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# Real world CLI practice: update from the CRITISCH registry

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for the CRITISCH collaborators

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## Disclosures

Speaker name:

**Arne Schwindt**

I have the following potential conflicts of interest to report:

- Consulting
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s)
- I do not have any potential conflict of interest



# Background

- First-line treatment strategies in CLI patients
- Multicentre, prospective, interdisciplinary, externally monitored registry
- 27 centres of excellence
- 01/2013-09/2014
- 1200 CLI patients (Rutherford 4-6)
- **First-line treatment strategies**
  - Endovascular first
  - Bypass surgery first
  - CFA/DFA patchplasty only
  - No vascular intervention

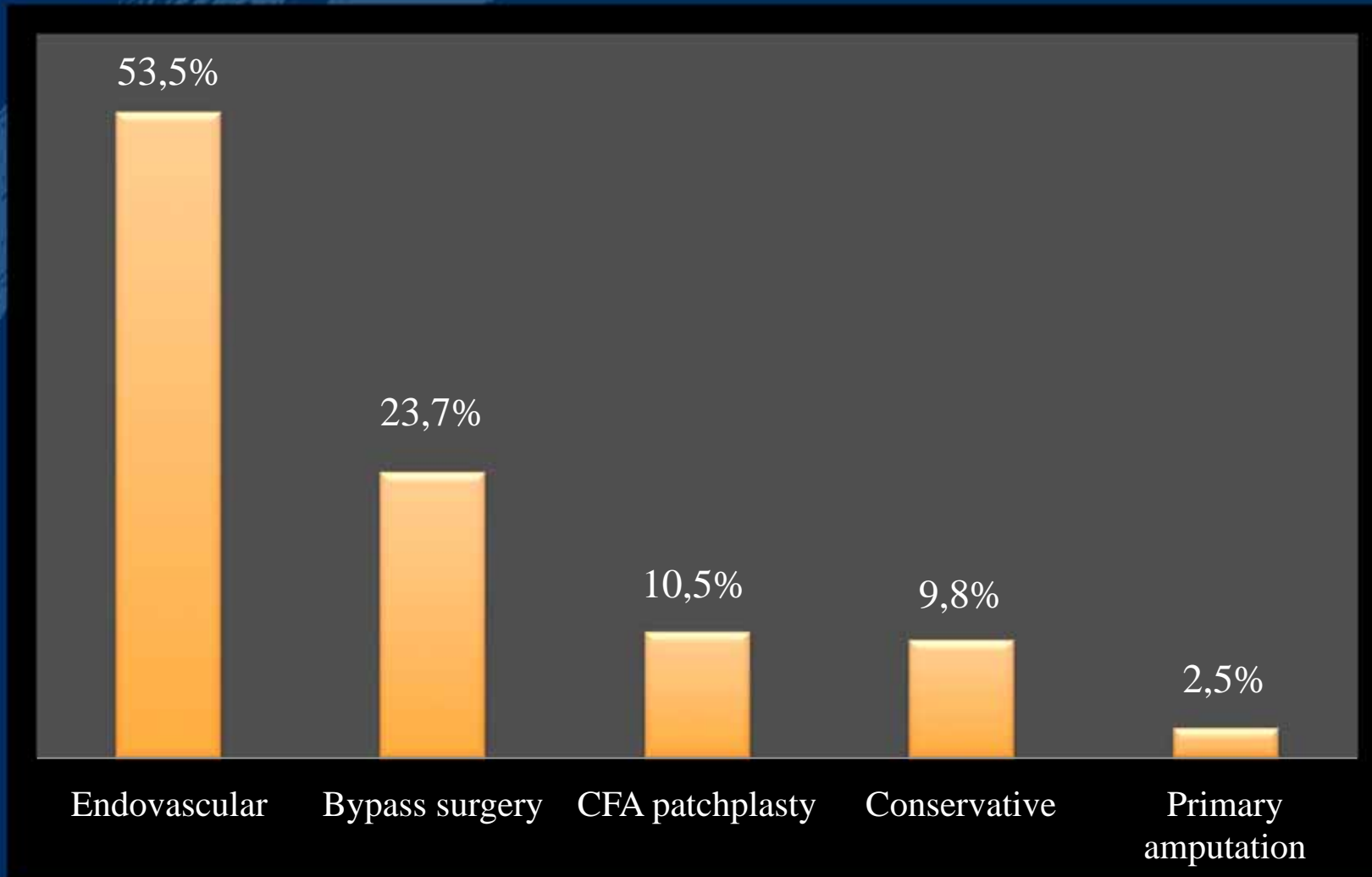
# Endpoints

- Major amputation/death (composite endpoint)
- Major amputation
- Death
- Hemodynamic failure<sup>1</sup>
- MACCE
- Reintervention

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<sup>1</sup>Conte MS et al. Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia. J Vasc Surg 2009;50:1462-73

# First-line treatment strategies



# Characteristics and demographics

	Endovascular	Bypass surgery	CFA/DFA patchplasty	No vascular intervention	
				Conservative	Primary amputation
Median age (years)	75	73	72	76	72.5
Males	405 (63%)	192 (68%)	78 (62%)	74 (63%)	19 (63%)
Coronary artery disease	298 (46%)	118 (42%)	60 (48%)	54 (46%)	15 (50%)
MI < 6 months	25 (4%)	17 (6%)	2 (2%)	5 (4%)	3 (10%)
Renal insufficiency (60<eGFR<15)	251 (39%)	86 (30%)	29 (23%)	46 (39%)	12 (40%)
Dialysis (eGFR<15)	65 (10%)	13 (5%)	11 (9%)	10 (8%)	3 (10%)
Diabetes mellitus	310 (48%)	136 (48%)	43 (34%)	54 (46%)	19 (63%)
Obesity	93 (14%)	40 (14%)	19 (15%)	15 (13%)	4 (13%)
Previous vascular intervention	251 (39%)	139 (49%)	40 (32%)	57 (48%)	13 (43%)
Previous stroke/TIA	73 (11%)	31 (11%)	17 (13%)	14 (12%)	9 (30%)
Current tobacco use	94 (15%)	89 (31%)	31 (25%)	16 (14%)	6 (20%)

# Anatomic characteristics

	Endovascular	Bypass surgery	CFA/DFA patchplasty	No vascular intervention	
				Conservative	Primary amputation
<b>Rutherford classification</b>					
Stage 4	141 (22%)	72 (25%)	47 (37%)	17 (14%)	2 (7%)
Stage 5	375 (58%)	140 (49%)	52 (41%)	73 (62%)	3 (10%)
Stage 6	126 (20%)	72 (25%)	27 (21%)	28 (24%)	25 (83%)
<b>TASC classification</b>					
TASC A	65 (10%)	2 (1%)	14 (11%)	5 (4%)	0 (0%)
TASC B	153 (24%)	17 (6%)	15 (12%)	15 (13%)	3 (10%)
TASC C	78 (12%)	44 (16%)	19 (15%)	4 (3%)	1 (3%)
TASC D	188 (29%)	198 (70%)	45 (36%)	43 (36%)	17 (57%)
not applicable	155 (24%)	22 (8%)	33 (26%)	51 (43%)	9 (30%)
<b>Run-off vessels</b>					
none	173 (27%)	31 (11%)	18 (14%)	32 (27%)	18 (60%)
one	277 (43%)	134 (47%)	43 (34%)	49 (42%)	9 (30%)
two	114 (18%)	76 (27%)	35 (28%)	24 (20%)	2 (7%)
three	78 (12%)	43 (15%)	30 (24%)	13 (11%)	1 (3%)



# Procedural characteristics (Endovascular / Bypass)

	Femoral vessels (n=347)		Popliteal vessels (n=272)		Tibial vessels (n=368)		Previous bypass (n=26)	
<b>Group I</b> Endovascular (N=642)	<b>PTA only</b>	125 (36.0%)	<b>PTA only</b>	104 (38.2%)	<b>PTA only</b>	259 (70.4%)	<b>PTA only</b>	8 (30.8%)
	<b>PTA + Stent</b>	141 (40.6%)	<b>PTA + Stent</b>	90 (33.1%)	<b>PTA + Stent</b>	24 (6.5%)	<b>PTA + Stent</b>	3 (11.5%)
	<b>DCB</b>	63 (18.2%)	<b>DCB</b>	53 (19.5%)	<b>DCB</b>	36 (9.8%)	<b>DCB</b>	2 (7.7%)
	<b>DCS</b>	6 (1.7%)	<b>DCS</b>	2 (0.7%)	<b>DCS</b>	12 (3.3%)	<b>DCS</b>	2 (7.7%)
	<b>Other</b>	38 (11.0%)	<b>Other</b>	32 (11.8%)	<b>Other</b>	22 (6.0%)	<b>Other</b>	12 (46.2%)
	<b>Failed to cross</b>	19 (5.5%)	<b>Failed to cross</b>	17 (6.3%)	<b>Failed to cross</b>	33 (9.0%)	<b>Failed to cross</b>	1 (3.8%)
<b>Group II</b> Bypass surgery (N=284)	<b>Leg vein</b>							151 (53.2%)
	<b>Arm vein</b>							11 (3.9%)
	<b>Combined leg and arm vein</b>							3 (1.1%)
	<b>Dacron</b>							32 (11.3%)
	<b>PTFE</b>							71 (25%)
	<b>Other</b>							22 (7.7%)

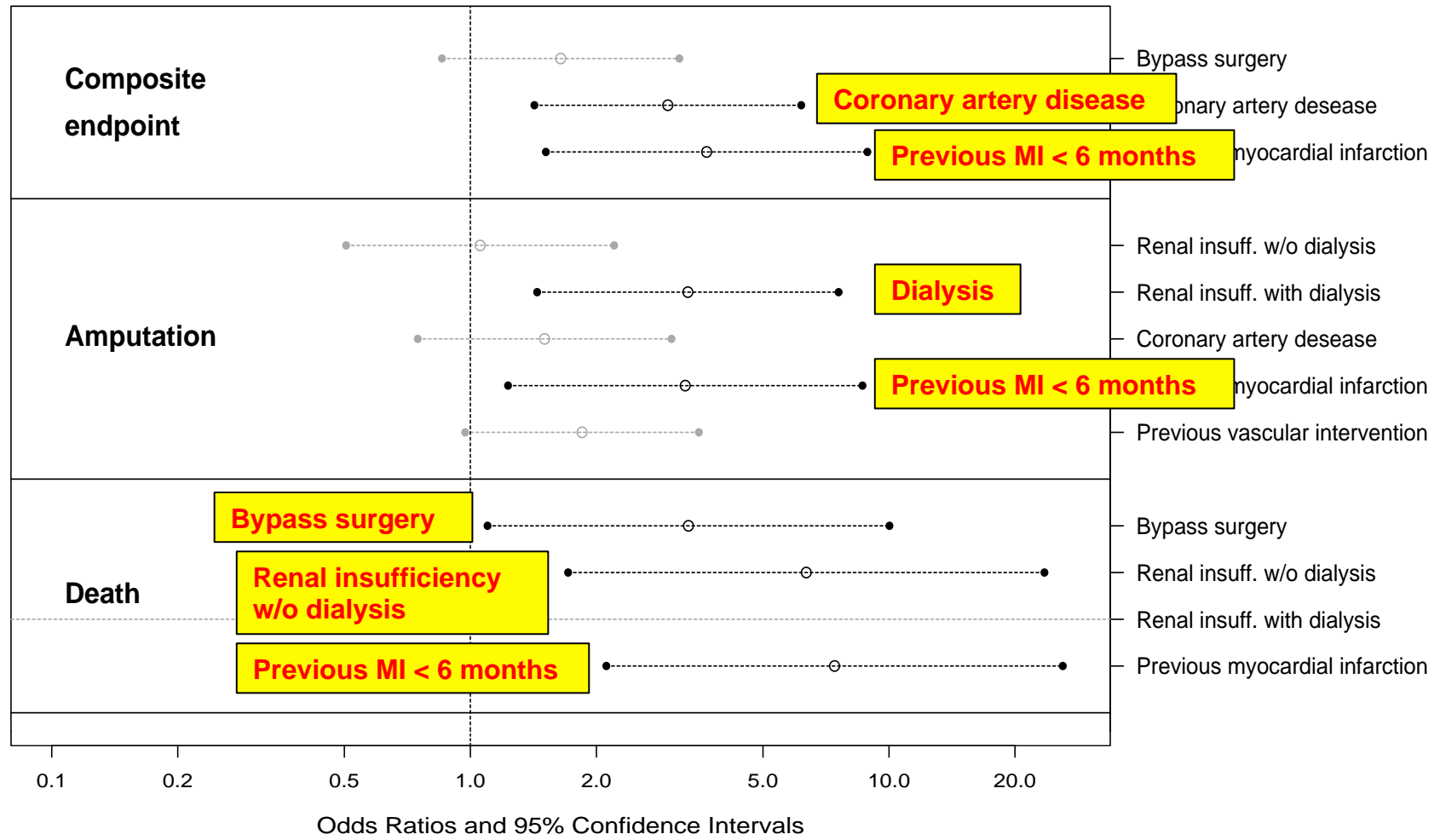


# Endpoints (unmatched analysis)

	Group I Endovascular N=642	Group II Bypass surgery N=284	Group III Patchplasty N=126	Group IV		p-value
				No vascular intervention		
				Conservative N=118	Primary amputation N=30	
Composite endpoint	24 (4%)	17 (6%)	8 (6%)	9 (8%)	-	0.172
Amputation	20 (3%)	10 (4%)	5 (4%)	6 (5%)	-	0.67
Death	6 (1%)	8 (3%)	4 (3%)	4 (3%)	3 (10%)	<b>0.003</b>
Hemodynamic failure	81 (13%)	24 (8%)	11 (9%)	107 (91%)	-	<b>&lt;0.001</b>
MACE <sup>1</sup>	23 (4%)	15 (5%)	8 (6%)	6 (5%)	4 (13%)	0.097
Reintervention	50 (8%)	33 (14%)	11 (9%)	6 (5%)	1 (3%)	<b>0.015</b>
<i>Endovascular</i>	32 (64%)	6 (9%)	5 (45%)	1 (17%)	0 (0%)	
<i>Open surgery</i>	18 (36%)	30 (91%)	6 (55%)	5 (83%)	1 (100%)	
Minor amputation	80 (12%)	39 (14%)	7 (6%)	5 (4%)	-	

# Risk factors

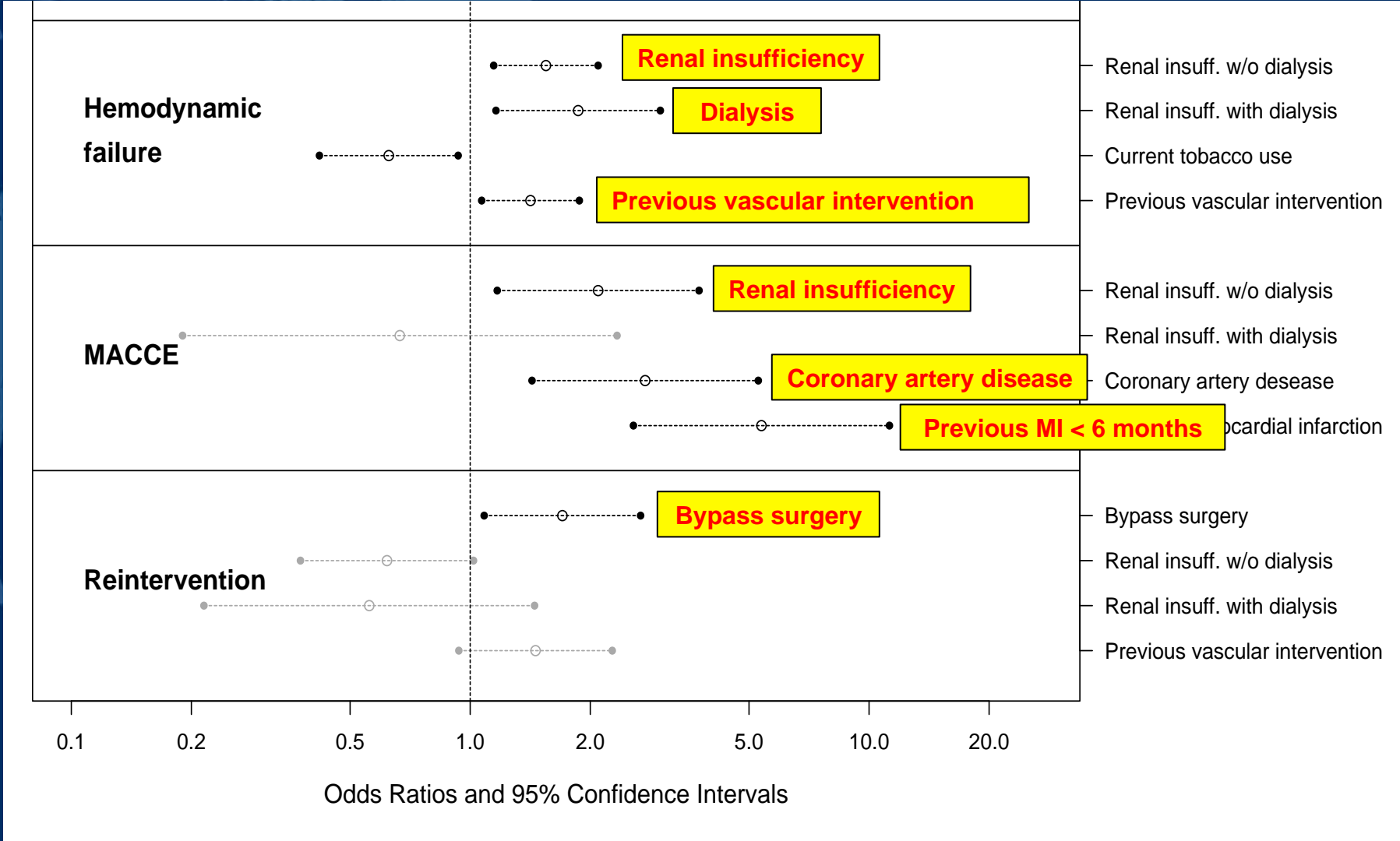
(Multivariate logistic regressions analysis)





# Endpoints

(Multivariate logistic regressions analysis)



Odds Ratios and 95% Confidence Intervals





# Thank you!

## CRITISCH Collaborators:

T. Schmitz-Rixen, MD, (Frankfurt), M. Steinbauer, MD, (Regensburg) , H.H. Eckstein, MD (Munich), W. Lang, MD, H. Schelzig, MD, (Duesseldorf), H.J. Florek, MD, (Freital), M. Storck, MD, (Karlsruhe), B. Weis-Müller, MD, (Moenchengladbach), D. Böckler, MD, (Heidelberg), A. Billing, MD, (Offenbach), T. Hupp, MD, (Stuttgart), S. E. Debus, MD, (Hamburg), M. Spohn, MD, (Bamberg), H. Reinecke, MD, (Muenster), Christian Schlensack, MD, (Tuebingen), Wojciech, Klonek, MD, (Cloppenburg), H. Wenk (Bremen), R.G. Ritter, MD, (Bielefeld), K.L. Schulte, MD, (Berlin), T. Keck, MD (Lübeck), K. Balzer, MD, (Bonn), B. Mühling, MD, (Biberach), F. Adili, MD (Darmstadt), T. Zeller, MD (Bad Krozingen)



# CRITISCH

Interdisciplinary Registry for Critical Limb Ischemia





# Thank you!

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