

## Cardiac Positioning using an Apical Suction Device Maintains Beating Heart Hemodynamics

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### ABSTRACT

**Background:** Cardiac positioning during off-pump coronary artery bypass (OPCAB) using deep pericardial sutures (DPS) typically results in some degree of hemodynamic compromise. We sought to determine whether cardiac positioning using an apical suction device was hemodynamically superior to DPS.

**Methods:** Five healthy pigs underwent sternotomy and instrumentation to measure right atrial (RA) pressure, left ventricular (LV) pressure and volume, and aortic pressure and flow. These variables were recorded at baseline, with simple attachment of the apical suction device (Xpose™ Access Device, Guidant, Inc.), and during exposure of the posterior descending artery (PDA) and obtuse marginal (OM) branches of the left circumflex artery using DPS and the apical suction device.

**Results:** Application of the apical suction device to the beating heart in neutral anatomic position did not result in any statistically significant change in hemodynamics compared to baseline except for a small decrease in RA pressure. DPS positioning resulted in statistically significant compromise in nearly all measured hemodynamic parameters, including cardiac output (-21% PDA, -30% OM), mean arterial pressure (-18% PDA, -26% OM), and stroke work (-31% PDA, -38% OM). In addition, LV end-diastolic pressure decreased (-59% PDA, -51% OM) while RA pressure increased (+17% PDA, +16% OM). Similar target exposure using the apical suction device resulted in near-baseline hemodynamics. The only statistically significant changes were a modest decrease in cardiac output (-18% OM) and RA pressure (-11% PDA).

**Conclusion:** DPS positioning significantly compromises hemodynamics due to reduced LV filling. The apical suction device provides good exposure with less hemodynamic compromise.

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### INTRODUCTION

Recent technical advances have allowed multivessel coronary artery bypass grafting (CABG) to be safely performed in selected patients without cardiopulmonary bypass (CPB) [Benetti 1991, Calafiore 1998, Jansen 1998, Spooner 1999]. Potential benefits of off-pump CABG (OPCAB) compared to conventional CABG with CPB may include reduced neurocognitive dysfunction [Diegeler 2000], myocardial injury [Penttila 2001], postoperative length of stay, hospital costs, and transfusion rate [Puskas 1999]. OPCAB may be particularly advantageous in selected high-risk patients such as elderly patients and those with certain comorbid conditions [Guler 2001, Kilo 2001].

Numerous positioning techniques and devices have been developed to facilitate access to target coronary vessels during OPCAB, these include deep pericardial sutures (DPS), surgical pads, and various stabilizers. Hemodynamic compromise associated with cardiac manipulation necessary for target vessel exposure, especially on the lateral and posterior walls, has proven to be a major challenge. This hemodynamic compromise may result in the need for pressor support and may lead to incomplete revascularization.

Several animal and human studies have demonstrated impaired biventricular function, especially right ventricular dysfunction, during cardiac displacement [Grundeman 1999, Nierich 2000, Mathison 2000]. This appears to be secondary to deformation of the cardiac chambers. During lateral and vertical displacement, the heart appears to buckle, resulting in compression of the right ventricle between the pericardium and the interventricular septum, which in turn reduces left ventricular filling and cardiac output. These effects may be reduced by specific maneuvers such as volume loading, deep Trendelenburg positioning [Grundeman 1997], and cardiac herniation into a widely open right pleural space [Hart 2001].

The Xpose™ Access Device (Guidant Corporation, Cupertino, CA) is a cardiac positioning device for use during OPCAB. It is comprised of a compliant suction cup, which conforms to the apex of the heart and is mounted to a sternal retractor via a multi-jointed, rigid shaft. The objective of this study was to examine parameters of cardiovascular function using DPS and the apical suction device during cardiac displacement. The DPS technique and the apical suction device were compared during cardiac positioning to access the

posterior descending artery (PDA) and obtuse marginal (OM) branches of the left circumflex via median sternotomy in a beating heart porcine model.

## MATERIAL AND METHODS

Five Yorkshire pigs (weight 45-60 kg) were used in this study. All animals received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" published by the National Institutes of Health (NIH publication 85-23, revised 1985), the European Convention on Animal Care, and the Harvard Standing Committee on Animals.

### Surgical Preparation and Instrumentation

After premedication with intramuscular telazol (5 mg/kg), the animals were intubated and mechanically ventilated (North American Drager, Telford, PA). Anesthesia was maintained with 2% isoflurane and 100% O<sub>2</sub>. An electrocardiogram was continuously recorded. Central venous access was established via the left internal jugular vein. Intravenous MgSO<sub>4</sub> (2 gm) and Lidocaine (50 mg) were given to prevent ventricular arrhythmias. After median sternotomy, the pericardium was incised.

Five-French Millar Micro-Tip pressure transducing catheters (Millar Instruments, Houston, TX) were inserted in the aortic root via the left femoral artery and the left ventricle. An electromagnetic flow probe (Carolina Medical Electronics, King, NC) was positioned around the aortic root and flow was measured using a square wave electromagnetic flowmeter (Carolina Medical Electronics, King, NC). A 7-French volume conductance catheter (Cordis Webster, Baldwin Park, CA) was placed in the left ventricle via the left carotid artery. A Sigma 5 volume transducer (Leycom, Zoetermeer, Netherlands) was used to measure continuous left ventricular volume and blood resistivity (required for volume calibration). A fluid manometer catheter (Viggo-Spectramed, Oxnard, CA) was inserted directly in the right atrium to measure mean atrial pressure.

Three deep pericardial sutures (DPS) were placed along an arc in the oblique sinus extending from the left superior pulmonary vein to the inferior vena cava. Continuous intravenous neosynephrine was titrated to an initial steady state mean arterial blood pressure of 60-70 mmHg prior to any intervention. No subsequent adjustments were made. The operating table was tilted 20 degrees in the head-down (Trendelenburg) position as is typically done during beating heart surgery.

### Experimental Protocol

Data was collected in each animal during six different experimental conditions, in order performed:

- 1) Baseline neutral position.
- 2) Baseline neutral position with apical suction device attachment.
- 3) Posterior descending artery (inferior wall) exposure with deep pericardial sutures (DPS).
- 4) Posterior descending artery (inferior wall) exposure with the apical suction device (Figure 1, ⊙).

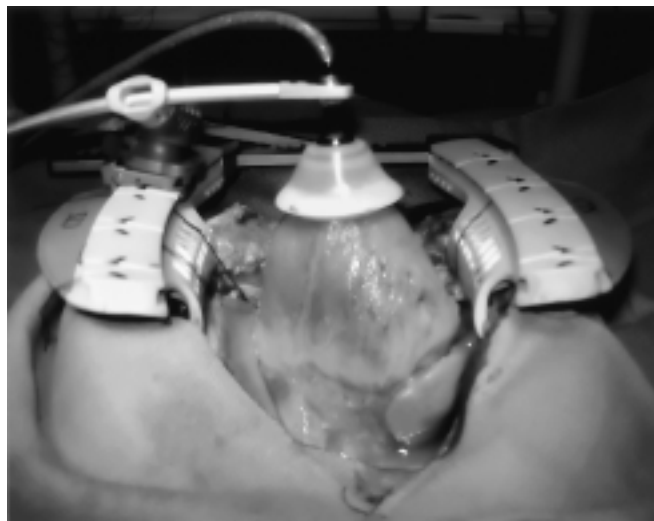


Figure 1. Vertical displacement of the beating porcine heart exposing the posterior descending artery (PDA) using the Xpose™ Access Device.

- 5) Obtuse marginal branches of the left circumflex artery (lateral free wall) exposure with DPS.
- 6) Obtuse marginal branches of the left circumflex artery (lateral free wall) exposure with the apical suction device.

For each condition listed above, data was collected after the heart had been in position for at least 5 minutes and the hemodynamic parameters had reached a steady state. The heart was returned to its neutral anatomic position for at least 5 minutes between maneuvers.

For conditions 3 and 5, the DPS were used to retract the pericardium to the left and caudad causing the now vertical heart to be displaced to the right and cephalad.

For conditions 4 and 6, the apical suction device was used to position the heart to access specified target coronary arteries. The device consists of a compliant suction cup that was attached to the heart apex with 250mm Hg of regulated wall suction. The apical suction cup is attached to a special sternal retractor via a multi-jointed, rigid shaft permitting customized cardiac positioning.

For inferior and lateral wall exposure (conditions 3 through 6), the DPS or the apical suction device positioned the heart until visualization and exposure of the coronary target vessel (PDA or OM branches) was deemed adequate for grafting.

Upon completion of the experiment, each heart was arrested with an intracardiac injection of potassium chloride.

### Data Collection and Analysis

Analog data were digitized at 200 Hz and stored on a personal computer using Lab View hardware and software (National Instruments, Austin, TX). The Lab View software, customized in our laboratory, was used for data analysis and calculations. With the ventilator off, steady-state hemodynamic parameters were calculated by averaging at least seven cardiac cycles in each experimental phase. Data runs containing premature ventricular contractions were excluded. Cardiac

Table 1. Hemodynamic Effects of Xpose™ Attachment without Cardiac Displacement

Parameters	Baseline	Xpose™ On		
	Mean ± SD	Mean ± SD	% Change <sup>a</sup>	p value <sup>b</sup>
Cardiac output (mL)	3.1 ± 0.56	2.8 ± 0.6	- 9.6%	0.13
Mean arterial pressure (mm Hg)	67.6 ± 3.2	68.2 ± 8.0	+ 0.8%	0.88
Stroke volume (mL)	39.1 ± 10.3	36.7 ± 7.0	- 4.0%	0.50
Stroke work (mm Hg x mL)	0.39 ± 0.10	0.36 ± 0.06	- 6.7%	0.43
LV end-diastolic pressure (mm Hg)	8.7 ± 1.4	10.2 ± 3.6	+ 16.7%	0.30
RA pressure (mm Hg)	7.2 ± 0.84	6.2 ± 0.45	- 13.2%	0.03

<sup>a</sup>Relative to Baseline Values<sup>b</sup>Comparison of Baseline vs. Xpose™ On

SD – standard deviation

output, mean aortic pressure, stroke volume (SV), stroke work (SW), end-diastolic pressure ( $P_{ed}$ ), and mean right atrial pressure were among the parameters calculated from these data.

### Statistical Analysis

All data are presented as mean  $\pm$  standard deviation (SD) and as a percent of baseline control. Repeated measures ANOVA were used to compare values under different conditions. Significant differences were established at  $p$  value less than 0.05.

## RESULTS

All 5 animals survived the entire experiment without arrhythmia or the need for inotropic support. In all animals, both deep pericardial sutures (DPS) and the apical suction device provided adequate target vessel exposure for both inferior and lateral walls.

### Attachment of the Apical Suction Device

The hemodynamic effects of simple attachment of the apical suction device to the apex of the heart are shown in Table 1, ⊕. Application of the device to the beating heart, resting in its neutral anatomic position, did not result in any statistically significant change in any of the measured hemodynamic parameters with the exception of a decrease in mean right atrial pressure from 7.2 to 6.2 mm Hg ( $p = 0.03$ ). There was a trend towards a modest decrease in cardiac output (CO) by 9.6% ( $p = 0.13$ ).

### Inferior LV Wall Access with Deep Pericardial Sutures vs. the Apical Suction Device

The hemodynamic effects of inferior wall exposure with DPS and the apical suction device are shown in Table 2, ⊕. Vertical displacement of the heart to access the posterior descending artery (PDA) with DPS resulted in a significant hemodynamic compromise. Specifically, stroke volume (SV), CO, mean arterial pressure (MAP), and stroke work (SW) fell by 16%, 22%, 18%, and 31%, respectively, compared to baseline (all  $p < 0.05$ ). In addition, we observed a reduction of left ventricular filling pressure and an increase of right ventricular filling pressure with DPS positioning. Specifically, left ventric-

ular end-diastolic pressure (LVEDP) decreased 59%, from a mean of 8.7 to 3.7 mm Hg ( $p = 0.001$ ), while RAP rose 16.7%, from a mean of 7.2 to 8.4 mm Hg ( $p = 0.02$ ).

In contrast, PDA access with the apical suction device was achieved with minimal hemodynamic compromise, comparable to that seen during simple apical suction device attachment. The 11% decrease in CO with the apical suction device was statistical significance ( $p = 0.02$ ) but was nearly identical to that seen with simple attachment of the device. In other words, there was no *additional* decrease in CO from vertical displacement of the heart after attachment of the apical suction device. The mean value of each hemodynamic parameter was compromised with DPS when compared to the apical suction device (all  $p < 0.05$ , except MAP  $p = 0.06$ ).

### Lateral LV Wall Access with Deep Pericardial Sutures vs. the Apical Suction Device

The hemodynamic effects of lateral wall exposure with DPS and the apical suction device are shown in Table 3, ⊕. The pattern is similar to that seen during inferior wall exposure, however the magnitude of compromise was somewhat greater across all parameters. For example with DPS, SV, CO, MAP, and SW fell 19%, 30%, 26%, and 38% compared to baseline values (all  $p < 0.05$ ). The changes in LV and RV filling pressures were nearly identical to those seen during inferior wall exposure.

Again, lateral LV wall access with the apical suction device was achieved with modest hemodynamic compromise. Although the 18% decrease in CO ( $p = 0.008$ ) was greater than with attachment of the apical suction device alone, it was significantly less than the 30% decrease seen with DPS ( $p = 0.001$ ). The mean value of each hemodynamic parameter was compromised with DPS when compared to the apical suction device (all  $p < 0.05$ ).

## COMMENT

Although off-pump coronary artery bypass (OPCAB) has enjoyed increasing popularity, hemodynamic compromise associated with exposure of the target vessels on the posterior and lateral walls remains a significant obstacle in many patients. The purpose of this study was to compare the

Table 2. Comparison of the Hemodynamic Effects of Deep Pericardial Sutures (DPS) and Xpose™ During Exposure of the Posterior Descending Artery.

Parameters	Baseline	DPS vs. Baseline			Xpose™ vs. Baseline			DPS vs. Xpose™
	Mean + SD	Mean + SD	% Change <sup>a</sup>	p value	Mean + SD	% Change <sup>a</sup>	p value	p value <sup>b</sup>
Cardiac output (mL)	3.1 ± 0.56	2.4 ± 0.55	- 21.5%	0.001	2.8 ± 0.54	- 11.3%	0.02	0.03
Mean arterial pressure (mm Hg)	67.6 ± 3.2	55.1 ± 8.6	- 18.3%	0.03	65.2 ± 12.4	- 3.6%	0.62	0.06
Stroke volume (mL)	39.1 ± 10.3	32.7 ± 8.2	- 15.8%	0.002	37.1 ± 7.5	- 3.8%	0.20	0.02
Stroke work (mm Hg x mL)	0.39 ± 0.10	0.27 ± 0.09	- 30.8%	0.002	0.35 ± 0.08	- 8.7%	0.17	0.02
LV end-diastolic pressure (mm Hg)	8.7 ± 1.4	3.7 ± 1.5	- 59.0%	0.006	9.3 ± 2.9	+ 5.8%	0.75	0.01
RA pressure (mm Hg)	7.2 ± 0.84	8.4 ± 1.5	+16.7%	0.02	6.4 ± 0.55	- 10.7%	0.08	0.001

<sup>a</sup>Relative to Baseline Values <sup>b</sup>Comparison of DPS vs. Xpose™ Means SD – standard deviation

hemodynamic changes encountered during positioning of the beating heart with deep pericardial sutures (DPS) and the apical suction device in a porcine model. Our hypothesis was that the apical suction device would provide adequate target vessel exposure with superior hemodynamics.

#### Attachment of the Apical Suction Device

Application of the apical suction device to the apex of a beating heart in its neutral anatomic position did not result in statistically significant changes in hemodynamic parameters compared to baseline. The one exception was mean right atrial pressure (RAP), which showed a small but statistically significant decrease from 7.2 to 6.2mm Hg. The clinical significance of this is unclear. Although not statistically significant, we observed a trend towards a modest decrease in cardiac output (approximate 10%) in 4 out of 5 animals. Although the device is designed with a swivel joint permitting long axis torsion and some long axis shortening, the portion of apical myocardium within the suction cup is immobilized. The decrease in cardiac output may reflect the loss of the contribution of the apex to overall left ventricular contraction. In a clinical setting, the effect of this loss of apical contraction would be difficult to predict and would depend on the specific pattern of regional dysfunction, if any.

#### Cardiac Displacement

Both posterior descending artery (PDA) and obtuse marginal (OM) branches access with DPS resulted in significant

hemodynamic compromise compared to baseline and access with the apical suction device. The reduction of left ventricular filling pressures and the concomitant increase of RAP with DPS suggest impaired right ventricular diastolic function. On visual inspection, DPS positioning of the heart clearly caused deformation of the thin walled right ventricle. During vertical displacement for PDA access, the heart appeared to collapse as the heavier left ventricle caused the right ventricle to buckle upon itself. Similarly, OM access with DPS appeared to result in compression as well as buckling of the RV between the interventricular septum, right hemisternum, and right pericardium (Figure 2a, ⊙). Although widely opening the right pleura and pericardium may have mitigated this effect somewhat, we do not think that this would have significantly reversed the observed effects. We could not test this technique in the porcine model because herniating the heart into the right hemithorax is not anatomically feasible.

We hypothesize that the apical suction device improved hemodynamics relative to DPS by restoring right ventricular diastolic function. Specifically, lifting the apex anteriorly out of the chest appeared to result in long axis elongation and unbuckling of the ventricles, particularly the right ventricle (Figure 2b, ⊙). Unlike DPS, the apical suction device provided PDA access with minimal hemodynamic compromise, essentially the same as that observed during attachment in the neutral position. For OM access, the apical suction device resulted in an 18% reduction in CO, compared to a 30% reduction with DPS ( $p < 0.05$ ). In addition, OM access using

Table 3. Comparison of the Hemodynamic Effects of Deep Pericardial Sutures (DPS) and Xpose™ During Exposure of the Obtuse Marginal Coronary Arteries.

Parameters	Baseline	DPS vs. Baseline			Xpose™ vs. Baseline			DPS vs. Xpose™
	Mean + SD	Mean + SD	% Change <sup>a</sup>	p value	Mean + SD	% Change <sup>a</sup>	p value	p value <sup>b</sup>
Cardiac output (mL)	3.1 ± 0.56	2.2 ± 0.46	- 30.0%	0.001	2.6 ± 0.54	- 17.7%	0.008	0.03
Mean arterial pressure (mm Hg)	67.6 ± 3.2	50.1 ± 5.1	- 25.6%	0.002	62.0 ± 9.8	- 8.3%	0.18	0.01
Stroke volume (mL)	39.1 ± 10.3	31.4 ± 9.7	- 19.4%	0.00	36.0 ± 8.0	- 6.7%	0.165	0.05
Stroke work (mm Hg x mL)	0.39 ± 0.10	0.24 ± 0.09	- 38.0%	0.002	0.32 ± 0.07	- 16.1%	0.06	0.04
LV end-diastolic pressure (mm Hg)	8.7 ± 1.4	4.4 ± 2.2	- 50.9%	0.001	8.3 ± 3.9	- 7.1%	0.09	0.02
RA pressure (mm Hg)	7.2 ± 0.84	8.4 ± 1.5	+ 16.2%	0.01	7.0 ± 1	- 2.4%	0.62	0.006

<sup>a</sup>Relative to Baseline Values <sup>b</sup>Comparison of DPS vs. Xpose™ Means SD – standard deviation.

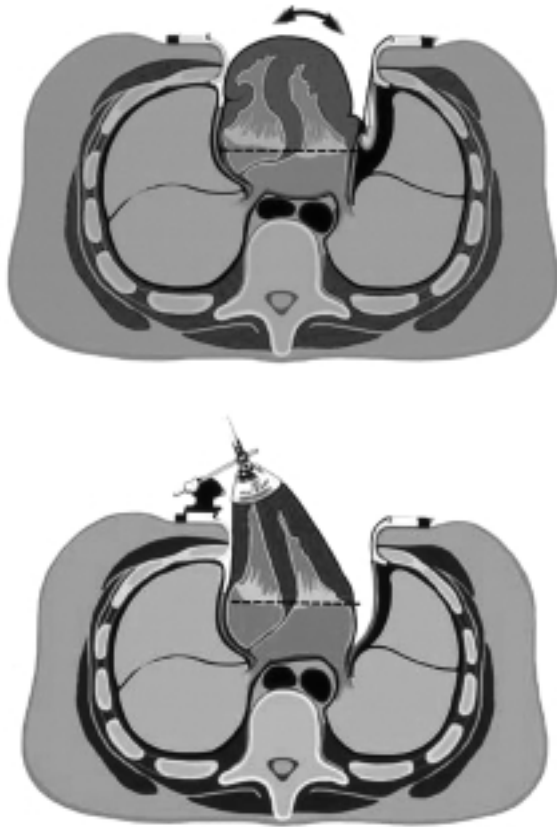


Figure 2. a) Illustration of obtuse marginal (OM) branches exposure using deep pericardial sutures (DPS) with deformation of the right ventricle resulting in RV diastolic dysfunction. b) Illustration of OM exposure using the Xpose™ Access Device with improved preservation of right ventricular geometry and exposure.

the apical suction device was superior to DPS with regards to all other hemodynamic parameters.

Although “adequate” exposure of target vessels was attained with both techniques, the apical suction device clearly provided better target vessel exposure compared to DPS under most circumstances. By fixing the heart at two points (apex and base), the apical suction device itself provides a degree of target area stabilization prior to application of the stabilizer foot. By lifting the apex out of the chest, the apical suction device appeared to elongate the collapsing left ventricular wall bringing the target area further out of the chest cavity. Finally, the device prevents the apex from flopping back and forth obstructing the surgeon’s line of sight to the target area.

### Comparison to Other Devices

Echocardiographic studies performed in a porcine model by Grundeman et al. using the Octopus Tissue Stabilization System (Medtronic, Minneapolis, MN) suction tissue stabilizer documented biventricular distortion, resulting primarily in right ventricular diastolic dysfunction, during vertical displacement [Grundeman 1999]. The superior hemodynamics

achieved with the apical suction device may result from the fact that it attaches to the apex not the anastomotic site. It is therefore capable of lifting, not merely rolling, the entire heart out of the chest, and preserving ventricular geometry.

De Paulis et al. recently described the use of an expandable surgical pad device (Sulzer Vascutek Ltd, Renfrewshire, Scotland) in humans during OPCAB [De Paulis 2000]. Although they found their expandable surgical pad provided adequate exposure to the inferior and lateral walls, they report an approximate 28% decrease in both cardiac output and systolic arterial pressure (SAP) with a significant rise in right sided filling pressures during exposure of the lateral wall. This expandable surgical pad, like DPS, *pushes* the heart into position as opposed to the apical suction device, which *lifts* the heart out of the chest. Therefore, one would not expect significant hemodynamic benefit with this expandable surgical pad compared to DPS.

### Study Limitations

Although the normal pig hearts used in this study are comparable to human hearts in shape and coronary anatomy, they may not precisely reflect the effects of this device in patients with ischemic heart disease and varying degrees of cardiac reserve. Displacement of the heart to access coronary targets in patients undergoing OPCAB results in various degrees of hemodynamic instability, especially during initial manipulation and prior to grafting.

In addition, the chest anatomy of the pig is somewhat different than in humans. The pig thorax is smaller and less barrel-shaped than humans, with a more vertically positioned heart. These anatomic differences prevent herniation of the heart into the right hemithorax, a clinical technique commonly used to assist left ventricular lateral free wall access.

Although right ventricular deformation during DPS positioning is apparent, the elevation in right ventricular filling pressures and reduction of left ventricular filling pressures are only circumstantial evidence of this deformation. A more detailed and direct analysis of ventricular geometric changes using echocardiography and ultrasonic crystals will be necessary to confirm these findings.

A final limitation of the study is that we did not investigate the added hemodynamic effects of the coronary stabilizer devices. We designed the study to focus on the effects of cardiac positioning techniques alone. We are, however, quite confident that the hemodynamic difference between DPS and the apical suction device would be the same or greater after coronary artery stabilization. It is our impression that one of the main advantages of the apical suction device is that it *uncouples* the positioning and stabilizing functions. As a result the stabilizer foot can be applied with the minimal amount of pressure required to stabilize a target coronary artery.

### CONCLUSION

In summary, these results support the hypothesis that the apical suction device, compared to DPS, provides adequate coronary target vessel access with superior hemodynamics.

The modest compromise in hemodynamic parameters associated with use of the apical suction device may be partly due to impairment of cardiac apex contractility. DPS was found to significantly compromise hemodynamics compared to baseline. Lateral and inferior wall access using the apical suction device was superior to DPS with regard to all hemodynamic parameters. This apical suction device should facilitate complete off-pump coronary revascularization in a greater proportion of patients, with less need for pressor support.

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