

DCB: PTA 2.0?

Scott Trerotola, MD

Faculty Disclosure

Consultant – B Braun, Teleflex, MedComp,
Cook, Bard PV, WL Gore, Lutonix

Other Financial or Material Support –
National PI, Lutonix AV trial

Royalty, Cook and Teleflex

- ePTFE
- ISR
- Fistula

1966 First Surgical
Fistula

First
Angioplasty 1977

1983 First Published Data
on PTA in Fistula

1997 KDOQI
Guidelines
Introduced

First Large, Prospective Controlled,
Randomized Cutting Balloon Trial:
Peripheral Cutting Balloon TM

2005

2010

First Large, Prospective,
Controlled, Randomized Stent
Graft Trial:
FLAIR® Endovascular Stent Graft

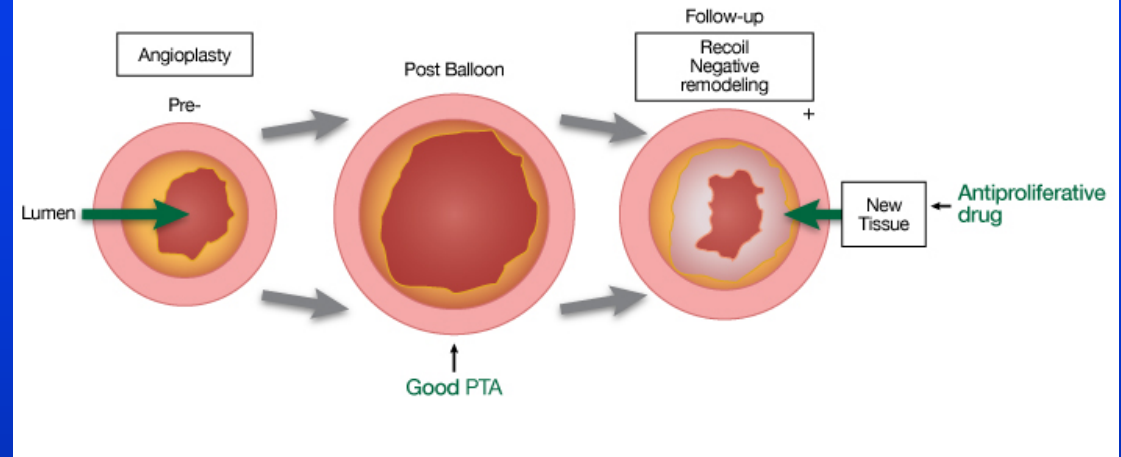
First Large, Prospective
Controlled Randomized Stent
Graft Trial
*FLUENCY® PLUS Endovascular
Stent Graft*

2015

2017

First in Fistula:
Large, Prospective Controlled
Randomized DCB Trial:
LUTONIX® 035 PTA Catheter

Restenosis

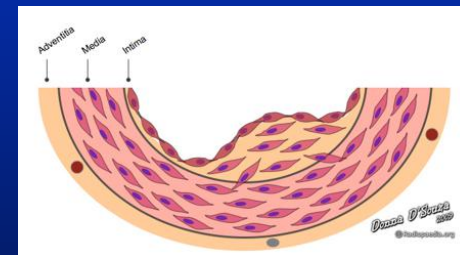
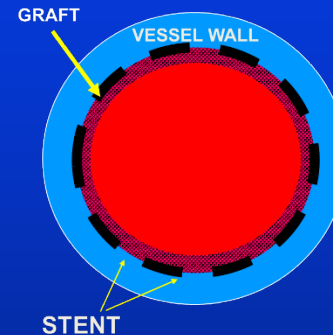


Graphic c/o Lutonix

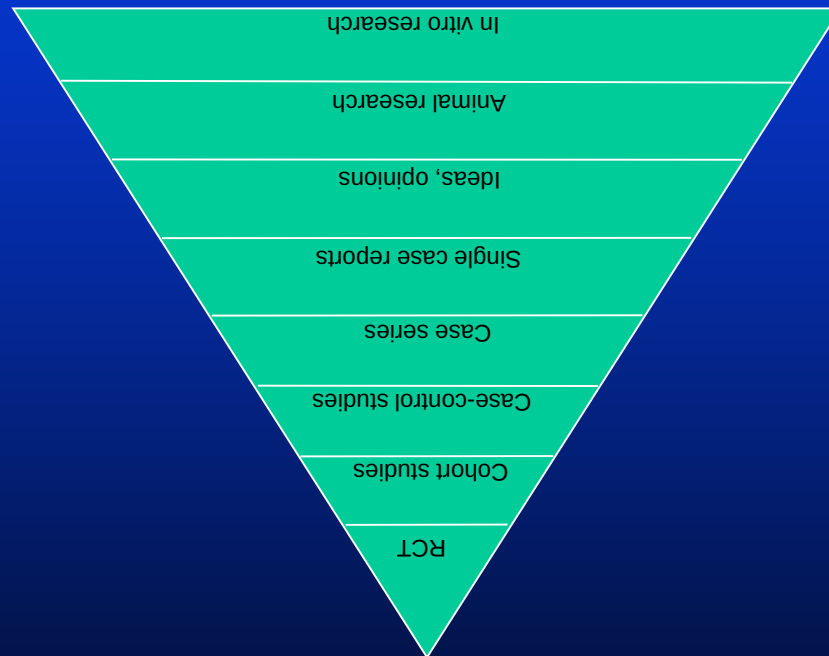
- Acute gain: PTA – elastic recoil
- Late loss: Intimal hyperplasia
- Stent devices can maximize acute gain
- Drug coating can minimize late loss
- Drug coated stent does both

PTA in Dialysis Circuits

- Some elastic recoil
 - Manageable with prolonged PTA
- Exuberant restenosis
 - Stent graft uses barrier approach
 - DCB uses chemical approach
 - Inhibit SMC migration



Evidence in DCB- refreshing



Author	Type	Results
Paclitaxel drug-eluting balloons to recurrent in-stent stenosis in autogenous dialysis fistulas: a retrospective study Swinnen et al. Journal Vascular Access (2015) epub	Retrospective n=37	12 Month 0% Reintervention 19% with POBA 69% with DCB
Paclitaxel-Coated Balloon Angioplasty for Symptomatic Central Vein Restenosis in Patients with Hemodialysis Fistulas Massmann et al. Journal of Endovascular Therapy 2015; 22: 74-79	Retrospective n=27	Restenosis Intervals 4 Months POBA 9 Months DCB
Drug-Eluting Balloon for the Treatment of Failing Hemodynamic Radiocephalic Arteriovenous Fistulas: Our Experience in the Treatment of Juxta-Anastomotic Stenoses Patanè D et al. J Vasc Access 2014 epub	Retrospective n=26	96% 6 Month TLPP 91% 12 Month TLPP

Author	Type	Results
Percutaneous Angioplasty Using a Paclitaxel-Coated Balloon Improves Target Lesion Restenosis on Inflow Lesions of Autogenous Radiocephalic Fistulas: A Pilot Study Lai et al. JVIR 2014; 25:535-541	RCT N=10 (20 lesions) AVF	TLR 251 days DCB 103 days POBA TLPP at 6 (p<0.01) and 12 months (P=NS) 70%, 20% DCB 0%, 0% POBA
Paclitaxel-Coated vs. Plain Balloon Angioplasty for Dysfunctional Arteriovenous Fistulae: One-Year Results of a Prospective Randomized Controlled Trial Kitrou et al. JVIR 2015;26:348-354	RCT n=40 AVF	TLR-free survival 308 days DCB vs 161 days POBA (p=0.03) ACPP 270 days DCB vs 161 (p=0.04)
Paclitaxel-Coated Balloon Angioplasty vs. Plain Balloon Dilation for the Treatment of Failing Dialysis Access: 6-Month Interim Results from a Prospective Randomized Controlled Trial Katsanos et al. J Endovasc Ther 2012;19:263-272	RCT n=40 Grafts+AVF	70% TLPP at 6 months DCB 25% TLPP at 6 Months POBA (P<0.001)

Author	Type	Results
Drug-eluting versus plain balloon angioplasty for the treatment of failing dialysis access: Final results and cost-effectiveness analysis from a prospective randomized controlled trial Kitrou et al, Eur J Radiol 2015;84:418-423	RCT n=40 Grafts+AVF	35% TLPP at 12 months DCB 5% TLPP at 12 months POBA (P<0.001)
Paclitaxel-coated balloons for the treatment of symptomatic central venous stenosis in dialysis access: Results from a randomized controlled trial Kitrou et al, JVIR 2017;28:811-817	RCT n=40 19 AVF/21G	Median intervention free patency better for DCB 179 vs 125 days P=0.026
Multicenter, Randomized Trial of Conventional Balloon Angioplasty versus Paclitaxel-Coated Balloon Angioplasty for the Treatment of Dysfunctioning Autologous Dialysis Fistulae Maleux et al, JVIR 2018, in press	RCT N=64 AVF	3,6,12 month primary patency for DCB angioplasty and PTA 88% vs 80% (P=.43), 67% vs 65% (P=.76), and 42% vs 39% (P =.95), respectively

More to come!

- PAVE (RCT-UK, M. Robson)
- DCB in cephalic arch restenosis (RCT-Israel, A. Verstandig, NCT02368197)
- APERTO (RCT-Netherlands, P. Pattynama, NCT02558153)
- DEBEFF (RCT-Saudi Arabia, N. Haq, NCT02632955)
- FISBAL (RCT-Spain, M. Vargas, NCT02565953)
- ABISS (RCT-France, R. Coscas, NCT02753998)
- FAVABED (RCT-France, J-F Heautot, NCT02913274)
- DEB (RCT-Canada, E. Therasse, NCT01928498)
- IN.Pact AV access trial (RCT, A Holden, R Lookstein)
- Lutonix AV (RCT-US, S. Trerotola, NCT02440022)
- DEBAPTA (RCT-Singapore, F. Irani, NCT01544907)

Lutonix AV Clinical Trial

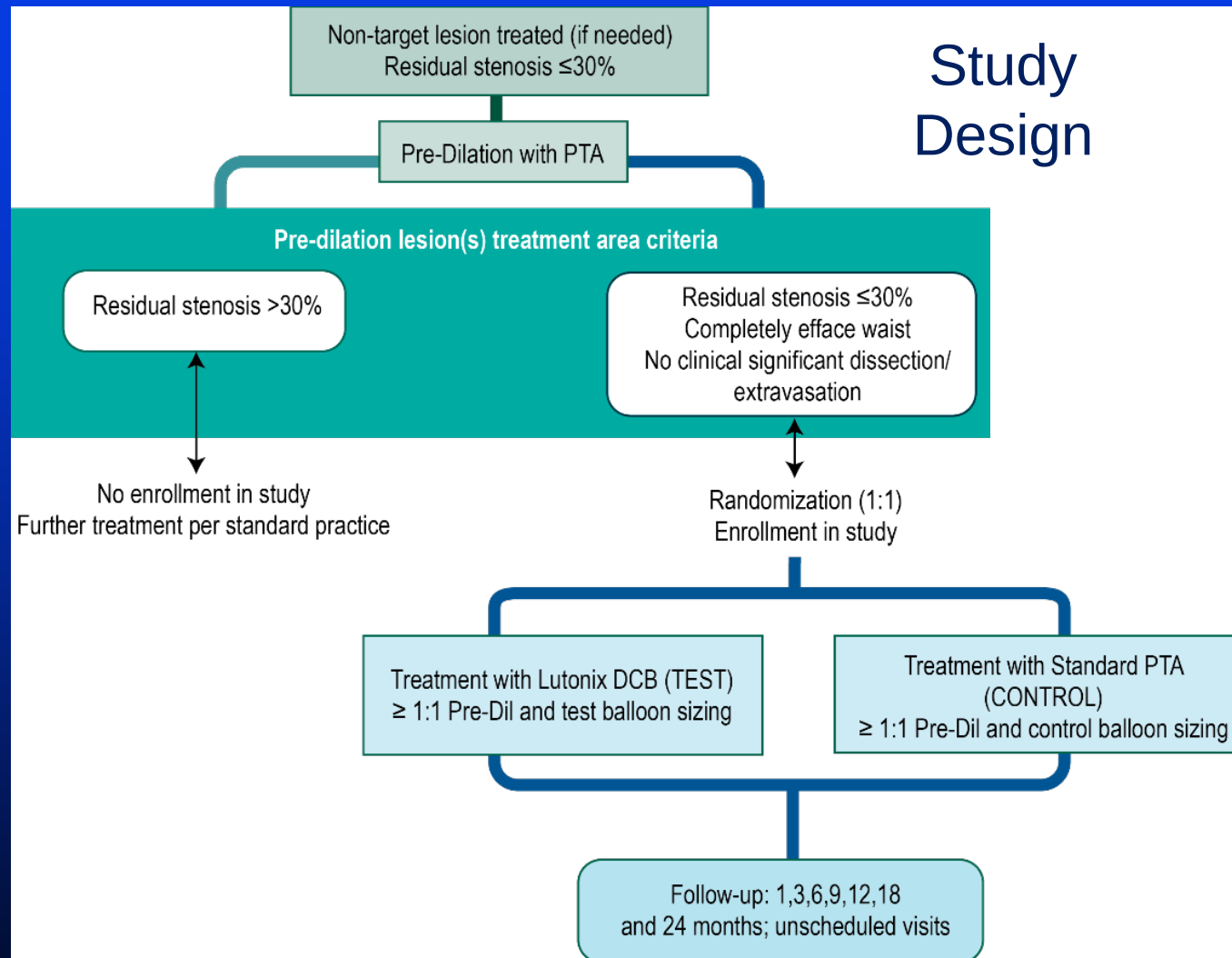
A Prospective, Global, Multicenter, Randomized, Controlled
Study Comparing LUTONIX® 035 AV Drug Coated Balloon
PTA Catheter vs. Standard Balloon PTA Catheter for the
Treatment of Dysfunctional AV Fistulae

Lutonix AV Clinical Trial

Study Design	Prospective, Global, Multicenter, Randomized, Core lab Blinded, Safety and Effectiveness
Objective	To assess the safety and effectiveness of the LUTONIX® 035 AV Drug Coated Balloon PTA Catheter in the treatment of dysfunctional AV fistulae
Number of Patients/Sites	285 randomized subjects at 23 clinical sites
Primary Effectiveness Endpoint	Target Lesion Primary Patency (TLPP) - 6 months
Primary Safety Endpoint	Freedom from any serious adverse event(s) involving the AV access circuit through 30 days
Follow Up	1, 3, 6, 9, 12, 18, 24 month visits
Status	First Subject: June 2015 Enrollment Completion: March 2016

Lutonix **AV** Clinical Trial

Study Design



Lutonix **AV** Clinical Trial

Target Lesion Locations

	DCB (n=141)	PTA (n=144)
Anastomotic (%)	4.3%	3.5%
Cephalic arch (%)	18.7%	22.5%
Cannulation zone (%)	4.3%	9.9%
Inflow (%)	33.8%	29.6%
Outflow (%)	24.5%	22.5%
Swing point (%)	14.4%	12.0%

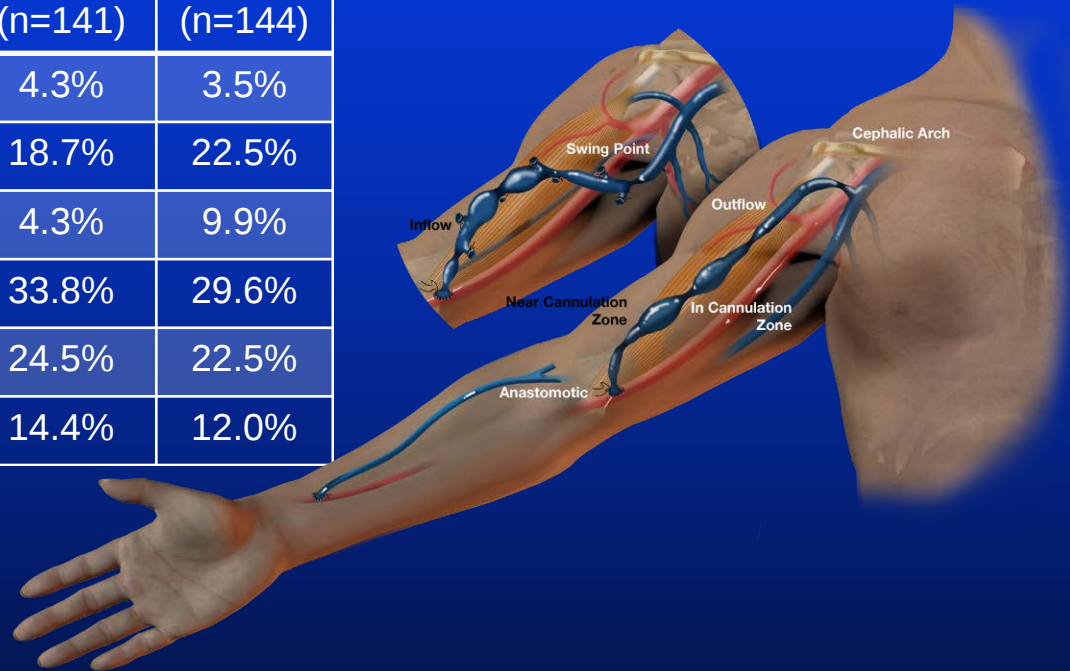
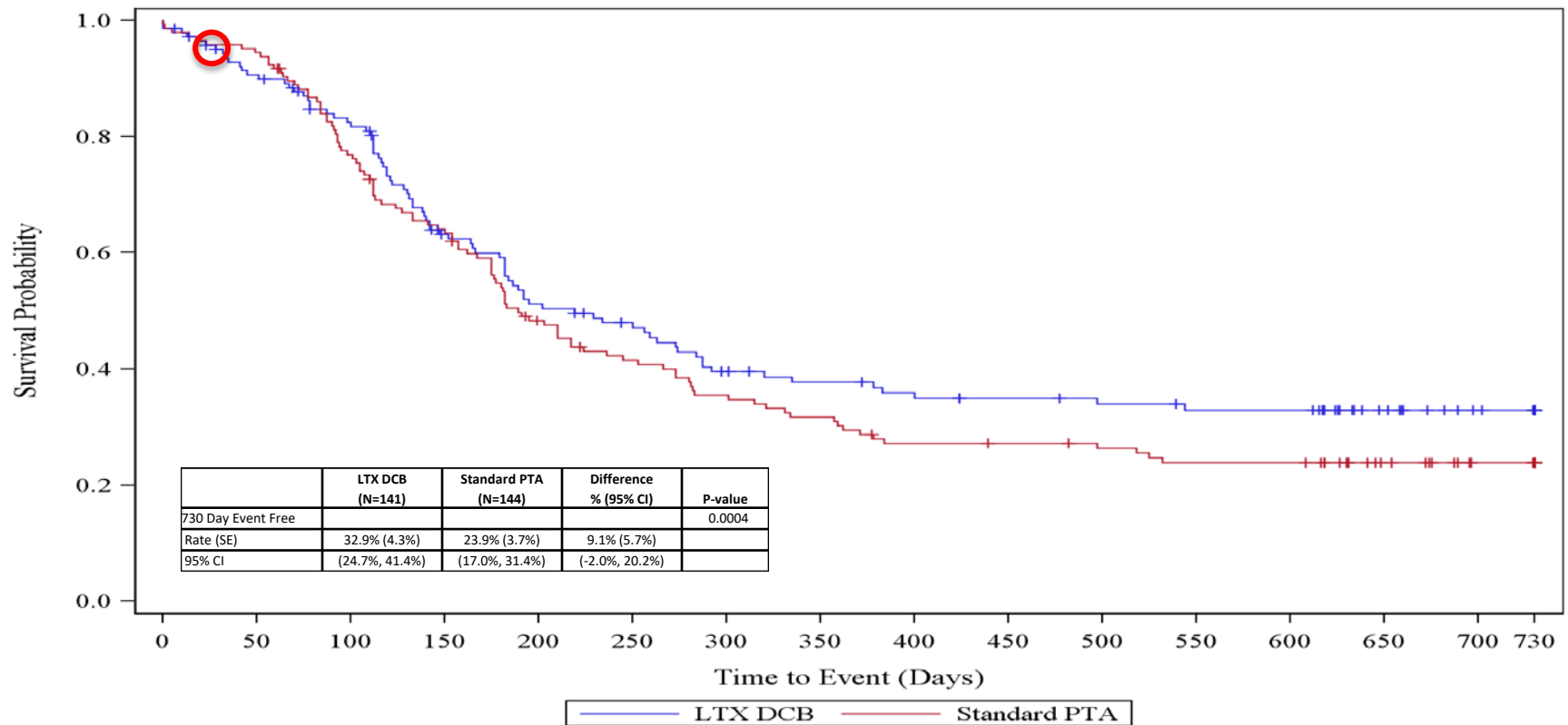


Image courtesy of Bard: illustration by Paul Schiffmacher

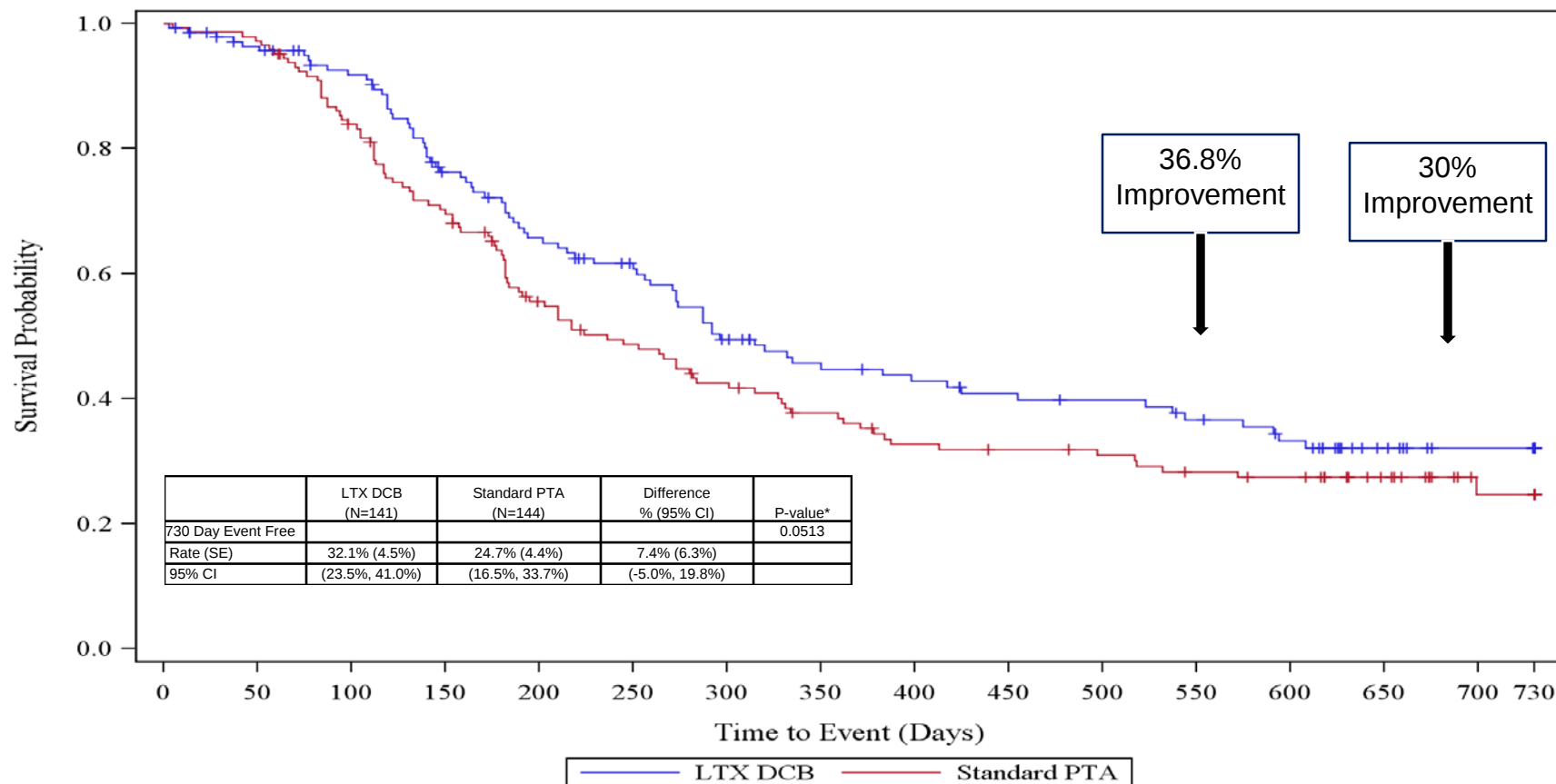
Lutonix AV Clinical Trial

Primary Safety Endpoint: Non-inferior to PTA



Lutonix AV Clinical Trial

TLPP Interim 24 month Results



Some new things to learn

- Geographic miss
 - Longer is better
- Contact time
 - Longer is better
- Transit time
 - Shorter is better
- Compliant balloons (old new)
 - Goldilocks inflation

Status of DCB in HD in US

- Only one DCB approved for AVF
 - Mature, dysfunctional, patent
 - Anastomosis to terminal arch inclusive
 - Not CVS
 - Not in-stent restenosis
 - Not immature fistulae
 - Not clotted AVF
 - Not grafts

DCB is PTA 2.0!

- New approach to restenosis in HD
- Evidence mounting
- More yet to come
 - Ongoing trials
 - Global registry n=324
 - Postmarket study n=213
 - IN.Pact 2/3 enrolled (~200/330)
 - Specific lesion locations
 - Different vessel preparation