THE NUTS AND BOLTS OF REAL WORLD IMPLANTABLE HEMODYNAMIC MONITORING

HEART FAILURE UPDATE 2019

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Background

- Burden of heart failure is well known to this audience (as is the cost)
  - Modest prognostic improvement over the years
  - >$2.8 billion/year[1]
- The cost, morbidity and mortality of HF are intimately linked to hospitalizations [1,2]
- Hospitalizations represent the most severe form of decompensation and rehospitalization rates remain high
- >90% of hospitalizations arise due to congestion[1]

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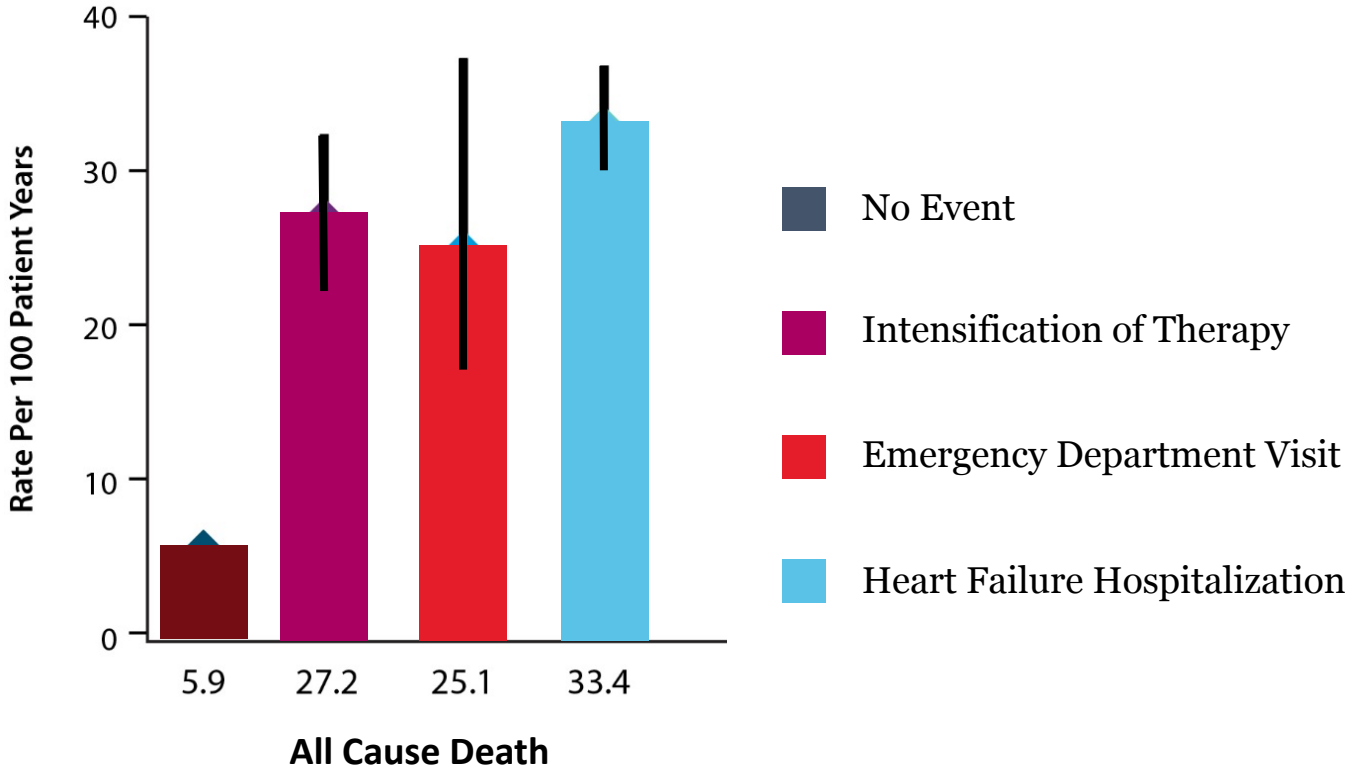
1. Heart and Stroke Foundation of Canada: 2016 Report on the Health of Canadians
2. Circulation Heart Failure 2014;7(4):590-595

Decompensation Events Requiring More Intensive Therapy are Associated with Higher Mortality Risk



All decompensation events were associated with a statistically significant increase in mortality risk.

Okumura N, et al. *Circulation*, 2016;133:2254-2262.

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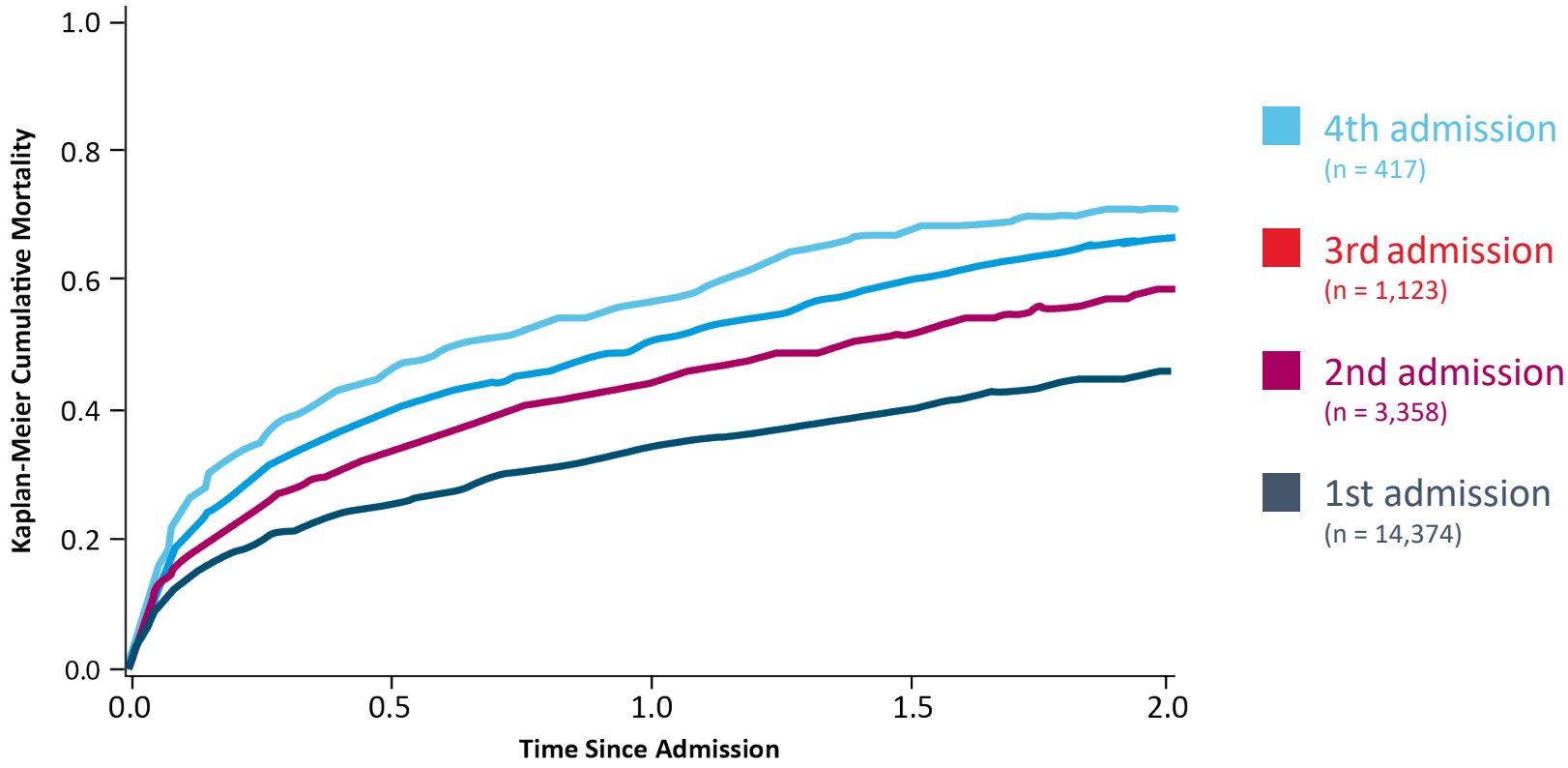
Long-term Mortality Risk Increases with Multiple Hospitalizations



Kaplan-Meier cumulative mortality curve all-cause mortality after each subsequent hospitalization for HF.

Setoguchi S, Stevenson LW, Schneeweiss S, *Am Heart J,* 2007;154:260-264.

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Prior attempts of remote-monitoring in HF

Physical examination: low sensitivity, late signs

Weight & symptoms or blood pressure:

- TELE-HF trial: no effect on HF hospitalizations
  - Telephone based voice response system with higher risk population than TIM-HF
  - Adherence was poor
- TIM-HF trial: no effect HF hospitalizations
  - Bluetooth enabled device following BP, weight, 3-lead ECG
  - Low risk HF population

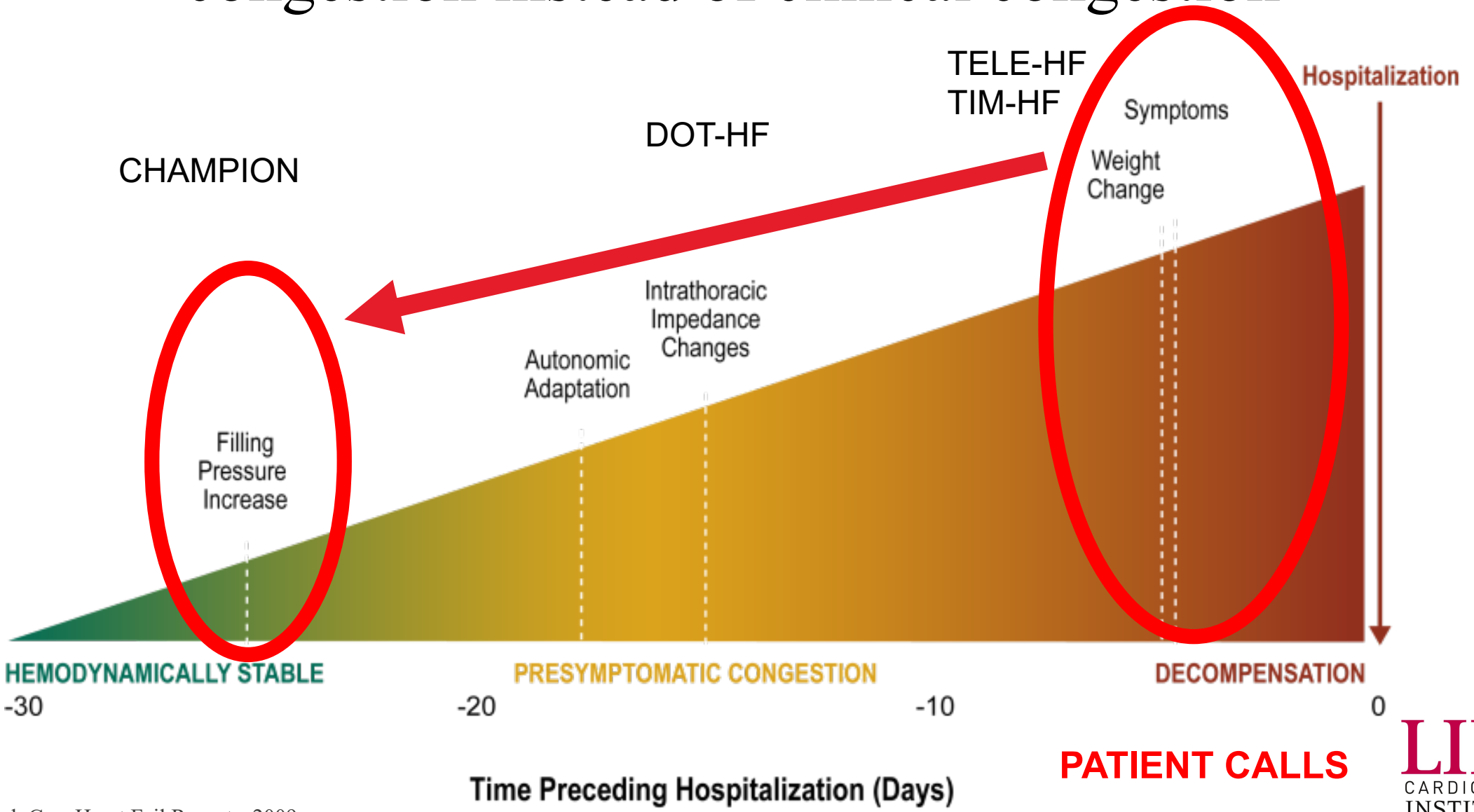
Intrathoracic impedance (optivol):

- DOT-HF trial: increase in HF hospitalizations

TRIAL	N	PARAMETER MONITORED	IMPACT ON HF HOSPITALIZATION	JOURNAL
TELE-HF[1]	1,653	Signs/symptoms, daily weights	None	*The New England Journal of Medicine, 2010*
TIM-HF[2]	710	Signs/symptoms, daily weights	None	*Circulation, 2011*
TEN-HMS[3]	426	Signs/symptoms, daily weights, BP, nurse telephone support	None	*Journal of the American College of Cardiology, 2005*
BEAT-HF[4]	1,437	Signs/symptoms, daily weights, nurse communications	None	*American Heart Association, 2016*
INH[5]	715	Signs/symptoms, telemonitoring, nurse coordinated DM	None	*Circulation Heart Failure, 2012*
DOT-HF[6]	335	Intrathoracic impedance with patient alert	Increased	*Circulation, 2011*
Optilink[7]	1,002	Intrathoracic impedance	None	*European Journal of Heart Failure, 2011*
REM-HF[8]	1,650	Remote monitoring via ICD, CRT-D or CRT-P	None	*European Society of Cardiology, 2017*
MORE CARE[9]	865	Remote monitoring of advanced diagnostics via CRT-D	None	*European Journal of Heart Failure, 2016*
Total	8,793			

1. Chaudhry SI, et al. *N Engl J Med*, 2010.
2. Koehler F, et al. *Circulation*, 2011.
3. Cleland JG, et al. *J Am Coll Cardiol*, 2005.
4. Ong MK, et al. *JAMA Intern Med*, 2016.
5. Angermann DE, et al. *Circ Heart Fail*, 2012.
6. van Veldhuisen DJ, et al. *Circulation*, 2011.
7. Brachmann J, et al. *Eur J Heart Fail*, 2011.
8. Cowie MR, *ESC,* 2016.
9. Boriani G, et al. *Eur J Heart Fail*, 2016.

The way forward in telemonitoring is to target hemodynamic congestion instead of clinical congestion



PATIENT CALLS

Adamson PB, et al. Curr Heart Fail Reports, 2009.

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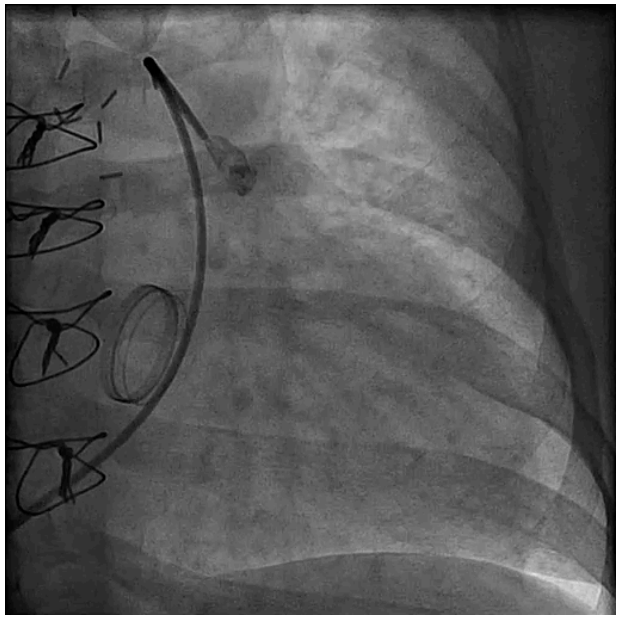
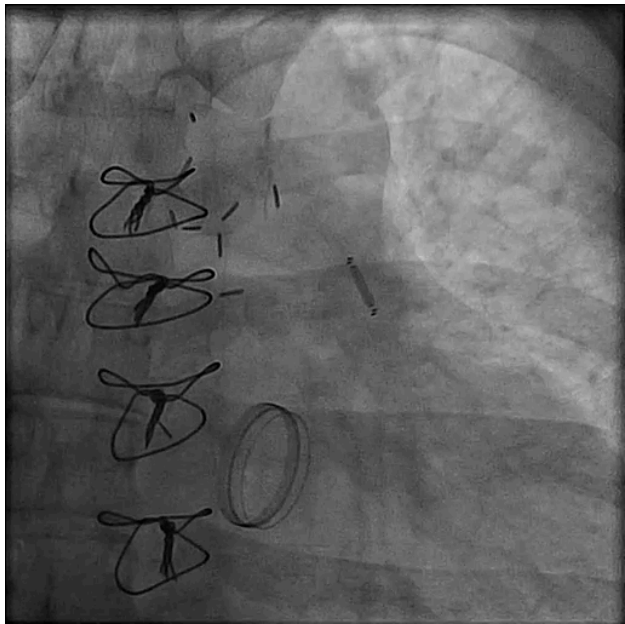
PULMONARY ARTERY PRESSURE MONITORING





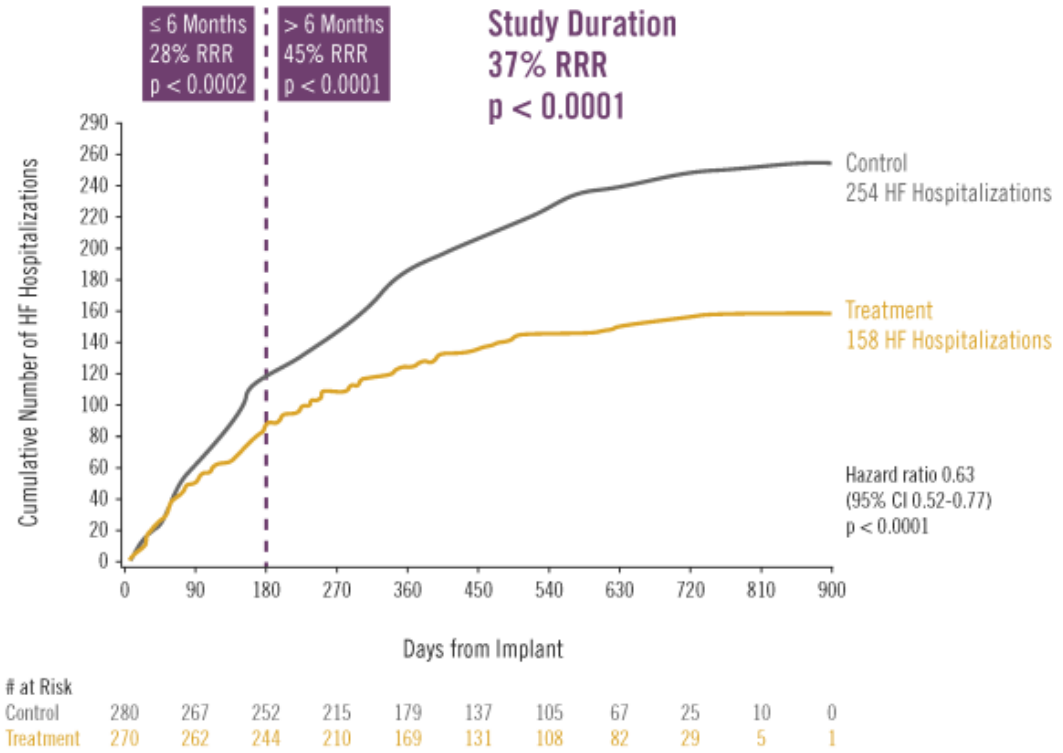
- Electrical resonance circuit – sensor measures PA pressure
- Distension of the membrane corresponds to a pressure shift (sPA, dPA)
- No wires or battery
- Inserted via right heart cath
- Ideal target is left lower/posterior pulmonary artery
- Minor complications comparable to right heart cath
- Completely endothelializes with ASA/Plavix x 1 month, then ASA
- Systemic anticoagulation held and restarted (no ASA,Plavix)

CHAMPION Clinical Trial: PA Pressure-guided Therapy Reduces HF Hospitalizations

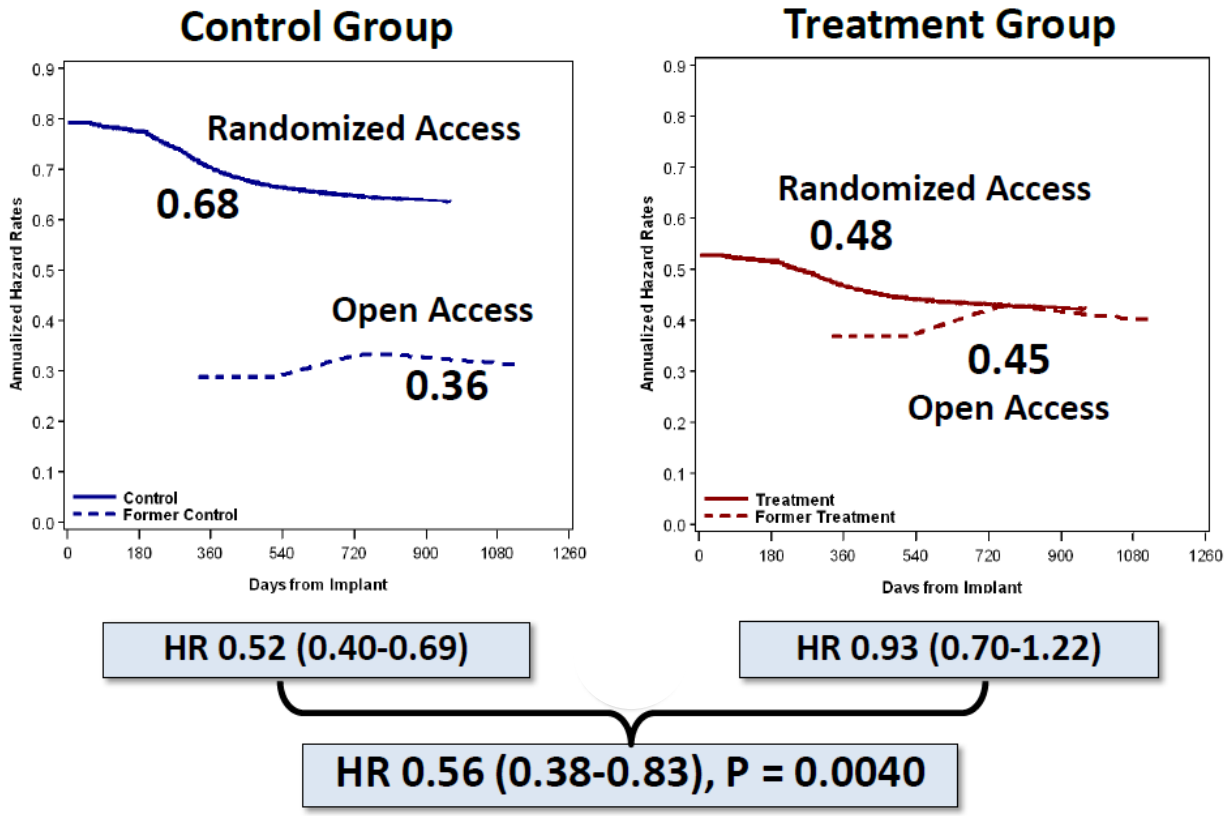
PA monitoring reduced HF hospitalizations by 37% (p<0.001) at mean 15 months follow –up

NNT = 4

MLWHF >5 point reduction



Abraham WT, et al. Lancet, 2011



Abraham et al., Lancet 2016

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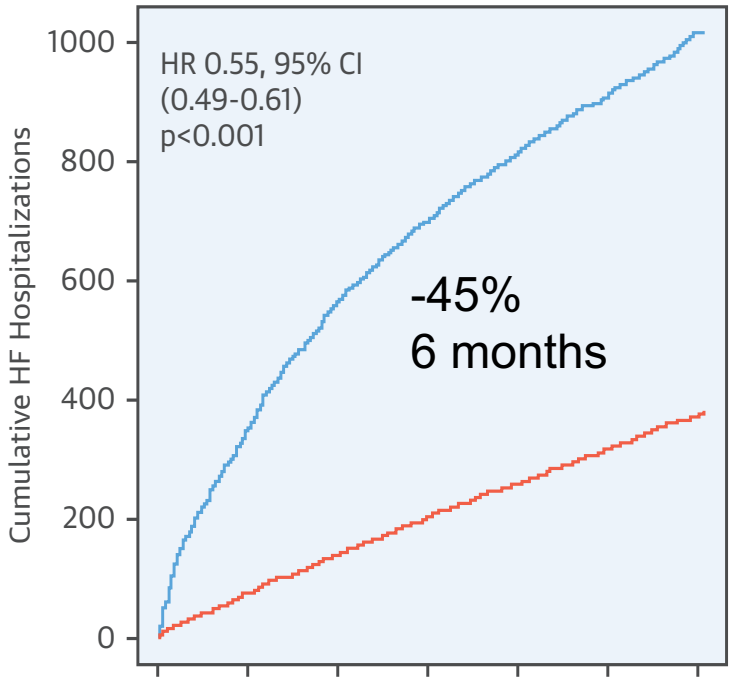
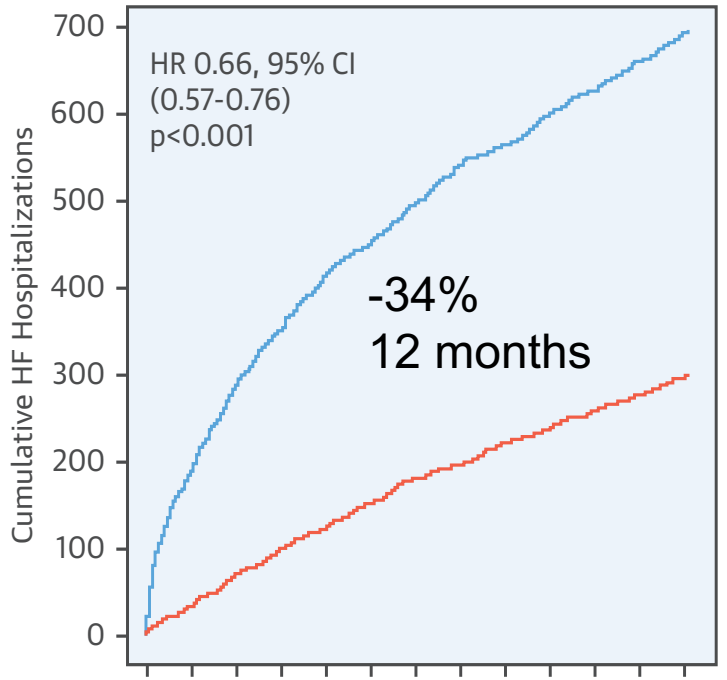
CardioMEMS Real World Data



Number at risk

Pre-implant	*1114*	*1114*	*1114*	*1114*	*1114*	*1114*	*1114*
Post-implant	*1114*	*1080*	*1049*	*1019*	*1002*	*976*	*955*



Number at risk

Pre-implant	*480*	*480*	*480*	*480*	*480*	*480*	*480*
Post-implant	*480*	*450*	*435*	*409*	*394*	*373*	*357*

Pre-implant HFH Post-implant HFH

1114 Medicare patients

Desai et al. JACC 2017;69(19) 2357-2365

Ambulatory hemodynamic monitoring added to standard care reduces HFH
Real world safety and effectiveness comparable to trial data
Further validates clinical trial evidence

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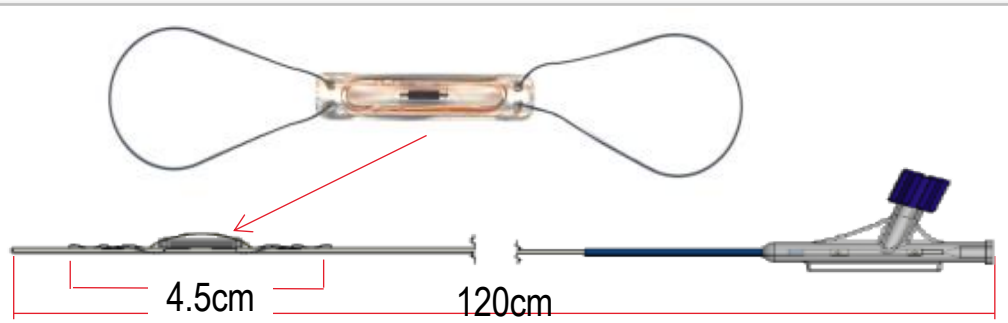
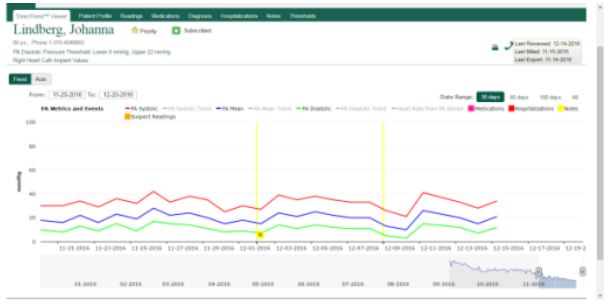
CardioMEMS™ HF System Overview

PA Pressure Sensor on Catheter Delivery System



Patient and Hospital Electronics System

Merlin.net™ Patient Care Network



sPA
dPA
mPA
PA trend
Heart rate
Adherence

Aim: Maintain normal mean PA 10-25mmHg + euvolemia state
Address accordingly with diuretics or vasodilators

IMPLEMENTING a CardioMEMS™ HF System program:

Patient Selection

1 2 3

Identify patients most likely to benefit.

Health Canada

NYHA III

IRRESPECTIVE OF LVEF

Clinical congestion

Previous HF hospitalization

ALSO CONSIDER…..

Need to respond to diuretics
Need to have blood pressure to work with
Need to be compliant and adherent
Avoid Stage D Heart failure - “end stage”

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Calgary Invasive Heart Failure Monitoring Program

Inclusion

- NYHA III chronic HF on maximally tolerated medical therapy
  - HFpEF and HFrEF eligible; no LVEF requirement
- Hospitalization for HF in past 12 months

Considerations

- Ideally ≥ 2 hospitalizations in past 12 months
- Frequent outpatient diuretic adjustments (≥2 per month for 3 consecutive months)
- Frequent decompensations requiring outpatient IV diuretics
- Difficult clinical volume assessment
- Geographic limitations impacting clinic access

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Calgary Invasive Heart Failure Monitoring Program

Exclusion

- eGFR < 25ml/kg/m^2
- Contraindication to Plavix + ECASA
- Health illiteracy
- History of non-compliance
- Inability to meet home technology requirements for remote transmission
- Active infection
- Recurrent PE
- Unable to tolerate right heart catheterization
- Mechanical right heart valves
- Known coagulation disorders
- Recent implant CRT ± D (<3months)
- Chest circumference >165cm (axillary level)
- Numerous retained pacemaker leads

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IMPLEMENTING a CardioMEMS™ HF System program

- Identify Implant Workflow
  - Where
    - Heart Function Clinic at Foothills Medical Centre
    - All nurses educated
  - What:
    - Pre procedure education visit, consent procedure, baseline assessments
    - QoL, 6MWT, financial assessment, labs, CXR
    - Anticoagulation assessment
  - Cath Lab Team trained and dedicated. Post procedure patient education and transmission
  - Nurses and MD monitor pressures MERLIN.net
  - Baseline RHC to correlate PAd to PCWP

- **Optimization Phase**
  - Medication adjustments to achieve target PA pressures
    - Diuretics, vasodilators
  - HF nurses contact patient with medication changes, arrange weekly labs during this phase
  - Daily assessment of pressures/ Treat trends over 3 days
  - Weekly team communication
  - PA pressures incorporated into HF nurse workflow
- Target Goal PA Pressures:
  - PA Pressure Systolic 15 – 35 mmHg
  - PA Pressure diastolic 8 – 20 mmHg
  - PA Pressure mean 10 – 25 mmHg

- **Maintenance Phase**
  - Prespecified PA range can be set to deliver email notification ONLY when PA readings fall outside a certain range
  - Algorithms for nurse led management can be developed

34F with Shone syndrome

- Patch aortoplasty for coarcation age 5
- Bicuspid normally functioning aortic valve
- Mechanical MV replacement September 2015 (UAH) – mitral stenosis
  - MVR 23mm On-X mechanical valve
    - Dysmorphous MV, hypoplastic aorta, well functioning bicuspid aortic valve
- Paroxysmal Atrial fibrillation
- Obesity

- Presented to Calgary transplant group for Heart Transplant, Heart/Lung
  - CPET submaximal: VO2 12ml/min/kg VE/VCO2 slope 50
  - TTE July 2018 LVEF 40% LVEDD 41mm, MV P/M gradients 33 / 9, PHT normal, HR76bpm, PHT, mild-mod RV dysfunction
  - Level 3 sleep testing– OSA confirmed – initiated CPAP
  - Severe pulmonary HTN on previous cath

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R+L with NO June 29 2018

PA 87/35/54mmHg

PCWP 32/40/32mmHg

RA 18/17/16mmHg

CO 4.26L/min CI 2.16L/min/m^2 (F)

3.83L/min CI 1.94L/min/m^2 (TD)

TPG 22 PVR 5.16 (F) 5.74 (TD)

SVR 1671 dynes*s*cm^5

MV gradient : 11mg, MVA 1.16cm^2

LVEDP 32mmHg

40ppm NO

PA. 81/36/50mmHg

PCWP 41/71/42mmHg

CO/CI(TD) 3.96L/min CI 2.01L/min/m^2

TPG 8 (owing to severely elevated PCWP)

PVR 2.02WU

BP128/64(88) mmHg

80ppm NO

PA 68/30(41)mmHg

PCWP 40/68/40mmHg

CO/CI(TD) 3.48L/min CI 1.77L/min/m^2

TPG 1

PVR <1WU

BP 132/62(89) mmHg

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- Outpatient attempts at oral therapy optimization
- LVEF 40%, occluded Circumflex artery identified (likely occurred during surgery 2015)
- Symptoms improved from NYHA IV – NYHA III
- Progress stalled after 2 weeks and admitted to hospital for inpatient treatment
- Admitted August 7 2018

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Management options being considered

1) Heart Lung Transplantation

Young, VO2 concerning, PHTN

Seemed a little aggressive this early on

2) MV excision with LVAD placement

Small ventricle

BTC by reducing pulmonary pressures?

Seemed a little aggressive this early on

3) Continue attempts at medical optimization

Is this MV really a problem???

+++LVEDP, LVEF 40% by echo

Is this all heart failure??

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- CardioMEMS implant September 7 2018
  - PA: 65/29(43) mmHg
  - PCWP 27/38/27 mmHg
  - RA 14/12/10 mmHg

PAd is the target for therapy with CardioMEMS therefore correlation with PCWP at implant RHC is important in management goals

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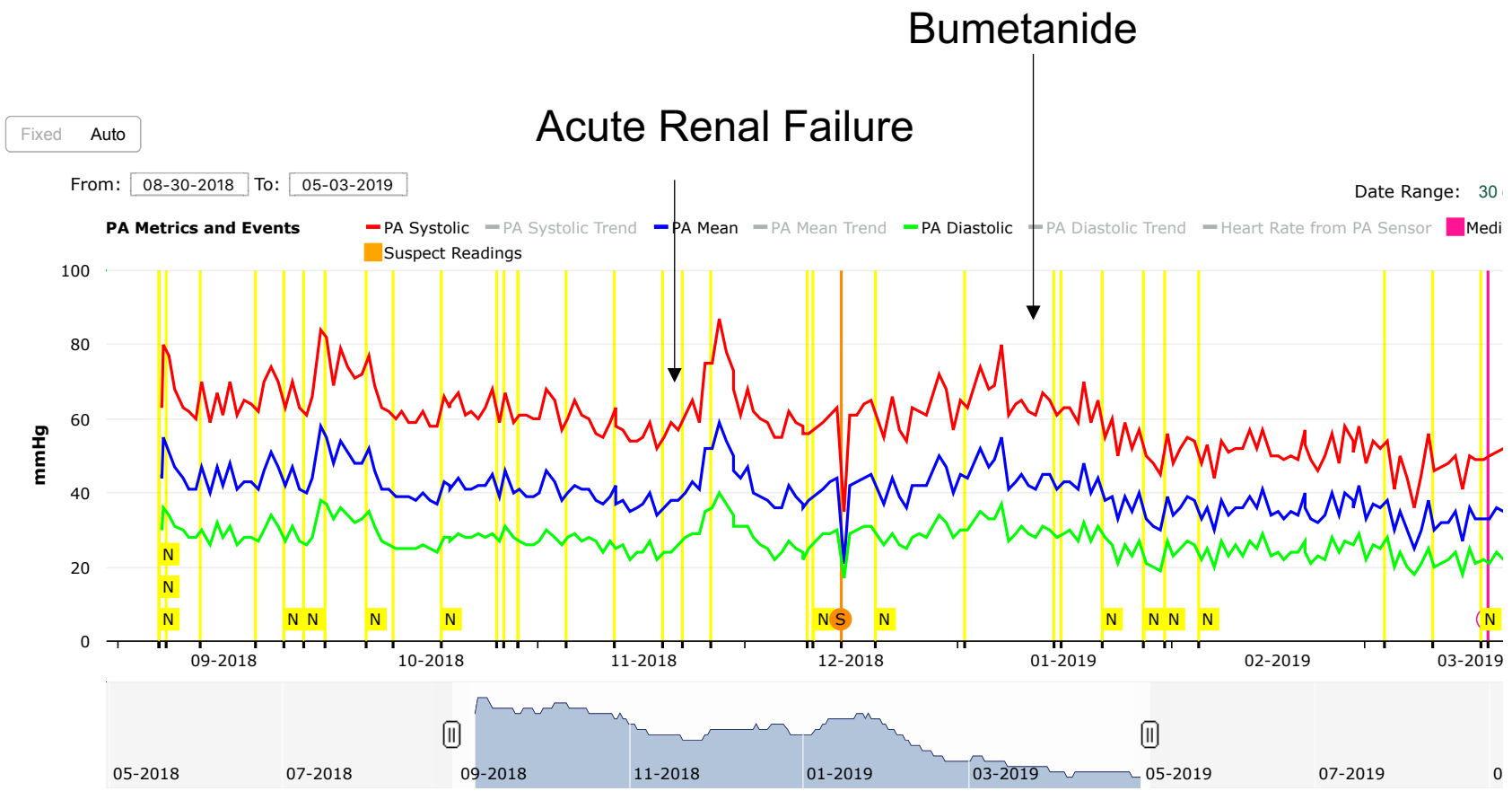
What we learned in 7 months

- CardioMEMS enables frequent medication changes
- Individualized therapy
  - ACEi, Entresto didn't improve much
  - Stalled on Lasix, spiro, zaroxlyn
  - Responded to nitrates, bumetanide, zaroxlyn, spironolactone
- Email communication with no clinic visits in 7 months
- NYHA II from NYHA IIIB
- 50% reduction in PA pressures
- VO2 max 12ml/min/kg VECO2 50 – May 2018
- VO2 max 14.7ml/min/kg VEVCO2 36 – January 2019
- VO2 max 15.5 ml/min/kg VEVCO2 33 – May 2019
- Requires massive doses of diuretics
- May 2019
  - Coreg 12.5mg BID
  - IMDUR 240mg BID
  - Bumex 2mg BID EOD, 3mg/2mg EOD
  - Zaroxlyn 2.5mg EOD
  - Spironolactone 50mg BID



- ***Restrictive CM related to her underlying congenital disease***

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Patient JL

- 73year old female
  - Afib, Hypothyroid, HTN, dyslipidemia, nonsmoker, no DM, no known CAD
  - GI Bleed with NOAC (GI angiodysplasia on colonscopy)
  - Bronchiectesis 2018 with pseudomonas on bronchoscopy
  - OSA intolerant to CPAP
- Active independent complaint patient
- Lives in assisted living, drives and travels with her ‘girls club’
- HFpEF diagnosed June 2016
  - SOB, clinical congestion with JVD
  - Echo
    - Normal LV systolic function
    - Mild LVH (septum 12mm). LV Mass 101.2g/m2
    - RV normal
    - No structural heart disease

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Patient JL

- 3 episodes of congestion in 2017 requiring intensification of diuretics
  - 1 requiring outpatient IV
- HR controlled by Holter monitor
- Persistent NYHA III symptoms 2018
- DC cardioversion for Afib March 2018
  - No effect on symptoms
  - Afib recurred 9 weeks later, left alone
- Pulmonary investigation for SOB/Abn CXR
  - Bronchiectesis with resultant moderate obstructive lung dz
- DOAC stopped due to recurrent GI bleeding
- Hospitalized May 2018 for ADHF

CardioMEMS implant September 7 2018

PA: 55/22(36)mmHg

PCWP: v25mmHg, mean18mmHg

RV: 58/3mmHg (edp 7)

RA: 8mmHg

CO: 4.3L/min CI: 2.5L/min/m^2

TPG: 18 PVR 4.18WU

- Plavix and ASA x 1 month – no GI bleeding

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10-26-2018, 09:10 AM	53 mmHg	27 mmHg	38 mmHg	104 bpm
10-25-2018, 08:55 AM	48 mmHg	26 mmHg	35 mmHg	114 bpm
10-24-2018, 07:31 AM	52 mmHg	27 mmHg	38 mmHg	114 bpm
10-23-2018, 08:17 AM	47 mmHg	26 mmHg	35 mmHg	104 bpm
10-22-2018, 07:54 AM	49 mmHg	26 mmHg	35 mmHg	108 bpm
10-21-2018, 09:43 AM	47 mmHg	24 mmHg	34 mmHg	107 bpm

Infiltrate on CXR
Treated with Ax

NYHA II from NYHA III
No clinical decompensations in 7 months

Spiro 25

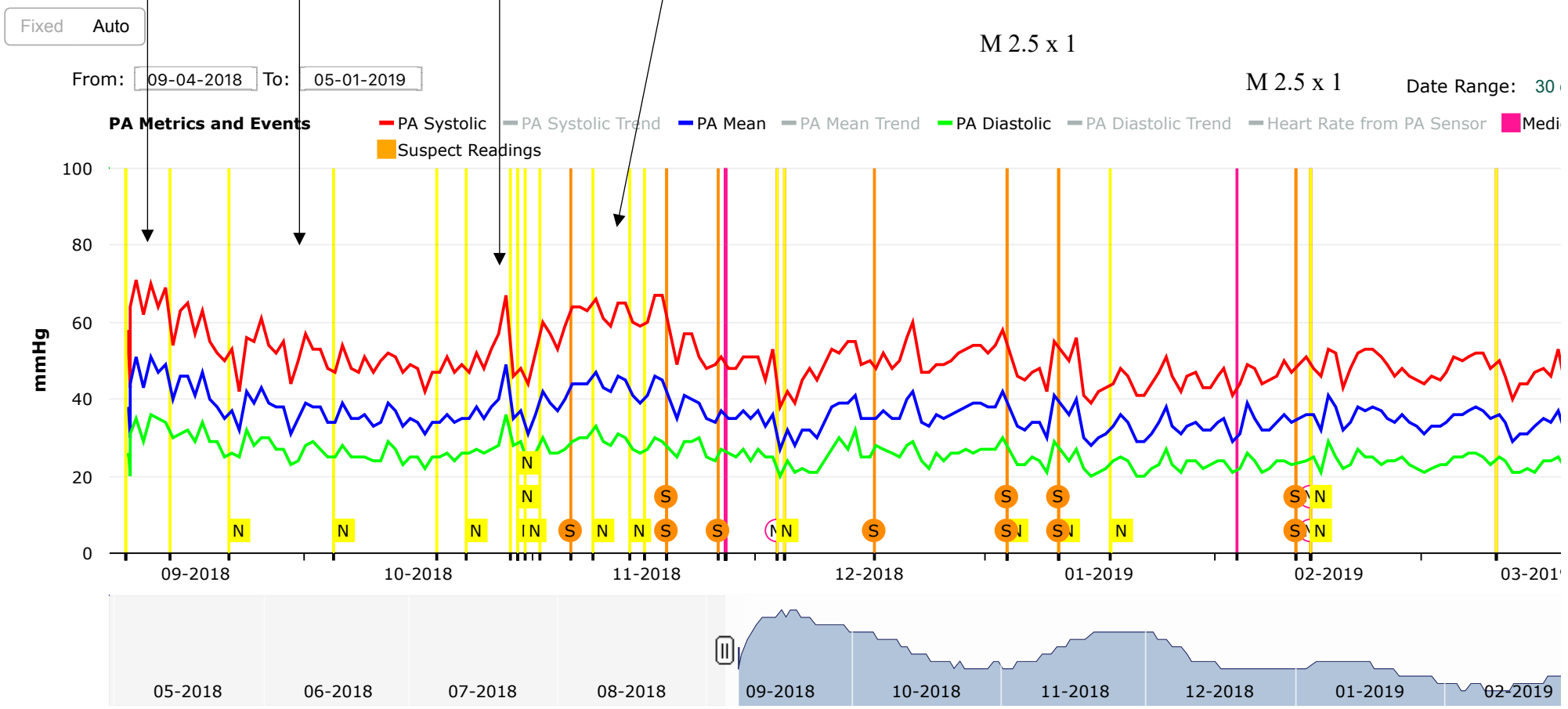
Spiro 50

M 2.5 x 1 dose
Diltiazem 240OD

Cough, tired, SOB

M 2.5 x 1

M 2.5 x 1



Benefits of PA pressure monitoring

- Takes the guess work out of things
- Personalize/tailor/individualize heart failure therapies
- Great opportunity to provide heart failure care to geographically remote/underserviced patients/areas
- Great for challenging patients
    - Difficult volume assessment, highly symptomatic with confirmed congestion, the cloud of comorbidities
- Perhaps the only intervention thus far demonstrating benefit for HFpEF
- COMPLIANT PATIENTS ARE KEY

Much to Learn…and Work Through

- Unlikely to be beneficial to a broad population of HF patients
    - Stable patients benefit?
- Cost!! Preventing HF hospitalizations may not be attractive business case.
    - “if a HF patient isn’t in the bed, someone else is”
    - Expensive technology that is difficult to afford in our system
    - More outcomes data is needed
- How best to incorporate this in the Canadian Context

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CardioMEMS in the Canadian Context

- Clearly improves HF management

  Hemodynamic congestion precedes clinical congestion

  Objective information to help tailor and individualize therapy

  Effects of therapy can be seen within days

  Patient engagement and self care

- Pressure feedback changes your practice

- Cost. Everything's expensive with fixed hospital budgets/Difficult administrative challenge. "If your heart failure patient isn't in that bed, another patient is…." Patient outcomes are priority.

- Who will MOST benefit

  Remote Monitoring applied broadly to a patient population is unlikely to be beneficial (and certainly not cost-effective)

  RPM should be:

  1) targeted to at risk patients

  2) used to directly improve patient care

- We need to work together to integrate this technology into our healthscape for the

- betterment of our patients

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THANK YOU!