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Decision-making in Follow-up After Endovascular Aneurysm Repair Based on Diameter and Volume Measurements: a Blinded Comparison

M. Prinssen[1], E. L. G. Verhoeven[2], H. J. M. Verhagen[1] and J. D. Blankensteijn*[1]

[1]*Department of Vascular Surgery, University Medical Center Utrecht, The Netherlands and*
[2]*Department of Surgery, Division of Vascular Surgery, University Hospital Groningen, The Netherlands*

Objective: *to assess whether volume, in addition to diameter, measurements facilitate decision-making after endovascular aneurysm repair (EVAR).*
Material/Methods: *patients (n = 82) with an immediately post-EVAR, and at least one follow-up (3–60 months), computed tomographic angiogram (CTA) were studied. The actual and all preceding proportional sac size changes were recorded. The resulting 347 diameter and 347 volume data were placed in random order and reviewed by three blinded observers who then recommended one of three treatment policies: "good/wait", "uncertain/intensify follow-up" or "not good/further diagnostics (Dx) or intervention (Rx)". The observers were instructed to consider changes of 10% relevant. One observer reviewed the graphs twice.*
Results: *the interobserver agreements (kappa) for the diameter were 0.92, 0.81 and 0.76 and for volumes 0.91, 0.88 and 0.86. The intra-observer agreement was 0.93 for both diameter and volume. Volume data resulted in significantly more "good/wait" decisions out to 36 months. Diameter data resulted in more "not good/Dx or Rx"-decisions out to 36 months (all $p < 0.005$).*
Conclusion: *post-EVAR aneurysm sac volume data appears to provide earlier reassurance, reduce unnecessary interventions and to be more sensitive to secondary problems than diameter data alone.*

Key Words: Endovascular aneurysm repair; Sac shrinkage; Diameter measurements; Volume measurements.

Introduction

Changes in the aneurysm sac size are used to determine the success of endovascular aneurysm repair (EVAR).[1,2] Although sac volume is thought by many to be superior to diameter,[3–7] to date, a rigorous comparison of the two has not been performed. The aim of this study was to assess whether volume, in addition to diameter, data facilitate decision-making after EVAR.

Patients and Methods

Between January 1994 and April 2002, 94 patients underwent EVAR using either the EVT/Ancure™ (Guidant, Menlo Park, CA, U.S.A.) endograft ($n = 90$) or the Excluder™ (Gore, Flagstaff, AZ, U.S.A.) endograft ($n = 4$). Spiral computed tomographic angiography (CTA) was performed at discharge, 6 and 12 months, and then annually. In case of endoleak, CTA was also performed at 3, 18 and 30 months. Patients ($n = 82$) were included in this study if the immediate postoperative, and at least one follow-up, CTA scan were available. Volume measurements were performed using semi-automatic and manual segmentation in axial slices on a graphical workstation (EasyVision, Philips Medical Systems, Best, The Netherlands). The aortic lumen was segmented using a threshold technique. Thrombus segmentation was fully manual. A contour was drawn along the outer border of the thrombus on each slice.[3] A central lumen line was drawn manually through the lumen of the aorta by positioning points in the centre of the lumen in the axial, sagittal and the coronal plane. Multiplanar reformats, perpendicular to this central lumen line were constructed. The maximum aneurysm diameter was measured in this reformatted set of images.

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* Please address all correspondence to: J. D. Blankensteijn, Chief, Division of Vascular Surgery, Department of Surgery, G04.232, University Medical Center, PO Box 85500, Utrecht 3508 GA, The Netherlands.

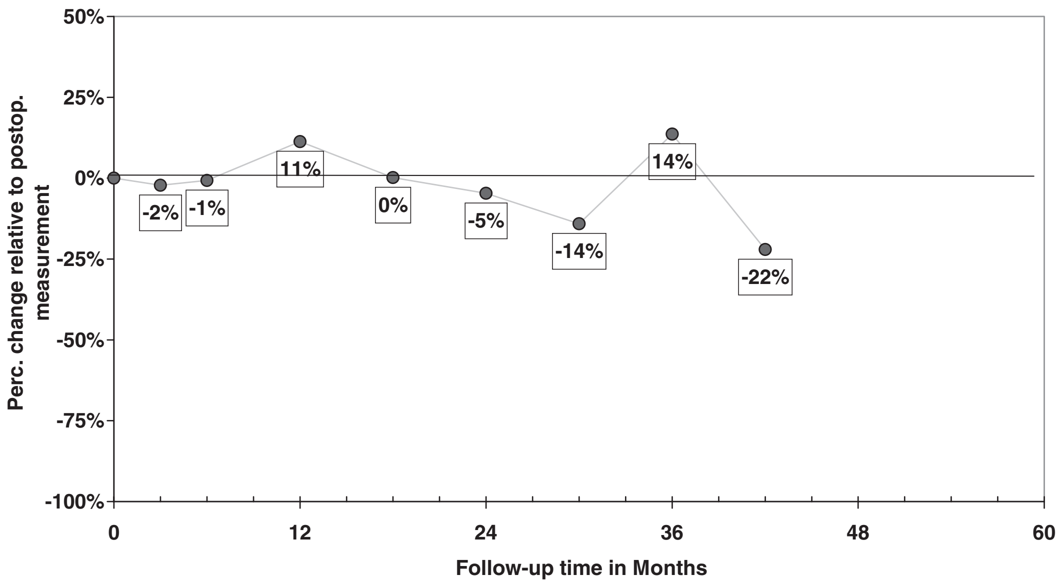

Fig. 1. Example of a graph, size changes are given relative (%) to the postoperative measurement.

For each follow-up CTA (range 3–60 months), volume and diameter graphs were constructed, depicting the actual and all preceding proportional sac size changes relative to the postoperative measurement (Fig. 1). A median (range) number of four (1–10) paired graphs per patient were constructed. A total of 347 volume and 347 diameter graphs were placed in random order and reviewed by three blinded vascular surgeons who recommended either "good/wait", "uncertain/intensify follow-up" or "not good/further diagnostics (Dx) or intervention (Rx)". The option "uncertain/intensify follow-up" was intended to lead to intensification of the follow-up except for the first year when follow-up was already scheduled at a 6-month interval. To avoid variation the observers were instructed to consider changes of more than 10% relevant.[8] In the first year postoperatively, an unchanged aneurysm size could be accepted, thereafter it should lead to further imaging. The following assumptions were made: the aneurysm had an initial size of at least 6.0 cm (surgical repair was indicated), age and/or clinical condition of the patient were not a contraindication to intervention and other CT findings (migration etc.) were irrelevant. Observers were unaware of any preceding interventions. The observers were asked to review all graphs in one day (with intervals) and were instructed not to reconsider their initial decisions. One observer blinded for his previous decisions reviewed two sets of all graphs.

The inter- and intra-observer agreements for both types of graphs were calculated using Kappa statistics. Kappa qualifies the level of agreement: possible values range from 1 (perfect agreement) via 0 (no agreement) to -1 (complete disagreement). Differences in treatment policies based on the volume and diameter graphs at each follow-up moment were analysed with McNemar's test. A p value < 0.05 was considered significant.

Results

The number of graphs at each follow-up moment per type of measurement is depicted in Figure 2. Mean and median follow-up were 20.3 and 18.0 months (range 3–60 months), respectively. The cross tabulations of agreement in treatment policies between observers are given in Table 1. The interobserver agreements (kappa) for the diameter-graphs were 0.92, 0.81 and 0.76 and for the volume-graphs 0.91, 0.88 and 0.86. The intra-observer agreement was 0.93 for both diameter and volume-graphs.

Table 2 shows the percentage of type of decision per type of measurement at each follow-up moment and the p-value (McNemar's test). As shown, successful exclusion was diagnosed in 60% of the patients after 6 months based on volume measurements and after 2 years based on diameter measurements.

Volume graphs allowed for more frequent "good/wait" decisions at all follow-up moments except 60 months, statistically significant up to 42 months. Conversely, more frequent "not good/Dx or Rx"-decisions were made based on diameter assessments, particularly at the 12, 24 and 36 month visits (all $p < 0.005$, McNemar) (Fig. 3).

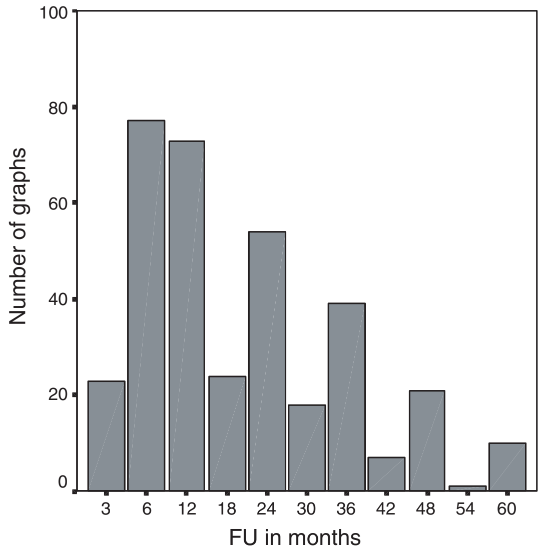

Fig. 2. Number of graphs at each follow-up moment.

Discussion

The present results confirm that volume measurements allow earlier determination of the aneurysm growth or shrinkage after EVAR because they are more sensitive to changes in the aneurysm size than diameter alone.[3–7] Importantly, this affects treatment policy in a significant number of cases. Especially during the first 12 months, volume measurements provided earlier reassurance of aneurysm exclusion. Successful exclusion (significant shrinkage) was diagnosed in more than 60% of the patients after 6 months, whereas diameter measurements only reached this rate at 2 years. Uncertainty about the status of the aneurysm, or even misinterpretation thereof, may lead to unnecessary, risky and expensive imaging or intervention. On the other hand, missing aneurysm growth is potentially dangerous because of the risk for rupture.

The number of patients diagnosed as "good/wait" on the basis of volume changes seems to decrease after 36 months and as a consequence the number of patients diagnosed as "not good/further diagnostics or intervention" seems to increase (Fig. 3). This observation may be due to secondary problems[7,9–12] that would not have been picked up by diameter data alone. The relatively high recurrence of secondary

Table 1. Cross tabulations of agreement in treatment policy between observers.

		Obs1A × Obs1B			Obs1A × Obs2			Obs1A × Obs3			Obs2 × Obs3		
		Good	Uncertain	Not good	Good	Uncertain	Not good	Good	Uncertain	Not good	Good	Uncertain	Not good
DIAM	Good	152	1		143	10		152	1		144	1	
	Uncertain	3	94	4	2	96	3	16	81	4	25	79	5
	Not Good		7	86		3	90	2	20	71	1	22	70
			Kappa	0.93		Kappa	0.92		Kappa	0.81		Kappa	0.76
VOL	Good	229	5		225	9		228	6		225	2	
	Uncertain	1	52	4	2	52	3	8	44	5	11	45	7
	Not Good		3	53		2	54		2	54		5	52
			Kappa	0.93		Kappa	0.91		Kappa	0.88		Kappa	0.86

Table 2. Percentage of type of decision per type of measurement at each follow-up moment and *p*-value (McNemar's test).

FU in months (N)	% Good/wait			% Not good			% Uncertain		
	Volume	Diameter	*p* value	Volume	Diameter	*p* value	Volume	Diameter	*p* value
3 (23)	33	10	<0.01	9	0	0.03	58	90	<0.01
6 (77)	66	35	<0.01	4	2	0.42	30	63	<0.01
12 (73)	76	46	<0.01	21	36	<0.01	4	18	<0.01
18 (24)	60	33	<0.01	25	44	<0.01	15	22	0.38
24 (54)	73	61	<0.01	15	31	<0.01	12	9	0.35
30 (18)	61	33	<0.01	33	30	0.73	6	37	<0.01
36 (39)	72	59	<0.01	15	33	<0.01	14	9	0.29
42 (7)	57	24	0.02	43	67	0.13	0	10	0.50
48 (21)	73	67	0.29	24	29	0.25	3	5	1.00
60 (10)	67	77	0.38	27	20	0.50	7	3	1.00

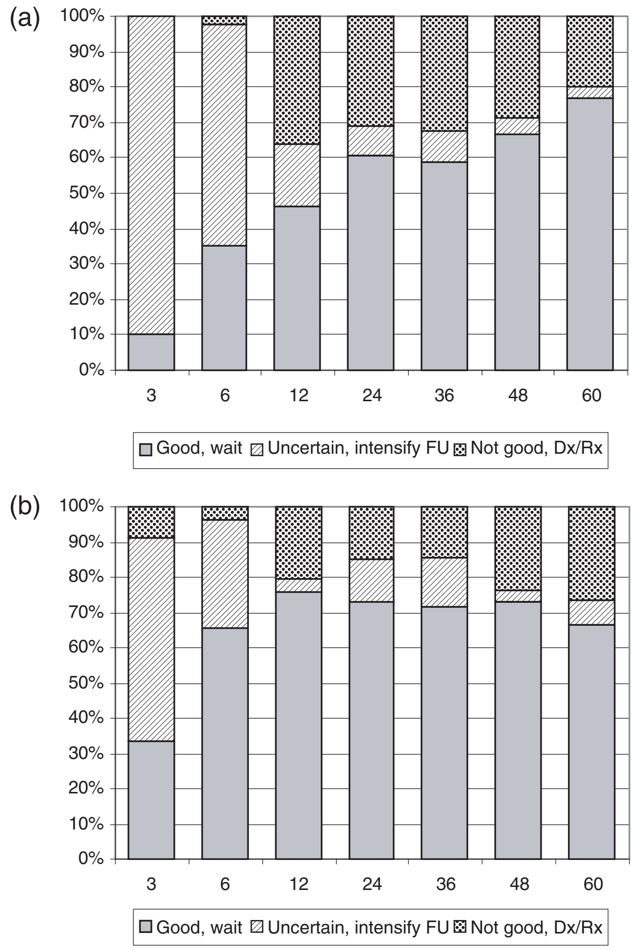

Fig. 3. Distribution of type of decision for the standard follow-up moments for the diameter graphs (a) and for the volume graphs (b).

problems after EVAR emphasizes the importance of also considering volume data.[13]

An additional advantage of using volume measurements is the ability to assess the effect of three-dimensional morphological changes on aneurysm exclusion and device failure. On the downside, volume measurements are rather time consuming and require dedicated personnel and advanced image-processing equipment. Future developments in automated data segmentation will probably speed up this process.

To conclude, post-EVAR aneurysm sac volume data appears to provide earlier reassurance, reduce unnecessary interventions and to be more sensitive to secondary problems than diameter data alone. Overall, we believe that the pros of volumetric analysis outweigh the cons and recommend it for all patients.

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