RIVAL Program

RadIal Versus femorAL access for coronary intervention study

A randomized comparison of RadIal Vs. femorAL access for coronary intervention in ACS (RIVAL)

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Population Health Research Institute

Health Through Knowledge

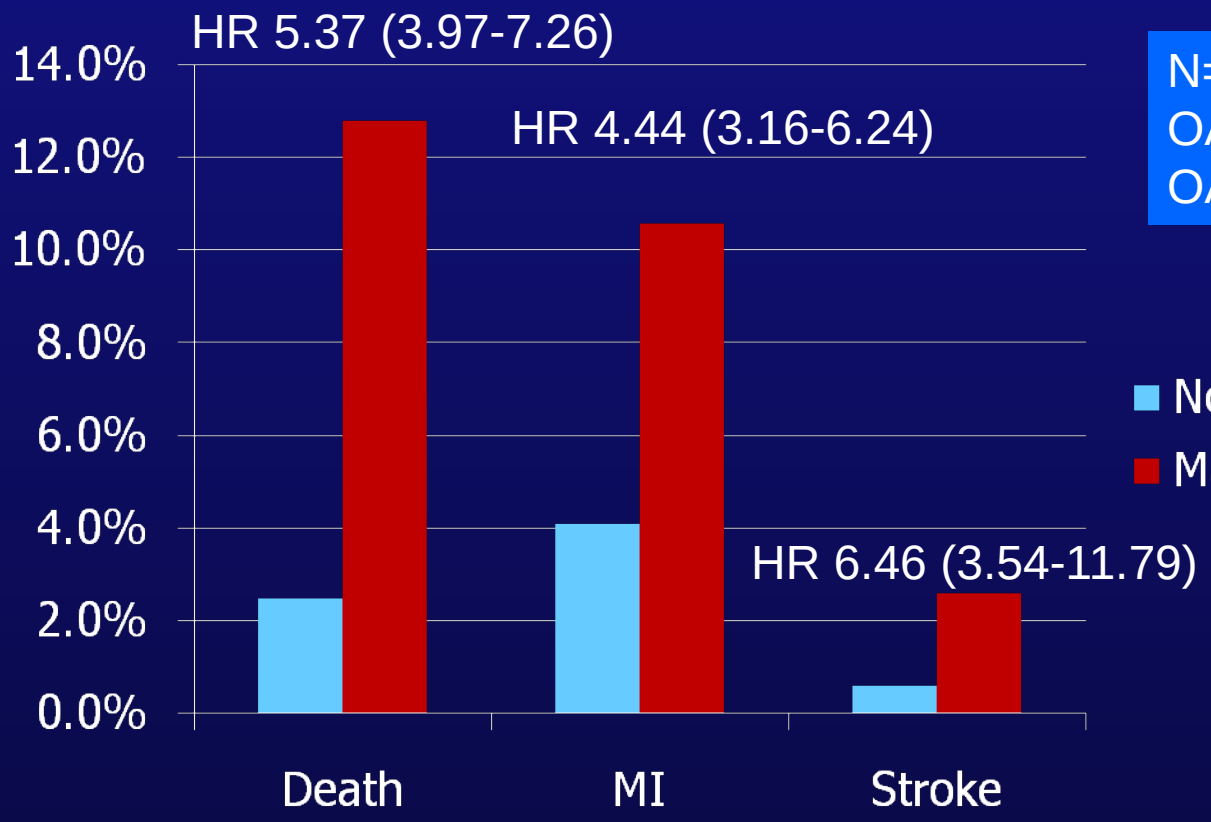
PHRI

Disclosures

Funded by:

- Sanofi-Aventis and Bristol-Myers Squibb (RIVAL sub-study of CURRENT/OASIS 7)
- Population Health Research Institute
- CANadian Network and Centre for Trials INternationally (CANNeCTIN, an initiative of Canadian Institutes of Health Research)

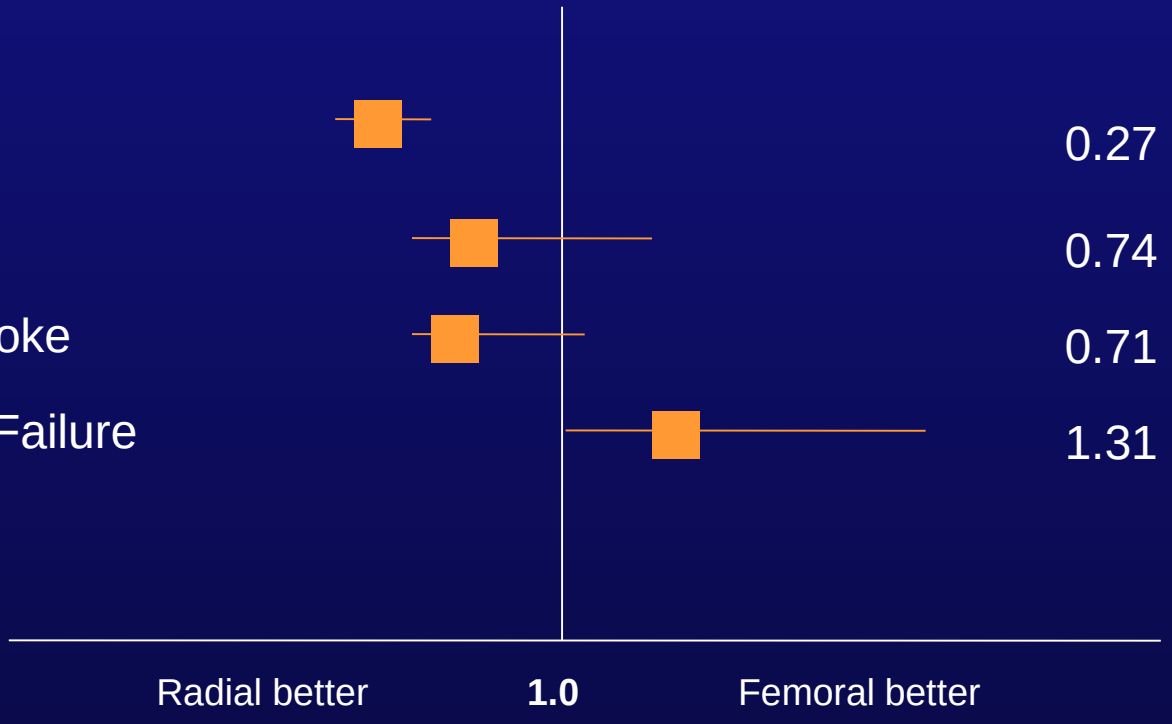
Bleeding is associated with Death and Ischemic Events



N=34,146
OASIS Registry,
OASIS 2, CURE trials

Eikelboom JW et al. *Circulation* 2006;114(8):774-82.

Prior Meta-analysis of 23 RCTs of Radial vs. Femoral (N=7030)



Jolly SS, et al. Am Heart J 2009;157:132-40.

RIVAL Study Objective

- To determine if Radial vs. Femoral access for coronary angiography/PCI can reduce the composite of death, MI, stroke or non-CABG major bleeding in ACS patients

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

Jolly SS et al. Am Heart J. 2011;161:254-60.

Definitions

Major Bleeding (CURRENT / OASIS 7)

- Fatal
- ≥ 2 units of Blood transfusion
- Hypotension requiring inotropes
- Requiring surgical intervention
- ICH or Intraocular bleeding leading to significant vision loss

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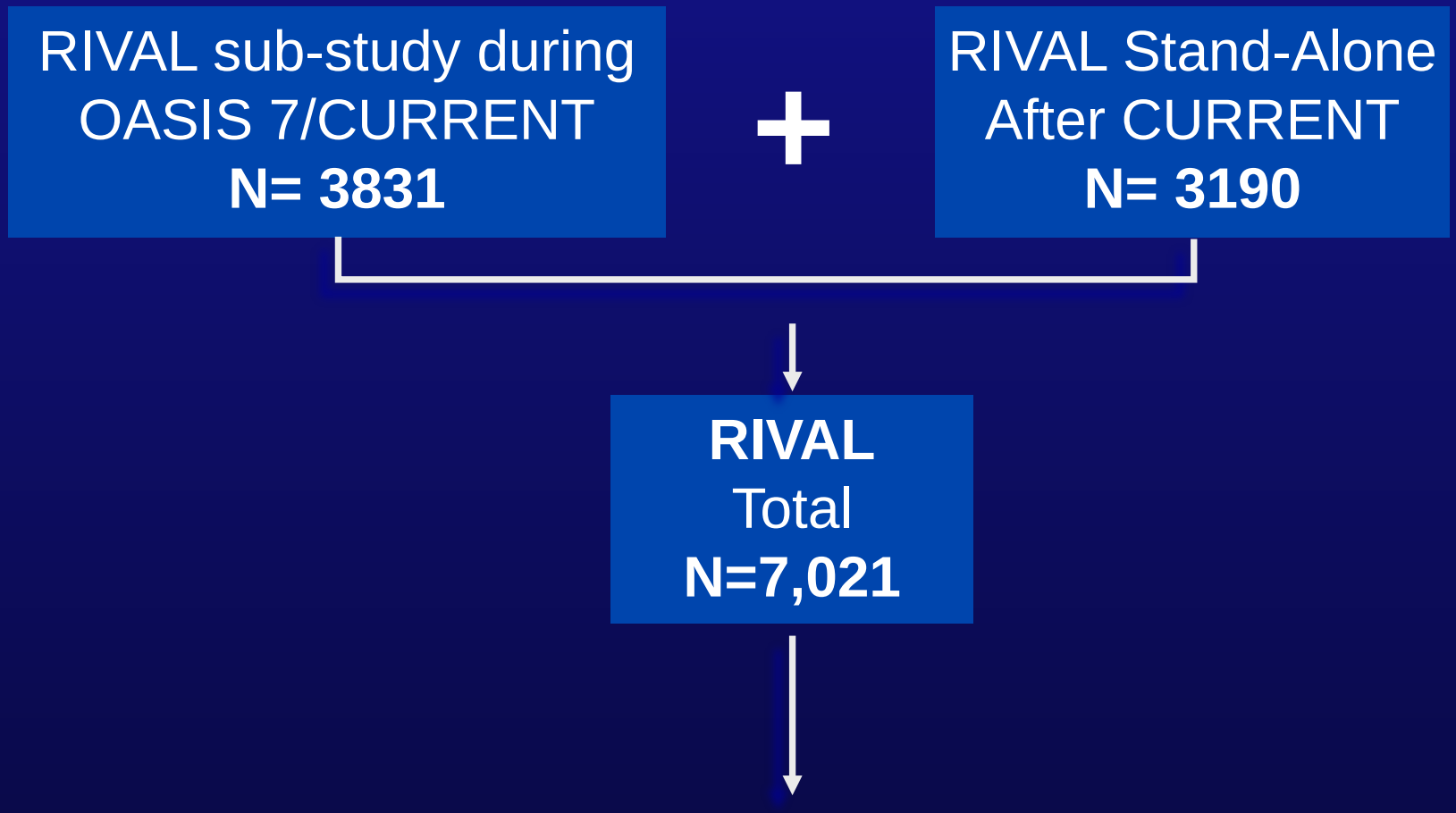
Major Vascular Access Site Complications

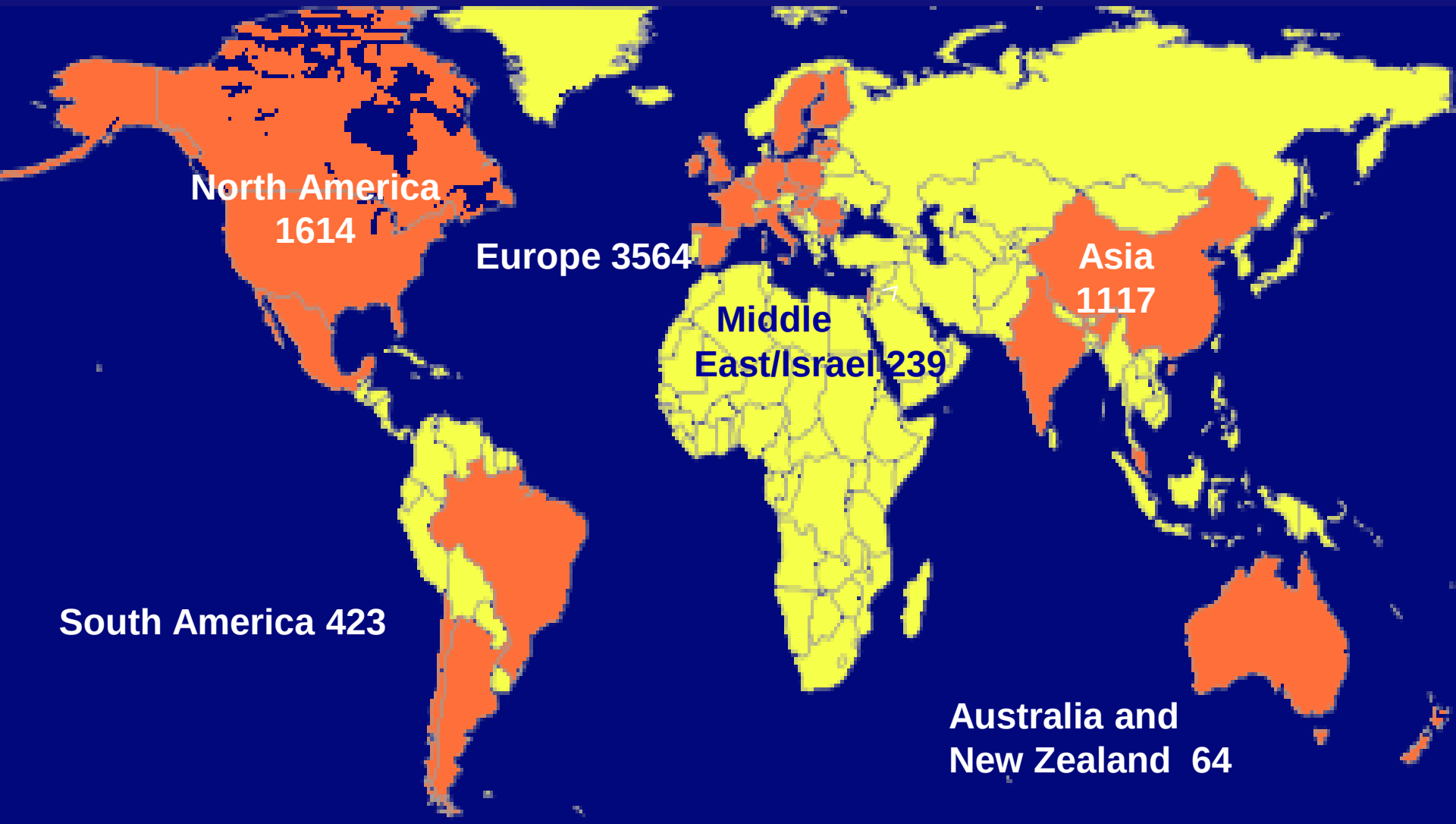
- Large hematoma
- Pseudoaneurysm requiring closure
- AV fistula
- Other vascular surgery related to the access site

Final Recruitment



CURRENT-OASIS 7. N Engl J Med. 2010;363:930-42.
Mehta SR, et al. Lancet. 2010; 376:1233-43.

International Study



Baseline Characteristics

	Radial (n =3507)	Femoral (n =3514)
Mean Age (years)	**62**	**62**
Male (%)	**74.1**	**72.9**
Diabetes (%)	**22.3**	**20.5**
Diagnosis at presentation		
UA (%)	**44.3**	**45.7**
NSTEMI (%)	**28.5**	**25.8**
STEMI (%)	**27.2**	**28.5**

Therapies - Initial Hospitalization

	Radial (n=3507) %	Femoral (n=3514) %
ASA	99.2	99.3
Clopidogrel	96.0	95.6
LMWH	51.5	51.8
UFH	33.3	31.6
Fondaparinux	10.9	10.8
Bivalirudin	2.2	3.1
GP IIb IIIa inhibitors	25.3	24.0
PCI	65.9	66.8
CABG	8.8	8.3

Operator Volume Procedure Characteristics

	Radial (n=3507)	Femoral (n=3514)	HR (95% CI)	P value
Operator Annual Volume				
PCI/year (median, IQR)	300 (190, 400)	300 (190,400)		
Percent Radial PCI (median, IQR)	40 (25,70)	40 (25, 70)		
PCI Success	95.4	95.2	1.01 (0.95-1.07)	0.83

- Vascular closure devices used in 26% of Femoral group

Primary and Secondary Outcomes

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

Other Outcomes

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

* Post Hoc analysis

Other Outcomes

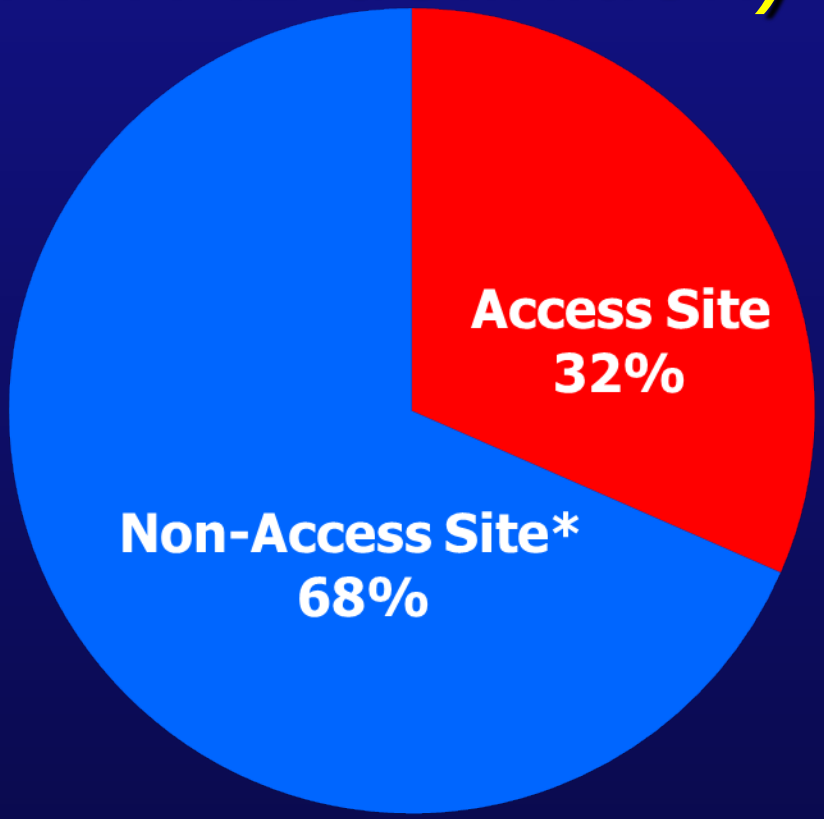
	Radial (n=3507) %	Femoral (n=3514) %	HR	95% CI	P
Death	1.3	1.5	0.86	0.58-1.29	0.47
MI	1.7	1.9	0.92	0.65-1.31	0.65
Stroke	0.6	0.4	1.43	0.72-2.83	0.30
Stent Thrombosis	0.7	1.2	0.63	0.34-1.17	0.14

Other Outcomes

	Radial (n=3507)	Femoral (n=3514)	P
Access site Cross-over (%)	7.6	2.0	<0.0001
PCI Procedure duration (min)	35	34	0.62
Fluoroscopy time (min)	9.3	8.0	<0.0001
Persistent pain at access site >2 weeks (%)	2.6	3.1	0.22
Patient prefers assigned access site for next procedure (%)	90	49	<0.0001

- Symptomatic radial occlusion requiring medical attention 0.2% in radial group

Site of Non-CABG Major Bleeds (RIVAL definition)

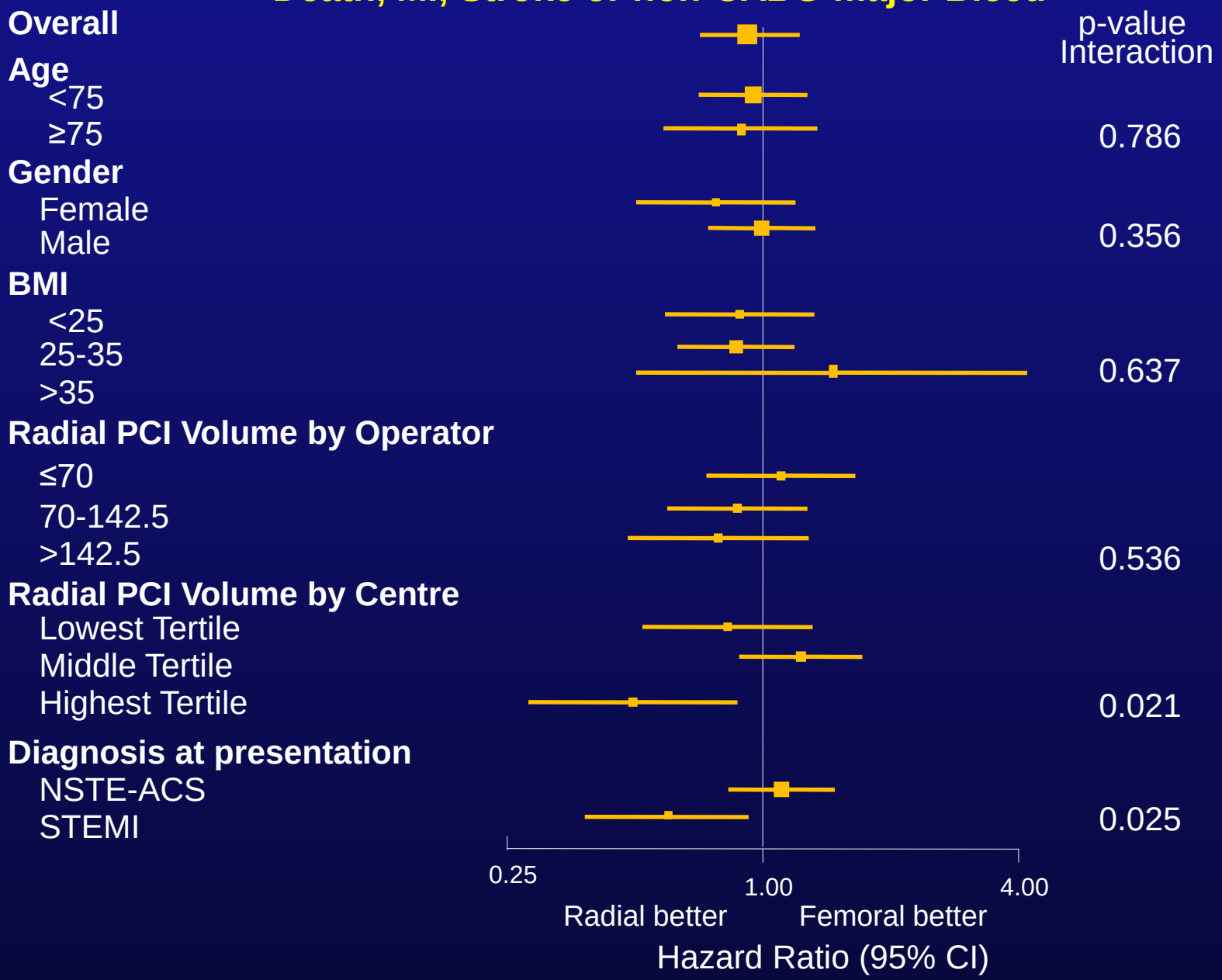


*Sites of Non Access site Bleed: Gastrointestinal (most common site), ICH, Pericardial Tamponade and Other

RIVAL

Subgroups: Primary Outcome

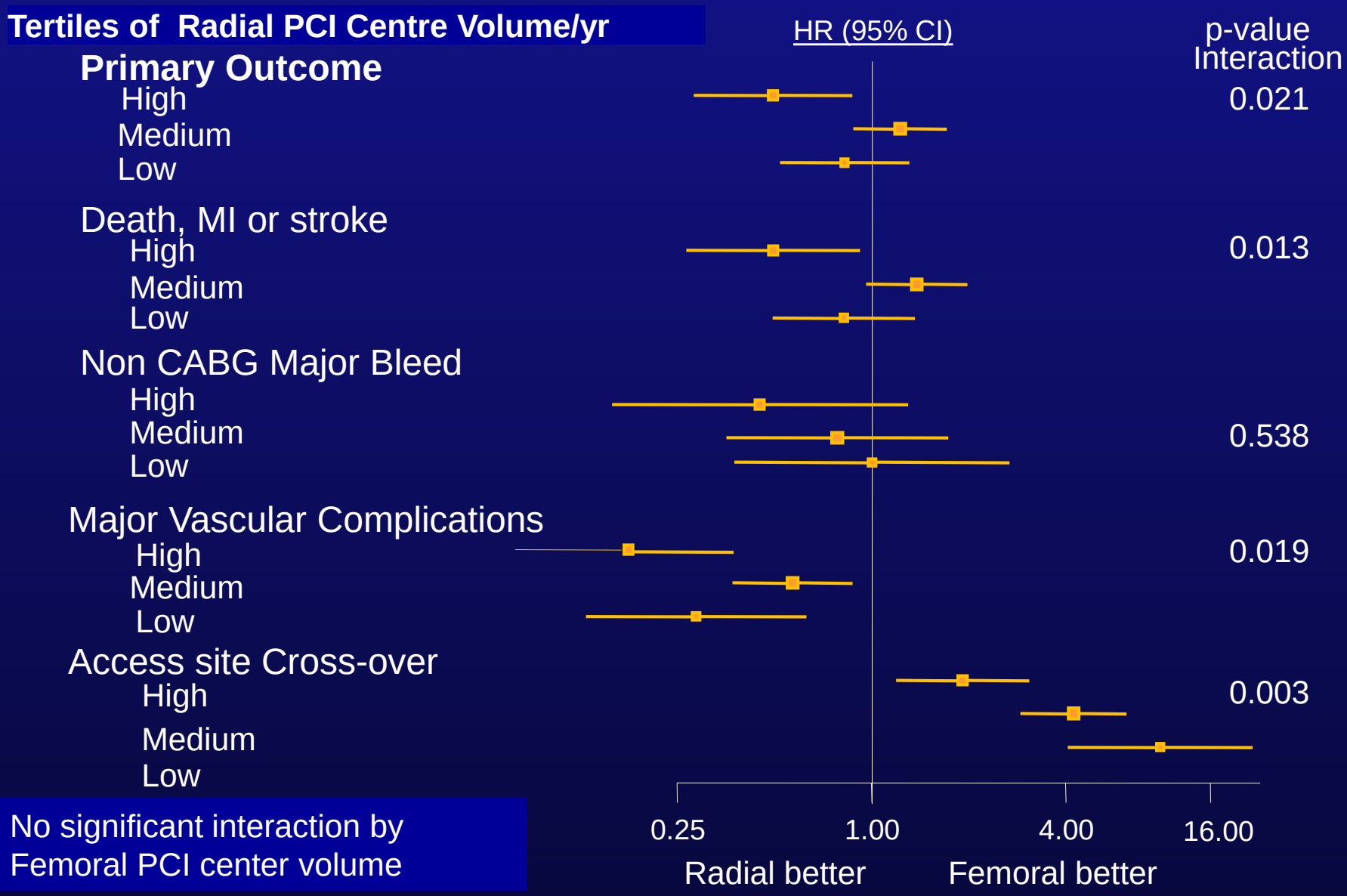
Death, MI, Stroke or non-CABG major Bleed



RIVAL

Results stratified by High*, Medium* and Low* Volume Radial Centres

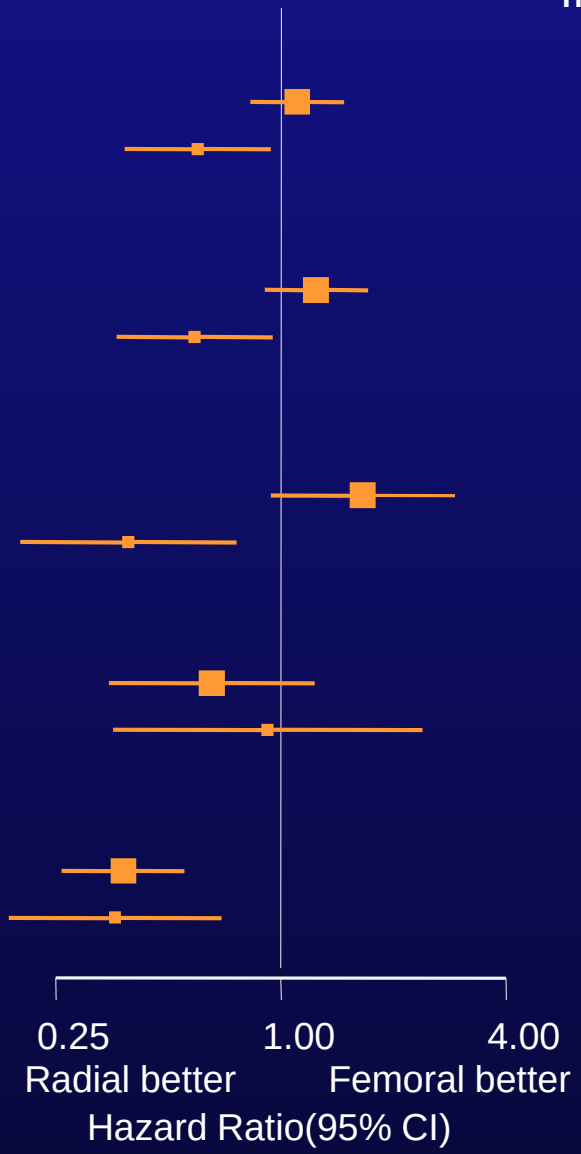
*High (>146 radial PCI/year/ median operator at centre), Medium (61-146), Low (≤60)



No significant interaction by Femoral PCI center volume

Outcomes stratified by STEMI vs. NSTEACS

	2N	% Radial	% Femoral	Interaction p-value
Primary Outcome				
NSTE/ACS	5063	3.8	3.5	
STEMI	1958	3.1	5.2	0.025
Death, MI or stroke				
NSTE/ACS	5063	3.4	2.7	
STEMI	1958	2.7	4.6	0.011
Death				
NSTE/ACS	5063	1.2	0.8	
STEMI	1958	1.3	3.2	0.001
Non CABG Major Bleed				
NSTE/ACS	5063	0.6	1.0	
STEMI	1958	0.8	0.9	0.56
Major Vascular Complications				
NSTE/ACS	5063	1.4	3.8	
STEMI	1958	1.3	3.5	0.89



Conclusion

- No significant difference between radial and femoral access in primary outcome of death, MI, stroke or non-CABG major bleeding
- Rates of primary outcome appeared to be lower with radial compared to femoral access in high volume radial centres and STEMI
- Radial had fewer major vascular complications with similar PCI success

Implications

- Both radial and femoral approaches are safe and effective
- Increasing experience may improve outcomes with radial access
- Clinicians and patients may choose radial because of its similar efficacy and reduced vascular complications

Available Online at www.lancet.com

Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial

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Summary

Background Small trials have suggested that radial access for percutaneous coronary intervention (PCI) reduces vascular complications and bleeding compared with femoral access. We aimed to assess whether radial access was superior to femoral access in patients with acute coronary syndromes (ACS) who were undergoing coronary angiography with possible intervention.

Methods The RadIal Vs femorAL access for coronary intervention (RIVAL) trial was a randomised, parallel group, multicentre trial. Patients with ACS were randomly assigned (1:1) by a 24 h computerised central automated voice response system to radial or femoral artery access. The primary outcome was a composite of death, myocardial infarction, stroke, or non-coronary artery bypass graft (non-CABG)-related major bleeding at 30 days. Key secondary outcomes were death, myocardial infarction, or stroke; and non-CABG-related major bleeding at 30 days. A masked central committee adjudicated the primary outcome, components of the primary outcome, and stent thrombosis. All other outcomes were as reported by the investigators. Patients and investigators were not masked to treatment allocation. Analyses were by intention to treat. This trial is registered with ClinicalTrials.gov, NCT01014273.

Findings Between June 6, 2006, and Nov 3, 2010, 7021 patients were enrolled from 158 hospitals in 32 countries. 3507 patients were randomly assigned to radial access and 3514 to femoral access. The primary outcome occurred in 128 (3·7%) of 3507 patients in the radial access group compared with 139 (4·0%) of 3514 in the femoral access group (hazard ratio [HR] 0·92, 95% CI 0·72–1·17; p=0·50). Of the six prespecified subgroups, there was a significant interaction for the primary outcome with benefit for radial access in highest tertile volume radial centres (HR 0·49, 95% CI 0·28–0·87; p=0·015) and in patients with ST-segment elevation myocardial infarction (0·60, 0·38–0·94; p=0·026). The rate of death, myocardial infarction, or stroke at 30 days was 112 (3·2%) of 3507 patients in the radial group compared with 114 (3·2%) of 3514 in the femoral group (HR 0·98, 95% CI 0·76–1·28; p=0·90). The rate of non-CABG-related major bleeding at 30 days was 24 (0·7%) of 3507 patients in the radial group compared with 33 (0·9%) of 3514 patients in the femoral group (HR 0·73, 95% CI 0·43–1·23; p=0·23). At 30 days, 42 of 3507 patients in the radial group had large haematoma compared with 106 of 3514 in the femoral group (HR 0·40, 95% CI 0·28–0·57; p<0·0001). Pseudoaneurysm needing closure occurred in seven of 3507 patients in the radial group compared with 23 of 3514 in the femoral group (HR 0·30, 95% CI 0·13–0·71; p=0·006).

Interpretation Radial and femoral are approaches are both safe and effective for PCI. However, the lower rate of local vascular complications may be a reason to use the radial approach.

Funding Sanofi-Aventis, Population Health Research Institute, and Canadian Network for Trials Internationally (CANNeCTIN), an initiative of the Canadian Institutes of Health Research.

Published Online
April 4, 2011
DOI:10.1016/S0140-6736(11)60404-2

See Online/Comment
DOI:10.1016/S0140-6736(11)60469-8

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Acknowledgements

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