DCBs for the Treatment of Symptomatic CVS in Dialysis Access. A European Mutli-center Retrospective Study of 87 patients.

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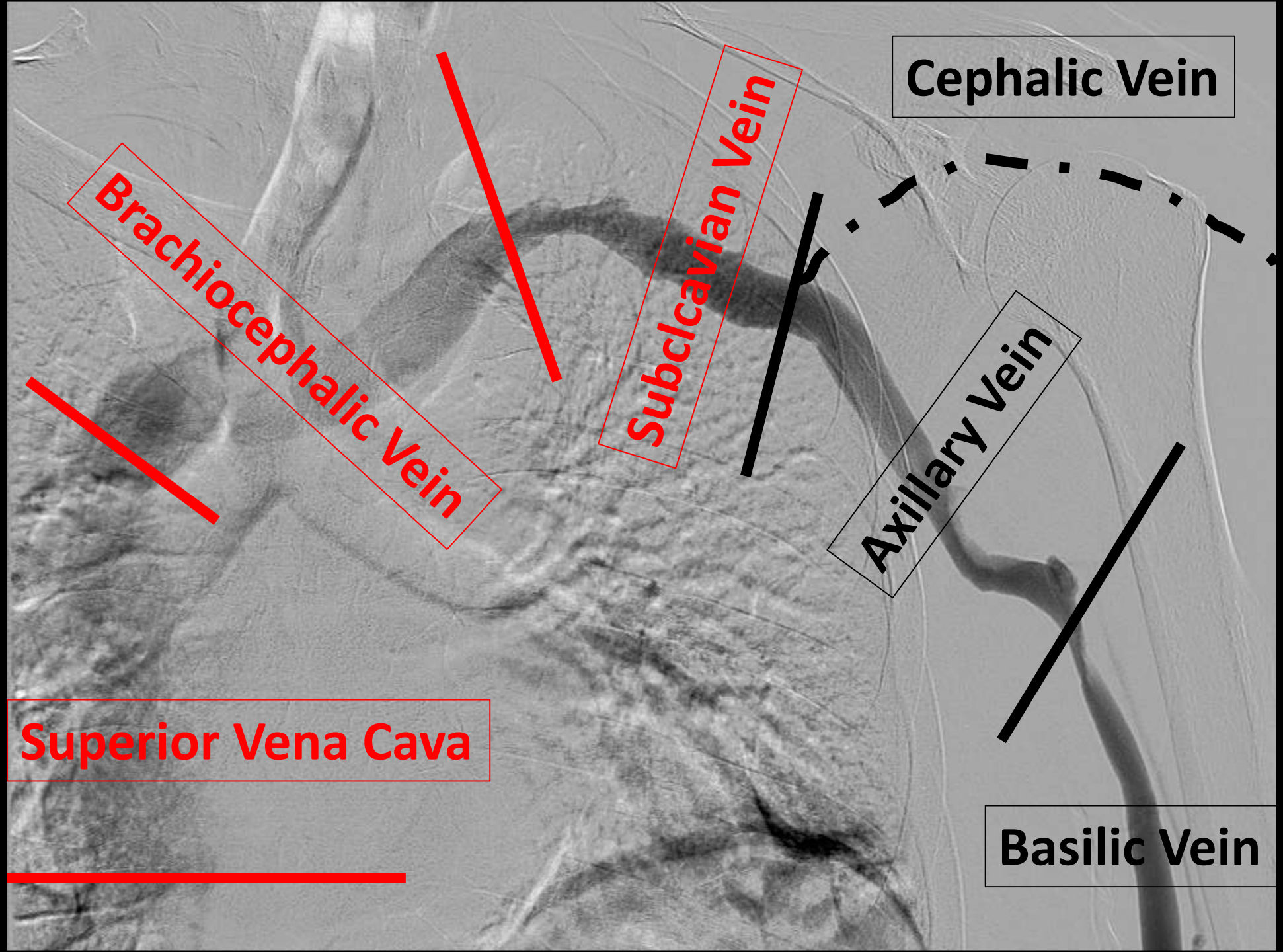
Disclosures

Consultant for BD


Cephalic Vein
Brachiocephalic Vein
Subclavian Vein
Axillary Vein
Superior Vena Cava
Basilic Vein

Why do we get CVS in Dialysis?

Prior or Current use of foreign materials

- Cardiac rhythm-related devices
- PICC lines
- Ports
- Central Venous Catheters (specially left-sided - subclavian)

Stenosis of venous outflow due to Dialysis

Gonsalves CF et al: Incidence of central vein stenosis and occlusion following upper extremity PICC and port placement. CVIR 2003;26:123-127.
da Costa SS et al.: Incidence and risk factors of upper extremity deep vein lesions after permanent transvenous pacemaker implant: a 6-month follow-up prospective study. Pacing Clin Electrophysiol 2002;25:1301-1306.
Teruya TH et al.: Symptomatic subclavian vein stenosis and occlusion in hemodialysis patients with transvenous pacemakers. Ann Vasc Surg 2003;17:526-529.
Kundu S: Review of central venous disease in hemodialysis patients. J Vasc Interv Radiol. 2010 Jul;21(7):963-8. doi: 10.1016/j.jvir.2010.01.044.

Treatment
Facts & Figures

PTA first (Technical failure: 10-30%)

Patency Rates: 28.9% @ 6 months

High-Pressure Balloon PTA

Patency Rates: 60% @ 6 months

Main Problem → Elastic recoil

Stent Placement: More aggressive treatment

Patency: As low as 25% @ 1 year

Agarwal AK et al.: How should symptomatic central vein stenosis be managed in hemodialysis patients? Semin Dialysis2014 May-Jun;27(3):278-81

Evidence so far..

Massmann et al. 2015

Retrospective analysis

Diabetic ESRD pts with AVFs

25 Restenotic Non-Occlusive Lesions treated with

Elutax SV DCB: 20 times (10 pts)

Plain Balloon Angioplasty: 32 times (15 pts)

Study included axillary veins

No vessel preparation

Outcome Measure: Freedom from target lesion revascularization

Significant difference in favor of DCB

Kitrou et al. 2017

RCT including 40 subjects (20 in each group)

De novo, Restenotic & Occluded Lesions were included

Device under investigation: Lutonix DCB

Primary Endpoint: Clinically-assessed intervention-free period

Significant difference in favor of DCB

What is the evidence so far?

<30 pts!!!!

The Study

Purpose

This was a multi-center single-arm retrospective analysis evaluating the outcomes of DCB use for the treatment of symptomatic central venous stenosis in arteriovenous dialysis access.

Baseline Characteristics

Number of Patients: 87

Number of Physicians Involved: 17 physicians

Centers participating: 11

- Interventional Radiology Dpt, Patras University Hospital, Greece
- Schön Klinik, Düsseldorf, Germany
- Institut Mutualiste Montsouris, Paris, France
- 2nd Radiology Dpt, Attikon University Hospital, Athens, Greece
- Policlinico Umberto I, Rome, Italy
- Hospital "S. Eugenio" Rome, Italy
- Ambroise Paré University Hospital, Paris, France
- Lumiar Vascular Access Center, NephroCare, Portugal
- St. Franziskus Hospital, Muenster, Germany
- Center for Vascular and Endovascular Surgery, University Hospital of Muenster, Germany
- Barts Health, NHS Trust, London, UK

Inclusion Criteria

Age >18 years and <90 years

Patient on Dialysis with an ipsilateral Arteriovenous Fistula (AVF) or Graft (AVG)

Stenosed central vein (Subclavian Vein, Innominate Vein, Superior Vena Cava)

Clinical Signs of Central Venous Stenosis

- Arm swelling, pain, tenderness, and/or erythema of the ipsilateral extremity
- Ipsilateral breast swelling
- Neck swelling
- Visible collateral venous network
- Inadequate dialysis performance

Exclusion Criteria

Stenosis <50% verified with DSA by visual estimation

Dialysis Access thrombosis

Pregnancy

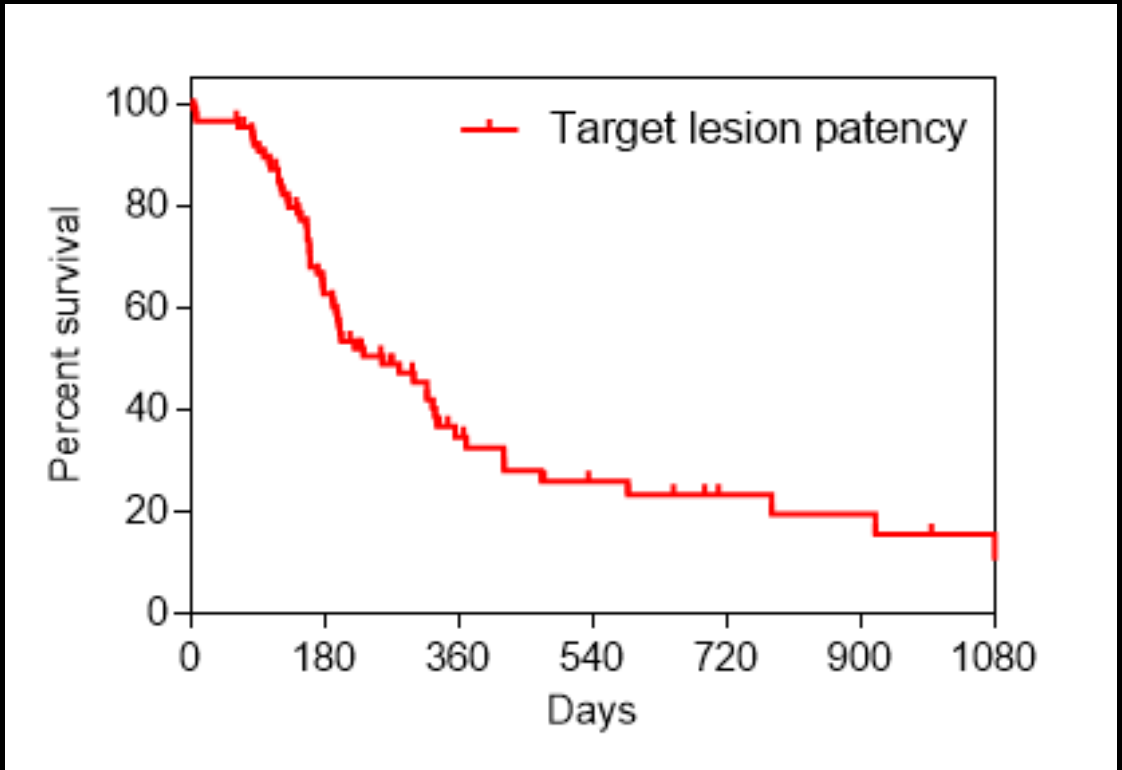
Infected vascular access

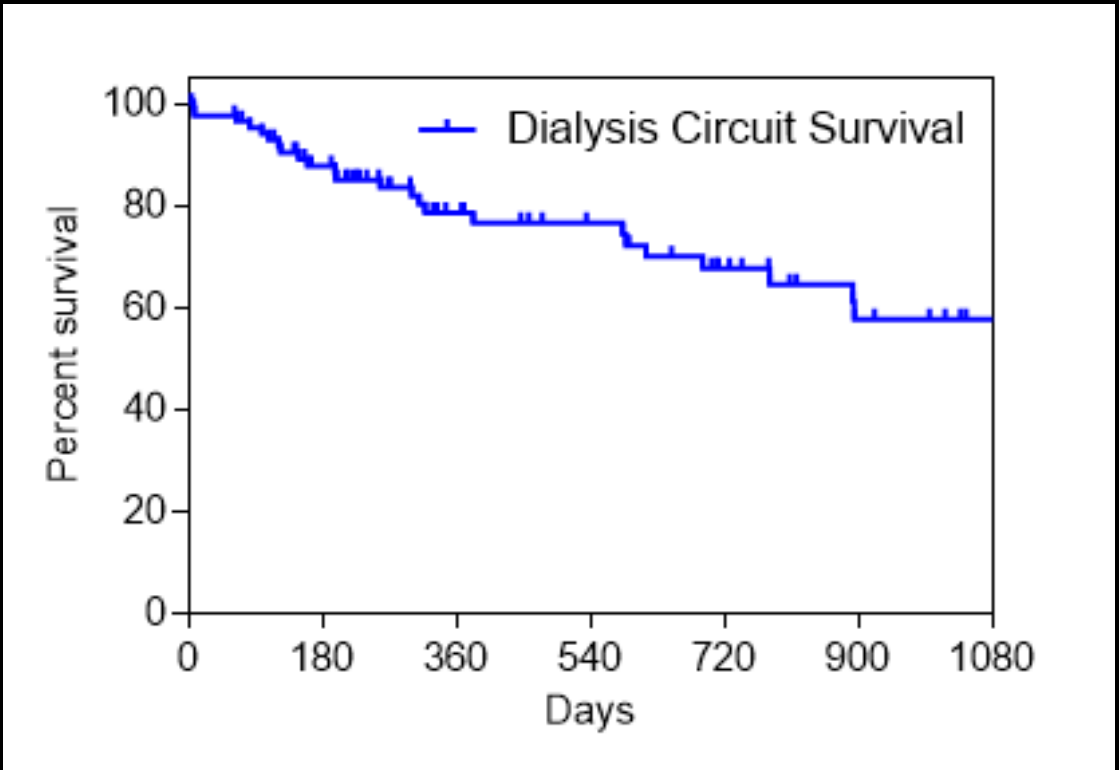
Outcome Measures

Clinically assessed intervention-free period of the treated segment at 6 months: A dialysis access circuit with no need for clinically driven target lesion repeat intervention for symptom recurrence and angiographic verification of the presence of CVS.

Procedure-related Minor & Major Complications

Results

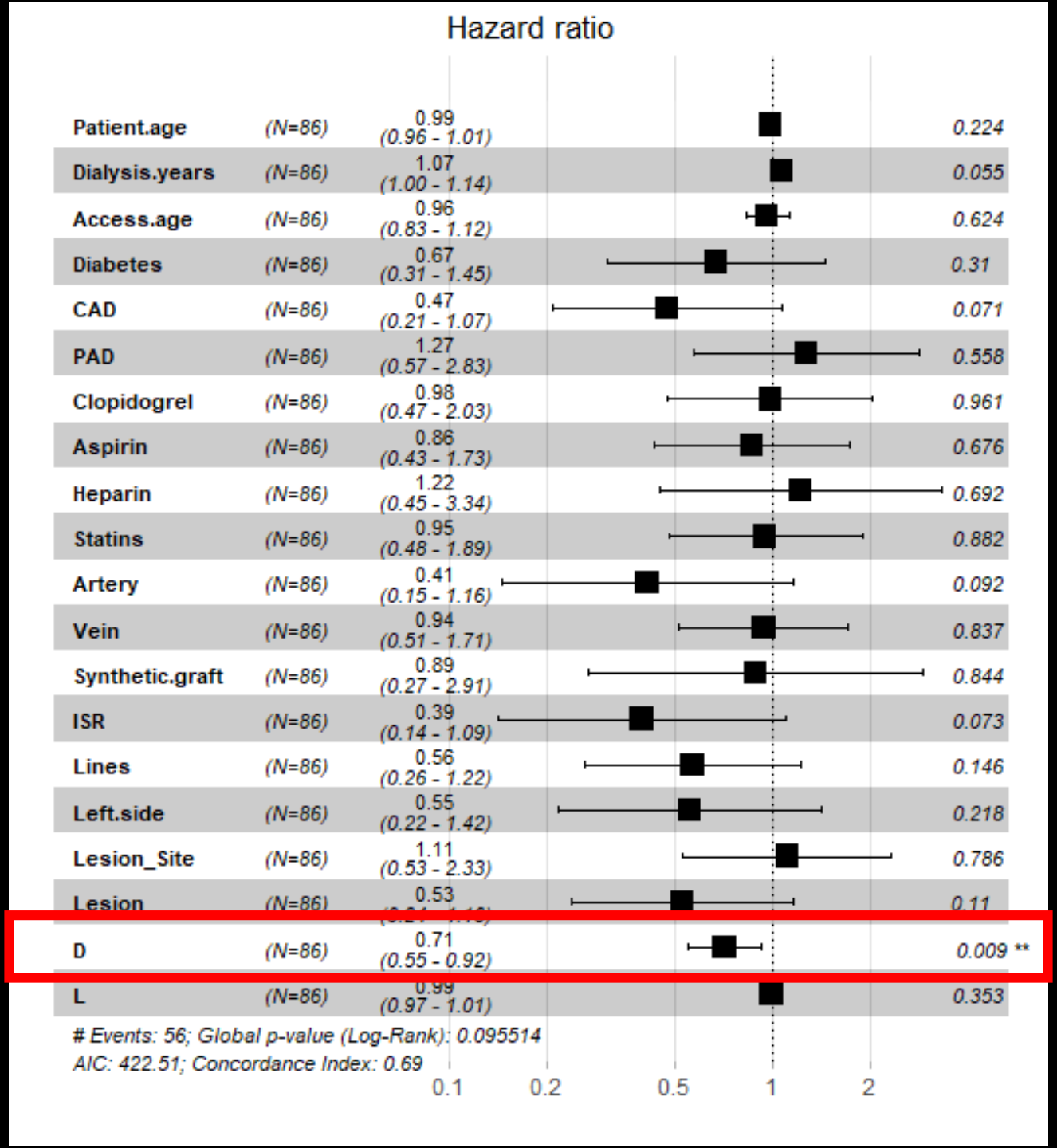

Target lesion patency
Percent survival
100
80
60
40
20
0
0
180
360
540
720
900
1080
Days


Dialysis Circuit Survival
Percent survival
100
80
60
40
20
0
0
180
360
540
720
900
1080
Days

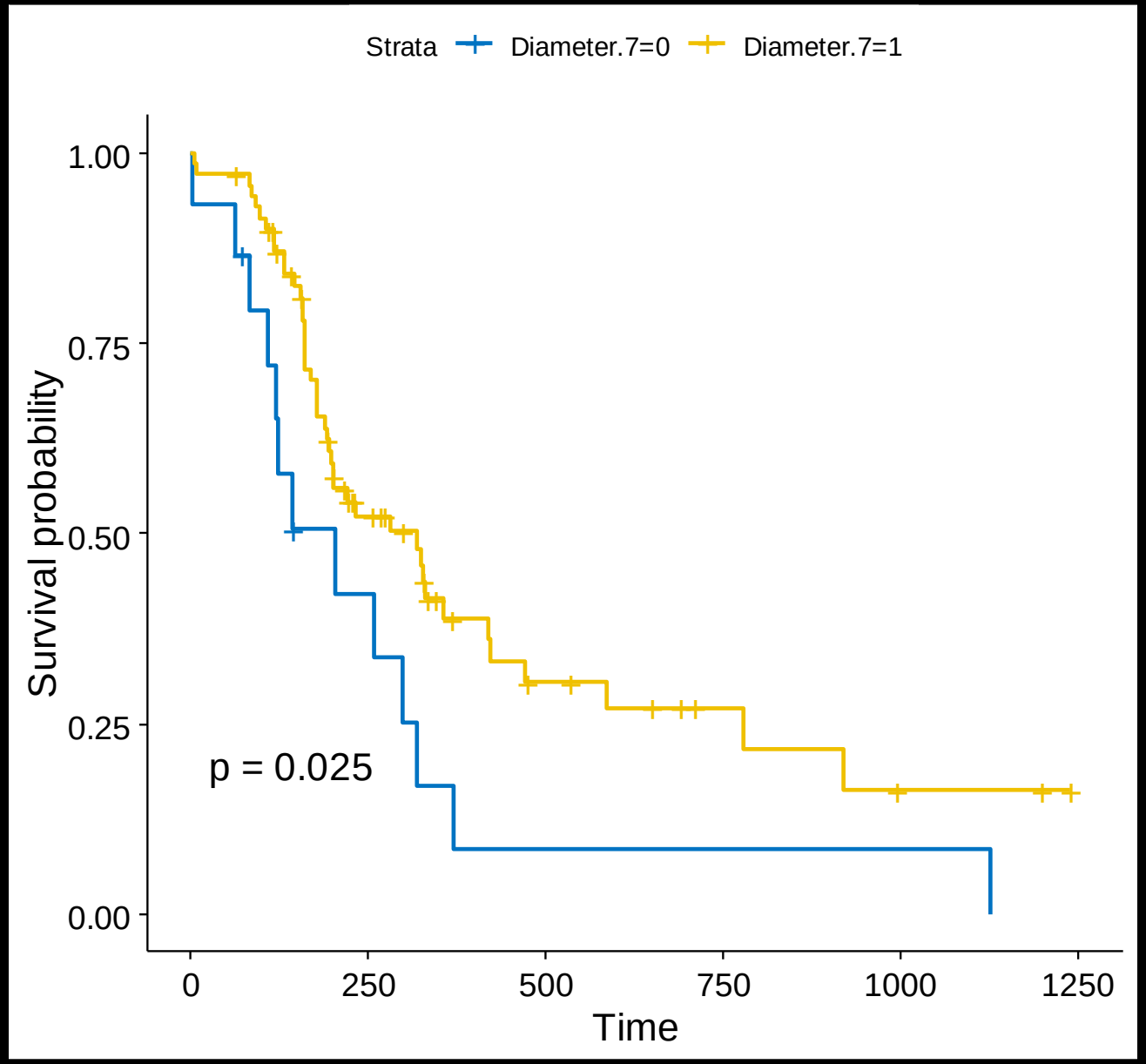
In numbers

Outcome Measures	@6 months	@12 months	@24 months
TLPP	62.7%	34.6%	23.3%
ACS	87.7%	78.5%	67.6%
PS	95%	91%	79.7%

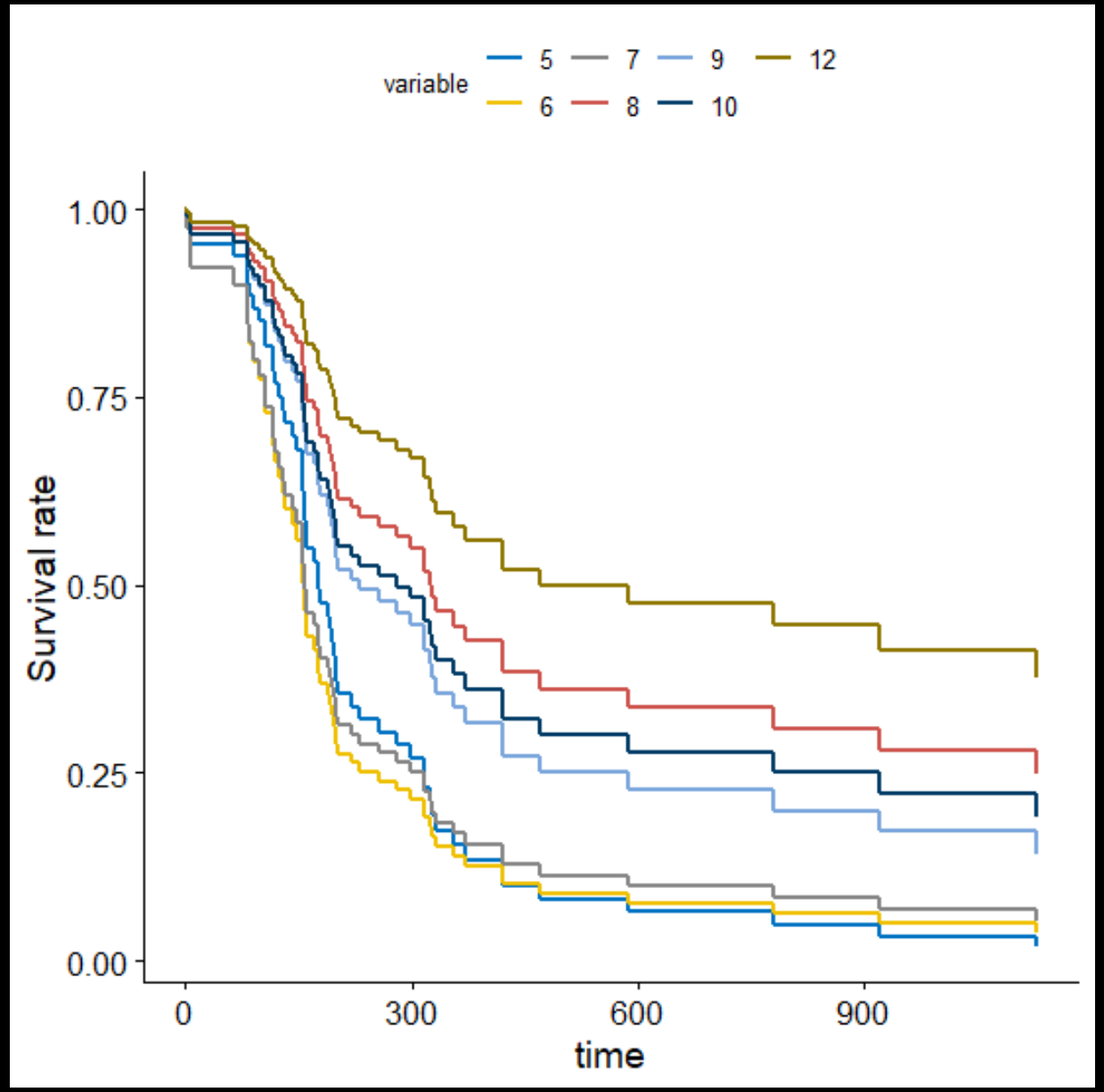
Cox Regression Analysis



Diameter 8-12mm vs 5-7mm



Diameter Adjusted Patency Curves



Conclusion

In this European Multi-center Retrospective Analysis, Drug-Coated Balloons used for the treatment of symptomatic Central Venous Stenosis in Dialysis patients was safe.

Efficacy was comparable to previous RCTs.

Balloon Size had a significant effect on patency rates.


ENDO
VASCULAR
ACCESS
EVA
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