The Role of LUTONIX® 035 DCB in AV Fistula Dysfunction Management in our Practice

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:
- Consulting (BARD)
- 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 opinions and clinical experiences presented herein are for informational purposes only and may not be predictive for all cases. Individual results may vary depending on a variety of patient specific attributes.
Introduction

• Pathophysiology of AV access stenosis
• Assessment of AV access stenoses using ultrasound and histology
• Implications for treatment strategies
• Ultrasound appearances guiding intervention
Pathology of AV stenoses

Venous intimal hyperplasia
Chang et al (2004) – Increase in proliferation index, intima and media in aggressive restenotic lesions vs primary stenotic lesions
Kim et al (2004) - Venous smooth muscle cells (saphenous vein) more sensitive to antiproliferative agents compared with aortic arterial smooth muscle cells


*Physician reported data
Pathology of AV stenoses


Haemodialysis vascular access dysfunction: A Cellular and Molecular Viewpoint.

Vascular remodelling/constriction and intimal hyperplasia implications for therapy

Angiography; what we don’t see
150 Consecutive DUS
[121 pts; 80M 41F; 21-87 years old (median 68)]
6-month period

64 No haemodynamically significant stenosis

36 JAS

41 Outflow vein Vein

9 Cephalic Arch

*Physician reported data
Results: Juxta-anastomotic stenoses

- 23/36 (64%) - Neointimal thickening on DUS
- 13/36 (36%) - No neointimal thickening on DUS

- Mean intimal thickness was 0.77mm (0-2.8mm).
- Mean vein diameter was 3.28mm (1.7-5.3mm).
- Mean luminal diameter was 2.5mm (0.7-4.6mm)

*Physician reported data.*
Types of stenosis: Ultrasound

• Yamamoto et al 2012 (46 patients)
  – Vascular constriction type
  – Neointimal proliferation type
  – Mixed type
• Bare metal stent placement; higher primary patency 6, 12, 18, 24 months
  – Vascular constriction type
    • 100%, 92%, 84% and 75%
  – Mixed type
    • 90%, 52%, 38% and 27%
  – Neo-Intimal proliferation type
    • 66%, 33%, 33% and 25%

Venous neo-intimal hyperplasia: Ultrasound and Histology Assessment

Left BCF Juxta-anastomotic vein B-mode U/S and H&E stain demonstrating neo-intimal hyperplasia

*Physician reported data.
Ultrasound and Histology assessment AV access stenoses

Right RCF juxta-anastomotic stenosis; B mode U/S demonstrating intimal hyperplasia. Histology specimen EVG stain demonstrating intimal hyperplasia

*Physician reported data
Ultrasound and Histology assessment AV access stenoses

Left RCF juxta-anastomotic vein; B-mode U/S no measurable intimal hyperplasia, histology H&E stain medial thickening.

*Physician reported data*
Targeting intimal hyperplasia with DCB: Case VW

- 12/01/2016 PTA poorly maturing fistula and poor flow
- Duplex restenosis
- 24/05/2016 PTA DCB (Lutonix)
- 31/08/2017 restenosis 15 months

*Physician reported data.*
Ultrasound restenosis 15 months post LUTONIX® 035 DCB
Histology assessment AV access stenoses post PTA

Right RCF B-mode U/S pre PTA demonstrating neo-intimal hyperplasia. Histology recurrent stenosis 306 days post PTA EVG stain demonstrating marked neointimal proliferation with fibrosis.
Successful angioplasty?

- Balloon dilation and vessel wall stretch
- Adventitial remodelling
- Prevention of restenosis/neointimal hyperplasia
Future developments

- Trials
  - AVF – Not uniform group
  - Stenosis type
    - Neo-intimal hyperplasia
    - Adverse adventitial remodeling/failure of vein dilation
    - Fibrosis
    - Mixed
  - Stenosis location
- Histopathology correlation with Ultrasound
Thank You

Don't worry, I'll find a good site soon.
INDICATIONS FOR USE
The Lutonix® 035 Drug Coated Balloon Catheter is intended for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature and for the treatment of obstructive lesions and decreasing the incidence of restenosis. In addition, the Lutonix® 035 Drug Coated Balloon Catheter is intended for PTA of native dialysis fistulae or synthetic grafts, opening narrowing and immature fistulae, to improve blood flow, and decreasing the incidence of restenosis.

CONTRAINDICATIONS
• Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children over the next 2 years. It is unknown whether paclitaxel will be excreted in human milk and there is a potential for adverse reaction in nursing infants from paclitaxel exposure.
• Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.

WARNINGS
• Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged or opened prior to intended use.
• Do not use after the “Use by” date.
• Do not use if product damage is evident.
• The LUTONIX® Catheter is for use in one patient only; do not reuse in another patient, reprocess or resterilize. Risks of reuse in another patient, reprocessing, or resterilization include:
  o Compromising the structural integrity of the device and/or device failure which, in turn, may result in patient injury, illness or death.
  o Creating a risk of device contamination and/or patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to patient injury, illness or death.
• Do not exceed the Rated Burst Pressure (RBP) recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over-pressurization, use of a pressure monitoring device is recommended.
• Use the recommended balloon inflation medium of contrast and sterile saline (≤50% contrast). Never use air or any gaseous medium to inflate the balloon as this may cause air emboli in case of balloon burst. This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds as this may cause allergic reaction (difficulty in breathing, skin rash, muscle pain).
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