Twelve-month Clinical Outcomes of Peripheral Arterial Disease Patients with or without Critical Limb Ischemia undergoing Percutaneous Transluminal Angioplasty

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Disclosure Information

I have nothing to disclose.

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Background

1. Percutaneous transluminal angioplasty (PTA) is considered as an effective treatment in patients (pts) with critical limb ischemia (CLI).

2. There are very limited data whether the procedural and clinical outcomes of symptomatic peripheral arterial disease (PAD) pts with CLI can be different with those of non-CLI following successful PTA.

Purpose

The purpose of this study was to compare the twelve-month clinical outcomes of PAD pts with CLI vs. without CLI in which successful PTA was performed.

Methods

1. Study Population

A total of 503 PAD pts (602 limbs, 1229 lesions) who underwent PTA from Sep 2004 to Dec 2013 were enrolled.

2. Study Group

CLI group	**(368 pts, 73.1%)**
Non-CLI group	**(200 pts, 26.9%)**

Methods

3. PTA procedure and Medical treatment

1) Diagnostic angiography and PTA was performed through either femoral or radial artery after administration of unfractionated heparin (70 to 100 U/kg).
2) Successful PTA was defined as the achievement of an angiographic residual stenosis < 50% in the presence of Thrombolysis in Myocardial Infarction (TIMI) blood flow grade 3.
3) Pts were encouraged to continue on taking medications including antiplatelet agents, beta-blockers, ACEi or ARBs, CCBs, and statins.

Methods

4. Study definitions and clinical follow-up

1) CLI was classified by the Fontaine (stage III-IV) or the Rutherford (grades 4-6) classification.
2) Total major adverse cardiac-cerebral events (MACCE) included total death, non-fatal MI, cerebral vascular accidents or cardiac revascularization.
3) Risk factors and past medical histories were thoroughly investigated and cumulative incidences of various events during hospital stay and up to 1 year were evaluated.

Methods

5. Statistical analysis

1) All statistical analyses were performed using SPSS 20.0.

2) Continuous variables were expressed as means ± standard deviation and were compared using unpaired t-test or Mann-Whitney rank-sum test.

3) Categorical data were expressed as percentages and were compared using chi-square statistics or Fisher's exact test.

4) A *P*-value of 0.05 was considered statistically significant.

6. Study Endpoints

The incidence of Limb salvage, target extremity revascularization (TER), TLR, mortality, cardiac death, PCI, MI, CVA and MACCEs were evaluated up to 12 months.

Results

Baseline Clinical Characteristics

Variables	Total (503 Pts)	CLI (368 Pts)	Non-CLI (135 Pts)	P Value
Male (n, %)	388 (77.1)	277 (75.2)	111 (82.2)	0.100
Age	67 ± 10	67 ± 9	67 ± 11	0.582
Body mass index (kg/m^2)	23 ± 3	23 ± 3	23 ± 3	0.167
Clinical presentations				
Active Wound (n, %)	318 (63.2)	318 (86.4)	0 (0.0)	< 0.001
Diabetic foot (n, %)	277 (55.0)	277 (75.2)	0 (0.0)	< 0.001
Gangrene (n, %)	116 (23.0)	116 (31.5)	0 (0.0)	< 0.001
Berger's disease (n, %)	16 (3.1)	14 (3.8)	2 (1.4)	0.257
Others (n, %)	29 (5.7)	2 (0.5)	27 (20.0)	< 0.001
Hypertension (n, %)	351 (69.7)	258 (70.1)	93 (68.8)	0.792
Diabetes mellitus (n, %)	373 (74.1)	319 (86.6)	54 (40.0)	< 0.001
Dyslipidemia (n, %)	44 (8.7)	20 (5.4)	24 (17.7)	< 0.001
Cerebral vascular accidents (n, %)	81 (16.1)	55 (14.9)	26 (19.2)	0.243
Chronic renal insufficiency (n, %)	141 (28.0)	128 (34.7)	13 (9.6)	< 0.001
Atrial fibrillation (n, %)	48 (9.5)	39 (10.5)	9 (6.6)	0.184
Smoking (n, %)	248 (49.3)	163 (44.2)	85 (62.9)	< 0.001
Alcohol (n, %)	170 (33.7)	114 (30.9)	56 (41.4)	0.027
Prior MI (n, %)	33 (6.5)	17 (4.6)	16 (11.8)	0.004
Laboratory findings				
HDL cholesterol (mg/dL)	37 ± 11	35 ± 11	42 ± 12	< 0.001
LDL cholesterol (mg/dL)	90 ± 36	88 ± 35	95 ± 36	0.098
hsCRP (mg/L)	20 ± 38	28 ± 48	8 ± 22	< 0.001
Creatinine (mg/dL)	2.2 ± 2.6	2.6 ± 3.1	1.2 ± 1.5	< 0.001

Angiographic Lesion Characteristics and Procedural complications

Variables	Total (1229 lesions)	CLI (947 lesions)	Non CLI (282 lesions)	P Value
Lesion site				
Iliac	185 (15.0)	84 (8.8)	101 (35.8)	< 0.001
Femoral	319 (25.9)	226 (23.8)	93 (32.9)	0.002
Popliteal	73 (5.9)	53 (5.5)	20 (7.0)	0.351
Tibio-peroneal	7 (0.5)	6 (0.6)	1 (0.3)	ns
Posterior tibial	228 (18.5)	208 (21.9)	20 (7.0)	< 0.001
Anterior tibial	298 (24.2)	260 (27.4)	38 (13.4)	< 0.001
Peroneal	119 (9.6)	110 (11.6)	9 (3.1)	< 0.001
Lesion length	99 ± 68	103 ± 71	86 ± 56	< 0.001
Calcification	324 (26.3)	263 (27.7)	61 (21.6)	0.040
Procedural characteristics				
Sub-intimal approach	298 (24.2)	230 (24.2)	68 (24.1)	0.952
Stent implantation	420 (34.1)	255 (26.9)	165 (58.5)	< 0.001
POBA	795 (64.6)	680 (71.8)	115 (40.7)	< 0.001
Procedural complications				
Hospital stay	45 ± 49	58 ± 60	11 ± 18	< 0.001
Pseudoaneurysm	7 (1.3)	2 (0.5)	5 (3.7)	0.017
Hemorrhagic stroke	3 (0.5)	0 (0.0)	3 (2.2)	0.019
Transfusion	196 (38.9)	167 (45.3)	29 (21.4)	< 0.001
Rupture	10 (0.8)	9 (0.9)	1 (0.3)	0.470
Perforation	53 (4.3)	44 (4.6)	9 (3.1)	0.291
Abrupt closure	9 (0.7)	9 (0.9)	0 (0.0)	0.224
Acute thrombosis	24 (1.9)	19 (2.0)	5 (1.7)	0.804
Angiographic success	974 (79.2)	736 (77.7)	238 (84.3)	0.015

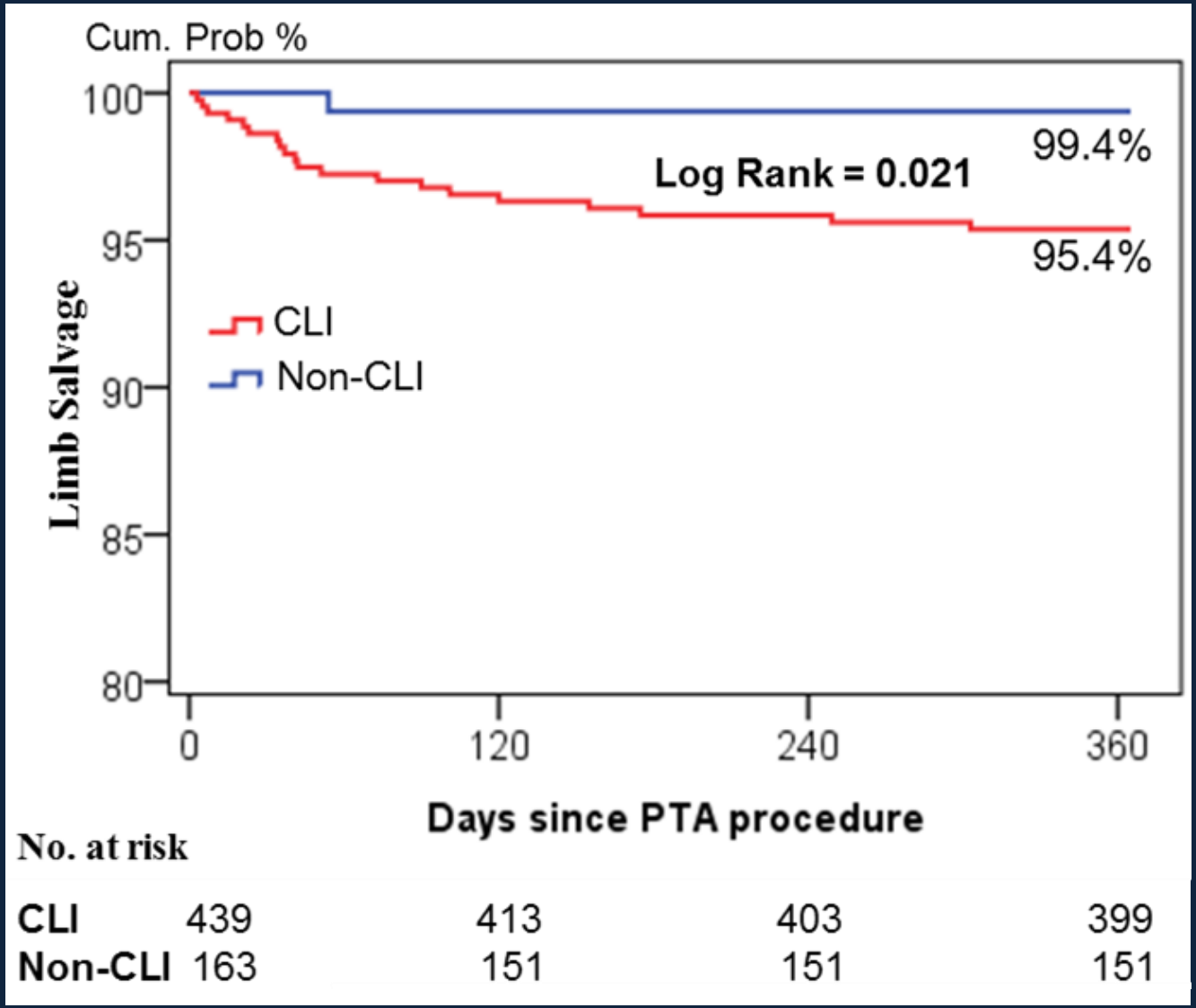
6 to 9-Month Angiographic Outcomes

Variables	CLI (n=125 Pts) (n=152 Limb)	Non CLI (n=67 Pts) (n=83 Limb)	Hazard ratio [95% C.I]	P Value
Restenosis	90 (59.2)	37 (44.5)	1.804 [1.051 - 3.097]	0.031
Total occlusion	71 (46.7)	21 (25.3)	2.587 [1.436 - 4.661]	0.001
Primary patency	61 (40.1)	45 (54.2)	0.566 [0.329 - 0.971]	0.038
Associated primary patency	67 (44.0)	51 (61.4)	0.494 [0.286 - 0.853]	0.011
Secondary patency	103 (67.7)	59 (71.0)	0.855 [0.476 - 1.533]	0.599
Non-occlusive (distal flow at least 1 artery)	132 (86.8)	74 (89.1)	0.802 [0.347 - 1.853]	0.606

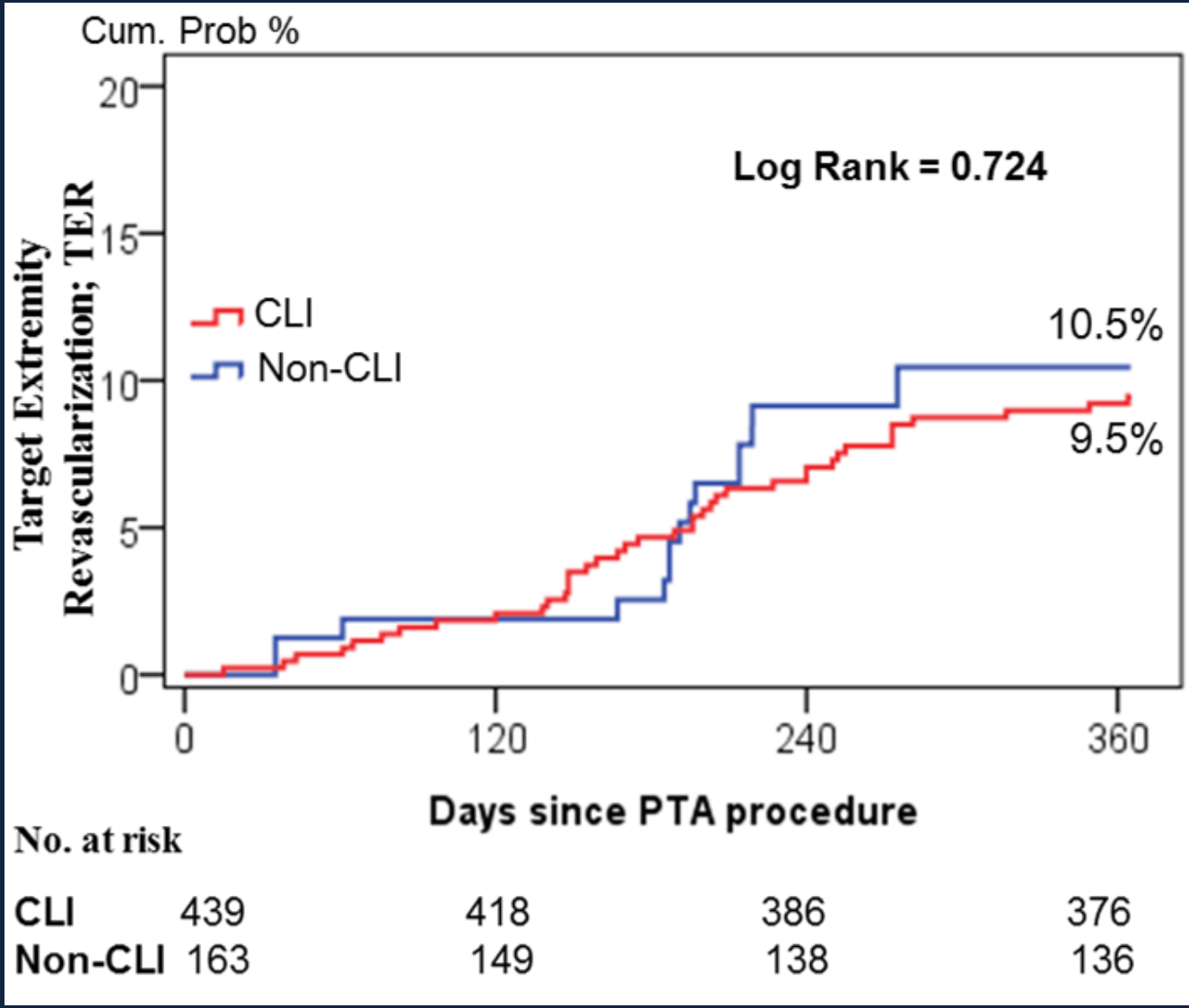
12-Month Clinical Outcomes

Variables	CLI (n=368 Pts)	Non CLI (n=135 Pts)	Hazard ratio [95% C.I]	P Value
Total death	19 (5.1)	9 (6.6)	0.762 [0.336 - 1.728]	0.515
Cardiac death	5 (1.3)	2 (1.4)	0.915 [0.175 - 4.778]	ns
Myocardial infarction	2 (0.5)	1 (0.7)	0.732 [0.065 - 8.141]	ns
PCI	7 (1.9)	5 (3.7)	0.504 [0.157 - 1.616]	0.319
Cerebral vascular accidents	2 (0.5)	2 (1.4)	0.363 [0.050 - 2.605]	0.293
MACCEs	27 (7.3)	15 (11.1)	0.633 [0.325 - 1.231]	0.175
Limb salvage	33 (92.5)	5 (97.0)	0.128 [0.017 – 0.963]	0.019
Repeat PTA	41 (9.3)	15 (9.2)	1.016 [0.546 - 1.890]	0.959
Target lesion revascularization	41 (9.3)	13 (7.9)	1.188 [0.619 - 2.280]	0.603
Target extremity revascularization	41 (9.3)	15 (9.2)	1.016 [0.546 - 1.890]	0.959
Target extremity surgery; amputations	80 (18.2)	1 (0.6)	36.10 [4.979 - 261.6]	< 0.001

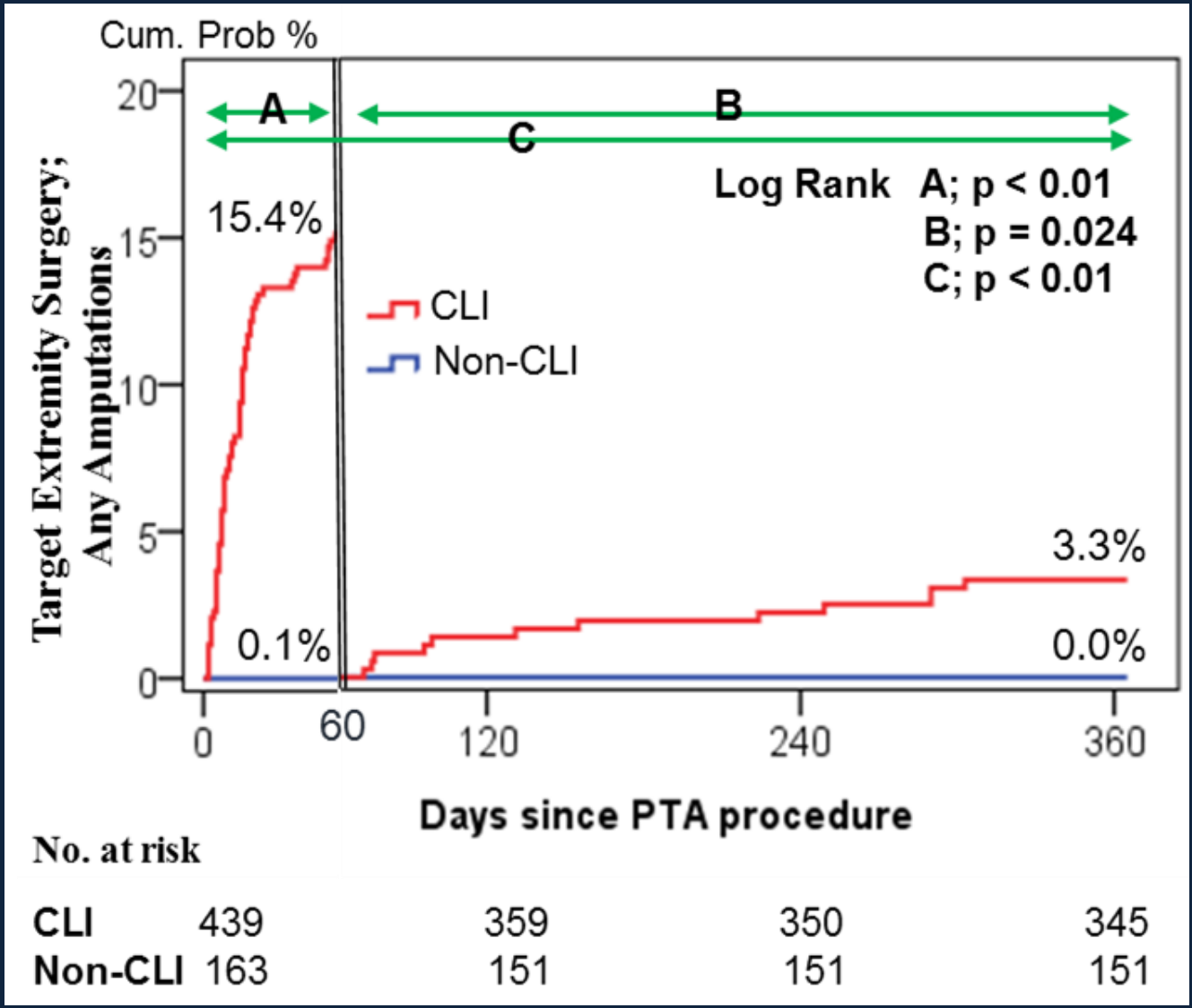
Kaplan-Meier Curves for Limb Salvage



Kaplan-Meier Curves for Target Extremity Revascularization



Kaplan-Meier Curves for Target Extremity Surgery



고려대학교구로병원
KOREA UNIVERSITY GURO HOSPITAL

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CCI Program

Complex Cardiovascular Intervention Program

Cardiovascular Center,
Korea Univ. Guro Hospital,
Seoul, Korea

March~, 2011

Seung-Woon, Rha MD.PhD

COURSE DIRECTOR

Seung-Woon Rha, MD., PhD.
FACC, FAHA, FSCAI, FESC, FAPSIC.

Associate Professor, Dept. of Internal Medicine, Medical College, Korea University
Director, Cardiovascular Intervention and Research,
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- CTO Summit, Course Director
- TCT AP (Angioplasty Summit) and Encore Seoul, Scientific Committee & Faculty
- KSC, KSIC, CCT, CVIT, TOPIC, CTO club meeting, Faculty
- Proctor and Faculty in Korean CTO club, TRI club and VIS (Vascular Intervention Seminar)

When	Every Tuesday & Thursday for / Mar.11, 2011 ~
Where	Korea University Guro Hospital, Seoul, Korea
Advisory Instructo	Dong-Joo Oh MD.PhD, FACC
Course Instructor	Seung-Woon Rha MD.PhD, FACC
Invited Mentors	1. Chael-Ung Choi (Korea Univ. Guro Hospital) 2. Sang-Ho Park (Soonchunhyang Univ. Hospital Cheonan) 3. Yun-Hyeong Cho (Kwandong Univ. College Of Medicine Myongji Hospital) 4. Amro Elnager (Benha Univ. Egypt)

COURSE OVERVIEW

1. Technical improvement in Complex Coronary & Peripheral Intervention
2. Clinical Research in Cardiovascular Field

LEARNING OBJECTIVES

1. Complex coronary & Endovascular Intervention
   - A. Complex coronary intervention : LM, CTO, Bifurcation, Diffuse long Muti-vessel disease, Small vessel disease, FFR, Coronary Anormaly
   - B. Complex Endovascular : Carotid, Subclavian, Renal, Iliofemoral, BTK, Mesentry, Vein Intervention, Aortic Aneurysm
2. Hands-on experience as an operator with mentors
3. Free discussion with experts
4. Clinical research program and paperwork
5. Visiting professors' activities : Lectures, Interesting case discussion
6. Challenging new devices and experiencing cutting edge technology
7. Improving English Proficiency

AGENDA

08:30 - 08:45	Opening Remarks & Introduction
08:45 - 12:30	TRA & TRI Session
12:30 - 13:30	Lunch
13:30 - 14:00	Round Table Meeting Topic review and Clinical Research Discussion
14:00 - 18:00	Complex Coronary & Peripheral Joint Live I
18:00 - 18:30	Dinner
18:30 - 19:00	Discussion for case of the day Meet the experts
19:00 -	Complex Coronary & Peripheral Joint Live II : Until Tired

CANDIDATE SELECTION CRITERIA

1. Current active academic position as a faculty in cardiovascular intervention field (Interventional Cardiology, Vascular Surgeon and Interventional Radiology)
2. Weekly for at least 6 – 12 months will be preferred
   1) 6-12 month : Chance of real practice
   2) <6 months : Mainly assisting job and Hand-on Experiance
   3) Single Visit : Observation

The 1st CCI Guro Live 2014

Complex Cardiovascular Intervention *for Young and Ambitious Doctors*

Date **October 24(Fri)~25(Sat), 2014**
Venue **Korea University Guro Hospital, Seoul, Korea**

Organized by **CIRI (Cardiovascular Intervention Research Institute), Korea University Guro Hospital**
Sponsored by **Cardiovascular Center, Korea University Guro Hospital**

Complex Cardiovascular Intervention

The 2nd

CCI Guro Live 2015

Complex Cardiovascular Intervention for Young and Ambitious Doctors

Date October 23-24, 2015
Venue Korea University Guro Hospital, Seoul, Korea

Honorary Course Director
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Won Heum Shim (Sejong Hospital, Korea)
Tae Hoon Ahn (Gachon University, Korea)
Myung-Ho Jeong (Chonnam National University, Korea)

Course Director
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Complex Cardiovascular Intervention

Complex Cardiovascular Intervention for Young and Ambitious Doctors

The 3rd CCI Guro Live 2016

Date: October 28-29, 2016
Venue: Korea University Guro Hospital, Seoul, Korea

Course Director
Seung-Woon Rha (Korea University , Korea)

Honorary Course Director
Dong-Joo Oh (Korea University, Korea)
Won Heum Shim (Sejong Hospital, Korea)
Tae Hoon Ahn (Gachon University, Korea)
Myung-Ho Jeong (Chonnam National University, Korea)
Jung Han Yoon (Wonju Christian Hospital, Korea)

Course Co-Director
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Yun-Hyeong Cho (Myongji Hospital, Korea)
Sang-Ho Park (Soonchunhyang University, Korea)
Woong Gil Choi (Konkuk University, Korea)
Ji Young Park (Eulji General Hospital, Korea)
Ji Hoon Ahn (Soonchunhyang University, Korea)

Special Topic

Complex Coronary CTO & Non-CTO
- TRI/TRA and Ach Provocation Test
- LM and Bifurcation intervention,
- Calcified and tortuous lesion intervention
- Device update and technical tips and tricks in CTO intervention

Complex Peripheral Intervention
- Aorta and Branched Vessel
- Aorto-iliac Intervention
- Femoro-popliteal CTO
- BTK CTO

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CCI 2016 Secretariat Tel: 02-3144-2227 Fax: 02-3144-2229 e-Mail: info@matekorea.com

CCI (Complex Cardiovascular Intervention)-Guro Live

- CCI Program; Every Tuesday (8;30am to until finish), http://ciri.or.kr (Cardiovascular Intervention Research Institute)
- Annual Guro Live

; Korea Univ Guro Hospital, Seoul. Korea

1. Complex Cardio-vascular Intervention Live
2. Dr Rha style; swrha617@yahoo.co.kr
3. Focused on
   1) Tips and tricks
   2) Experiencing newer devices
   3) Young and ambitious interventionists from Korea and other countries

**** CCI Guro Live 2016; *Oct 28-29, 2016***

Day1; Complex Coronary Intervention

Day2; Complex Periheral Intervention

Save the Date !!

CCI Guro Live 2016

October 28~29, 2016

Korea University Guro Hospital, Seoul, Korea

Conclusion

1. The development of excellent devices, procedural techniques, and optimal medical therapy have improved clinical outcomes of patients with PAD.
2. However, patients with CLI still had a higher risk of amputation and lesser limb salvage rates despite successful revascularization.
3. Further studies will be needed to improve clinical outcomes of patients with PAD, especially presenting with CLI.

Thank you for your attention

Visit www.CIRI.or.kr for more information

CIRI

Cardiovascular Intervention Research Institute

President

Seung-Woon Rha, MD., PhD.,

FACC, FAHA, FSCAI, FESC, FAPSIC.

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      ; Every Tuesday (Full day)
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   :Joint Live and Research Program

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4. CCI Educational Program
   1) Publication and Abstracts
   2) Lecture Slide
   3) Complex Case
   4) Broadcasting Information