

Radial vs. Femoral Access for Coronary Intervention

A perspective from Population Health Research Institute

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Disclosures

- Received honoraria from Sanofi Aventis and Glaxo Smith Kline
- Grant support from Medtronic



OASIS 5: A Randomized, Double-Blind, Double-Dummy Trial

20,078 Patients with NSTEMI ACS, Chest discomfort < 24 hours
2 of 3: Age > 60, ST Segment Δ , \uparrow cardiac markers

Exclude

Age < 21
Any contra-ind to Enox
Hem stroke < 12 mo.
Creat > 3 mg/dL/265 μ mol/L

Aspirin, Clopidogrel, GPIIb/IIIa inhibitor, planned Cath/PCI as per local practice

Randomization

Fondaparinux

2.5 mg subcut daily up to 8 days or hospital discharge

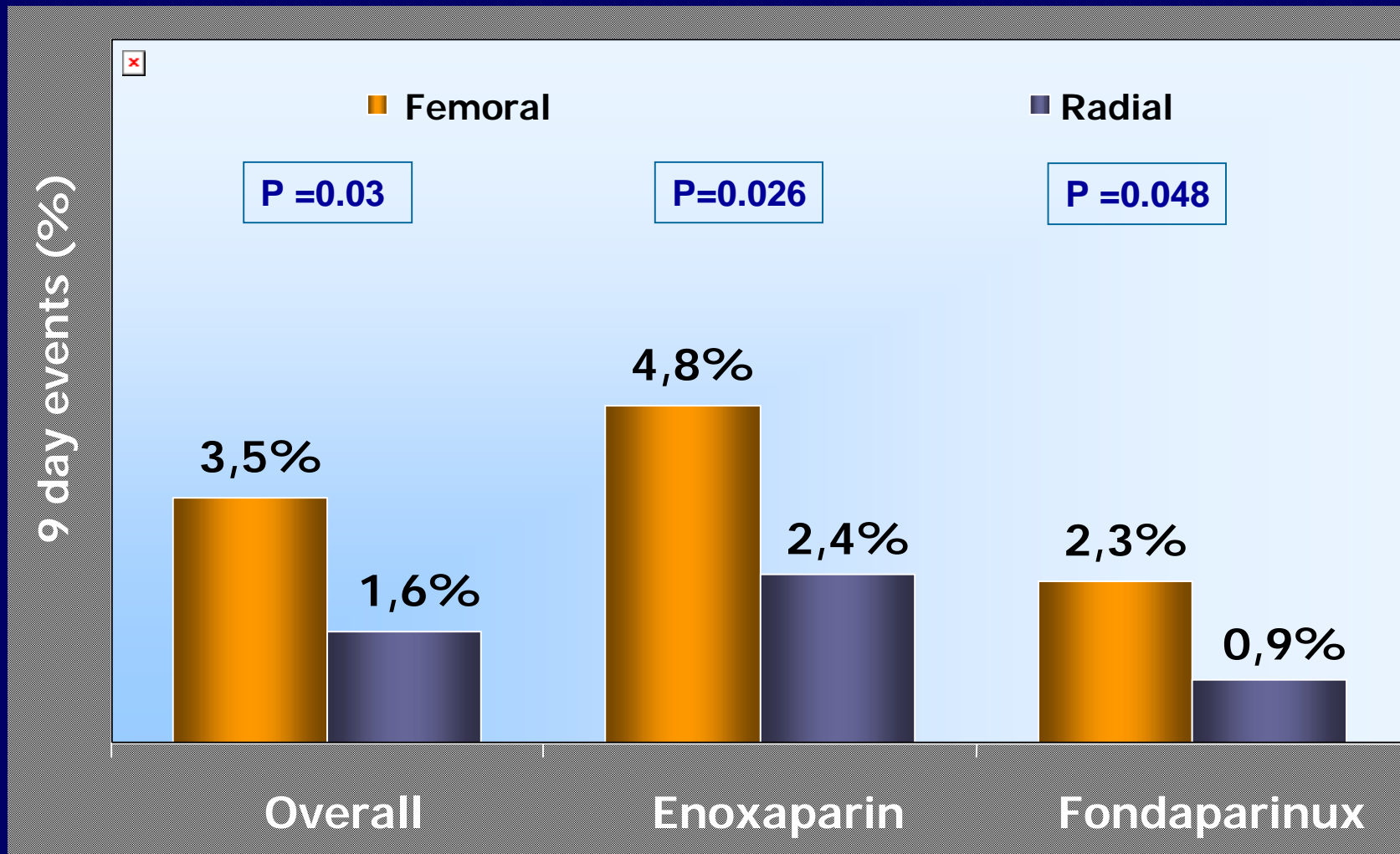
Mean treatment : 5.4 days
Mean time to PCI: 2.4 days

Enoxaparin

1 mg/kg subcut bid for 2-8 days
1 mg/kg subcut daily if CrCl < 30 mL/min

Mean treatment : 5.2 days
Mean time to PCI: 2.6 days

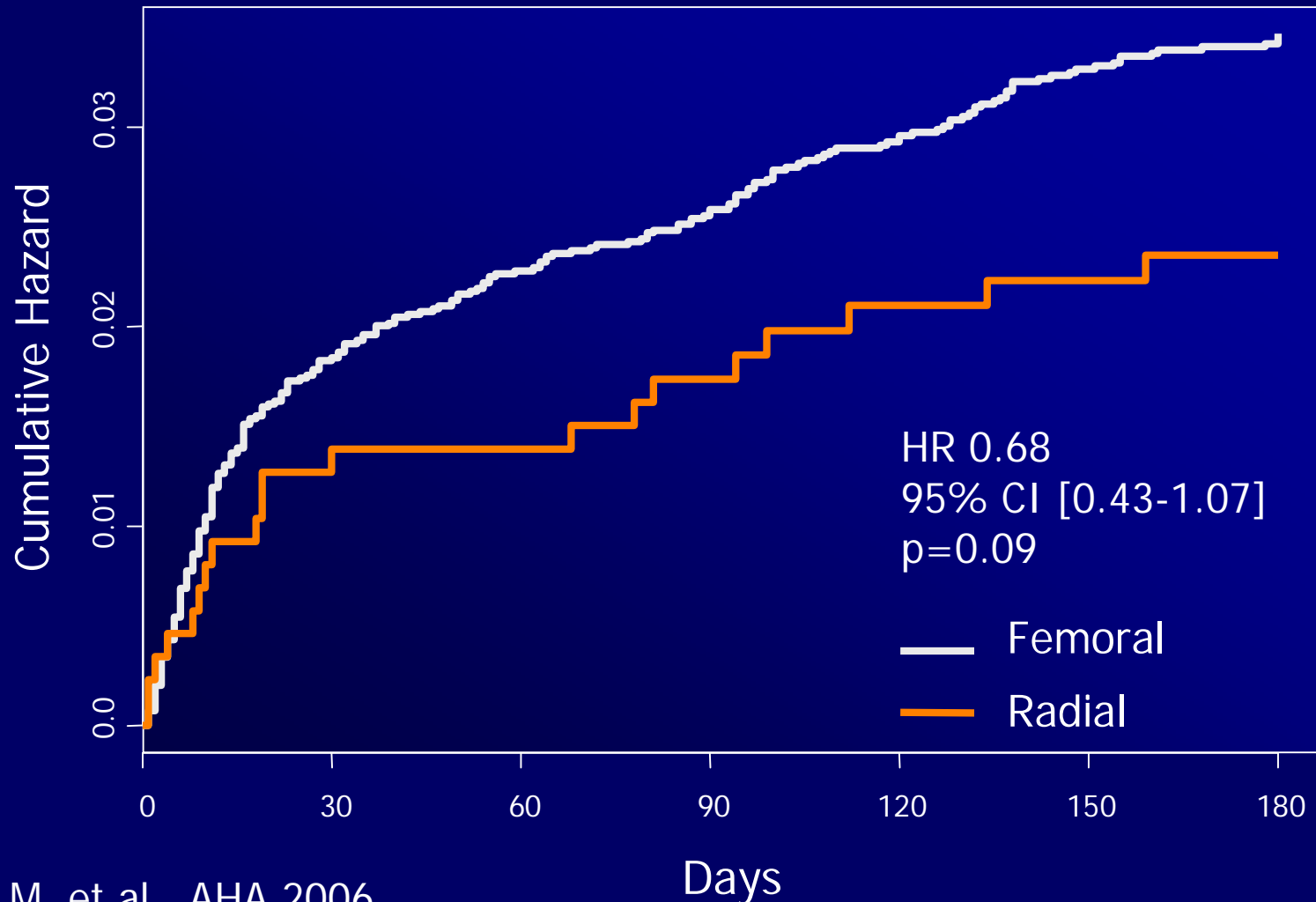
Radial vs. Femoral Access in OASIS 5 trial



Hamon M, et al. AHA 2006 (during blind study drug administration)

Mortality at 6 months of Radial vs. Femoral Access from OASIS 5

Radial vs. Femoral



New Paradigms:

- 1) Major bleeding is as important as MI, in terms of predicting subsequent mortality
- 2) Major Bleeding events may lead to death and Recurrent MI

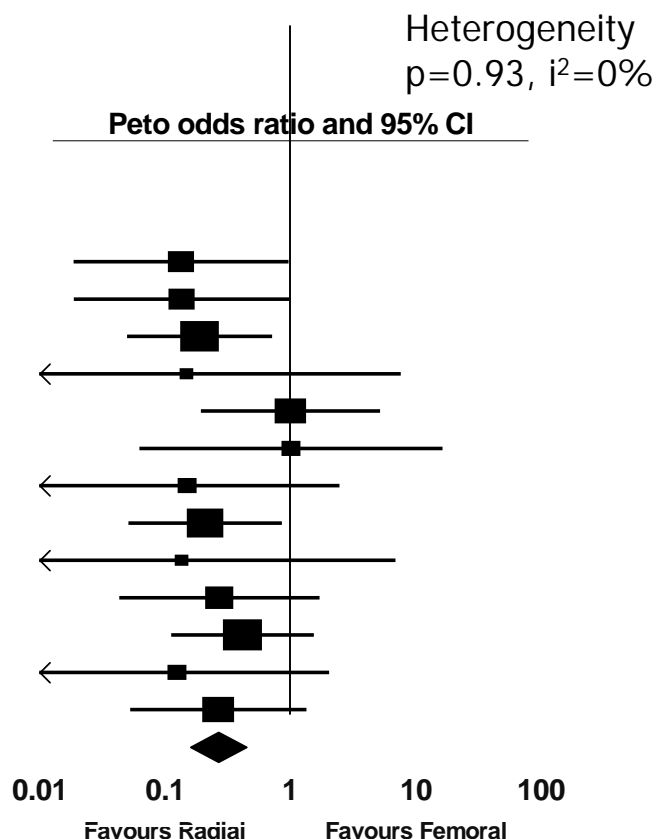
Ndrepepa G, et al. *JACC*. 2008;51(7):690-7.

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

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	0.27



OR 0.27 (95% CI 0.16, 0.45) $p < 0.001$

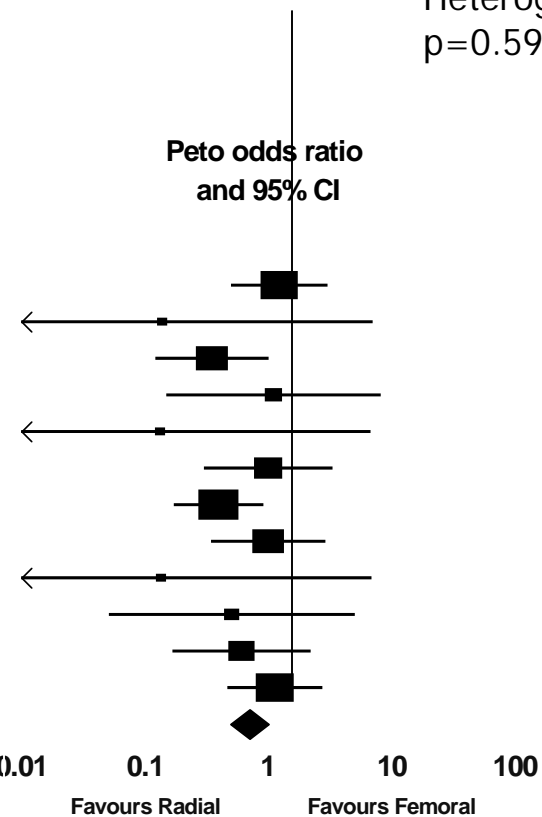
Updated Meta-analysis of Radial vs. Femoral RCTs

Death, MI or Stroke

Heterogeneity
 $p=0.59$, $i^2=0\%$

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	0.71



OR 0.71 (95% CI 0.49, 1.01) $p=0.058$

- Trend for a reduction in death, MI or stroke with radial

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

RIVAL study: Radial Vs. femoral access for coronary intervention in patients with acute coronary syndromes study

Principal Investigator: Sanjit Jolly MD, MSc

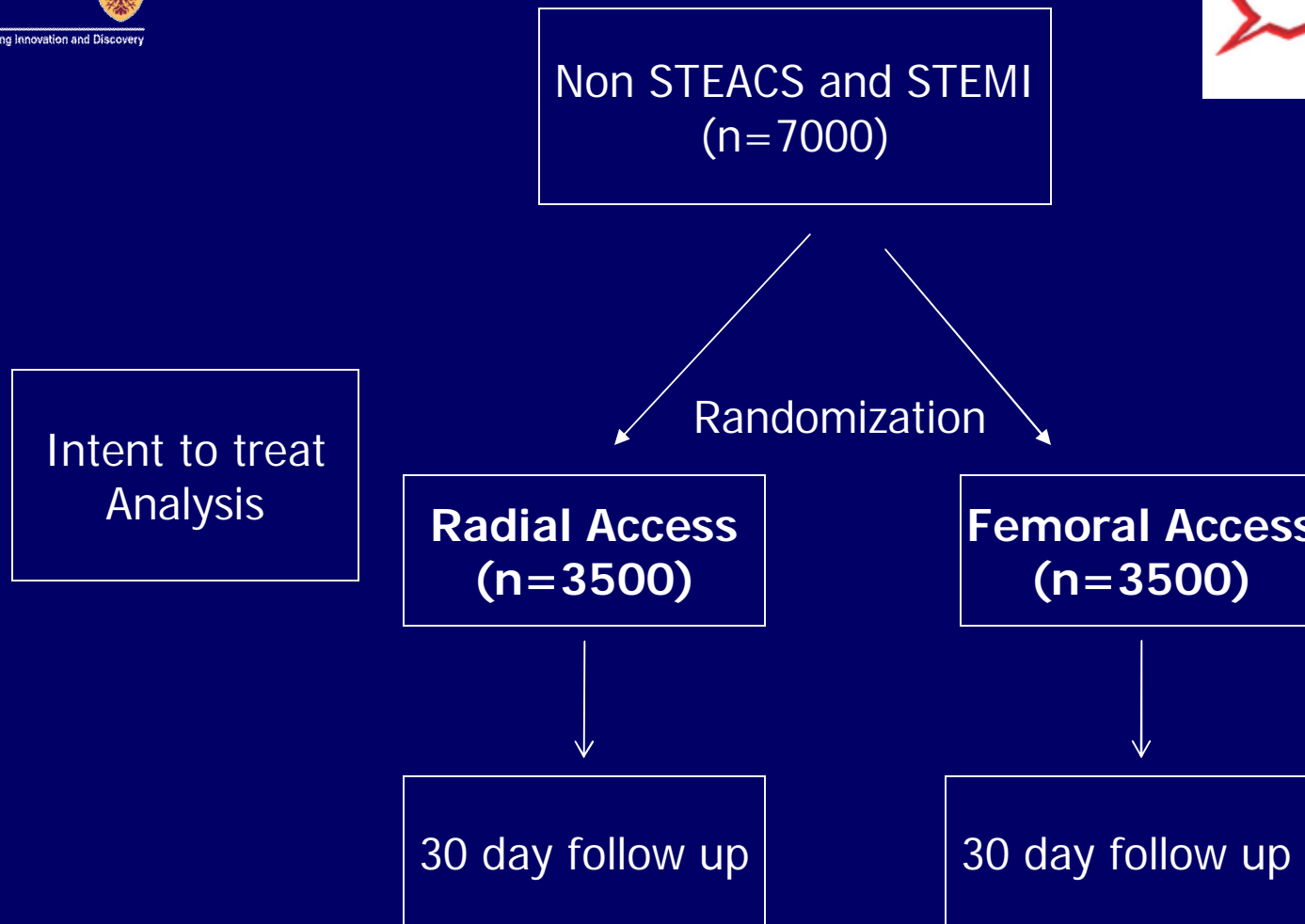
Co-Principal Investigator: Shamir Mehta MD, MSc

RIVAL trial

- Definitive Multicenter trial of Radial vs. Femoral Access (N=7000)
- Includes patient with Non ST elevation acute coronary syndromes and STEMI
- Started as a sub-study of the OASIS 7-CURRENT trial
- Continued and has recruited more than 6000 patients in 32 countries (including the U.S.)

Hypothesis of RIVAL trial

- Radial access site PCI will be associated with significantly less major bleeding and access site complications compared with a femoral approach
- This reduction in bleeding complications will translate into lower rates of death and ischemic complications



**Primary Outcome: Death, MI, stroke
or major bleeding at 30 days**

Inclusion Criteria

1. UA/NSTEMI patients AND STEMI patients
2. Suitable candidate for either radial or femoral artery PCI
3. Randomized during index hospitalization for acute coronary syndrome
4. Intent to perform same-sitting angiography and PCI
5. Palpable radial artery with a documented normal Allen's Test
6. Acceptance by operator to use whichever route is assigned by the randomization process
7. Previous experience of the operator with at least 50 cases of radial artery access within the last year
8. Written informed consent

Outcomes

- Primary outcome: Death, MI, Stroke or Major bleeding
- Secondary outcomes:
 - Components of primary outcome
 - Non-CABG major bleeding
 - Access site complications
 - Procedural time
 - PCI complication rates
 - Fluoroscopy time
 - Radiation dose
 - Access site cross-over
 - PCI failure rate

Study Definitions

- Major bleeding:
 - Fatal,
 - hypotension requiring inotropes,
 - requiring surgery (other than vascular site repair),
 - requiring 2 units of red blood cells, or
 - Drop in 3 g/dl of Hb or greater
 - Intracranial hemorrhage
- Vascular Access site complication:
 - Pseudoaneuysm requiring treatment, AV fistula, large hematoma requiring prolonged hospitalization, limb ischemia or damage to adjacent nerve

Summary

- RIVAL trial has potential to show that radial access reduces important clinical outcomes and influence practice