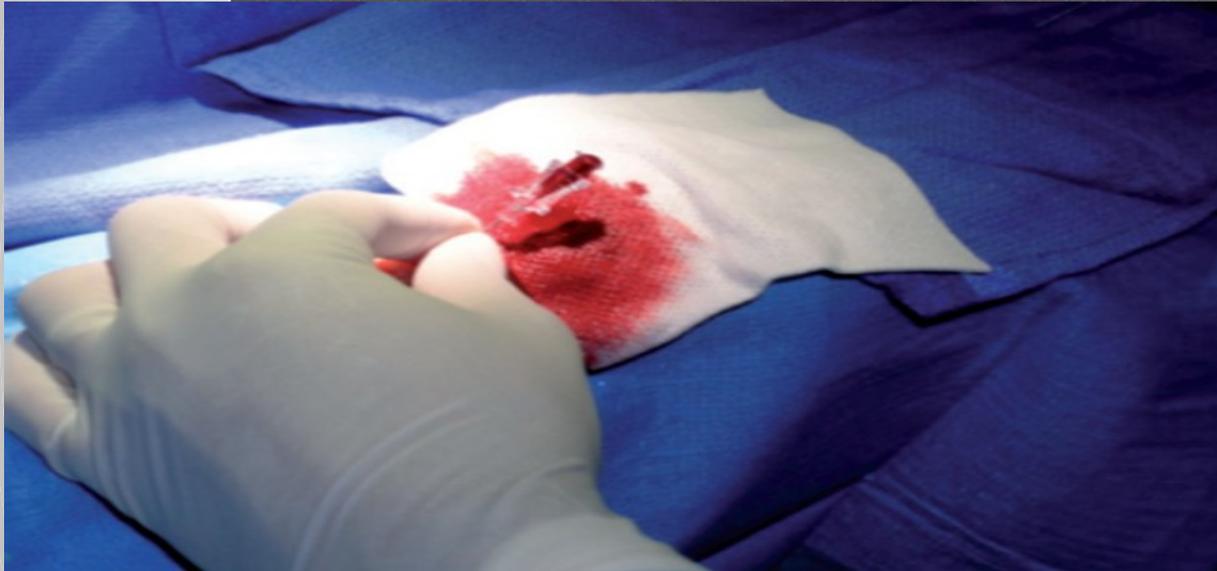


TRANSRADIAL CARDIAC CATHETERIZATION



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April 13, 2013

TOPICS

Historical perspective and current trends

Rationale for the radial approach

- Bleeding complications

Comparison of radial and femoral access

Transradial STEMI program

Some radial specific issues

Educational resources and training

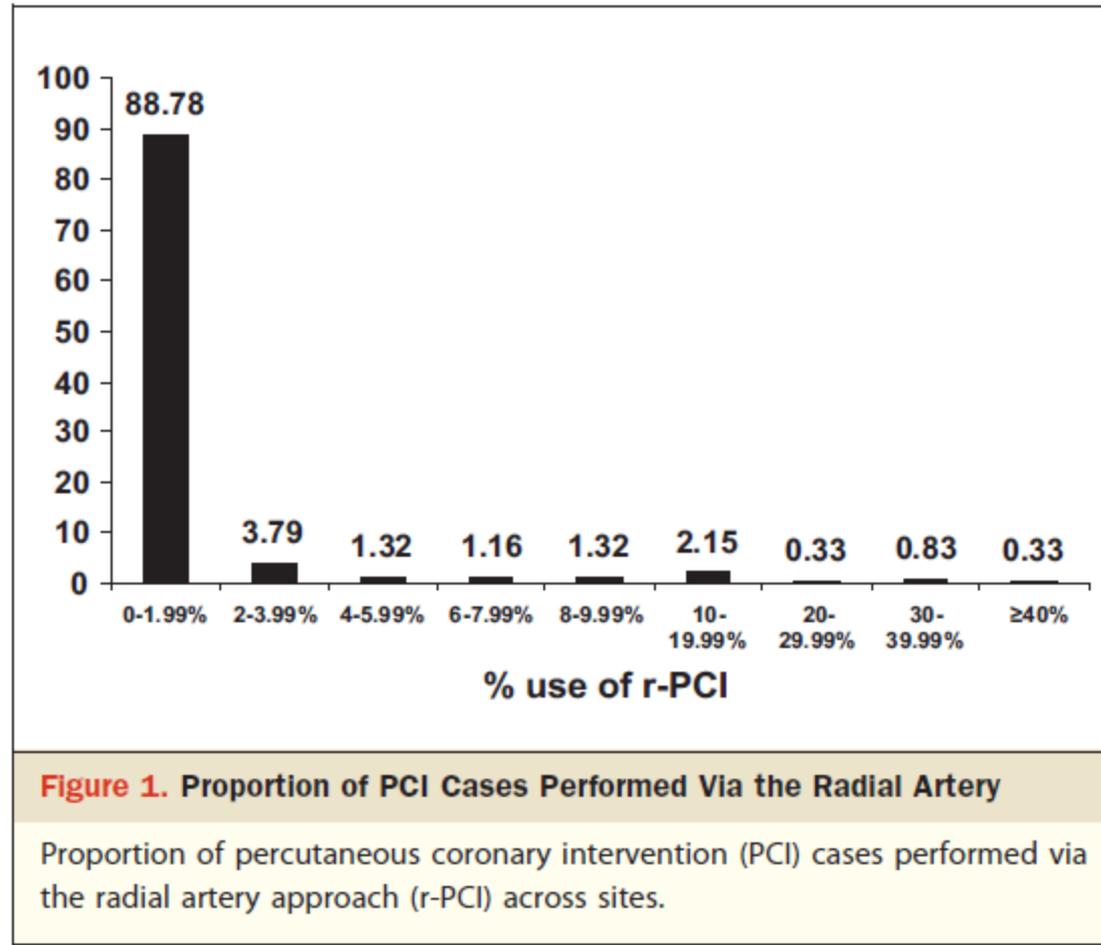
OBJECTIVES

- 媿 Understand transradial approach to cardiac catheterization
- 媿 Discuss risks and benefits of transradial approach
- 媿 Key goals for developing an aggressive transradial approach
- 媿 Identify education and resources for catheterization

Historical Perspective

- 1948: First attempted transradial coronary angiogram using **radial cut-down**
- 8-10 F catheters: too large for most radials
- 1989: Campeau reported first 100 cases of **percutaneous** transradial coronary angiograms
- 1993: First transradial coronary angioplasty with stent implantation performed
 - Performed using 6F guide catheter

Current Trends



Current Trends

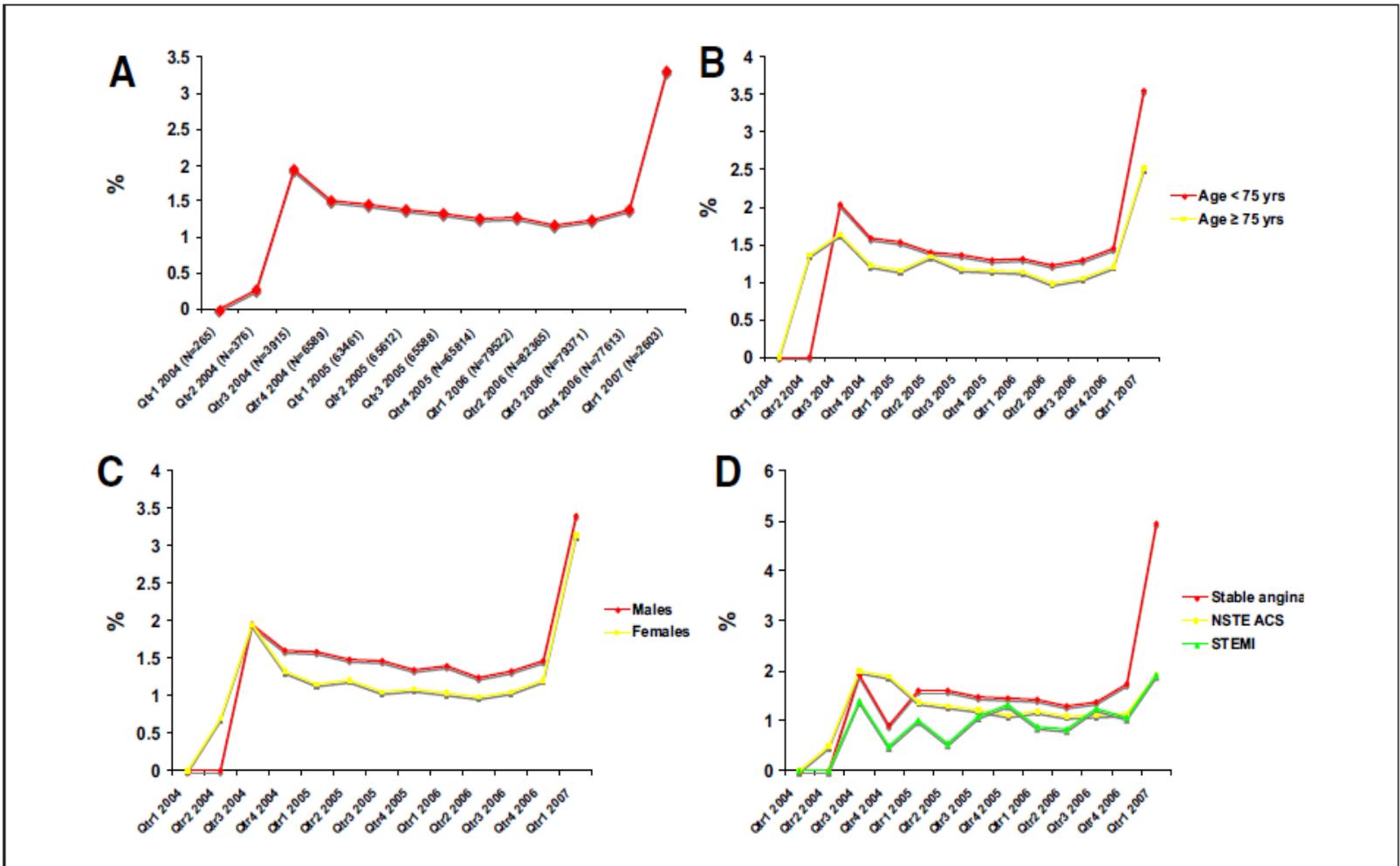


Figure 2. Trend in the Use of r-PCI Over Time in Key Subgroups
 Trend in the use of the radial approach to percutaneous coronary intervention (r-PCI) over time in (A) the overall dataset; (B) patients age <75 and ≥75 years; (C) men and women; (D) patients with stable angina, non-ST-segment elevation acute coronary syndrome (NSTEMI), and ST-segment elevation myocardial infarction (STEMI).

Rationale for use of TRA

Advantages:

- Reduced risk of major bleeding
- Improved patient comfort and convenience
- Immediate ambulation
- Reduced inpatient time and cost, faster turnover of beds

Bleeding Complications

Advances in antiplatelet and anticoagulant therapies in patients with ACS undergoing PCI have reduced ischemic events and improved overall outcomes

Bleeding complications have remained relatively constant in cardiac cath/PCI

Bleeding associated with increase risk of mortality, recurrent MI and stroke

Meta-analysis of Bleeding in ACS

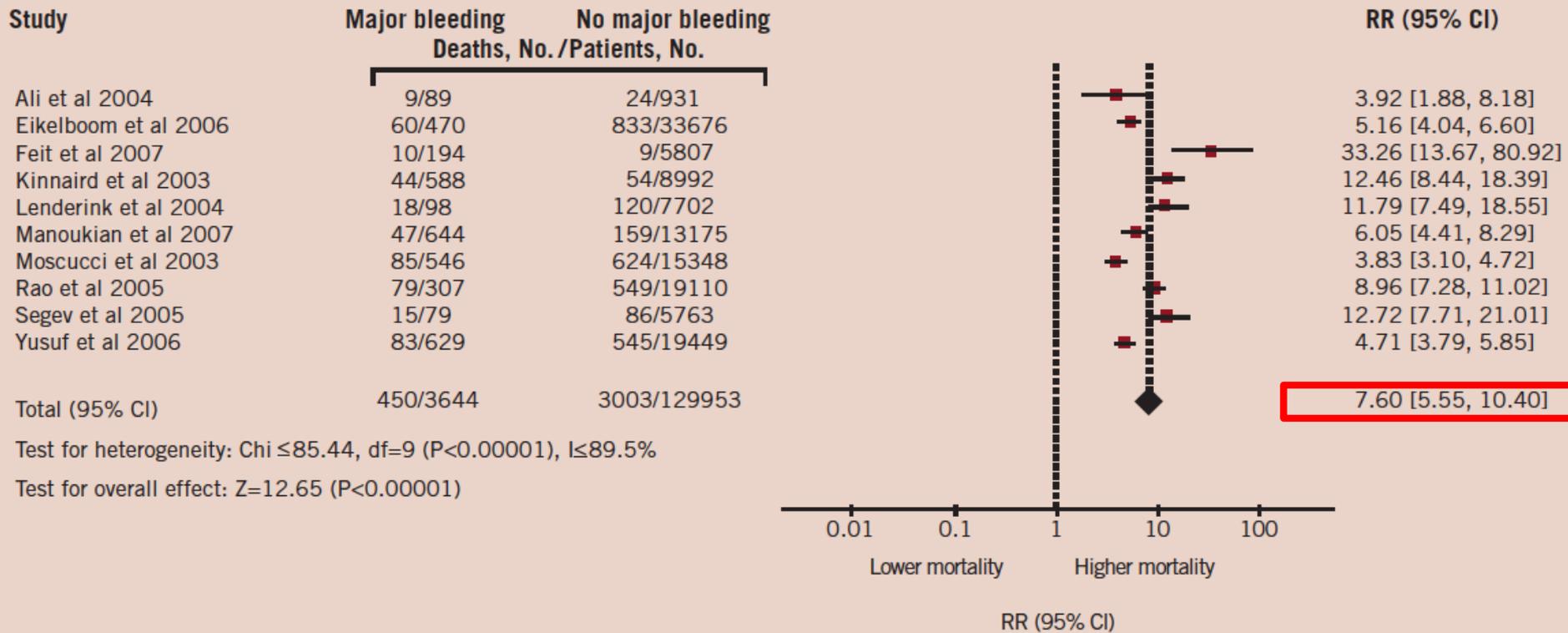


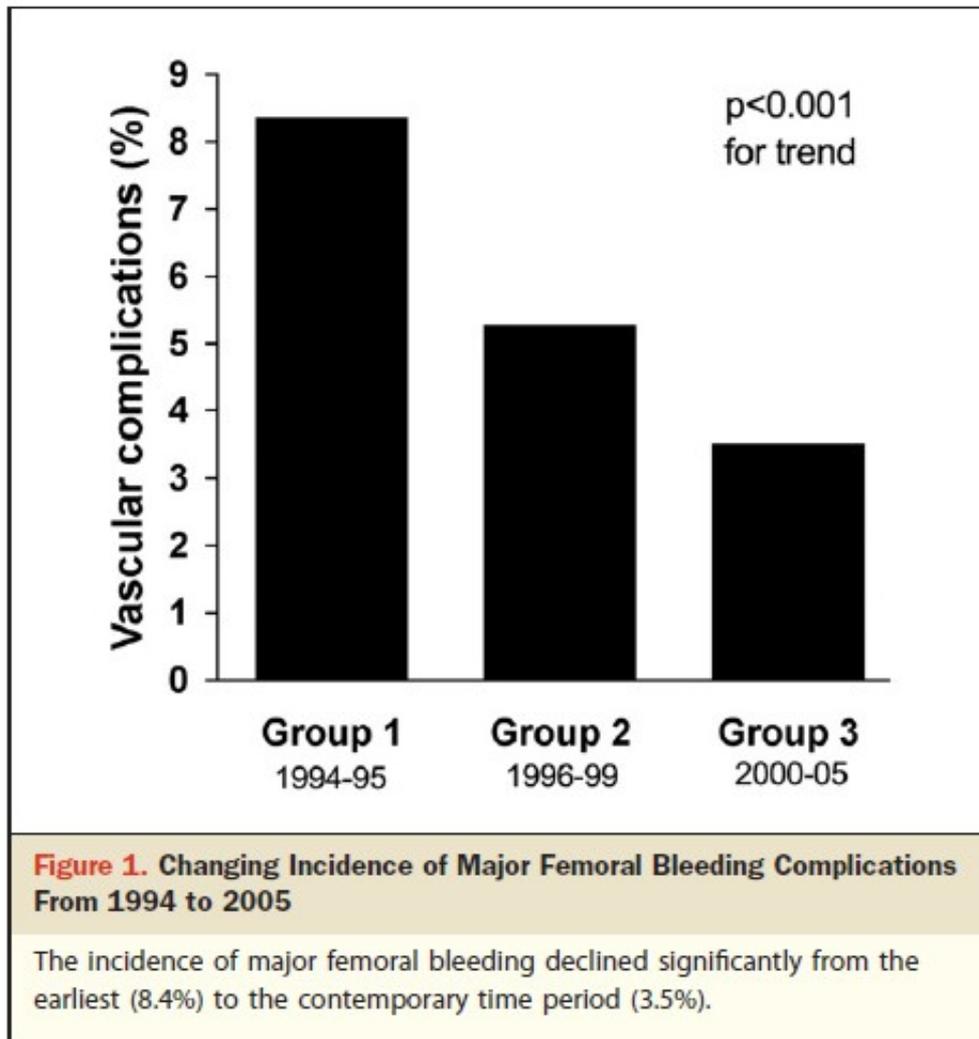
Figure 2. Pooled relative risks of mortality increase in patients with ACS and major bleeding: random-effects meta-analysis of 10 studies.

Major Femoral Bleeding Post-PCI

- Mayo clinic PCI database 1994-2005
- Changes in type, intensity and duration of anticoagulation protocols over time

	Group 1 1994-1995	Group 2 1996-1999	Group 3 2000-2005
n	2441	6207	9253
Sheath size (F)	8.2 ± 0.7	7.8 ± 0.9	6.4 ± 0.8
GP lib/IIIa use	27 (1%)	2536 (41%)	5328 (58%)
Peak ACT	405 ± 110	339 ± 79	312 ± 61
Heparin post procedure	1995 (80%)	2215 (36%)	2456 (27%)

Major Femoral Bleeding Post-PCI



OASIS-5: Fondaparinux

Comparison of Fondaparinux vs Enoxaparin in patients with ACS

Time and Outcome	Enoxaparin (N= 10,021) <i>no. of events (% of patients)</i>	Fondaparinux (N= 10,057) <i>no. of events (% of patients)</i>	Hazard Ratio (95% CI)	P Value for Superiority
9 Days				
Death, MI, or refractory ischemia	573 (5.7)	579 (5.8)	1.01 (0.90–1.13)	NA
Death or MI†	412 (4.1)	409 (4.1)	0.99 (0.86–1.13)	NA
Death	186 (1.9)	177 (1.8)	0.95 (0.77–1.17)	NA
MI	264 (2.7)	263 (2.6)	0.99 (0.84–1.18)	NA
Refractory ischemia	188 (1.9)	194 (1.9)	1.03 (0.84–1.26)	NA
Stroke	45 (0.5)	37 (0.4)	0.82 (0.53–1.27)	NA
Major bleeding	412 (4.1)	217 (2.2)	0.52 (0.44–0.61)	<0.001
Death, MI, refractory ischemia, or major bleeding	905 (9.0)	737 (7.3)	0.81 (0.73–0.89)	<0.001
Death, MI, or stroke	446 (4.5)	435 (4.3)	0.97 (0.85–1.11)	0.67

OASIS-5: Fondaparinux

Regardless of Treatment Arm, those who suffered a major bleeding event had worse outcomes at 30 days:

- Increased risk of death (13.2% vs 2.8%)
- Increased risk of MI (11.9% vs 3.6%)
- Increased risk of stroke (3.5% vs 0.7%)

Choice of Access Site in ACUITY

媿 Femoral site chosen in 93.8%

媿 Radial site chosen in 6.2%

媿 Subgroup analysis with some important differences in baseline characteristics:

- Femoral approach more commonly used in:
 - Older patients
 - Females
 - Established CAD
 - Enrolled in the US

Choice of Access Site in ACUITY

No difference in composite outcome of death / MI / ischemia at 30 days or at 1 year

Bleeding:

	Radial	Femoral	P-value
Access site bleeding	0.9%	2.1%	0.009
TIMI non-CABG major bleeding	1.0%	1.5%	0.37
Non-CABG major bleeding	3.0%	4.8%	0.03

MORTAL Study

婚 British Columbia Cardiac Registry (similar to NCDR) used to evaluate patients who had undergone PCI from 1999-2005

婚 Cross-referenced with Central Transfusion Registry to identify patients transfused within 10 days of PCI

婚 Objective:

- To determine association of arterial access site (radial vs femoral) with transfusion and mortality

MORTAL Study

Baseline characteristics: multiple variables with statistically significant differences

Variable	Radial N = 7,972	Femoral N = 30,900	P-value
Elective	32.4%	26.3%	< 0.01
Urgent	55.3%	62.4%	< 0.01
Dialysis	0.7%	1.8%	< 0.01
Prior MI	25.5%	34.1%	< 0.01
Prior CABG	6.9%	13.5%	< 0.01
**Liver/GI comorbidities	2.4%	6.9%	< 0.01
**Malignancy	2.3%	7.2%	< 0.01

MORTAL Study - Transfusion

媿 Odds Ratios (adjusted for baseline characteristics) for mortality related to receiving transfusion vs no transfusion:

- 30 day: 4.01 (95% CI 3.08 to 5.22)
- 1 year: 3.58 (95% CI 2.94 to 4.36)

媿 Propensity Score Matching confirmed higher risk of 30d and 1year mortality if transfused

MORTAL Study - Access Site

- Odds Ratios (adjusted for baseline characteristics) for receiving a transfusion based on Radial vs Femoral access:
 - 0.59 (95% CI 0.48 to 0.73), $p < 0.001$
- Adjusted OR for mortality: TRA v TFA
 - 30 day: 0.71 (95% CI 0.61 to 0.82) $p < 0.001$
 - 1 year: 0.83 (95% CI 0.71 to 0.98) $P < 0.001$
- If only non-transfused procedures analyzed, difference in mortality non-significant
 - Supports hypothesis that mortality difference closely linked with need for transfusion

Mortality & Bleeding / Transfusion

Table 1 Studies of the Impact of Major Bleeding on Mortality After PCI

Author/Study (Ref. #)	Patients (n)	Patient Population	STEMI Included?	Definition	Frequency of Blood Transfusion (%)	Impact of Bleeding on Mortality [95% Confidence Interval]	p Value
Kinnaird et al. (1)	10,974	Unselected	Yes	TIMI	5.4	30-day adjusted OR: 3.5 [1.9-6.7]	<0.0001
REPLACE-2 (2)	6,001	Elective and 'urgent' PCI	No	Protocol†	3.2	1-year adjusted OR: 2.66 [1.44-4.92]	0.002
Ndrepepa et al. (3)	5,348	Elective, ACS	No	TIMI	4.0	1-year adjusted HR: 2.96 [1.96-4.48]	<0.0001
ACUITY (4)	13,819	ACS only	No	Protocol†	4.7	30-day OR: 7.55 [4.68-12.18]	<0.0001
Kim et al. (5)	6,799	Unselected	Yes	Protocol†	8.0	1-year RR: 2.03 (transfused patients)	0.0028
Doyle et al. (6)	17,901	Unselected	Yes	Protocol†	4.8	30-day adjusted HR: 9.96 [6.94-14.3]	<0.0001
GRACE registry (7)*	24,045	ACS	Yes	Protocol†	3.9	In-hospital adjusted OR: 1.64 [1.18-2.28]	<0.0001
Yatskar et al. (8)	6,656	Unselected	Yes	Protocol†	1.8	In-hospital adjusted OR: 3.59 [1.66-7.77] 1-year adjusted HR: 1.65 [1.01-2.70]	0.001 0.048

Table 2 Studies of the Impact of Blood Transfusion on Mortality After PCI

Author (Ref. #)	Patients (n)	Patient Population	STEMI Included?	Frequency of Blood Transfusion (%)	Impact of Transfusion on Mortality [95% Confidence Interval]	p Value
Jani et al. (12)	4,623	Anemic patients with MI	Yes	22.3	In-hospital, adjusted OR: 2.02 [1.47-2.79]	<0.0001
Doyle et al. (6)	17,901	Unselected	Yes	6.8	30 days, 1-2 U adjusted HR: 8.9 [6.3-12.6] 3+ U adjusted HR: 18.1 [13.7-24]	<0.0001 <0.0001
Kinnaird et al. (1)	10,974	Unselected	Yes	5.4	1 year, OR per unit transfused: 1.47 [1.36-1.55]	<0.0001
Kim et al. (5)*	567*	Severe bleeding	Yes	25.7	1 year, RR: 2.03	0.0028
Chase et al. (13)	38,872	Unselected	Yes	3.5	30-day adjusted OR: 4.01 [3.08-5.22] 1-year adjusted OR: 3.58 [2.94-4.36]	<0.0001 <0.0001

RIVIERA Study

媿 Multinational prospective observation study to determine predictors of adverse outcomes following PCI

媿 7962 patients from 23 countries

媿 Both elective (92%) and primary PCI (8%)

媿 Radial approach: 841 pts (10.6%)

媿 Femoral approach: 7062 pts (89.2%)

RIVIERA Study: Death / MI

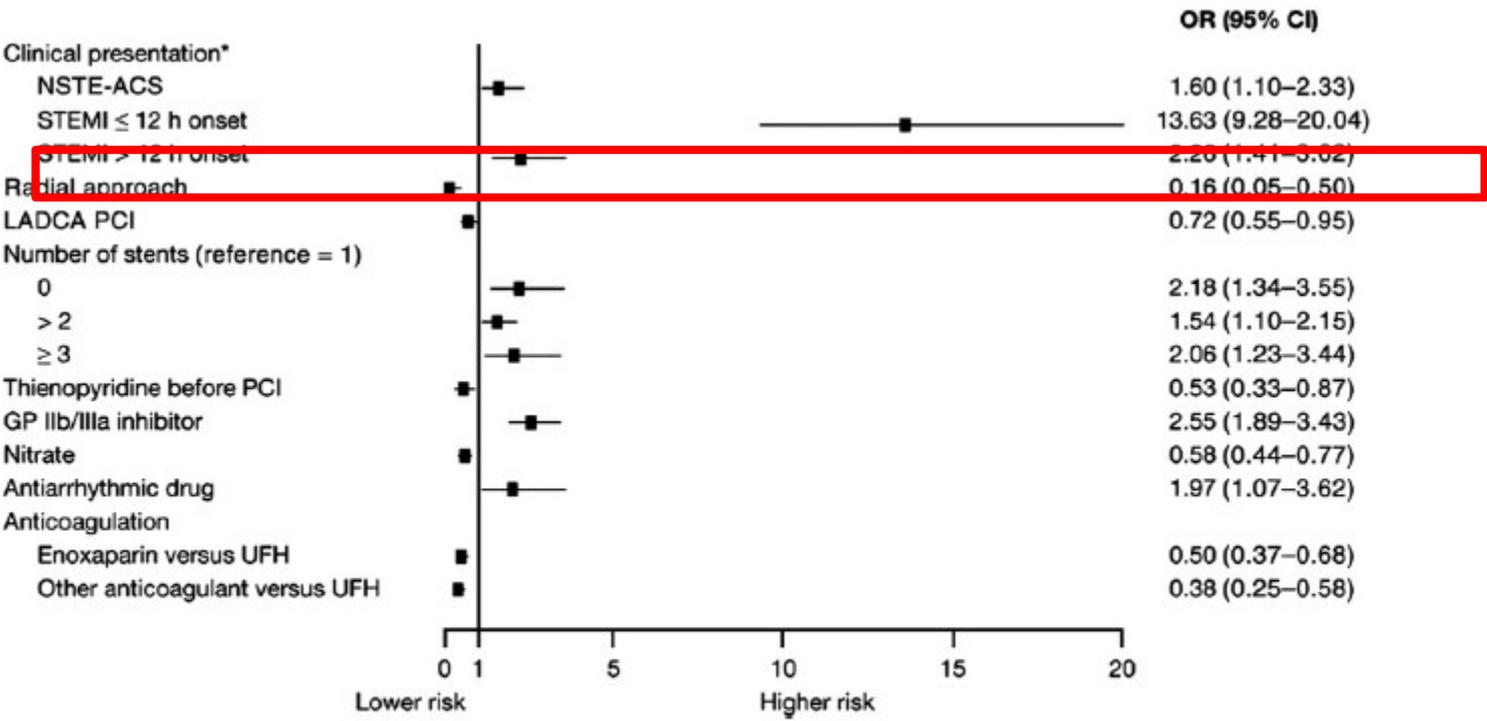


Fig. 1. Independent predictors of death or myocardial infarction. *Reference is asymptomatic or unstable angina. CI, confidence interval; GP; glycoprotein; LADCA, left anterior descending coronary artery; NSTEMI-ACS, non-ST-segment elevation acute coronary syndrome; OR, odds ratio; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; UFH, unfractionated heparin.

RIVIERA Study: Bleeding

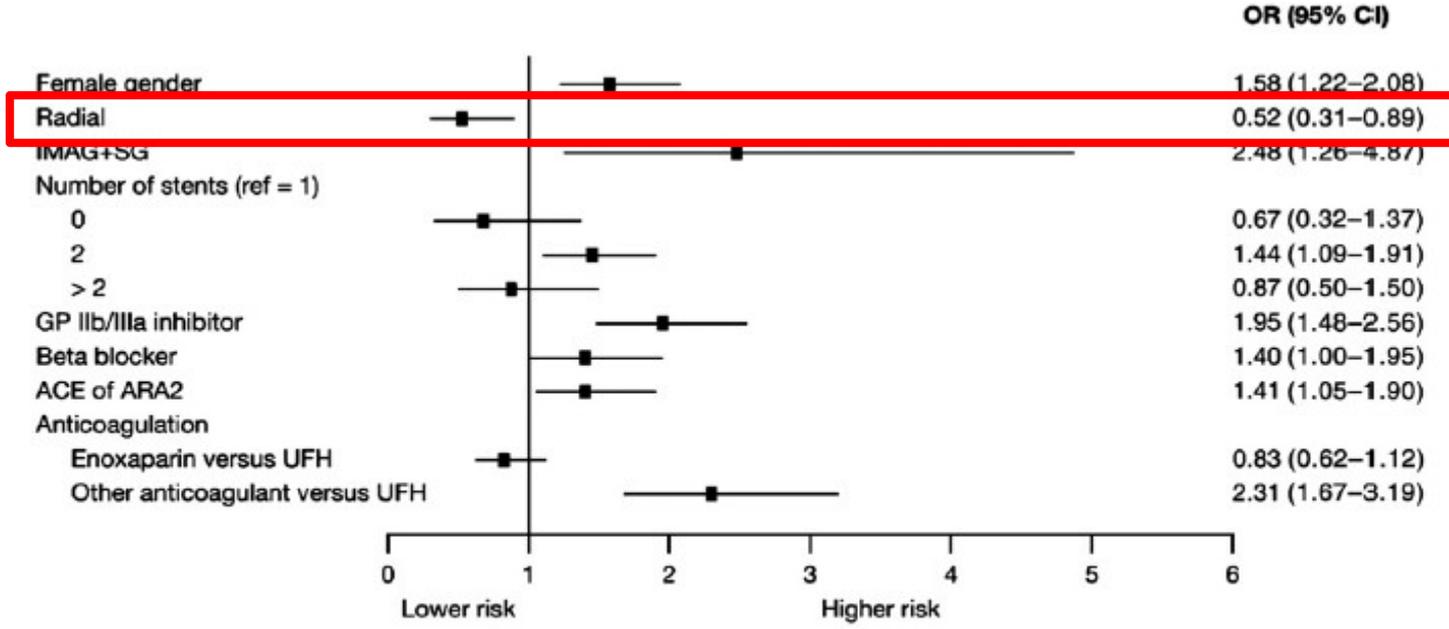
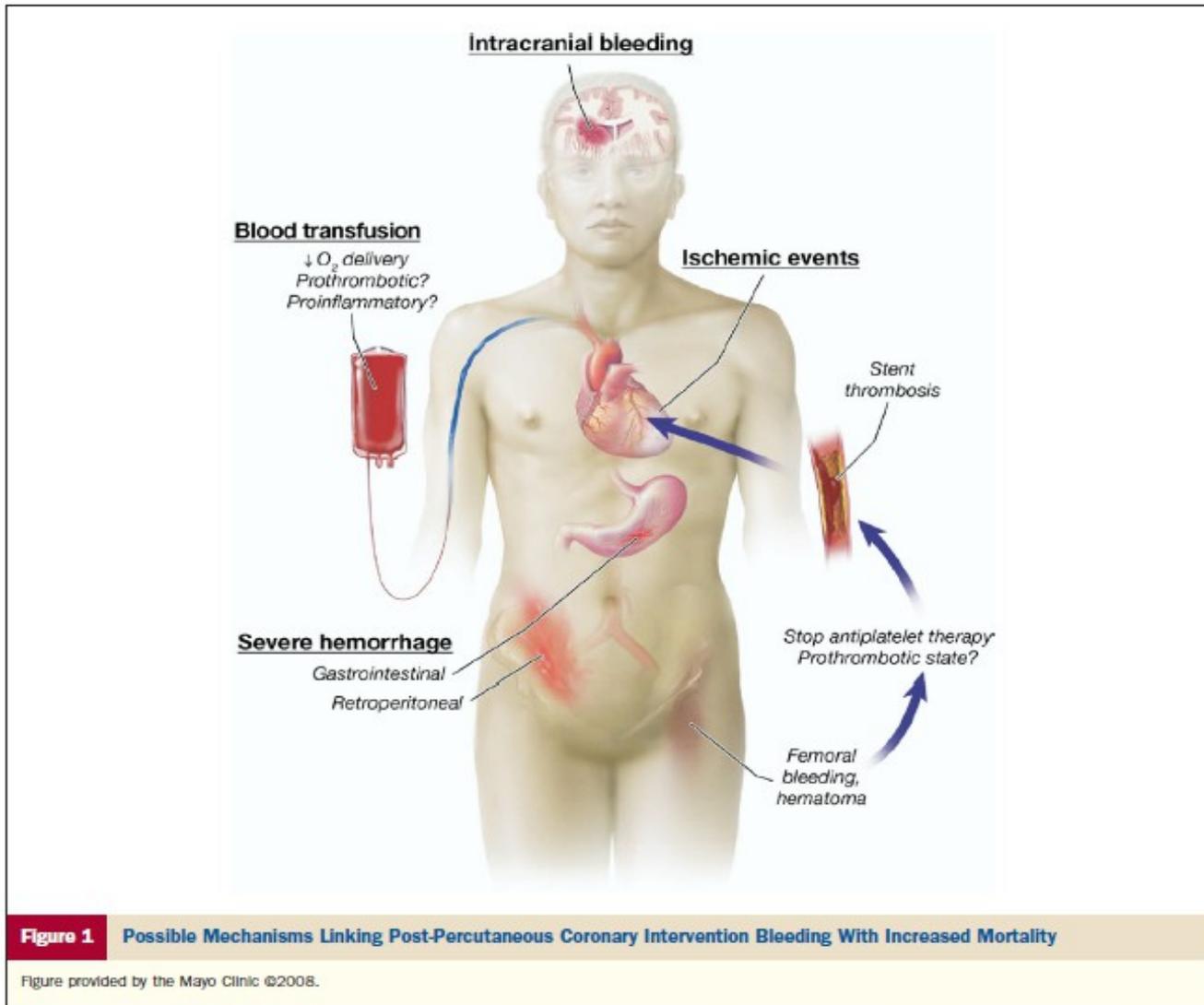


Fig. 2. Independent predictors of bleeding. ACE, angiotensin-converting enzyme; ARA, adenosine receptor antagonist; CI, confidence interval; GP, glycoprotein; IMAG+SG, internal mammary artery graft or saphenous graft; OR, odds ratio; UFH, unfractionated heparin.

Mechanisms for Increased Mortality



Why all this talk about bleeding?

媿 Bleeding complications are a big deal

媿 Needing a transfusion after cath is a marker of high risk - strongly (perhaps even causally) related to adverse events

媿 Efforts to further reduce risk of bleeding and reduce the chance of needing a transfusion are of utmost importance

Meta-analysis Radial vs Femoral

12 RCTs included spanning 1994-2003
evaluating Coronary Angiography and/or PCI
from TR vs TF approach

Total of 3224 pts

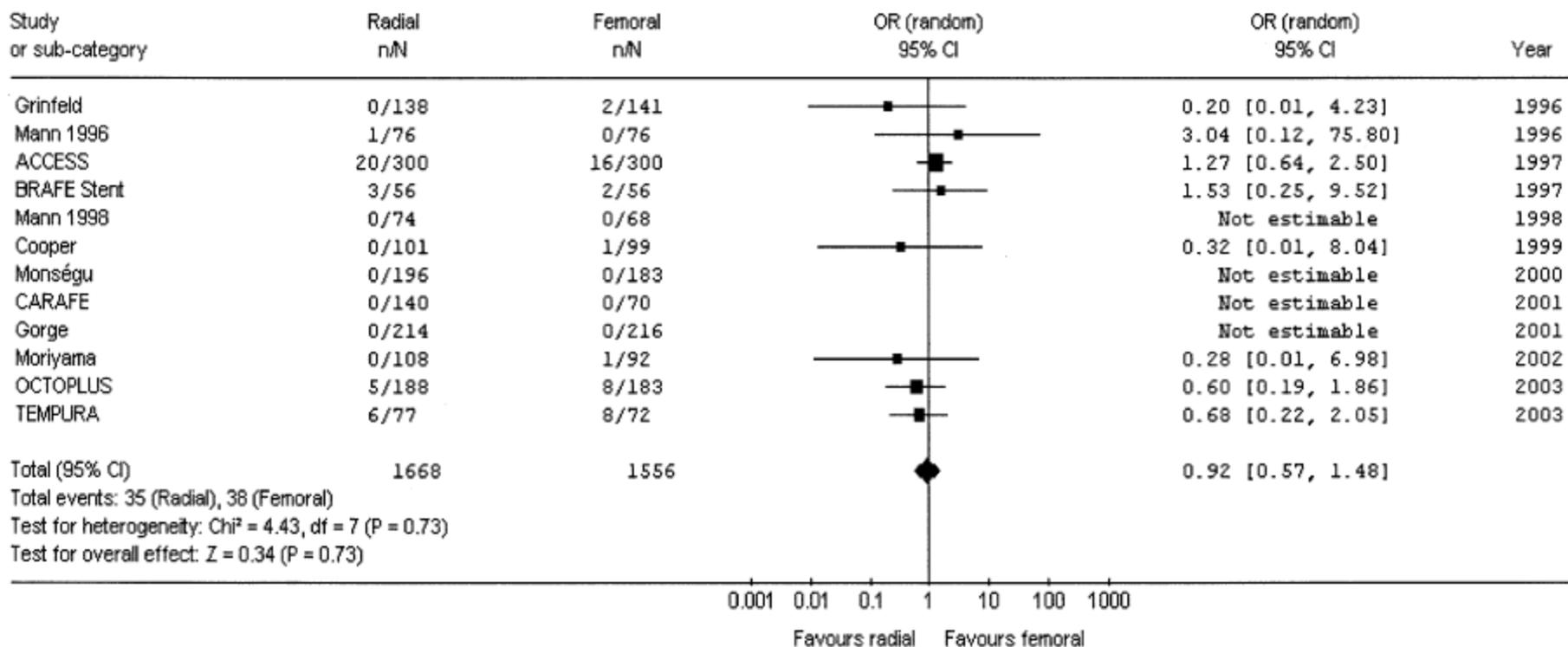
- 1668 Transradial
- 1556 Transfemoral

7 studies - Diagnostic only

5 studies - PCI: of these 2 in ACS/AMI

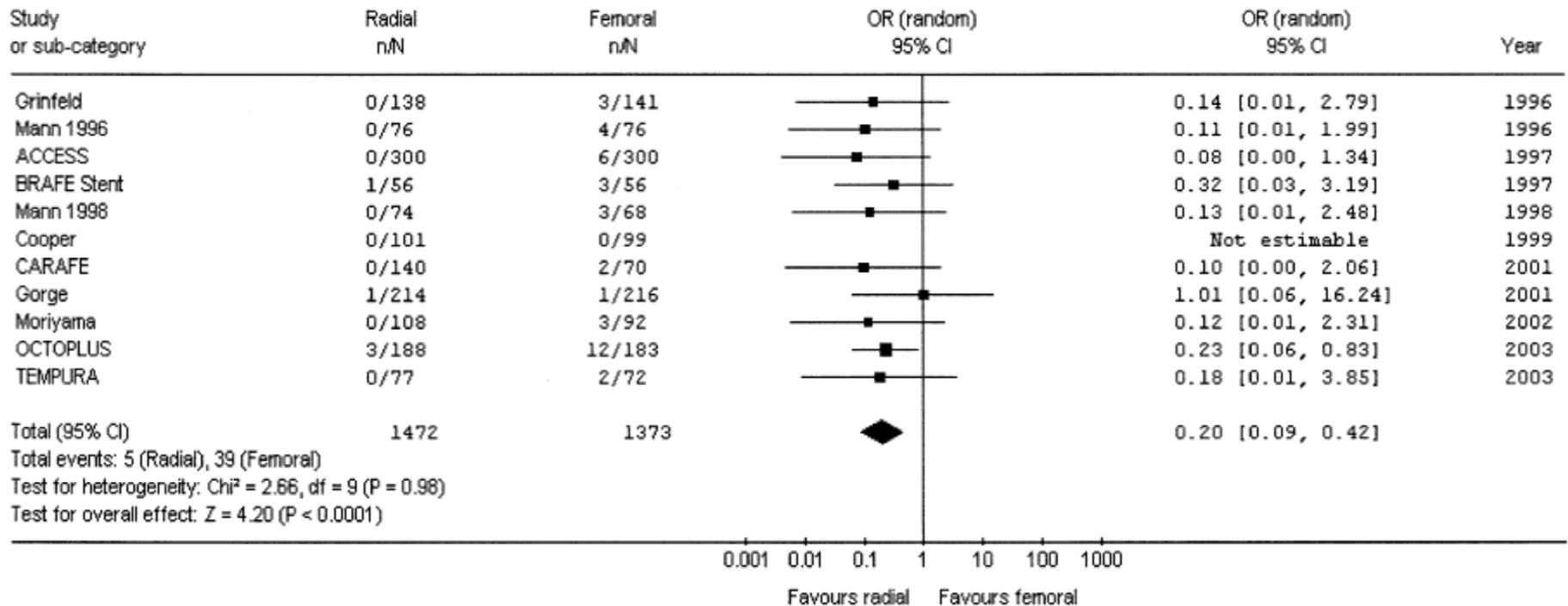
Meta-analysis - MACE

Comparison: Radial vs Femoral approach
Outcome: MACE



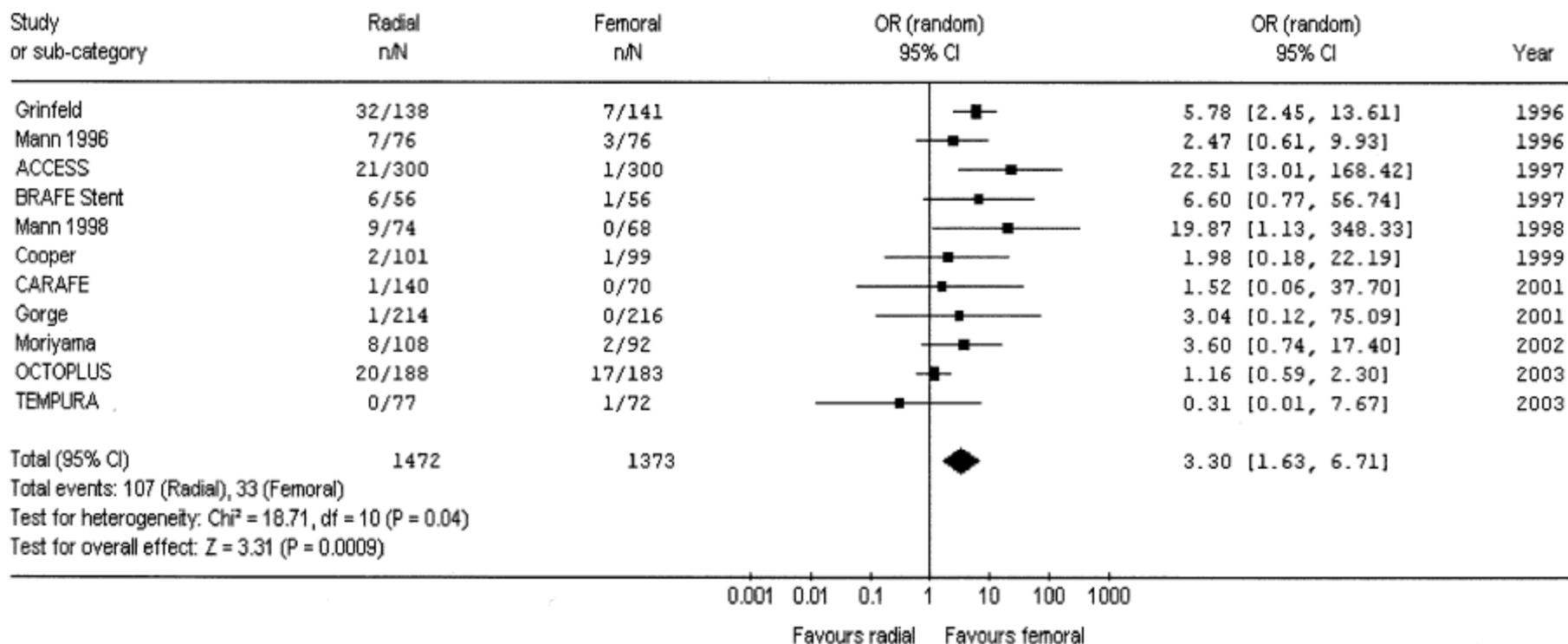
Meta-analysis - Entry Site Complications

Comparison: Radial vs Femoral approach
 Outcome: Entry site complications



Meta-analysis - Procedural Failure

Comparison: Radial vs Femoral approach
Outcome: Procedural failure



Meta-analysis: Secondary Endpoints

Significant heterogeneity

- Fluoroscopy time shorter for Femoral
 - TFA - 7.8 min vs TRA - 8.9 min
 - (Diff: 1.05, 95% CI diff: 0.51 to 1.60, $p < 0.001$)
- Mean hospital stay shorter for Radial
 - TFA - 2.4 days vs TRA - 1.8 days
 - (Diff: 0.55, 95% CI diff: 0.29 to 0.82, $p < 0.001$)
- Total hospital charge lower for Radial

Meta-analysis 2: - Radial vs Femoral

- 23 studies included spanning 1993 - 2007
- Major Bleeding:
 - Radial: 0.5% (13 / 2390 pts)
 - Femoral: 2.3% (48 / 2068 pts)
OR: 0.27 (95% CI 0.16 - 0.45, $p < 0.001$)
- Trend towards reduced composite of death / MI / stroke
🔥 OR: 0.71 (95% CI 0.49 - 1.01, $p = 0.058$)
- Trend towards reduced mortality
🔥 OR 0.74 (95% CI 0.42 - 1.30, $p = 0.29$)

Radial PCI in STEMI

Single center longitudinal cohort study

530 patients with STEMI undergoing primary PCI < 12hrs enrolled in registry

Access: chosen at discretion of operator

Default access = Radial, with Femoral access used if unfavorable Allen test or h/o CABG

Baseline characteristics:

- Radial group more likely to be older, male, higher BMI, less likely to have prior MI

Radial PCI in STEMI - MACE

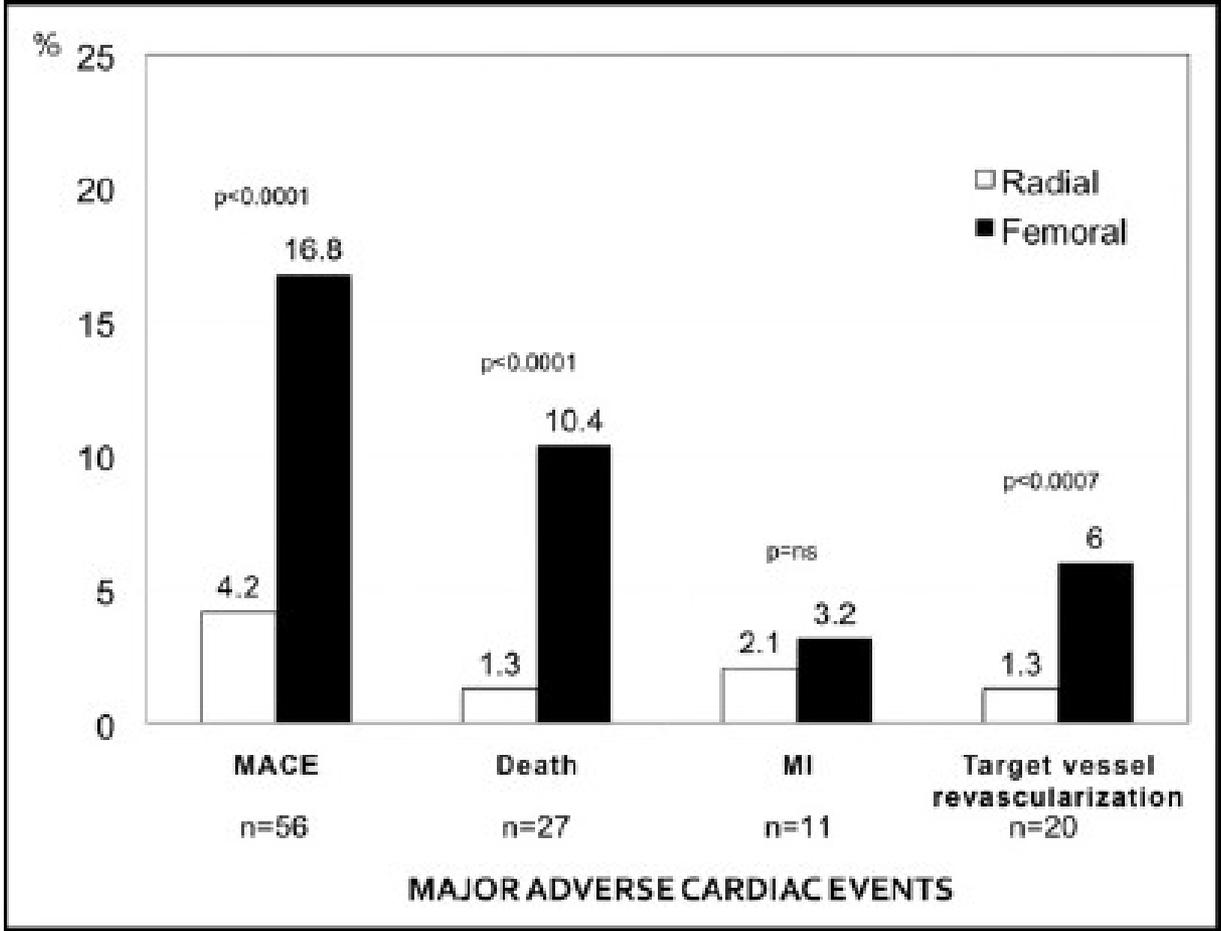
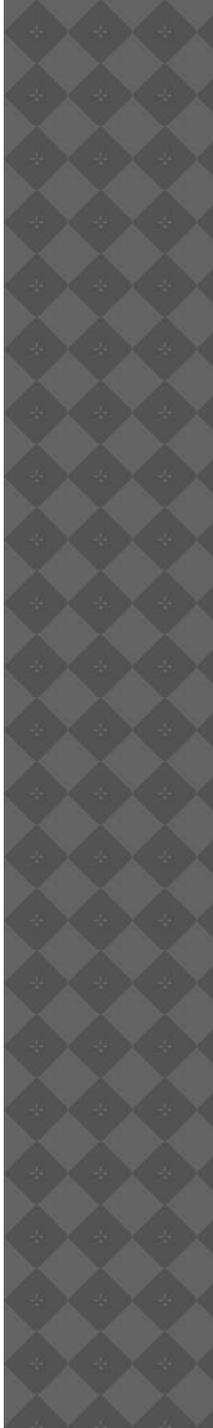


Figure 1. MACE at 1 year of follow-up. Chart labels represent percentages of each event. Data in axis represent absolute value of each event.

Azmendi et al, Am J Card 2010; 106(2): 148-







Transradial disadvantages

嬭 Longer procedure time

嬭 Increased door to balloon time in STEMI pts

嬭 Radial artery occlusion/lack of conduit

嬭 Increased radiation exposure for patient/staff/physicians

From brachial to Transfemoral approach

媿 Dominant strategy since Dr Melvin Judkins

媿 Large vessels

媿 Preformed catheters

媿 Avoided cutdowns (Brachial artery Sones)

媿 Could tolerate larger catheter size

媿 Could be repeated

媿 Percutaneous

媿 Anatomy straightforward

Transfemoral potential pitfalls

媿 **Entry site critical**

媿 **Landmarks sometimes very problematic**

媿 **The Red Sea**

媿 **Space for unrecognized blood collections**

媿 **Hemostasis**

媿 **Peripheral arterial disease**

Door-to-Balloon time

Single-center observational study 2005-9

4 PCI operators

- 1 preferred TF, 1 preferred TR, 2 no preference - all trained in both

240 consecutive STEMI cases

205 undergoing successful PCI

- 124 trans-radial
- 116 trans-femoral

Door-to-Balloon time

TABLE II. Procedural and Process Times Measured from Door to Balloon

	Radial (<i>n</i> = 124)	Femoral (<i>n</i> = 116)	<i>P</i> value
Door to ECG (min)	9.1 ± 9.3	9.9 ± 10.3	0.55
ECG to HA (min)	5.5 ± 6.7	7.9 ± 11.5	0.05
HA activation to team arrival (min)	22.5 ± 11.9	23.1 ± 10.1	0.68
Team arrival to patient arrival in lab (min)	11.6 ± 6.6	13.3 ± 7.5	0.07
Arrival in cath lab to balloon inflation (min)	28.4 ± 11.3	32.7 ± 12.4	0.01
Case start to access time (min)	12.5 ± 5.4	10.5 ± 5.7	0.005
Time from access to balloon inflation (min)	18.3 ± 10.8	24.1 ± 11.7	<0.001
Door to balloon time (min)	76.4 ± 26.4	86.5 ± 27.6	0.008
Number of total coronary catheters used (min)	2.9 ± 1.0	3.1 ± 0.8	0.02
Fluoroscopy time (min)	12.5 ± 7.9	15.2 ± 10.1	0.02
Contrast given (mL)	168.5 ± 66.6	186.7 ± 68.2	0.04

ECG = electrocardiogram, HA = heart alert.

Radiation Exposure

- Study performed in Germany where one experienced operator (>1500 radial cases) performed coronary angiography ± PCI
- Pts randomized to TR or TF approach
- Radiation dosimeter used to measure operator exposure in μSv
- Patient radiation dose measured in terms of dose-area product ($\text{Gy}\cdot\text{cm}^2$) and fluoroscopy time

Radiation Exposure

TABLE II. Fluoroscopy Time and Radiation Measurements

	Femoral	Radial	<i>P</i>
Coronary angiography (n)	103	92	
Fluoroscopy time (min)	1.7 ± 1.4	2.8 ± 2.1	< 0.001
Dose-area product (Gy · cm ²)	13.1 ± 8.5	15.1 ± 8.4	< 0.05
Radiation exposure (μSv) ^a	32 ± 39	64 ± 55	< 0.001
Percutaneous intervention (n)	48	54	
Fluoroscopy time (min)	10.4 ± 6.8	11.4 ± 8.4	NS
Dose-area product (Gy · cm ²)	51.0 ± 29.4	46.3 ± 28.7	NS
Radiation exposure (μSv) ^a	110 ± 115	166 ± 188	< 0.05

- Potential for increased radiation exposure both to patient and operator
- Close attention to techniques and precautions for minimizing exposure needed

Radial Artery Occlusion

- Incidence post TRA:
 - 5% based on clinical diagnosis
 - 9% based on ultrasonography
- Risk of RAO independently associated with
 - sheath/artery ratio > 1
 - Lack of peri-procedural anticoagulation
- Hand ischemia rare, but RAO has implications for:
 - access for subsequent coronary angiography
 - future use of radial artery as graft for CABG or fistula for HD

Patent Hemostasis Reduces RAO

- PROPHET: 436 patients randomized to:
 - Conventional Hemostasis
 - ☹ Hemoband applied with immediate sheath removal
 - ☹ Band removed after 2 hrs
 - ☹ Radial patency was checked using Barbeau's test but pressure not adjusted (43% were occlusive)
 - Patent Hemostasis
 - ☹ Pulse oximeter sensor applied to index finger
 - ☹ Ulnar artery occluded with manual pressure
 - ☹ Hemoband applied as above, loosened until signal returned → confirms radial patent
 - ☹ Band removed after 2 hrs as above

Learning Curve

媿 Trans-radial approach perceived as more difficult to learn than trans-femoral

- Small sized vessel
- Prone to spasm
- Higher percentage of anatomic variation
- Can be difficult to transverse the subclavian and aortic arch

Learning Curve

Early studies report failure rates of:

- First 50 cases: around 10%
- First 500 cases: 3-4%
- After 1000 cases: approx 1%

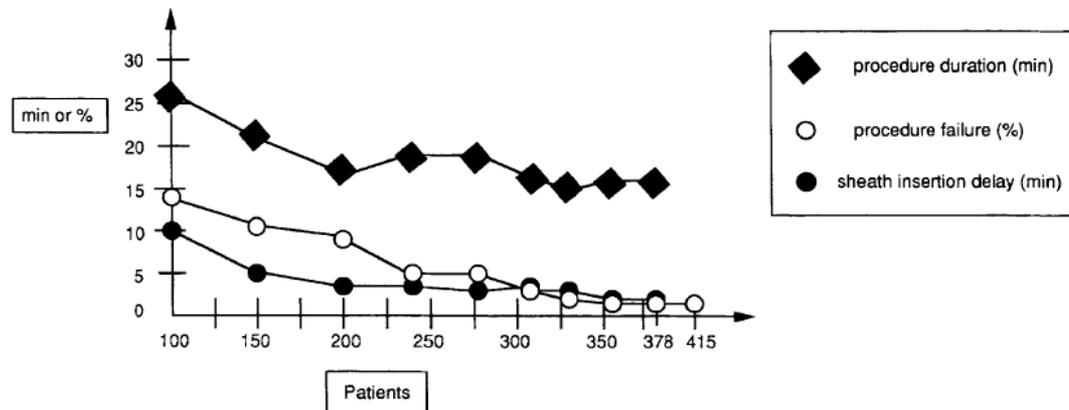
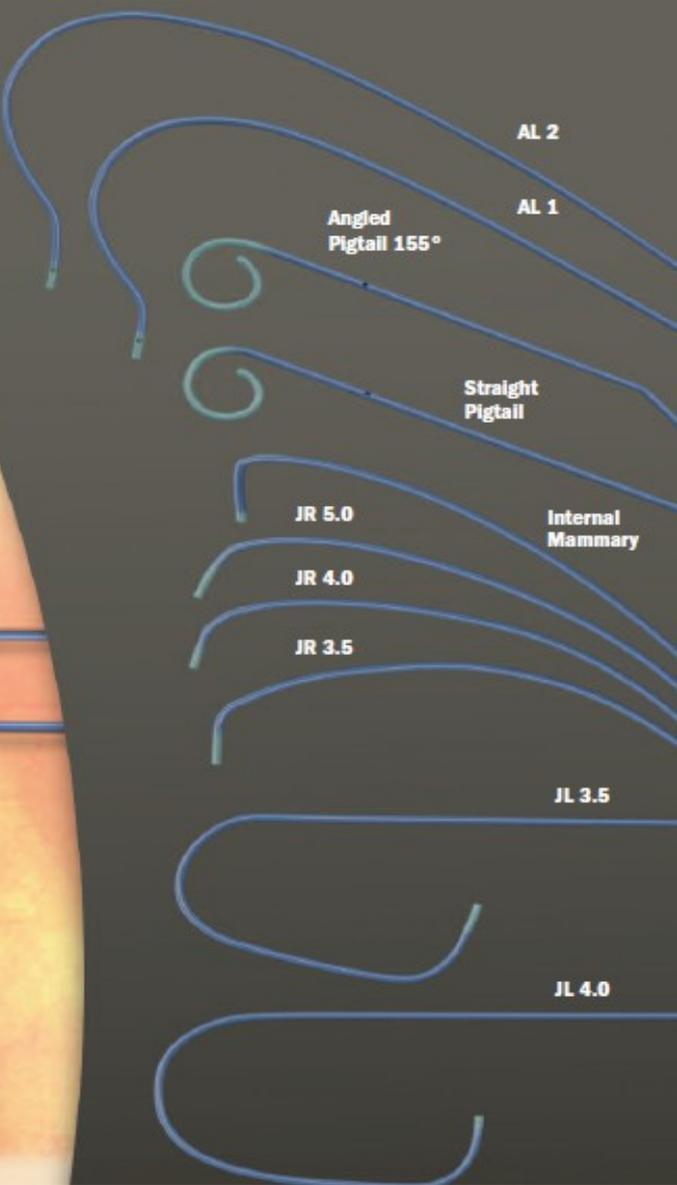
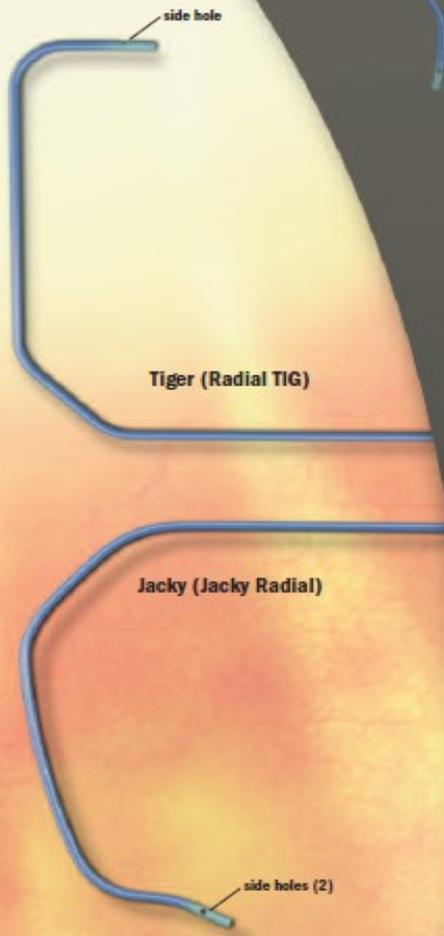


Fig. 5. Learning curve procedure failure rate, sheath insertion delay, and procedure duration.

Catheters

Featuring Terumo's Exclusive Tiger and Jacky Shapes

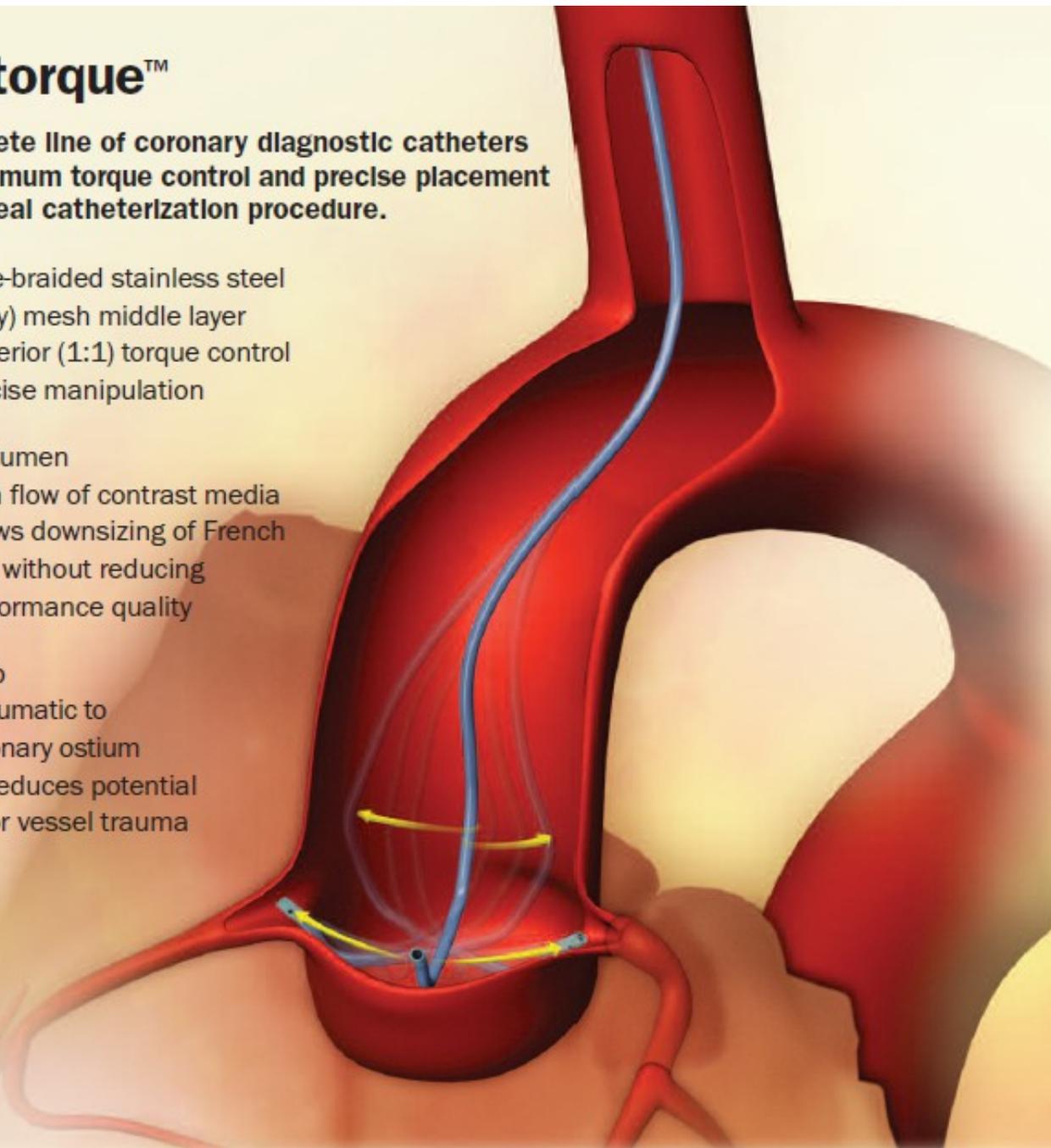
- Enables angiography of both RCA and LCA with one catheter
- Eliminates catheter exchange step
- Shortens procedure and fluoroscopic time
- Engages with simple clockwise and counterclockwise rotation
- Enhances ease of use
- Two unique shapes specially designed for right transradial approach
- Tiger shape, with straight distal soft tip
- Jacky shape, with outward distal soft tip
- Tiger and Jacky shapes are available in two sizes for various anatomy



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- Soft tip
 - Atraumatic to coronary ostium
 - Reduces potential for vessel trauma



Transradial benefits

媿 Reduces the risk of bleeding complications, swelling and back pain, especially in women, obese patients, elderly patients and those with peripheral vascular disease (PVD)

媿 Has better first-time success rates for accessing arteries in obese patients and patients with PVD

媿 Improves patient outcomes and overall experiences

媿 Enables patients to be mobile almost immediately after the procedure

媿 Shorter hospital stay

Summary

- Trans-radial PCI is a safe and effective alternative to the trans-femoral approach, both for elective and emergent cases
- Associated with reduction in bleeding complications and need for transfusion
- High success rates after initial learning curve period

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