

ProCE, Inc. presents:

Acute Decompensated Heart Failure: Exciting New Treatment Options

www.heartfailureCME.com

Welcome to the ProCE Webconference

The following archived program was originally recorded on January 20, 2004 and was originally presented as a live web conference activity.



Speaker:

W. Frank Peacock, MD, FACEP
The Cleveland Clinic

Please return to HeartfailureCME.com to view the webconference archive.

This program has been funded through an unrestricted educational grant from Scios, Inc.

Powered by:




System Requirements (Internet Browser with Javascript Enabled)
Internet Explorer (4.0 or higher) or Netscape browser (4.0 or higher)

HF Demographics

If hospitalized with HF:

75% of men

85% of women

Are > 65 years old

Incidence

10/1,000 if > 65years old

Mortality:

After 1 hospitalization

4 year mortality = 61%

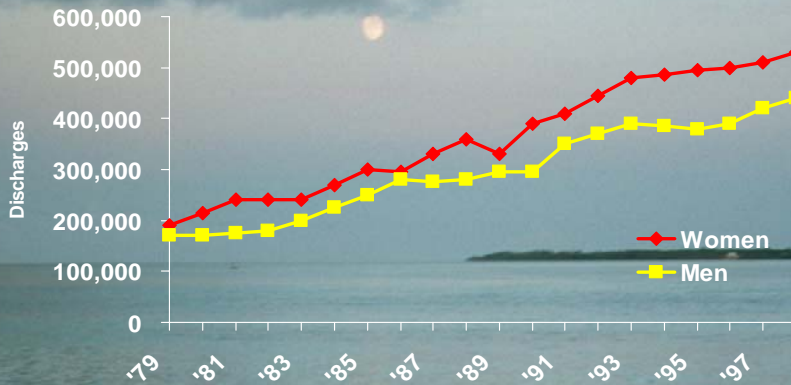
After Acute Pulm Edema

17% in hospital death



Heart Failure Hospitalizations

The number of heart failure hospitalizations is increasing



AHA, 1998 Heart and Statistical Update
NCHS, National Center for Health Statistics

AHA Heart and Stroke Statistical Update 2001

CDC/NCHS: Hospital discharges include patients both living and dead.

1999

962,000 HF discharges (155% ↑ since 1982)

~ 60% of HF d/c's are re-hospitalized by 6 M

2002

Direct inpatient HF costs > \$15 Billion

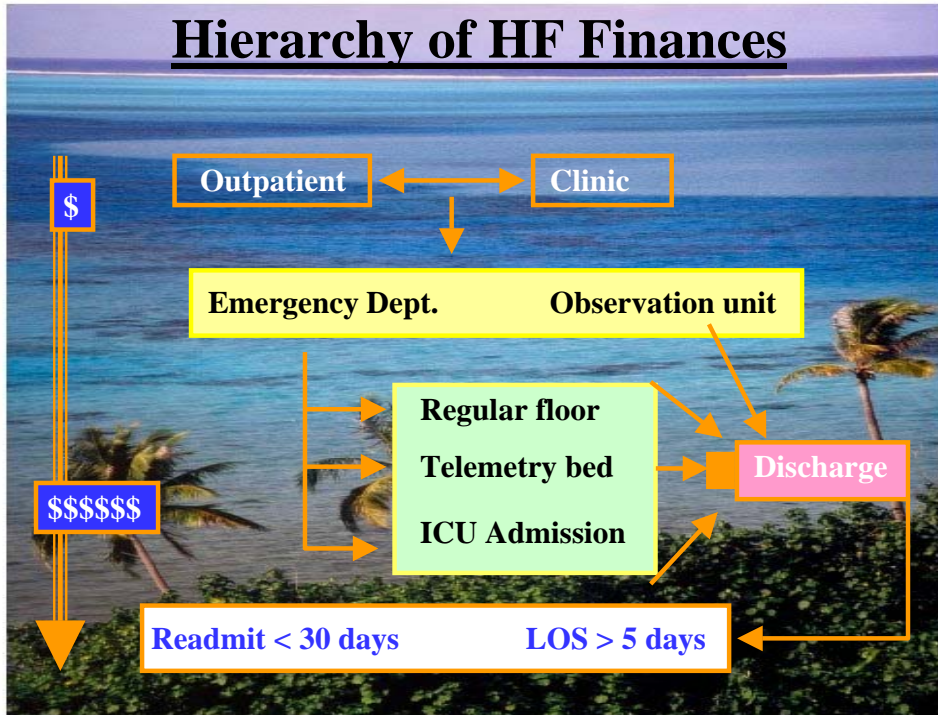
Outpatient costs will be similar, or more

\$30,000,000,000.00

30 Billion in Context:

**Exceeds the GDP of Ecuador, Oman, Kuwait,
Boca Raton, or Honolulu**

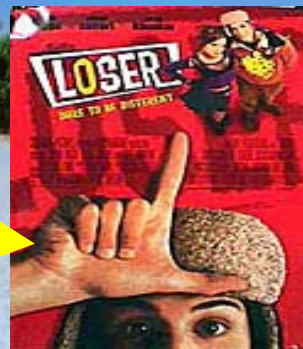
Hierarchy of HF Finances



How CMS does it? LOS

Medicare: DRG 127
5 days = break even

Day number 6
(Really want them out by
day #4 so can make margin)



The average US hospital
loses \$1,288 PER HF ADMIT

CMS National 2001 Inpatient Discharge database MEDPAR, DRG 427

Intensity
of Service

\$30



Level of care (examples)

\$400

- HF ICU admission.....\$1,500 per day
- Telemetry bed.....\$1,100 per day
- Regular floor.....\$850 per day



**Revisits are
financially deadly**

Same DRG revisit within
1 month is free



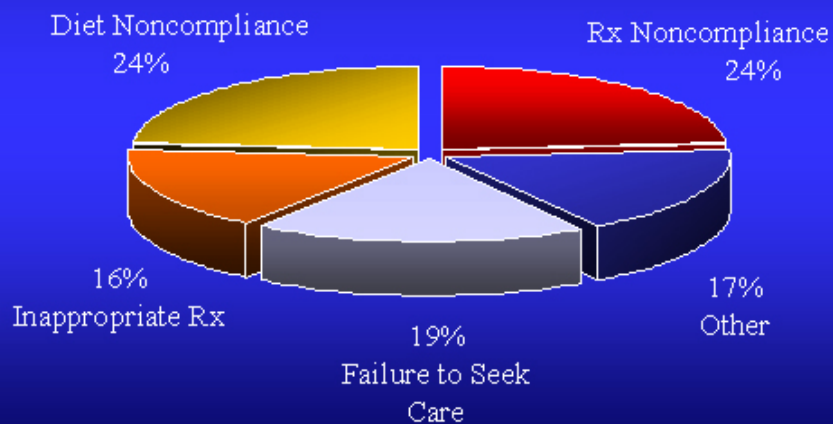
Where does the money go?



- HF Patient treated for 2 days with albuterol?
 - ↑ LOS
- What is the cost of initial non-aggressive therapy?
 - ↑ LOS
- What are the costs of complications from therapy?
 - ↑↑↑ LOS

Mean pharmacy costs for HF are
~10% of total hospitalization costs

Causes of Hospital Readmission for Congestive Heart Failure



Vinson J Am Geriatr Soc 1990;38:1290-5

Diagnosing HF

- Primary care diagnosis
 - Correct dx in
 - 18% females
 - 36% of males
- Emergency Department
 - 12% wrong diagnosis
 - 6% overdiagnosed
 - 6% underdiagnosed

Confounders

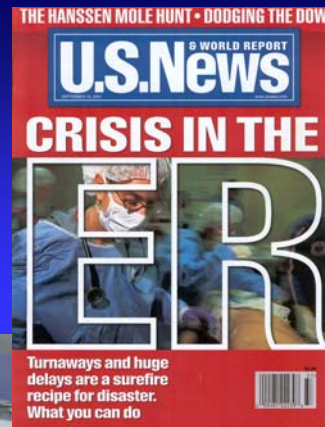
Female

Overweight

Coexisting disease

Remes J. Eur Heart J 12:3, 15-21, 1991
Dao Q. JACC 37(2), 379-85, 2001.

Sunday in the ER



The Hall and the S₃



Our Pets

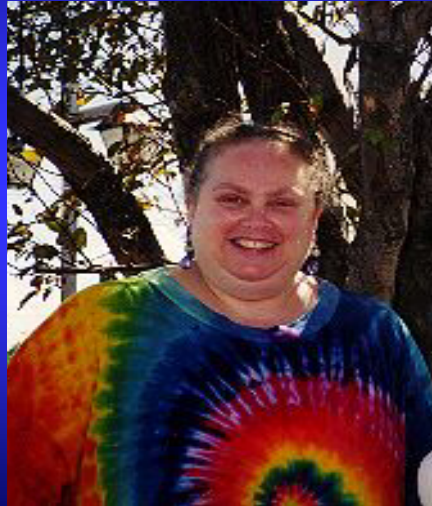
25-45% of dogs & cats
are obese.
A major health
problem in pets
Especially in 6-12 yo's
[42-84 human yrs]
Causes
Overeating
Sedentary



History and Physical

- JVD/AJR
 - The other good H&P finding

- US obesity epidemic
 - < 50% exercise more than occasionally
 - Colorado...the thinnest state, only 13% obese



How good are the tests?

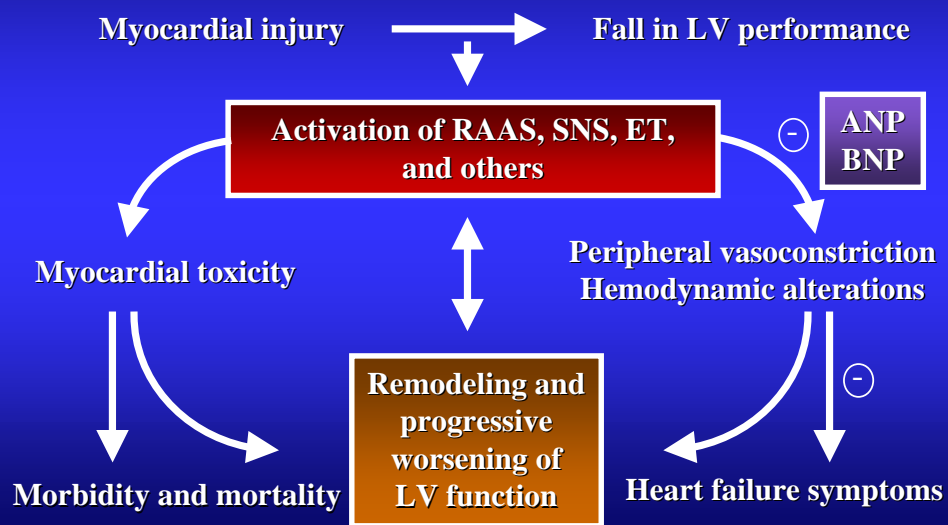
- CXR
 - Miss 20% of echo proven cardiomegaly
 - Detection of pleural effusion if supine
 - 67% Sensitivity
 - 70% Specificity
 - Even worse if done portable

Kono T. Jap Circ 56(4), 353-59, 1992
Ruskin JA. AJR 148: 681-83, 1987

How good is the H&P?

Variable	Sensitivity	Specificity	Accuracy
Hx of HF	62	94	80
Dyspnea	56	53	54
Orthopnea	47	88	72
Rales	56	80	70
S3	20	99	66
JVD	39	94	72
Edema	67	68	68

Heart Failure Pathophysiology “Your 15 again”



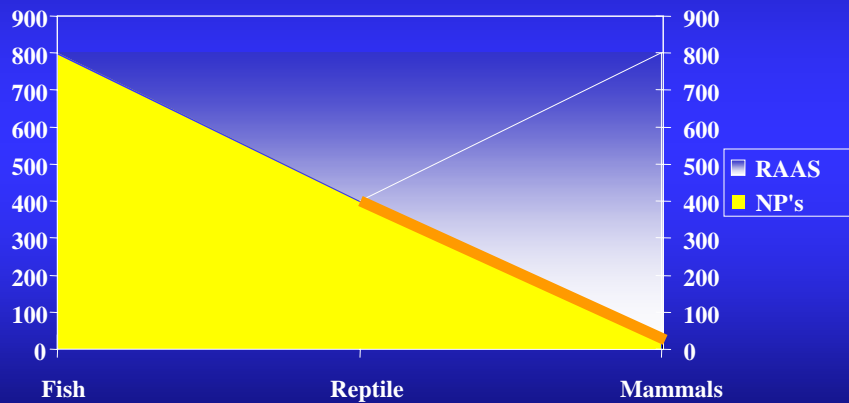
Natriuretic Peptides: Origin and Stimulus of Release

Peptide	Primary Origin	Stimulus of Release
ANP	Cardiac atria	Atrial distension
BNP	Ventricular myocardium	Ventricular overload
CNP	Endothelium	Shear stress of endothelium

ANP = Atrial Natriuretic Peptide
 BNP = B-type Natriuretic Peptide
 CNP = C-type Natriuretic Peptide

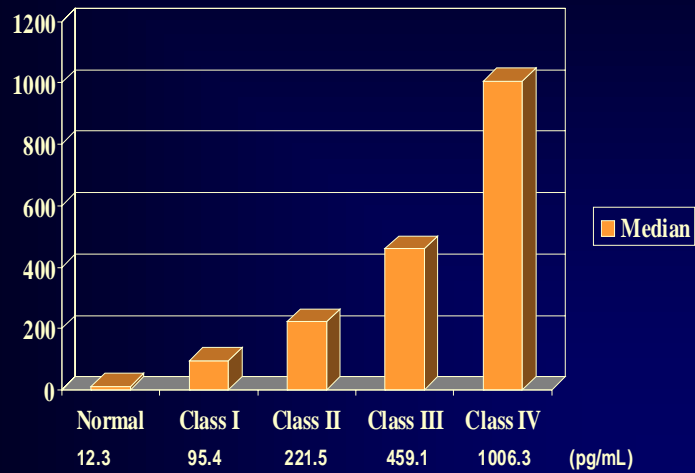
Adapted from Burnett JC, *J Hypertens* 2000;17(Suppl 1):S37-S43

Natriuretic Peptide Teleology



Fish ANP ~ 800 pg/mL

BNP vs. NYHA Classification



Triage® BNP Test Package Insert

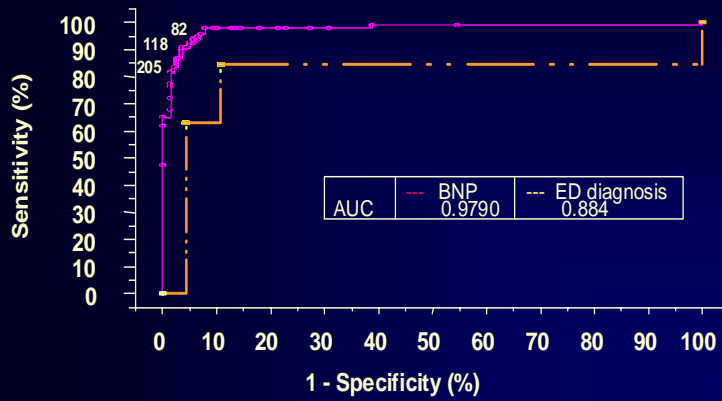
The Triage BNP® Test



The Triage® Meter Platform

- 2 cc's Whole Blood
- ~ 15 Minute Time to Result
- Quantitative Measurements
- Currently not available on any other platform

ROC Curve: BNP and ED Diagnosis



Dao, Q., Maisel, A. et al. *J. American College of Cardiology*, Vol 37, No. 2, 2001

Univariate Analysis

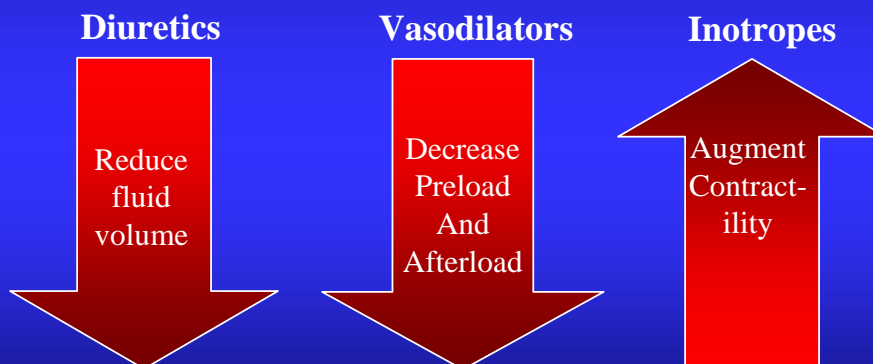
Variable	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Accuracy (%)
BNP Level (pg/ml)					
80	98 (93-100)	92 (86-96)	90 (82-94)	98 (94-100)	95
100	94 (89-97)	94 (89-97)	92 (85-96)	96 (91-98)	94
115	90 (83-95)	96 (91-98)	94 (87-97)	94 (88-97)	94
120	90 (82-95)	96 (92-99)	95 (88-98)	93 (88-96)	94
150	87 (78-92)	97 (93-99)	95 (89-98)	91 (85-95)	93

Dao, Q., Maisel, A. et al. *J. American College of Cardiology*, Vol 37, No. 2, 2001

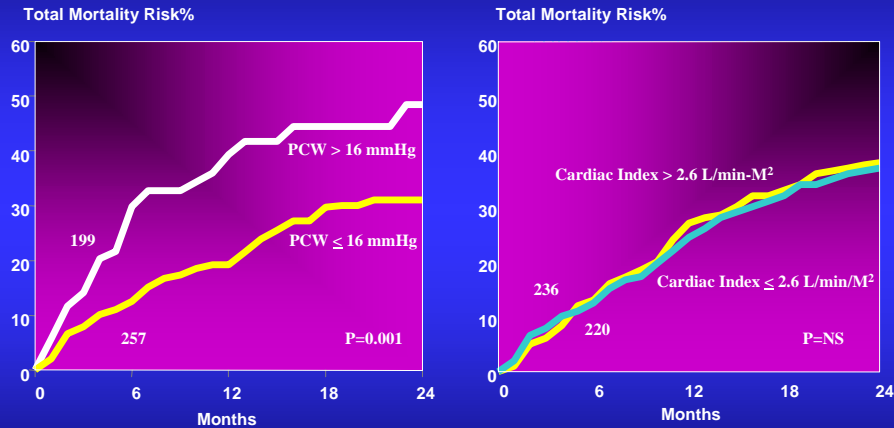
BNP Levels in Clinical Use

- **Low BNP** (< 100 pg/mL)
 - The symptoms are NOT due to HF
 - Think of a different diagnosis (COPD, etc)
- **Medium BNP** (between 100-600 pg/mL)
 - Consider the differential (PE, 1° Pulm HTN, etc)
 - Compare to prior BNP levels
- **High BNP** (> 600 pg/mL)
 - HF is probably the diagnosis
- **Trending**
 - post-therapy: may help identify higher risk patients

Current Treatment of Acute Heart Failure

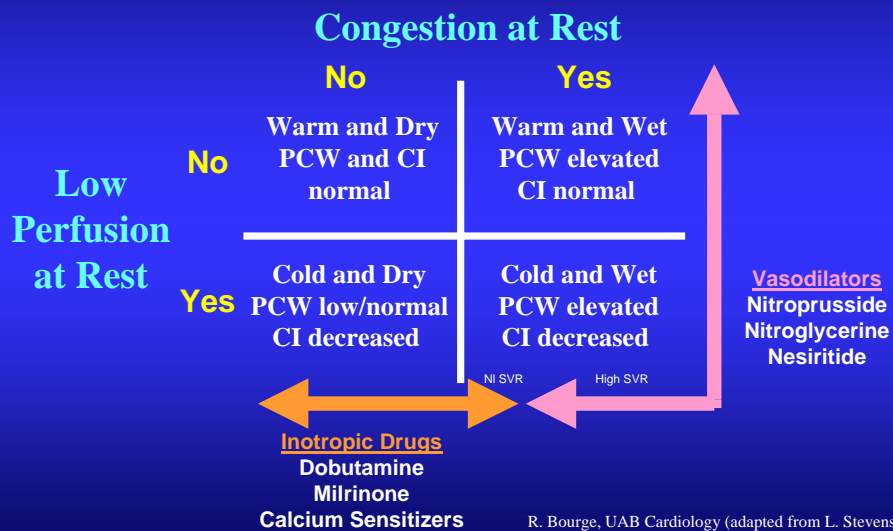


Early Response of PCW but not CI Predicts Subsequent Mortality in Advanced Heart Failure



Final hemodynamic measurement in 456 advanced HF patients after tailored vasodilator therapy
Fonarow *Circulation* 1994;90:1-488

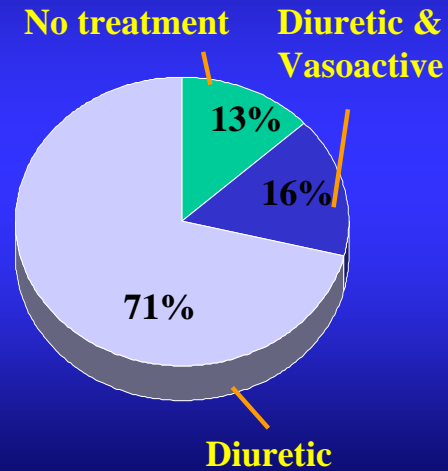
Profiles and Therapies of Advanced Heart Failure



R. Bourge, UAB Cardiology (adapted from L. Stevenson)
Stevenson LW. *Eur J Heart Failure* 1999;1:251-257

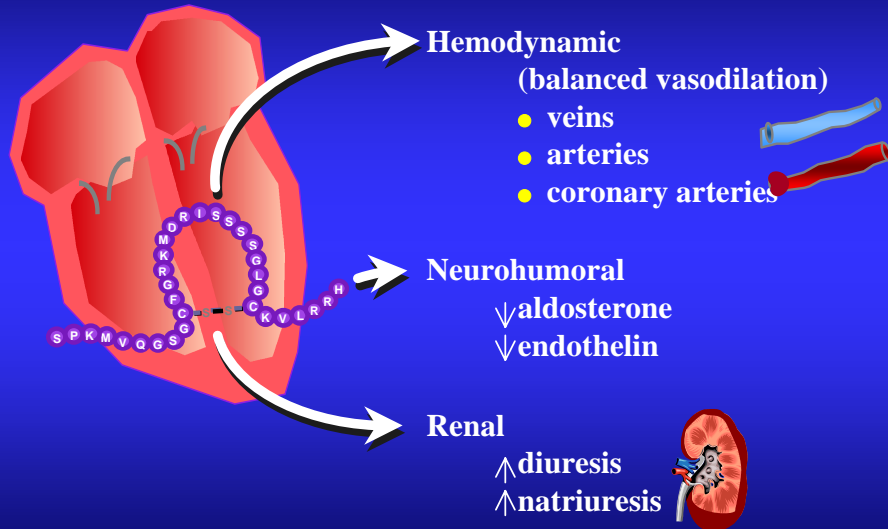
ED Treatment: 2003

- ADHERE 2nd Quarter 2003
- 100,000 HF pts, d/c'd w/ 1^o diagnosis of DRG 127
- Vasoactive definition
 - Milrinone, dobutamine, dopamine, nitroglycerin, nitroprusside, nesiritide
- "No tx" = 10% if correct for EMS therapy

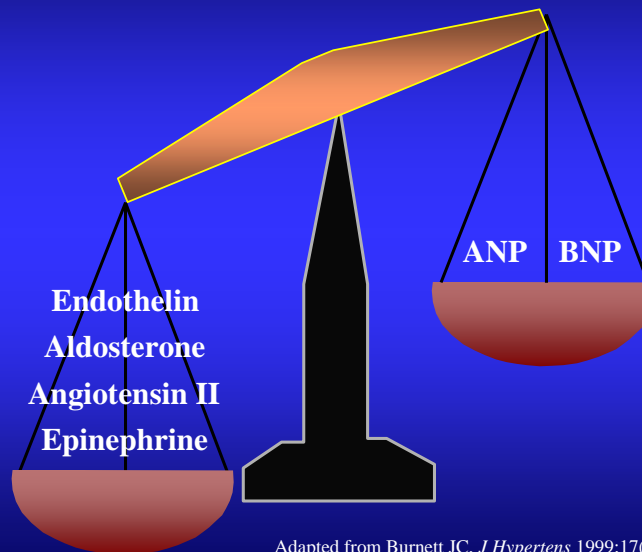


Natriuretic Peptide Physiology

Pharmacologic Actions of Human BNP



The Natriuretic Peptide System is Overwhelmed in Acute Decompensated Heart Failure



Adapted from Burnett JC, *J Hypertens* 1999;17(Suppl 1):S37-S43

Physiologic Effects of the RAAS and NPS

RAAS (Renin-Angiotensin Aldosterone System)

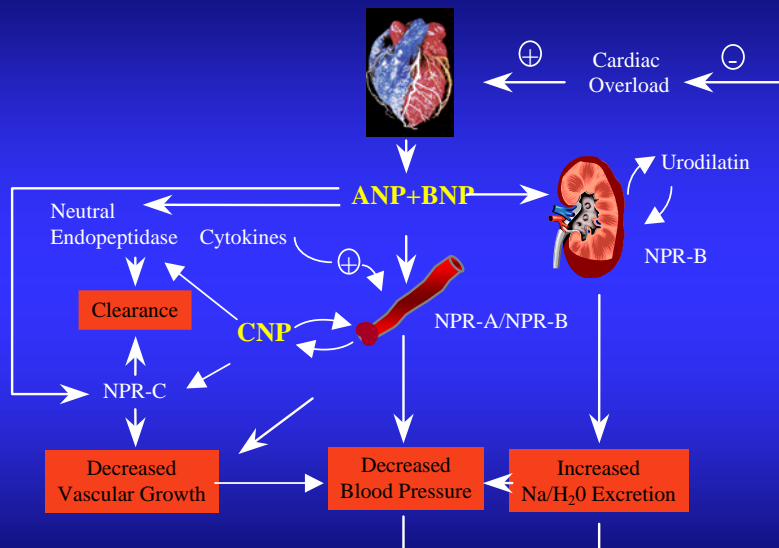
Activation of AT ₁ receptors by angiotensin II	Vasoconstriction Sodium retention Increased aldosterone release Increased cellular growth Increased sympathetic nervous activity
---	--

NPS (Natriuretic Peptide System)

ANP, BNP	Vasodilation Sodium excretion Decreased aldosterone levels Inhibition of RAAS Inhibition of sympathetic nervous activity
CNP	Vasodilation Decreased vascular smooth muscle growth Decreased aldosterone levels

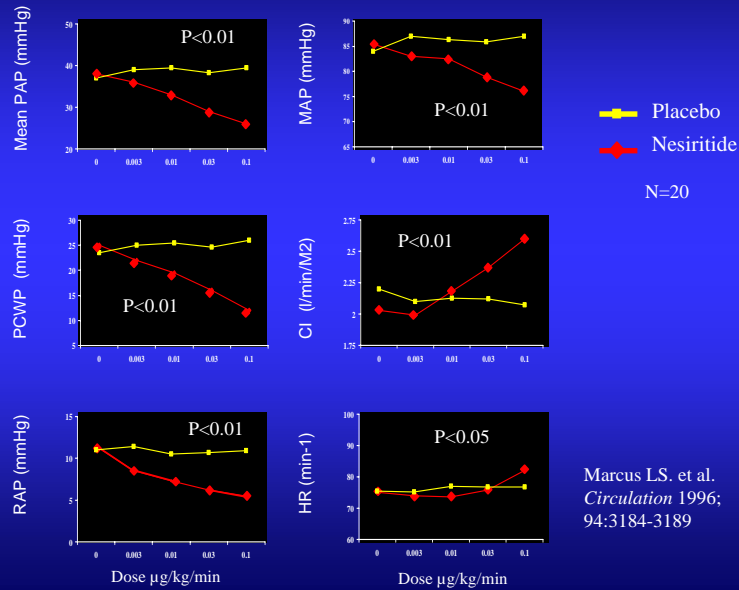
Adapted from Burnett JC, *J Hypertens* 1999;17(Suppl 1):S37-S43

Physiology of Natriuretic Peptides

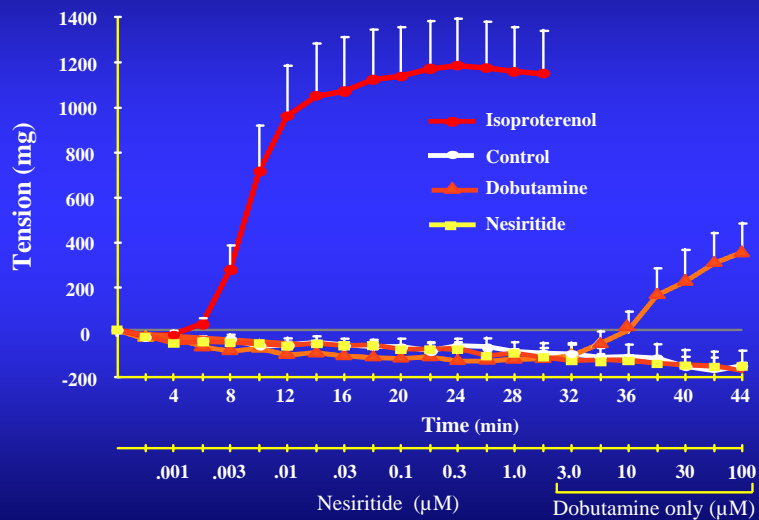


Adapted from Wilkins MR, Redondo J, Brown LA. *Lancet* 1997;349:1307-1310

Hemodynamics of hBNP

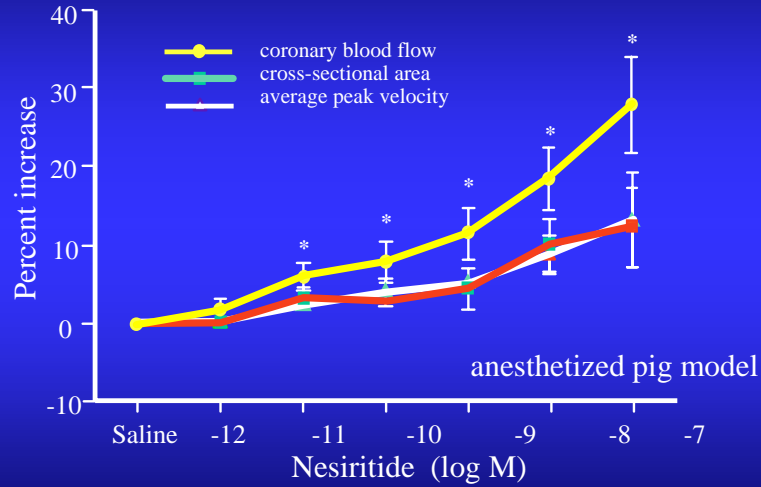


Lack of Direct Inotropic Effect with Nesiritide: Human Trabecular Tissue *in-Vitro*



Roden RL, et al. *J Cardiac Failure* 1998;4(3):19

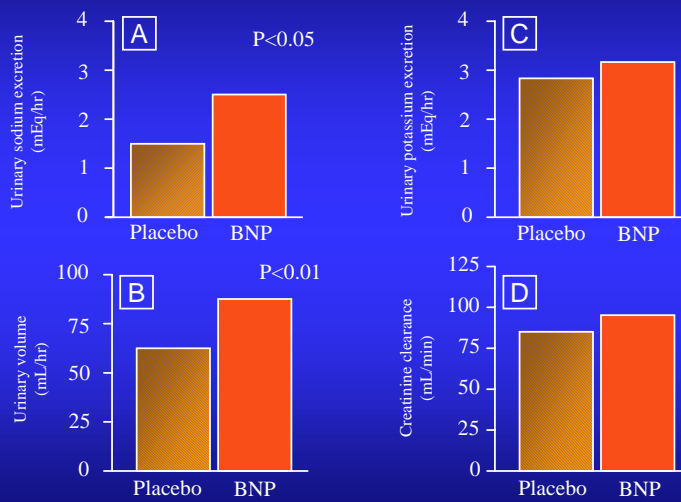
Coronary Vasodilation of Nesiritide



Zellner C. et al. *Am J Physiol* 1999;276:H1049-57

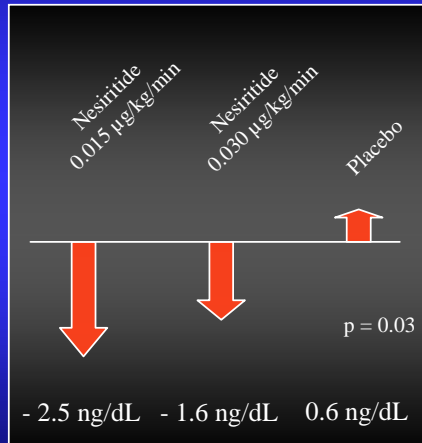
* P < 0.01

Urinary Excretion Data for hBNP



Effects on Nesiritide on Neurohormones

Plasma Aldosterone



Plasma Norepinephrine

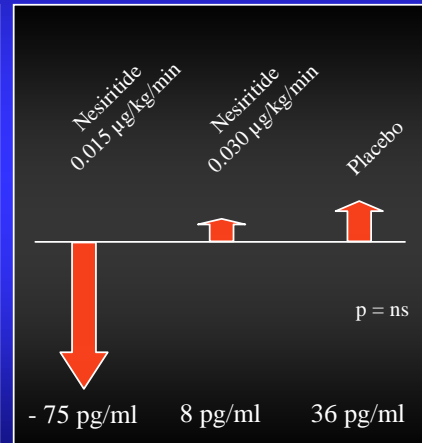
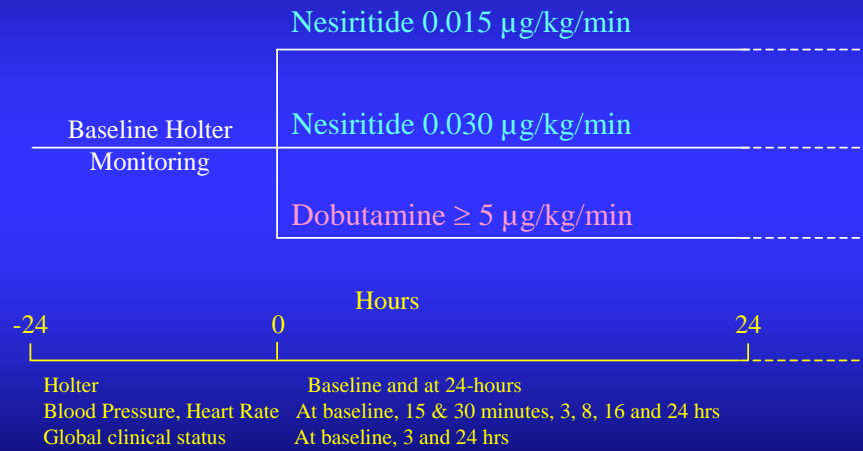


Figure adapted from data published in Colucci WS et al. *N Engl J Med* 2000;343:246-53

Clinical Effects of Natriuretic Peptides

PRECEDENT: Study Design



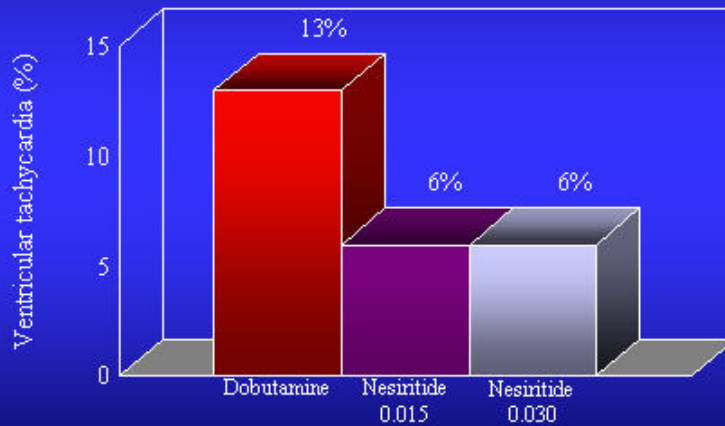
Burger AJ. et al. *J Cardiac Failure* 1999;5 (Suppl 1):178

PRECEDENT: Primary Endpoints

Holter Endpoint	Dobutamine (n = 28)	Nesiritide 0.015 µg/kg/min (n = 28)	Nesiritide 0.030 µg/kg/min (n = 29)	P value
PVCs/hour	+56 ± 148	-1 ± 62	-8 ± 60	0.038
Repetitive beats	+5 ± 14	-3 ± 11	-1 ± 4	0.020
Heart rate (beats/min)	+4 ± 8	0 ± 6	-1 ± 6	0.042

Burger AJ. et al. *J Cardiac Failure* 1999;5 (Suppl 1):178

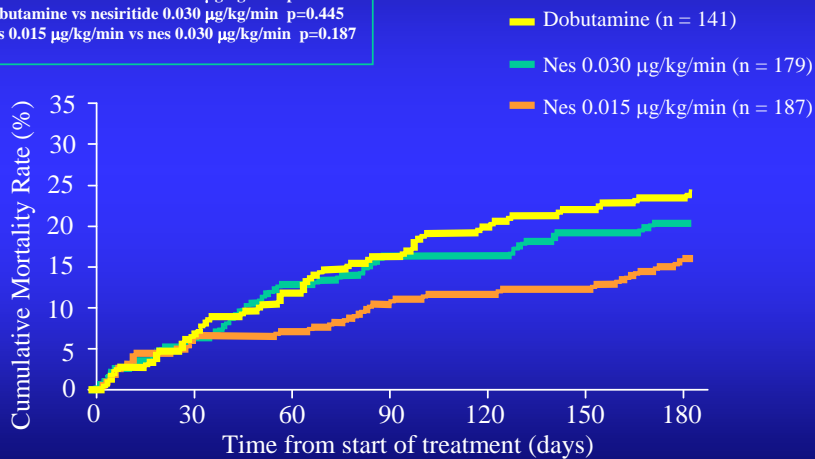
PRECEDENT: Effect on Ventricular Tachycardia



Burger AJ et al. The PRECEDENT Study *J Cardiac Fail* 1999;5 (Suppl 1):178

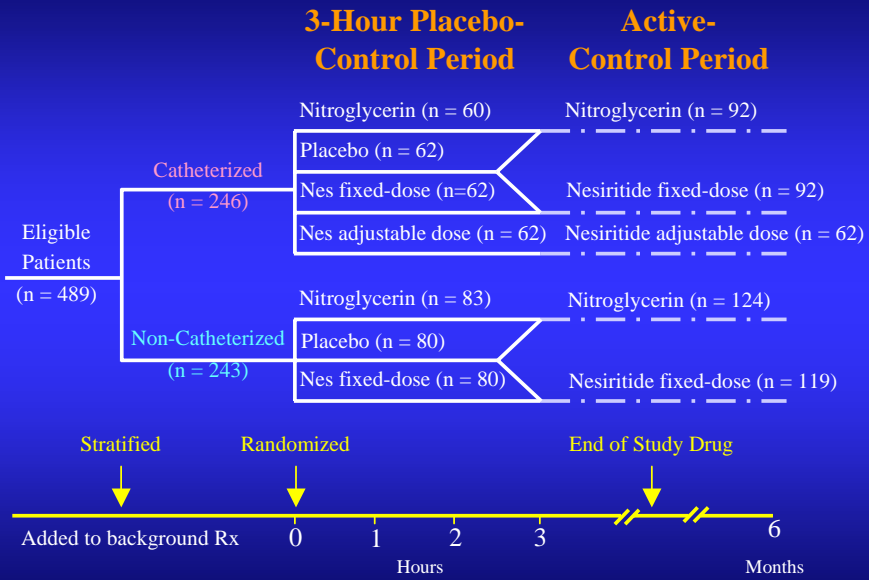
Effect of Short-term Nesiritide or Dobutamine Therapy on 6 Month Survival

Log - rank Test:
 Dobutamine vs nesiritide 0.015 $\mu\text{g}/\text{kg}/\text{min}$ $p=0.041$
 Dobutamine vs nesiritide 0.030 $\mu\text{g}/\text{kg}/\text{min}$ $p=0.445$
 Nes 0.015 $\mu\text{g}/\text{kg}/\text{min}$ vs nes 0.030 $\mu\text{g}/\text{kg}/\text{min}$ $p=0.187$



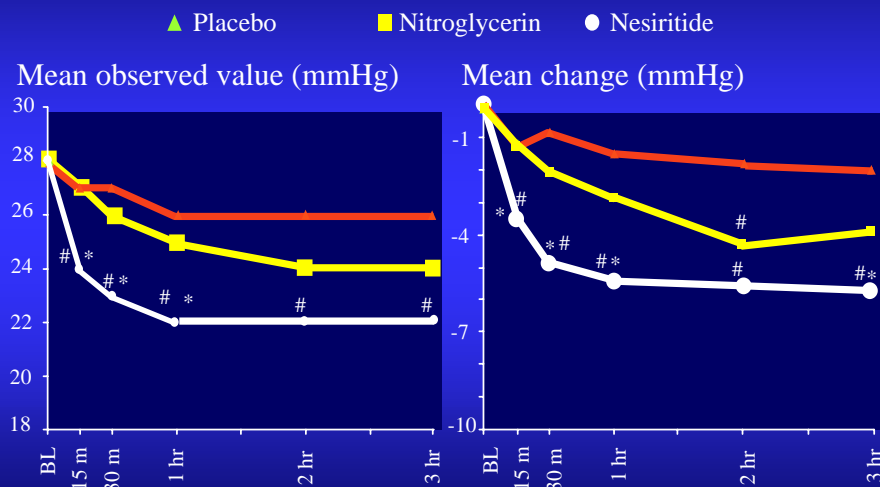
Elkayam U. et al, *J. Cardiac Failure* 2000;6 (Suppl 2):169

VMAC Study Design



Young JB et al. AHA Meeting 2000 Late Breaking Trials Session

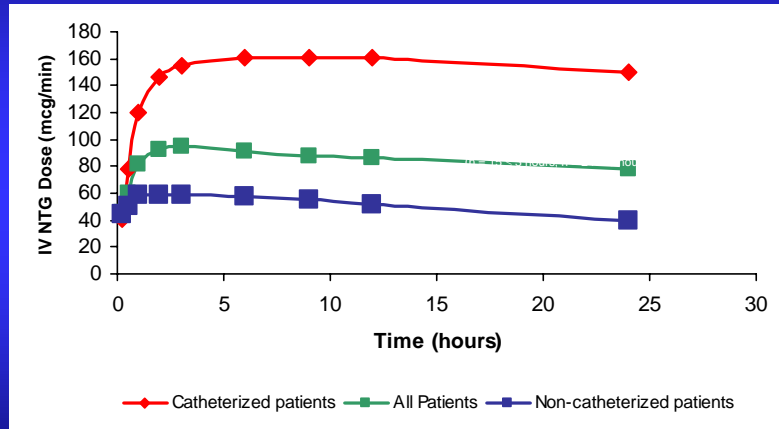
VMAC Primary Endpoint: PCWP through 3 Hours



Young JB et al. AHA Meeting 2000 Late Breaking Trials Session

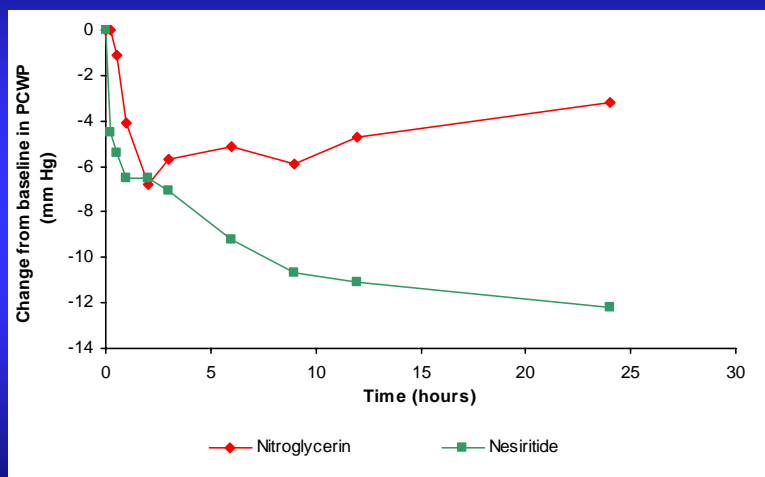
p < 0.05 versus placebo
* p < 0.05 versus NTG

IV Nitroglycerin vs. Time (USC subset of VMAC Patients)



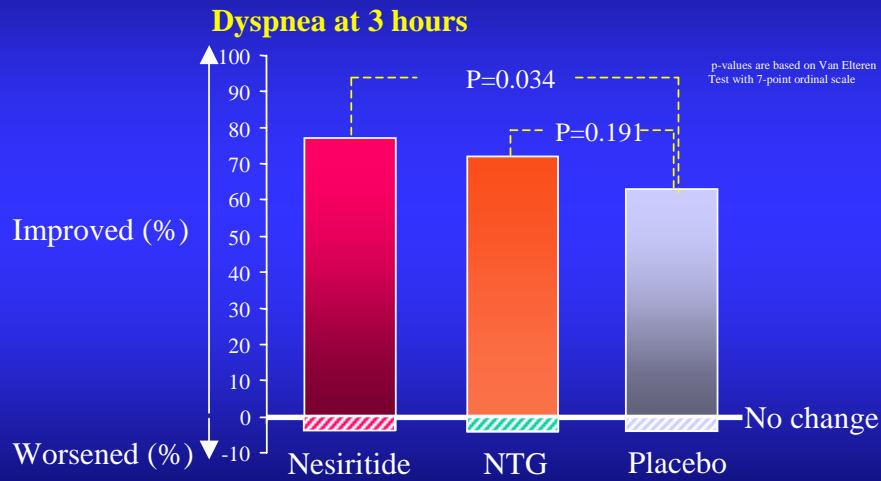
Elkayam U for the VMAC Study Group. Superior Hemodynamic Effect of Nesiritide (B-Type Natriuretic Peptide) Compared to High Dose Nitroglycerin (NTG) in Patients With Decompensated Heart Failure. NAIIP Fifth Annual Meeting Research and Clinical Vignette Abstract Book 2002; Page 7

Change in PCWP – IV Nitroglycerin vs. Nesiritide (USC subset of VMAC Patients)



Elkayam U for the VMAC Study Group. Superior Hemodynamic Effect of Nesiritide (B-Type Natriuretic Peptide) Compared to High Dose Nitroglycerin (NTG) in Patients With Decompensated Heart Failure. NAIIP Fifth Annual Meeting Research and Clinical Vignette Abstract Book 2002; Page 7

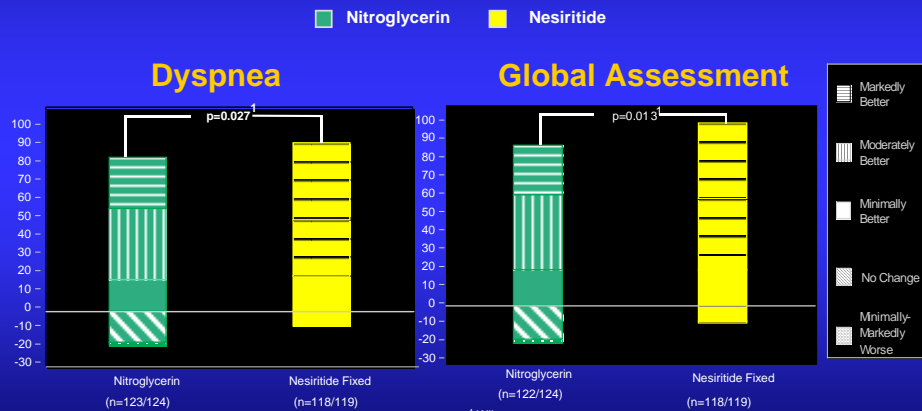
VMAC Primary Endpoint



Young JB et al. AHA Meeting 2000 Late Breaking Trials Session

VMAC: Symptoms at 24 Hours

Non-Catheterized Subjects as Randomized



¹ Wilcoxon

¹ Wilcoxon

Young JB et al. AHA Meeting 2000 Late Breaking Trials Session

Adverse Events in VMAC Placebo-Controlled Period

Adverse Event	NTG (n = 143)	Nesiritide (n = 204)	Placebo (n = 142)	P value
Any adverse event	39 (27%)	36 (18%)	20 (14%)	0.015
Headache	17 (12%)	11 (5%)	3 (2%)	0.003
Hypotension	6 (4%)	5 (2%)	0 (0%)	0.031
Symptomatic hypotension	2 (1%)	1 (0.5%)	0 (0%)	0.481
Abdominal pain	4 (3%)	0 (0%)	0 (0%)	0.014

Young JB et al. *AHA Meeting 2000 Late Breaking Trials Session*

VMAC Adverse Events Nesiritide Vs Nitroglycerin First 24 Hours

Adverse Event	Nitroglycerin (n = 216)	Nesiritide (n = 273)	p-value ¹
Any adverse event	146 (68%)	140 (51%)	< 0.001
Headache	44 (20%)	21 (8%)	< 0.001
Symptomatic hypotension	10 (5%)	12 (4%)	1.000
Ventriculartachycardia	11 (5%)	9 (3%)	0.362
Nausea	13 (6%)	10 (4%)	0.283
Abdominal pain	11 (5%)	4 (1%)	0.032
Dizziness	4 (2%)	7 (3%)	0.762

Young JB et al. *AHA Meeting 2000 Late Breaking Trials Session*

¹ Fisher's test

Recommended Use of Nesiritide

■ Indication:

- Acute decompensated HF without cardiogenic shock or systemic hypoperfusion

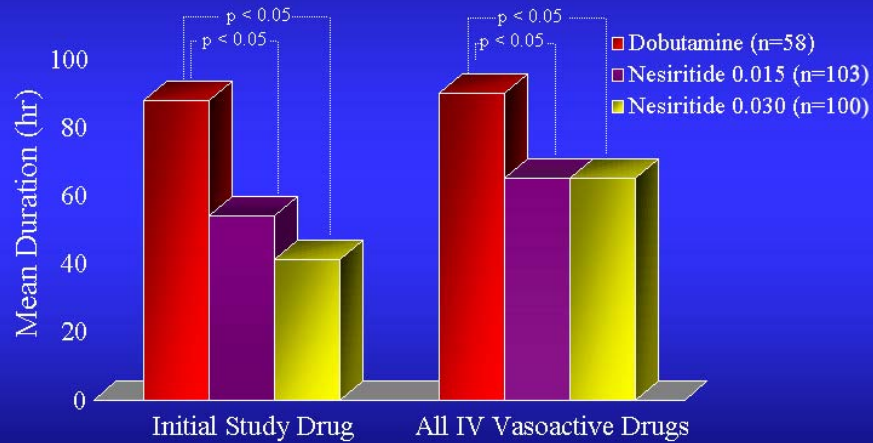
■ Administration:

- Initial bolus dose (2 $\mu\text{g}/\text{kg}$), then
- Fixed-dose infusion (0.01 $\mu\text{g}/\text{kg}/\text{min}$)
- If greater hemodynamic effect needed
 - May increase infusion rate in increments of 0.005 $\mu\text{g}/\text{kg}/\text{min}$, q3 hours, to a maximum of 0.03 $\mu\text{g}/\text{kg}/\text{min}$

Natriuretic Peptides

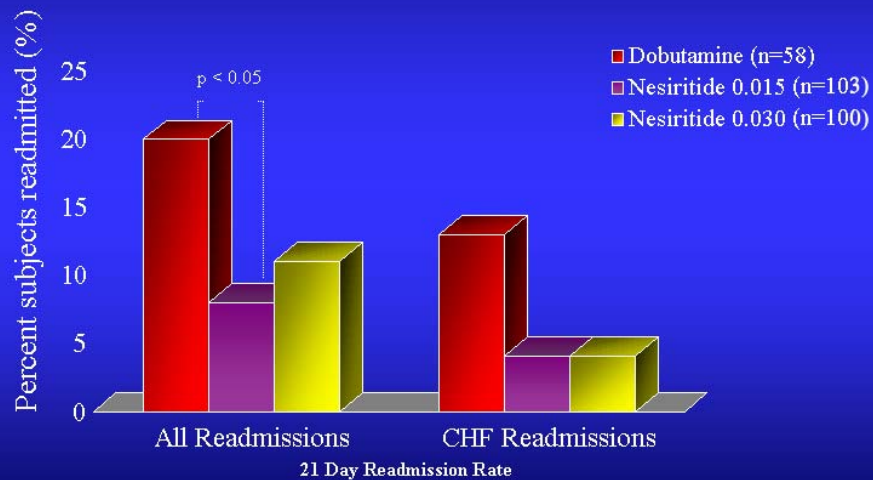
Cost Analysis

Duration of IV Administration Required in Acutely Decompensated HF



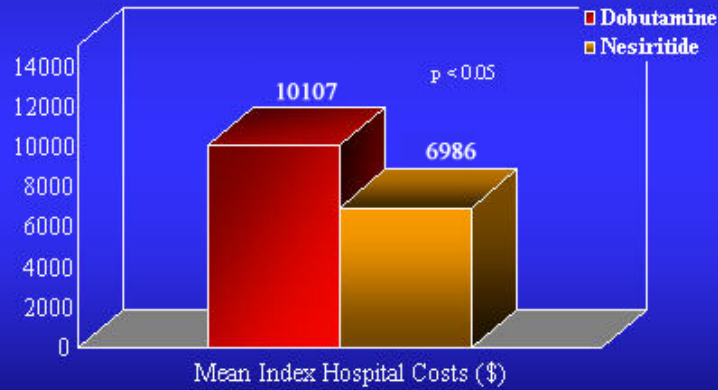
Duration of administration of intravenous agent administration till the patient was stabilized on oral medications
Silver MA. et al. *J. Cardiac Failure* 1998;4(3, Suppl 1):150A

Nesiritide Vs Dobutamine: Hospital Readmission Rate



Silver MA. et al. *J. Cardiac Failure* 1998;4(3, Suppl 1):150A

Economic Implications: Nesiritide vs. Dobutamine



Regression analysis of National Hospital Database with Monte Carlo Simulation with 1000 patients per group
De Lissovoy G et al. 5th Annual Scientific Session of the HFSA 2001

Nesiritide in the CCU

130 consecutive CCU adHF discharges
Nesiritide patients with greater severity of illness

	Nes (n = 58)	No Nes (n = 72)	P value
Systolic BP*	115	126	0.011
Sodium	137	137	0.759
BUN	50	40	0.067
Creatinine*	1.97	1.57	0.023
EF*	18	24	0.023
QRS duration*	152	130	0.005
On ACEI/ARB (%)	93	86.5	0.54
On B-Blockers (%)	59	69	0.45

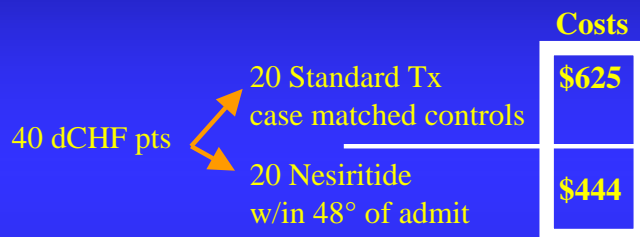
Chang R, ACC 2003

Nesiritide in the CCU: Results

	Nes (n = 58)	No Nes (n = 72)	P value
Δ BUN	-1.9	-1.4	0.843
Δ Creatinine	-0.11	-0.01	0.636
Δ Weight (lbs)	10.5	11	0.740
LOS (days)	2.87	3.79	0.002

Chang R, ACC 2003

Nesiritide vs Nitroglycerin Cost-Effectiveness for dCHF



Nesiritide

- Shorter LOS (-9.25 CCU hrs, -20 hosp hrs)
- Fewer other meds (-2.7 diuretic, and 2.5 KCL doses)
- Less dopamine, dobutamine, IV nitroglycerin, milrinone
- Fewer KP-7 (-2.3)

Hilleman DE, et al.. HFSA, 2002

Natriuretic Peptides:

The New Stuff

ADHERE Registry

- 260 hospitals
- Discharge Diagnosis DRG 127
- 46,599 patients
 - Excluded MI, or BP < 90 mmHg
- IV vasoactive therapy
 - Nesiritide, nitroglycerin
 - Nitroprusside
 - Milrinone, dopamine, dobutamine, etc

Peacock, et al, Ann of EM, 2003

ADHERE Registry

■ Stats:

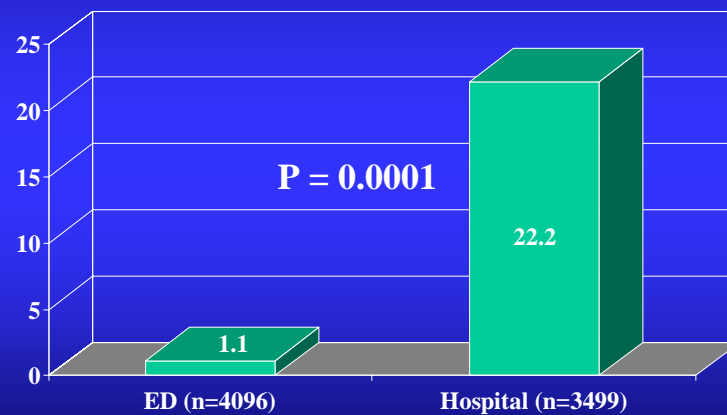
- Wilcoxon for continuous or ordinal variables
- CHM Chi Square for differences in proportions

■ Results

- ED initiation N = 4096
- Hospital initiation N = 3499

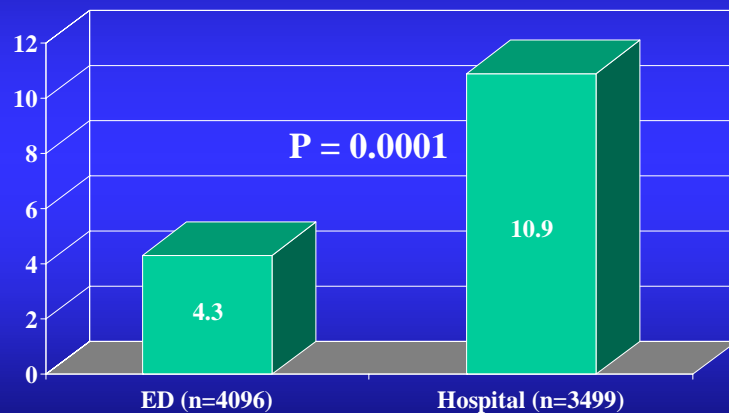
Peacock, et al, Ann of EM, 2003

Time to Treatment (hrs) vs. Where Vasoactive Started



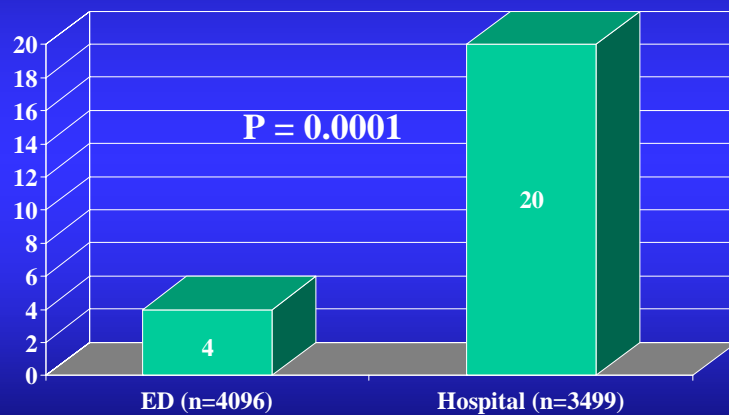
Peacock, et al, Ann of EM, 2003

Mortality vs. Where Vasoactive Started



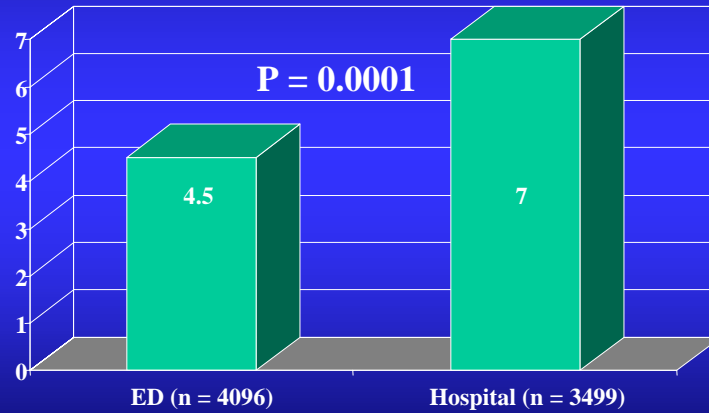
Peacock, et al, Ann of EM, 2003

ICU Transfer vs. Where Vasoactive Started



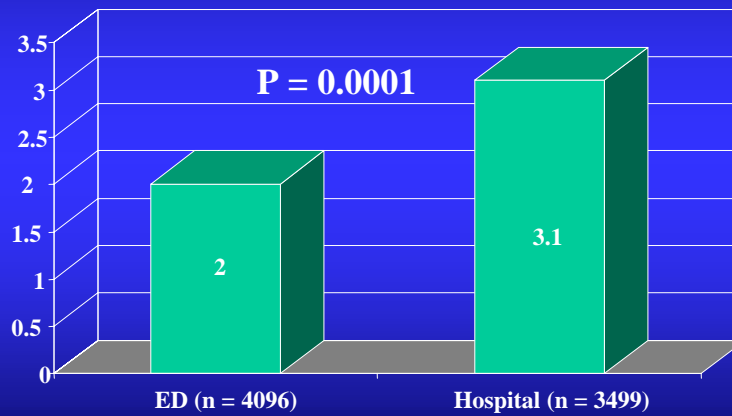
Peacock, et al, Ann of EM, 2003

Hospital LOS (days) vs. Where Vasoactive Started



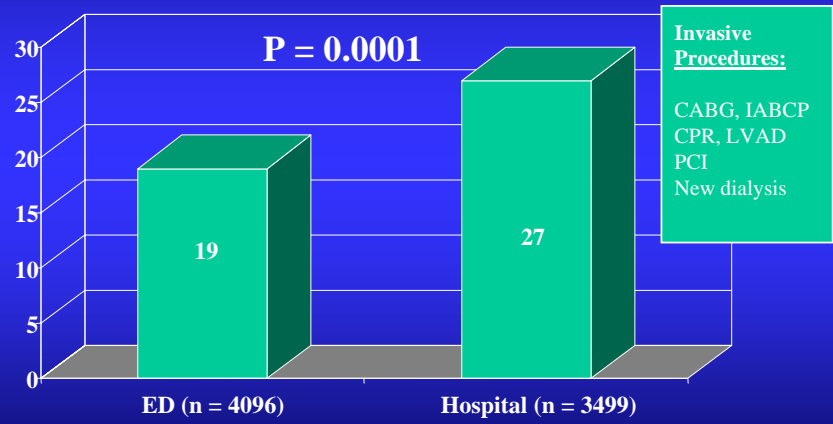
Peacock, et al, Ann of EM, 2003

ICU LOS (median days) vs. Where Vasoactive Started



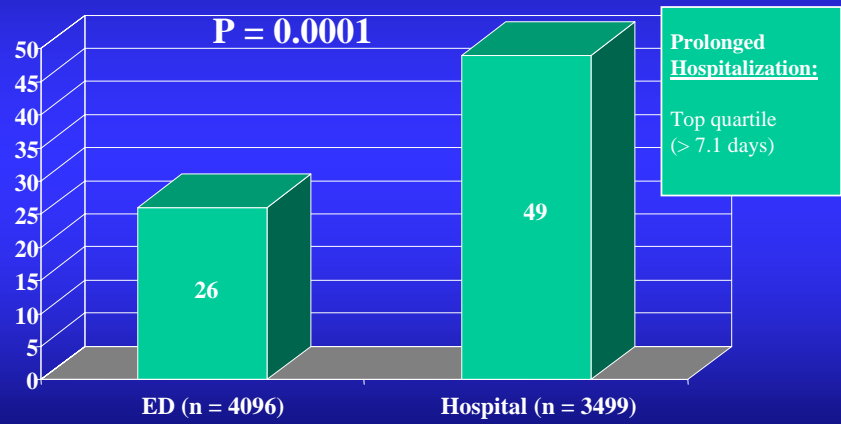
Peacock, et al, Ann of EM, 2003

Invasive Procedures (%) vs. Where Vasodilator Started



Peacock, et al, Ann of EM, 2003

Prolonged Hospitalization vs. Where Vasodilator Started



Peacock, et al, Ann of EM, 2003

Limitations

■ Registry data

- Describes associations only
- Does not elucidate cause and effect
- Variables are uncontrolled

■ Strengths

- Big honkin' numbers

Peacock, et al, Ann of EM, 2003

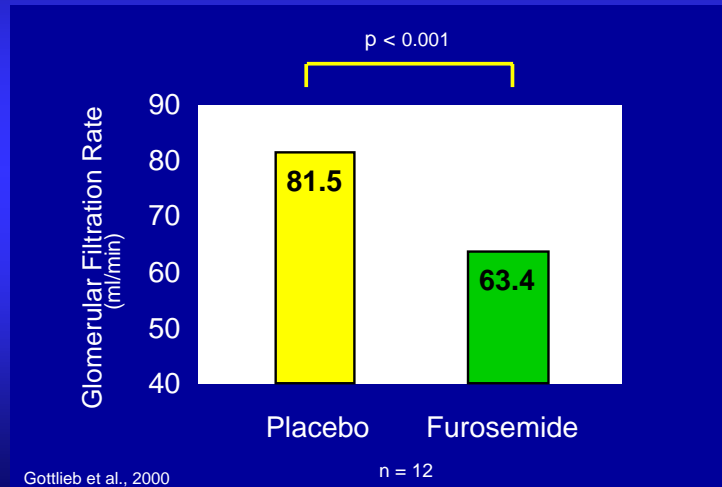
Conclusions

■ Early initiation of vasoactive agents is associated with:

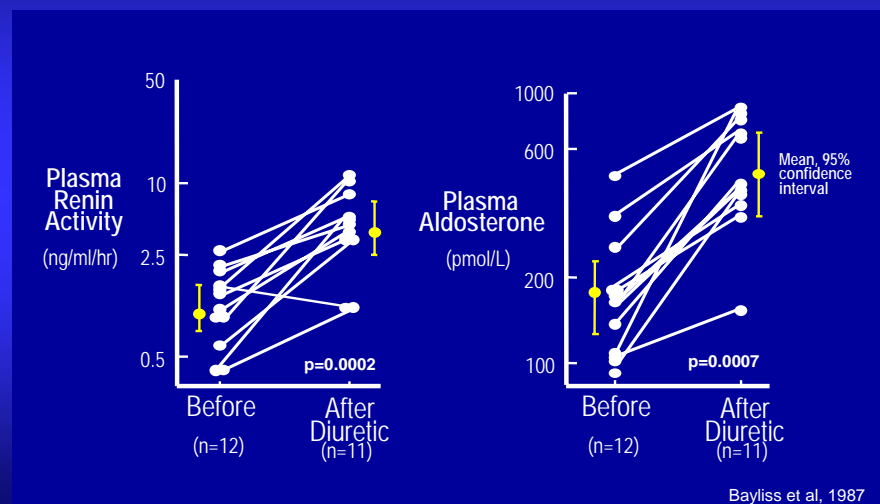
- Fewer deaths
- Fewer invasive procedures
- Fewer ICU transfers
- Shorter ICU and hospital LOS

Peacock, et al, Ann of EM, 2003

Loop diuretics diminish GFR in patients with heart failure

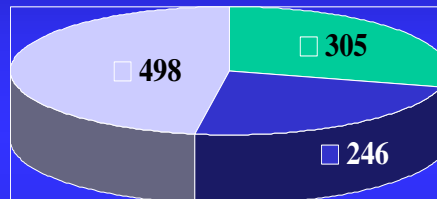


Diuretics activate neurohormonal systems in heart failure



SAFETY Study

- Comparative
 - Standard tx vs. Nes
- Precedent
 - Dobutamine vs. Nes
- VMAC
 - Nitroglycerin vs. Nes
- Nesiritide N= 639
- Control N= 401



SAFETY Study

- Demographics
 - 62 ± 13.7 yrs, 68% male
 - 37% NYHA class IV at baseline
 - 87% systolic dysfunction
- Hypotension:
 - No difference between controls and Nesiritide at recommended doses ($p > 0.05$)

SAFETY Study

Event	Control	Nesiritide	P value
V. Tach	11% (dobutamin)	5%	0.015
Headache	15% (20% if ntg)	8%	0.001
Bradycardia	< 1%	3% (n = 21) (only 3 tx'd)	0.002

SAFETY Study

- Control group had more:
 - Infusion site pain ($p < 0.05$)
 - Dizziness ($p < 0.05$)

- Nesiritide: creatinine increase:
 - Mean of 0.1 mg/dL ($p > 0.05$)
 - maximim 3.8 mg/dL
 - $p < 0.05$ only in the subgroup that exceeded recommended dosing

SAFETY Study

- Conclusion:
- Nesiritide is safe and generally well tolerated in acutely decompensated congestive HF.

Nesiritide: Hypotension

- At recommended doses; incidence of symptomatic hypotension is 0.5% in first 3 hours, 4% at 24 hours
 - Mean duration of symptomatic hypotension: 2.2 hours
- If hypotension occurs:
 - Reduce dose or discontinue nesiritide
 - Consider MI, misdiagnosis, or pre-load dependent state
- If nesiritide needs to be initiated after patient is stabilized:
 - Skip bolus
 - restart at 30% of the infusion dose

Nesiritide in ACS

- 61 VMAC with ACS
 - ACS defined as:
 - ECG or marker changes, USA
 - PTCA, CABG, CVS death
 - Intervention:
 - std tx w/ ntg or nesiritide
 - Demographics
 - Mean age 63.6y, 54% male, Mean EF 34%
 - 43% white, 34% hispanic, 15% Afr Am



Peacock, et al, JHF 2003

Nesiritide vs. Nitroglycerin ACS

- Mortality is the same ($p > 0.05$)
- No difference in Δ PCWP ($p > 0.05$)
- No difference in hypotension rates ($p > 0.05$)

Peacock, et al, JHF 2003

Nesiritide in ACS: Dyspnea score

- Overall no difference
 - No patient worsened
- Mark-Mod better
 - 6 hours ($p = 0.146$)
 - Ntg 15(45%)
 - Nst 16 (62%)
 - 24 hours ($p = 0.209$)
 - Ntg 21(63%)
 - Nst 19 (70%)
- No Swan group
- Mark-Mod better
 - 6 hours ($p > 0.05$)
 - No difference
 - 24 hours ($p = 0.031$)
 - Ntg 55%
 - Nst 75%
- At least min better
 - Ntg 71%
 - Nst 100%

Peacock, et al, JHF 2003

Nesiritide in ACS: Global Clinical Score

- Overall ($p > 0.05$)
 - None with worse score
 - 6 hr Mark-Mod better
 - Ntg 45 %
 - Nst 63 %
 - 24 hr Mark-Mod better
 - Ntg 59 %
 - Nst 67 %
- Non-SG
 - 6 hour Mark-Mod better
 - Ntg 32 %
 - Nst 75 % ($p = 0.031$)
 - 24 hour Mark-Mod better
 - Ntg 52%
 - Nst 75% ($p = 0.029$)

Peacock, et al, JHF 2003

VMAC & ACS Readmits

	Nitro	Nesiritide	P value
Overall 30 day Readmit	19%	8%	0.449
Overall multiple 30 day readmits	20%	8%	0.305
No PAC: 30 day readmit	17%	0%	0.276

P > 0.05

Peacock, et al. JHF 2003

The ED Observation Unit

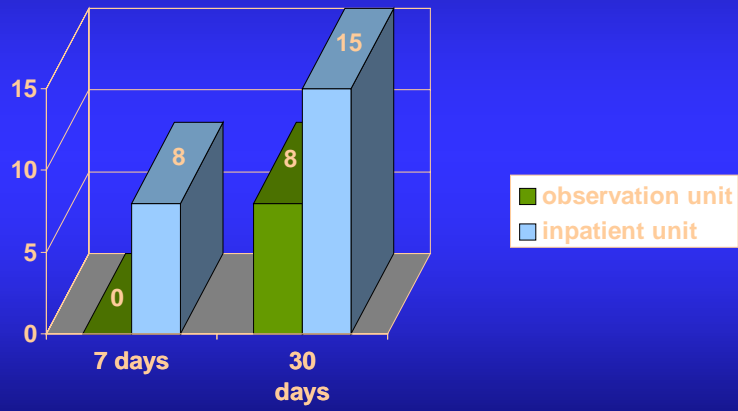
Observation Unit

- April 1, 2002 CMS approved APC
 - (ambulatory payment code)
 - Outpatient HF treatment in ED OU
 - Management without “hospitalization”
 - Revisits within 30 days can be re-imbursed

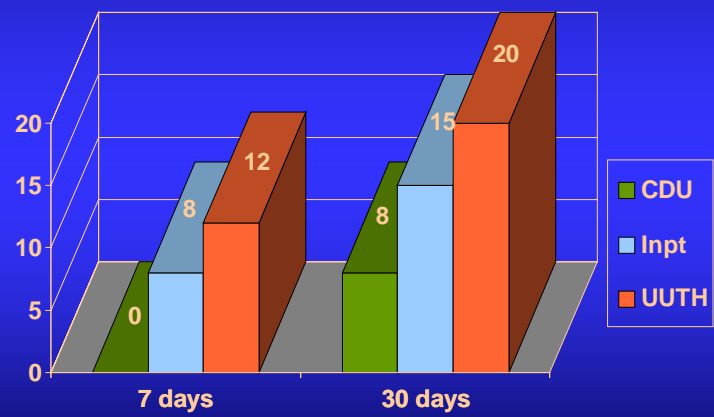
Observation Unit

- Outpatient unit with limited LOS
 - 24 hours maximum
- Eligibility
 - “Relatively” stable, Nursing ratio 3-4:1
 - Unclear diagnosis
 - Conditions that may benefit from short, intensive therapies
 - Asthma, chest pain, HF

Re-admissions (%)



OH-PRO Re-admissions



OU HF Entry

Must have 1 from each category

- History
 - Orthopnea, DOE, PND, SOB
 - Swelling of legs or abdomen, Weight gain
- Physical Exam
 - JVD, HJR, S₃/S₄, Inspiratory rales, Peripheral edema
- Chest X-Ray
 - Cardiomegaly, PVC, Kerley B lines,
 - Pulmonary edema, Pleural effusion
- BNP > 100 pg/mL

HF Protocol Exclusions

- Chronic renal failure requiring dialysis
- Temperature > 38.5
- Peak flow < 50% of predicted, with wheezing
- Require an IV vasoactive medication
- Clinically significant arrhythmia
- ECG with diagnostic criteria for acute MI or ischemia
- CXR with pulmonary infiltrates
- Abnormal cardiac markers

OU HF Protocol

- Nursing driven standard orders
 - Diuretic & ACEI algorithms
 - Aggressive fluid management monitoring
 - admission weights, strict I & O's
 - fluid restriction, low Na+ diet
 - K⁺ and Mg⁺⁺ dosing
 - AMI R/O, echocardiography
 - Patient education (movie, bedside teaching)
 - SW and dietary consults
 - D/C planning, HF consultation

Peacock WF. *Emerg Med Clin North Am.* February 2001

OU Discharge

- Patient reports subjective improvement
- Ambulatory, without long suffering orthostasis
- Resting HR < 100 beats/min, BP > 80 mmHg
- Total urine output > 1 L, and > 30 cc/hr or 0.5 cc/kg/hr
- Room air O₂ sat > 90% (unless on home O₂)
- No CKMB > 8.8 ng/ml, or troponin T > 0.1
- No ischemic CP or clinically significant arrhythmia
- Stable electrolyte profile

Results

- 154 patients enrolled
 - 60% male, mean age 67.9 y (31-96, SD = 13.2)
 - 149 (97%) primarily cared for at our facility

- 50 entered before, and 104 after, protocol began
- 6 (12%) of pre, and 1 (1%) of post-protocol group lost to follow up

90 Day Outcomes

	Before	After	Δ (%)	P
HF revisits (%)	90	51	44	0.000
HF re-hosp (%)	77	50	36	0.007
Death (%)	4	1	75	0.096

Peacock, et al, CHF, 2001

OU Diuretic & VD Protocol Impact

	Before	After
OU Volume	18%	26%
Discharges	33%	42%
Inpatient LOS	4.4 days	3.6 days
Inpatient Acuity	25%	36%

Total Costs Decrease

- Total costs decrease by \$37,217
- Per case costs:
 - Unchanged if discharged from ED
 - OU costs increase \$81
- Savings due to admission avoidance
- Annualized savings: \$89,321

Peacock, et al, CHF, 2001

Hospital Outpatient

“Observation Services” Criteria

- Payer
- Site of Service
 - Hospital Outpatient
- Clinical Requirements
 - Diagnosis
 - Length of Stay
 - Diagnostic Tests

Medicare

- Hospital Emergency Room
- Hospital outpatient observation unit
- Hospital outpatient heart failure clinic
- Hospital outpatient infusion clinic

- ICD-9 Diagnosis Code for CHF
 - List of acceptable codes from CMS includes 428.0-428.33
- Observation Min. 8 hrs-Max. 48hrs
- Diagnostic Tests Performed
 - Pulse Oximetry
 - Electrocardiogram
 - Chest X-Ray

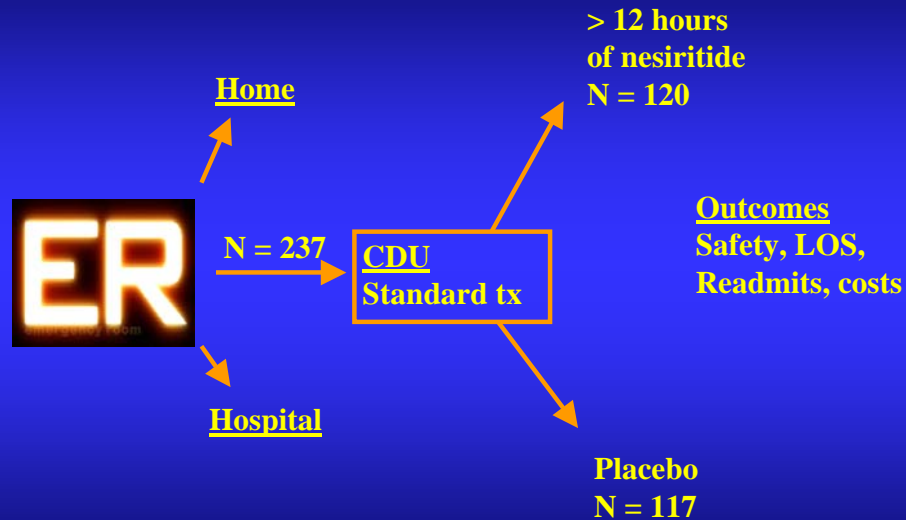
Observation Services

April 1, 2002			January 1, 2003		
Code	Description	Allowable	Code	Description	Allowable
APC 120	Infusion therapy other than chemo	\$157.80	APC 120	Infusion therapy other than chemo	+\$56.85
APC 9114	Natreacor	\$354.90	APC 9114	Natreacor	\$433.20
APC 0339	Observation care by facility to patient	\$351.24	APC 0339	Observation care by facility to patient	\$376.47
		Total Provider Reimbursement			\$866.52
		\$863.94			

Jan 1, 2002 Natreacor administered in observation was reimbursed \$80.49

Payments are means. 2002 from Code Manager 2002, AMA. 2003 from 2003 APC Final Rule

PROACTION



Peacock, et al, ACC 2003

Proaction Safety Results

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

- Symptomatic ↓ BP
 - At 3 hours: 2 nes, 1 plac
 - 3-15 hours: 3 nesiritide
- All ↓ BP rated as mild-mod, transient
- No adverse sequale

Peacock, et al, ACC 2003

Proaction Mortality

- No differences in 7 & 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 wks:
 - Standard therapy (1): sudden death
 - Nesiritide (3): apnea, unexplained, CHF

Peacock, et al, ACC 2003

Proaction Outcomes

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

$P = 0.057$

Peacock, et al, ACC 2003

Proaction Outcomes

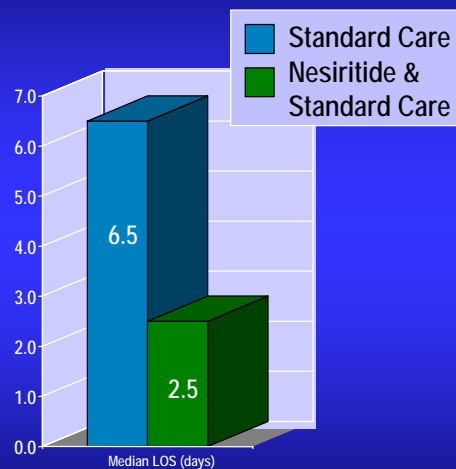
If admitted to the hospital from the CDU

- 57% ↓ in re-hospitalizations with nesiritide
 - 23% standard therapy, 10% nesiritide
 - 23% standard therapy readmit consistent w/ HCFA data
- If re-hospitalized: 45% ↓ LOS with nesiritide
 - 8.3 days standard therapy, 4.6 days
- Cost analysis: no difference between nesiritide and standard therapy.

Peacock, et al, ACC 2003

30 Day Outcomes

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



Peacock, et al, ACC 2003

P = 0.032

Proaction: Δ BP Based on Baseline Thirds

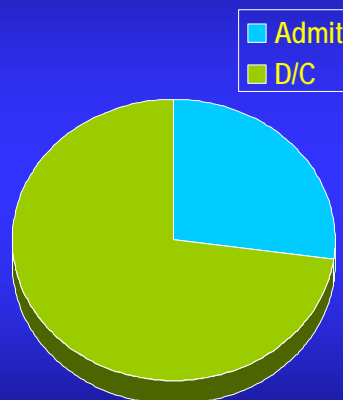
- Δ SBP is a function of the baseline SBP
 - NES
 - baseline SBP \leq 100 mmHg 1.24% decline
 - SBP \geq 140 mmHg 18% decline
 - Standard care
 - baseline SBP \leq 100 mmHg 17% increase
 - SBP \geq 140 mmHg 5.3% decrease
- Heart rate at 6 hours
 - Nesiritide: 5% decrease
 - Standard care: 1% decrease
 - ($p = 0.029$).

Peacock, et al, HFSA, 2003

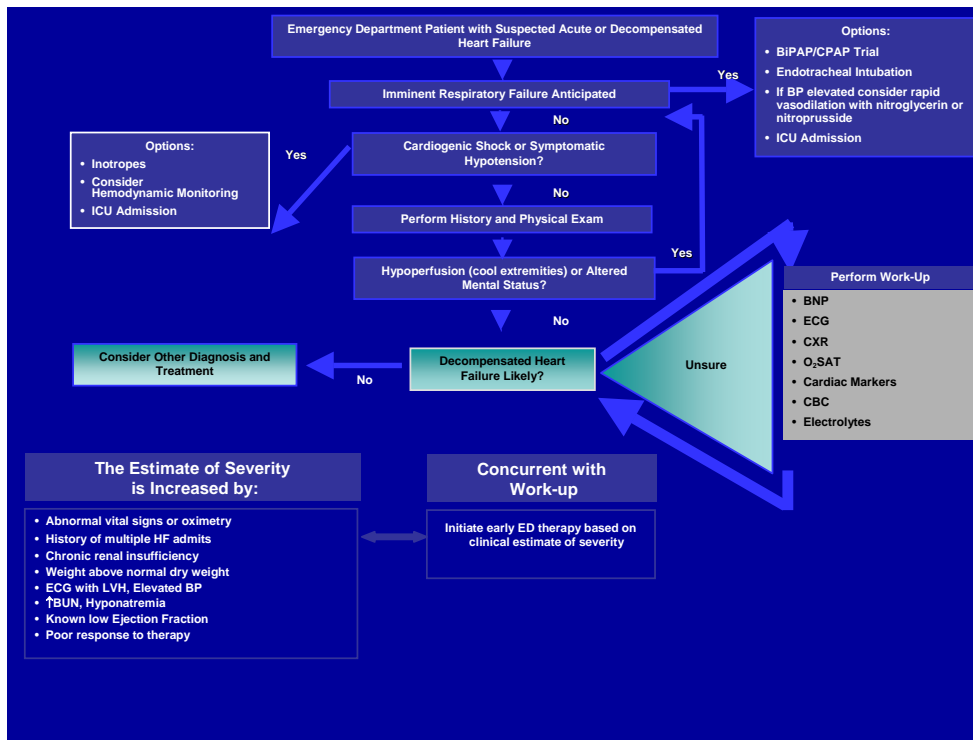
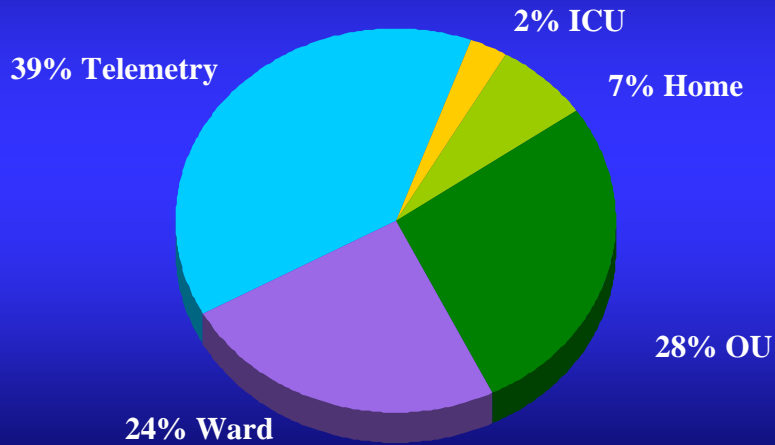
CHF in 2002

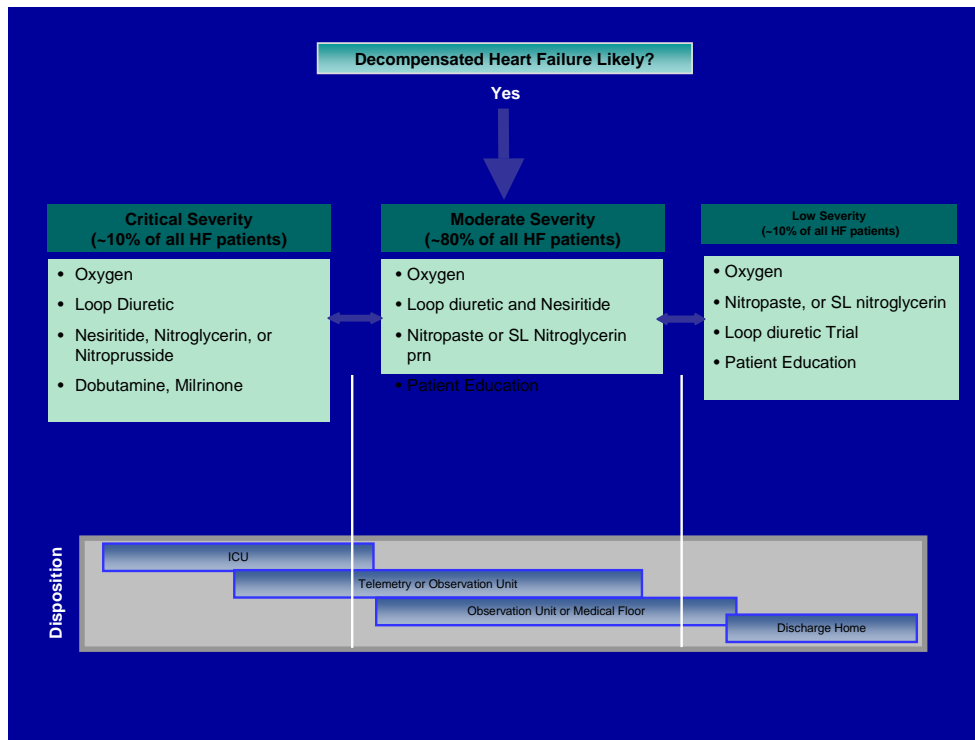
- 252 CHF OU admits
- Mean LOS 19.5 hours

- 183 discharged (72.6%)
- 69 admissions (27.4%)



Emergency Department Heart Failure Disposition in 2002





Thank you for participating in this program.