

ADVANCES IN QUALITY & OUTCOMES: A Data Managers Meeting

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STS Intermacs Patient Profiles

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STS InterMACs Patient Profiles

- Provides important prognostic information for patients with advanced heart failure receiving mechanical circulatory support



INTERMACS Profiles of Advanced Heart Failure: The Current Picture

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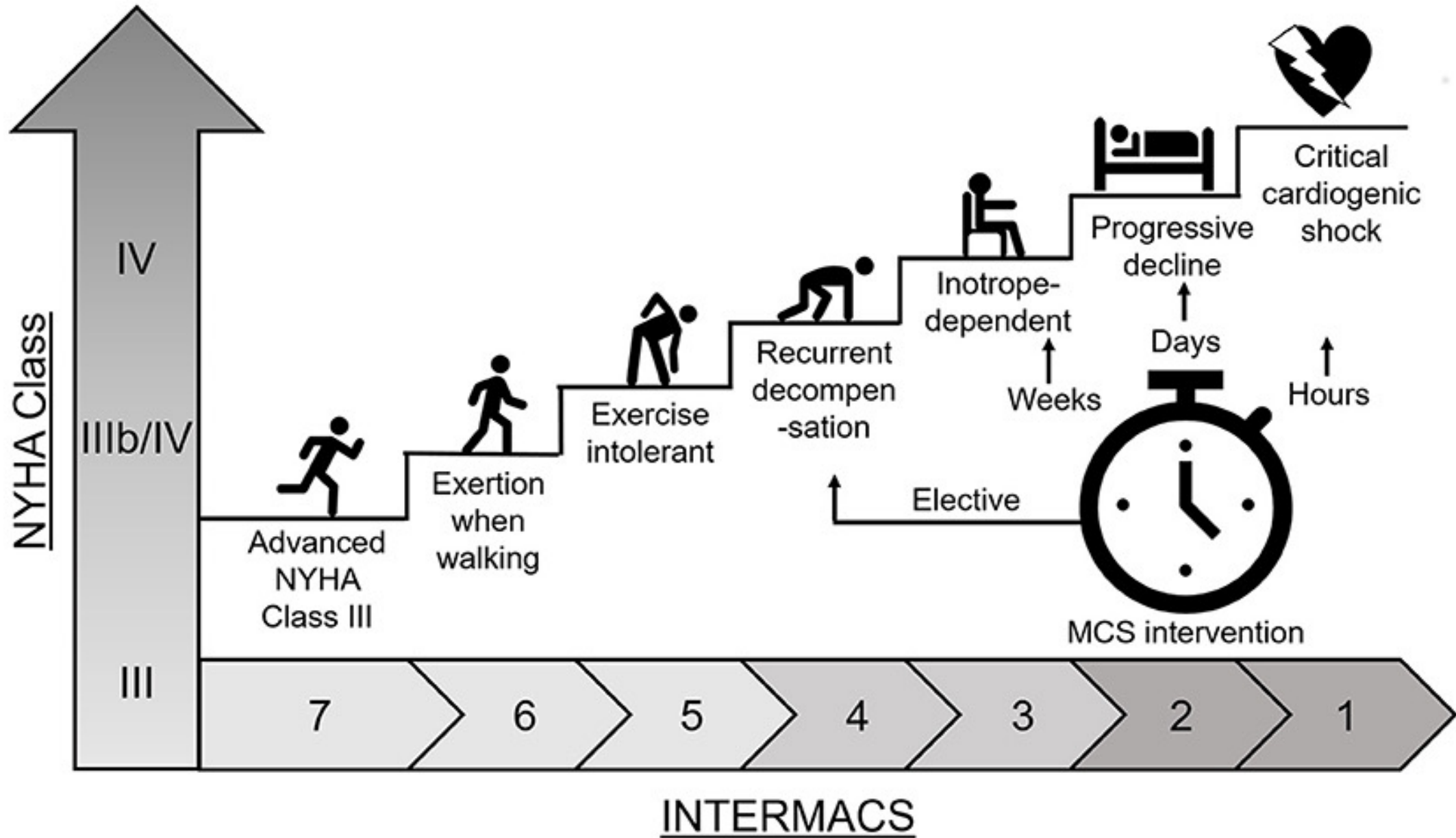
- Background:** The current classification of patients with New York Heart Association Class IV symptoms does not offer adequate description to allow optimal selection of patients for the current options of medical and pacing therapies, cardiac transplantation and mechanical circulatory support.
- Methods:** Seven clinical profiles and an arrhythmia modifier were developed and implemented into the first year of data collection for the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS). The INTERMACS Coordinators' Council provided ongoing feedback regarding the characterization of patients receiving implantable devices.
- Results:** The definition of 7 clinical profiles revealed that 80% of current devices are being used in the 2 profiles with the highest levels of clinical compromise. The INTERMACS Coordinators' Council helped to identify gaps in the characterization of hospitalized patients on temporary assist devices and of homebound patients with resting symptoms, which has led to revised definitions of Profile 3 and 4 and the addition of 2 new modifiers, for temporary circulatory support devices in the hospital, and for frequent rehospitalization of patients at home.
- Conclusions:** Patients considered for mechanical circulatory support can now be classified using the 7 profiles plus 3 modifiers developed through INTERMACS. Further understanding these profiles and their impact on outcome should help to better select patients and therapies in the advanced stages of disease. *J Heart Lung Transplant* 2009;28:535-41. Copyright © 2009 by the International Society for Heart and Lung Transplantation.

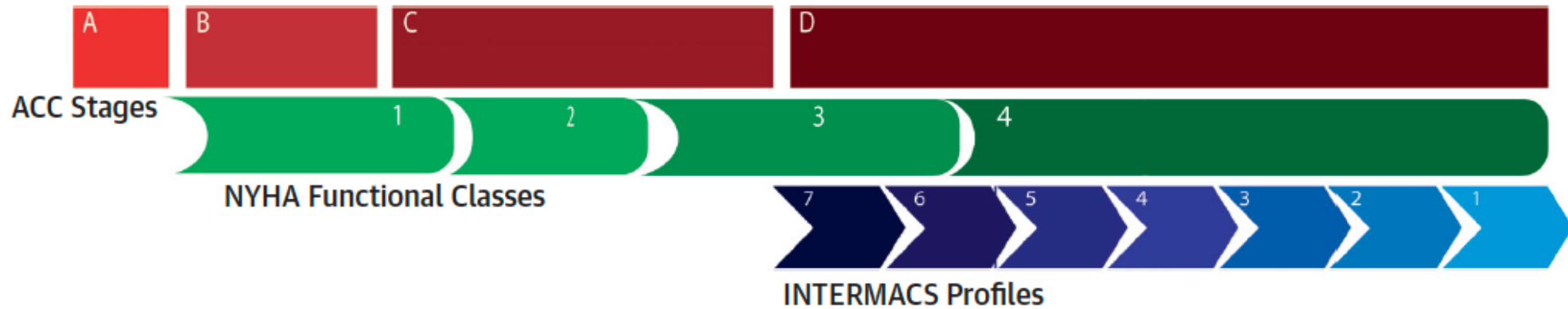


STS InterMACs Patient Profiles

- Initially developed to overcome the limitations of the New York Heart Association (NYHA) classification for patients being evaluated for MCS therapy
- InterMACs Patient Profiles were intended to discern relative differences of patients with advanced NYHA class III and IV symptoms







ACC Stages

A: Patient is at high risk for developing heart failure but has no functional or structural heart disorder

B: Structural heart disorder without symptoms

C: Past or current symptoms or heart failure associated with structural disorder

D: Advanced heart disease requiring hospital-based support, transplant, or palliative care

NYHA Functional Classes

I: No limitation in normal physical activity

II: Mild symptoms with normal activity

III: Markedly symptomatic during daily activities, asymptomatic only at rest

IV: Severe limitations, symptoms even at rest

INTERMACS Profiles

Profile 1: Critical Cardiogenic Shock

Profile 2: Progressive Decline

Profile 3: Stable, But Inotrope Dependent

Profile 4: Resting Symptoms

Profile 5: Exertion Intolerant

Profile 6: Exertion Limited

Profile 7: Advanced NYHA Class III

Truby, L.K. et al. *J Am Coll Cardiol HF*. 2020;8(7):523-36.



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STS Intermacros Patient Profiles

- **Intermacros[®] 1: Critical cardiogenic shock**
 - describes a patient who is “crashing and burning”, in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels.



STS Intermacros Patient Profiles

- **Intermacros[®] 2: Progressive decline**
 - Describes a patient who has been demonstrated “dependent” on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, fluid retention, or other major status indicator.
 - Patient profile 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions *cannot be maintained* due to tachyarrhythmias, clinical ischemia, or other intolerance.



STS Intermacros Patient Profiles

- **Intermacros[®] 3: Stable but inotrope dependent**
 - Describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal).
 - It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between a patient who is truly stable at Patient Profile 3 and a patient who has unappreciated decline rendering them Patient Profile 2. This patient may be either at home or in the hospital.



STS InterMACs Patient Profiles

- **InterMACs[®] 4: Resting symptoms**
 - Describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with activities of daily living (ADL). He or she may have orthopnea, shortness of breath during ADL such as dressing or bathing, gastrointestinal symptoms (abdominal discomfort, nausea, poor appetite), disabling ascites or severe lower extremity edema.
 - This patient should be carefully considered for more intensive management and surveillance programs, which may in some cases, reveal poor compliance that would compromise outcomes with any therapy.



STS Intermacros Patient Profiles

- **Intermacros[®] 5: Exertion Intolerant**
 - Describes a patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or housebound. This patient has no congestive symptoms, but may have chronically elevated volume status, frequently with renal dysfunction, and may be characterized as exercise intolerant.



STS Intermacros Patient Profiles

- **Intermacros[®] 6: Exertion Limited**
 - Describes a patient who is comfortable at rest without evidence of fluid overload, but who is able to do some mild activity. Activities of daily living are comfortable and minor activities outside the home such as visiting friends or going to a restaurant can be performed, but fatigue results within a few minutes of any meaningful physical exertion. This patient has occasional episodes of worsening symptoms and is likely to have had a hospitalization for heart failure within the past year.



STS InterMACs Patient Profiles

- **InterMACs[®] 7: Advanced NYHA Class 3**
 - Describes a patient who is clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. This patient is usually able to walk more than a block. Any decompensation requiring intravenous diuretics or hospitalization within the previous month should make this person a Patient Profile 6 or lower.



STS Intermacros Patient Profiles

Intermacros[®] Patient Profile at time of implant: Select one.

These profiles will provide a *general* clinical description of the patients receiving **LVAD** or **TAH** implants. If there is significant clinical change between the initial decision to implant and the actual implant procedure, then the profile closest to the time of implant should be recorded. Patients admitted electively for implant should be described by the profile just prior to admission.



Advantages

- Easy to assess
- Has provided important discrimination in determining patient prognosis
 - Survival with medical therapy alone
 - Survival following LVAD implantation



INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) Profiling Identifies Ambulatory Patients at High Risk on Medical Therapy After Hospitalizations for Heart Failure

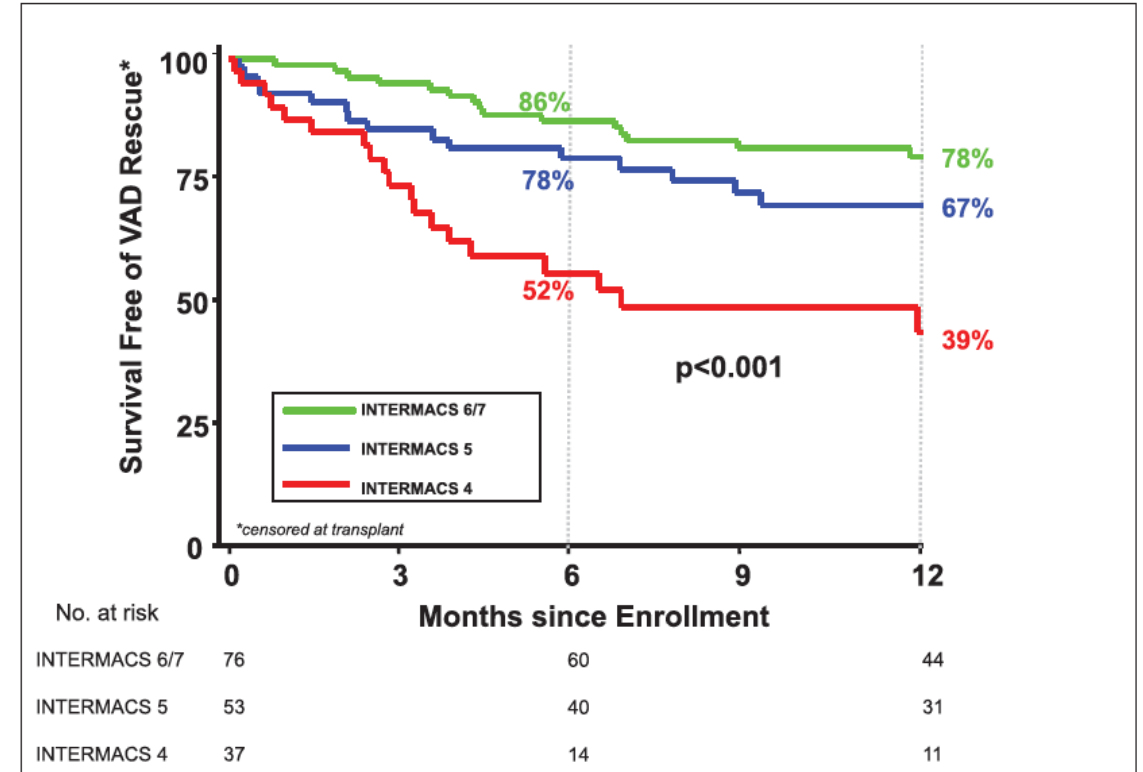
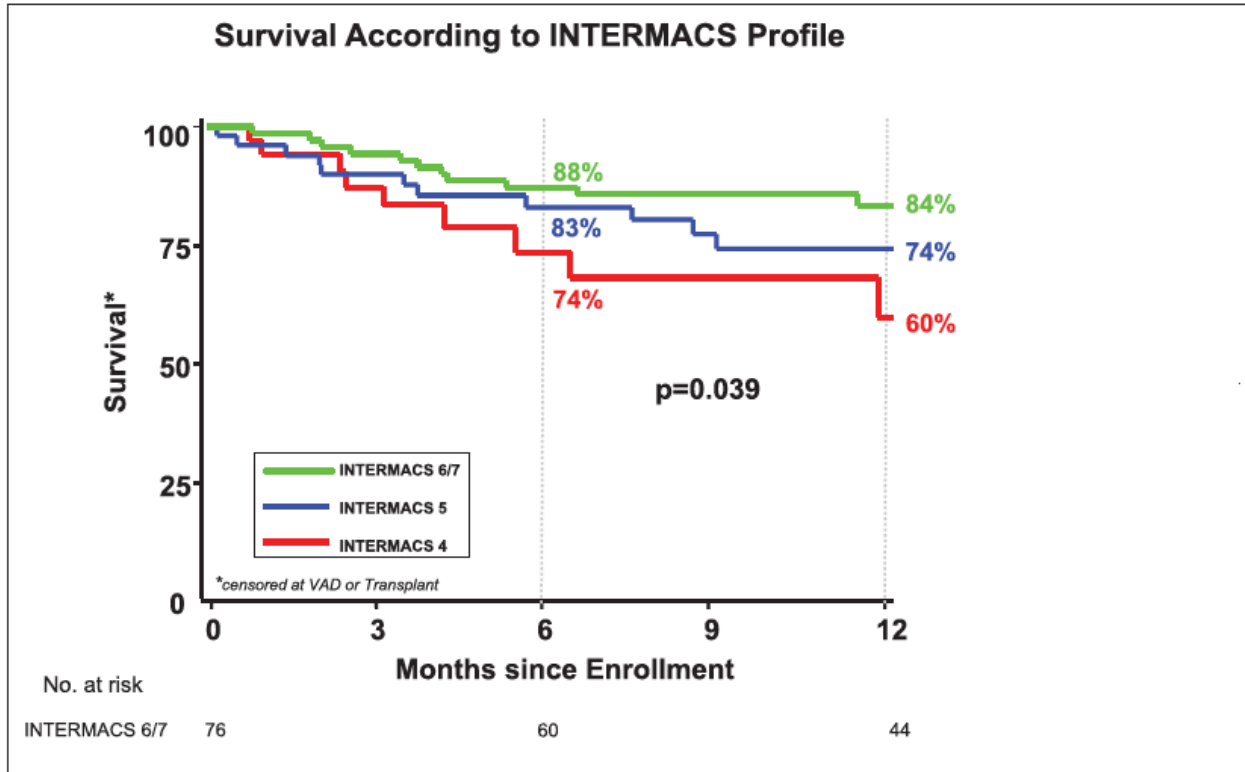
Garrick C. Stewart, MD, MPH; Michelle M. Kittleson, MD; Parag C. Patel, MD;
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Jeffrey J. Teuteberg, MD; Lynne W. Stevenson, MD

Circ Heart Fail. 2016;9:e003032.

DOI: 10.1161/CIRCHEARTFAILURE.116.003032.



STS Intermacs Patient Profiles



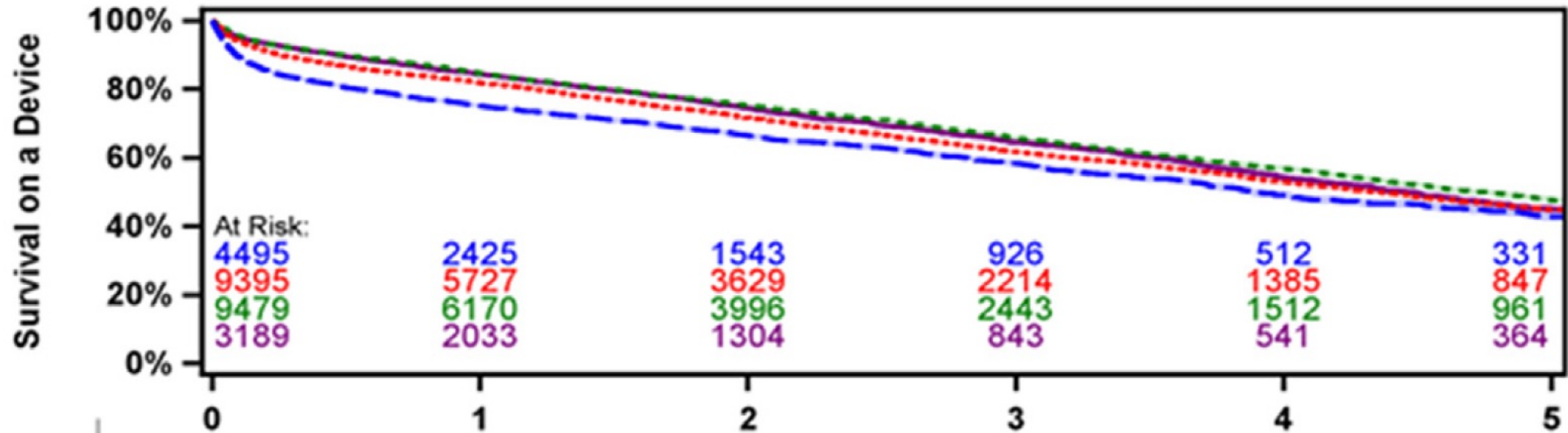
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 DOI: 10.1161/CIRCHEARTFAILURE.116.003032.



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Survival for Primary CF LVAD by Patient Profile (n=27,245)

Intermacs: January 1, 2012 - December 31, 2021



Years	1	2	3	4
1	75.1%	81.9%	84.7%	84.4%
2	66.5%	71.7%	75.3%	74.5%
3	58.4%	61.9%	65.8%	64.5%
4	49.0%	53.1%	56.9%	54.4%
5	42.8%	44.8%	47.6%	45.1%

Years After Device Implant

- — — — 1. Critical Cardiogenic Shock (n = 4495, Deaths = 1622)
- 2. Progressive Decline (n = 9395, Deaths = 3072)
- . - . - . 3. Stable but Inotrope Dependent (n = 9479, Deaths = 2855)
- 4. Resting Symptoms (n = 3189, Deaths = 1016)

Shaded areas indicate 70% confidence limits

p (log-rank) = <.0001

Event: Death (censored at transplant or cessation of support)



Limitations

- Subjective and assignment of Patient Profiles are dependent on assessor's interpretation of the patient's condition
- Variation in timing of the assessment. Patient condition can change substantially in a short period of time



INTERMACS profiles and modifiers: Heterogeneity of patient classification and the impact of modifiers on predicting patient outcome



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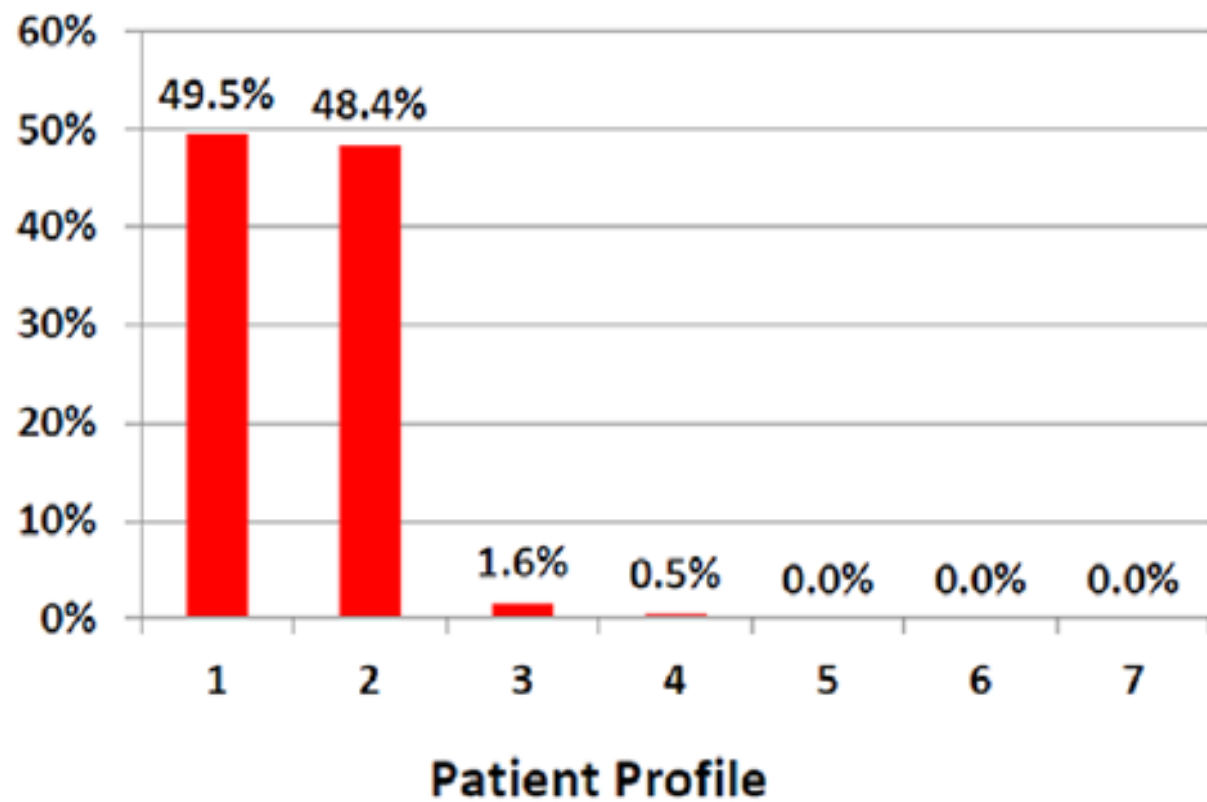


Patient Scenario C

- A 56-year-old man with chronic non-ischemic heart failure (EF $\leq 10\%$) admitted with 20-pound weight gain, nausea, and vomiting with SBP 83/68 mm Hg and HR 120 beats/min. He is on 100 mg daily torsemide at home. First hospital admission in 1 year. Not on home inotropes.
- Currently, patient is in ICU on intraaortic balloon pump on vasopressin 0.04 U/min, milrinone 0.5 $\mu\text{g}/\text{kg}/\text{min}$, dobutamine 5 $\mu\text{g}/\text{kg}/\text{min}$, and norepinephrine bitartrate (Levophed) 12 $\mu\text{g}/\text{min}$.
- Blood pressure is 85/65 mm Hg, and heart rate is 125 beats/min. Swan-Ganz catheter measurements: RA 14 mm Hg, PA 53/30 mm Hg, WP 27 mm Hg, CI 1.5 liters/min/m².
- He is making urine with intravenous diuretics. Day of operation: Cr 1.7 mg/dl (baseline 1.0 mg/dl), INR 1.5 (no warfarin), ALT 100 IU/liter.
- He is not on a ventilator.



C



STS InterMACS Patient Profiles

- Institutional INTERMACS profile assignment was variable (63% assigned by cardiologists/surgeons; 10% by research coordinators; 27% by physician extenders)
- Substantial heterogeneity exists in the process and assignment of INTERMACS profiles
- This heterogeneity could affect mortality estimates used for risk stratification.



THE SOCIETY OF THORACIC SURGEONS INTERMACS ANNUAL REPORT

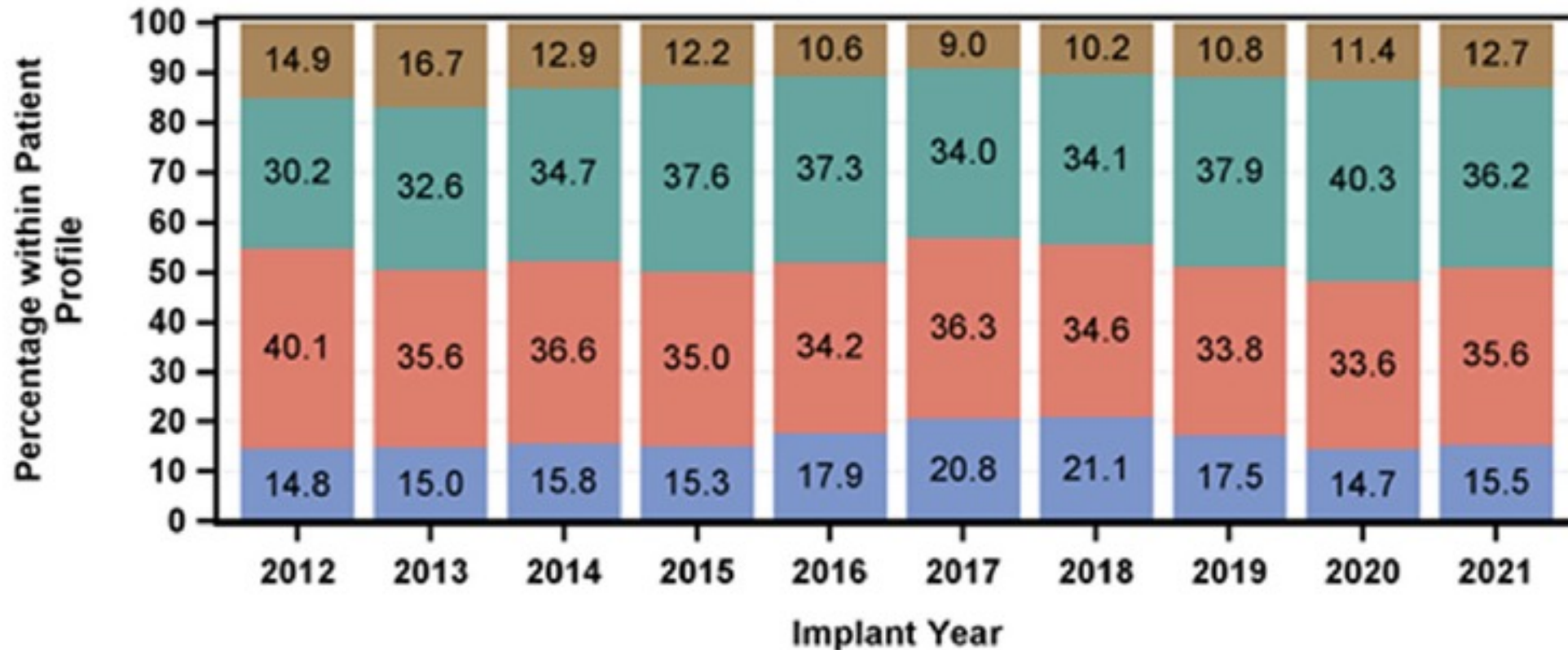
The Society of Thoracic Surgeons Intermacs 2022 Annual Report: Focus on the 2018 Heart Transplant Allocation System



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**Patient Profile for Primary CF LVAD (n=27,245)
Intermacs: January 1, 2012 - December 31, 2021**



Patient Profile

- 1. Critical Cardiogenic Shock
- 2. Progressive Decline
- 3. Stable but Inotrope Dependent
- 4. Resting Symptoms

Profiles 5-7 comprise <3% of implants and not depicted in this figure



STS InterMACs Patient Profiles

- Easily applied subjective assessment of patient status
- Needs uniformity in application for clinical use
- Develop protocol for consistent assessment including assessors and timing of assessment





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