the endosystems and adequate sealing of the endobags (no type I and II endoleaks), the pre-filled saline is withdrawn from the endobags and the same amount of polymer is injected, again until a fill pressure of 180 mmHg has been reached. In case of any sealing issues, a secondary fill with additional polymer can be done. It is of the utmost importance not to expand the volume of the AAA during filling of the endobags to avoid the risk of rupture. It would be advantageous to determine whether the Nellix endobags and stents increase unfavorable aortoiliac characteristics such as supra- and infrarenal angulation, aortic volume expansion, and common or external iliac artery tortuosity, that may lead to post-EVAS complications like type IA endoleaks, aortic rupture, and thrombotic events, respectively. So far, limited data are available regarding eventual changes in pre- and post-EVAS aortoiliac characteristics, which is the subject of this study.

MATERIALS AND METHODS

The local St. Antonius Hospital ethical committee approved this study.

Patient population

From July 2013 to July 2014, 27 patients underwent elective EVAS of infrarenal AAAs with the Nellix endosystem and were included in this study. Pre-procedural computed tomography (CT) scans were acquired within 3 months before surgery and follow up scans were acquired 4—6 weeks post-EVAS. Anatomical characteristics of all patients were within the Nellix instructions for use, including non-aneurysmal neck length of $\geq$10 mm, aortic neck diameter of 18—32 mm, maximum aortic blood flow lumen diameter of $\leq$60 mm, and common iliac artery diameter of 8—35 mm. The aim in all procedures was for a primary fill pressure of 180 mmHg, which was considered sufficient to gain an adequate seal and within a safe range of pressure that could be exerted on the aortic wall, thereby not risking per-operative aneurysmal perforation during filling of the endobags.

Imaging/data

CT angiograms were performed with a 256 slice CT scanner (Philips Healthcare, Eindhoven, the Netherlands) and were acquired with a tube voltage of 120 kV, tube current time product of 180 mAs, increment of 0.75 mm, pitch of 0.9 and collimation of 128 mm $\times$ 0.625 mm. CT scans were reconstructed at 1.5 mm slice thickness. Xenetix300 contrast was administered intravenously at a rate of 4 mL/s, administering, respectively, 80 and 60 mL for pre- and post-procedural acquisitions. Scan acquisition was performed during the arterial phase, using bolus triggering with a threshold of 100 HU.

Data analysis

Specific AAA and iliac artery measurements were performed on the pre-procedural and 1 month post-EVAS CT angiograms using a 3Mensio workstation (3Mensio Medical Imaging BV, Bilthoven, the Netherlands). Measurements were performed on 3 dimensional (3D) vessel segmentations in 3Mensio, including vessel view (Fig. 1A and B) and stretched view (Fig. 1C and D) visualizations. 3D visualizations were obtained by following the standard actions of AAA analysis in 3Mensio, including segmentation of the contrast enhanced lumen and reconstruction of a center lumen line (CLL). For the post-EVAS CT scan, the CLL was reconstructed through the center of the endobags. For reproducible measurements of AAA length, the CLL reconstruction started at the distal edge of the lowest renal artery and ended at the aortic bifurcation.

AAA specific measurements

- Diameters (mm). Diameters were measured in two orthogonal directions that were used to compute the average diameter for different levels:
  - Baseline (lowermost renal artery);
  - 5 mm, 10 mm, and 15 mm below the lowest renal artery;
  - Maximum AAA diameter.

- Length (mm). AAA length was measured over the CLL, from the lowest renal artery to the aortic bifurcation.
- Angulation (°). Maximum supra- and infrarenal angulations were measured pre- and post-EVAS. Angulations were calculated with the tortuosity tool, measuring the curvature of the centerline. Maximum supra- and infrarenal angulations were defined as the maximum angle of the centerline proximal and distal from the lowest renal artery, respectively.
- Volume (mL). The entire volume of the aneurysm (between the lowest renal artery and the aortic bifurcation) was calculated pre- and post-EVAS. Flow lumen volume of the aorta pre-EVAS and the volume of the endobags plus stents were calculated post-EVAS. The function in 3Mensio that automatically segments volume was used to measure flow lumen volume, and custom volume segmentation was used to measure the entire AAA volume and the endobags volume. Pre-EVAS thrombus volume was calculated from the difference between AAA volume and flow lumen volume, whereas the post-EVAS thrombus volume was calculated from the difference between AAA volume and the volume of the Nellix endobags, including the balloon expandable stents.

3D visualizations of the common and external iliac arteries were similarly performed. CLLs were reconstructed for both iliac arteries, starting at the origin of the common iliac arteries and extending to the distal external iliac arteries. Post-EVAS the CLL was reconstructed through the center of the EVAS stent and continued in the lumen of the native external iliac artery.

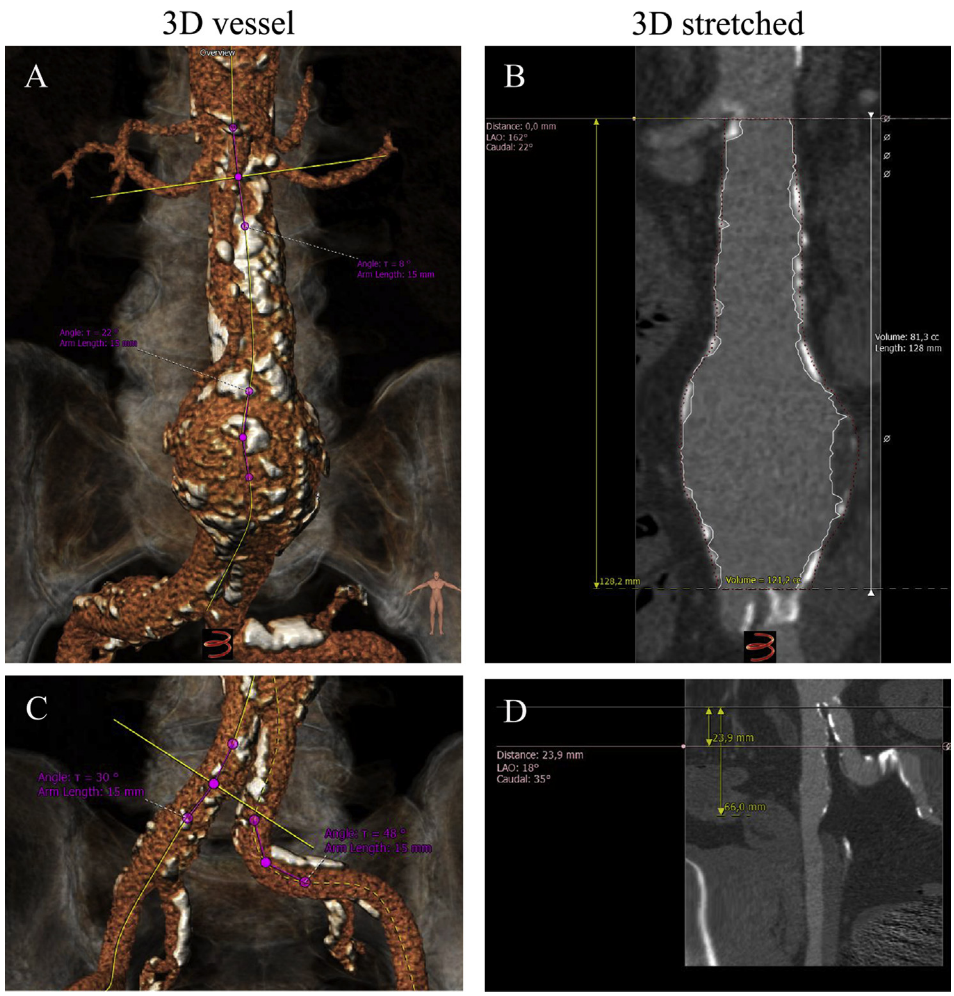

Figure 1. Example of pre-EVAS AAA and iliac visualizations in 3Mensio. (A) and (C) depict the 3D overview that was used for angulation measurements. (B) and (D) show the stretched views that were used for AAA diameter, length, and volume measurements and iliac length, angulation, and sealing zone measurements.

Common iliac artery measurements

- Length (mm). Iliac artery length was measured between the origin of the common iliac arteries and the iliac bifurcation (proximal edge of the internal iliac artery).
- Angulation (°). The maximum angle of the common iliac arteries was measured pre- and post-EVAS with the tortuosity tool. The location of the maximum angulation pre- and post-EVAS was identified.

Statistics

Measurement outcomes were analyzed with IBM SPSS 22.0 software (IBM Corp, Armonk, NY, USA). A Shapiro-Wilk test was performed to assess normal distribution of the data. For normally distributed data, mean and standard deviations were calculated and a parametric paired samples *t* test was performed to compare pre- and post-EVAS measurements of aortoiliac anatomy. In case of skewed data, median and interquartile ranges were calculated and pre- and post-procedural measurements were compared with a related samples Wilcoxon ranked-signed test. Outcomes were considered significant at a p value $< .05$. Moreover, a scatter plot was calculated to compare the location of the distal end of the stents with the location of maximum iliac artery angulation post-EVAS.

RESULTS

All 27 patients (25 male; mean age 73 years, SD 5 years) underwent an uneventful EVAS procedure. The average surgery time was 72 minutes (range 55—112 minutes), and blood loss was 99 mL (SD 54 mL). Completion angiography showed that none of the patients had a type I or II endoleak. In four patients, one of the EVAS systems had to be extended with a self expandable bare metal stent for better alignment with the native common iliac artery. In one patient there appeared to be a dissection of the external iliac artery, which was also treated with an uncovered self expandable stent. All other procedures were uneventful. The mean hospital stay was 2 days. The 30 day mortality rate was 0%. CT scans at 30 days showed no type I or II endoleaks.

Pre- and post-EVAS AAA characteristics are reported in Table 1. There were no significant changes in the mean

Table 1. AAA characteristics before and after EVAS ($N = 27$).

Characteristics	Pre-EVAS		Post-EVAS		Paired samples test (pre-post)			
	Mean	Range	Mean	Range	Mean difference	SD	95% CI of the difference	*p*-value
Aortic neck diameter (mm)								
Baseline (lowermost renal artery)	22.8	18.5—27	22.9	19—28	0	1.1	−0.5 to 0.4	.97
Baseline +5 mm	23.4	18.8—28	23.3	19.5—28.5	0.1	1.2	−0.4 to 0.6	.64
Baseline +10 mm	24.1	19.3—28	24.2	20.5—30.5	−0.1	1.4	−0.7 to 0.5	.74
Baseline +15 mm	25	19.5—33.5	25.5	21—33.3	−0.5	1.9	0.4 to −1.3	.15
Aortic neck angulation (degrees)								
AAA suprarenal	17.4	5—57	15.7	4—53	1.7	7.4	1.4 to −1.3	.25
Infrarenal	36.3	15—57	32.6	11—59	3.7	11.8	2.3 to −1.0	.12
AAA diameter (mm)	54.8	35—80	55.8	35—71	−1	6.4	1.2 to −3.5	.43
AAA length (mm)	125.7	85—163.5	123.1	83—156.5	2.6	4.5	0.9 to 0.8	.01
Volume (mL)								
AAA flow lumen volume/endobag plus stent volume	87.2	33.7—146.2	91.8	35.1—167.7	−4.4	10.4	2.0 to −8.6	.04
AAA thrombus volume	65.5	9.1—155	62.3	11.2—143.1	3.2	10.6	2.0 to −1.1	.04
Total AAA volume	152.8	42.8—301.2	154.1	46.3—307.9	−1.3	6.5	1.2 to −3.9	.31

infrarenal neck diameter (baseline: 22.8 mm vs. 22.9 mm, baseline+5: 23.4 mm vs. 23.3 mm, baseline+10: 24.1 mm vs. 24.2 mm, and baseline+15: 25 mm vs. 25.5 mm), in suprarenal angulation (17.4° vs. 15.7°), or in infrarenal neck angulation (36.3° vs. 32.6°). No significant differences were found in the diameter of the aneurysm (54.8 mm vs. 55.8 mm), or the volume of the aneurysm (152.8 mL vs. 154.1 mL). Small, but significant changes appeared in the length of the aneurysm (125.7 mm vs. 123.1 mm), flow lumen volume (87.2 mL vs. 91.8 mL), and aortic thrombus volume (65.5 mL vs. 62.3 mL).

Iliac artery characteristics pre- and post-EVAS are summarized in Table 2. The mean sealing lengths for the right and left common iliac arteries were 31.6 and 33.1 mm, respectively. Significant pre- and post-procedural differences were found in changes in the length of the common iliac arteries and maximum angulation (37.4° vs. 32.3° and 43.9° vs. 38.4°, respectively, for the right and left iliac arteries). The location of the maximum angulation, with the origin of the common iliac artery as a reference point, changed significantly for both the right and left common iliac arteries (25.2 to 33.4 mm and 25.3 to 31.6 mm, respectively). The location of maximum angulation post-EVAS appeared to be at the distal end of the Nellix stents (right common iliac artery: 33.4 mm vs. 31.6 mm; left common iliac artery: 31.6 vs. 33.1 mm). The mean difference between the location of maximum angulation and distal end of the stent was +1.9 mm (standard deviation [SD] 20.2; 95% confidence interval [CI] −9.8 to 6.1; $p = .64$) and −1.5 mm (SD, 21.8; 95% CI −7.1 to 10.1; $p = .73$) for the right and left iliac arteries, respectively, suggesting an association between the location of the maximum angulation and the distal landing zone. The outcomes are illustrated by the scatter plot in Fig. 2, comparing the location of the distal end of the stent with the location of maximum angulation post-EVAS for both the right and left common iliac arteries. The figure shows that the location of maximum angulation post-EVAS varies with reference to the distal end of the stents. After a median follow up of 7 months none of the studied patients suffered from either Nellix or iliac artery obstruction.

DISCUSSION

The use of a sac-anchoring endoprosthesis for endovascular aortic aneurysm repair does not significantly change the diameters of the infrarenal neck or supra- and infrarenal angulation. However, a significant decrease in ILT volume was determined without an increase in AAA diameter and AAA volume. No type I or II endoleaks were determined at the 30 day post-EVAS CT scan. As well as the maximum angulation, the lengths of the iliac arteries were reduced, suggesting straightening of the iliac arteries caused by the Nellix stents post-EVAS. Significant changes were noted in AAA length, probably because of a combination of slight straightening of the infrarenal neck (mean difference: — 3.7°, not significant) and slight increase in the aortic volume. However, the average aortic length changed by <3 mm, which is not clinically important, and these changes will not lead to overestimation of the required length of the stents to gain an adequate seal.

The results of this study are in line with former analyses of first-generation EVAS devices.[2,6] The current study conducted a more detailed overview of peri-procedural changes in aortoiliac anatomy with EVAS using a newer generation device. Modifications of the aortoiliac anatomy are caused by different independent factors: aneurysm volume and length modifications are caused by filling of the endobags, whereas changes in iliac angulations and lengths are caused by the distal part of the endobags, but mainly the distal stents. Measurements were performed according to standards that have been reported for measurements of aortic[7] and iliac characteristics,[8] using anatomical landmarks to improve reproducibility of the measurements. Furthermore, the changes in iliac angulation were evaluated post-EVAS.

Table 2. Summary iliac arteries characteristics and outcome of paired samples test ($N = 27$).

Characteristics	Pre-EVAS		Post-EVAS		Paired samples test			
	Mean	Range	Mean	Range	Mean difference	SD	95% CI of the difference	*p*-value
Iliac arteries length (mm)								
Right	58.9	32–94	57.2	31–94	1.7	5.4	−0.5 to 3.9	.12
Left	57.6	33–100	55.3	29–90	2.4	4.9	0.4 to 4.3	.02
Maximum angulation (degrees)								
Right	37.4	8–76	32.3	8–59	5.1	10.9	0.8 to 9.4	.02
Left	43.9	13–86	38.4	5–79	5.5	11.7	0.9 to 10.1	.02
Location maximum angle (mm)								
Right	25.2	4–60	33.4	5–60	−8.2	16.7	−14.8 to −1.6	.02
Left	25.3	3–90	31.6	3–67	−6.3	15.9	−12.6 to −0.1	.05

Literature has shown that some intraluminal thrombi (ILT), or at least parts of the thrombus, may vary in volume because of external compression. In a recent review by Labruto and coworkers,[9] it has been shown that not all thrombi are organized, some are minimally organized, or contain unorganized (i.e. mostly fluid) parts.[9] These unorganized parts can be compressed by squeezing the fluid components. Magnetic resonance imaging (MRI) is most accurate for ILT depiction and determination of differences in the internal structure of ILT. It is a limitation of this current study that no MRI was performed of patients with a significant decrease in aortic thrombus volume. This is the subject of another study, as well as in-vitro compression tests of explanted aortic thrombi after open aortic aneurysm repair.

Wilson and coworkers[10] showed in their extensive review that the biochemomechanics of ILT are dynamic, and that thrombus should not be treated as an inert and homogeneous substance. Most ILT consists of three layers (luminal, medial, and abluminal) and in some patients a liquid interface has been found between the abluminal layer and the aortic wall. This liquid interface can be squeezed. Besides, the matrix of the abluminal layer is almost completely degraded and soft. According to the law of physics thrombus cannot be compressed. Truijers and coworkers studied changes in the volume of thrombus in AAA during the cardiac cycle.[11] Large inter-patient variability was found for volume changes (0.2–13.5 mL), which was independent of pulse pressure, initial thrombus volume, and aneurysm size. In the present study, a larger variability was determined for changes of thrombus volume (−21.7–20 mL), which was also independent of aneurysm size. Large inter-patient variability in changes of AAA thrombus volume may depend on the size of the liquid interface, suggesting that liquids maybe squeezed out of the ILT into patent branches (e.g. lumbar arteries and inferior mesenteric artery) which could explain the lost thrombus volume. The aneurysm sac in one patient was not completely filled by the endobags, which induced additional thrombus formation.

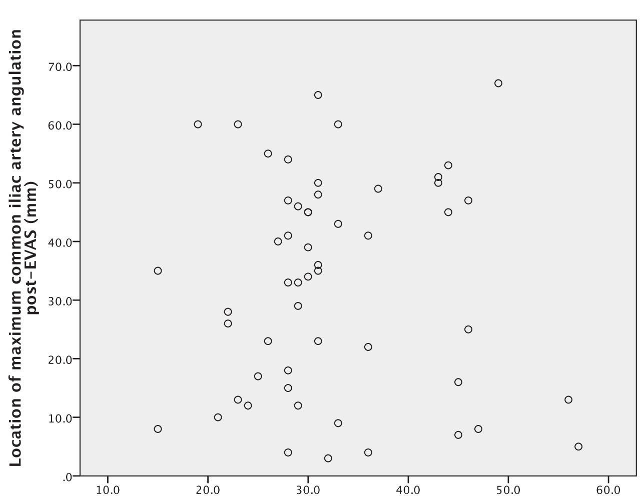

Figure 2. Location of the distal end of the stent vs. the location of maximum angulation post-EVAS for both the right and left common iliac arteries. The locations (mm) are measured with reference to the right and left common iliac artery origin, respectively.

On the other hand, the interface between thrombus and flow lumen might be hard to define properly on the CT scans in some patients (because of poor cardiac output, asymmetrical or irregular thrombus load, no proper arterial phase CT scans, etc.). This limitation may influence the accuracy of the present thrombus volume measurements. However, the inter-observer tests for AAA and thrombus volume measurements showed good agreement between two observers.

Fill pressures of 180 mmHg appear to be safe and do not lead to an increase in the total AAA volume. The fill pressures in the current study were sufficient for an adequate seal, because no endoleaks were found at the 1 month follow up.

Suprarenal and infrarenal angulation remained unchanged because of the lack of suprarenal fixation of the Nellix endosystem. Moreover, the most proximal and uncovered stents of the balloon expandable Nellix stents are in the center of the inflated endobags and do not attach to the infrarenal neck, which might also explain the unchanged infrarenal neck angulation. Recently, Coulston and coworkers evaluated the effects of three different EVAR stents on straightening of the aortoiliac anatomy after elective treatment of AAA.[12] Straightening of the infrarenal aorta and iliac arteries was found. As it appears for all EVAR procedures, the stent delivery devices partially straightened the infrarenal aorta and iliac arteries. This straightened configuration will be partially sustained by the stent grafts after the delivery devices and stiff guidewires are withdrawn. Other than the commercially available modular endografts, the polymer of the Nellix systems might induce slight straightening.

Fig. 2 shows substantial variability regarding the location of the maximum iliac artery angulation post-EVAS with reference to the distal end of the stents. The location of the maximum angulation changed from inside to outside the final distal end of the Nellix endosystems, and vice versa, in a significant number of patients. Predicting where the maximum angulation will be post-EVAS is difficult. Physicians should focus on the distal ends of the relative stiff Nellix stents and perform a completion angiogram without stiff guidewires. In case of non-alignment of the stents to the iliac arteries, or kinking of the arteries, the use of self expandable stents to extend the Nellix endosystems is advised for improved alignment and to minimize the risk of thrombosis. Another reason for post-EVAS thrombosis is the occurrence of pillowing of the endobags into the Nellix stents during curing of the polymer. According to the instructions for use, the Nellix balloons should be inflated during polymer curing (2—3 minutes) to avoid pillowing.

Because there appear to be only minimal differences in aortoiliac lengths pre- and post-EVAS, it is suggested that pre-procedural length measurements are accurate for measuring stent lengths. Device lengths are currently determined peri-procedurally by calculating the length between the lowest renal artery and the distal landing zones, which is performed with a calibration catheter under fluoroscopic guidance. Accurate pre-procedural length measurements could diminish the need for peri-procedural length measurements, thus reducing fluoroscopy time and potentially further simplifying the procedure.

Study limitations

One of the major limitations of the present study is the lack of data regarding eventual changes in aortoiliac morphology beyond 1 month. So far, the median clinical follow up of the patients is 7 months, and there have been no Nellix or iliac artery obstructions. Moreover, the patients who were included in this study consisted of the first 27 cases in one single center, including mostly patients who had straightforward anatomy, with an average infrarenal neck angulation of 36.3° (range 15°—57°). Changes in supra- and infrarenal neck angulations may be less pronounced in this group of patients. Another limitation is that intra- and inter-observer variability for angulation measurements were not assessed in the current study. However, recently inter-observer variability was determined in a group of 35 patients pre- and post endovascular abdominal aortic aneurysm repair. Angulation measurements were performed using digital callipers over the center lumen line. Variability appeared to be low, with an average intraclass correlation coefficient around 0.7 for pre- and post-procedural angulation measurements of the supra- and infrarenal aorta (unpublished data). It has been shown that variability of length measurements using 3Mensio software is low.[13,14] Moreover, methods that have been used to measure infrarenal neck and AAA diameter and volume have shown good intra- and inter-observer agreement,[14] and were not re-examined in this study.

Because measurements were performed at static CT acquisitions, dynamic changes that occur during the cardiac cycle were excluded. Studies have shown that these dynamic changes may contribute to significant changes in AAA diameter[15,16] and thrombus and flow lumen volume.[11] In the present study, variability in measurements was largest for thrombus and flow lumen volume, which would be interesting to examine using dynamic imaging modalities. In addition, Van 't Veer et al. demonstrated a significant association between intra-aneurysmal pressure and the entire AAA volume.[17] In the present study, it was expected that larger endobag fill pressures would lead to a larger increase in AAA volume. Similarly, larger fill pressures might also explain large inter-patient variability regarding changes in thrombus volume.

CONCLUSIONS

The use of the EVAS endosystem does not change aortic neck angulation or total aortic aneurysm volume. Filling of the endobags to a pressure of 180 mmHg may cause lost thrombus volume in some patients, probably because of squeezing of liquid components into branch arteries. No type I or II endoleaks were found at 1 month follow up. The average maximum iliac artery angulation will be decreased after implantation of the stents, but whether the location of this angulation will be displaced is hard to predict. Completion angiography should be performed without stiff guidewires, and also focus on the alignment of the distal end of the stents in the iliac arteries. The absolute differences in pre- and post-EVAS aortoiliac lengths were small, so pre-operative sizing is accurate for selection of the stent lengths.

CONFLICT OF INTEREST

None.

FUNDING

None.

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