How I use DCB for AV access maintenance

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Disclosures

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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
“The only real valuable thing is intuition.”

-Albert Einstein
Don't trust your gut all the time.

by Favio Vázquez
Drug-Coated Balloon Angioplasty in Hemodialysis Circuits: A Systematic Review and Meta-Analysis.

Kennedy SA, Malhotra SY, Baehner MP, Jabar A, Rajan CR.

Abstract

PURPOSE: To perform a systematic review and meta-analysis assessing patency outcomes following drug-coated balloon angioplasty (DCBA) in hemodialysis circuits.

MATERIALS AND METHODS: MEDLINE and EMBASE systematic searches were performed from inception to November 2018 to identify comparative studies assessing DCBA vs plain old balloon angioplasty (POBA) in hemodialysis circuits. Abstract selection, data extraction, and quality assessment were performed by 2 independent reviewers. Primary analyses were performed by 2 independent reviewers.

RESULTS: Twelve studies comprising 698 patients were included. There was a significant improvement in patency among AVF after DCBA vs POBA at 3, 6, 12, and 24 months (odds ratio 0.56 [95% confidence interval 0.36-0.84]; odds ratio 0.40 [95% confidence interval 0.23-0.70]; odds ratio 0.39 [95% confidence interval 0.25-0.61]; and odds ratio 0.20 [95% confidence interval, 0.07-0.59]). This benefit persisted on subgroup analysis of randomized controlled trials (RCTs). Meta-analyses of results specific to AVFs could not be performed, as only 1 RCT was identified that reported DCBA. Hemodialysis-associated central venous stenosis did not demonstrate a significant difference in patency rates between DCBA and POBA on meta-analysis. Twelve-month mortality and same-day complication rates did not differ between arms.

CONCLUSIONS: Significant improvement in patency was identified with DCBA in AVF at 3, 6, 12, and 24 months. A single comparative study identified benefit of DCBA use in the AVG group. No significant benefit was identified with DCBA for central veins.

IN.PACT AV Access - 6-month Kaplan-Meier Plots

Target Lesion Primary Patency

Access Circuit Primary Patency

The Lutonix AV Randomized Trial of Paclitaxel-Coated Balloons in Arteriovenous Fistula Stenosis: 2-Year Results and Subgroup Analysis

Scott O. Trerotola, MD, Theodore F. Saad, MD, and
Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos, MD, PhD, MSc, EBIR; Stavros Spiliopoulos, MD, PhD; Panagiotis Kitrou, MD, PhD; Miltiadis Krokidis, MD, PhD; Dimitrios Karnabatidis, MD, PhD

Background—Several randomized controlled trials (RCTs) have already shown that paclitaxel-coated balloons and stents significantly reduce the rates of vessel restenosis and target lesion revascularization after lower extremity interventions.

Methods and Results—A systematic review and meta-analysis of RCTs investigating paclitaxel-coated devices in the femoral and/or popliteal arteries was performed. The primary safety measure was all-cause patient death. Risk ratios and risk differences were pooled with a random effects model. In all, 28 RCTs with 4663 patients (89% intermittent claudication) were analyzed. All-cause patient death at 1 year (28 RCTs with 4432 cases) was similar between paclitaxel-coated devices and control arms (2.3% versus 2.3% crude risk of death; risk ratio, 1.08; 95% CI, 0.72–1.61). All-cause death at 2 years (12 RCTs with 2316 cases) was significantly increased in the case of paclitaxel versus control (7.2% versus 3.8% crude risk of death; risk ratio, 1.88; 95% CI, 1.15–2.47; number-needed-to-harm, 29 patients [95% CI, 19–59]). All-cause death up to 5 years (3 RCTs with 863 cases) increased further in the case of paclitaxel (14.7% versus 8.1% crude risk of death; risk ratio, 1.93; 95% CI, 1.27–2.93; number-needed-to-harm, 14 patients [95% CI, 9–32]). Meta-regression showed a significant relationship between exposure to paclitaxel (dose-time product) and absolute risk of death (0.4±0.1% excess risk of death per paclitaxel mg-year; P<0.001). Trial sequential analysis excluded false-positive findings with 99% certainty (2-sided α, 1.0%).

Conclusions—There is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs. Further investigations are urgently warranted.

Clinical Trial Registration—URL: www.ord.york.ac.uk/PROSPERO. Unique identifier: CRD42018099447. (J Am Heart Assoc. 2018;7:e011245. DOI: 10.1161/JAHA.118.011245.)
Risk of Death and Amputation with Use of Paclitaxel-Coated Balloons in the Infrapopliteal Arteries for Treatment of Critical Limb Ischemia: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos, MD, MSc, PhD, Stavros Spiliopoulos, MD, PhD, Panagiotis Kitrou, MD, PhD, Miltiadis Krokidis, MD, PhD, Ioannis Paraskevopoulos, MD, PhD, and Dimitrios Karnabatidis, MD, PhD

ABSTRACT

A formal systematic review and study-level meta-analysis of randomized controlled trials investigating treatment of the infrapopliteal arteries with paclitaxel-coated balloons compared with conventional balloon angioplasty for critical limb ischemia (CLI) was conducted. Medical databases and online content were last searched in September 2019. The primary safety and efficacy endpoint was amputation-free survival defined as freedom from all-cause death and major amputation. Target lesion revascularization (TLR) constituted a secondary efficacy endpoint. Summary effects were synthesized with a random-effects model. Some 8 randomized controlled trials with 1,420 patients (97% CLI) were analyzed up to 1 year follow-up. Amputation-free survival was significantly worse in case of paclitaxel (13.7% crude risk of death or limb loss compared to 9.4% in case of uncoated balloon angioplasty; hazard ratio 1.52; 95% confidence interval: 1.12–2.07, p = .008). TLR was significantly reduced in case of paclitaxel (11.8% crude risk of TLR versus 25.6% in control; risk ratio 0.53; 95% confidence interval: 0.35–0.81, p = .004). The harm signal was evident when examining the high-dose (3.0–3.5 μg/mm²) devices, but attenuated below significance in case of a low-dose (2.0 μg/mm²) device. Actual causes remain largely unknown, but non-target paclitaxel embolization is a plausible mechanism.
YOU'VE PISSED ME OFF NOW
Paclitaxel-coated Angioplasty: A Comparative Study

Norman H. Kumins, MD
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ABSTRACT
Objective: Long-term safety and effectiveness of paclitaxel-coated angioplasty using the IN.PACT AV DCB compared to standard percutaneous transluminal angioplasty (PTA) for femoropopliteal peripheral artery disease.

Methods: We conducted a prospective, randomized, multicenter study comparing the safety and efficacy of the IN.PACT AV DCB to standard PTA in patients with femoropopliteal peripheral artery disease. The primary outcome was freedom from all-cause death, major amputation, and target lesion revascularization at 3 years. The secondary outcomes included adverse events and quality of life assessments.

Results: In the study group, the IN.PACT AV DCB was associated with superior outcomes compared to standard PTA. The freedom from all-cause death at 3 years was 90.6% for the IN.PACT AV DCB versus 90.4% for standard PTA (log-rank p-value = 0.931). The incidence of major amputation and target lesion revascularization was significantly lower in the IN.PACT AV DCB group. No significant differences were observed in terms of adverse events or quality of life assessments.

Conclusions: The IN.PACT AV DCB is an effective and safe treatment option for femoropopliteal peripheral artery disease, offering superior outcomes compared to standard PTA. Further research is needed to evaluate the long-term benefits and cost-effectiveness of this novel technology.

Keywords: Paclitaxel-coated angioplasty, femoropopliteal disease, in-stent restenosis, end-stage renal disease, pulseless electrical activity.
EXTRA! EXTRA!
INNOCENT
UNTIL
PROVEN
GUILTY
Our Algorithm

AVF Dysfunction with indication for PTA / Regardless of lesions location

>2 per year / or less than 6 months interval
No evidence of extrinsic compression
Intimal Hyperplasia on Ultrasound
Stented Lesions

First PTA or not very frequent

POBA - long (3 minutes – repeated) inflations and no residual stenosis is very important for good results

DCB – cover the entire length of the lesion

POBA Regular balloons with high RBP and if needed high pressure balloons

Consider covered stents for stented and highly recurrent lesions that do not respond to DCB
Patient 1
Patient 1
Patient 2
Patient 2
Our Recommendations

• Cautious use of DCB acceptable – effective and should be considered when POBA PTA is not lasting enough

• Reduction of interventions
  – Patient satisfaction, quality of life and comfort
  – Secondary prevention of AVF thrombosis & morbidity
  – Cost saving
Thank you for your attention
How I use DCB for AV access maintenance

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