Performance of Luminor drug eluting balloon for revascularization in chronic limb ischemia: a Spanish prospective multicentre registry.

Clinical trials.gov identifier: NCT02458911

V. Riambau, F. Acín, N. Mosquera, M. de Blas, M. Alonso, A. Giménez-Gaibar, on behalf of the LUMINOR Registry collaborators

Background

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

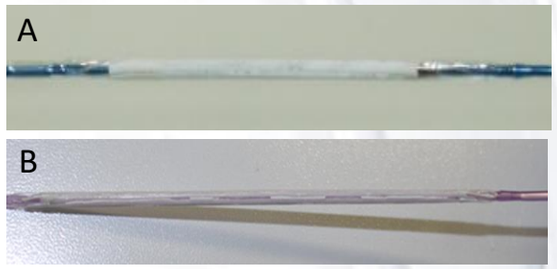


Fig.1. Macroscopic aspect of Luminor DCBs with an uniform coating (A) in comparison with a competitor (B)

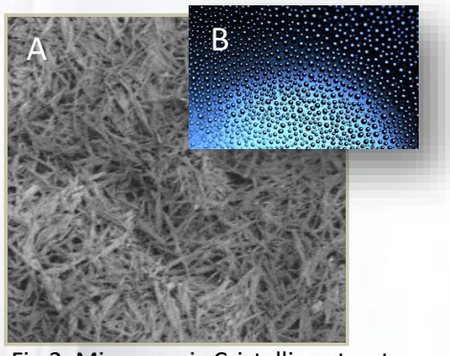


Fig.2. Microscopic Cristalline structure of Paclitaxel coating (A) and ultrsonic coating technology by nanodrops (B)

Material and Methods

Luminor Registry is an observational, prospective, multicentre 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.

The **primary objective** is 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.

A total of **250 validated** Rutherford 2-5 cases will be recruited during a 15-month period following an intention to treat basis. All the procedures should follow the instructions for use. Primary stenting or atherectomy are excluded. Adjuvant drug treatment is applied for all patients [Clopidogrel 75 mgr/day + ASA 100 mgr/day (one month) and ASA 100 mgr/day (indefinite)].

Results

Since Q3 2014, **143 cases** with **165 lesions** (81 CTO and 84 stenosis) have been included and monitored (Table 1). Those were split as 101 FP and 36 BTK vessels treated. 14 cases combined both segments (Table 2). 7 of them were in-stent stenosis. It is important to emphasize that **72% of patients were classified as Rutherford 4 or higher** (Table 1). **Technical success was achieved in 99.7% of the cases**. **Bailout stenting** was necessary in 13 lesions (**7.8%**). 30-day-mortality was **1.4%**. At 6 month-follow-up **(mean follow-up of 2.06 months, r:1-12 months), 6-month-**mortality was 9.4%; other medical complications were detected in 8 patients (5.6%); 9 **major amputations** (**8.3%**) occurred and the TLR was 6.3%. **Freedom from TLR was 93.7%.**

Table 1. Baseline Demographics

Patients	143
Lesions	165
Male	75,6%
Age, years	70,6
Diabetes	70,4%
Smoking and ex-smoking	58,5%
Arterial Hypertension	80,0%
Hyperlipidemia	58,5%
Chronic Renal Failure	19,3%
Rutherford Class	
2	8,4%
3	19,6%
4	14,7%
5	57,3%

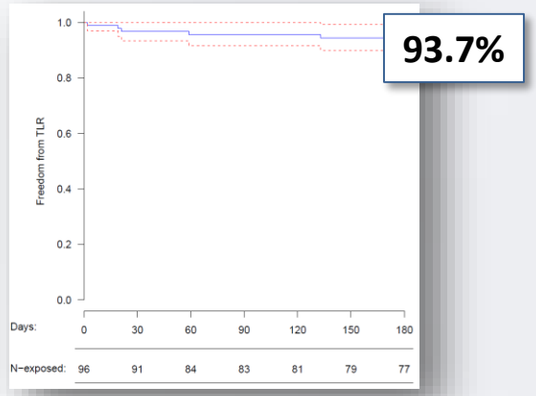
Table 2. Lesion Characteristics

Lesion length (mm)	68,2
Chronic Total Occlusions	49,1%
Stenosis	50,9%
Target Vessels	
Femoropopliteal	66,9%
Below the Knee	23,8%
Combined segments	9,3%

Table 3. Main interim results

30-day-mortality	1,4%
6-Month Follow-up (96 patients)	
All-cause mortality	9,4%
Major amputations	8,3%
TLR	6,3%

Fig.3 Freedom of TLR up to 6 month-follow-up



Conclusions

LUMINOR Spanish registry will complete the recruitment period by March 2016. Interim and final results will be published in future reports. Initial primary endpoints are encouraging taking into account the ischemic status severity of this cohort of patients.