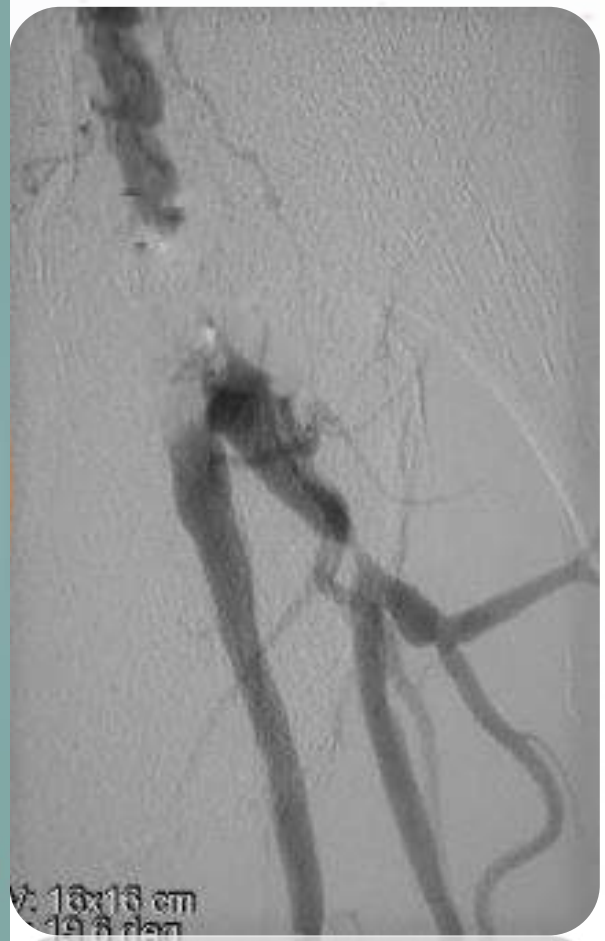
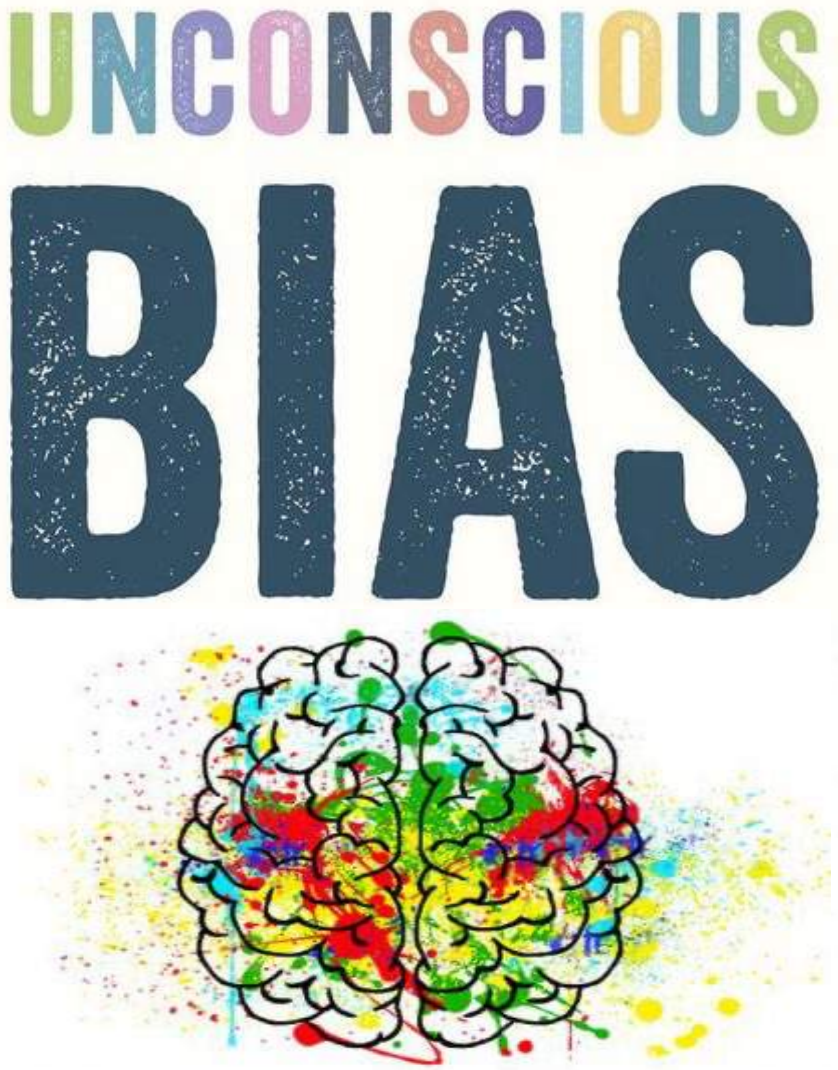
Introduction





Eminent program 19/10/2021

- **Debate**: Treatment of the CFA endovascularly: Yes or No?

  Treating the CFA endovascularly: PROS *Wouter Lansink*
  Treating the CFA endovascularly: CONS *Giovanni Torsello*

➢ Discussion: When to consider endovascular treatment for CFA and when to consider surgery?

- **Lecture**: The evidence behind the CFA treatment: everything you need to know! *Koen Deloose*

➢ Discussion: For how long surgery will continue to be the gold standard of treating the CFA?

- **Recorded case**: Treating the CFA with Interwoven nitinol stent – Step by Step *Andrej Schmidt*

➢ Discussion: Stenting the CFA – my experience and considerations

Polling question

What is your preferred treatment option for CFA lesions?

a. Surgery only – should be the only treatment option for CFA
b. Surgery only but interested to learn more about endovascular treatment options
c. Surgery first but endovascular if patient requires
d. Endovascular treatment using Supera stent
e. Other Endovascular treatment.

The evidence behind the CFA treatment: everything you need to know!

Koen Deloose, MD
Head Dept Vascular Surgery
AZ Sint Blasius
Dendermonde, Belgium

Disclosure slide

Speaker name: Koen Deloose, MD

❑ I have the following potential conflicts of interest to report:

☒ Consulting: Abbott, Asahi, Biotronik, Boston Scientific, Cook, CTI vascular, CyndRX, Getinge Maquet, Gore, iVascular, Medtronic, Terumo

❑ Stockholder of a healthcare company

❑ Employment in industry

❑ Owner of a healthcare company

❑ Other(s)

❑ I do not have any potential conflict of interest

CFE

First author (year)	No. patients	CLI (%)	ESRF (%)	Mortality (%)	TS (%)	PP (%)	APP (%)	LS (%)	
Mukherjee (1989)[2]	29	41	ND	0	100	94	94	ND	Ann Surg 1987; 206:403-413
Hoch (1999)[3]	37	79	ND	ND	100	92	92	ND	Vasc Endovasc Surg 1999; 33:461-70
Nelson (2002)[4]	34	59	0	0	100	84†	97†	ND	J Vasc Surg 2002; 35:1107-1113
Kang (2008)[5]	65	32	ND	0	100	91	100	100	J Vasc Surg 2008;48:872-7
Kechagias (2008)[6]	111	31	3	1.8	ND	ND	ND	94	World J Surg 2008;32:51-54
Al-Khoury (2009)[7]	105	35	7	1.0	100	100	100	ND	J Vasc Surg 2009; 50:784-89
Ballotta (2010)[8]	121	40	1	0	100	96	100	ND	Surgery 2010;147:268-274
Malgor (2012)[9]									Ann Vasc Surg 2012; 26:946-956
(A)	169	33	7	1.2	100	100	100	ND	
(B)	93	60	7	1.1	98	92	100	ND	
Nishibe (2015)[10]	38	13	32	0	100	85‡	94‡	97‡	Ann Vasc Surg 2015; 29:1501-1507
Present study	118	36	26	1.7	99	99	100	95	Circulation Journal japan 2016; 80:964-69

†One-year follow-up; ‡4-year follow-up. (A) CFE alone; (B) CFE with distal bypass. APP, assisted-primary patency rate at 5 years; CFE, common femoral artery endarterectomy; LS, limb salvage rate at 5 years; ND, not described; PP, primary patency rate at 5 years; TS, technical success. Other abbreviations as in Table 1.

@ 5Years

CFE

recurrent arterial or graft stenosis. Primary and secondary patency rates and graft failure rates were defined with the criteria previously described by Ahn[15] and Rutherford.[16]

Criteria for patency

Articles in scientific journals should only accept patency rates that are based on objective findings. A bypass graft or otherwise reconstructed arterial segment may be considered patent when one of the following five criteria is met. Beyond the last date of such proof of patency, they must be considered lost to follow-up.

1. Demonstrably patent graft by an accepted vascular imaging technique, such as arteriography, Duplex ultrasound color-flow scan, or magnetic resonance imaging.
2. The presence of a palpable pulse, or the recording of a biphasic or triphasic Doppler wave form at *two* points directly over a *superficially* placed graft.
3. Maintenance of the achieved improvement in the *appropriate* segmental limb pressure index, that is, not more than 0.10 below the highest postoperative index. Although a greater reduction in pressure index may occur and the graft or reopened segment may still be patent, *imaging proof is required in these instances or any other doubtful or marginal circumstances covered under criteria 2, 3, or 4.* To avoid the confusing effects of distal runoff disease, the most appropriate pressure index for this purpose is at the next level beyond the revascularized segment or distal anastomosis (see comment below).
4. Maintenance of a plethysmographic tracing distal to the reconstruction that is at least 50% or 5 mm greater in magnitude than the preoperative value and close to the postoperative value. (This is the weakest criterion and acceptable *only* when accurate pressures cannot be measured, as with calcific arteritis in a diabetic patient. However, even in such cases, stronger evidence of patency, in the form of imaging, is clearly preferred.)
5. Direct observation of patency at operation or postmortem examination.

Rutherford R et al. JVS 1997 (Sept);26(3):517-38

Ann Surg 1987; 206:403-413

Vasc Endovasc Surg 1999; 33:461-70

J Vasc Surg 2002; 35:1107-1113

J Vasc Surg 2008;48:872-7

World J Surg 2008;32:51-54

J Vasc Surg 2009; 50:784-89

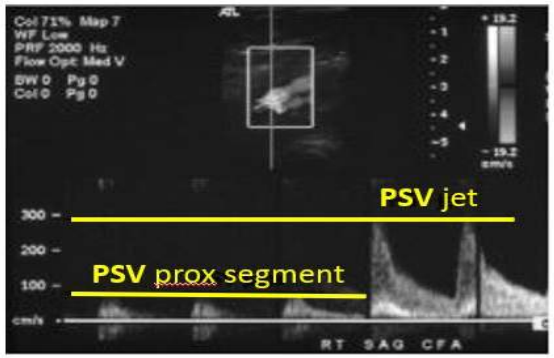
Surgery 2010;147:268-274

Ann Vasc Surg 2012; 26:946-956

Ann Vasc Surg 2015; 29:1501-1507

Circulation Journal japan 2016; 80:964-69

PSVR (V r) =
PSV (jet) / PSV (prox segment)



CFE

Original Research Article

SJS SCANDINAVIAN JOURNAL OF SURGERY

LONG-TERM OUTCOME OF COMMON FEMORAL ARTERY ENDARTERECTOMY IN OCTOGENARIANS AND NON-OCTOGENARIANS

C. Uhl[1], H. Götzke[1], F. Zeman[2], S. Woronowicz[1], T. Betz[1], I. Töpel[1], M. Steinbauer[1]

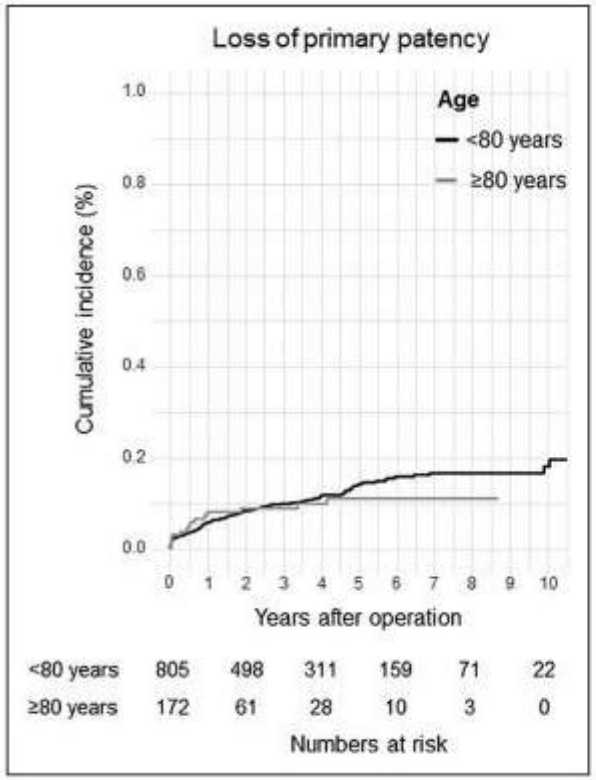
Retrospective, single center study

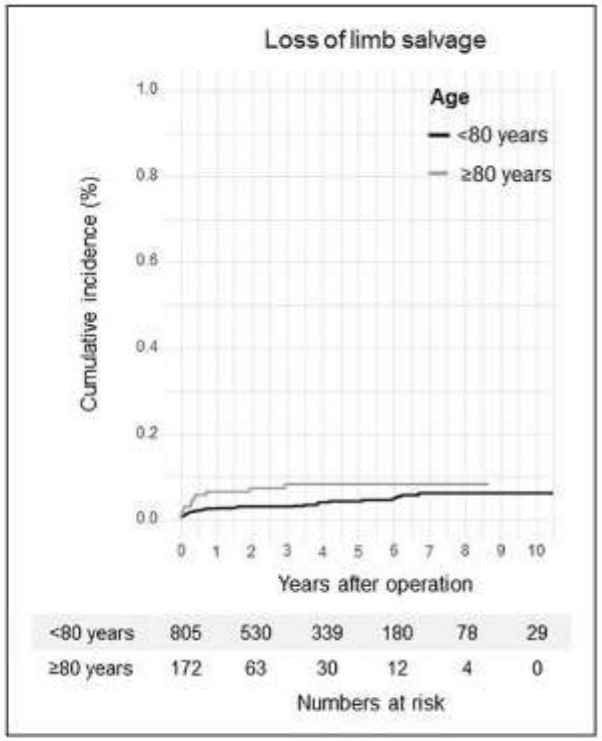
- 977 patients (61,5 % CI – 38,5 % CLTI)
- 40% hybrid procedures

- Real PSV measurements (>2,5m/sec and >50% diameter reduction)
- 2 groups (>80yr : 17,6% and <80yr : 82,4%)

Primary patency @7yr : 84,2%
LSR @7yr : 93,7%

Mortality rate @30days : overall 2,7%
<80yr : 1,67%
>80yr : 7,6 %
p < 0.001





CFE

1843 CFE's reported from 2005-2010 (ACS -NSQIP database)

Table I. Patient demographics and comorbidities

Variables	*Mean ± SD or No. (%) (N = 1843)*
Age,[a] years	69.2 ± 11.6
Nonindependent status[a]	239 (13)
Weight, kg	78 ± 18.6
Albumin < 3 mg/dL	113 (6.1)
Female sex	742 (40.3)
Race	
Black	122 (6.6)
White	1138 (61.8)
Other	583 (31.6)
Emergency surgery[a]	236 (12.8)
ASA class 4 or 5[a]	378 (20.5)
Pre-op sepsis[a]	91 (5.0)
Diabetes	614 (33.3)
Hypertension	1558 (84.5)
Peripheral vascular disease	772 (41.9)
Rest pain	527 (28.6)
Congestive heart failure	56 (3.0)
History of	
Angina	81 (4.4)
Myocardial infarction	88 (4.8)
PCI	428 (23.2)
Cardiac surgery	467 (25.3)
Transient ischemic attack	154 (8.4)
Stroke	116 (6.3)
Smoker	636 (34.5)
COPD	252 (13.7)
Pneumonia	9 (0.5)
Steroid use	93 (5.1)
Acute kidney injury	20 (1.1)
Dialysis[a]	66 (3.6)

ASA class, American Society of Anesthesiologists Physical Status Classification; *COPD*, chronic obstructive pulmonary disease; *PCI*, percutaneous coronary intervention; *SD*, standard deviation.
[a]Independent predictors of 30-day mortality.

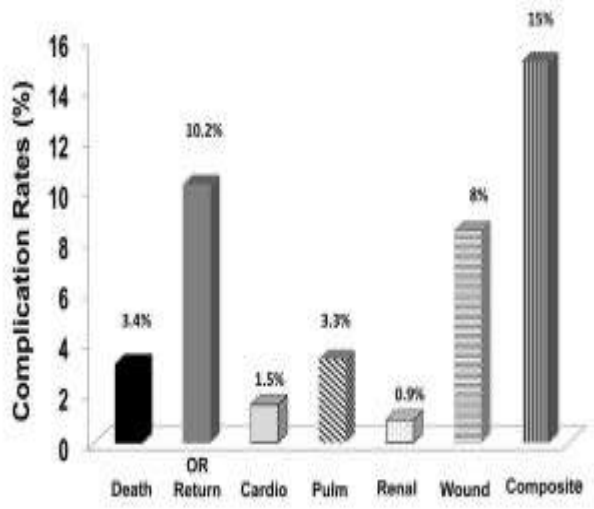


Fig 1. Thirty-day post-operative complications after common femoral endarterectomy (CFE). Major organ dysfunction (cardiac, pulmonary, renal) was rare, but wound-related complications and operative reintervention rates were high. The mortality rate was relatively high at 3.4%. *OR*, Operating room.

Table II. Intraoperative and postoperative outcomes

Outcomes	*Mean ± SD or No. (%)*
Intraoperative	
Operative time, hours	2.4 ± 1.16
Transfusion >4 units	51 (2.8)
Postoperative	
Mortality	62 (3.4)
Return to the operating room	188 (10.2)
Wound complications	147 (8)
Superficial infection	109 (5.9)
Deep wound infection	37 (2.0)
Wound dehiscence	15 (0.8)
Pneumonia	29 (1.6)
Prolonged intubation	26 (1.4)
Genitourinary tract infection	29 (1.6)
Sepsis	30 (1.6)
Septic shock	19 (1.0)
Graft failure	21 (1.1)
Cardiac arrest	17 (0.9)
Myocardial infarction	11 (0.6)
Acute kidney injury	5 (0.3)
Dialysis	11 (0.6)
Deep vein thrombosis	15 (0.8)
Pulmonary embolism	2 (0.1)

SD, Standard deviation.

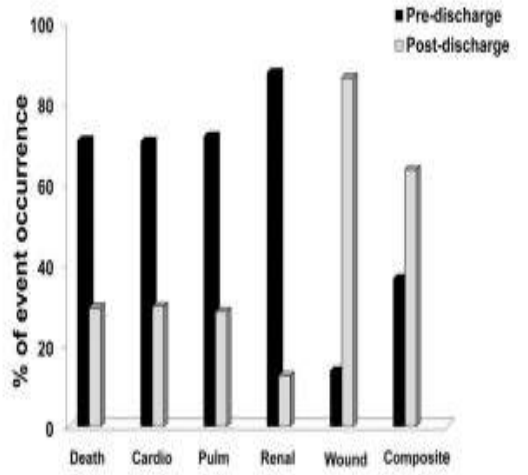


Fig 2. Distribution of major complications before and after hospital discharge. This graph provides another perspective to the distribution of postoperative complications reported in Table III. A significant percentage (30%) of deaths and cardiac and pulmonary complications occurred after hospital discharge. Most wound-related complications occurred after hospital discharge.

CONCLUSIONS: CFE is not as "benign" a procedure as previously believed. The risks of death and wound complications are not insignificant, and a high percentage of these complications occurred after patients were discharged from the hospital. Patients should be carefully selected, especially in the elderly population, and close postoperative follow-up should be considered.

Nguyen B et al. J Vasc Surg 2015;61:1489-94

What about the endovascular alternatives?

Author, date	Type study	Limbs (n)	Angioplasty only (n)	Stenting (n)	Atherectomy (n)	Primary patency (%)	Mean FU (m)	Technical success (%)
Stricker,2004	retro	33	0	33	0	86	30	100
Dick,2006	retro	55	47	0	0	71	13	85
Cotroneo,2010	retro	27	27	0	0	57,9	9,4	100
Bonvini,2011	retro	360	227	133	0	87,5	12	
Baumann,2011	retro	104	74	28	0	54	16	98
Azéma, 2011	pro	40	0	40	0	90	12	100
Paris,2011	retro	26	0	26	0	88	31	100
Davies, 2013	retro	121	107	1	0	75	12	90
Soga, 2013	retro	111	98	10	0	47	60	97
Bonvini,2013	retro	97	46	37	0	80	12	92
Linni, 2014	RCT (CFE)	116	0	58 (BAS)	0	80	12	97,5
Thiney, 2015	pro	53	0	53	0	92,5	24	na
Mehta, 2016	retro	167	114	15	38	78	20	na
Gouëffic, 2017	RCT (CFE)	117 (56)	0	56	0	90	24	94,6
Deloose, 2019	pro	100	0	100	0	95,2	12	100

(1) JEVT 2004;11:281-6
(2) JEVT 2006;13:221-228
(3) Cardiovasc Intervent Radiol 2010;33:921-28
(4) JACC 2011;58(8):792-8
(5) J Vasc Surg 2011;53:1000-6
(6) Eur J Vasc Endovasc Surg 2011;41:787-793
(7) Vasc Med 2011;16:109-112
(8) Vasc Endovascar Surg 2013;47:423-428
(9) Cardiovasc Interv Ther 2013;28:250-57
(10) J Vasc Interv Radiol 2013;24:175-183
(11) JEVT 2014;21:493-502
(12) Ann Vasc Surg 2015;29(5):960-7
(13) J Vasc Surg 2016;64(2):369-79
(14) JACC 2017;10(13):1344-54
(15) J Vasc Surg 2019, under review

What about the endovascular alternatives?

EuroIntervention. 2017 Feb 20;12(14):1789-1794. doi: 10.4244/EIJ-D-15-00187.

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

Angelo Cioppa [1], Eugenio Stabile, Luigi Salemme, Grigore Popusoi, Armando Pucciarelli, Fortunato Iacovelli, Antonella Arcari, Enrico Coscioni, Bruno Trimarco, Giovanni Esposito, Tullio Tesorio

Single-center, prospective study

- 30 patients
- Directional atherectomy + DCB (IN.PACT Admiral)
- 20% CTO's
- 10% bail-out stenting

1yr primary patency : 93.4%
1yr freedom from TLR : 96.7%

What about the endovascular alternatives?

Directional Atherectomy With Antirestenotic Therapy vs Drug-Coated Balloon Angioplasty Alone for Common Femoral Artery Atherosclerotic Disease

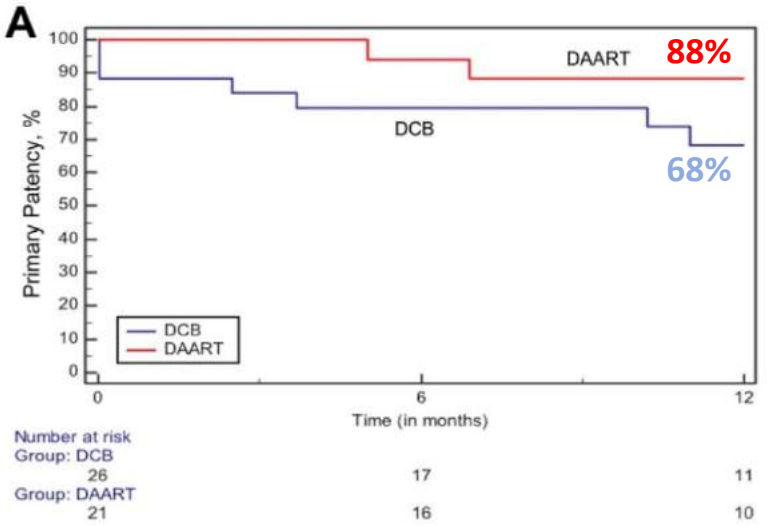
2018, Vol. 25(1) 92–99

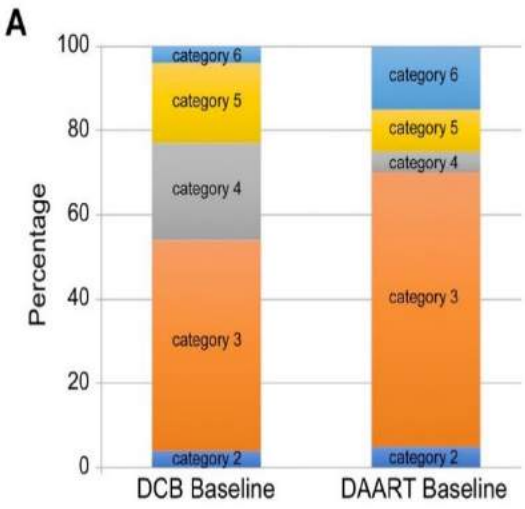
DOI: 10.1177/1526602817748319
www.jevt.org
SAGE

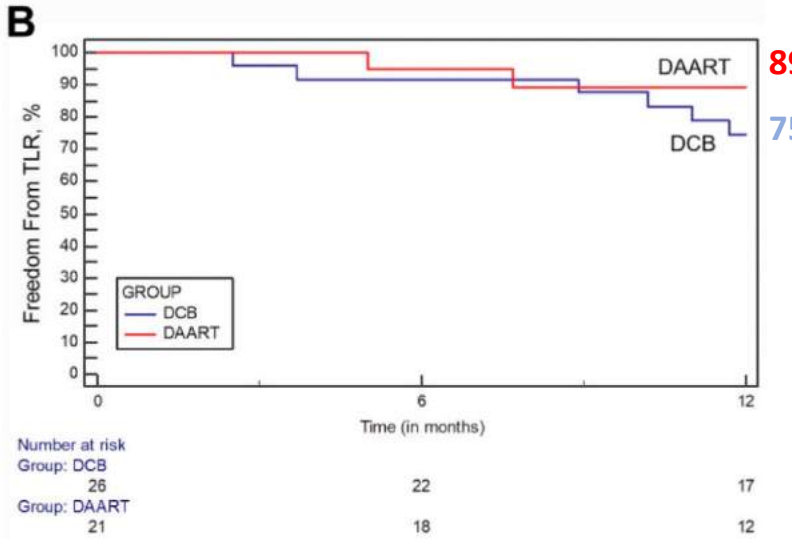
Konstantinos Stavroulakis, MD[I], Arne Schwindt, MD[I], Giovanni Torsello, MD[I], Efthymios Beropoulis, MD[I], Arne Stachmann, MD[I], Christiane Hericks, MD[I], Leonie Bollenberg, MD[I], and Theodosios Bisdas, MD, PhD[I]

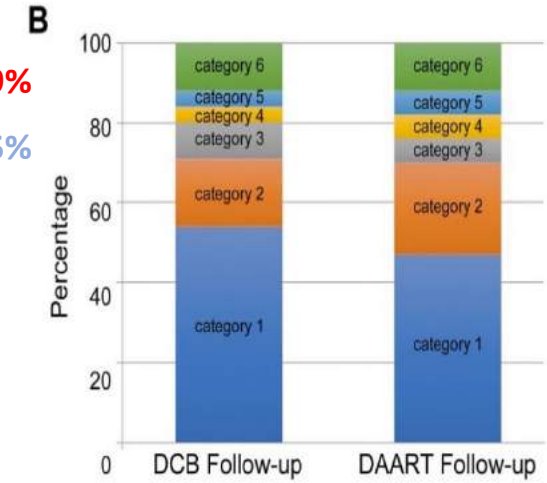
Single-center, retrospective study

- 47 patients
- 26 DCB versus 21 DAART









What about the endovascular alternatives?

PESTO-CFA Study

Percutaneous Intervention versus Surgery in the Treatment of Common Femoral Artery Lesions
A prospective, multi-centre, randomised study

Title:	PESTO-CFA
Aim:	Non inferiority study comparing DCB based endovascular therapy and surgical therapy in the treatment of atherosclerotic CFA disease
Study design:	Prospective, multicenter, randomized, controlled study , 1:1 randomization Follow-up at 6 months, 1, 2 and 5 years
Patient recruitment:	320 patients. Study duration 6.5 years (recruitment time 18 months, follow-up 5 years)

What about the endovascular alternatives?

Author, date	Type study	Limbs (n)	Angioplasty only (n)	Stenting (n)	Atherectomy (n)	Primary patency (%)	Mean FU (m)	Technical success (%)
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Davies, 2013	retro	121	107	1	0	75	12	90
Soga, 2013	retro	111	98	10	0	47	60	97
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(13) J Vasc Surg 2016;64(2):369-79
(14) JACC 2017;10(13):1344-54
(15) J Vasc Surg 2019, under review

What about the endovascular alternatives?

Systematic Review and Proportional Meta-Analysis of Endarterectomy and Endovascular Therapy with Routine or Selective Stenting for Common Femoral Artery Atherosclerotic Disease

Khalid Hamid Changal,[1] Mubbasher Ameer Syed,[2] Tawseef Dar,[3] Muhammad Asif Mangi,[2] and Mujeeb Abdul Sheikh[4]

[1]*Internal Medicine, Mercy Health St. Vincent Medical Center, Toledo, OH, USA*
[2]*Cardiovascular Medicine, University of Toledo College of Medicine and Life Sciences, Toledo, OH, USA*
[3]*Cardiology Division, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, USA*
[4]*Cardiovascular Medicine and Interventional Cardiology, University of Toledo College of Medicine and Life Sciences, 3065 Arlington Ave. Toledo, OH 43614, USA*

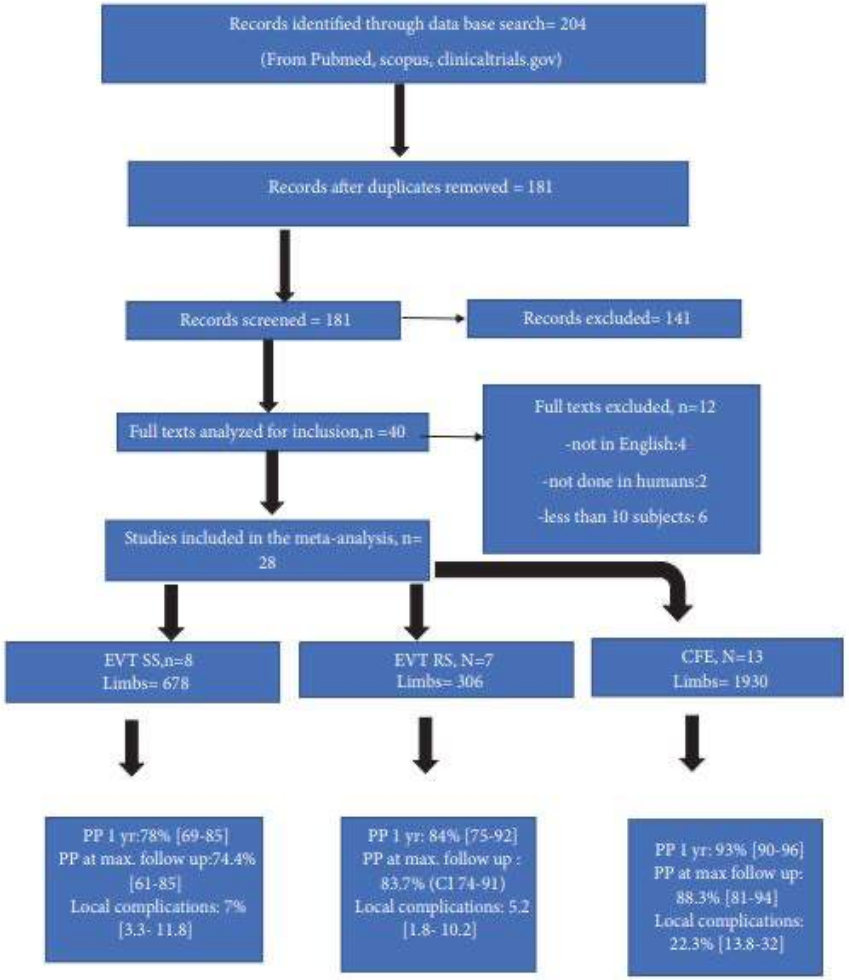
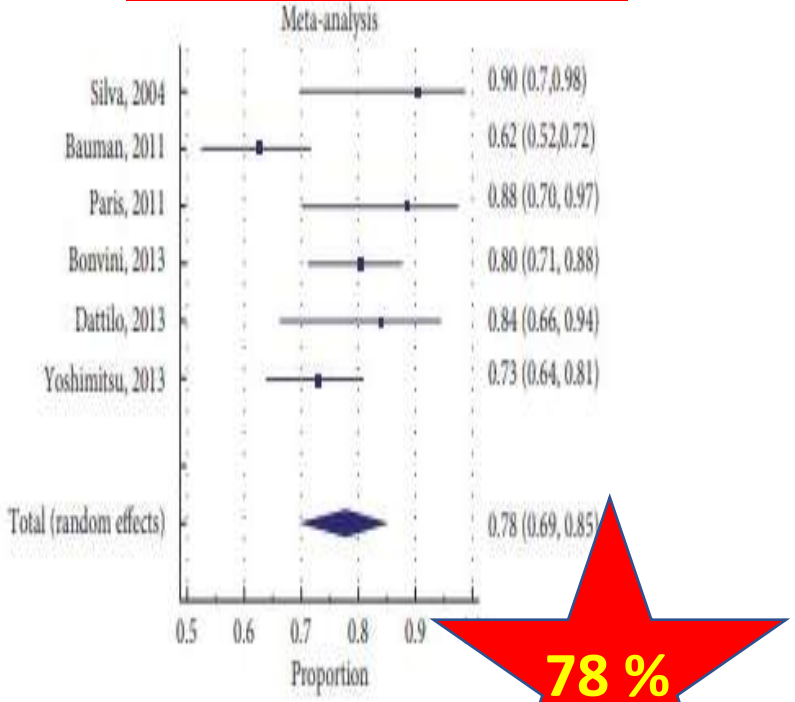


FIGURE 1: Flowsheet summarizing the selection of studies and main results.

J Intervent Cardiology, Vol 73, Issue 9, Suppl 1, 12 March 2019 ; pg 2065

What about the endovascular alternatives?

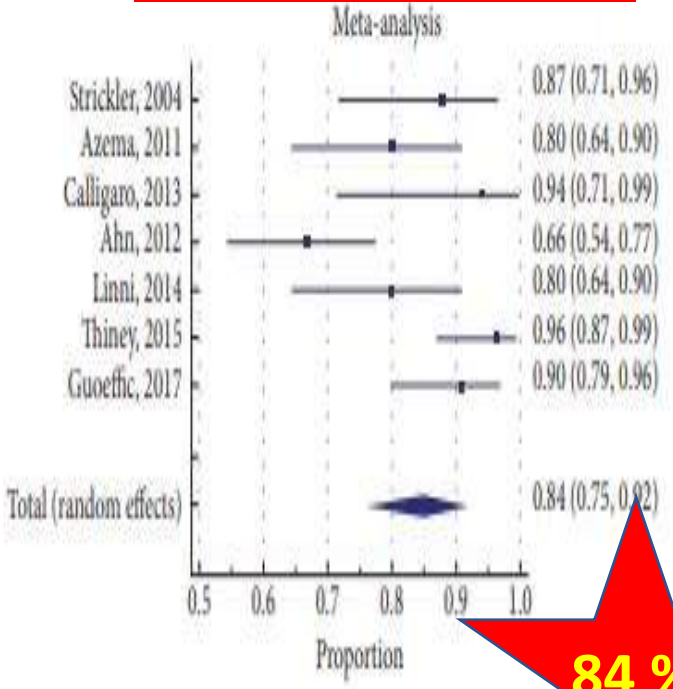
Selective stenting



78 %

FIGURE 2: Forrest plot for PP (Primary patency) at 1 year in EVTSS (Endovascular thera... ...selecti... ...g) group.

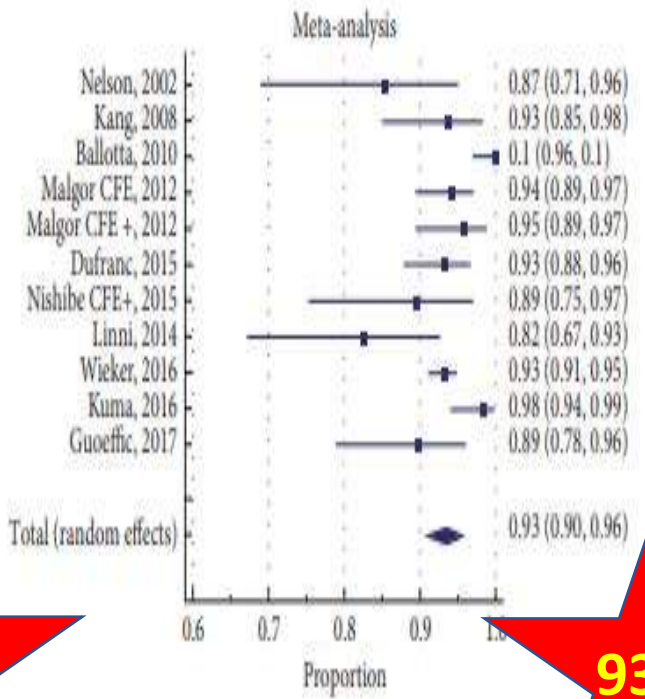
Routine stenting



84 %

FIGURE 4: Forest plot for primary patency at 1 year in EVT... ...oup.

CFE



93 %

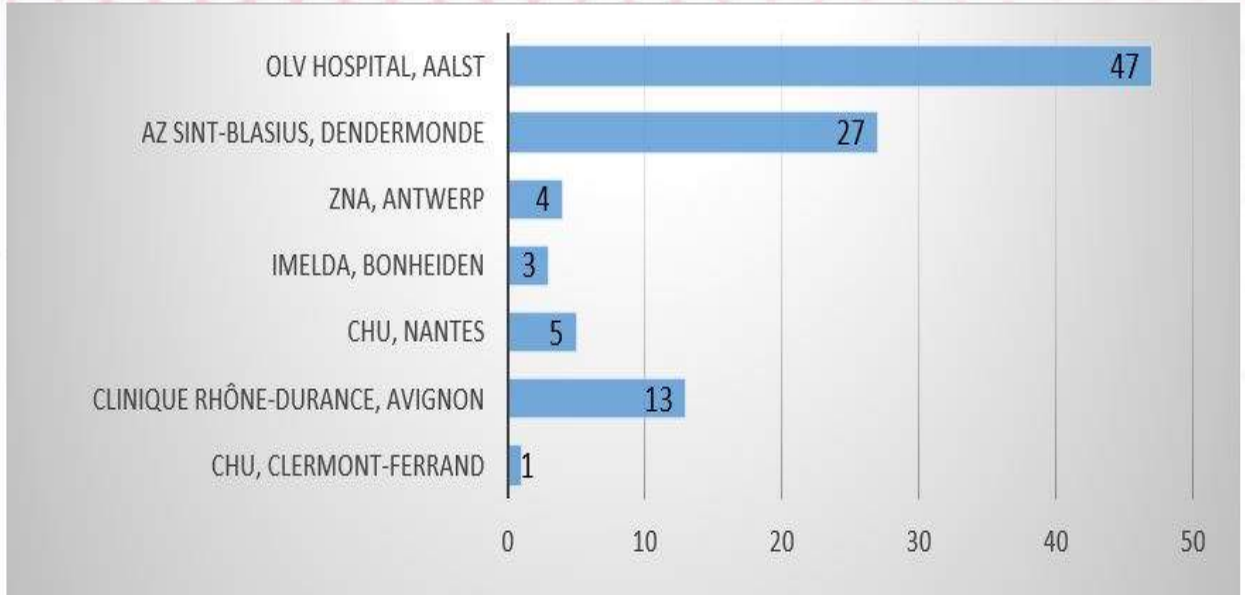
FIGURE 6: Forrest plot for PP at 1 year in CFE group.

J Intervent Cardiology, Vol 73, Issue 9, Suppl 1, 12 March 2019 ; pg 2065

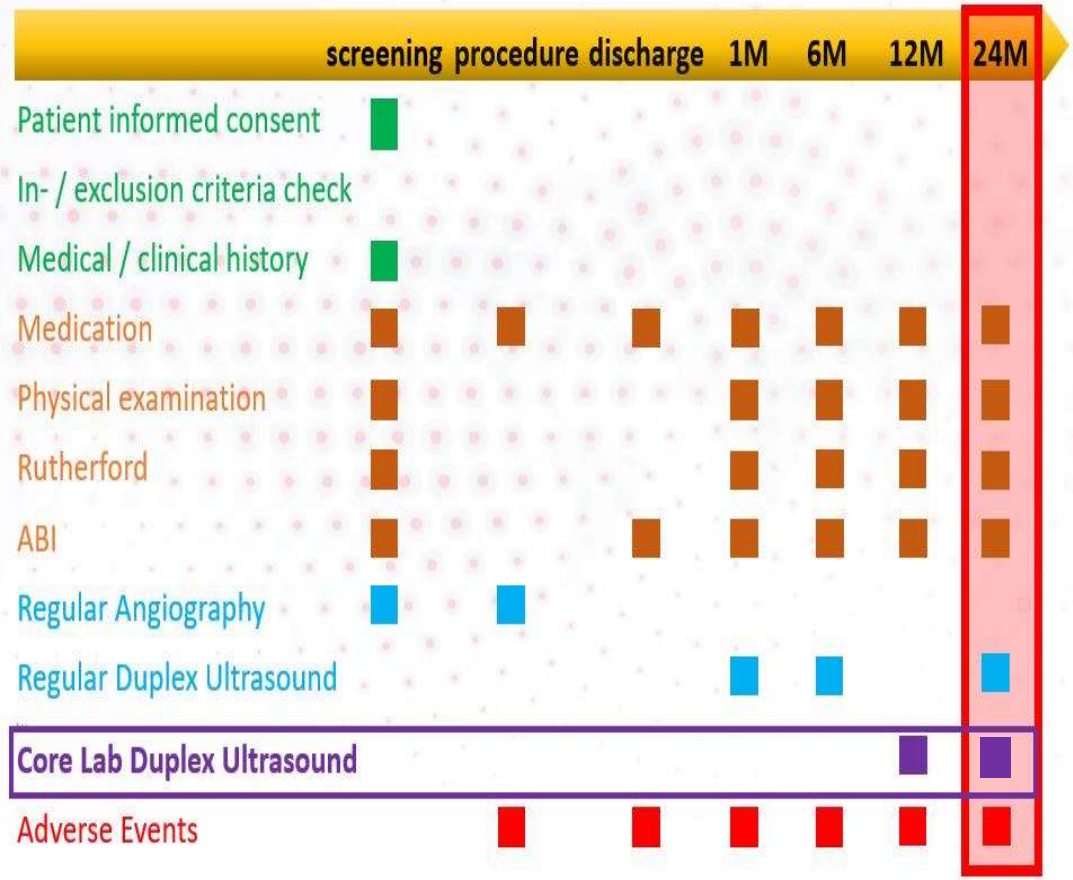
What about the endovascular alternatives?

VMI-CFA trial

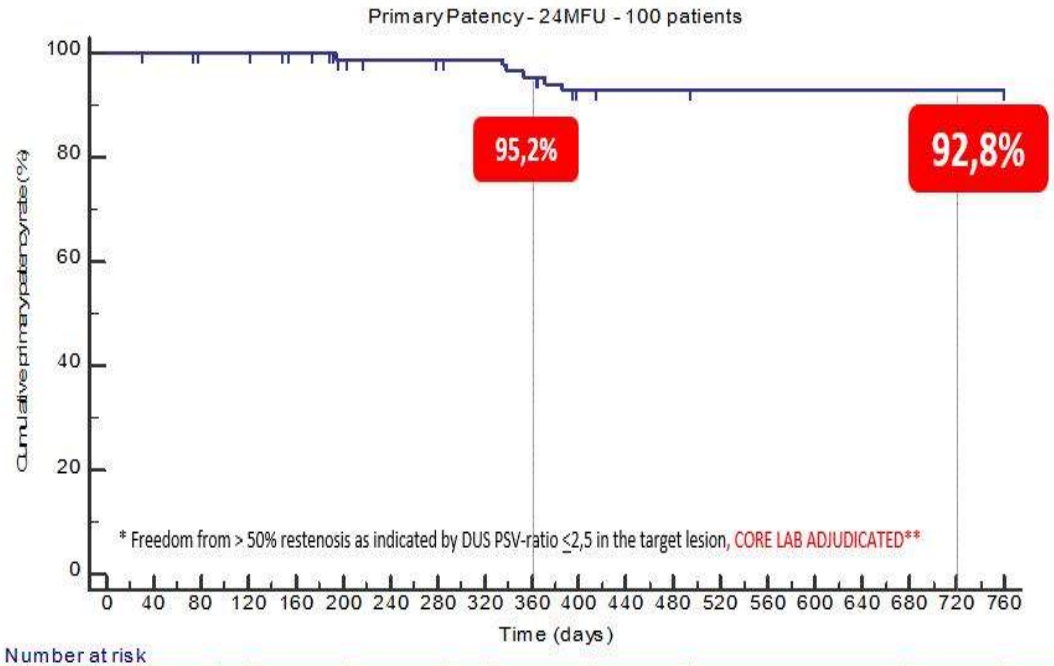
Prospective, multicenter, single arm trial to evaluate the Supera Peripheral Vascular Mimetic Implant Device (Abbott Vascular) for symptomatic (RB 2-4) CFA disease treatment



TIMELINE



1 - 2 year primary patency*



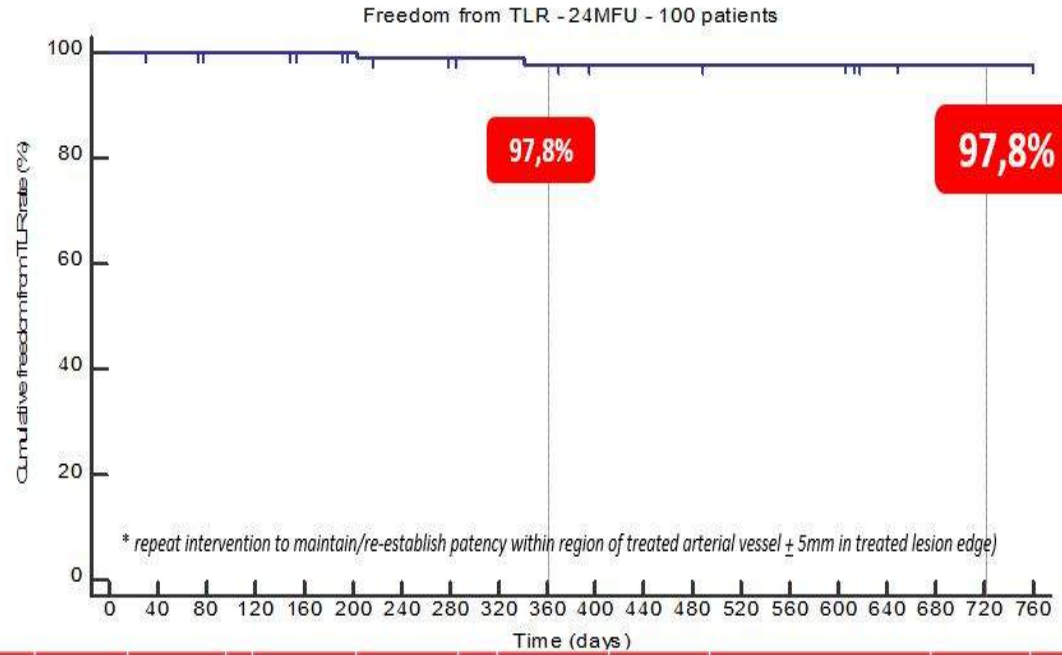
Number at risk

time	baseline	1MFU (30 days)	6MFU (180 days)	6MFU (210 days)	12MFU (365 days)	12MFU (395 days)	24MFU (730 days)	24MFU (760 days)
at risk	100	99	91	84	78	76	66	18
%	100	100	100	98,9	95,2	92,8	92,8	92,8

**EuroImaging Srl, Rome, Italy

Primary safety endpoint	30 days	6 months	12 months	24 months
Device or procedure related death (N)	0	0	0	0
CD-TLR (N)	0	1	2	2
Target limb major amputation (N)	0	0	0	0

1 - 2 year freedom from TLR*



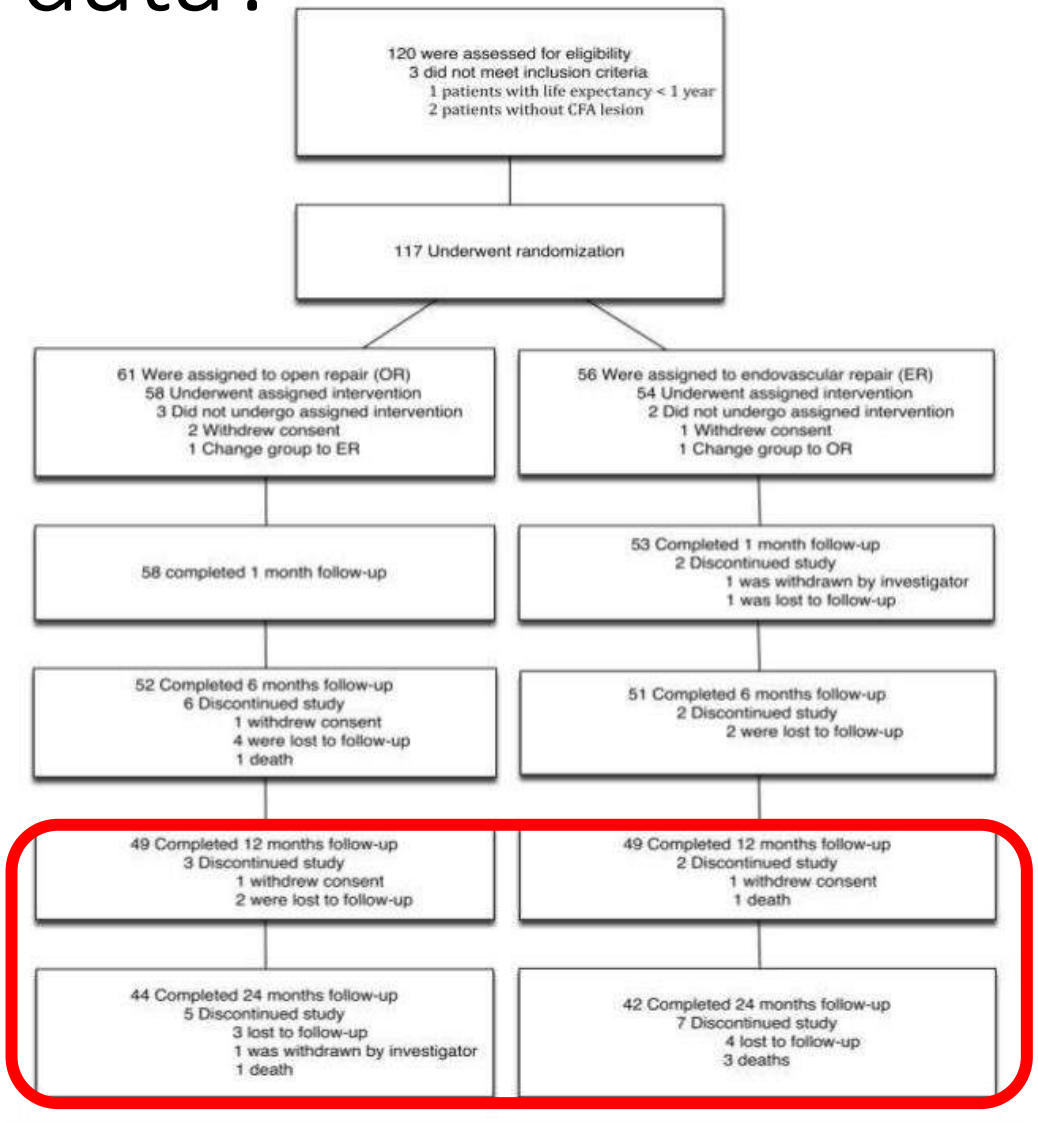
time	baseline	1MFU (30 days)	6MFU (180 days)	6MFU (210 days)	12MFU (365 days)	12MFU (395 days)	24MFU (730 days)	24MFU (760 days)
at risk	100	99	95	92	88	88	80	29
%	100	100	100	98,9	97,8	97,8	97,8	97,8

What about randomized data?

TECCO trial

- **Investigator initiated study**
- **RCT multicenter and controlled**
- **Rigorous data collection process, independent**
- **Adjudication by:**
  - *Duplex ultrasound core laboratory*
  - *Data safety monitoring board*
- **Follow-up includes**
  - 1, 6, 12, and 24-month clinical assessment
  - 1, 12 and 24-month stent x-ray
- **Monitoring with 100% source data verification**

- **Modified intent to treat analysis / Per protocol analysis**
- **Sample size calculation: 120 patients**
- **Randomly assigned in a 1:1 ratio**
- **80% power** *to detect a between-group difference of 20% percentage points in the morbid-mortality rate at a two-sided alpha level of 0.05 (25% in the surgery group and 5% in the stenting group).*



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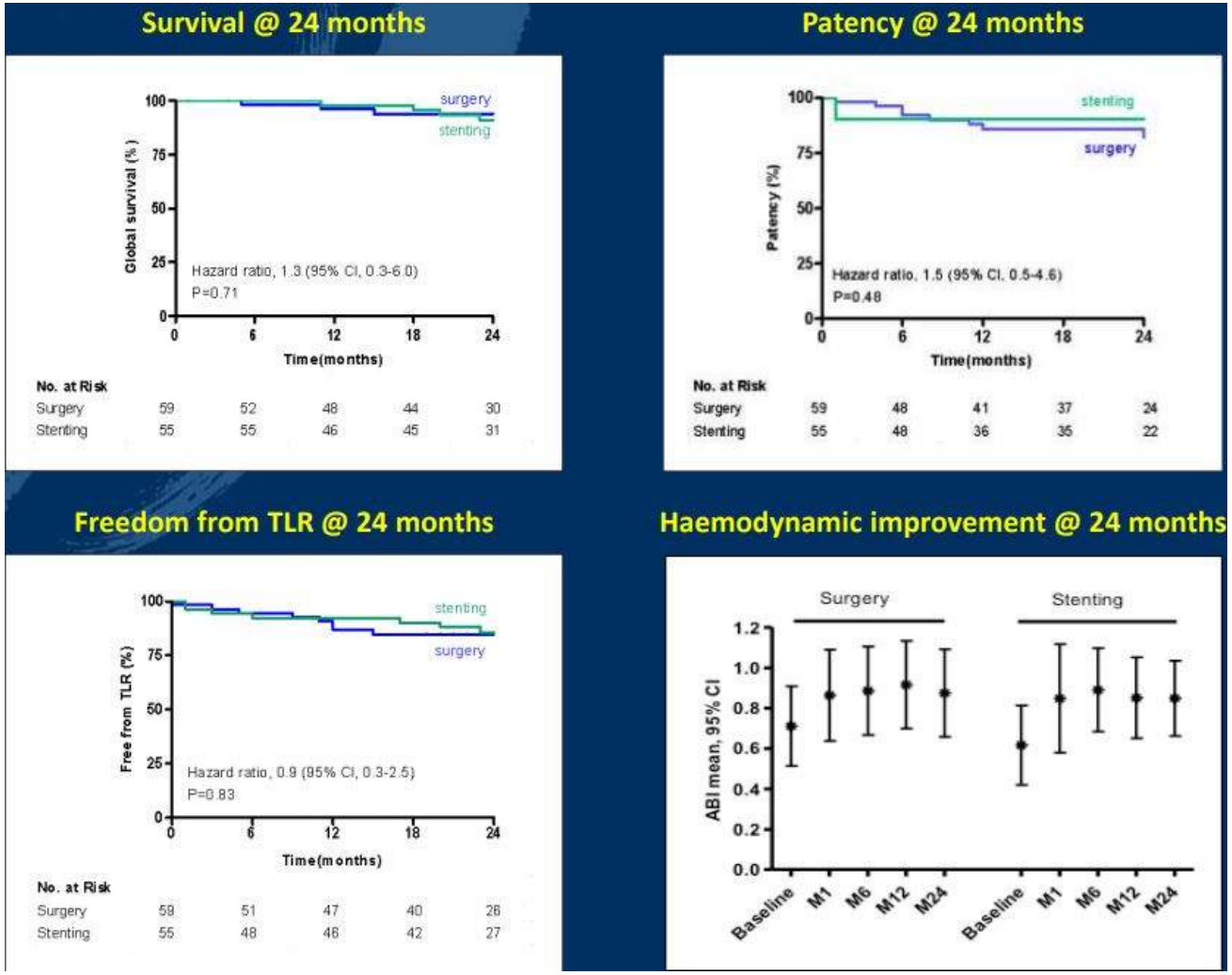
What about randomized data?

TECCO trial

Per protocol analysis

	Surgery (n=58)	Stenting (n=47)	p
Morbid-mortality rate @ 1 month, n (%)	16 (26)	3 (6.4)	0.005

	Surgery (N=61)	*Stenting (N=56)*
Hematoma	*3 (5)*	*0 (0)*
Thrombosis	*0 (0)*	*1 (1.8)*
Lymphorrhea	*2 (3.2)*	*0 (0)*
Delayed wound healing	*10 (16.4)*	*0 (0)*
False aneurysm	*0 (0)*	*0 (0)*
Arteriovenous fistula	*0 (0)*	*0 (0)*
Paresthesia	*4 (6.5)*	*0 (0)*
Local infection	*3 (5)*	*1 (1.8)*
Vascular perforation	*0 (0)*	*1 (1.8)*



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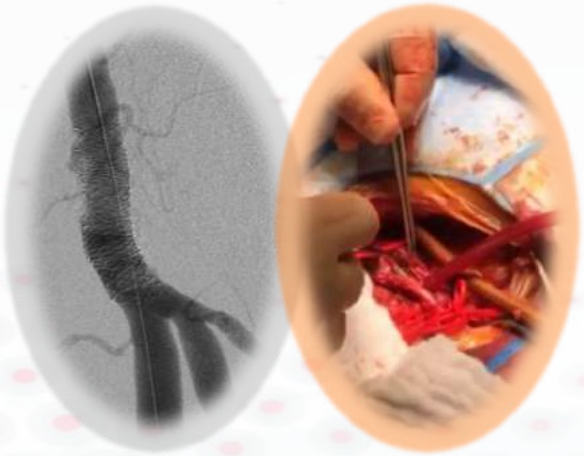
What about randomized data?



SUPERSURG RCT

Evaluation of the safety and efficacy of the endovascular treatment of stenotic, restenotic or occlusive lesions of the CFA with **Supera** stent compared to **surg**ical CFA Endarterectomy

286 patients

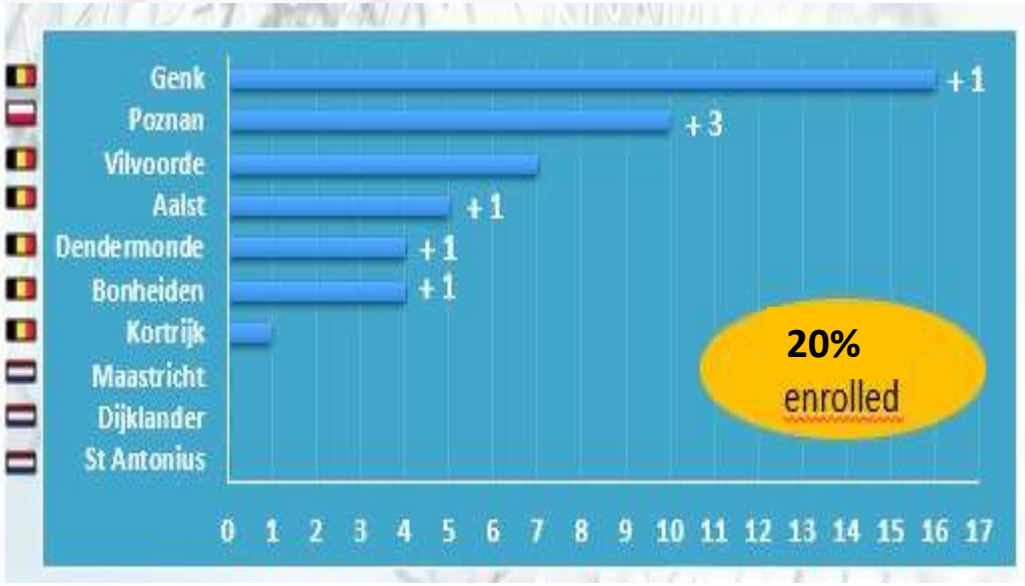
1:1 Randomization

Stratification: BMI – Azéma - Calcium

A.Z. Sint-Blasius@Dendermonde
Onze-Lieve Vrouwziekenhuis@Aalst
Ziekenhuis Oost-Limburg@Genk
Az Groeninge@Kortrijk
A.Z. Jan Portaels@Vilvoorde
Imelda@Bonheiden

St. Antonius Ziekenhuis@Utrecht
Heart+Vascular center@Maastricht
Dijklander Ziekenhuis@Hoorn

Hospital of Lord's Transfiguration@Poznań



57 patients out of 286 have been enrolled

Take home messages

- **CFE**-success is built on outstanding and durable patency results
- Caveat assessment methods
- Caveat morbidity-mortality, especially in older and more fragile population
- **Endovascular methods** are looking for safer and as efficient data in comparison with CFE
- Angioplasty alone is not a valuable alternative
- **DAART or Stenting** (with particular dedicated stents?) is evoluting in the good direction
- Randomized data are on their way…

Polling question

What is your preferred treatment option for CFA lesions?

a. Surgery only – should be the only treatment option for CFA
b. Surgery only but interested to learn more about endovascular treatment options
c. Surgery first but endovascular if patient requires
d. Endovascular treatment using Supera stent
e. Other Endovascular treatment.