Introduction of Korea TRI prospective registry

Seung-Hwan, Lee MD, PhD Yonsei University Wonju College of Medicine

Be half of TRIWG

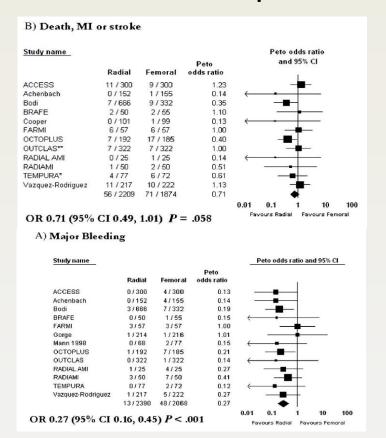


INTRODUCTION

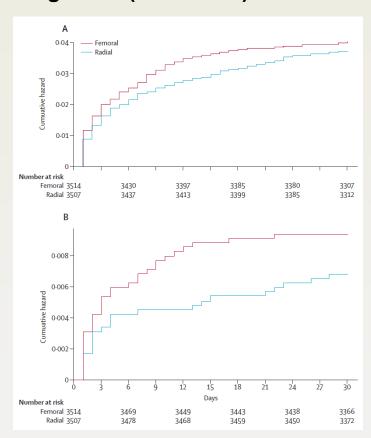


Efficacy of TRI

23 RCTs from 1980 to April 2008



Large RCT (RIVAL trial)



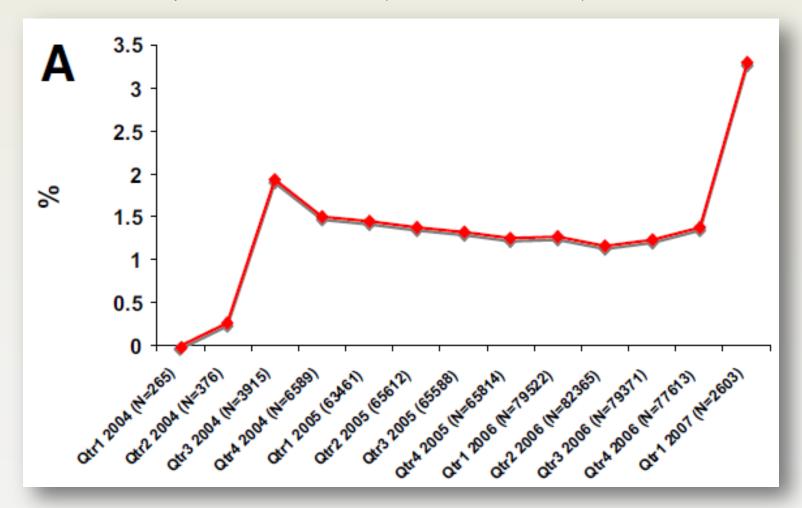
Radial access reduced major bleeding and there was a corresponding trend for reduction in ischemic events compared to femoral access

Am Heart J 2009;157:132-40 / Lancet 2011;377:1409-20



Trend in the use of TRI in US

Data from 593,094 procedures in the NCDR (606 sites; 2004 to 2007)



JACC 2008;4:379-86

2011 ACCF/AHA/SCAI PCI guideline

Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: A systematic review and meta-analysis of randomized trials

Sanjit S. Jolly, MD, a Shoaib Amlani, MD, a Martial Hamon, MD, salim Yusuf, MBBS, D Phil, a and Shamir R. Mehta, MD, MSc Hamilton, Ontario, Canada; and Caen, France

Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial

Sanjit SJolly, Salim Yusuf, John Caims, Kari Niemela, Denis Xavier, Petr Widirnsky, Andrzej Budaj, Matti Niemela, Vicent Valentin, Basil S Lewis, Alvan Avezum, Philippe Gobriel Steg, Sanil V Roa, Peggy Gao, Rizwan Afzal, Campbell D Joyner, Susan Chrolavicius, Shamii R Mehta, for the RNAL trial qrough.



JACC: CARDIOVASCULAR INTERVENTIONS

VOL. 1, NO. 3, 2008 ISSN 1936-8798/08/534.00

Trends in Vascular Complications After Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention Via the Femoral Artery, 1998 to 2007

Robert J. Applegate, MD, FACC, Matthew T. Sacrinty, MPH, Michael A. Kutcher, MD, FACC, Frederic R. Kahl, MD, FACC, Sanjay K. Gandhi, MD, FACC, Renato M. Santos, MD, FACC, William C. Little, MD, FACC

Winston-Salem, North Carolina







5.1. Vascular Access: Recommendation

CLASS IIa

1. The use of radial artery access can be useful to decrease access site complications (255,260,356–362). (Level of Evidence: A)

JACC 2011;58:e44-122



Published Articles about TRI

Authors	Year	Journal	Type of article	Comparison	Outcome
Arzamendi, D., H. Q. Ly, et al.	2010	Am J Cardiol	Prospective	TRI vs. TFI	Clinical outcome
Rathore, S., R. H. Stables, et al.	2010	Catheter Cardiovasc Interv	RCT	Hemostatic method	Procedural outcome
Mamas, M., S. D'Souza, et al.	2010	Catheter Cardiovasc Interv	Prospective		Procedural outcome
Jia, D. A., Y. J. Zhou, et al.	2010	Chin Med J	Prospective		Radial a. spasm
Siudak, Z., B. Zawislak, et al.	2010	Coron Artery Dis	Obervational	TRI vs. TFI	Bleeding
Bagur, et al.	2010	<u>Indian Heart J</u>	Retrospective	TRI vs. TFI	Clinical outcome
Wang, L., Y. Yang, et al.	2010	Int J Cardiol	Retrospective	TRI vs. TFI	Trend
Sciahbasi, A., E. Romagnoli, et al.	2011	Am Heart J	RCT	Left vs. Right	Procedural outcome
Looi, J. L., A. Cave, et al.	2011	Am J Cardiol	Retrospective	TRI vs. TFI	Learning curve
Kanei, Y., N. C. Nakra, et al.	2011	Am J Cardiol	RCT	Left vs. Right	Procedural outcome
Farman, M. T., N. U. Khan, et al.	2011	Anadolu Kardiyol Derg	Obervational	TRI vs. TFI	Radiation exposure
From, A. M., M. R. Bell, et al.	2011	Catheter Cardiovasc Interv	Retrospective		Procedural outcome
Turner, S., M. Sacrinty, et al.	2011	Catheter Cardiovasc Interv	Retrospective	TRI vs. TFI	Trend
Ball, W. T., W. Sharieff, et al.	2011	Circ Cardiovasc Interv	Prospective		Learning curve
Chiam, P. T., B. Liu, et al.	2011	<u>EuroIntervention</u>	Retrospective	Catheter	Procedural outcome
Biondi-Zoccai, G., A. Sciahbasi, et al.	2011	Int J Cardiol.	Meta-analysis	Left vs. Right	Procedural outcome
Norgaz, T., S. Gorgulu, et al.	2011	J Interv Cardiol	Prospective		Anatomy
Sciahbasi, A., M. Mancone, et al.	2011	J Interv Cardiol	Prospective		Procedural outcome
Egred, M.	2011	J Interv Cardiol	Retrospective		Procedural outcome
Kristic, I. and J. Lukenda	2011	J Invasive Cardiol	Meta-analysis		Radial a. spasm
Mercuri, M., S. Mehta, et al.	2011	JACC Cardiovasc Interv	Prospective	TRI vs. TFI	Radiation exposure
Chodor, P., T. Kurek, et al.	2011	Kardiol Pol	RCT	TRI vs. TFI	Clinical outcome
Youn, Y. J., J. Yoon, et al.	2011	Korean Circ J	Prospective		Procedural outcome
Youn, Y. J., W. T. Kim, et al.	2011	Korean Circ J	RCT	Spasmolytics	Procedural outcome
Jolly, S. S., S. Yusuf, et al.	2011	<u>Lancet</u>	RCT	TRI vs. TFI	Clinical outcome
Burzotta, F., C. Trani, et al.	2012	Am Heart J	Prospective		Vascular complication
Sciahbasi, A., F. Burzotta, et al.	2012	Cardiovasc Revasc Med	RCT	TRI vs. TFI	Procedural outcome
Ho, H. H., F. H. Jafary, et al.	2012	Cardiovasc Revasc Med	Meta-analysis		Radial a. spasm
Mamas, M. A., K. Ratib, et al.	2012	<u>Heart</u>	Meta-analysis	TRI vs. TFI	Clinical outcome
Chow, J., C. H. Tan, et al.	2012	J Interv Cardiol	Retrospective		Procedural outcome
Dominici, M., R. Diletti, et al.	2012	J Interv Cardiol	Prospective	Left vs. Right	Procedural outcome
Valgimigli, M., F. Saia, et al.	2012	JACC Cardiovasc Interv	Retrospective	TRI vs. TFI	Clinical outcome
Uhlemann, M., S. Mobius-Winkler, et al.	2012	JACC Cardiovasc Interv	Prospective		Vascular complication



Published Articles about TRI

Journal Name	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
Am Heart J							1		1	1	3
Am J Cardiol	1	2						1	2		6
Catheter Cardiovasc Interv	2	1	1	2		3	3	2	2		16
Circ Cardiovasc Interv									1		1
Circ J					1		1				2
Coron Artery Dis								1			1
Eur Heart J						1					1
EuroIntervention							1		1		2
Heart						1	1			1	3
Int J Cardiol			1				1	1	1		4
J Am Coll Cardiol		1									1
J Interv Cardiol				1		2			3	2	8
J Invasive Cardiol		1		1	1				1		4
JACC Cardiovasc Interv						1	1		1	2	5
Korean Circ J				1					2		3
Lancet									1		1
Yonsei Med J			1	1							2
Total	3	5	3	6	2	8	9	5	16	6	63



RETROSPECTIVE REGISTRY



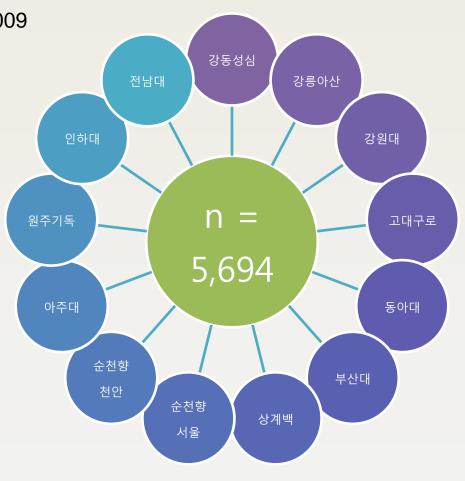
Methods: TRI Working Group Retrospective Registry

16 institutes in Korea

Data for patients underwent PCI in 2009

TRI Working Group





Published abstract and Study title from TRI retrospective registry

Published Abstract		번호	요약 제목
From TRI retrospective registry		1	TRI vs. TFI in routine PCI
TRI vs. TFI in Routine PCI	추계 2010	2	TRI vs. TFI in STEMI
		3	TRI vs. TFI in NSTEMI
Lt radial vs. Rt radial PCI	추계 2010	4	Crossover rate and predictors
		5	Lt. TRI vs. Rt. TRI
TRI vs. TFI in AMI	추계 2010	6	TRI vs. TFI in diffuse long lesion
		7	TRI vs. TFI in bifurcation lesion
Adverse CVA events associated with TRI (Preliminary report from Korean TRIWG registry)	추계 2011	8	TRI vs. TFI in CTO lesion
() -		9	TRI vs. TFI in muti-vessel disease
The Effect of Age on Procedural Success Rate in TRI: Results from the TRI Retrospective Registry	추계 2011	10	TRI and TFI on admission duration
,		11	Age effect on TRI and TFI
The Impact of TRI Approach for In-Hospital Major Bleeding in NSTEMI Patients at Moderate to Very	추계 2011	12	Gender effect on TRI and TFI
High CRUSADE Bleeding Scores : From TRI-Registry		13	Closure methods and devices
Clinical outcome of TRI versus TFI approach for PCI in bifurcation lesions : TRI retrospective registry	추계 2011	14	CVA event
, , ,		15	Impact of TRI according to CRUSADE score
Incidence and Predictors of Crossover from Radial to another Vascular Access Site in Patients Underwent	추계 2011	17	UFH vs. LMWH on bleeding
PCI: Report from the TRI Working Group Retrospective Registry in Korea		16	Radial angiogrpahy during TRI



PROSPECTIVE REGISTRY



TRI Prospective Registry

Prospective TRI registry 1

연구기관의 선정

중재시술연구회 회원 중, <mark>연구자 주도 임상 시험</mark>으로 진행되는 TRIWG prospective registry 공동 연구에 대해

- 1. 연구 인력이 준비되어 있으며,
- 2. 향후 데이터 병합을 위한 자체 PCI 관련 데이터베이스를 갖추고 있고,
- 3. 연구비 없이 순수한 학문적 열성으로
- 4. 최소 3개월에서 최대 6개월 동안

함께 연구를 진행할 기관의 신청을 받아 진행 예정

CASE REPORT FORM Multicenter Prospective Registry (ver. 3.0)



작성일: 2012. 06. 03
작성자: 윤영진 (연세대학교 원주의과대학교)
감수: 윤정한 (연세대학교 원주의과대학교)
/ 이승환 (연세대학교 원주의과대학교)

본 문서는 TRI WC에서 진행하는 전향적 동독 연구를 위한 중에 보고서입니다. 본 문의 내용은 저작권에 의해 보호받습니다. 본문의 내용 전체 혹은 일부를 발췌하는 것은 불법이며, 대한민국 법률에 의해 법적 조치를 받을 수 있습니다.

1

Structure of TRI prospective registry

Demographics

Admission Data (Diagnosis, Past history, Laboratory finding, Echocardiographic, etc.) **Antiplatelets**

Operator information

Access Site

Radial angiography

Catheter

Compression

Access site complication

Bleeding

Discharge Data (discharge medication, clinical outcome)

Access patency @ 1m

Clinical outcome @ 1Y

CAG result

PCI data

Procedure time
Contrast volume
Fluro. time and voluem

TRI prospective registry

Database from institute

Demographic Data

Demographic data			
ate of enrollment		(YYYY-MM-DD) 현재날짜클리	
lame of institute:		(Log-in시 자동 생성)	
Code of institute:		(Log-in시 자동 생성)	
Study protocol ID		(자동생성)	
Medical record number			
Patient name (initial):		_	
lge:		_	
Sex:	□ M / □M		

-3

Operator information

Characterization of Operator Learning Curve for Transradial Coronary Interventions

Warren T. Ball, MD, FRCPC; Waseem Sharieff, MD, PhD; Sanjit S. Jolly, MD, FRCPC; Tony Hong, MRT; Michael J.B. Kutryk, MD, PhD, FRCPC; John J. Graham, MB, ChB, MRCP; Neil P. Fam, MD, FRCPC; Robert J. Chisholm, MD, FRCPC: Asim N, Cheema, MD, PhD, FRCPC

Background—Transradial percutaneous coronary intervention (TR-PCI) improves clinical outcomes compared to the transfemoral (TF) approach. However, inadequate training and experience has limited widespread adoption by interventional cardiologists.

Methods and Results—Clinical and procedural characteristics for TR-PCI were prospectively collected from 1999 to 2008.

To identify minimum case volume for optimum clinical benefit, single-vessel TR-PCI cases were chronologically ranked and stratified into 1 to 50, 51 to 100, 101 to 150 and 151 to 300 case volume groups for operators starting the TR approach at the study institution. Cases by operators with a >300 TR-PCI case volume comprised the control group.

TR-PCI failure rates, contrast use, guide usage, and fluoroscopy time were compared among groups. A total of 1672

patients unc group comp (180±79 n Fluoroscop! P=0.04) an tortuousity correlated v increments

outcomes c

expand thei

Learning Curve in Transradial Coronary Angiography

Jen Li Looi, MD, Andrew Cave, BTech, and Seif El-Jack, MD*

Transradial (TR) cardiac catheterization is underused, possibly because of perceived technical difficulty and longer procedure times. We compared TR to transfemoral (TF) coronary angiography as performed by experienced TF angiographers with varying TR skills. Data were analyzed for diagnostic angiography without ad hoc intervention over a 12month period comparing TR to TF procedural and fluoroscopic times, contrast volume, and complication rates. Further analysis was performed according to operators' TR experience (radial expert [REx] vs non-radial expert [nREx]). In total 1,001 patients were identified (661 TR and 340 TF cases) with nRExs performing an average of 63 TR procedures each. All TF procedures were successful and 92% were successful for TR angiography; complication rates were similar regardless of access. Compared to TF procedures fluoroscopic times were longer in the all-operator TR group (5.3 vs 4.0 minutes, p < 0.01) but total procedural times were not (TR vs TF 24 vs 22 minutes, p = NS). In the TR group nRExs had longer fluoroscopic and procedural times compared to RExs in the first 3 months of radial experience (8 vs 4.4 minutes, p = 0.02, and 32 vs 22 minutes, p < 0.01, respectively); however, the 2 were equivalent in the final 3 months of analysis (5.2 vs 4.5 and 26 vs 19 minutes for nRExs and RExs, respectively, p = NS). Within the nREX group parameters improved in the last compared to the first 6 months (fluoroscopy 6 vs 7.3 minutes, p = 0.04; procedure time 26 vs 30 minutes, p = 0.04). In conclusion, TR coronary procedures appear to be a comparable alternative to TF procedures with a relatively short technical learning curve. © 2011 Elsevier Inc. All rights reserved. (Am J Cardiol 2011; 108:1092-1095)

Operator Information

Name of operator:

Age of operator:

Experience of TRA: (select one from operator experience variables)

Experience of TRI: (select one from operator experience variables)

Experience of TFA: (select one from operator experience variables)

Experience of TFI: (select one from operator experience variables)

Preference of approach site

1. Transradial 2. Transfemoral

Routine angiography: 1. Always (꼭 확인한다.)

2. When needed (필요한 경우에만 확인한다.)

Never (절대 확인하지 않는다.)

Compression duration (일반적인 지혈 시간)

1. ≤ 1 hr

2. > 1 hr or ≤ 4 hrs

3. > 4 hrs or ≤ 8 hrs

4. > 8 hrs or ≤ 12 hrs

5. > 12 hrs or ≤ 24 hrs

6. > 24 hrs

Operator experience variables¹

1. < 50 2. 50-99 3. 100-249

100-249 4. 250-499 5. ≥ 500

Operator name 은 lookup 으로 관리할 예정임. 해당 기관에서는 해당 기관의 operator 만 선택이 가능.

아마 기관에서는 애 이 기관의 아마리아 본 본국에 기공 Operator 정보는 최초 한 번만 등록함.

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Circ CI 2011;4:336-41 / AJC 2011;108:1092-5



Angiographic Data

Randomized Comparison of Transradial Coronary Angiography Via Right or Left Radial Artery Approaches

Procedure characteristics and outcome						
Variable	Right (n = 98)	Left $(n = 91)$	p Value			
Ad hoc percutaneous coronary intervention	19 (19%)	24 (26%)	0.332			
Number of punctures	1.5 ± 0.9	1.5 ± 0.7	1.000			
Number of catheters	1.4 ± 0.7	2.2 ± 1.0	< 0.001			

Use o RADIal versus femoral approach for percutaneous
Use o coronary interventions in patients with
Osti Acute Myocardial Infarction (RADIAMI):
Proce A prospective, randomized, single-center clinical trial

 Table 3. Time intervals during coronary angiography and percutaneous coronary intervention.

SUIII \					
Multi	Time from admission to (door to)	Entire study group (n = 100)	Group I (n = 50) (transradial)	Group II (n = 50) (transfemoral)	Р
Vonse		(11 - 100)	(transradiar)	(transferriorar)	
	Arrival in the Cath Lab [min]	35.7 ± 21.6	37.8 ± 21.0	33.7 ± 22.2	NS
Contr	Sheath positioning [min]	49.1 ± 22.9	53.7 ± 21.9	44.4 ± 23.1	0.04
luor	First contrast injection [min]	56.0 ± 25.1	62.3 ± 25.5	50.2 ± 23.8	0.02*
Tuon	Balloon positioning [min] (door to balloon)	69.1 ± 27.9	76.9 ± 25.9	64.6 ± 26.9	0.02*
Diagn	Stent implantation [min] (door to stent)	77.9 ± 27.2	83.2 ± 26.3	72.3 ± 27.3	0.05
Percu	End of intervention [min]	92.7 ± 28.7	98.7 ± 26.8	88.7 ± 30.1	0.17
cicu	Arrival in the Cath Lab-sheath positioning time [min]	13.6 ± 7.4	15.7 ± 7.8	11.4 ± 6.4	0.0028
inte	Sheath-injection time [min]	6.6 ± 6.4	8.6 ± 7.8	4.5 ± 3.3	*8000.0
Proce	Injection-balloon time [min]	15.1 ± 7.9	15.6 ± 8.7	14.6 ± 7.1	NS
roce	Balloon-stent time [min]	8.0 ± 4.9	7.3 ± 4.6	8.7 ± 5.2	0.21
Room	Stent-end of intervention time [min]	14.4 ± 10.6	13.3 ± 8.6	15.5 ± 12.4	0.31
	Procedure time [min]	56.8 ± 18.1	58.3 ± 17.8	55.1 ± 18.4	0.38
Dat	Time from the end of intervention to sheath removal [h]			8.9 ± 6.7	
Date	*Mann-Whitney U test				

1 st visit date:(YY	YY-MM-DD) 현재날짜클릭
1 st visit CAG it M-DD)	
•	
	력/시계를 이용한 수동 입력 모두 가능)
1 st cath. room arrival time	(YYYY-MM-DD HH:MM) 현재시간클릭
1 st puncture starting time	(YYYY-MM-DD HH:MM) 현재시간클릭
1 st puncture success time	(YYYY-MM-DD HH:MM) 현재시간클릭
1 st puncture time	min (자동계산: 1 st puncture success time - 1 st puncture starting time)
1 st CAG starting time	(YYYY-MM-DD HH:MM) 현재시간클릭
1 st CAG ending time	
1st CAG ending time	(YYYY-MM-DD HH:MM) 현재시간클릭 min
1 ono uno	(자동계산: 1 st CAG ending time - 1 st CAG starting time)
1st PCI starting time	(YYYY-MM-DD HH:MM) 현재시간클릭
1st PCI ending time	(YYYY-MM-DD HH:MM) 현재시간 클 릭
1 st PCI time	min
	(자동계산: 1 st PCI ending time - 1 st PCI starting time)
1 st visit total procedure time	min
	(자동계산: 1 st puncture time + 1 st CAG time + 1 st PCI time)
Contrast data	
1 st visit contrast volume for CAG	ml (소수점 0)
1st visit contrast volume for PCI	ml (소수점 0) (자동계산: total - vol. for CAG)
1 st visit total contrast volume	ml (소수점 0)
Fluoroscopy data	
1 st visit fluoroscopy time for CAG	min (소수점 1)
1 st visit fluoroscopy time for PCI	min (소수점 1) (자동계산: total - for CAG)
1 st visit total fluoroscopy time	min (소수점 1)
1st visit fluoroscopy dose for CAG	(DAP)Gycm2 (소수점 1)
1st visit fluoroscopy dose for PCI (DAP)Gycm2 (소수점 1) (자동계산: total - for CAG)
1 st visit total fluoroscopy dose (DA	P)Gycm2 (소수점 1)
정의	
Puncture starting time 은 국소 마취제 투여를	시작하는 시각으로 한다.
Puncture success time ⊖ sheath insertion 0	
CAG starting time 은 catheter 를 sheath 에 십 CAG ending time 은 CAG 를 종료하 시각으로	
PCI start time a catheter = sheath 01 At 015	= :

,

PCI ending time 은 모든 PCI 가 종료된 시각으로 한다.

Cardiol J 2009;16:332-40 / AJC 2011;107:195-197



Access Site

Vascular complications and access crossover in 10,676 transradial percutaneous coronary procedures

Francesco Burzotta, MD, PhD, ^a Carlo Trani, MD, ^a Mario Attilio Mazzari, MD, Antonella Tommasino, MD, Giampaolo Niccoli, MD, PhD, Italo Porto, MD, PhD, Antonio Maria Leone, MD, PhD, Giovanni Tinelli, MD, Valentina Coluccia, MD, Maria De Vita, MD, Marta Brancati, MD, Rocco Mongiardo, MD, Giovanni Schiavoni, MD, and Filippo Crea, MD *Rome, Italy*

Background Randomized trials have shown that transradial approach, compared with transfemoral, reduces vascular complications (VCs) of coronary procedures in selected patients. Yet, radial approach is associated to a variety of access-site VC as well as to a higher failure rate compared with femoral access.

Methods At our institution, from May 2005 to May 2010, we prospectively assessed the occurrence and outcome of VC in consecutive patients undergoing transradial percutaneous coronary procedures performed by trained radial operators. The need of access crossover to complete the procedure was also prospectively investigated. Vascular complications were classified as "radial related" or "nonradial related" (in the case of access crossover). Vascular complications were also classified "major" if requiring surgery and/or blood transfusions or causing hemoglobin drop >3 g/dL.

Results Ten thousand six hundred seventy-six procedures were performed using a right radial (87.5%), left radial (12.4%), or ulnar (0.1%) artery as primary access. A total of 53 VCs (0.5%) were observed: 44 (83%) radial related and 9 (17%) nonradial related. Major VCs occurred in 16 patients only (0.2%) and were radial related in 10 (62.5%) and nonradial related in 6 (37.5%) patients. Vascular complications rate was stable during the study and independent of operator's experience. Access crossover rate was 4.9%, differed according to the operator radial experience and significantly decreased over time.

Conclusions The present study, conducted in a center with high volume of radial procedures, shows that transradial approach is associated with a very low rate of VC, which is stable over time. On the contrary, access crossover rate decreased over time and differed according to operator (radial) experience. (Am Heart J 2012;163:230-8.)

	igiograpino data – Acc			
	ess site for CAG (Final scular access site for C	**		
	Access site variables ¹			
- -	1. Femoral, Rt.	3. Radial, Rt.	5. Brachial, Rt.	7. Ulnar, Rt.
:	2. Femoral, Lt.	4. Radial, Lt.	6. Brachial, Lt.	8. Ulnar, Lt.
Int	troducer sheath for CAG	(select one)		
	Introducer sheath vari	ables ²		
- -	1. 4-Fr. (or 4½-Fr.)	2. 5-Fr. (or 51/2-Fr.)	3. 6-Fr. (or 61/2-Fr.)	
4	4. 7-Fr. (or 7½-Fr.)	5. 8-Fr. (or 8½-Fr.)	6. Sheathless GC	
	7. Other ()			
Va	ess site for PCI (Final uscular access site for P troducer sheath for PCI	CI (select one from t or	•	ch)
Cros	ssover of access site		□ No / ver o (클릭시에만	아래 내용 활성화)
Ch	nange of access site			
	Initial access site		(select one from te site sit	e variables ¹ "si
	2 nd access site (중간단기	ᅨ 없으면 생략)	(select one from te site sit	e variables ¹ "si
	3 rd access site (중간단기	예 없으면 생략)	(select one from te site sit	e variables ¹ ″si
	Final access site		(select one from "select o	ne from ables ¹ "bl
Re	eason for crossover (sel	ect all)		
	□(select all)ossove	ers (Puncture Fa	ailure	
	□ Vasospasm		□ Vessel tortuosity	
	□eNeed for larger	catheter	☐ Complication	of radial artery
	□CHemodynamic	instability	☐ Contraindicat	ion of radial approach
	□ontrain artery occ	clusion	☐ Other ()

6

Access Site Preparation

Eutectic Mixture of Local Anesthesia Cream Can Reduce Both the Radial Pain and Sympathetic Response During Transradial Coronary Angiography

Young Jin Youn, MD, Woo-Taek Kim, MD, Jun-Won Lee, MD, Sung-Gyun Ahn, MD, Min-Soo Ahn, MD, Jang-Young Kim, MD, Byung-Su Yoo, MD, Seung-Hwan Lee, MD, Junghan Yoon, MD, and Kyung-Hoon Choe, MD Division of Cardiology, Department of Internal Medicine, Wonju College of Medicine, Yonsei University, Wonju, Korea

ABSTRACT

Background and Objectives: Radial artery spasm is one of the most common complications of transradial coronary angiography (TRA): the radial artery is prone to cathecholamine-induced contraction and radial pain during TRA could increase the sympathetic tone. The object of this study was to evaluate whether the eutectic mixture of local anesthesia (EMLA) cream, in addition to lidocaine infiltration, could reduce the sympathetic response by reducing radial pain during TRA. Subjects and Methods: Seventy-six patients were randomized 1:1 to either EMLA or control groups. Radial pain was measured by the visual analogue scale (VAS) and the verbal rating scale (VRS-4). Sympathetic response, including systolic (SBP) and diastolic blood pressure (DBP), pulse rate (PR), stroke volume (SV) and total peripheral resistance (TPR), was measured

by photog group (V. EMLA gr min: 2 vs. ing TRA, thetic res

KEY WO

Prevention of Arterial Spasm During Percutaneous Coronary Interventions Through Radial Artery:

The SPASM Study

Olivier Varenne, ^{1*} Arnaud Jégou, ¹ MD, Remy Cohen, ¹ MD, Jean Philippe Empana, ² MD, PhD, Emmanuel Salengro, ¹ MD, Alice Ohanessian, ¹ MD, Cédric Gaultier, ¹ MD, PhIlippe Allouch, ¹ MD, Sylvie Walspurger, ¹ Olivier Margot, ¹ Abdel El Hallack, ¹ MD, PhD, Xavier Jouven, ¹ MD, Simon Weber, ¹ MD, PhD, and Christian Spaulding, ^{1,2} MD

Aims: Radial artery spasm remains the major limitation of transradial approach for percutaneous coronary interventions. The aim of our study was to evaluate the efficacy of vasodilators in the prevention of radial artery spasm during percutaneous coronary interventions. Methods and results: 1,219 patients were consecutively randomized to receive placebo (n = 198), molsidomine 1 mg (n = 203), verapamil 2.5 mg (n = 409), 5 mg (n = 203) or verapamil 2.5 mg and molsidomine 1 mg (n = 206). All drugs were administered through the arterial sheath. The primary end point was the occurrence of a radial artery spasm defined by the operator as severe limitation of the catheter movement, with or without angiographic confirmation. Main characteristics including age, sex, wrist and arterial sheath diameters and procedure duration were identical across the groups. The rate of radial artery spasm was lowest in patients receiving verapamil and molsidomine (4.9%), compared to verapamil 2.5 mg or 5 mg (8.3 and 7.9%), or molsidomine 1 mg (13.3%); and placebo (22.2%) (P < 0.0001). Conclusion: Radial artery spasm during transradial percutaneous interventions was effectively prevented by the administration of vasodilators. The combination of verapamil 2.5 mg and molsidomine 1 mg provided the strongest relative risk reduction of spasm compared to placebo and should therefore be recommended during percutaneous coronary interventions through the radial approach. © 2006 Wiley-Liss, Inc.

Key words: radial spasm; vasodilators; percutaneous coronary intervention

Angiographic data - Access site preparation

Access site preparation Use of EMLA or local anesthetic cream on access site □ No / □ Yes Use of systemic sedatives or minor tranquilizer □ No / □ Yes Brand name (동일하게 사용하면 추후 일괄 처리) Generic name (동일하게 사용하면 추후 일괄 처리) Route of administration □ PO / □ IV / □ Other (Modified Allen's test before radial puncture □ No / □ Yes Result of Allen's test: □ Positive (Intact ulnar a.) □ Negative (> 10 sec) Puncture needle (final use only) Puncture needle size: gauge Puncture needle material: □ Plastic (Vinca) / □ Metal Use of spasmolytics (IA) □ No (default) / □ Yes (아래 항목 활성화) Nitrate п No / п Yes Nicorandil □ No / □ Yes Verapamil □ No / □ Yes Diltiazem □ No / □ Yes Other □ No / □ Yes (

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KCJ 2011;41:726-32 / CCI 2006;68:231-5



Prospective TRI registry 8

Radial angiography

Anatomical consideration of the radial artery for transradial coronary procedures: arterial diameter, branching anomaly and vessel tortuosity

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> Received 4 November 2003; received in revised form 9 January 2004; accepted 5 March 2004 Available online 30 July 2004

Abstract

Background: The radial artery is currently regarded as a useful vascular access site for coronary procedures. Adequate anatomical information of the radial artery should be helpful in performing the transradial coronary procedure. Therefore, we tried to evaluate the size of radial artery, the incidence and clinical significance of anomalous branching patterns and tortuosity of the radial artery related with transradial coronary procedure.

Materials and method: In 1191 cases, mean radial arterial diameter (RAD) was measured before and after the procedure using a twodimensional ultrasound and retrograde radial artery angiography was performed before the transmital in coronary procedure in all patients. Branching aromaly tetruscity of the radial artery and procedural characteristics, including procedure times and lead vascular complications.

Arterial Anatomic Variations and Its Influence on Transradial Coronary Procedural Outcome

TUGRUL NORGAZ, M.D., SEVKET GORGULU, M.D., and SINAN DAGDELEN, M.D.

From the Cardiology Department, Acibadem University, Istanbul, Turkey

Objectives: Our aim was to establish the frequency of arterial anatomic variations and its relation to coronary procedural outcome in patients undergoing a first transradial coronary procedure.

Methods: This was a single-center prospective study. A total of 1,446 consecutive patients undergoing their first transradial coronary procedure were recruited. Retrograde radial arteriography was performed to define radial artery anatomy. If the operator encountered serious problems during crossing the subclavian-aortic truncus, retrograde subclavian arteriography was also performed. Patient demographics, procedural data, such as total procedural duration, the number of catheters and guidewires used, the amount of contrast media usage, dose area product (DAP) and fluoroscopy time, and vascular compilications were recorded.

Results: Anatomic variations were noted in 270 (18.6%) and these patients were significantly older (mean age 64.4 \pm 10.4 vs. 59.2 \pm 10.8 years, P < 0.001) and more commonly female (46% vs. 33%, P < 0.001) with significantly higher procedural failure rates (8.8% vs. 5.6%, P = 0.006). In addition, procedural duration (P < 0.001) and fluoroscopy time (P < 0.001) were statistically longer in patients with anatomic variations. Anatomic variations also had an adverse impact on the amount of contrast agent usage (63.9 \pm 28.3 mL vs. 59.1 \pm 25.3 mL, P = 0.006) and minor vascular complication rate (P = 0.007).

Conclusions: This study indicates that anatomic variation of the arterial path has an adverse impact on transradial coronary procedural outcome. (J Interven Cardiol 2011;00:1–9)

IJC 2005;101:421-7 / J Interv Cardiol 2011;Epub

W

Angiographic data – Radial angiography (시행하면 반드시 기입)

Radial angiography

No /

Yes /

For need

Anomaly □ No / □ Yes (Yes 시에 아래 활성화)

At distal RA (select one from "vessel tortuosity variables³")

At middle RA (select one from "vessel tortuosity variables³")

At proximal RA (select one from "vessel tortuosity variables³")

At brachial artery (select one from "vessel tortuosity variables³")

At subclavian artery (select one from "vessel tortuosity variables³")

At aorta (select one from "vessel tortuosity variables³")

Vessel tortuosity variables³ (default = 1. No anomaly)

1. No anomaly 2. S-shaped (severe tortuosity)

Ω-shaped (loop)

*Presence of bilateral radial αilateral rad □ Not evaluated / □ No / □ Yes

' 편축에 축에 t evaluated 확인시 가급적 양축 evaluation 해주세요.

Presence of arteria lusoria □ Not evaluated / □ No / □ Yes

Antiplatelets and Bleeding

Effect on Bleeding, Time to Revascularization, and One-Year Clinical Outcomes of the Radial Approach During Primary Percutaneous Coronary Intervention in Patients With ST-Segment **Elevation Myocardial Infarction**

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> The radial approach during percutaneous coronary intervention (PCI) has been reported to reduce the incidence of bleeding complications. However, the radial approach still accounts for <10% of procedures worldwide and only 1% in the United States. Our objective was to

Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: A systematic review and meta-analysis of randomized trials

Sanjit S. Jolly, MD, a Shoaib Amlani, MD, a Martial Hamon, MD, b Salim Yusuf, MBBS, D Phil, a and Shamir R. Mehta, MD, MSc a Hamilton, Ontario, Canada; and Caen, France

Background Small randomized trials have demonstrated that radial access reduces access site complications compared to a femoral approach. The objective of this meta-analysis was to determine if radial access reduces major bleeding and as a result can reduce death and ischemic events compared to femoral access.

Methods MEDLINE, EMBASE, and CENTRAL were searched from 1980 to April 2008. Relevant conference abstracts from 2005 to April 2008 were searched. Randomized trials comparing radial versus femoral access coronary anaiography or intervention that reported major bleeding, death, myocardial infarction, and procedural or fluoroscopy time were included. A fixed-effects model was used with a random effects for sensitivity analysis.

Results Radial access reduced major bleeding by 73% compared to femoral access (0.05% vs 2.3%, OR 0.27 [95% CI 0.16, 0.45], P < .001). There was a trend for reductions in the composite of death, myocardial infarction, or stroke (2.5% vs 3.8%, OR 0.71 [95% CI 0.49-1.01], P = .058) as well as death (1.2% vs 1.8% OR 0.74 [95% CI 0.42-1.30], P = .29). There was a trend for higher rate of inability to the cross lesion with wire, balloon, or stent during percutaneous coronary intervention with radial access (4.7% vs 3.4% OR 1.29 [95% CI 0.87, 1.94], P = .21). Radial access reduced hospital stay by 0.4 days (95% CI 0.2-0.5, P = .0001).

Conclusions Radial access reduced major bleeding and there was a corresponding trend for reduction in ischemic events compared to femoral access. Large randomized trials are needed to confirm the benefit of radial access on death and ischemic events. (Am Heart J 2009; 157:132-40.)

Bleeding complication data (퇴원시 입력)

Bleeding Academic Research Consortium (BARC) definition (select one)

1. Type 0 (default)	2. Type 1	3. Type 2
4. Type 3a	5. Type 3b	6. Type 3c
7. Type 4	8. Type 5a	9. Type 5b

BARC definition 에서 1을 제외한 경우 아래 활성화

ype of bleeding (select all)				
□ Intracranial	□ GI		□ GU	
□ Hemoptysis	□ Hemoper	icardium	□ Retroperitonea	I
□ Epistaxis	□ Gingival b	bleeding	□ Pharyngeal/ora	l bleeding
□ Subcutaneous/dermal	□ Vascular	access site	Oozing at punc	ture site
□ Hematoma ≥ 5cm at acces	s site			
□ Access site bleeding requir	ring intervention/s	surgery		
□ Other ()	
ransfusion				
Total used packed RBC	unit	Total used	platelet conc.	_unit
Total used FFP	unit	Total wood	whole blood	unit

Laboratory finding

Initial Hb:	g/dl	Nadir Hb:	g/dl
Initial platelet	x10 ⁶ /L	Nadir platelet	x10 ⁶ /L

Antiplatelet agent

	Before procedure	During procedure	After procedure
UFH	□ No / □ Yes	□ No / □ Yes	□ No / □ Yes
Route	□ IV / □ IC	□ IV / □ IC	□ IV / □ IC
Dose			
LMWH	□ No / □ Yes	□ No / □ Yes	□ No / □ Yes
Route	□ IV / □ IC / □ SC	□ IV / □ IC / □ SC	□ IV / □ IC /□ SC
Dose			
GPIIb/IIIa inhibitor	□ No / □ Yes	□ No / □ Yes	□ No / □ Yes
Name			
Route	□ IV bolus / □ IV cont. / □ IC	□ IV bolus / □ IV cont. / □ IC	□ IV bolus / □ IV cont. / □ IC
Dose			

AJC 2010;106:148-54 / AHJ 2009;157:132-40



Access site complication and patency

Access site complication data

Access Site Complication

Site of complication (select one from iontion the spasmolyti1"se

Classification of access site complication

•	
Perforation during procedure	□ No / □ Yes
Pseudoaneurysm or aneurysm	□ No / □ Yes
Dissection	□ No / □ Yes
Occlusion	□ No / □ Yes
Compartment SD requiring surgical maneuver	□ No / □ Yes
Hematoma requiring transfusion	□ No / □ Yes
Major hematoma (>5cm)	□ No / □ Yes
Minor hematoma	□ No / □ Yes
Retroperitoneal hematoma	□ No / □ Yes
Intraabdominal hemorrhage	□ No / □ Yes
AV fistula (FU 중에 확인되면 입력해주세요)	□ No / □ Yes
Infection / discharge (FU 중에 확인되면 입력해주세요)	□ No / □ Yes
Ulceration (FU 중에 확인되면 입력해주세요)	□ No / □ Yes
Other	

Follow-up data at first visit (within 1 month)				
Visit date: <u>YYYY-MM</u> -DD				
Method of follow-up:		1. Revisit 2.	Telephone	
Patency of approach sit				
Site (select one from "Acc	cess site variables ¹ ")			
Access site variable	es ¹			
1. Femoral, Rt.	3. Radial, Rt.	5. Brachial, Rt.	7. Ulnar, Rt.	
2. Femoral, Lt.	4. Radial, Lt.	6. Brachial, Lt.	8. Ulnar, Lt.	
Clinical patency (Evaluated 에서 아래 항목 활성화)		1. Not evaluated / 2. Evaluated / 3. Unknown		
Pulsation (select one)		1. Intact		
		2. Diminished		
		3. Absent		
		4. Bounding (aneury	sm)	
		5. Unchecked		
Sensory (select one)		1. Normal		
		2. Hypoethesia		
		3. Paresthesia (inclu	ding tingling sensation)	
		4. Unchecked		
Infection		□ No / □ Yes		
Patency by ultrasound (Evaluated 에서 아래 항목 활성화)		1. Not evaluated / 2. Evaluated / 3. Unknown		
Sonographic confirm	ation (select one)	1. Patent		
		2. Narrowed (>50%[OS)	
		3. Occluded		
Radial artery diameter	er by US			
Proximal reference	e diameter	mm		
Distal reference diameter		mm		
Reference diameter		mm (reference 만 입력해도 무관)		
Minimal luminal diameter		mm		

Compression method

A Randomized Comparison of TR Band and Radistop Hemostatic Compression Devices After Transradial Coronary Intervention

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Background: The transradial route for coronary intervention has proven to be safe, effec-

Transradial access compared with femoral puncture closure devices in percutaneous coronary procedures

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Abstract

Background: Transradial access (RA) is associated with less complications and is preferred by patients. Vascular closure devices (VCDs) may improve discomfort and may reduce complications associated with transfemoral access. Aim was to evaluate complications and discomfort associated with percutaneous coronary procedures employing RA or VCDs.

Methods: We enrolled 1492 consecutive patients who underwent percutaneous coronary procedures with RA (604 procedures), femoral approach with manual compression (MC) (276 procedures), or with either Angioseal™ (311 procedures) or Starclose™ (301 procedures) closure device. Discomfort was assessed using procedure-specific questions. Major vascular complications were evaluated during hospitalization.

Results: RA significantly reduced major complications (0.7%) compared to either the MC (2.9%, p=0.03) or the VCDs (Starclose[™] 2.7%, Angioseal[™] 3.9%, p=0.003). There were no significant differences in major complications between MC and either the Angioseal[™] or the Starclose[™]. At multivariate analysis the RA was predictor of reduced complications (OR 0.26, 95% CI 0.08–0.85, p=0.03 vs MC, and OR 0.19, 95% CI 0.07–0.57, p=0.003 vs VCDs). The RA was associated with a significant reduction in procedural discomfort with 44.2% of patients referring no discomfort (p<0.0001). Starclose[™] and Angioseal[™] were better tolerated than MC (27.8%, 29.3% and 8.9% patients respectively without discomfort, p<0.0001).

Conclusions: RA is associated with a significant reduction in major vascular complications compared to femoral approach even if two different VCDs are employed. VCDs are better tolerated than MC but the RA was associated with the lowest discomfort.

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Keywords: Radial; Vascular closure device; Angioseal; Starclose

Compression or closure devices

First closure device

Site (select one from "access site variables"

Access site variables¹

1. Femoral, Rt. 3. Radial, Rt. 5. Brachial, Rt. 7. Ulnar, Rt. 2. Femoral, Lt. 4. Radial, Lt. 6. Brachial, Lt. 8. Ulnar, Lt.

Closure device name

 1. No use (Manual Compression)
 2. Radistop

 3. Percloser
 4. Starcloser

 5. Angioseal
 6. Other

Second closure device

Site (select one from "access site variables1")

Access site variables¹

 1. Femoral, Rt.
 3. Radial, Rt.
 5. Brachial, Rt.
 7. Ulnar, Rt.

 2. Femoral, Lt.
 4. Radial, Lt.
 6. Brachial, Lt.
 8. Ulnar, Lt.

Closure device name

1. No use (Manual Compression) 2. Radistop
3. Percloser 4. Starcloser
5. Angioseal 6. Other

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CCI 2010;76:660 / IJC 2009;137:199-205

Catheter and Wire

ORIGINAL INVESTIGATION

Reducing Needle-To-Balloon Time by Using a Single Guiding Catheter during Transradial Primary Coronary Intervention

KEON-WOONG MOON, M.D., PH.D, JI-HOON KIM, M.D., JU-YOUN KIM, M.D., MI-HYANG JUNG, M.D., GEE-HEE KIM, M.D., KI-DONG YOO, M.D., PH.D., and CHUL-MIN KIM, M.D., PH.D.

From the Department of Internal Medicine, St. Vincent's Hospital, The Catholic University of Korea, Suwon, South Korea

Objectives and Background: It is unknown whether using a single guiding catheter for both nonculprit and culprit vessel angiography and intervention during transradial primary percutaneous coronary intervention (PCI)

Feasibility of Transradial Coronary Intervention Using a Sheathless Guiding Catheter in Patients With Small Radial Artery

Young Jin Youn, MD, Junghan Yoon, MD, Sang Woo Han, MD, Jun-Won Lee, MD, Joong Kyung Sung, MD, Sung-Gyun Ahn, MD, Jang-Young Kim, MD, Byung-Su Yoo, MD, Seung-Hwan Lee, MD, and Kyung-Hoon Choe, MD Division of Cardiology, Wonju College of Medicine, Yonsei University, Wonju, Korea

ABSTRACT

Background and Objectives: Transradial coronary angiography and intervention are increasing in frequency due to lower major vascular access site complications and the potential for early mobilization. However, the small size of the radial artery (RA) is a major limitation of this technique. A sheathless guiding catheter (GC) has recently been introduced that has a 1-2 French smaller diameter compared with the corresponding introducer sheath. This catheter also has a hydrophilic coating along its entire length. We evaluated the feasibility of using a sheathless GC in patients who have small radial arteries. Subjects and Methods: The procedural results were evaluated in patients with small radial arteries (diameter <2.3 mm) who underwent transradial coronary intervention using a sheathless GC. Results: A total of 25 (male: 9) patients with 29 lesions were enrolled. The mean RA diameter was 1.81±0.26 mm. 44% of the patients had stable angina and 50.0% had acute coronary syndrome. The procedural success rate was 93.1%. Two patients (6.9%) had chronic total occlusive lesions that could not be crossed with a guide-wire despite good guiding support. An intravascular ultrasound could be used for all of the treated lesions. Multi-vessel intervention was performed in 29.2% of the patients. Two bifurcated lesions were treated with a kissing balloon technique, and one with a modified T-stenting technique. No catheter related complications were reported. Conclusion: The use of a sheathless GC is feasible in patients with small radial arteries without catheter related complications. (Korean Circ J 2011;41:143-148)

KEY WORDS: Coronary intervention; Radial artery; Vascular access.

Angiographic data - Wire and Catheter

Used guide-wire for approach (not for coronary artery)

Name of 0.035" guide-wire

Terumo J □ No / □ Yes

Terumo 1.5J □ No / □ Yes

Terumo angled □ No / □ Yes

Tefron □ No / □ Yes

Other

Use of 0.014" quide-wire □ No use / □ Yes

Catheter Data

Bilateral injection with single catheter □ No / □ Yes

(Yes 인 경우, right catheter 정보 입력되면 left catheter 에 자동으로 복사되어 입력)

Catheter for CAG (Final use)

•	Right	Left
Name	Lookup menu 로 관리	Lookup menu 로 관리
Length or shape	소수점 2 자리	소수점 2 자리
Diameter (Fr.)	소수점 1 자리	소수점 1 자리
Side hole	□ Yes / □ No	□ Yes / □ No
Total number of used catheter	Default = 1	Default = 1

Catheter for PCI (Final use)

	Right	Left
Name	Lookup menu 로 관리	Lookup menu 로 관리
Length or shape	소수점 2 자리	소수점 2 자리
Diameter (Fr.)	소수점 1 자리	소수점 1자리
Side hole	□ Yes / □ No	□ Yes / □ No
Total number of used catheter	Default = 0	Default = 0

정의 Catheter 에서 작성법은 아래와 같다. 에를 들어, 4Fr ALI catheter 는 Name: AL / Length or shape: 1 / diameter: 4 6Fx XB 3.5 catheter 는 Name: XB / Length or shape: 3.5 / diameter: 6 와 같은 방법으로 표시하다.

Single catheter 로 LCA 와 RCA 모두 촬영하였다면, 같은 카테터를 양 쪽에 입력한다.

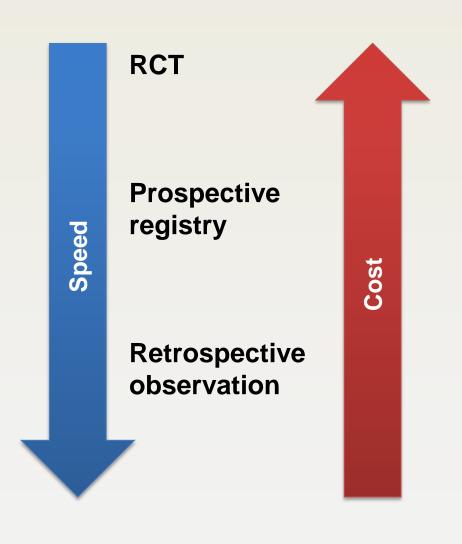
13

JIC 2012; Epub / KCJ 2011; 41:143-148



Conclusion

RCT	Observational study
Establish the efficacy and safety	Demonstrate the causal relationship
	Difficult to avoid bias
Not real world setting	Real world practice setting
Limited to non-rare condition	
Limited duration of trial	
Need for lots of cost	



Conclusion

