

APOLLO Results

A PrOspective observational study using ELUTAX SV drug-eluting baLLOons for below the knee treatment

ClinicalTrials.gov Identifier: NCT02539940

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Disclosure

Speaker name:

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I have the following potential conflicts of interest related to the presentation to report:

- Research grant from Aachen Resonance, AB Medica

Patients

	N = 164
age	74,7 ± 9,2
sex	
female	33,5%
male	66,5%
Diabetes mellitus	79,9%
hyperlipidemia	55,3%
BMI > 30	43,8%
hypertonia	90,2%
Smoker, total	45,2%
active	11,6%
Renal insufficiency	57,3%

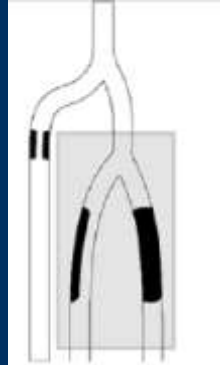
Patients

	N = 164
ABI (n = 83)	0,91 ± 0,46
< 0,5	15,7%
≥ 1,3	26,5%
Rutherford category	
3	4,3%
4	17,7%
5	66,5%
6	11,6%
Previous amputations	25,6%

TASC Classification infrapopliteal

TASC A lesions

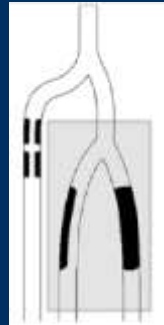
Single focal stenosis, ≤ 5 cm in length, in the target tibial artery with occlusion or stenosis of similar or worse severity in the other tibial arteries.



29,6%

TASC B lesions

Multiple stenoses, each ≤ 5 cm in length, or total length ≤ 10 cm or single occlusion ≤ 3 cm in length, in the target tibial artery with occlusion or stenosis of similar or worse severity in the other tibial arteries.

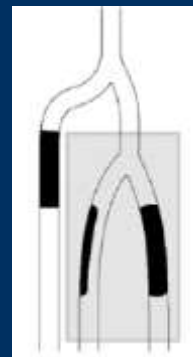
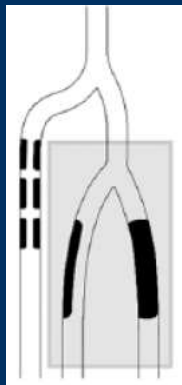


42,0%

TASC Classification infrapopliteal

TASC C lesions

Multiple stenoses in the target tibial artery and/or single occlusion with total lesion length >10 cm with occlusion or stenosis of similar or worse severity in the other tibial arteries.



24,1%

TASC D lesions

Multiple occlusions involving the target tibial artery with total lesion length >10 cm or dense lesion calcification or non-visualization of collaterals. The other tibial arteries occluded or dense calcification.



4,3%

Lesions

	N = 248
Affected areas (N=273)	
A. poplitea	10,6%
Tibioperonealer Stamm	15,4%
A. tibialis anterior	36,6%
A. fibularis	20,1%
A. tibialis posterior	17,2%
Lesion length	71,2 ± 76,5 mm
total	107,2 ± 92,6 mm
Occlusion (CTO)	42,7%
Severe aortic calcification*	26,5% (22/83)

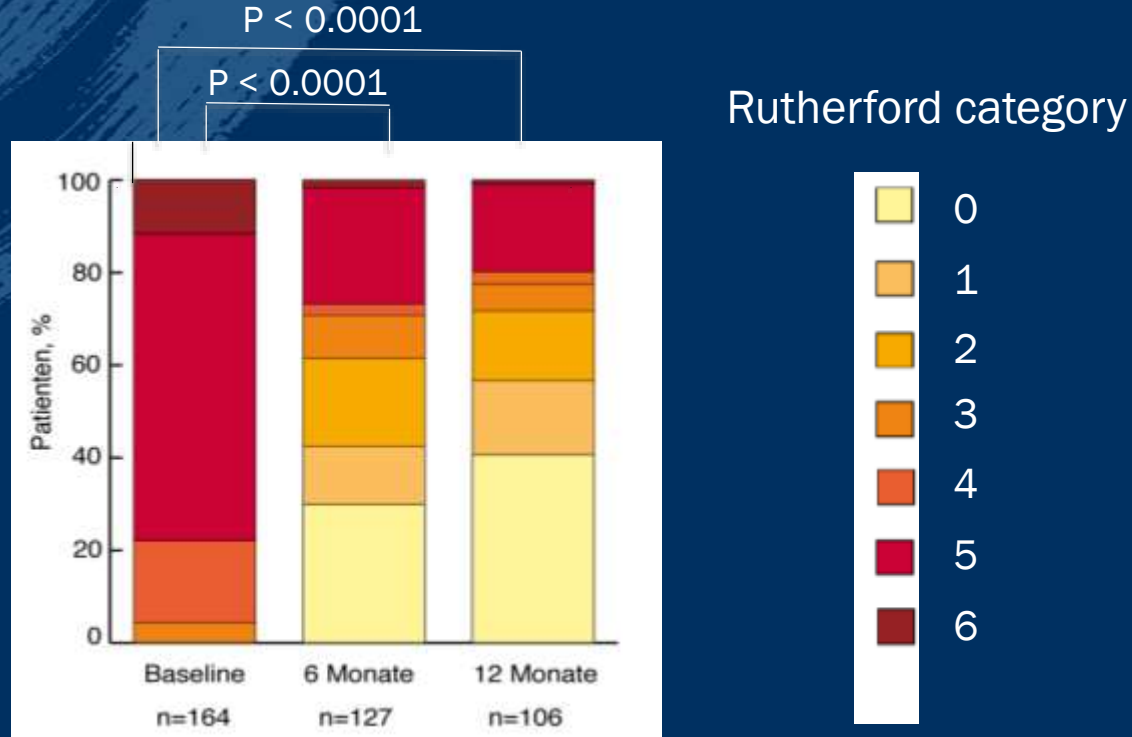
* Media sclerosis

*media sclerosis

Procedure

Pre-dilatation	67,5%
DCB used	286 (1,2 pro Läsion)
DCB length	86,4 ± 43,8 mm
Diameter	2,9 ± 2,2 mm
Max. pressure	8,5 ± 2,0 mm
Duration of inflation	114,4 ± 34,7 Sekunden
Postdilatation	11,0%
Bailout Stenting	3,1%

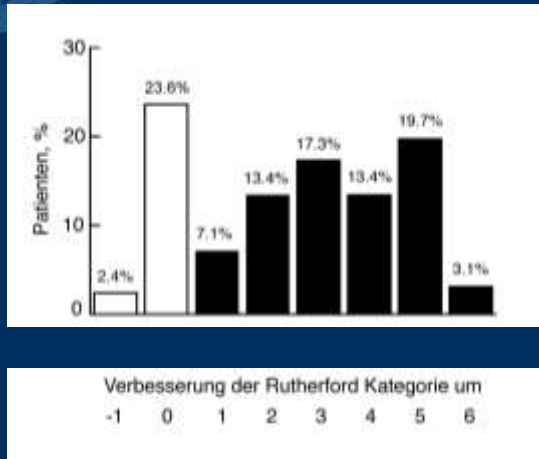
Primary Endpoint: Clinical Improvement



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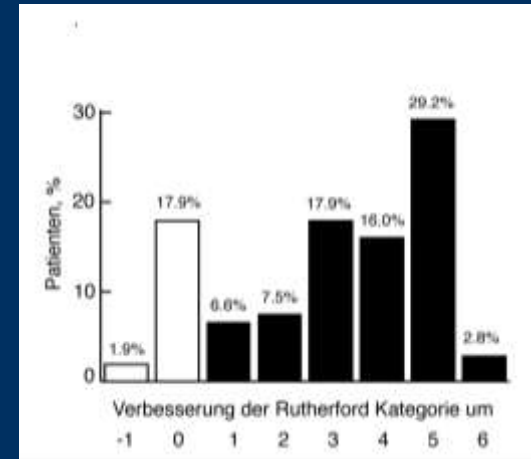
6 months

Improvement of
 ≥ 1 Rutherford
category: **74.0%**



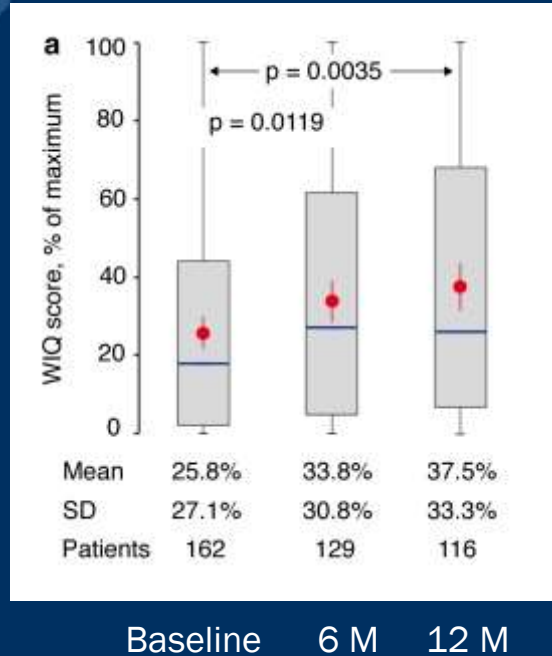
12 months

Improvement of
 ≥ 1 Rutherford
category: **80.2%**



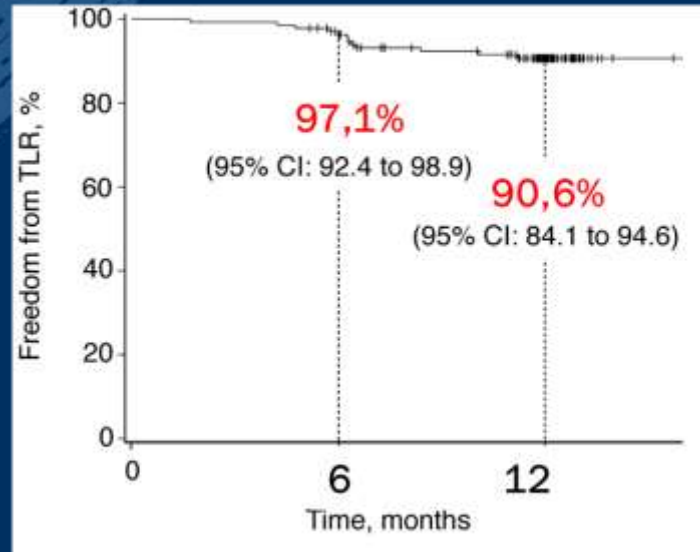
Quality of Life

WIQ Score



Revascularisation

No Revascularisation
of the target lesion (TLR)



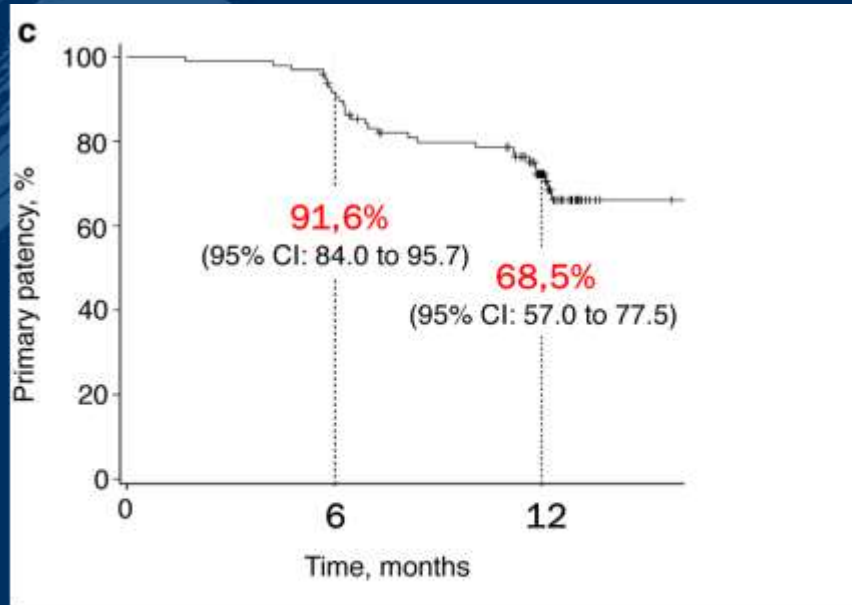
Patients at risk

164

128

74

Primary patency



Patients at risk

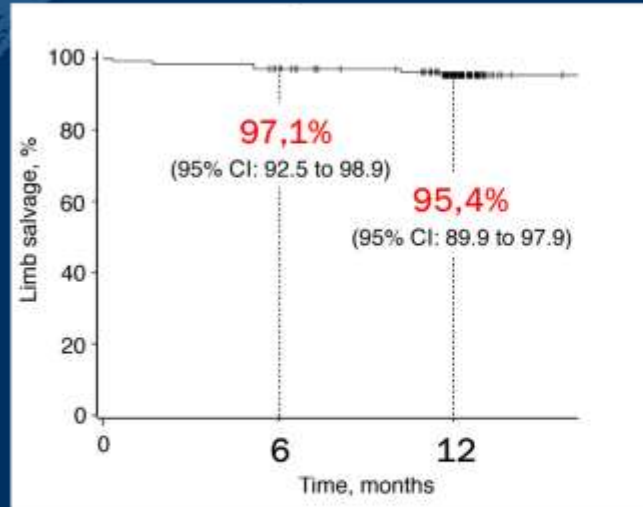
164

86

45

Amputation

Limbs preserved*



Patients at risk

164

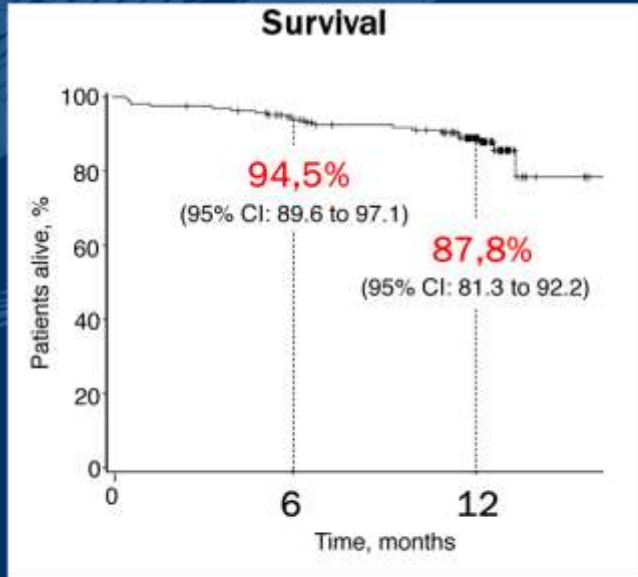
130

81

* Major Amputation: proximal to transmetatarsal

** Minor Amputation: transmetatarsal or distal

Mortality



Patients at risk

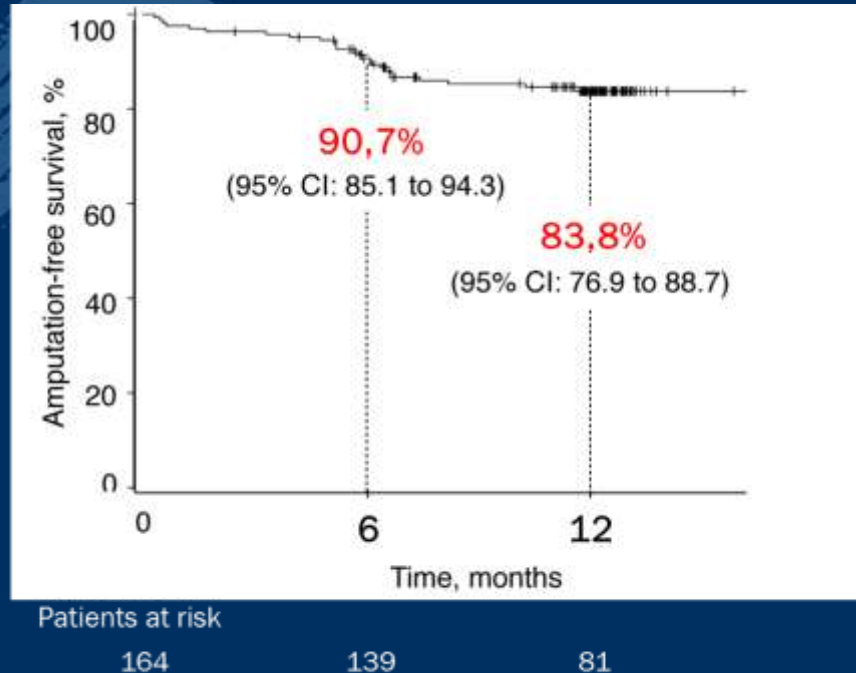
164

145

92

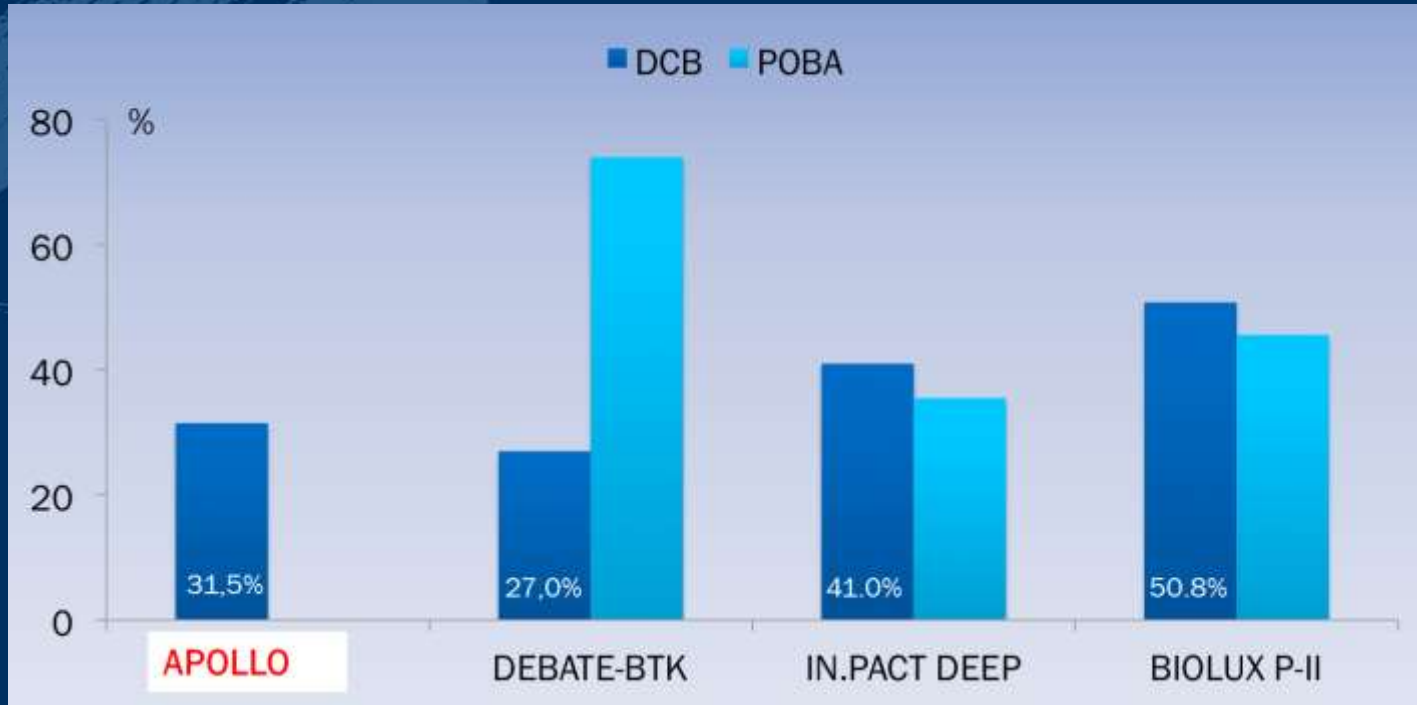
Cause of death	20 Patients
Heart failure	5/20 (25%)
sepsis	4/20 (20%)
stroke	2/20 (10%)
Renal insufficiency	2/20 (10%)
pneumonia	2/20 (10%)
bleeding	2/20 (10%)
Heart attack	1/20 (5%)
Arrhythmia	1/20 (5%)
Unknown	1/20 (5%)

Survival: Freedom of Amputation*

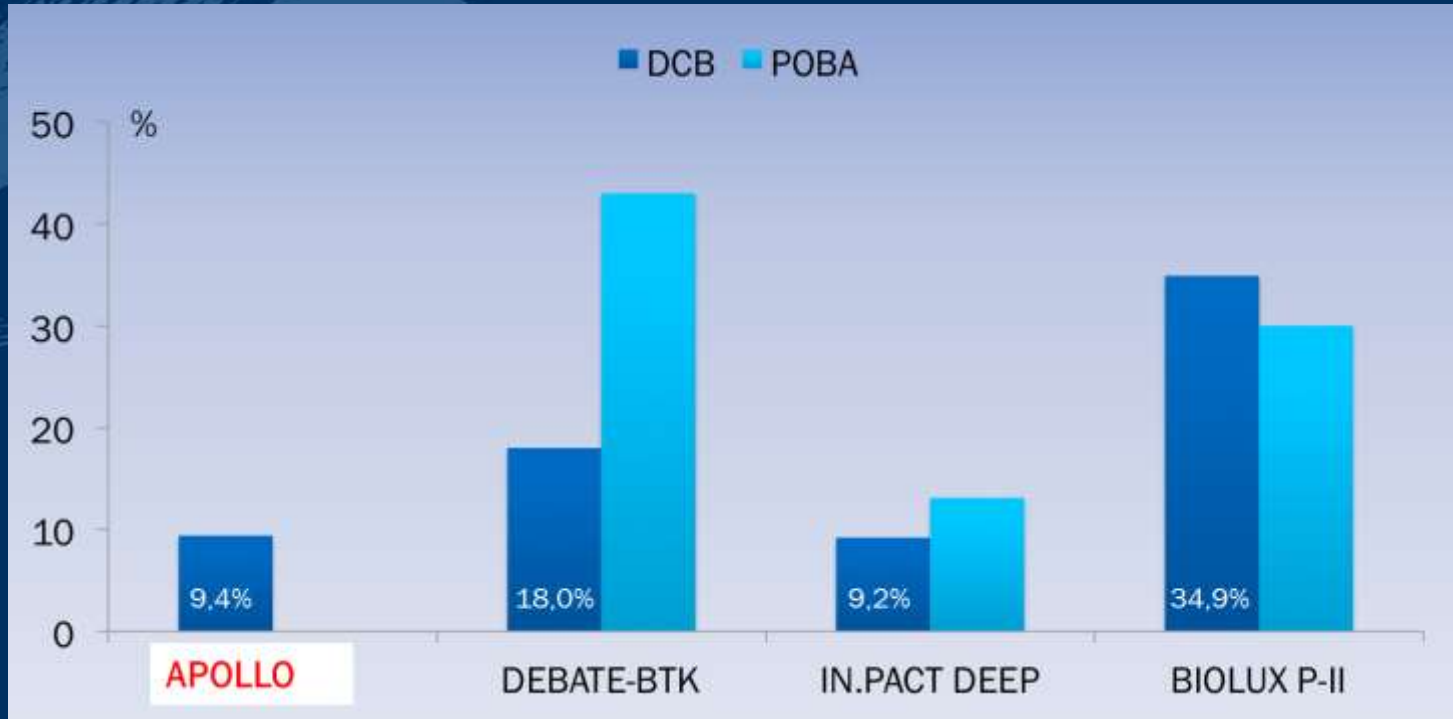


* alive without Major Amputation

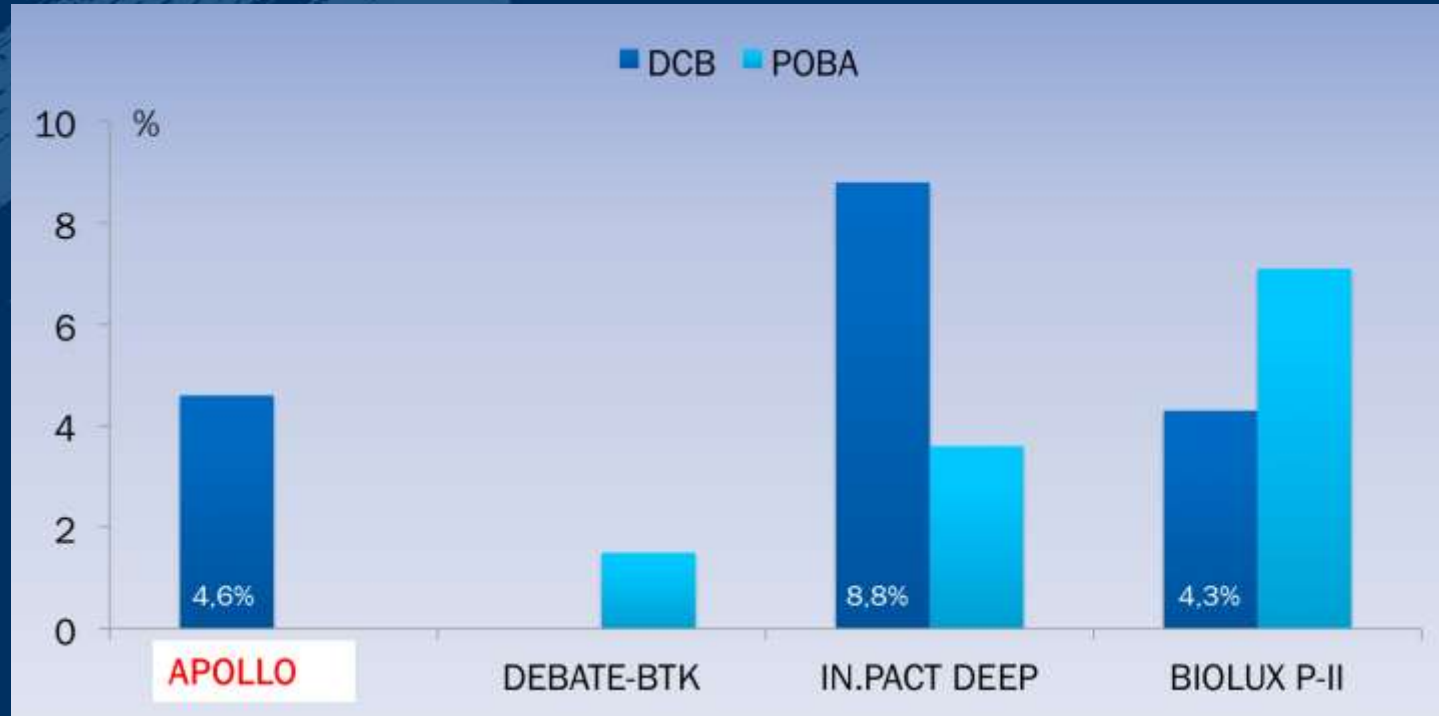
Comparison Restenosis: Incidence 12 Months



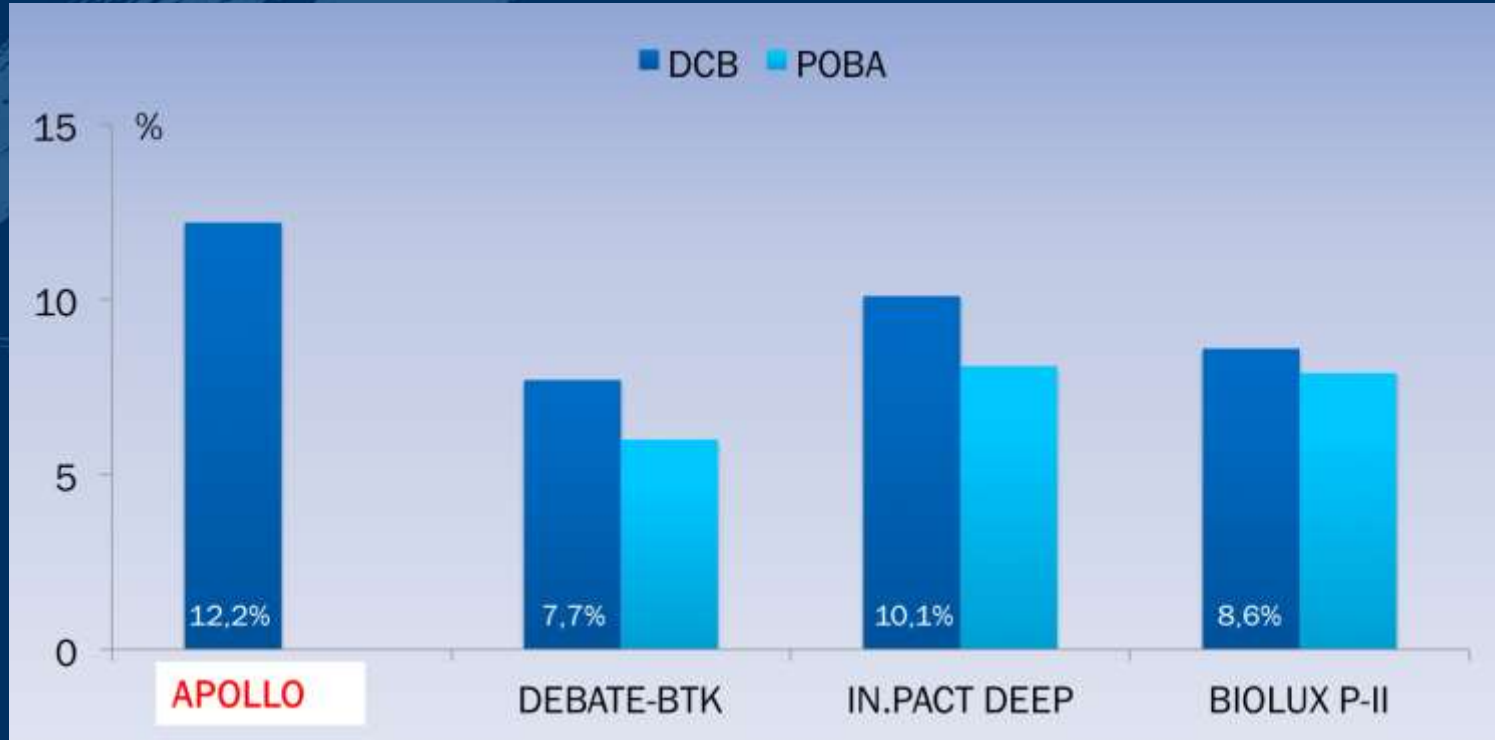
Comparison TLR: 12 Months



Comparison Major Amputation 12 months



Comparison Mortality: 12 Months



ELUTAX SV DCB Angioplasty of infrapopliteal lesions in patients with CLI was associated with

- clinical improvement
- Improving the quality of life
- repeated revascularization in about 20% of patients
 - minor amputations in 20% of patients
 - major amputations in almost 5% of patients
- amputation-free survival of about 84% of patients

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