Enhanced External Counterpulsation (EECP)- Role in Management of Heart Failure

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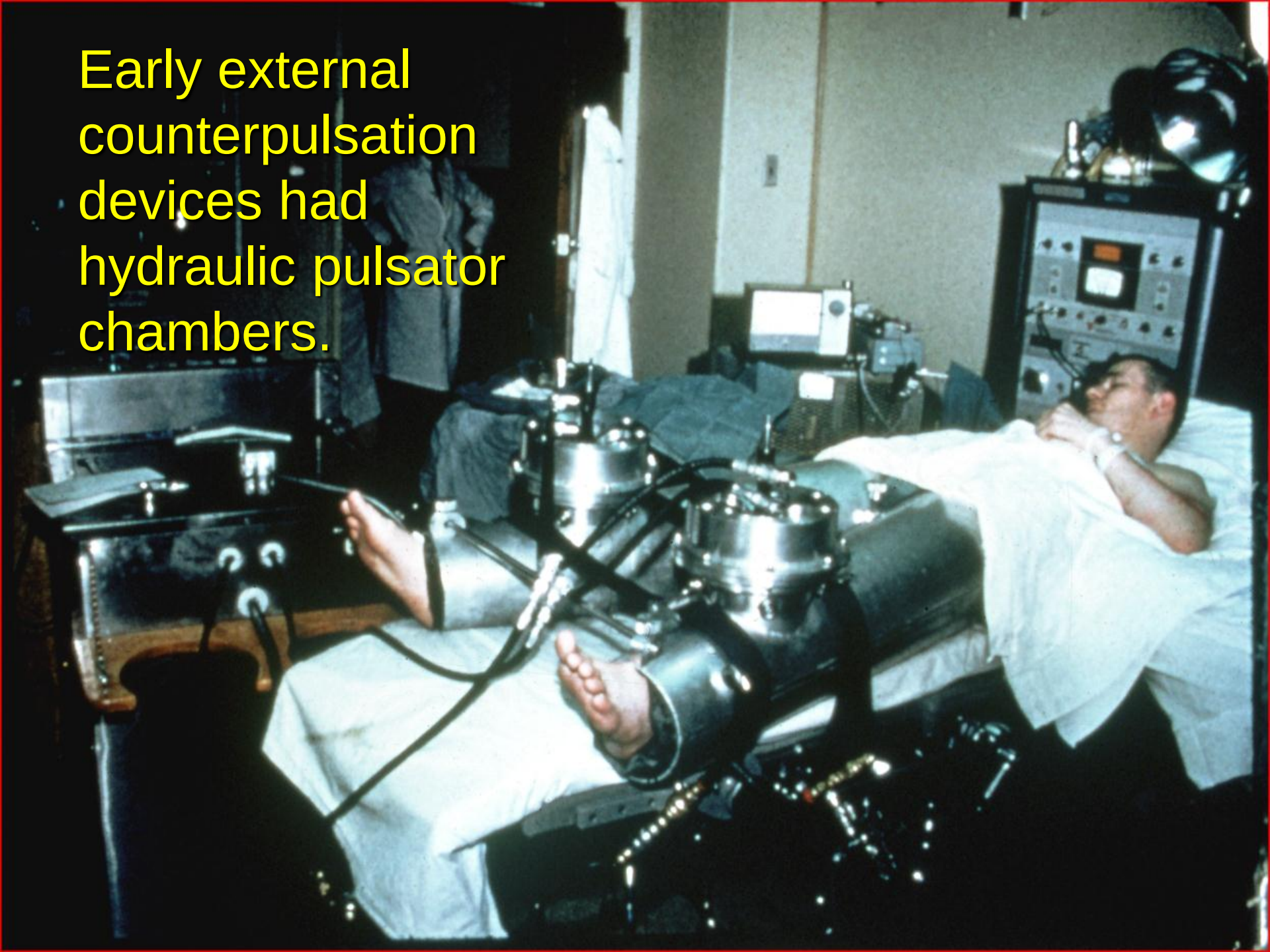
History of External Counterpulsation

1950's: - Kantrowitz Brothers - diastolic augmentation
- Sarnoff - LV unloading
- Birtwell - combined concepts
- Gorlin - defined counterpulsation

1960's: - Birtwell & Soroff - Dennis- Osborne – hydraulic external counterpulsation

1970's: - Soroff - cardiogenic shock
- Banas - stable angina
- Amsterdam - acute MI

1980's: - Failure to gain acceptance
- China; redeveloped technology- pneumatic system
- Soroff, Hui, Zheng collaboration at Stony Brook


Early external counterpulsation devices had hydraulic pulsator chambers.

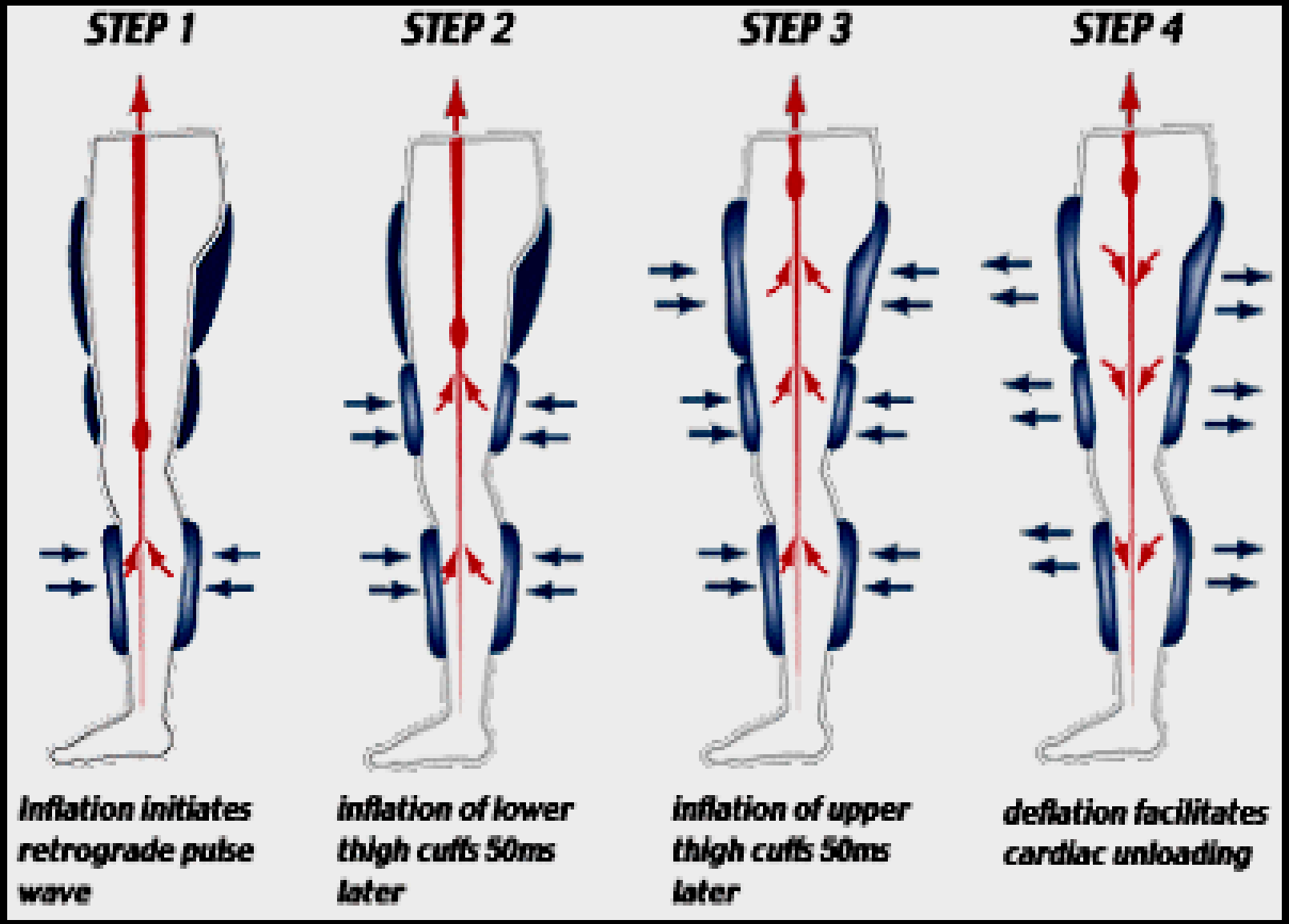
- In the early 1980’s, a Chinese group lead byZ.S. Zheng redeveloped technology- pneumatic system
- Their positive clinical experience led to the installation of more than 1500 external counterpulsation units in China

EECP-Pneumatic device

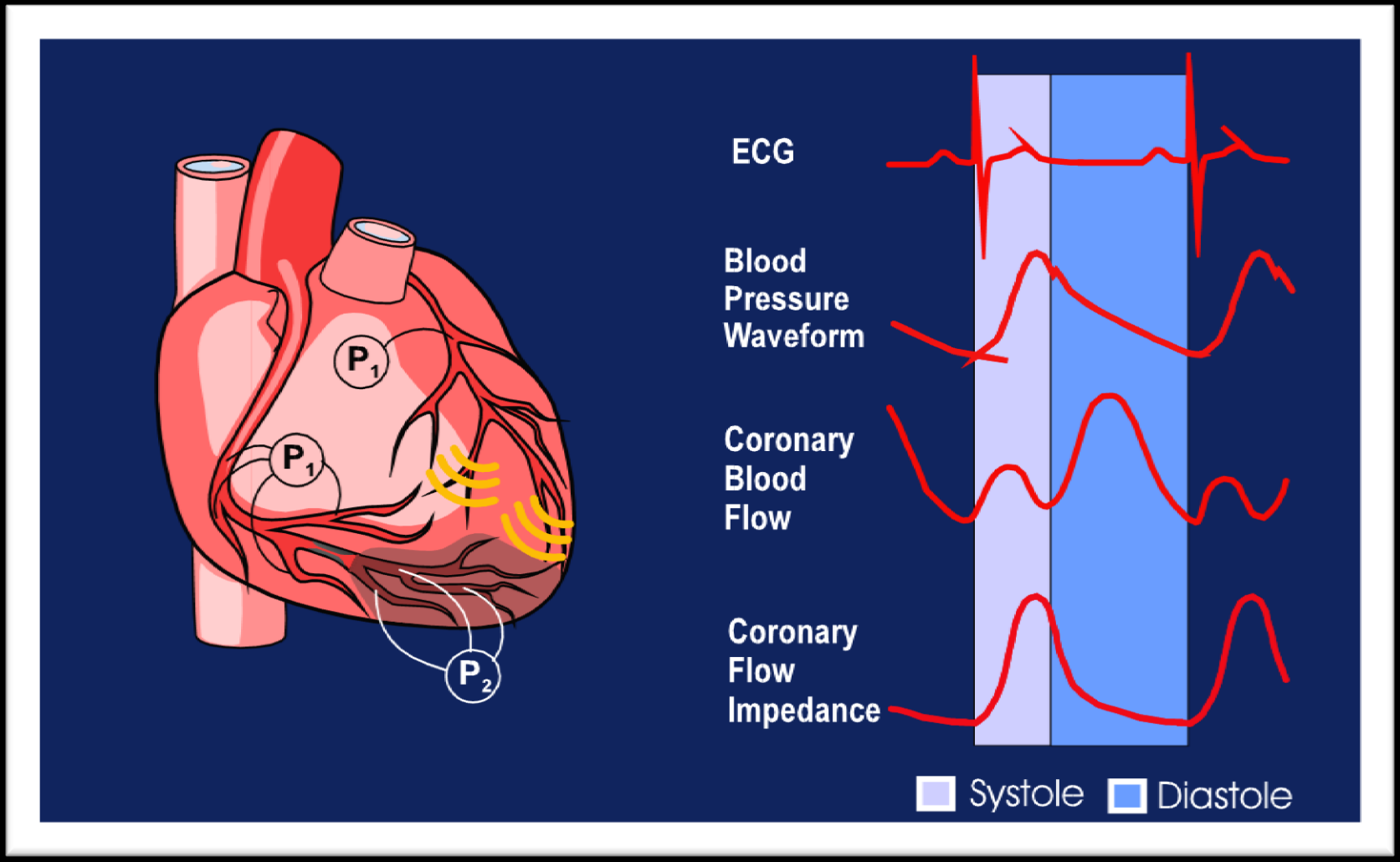
EECP-Mechanism

- Involves the use of three paired inflatable cuffs wrapped around the patient's lower extremities
- The patient is connected to an ECG monitor and a finger plethysmograph
- Pressures in the range of 250-275 mmHg applied
- Treatment course consists of 35 one-hour sessions 1 hour per day over 7 weeks

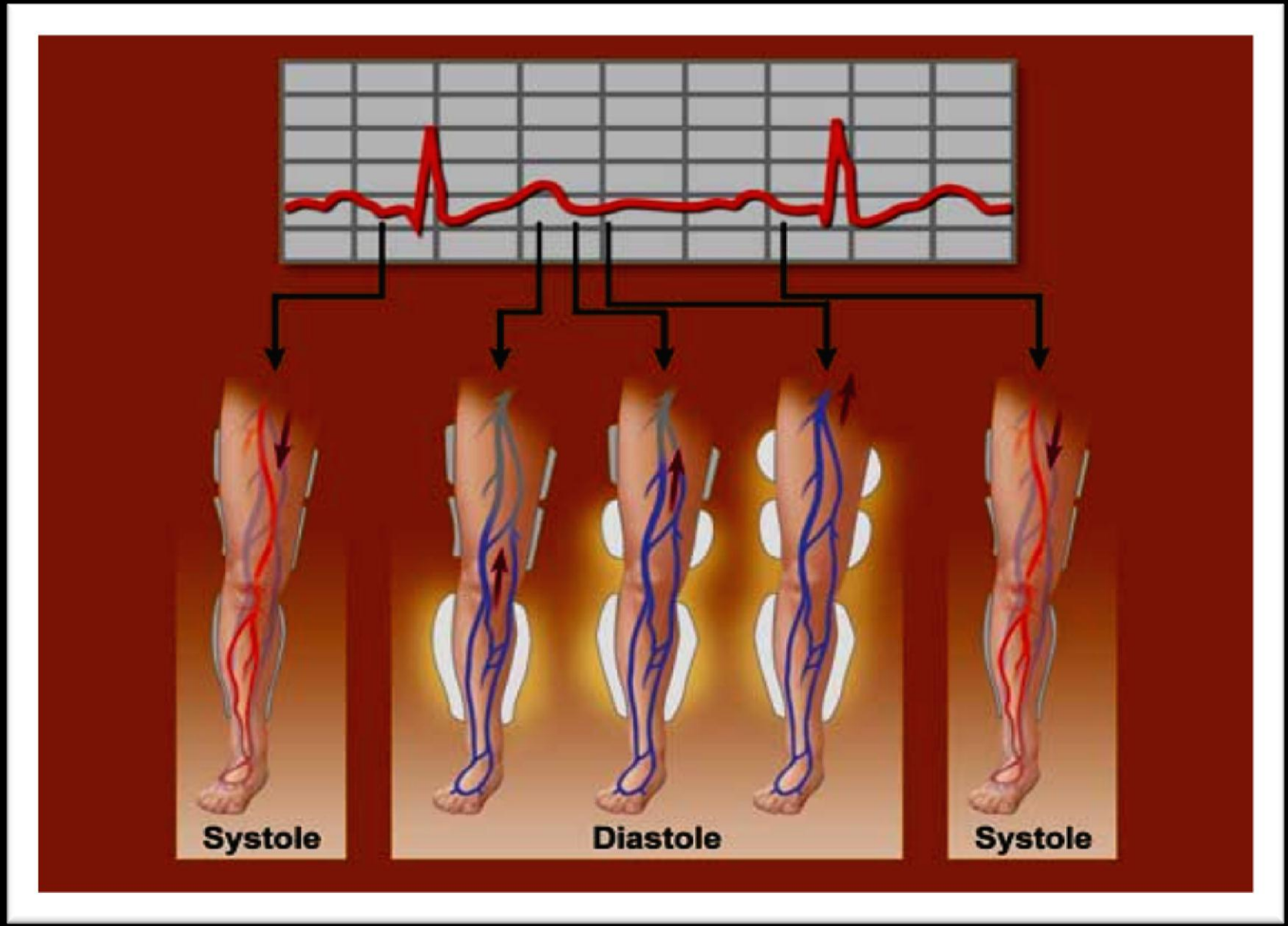
The cuffs are sequentially inflated (calves → lower thighs → upper thighs) during diastole

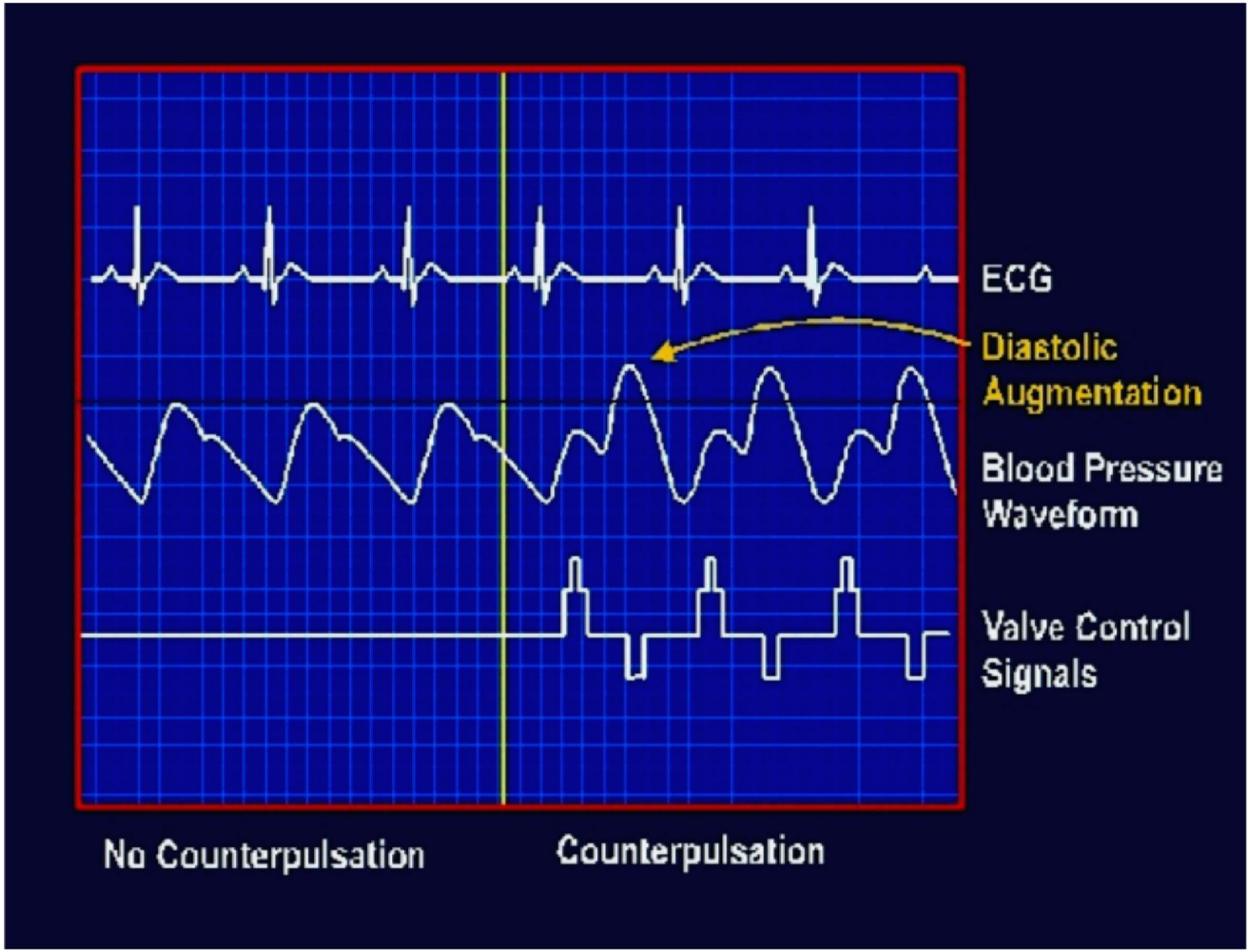


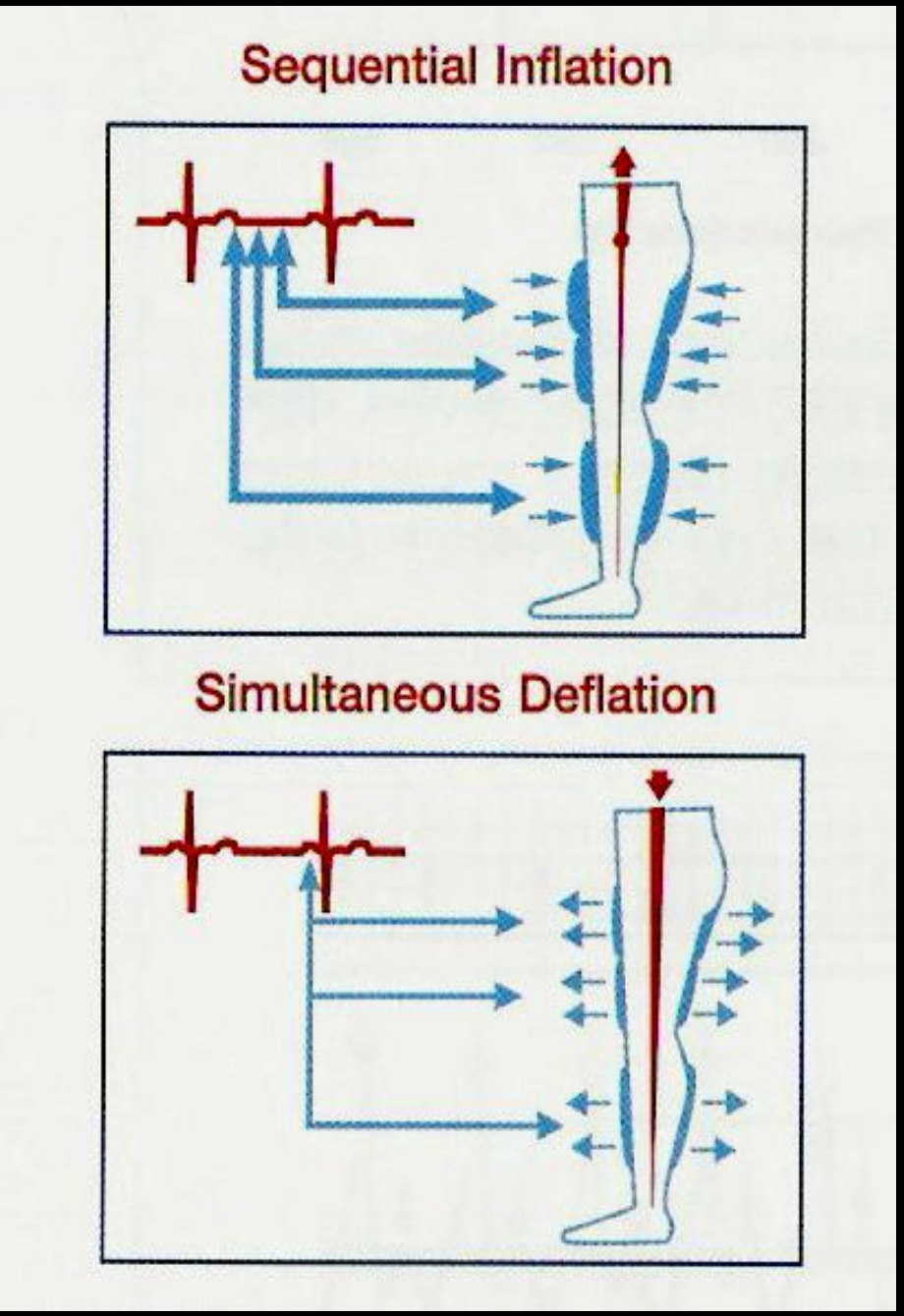
The R wave of the ECG is used as the trigger for inflation and deflation



All pressure is released at the onset of systole



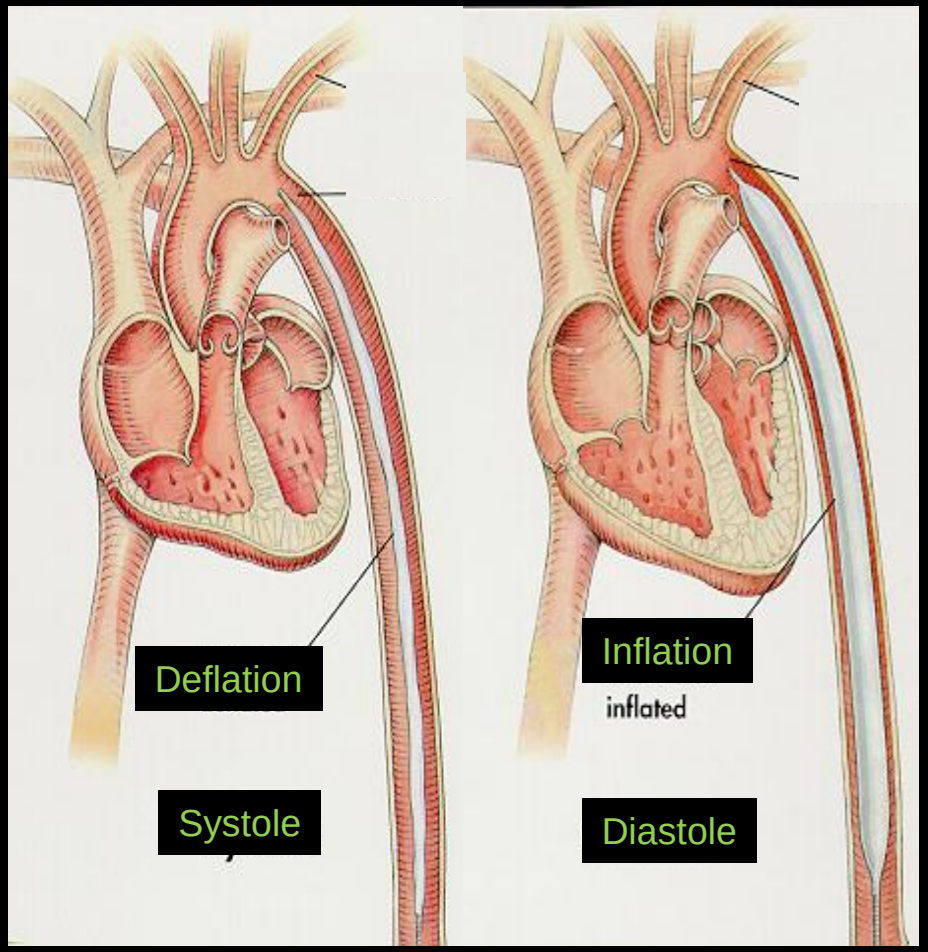

ECG
Diastolic Augmentation
Blood Pressure Waveform
Valve Control Signals
No Counterpulsation
Counterpulsation

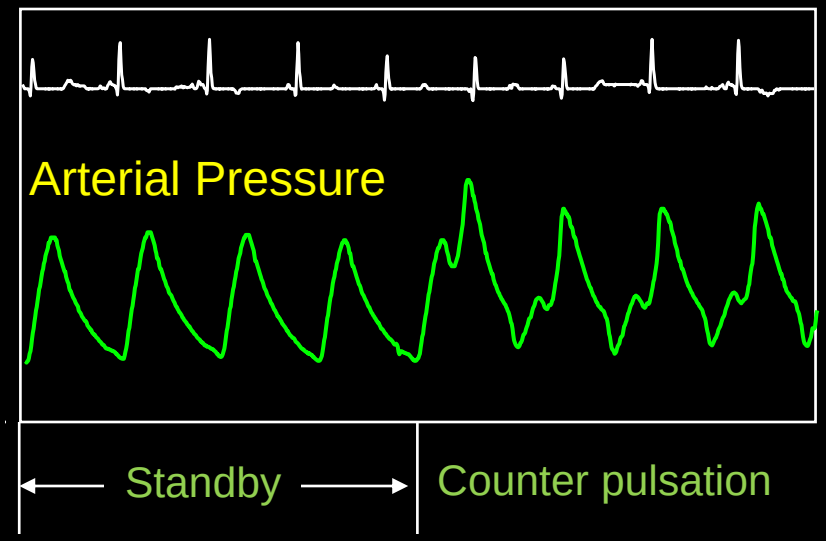


- ⇑ diastolic pressure
- ⇑ intracoronary perfusion pressure
- ⇑ myocardial perfusion
- ⇑ venous return
- ⇑ preload
- ⇑ cardiac output

- ⇓ systemic vascular resistance
- ⇓ cardiac workload
- ⇓ myocardial O_2 consumption
- ⇓ afterload

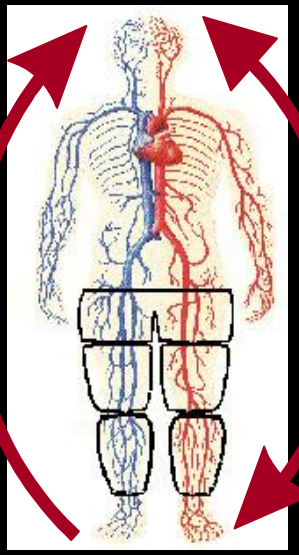
Intra-Aortic Balloon Pump





Increased Venous Return

Diastolic Augmentation



Improve LV Diastolic Filling

Systolic Unloading

Mechanism of Effect in angina & HF

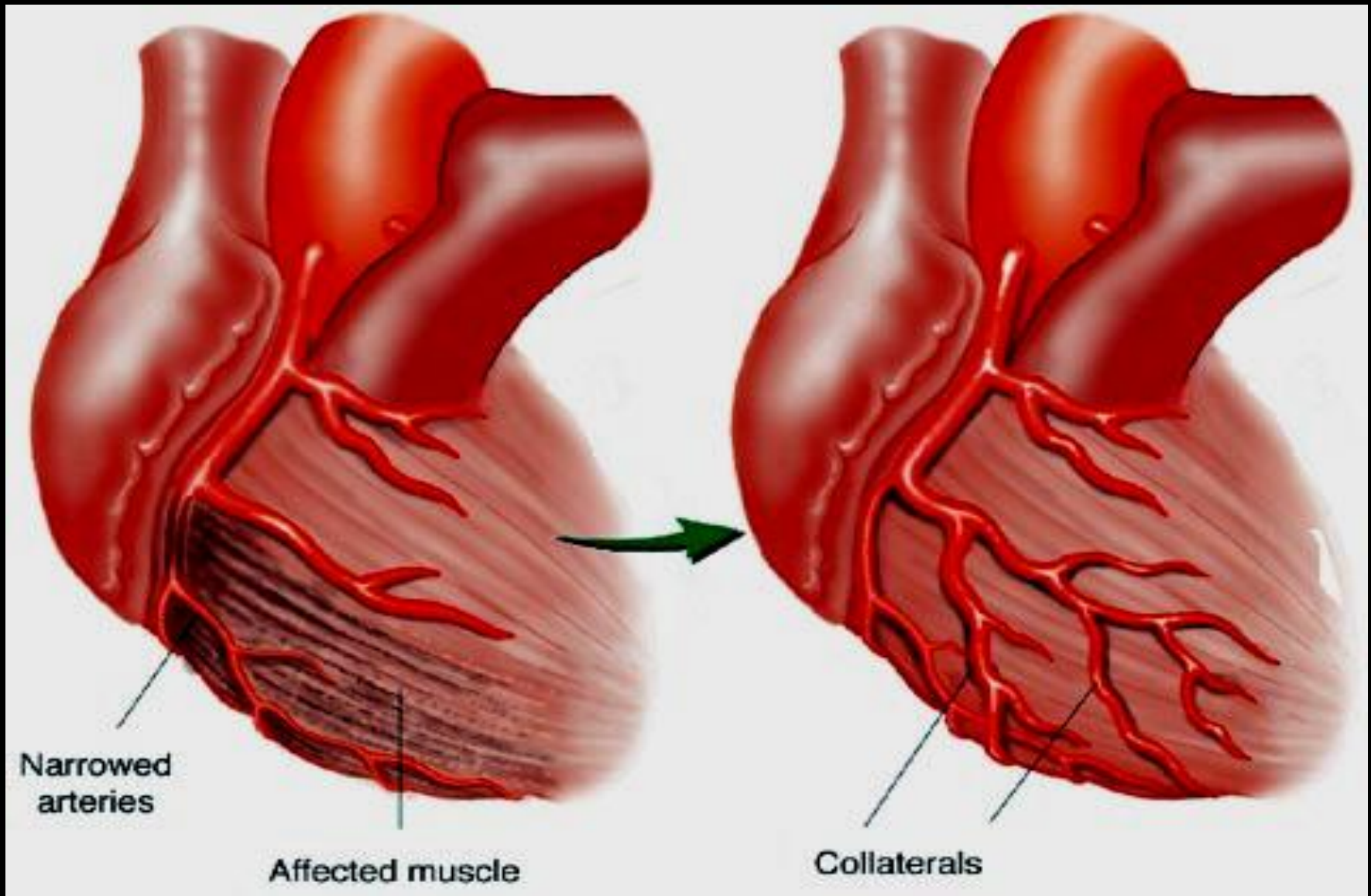
EECP believed to increase the development of collateral circulation resulting in improved myocardial perfusion

Chronic exposure to EECP increases shear stress in the coronary circulation

Shear stress results in a cascade of growth factors which stimulate angiogenesis

Clin Cardiol 1999;22:173-178

Increased transmyocardial pressure open collaterals



EECP is a recently approved treatment modality for selected patients with Heart failure

Indications for EECP Therapy

A. Chronic CAD Primary utilization of EECP to revascularize Anginal Patient refractory to Medical treatment

B. Surgery /PTCA not contemplated

Patient refused
Diffuse distal disease.
Target lesion is inaccessible.
Co-morbid states create high risk
LV dysfunction – High risk CABG.
Restenosis after PTCA
CABG graft occlusion

C. Preparation for Revascularization

Severe LV Dysfunction with lot of hibernation to stabilize Heart Function.
Waiting due to some other reason.

D. Heart Failure Non-Ischemic Cardiomyopathy
Ischemic Cardiomyopathy
Patient with LV Dysfunction
Patient with moderate to severe levels of CHF.

E. Cardiac X Syndrome. .

- The first multicenter randomized sham-controlled trial was the MUlticenter STudy of Enhanced External CounterPulsation (MUST-EECP)

- MUST-EECP compared full EECP treatment –vs- sham on exercise treadmill scores and subjective angina

Follow-up analysis of patients in the MUST-EECP trial at 1 yr showed greater improvement in the health-related quality of life measures in the active treatment group

More Studies…

Published Controlled & Uncontrolled Trials of EECP Therapy in Patients With Stable Angina[1]

Study (Ref.)	Year	N	Treatment Duration (h)	Angina (% ≥1 CCS)*[2]	Nitrate Use	Exercise Tolerance	Time to ST Depression	Cardiac Perfusion (%)*
Lawson et al.	1998	60	35	↓		↑		↑(75)
Arora et al.	1999	139	35	↓	↓	↑	↑	
Lawson et al.	2000	33	35-36	↓	↓			↑(79)
Lawson et al.	2000	2,289	35	↓(74)*				
Urano et al.	2001	12	35			↑	↑	↑
Masuda et al.	2001	11	35			↑	↑	↑
Stys et al.	2001	395	35	↓(88)*				
Barsness et al.	2001	978	35	↓(81)*	↓			
Stys et al.	2002	175	35	↓(85)		↑		↑(83)

[1] Adapted from Bonetti, et al[16]

* % of patients for whom this criterion applies are listed in parentheses.

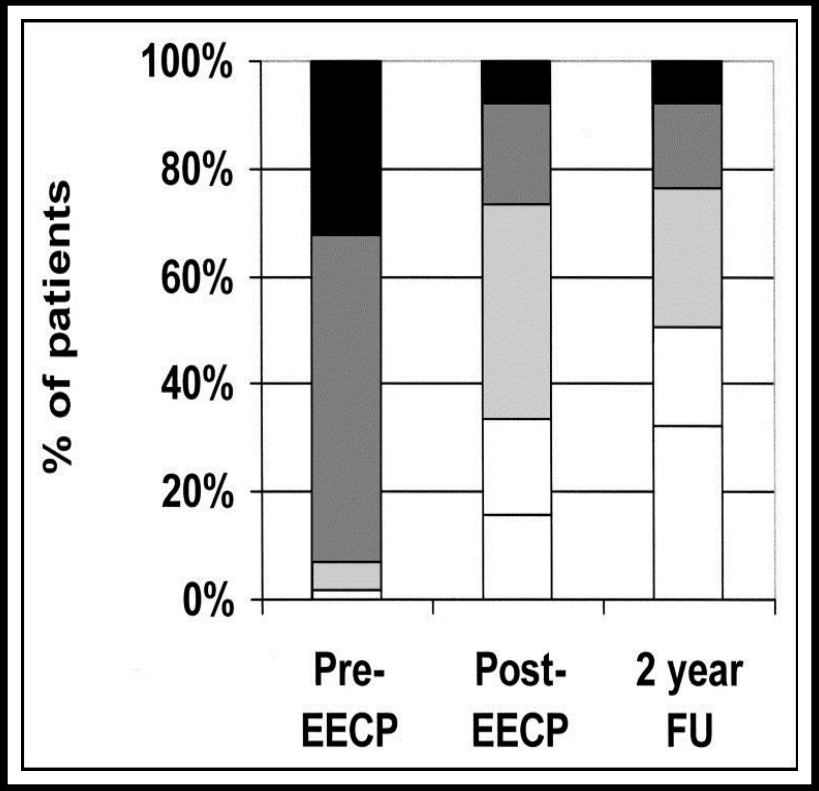
[2] CCS = Canadian Cardiovascular Society

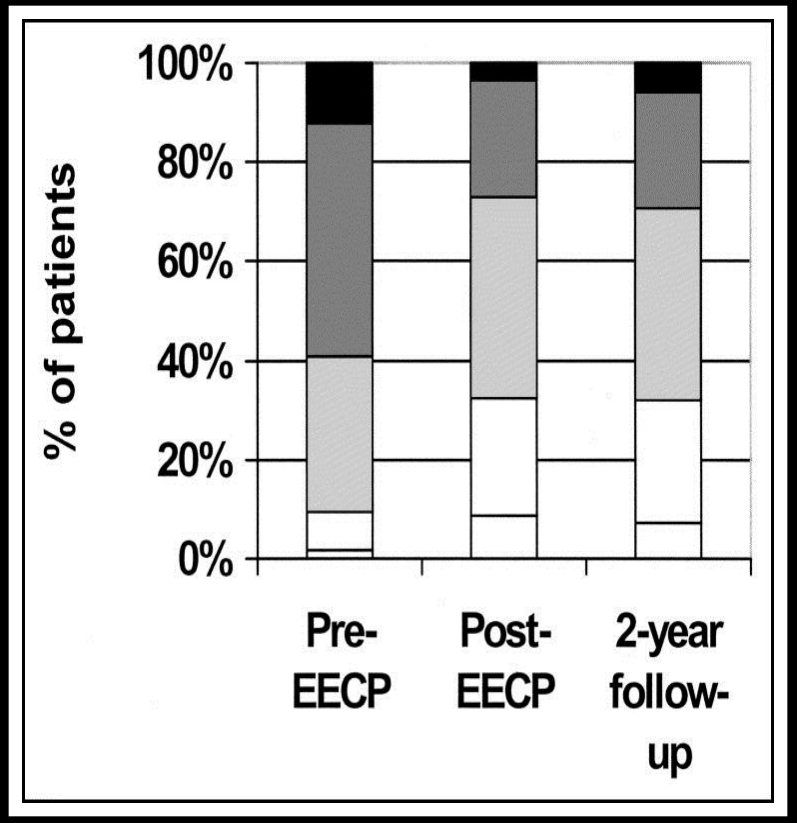
↓ = Reduced, ↑ = Increased

In January 1998, Phase 1 of the International EECP Patient Registry (IEPR) was established to document patient characteristics, safety, efficacy, and long-term outcomes of EECP therapy

Two-Year Clinical Outcomes After Enhanced External Counterpulsation (EECP) Therapy in Patients With Refractory Angina Pectoris and Left Ventricular Dysfunction (Report from the International EECP Patient Registry)

Ozlem Soran, MD, MPH, Elizabeth D. Kennard, PhD, Abdallah Georges Kfoury, MD, Sheryl F. Kelsey, PhD and IEPR Investigators





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DOI: 10.1016/j.amjcard.2005.07.122

Analysis of long-term outcomes demonstrate that the clinical benefits achieved with EECP are sustained up to at least 24 months

A modified course of Enhanced External Counterpulsation improved myocardial perfusion in patients with severe left ventricular dysfunction

Pradeep G.Nayar[1], S.Ramasamy[1],Madhu.N.Sankar[1], K.M.Cherian[1] ,William E Lawson[2] and John CK Hui[2]

[1]Frontier Lifeline & Dr.K.M.Cherain Heart Foundation, [2]Cardiology, SUNY at Stony Brook, NY, USA

Standard treatment protocol

One (1) hour per day
Six (6) days per week.
Six (6) weeks

Modified treatment protocol

Two (2) hours per day
Six (6) days per week.
Three (3) weeks

EECP Therapy Treatment
For
Angina & Heart Failure

Short course treatment protocol

One (1) hour per day
10-15 sessions.
Seven(7) days per week

Summary

Short course of EECP in patient with Severe LV Dysfunction prior to CABG improves myocardial perfusion and LV contractility.

Short course EECP can reduce post CABG hospitalization and IABP insertion.

Effect of Enhanced External Counterpulsation on Ejection Fraction in Patients with Ischemic Heart Disease

William E Lawson[1], Himanshu Padh[2], Subramanian Ramasamy[3], John CK Hui[1]

- **EECP significantly improved LV ejection fraction, stroke volume, cardiac output in patients with ischemic heart disease and**
  - Left ventricular EF > 35%
  - Left ventricular EF ≤ 35%
- The increase in Left Ventricular EF is mediated predominately by a decrease in end-systolic volumes.

Journal of American college of cardiology March 11,2008 Volume51 ,No 10 (Sup A)

PEECH Trial

Prospective Evaluation of EECP in Congestive Heart Failure (PEECH) Trial

PEECH Trial

187 patients with stable heart failure with NYHA class II/III symptoms,
Ischemic or non-ischemic etiology, LVEF ≤35%, optimal pharmacologic therapy, ability to exercise ≥3 minutes, limited by SOB or fatigue (not angina)
24% female, mean age 63 years
76% received ACE-inhibitors, 19% ARB, 85% beta-blockers

EECP + ACE-Inhibitors or EECP + ARB & beta-blockers,
EECP as 35, 1 hour sessions for 7 weeks
n=93

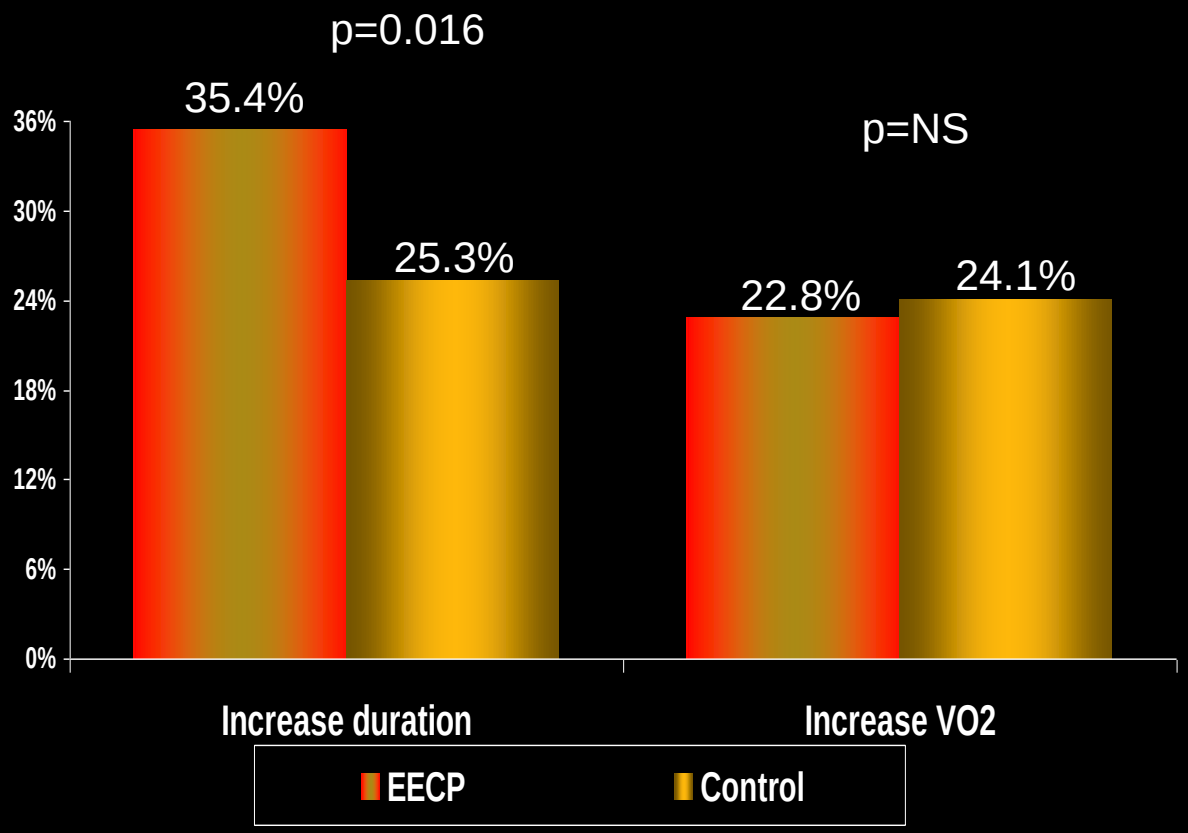
ACE Inhibitors or ARB & beta-blockers
n=94

Primary Endpoint: Percentage of subjects with 1)at least a 60 second increase in exercise duration from baseline to 6 months or 2) at least 1.25 ml/min/kg increase in peak VO2 from baseline to 6 months

Secondary Endpoint: Adverse events or changes in exercise duration and peak VO2, NYHA classification, quality of life

PEECH Trial: Primary Endpoint

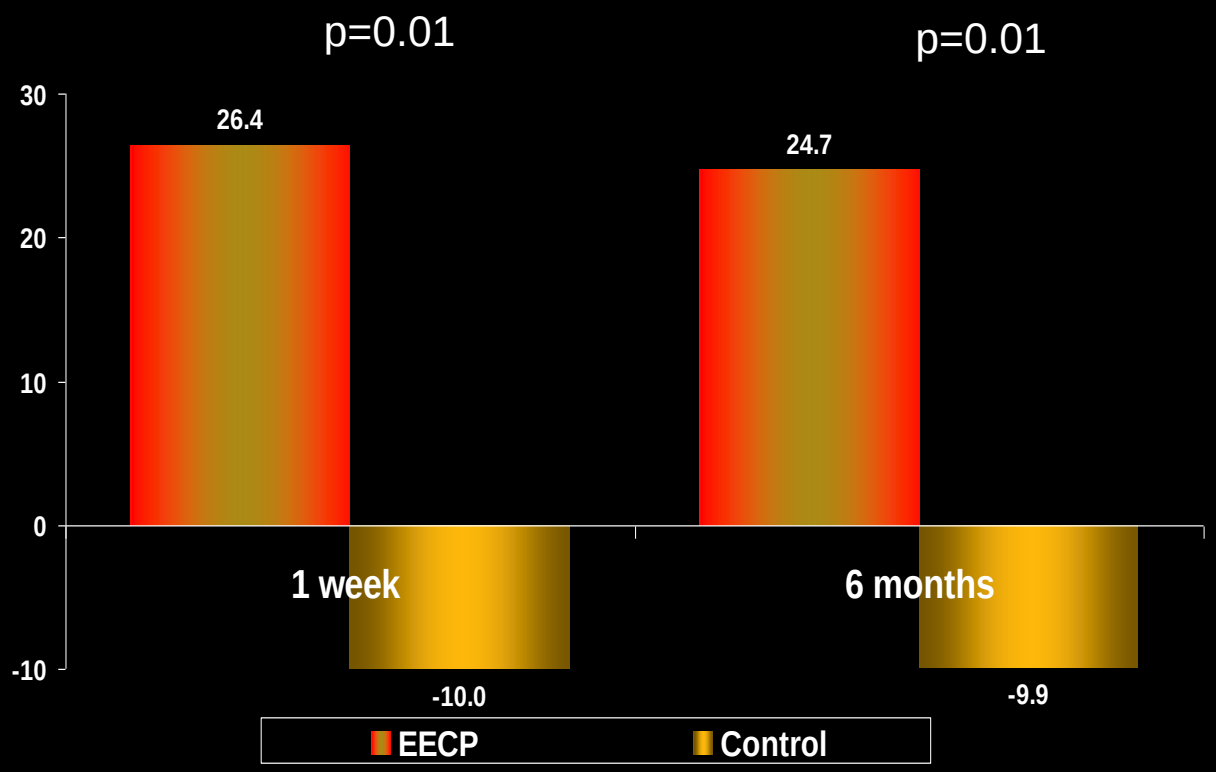
Primary endpoints of increase in excercise duration at 6 months & increase in peak VO2



- The primary endpoint of increase in exercise duration by at least 60 seconds occurred more frequently in the EECP group compared with the control group at a 6 month follow-up.

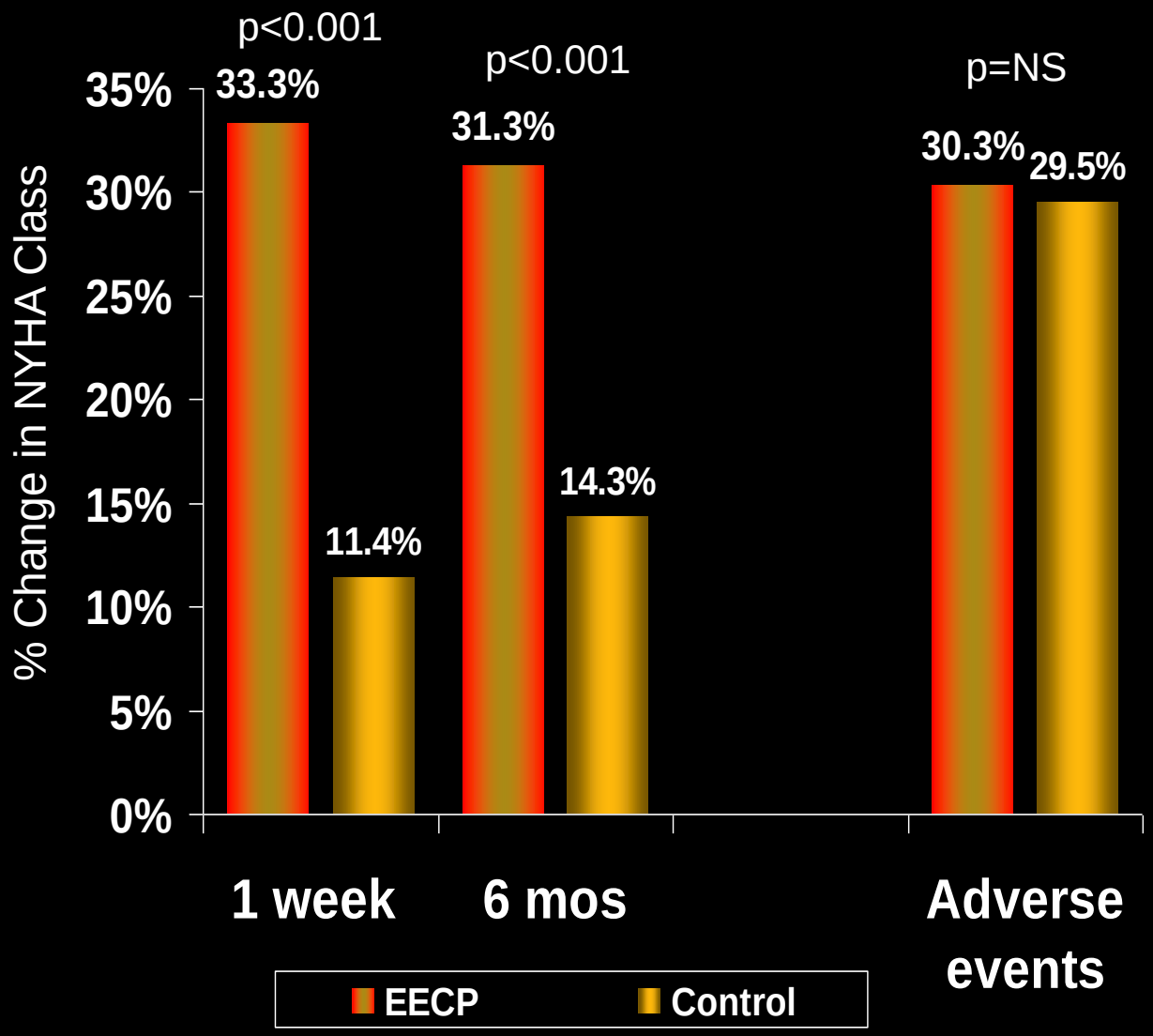
- The co-primary endpoint of increase in peak VO2 of at least 1.25 ml/min/kg was the same between the two groups.

PEECH Trial: Secondary Endpoint of Change in Exercise Duration



- The change in exercise duration was longer in the EECP group versus the control group, which actually had a decrease in exercise duration at 1 week and 6 months.
- The increase in the EECP group's exercise duration was maintained at the 6 month follow-up.

PEECH Trial: Secondary Endpoint



- There was more improvement in NYHA classification in the EECP group compared to the control group.

- The was no significant difference in the occurrence of serious adverse events between groups.

Evaluation Of EECP in Congestive Heart Failure (PEECH) trial (n=187), four sets of registry data ranging from 127 to 1958 and one case series (n=32)

There were numerous methodological limitations to the registry data and case series such as lack of comparison group, conclusions based on subjective assessment and lack of completion of the case series study for HF

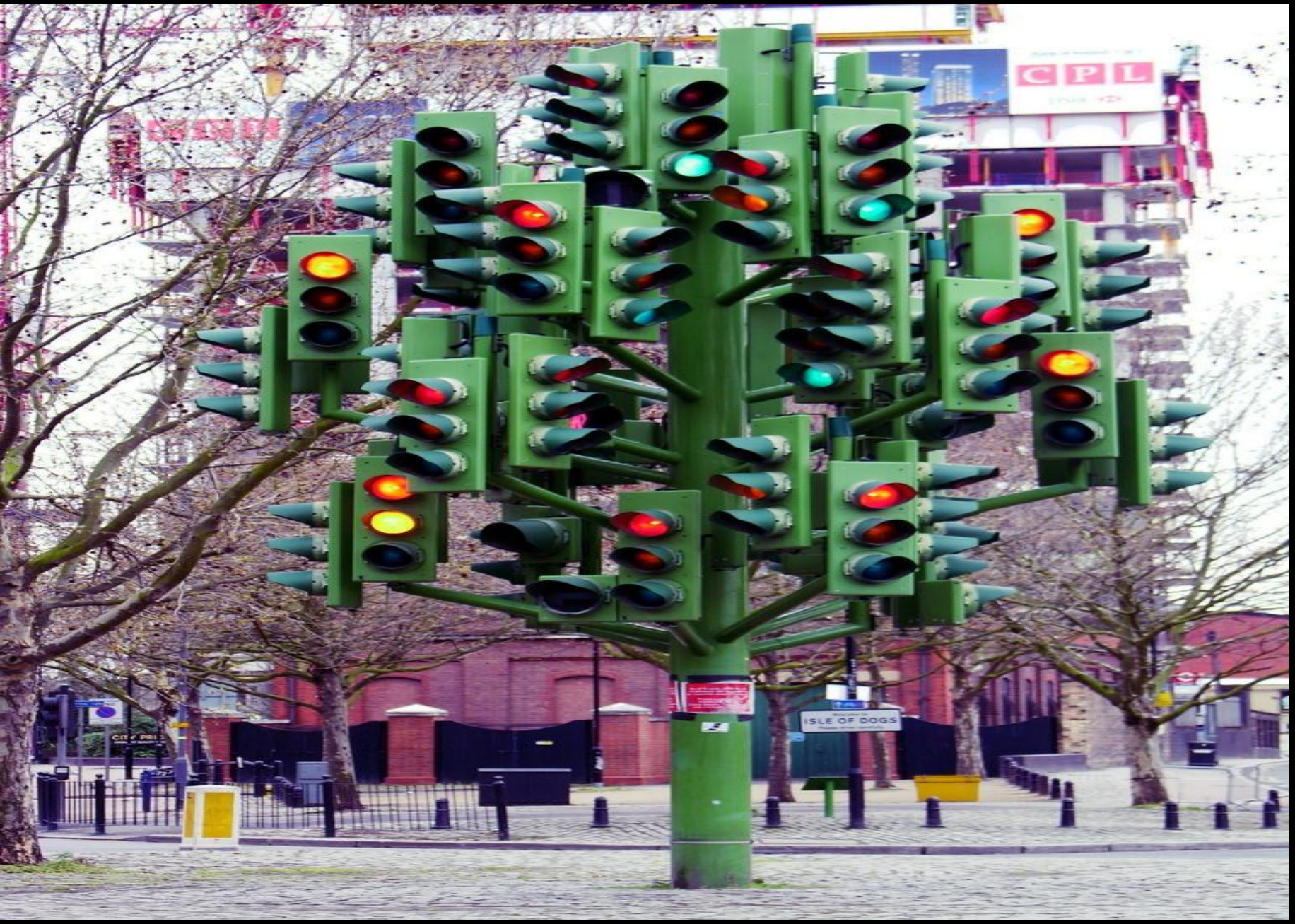
In the studies that investigated EECP for HF ‘ adverse events (AEs) incude major adverse cardiac events (MACEs), death, PCI & incidence of all-cause hospitalisations, and rates ranged from 5% to 72%

Health Technology Assessment 2009; Vol. 13: No.24

EECP for Heart Failure: Is the Juice Worth the Squeeze

We need to know much more about EECP in HF before it is used (and reimbursed) for HF care

Journal Watch Cardiology September 27, 2006


CPL
ISLE OF DOGS


ONE WAY

Conclusions

EECP - Refractory angina and heart failure

RCTs indicate that EECP may be beneficial in both chronic stable angina & HF

Registry data & case series also suggest that EECP may improve patient outcomes such as improved LVEF, NYHA functional class, decreased rate of exacerbation & improved QoL

EECP is safe in HF but its efficacy is still uncertain

Long-term follow-up trials are required to investigate the benefits of EECP in HF