## ADVANCES IN INTRAVASCULAR IMAGING: REAL WORLD EVIDENCE AND EXPERT CONSENSUS

### LINC 2022

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## Why is Peripheral Intravascular Imaging Needed?

## Guidelines have expanded the indication and number of endovascular interventions



#### Lower extremity amputation continues to increase



### **Use of IVUS Clearly Leads to Better Outcomes in Coronary Interventions**

### **37% reduction in CV Death**

	IVU	s	Ang	io		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
AIR-CTO 2015	3	115	4	115	1.1%	0.75 [0.17, 3.28]	
AVID 2009	12	395	7	406	2.9%	1.76 [0.70, 4.43]	+
CHEN et al 2012	0	123	4	123	0.3%	0.11 [0.01, 2.04]	<
Choi et al	98	1647	416	4331	53.6%	0.62 [0.50, 0.77]	
CTO-IVUS 2015	0	201	2	201	0.3%	0.20 [0.01, 4.14]	· · · · · ·
De la Torre Hernandez 2014	17	505	30	505	7.2%	0.57 [0.32, 1.01]	
DIPOL 2007	1	83	1	80	0.3%	0.96 [0.06, 15.15]	
EXELLENT 2013	2	463	2	463	0.6%	1.00 [0.14, 7.07]	
Gao et al 2014	5	291	15	291	2.4%	0.33 [0.12, 0.91]	
HOME DES IVUS 2010	3	105	2	105	0.8%	1.50 [0.26, 8.79]	
Hong et al 2014	2	201	5	201	0.9%	0.40 [0.08, 2.04]	
IVUS-XPL 2015	3	700	5	700	1.2%	0.60 [0.14, 2.50]	
Kim et al 2013	0	269	1	274	0.2%	0.34 [0.01, 8.30]	
MATRIX 2011	5	548	10	548	2.1%	0.50 [0.17, 1.45]	
OPTICUS 2001	5	273	1	275	0.5%	5.04 [0.59, 42.83]	
Roy et al 2008	16	884	24	884	6.2%	0.67 [0.36, 1.25]	
Ultimate 2018	5	724	10	724	2.1%	0.50 [0.17, 1.46]	
Wakabayashi et al 2012	12	637	28	637	5.4%	0.43 [0.22, 0.84]	
Witzenbichler et al 2014	27	3349	60	5234	11.9%	0.70 [0.45, 1.11]	
Total (95% CI)		11513		16097	100.0%	0.63 [0.54, 0.73]	•
Total events	216		627				
Heterogeneity: Tau <sup>2</sup> = 0.00; Ch	$ni^2 = 15.6$	5, df =	18 (P = 0	).62); l <sup>2</sup>	= 0%		
Test for overall effect: Z = 5.91	(P < 0.0	0001)					
		TVUS ANGIO					

#### 29% reduction in MI

	IVU	s	Ang	io		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
AIR-CTO 2015	18	115	15	115	6.7%	1.20 [0.64, 2.26]	+-
AVID 2009	25	395	19	406	7.5%	1.35 [0.76, 2.42]	+
CHEN et al 2012	4	123	12	123	2.8%	0.33 [0.11, 1.01]	
Choi et al	56	1674	213	4331	14.7%	0.68 [0.51, 0.91]	-
CTO-IVUS 2015	0	201	2	201	0.4%	0.20 [0.01, 4.14]	
De la Torre Hernandez 2014	23	505	33	505	8.7%	0.70 [0.42, 1.17]	
DIPOL 2007	1	83	4	80	0.8%	0.24 [0.03, 2.11]	
EXELLENT 2013	10	463	2	463	1.6%	5.00 [1.10, 22.69]	
Gao et al 2014	36	291	44	291	11.2%	0.82 [0.54, 1.23]	-
HOME DES IVUS 2010	1	105	4	105	0.8%	0.25 [0.03, 2.20]	
Hong et al 2014	2	201	8	201	1.5%	0.25 [0.05, 1.16]	
IVUS-XPL 2015	0	700	1	700	0.4%	0.33 [0.01, 8.17]	
Kim et al 2013	0	269	2	274	0.4%	0.20 [0.01, 4.22]	
MATRIX 2011	10	548	31	548	5.8%	0.32 [0.16, 0.65]	
OPTICUS 2001	6	273	10	275	3.3%	0.60 [0.22, 1.64]	-+
Roy et al 2008	18	884	26	884	7.3%	0.69 [0.38, 1.25]	-
Ultimate 2018	10	724	13	724	4.6%	0.77 [0.34, 1.74]	-+
Wakabayashi et al 2012	13	637	18	637	5.8%	0.72 [0.36, 1.46]	-
Witzenbichler et al 2014	81	3349	188	5234	15.7%	0.67 [0.52, 0.87]	-
Total (95% CI)		11540		16097	100.0%	0.71 [0.58, 0.86]	•
Total events	314		645				
Heterogeneity: Tau <sup>2</sup> = 0.05; C	hi² = 26.4	4, df =	18 (P = 0	0.09); l <sup>2</sup>	= 32%		
Test for overall effect: $Z = 3.4$	0 (P = 0.0)	007)					0.001 0.1 1 10 10
							IVUS Angio

### **19% reduction in TLR**

	IVU	5	Ang	io		Risk Ratio	Risk Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI	
AIR-CTO 2015	5	115	9	115	1.8%	0.56 [0.19, 1.61]	+	
AVID 2009	39	395	45	406	7.6%	0.89 [0.59, 1.34]	-+	
CHEN et al 2012	11	123	13	123	3.2%	0.85 [0.39, 1.81]	-+-	
Choi et al	86	1674	275	4331	12.0%	0.81 [0.64, 1.02]		
CTO-IVUS 2015	5	201	10	201	1.8%	0.50 [0.17, 1.44]		
De la Torre Hernandez 2014	39	505	32	505	6.7%	1.22 [0.78, 1.91]	+-	
DIPOL 2007	3	83	6	80	1.2%	0.48 [0.12, 1.86]		
EXELLENT 2013	9	463	8	463	2.2%	1.13 [0.44, 2.89]	_ <del>_</del>	
Gao et al 2014	8	291	24	291	3.0%	0.33 [0.15, 0.73]		
HOME DES IVUS 2010	6	105	6	105	1.7%	1.00 [0.33, 3.00]		
Hong et al 2014	17	201	17	201	4.2%	1.00 [0.53, 1.90]		
IVUS-XPL 2015	17	700	33	700	4.9%	0.52 [0.29, 0.92]		
Kim et al 2013	12	269	18	274	3.6%	0.68 [0.33, 1.38]	-+	
MATRIX 2011	60	548	66	548	9.4%	0.91 [0.65, 1.26]	-+	
OPTICUS 2001	31	273	30	275	6.4%	1.04 [0.65, 1.67]	+	
Roy et al 2008	61	884	43	884	8.2%	1.42 [0.97, 2.07]	+ <b>-</b> -	
Ultimate 2018	20	724	37	724	5.4%	0.54 [0.32, 0.92]		
Wakabayashi et al 2012	34	637	45	637	7.1%	0.76 [0.49, 1.16]		
Witzenbichler et al 2014	51	3349	124	5234	9.6%	0.64 [0.47, 0.89]	-	
Total (95% CI)		11540		16097	100.0%	0.81 [0.70, 0.94]	•	
Total events	514		841					
Heterogeneity: Tau <sup>2</sup> = 0.03; Ch	$ni^2 = 27.9$	5, df =	18 (P = 0)	.06); l <sup>2</sup>	= 36%			
Test for overall effect: $Z = 2.71$	(P = 0.00	07)					IVUS Angio	

### **43% reduction in Stent Thrombosis**

	IVU	s	Ang	io		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
AIR-CTO 2015	2	115	7	115	3.6%	0.29 [0.06, 1.35]	
AVID 2009	5	395	4	406	4.7%	1.28 [0.35, 4.75]	
CHEN et al 2012	1	123	10	123	2.2%	0.10 [0.01, 0.77]	
Choi et al	35	1674	147	4331	16.4%	0.62 [0.43, 0.89]	
CTO-IVUS 2015	0	201	3	201	1.1%	0.14 [0.01, 2.75]	← − − −
De la Torre Hernandez 2014	3	505	11	505	4.9%	0.27 [0.08, 0.97]	
DIPOL 2007	0	83	0	80		Not estimable	
EXELLENT 2013	1	463	1	463	1.3%	1.00 [0.06, 15.94]	
Gao et al 2014	1	291	7	291	2.2%	0.14 [0.02, 1.15]	
HOME DES IVUS 2010	4	105	6	105	5.2%	0.67 [0.19, 2.29]	
Hong et al 2014	0	201	6	201	1.2%	0.08 [0.00, 1.36]	← · · · · · · · · · · · · · · · · · · ·
IVUS-XPL 2015	2	700	2	700	2.4%	1.00 [0.14, 7.08]	
Kim et al 2013	1	269	1	274	1.3%	1.02 [0.06, 16.20]	
MATRIX 2011	3	548	5	548	4.1%	0.60 [0.14, 2.50]	
OPTICUS 2001	67	273	63	275	17.6%	1.07 [0.79, 1.45]	+
Roy et al 2008	6	884	18	884	7.8%	0.33 [0.13, 0.84]	
Ultimate 2018	1	724	5	724	2.1%	0.20 [0.02, 1.71]	
Wakabayashi et al 2012	10	637	11	637	8.6%	0.91 [0.39, 2.13]	
Witzenbichler et al 2014	18	3349	53	5234	13.3%	0.53 [0.31, 0.90]	
Total (95% CI)		11540		16097	100.0%	0.57 [0.41, 0.79]	◆
Total events	160		360				
Heterogeneity: Tau <sup>2</sup> = 0.13; C	$hi^2 = 28.1$	8, df =	17 (P = 0	.04); l <sup>2</sup>	= 40%		
Test for overall effect: Z = 3.42	I (P = 0.0)	006)					U.UI U.I I IO 100
							IVUS Angio

Darmoch F, et al. JAHA. 2020.

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## **IVUS vs Angiography to Evaluate Vascular Characteristics**

Characteristics	IVUS	Angiography
Stenosis / Plaque burden	+++	++
Plaque morphology (soft /fib/cal)	+++	-
Lesion length	+++	++
Lesion eccentricity	+++	++
Guidewire orientation (sub/intra)	+++	-
Adherent thrombus	+++	+
Dissection	+++	++
Stent apposition	+++	++
Flow	-	+++

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+ Fair; ++ Good; +++ Excellent; - Not applicable

Adapted from Mosarla R and Secemsky E. ACC Journal 2020.



## **Peripheral Angiography - What We See vs Reality**

IVUS offers additional clinically relevant detail when assessing vessel size (1), plaque composition and distribution (2,3) and the presence and severity of dissection (4). This knowledge aids device selection and sizing and has been shown to lower rates of reinterventions and amputations (5).





What we see: 30% stenosis

#### Reality: 75% stenosis

#### What we see: patent vessel

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**Reality:** deep dissection extending into the adventitia

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# **Summarizing the Data for Arterial IVUS**

### Arterial Studies (N=29):

- 25 cohort studies, 4 case-series, N=95,192 patients
- Studies Examined:
  - 18/29: Device sizing, placement, and optimization
  - 6/29:Evaluation of lesion characteristics and severity
  - 3/29: Management of arterial dissections
  - 2/29: Reentry of chronic total occlusions

### **Grading Level of Evidence**

• 23/29 (79.3%) received a Level 2b rating, the second highest level of evidence rating



Records after duplicates removed

(n = 3312)

### **Arterial Studies**

Potentially relevant studies

N = 4936

Natesan S, et al. Intravascular Ultrasound in Peripheral Venous and Arterial Interventions: A Contemporary Systematic Review and Grading the Quality of Evidence. In Submission.

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### **CMS Data Analysis: Opportunities to Improve Outcomes With IVUS**

543,488 Medicare beneficiaries underwent lower extremity PVI from 2016-2019
63,372 patients (11.7%) treated with IVUS



\*Consistent findings for claudication, CLI, Other PAD, Iliac, SFA/pop, Tibial

Days

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### **Expert Consensus: IVUS-Guided Lower Limb Revascularization**

# 15 world-renown experts answered 72 questions regarding the role of IVUS during lower extremity arterial intervention

#### Institution Specialty Name Ehrin Armstrong, MD Adventist Heart and Vascular IC **Baylor College of Medicine** VS Miguel Montero-Baker, MD Marianne Brodmann, MD Medical University of Graz Angiologist Bryan Fisher, MD The Surgical Clinic VS Osamu lida, MD Kansai Rosai Hospital IC Jun Li, MD University Hospitals IC Peter Monteleone, MD University of Texas, Austin IC Advanced Cardiac & Vascular IC Jihad Mustapha, MD Centers Krishna Rocha-Singh, MD Prairie Cardiovascular IC IR Advanced Interventional & John Rundback, MD Vascular Services VS University of California, San Peter Schneider, MD Francisco Midwest Cardiovascular IC Nicolas W. Shammas, MD Research Foundation Mehdi H. Shishehbor, DO University Hospitals IC Peter Soukas, MD The Miriam Hospital IC Mitchell Weinberg, MD IC Northwell Health

### **Arterial Experts**

	Pre Interve	- ntion	Int Proce	ra- edure	Post- Intervention Optimization	
lliac	3/6	3/6	2/3	1/3	2/3	1/3
SFA-Pop	4/6 2/6		3/3		3/3	
Tibial	6/6	5	3/3		3/3	

Score	Appropriateness
7-9	Appropriate for specific indication
4-6	May Be Appropriate for specific indication
1-3	Rarely Appropriate for specific indication

Secemsky, E, et al. VIVA. 2021.

# Conclusions

- Use of IVUS during peripheral artery intervention has the potential to improve outcomes
  - Established benefits during coronary intervention
  - Increasing data in the periphery to support its use
  - Expert consensus recommends use in the majority of arterial procedural scenarios
- Efforts should focus on integrating IVUS use into routine practice and advancing imaging interpretation for new and experienced users



## Thank you



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