CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
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Will current stent grafts offer better results than those used in RCT?

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www.cacvs.org

Disclosure

Speaker name: Marc RHM van Sambeek

I have the following potential conflicts of interest to report:

Consulting and speakersfee

WL Gore & Associates

Medtronic

Unrestricted research grants

Medtronic

Abbott Vascular

DREAM Trial 2000-2003
EVAR I Trial 1999-2003
ACE Trial 2003-2008
Over Trial 2002-2008

Zenith, Talent, Excluder, Lifepath, AneurX, Quantum LP Ancure, Endologix

ENGAGE registry 2009-2011

Endurant

Secondary interventions following endovascular abdominal aortic aneurysm repair using current endografts. A EUROSTAR report

Roel Hobo, MSc, and Jacob Buth, MD, on behalf of EUROSTAR collaborators,
Eindhoven, The Netherlands

Objective: The purpose of this study was to evaluate the need for secondary interventions after endovascular abdominal aortic aneurysm repair with current stent-grafts.
Methods: Studied were data from 2846 patients treated from December 1999 until December 2004. The data were recorded from the EUROSTAR registry. The only patients studied were those with a follow-up of at least 12 months or until they had a secondary intervention within the first 12 months. The cumulative incidences of secondary transabdominal, extra-anatomic, and transfemoral interventions during follow-up (after the first postoperative month) were investigated.
Results: A secondary intervention was performed in 247 patients (8.7%) at a mean of 12 months after the initial procedure within a follow-up period of a mean of 23 ± 12 months. Of these, 57 (23%) transabdominal, 43 (16%) involved an extra-anatomic bypass, and 147 (60%) were by transfemoral approach. The cumulative incidence of secondary interventions was 6.0%, 8.7%, 12%, and 14% at 1, 2, 3, and 4 years, respectively. This corresponded with an annual rate of secondary interventions of 4.6%, which was remarkably lower than in a previously published EUROSTAR study of patients treated before 1999. Type I endoleaks (33% of procedures), migration (16%), and rupture (8.8%) were the most frequent reasons for secondary transabdominal interventions. Graft limb thrombosis was the indication for extra-anatomic bypass (60%). Type I endoleak (17%), type II endoleak (23%), device limb stenosis (14%), thrombosis (23%), and device migration (14%) were the most frequent reasons for secondary transfemoral interventions. Operative mortality was higher after secondary transabdominal interventions (12.3%, $P = .007$) compared with transfemoral interventions (2.7%). Overall survival was lower in patients with secondary transabdominal ($P = .016$) and extra-anatomic interventions ($P < .0001$) compared with patients without a secondary intervention.
Conclusion: Although the incidence of secondary interventions after endovascular aneurysm repair has substantially decreased in recent years, continuing need for surveillance for device-related complications remains necessary. (J Vasc Surg 2006;43:896-902.)

Endovascular treatment of abdominal aortic aneurysms (AAA) has been used successfully for more than a decade.[1-3] Recently, two randomized trials demonstrated that aneurysm-related mortality was lower in patients with endovascular repair than in those with open repair of their aneurysm during a follow-up period of 4 years.[2,3] Despite this favorable mid-term outcome, the long-term durability remains a subject of concern, and life-long surveillance to observe satisfactory endograft function is considered essential.[4-8]

Device-related complications such as endoleak and graft migration were frequently observed. These events are associated with an increased risk for aneurysm rupture and therefore need to be identified as early as possible.[9,10] Graft thrombosis may cause also considerable symptoms. These adverse events are repaired by a secondary intervention.[4,11-13]

The incidence of secondary interventions may be considered a surrogate parameter of impending failure of treatment while also representing an important factor to maintain the long-term functionality of the stent-graft repair. Secondary procedures can be categorized according to the invasiveness of the procedure: (1) transabdominal interventions (either with conversion to open repair or with preservation of the endograft), (2) extra-anatomic interventions, and (3) transfemoral interventions.

The need for secondary interventions after endovascular AAA repair had been investigated previously by using the EUROSTAR database.[4] In this previous assessment, however, the study outcome was primarily determined by the early generation stent-grafts. New developments in endograft design most likely will provide better outcome results.[14] In the present EUROSTAR review, the need for secondary interventions according to current treatment was reassessed.

METHODS

Design. The project of European collaborators on stent-graft techniques for AAA repair (EUROSTAR) reg-

From the EUROSTAR Data Registry Centre, Catharina Hospital, Eindhoven, The Netherlands.
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Reprint requests: R. Hobo, Department of Surgery, Catharina Hospital, PO box 1350, 5602 ZA Eindhoven, The Netherlands (e-mail: eurostar@kac.nl).
CME article
0741-5214/$32.00

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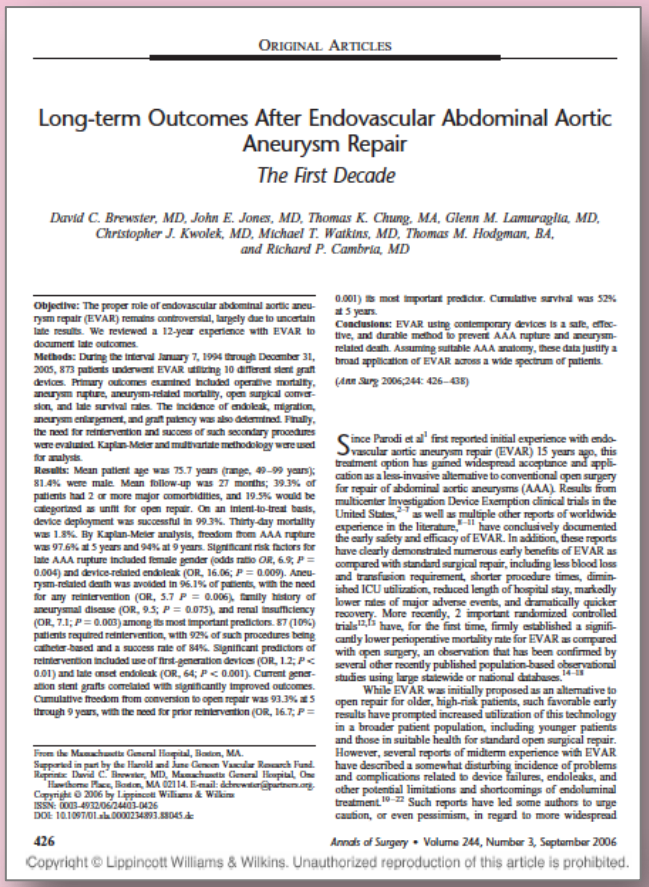
EUROSTAR REGISTRY

The incidence of secondary interventions has substantially decreased in the recent years

Hobo R, et al.
J Vasc Surg 2006;43:896-902



ORIGINAL ARTICLES

Long-term Outcomes After Endovascular Abdominal Aortic Aneurysm Repair

The First Decade

David C. Brewster, MD, John E. Jones, MD, Thomas K. Chung, MA, Glenn M. Lamuraglia, MD, Christopher J. Kwolek, MD, Michael T. Watkins, MD, Thomas M. Hodgman, BA, and Richard P. Cambria, MD

Objective: The proper role of endovascular abdominal aortic aneurysm repair (EVAR) remains controversial, largely due to uncertain late results. We reviewed a 12-year experience with EVAR to document late outcomes.

Methods: During the interval January 7, 1994 through December 31, 2005, 873 patients underwent EVAR utilizing 10 different stent graft devices. Primary outcomes examined included operative mortality, aneurysm rupture, aneurysm-related mortality, open surgical conversion, and late survival rates. The incidence of endoleak, migration, aneurysm enlargement, and graft patency was also determined. Finally, the need for reintervention and success of such secondary procedures were evaluated. Kaplan-Meier and multivariate methodology were used for analysis.

Results: Mean patient age was 75.7 years (range, 49–99 years); 81.4% were male. Mean follow-up was 27 months; 39.3% of patients had 2 or more major comorbidities, and 19.5% would be categorized as unfit for open repair. On an intent-to-treat basis, device deployment was successful in 99.3%. Thirty-day mortality was 1.8%. By Kaplan-Meier analysis, freedom from AAA rupture was 97.6% at 5 years and 94% at 9 years. Significant risk factors for late AAA rupture included female gender (odds ratio *OR*, 6.9; $P = 0.004$) and device-related endoleak (OR, 16.06; $P = 0.009$). Aneurysm-related death was avoided in 96.1% of patients, with the need for any reintervention (OR, 5.7 $P = 0.006$), family history of aneurysmal disease (OR, 9.5; $P = 0.075$), and renal insufficiency (OR, 7.1; $P = 0.003$) among its most important predictors. 87 (10%) patients required reintervention, with 92% of such procedures being catheter-based and a success rate of 84%. Significant predictors of reintervention included use of first-generation devices (OR, 1.2; $P < 0.01$) and late onset endoleak (OR, 64; $P < 0.001$). Current generation stent grafts correlated with significantly improved outcomes. Cumulative freedom from conversion to open repair was 93.3% at 5 through 9 years, with the need for prior reintervention (OR, 16.7; $P = 0.001$) its most important predictor. Cumulative survival was 52% at 5 years.

Conclusions: EVAR using contemporary devices is a safe, effective, and durable method to prevent AAA rupture and aneurysm-related death. Assuming suitable AAA anatomy, these data justify a broad application of EVAR across a wide spectrum of patients.

(*Ann Surg* 2006;244: 426–438)

Since Parodi et al[1] first reported initial experience with endovascular aortic aneurysm repair (EVAR) 15 years ago, this treatment option has gained widespread acceptance and application as a less-invasive alternative to conventional open surgery for repair of abdominal aortic aneurysms (AAA). Results from multicenter Investigation Device Exemption clinical trials in the United States,[2–7] as well as multiple other reports of worldwide experience in the literature,[8–11] have conclusively documented the early safety and efficacy of EVAR. In addition, these reports have clearly demonstrated numerous early benefits of EVAR as compared with standard surgical repair, including less blood loss and transfusion requirement, shorter procedure times, diminished ICU utilization, reduced length of hospital stay, markedly lower rates of major adverse events, and dramatically quicker recovery. More recently, 2 important randomized controlled trials[12,13] have, for the first time, firmly established a significantly lower perioperative mortality rate for EVAR as compared with open surgery, an observation that has been confirmed by several other recently published population-based observational studies using large statewide or national databases.[14–18]

While EVAR was initially proposed as an alternative to open repair for older, high-risk patients, such favorable early results have prompted increased utilization of this technology in a broader patient population, including younger patients and those in suitable health for standard open surgical repair. However, several reports of midterm experience with EVAR have described a somewhat disturbing incidence of problems and complications related to device failures, endoleaks, and other potential limitations and shortcomings of endoluminal treatment.[19–22] Such reports have led some authors to urge caution, or even pessimism, in regard to more widespread

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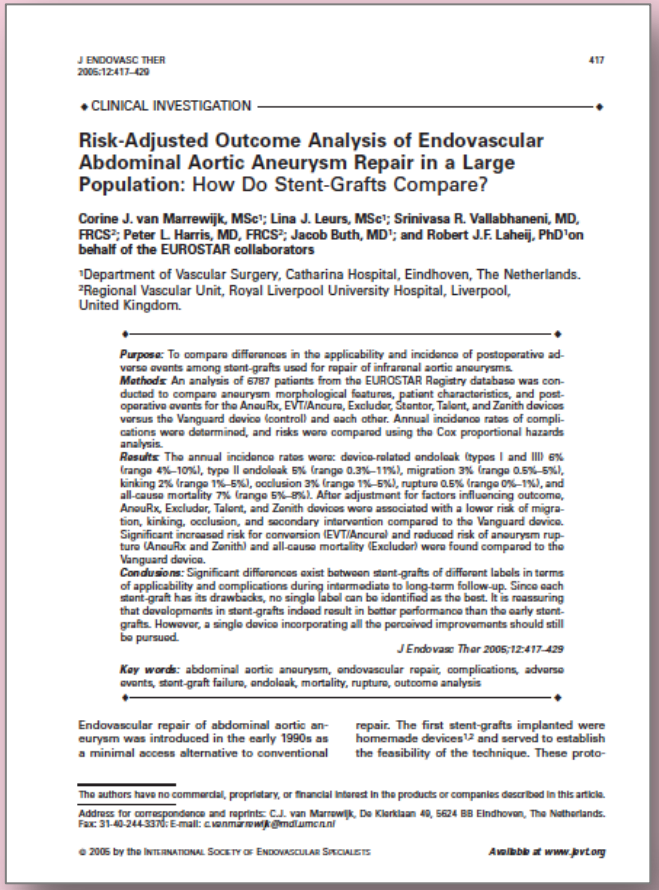
Differences exist between endografts of different labels in terms of applicability and complications during long-term follow-up

Brewster DC, et al.
Ann Surg 2006;244:426-38



J ENDOVASC THER
2005;12:417–429

◆ CLINICAL INVESTIGATION

Risk-Adjusted Outcome Analysis of Endovascular Abdominal Aortic Aneurysm Repair in a Large Population: How Do Stent-Grafts Compare?

Corine J. van Marrewijk, MSc[1]; Lina J. Leurs, MSc[1]; Srinivasa R. Vallabhaneni, MD, FRCS[2]; Peter L. Harris, MD, FRCS[2]; Jacob Buth, MD[1]; and Robert J.F. Laheij, PhD[1]on behalf of the EUROSTAR collaborators

[1]Department of Vascular Surgery, Catharina Hospital, Eindhoven, The Netherlands.
[2]Regional Vascular Unit, Royal Liverpool University Hospital, Liverpool, United Kingdom.

Purpose: To compare differences in the applicability and incidence of postoperative adverse events among stent-grafts used for repair of infrarenal aortic aneurysms.
Methods: An analysis of 6787 patients from the EUROSTAR Registry database was conducted to compare aneurysm morphological features, patient characteristics, and postoperative events for the AneuRx, EVT/Ancure, Excluder, Stentor, Talent, and Zenith devices versus the Vanguard device (control) and each other. Annual incidence rates of complications were determined, and risks were compared using the Cox proportional hazards analysis.
Results: The annual incidence rates were: device-related endoleak (types I and III) 6% (range 4%–10%), type II endoleak 5% (range 0.3%–11%), migration 3% (range 0.5%–5%), kinking 2% (range 1%–5%), occlusion 3% (range 1%–5%), rupture 0.5% (range 0%–1%), and all-cause mortality 7% (range 5%–8%). After adjustment for factors influencing outcome, AneuRx, Excluder, Talent, and Zenith devices were associated with a lower risk of migration, kinking, occlusion, and secondary intervention compared to the Vanguard device. Significant increased risk for conversion (EVT/Ancure) and reduced risk of aneurysm rupture (AneuRx and Zenith) and all-cause mortality (Excluder) were found compared to the Vanguard device.
Conclusions: Significant differences exist between stent-grafts of different labels in terms of applicability and complications during intermediate to long-term follow-up. Since each stent-graft has its drawbacks, no single label can be identified as the best. It is reassuring that developments in stent-grafts indeed result in better performance than the early stent-grafts. However, a single device incorporating all the perceived improvements should still be pursued.
J Endovasc Ther 2005;12:417–429

Key words: abdominal aortic aneurysm, endovascular repair, complications, adverse events, stent-graft failure, endoleak, mortality, rupture, outcome analysis

Endovascular repair of abdominal aortic aneurysm was introduced in the early 1990s as a minimal access alternative to conventional repair. The first stent-grafts implanted were homemade devices[1,2] and served to establish the feasibility of the technique. These proto-

The authors have no commercial, proprietary, or financial interest in the products or companies described in this article.

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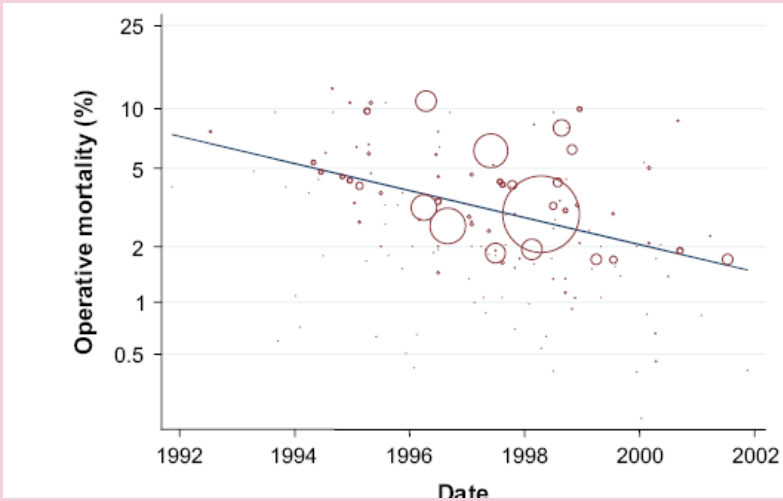
 Available at www.jvt.org

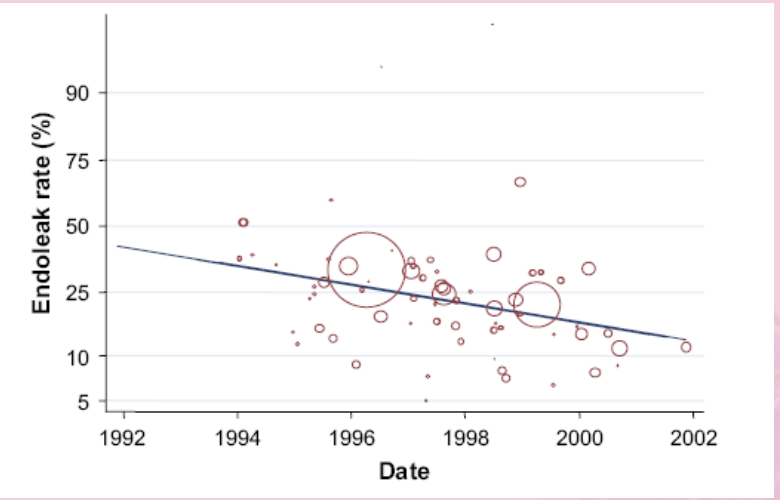
EUROSTAR REGISTRY

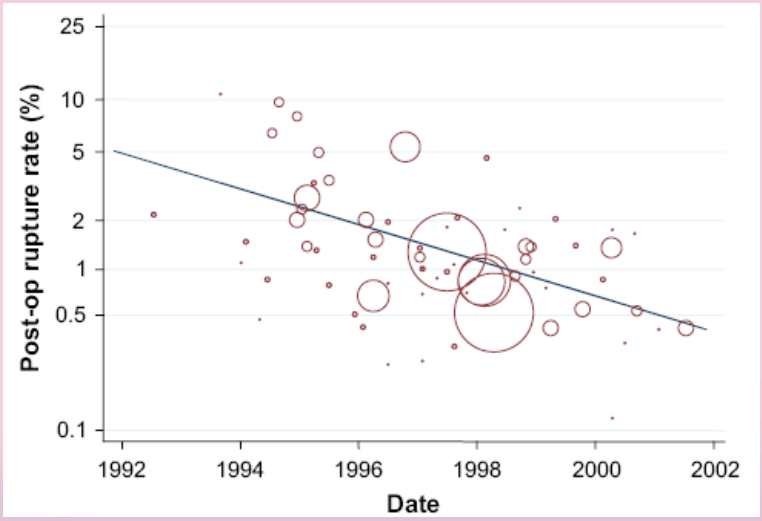
Developments in endografts result in better performance than early endografts

EUROSTAR Collaborators.
J Endovasc Ther 2005;12:417-429

Results over Time







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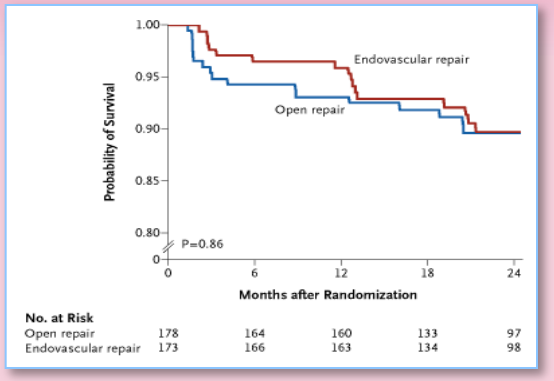
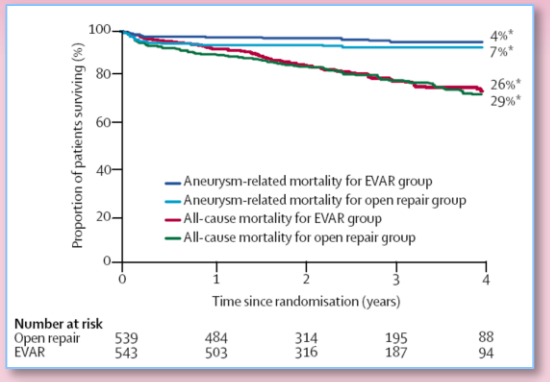
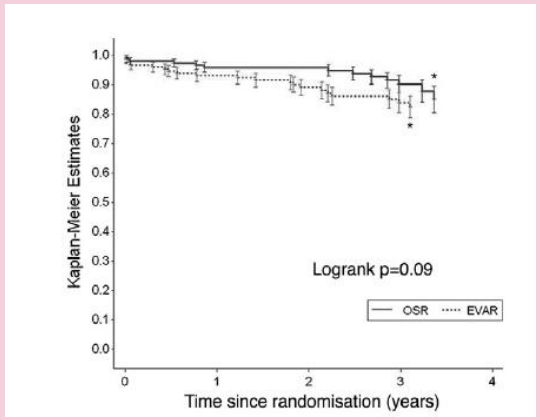
EJVES 2007; 33:154-171



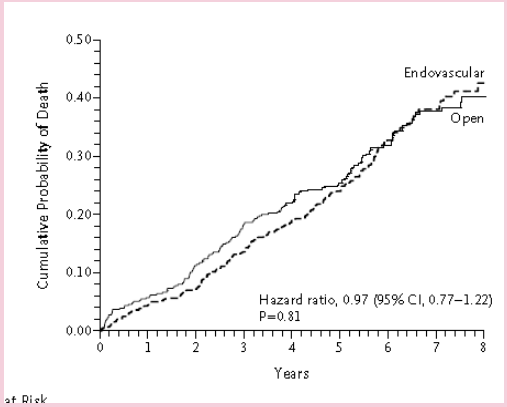
DREAM Trial
N Engl J Med. 2005;35:2398-405



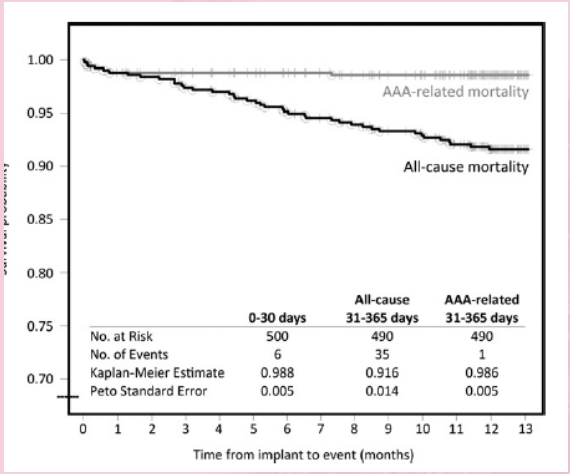
EVAR Trial
Lancet. 2005;365:2179-86



ACE Trial
J Vas 2011;53:1167-73-405



OVER Trial
N Engl J Med 2012;367:1988-97



ENGAGE Registry
Eur J Vasc Endovasc Surg 2012;44:369-75

Endograft specific outcome

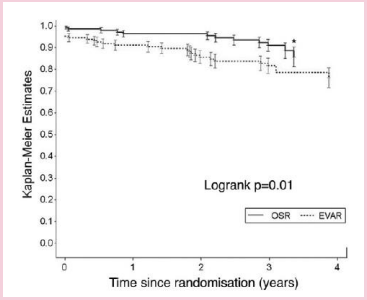
	Criteria	Endurant	Talent	Zenith Flex	Gore Excluder	Vascutek Anaconda
	Minimum Treatable Neck Length	10mm	10mm	15mm	15mm	15mm
	Maximum Treatable Infrarenal Angulation	75˚	60˚	60˚	60˚	60˚
	Max Treatable Aortic Neck Diameter	32mm	32mm	32mm	28mm	31mm
	Max Treatable Iliac Diameter	25mm	22mm	20mm	18mm	21mm
	# of Main Body Configurations	3	2	2	1	1
	Min Access Profile (28mm graft)	20F	22F	23.5F	21F	22.5F

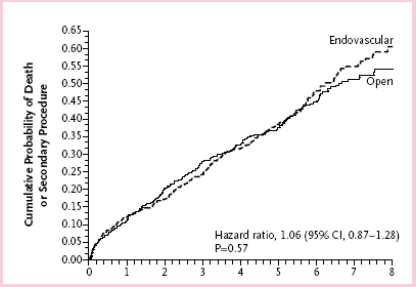
Remarkable at baseline

- 16.1% sAAA
- 10.6% ASA IV
- 17.9% outside IFU

(exclusion DREAM/EVAR1)

Possibility to compare?





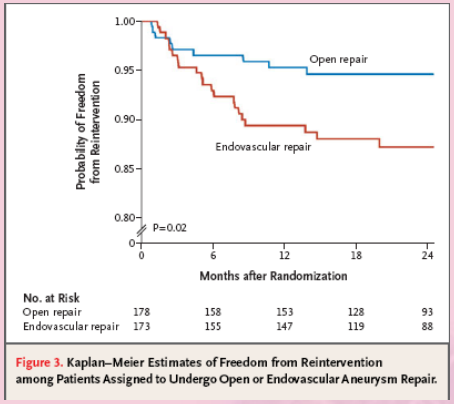
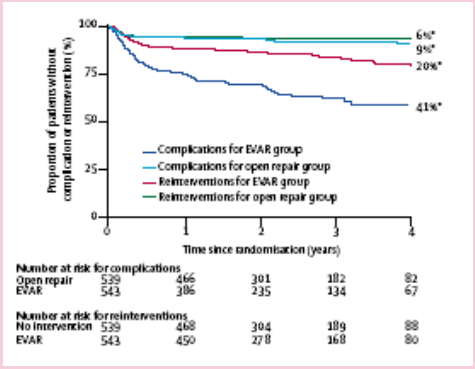
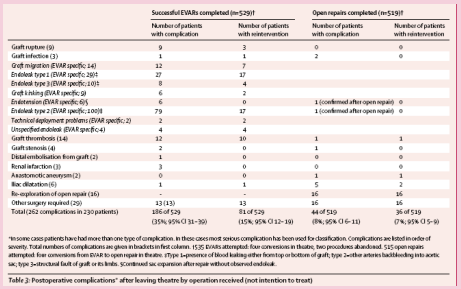


Figure 3. Kaplan–Meier Estimates of Freedom from Reintervention among Patients Assigned to Undergo Open or Endovascular Aneurysm Repair.

Survival or reintervention



Death or reintervention



	Successful EVARs completed (n=529)†		Open repairs completed (n=519)†	
	Number of patients with complication	Number of patients with reintervention	Number of patients with complication	Number of patients with reintervention
Graft rupture (9)	9	3	0	0
Graft infection (3)	1	1	2	0
Graft migration (EVAR specific-14)	12	7		
Endoleak type 1 (EVAR specific-26)‡	27	17		
Endoleak type 3 (EVAR specific-10)‡	8	4		
Graft kinking (EVAR specific-2)	6	2		
Endotension (EVAR specific-6)‡	6	0	1 (confirmed after open repair)	0
Endoleak type 2 (EVAR specific-100)‡	79	37	1 (confirmed after open repair)	0
Technical deployment problems (EVAR specific-2)	2	2		
Unspecified endoleak (EVAR specific-4)	4	4		
Graft thrombosis (14)	12	10	1	1
Graft stenosis (4)	2	0	1	0
Distal embolisation from graft (2)	1	0	0	0
Renal infarction (3)	3	0	0	0
Anastomotic aneurysm (2)	0	0	1	1
Iliac dilatation (6)	1	1	5	2
Re-exploration of open repair (16)	-	-	16	16
Other surgery required (25)	13 (13)	13	16	16
Total (262 complications in 230 patients)	186 of 529 (35%; 95% CI 31–39)	81 of 529 (15%; 95% CI 12–18)	44 of 519 (8%; 95% CI 6–11)	36 of 519 (7%; 95% CI 5–9)

*In some cases patients have had more than one type of complication. In these cases most serious complication has been used for classification. Complications are listed in order of severity. Total numbers of complications are given in brackets in first column. †535 EVARs attempted: four conversions in theatre, two procedures abandoned. 525 open repairs attempted: four conversions from EVAR to open repair in theatre. ‡Type 1=presence of blood leaking either from top or bottom of graft; type 2=other arteries backbleeding into aortic sac; type 3=structural fault of graft or its limbs. §Continued sac expansion after repair without observed endoleak.

Table 2: Postoperative complications* after leaving theatre by operation received (not intention to treat)

	Number of Patients							
Cause of Death	Before Surgery†		In the Hospital		After Discharge		Overall	
	Open Repair (N=578)	Endovascular Repair (N=574)	Open Repair (N=34)	Endovascular Repair (N=17)	Open Repair (N=66)	Endovascular Repair (N=39)	Open Repair (N=578)	Endovascular Repair (N=574)
All causes	1	1	8	3	9	12	18	30
Cardiovascular causes	0	0	3	1	3	2	2	7
Myocardial infarction	0	0	1	1	0	1	1	3
Cardiac arrest	0	0	1	0	3	3	3	3
Congestive heart failure	0	0	0	0	0	3	0	3
Stroke	0	0	0	0	1	1	1	1
Aneurysm-related, noncardiovascular causes	1	0	3‡	1‡	1‡	1‡	8	3
Cancer	0	0	0	0	3	4	3	4
Other	0	1	0	0	1§	1††	1	2
Unknown	0	0	0	0	2‡‡	2‡‡	2	2

Table 3. Causes of Death after Open and Endovascular Repair of Abdominal Aortic Aneurysm.

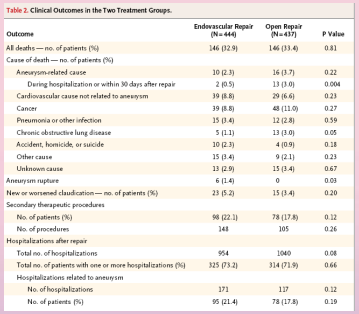
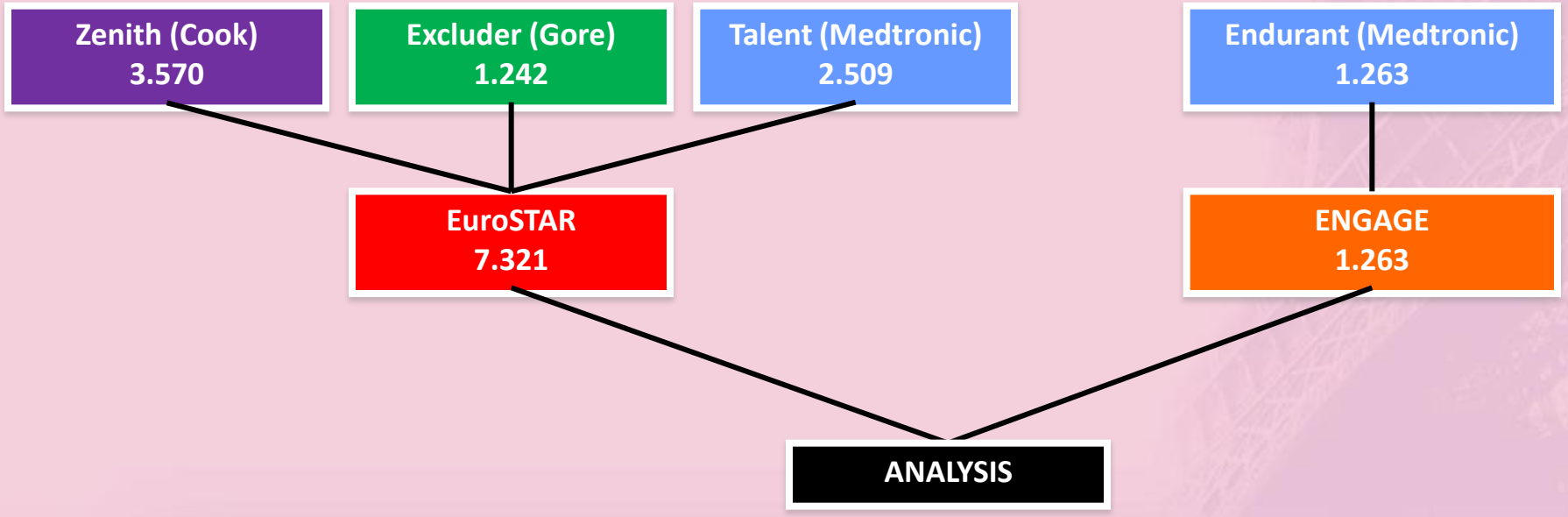


Table 2. Clinical Outcomes in the Two Treatment Groups.

Outcome	Endovascular Repair (N = 444)	Open Repair (N = 437)	P Value
All deaths — no. of patients (%)	146 (32.9)	146 (33.4)	0.81
Cause of death — no. of patients (%)			
Aneurysm-related cause	10 (2.3)	16 (3.7)	0.22
During hospitalization or within 30 days after repair	2 (0.5)	13 (3.0)	0.004
Cardiovascular cause not related to aneurysm	39 (8.8)	29 (6.6)	0.23
Cancer	39 (8.8)	48 (11.0)	0.27
Pneumonia or other infection	15 (3.4)	12 (2.8)	0.59
Chronic obstructive lung disease	5 (1.1)	13 (3.0)	0.05
Accident, homicide, or suicide	10 (2.3)	4 (0.9)	0.18
Other cause	15 (3.4)	9 (2.1)	0.23
Unknown cause	13 (2.9)	15 (3.4)	0.67
Aneurysm rupture	6 (1.4)	0	0.03
New or worsened claudication — no. of patients (%)	23 (5.2)	15 (3.4)	0.20
Secondary therapeutic procedures			
No. of patients (%)	98 (22.1)	78 (17.8)	0.12
No. of procedures	148	105	0.26
Hospitalizations after repair			
Total no. of hospitalizations	954	1040	0.08
Total no. of patients with one or more hospitalizations (%)	325 (73.2)	314 (71.9)	0.66
Hospitalizations related to aneurysm			
No. of hospitalizations	171	117	0.12
No. of patients (%)	95 (21.4)	78 (17.8)	0.19

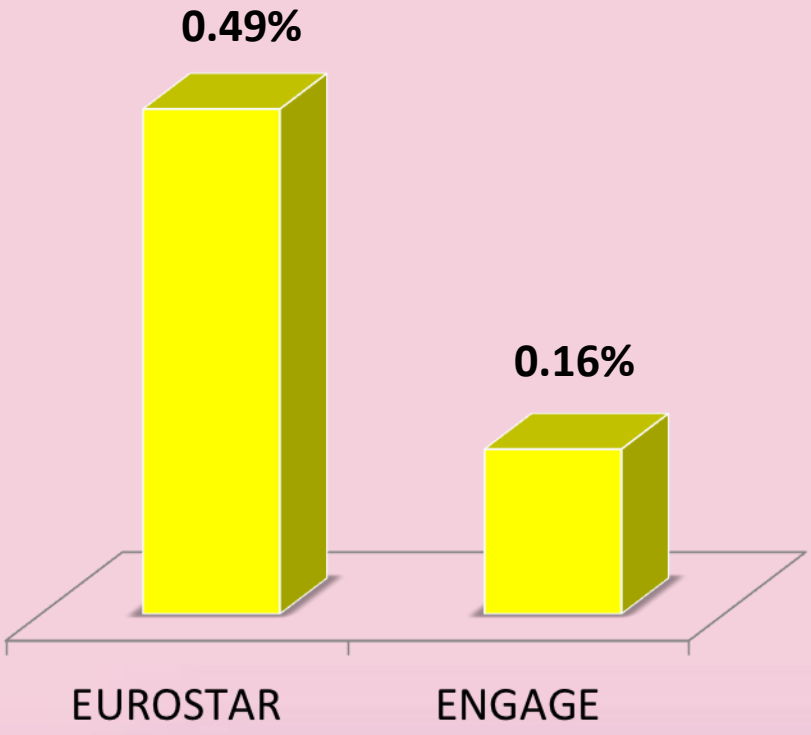
EuroSTAR (n= 7.321)
January ’98 - December ’06

ENGAGE (n= 1.263)
March ‘09 - April ‘11



Conversion to open surgery

Intra-operative



Intra-operative

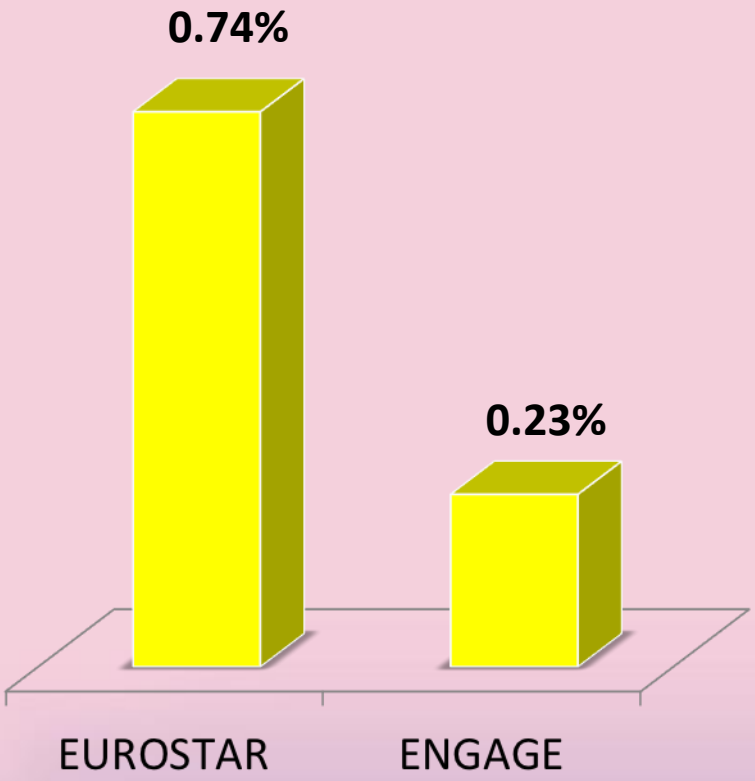
EUROSTAR: 0.49% (0.35-0.68)

ENGAGE: 0.16% (0.03-0.61)

p = 0.09

Conversion to open surgery

Within 30 days



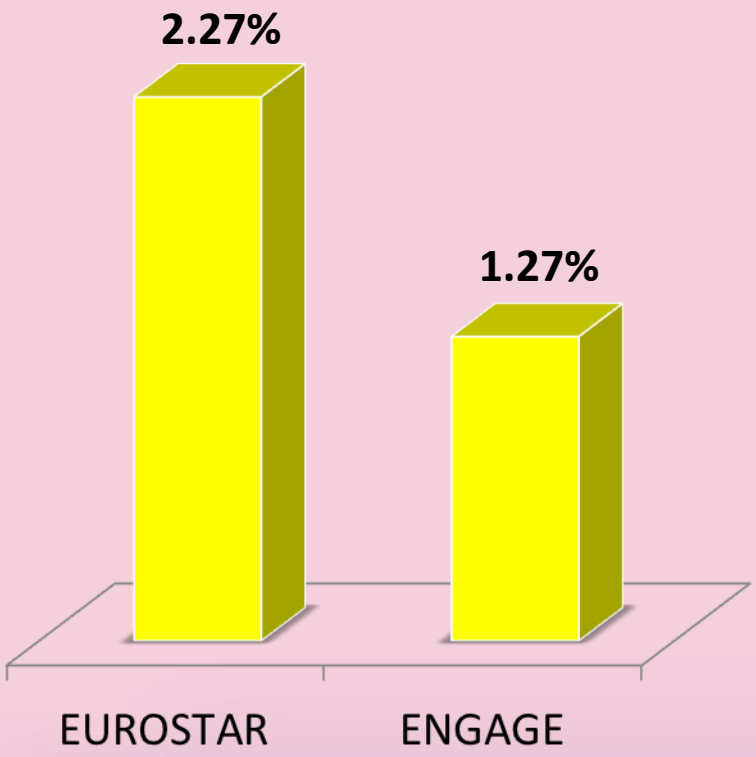
Within 30 days

EUROSTAR: 0.74% (0.56-0.96)

ENGAGE: 0.23% (0.05-0.73)

p = 0.04

Mortality
Within 30 days



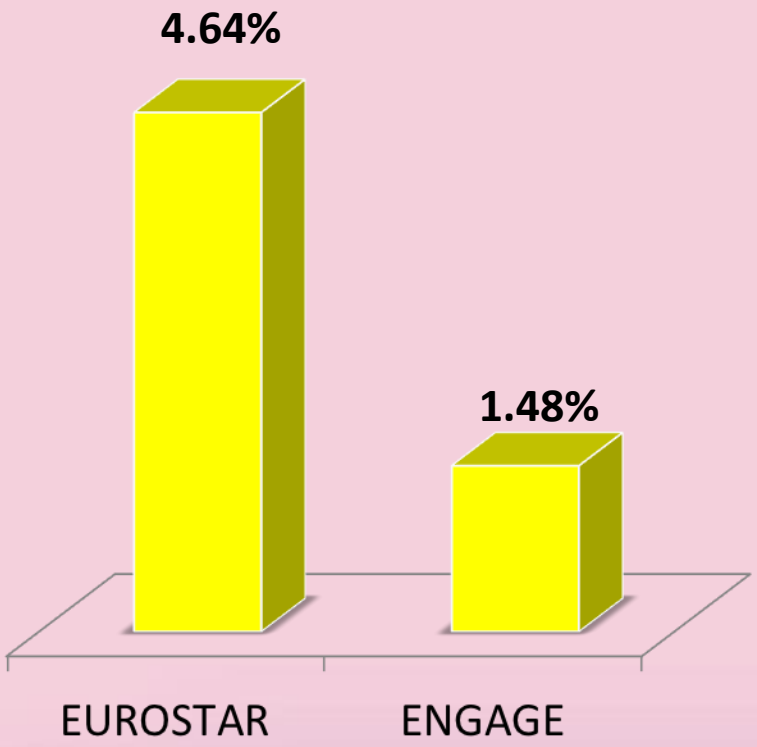
30-day mortality

EUROSTAR: 2.27% (1.95-2.36)
ENGAGE: 1.27% (0.76-2.07)

p = 0.02

Endoleak Type I & III

At 30 days



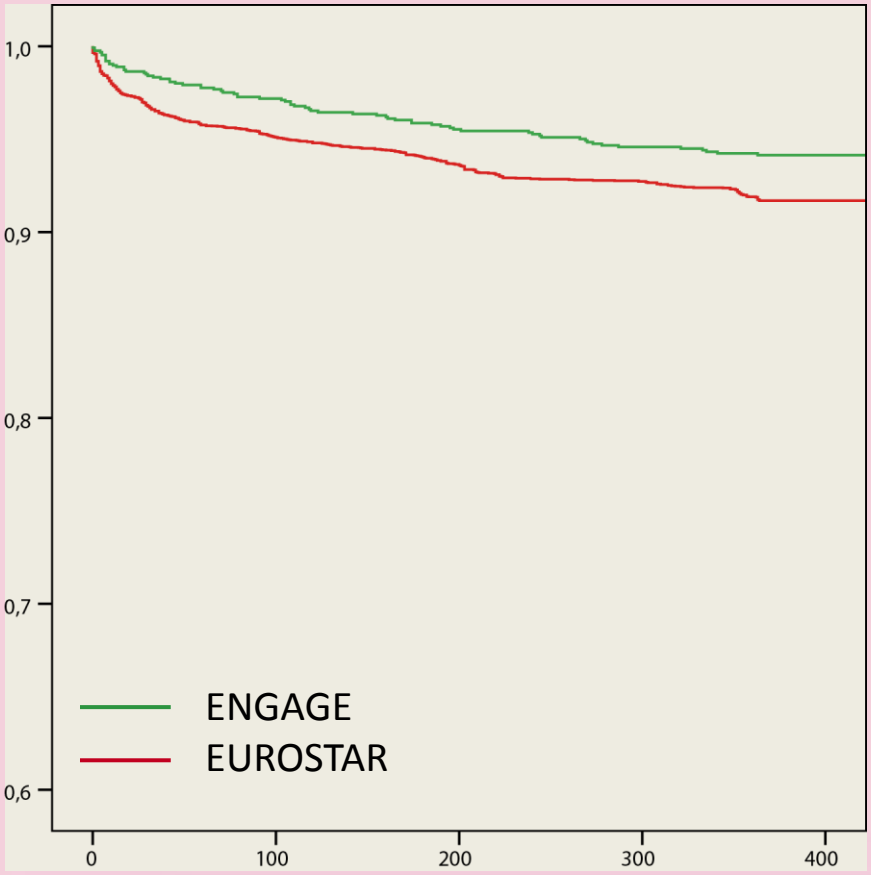
30-day Type- I & III endoleaks

EUROSTAR: 4.64% (4.01-5.37)

ENGAGE: 1.48% (0.91-2.37)

p < 0.01

Intervention free survival



After 30 days

EUROSTAR: 97.62% ± 0.2

ENGAGE: 98.41% ± 0.3

p = 0.02

After 365 days

EUROSTAR: 91.73% ± 0.4

ENGAGE: 94.14% ± 0.7

p = 0.02

Conclusion

EVAR is getting better

Due to better insight in the pathophysiology of AAA and because new generation endografts seem to perform better