#### Summit TCT Asia Pacific 2009

April 22-24, 2009

The Convention Center of Sheraton Grande Walkerhill Hotel, Seoul, Korea

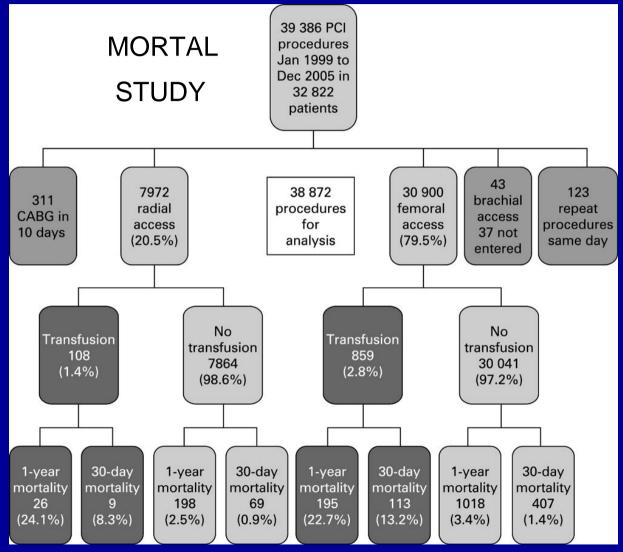
## Radial Artery Access Improving Outcomes and Decreasing Costs

Howard A. Cohen, MD, FACC, FSCAI Director, Division of Cardiac Intervention Co-Director, Cardiac Catheterization Laboratories Lenox Hill Heart & Vascular Institute

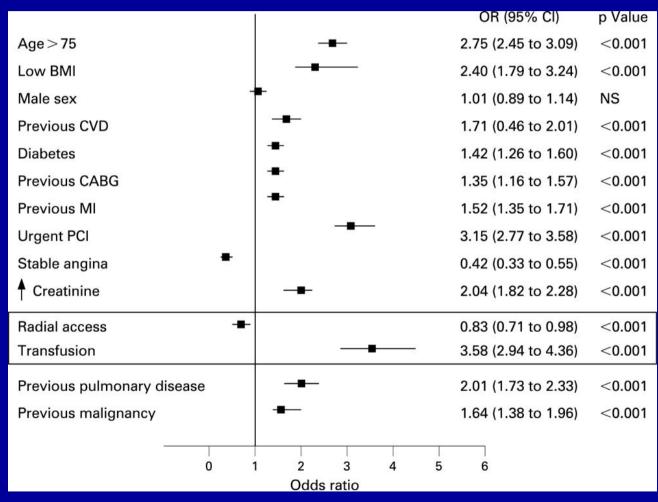


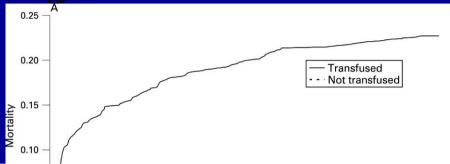
#### **DISCLOSURE**

Nothing to disclose



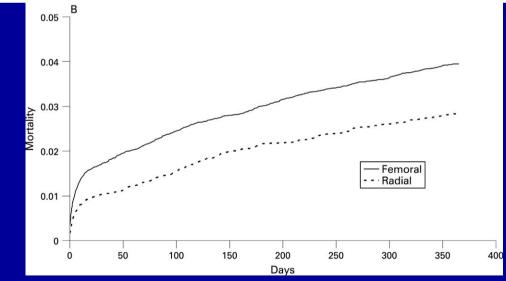
#### Predictors of 1-Year Mortality in the Mortal Study





Bleeding requiring is bad and is associated with increased mortality

Trans-radial access decreases bleeding and is associated with Decreased mortality



Journal of the American College of Cardiology © 2004 by the American College of Cardiology Foundation Published by Elsevier Inc. Vol. 44, No. 9, 2004 ISSN 0735-1097/04/\$30.00 doi:10.1016/j.jacc.2004.05.085

#### Cost-Effectiveness and Cardiac Interventions

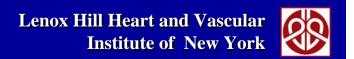
Economic Evaluation of Bivalirudin With Provisional Glycoprotein IIb/IIIa Inhibition Versus Heparin With Routine Glycoprotein IIb/IIIa Inhibition for Percutaneous Coronary Intervention

Results From the REPLACE-2 Trial

David J. Cohen, MD, MSc,\*† A. Michael Lincoff, MD,‡ Tara A. Lavelle, BS,† Huei-Ling Chen, PHD,† Ameet Bakhai, MD,\*† Ronna H. Berezin, MPH,† Daniel Jackman, MD,§ Ian J. Sarembock, MB, CHB,|| Eric J. Topol, MD,‡ on behalf of the REPLACE-2 Investigators

Boston and Brookline, Massachusetts; Tyler, Texas; Charlottesville, Virginia; and Cleveland, Ohio

"...hospital savings were due primarily to a reduction in major bleeding."



#### Impact of Major Bleeding on 30-Day Mortality and Clinical Outcomes in Patients With Acute Coronary Syndromes

An Analysis From the ACUITY Trial

Steven V. Manoukian, MD, FACC,\* Frederick Feit, MD, FACC,† Roxana Mehran, MD, FACC,‡

Michele D. Voeltz, MD,\* Ramin Ebrahimi, MD, FACC, Martial Hamon, MD,

George D. Dangas, MD, PHD, FACC, A. Michael Lincoff, MD, FACC,

Harvey D. White, DSc, FACC# Jeffrey W. Moses, MD, FACC,‡ Spencer B. King III, MD, MACC\*\*

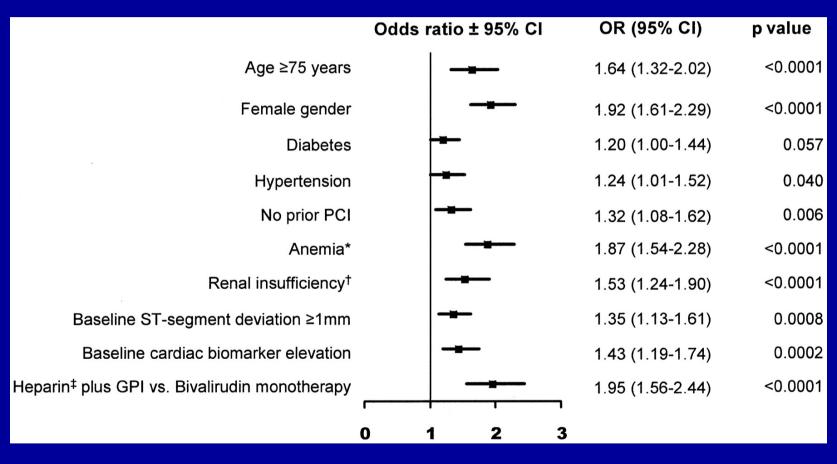
E. Magnus Ohman, MD, FACC, †† Gregg W. Stone, MD, FACC ‡

Atlanta, Georgia; Los Angeles, California; New York, New York; Caen, France; Cleveland, Ohio; Auckland, New Zealand; and Durham, North Carolina

J Am Coll Cardiol 2007;49:1362-8

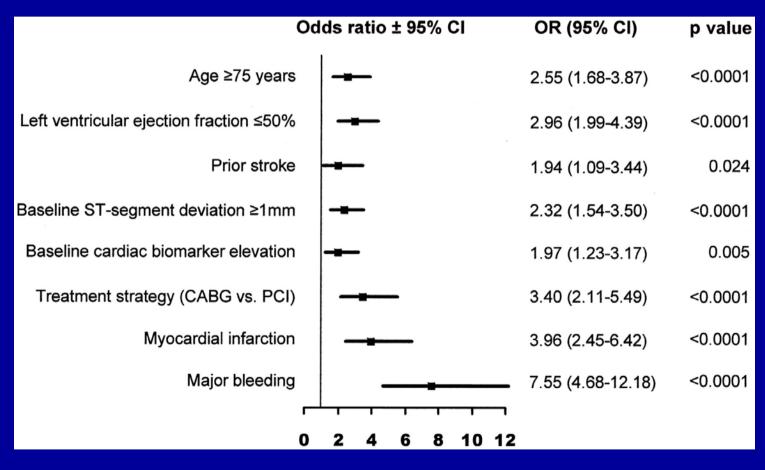


#### INDEPENDENT PREDICTORS OF MAJOR BLEEDING



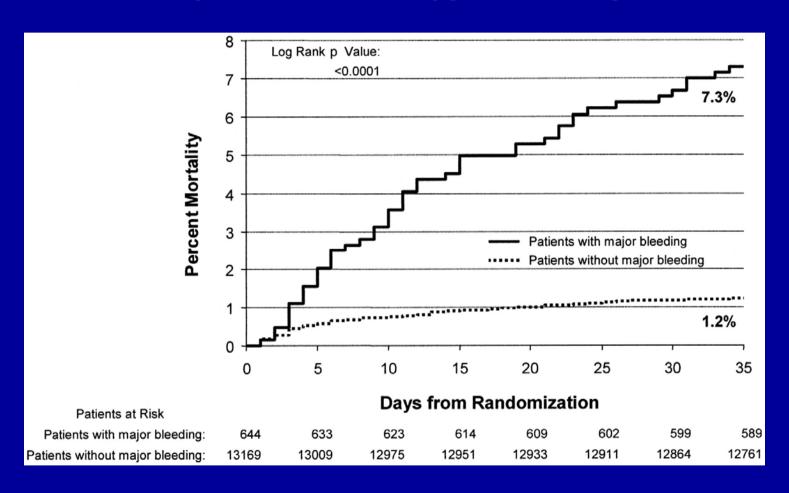


#### INDEPENDENT PREDICTORS OF MORTALITY





#### MORTALITY AND MAJOR BLEEDING





#### **Types of Major Bleeding by Treatment Group**

Table 2

Types of Major Bleeding by Treatment Group

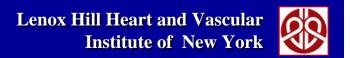
	Heparin (Unfractionated or Enoxaparin) Plus a Glycoprotein IIb/IIIa Inhibitor (n = 4,603)	Bivalirudin Plus a Glycoprotein Ilb/Illa Inhibitor (n = 4,604)	Risk Ratio [95% Confidence Interval]	p <sub>1</sub> Value*	Bivalirudin Monotherapy (n = 4,612)	Risk Ratio [95% Confidence Interval]	p <sub>2</sub> Value†
Major bleeding (not CABG-related) (primary end point)	262 (5.7%)	243 (5.3%)	0.93 [0.78 <b>-1.1</b> 0]	0.38	139 (3.0%)	0.53 [0.43-0.65]	<0.0001
Intracranial	3 (0.07%)	3 (0.07%)		1.00§	3 (0.07%)		1.00§
Retroperitoneal	24 (0.5%)	26 (0.6%)		0.78	7 (0.2%)		< 0.01
Access site bleeding	117 (2.5%)	117 (2.5%)		1.00	38 (0.8%)		< 0.0001
Requiring intervention or surgery	24 (0.5%)	28 (0.6%)		0.58	14 (0.3%)		0.10
Hematoma ≥5 cm	102 (2.2%)	101 (2.2%)		0.94	32 (0.7%)		< 0.0001
Hemoglobin decrease ≥3 g/dl with overt source	102 (2.2%)	83 (1.8%)		0.16	45 (1.0%)		<0.0001
Hemoglobin decrease ≥4 g/dl without overt source	39 (0.8%)	33 (0.7%)		0.48	33 (0.7%)		0.47
Blood transfusion	125 (2.7%)	119 (2.6%)		0.70	75 (1.6%)		0.0003
Reoperation for bleeding	2 (0.04%)	5 (0.1%)		0.459	4 (0.1%)		0.69§
Thrombocytopenia (acquired)‡	511 (11.1%)	497 (10.8%)		0.64	457 (9.9%)		0.06



Arterial Access-Site-Related Outcomes of Patients Undergoing Invasive Coronary Procedures for ACS – PRESTO-ACS Vascular Substudy

- Presto-ACS Italian MC observational study to compare outcomes of high risk NSTE ACS treated with routine invasive or selective invasive strategy
- Site related outcomes of patients who underwent invasive coronary procedure comparing TR and FA access
- 1305 patients with 90% (863 FA and 307 TR) follow-up
- 1° EP in hospital and 1 year MI + death (any cause) and 2° EP in-hospital bleeding and net clinical EP (1° + bleeding)

Sciahbasi et al. Am J Cardiol 209;103:796-800



PRESTO ACS Vascular Substudy - Death or MI 1yr Multivariate analysis

Variable	Odds Ratio	95% CI	p Value
Bleeding	11.5	3.8-35	<0.0001
GFR <60 Cc/min	7.7	2.6-23	<0.0001
EF<35%	4.5	3.8-35	<0.0001



PRESTO ACS Vascular Substudy - Death/MI/Bleeding at 1yr Multivariate analysis

Variable	Odds Ratio	95% CI	p Value
TRA	0.6	0.3-1.0	<0.05
GFR<60 cc/min	2.0	1.2-3.3	0.01
EF<35%	2.7	1.5-4.8	0.001
DM	1.7	1.12-2.7	0.01

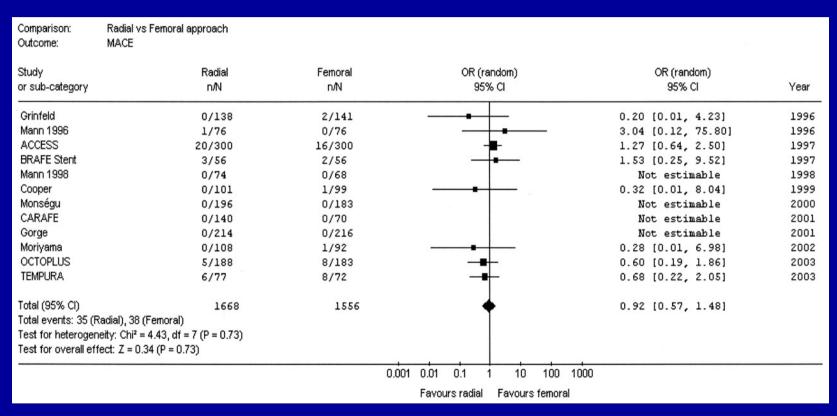
PRESTO ACS Vascular Substudy-Clinical, Procedural and Pharmacolgic characteristics

Variable	TRA	FA	p Value
Age	65±11	68±11	0.0005
Men	73%	66%	0.02
Thienopyr	90%	83%	0.008
GPIIbIIIa RA's	52%	34%	<0.0001

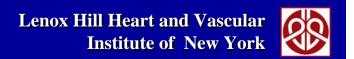
# Radial vs Femoral Access for Coronary Angiography or PCI and the Impact on Major Bleeding and Ischemic Events: A Systematic Review and Meta-analysis of Randomized Trials

Variable	TRA	TFA	Odds Ratio/CI	p Value
Major	0.05%	2.3%	0.27	p<0.001
Bleeding			0.16,0.45	
D, MI,	2.5%	3.8%	0.71	p=0.58
Stroke			0.49, 1.01	
Death	1.2%	1.8%	0.74	p=0.29
			0.42,1.30	
LOS	↓0.4 days			p=0.0001
			0.2-0.5	

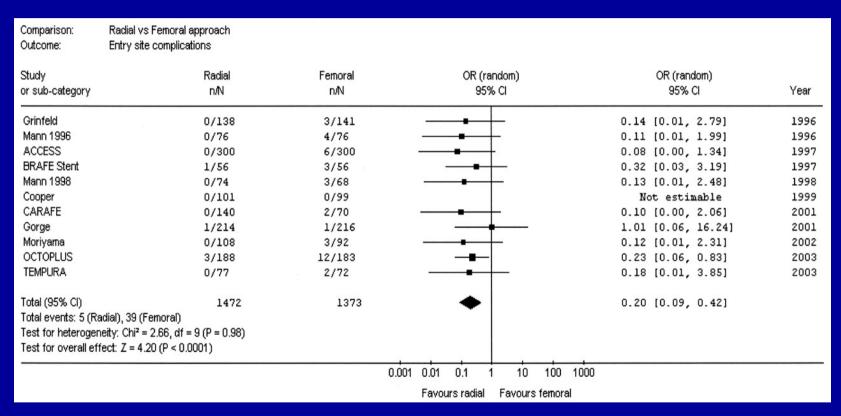
#### Overall risk of major adverse cardiovascular events (MACE)



Agostoni, P. et al. J Am Coll Cardiol 2004;44:349-356



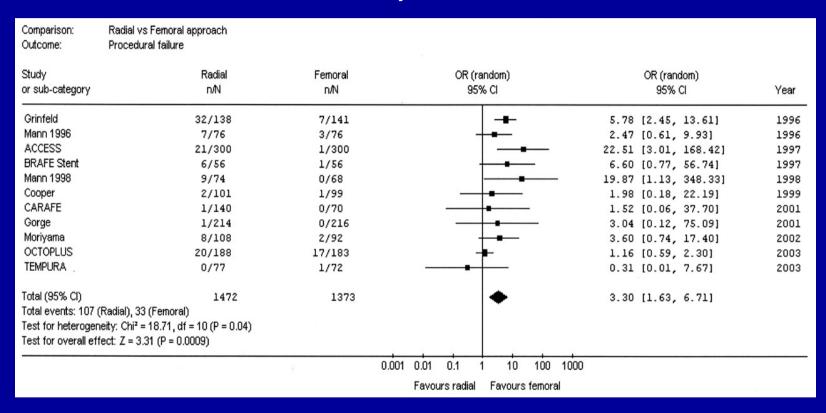
#### **Overall risk of entry site complications**



Agostoni, P. et al. J Am Coll Cardiol 2004;44:349-356



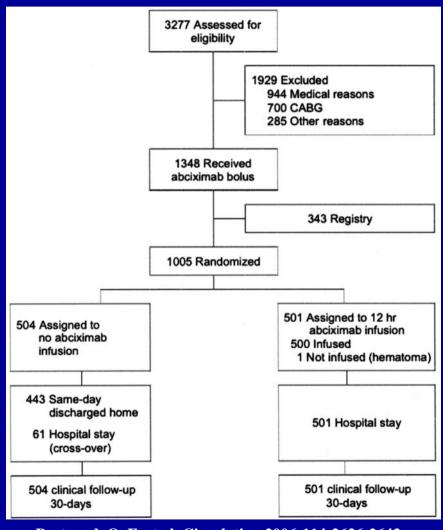
#### Overall risk of procedural failure



Agostoni, P. et al. J Am Coll Cardiol 2004;44:349-356



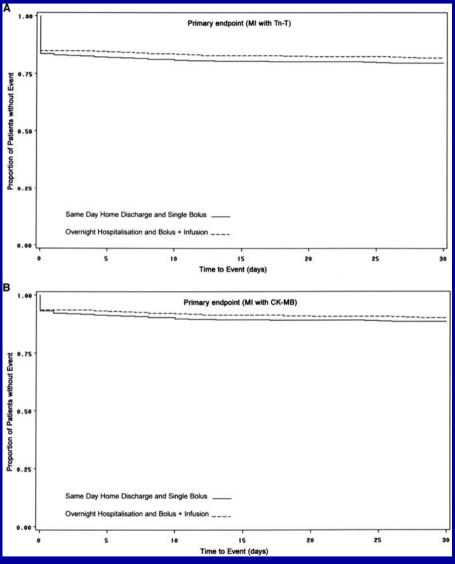
# A Randomized Study Comparing Same-Day Home D/C and Abciximab Only to Overnight Hospitalization and Abciximab Bolus and Infusion After Transradial Coronary Stent Implantation







#### EFS Curves for Primary EP's with Tn-T and CK-MB at 30 Days



Bertrand, O. F. et al. Circulation 2006;114:2636-2643

#### Costs

- TRA decreases bleeding and thereby decreases costs
- Closure device \$0-25 vs \$200/case
- TRA may allows for safe outpatient PCI (stenting) and thereby decrease costs

#### Outcomes

- TRA definitely decreases bleeding
- Observational studies and Meta-analysis suggest that TRA decreases short and longterm outcomes
- RCT's are needed to prove that TR vs FA access decreases short and long-term outcomes