End Stage Heart Failure

For St. Vincent's

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Advanced Heart Failure | Heart Transplantation | Mechanical Circulatory Support | Pulmonary Vascular Disease

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I have no conflicts of interest.

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Objectives

- Review of heart failure pathophysiology
- Review of chronic heart failure management
- Overview of advanced therapies
  - Mechanical Circulatory Support (LVAD)
  - Heart transplantation
  - (Palliative) inotropic support

Throughout, case illustrations!

Case 1 : Mr. R

- 61 M w/ history of coronary artery disease s/p CABG (2007)
- Dx'd with CHF due to ischemic cardiomyopathy (2007)
- Multiple PCIs since then, not amenable to further revascularization
- Echo: LVEF 15%, moderate MR; LVEDD 8.5 cm, mildly dilated RV, normal RV function
- Hx HTN, HLD, possible OSA

- Recently admitted for acute decompensated HF, diuresed with milrinone, could not be weaned.
- Discharged home on milrinone.

Case 1 : Mr. R

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Case 1 : Mr. R

- Very functional gentleman until functional decline recently
- So he was admitted from clinic for expedited evaluation

Case 1 : Mr. R

Diagnostic Tests

Routine Labs + 24 hr Cr Cl
T-Spot TB test
Chest Xrays / CT
Sinus Xrays / CT
CT Abdomen w/o contrast
Abdominal US/ CT w/contrast
Carotid Ultrasound
ABIs
Dexa Scan
Gastric Emptying Study
VQ Scan
24 Hour pH/ Esophageal Manometry
Barium Swallow
Colonoscopy

Consults

Transplant Education Class
VAD Education Class
Neuropsych Consult
Social Consult
Nutrition Consult
Pharmacy Consult
Dental Consult

Mammogram
OBGYN Consult

Case 1 : Mr. R

- Meanwhile… he underwent RHC which revealed:

  RA 15, PA 60/28/42, PW 35, PA sat 52%, FCI 1.78

- So, intra-aortic balloon pump was inserted and Swan-Ganz catheter was left in place for ongoing hemodynamic guidance
- Diuresis was augmented

Case 1 : Mr. R

Advanced therapy evaluation revealed some key elements:

- Pulmonary fibrosis lower lobes, scarring, pneumonitis? History of lung injury from occupational exposures
- 6' 4" with BMI 27, blood type O
- Adequate support system and commitment to therapy

Meanwhile, clinically:

- Hemodynamics have improved w/ IABP and diuresis (CVP is now single digits) with MVO2 ~55%
- But starting to have some ventricular ectopy…

Case 1 : Mr. R

Case was reviewed in our weekly multidisciplinary meeting:

- Transplant would be tough!
- But, his organ function is still quite good
- LVAD may his best option right now

Case 1 : Mr. R

- Mr. S underwent LVAD as destination therapy.

- One year later, he is alive and mostly well…
- Main problems:
  - Recurrent pleural effusion requiring VATS 6 mos. after implant
  - Occasional volume overload requiring IV diuresis
  - Syncopal event possibly related to dehydration
  - Migraines
  - Thoracotomy site infection requiring surgical debridement, wound vac, IV then oral antibiotics

Palliative inotropes

- Systematic Review and Meta-Analysis of 66 studies of long-term use of IV inotropes in outpatients with HF
- Pooled rates per 100 person-months:
  - Death 4.2
  - All-cause hospitalization 22.2
  - Central line infection 3.6
  - ICD shock 2.4
- Improvements in NYHA functional class were greater in patients on inotropes vs. controls
- No significant difference in mortality risk in patients on inotropes vs. controls

Nizamic T, Murad MH, Allen LA, McIlvennan CK, Wordingham SE, Matlock DD, Dunlay SM. Ambulatory Inotrope Infusions in Advanced Heart Failure: A Systematic Review and Meta-Analysis. JACC Heart Fail. 2018 Sep;6(9):757-767.

Palliative inotropes

Bottom line

- Long-term inotropes in outpatients with HF can improve quality of life but does not improve survival

- Higher quality evidence is needed because anecdotally, it might?

Nizamic T, Murad MH, Allen LA, McIlvennan CK, Wordingham SE, Matlock DD, Dunlay SM. Ambulatory Inotrope Infusions in Advanced Heart Failure: A Systematic Review and Meta-Analysis. JACC Heart Fail. 2018 Sep;6(9):757-767.

Heart Failure Pathophysiology

What happens after myocardial injury?

- Decrease in cardiac output
- Decrease in arterial pressure
- Increase in central venous pressure

Heart Failure Pathophysiology

Compensatory mechanisms

1. Sympathetic stimulation on the heart, peripheral vascular system
2. Renin-angiotensin-aldosterone activation
3. Cardiac remodeling

Short-term benefit in maintaining cardiac output, but not intended nor effective for chronic compensation

Guyton and Hall Textbook of Medical Physiology, Hall, John E. 2016.

Heart Failure Pathophysiology

Effect of sympathetic stimulation

- Arterial pressure is mediated acutely by nervous reflex mechanisms which adapt
- A primary purpose of the arterial baroreceptor system is to reduce the minute-by-minute variation in arterial pressure to about one third that which would occur if the baroreceptor system was not present

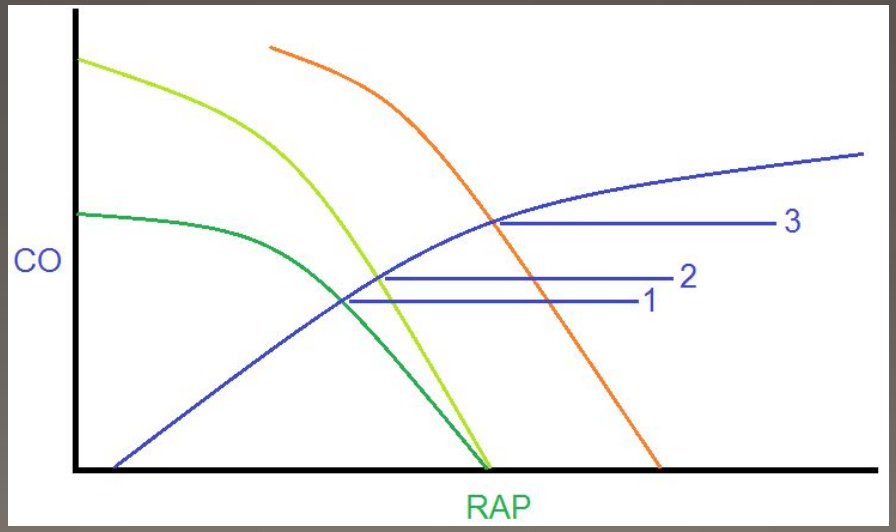
Guyton and Hall Textbook of Medical Physiology, Hall, John E. 2016.

Heart Failure Pathophysiology

Effect of RAAS activation

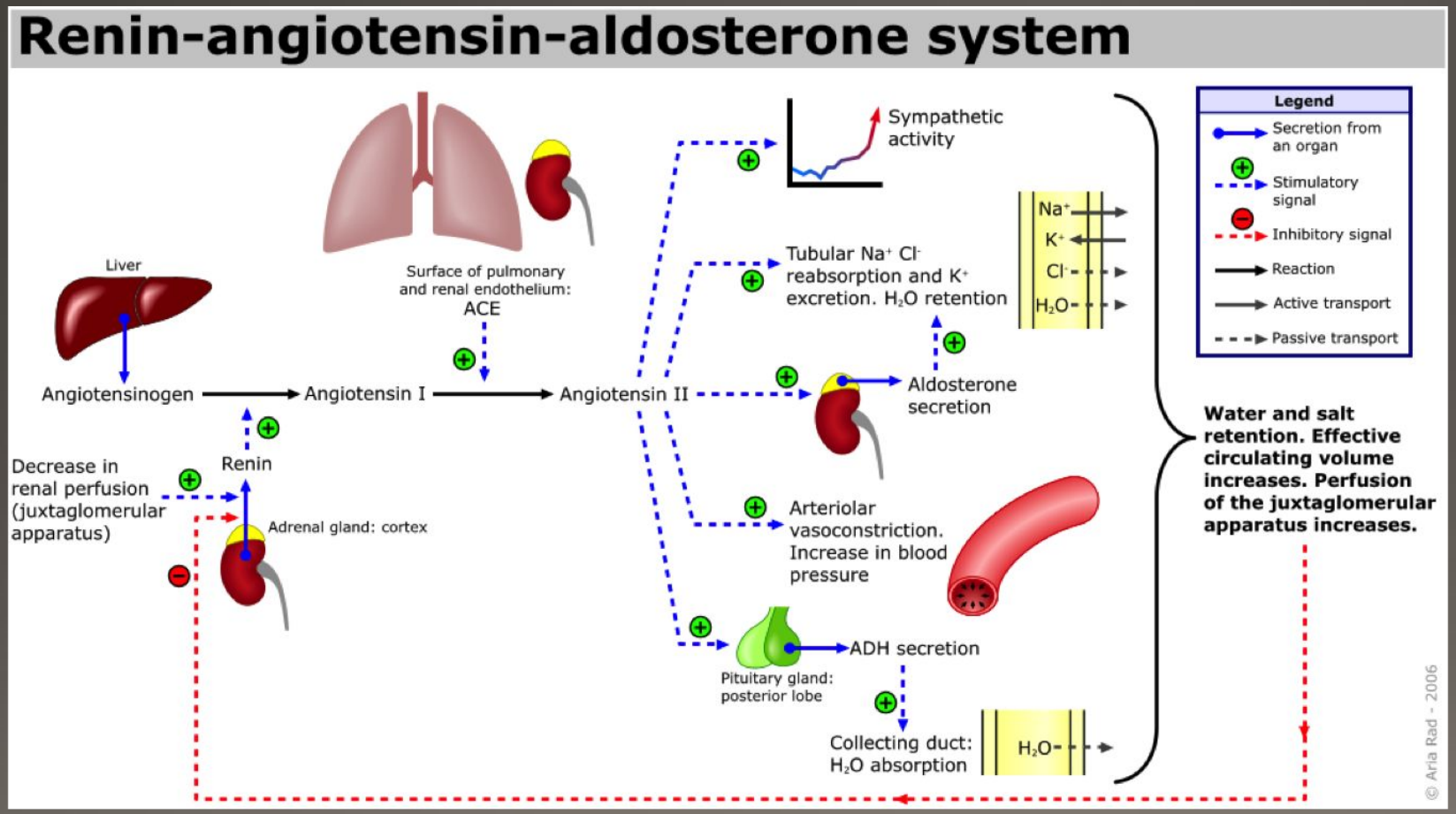
- Increases the mean circulatory filling pressure
- Distends the veins further reducing venous resistance

Both serve to increase venous return to the heart



Heart Failure Pathophysiology

Effect of RAAS activation



Heart Failure Pathophysiology

Compensatory mechanisms are imperfect

Arterial vasoconstriction improves blood pressure (perfusing pressure) but reduces cardiac output (increased afterload)

Fluid retention by the kidneys increases preload to increase stroke volume, but simultaneously increases venous pressure and congestive symptoms

Comprehensive Physiology. A modern view of heart failure: practical applications of cardiovascular physiology. Katz AM. 2011.

Heart Failure Pathophysiology

Medication effects compete

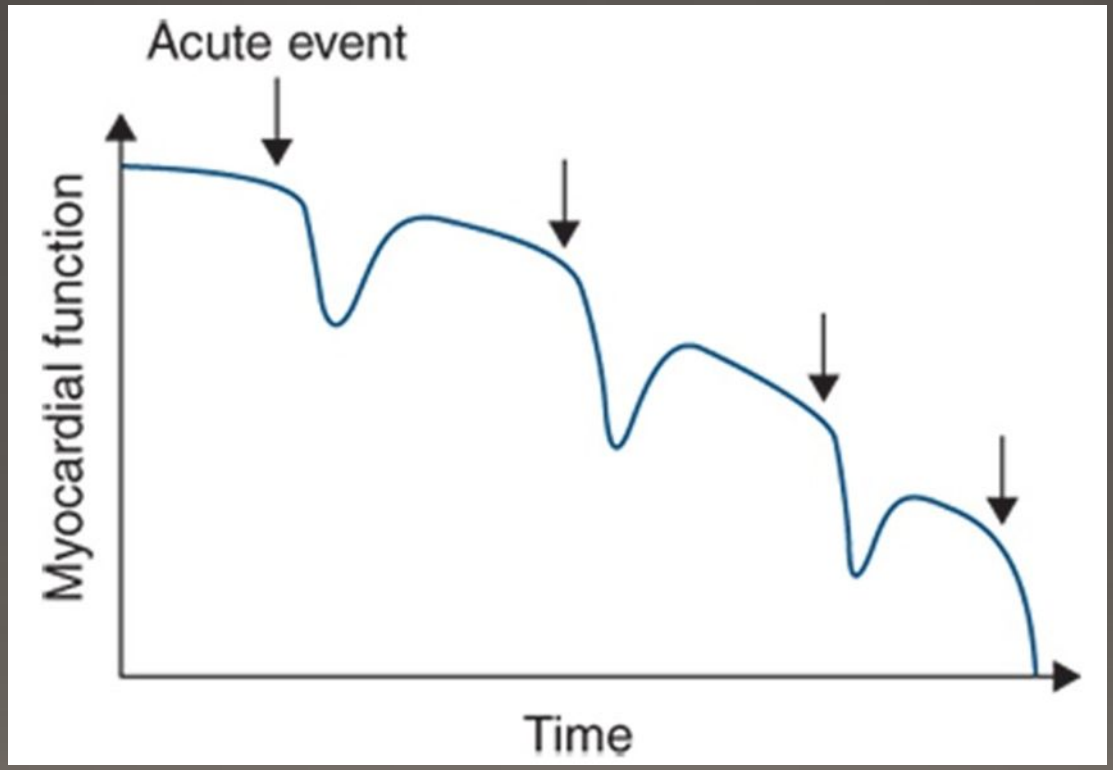
Diuretics can relieve increased venous pressure at the expense of preload and worsened cardiac output

Conversely, the beneficial effect of diuretics is that they reduce end-diastolic volume which decreases wall stress which decreases energy expenditure

Comprehensive Physiology. A modern view of heart failure: practical applications of cardiovascular physiology. Katz AM. 2011.

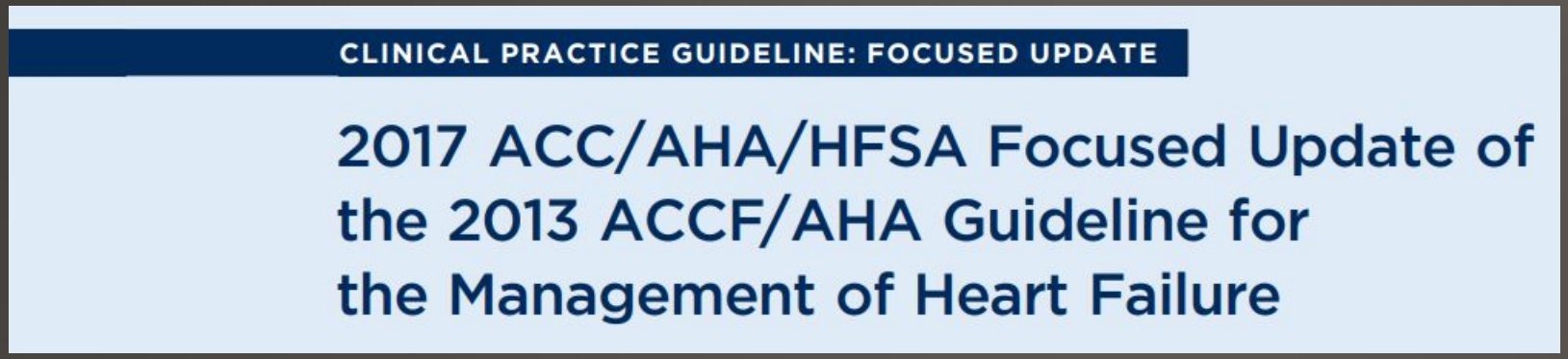
Guyton and Hall Textbook of Medical Physiology, Hall, John E. 2016.

Heart Failure Pathophysiology



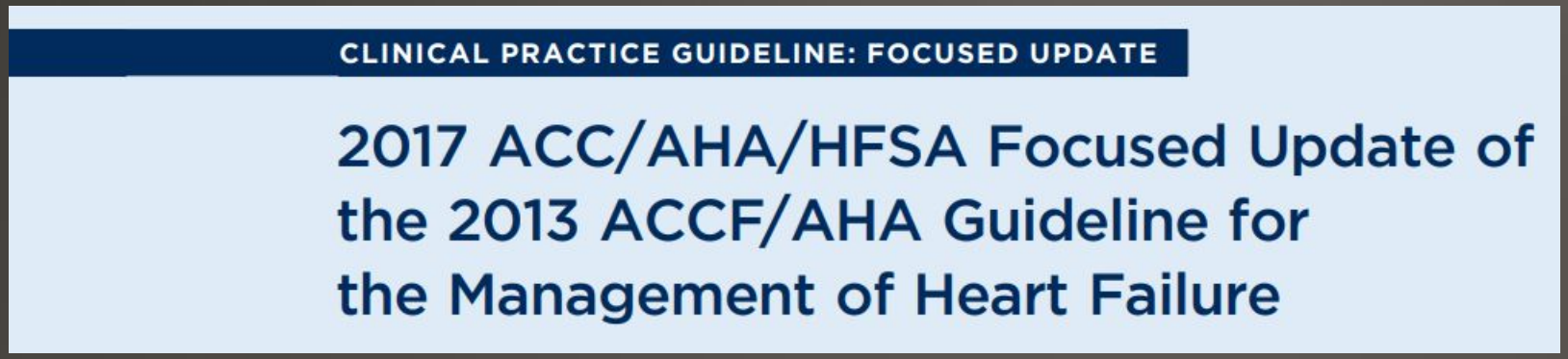
Gheorghiade M, De Luca L, Fonarow GC, et al: Pathophysiologic targets in the early phase of acute heart failure syndromes. Am J Cardiol. 2005 Sep 19;96(6A):11G-17G.

Chronic Heart Failure Management



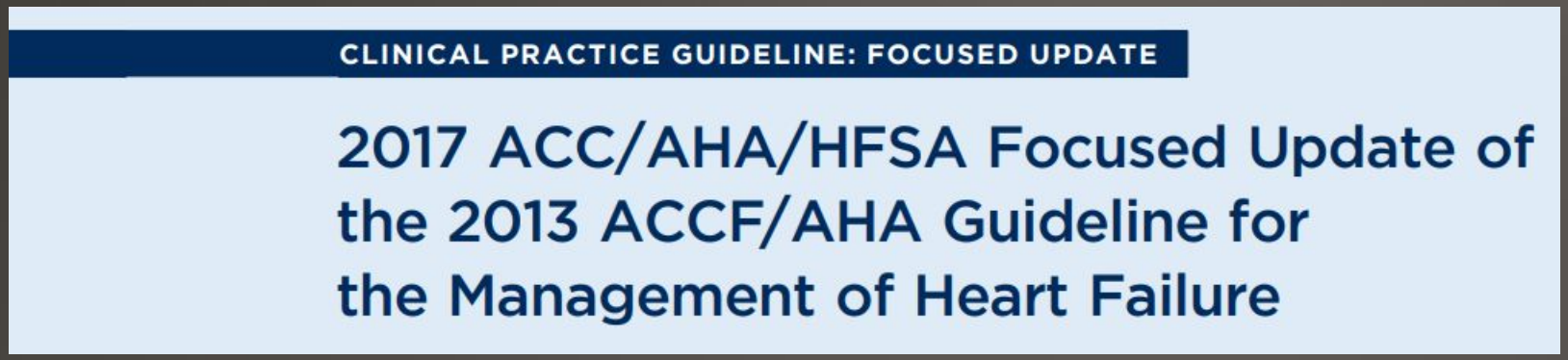
- Remember! ACEi, ARB, or ARNI reduce morbidity and mortality in conjunction with Bblocker and aldosterone antagonist
- Consider switching ACEi/ARB to ARNI for patients tolerating it, who still have NYHA class II or III symptoms
- Let 36 hrs lapse before ARNI, do not give ARNI to patients with history of angioedema

Chronic Heart Failure Management



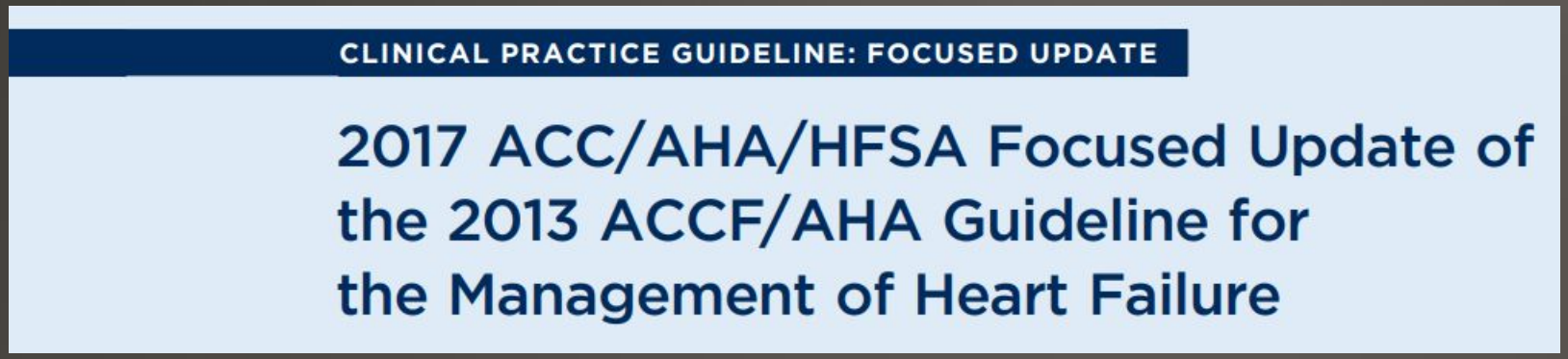
- Consider ivabridine to reduce hospitalizations for patients who have NYHA II or III symptoms, are on maximally tolerated Bblocker, in NSR with HR ≥70 bpm
- Diuretics as needed
- Hydralazine/ Nitrates for black patients with NHYA class III-IV symptoms (after Bblocker and RAAS inhibition)

Chronic Heart Failure Management



- Don't forget ICD as primary prophylaxis for patients with LVEF ≤35% and NYHA class II-III symptoms (must have >1 year life expectancy and be >40 days post-MI)
- Don't forget CRT-D for patients with LVEF ≤35% and NYHA class II-IV symptoms, NSR, LBBB (QRS ≥150 msec)

Chronic Heart Failure Management



- Improved? □ Keep following, optimizing therapy
- Refractory symptoms?

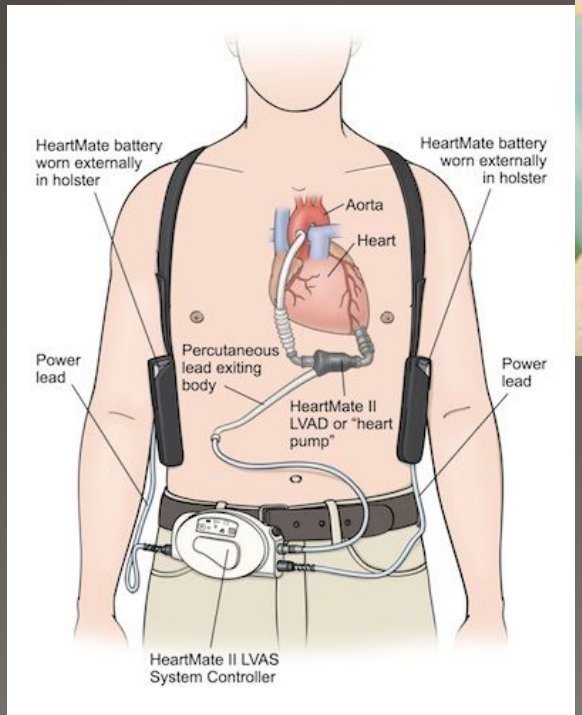
Refractory Symptoms

- Functional decline, worsening symptoms
- ICD shocks or syncope
- Dose reduction/ discontinuation of GDMT
- End-organ dysfunction
- Refractory angina
- Refractory, life-threatening arrhythmia
- Inotrope-dependence
- Change in hospitalization pattern

- Consider referral to UAB Advanced Heart Failure Clinic

Advanced Therapies

- Palliative Care
  - Home inotropic support
- LVAD
- Heart Transplantation



Pictures from Google

Palliative Care

- Illness burden and palliative care needs comparable to patients with cancer, but not offered consistently
- Not either/ or!
- Barriers:
  - Unpredictable trajectory of heart failure
  - Gradual illness can encourage denial
  - Lack of communication skills/ re: prognosis
  - No one tool to assess palliative care needs
  - Missing data, lack of gold standard in literature
  - Demand exceeds supply?

Remawi, B.N., Gadoud, A., Murphy, I.M.J. *et al.* Palliative care needs-assessment and measurement tools used in patients with heart failure: a systematic mixed-studies review with narrative synthesis. *Heart Fail Rev* (2020).

Case 2 : Ms. Q

- 29 F w/ history of poorly controlled type I DM (neuropathy, retinopathy? HgbA1c 14 last year), hypothyroidism, presented to the hospital with 1 week lower extremity swelling and increased dyspnea
- Currently 27 weeks pregnant
- During last pregnancy 2 years ago, developed pre-eclampsia and was delivered by c-section
- Echo revealed biventricular failure, LVEF 15% (new diagnosis)

Case 2 : Ms. Q

- Despite diuresis attempts, she devolves into cardiogenic shock: elevated lactate, worsening AKI
- She was transferred to ICU and PA catheter was placed which revealed PA sat 27%, calculating to Fick CI 1.2
- Dobutamine was initiated for inotropic support
- Hemodynamics improved (PA sat 63%, Fick CI 2.4), UOP improved
- Multidisciplinary decision (Cardiology, OB, Anesthesia, CV Surgery) to proceed with planned c-section in OR with femoral sheaths in place should VA ECMO be needed

Case 2 : Ms. Q

- Meanwhile… uptitrating hydralazine for afterload reduction (no Bblocker when on dobutamine)
- Dobutamine also increased for worsening hemodynamics
- Lasix gtt initiated for volume management
- Nitroglycerin gtt initiated for afterload reduction
- C-section performed successfully at 28 weeks, baby premature, transferred to NICU
- Ms. Q came back to ICU feeling okay, still on dobutamine, epi, levo
- Became more hypotensive, MVO_2 down to 27%

Case 2 : Ms. Q

- She was rushed to cath lab for IABP placement, but due to tenuous hemodynamics, she required cannulation for VA ECMO as well
- Coronary angiogram was also performed and was normal
- With ECMO support, her vital signs stabilized, MVO_2 and urine output improved

Case 2 : Ms. Q

- Over the next few days, there was little improvement in LV function
- She became somewhat altered briefly, but this resolved
- She was empirically started on anticoagulation and antibiotics, and was continued on diuretic, insulin, nitroglycerin, and dobutamine gtt
- Since LV function was not recovering and ECMO was unable to be weaned, an (abbreviated!!) advanced therapy evaluation was begun

Case 2 : Ms. Q

- Unfortunately, due to poorly controlled diabetes with complications she was not a transplant candidate
- She was however determined to be a suitable VAD candidate
- Meanwhile, she was able to ambulate 400 feet (**with** ECMO cannulas in place)
- Despite not being able to see her baby, she was motivated to get the VAD so she can begin recovery and return to independence

Case 2 : Ms. Q

- Post-op, she did very well and was discharged from the hospital 10 days after LVAD implant
- 6 weeks after discharge she underwent repeat Echo which still shows no significant myocardial recovery
- We continue to uptitrate guideline-directed medical therapy for HF including Bblocker, ACEi, aldosterone antagonist
- She has been briefly hospitalized since discharge for driveline infection

Case 2 : Ms. Q

- 3 mos. later her baby is doing well and finally home
- At her most recent visit, she is NYHA class I and doing well, no new complications

"Destination" vs. "Bridge"

- LVADs can be implanted as either destination therapy OR bridge to transplant
  - Irreversible contraindications to transplant
  - No contraindication to transplant (but too sick to wait)
  - Current but possible reversible condition barring transplant

LVAD Complications

Hemocompatibility

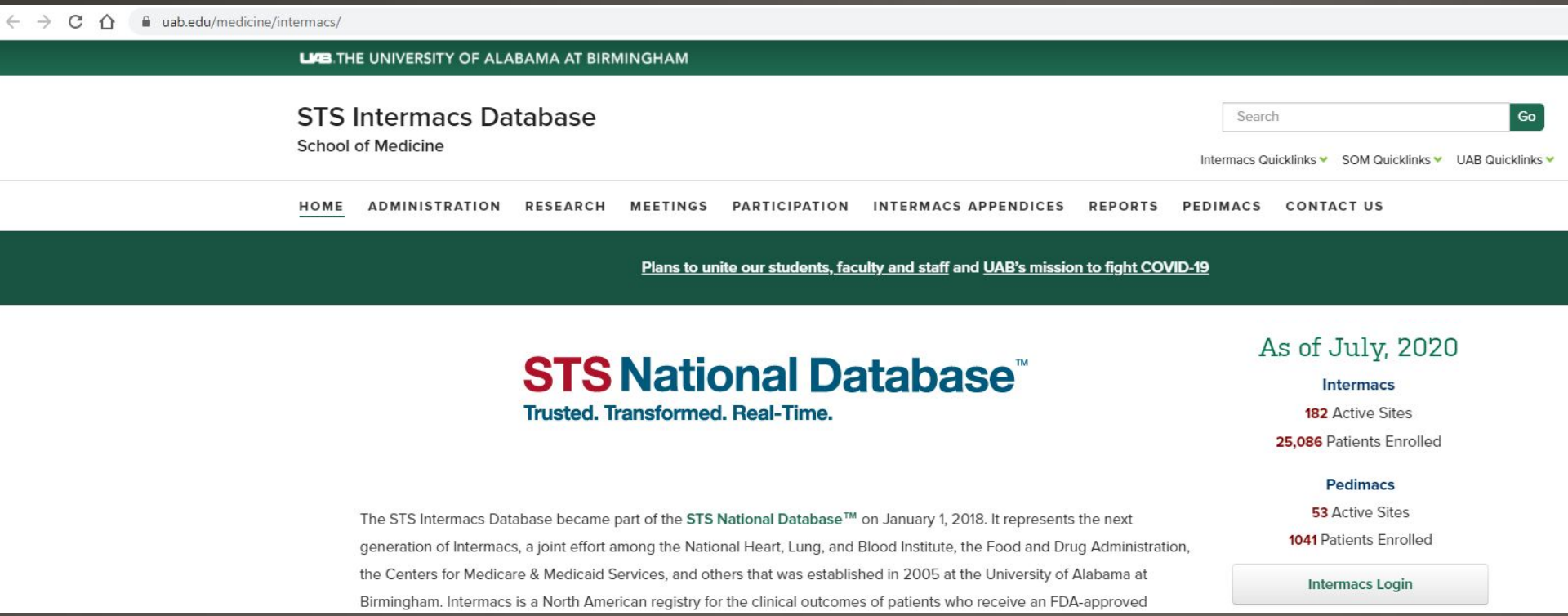
- Stroke (ischemic) or intracranial hemorrhage
- Pump thrombosis
- GI bleed, other excessive bleeding

- Device-related infection
  - Driveline site
  - Thoracotomy site, sternal wound
  - Bacteremia (VAD endocarditis)
- Device malfunction

Intermacs Database

- Established in 2005 here at the University of Alabama at Birmingham as a North American registry to record and report clinical outcomes on patients who receive FDA-approved mechanical circulatory support to treat advanced heart failure
- Became part of the Society of Thoracic Surgeons in 2018, now a joint effort among the NHLBI, the FDA, and the CMMS.

Intermacs Database



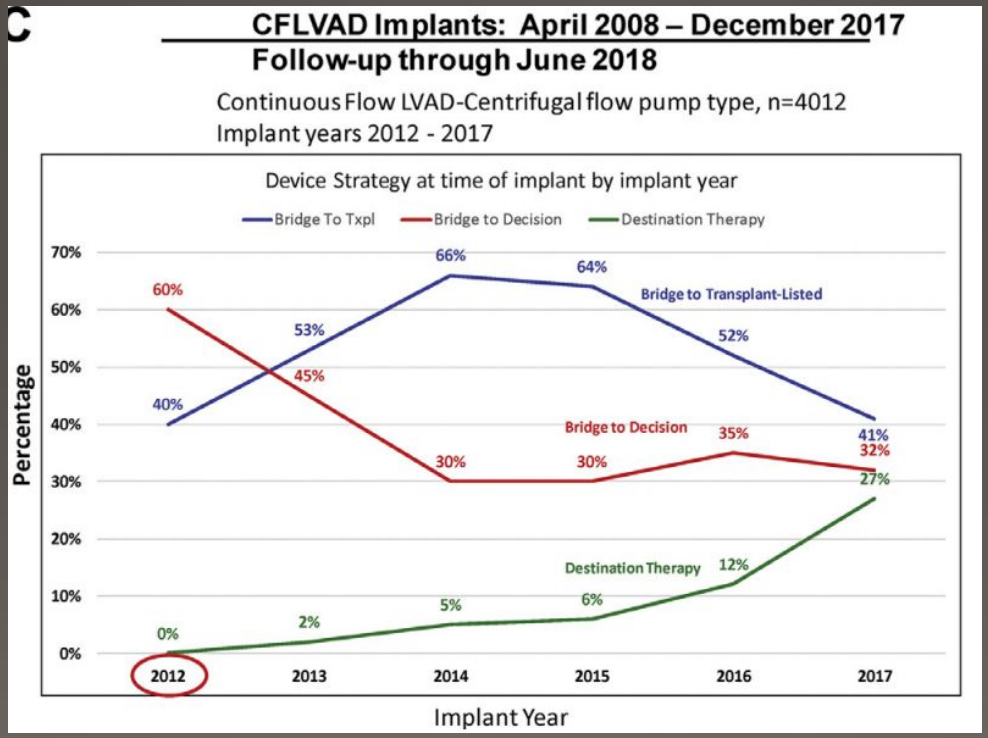
Intermacs Database

- Includes 18,500+ patients implanted with LVAD between 2006 – 2017
- 51% were in cardiogenic shock pre-op
- 1 year survival is 83%, 5 year survival 46%
- Much lower survival rates for those who require concomitant RVAD support
- Only 20% made it through the first year without readmission to the hospital for any reason

Kormos RL, Cowger J, Pagani FD, Teuteberg JJ, Goldstein DJ, Jacobs JP, Higgins RS, Stevenson LW, Stehlik J, Atluri P, Grady KL, Kirklin JK. The Society of Thoracic Surgeons Intermacs database annual report: Evolving indications, outcomes, and scientific partnerships. J Heart Lung Transplant. 2019 Feb;38(2):114-126.

Intermacs Database

- Increasingly more LVADs are implanted as destination therapy (now 48%)



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Intermacs Database

- At 1 year,
  - Stroke – 13-20% patients
  - GI bleed – 20-25% patients
  - VAD-related infection – 25-28% patients

- How do VAD patients die?
  - 19% neurologic dysfunction
  - 15% multisystem organ dysfunction

Kormos RL, Cowger J, Pagani FD, Teuteberg JJ, Goldstein DJ, Jacobs JP, Higgins RS, Stevenson LW, Stehlik J, Atluri P, Grady KL, Kirklin JK. The Society of Thoracic Surgeons Intermacs database annual report: Evolving indications, outcomes, and scientific partnerships. J Heart Lung Transplant. 2019 Feb;38(2):114-126.

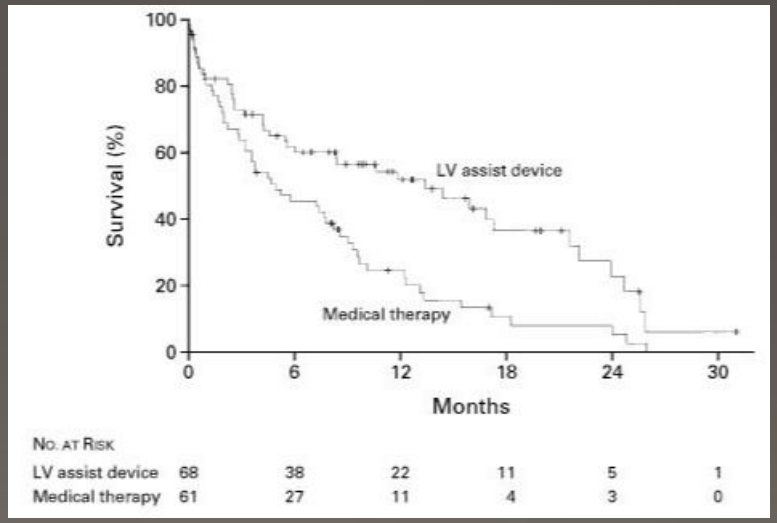
Why LVAD?

- 129 patients with end-stage heart failure, ineligible for heart transplant, randomized to receive either optimal medical therapy or LVAD
- Quality of life significantly improved in the patients with LVAD

Rose EA, Gelijns AC, Moskowitz AJ, Heitjan DF, Stevenson LW, Dembitsky W, Long JW, Ascheim DD, Tierney AR, Levitan RG, Watson JT, Meier P, Ronan NS, Shapiro PA, Lazar RM, Miller LW, Gupta L, Frazier OH, Desvigne-Nickens P, Oz MC, Poirier VL; Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term use of a left ventricular assist device for end-stage heart failure. N Engl J Med. 2001 Nov 15;345(20):1435-43.

Why LVAD?

- Reduction of 48% in the risk of death from any cause in the group who received the LVAD
- Survival at 1 year: 52% in patients with LVAD vs. 25% in patients with medical therapy alone



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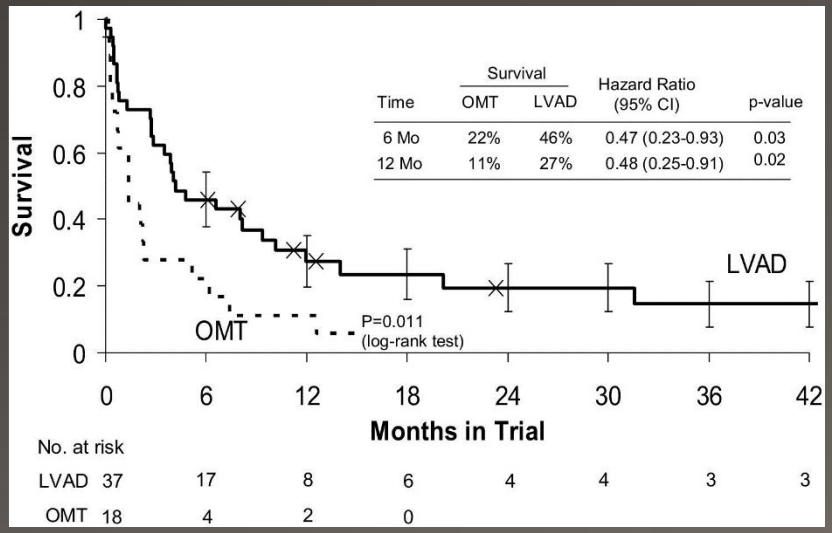
Why LVAD?

- 55 patients who were inotrope-dependent (failed wean) but not eligible for heart transplant offered LVAD
- LVAD treated patients had superior survival rates at 6 mos. (46% vs. 22%) and 1 year (27% vs. 11%)

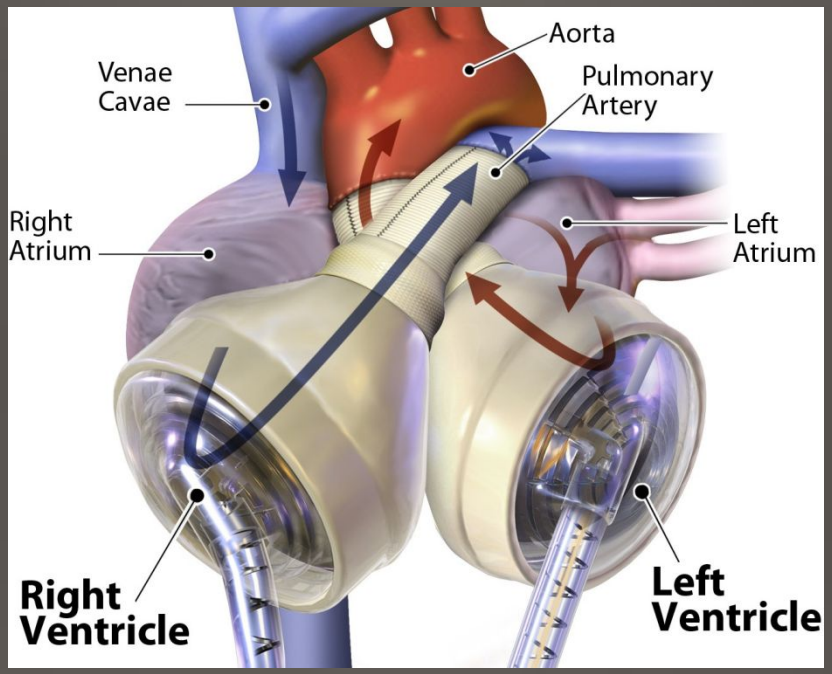


Rogers JG, Butler J, Lansman SL, Gass A, Portner PM, Pasque MK, Pierson RN 3rd; INTrEPID Investigators. Chronic mechanical circulatory support for inotrope-dependent heart failure patients who are not transplant candidates: results of the INTrEPID Trial. J Am Coll Cardiol. 2007 Aug 21;50(8):741-7.

Case 3 : Mr. A

- 33 M transferred from a community hospital in cardiogenic shock, no significant past medical history
- Quit tobacco and marijuana 6 mos. earlier
- Evaluated and determined to be a good candidate for advanced therapies, but he was tall, big, blood type O
- Native heart had poor anatomy for LVAD alone

Case 3 : Mr. A



- 10 days after transfer, and due to impending circulatory collapse, he underwent total artificial heart (TAH) as bridge to transplant
- Listed status 2

Case 3 : Mr. A

- While hospitalized with the TAH, he recovered enough to ambulate
- We treated malnutrition and depression, as well as acute kidney injury, possibly related to shear stress/ hemolysis vs. sepsis, all of which improved
- He also suffered a possible TIA, manifested by brief word-finding difficulties/ dysarthria which also resolved

Case 3 : Mr. A

- 2 mos. after TAH, donor organ became available and he underwent transplant
- Post-op he was treated with IV antibiotics for 6 weeks due to mediastinal pus noted around TAH at the time of transplant
- He was discharged home 3 weeks after heart transplant

Case 3 : Mr. A

Post-transplant issues:

- Early post-op, biopsies revealed 2 episodes of acute cellular rejection, treated successfully with pulse steroids
- Pseudoaneurysm of aortic arch/ descending aorta, s/p TEVAR by aorta surgeon 3 mos. after transplant
- Mild CKD, baseline Cr now 1.5
- Mild left 5th digit numbness, possible ulnar neuropathy from OR positioning?
- Depression, malnutrition much improved

Case 3 : Mr. A

- One year later, he still feels great and is active
- Unfortunately he admits to occasionally skipping doses of tacrolimus, which has led to another acute cellular rejection on most recent biopsy
- Thankfully, biventricular allograft function is still normal

Heart Transplant – History

- Dr. Christiaan Barnard performed the first heart transplant in South Africa 50 years ago (December 3, 1967)

Figure 10. Louis Washkansky as a patient in Groote Schuur Hospital (with Barnard after the heart transplant).

Figure 11. Denise Darvall, the first heart donor.

Cooper DKC. Christiaan Barnard-The surgeon who dared: The story of the first human-to-human heart transplant. Glob Cardiol Sci Pract. 2018;2018(2):11. /

Heart Transplant – History

- Mr. Washansky died after 18 days, apparently from pneumonia, no evidence of rejection or surgical failure

Cooper DKC. Christiaan Barnard-The surgeon who dared: The story of the first human-to-human heart transplant. Glob Cardiol Sci Pract. 2018;2018(2):11. /

Heart Transplant – History

- Discovery of cyclosporine and its efficacy at preventing allograft rejection in the 1970s added another class of agents to our immunosuppression arsenal: calcineurin inhibitors

- Use of cyclosporine significantly improved life expectancy first in kidney transplant recipients, then in heart transplant recipients

- Heart transplant remains definitive therapy for end-stage heart failure

Heart Transplant – Now

- Approximately 5000 transplants performed each year worldwide
- According to ISHLT, median survival is currently 12.2 years
- Survival rates have progressively improved despite older donors, and older and sicker recipients

Previato M, Osto E, Kerkhof PLM, Parry G, Tona F. Heart Transplantation Survival and Sex-Related Differences. Adv Exp Med Biol. 2018;1065:379-388.

Heart Transplant

Challenges

- Limited donor pool
  - Waitlist mortality
- Allograft rejection
  - Greatest risk in first 6 mos.
- Immunosuppression
  - Side effects of calcineurin inhibitors
- Cardiac allograft vasculopathy
  - Dissimilar to native atherosclerosis

Shah, K.S., Kittleson, M.M. & Kobashigawa, J.A. Updates on Heart Transplantation. Curr Heart Fail Rep 16, 150–156 (2019).

Heart Transplant

An Evolving Field

- Greater emphasis on equity
- Expanding the donor pool: hepatitis C + donors, older age
- Advancements in our ability to detect rejection, allograft vasculopathy
- Personalized/ precision care to guide individualized immunosuppression regimens

Shah, K.S., Kittleson, M.M. & Kobashigawa, J.A. Updates on Heart Transplantation. Curr Heart Fail Rep 16, 150–156 (2019).

Heart Transplant

- In an effort to reduce waitlist mortality, a number of modifications to the US adult donor heart allocation system went into effect October 2018

Criteria Requirements in Adult Heart Allocation Policy

See policy for extensive criteria requirements

Status	Criteria	Admitted to hospital that registered candidate	Cardiogenic Shock	Primary Mechanical Circulatory Support Devices: VA ECMO	Discharge-able VAD	Non-Discharge-able VAD	Percu-taneous Device	TAH	IABP	Requires time spent at previous status	Use of Inotropes	V-Tach or V-Fib	Eligible for extension
Status 1	VA ECMO	*	*	*									RRB
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	*				*							Y
	MCSD with life threatening ventricular arrhythmia	*		*	*	*	*	*	*			*	Y
Status 2	Non-dischargeable, surgically implanted, non-endovascular left ventricular support device (LVAD)	*				*							RRB
	TAH, BiVAD, RVAD, or VAD for single ventricle patients				*	*		*					Y
	MCSD with malfunction	*		*	*	*	*	*	*				Y
	Percutaneous endovascular MCSD	*	*				*						RRB
	Intra-Aortic Balloon Pump (IABP)	*	*						*				RRB
	Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)	*										*	Y
Status 3	Dischargeable LVAD for discretionary 30 days				*								N
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	*	*								*		Y
	MCSD with Hemolysis			*	*	*	*	*	*				Y
	MCSD with Pump Thrombosis			*	*	*	*	*	*				Y
	MCSD with Right Heart Failure			*	*	*	*	*	*		*		Y
	MCSD with Device Infection			*	*	*	*	*	*				Y
	MCSD with Mucosal Bleeding	*		*	*	*	*	*	*				Y
	MCSD with Aortic Insufficiency (AI)			*	*	*	*	*	*				Y
	VA ECMO after 7 Days	*		*						*			Y
	Non-dischargeable, surgically implanted, non-endovascular LVAD after 14 Days	*				*				*			Y
	Percutaneous Endovascular Circulatory Support Device after 14 Days	*					*			*			Y
	IABP after 14 Days	*							*	*			Y
Status 4	Dischargeable LVAD without discretionary 30 days				*								Y
	Inotropes without Hemodynamic Monitoring										*		Y
	Congenital Heart Disease												Y
	Ischemic Heart Disease with Intractable Angina												Y
	Amyloidosis, or Hypertrophic or Restrictive Cardiomyopathy												Y
	Heart Re-transplant												Y
Status 5	On the Waitlist for at least one other organ at the same hospital												Y
Status 6	Adult Candidate Suitable for Transplant												Y

https://optn.transplant.hrsa.gov/

Heart Transplant

In summary:

- Expanded statuses (previously 4, now 1 through 7) to prioritize sicker patients/ those requiring more support above less sick ones

- Expanded the region from which donor hearts could be matched to waiting patients to prioritize sicker patients above less sick ones

Heart Transplant

In summary:

- Expanded statuses (previously 4, now 1 through 7) to prioritize sicker patients/ those requiring more support above less sick ones

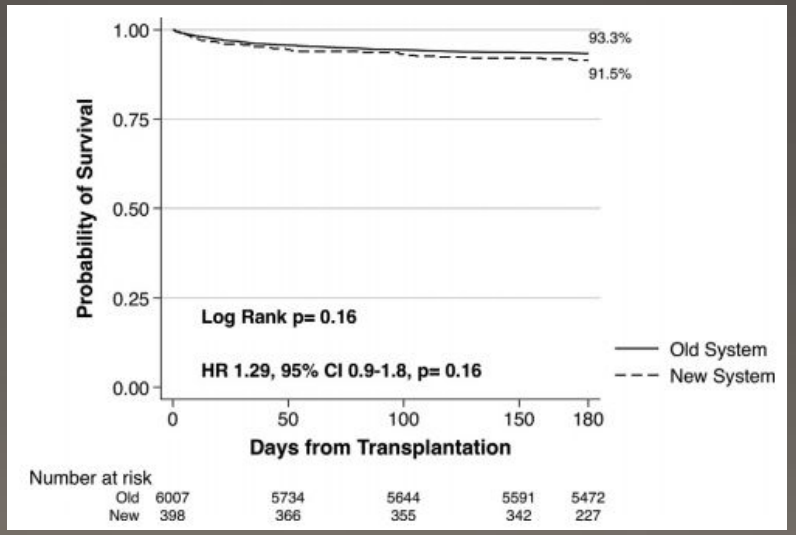
? Even if it means patients may do worse because they are sicker?

- Expanded the region from which donor hearts could be matched to waiting patients to prioritize sicker patients above less sick ones

? Even if it means longer ischemic time which may impact organ function?

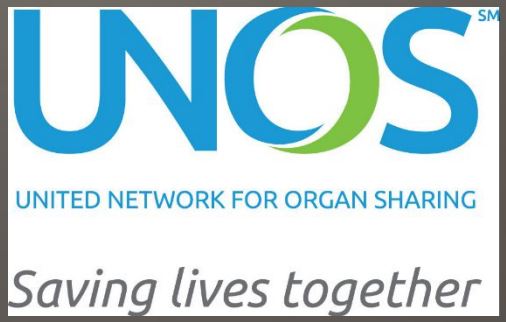
Heart Transplant

- Data from the United Network for Organ Sharing (UNOS) registry suggests 180-day survival has remained stable in new system: 91.5%, vs. 93.3%
- A similar, significant decrease was noted in waitlist mortality from 3.9% to 2.3% (p=0.002) associated with new allocation system



Hanff TC, Harhay MO, Kimmel SE, Birati EY, Acker MA. Update to an early investigation of outcomes with the new 2018 donor heart allocation system in the United States. J Heart Lung Transplant. 2020 Jul;39(7):725-726.

Heart Transplant



- The new allocation system will continue to be reviewed carefully, and perhaps modified in the future
- "A lifesaving transplant for everyone in need"

https://unos.org/about/mission-values/

Objectives

- Review of heart failure pathophysiology
- Review of chronic heart failure management
- Overview of advanced therapies
  - Mechanical Circulatory Support (LVAD)
  - Heart transplantation
  - (Palliative) inotropic support

Throughout, case illustrations!

Happy to take questions!

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Advanced Heart Failure | Heart Transplantation | Mechanical Circulatory Support | Pulmonary Vascular Disease

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