

**OPTIMIZING OUTCOME WITH MECHANICAL SUPPORT IN
CARDIOGENIC SHOCK:
WOULD MORE (DIASTOLIC) AUGMENTATION IN IABC
BE BENEFICIAL?**

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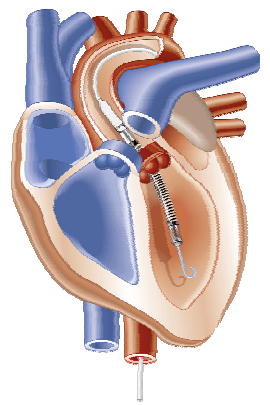
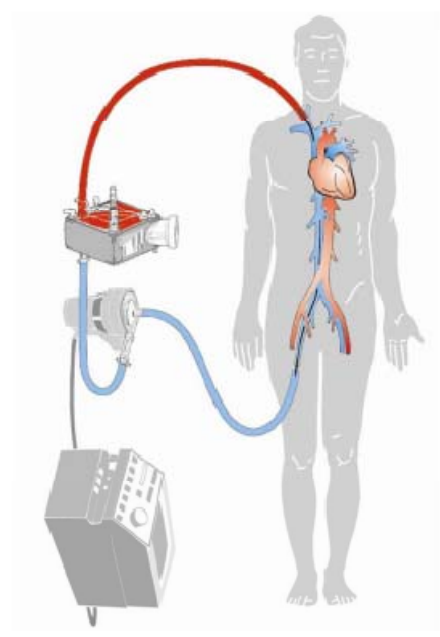


LIFE SAVING THERAPIES FOR ACUTE AND HIGH RISK PATIENTS: AVAILABLE PERCUTANEOUS CARDIAC ASSIST DEVICES

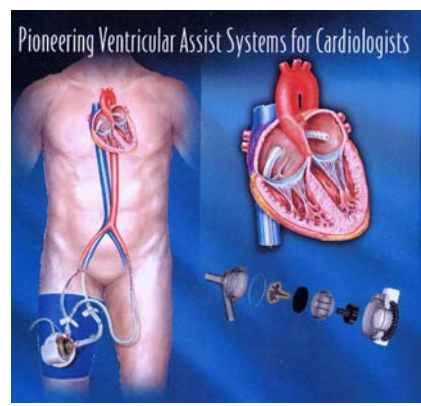


IABC

cardiopulmonary support (CPS)



Impella LP 2.5 / 5.0



TandemHeart



THEORETICAL ASPECTS OF IABC



IABC (**I**ntra-**A**ortic **B**alloon **C**ounterpulsation):

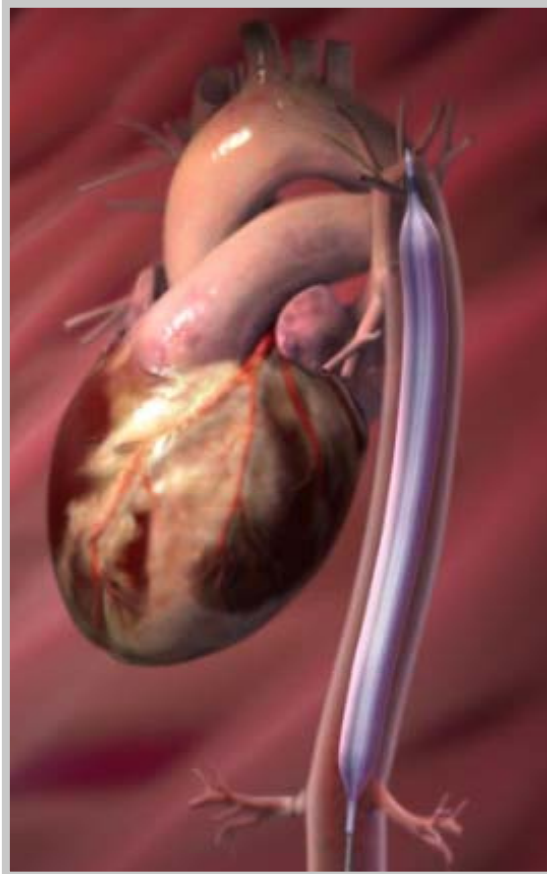
- Therapy strategy for support of the left ventricle in case of myocardial dysfunction (left ventricle failure)
- Developed over 40 years ago
- Main goals of IABC are an **increase** of coronary perfusion and a **decrease** of myocardial oxygen demand
- Top indication for IABC is **cardiogenic shock**
- Recommended indications for IABC are **pre-operative and pre-interventional usage for „high risk patients“**

THE IAB PUMP

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IAB INFLATION - DIASTOLE



- **Augmentation** of diastolic pressure
- **Increase** coronary perfusion
- **Increase** Myocardial Oxygen Supply

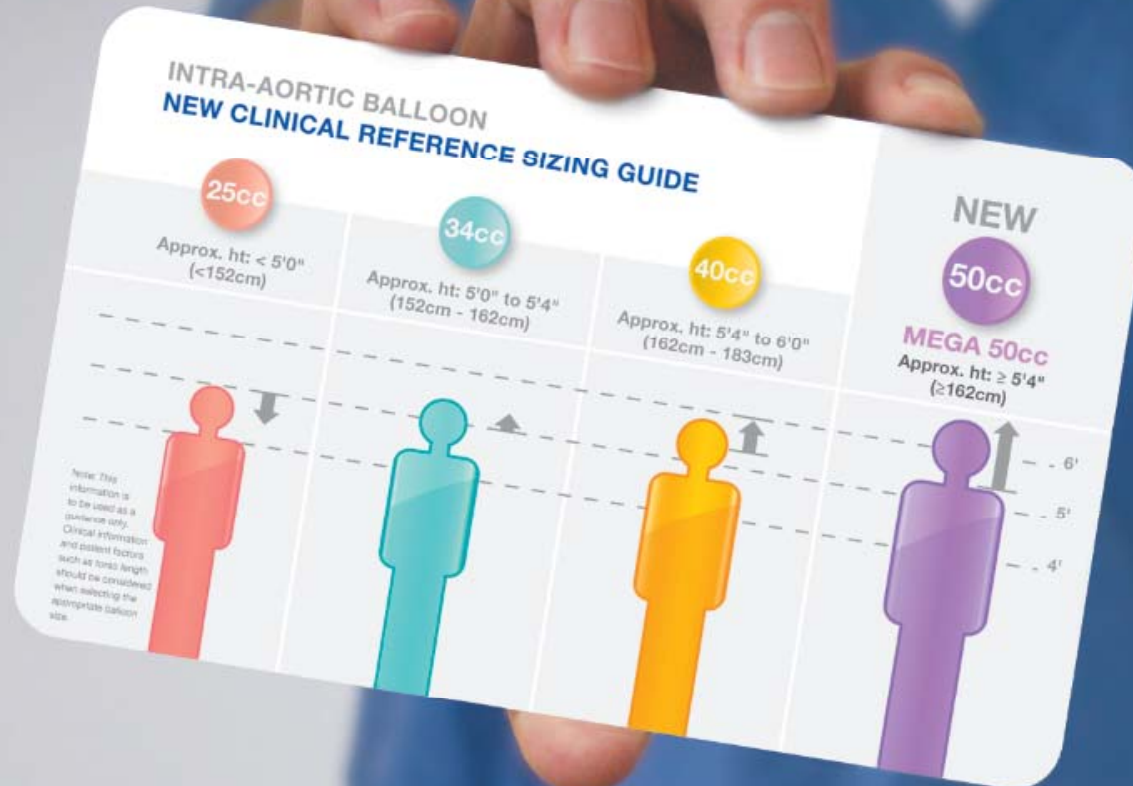
IAB DEFLATION - SYSTOLE



- **Decrease** afterload
- **Decrease** cardiac work
- **Decrease** myocardial oxygen consumption
- **Increase** cardiac output

MEGA™: WOULD MORE AUGMENTATION BE BENEFICIAL?

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Enhanced Augmentation of Cardiac Output for Different Counterpulsation Modes Using a New Intra-Aortic Balloon and Catheter

Cath Lab Digest: Catalin Boiangiu et al_PUBLICATION DATE:
Jun 01 2010

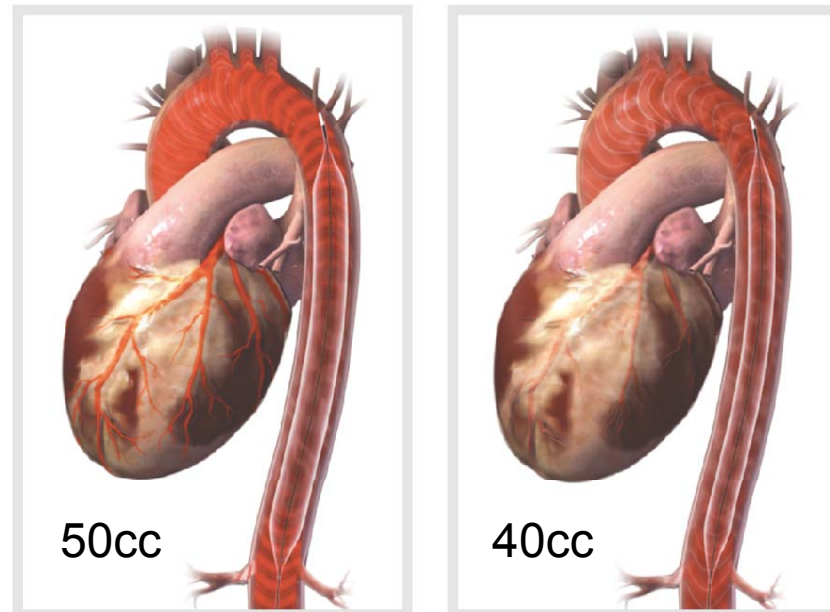
Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician. Refer to package insert for current indications, warnings, contraindications, precautions and instructions for use.
ML-0221-01

INTRODUCTION

- Benefits of balloon counterpulsation depend on several patient specific factors:
 - balloon-to-aorta cross-sectional area
 - aortic wall compliance
 - heart rate
 - peripheral vascular resistance
- The authors evaluated the new MEGA™ 50cc IAB catheter offering 25% more blood displacement than the conventional 40cc IAB catheter

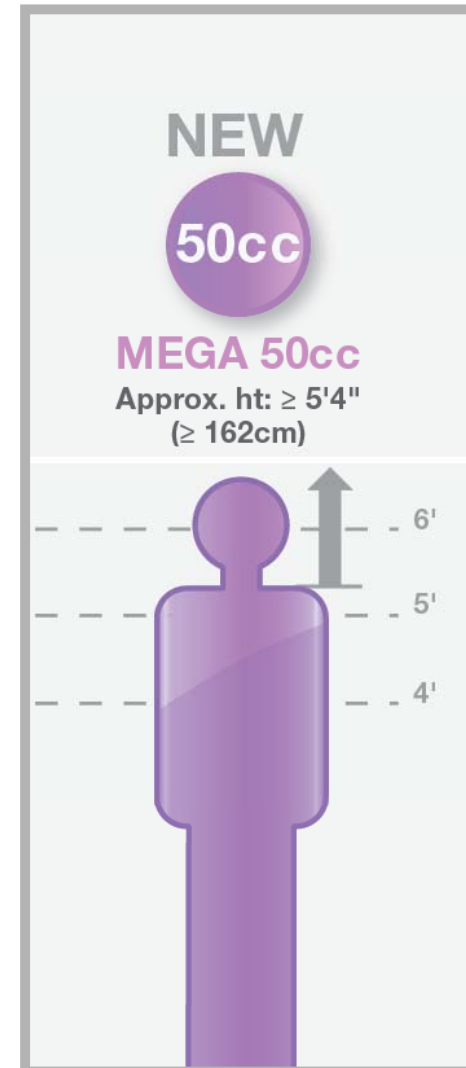
1. Improved Performance Compared to 40cc IABs

- 25% more blood volume displacement
- Improved unloading and augmentation
- Delivering 10cc more volume at a comparable speed



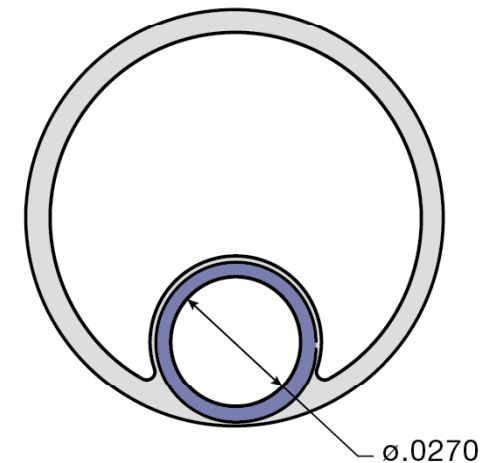
2. Greater Application

- For patients 5'4" (162cm) and taller
- The benefits of a 50cc are now available for smaller patients



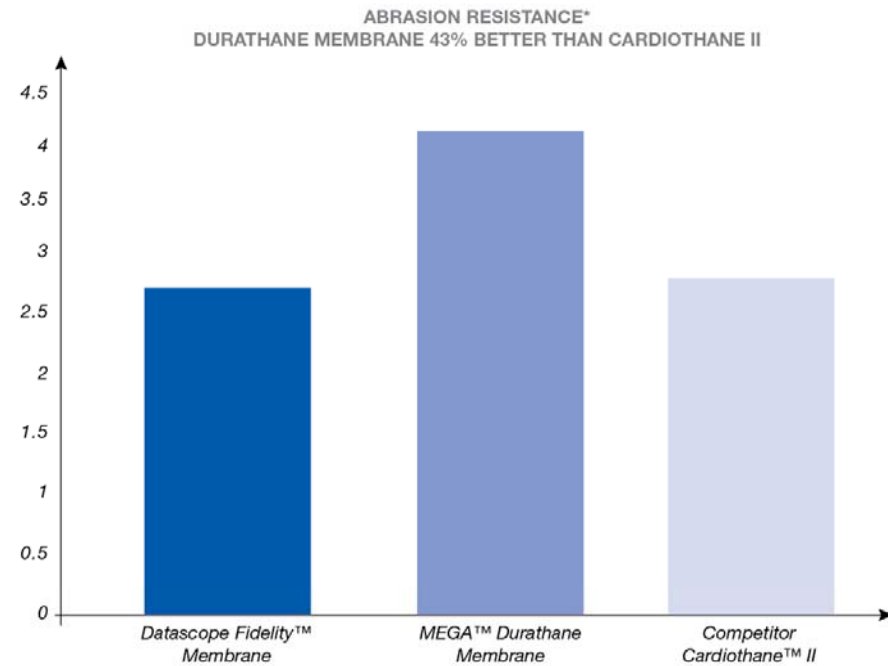
3. True 8Fr. IAB Catheter

- Shaft design is 8Fr.
- Unique balloon wrap provides an 8Fr. profile
- No step down
- Reduced catheter cross sectional area by 24% vs. 10.5Fr.
- Can be used with 8Fr. sheath or inserted sheathless
- Fluid-filled inner lumen 0.027"

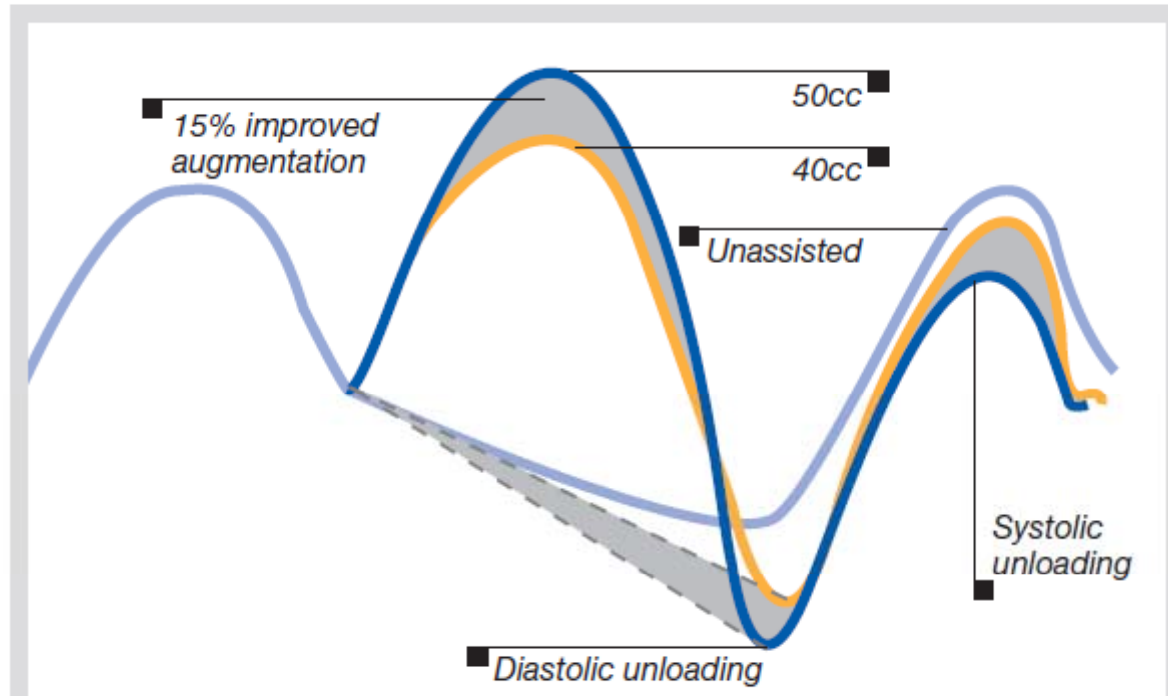


4. Durathane Blow-Molded Balloon Membrane Benefits

- Abrasion Resistance Improved 43%
- Improved Fatigue Resistance
- Reduced Insertion Force
- Immediate Inflation at Start-up



MEGA – IMPROVED UNLOADING AND AUGMENTATION SHEET



MEGA 8Fr. 50cc when compared to 40cc IAB catheters showed:

On average 58% more systolic unloading

On average 15% improved augmentation area under the curve

Reduction in aortic end diastolic pressure

CASE PRESENTATION

- A 60 year-old man presented with a large antero-septal STEMI to a satellite hospital
- Antithrombotic therapy was instituted with aspirin, clopidogrel, and intravenous heparin
- In the absence of primary PCI capabilities, thrombolysis with intravenous tPA (tissue plasminogen activator) was attempted, without success
- The patient continued to have chest pain and developed ventricular tachycardia requiring electrical cardioversion and antiarrhythmic intravenous infusion
- He was transferred to this tertiary hospital for emergent/rescue PCI
- Findings: 90% proximal LAD stenosis, and 95% stenosis in the mid-segment of the LAD.
- Successful PCI with drug-eluting stents was performed with restoration of normal (TIMI-3) flow through LAD.
- Due to persistent systemic hypotension during the procedure, a 50 cc. Mega™ intra-aortic balloon was inserted for hemodynamic support

METHODS

- Augmentation in cardiac output can be demonstrated using various methods
- Doppler echocardiography [noninvasive] was used to assess the beneficial effect of counterpulsation
- Pulsatile flow through the aortic valve generates variable velocities during ejection. The sum of these velocities – the time-velocity integral [TVI] = the area under the Doppler velocity profile

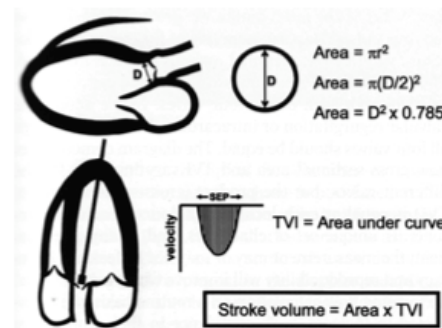


Figure 1. Schematic depiction of the method for estimating transvalvular flow using Doppler echocardiography. D = diameter; TVI = time-velocity integral. Reprinted from Armstrong et al.,⁴ with permission.

- The product of TVI and cross-sectional area of the aortic annulus = the stroke volume

METHODS

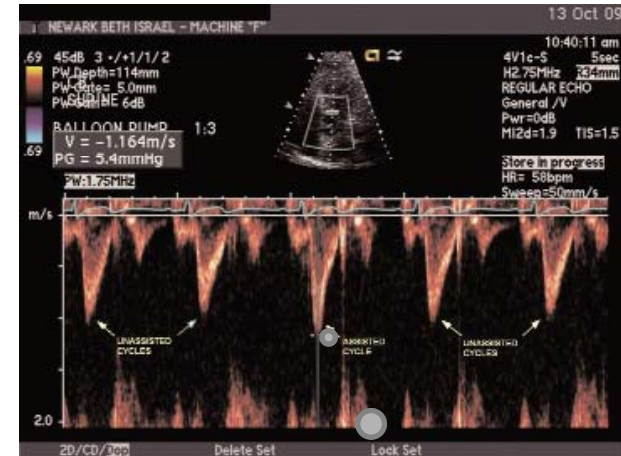
- Doppler echocardiography was performed during counterpulsation with measurements of the aortic annulus and TVI in different assist modes
- The measurements for TVI were performed both in continuous-wave and pulsed-wave modes
- Pulse-wave-measured TVI values were used for these calculations.
- Pulsed- and continuous-wave Doppler tracings were recorded after ≥ 5 minutes had elapsed in each assist mode (no Standby mode)
- TVI measurements were performed for 5 consecutive cardiac cycles and averaged according to the current American Society of Echocardiography(ASE) recommendation
- Calculations were measured for stroke volume and cardiac output at an average heart rate of 60 beats per minute [bpm]

METHODS

Estimate of the absolute increase in cardiac output using IABP in various assist modes

- Surrogate baseline:
 - Stroke volume: 74.4 mL
 - Cardiac output: 4.46L/min
 - Heart rate: 60 bpm
 - TVI = 17.3 cm
- Evaluation of the relative augmentation with the IABP in all 3 assist modes were made

Pulsed-wave-mode Doppler showing time-velocity integral of the flow across the aortic valve in 1:3 assist mode. Green arrow represents the TVI for the cycle immediately preceding the assisted one.



Using TVI for the cycle preceding the assisted one in the 1:3 mode. This value is the lowest in all observed modes and most closely estimates a "baseline," unassisted cycle.

Table 1. Measurements and Calculations for Different Assist Modes

Assist mode	Time-velocity integral (cm)	Stroke volume (mL)	Cardiac output (L/min)
1:1	19.92	85.66	5.14
1:2	18.92	81.36	4.88
1:3	18.08	77.74	4.66

RESULTS

- Augmentation was calculated as 15%, 9%, and 4% in the 1:1, 1:2, 1:3 modes respectively and CO was significantly increased
- 1:1 mode demonstrated an additional 10.2% increase in stroke volume and 4.6% increase in 1:2 mode
- These findings, which demonstrated higher average augmentations than using smaller volume IAB catheters reported in other papers, appear to be related to the 50cc IAB catheter

Table 2. Calculated Relative Augmentation of Cardiac Output for Various Assist Modes

Assist mode	Time-velocity integral (cm)	Cardiac output (L/min)	Relative augmentation (%)
1:1	19.92	5.14	15.25
1:2	18.92	4.88	9.42
1:3	18.08	4.66	4.48
"Baseline"	17.30	4.46	Reference

- The increase in blood volume displacement appears not to be the only benefit during inflation but also the larger diameter of the inflated balloon, [17.4 mm] compared to the 40 cc [15 mm] that reduces the cross-sectional aorta-to-balloon ratio.
- An further benefit is the lower caliber shaft which can translate into a true reduction in the incidence of vascular complications as published “***Comparison of outcomes after 8 vs. 9.5 French size intra-aortic balloon counterpulsation catheters based on 9,332 patients in the prospective Benchmark® Registry.***”
Catheterization and Cardiovascular Interventions 2002;56(2):200-206.

DISCUSSION

- Larger blood volume displacement during inflation
- Larger diameter of the inflated balloon reduces the cross-sectional aorta-to-balloon ratio, thus improving augmentation
 - Balloon inflated diameter: 50cc [17.4 mm] compared to the 40 cc [15 mm]: 16% more
 - Aorta cross-sectional area: 50cc 237.66 mm² vs. 40cc 176.625 mm² 34.55% more
- Same insertion point (8Fr.) as the 40 cc balloon catheter:
 - Less vascular complications
 - Use in patients with peripheral vascular disease
- Same length as the 40cc balloon:
 - Can be use in patients 5'4" (162 cm) and taller for enhanced augmentation

- New case report was published by Dr. Nair's in Journal of Invasive Cardiology, April 2011:

Improvement in Hemodynamics with a New, Larger-Volume (50cc) Intra-Aortic Balloon for High-Risk Percutaneous Coronary Intervention

- Statement: „In our patient (162,6cm), the use of a new larger-volume IAB, which provides 25% greater blood volume displacement compared with the 40 cc balloon, produced remarkable diastolic augmentation and increased the diastolic aortic pressure by ~110mmHg over the baseline level that resulted in improved hemodynamics.“
- Further research is warranted to investigate the exact mechanisms and implications

TAKE HOME MESSAGE & CONCLUSION

- Use of a larger volume, improved, potentially safer counterpulsation balloon appears to provide enhanced cardiac augmentation
- The mechanisms and implications of this effect warrant further research
- **MORE AUGMENTATION COULD DEFINITELY BE BENEFICIAL 😊**

