

### Which is better route for PCI: Transradial/Transfemoral??

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# Historical Perspective of Trans-radial angiography

- 1948: First attempted transradial coronary angiogram using radial cut-down
  - 8-10 F catheters: too big for the radial artery!
- 1989: Campeau reported first 100 cases of percutaneous transradial coronary angiogram
- 1993: First transradial coronary angioplasty with stent implantation performed - Dr. Kiemeneij (Amsterdam, Netherlands)
  - Performed using 6F guide catheter

# TRANS FEMORAL ROUTE

- Gold standard
- Easy to perform
- Less radiation
- Fluoroscopy time is less

# **Femoral Complications**

- Hematoma (2.6-6%).
- Retroperitoneal hematoma (0.15-0.5%)
- Pseudoaneurysm (0.1-1.5%)
- AV fistulae (0.2-2.1%)
- Arterial dissection (0.01-0.4%).
- Arterial thrombosis(<0.5%).



#### **Incidence of Major Bleeding Post-PCI (Femoral)**

#### • Mayo clinic PCI database 1994-2005



#### Doyle et al, JACC Interventions 2008 ; 1: 202-9

# Bleeding/Blood transfusions associated with increase risk of mortality, recurrent MI and stroke

Table 1         Studies of the impact of Major Bleeding on Mortality Ifter PCI							
Author/Study (Ref. #)	Patients (n)	Patient Population	STEMI Included?	Definition	Frequency of Bloo Transfusion (%)	d 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	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 [1.18-228]	<0.0001
Yatskar et al. (8)	6,656	Unselected	Yes	Protocol†	1.8	In-hospital adjusted OR: 3.59 [1.66-7.77]	0.001
						1-year adjusted HD: 1.05 [1.01-2.70]	0.048
Table 2         Studies of the Impact of Blood Transfusion on Mortality After PCI							
Author (Ref. #)	Patients (n)	Patient Population	STEMI Included?	Frequen Transf	cy of Blood usion (%)	Impact of Transfusion on Mortality [95% Confidence Interval]	p Value
Jani et al. (12)	4,623	Anemic patients with MI	Yes	2	22.3 In-bo	spital, adjusted OR: 2.02 [1.47-2.79]	<0.0001
Doyle et al. (6)	17,901	Unselected	Yes		6.8 30 d 3+ L	ays, 1–2 U adjusted HR: 8.9 [6.3–12.6] J adjusted HR: 18.1 [13.7–24]	<0.0001 <0.0001
Kinnaird et al. (1)	10,974	Unselected	Yes		5.4 1 vea	ar, OR per unit transfused: 1.47 [1.36-1.55]	<0.0001
Kim et al. (5)*	567*	Severe bleeding	Yes	2	25.7 <b>1</b> vea	ar, RR: 2.03	0.0028
Chase et al. (13)	38,872	Unselected	Yes		3.5 30-d	v adjusted OR: 4.01 [3.08-5.22]	<0.0001

1-year adjusted OR: 3.58 [2.94-4.36

< 0.0001

 Hence, the need has evolved to develop an alternative to the femoral technique which is also patient friendly

#### Why Not Brachial ?

- An end artery : unforgiving of occlusion
- More mobile
- Compression cumbersome
- Upper extremity needs prolonged immobilization & observation



#### Now trans radial is expanding universally for as many patients as possible

 European Society of Cardiology: "Transradial Access Should Be 1st Choice for Angioplasty" EuroIntervention 2013;8:1242-1251

### Rationale for use of TRA

# Radial artery Ulna artery Interosseous artery

- Advantages :
  - Homeostasis easy to achieve
  - Reduced risk of bleeding
  - No major nerves or veins located rice and
  - Extensive palmar collaterals
  - Improved patient comfort and convenience
  - Immediate ambulation
  - Reduced inpatient time and cost, faster turnover of beds
  - Low workload of nursing staff, reducing cost.

### **Radial Access**



### **Radial Access Advantages**

- Very low risk of bleeding or pseudoaneurysm.
- No ischemic complications in case of occlusion if the palmar arc is permeable.
- Very low risk of arteriovenous fistula or nerve damage.
- Hemostasis is simpler.
- Save staff time and labor (sheath manipulation and groin monitorization).
- Save on costs and complications of vascular closure devices.

# Radial PCI one week after femoral primary PCI



Technically more demanding

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

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

With better operator experience, most problems can be circumvented

### **Complex anatomy**



### Radial spasm







#### Possible concerns of TRA

 Increase radiation exposure : especially due to increased procedure times early on

Radial artery occlusion

Use of RA for subsequently CABG

#### **? Increase radiation exposure**

#### **TABLE II. Fluoroscopy Time and Radiation Measurements**

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

- Potential for increased radiation exposure both to patient and operator
- In experienced hands, no difference in procedure time/radiation exposure in TR vs TF approaches

Lange et al, CCI 2006; 67: 12-16

### **Radial Artery Occlusion**

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

#### **Right or Left Radial Artery**

#### Usually prefers right radial

- Same side of the table
- Easier to access ascending aorta
- For CABG Surgeons use the left radial first

#### Left radial preferred in

- Descending Aortogram using a pigtail catheter
- Selective cannulation of Renal arteries
   ( with longer catheters) eg. Renal angioplasty

### **Radial Access Drawbacks**

- Negative Allen's risk(<10%) ???</p>
- Spasm (mainly in very tiny arteries).
- Difficult guide management (subclavian, brachiocephalic trunk curves....).
- Respiratory induced guide deplacement.
- Femoral area is used anyway if IABP or temporary PM is needed.

# **Grateful Post-procedure**

Immediate withdrawal of introducer (regardless of anticoagulation / antiplatelet).









#### **Interventional Cardiology**

Adoption of Radial Access and Comparison of Outcomes to Femoral Access in Percutaneous Coronary Intervention An Updated Report from the National Cardiovascular Data Registry (2007–2012)

Dmitriy N. Feldman, MD; Rajesh V. Swaminathan, MD; Lisa A. Kaltenbach, MS; Dmitri V. Baklanov, MD; Luke K. Kim, MD; S. Chiu Wong, MD; Robert M. Minutello, MD; John C. Messenger, MD; Issam Moussa, MD; Kirk N. Garratt, MD; Robert N. Piana, MD; William B. Hillegass, MD; Mauricio G. Cohen, MD; Ian C. Gilchrist, MD; Sunil V. Rao, MD

#### Trends of use of r-PCI over time



20

The proportion of r-PCI procedures accounted for 6.33% of total procedures (n=178,643), increasing from 1.18% in the 1<sup>st</sup> quarter of 2007 to 16.07% in the 3<sup>rd</sup> quarter of 2012 (*P*<0.01).

2012 - Ott

2012 - Qtr



Figure 3. Trend in the use of r-PCI over time in the overall data set and key subgroups. Trend in the use of r-PCI over time in the overall

### **Outcomes in PCI**



**Figure 5.** Unadjusted rates of the primary outcomes of r-PCI and f-PCI. Unadjusted rates of procedure success, vascular complications, and bleeding complications between the r-PCI and the f-PCI. f-PCI indicates femoral approach to percutaneous coronary intervention; and r-PCI, radial approach to percutaneous coronary intervention.

Trials comparing transradial versus transfemoral approach

#### **STEMI-RADIAL**

#### A PROSPECTIVE RANDOMIZED TRIAL OF RADIAL VS. FEMORAL ACCESS IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

<u>I Bernat</u>, D Horak, J Stasek, M Mates, P Ostadal, J Pesek, V Hrabos, J Dusek, J Koza, Z Sembera, M Brtko, O Aschermann, M Smid, P Polansky, AA Mawiri, J Bis, J Vojacek,

O Costerousse, OF Bertrand, R Rokyta

University Hospital and Faculty of Medicine Pilsen, Regional Hospital Liberec, University Hospital Hradec Kralove, Na Homolce Hospital Prague, Université Laval Quebec. Czech Republic, Canada (ClinicalTrials.gov. NCT 00136187)

### STEMI-RADIAL - objectives

To compare radial vs femoral approach in

primary PCI for patients with STEMI < 12 hours

in very high volume radial centers

> 80% radial primary PCI

# **STEMI-RADIAL end-points**

- Primary
- HORIZONS-AMI bleeding and access site complication \*
- Secondary
- MACE (death, MI, stroke)
- NACE
  - crossover
  - angiographic success
  - contrast volume
  - procedural and fluoroscopic times
  - ICU stay

\* Hematoma ≥15cm

#### **STEMI RADIAL - results** 30-day bleeding and access site compl.



Bleeding and acess site complication is significantly less.

#### **STEMI RADIAL - results**

#### 30-day MACE



**MACE** = composite of death, myocardial infarction and stroke

### STEMI RADIAL - results 30-day NACE



Net Adverse Clinical Event (*NACE*) = MACE + major bleeding MACE = composite of death, myocardial infarction and stroke

### Conclusion

- In patients with STEMI <12 hrs, radial approach was associated with a significant lower incidence of major bleeding and access site complications and a significant better net clinical benefit.
- Moreover radial approach reduced significantly ICU stay and contrast volume compared to femoral approach.
- Our results support the use of radial approach in primary PCI in high volume centers as a first choice.

A RANDOMIZED COMPARISON OF RADIAL VS. FEMORAL ACCESS FOR CORONARY INTERVENTION IN ACS (RIVAL)

> SS Jolly, S Yusuf, J Cairns, K Niemela, D Xavier, P Widimsky, A Budaj, M Niemela, V Valentin, BS Lewis, A Avezum, PG Steg, SV Rao, P Gao, R Afzal, CD Joyner, S Chrolavicius, SR Mehta on behalf of the RIVAL investigators

### **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)



**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.

#### **Other Outcomes**

	Radial (n=3507) %	Femoral (n=3514) %	HR	95% CI	Р
Major Vascular Access Site Complications	1.4	3.7	0.37	0.27-0.52	<0.0001
Other Definitions of M	lajor Ble	eding			
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	Ρ
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)	Р
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

#### 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

**RADIAL VERSUS FEMORAL RANDOMIZED INVESTIGATION IN ST ELEVATION ACUTE CORONARY SYNDROME THE RIFLE STEACS STUDY** Enrico Romagnoli, MD PhD

> Principal investigators: Enrico Romagnoli, MD PhD Giuseppe Biondi-Zoccai, MD Giuseppe Sangiorgi, MD

### **RIFLE STEACS – end-points**

- Net adverse clinical events (NACE) at 30 days, defined as the composite of cardiac death, myocardial infarction (MI), target lesion revascularization, stroke, or non-coronary artery bypass graft (non-CABG)-related bleeding.
- Non CABG-related bleeding at 30 days (corresponding to type 2, type 3 and type 5 of BARC classification).

### **RIFLE STEACS - flow chart**

#### Design

#### • DESIGN:

Prospective, randomized (1:1), parallel group, multi-center trial.

- INCLUSION CRITERIA: all ST Elevation Myocardial infarction (STEMI) eligible for primary percutaneous coronary intervention.
- ESCLUSION CRITERIA: contraindication to any of both percutaneous arterial access.

international normalized ratio (INR) > 2.0.

1001 patients enrolled between January 2009 and July 2011 in 4 clinical sites in Italy



Intention-to-treat analysis



#### **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 bleeding rate**



### **RIFLE STEACS - conclusions**



- Radial access in patients with STEMI is associated with significant clinical benefit, in terms of both bleeding and cardiac mortality.
- Radial approach should thus no more be considered a valid alternative to femoral one, but become the recommended access site for STEMI.

## **BIFURCATION LESIONS**

#### Abstract 16588: Comparison of Radial versus Femoral Approach in Patients With Coronary Bifurcation Lesions Treated With Percutaneous Coronary Intervention

Mi youn Park, Jong Min Lee, Ki-Bae Seung, Suk Min Seo, Eun Ho Choo, Tae Hoon Kim, Yoon-Seok Koh, Chan Joon Kim, Hun Jun Park, Sang-Hyun Ihm, Pum Joon Kim, Kiyuk Chang, Wook Sung Chung, Hyun chul Kwon, Hyo Soo Kim, Myung Ho Jeong, Yang Soo Jang, and Seung Jung ParkUijeongbu St. Mary's Hosp, Uijeongbu, Korea, Republic of; Catholic Med Cntr, Seoul, Korea, Republic of; Samsung Med Cntr, Seoul, Korea, Republic of; Seoul National Univ, Seoul, Korea, Republic of; Chonnam National Univ, Gwangju, Korea, Republic of; Yonsei Med Cntr, Seoul, Korea, Republic of; Asan Med Cntr, Seoul, Korea, Republic of

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#### Abstract

Background: Transradial approach has been increasingly used as an alternative to femoral access. However there is limited data comparing these two approaches in coronary bifurcation lesions.

**Methods:** 1691 Patients who received percutaneous coronary intervention (PCI) for non-left main bifurcation lesions were enrolled from 16 centers in Korea between January 2004 and June 2006. According to operator choice, femoral access was utilized in 1173 patients (69.4%) and radial access in 518 patients (30.6%). We compared procedural success rate and major cardiac adverse events including death, myocardial infarction and unplanned revascularization.

**Results:** There is no significant difference in procedural success rate of main branch stenting (femoral vs. radial: 98.6 % vs. 99.6 %, p=0.076) and side branch stenting (66.4 % vs. 62.2 %, p=0.097). Over median 671 days, transradial approach is not associated with higher occurrence rate of major cardiac adverse events compared to femoral approach (Table).

Conclusions: Transradial approach may be an effective and safe alternative in treatment of coronary bifurcation lesions.

### CTO

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#### CORONARY ARTERY DISEASE

#### Short- and Long-Term Follow-up of Percutaneous Coronary Intervention for Chronic Total Occlusion through Transradial Approach: Tips for Successful Procedure from a Single-Center Experience

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**Background:** There are limited data regarding transradial percutaneous coronary intervention (PCI) for chronic total occlusion (CTO).

**Objective:** To assess the feasibility and safety of transradial coronary intervention (TRI) for CTO lesions, we analyzed our experience in PCI treatment of CTO lesion through transradial approach for the past 6 years. **Methods:** From January 2003 to May 2009, among 134 CTO lesions, on which we performed PCI, 120 lesions were performed from transradial approach.

**Results:** Technical success for transradial CTO was 80%. Complication of access bleeding was zero. The most commonly selected guiding wire was Wave 3 for right coronary artery (RCA) lesions (82%) and Voda left for Left Coronary Artery (LCA) lesions (91%). The average number of wires used during procedure was  $2.2 \pm 0.8$ . Tapered wire was used in 8% of the cases, Rotablator was performed in 4.1% of cases, and Tornus catheter was performed in 12.5% of cases. The mean procedure time was  $83 \pm 39$  minutes. The mean volume of contrast medium used was  $228 \pm 92$  mL. There were two coronary artery perforations during procedure and one in-hospital cardiac death. Patients were followed up for  $36 \pm 21$  months; restenosis rate was 19.5%–26.7% for bare metal stent (BMS) and 9.8% for drug-eluting stents (DES). Overall major adverse cardiac events (MACE) rate was 11.7%.

Conclusion: It was demonstrated that transradial PCI for CTO lesions is safe, minimizing vascular complications without increasing procedural time and contrast use. (J Interven Cardiol 2011;24:137–143)

# Radial Approach and Bleeding and Vascular Complications

Radial artery-

- ✓ Superficial.
- ✓ Smaller caliber.
- Lacks an important structure or potential spaces (such as retroperitoneal space)
- ✓ Easily compressible.
- Observational and smaller randomized trials have found a significant reduction in the rate of major bleeding and major vascular access site complications with radial compared with femoral access in patients undergoing PCI, even when femoral vascular closure devices are used.

#### Radial Approach and Nonbleeding Outcomes

 Patient preference for Radial PCI, results in certain patient groups, access site crossover, and costs.

 In the RIVAL trial, 90% of patients assigned to radial access preferred it for their next procedure compared with only 49% of patients assigned to femoral who preferred femoral access for a subsequent procedure (p < 0.0001).</li>

#### Does the Evidence Support a Radial First, Femoral as Bailout Approach?

- Deciding between 2 therapeutic strategies involves weighing the risks and benefits of each.
- Although the default vascular access for PCI has traditionally been via the femoral artery, the bulk of evidence calls for a re-evaluation of this dogma.
- PCI-related bleeding and vascular complications are associated with increased morbidity, mortality, and costs.
- Evidence shows that radial approach is safer, preferred by patients, associated with reduced mortality in primary PCI, and is associated with lower hospital costs.

#### **Negotiating to the Ascending Aorta**

- In typical patients, the iliac system provides little if any impediment to access the aorta.
- Traversing the arm requires skill in overcoming obstacles that are rare in the iliac- spasm; intrinsically small vessel size; blind alleys such as accessory radial branches, severe tortuosity, and complete loops; entry into small side branches that can result in perforation and compartment syndrome.

#### How often is each of these factors responsible for failure to reach the ascending aorta?

Data from a subset of 3,190 patients in the RIVAL trial included <u>failure of TRA</u> due to <u>radial spasm</u> in 5.0%, <u>radial artery loop</u> in 1.3%, and <u>subclavian</u> <u>tortuosity in 1.9%</u>. By contrast, iliac tortuosity accounted for failure in only 0.6% of patients, as did peripheral vascular disease in the femoral cohort.

### The TRA Learning Curve

- A learning curve refers to the ability of operators to gain proficiency as they repeatedly perform a certain task.
- It is obvious that such a curve would exist for both TFA and TRA; with the learning curve for TRA being higher than TFA.
- Ball et al. recently studied this issue in a rigorous fashion among 28 operators performing the first 1,628 PCI procedures by TRA at their institutions and concluded that a case volume of at least 50 PCIs is required to achieve proficiency similar to that of experienced operators (>300 cases).

#### **MANAGEMENT OF THE LEARNING CURVE**

- To start with, it is suggested that one use 5 Fr sheaths and catheters for diagnostic procedures and then move to 5 or 6 Fr for easy angioplasties.
- After the first 50 cases, the feasibility of radial and femoral access procedures should equalise.
- It is essential to assess progress by monitoring procedural success rate, duration and X-ray doses.



#### Figure 1 Proposed Algorithm for Arterial Access in Patients Undergoing PCI

Procedures performed with hemodynamic support devices require concomitant femoral arterial access. Procedural complications that require treatment with a covered stent, for example, coronary perforation, will require bailout femoral arterial access in order to use large-bore guiding catheters that can accommodate the device. PCI = percutaneous coronary intervention.

Sunil V. Rao, MD, Zoltan G. Turi, MD et al; Radial Versus Femoral Access; JACC Vol. 62, No. 17, Suppl S, 2013October 22, 2013:S11–S20

## Conclusions

- The femoral and radial accesses are two equally valid options. Operator experience is the deciding factor for choosing one approach or other. Radial learning curve steeper.
- Bleeding complications are lower with transradial access. (at the expense of failed accesses rate slightly higher -switch).
- Radial access in patients with STEMI is associated with significant clinical benefits, in terms of both lower morbidity and cardiac mortality. Thus, it should become the recommended approach in these patients, provided adequate operator and center expertise is present.
- The hospitalization time was significantly lower with radial access, and the total procedure time also.
- Complex procedures (tortuosity, IABP, CTOs, etc..): Femoral required.

# CHANGE IS THE ONLY CONSTANT



## TAKE HOME MESSAGE

 In nearby future transradial PCI will replace transfemoral PCI
 More cost effective then femoral route

• Low workload for nursing staff

THANKS