

## ACOART-BTK 5-YEAR RESULTS

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### Disclosure

- Speaker name: Francesco Liistro
- I have the following potential conflicts of interest to report:
  - Consulting: Medtronic, Philips, Biotronic
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s)
  - I do not have any potential conflict of interest

### ACOART BTK: Study Design and Key Eligibility Criteria

#### Key Inclusions

- RC 4-5-6
- Stenosis / occlusions >40 mm in at least 1 tibial vessel with distal run-off

#### Key Exclusions

- Allergy to Paclitaxel
- Contraindication for combined antiplatelet treatment
- Life expectancy <1 year

• Primary Endpoint: 6-month Late Loss by independent core lab  
• Secondary Endpoints: 12-month TLR; major amputation

### Patients Clinical/procedural Characteristics

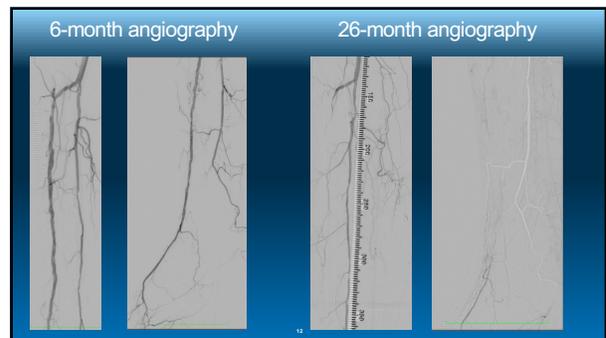
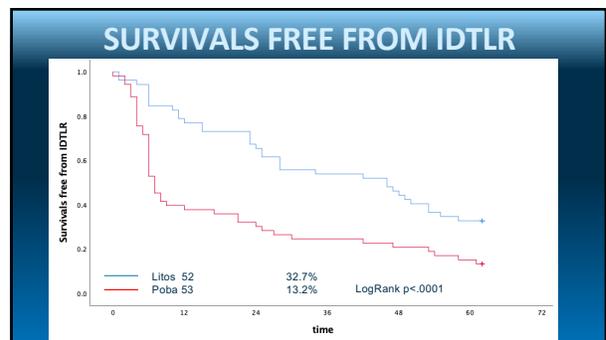
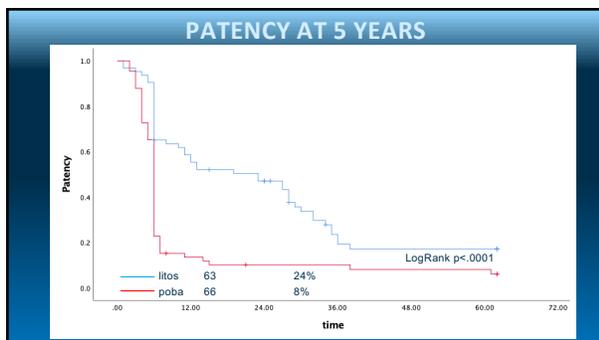
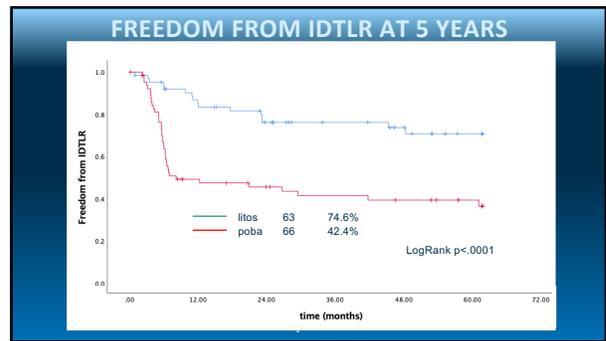
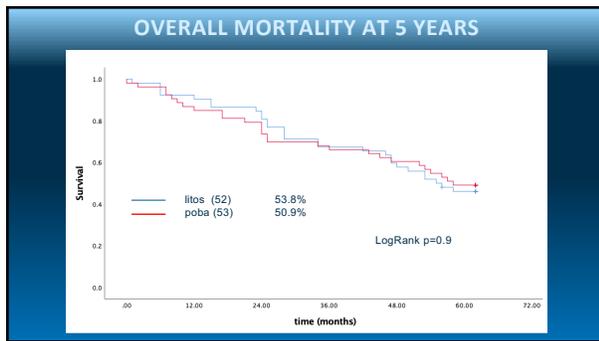
	LITOS	POBA	P value
Patients/lesions Nr	52/62	53/66	
Diabetes	52(100)	49(93)	0.06
Creatinine (mg/dL)	1,46±1,54	1,31±1,09	0.5
Rutherford class 4	4(7)	3(5)	0.7
5	50(93)	51(95)	
CTO	42(68)	44(67)	0.8
Calcification 3	16(25.8)	16(24.2)	0.3
4	22(35.5)	28(42.4)	0.3
Lesion Length	168.3±109.1	187.9±113.3	0.3
ATA	40(64.5)	44(66.7)	0.9
RVD pre	2.68±0.43	2.74±0.19	0.4

### Angiographic Outcome at 6 Months

	LITOS	POBA	p value
Lesion available	58/62(93.3)	62/66(93.9)	0.9
RVD	3.10±0.62	2.61±0.52	<0.001
MLD	1.56±0.85	0.56±0.65	<0.001
DS%	42.9±29.9	79.7±24.2	<0.001
LLL	0.51±0.60	1.31±0.72	<0.001
TVA (mm <sup>2</sup> )	440.75±308.83	217.34±236.34	<0.001
TVAL(%)	5.87±23.16	51.37±36.27	<0.001
Restenosis >50%	22(37.9)	54(87.1)	<0.001
Occlusion	5(8.6)	30(48.4)	<0.001
TLR	6/54(11)	27/59(46)	<.001
Major Amputation	0	0	-

### Clinical Outcome at 5 years follow-up

	LITOS 52 pat	POBA 53 pat	p value
Death	28(54)	27(51)	0.8
AMI	3(6)	7(13)	0.2
TLR	16/63(25.4)	38/66(57.6)	<.001
Major Amputation	1	0	-
Patency	15/63 (24)	5/66 (8)	<.001
Healed	22/24	22/26	0.3



### Conclusion

- Litos DCB shows efficacy and safety in the treatment of complex BTK lesions in CLI patients at 5 years
- Major amputation is more close to 0 than 1 when patients are followed in a foot healing program with continuous healing surveillance
- No difference in mortality was observed in the 5-year period
- The advantage in TLR remains at 5 years but patency becomes poor also in DCB group

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