Lutonix in AV fistula and Early look AV IDE trial data

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Lutonix in AV fistula and final AV IDE trial data

Disclosure

Speaker name: Jackie P Ho

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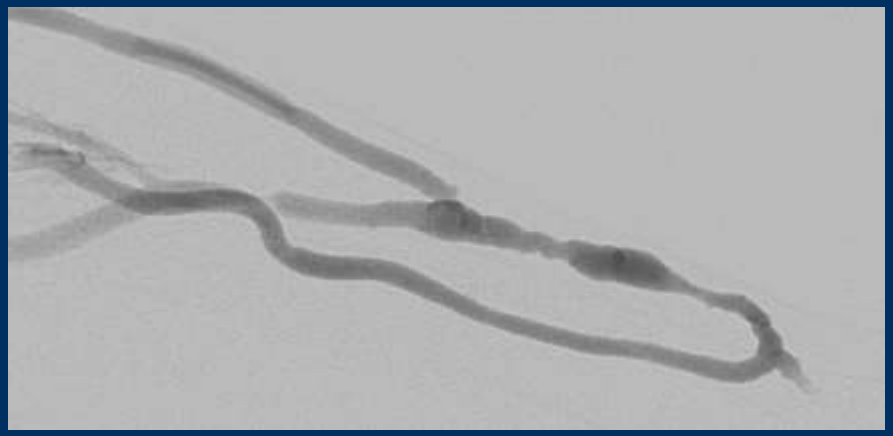
I have the following potential conflicts of interest to report:

- ☐ 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

Once a stenosis developed in HD access, it nearly always recur

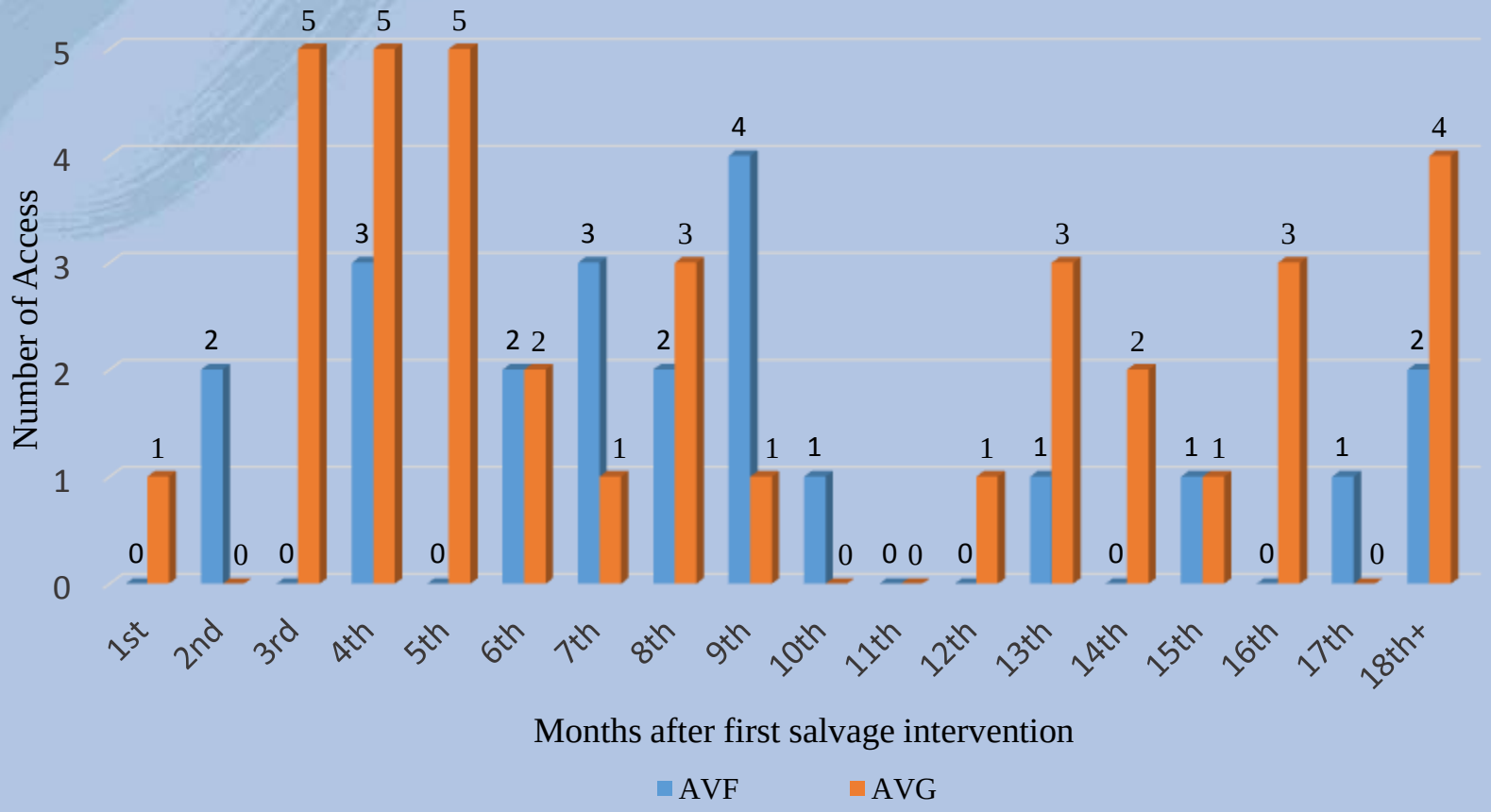


4 months later

About 50% HD access develop re-stenosis 6m after plain balloon angioplasty

NUH retrospective study of re-stenosis pattern

- Between January 2009 & June 2012
- Consecutive ESRF patients who developed first-time stenosis in the HD access (AVF & AVG)
- 114 patients, 54 AVFs & 60 AVGs. Rx with plain/cutting balloon



LINC

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 (NCT01174472)

Panagiotis M. Kitrou[a,*], Konstantinos Katsanos[b], Stavros Spiliopoulos[a], Dimitris Karnabatidis[a], Dimitris Siablis[a]

- Single center RCT
- DCB vs plain balloon for AVFs & AVGs (n = 40)
- Follow-up 1 year after intervention
- Angiographic follow up every 2 months

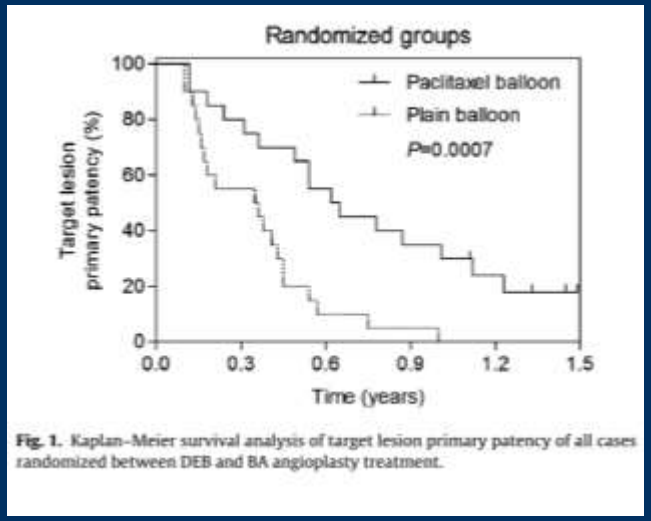


Fig. 1. Kaplan–Meier survival analysis of target lesion primary patency of all cases randomized between DEB and BA angioplasty treatment.

- End point i) technical success ii) target lesion primary patency at 1 year
- Incremental net benefit (INB) and incremental cost effectiveness ratio (ICER) were calculated

Prospective randomized trial comparing drugeluting balloon versus conventional percutaneous transluminal angioplasty (DEBAPTA) for the treatment of hemodialysis arteriovenous fistula or arteriovenous graft stenoses

Tay KH et al

DCB RCT for both AVF & AVG

DCB arm with better primary patency at 6 months

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

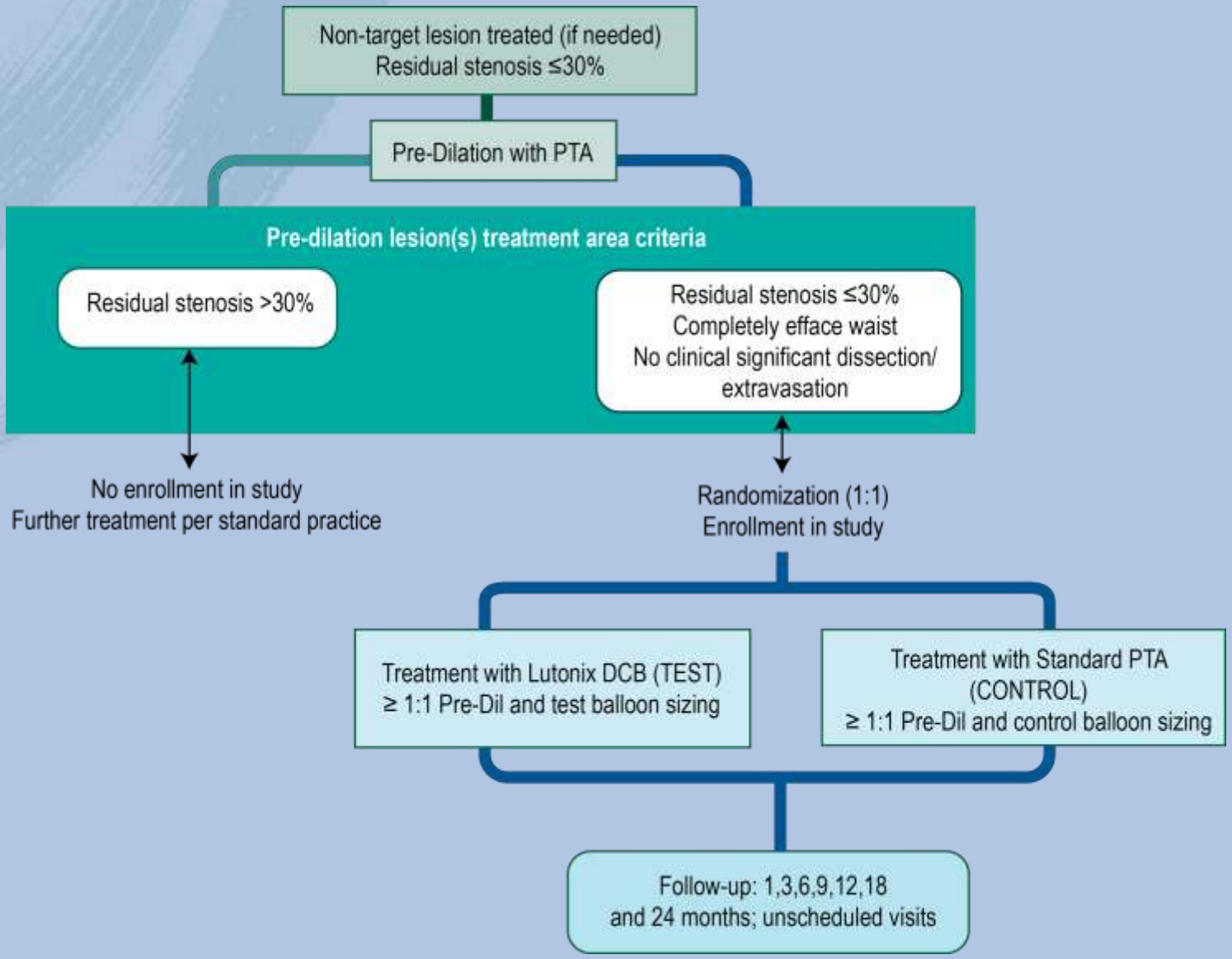
Lutonix AV Clinical Trial Design

Study Design	Prospective, Multicenter, Randomized, 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 AVF
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 AVF circuit through 30 days
Follow Up	1, 3, 6, 9, 12, 18, 24 month visits. Clinical follow-up & assessment
Status	First Subject: June 2015 Enrollment Completion: March 2016

Inclusion & Exclusion Criterae

	Inclusion	Exclusion
Clinical	Male or non-pregnant female ≥21 years old	Thrombosed access
	Upper extremity AVF w/clinical, physiological, or hemodynamic abnormality	Lower extremity access
	Fistula created >30 days >1 hemodialysis session with 2 needles Or Catheter removed > 30 days	Central veins
Angiographic	Length ≤10 cm 50% stenosis	>2 lesions in circuit Secondary non-target lesions that cannot be successfully treated
	Successful pre-dilation Diameter 4-12 mm	Central veins as a secondary lesion, which is clinically significant Bare or covered stent in target or secondary non-target lesions

Study Design



Results - Demographics

Variable	LUTONIX® 035 DCB (N=141)	Control (N=144)
Age	63.6	61.0
Male, n (%)	61.7%	59.0%
Hypertension, n (%)	94.3%	98.6%
Diabetes mellitus, n (%)	58.2%	65.3%
Dyslipidemia, n (%)	60.3%	58.3%
Current smoking, n (%)	13.5%	14.6%
Peripheral arterial disease, n (%)	9.9%	18.1%
Coronary heart disease, n (%)	30.5%	27.8%

Results – AVF info

AVF location	LUTONIX® 035 DCB (N=141)	Control (N=144)
Upper arm	61.7%	73.4%
Antecubital fossa	5.0%	4.9%
Forearm	33.3%	21.7%

Results – AVF info

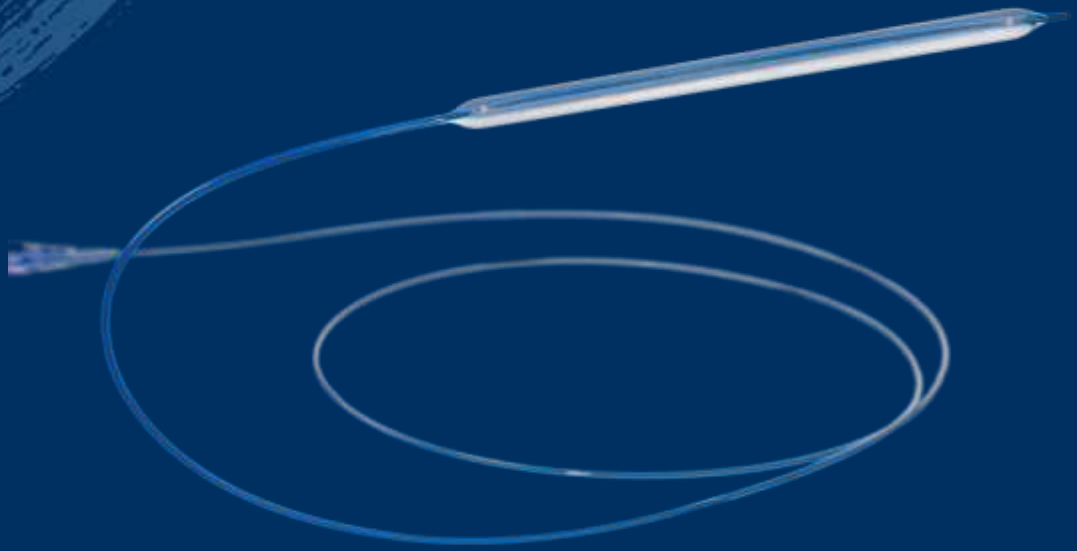
	DCB (n=141)	PTA (n=144)
Anastomotic (%)	4.3%	3.5%
Cephalic arch (%)	18.7%	22.5%
Cannulation zone (%)	4.3%	9.9%
Inflow (%)	33.8%	29.6%
Outflow (%)	24.5%	22.5%
Swing point (%)	14.4%	12.0%

	DCB (n=141)	PTA (n=144)
Subclavian vein (%)	0.7%	0.0%
Brachial vein (%)	0.7%	0.7%
Cephalic vein (%)	68.8%	67.4%
Basilic vein (%)	25.5%	28.5%
Median cubital vein (%)	1.4%	0.7%
Other (%)	2.8%	2.8%

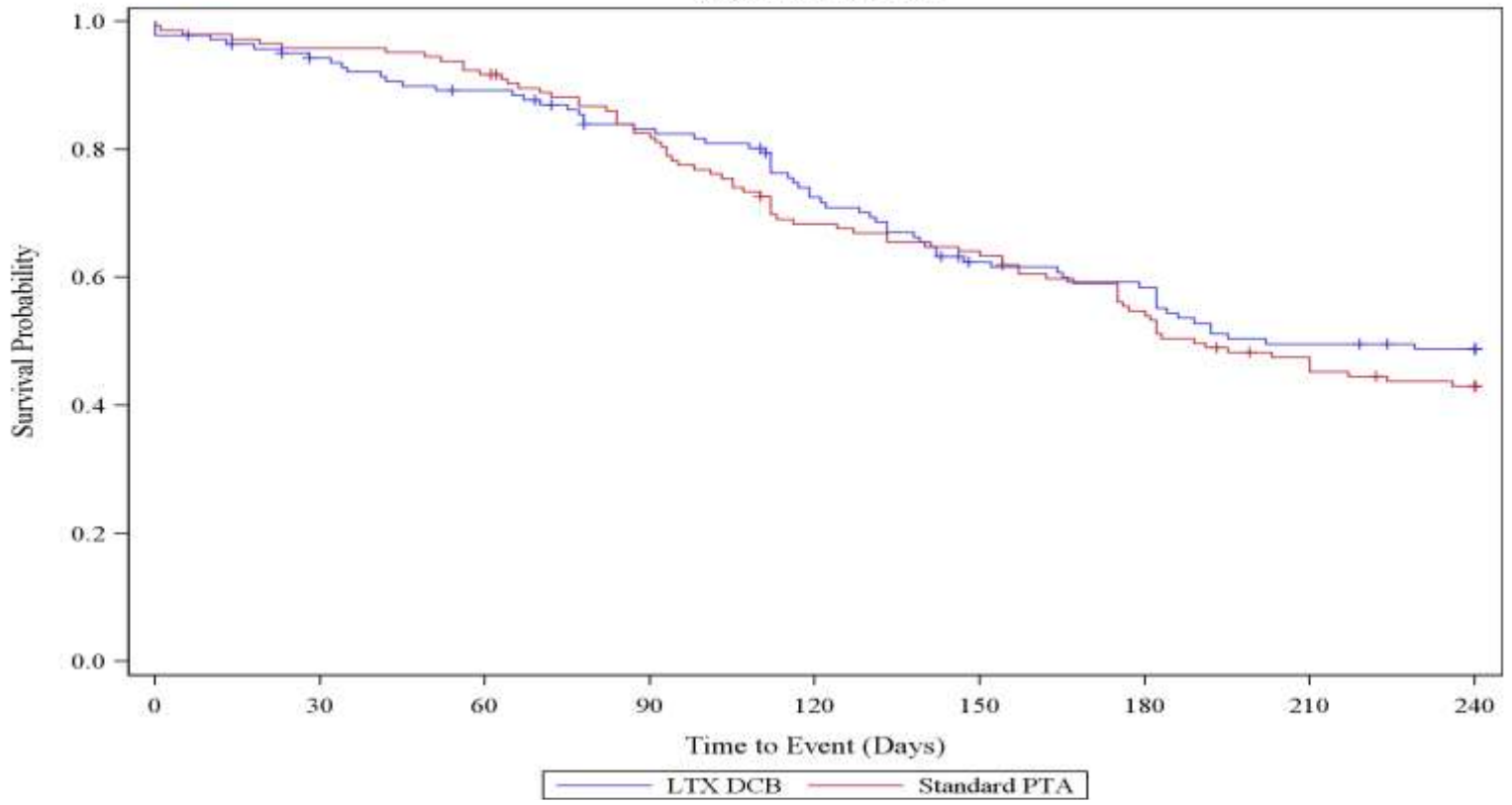
Results – Lesion Characteristics

	DCB (N=141)	PTA (N=144)
De novo (%)	30.5%	27.1%
Tandem (%)	2.8%	7.0%
Mean target lesion length, mm (±SD)	28.4 ± 15.09	29.5 ± 18.69

First Look Results

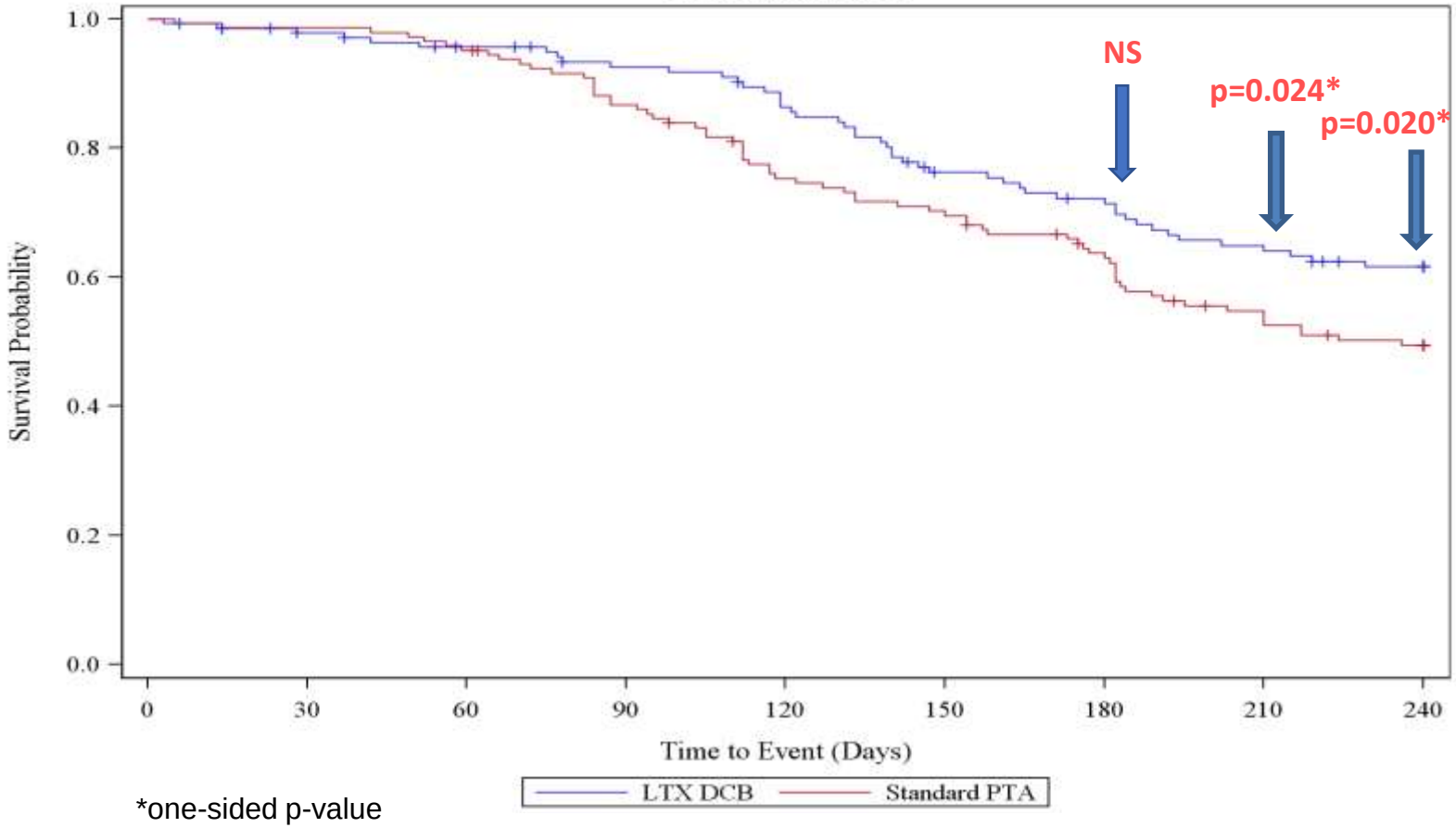


Results - Primary Safety



95% CI of the rate and the rate difference at each time point were calculated based on normal approximation and one-sided p-value is from test for non-inferiority, with 10% as non-inferiority margin.

Results - Target Lesion Primary Patency



*one-sided p-value

Number of Interventions required to maintain TLP

	LTX DCB (n=141)	Standard PTA (n=144)	P-value*
Number of interventions, 180 days	44	64	0.068
Number of interventions, 210 days	58	86	0.022
Number of interventions, 240 days	66	94	0.024

Summary

- Early results, by 240 days:
  - Safety outcomes are non-inferior to PTA
  - Primary patency suggests efficacy benefit
  - 29.8% fewer interventions required to maintain TLP in DCB arm
- Ongoing clinical trial until all subjects reach 24 months

Conclusion

- Encouraging Level 1 evidence to show the effectiveness of DCB to prolong the time of recurrent AVF stenosis
- Further studies needed to review the effect of Paclitaxel on other types of hemodialysis access lesions (eg AVG, central vein etc)
- Further studies needed to evaluate the effect of Paclitexel in Asian patients' hemodialysis accesses

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