EV Clinical Update

LUMINOR registry

Results

Since Q3 2014 until Q2 2016, **215 cases** with **252 lesions** (121 CTO and 131 stenosis) have been included and monitored (Table 1). Those were split as **154 FP** and **86 BTK** vessels treated. 12 cases combined both segments (Table 2). It is important to emphasize that **72%** of patients were classified as **Rutherford 4 or 5** (Table 1). **Technical success** was achieved in **94,9%** of the cases. **Bailout stenting** was necessary in 15 lesions **(6%)**.

Table 2. Lesion Characteristics

Lesion length (mm)	**77,8 (20-200)**
Chronic Total Occlusions	**48,0%**
Stenosis	**52,0%**
Target Vessels	
Femoropopliteal	**61,2%**
Below the Knee	**34,2%**
Combined segments	**4,6%**

Table 1. Baseline Demographics

	Patients	%
Patients		**215**
Lesions		**252**
Male	**156**	**72,6%**
Age, years		**70,6±11,7**
Diabetes	**140**	**65,1%**
Smoking and ex-smoking	**136**	**63,3%**
Arterial Hypertension	**175**	**81,4%**
Hyperlipidemia	**124**	**57,7%**
Chronic Renal Failure	**51**	**23,7%**
Rutherford Class		
2	**13**	**6,1%**
3	**47**	**22,1%**
4	**25**	**11,7%**
5	**128**	**60,1%**

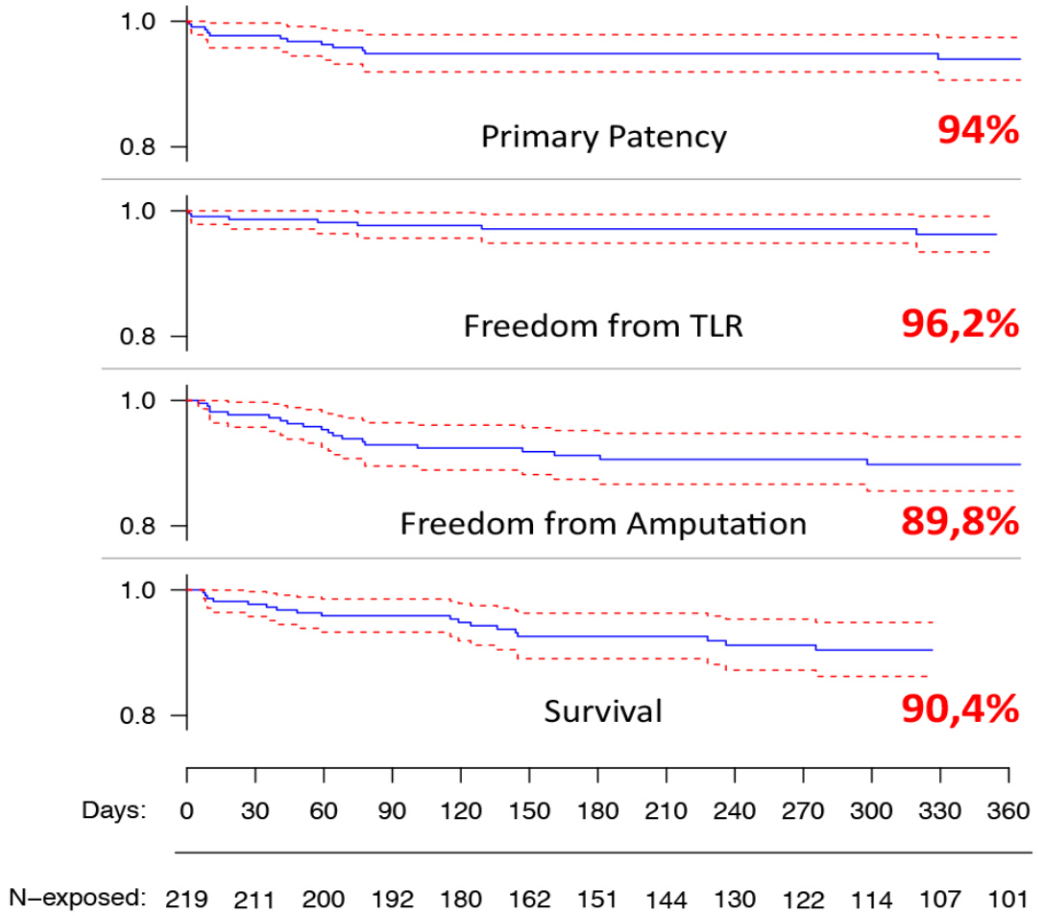
Results

30-day-mortality was **1,9%**. Until now, 145 patients have reached 6 months of follow-up and 108 patients 1 year.

At 1 year, **primary patency** was **94,0%, freedom from TLR 96,2%, freedom from major amputation 89,8%** and **survival 90,4%**.

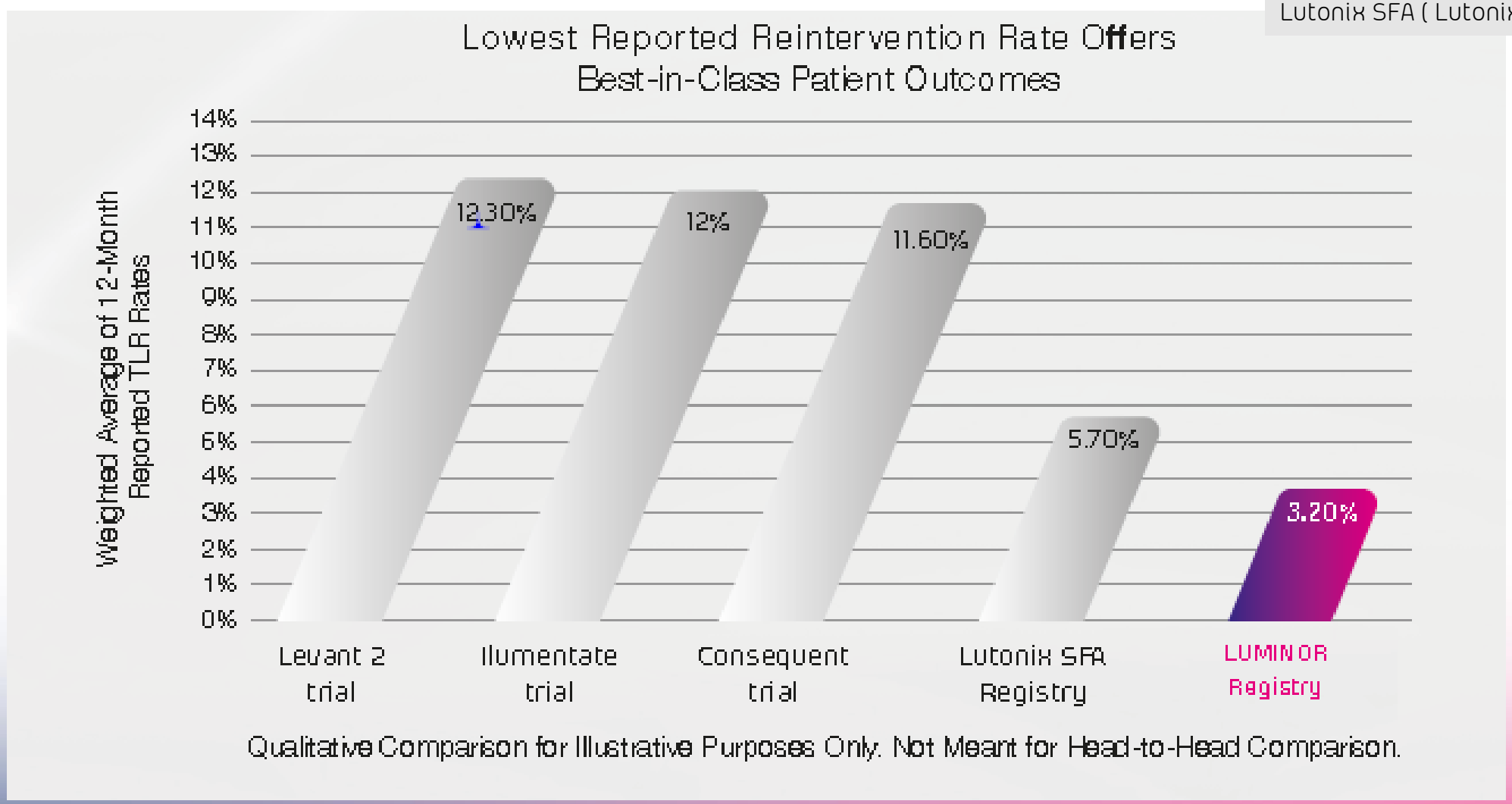
Table 3. **Main interim results**

	%
30-Days follow-up (211 patients)	
All-cause mortality	**1,9%**
Major amputations	**1,9%**
TLR	**1,4%**



Luminor Registry vs Competition

Consequent (Sequent Please – Bbraun)
Illumenate (Stellarex - Spectranetics)
Levant 2 (Lutonix - Bard)
Lutonix SFA (Lutonix – Bard)



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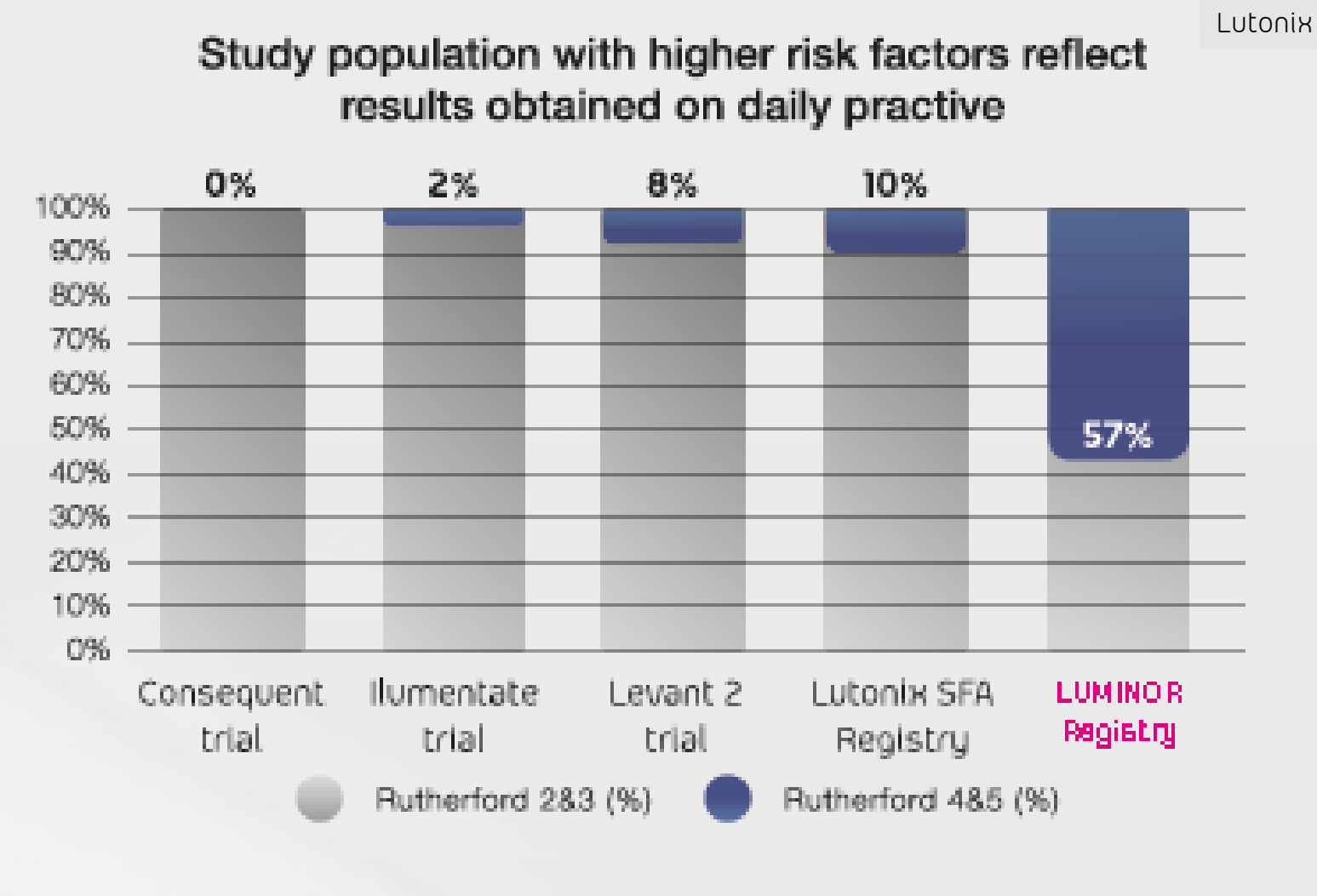


iVascular

Results

Since Q3 2014 until Q2 2016, **215 cases** with **252 lesions** (121 CTO and 131 stenosis) have been included and monitored. Those were split as **154 FP** and **86 BTK** vessels treated. 12 cases combined both segments.

In the BTK subgroup the baseline demographics (Table 1) and lesion characteristics (Table 2) shown the ischemic status severity of patients. It is important to emphasize that **93%** of patients were classified as **Rutherford 4 or 5** (Table 1). **Technical success** was achieved in **97,4%** of the cases. **Bailout stenting** was necessary in 3 lesions **(2,6%).**

Table 2. Lesion Characteristics

Lesion length (mm)	**77,9 (20-200)**
Chronic Total Occlusions	**61,2%**
Stenosis	**38,8%**

Table 1. Baseline Demographics

	Patients	%
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%**

iVascular

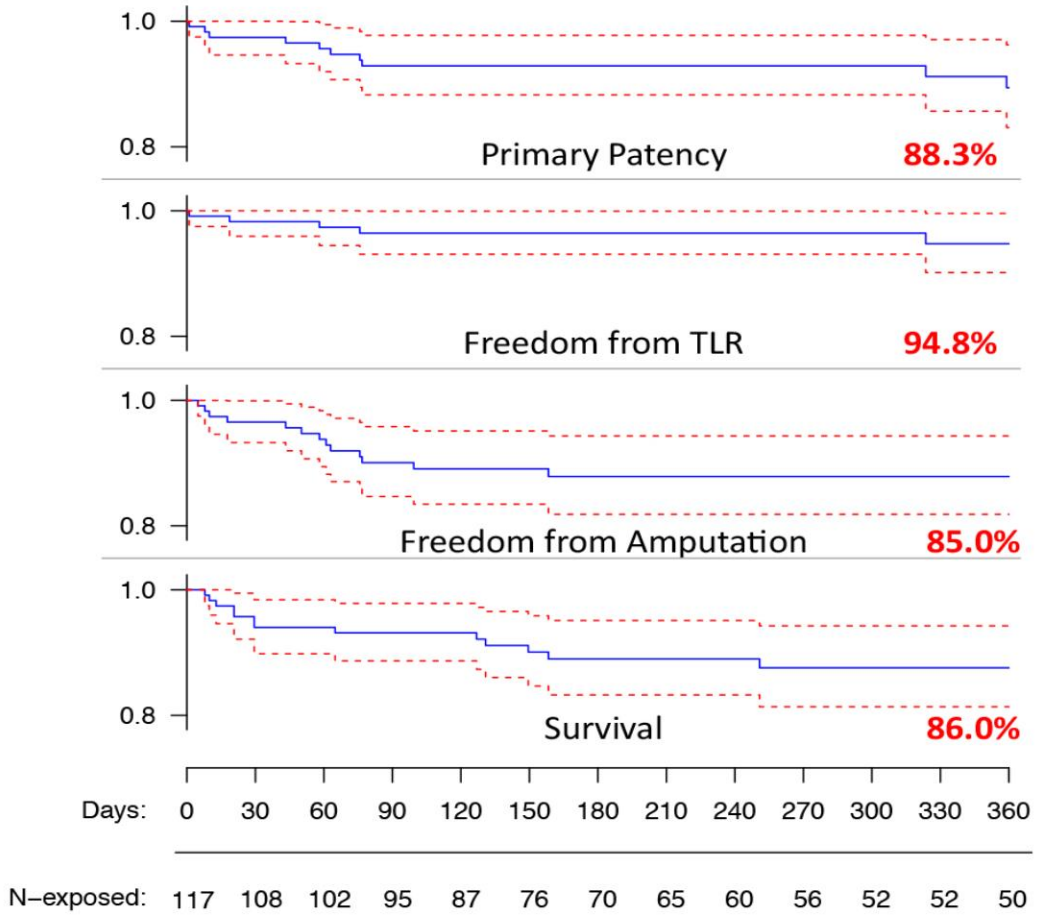
Results

30-day-mortality was **7,1%**.

At 1 year, **primary patency** was **88,3%, freedom from TLR 94,8%, freedom from major amputation 85,0%** and **survival 86,0%**.

Table 3. **Main interim results**

	%
30-Days follow-up (98 patients)	
All-cause mortality	**7,1%**
Major amputations	**5,1%**
TLR	**0%**



Luminor Registry

- 12M interim analysis going to be published at *Angiology*
- Final results expected in July 2017 (to be presented at CIRSE 2017)

EFFPAC

- Follow up moving forward
- No new data to be presented before CIRSE 2017

ILIADE

- 6 centers in Italy
- PI: Prof Carlo Setacci (Siena)
- 120 patients
- Luminor with CLI in femoropopliteal lesions
- Primary endpoints: primary patency at 1, 6, 12 and 24 months
- Secondary endpoints: Limb salvage at 1, 6 12 and 24 months – Bail-out stenting assessment

Combination Therapy in TASC C&D lesions

- Belgium (extended to France?) registry
- PI: Dr Koen Deloose (Dendermonde)
- 100 patients
- Luminor 35 or 18 in TASC C&D lesions, followed by iVolution
- Primary endpoint: 12 months TLR
- Secondary endpoints: 6 months TLR, MAE at 12 months, Rutherford improvement

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Thank you!