

*Can the Seattle Heart Failure Model
assist in the selection of LVAD
patients?*

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Financial Disclosures

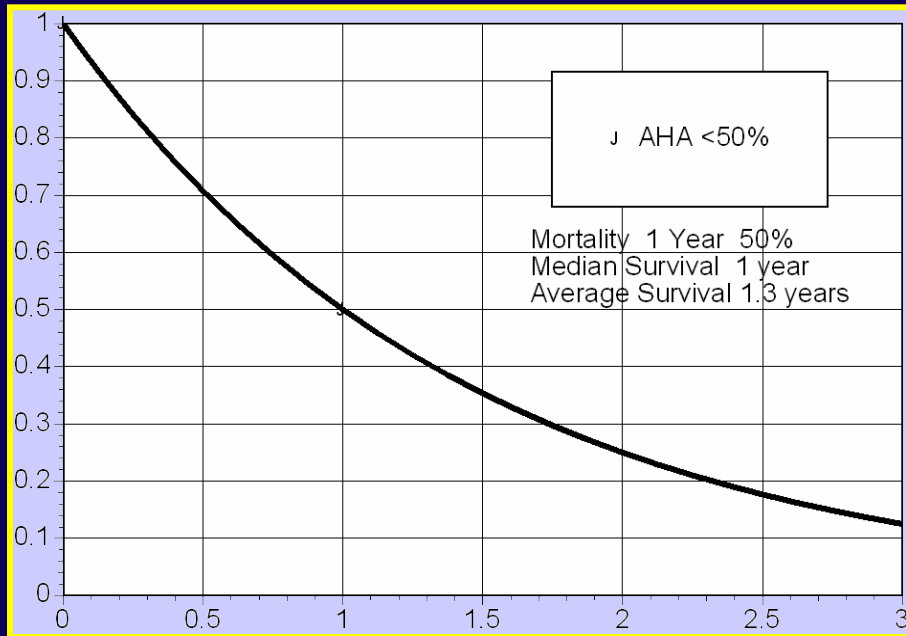
- Research Funding - SHFM
 - HeartWare, Thoractec, NHLBI, General Electric, CardioMems
- Steering Committee/Endpoint Committee
 - Amgen, Cardiomechs
- Honoraria/Consultant/Editorial Board
 - Cardiac Dimensions, GlaxoSmithKline, BoehringerIngelheim
- Stock Options
 - Cardiac Dimensions
- Licensing
 - University of Washington Center for Commercialization holds the copyright to the Seattle Heart Failure Model
 - Epocrates for inclusion of SHFM in the American College of Cardiology Toolkit

Can SHFM assist in MEDCAC Question #1?

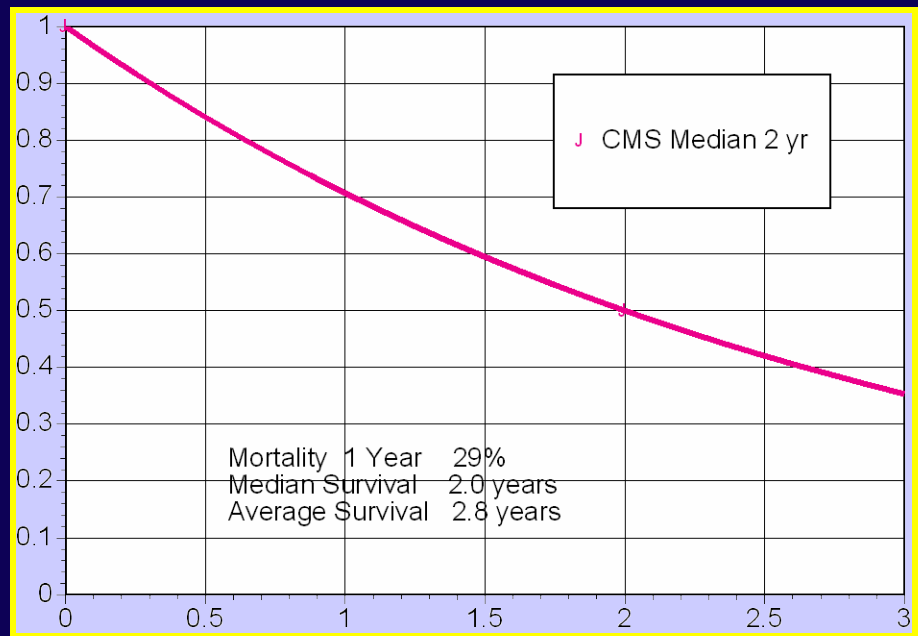
The primary focus of this MEDCAC meeting is the consideration of evidence that may support prospective identification of patients who are likely to experience clinically meaningful changes in outcomes from placement of a VAD.

Among outcomes, CMS is most interested in mortality, adverse events, patient function and quality of life.

LVADs - What risk is appropriate



AHA 1 year Survival <50%



CMS <2 Year Survival

REVIVE-IT – NHLBI Pilot Trial

Randomized trial of LVAD in NYHA 3 with ~30% annual mortality

Entry criteria of SHFM mortality $\geq 16.5\%$ /year

Seattle Heart Failure Model

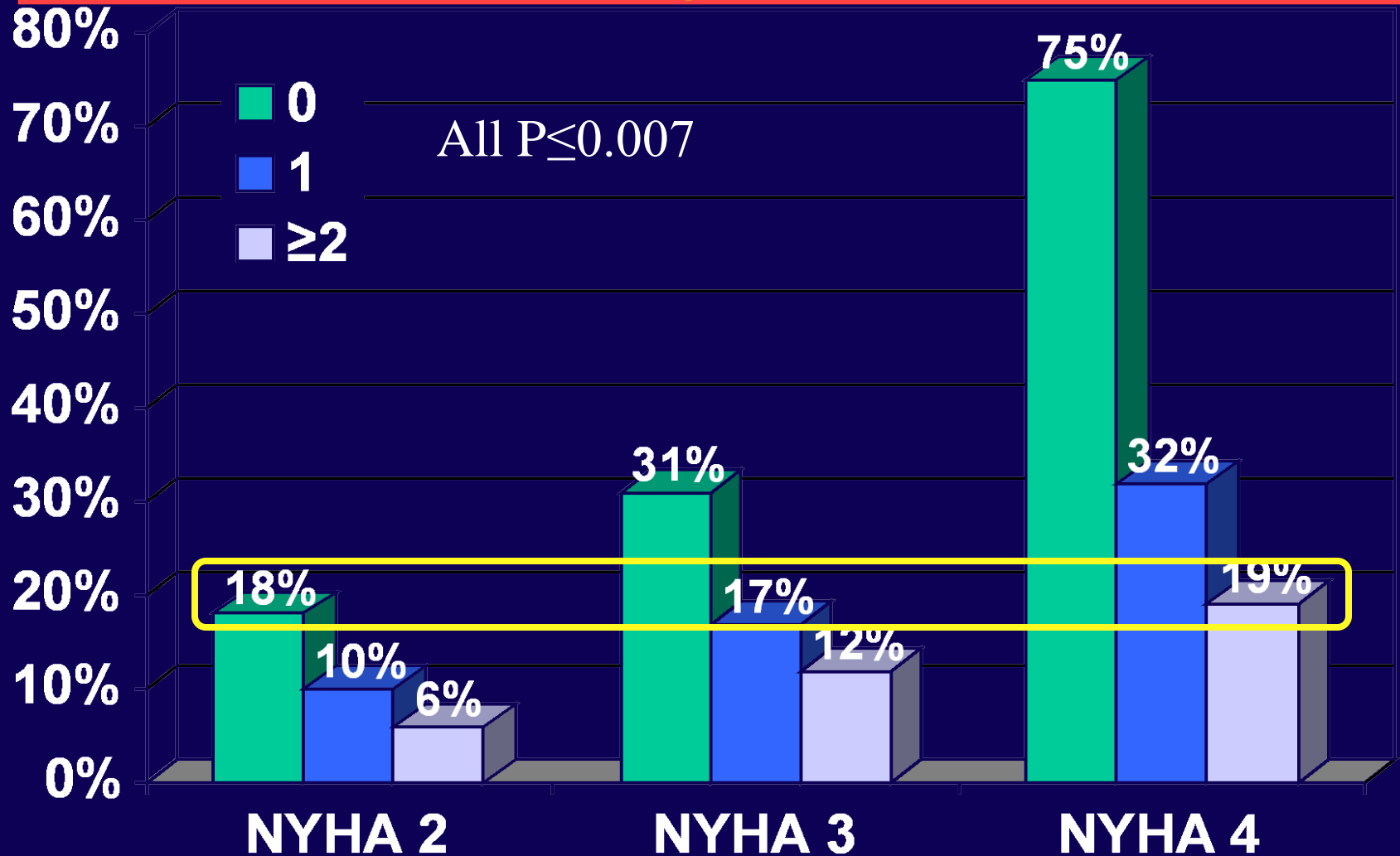
Prognostic Predictors

- **Clinical**

	<u>Adverse Risk</u>
– Age	Older
– Gender	Male
– Etiology	Ischemic
– SBP	Low
– LVEF	Low
– NYHA Class	High
- **Medications**
 - ACEI
 - ARB
 - Beta Blocker
 - Statin
 - Aldosterone Blocker
 - Allopurinol
 - Loop Diuretic Daily Dose
- **Biomarkers**

– Sodium	Low
– Cholesterol	Low
– % lymphocytes	Low
– Hemoglobin	Low or High
– Uric acid	High
- **Devices**
 - ICD
 - CRT±ICD
 - LVAD

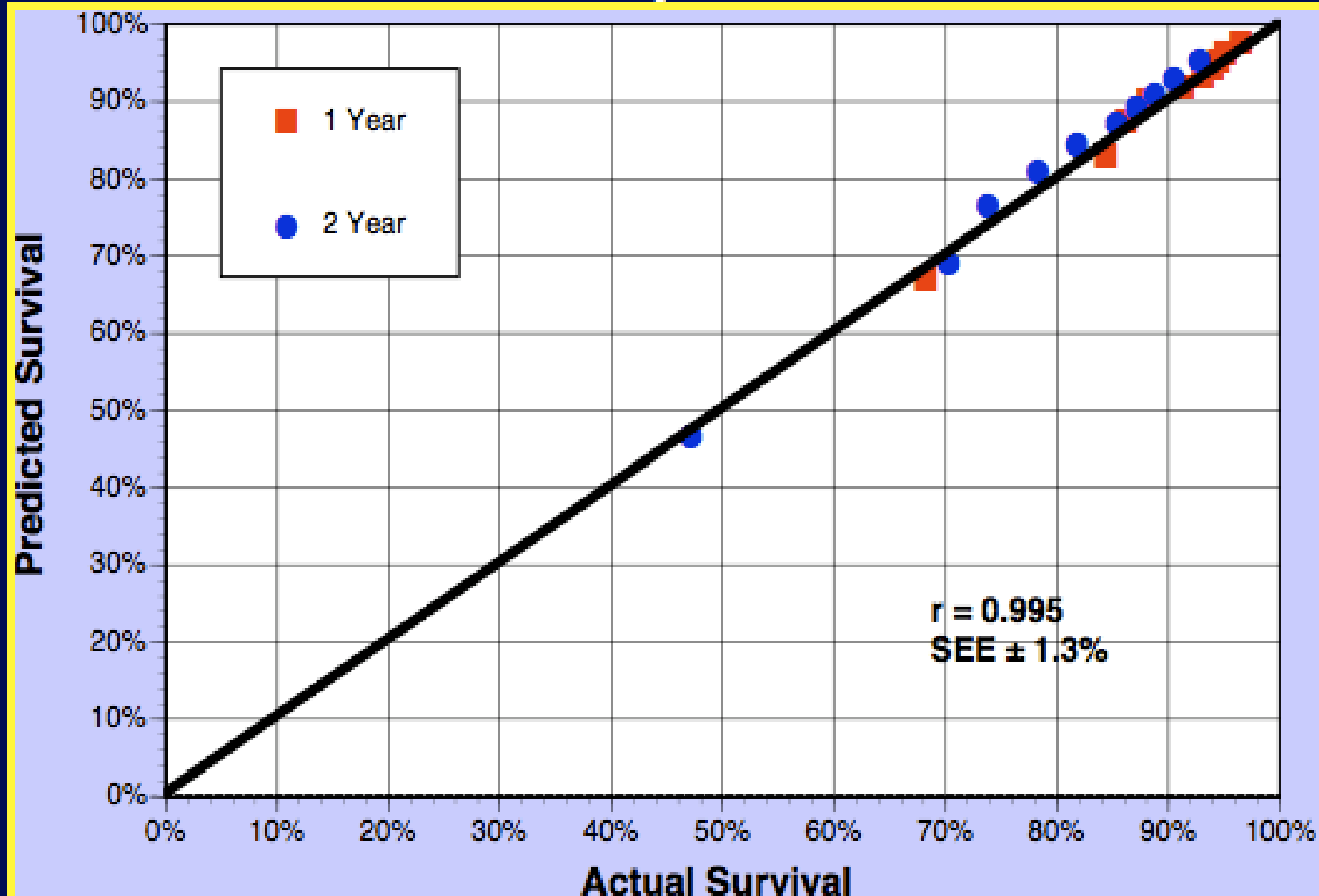
Impact of Heart Failure Medications on 1 Yr. Mortality in 6,194 Patients



Each HF med associated with ~1 NYHA Class lower Mortality

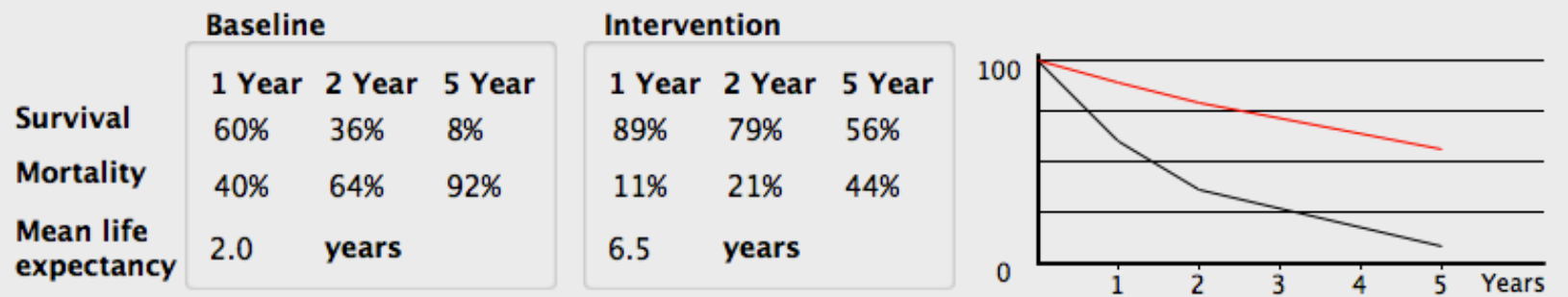
SHFM - Validation in 10,000 patients

Circ 2006;113:1424



98% of events were Death

1 year ROC 0.725



Clinical

Age: 65

Gender: Male

NYHA Class: 3A

Weight (kg): 80

EF: 25

Syst BP: 100

☒ Ischemic

Medications

☐ ACE-I

☐ Beta-blocker

☐ ARB

☐ Statin

☐ Allopurinol

☐ Aldosterone blocker

Diuretics

Furosemide: 160

Bumetanide: 0

Torsemide: 0

Metolazone: 0

HCTZ: 0

Lab Data

Hgb (g/dL): 13

Lymphocyte %: 20

Uric Acid (mg/dL): 8.5

Total Chol (mg/dL): 180

Sodium: 135

☒ QRS > 120 msec

Devices

☒ None

☐ BiV Pacer

☐ ICD

☐ BiV ICD

Default Values

Interventions

☒ ACE-I

☐ ARB

☒ Beta-blocker

☐ Statin

☒ Aldosterone blocker

Devices

☐ None

☐ BiV Pacer

☐ ICD

☒ BiV ICD

☐ LVAD

Note: Some devices may be disabled if CMS clinical criteria are not met

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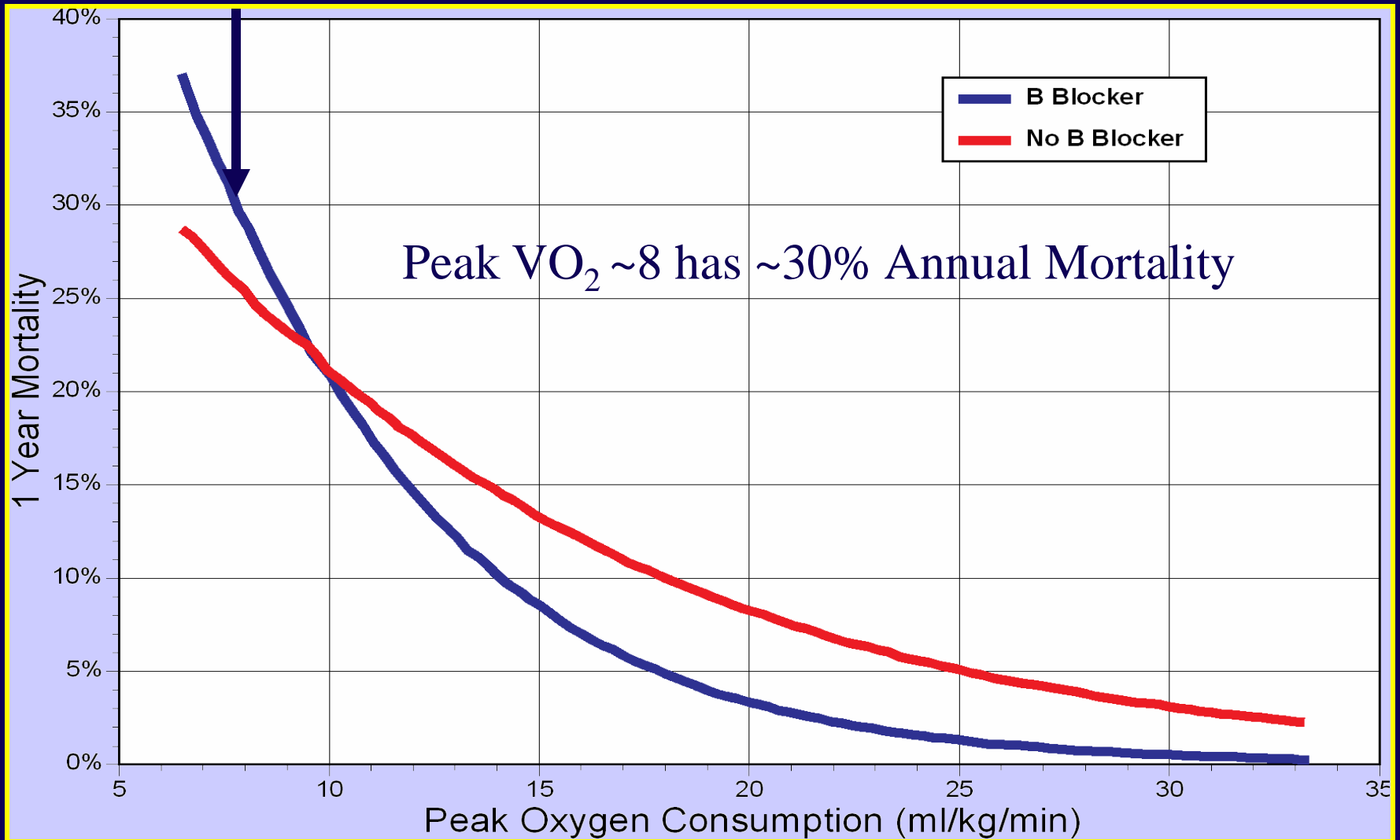
Optimum Medical Therapy may preclude the need for a LVAD
[Http://SeattleHeartFailureModel.org](http://SeattleHeartFailureModel.org)

INTERMACS - Risk Stratification for LVADs

J Heart Lung Transplant 2010;29;1

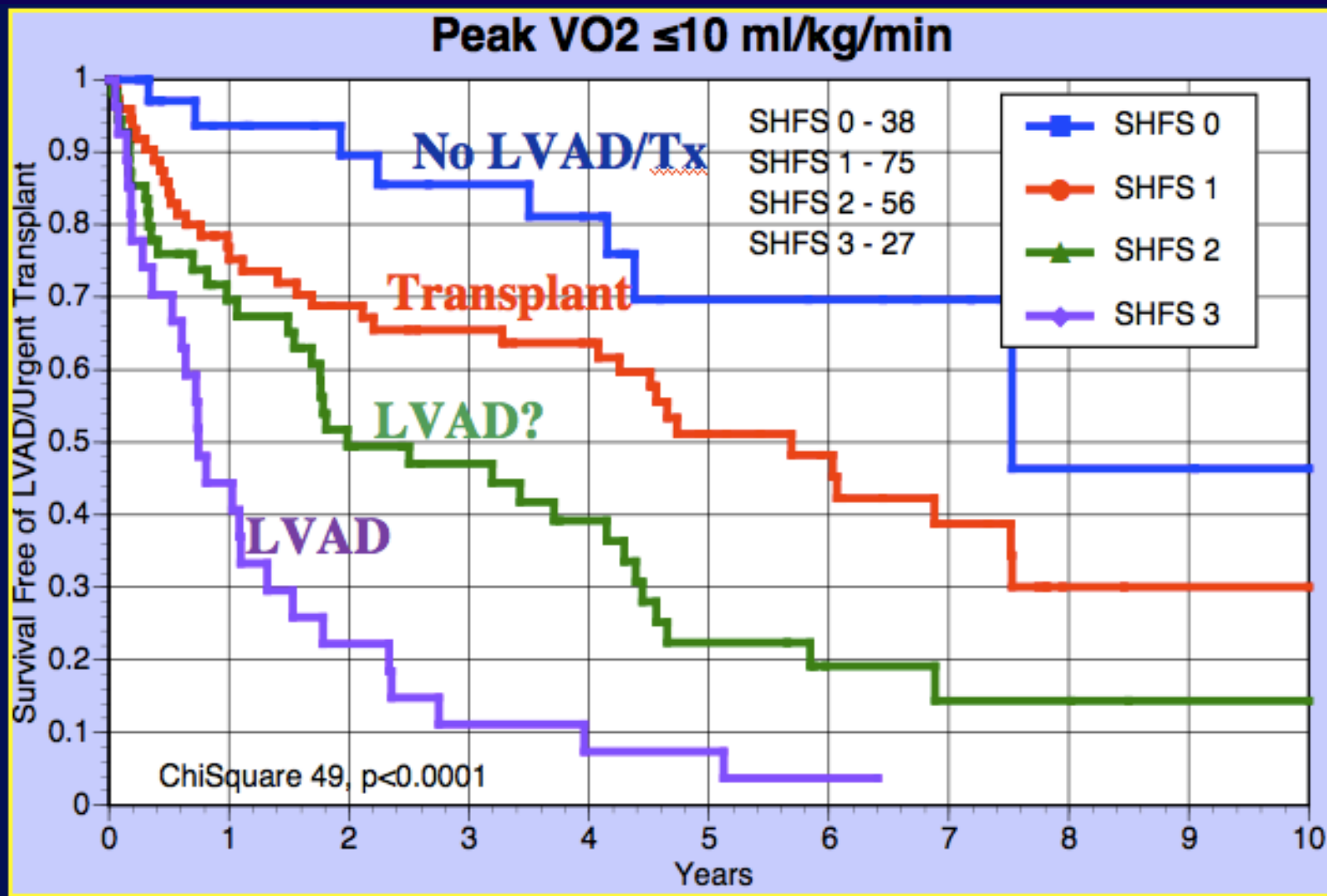
- INTERMACS 1-3
 - LVAD Better than Medical Therapy - 1 year survival
 - Risk model is likely not necessary
 - 1 - Critical Cardiogenic Shock ~70%
 - 2 - Declining on Inotropes ~70%
 - 3 - Stable on Inotropes ~85%
- INTERMACS 4-7
 - Uncertain if LVAD improves mortality ~75%
 - Risk model should be very helpful
 - 4 - Recurrent Advanced Heart Failure
 - 5 - Exertional Intolerant
 - 6 - Exertion Limited
 - 7 - Advanced NYHA III

LVAD Decision - Peak VO_2



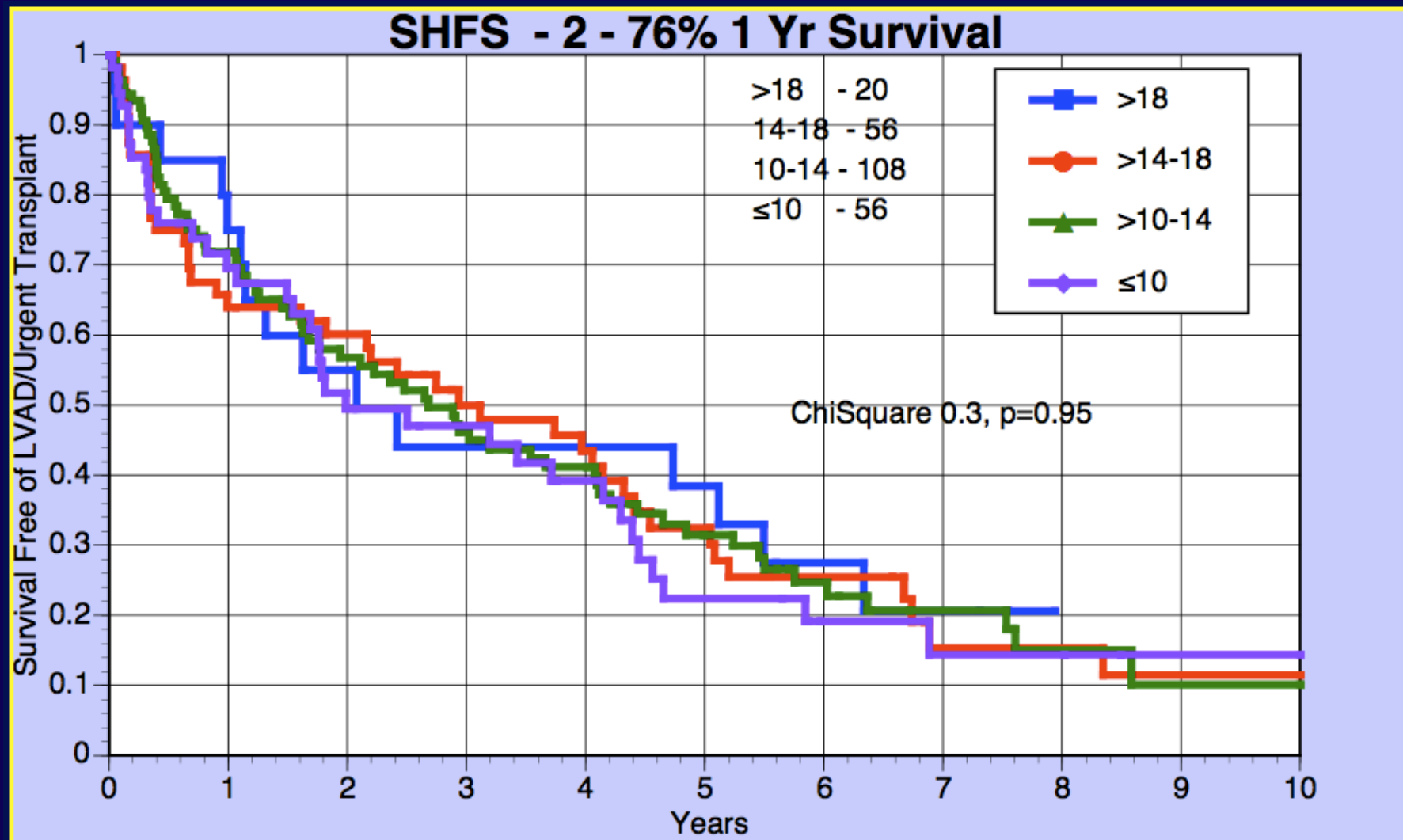
Does SHFM add to Peak $VO_2 \leq 10$?

J Heart Lung Trans 2012;31:817



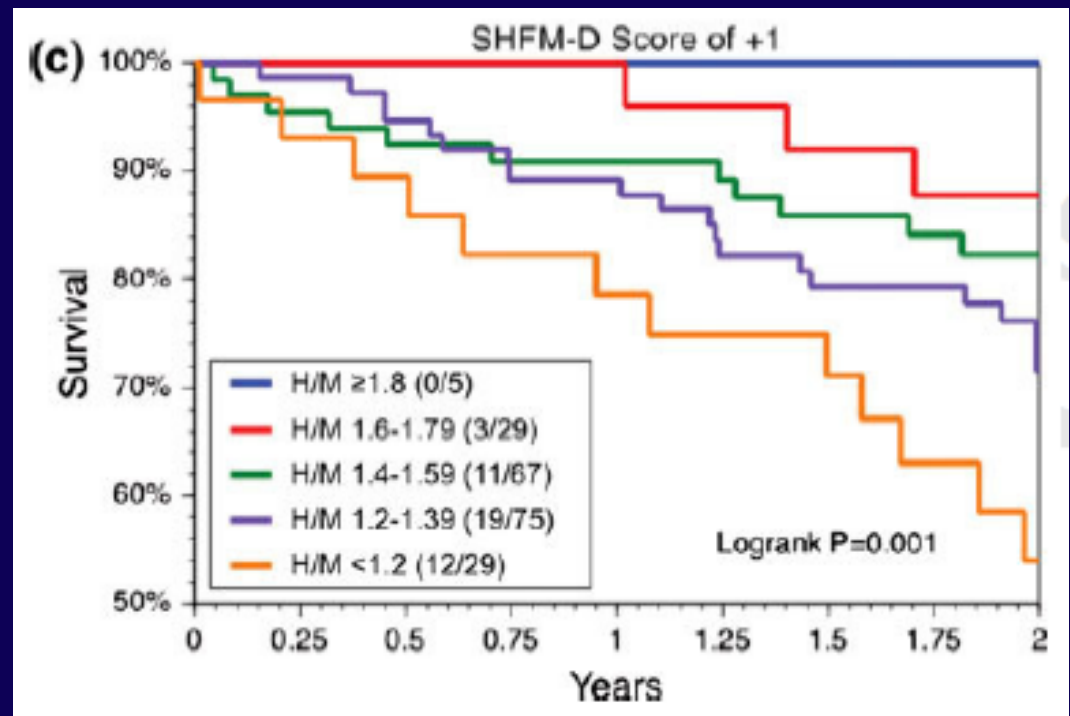
Does Peak VO_2 add to SHFM?

J Heart Lung Trans 2012;31:817



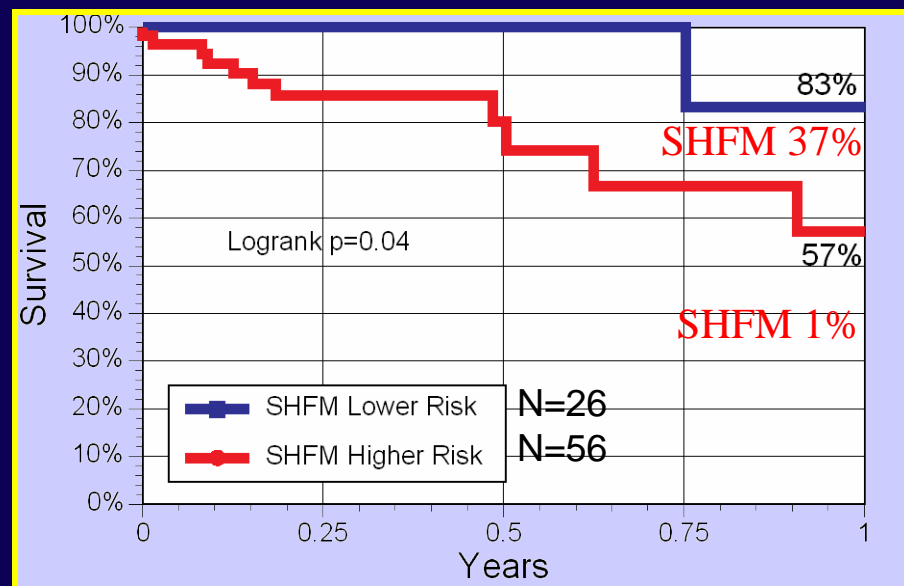
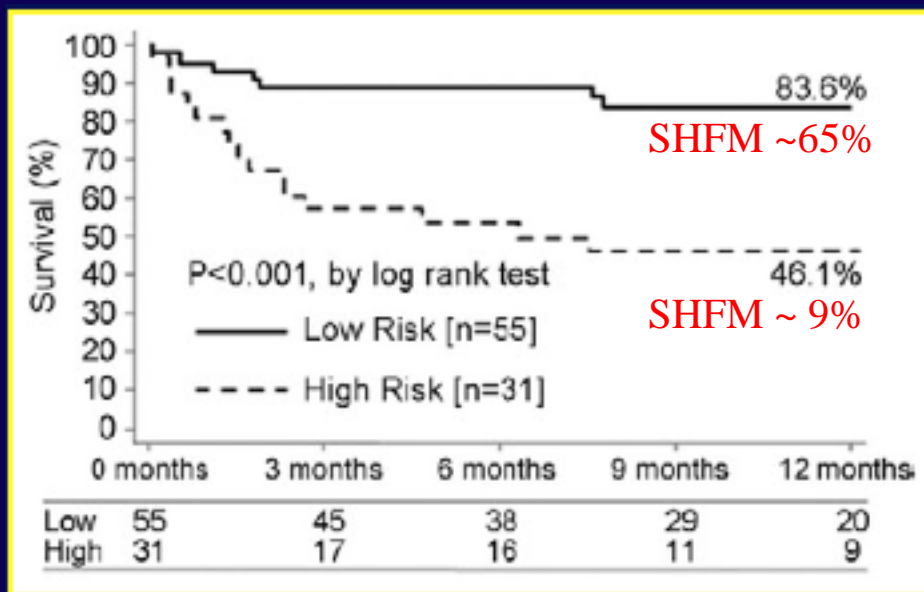
Can we improve SHFM risk stratification?

- Peak VO_2 , ST2, BNP – ROC AUC change all $p=\text{NS}$
- MIBG – iodine-123 meta-iodobenzylguanidine
 - Cardiac sympathetic activity imaging agent
 - ROC AUC +0.039
 - $p=0.026$



SHFM and LVAD Survival

Lower risk patients have Superior LVAD Outcomes



Johns Hopkins - 86 HM II

SHFM p=0.001

INTERMACS p=0.04

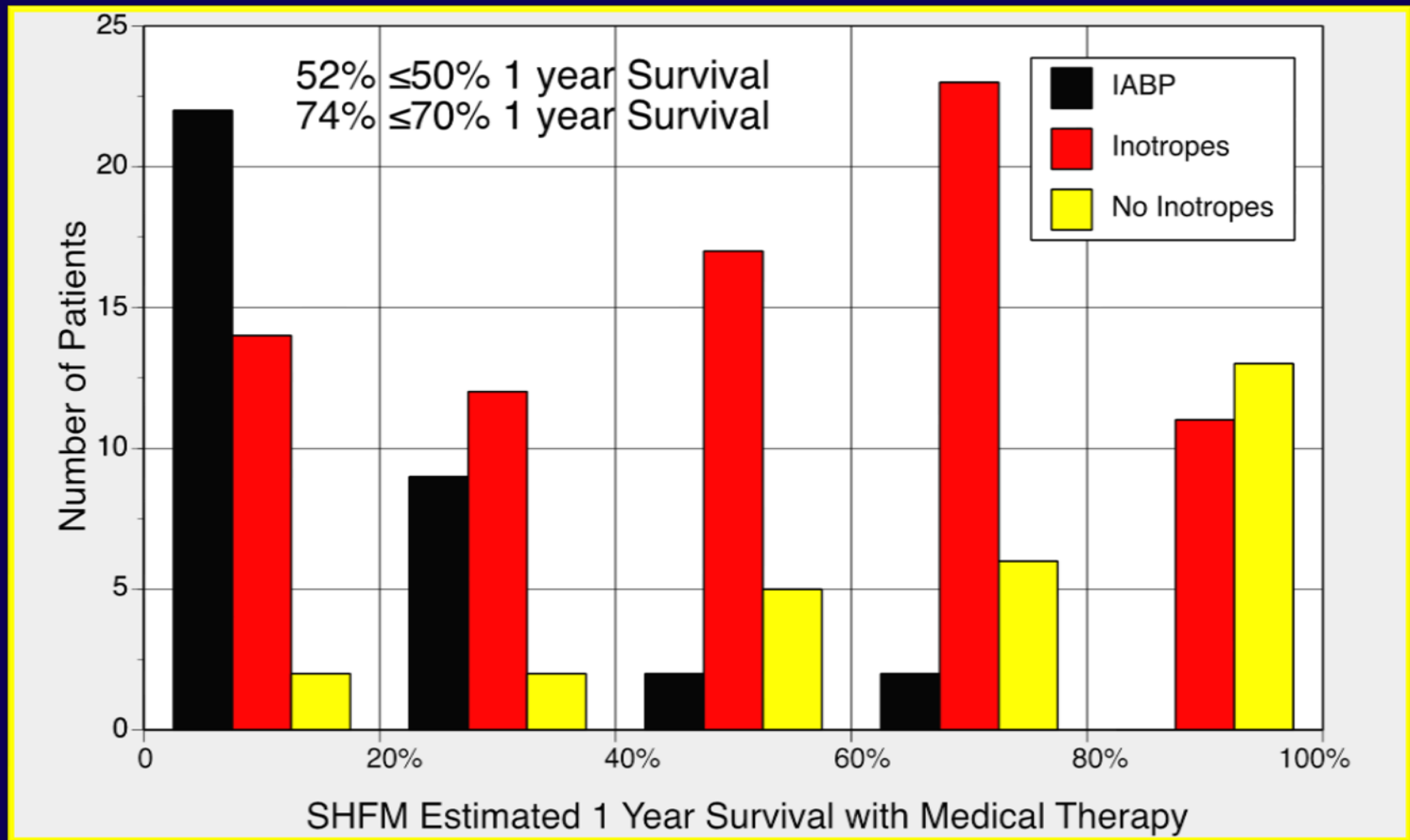
SHFM <50% at 180 days

University of Washington

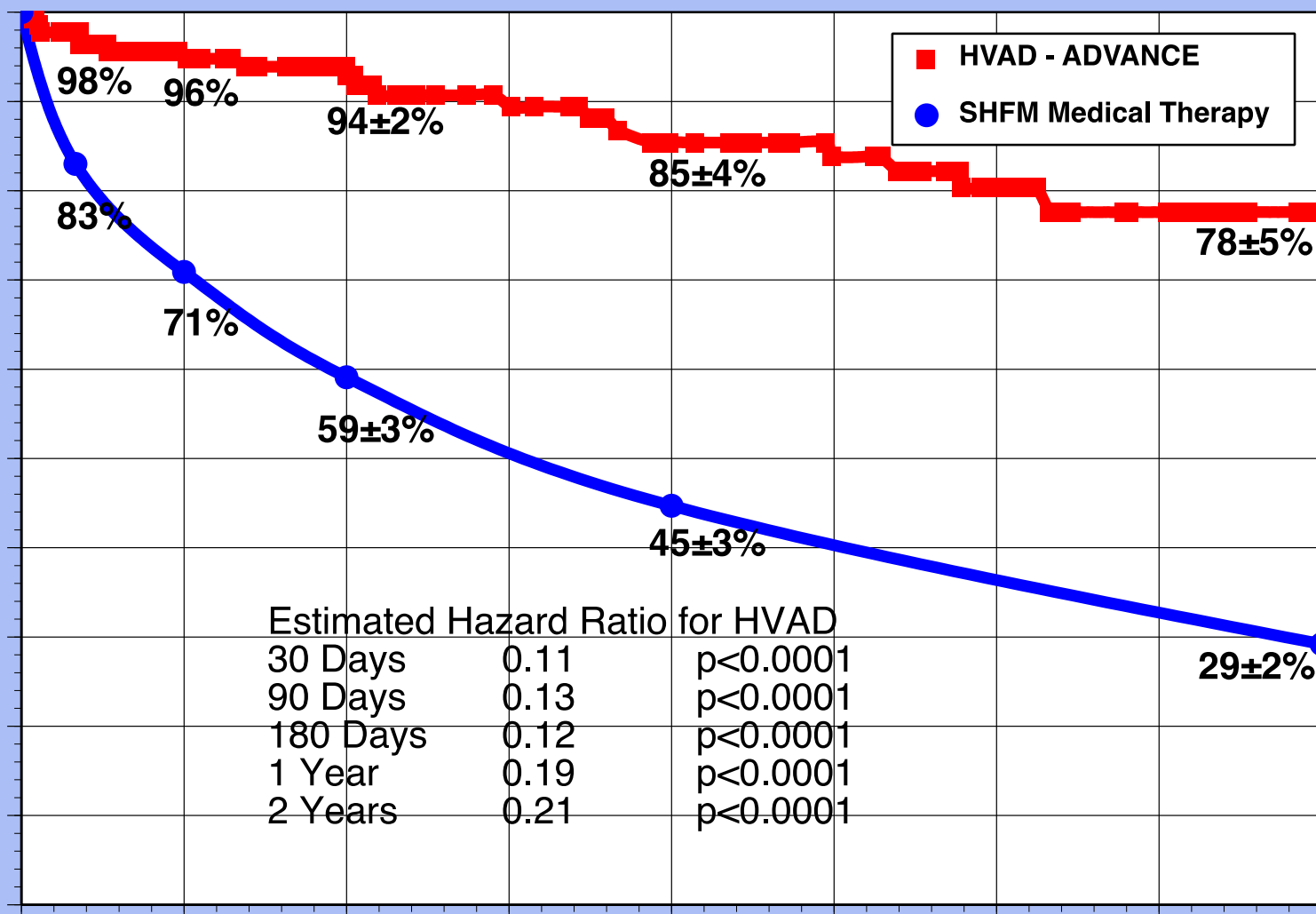
82 LVADs - VE/XVE/HMII

SHFM <25% at 180 days

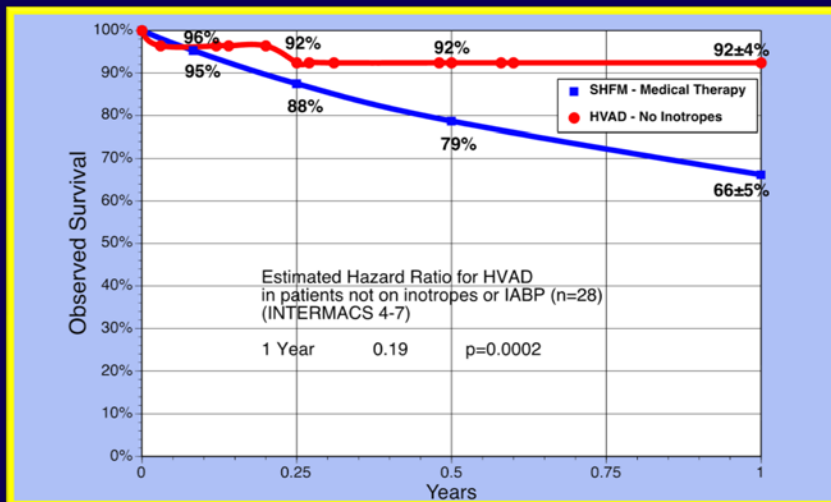
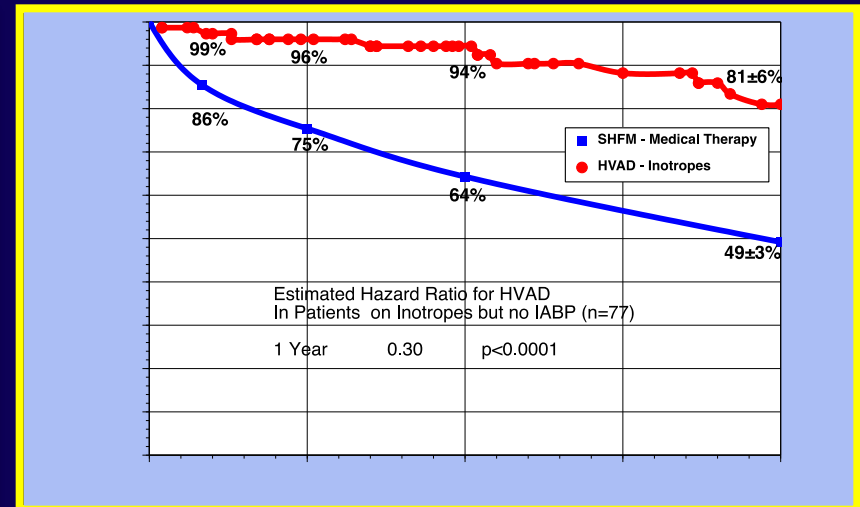
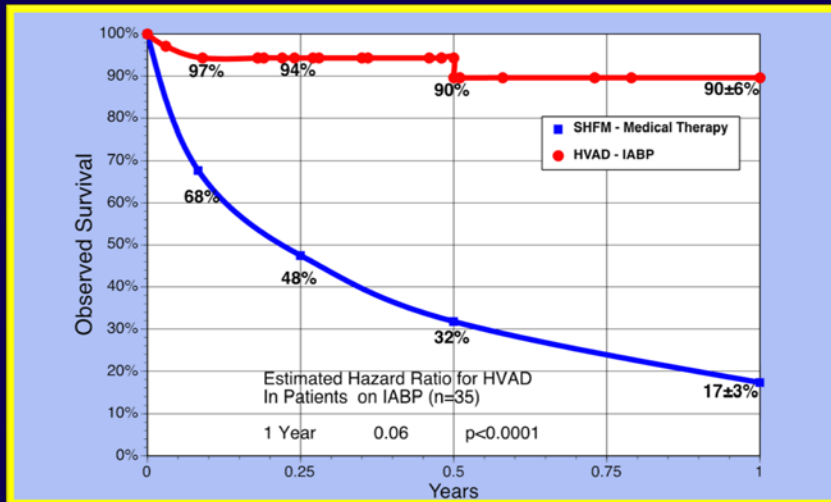
HeartWare BTT Patients (ADVANCE) Predicted SHFM Medical Survival



HeartWare ADVANCE



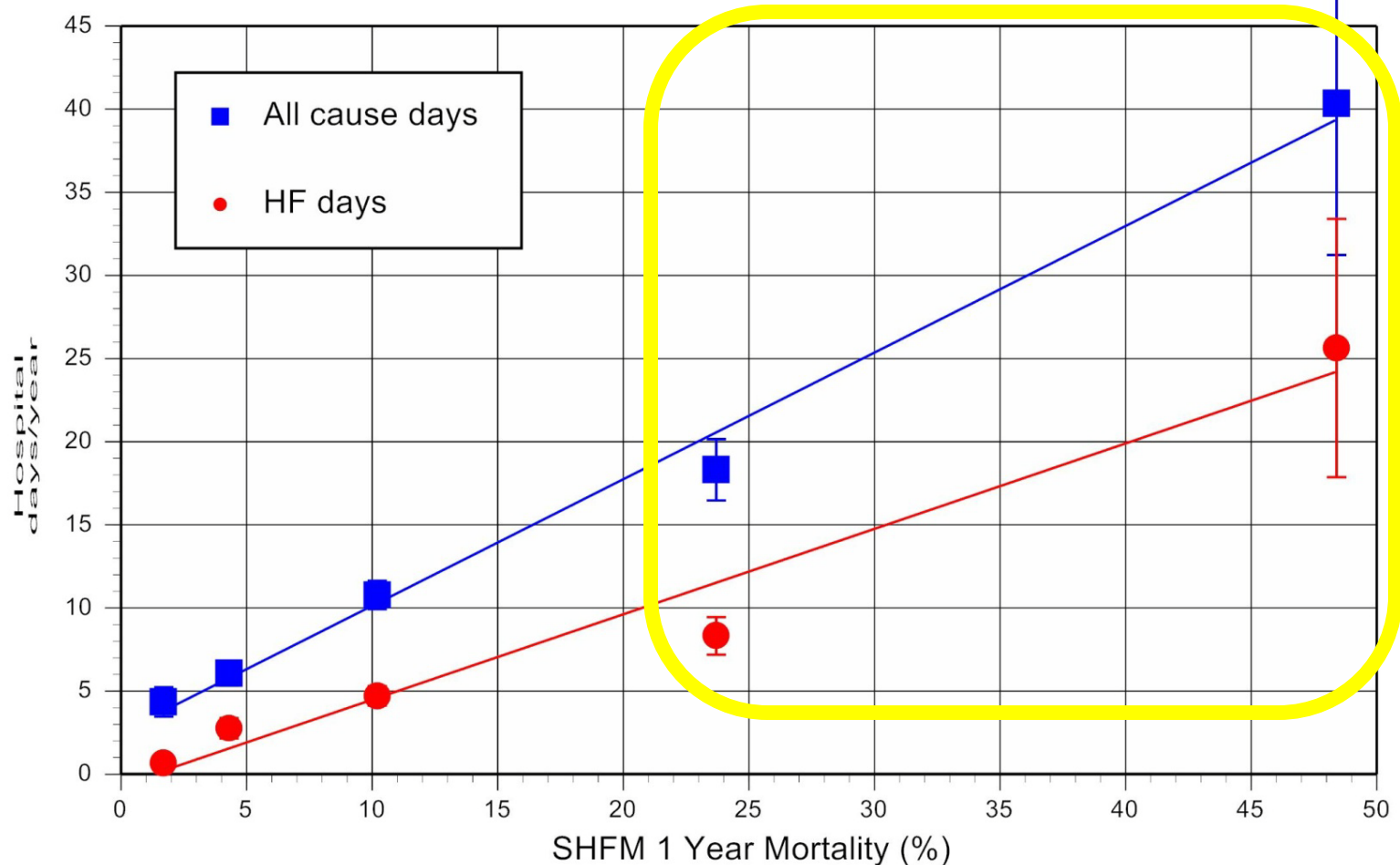
SHFM - ADVANCE IABP and Inotrope use



Similar outcomes with
varying baseline risk

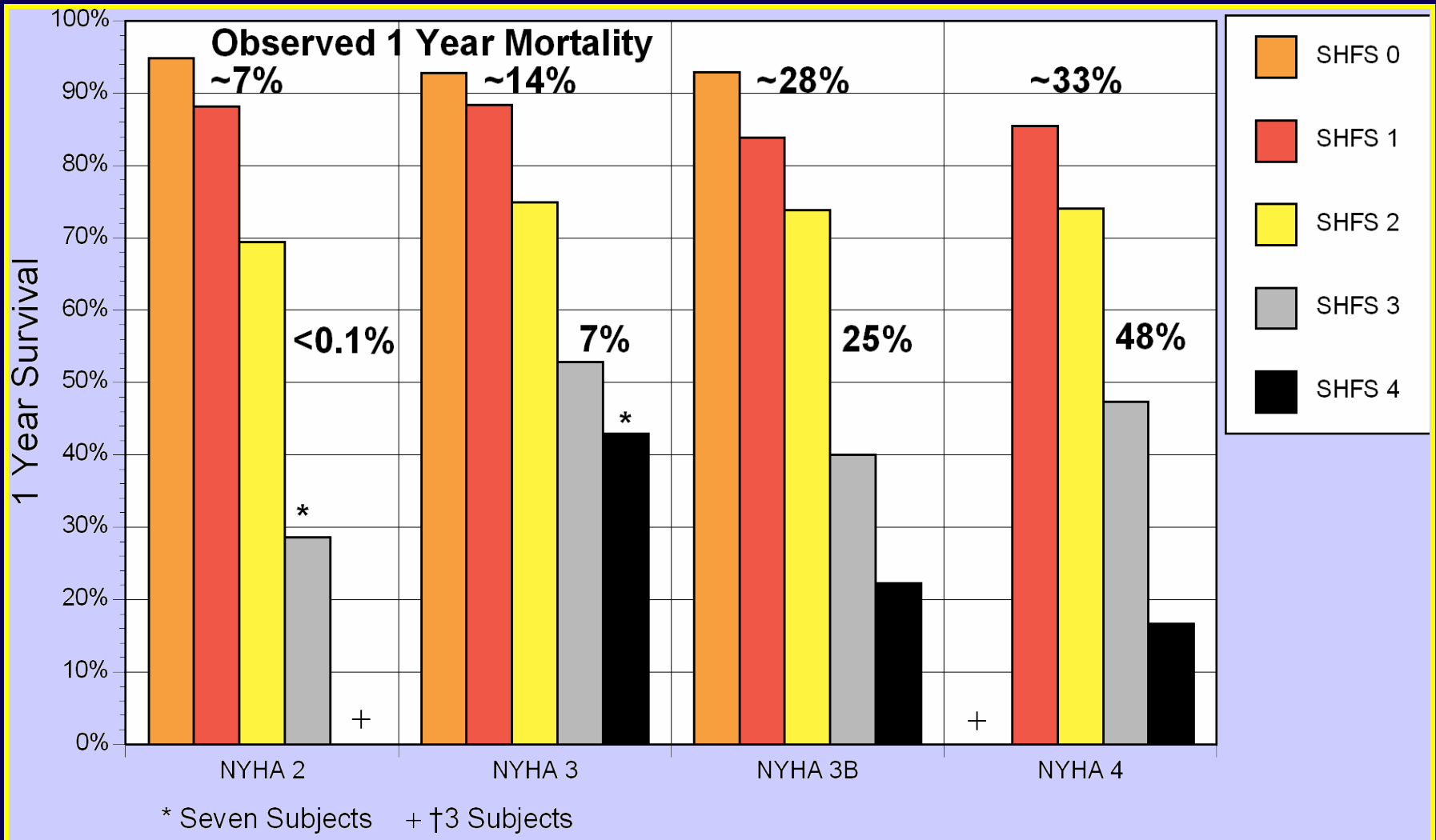
SHFM was not
predictive of HVAD
outcomes

SHFM Annual Mortality correlates with Hospital Days/yr



Seattle Heart Failure Score

% of patients with $\geq 30\%$ annual mortality



~7,000 ambulatory HF patients in the original SHFM publication

Conclusions

- SHFM is a widely validated and accepted model that may have utility in identifying high risk ambulatory HF patients who may be appropriate for LVADs.
- Application of the SHFM as a virtual control group estimated an ~80% reduction in mortality with a LVAD in the ADVANCE trial.
- The simple SHFM variables should be collected in LVAD trials and INTERMACS to allow estimation of the medical risk of patients receiving a LVAD. ROADMAP and REVIVE-IT will be collecting these variables.