Drug Coated Balloons in Vascular Access

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Vascular Access

% of failing access to total ESRD patient admissions

~20%

Catheter-based procedures recanalization success

US annual healthcare costs

~1 billion \$

~80%

Bittl JA, JACC Cardiovascular Interventions 2010 KDOQI, National Kidney Foundation, 2006 Updates

Vascular Access Treatment



National Kidney Foundation

2006 Updates Clinical Practice Guidelines and Recommendations



Hemodialysis Adequacy

- Peritoneal Dialysis Adequacy
- Vascular Access

Gold Standard Plain Balloon Angioplasty (PBA)

> Residual Stenosis <30%

Primary Patency >50% @ 1year for AVF >50% @ 6month for AVG

AVG Treatment

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Stent Graft versus Balloon Angioplasty for Failing Dialysis-Access Grafts

Ziv J. Haskal, M.D., Scott Trerotola, M.D., Bart Dolmatch, M.D., Earl Schuman, M.D., Sanford Altman, M.D., Samuel Mietling, M.D., Scott Berman, M.D., Gordon McLennan, M.D., Clayton Trimmer, D.O., John Ross, M.D., and Thomas Vesely, M.D.

ABSTRACT

BACKGROUND

The leading cause of failure of a prosthetic arteriovenous hemodialysis-access graft is venous anastomotic stenosis. Balloon angioplasty, the first-line therapy, has a tendency to lead to subsequent recoil and restenosis; however, no other therapies have yet proved to be more effective. This study was designed to compare conventional balloon angioplasty with an expanded polytetrafluoroethylene endovascular stent graft for revision of venous anastomotic stenosis in failing hemodialysis grafts.

METHODS

We conducted a prospective, multicenter trial, randomly assigning 190 patients who were undergoing hemodialysis and who had a venous anastomotic stenosis to undergo either balloon angioplasty alone or balloon angioplasty plus placement of the stent graft. Primary end points included patency of the treatment area and patency of the entire vascular access circuit.

RESULTS

At 6 months, the incidence of patency of the treatment area was significantly greater in the stent-graft group than in the balloon-angioplasty group (51% vs. 23%, P<0.001), as was the incidence of patency of the access circuit (38% vs. 20%, P=0.008). In addition, the incidence of freedom from subsequent interventions at 6 months was significantly greater in the stent-graft group than in the balloon-angioplasty group (32% vs. 16%, P=0.03 by the log-rank test and P=0.04 by the Wilcoxon rank-sum test). The incidence of binary restensis at 6 months was greater in the balloon-angioplasty group than in the stent-graft group (78% vs. 28%, P<0.001). The incidences of adverse events at 6 months were equivalent in the two treatment groups, with the exception of restensis, which occurred more frequently in the balloon-angioplasty group (P<0.001).

CONCLUSIONS

In this study, percutaneous revision of venous anastomotic stenosis in patients with a prosthetic hemodialysis graft was improved with the use of a stent graft, which appears to provide longer-term and superior patency and freedom from repeat interventions than standard balloon angioplasty. (ClinicalTrials.gov number, NCT00678249.) Prospective Multicenter Controlled Trial 190pt with stenosis at the venous juxta-anastomotic site of their AVG

Group PTA only PTA (97 pt)

Group S.G. PTA + S.G. deployment (93 pt)

N. Engl J Med 2010;362: 494-503)

AVG Treatment



Lesion Primary Patency @ 6 month Group S.G.: 51% Group PTA: 23% P<0.001



Circuit Primary Patency @ 6 month Group S.G.: 38% Group PTA: 20% P=0.008

Haskal ZJ, Trerotola S, Dolmatch B. Stent Graft versus Balloon Angioplasty for Failing Dialysis-Access Grafts, N. Engl J Med 2010;362: 494-503

AVG Treatment



Dialysis Access Grafts: Anatomic location of Venous Stenosis and results of angioplasty, Robert Y. Katerman, Radiology 1995; 195:135-139

What about the rest of the cases?

~50% of the AVGs stenose in places other than the venous anastomotic site

No data available for the Fistulae (where the second s

Arterial part of Vascular Access

What about PCBs?

Paclitaxel-Coated Balloons

- PCB used in the SFA
- **DES-like Efficacy**
- BMS-like Safety
- Balloon-like Deliverability
- Nothing Left Behind

- ↓ LLL /neointima mm²
- Uuration of DAPT
- ↑ Technical Success rate
- ↓ % Stenting rate

Tepe G. et al, Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg, N Engl J Med, 2008

Randomized Single-Center Controlled Trial

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		Clinical Trials.gov Identifier:	NCT01174472		
	Ì	Information provided by:	University of Patras		
		Sponsor:	University of Patras		

Study Aim

To compare the safety and effectiveness of paclitaxel-coated balloon (PCB) VS

plain balloon angioplasty (PBA)

for the treatment of

venous stenosis of dysfunctional dialysis access

Study Design

Inclusion criteria:

- Clinical diagnosis of dysfunctional dialysis access with significant angiographic stenosis
- Patients with AVF or AVG

Exclusion criteria:

- Severe allergy to contrast media
- Intolerance to aspirin and/or clopidogrel
- Systemic coagulopathy or hypercoagulation disorders

Paclitaxel-Coated Balloon

Device used: IN.PACT Admiral

Sizes:

Diameters: 4-7 mm Lengths: 40-120 mm

Drug: PACLITAXEL 3µg/mm² antiproliferative drug, lipophilic

Spacer: UREA

hydrophilic

Baseline Variables

	Group PCB	Group PBA
Subjects (n)	20 lesions	20 lesions
Gender (M/F)	15M / 5F	14M / 6F
Age (years)	65.7 ± 13.2	62.5 ± 15.4
Dialysis access	13AVG / 7AVF	13AVG / 7AVF
AV age (years)	2.5 ± 2.0	2.5 ± 3.2

Study Endpoints

Technical success

Residual stenosis <30%

Minor & major complications

Target lesion primary patency @ 1 year

Defined as the angiographic visualization of a patent lesion or circuit with <50% angiographic restenosis and no need for any repeat procedures during the follow-up period

Results @ 6 months



Results @ 6 months

J ENDOVASC THER	
2012;19:263-272	

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♦ CLINICAL INVESTIGATION –

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

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Results @ 1 year



PCB in Fistulae sub-group analysis



PCB in Fistulae

Randomised Single-Center Control Trial

- May 2011 September 2012
- 40 pt 40 Fistulae
 - Group PCB n=20
 - Group PBA n=20

Baseline variables equally distributed b/w the two groups

Six month results awaited in April

Study Aim

To compare the safety and effectiveness of paclitaxel-coated balloon (PCB) VS

plain balloon angioplasty (PBA)

for the treatment of

stenosis of dysfunctional Arterio-Venous Fistula

PCB in Fistulae (Interim Results)



Group PCB: 10/20, Group PBA: 2/20, p=0.056 by Log Rank test

Thank You