Georgia Cardio Conference

Alliance of Cardiovascular Professionals

RADIAL ACCESS

The latest fad
or here to stay?

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March 21, 2015

Disclosures

- No relevant disclosures
- Consultant
  - 2009-present, Boston Clinical Research Institute
    - Eli Lilly
    - Roche
    - Novo Nordisk
    - Astellas
  - 2012, Verathon, Inc.
- Legal malpractice consulting

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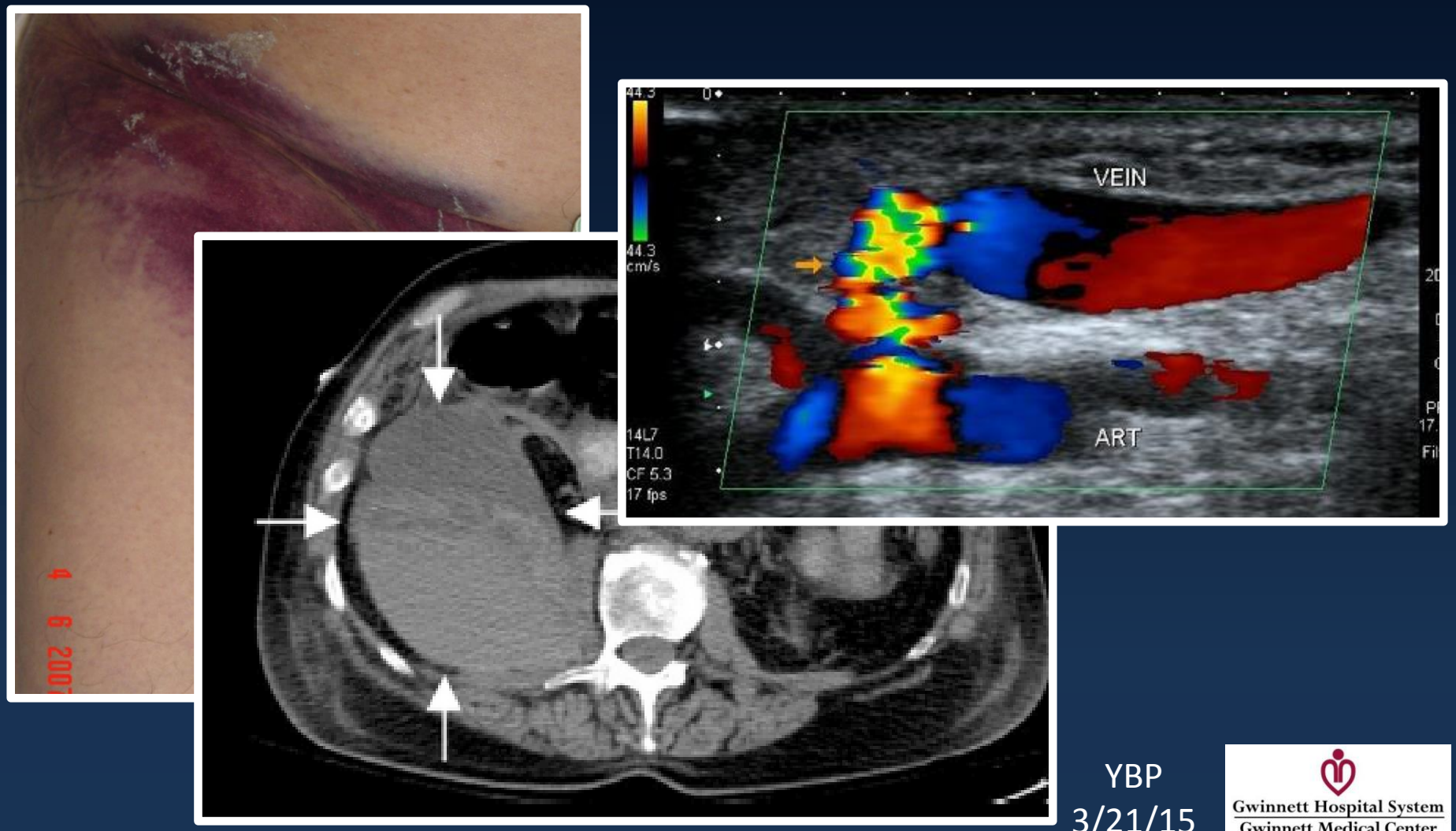
Outline

- Background of radial access
- Importance of hemorrhagic events
- Use of radial access in the US
- Studies comparing radial with femoral
  - Clinical outcomes and cost effectiveness
- Drawbacks
- Conclusions

Radial artery catheterization



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Background

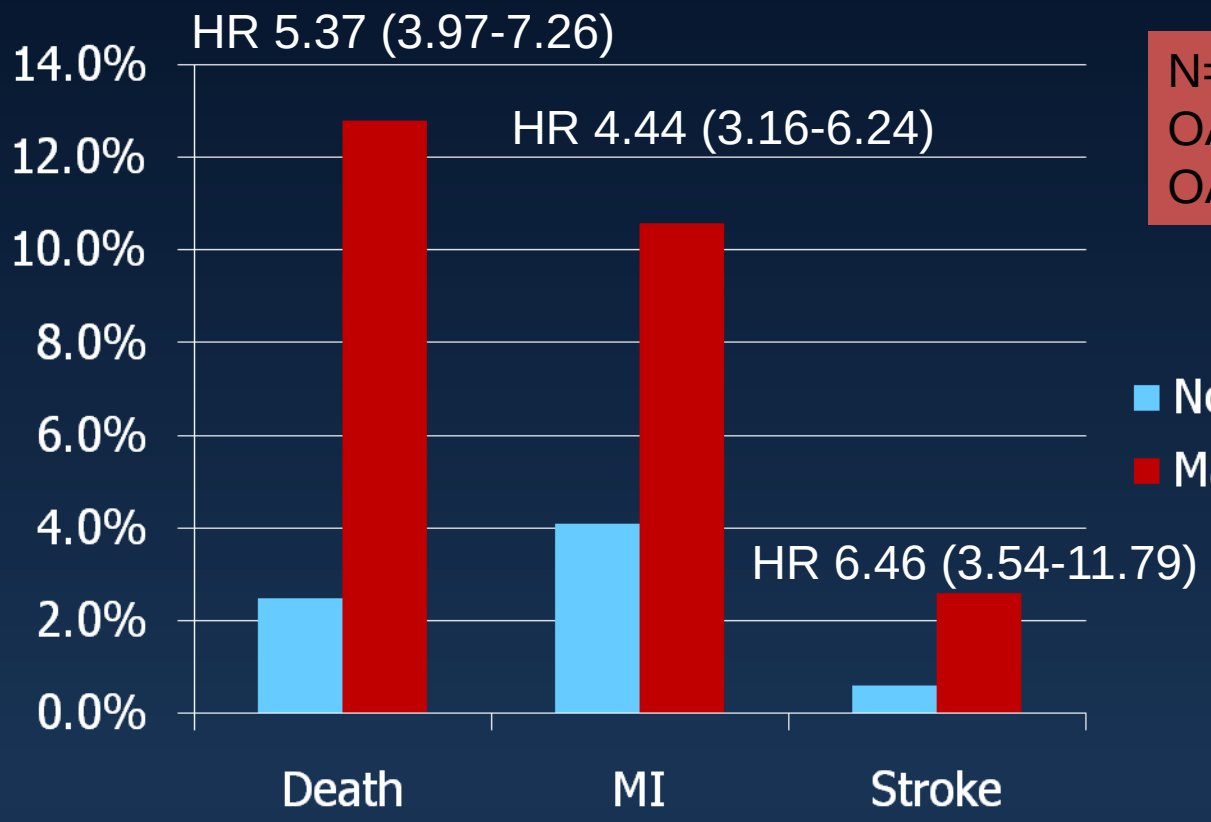
- Coronary angiography via a percutaneous femoral approach has been the standard
- As catheter size has decreased, the radial approach has become feasible
- First coronary angiogram via the radial approach was reported in 1989
- First PCI was performed in 1993

Campeau L. Cathet Cardiovasc Diagn 1989;16:3–7
Kiemeneij F et al. Am Heart J 1995;130:14–21

Why radial?

- Therapies to improve outcomes among patients with CAD and ACS have improved significantly
- The rate of death, MI and stroke following CV procedures has sharply declined
- In addition, it has become clear that bleeding is associated with worse outcomes

Bleeding and bad outcomes



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

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

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Bleeding and mortality

Author/Study (Ref. #)	Patients (n)	Patient Population	Frequency of Blood Transfusion (%)	Impact of Bleeding on Mortality [95% Confidence Interval]	p Value
Kinnaird et al. (1)	10,974	Unselected	5.4	30-day adjusted OR: 3.5 [1.9–6.7]	<0.0001
REPLACE-2 (2)	6,001	Elective and 'urgent' PCI	3.2	1-year adjusted OR: 2.66 [1.44–4.92]	0.002
Ndrepepa et al. (3)	5,348	Elective, ACS	4.0	1-year adjusted HR: 2.96 [1.96–4.48]	<0.0001
ACUITY (4)	13,819	ACS only	4.7	30-day OR: 7.55 [4.68–12.18]	<0.0001
Kim et al. (5)	6,799	Unselected	8.0	1-year RR: 2.03 (transfused patients)	0.0028
Doyle et al. (6)	17,901	Unselected	4.8	30-day adjusted HR: 9.96 [6.94–14.3]	<0.0001
GRACE registry (7)*	24,045	ACS	3.9	In-hospital adjusted OR: 1.64 [1.18–2.28]	<0.0001
Yatskar et al. (8)	6,656	Unselected	1.8	In-hospital adjusted OR: 3.59 [1.66–7.77]	0.001
				1-year adjusted HR: 1.65 [1.01–2.70]	0.048

Doyle *et al. J Am Coll Cardiol.* 2009;53:2019-27

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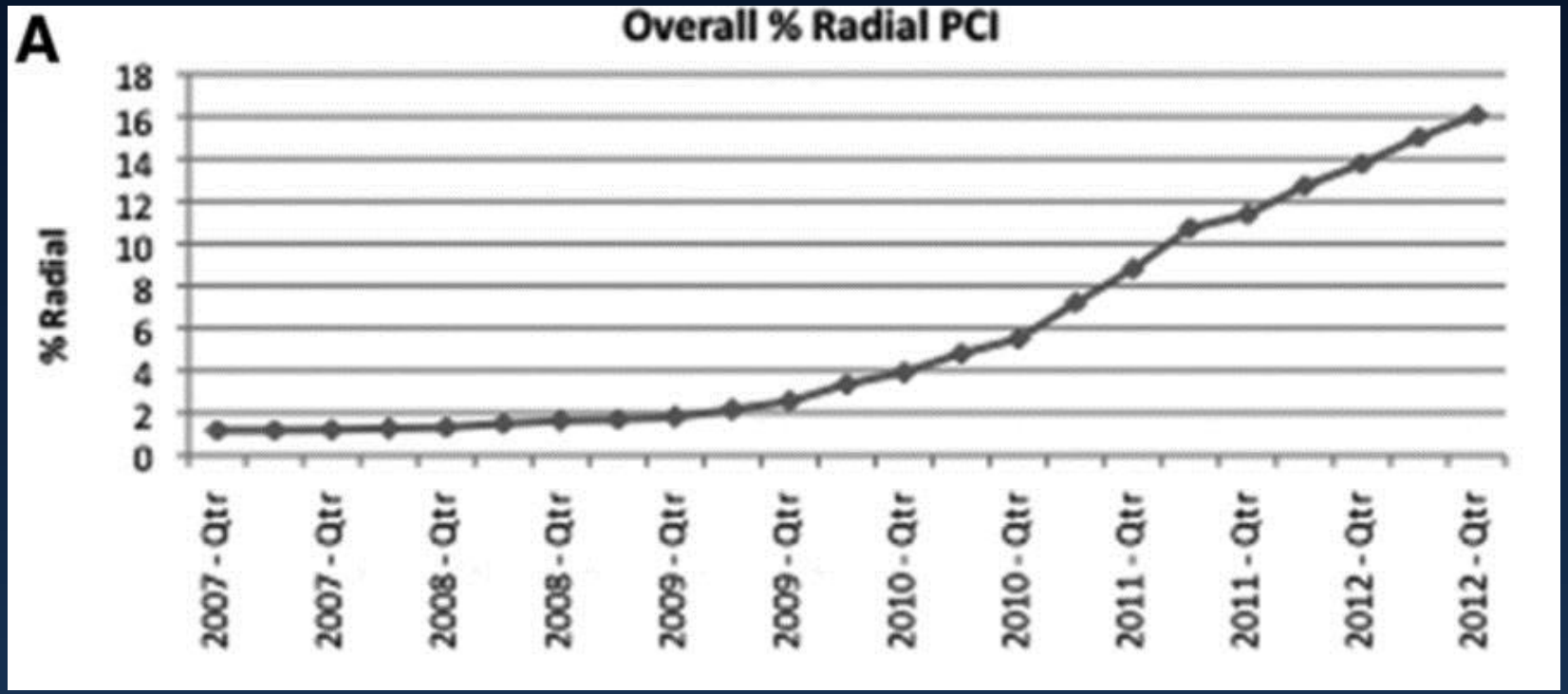
Bleeding reduction strategies

- Because of this, strategies to reduce bleeding have become more prominent
  - Lower heparin dosing during PCI
  - Less frequent use of GP IIb/IIIa inhibitors
  - Bivalirudin (Angiomax)
  - Femoral artery closure devices
  - Radial approach

Radial approach increasing



Feldman DN *et al. Circulation*. 2013;127:2295-2306

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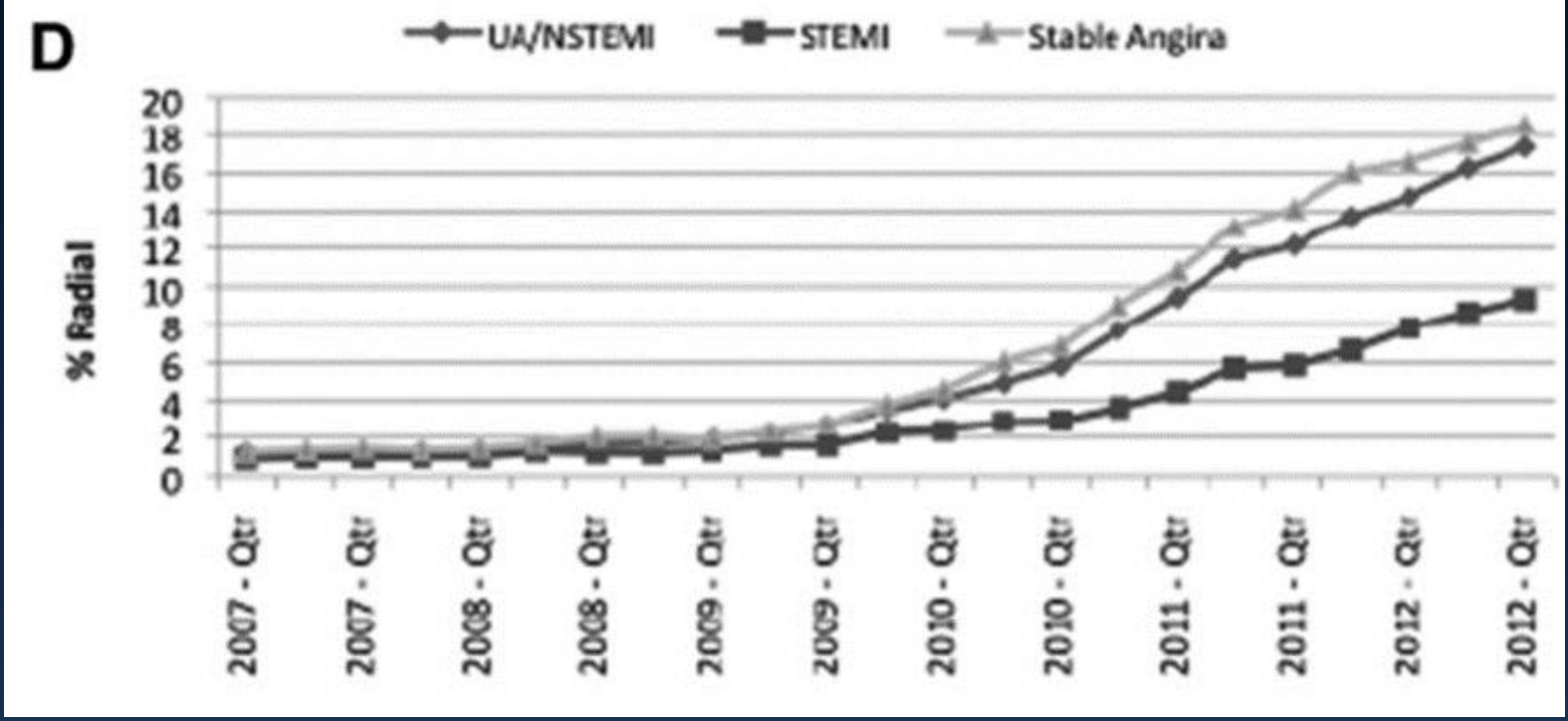
Radial approach increasing



Feldman DN *et al. Circulation*. 2013;127:2295-2306

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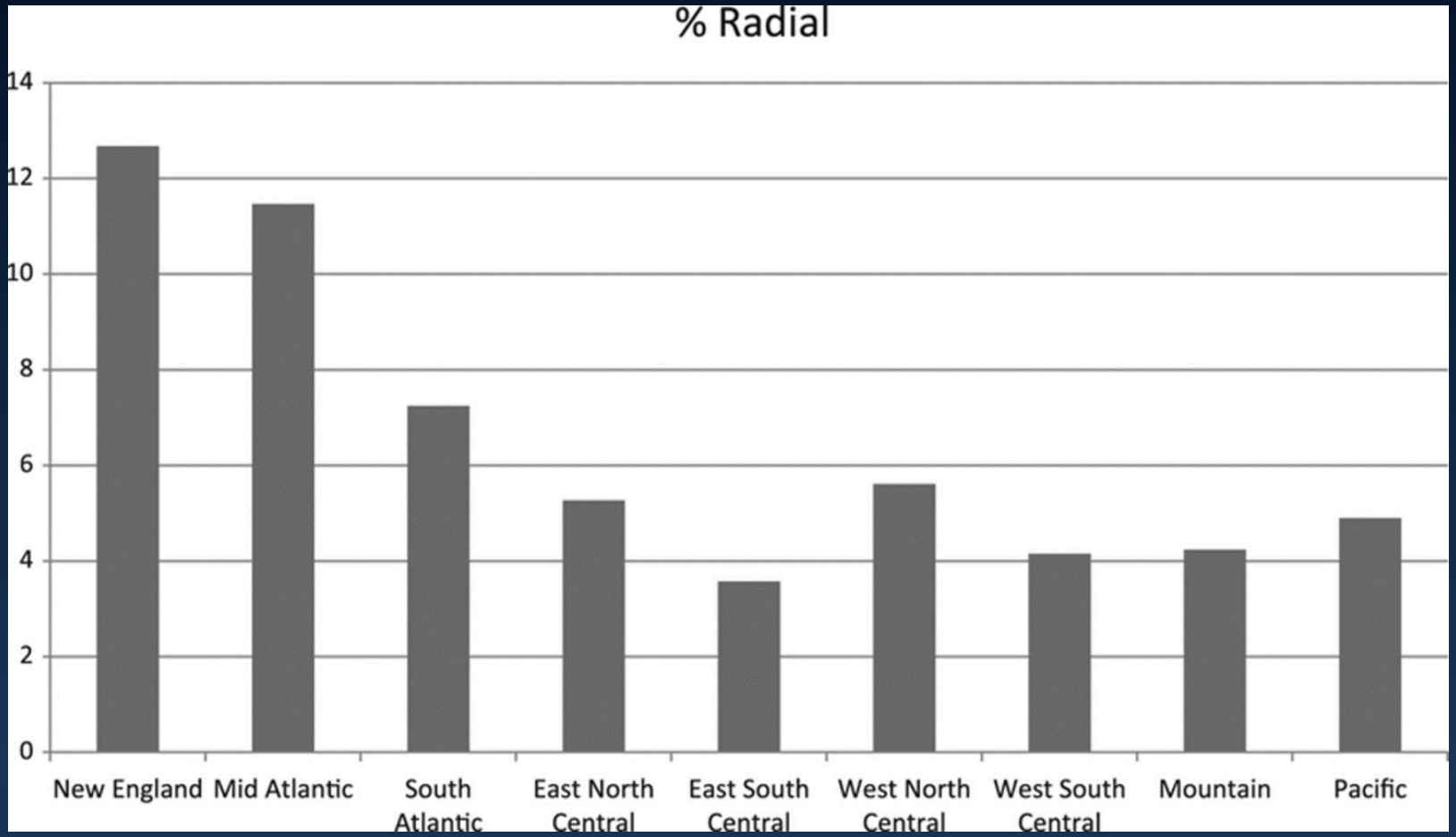
Geographic variability



Feldman DN *et al. Circulation*. 2013;127:2295-2306

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Randomized studies

- Early small randomized studies demonstrated the feasibility of radial artery catheterization
- Most were small and single-center
- All demonstrated significant reductions in access site bleeding and improved patient satisfaction

Meta analysis of small studies

- 12 RCTs from 1994-2003
  - 7 were diagnostic only
  - 5 included patients undergoing PCI
  - Only 2 included patients with ACS
- Total of 3,224 patients

Agostoni *et al, J Am Coll Cardiol* 2004;44:349-56

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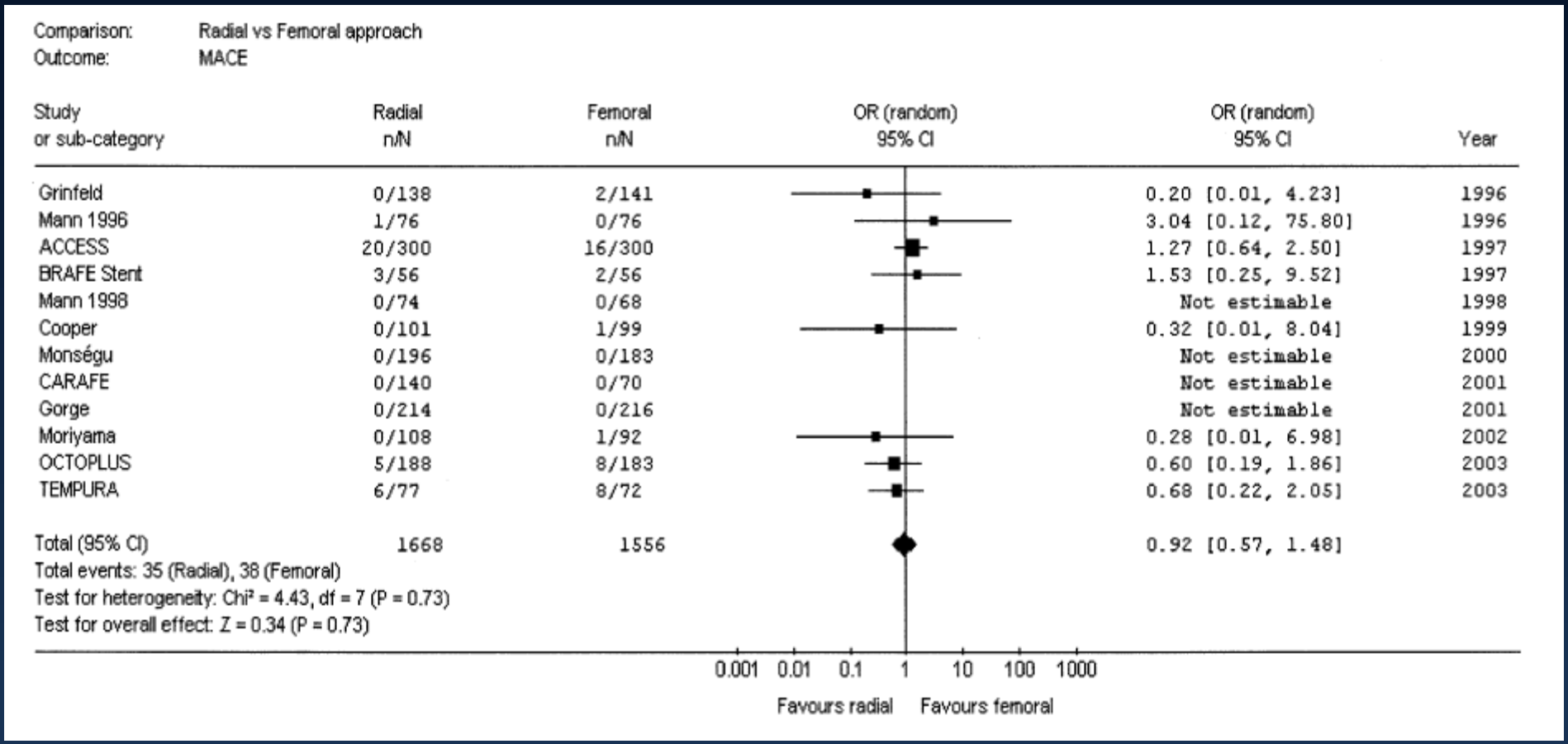
Major adverse CV events



Agostoni *et al, J Am Coll Cardiol* 2004;44:349-56

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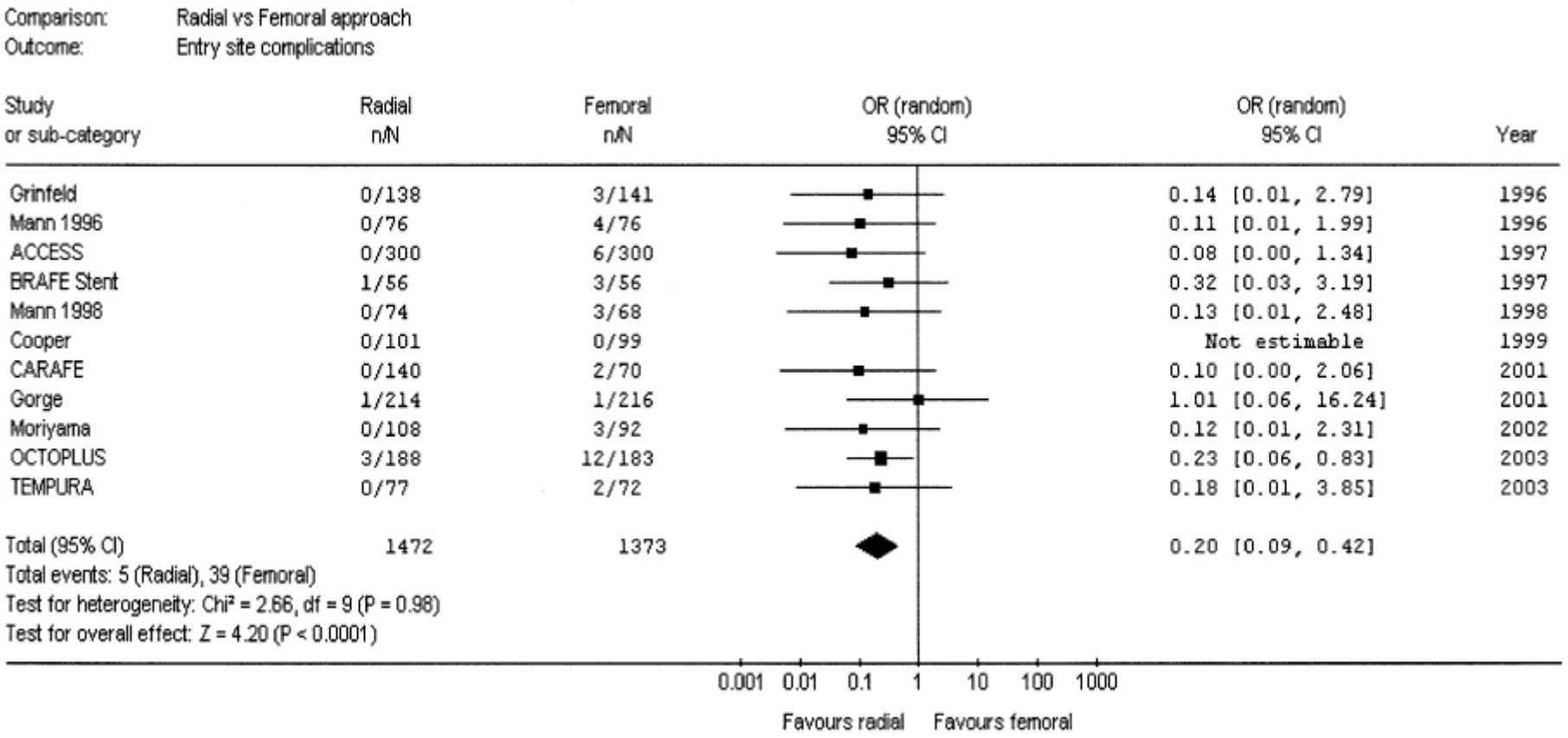
Access site complications



Agostoni *et al, J Am Coll Cardiol* 2004;44:349-56

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Secondary endpoints

- Longer fluoroscopy time for radial
  - 8.9 minutes vs. 7.8 minutes, $p<0.001$
- Mean hospital stay shorter for radial
  - 1.8 days vs. 2.4 days, $p<0.001$
- Total hospital charge lower for radial

Agostoni *et al, J Am Coll Cardiol* 2004;44:349-56

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Larger meta analysis

- 23 studies from 1993-2007
- Major bleeding
  - Radial 0.5% vs. Femoral 2.3%, p<0.001
  - Odds ratio 0.27 (95% CI 0.16-0.45)
- Trend toward lower death, MI and stroke
  - Odds ratio 0.71 (95% CI 0.49-1.01), p=0.058
- No significant difference in mortality
  - Odds ratio 0.74 (95% CI 0.42-1.30), p=0.29

Jolly *et al. Am Heart J* 2009;157:132-40)

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RIVAL study (STEMI and NSTEMI)

	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

Jolly SS *et al. Lancet*. 2011;377:1409-1420.

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RIVAL study (STEMI and NSTEMI)

	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

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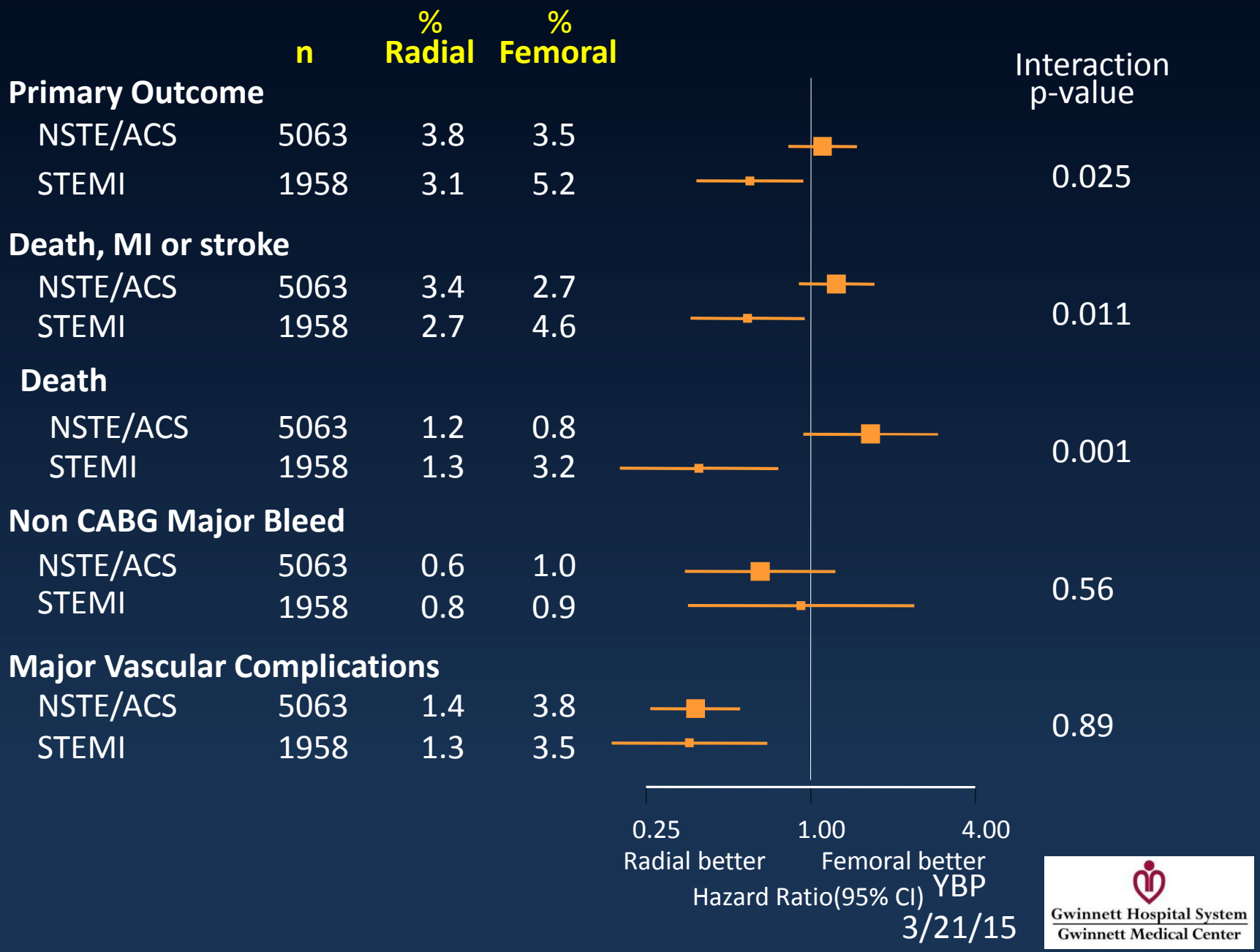
n
% Radial
% Femoral
Interaction p-value
Primary Outcome
NSTE/ACS 5063 3.8 3.5
STEMI 1958 3.1 5.2
0.025
Death, MI or stroke
NSTE/ACS 5063 3.4 2.7
STEMI 1958 2.7 4.6
0.011
Death
NSTE/ACS 5063 1.2 0.8
STEMI 1958 1.3 3.2
0.001
Non CABG Major Bleed
NSTE/ACS 5063 0.6 1.0
STEMI 1958 0.8 0.9
0.56
Major Vascular Complications
NSTE/ACS 5063 1.4 3.8
STEMI 1958 1.3 3.5
0.89
0.25
1.00
4.00
Radial better
Femoral better
Hazard Ratio(95% CI)
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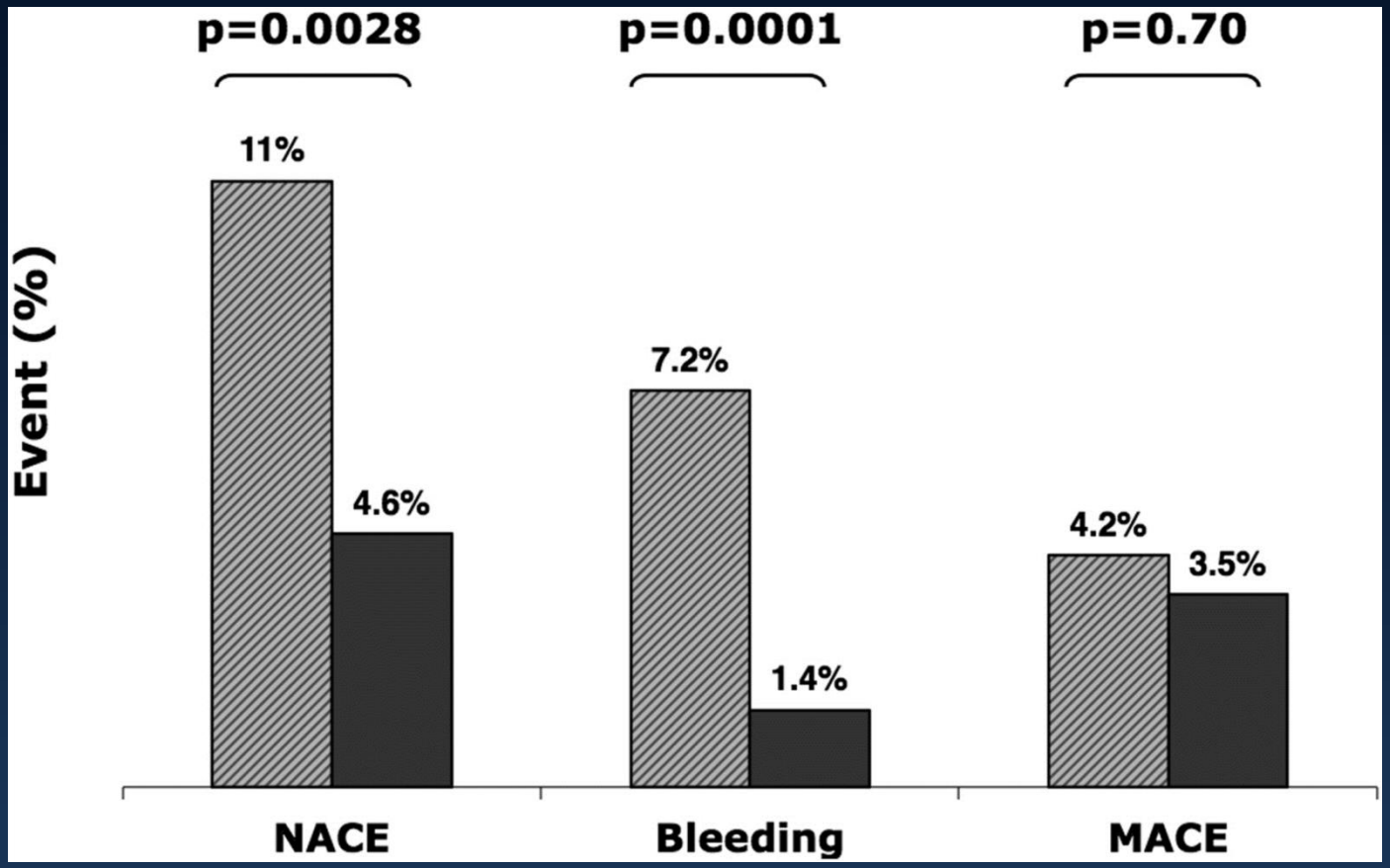
STEMI-RADIAL



- Bernat I *et al. J Am Coll Cardiol*. 2014;63(10):964-972

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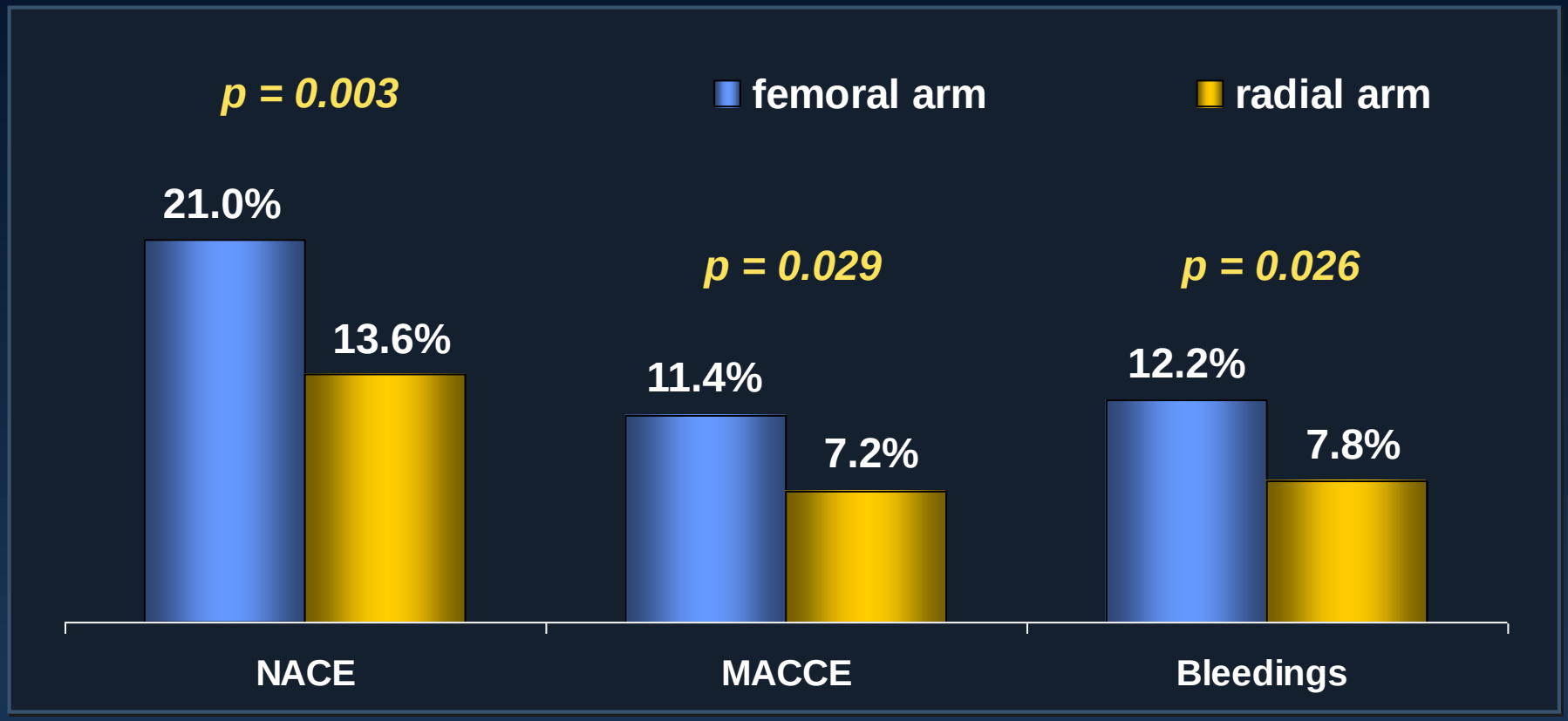
RIFLE (STEMI only)



- Romagnoli E *et al. J Am Coll Cardiol*. 2012;60:2481-2489

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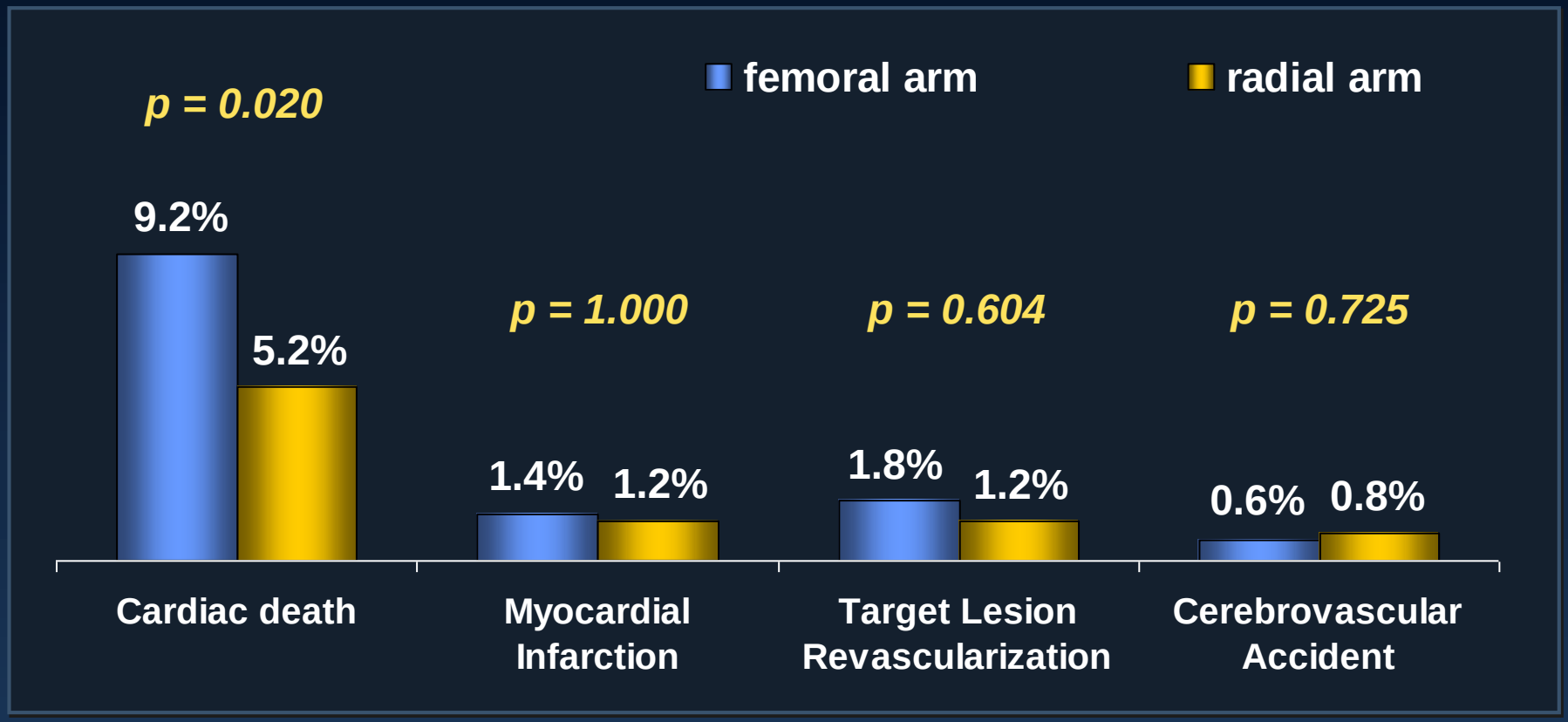
RIFLE (STEMI only)



- Romagnoli E *et al. J Am Coll Cardiol*. 2012;60:2481-2489

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MATRIX (all ACS)

End point	Radial (n=4,197), %	Femoral (n=4,207), %	p-value
MACE	8.8	10.3	0.031
Net adverse clinical events	9.8	11.7	0.009
All-cause mortality	1.6	2.2	0.045
MI	7.2	7.9	0.20
Stroke	0.4	0.4	0.20
BARC 3 or 5 bleeding	1.6	2.3	0.013

- **Valgimigli M *et al. Lancet*. 2015; online first**

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SAFE-PCI

- Women are frequently underrepresented in randomized studies
- Women have higher rates of access site bleeding in femoral cases
- Women have smaller radial arteries
- Randomized 1,787 women at 60 US sites to radial vs. femoral approach

SAFE-PCI

	Radial (N=290)	Femoral (N=291)	P
Procedure duration (min)	51.6 ± 32.3	49.9 ± 30.5	0.46
Total radiation dose (mGy)	1604 ± 1394	1472 ± 1274	0.26
Total contrast volume (mL)	152.7 ± 76.9	165.6 ± 82.7	0.03
Patient prefers assigned access site for next procedure	71.9%	23.5%	<0.01

Rao SV *et al. J Am Coll Cardiol Intrv*. 2014;7:857-867

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SAFE-PCI

	Radial (N=893)	Femoral (N=894)	OR (95% CI)	P
BARC 2, 3, 5 bleeding or Vasc Complications	0.6%	1.7%	0.3 (0.1-0.9)	0.03
Access site crossover	6.7%	1.9%	3.7 (2.1-6.4)	<0.001

Rao SV *et al. J Am Coll Cardiol Intrv*. 2014;7:857-867

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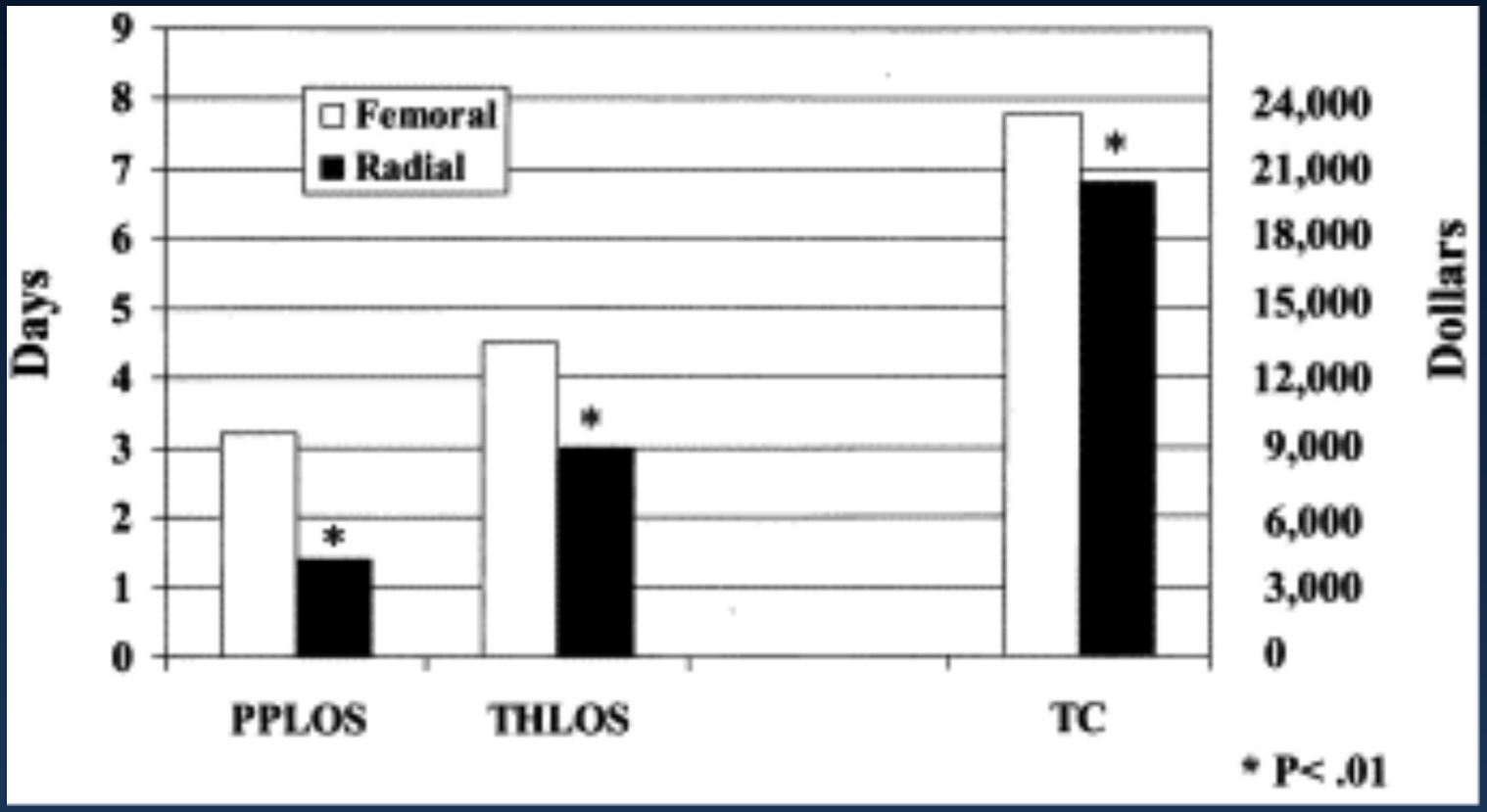
Reduction in length of stay, cost



Mann T *et al. J Am Coll Cardiol*. 1998;32(3):572-6

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Cost effectiveness

- Radial PCI reduces costs via two main mechanisms
  - Shorter hospital stay
  - Lower bleeding event rate
- Radial access reduces the cost per PCI by $800-$1,300 depending on the study
  - Over 1,200 PCIs and 2,100 catheterizations without PCI performed at GMC per year

Mann T *et al. J Am Coll Cardiol*. 1998;32(3):572-6
Applegate E *et al. Catheter Cardiovasc Interv.* 2013;82(4):e375-84
Amin AP *et al. JACC Cardiovasc Interv.* 2013;6(8):827-34

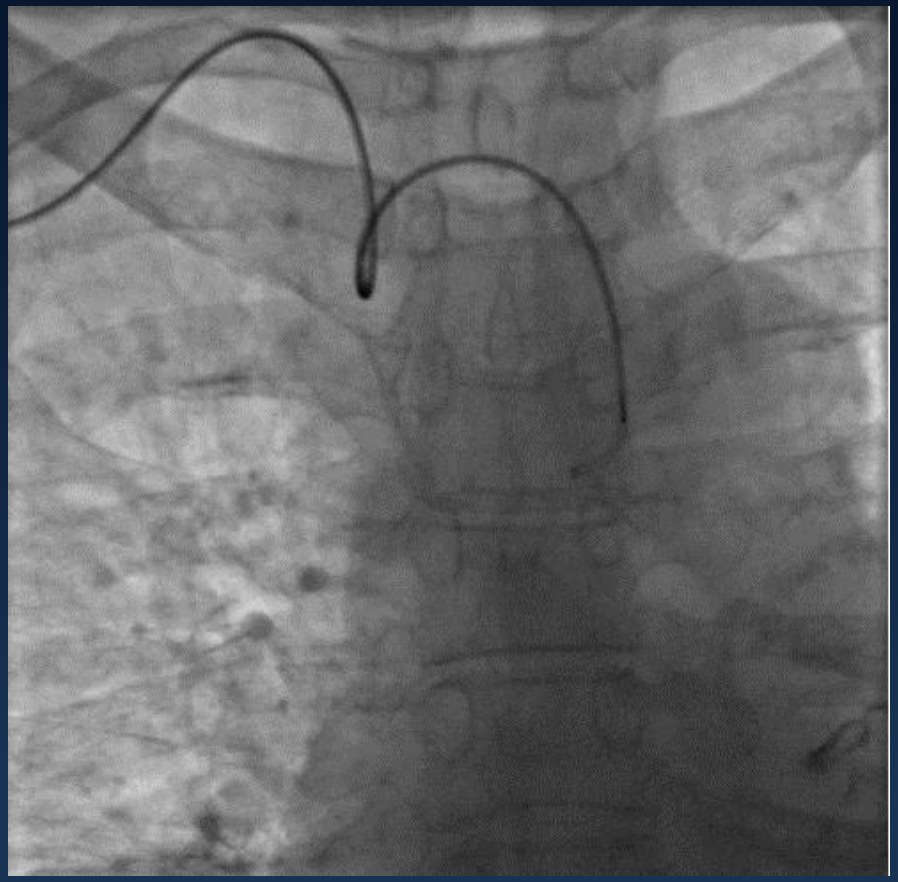
So what are the downsides?

- Higher crossover rate
  - 4-7% based on randomized studies
  - Note that crossover rate from femoral to radial was about 2% in randomized studies
- Increased radiation exposure
  - Seen predominantly in older studies and the gap is diminishing

So what are the downsides?

- Radial artery occlusion
  - Symptomatic in about 2-3%
  - Rarely long-term consequences
  - Unknown consequences for subsequent access or use as a bypass conduit
- Steep learning curve for operators, staff
  - Spasm, anatomic differences
  - Different setup

Learning curve



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Learning curve

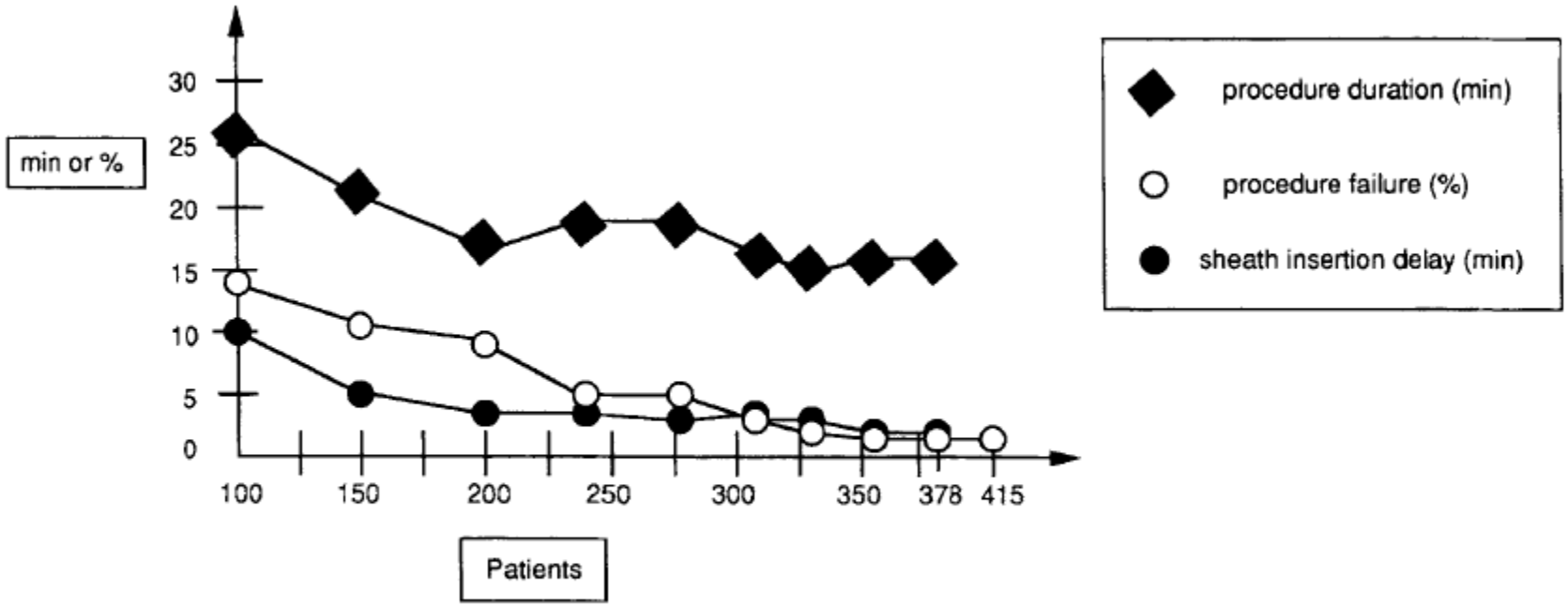

Fig. 5. Learning curve procedure failure rate, sheath insertion delay, and procedure duration.

Spaulding *et al. Cath Cardiovasc Diagnosis* 1996;39:365-370

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Conclusions

- Radial artery catheterization is preferred by patients
- Radial artery catheterization reduces bleeding events and may improve mortality among STEMI patients and patients at high risk of bleeding
- Radial artery catheterization reduces hospital costs

Fad or here to stay?

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