5° JMC – Joint Meeting with Mayo Clinic
Torino, 15 – 16 October 2009

The critically ill patient in the cardiac intensive care

Invasive and non invasive monitoring methods in advanced heart failure.

S. Ghio,
Divisione di Cardiologia,
IRCCS Policlinico S Matteo, Pavia.

The role of hemodynamic evaluation in ACUTE heart failure

Is right heart hemodynamic profile necessary in patients with acute heart failure:

- to optimize therapy ?
- to stratify the risk ?

ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008‡

The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2008 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association of the ESC (HFA) and endorsed by the European Society of Intensive Care Medicine (ESICM)

European Heart Journal (2008) **29**, 2388–2442

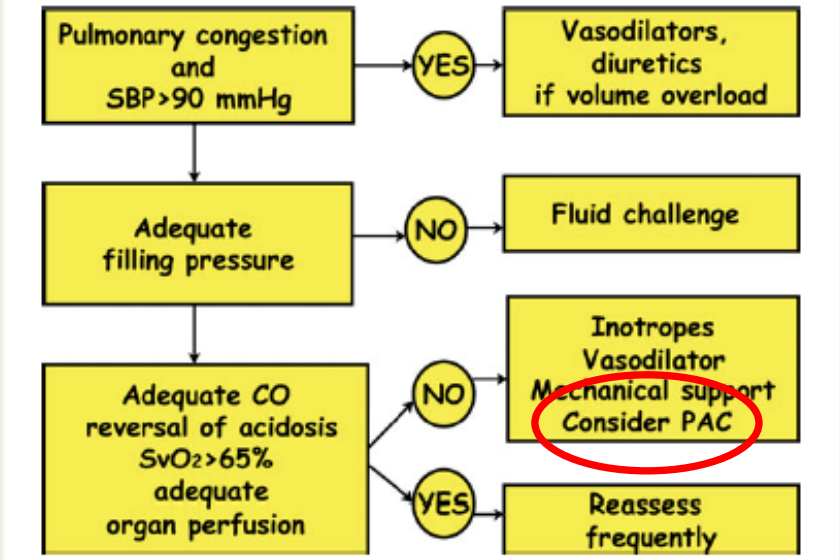

Figure 8 AHF treatment strategy according to LV filling pressure.

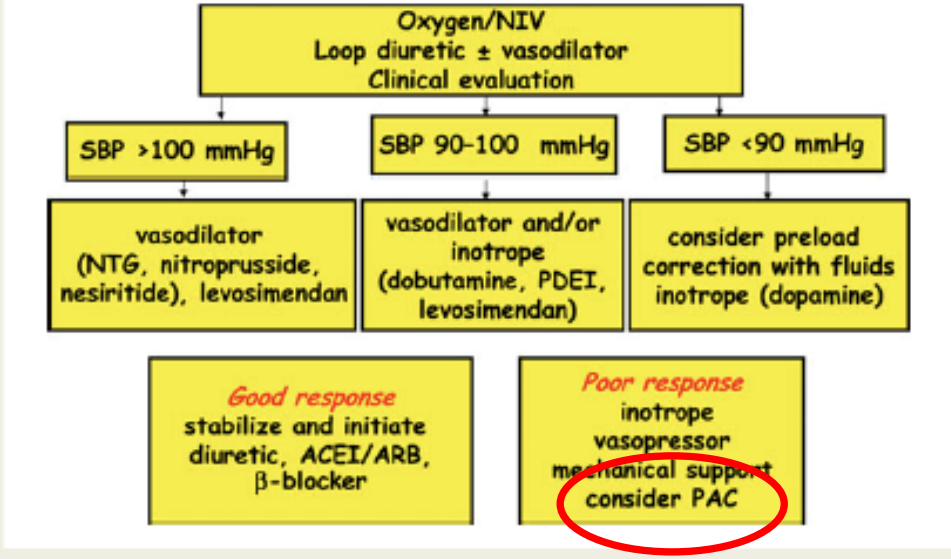

Figure 7 AHF treatment strategy according to systolic blood pressure.

ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008‡

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European Heart Journal (2008) **29**, 2388–2442

Monitoring of haemodynamic variables by means of a pulmonary arterial catheter (PAC) may be considered in hospitalized patients with cardiogenic/non-cardiogenic shock or to monitor treatment in patients with severe HF not responding to appropriate treatment. However, the use of a PAC has not been shown to improve outcomes.

The Effectiveness of Right Heart Catheterization in the Initial Care of Critically Ill Patients

Objective.—To examine the association between the use of right heart catheterization (RHC) during the first 24 hours of care in the intensive care unit (ICU) and subsequent survival, length of stay, intensity of care, and cost of care.

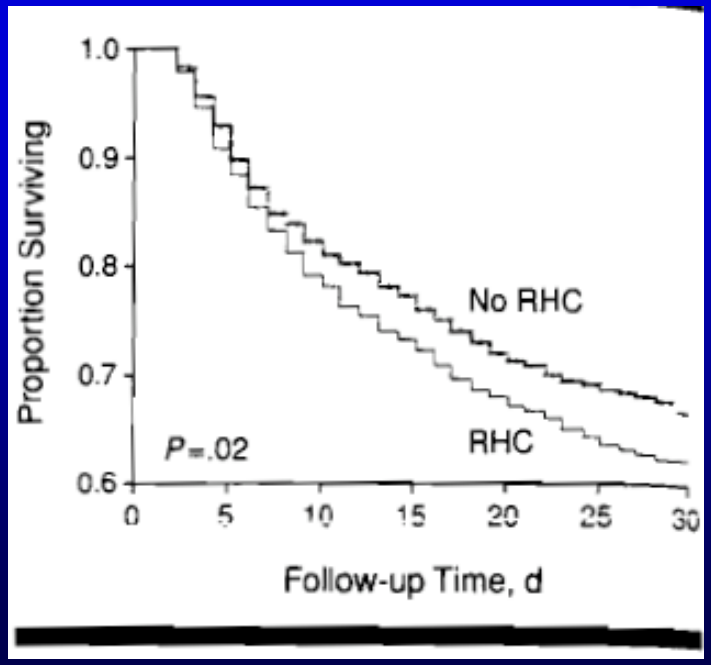
Design.—Prospective cohort study.

Setting.—Five US teaching hospitals between 1989 and 1994.

Subjects.—A total of 5735 critically ill adult patients receiving care in an ICU for 1 of 9 prespecified disease categories.

SUPPORT Investigators

JAMA, September 18, 1996—Vol 276, No. 11



Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness

The ESCAPE Trial

The ESCAPE Investigators and ESCAPE Study Coordinators*

JAMA. 2005;294:1625-1633

Figure 1. CONSORT Diagram

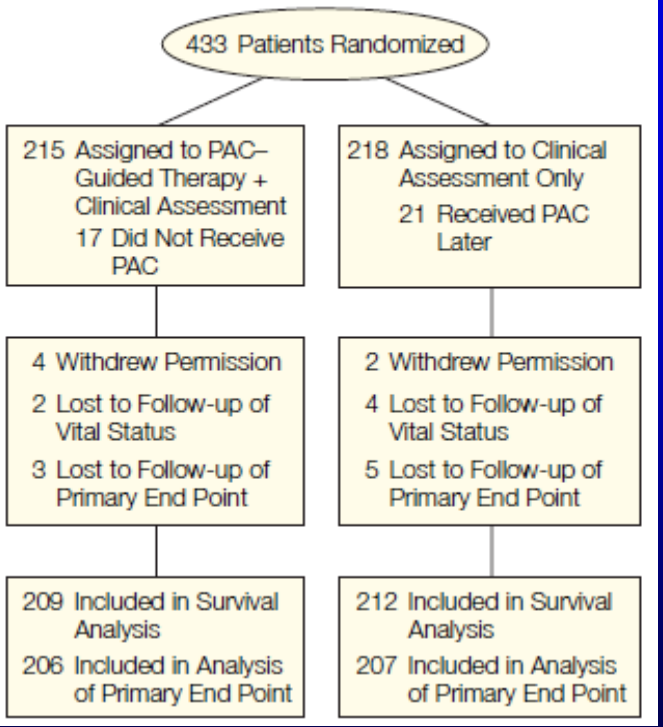
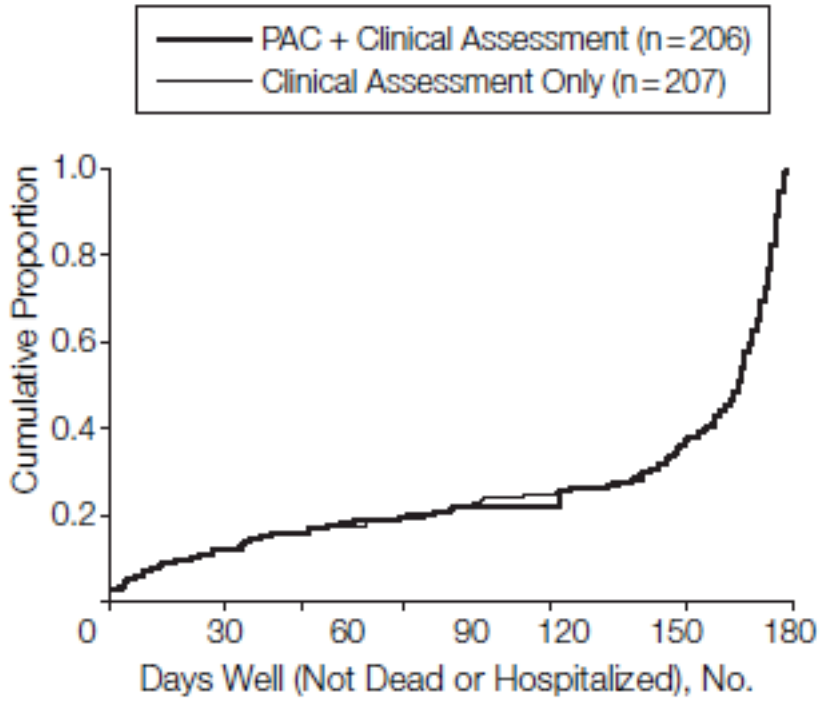


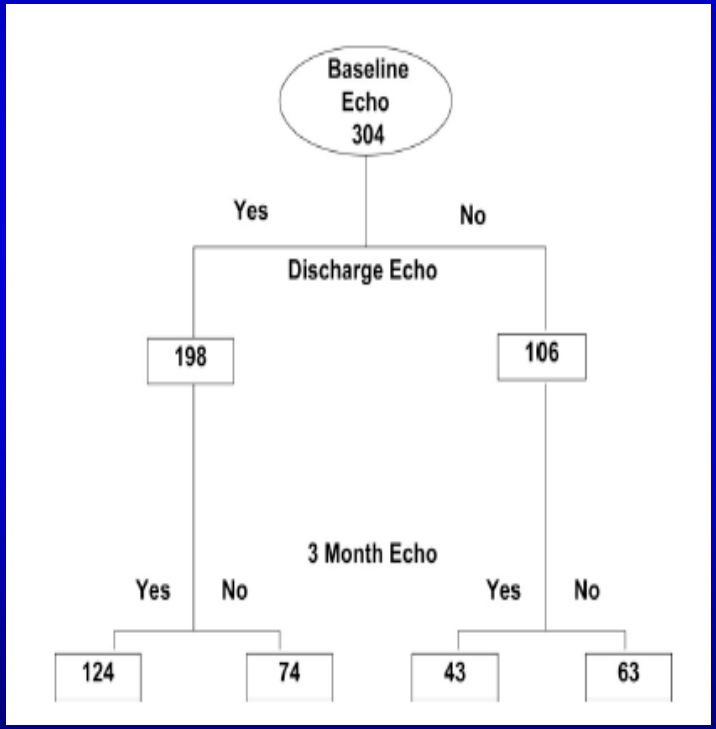
Figure 2. Cumulative Primary End Point (Days Alive and Out of Hospital)

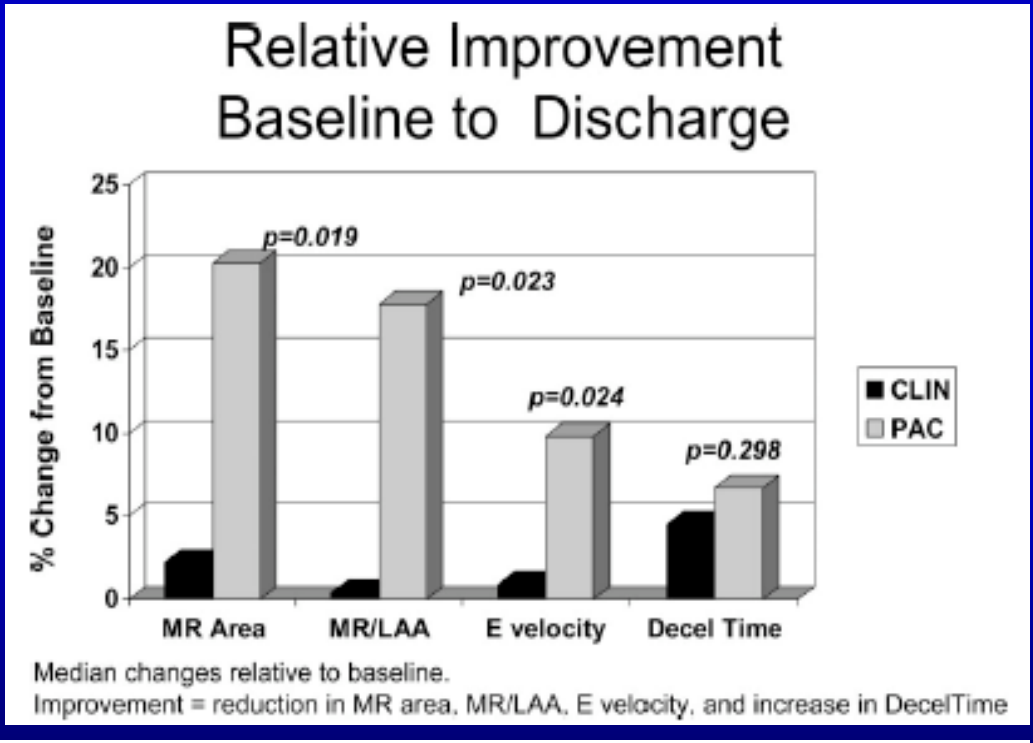


Reduction in Mitral Regurgitation During Therapy Guided by Measured Filling Pressures in the ESCAPE Trial

Maryse Palardy, MD; Lynne W. Stevenson, MD; Gudaye Tasissa, PhD; Michele A. Hamilton, MD; Robert C. Bourge, MD; Thomas G. DiSalvo, MD; Uri Elkayam, MD; James A. Hill, MD; Sharon C. Reimold, MD; for the ESCAPE Investigators

Circ Heart Fail. 2009;2:181-188





Median changes relative to baseline.
Improvement = reduction in MR area, MR/LAA, E velocity, and increase in DecelTime

Conclusions—During hospitalization, therapy guided by PAC to reduce left-sided pressures improved MR and related filling patterns more than therapy guided clinically by evidence of systemic venous congestion. This early reduction did not translate into improved outcomes out of the hospital, where volume status reverted toward baseline.

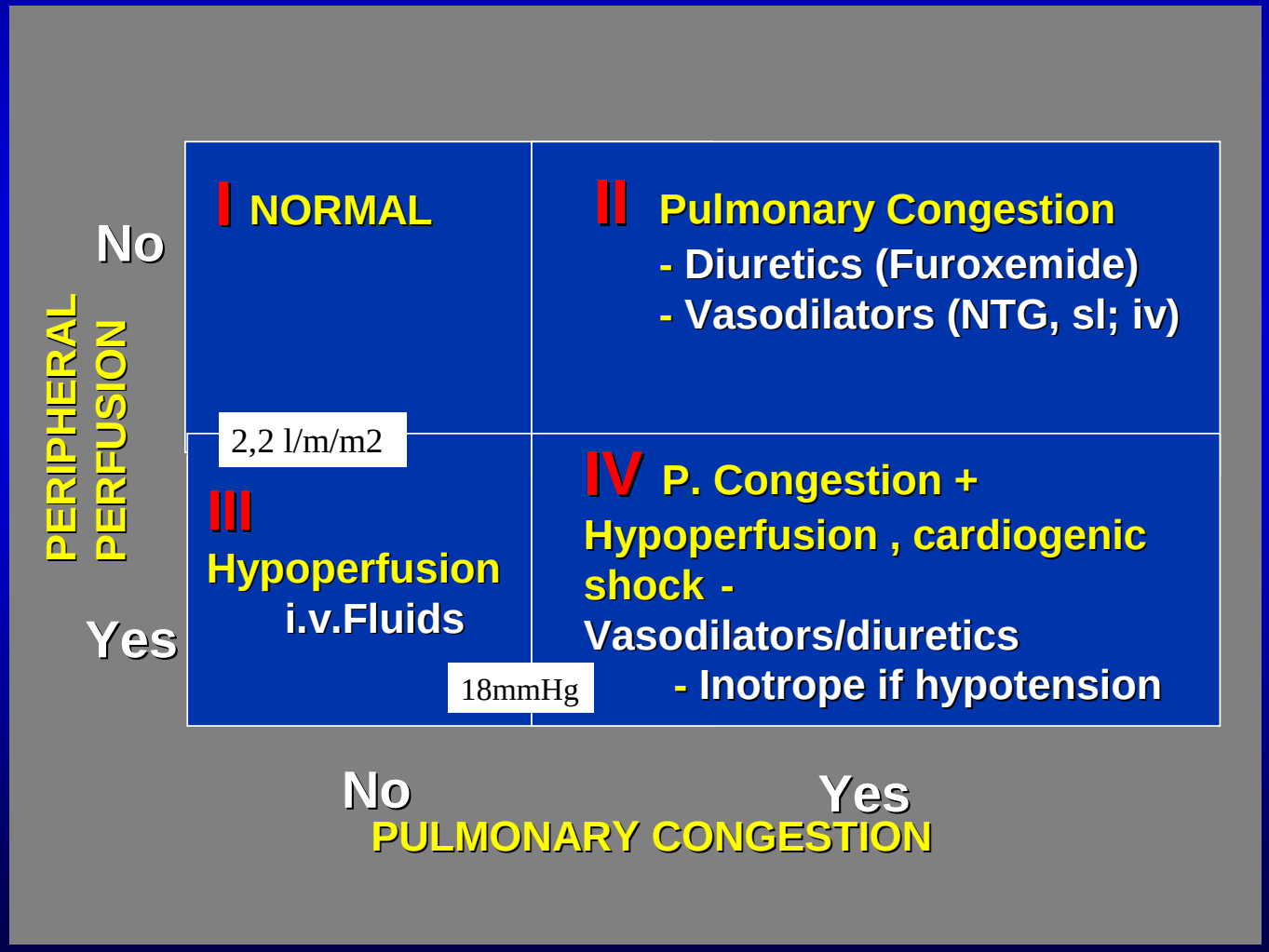
Any role for hemodynamic evaluation in ACUTE heart failure ?

Is right heart hemodynamic profile necessary in patients with acute heart failure:

- to optimize therapy ?
- to stratify the risk ?

Correlative classification of clinical and hemodynamic function after AMI

Forrester JS, Am J Cardiol 1977



Mortalità:

Gr1: 2.2%

Gr2: 10.1%

Gr3: 22.4%

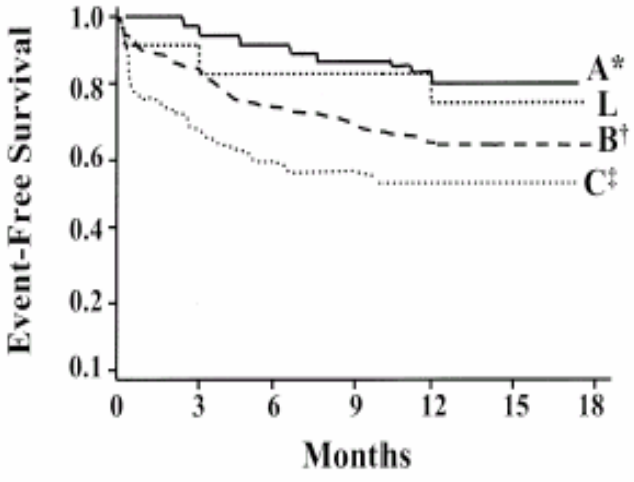
Gr4: 55.5%

Clinical assessment identifies hemodynamic profiles that predict outcomes in pts with NYHA Class III/IV HF.

Nohria A et al. J Am Coll Cardiol J 2003

Clinical evaluation of congestion and perfusion

ADEQUATE PERFUSION	CONGESTION: –	CONGESTION: +
+	**A** *dry-warm* *(N=123)*	**B** *wet-warm* *(N=222)*
–	**L** *dry-cold* *(N=16)*	**C** *wet-cold* *(N=91)*



NO. AT RISK							
Profile A	51	51	48	45	42	34	26
Profile B	182	153	130	119	108	95	85
Profile C	81	54	44	40	38	35	27
Profile L	12	11	10	10	9	9	6

Figure 3. Kaplan-Meier survival curves according to the clinical profiles in patients with New York Heart Association functional class III/IV heart failure. The end point shown is one-year mortality + urgent transplantation. Patients with profiles B and C had worse outcomes than profile A. Profile L had too few patients for meaningful statistical analysis. The survival for profiles B and C did not differ significantly after Bonferroni correction. *$p = 0.015$ for profile A versus profile B, †$p = 0.04$ for profile B versus profile C, ‡$p < 0.001$ for profile A versus profile C.

Comparison of echocardiography and BNP for monitoring response to treatment in AHF

Gackowski A, Eur Heart J 2004

95 pts admitted because of AHF; serial BNP and echo evaluations; 60 days f-up (37 events)

1. **BNP decrease >10% at day 2**
2. **BNP decrease <300 pg/ml at day 7**

predict a better outcome.

Any role for hemodynamic evaluation in ACUTE heart failure ?

Is right heart hemodynamic profile necessary in patients with acute heart failure:

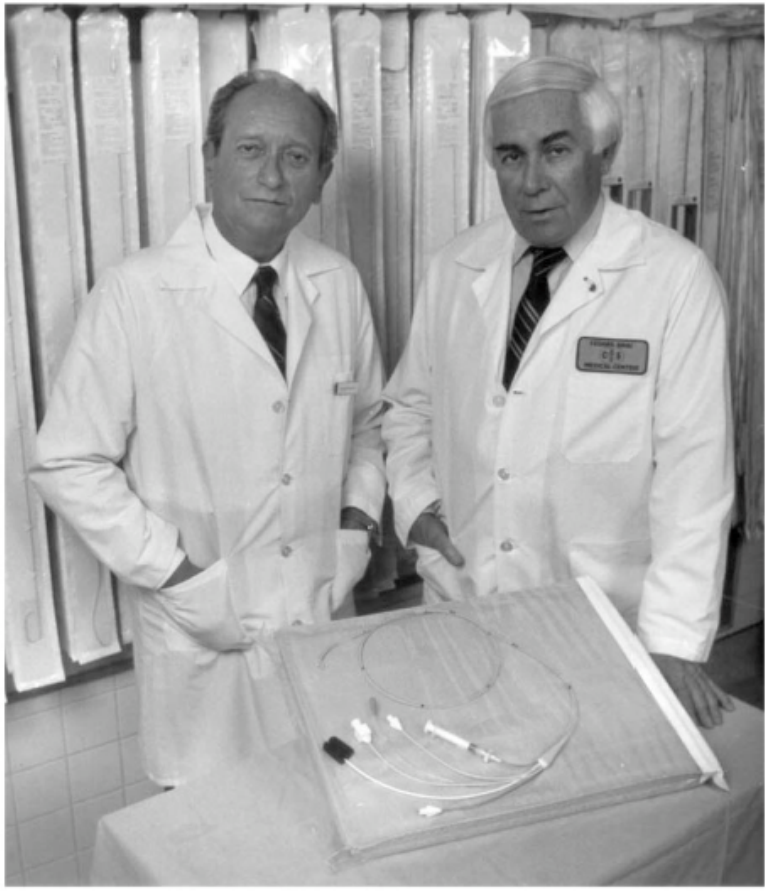
- **to optimize therapy ?** *Only in selected patients.*
- **to stratify the risk ?** *It can be more easily done with a clinical or BNP evaluation.*

The Swan-Ganz Catheters: Past, Present, and Future

A Viewpoint

Kanu Chatterjee, MB, FRCP(Lond), FRCP(Edin)

Circulation. 2009;119:147-152.



William Ganz and H.J.C. Swan

tions, including death. However, it is still necessary in patients with cardiogenic shock, for the differential diagnosis of pulmonary arterial hypertension, and for diagnosis and treatment of uncommon causes and complications of heart failure.

?

The role of hemodynamic evaluation in CHRONIC heart failure

- The right heart hemodynamic profile characterizes the pathophysiology of HF in the single pt and therefore it might be useful for:

1) therapeutic optimization, 2) prognostic stratification.

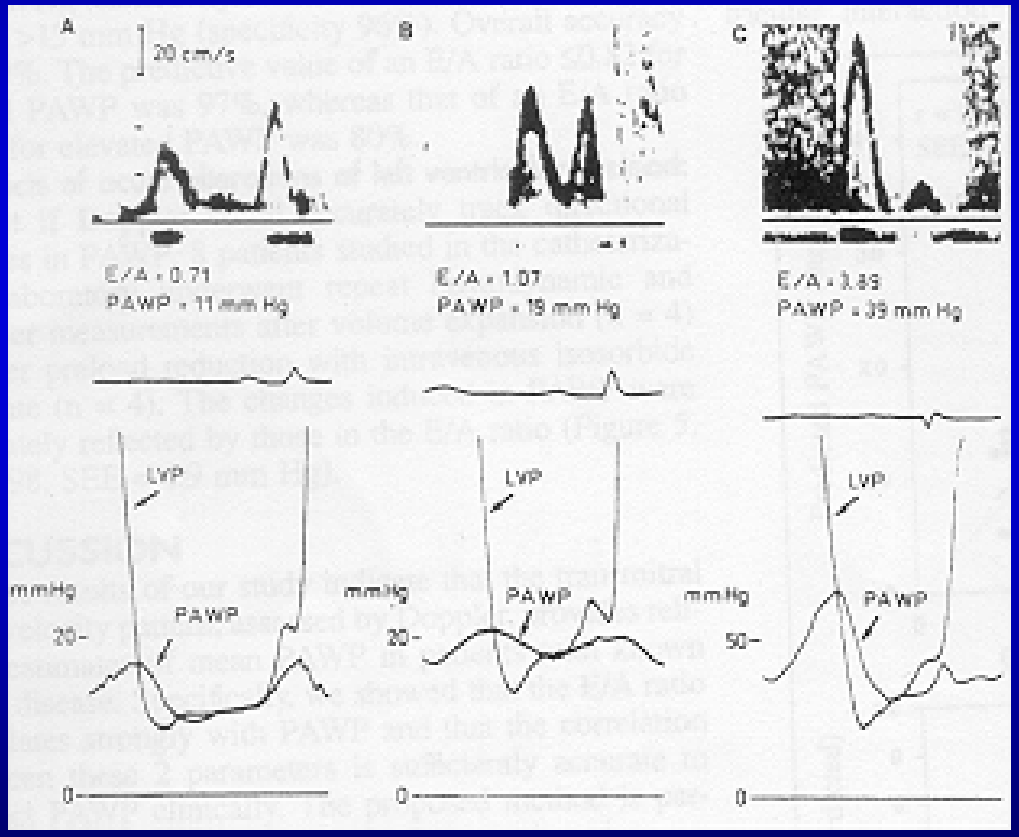
The role of non invasive hemodynamic evaluation in CHRONIC heart failure

- Usually non-invasive evaluation with Doppler echocardiography; right heart catheterization is limited to selected situations.

All most important hemodynamic parameters can be estimated with echo:

- Pulmonary capillary wedge pressure
- Pulmonary artery pressure (S,D)
- Right atrial pressure
- Cardiac output
- Pulmonary vascular resistance

Estimate of wedge pressure at Doppler echo: transmitral flow pattern.



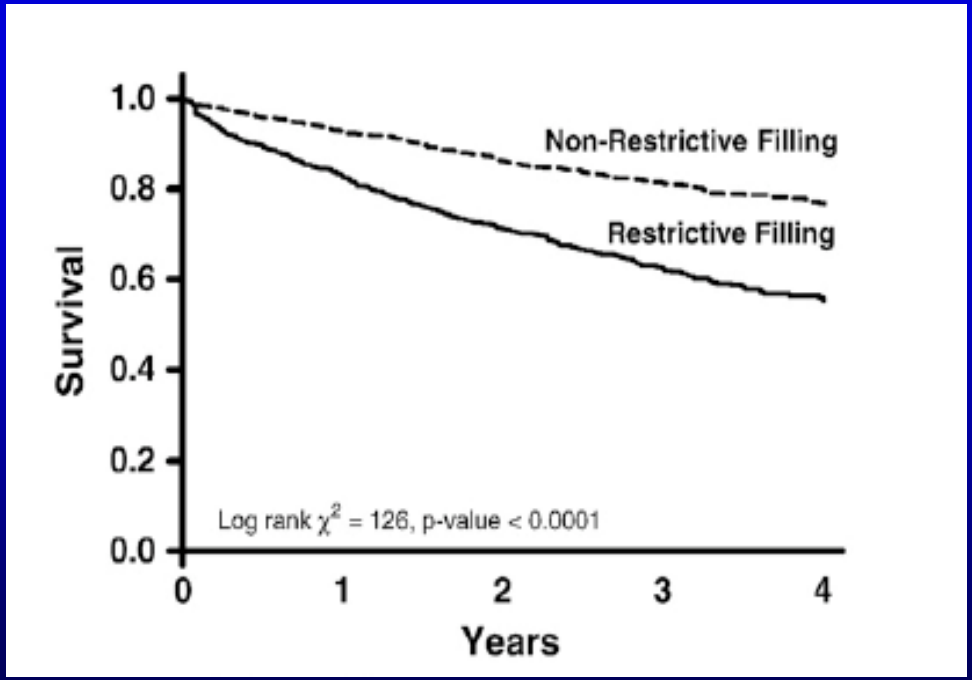
- **E/A <1 - DT >220ms**
  PWP < 12mmHg
- **E/A =1-1.5 - DT 130- 220ms**
  PWP = 12-18mmHg
- **E/A > 1 - DT < 130ms**
  PWP > 18mmHg

Independence of restrictive filling pattern and LV ejection fraction with mortality in heart failure: An individual patient meta-analysis

Meta-analysis Research Group in Echocardiography (MeRGE) Heart Failure Collaborators *

European Journal of Heart Failure 10 (2008) 786–792

- **3540 pts enrolled in 18 studies**
- **Collated at the MeRGE coordinating center (Auckland)**
- **Best DT cut off = 140 ms.**
- **DT was independent of age, etiology (IHD vs non IHD), degree of LV dysfunction (EF<30%, 30-45%, > 45%).**



The role of non invasive hemodynamic evaluation in CHRONIC heart failure

- We still do not know how to use echo hemodynamic information to optimize treatment.
- No validated approach - No expert consensus.

Treatment of HF guided by N-BNP.

Troughton RW, Lancet 2000;355:1126

69 pts with LVEF<40% randomized to treatment guided by clinical acumen or by N-BNP levels

In a median f-up period of 9.5 months, less events recorded in BNP vs clinical group

STARS-BNP Multicenter Study.

Jourdain P, JACC 2007;49:1733

220 HF pts under optimal medical treatment randomized to treatment guided by clinical acumen or by BNP levels (goal<100 pg/ml)

In a median f-up period of 15 months, less events recorded in BNP vs clinical group

A role for invasive hemodynamic monitoring to prevent ACUTE heart failure ?

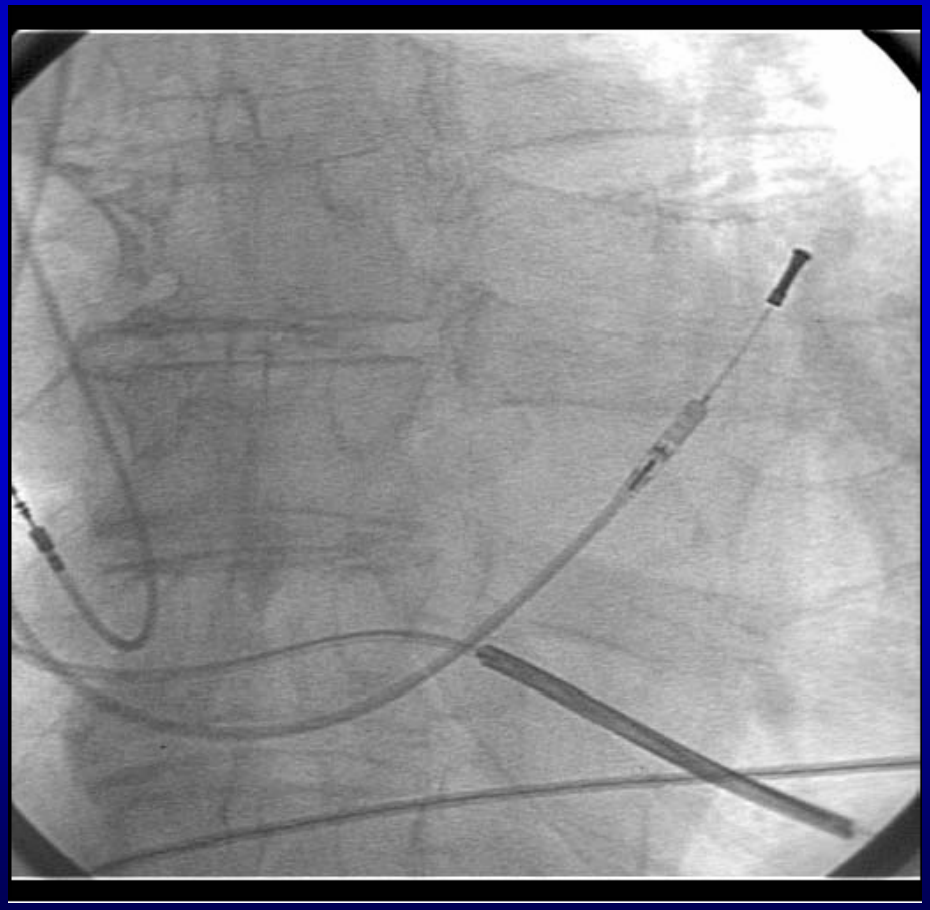
- Continuous right heart hemodynamic monitoring in patients with chronic heart failure might be helpful in deciding therapy and potentially in preventing episodes of worsening heart failure.

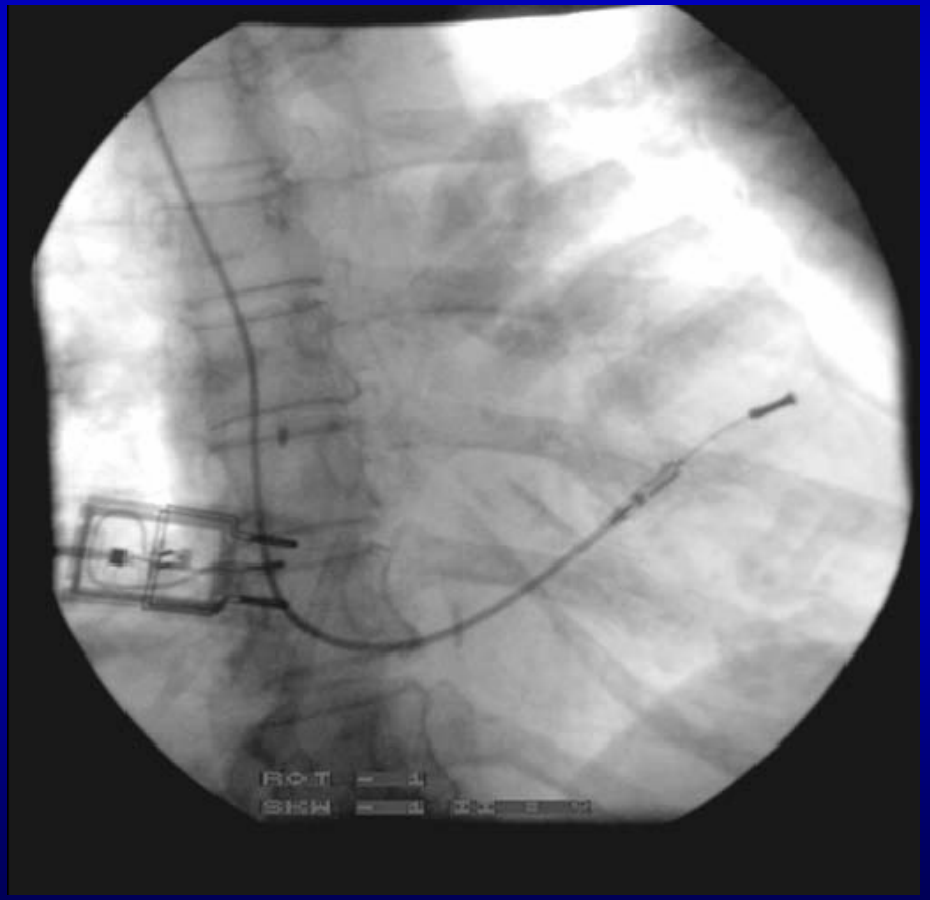
Ambulatory Hemodynamic Monitoring

System components

- **Implantable Hemodynamic Monitor**
  - Pressure sensor implanted in RVOT (implant technique similar to PM)
- **External Pressure Reference**
  - external device which measures barometric pressure
- **Remote Monitor**
  - Home unit: allows patients to send Chronicle data to physician
- **Chronicle® Information Network**
  - Web site: allows clinicians to view and evaluate data over time

Pressure Sensor Lead Implant in RVOT





Chronicle® parameters collection

- **Primary Hemodynamic Data**
  - RV Diastolic and Systolic Pressure
  - Estimated Pulmonary Artery Diastolic pressure (ePAD)
- **Secondary Hemodynamic Trend Data**
  - Max $\pm$ dP/dt
  - Pre-Ejection and Systolic Time Intervals
- **Other Trend Data**
  - Heart Rate
  - Activity Level
  - Core Temperature

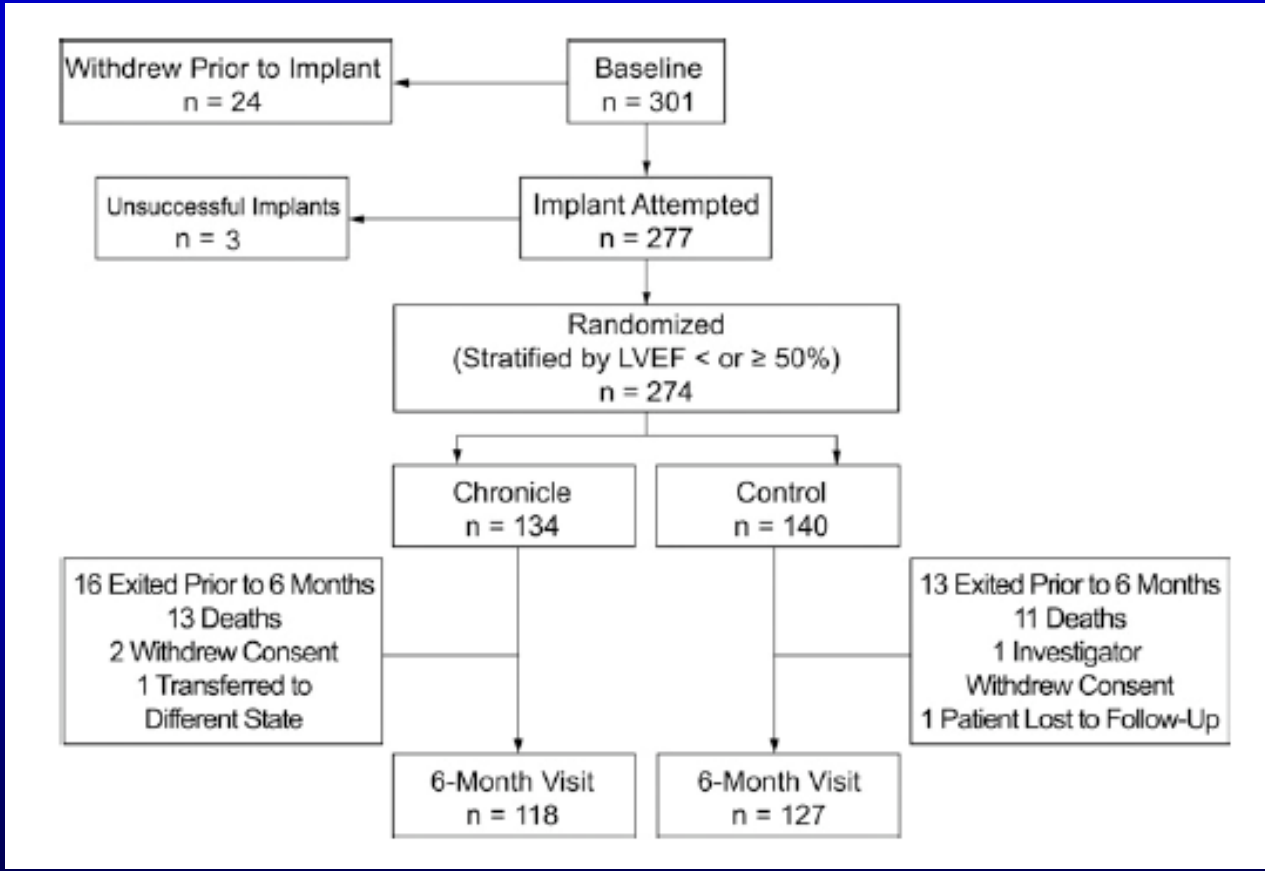
Randomized Controlled Trial of an Implantable Continuous Hemodynamic Monitor in Patients With Advanced Heart Failure

The COMPASS-HF Study

Bourge *et al.* JACC Vol. 51, No. 11, 2008

Enrolling criteria:

- NYHA III or IV HF
- optimal medical therapy for at least 3 m.
- managed in centers with HF programs
- at least 1 HF hospitalization in previous 6 m.



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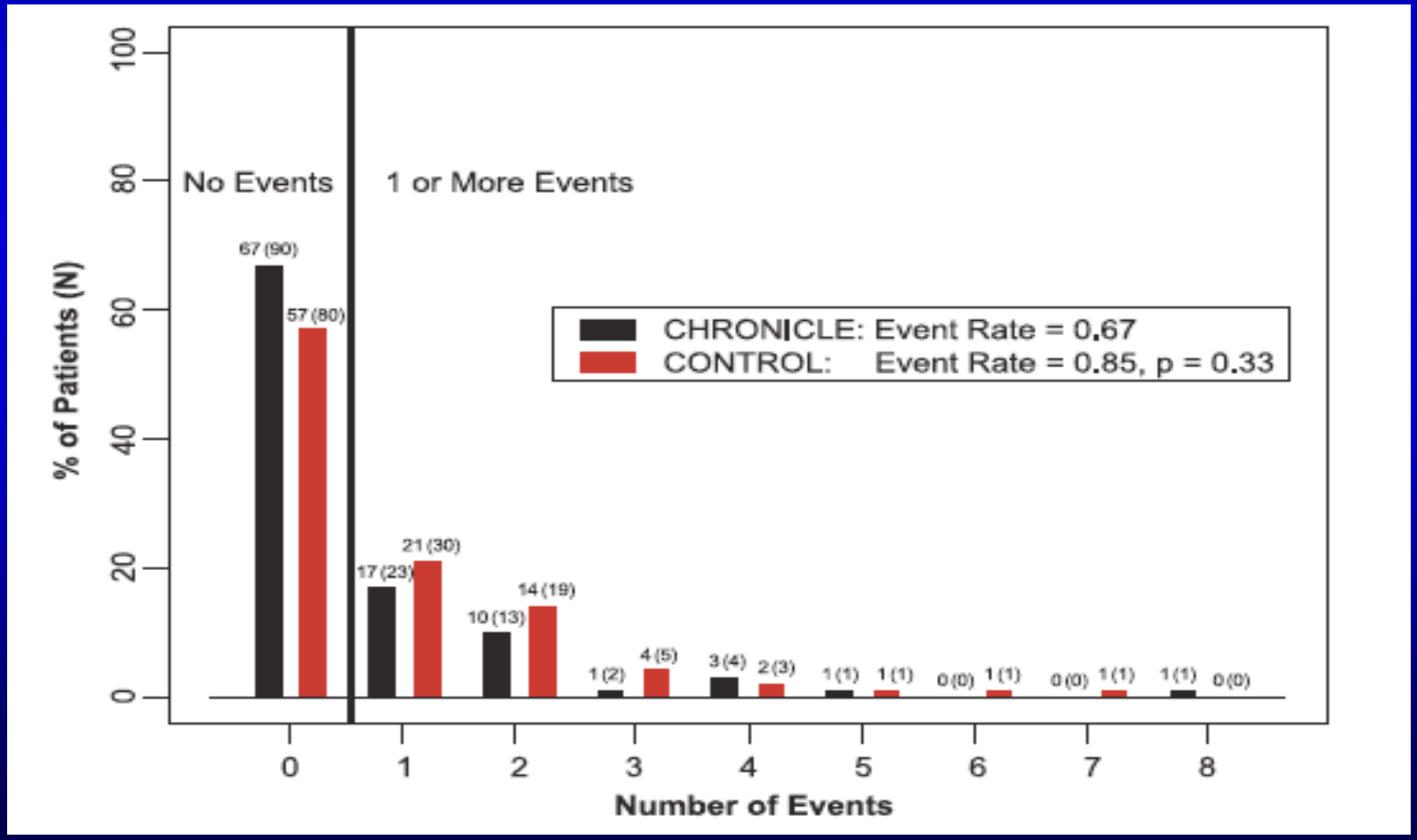


Randomized Controlled Trial of an Implantable Continuous Hemodynamic Monitor in Patients With Advanced Heart Failure

The COMPASS-HF Study

Bourge *et al.* JACC Vol. 51, No. 11, 2008

Given the amount of information provided by the ICHM, there is the question of training and widespread adoption of this technology. A learning curve is to be expected in association with the routine integration of intracardiac pressures into clinical practice. Moreover, the ICHM generates large amounts of data in each patient that

The equation:
volume expansion = increase in ePAD and increase in RVSP may not necessarily hold true in all cases of worsening HF, especially in pts with RV failure.

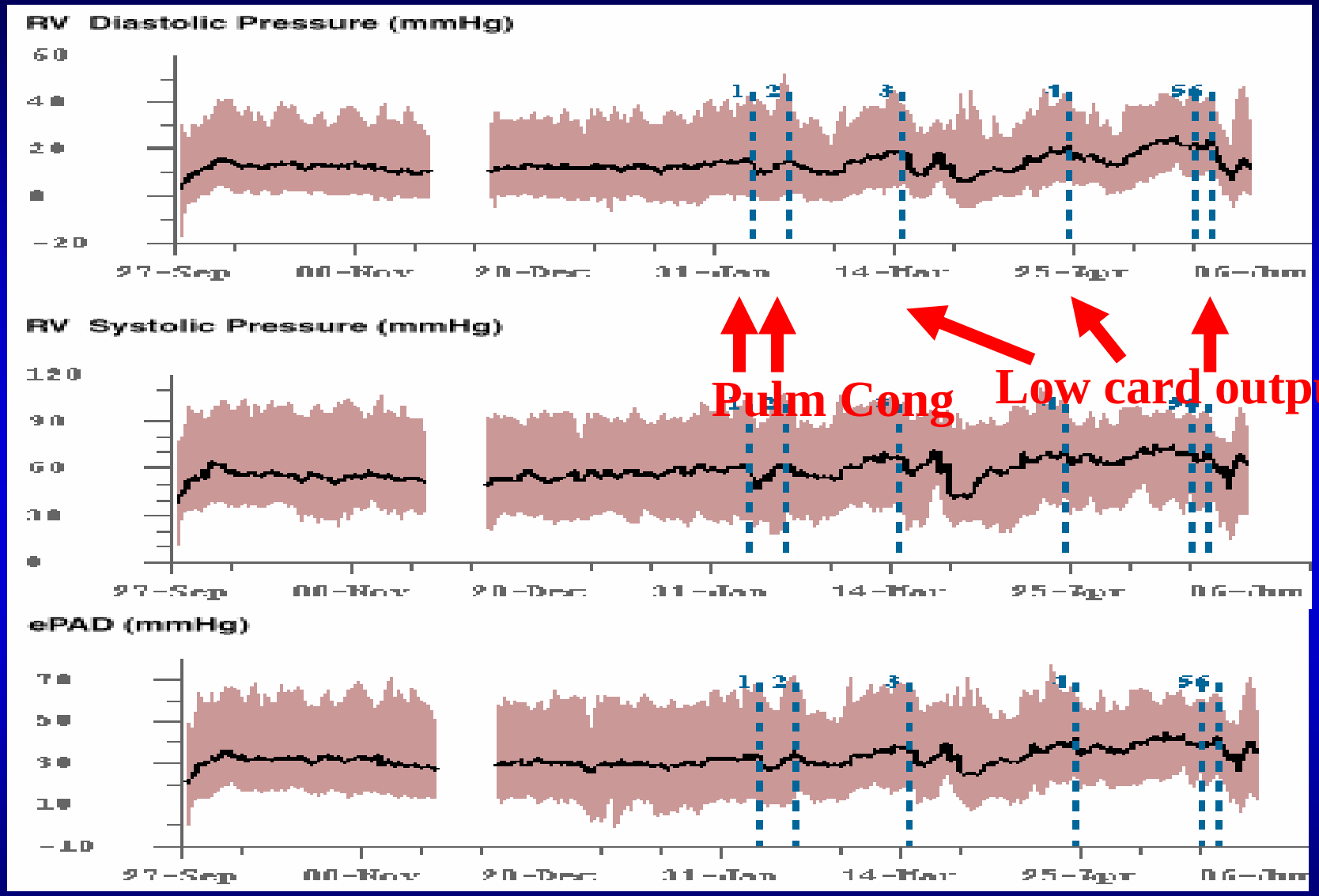
Hemodynamic changes before acute heart failure episodes in patients with advanced systolic left ventricular dysfunction

Stefano Ghio[a], Alessandra Serio[a], Maurizio Mangiavacchi[b], Barbro Kjellström[c], Sergio Valsecchi[d], Ilaria Vicini[d], Carlo Campana[a], Maurizio Gasparini[b], Edoardo Gronda[b] and Luigi Tavazzi[a]

J Cardiovasc Med 9:799–804 © 2008

10 advanced NYHA IV HF pts, follow-up 15±12 months.
18 hospitalisations due to acute HF; 10 low cardiac output (LCO) episodes and 8 pulmonary congestion episodes.

RVSP and **ePAD** increased before six hospitalisations and decreased before three episodes; **RVDP** increased before ten hospitalisations and decreased before one.
RVDP increase was 16±24 % before pulmonary congestion episodes and 29±32 % before LCO episodes.



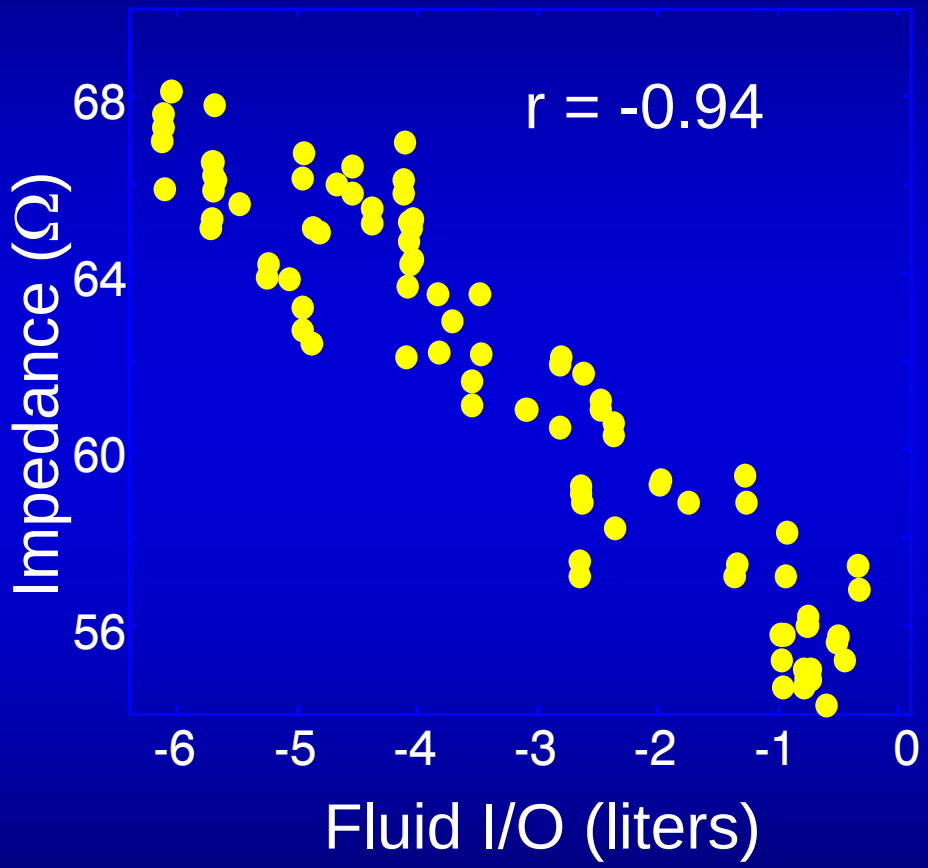
Patient n°1

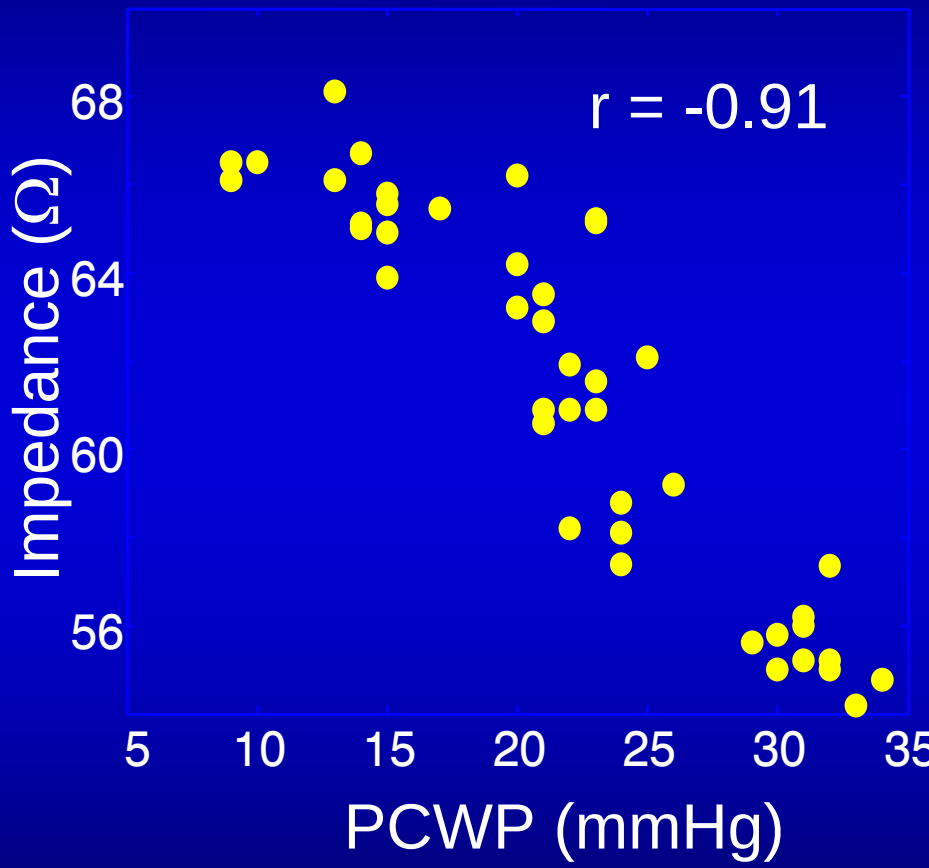
5 HF hospitalizations

Ambulatory Transthoracic Impedance Monitoring

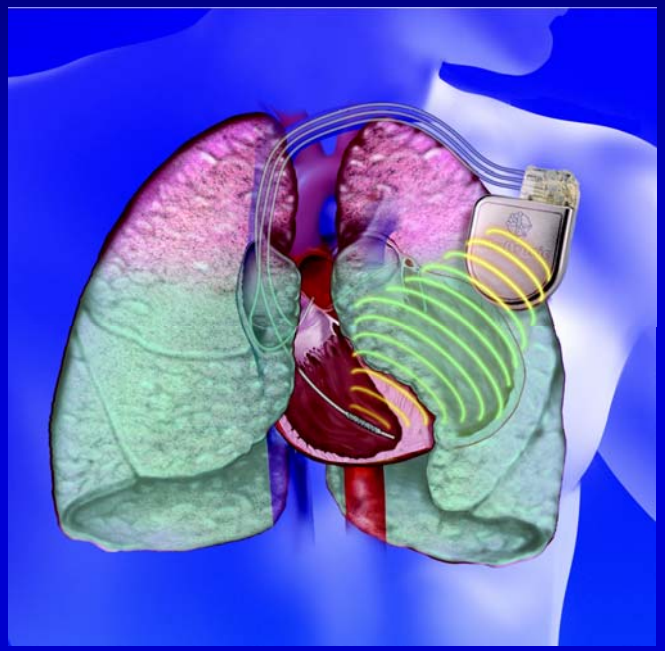
Rationale:

fluid retention decreases transthoracic impedance





InSync Sentry™ Physical Characteristics



- Impedance measured from RV Coil to Can
- Impedances averaged from 12 noon to 5 pm
- OptiVol Fluid Status Monitoring is initialized 31 d. after implant
- Programmable parameters: OptiVol Threshold, Patient Alert

Clinical utility of intrathoracic impedance monitoring to alert patients with an implanted device of deteriorating chronic heart failure

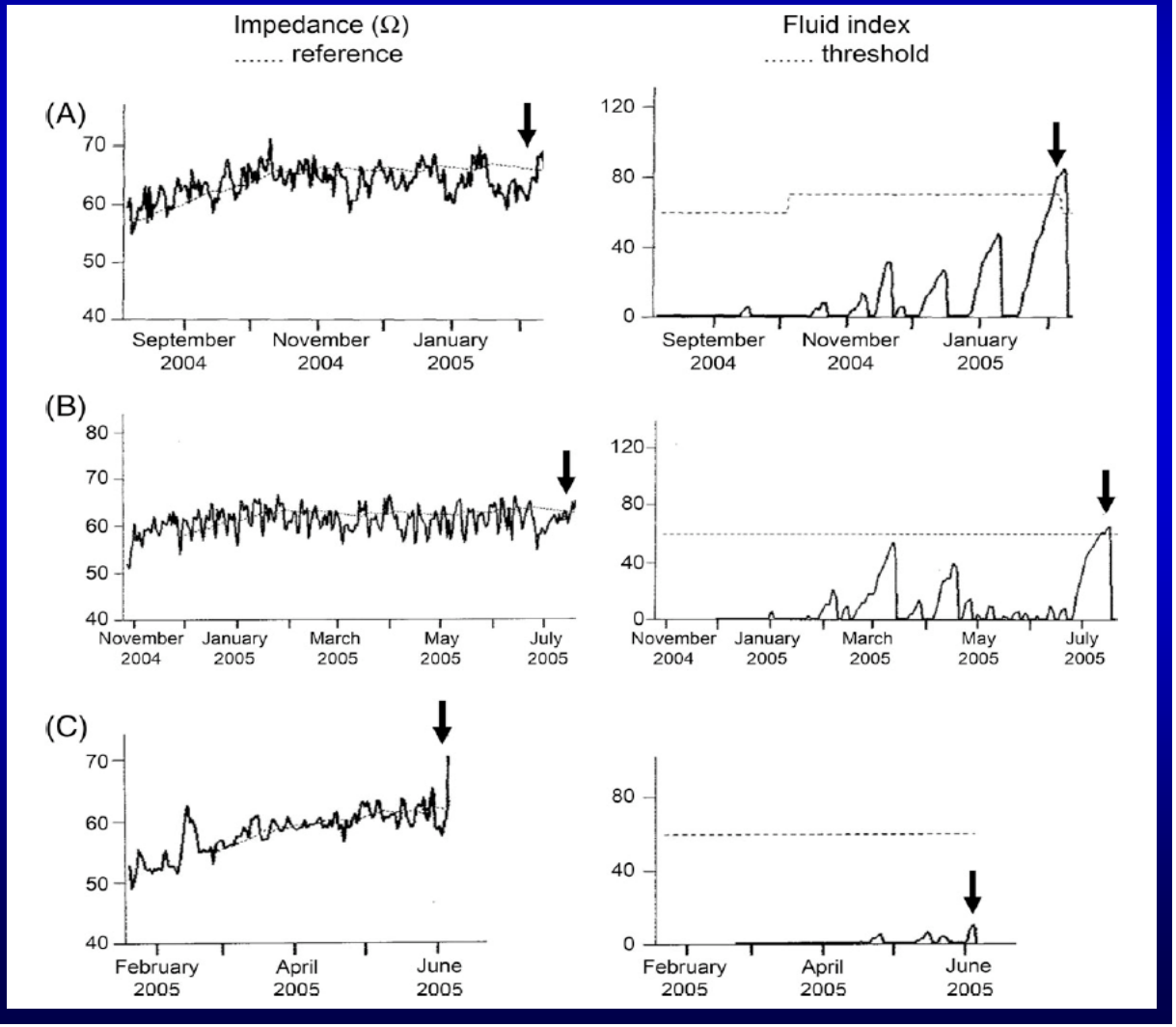
Dirk Vollmann[1]*, Herbert Nägele[2], Patrick Schauerte[3], Uwe Wiegand[4], Christian Butter[5], Gabriele Zanotto[6], Aurelio Quesada[7], Axel Guthmann[8], Michael R.S. Hill[9], and Barbara Lamp[10] for the European InSync Sentry Observational Study Investigators

European Heart Journal (2007) **28**, 1835–1840

373 patients studied.
53 alerts during a median of 4.2 months.

The alert detected clinical HF deterioration with a 60% sensitivity and a positive predictive value of 60%.

Examples:
A: true positive
B: false positive
C: false negative



Rationale and Design of a Prospective Trial to Assess the Sensitivity and Positive Predictive Value of Implantable Intrathoracic Impedance Monitoring in the Prediction of Heart Failure Hospitalizations: The SENSE-HF Study

Journal of Cardiac Failure Vol. 15 No. 5 2009

The Sensitivity of the InSync Sentry feature for the Prediction of Heart Failure (ie, SENSE-HF) trial is a prospective multicenter international study designed to evaluate the sensitivity and positive predictive value (PPV) of the intrathoracic impedance diagnostic tool, OptiVol, present in Medtronic implantable devices. A total of 500 patients will be enrolled in the trial, with follow-up for up to 24 months. The study has 3 phases.

“SENSE HF”

Sensitivity of the InSync **Se**ntry OptiVol feature for the prediction of **H**eart **F**ailure

Phase I: 6 months duration
Blinded OptiVol Monitoring
Evaluate sensitivity of Trend data for HF hospitalizations

Phase II:
Patient alert turned on; physician may not change therapy
Evaluate prediction of HF event based on patient alert

Phase III:
Physician may use information for patient management
Clinical usefulness of Optivol monitoring

Can monitoring of intrathoracic impedance reduce morbidity and mortality in patients with chronic heart failure? Rationale and design of the Diagnostic Outcome Trial in Heart Failure (DOT-HF)☆

European Journal of Heart Failure 10 (2008) 907–916

Background: Chronic heart failure is associated with frequent hospitalisations which are often due to volume-overload decompensation. Monitoring of intrathoracic impedance, measured from an implanted device, can detect increases in pulmonary fluid retention early and facilitate timely treatment interventions.

Objective: The DOT-HF trial is designed to investigate if ambulatory monitoring of intrathoracic impedance together with other device-based diagnostic information can reduce morbidity and mortality in patients with chronic heart failure who are treated with cardiac resynchronization therapy (CRT) and/or an implantable defibrillator (ICD).

Methods: Approximately 2400 patients will be randomised in a 1:1 fashion to a management strategy with access to the diagnostic information from the implantable device ("access arm"), or a "control arm", where this information is not made available. Study subjects fulfil standard indications for

5° JMC – Joint Meeting with Mayo Clinic
Torino, 15 – 16 October 2009

The critically ill patient in the cardiac intensive care

Invasive and non invasive monitoring methods in advanced heart failure.

1. **It is not necessary to be always invasive to treat the acute patient.**
2. **It seems useful to be aggressive (and invasive) during the chronic phase to prevent instabilizations.**