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Pulsatile Distension of the Proximal Aneurysm Neck is Larger in Patients with Stent Graft Migration

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Abstract *Purpose:* The proximal abdominal aortic aneurysm (AAA) neck expands significantly during the cardiac cycle, both before and after endovascular aneurysm repair (EVAR). Clinical consequences of this pulsatility were anticipated but have never been reported. This study investigated whether there is a relation between stent graft migration and preoperatively measured pulsatility of the proximal aneurysm neck.

Methods: EVAR patients with a preoperative dynamic computed tomography angiography (CTA), an immediate postoperative, and a CTA at 3 years after EVAR were included. The preoperative dynamic CTAs consisted of eight images per heartbeat. Aortic diameter and area changes per heartbeat were measured at two levels: (A) 3 cm above and (B) 1 cm below the most distal renal artery. Postoperatively, the distance between the most distal renal artery and the most proximal stent graft ring was measured. Two patient groups were distinguished according to whether migration during follow-up occurred (group 1) or had not occurred (group 2). The aneurysm neck dynamics of the two groups were compared by using the *t*-test for unpaired data and multivariable logistic regression analyses were performed. Mean values are presented with the standard deviation.

Results: Included were 26 patients (19 Talent, 6 Excluder and 1 Lifepath). Stent graft migration of $\geq$5 mm occurred in 11 patients (group 1). The pulsatility of the AAA neck in these patients was compared with the pulsatility in 15 patients with no graft migration (group 2). There were no significant differences in aortic neck characteristics (angulation, length and diameter) or degree of stent graft oversizing between the two groups. At level A in group 1 versus group 2, the diameter increase during the cardiac cycle was 2.0 ± 0.3 versus 1.7 ± 0.3 mm and the aortic area increase was 49 ± 15 versus 33 ± 12 mm^2. At level B in group 1 versus group 2, the diameter increase per heartbeat was 1.8 ± 0.3 versus 1.6 ± 0.4 mm, and the area increase was 37 ± 10 versus 25 ± 15 mm^2. The heartbeat-dependent diameter and area changes at both levels were significantly higher in group 1 compared with group 2. Multivariate

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regression analysis showed suprarenal aortic pulsatility was a significant predictor for stent graft migration after 3 years.

Conclusion: The preoperative heartbeat-dependent aneurysm neck distension is significantly associated with stent graft migration after 3 years. The aortic pulsatility in patients with stent graft migration is significantly higher than the pulsatility in patients without stent graft migration.

Adequate fixation and complete sealing of a stent graft in an abdominal aortic aneurysm (AAA) neck is considered one of the most crucial aspects of endovascular aneurysm repair (EVAR).[1] Inadequate proximal fixation or sealing might lead to stent graft migration, thereby compromising the results of EVAR.[1,2] Several morphologic features of the proximal aneurysm neck, including neck length, diameter and angulation, are related to stent graft sealing and fixation-related complications.[3–6]

The proximal sealing and fixation zone of a stent graft in the aneurysm neck expands significantly per heartbeat, both preoperatively and postoperatively.[7,8] Preoperatively, this aortic pulsatility could complicate the process of stent graft selection and sizing, which is most commonly based on static computed tomography angiography (CTA) images. Postoperatively, stent grafts should be able to withstand and adapt to millions of repetitive heartbeat-dependent aortic wall movements to prevent stent graft migration.

The diameter variation of the proximal aneurysm neck of individual patients ranges from less than 1 mm to up to 4 mm or more during the cardiac cycle.[8] More severe pulsatility in the aneurysm neck is likely to increase the demand on the fixation and sealing zone of the stent graft. Patients with more aneurysm neck pulsatility are therefore probably more prone to stent graft sealing and fixation-related complications after EVAR than patients with less pulsatility. Although aneurysm neck pulsatility has been studied before, to our knowledge, the relation between aneurysm neck pulsatility and EVAR outcome has never been studied.

It is, therefore, the purpose of this study to investigate whether there is a relation between the preoperative aneurysm neck pulsatility and stent graft migration. Our hypothesis is that heartbeat-dependent aneurysm neck distension is larger in patients with stent graft migration than in patients without stent graft migration.

Methods

Patients

From our prospectively collected AAA database, we selected all AAA patients with a preoperative dynamic CTA, an immediate postoperative ($\leq$7 days after EVAR) and a CTA at 3 years after EVAR. These three CTA scans were available for 26 AAA patients (21 men, median age 73 years, range, 50–82 years). The stent graft characteristics and clinical course of these patients during follow-up were investigated.

Imaging

The dynamic preoperative and static postoperative CTA scans were performed on a 64-slice or 256-slice CT scanner (Philips Medical Systems, Best, The Netherlands; values for the 265-slice scanner stated between parentheses) with a standardised acquisition protocol. Scan parameters were: slice thickness, 0.9 mm (0.9 mm); increment, 0.7 mm (0.7 mm); collimation, 64 × 0.625 mm (128 × 0.625 mm); and pitch 0.25 (0.2). Field of view was 250 × 250 mm (250 × 250 mm), and the reconstructed matrix size was 512 × 512 (512 × 512), resulting in a voxel size of 0.5 × 0.5 × 0.9 mm (0.5 × 0.5 × 0.9 mm). Radiation exposure parameters were 120 kVp (120 kVp) and 300 mAs (250 mAs), resulting in a CT dose index ($CTDI_{vol}$) of 17.6 mGy (16.5 mGy). Intravenous nonionic contrast (120 ml; Iopromide, Schering, Berlin, Germany), followed by a 60-ml saline chaser bolus, was injected at a rate of 6 ml s^{-1}. The scan was started using bolus-triggering software with a threshold of 100 HU over baseline. Retrospectively, electrocardiogram-gated reconstructions were made at eight equidistant time points covering the cardiac cycle on the (preoperative) CTAs. All scans were acquired during a single breath-hold.

All preoperative and postoperative CTA data sets were transferred to a 3 Surgery 4.0 workstation (3Mensio Medical Imaging B.V., Bilthoven, The Netherlands) for analysis. The dynamic images were analysed using a custom-made dynamic extension tool for this software.

Preoperative dynamic CTA analysis

An aortic centre lumen line (CLL) was automatically constructed by placement of a proximal start and distal end point in the aortic lumen. Aortic CLL spline points were thereafter manually checked and corrected, if necessary.

Multiplanar reconstructions of the eight images per cardiac cycle were made perpendicular to the aortic CLL at two levels: 3 cm above the most distal renal artery (level A) and 1 cm below the most distal renal artery (level B).

A semi-automatic segmentation of the aortic lumen of the eight images per cardiac cycle was performed at those levels. A seeding point was placed manually inside the aortic lumen, and a region-growing algorithm was applied thereafter to automatically segment the aorta. The segmentations were reviewed and minor corrections were made manually, if necessary.

After segmentation of the aortic lumen, areas and minimum/maximum diameters were calculated. Diameter measurements were performed through the centre of mass of the aortic lumen over 180 axes (with an angular increment of 1°) during the cardiac cycle. The pulsatility was calculated as the difference between the minimum and maximum area and average minimum and maximum diameter over 180 axes.

The following AAA characteristics were measured on the preoperative CTA scans as well: AAA neck length, calcification and thrombus in the AAA neck, suprarenal and infrarenal angulation of the AAA neck, maximum AAA diameter and AAA volume. The aortic neck length was measured along the CLL from the most distal renal artery to the most proximal side of aneurysmal dilatation. The thrombus and calcification lining the aortic neck wall were visually quantified 10 mm below the most distal renal artery. The aortic neck angulation and AAA volume were measured according to earlier published protocols.[9,10] Diameters were measured perpendicular to the CLL.

Postoperative CTA analysis

A reconstructed stretch view of the aorta was generated around a semi-automatically constructed aortic CLL on all postoperative CTAs. The distance between the most distal renal artery and the most proximal stent graft ring was measured on the reconstructions on the direct postoperative CTA and also on the CTA performed 3 years after EVAR. Stent graft migration was defined as a migration of the most proximal stent graft ring of $\geq$5 mm during this 3-year follow-up. Patients with an intervention for stent graft migration during follow-up or stent graft migration of $\geq$5 mm after 3 years were designated as group 1 and those with no stent graft migration were group 2.

The diameter of the aorta 10 mm below the most distal renal artery was measured on the direct postoperative CTA and on the CTA performed 3 years after EVAR. The difference between these diameters is defined as the postoperative aneurysm neck dilatation. Maximum AAA diameters and AAA volumes were measured on CTAs performed after 3 years. Diameters were measured perpendicular to a CLL.

Statistics

Data on area and diameter change per heartbeat are presented as mean ± standard deviation and range. Statistical analysis of changes in area and diameters per heartbeat was performed using the *t*-test for paired data. The AAA characteristics, postoperative aneurysm neck dilatation, minimum area, minimum diameter and area and diameter changes per heartbeat in the two groups were compared by using the *t*-test for unpaired data. Univariable and multivariable logistic regression analyses were performed to assess the association between AAA characteristics, postoperative aneurysm neck dilatation, minimum area, minimum diameter, area and diameter changes per heartbeat and dichotomous data on stent graft migration. All significant parameters after univariable analyses were added to the multivariable analysis. Statistical significance was assumed at $P < 0.05$.

The distance between the renal arteries and the most proximal stent graft ring was measured twice by the first observer and once by a second observer. Intraobserver and interobserver variability of area and diameter measurements were calculated according to Bland and Altman.[11] All measurements were performed blinded of migration outcome and independently from the other observations.

Results

The study included 26 asymptomatic AAA patients with the following baseline characteristics: mean aneurysm diameter, 60 ± 9 mm (range, 44–78 mm); mean aneurysm neck length, 3.5 ± 1.3 cm (range, 1.1–6.0 cm); mean suprarenal angulation, 26° ± 18° (range, 0–94°); and mean infrarenal angulation, 43° ± 17° (range, 5–68°). Stent grafts used were the Talent (Medtronic, Minneapolis, MN, USA) in 19 patients, the Excluder (Gore, Flagstaff, AZ, USA) in six patients and the Lifepath (Edwards Lifesciences, Irvine, CA, USA) in one patient. The mean stent graft oversizing was 21% ± 6% (range, 9–35%). The mean postoperative aneurysm neck dilatation during the 3-year follow-up was 1.5 ± 1.9 mm (range, 0–5 mm). The mean decrease in maximum AAA diameter after 3 years was 3 ± 10 mm (range, −12–30 mm) and the mean AAA volume decrease was 23 ± 65 ml (range, −88–182 ml).

Group 1 consisted of patients with an intervention for stent graft migration during follow-up or stent graft migration of $\geq$5 mm after 3 years. Nine patients had $\geq$5 mm stent graft migration after 3 years, and two other patients had an intervention to treat stent graft migration during follow-up. An aortic extension cuff was placed endovascularly in one patient after 2 years, and an open AAA repair was performed in another patient 2 years after EVAR. Group 1 thus consisted of 11 patients and group 2 consisted of the other 15 patients. The subdivision of the 26 patients into the two groups was the same using the first or the second measurements of the first observer or the measurements of the second observer.

An overview of the baseline characteristics of the patients in groups 1 and 2 can be found in Table 1. There were no patients with calcifications lining >25% of the aneurysm neck. One patient in both groups had a thrombus lining 25–50% of the aneurysm neck. There were no significant differences between the baseline characteristics of the two groups and there was no significant postoperative aneurysm neck dilatation in both groups.

Mean aortic diameter

The preoperative aortic diameter demonstrated significant changes during the cardiac cycle in all patients at both measured levels ($P < 0.001$).

The mean diameter change 3 cm above the most distal renal artery (level A) was 8.3% ± 1.5% (range, 6.0–11.8%) in patients of group 1 (migration) and 7.3% ± 1.3% (range, 5.8–9.3%) in patients of group 2 (no migration). The mean diameter change 1 cm below the most distal renal artery (level B) was 8.4% ± 1.4% (range, 6.6–11.2%) in group 1 and 6.9% ± 1.1% (range, 4.8–8.6%) in group 2. The corresponding absolute values and *p*-values related to group comparisons can be found in Table 2. The differences between the mean minimum diameters of the two groups at

Table 1 The abdominal aortic aneurysm (AAA) characteristics of the patients in both groups (group 1 = stent graft migration; group 2 = no stent graft migration). There were no significant differences between the baseline characteristics of the 2 groups, as can be seen.

	Group 1	Group 2	*P* value
Number of patients (*n*)	11	15	
AAA diameter (mm)	60.4	59.7	0.9
Stent graft type			
Talent	10	9	
Excluder	1	5	
Lifepath		1	
AAA neck length (mm)	33.2	37.2	0.5
Suprarenal Angulation (°)	32	21	0.1
Infrarenal Angulation (°)	49	39	0.1
Stentgraft Oversizing (%)	20%	22%	0.6
Neck dilatation during FU (mm)	1.7	1.4	0.5
Diameter decrease (mm)	1.5	4.4	0.2
Volume decrease (ml)	23.4	22.1	0.5

both levels were not significant. The mean diameter change at both levels was significantly higher in group 1 (patients with migration) than in group 2. The intraobserver repeatability for diameter changes was 0.9 mm, and the interobserver variability was 0.6 mm.

Mean aortic area

The mean area change 3 cm above the most distal renal artery (level A) was 10.3% ± 3.6% (range, 5.7–15.6%) in patients of group 1 and 7.4% ± 2.3% (range, 3.7–12.3%) in patients of group 2. The mean area change 1 cm below the most distal renal artery (level B) was 9.5% ± 2.7% (range, 5.8–14.5%) in group 1 and 6.0% ± 2.6% (range, 3.0–11.1%) in group 2. The corresponding absolute values can be found in Table 3. There were no significant differences between the mean minimum areas of the two groups at both levels. The mean area change at both levels was significantly higher in group 1 (patients with migration) than in group 2. The intraobserver repeatability for area changes was 17 mm^2 and the interobserver repeatability for area changes was 26 mm^2.

Table 2 Absolute values of the mean diameter change (mm) per cardiac cycle. The heartbeat-dependent diameter increase at both levels was significantly higher in patients of group 1 than in patients of group 2. There were no statistically significant differences between the mean minimum diameters of the 2 groups.

	Group 1	Group 2	*P* Value
Suprarenal			
Diameter change	2.0 ± 0.3	1.7 ± 0.3	0.03
Minimum diameter	24.2 ± 2.0	23.3 ± 1.7	0.2
Maximum diameter	26.2 ± 1.9	25.0 ± 1.9	
Infrarenal			
Diameter change	1.8 ± 0.3	1.6 ± 0.4	0.04
Minimum diameter	21.8 ± 2.1	22.3 ± 3.4	0.7
Maximum diameter	23.7 ± 2.1	23.8 ± 3.7	

Table 3 Absolute values of the mean area change (mm^2) per cardiac cycle. The heartbeat-dependent area increase at both levels was significantly higher in patients of group 1 than in patients of group 2. There were no statistically significant differences between the mean minimum areas of the 2 groups.

	Group 1	Group 2	*P* Value
Suprarenal			
Area change	48 ± 15	33 ± 12	<0.01
Minimum area	479 ± 76	445 ± 64	0.2
Maximum area	528 ± 77	478 ± 70	
Infrarenal			
Area change	39 ± 10	25 ± 15	0.03
Minimum area	393 ± 71	415 ± 127	0.6
Maximum area	430 ± 74	440 ± 138	

Logistic regression

Univariable logistic regression analyses showed that the mean diameter and area change at both levels were significantly associated with stent graft migration after 3 years. The AAA characteristics, postoperative aneurysm neck dilatation, stent graft oversizing and the diameter and volume decrease after 3 years were not statistically significantly associated with stent graft migration after 3 years. In multivariable logistic regression analysis, the suprarenal area change per heartbeat was the only significant independent predictor of stent graft migration after 3 years (odds ratio, 1.1; 95% confidence interval (CI), 1.013–1.21; $P = 0.04$).

Discussion

This study shows that the preoperative aneurysm neck pulsatility is significantly associated with stent graft migration after 3 years and is significantly higher in patients with stent graft migration than in patients without stent graft migration. We believe that this study is the first to confirm a relation between aneurysm neck dynamics and stent graft fixation-related problems during follow-up. Previous dynamic studies have shown, similar to this study, that the aneurysm neck pulsatility at several for EVAR relevant levels is significant.[8] A correlation between preoperative pulsatility of the aneurysm neck and stent graft fixation and sealing has been suspected from the findings in these previous studies.

Most AAA patients undergo static CTA imaging preoperatively, and we are currently not able to predict from these images which patients will have a large heartbeat-dependent aneurysm neck distension. Although an earlier study found that the aneurysm neck pulsatility in young healthy persons is larger than in AAA patients, we do not know whether younger AAA patients have a larger pulsatility than older AAA patients.[8,12] It would, however, be useful to be able to preoperatively measure, which patients have a higher aneurysm neck pulsatility: A dynamic CTA could be obtained for stent graft selection and sizing, and therapy could possibly be adapted to the dynamics in the aneurysm neck.

The most optimal treatment option for AAA patients with a large aneurysm neck pulsatility is not known. An open repair instead of an endovascular repair in these patients might be considered. Moreover, if EVAR is considered the treatment of choice in a patient with a high pulsatility, the stent graft choice or oversizing might be adapted in these patients; for instance, a stent graft with an active proximal fixation technique, such as hooks or barbs, might be considered. Besides, a longer aneurysm neck might be required for stent graft fixation to prevent future complications. Additionally, a more liberal oversizing regimen in patients with a high pulsatility might be considered.

The multivariate analysis performed in this study showed that the aortic suprarenal area increase was significantly associated with stent graft migration. The aortic pulsatilities at several levels in the aorta are correlated to each other, and only the pulsatility at the level of the most significant difference was an independent predictor for stent graft migration after 3 years.

A limitation of our study might be that the relation between preoperative aneurysm neck dynamics and postoperative stent graft migration was investigated. The decision to investigate the preoperative aneurysm neck dynamics was made for several reasons. First, the postoperative aneurysm neck dynamics are comparable with the preoperative dynamics.[2] The implantation of the Talent and Excluder stent grafts do not seem to influence the movement of the aortic wall, either in heartbeat-dependent distension or in direction of distension.[2] Second, it is our experience that the investigation of the postoperative pulsatility is less reliable than the measurement of the preoperative pulsatility. The measurement of the postoperative pulsatility is influenced negatively by scattering of the stent graft. Third, the relation between preoperative aneurysm neck pulsatility and postoperative stent graft migration might be of help in decisions on EVAR suitability in the future. Future studies investigating whether there are absolute pulsatility values, which make postoperative complications either more likely or unlikely, can therefore be of great value in EVAR planning.

Another limitation might be that a higher migration rate in our study was found compared to other studies.[1] We, however, believe that this is mainly caused by the definition of migration. In our study, migration was defined as a migration of $\geq$5 mm, whilst other studies use a migration of $\geq$10 mm as a definition of migration.[13]

The intraobserver and interobserver variability of the preoperative aortic area and diameter measurements in this study were small, making the dynamic results reliable. On top of this, it is important to note that the distance between the most distal renal artery and the proximal stent graft ring was measured three times, independently and blinded. The classification of the included patients in the two groups was completely the same using these different measurements.

The patients included in this study were treated with three different types of stent grafts, both with and without suprarenal bare stents. The Excluder and Lifepath stent graft were, however, used in a very small number. It is therefore impossible to make a useful comparison between the several stent grafts used in this study.

A stent graft design should be able to adapt to — and withstand — the continuous pulsatile and asymmetric distension of the aorta. It is therefore likely that not only patients with short, angulated, calcified and thrombosed aneurysm necks, but also patients with higher aneurysm neck dynamics are more prone to stent graft migration than others.[3–6] A more firm proximal fixation of a stent graft, not only relying on radial force but also with hooks or barbs, might possibly prevent stent graft migration. Moreover, the use of dynamic images might optimise the preoperative process of patient selection and stent graft sizing.

Conclusion

Aortic heartbeat-dependent pulsatility is significantly associated with stent graft migration. Patients with stent graft migration 3 years after EVAR have significantly higher preoperative aneurysm neck pulsatility during the cardiac cycle than patients without stent graft migration.

Conflict of Interest

None.

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