BARI 2D

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Racial Differences in the Association between Clinical Measures and Self-Reported Health Status in Bypass Angioplasty Revascularization Investigation Type 2 Diabetes (BARI 2D)

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BARI 2D

- The Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) Trial is sponsored by the National Heart, Lung and Blood Institute (NHLBI) and receives substantial funding from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
- The BARI 2D Trial is coordinated by the Epidemiology Data Center at the University of Pittsburgh, Graduate School of Public Health.

BARI 2D Additional Sponsors

- BARI 2D receives significant supplemental funding from
  - GlaxoSmithKline
  - Bristol-Myers Squibb Medical Imaging, Inc.
  - Astellas Pharma US, Inc.
  - Merck & Co., Inc
  - Abbott Laboratories, Inc.
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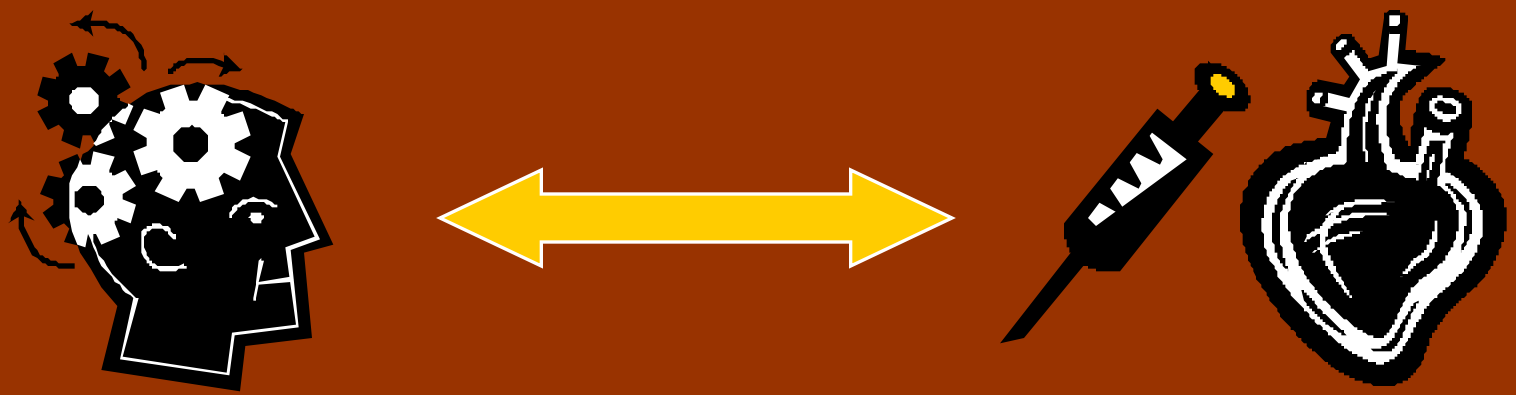
Background

- Risk factors for Type 2 diabetes and coronary artery disease (CAD) are more prevalent in Black non-Hispanic compared to White non-Hispanic subjects.

- Racial differences in perceived health status have also been reported in several patient populations.

Goal

To investigate self-reported health status in Black and White BARI 2D patients with diabetes and CAD using selected clinical variables.



BARI 2D

In patients with Type 2 diabetes and stable, documented CAD, to simultaneously test whether 5-year mortality is lower if…

- Myocardial ischemia is treated by:
  - immediate revascularization plus aggressive medical therapy *versus*
  - aggressive medical therapy alone
- Diabetes is treated by:
  - an insulin providing strategy *versus*
  - an insulin sensitizing strategy

BARI 2D Randomization: 2x2 Factorial Design (N=2321)

Ischemia Control Strategy

Diabetes Control Strategy	Revascularization	Medical Therapy
Insulin Providing	579	585
Insulin Sensitizing	568	589

Methods

Patient Population

- BARI 2D Inclusion Criteria
  - Type 2 diabetes mellitus
  - Documented CAD (at least one stenosis $\geq$ 50%) suitable for elective revascularization
  - Documented ischemia
  - No prior CABG or PCI within the last 12 months
- Only Black (n=333) and White (n=866) non-Hispanic patients enrolled at U.S. clinical sites were analyzed (N=1199).

Self-Rated Health

- Item 1 of the SF-36 was used to measure the primary outcome of self-reported health as either "Fair/Poor" or "Good/Very Good/Excellent."
  - *"In general would you say your health is…?"*
- Models were constructed to examine the influence of objective measures of clinical health status on perceived health status.

Results

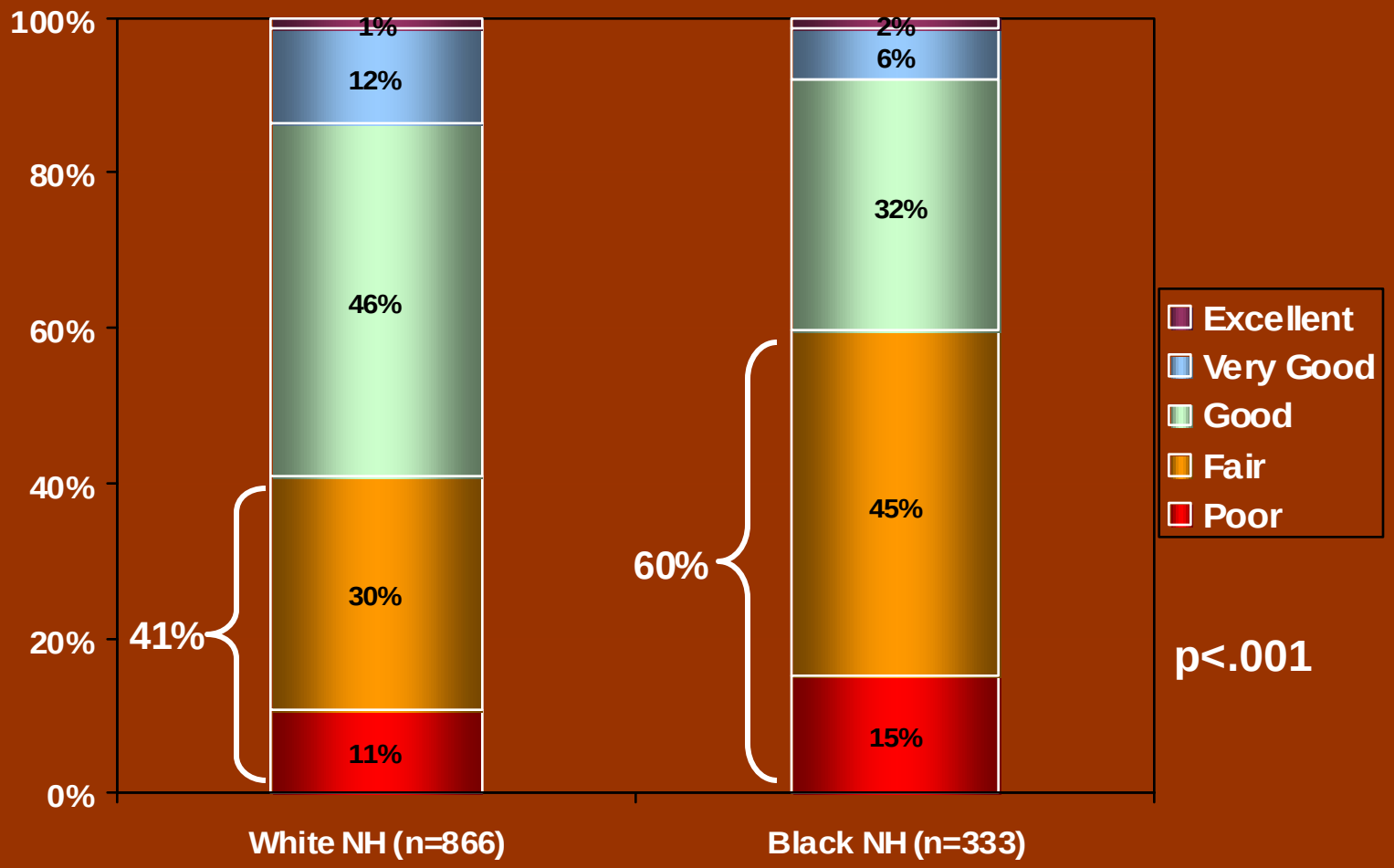
Baseline Tables by Race

DEMOGRAPHICS (%)	White NH (n=866)	Black NH (n=333)	P-value
Male	75.5	49.8	<.001
Age (mean, SD)	63.9, 8.9	61.4, 9.7	<.001
Post high school education	40.4	57.0	<.001
Insurance			0.003
Medicare/Other	55.3	50.9	
Private	40.6	39.5	
None	4.2	9.6	
Exercise regularly	25.7	26.2	ns
Working/Employed	43.3	38.2	ns
Married/spouse like relationship	73.4	46.2	<.001

Baseline Tables by Race

CLINICAL (%)	White NH (n=866)	Black NH (n=333)	P-value
Chronic renal dysfunction	3.7	7.3	0.009
Hx of chronic heart failure (CHF)	8.6	10.6	n.s.
Hx of myocardial infarction	31.6	27.3	n.s.
Hx of hypoglycemic episode	29.7	25.5	<.001
Current insulin use	29.8	43.8	<.001
HbA1c, mean, SD	7.4, 1.4	8.0, 1.8	.0014

Self-Rated Health at Baseline by Race

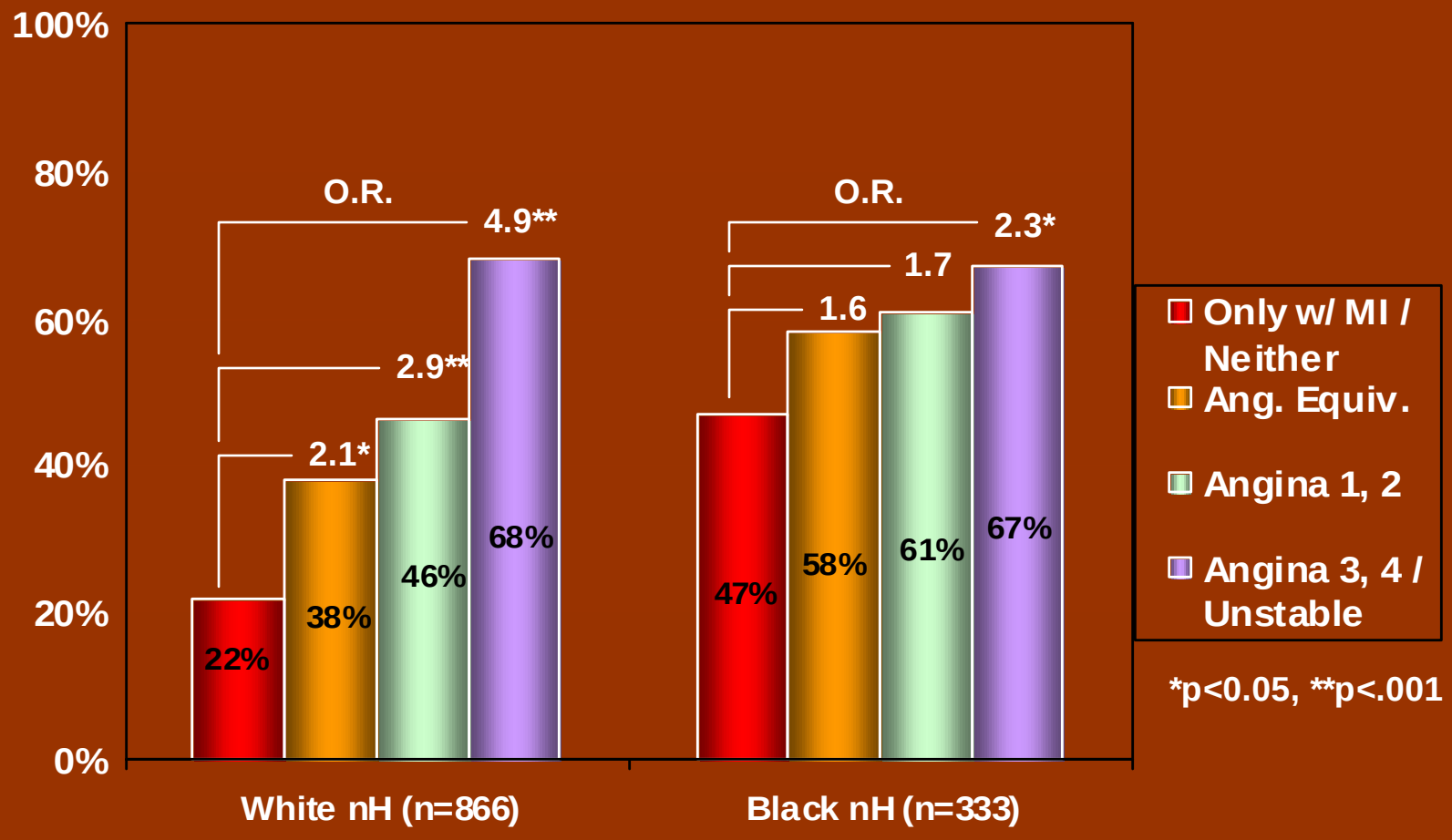


Independent Predictors of Fair/Poor Self-rated Health

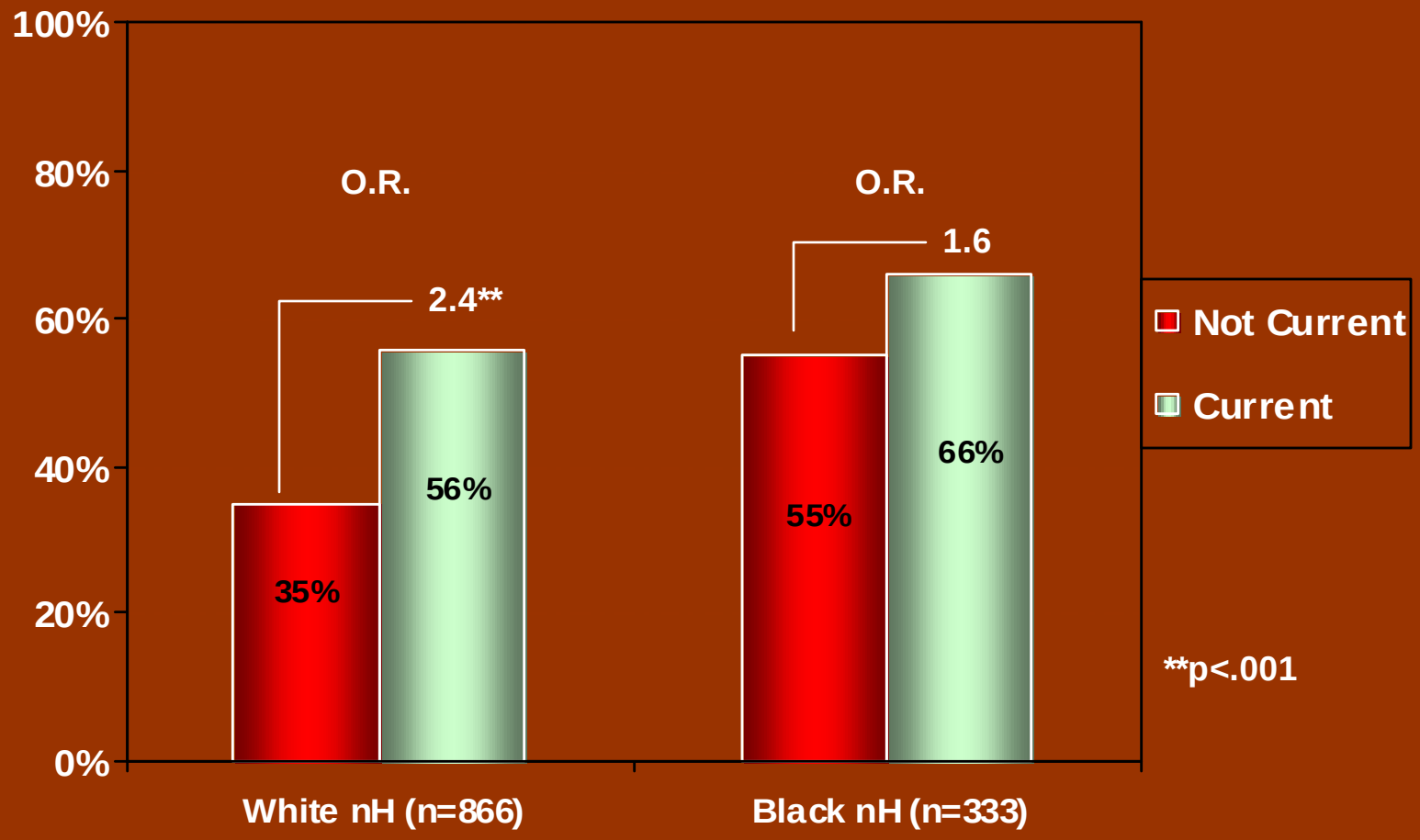
VARIABLE	Adjusted Odds Ratio	95% C.I.		P-value
Black NH (vs. White NH)	**1.79**	**1.29**	**2.48**	**<.001**
Female	0.91	0.68	1.24	0.56
Age at study entry (per 5 yrs)	0.80	0.74	0.87	<.001
Post high school education	0.78	0.59	1.03	0.08
Working/employed	0.52	0.38	0.70	<.001
Exercise regularly	0.58	0.42	0.80	<.001
Sitting blood pressure >= 140/90	1.72	1.25	2.35	<.001
MNSI screening score (per point)	1.30	1.23	1.37	<.001
History of myocardial infarction	1.50	1.11	2.02	0.01
Stable CCS 3, 4 or Unstable angina (vs. no angina)	1.44	1.01	2.03	0.04
Number of lesions (per lesion)	1.06	1.00	1.13	0.06
Major ECG	1.34	0.98	1.85	0.07
Current insulin use	1.36	1.01	1.82	0.04

C-statistic = 0.78

Percent Fair/Poor by Race and Angina Status



Percent Fair/Poor by Race and Current Insulin Use



Multivariate Associations with Fair/Poor Health Stratified by Race

VARIABLE	White NH (n=866)		Black NH (n=333)	
	O.R.	P-value	O.R.	P-value
Female	0.61	0.02	1.26	0.39
Age at study entry (per 5 yrs)	0.79	<.001	0.82	0.01
Post high school education	0.65	0.02	1.36	0.28
History of MI	1.61	0.01	1.32	0.36
MNSI screening score (per point)	1.33	<.001	1.21	<.001
Current insulin use	1.62	0.01	1.05	0.85
Stable CCS 3, 4 or Unstable angina (vs. no angina)	2.65	<.001	1.57	0.19

Conclusions

Fair/Poor Health

- Black BARI 2D patients have lower self-rated health with or without adjustments for confounding risk factors.
- Demographics and clinical measures associated with Fair/Poor health included
  - Lower education level
  - Unmarried
  - Unemployed or disabled
  - Less well controlled diabetes, blood pressure and LDL

Fair/Poor Health by Race

- Among White patients, numerous factors were independently associated with a Fair/Poor rating:
  - Lower education level
  - Clinical history of congestive heart failure
  - Renal dysfunction
  - Hypoglycemia
- Among Black patients, most of these factors were not associated with self-rated health and the estimated effect sizes for these clinical factors were consistently weaker.

Fair/Poor Health: Black Patients

- Reported health status may be influenced by health conditions unaccounted for in BARI 2D.
  - Dental (i.e. tooth decay)
  - Psychosocial (i.e. depression)
  - Arthritis
  - Cancer
  - Respiratory diseases
- The burden of these conditions may be disproportionately distributed between the races.

Health Pessimism

- Health pessimism more common in Black patients
  - Relatively healthy individuals rate their health as fair or poor. (Ferraro, 1993)
- Self-rated health appears less predictive of mortality in African American populations compared to White populations, but may reflect other important health issues. (Lee, 2007)

Conclusions

- Black BARI 2D patients were more likely to have Fair/Poor self-rated health regardless of clinical health status.
- Standard cardiovascular risk factors were less strongly associated with self-rated health in the Black population relative to the White population.