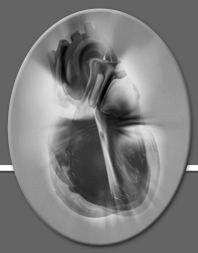
PROACTION Study



***P*rospective *R*andomized *O*utcomes study of *A*cutely decompensated *C*HF *T*reated *I*nitially as *O*utpatients with *N*esiritide**

W. F. Peacock, MD
ACC, Chicago, 2003
***JACC.* 2003;41(6 suppl A):336A.**

THE CLEVELAND CLINIC FOUNDATION

PROACTION Study

- **Objective:**
  - **Evaluate safety and efficacy of nesiritide for the treatment of decompensated heart failure in emergency departments (ED)**

THE CLEVELAND CLINIC FOUNDATION

Peacock WF, et al. *JACC.* 2003;41(6 suppl A):336A.

PROACTION Study

- **38 centers**
  - double-blind, randomized, placebo-controlled
- **Entry:**
  - ADHF and dyspnea at rest or with minimal activity
- **Randomized 1:1**
  - standard care with nesiritide or placebo, for a minimum of 12 hours
- **After 24 hours, patients hospitalized or discharged**

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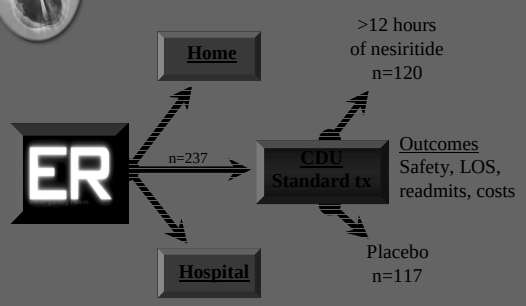
Peacock WF, et al. *JACC.* 2003;41(6 suppl A):336A.

PROACTION Study



Peacock WF, et al. *JACC*. 2003;41(6 suppl A):336A.

PROACTION Safety Results

- **56% male, mean age 66**
- **47% white, 46% African American**
- **61% NYHA III/IV**

- **Symptomatic ↓ BP**
  - At 3 hours: 2 nesiritide, 1 placebo
  - 3-15 hours: 3 nesiritide
- **All ↓ BP rated as mild-mod, transient**
- **No adverse sequelae**

Peacock WF, et al. *JACC*. 2003;41(6 suppl A):336A.

PROACTION Mortality

- **No statistically significant differences in 7- and 30-day mortality (p>0.05)**
  - **Overall rate 2.5% (5 nesiritide, 1 standard therapy)**
- **None rated as related to study**
  - **2 within 48 hours (on nesiritide):**
    - liver cancer, accidental trauma
  - **4 after 2 weeks:**
    - standard therapy (1): sudden death
    - nesiritide (3): apnea, unexplained, CHF

Peacock WF, et al. *JACC*. 2003;41(6 suppl A):336A.

PROACTION Outcomes

- **11% ↓ in readmissions**
  - 55% standard therapy, 49% nesiritide
- **21% ↓ in HF readmissions**
  - 38% standard therapy, 30% nesiritide
- **29% ↓ in NYHA III/IV readmissions**
  - 42% standard therapy, 30% nesiritide

p=0.057

The Cleveland Clinic Foundation

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PROACTION Outcomes

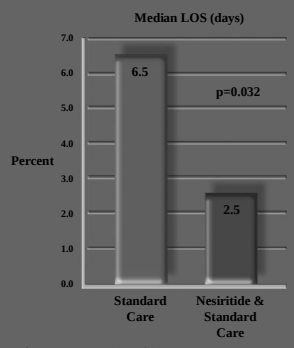
- **If admitted to the hospital from the CDU:**
  - **57% ↓ in rehospitalizations with nesiritide**
    - 23% standard therapy, 10% nesiritide
    - 23% standard therapy readmit consistent w/HCFA data
  - **If rehospitalized: 45% ↓ LOS with nesiritide**
    - 8.3 days standard therapy, 4.6 days nesiritide
- **Cost analysis: no difference between nesiritide and standard therapy**

The Cleveland Clinic Foundation

Peacock WF, et al. *JACC*. 2003;41(6 suppl A):336A.

PROACTION Outcomes

- **Nesiritide did not change index visit LOS**
- **Nesiritide combined with standard care decreased 30-day LOS >50%**



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PROACTION: Δ in BP Relative to Baseline

Δ in SBP is a function of the baseline SBP

NES	**SBP ≤100 mm Hg**	**1.24% decline**
	SBP ≥140 mm Hg	**18% decline**
Std care	**SBP ≤100 mm Hg**	**17% increase**
	SBP ≥140 mm Hg	**5.3% decline**

Heart rate at 6 hours

Nesiritide: **5% decrease**

Standard care: **1% decrease** (p=0.029)

The Cleveland Clinic Foundation

Peacock WF, et al. HFSA. 2003.

PROACTION Conclusions

Nesiritide:

- **No need for hemodynamic monitoring**
- **Viable in observation unit**
- **Improves outcomes**
- **Cost-effective**

The Cleveland Clinic Foundation