



MEET 2015
MULTIDISCIPLINARY EUROPEAN
ENDOASCULAR THERAPY

**BUILDING
ENDOASCULAR
SYNERGIES**

Bare metal stent in BTK disease

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BORDEAUX

Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

CRITICAL LIMB ISCHEMIA

- Multi-level disease
- High burden of comorbidity
- Limited life span

TREATMENT AIMS IN CLI

- Wound healing
- Limb salvage
- Maintained ambulation
- Increase in
 - Quality of life
 - Lifespan

CLI TREATMENT IN BTK

- Several studies have demonstrated that surgical revascularisation is the standard treatment for limb salvage in patients with CLI due to atherosclerotic disease of infrapopliteal arteries
- Endovascular interventions of infrapopliteal lesions represent a far less invasive option and are now considered a valid alternative to surgical bypass in many cases
- The choice of endovascular treatment may be supported by presence of major comorbidities and hence high risk for open interventions

TREATMENT OF CRITICAL LIMB ISCHAEMIA

ESVS RECOMMENDATIONS

- Endovascular treatment of infrapopliteal arteries has the potential to achieve similar limb salvage rates with less procedural morbidity and mortality than surgical bypass
- Angioplasty as the first-line therapeutic modality for patients with CLI and infrapopliteal lesion is reasonable in the majority of cases, considering that the interventional procedure should not preclude future surgical intervention (Level 4; Grade C)

Setacci C et al. Chapter IV: Treatment of Critical Limb Ischaemia. EJVES 2011;42:S43–S59

RESULTS IN CLI TREATMENT OBJECTIVE PERFORMANCE GOALS

- Primary efficacy endpoints:
 - **76.9%** freedom from perioperative (30-day) death or any major adverse limb event (amputation or major re-intervention)
 - **76.5%** primary amputation-free survival at 1 year
- Based on evidence from RCTs of patients treated by surgical autogenous vein bypass (3 RCTs: 838 patients)
- The most suitable current framework for non-randomised comparisons, for evaluating outcomes after endovascular treatments for CLI

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.

OBJECTIVE OF OUR STUDY

To evaluate the perioperative and follow-up results of stent implantation on BTK arteries

- Single center experience from 2009 to 2011
- Analysis of a prospective registry
- All consecutive patients were included

USE OF STENTS IN BTK

SES

ASTRON PULSAR	4 x	40-80	
PULSAR-18	4 x	120-200	(BIOTRONIC)
XPERT	3-4 x	20-60	(ABBOTT)

BES

PRO-Kinetic Explorer	2-3 x	20-30	(BIOTRONIC)
CARBOSTENT	2.5-3.5 x	15-25	(CID)

SES Proximal 1/3 of tibial arteries

Long Lesions up to 200 mm

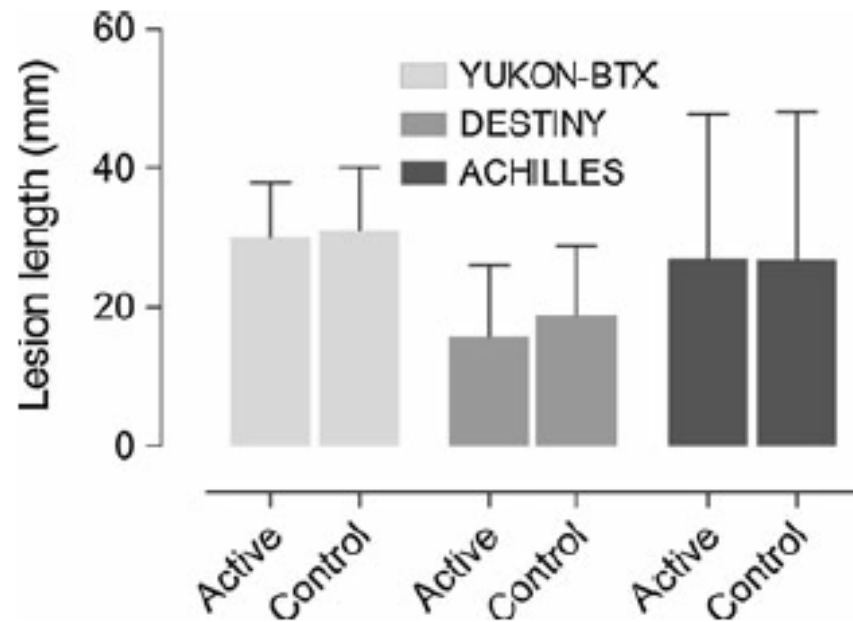
BES Middle 1/3 of tibial arteries

Short Lesions

Mean length : 86 mm +/- 7 mm

Mean length 86 mm

- Compared to mean length in RCT DES



PATIENT DEMOGRAPHICS

<i>Variable</i>	<i>Patients No. (%)</i>
	<i>Tot. 101</i>
<i>Age, mean ± SD, yrs</i>	<i>72.3 ± 9.8</i>
Male	81 (80.2)
Female	20 (19.8)
Diabetes mellitus	85 (84.1)
Hypertension	72 (71.2)
Hyperlipidemia	65 (64.3)
Coronary Artery Disease	51 (50.4)
Chronic heart failure	32 (31.6)
History of Smoking	39 (38.6)
Active smoker	14 (13.8)
Renal insufficiency (cr.≥1.5 mg/dL)	29 (28.7)
Cerebrovascular Disease	18 (17.8)
Follow-up time, <i>mean ± SD, months</i>	<i>12.5 ± 11.9</i>

CLINICAL PRESENTATION

RUTHERFORD CATEGORY

No. (%)

4

7 (7)

5

75 (74)

6

19 (19)

94 (93%)

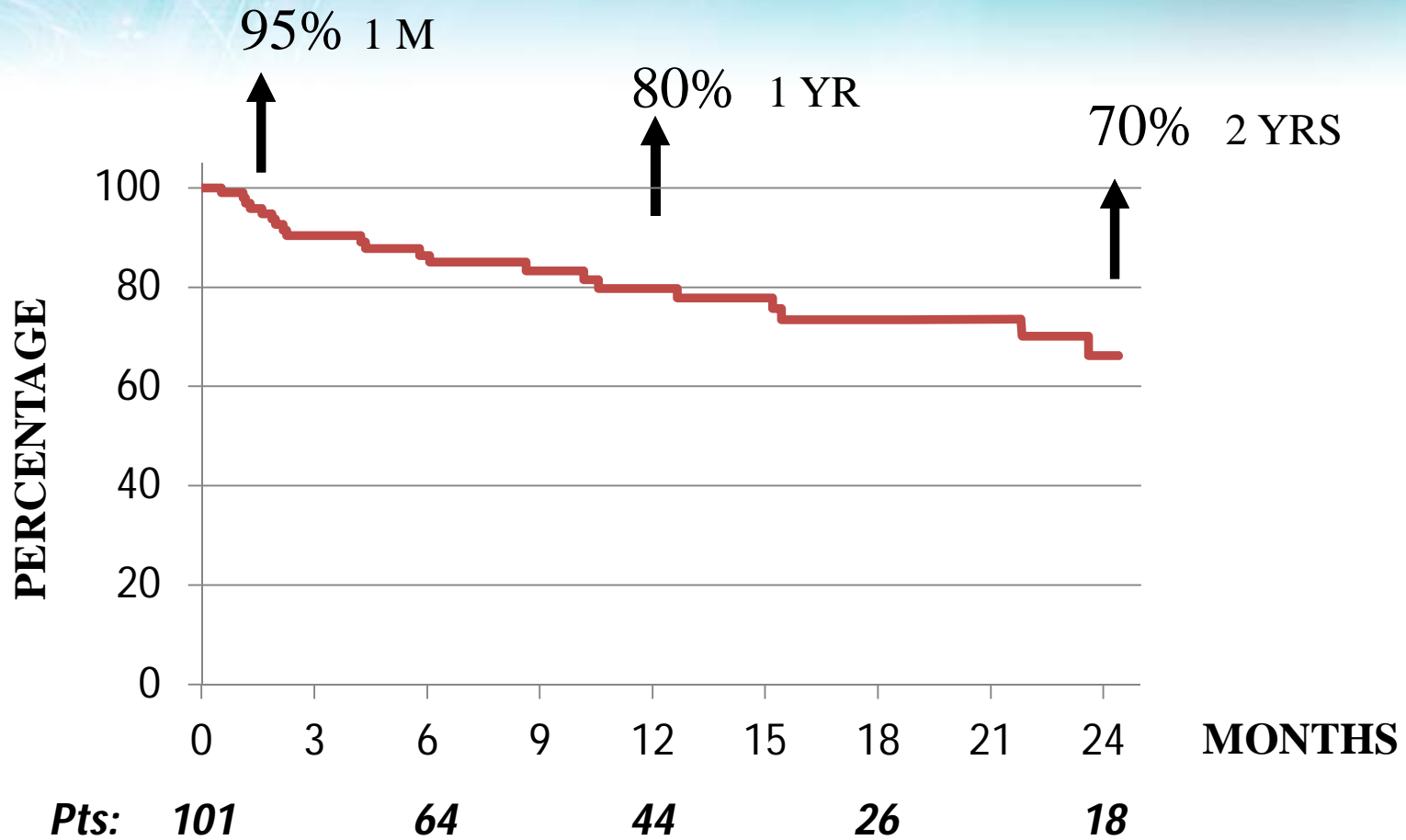
ISCHEMIC
FOOT
LESIONS

Patients clinically different

Trial	YUKON-BTX		DESTINY		ACHILLES	
	Active	Control	Active	Control	Active	Control
Assigned study arms						
Study arms (<i>n</i>)	82	79	74	66	99	101
Age (year)	73.4 ± 8.0	72.3 ± 9.0	75.0 ± 8.0	76.0 ± 8.4	72.4 ± 9.4	74.3 ± 8.2
Male sex	56/82	51/79	45/74	44/66	67/99	76/101
Smoking habit	23/82	23/79	23/74	22/66	38/99	27/101
Hypertension	75/82	70/79	47/74	49/66	89/99	92/101
Hyperlipidemia	63/82	60/79	28/74	25/66	77/99	69/101
Diabetes	47/82	40/79	44/74	33/66	64/99	65/101
Renal insufficiency	29/82	28/79	22/74	22/66	N/A	N/A
Claudication	40/82	46/79	0/74	0/66	38/99	40/101
CLI	42/82	33/79	74/74	66/66	61/99	61/101
Rutherford–Becker	3.9 ± 1.0	3.7 ± 1.0	4.5 ± 0.5	4.6 ± 0.5	4.1 ± 0.9	4.0 ± 0.9
Lesions treated (<i>n</i>)	82	79	78	76	113	115
CTOs	19/82	17/79	12/78	13/76	92/113	87/115
Lesion length (mm)	30.0 ± 8.0	31.0 ± 9.0	15.9 ± 10.2	18.9 ± 10.0	26.9 ± 20.9	26.8 ± 21.3

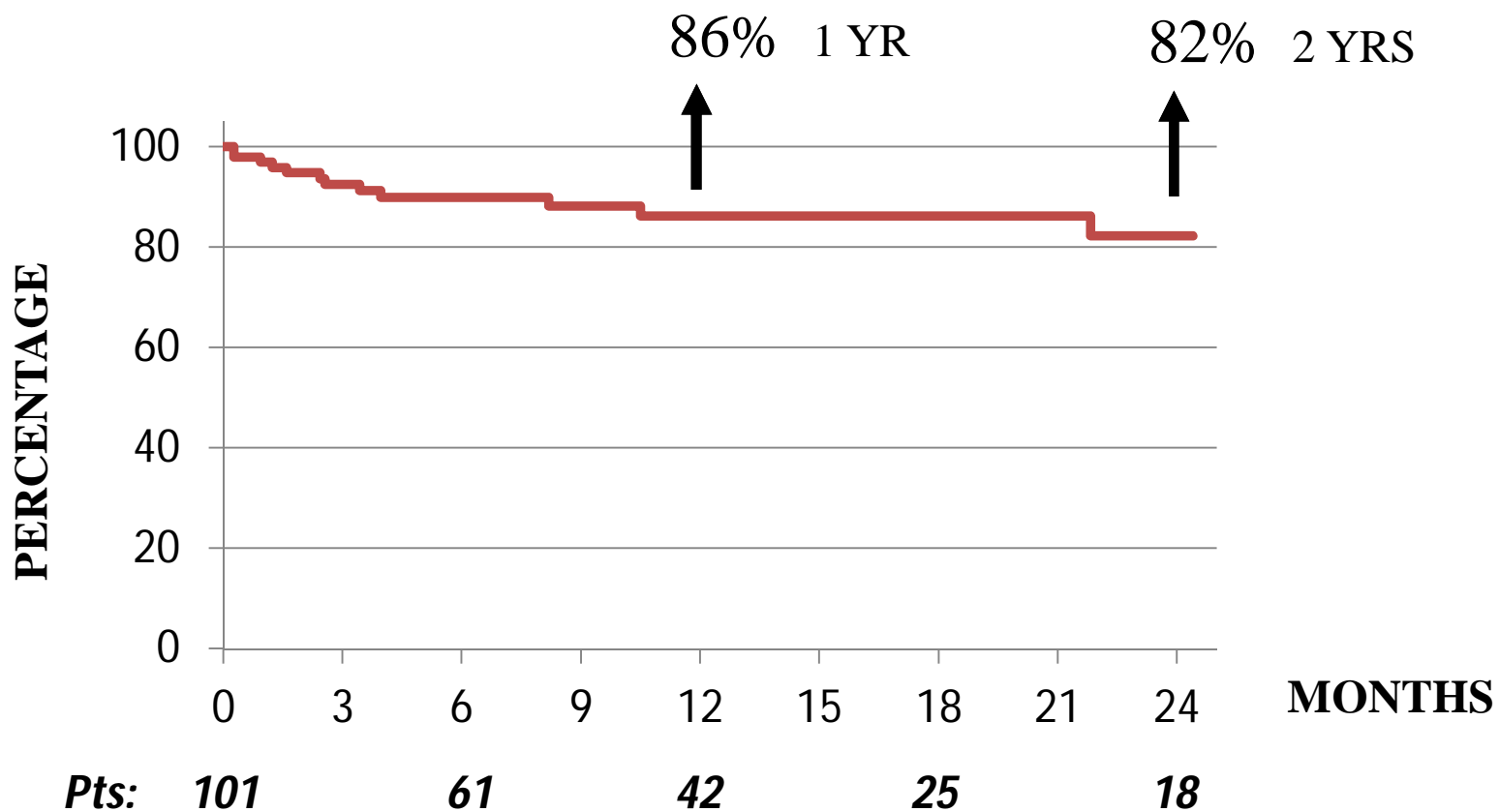
SURVIVAL

KAPLAN-MEIER ESTIMATES

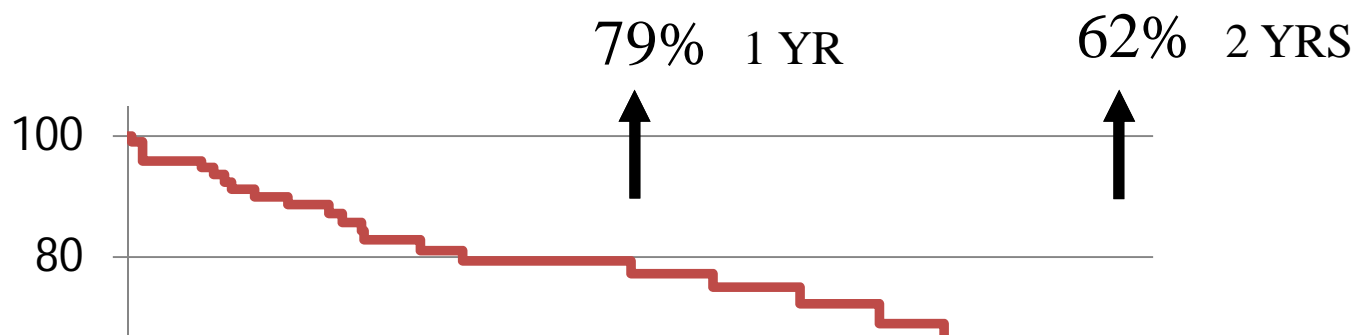


AMPUTATION-FREE SURVIVAL

KAPLAN-MEIER ESTIMATES



TLR-FREE SURVIVAL KAPLAN-MEIER ESTIMATES

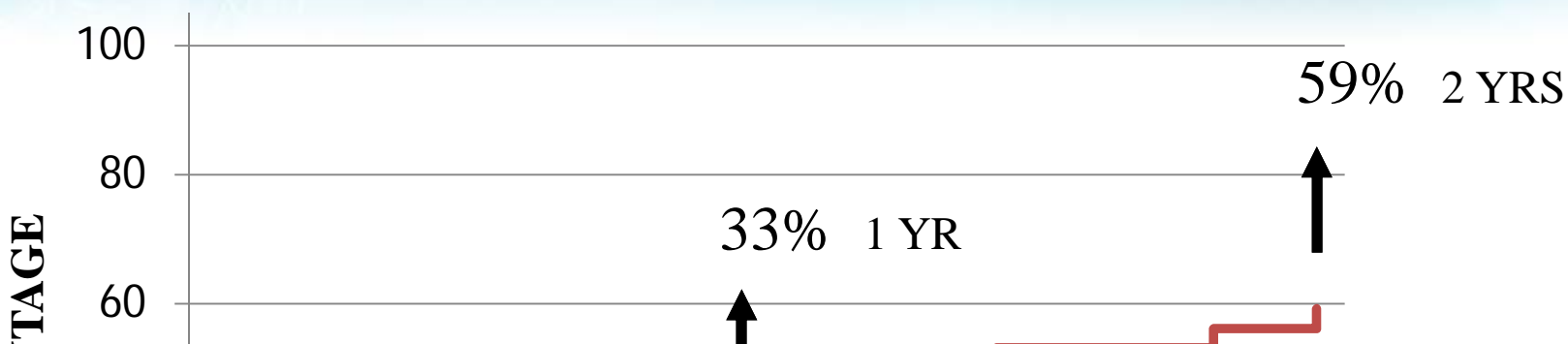


Endpoint	Outcomes (%)	Pooled RR (95 % CI)	<i>p</i>	NNT (95 % CI)
Primary patency	80.0 vs. 58.5	1.37 (1.18–1.58)	<0.0001	4.8 (3.2–8.3)
Patient survival	85.5 vs. 86.6	0.99 (0.92–1.06)	0.7500	N/A
Limb amputation	6.40 vs. 10.8	0.60 (0.32–1.13)	0.1100	N/A
TLR events	9.90 vs. 22.0	0.45 (0.28–0.73)	0.0010	8.3 (5.3–20.0)
Event-free survival	72.2 vs. 57.3	1.26 (1.10–1.44)	0.0006	6.7 (4.4–14.3)
Wound healing	76.8 vs. 59.7	1.29 (1.02–1.62)	0.0400	5.9 (3.1–50.0)
Rutherford shift	79.0 vs. 69.6	1.13 (1.002–1.275)	0.0450	11.1 (5.6–250)

0 3 6 9 12 15 18 21 24 **MONTHS**

Pts: 101 55 39 23 16

PRIMARY SUSTAINED CLINICAL IMPROVEMENT KAPLAN-MEIER ESTIMATES



Endpoint	Outcomes (%)	Pooled RR (95 % CI)	<i>p</i>	NNT (95 % CI)
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Pts: 101

58

38

20

14

RESULTS OF BTK STENTING

Major adverse event-free	@ 1 month	excellent
Amputation-free	@ 1 & 2 years	excellent
TLR-free	@ 1 & 2 years	good
Sustained Clinical Improvement	@ 1 & 2 years	fair

WOUND HEALING

Complete wound healing in ischemic foot lesions:

1/3 @ 1 year

2/3 @ 2 years

Need for

- Multidisciplinary approach
- Early detection
- Diabetic foot care
- Effective management of foot problems
- Patient education (proper foot care and footwear)
- Scheduled follow-up

CONCLUSION

- BTK stenting is ALSO efficient

