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Clinical use and safety of the Lutonix DCB for the treatment of BTK: interim data from a prospective registry

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Conflict of Interest - Disclosure

Within the past 24 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

1. Employment or Leadership Position

No

2. Advisory Role or Expert Testimony

Cook

3. Stock Ownership

No

4. Patent, Copyright, Licensing

No

5. Honoraria

Abbott, Cook, Medtronic, **Bard**, Bolton/Vascutek, Baxter, Medistim

6. Financing of Scientific Research

No

7. Other Financial Relationships

No

BTK Revascularization Challenges

- Long, complex, often calcified nature of lesions[1]
- Often associated with multilevel disease, thus success inflow- and outflow-dependent[2]
- High restenosis rate[3]
- Limb salvage poorly correlated to primary patency[3]
- Literature landscape dominated by small series and case studies, with limited Level I evidence

1.Liistro F, et al. Circ 128:615-21 (2013).
2.Norgren L, et al. J Vasc Surg 45:S5-67 (2007). 3.Kudo T, et al. J Vasc Surg 41:423-35 (2005).

Look at the Global Lutonix® DCB BTK Registry Study 6 Month Outcomes

A Prospective, Multicenter, Single-Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix® 014 Drug Coated Balloon PTA Catheter for Treatment of Below-the-Knee (BTK) Arteries

Study Design

Study Design	Prospective, Multicenter, Single Arm Registry
Objective	To demonstrate safety and assess the clinical use and outcomes of the Lutonix® 014 DCB for treatment of stenosis or occlusion of native below-the-knee arteries in a heterogeneous patient population in real world clinical practice
Number of patients/sites	Up to 500 subjects to be enrolled at up to 35 international sites
Key Inclusion Criteria	Rutherford Class: 3-5,≥ 70% stenosis lesion, target vessel(s) reconstitute(s) at or above the ankle with inline flow to at least one patent
Key Exclusion Criteria	Neurotrophic ulcer or heel pressure ulcer or ulcer potentially involving calcaneus (index limb)
Primary Endpoints	Safety: Freedom from BTK MALE+POD at 30-days Efficacy: Freedom from TLR at 6 months
Follow-up	1, 6, 12 and 24 Months

Demographics / Baseline Characteristics

Description	BTK Registry (N=314)
Age (Years), Mean ± SD (n)	73.5 ± 9.54 (314)
Gender (n/N) Female Male	 28.7% (90/314) 71.3% (224/314)
BMI ≥30 kg/m² (n/N)	24.6% (76/309)
Hypertension (n/N)	86.9% (273/314)
Dyslipidemia (n/N)	61.8% (194/314)
Current/Previous Smoker (n/N)	50.6% (159/314)
Diabetes (n/N)	62.7% (197/314)
Rutherford Category (n/N) 3 4 5	 24.3% (76/313) 10.2% (32/313) 65.5% (205/313)

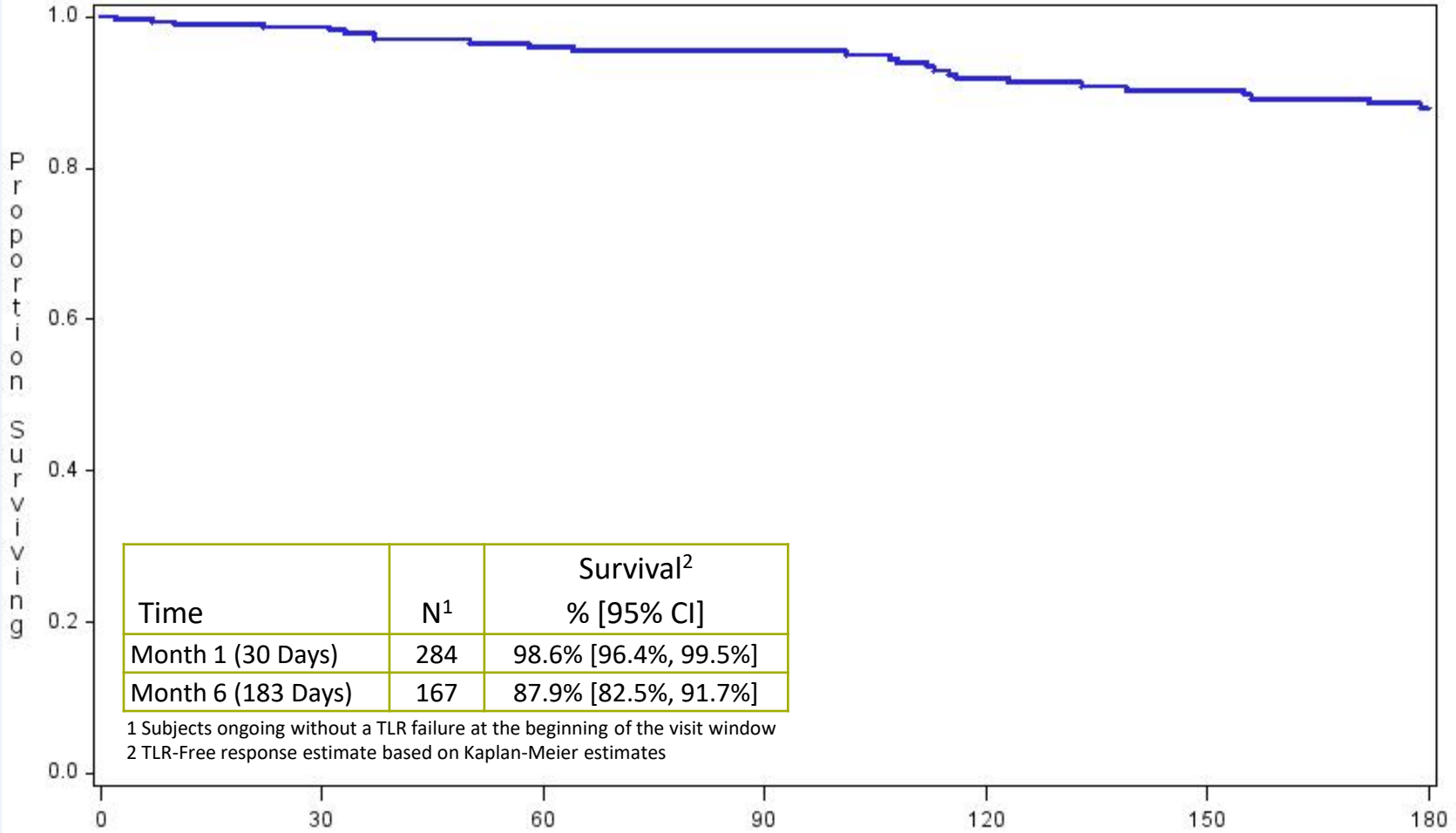
Safety Profile

Freedom From	N[1]	Survival[2] % [95% CI]
All Cause Death Survival	179	91.2% [86.3%, 94.4%]
Major Amputation	177	97.1% [93.6%, 98.7%]
Re-intervention for Thrombosis/Thrombolysis	174	95.2% [91.2%, 97.5%]
Re-intervention For Distal Embolization	179	100.0% [NA, NA]
TVR	166	88.0% [82.7%, 91.8%]
Unexpected Device or Drug Related Event	179	100.0% [NA, NA]

[1]Subjects ongoing without a failure at the beginning of the visit window
[2]Survivor rate based on Kaplan-Meier Estimate

Data presented is interim, site reported, and subject to change

Freedom from TLR



Time	N[1]	Survival[2] % [95% CI]
Month 1 (30 Days)	284	98.6% [96.4%, 99.5%]
Month 6 (183 Days)	167	87.9% [82.5%, 91.7%]

1 Subjects ongoing without a TLR failure at the beginning of the visit window
2 TLR-Free response estimate based on Kaplan-Meier estimates

Data presented is interim, site reported, and subject to change

Conclusion

- Only BTK multi center completed (inclusion) registry study
- Freedom from TLR 87.9%
- Less than 3% Major Amputation Rate

BUT

- We have to wait for the final data

  DEB has no obvious advantage in the treatment of infrapopliteal disease (available data)

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