

# Can Radial Approach Reduces PCI Hard Events?

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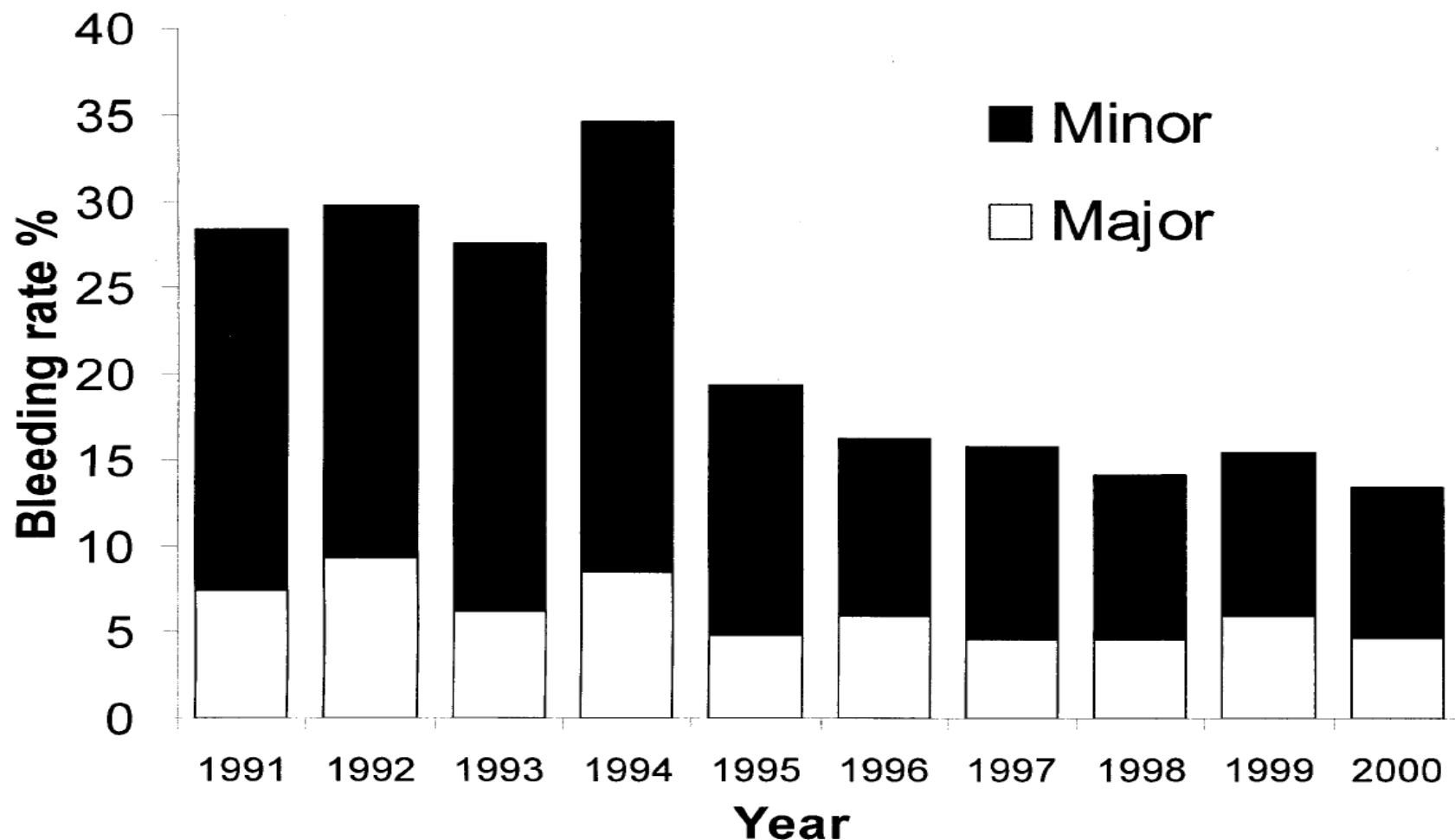


Busan, Korea, december 8-9, 2011

# **Approach related vascular complications: the major concern in modern PCI**

# Rates of Bleeding in PCI

## Washington Hospital Center (N=10,974)



# Predictors of Major Bleeding in PCI

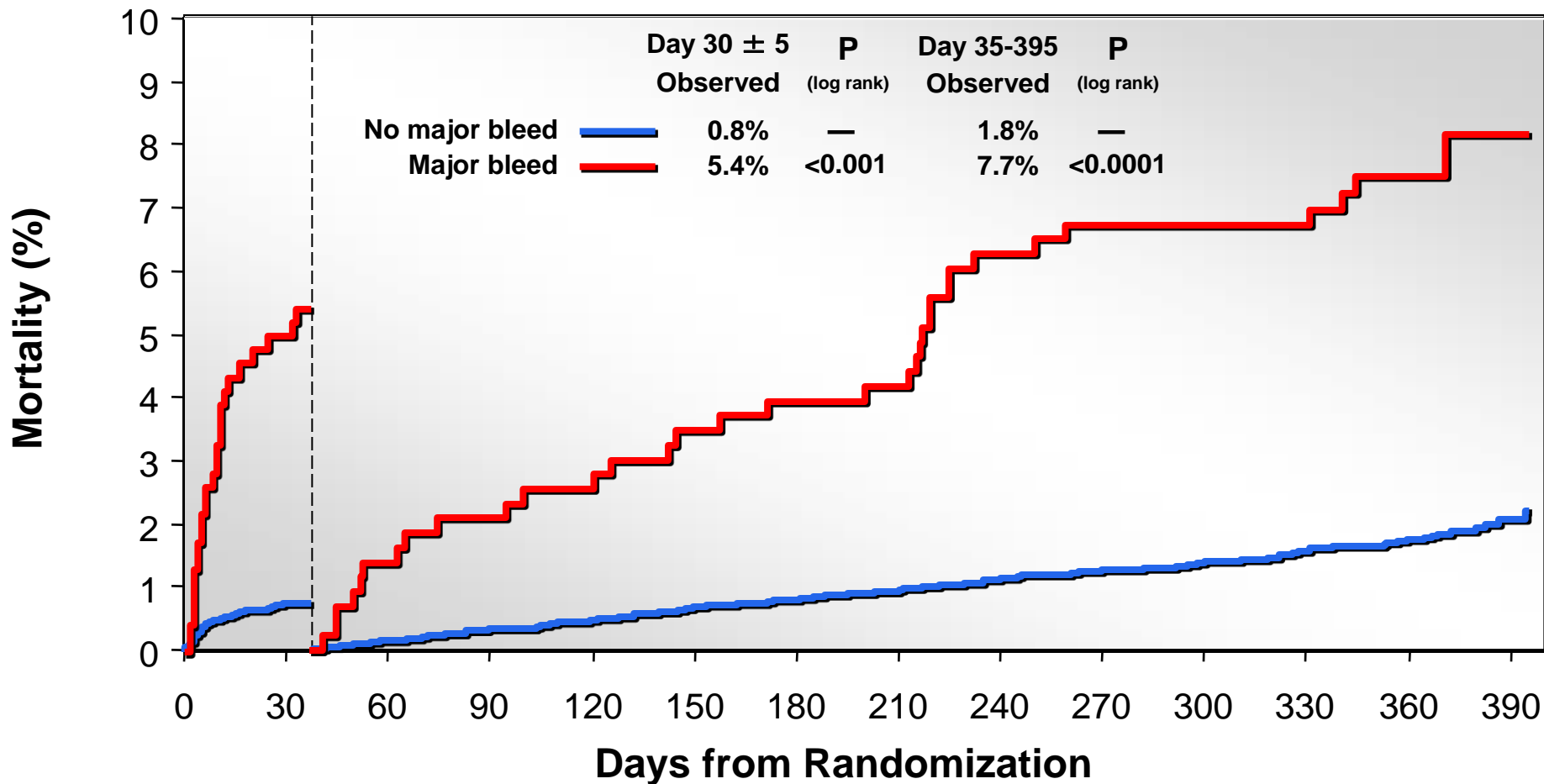
## The REPLACE-2 Trial (N=6,010)

<b>Variable</b>	<b>OR</b>	<b>95% CI</b>	<b>p-value</b>
<b><i>Baseline risk factors</i></b>			
Age ≥ 75	1.482	1.01, 2.18	0.045
Gender (Female)	1.535	1.12, 1.10	0.007
Creatinine Clearance	1.008	1.00, 1.01	0.006
Anemia	1.403	1.02, 1.94	0.040
Prior Angina	1.589	1.08, 2.35	0.02
Prior PCI	0.629	0.45, 0.88	0.007
Prior Thienopyridine	0.601	0.39, 0.93	0.023
<b><i>Peri-procedural risk factors</i></b>			
Treatment Group (Heparin + GPI vs. bivalirudin)	1.969	1.37, 2.84	0.0003
Provisional GPI received	2.679	1.59, 4.51	0.0002
Procedure Duration >1h	2.049	1.22, 3.45	0.007
Time to Sheath Removal >6h	1.614	1.06, 2.45	0.024
Intensive Care Unit stay (days)	1.25	1.18, 1.32	<0.0001
Intra-aortic Balloon Pump	8.705	3.43, 22.07	<0.0001

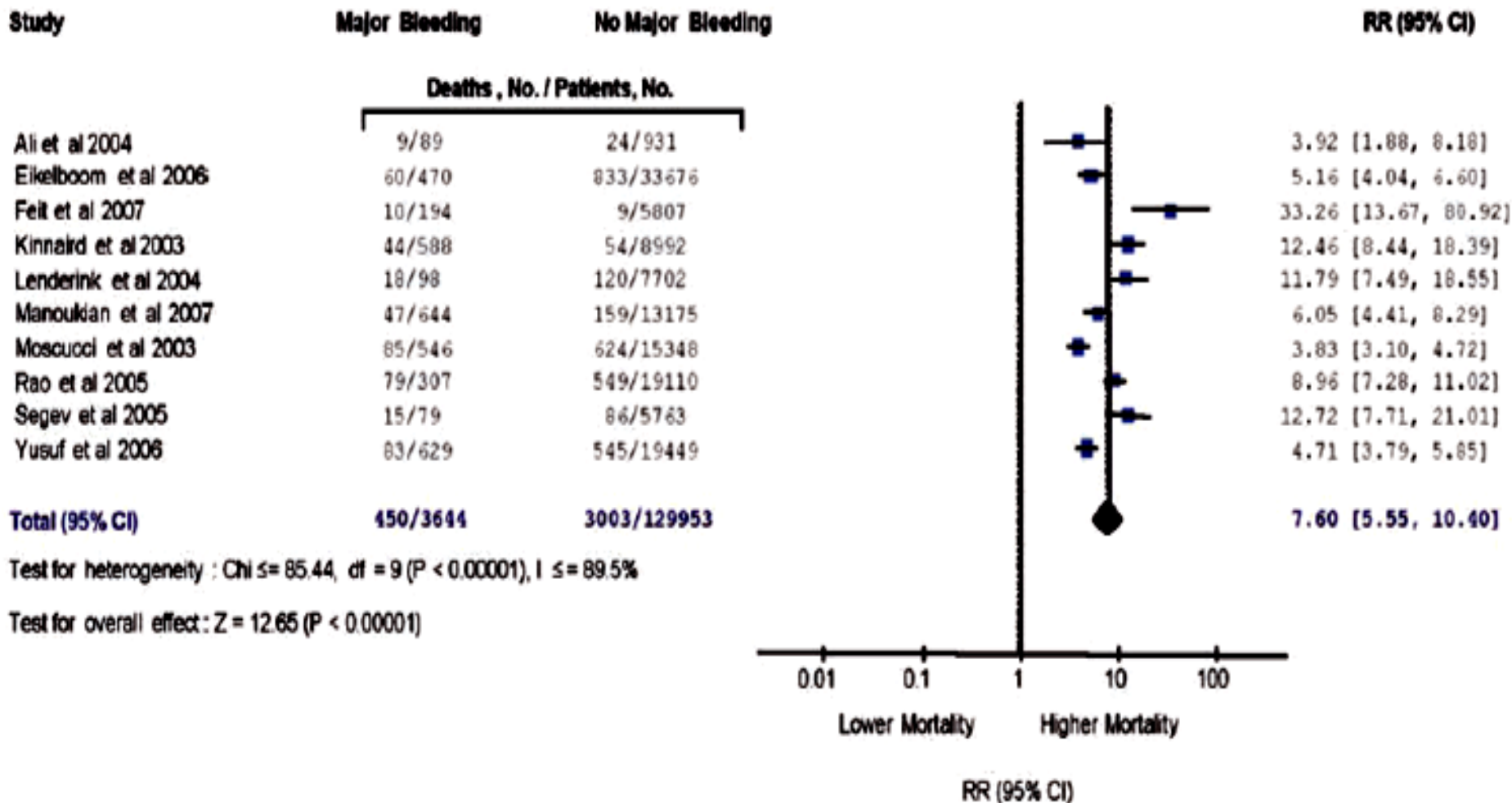
Major Bleeding (Overall 3.2%)

# ACUITY PCI: Major Bleeding

## Long-Term (1-Year) Mortality Landmark Analysis

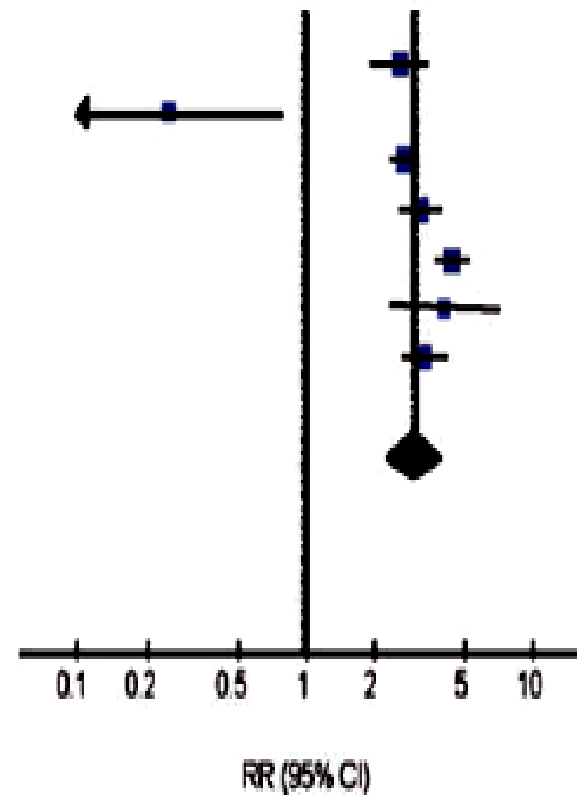


# Pooled relative risk of mortality increase in patients with ACS and major bleeding



# Pooled relative risk of MI increase in patients with ACS and major bleeding

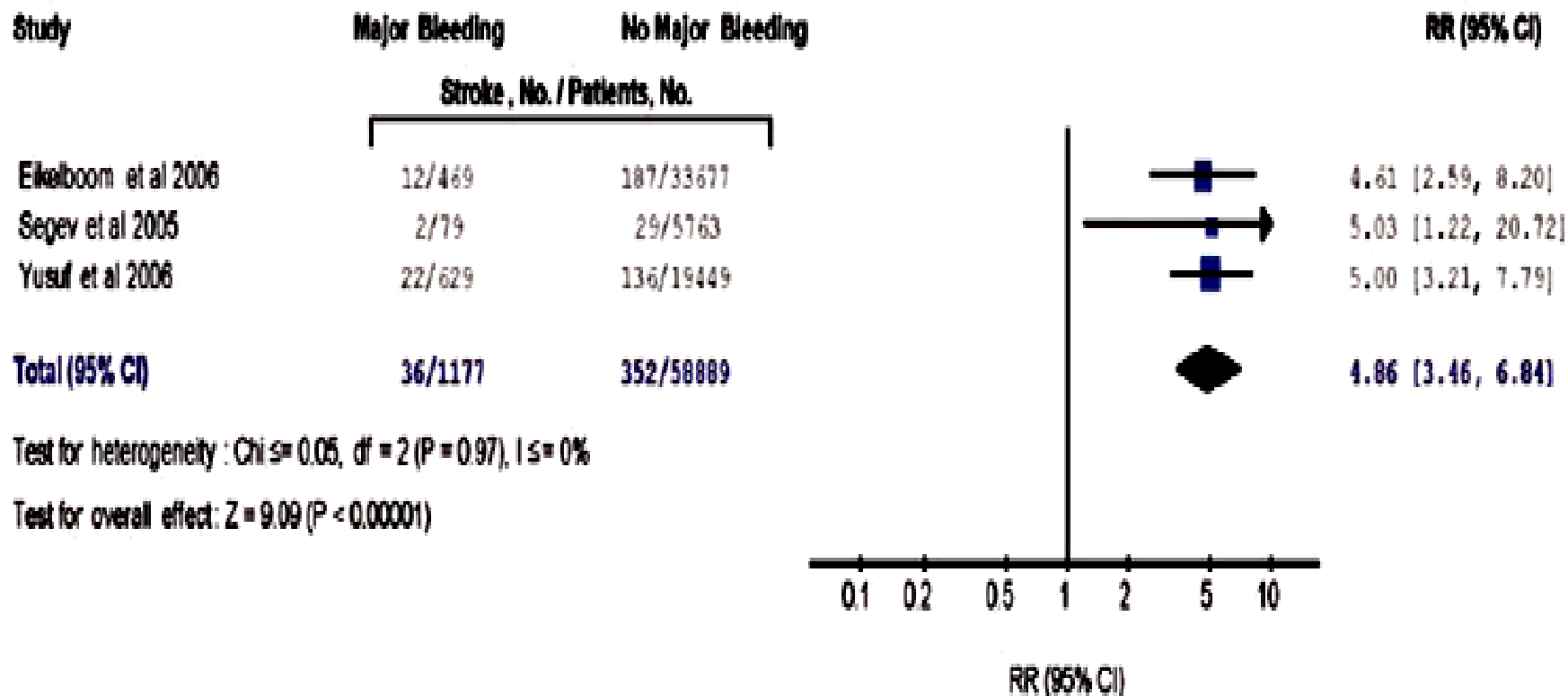
Study	Major Bleeding	No Major Bleeding	RR (95% CI)
	Myocardial infarction, No. / Patients, No.		
Eikelboom et al 2008	46/436	1375/33710	2.59 [1.96, 3.42]
Feit et al 2007	3/194	354/5807	0.25 [0.08, 0.78]
Kinnaird et al 2003	188/588	1079/8992	2.66 [2.34, 3.04]
Manoukian et al 2007	94/644	610/13175	3.15 [2.58, 3.86]
Rao et al 2005	100/306	1412/19110	4.42 [3.74, 5.23]
Segev et al 2005	12/79	219/5763	4.00 [2.34, 6.84]
Yusuf et al 2008	75/629	700/19449	3.31 [2.65, 4.15]
<b>Total (95% CI)</b>	<b>518/2876</b>	<b>5749/106006</b>	<b>2.93 [2.26, 3.80]</b>



Test for heterogeneity:  $\chi^2 = 47.33$ ,  $df = 6$  ( $P < 0.00001$ ),  $I^2 = 87.3\%$

Test for overall effect:  $Z = 8.14$  ( $P < 0.00001$ )

# Pooled relative risk of stroke increase in patients with ACS and major bleeding





# **Transradial approach for diagnosis and PCI nearly abolishes the vascular complications**

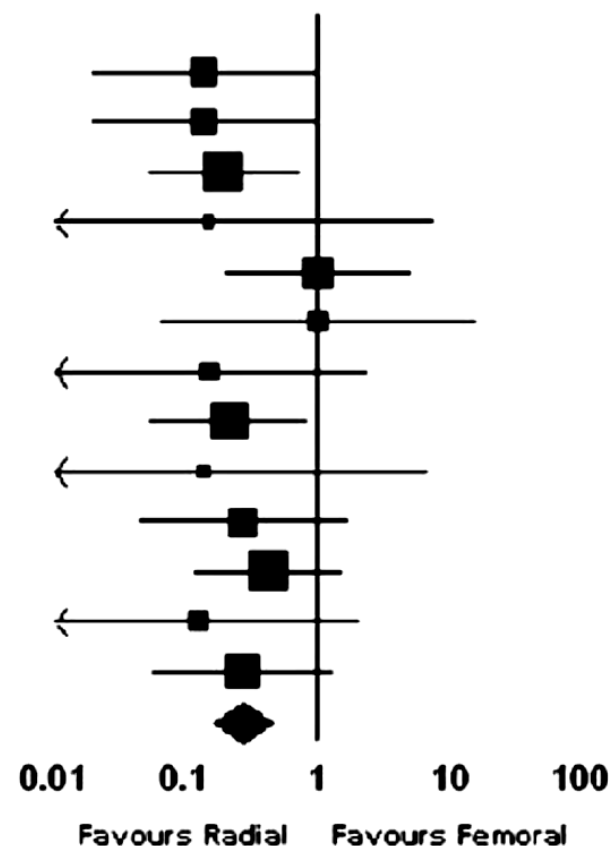
# Radial vs femoral access for coronary angiography or intervention: meta-analysis of RCTs

## Major bleeding

Study name

	Radial	Femoral	Peto odds ratio
ACCESS	0 / 300	4 / 300	0.13
Achenbach	0 / 152	4 / 155	0.14
Bodi	3 / 666	7 / 332	0.19
BRAFE	0 / 50	1 / 55	0.15
FARMI	3 / 57	3 / 57	1.00
Gorge	1 / 214	1 / 216	1.01
Mann 1998	0 / 68	2 / 77	0.15
OCTOPLUS	1 / 192	7 / 185	0.21
OUTCLAS	0 / 322	1 / 322	0.14
RADIAL AMI	1 / 25	4 / 25	0.27
RADIAMI	3 / 50	7 / 50	0.41
TEMPURA	0 / 77	2 / 72	0.12
Vazquez-Rodriguez	1 / 217	5 / 222	0.27
	13 / 2390	48 / 2068	<b>0.27</b>

Peto odds ratio and 95% CI



**OR 0.27 (95% CI 0.16, 0.45)  $P < .001$**

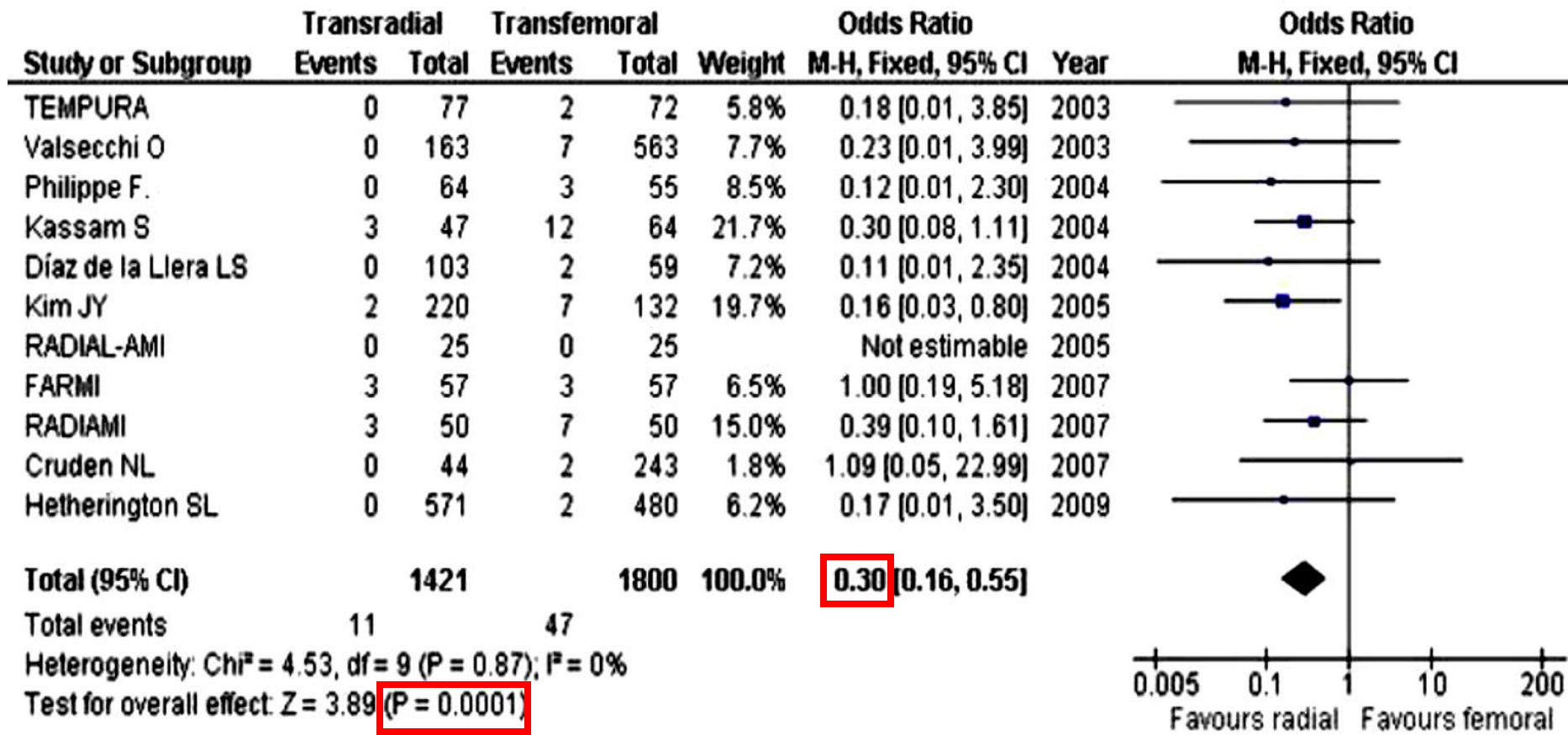
# Radial vs femoral access for coronary angiography or intervention:meta-analysis of randomized trials

## Sub-group analysis for major bleeding by clinical characteristics of studies

Subgroup	No. of studies (no. of patients)	OR (95% CI)	P
Mean age > 70	2 (684)	0.18 (0.06, 0.57)	.003
Mean age < 70	16 (4807)	0.30 (0.17, 0.53)	<.001
Radial expert	12 (4531)	0.23 (0.13, 0.42)	<.001
Non-radial expert	6 (960)	0.39 (0.15, 1.01)	.05
Diagnostic-only studies	3 (1030)	1.01 (0.06, 16.2)	1.0
Intervention studies	15 (4461)	0.25 (0.15, 0.43)	<.001
Primary or rescue PCI	5 (852)	0.39 (0.18, 0.82)	.013
Closure device studies	4 (1101)	0.21 (0.09, 0.49)	<.001
Unpublished	5 (2274)	0.28 (0.13, 0.56)	<.001
Published	13 (3217)	0.26 (0.12, 0.54)	<.001
Modern era (1999-present)	10 (3608)	0.29 (0.17, 0.50)	<.001

# TRA vs. TFA for PCI in AMI. A Meta-Analysis

## Major bleeding



# Increased Risk of Complications with a Transradial Approach: SCAAR registry

(30 centers)(2000-2004)

n	Transradial 7962	Transfemoral 48682	p
% PCI (%)	44	41	
Age (years)	64.4±10.5	65.2±10.9	
Female gender (%)	27.1	33.0	
Previous CABG (%)	5.4	12.0	
ST+ MI (%)	2.8	8.9	
Left main/3 vessel disease (%)	24.0	30.3	
Complications overall (%)	5.7	4.6	<0.001
Neurological complications (%)	0.4	0.2	0.007
Myocardial infarctions (%)	1.0	0.5	<0.001
Bleedings at the access site (%)	1.1	1.5	

# TIA or stroke during PCI: is the radial route a risk factor ?

## Results from 2 large nationwide registries in France

N= 4820	%	p
Female vs male	0.79 / 0.19	.003
Previous stroke or TIA (yes / no)	1.19 / 0.26	.01
EF <40% (yes / no)	1.04 / 0.14	.003
Stable / non ST + ACS / ST + ACS	0.09 / 0.40 / 0.61	.03
Sheath size (5F / 6F / 7F)	0.24 / 0.20 / 1.19	.204
<b>Femoral / Radial route</b>	<b>0.39 / 0.19</b>	<b>.208</b>

**Does radial approach reduces the mortality of interventional cardiology ?**

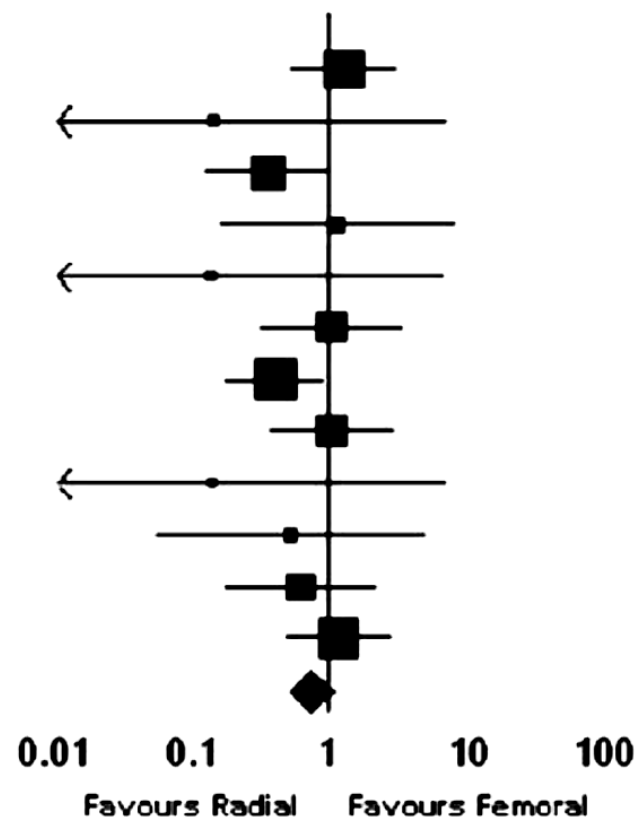
# Radial vs femoral access for coronary angiography or intervention: meta-analysis of RCTs

## Death, MI or Stroke

### Study name

	Radial	Femoral	Peto odds ratio
ACCESS	11 / 300	9 / 300	1.23
Achenbach	0 / 152	1 / 155	0.14
Bodi	7 / 666	9 / 332	0.35
BRAFE	2 / 50	2 / 55	1.10
Cooper	0 / 101	1 / 99	0.13
FARMI	6 / 57	6 / 57	1.00
OCTOPLUS	7 / 192	17 / 185	0.40
OUTCLAS**	7 / 322	7 / 322	1.00
RADIAL AMI	0 / 25	1 / 25	0.14
RADIAMI	1 / 50	2 / 50	0.51
TEMPURA*	4 / 77	6 / 72	0.61
Vazquez-Rodriguez	11 / 217	10 / 222	1.13
	56 / 2209	71 / 1874	<b>0.71</b>

### Peto odds ratio and 95% CI



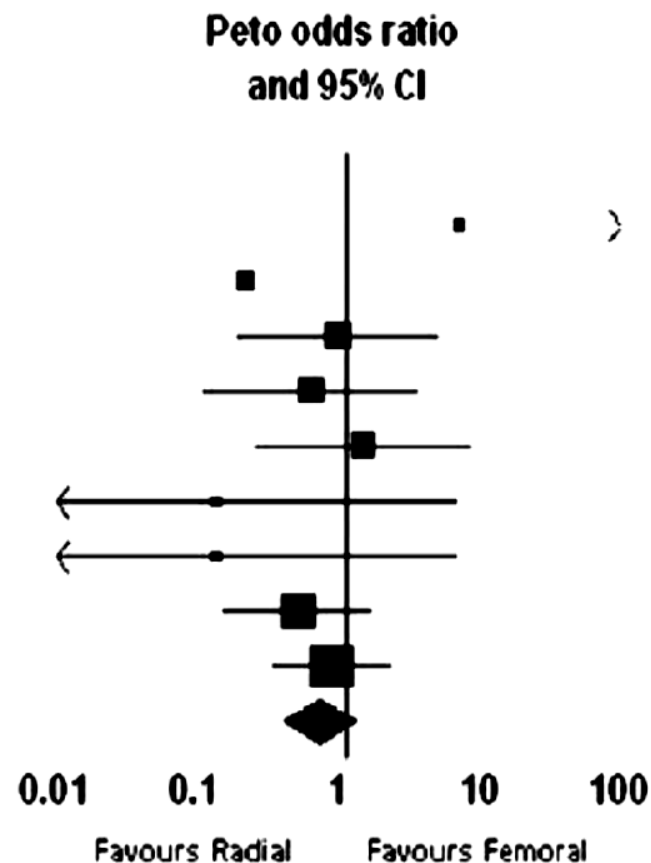
**OR 0.71 (95% CI 0.49, 1.01)  $P = .058$**



# Radial vs femoral access for coronary angiography or intervention: meta-analysis of RCTs

## Death

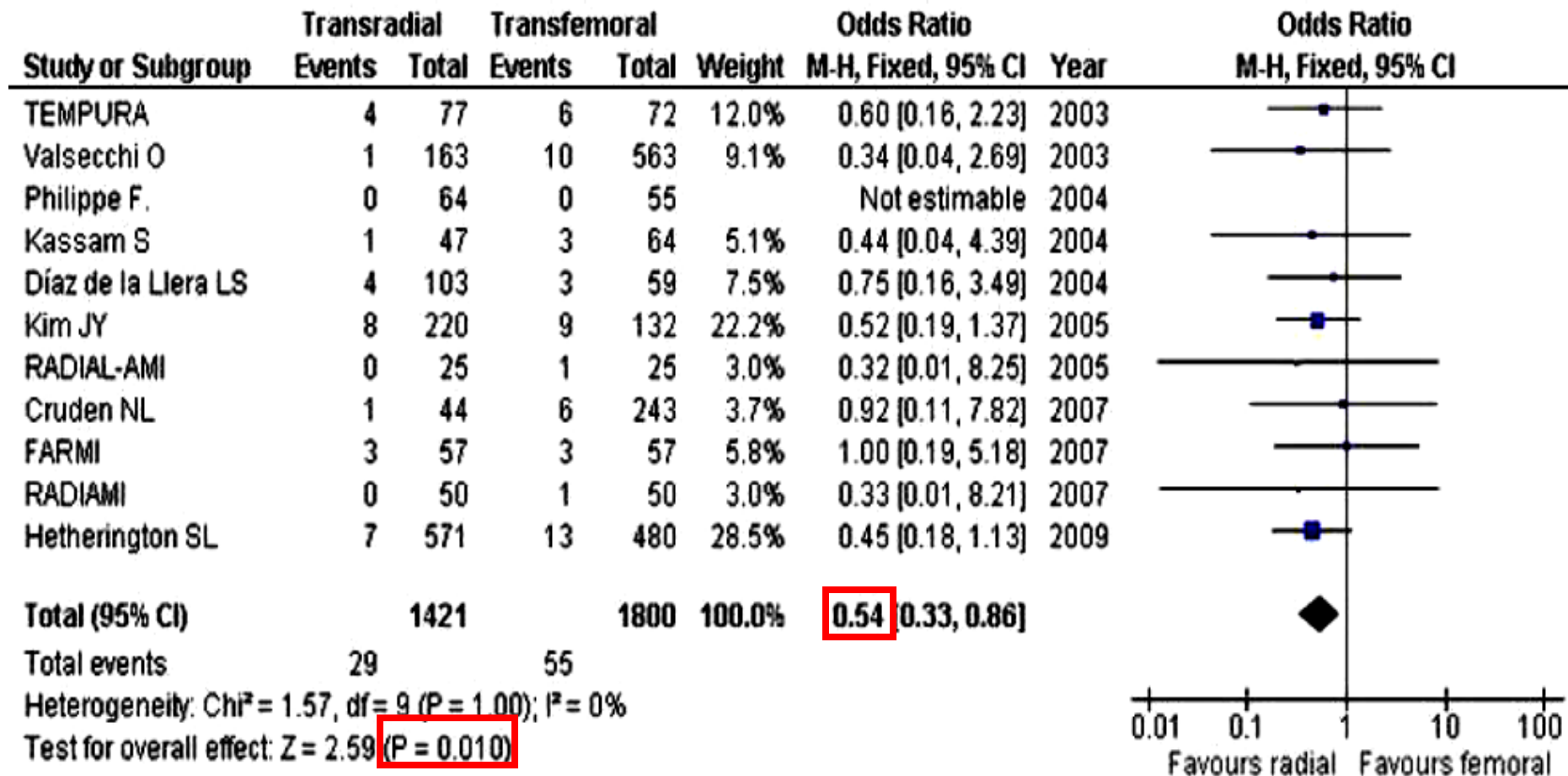
Study name	Dead / Total		Peto odds ratio
	Radial	Femoral	
ACCESS	1 / 300	0 / 300	7.39
Bodi	1 / 666	2 / 332	0.22
FARMI	3 / 57	3 / 57	1.00
OCTOPLUS	2 / 192	3 / 185	0.64
OUTCLAS	3 / 322	2 / 322	1.50
RADIAL AMI	0 / 25	1 / 25	0.14
RADIAMI	0 / 50	1 / 50	0.14
TEMPURA	4 / 77	7 / 72	0.52
Vazquez-Rodriguez	8 / 217	9 / 222	0.91
	22 / 1906	28 / 1565	0.74



**OR 0.74 (95% CI 0.42, 1.30)  $P = .29$**

# TRA vs. TFA for PCI in AMI. A Meta-Analysis

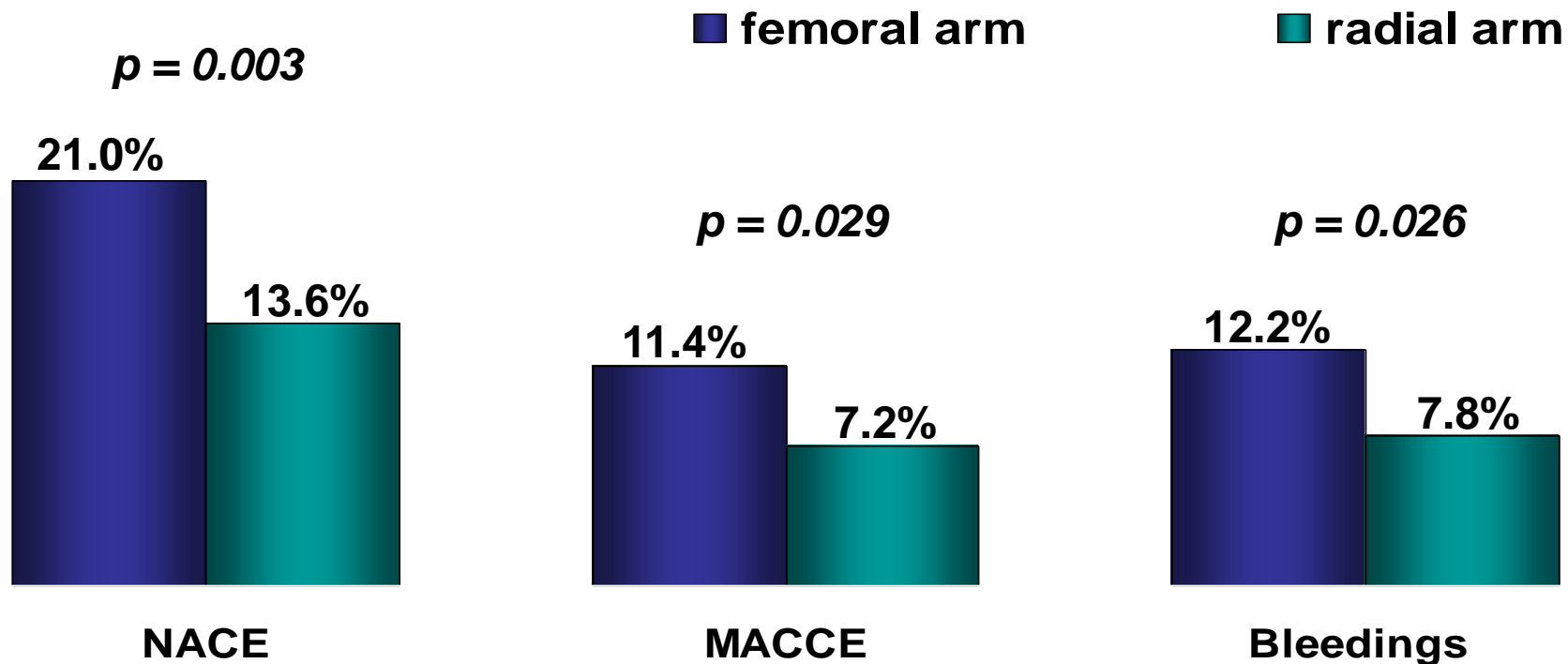
## Death





# RIFLE STEACS – results

30-day NACE rate

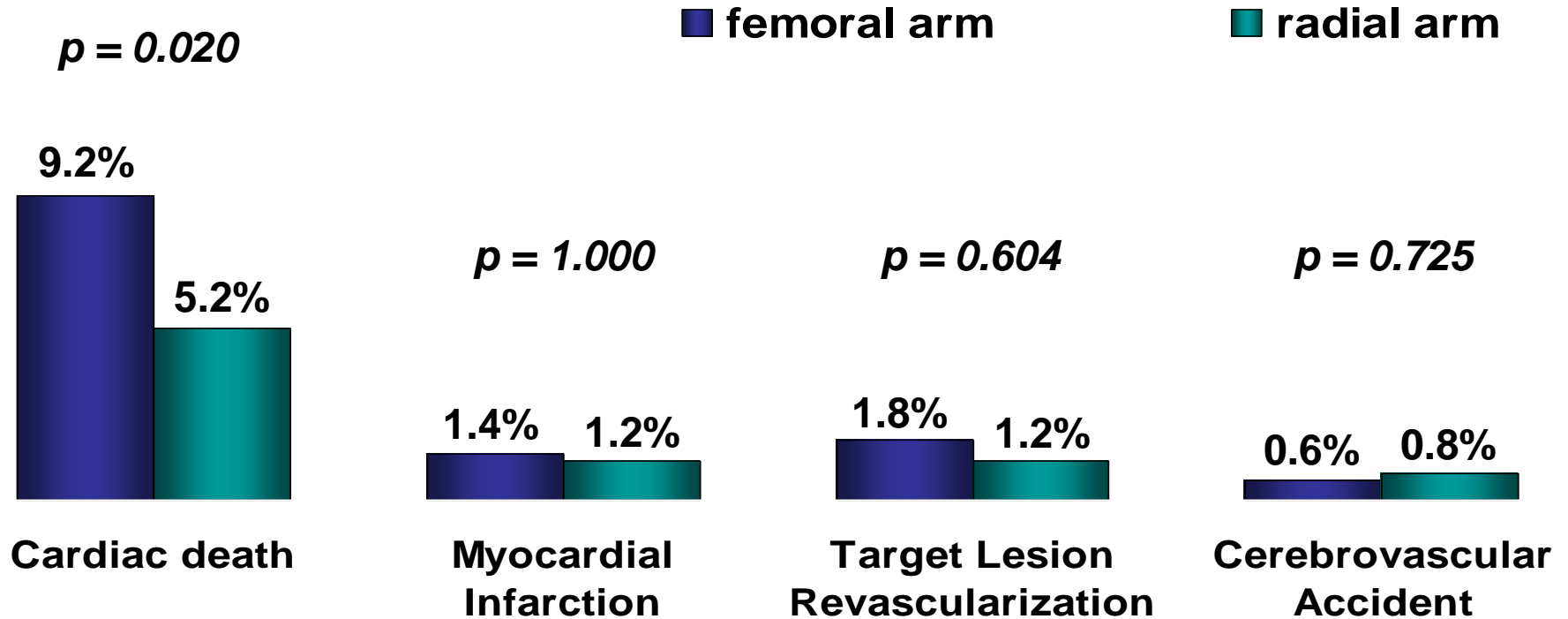


- Net Adverse Clinical Event (NACE) = MACCE + bleeding
- Major Adverse Cardiac and Cerebrovascular event (MACCE) = composite of cardiac death, myocardial infarction, target lesion revascularization, stroke



# RIFLE STEACS – results

30-day MACCE rate



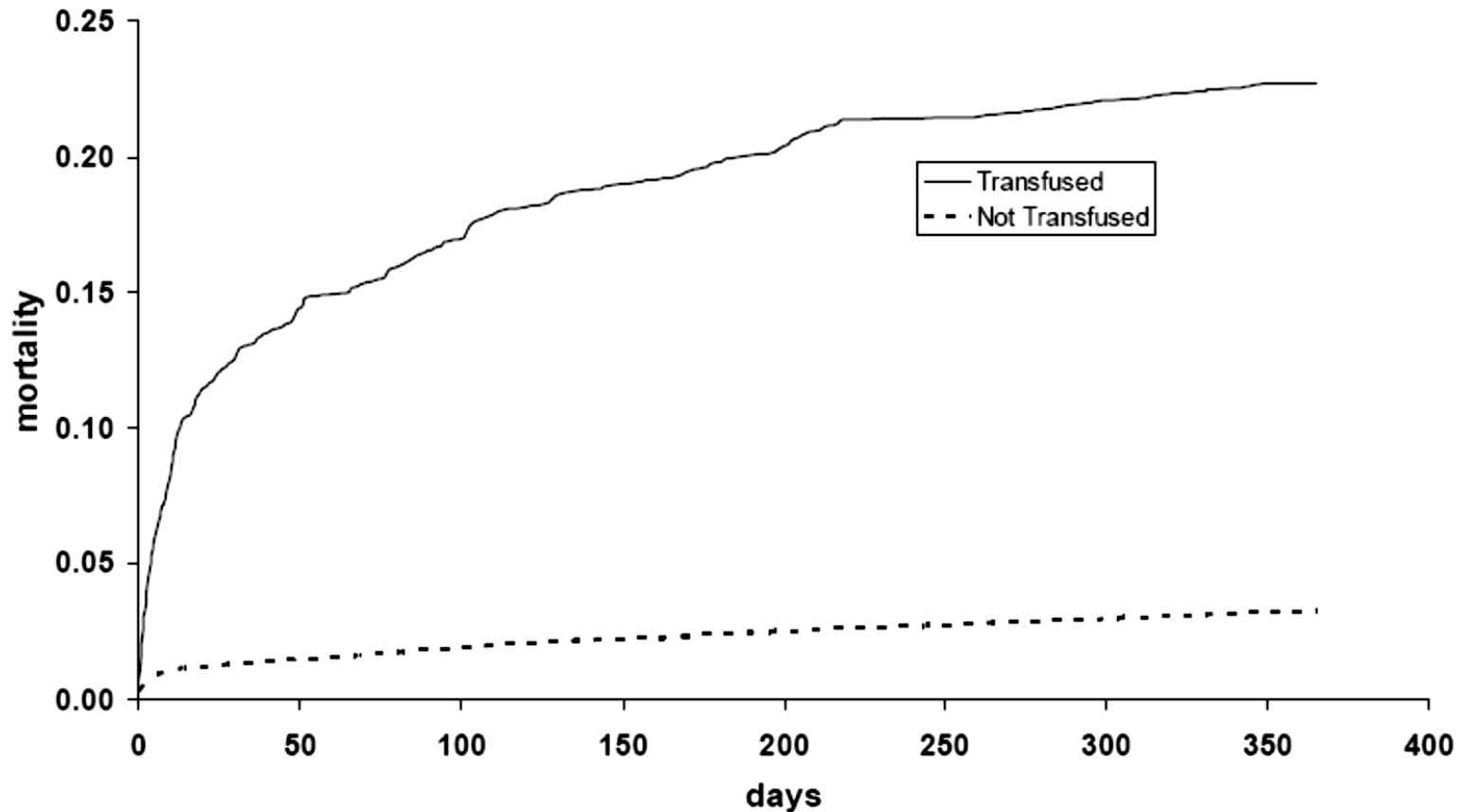
# The M.O.R.T.A.L Study: (Mortality benefit of Reduced Transfusion After PCI via the Arm or Leg)

## Methods: data linkage

- The *British Columbia Cardiac Registry* PCI patients in BC 1999-2005 demographics & procedure details
- The *Central Transfusion Registry* (CTR) will cross reference packed red cells transfusion by medical records number (PHN) within a window of 9 days after PCI excluding CABG
- The BC *Vital Statistics* status; alive or dead at 30 days, 1 year post PCI.

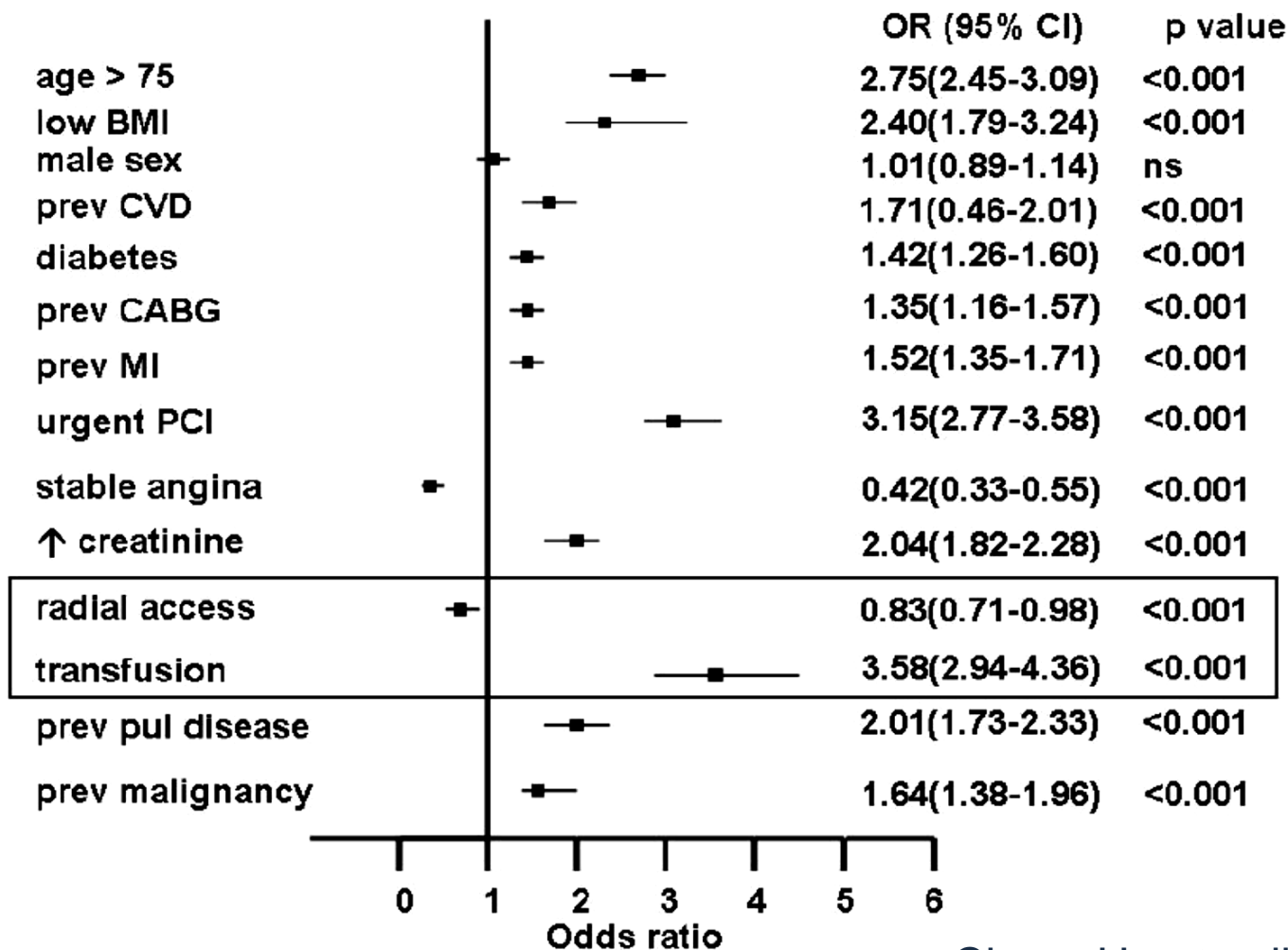
# The M.O.R.T.A.L Study: (Mortality benefit of Reduced Transfusion After PCI via the Arm or Leg)

Unadjusted Kaplan-Meier Curves for Transfusion Status



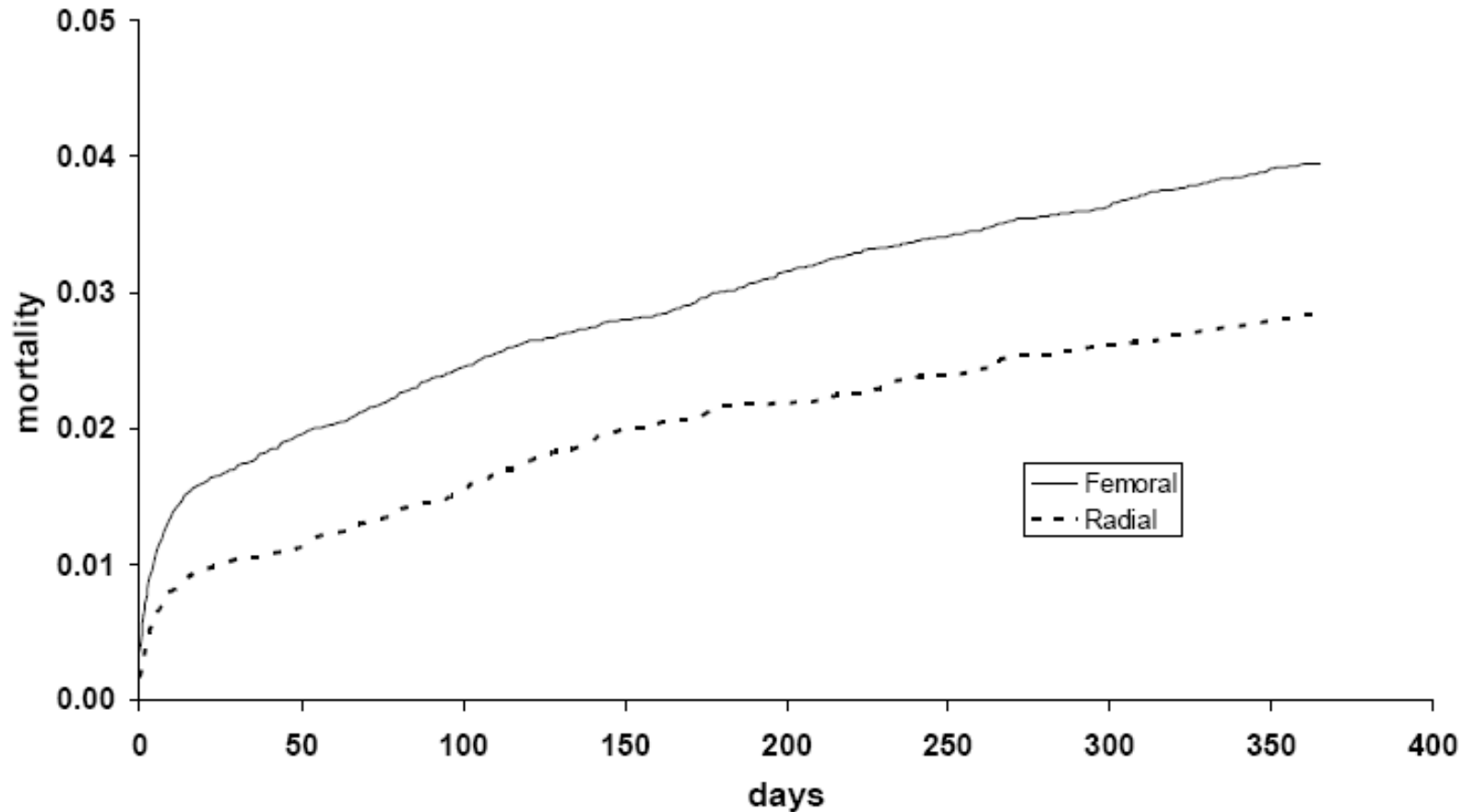
# The M.O.R.T.A.L Study: (Mortality benefit of Reduced Transfusion After PCI via the Arm or Leg)

Adjusted Odds Ratios for 1 Year Mortality



# The M.O.R.T.A.L Study: (Mortality benefit of Reduced Transfusion After PCI via the Arm or Leg)

Unadjusted Kaplan-Meier Curves for Radial versus Femoral





# RIVAL Study Design

**NSTE-ACS and STEMI  
(n=7021)**

## Key Inclusion:

- Intact dual circulation of hand required
- Interventionalist experienced with both (minimum 50 radial procedures in last year)

## Randomization

**Radial Access  
(n=3507)**

**Femoral Access  
(n=3514)**

**Blinded Adjudication of Outcomes**

**Primary Outcome: Death, MI, stroke  
or non-CABG-related Major Bleeding at 30 days**

# Primary and Secondary Outcomes

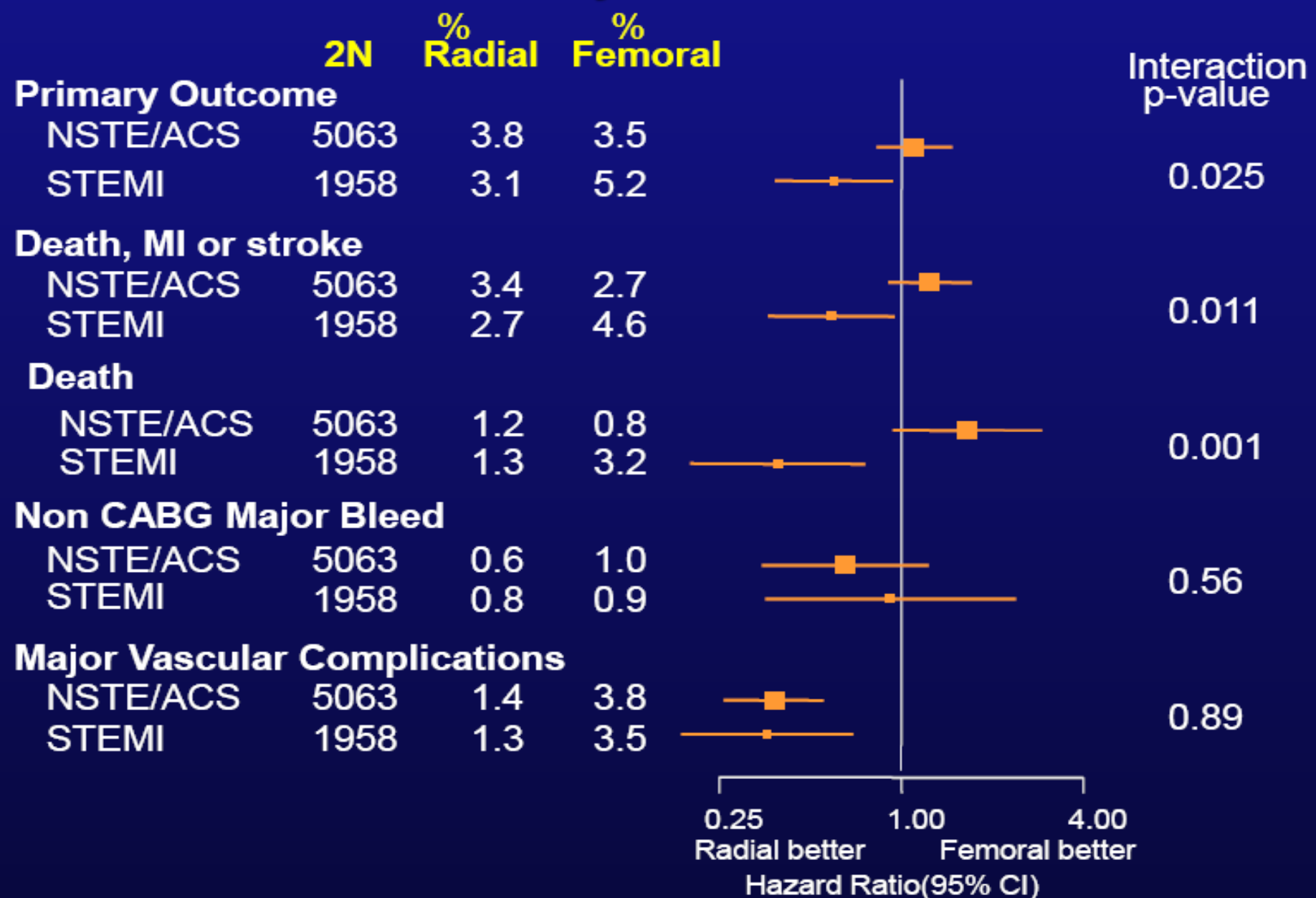
	<b>Radial</b> (n=3507) %	<b>Femoral</b> (n=3514) %	<b>HR</b>	<b>95% CI</b>	<b>P</b>
<b>Primary Outcome</b>					
Death, MI, Stroke, Non-CABG Major Bleed	<b>3.7</b>	<b>4.0</b>	0.92	0.72-1.17	0.50
<b>Secondary Outcomes</b>					
Death, MI, Stroke	<b>3.2</b>	<b>3.2</b>	0.98	0.77-1.28	0.90
Non-CABG Major Bleeding	<b>0.7</b>	<b>0.9</b>	0.73	0.43-1.23	0.23

# Other Outcomes

	<b>Radial</b> (n=3507) %	<b>Femoral</b> (n=3514) %	<b>HR</b>	<b>95% CI</b>	<b>P</b>
Major Vascular Access Site Complications	<b>1.4</b>	<b>3.7</b>	0.37	0.27-0.52	<0.0001
<b>Other Definitions of Major Bleeding</b>					
TIMI Non-CABG Major Bleeding	<b>0.5</b>	<b>0.5</b>	1.00	0.53-1.89	1.00
ACUITY Non-CABG Major Bleeding*	<b>1.9</b>	<b>4.5</b>	0.43	0.32-0.57	<0.0001

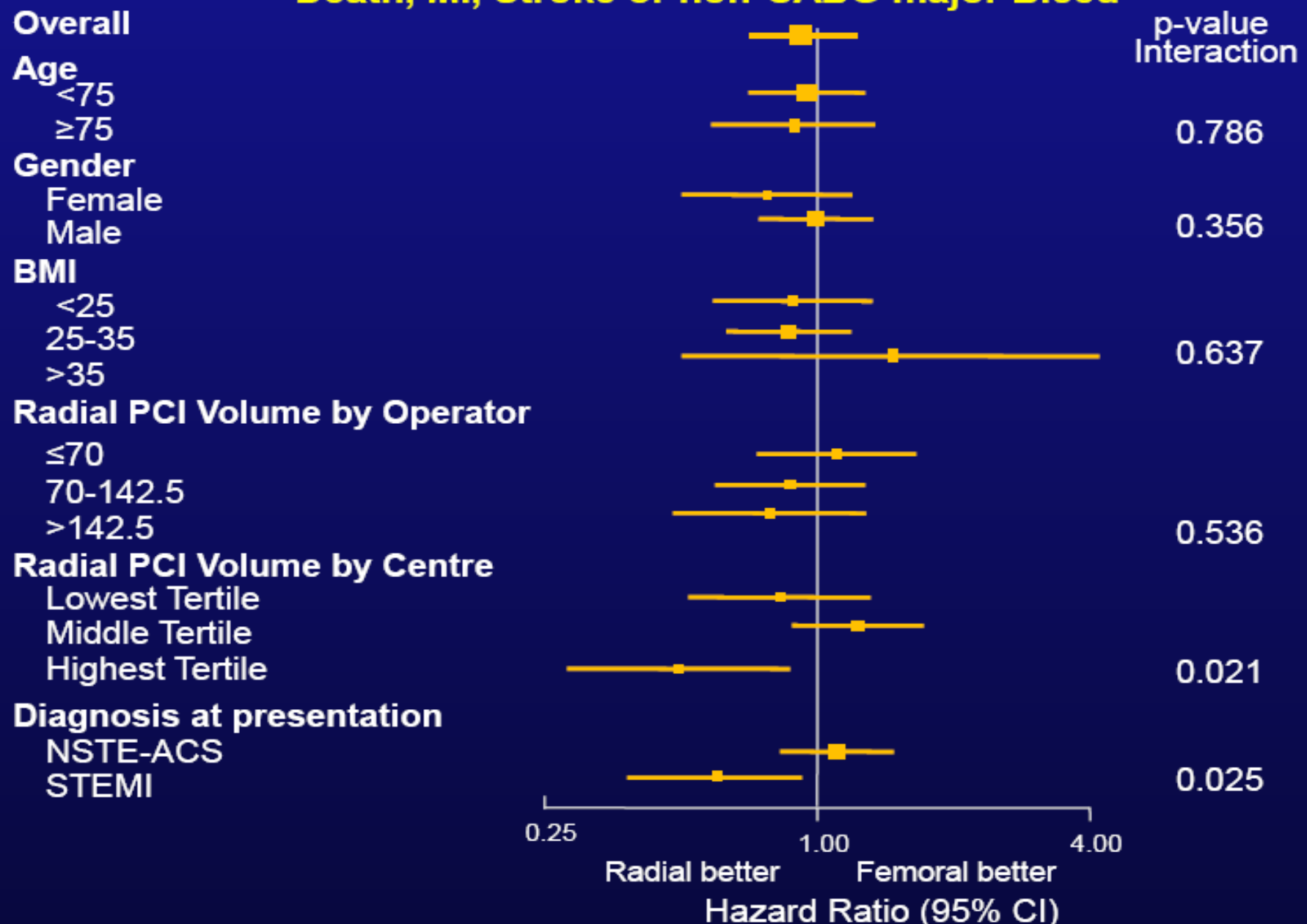
\* Post Hoc analysis

# Outcomes stratified by STEMI vs. NSTEMI/ACS



# Subgroups: Primary Outcome

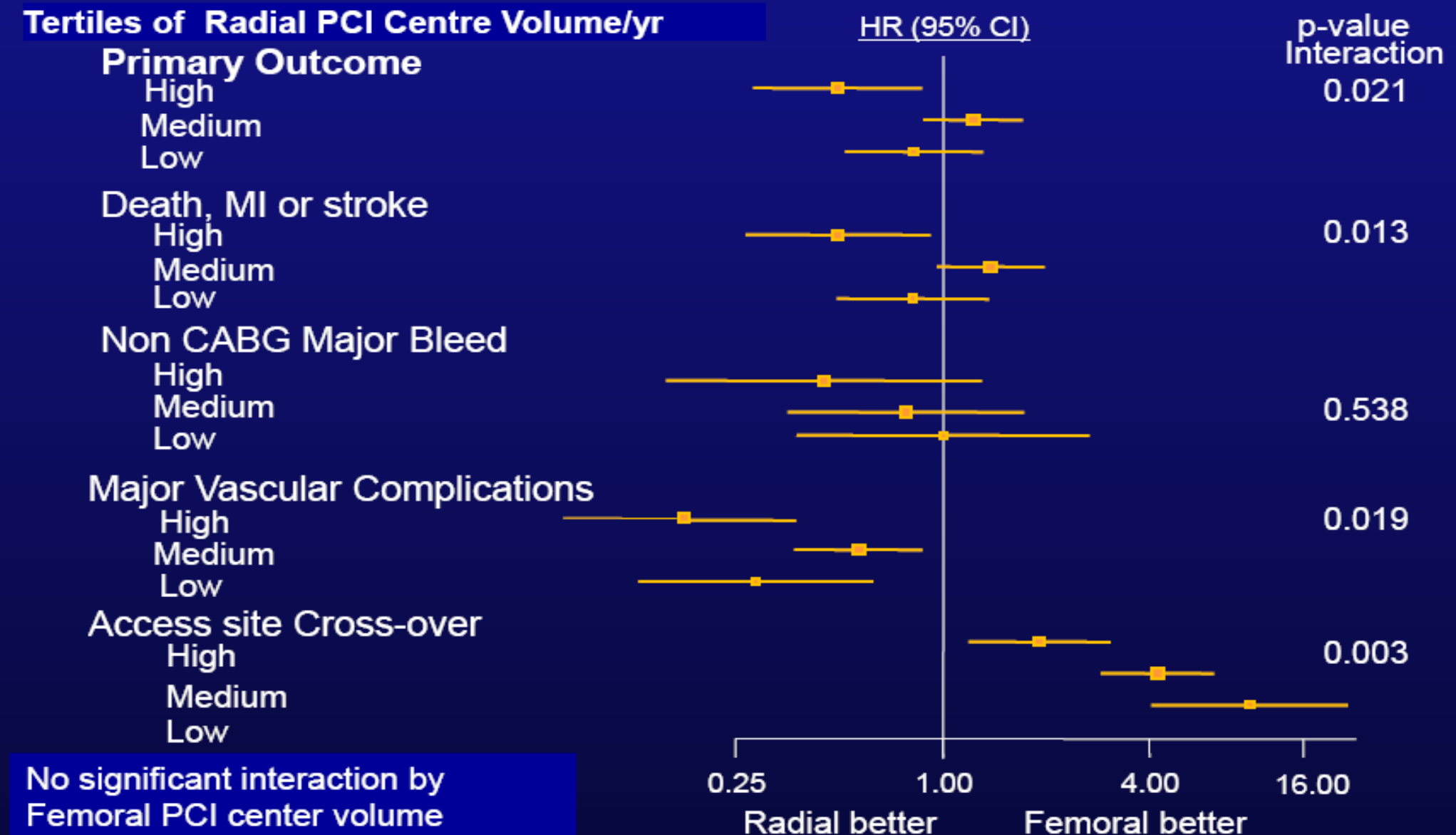
Death, MI, Stroke or non-CABG major Bleed



## Results stratified by

## High\*, Medium\* and Low\* Volume Radial Centres

\*High (&gt;146 radial PCI/year/ median operator at centre), Medium (61-146), Low (≤60)



## Outcomes by access site used to complete the procedure

	Radial	Femoral	n
Crossover (failure)(%)	7	0.9	
Primary endpoint (%)	3.4	4.1	0.14
Death/MI/Stroke (%)	3.1	3.3	0.52
Non CABG maj. bleed (%)	0.6	1.0	0.025
Access site maj. Bleed (n)	0	18	

## Conclusions

- Access site complications are a major concern for modern coronary interventional cardiology
- Risk of acute and mid term Mortality, MI and Stroke are related to the rate of major bleeding
- Radial approach reduces near abolishes the risk of access related major complications
- MORTAL study and metaanalysis suggest a mortality reduction with transradial approach (specially for STEMI: RIFFLE)



## Conclusions

- RIVAL: similar rates of the composite of death, myocardial infarction, stroke, or non-CABG-related major bleeding
- RIVAL: subgroup analysis confirm a reduction of mortality for STEMI
- RIVAL: Primary endpoint, Death/MI/Stroke, Major non CABG bleeding are reduced with a trend for Death in highest tercile of radial approach volume
- RIVAL: effectiveness of radial access might be linked to expertise and volume