

# Complications with traditional pacing devices

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Danish Pacemaker and ICD Register



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## MY CONFLICTS OF INTEREST ARE

Unrestricted research grants from:

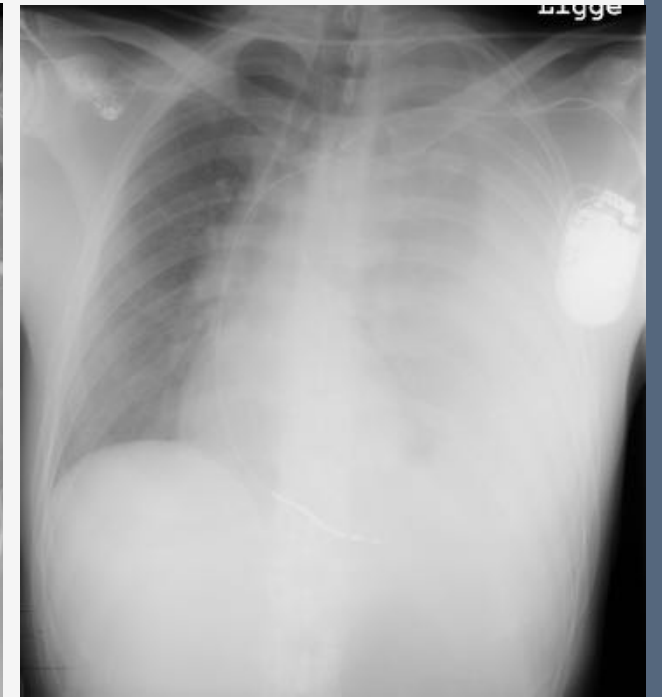
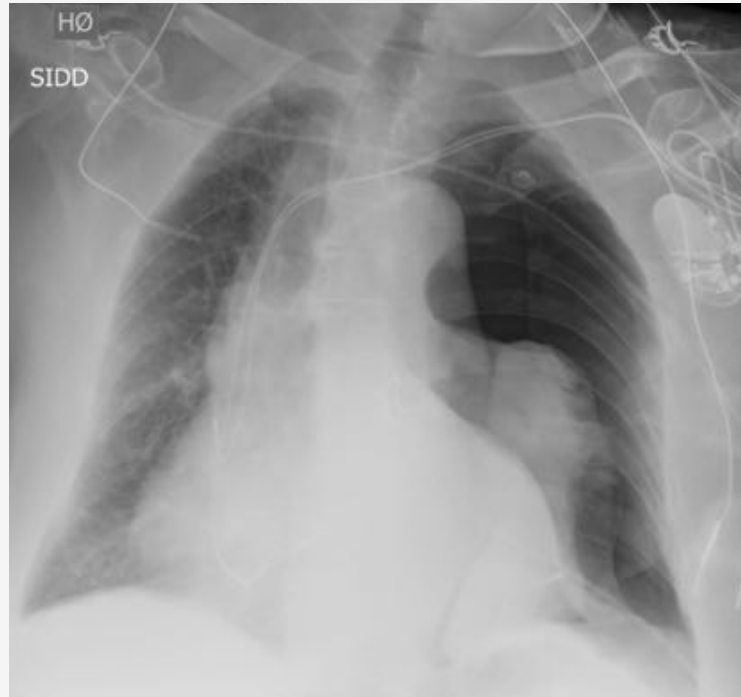
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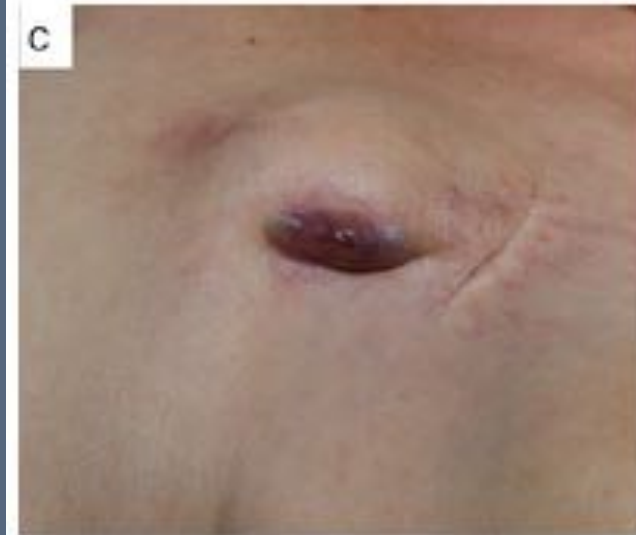
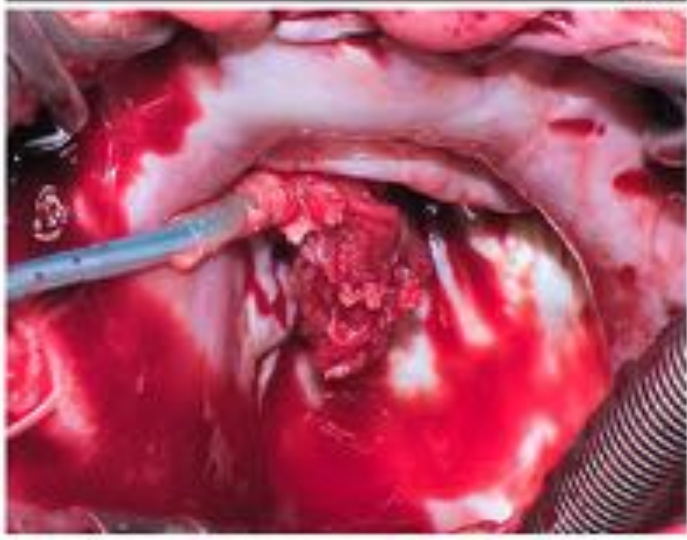
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# Complications



Re-intervention (lead-related, pocket revision because of pain, haematoma, Twiddler's syndrome, etc);  
Pneumothorax; Cardiac perforation; Deep venous thrombosis; Stroke; Myocardial infarction;  
Procedure related death; Haematoma conservatively treated; Wound infection.

# Device infections



# Complications are associated with increased...

## Morbidity

*Sohail 2007, Baddour 2010, Nery 2010*

## Health care costs

*Reynolds 2006, Swindle 2010, Greenspon 2011*

## Mortality

*Lee 2010, Cheng 2010, Krahn 2011*

# The leadless era

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Leadless pacing  $\approx$  VVI pacing

Specific data on VVI complications  
- in a contemporary setting –  
is scarce

# VVI data

## Complication rates from VVI procedures

From another era:

Technology

Operator experience

Venous access

From RCTS:

Strict patient selection criteria

More experienced operators

# Single-centre, UK

N = 2019 (85.8% VVI)

1987 – 93

FU: 6w

## Early Complications After Dual Chamber Versus Single Chamber Pacemaker Implantation

A. CHAUHAN, A.A. GRACE, S.A. NEWELL, D.L. STONE, L.M. SHAPIRO, P.M. SCHOFIELD, and M.C. PETCH

PACE 1994

**Table IV.**  
Total Complications of Single Chamber Versus Dual Chamber Pacemakers

	VVI Pacemakers	Dual Chamber Pacemakers
Deaths	2	0
Pneumothorax	10 (0.6%)	2 (0.7%)
Wound infection	11 (0.6%)	6 (2.1%)
Hematoma	9 (0.5%)	2 (0.7%)
Chylocele	1	0
Lead displacement	18 (1%)	15 (5.2%)*
Atrial	—	11 (3.8%)
Ventricular	18	4 (1.4%)
Total	51 (2.9%)	25 (8.7%)*

\* P < 0.05



# CTOPP trial

N = 2568 (57% VVI)

FU: Perioperative

## EFFECTS OF PHYSIOLOGIC PACING VERSUS VENTRICULAR PACING ON THE RISK OF STROKE AND DEATH DUE TO CARDIOVASCULAR CAUSES

STUART J. CONNOLLY, M.D., CHARLES R. KERR, M.D., MICHAEL GENT, D.Sc., ROBIN S. ROBERTS, M.TECH., SALIM YUSUF, M.D., ANNE M. GILLIS, M.D., MAGDI H. SAMI, M.D., MARIO TALAJIC, M.D., ANTHONY S.L. TANG, M.D., GEORGE J. KLEIN, M.D., CHING LAU, M.D., AND DAVID M. NEWMAN, M.D.,  
FOR THE CANADIAN TRIAL OF PHYSIOLOGIC PACING INVESTIGATORS\*

NEJM 2000

**TABLE 1. INCIDENCE OF PERIOPERATIVE COMPLICATIONS.\***

COMPLICATION	VENTRICULAR PACING (N= 1471)	PHYSIOLOGIC PACING (N= 1084)	P VALUE
	% of patients		
Any	3.8	9.0	<0.001
Pneumothorax	1.4	1.8	0.42
Hemorrhage	0.4	0.2	0.32
Inadequate pacing	0.3	1.3	0.002
Inadequate sensing	0.5	2.2	<0.001
Device malfunction	0.1	0.2	0.40
Lead dislodgment	1.4	4.2	<0.001

\*Only patients who received a pacemaker are included. Some patients had more than one complication.

# Single centre study, Germany

N = 1214 (36% VVI)

1990 – 2001

## Long-Term Complication Rates in Ventricular, Single Lead VDD, and Dual Chamber Pacing

UWE K.H. WIEGAND, FRANK BODE, HENDRIK BONNEMEIER, FRANK EBERHARD, MONIKA SCHLEI, and WERNER PETERS

PACE 2003

Table III.  
Complications of Pacing Requiring Surgical Interventions

Complication	DDD	VDD	VVI	All
<b>Pacemaker pocket complications (%)</b>	<b>1.75</b>	<b>0.81</b>	<b>0.68</b>	<b>1.07</b>
Pocket bleeding* (%)	1.00	0.54	0.00	0.49
Pocket erosion (%)	0.25	0.00	0.45	0.25
Pocket or lead infection (%)	0.50	0.27	0.23	0.33
<b>Atrial lead related complications (%)</b>	<b>2.25</b>	<b>0.54</b>	–	<b>0.90</b>
Early dislodgment (%)	1.50	0.00	–	0.49
Symptomatic undersensing or exit block (%)	0.50	0.54	–	0.33
Insulation defect (%)	0.25	0.00	–	0.09
<b>Ventricular lead related complications (%)</b>	<b>1.25</b>	<b>1.35</b>	<b>1.35</b>	<b>1.32</b>
Early (micro)dislodgement (%)	0.50	0.27	0.45	0.41
Exitblock during follow-up (%)	0.25	0.27	0.00	0.16
Undersensing/Oversensing (%)	0.00	0.27	0.23	0.16
Insulation defect (%)	0.25	0.54	0.45	0.41
Lead perforation (%)	0.25	0.00	0.23	0.16
Pneumothorax with need for drainage (%)	1.50	0.27	0.00	0.58
Sinus node syndrome in VDD (%)	–	0.27	–	0.09
Pacemaker syndrome (%)	0.00	0.00	0.67	0.25
<b>Overall complication rate (%)</b>	<b>6.75*</b>	<b>3.23</b>	<b>2.71</b>	<b>4.20</b>

	VVI
Overall	2.71 %
Pneumothorax	0.00 %
Bleeding	0.00 %
Perforation	0.23 %
Device infection	0.23 %
Lead complication	1.12 %

**Table 3** Complications within 2 months and during long-term follow-up occurring in 1517 patients with a first pacemaker

	Within 2 months		During follow-up	
	n	%	n	%
Traumatic complications—total	42	2.77	1	0.07
Perforation of cardiac structure	6	0.40	1	0.07
Pneumo(hemo)thorax	34	2.24	0	0
Pericardial effusion	2	0.13	0	0
Lead related complications—total	84	5.54	84	5.54
Lead fracture*	2	0.13	6	0.40
Lead dislocation or disconnection*	50	3.30	24	1.58
Insulation problem*	4	0.26	11	0.73
Infection (ie, lead endocarditis)*	0	0	3	0.20
Stimulation threshold problem	12	0.79	26	1.71
Diaphragm or pocket stimulation	11	0.73	10	0.66
Diaphragm or pocket stimulation*	0	0	1	0.07
Other†	5	0.33	3	0.20
Pocket complications—total	72	4.75	49	3.23
Hematoma	44	2.90	1	0.07
Difficult to control bleeding*	4	0.26	2	0.13
Infection	10	0.66	4	0.26
Infection*	4	0.26	8	0.53
Discomfort due to pocket or pacemaker	1	0.07	17	1.12
Discomfort due to pocket or pacemaker*	2	0.13	9	0.59
Skin erosion	7	0.46	8	0.53
Pulse generator problem—total	5	0.33	23	1.52
Problem with connection screw	5	0.33	0	0
Manufacturer recall	0	0	5	0.33
Manufacturer recall*	0	0	6	0.40
Reset to default settings	0	0	4	0.26
Device cannot be programmed	0	0	2	0.13
Pacemaker tachycardia	0	0	2	0.13
Malfunction of software algorithm	0	0	4	0.26
Total number of complications in need of reoperation	64	4.22	61	4.02
Number of patients experiencing a complication	188	12.4	140	9.20

## Incidence and predictors of short- and long-term complications in pacemaker therapy: The FOLLOWPACE study

Erik O. Udo, MD,<sup>\*,†</sup> Nicolaas P.A. Zuithoff,<sup>†</sup> Norbert M. van Hemel, MD, PhD,<sup>\*</sup> Carel C. de Cock, MD, PhD,<sup>‡</sup> Thijs Hendriks,<sup>‡</sup> Pieter A. Doevendans, MD, PhD,<sup>\*</sup> Karel G.M. Moons, PhD<sup>‡</sup>

*Heart Rhythm* 2012

	Any PM at 2m
Overall	12.4 %
Pneumothorax	2.24 %
Haematoma	2.90 %
Perforation	0.53 %
Device infection	0.92 %
Lead complication (RA+RV)	5.54 %

Danish ICD Register

D I R DENMARK



Danish Pacemaker Register

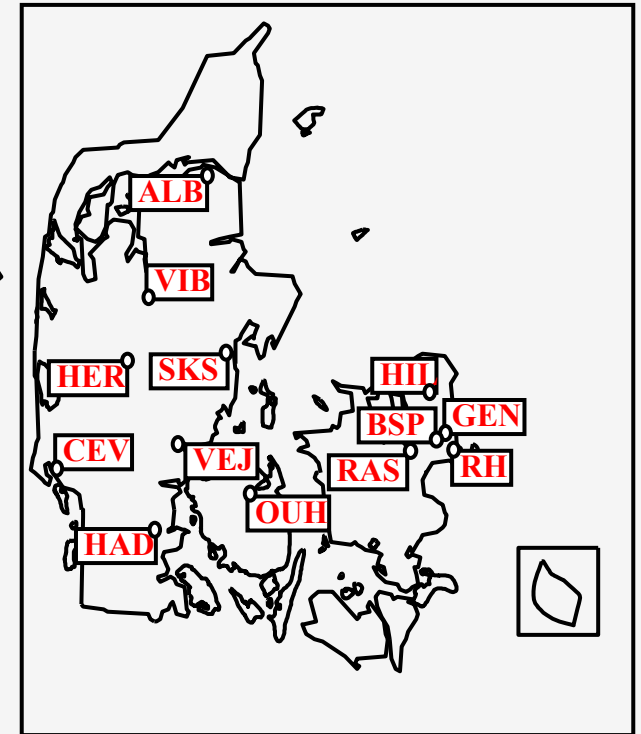
D P R DENMARK



Established in 1982

Contains data on all Danish  
device procedures

14 implanting centres



Danish ICD Register

D I R



D E N M A R K

Danish Pacemaker Register

D P R



D E N M A R K

Complication registration:

1982: Removal of hardware

1997: Major complications, first PM and CRT-P (3 months)

2009: Any complication, any procedures (no time limit)

# Danish national study 1997-2008

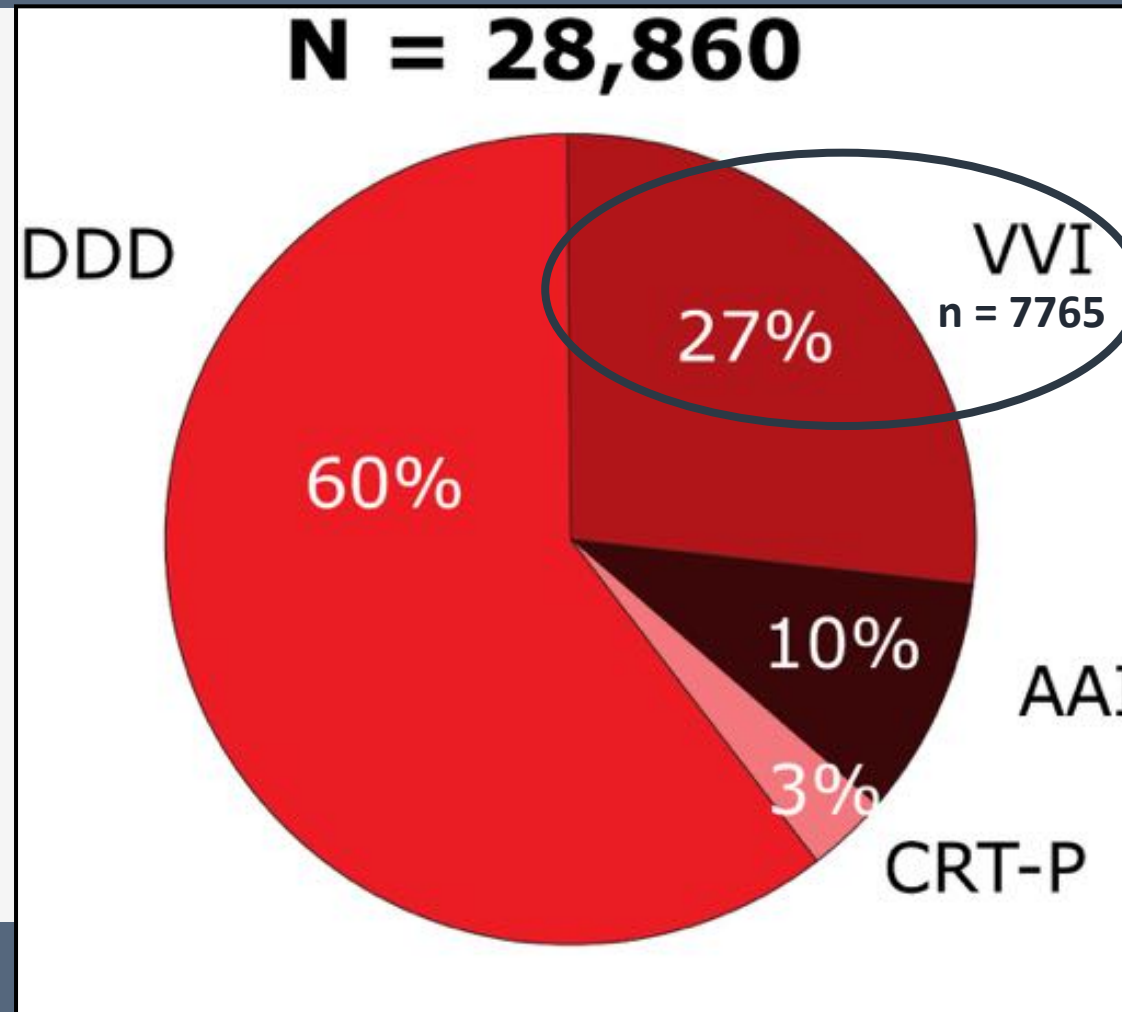
Population-based cohort study

All Danish primary PM or CRT-P implantations

1997-2008

Outcome: lead complication within first 3 months  
pneumothorax requiring drainage  
cardiac perforation

# Danish national study 1997-2008



# Lead complications

## Risk factors for lead complications in cardiac pacing: A population-based cohort study of 28,860 Danish patients

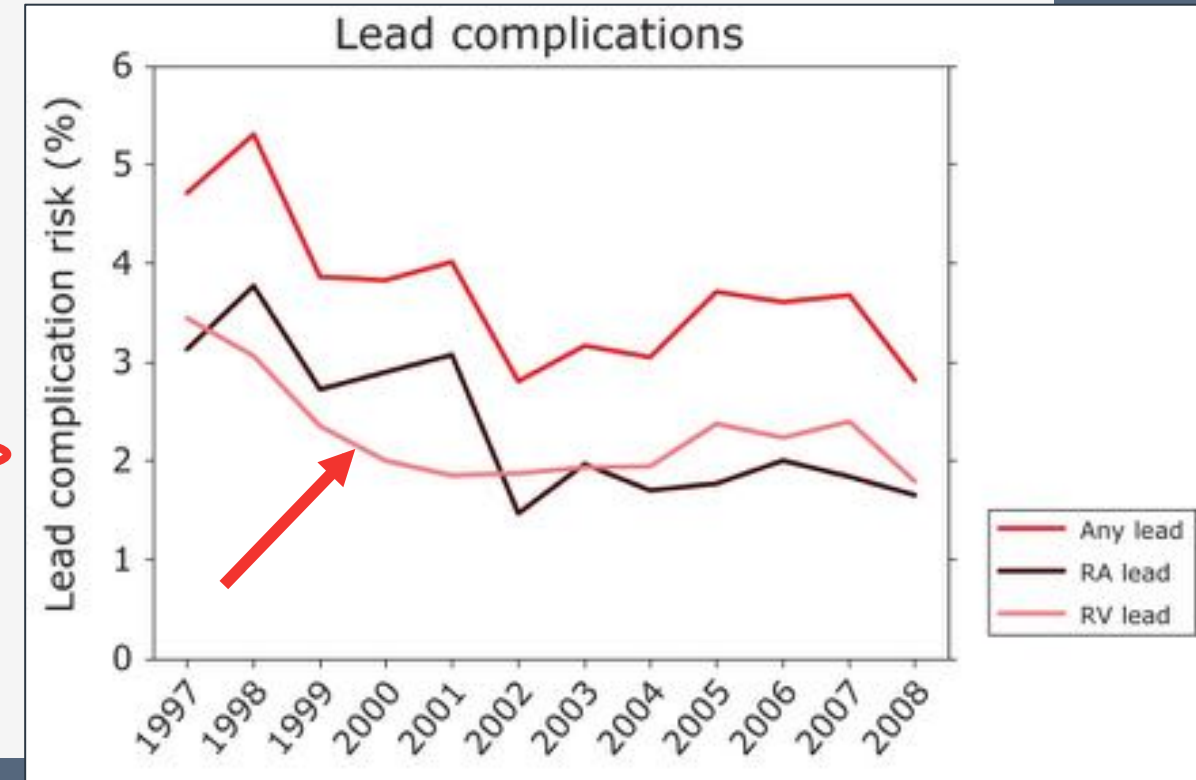
Rikke Esberg Kirkfeldt, MD,<sup>\*†</sup> Jens Brock Johansen, MD, PhD,<sup>†‡</sup> Ellen Aagaard Nohr, PhD,<sup>§</sup> Mogens Moller, MD, DMSc,<sup>†‡</sup> Per Arnsbo, BScEE,<sup>†‡</sup> Jens Cosedis Nielsen, MD, PhD, DMSc<sup>\*</sup>

*Heart Rhythm 2011*

**Table 2** Lead complication risks after device implantations: The Danish Pacemaker Register 1997–2008

Lead type	Total number	Lead complications	Risk (%)	95% CI
RA lead	21,024	472	2.3	2.0–2.5
RV lead	26,079	575	2.2	2.0–2.4
LV lead	884	38	4.3	3.1–5.9
Any lead	28,860	1,048	3.6	3.4–3.9

CI = confidence interval; LV = left ventricular; other abbreviations as in Table 1.





# Danish national study 1997-2008

Pneumothorax:

n = 190 (0.7%)

## Pneumothorax in cardiac pacing: a population-based cohort study of 28 860 Danish patients

Rikke Esberg Kirkfeldt<sup>1,4\*</sup>, Jens Brock Johansen<sup>2,4</sup>, Ellen Aagaard Nohr<sup>3</sup>, Mogens Moller<sup>2,4</sup>, Per Arnsbo<sup>2,4</sup>, and Jens Cosedis Nielsen<sup>1</sup>

*Europace 2012*

Device type	
Single lead atrial device	0.7
<u>Single lead ventricular device<sup>b</sup></u>	<u>0.5</u>
Dual-chamber device	0.7
Cardiac resynchronization therapy device	0.7

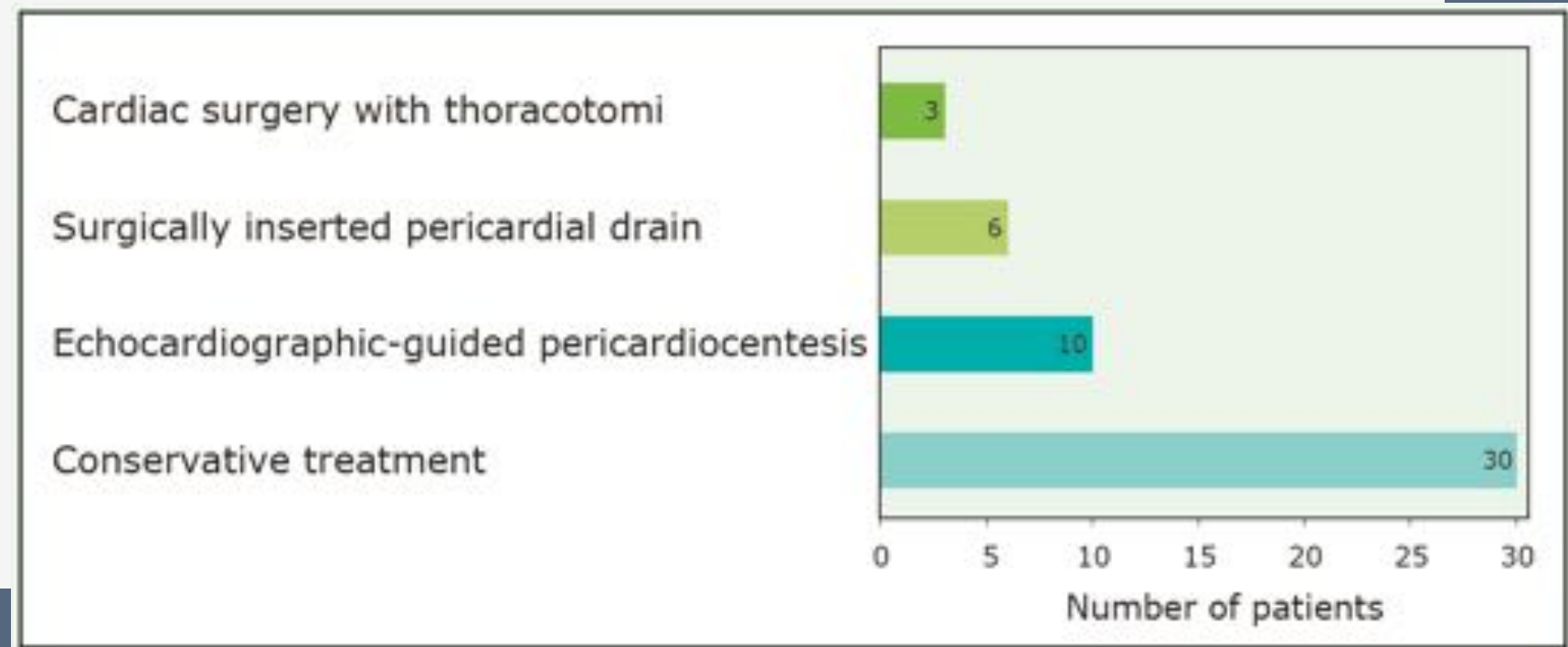
Venous access technique	
<u>Cephalic vein cut-down<sup>b</sup></u>	<u>0.2</u>
Subclavian vein puncture	1.2
Both cephalic vein cut-down and subclavian vein puncture	0.9

# Danish national study 1997-2008

Cardiac perforation:

n = 49 (0.2%)

(RV n = 45)



# Danish national study 2010-2011

Prospective, population-based cohort study

All Danish device patients

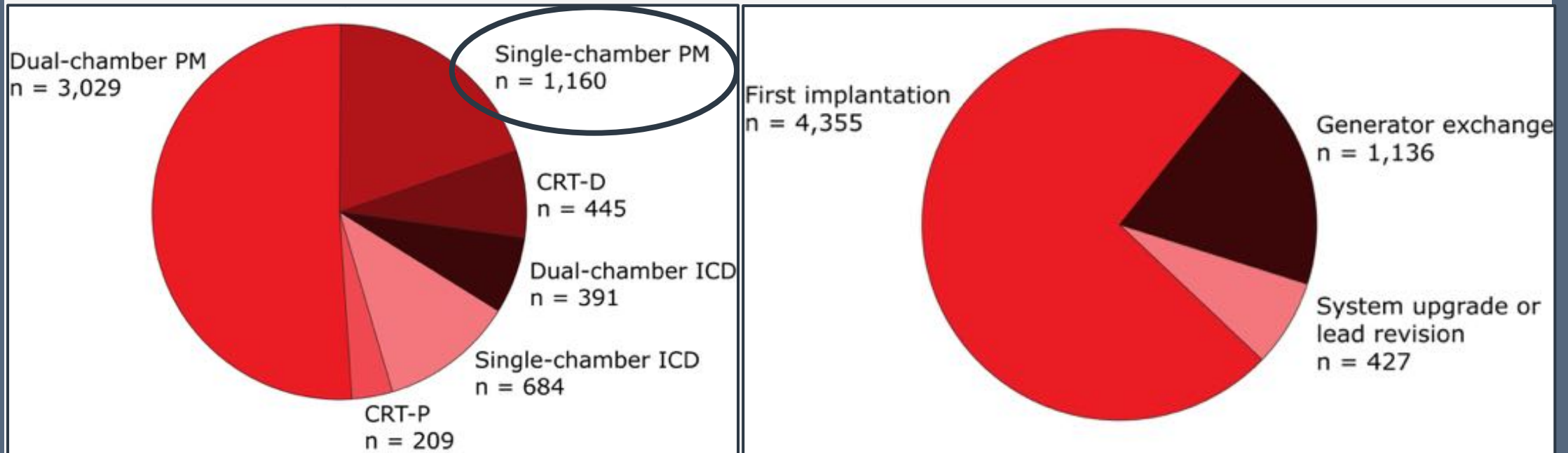
May 2010 to April 2011

Outcome: any complication within first 6 months

Review of *all* patient charts

# Danish national study 2010-2011

N=5,918

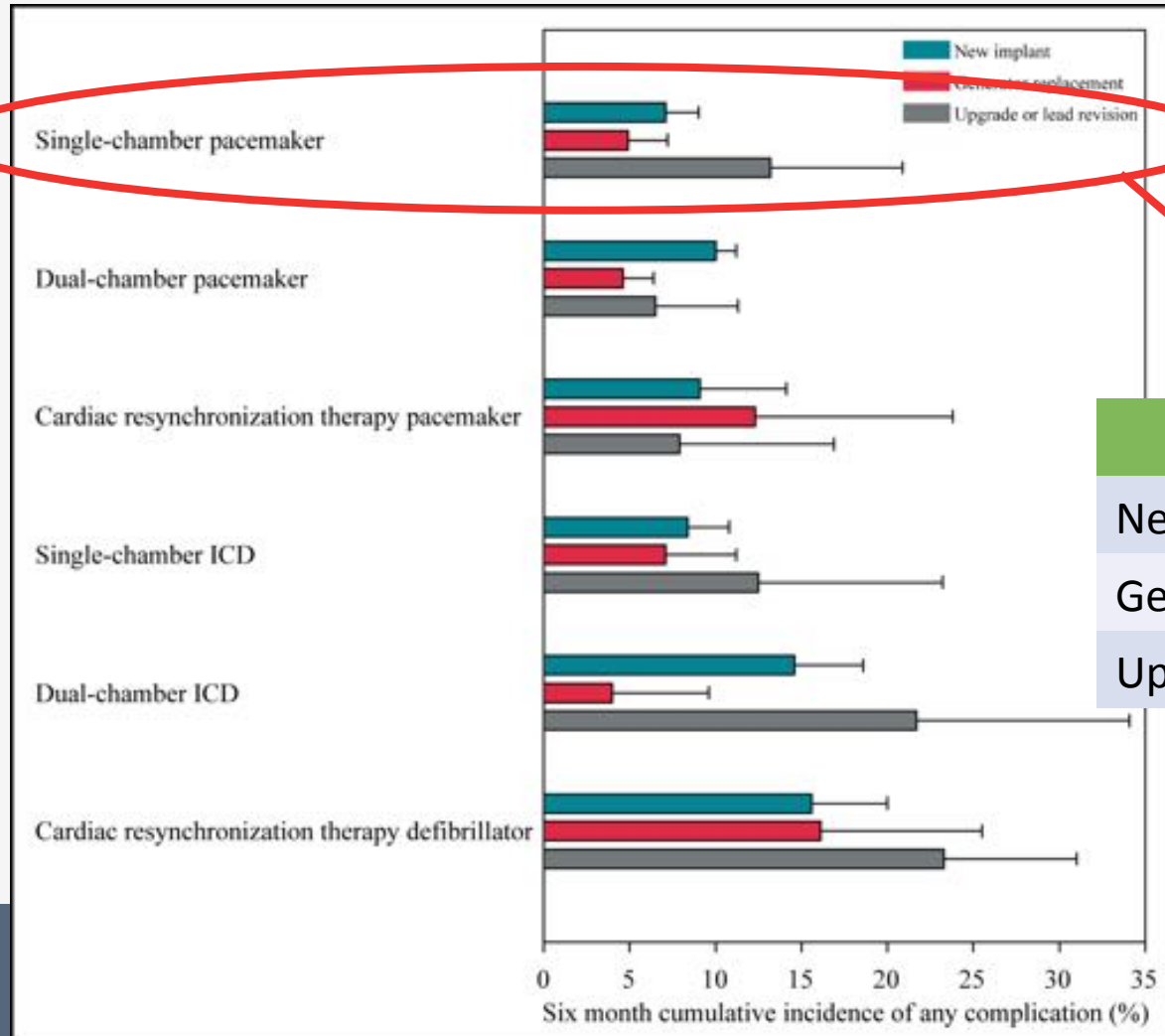


# Danish national study 2010-2011

## Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark

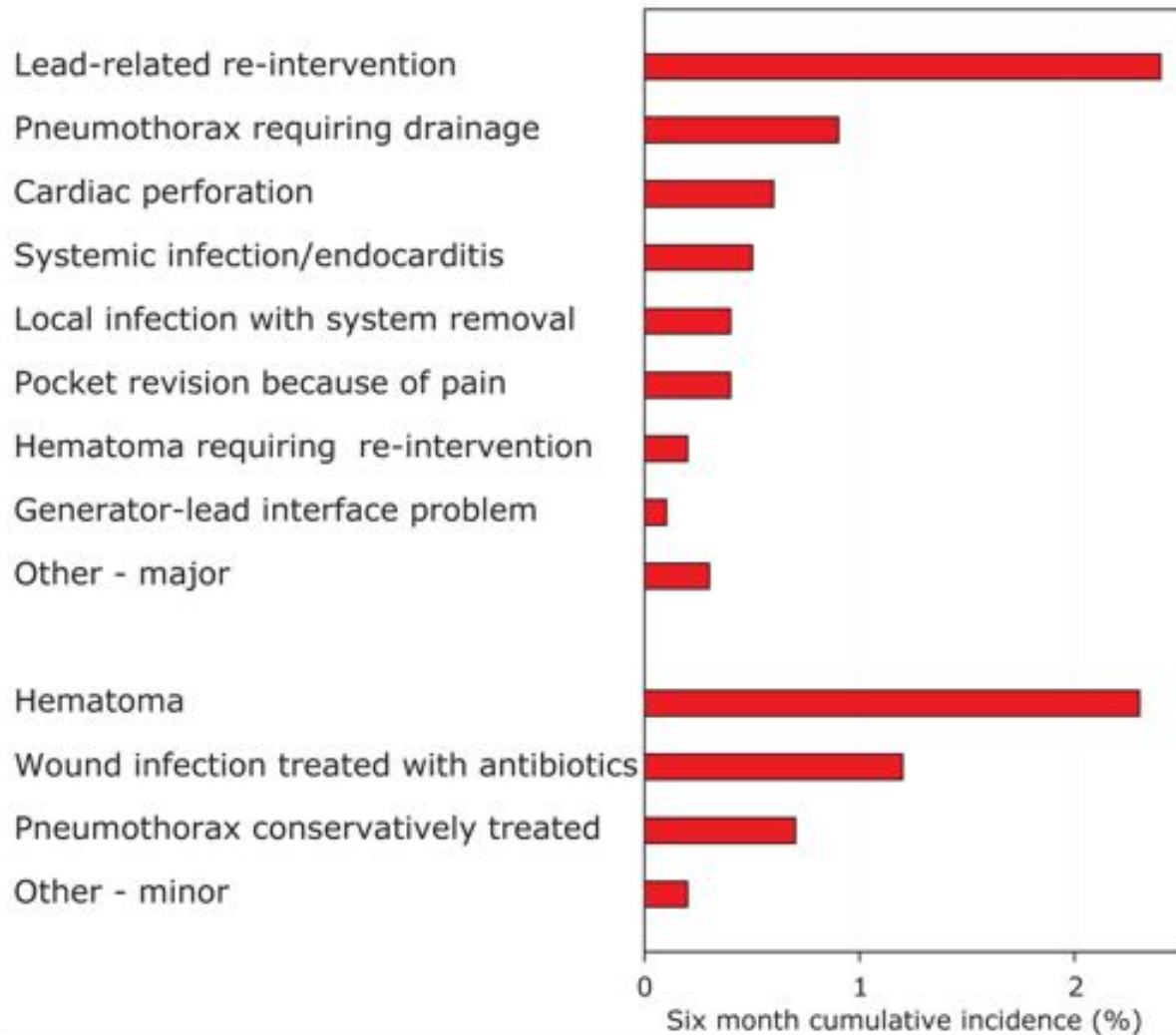
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*European Heart Journal 2014*



Any complication	
New implant	7.1%
Generator replacement	4.9%
Upgrade or lead revision	13.2%

# Danish national study 2010-2011



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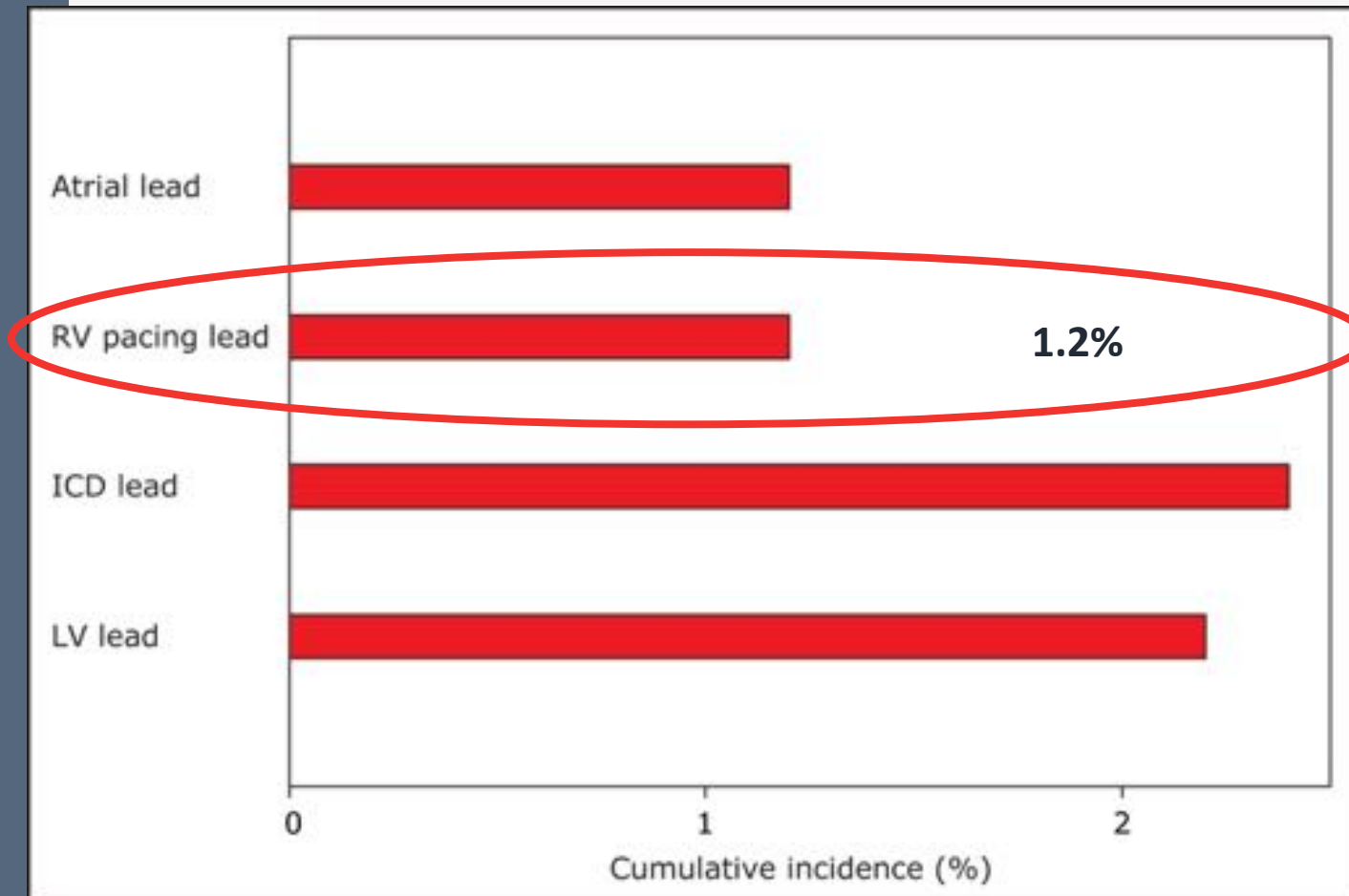
*European Heart Journal 2014*

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*European Heart Journal 2014*

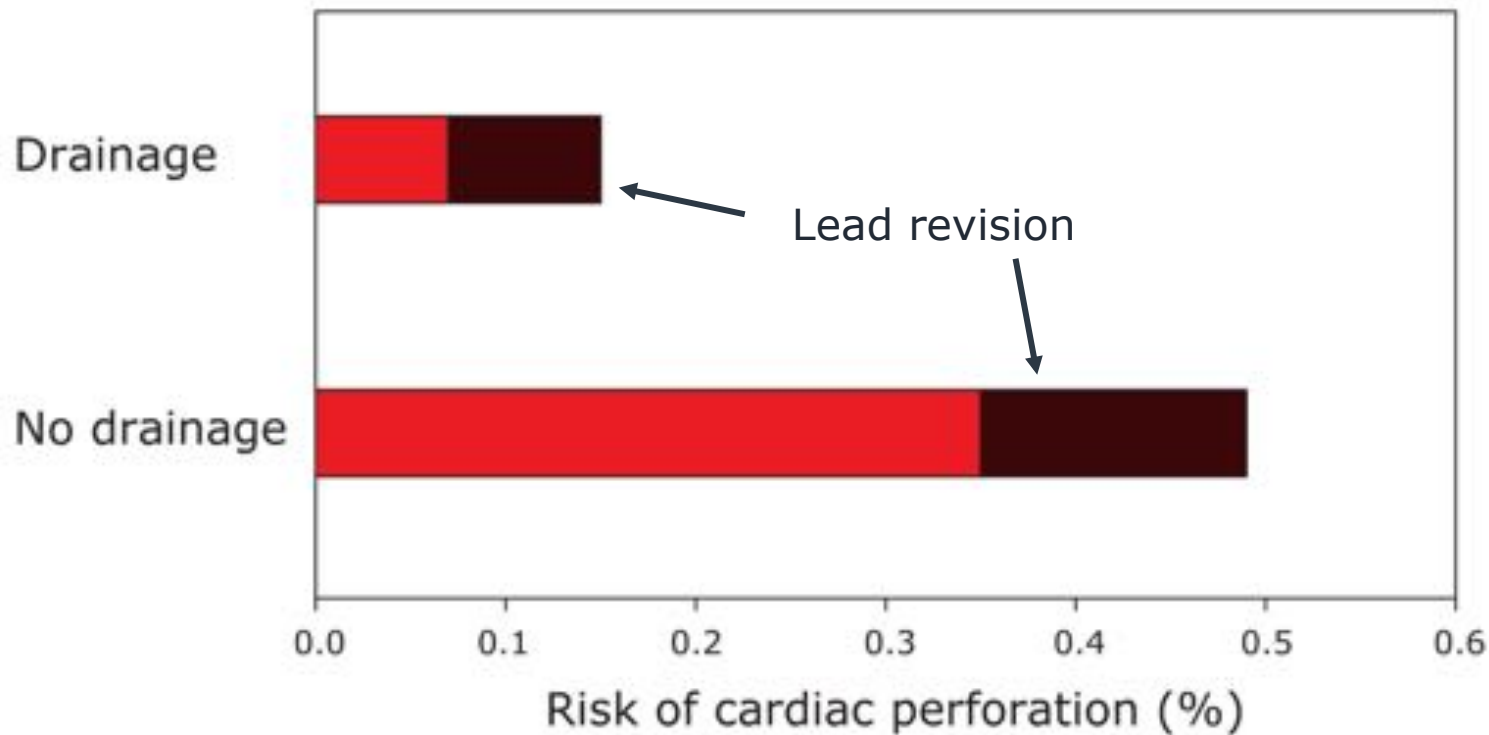


# Danish national study 2010-2011

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*European Heart Journal 2014*





Specific data on VVI complications  
- in a contemporary setting –  
is scarce

Short term complications	Risk (%)
<b>Any</b>	7
<b>Lead</b>	1-2
<b>Pneumothorax</b>	0.5
<b>Infection</b>	0.5-1
<b>Perforation</b>	0.2-1
<b>Haematoma</b>	2-3
<b>Procedure-related mortality</b>	0

Thank you