The DREAM Trial: Are There Long-Term Survival Benefits of EVAR?

Philippe Cuypers

Jan Blankensteijn

On behalf of the DREAM investigators

EVAR vs open surgery: RCT

- EVAR-1 UK
- DREAM Netherlands
- OVER US
- ACE France

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A Randomized Trial Comparing Conventional and Endovascular Repair of Abdominal Aortic Aneurysms

Monique Prinssen, M.D., Eric L.G. Verhoeven, M.D., Jaap Buth, M.D., Philippe W.M. Cuypers, M.D., Marc R.H.M. van Sambeek, M.D., Ron Balm, M.D., Erik Buskens, M.D., Diederick E. Grobbee, M.D., and Jan D. Blankensteijn, M.D., for the Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial Group*

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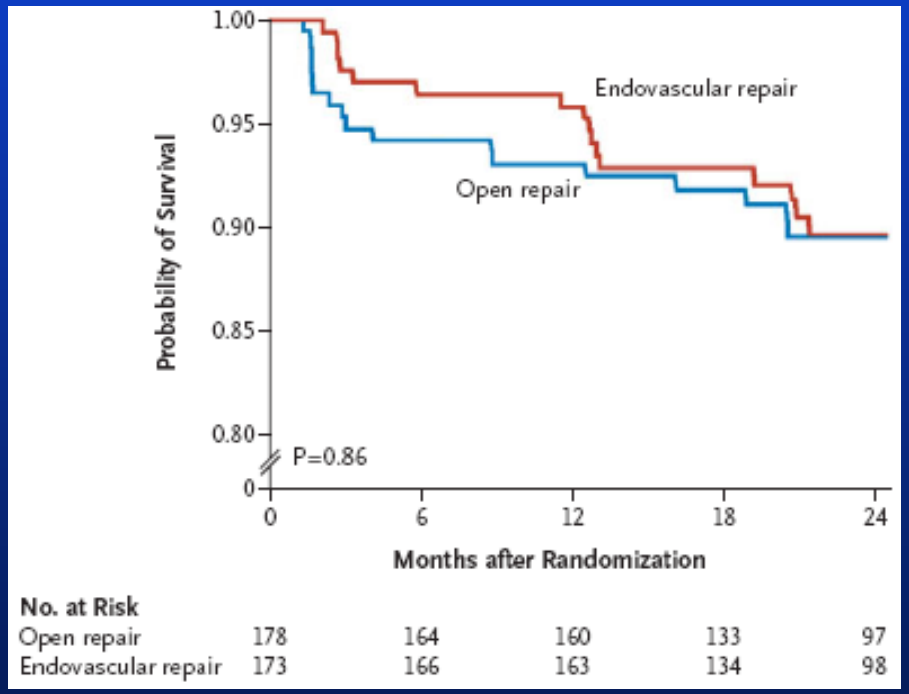
Table 4. End Points and Operative Complications.*

Variable	Open Repair (N=174)	Endovascular Repair (N=171)	Risk Ratio (95% CI)	P Value
	no. of patients (%)			
End point†				
Operative mortality	8 (4.6)	2 (1.2)	3.9 (0.9–32.9)	0.10

2 years outcome of DREAM



Cum. rates of AAA-relatedmortality:

-OR: 5.7%
-EVAR: 2.1%

(95% CI 0.5 - 7.9, P=0.05)

dream-on

- Extension of follow-up
- Beyond 2 years postoperatively
- New Informed Consent
- Patients:
  - 32 (of 315 alive at 2 years) declined

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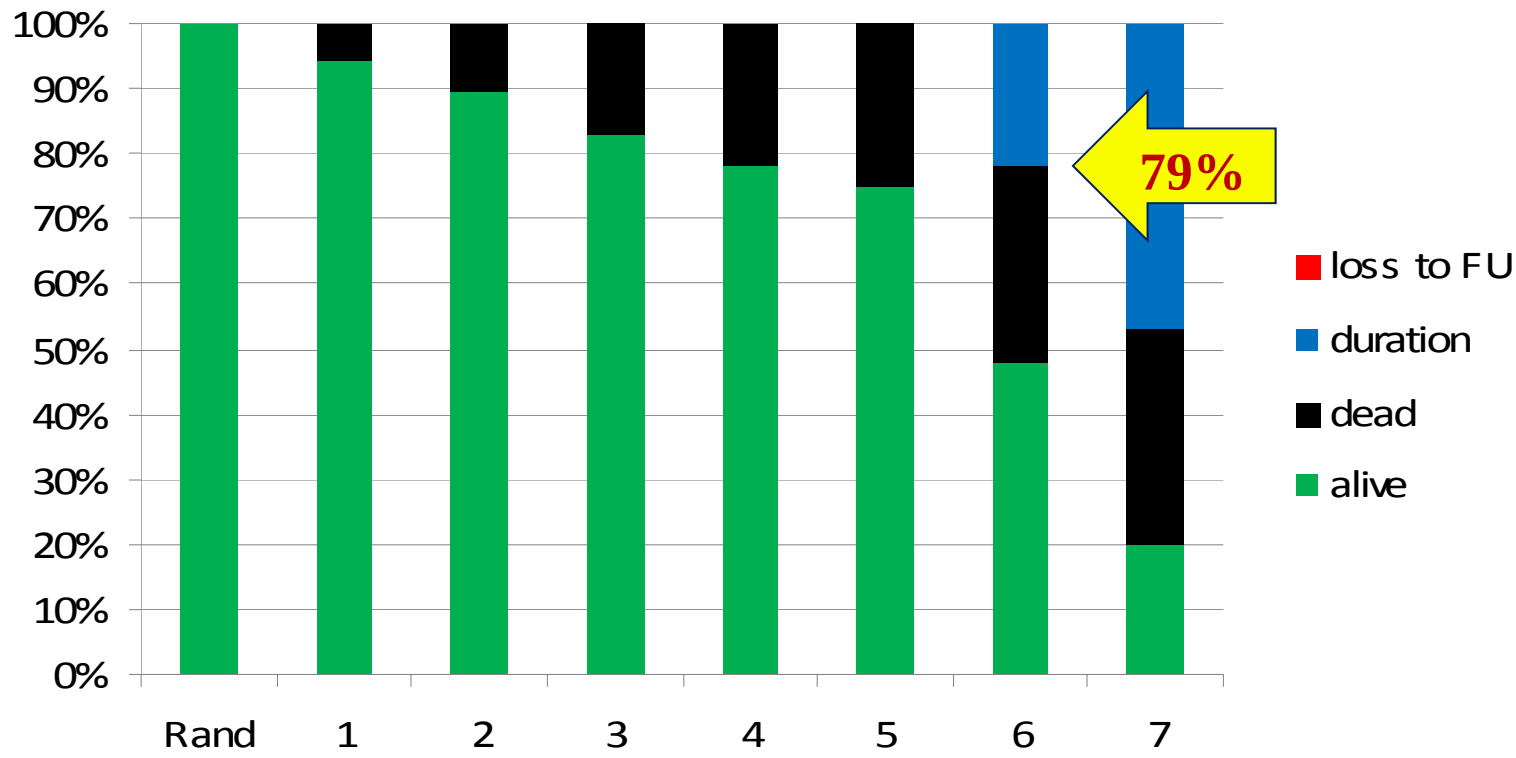
Current completeness of Follow-up DREAM-ON



Median follow-up: 6.4 years (range 5.1 to 8.2 years).

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Long-Term Outcome of Open or Endovascular Repair of Abdominal Aortic Aneurysm

Jorg L. De Bruin, M.D., Annette F. Baas, M.D., Jaap Buth, M.D., Monique Prinssen, M.D., Eric L.G. Verhoeven, M.D., Philippe W.M. Cuypers, M.D., Marc R.H.M. van Sambeek, M.D., Ron Balm, M.D., Diederick E. Grobbee, M.D., and Jan D. Blankensteijn, M.D., for the DREAM Study Group*

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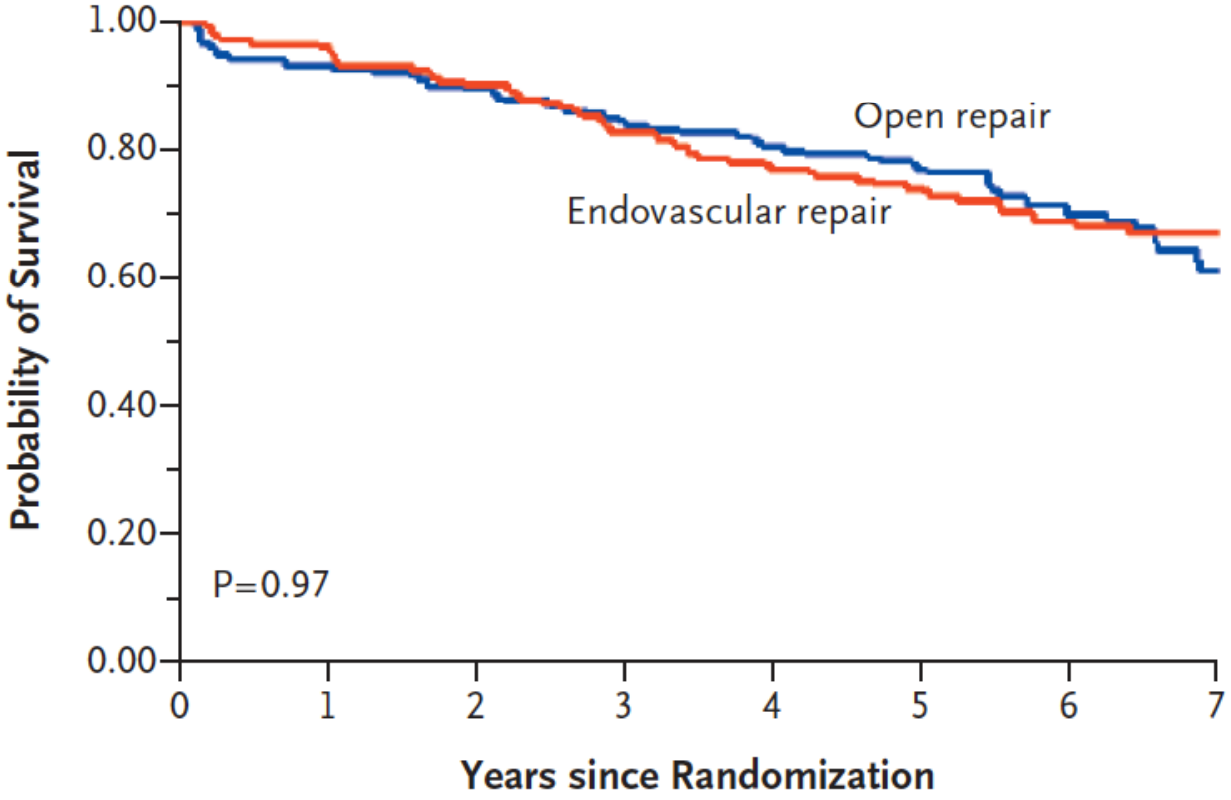
Overall Survival

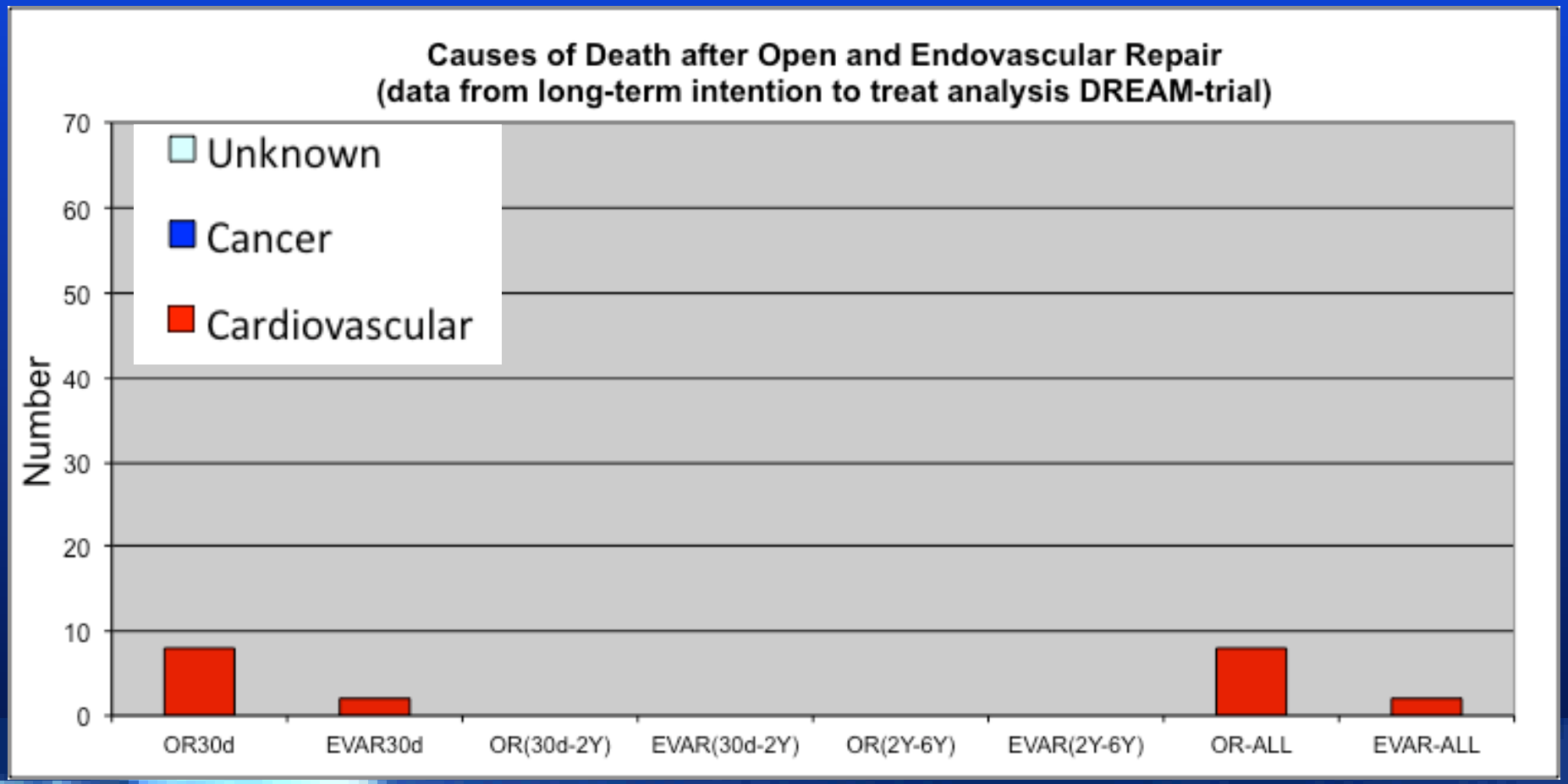
-Intention to TreatAnalysis-



No. at Risk								
Open repair	178	166	159	150	143	137	88	36
Endovascular repair	173	166	156	143	133	128	83	39

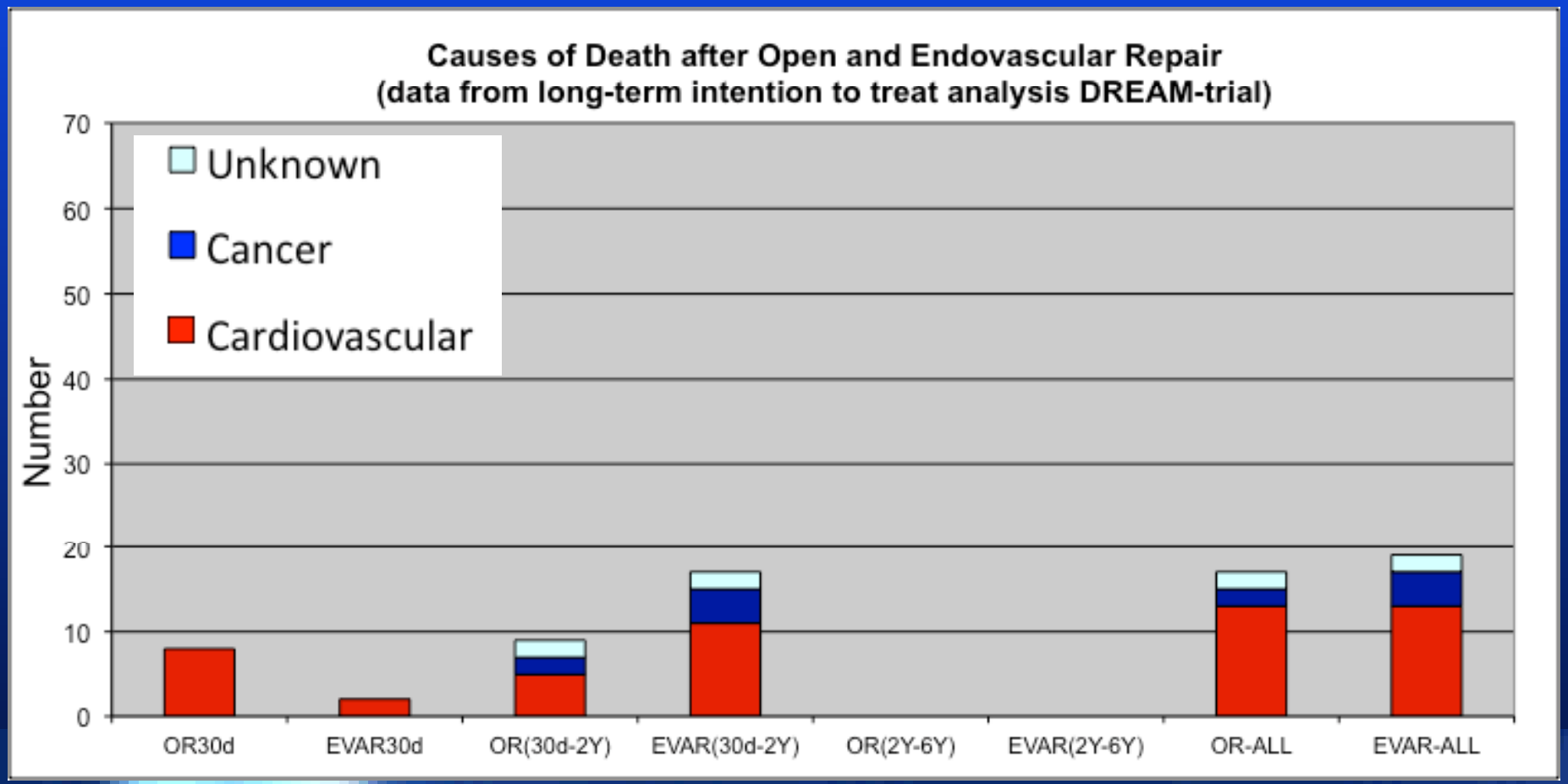
Summary of Causes of Death

-Intention to TreatAnalysis-



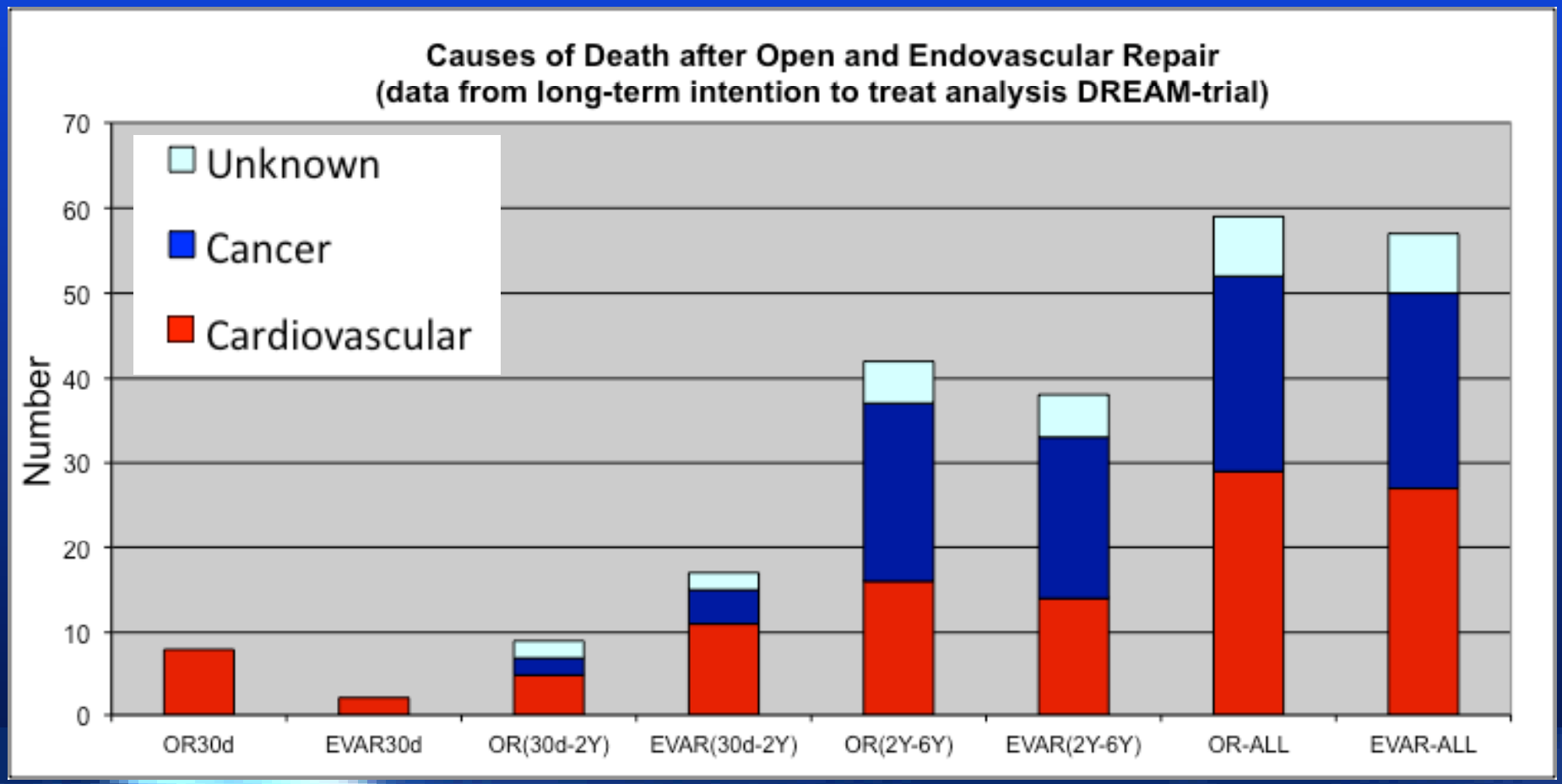
Summary of Causes of Death

-Intention to TreatAnalysis-



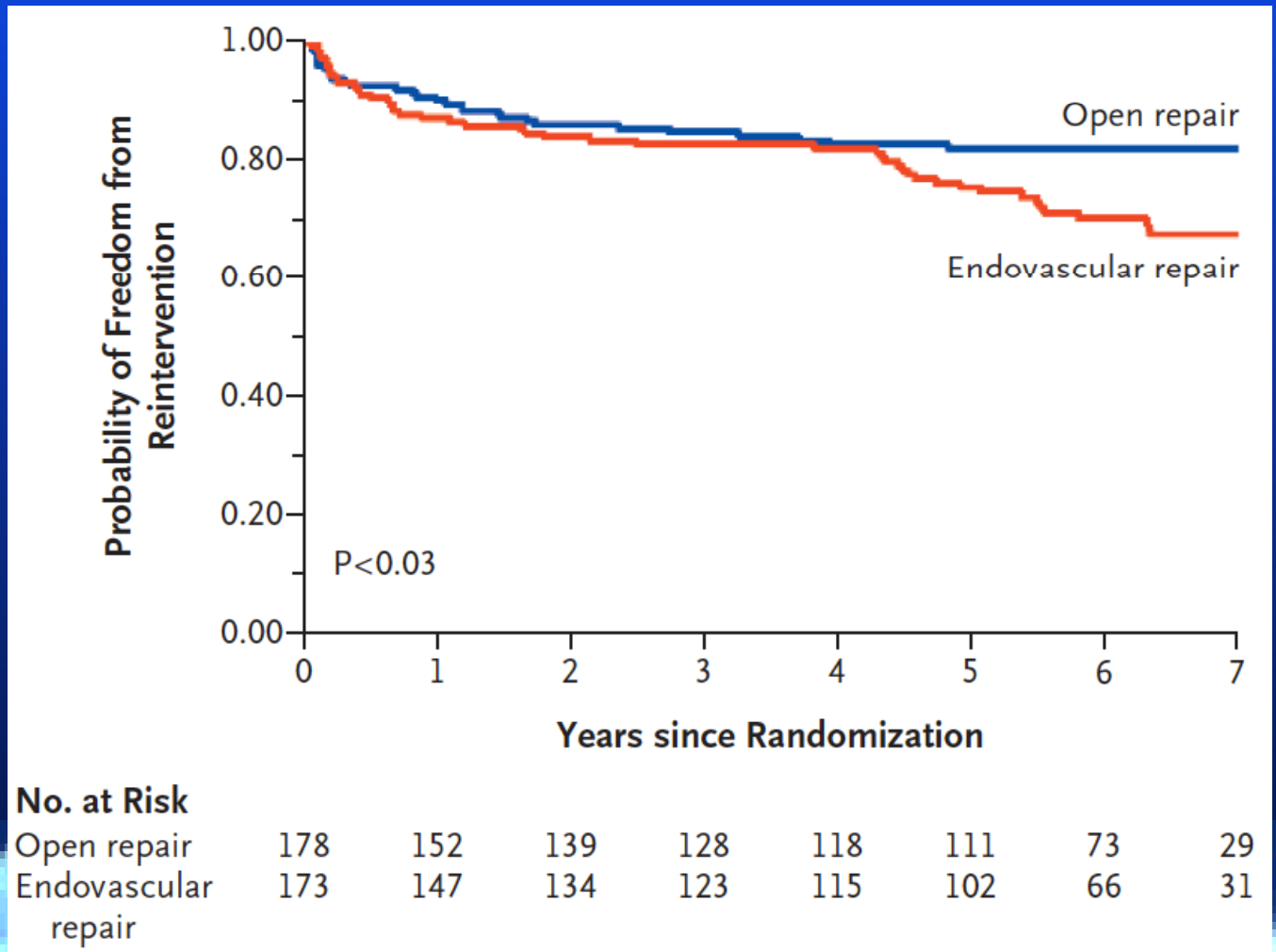
Summary of Causes of Death

-Intention to TreatAnalysis-



FreedomfromReintervention

-Intention to TreatAnalysis-



No. at Risk								
Open repair	178	152	139	128	118	111	73	29
Endovascular repair	173	147	134	123	115	102	66	31

Indicationfor First Reintervention

Indication	Open Repair (N=178)	Endovascular Repair (N=173)	Total (N=351)
	no. of patients		
Any indication	30	48	78
Graft-related indication			
Any	4	36	40
Thrombo-occlusive disease	3	12	15
Endoleak type 1*	0	12	12
Migration	0	7	7
Prosthesis infection	0	2	2
Endotension	0	1	1
Material failure	0	1	1
Para-anastomotic aneurysm	1	0	1
Aneurysm rupture	0	1	1

Indication	Open Repair (N=178)	Endovascular Repair (N=173)	Total (N=351)
		no. of patients	
Wound-related indication			
Any	15	3	18
Incisional hernia	14	0	14
Wound infection	1	2	3
Miscellaneous	0	1	1
Local or systemic indication			
Any	11	9	20
Bleeding	5	2	7
Endoleak type 2*	2†	6	8
Bowel resection or ileus	3‡	0	3
Miscellaneous§	1	1	2

Reinterventionsby type and rank#

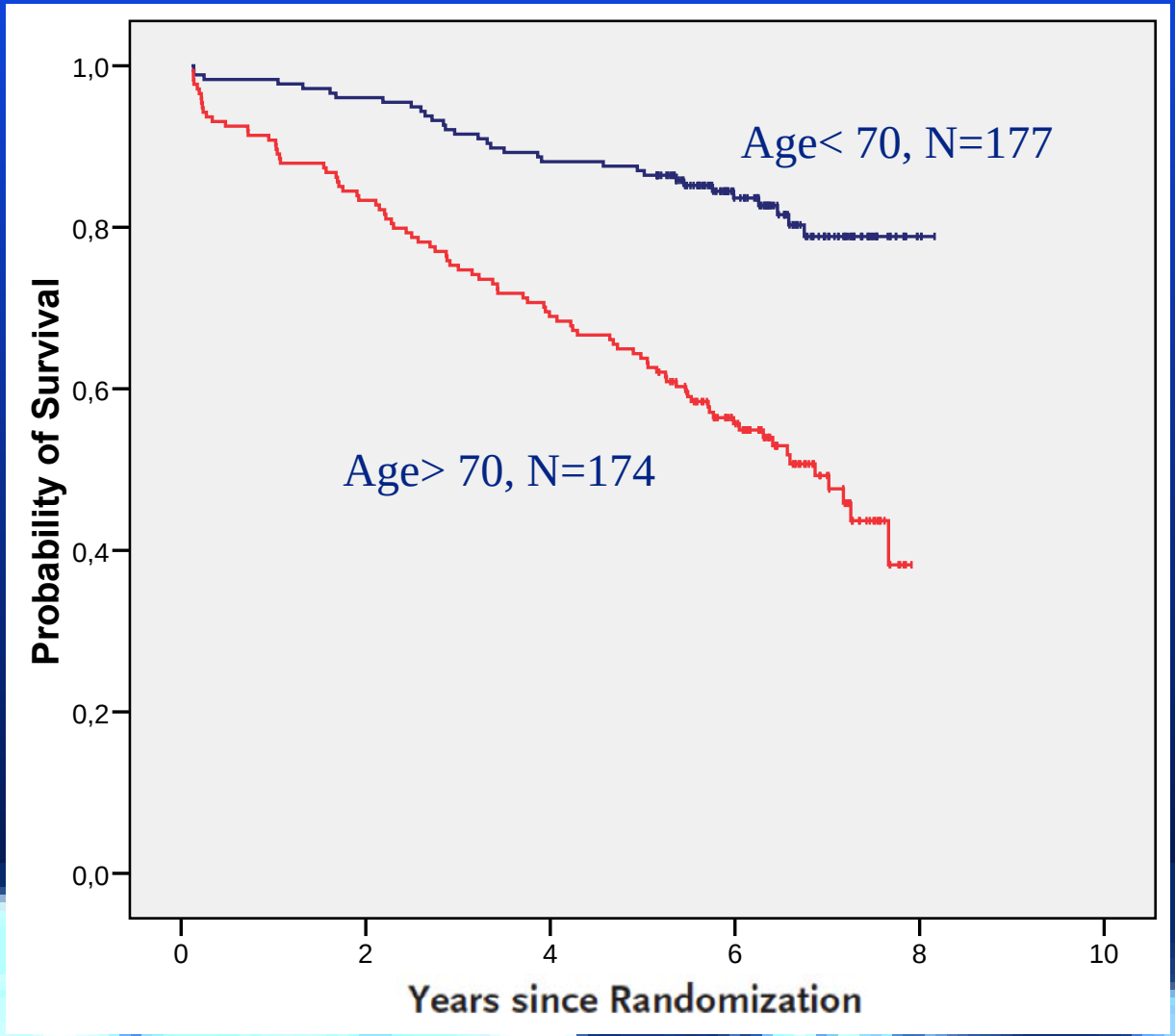
	Open Repair			Endovascular Repair			Total		
	1st	2nd	3rd	1st	2nd	3rd	1st	2nd	3rd
	reintervention			reintervention			reintervention		
Open surgical reintervention	27	6	2	22	10	6	49	16	8
Endovascular reintervention	3	2		20	4	1	23	6	1
Hybrid open/endovascular				5			5		
Laparoscopic reintervention		1		1			1	1	

Cox-regression Mortality

Covariant	*B*	*95% CL*	*Pvalue*
Age> 70	3,7	2,4-5,6	<0,005
CardiacHx	2,1	1,4-3,0	<0,005
Tobacco	2,1	1,4-3,2	<0,005
RenalFailure	1,3	0,7-2,3	0,363
Randomisation	0,9	0,6-1,3	0,470
Gender	0,7	0,4-1,5	0,386
Statin use	0,6	0,4-0,9	0,007

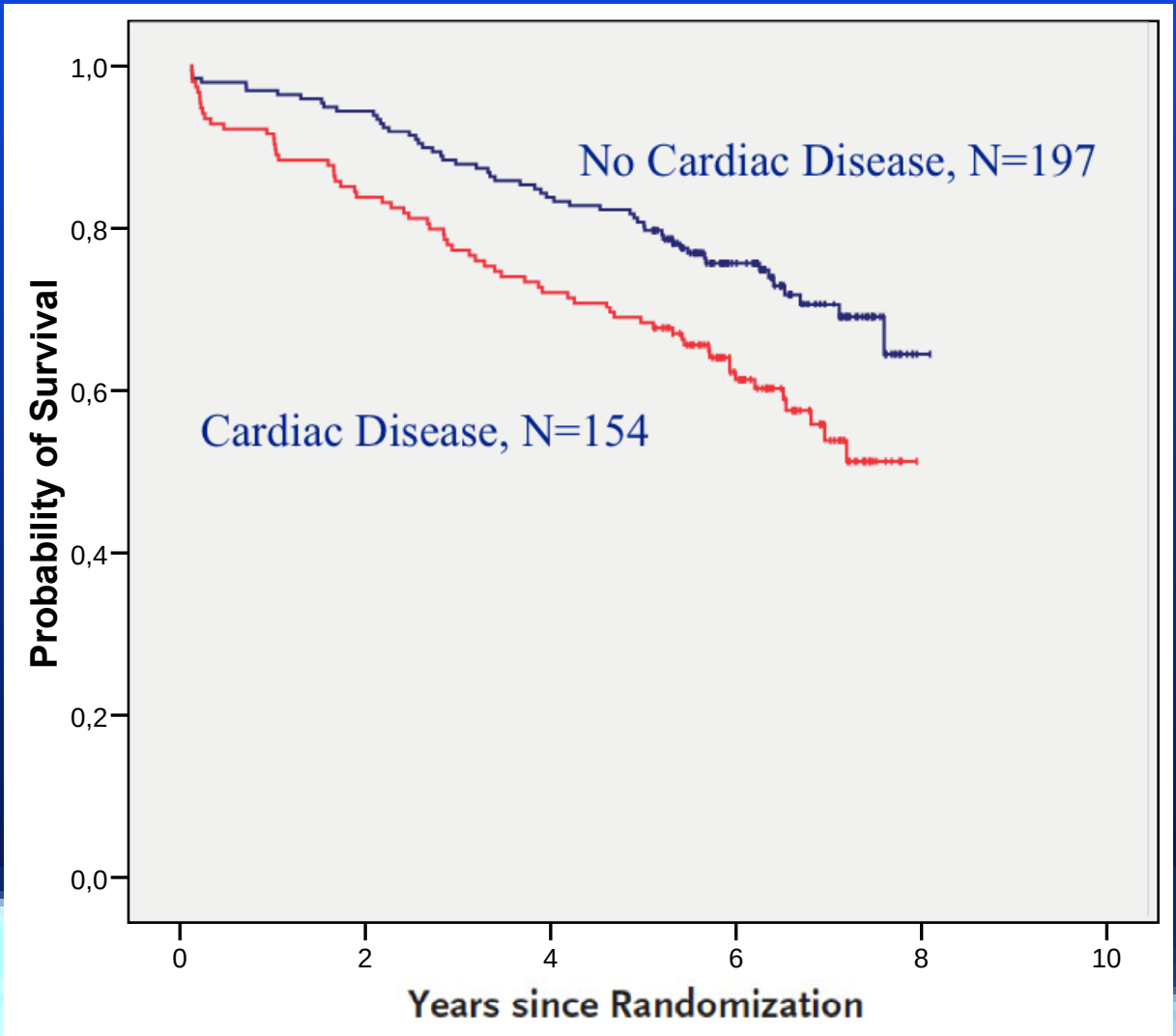
Overall Survival

- byAge -



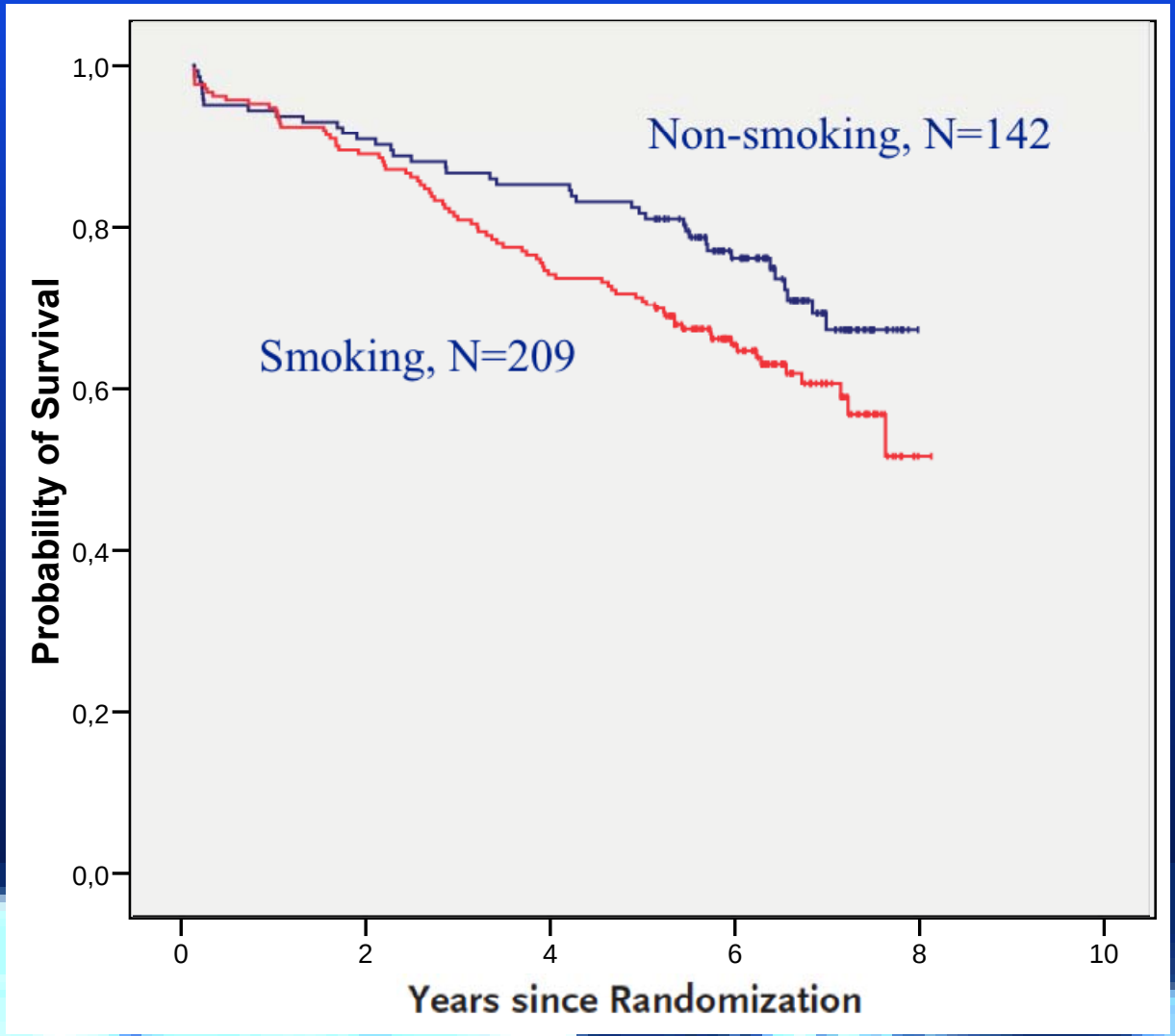
Overall Survival

- byCardiacDisease -



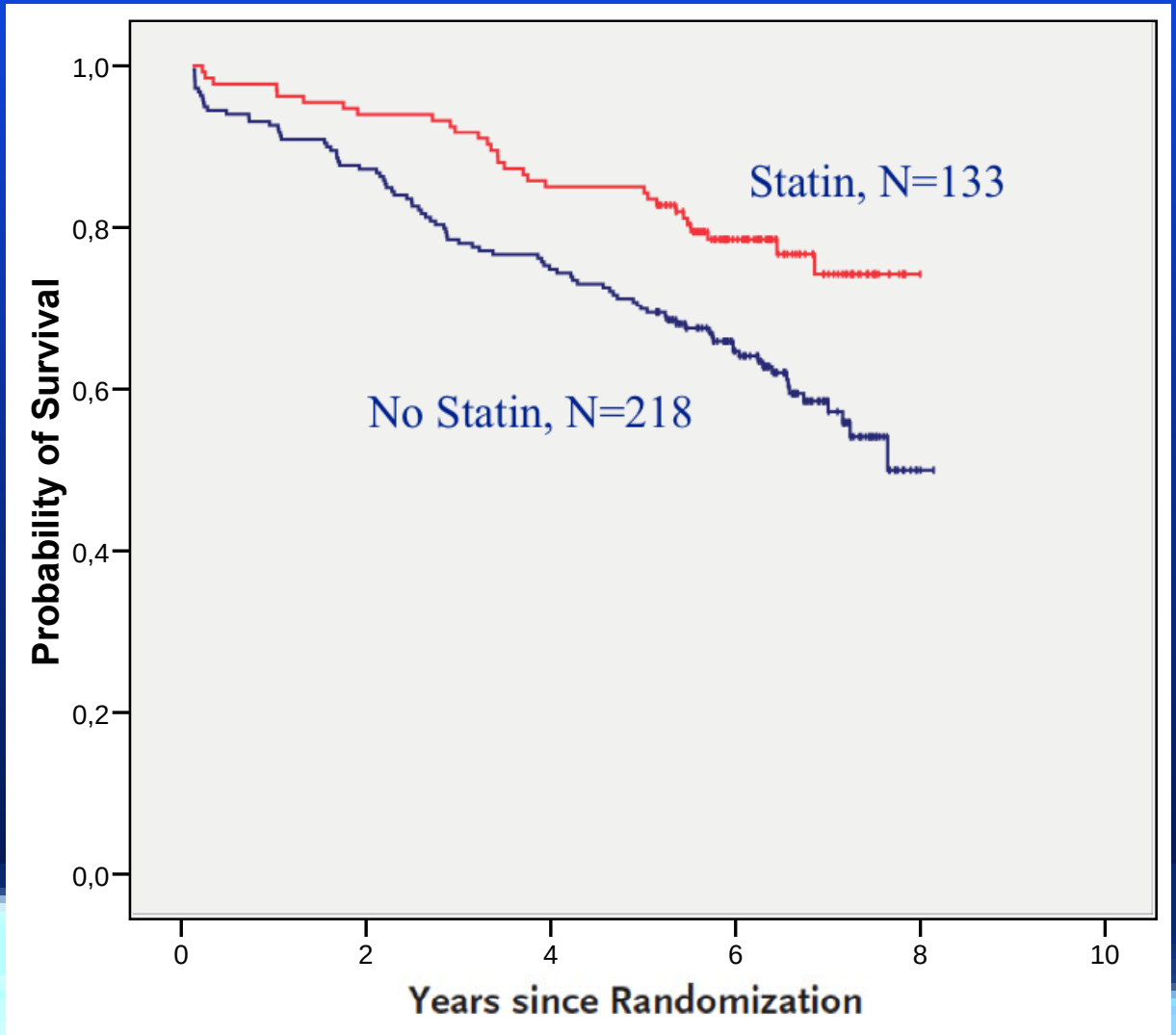
Overall Survival

- by Tobacco Use -

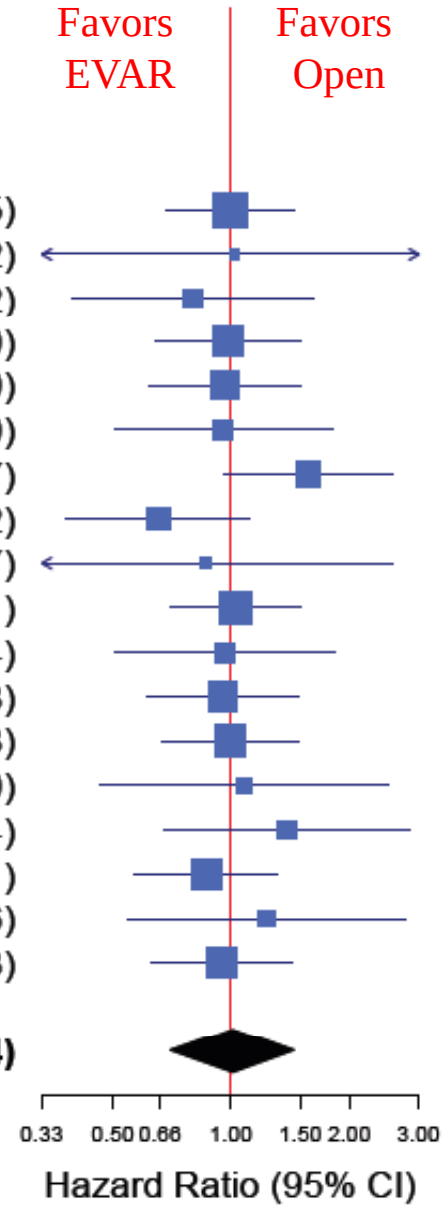


Overall Survival

- by Statin Use -



Variable	Subgroup	Pat (N)	Dth (N)	HR (95% CI)
Gender	male	322	109	0.99 (0.68-1.45)
	female	29	9	1.02 (0.27-3.82)
Age	<70	177	32	0.80 (0.40-1.62)
	>70	174	86	0.98 (0.64-1.50)
Tobacco	yes	209	79	0.97 (0.62-1.50)
	no	142	39	0.95 (0.50-1.80)
Cardiac dis	yes	154	64	1.57 (0.96-2.57)
	no	197	54	0.65 (0.38-1.12)
Renal dis	yes	28	13	0.86 (0.29-2.57)
	no	323	105	1.03 (0.70-1.51)
Pulmonary dis	yes	81	38	0.96 (0.51-1.84)
	no	270	80	0.95 (0.61-1.48)
AAA size	<70mm	300	96	0.99 (0.66-1.48)
	>70mm	51	22	1.08 (0.46-2.50)
Statin use	yes	133	30	1.39 (0.68-2.84)
	no	218	88	0.86 (0.59-1.31)
Reintervention	yes	78	26	1.23 (0.55-2.76)
	no	273	92	0.95 (0.63-1.43)
OVERALL		**351**	**118**	**1.01 (0.70-1.44)**



Short term benefit of EVAR over OR (3 RCT)

Can this be offset by any of the folllowing longterm outcomes ?

Lower operative mortality for EVAR

No incisional hernia after EVAR

Overall survival similar

QOL and SD similar

Higher reintervention rate for EVAR

Higher costs for EVAR

Conclusions

Six years after randomization:

- **There are no long-term survival benefits of EVAR**
- **This is due to a –mostly cardiovascular- "catch-up" mortality in the first two years after EVAR**
- **There is a higher rate of –mostly endovascular- secondary interventions after EVAR**
- **The sharp increase of reinterventions 4 years after EVAR is alarming but requires confirmation from other long-term studies**
- **Typical risk factors explain long-term mortality, further analysis is required**

DREAM Trial Centers

NETHERLANDS:

- *Catharina Hospital Eindhoven*
  – J Buth, AV Tielbeek
- *University Medical Center Utrecht*
  – JD Blankensteijn
- *Academic Medical Center Amsterdam*
  – R Balm, JA Reekers
- *Erasmus Medical Center Rotterdam*
  – MRHM van Sambeek, P Pattynama
- *University Hospital Groningen*
  – ELG Verhoeven, T. Prins
- *St. Franciscus Gasthuis Rotterdam*
  – AC van der Ham, JJIM van der Velden
- *Rijnstate Hospital Arnhem*
  – SMM van Sterkenburg, GB ten Haken
- *Leyenburg Hospital 's Gravenhage*
  – CMA Bruijninckx, H van Overhagen
- *Albert Schweitzer Hospital Dordrecht*
  – RP Tutein Nolthenius, TR Hendriksz
- *Atrium Medical Center Heerlen*
  – JAW Teijink, HF Odink
- *MC Rijnmond Zuid Rotterdam*
  – AAEA de Smet, D Vroegindeweij
- *Jeroen Bosch Hospital den Bosch*
  – RMM van Loenhout, MJ Rutten
- *St. Elisabeth Hospital Tilburg*
  – *JF Hamming, LEH Lampmann*
- *Maxima Medical Center Veldhoven*
  – *MHM Bender, H Pasmans*
- *OLVG, Amsterdam*
  – *AC Vahl, C de Vries*
- *Meander Medical Center Amersfoort*
  – *AJC Mackaay*
- *Vlietland Hospital Schiedam*
  – *LMC van Dortmont*
- *University Medical Center Nijmegen*
  – *D van der Vliet; L Schultze Kool*
- *Martini Hospital Groningen*
  – *JHB Boomsma, HR van Dop*
- *MC Haaglanden 's Gravenhage*
  – *JCA de Mol van Otterloo, TPW de Rooij*
- *Hospital Bernhoven Oss – TM Smits*
- *Oosterschelde Hospital Goes – EN Yilmaz*
- *VU Medical Center Amsterdam*
  – *W Wisselink, FG van den Berg*
- *Leiden University Medical Center*
  – *MJT Visser, E van der Linden)*
- *University Medical Center Maastricht*
  – *GWH Schurink, M. de Haan*
- *Bronovo Hospital den Haag – HJ Smeets*

BELGIUM:

St Jozef Hospital Turnhout
– P Stabel

St. Trudo Hospital St. Truiden
– F van Elst

University Hospital Antwerpen
– J Poniewierski

University Medical Center Gent
– FEG Vermassen

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