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First in Human Experience with the Second Heart Assist Device

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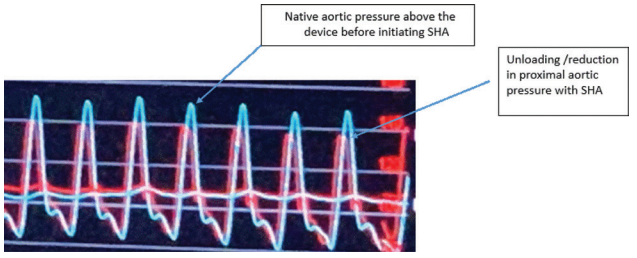
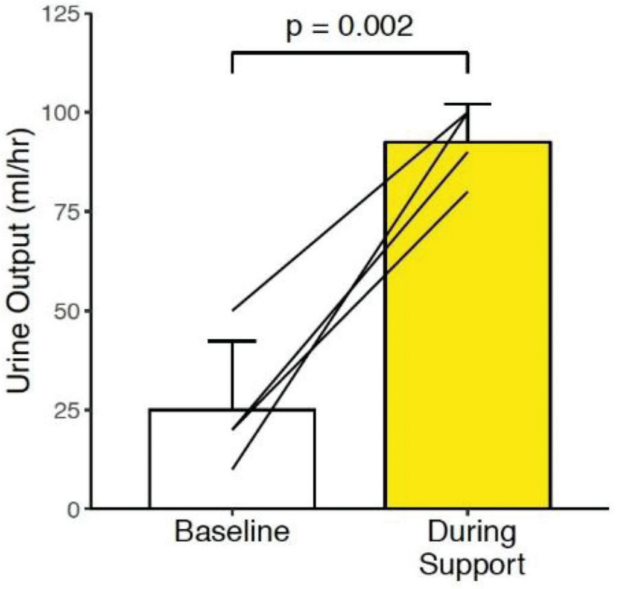
Study:
The Second Heart Assist Device is an impeller driven percutaneous temporary mechanical circulatory support device placed in the descending aorta that provides augmented pulsatile flow to the kidney and circulation. This First in Human study was designed to demonstrate the safety and feasibility of the device for support of patients undergoing high-risk percutaneous coronary intervention at a single center, Sanatorio Italiano, in Asuncion, Paraguay.
Methods: Four patients with reduced ejection fraction (30-40%) and complex coronary anatomy, underwent support with the Second Heart Assist device during elective PCI performed by radial approach.
Results: All patients had successful insertion of the SHA device via femoral access in less than two minutes. The pump was increased in speed to achieve a minimum of 10mmHg gradient across the pump, which averaged 8,500 RPMs (7,000-10,000). The duration of support was one hour in all patients. All patients had PCI of two vessels without complication or hemodynamic compromise. The device was removed percutaneously in all patients, and no patient experienced a serious Adverse Event. There was a four-fold average increase in urine output from baseline to end of support (mean 25 to 92.5 ml/min, and no increase in creatinine at discharge. (GFR data)





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Device-Specific Adverse Event Profile May Favor Surgically Implanted Impella 5.0/LD

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Study: The Impella (Abiomed, Danvers, MA) ventricular support system is a family of temporary mechanical circulatory support devices designed to treat patients with cardiogenic shock. These devices include the percutaneously implanted 2.5/CP and the surgically implanted 5.0/LD. Data to assess adverse outcomes and help guide decision-making between Impella CP and 5.0/LD devices is limited. The purpose of this study was to compare the characteristics and clinical outcomes between Impella CP and 5.0/LD at our institution.
Methods: From December 1, 2014 to October 31, 2019 a total of 117 patients underwent Impella implantation regardless of indication or device type. Of these, 82 patients were supported for greater than 24-hour duration. Baseline patient characteristics and outcomes were reviewed retrospectively. Groups were stratified based on either initial Impella CP or 5.0/LD placement and their clinical outcomes compared.
Results: Impella CP was implanted in 56 patients (median age: 60.5 years, male 71.4%) and Impella 5.0/LD (median age: 65.5 years, male 84.6%) were implanted in 26 patients. Regardless of the indication for Impella placement, 24 patients with Impella CP required additional mechanical support and were upgraded to either Impella 5.0/LD or extracorporeal membrane oxygenation (ECMO) (p=0.005). Patients with Impella CP had increased incidence of hemolysis defined as the presence of gross hematuria and elevated lactated dehydrogenase (Table 1). Patients with Impella 5.0/LD were more likely to survive from Impella and survive to discharge. Data from this study suggests that Impella 5.0/LD may have a more favorable device-specific adverse event profile compared to Impella CP.

Table 1. Baseline patient characteristics and clinical outcomes for patients placed on Impella support for >24 hour duration (total number (n) = 82 patients).

	Impella CP (n = 56)	Impella 5/LD (n = 26)	p-value
Recipient Characteristics			
Age (years)	60.50 [52.00-73.00]	65.5 [55.25-70.25]	0.788
Gender			0.272
Male	40 (71.4%)	22 (84.6%)	
Female	16 (28.6%)	4 (15.4%)	
Race			1.000
White	29 (51.8%)	13 (50.0%)	
Other	27 (48.2%)	13 (50.0%)	
Body mass index (BMI) ≥ 30 kg/m²	22 (39.3%)	7 (26.9%)	0.328
Indications for Impella			<0.0001
Acute decompensated heart failure (ADHF)	30 (53.6%)	4 (15.4%)	
Acute myocardial infarction cardiogenic shock (AMICS)	13 (23.2%)	2 (7.7%)	
High-risk electrophysiology (EP) procedure	1 (1.8%)	0 (0.0%)	
High-risk percutaneous coronary intervention (PCI) procedure	1 (1.8%)	0 (0.0%)	
Myocarditis	3 (5.4%)	0 (0.0%)	
Post-cardiac surgery	8 (14.3%)	20 (76.9%)	
Cannulation Site			<0.0001
Central	0 (0%)	18 (69.2%)	
L femoral	13 (23.2%)	1 (3.8%)	
R femoral	40 (71.4%)	0 (0.0%)	
R axillary	3 (5.4%)	7 (26.9%)	
Clinical Outcomes			
Upgraded to Extracorporeal Membrane Oxygenation (ECMO)	20 (35.7%)	3 (11.5%)	0.033
Upgraded to Impella 5/LD	7 (12.5%)	0 (0.0%)	0.091
Support Upgraded (ECMO or Impella 5/LD)	24 (42.9%)	3 (11.5%)	0.005
Impella Outcome			0.026
Death on Impella	17 (30.4%)	2 (7.7%)	
Survival from Impella	39 (69.6%)	24 (92.3%)	
Discharge Outcome			0.006
Survival to Discharge	29 (51.8%)	22 (84.6%)	
Non-survival to Discharge	27 (48.2%)	4 (15.4%)	
Creatinine ≥ 1.5mg/dL on Impella	34 (61.8%)	11 (42.3%)	0.150
Creatinine ≥ 2.0mg/dL on Impella	22 (40.0%)	8 (30.8%)	0.469
CRRT/HD	18 (32.1%)	7 (26.9%)	0.798
LDH ≥ 2 times upper limit of normal (i.e. ≥560 U/L)	36 (92.3%)	9 (47.4%)	<0.0001
Hematuria	26 (46.4%)	6 (23.1%)	0.005

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