

HEMODYNAMIC MONITORING DEVICES IN HEART FAILURE

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Presenter Disclosure Information

HEMODYNAMIC AMBULATORY MONITORING IN HEART FAILURE

ALAN B MILLER MD

I will discuss off label use and/or investigational use in my presentation.

I have financial relationships to disclose:

Employee of: university of florida

Consultant for: st judes medical, novartis, biocontrol, pfizer, nih, respicardia, sensible medical, celadon, Covance, Lilly.

Stockholder in:none

Research support from: ccs-otsuka

Honoraria from:none

Speaker bureau:none

ENDPOINT COMMITTEES— ARE THEY NEEDED?

- Provide consistency
- Guided by protocol
- Report to the steering committee
- Provide data to the DSMB which determines the course of the study
- Blinded so not biased regarding outcome

ADJUDICATE

- To hear-determine-and settle (a case) by judicial procedure

ENDPOINT METHODOLOGY

- Development of charter
- Definitions-compatible with protocol
- Process-face-to-face; fax; phone; fed-ex; virtual; combination
- Need-source documentation

ENDPOINT COMMITTEE COMPOSITION

- Homogeneous group of heart failure specialists
- Heterogeneous regarding academic/practice
- “Chemistry” integral to the process
- Commitment to the task

Compass HF

- Class III and IV
- Lead with sensor at tip implanted like pacemaker
- All patients implanted
- All patients transmitted data

Chronicle

Introduction to Hemodynamic Monitoring (HMM)

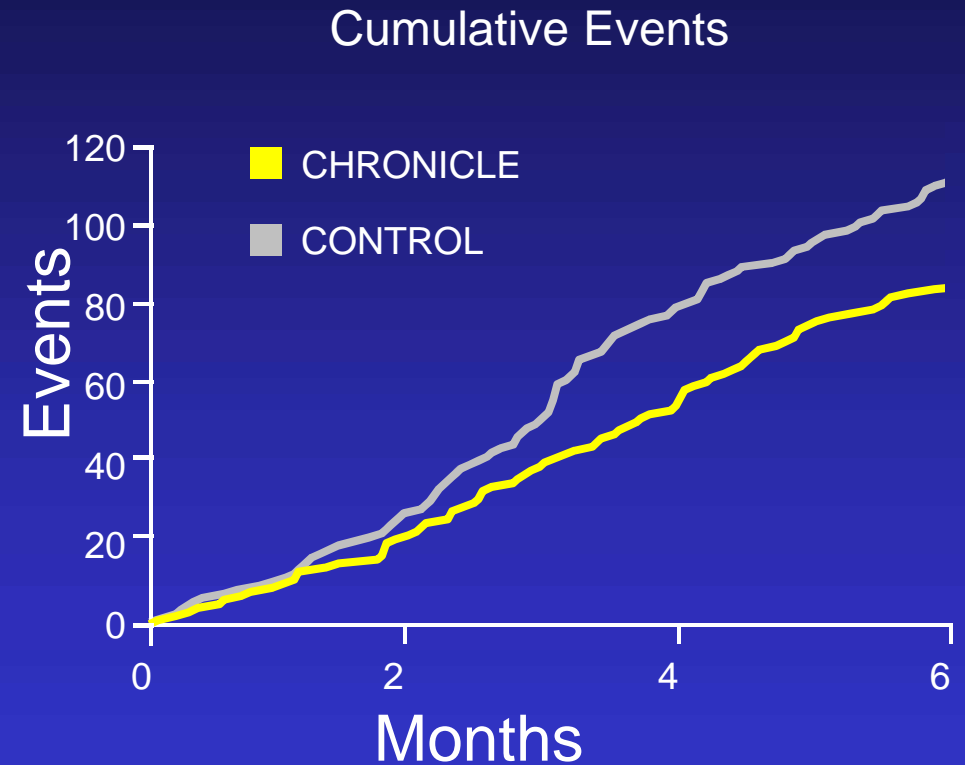


- Pressures
 - Right Ventricular (RV) Systolic and Diastolic Pressures
 - Estimated Pulmonary Artery Diastolic Pressure (ePAD)
- Heart Rate, Temperature, Activity

Primary Effectiveness Objective (Results)

	CHRONICLE (n=134)	CONTROL (n=140)
# of Pts with Events	44	60
Total HF-Related Events	84	113
Hospitalizations	72	99
Emergency Dept Visits	10	11
Urgent Clinic Visits	2	3
Event Rate / 6 months	0.67	0.85
% Reduction in Event Rate	21%	

p=0.33



ISSUES

- Measured RV outflow pressures
- PA pressures estimated
- Primary outcome not met
- Treating physicians did not change meds
- Adjudication definitions did not specifically address low output state

CHAMPION Hypothesis

The hypothesis of the CHAMPION trial is that heart failure management using pulmonary artery pressures reduces the rate of heart failure hospitalizations

The key to adequate testing of this hypothesis is that pressures should be used for the basis of clinical decision making

The Ambulatory Hemodynamic Pressure Measurement System

Catheter-based delivery system



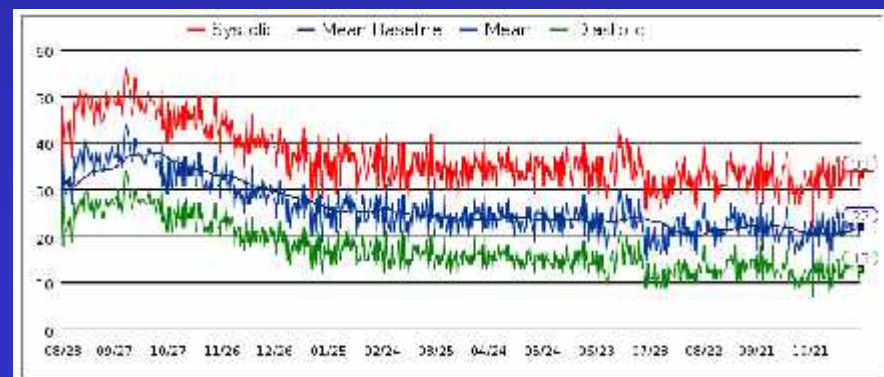
MEMS-based pressure sensor



Readout electronics

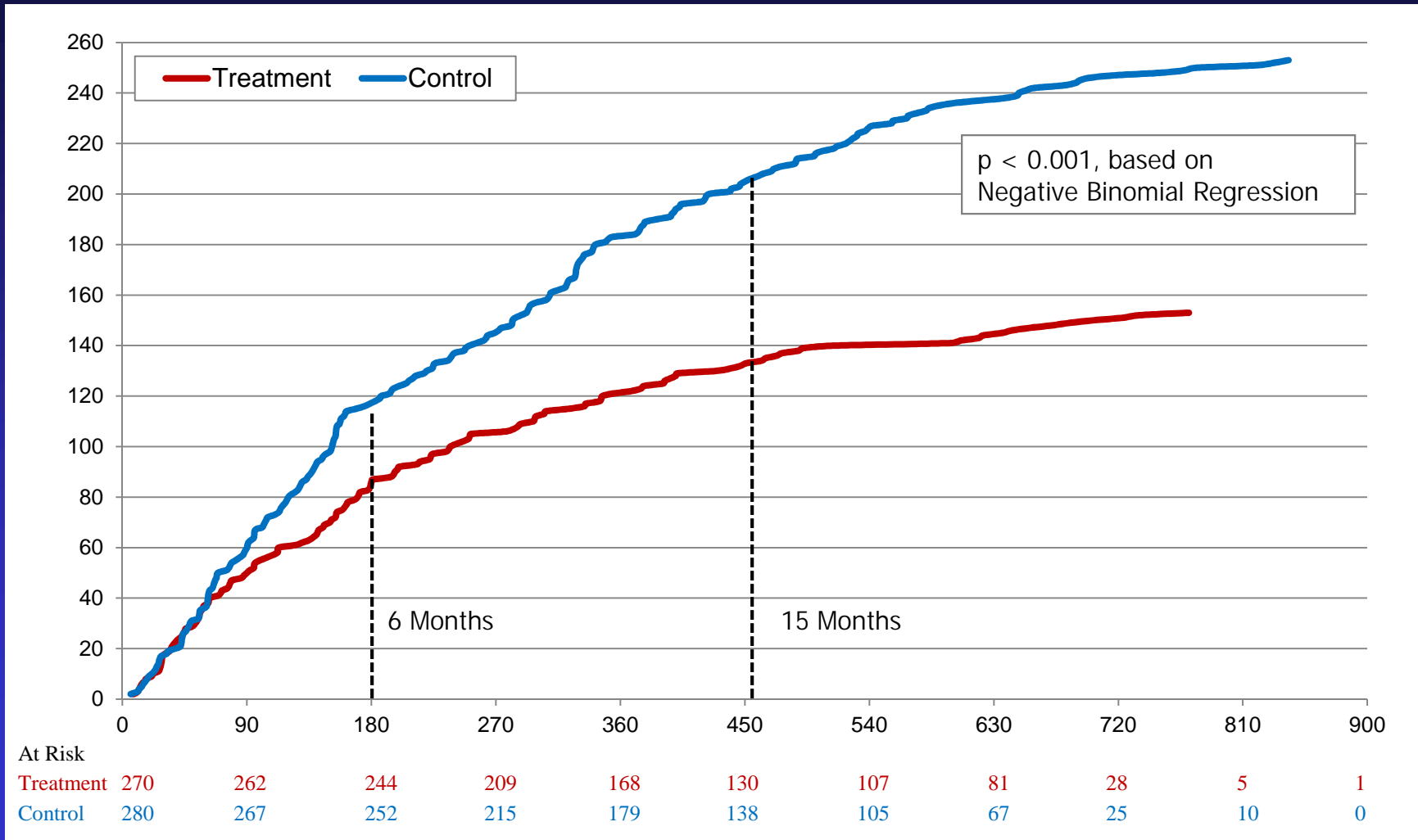


Measurement database



Cumulative HF Hospitalizations Over Entire Randomized Follow-Up Period

Cumulative Number of HF Hospitalizations



Days from Implant

ISSUES

- Small company-first big trial

Members of adjudication committee selected by interview process

Initial difficulty finding committee leader (sponsor)

All patients implanted and had RHC

Novel concept

Issue with endpoint by sponsor

No approval first panel – sponsor calls

LAPTOP

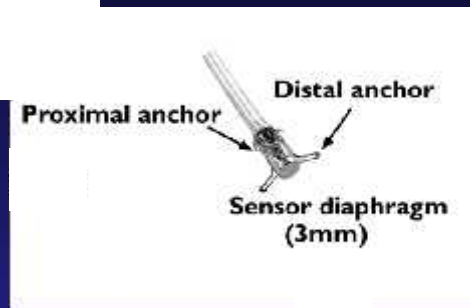
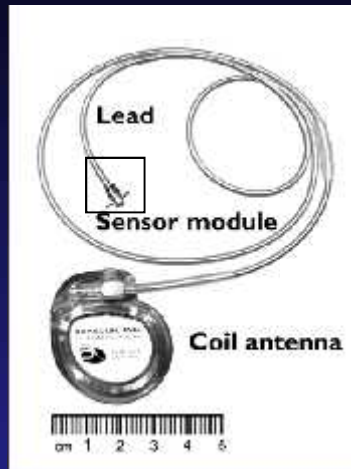
Complex implant

Device is delivered on catheter via atrial septal puncture

- Patient activated
- Pressures available via internet

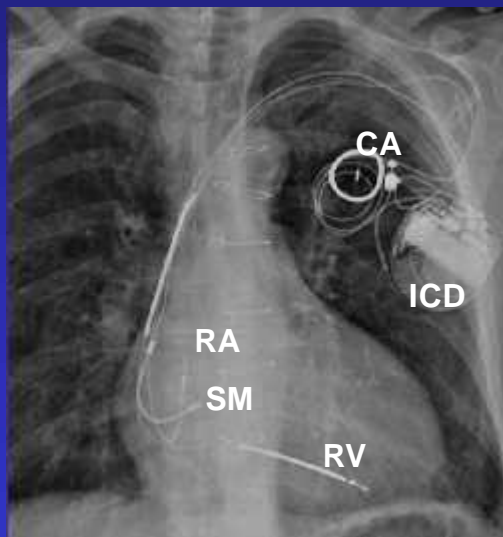
Treatment plan developed for each patient

HeartPOD™ HF Monitoring and Therapy System



Top, Implantable sensor lead and coil antenna.

Bottom left, Chest radiograph of LAP system implanted from the left axillary vein. CA, coil antenna; SM, sensor module. There was an existing dual-chamber ICD.



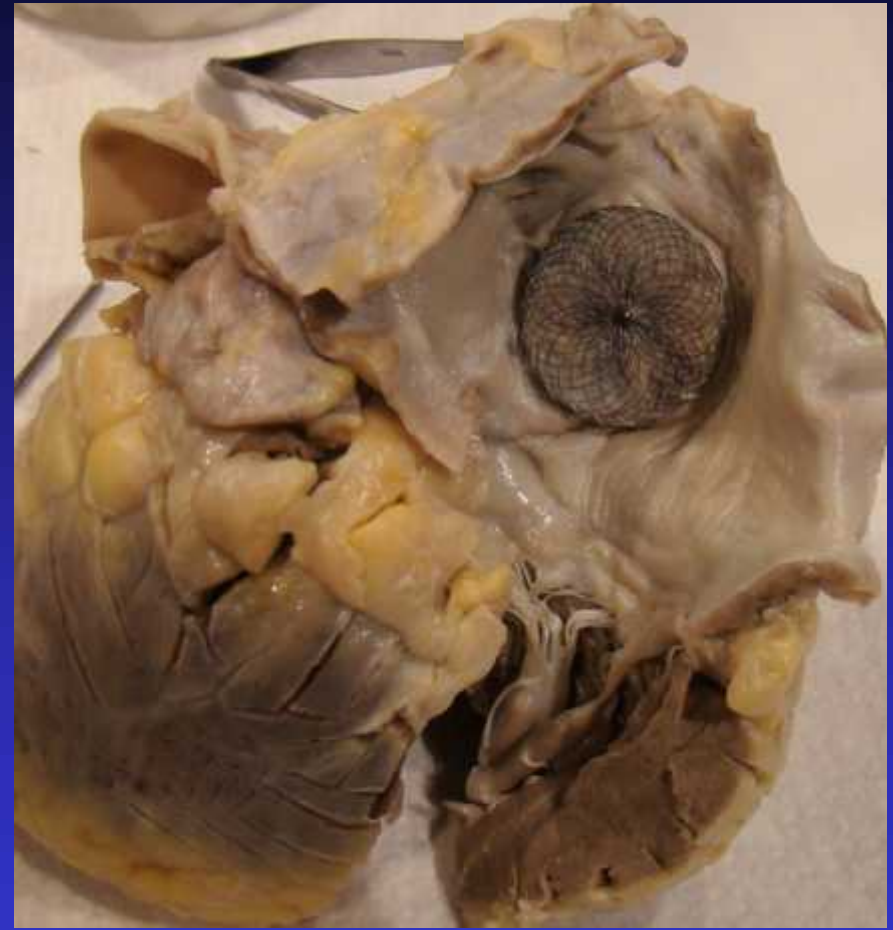
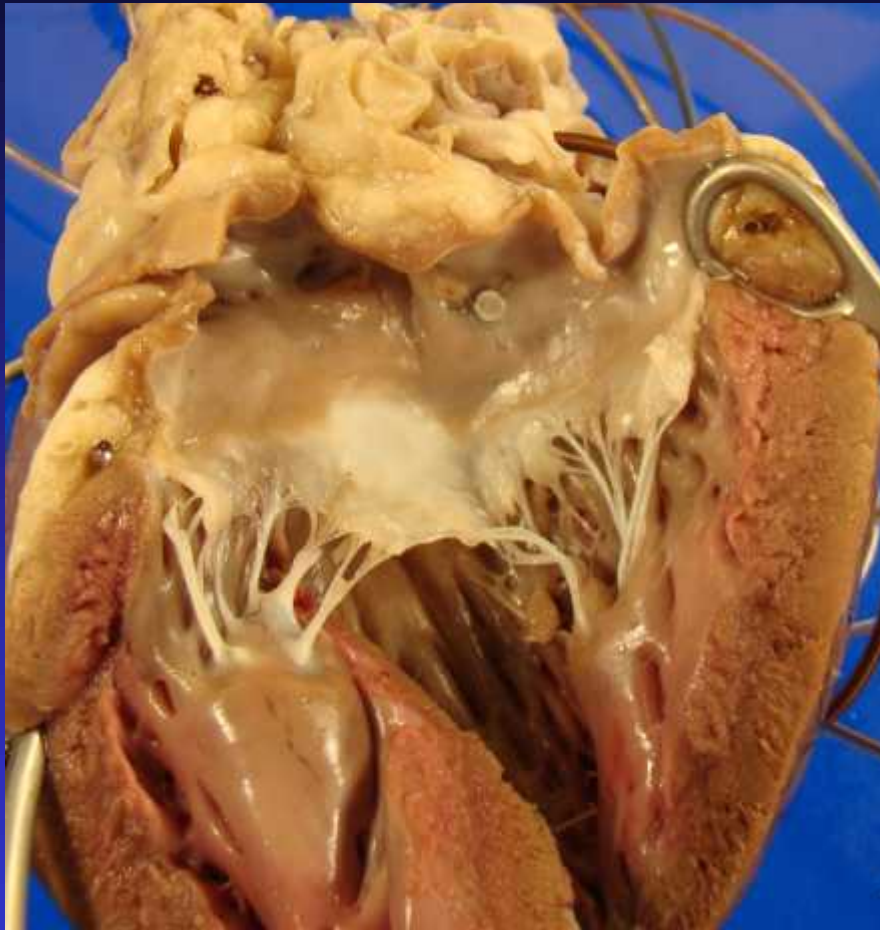
Bottom right, Patient Advisor Module (PAM™) used by patients to communicate with the implanted sensor lead.

Caution: Investigational Device, Limited by Federal Law to Investigational Use

Ritzema J, et al. Physician-Directed Patient Self-Management of Left Atrial Pressure in Advanced Heart Failure. *Circulation* 2010; 121: 1096-1097

The Cardiovascular Center
at SHANDS Jacksonville

*Comparison of HeartPOD ISL to
Amplatzer Septal Closure Device*



ISSUES

- Very complex procedure to implant
- Blinding difficult-1/2 implanted and 1/2 control-only received PAM
- Committee changed sponsor personnel early
- Adjudication process unusual
- Each member adjudicated all events
- all events during hospitalization adjudicated

ISSUES 2

- Positives
 - Committee chemistry excellent
 - Meetings all F to F
 - Data for adjudication generally good
- Negatives
 - Trial stopped by DSMB-very low likelihood of achieving primary endpoint in the face of up-front risk to patients (4 aortic perforations at end)