Recurrent lesions in AV access
&
Initial DCB experience in India

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Disclosure

Speaker name:

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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

Culprit sites in AV access Circuit

1. Anastomotic,
2. Swing point/JXA,
3. Outflow vein,
4. Cannulation zone, &
5. Cephalic arch,

Proposed etiology: Trauma during surgery, Adventitial ischemia, Twisting or kinking of vein during surgery, Altered flow dynamics (end-to-side anastomosis), repeated trauma with pricks, cephalic arch flow dynamics changes &

……sometimes may be we Don't know exact cause & it just keeps on happening (I call it "BAD" Veins)

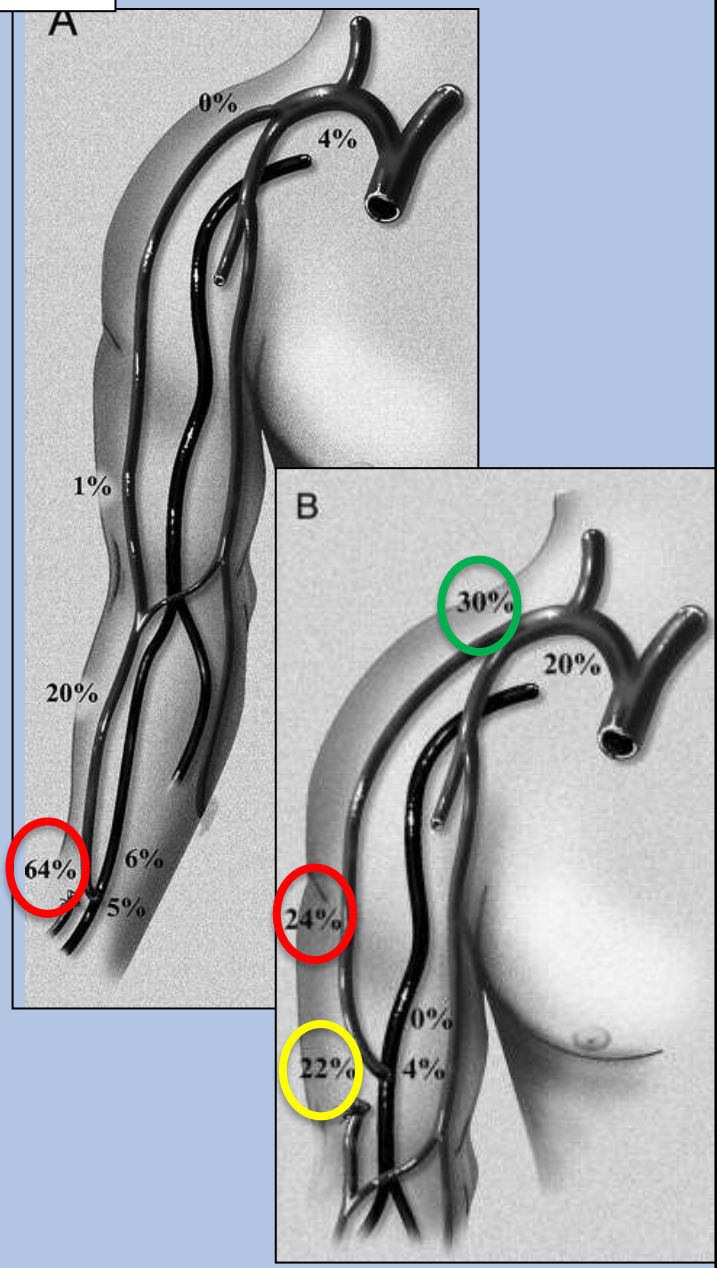
Facts

In RC-AVF:

- ✓ 55–75% of the stenoses are located close to the AV anastomosis (Swing point/JXA) and 25% in the venous outflow tract.

In BC AV fistulae, the typical location (30-40%) is at the junction of the cephalic with the Subclavian vein and in **BB AVF** the location is the junction of basilic with the axillary vein, respectively.

In **AV Graft (AVG)**, the typical location is at the graft venous anastomosis.



Pathophysiology of Stenosis in AVF

- ✓ **Different from PAD**
- ✓ **Nonphysiologic flow** dynamics (Direct A-V connection)
- ✓ **Tangential wall and shear stress with flow turbulence** throughout the circuit.
- ✓ **Smooth muscle cell (SMC) hyperplasia**
- ✓ **Repetitive needle punctures**
- ✓ **Chronic inflammation present in dialysis patients** produce endothelial dysfunction due to oxidative stress

Current Status of AVF interventions

- ✓ **Simple Stenosis:** Standard PTA is still first treatment option.
- ✓ **Persistent stenosis :** These ‘hard’ stenoses can be treated with cutting balloons or ultrahigh pressure balloons (> 30 atm)
- ✓ **Recurring stenosis:** Current practice include repeated standard PTA vs. may be stent placement, &/or surgically revision.
- ✓ **What's HOT:** Role of DCB: What we have learned?

Role of DCB

PACLITAXEL is a lipophilic, cytotoxic agent that halts the progression of mitosis from prophase to metaphase. The end result is that treated cells cannot divide. In a simpler words, paclitaxel halts SMC proliferation at the angioplasty site and reduces NIH.

Lutonix AV Clinical Trial Summary

A Prospective, Global, Multicenter, Randomized, Controlled Study Comparing LUTONIX® 035 AV Drug Coated Balloon PTA Catheter vs. Standard Balloon PTA Catheter for the Treatment of Dysfunctional AV Fistulae

- ✓ Trial incorporated a wide variety of lesions/fistula types
- ✓ 240 day results were demonstrated:
  - Safety outcomes non-inferior to PTA
  - Target lesion primary patency (TLP)
    - 61.6% DCB vs. 49.4% PTA (Δ 12.2% p = 0.02)*
- 29.8% fewer interventions required to maintain TLP in DCB arm

*one-sided P-value

Caution: Investigational Device, Limited by United States Law to Investigational Use.

Lutonix AV Clinical Trial

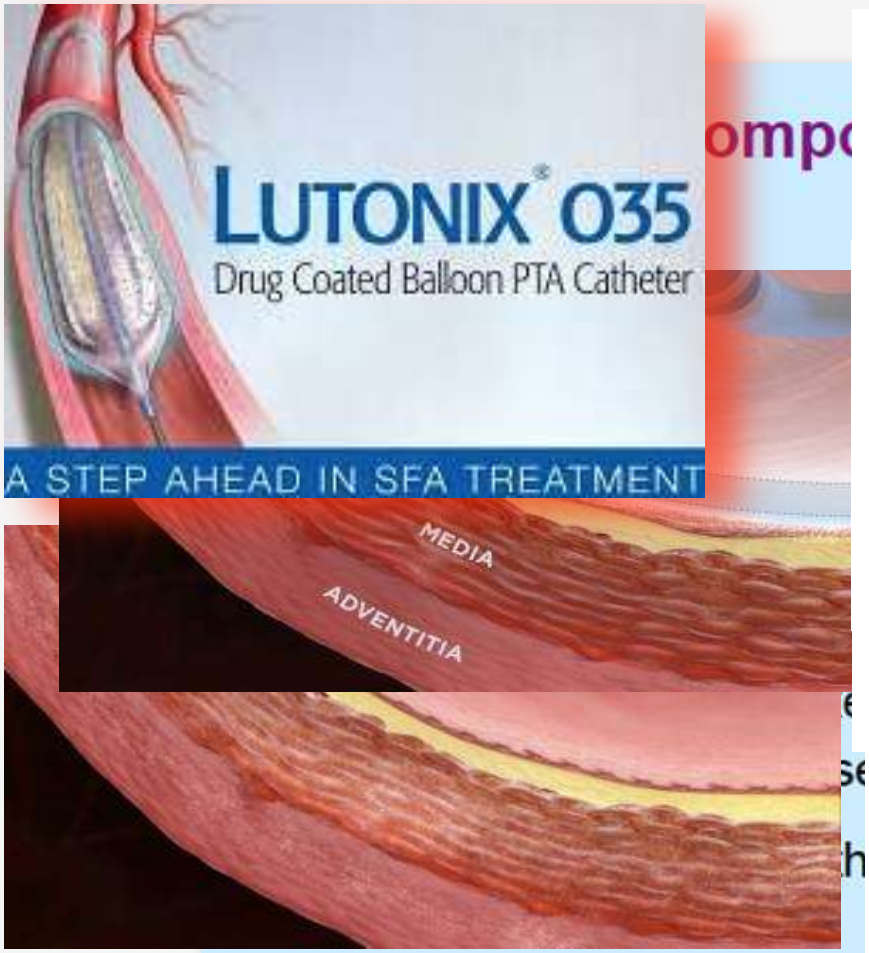
Number of Interventions Required to Maintain TLP at 240 Days

	LTX DCB (n=141)	Standard PTA (n=144)	P-value*
Number of interventions	66	94	0.024
n	141	144	
Mean (SD)	0.47 (0.732)	0.65 (0.805)	
Median	0	0	
Min – Max	0 - 3	0 - 4	

*Two-sided P-value

Caution: Investigational Device, Limited by United States Law to Investigational Use.

Drug Based Technologies in Peripheral Interventions



1. 30 second minimum inflation transfers drug to endoluminal surface delivering a therapeutic dose
2. PTX diffuses into the vessel wall from an endoluminal reservoir
3. Over time, therapeutic drug levels are sustained in deep cell layers after endothelial drug levels become sub-therapeutic
4. Drug continues to inhibit restenosis in vessel wall while allowing the lumen to restore and re-endothelialize

Our Protocol

Clinical suspicion of stenosis + Target lesion detected on US/Doppler

↓

Fistuloplasty with Standard/high/Ultra high pressure/cutting balloon

↓

Aggressive Monthly surveillance on US/Doppler and frequent visits to Dialysis Center & 1:1 interaction with Technicians/Nephrologists/patients

↓

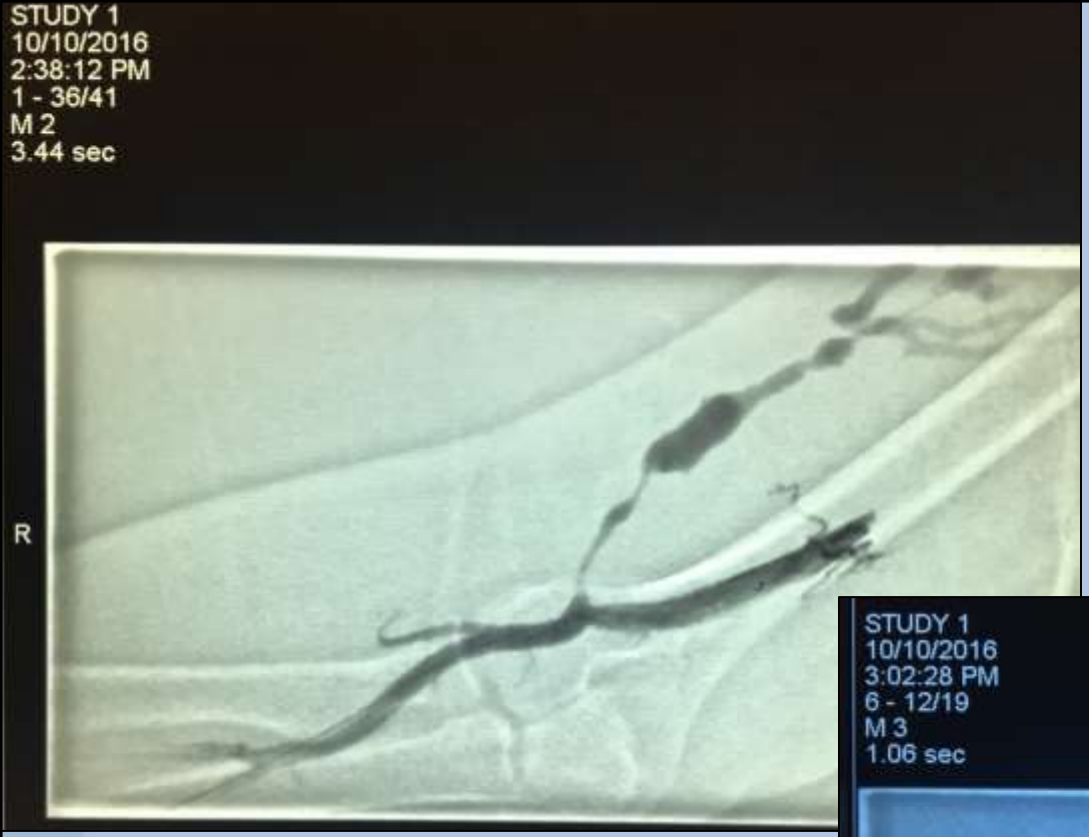
If Early recurrence with need for repeat PTA in </= 2 months of Std.PTA

↓

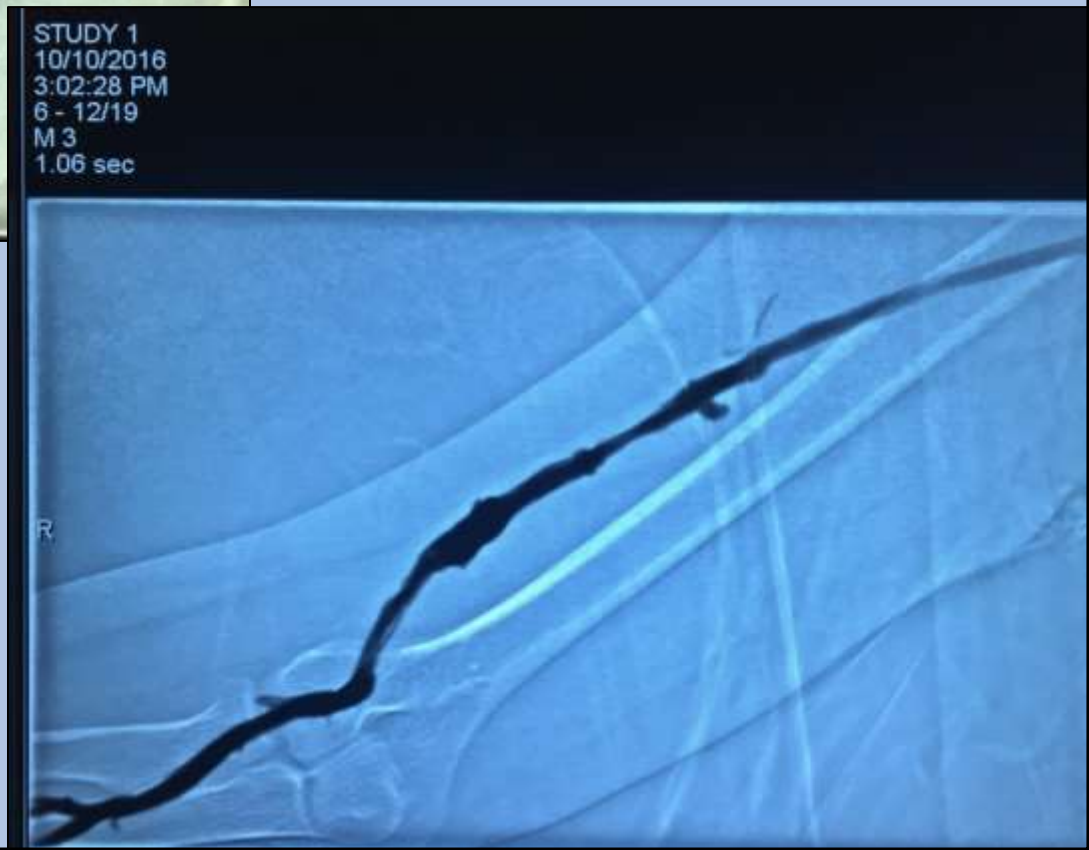
Plan for DCB

↓

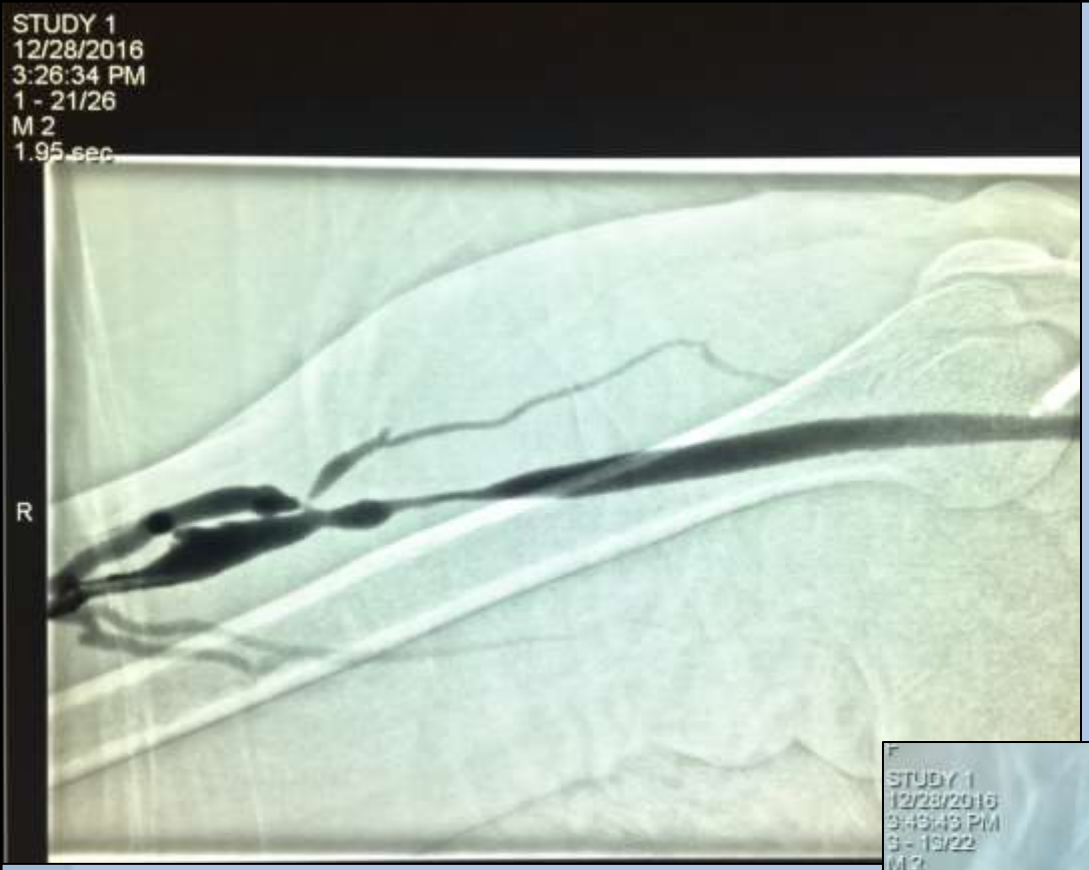
DCB protocol: Pre-dilatation with routine/HP/UHP/Cutting Balloon followed by DCB balloon



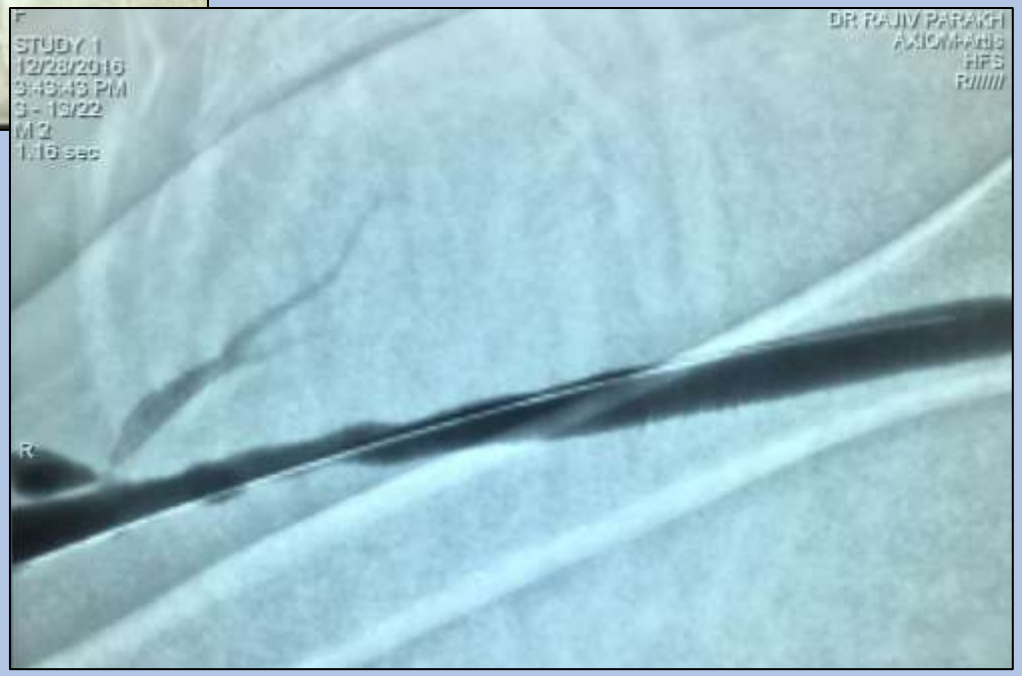
10th OCT 2016

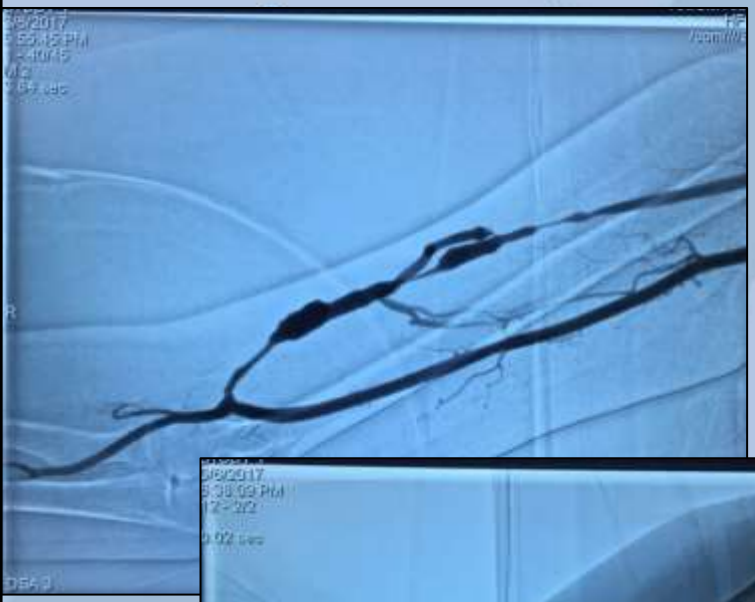


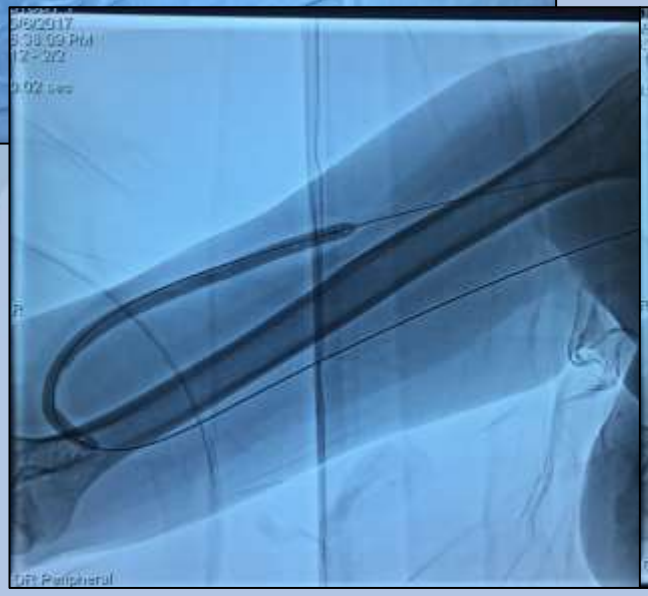
44 y/F
CKD
On HD via Left BCAVF

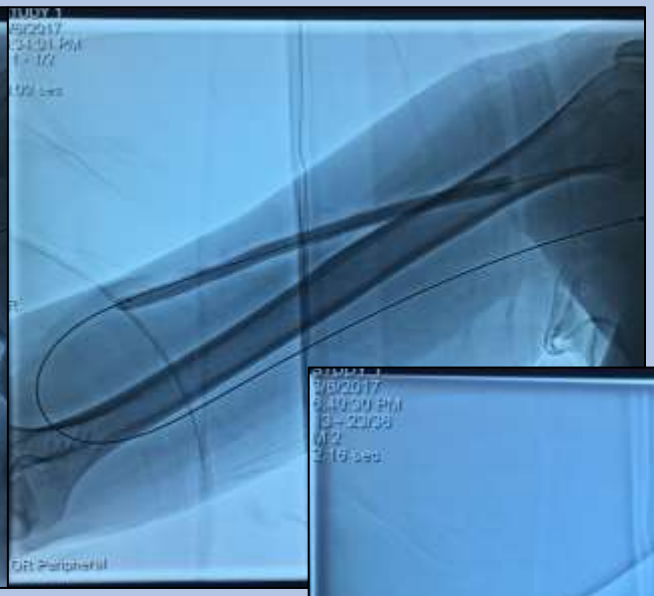


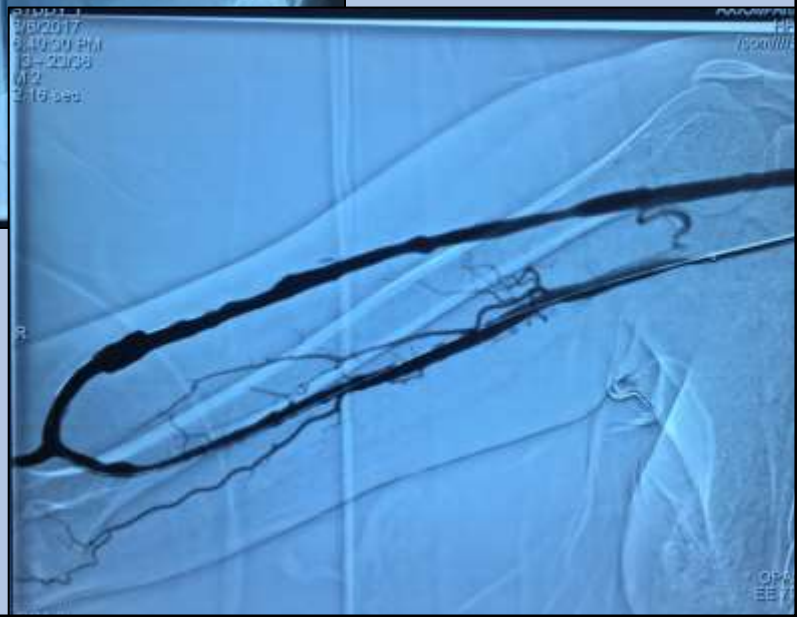
28th Dec 2016
(2 Months 18 days)



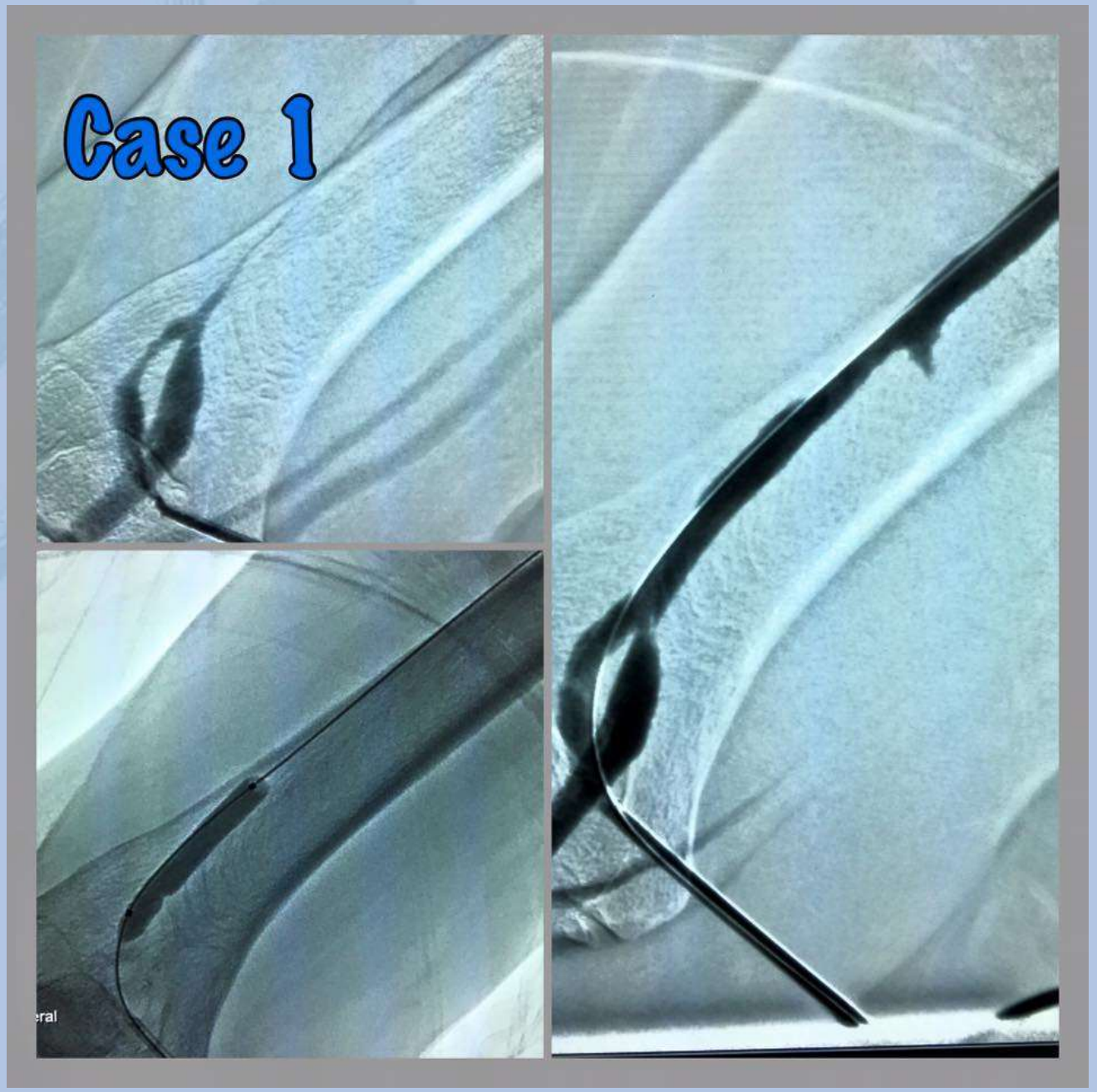








6th March 2017
(2 months 9 days)


Case 1


Case 3

Our Single Center
Initial Experience with DCB in India

Total no of cases (n)= 43

Male (%)= 70%

Mean Age (yrs.)= 52

Type of AVF

- RC (40%)
- BC (60%)

Target Lesion location(%):

- Anastomotic: 5 %
- JXA/Swing point: 25%
- In Cannulation Zone: 10%
- Outflow: 40%
- Cephalic arch: 20%

Our Observations

- ✓ **Technical Success** = 100%
- ✓ **DCB used:** Lutonix (BARD) / In.Pact DEB
- ✓ **INCLUSION:** Only those lesions requiring recurrent early PTA i.e. within 2 months of undergoing standard PTA.
- ✓ **RESULTS:** There was definitive improved TLP with DCB over Standard PTA i.e. we gained on an average 45 days over & above standard PTA (range 30 days to 90 days)

BIG QUESTION: Economic rationale of newer technologies?

If a patient undergoes 2 monthly standard PTA, Then Yearly expense of Only Balloon :

- ✓ Standard Balloon 6x $300 =$1800 **vs**. DCB 3.5 x $700 + $ 300 (Predilation) = $3500
- ✓ However when we compare total expenses including the Hospital admission charges, investigations, procedure charges, accessories used, transport and in addition the family time it justifies the higher initial outlay.

CONCLUSION

- ✓ In recent years, DCB have emerged as a potential alternative to combat recurrent stenosis in HD Access circuit.
- ✓ We have also gathered that DCB is safe, effective & provides superior reintervention-free intervals when compared to Std. PTA

Still, several issues remain to be answered:

1. Not yet very clear which lesions will benefit best from this technology, as not all lesions are the same.
2. Lesion preparation (Pre or Post dilation) is another issue that merits further investigation
3. Need for High-pressure DCBs to decrease procedural cost and time.
4. Safety time margin of reusing DCB angioplasty in the same lesion needs further data (Systemic toxicity?).

THANKS

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