

Distal radial approach in coronary intervention

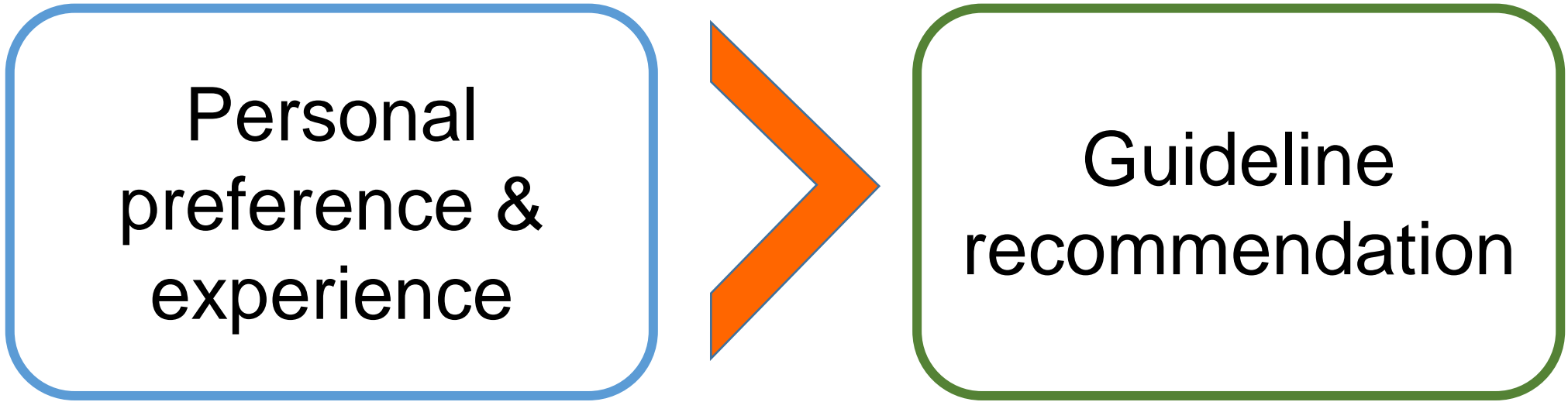
: default or alternative?

Jun-Won Lee

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Yonsei University Wonju College of Medicine

What 'default' means?

The 'default' is usually the setting that **most users** would probably choose.



Personal
preference &
experience

The diagram consists of two rounded rectangular boxes. The left box has a blue border and contains the text 'Personal preference & experience'. An orange arrow points from this box to the right box. The right box has a green border and contains the text 'Guideline recommendation'.

Guideline
recommendation

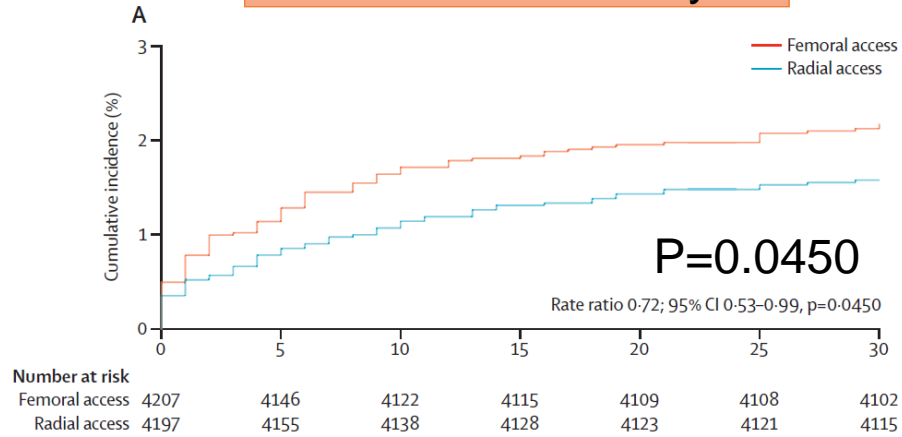
TRI for STEMI

Table 1. Recent Studies Demonstrating Reduced Bleeding and Mortality With TRI for STEMI

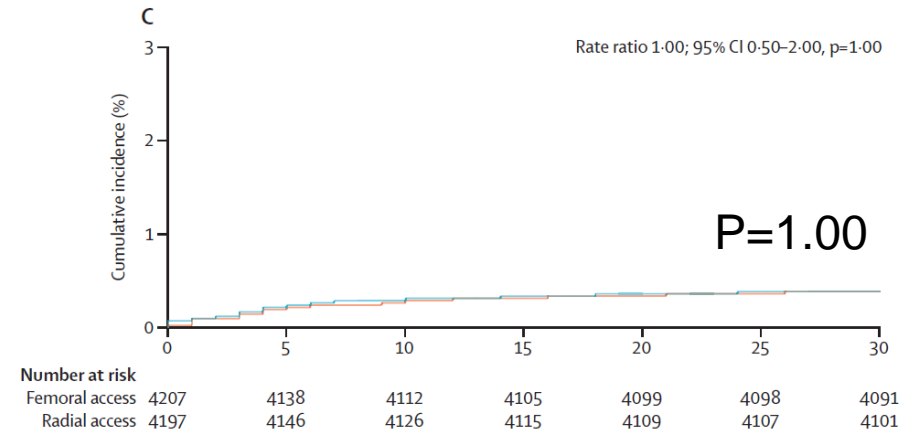
First Author (Ref. #)	Year	Study Type	Sample Size	Bleeding ORs TR vs. TF	Mortality ORs TR vs. TF	NNT to Prevent 1 Bleeding Event	NNT to Prevent 1 Death
Mehta et al. (10)	2012	Multicenter RCT; STEMI subgroup	1,958	0.49 (0.28–0.84)	0.39 (0.20–0.76)	48	52
Romagnoli et al. (11)	2012	Multicenter RCT	1,001	0.64 (0.44–0.94)	0.57 (0.36–0.90)	23	25
Jang et al. (9)	2012	Meta-analysis of 21 studies	8,534	0.32 (0.22–0.48)	0.55 (0.42–0.72)	65	53
Joyal et al. (12)	2012	Meta-analysis of 10 RCTs	3,347	0.63 (0.35–1.12)	0.53 (0.33–0.84)	NA	61
Baklanov et al. (3)	2013	Observational	90,879	0.62 (0.53–0.72)	0.76 (0.57–0.99)	25	207

MATRIX trial

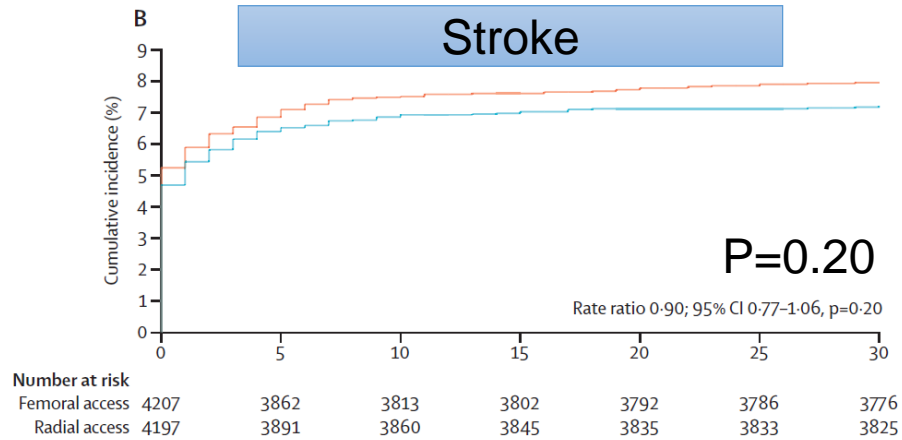
All cause mortality



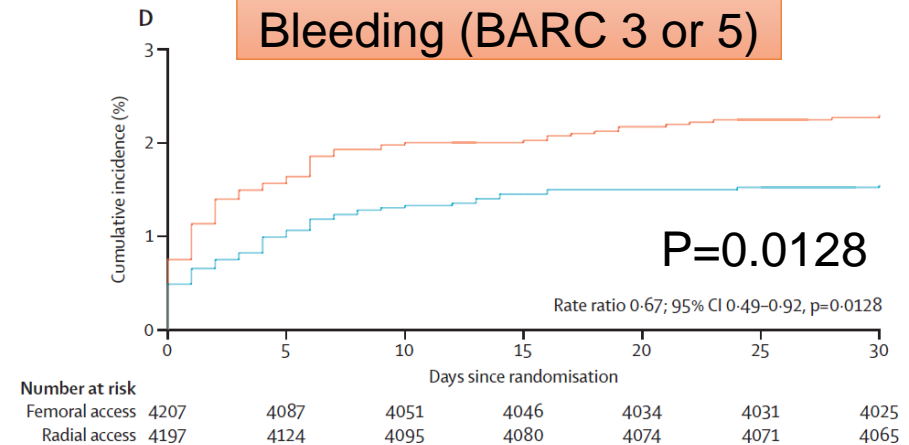
Myocardial infarction



Stroke



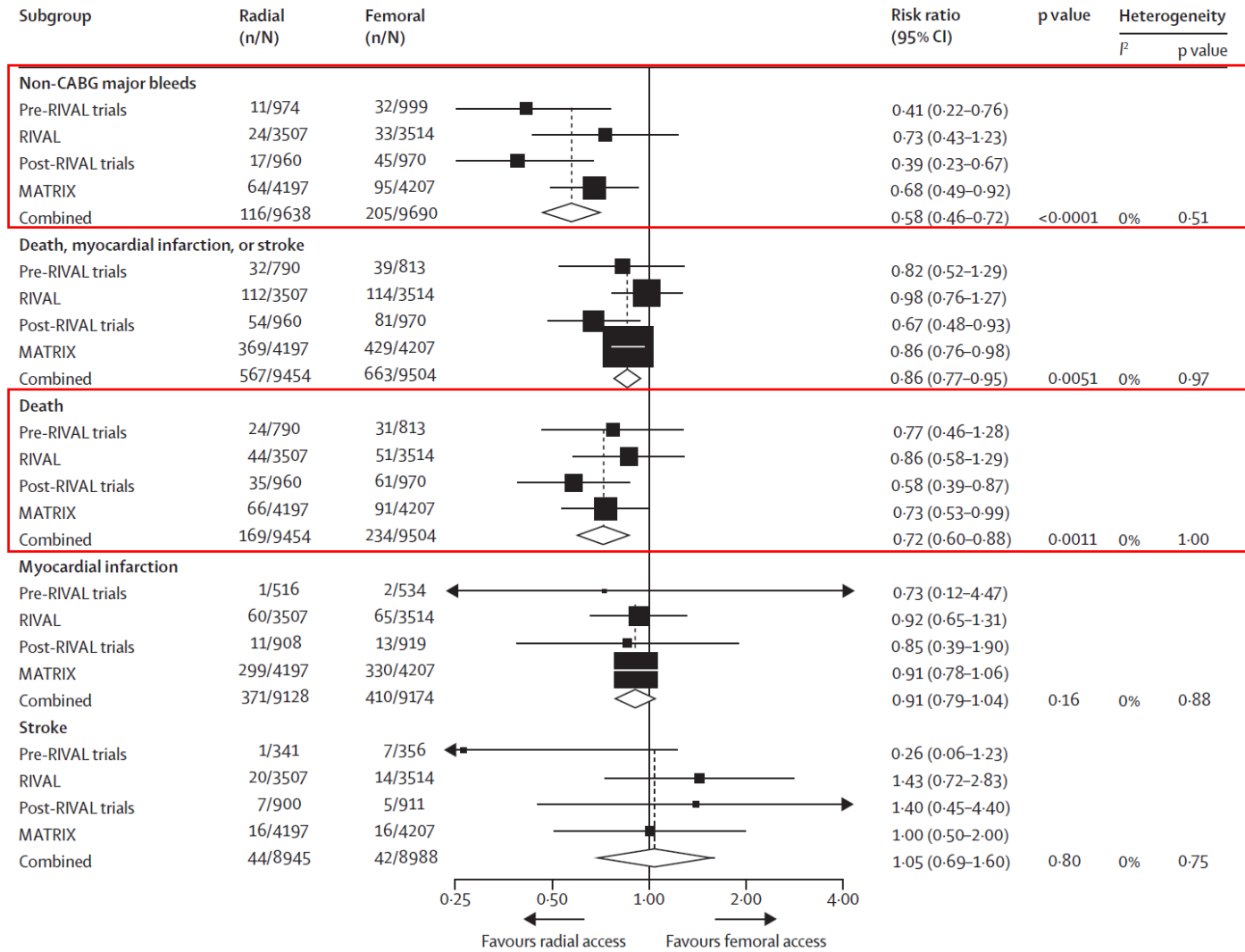
Bleeding (BARC 3 or 5)



MATRIX trial

	Radial access (n=4197)	Femoral access (n=4207)	Rate ratio (95% CI)	p value
Bleeding	350 (8.4%)	606 (14.6%)	0.55 (0.48-0.63)	<0.0001
BARC classification				
Type 1	168 (4.0%)	306 (7.4%)	0.54 (0.44-0.65)	<0.0001
Type 2	127 (3.1%)	215 (5.2%)	0.58 (0.47-0.73)	<0.0001
Type 3	54 (1.3%)	84 (2.1%)	0.64 (0.45-0.90)	0.0098
Type 3a	29 (0.7%)	44 (1.1%)	0.66 (0.41-1.05)	0.08
Type 3b	23 (0.6%)	37 (0.9%)	0.62 (0.37-1.04)	0.07
Type 3c	2 (0.0%)	4 (0.1%)	0.50 (0.09-2.72)	0.41
Type 4	6 (0.1%)	6 (0.1%)	1.00 (0.32-3.10)	1.00
Type 5	10 (0.2%)	11 (0.3%)	0.91 (0.39-2.14)	0.82
Type 5a	6 (0.1%)	9 (0.2%)	0.67 (0.24-1.87)	0.44
Type 5b	4 (0.1%)	2 (0.0%)	2.00 (0.37-10.92)	0.41
Type 3 or 5	64 (1.6%)	95 (2.3%)	0.67 (0.49-0.92)	0.0128
Related to access site	16 (0.4%)	43 (1.1%)	0.37 (0.21-0.66)	0.0004
Not related to access site	48 (1.2%)	52 (1.3%)	0.92 (0.62-1.36)	0.68
Type 2, 3, or 5	189 (4.6%)	307 (7.4%)	0.60 (0.50-0.73)	<0.0001
Related to access site	69 (1.7%)	197 (4.8%)	0.34 (0.26-0.45)	<0.0001
Not related to access site	121 (2.9%)	115 (2.8%)	1.05 (0.81-1.36)	0.70

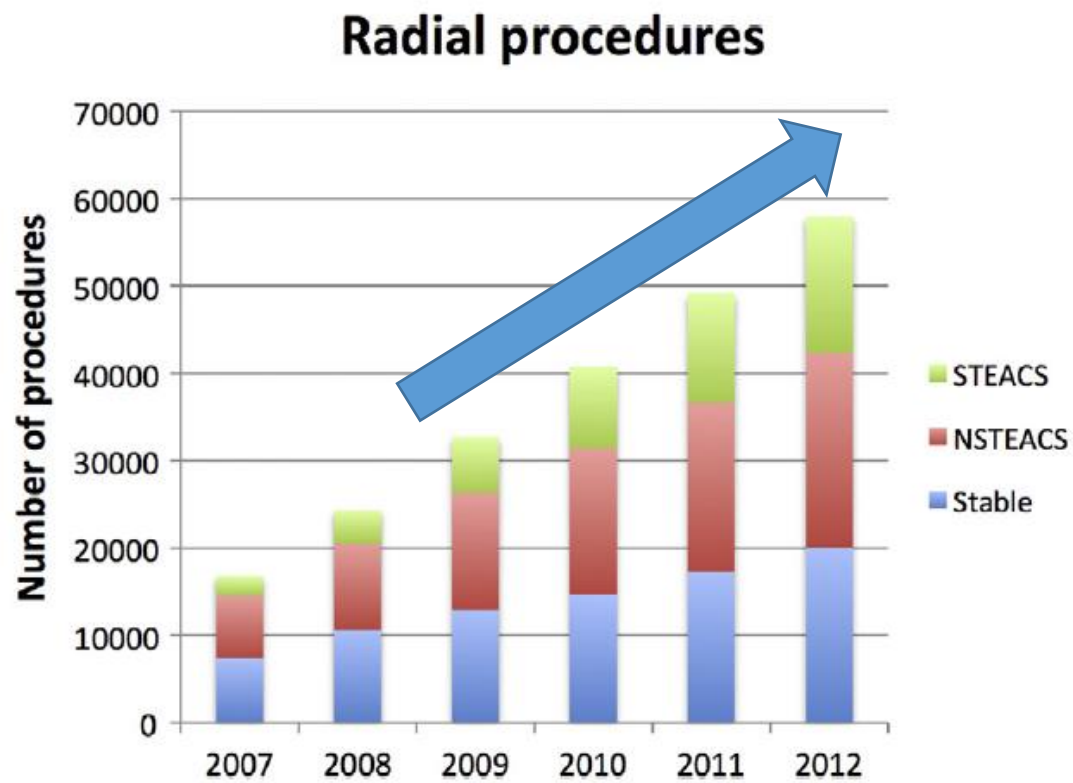
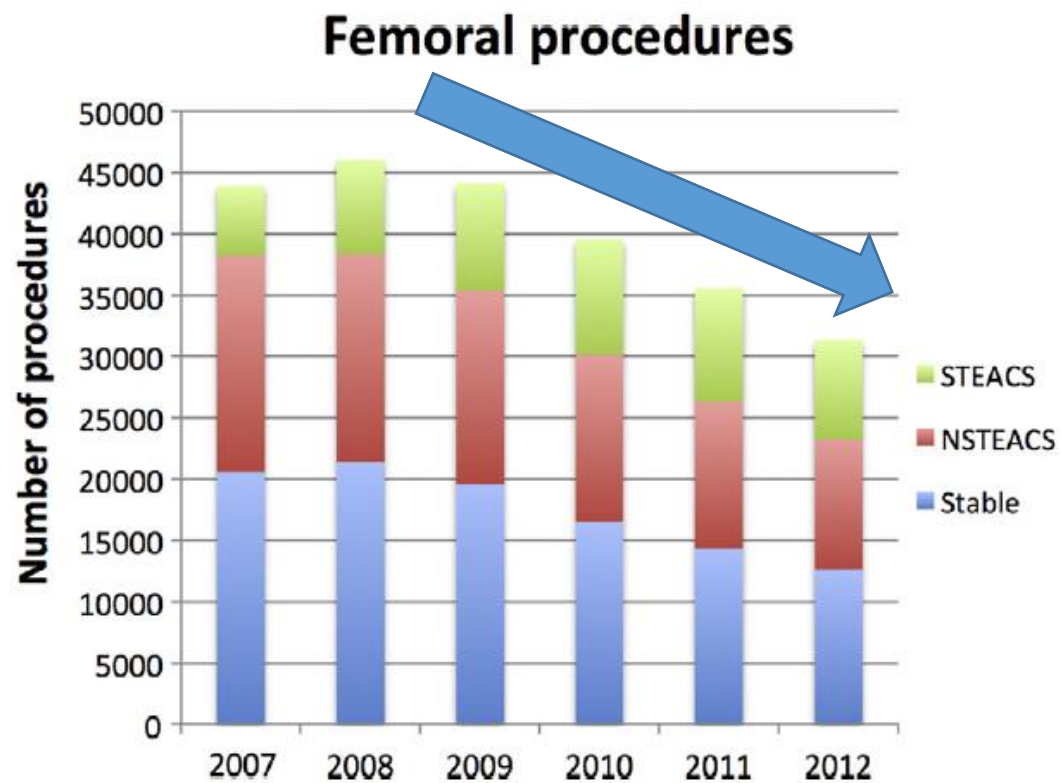
Meta-analysis



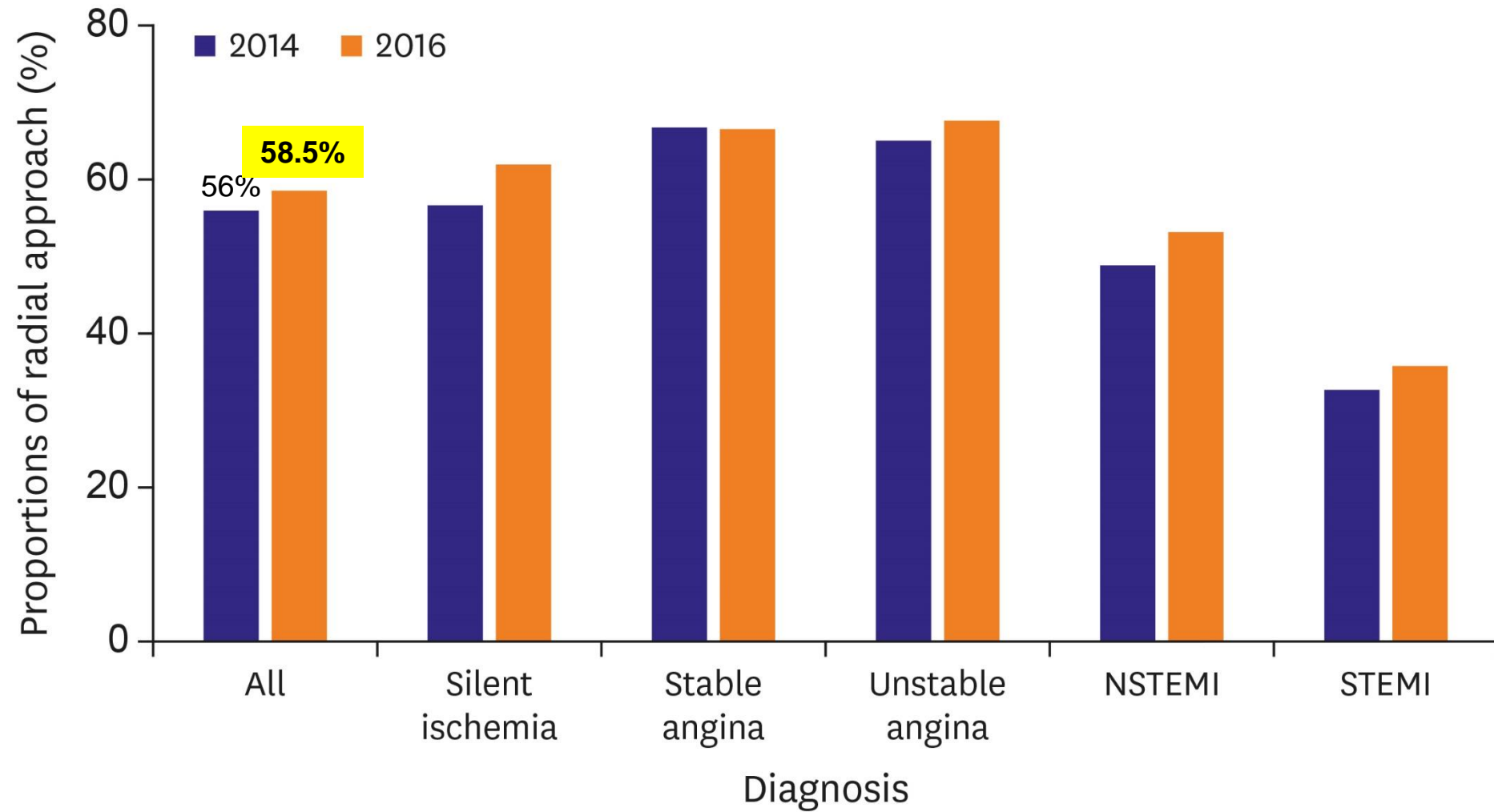
Default vascular access

Recommendation	Class	Level
2017 ESC STEMI guideline		
Radial access is recommended over femoral access if performed by experience radial operator.	I	A
2018 ESC guideline on myocardial revascularization		
Radial access is recommended as the standard approach , unless there are overriding procedural considerations .	I	A

Use of access site in UK

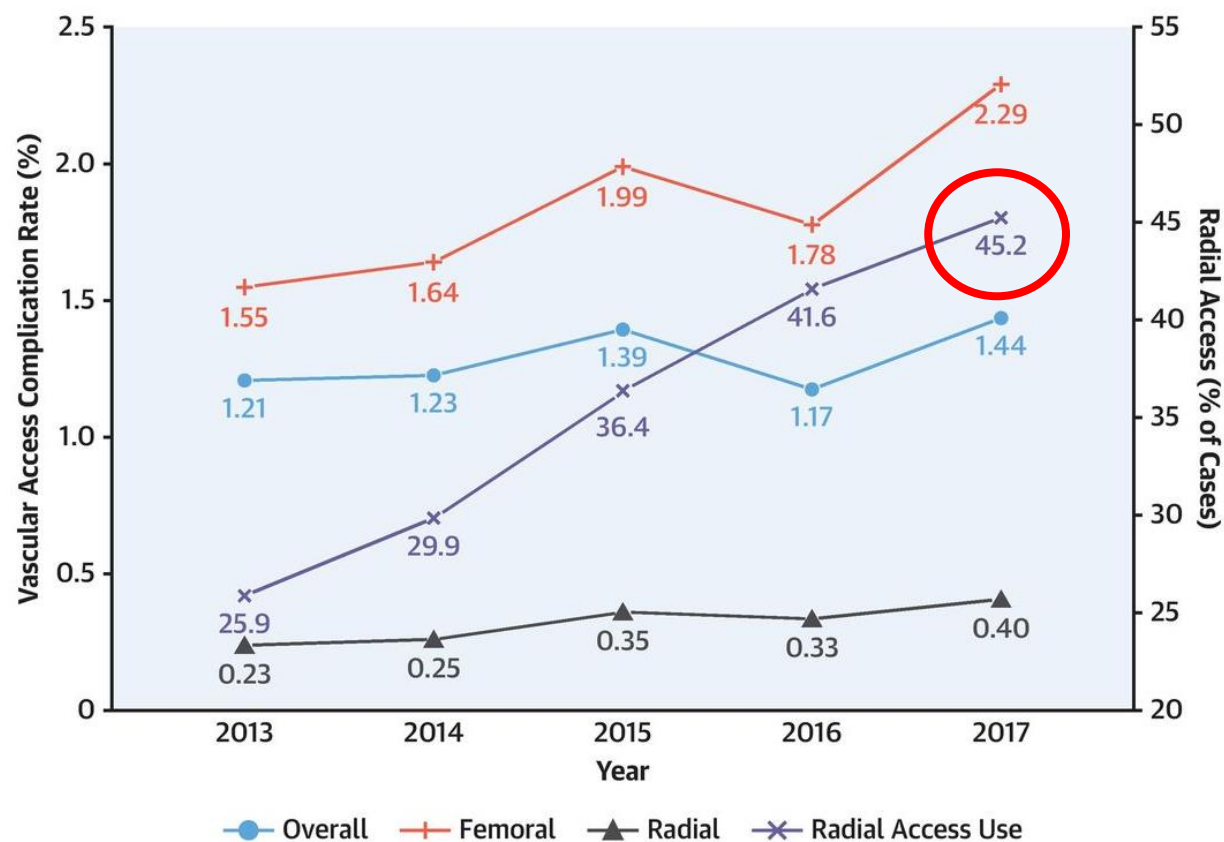


K-PCI registry (radial access rate)



Radial access use in Michigan

CENTRAL ILLUSTRATION: Annual Rates of Transradial Percutaneous Coronary Intervention and Complications Stratified by Primary Vascular Access Site

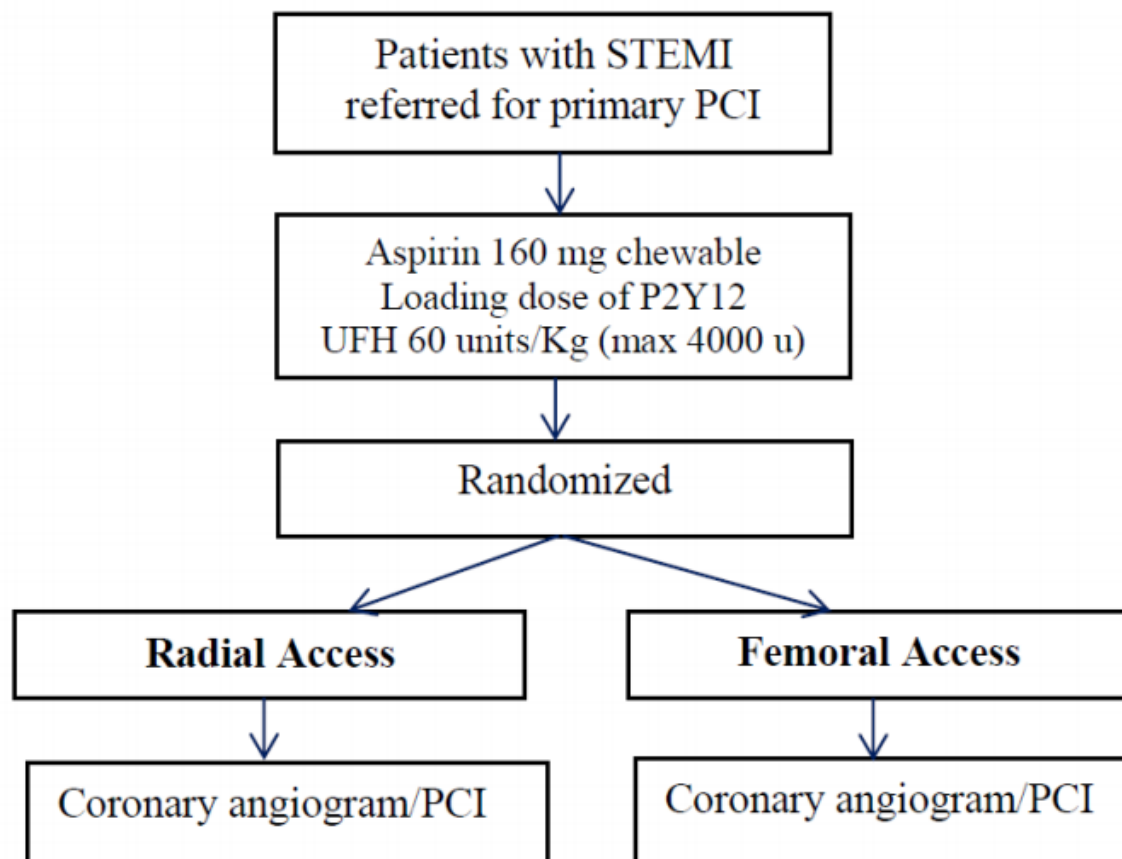


Consideration for default route

STEMI, Multivessel disease, CTO,
Unprotected left main, Calcified lesion

Procedure-related	Patient-related
Operator comfortable	Safety - Bleeding
Operator confident	Efficacy - Mortality

SAFARI-STEMI trial



Primary outcome:

- all-cause mortality measured at 30 days

Key secondary outcomes at 30 days:

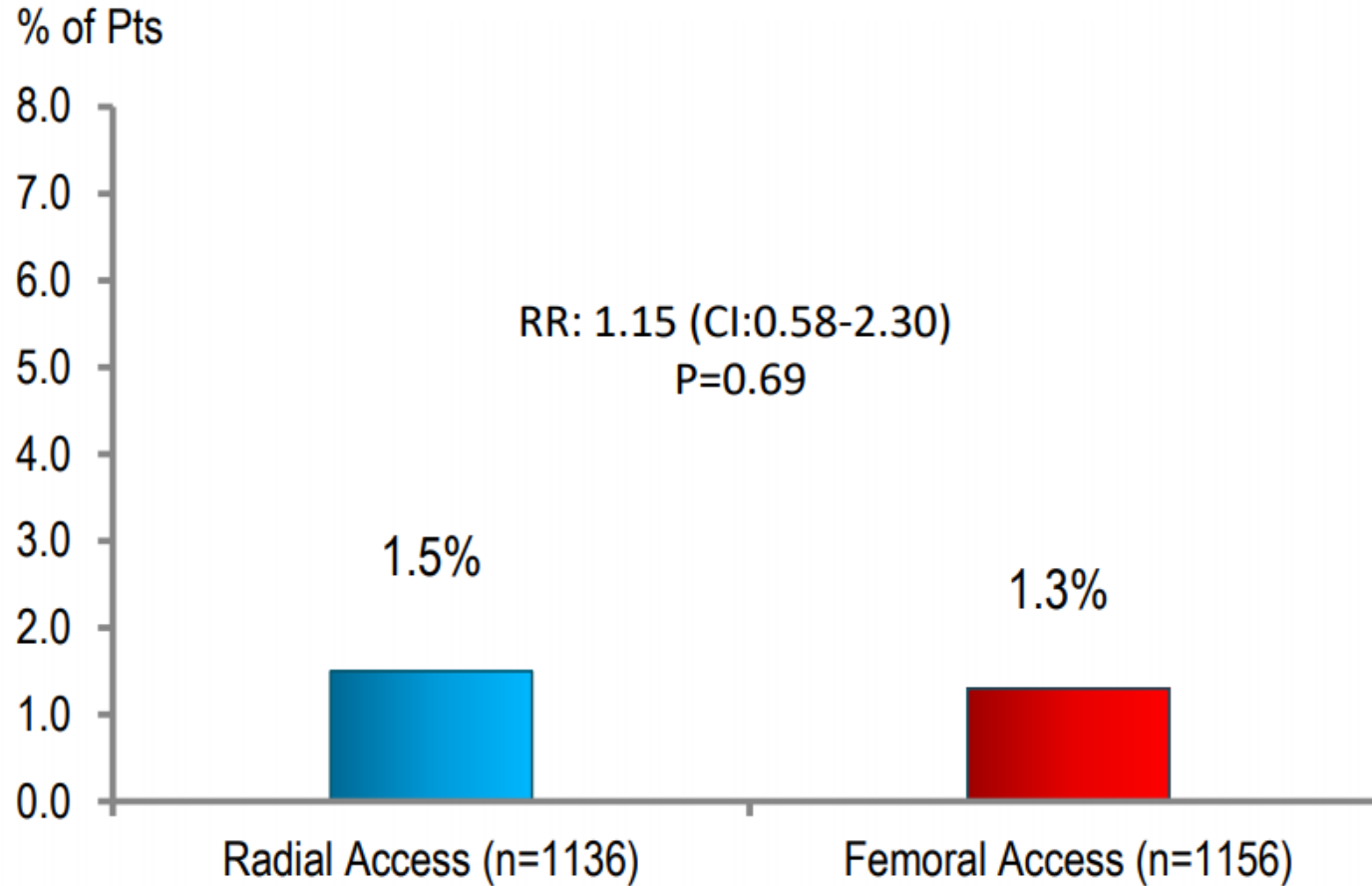
- stroke
- reinfarction
- stent thrombosis
- bleeding (TIMI definition)

Sample size

2442 patients per group
(Total 4884 patients)

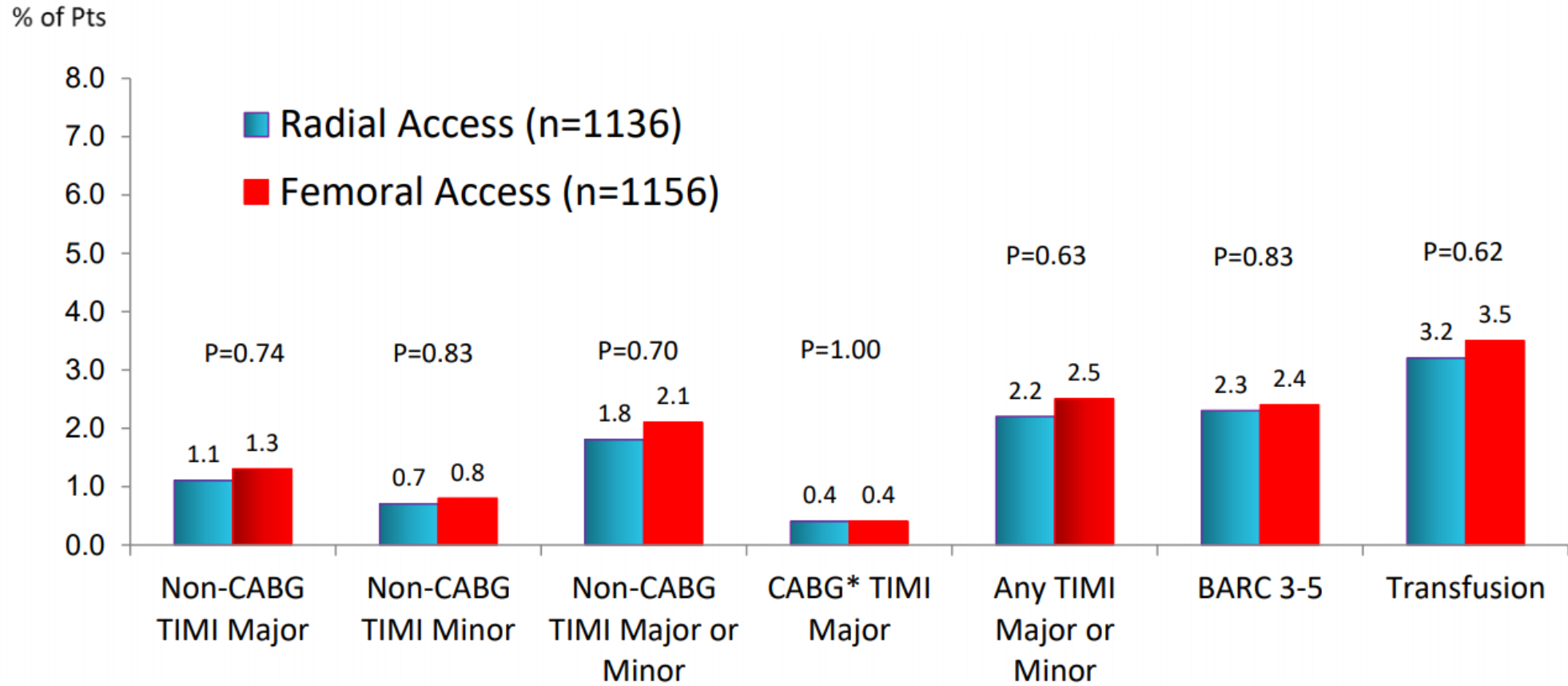
SAFARI-STEMI trial

Primary outcome: 30-day mortality



SAFARI-STEMI trial

Bleeding at 30 days



*CABG done in 3.8% radial and 3.5% femoral

Default routes & clinical outcomes

Table IV. Twenty-eight-day clinical outcomes by default radial and default femoral operators

	<u>Radial operators</u>	<u>Femoral operators</u>	<i>P</i>
	(n = 1575)	(n = 229)	
Outcomes			
MACE	111/1575 (7%)	16/229 (7%)	.97
Mortality	73/1575 (4.6%)	9/229 (3.9%)	.63
Major bleed	49/1575 (3.1%)	11/229 (4.8%)	.18
Access site related	8/1575 (0.5%)	4/229 (1.7%)	.055
Minor bleed	142/1575 (9%)	38/229 (16.6%)	<.001
Access site related	82/1575 (5.2%)	32/229 (14.0%)	<.001
Any bleed	186/1575 (11.8%)	48/229 (21%)	<.001

Table VI. Twenty-eight-day clinical outcomes in cases where FA was used, by default radial and default femoral operators

	<u>Radial operators</u>	<u>Femoral operators</u>	<i>P</i>
	(n = 122)	(n = 210)	
Outcomes			
MACE	22/122 (18%)	14/210 (6.7%)	.003
Mortality	20/122 (16.4%)	7/210 (3.3%)	.001
Major bleed	11/122 (9%)	11/210 (5.2%)	<.001
Access site related	3/122 (2.5%)	4/210 (1.9%)	.71
Minor bleed	24/122 (19.7%)	38/210 (18.1%)	.72
Access site related	23/122 (18.9%)	32/210 (15.2%)	.45
Any bleed	33/122 (27%)	48/210 (22.9%)	.39

Comfortable

Safe

DRA

Confident

Effective

Comfortable position for the operators



Left groin



Right groin



Left straight

Japanese doctors : Right distal radial

Comfortable

Safe

DRA

Confident

Effective

Distal radial access: Confident? No, lack of evidence

Randomized studies	Non randomized studies	Case reports
1. Koutouzis et al. 2018 (200 pts)	1. Kiemeneij. 2017 (70 pts)	1. Kontopodis et al. 2018
	2. Roghani-Dehkordi et al. 2018 (235 pts)	2. Latsios et al. 2018
	3. Lee et al. LeDRA study. 2018 (200 pts)	3. Pua et al. 2018
	4. Kim et al. 2018 (150 pts)	4. Kim et al. 2018
	5. Coughlan et al. 2018 (94 pts)	5. Berezhnoi et al. 2018
	6. Soydan et al. 2018 (54 pts)	6. Sheikh et al. 2018
	7. Valsecchi et al. 2018 (52 pts)	7. Bayam et al. 2018
	8. Ziakas et al. 2018 (49 pts)	
	9. Gasparini et al. 2018 (41 CTO pts)	
	10. Al-Azizi et al. (22 pts)	

Comfortable

Safe

DRA

Confident

Effective

Real-world experience of the left distal transradial approach for coronary angiography and percutaneous coronary intervention: a prospective observational study (LeDRA)



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Department of Internal Medicine, Yonsei University Wonju College of Medicine, Wonju, Republic of Korea

Primary endpoints		
CAG success		187/187 (100)
PCI success		86/87 (98.9)
Secondary endpoints		
Puncture success		191/200 (95.5)
Crossover		9 (4.5)
Left radial		7 (3.5)
Right distal radial		2 (1)
Clinical diagnosis	Stable angina	38 (19)
	Unstable angina	74 (37)
	NSTEMI	45 (22.5)
	STEMI	17 (8.5)
	Others	26 (13)
At admission		15/191 (7.9)
BARC bleeding type 2, 3, 5		0 (0)
Minor haematoma		14 (7.4)
Haematoma grade	<2 cm	10 (5.2)
	2-5 cm	1 (0.5)
	>5 cm	3 (1.6)
Distal radial artery occlusion		0 (0)
Perforation		0 (0)
Pseudoaneurysm		0 (0)
Dissection		1 (0.5)
Arteriovenous fistula		0 (0)
1-month follow-up by ultrasonography		2/141 (1.4)
Distal radial artery occlusion		0 (0)
Neuropathy		2 (1.4)

Comfortable

Safe

DRA

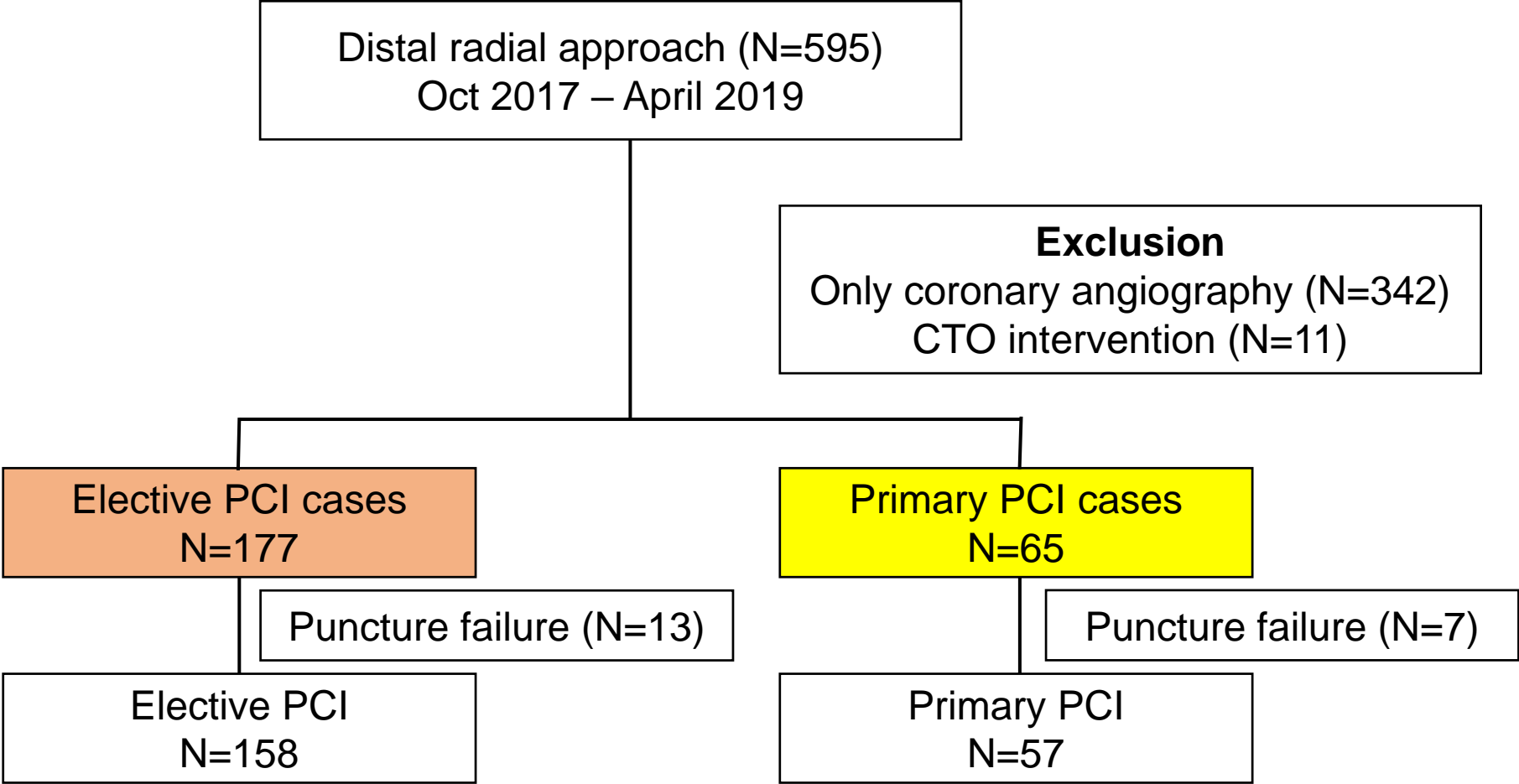
Confident

Effective

PCI for lesion complexity

Patients who underwent PCI (n=87)		
PCI performed		87/191 (45.5)
Ad hoc		78/87 (89.7)
Staged		9/87 (10.3)
Culprit lesion	Left main	6 (6.9)
	Left anterior descending	47 (54)
	Left circumflex	6 (6.9)
	Right coronary artery	28 (32.2)
Bifurcation		28 (32.2)
In-stent restenosis		9 (10.3)
Chronic total occlusion		8 (9.8)
Guiding catheter	5 Fr	5 (5.7)
	Sheathless 6.5 Fr	19 (21.8)
	6 Fr	62 (71.3)
	7 Fr	1 (1.1)
Use of IVUS		55 (63.2)

DRA : Primary vs. Elective



Results

	Elective PCI	Primary PCI	P value
	N=177	N=65	
Crossover	19 (10.7)	8 (12.3)	0.73
Puncture failure	13 (7.3)	7 (10.8)	0.391
Vessel Tortuosity	4 (2.3)	0 (0)	0.222
GW passing failure	2 (1.1)	0 (0)	0.389
SCA total occlusion	0 (0)	1 (1.5)	0.098
RA total occlusion	1 (0.6)	0 (0)	0.544

Values are n (%).

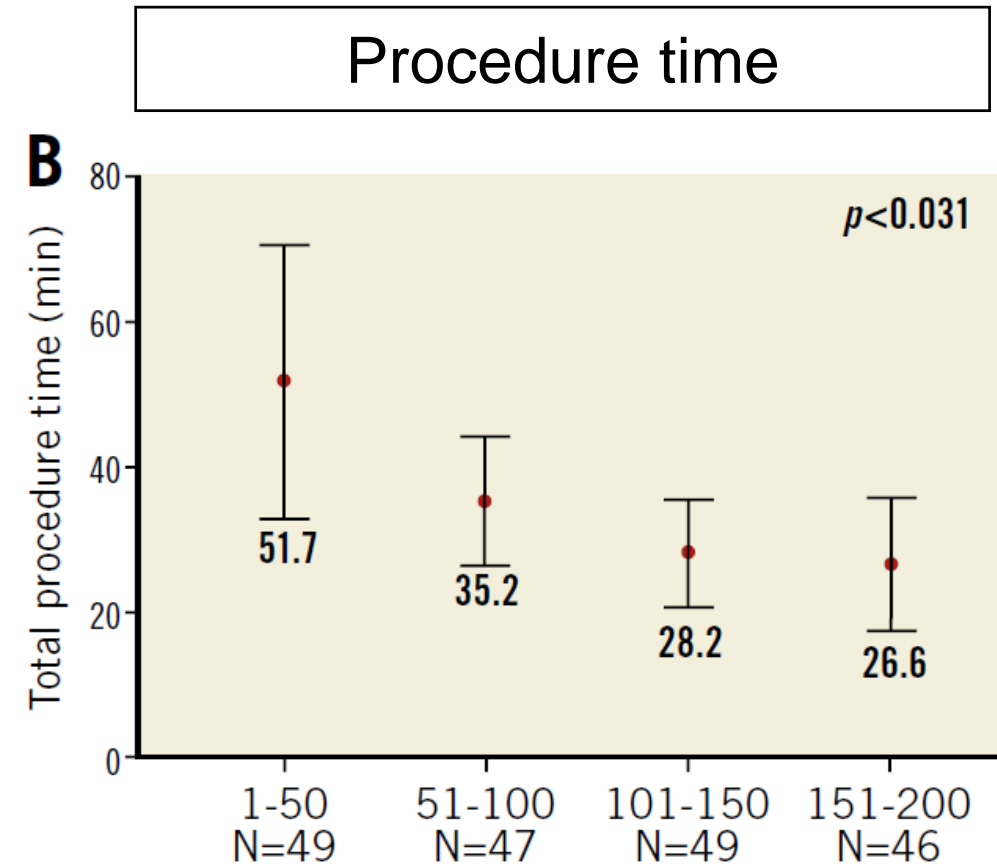
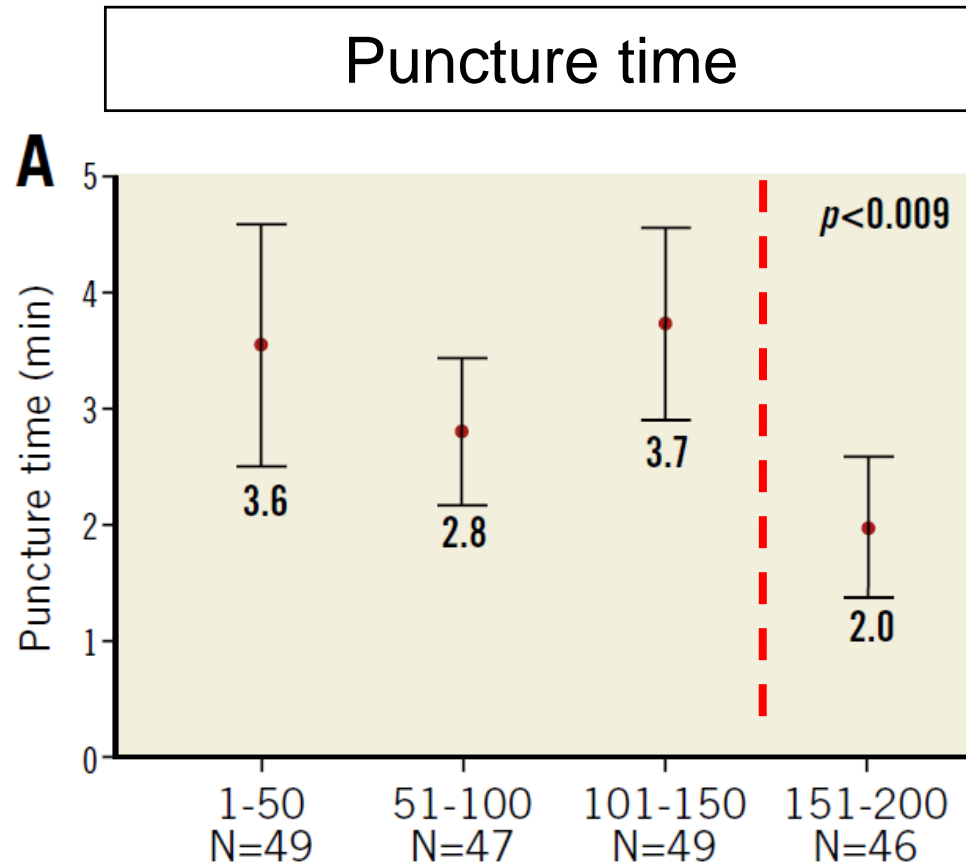
GW, guidewire; SCA, subclavian artery; RA, radial artery

	Elective PCI N=158	Primary PCI N=57	
Left distal radial approach	148 (93.7)	56 (98.2)	0.179
Total used stent, n	1.97±1.24	1.84±1.04	0.490
Total stent length, mm	36.7±22.2	35.3±16.9	0.677
Mean stent diameter, mm	3.08±0.49	3.23±0.50	0.053
Use of IVUS	128 (83.1)	40 (70.2)	0.038
Puncture time, min	2.3±2.2	1.8±2.1	0.166
CAG time, min	6.2±4.2	3.5±1.5	<0.001
PCI time, min	38.5±25.1	36.9±16.0	0.640
Total procedure time, min	57.1±27.2	46.3±16.6	0.001
Total contrast volume, mL	159.0±53.6	167.4±47.8	0.299
Fluoroscopic time, min	16.3±11.2	13.2±7.6	0.025
Fluoroscopic dose,	156.0±96.0	178.1±93.2	0.135
Access site complication	18 (20.7)	1 (4.3)	0.065
Perforation	1 (0.7)	0 (0)	0.544
Major hematoma	2 (1.3)	0 (0)	0.389
Minor hematoma	15 (10.0)	1 (1.8)	0.053

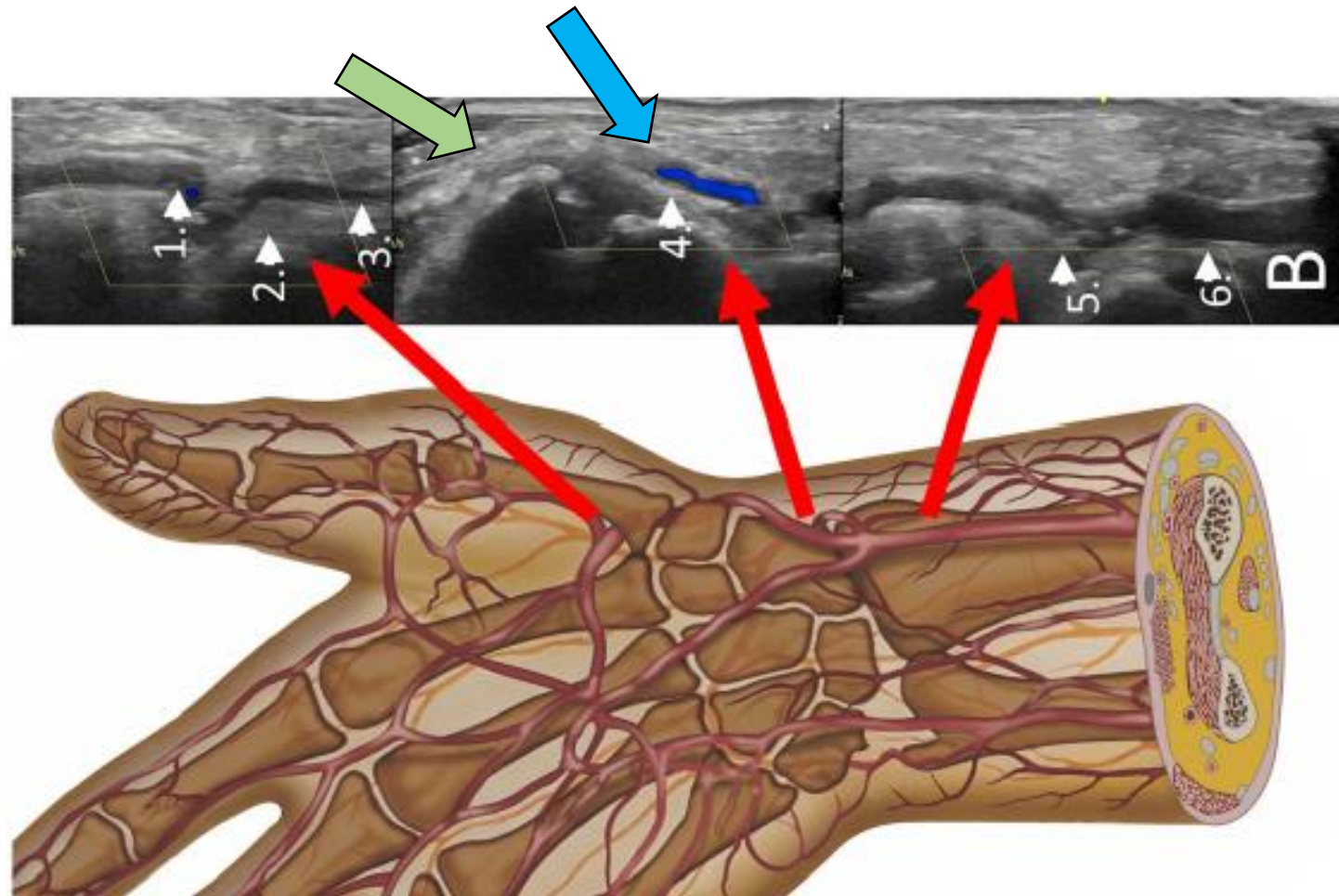
Hurdles to overcome

1. Learning curve for puncture
2. Smaller diameter for PCI

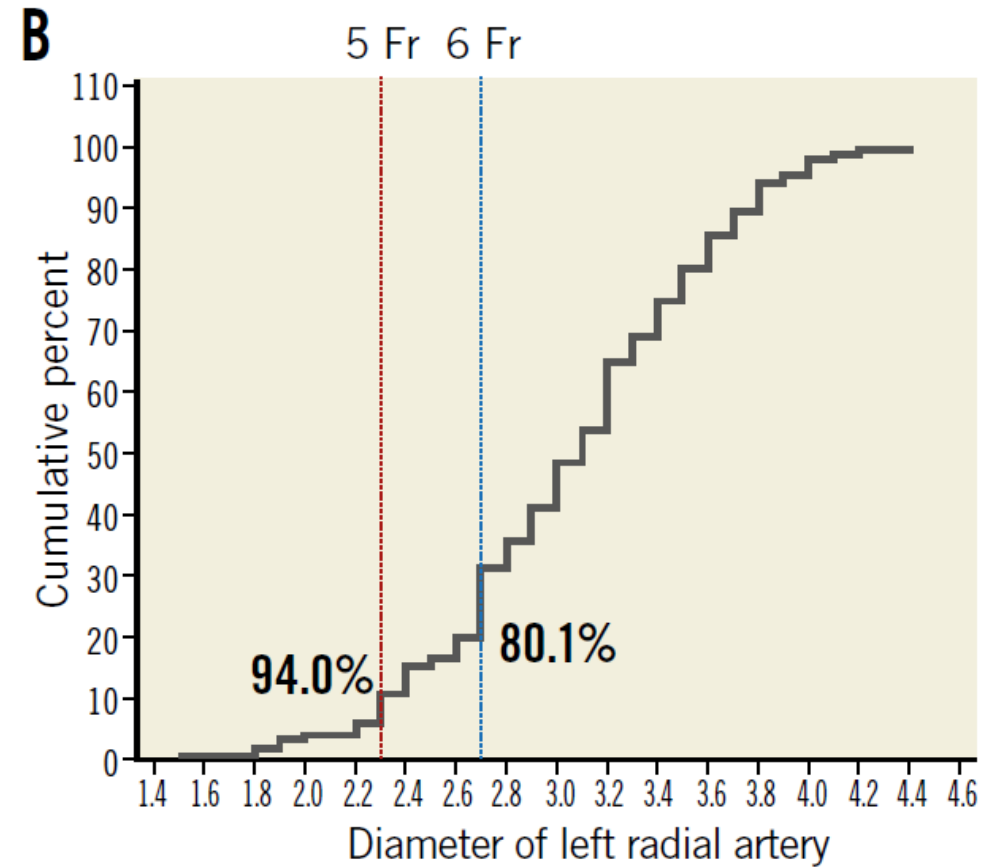
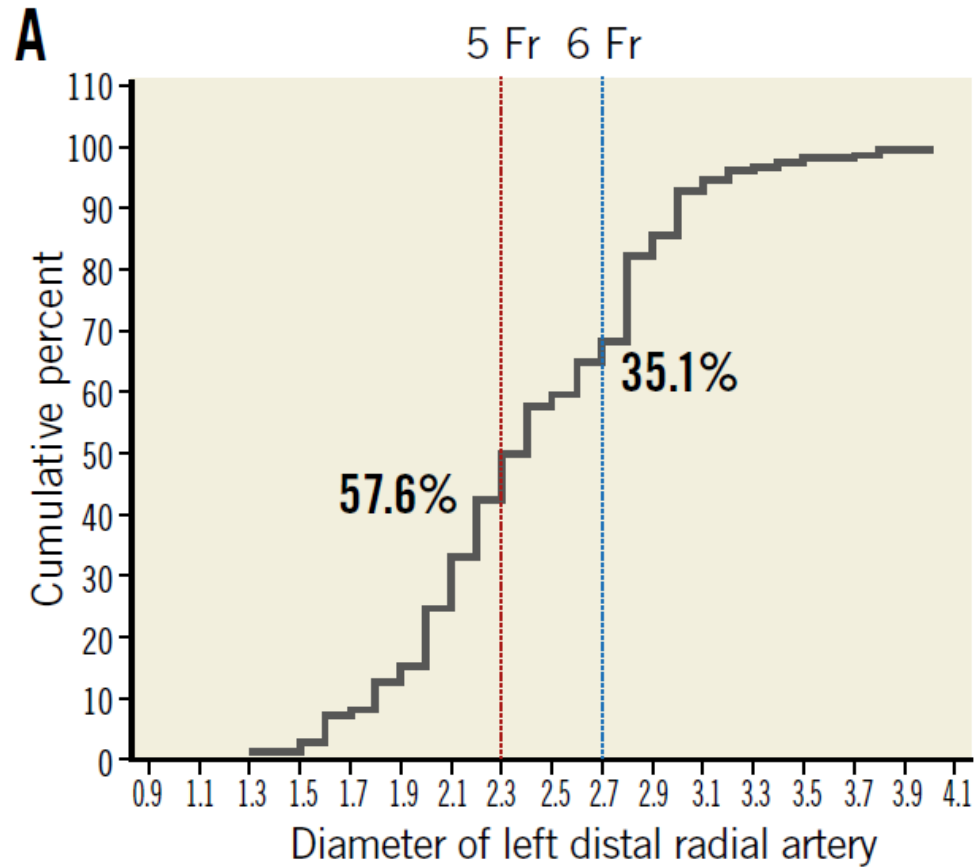
Learning curve



Depth of distal radial artery



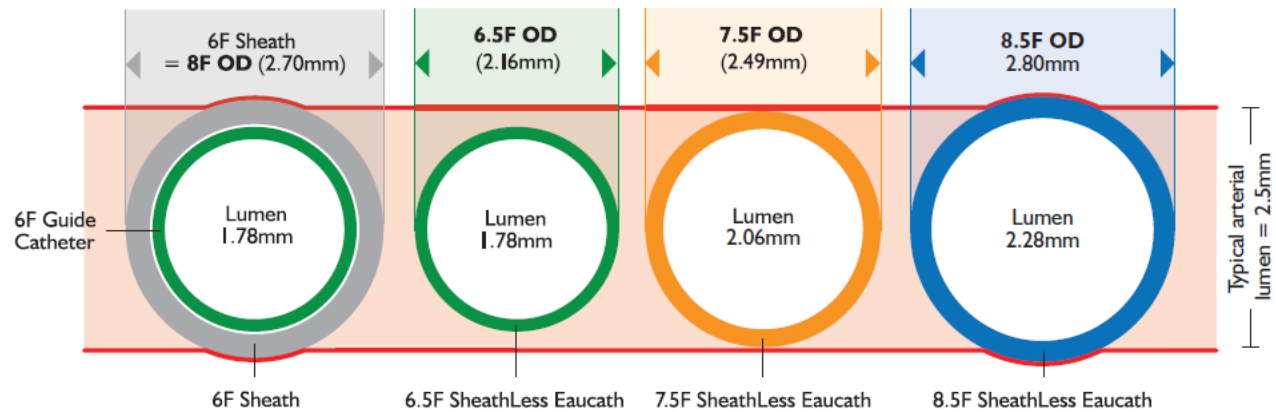
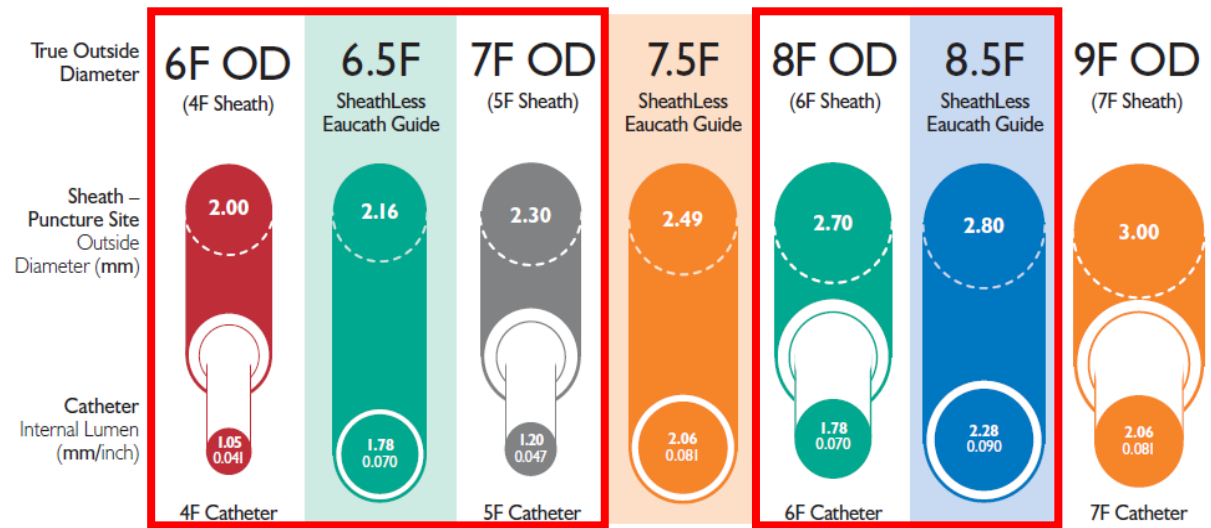
Size does matter



Be familiar with Sheathless GC

	6Fr Guiding System	6.5Fr SheathLess	7.5Fr SheathLess
O.D. (mm)	2.50~2.70	2.16	2.49
I.D. (mm /inch)	1.78	1.78	2.06
Deep Seating	Not applicable shaft stiffness	Applicable	Not applicable shaft stiffness
Kissing Balloon Technique	Applicable (Balloon catheter smaller than 2.6Fr)	Applicable (Balloon catheter smaller than 2.6Fr)	Applicable
Cutting Balloon	~3.50mm	~3.50mm	~4.00mm
Rotablator	~1.75mm	~1.75mm	~2.00mm

Sheathless guiding catheter



Glidesheath slender



Sheath O.D.	Max. GC Size	O.D.	I.D.	Thickness
5Fr OD Sheath	6Fr GC	2.45	2.22	0.12




Clinicaltrials.gov (12 trials)

Row	Saved	Status	Study Title	Interventions	NCT Number	Locations
1	<input checked="" type="checkbox"/>	Not yet recruiting NEW	Distal Versus COventional RADIAL Access for Coronary Angiography and Intervention	<ul style="list-style-type: none"> Procedure: Coronary angiography and or Percutaneous coronary Intervention 	NCT04171570	<ul style="list-style-type: none"> Cliniques Universitaires Saint-Luc Brussels, Belgium Hôpital Civil Marie Curie Charleroi, Belgium Klinikum Minden Minden, Germany (and 8 more...)
2	<input checked="" type="checkbox"/>	Recruiting	Distal Radial Artery vs. Forearm Radial Artery For Cardiac Catheterization	<ul style="list-style-type: none"> Procedure: distal radial artery access in coronary angiography and angioplasty Procedure: Forearm radial artery access in coronary angiography and angioplasty 	NCT04125992	<ul style="list-style-type: none"> An-Najah National University Hospital Nablus, Palestinian Territory, occupied
3	<input checked="" type="checkbox"/>	Recruiting	Korean Prospective Registry for Evaluating the Safety and Efficacy of Distal Radial Approach (KODRA)	<ul style="list-style-type: none"> Procedure: Distal radial approach 	NCT04080700	<ul style="list-style-type: none"> Yongin Severance Hospital Yongin-si, Gyeonggi-do, Korea, Republic of The Catholic university of Korea Bucheon St. Mary's hospital Bucheon, Korea, Republic of Inje University Busan Paik Hospital Busan, Korea, Republic of (and 12 more...)
4	<input checked="" type="checkbox"/>	Not yet recruiting	Randomized Comparison of Radiation Exposure in Coronary Angiography Between Right Conventional and Left Distal Radial Artery Approach	<ul style="list-style-type: none"> Procedure: artery puncture and coronary angiography 	NCT04023838	
5	<input checked="" type="checkbox"/>	Recruiting	Anatomical snuffbox for Coronary anGiography and IntervEntions	<ul style="list-style-type: none"> Procedure: Coronary angiography +/- percutaneous coronary intervention 	NCT03986151	<ul style="list-style-type: none"> University Hospital of Patras Patras, Achaia, Greece
6	<input checked="" type="checkbox"/>	Recruiting	Optimal Hemostasis Duration for Percutaneous Coronary Intervention Via Snuffbox Approach	<ul style="list-style-type: none"> Procedure: Percutaneous coronary intervention via snuffbox approach 	NCT03863652	<ul style="list-style-type: none"> Chonnam National University Hospital Gwangju, Korea, Republic of
7	<input checked="" type="checkbox"/>	Recruiting	The Distal (Snuffbox) Radial arTERy Access for Coronary Angiography and IntervEntions (SUPER-Prospective)	<ul style="list-style-type: none"> Procedure: Left heart catheterization 	NCT03794687	<ul style="list-style-type: none"> University of Florida Jacksonville, Florida, United States
8	<input checked="" type="checkbox"/>	Active, not recruiting	Observational Study of Hand Function After Distal Transradial Access for Angiography		NCT03789279	<ul style="list-style-type: none"> University of Glasgow/Golden Jubilee Research Foundation Glasgow, United Kingdom
9	<input checked="" type="checkbox"/>	Recruiting	Comparison of Success Rate Between Distal Radial Approach and Radial Approach in STEMI	<ul style="list-style-type: none"> Procedure: Distal radial artery Procedure: Radial artery 	NCT03611725	<ul style="list-style-type: none"> Wonju Severance Christian Hospital Wonju, Gangwon-do, Korea, Republic of
10	<input checked="" type="checkbox"/>	Not yet recruiting	Comparison of Two Radial Artery Segments Related to "Old-Fashioned" Radial and New Snuff Box Vessel Approach by US	<ul style="list-style-type: none"> Diagnostic Test: Ultrasound examination of radial arteries 	NCT03486470	
11	<input checked="" type="checkbox"/>	Recruiting	Snuff-box Deep Palmar Arch Artery Versus Radial Angiography	<ul style="list-style-type: none"> Procedure: Radial Procedure: Palmar 	NCT03373565	<ul style="list-style-type: none"> Hormozgan University of Medical Sciences Bandar Abbas, Hormozgan, Iran, Islamic Republic of
12	<input checked="" type="checkbox"/>	Completed	The Procedural Success and Complication Rate of the Left Distal Radial Approach	<ul style="list-style-type: none"> Procedure: IdTRA 	NCT03292367	<ul style="list-style-type: none"> Yonsei University Wonju College of Medicine, Wonju Severance Christian Hospital Wonju, Gangwon-do, Korea, Republic of

KODRA by K-TRI

Korean Prospective Registry for Evaluating the Safety and Efficacy of Distal Radial Approach (KODRA)

 The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

Sponsor:

Wonju Severance Christian Hospital

Information provided by (Responsible Party):

Seung Hwan Lee, Wonju Severance Christian Hospital

ClinicalTrials.gov Identifier: NCT04080700

[Recruitment Status](#) ⓘ : Recruiting

[First Posted](#) ⓘ : September 6, 2019

[Last Update Posted](#) ⓘ : November 6, 2019

See [Contacts and Locations](#)

Target patients N=4873

Random study (RA vs DRA)

DISTal Versus CONventional RADIAL Access for Coronary Angiography and Intervention

The objective of this study is to demonstrate the superiority of Distal Radial Access (DTRA) to Conventional Transradial Access (CTRA) regarding forearm radial artery occlusion (RAO).

This trial plans to include 1300 patients in around 12 locations around the world (11 participating sites in Europe and 1 participating site in Japan).

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
Coronary Disease	Procedure: Coronary angiography and or Percutaneous coronary Intervention	Not Applicable

ClinicalTrials.gov Identifier: NCT04171570

Recruitment Status ⓘ : Not yet recruiting

First Posted ⓘ : November 21, 2019

Last Update Posted ⓘ : November 22, 2019

See [Contacts and Locations](#)

Study Type ⓘ : Interventional (Clinical Trial)

Estimated Enrollment ⓘ : 1300 participants

Allocation: Randomized

Sponsor:

Terumo Europe N.V.

Collaborator:

Cromsource

Information provided by (Responsible Party):

Terumo Europe N.V.

Belgium

Cliniques Universitaires Saint-Luc

Brussels, Belgium

Contact: Joëlle Kefer, Prof.

Principal Investigator: Joëlle Kefer, Prof.

Hôpital Civil Marie Curie

Charleroi, Belgium

Contact: Adel Aminian, Dr.

Principal Investigator: Adel Aminian, Dr.

Japan

Shonan Kamakura General Hospital

Kanagawa, Japan

Contact: Shigeru Saito, Dr.

Principal Investigator: Shigeru Saito, Dr.

Summary

1. **'Default route'** in coronary intervention should be **safe and effective**.
Ex) femoral access could be safer and more effective in femoral default operator.
2. **Distal radial approach** is an attractive **'alternative'** route, if the addressed issues and limitations could be adequately handled.
3. **For me, distal radial artery is a default route in daily practice**.
(CAG based on 4Fr sheath → Guiding catheter selection according to vessel size).
4. **Evidences** are waiting for this approach from several clinical studies .