



The 44th Annual International Congress of the
**EGYPTIAN SOCIETY OF
 CARDIOLOGY**
 CardioEgyt2017

What 's new in CHF devices?

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2017



Why Should I Care About Heart Failure?

■ Prevalence

Worldwide, 22 million
 United States, 5 million

■ Incidence

Worldwide, 2 million new cases annually
 United States, 500,000 new cases annually

About 300,000 people die each year of heart-failure related causes.

Heart failure is the single most common cause of hospitalization in the United States for people over the age of 65.

■ These patients live in your community.

Goals of Heart Failure Management

1. Improving symptoms and quality of life
2. Slowing the progression or reversing cardiac and peripheral dysfunction
3. Reducing mortality

Addressing Heart Failure in 2013



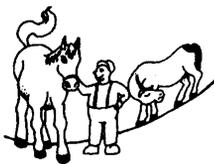
WHIP THE HORSE



UNLOAD THE WAGON



SLOW THE HORSE



GET A NEW HORSE



GET A TRACTOR



HEAL THE HORSE

Katz AM
Heart Failure

Heart Failure Device Therapy

- ▶ Implanted electrical devices: ICD, CRT
- ▶ Mechanical circulatory support devices
 - Short term versus durable devices
- ▶ Valvular closure or replacement devices
- ▶ Monitoring devices
- ▶ Stimulation HF devices
- ▶ Personal wearable devices.

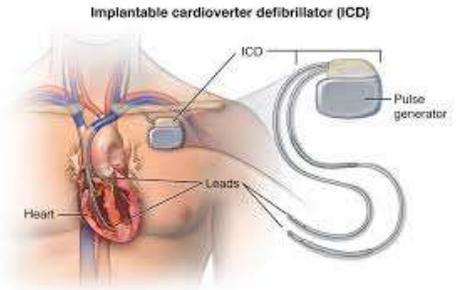
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Implantable Cardiac Defibrillators

Device implantable inside the body, able to perform cardioversion, defibrillation, and pacing of the heart.

reduce the risk of sudden death

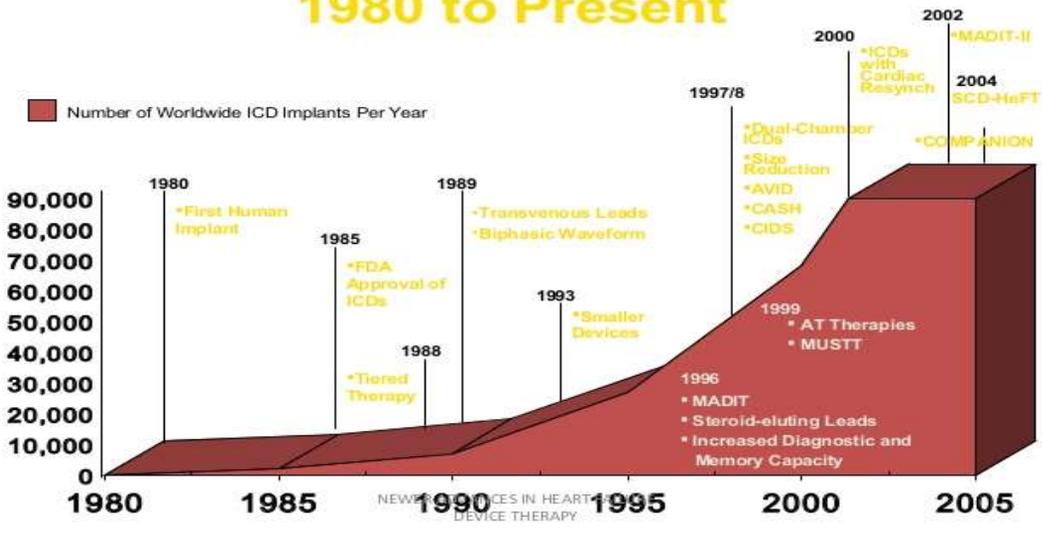


B-ROLL

Heart Animation

Sudden cardiac death and combination therapy

Evolution of ICD Therapy: 1980 to Present



Indications of ICD in chronic heart failure

Secondary prevention

An ICD is recommended in patients who have recovered from a ventricular arrhythmia causing haemodynamic instability, and who are expected to survive for >1 year with good functional status

Class IA

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

Primary prevention

An ICD is recommended in patients with symptomatic HF (NYHA Class II–III), and an LVEF $\leq 35\%$ despite ≥ 3 months of OMT, provided they are expected to survive > one year with good functional status, and they have:

IHD (unless they have had an MI in the prior 40 days) class I A

DCM class I B

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

Primary prevention

An ICD is recommended in patients with asymptomatic LV systolic dysfunction (LVEF \leq 30%)

IHD (unless they have had an MI in the prior 40 days) class I B

DCM (who receive OMT) class I B

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

Cardiac Resynchronization Therapy (CRT)

- ▶ Cardiac resynchronization refers to pacing techniques that change the degree of atrial and ventricular electromechanical asynchrony in patients with major atrial and ventricular conduction defects.
- ▶ It acts by pre-exciting the left lateral ventricular wall acting as electrical bypass together with atrial sequential pacing , thus to restore normal contraction pattern.
- ▶ IT improves symptoms, morbidity , quality of life and mortality

B-ROLL

Heart Animation

**Implanted system without therapy
transitioning to with therapy**

Cardiac Resynchronization Therapy (CRT)

- ▶ LVEF <35%
- ▶ NYHA class II – IV
- ▶ QRS > 130 ms with LBBB
- ▶ Optimal medical therapy

Class I

- ▶ LVEF <35%
- ▶ NYHA class II – IV
- ▶ QRS > 150 ms with non LBBB
- ▶ Optimal medical therapy

Class II a

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

2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

Therapy	All studies		NYHA III or IV HF	
	Overall mortality (%)	Probability of best treatment	Overall mortality (%)	Probability of best treatment
Medical	14.0	0	13.7	0
CRT	10.3	0.14	10.5	0.27
ICD	10.6	0.10	12.2	0.08
CRT + ICD	9.1	0.75	9.7	0.62

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).

Clinical guidance to the choice of CRT-P or CRT-D in primary prevention

Factors favouring CRT-P	Factors favouring CRT-D
Advanced heart failure	Life expectancy >1 year
Severe renal insufficiency or dialysis	Stable heart failure, NYHA II
Other major co-morbidities	Ischaemic heart disease (low and intermediate MADIT risk score)
Frailty	Lack of comorbidities
Cachexia	

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Ventricular Assist Device (VAD)

A mechanical circulatory device used to partially or completely replace the function of either the left ventricle (LVAD); the right ventricle (RVAD); or both ventricles (BiVAD)

Long-Term LVAD

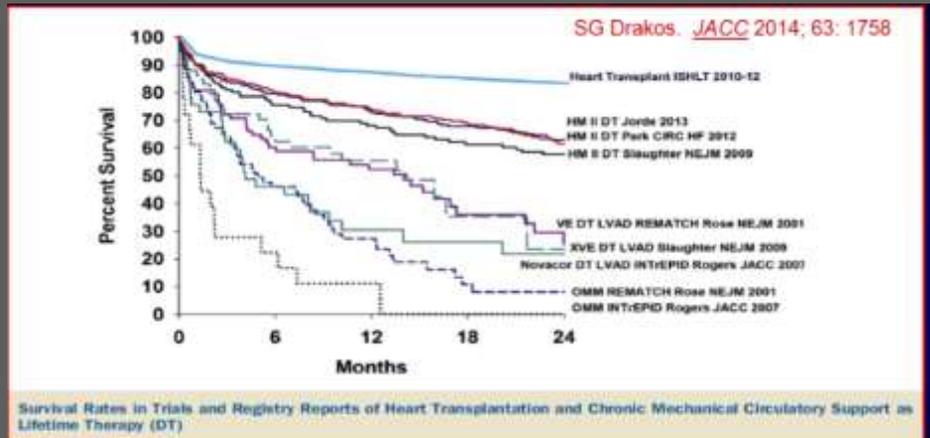
Implanted surgically with the intention of support for months to years

Short-Term LVAD

Utilized for urgent/ emergent support over the course of days to weeks

Indications for mechanical circulatory support

Bridge to decision (BTD)/ Bridge to bridge (BTB)	Use of short-term MCS (e.g. ECLS or ECMO) in patients with cardiogenic shock until haemodynamics and end-organ perfusion are stabilized,
Bridge to candidacy (BTC)	Use of MCS (usually LVAD) to improve end-organ function in order to make an ineligible patient eligible for heart transplantation.
Bridge to transplantation (BTT)	Use of MCS (LVAD or BiVAD) to keep patient alive who is otherwise at high risk of death before transplantation until a donor organ becomes available.
Bridge to recovery (BTR)	Use of MCS (typically LVAD) to keep patient alive until cardiac function recovers sufficiently to remove MCS.
Destination therapy (DT)	Long-term use of MCS (LVAD) as an alternative to transplantation in patients with end-stage HF ineligible for transplantation or long-term waiting for heart transplantation.



VADs are getting better, but heart transplant is still the gold standard.

INTERMACS SCORE

Interagency Registry for Mechanically Assisted Circulatory Support

intermacs

INTERMACS: Patient Selection

Patient Profile/ Status: INTERMACS Levels

1. Critical cardiogenic shock
2. Progressive decline
3. Stable but inotrope dependent
4. Recurrent advanced HF
5. Exertion intolerant
6. Exertion limited
7. Advanced NYHA III

Long-Term LVAD

Ideal candidates are INTERMACS classes 3-4

Short-Term LVAD

Candidates are INTERMACS classes 1-2

Not a LVAD Candidate

INTERMACS 1 or those with multisystem organ failure

Lietz and Miller
Curr Opin Cardiol
2009, 24:246-251

Long-term placement

Bridge to Transplantation (BTT)

- Patient is approved and currently listed for transplant
- NYHA IV
- Failed maximized medical therapy

<http://www.cms.gov/medicare-coverage-database>

Destination Therapy (DT)

- Not a heart transplant candidate
- NYHA IV
- LVEF <25%
- Maximized medical therapy >45 of 60 days; IABP for 7 days; OR 14 days
- Functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min
- Life expectancy < 2 years

Adult FDA Approved LVADs

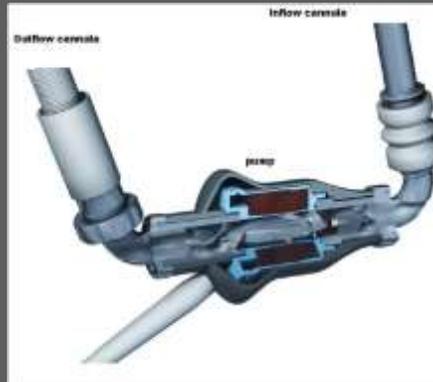
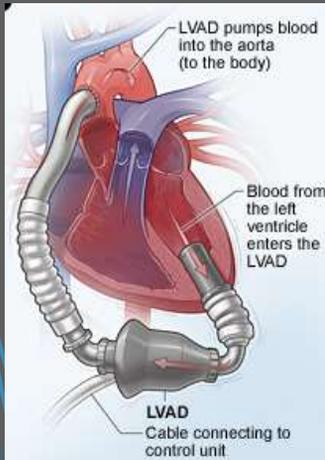
Bridge to Transplantation (BTT)

HeartMate II (Thoratec)
HeartWare (HeartWare)
PVAD (Thoratec)
IVAD (Thoratec)

Destination Therapy (DT) HeartMate II (Thoratec)



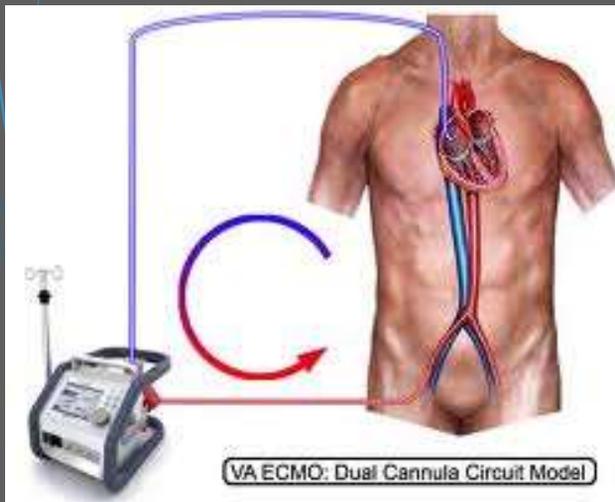
HeartMate II (Thoratec)



Variations of Short-Term VADs

- ▶ Impella 2.5 and 5.0
- ▶ Tandem Heart
- ▶ CentriMag
- ▶ ECMO (V-A)

ECMO (VA)



- Used for patients with a combination of acute cardiac and respiratory failure
- A cannula takes deoxygenated blood from a central vein or the right atrium, pumps it past the oxygenator, and then returns the oxygenated blood, under pressure, to the arterial side of the circulation
- Can be used for days to weeks

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Mitral Clip



A meta-analysis of MitraClip system versus surgery for treatment of severe mitral regurgitation

Ann Cardiothorac Surg 2013;2(6):683-692

Benjamin Wan¹, Mohammad Rahnavardi¹, David H. Tian¹, Kevin Phan^{1,2}, Stine Munkholm-Larsen^{1,3}, Paul G. Bannon^{1,2}, Tristan D. Yan^{1,2}

survival at 12 months in patients with severe MR

Study or Subgroup	MitraClip		Surgery		Weight	Odds Ratio M-H, Random, 95% CI	Odds Ratio M-H, Random, 95% CI
	Events	Total	Events	Total			
Feldman	11	181	5	89	46.5%	1.09 [0.37, 3.23]	
Paranskaya	2	24	0	26	5.8%	5.89 [0.27, 129.15]	
Taramasso	6	52	10	91	47.7%	1.06 [0.36, 3.10]	
Total (95% CI)		257		206	100.0%	1.18 [0.56, 2.48]	
Total events	19		15				
Heterogeneity: Tau ² = 0.00; Chi ² = 1.11, df = 2 (P = 0.57); I ² = 0%							
Test for overall effect: Z = 0.44 (P = 0.66)							

“we conclude the non-inferiority of the MitraClip as a treatment for severe, symptomatic MR, in comparison to conventional valvular surgery. Despite a higher risk profile in the MitraClip patients, the clinical outcomes were comparable although surgery was more effective in reducing MR in the early post procedure period. “

Heart Failure Device Therapy

- ▶ Implanted electrical devices: ICD, CRT
- ▶ Mechanical circulatory support devices
 - Short term versus durable devices
- ▶ Valvular closure or replacement devices
- ▶ **Monitoring devices**
 - Invasive or non invasive
- ▶ Stimulation HF devices
- ▶ Personal wearable devices.

Purpose of Mentoring

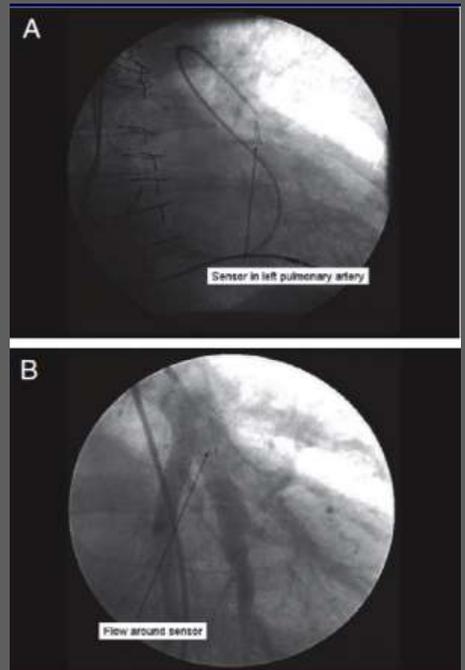
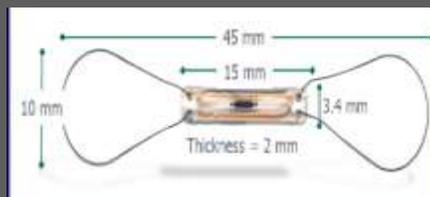
- ▶ **Early Detection of Clinical Decompensation**
 - Crisis Detection & Management
- ▶ **Ensuring Compensation**
 - Prevention
- ▶ **Measuring Response to Therapy**

Wearable or Ingestible Monitors



CARDIOMEMS™ HF SYSTEM

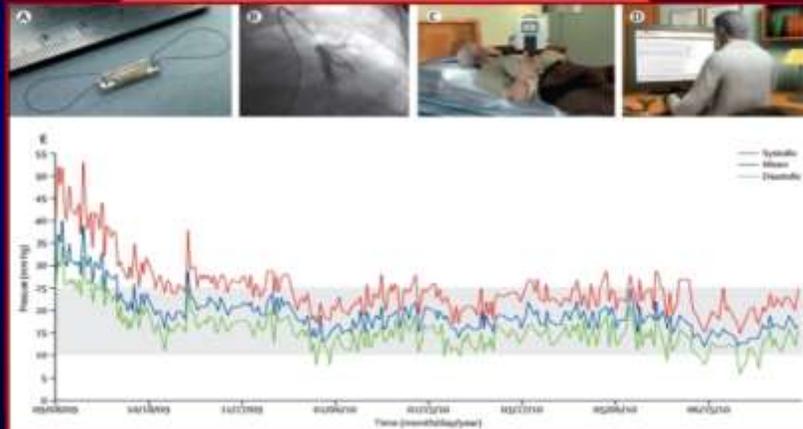
- The pulmonary artery pressure sensor is implanted via a right heart catheterization procedure via femoral vein approach.



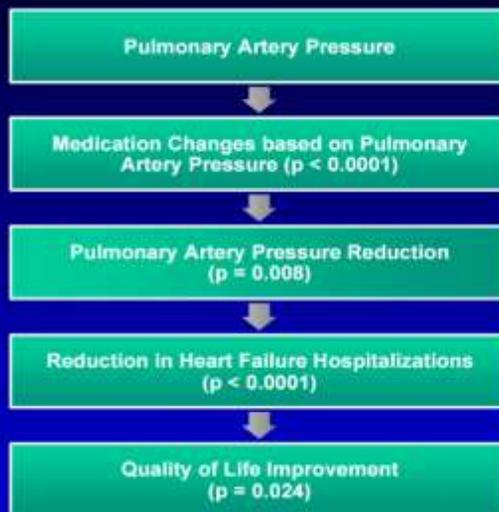
Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial

William T Abraham, Philip B Adamson, Robert C Bourge, Mark F Aaron, Maria Rosa Costanzo, Lynne W Stevenson, Warren Strickland, Suresh Neelagari, Nirav Raval, Steven Krueger, Stanislaw Weiner, David Shavelle, Bradley Jeffries, Jay S Yodanis, for the CHAMPION Trial Study Group*

- www.thelancet.com Vol 377 February 19, 2011



CHAMPION CLINICAL TRIAL



Managing pressures to target goal ranges:

- PA Pressure systolic 15–35 mmHg
- PA Pressure diastolic 8–20 mmHg
- PA Pressure mean 10–25 mmHg

REDUCTION IN HEART FAILURE HOSPITALIZATIONS



*from an average of 15 months

Abraham WT, et al. Lancet, 2011.

Recommendations for exercise, multidisciplinary management and monitoring of patients with heart failure

Monitoring of pulmonary artery pressures using a wireless implantable haemodynamic monitoring system (CardioMEMS) may be considered in symptomatic patients with HF with previous HF hospitalization in order to reduce the risk of recurrent HF hospitalization.

IIIb

Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFREF (LVEF \leq 35%) in order to improve clinical outcomes.

IIIb

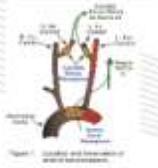
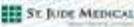
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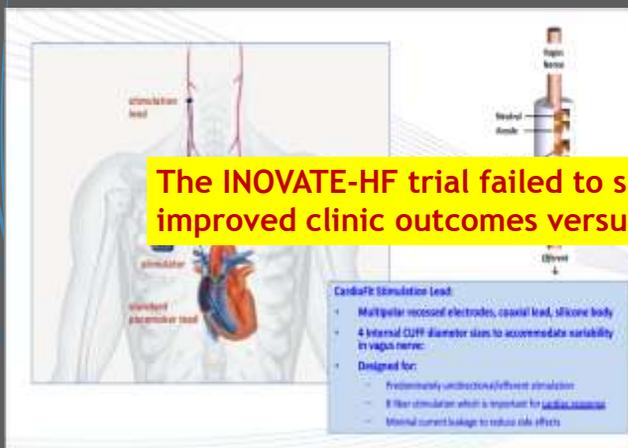
Autonomic nervous system modulation

A Family of Emerging Therapy in Clinical Stages

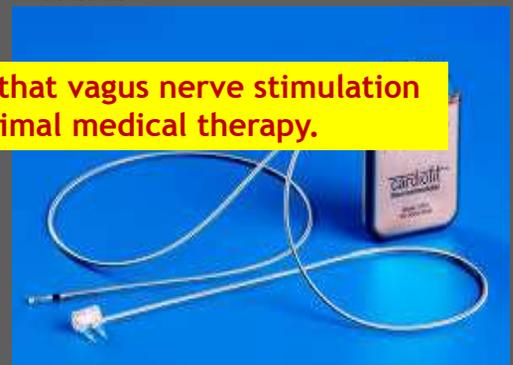
Target	Vagal Stimulation	Spinal Stimulation	Baroreceptor Stimulation	Renal Denervation
				
Disease	Low EF HF	Low EF HF	HTN / HF	HTN / HF
Investments	  	 	 	   

CardioFit® System

vagal nerve stimulation



- the first device designed to increase the effect of the parasympathetic branch.



The INOVATE-HF trial failed to show that vagus nerve stimulation improved clinic outcomes versus optimal medical therapy.

AND THAT'S ALL I HAVE



TO SAY ABOUT THAT.