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

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ABSTRACT: A primary cause of adverse outcomes among high-risk patients undergoing percutaneous coronary intervention (PCI) may be a diminished capacity to tolerate the hemodynamic and ischemic insults that can occur during the procedure. A common means of mechanical support during PCI has been the intra-aortic balloon pump (IABP). We describe successful periprocedural mechanical support with a new, 50 cc IABP in a patient with both severe left ventricular dysfunction and extensive coronary arteriosclerosis, for whom PCI with stenting was indicated. The prophylactic use of this 50 cc IABP, which traditionally would be contraindicated because of the patient's height (162.6 cm), markedly increased the diastolic aortic pressure (by ~110 mmHg) over the baseline level, while promptly reducing left-sided heart pressures. This finding appears to exceed the average diastolic augmentation reported for smaller-volume balloons. Although the role of the IABP in high-risk PCI remains controversial, further research is warranted to clarify and compare this new 50 cc IABP to smaller-volume balloons, and ascertain whether the observed hemodynamic benefits can translate into improved clinical outcomes among patients requiring mechanical support during PCI.

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The development of adverse outcomes among high-risk patients undergoing percutaneous coronary intervention (PCI) is often multifactorial. A primary cause, however, may be a diminished capacity to tolerate the hemodynamic and ischemic insults that can occur during the procedure. Thus in selected high-risk patients undergoing PCI, mechanical support, including the intra-aortic balloon pump (IABP), is sometimes used periprocedurally to prevent the potential for hemodynamic instability or ischemic compromise. Although studies have reported improved outcomes with IABP support among high-risk patients undergoing PCI,¹⁻⁶ a recent randomized trial of elective versus no planned IABP use showed no significant differences in major adverse cardiac events (MACE) at discharge or in all-cause mortality 6 months after PCI in 301 patients in the U.K. who had severe left ventricular dysfunction and extensive coronary disease.⁷

IABP technology has now evolved such that smaller patients now might safely receive the benefits presumed to accrue from insertion of larger balloon catheters. We describe the successful augmentation of left heart function and reduction in right and left heart pressures achieved with the use of a novel 50 cc IABP for support in a patient with both severe left ventricular dysfunction and severe coronary arteriosclerosis, for whom PCI with stenting was indicated.

Case Presentation

A 75-year-old man with chronic ischemic cardiomyopathy (ejection fraction 25%), noninsulin-dependent diabetes mellitus, hypertension and dyslipidemia was referred to our institution after several weeks of worsening shortness of breath and fatigue. His breathing became labored with minimal activity (New York Heart Association Class III). He reported no chest discomfort. Additional medical history included 3-vessel coronary artery bypass grafting after myocardial infarction and left carotid endarterectomy, both 20 years previously, and an implantable defibrillator placed 10 years previously. His outpatient medical regimen included warfarin for left ventricular dysfunction, furosemide, fenofibrate, digoxin, enalapril, metoprolol, rosiglitazone and simvastatin.

Electrocardiography revealed sinus bradycardia and left anterior fascicular block. His body mass index was 20.6 kg/m² (height: 162.6 cm; weight: 54.5 kg). He had an elevated jugular venous pressure (10 cm), clear lung fields, regular bradycardic rhythm, 2/6 holosystolic murmur at the apex, no edema of the lower extremities and bilateral femoral bruits. Laboratory assessment revealed a mildly abnormal glomerular filtration rate (59 ml/min/1.73 m²), hypoalbuminemia (3.0 gm/dl), mildly abnormal liver function tests (total bilirubin, 1.4 mg/dl; aspartate aminotransferase, 75 IU/l), and pancytopenia with marked thrombocytopenia (white cell count, 3.4 × 10⁹/l; hematocrit, 31%; platelet count, 47 × 10⁹/l). Troponin levels were within normal limits; however, the brain natriuretic peptide level was markedly elevated (3160 pg/ml).

Given his progressive symptoms and remote history of bypass surgery, the patient underwent right- and left-heart catheterization. The invasive hemodynamic findings are shown in Table 1. His cardiac index was 1.6 l/min/m², the pulmonary artery oxygen saturation was 60% and arterial oxygen saturation was 92% on room air.

Coronary angiography revealed severe disease in his native vessels and extensive aortic calcification (Figures 1 and 2). The left main coronary artery had a calcified 70% stenosis at the ostium; the left anterior descending (LAD) coronary artery had a diffuse,

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Table 1. Hemodynamic variables at initial heart catheterization and before and 45 minutes after periprocedural intra-aortic balloon pump insertion.

Pressure	Initial Catheterization	Before IABP Insertion	During IABP Use
Right atrium	8	2	1
Right ventricle	72/8	65/2	35/1
Pulmonary artery	72/20	65/16	35/6
Pulmonary artery, mean	57	33	15
Pulmonary capillary wedge pressure	19	16	5

All values are mmHg.
IABP = intraaortic balloon pump.

proximal 80% stenosis followed by 100% occlusion in the mid-vessel; the left circumflex artery had an 80% proximal stenosis with 100% occlusion of the first obtuse marginal branch; and the dominant right coronary artery (RCA) was proximally occluded. The saphenous vein graft (SVG) to the RCA was occluded, and patent grafts were anastomosed to the second obtuse marginal and mid-LAD. However, the SVG to the LAD had a high-grade 80% stenosis in the midportion of the graft. The distal LAD and septal perforators provided the only perfusion to the RCA territory via collateral vessels (Figure 2).

Given his severely elevated filling pressures, the patient was admitted for diuresis. Some of his symptoms were thought to relate to ischemia from the stenosis in the SVG-to-LAD graft. Because he was considered unsuitable for surgical revascularization due to his several comorbid conditions, his best option was considered to be PCI. The procedure was considered high risk given his low ejection fraction and severity of coronary disease. Any loss of flow through the SVG to the LAD would compromise flow not only to the anterior wall but also to the inferior wall territory supplied by collaterals from the LAD.

After 3 days of diuresis and platelet transfusion, he underwent successful high-risk PCI of the SVG-to-LAD graft using a 3.0 mm × 18 mm everolimus-eluting stent dilated to 20 atm and distal embolic protection (Figure 3). Final angiography revealed 0% residual stenosis and a thrombolysis in myocardial infarction (TIMI) flow grade of 3.

A 50 cc, 8 Fr intra-aortic balloon (IAB) (*MEGA™*, Maquet Cardiovascular, Wayne, New Jersey) was placed before PCI for added hemodynamic support. Figure 4 and Table 2 present the hemodynamic situation before IAB insertion. As shown in Figure 5, the use of IABP resulted in an increase in diastolic aortic pressure of ~110 mmHg over the baseline level. The patient's hemodynamic profile remained stable during stent deployment and expansion (data not shown). Figure 4 and Table 2 also present the hemodynamic picture at 45 minutes after PCI, while the patient was receiving IABP support at 1:1 assist. In addition to increased diastolic aortic pressure, the right atrial, right ventricular, pulmonary artery and pulmonary capillary wedge pressures were all reduced substantially during IABP use, indicating enhanced circulation.

The patient began treatment with clopidogrel and aspirin and discontinued warfarin use. He was discharged in good condition 3 days later. At 1- and 6-month follow up, he reported significantly less dyspnea and fatigue. Based upon his symptoms, he was rated as New York Heart Association Class I.

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Discussion

Factors that can increase the risk of in-hospital complications of PCI include advanced age, shock, renal insufficiency, urgency of the procedure, heart failure, the presence of thrombus, peripheral arterial disease, recent myocardial infarction and left main or multivessel coronary disease.^{8,9} Patients with congestive heart failure and left

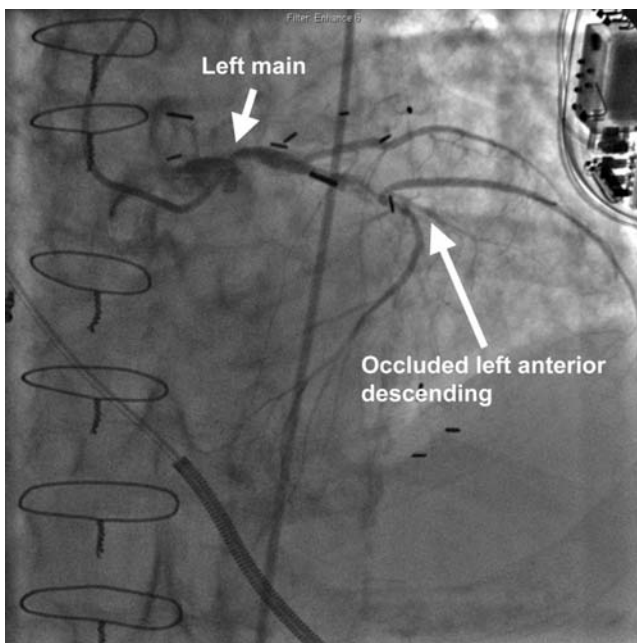


Figure 1. Angiogram showing severe left main disease and complete occlusion of the mid-left anterior descending coronary artery (arrows).

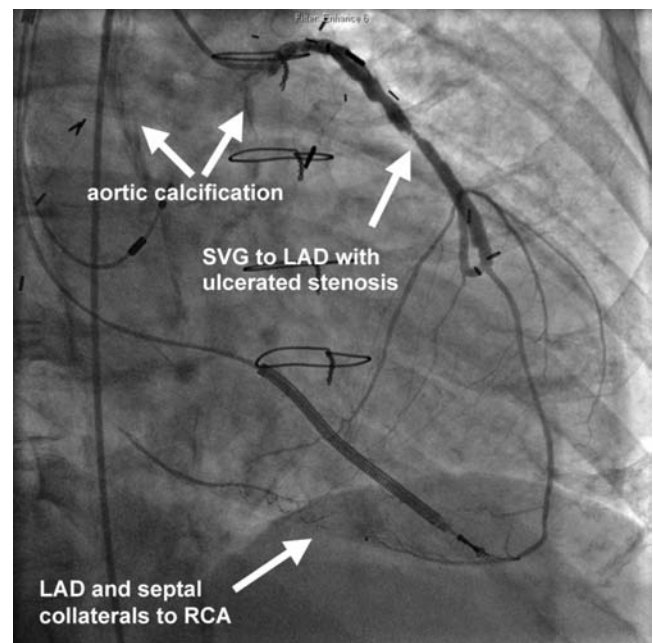


Figure 2. Angiogram showing severe left main disease and complete occlusion of the mid-left anterior descending coronary artery (arrows).

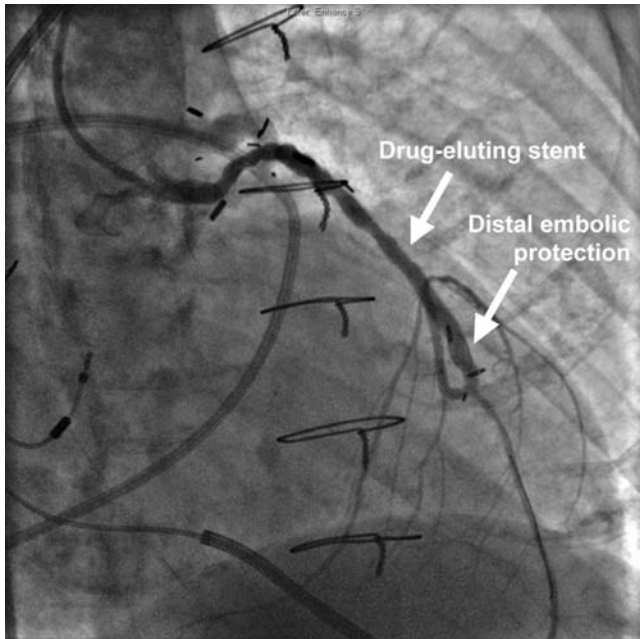


Figure 3. Successful percutaneous coronary intervention of the saphenous vein graft to the left anterior descending coronary artery using a 3.0 mm × 18 mm everolimus-eluting stent and distal embolic protection.

ventricular systolic dysfunction are at particularly increased risk for adverse in-hospital and long-term outcomes after PCI.^{10–12} Although the cause of adverse outcomes among these patients is often multifactorial, these outcomes may partially relate to a reduced capacity to tolerate the hemodynamic or ischemic insults that can occur with PCI. Thus, selected patients with high-risk features undergoing PCI also receive mechanical support periprocedurally. IABP is often used for this purpose.

The IABP was first used clinically in 1968 in patients who developed cardiogenic shock after acute myocardial infarction.¹³ The three primary goals of IABP use remain to increase coronary perfusion, reduce left ventricular afterload and increase cardiac output. Balloon inflation during early diastole and deflation during end-diastole each provide their own beneficial hemodynamic effects (Table 1). Deflation during end-diastole actively draws blood from the central aorta and thus reduces aortic systolic pressure and left ventricular end-diastolic pressure by an estimated 8.9–26.6% and 25–40%, respectively.^{14,15} Diastolic augmentation occurring with balloon inflation can improve coronary perfusion by 5–15%, and, in association with reduced afterload, result in improved myocardial contractility.^{16,17} As a consequence, cardiac output can increase by as much as 50%.^{15,18,19}

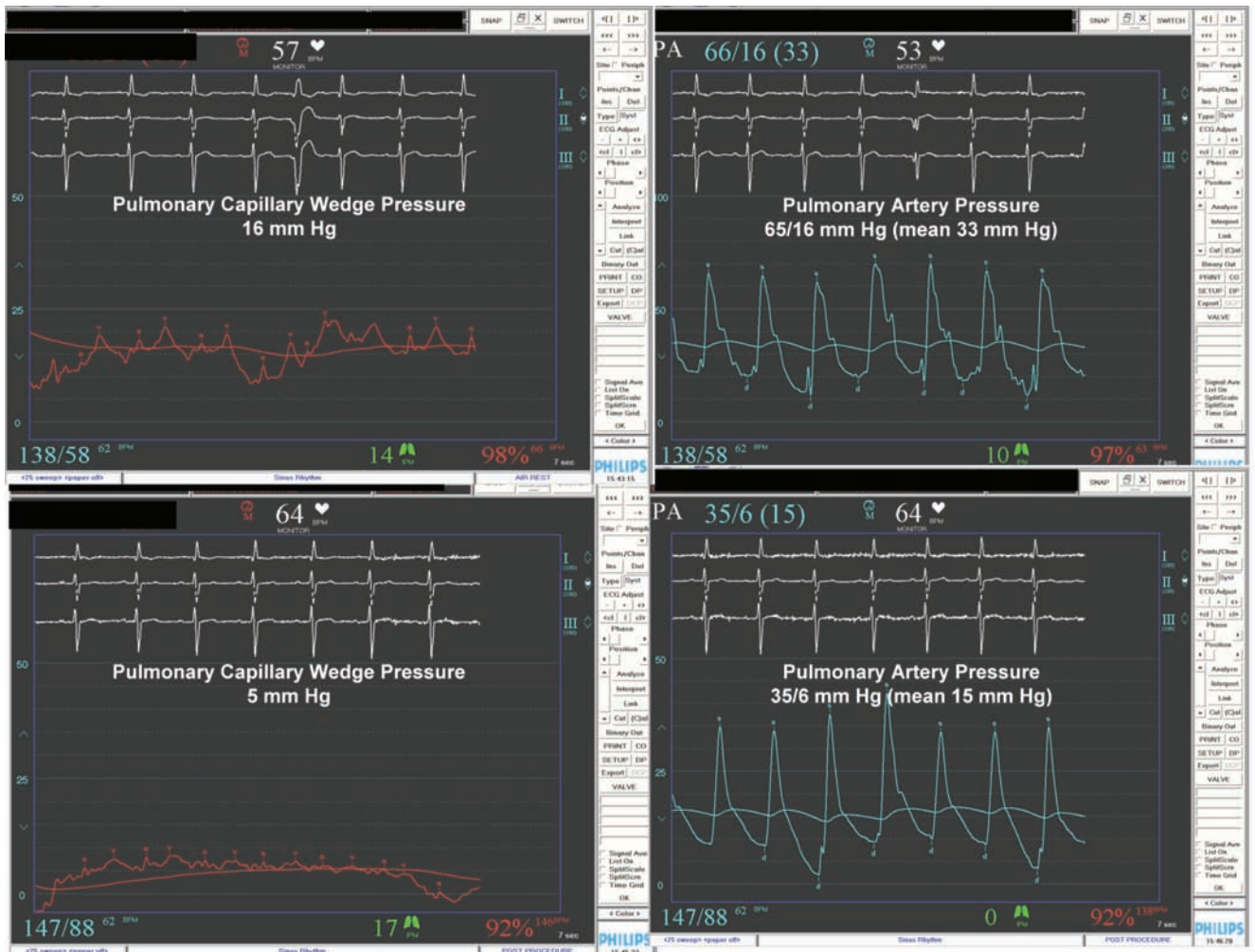


Figure 4. Pulmonary capillary wedge pressure (left) and pulmonary artery pressure (right) before (top) and after (bottom) insertion of the intra-aortic balloon pump.

Table 2. Hemodynamic effects of intra-aortic balloon pump therapy.

Balloon Deflation (systole)	Balloon Inflation (diastole)
↓ Systolic pressure	↑ Diastolic pressure
↓ Afterload	↑ Coronary flow and O ₂ supply
↑ Stroke volume	↑ Ejection and cardiac output
↓ End-diastolic volume	↓ End-diastolic volume
↓ Myocardial consumption	↓ End-diastolic pressure

IABs have long been used electively during high-risk PCI and emergently in cases of periprocedural hemodynamic instability.¹⁻⁶ However, although prophylactic IABP support for high-risk PCI has been independently associated with higher 6-month survival⁵ and reduced intraprocedural complications⁶ in selected series, a recent randomized trial showed no benefit in terms of MACE at hospital discharge or all-cause mortality at 6 months.⁷ Elective IABP in high-risk PCI has consistently been associated with comparable or reduced rates of major procedural complications, major or minor bleeding and access-site complications.⁵⁻⁷ Thus, the role of prophylactic IABP in high-risk PCI remains unclear.

In our patient, the use of a new, larger-volume IAB, which provides 25% greater blood volume displacement compared with the 40 cc balloon,²⁰ produced remarkable diastolic augmentation that resulted in improved hemodynamics. Despite the patient's severe pulmonary hypertension, within 1 hour after beginning IABP support, his transpulmonary gradient had improved from 17 mmHg to 10 mmHg. In our patient's case, the decision for IABP support was driven by the extent of coronary artery disease and amount of myocardium at risk. If flow in the LAD had become compromised during PCI, the risk of hemodynamic collapse would have been substantial because of reduced perfusion, not only in the LAD territory, but also in the RCA territory supplied by LAD collateral flow.

In the past, this patient might have been considered ineligible to receive a 50 cc balloon, because his small body surface area could have made insertion of a 9.5 Fr catheter problematic. Development of a 50 cc balloon catheter that uses a true 8 Fr shaft allows the possibility of safer introduction of the larger-volume balloon in

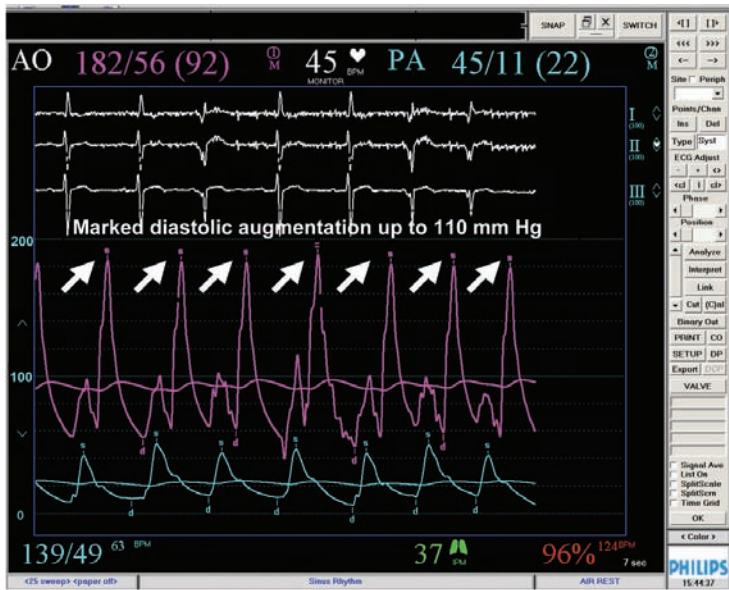


Figure 5. Marked diastolic augmentation of aortic pressures observed with intra-aortic balloon pump use.

Table 3. Diastolic augmentation with intra-aortic balloon pump.

Study	n	Population	Balloon Size	Assist Mode	Findings
Peak aortic diastolic pressure					
Papaioannou 2001 ²⁴	15	Post-MI cardiogenic shock	40 cc	1:1	97.4 ± 17.7 mmHg
Papaioannou 2002 ²⁵	20	Post-MI cardiogenic shock	40 cc	1:1	100.9 ± 18.9 mmHg
Current case	1	High-risk PCI	50 cc	1:1	~180 mmHg
Decrease in end-diastolic pressure					
Papaioannou 2001 ²⁴	15	Post-MI cardiogenic shock	40 cc	1:1	7.5 mmHg
Papaioannou 2002 ²⁵	20	Post-MI cardiogenic shock	40 cc	1:1	7.9 mmHg
Current case	1	High-risk PCI	50 cc	1:1	19 mmHg
Increase in mean aortic diastolic pressure					
Williams 1982 ²¹	6	CAD, unstable angina	40 cc	1:1	From 82 to 96 mmHg
Fuchs 1983 ²²	7	Unstable angina	40 cc	1:1	From 77 to 99 mmHg
Yoshitani 2007 ²⁶	16	High-risk angioplasty	35 cc	1:1	From 81.2 to 98.1 mmHg
Current case	1	High-risk PCI	50 cc	1:2	From 49.9 to 92.4 mmHg
Increase in diastolic pressure from at the dicrotic notch to during peak augmentation					
Williams 1982 ²¹	6	CAD, unstable angina	40 cc	1:1	54 mmHg
Kolyva 2009 ²⁷	25	LVAD implantation	34, 40, or 50 cc	1:1	21.1 mmHg
Current case	1	High-risk PCI	50 cc	1:1	~110 mmHg

CAD = coronary artery disease; MI = myocardial infarction; PCI = percutaneous coronary intervention; LVAD = left ventricular assist device.

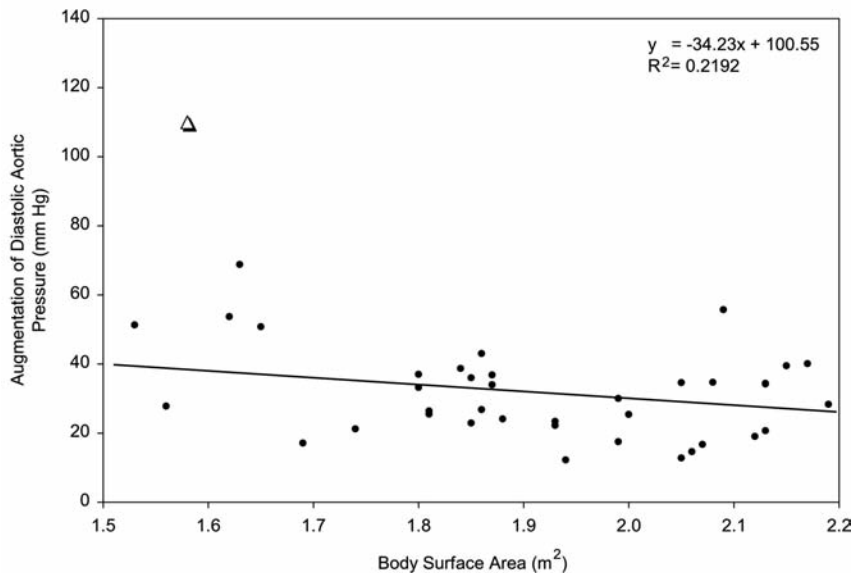


Figure 6. Augmentation of diastolic aortic pressure from beginning to end of intra-aortic balloon inflation. Data are from patients in the Kern study²⁸ (circles) in whom 40 cc balloons were used, and from the current case (triangle), which reflects use of a 50 cc balloon.

smaller patients. This offers two potential advantages. First, the larger blood volume displaced with the 50 cc balloon catheter appears to result in greater diastolic pressure augmentation than observed with smaller devices (Table 3),^{21–27} particularly among smaller patients (Figure 6).²⁸ This phenomenon might, in turn, enhance coronary perfusion and hemodynamic support. Second, the ability to use a smaller shaft has generally been associated with reduced limb ischemia, even among patients undergoing high-risk revascularization procedures.²⁹

Characteristics of this new IABP device — larger balloon volume, smaller insertion sheath — might offer advantages in terms of both superior hemodynamic support and reduced potential for vascular complications. Additional research should clarify the hemodynamic effects observed with this 50 cc balloon versus lower-volume versions and determine how these effects may relate to clinical outcomes in patients requiring mechanical support. In addition, although the elective use of an IABP in patients undergoing high-risk PCI remains controversial, future studies should also investigate whether use of this new device might be associated with enhanced coronary perfusion and outcomes in this specific population.

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