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# Drug-eluting stents in BTK intervention



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# Treatment of CLI

SOPC Guidelines Cardiovasc Intervent Radiol 2013

## Control

Pain

Infection

Atherosclerosis

Anticoagulation

**Revascularization**



# DES in BTK intervention

Revascularization BTK

Surgery vs endovascular Rx

DES

Diabetes

Conclusions

# Meta-analysis of infrapopliteal angioplasty for chronic CLI

(Romiti M et al, J Vasc Surg 2008)

	PTA	Bypass
Primary patency 6 months	65.0 ± 7.0	85.8 ± 2.1 <0.05
Primary patency 12 months	58.1 ± 4.6	81.5 ± 2.0 <0.05
Limb salvage 6 months	88.2 ± 4.4	90.9 ± 1.9 NS
Limb salvage 12 months	86.0 ± 2.7	88.5 ± 2.2 NS

# Infrapopliteal PTA versus bypass surgery as first-line strategies in CLI

A propensity score analysis  
Söderström MI et al, Ann Surg 2010

	1 year salvage	1 year amputation free survival	5 year salvage	5 year amputation free survival
CLI (n=1023)				
PTA (n=262)	85.5%	64.4%	75.3%	37.7%
Bypass surgery (n=761)	82.2%	65.9%	76.0%	37.3%

# DES in BTK intervention

## Revascularization BTK

Surgery vs endovascular Rx

DES to decrease restenosis

Diabetes

Conclusions

# Systematic Review of infrapopliteal DES: A meta-analysis of randomized controlled trials

Katsanos K et al, Cardiovasc Intervent Radiol 2013

## 3 RCTs with 501 patients

Achilles: DES vs PTA in CLI & IC, n=200

Destiny: DES vs BMS in CLI, n=140

Yukon-BTX: DES vs BMS in CLI & IC, n=161

Relatively short and focal infrapopliteal lesions



# Systematic Review of infrapopliteal DES: A meta-analysis of randomized controlled trials

Katsanos K et al, Cardiovasc Intervent Radiol 2013

<b>Results at 1 year</b>	<b>DES</b>	<b>PTA/BMS</b>	<b>P=</b>
Primary patency	80.0%	58.8%	<0.0001
Rutherford class. improvement	79.0%	69.6%	0.045
Wound healing	76.8%	59.7%	0.04
TLR	9.9%	22.0%	0.001
Event-free survival	72.2%	57.3%	<0.0001
Survival	85.5%	86.6%	0.75
Amputation	6.4%	10.8%	0.11

# Yukon BTX TRIAL. Long-term results

Rastan A, J Am Coll Cardiol 2012

	<b>Sirolimus-DES</b>	<b>BMS</b>
Follow-up	1005±139 d	1027±123d
Event free survival	65.8%	44.6% (P=0.02)
Major amputation	2.7 %	12.9%
TVR	9.2%	20.0%
Death	22.6%	24.0%

# PADI

## CLI: PTA±BMS vs DES for infrapopliteal lesions

Circ Cardiovasc Interv 2016

Multi-center randomized two-arm study

136 patients with 144 limbs

CLI, Rutherford 4-6

De novo stenoses or occlusions below knee joint

Vessel diameter 2-6 mm, length  $\leq$  90 mm

PTA±BMS or paclitaxel-DES (Taxus liberte)

Heparin, Aspirin, Clopidogrel

# Primary endpoint, patency per lesion (CTA at 6 months)

(PADI, Circ Cardiovasc Interv 2016)

	<b>PTA±BMS</b>	<b>DES</b>	<b>p value</b>
	n=54 limbs	n=62 limbs	
<b>Modified intention to treat analysis</b>	n=77 lesions	n=98 lesions	
Lesions with preserved patency	27 (35.1)	47 (48.0)	0.096
<b>Per protocol analysis</b>	n=77 lesions	n=81 lesions	
Lesions with preserved patency	27 (35.1)	42 (51.9)	0.037

Values are n(%).

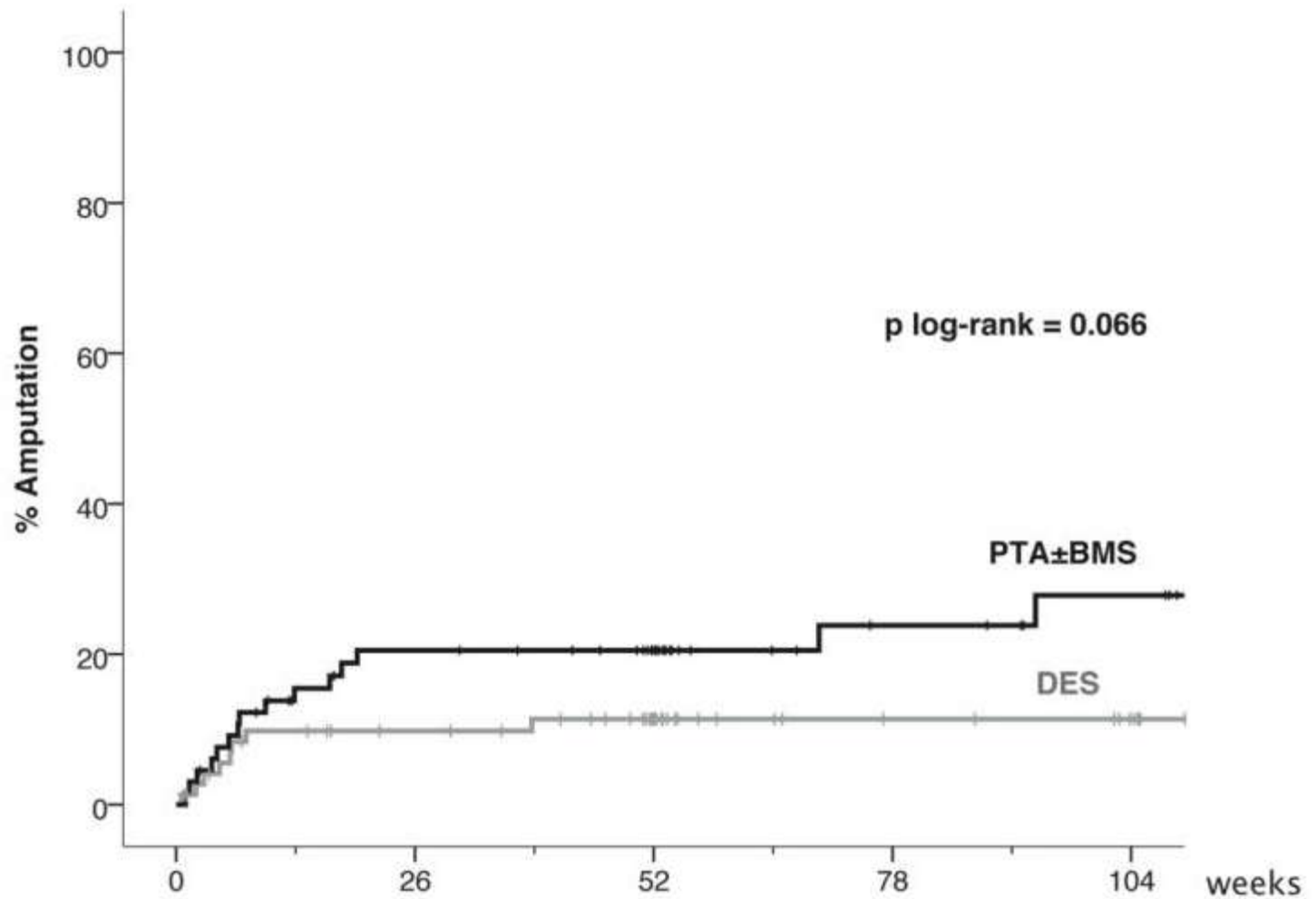
# Primary endpoint per lesion

PADI, Circ Cardiovasc Interv 2016

<b>Modified intention to treat analysis</b>	<b>PTA±BMS</b>	<b>DES</b>	<b>p value</b>
	n=54 limbs	n=62 limbs	
	n=77 lesions	n=98 lesions	
Lesions with preserved patency	27 (35.1)	47 (48.0)	0.096
Ordinal score:			0.041
≤50% stenotic	27 (35.1)	47 (48.0)	
>50% stenotic	23 (29.9)	15 (15.3)	
Occluded	7 (9.1)	19 (19.4)	
Amputation/CLI related death/treatment in interim	20 (26.0)	17 (17.3)	

Values are n(%).

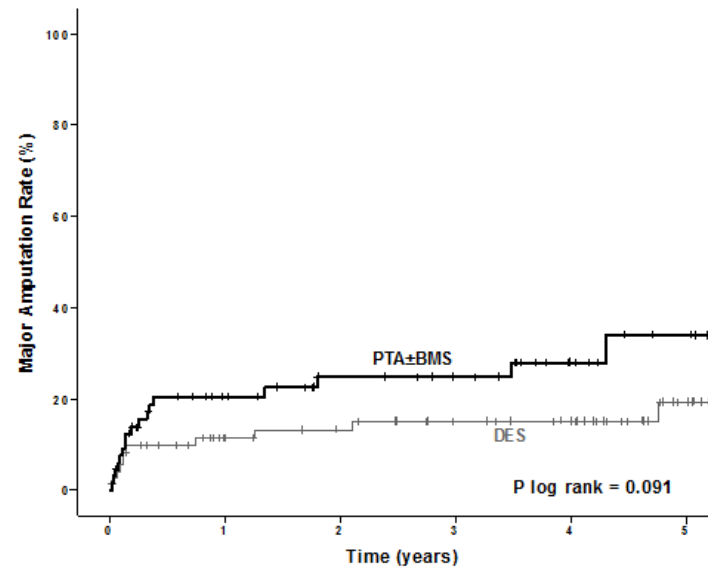
# Major amputations (PADI, Circ cardiovasc Interv 2016)



numbers (limbs) at risk

DES	74	59	47	32	28
PTA±BMS	66	47	38	22	18

# Estimated 5-year cumulative incidence rates of major amputation per limb. PADI. JAHA 2017

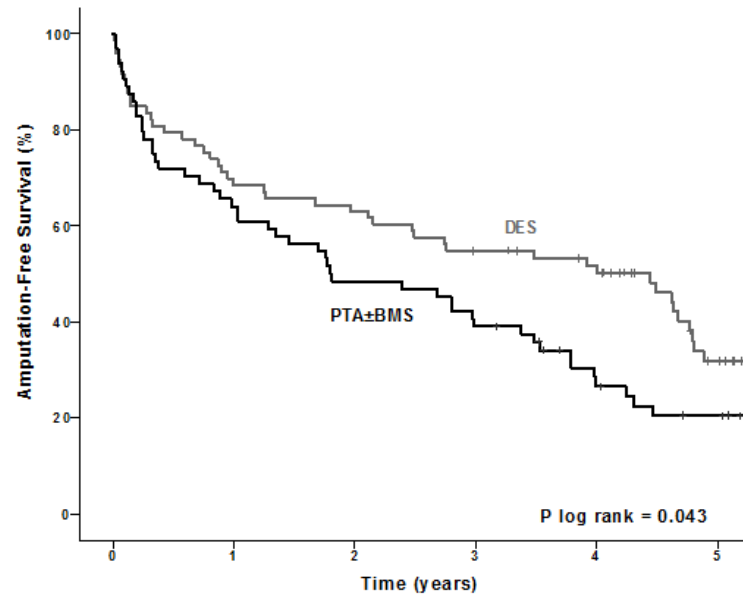


Numbers at risk

Years	0	1	2	3	4	5
DES	74	51	46	39	33	14
PTA±BMS	66	42	32	26	15	9

# Estimated 5-year cumulative incidence rates of amputation free survival per patient.

## PADI, JAHA 2017



Numbers at risk

Years	0	1	2	3	4	5
DES	73	50	46	39	33	14
PTA±BMS	64	41	31	25	14	9



# DES in BTK intervention

Revascularization BTK

Surgery vs endovascular Rx

DES

Diabetes

Conclusions

Diabetes is associated with decreased limb survival in CLI.

Pooled data from two RCT's.

Spreen MI et al, Diabetes Care 2016

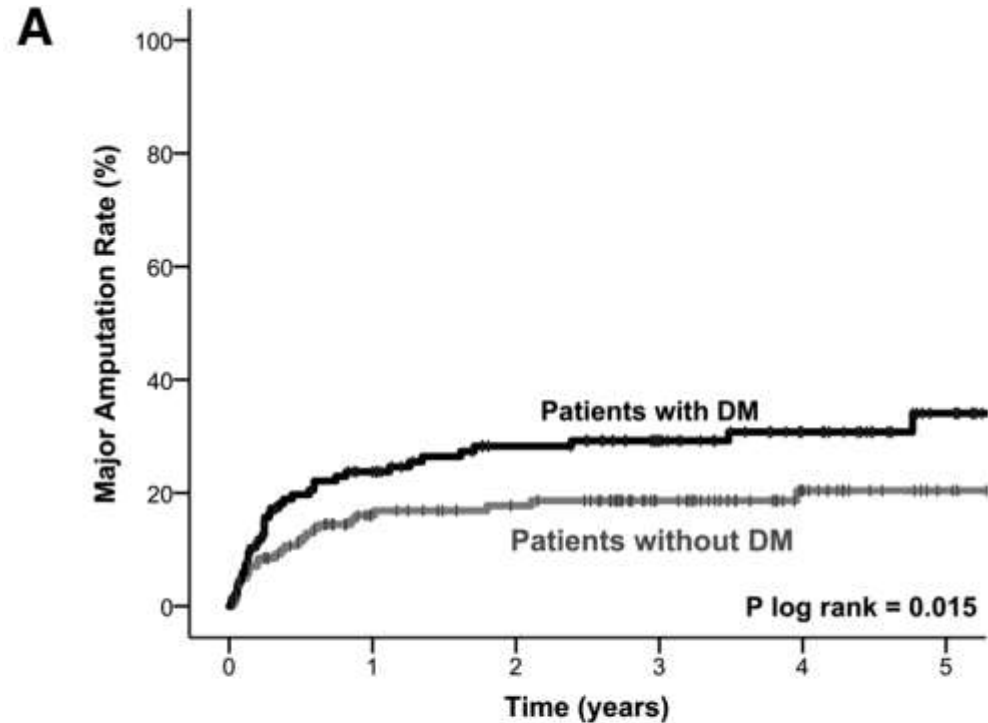
PADI trial, PTA±BMS vs DES in CLI BTK n=137

JUVENTAS trial, +/- infusion of bone marrow cells in CLI with severe PAD BTK n=160

N=281 with Rutherford 4-6

138 (49.1%) with DM

# Diabetes is associated with decreased limb survival in CLI. Diabetes Care 2016



numbers at risk

	0	1	2	3	4	5
DM +	138	90	75	54	36	16
DM -	143	101	92	66	43	28

n

# Diabetes is associated with decreased limb survival in CLI. Diabetes Care 2016

Table 3

Results of Cox proportional hazards regression analysis of variables for prediction of major amputation

Variables at baseline	HR	95% CI	P value*
Univariate analysis			
DM	1.87	1.12-3.12	0.017
Multivariate analysis			
Age	1.01	0.99-1.03	0.29
DM	1.59	0.91-2.78	0.11
Stroke	0.88	0.45-1.70	0.70
Coronary disease	1.02	0.59-1.75	0.95
PAD	1.47	0.73-2.95	0.28
Former smoker	0.91	0.45-1.81	0.78
Current smoker	1.39	0.65-2.98	0.40
eGFR <30 mL/min/1.73 m <sup>2</sup>	1.59	0.81-3.13	0.18
Rutherford category	2.03	1.28-3.21	0.003
ABI <0.7	1.26	0.68-2.32	0.46
ABI >1.4	2.62	1.23-5.57	0.012
Multivariate analysis, best performing model			
DM	1.56	0.92-2.65	0.10
Rutherford category	1.95	1.24-3.06	0.004
ABI <0.7	1.32	0.73-2.41	0.36
ABI >1.4	2.78	1.37-5.64	0.005

\*Stratified by randomization.

# DES in BTK intervention

## Revascularization BTK

Surgery vs endovascular Rx

DEB

DES

Conclusions

# DES in BTK intervention

## Conclusions

Clinical results BTK endovascular = surgical

Improved patency is consistently reported for DES BTK

Tendency towards better clinical results BTK & DES

Results in DM seem worse than in non-DM BTK irrespect. Rx

Concept of DES BTK seems to work

Longer flexible DES

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