Dilemmas with implanted cardiac devices towards the end of life

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Building healthier lives

BCS SPRING CONFERENCE 2017

Sage Gateshead
26 April 2017

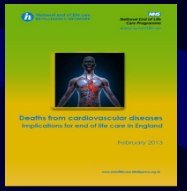
Statement of disclosure

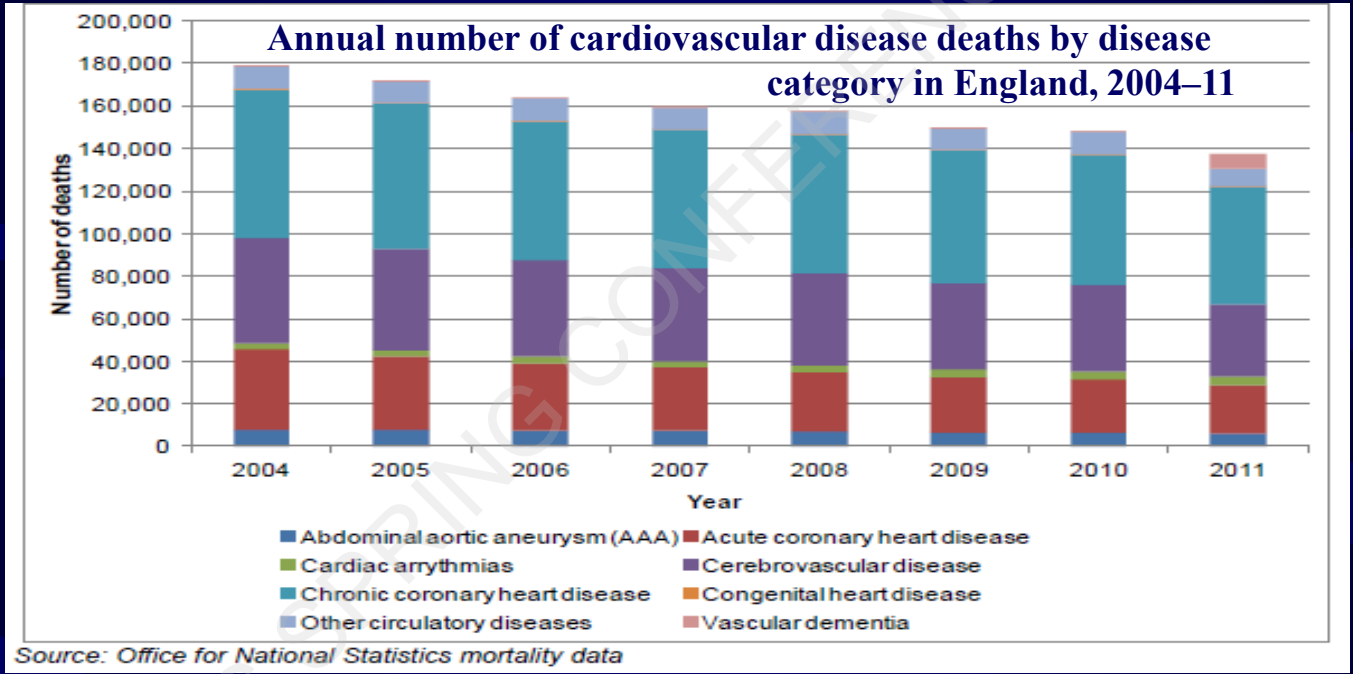
Support from Servier, Novartis, Vifor

My clinical *alma mater*

Glasgow Royal Infirmary –founded 1794

Deaths from cardiovascular diseases in England - implications for end of life care





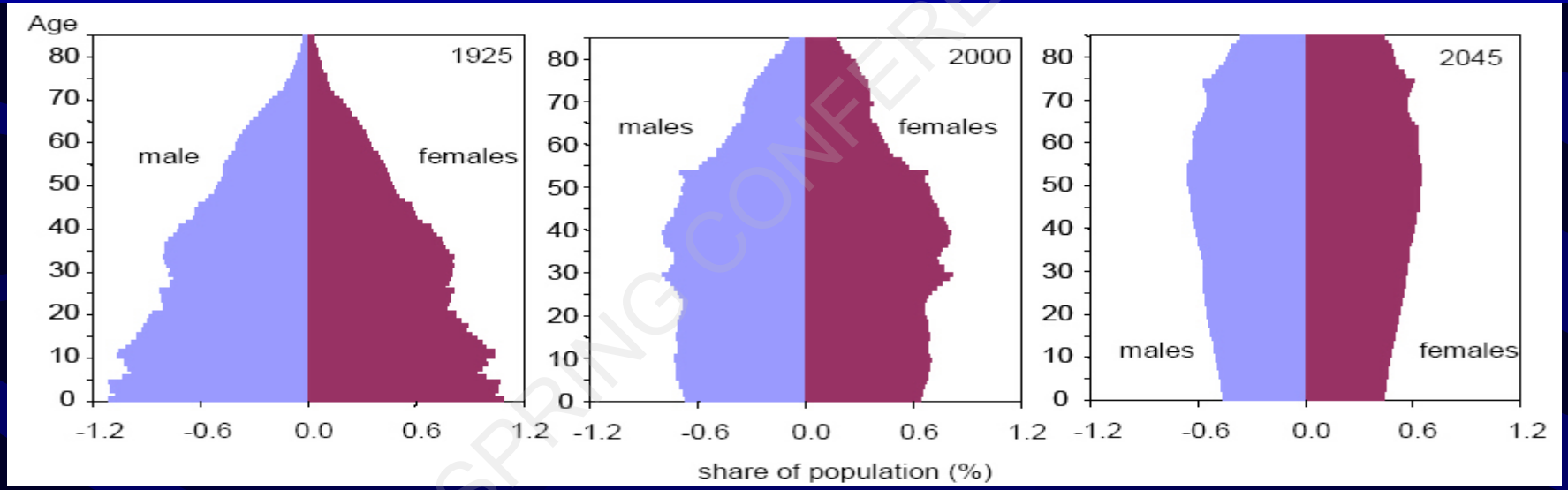
Source: Office for National Statistics mortality data

National end of life care INTELLIGENCE NETWORK

February 2013

Population dynamics will increase need

From pyramid to coffin



Anticipated 46% increase in heart failure prevalence by 2030

AHA Heart Disease and Stroke Statistics—2016 Update

Definitions of heart failure

Physiological:

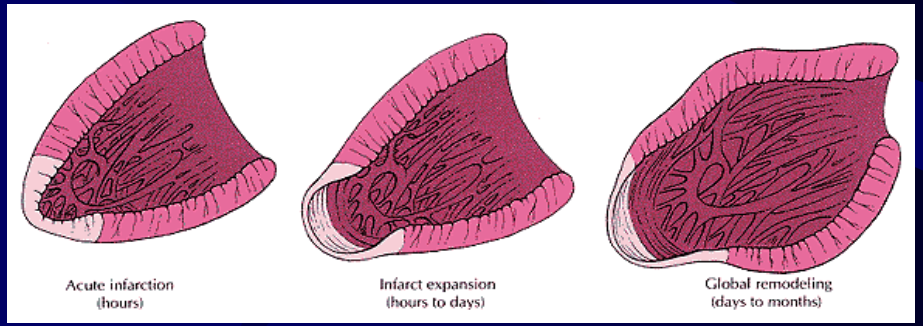
Inability of the heart to pump sufficient oxygenated blood to the metabolising tissues despite an adequate filling pressure.

Clinical:

Clinical syndrome consisting of symptoms such as breathlessness, fatigue, and congestion caused by cardiac dysfunction.

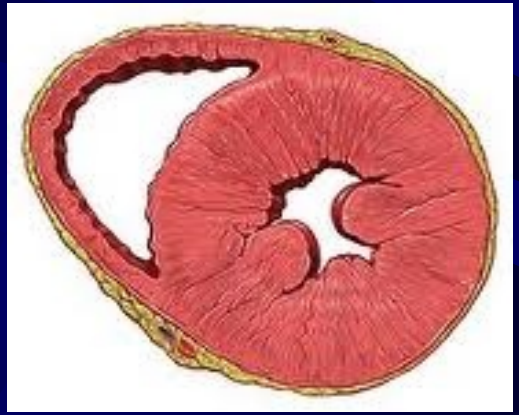
Systolic heart failure (HFrEF: < 40%)

- LVSD – Left Ventricular Systolic Dysfunction
- Most common type of HF: 60-70%
- LV is usually enlarged
- Common causes CAD / hypertension / diabetes
- Fails to contract normally due to scar or ischemia
- Mortality 10% per annum

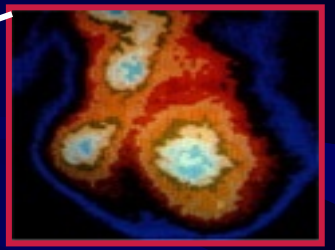


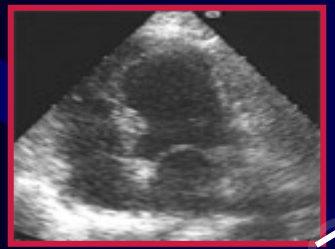
Diastolic dysfunction (HFpEF: ≥ 50%)

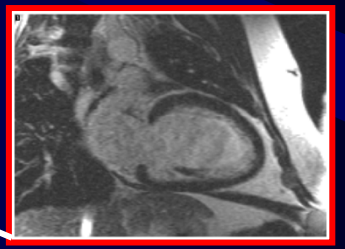
- Accounts for 20-40% of patients
- Ventricles are normal-sized with normal emptying
- Impairment in the ability of the ventricles to fill with blood during diastole due to poor relaxation
- Stiff myocardium due to hypertrophy
- Hypertension is the commonest cause
- Generally older women
- This carries a 5-8% mortality per annum



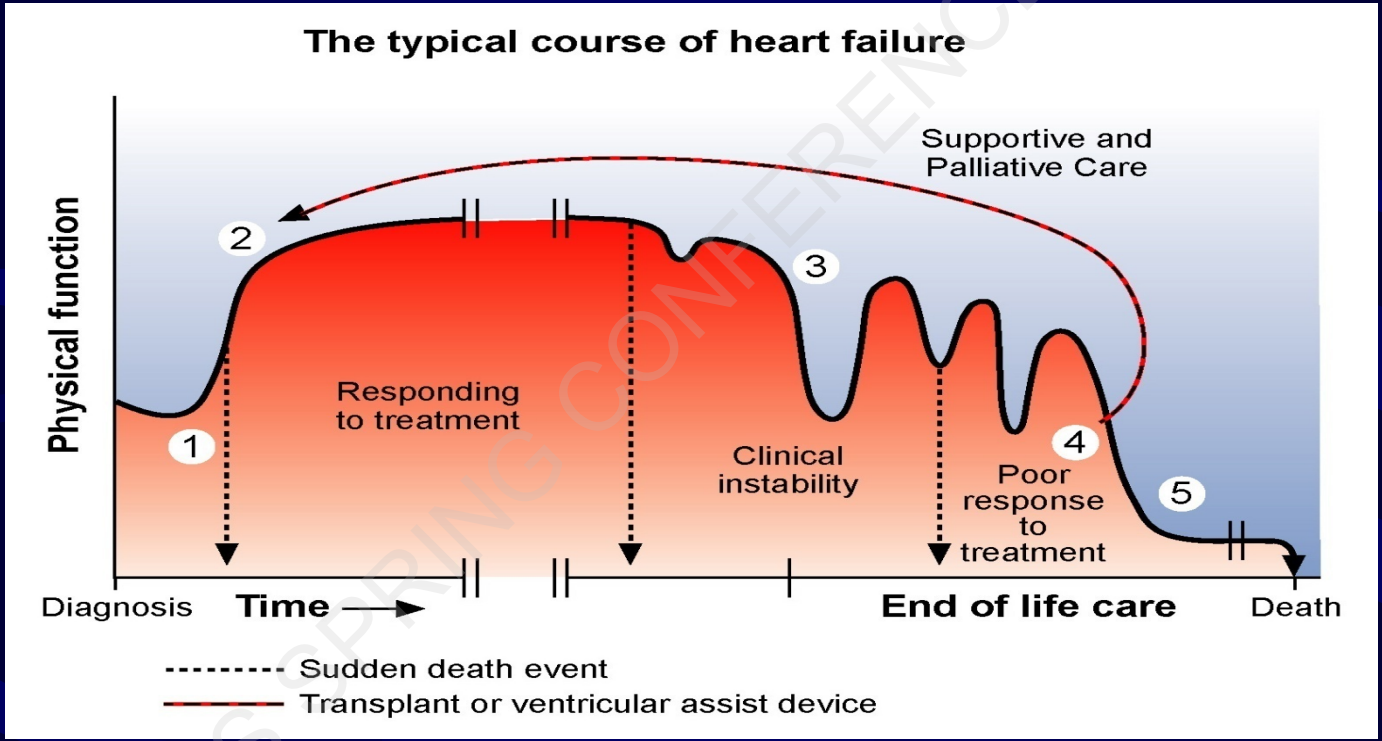
Does my heart look big in this?







The heart failure disease trajectory



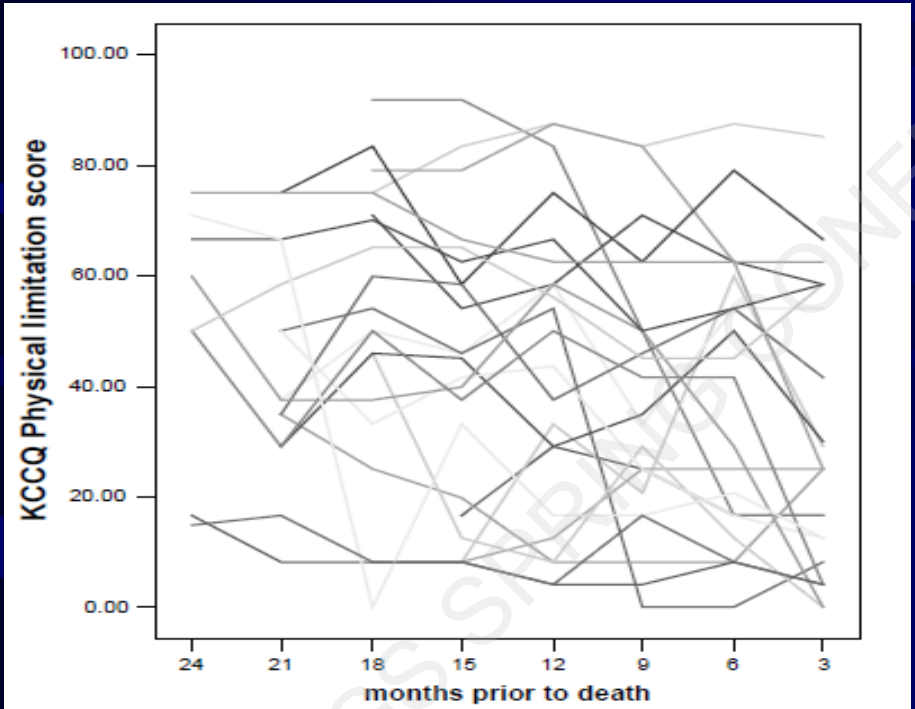
Modified from Goodlin, S. J. *JACC.* 2009;54:386-396

Reality of ‘dying’ in the elderly

- Lengthy period of decline: uneven course
- Multiple chronic medical conditions
- Progressive losses: independence; control
- Heavy burden of symptoms: multifactorial
- Substantial care needs: often overwhelming for family caregivers
- Difficulty with prognostication

Fifty shades of dying

Every heart failure patient's trajectory is unique



Gott M *et al. Palliat Med* (2007); 21: 95-9

Trajectories of physical decline (KCCQ) in heart failure patients over 24 months prior to death (n = 27)

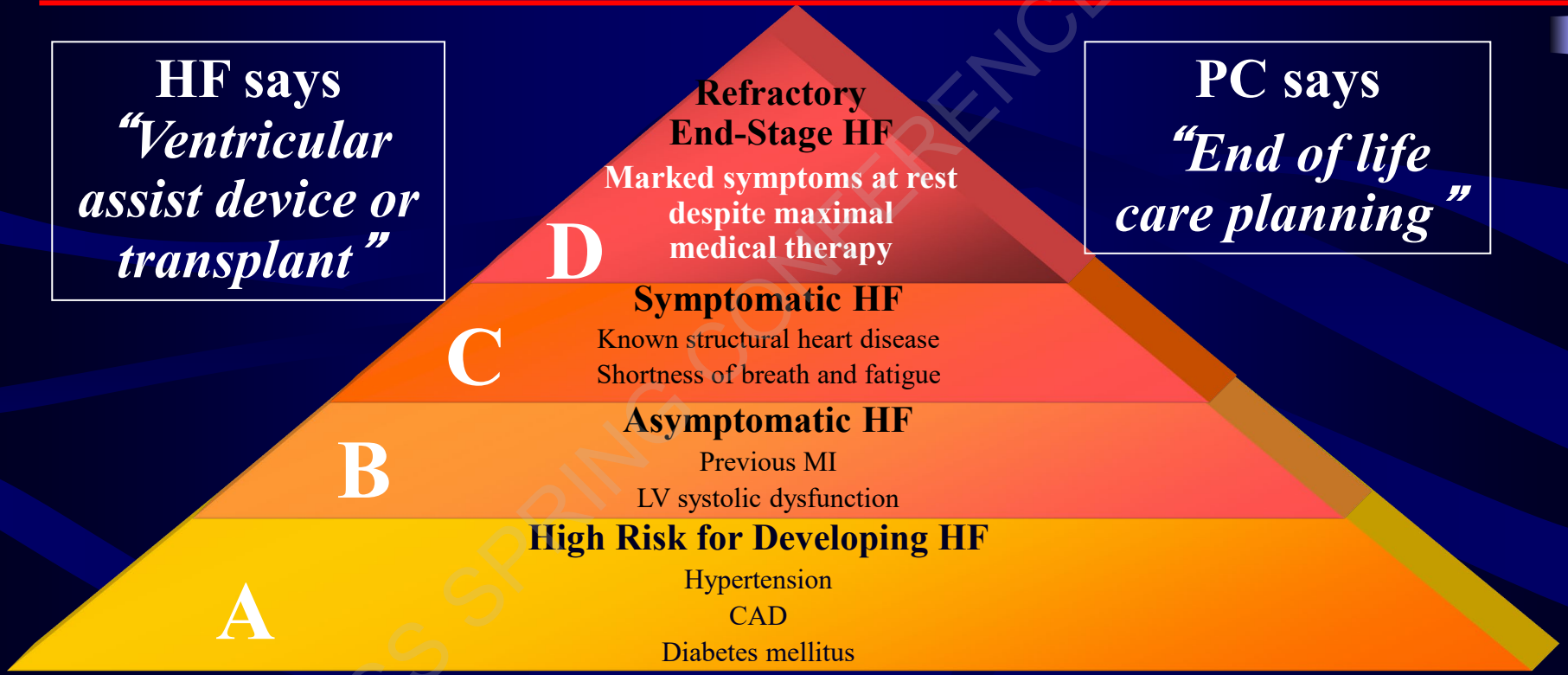
Treatment protocols for the patient with HFrEF

Stage A	Stage B	Stage C	Stage D
At high risk, no structural disease	Structural heart disease, asymptomatic	Structural heart disease with prior/ current symptoms of HF	Refractory HF requiring specialized interventions
Therapy • Treat Hypertension • Treat lipid disorders • Encourage regular exercise • Discourage alcohol intake • ACE inhibition	**Therapy** • All measures under stage A • ACE inhibitors in appropriate patients • Beta-blockers in appropriate patients	**Therapy** • All measures under stage A Drugs: • Diuretics, ACE inhibitors • Beta-blockers • Aldosterone antagonists	**Therapy** • All measures under stages A,B, and C • **Mechanical / electrical devices** • Heart Tx • Inotropic infusions for palliation • Hospice care

Hunt, SA *et al*. ACC/AHA Guidelines CHF, 2001.

Conflicting advice to patient at Stage D?

HF says
"Ventricular assist device or transplant"



PC says
"End of life care planning"

Hunt SA et al. *JACC* 2001;38:2101–13.

HF care – a protocol driven paradigm

Spencer Tunick

Challenges to initiating PC

- The culture of HF care favours a medical model and is treatment focussed.
- Evidence based intervention is often the default position.
- Patients' preferences may be unexplored or they may be disempowered by technicalities or lack capacity.
- A structure of sub-speciality silo working.
- There is a reluctance to discuss prognosis in the face of uncertainty.
- Difficulty in recognising when established therapies are futile.

Ethical challenges in HF care

Therapy may become inconsistent with patients' wishes or the evolving disease trajectory

Ventricular assist devices:

- bridge to recovery
- bridge to transplant
- destination therapy

Transplantation: distributive justice

Device therapy:

- Cardiac resynchronisation
- Implantable cardioverter defibrillators (ICDs)

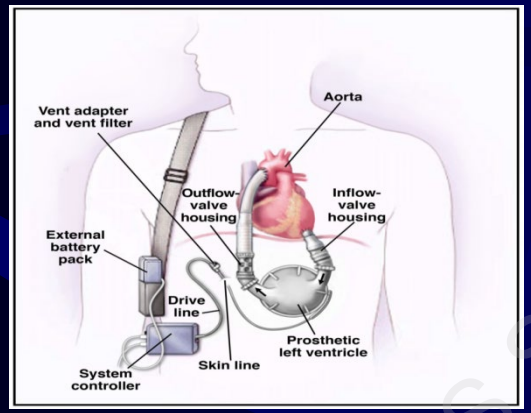
Ventricular assist devices

Advances in Heart Failure

Comprehensive Care for Mechanical Circulatory Support
A New Frontier for Synergy With Palliative Care

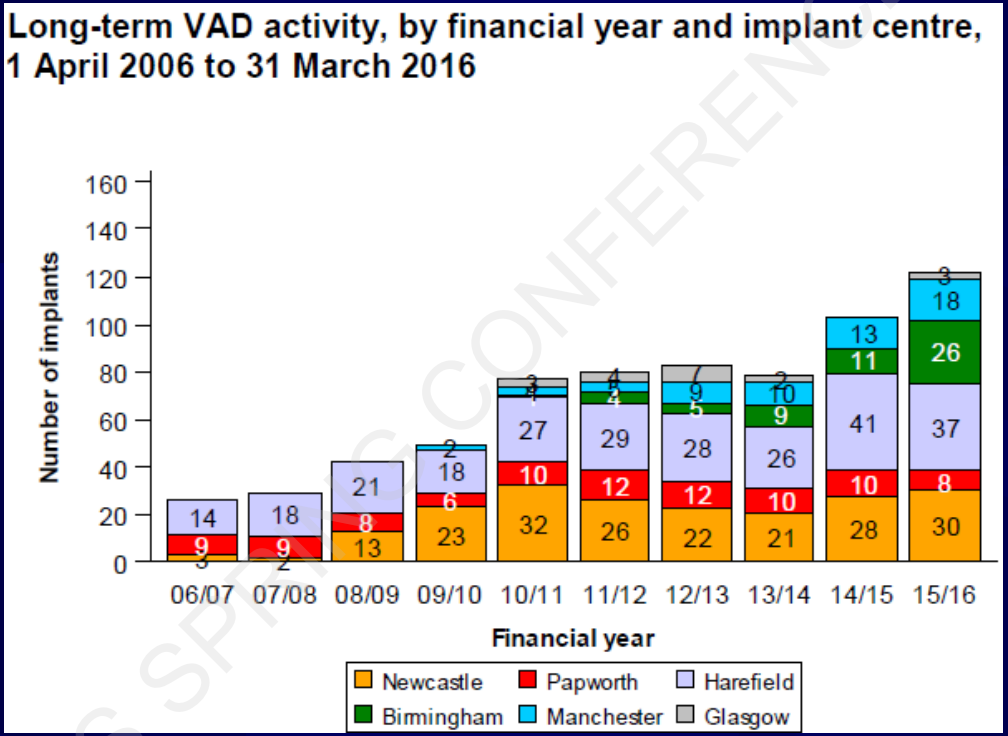
Nathan E. Goldstein, MD; Christopher W. May, MD; Diane E. Meier, MD

Circ Heart Fail. 2011;4:519-27



Life-sustaining medical devices at the end of life. McKenna M *et al*, *BMJ Support Palliat Care* 2013; 3(1): 5-7.

LVAD activity – niche market

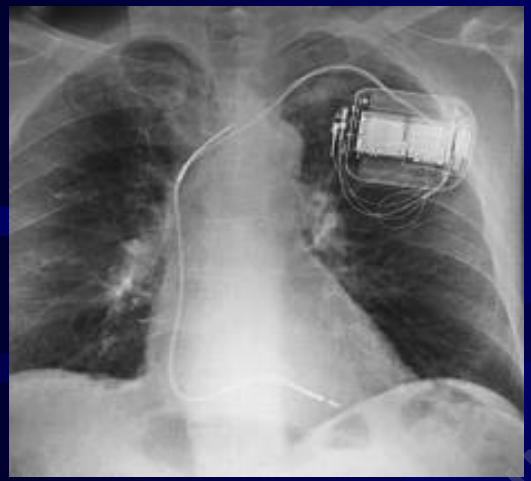


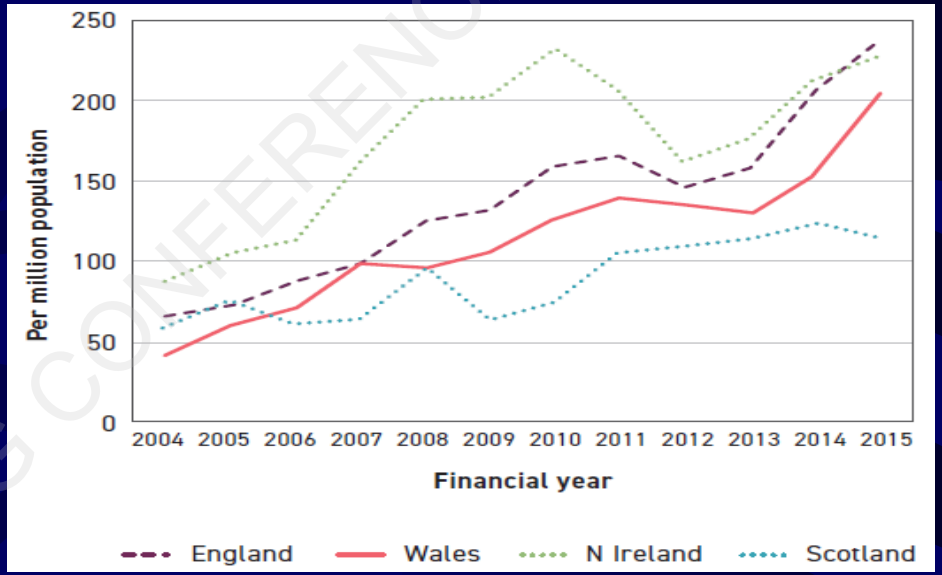
n = 122 for 2015-16

Annual Report on Ventricular Assist Devices 2015-16

NHS Blood and Transplant

New ICD implant trends





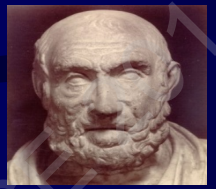
For the UK, 225 / million population for 2015-16

BHRS British Heart Rhythm Society

National Audit of Cardiac Rhythm Management Devices

NICOR

Primum non nocere ?



Defibrillators are implanted for the primary or secondary prevention of Sudden Cardiac Death in patients who have had a life-threatening ventricular arrhythmia or at risk of developing such arrhythmias.

(NICE TA314, June 2014: HF with EF ≤ 35%)

But –

patients about to die with end-stage HF or an unrelated terminal illness often exhibit metabolic and biochemical derangement and complex agonal arrhythmias that could trigger multiple ICD discharges.

ICD shocks in dying patients

Data from beyond the grave

Karolinska Institutet, Stockholm

Analysed intracardiac electrograms in 125 explanted ICDs

> A third of patients had VT in the last hour of life

Devices remained active in 65% with DNAR orders

- of these, almost 25% received at least 1 shock on the last day alive

Kinch Westerdahl *et al*, *Circulation*, 2014, 129: 422-9

ICD discussions at the end of life

100 NOK interviewed about ICD management

Deaths were classified into one of 4 groups:

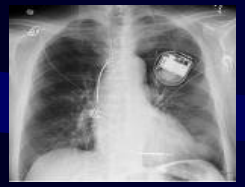
- Sudden cardiac 9%, Non-sudden cardiac 51%
- Sudden non-cardiac 4%, Non-sudden non-cardiac 36%

Any discussion	27
Deactivation requested	21

Time interval between discussion on deactivation and death:

Days	76%
Hours	22%
Minutes	4%

Goldstein NE , *Ann Int Med*, 141(11): 835, 2004



‘Informed consent’ at time of decision to insert an ICD?

- Göteborg study - 31 patients - moderate HF and history of malignant arrhythmia
- None received information about:
  - alternative treatment with antiarrhythmic drugs
  - estimated risk of fatal arrhythmia
  - expected time of survival from HF itself
- Patients did not complain about the lack of information or lack of participation in decision-making
- None regretted their decision
- Passively accepted health professionals’ advice

Sahlgrenska Hospital, Göteborg **Ågård A. *et al.* *J Med Ethics* 2007;33: 514-8**

Persuasive language of cardiologists

Choice architecture.....nudging?

- *"The ICD is a lifesaver".*
- *"The ICD will prolong your life; without it, there is a very high chance of sudden death".*
- *"This will decrease your risk of dying suddenly by greater than 50%".*
- *"The main benefit is prevention of lethal arrhythmia".*
- *"The ICD is a safety mechanism for preventing you from being taken away".*

Hauptman PJ *et al, JAMA Intern Med* 2013; 173:571-7.

Device anthropomorphism

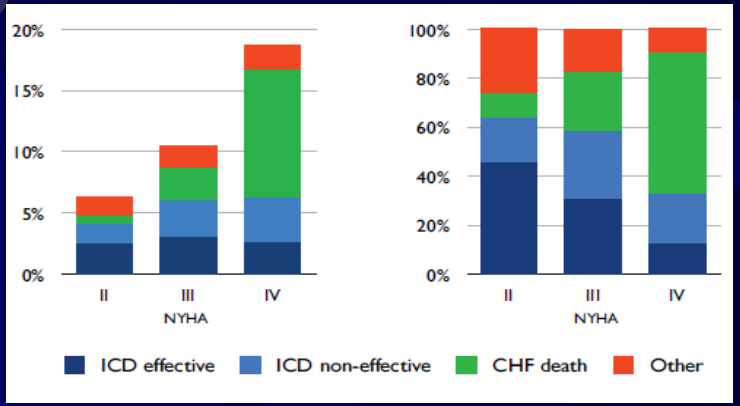
ICD patients' positive analogies

- *"Security. . .like an insurance policy".*
- *"Watcher. .standing in the background. . . .watching over you".*
- *"Guardian angel".*
- *"Seat belt".*
- *"Safety net".*
- *"It's like having a cardiologist in me".*

Hauptman PJ *et al, JAMA Intern Med* 2013; 173:571-7.

ICDs and the typical HF cohort

- Elderly patients (>75) were excluded from many of the major ICD trials
- ICDs improve long term survival in those with cardiac disease - may result in recipients living long enough to develop new comorbidities such as PVD, CVA, renal failure, dementia or cancer
- Until recently, little information about how to manage those with HF who progress to Stage D



Hard wired to survive

'Ironic technology'

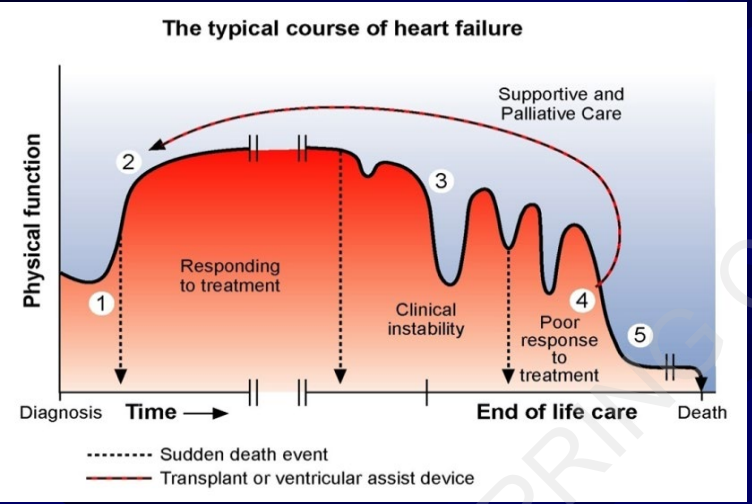
"I have an ICD and a pacemaker. It's prolonged my life a little bit. But the longer it prolongs my life, the more things happen to me that it can't correct. So the question is, do you want to have those effects, or do you want to end it all?"

— 86 year old man.

Kaufman SR. *Soc Sci Med* 2011; 72:6-14.

Review preferences:
? ICD deactivation / non-replacement

2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death



Goodlin SJ. *JACC* 2009, 54:386-96

Management of end-of-life issues

Recommendations	Class[a]	Level[b]	Ref.[c]
Discussion of end-of-life issues with patients who qualify for the implant of an ICD should be considered before implantation and at significant points along the illness trajectory.	IIa	C	805, 806

Eur Heart J, 2015, 36:2793-867

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

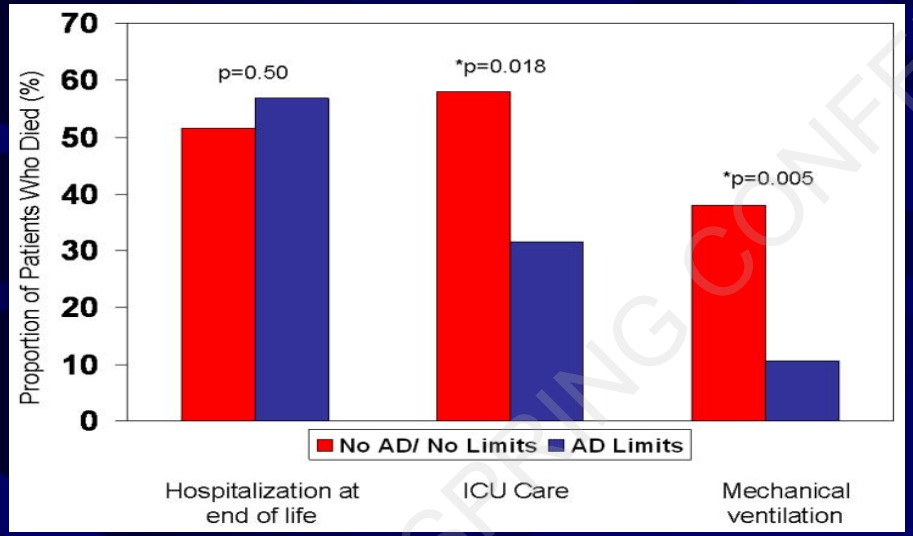
Key components of HF palliative care service

Focus on improving or maintaining the quality of life of a patient and his/her family as well as possible until he/she dies.
Frequent assessment of symptoms (including dyspnoea and pain) resulting from advanced heart failure and other co-morbidities and focus on symptom relief.
Access for the patient and his/her family to psychological support and spiritual care according to need.
Advanced care planning, taking account of preferences for place of death and resuscitation (which may include deactivating devices, such as pacemaker and/or implantable cardioverter defibrillator).

Eur Heart J. 2016; 37:2129

Advance directives in community patients with heart failure

Olmsted County, MN



n = 608, NYHA 3 /4
27% mortality at 1.8 y

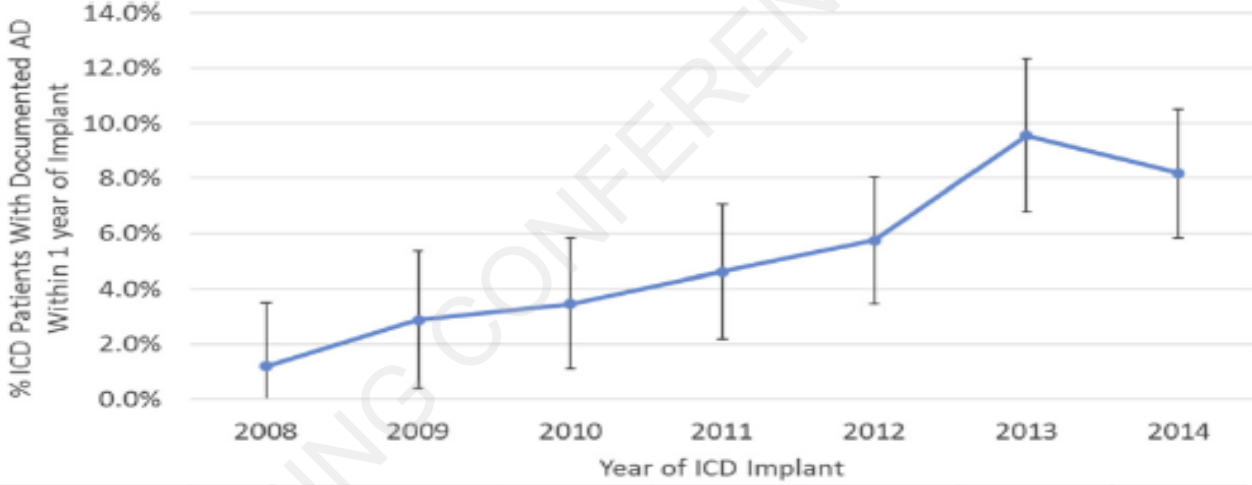
Advance directive	**41%**
Proxy	90%
CPR	41%
Mech ventilation	39%
Haemodialysis	10%

Dunlay SM *et al, Circ Cardiovasc Qual Outcomes* 2012, 5:283-9

Advance directives in ICD recipients

Atlanta, GA

n = 2549



# ICD Implants	84	174	231	282	400	429	526
% with Documented AD	1.2%	2.9%	3.5%	4.6%	5.8%	9.6%	8.2%

Only one AD was device specific

Merchant FM *et al. Heart Rhythm.* 2017 Feb 20

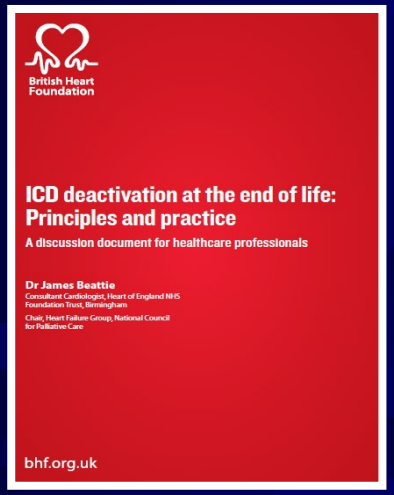
European consensus statement

EHRA Expert Consensus Statement on the management of cardiovascular implantable electronic devices in patients nearing end of life or requesting withdrawal of therapy

Luigi Padeletti[1*], David O. Arnar[2], Lorenzo Boncinelli[3], Johannes Brachman[4], John A. Camm[5], Jean Claude Daubert[6], Sarah Kassam[6], Luc Deliens[7], Michael Glikson[8], David Hayes[9], Carsten Israel[10], Rachel Lampert[11], Trudie Lobban[12], Pekka Raatikainen[13], Gil Siegal[14], and Panos Vardas[15]

Europace 2010, 12(10):1480-9

ICD therapy at the end of life



2013

2014

Deactivating the shock function of an implantable cardioverter defibrillator (ICD) towards the end of life

Resuscitation Council (UK) | British Cardiovascular Society | THE NATIONAL COUNCIL FOR PALLIATIVE CARE

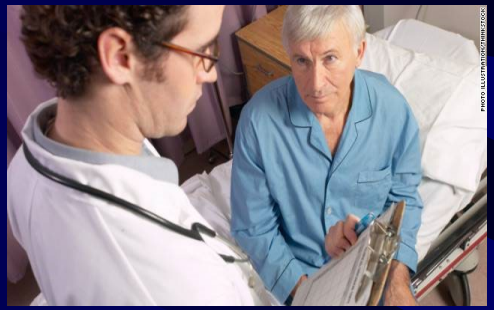
Heart 2016 Jun;102 Suppl 7:A1-A17.

HF ICD care – walking the ethical tightrope

Clinical scenarios

Competent patient: DNAR but chooses to maintain active ICD

- ethically we must accept patient's choice



Competent patient: Active ICD – requests deactivation

- examine rationality of request
- explore alternatives – antiarrythmics
- exclude depression
- accept

Dying patient / distress: Lacks decision making capacity – ICD active

- exclude any reversible elements that may impair capacity
- seek guidance from carer on any previously declared policy
- independent review by health care professional or ethicict
- the best interests principle should apply

Dilemmas with implanted cardiac devices towards the end of life

- Clinical dilemmas are common in dealing with the evolving complexity of evidence based advanced HF care.

- Health professionals need to ensure that treatment is personalised, remains appropriate, and held within an ethical framework.

- Goals of care and the continuing utility of implanted devices need to be reviewed openly and regularly with patients and families to ensure best interests are maintained.

- This demands multidisciplinary consensus development and the means to facilitate the prospective withdrawal of any redundant / futile therapies as the focus of care changes to symptom relief towards the end of life.

The Goldilocks principle

Getting it just right.....