



Swedish experiences:
SCAAR, a success story

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Number of cases annually: 80 000

RIKS-HIA 73 CCU hospitals, 100%

SCAAR 30 PCI hospitals, 100%

Percutaneous valves 7 hospitals, 100%

Heart surgery 7 hospitals, 100%

Secondary prevention 65 hospitals, 85%

Cardiogenetic registry New

>300 variables (Baseline data, procedural and outcome measures)

At monitoring: 95-96% agreement between files and registry.

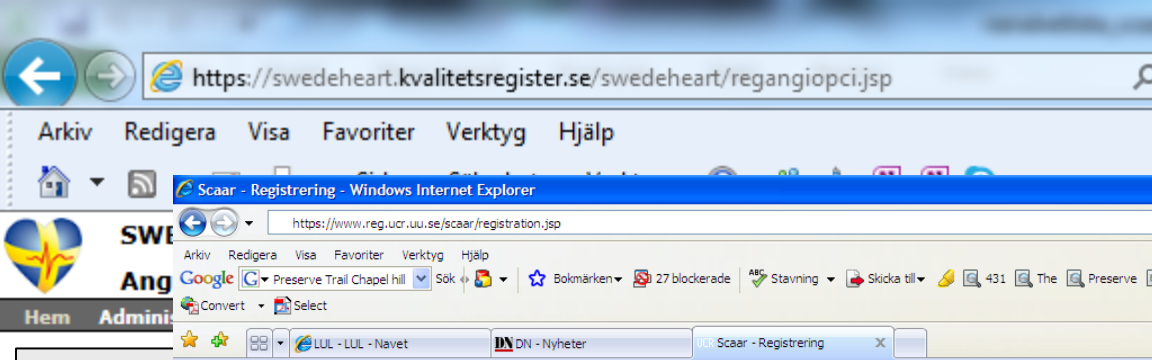


Number of cases annually: 80 000

100-200 variables per patient

- **Patients characteristics**
- **Procedural details** (lesions, stents, devices etc.)
- **Pharmacological treatment**
- **Complications**

At monitoring: 95-96% agreement between files and registry.



- Name, per
- Akut vårdked
- Händelser under
- START ok !
- Angio/PCI Avd.
- Angio+PC
- Referred fro
- Patienten kommer
- Ange vårdenhet
- Administr
- Date of proc
- Type of reg
- Office /call s
- Local hosp
- Clinical ba
- Body length
- Body length
- S-creatinine
- Creatinine c
- Prior PCI
- Prior CABG
- Diabetes
- Smoking
- Angiogra
- Behandlad hypert

Punktionsdatum och klockslag

Angiografi

Angiografiskt fynd

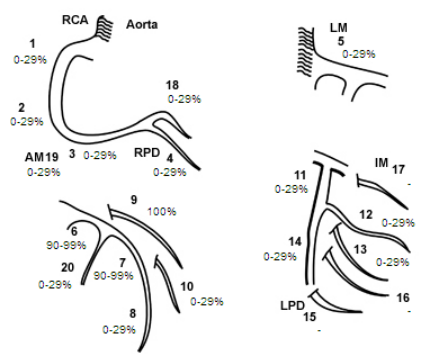
Stenos/okklusion i CABG-graft *

Stenos/okklusion i tidigare PCI-behandlat segment *

Fynd

Restenos / Okklusion

Signifikant återförträngning i tidigare behandlat kärlsegment.



Graft till Segment Stenosgrad

History is presented and all previously implanted stents have to be checked

Segment historik / Restenos

Datum	Segment	Graft	Procedur	Restenos	Oklusion
2008-05-14	6	Nej	Ballong + Stent	<input type="text" value="2 Ja"/> *	<input type="text" value="1 Nej"/> *
2008-05-14	7	Nej	Ballong + Stent	<input type="text" value="2 Ja"/> *	<input type="text" value="1 Nej"/> *

Stentnamn: BS Liberte
 diameter: 3.00
 längd: 8

Angiografi avslut

Täta restenos i bägge LAG stenten

Angio fritext för utlåtande

Primärt beslut *

Avböjd från operation *

Spara

PCI

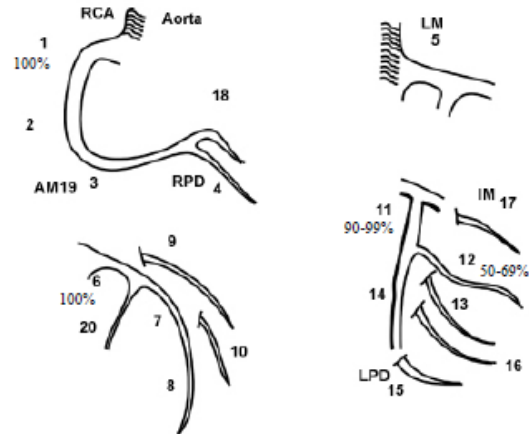
Operatör *

Behandlade segment

Utlåtande Koronarangiografi / PCI
Uppsala PCI 2012-09-20

Koronarangiografi

fynd:



Graft typ.	Till segment	Stenosgrad
Vengraft	Andra diagonal (10)	70-89%
Vengraft	Första obtusa marginal (12)	70-89%
Artärgraft	Mellersta LAD (7)	100%

Angio kommentar: Nativa vä försörjer LCx/Om men har tät stenosis. Ett delvis trombotiserat vengraft försörjer LAD, LCx och distala RCA. RCA ockluderad eller stenoserad.

Angiograför: Bo Lagerqvist

PCI

Behandlade kärlsegment:

Proximala LCx (11) Ej lyckad Ballong + Stent Abbott Xience Xpedition (DES) diam: 2.50mm längd: 18mm

Proximala LAD (6) Ej lyckad Ledarförsök

PCI kommentar: Stentar upp LCx stenoen försöker komma ut ut LAD men lyckas ej.

Annan invasiv terapi: Ingen

Övrig diagnostik vid PCI: Ingen

Antitrombotisk medicinering vid ingreppet: Heparin, Bivalirudin (Angiox)

Operatör: Bo Lagerqvist

Utlåtande Kranskärlsröntgen / PCI 2013-04-09

Kranskärlsröntgen

Du har genomgått röntgen av hjärtats kranskärl på grund av hjärtinfarkt 2013-04-09. Undersökningen visar att vänster kranskärl har 2 förträngningar samt att höger kranskärl har 1 stopp.

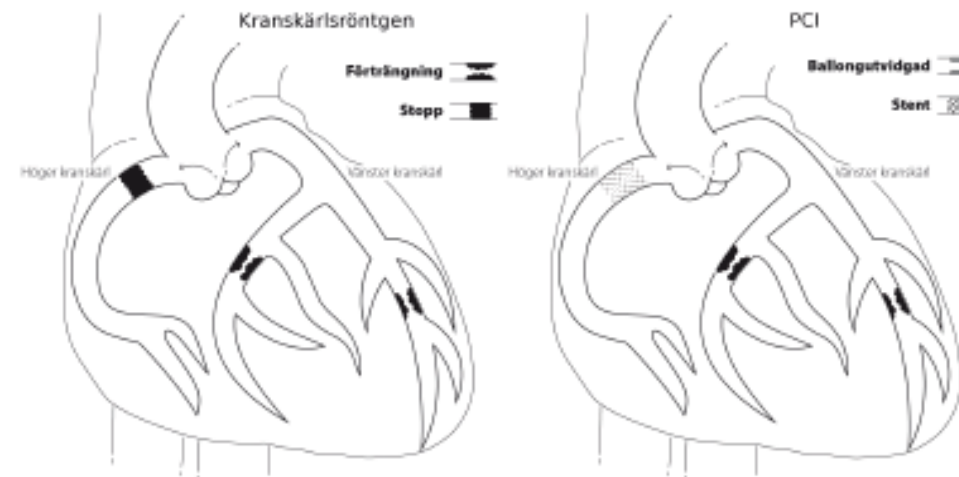
PCI (Kranskärlsvidgning)

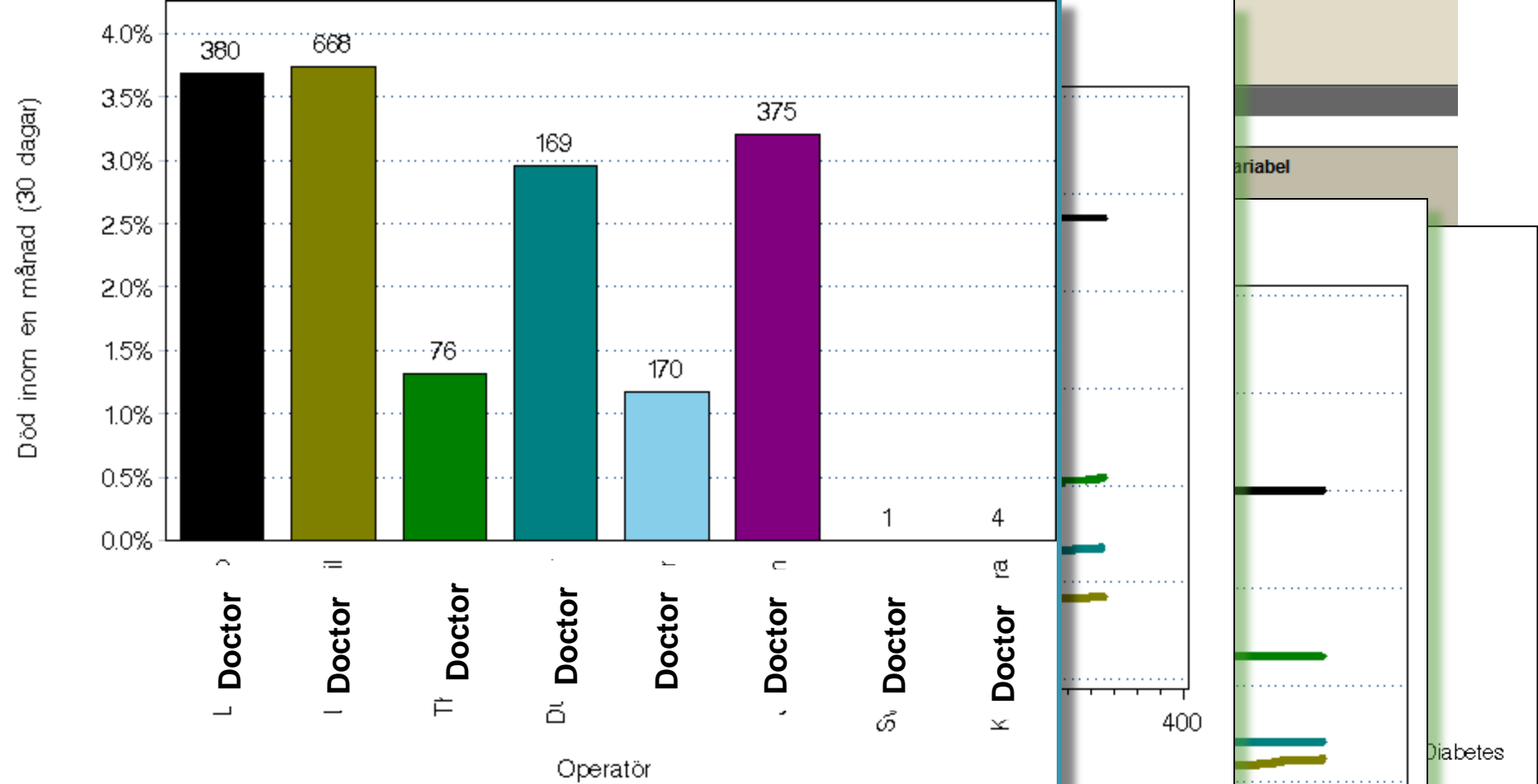
Du har 2013-04-09 genomgått anläggande av 1 stent i höger kranskärl.

Under proceduren användes en liten sug för att ta bort koagler i kranskärlen.

Under proceduren användes läkemedelsbärande stent.

Undersökningen genomfördes genom en artär i armen och stickstället förslöts med tryckförband.





Död inom en månad (30 dagar)

Diabetes

Diabetes

- Okänt
- Ja, insulinbehandlad
- Nej
- Ja, ej insulinbehandlad

I denna tabell/graf visas data som uppfyller följande:
 Sjukhus: Akademiska
 Datum: 2005-08-23 - 2007-08-23
 Alla PCI
 Analysvariabler: Död inom ett år (385 dagar) * Diabetes men endast första registreringen per patient inom urvalet
 Filnamn: sc2_120.sas, v2008-01-23

Diabetes

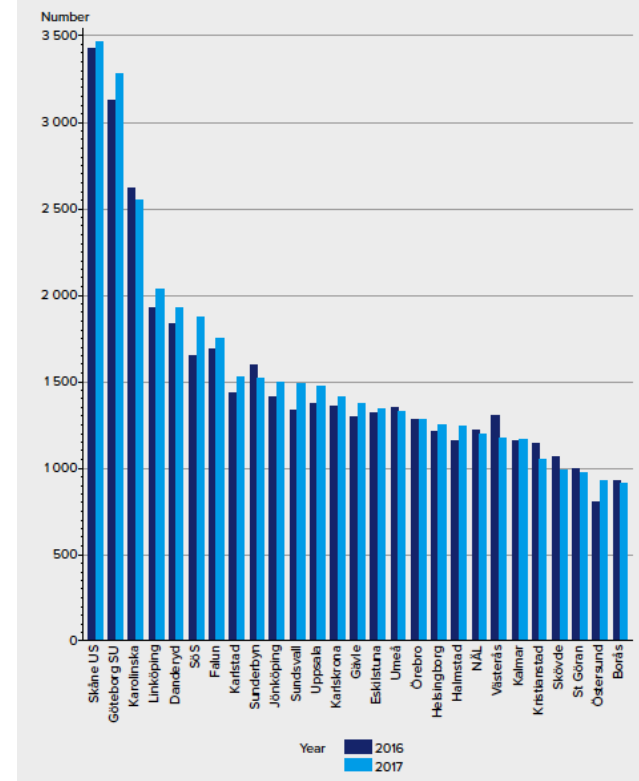
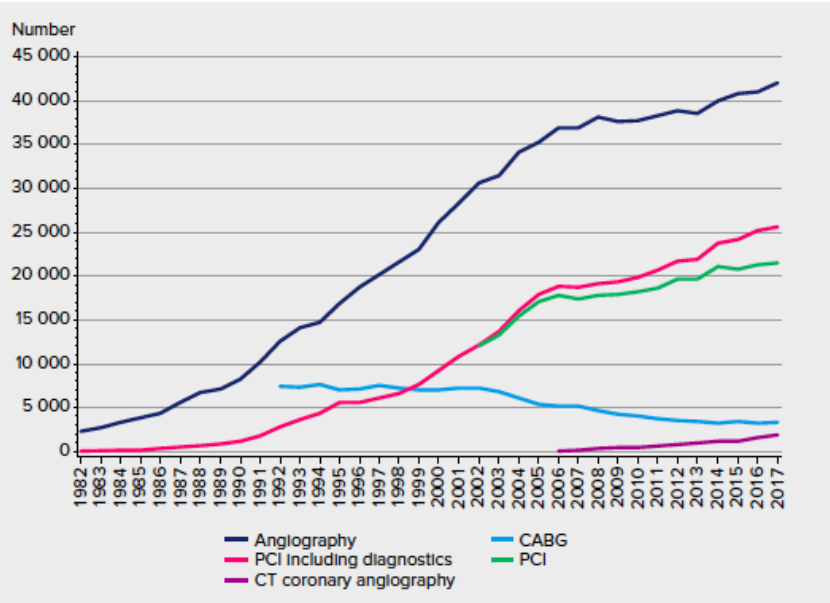
- Okänt
- Ja, insulinbehandlad
- Nej
- Ja, ej insulinbehandlad

I denna tabell/graf visas data som uppfyller följande:
 Sjukhus: Akademiska
 Datum: 2005-08-23 - 2007-08-23
 Alla PCI
 Analysvariabler: Död inom ett år (385 dagar) * &analysvar2

Distal protection
 Pacemaker
 Trombectomy
 Annat

Analysvariabler: Död inom ett år (385 dagar) * Diabetes men endast första registreringen per patient inom urvalet
 Filnamn: sc2_120.sas, v2008-01-23

SCAAR



Quality indices

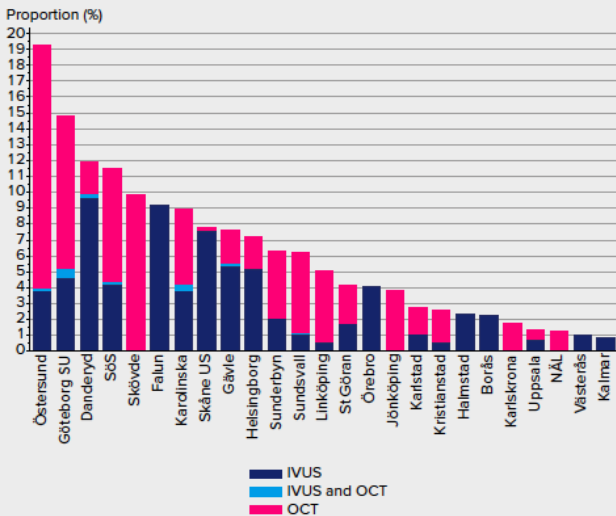


Figure 30. Proportion of PCIs using IVUS or OCT, per hospital, 2017.

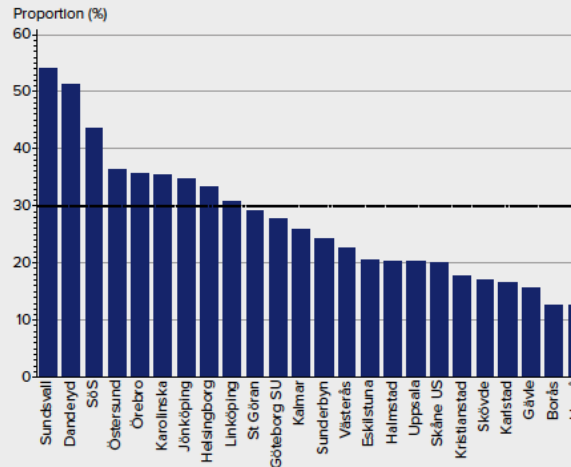


Figure 33. Proportion of coronary angiography in stable coronary artery disease where used, per hospital, 2017.

Reference line: Recommended average use of intracoronary pressure measurement.

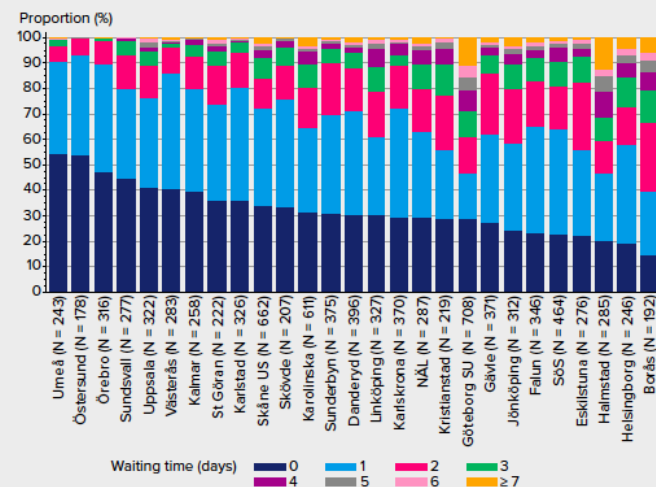


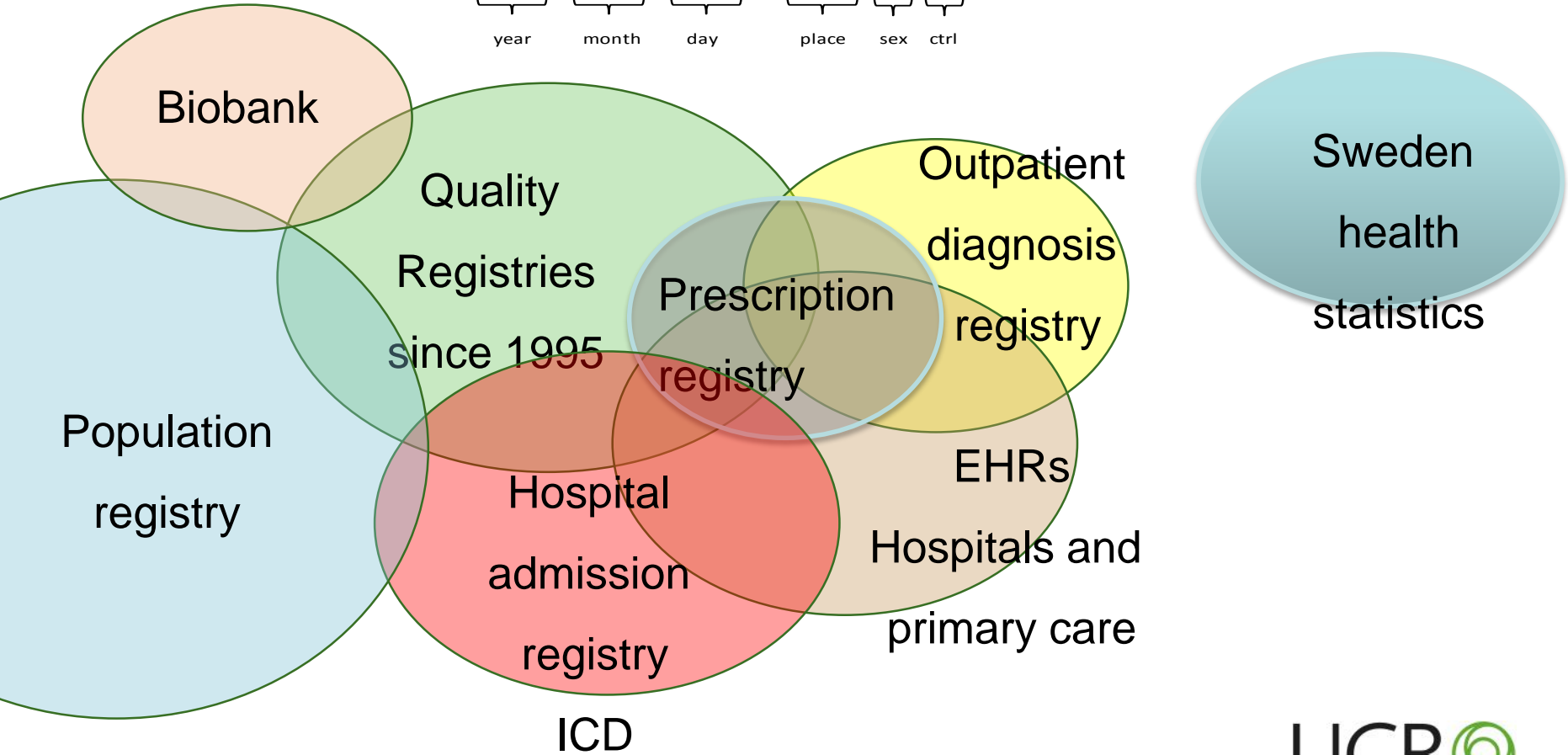
Figure 72. Distribution of waiting time (days from admission to coronary angiography) for NSTEMI patients, per hospital with >10 patients, 2017.

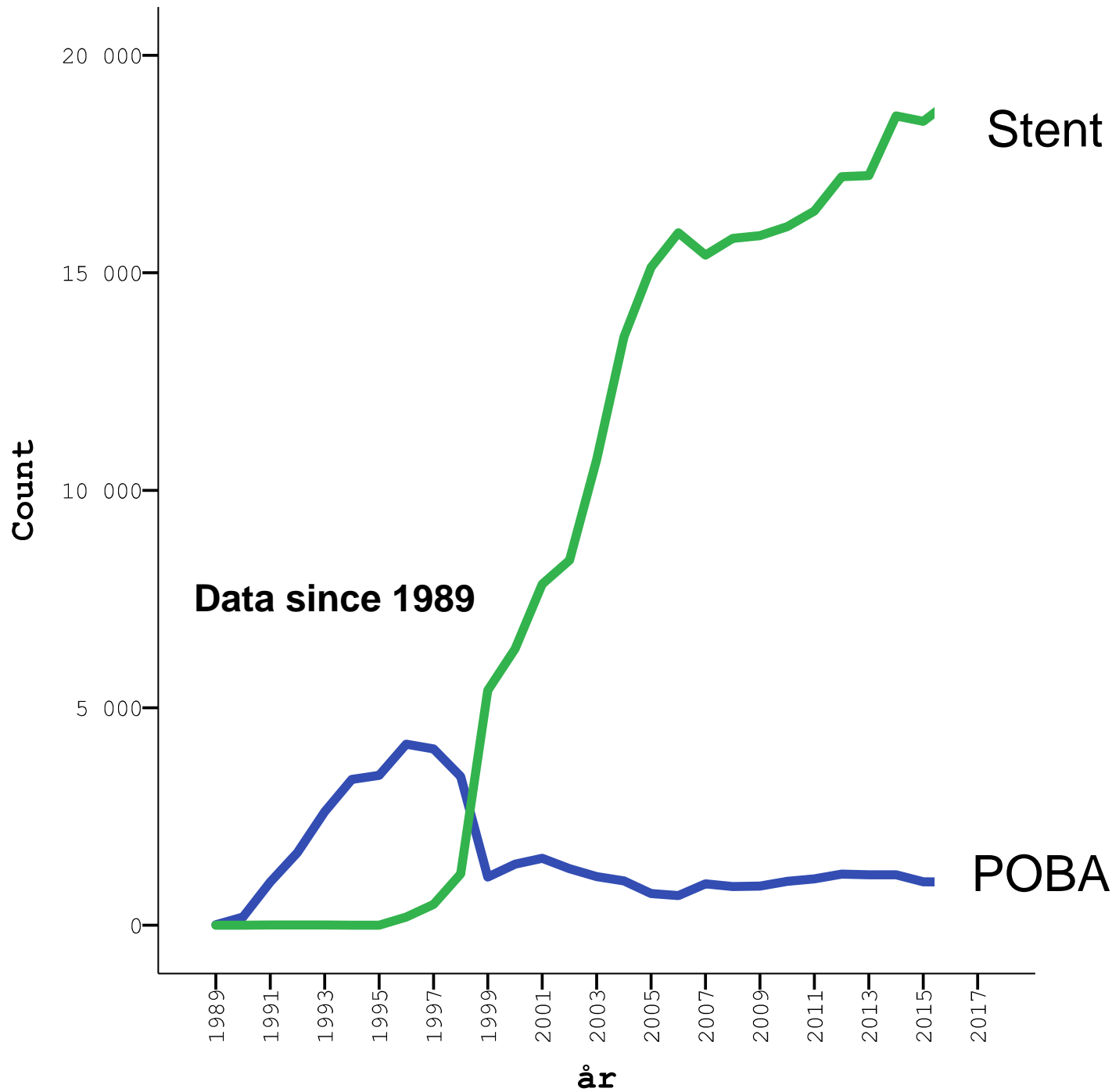
Data bases in Sweden based on personal number with patient characteristics, treatments and outcomes

Since 1947

540219-9750

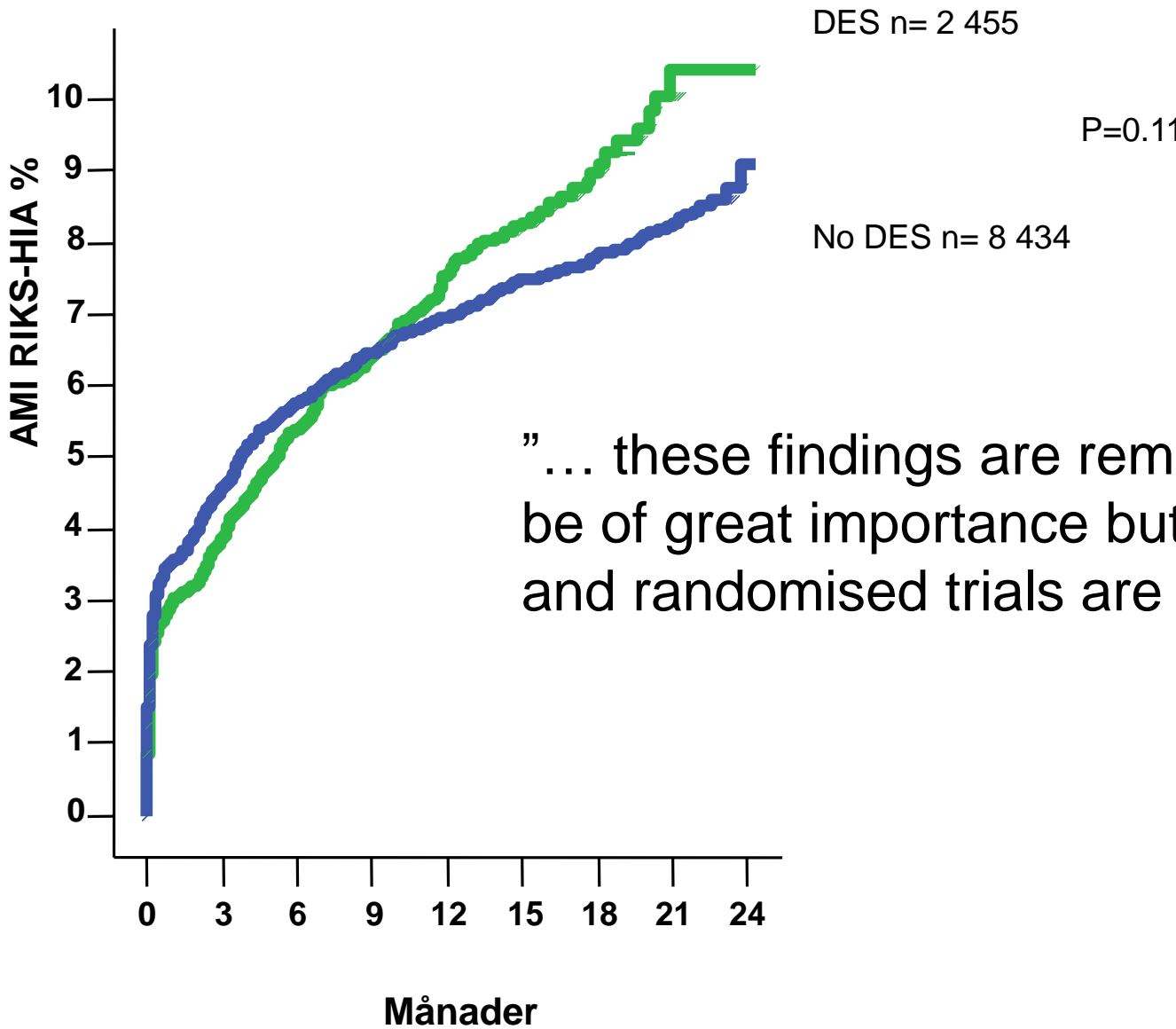
year month day place sex ctrl





Patients with stents 2003

SCAAR annual report 2004



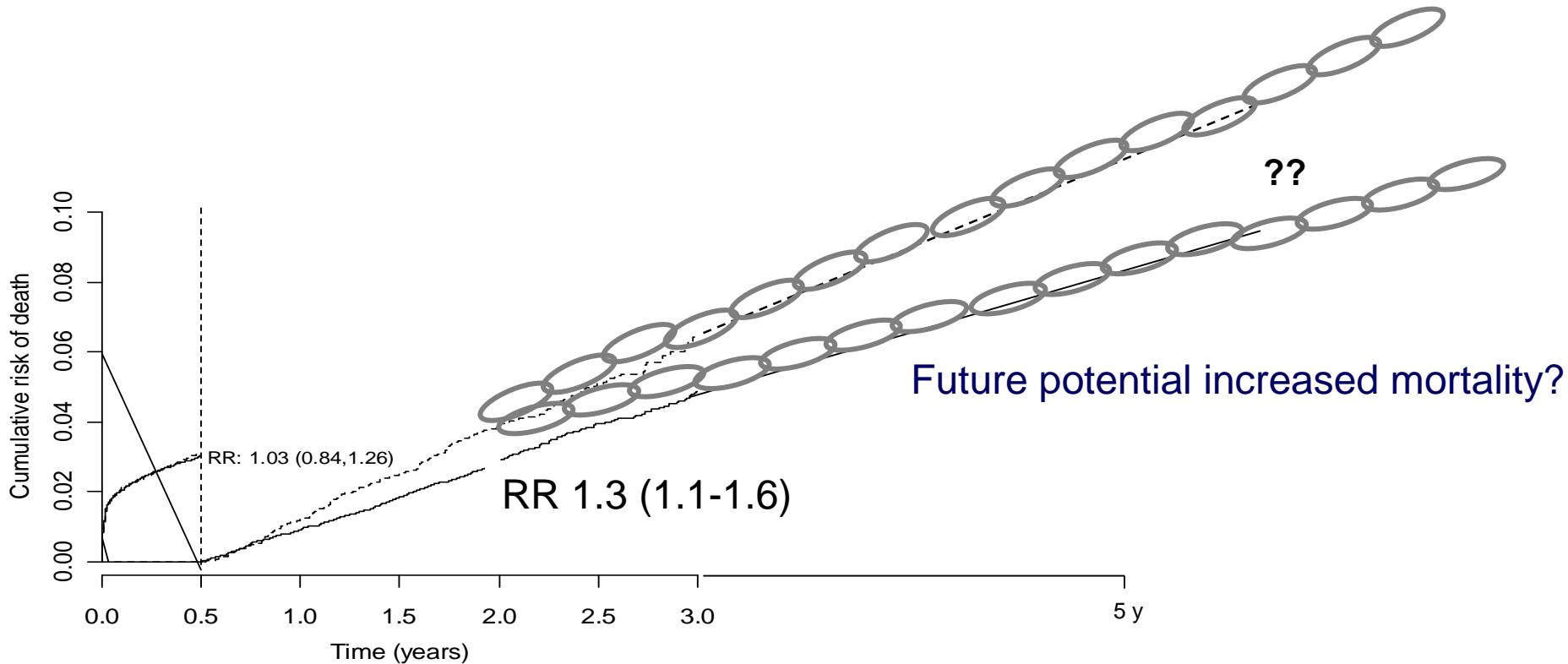
”... these findings are remarkable and may be of great importance but longer follow-up and randomised trials are needed.”



Long-Term Outcomes with Drug-Eluting Stents versus Bare-Metal Stents in Sweden

Bo Lagerqvist, M.D., Ph.D., Stefan K. James, M.D., Ph.D.,
Ulf Stenestrand, M.D., Ph.D., Johan Lindbäck, M.Sc., Tage Nilsson, M.D., Ph.D.,
and Lars Wallentin, M.D., Ph.D., for the SCAAR Study Group*

**Patients enrolled 2003-2004 and
followed max 3 years
N=19 771**



The SCAAR Scare

SCAAR

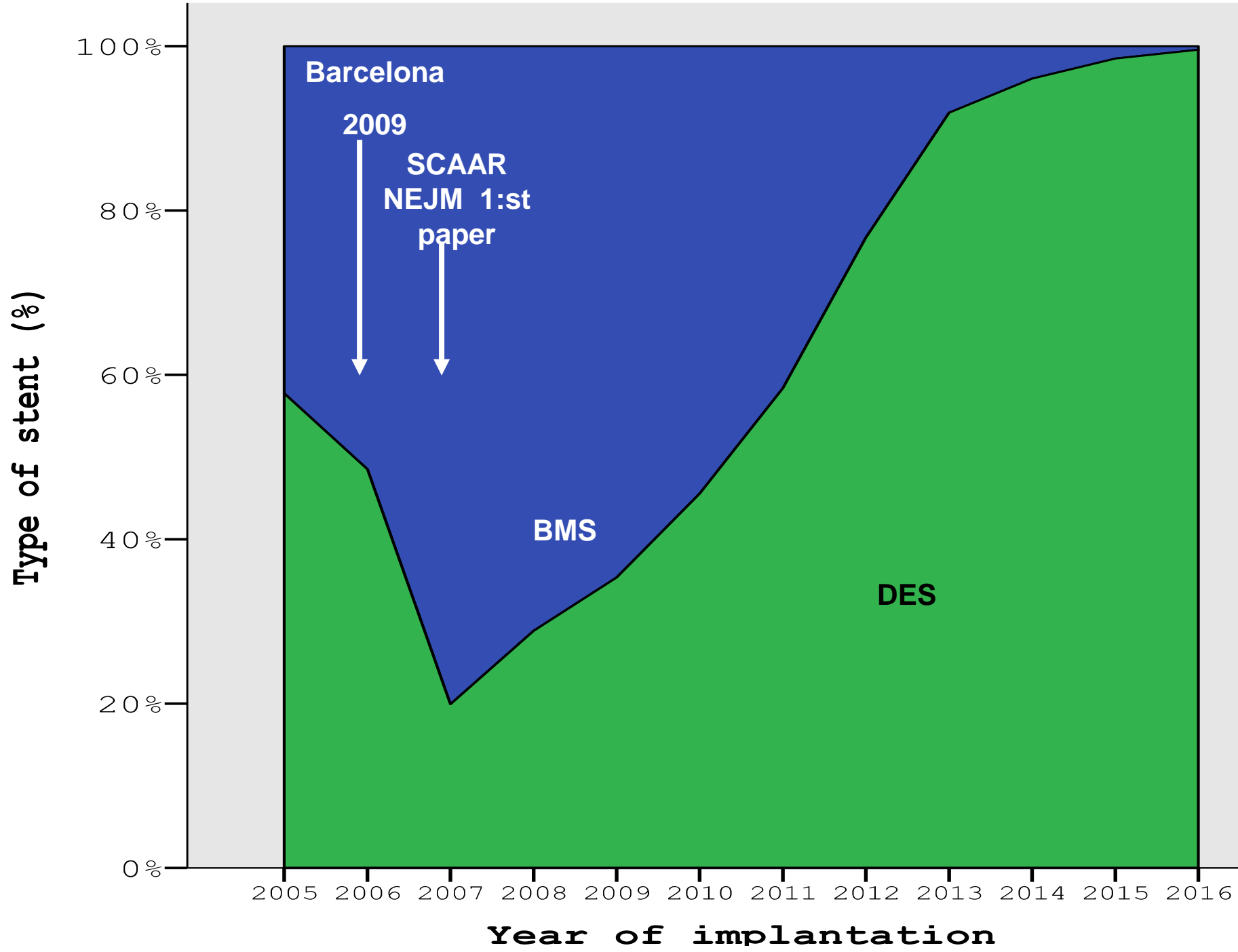
“The SCAAR registry is contaminated with flawed data....” M Leon 2007

“This clearly shows how inappropriate registry studies are....” Kastrati 2007

“What is rotten in the kingdom of Sweden”
P. Serruys 2008

BMS vs DMS

Bare metal stents vs. Death metal stents



Barcelona

2009

**SCAAR
NEJM 1:st
paper**

BMS

DES

Type of stent (%)

Year of implantation

Type of stent (%)

100%
80%
60%
40%
20%
0%

2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016

Barcelona

2009

SCAAR
NEJM 1:st
paper

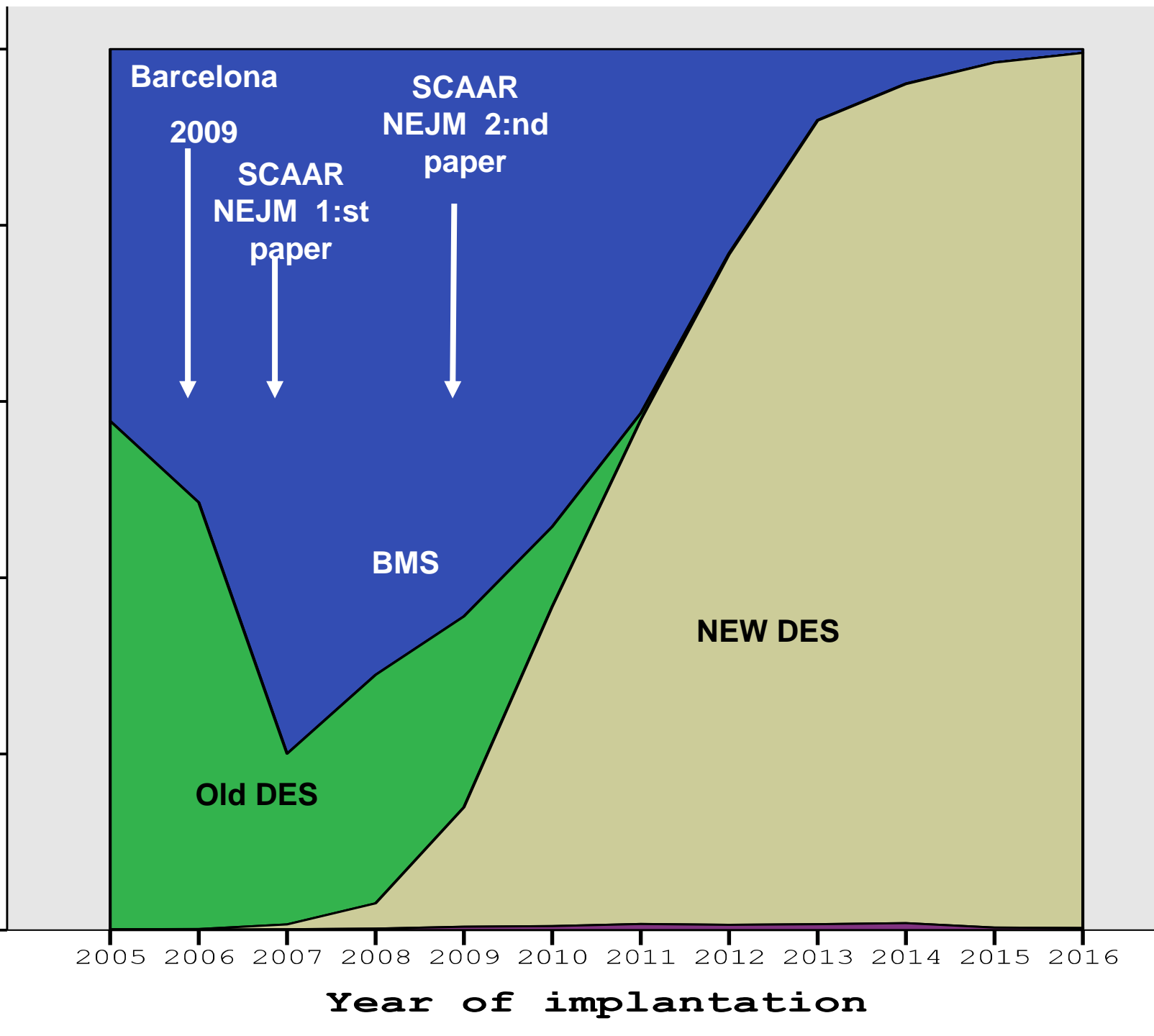
SCAAR
NEJM 2:nd
paper

BMS

Old DES

NEW DES

Year of implantation

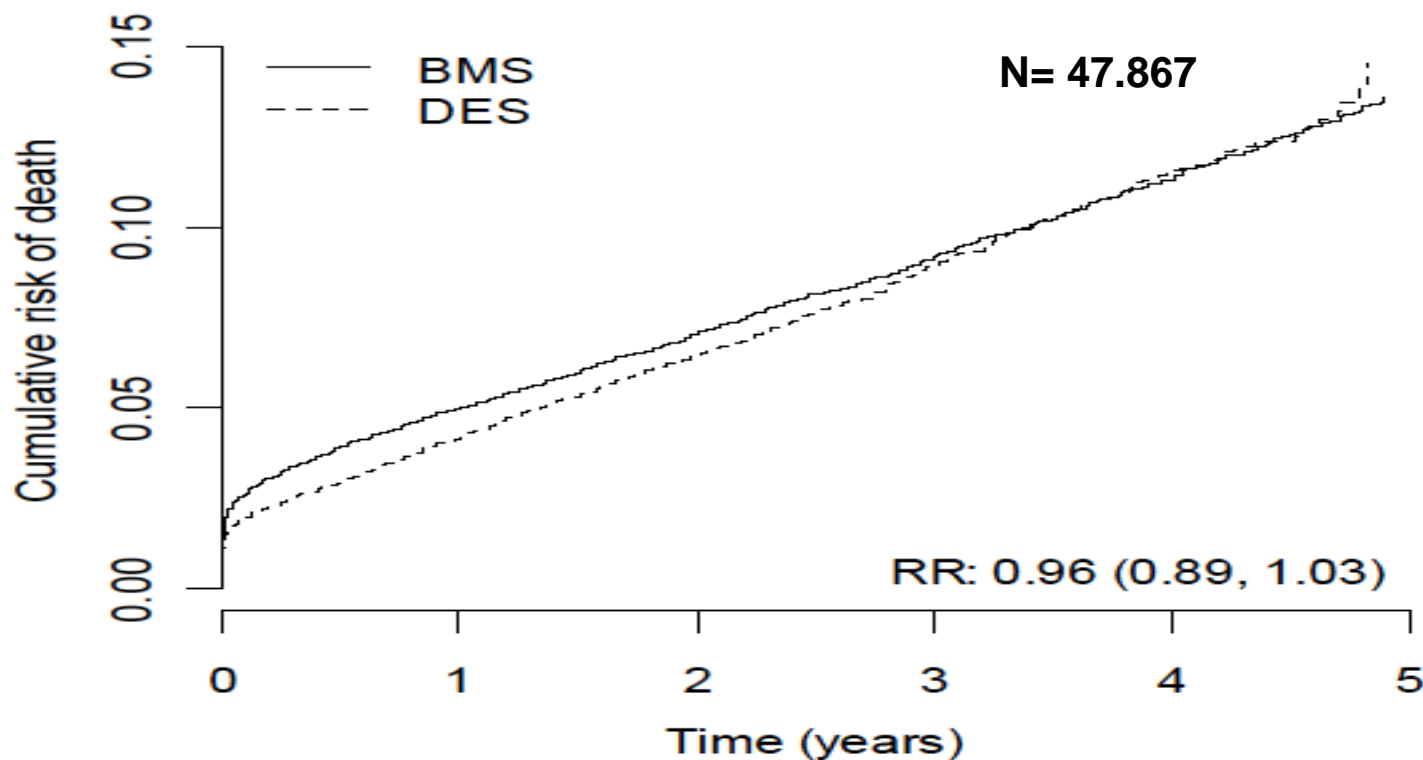




Long-Term Safety and Efficacy of Drug-Eluting
versus Bare-Metal Stents in Sweden

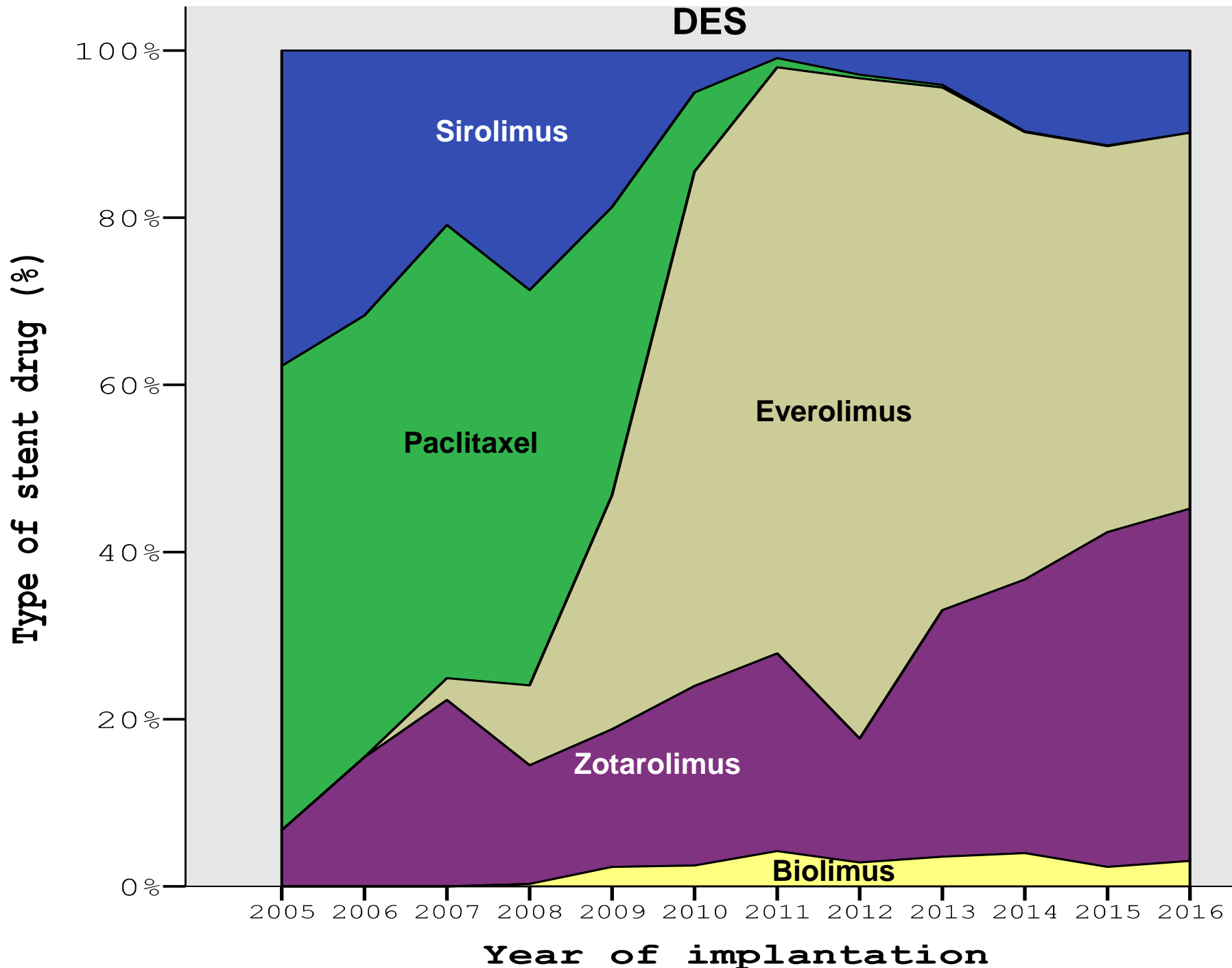
Stefan K. James, M.D., Ph.D., Ulf Stenestrand, M.D., Ph.D., Johan Lindbäck, M.Sc., Jörg Carlsson, M.D., Ph.D.,
Fredrik Scherstén, M.D., Ph.D., Tage Nilsson, M.D., Ph.D., Lars Wallentin, M.D., Ph.D., and Bo Lagerqvist, M.D., Ph.D.,
for the SCAAR Study Group*

Patients enrolled 2003-2006 and
followed max 5 years



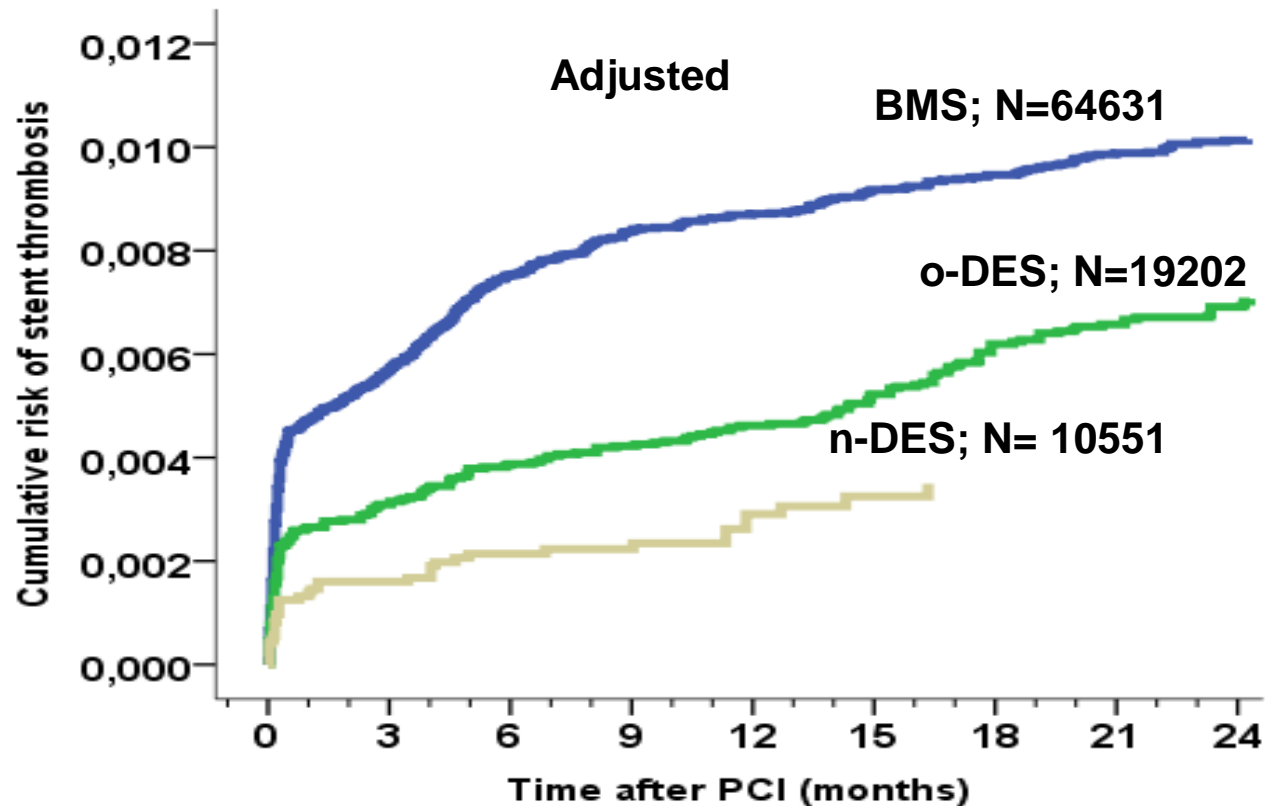
BMS	28286	26843	19429	13592	6682	7
DES	19681	18893	12691	6065	1964	0

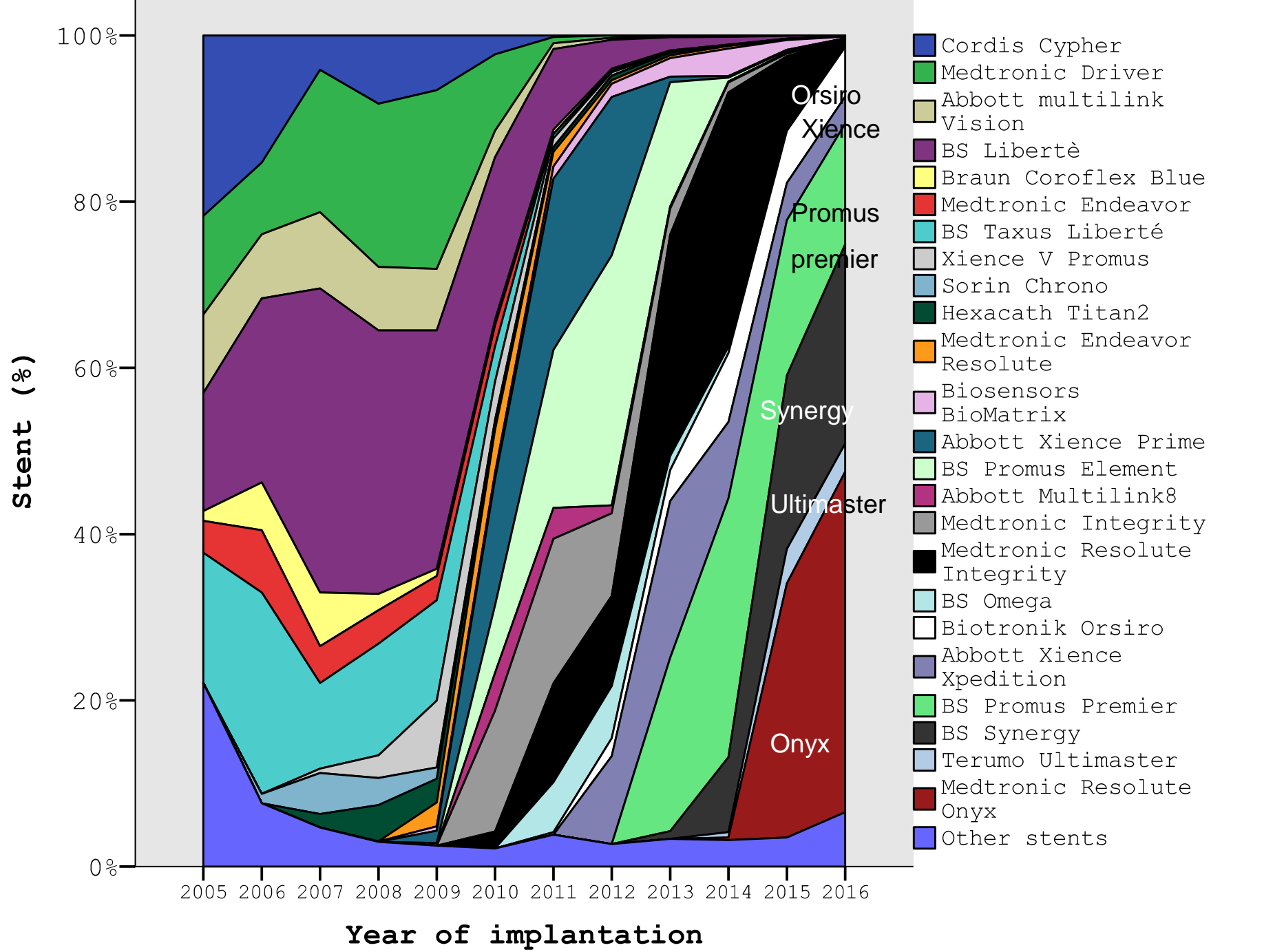




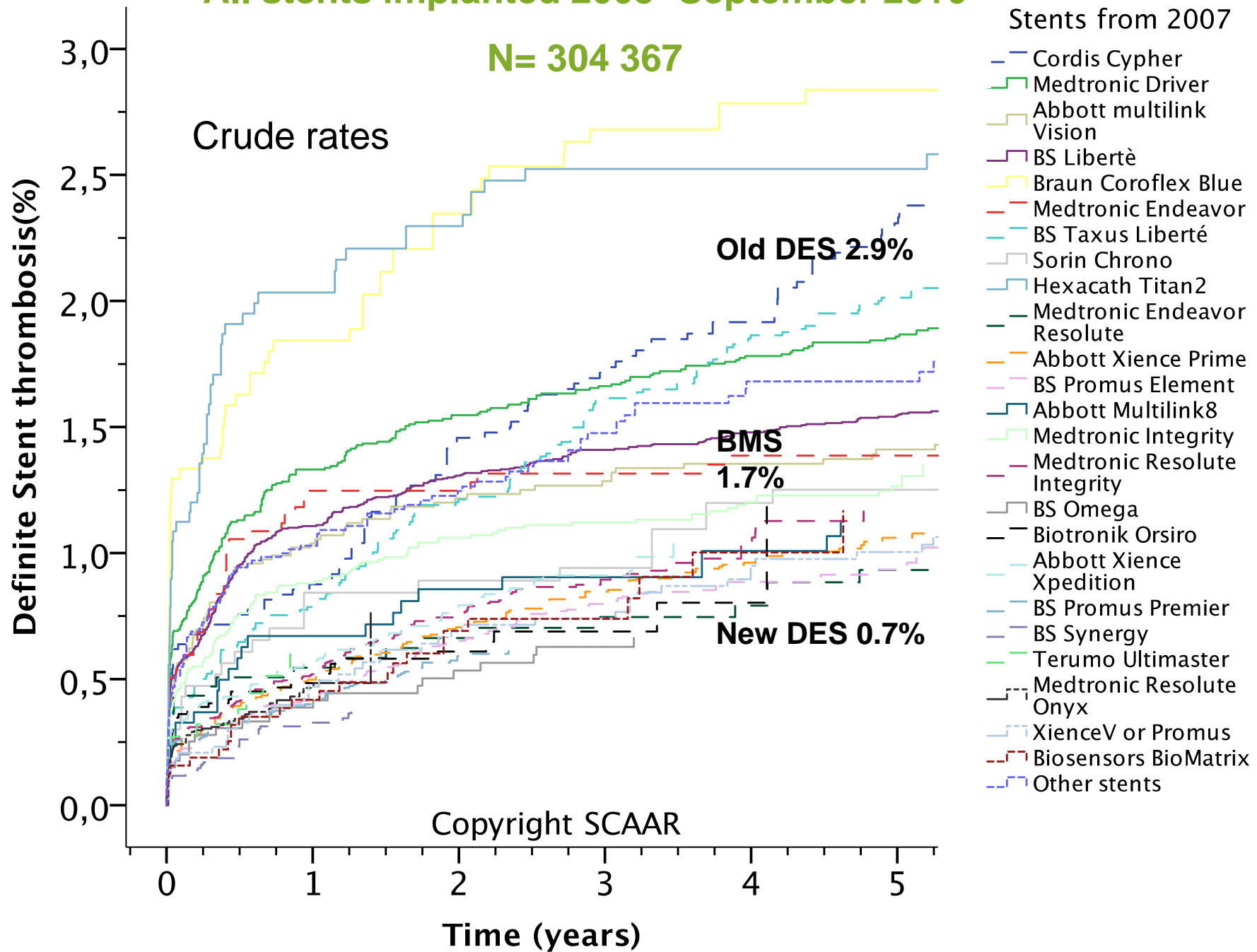
Lower risk of stent thrombosis and restenosis with unrestricted use of 'new-generation' drug-eluting stents: a report from the nationwide Swedish Coronary Angiography and Angioplasty Registry (SCAAR)

Giovanna Sarno¹, Bo Lagerqvist¹, Ole Fröbert², Johan Nilsson³, Göran Olivecrona⁴, Elmira Omerovic⁵, Nawzad Saleh⁶, Dimitris Venetizanos⁷, and Stefan James^{1*}





All stents implanted 2005- September 2016



Register based Randomized Clinical trials- R-RCT

Prospective randomized trial that uses a clinical registry for one or several major functions for trial conduct and outcomes reporting.

PERSPECTIVES

OPINION

Registry-based randomized clinical trials—a new clinical trial paradigm

Stefan James, Sunil V. Rao and Christopher B. Granger

Abstract | Randomized clinical trials provide the foundation of clinical evidence to guide physicians in their selection of treatment options. Importantly, randomization is the only reliable method to control for confounding factors when comparing treatment groups. However, randomized trials have limitations, including the increasingly prohibitive costs of conducting adequately powered studies. Local and national regulatory requirements, delays in approval, and unnecessary trial processes have led to increased costs and decreased efficiency. Another limitation is that clinical trials involve selected patients who are treated according to protocols that might not represent real-world practice. A possible solution is registry-based randomized clinical trials. By including a randomization module in a large inclusive clinical registry with unselected consecutive enrolment, the advantages of a prospective randomized trial can be combined with the strengths of a large-scale all-comers clinical registry. We believe that prospective registry-based randomized clinical trials are a powerful tool for conducting studies efficiently and cost-effectively.

James, S. *et al. Nat. Rev. Cardiol.* **12**, 312–316 (2015); published online 17 March 2015;
[doi:10.1038/nrcardio.2015.33](https://doi.org/10.1038/nrcardio.2015.33)



SWEDEHEART - Windows Internet Explorer

https://test.ucr.uu.se/swedeheart/patientOverview.jsp

Arkiv Redigera Visa Favoriter Verktyg Hjälp

Windows Live Bing Senaste aktivitet

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DN.se - Nyheter - D... Post E-post :: Inkorg (2)

Randomize and store data

Stresskardiomyopati	
Primärt beslut	9 PCI ad ho
Avböjd från operation	

TASTE

Did the patient consent?		*
Are inclusion and exclusion criteria met?		*

Randomisera & Spara

Spara

PCI

Operatör		*
----------	--	---

Segment

Segmentnummer	
Graft	0 Nej
Nummer på stenosis i samma segment	1 Första
Oklusion	
Stenostyp	
Stenosklass	
Procedurtyp	
Lokal framgång	

Återställ segmentformulär

Spara/Lägg till segment

Vill patient vara med i Taste-studien

Munligt samtycke har inhämtats efter följande information och fråga:

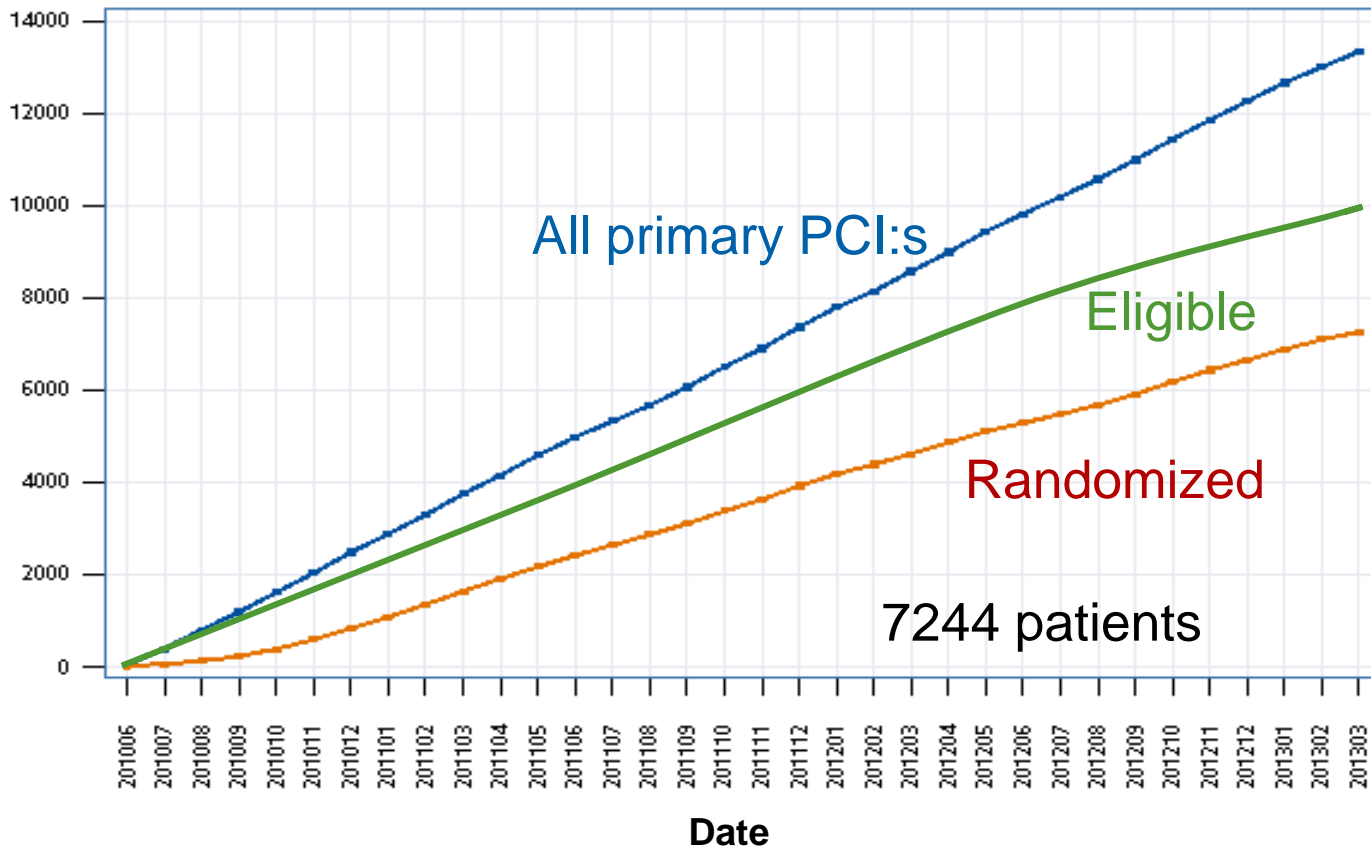
Du har drabbats av en akut hjärtinfarkt. Det innebär att det finns en blodpropp som har stoppat blodflödet i ett av dina kranskär. Tidigare undersökningar har visat att blodflödet återhämtar sig snabbare om man suger ut en del av blodproppen med en liten sugkateter. Vi vet dock inte proppsugning minskar dödligheten efter hjärtinfarkt eller minskar risken för ny hjärtinfarkt eller för hjärtsvikt. Vi gör därför en vetenskaplig studie som innebär att hälften av patienterna får proppsugning innan vanlig ballongvidging sker och hälften av patienterna får sedvanlig ballongvidging. Sedan följer vi resultaten av behandlingen via våra hjärt-kärl register. Studien innebär inga extra provtagningar eller besök.

Vi undrar om du accepterar att delta i denna studie. Om du

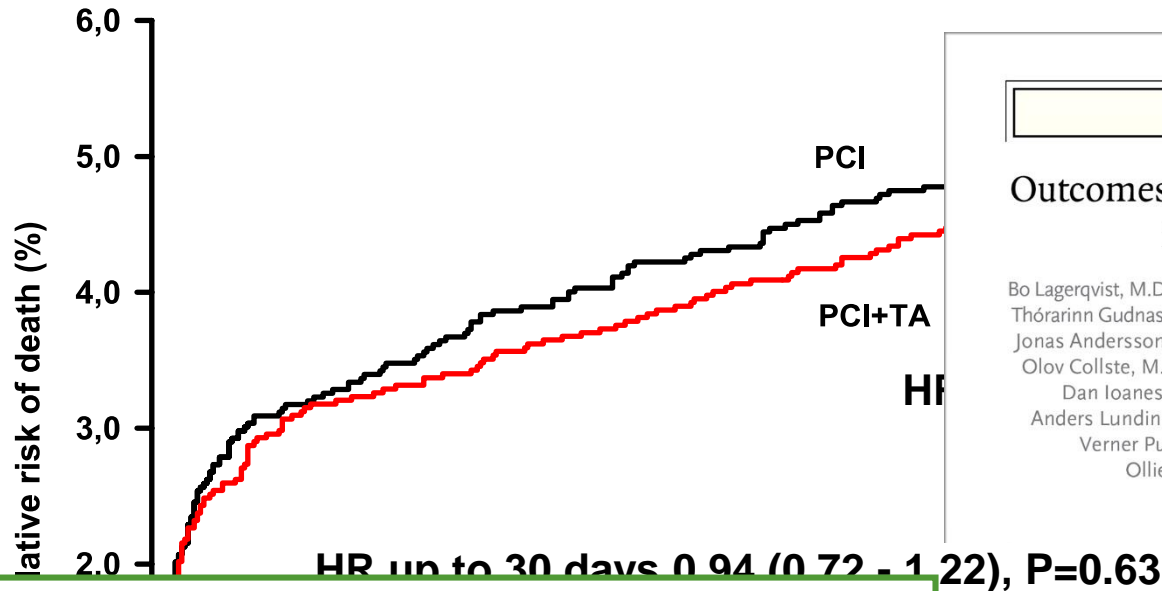
TASTE

TASTE inclusion rate

Patients



The simplest and most pragmatic design



ORIGINAL ARTICLE

Outcomes 1 Year after Thrombus Aspiration for Myocardial Infarction

Bo Lagerqvist, M.D., Ph.D., Ole Fröbert, M.D., Ph.D., Göran K. Olivecrona, M.D., Ph.D., Thórarinn Gudnason, M.D., Ph.D., Michael Maeng, M.D., Ph.D., Patrik Alström, M.D., Jonas Andersson, M.D., Ph.D., Fredrik Calais, M.D., Jörg Carlsson, M.D., Ph.D., Olov Collste, M.D., Matthias Götzberg, M.D., Ph.D., Peter Hårdhammar, M.D., Dan Ioanes, M.D., Anders Kallryd, M.D., Rickard Linder, M.D., Ph.D., Anders Lundin, M.D., Jacob Odenstedt, M.D., Elmir Omerovic, M.D., Ph.D., Verner Puskar, M.D., Tim Tödt, M.D., Ph.D., Eva Zelleroth, M.D., Ollie Östlund, Ph.D., and Stefan K. James, M.D., Ph.D.

Perspective

The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?

Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.

The randomized trial is one of the most powerful tools clinical researchers possess, a tool that enables them to evaluate the effectiveness of new (or established) therapies while accounting for

United States and abroad have collected vast amounts of data from patients with acute coronary syndromes, stable coronary disease, and heart failure, as well as








The NEW ENGLAND JOURNAL of MEDICINE

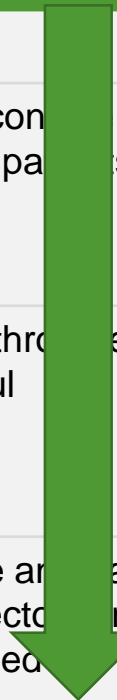
ORIGINAL ARTICLE

Thrombus Aspiration during ST-Segment Elevation Myocardial Infarction

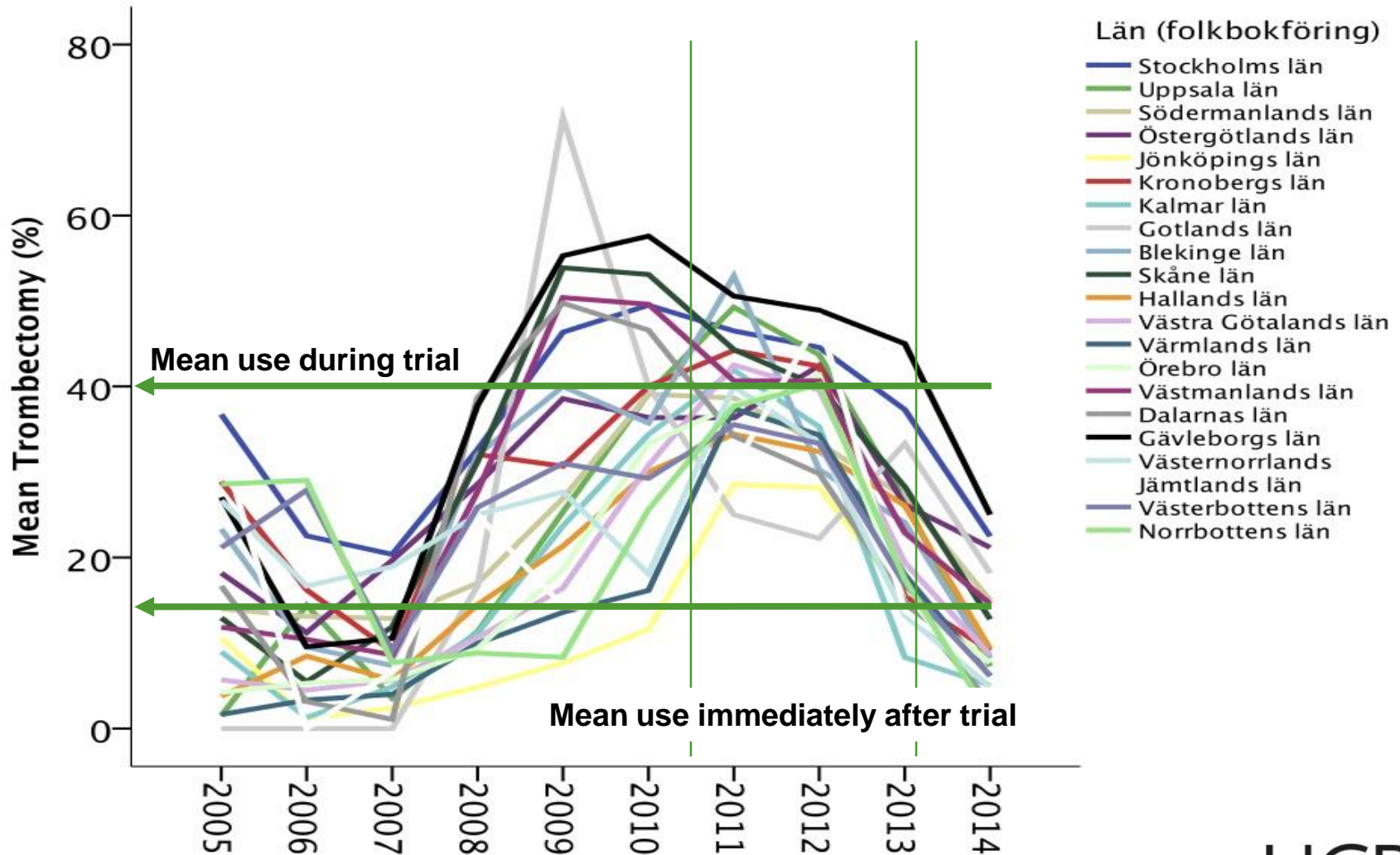
Ole Fröbert, M.D., Ph.D., Bo Lagerqvist, M.D., Ph.D., Göran K. Olivecrona, M.D., Ph.D., Elmir Omerovic, M.D., Ph.D., Thorarinn Gudnason, M.D., Ph.D., Michael Maeng, M.D., Ph.D., Mikael Aasa, M.D., Ph.D., Oskar Angerås, M.D., Fredrik Calais, M.D., Mikael Danielewicz, M.D., David Erlinge, M.D., Ph.D., Lars Hellsten, M.D., Ulf Jensen, M.D., Ph.D., Agneta C. Johansson, M.D., Amra Kåregren, M.D., Johan Nilsson, M.D., Ph.D., Lotta Robertson, M.D., Lennart Sandhall, M.D., Iwar Sjögren, M.D., Ollie Östlund, Ph.D., Jan Harnek, M.D., Ph.D., and Stefan K. James, M.D., Ph.D.

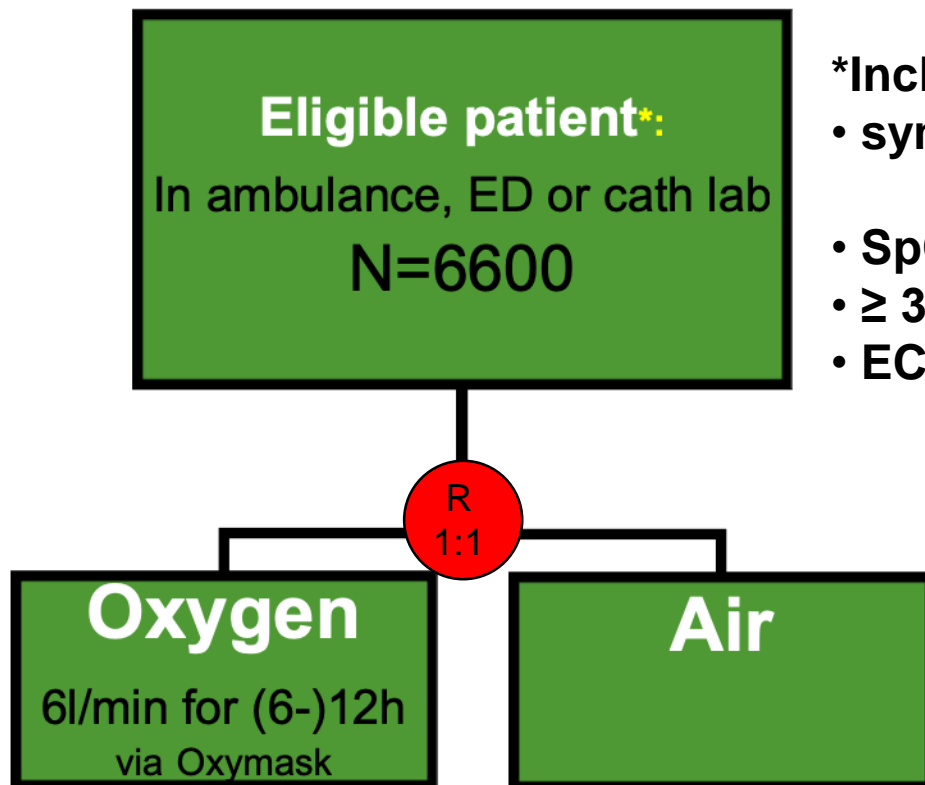
Guidelines

Title	Citation		Class	LOE
 2012 ESC Guidelines ST-segment elevation myocardial infarction .	European Heart Journal 2012 Oct;33(20):2569-619	Routine aspiration should be considered	IIa	B
 2014 ESC/EACTS guidelines on myocardial revascularization	Eur Heart J. 2014 Oct 1;35(37):2541-619	May be considered in selected patients	IIb	A
  2015 ACC/AHA focused update PPCI	JACC	Routine thrombectomy not useful	III	A
  2015 ACC/AHA focused update PPCI	JACC	Selective angioplasty established	IIb	C
 2017 ESC Guidelines ST-segment elevation myocardial infarction	European Heart Journal 2017	Routine use of thrombus aspiration is not recommended.	III	A



Thrombus aspiration post Taste





*Inclusion criteria:

- symptoms suggestive of AMI within 6h
- SpO₂ ≥ 90%
- ≥ 30y
- ECG changes indicating ischemia and/or elevated troponin levels

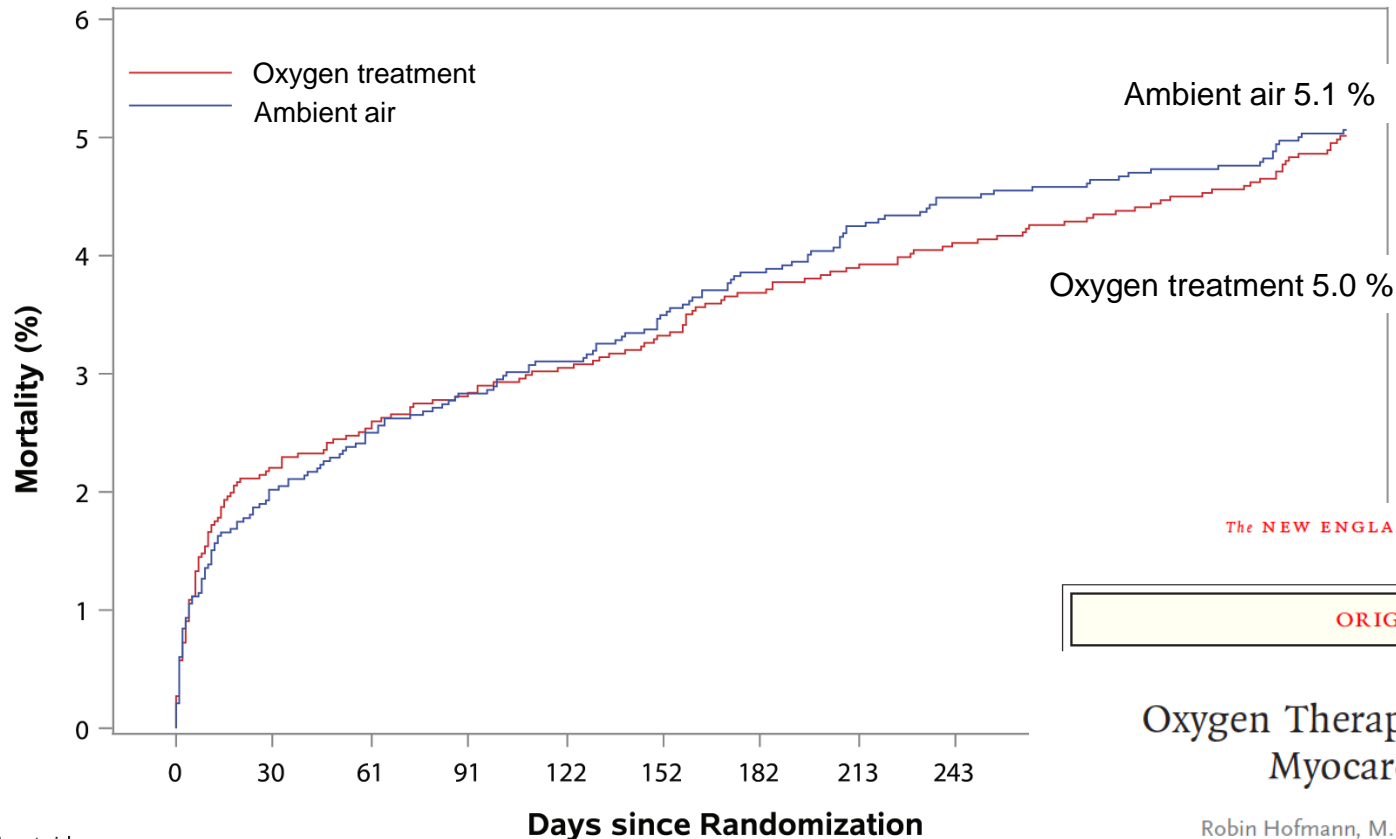
Primary Endpoint: 1-year total mortality

Additional secondary endpoint and sub studies

Data analysis through SWEDEHEART registry and national mortality registry

Funding:

Primary Endpoint up to 365 days



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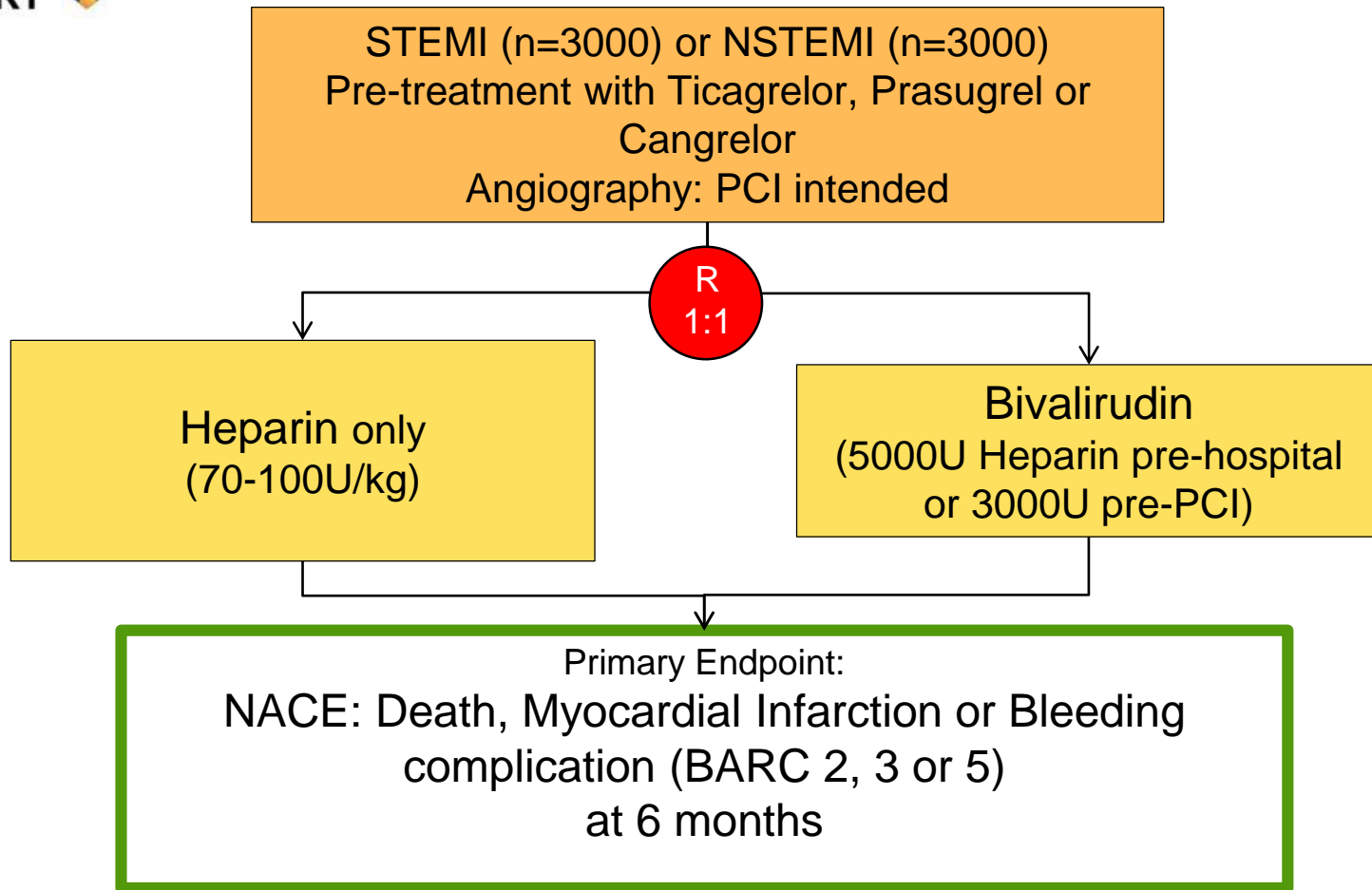
ORIGINAL ARTICLE

Oxygen Therapy in Suspected Acute Myocardial Infarction

Robin Hofmann, M.D., Stefan K. James, M.D., Ph.D.,
 Tomas Jernberg, M.D., Ph.D., Bertil Lindahl, M.D., Ph.D.,
 David Erlinge, M.D., Ph.D., Nils Witt, M.D., Ph.D., Gabriel Arefalk, M.D.,
 Mats Frick, M.D., Ph.D., Joakim Alfredsson, M.D., Ph.D.,
 Lennart Nilsson, M.D., Ph.D., Annica Ravn-Fischer, M.D., Ph.D.,
 Elmir Omerovic, M.D., Ph.D., Thomas Kellerth, M.D., David Sparv, B.Sc.,
 Ulf Ekelund, M.D., Ph.D., Rickard Linder, M.D., Ph.D.,
 Mattias Ekström, M.D., Ph.D., Jörg Lauermaun, M.D., Urban Haaga, B.Sc.,
 John Pernow, M.D., Ph.D., Ollie Östlund, Ph.D., Johan Herlitz, M.D., Ph.D.,
 and Leif Svensson, M.D., Ph.D., for the DETO2X–SWEDEHEART Investigators*

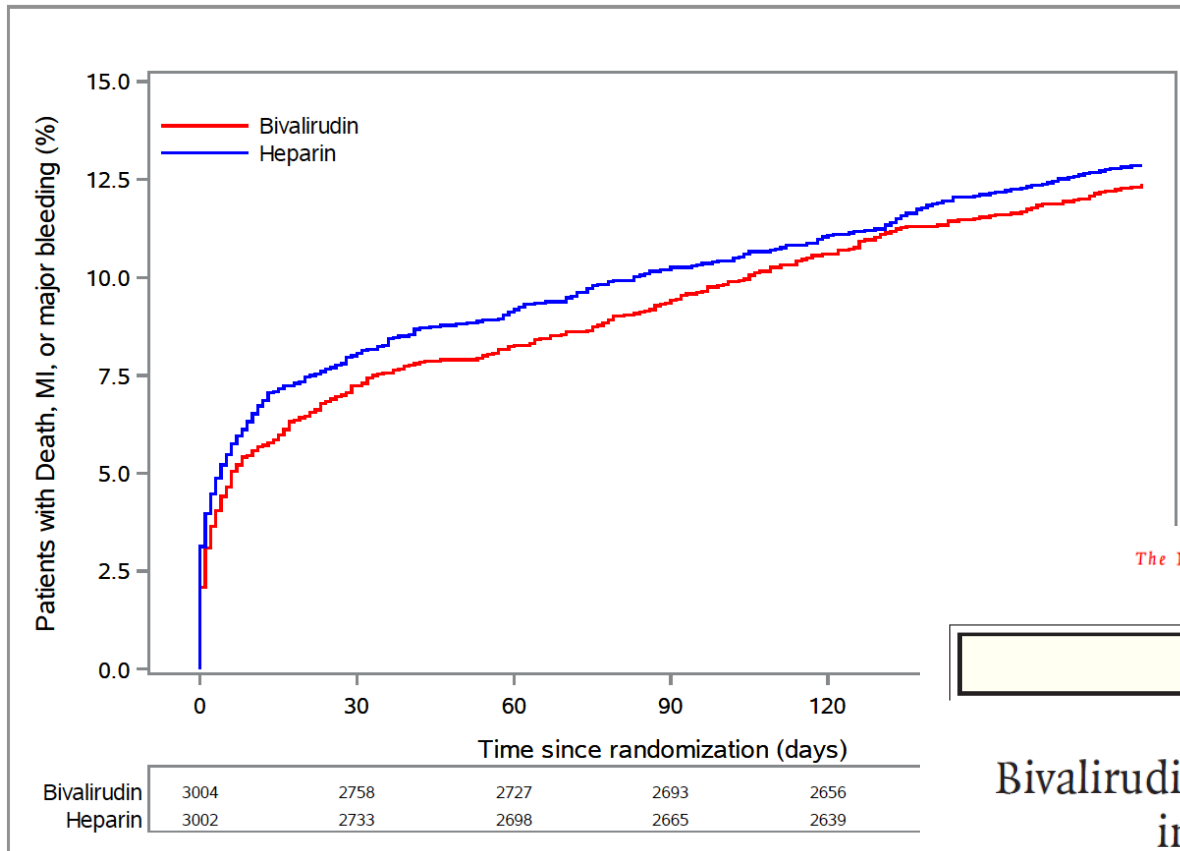
No. at risk	Days since Randomization									
	0	30	61	91	122	152	182	213	243	
Oxygen treatment	3311	3238	3227	3218	3210	3201	3189	3182	3175	
Ambient air	3318	3251	3235	3224	3215	3202	3190	3177	3169	

VALIDATE (R-RCT)



- FU: Register data, combined with phone call endpoint follow up and CEC
- Funding: Heart-lung foundation. Swedish research council, Astra Zeneca, The Medicines company.

Primary Endpoint at 180 days



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ORIGINAL ARTICLE

Bivalirudin versus Heparin Monotherapy in Myocardial Infarction

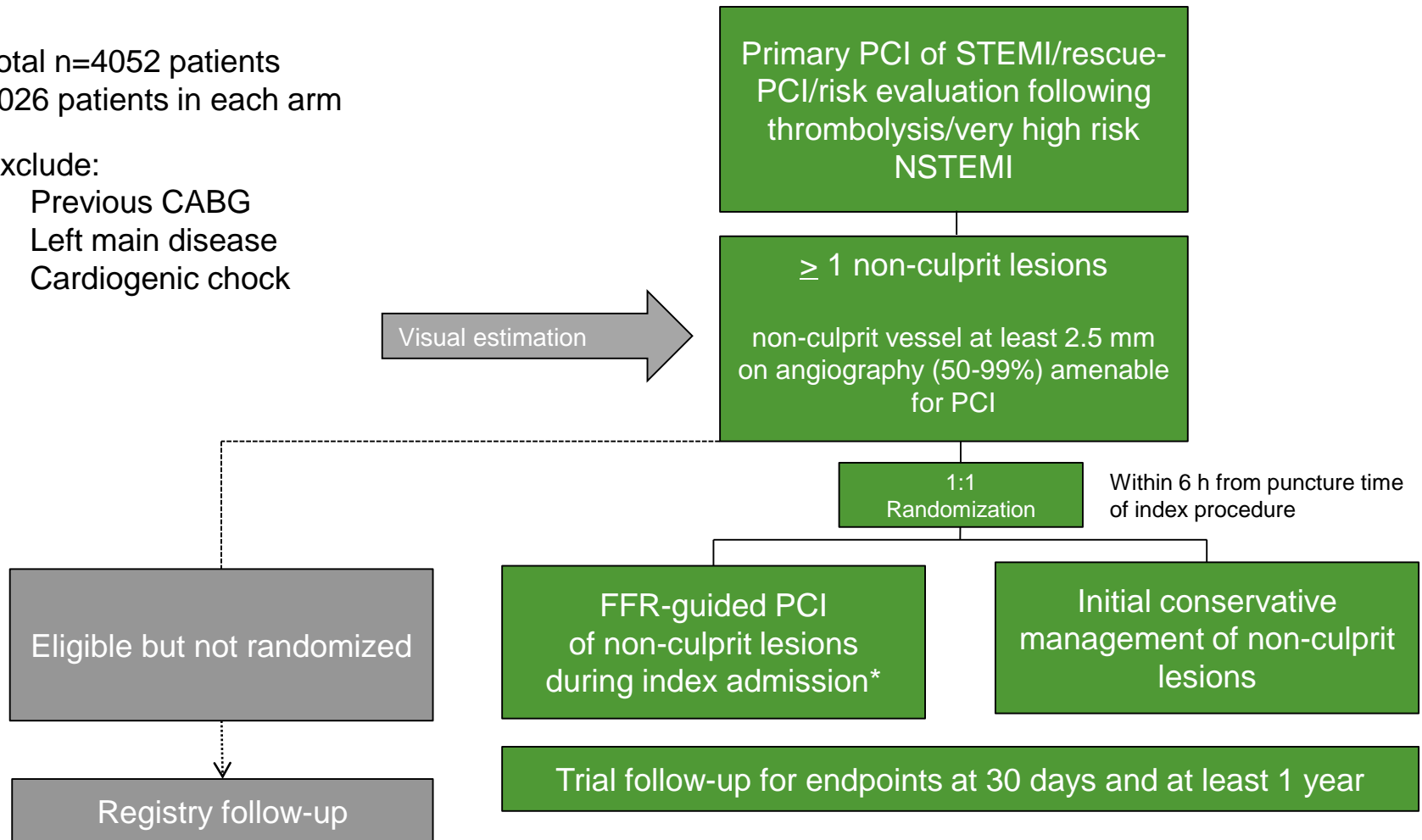
D. Erlinge, E. Omerovic, O. Fröbert, R. Linder, M. Danielewicz, M. Hamid, E. Swahn, L. Henareh, H. Wagner, P. Hårdhammar, I. Sjögren, J. Stewart, P. Grimfjärd, J. Jensen, M. Aasa, L. Robertsson, P. Lindroos, J. Haupt, H. Wikström, A. Ulvenstam, P. Bhiladvala, B. Lindvall, A. Lundin, T. Tödt, D. Ioanes, T. Råmunddal, T. Kellerth, L. Zagazdzon, M. Göteborg, J. Andersson, O. Angerås, O. Östlund, B. Lagerqvist, C. Held, L. Wallentin, F. Scherstén, P. Eriksson, S. Koul, and S. James

FULL REVASC

Total n=4052 patients
2026 patients in each arm

Exclude:

- Previous CABG
- Left main disease
- Cardiogenic shock



Visual estimation

1:1
Randomization

Within 6 h from puncture time of index procedure

Eligible but not randomized

Registry follow-up

FFR-guided PCI of non-culprit lesions during index admission*

Initial conservative management of non-culprit lesions

Trial follow-up for endpoints at 30 days and at least 1 year

**Admission meaning initial PCI-capable unit or after transfer to another PCI-capable unit*

Synthesized new evidence

2015: High quality systematic reviews (20 trials, 21660 patients)
Moderate certainty evidence (4 fewer MI, 6 more strokes)

E Dib et al. BMC Cardiovascular Disorders (2016) 16:121
 DOI 10.1186/s12916-016-0284-4

BMC Cardiovascular Disorders

RESEARCH ARTICLE

Open Access

Aspiration thrombectomy prior to percutaneous coronary intervention in ST-elevation myocardial infarction: a systematic review and meta-analysis

Regina El Dib^{1,2}, Frederick Alan Spencer^{3*}, Erica Aranha Suzumura⁴, Huda Coma⁵, Joey Kwong⁶, Gordon Henry Gayatt^{7*} and Per Olav Vandvik^{8,10}



Randomized Trial of Primary PCI with or without Routine Manual Thrombectomy

ORIGINAL ARTICLE

Outcomes 1 Year after Thrombus Aspiration for Myocardial Infarction

Produced more reliable and relevant evidence
2014: TASTE (n=7244)
2015: TOTAL (n= 10732)
Negative results

Evidence Ecosystem reducing waste
Thrombus aspiration for MI Loop 2 2014-2017

Updated and disseminated guidance
2015: ACC/ AHA guidelines
2017: ESC guidelines
Strong recommendations against



European Heart Journal (2012) 33, 2001–2002
 doi:10.1093/eurheartj/ehs217

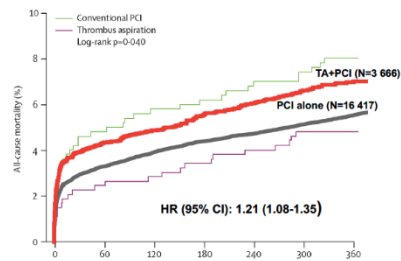
2012 ESC Guidelines on acute myocardial infarction (STEMI)

Achievements in access to primary PCI have shifted the focus of ESC Guidelines towards quality control with new targets for treatment times



data

TAPAS / Swedish registry data



SART

Vlaar, P.J. et al. *The Lancet* 2008; 371:1915-20
 Fröbert, O. et al. *Int J Cardiol.* 2010; 145:572-3



De-implemented and evaluated in Sweden, what about the rest of the world?
2014-2015: Swedish national online registry
 rapid de-implementation of thrombus aspir (PCI patients), immediately following TAS before systematic review and guidelines up

