SOCIEDADE BRASILEIRA
DE ANGIOLOGIA E DE CIRURGIA VASCULAR

REGIONAL DO RIO GRANDE DO SUL

DRUG ELUTING BALLOON ANGIOPLASTY IN ARTERIOVENOUS FISTULA FAILURE

Nicola Troisi, MD

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GUIDELINES

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Guidelines

EDTA Guidlines
The guidelines of the EDTA can be find here (English) >

Spanish Clinical Guidelines on Vascular Access for Haemodialysis.
The clinical guidelines on Vascular Access for Haemodialysis can be find here >
(Spanish version, the English version will be available soon)

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GUIDELINES – VAS 2007

Nephrol Dial Transplant (2007) 22 [Suppl 2]: ii88–ii117
doi:10.1093/ndt/gfm021

NDT
Nephrology Dialysis Transplantation

EBPG on Vascular Access

Jan Tordoir[1], Bernard Canaud[2], Patrick Haage[3], Klaus Konner[4], Ali Basci[5], Denis Fouque[6], Jeroen Kooman[7], Alejandro Martin-Malo[8], Luciano Pedrini[9], Francesco Pizzarelli[10], James Tattersall[11], Marianne Vennegoor[12], Christoph Wanner[13], Piet ter Wee[14] and Raymond Vanholder[15]

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GUIDELINES – VAS 2007

7. Treatment of stenosis and thrombosis in AV fistulae and AV grafts

Guideline 7.1. For venous outflow stenosis percutaneous transluminal angioplasty (PTA) is the first treatment option (Evidence level III).

Guideline 7.2. Thrombosed autogenous and graft fistulae should be treated either by interventional radiology or surgery. Individual centres should review their results and select the modality that produces the best results for that centre (Evidence level III).

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GUIDELINES – VAS 2007

7. Treatment of stenosis and thrombosis in AV fistulae and AV grafts

Recommendations for further research

Development of better catheter and balloon designs and (drug-eluting) stents may improve the outcome of interventional access treatment.

GUIDELINES – VAS 2007

7. Treatment of stenosis and thrombosis in AV fistulae and AV grafts

2007!!!!!!!!!!

Recommendations for further research

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GUIDELINES – GEMAV 2017

NEFROLOGIA 2017; 37(Supl 1):1-192

nefrología
Revista de la Sociedad Española de Nefrología
www.revistanefrologia.com

Guía Clínica Española del Acceso Vascular para Hemodiálisis

José Ibeas[a,], Ramon Roca-Tey[b], Joaquín Vallespín[c], Teresa Moreno[d], Guillermo Moñux[e], Anna Martí-Monrós[f], José Luis del Pozo[g], Enrique Gruss[h], Manel Ramírez de Arellano[i], Néstor Fontseré[j], María Dolores Arenas[k], José Luis Merino[l], José García-Revillo[m], Pilar Caro[n], Cristina López-Espada[ñ], Antonio Giménez-Gaibar[c], Milagros Fernández-Lucas[o], Pablo Valdés[p], Fidel Fernández-Quesada[ñ], Natalia de la Fuente[q], David Hernán[r], Patricia Arribas[s], María Dolores Sánchez de la Nieta[t], María Teresa Martínez[u], Ángel Barba[q]; por el Grupo Español Multidisciplinar del Acceso Vascular (GEMAV)*

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GUIDELINES – GEMAV 2017

5.1. Tratamiento de la estenosis

Recomendaciones

(•) NUEVA R 5.1.1) *Se sugiere el tratamiento quirúrgico en las estenosis yuxtaanastomóticas de las fístulas arteriovenosas nativas, siempre que no requiera la colocación de un catéter venoso central*

(•) NUEVA R 5.1.2) *Se sugiere el tratamiento de las estenosis yuxtaanastomóticas venosas de las fístulas arteriovenosas protésicas mediante angioplastia o tratamiento quirúrgico indistintamente*

NUEVA R 5.1.3) *Se sugiere inicialmente el tratamiento mediante angioplastia de la estenosis no yuxtaanastomóticas de la fístula arteriovenosa nativa por ser menos invasiva que la cirugía*

R 5.1.4) *Se recomienda la realización de una fistulografía ante la sospecha clínica de una estenosis venosa central*

(•) NUEVA R 5.1.5) *Se recomienda tratar solo las estenosis de venas centrales que sean sintomáticas*

(•) NUEVA R 5.1.6) *Se recomienda como primera opción de tratamiento en las estenosis centrales la terapia endovascular mediante angioplastia transluminal percutánea con balón*

(•) NUEVA R 5.1.7) *Se sugiere limitar la utilización de stents a casos seleccionados de fracaso técnico de la angioplastia y recidiva frecuente de la estenosis, y se recomienda no utilizarlos en confluentes venosos*

NUEVA R 5.1.8) *En las estenosis del arco de la vena cefálica se sugiere el tratamiento inicial mediante angioplastia; asimismo se puede considerar el tratamiento mediante la colocación de endoprótesis vasculares o mediante la transposición quirúrgica de la vena cefálica*

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ELSEVIER

Tech Vasc Interventional Rad 20:2-8 Published by Elsevier Inc.

Techniques in Vascular and Interventional Radiology

Vascular Access Guidelines: Summary, Rationale, and Controversies

Adrian Sequeira, MD,* Mihran Naljayan, MD,† and Tushar J. Vachharajani, MD, FASN‡

Future Direction

Guidelines and protocols will continue to evolve with improved understanding of access pathophysiology, better tools for endovascular therapy, and better training opportunities for all stakeholders.

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BACKGROUND

JVasc Access 2014; 15 (6): 439-447
DOI: 10.5301/jva.5000271

REVIEW

The eternal tale of dialysis access vessels and restenosis: are drug-eluting balloons the solution?

Rupert H. Portugaller, Peter I. Kalmar, Hannes Deutschmann

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ABSTRACT

In dialysis access fistulas and grafts, percutaneous transluminal angioplasty (PTA) is frequently followed by restenosis development, which results in repeated periodical re-interventions. The technique of drug-eluting balloon (DEB) angioplasty has shown promising results in the treatment of femoropopliteal arteriosclerotic lesions. In contrast to arteriosclerotic arteries, dialysis access vessels host unfavorable hemodynamics due to the direct conduction of high-pressure fluid into a low-pressure system. Hence, the beneficial effect of DEB angioplasty may be limited in this system. However, a first prospective randomized trial on 40 patients with arteriovenous fistula or graft stenoses exhibited a significantly higher 6-month primary patency of the treated lesions after DEB angioplasty than after uncoated balloon angioplasty

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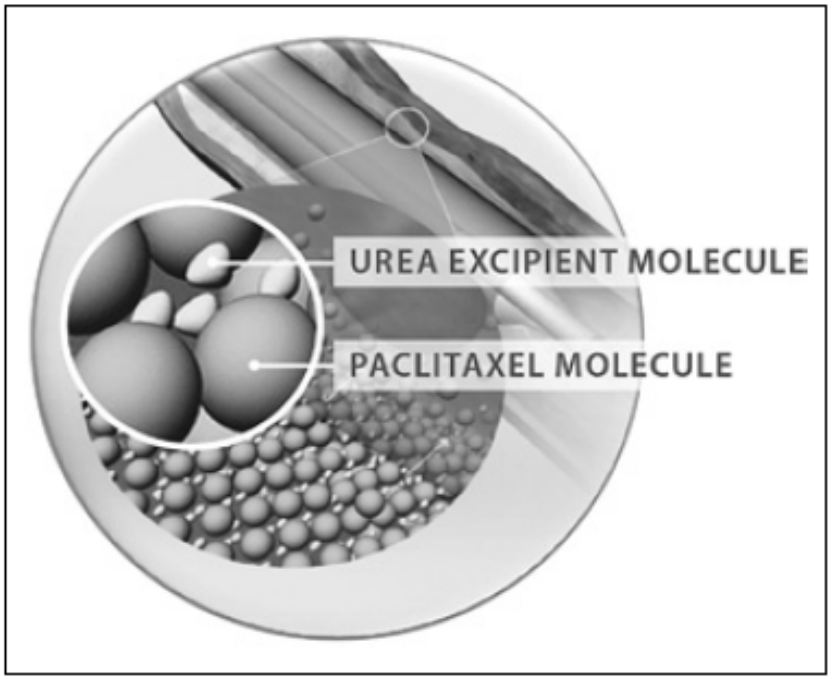
BACKGROUND

The eternal tale of dialysis access vessels and restenosis: are drug-eluting balloons the solution?

Endothelial cells are supposed to terminate intimal proliferation by releasing nitric oxide (NO) and heparin sulfate, which both have shown to inhibit smooth muscle cell growth *in vitro* (11-13). NO decreases the synthesis of collagen by VSMCs and the recruitment of circulating inflammatory cells, which have the potential to release growth factors as well (14, 15). However, after repeated mechanical injury, endothelial cells lose their ability to synthesize NO (16). Ongoing mechanical stress and injuries are frequent features in artificial vascular environments such as arterial bypasses and hemodialysis fistulas and grafts.

BACKGROUND

The eternal tale of dialysis access vessels and restenosis: are drug-eluting balloons the solution?



transfer (62). The coating of a DEB usually consists of the drug itself, most commonly paclitaxel, and an excipient such as urea, iopromide, or shellac designed to attach the drug to the balloon and to permit a uniform penetration of the drug into the vessel wall (Fig. 3) (58, 63, 64). A variety of excipients have already been tested; however, no consensus has yet been achieved regarding the optimal drug carrier matrix for DEBs (65). In a recent animal experiment, phospholipid-based nano-spheres revealed potential to transfer great amounts of an anti-proliferative drug to all layers of the vessel wall with consecutive high tissue concentrations that persisted days after application (66).

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RANDOMIZED TRIAL

Paclitaxel-Coated Balloon Angioplasty vs. Plain Balloon Dilation for the Treatment of Failing Dialysis Access: 6-Month Interim Results From a Prospective Randomized Controlled Trial

Konstantinos Katsanos, MSc, MD, PhD, EBIR; Dimitris Karnabatidis, MD, PhD; Panagiotis Kitrou, MD; Stavros Spiliopoulos, MD, PhD; Nikolaos Christeas, MD; and Dimitris Siablis, MD, PhD

Department of Diagnostic and Interventional Radiology, Patras University Hospital, School of Medicine, Rion, Greece.

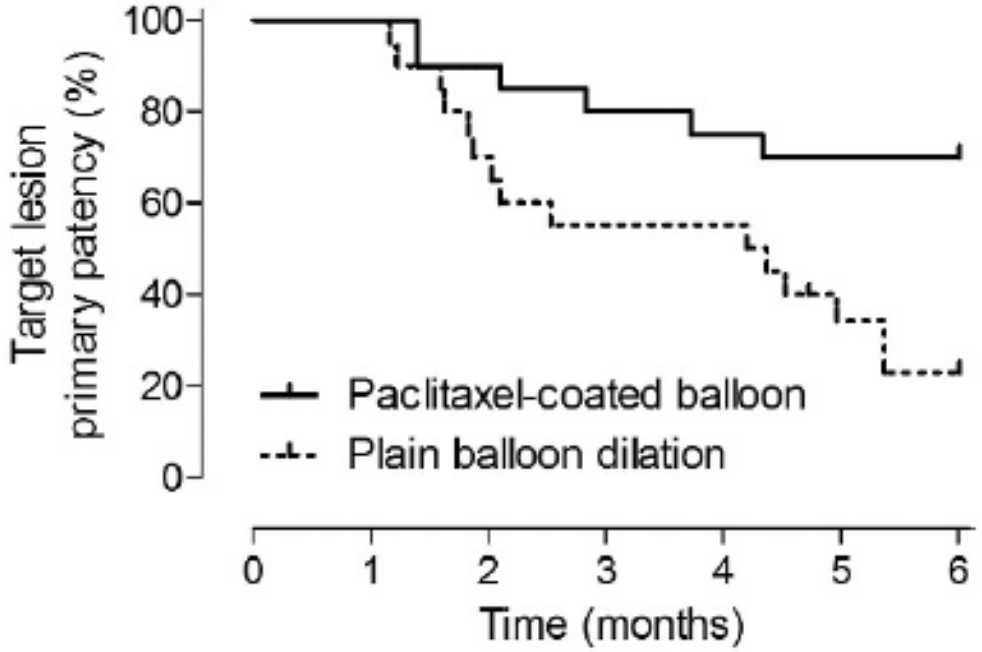
Methods: The enrollment criteria for this non-inferiority hypothesis trial included clinical signs of failing dialysis access with angiographic documentation of a significant venous stenotic lesion in patients with AVF or AVG circuits. From March to December 2010, 40 patients (29 men; mean age 64.1±14.3 years) were randomized to undergo either PCB dilation (n=20) or standard BA (n=20) of a stenosed venous outflow lesion. Regular

Conclusion: PCB angioplasty improves patency after angioplasty of venous stenoses of failing vascular access used for dialysis.

J Endovasc Ther. 2012;19:263–272

RANDOMIZED TRIAL

Paclitaxel-Coated Balloon Angioplasty vs. Plain Balloon Dilation for the Treatment of Failing Dialysis Access:
6-Month Interim Results From a Prospective Randomized Controlled Trial



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COST-EFFECTIVENESS

Contents lists available at ScienceDirect

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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)

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

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unadjusted HR = 0.27 [95%CI: 0.13–0.58]; Cox adjusted HR = 0.23 [95%CI: 0.10–0.50]). ICER was 2198 Euros (€) per primary patency year of dialysis access gained. INB was 1068€ (95%CI: 31–2105€) for a willingness-to-pay (WTP) threshold of 5000€ (corresponding acceptability probability >97%).
Conclusion: DEB angioplasty may be a cost-effective option that significantly improves patency after angioplasty of venous stenoses of failing vascular dialysis access. Further large-scale randomized trials are warranted.

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IN-STENT STENOSIS

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ISSN 1129-7298

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DOI: 10.5301/jva.5000396

ORIGINAL ARTICLE

Open Access

Paclitaxel drug-eluting balloons to recurrent in-stent stenoses in autogenous dialysis fistulas: a retrospective study

Jan "John" Swinnen[1], Assad Zahid[2], David C.A. Burgess[3]

[1] Department of Surgery, Westmead Hospital, Wentworthville, Sydney, NSW - Australia
[2] Westmead Hospital, Westmead, NSW - Australia
[3] Blacktown Hospital, Blacktown, NSW - Australia

Results: From 1 September 2010 to 1 December 2013, we treated 625 AVF stenoses with endovascular techniques. In 86 of these stenoses, DEBs were used. Of the 86 DEB interventions, 37 were included for this study, 49 were excluded. In the study group, there was a significant difference in "re-intervention-free percentage at 12 months" before and after DEB: 19% vs. 69%. The hazard ratio for "DEBpresent" vs. "DEBabsent" was 0.23 (95% CI 0.14 to 0.36, p<0.001).

Conclusions: This retrospective study suggests that DEBs significantly reduce re-intervention on recurrent in-stent AVF stenoses.

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IN-STENT STENOSIS

Paclitaxel drug-eluting balloons to recurrent in-stent stenoses in autogenous dialysis fistulas: a retrospective study

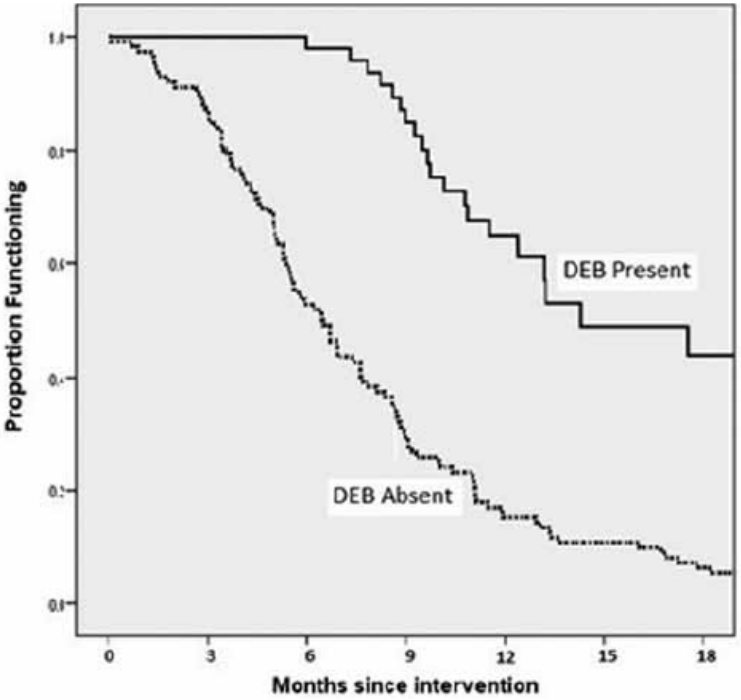

Fig. 3 - The marginal proportional hazards model for drug-eluting balloon present vs. absent across the multiple recurrences observed for each lesion. The hazard ratio for DEB present vs. absent was 0.23 (95% CI 0.14 to 0.36, p<0.001).

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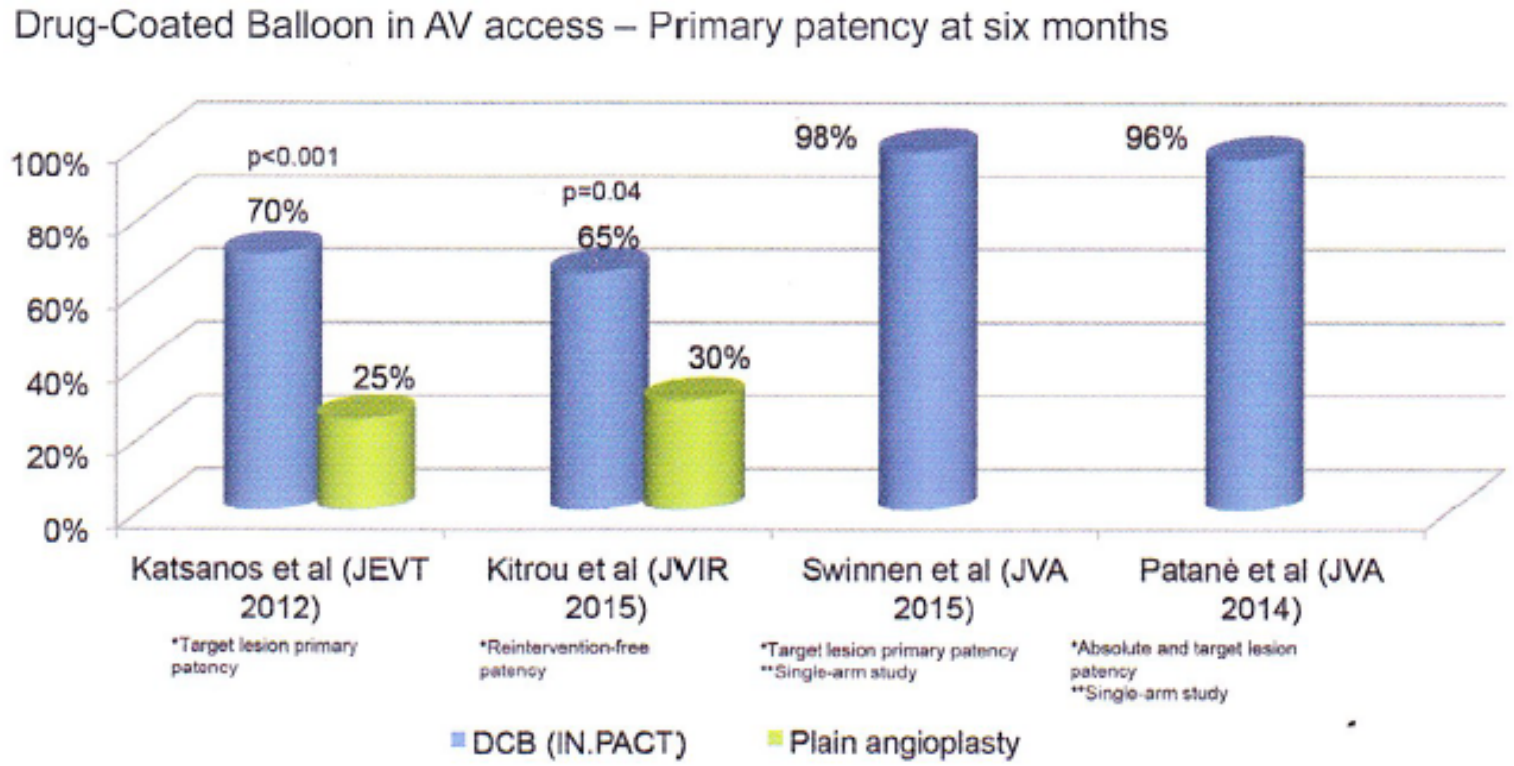
SUMMARY



vascularnews April 2016

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DECISIONAL ALGORITHM

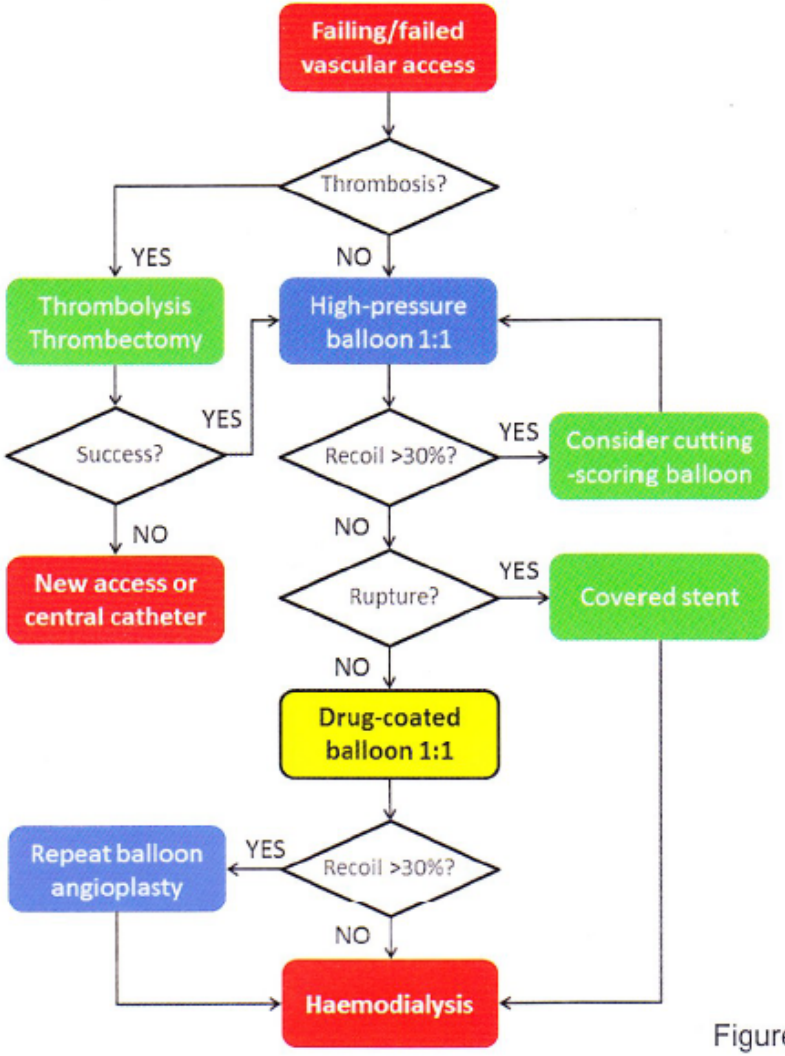

Figure 1

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April 2016

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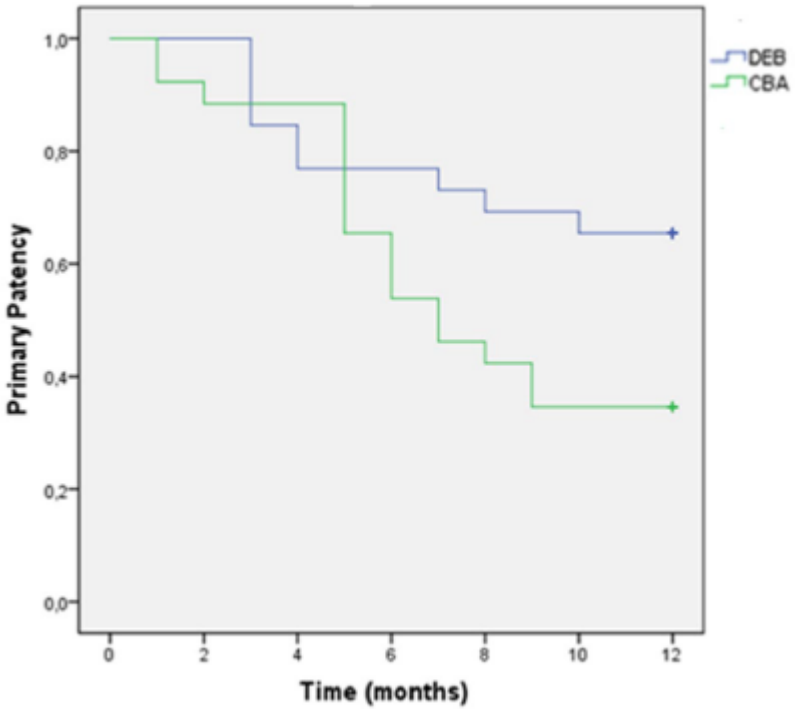
FREEWAY DCBs 2016

The primary patency of drug-eluting balloon versus conventional balloon angioplasty in hemodialysis patients with arteriovenous fistula stenoses

Received: 22 February 2016 / Accepted: 15 August 2016

Mehmet Burak Çildağ[1] · Ömer Faruk Kutsi Köseoğlu[1] · Hakan Akdam[2] · Yavuz Yeniçerioğlu[2]



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MIXED DCBs 2017

International Angiology 2017 ????;36(??):000-000
DOI: 10.23736/S0392-9590.17.03886-X

ORIGINAL ARTICLE

Drug-coated balloons reduce the risk of recurrent restenosis in arteriovenous fistulas and prosthetic grafts for hemodialysis

Nicola TROISI [1] *, Pierfrancesco FROSINI [1], Chiara SOMMA [2], Eugenio ROMANO [1], Azzurra GUIDOTTI [1], Pietro C. DATTOLO [2], Giuseppe FERRO [2], Emiliano CHISCI [1], Stefano MICHELAGNOLI [1]

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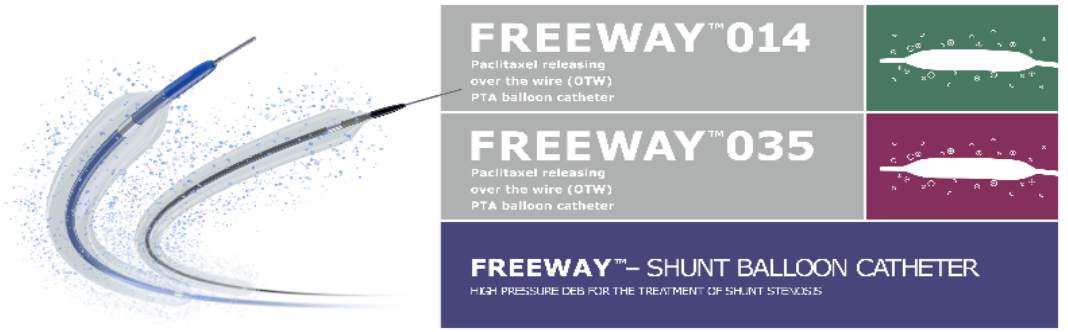
OUR FREEWAY STUDY



Aim of this study was to evaluate the early and mid-term outcomes of drug-coated balloons (DCBs) in hemodialysis patients with recurrent stenosis of arteriovenous fistula, paying particular attention to their impact to the risk of new restenosis and the time to the new restenotic lesion

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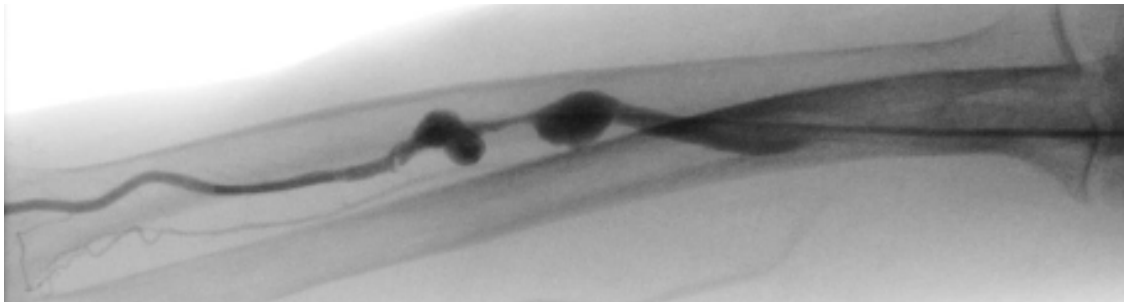
METHODS



- ✓ Between July 2013 and December 2016 27 hemodialysis patients with recurrent stenosis of arteriovenous fistula underwent endovascular treatment with a DCB at our center

- ✓ All patients were previously treated at the target lesion with a standard balloon angioplasty (BA)

- ✓ All data concerning the procedures were prospectively collected in a dedicated database with about 80 fields

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STATISTICAL ANALYSIS

- ✓ The intervals in months between the standard BA and the procedure with DCB (time BA-DCB) and between the procedure with DCB and the new restenotic lesion (time DCB-restenosis) were evaluated and compared with T-test

- ✓ Estimated outcomes at 2 years in terms of survival, primary patency, primary assisted patency, secondary patency, and freedom from target lesion restenosis were assessed with Kaplan-Meier curves

- ✓ Statistical significance was defined at the P <.05 level

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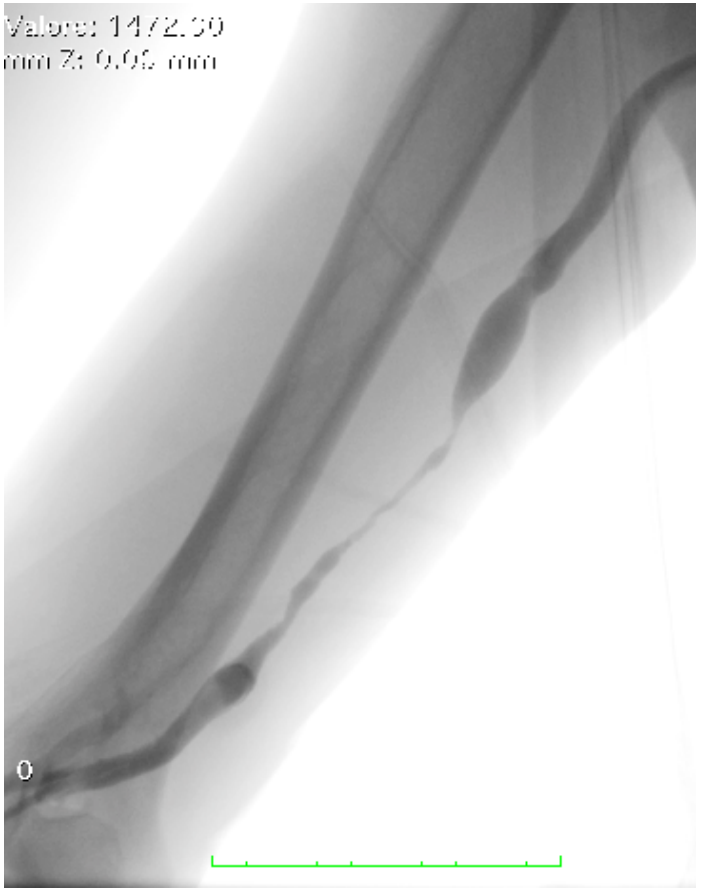
RESULTS - AVF

- Most of patients were males (15, 55.6%) with a mean age of 66.1 years (range 13-90)
- Arteriovenous fistula was distal in 8 cases (29.6%), mid-arm in 3 cases (11.1%), and proximal in 16 cases (59.3%)
- In 4 cases (14.8%) a prosthetic graft was present



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RESULTS - INTRAOPERATIVE

- In all patients a predilatation was performed (in 2 cases with cutting balloon)
- Intraprocedural technical success was obtained in 96.3% of the cases
- In one patient the procedure was interrupted due to acute recoil and massive bleeding at the access site

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FOLLOW-UP – ABSENCE OF TLR

- During the follow-up (mean duration 13.6 months, range 2-33) 13 patients (48.1%) developed a new restenotic lesion with an estimated 2-year absence of TLR of 30.2%

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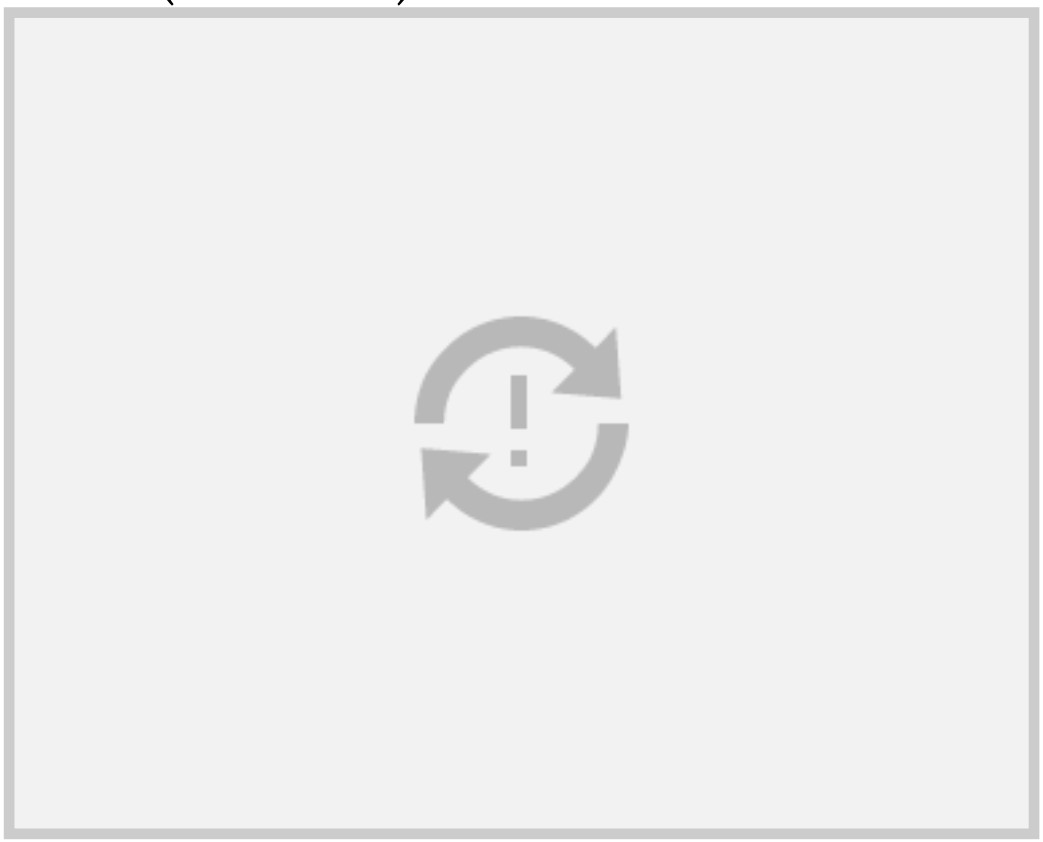
FOLLOW-UP – RESTENOSIS

- Mean time BA-DCB was 4.8 months, and the mean time DCB-restenosis was 7.6 months with a statistically significant difference at T-test (P<0.001)



FOLLOW-UP – 2-YEAR OUTCOMES

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FOLLOW-UP – 2-YEAR OUTCOMES

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FOLLOW-UP – 2-YEAR OUTCOMES

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CONCLUSIONS

- ✓ In our experience DCBs were effective in the treatment of recurrent stenosis in hemodialysis patients with failing arteriovenous fistula

- ✓ During the follow-up about half of patients had no new restenosis at the target lesion

- ✓ Furthermore, the time to a new restenosis was much longer compared to recurrence of stenosis after standard balloon angioplasty

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PAPER IN PRESS

Online version at http://www.minervamedica.it

Minerva Cardioangiologica 2017 ????;65(??):000-000
DOI: 10.23736/S0026-4725.17.04534-0

ORIGINAL ARTICLE

Freeway paclitaxel-releasing balloons to treat recurrent stenosis of arteriovenous fistula in hemodialysis patients

Nicola TROISI *, Piefrancesco FROSINI, Eugenio ROMANO, Azzurra GUIDOTTI, Emiliano CHISCI, Stefano MICHELAGNOLI

Department of Surgery, Unit of Vascular and Endovascular Surgery, San Giovanni di Dio Hospital, Florence, Italy

*Corresponding author: Nicola Troisi, Department of Surgery, Unit of Vascular and Endovascular Surgery, San Giovanni di Dio Hospital, Via di Torregalli 3, 50143 Florence, Italy. E-mail: troisimd@gmail.com

TAKE HOME MESSAGE

✓ The great difference in terms of primary, primary assisted and secondary patencies at 2 years demonstrates that a rigorous collaboration between nephrologists and interventional radiologists/vascular surgeons is mandatory to avoid the failure of the vascular access

THE FUTURE IS NOW…

Department of Surgery, Vascular and Endovascular Surgery Unit

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FREEWAY™ 035 AV Shunt: Key Selling Points

Eurocor

High pressure DEB for the treatment of shunt stenosis

- Protects AV fistulas and shunt grafts from early restenosis by opening the artery and delivering paclitaxel, an anti-proliferative agent, to the vessel wall

Reduces re-intervention

- Feasibility study presented at LINC 2015, showed a low re-intervention rate of 11% at follow up
- Registry presented at LINC 2017 showed significant longer time to re-intervention after FREEWAY™ PTA

FREEWAY™ 035: Registry

Eurocor

AV Fistula Registry

- 33 lesions
- DEB dilatation with mandatory predilatation
- Planned follow-up by ultrasound: 3-4 months
- St. Joseph Hospital Berlin

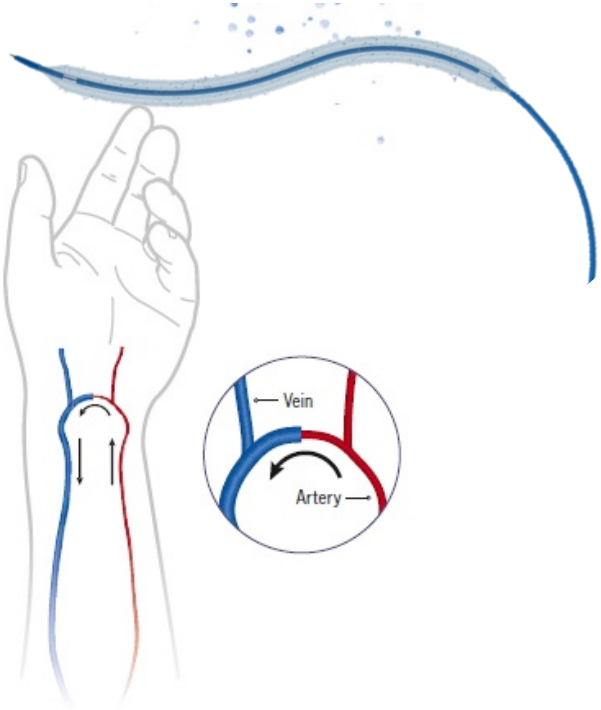
FREEWAY™ 035: Registry

Eurocor

AV Fistula Registry

BASELINE LESIONS (N=33)

ACCESS TYPE	
AV-Fistula (Cimino)	30.3 %
AV-Fistula Basilic	6.1 %
AV-Fistula Cephalic	18.2 %
AV-Graft	45.5 %
Target Lesion Location	
Arterial	6.1 %
Venous	90.9 %
Anastomosis	3.0 %
Lesion Characteristics	
Reference Vessel Diameter [mm]	5.80 ± 0.76
Lesion Length [mm]	16.17 ± 11.67



FREEWAY™ 035: Registry

Eurocor

AV Fistula Registry

PROCEDURAL DATA

	Pre-Interention	Post-Intervention
Minimal Lumen Diameter [mm]	1.97 ± 0.69	4.58 ± 0.62
Stenosis Percentage	84.09 %	30.88 %

FOLLOW UP 120 ± 49 days

REVASCULARIZATIONS DURING FOLLOW UP

FOLLOW UP (N=18)	
Re-Intervention	11.0%

FLOW COMPARISON (DUS)

	Discharge	Follow-Up (N=18)
Flow [ml/min]	806 ± 307	703.68 ± 255

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