PCB for Symptomatic CVS of DA

Randomized Control Trial

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Disclosure

Speaker name:

Dr. D. Karnabatidis

I have the following potential conflicts of interest to report:

- ☒ Consulting (Bard, Medtronic, Boston, Alvimedica, Rondis)
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

Facts &Figures

Anatomic location (Distal to cephalic arch):

Subclavian

Brachiocephalic

SVC

Main cause of CVS in dialysis patients:

Prior insertion of foreign materials

(CVCs, PICCs, Ports, Cardiac-Rhythm Related Devices)

Stenosis of venous outflow due to dialysis use

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.

Facts &Figures

PTA first (Technical failure: 10-30%)

Patency Rates:

- 28.9% @ 6 months
- 25% @ 1 year

High-Pressure Balloon PTA

Patency Rates:

- 60% @ 6 months
- 30% @ 1 year (60% with repeated angioplasty BUT no stent placement)

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

PCB in Dialysis Access

2015 Kitrou et al EJR (prospective):

40 patients (AVF+AVG) – 20 DCB

@12 months: 35% vs. 5% ($p<0.001$)

2015 Kitrou et al JVIR (prospective):

40 patients (AVF) – 20 DCB

@12months: 20% vs. 0% ($p=0.03$)

2017 Kitrou et al CVIR (retrospective):

39 pts (AVF+AVG) – 39 DCB

@6 months: 72.2%

The Study

CLINICAL STUDY

Paclitaxel-Coated Balloons for the Treatment of Symptomatic Central Venous Stenosis in Dialysis Access: Results from a Randomized Controlled Trial

Panagiotis M. Kitrou, MD, MSc, PhD, Panagiotis Papadimatos, MD, Stavros Spiliopoulos, MD, PhD, Konstantinos Katsanos, MD, MSc, PhD, Nicolaos Christeas, MD, Elias Brountzos, MD, PhD, and Dimitrios Karnabatidis, MD, PhD

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Purpose

To compare the Safety and Effectiveness

Of PCB vs. PTA for the treatment

Of Symptomatic Central Venous Stenosis

Of AVGs and AVFs

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Inclusion Criteria

Symptomatic Central Venous Stenosis

Ipsilateral AVGs + AVFs

Distal to Cephalic Arch (Subclavian, Brachiocephalic, VC)

Angiographic Verification

De Novo + Restenosis

Multiple Stenosis treated

"Real Life Inclusion Criteria"

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Devices

PCB group:

Lutonix® 035 (C.R.BARD New Jersey, USA)

PTA group:

Atlas Gold, Conquest, Dorado, Mustang etc

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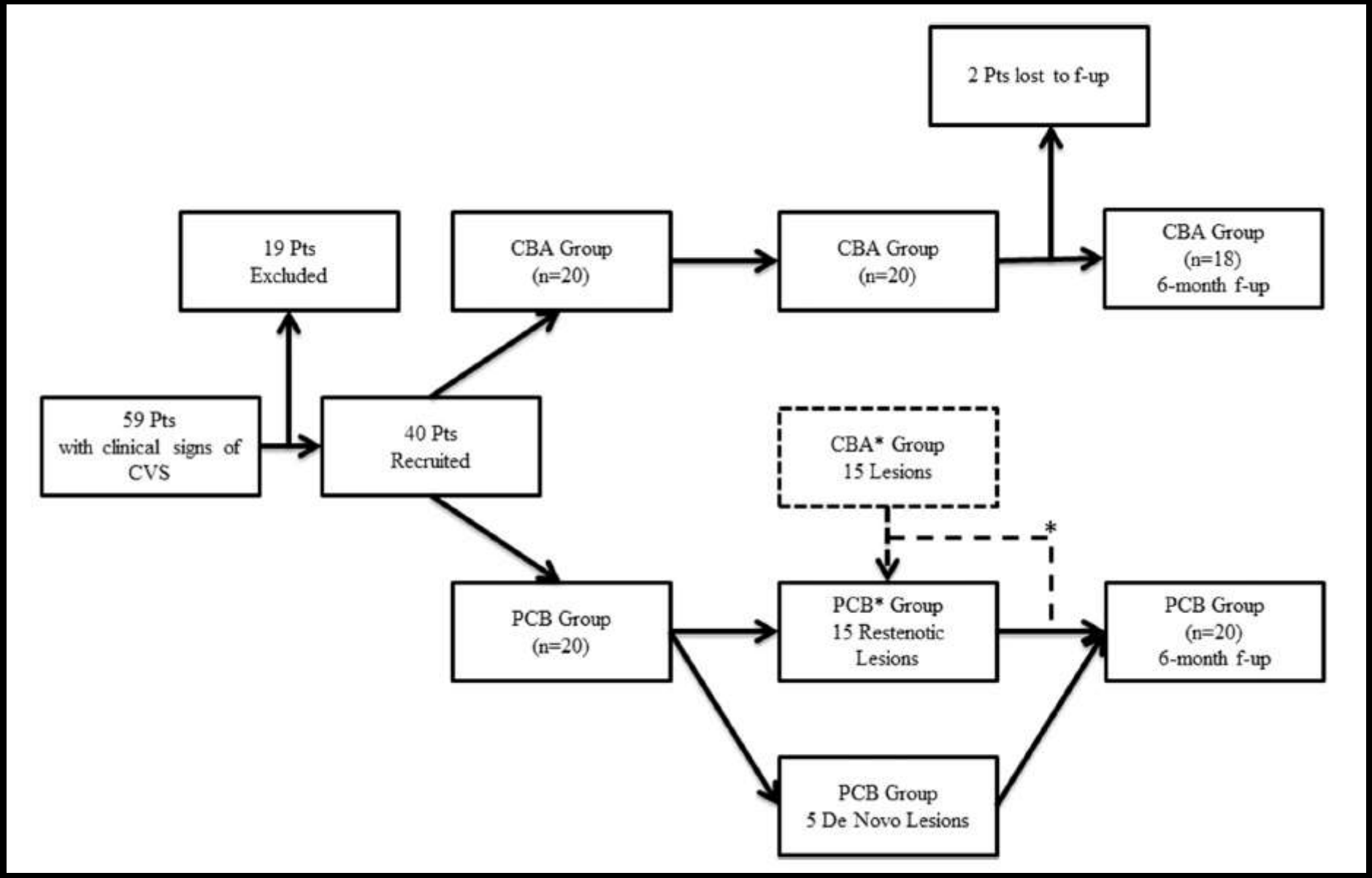
Flowchart



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Endpoints

Primary:

Clinically-assessed Intervention-Free Period (IFP)

@ 6 months

Secondary:

Minor or Major Complications

Longitudinal Comparison of treatments

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Baseline Variables

40 pts (20 pts in each group)

20 months recruitment period

Baseline variables equally distributed b/w groups

Two patients from PTA group were lost to f-up

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Baseline Variables

	Group PCB	Group PTA	
Number of pts	20	20	
Male	13	14	n.s.
Vascular Access			
AVG	10	11	n.s.
AVF	10	9	n.s.
Age	2.83	2.42	n.s.
Prior CVC insertion	13	12	n.s.
De novo lesions	5	8	n.s.
Lesion site			
Subclavian	12	13	n.s.
Anonymous	5	5	n.s.
SVC	3	2	n.s.

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Baseline Variables

For PCB Group

23 devices in 20 patients

15 used in 12 Subclavian veins

4 in Brachiocephalic Vein

4 in Superior Vena Cava

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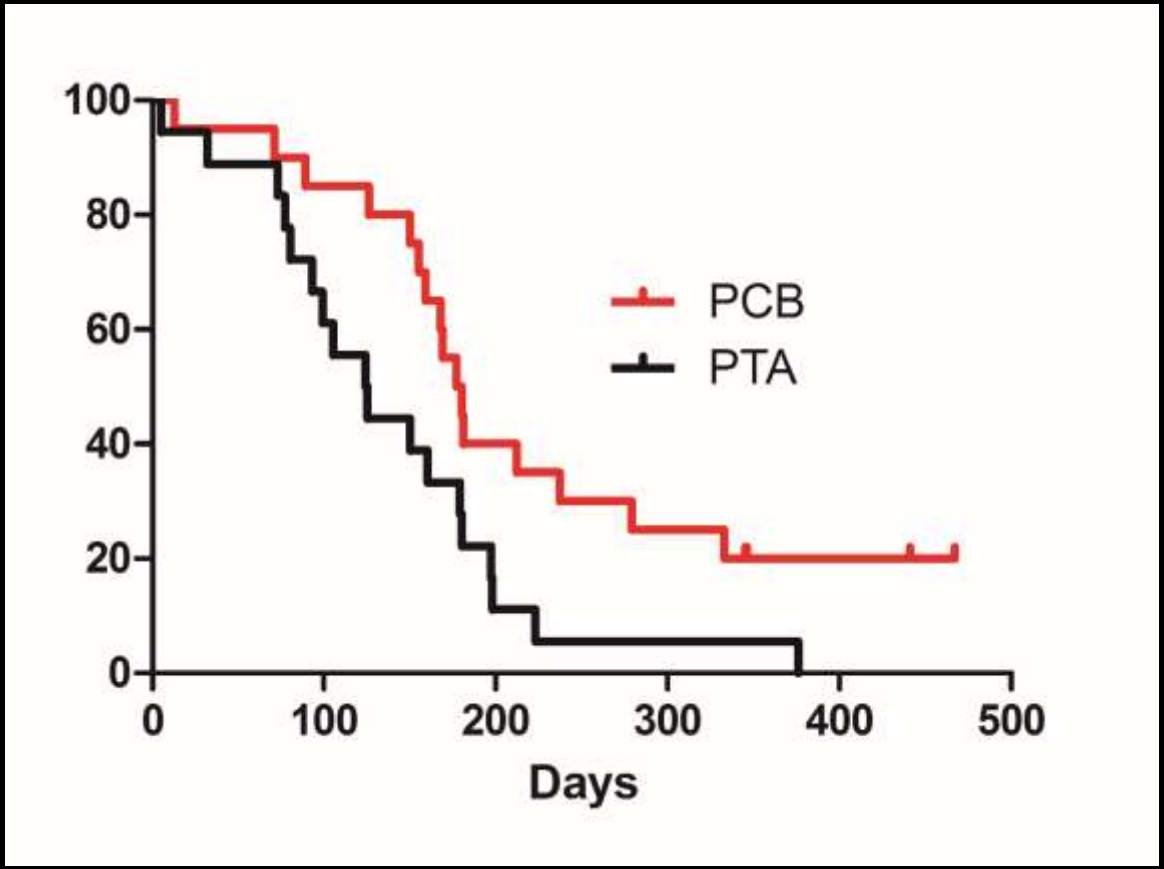
Results

PCB vs. PTA



Median Survival: PCB group 179days vs. 124.5days PTA group

HR: 0.4212 (CI: 0.2041 – 0.8690); p=0.019 (Log-rank Mantel-Cox Test)

@ 6months: 50% (10/20) vs. 28.5% (4/18)

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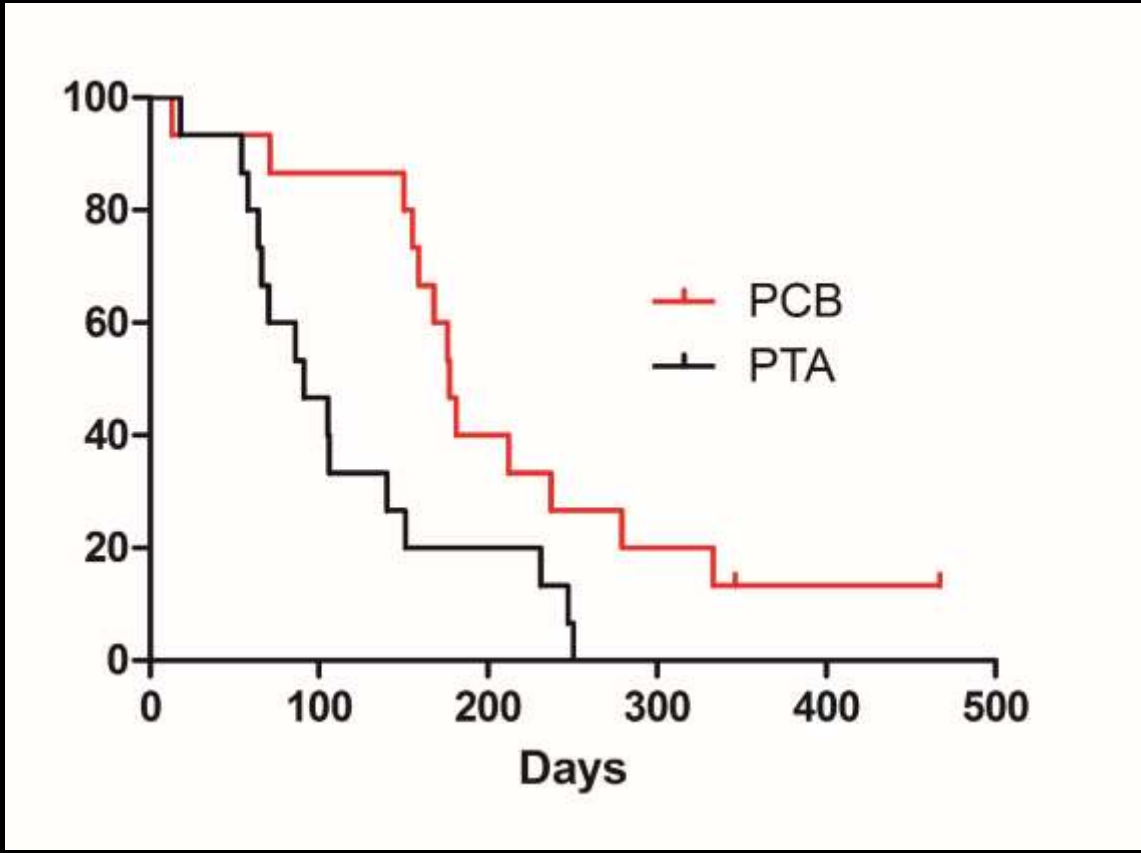
Longitudinal Analysis



Median Survival: PCB group 177days vs. 91days PTA group

HR: 0.3384 (CI: 0.1479 – 0.7742); p=0.01 (Log-rank Mantel-Cox Test)

15 cases of restenosis in PCB group

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Limitations

Small number of patients

Unable to perform sub-group analysis in order to answer certain interesting questions

Single-Center

No Core Lab

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Conclusion

In this RCT, PCBs had significantly better results compared to PTA in the treatment of symptomatic central venous stenosis of vascular access

Larger multi-center trials with larger number of subjects are needed to prove abovementioned results in order to change standard of practice

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