Danish Registers

Christian Torp-Pedersen
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Controls trials versus observational studies

- For a controlled trial the number of patients, data definitions, follow up, endpoint are specified clearly in advance
- For an observational study the power is (always) too high or too low. The quality of data and therefore many definitions need to be derived as part of the study

Influence of Gender on Short- and Long-Term Mortality After Acute Myocardial Infarction

Lars Køber, MD, Christian Torp-Pedersen, MD, Michael Ottesen, MD, Susanne Rasmussen, MD, Mads Lessing, MD, and Knud Skagen, MD, on behalf of the TRACE study group

The aim of this study was to assess differences in short- and long-term mortality between male and female patients with acute myocardial infarction (AMI). The study population consisted of 6,676 consecutive patients admitted alive with an enzyme-confirmed AMI to 27 Danish hospitals from 1990 to 1992. Five patients were excluded because of missing information. Female patients (n = 2,170) were on average 5 years older than male patients (n = 4,501, p <0.001), had lower body mass index, and more often had diabetes, hypertension, and congestive heart failure. Left ventricular systolic function was the same for men and women. Women received thrombolytic therapy less often. The 1-year mortality for female patients was 28 ± 1% and for men 21 ± 1% (p <0.001). The unadjusted risk ratio associated with male gender in a proportional-hazards model was 0.76 (95% confidence intervals [CI] 0.70 to 0.83). Adjustment for age removed the importance of gender, and the risk ratio associated with male gender was 1.06 (95% CI 0.97 to 1.2, p = 0.2). An introduction of further variables in the model did not change this. Subdividing mortality into 6-day, 30-day, and late mortality demonstrated a significantly increased mortality in women in the short-term (6 and 30 days), with a risk ratio in men of 0.58 (95% CI 0.42 to 0.81) and 0.80 (95% CI 0.65 to 0.99), respectively. From day 30 onward there was an increased mortality in men with a risk ratio of 1.16 (95% CI 1.03 to 1.31, p = 0.01). Thus, women admitted alive to the hospital with an AMI have an increased long-term mortality that is explained by their older age. However, short-term mortality in women seems to increase independently of other risk factors, but is later followed by an increase in mortality in men.

(Am J Cardiol 1996;77:1052–1056)

A substantial number of studies have demonstrated ... to 27 Danish coronary care units were registered and

TABLE 1 Patient Characteristics

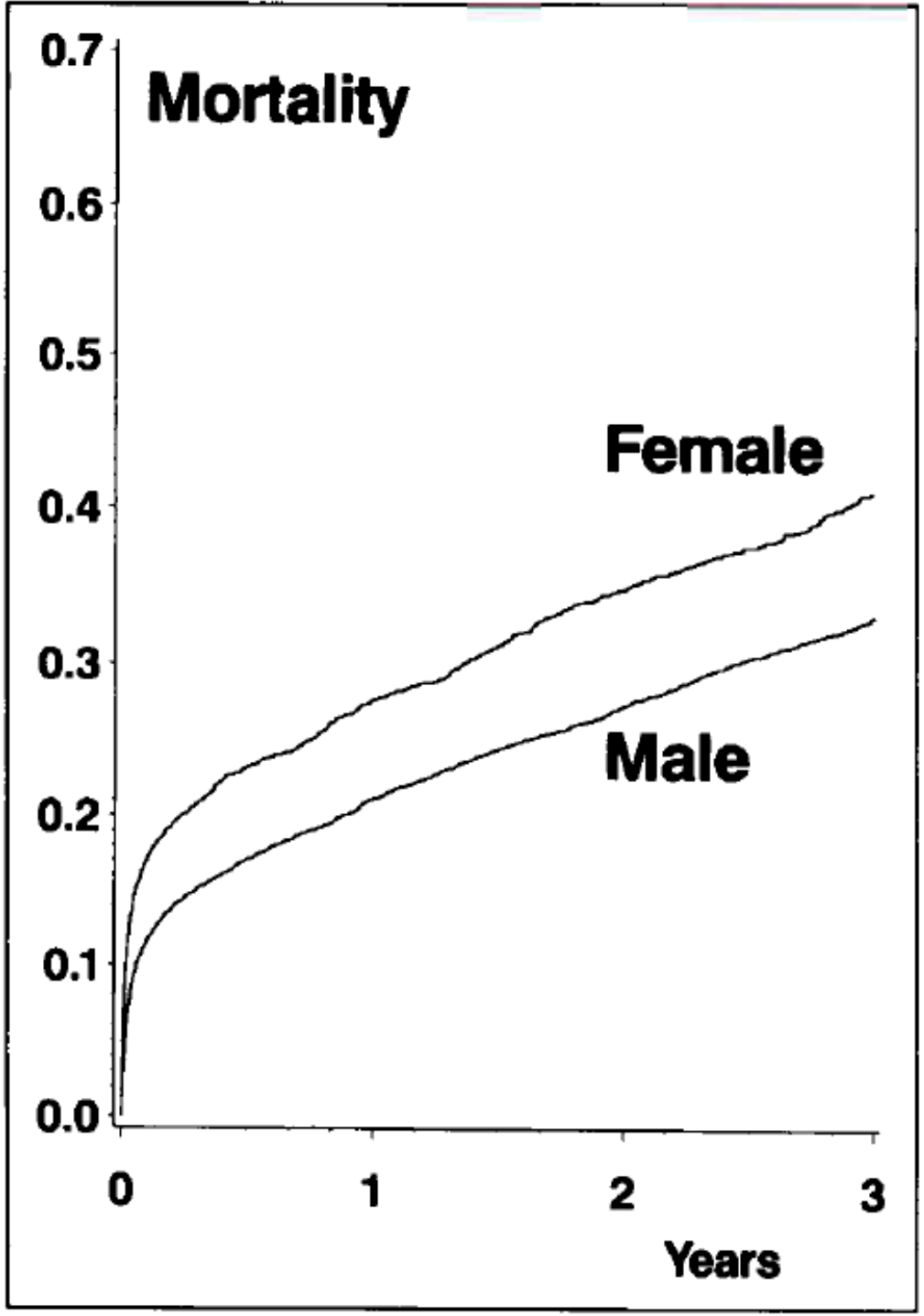
Parameter	Women (n = 2,170)	Men (n = 4,501)	p Value
Age (yr)	72 (51–86)	67 (45–82)	<0.001
Body mass index	25 (18–33)	26 (21–32)	<0.001
Wall motion index	1.4 (0.8–2)	1.4 (0.7–2)	0.08
Creatinine (μmol/L)	91	102	<0.001
Max. CKB/CK-MB	49 (13–227)	53 (14–226)	0.003
Current smoker	44%	55%	<0.001
Angina	38%	36%	0.39
Previous AMI	19%	25%	<0.001
Diabetes mellitus	14%	9.3%	<0.001
Systemic hypertension (history)	28%	20%	<0.001
Electrocardiogram			0.13
Normal	12%	13%	
Non–Q-wave AMI	21%	20%	
Anterior Q-wave AMI	26%	26%	
Inferior Q-wave AMI	29%	32%	
Initial symptoms			0.001
Chest pain	65%	69%	
Dyspnea	6%	5%	
Dyspnea and chest pain	21%	20%	
Other symptoms	7%	5%	
Congestive heart failure	60%	50%	<0.001
Ventricular fibrillation	7.3%	7.1%	0.12
Delay from symptom to hospitalization	3.5 (0–48)	2.8 (0–38)	<0.001
Thrombolytic therapy	34%	44%	<0.001

AMI = acute myocardial infarction; CK = creatinine kinase.

TABLE II Selected Baseline Characteristics Subgrouped by Age

Variables	Age (yr)	Women	Men	p Value
Congestive heart failure	≤55	27%	24%	0.50
	55.1–65	49%	41%	0.007
	65.1–75	58%	58%	0.92
	>75	74%	73%	0.61
Diabetes mellitus	≤55	11%	5.7%	0.008
	55.1–65	11%	9%	0.39
	65.1–75	15%	10%	0.003
	>75	15%	11%	0.03
History of systemic hypertension	≤55	22%	14%	0.004
	55.1–65	28%	21%	0.003
	65.1–75	29%	24%	0.007
	>75	28%	19%	<0.001
Previous AMI	≤55	8%	17%	0.003
	55.1–65	14%	24%	<0.001
	65.1–75	21%	29%	<0.001
	>75	22%	29%	0.001
Current smoker	≤55	82%	76%	0.14
	55.1–65	68%	64%	0.10
	65.1–75	48%	49%	0.69
	>75	24%	34%	<0.001
Thrombolytic therapy	≤55	50%	55%	0.31
	55.1–65	56%	52%	0.20
	65.1–75	37%	45%	<0.001
	>75	19%	24%	0.03

AMI = acute myocardial infarction.


Mortality
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
Female
Male
0
1
2
3
Years

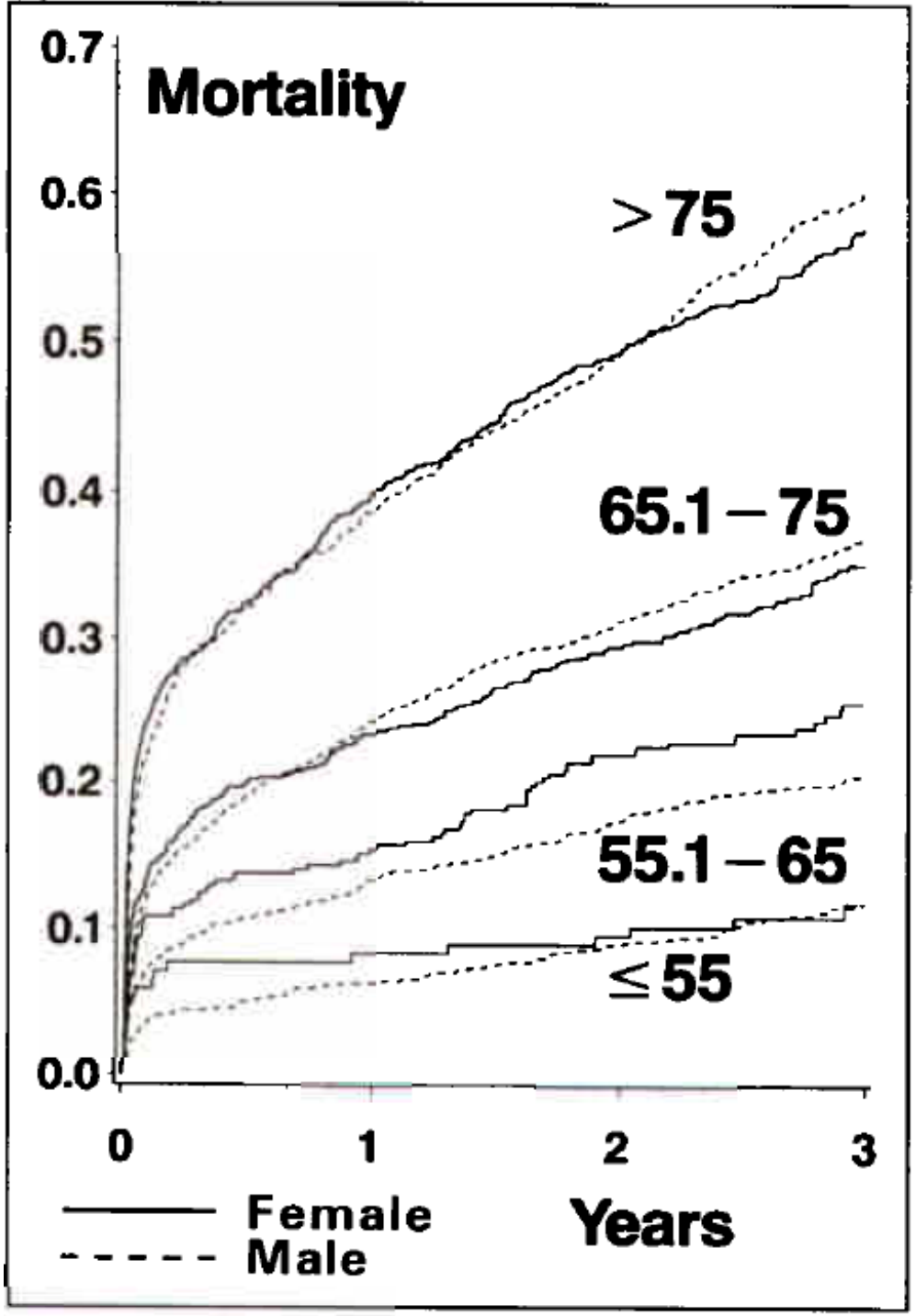

Mortality
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
> 75
65.1 – 75
55.1 – 65
≤ 55
0
1
2
3
Years
Female
Male

TABLE III Three Proportional-Hazards Models of Total Survival with Stepwise Addition of Variables

Variables	p Value	Risk Ratio	95% CI
	Model 1		
Male gender	<0.001	0.76	0.70–0.83
	Model 2		
Male gender	0.20	1.06	0.97–1.15
Age	<0.001	1.07	1.06–1.07
	Model 3		
Male gender	0.75	1.06	0.96–1.17
Body mass index	0.07	0.99	0.98–1.0
Previous AMI	0.77	1.0	0.9–1.1
Angina pectoris	0.001	1.2	1.1–1.3
Creatinine	<0.001	1.002	1.002–1.003
Congestive heart failure	<0.001	2.3	2.0–2.6
Diabetes mellitus	<0.001	1.3	1.1–1.4
Age	<0.001	1.04	1.04–1.05
Wall motion index	<0.001	2.5	2.3–2.8
Systemic hypertension	0.006	1.2	1.1–1.3
Thrombolytic therapy	<0.001	0.7	0.6–0.8

AMI = acute myocardial infarction; CI = confidence interval.

Increased risk of *Staphylococcus aureus* bacteremia in hemodialysis—A nationwide study

Mavish S. CHAUDRY,[3] Gunnar H. GISLASON,[3,11] Anne-Lise KAMPER,[1] Marianne RIX,[1] Anders R. LARSEN,[5] Andreas PETERSEN,[5] Paal S. ANDERSEN,[5,4] Robert L. SKOV,[5] Emil L. FOSBØL,[2] Henrik WESTH,[6] Henrik C. SCHØNHEYDER,[7,10] Thomas L. BENFIELD,[6] Vance G. FOWLER Jr,[12] Christian TORP-PEDERSEN,[8,9] Niels E. BRUUN[3,10]

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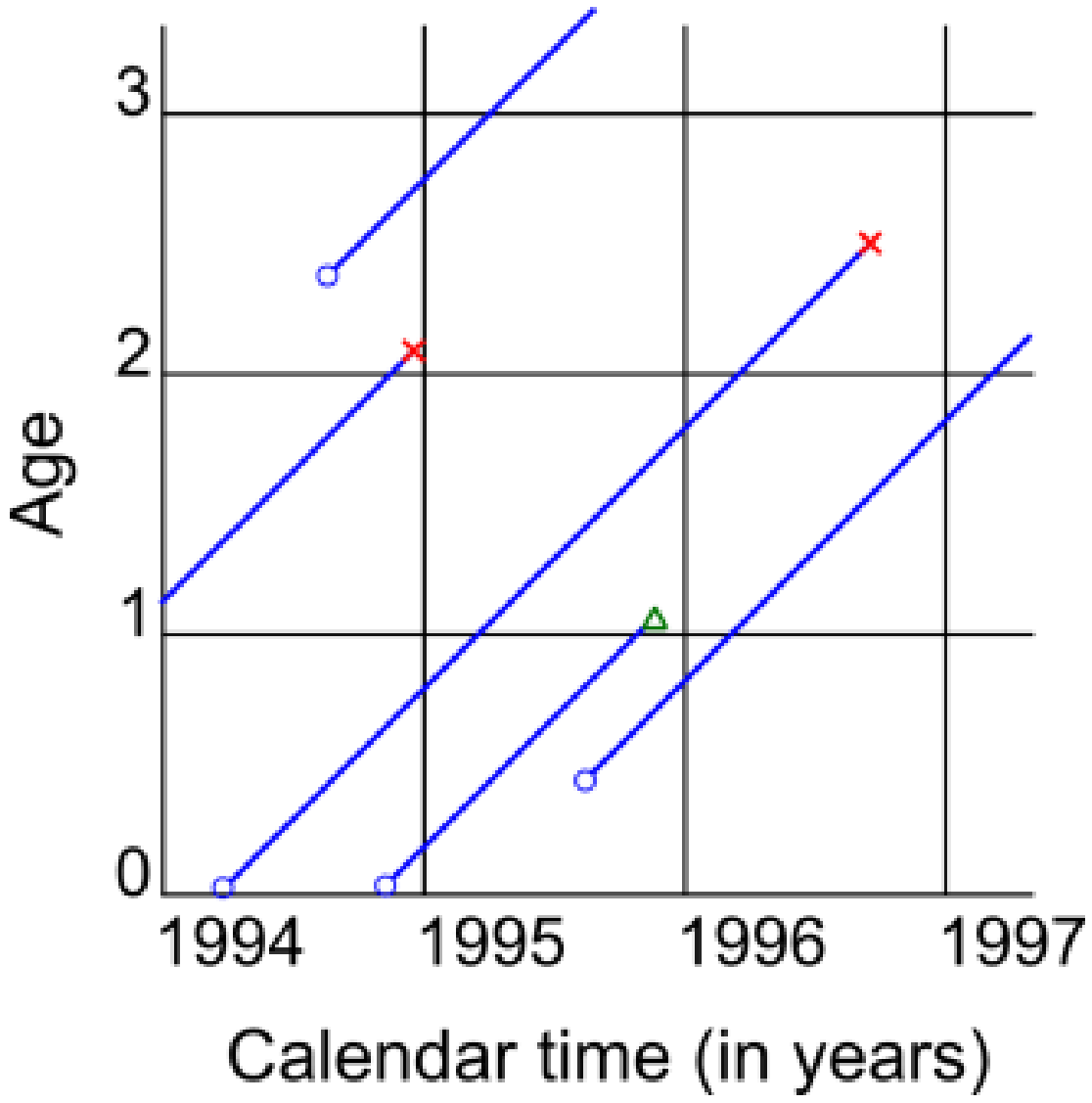
Table 1 Characteristics of study population at baseline

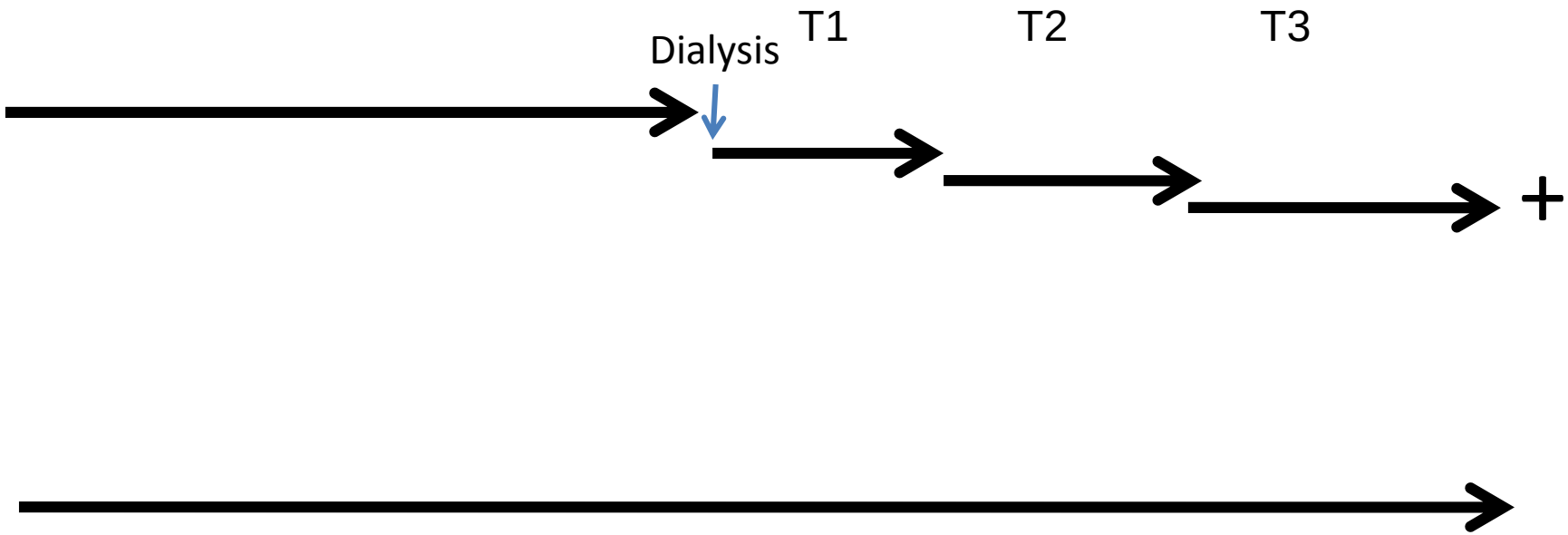
Characteristics	Hemodialysis	Peritoneal dialysis	Kidney transplant (preemptive)	Total (N%)
Total (N%)	6826 (68)	2882 (29)	289 (3)	9997 (100)
Age (years)[a]	65 ± 15	59 ± 15	41 ± 16	62.3 ± 16
		Preexisting heart valve disease		
Aortic valve	285 (4)	111 (3.6)	5 (2)	401 (4)
Mitral valve	172 (2.5)	56 (2)	6 (2)	234 (2.3)
		Comorbidity		
Myocardial infarction	621 (9)	185 (7)	4 (1.4)	810 (8)
Diabetes with complication	1924 (29)	759 (27)	47 (17)	2730 (28)
Diabetes	2133 (31)	818 (29)	48 (17)	2999 (31)
Chronic obstructive lung disease	518 (8)	120 (4)	<4	639 (7)
Peripheral vascular disease	791 (12)	189 (7)	<4	982 (10)
Liver disease	175 (2.5)	35 (1.2)	<4	212 (2.1)
Ischemic heart disease	1476 (22)	496 (18)	15 (5)	1987 (20)
Cardiac arrhythmia disorder	883 (13)	215 (8)	8 (3)	1106 (11)
Previous atrial fibrillation/flutter	746 (11)	174 (6)	5 (2)	925 (9)
Chronic heart failure	1185 (18)	316 (11)	< 4	1503 (15)
		Etiology of kidney disease		
Diabetes mellitus	1663 (24)	713 (24)	44 (15)	2420 (24)
Chronic glomerulonephritis	523 (8)	383 (13)	66 (23)	1024 (10)
Vascular and hypertensive nephropathy	855 (13)	365 (13)	15 (5)	1235 (12)
Polycystic kidney disease	386 (6)	253 (9)	46 (16)	685 (7)
Chronic tubulointerstitial nephropathy	340 (5)	115 (4)	17 (6)	472 (5)
Other	1254 (18)	369 (13)	55 (19)	1678 (17)
Unknown	1805 (26)	684 (25)	46 (16)	2535 (25)

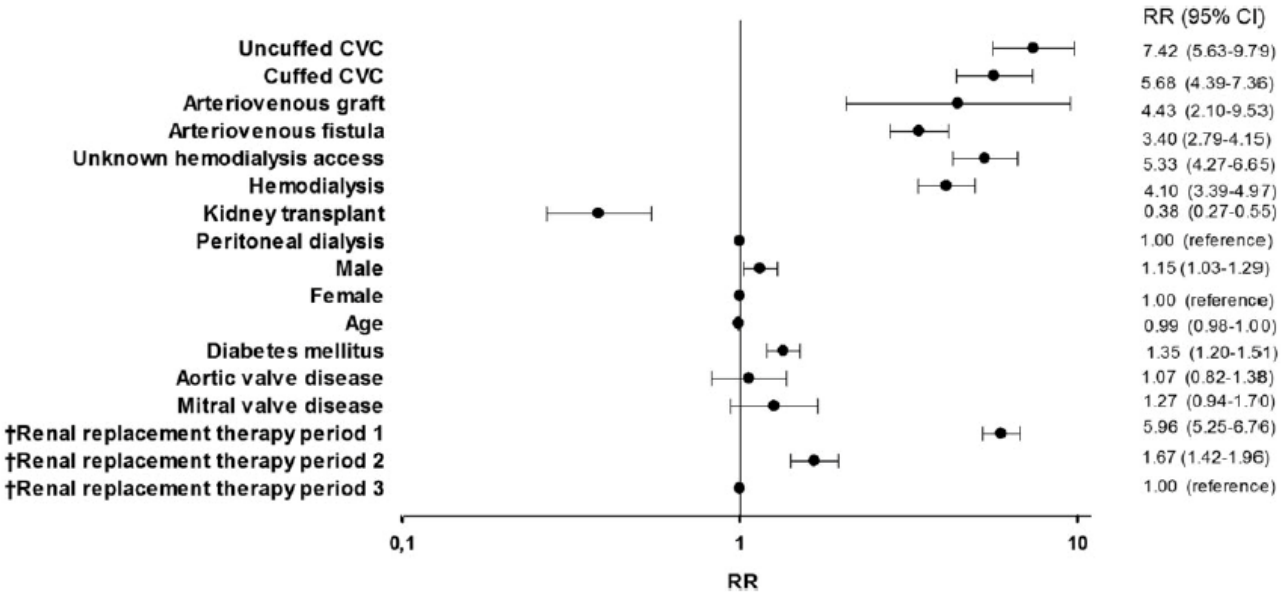
[a]Values are given as mean, +/− SD or N (%)

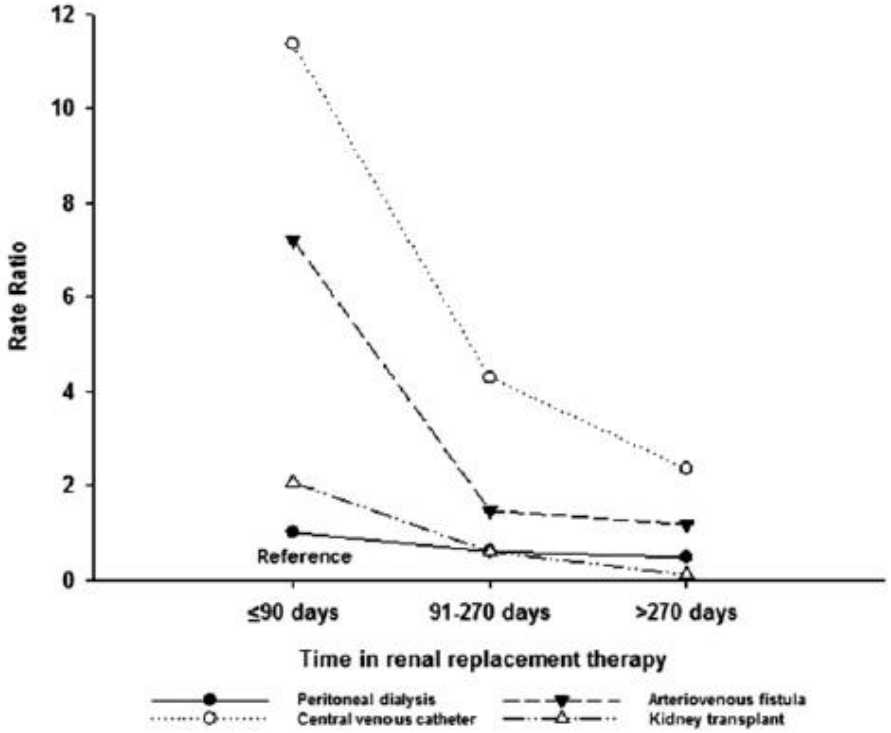
Lexis diagram



Splitting!




RR (95% CI)
Uncuffed CVC
Cuffed CVC
Arteriovenous graft
Arteriovenous fistula
Unknown hemodialysis access
Hemodialysis
Kidney transplant
Peritoneal dialysis
Male
Female
Age
Diabetes mellitus
Aortic valve disease
Mitral valve disease
†Renal replacement therapy period 1
†Renal replacement therapy period 2
†Renal replacement therapy period 3
7.42 (5.63-9.79)
5.68 (4.39-7.36)
4.43 (2.10-9.53)
3.40 (2.79-4.15)
5.33 (4.27-6.65)
4.10 (3.39-4.97)
0.38 (0.27-0.55)
1.00 (reference)
1.15 (1.03-1.29)
1.00 (reference)
0.99 (0.98-1.00)
1.35 (1.20-1.51)
1.07 (0.82-1.38)
1.27 (0.94-1.70)
5.96 (5.25-6.76)
1.67 (1.42-1.96)
1.00 (reference)
0,1
1
10
RR


Rate Ratio
12
10
8
6
4
2
0
Reference
≤90 days
91-270 days
>270 days
Time in renal replacement therapy
Peritoneal dialysis
Central venous catheter
Arteriovenous fistula
Kidney transplant

Ambulatory Blood Pressure and Mortality
A Population-Based Study

Tine Willum Hansen, Jørgen Jeppesen, Susanne Rasmussen, Hans Ibsen, Christian Torp-Pedersen

Abstract—The relationship between ambulatory blood pressure and mortality in a general Western population is unknown. Therefore, we conducted this prospective study of a random sample of 1700 Danish men and women, aged 41 to 72 years, without major cardiovascular diseases. At baseline, ambulatory blood pressure, office blood pressure, and other risk factors were recorded. After a mean period of 9.5 years, 174 had died: 63 were cardiovascular deaths. In multivariate proportional hazards models, adjusted for other risk factors of significance, the relative risk of cardiovascular mortality (95% confidence interval) associated with 10 mm Hg increments in systolic and 5 mm Hg increments in diastolic ambulatory blood pressure were 1.51 (1.28 to 1.77) and 1.43 (1.26 to 1.61). The corresponding figures for all cause mortality were 1.18 (1.06 to 1.31) and 1.18 (1.09 to 1.28). The relative risks of cardiovascular mortality were lower for office blood pressure, and office blood pressure did not predict all cause mortality. When ambulatory and office blood pressures were entered in the same multivariate models, only the ambulatory blood pressures were significant predictors of all cause mortality and cardiovascular mortality. The relationship between ambulatory blood pressures and risk of mortality was log-linear, with no indication of a threshold. The absolute risk of mortality was also dependent on age and smoking status, and an upper "acceptable" ambulatory blood pressure based on risk of mortality could only be defined when other risk factors were taken into account. In conclusion, ambulatory blood pressure provided prognostic information on mortality above and beyond that of office blood pressure. (***Hypertension***. **2005;45:1-6.**)

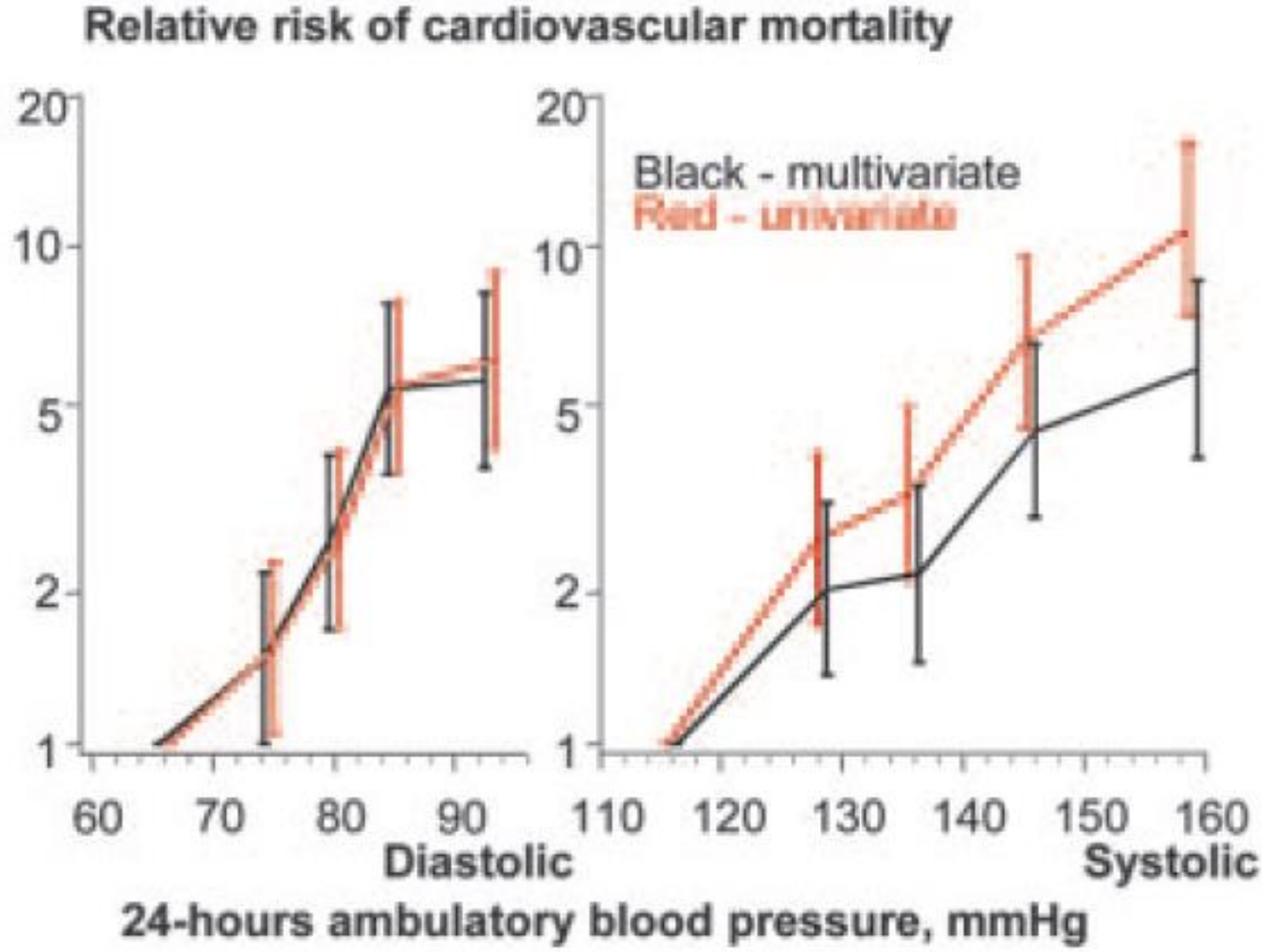

Relative risk of cardiovascular mortality
20
10
5
2
1
60
70
80
90
Diastolic
20
10
5
2
1
110
120
130
140
150
160
Systolic
Black - multivariate
Red - univariate
24-hours ambulatory blood pressure, mmHg

TABLE 2. Relative Risks (95% Confidence Interval) Per 10-mm Hg Increase in Systolic Blood Pressure and Per 5-mm Hg Increase in Diastolic Blood Pressure for All-Cause Mortality

Variables	Univariate	Adjusted
Ambulatory blood pressure		
Systolic 24-h	1.39 (1.26–1.54)‡	1.18 (1.06–1.31)†
Systolic daytime	1.36 (1.23–1.50)‡	1.15 (1.04–1.28)†
Systolic nighttime	1.36 (1.24–1.49)‡	1.19 (1.08–1.30)†
Diastolic 24-h	1.18 (1.09–1.28)‡	1.18 (1.09–1.28)‡
Diastolic daytime	1.16 (1.08–1.25)‡	1.16 (1.08–1.26)‡
Diastolic nighttime	1.18 (1.10–1.27)‡	1.16 (1.08–1.25)‡
Office blood pressure		
Systolic	1.24 (1.15–1.33)‡	1.05 (0.96–1.14)
Diastolic	1.08 (1.01–1.16)*	1.06 (0.99–1.14)

In multivariate analysis adjusted for age, smoking status, alcohol consumption, and physical activity.

*$P<0.05$.

†$P<0.01$.

‡$P<0.0001$.

European Heart Journal (2017) **0**, 1–9
doi:10.1093/eurheartj/ehx464

CLINICAL RESEARCH
Hypertension

Office blood pressure or ambulatory blood pressure for the prediction of cardiovascular events

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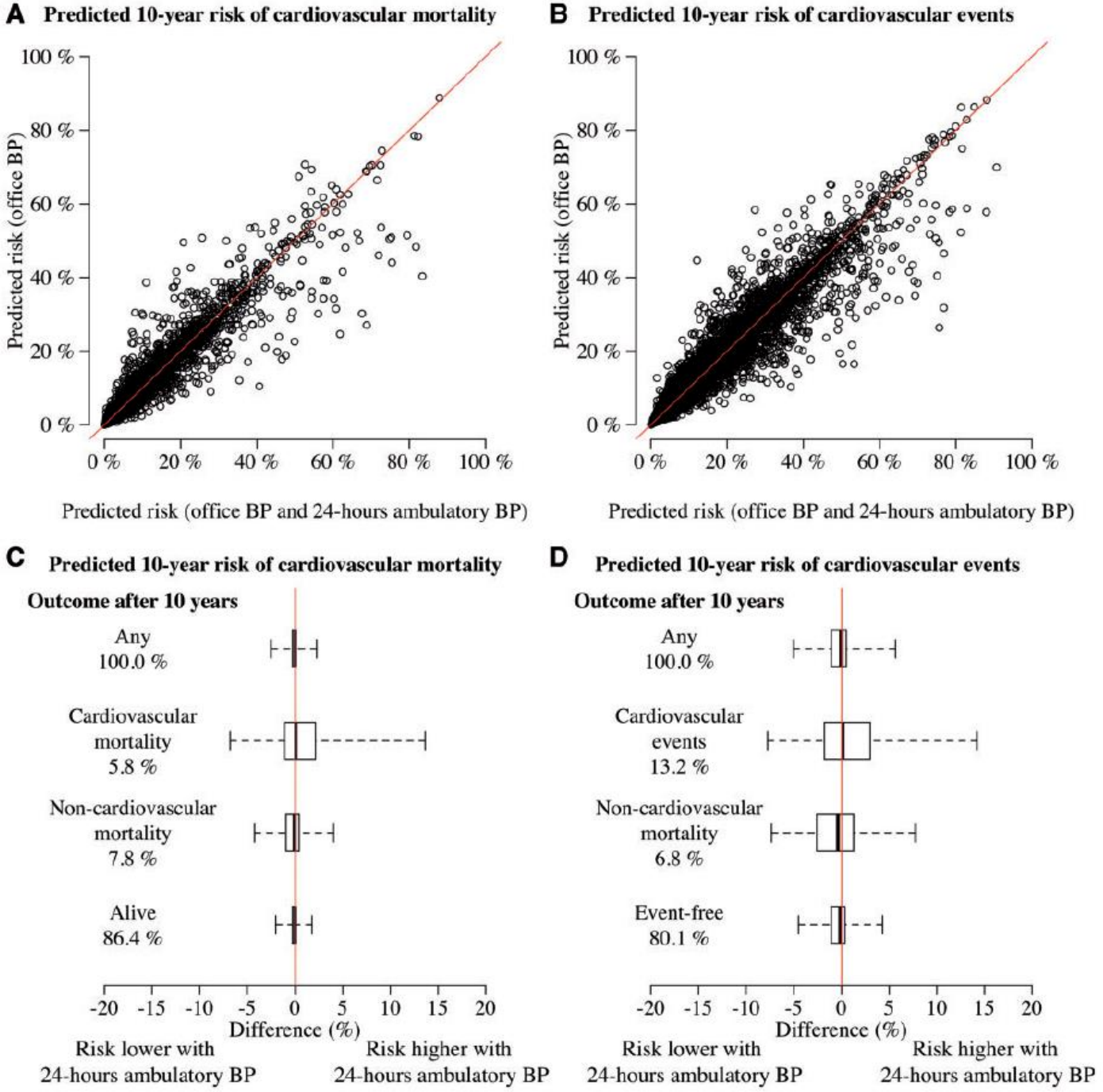
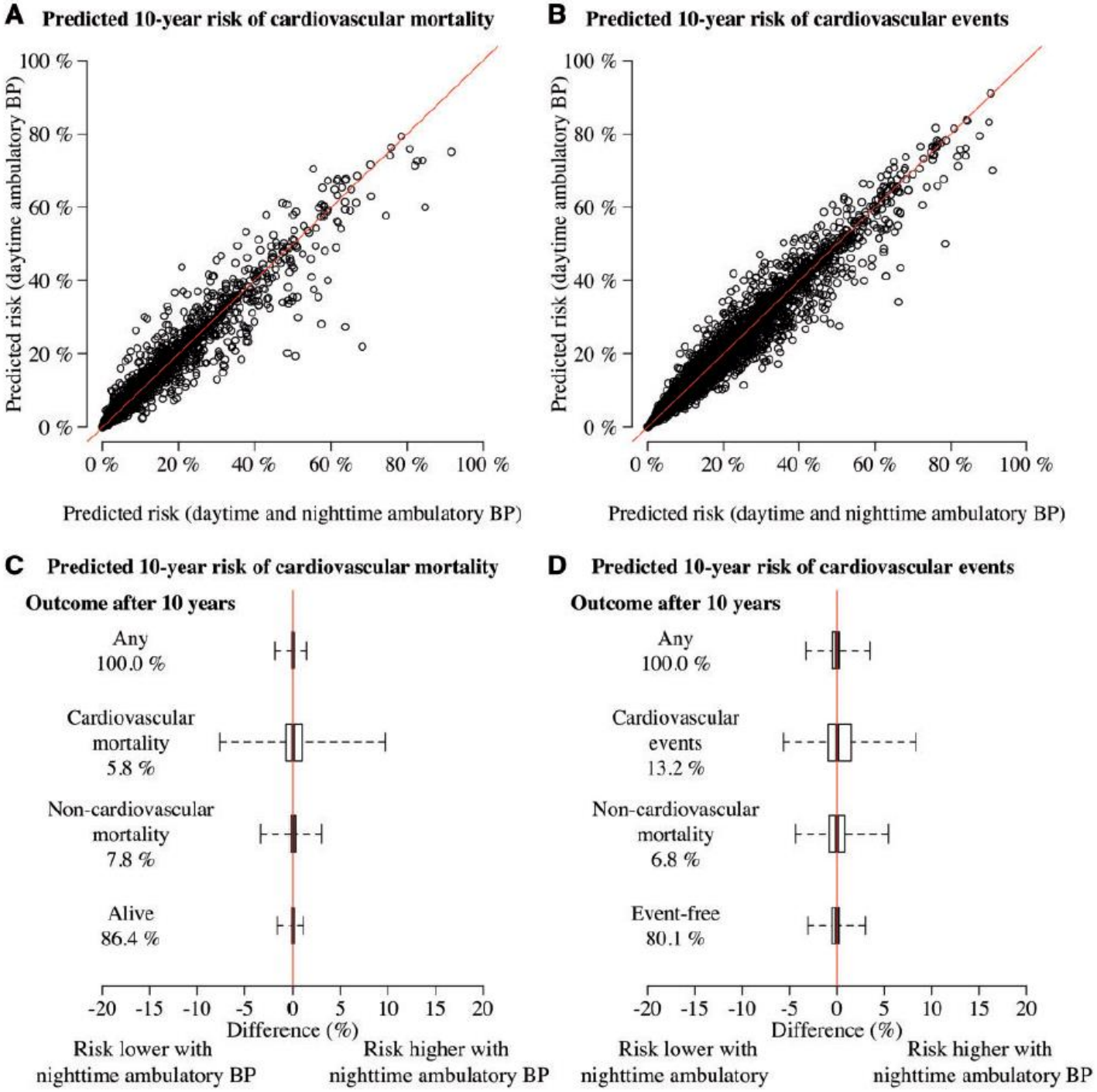

A Predicted 10-year risk of cardiovascular mortality
Predicted risk (office BP)
100 %
80 %
60 %
40 %
20 %
0 %
0 %
20 %
40 %
60 %
80 %
100 %
Predicted risk (office BP and 24-hours ambulatory BP)
B Predicted 10-year risk of cardiovascular events
Predicted risk (office BP)
Predicted risk (office BP and 24-hours ambulatory BP)
C Predicted 10-year risk of cardiovascular mortality
Outcome after 10 years
Any
100.0 %
Cardiovascular
mortality
5.8 %
Non-cardiovascular
mortality
7.8 %
Alive
86.4 %
-20 -15 -10 -5 0 5 10 15 20
Difference (%)
Risk lower with
24-hours ambulatory BP
Risk higher with
24-hours ambulatory BP
D Predicted 10-year risk of cardiovascular events
Outcome after 10 years
Any
100.0 %
Cardiovascular
events
13.2 %
Non-cardiovascular
mortality
6.8 %
Event-free
80.1 %
-20 -15 -10 -5 0 5 10 15 20
Difference (%)
Risk lower with
24-hours ambulatory BP
Risk higher with
24-hours ambulatory BP


A
Predicted 10-year risk of cardiovascular mortality
Predicted risk (daytime ambulatory BP)
100 %
80 %
60 %
40 %
20 %
0 %
0 %
20 %
40 %
60 %
80 %
100 %
Predicted risk (daytime and nighttime ambulatory BP)
B
Predicted 10-year risk of cardiovascular events
Predicted risk (daytime ambulatory BP)
Predicted risk (daytime and nighttime ambulatory BP)
C
Predicted 10-year risk of cardiovascular mortality
Outcome after 10 years
Any
100.0 %
Cardiovascular
mortality
5.8 %
Non-cardiovascular
mortality
7.8 %
Alive
86.4 %
-20 -15 -10 -5 0 5 10 15 20
Difference (%)
Risk lower with
nighttime ambulatory BP
Risk higher with
nighttime ambulatory BP
D
Predicted 10-year risk of cardiovascular events
Outcome after 10 years
Any
100.0 %
Cardiovascular
events
13.2 %
Non-cardiovascular
mortality
6.8 %
Event-free
80.1 %
-20 -15 -10 -5 0 5 10 15 20
Difference (%)
Risk lower with
nighttime ambulatory
Risk higher with
nighttime ambulatory BP

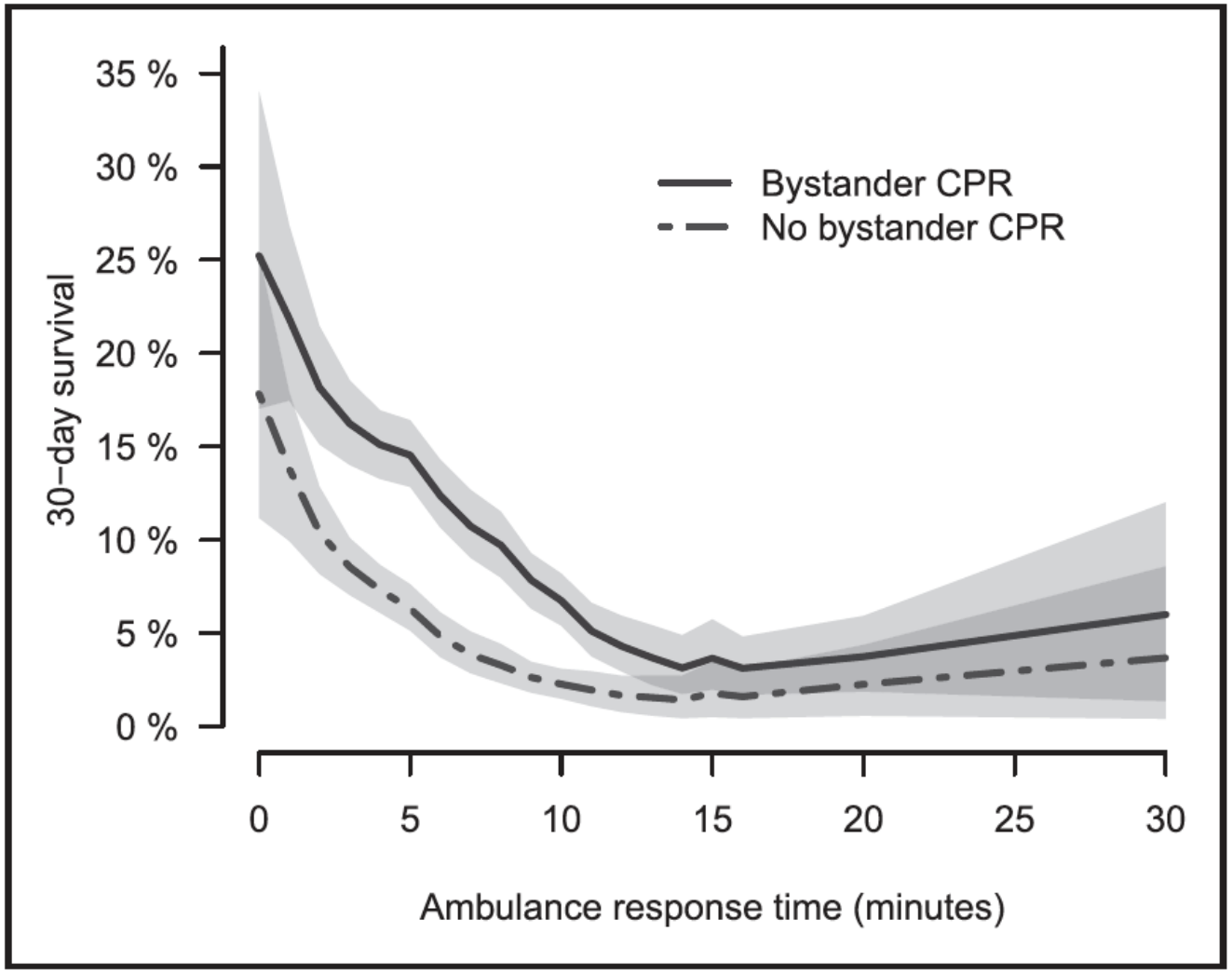
Cardiac Arrest

Survival is a fraction

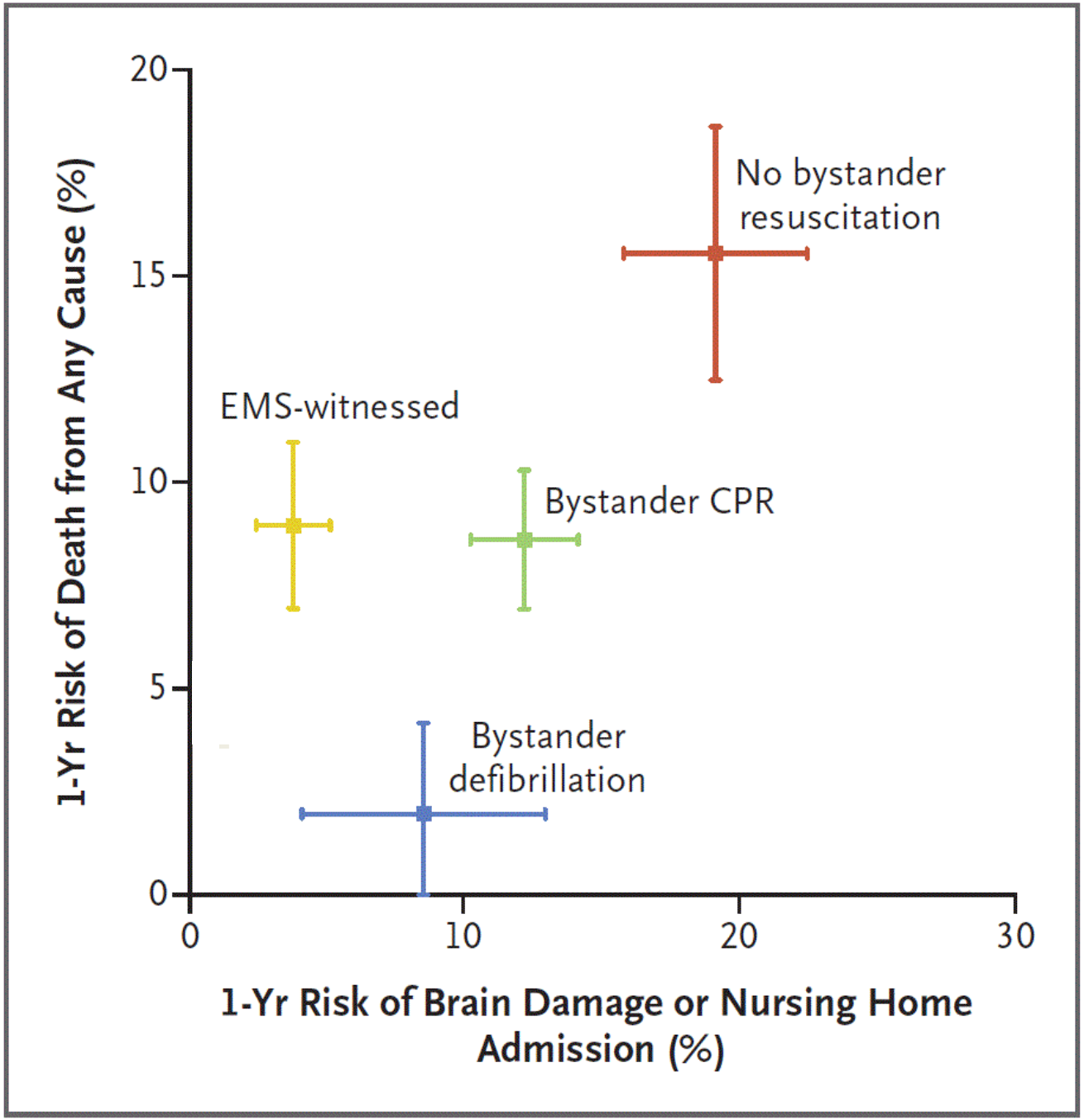
$$\frac{Number\ of\ survivors}{Total\ number\ of\ arrests}$$

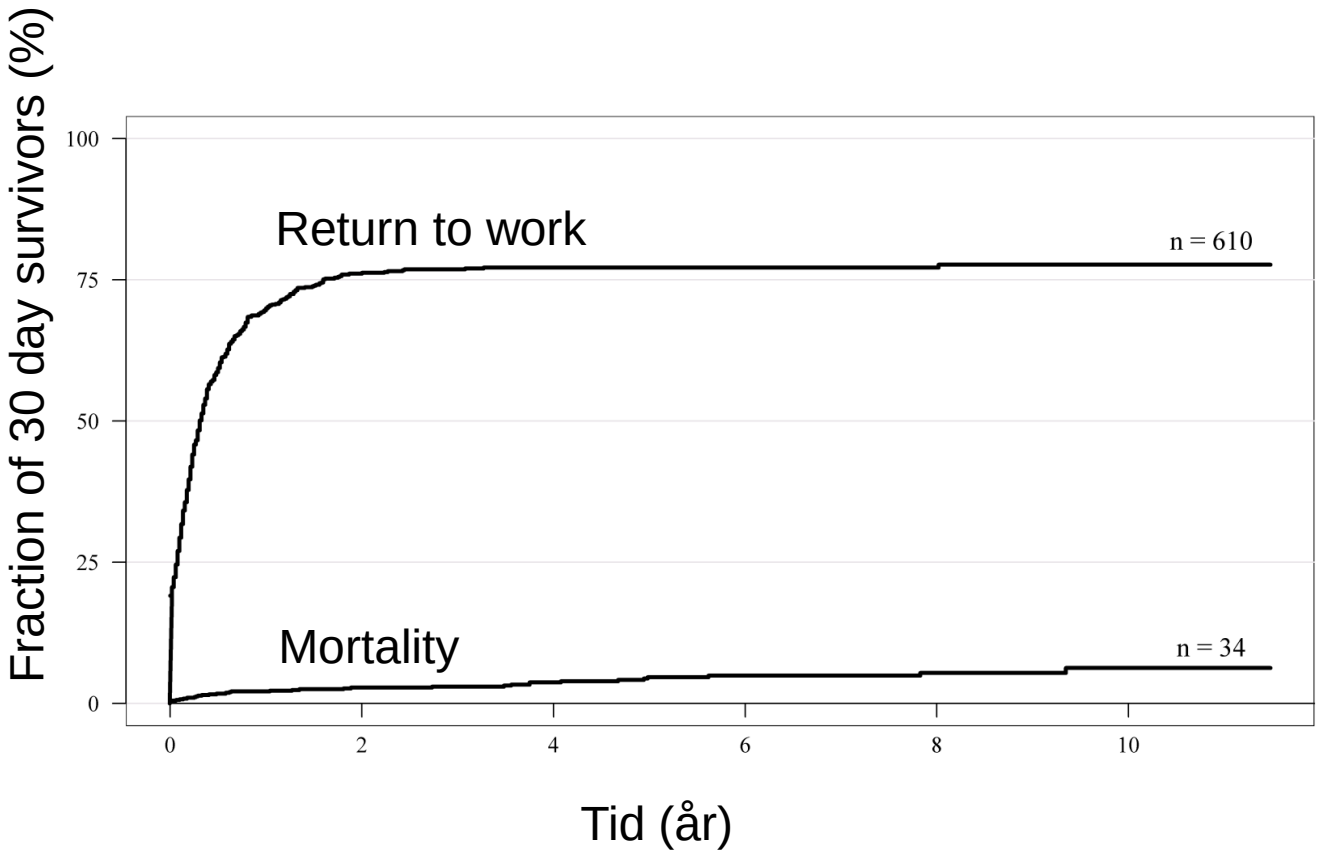
Wissenberg, JAMA, 2013

G-modelling



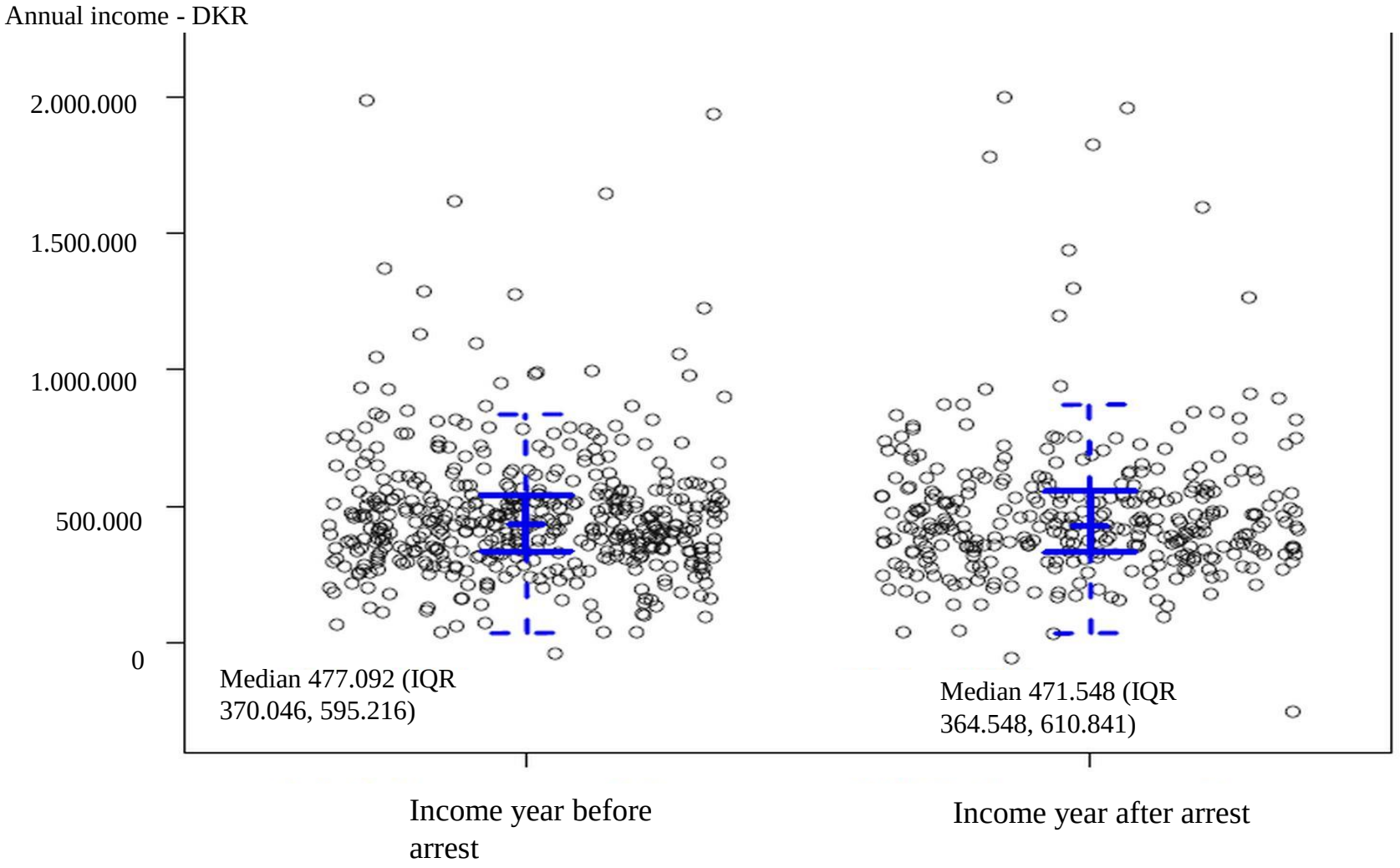
Rajan, Circulation, 2016


20
15
10
5
0
0
10
20
30
1-Yr Risk of Death from Any Cause (%)
1-Yr Risk of Brain Damage or Nursing Home Admission (%)
No bystander resuscitation
EMS-witnessed
Bystander CPR
Bystander defibrillation



Kragholm, Circulation, 2015

Income before and after arrest?



Big numbers – low precision

Protected environmen

- Danish registries can in general only be accessed in highly controlled and monitored servers in Statistics Denmark or Danish Board of Health
- Data on individuals and companies are encrypted and may not be exported
- Data can only be accessed fort important studies relevant for the population

Statistics Denmark

STATISTICS DENMARK

SEARCH

SUBJECTS

Population and elections

Living conditions

Education and knowledge

Culture and National Church

Labour, income and wealth

Prices and consumption

National accounts and government finances

Money and credit market

External economy

Business sector in general

Business sectors

Geography, environment and energy

Danish Board of Health

Forskerservice

- Forskerservice Klassisk
- Forskermaskinen
- Ansøgningsskema
- Priser
- Service
- Datasikkerhed

Forskerservice

Forskerservice under Sundhedsdatastyrelsen arbejder for at understøtte registerforskningen i Danmark. Er du forsker og har brug for data i forbindelse med din forskning, kan du via Forskerservice søge om registerdata på sundhedsområdet.

Forskerservice giver adgang til sundhedsdata på to måder. Afhængigt af dine konkrete behov kan du vælge at søge om adgang til data via Forskerservice Klassisk eller via Forskermaskinen.

Forskerservice Klassisk

Forskerservice Klassisk leverer dataudtræk, som er nøje tilpasset til det enkelte forskningsprojekt.

Forskerservice Klassisk er især relevant for forskere, der enten har behov for at koble data fra Sundhedsdatastyrelsen med andre data eller har behov for adgang til journaler og lignende.

Forskerservice Klassisk leverer data fra stort set alle Sundhedsdatastyrelsens nationale registre, dog ikke fra Lægemiddelsstatistikregisteret.

Læs mere om Forskerservice Klassisk

Kontakt

Forskerservice

Mandag - Fredag: 9.30 - 12.00

E: forskerservice@sundhedsdata.dk
T: 3268 5116

Clinical Databases

- 32 Databases
- Based on quality measurements for hospitals
- Examples
  Cardiac arrest register
  Stroke Register
  Cardiac procedure register
  Atrial fibrillation register
  Electrophysiology register
  Pacemaker/ICD register

Take home

- With trials you know what you are doing – with registers you know when you have done it.
- Analysis of observationsl data is much more flexible, challenging and uncertain than with controlled trial data.
- Most of what we know comes from observational data.