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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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.

Long-term Mortality Risk Increases with Multiple Hospitalizations

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

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
  - Intrathoracic impedance with patient alert

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>N</th>
<th>PARAMETER MONITORED</th>
<th>IMPACT ON HF HOSPITALIZATION</th>
<th>JOURNAL</th>
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<tbody>
<tr>
<td>TELE-HF</td>
<td>1,653</td>
<td>Signs/symptoms, daily weights</td>
<td>None</td>
<td>The New England Journal of Medicine, 2010</td>
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<td>TIM-HF</td>
<td>710</td>
<td>Signs/symptoms, daily weights</td>
<td>None</td>
<td>Circulation, 2011</td>
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<td>TEN-HMS</td>
<td>426</td>
<td>Signs/symptoms, daily weights, BP, nurse telephone support</td>
<td>None</td>
<td>Journal of the American College of Cardiology, 2005</td>
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<td>BEAT-HF</td>
<td>1,437</td>
<td>Signs/symptoms, daily weights, nurse communications</td>
<td>None</td>
<td>American Heart Association, 2016</td>
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<td>INH</td>
<td>715</td>
<td>Signs/symptoms, telemonitoring, nurse coordinated DM</td>
<td>None</td>
<td>Circulation Heart Failure, 2012</td>
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<td>DOT-HF</td>
<td>335</td>
<td>Intrathoracic impedance with patient alert</td>
<td>Increasedmission</td>
<td>Circulation, 2011</td>
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<td>Optilink</td>
<td>1,002</td>
<td>Intrathoracic impedance</td>
<td>None</td>
<td>European Journal of Heart Failure, 2011</td>
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<tr>
<td>REM-HF</td>
<td>1,650</td>
<td>Remote monitoring via ICD, CRT-D or CRT-P</td>
<td>None</td>
<td>European Society of Cardiology, 2017</td>
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<td>MORE CARE</td>
<td>865</td>
<td>Remote monitoring of advanced diagnostics via CRT-D</td>
<td>None</td>
<td>European Journal of Heart Failure, 2016</td>
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<td>Total</td>
<td>8,793</td>
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The way forward in telemonitoring is to target hemodynamic congestion instead of clinical congestion.

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 et al., Lancet 2016
CardioMEMS Real World Data

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

**PA Pressure Sensor on Catheter Delivery System**

**Patient and Hospital Electronics System**

**Merlin.net™ Patient Care Network**

Aim: Maintain normal mean PA 10-25mmHg + euvolemia state
Address accordingly with diuretics or vasodilators
IMPLEMENTING a CardioMEMS™ HF System program:

Patient Selection

1. 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”
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
Calgary Invasive Heart Failure Monitoring Program

Exclusion

• eGFR < 25ml/kg/m²
• 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
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 coarctation 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
R+L with NO June 29 2018

40ppm NO

PA. 81/36/50mmHg
PCWP 41/71/42mmHg
CO/CI(TD) 3.96L/min CI 2.01L/min/m²
TPG 8 (owing to severely elevated PCWP)
PVR 2.02WU
BP128/64(88) mmHg

PA 87/35/54mmHg
PCWP 32/40/32mmHg
RA 18/17/16mmHg
CO 4.26L/min CI 2.16L/min/m² (F)
   3.83L/min CI 1.94L/min/m² (TD)
TPG 22 PVR 5.16 (F) 5.74 (TD)
SVR 1671 dynes*s*cm⁵
MV gradient : 11mg, MVA 1.16cm²
LVEDP 32mmHg

80ppm NO

PA 68/30(41)mmHg
PCWP 40/68/40mmHg
CO/CI(TD) 3.48L/min CI 1.77L/min/m²
TPG 1
PVR <1WU
BP 132/62(89) mmHg
• 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
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??
• 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
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 VEVO2 50 – May 2018
- VO2 max 14.7ml/min/kg VEVO2 36 – January 2019
- VO2 max 15.5 ml/min/kg VEVO2 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
Patient JL

- 73-year-old female
  - Afib, Hypothyroid, HTN, dyslipidemia, nonsmoker, no DM, no known CAD
  - GI Bleed with NOAC (GI angiodysplasia on colonoscopy)
  - Bronchiectasis 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
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
  - Bronchiectasis with resultant moderate obstructive lung dz

- DOAC stopped due to recurrent GI bleeding

- Hospitalized May 2018 for ADHF
PA: 55/22 (36) mmHg
PCWP: v25 mmHg, mean 18 mmHg
RV: 58/3 mmHg (edp 7)
RA: 8 mmHg
CO: 4.3 L/min  CI: 2.5 L/min/m²
TPG: 18 PVR 4.18 WU

- Plavix and ASA x 1 month – no GI bleeding
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

Infiltrate on CXR
Treated with Ax
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
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