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Changing the paradigm of DCB in BTK: encouraging new results in complex lesions

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on behalf of the LUMINOR collaborators

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Disclosures

Consultant: Bolton Medical/ Medtronic/ Cordis/ iVascular

Proctor: Cook/ Bolton Medical/ Medtronic/Cordis

Background

Luminor is a new drug-coated angioplasty balloon from iVascular (CE-marked), with the unique TransferTech® technology that provides a durable crystalline coating.

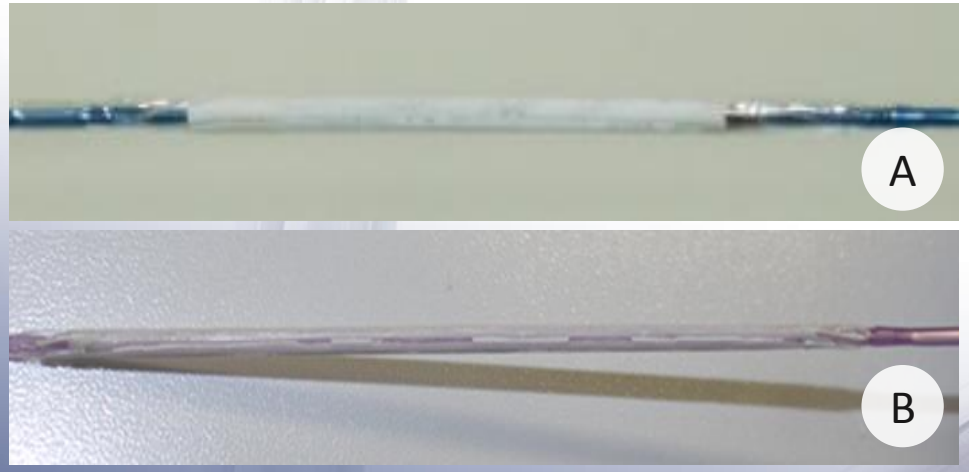

Fig. 1 Macroscopic aspect of Luminor DCBs with an uniform coating (A) in comparison with a competitor (B)

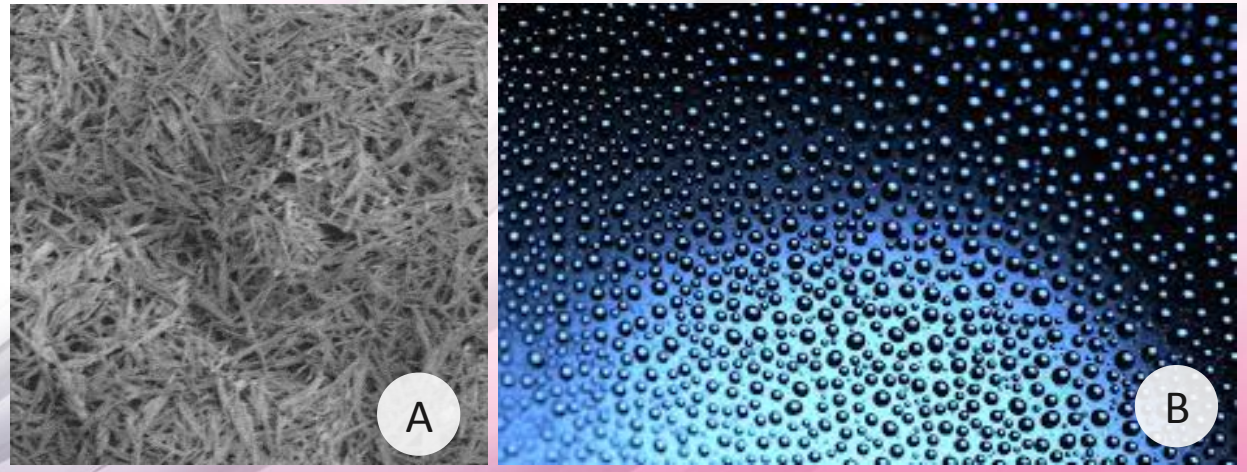

Fig. 2 Microscopic Cristalline structure of Paclitaxel coating (A) and ultrasonic coating technology by nanodrops (B)

Material and Methods

Luminor Registry is an observational, prospective, multicenter study with single-arm treatment for stenotic or occlusive lesions or in-stent stenosis of the femoro-popliteal (FP) and below the knee (BTK) vessels. *Clinical trials.gov identifier: NCT02458911*

PRIMARY ENDPOINTS

To analyse the performance of Luminor 14 and 35 in terms of **primary patency**, defined as freedom from >50% restenosis as indicated by duplex ultrasound peak systolic velocity ratio (PSVR) <3 in the target vessel with no re-intervention, and freedom of serious adverse events defined as **death**, **amputation** and **TLR** during a minimum of **12-month** follow-up period.

SECONDARY ENDPOINTS

Include quality of life assessment and other clinical or hemodynamic complications.

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Material and Methods

- A total of 219 validated Rutherford 2-5 cases have been recruited during a 15-month period following an intention to treat basis.
- All the procedures have followed the instructions for use.
- Primary stenting or atherectomy were excluded.
- Adjuvant drug treatment was applied for all patients [Clopidogrel 75 mgr/day + ASA 100 mgr/day (one month) and ASA 100 mgr/day (indefinite)].

Material and Methods (BTK)

Demographics	N	%
Patients	98	
Lesions	116	
Male	70	71.4
Age (years)	72.6±11.4	
Diabetes	73	74.5
Smoking and ex-smoking	51	52.0
Arterial Hypertension	83	84.7
Hyperlipidemia	52	53.1
Chronic Renal Failure	27	27.6
Rutherford Class		
2	2	2.1
3	5	5.2
4	7	7.2
5	84	85.6

Material and Methods

Lesion characteristics	
Lesion length (mm)	77.9 (20-200)
Chronic Total Occlusions (CTO)	61.2
Stenosis	38.8

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Early Results

30-Days follow-up	
All-cause mortality	7.1%
Major amputations	5.1%
TLR	0%

%

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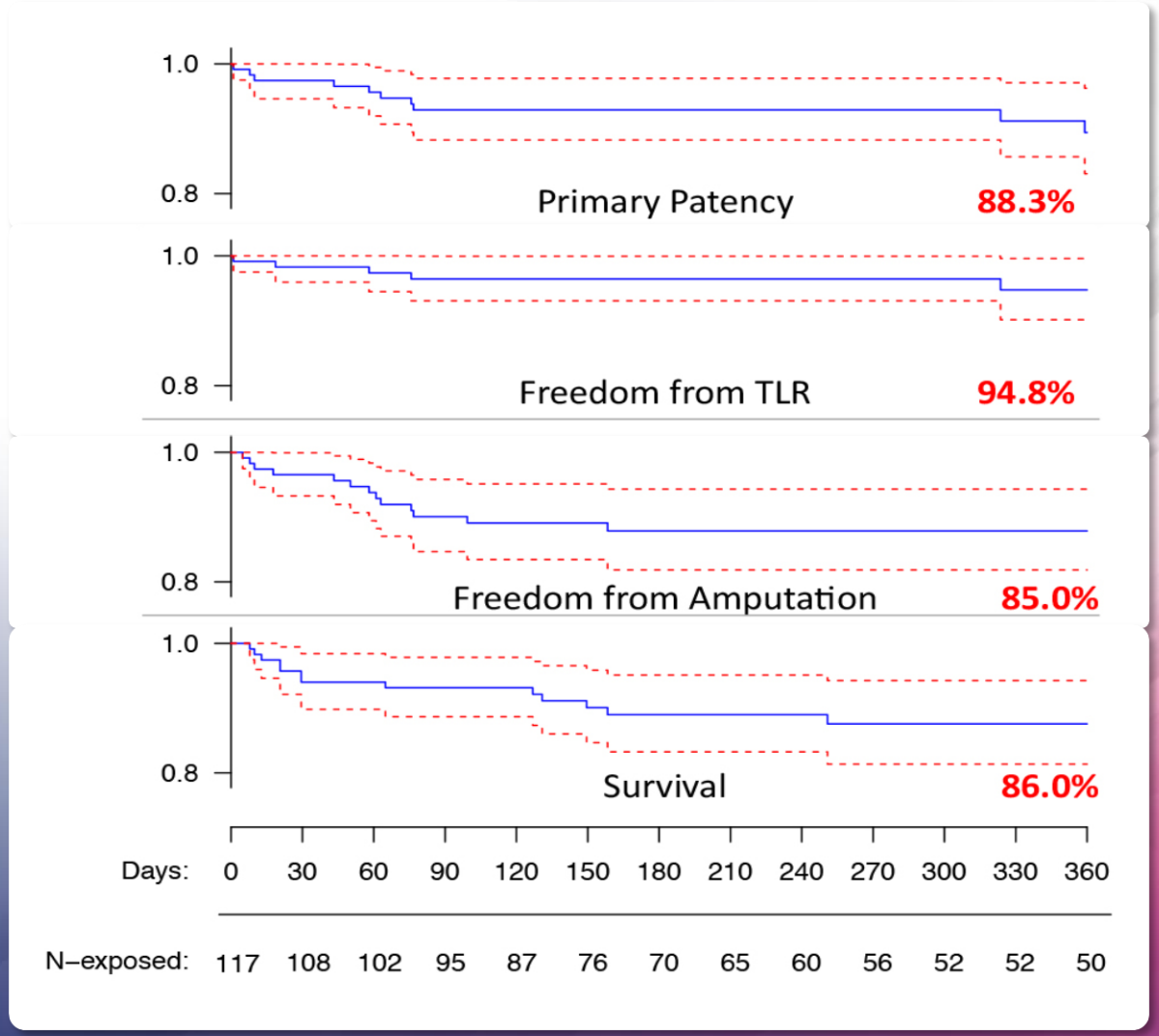
Results @ 1 year follow-up



Summary

LUMINOR Spanish registry will complete the final results by May 2017. Final results will be published in future reports.

Initial primary outcomes in BTK population are encouraging taking into account the severe ischemic status of this cohort of patients.

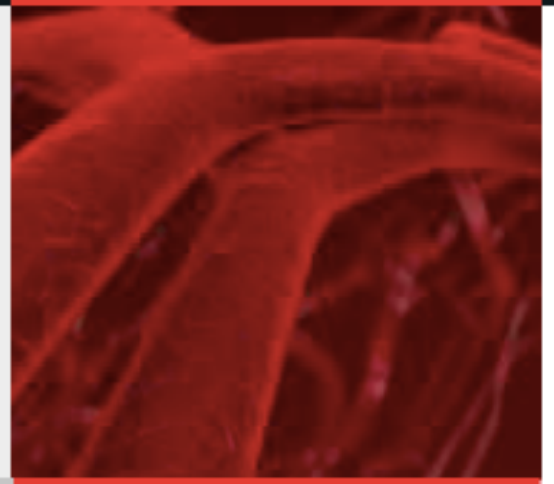
LUMINOR registry Participants

Hospital	PI	Collaborator 1	Collaborator 2
1- H. Getafe	Dr Francisco Acín	Dra. Cristina Cañibano Domínguez	Dr. Ignacio Michel Guisasola
2- H. La Paz	Dr. Luis Riera del Moral		
3- H. Clínic	Dr. Vicente Riambau	Dr. Xavier Yugueros	Dr. Gaspar Mestres
4- H. Parc Taulí	Dr. Antonio Giménez Gaibar	Dra. Sara Rioja Artal	Dra. Elena González Cañas.
5- H. Ourense	Dr. Nilo Mosquera Arochena	Dr Ignacio García Fernández	Dra Rebeca Vazquez Dopazo
6- H. Asturias	Dr. Manuel Alonso	Dra. Carol Padron Encalada	
7- H. Burgos	Dr. Francisco Medina	Dr. Ignacio Agúndez Gómez	Dra. Monica Herrero Bernabé
8- H. Basurto	Dra Reyes Vega	Dr. Ricardo Asensio Garcia	Dra. Esther Bravo Ruiz
9- H. Donostia	Dr. Mariano Juan de Blas Bravo	Dra. Ainhoa Garcia	Dr. Jose María Egaña
10- H. Cruces	Dr. Juan Luis Fonseca Legrand	Dra. Ana Apodaka	Dra. Ederi Mikelarena Monteiro

Status Update on Key Points & Beyond

SITE

12th International Symposium on Endovascular Therapeutics



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