LUTONIX AV Registry

A Prospective, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix® Drug Coated Balloon PTA Catheter for Treatment of Dysfunctional AV Fistulae and Grafts

Interim 6 Months Outcomes

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

Conflicts of Interest

- Consulting and travel fees:
  - BD
  - Boston Scientific
  - Medtronic

Lutonix AV Registry
Study Design

Study Design	**A Prospective, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix® Drug Coated Balloon PTA Catheter for Treatment of Dysfunctional Native and Synthetic AV Fistulae**
Objective	**To demonstrate safety and assess the clinical use and outcomes of the Lutonix® DCB for treatment of dysfunctional AV fistulae located in the arm in a heterogeneous patient population in real world clinical practice.**
Number of Subjects /Sites	**Up to 300 subjects will be enrolled at up to 30 international sites.**
Primary Endpoints	***Efficacy*: Target Lesion Primary Patency (TLPP) through 6 months.** ***Safety*: Freedom from any serious adverse event(s) involving the AV access circuit through 30 days**
Follow-up	**Clinical assessment at 6 months.** **Clinical or telephone assessment at 3 and 12 months**

Lutonix AV Registry
Demographics

	DCB (n=236)
Mean Age	67.0 ± 13.3
Male, (%), (n/N)	56.4% (133/236)
Hypertension, (%), (n/N)	74.9% (176/235)
Diabetes Mellitus, (%), (n/N)	42.6% (100/235)
Dyslipidemia, (%), (n/N)	26.4% (62/235)
Current Smoking, (%), (n/N)	7.7% (18/235)

Data shown is interim, site reported and subject to change

Lutonix AV Registry
Access Details

Fistula Locations	DCB (n=236)
Upper Arm, %, (n/N)	53.8% (126/234)
Antecubital Fossa, %, (n/N)	12.8% (30/234)
Forearm, %, (n/N)	33.3% (78/234)

Access Type	DCB (n=236)
Native, %, (n/N)	75.6% (177/234)
Synthetic Graft, %, (n/N)	24.4% (57/234)

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Lutonix AV Registry
Lesion Characteristics

	DCB (n=236)
Restenotic, % (n/N)	47.6% (139/292)
In-stent Restenosis, % (n/N)	11.4% (16/140)
Mean Target Lesion Length, mm (SD)	41.3 ± 29.39 (235)
Central Vein Lesion Location	7.5% (22/292)
Number of Target Lesions Treated with DCB, % (n/N)	
1	79.2% (187/236
2 – 4	20.8% (49/236)

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Lutonix AV Registry

Lesions Treated by Vessels

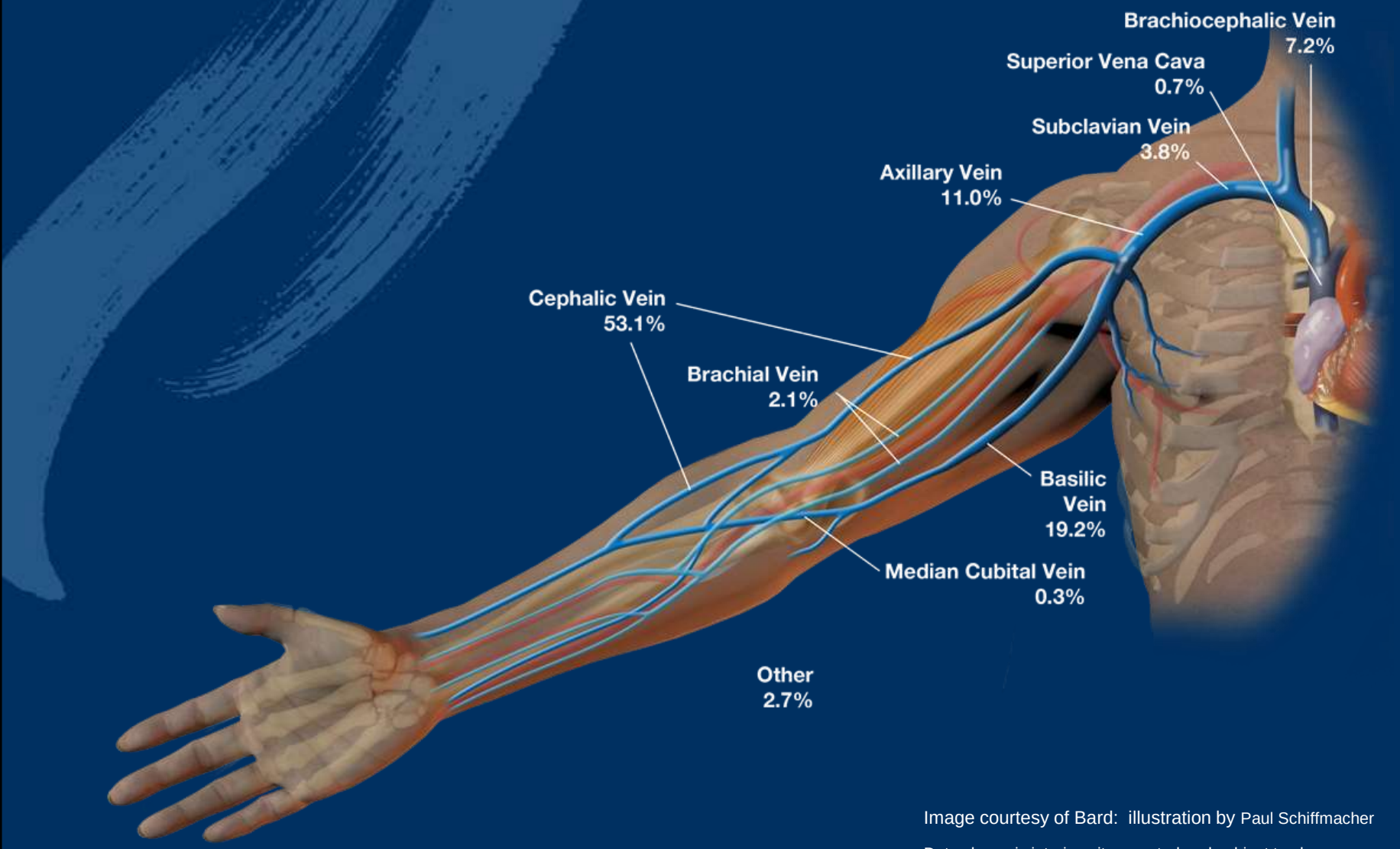

Image courtesy of Bard: illustration by Paul Schiffmacher

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Lutonix AV Registry
Primary Safety at 30 Days

Measure	Success % (n/N)	95% CI[1]
Primary Safety Endpoint[2]	99.4% (155/156)	96.5%, 100.0%

[1] Exact binomial confidence interval

[2]Primary safety event success is absence of any SAE related to access circuit within 30 days of treatment

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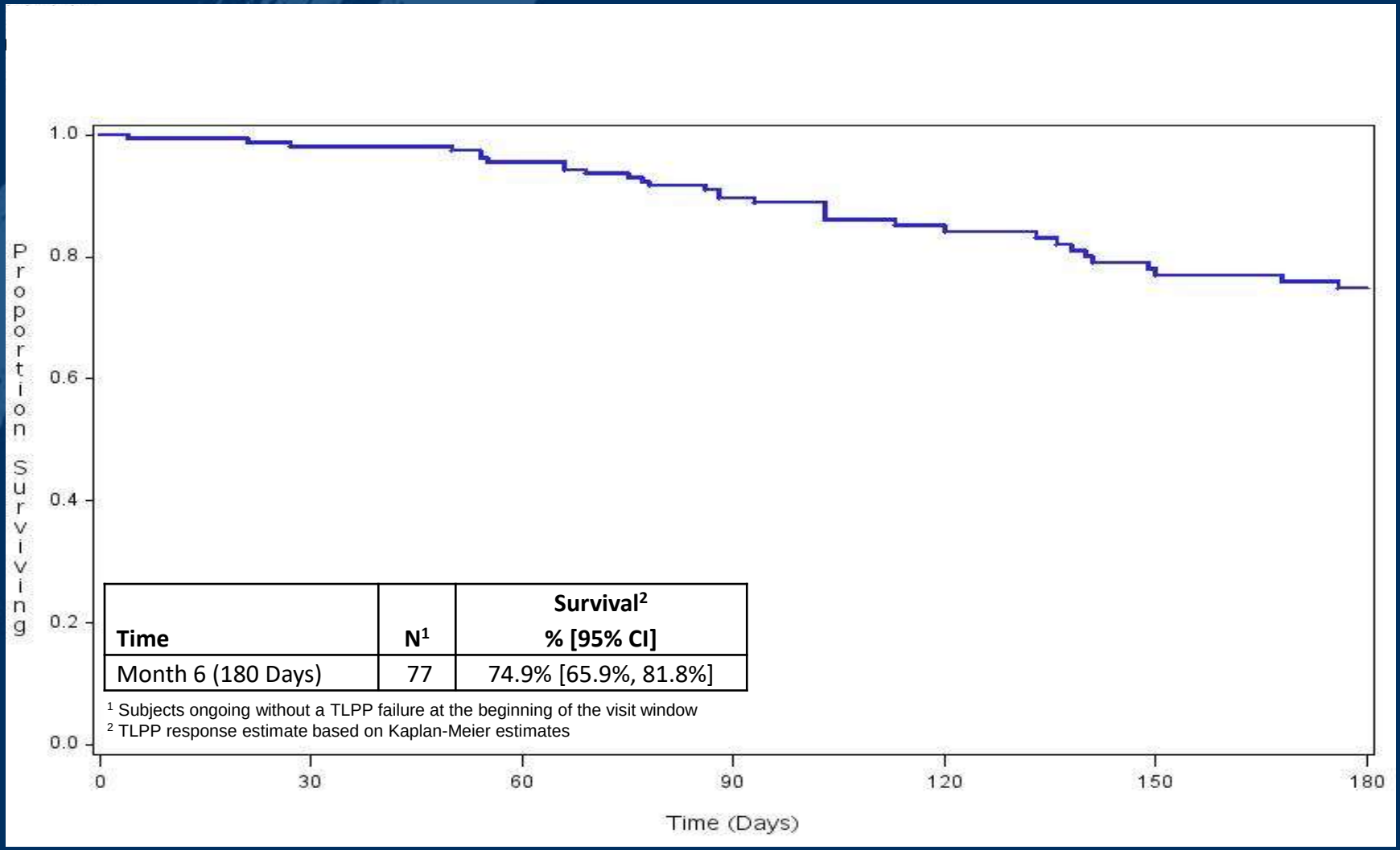
Lutonix AV Registry
TLPP at 180 Days



Time	N[1]	Survival[2] % [95% CI]
Month 6 (180 Days)	77	74.9% [65.9%, 81.8%]

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

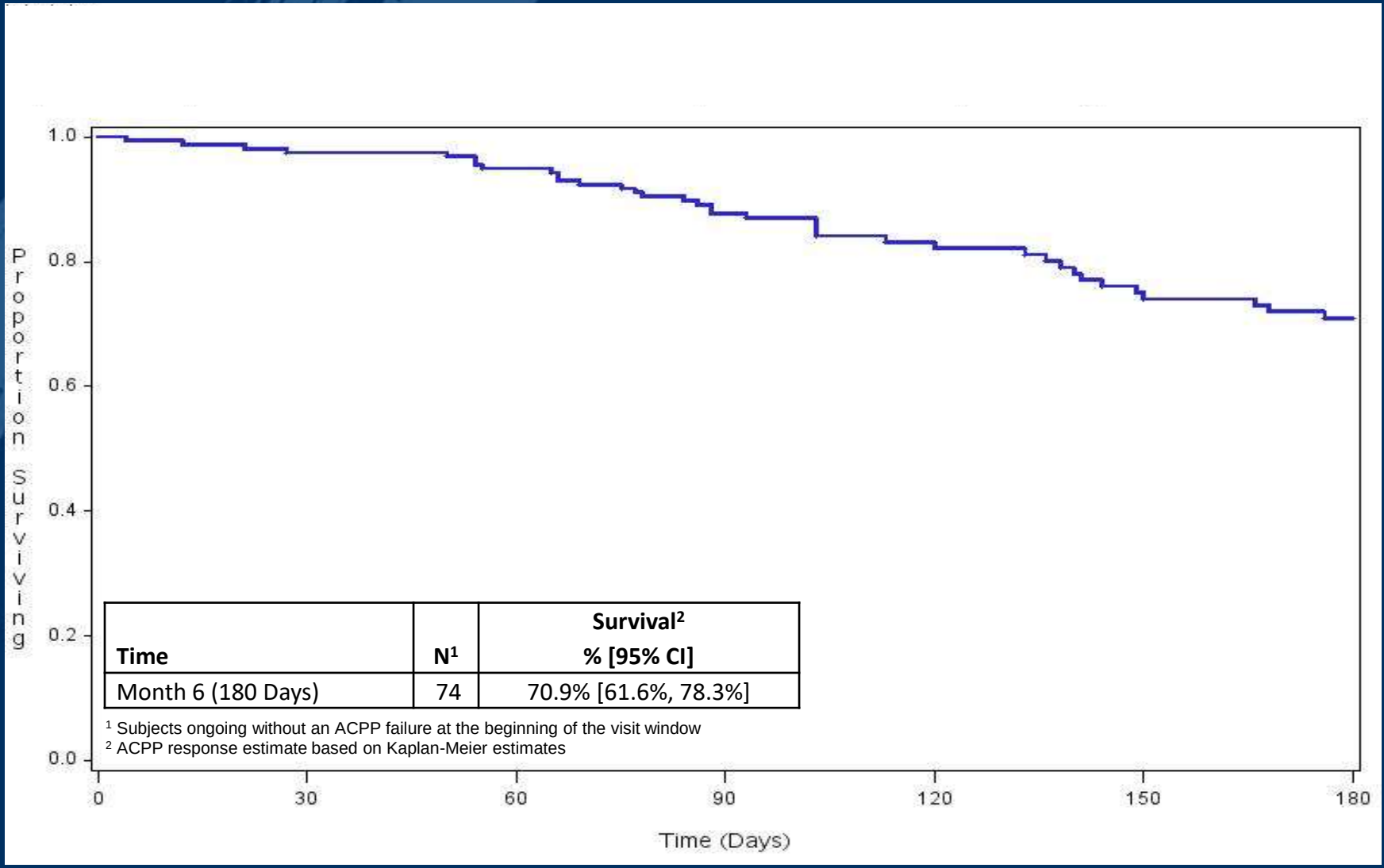
Data shown is interim, site reported and subject to change

6 Month TLPP

Title	6 Month TLPP
Lutonix AV Global Registry	74.9%*
Lutonix AV IDE Clinical Trial	71.4%
Kitrou et al. Paclitaxel-Coated Balloons for the Treatment of Dysfuntional Dialysis Access. Results from a Single-Center, Retrospective Analysis Cardiovasc. Intervent Radiol DOI 10.1007/s00270-016-1479-y	72.2%

*Data shown is interim, site reported and subject to change

Lutonix AV Registry
ACPP at 180 Days



Time	N[1]	Survival[2] % [95% CI]
Month 6 (180 Days)	74	70.9% [61.6%, 78.3%]

[1] Subjects ongoing without an ACPP failure at the beginning of the visit window
[2] ACPP response estimate based on Kaplan-Meier estimates

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Lutonix AV Clinical Program

Title	Number of DCB Subjects
Lutonix AV Clinical Trial - Follow-up	N=285
Lutonix AV Real World Global Registry - Enrolling	N=300
Lutonix AV Post Approval Study - Start-up	N=213

- First and only DCB with Level 1 Data – multi-center
- First and only DCB with FDA approval in dysfunctional fistulae
- Only Ongoing AV Real World Global Registry Study – 236 enrolled
- AV Post Approval Study – 2Q/18

Most DCB Data in AV FISTULA

DCB Published Studies

Author (year)	Type	Group	Device Category	Pts	VA	F-up	Primary Endpoint	Results	Sig.	Device Type	Comments
Kitrou et al. (2017)	RCT	SG	PCB	20	AVF AVG	6	IFP	179d	s.s.	Lutonix 035, BARD PV	Central Venous Stenosis
		CG	PTA	20				124.5d			
Troisi et al. (2017)	RA	SG	PCB	38	AVF AVG	14.3	TLPP	7.9m	s.s.	Freeway Eurocor - IN.PACT Medtronic - Ranger Boston	Longitudinal Comparison of treatments
		CG	PTA					6.4m			
Kitrou et al. (2016)	RA	SG	PCB	39	AVF AVG	6	TLPP	75%	n.a.	Lutonix 035, BARD PV	Comparison between 1st & 2nd treatment
Verbeeck et al. (2016)	PS	SG	PCB	41	AVF	12	TLPP	60%	n.a.	IN.PACT, Medtronic	Venous Stenosis
Swinnen et al. (2015)	RA	SG	PCB	37	AVF	12	RFP	69%	s.s.	IN.PACT, Medtronic	In-stent Restenosis
		CG	PTA	37				19%		n.a.	
Massmann et al. (2015)	RA	SG	PCB	15	AVF	n.a.	RI	9m	s.s.	Elutax-SV, Aachen Resonance	CVS Included, CB+HPB used if needed
Lai te al. (2014)	PS	SG	PCB	10	AVF	12	TLPP	20%	n.s.	SeQuent Please, B Braun	Concomitant lesions in same patient.
		CG	PTA	10				0%		FoxPlus, Abott Invatec, Medtronic	
Patane et al. (2014)	RA	SG	PCB	26	AVF	24	TLPP	57.8%	n.a.	IN.PACT, Medtronic	Anastomotic Stenosis
Kitrou et al. (2014)	RCT	SG	PCB	20	AVF	12	MS	308d	s.s.	IN.PACT, Medtronic	No pre-dilation
		CG	HPB	20				161d		OJ HPB	
Kitrou et al. (2014)	RCT	SG	PCB	20	AVF AVG	12	TLPP	35%	s.s.	IN.PACT, Medtronic	No Pre-dilation
		CG	HPB	20				5%		OJ HPB	

***SG**: Study Group, **CG**: Control Group, **OJ**: Operator's Judgement, **IFP**: Intervention-Free Period, **RA**: Retrospective Analysis, **VJA**: Venous Juxta-Anastomotic, **MSF**: Maximum Study Follow-up, **MF**: Mean Follow-up, **MS**: Median Survival, **CVS**: Central Venous Stenosis, **RLA**: Retrospective Longitudinal Analysis, **s.s.**: statistically significant, **n.s.**: non-significant, **n.a.**: not available, **MPI**: Men Patency Interval, **TLPP**: Target Lesion Primary Patency, **RI**: Restenosis Interval, **RFP**: Re-intervnetion Free Percentage, **APP**: Assisted Primary Patency*

Lutonix AV Registry Summary

- First and Only Global DCB Multicenter Registry in AV
  - ✓ Fistula
  - ✓ Grafts
  - ✓ Central Veins
  - ✓ Restenotic lesions and ISR
- Larger patient population than existing published data
- At 180 Days
  - **Safety**
    - Consistent with Lutonix® DCB reported outcomes
  - **Efficacy**
    - TLPP - 74.9%
    - ACPP - 70.9%

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