

# Bridge to transplant with impella : what are the outcomes?

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# Conflicts of interest

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ABIOMED

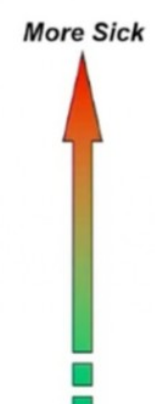
ABBOTT

# Background

Various etiology of cardiogenic shock :

- Decompensation of chronic heart disease
- Acute myocardial infarction
- Myocarditis
- Toxic

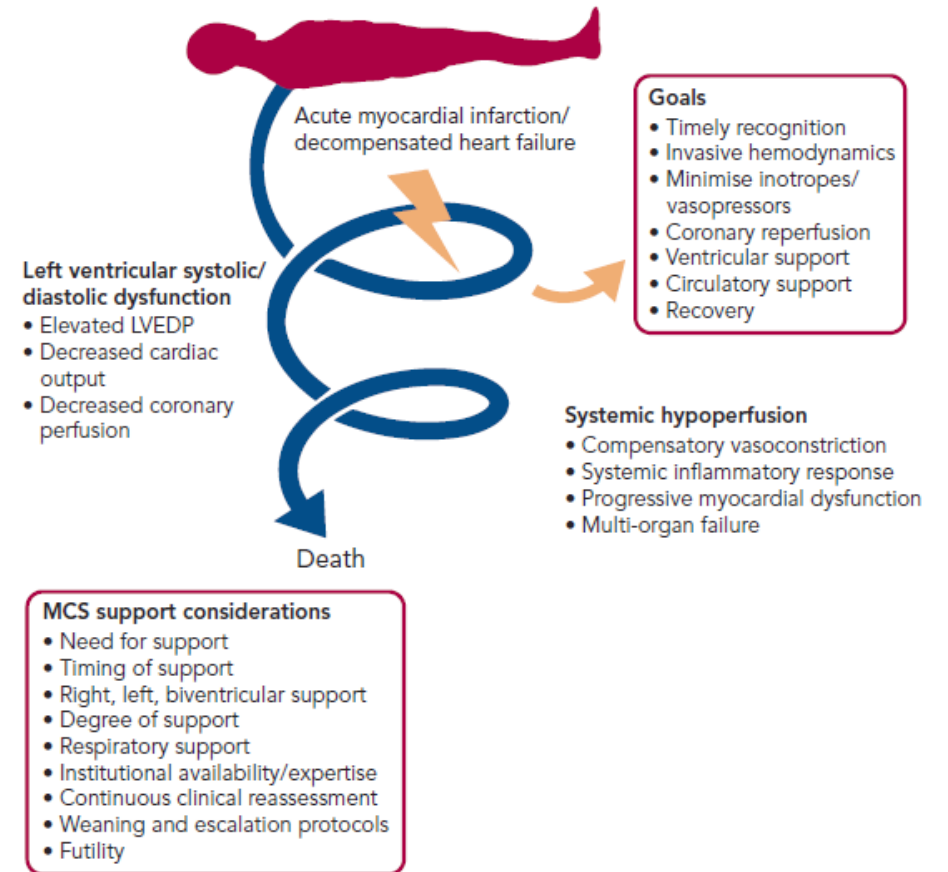
**INTERMACS Profiles** Interagency Registry of Mechanically Assisted Circulatory Support



| Profile | Patient Characteristics  | Inotrope |
|---------|--|----------|
| 1       | Critical cardiogenic shock despite escalating support  | X        |
| 2       | Progressive decline despite inotropes  | X        |
| 3       | Clinically stable but inotrope dependent   | X        |
| 4       | Recurrent, not refractory, advanced heart failure  |          |
| 5       | Exertion intolerant but comfortable at rest and able to perform ADL with slight difficulty     |          |
| 6       | Exertion limited; able to perform mild activity, but fatigued within a few minutes of exertion |          |
| 7       | Advanced NYHA Class III  |          |

ACC.21 Stevenson LW, et al. JHLT 2009;28:535-41.

## Cardiogenic shock pathophysiology and management



LVEDP = left ventricular end-diastolic pressure; MCS = mechanical circulatory support. Reproduced and modified with permission from Abiomed.

# Heart support in cardiogenic shock

- **Hemodynamic support :**

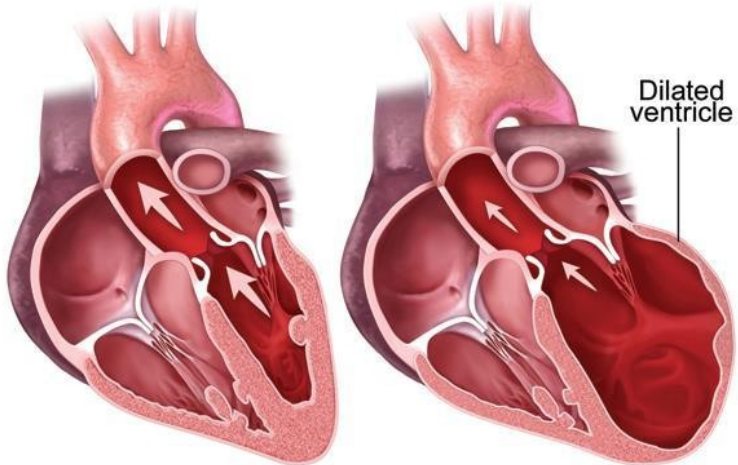
- ECLS (femoro-femoral access), for bi-ventricular or mono-ventriculaire failure
- Impella 5.0 (axillary access) for LV failure only or predominantly

- **ECLS :** Respiratory and Circulatory support

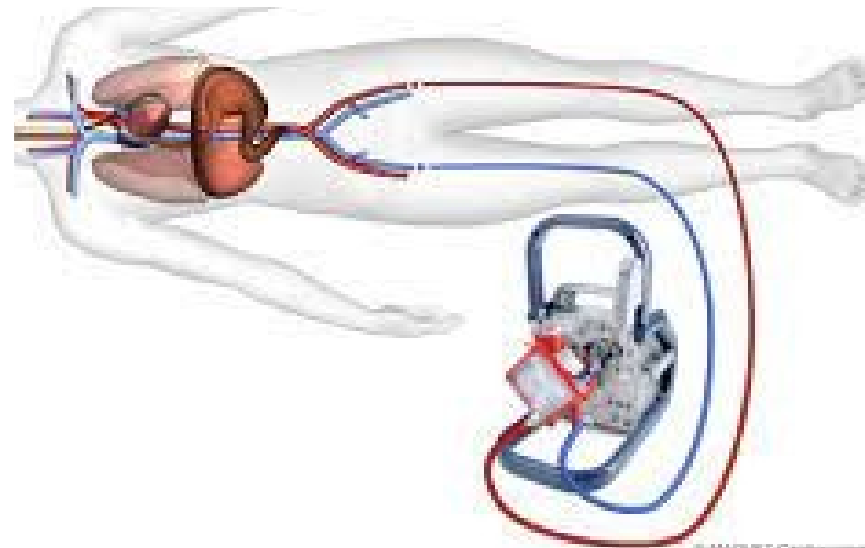
- **Impella :** Circulatory support

Normal Heart

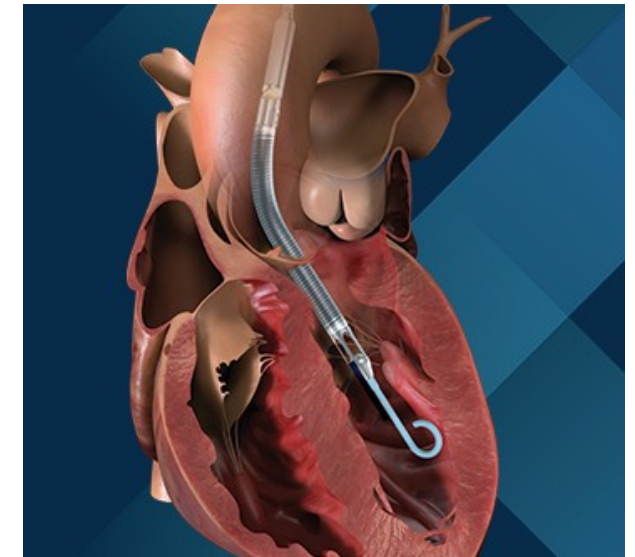
Dilated Cardiomyopathy



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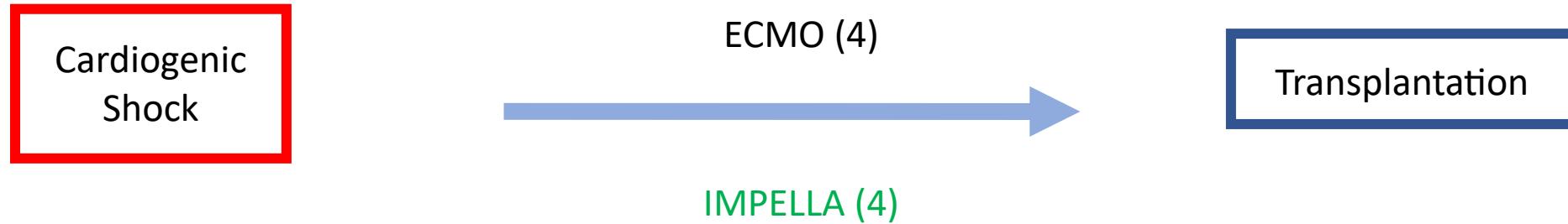


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# Impella 5.0 : bridge to heart transplantation

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Between : 2016-2018 (arrivée du score cœur)

Patient :

- Mean age = 55 / 56 years, SC 1,65/1,85
- More myocardial ischemia etiology in IMPELLA group, only medical etiology
- More terminal heart failure : ECMO group

# Impella 5.0 : bridge to heart transplantation

## ***Average support time***

- ECLS group = 6,5 days
- IMPELLA group = 12,25 days

## ***During support, adverse outcome :***

Sepsis : 25% vs 60 %.

Hemorrhage : 0% vs 40 %.

Revision surgery : 0% vs 50%

## ***After transplantation :***

- Sepsis (pulmonary or subcutaneous) : 0% vs 75%, self-limiting.
- Inotropic support after transplantation = 3 vs 10 days
- Extubation delay : 1,5 vs 5,25 Days
- Time in IC Unit : 8,75 vs 18,8 Days
- Temporary support after transplantation : 0 % vs 50%

## **1-year Survival**

**100% vs 80%**

**BUT : 1 Death for mesenteric ischaemia**

# Impella 5.0 : bridge to heart transplantation

First 100 patients, from January 2014 through September 2018 (axillary Impella 5.0 insertion)  
Prospective recording and retro-spective analysis

All patients, bridged with Impella device to (1) recovery, (2) durable device, or (3) heart transplantation  
Assign patients to individual groups as early as possible. Limit potential bias, patients assigned to groups during the first consensus by our multidisciplinary team.

## (3) Bridge to Transplantation

47 patients

78.7% underwent successful heart transplantation.

Patients listed before implantation, improved success rate to transplantation, 83.7% vs those not listed earlier 60.0%.

All patients, survived to discharge.

Median duration of Impella : 15.0 days (IQR, 7, 28.0).

## A New Paradigm in Mechanical Circulatory Support: 100-Patient Experience

Joshua S. Chung, MD, Dominic Emerson, MD, Danny Ramzy, MD, PhD, Akbarshakh Akhmerov, MD, Dominick Megna, MD, Fardad Esmailian, MD, Jon Kobashigawa, MD, Robert M. Cole, MD, Jaime Moriguchi, MD, and Alfredo Trento, MD

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# Impella 5.0 : bridge to heart transplantation

| Outcomes and Complications                    | Bridge to Recovery<br>n = 30 | Bridge to Durable Device<br>n = 23 | Bridge to Transplantation<br>n = 47 | All patients<br>N = 100   | P Value |
|---|------------------------------|------------------------------------|-------------------------------------|---------------------------|---------|
| Number of Impella 5.0 devices                 | 1.1 ± 0.3                    | 1.1 ± 0.3                          | 1.2 ± 0.4                           | 1.1 ± 0.3                 | .356    |
| Duration of Impella 5.0 (d)                   | 9.0 [4.8, 15.3]              | 16.0 [8.0, 28.0]                   | 15.0 [7.0, 28.0]                    | 12.5 [7.0, 23.8]          | .009    |
| Survival at discharge <sup>a</sup>            | 14 (46.7)                    | 11 (47.8)                          | 38 (80.9)                           | 64 (64.0)                 | .004    |
| 30-d survival                                 | 15 (50.0)                    | 15 (65.2)                          | 39 (83.0)                           | 69 (69.0)                 | .009    |
| 6-mo survival                                 | 12 (40.0)                    | 11 (47.8)                          | 37 (78.7)                           | 60 (60.0)                 | .001    |
| 1-y survival                                  | 10 (33.3)                    | 9 (39.1)                           | 35 (74.5)                           | 54 (54.0)                 | .001    |
| Survival at discharge by implant year:        |                              |                                    |                                     |                           |         |
| 2014-2016                                     | 4/10 (40.0)                  | 3/9 (33.3)                         | 14/16 (87.5)                        | 21/35 (60.0)              | .009    |
| 2017-2018                                     | 11/20 (55.0)                 | 8/14 (57.1)                        | 24/31 (77.4)                        | 43/65 (66.2)              | .185    |
| Recovered (Impella explanted)                 | 18 (60.0)                    | NA                                 | NA                                  | NA                        | NA      |
| Survival of recovered                         | 14/18 (77.8)                 | NA                                 | NA                                  | NA                        | NA      |
| Durable MCS implanted                         | NA                           | 14 (60.9)                          | NA                                  | NA                        | NA      |
| Survival at discharge after dMCS              | NA                           | 11/14 (78.6)                       | NA                                  | NA                        | NA      |
| HW  | NA                           | 7/10 (70.0)                        | NA                                  | NA                        | NA      |
| HM2   | NA                           | 1/1 (100)                          | NA                                  | NA                        | NA      |
| HM3   | NA                           | 1/1 (100)                          | NA                                  | NA                        | NA      |
| TAH   | NA                           | 2/2 (100)                          | NA                                  | NA                        | NA      |
| Transplanted                                  | NA                           | 3 (13.0) <sup>b</sup>              | 37 (78.7)                           | 40 (40.0)                 | NA      |
| Listed for OHT before Impella 5.0             | NA                           | 2/3 (66.7)                         | 37/47 (78.7)                        | 39/40 (97.5)              | NA      |
| Transplanted                                  | NA                           | NA                                 | 31/37 (83.8)                        | NA                        | NA      |
| Survival after OHT                            | NA                           | 3/3 (100)                          | 37/37 (100)                         | 40/40 (100)               | NA      |
| Stroke  | 3 (10.0)                     | 5 (21.7)                           | 2 (4.3)                             | 10 (10.0)                 | .073    |
| Clinically significant hemolysis <sup>c</sup> | 3/23 (13.0)                  | 5/19 (26.3)                        | 8/44 (18.2)                         | 16/86 <sup>c</sup> (18.6) | .543    |
| Device exchange in operating room             | 2 (6.7)                      | 3 (13.0)                           | 8 (17.0)                            | 13 (13.0)                 | .420    |

<sup>a</sup>Date of discharge >30 days post device implantation in some cases; <sup>b</sup>After durable device; <sup>c</sup>Isolated Impella 5.0 (n=86).

Data are presented as absolute numbers (%), means ± SD, or medians [quartile 1, quartile 3].

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# Impella 5.0 : bridge to heart transplantation

Change in US allocation system for transplantation : Impella 5.0 = high priority status 2 listing.

Data source : the United Network for Organ Sharing (UNOS) registry.

Adults ( $\geq 18$  years), bridged to OHT with Impella 5.0 device,

January 1, 2010 to December 31, 2018.

TABLE 2 Waitlist outcomes in patients supported with Impella 5.0

|                             | Impella 5.0<br>(n = 236) |
|-----------------------------|--------------------------|
| Reason for waitlist removal |                          |
| Transplanted                | 57 (24.1%)               |
| Recovered                   | 31 (13.0%)               |
| Deteriorated                | 14 (5.9%)                |
| Died                        | 33 (14.1%)               |
| Converted to durable LVAD   | 87 (37.0%)               |
| Device malfunction          | 14 (5.9%)                |
| Waitlist cause of death     |                          |
| Infection                   | 3 (8.3%)                 |
| Cardiovascular              | 8 (25.0%)                |
| Cerebrovascular             | 6 (16.7%)                |
| Multisystem organ failure   | 14 (41.6%)               |
| Other                       | 2 (6.1%)                 |
| Time on device (d)          | 13 [IQR 7, 20]           |
| Time on waitlist (d)        | 29 [IQR 9, 176]          |

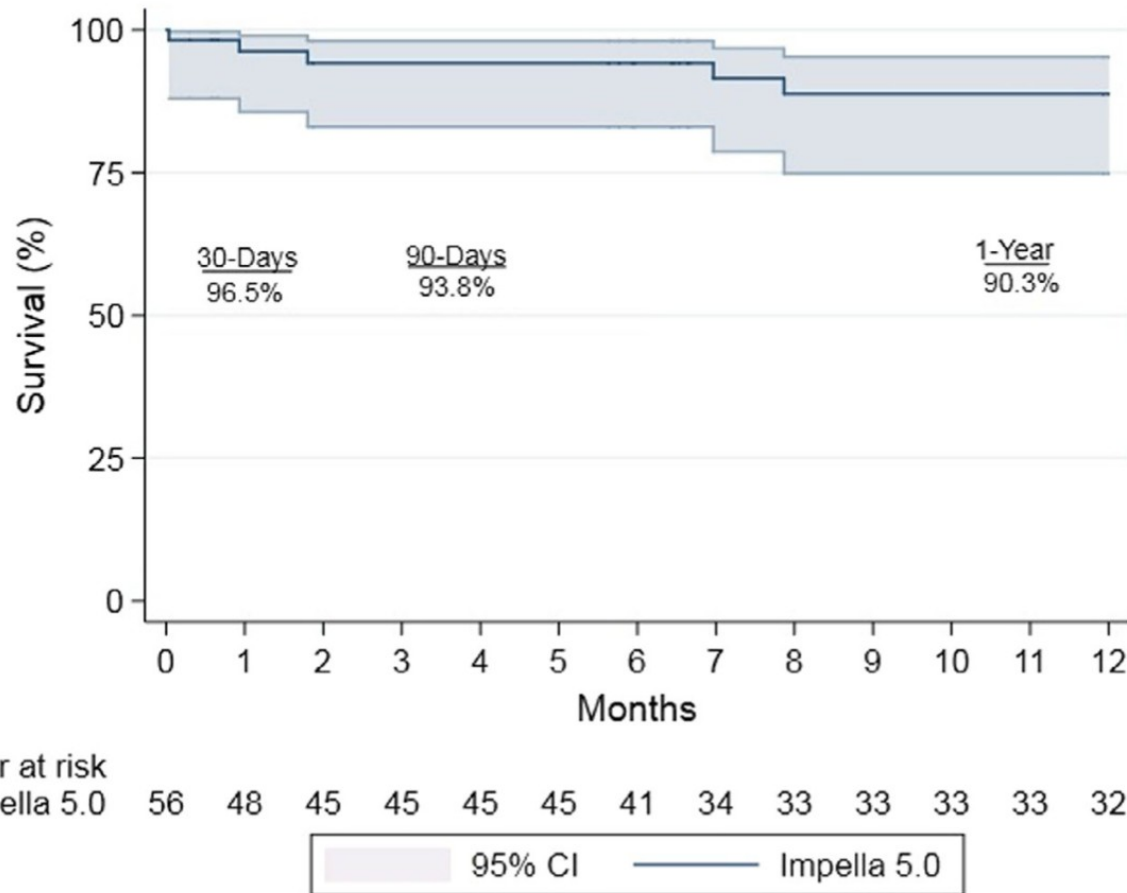
## Direct bridging to cardiac transplantation with the surgically implanted Impella 5.0 device

Laura Seese<sup>1,2</sup> | Gavin Hickey<sup>2,3</sup> | Mary E. Keebler<sup>2,3</sup> | Michael A. Mathier<sup>2,3</sup> | Ibrahim Sultan<sup>1,2</sup> | Thomas G. Gleason<sup>1,2</sup> | Catalin Toma<sup>2,3</sup> | Arman Kilic;

*Clinical transplantation*

*Division of Cardiac Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania*

# Impella 5.0 : bridge to heart transplantation



**TABLE 4** Post-transplant outcomes in patients bridged with Impella 5.0 to OHT

|  | Impella 5.0<br>(n = 57) |
|--|-------------------------|
| New-onset dialysis                       | 5 (8.8%)                |
| Cerebrovascular accident                 | 1 (1.8%)                |
| Pacemaker implant                        | 1 (1.8%)                |
| Prolonged ventilator support (>48 h)     | 0 (0.0%)                |
| Length of stay (d)                       | 15 [IQR 11,21]          |
| Rejection requiring treatment within 1 y | 4 (7.0%)                |
| 30-day mortality                         | 2 (3.5%)                |

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# Impella 5.0 : bridge to heart transplantation

UK, IMPELLA 5.0 patients : high-priority allocation, “super-urgent” status.

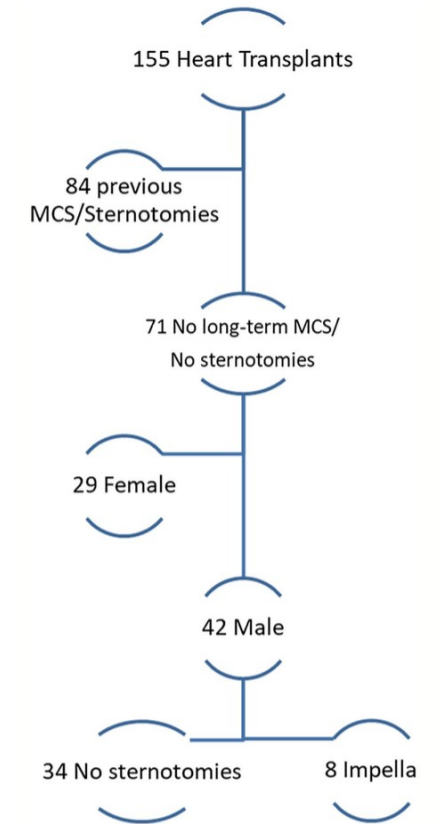
Study, compared perioperative and short-term outcomes (up to 6-months)

Patients undergoing HTx following bridging with Impella 5.0 versus those without pre-operative MCS.

Retrospective study, January 2014 to March 2019.

Group 1 : no need for pre-operative MCS and Group 2 : IMPELLA 5.0 support (INTERMACS 2)

Mean time of support :  $16 \pm 17$  days.



## Outcomes of heart transplantation in patients bridged with Impella 5.0: Comparison with native chest transplanted patients without preoperative mechanical circulatory support

María Monteagudo-Vela<sup>1</sup> | Vasileios Panoulas<sup>2</sup> | Diana García-Saez<sup>1</sup> | Fabio de Robertis<sup>1</sup> | Ulrich Stock<sup>1</sup> | Andre Rudiger Simon<sup>1</sup>; *Artificial Organs.*

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# Impella 5.0 :bridge to heart transplantation

Groupe 2 : 6 patient with moderate/severe RV failure, left ventricular unloading alone sufficed to bridge these patients to transplantation

Immediate restoration of output = end-organ recovery, early extubation and mobilization.

Prevent muscular or neurological deconditioning

TABLE 3 Recipient preoperative characteristics

| Variable                        | Group 1 No MCS         | Group 2 Impella | P value |
|---------------------------------|------------------------|-----------------|---------|
| Recipient Age (years)           | 48.76 ± 10.7           | 49.13 ± 16.5    | .93     |
| Recipient Height (cm)           | 175 ± 8                | 179 ± 7         | .14     |
| Recipient Weight (kg)           | 77 ± 11                | 77 ± 9          | .92     |
| Recipient Listing               |                        |                 |         |
| Routine                         | 6 (17.6)               | 0               |         |
| Urgent                          | 28 (82.4)              | 0               |         |
| Super-Urgent                    | 0                      | 8 (100)         |         |
| INTERMACS                       | 4-5 (17.6)<br>3 (82.4) | 2 (100)         |         |
| Time on the waiting list (Days) | 62 ± 49                | 16 ± 17         | .03     |
| Pre-HTx Creatinine (μmol/L)     | 103.6 ± 27.7           | 108.6 ± 41      | .67     |
| Pre-HTx Bilirubin (μmol/L)      | 17.8 ± 11              | 32.6 ± 19       | .07     |
| Pre-HTx ALT (IU/L)              | 25 (19-35)             | 35 (19-118)     | .06     |
| Pre-HTx ALP (IU/L)              | 100.7 ± 51             | 102.8 ± 54      | .91     |

## Outcomes of heart transplantation in patients bridged with Impella 5.0: Comparison with native chest transplanted patients without preoperative mechanical circulatory support

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# Impella 5.0 : bridge to heart transplantation

**TABLE 6** Postoperative complications after HTx

| Variable                                  | Group 1<br>No MCS | Group 2<br>Impella | P value |
|---|-------------------|--------------------|---------|
| ECMO post-HTx                             | 6 (17,6)          | 2 (25)             | .63     |
| Gastrointestinal ischemia                 | 3 (8,8)           | 0                  | 1       |
| Reexploration due to bleeding             | 8 (23,5)          | 1 (12,5)           | .66     |
| Need of tracheostomy                      | 5 (14,7)          | 3 (37,5)           | .162    |
| Duration of mechanical ventilation (days) | 2 (1-6)           | 2,5 (1-9,75)       | 1       |
| Neurological event                        | 3 (8,8)           | 1 (12,5)           | 1       |
| Duration of hemofiltration (weeks)        | 1 (1-4,5)         | 1 (1-4,5)          | .937    |
| Need for hemofiltration (n (%))           | 27 (79,4)         | 7 (87,5)           | .35     |

**TABLE 7** Length of stay and survival compared by groups

| Variable          | No MCS     | Impella      | P value |
|-------------------|------------|--------------|---------|
| Days in ITU       | 6,5 (4-13) | 7,5 (5,5-20) | .45     |
| Days in hospital  | 32 (20-55) | 39 (30-48)   | .62     |
| Survival 30 days  | 94,1       | 87,5         | .47     |
| Survival 6 months | 94,1       | 87,5         | .51     |

Note: Results are presented as Median (IQR) or %.

Impella 5.0 : Feasible and Realistic option for patients in profound cardiogenic shock as bridge to HTx.

Restoration of output = end-organ recovery, early extubation and mobilization.  
Prevent muscular or neurological deconditioning

Outcomes : no difference between 2 groups

## Outcomes of heart transplantation in patients bridged with Impella 5.0: Comparison with native chest transplanted patients without preoperative mechanical circulatory support

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# Summary

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This data interesting about outcomes of OHT in recipients who were directly bridged from Impella 5.0 support.

The principal finding was that Impella 5.0 can be used as a direct bridge to OHT with good survival and minimal post-transplant morbidity.

Overall, these data support the utilization of Impella 5.0 as a bridge to OHT in select patients with refractory shock

Outcomes seems do not differ from those patients on waiting list without other organ dysfunction, no redo surgeries, or pre-operative MCS.

Support with the Impella 5.0 led to a recovery of end-organ function and allowed us to bridge patients to HTx without an increase in the early and long-term survival.

