Heart Failure and Hospitalization

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Outline

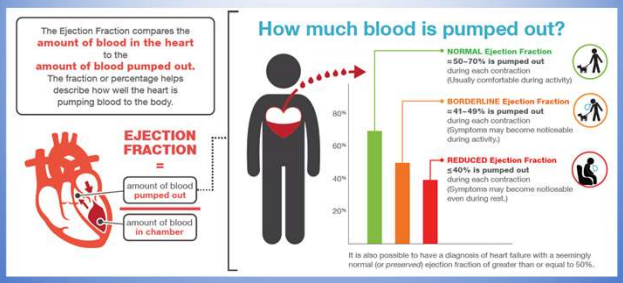
- Scope of the Problem
- Identifying High Risk Patients
- Current Treatments
- Future of Heart Failure Management

What is heart failure?

- **Heart failure** is a clinical entity of *findings and symptoms* which stems from the body's inability to pump enough blood to meet the need for circulation of oxygen and nutrients

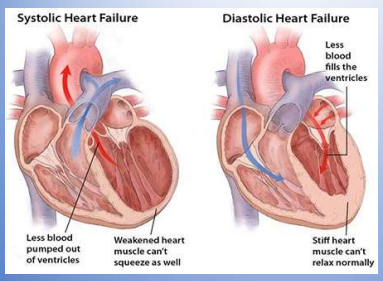
- **Symptoms** can include:
  - Shortness of breath
  - Chest pain
  - Difficulty lying flat (orthopnea), waking up from sleep due to shortness of breath (paroxysmal nocturnal dyspnea)
  - Fluid retention→ Abdominal bloating and Leg swelling
  - Poor appetite and weight loss

What is heart failure?



www.RiseAboveHF.org

What is heart failure?



- **Systolic Heart Failure**
  - Acute MI or Coronary Artery Disease
  - Arrhythmia
  - Hypertension
  - Alcohol Use
  - Genetic Abnormalities
- **Diastolic Heart Failure**
  - Hypertension
  - Diabetes
  - Kidney disease
  - Genetic Abnormalities

https://www.cardiologistmidtownnyc.com/conditions/heart-failure-cardiomyopathy-enlarged-heart/

Scope of the Problem

- Recent data report there are approximately 6.5 million people in the U.S. >20 years of age living with heart failure
- Projections show this will increase 46% from 2012 to 2030 resulting in nearly >8 million people with heart failure
- There are nearly 1 million hospitalizations per year where heart failure is the *primary* diagnosis
- In 2012 there were an estimated $30.7 billion in costs for HF with an projected rise of 127% by 2030 to $69.7 billion

Temporal Trends in the Age-Adjusted Incidence of Heart Failure

Period	Men		Women	
	Incidence of heart failure rate/100,000 person-yr	Rate ratio	Incidence of heart failure rate/100,000 person-yr	Rate ratio
1950–1969†	627 (475–779)	1.00	420 (336–504)	1.00
1970–1979	563 (437–689)	0.87 (0.67–1.14)	311 (249–373)	0.63 (0.47–0.84)
1980–1989	536 (448–623)	0.87 (0.67–1.13)	298 (247–350)	0.60 (0.45–0.79)
1990–1999	564 (463–665)	0.93 (0.71–1.23)	327 (266–388)	0.69 (0.51–0.93)

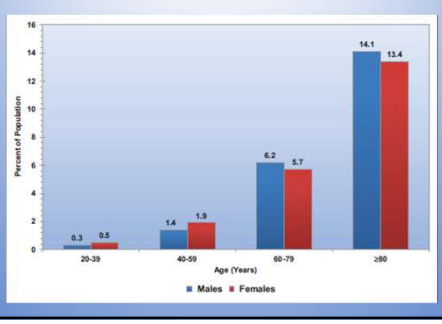
Levy D et al. NEJM. 2002;347:18

	1979-1984	1985-1990	1991-1995	1996-2000
Men				
Incidence per 100 000 (95% CI)	360 (323-396)	390 (354-425)	375 (340-409)	383 (351-415)
RR (95% CI)	1.00	1.07 (0.94-1.22)	1.01 (0.88-1.15)	1.04 (0.92-1.18)
Women				
Incidence per 100 000 (95% CI)	284 (260-307)	292 (270-315)	260 (238-282)	315 (292-338)
RR (95% CI)	1.00	1.04 (0.93-1.16)	0.93 (0.83-1.05)	1.11 (1.00-1.24)

Abbreviations: CI, confidence interval; RR, relative risk.

JAMA 2004; 292:344-350

Prevalence of Heart Failure for Adults >20 years



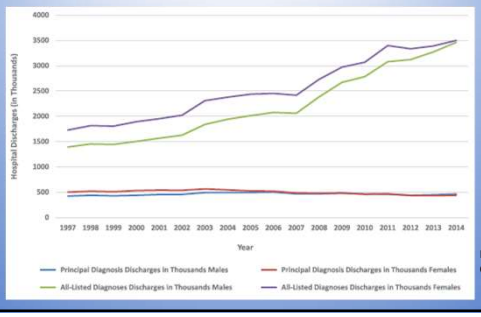
Benjamin et al, Circulation 2018.

Heart Failure Prevalence

Sex	Year									
	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Female	86 450 (86.3)	94 726 (94.0)	101 024 (100.4)	105 932 (105.6)	109 381 (109.7)	111 230 (112.4)	113 068 (114.4)	114 593 (114.4)	116 732 (114.6)	118 485 (115.1)
Male	53 390 (95.4)	58 456 (103.7)	62 520 (110.4)	66 309 (117.1)	68 942 (122.6)	70 465 (125.6)	72 133 (127.9)	74 177 (128.3)	76 376 (128.2)	78 709 (129.2)
Total	**139 840** (89.9)	**153 182** (97.9)	**163 544** (104.4)	**172 241** (110.3)	178 323 (114.9)	**181 695** (117.8)	**185 201** (119.9)	**188 770** (120.1)	**193 108** (120.2)	**197 194** (121.0)

Curtis L, et al. Arch Int Med. 2008. 168:418-424

Hospital Discharges for Heart Failure by Sex



Benjamin et al, Circulation 2018.

Heart Failure Hospitalization Rates

Table 2. Heart Failure Hospitalization Rates, 1998-2008[a]

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Person-years	36 983 186	36 161 066	36 442 269	27 309 540	27 960 936	28 455 641	28 793 264	29 773 682	28 070 367	27 505 603	27 297 535
HF hospitalization rate per 100 000 person-years	2845	2656	2612	2542	2466	2496	2459	2333	2229	2116	1997
No. unique HF patients per 100 000 person-years	2014	1935	1933	1906	1833	1851	1815	1724	1631	1533	1462
Observed HF hospitalization rate per 100 000 person-years											
Age, y											
65-74	1783	1614	1564	1514	1468	1462	1416	1328	1229	1145	1026
75-84	3582	3294	3203	3121	3027	3065	3027	2859	2717	2586	2403
≥85	5748	5453	5406	5297	5192	5272	5255	5081	4899	4757	4519
Male	2944	2716	2624	2565	2509	2548	2536	2437	2324	2212	2055
Female	2776	2613	2603	2527	2439	2451	2402	2250	2149	2046	1953
White race	2749	2555	2505	2435	2361	2390	2356	2226	2121	2024	1878
White male	2882	2650	2598	2493	2434	2472	2465	2356	2251	2146	2000
White female	2656	2490	2474	2395	2310	2330	2277	2132	2026	1933	1786
Black race	4311	4124	4005	3969	3938	3940	3885	3757	3669	3503	3209
Black male	4142	3909	3727	3749	3701	3706	3772	3759	3635	3451	3201
Black female	4410	4235	4172	4103	4004	4049	3955	3905	3691	3537	3215
Other race[b]	2187	2177	2215	2129	2067	2053	1980	1987	1753	1627	1470
Other-race male	2280	2212	2192	2095	2090	2073	2017	1939	1781	1672	1492
Other-race female	2138	2154	2231	2154	2049	2039	1953	1948	1731	1593	1454
Risk-adjusted HF hospitalization rate per 100 000 person-years[c]	2845	2752	2697	2622	2542	2566	2525	2362	2272	2163	2007

Chen J, et al. JAMA 2011;306:1669-1678

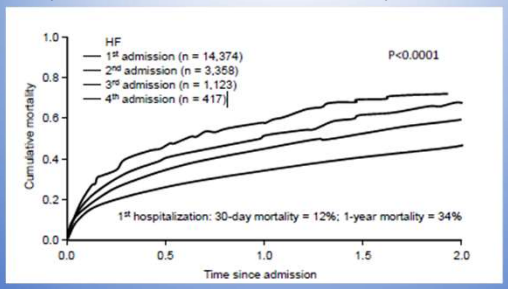
Why should we care about hospitalization?

Table 3. One-Year Mortality Rates After Heart Failure Hospitalization, 1999-2008[a]

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
HF hospitalizations, No.	506 234	511 176	513 158	513 205	526 617	521 486	495 929	457 777	421 764	398 953
Overall rate, %	31.7	31.4	31.9	31.2	31.1	30.6	30.7	30.7	31.7	32.0
Rate by age, %										
65-74 y	23.6	23.4	23.4	22.5	22.4	21.7	21.4	20.9	21.7	22.0
75-84 y	31.1	30.5	31.1	30.5	30.1	29.6	29.3	29.1	30.1	30.3
≥85 y	42.3	42.4	42.9	42.4	42.6	41.9	42.4	42.2	43.0	42.7
Men, %	33.6	33.4	33.9	33.0	32.7	32.0	31.5	31.5	32.5	33.1
Women, %	30.4	30.1	30.4	29.8	29.9	29.6	30.1	30.0	31.1	31.1
White race, %	32.6	32.2	32.7	32.1	32.0	31.5	31.6	31.6	32.6	33.0
White male	34.5	34.1	34.8	33.9	33.5	32.8	32.2	32.3	33.3	34.1
White female	31.3	30.8	31.2	30.7	30.9	30.6	31.0	31.0	32.0	32.1
Black race, %	26.6	26.3	26.6	25.7	25.8	25.5	25.6	25.4	26.5	26.2
Black male	27.9	27.8	28.1	27.1	27.3	26.7	26.3	26.4	26.9	26.9
Black female	25.8	25.5	25.8	25.0	25.0	24.7	25.2	24.9	26.2	25.8
Other race, %[b]	27.9	29.0	28.5	28.1	28.3	27.3	27.8	27.7	28.0	28.7
Other-race male	29.6	30.5	29.8	29.7	29.7	28.9	28.8	28.3	28.9	29.0
Other-race female	26.8	27.9	27.8	26.9	27.2	26.1	27.1	27.2	27.3	28.5
Risk-adjusted 1-year mortality, %[c]	31.7	31.4	31.8	30.9	30.7	29.8	29.4	28.2	29.6	29.6

Chen J, et al. JAMA 2011;306:1669-1678

Why should we care about hospitalization?

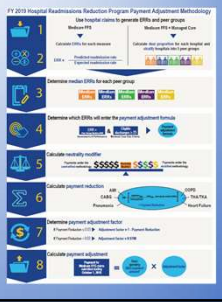


Hospital Readmissions Reduction Program (HRRP)

- A CMS program inducted in 2012 to reduce excess readmissions to inpatient prospective payment hospitals
- Defined readmission within 30 days of discharge from the same or another subsection hospital for *any reason*
- Tracked conditions included were acute myocardial infarction, ***heart failure*** and pneumonia. Later expanded to include patients admitted for coronary artery bypass grafting surgery (CABG), total knee or hip arthroplasty surgery and chronic obstructive pulmonary disease (COPD).

Hospital Readmissions Reduction Program (HRRP)

- The maximum penalty has been rising from 2013 to 2015 from 1% to now 3%.
- For FY 2019 hospitals will be stratified into peer groups based on the number of qualified services



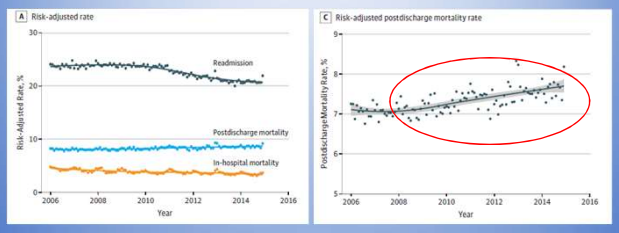
Hospital Readmissions Reduction Program (HRRP)

- In its first year, the HRRP penalized 2,213 hospitals a total of $280 million dollars for excessive readmission rates.
  - This included 70% of eligible hospitals with 60% receiving a penalty of <1% and 10% receiving the maximal penalty
- By 2014, there were 2,610 hospitals penalized with 39 receiving the maximum penalty of 3% due to added conditions

Hospital Readmissions Reduction Program (HRRP)

Circulation. 2015 May 19; 131(20): 1796–1803

Hospital Readmissions Reduction Program (HRRP) – *Effects on HF Post-Discharge Mortality*



JAMA Network Open. 2018;1(5):e182777. doi:10.1001/jamanetworkopen.2018.2777

Outline

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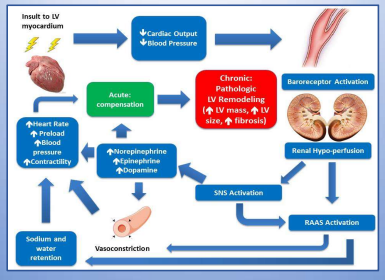
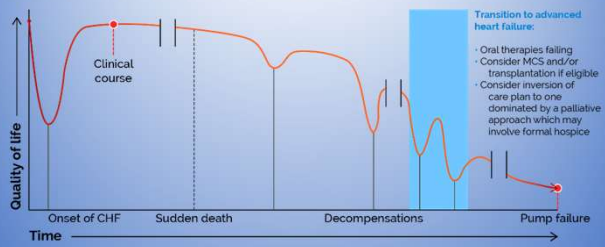
- Identifying High Risk Patients
- Current Treatments
- Future of Heart Failure Management

Heart Failure is a Multiorgan Process



Cunningham et al, Neurohormonal Blockade, 2018 In: The Encyclopedia of Cardiovascular Research and Medicine

Natural History of Heart Failure



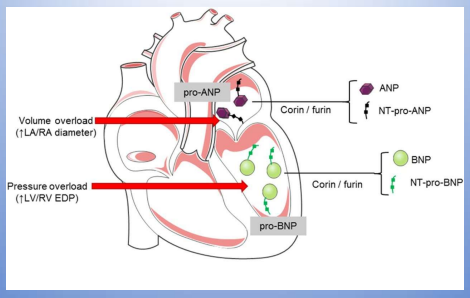
Can we identify patients at risk for hospitalization or dying?

- Biomarkers
  - Brain natriuretic peptide
  - Troponin
- Timing of Discharge – how do we ensure success?
- After hospital care
  - Follow up visits
  - Continued monitoring

Use of Biomarkers to Predict Mortality and Readmission

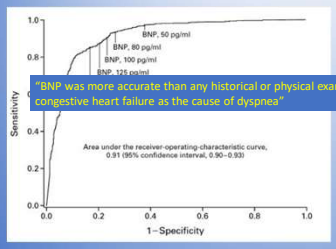
- *Brain natriuretic peptide (BNP)* is measured in heart failure patients to guide diagnosis and to provide prognosis
- BNP is released from myocardial tissue in response to wall stress, i.e. increased filling pressures within the heart or volume overload
- It has beneficial physiologic effects including vasodilation, decrease production of circulating maladaptive hormones and promoting diuresis in the kidneys

Brain Natriuretic Peptide



Singh JSS, Heart 2017;103:1569-1577

BNP Assists with Diagnosing Heart Failure

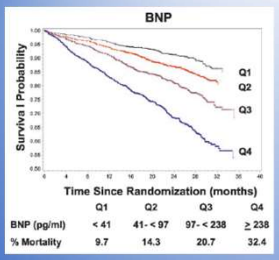


BNP	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Accuracy
					79
80	93 (91–95)	74 (70–77)	77 (76–80)	92 (89–94)	83
100	90 (88–92)	76 (73–79)	79 (76–81)	89 (87–91)	83
125	87 (85–90)	79 (76–82)	80 (78–83)	87 (84–89)	83
150	85 (82–88)	83 (80–85)	83 (80–85)	85 (83–88)	84

"BNP was more accurate than any historical or physical exam findings or laboratory values in identifying congestive heart failure as the cause of dyspnea"

Maisel AS et al, N Engl J Med. 2002;347:161-167.

BNP Assists with Predicting Outcomes in Heart Failure Patients

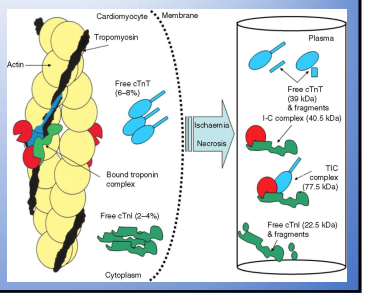


	Q1	Q2	Q3	Q4
BNP (pg/ml)	< 41	41- < 97	97- < 238	≥ 238
% Mortality	9.7	14.3	20.7	32.4

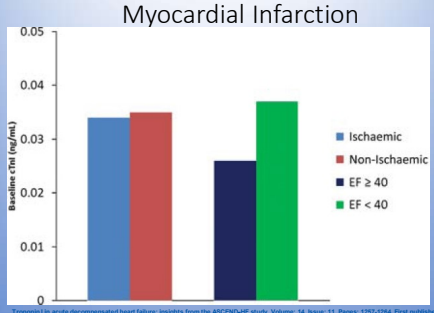
Anand et al., Circulation 2003

Troponin is Not Just for Predicting Acute Myocardial Infarction

- A ***troponin*** blood test measures the level of the troponin protein circulating in the blood
- Elevation of troponin occurs when myocardial cells die and leak this protein into the blood stream

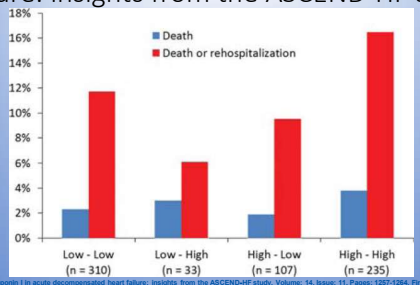


Troponin I is Not Just for Predicting Acute Myocardial Infarction



Troponin I in acute decompensated heart failure: insights from the ASCEND-HF study, Volume: 14, Issue: 11, Pages: 1257-1264, First published: 18 February 2014, DOI: (10.1093/eurjhf/hfs110)

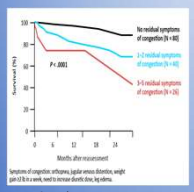
Troponin I in acute decompensated heart failure: insights from the ASCEND-HF study



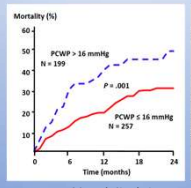
Troponin I in acute decompensated heart failure: insights from the ASCEND-HF study, Volume: 14, Issue: 11, Pages: 1257-1264, First published: 18 February 2014, DOI: (10.1093/eurjhf/hfs110)

Who is ready to be discharged?

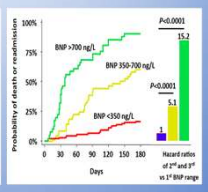
- Persistent or subclinical congestion at discharge is associated with increased mortality and risk for HF hospitalization



Lucas C, et al. *Am Heart J.* 2000;140:840-847.



Fonarow GC, et al. *Circulation.* 1994;90(pt. 2):1-488.



Logeart D, et al. *J Am Coll Cardiol.* 2004;43:635-641

Does Follow up Matter?

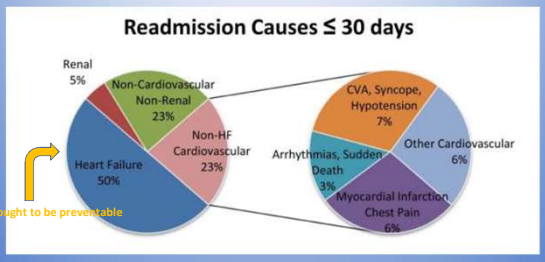
Table 3. Rates of Mortality, Readmission, and Mortality or Readmission at 30 Days by Quartile of Hospital Rate of Early Follow-up

Variable	Percentage Rate of Early Follow-up by Quartile, No. (%) 1 (<32.4)	2 (32.4-37.9)	3 (38.3-44.5)	4 (>44.5)	*P* Value
No. of patients	7081	8662	7812	6581	
Event, 30 d					
Mortality[a]	353 (5.0)	417 (4.8)	352 (4.5)	297 (4.5)	.44
Readmission[b]	1658 (23.3)	1787 (20.5)	1606 (20.5)	1377 (20.9)	<.001
Mortality or readmission[a]	1849 (26.1)	2015 (23.3)	1813 (23.2)	1544 (23.5)	<.001

[a]Based on proportion of events.
[b]Based on cumulative incidence function.

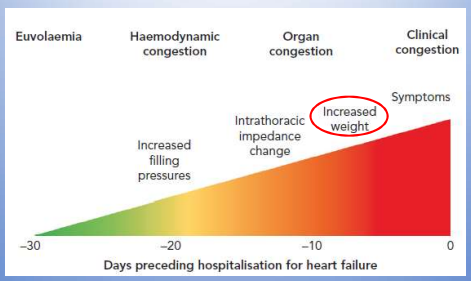
Hernandez et al. JAMA 2010;303:1716-1722.

Recurrent congestive heart failure most common reason for readmission



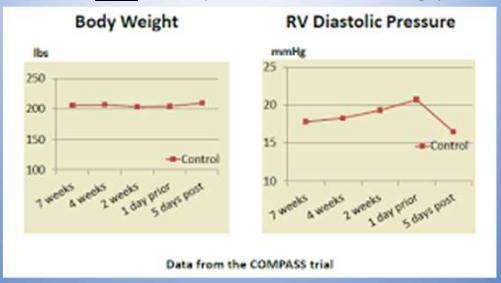
Vader, et al. J Card Fail 2016

How do we prevent readmission?



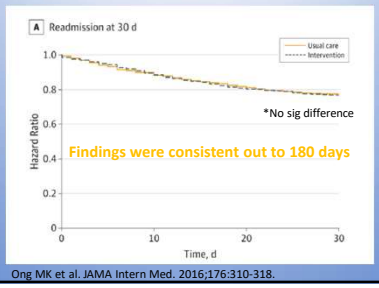
Adapted from Adamson et al, Curr Heart Fail Reports, 2009.

Weight does not always track with filling pressures



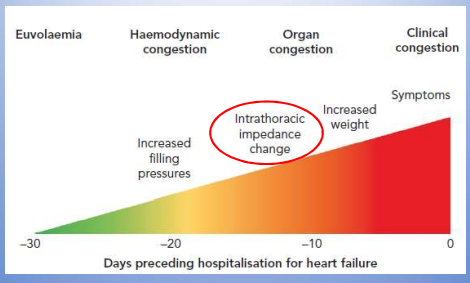
Renlund D, et al. Circulation 2007; 116:II_599

Telemonitoring of Weight Does NOT reduce readmissions



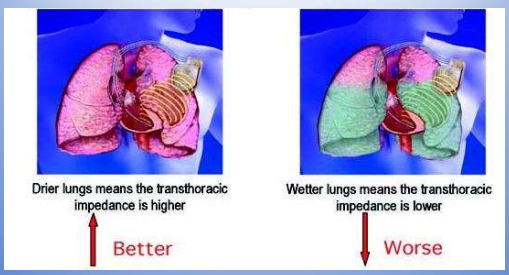
Ong MK et al. JAMA Intern Med. 2016;176:310-318.

How do we prevent readmission?



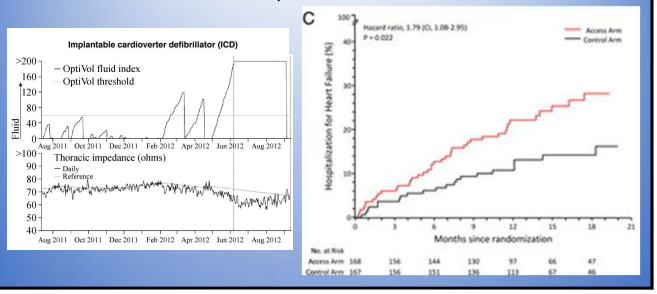
Adapted from Adamson et al, Curr Heart Fail Reports, 2009.

Thoracic Bioimpedance

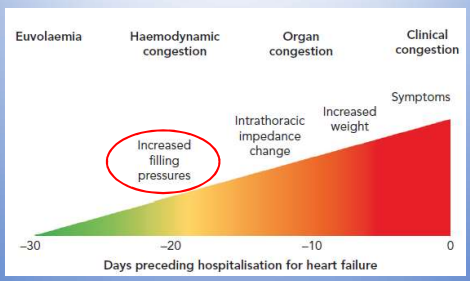


http://www.jlgh.org/Past-Issues/Volume-1---Issue-1/Thoracic-Impedance.aspx

Impedance Monitoring Does NOT Reduce Hospitalization

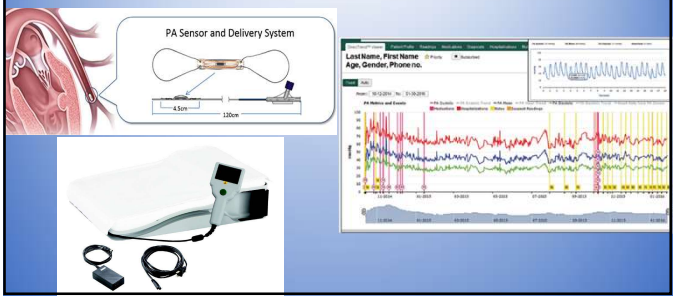


How do we prevent readmission?

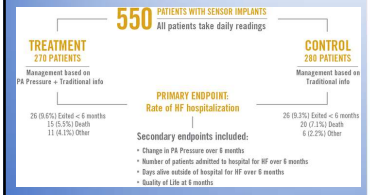


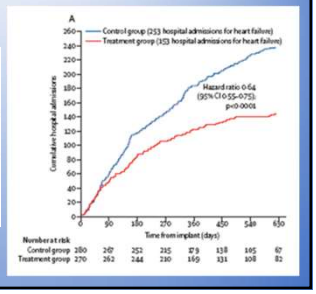
Adapted from Adamson et al, Curr Heart Fail Reports, 2009.

Implantable PA Pressure Monitor



Remote Monitoring of PA Pressures DOES Reduce Hospitalizations

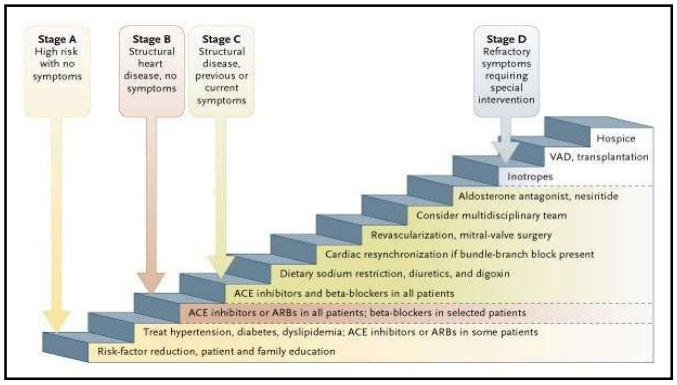




Abraham WT, et al. Lancet, 2011;377:658-666.

Outline

- Scope of the Problem
- Identifying High Risk Patients
- Current Treatments
- Future of Heart Failure Management



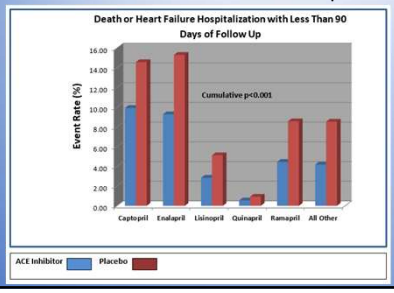
Beta-Blockers Reduce Death and Hospitalization in Heart Failure

Study	CIBIS[67]	Carvedilol Heart Failure Study Group[68]	CIBIS II[57]	MERIT-HF[55]
Medication	Bisoprolol 5 mg daily versus Placebo (51% reached max dose)	Carvedilol 25 to 50 mg twice daily* versus Placebo (MDD=45 mg)	Bisoprolol 10 mg daily versus Placebo (43% reached max dose)	Metoprolol CR/XL (Succinate) 200 mg daily versus Placebo (MDD=159 mg daily)
Study Subjects	641 Patients with LVEF ≤40% and NYHA Class III or IV heart failure	1094 Patients with LVEF ≤35% and 3 months of heart failure symptoms	2647 Patients with LVEF ≤35% and NYHA Class III or IV heart failure	3991 Patients with LVEF ≤40% and NYHA Class III-IV heart failure
Key Points	• Reduced CHF Hospitalization (p<0.01) • Nonsignificant reduction in mortality (RRR=20%, p=0.22) • Improvement in NYHA Class (p=0.03)	• 65% RRR in death (95% CI 0.2-0.61, p<0.001) • Reduced CHF hospitalization (RRR=27%, p<0.036)	• 44% RRR in death (95% CI 0.54-0.81, p<0.001) • Reduced all cause and CHF hospitalization (p<0.0049 and p<0.001, respectively) • Reduced hospitalization for VT and VF	• 44% RRR in death (95% CI 0.53-0.81, p<0.001) • Reduction in progression of heart failure at 18 months (p=0.0023)

Abbreviations: MDD, Mean daily dose; LVEF, Left ventricular ejection fraction; CHF, congestive heart failure; RRR, relative risk reduction; VT, ventricular tachycardia; VF, ventricular fibrillation
*There was a run-in phase of carvedilol 6.25 mg BID for all patients

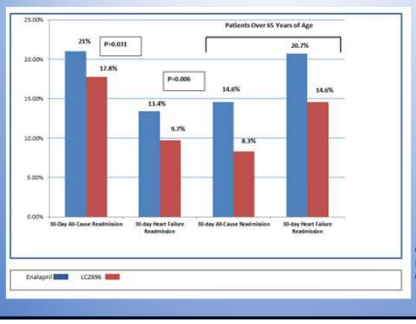
Cunningham et al, Neurohormonal Blockade, 2018 In: The Encyclopedia of Cardiovascular Research and Medicine

Angiotensin-Converting Enzyme Inhibitors Decrease Death and Rehospitalization



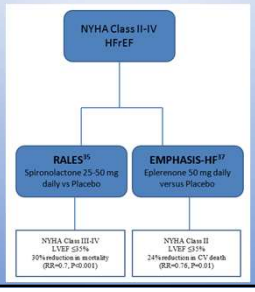
Cunningham et al, Neurohormonal Blockade, 2018 In: The Encyclopedia of Cardiovascular Research and Medicine

Entresto Decreases HF Admissions Over Enalapril



Cunningham et al, Neurohormonal Blockade, 2018 In: The Encyclopedia of Cardiovascular Research and Medicine

Spironolactone Decreases Death and Admission in Heart Failure



Cunningham et al, Neurohormonal Blockade, 2018 In: The Encyclopedia of Cardiovascular Research and Medicine

Each Therapy Has ADDITIVE Benefits

Therapy	RR in Mortality (%)	RR in HF Hospitalization (%)
ACE Inhibitor or ARB	17	31
Beta-Blocker	34	41
Aldosterone Antagonist	30	35
ARNI	26	28

Abbreviations: RR, relative reduction; ACE, angiotensin converting enzyme; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor.
The estimated benefit of ARNI is based on its use instead of ACE inhibitors or ARBs.

Adapted from: Yancy, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure - A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;138:e270.

What Happens When Medications Are Not Enough?

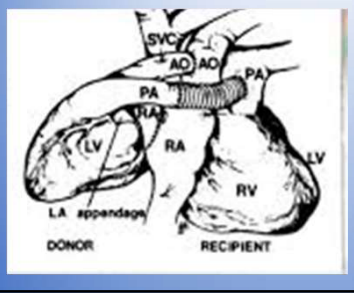
1. Severe symptoms of HF with dyspnea and/or fatigue at rest or with minimal exertion (NYHA class III or IV)	**Symptoms with dressing, showering or at rest**
2. Episodes of fluid retention (pulmonary and/or systemic congestion, peripheral edema) and/or reduced cardiac output at rest (peripheral hypoperfusion)	**Fluid retention despite high doses of diuretics**
3. Objective evidence of severe cardiac dysfunction shown by at least 1 of the following: a. LVEF <30% b. Pseudonormal or restrictive mitral inflow pattern c. Mean PCWP ≥16 mm Hg and/or RAP ≥12 mm Hg by PA catheterization d. High BNP or NT-proBNP plasma levels in the absence of noncardiac causes	**LVEF <30%**
4. Severe impairment of functional capacity shown by 1 of the following: a. Inability to exercise b. 6-Minute walk distance <300 m c. Peak Vo_2 <12 to 14 mL/kg/min	
5. History of ≥1 HF hospitalization in past 6 mo	**2 or more hospitalizations in 6 months**
6. Presence of all the previous features despite "attempts to optimize" therapy, including diuretics and GDMT, unless these are poorly tolerated or contraindicated, and CRT when indicated	**Having to decrease or stop meds due to low blood pressure**

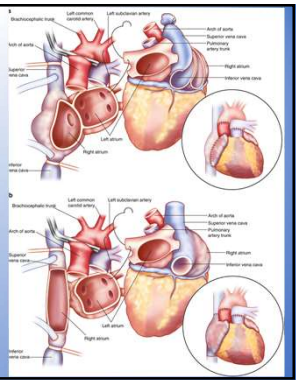
Yancy, et al. 2013 ACCF/AHA Heart Failure Guideline

Advanced Heart Failure Therapies

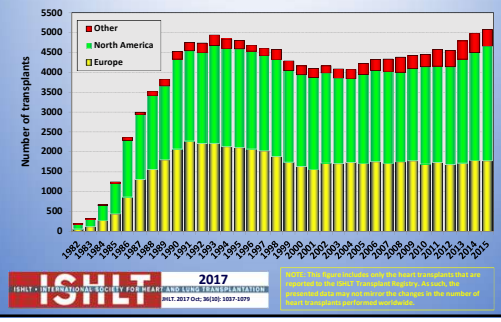
- Heart Transplant
  - Requires immunosuppressive medications for life
  - Outcomes are good – 90% survival at 1 year and 50% at 11 years
- Left Ventricular Assist Devices (LVADs)
  - Can be implanted as a bridge to transplant (BTT) or destination therapy (DT)
  - Requires anticoagulation with Coumadin/Warfarin
  - Can be associated with complications including infection, stroke and right heart failure
  - For those awaiting transplant, most recent survival is 85% at 1 year

Heart Transplant

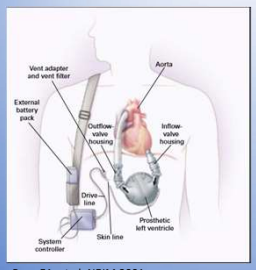




Adult and Pediatric Heart Transplants: Number of Transplants by Year and Location



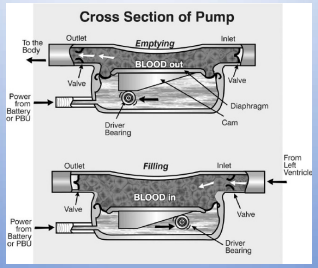
HeartMate



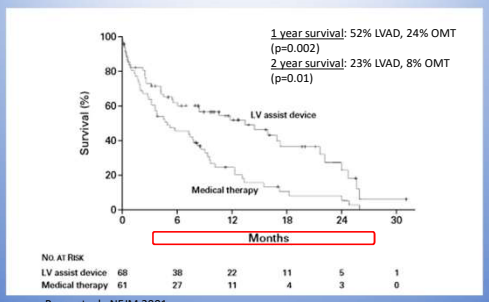
- HeartMate XVE
  - Implantation: Intra-abdominal
  - Approved by FDA for use as BTT and DT in November 2002
  - Weighs 1150 grams

Rose EA, et al. NEJM 2001

HeartMate



HeartMate - REMATCH



1 year survival: 52% LVAD, 24% OMT (p=0.002)
2 year survival: 23% LVAD, 8% OMT (p=0.01)

Rose, et. al. NEJM 2001.

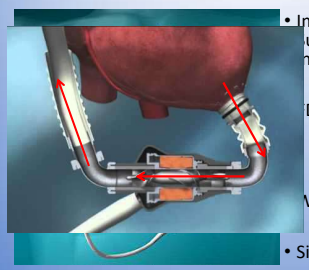
HeartMate - REMATCH

Cause of Death	Medical-Therapy Group	LVAD Group	Total
	no. of patients		
Left ventricular dysfunction	50	1	51
Sepsis	1	17	18
Failure of LVAD	0	7	7
Miscellaneous noncardiovascular causes	0	5	5
Cerebrovascular disease	0	4	4
Miscellaneous cardiovascular causes	1	2	3
Pulmonary embolism	0	2	2
Acute myocardial infarction	1	0	1
Cardiac procedure	1	0	1
Perioperative bleeding	0	1	1
Unknown	0	2	2
Total	54	41	95

Scale†	One Year		P Value
	No. assessed/ total no. (%)	Score	
SF-36			
Physical function			0.01
LVAD group	23/24 (96)	46±19	
Medical-therapy group	6/11 (55)	21±21	
Emotional role			0.03
LVAD group	23/24 (96)	64±45	
Medical-therapy group	6/11 (55)	17±28	
Minnesota Living with Heart Failure			0.11
LVAD group	23/24 (96)	41±22	
Medical-therapy group	6/11 (55)	58±21	
Beck Depression Inventory			0.04
LVAD group	22/24 (92)	8±7	
Medical-therapy group	5/11 (45)	13±7	
Median NYHA class			<0.001
LVAD group	24/24 (100)	II	
Medical-therapy group	7/11 (64)	IV	

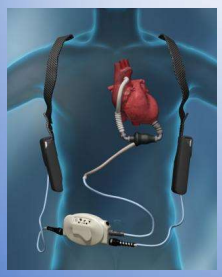
Rose, et. al. NEJM 2001.

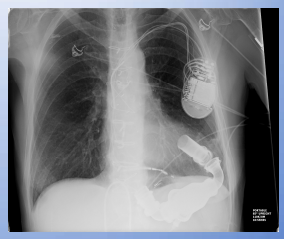
HeartMate II



- Implantation: ubdiaphragmatic or ntrathoracic
- DA approved
  - BTT in 2008
  - DT in 2010
- Veighs 281 grams
- Single moving rotor

HeartMate 2





HeartMate II - DT

1.0

Table 2. Primary End Point and Hazard Ratios, According to Treatment Group.*

End Point	Continuous-Flow LVAD (N=134)	Pulsatile-Flow LVAD (N=66)	Hazard Ratio (95% CI)	P Value
	no. (% [95% CI])			
Survival free from disabling stroke and reoperation to repair or replace LVAD at 2 yr (primary composite end point)	62 (46 [38–55])	7 (11 [3–18])		<0.001
First event that prevented patient from reaching the primary end point				
Disabling stroke†	15 (11 [6–17])	8 (12 [4–20])	0.78 (0.33–1.82)	0.56
Reoperation to repair or replace pump‡	13 (10 [5–15])	24 (36 [25–48])	0.18 (0.09–0.37)	<0.001
Death within 2 yr after implantation	44 (33 [25–41])	27 (41 [29–53])	0.59 (0.35–0.99)	0.048
Any	72 (54 [45–62])	59 (89 [82–97])	0.38 (0.27–0.54)	<0.001

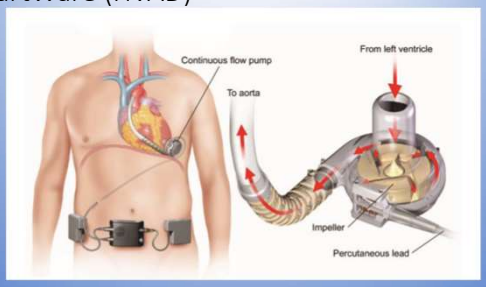
Continuous-flow LVAD	133	95	82	69	62
Pulsatile-flow LVAD	59	32	19	5	2

Slaughter MS, et al. NEJM 2009.

Outline

- Scope of the Problem
- Identifying High Risk Patients
- Current Treatments
- Future of Heart Failure Management

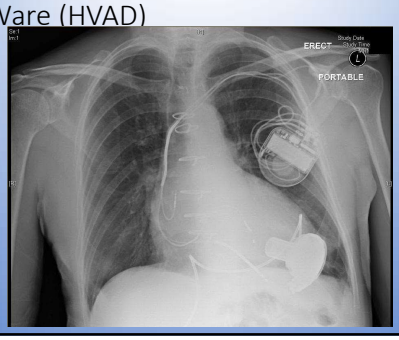
HeartWare (HVAD)



HeartWare (HVAD)

- Implantation: Intrapericardial
- *Partially* magnetically levitated
- Weight 145 grams
- FDA Approved
  - BTT in November 2012
  - DT in September 2017

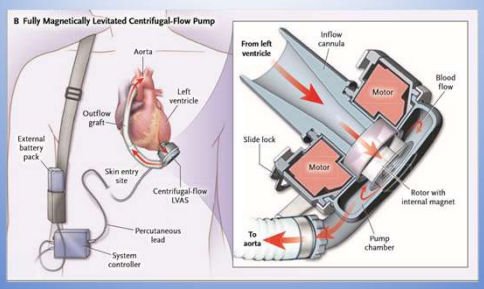
HeartWare (HVAD)



HeartWare (HVAD) - ADVANCE

- Enrollment of 140 patients to the HVAD device with comparison to registry of 499 axial-flow device recipients
- All patients were enrolled as a BTT strategy
- Primary outcome was non-inferiority of survival at 180 days

HeartMate III



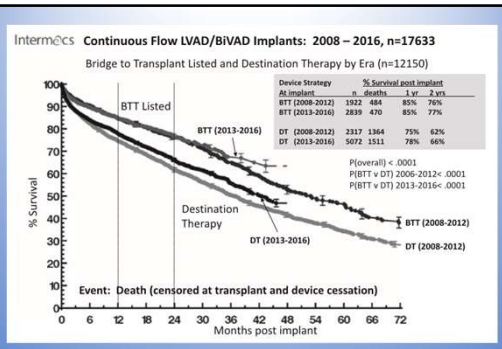
Mehra, et al. NEJM. 2017.

HeartMate III – MOMENTUM 3

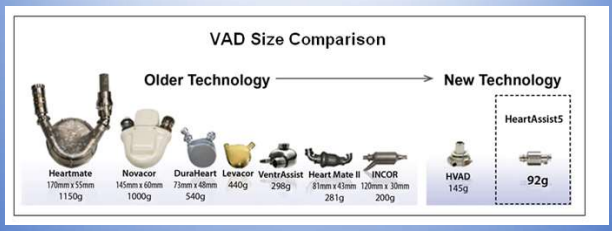
Table 3. Major Adverse Events in the Per-Protocol Population.*

Event	Centrifugal-Flow Pump Group (N=151)		Axial-Flow Pump Group (N=138)		Relative Risk (95% CI)	P Value
	no. of patients with events (%)	*no. of events*	*no. of patients with events (%)*	*no. of events*		
Suspected or confirmed pump thrombosis	0	0	14 (10.1)	18	NA	<0.001
Stroke						
Any stroke	12 (7.9)	12	15 (10.9)	17	0.73 (0.35–1.51)	0.39
Hemorrhagic stroke	4 (2.6)	4	8 (5.8)	8	0.46 (0.14–1.48)	0.18
Ischemic stroke	8 (5.3)	8	9 (6.5)	9	0.81 (0.32–2.05)	0.66
Disabling stroke	9 (6.0)	9	5 (3.6)	5	1.65 (0.57–4.79)	0.36
Other neurologic event†	9 (6.0)	9	8 (5.8)	8	1.03 (0.41–2.59)	0.95
Bleeding						
Any bleeding	50 (33.1)	100	54 (39.1)	98	0.85 (0.62–1.15)	0.29
Bleeding requiring surgery	15 (9.9)	15	19 (13.8)	21	0.72 (0.38–1.36)	0.31
Gastrointestinal bleeding	24 (15.9)	47	21 (15.2)	36	1.04 (0.61–1.79)	0.87
Centrifugal-flow pump	152	146	138	135	130	128	127
Axial-flow pump	142	125	119	116	110	106	103

Mehra, et al. NEJM. 2017.



Smaller Devices, Less Complications



Questions?