

LINC 2022 Teaser session on hot topics, pioneering techniques, and latest data in peripheral arterial interventions

Treating common femoral artery steno-occlusive lesions
with an endovascular approach using DA+DCB:
Three-year follow-up in 75 patients

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Disclosure

Speaker name:

Angelo Cioppa, MD

I have the following potential conflicts of interest to report:

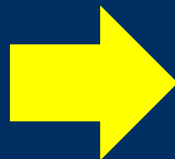
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☒ I do not have any potential conflict of interest

Endovascular Treatment for CFA: *Stent*

Common Femoral Artery

NO ENDOVASCULAR

NO STENT



Treatment Strategie

- ✓ *Surgical*
 - ✓ Bypass
 - ✓ Endarterectomy
- ✓ *Endovascular*
 - ✓ Balloon (POBA - DCB)
 - ✓ Stenting (SES - BES - BAS)
 - ✓ Bebulking (ELCA-DA)

Combination of the above

CFA Stent Studies

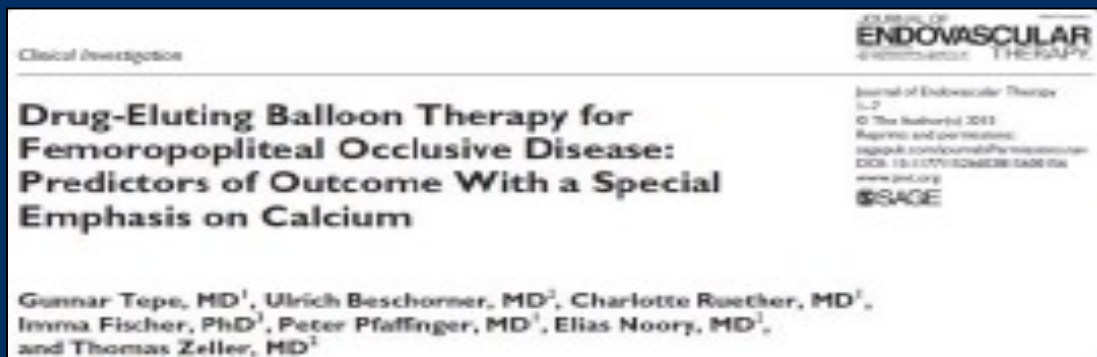
	N	Stenting(%)	ISR(%)
<i>Azema 2011</i>	(50)	80,0%	20,0%
<i>Bonvini 2011</i>	(360)	36,9%	18,9%
<i>Bonvini 2013</i>	(98)	38,1%	14,1%
<i>TECCO 2017</i>	(56)	100%	18,5%

- ✓ Stent is Better than POBA
 - ✓ Bonvini 2013
- ✓ Stent is Effective as CEA
 - ✓ TECCO study
- BUT**
- ✓ Restenosis Issue Remains
- ✓ Stent could limit further treatment

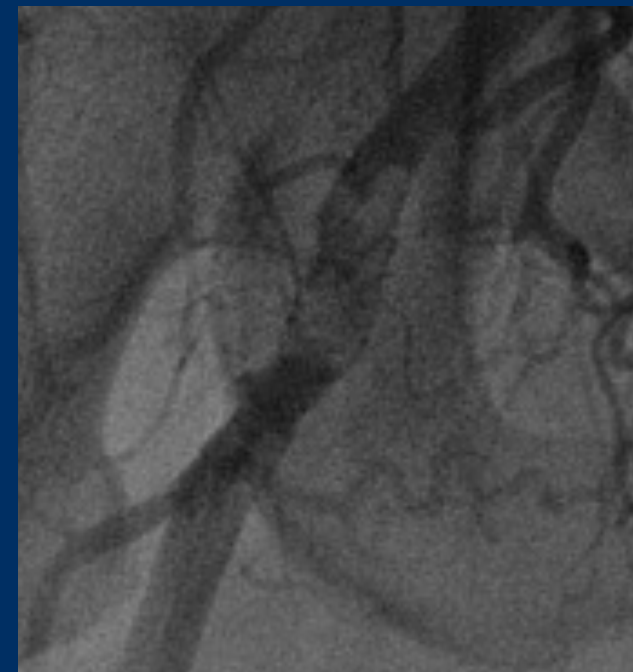
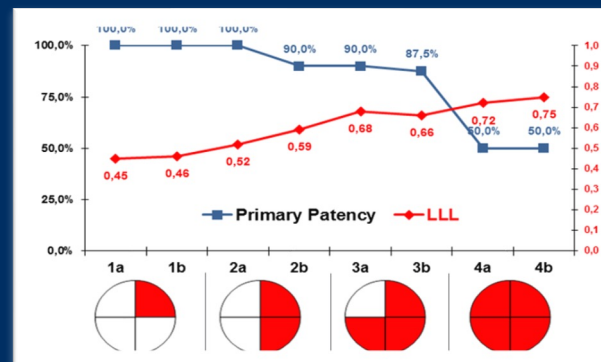


Endovascular Treatment for CFA: *Drug Eluting Balloons*

Well Known Lack of the efficacy of DCBs in Calcified Lesions lesions



12-month Results



Vessel Preparation with directional atherectomy and drug-coated balloon (DCB) in treating peripheral artery disease (PAD) can help achieve excellent patient outcomes.

Combined Therapy: *Atherectomy/DCB*

“Common Femoral Artery”

Endoarteriectomy

Proven acute and long-term
Results

Plaque excision

No additional materials

- ✓ Invasive
- ✓ Complications
- ✓ Patient discomfort

Endovascular

Less invasive

Re-doing

Safety

Patient compliance

- ✓ No advantage vs CEA
- ✓ Stent implantation
- ✓ Compromise further treatment options.

Ideal - Technique

Good acute and long-term results

No additional materials (stent)

Less invasive and Safe

Improve DCBs efficacy

Good patient's compliance

Combined use of directional atherectomy and drug-coated balloon for the endovascular treatment of common femoral artery disease: immediate and one-year outcomes

Angelo Cioppa¹, MD; Eugenio Stabile^{2*}, MD, PhD; Luigi Salemme¹, MD; Grigore Popusoi¹, MD; Armando Pucciarelli¹, MD; Fortunato Iacovelli¹, MD, PhD; Antonella Arcari¹, BS; Enrico Coscioni³, MD; Bruno Trimarco², MD; Giovanni Esposito², MD; Tullio Tesorio¹, MD

Follow-up completion	30 (100%)
Rutheford Class	2,2±1.2
ABI	0,8±0,1
Major or Minor amputations in CLI patients	1 (3%)
Limb salvage rate (CLI patients)	8/8 (100%)
Re-hospitalizations (any reasons)	5 (16%)*
Restenosis Rate (>50%)	3 (10%)
Repeat percutaneous transluminal angioplasty	2 (6%)
In-stent Restenoses	1/3 (30%)
12 M secondary patency	29 (97%)
pz sent to surgery	1 (3%)

EuroIntervention 2017;12:1789-1794



Catheterization & Cardiovascular Interventions



SCAI
Society for Cardiovascular
Angiography & Interventions

Original Studies

Three-year outcome of directional atherectomy and drug coated balloon for the treatment of common femoral artery steno-occlusive lesions

Angelo Cioppa MD ✉, Michele Franzese MD, Donato Gerardi MD, Armando Pucciarelli MD, Grigore Popusoi MD, Eugenio Stabile MD, PhD, Luigi Salemme MD, Lidia Sada MD, Sebastiano Verdoliva MD, Osvaldo Burattini MD, Luigi Fimiani MD, Marco Ferrone MD, Giuseppe Di Gioia MD, Attilio Leone MD, Giovanni Esposito MD, PhD, Tullio Tesorio MD

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2014-2018, 131 patients underwent PTA of CFA in our institution due to CLI (28 [21,2%]) or LLC (103 [78,8%]).



DAART Performed in 96
3Y FU completed in 75

Demographic

Number of Pz	75
N. Of Lesions	75
Male gender	60 (80%)
Age (years)	74 ±15
Hypertension	58(77,3%)
Dyslipidemia	46 (64.,1%)
Smoking status:	
Previous smoker	47(65,3%)
Current smoker	6 (8%)
Diabetes :	37(52,9%)
NIDDM	25 (35,9%)
IDDDM	12 (17%)
Renal failure:	16 (21,3%)
CC <30 ml/min	10 (12,8%)
Dialysis	6 (5,5%)

Clinical Presentation

Ruth. class .	N(%)	ABI
≤ 3	44(58,6%)	0.75 ± 0.13
4	20 (25.6%)	0.58 ± 0.12
5	7 (9,0%)	0.31 ± 0.06
6	4 (5,1%)	0.26 ± 0.20

Baseline Ruth Class was 3,2±2,2

Angiographic Findings



Nr of lesions	75
TCFA (1-0-0)	17(22,5%)
Bifurcated Lesion	58(78,1%)
CFA + SFA (1-1-0)	34(47,7%)
CFS+ SFA + PFA (1-1-1)	15(19,7%)
CFA + PFA (1-0-1)	9(10,7%)
Conc. Treat. In/outflow	25(31,3%)

PROCEDURE

Contralateral femoral cross-over access with 8-7F Sheath

Distal embolization Protection Device

Pre-dilatations limited to total occlusion with undersized balloon.

Both diseased SFA and PFA were treated with DA and DCB on both.

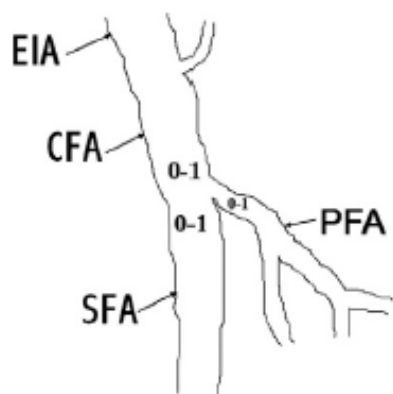
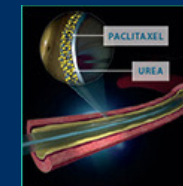
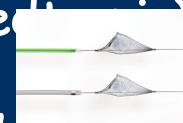
Stent used only as bail-out

MATERIALS

Spider Filter 5-7 mm (Medtronic)

TurboHawk/HawkOne (Medtronic)

DCB: In-Pact Admiral (Medtronic)



LESIONS CHARACTERISTICS

Total occlusion	20 (26%)
MLL (mm)	48,0±17
MLD (mm)	0,8±0,9
Bifurcation	58(72,5%)
Calcium Score > 3	64 (80%)

Follow-up

- Patients were followed clinically (free walking distance and ABI) and with DUS at 1, 3 and every 6 months.
- Patients with impaired functional status and/or duplex deterioration were referred to angiographic evaluation.



Procedural Results



- **Procedural success was 100%**.(crossing the lesion and treating the lesion with DAART)
- **No distal embolization occurred.**

In 31 cases a significant amount of debris was found in the distal protection system.

- **No procedure or access site complication.** (Perforation, A-V fistula)

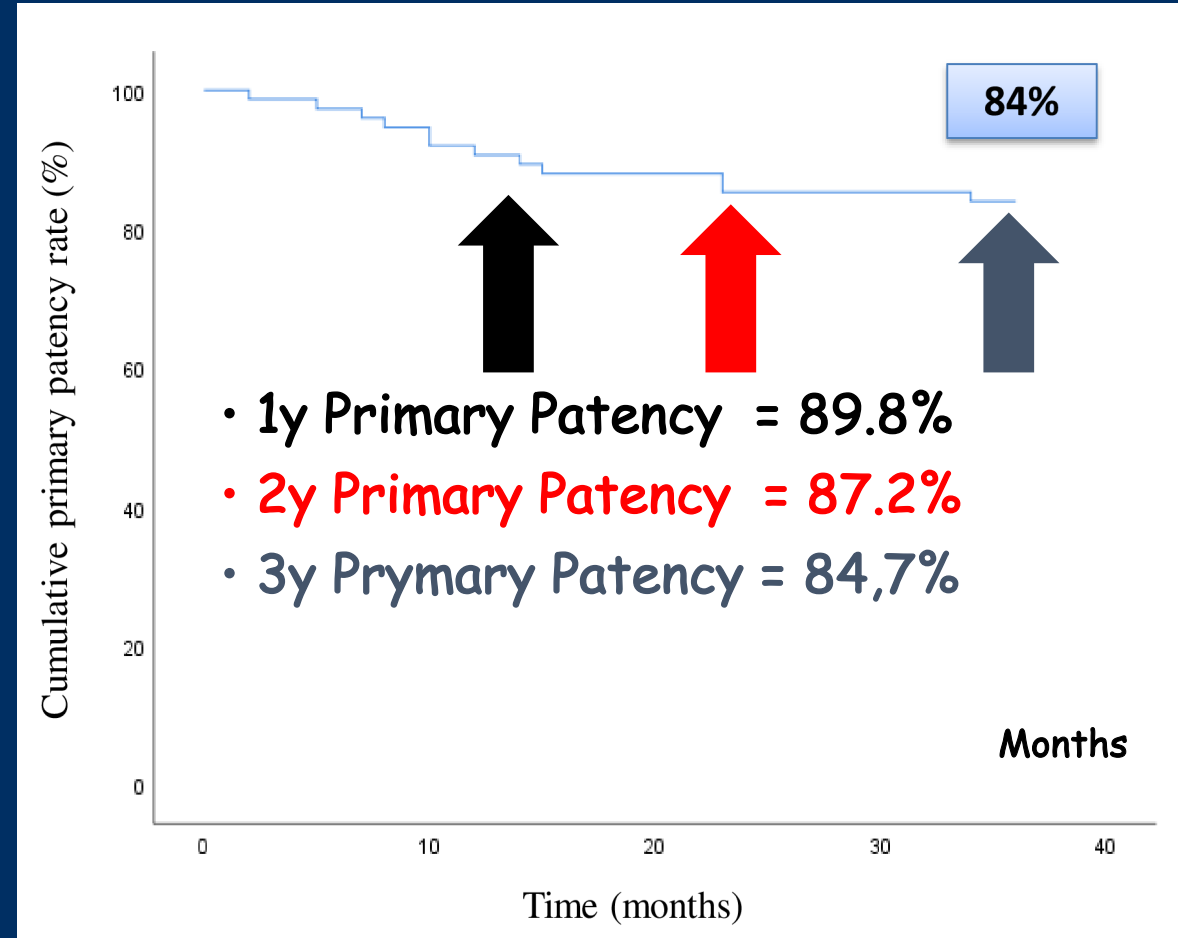
Acute Outcome

- **Acute angiographic success was 100%** (residual stenosis<30%).
- **Bailout stenting was used in 6 cases (8%).**
- **No death and or major amputation in the first 30 Days.**



Long-term FU (36 months)

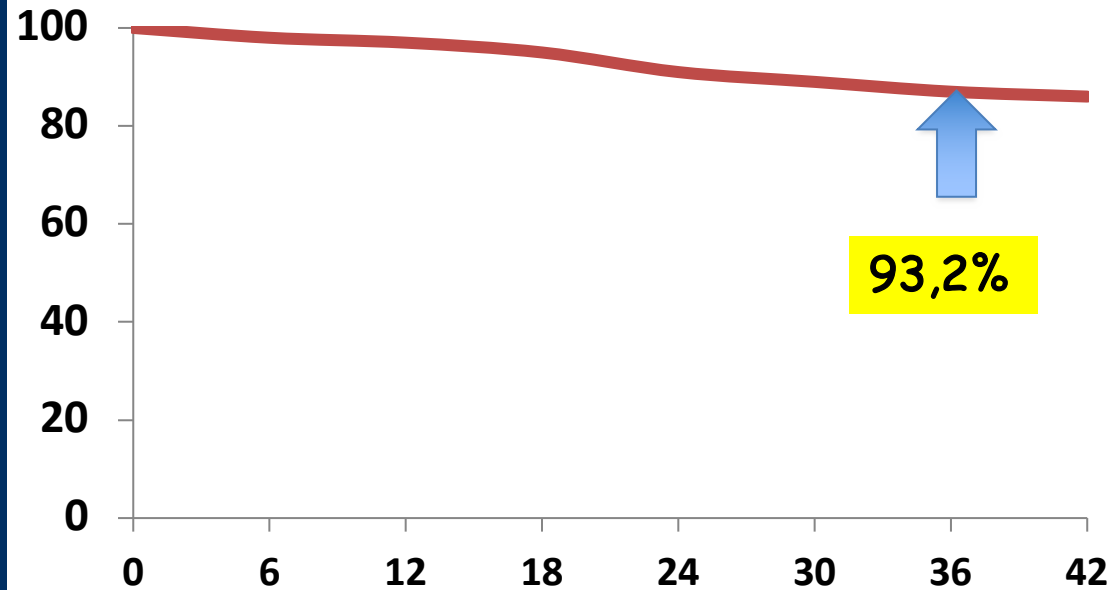
Any Amputation 1/75 (1,2%)
Death 2/75 (2,6%)
limb salvage rate (CLI) 27/28(98%)
Symptoms Driven Rev 12 (16%)
DUS RR (PSVR>2,4) 13(17.7%)
ISR 3/4 (75%)
TL Repeated Rev. 8
Sent to surgery 4



	0-12 m	0-24 m	0-36 m
Death	1 (1.2%)	2 (1.2%)	2 (2.5%)
Amputation	0%	1(1,2%)	1(1,2%)
TLR	1 (1.2%)	10(13,3%)	12(16%)

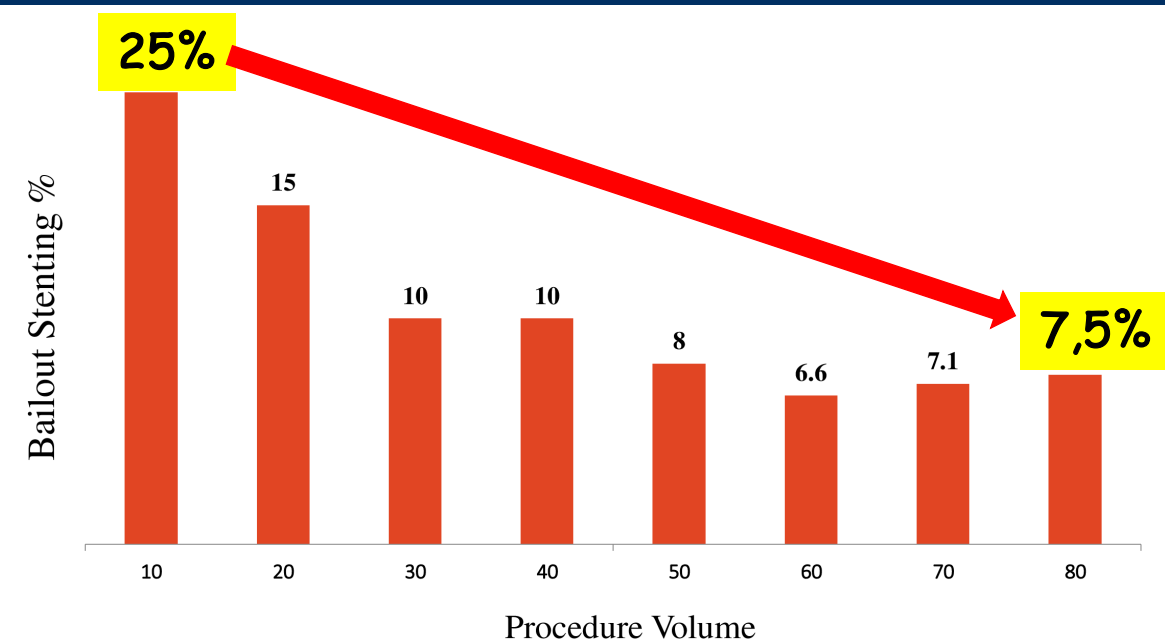
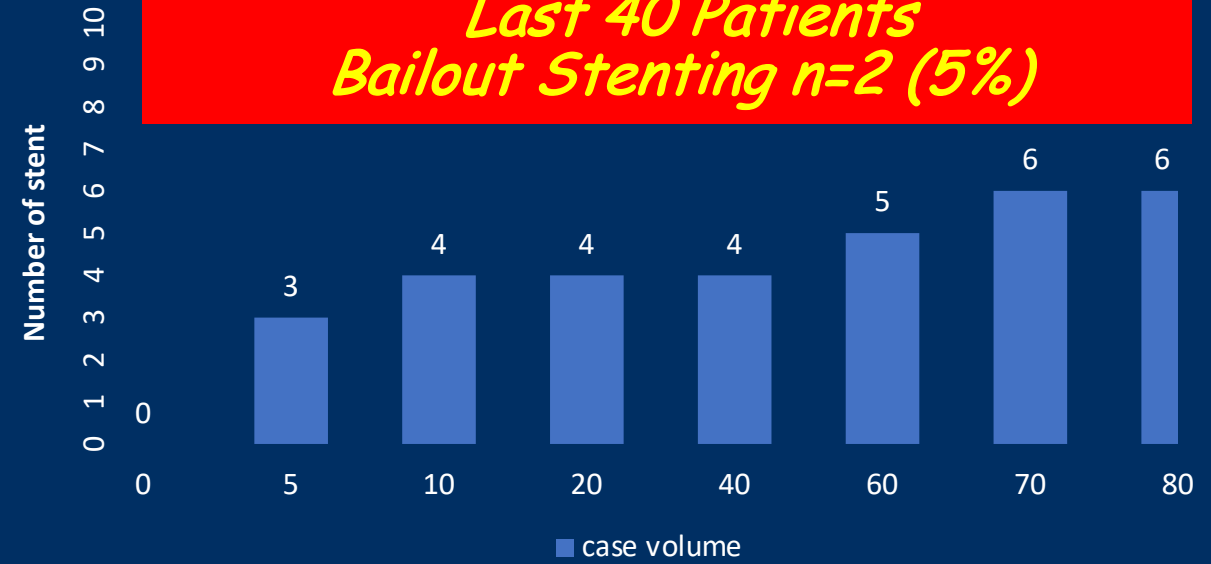
Long-term FU (36 months)

Secondary Patency (%)



	0-12 m	0-24 m	0-36 m
Re-PTA	1 (1,2%)	6 (8%)	8 (10,6%)
Surgery	1 (1,2%)	4 (5,3%)	4 (5,3%)

Last 40 Patients
Bailout Stenting n=2 (5%)



CONCLUSIONS

Our data suggest that endovascular therapy of CFA is safe and effective in the long run.

We believe that DA+DCB strategy may have some advantages compared to the other EVTs:

- Similar to surgery but "less invasive" (plaque removal).
- Improves DCB efficacy in calcified lesion.
- Applies the "leaving nothing behind" theory reducing Bailout Stenting.

It's time to start a randomised trial to compare DAART to Surgery and/or other endovascular strategies.