

Very long-term follow-up up to 15 years of the Dutch Randomized Endovascular Aneurysm Repair Management (DREAM)-Trial

*ThG van Schaik, JL de Bruin, MRHM van Sambeek,
JM Verhagen, CJ Zeebregts, R Balm, AC van der Ham, AG Krasznai,
OHJ Koning, RP Tutein Nolthenius, JA van Herwaarden, M Prinssen,
DE Grobbee, KK Yeung, JD Blankensteijn, for the DREAM Study Group*

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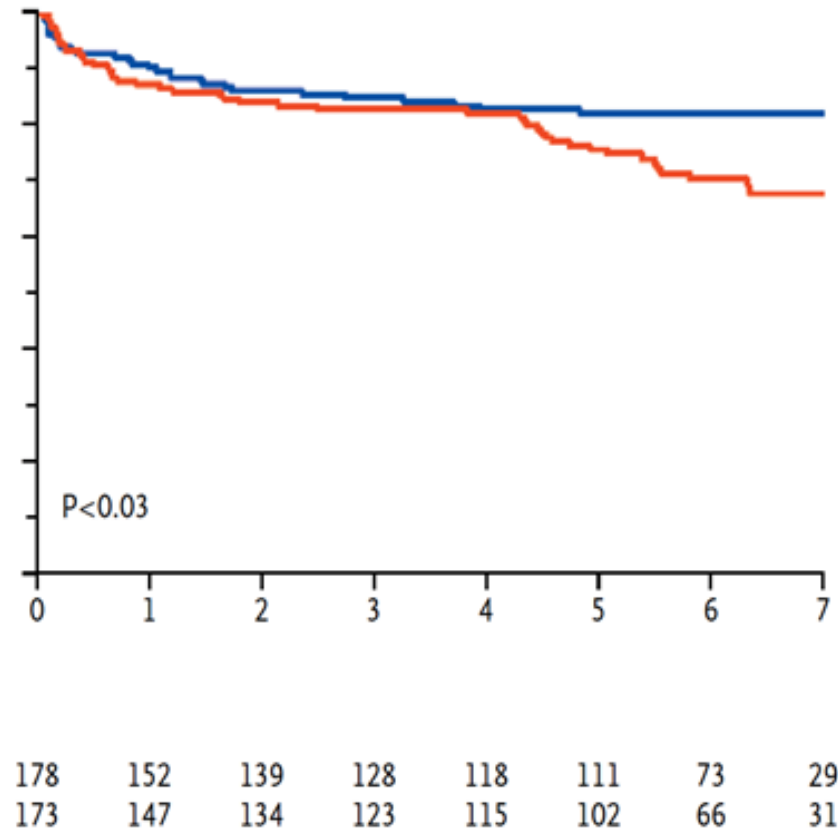
Coauthor	Disclosures
MRHM van Sambeek	Personal fee and research grants - WL Gore, Medtronic & Philips Medical
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JD Blankensteijn	Consultant – WL Gore & Endologix
HJM Verhagen,	Personal fee and research grants – Medtronic, WL Gore, Philips, Endologix & Arsenal AAA
ThG van Schaik, JL de Bruin, CJ Zeebregts, R Balm, OHJ Koning, RP Tutein Nolthenius, M Prinssen, DE Grobbee and KK Yeung	Nothing to declare

- Dutch Randomized Endovascular Aneurysm Repair Management (DREAM)-Trial
- Multicenter RCT
- Comparing elective open and endovascular aneurysm repair

- Including patients between 2000-2003
- 26 centers in the Netherlands
- 4 centers in Belgium
- 351 patients with infrarenal abdominal aortic aneurysms > 5cm



- Initial survival benefit¹
- Equal overall survival after 6 years²
- Despite an increased risk of secondary intervention²



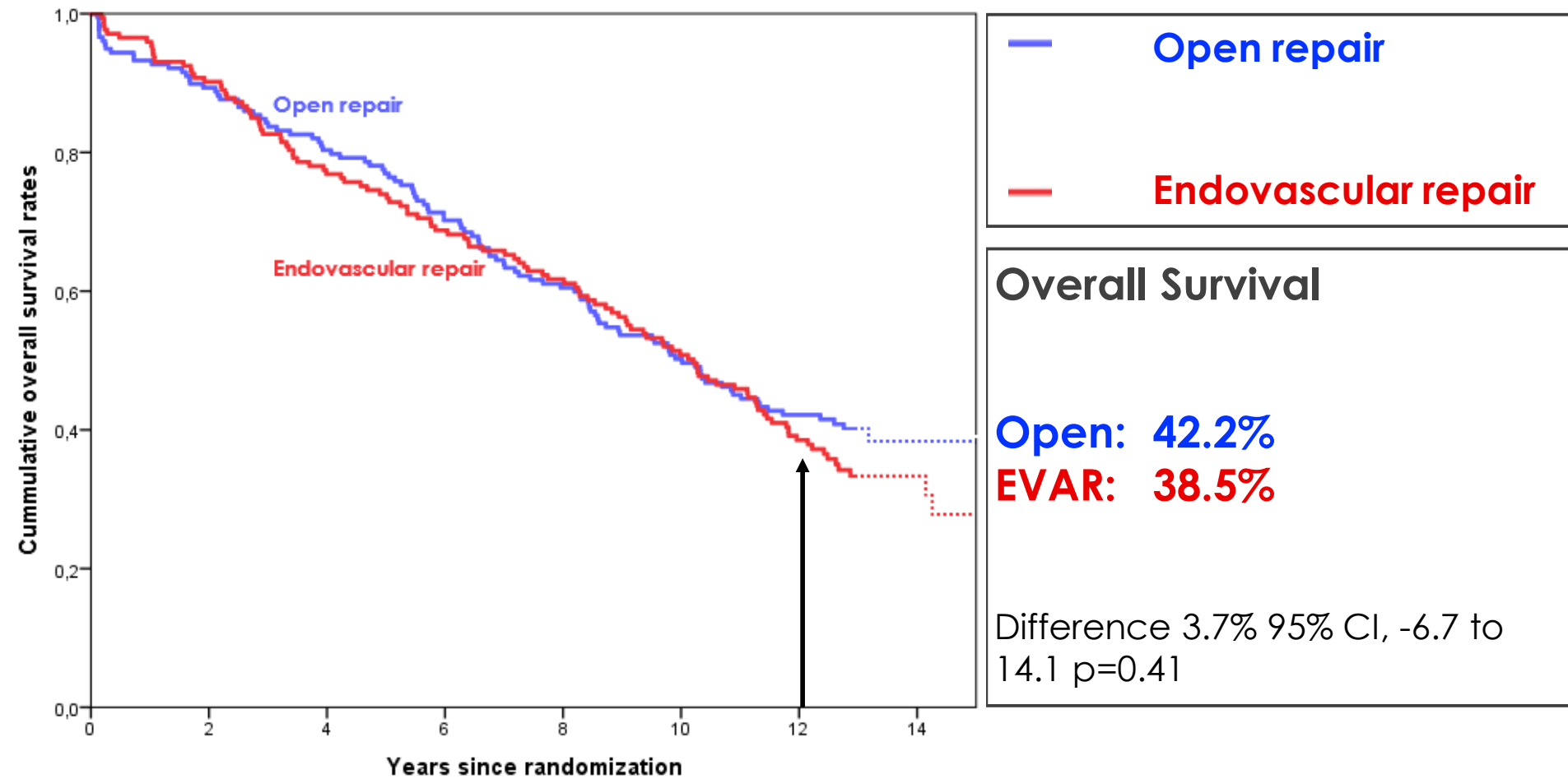
1. Prinssen M, Verhoeven EL, Buth J, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. *N Engl J Med* 2004;351:1607-18.

2. De Bruin JL, Baas AF, Buth J, Prinssen M, Long-Term Outcome of Open or Endovascular Repair of Abdominal Aortic Aneurysm; *N Engl J Med* 2010;362:1881-9.

- A persistent increased rate of secondary interventions after EVAR leads to a long-term survival disadvantage
- Very long-term follow-up may be required to demonstrate this effect
- Aim: To compare survival and reintervention rates, 12-15 years after randomization in the DREAM-trial

- Enrollment:
 - Open repair: 178 patients
 - Endovascular repair: 173 patients
- Retrospective updated follow-up 12-15 years after randomization
 - Medical records
 - Contacting patients, relatives and general practitioners
- Kaplan-Meier method (intention-to-treat)
 - Survival
 - Freedom from reintervention
- Event rate per 100 person year (EPPY)-analysis
 - Causes of death
 - Reintervention indications

- Completeness of follow-up 98.2%
- Median follow-up 10.1 years (IQR 5,0-12,5)
- Lost-to follow-up (n=8):
 - Open repair: 3
 - Endovascular repair: 5



EVAR	173	156	133	117	103	83	62	14
OSR	178	159	143	123	106	88	71	24

Causes of death (entire follow-up)



Causes	Events (rate per 100 person years)			
	Open (n=178)	Endo (n=173)	Rate ratio*	P-value
All cause	107 (6.7)	113 (7.5)	0,90	0,42
Aneurysm related	12 (0.8)	8 (0.5)	1,42	0,45
• Aneurysm rupture	2 (0.1)	2 (0.1)	0,95	0,96
• Graft infection	2 (0.1)	2 (0.1)	0,95	0,96
• 30 days post reintervention	8 (0.5)	4 (0.3)	1,89	0,31
Cardiovascular	29 (1.8)	24 (1.6)	1,14	0,63
Pulmonary	13 (0.8)	9 (0.6)	1,37	0,48
Malignant disease	30 (1.9)	34 (2.3)	0,83	0,47
Miscellaneous	6 (0.4)	14 (0.9)	0,41	0,06
Unknown	17 (1.1)	24 (1.6)	0,67	0,21

* Conditional maximum likelihood estimate rate ratio

Causes of death (>10 years)



Events (rate per 100 person years)

Causes	Open (n=178)	Endo (n=173)	Rate ratio*	P-value
All cause	19 (7.3)	29 (13.4)	0,54	0,04
Aneurysm related	0 (0.0)	3 (1.4)	0,00	0,09
• Aneurysm rupture	0 (0.0)	2 (0.9)	0,00	0,09
• Graft infection	0 (0.0)	0 (0.0)	0,00	0,21
• 30 days post reintervention	0 (0.0)	1 (0.5)	0,00	0,45
Cardiovascular	5 (1.9)	2 (0.9)	2,07	0,41
Pulmonary	5 (1.9)	2 (0.9)	2,07	0,41
Malignant disease	4 (1,5)	9 (4.2)	0,37	0,09
Miscellaneous	1 (0.5)	2 (0.9)	0,41	0,52
Unknown	4 (1.5)	11 (5,1)	0,30	0,03

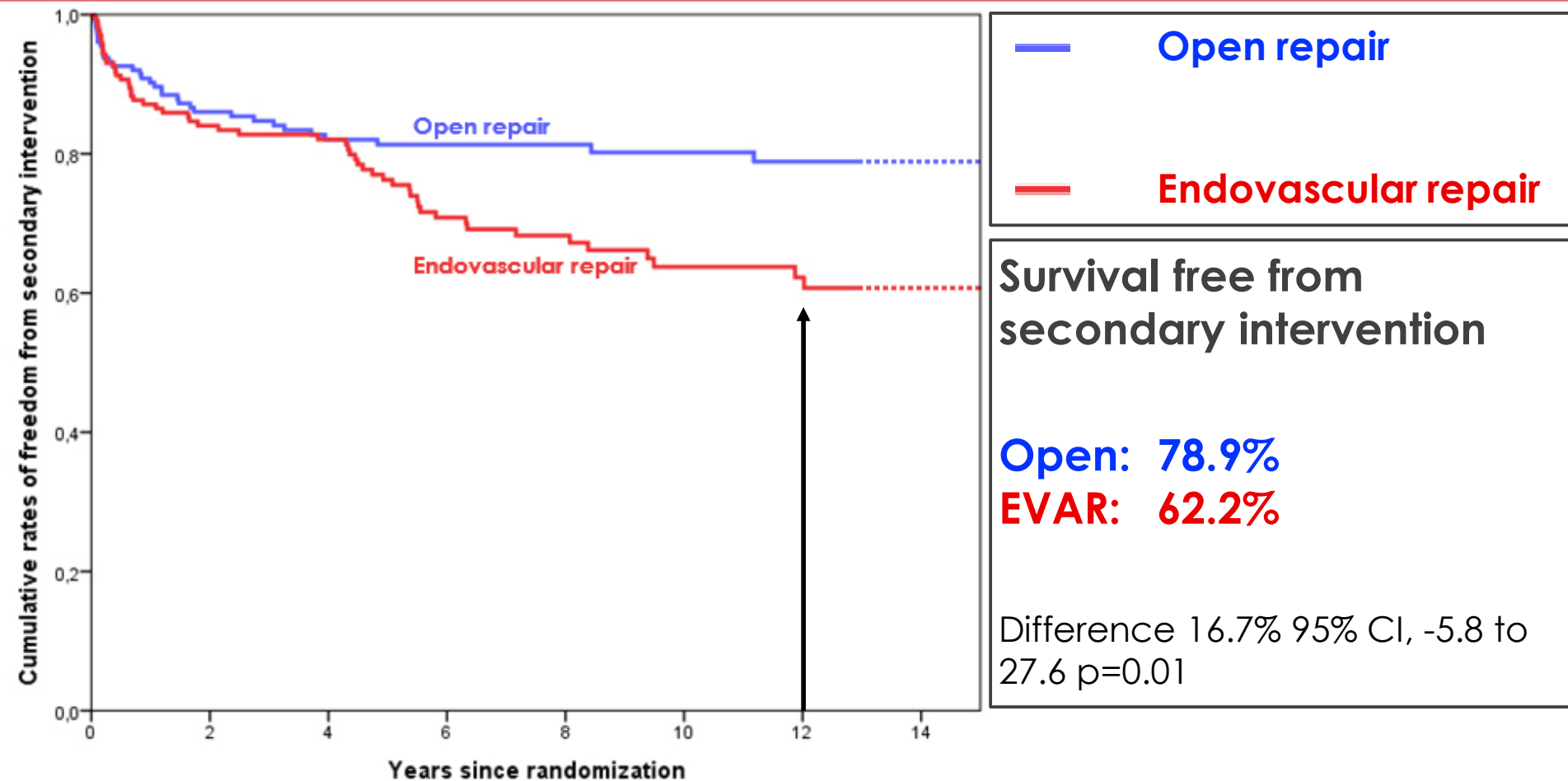
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Miscellaneous	1 (0.5)	2 (0.9)	0,41	0,52
Unknown	4 (1.5)	11 (5,1)	0,30	0,03
Rupture, Reintervention, or Malignant disease	4 (1.5)	12 (5.6)	0,28	0,02

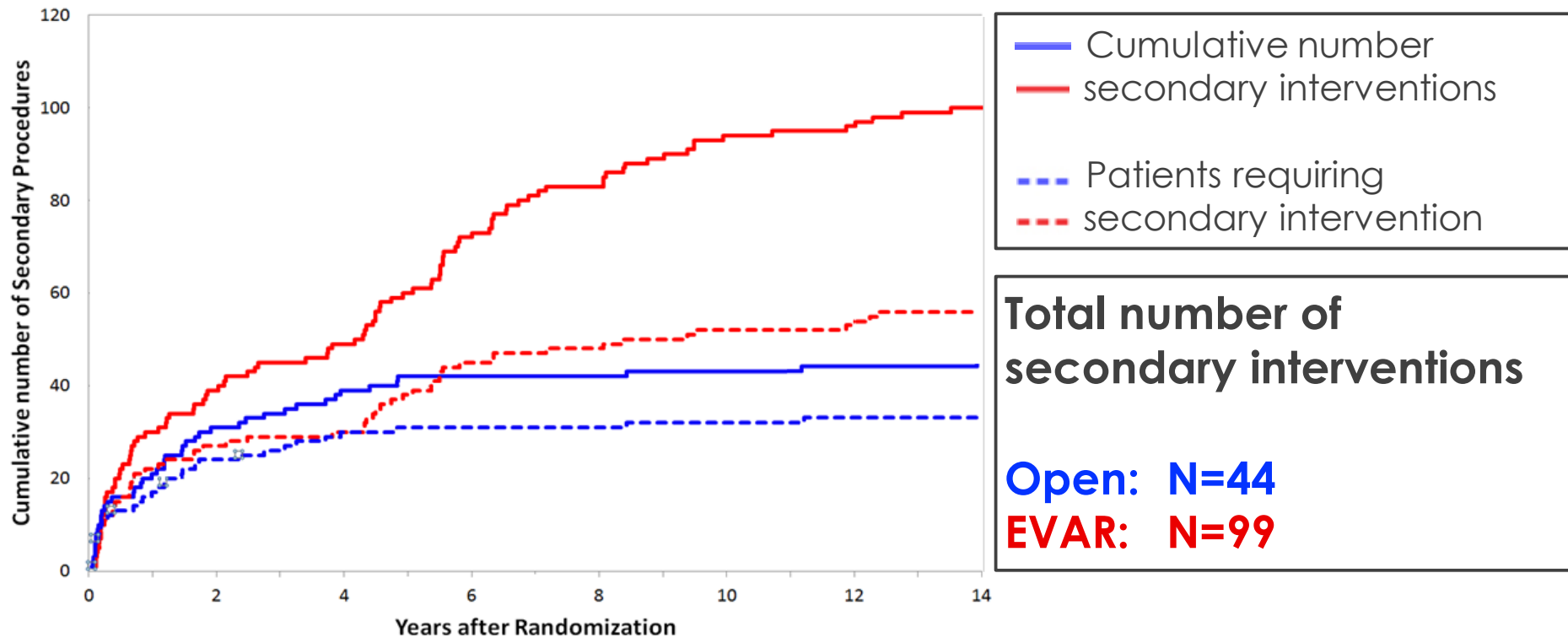
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Freedom from reintervention



EVAI	173	134	115	87	67	51	41	10
OSR	178	139	118	94	73	67	58	20

Secondary interventions



Total number of secondary interventions

Open: N=44

EVAR: N=99

Open	178	139	118	94	73	67	58	20
EVAR	173	134	115	87	67	51	41	10

Secondary intervention indications



Indication for Reintervention	Events (rate per 100 person years)			
	Open (n=178)	Endo (n=173)	Rate ratio*	P-value
Any Indication	44 (2.8)	99 (6.6)	0.42	<0.001
Aneurysm-related indication	12 (0.8)	75 (5.0)	0.15	<0.001
Incomplete exclusion	2	47	0.04	<0.001
Para-anastomotic aneurysm	4	2	1.89	0.49
Prosthesis infection	0	6	0	0.01
Thrombo-occlusive	6	20	0.28	0.004
Wound-related indication	20 (1.3)	11 (0.7)	1.72	0.15
Wound complications	1	6	0.15	0.06
Incisional hernia	19	5	3.60	0.006
Local or Systemic indication	12 (0.8)	13 (0.9)	0.87	0.73
Bleeding	7	6	1.10	0.87
Bowel resection or Ileus	5	3	1.58	0.56
Miscellaneous	0	4	0	0.06

* Conditional maximum likelihood estimate rate ratio

- Similar overall survival rates, despite an increased risk on secondary interventions
- Explanation:
 - Secondary interventions do not influence overall survival
 - Overall survival after endovascular repair would be superior

- Half of patients survive after 10 years
- No difference in overall survival between groups
- Twofold risk of secondary intervention after endovascular repair
- Deaths > 10 years associated with EVAR durability and follow-up related radiation?

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Baseline characteristics



Characteristic	Open repair (N=178)	Endovascular repair (N=173)	P Value
Age – yrs	69.6±6.8	70.7±6.6	0.13
Male sex – no. (%)	161 (90)	161 (93)	0.44
Diabetes Mellitus	9.6	10.4	0.86
Tobacco Use	55.1	64.2	0.10
Hypertension	54.5	58.4	0.52
Hyperlipidemia	52.6	47.0	0.33
Carotid Disease	15.2	14.5	0.88
Cardiac Disease	46.6	41.0	0.33
Renal Disease	8.4	7.5	0.85
Pulmonary Disease	18.5	27.7	0.04
Sum of SVS/ISCVS risk-factor scores†	4.5±2.5	4.4±2.5	0.61
FEV ₁ – liters/sec	2.6±0.7	2.5±0.7	0.27
Body-mass Index	26.6±4.1	26.3±3.4	0.47
ASA I healthy status	44 (25)	37 (22)	0.53
ASA II mild systemic disease	110 (62)	122 (71)	0.09
ASA III severe systemic disease	24 (14)	14 (8)	0.12