

LINC



# LUTONIX DCB in AV Access: A Single Center Experience

Dr Kate Steiner

Consultant Interventional Radiologist

East and North Hertfordshire



NHS Trust

# Disclosure

Speaker name:

.....

I have the following potential conflicts of interest to report:

- Consulting – Bard and Boston Scientific
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
  
- I do not have any potential conflict of interest

# Disclaimer

- The opinions and clinical experiences resented 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.
- The results and data presented herein reflect Dr. Steiner's clinical experience in a single-center, investigator-initiated and funded study. These results have not been published or peer-reviewed. Bard /Lutonix has not sponsored or funded these studies, nor has Bard/Lutonix validated underlying test methods or data presented herein.
- These results are presented for general education purposes only and may not be predictive for all patients or of Lutonix DCB usage.






# Disclaimer, continued

- The physician has been compensated by Lutonix for the time and effort to present this information.
- Any discussion regarding Bard products during the presentation today is limited to information that is consistent with the CE Marking and clearances for those products. Please consult Bard/Lutonix product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.

# Introduction

- Use of DCB in femoropopliteal arterial lesions well established
- Use in AV fistulas not well studied
  - Restenosis
  - Repeat interventions
  - Loss of fistula
  - Failure to mature
  - Dialysis per fistula/line dialysis

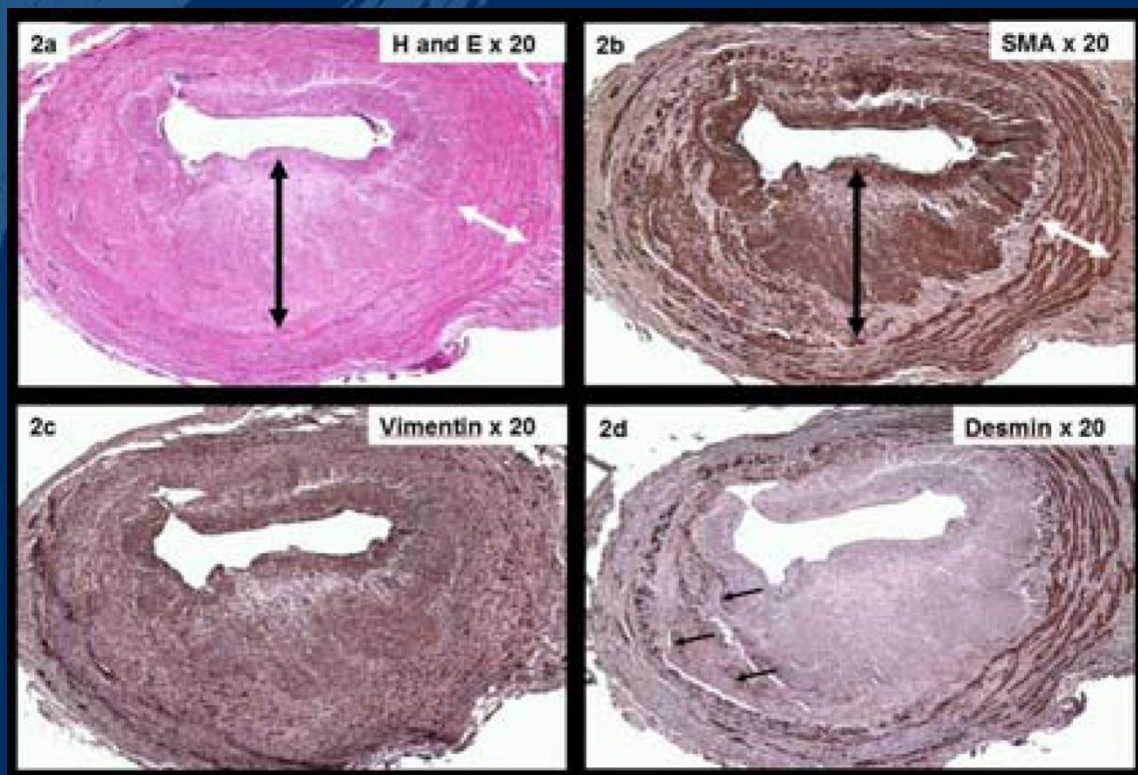
# Physiology AV fistulas

- High pressure  Low Pressure  
Vessel wall stress  Endothelial NO
- High Shear stress gradient  Endothelial cell damage  
Intimal hyperplasia
- Compliance mismatch  Pulsatile wall stress  
Intimal hyperplasia
- Traumatic Balloon dilation  Neointimal proliferation

# Histology 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

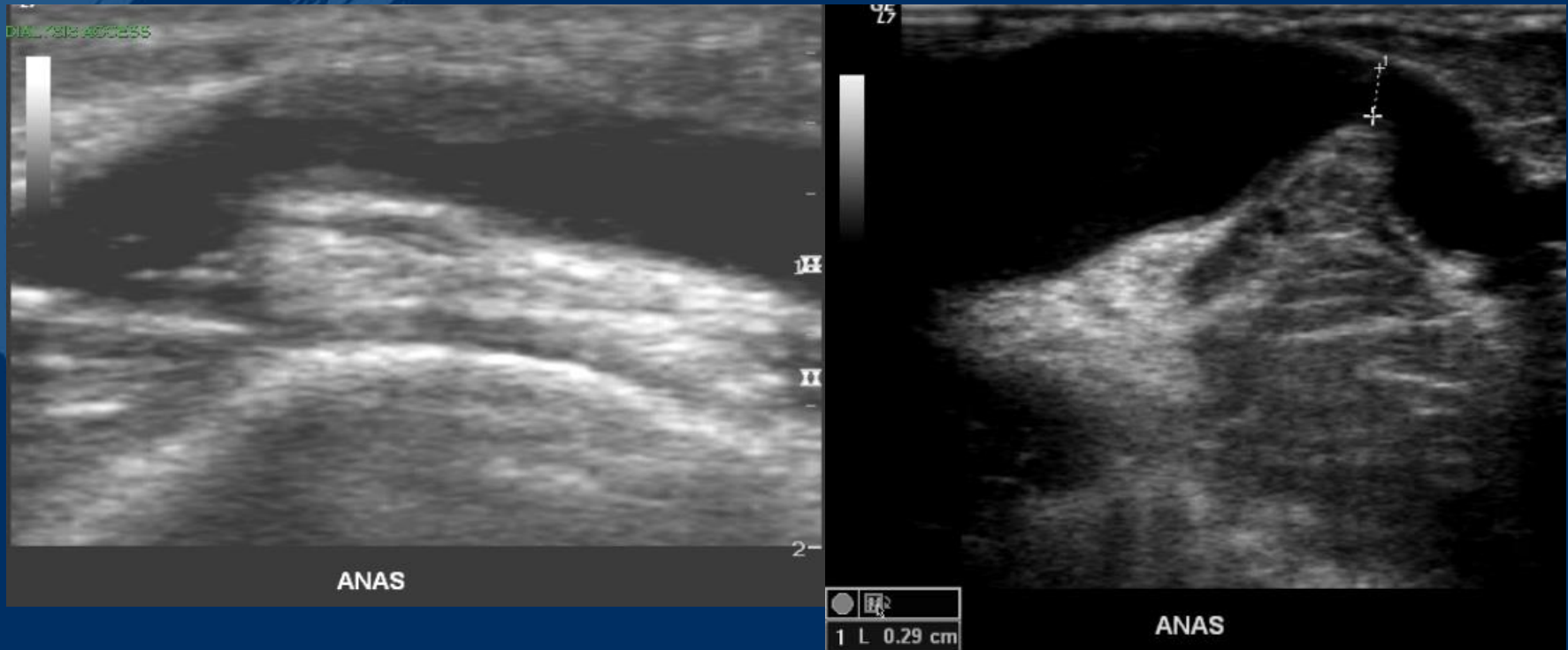


Chang CJ, Ko PJ, Hsu LA, Ko YS, Ko YL, Chen CF, Huang

CC, Hsu TS, Lee YS, Pang JH: Highly increased cell proliferation activity in the restenotic hemodialysis vascular access after percutaneous transluminal angioplasty: Implication in prevention of restenosis. *Am J Kidney Dis* 43: 74–84, 2004

# Venous Intimal Hyperplasia

- Duplex native AV fistulas
  - Intimal hyperplasia
  - Fibrotic stenosis





# Fistuloplasty of Juxta-anastomotic stenoses :Plain balloon fistuloplasty vs DCB

Walton H, Errete L, Ramskold L, Cloran J, Guest M, Selvakumar S, Metcalfe M, Steiner K

- Native AV fistulas
- Juxta-anastomotic stenosis
- 93 Consecutive Patients
  - 75 PBA (81%)
  - 18 DEB (Lutonix Bard)(19%)
- 20 month period
- Technical success rate 100%
- No complications

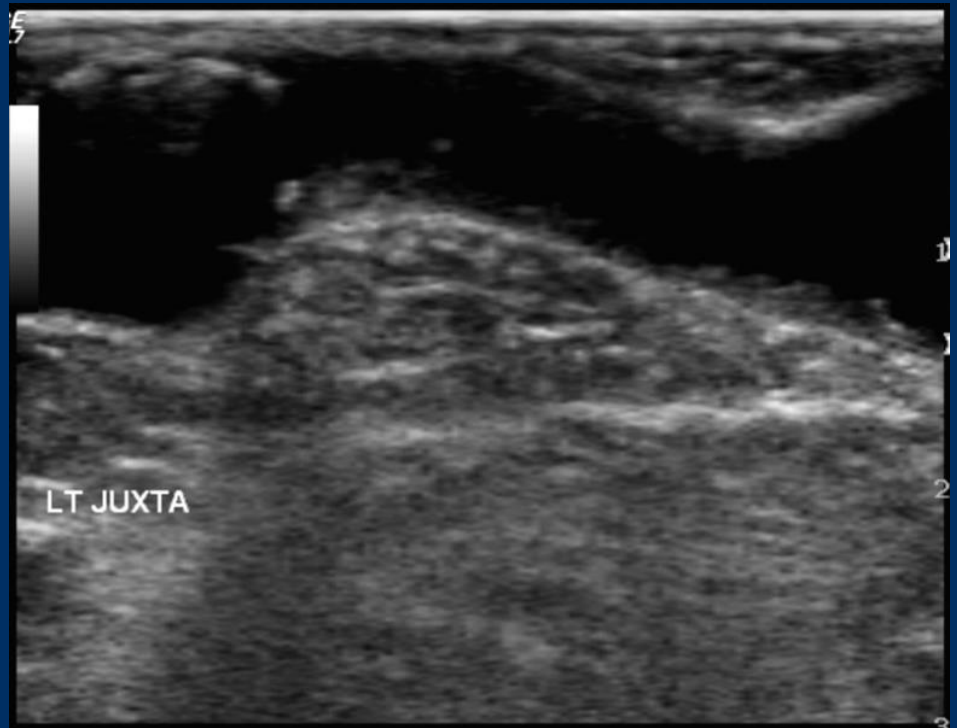
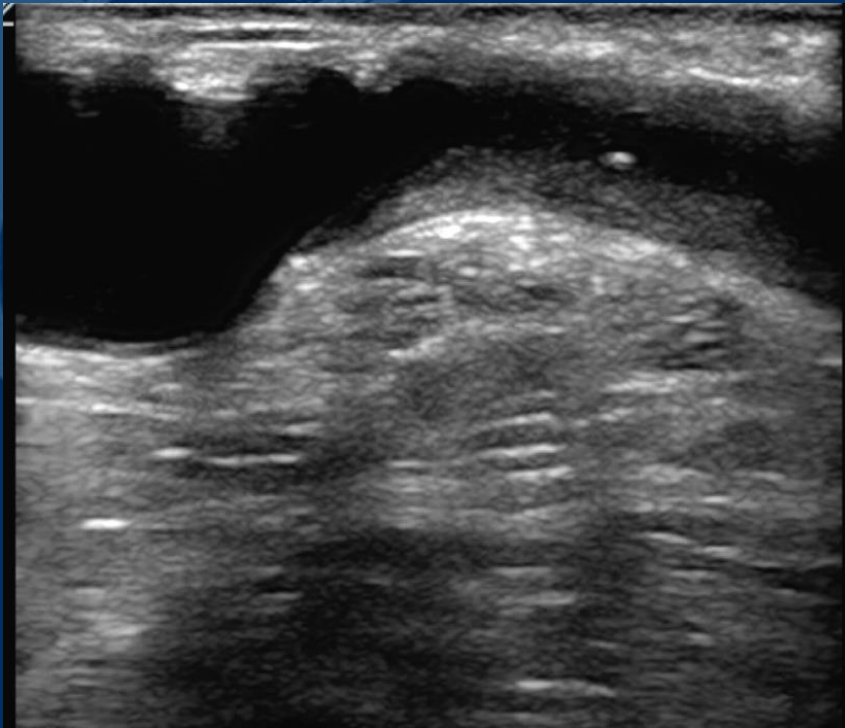
# Results

<b>Primary Patency</b>	<b>PBA</b>	<b>DCB</b>	<b>P-Value</b>
<b>3 Months</b>	<b>96%</b>	<b>100%</b>	<b>0.2</b>
<b>6 Months</b>	<b>68%</b>	<b>92%</b>	<b>0.048</b>
<b>12 Months</b>	<b>33% (n=30)</b>	<b>80% (n=5)</b>	<b>0.024</b>

<b>Primary Assisted Patency</b>	<b>PBA</b>	<b>DCB</b>	<b>P-Value</b>
<b>3 Months</b>	<b>100%</b>	<b>100%</b>	<b>N/A</b>
<b>6 Months</b>	<b>98%</b>	<b>100%</b>	<b>0.32</b>
<b>12 Months</b>	<b>87%</b>	<b>100%</b>	<b>0.19</b>

# Results

	PBA	DCB
Increase in Volume Flow (Mls/min)	399	693



# Further Follow up

20 consecutive patients DCB – 1 died  
12 months 12 patients - 3 transplanted  
- 1 died

<b>DCB</b>	<b>3 Months</b>	<b>6 Months</b>	<b>12 Months</b>
<b>Primary Patency</b>	<b>100%</b>	<b>94%</b>	<b>64%</b>
<b>Primary Assisted Patency</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

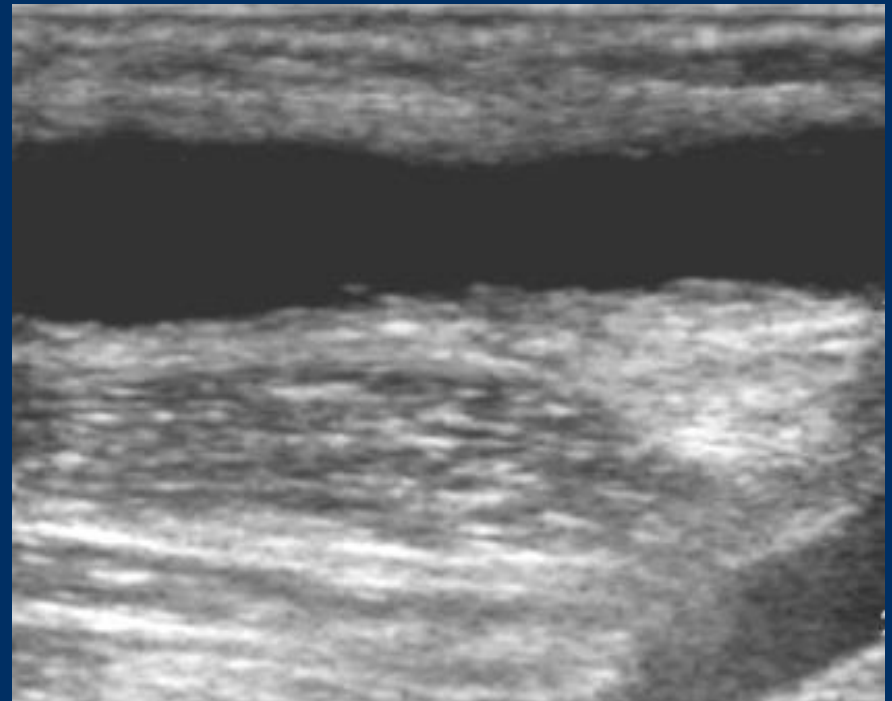
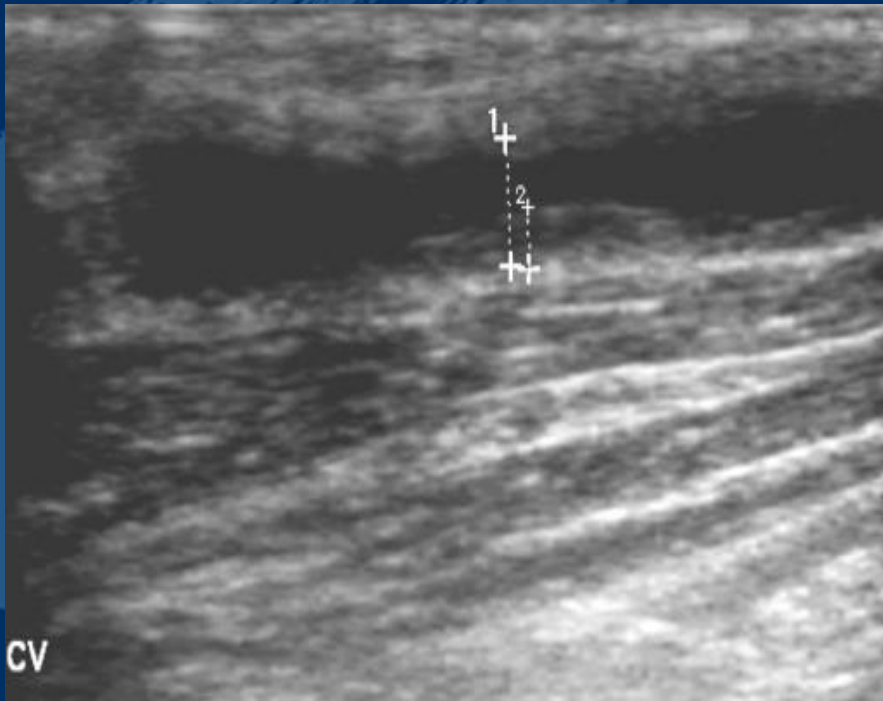
# Juxta-anastomotic fistuloplasty DCB

- Patane et al 2014
  - 26 consecutive patients mature RCF
  - Juxta-anastomotic stenoses DCB
  - Technical and clinical success 100%
  - No complications
  - PP 6 months 96% 12 months 82%
  - SP 24 months 95%
  - Only one fistula lost
- Mortamais et al 2013
  - PBA Juxta-anastomotic lesions
  - SP 12 months 76.1%

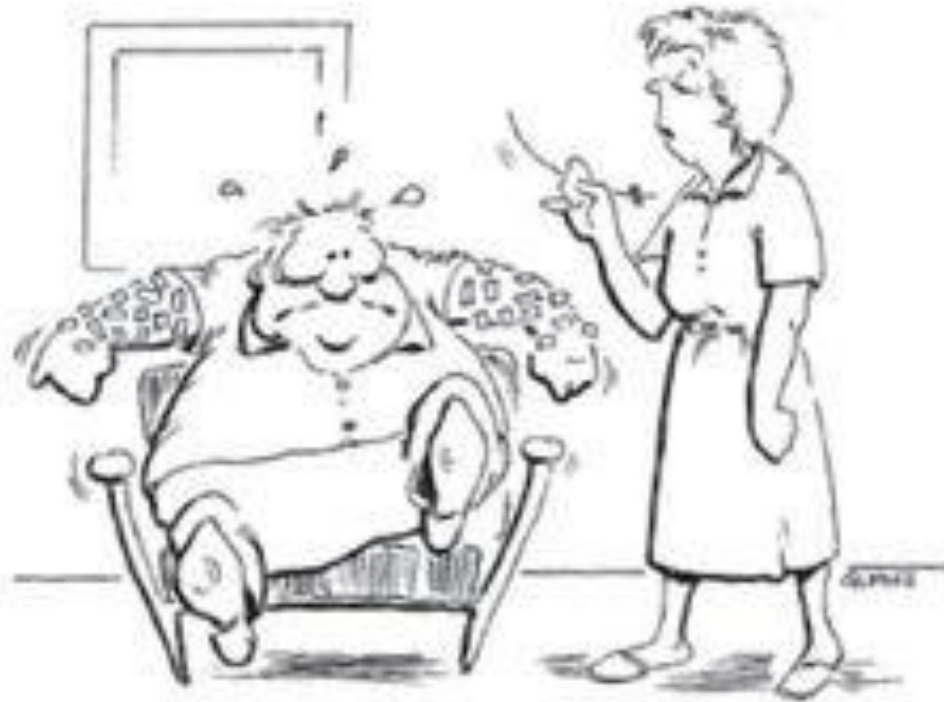
# Conclusions

- Balloon angioplasty of juxta-anastomotic stenoses using DCB is safe and effective
- DCB group
  - Primary patency rates higher ( $p < 0.05$  at 6 months)
  - Less repeat interventions
  - Greater increase in Volume Flow
- Larger numbers, prospective randomised control trials are needed.
- Cost analysis

# Venous intimal hyperplasia; A target for drug elution?



# Thank You



Don't worry, I'll find a good site soon.



LINC



# LUTONIX DCB in AV Access: A Single Center Experience

Dr Kate Steiner

Consultant Interventional Radiologist

East and North Hertfordshire



NHS Trust