Significant sac retraction after endovascular aneurysm repair is a robust indicator of durable treatment success

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Objectives: **The principal aim of this study was to demonstrate that significant sac retraction (SSR) was a predictive marker of durable success after endovascular aortic repair (EVAR). If verified, follow-up (FU) of patients with SSR may become unnecessary. In addition, the clinical features of the patients and aneurysms were analyzed to identify predictive factors of SSR.**

Methods: **A group of 371 patients treated by EVAR had a complete clinical exam, computed tomography (CT) scan, and duplex scan follow-up. Data were collected prospectively and analyzed retrospectively. We assessed the difference between the largest diameter of the aneurysm (D) and the diameter of the stent-graft body (D1) on each postoperative CT scan. SSR was defined as a minimum of 75% reduction of this difference between the first and any of the following CT scans. Treatment success was defined as survival free of aneurysm-related death, type I or III endoleak, aneurysm expansion exceeding 5 mm, rupture, surgical conversion, migration, and graft occlusion. To assess the predictive factors of SSR, we performed a multivariable analysis and a logistic regression of the most significant variables.**

Results: **SSR was observed in 24.8% (92/371) of the patients after an average of 26 ± 21 months of FU. The mean duration of FU in this group was 50 ± 26 months (vs 45 ± 25 months; P = NS). Survival was significantly longer in the SSR group (96 ± 3 months vs 93 ± 3 months; $P < .05$). No rupture, surgical, or endovascular conversion was reported in the SSR group. The frequency of type I (2.2% vs 15.4%; $P < .001$), type II (3.3% vs 29.4%; $P < 10^{-6}$), and secondary interventions (3.3% vs 13.3%;$P < .05$) was lower in the SSR group. All type I and III endoleaks were diagnosed and treated before SSR detection. Since SSR was detected, treatment success remained until last follow-up in 98.9% (91 of 92) of the patients. The independent predictive factors of SSR were abdominal aortic aneurysm (AAA) diameter <55 mm (odds ratio [OR] 3.91; 95% confidence interval [CI]: 2.16-7.11), infra renal aorta diameter <23 mm (OR 2.96; 95% CI: 1.74-5.03), and a proximal neck length >22 mm (OR 2.41; 95% CI: 1.42-4.10).**

Conclusion: **In this series, SSR was accurately predictive of a durable success after EVAR. It occurred mostly in patients with a favorable anatomy. Less intensive follow-up work up seems to be safe in patients with SSR. (J Vasc Surg 2010; 52:878-83.)**

Since the first use of a stent-graft reported by Volodos,[1] it is now established that endovascular aortic repair (EVAR) is the less invasive alternative to conventional surgery for the treatment of abdominal aortic aneurysm (AAA). The results of the principal randomized trials[2,3] and studies of international registries[4-6] have demonstrated the short-term benefits of endovascular surgery over conventional surgery: lower early postoperative mortality and morbidity rates, less blood loss, shorter hospital and intensive care stays, and a quicker return to active life. The mechanical deterioration of stent grafts and endoleaks observed in medium- and long-term studies[7,8] has led to indefinite periods of post-surgical monitoring for patients treated with EVAR. Noll et al[9] showed, that at 5 years, the radiological follow-up by computed tomography (CT) scan of patients without endoleak was responsible for an overall cost increase of 32.5%. Therefore, it would be valuable to identify factors reproducibly predictive of long-term clinical success authorizing a simplification of the follow-up. The concept of significant sac retraction (SSR) was first described in 2000. Rhee et al defined SSR as an aneurysmal sac diameter less than 3.5 cm after EVAR,[10] whereas complete resolution of the aneurysm was defined by the American consensus conference[11] as a decrease by more than 90% of the extraluminal volume. So far, no study has analyzed either the correlation between SSR and treatment success or the persistence in time of an SSR. The aim of this study was to investigate the correlation between SSR and treatment success, the durability of treatment success in SSR patients, and the predictive factors of SSR.

METHODS

Between January 1995 and December 2006, 371 patients were followed at Henri Mondor Hospital in Créteil following non-emergency treatment for infra-renal AAA by

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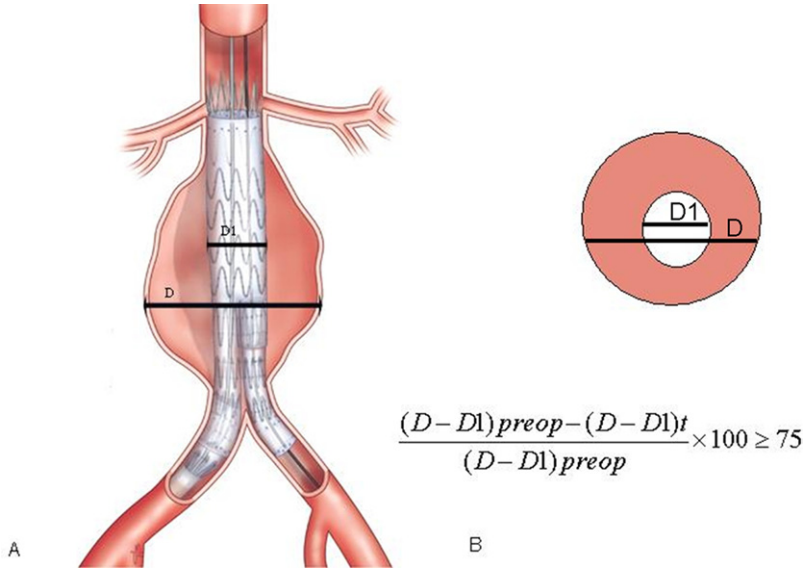

Fig 1. Definition of SSR. **A,** Sagittal view. **B,** Transversal view. *Preop,* Preoperative; *t,* time point in follow-up.

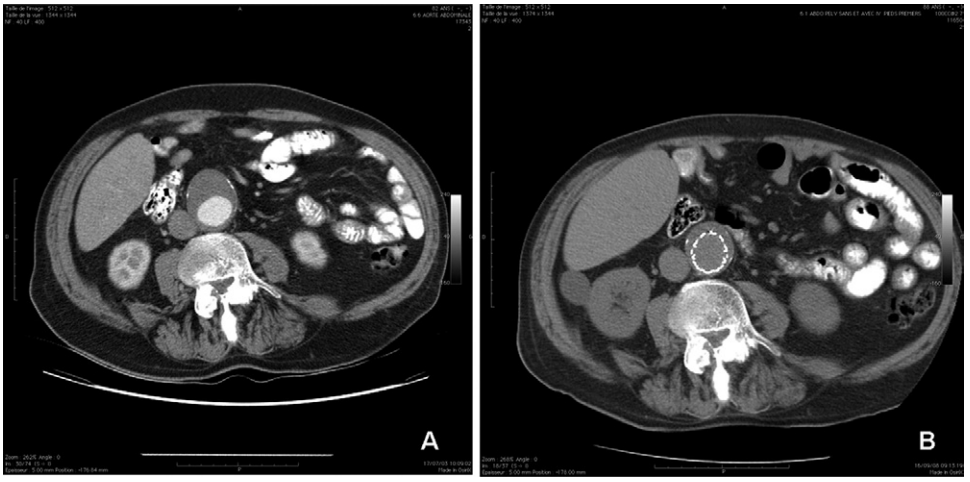

Fig 2. SSR in a patient with a 55 cm AAA, at 2 years of follow-up. **A,** Preoperative CT angiography. Aneurysm diameter, D = 55 mm. Stent graft diameter, D1 = 28 mm. **B,** Postsurgical CT angiography at 2 years of follow-up. Aneurysm diameter, D = 33 mm. Stent graft diameter. D1 = 28 mm.

EVAR. Patients treated for thoracic aortic aneurysm, thoracoabdominal aortic aneurysm, symptomatic or ruptured aneurysm, infectious aneurysm, anastomotic pseudoaneurysm, or isolated iliac aneurysm were not included in this study. Clinical, demographic, and radiological data were collected prospectively in a specific, computerized database (Logit, Fontenay Sous Bois, France). AAA treatment was considered when the maximal diameter was at least 50 mm and/or when an increase in the maximal diameter of at least 5 mm was observed over a period of 6 months. Endovascular treatment was considered when the patient was not eligible for open surgery regarding the French National Agency of Health Accreditation and Evaluation criteria,[12] or when the patient expressed a desire to undergo stent graft implantation, having displayed the anatomical requirements listed in the American consensus document published in 1997.[13] Stent grafts were usually implanted under general anaesthesia. Clinical and CT angiography follow-up were scheduled at 1 month, 6 months, 12 months, and 18 months after EVAR, and annually thereafter. CT angiograms were interpreted by a vascular surgeon and a vascular radiologist.

Judgment criteria. We studied the difference between the largest diameter of the aneurysm (D) and the diameter of the body of the stent graft (D1). SSR was

Table I. Demographic and clinical characteristics of the patients

	Total population (n = 371)	*SSR group (n = 92)*	*Non-SSR group (n = 279)*	P *value*
Age (years; mean ± SD)	73 ± 9	71 ± 8	74 ± 9	<.05
Diabetes	45 (12.1%)	9 (9.8%)	36 (12.9%)	.41
Obesity (body mass index >30)	47 (12.7%)	10 (10.9%)	37 (13.3%)	.53
Severe respiratory insufficiency	20 (5.4%)	5 (5.4%)	15 (5.4%)	.99
Symptomatic carotid lesions	20 (5.4%)	5 (5.4%)	15 (5.4%)	.99
End-stage renal failure	10 (2.7%)	2 (2.2%)	8 (2.9%)	.71
Angor	82 (22.1%)	20 (21.7%)	62 (22.2%)	.89
Major dyslipidemia	38 (10.2%)	8 (8.7%)	30 (10.8%)	.56
Poorly-controlled arterial hypertension	5 (1.3%)	1 (1.1%)	4 (1.4%)	.80
Active smoker	25 (6.7%)	7 (7.6%)	18 (6.4%)	.71

SSR, Significant sac reduction.

Table II. Different type of endografts implanted

First generation endograft	*Second generation endograft*
• Vanguard (n = 39; Boston Scientific, Natick, Mass), • EVT (n = 7; EndoVascular Technologies, Menlo Park, Calif) • Stenford device (n = 6; Stenford Groupe Valendons SA, Nanterre, France) • First-generation Gore device (n = 3) (W.L. Gore & Associates, Flagstaff, Ariz)	• Zenith (n = 266; Cook, Bloomington, Ind), • Excluder (n = 27; W.L. Gore & Associates, Flagstaff, Ariz), • AneuRx (n = 16; Medtronic, Minneapolis, Minn) • Talent (n = 7; Medtronic, Minneapolis, Minn).

defined as a decrease in this difference greater than 75% at a time point *t* during follow-up (Figs 1 and 2).

$$\frac{(D-D1)preop-(D-D1)t}{(D-D1)preop}\times 100 \geq 75$$

Until 2001, measurements were made manually from CT angiograms using a pair of compasses. After 2001, measurements were made on a Netvantage Windows Volume Show 3 platform (Infragistics, Elstree, United Kingdom) on the basis of a three-dimensional reconstruction. We used the definition of treatment success proposed by the American Vascular Surgery Society in 2002. Success was defined as the absence of aneurysm-related mortality, an absence of type I and III endoleaks, an absence of type II endoleaks responsible for aneurysmal growth, an absence of aneurysmal expansion by more than 5 mm or 20%, an absence of rupture or surgical conversion, and an absence of stent graft migration or failure.[14] By extension, a treatment failure was defined if any of the above listed complications was present. We searched for predictive factors of SSR in preoperative data, focusing essentially on surgical risk factors and AAA anatomy. We also compared outcomes of patients with SSR according to our definition with outcomes of patients with SSR according to previously used definitions.[10,11]

Statistical analysis. Statistical analysis was carried out with SAS version 9.1 (SAS Inc, Cary, NC), by the Clinical Research Unit of the University of Créteil (Dr Patrick Cunin). Quantitative data were expressed as means ± standard deviations, and qualitative data as a percentage. We used χ^2 tests to compare qualitative variables and *t* tests to compare quantitative variables. The level of significance was fixed at $P = .05$. The threshold giving the best sensitivity/specificity ratio for quantitative variables was identified by plotting receiver operating characteristics (ROC) curves. A multivariate analysis was carried out. As the variable analyzed was qualitative, logistic regression was carried out. A stepwise descending procedure was used. Kaplan-Meier survival analysis was used for follow-up study. Log rank tests were used to compare the duration of follow-up between several groups. Cox models were used for the multivariate analysis of follow up duration.

RESULTS

Demographics. This population was at high cardiovascular risk (Table I), and 40% of the patients had associated cardiac, carotid, or lower limb vascular disease. Eight different types of stent grafts were used. We classified the stent grafts as "first-generation" or "second-generation" (Table II). The mean duration of follow-up was 46 ± 25 months (Table III). The size of the aneurysm remained stable in 24.2% of the patients (90/371; change of less than 5 mm); it increased by more than 5 mm in 10.0% of the patients (37/371) and decreased by at least 5 mm in 65.8% of the patients (244/371). SSR was found in 24.8% of patients (92/371).

The SSR event. The mean time to SSR detection was 23 ± 3 months. The mean follow-up duration after the detection of SSR was 26 ± 21 months. No rupture, surgical, or endovascular conversion was reported in the SSR group (Table III). All the type I and III endoleaks in the SSR group were diagnosed and treated before the detection

Table III. Postsurgical follow-up

	Total population (n = 371)	*SSR group (n = 92)*	*Non-SSR group (n = 279)*	P
Mean follow-up ± SD (months)	46 ± 25	50 ± 26	45 ± 25	NS
Death				
N (%)	68 (18.3)	10 (10.9)	58 (20.8)	<.05
Rupture				
N (%)	3 (0.8)	0	3 (1.1)	NS
Surgical conversion				
N (%)	13 (3.5)	0	13 (4.7)	<.05
Type I endoleak				
N (%)	45 (12.1)	2 (2.2)	43 (15.4)	<.001
Type III endoleak				
N (%)	6 (1.6)	1 (1.1)	5 (1.8)	NS
Type II endoleak				
N (%)	85 (22.9)	3 (3.3)	82 (29.4)	<.0001
Persistent type II endoleak				
N (%)	38 (10.5)	1 (1.0)	39 (13.3)	<.001
Secondary intervention				
N (%)	43 (11.6)	3 (3.3)	40 (14.3)	<.05
Lost to follow-up				
N (%)	49 (13.2)	2 (2.2)	47 (16.8)	<.001

SSR, Significant sac reduction.

Table IV. Correlation between SSR and clinical treatment success; comparison between current definition and literature definitions

SSR definition	*Incidence*	*Sensibility*	*Specificity*	*Positive predictive value*	*Negative predictive value*
<75%	25% (92/371)	33%	98.9%	98.9%	34%
<90%[a]	4.8% (18/371)	6.5%	100%	100%	27%
<35 mm[b]	18% (67/371)	24%	100%	100%	31%

[a]Decrease in this difference between the largest diameter of the aneurysm (D) and the diameter of the body of the stent graft (D1) greater than 90% at a time point t during follow-up.
[b]Aneurysm sac smaller than 3.5 cm.

of SSR. One patient presented renewed growth of the aneurysm. In that case, SSR was detected at 12 months, but the patient developed a persistent type II endoleak. At 24 months, his aneurysm sac re-expanded to 50 mm. He was treated by inferior mesenteric and lumbar artery embolisation. At his last follow-up, the aneurysm size remained stable. Except for one patient with a type I endoleak, all complications in the TRS group (one type I endoleak, one type III endoleak, and one persistent type II endoleak) were diagnosed in patients initially treated with a first-generation endograft. At the time of SSR diagnosis, mean diameter of the aneurysm sac was 35 ± 3 mm, and the mean decrease in the difference between D and D1 was 82% ± 8%. SSR was highly predictive of treatment success with a specificity value and a positive predictive value of 98.9%. Using the current definition, sensibility and negative predictive value of SSR were higher than using definitions previously reported (Table IV).

Predictive factors of SSR. Three preoperative factors were significantly different between SSR and non-SSR patients: the preoperative maximal anterior-posterior diameter, the maximal diameter of the suprarenal, and the proximal neck length (Table V). The thresholds were determined and odds ratios (OR) were calculated. Three predictive factors of SSR were found: a preoperative external diameter smaller or equal to 55 mm (OR 3.91 [95% confidence interval (CI): 2.16-7.11]), a supra-renal aortic diameter smaller or equal to 23 mm (OR 2.96 [95% CI: 1.74-5.03]), and a proximal neck length exceeding 22 mm (OR 2.41 [95% CI: 1.42-4.10]).

DISCUSSION

We found that SSR was an excellent indicator of treatment success with a positive predictive value and a specificity of 98.9%. The mean time between the detection of SSR and the end of follow-up was 26 ± 21 months. During this period, only one patient displayed renewed growth of the aneurysm. We can therefore assume, within the limitations of our study, that the presence of SSR at 24 months of follow-up is correlated with a high probability of long-term treatment success.

Definition of SSR. Currently, two different definitions of SSR are available in the literature. Based on volumetric assessment, SSR is assessed when the non-luminal aneurysm volume (comprised between the stent graft and the inner aneurysm sac wall) is less than 10% of the original

Table V. Anatomic AAA characteristics and stent graft specificities

	Total population (n = 371)	*SSR group (n = 92)*	*Non-SSR group (n = 279)*	P
Mean external diameter of the AAA (mm) ± SD	57 ± 9	53 ± 5	58 ± 9	<.0001
Mean diameter of the subrenal aorta (mm) ± SD	25 ± 11	24 ± 3	25 ± 3	<.001
Mean length of proximal neck (mm) ± SD	25 ± 10	27 ± 11	24 ± 10	<.05
Hypogastric aneurysm N (%)	17 (4.6)	2 (2.2)	15 (5.4)	.20
Absence of thrombus N (%)	74 (19.9)	16 (17.4)	58 (20.8)	.46
1st-generation stent graft N (%)	82 (22.2)	16 (17.4)	66 (23.7)	.20
Degressive stent graft N (%)	70 (18.9)	14 (15.2)	56 (20.1)	.30
Aortic extension N (%)	14 (3.8)	4 (4.3)	10 (3.6)	.11

SSR, Significant sac reduction.

non-luminal volume noted after endograft implantation.[11,15] Volumetric measurements provide a reliable, non-invasive method for studying morphological aneurysm changes. This approach, however, is difficult to apply routinely as it requires a sophisticated, computerized technical platform, highly complex algorithms, and is time consuming (60 minutes).[16] Conversely, aneurysm sac diameter assessment is easy, reproducible, and reliable when studying changes greater than 10% or 5 mm.[11,17] Based on diameter study, Rhee et al defined SSR as an aneurysmal sac with a diameter smaller than 3.5 cm. This series included 70 patients followed up for 24 months. Overall, 44% of patients were lost to follow-up, and 16% had an SSR.[10] In our series, using the definition of Rhee et al or the American consensus volumetric definition would have respectively decreased the incidence of SSR to 18% (67/371) and 4.8% (18/371). Our definition of SSR is based on a two-dimensional study of the non-luminal space and evaluates 75% shrinkage, increasing consequently SSR incidence without losing its high positive predictive value for treatment success.

The limitations of SSR. To be useful, a predictive factor must be reliable, reproducible, easy to interpret, sensitive, and specific. The principal limitation of our marker is its lack of sensitivity (33%). The fact that some aneurysms do not retract despite the absence of detectable complications[18] may explain this lack of sensibility to detect all treatment success. However, our definition of SSR appears to be more sensitive than the previous ones published in the literature (Table IV).

Consequences for follow-up. The currently recommended follow-up program for aortic stent grafts is problematic for three major reasons: it involves repeated irradiation, the contrast agent is nephrotoxic, and the process is costly.[19] Noll et al[9] showed that the total cost of aortic stent graft implantation and follow-up was $20,000, with a mean cost of follow-up at 5 years of $11,351 per patient. The extra expenditure was due to secondary interventions (57%) and radiological examinations (32.5%). Our results suggest that, in patients with SSR at 2 years of follow-up (especially patients treated with second generation endografts), it may be safe to reduce the intensity of follow-up. By proposing to switch to a 2-year interval rather than yearly, the overall additional cost of 25% of EVAR patients will be halved, and therefore the mean overall cost of EVAR follow-up at 5 years will be reduced by 10%. A total stop of surveillance in this sub-group of patients could be proposed; however, we do think that further studies including more patients and longer follow-up are needed.

Predictive factors of SSR. It is not surprising that predictive factors of SSR are anatomic. Correlation between treatment success and favorable aneurysm anatomy has intensively been reported in the literature. Cambria et al showed that a proximal aortic neck greater than 26 mm in diameter or shorter than 15 mm in length was associated with a significantly higher risk of perioperative mortality, aneurysm-associated mortality, and secondary interventions.[20,21] In many studies, small aneurysms (<55mm) were correlated with better outcomes.[22-24] Armon et al proved that small aneurysms are more suitable for endovascular treatment, as their anatomy tends to be more compatible with stent graft implantation.[25] As a consequence, current studies are investigating the benefice of an early EVAR for AAA smaller than 55 mm.[26] Other factors favoring aneurysm shrinkage are also present in the literature, but were not found to be significant in our series. Bertges et al[27] found that shrinkage was correlated with the type and the manufacturer of the stent graft implanted. We noticed that patients who had a first-generation endograft were less prone to SSR, but the difference was not significant. Also, almost all complications that occurred in the SSR group concerned first-generation endografts, although the efficient management of these complications authorized a secondary SSR. The presence and the volume of mural thrombus have also been correlated to less aneurysm shrinkage,[23,28] but their possible role and significance remain a matter of debate.[29] We did not evaluate mural thrombi by quantitative measurements of volume

in our series. This evaluation bias may account for the absence of correlation between mural thrombus and SSR in our study.

CONCLUSION

SSR, defined as a decrease greater than 75% in the difference between the largest diameter of the aneurysm (D) and the diameter of the body of the stent graft (D1), appears to be a reliable prognostic factor of the long-term success of endovascular treatment for AAA. If long-term follow-up studies (10 years) confirm this stability, it would be legitimate to carry out less intensive monitoring from the second year of follow-up, with longer intervals between consultations and imaging. This would significantly decrease the costs associated with endovascular treatment. Anatomic feasibility is correlated with the occurrence of SSR, and, therefore, with long-term treatment success. It remains the major parameter to take into account when choosing the AAA treatment modality.

AUTHOR CONTRIBUTIONS

Conception and design: RH, JPB
Analysis and interpretation: RH, MM, JPB
Data collection: RH, JPB
Writing the article: RH, JPB
Critical revision of the article: RH, JPB
Final approval of the article: JPB
Statistical analysis: RH, MM
Obtained funding: N/A
Overall responsibility: JPB

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