

A lifetime of specialist care

# Options HF C-Pulse System European MultiCentre Study

## *Case Presentation*

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EU: C-Pulse is CE Marked

US: Caution: Investigational Device. Limited by Federal (or United States) law,<sup>1</sup>  
to investigational use.

# OPTIONS HF: Key Study Qualifications

## Major Inclusion Criteria

- LVEF  $\leq 35\%$
- Both ischemic/non-ischemic
- NYHA Class III/Ambulatory Class IV
- On Optimal Medical Therapy
- Evaluated or have CRT/CRT-D

## Major Exclusion Criteria

- Ascending aortic calcification or CABG
- Mitral Valve Incompetence, Grade 4+
- Aortic Valve Incompetence, Grade 2-4+

54 yr old male patient

Blood Group: A Rh D Positive

Height: 5ft 11inch

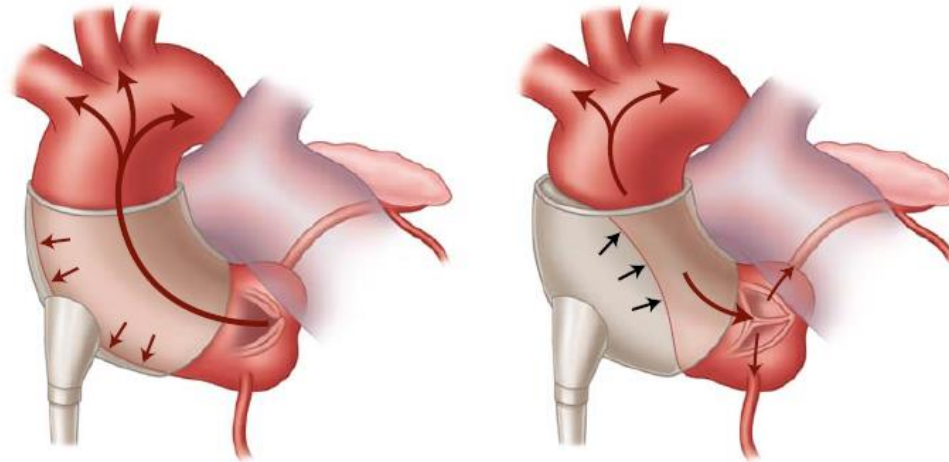
Wt: 90.6kg

Body Mass Index: 28

# Background

- Acute myocardial infarction whilst on vacation in 2002 (required resuscitation following cardiac arrest)
- Primary percutaneous coronary intervention to right coronary artery (RCA) & left anterior descending (LAD) artery (the latter was unsuccessful resulting in LAD obstruction). Circumflex artery unobstructed
- Persistent New York Heart Association Class III symptoms since 2002, fatigue and shortness of breath on minimal exertion, loss of employment
- Atrial fibrillation treated with:
  - AV node ablation: 1 Nov 2012
  - Biventricular ICD pacemaker
- Type 2 diabetes
- Advanced heart failure with C-Pulse system intended as a bridge to heart transplantation

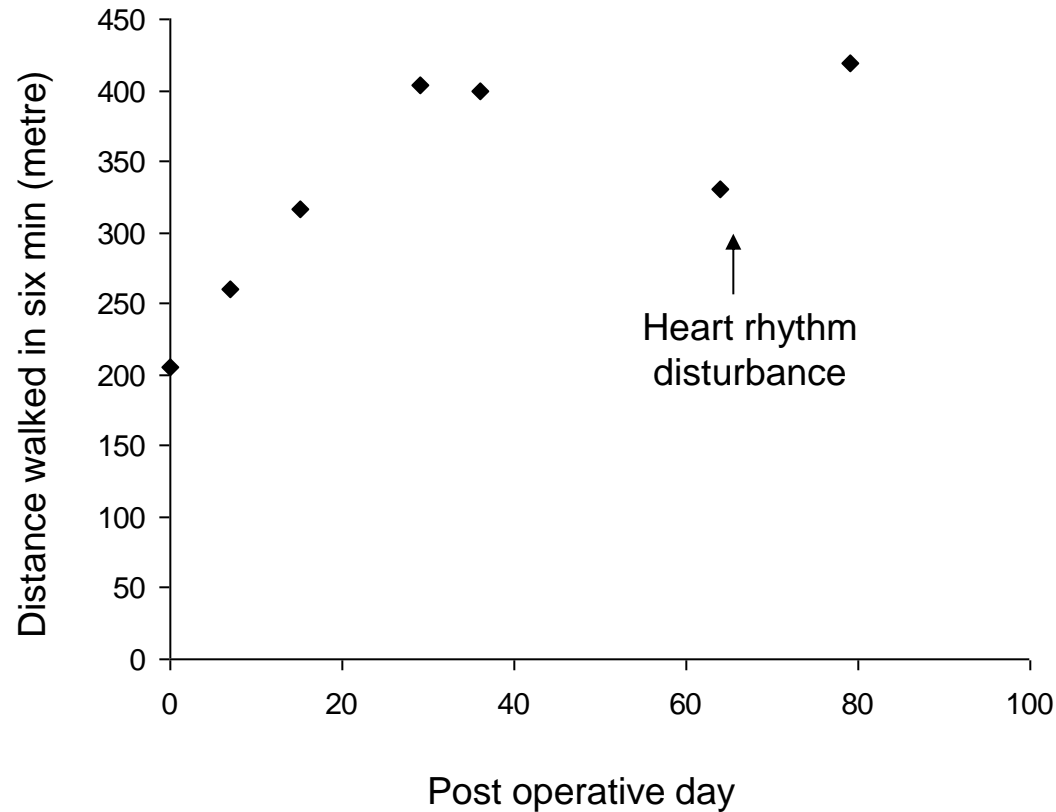
- Fulfilled multi-centre study entry criteria
- C-Pulse implanted at Harefield Hospital, London on 16 June 2014
- The first C-Pulse case in the UK



# Post-operatively

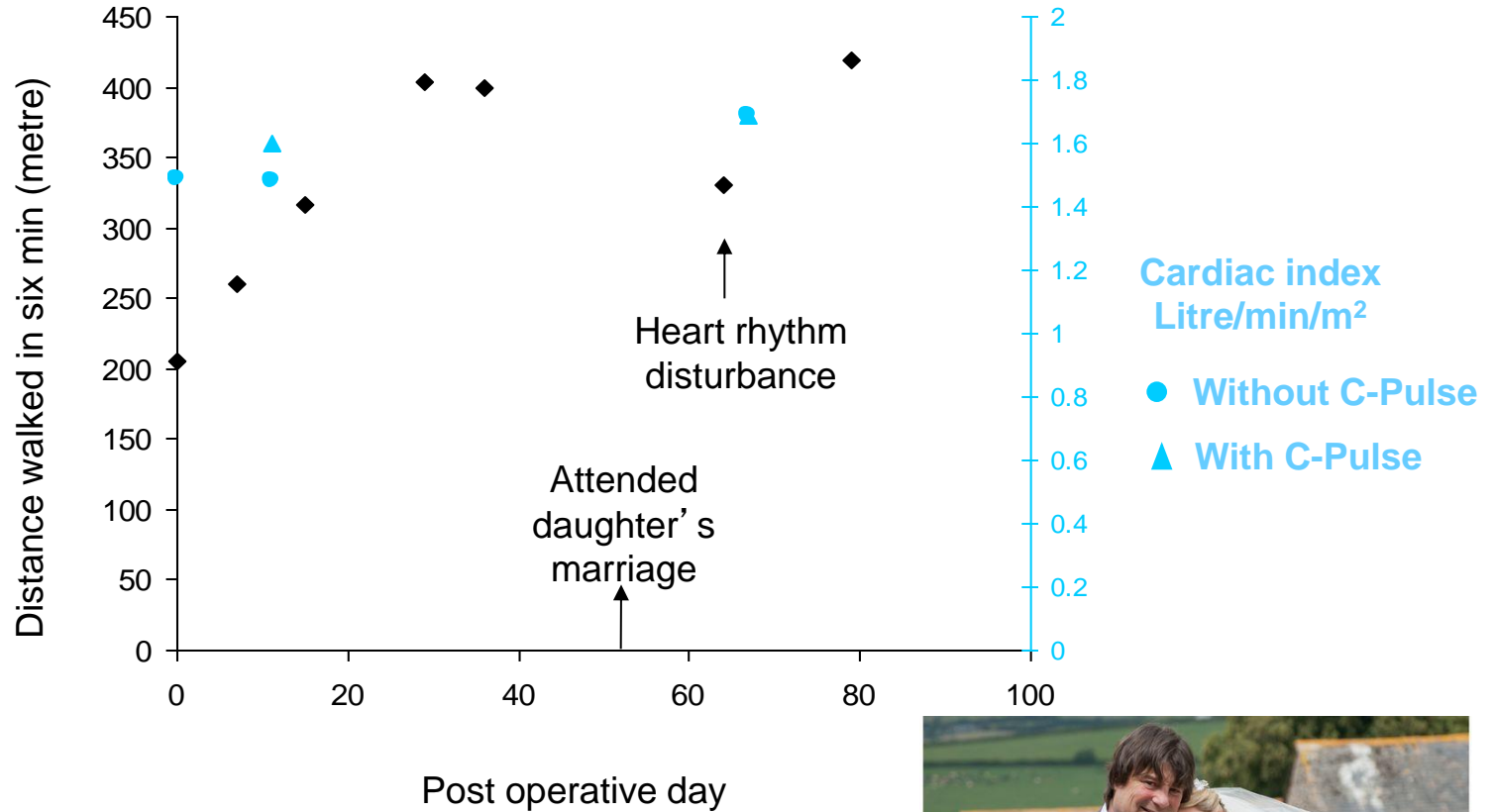
- Uncomplicated surgical procedure and short Intensive Care Unit stay (28 hours)
- Increased inflammatory markers after surgery
  - No source of infection identified
  - Given empirical antibiotic therapy
- Continuing signs of heart failure reflecting poor pre-operative heart function
  - Treated with high dose diuretics.
- Discharged home on post operative day 22
- Readmitted post operative day 47 to 52 with diarrhoea possibly due to antibiotic therapy
- Readmitted post operative day 64 to 79 with deterioration in exercise capacity attributed to heart rhythm disturbance
  - Treated with short course of i.v. milrinone and higher beta blocker dose

## Functional capacity improvement as a result of C-Pulse therapy



- New ventricular ectopies may be an early sign that previously-thought ischemic (or lost) tissue is being perfused

# Functional capacity improvement and changes in heart function as a result of C-Pulse therapy





# Summary

- 54 year old man
- Advanced heart failure due to ischaemic cardiomyopathy
- Uneventful C-Pulse implantation as a bridge to heart transplant
- Has needed medical management for heart failure since surgery
- Limited improvement in resting hemodynamics
- Yet marked improvement in functional capacity possibly due to increased blood perfusion
- Remains a suitable candidate on the active heart transplant list

# Implications

- Caution: Single patient experience
- Preliminary findings concur with large scale studies with B-blockers<sup>1,2</sup> and cardiac resynchronisation therapy pacemakers<sup>3</sup>
  - Subtle improvements in heart function can result in clinically important benefits, i.e. improved exercise tolerance and quality of life.

1.NEJM 1996; 334:1349

2.NEJM 2001;344:1651

3. NEJM 2002;346:1845