REWIRING THE REFLEX: NEUROMODULATION & BAROSTIM IN HF CARE

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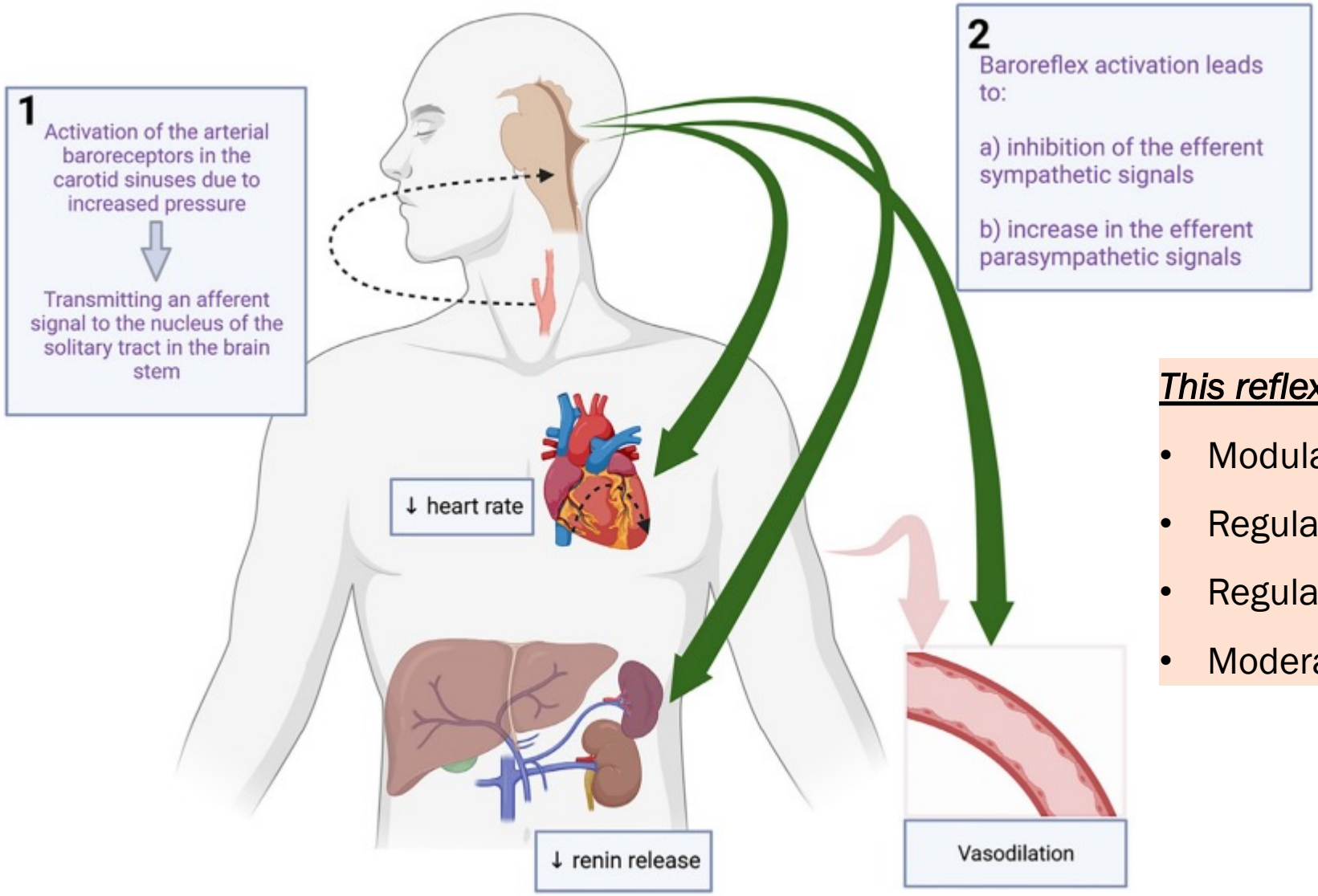
DISCLOSURES

None

BAROREFLEX



This reflex:

- Modulates cardiac output
- Regulates BP
- Regulars RAAS + Vasopressin
- Moderates electrophysiology

Salah HM et al. Baroreflex Function in Cardiovascular Disease. J Card Fail. 2025 Jan;31(1):117-126.

BAROREFLEX IMPAIRMENT IN HF

HALLMARK: SYMPATHETIC OVERACTIVITY

Degree of sympathetic overactivity is based on HF phenotype:

HFrEF > HFmrEF > HFpEF

- The exact mechanism not fully understood:
- Elevated angiotensin II levels and decreased baroreflex sensitivity
- Renal sympathetic activity with resultant increased cardiorenal norepinephrine spillover

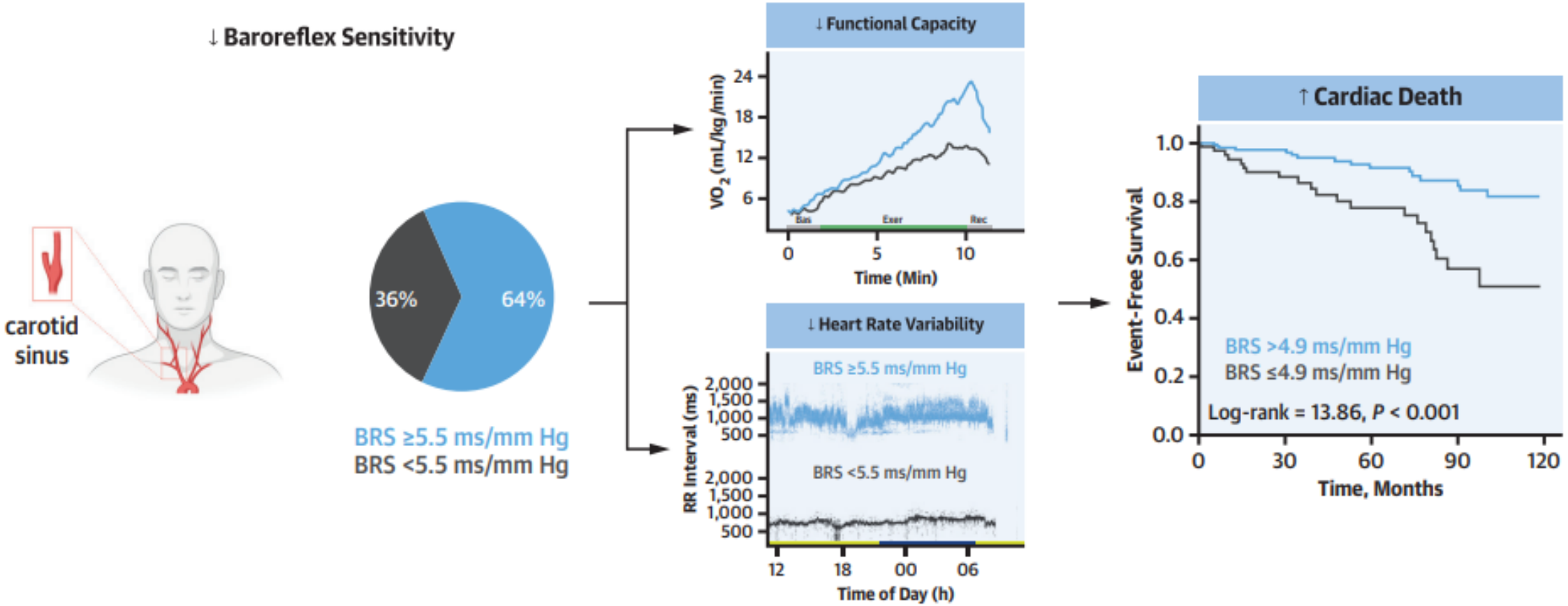
Excess hormones create a chemo-toxic milieu!

This is the basis of neurohormonal blockade in HF

Salah HM et al. Baroreflex Function in Cardiovascular Disease. J Card Fail. 2025 Jan;31(1):117-126.

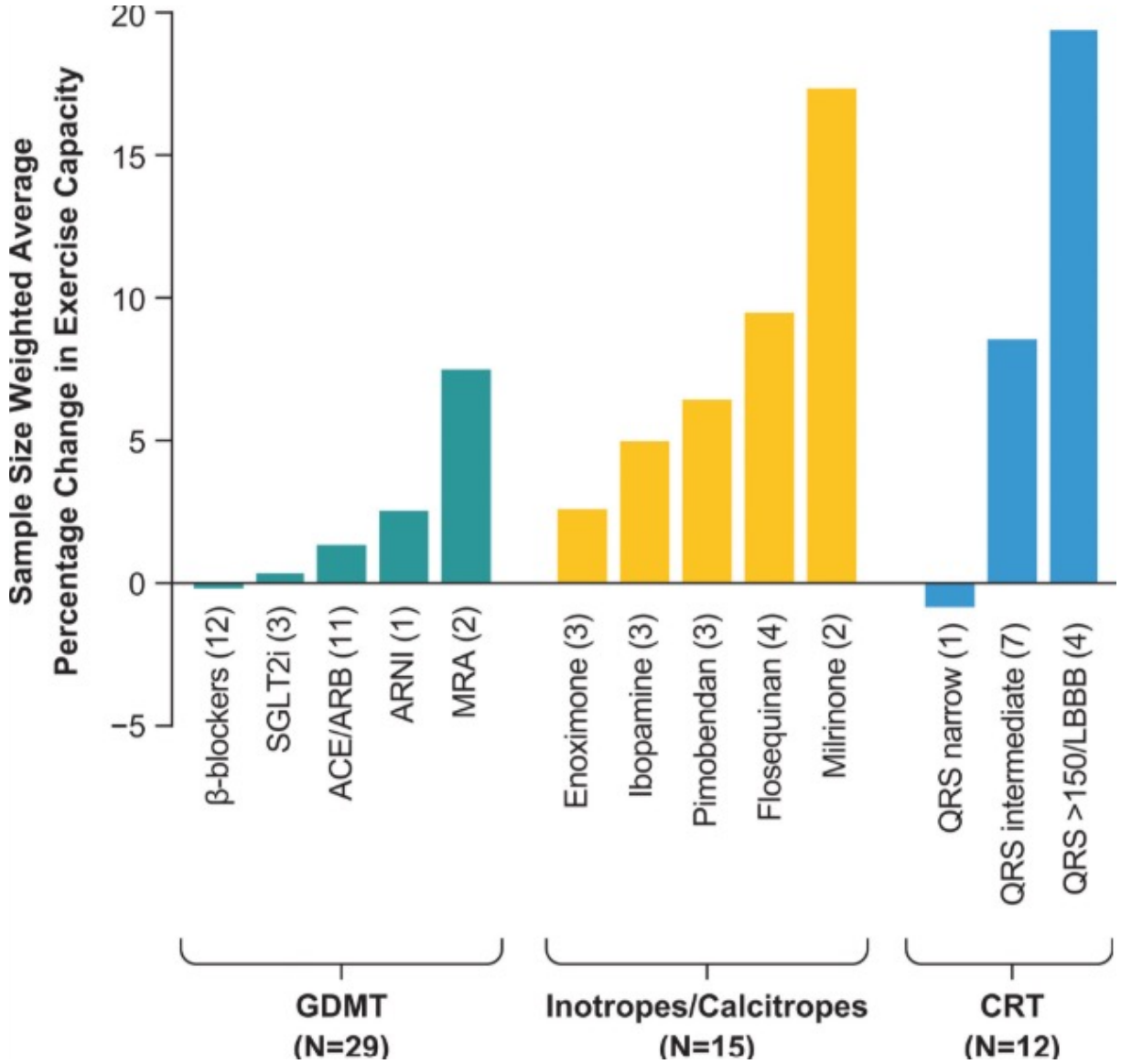
BAROREFLEX IMPAIRMENT IN HF

Giannoni et al 2022: 425 pts with average EF 32% on GDMT, decreased vs. normal BRS



Giannoni A, et al. Chemoreflex and Baroreflex Sensitivity Hold a Strong Prognostic Value in Chronic Heart Failure. JACC Heart Fail. 2022 Sep;10(9):662-676.

THE GAP WITH GDMT



Lewis GD, et al. Developments in Exercise Capacity Assessment in Heart Failure... Circ Heart Fail. 2022 May;15(5):e008970.

THE GAP WITH GDMT

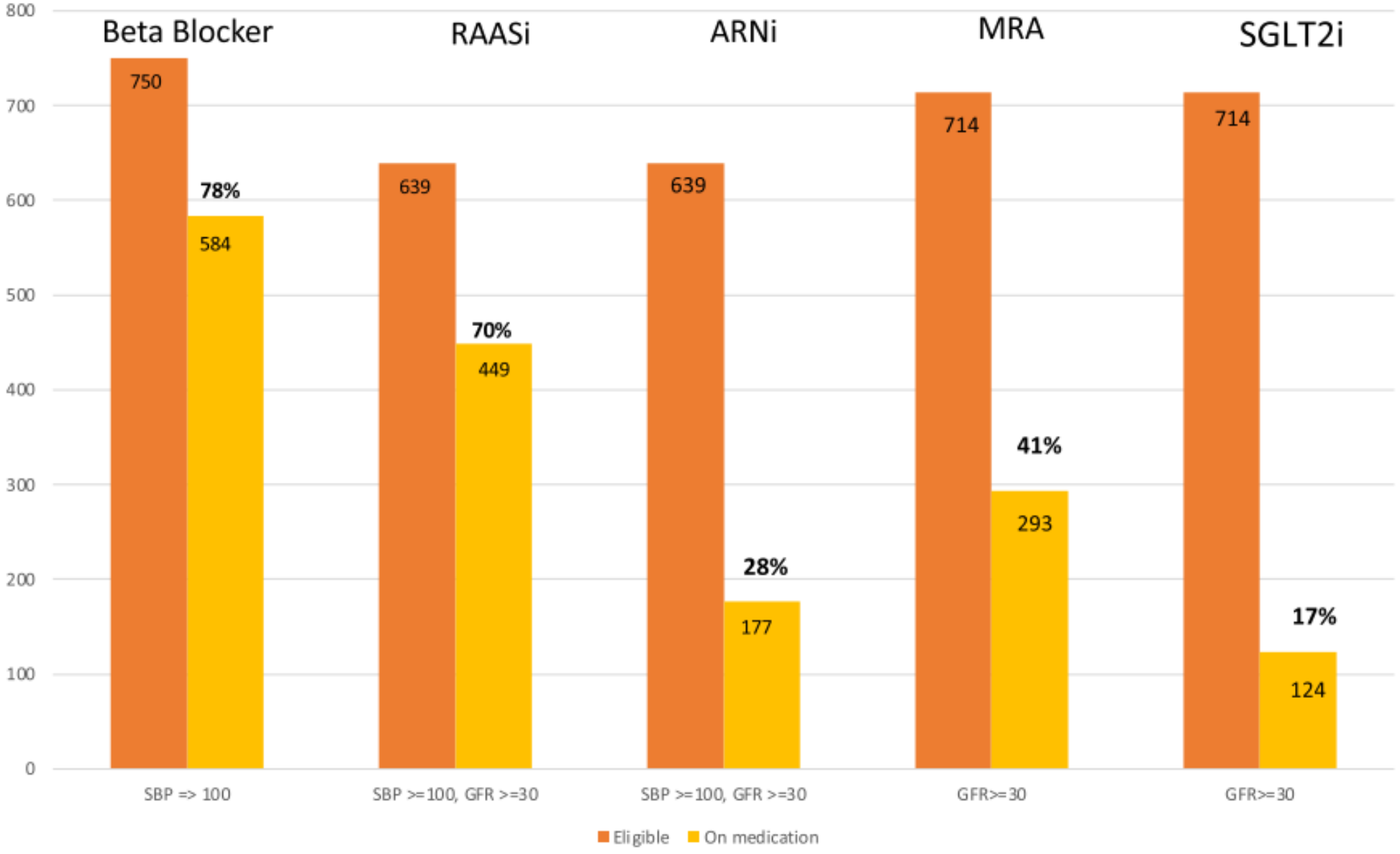
Agrawal et al, 2024

- Retrospective analysis across 7 community hospitals in Maryland
- 1236 patients on hospital discharge
- Ages 18 – 80 (mean 62) with HFrEF
- 35% were female, 58.9% black
- 90% seen by cardiologist, 46% on teaching service, average length of stay 5 days
- Private payer 50.4%, Medicare 37.6%, Medicaid 10.2%

Only 1% of eligible patients were simultaneously treated with *target doses* of ALL 4 CLASSES OF GDMT

7% of patients were on no GDMT at discharge

Agrawal S et al. Prescription Patterns in Management of Heart Failure and Its Association With Readmissions. J Card Fail. 2024 Sep 25:S1071-9164(24)00410-X.



>75% of patients eligible for quadruple therapy!

WHAT ABOUT MODULATING THE BAROREFLEX?

Barostim™

1 Activation of the arterial baroreceptors in the carotid sinuses due to increased pressure

↓

Transmitting an afferent signal to the nucleus of the solitary tract in the brain stem

2 Baroreflex activation leads to:

a) inhibition of the efferent sympathetic signals

b) increase in the efferent parasympathetic signals

↓ heart rate

↓ renin release

Vasodilation

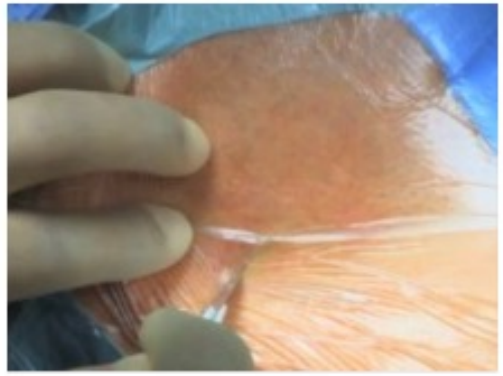
Carotid baroreflex stimulation via external pulses!

Overcome the suppressed response by sympathetic overstimulation in chronic HF

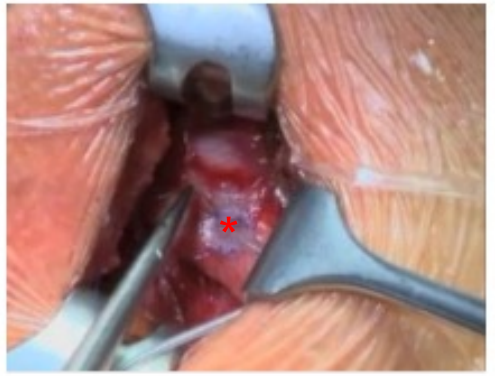
BAROSTIM IMPLANT

Implantable pulse generator + carotid lead

Small Incision in Neck



Electrode sutured to Carotid Artery

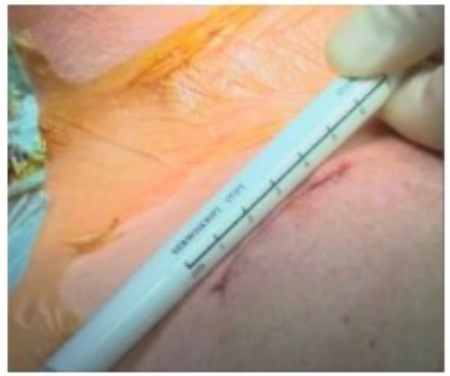


Lead tunneled to pectoral pocket

Lead connected to device and placed in pocket

Incision in neck closed

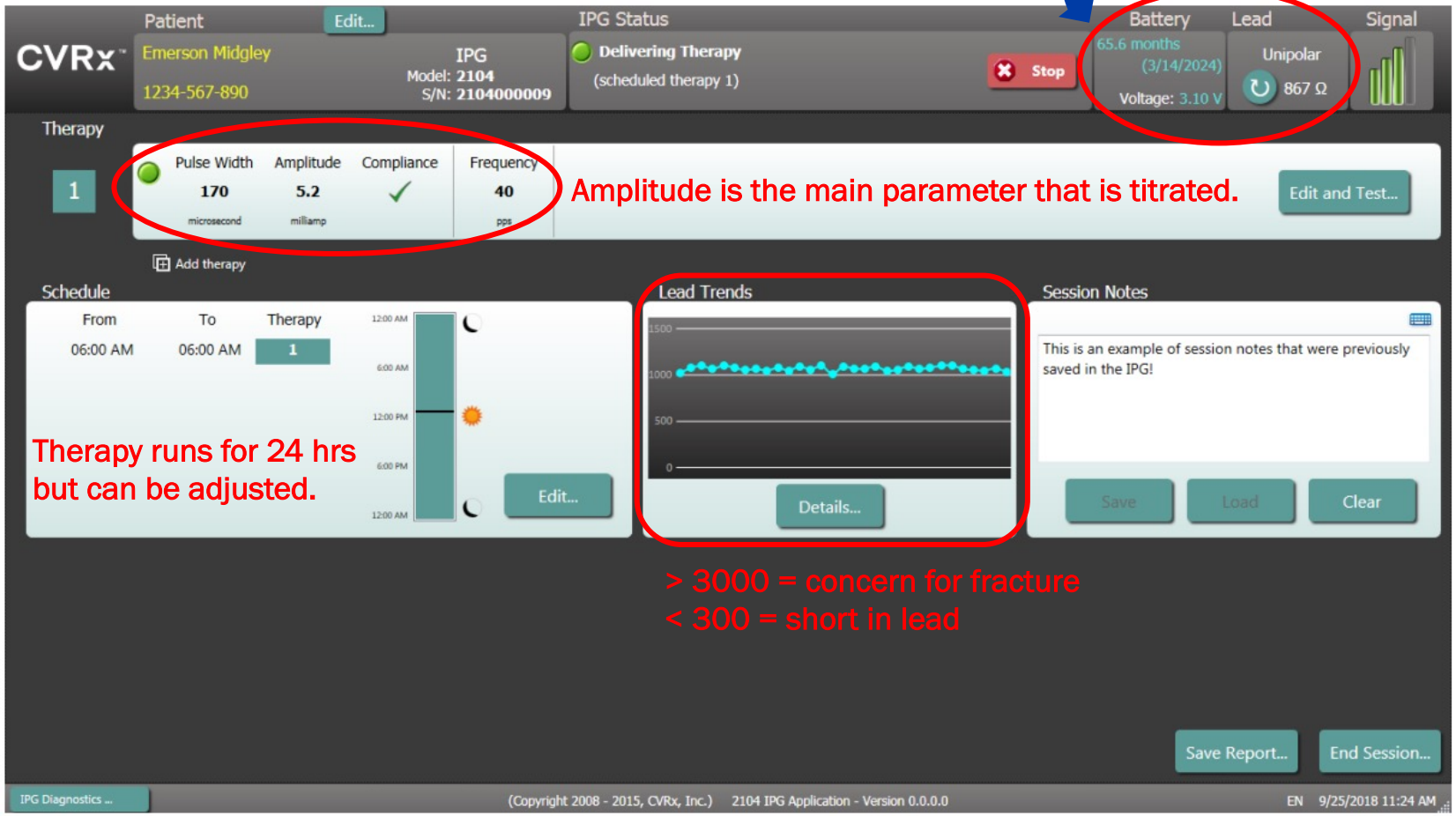
Pocket incision closed

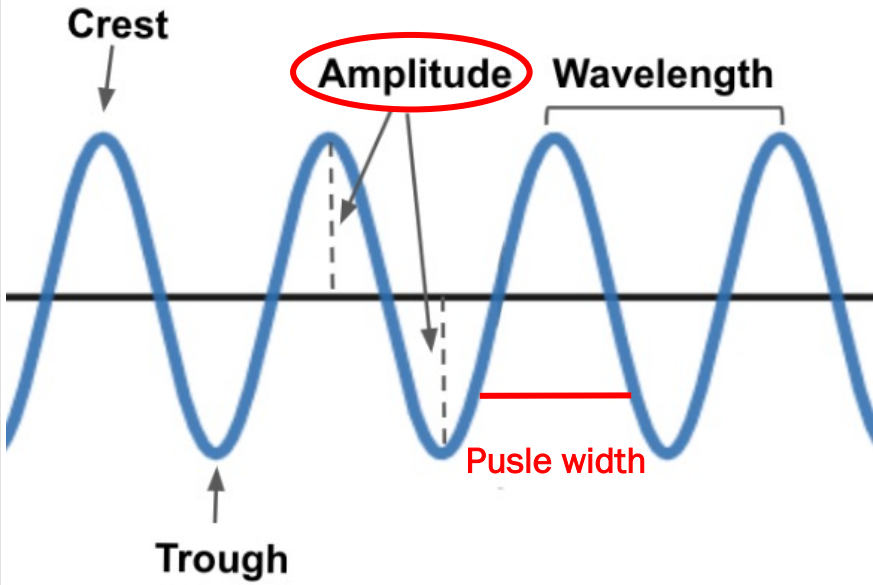


Slide courtesy of CVRx

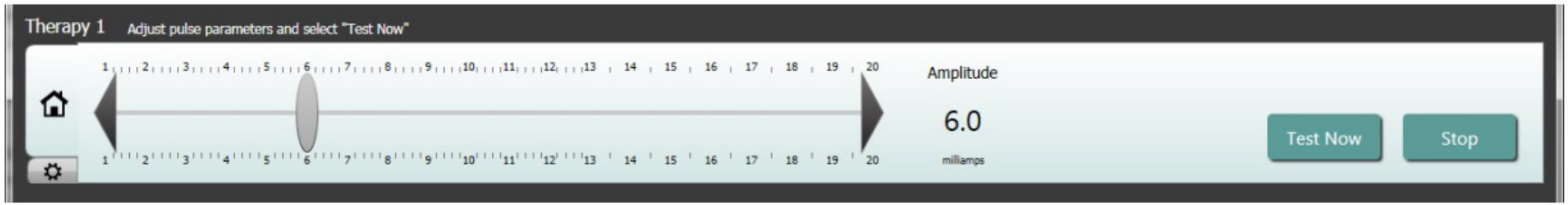
BAROSTIM PROGRAMING

Average battery life of 5 years with no charging required

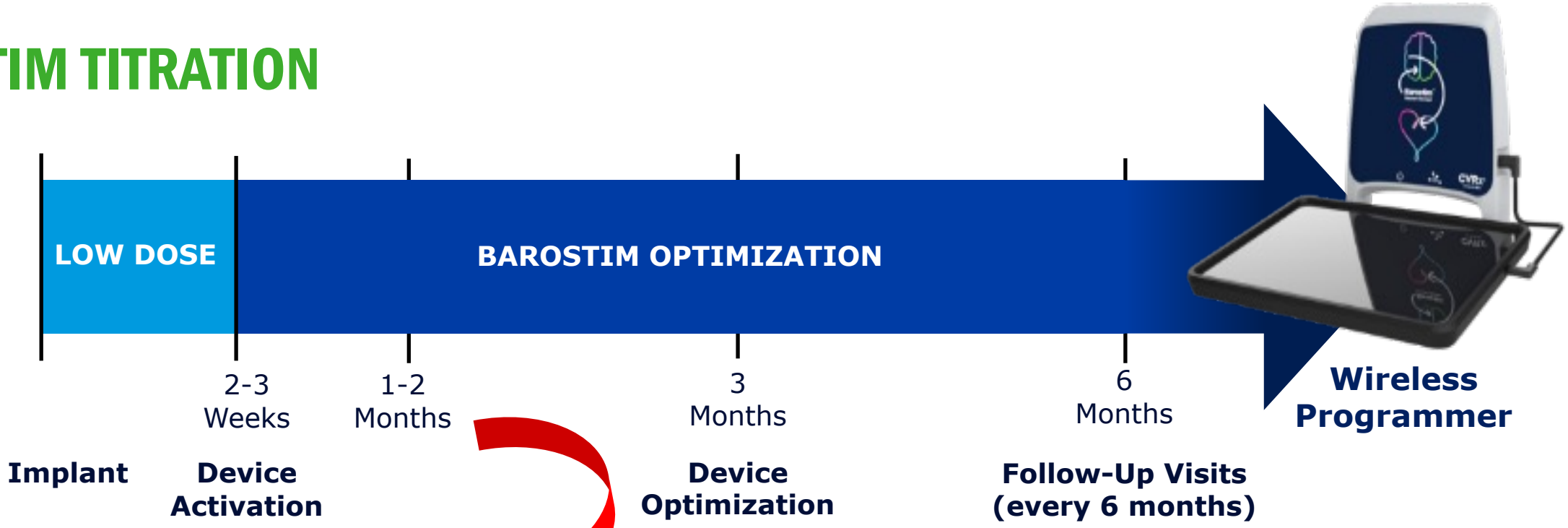




Frequency = # pulses per sec



BAROSTIM TITRATION



SAMPLE TITRATION (not standardized)

	Implant	Week 2	Week 4	Week 6	Week 8
Device Amplitude	1mA	2mA	4mA	6mA	8mA

Frist tiration should be NO MORE than 50% of the amplitude at implant.

From there, max 2mA increase per titration setting.

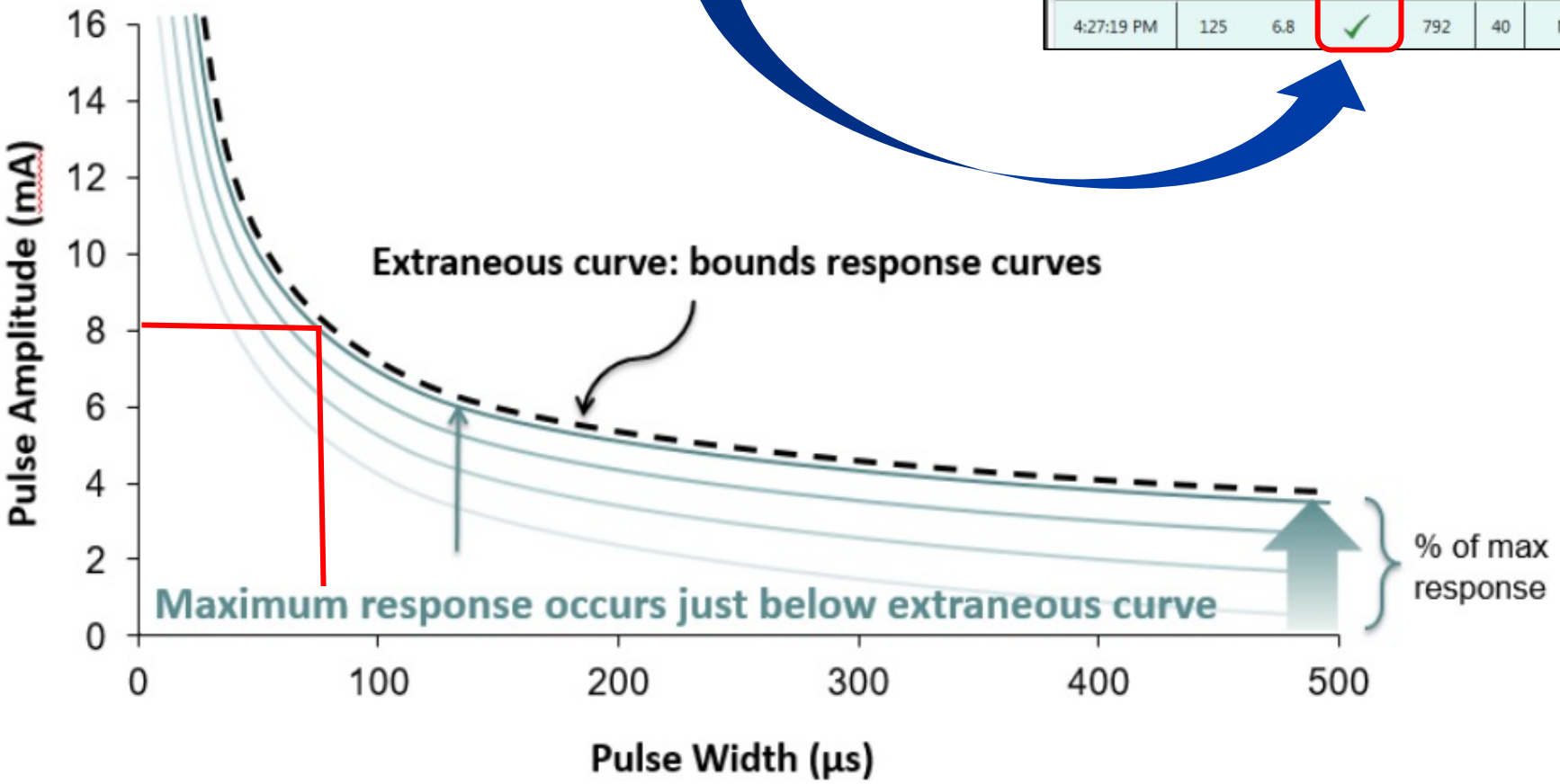
MAX DOSE TITRATION

Device runs a compliance check with each setting change to ensure desired therapies are being delivered.

Patient Response Log

Pulse Width	Amplitude	Compliance	Frequency	Burst	Battery	Elapsed Time
125	7.0	---	40	N/A	- month(s)	00:03

Time	Width	Ampl.	Compl.	Imp.	Freq.	Dur/Int	Battery	Elapsed	Sys	Dias	HR	Notes
3:24:01 PM	125	6.0	✓	834	40	N/A						Copy of Therapy 1
4:26:14 PM	125	6.4	✓	805	40	N/A	67.1	14:45				
4:26:51 PM	125	6.8	✓	841	40	N/A	60.4	00:38				
4:27:19 PM	125	6.8	✓	792	40	N/A	62.9	00:27				



- Titration typically goes to 8mA.
- Titration limited by extraneous stimulation -sensations, jaw or neck pain, difficulty speaking or swallowing) AND
- stimulation capabilities of the device (i.e. failed compliance)
- If 2 mA causes symptoms, consider a reduction in pulse width (from 125uS to 65uS) combined with an increase in Pulse Amplitude.

EARLY STUDIES – HOPE4HF TRIAL

Abraham et al. 2015

- 146 pts across 45 sites in US, Canada & Europe, NYHA class III, LVEF < 35% on chronic stable GMDT
- Endpoint: safety MANCE, change in NYHA class, QOL, 6MWT at 6 months

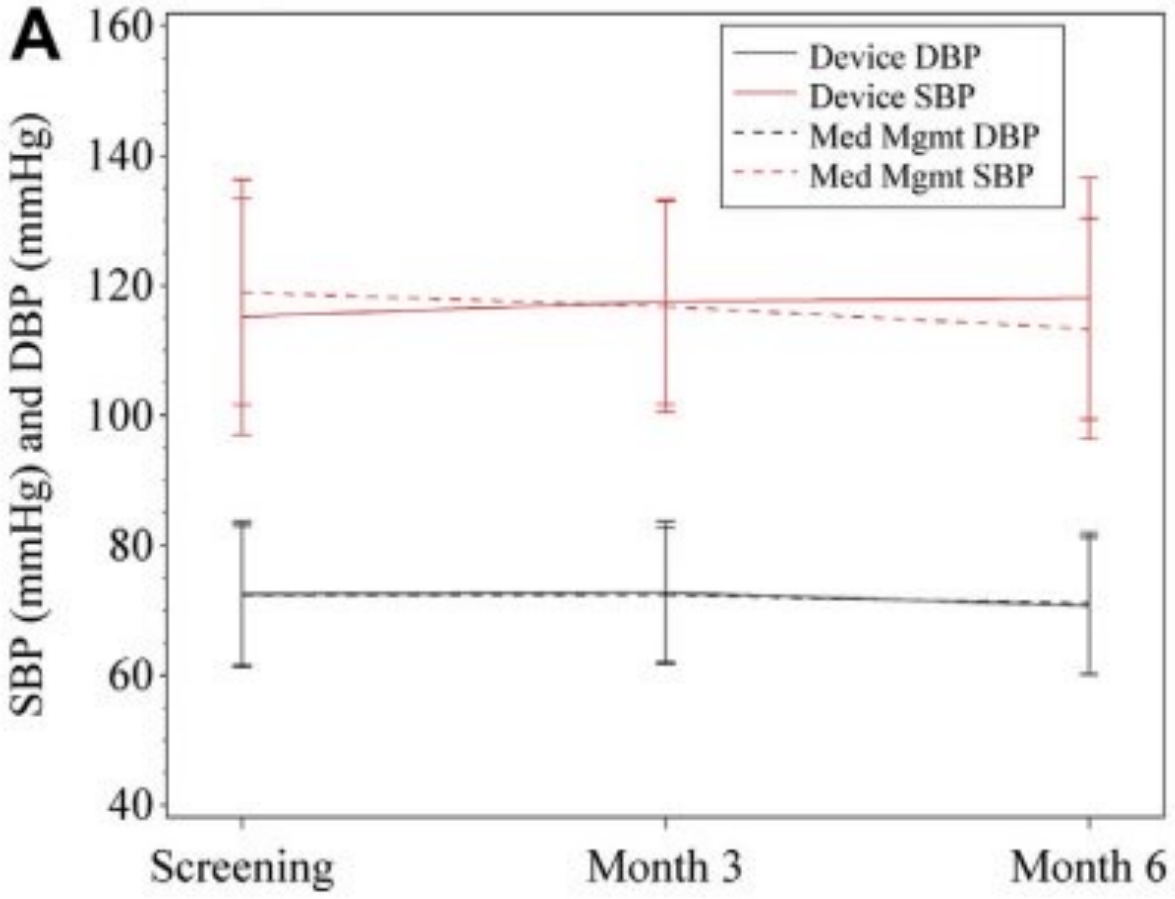
	Treatment Group		Control Group		Difference	
	n	Mean ± SE	n	Mean ± SE	Mean ± SE	p Value
NYHA functional class (% improved, same, worse)	64	55%, 42%, 3%	54	24%, 67%, 9%	0.002	
MLWHFQ QoL	64	−17.4* ± 2.8	54	2.1 ± 3.1	−19.5 ± 4.2	<0.001
6MHW distance (m)	56	59.6* ± 14.1	43	1.5 ± 13.2	58.1 ± 19.8	0.004

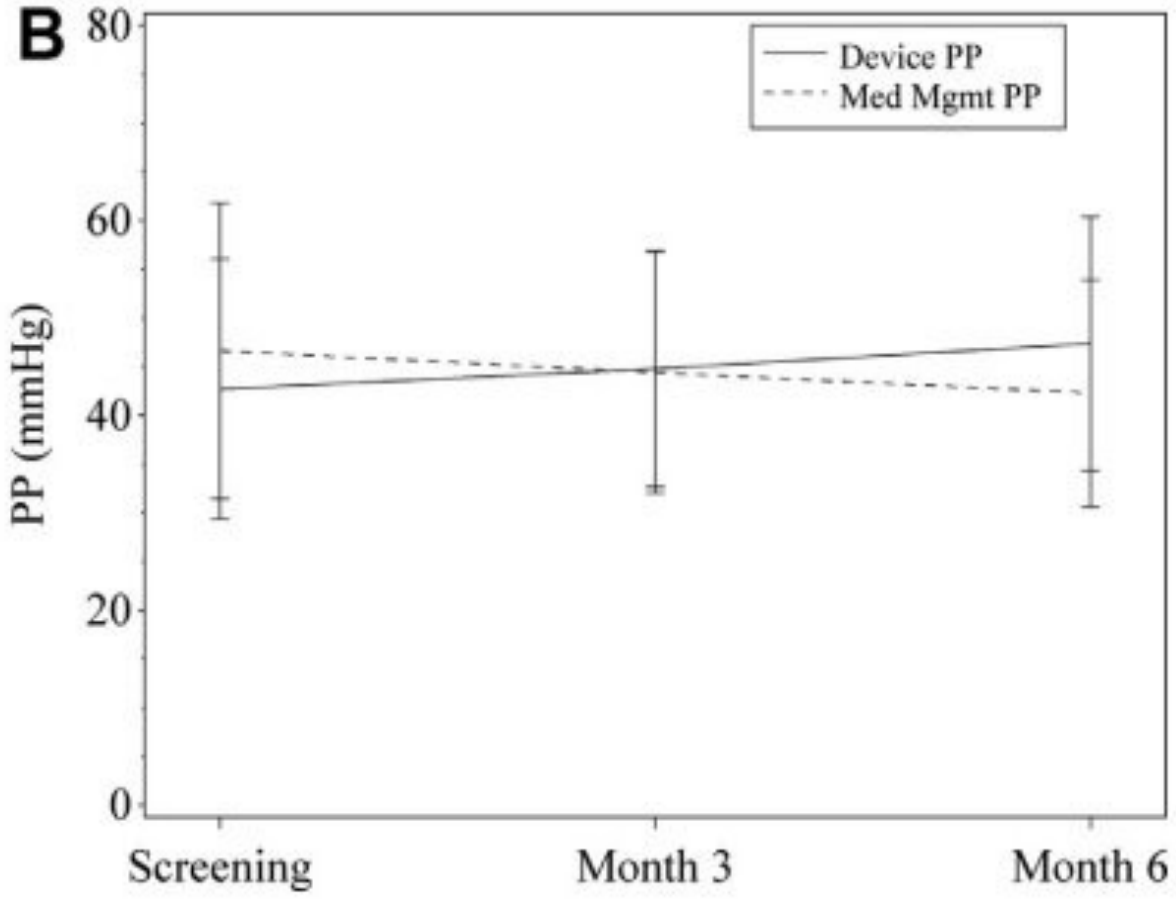
MANCE free rate 97.2%
2 hematomas- procedural complication

	Treatment Group	Control Group
Age, yrs	64 ± 11 (71)	66 ± 12 (69)
Female	12.7 (9/71)	15.9 (11/69)
Race (Caucasian)	81.7 (58/71)	89.9 (62/69)
Geography (U.S./Europe/Canada)	53 (40)/45 (34)/3 (2)	46 (32)/51 (36)/3 (2)
Coronary artery disease	66.2 (47/71)	68.1 (47/69)
Atrial fibrillation	45.1 (32/71)	43.5 (30/69)
Diabetes mellitus type 2	36.6 (26/71)	33.3 (23/69)
Hypertension	57.6 (19/33)	56.8 (21/37)
Chronic kidney disease	33.8 (24/71)	24.6 (17/69)
NYHA functional class III	98.6 (70/71)	100.0 (69/69)
6-min walk, m	297 ± 79 (69)	308 ± 85 (67)
MLWHFQ QoL*	51 ± 21 (70)	43 ± 22 (69)
BMI, kg/m^2	29 ± 5 (71)	29 ± 5 (69)
SBP, mm Hg	115 ± 18 (71)	119 ± 17 (69)
DBP, mm Hg	72 ± 11 (71)	73 ± 11 (69)
HR, beats/min	73 ± 11 (71)	75 ± 12 (66)
eGFR, ml/min	58 ± 21 (58)	59 ± 19 (61)
Creatinine, mg/dl	1.4 ± 0.5 (58)	1.3 ± 0.4 (61)
Cystatin C, mg/l	1.3 ± 0.6 (37)	1.3 ± 0.4 (32)
NT-proBNP, pg/ml	1,422 (455–4,559) (49)	1,172 (548–2,558) (47)
BNP*, pg/ml	123 (47–417) (17)	209 (34–517) (12)
LVEF, %	24 ± 7 (70)	25 ± 7 (67)
CRT	33.8 (24/71)	30.4 (21/69)
ICD	88.7 (63/71)	85.5 (59/69)
HF hospitalization rate before randomization	0.63 ± 1.47 (57)	0.36 ± 1.12 (50)
Number of medications	4.8 ± 1.6 (70)	4.4 ± 1.9 (68)
ACE inhibitors/ARBs	78.9 (56/71)	79.4 (54/68)
Beta-blockers	87.3 (62/71)	85.3 (58/68)
Calcium-channel blockers	5.6 (4/71)	8.8 (6/68)
Digitalis	21.1 (15/71)	10.3 (7/68)
Diuretic agents	93.0 (66/71)	77.9 (53/68)
Ivabradine	4.2 (3/71)	1.5 (1/68)
MRA	59.2 (42/71)	50.0 (34/68)

Abraham WT et al. Baroreflex Activation Therapy for the Treatment of Heart Failure With a Reduced Ejection Fraction. JACC Heart Fail. 2015 Jun;3(6):487-496.

EFFECT ON BLOOD PRESSURE





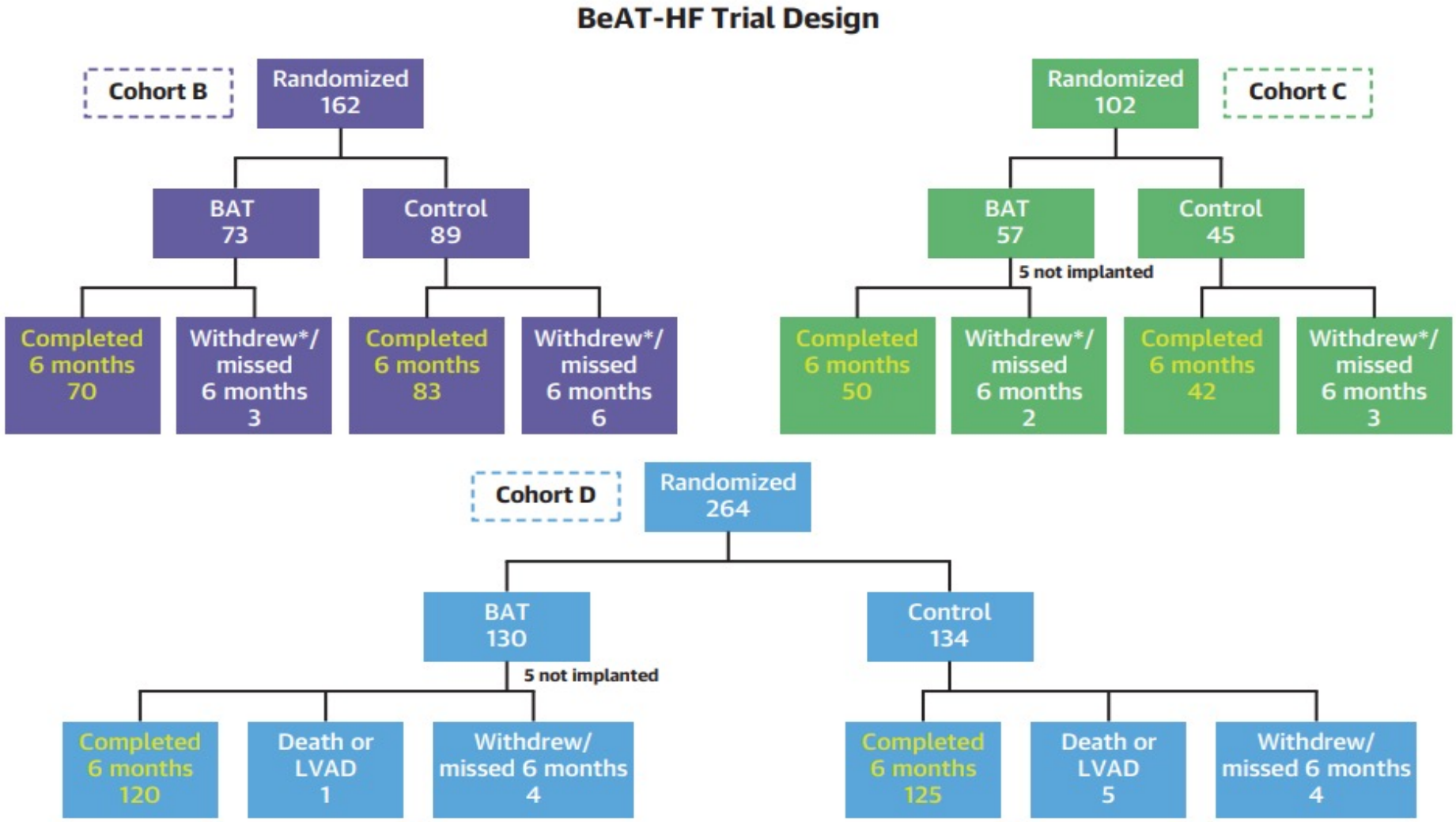
0.67% had symptoms with device titration that required attention beyond device reprogramming

Abraham WT et al. Baroreflex Activation Therapy for the Treatment of Heart Failure With a Reduced Ejection Fraction. JACC Heart Fail. 2015 Jun;3(6):487-496.

BEAT-HF TRIAL

Zile et al, 2020

- Multi center RCT, 1:1 Barostim vs. med management (unblinded)--> Effectiveness & Safety Endpoints
- 408 pts NYHA functional II or III, EF < 35%, GDMT stable X 4 weeks, no CRT



Zile MR, et al. J Am Coll Cardiol. 2020 Jul 7;76(1):1-13.

BEAT-HF TRIAL

TABLE 1 Baseline Demographic Characteristics and Treatment for Cohort D

	Control (n = 134)	BAT (n = 130)	Total (N = 264)	p Value
Race				
Asian	1.5	2.3	1.9	0.680
Black or African American	15.0	18.0	17.0	0.510
White	72.0	75.0	73.0	0.677
Other/Unknown	12.0	4.6	8.3	0.044
Female	22.0	18.0	20.0	0.542
Age at screening, yrs	63 ± 10	62 ± 11	62 ± 11	0.614
Age ≥65 yrs	43.0	42.0	42.0	0.804
Body mass index, kg/m^2	31 ± 5	31 ± 5	31 ± 5	0.699
Systolic blood pressure, mm Hg	121 ± 16	120 ± 17	121 ± 16	0.385
Diastolic blood pressure, mm Hg	73 ± 10	73 ± 10	73 ± 10	0.618
Heart rate, beats/min	75 ± 11	75 ± 10	75 ± 11	0.864
eGFR at screening	61.9 ± 19.5	63.6 ± 16.8	62.7 ± 18.2	0.430
Core lab NT-proBNP, pg/ml*	765 (479–1,052)	731 (475–1,021)	743 (477–1,031)	0.786
NYHA functional class III	95.0	93.0	94.0	0.614
6-min walk, m	294 ± 73	316 ± 68	305 ± 71	0.015
Quality of life	52 ± 24	53 ± 24	53 ± 24	0.800
LV ejection fraction, %	28 ± 6	27 ± 7	27 ± 6	0.192
QRS interval at screening	110.5 ± 25.6	108.9 ± 17.6	109.7 ± 22.0	0.545
Left bundle branch block	0.7	2.3	1.5	0.365

Low female %, higher SBP average (? On max GDMT)

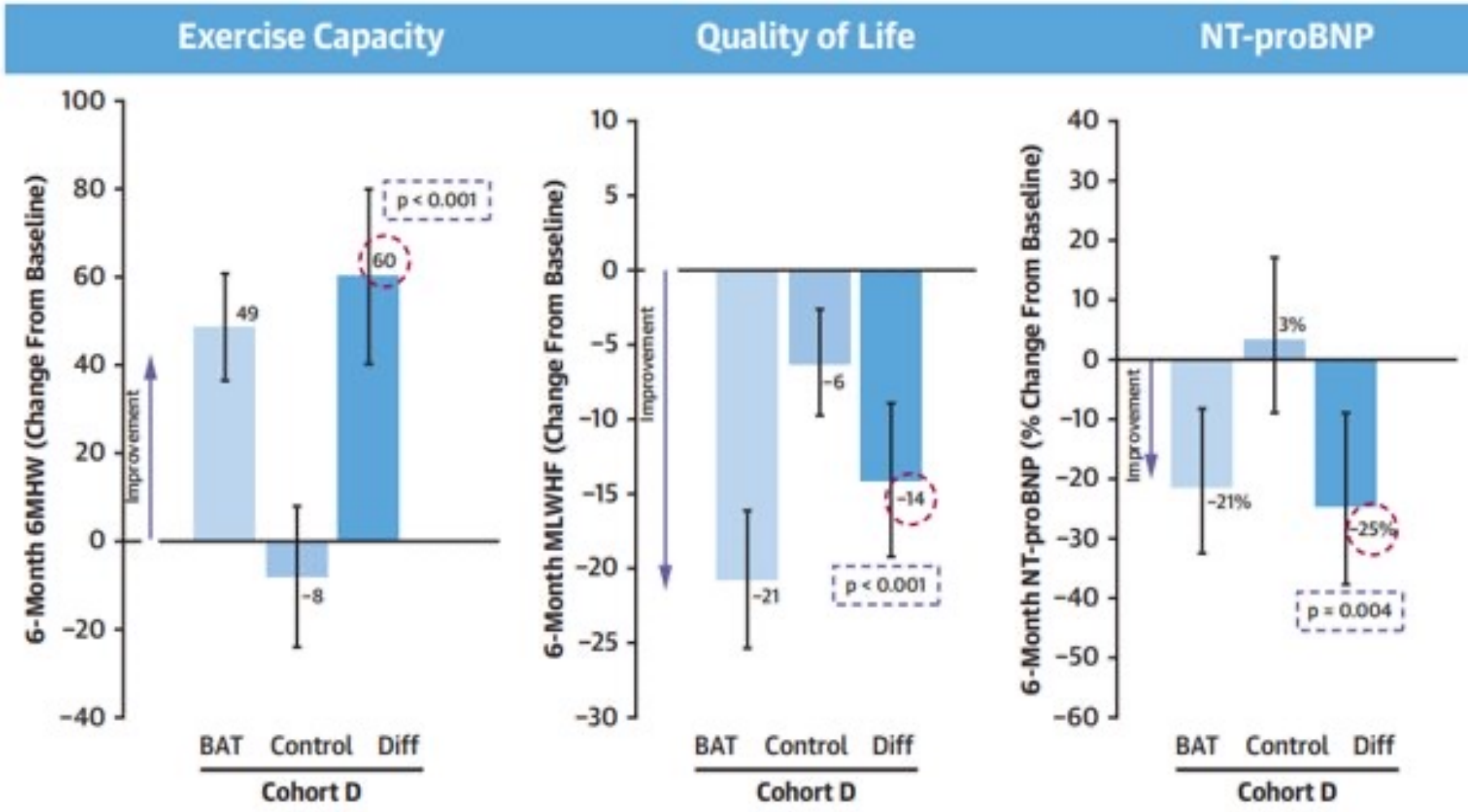
BEAT-HF TRIAL

TABLE 1 Baseline Demographic Characteristics and Treatment for Cohort D

	Control (n = 134)	BAT (n = 130)	Total (N = 264)	p Value
AF (screening ECG)	10.0	9.2	9.5	1.000
AF (medical history)	43.0	29.0	36.0	0.029
Paroxysmal AF	28.0	19.0	24.0	0.086
Permanent AF	2.2	3.8	3.0	0.495
Persistent AF	11.0	5.4	8.3	0.118
At least 1 HF hospitalization	51.0	42.0	46.0	0.140
No. of HF hospitalizations	0.7 ± 0.8	0.6 ± 1.0	0.6 ± 0.9	0.815
No. of medications	4.1 ± 1.4	3.9 ± 1.2	4.0 ± 1.3	0.228
ACE inhibitor/ARB	59.0	58.0	58.0	0.901
ARNI (sacubitril/valsartan)	26.0	32.0	29.0	0.344
ACE/ARB/ARNI	84.0	88.0	86.0	0.372
Beta-blocker	95.0	95.0	95.0	1.000
Digitalis	16.0	16.0	16.0	1.000
Diuretic	87.0	85.0	86.0	0.596
Ivabradine	4.5	2.3	3.4	0.501
MRA	42.0	48.0	45.0	0.322
ICD	79.0	78.0	78.0	0.881

No SLGT2i, low ARNi use

TOP LINE RESULTS (COHORT D)
INTENDED CLINICAL USE POPULATION



Did not examine CV morbidity and mortality OR HFH

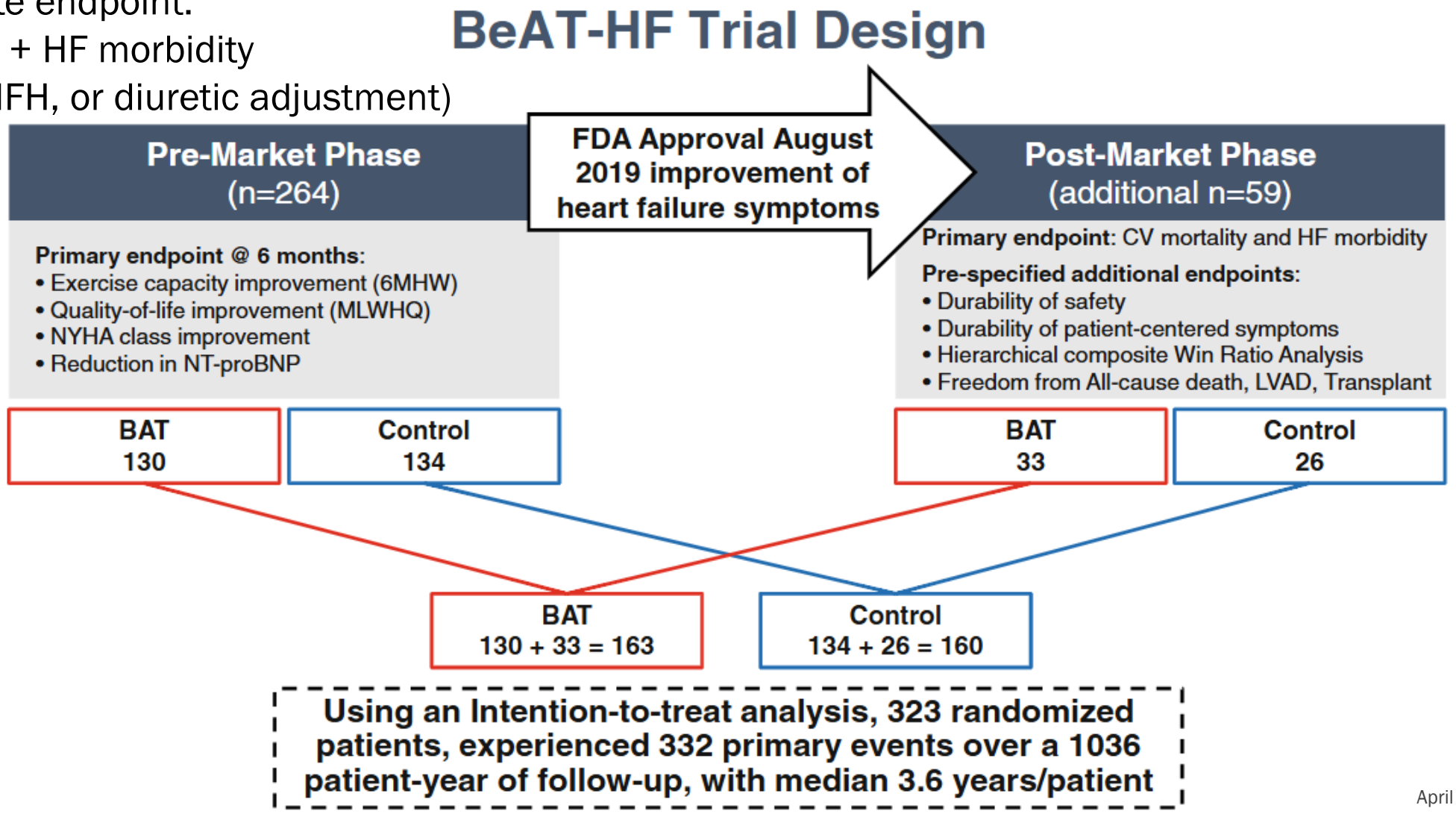
LONG TERM OUTCOMES

Zile et al, 2024

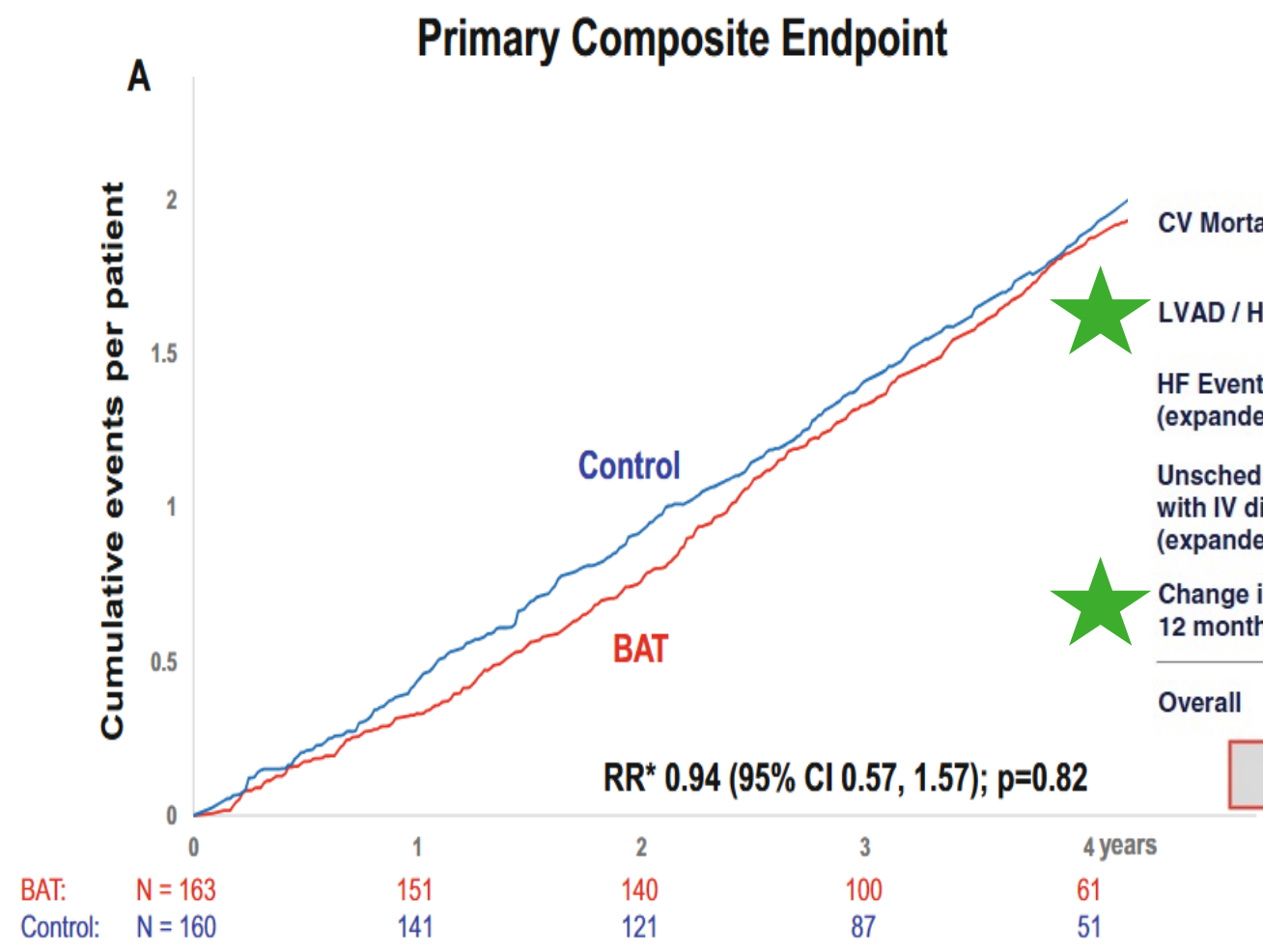
Composite endpoint:

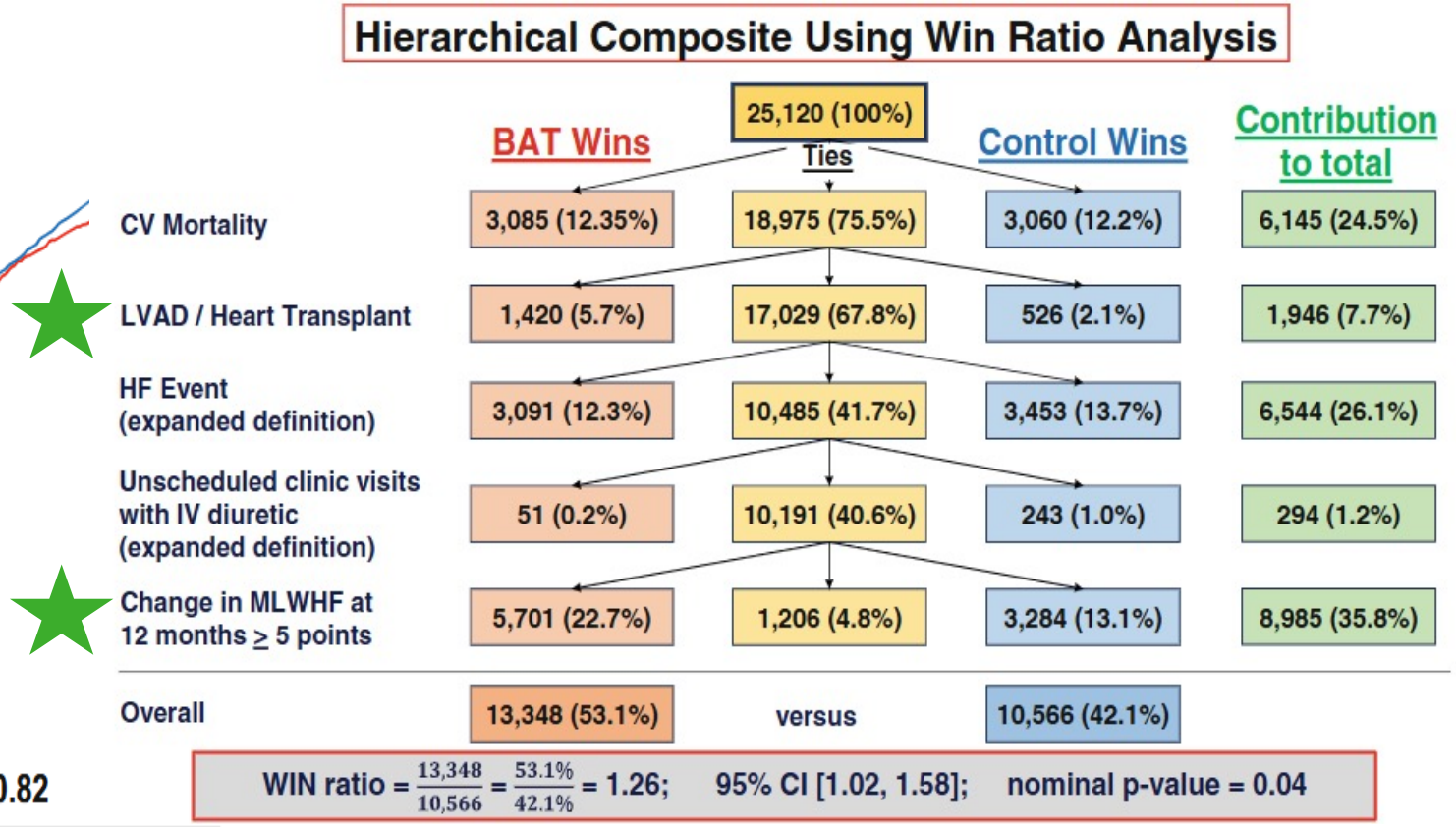
CV death + HF morbidity

(Adv tx, HFH, or diuretic adjustment)

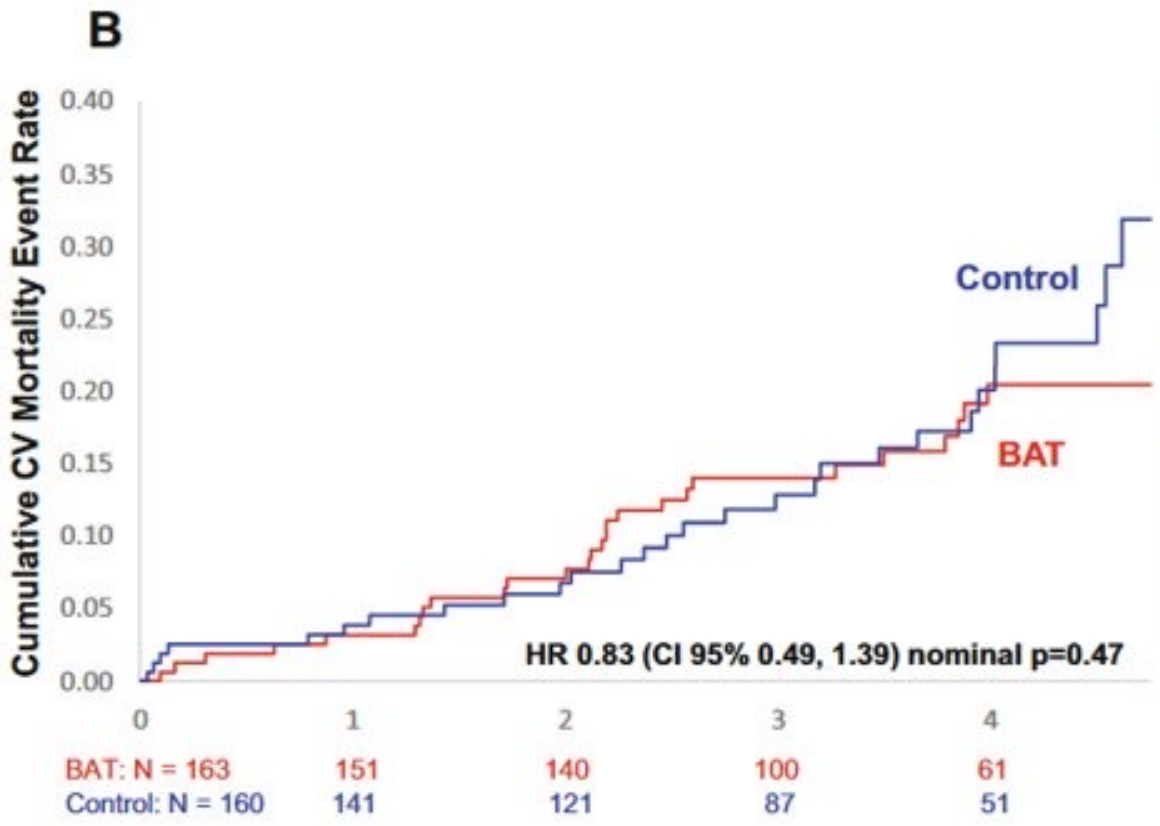


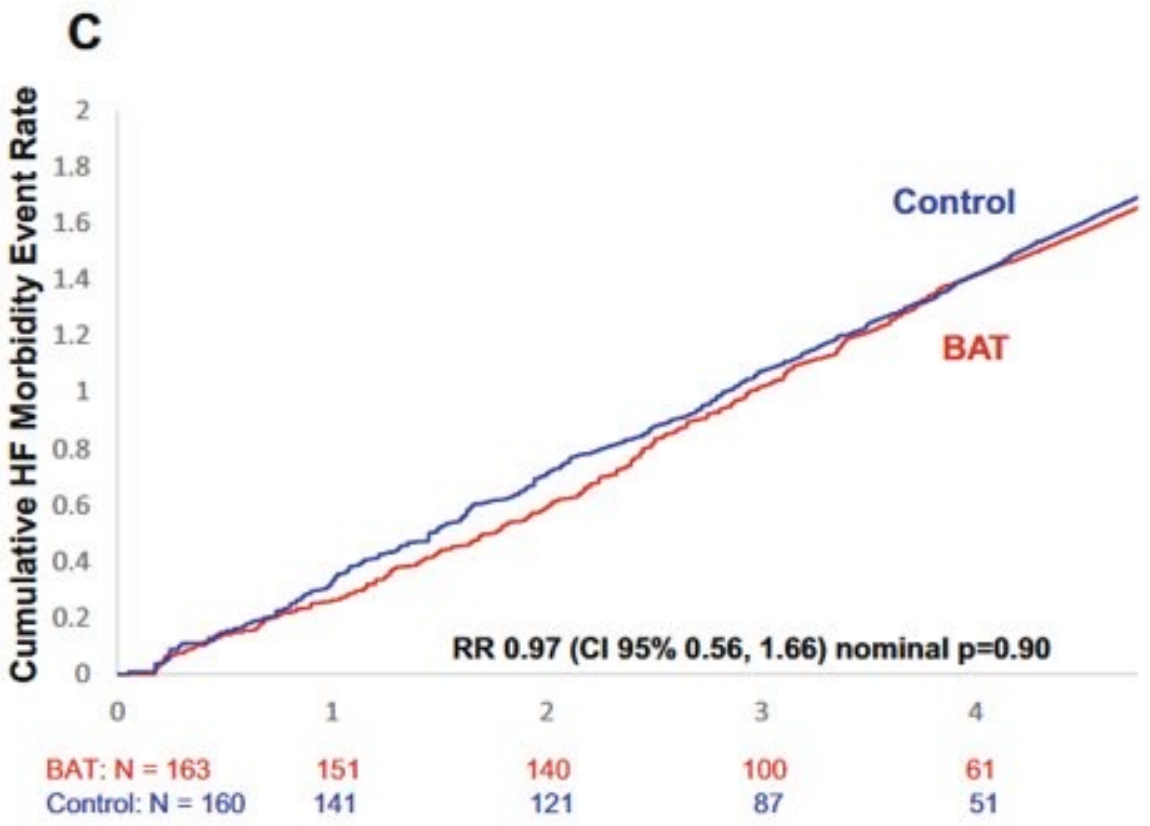
COMPOSITE ENDPOINTS



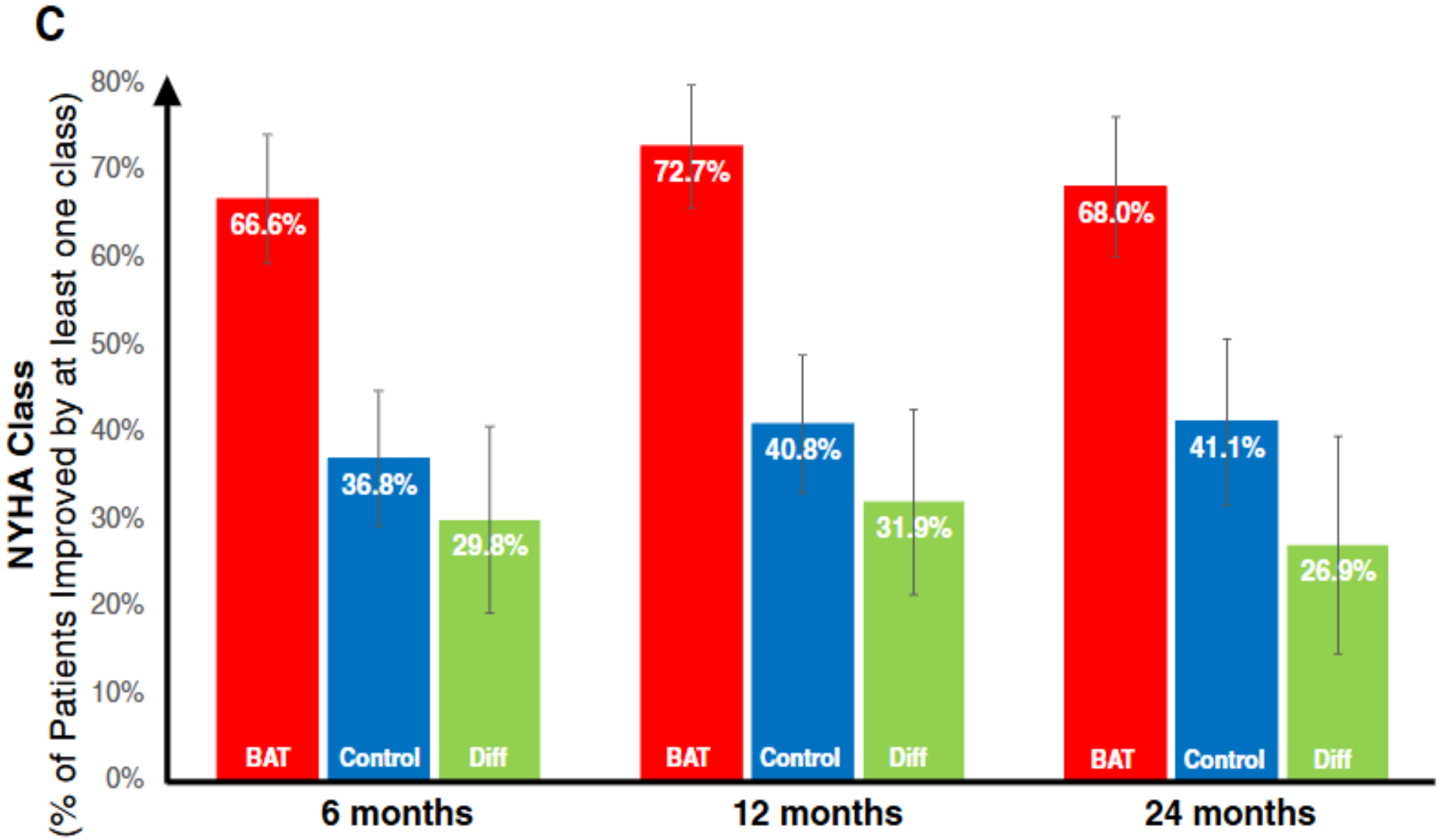


COMPOSITE ENDPOINTS

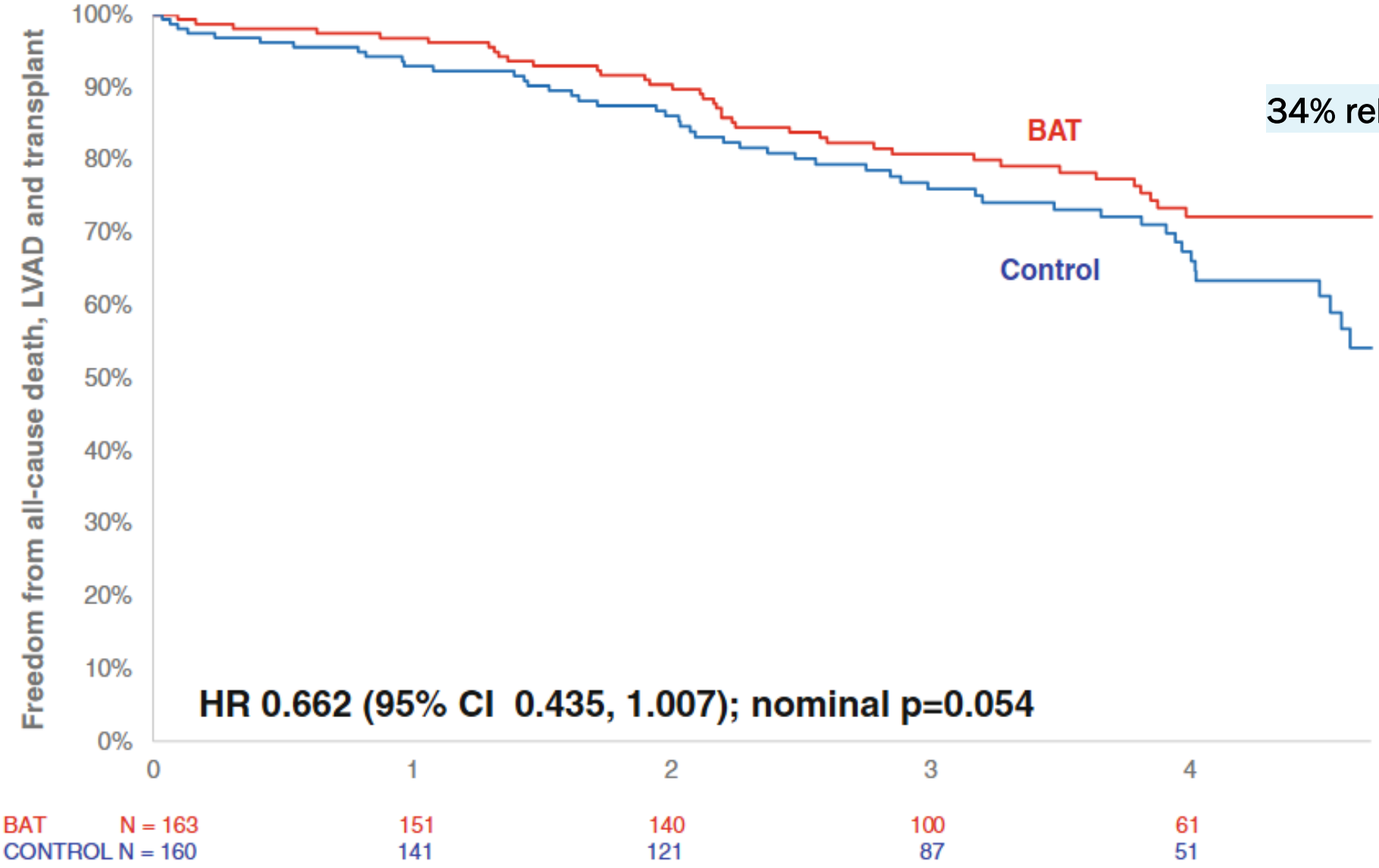




DURABILITY OF PATIENT CENTERED OUTCOMES



FREEDOM FROM ALL-CAUSE DEATH, TXP OR LVAD



34% relative risk reduction

LONG TERM SAFETY OUTCOMES

97% MANCE Free Rate

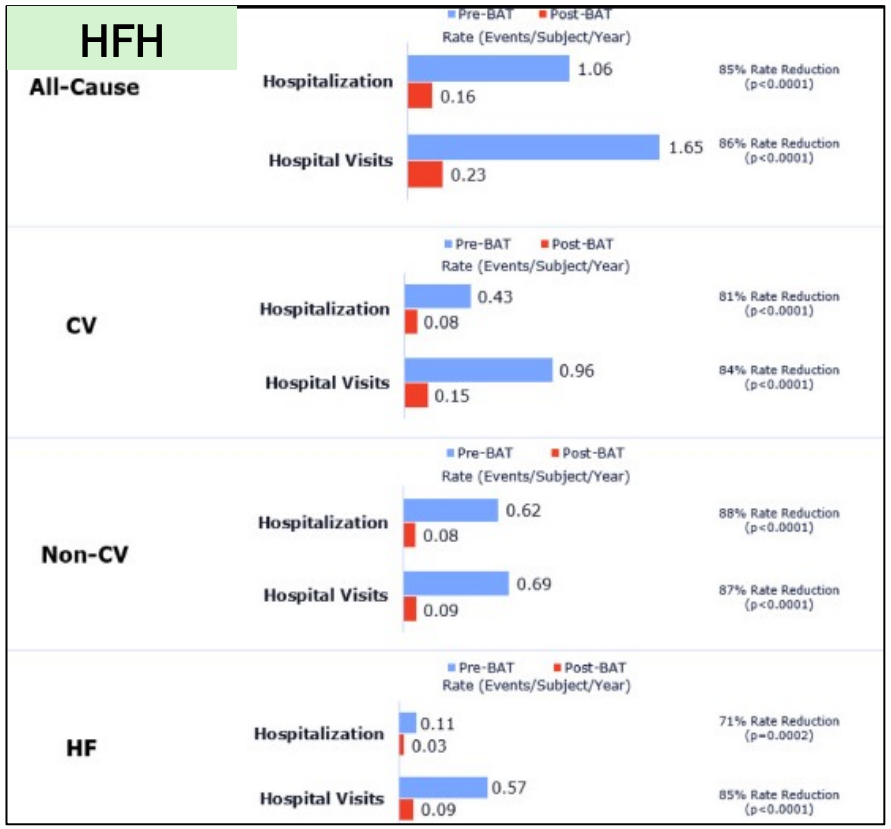
(154/159 pts implanted)

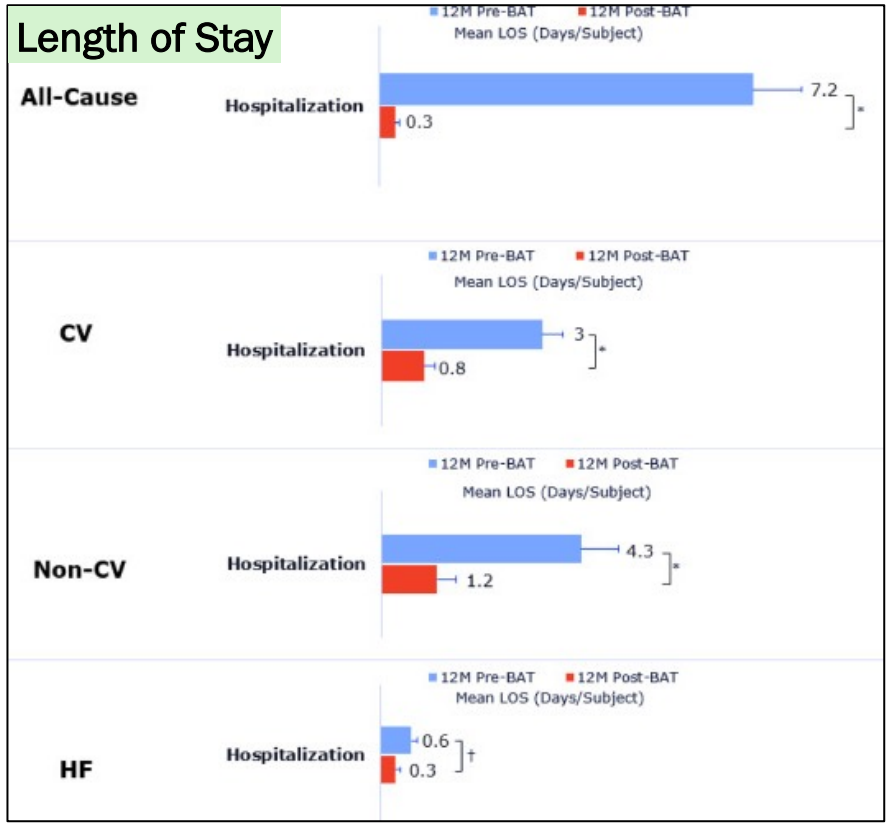
- 2 infections that needed explant
- 1 right neck pain that required lead repositioning
- 1 stroke
- 1 HFH

HEALTHCARE UTILIZATION

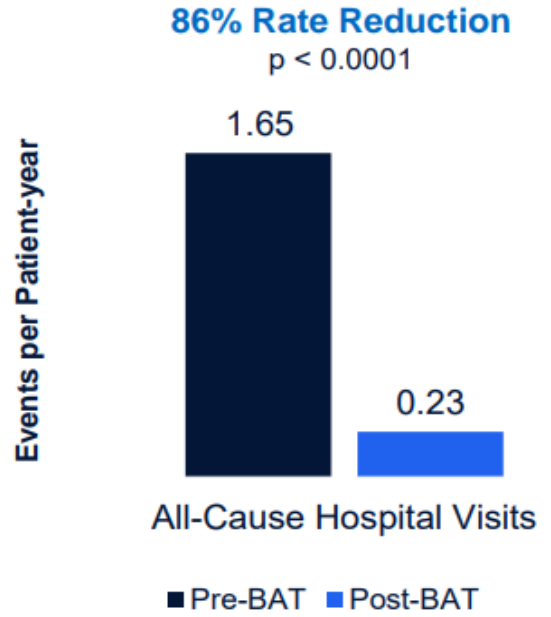
Abraham, J et al. 2025

- Premier Healthcare Chargemaster Database --> 1,300 healthcare facilities
- 306 patients, 66 yo (mean), 25.8% female, 21.2% Black
- Time Interval: 1/1/2016 and 06/30/2023 (12 months pre-implant to entire post-BAT interval)





Variable	N (%) or Mean ± SD
Age (years)	66.4 ± 12.1
Female	79 (25.8%)
Race	
Asian	3 (1.0%)
Black	65 (21.2%)
White	221 (72.2%)
Other	13 (4.2%)
Unable to Determine	4 (1.3%)
Ethnicity	
Hispanic or Latino	18 (5.9%)
Not Hispanic or Latino	269 (87.9%)
Unable to Determine	19 (6.2%)
NT-proBNP (pg/mL)	3180.8 ± 2594 (N=53)
eGFR	53.7 ± 20.3 (N=99)
Baseline Medical History	
Chronic Kidney Disease	85 (27.8%)
Diabetes Mellitus Type I	3 (1.0%)
Diabetes Mellitus Type II	106 (34.6%)
Coronary Artery Disease	131 (42.8%)
Myocardial Infarction	101 (33.0%)
Atrial Fibrillation	86 (28.1%)
Baseline Interventions and Surgical History	
PCI	85 (27.8%)
ICD/CRT-D	162 (52.9%)
CRT-P	56 (18.3%)
LVAD	3 (1.0%)
CABG	65 (21.2%)



Abraham J, et al. Real-World Analysis of Health Care Utilization With Baroreflex Activation Therapy for Heart Failure. J Card Fail. 2025 Aug;31(8):1349-1353

EFFECTS ON CPET

Yaranov, D et al, 2025 (TCT presentation) ~ Baptist Memorial Hospital, Memphis, TN

- 20 patients, CPET pre and 3+ months post Barostim

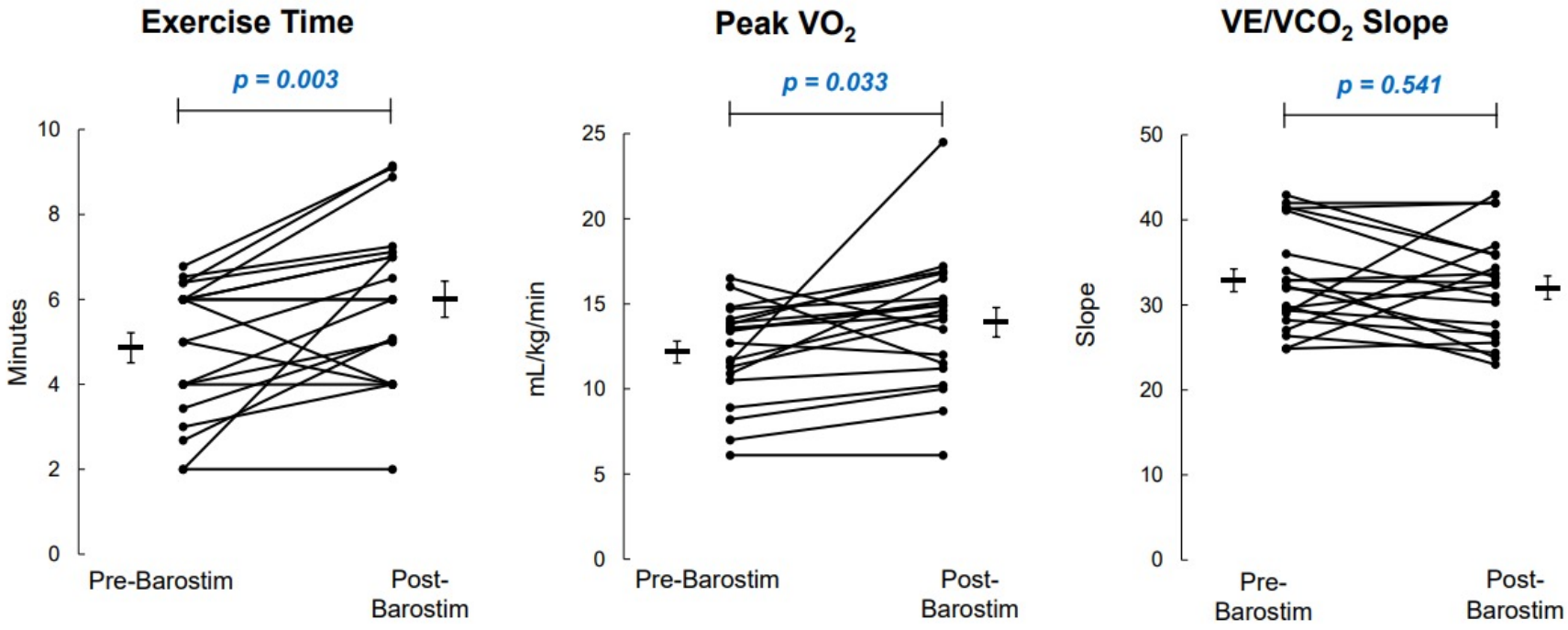
Baseline Characteristics

Variable	Mean ± SD or N (%)
Age (years)	55 ± 13
Gender: Female	7 (35%)
Race: White	15 (75%)
BMI (kg/m2)	30 ± 4
LVEF (%)	23 ± 5
NYHA Class III	18 (90%)

Variable	Mean ± SD or N (%)
eGFR <60 ml/min/1.73 m2	10 (50%)
NT-proBNP (pg/mL)*	386 (120.5,764.3)
Creatinine (mg/dL)	1.3 ± 0.5
Diabetes	12 (60%)
Coronary artery disease	12 (60%)
Atrial fibrillation	4 (20%)

*Results reported as median (IQR)

Results



- Exercise time increased from 4.9 ± 1.6 to 6.0 ± 1.9 minutes

  (Δ = 1.1 minutes; p = 0.003).
- Peak VO2 increased from 12.2 ± 2.9 to 13.9 ± 3.9 mL/kg/min

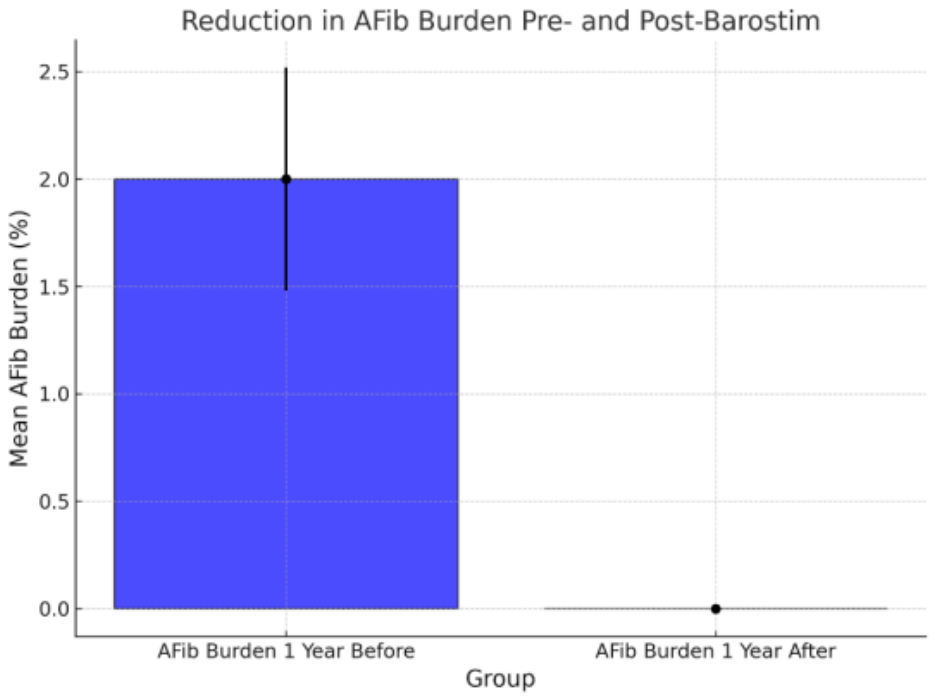
  (Δ = 1.7 mL/kg/min; p = 0.033).
- No change was observed in VE/VCO2 slope

  (Δ = -0.9; p = 0.541).

EFFECTS ON ARRHYTHMIAS

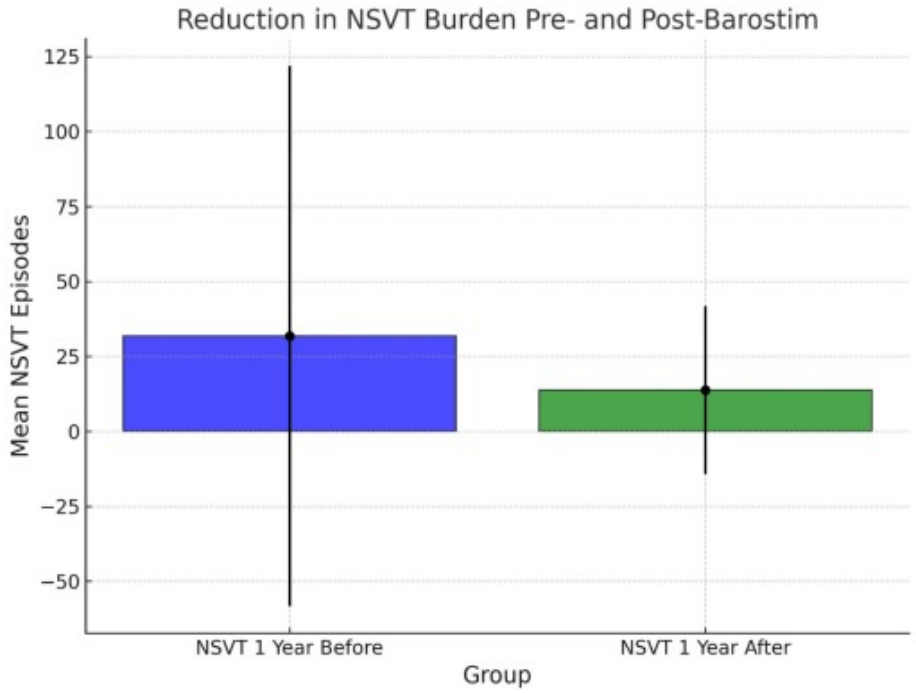
Single center experience, Prisma Health

AFib (n=28)



Group	Mean Burden (%)	Std Dev (%)
AFib Burden 1 Year Before	2.0	0.52
AFib Burden 1 Year After	0.0	0.005

NSVT



Group	Mean Episodes	Standard Deviation
NSVT 1 Year Before	31.79	90.13
NSVT 1 Year After	13.76	28.01

Northwell Intermediate Heart Failure Device Algorithm

***Symptomatic* HF, LVEF < 45%, on optimal GDMT**

↓

Not a CRT candidate OR CRT non-responder

No clinical improvement > 3-6 months post implant despite:
Bi-V pacing > 90%, appropriate LV lead placement, maintenance of sinus rhythm, and device optimization by EP team

↓

HF Risk Stratification
6MWT, CPET, Right Heart Catheterization

No high-risk features...evaluate EF

LVEF <25% | **LVEF 25-35%** | **LVEF 35-40%**

Consider BAT (Barostim)
If NT pro BNP < 1600, NYHA III or recent II, and no sub-cutaneous ICD

Consider CCM
if NYHA III
Evaluate risk of device related TR, especially if existing transvenous device (e.g PPM/ICD)

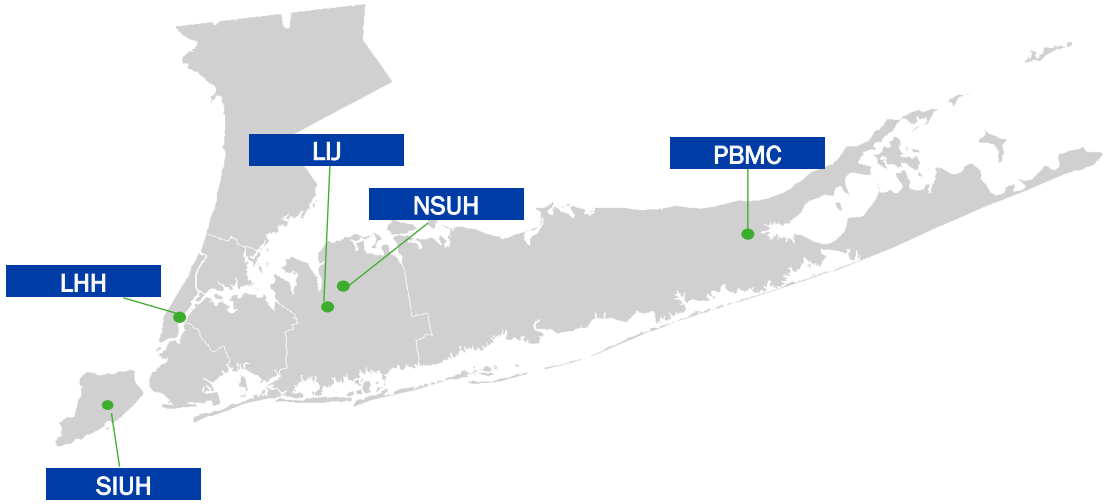
HIGH RISK FEATURES:
CI < 2.2
< 350 m on 6MWT
VO2 max < 14 mg/kg/min
or < 12 (on beta blocker)
VE/VCO2 slope > 34
NYHA class IV

Referral for LVAD or Heart Transplant Evaluation
(if life expectancy > 1 yr)

CCM = Cardiac Contractility Modulation
BAT = Baroreflex Activation Therapy

BAROSTIM @ NORTHWELL

Site	# Implanted	Primary Implanter
PBMC	16	John Kassotis (EP) Luis Santini (Vascular)
LHH	10	Stavros Mountantanokis (EP) Alfio Carrocio (Vascular)
NSUH	1	Dean Smith (CTS) James Gabriels (EP)
LIJ	4	Haisam Ismail (EP)
SIH	Coming soon	
TOTAL:	31	



Northwell Research Trials:

Systemwide database

- Anti-Inflammatory and Autonomic Effects of Baroreflex Activation Therapy in HFrEF
  - PI: LHH, Dr. Stavros Mountantonakis

- Optimizing the Management of Patients with HFrEF (Use of Barostim and Cardiomems)
  - PI: PBMC, Dr. John Kassotis

SUCCESS STORY

79yo M

- Ischemic CM s/p MI X 2 (age 40 and 60) followed by CABG (2019) and dual-chamber ICD (2022), AF, and HTN
- LVEF 35-40%, LVEDD 5.6cm, trace MR, mild TR, inferior WMA
- No HFH but did have inappropriate shocks for AF 4/2023

Barostim Implant Date: 6/14/2023, fully titrated by 11/29/23

Final Titration: Amplitude 8m A, PW 125, Frequency 40

	Pre BAT	Post BAT
6MWT	365m	514m
NYHA class	III	I
GDMT	Metoprolol XL 100mg QD	Metoprolol XL 100mg QD Ramapril 5mg daily Farxiga 10mg daily
Diuretics	none	none
Average BP	110/66	110/65 (@max titration)

A new love for life

After years on the sidelines, a novel heart implant changed everything for Randolph Gunzer.

"It's amazing. Barostim is one of those modern things that works — and I'm glad I did it."

— Randolph Gunzer

Since Gunzer received the Barostim device, he's never had another thought about turning off his defibrillator. Instead, he's focused on doing the things he loves, whether it's something simple, like taking his 18-year-old rescue dog, Axl Rose, to the dog park, or a bigger adventure.

"I feel so much younger now"

In fact, just eight months after the Barostim procedure, Gunzer traveled to Austria with his partner Cecilia. He walked up a steep mountain road while sightseeing in the Alps and the only thing that made him feel breathless were the views.

"I went up this thing with no effort at all. I mean, my legs felt a little tired, but my heart felt great," he says.