From the Society for Vascular Surgery

Incidence and treatment results of Endurant endograft occlusion

Laura van Zeggeren, MD,[a] Frederico Bastos Gonçalves, MD,[b] Joost A. van Herwaarden, MD, PhD,[c] Herman J. A. Zandvoort, MD,[c] Debora A. B. Werson, MPA,[a] Jan-Albert Vos, MD, PhD,[d] Frans L. Moll, MD, PhD,[c] Hence J. Verhagen, MD, PhD,[b] and Jean-Paul P. M. de Vries, MD, PhD,[a]
Nieuwegein, Rotterdam, and Utrecht, The Netherlands

Objective: **The Endurant endograft (Medtronic Inc, Minneapolis, Minn) is a new-generation device specifically developed to perform well in complex abdominal aortic aneurysm anatomy. Previous reports on the 1- and 2-year results of endovascular aneurysm repair (EVAR) with the Endurant endograft showed excellent outcome, including prevention of migration and type I endoleaks, but occurrence and outcome of post-EVAR occlusion have not been determined in a large multicenter patient cohort with midterm follow-up, which is the objective of this study.**

Methods: **Data of consecutive patients treated with the Endurant from December 2007 to April 2012 in three Dutch tertiary vascular referral hospitals were prospectively gathered and retrospectively analyzed. Follow-up consisted of regular office visits, computed tomography angiography at 1 and 12 months after EVAR, and subsequently, duplex ultrasound imaging or computed tomography angiography at regular intervals. Patients with ruptured aneurysms or with earlier abdominal aortic surgery were excluded. The incidence and clinical outcome of endograft occlusions were analyzed. An expert review board assessed all cases in the search for possible causes of occlusion.**

Results: **Included were 496 patients (87.7% male), who were a median age of 74 years (range, 68-78 years). Median follow-up was 1.7 years (range, 0-4.6 years). Twenty graft occlusions (4.0%) occurred during follow-up. Median time between primary EVAR and detection of the occlusion was 1 month, with 55% occurring ≤60 postoperative days and 90% ≤1 year. No association was found between occlusion and sex ($P = .28$), age ($P = .96$), or use of an aortouniiliac device ($P = .66$). Technical error was the considered cause of the occlusion in 12 patients (60%). The estimated freedom from occlusion was 98.4% at 30 days, 95.7% at 1 year, and 95.3% at 3 years. Presenting symptoms of occlusion were acute limb ischemia in 50%. Treatment was surgical (75%) or percutaneous (25%). Successful revascularization was achieved in 17 of 20 patients, but reocclusions occurred in five, resulting in a transfemoral amputation in one patient. Occlusion-related mortality was 0.6% (3 of 496).**

Conclusions: **At a median follow-up of 1.7 years, Endurant endograft occlusion occurred in 4.0% of 496 patients. Most occlusions occurred ≤2 months after EVAR, and rarely after 1 year. A technical justification for occlusion could be found for 60% of patients. A more liberal intraoperative and early postoperative (re)intervention strategy may reduce the occlusion rates and improve outcome. (J Vasc Surg 2013;57:1246-54.)**

Aortic endograft occlusion is a known complication after endovascular aneurysm repair (EVAR),[1-6] with a reported incidence of 0% to 7.2%, with significant variability (Table I).[2,4-25] Although most of the newer-generation endografts have been associated with lower incidences of graft occlusion compared with first-generation endografts,[5,10] occlusion remains one of the major causes of secondary interventions and rehospitalization after EVAR.[13,26,27]

The Endurant stent graft (Medtronic Inc, Minneapolis, Minn), one of the newest-generation endovascular devices, was specifically developed to perform well in complex abdominal aortic aneurysm (AAA) anatomy. However, treatment of more complex AAA anatomies may result in higher rates of complications, including stent graft occlusion. Previous reports on the 1-year and 2-year results of the Endurant endograft showed excellent outcome, including prevention of migration and type IA endoleaks.[21-24] However, the occurrence and outcome of occlusions after EVAR have not yet been determined in a large multicenter patient cohort with midterm follow-up, which is the objective of this study.

METHODS

Data of all consecutive patients treated with an Endurant endograft between December 2007 and April 2012 in three Dutch tertiary vascular referral hospitals (University Medical Center, Utrecht; Erasmus University Medical Center, Rotterdam; and St. Antonius Hospital, Nieuwegein) were prospectively gathered and retrospectively reviewed.

From the Departments of Vascular Surgery at St. Antonius Hospital, Nieuwegein[a]; the Erasmus Medical Center, Rotterdam[b]; the University Medical Center, Utrecht[c]; and the Department of Interventional Radiology, St. Antonius Hospital, Nieuwegein.[d]

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Reprint requests: Jean-Paul P. M. de Vries, MD, PhD, Department of Vascular Surgery, St. Antonius Hospital, PO Box 2500, 3430 EM Nieuwegein, The Netherlands (e-mail: j.vries@antoniusziekenhuis.nl).

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Table I. Reported rates of limb thrombosis in literature

Study (first author)	*Year*	*No.*	*Endovascular devices used*	*Follow-up duration*	*Incidence of occlusion (%)*	*Occlusion-related mortality (%)*
Carroccio[2]	2002	351	Mixed	20 months	3.7	0
Erzurum[4]	2004	823	Mixed	24.2 months	2.7	0.12
Cochennec[5]	2007	460	Mixed	23 months	7.2	3
Maleux[6]	2008	288	Mixed	39 months	3.1	0
EVAR 1[7]	2010	624	Mixed	6 years	3.2	Not stated
EVAR 2[8]	2010	229	Mixed	3.1 years	2.2	Not stated
DREAM[9]	2010	178	Mixed	6.4 years	6.7[a]	Not stated
Van Marrewijk (EUROSTAR)[10]	2005	6787	Mixed	21 months	5	Not stated
Mehta, et al [11]	2010	1768	Mixed	34 months	1.4	0.05
Karthikesalingam[12]	2010	553	Mixed	31 months	1.1	Not stated
Conrad[13]	2009	832	Mixed	35 months	2.9	0
Abbruzzese[14]	2008	565	Mixed	30 months	6[b]	0.35
Bos[15]	2009	92	Excluder[c]	36 months	0	0
Maleux[16]	2012	121	Excluder	4.05 years	1.6	Not stated
Bastos Gonçalves[17]	2012	144	Excluder	5 years	1.4	0
Mertens[18]	2011	143	Zenith[d]	66 months	5.6	Not stated
Sivamurthy[19]	2006	248	Zenith	24 months	5.2	0
Jean-Baptiste[20]	2009	447	Zenith	24 months	1.8	0
Torsello[21]	2010	45	Endurant[e]	30 days	2.2	0
Troisi[22]	2010	156	Endurant	9 months	1.9	0
Van Keulen[23]	2011	100	Endurant	1 year	3.0	1
Rouwet[24]	2011	80	Endurant	1 year	1.3	0
Stokmans[25]	2012	1151	Endurant	30 days	2.0	Not stated
Current study	2012	496	Endurant	1.7 years	4.0	0.6

DREAM, Dutch Randomised Endovascular Aneurysm Management; *EUROSTAR,* European Collaborators on Stent-Graft Techniques for Aortic Aneurysm Repair; *EVAR 1,* Comparison of Endovascular Aneurysm Repair with Open Repair in Patients with Abdominal Aortic Aneurysm; *EVAR 2,* United Kingdom Endovascular Aneurysm Repair 2.

[a]Includes all thrombo-occlusive complications.

[b]Intervention for thrombosis or stenosis.

[c]W. L. Gore and Assoc, Flagstaff, Ariz.

[d]Cook, Bloomington, Ind.

[e]Medtronic, Minneapolis, Minn.

Included were all patients treated electively for an infrarenal AAA or aneurysm of the common iliac artery, or both. The study excluded patients with ruptured AAAs or patients who had previously undergone abdominal surgery.

EVAR at the three institutions is performed by board-certified vascular surgeons and interventional radiologists, who perform at least 50 EVAR procedures yearly.

Follow-up assessment. Follow-up consists of regular office visits at 1 and 12 months and yearly thereafter. Computed tomography angiography (CTA) is routinely performed ≤30 days after the index procedure and at 1 year, and subsequently, the choice of imaging modality is individualized (eg, duplex ultrasound [DUS] imaging or CTA). Follow-up duration was calculated until the day of the last imaging examination performed to ensure that the study also included asymptomatic occlusions.

The study group included all patients with endograft occlusion on imaging examinations. Early occlusion was defined as occurring ≤60 days of the index procedure, and delayed occlusion was defined as occurring at a later stage. CTAs or DUS images of asymptomatic patients were not evaluated for the presence of nonhemodynamically significant stenosis, but we did identify all patients who were treated for an asymptomatic preocclusive limb lesion.

Stent graft occlusions were identified during the postoperative hospital stay after the primary EVAR procedure, at office visits during follow-up, or at emergency department visits when the onset of symptoms was acute. All patients included in the study group presented with symptoms, which were classified according to Rutherford et al.[28] Presence of graft occlusion was confirmed by CTA, angiography, or magnetic resonance angiography (MRA; Fig 1). The decision whether to treat an occlusion and the type of intervention were at the discretion of the treating vascular team. Presenting symptoms, treatment, and outcome after treatment of patients with a graft occlusion were recorded according to the Reporting Standards for Endovascular Aortic Aneurysm Repair.[29]

A review board evaluated all imaging studies and interventional details of the patients included in the study group during a consensus meeting. The review board included vascular surgeons and interventional radiologists from the study hospitals and three interventionists from unrelated hospitals, not involved in any aspects of the study. All review board members were very experienced in endovascular aortic procedures. The probable causes of occlusion in each individual case were discussed, and a conclusion was reached by consensus.

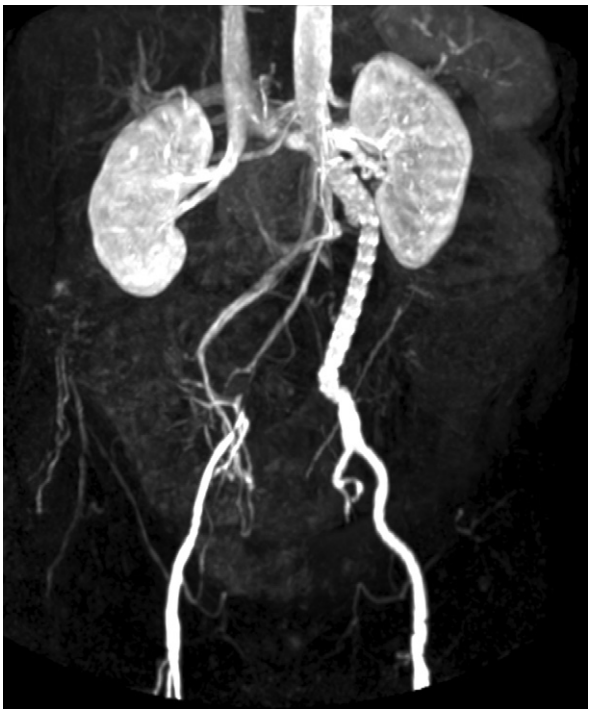

Fig 1. Endograft occlusion is confirmed by magnetic resonance angiography (MRA).

Statistical analysis. Categoric variables are reported as counts and percentages and continuous variables as means ± standard deviation or medians (interquartile range), according to the normality in distribution. Association between early and delayed occlusion and sex, type of endograft (aortouniiliac [AUI] or bifurcated), and treating hospital was tested using logistic regression and Cox regression χ^2 tests, respectively. Association with age was tested using the nonparametric Mann-Whitney *U* test. Kaplan-Meier estimates for freedom from occlusion were obtained for the overall population. Differences were considered significant at $P < .05$. Statistical analysis was performed with SPSS 20.0 software (SPSS Inc, Chicago, Ill).

RESULTS

From December 2007 to April 2012, 631 patients with an aneurysm of the infrarenal abdominal aorta or common iliac artery, or both, were treated with an Endurant stent graft. The study excluded 95 patients who were treated for a ruptured aneurysm and 40 patients with earlier abdominal aortic surgery, resulting in 496 patients (435 men [87.7%]) included in this study. Median age at time of primary EVAR was 74 years (range, 68-78 years; Table II).

Details of the primary EVAR procedure. An AUI stent graft was implanted in 38 patients (7.7%), and a bifurcated device was used in 458 (92.3%), yielding 954 graft limbs at risk for occlusion. No patients had signs of (imminent) endograft occlusion at the end of the initial procedure, which was checked with a completion angiogram.

Table II. Patient and operative characteristics

Variable	*No. (%) or median (IQR)*
Patients	496
Male	435 (87.7)
Age, years	74 (68-78)
Aortouniiliac stent raft	38 (7.7)
Graft limbs at risk	954

IQR, Interquartile range.

Table III. Early and midterm outcome

Variable	*No. (%) or median (IQR)*
Patients	496
30-day outcome	
Overall 30-day mortality	4 (0.8)
30-day EVAR-related mortality	1 (0.2)
Patients with occlusion	7 (1.4)
30-day occlusion-related mortality	1 (0.2)
Midterm outcome	
Follow-up, years	1.7 (0-4.6)
All-cause mortality	65 (13.1)
Overall EVAR-related mortality	6 (1.2)
Patients with occlusion	20 (4.0)
Occlusion-related mortality	3 (0.6)

EVAR, Endovascular aneurysm repair; *IQR*, interquartile range.

Outcome at 30 days. All-cause 30-day mortality was 0.8% (n = 4; Table III). Thirty-day occlusion-related mortality was 0.2% (n = 1). This patient died of ischemic complications after unsuccessful embolectomy of an occluded graft limb that developed 1 day postoperatively in the presence of pre-existent severe atherosclerosis and a previous bilateral above-knee amputation. All other patients died of nonsurgical complications.

Midterm results. Median follow-up was 1.7 years (range, 0-4.6 years). Five patients were lost to follow-up. All-cause mortality during follow-up was 13.1% (n = 65), with aneurysm-related mortality in six (1.2%). No patients died of AAA rupture. Three patients (0.6%) died of complications resulting from stent graft infection.

Endograft occlusions. During follow-up, there were 20 endograft occlusions (4.0%). Mortality was occlusion-related in three patients (0.6%). These patients died of ischemic complications after unsuccessful revascularization (n = 1), reperfusion syndrome (n = 1), and during open conversion of an inflammatory aneurysm with significant retroperitoneal fibrosis, due to uncontrollable bleeding from aortic laceration at the site of cross-clamping (n = 1). No association could be found between occlusion and sex ($P = .28$), age ($P = .96$), or use of an AUI device ($P = .66$). Overall, the treating hospital had no significant association with the chance of occlusion ($P = .08$), but looking specifically at early occlusions, a difference in hospitals could be found (odds ratio, 3.08; 95% confidence interval, 1.13-8.39; $P = .028$). The estimated freedom from occlusion was 98.4% at 30 days, 95.7% at 1 year, and 95.3% at 3 years (Fig 2).

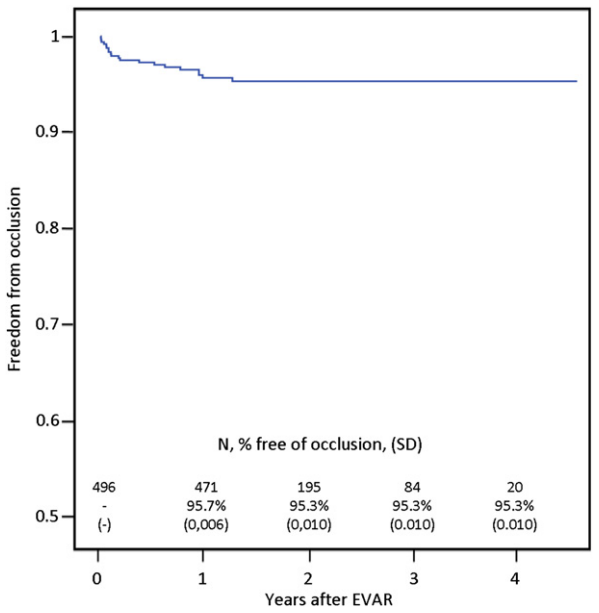

Fig 2. Kaplan-Meier curve shows the rate of freedom from occlusion at 4 years after endovascular aneurysm repair (*EVAR*). *SD,* Standard deviation.

Two patients were treated for an asymptomatic preocclusive limb lesion (an asymptomatic and documented progressive thrombus of a graft limb) that was found on routine postoperative imaging. They were successfully treated with oral anticoagulation (acenocoumarol, n = 1) or surgically with relining of the former endograft limb with a new Endurant endograft limb (n = 1). These patients were not included in the occlusion group but are mentioned here as part of a possible spectrum of thrombotic complications that could eventually lead to occlusion if left untreated. In addition, one patient developed a symptomatic stenosis after an occlusion of the contralateral endograft limb, also prompting intervention.

Clinical presentation of occlusion. Presenting symptoms in 10 of the 20 patients with occlusion were acute ischemia with numbness, sensory loss, but no rest pain in three (15%), with an occlusion (Rutherford IIa) or acute ischemia with rest pain or loss of motor function, or both, in seven (35%; Rutherford IIb). The remaining 10 (50%) presented with claudication without rest pain (Rutherford stage I-III) and were diagnosed during regular follow-up (Table IV).

Detailed analysis of patients with occlusion. Occlusion occurred in two AUIs (5.2% of all AUIs) and in 18 bifurcated stent grafts (3.9% of all bifurcated endografts). Total occlusion of the endograft occurred in three patients. In patients with only one affected limb, no significant difference could be found regarding the side of occlusion, with 10 of 17 (58%) noted as contralateral limb occlusions.

Median time between primary EVAR and detection of the occlusion was 1 month (range, 0-15 months), with

Table IV. Symptoms

Variable	*No. (%)*
Occlusions	20 (4.0)
Asymptomatic occlusions	0 (0)
Acute symptoms	
Rutherford class[a]	
IIa	3 (15)
IIb	7 (35)
Nonacute symptoms	
Rutherford class I-III[b]	10 (50)

[a]Acute ischemia.
[b]Chronic limb ischemia.

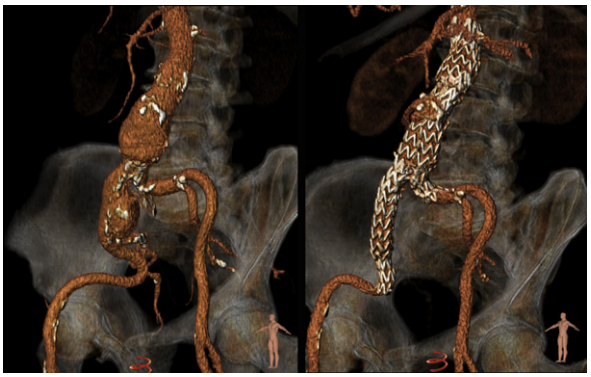

Fig 3. Left, Tortuous right external iliac artery in a patient with both infrarenal aortic aneurysm and right common iliac artery aneurysm. **Right,** The right limb of the Endurant endograft has been positioned in the kink of the right external iliac artery, which limits the flow considerably. This patient later developed a right limb graft occlusion.

55% (11 of 20) occurring within the first 60 postoperative days (early occlusions), 35% (7 of 20) between 2 and 12 months, and 10% at >12 months after EVAR.

All patients were prescribed a platelet aggregation inhibitor (n = 16) or a vitamin K antagonist (n = 4) at the time of occlusion.

In 12 patients (60%), a technical error was considered to be the cause of the occlusion, including extreme oversizing, positioning of the graft in a kink of the iliac vessel limiting outflow considerably (Fig 3), performance of the completion angiogram without removing the stiff guidewire, or an overlooked indication for percutaneous transluminal angioplasty/stenting, both within the endograft limb or resulting from the presence of a hemodynamically significant stenosis of flow-limiting dissection in the external iliac artery during the initial procedure. No technical cause for the obstruction was found in the other eight (40%). An outflow problem was identified in two of these patients, and two presented with very challenging anatomy, with severe tortuosity of the iliac arteries or a narrow aortic bifurcation, which might have been the cause for the occlusion. For the other six patients, the occlusion remained unexplained.

Overall, there was a violation of the instructions for use in six of 20 (30%) patients. Oversizing was considered

Table V. Anatomic and operative details of patients with occlusion

Pt	*Days to occlusion*	*Occluded side*	*History of PAD*	*Severe iliac tortuosity*	*Within IFU*	*Extension to IEA*	*Open IIA*	*Iliac component diameter*	*Iliac oversizing, %*	*Stiff wire removed*
1	1	Left (I)	Yes	No	No	Yes	No	24	14	Yes
2	2	Left (C)	No	No	Yes	No	Yes	13	44	Yes
3	3	Right (C)	No	Yes	Yes	No	Yes	13	8	Yes
4	12	Right (I)	Yes	No	Yes	No	No	16	60	Yes
5	20	Right (C)	Yes	No	Yes	No	Yes	10	11	Yes
6	21	Right (I)	No	No	Yes	Yes	No	13	30	Yes
7	28	Right (C)	No	Yes	No	Yes	No	10	43	No
8	32	Right (I)	Yes	No	No	Yes	Yes	24	5	No
9	34	AUI	Yes	Yes	Yes	No	Yes	13	18	Yes
10	40	Left (I)	No	No	Yes	Yes	No	16	14	Yes
11	42	Right (C)	No	No	Yes	No	No	13	30	Yes
12	62	Left (C)	No	Yes	No	Yes	No	13	30	Yes
13	121	Left (C)	No	No	Yes	Yes	No	13	44	Yes
14	183	Body	No	No	Yes	No	Yes	R:13, L:10	18/10	Yes
15	186	Left (I)	No	No	Yes	No	Yes	24	33	Yes
16	275	Right (C)	No	No	Yes	No	Yes	10	10	Yes
17	341	Right (I)	No	No	Yes	No	Yes	16	33	Yes
18	241	Right (C)	No	Yes	No	Yes	No	16	33	Yes
19	457	Right (C)	No	Yes	Yes	No	Yes	24	9	Yes
20	458	AUI	No	No	No	No	Yes	20	20	Yes

AUI, Aortouniiliac; *C,* contralateral; *I,* ipsilateral; *IEA,* external iliac artery; *IFU,* instructions for use; *IIA,* internal iliac artery; *L,* left; *PAD,* peripheral arterial disease; *R,* right.

excessive (20% to 35%) in three patients, and extreme (>35%) in four patients. Nine patients had one or more risk factors for occlusion, including three with a known malignancy at time of occlusion and seven with a medical history of stroke or cardiac arrhythmia. Details on the individual patients with endograft occlusion are presented in Table V and Fig 4.

In four of 20 patients (20%), an in-graft stenosis was reported on follow-up imaging before the occlusion, which might have been a risk factor for the future occlusion. No treatment was started at the time of these investigations because of absence of clinical symptoms and absence of >50% luminal stenosis. The occlusion in another four patients was already present on the first follow-up imaging.

Treatment. Different treatment modalities were used depending on the clinical presentation, the patient's physical status, and the underlying cause of occlusion. Open surgical treatment was performed in 15 patients (75%) with occlusion, comprising embolectomy (n = 4), graft extension (n = 1), femorofemoral crossover bypass (n = 5), axillofemoral bypass (n = 2), and embolectomy with stent placement (n = 3). In four of these patients, an initial attempt was made to perform catheter-based thrombolysis but this was unsuccessful.

Percutaneous treatment was successfully performed in five (25%), including thrombolysis with (n = 4) or without (n = 1) additional percutaneous transluminal angioplasty/stent placement (Table VI).

Treatment results. Successful revascularization was achieved in 17 of 20 occlusions (85%). The remaining three patients died as a result of ischemia-related (n = 2) or intraoperative bleeding (n = 1) complications, as described previously.

After successful revascularization reocclusion occurred in five of 17 patients (29.4%), including occlusion of a femorofemoral crossover bypass (n = 2) and reocclusion after thrombolysis in combination with stent placement (n = 2) or after surgical embolectomy (n = 1). Time to reocclusion varied from 2 weeks to 7 months after the initial revascularization. Reocclusion presented as acute ischemia in these five patients, and invasive treatment was performed to restore vascularization with a femorofemoral crossover bypass (n = 2), thrombolysis (n = 1), or thrombectomy and extension of the graft limb (n = 1). Revascularization failed in one patient, resulting in above-knee amputation.

DISCUSSION

In this cohort of 496 patients treated with an Endurant endograft and monitored for a median of 1.7 years, 20 occlusions occurred (4.0%). Occlusion-related mortality was 0.6% overall (3 of 496) and 15% (3 of 20) in the occlusion group.

EVAR has been increasingly used to treat AAAs. Early advantages of EVAR over open surgical repair are well known,[30-33] and new-generation endografts have been developed in recent years to broaden the treatment range. The Endurant endoprosthesis, with a hydrophilic coating, smaller delivery system, and increased flexibility, was specially designed to overcome complex aortoiliac anatomy. With these expanding indications, it is important to assess the occurrence of subsequent complications, such as stent graft or access artery occlusion, and the need for secondary interventions to obtain patency during follow-up.

Previous evaluations of the Endurant stent graft found the incidence of graft-related occlusion varied from 1.3% to 3%.[21-24] These occlusion rates are comparable to those in

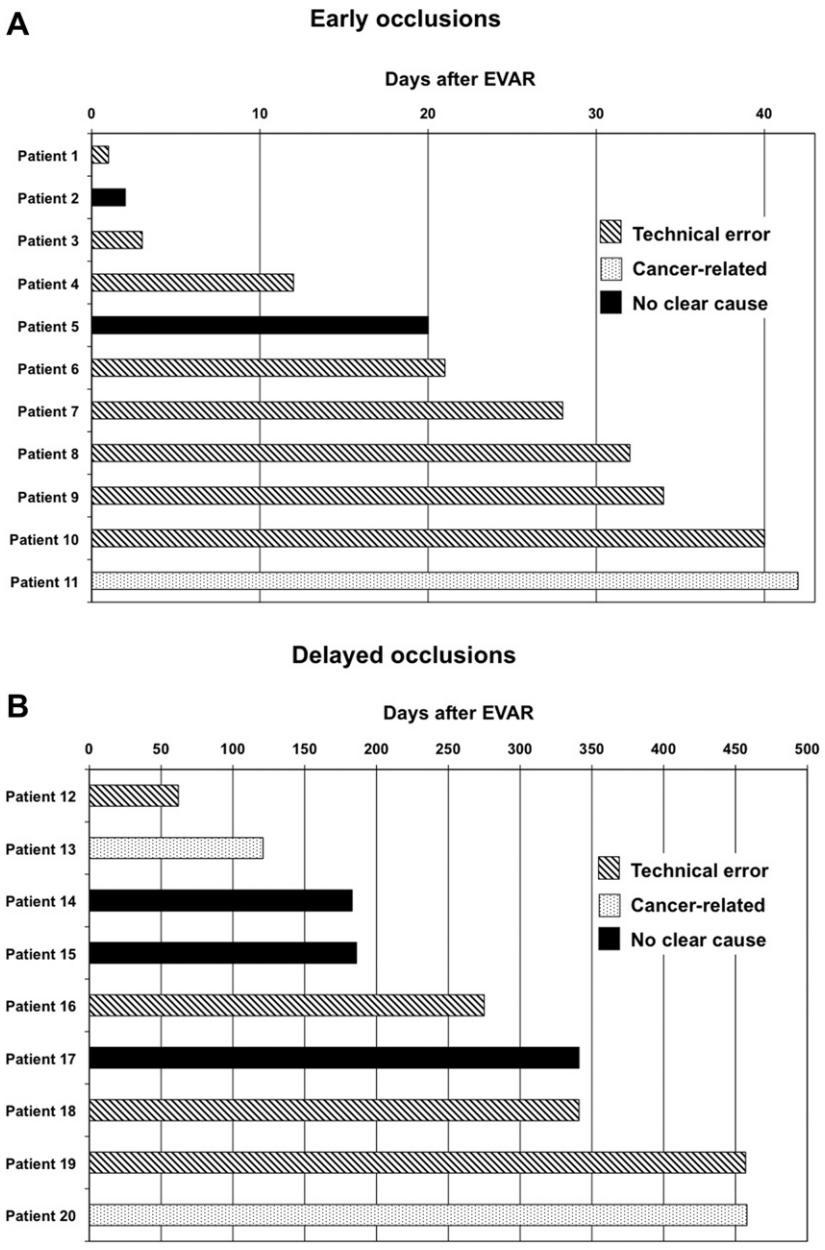

Fig 4. Overview of time to occlusion and the probable cause of occlusion is shown for **(A)** early occlusion occurring within the first 60 postoperative days and **(B)** delayed occlusion. *EVAR,* Endovascular aneurysm repair.

the present study, but we acknowledge that there is some overlap of patients in these studies and ours.

Makaroun et al[34] recently published the results from the United States regulatory trial of the Endurant Stent Graft System.[34] They found an occlusion rate of 2.7% at 1 year, with all four cases occurring within the first 60 days.

In a European multicenter study by Torsello et al[21] of 45 patients treated with the Endurant stent graft, one graft limb thrombosis (2.2%) was diagnosed at 30 days of follow-up, which was successfully treated.[21] No other occlusions occurred during 1 year of follow-up. Troisi et al[22] performed a single-center study to evaluate results of the Endurant stent graft in 156 patients with a mean follow-up of 9 months. The endograft occlusion rate was 1.9% (n = 3), and all three patients were treated successfully. The rates of occlusion of these reports are, therefore, comparable to the results of this study.

A wide range (0%-7.2%) of graft occlusions has been reported in follow-up studies of other EVAR devices.[2,4-25] The publication dates, institutional characteristics, follow-up duration, and patient cohorts in these studies are very heterogenic, which may explain the variability in occlusion

Table VI. Treatment

Variable	*No. (%)*
Open surgery	15 (75)
Embolectomy	4 (20)
Graft extension	1 (5)
Femorofemoral crossover bypass	5 (25)
Axillofemoral bypass	2 (10)
Embolectomy with stent	3 (15)
Initial thrombolysis attempt	4
Percutaneous intervention	5 (25)
Thrombolysis/PTA with stent	4 (13.6)
Thrombolysis/PTA without stent	1 (4.5)

PTA, Percutaneous transluminal angioplasty.

rates even within single-graft studies. In our own study, where institutional protocols are very similar, a significant difference was still found in the occlusion rates of the participating hospitals.

More than half of all occlusions in this study occurred ≤2 months after EVAR, and 90% occurred within the first year. This observation is in agreement with previous publications[2,5] and alerts to the importance of careful observation and patient information, especially during the first year after EVAR. In this study we used a review board to come to a consensus on possible causes for limb occlusion. This review board concluded that a technical error was responsible for occlusion in 60% of all patients and in 73% of those with early occlusions. A more liberal intraoperative and early postoperative (re)intervention strategy may reduce the occlusion rates and improve outcome. Importantly, completion angiography should be performed after removal of the stiff guidewire and the imaging thoroughly checked to assess for irregularities or stenosis. This should also include rotational views in which the angled and tortuous iliac arteries are perpendicularly visualized. Direct pressure measurements at the sheaths after all endovascular material is removed may also aid in the identification of any hemodynamic obstruction to flow.

We observed a significant proportion of patients with a history of peripheral arterial disease, with poor outflow vessels, and very challenging iliac anatomy, possibly increasing the risk of occlusion. Facilitating iliac access with improved delivery systems may have the perverse effect of increasing the risk of occlusive complications. Although we cannot objectively demonstrate that these factors increase risk significantly, treatment of patients with major obstructive disease and very unfavorable anatomy undoubtedly increases the chance of endograft occlusion.

Occlusion in five patients occurred without any suggestive cause. Aneurysm remodeling might play an important role in patients with delayed occlusion, but this remains unproven. Circumferential thrombus deposition, occurring in >20% of patients, also may increase risk.

Mestres et al[35] found that the presence of intragraft mural thrombus significantly increased the risk of endograft occlusion. However, the study by Wegener et al[36] found no association with graft occlusion, and the thrombotic deposits in 15% disappeared completely during follow-up, without specific therapy. It is known from clinical practice that some patients are prone to thrombosis of vascular conduits, a problem seldom investigated. This may be a result of a genetically determined variability to foreign body response or antiplatelet resistance, or as a result of sheer stress, and may correspond to patients without obvious underlying causes for thrombosis and with recurrent events. Nine patients in the occlusion group presented with one or more possible risk factors for thrombosis in their medical history, including malignancy, cardiac arrhythmias, or cerebrovascular accident or transient ischemic attack, that might have contributed to the development of the occlusion.

Clinical presentation of occlusion was acute in only 50% of patients, with the remaining presenting with claudication. Other studies report higher percentages of acute presentation.[5,37] The risk was naturally higher in patients with acute limb ischemia, where all of the deaths occurred, and the clinical consequences of this complication should not be underestimated.

All patients in our study required an intervention to reestablish flow to the ischemic extremity, and open surgery was preferred for most patients. Although initial revascularization was successful in >80%, we observed a reocclusion rate of 29.4%, all of which required secondary intervention. We do not have a clear explanation for this high reocclusion rate, although an outflow obstruction may have been a contributing factor in at least three patients.

Numerous causes and predictive factors for graft obstruction have been suggested in the literature, such as extension of the graft limb to the external iliac artery,[2,4] smaller limb diameter,[2] AUI endograft,[35] younger age,[5] the presence of thrombus in the native aorta,[26] or type of device.[1,4,10,37,38] In the present study, we evaluated sex and older age (>65 years) and found no significant association with occurrence of occlusion. Also, the type of device (bifurcated vs AUI endograft) did not influence the outcome.

One of the limitations of this study is its retrospective design. Also, we could not obtain detailed anatomic information for patients without occlusions, and analysis of risk factors for occlusion is limited. Our data suggest, however, that additional factors other than the stent graft material may play an important part in the occlusion rates, particularly on the patient selection criteria or institutional policies on additional intraoperative or postoperative preventive intervention.

CONCLUSIONS

Endograft occlusion after EVAR is an important complication that persists with newer-generation devices. In this study, occlusion occurred in 4.0% of patients treated with the Endurant stent graft during a median follow-up of 1.7 years. The risk of occlusion is higher within the first 2 months after EVAR, rarely occurring after 1 year. The estimated freedom from occlusion at 30 days, 1 year, and

3 years was 98.4%, 95.7%, and 95.3%, respectively. A technical justification for occlusion could be found for 60% of patients. These correspond to most early events and could potentially be prevented by adopting a more aggressive strategy for identification and treatment of intraoperative and early postoperative signs of kinking, stenosis, or irregularities. Still, the reason for occlusion in a number of patients is unexplained. Institutional practice and case-mix may influence occlusion rates significantly.

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AUTHOR CONTRIBUTIONS

Conception and design: LZ, JV, FBG
Analysis and interpretation: LZ, FBG, JV, JH, HV
Data collection: LZ, FBG, HZ, DW
Writing the article: LZ, FBG, JV
Critical revision of the article: JH, HZ, DW, JV, FM, HV
Final approval of the article: LZ, JV, FBG, JH, HZ, DW, JV, FM, HV
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LZ and FBG contributed equally to this article and share first authorship.

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DISCUSSION

Dr Gustavo Oderich (*Rochester, Minn*). I would like to congratulate you on a very important paper. I think the topic is very pertinent now that we are exploring using lower-profile stents for infrarenal aneurysms. A little bit more about your methodology. Can you tell us whether you analyzed other thromboembolic events in addition to the classic end point of limb occlusion? It would be ideal for future comparisons with other devices to have more granularity on thrombus formation and changes in the ankle-brachial index. Also, have you evaluated changes such as nonocclusive thrombus formation in the limbs using repeated computed tomography (CT) scans?

Dr Laura van Zeggeren. Thank you. In this study, we focused on patients who had a symptomatic obstruction, defined as clinical symptoms of limb ischemia in combination with a complete occlusion of the endograft (body or a limb) or stenosis. In the majority of patients, we found a complete occlusion, but there were also patients who presented with claudication and who had a significant stenosis or thrombus of one of the graft limbs. Ankle-brachial index data were not available in this study. We did not analyze CT scans of asymptomatic patients for the presence of thrombus or stenosis in the current study.

Dr Ian Loftus (*London, UK*). Can you tell us any more about the native anatomy here as to whether these were predictable or not? These are very high limb occlusion rates. If you included the asymptomatic obstructions, this must be closer to 8%. So is this a problem with the device or is it because the low profile device is pushing the boundaries of what you can treat?

Dr van Zeggeren. This is a very interesting question. In the present study we only evaluated patients with a symptomatic obstruction so we cannot say anything about the asymptomatic obstruction rate. Now that we have found an endograft obstruction rate of 4.0%, it is indeed essential to further investigate whether there is a relationship between complex anatomy and graft obstruction and to identify other possible risk factors in order to get a better understanding of the pathophysiology of graft obstruction and answer your last question.

Dr John Ricotta (*Washington, DC*). Did the patients who obstructed have what looked like difficult anatomy when you looked at their preoperative CT scans?

Dr van Zeggeren: We did look at the preoperative scans and there certainly were patients with difficult anatomy, but in this stage of the study, we cannot statistically evaluate whether this is a risk factor for obstruction because we did not evaluate CT scans of patients without symptomatic obstructions. As mentioned earlier, it is worthwhile—and we are about—to further investigate this in order to extract predictive factors for obstruction and learn more about patients and endografts at risk.

Dr Jean-Paul de Vries (*Nieuwegein, The Netherlands*). I am the senior author of the manuscript. Approximately 30% of the patients were treated outside the instructions for use, and this was mainly because of the proximal infrarenal necks, with heavy angulation, large diameter, or short necks. Concerning the access arteries, perhaps a small percentage of the patients were outside the instructions for use.

Dr Gale Tang (*Seattle, Wash*). Speaking to that, did you look at how many of these devices were extended into the external iliac, or were these patients with very small external iliac diameters?

Dr van Zeggeren. That is a good question, especially because extension of the graft into the external iliac artery has been described as risk factor for graft obstruction in the literature. In a small percentage of patients in the obstruction group, there was extension of the graft into the iliac artery. We did not have data on the external iliac artery diameters of the whole population or whether they were deployed in the external iliac artery and, therefore, did not separately analyze this in the obstruction group. However, we will more closely look at the iliac anatomy of the patients in the obstruction group to get a better understanding of possible risk factors that can be evaluated in the future.

Dr Edward Woo (*Philadelphia, Pa*). One other question: You have a high majority of patients that you bailed out with surgical methods. Were all of these patients attempted percutaneously first; and if not, how come?

Dr van Zeggeren. Almost all of the patients who were treated surgically were directly treated surgically. Four patients had first an endovascular attempt to treat the graft occlusion, but these were not successful.

Dr Woo. Do you know why not?

Dr van Zeggeren. An attempt was made to start thrombolysis, but we could not pass the obstruction with guidewires.