LUTONIX® Drug Coated Balloon Patras Single Center Experience

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- The opinions and clinical experiences resented herein are for informational purposes only and may not be predictive for all cases. Individual results may vary depending on a variety of patient specific attributes.
- The results and data presented herein reflect Dr. Karnabatidis' clinical experience in a single-center, investigator-initiated and funded study. These results have not been published or peer-reviewed. Bard /Lutonix has not sponsored or funded these studies, nor has Bard/Lutonix validated underlying test methods or data presented herein.
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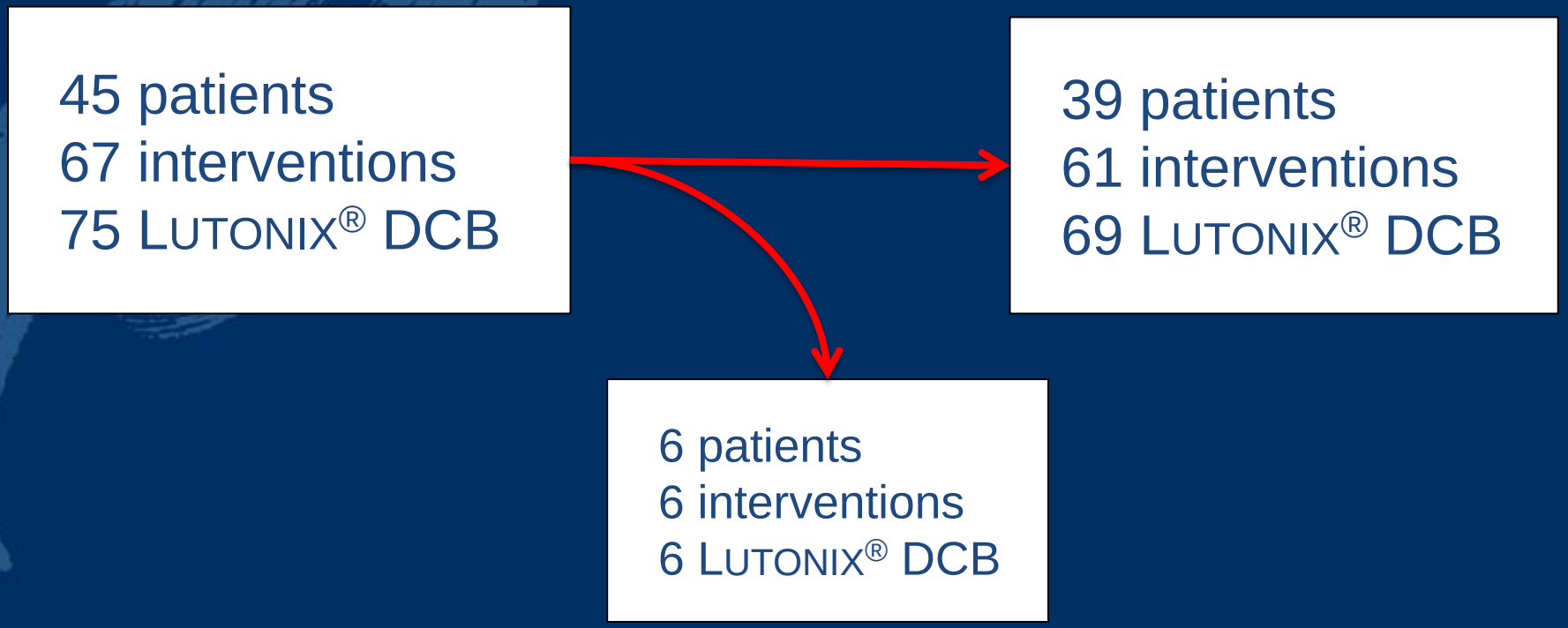
LUTONIX® DCB in Vascular Access

Single-Center Retrospective Analysis

January 2014 – August 2015



**Lesions distal to cephalic arch not included*

Baseline Variables

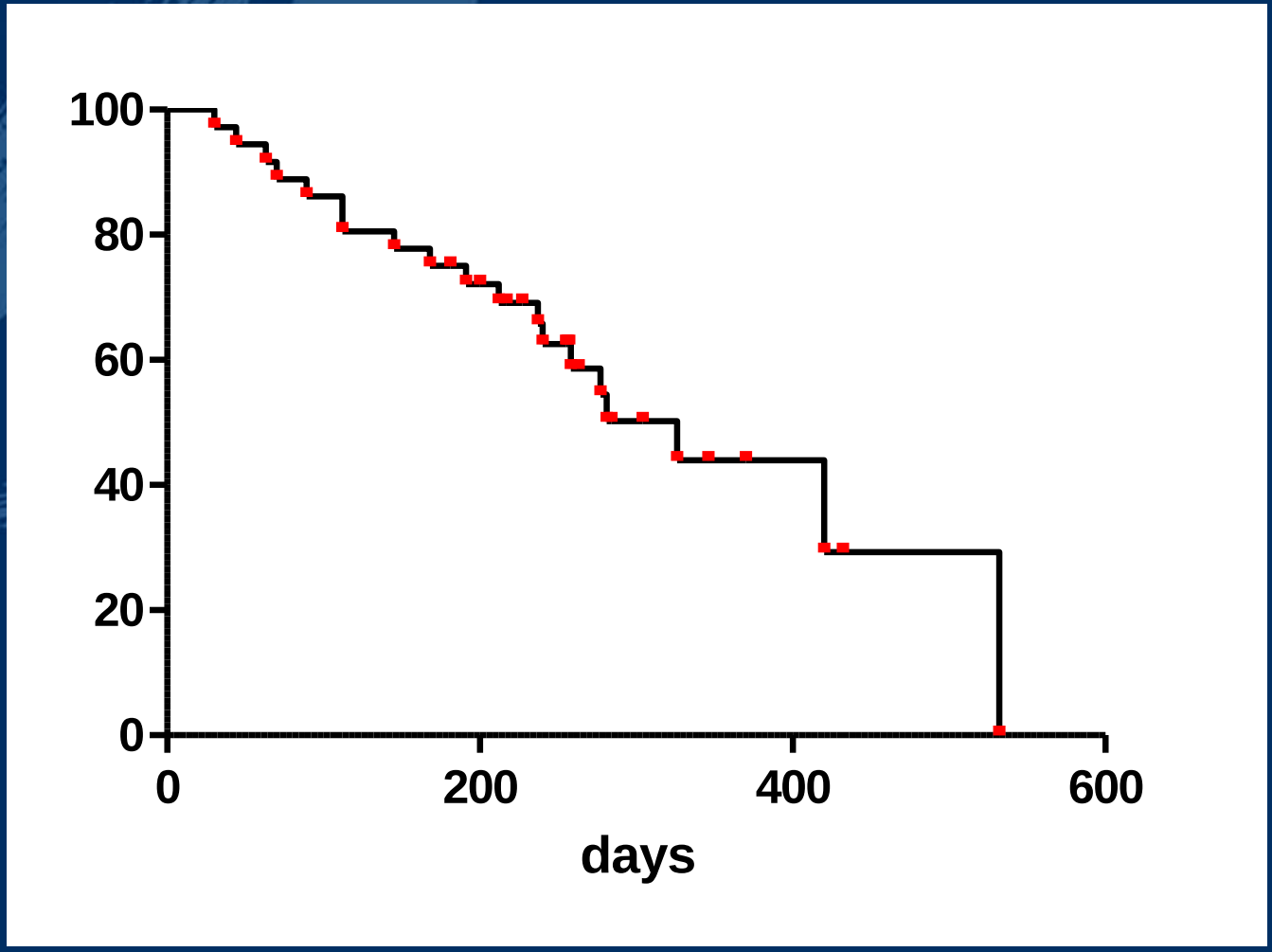
Number of Patients: 39 (23 men; 59%)

Vascular Access	39	
AVF	20	51.3%
AVG	19	48.7%
De Novo	14	35.9%
Re-intervention	25	64.1%

Balloon diameter: 6.59mm
Balloon length: 73.41mm

Side	39	
Left	23	59%
Right	16	41%
Site	**39**	
Cephalic	23	58.97%
Axillary	14	35.9%
Basilic	2	5.13%

Target Lesion Primary Patency



Median Survival: 326 days

@ 6 months: 75%

Literature*

2012 JEVT Patras RCT (AVG + AVF)

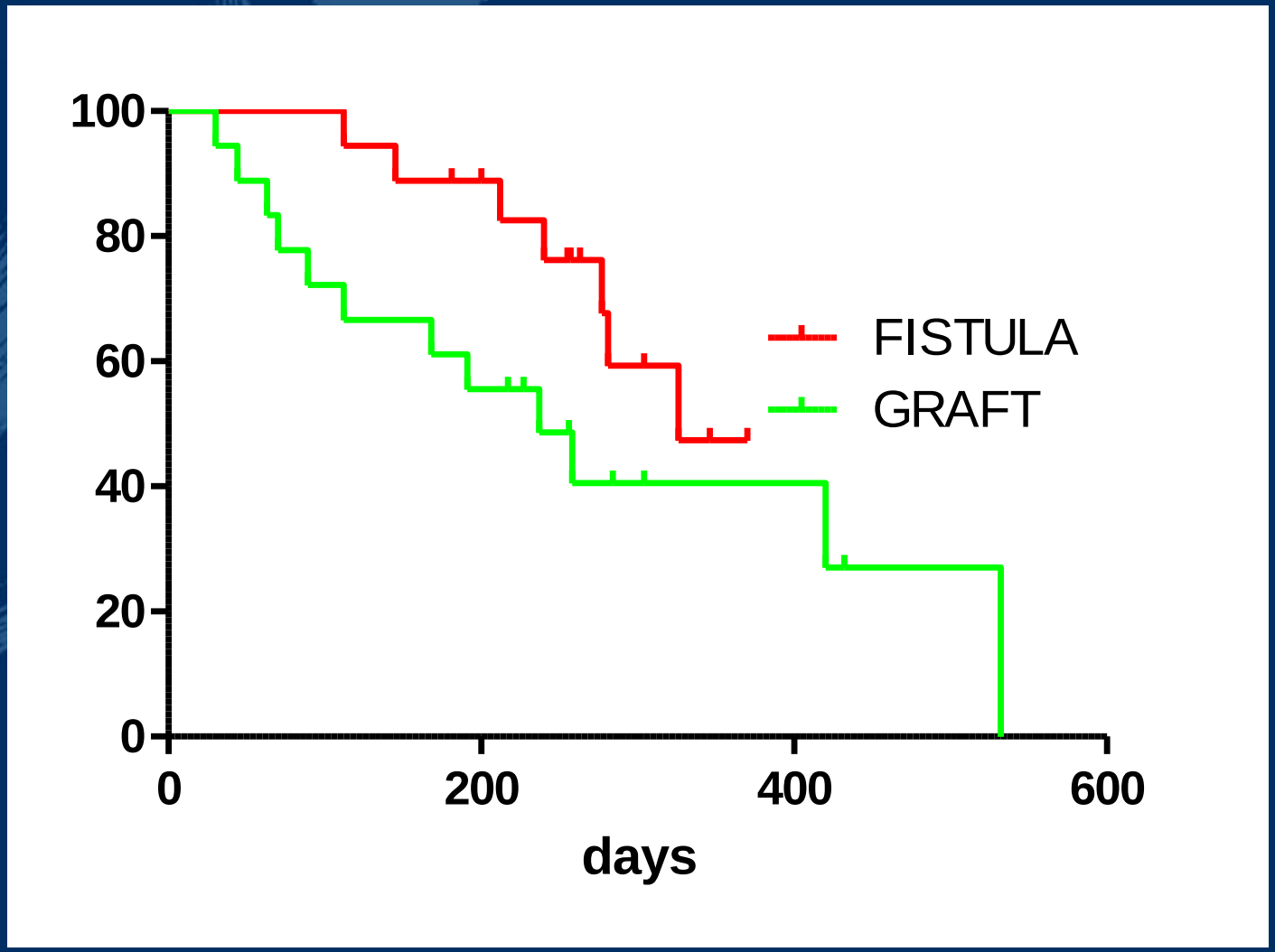
INPACT™ (Invatec-Medtronic, Brescia, Italy) vs. PTA at 6 months: 70%

2014 JVIR prospective single-arm (AVF)

SeQuent Please™ (B Braun, Berlin, Germany) at 6 months: 70%

* Clinical Results reported in the literature with DCBs in the published literature may be different from LUTONIX® DCB outcomes. Different devices and study designs may yield different clinical results.

AVF Vs. AVG



Median Survival: Fistula 326 Vs. 237 Graft

(p=0.15 Log-rank test; HR: 0.4909 95% CI: 0.1862–1.294)

LUTONIX® DCB Re-Interventions

39 patients

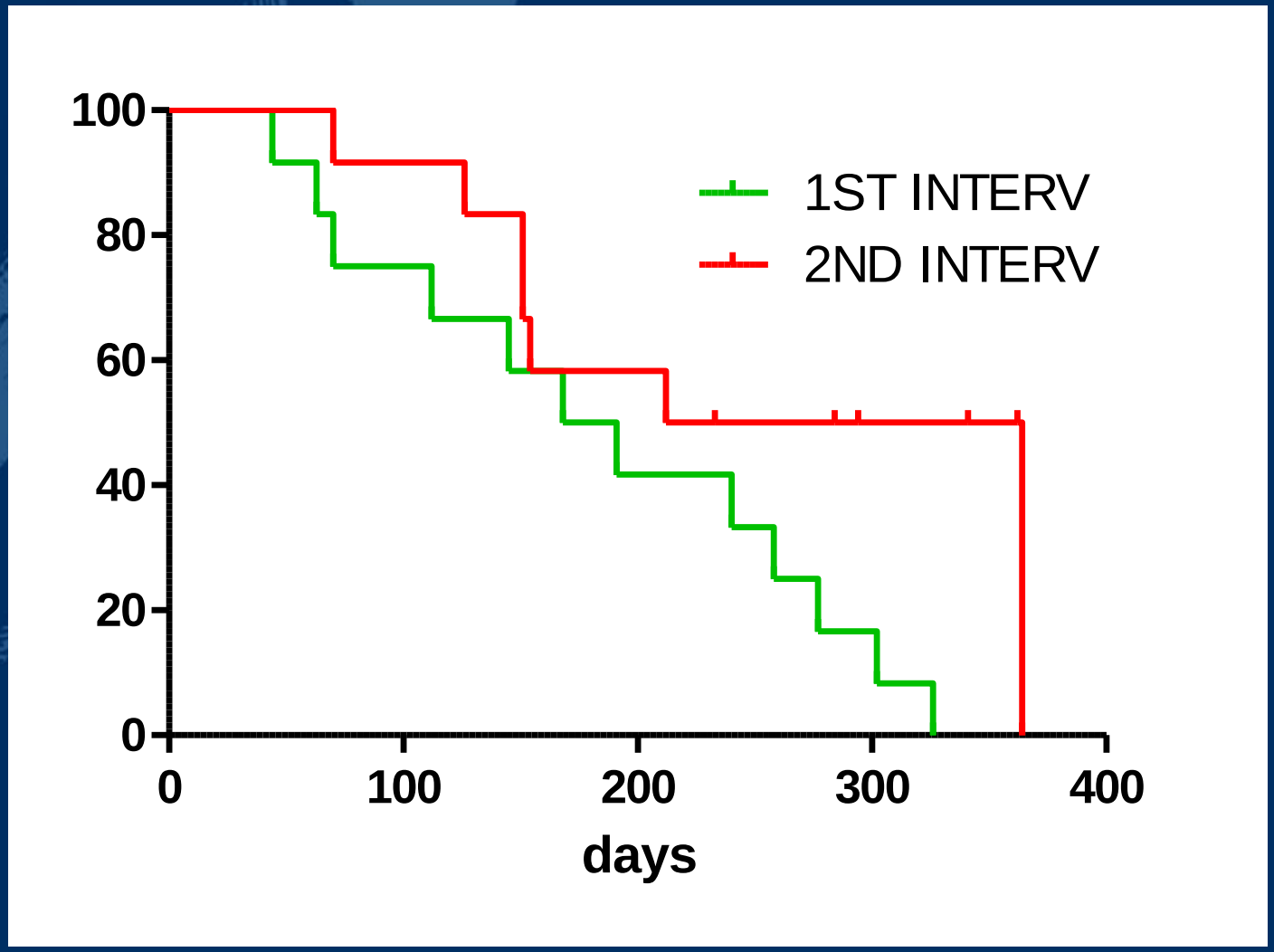
61 Interventions

69 LUTONIX® DCB

14 Patients received a 2nd or 3rd or 4th DCB angioplasty

Comparison of 1st vs. 2nd intervention in a longitudinal manner

1ST Vs. 2nd Intervention



Median Survival: 1ST Int 179.5 Vs. 278 2nd Int

(p=0.0452 Log-rank test; HR: 2.623 95% CI: 1.021–6.740)

Summary

LUTONIX® DCB Retro Analysis in this single center study showed:

- DCB results in AVF were better compared to AVG
- Additional intervention showed more favorable results

DCB for Symptomatic CVS

Randomized Single-Center Control Trial

Interim Results*

* - Data presented are preliminary, single-site reported and subject to change upon finalization / adjudication

Aim

To compare the Safety and Effectiveness of:

- DCB vs. PTA for the treatment
- Symptomatic Central Venous Stenosis
- AVGs and AVFs

Inclusion Criteria

Sympomatic Central Venous Stenosis

Angiographic Verification

Distal to Cephalic Arch (Subclavian, Anonymous, VC)

De Novo + Restenosis

AVGs + AVFs

Multiple Stenosis treated

“Real Life Inclusion Criteria”

Randomization

Angiographic verification

Lesion diameter visual estimation

If DCB group: predilation with 1mm smaller PTA balloon + PCB ± post dilation

If PTA group: HPB ± Post dilation with higher diameter HPB and/or longer inflation

Devices

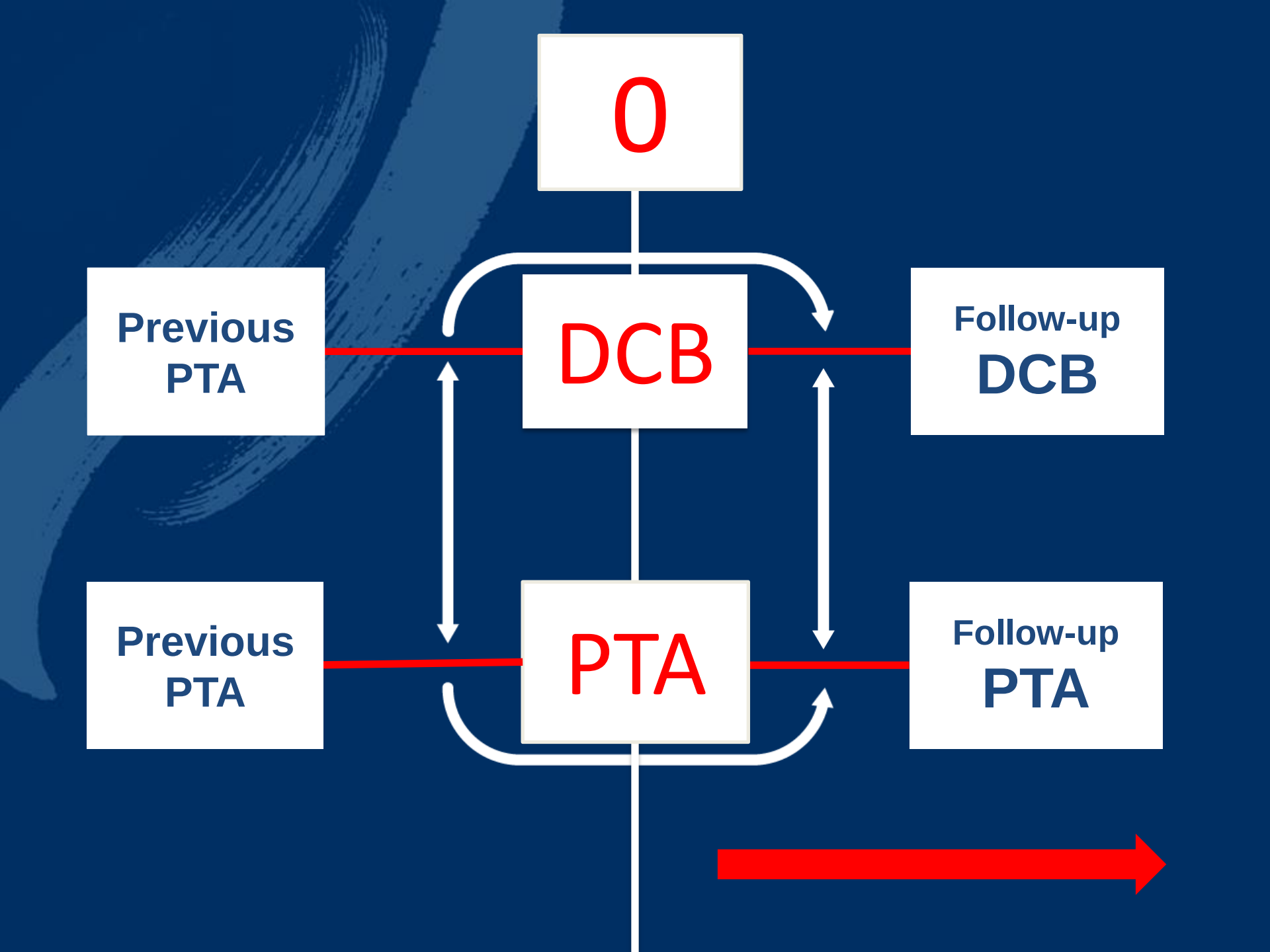
DCB group:

LUTONIX® 035

PTA group:

ATLAS GOLD®, CONQUEST®, DORADO®, Mars™, Mustang™, RIVAL®, Evercross™, Armada™

Flowchart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Previous PTA
DCB
Follow-up DCB
Previous PTA
PTA
Follow-up PTA

Endpoints

Primary:

Target Lesion Primary Patency @ 6 months

Secondary:

Minor or Major Complications

Longitudinal Comparison of treatments

Baseline Variables

20 patients in each group

Baseline variables were equally distributed between the two groups

Two patients from the PTA group were lost to f-up

Baseline Variables

For DCB Group

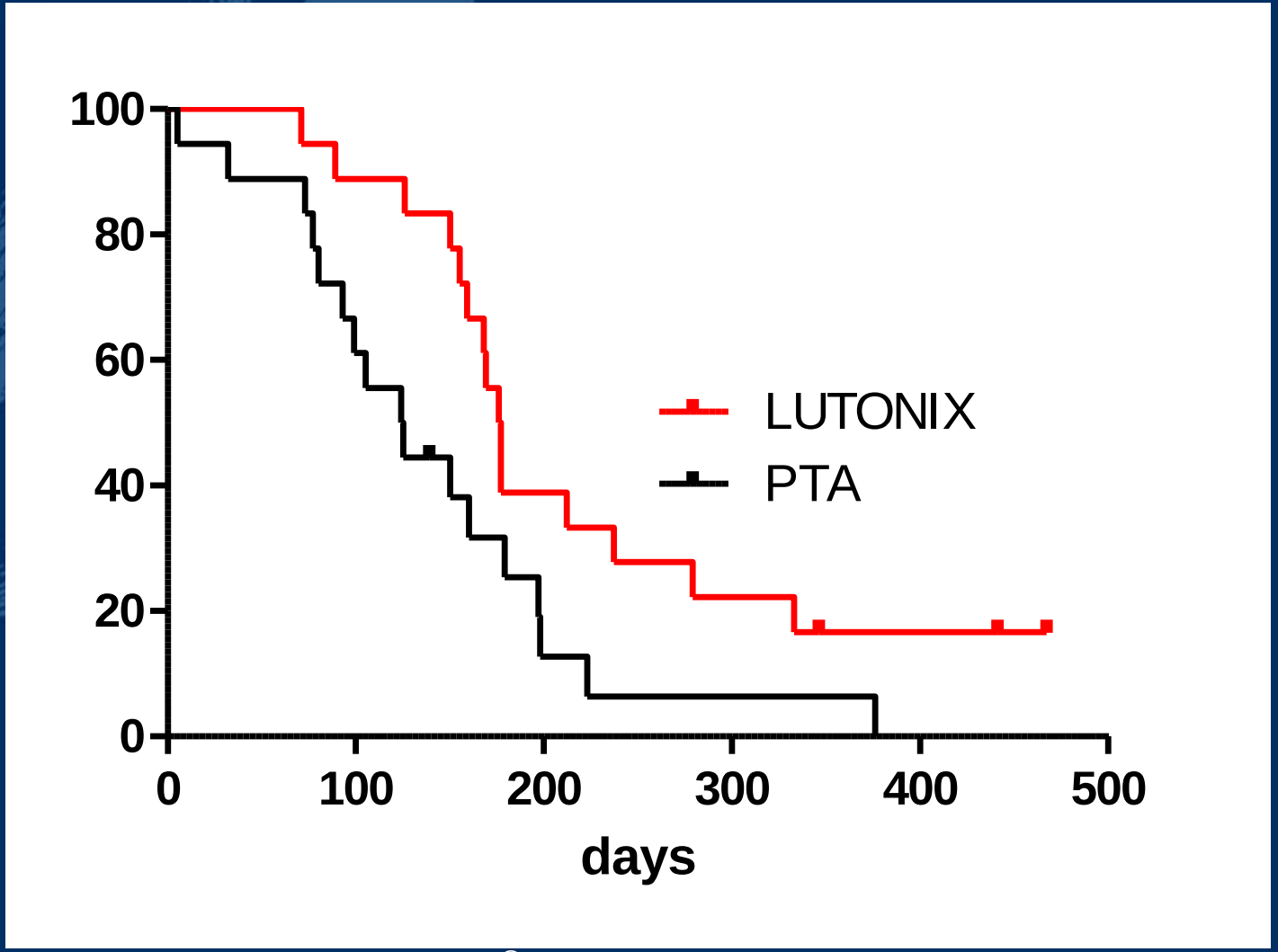
23 devices in 20 patients

15 used in 12 subclavian veins

4 in Vena Cava

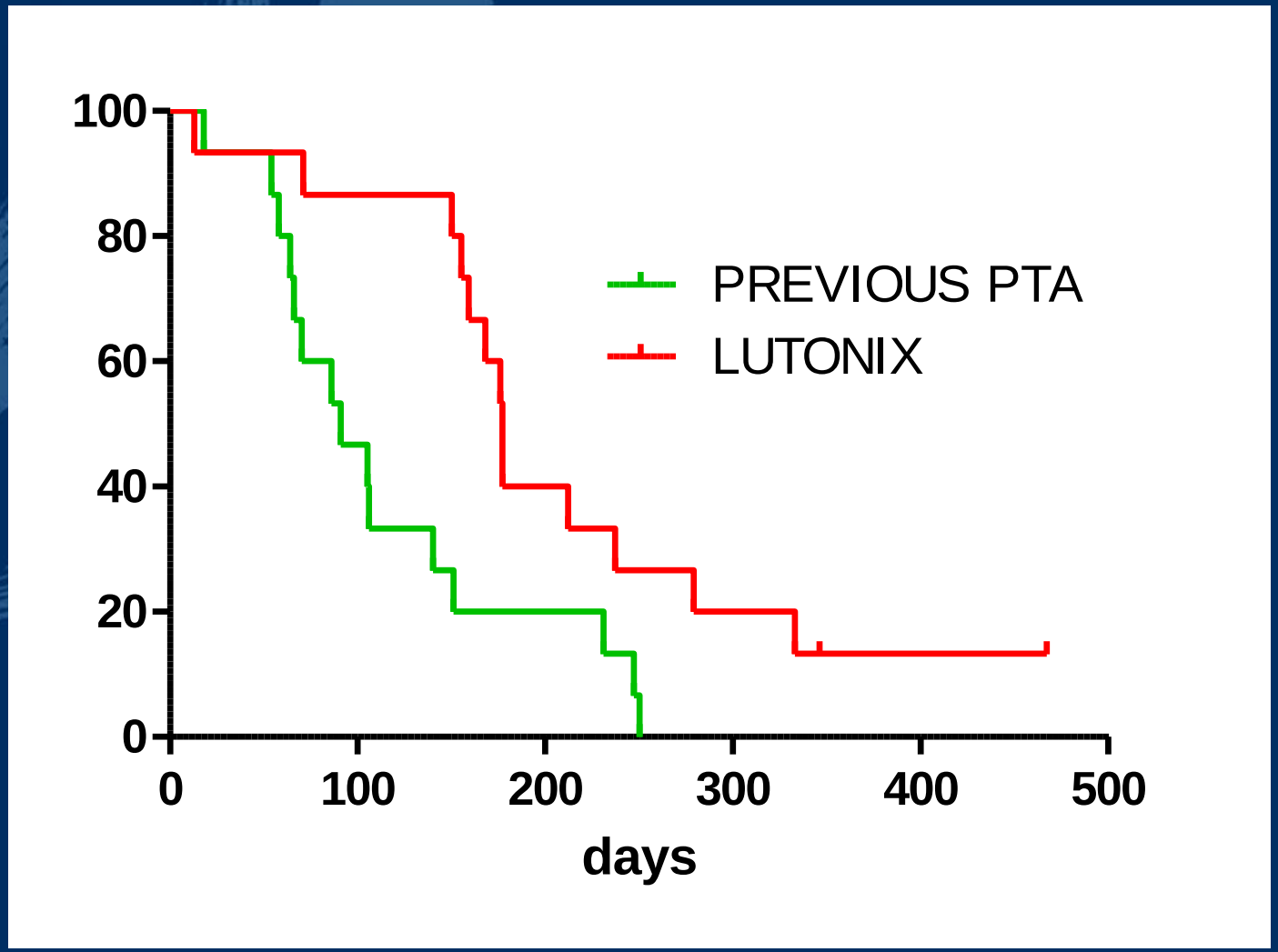
4 in Anonymous Vein

DCB vs. PTA



Median Survival: LUTONIX® 176.5 days Vs. 124.5 days PTA
p=0.03 (Log-rank); HR: 0.4415 (95% CI: 0.2103-0.9271)

PCB vs. Previous PTA



Median Survival: LUTONIX® 177 days Vs. 91 days PTA
p=0.01 (Log-rank); HR: 2.999 (95% CI: 1.306-6.888)
15/20 cases

Conclusion

These single-center clinical experiences of the LUTONIX® DCB in the treatment of AV stenosis are encouraging and warrant further investigation such as well designed randomized studies

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