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Center of Research on Psychology in Somatic diseases

Psychological issues - state of the art

Susanne S. Pedersen, Professor of Cardiac Psychology

Disclosures of conflict of interest

Speaker or consultancy fees from:

- **Medtronic**
- **St. Jude Medical**
- **Cameron Health**
- **Sanofi Aventis**

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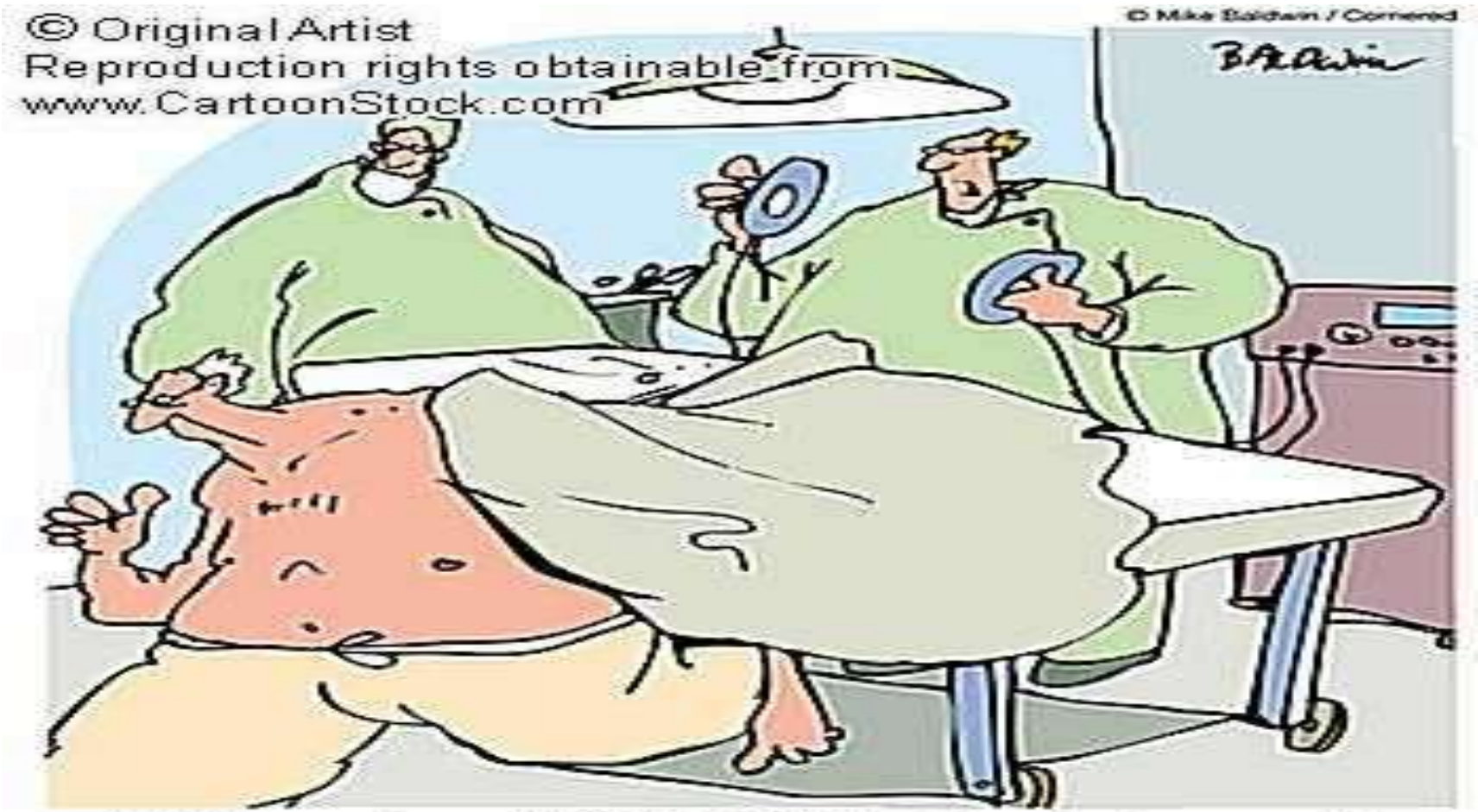
Overview

- Living with an ICD – the patient perspective:
  - Expanding indications
  - Potential hardware malfunctioning and device advisories
  - ICD shocks
- A subgroup of high-risk patients
- ICD shock – the paradox
- Take home message



"When I yell 'CLEAR' that doesn't mean you."

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ICD therapy: Survival benefits

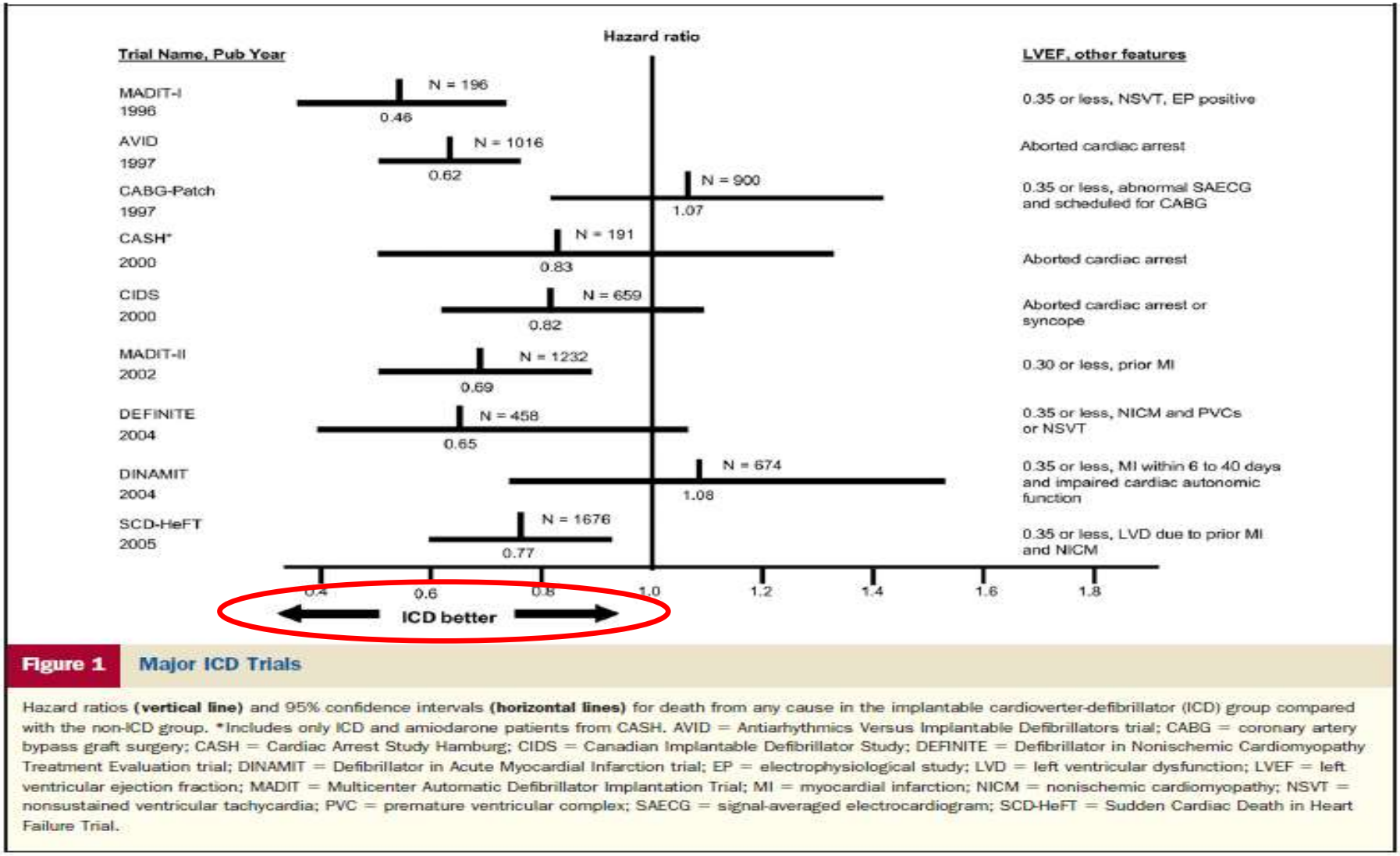
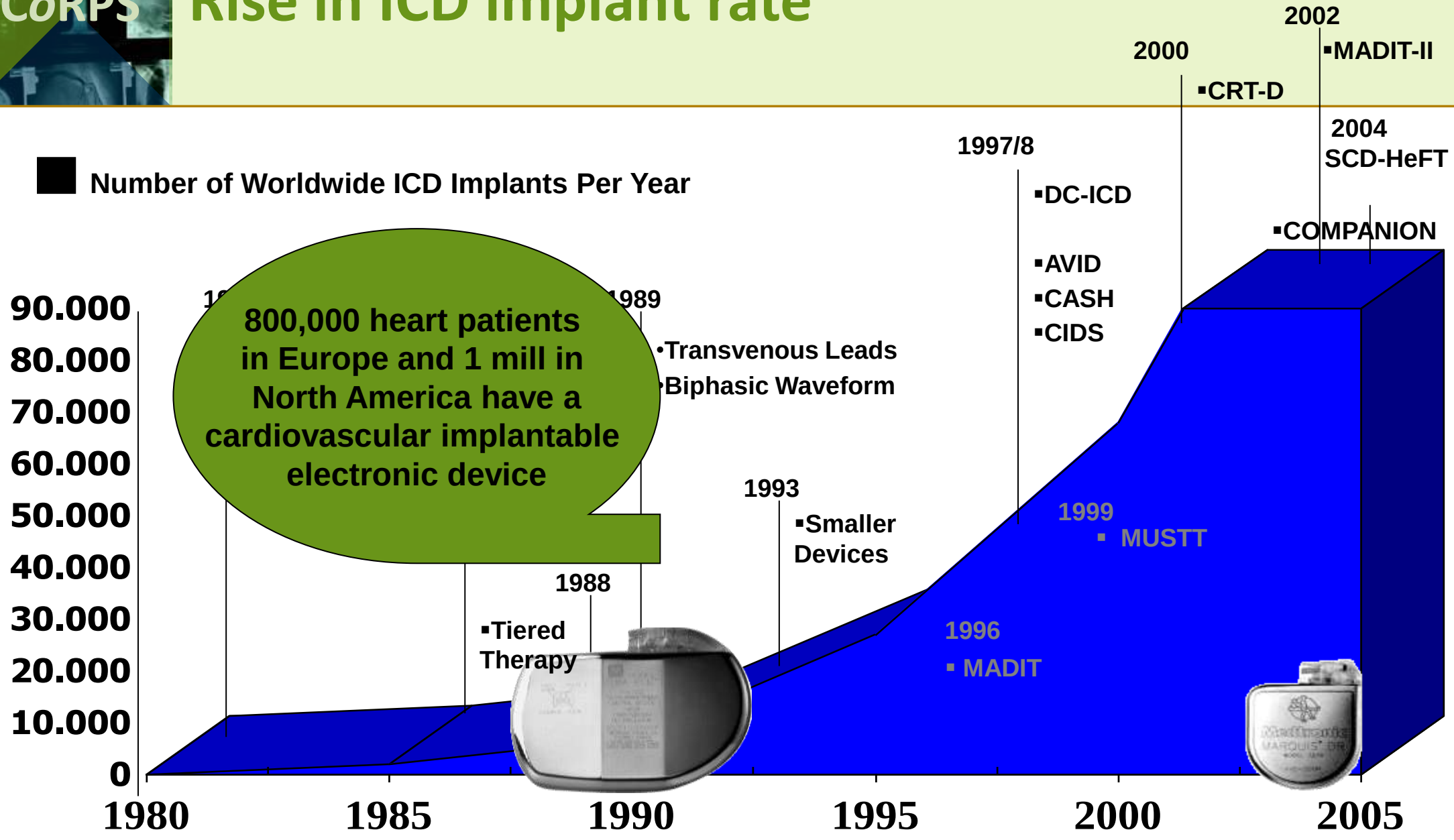


Figure 1 **Major ICD Trials**

Hazard ratios **(vertical line)** and 95% confidence intervals **(horizontal lines)** for death from any cause in the implantable cardioverter-defibrillator (ICD) group compared with the non-ICD group. *Includes only ICD and amiodarone patients from CASH. AVID = Antiarrhythmics Versus Implantable Defibrillators trial; CABG = coronary artery bypass graft surgery; CASH = Cardiac Arrest Study Hamburg; CIDS = Canadian Implantable Defibrillator Study; DEFINITE = Defibrillator in Nonischemic Cardiomyopathy Treatment Evaluation trial; DINAMIT = Defibrillator in Acute Myocardial Infarction trial; EP = electrophysiological study; LVD = left ventricular dysfunction; LVEF = left ventricular ejection fraction; MADIT = Multicenter Automatic Defibrillator Implantation Trial; MI = myocardial infarction; NICM = nonischemic cardiomyopathy; NSVT = nonsustained ventricular tachycardia; PVC = premature ventricular complex; SAECG = signal-averaged electrocardiogram; SCD-HeFT = Sudden Cardiac Death in Heart Failure Trial.

Epstein, J Am Coll Cardiol 2008;52:1122-7

Rise in ICD implant rate



Crespo et al. Am J Med Sci 2005;329:238-46

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Impact of ICD indication on patient reported outcomes

Table 1. Overview of studies on the impact of ICD indication on patient-centered outcomes

Authors	*N*	*Study design*	*Follow-up*	*Questionnaire(s)*	*Disease-specific questionnaire used*	*Endpoint(s)*	*Impact of indication*
Bilge et al.[13]	91	Cross-sectional (3 to 60+ months after ICD implantation)	-	HADS[1]	No	Anxiety; depression	No significant impact
Groeneveld et al.[14]	120	Cross-sectional (median = 2 yrs)	-	Euro-QoL[1]; SF-12[1]; Health Utilities Index-Mark 3[1]; FPAS[2]; Essential ICD QoL Domains[2]	Yes	General and ICD-specific QoL	No significant impact
Pedersen, et al.[15]	154	Prospective	3 months	SF-36[1]	No	QoL	No significant impact
Pedersen, et al.[16]	176	Prospective	6 months	HADS[1]	No	Anxiety; depression	No significant impact
Sweeney et al.[17]	426	RCT	12 months	SF-36[1]	No	QoL	No significant impact
Van den Broek et al.[18]	308	Prospective	2 months	STAI[1]; HAM-A[1]	No	Anxiety	No significant impact
Van den Broek et al.[19]	165	Prospective	2 months	HCS[2]; ICDC[2]; HAM-A[1]	Yes	Feelings of disability; cardiopulmonary symptoms; ICD concerns; anxiety	No significant impact

No impact

N = sample size; FPAS = Florida Patient Acceptance Survey; HADS = Hospital Anxiety and Depression Scale; HAM-A = Hamilton Rating Scale for Anxiety; HCS = Health Complaints Scale; ICDC = ICD Concerns questionnaire: QoL = quality of life; RCT = randomized controlled trial; SF-12; Short Form Health Survey 12; SF-36 = Short Form Health Survey 36; STAI = Spielberger State-Trait Anxiety Index

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Impact of device advisories on patient reported outcomes

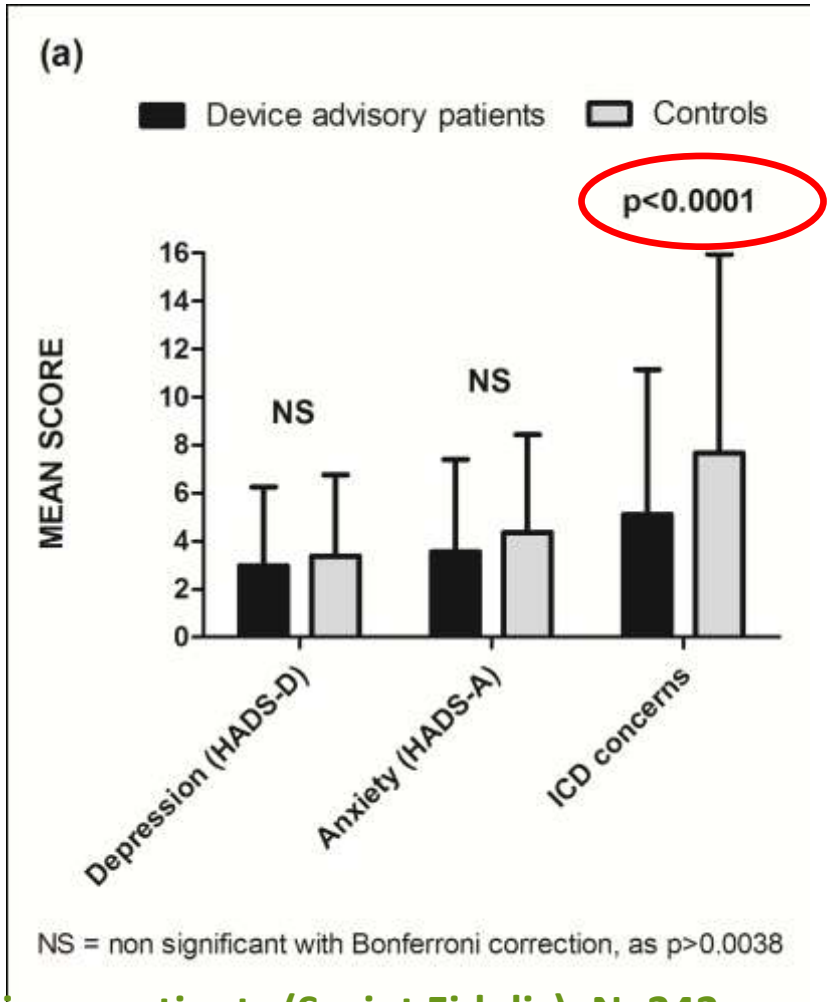
Table 1. Overview of studies on the impact of device advisories on patient-centered outcomes

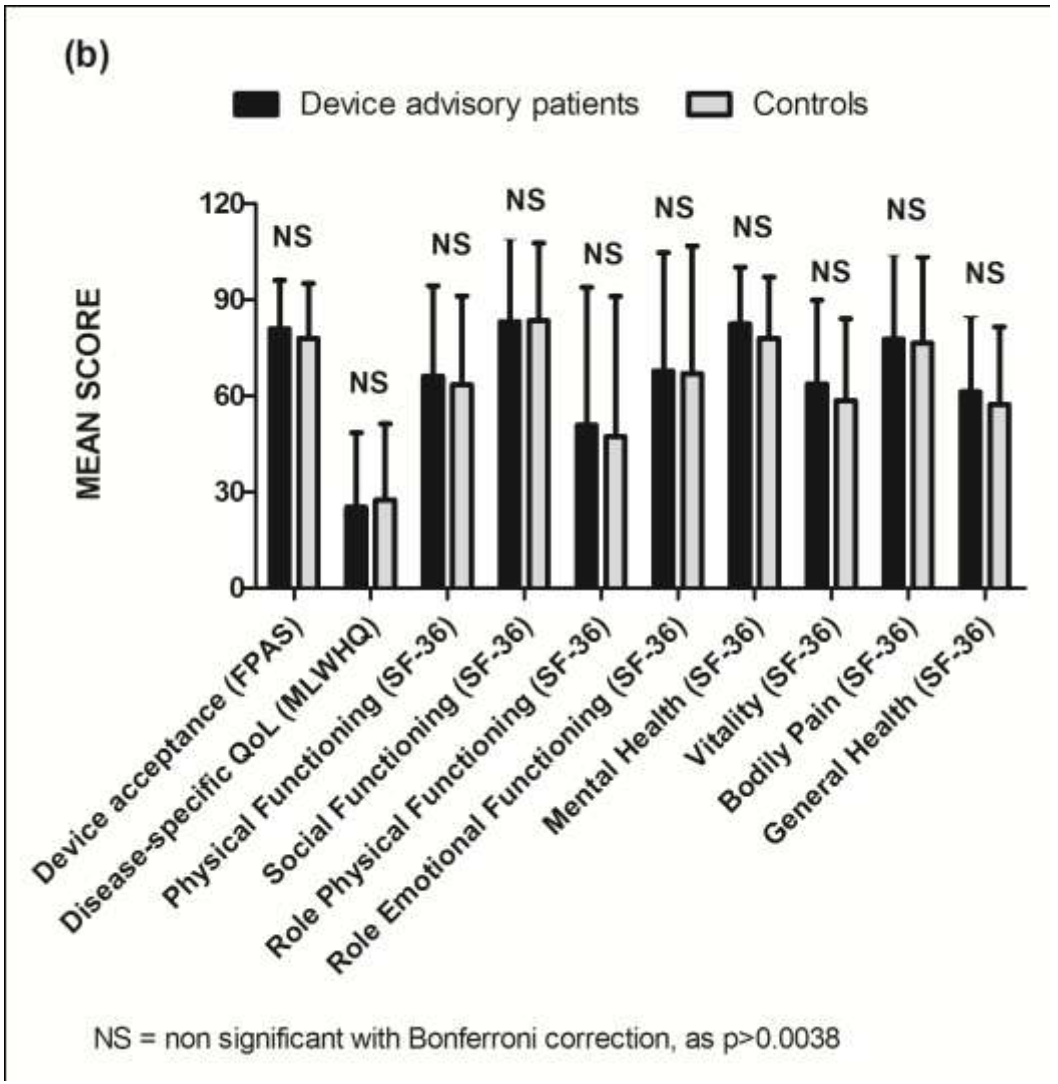
Authors	*Advisory*	*N*	*Response rate*	*Study design*	*Time between advisory and assessment*	*Endpoint*	*Impact of device advisory*
Birnie et al. (2009) (18)	Class II advisory (Medtronic)	86 advisory patients; 94 controls	Patients 70.5% Controls 70.1%	Case-control	> 24 months	Device acceptance[2]	No significant impact
van den Broek et al. (2006) (13)	Class II advisory (Medtronic)	33 advisory patients	90%	Prospective; 14 ± 4 month follow-up	< 2 months*	Anxiety[1]	Increase in the number of anxious patients from 6.1% pre compared to 24.2% post advisory
Cuculi et al. (2006) (14)	Class I advisory (Guidant)	30 advisory patients; 25 controls	*not mentioned*	Case-control	< 1 month	Distress[1]	No significant impact; 3 distress measures were significantly higher in the controls
Gibson et al. (2008) (15)	Class I advisory: 13/31 (42%) (Guidant)	31 advisory patients; 50 controls	89%	Case-control	<1 to >4 months	Distress[1]; QoL[1]	No significant impact
Sneed et al. (1994) (16)	Class II advisory (Guidant)	21 advisory patients; 21 caregivers	100%	Prospective, case-control; 1-month follow-up	1 to 3 months	Distress[2]; uncertainty[2]; confidence in device[2]	Patient and caregiver confidence decreased; anxiety increased in patients and confusion in caregivers over time
Undavia et al. (2008) (17)	Class I advisory: 43/61 (70%) (*not mentioned*)	61 advisory patients; 43 controls	90%	Case-control	7.6 ± 1.6 months	Anxiety[1]; depression[1]; QoL[2]	No significant impact

Mixed evidence

QoL = Quality of life; [1] Generic measure; [2] Disease-specific measure; * conveyed via personal communication with the author

Impact of device advisories on patient reported outcomes – Danish study





Advisory patients (Sprint Fidelis): N=343
Non-advisory controls: N=510

Pedersen, Versteeg, Nielsen, Mortensen & Johansen. Submitted

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ICD shock is a critical event for patients

- **It is physically painful (6 on a 0-10 point pain scale)**
- ***"It's like getting kicked in the chest by a big horse!"***

Ahmad et al. PACE 2000;23:931-33

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General belief – ICD shock explains all distress in ICD patients

- *"Most research has pointed to ICD shock as the primary culprit if reductions in quality of life occur…"*
- *"Implantable cardioverter defibrillator (ICD) patients potentially face significant psychological distress because of their risk for life-threatening arrhythmias and the occurrence of ICD shock…"*
- *"Those individuals who experience an ICD shock relate greater levels of psychological distress, anxiety, anger, and depression than those who do not…"*

Sears et al. Circulation 2005;111:e380-2; Sears et al. PACE 2007;30:858-64; Raitt J Am Coll Cardiol 2008;51:1366-8

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Continuum of shock response

Table 5 Continuum of shocks, coping, and distress

	Arrhythmia	Coping	Distress	Feelings, thoughts, and behaviours
Continuum	No arrhythmia	Optimism	Reassurance	ICD as 'guardian angel'
		Active coping	Successful adjustment	ICD doesn't bother me
	ATP only	Faith in doctors	Realistic fear	ICD may fail
	Single shock	Depressive coping	Adjustment disorder	Uncertain if ICD keeps me safe
			Shock phobia	Avoid activities that might trigger shocks
	Multiple shocks	Distraction/denial	Moderate depression/agoraphobia	Avoid any activities, withdraw
	Electric storm	Catastrophizing	Dysthymia/generalized anxiety	Lose interest/confidence in life, permanent worry
		Resignation	PTSD/personality change	Permanent threat and arousal
			Severe/recurrent depression	Wanting to be dead

Modified from Sears and Conti.[12]

Braunschweig, Boriani, ... Pedersen et al., Europace 2010;12:1673-90

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Predictors of quality of life (8 months)

	Age, LVEF	Psychological variables*	Shocks	Total variance
General health	21.2%	39.9%	3.5%	64.5%
Mental health	13.7%	27.4%	0.7%	41.8%
Physical health	23.4%	24.1%	7.3%	54.8%

** Social support, optimism, depression, anxiety*

Sears et al. Psychosomatics 2005;46:451-7

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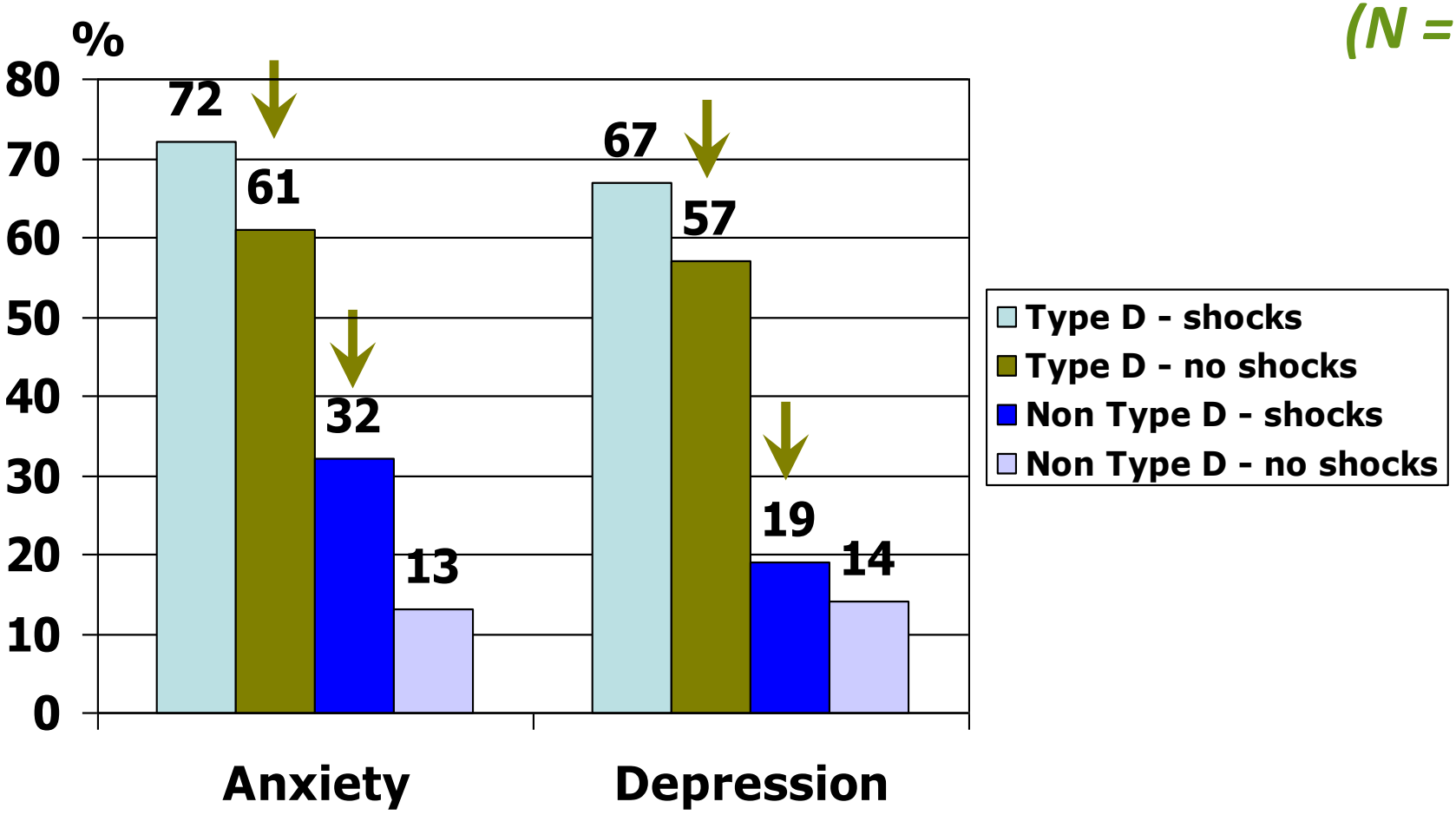
Prevalence of anxiety and depression in patients stratified by Type D and shocks

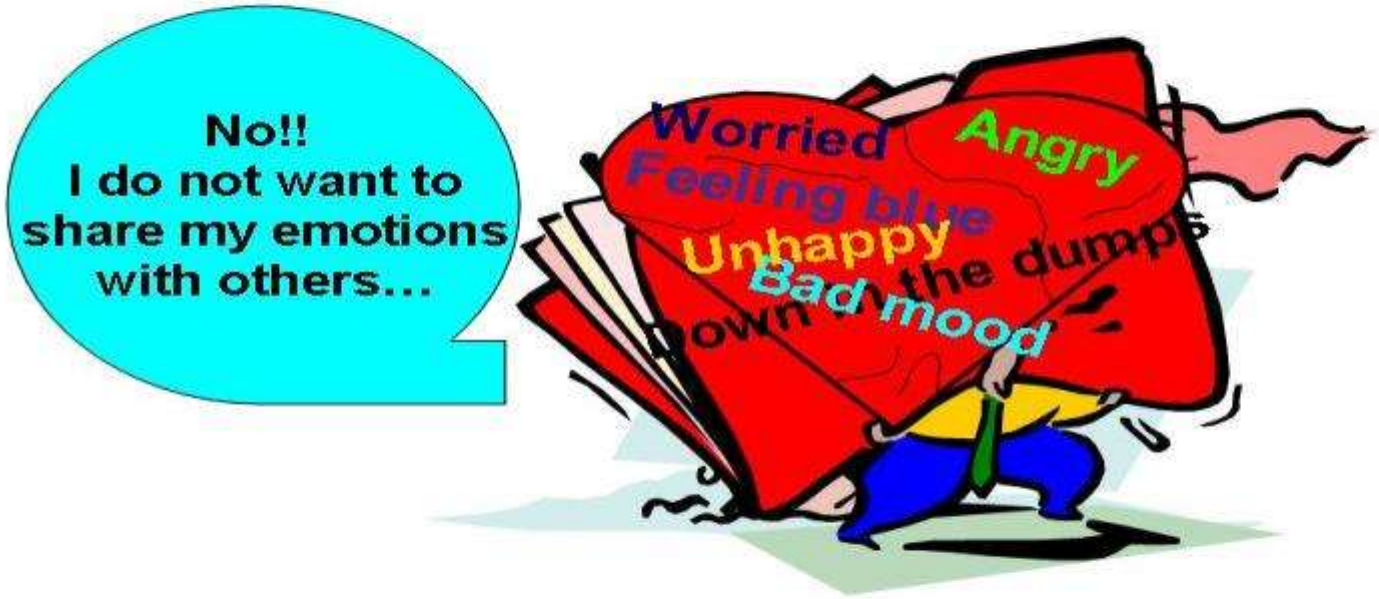
(N = 182)



Pedersen et al. Psychosom Med 2004;66:714-9

Type D (distressed) personality

The burden of increased negative emotions and inhibition



Pedersen & Denollet. Curr Cardiol Rev 2006;2:205-13
Denollet et al. Circulation Cardiovasc Qual Outcomes 2010;3:546-5

Prevalence of anxiety and depression in patients stratified by Type D and shocks

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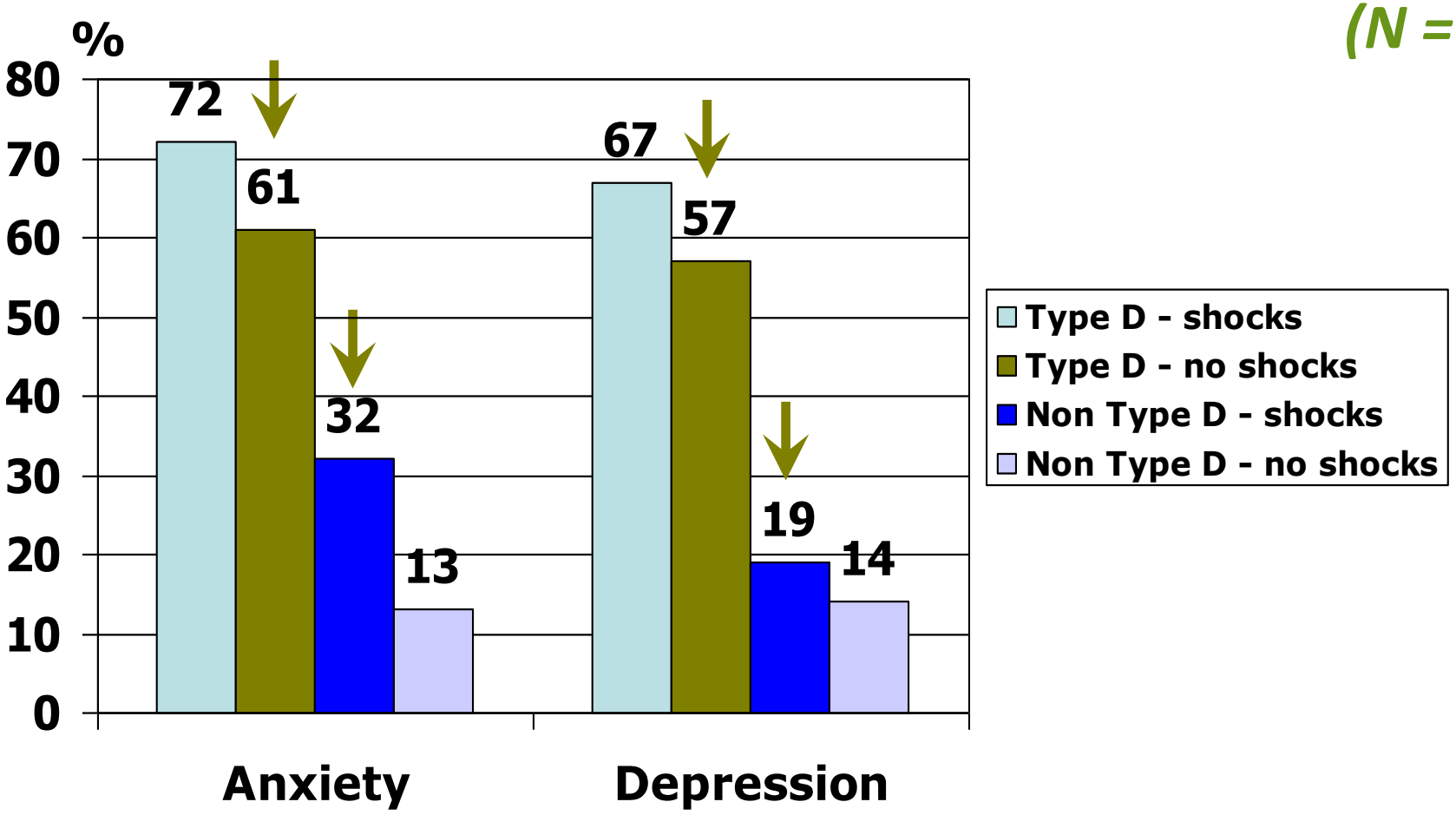
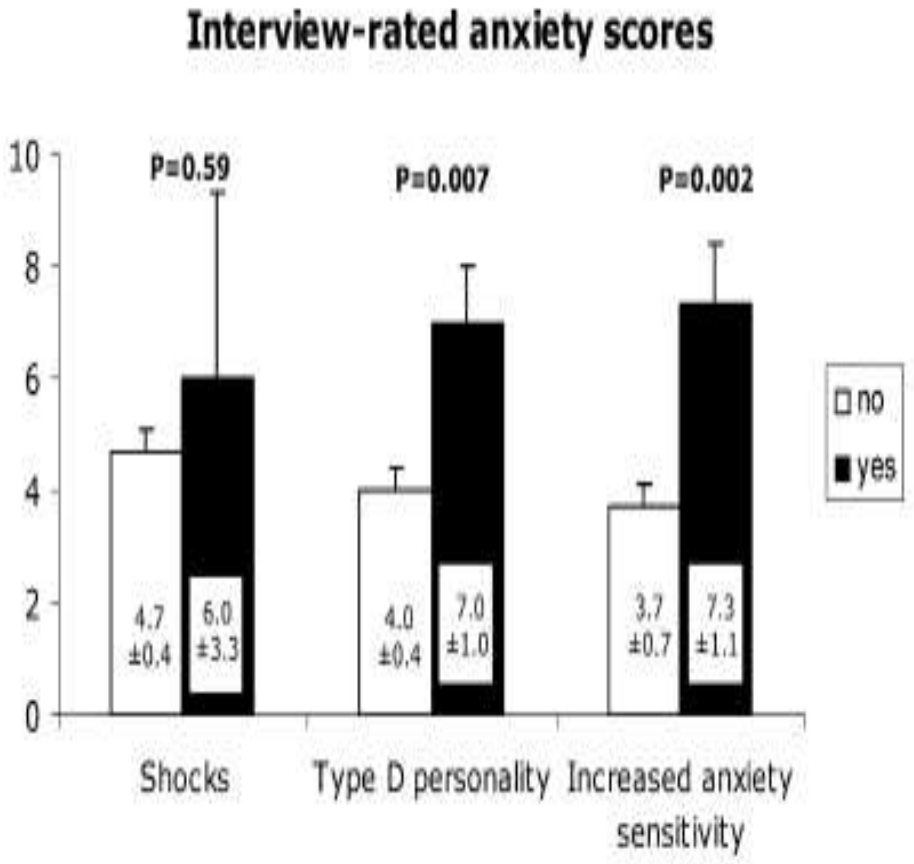


Pedersen et al. Psychosom Med 2004;66:714-9

Shocks, Type D and anxiety sensitivity as predictor of interview-rated anxiety

(N = 308)



Multivariate Predictors of Interviewer-Rated Anxiety at 2 Months Following ICD Implantation

	Interviewer-Rated Anxiety	
	β	P
Type D personality	0.18	0.021
Anxiety sensitivity	0.19	0.016
Shocks	0.01	0.90
Demographics		
Female	0.05	0.58
No partner	−0.01	0.90
Low education*	0.03	0.71
Age	−0.09	0.25
Clinical variables		
Secondary prevention	0.05	0.50
Ischemic heart disease†	0.06	0.45
Comorbidity‡	0.08	0.27

*Less than 13 years of education.
†Previous MI, PCI, CABG.
‡Lung, renal, and/or rheumatic disease, and/or diabetes.

Van den Broek et al, PACE 2008;31:850-7

Shocks, Type D and anxiety sensitivity as predictor of self-reported anxiety*

(N = 308)

- **Main effects for Type D ($p<.0001$) and anxiety sensitivity ($p=.0001$), but not shocks ($p=.30$)**
- **No significant change in anxiety during follow-up ($p=.10$), but significant time *by* shocks effect ($p=.003$)**

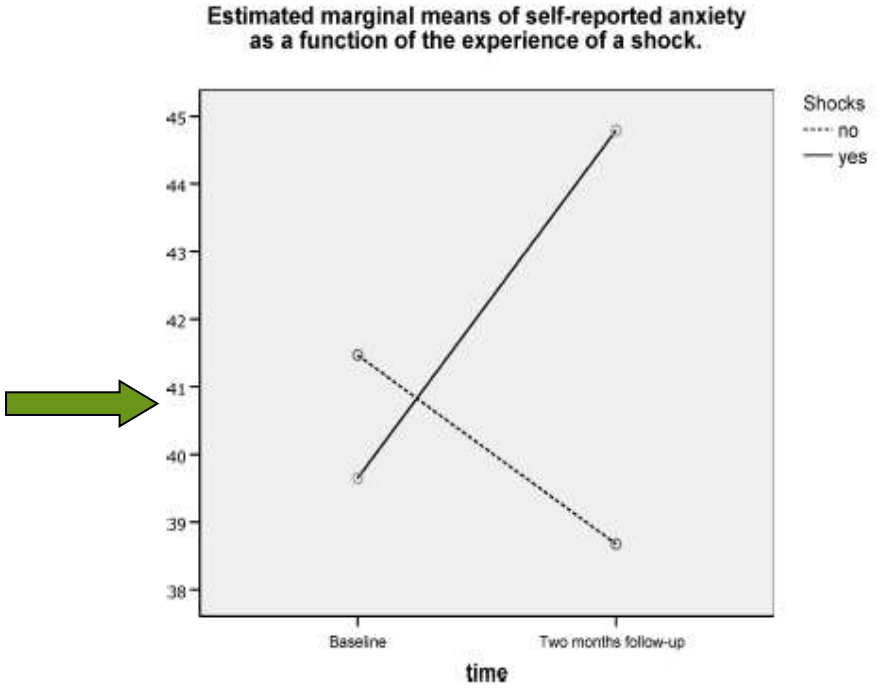


Figure 1. *Estimated marginal means of self-reported anxiety as a function the experience of a shock.*

*Assessed with STAI at baseline and 2 months

Adjusting for anxiety sensitivity, Type D, age, shocks, gender, marital status, education, ICD indication, and age (ANCOVA with repeated measures)

Van den Broek et al, PACE 2008;31:850-7

Correlates of anxiety and depression

	Anxiety OR [95% CI]	Depression OR [95% CI]
Female gender	2.38 [1.32-4.29]†	ns
Age	ns	ns
Living with a spouse	ns	ns
Non-ischaemic etiology	ns	ns
Symptomatic CHF	5.15 [3.08-8.63]‡	6.82 [3.77-12.39]‡
Co-morbidity	ns	ns
ICD-related complications	ns	ns
ICD shocks	2.21 [1.32-3.72]†	2.00 [1.06-3.80]*
Years with ICD therapy	ns	ns
Current smoking	ns	ns
Amiodarone	ns	ns
Other antiarrhythmic medication	ns	ns
Psychotropic medication	ns	2.75 [1.40-5.40]†

(N = 610)

* $P < 0.05$; † $P < 0.01$; ‡ $P < 0.001$

Johansen, Pedersen et al. Europace 2008;10:545-51

Correlates of poor device acceptance (FPAS)

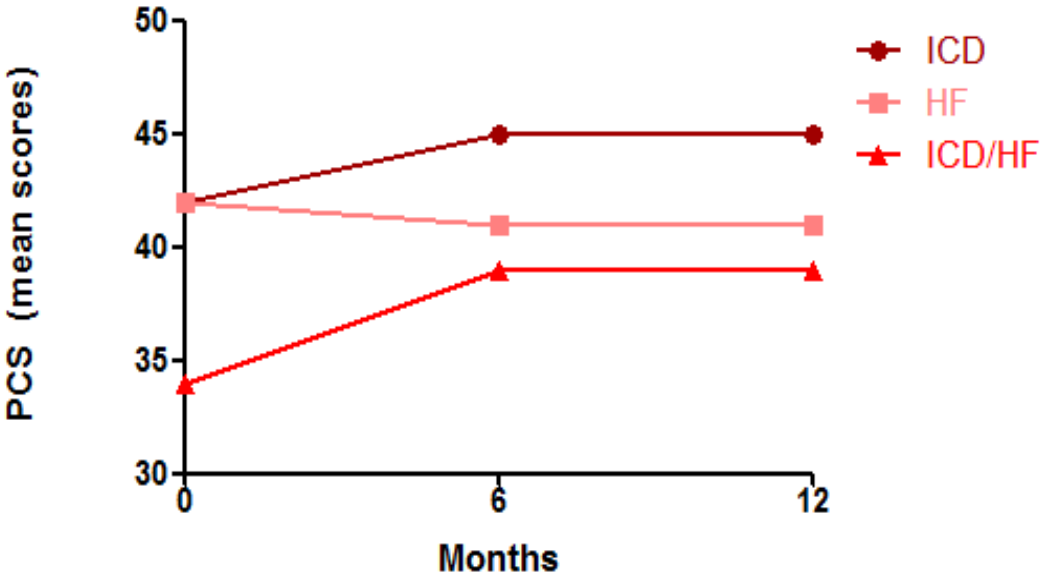
(N = 566)

	OR	[95% CI]	*p*
Demographic			
Female gender	0.62	[0.32-1.20]	.16
Age	1.03	[1.01-1.05]	.003
Partner/living together	0.53	[0.31-0.91]	.021
Clinical			
Non-ischemic etiology	1.17	[0.69-1.98]	.56
Symptomatic heart failure	3.59	[2.12-6.08]	<.001
Cardiac resynchronization therapy	0.91	[0.51-1.62]	.74
Co morbidity	1.13	[0.65-1.97]	.67
Device-related complications	1.46	[0.61-3.49]	.40
Shocks	0.87	[0.51-1.47]	.59
Years since implantation	0.93	[0.86-1.02]	.12
Psychological			
Type D personality	3.51	[1.95-6.30]	<.001
Anxiety	2.33	[1.24-4.38]	.009
Depressive symptoms	2.24	[1.00-5.00]	.049
ICD concerns	4.16	[2.55-6.80]	<.001

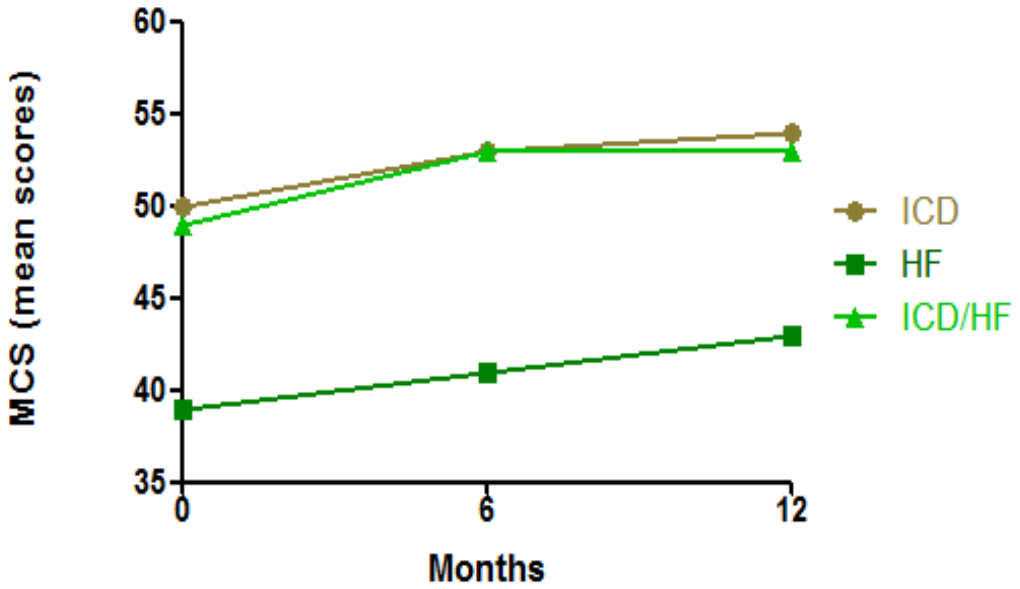
Pedersen, Sears et al. PACE 2008;31:1168-77

Perhaps the relationship is more complex – the ICD or underlying disease...

SF-36 Physical Component Summary



SF-36 Mental Component Summary



Habibovic, Pelle, Versteeg... & Pedersen. In preparation

Clinical trials: Effect of shocks on quality of life

Trial	Recruitment	Fu mths	Programming	Shock effect	Dose-response
Primary prevention					
CABG-PATCH	1990-1996	6	Shock only	No	-
AMIOVIRT	1996-2000	12	ATP and shock?	No	-
SCD-HEFT	1997-2001	30	Shock only	Mixed	No
MADIT-II	1997-2001	36	Shock only	Mixed	No
DEFINITE	1998-2002	36 (6	Shock only	Mixed	-
Secondary prevention					
CIDS	1990-1997	12	ATP and shock	No	Yes
AVID	1993-1997	12	ATP and shock	Yes	Yes

Inconclusive

Pedersen, van den Broek, Theuns et al. PACE 2010;33:1430-1436

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ICD therapy: Benefits

- ICD is described as a **life-saver** by the majority of patients
- Majority of patients **do well**, despite ICD shocks, device recalls, complications, and expanding indications

		Baseline anxiety symptoms (n=332)	
		Normal levels (Score 0-7)	*Probable clinical levels (Score ≥ 8)*
12-month anxiety symptoms	*Normal levels (Score 0-7)*	**70.2% (233)**	14.2% (47)
	Probable clinical levels (Score ≥ 8)	5.7% (19)	**9.9% (33)**

		Baseline depressive symptoms (n=332)	
		Normal levels (Score 0-7)	*Probable clinical levels (Score ≥ 8)*
12-month depressive symptoms	*Normal levels (Score 0-7)*	**69.0% (229)**	10.2% (34)
	Probable clinical levels (Score ≥ 8)	8.1% (27)	**12.7% (42)**

Epstein, J Am Coll Cardiol 2008; Sears & Conti. Heart 2002;
Pedersen, Hoogegt, Jordaens & Theuns. Submitted

Key characteristics of patients at risk of distress and poor quality of life

- **Clinical:** Shocks, diabetes, (worsening of) heart failure
- **Demographic:** Female gender, age, no partner
- **Psychological:** Type D personality, clustering of psychosocial risk factors, prior distress, poor social support
- **Medication:** Psychotropic, amiodarone

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Depression and time to first VT/VF

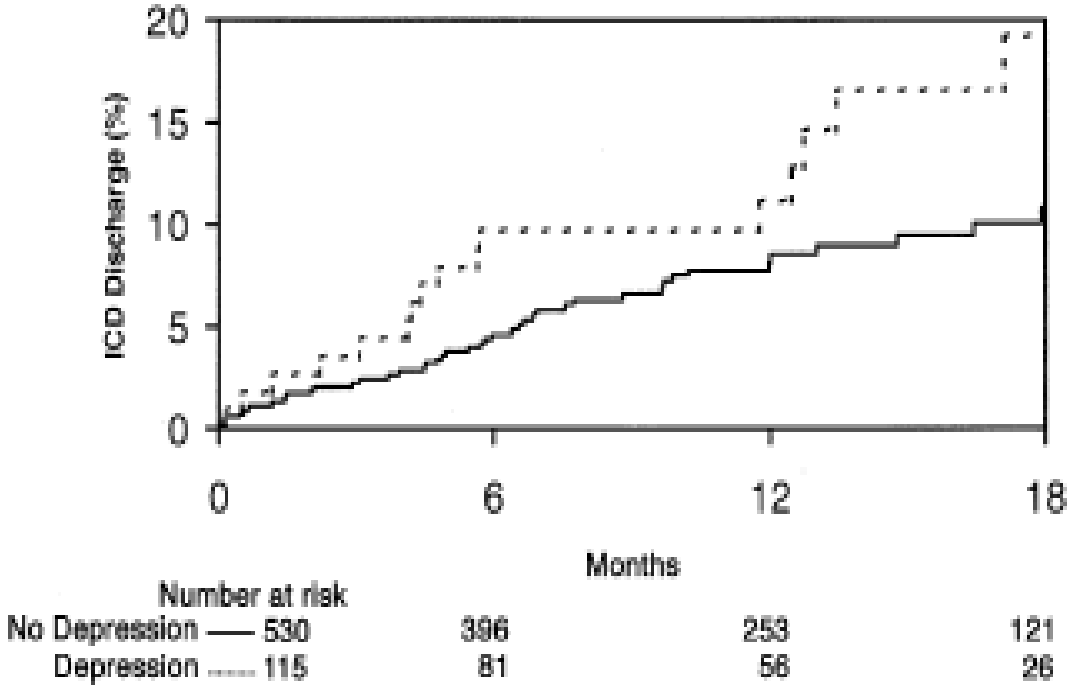

Figure 1. Time to first appropriate implantable cardioverter-defibrillator (ICD) discharge by presence of depression according to Centers for Epidemiologic Studies-Depression scale score ≥16 ($p = 0.02$, log-rank test).

Adjusted analysis:

- HR: 3.2 – time to first shock for VT/VF
- HR: 3.2 – all shocks for VT/VF including recurrent episodes

Whang, Sears et al. J Am Coll Cardiol 2005;45:1090-5

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Posttraumatic stress symptoms and mortality

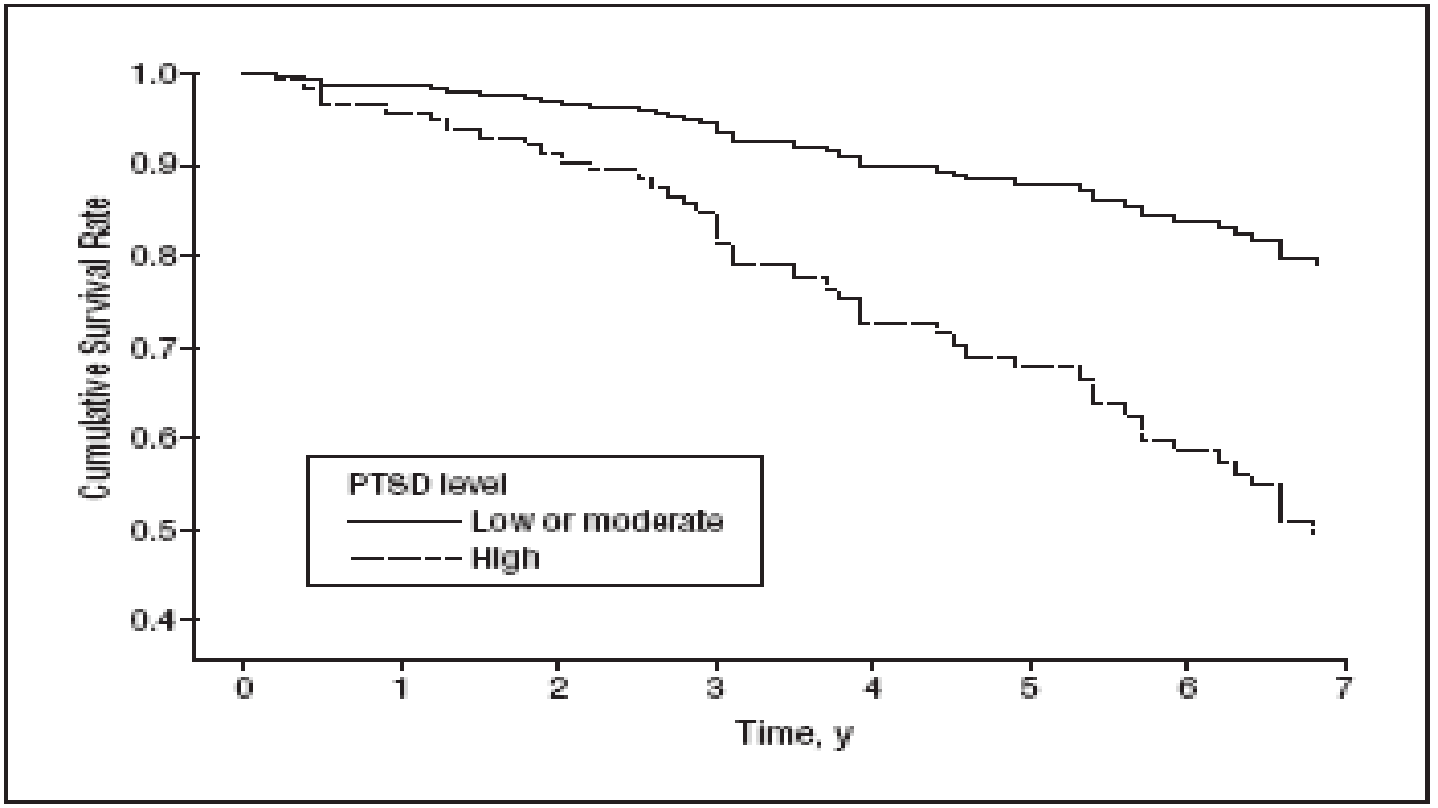


Figure 2. Long-term mortality risk in patients with an implantable cardioverter-defibrillator stratified for posttraumatic stress disorder (PTSD) symptoms (adjusted survival curve) adjusted for age, sex, survey, PTSD, anxiety, depression, prior resuscitation, number of shocks, left ventricular ejection fraction, and time of implantation before enrollment.

Ladwig et al. Arch Gen Psychiatry 2008;65:1325-30

Clustering of Type D personality and high ICD pre-implantation concerns and mortality

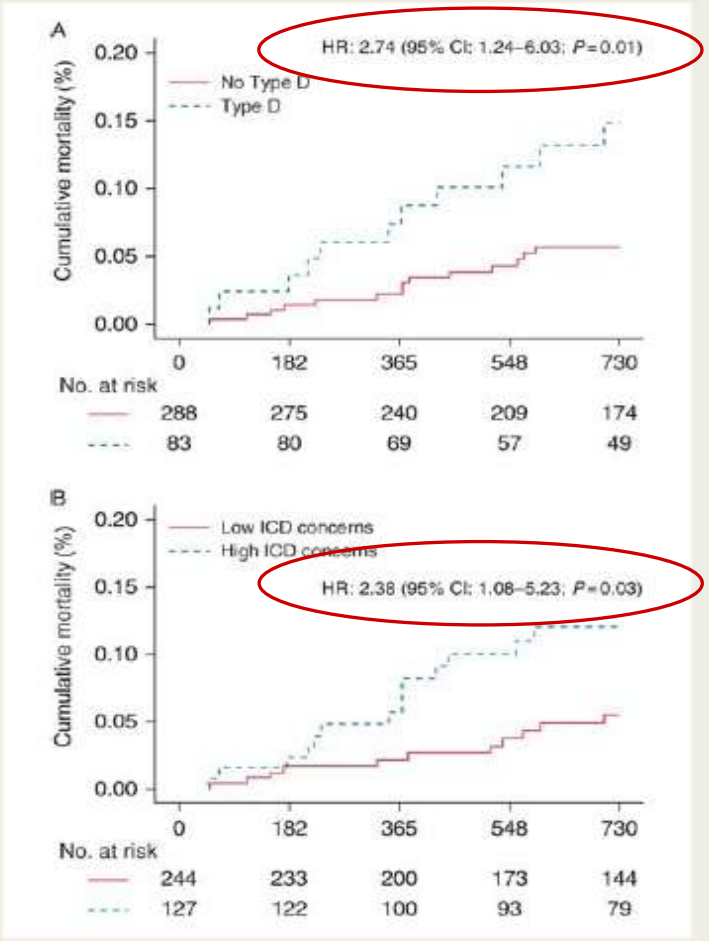
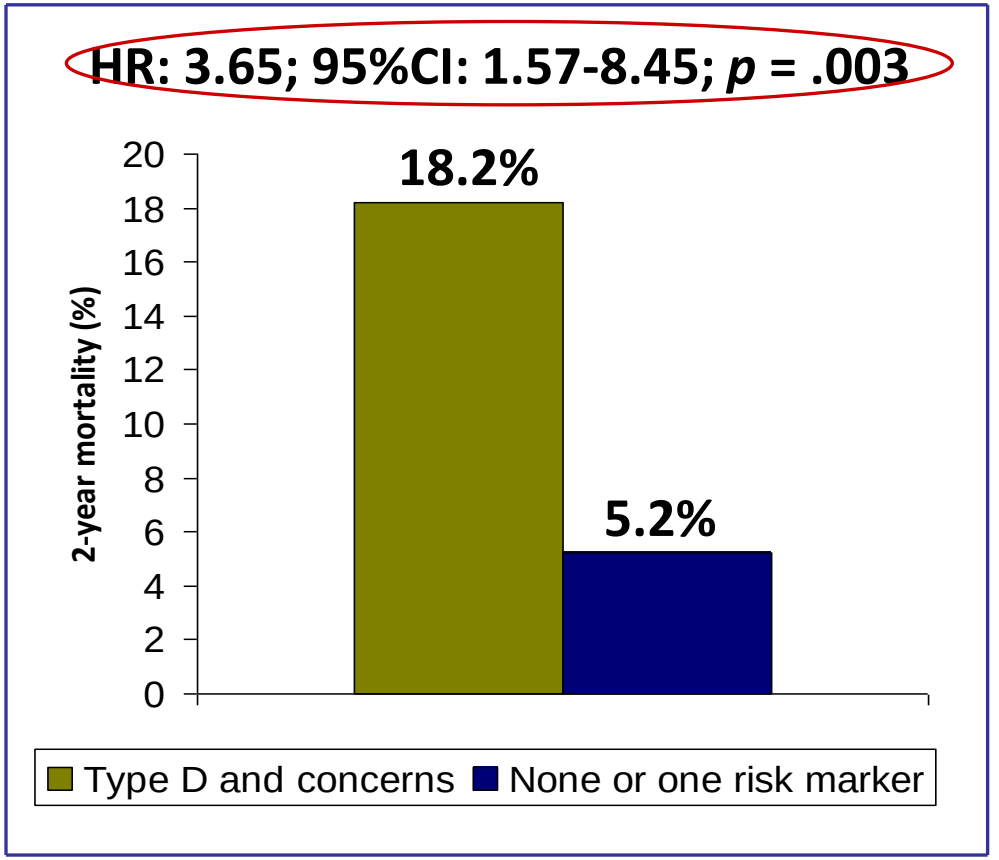


Figure 1 Kaplan-Meier curves for the time to mortality stratified by (*A*) Type D personality and (*B*) high levels of ICD concerns.

N = 371



Pedersen et al. Europace 2010;12:1446-52

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ICD shock - the paradox

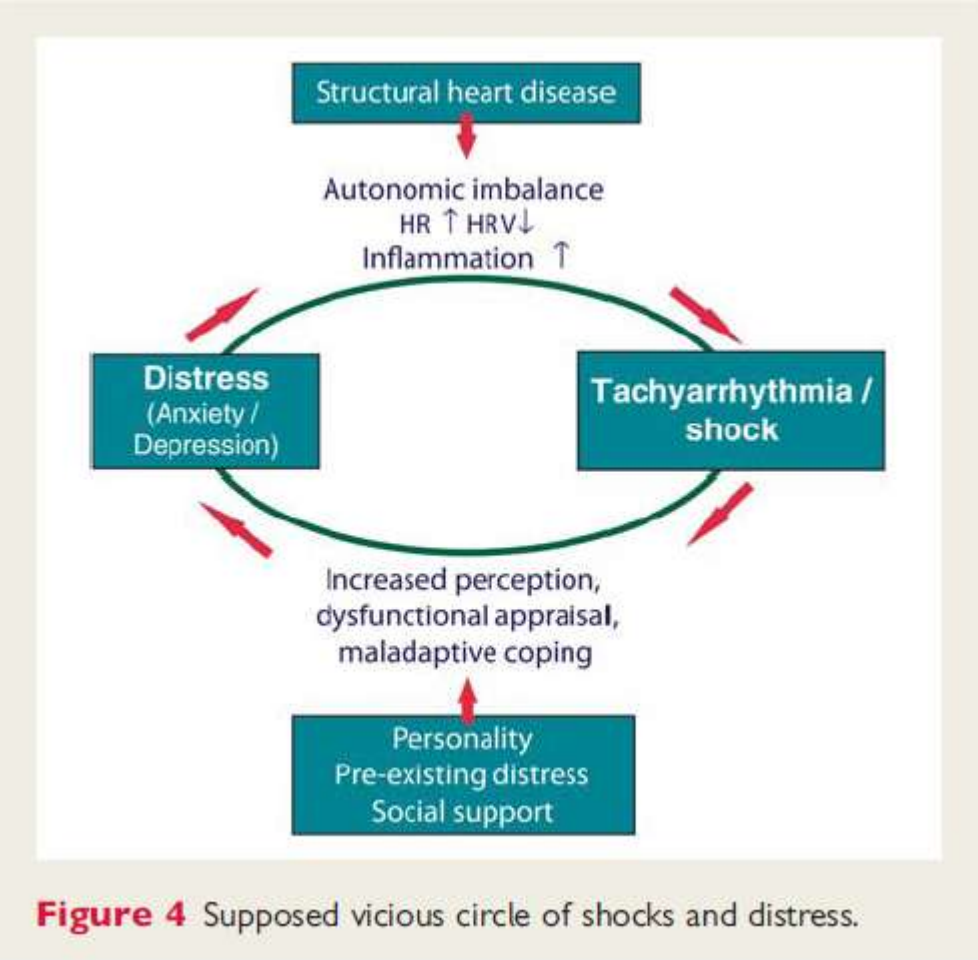

Figure 4 Supposed vicious circle of shocks and distress.

Safety?

Danger?

Braunschweig, Boriani, ... Pedersen et al., Europace 2010;12:1673-90

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Take home message...

- The **majority** of ICD patients **do well** with an ICD
- **A subgroup (25%)** of ICD patients is **at risk** of psychological distress, poor quality of life, and mortality
- Shocks may be **one** determinant – do not forget the **psychological profile** of the patient
- **Changes** in **clinical variables**, such as **worsening of heart failure** and medication should be assessed
- Questionable whether **new features to reduce ICD shocks** will alleviate distress in **all** patients

Shock viewpoint and counter viewpoint

VIEWPOINTS

Shock as a Determinant of Poor Patient-Centered Outcomes in Implantable Cardioverter Defibrillator Patients: Is There More to It Than Meets the Eye?

SUSANNE S. PEDERSEN, PH.D.,*,† KRISTA C. VAN DEN BROEK, PH.D.,*
MARTHA VAN DEN BERG, M.Sc.,* and DOMINIC A. M. J. THEUNS, PH.D.†
From *CoRPS – Center of Research on Psychology in Somatic diseases, Tilburg University, Tilburg, The Netherlands; and †Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands

Given that programming of the ICD is changing, leading to fewer shocks and improved quality of life, it may be timely to also examine the influence of other determinants (e.g. heart failure progression and personality) of patient-reported outcomes...

to be able to draw firm conclusions about the impact of ICD shocks on individual patients. We also need to acknowledge that the impact of shocks on psychological functioning and quality of life may not be as straightforward as previously assumed. Given that programming of the ICD is changing, leading to fewer shocks and improved quality of life, it may be timely to also examine the influence of other determinants (e.g., heart failure progression and the patient's psychological profile) of patient-centered outcomes both in research and in clinical practice. (PACE 2010; 33:1430–1436)

Pedersen, van den Broek, Theuns et al. PACE 2010;33:1430-6
Sears et al. PACE 2010;33:1437-41

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Europace (2010) **12**, 1673–1690
doi:10.1093/europace/euq316

CONSENSUS STATEMENT

Management of patients receiving implantable cardiac defibrillator shocks

Recommendations for acute and long-term patient management

Frieder Braunschweig (Chair)[1]*, Giuseppe Boriani (Co-chair)[2], Alexander Bauer[3], Robert Hatala[4], Christoph Herrmann-Lingen[5], Josef Kautzner[6], Susanne S. Pedersen[7], Steen Pehrson[8], Renato Ricci[9], and Martin J. Schalij[10]

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Device Conference, 3-4 November 2011, Tilburg, the Netherlands

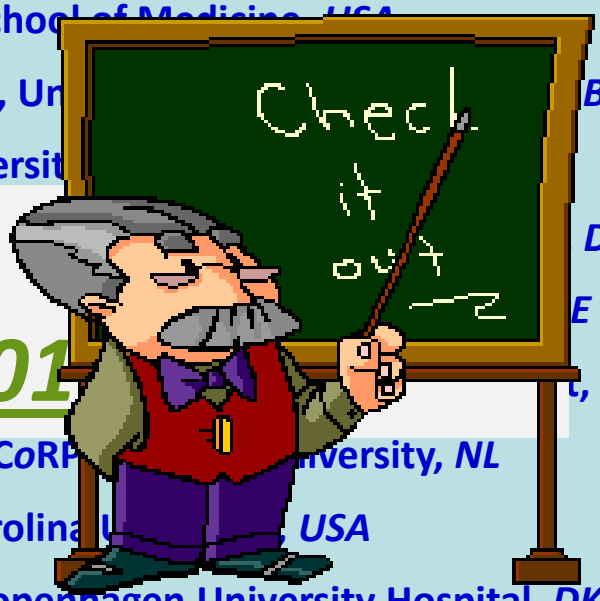
Living in a Device World: Focus on Recent Challenges and Tools to Improve Clinical Care for Patients with an Implantable Cardioverter Defibrillator

Themes

- OVERCOMING THE SHOCK OF THE ICD
- ICD REGISTRIES AND THE INCLUSION OF THE PATIENT PERSPECTIVE
- DEACTIVATION OF THE ICD AND END OF LIFE
- COMMUNICATION
- SEXUALITY IN ICD PATIENTS
- BEHAVIORAL INTERVENTIONS
- LOOKING INTO THE FUTURE

Selection of invited faculty

- Nico Blom (MD, PhD), Leiden University Medical Center, *NL*
- Matthew Burg (PhD), Yale School of Medicine, *USA*
- Viviane Conraads (MD, PhD), Ur *BE*
- Dorothy Frizelle (PhD), Universit *DK*
- *E*
- *, NL*
- Susanne S. Pedersen (PhD), CoRP iversity, *NL*
- Samuel Sears (PhD), East Carolina U *USA*
- Steen Pehrson (MD, PhD), Copenhagen University Hospital, *DK*
- Dominic Theuns (PhD), Erasmus Medical Center Rotterdam, *NL*



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