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# Right Ventricular Failure Following Left Ventricular Assist Device Implant: An Intermacs Analysis

Themistokles Chamogeorgakis

I Toumpoulis

David E. Lanfear

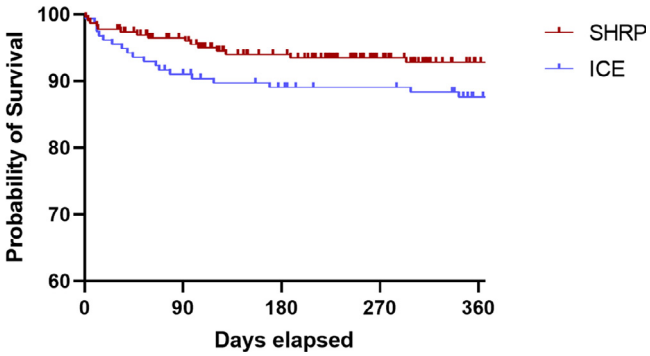
Celeste Williams

A Koliopoulou

*See next page for additional authors*

## Authors

Themistokles Chamogeorgakis, I Toumpoulis, David E. Lanfear, Celeste Williams, A Koliopoulou, S Adamopoulos, and Jennifer A. Cowger

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### Improved Clinical Outcomes Associated with the Impella 5.5 Compared to the Impella 5.0 in Contemporary Cardiogenic Shock and Heart Failure Patients

*D. Ramzy,[1] E.G. Soltesz,[2] S.C. Silvestry,[3] S.A. Hall,[4] and D.A. D'Alessandro.[5] [1]Cardiac Surgery, Cedars-Sinai Med Ctr, Los Angeles, CA; [2]Thoracic and Cardiovascular Surgery, Cleveland Clinic, Cleveland, OH; [3]Advent Health Transplant Institute, Orlando, FL; [4]Baylor Heart and Vascular Institute, Dallas, TX; and the [5]Massachusetts General Hospital, Boston, MA.*

**Purpose:** To compare outcomes in patients treated with the surgically implanted Impella 5.5 vs Impella 5.0 heart pumps for acute myocardial infarction complicated by cardiogenic shock (AMICS), post cardiotomy cardiogenic shock (PCCS), or acute decompensated heart failure (ADHF).
**Methods:** A retrospective analysis included all Impella 5.5 and Impella 5.0 implanted for AMICS, PCCS and ADHF between October 2019 and December 2020. The IQ registry is an FDA-mandated quality assurance database that captures baseline characteristics and outcomes through device explant. Patients receiving extracorporeal membrane oxygenation before/during Impella use were excluded. Those with aborted placement or unknown outcome were not included for assessment of clinical outcome. We examined ability to wean off support, bridge to other therapy, and duration of support.
**Results:** There was no significant difference in gender distribution, baseline LVEF, or pulmonary artery catheterization use in 5.5 vs. 5.0 patients. AMICS 5.5 patients were significantly younger (median 62 vs 66 years, p<0.001). Patients treated with the 5.5 had significantly higher survival in all 3 subgroups (AMICS, 70.5% vs 56.8%, p=0.005; ADHF, 88.1% vs 76.9%, p=0.001; PCCS, 76.1% vs 55.7%, p=0.003) (Table 1). Duration of support was significantly longer in AMICS 5.5 patients vs 5.0 patients (median 9.2 vs 6.1 days, p=0.008) and ADHF 5.5 patients vs 5.0 patients (median 10.7 vs 8.1 days, p<0.001). Rates of hemolysis, cerebrovascular accident, vascular injury and bleeding were statistically similar, with the exception of significantly lower hemolysis rates in cardiomyopathy patients treated with the Impella 5.5.
**Conclusion:** Outcomes were significantly improved with the Impella 5.5 when compared to the Impella 5.0 across all analyzed indications in contemporary patients, though further analysis remains to determine whether this owes to the device redesign or higher flow capability.

**Table 1.** Clinical outcomes through device explant in patients treated with the Impella 5.5 or 5.0 for AMICS, PCCS, and cardiomyopathy

| | AMICS | | | Cardiomyopathy | | | PCCS | | |
|---|---|---|---|---|---|---|---|---|---|
| | Impella 5.0 (N=278) | Impella 5.5 (N=156) | P value | Impella 5.0 (N=225) | Impella 5.5 (N=270) | P value | Impella 5.0 (N=88) | Impella 5.5 (N=117) | P value |
| **Successfully weaned or bridged to therapy** | 158/278 (56.8) | 110/156 (70.5) | 0.005 | 173/225 (76.9) | 238/270 (88.1) | 0.001 | 49/88 (55.7) | 89/117 (76.1) | 0.003 |
| Successfully weaned | 118/278 (42.4) | 78/156 (50.0) | 0.133 | 70/225 (35.1) | 91/270 (33.7) | 0.776 | 46/88 (52.3) | 82/117 (70.1) | 0.013 |
| Bridged to therapy | 40/278 (14.4) | 32/156 (20.5) | 0.108 | 94/225 (41.8) | 147/270 (54.4) | <0.0001 | 3/88 (3.4) | 7/117 (6.0) | 0.521 |
| **Expired on support or withdrawal of care** | 120/278 (43.2) | 46/156 (29.5) | 0.005 | 52/225 (23.1) | 32/270 (11.9) | 0.001 | 39/88 (44.3) | 28/117 (23.9) | 0.003 |
| Hemolysis | 10/278 (3.6) | 5/156 (3.2) | >0.99 | 21/225 (9.3) | 8/270 (3.0) | 0.003 | 1/88 (1.1) | 2/117 (1.7) | >0.99 |
| CVA | 3/278 (1.1) | 5/156 (3.2) | 0.143 | 2/225 (0.9) | 6/270 (2.2) | 0.301 | 1/88 (1.1) | 2/117 (1.7) | >0.99 |
| Bleeding | 5/278 (1.8) | 1/156 (0.6) | 0.426 | 5/225 (2.2) | 3/270 (1.1) | 0.478 | 6/88 (6.8) | 3/117 (2.6) | 0.177 |
| Vascular injury | 0/278 (0.0) | 1/156 (0.6) | 0.359 | 1/225 (0.4) | 0/270 (0.0) | 0.455 | 0/88 (0.0) | 0/117 (0.0) | >0.99 |
| **Duration of support, days** | 8.7 ± 9.5 (278) | 13.2 ± 20.2 (156) | 0.008 | 11.4 ± 10.6 (225) | 15.1 ± 13.4 (270) | <0.001 | 6.6 ± 8.3 (88) | 10.2 ± 23.5 (117) | 0.127 |

Categorical data is presented as numerator/denominator (percentage); continuous data as mean ± standard deviation (denominator). Patients with aborted Impella placement, unknown outcome, or outcome of "on support" (i.e., unknown outcome) were not included in denominators for clinical outcomes nor calculation of duration of support values (63 patients had aborted placement, 35 had unknown outcome, and 6 remained on support [also unknown outcome]). AMICS, acute myocardial infarction complicated by cardiogenic shock; CVA, cerebrovascular accident; PCCS, post cardiotomy cardiogenic shock.
* Other complications observed on support include hemolysis, stroke, thrombus, ischemia, renal failure, systemic organ failure, arrythmia, and other.

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### Right Ventricular Failure Following Left Ventricular Assist Device Implant: An Intermacs Analysis

*T. Chamogeorgakis,[1] I. Toumpoulis,[2] D. Lanfear,[3] C. Williams,[3] A. Koliopoulou,[4] S. Adamopoulos,[4] and J. Cowger.[3] [1]Henry Ford Health System/Transplant Institute, Detroit, MI; [2]University of Athens, School of Medicine, Athens, Greece; [3]Henry Ford Health System, Detroit, MI; and the [4]Onassis Cardiac Surgery Center, Athens, Greece.*

**Purpose:** Right heart failure (RHF) management following LVAD include inotropes, right ventricular mechanical support and heart transplant. We analyzed the outcomes of severe RHF following implant of a fully magnetically levitated or hybrid magnetic centrifugal durable LVAD.
**Methods:** In this INTERMACS analysis we identified patients who developed severe RHF following LVAD from 2013 until 2020 as bridge to recovery or transplant. Patients were categorized in three groups based on RHF treatment strategy: inotrope support (group 1), temporary mechanical support (group 2), and durable centrifugal RVAD (group 3). Kaplan Meier and Cox-regression survival analysis between groups was undertaken. Logistic regression analysis for new onset dialysis was conducted.
**Results:** 2509 patients developed severe RHF after LVAD. 2199 (87.6%) patients were managed with inotropes (group 1), 233 (9.3%) with temporary RVAD (group 2) and 77 (3.1%) with durable RVAD (group 3). Group 1 had fewer patients with INTERMACS profile 1 and 2 (21.6%, p<0.001). One year survival was 84.6%, 59.3%, and 63.8% in groups 1,2, and 3 (mortality HR=2.4 and 3.3 for groups 2 and 3 vs. group 1, p<0.05). One year survival to transplant was 27%, 36.5%, and 53.6% in groups 1, 2, and 3, respectively (p<0.05). Group 2 had higher incidence of new onset dialysis (42.6%, p=0.049).
**Conclusion:** Survival with RHF following LVAD implant varies based on treatment strategy; inotrope support is associated with increased survival. Patients with durable RVAD are more likely to survive to transplant. Patient selection studies for durable RVAD with contraindications for transplant are necessary.

**Patients demographics:** Preoperative labs, hemodynamics, and echocardiography data are shown according to right heart failure management

| Variable | Inotropes Group 1 (n=2199) | Temp RVAD Group 2 (n=233) | Durable RVAD Group 3 (n=77) | P value |
|---|---|---|---|---|
| Age, mean±SD | 53.7±11.8 | 52.5±13.3 | 46.4±14.1 | <0.001 |
| Female, n (%) | 480 (21.8) | 63 (27.0) | 17 (22.1) | 0.205 |
| White, n (%) | 1347 (61.3) | 159 (68.2) | 46 (59.7) | 0.105 |
| Weight (kg), mean±SD | 88.6±22.9 | 83.9±20.2 | 91.1±27.8 | 0.006 |
| BMI (kg/m$^2$), mean±SD | 28.7±7.0 | 27.4±6.0 | 28.4±7.2 | 0.035 |
| BSA (m$^2$), mean±SD | 2.1±0.3 | 2.0±0.3 | 2.1±0.4 | 0.012 |
| Profile | | | | <0.001 |
| 1 (n, %) | 475 (21.6) | 129 (55.4) | 45 (58.4) | - |
| 2 (n, %) | 824 (37.5) | 61 (26.2) | 21 (27.3) | - |
| Previous cardiac operation: none | 1596 (72.6) | 151 (64.8) | 46 (59.7) | 0.003 |
| Concomitant surgical procedure | 1188 (54.0) | 43 (18.5) | 20 (26.0) | <0.001 |
| RV function on preop. echo: | | | | <0.001 |
| mod-severe hypokinesis | 244 (11.1) | 18 (7.7) | 8 (10.4) | - |
| severe hypokinesis | 6 (0.3) | 0 (0) | 0 (0) | - |
| Tricuspid insufficiency on preop echo | | | | 0.018 |
| Moderate (n, %) | 172 (7.8) | 16 (6.9) | 1 (1.3) | - |
| severe (n, %) | 198 (9.0) | 37 (15.9) | 8 (10.4) | - |
| Clamp time, minutes median (IQR) | 328 (14.9) | 36 (15.5) | 12 (15.6) | 0.018 |
| CPB time, minutes mean±SD | 97±108 | 134±63 | 172±124 | <0.001 |
| Pulmonary systolic pressure, mean±SD | 51.3±14.8 | 46.4±14.8 | 43.7±13.7 | <0.001 |
| Pulmonary diastolic pressure, mean±SD | 26.3±9.0 | 25.1±9.1 | 24.1±8.4 | 0.045 |
| RA pressure, mean±SD | 14.1±8.3 | 15.7±8.3 | 16.8±7.3 | 0.011 |
| Hemoglobin (g/dl), mean±SD | 10.9±2.2 | 9.9±2.2 | 9.8±2.0 | <0.001 |
| Platelets (count x 10$^3$/µl), mean±SD | 192.2±78.3 | 168.4±89.6 | 165.7±91.3 | <0.001 |
| Albumin (g/dl), mean±SD | 3.4±0.6 | 3.1±0.6 | 3.2±0.7 | <0.001 |
| Bilirubin (mg/dl), mean±SD | 1.7±2.0 | 2.1±2.8 | 2.3±3.2 | 0.002 |
| BUN (mg/dl), mean±SD | 31.3±18.2 | 32.7±20.2 | 32.2±22.3 | 0.523 |
| Creatinine (mg/dl), mean±SD | 1.5±0.8 | 1.6±1.0 | 1.3±0.6 | 0.095 |
| SGOT (AST) (units/l), mean±SD | 63.2±268.3 | 138.9±500.3 | 84.3±173.0 | 0.001 |
| SGPT (ALT) (units/l), mean±SD | 70.3±227.6 | 141.9±409.8 | 78.7±163.6 | <0.001 |
| INR, mean±SD | 1.3±0.6 | 1.4±0.4 | 1.4±0.4 | 0.515 |