LINC

Intravascular Lithotripsy for Complex (calcified) Iliofemoral Disease

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Disclosures

I have the following potential conflicts of interest to report:

Proctor-Abbott Vascular, Cardiovascular Systems, Inc

Consultant-Cardiovascular Systems, Inc, Shockwave Medical

Advisory Board-Shockwave Medical

Challenges with Calcium in Lower Limb Revascularization

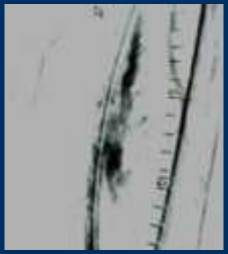
Calcification restricts vessel expansion resulting in higher residual stenosis and lower procedural effectiveness

Calcified lesions often require high balloon inflation pressure or adjunctive devices

Complications following treatment with endovascular procedures more frequent in calcified lesions

Dissections

Perforations



Embolization

Vessel Recoil

Incomplete Stent Expansion

Images Courtesy of: 1) Dr Hector Dourron, Wellstar Cobb Hospital, 2) Case Presented at LINC 2016
*Baumann et al, Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia, J Endovasc Ther 2014

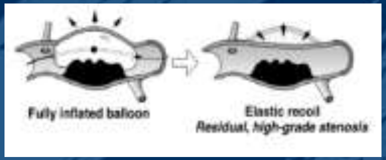
Calcification in CFA Disease

- Calcification is common in CFA disease
- Common Femoral Endarterectomy (CFE) is the standard of care for common femoral artery stenosis
- CFE is associated with good long-term patency, but
  - It is not a benign procedure
  - Not all patients are candidate
  - It is associated with extended LOS

- Endovascular interventions are growing in acceptance and have
  - High technical success rates
  - Higher reintervention rates

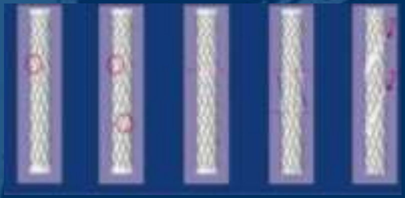
Challenges with Current Endovascular Options

Despite the improving endovascular outcomes in complex CFA lesions, the challenge remains for a solution that is safe, achieving luminal gain while preserving the access point for future interventions



PTA

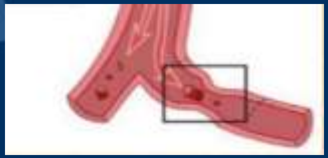
- Risk of dissection and plaque shift
- Inability to fully dilate results in high acute failure rate requiring a stent



Jaff, M Cardiac Interventions, 2007

Stenting

- Traditionally - No Stent Zone!
- Can move and fracture due to hip mobility
- Stents can be crushed by large eccentric plaques
- May eliminate access point for future procedures
- Can jail the profunda, vital for distal collateralization
- Newer stent designs show promise, but limited data



Atherectomy

- Risk of embolization
- Multiple filters needed to protect both SFA and Profunda
- Operator Dependent
- Limited evidence to date; Atherectomy + DCB studies are ongoing

Intravascular Lithotripsy (IVL): Localized Lithotripsy to Treat Cardiovascular Calcium

Inspired by urological applications, but designed for cardiovascular system

Lithotripsy

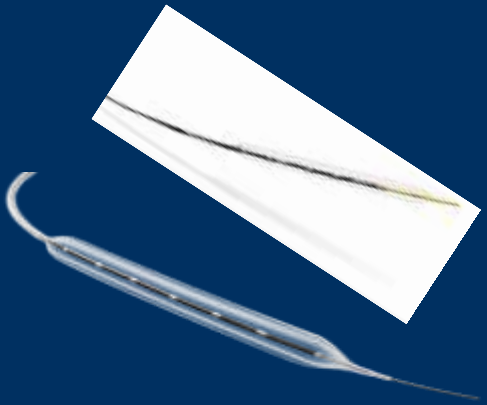
30 years of safety data
in kidney stone treatment

Sonic Pressure Waves preferentially impact hard tissue, disrupt calcium, leave soft tissue undisturbed

Cardiovascular Lithotripsy

Miniaturized and arrayed Lithotripsy Emitters for localized lithotripsy at the site of the vascular calcium

Optimized for the Treatment of Cardiovascular Calcium



Peripheral IVL Catheters

Intravascular Lithotripsy (IVL):
Localized Lithotripsy to Treat Cardiovascular Calcium

- Expanding and collapsing vapor bubble creates a short burst of **sonic pressure waves within the balloon,** which is inflated from 2-6 atm

Sonic pressure waves travel through the vessel with an effective pressure of **~50 atm per pulse**.

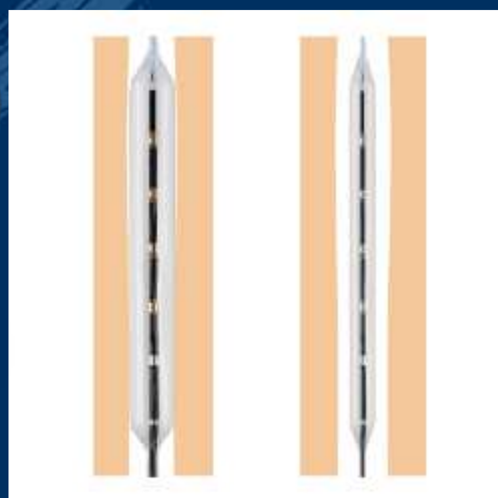
A **localized field effect** within the vessel fractures both **intimal and medial** calcium.

Optimal Technique Optimizes Therapeutic Energy

Oversize Device 10% vs RVD

Wall apposition facilitates efficient energy transfer. Optimized balloon sizing leads to improved patency

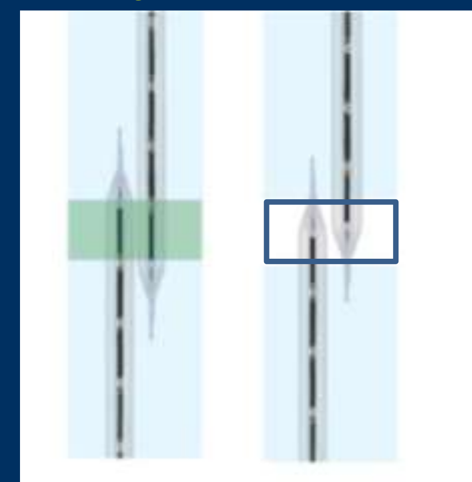
Optimal Undersized



Overlap Segments by 1 cm

The sonic pressure waves create a spherical field effect that drops as the longitudinal distance from the emitters increases

Full Therapeutic Coverage Therapeutic Miss



IVL Impact on Cardiovascular Calcium

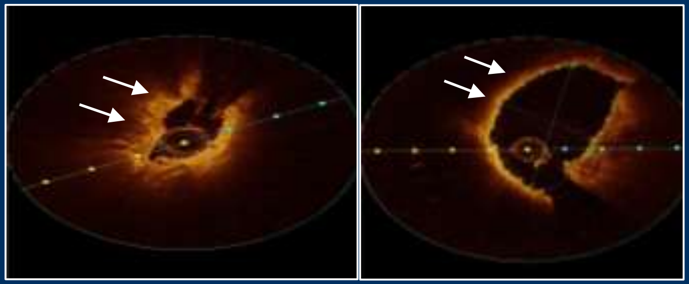
OCT demonstrated calcium disruption leading to **acute luminal gain and alteration in vessel compliance** in both **peripheral and coronary arteries**

Coronary Arteries

Pre

Post

Peripheral Arteries



Pre

Post

Advantages of IVL

- Simple device over 0.014 wire, minimal learning curve
- Therapy allows vessel expansion at low pressure, usually 2-6 ATM, reducing risk of barotrauma and need for bail-out stenting
- No embolic protection needed

Challenges of IVL

- Currently one length (60mm) is available
- Codes /bills as PTA
- Not low profile

CFA Case Series With IVL

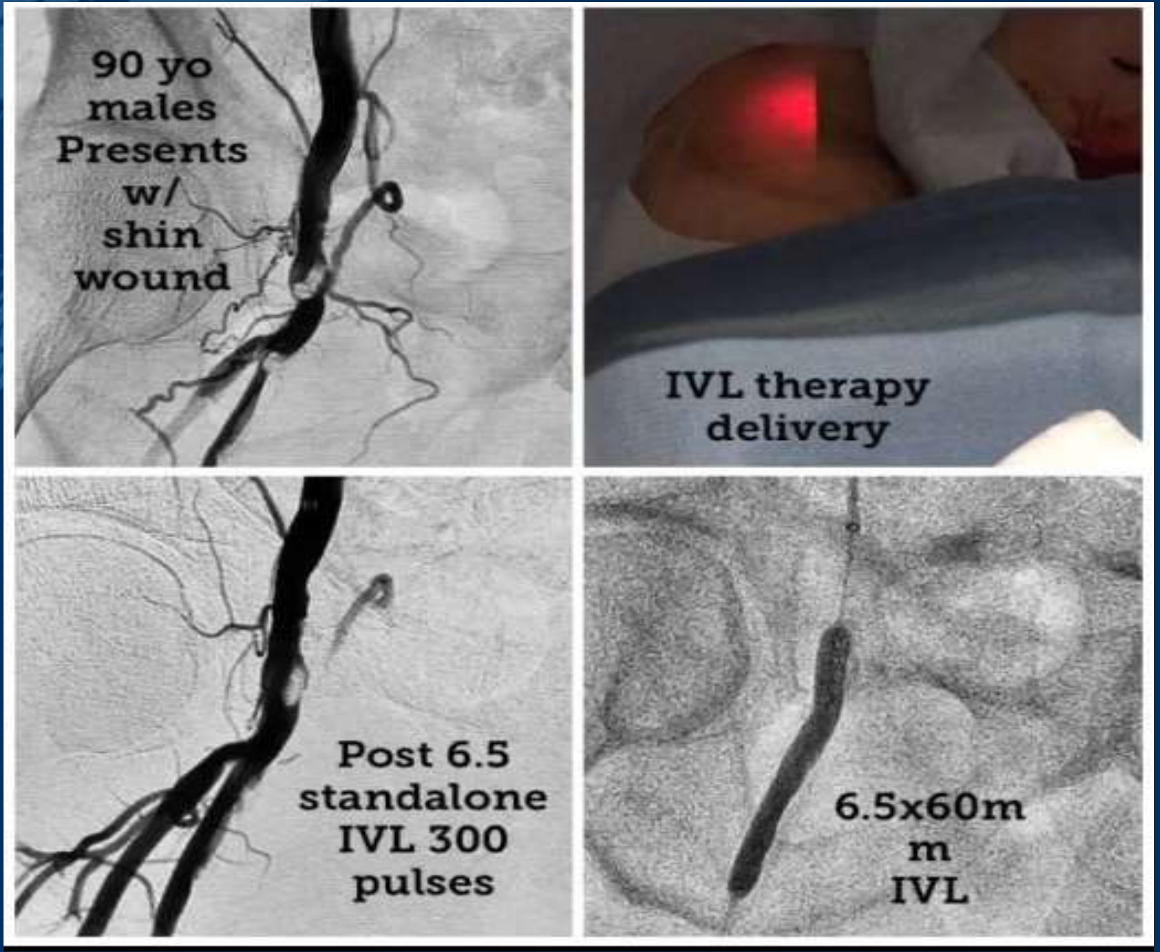
Results from the early common femoral experience have similar results in both acute performance and safety as was seen in Disrupt PAD I/II and Disrupt BTK

Procedural Characteristics	N = 21
Pre-dilatation, %	0.0% (0)
Successful IVL delivery	100.0% (21)
Adjunctive Technology, %	
Drug-Coated Balloon	85.7% (18)
Atherectomy	4.7% (1)
Stand-alone IVL	9.5% (2)
Stents, %	0.0 % (0)

Brodmann, et al, *manuscript submitted*

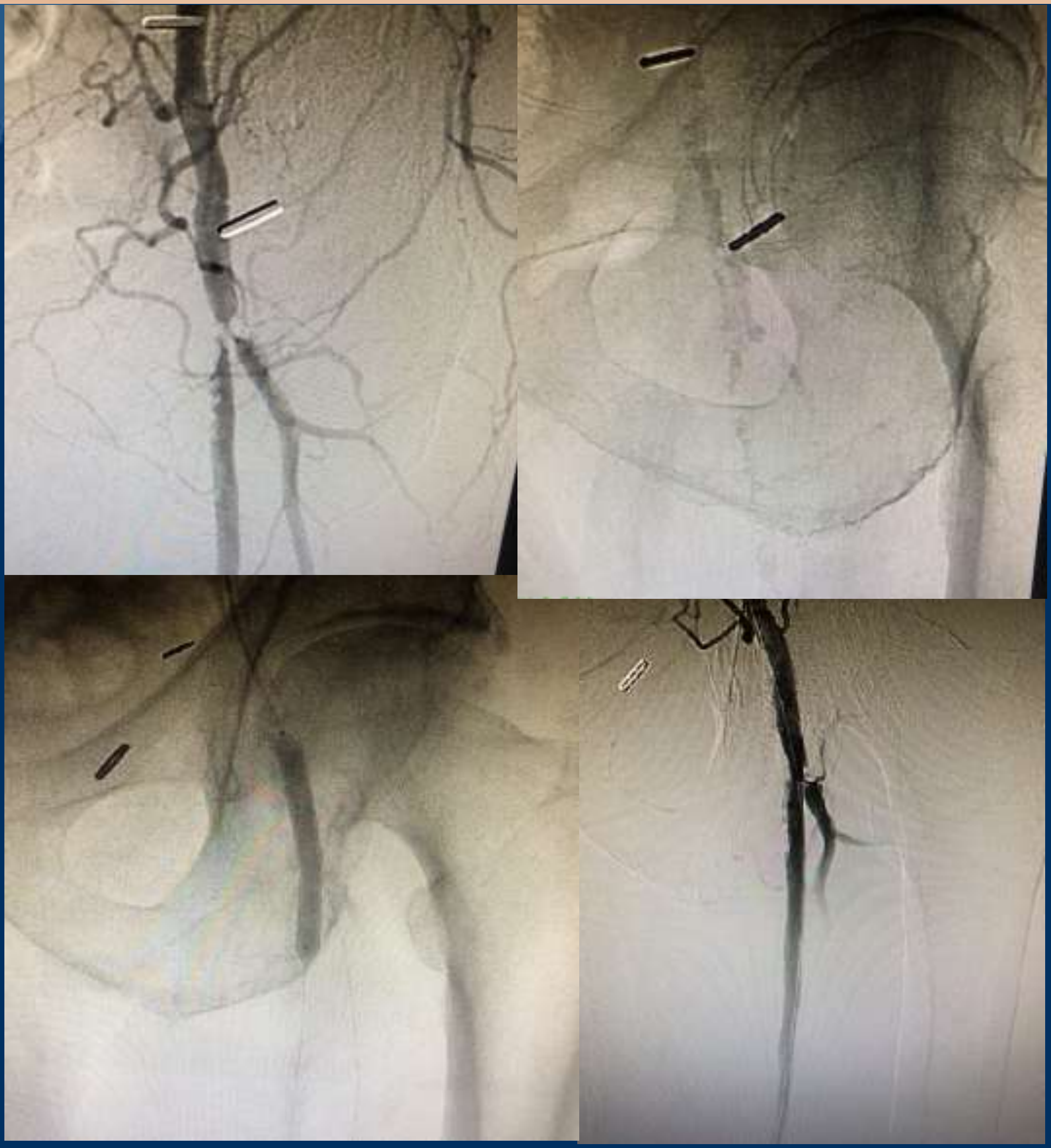
Core lab adjudicated

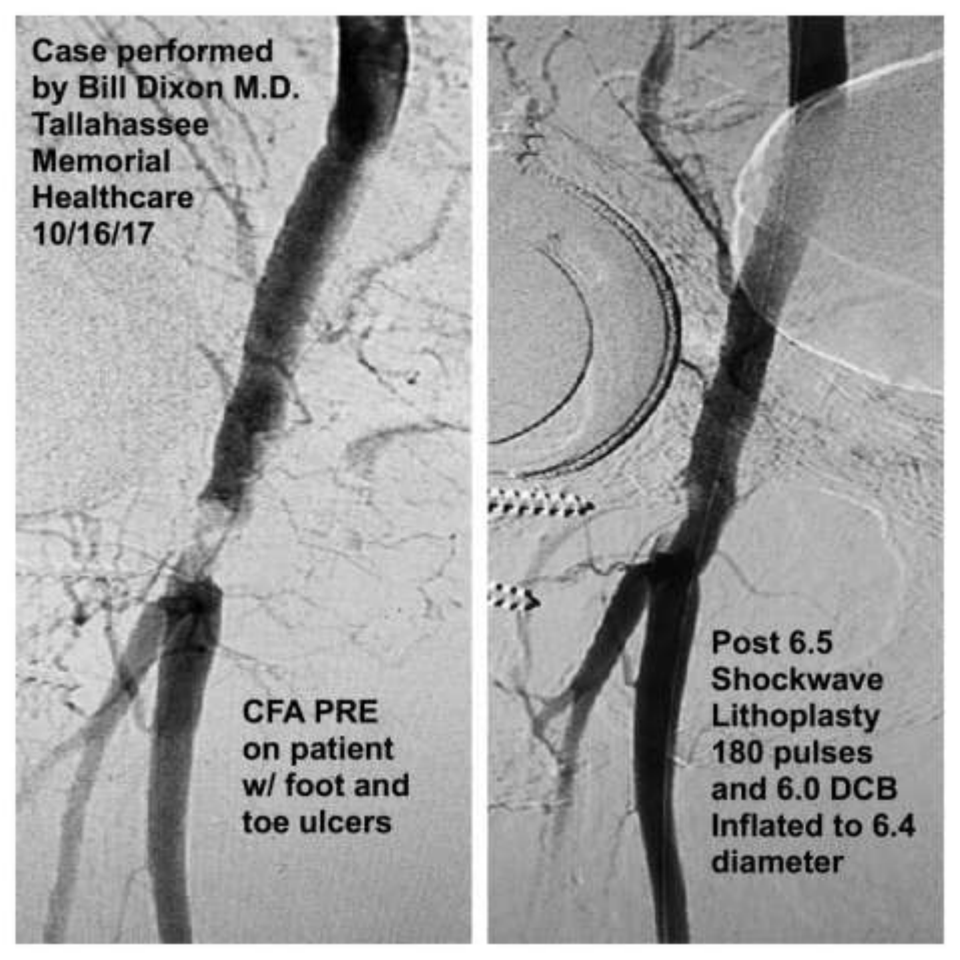
- 100% of patients had moderate or severe calcifications
- No vascular complications including flow-limiting dissections, perforation, distal embolization


90 yo
males
Presents
w/
shin
wound
IVL therapy
delivery
Post 6.5
standalone
IVL 300
pulses
6.5x60m
m
IVL

80y/o male with limiting claudication

6.5 x 60mm IVL standalone




Case performed
by Bill Dixon M.D.
Tallahassee
Memorial
Healthcare
10/16/17
CFA PRE
on patient
w/ foot and
toe ulcers
Post 6.5
Shockwave
Lithoplasty
180 pulses
and 6.0 DCB
Inflated to 6.4
diameter

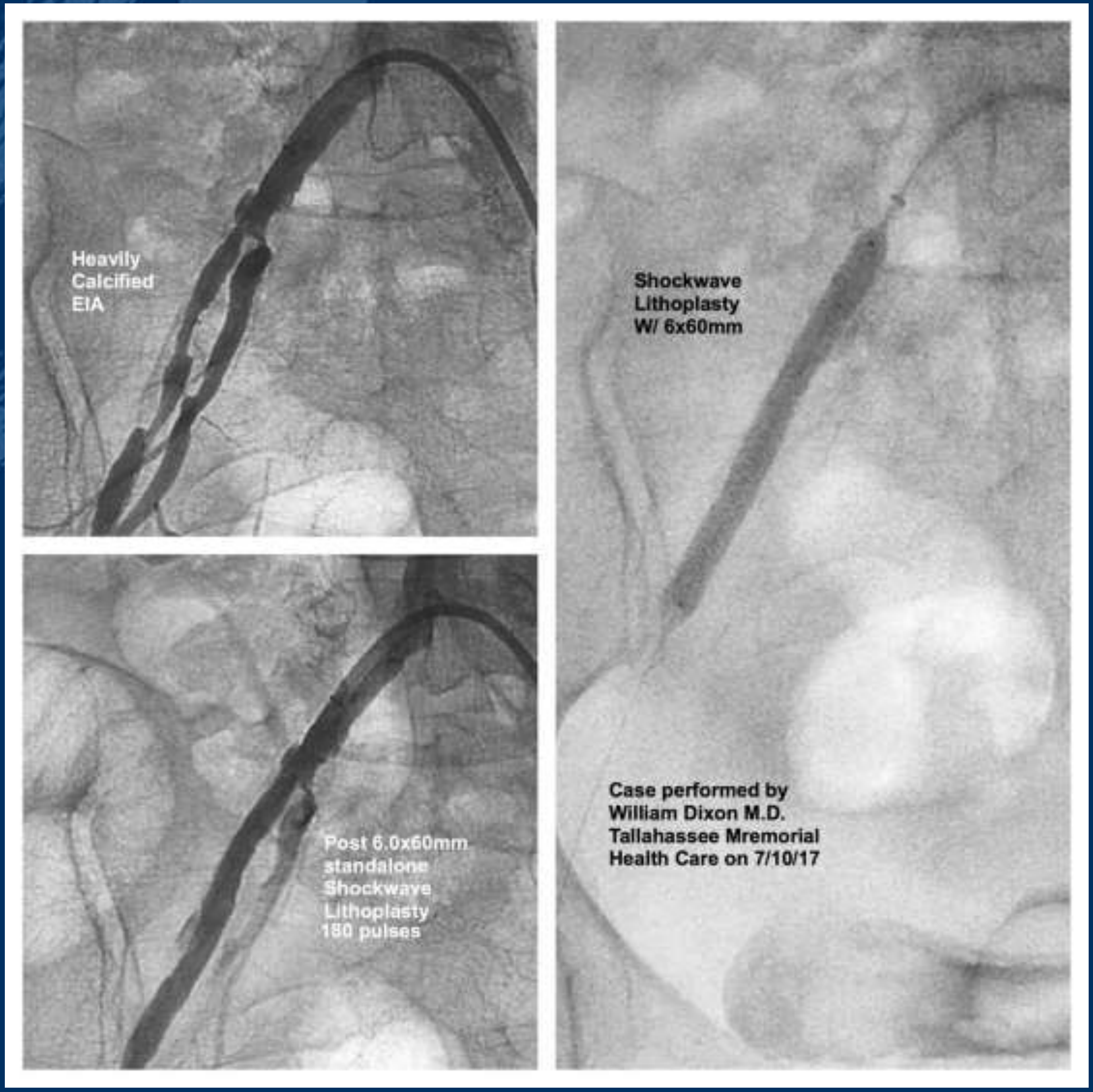
IVL in Iliac Arteries

- Used as standalone or predilation for stenting
- Low pressure decreases risk of dissection/rupture
- No jailing of internal iliac artery
- May reduce the need for stent placement in external iliac
- Facilitates large bore access

IVL in Iliac Arteries

- IVL Enables
  - Transfemoral access, demonstrated improved safety over alternative access strategies for TAVR
  - Endovascular treatment without stent or additional surgical intervention
  - Full/unrestricted stent or stent-graft expansion
  - Difficult EVAR, TEVAR, and TAVR

IVL in Iliac Arteries



Large Bore Access – Pre-TAVR

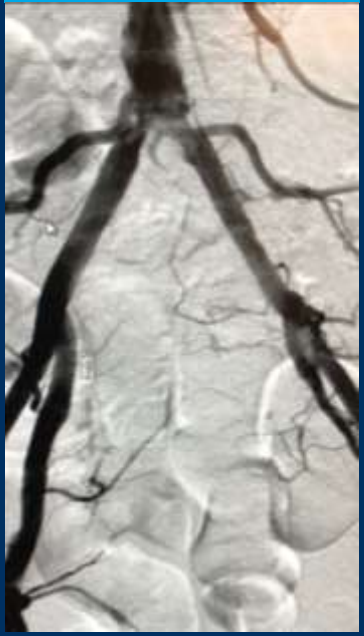
No-Option Aortic Regurgitation Patient

SHOCKWAVE MEDICAL
CASE STUDY
Case courtesy of: Dr. Brian Kolski

Pre-Treatment Angiogram

Bilateral Iliac IVL Treatment

Post-IVL and successful TAVR



Case Highlight:

- 85 year old with critical aortic stenosis & severe claudication with rest pain
- Not a surgical candidate due to lung disease
- No transcaval or subclavian access option available
- Pre-procedure angiogram demonstrating significant narrowing of bilateral iliac arteries
- Near occlusion of distal aorta

Why IVL?

- IVL has been shown to safely and effectively treat calcified Iliacs in advanced of TAVI delivery, allowing safe transfemoral delivery[1]
- Complication rate with IVL in Pre-TAVI use is very low with a no perforations and no stents placed[1]

Outcome

- Post-IVL iliac arteries allowing safe passage of a Medtronic Evolut R 26mm TAVR device (minimum vessel diameter required >5.5mm)
- Patient discharged following day

1. Di Mario C. et al, A Prospective Registry of Intravascular Lithotripsy-Enabled Vascular Access for Transfemoral Transcatheter Aortic Valve Replacement, JACC: CI, Mar 2019

Large Bore Access – Pre-EVAR
Calcified Iliac Treatment prior to AAA Graft delivery

SHOCKWAVE MEDICAL
CASE STUDY
Case courtesy of: Dr. David Caparrelli

Pre-Treatment Angiogram

Iliac
IVL Treatment

Safe Delivery of EVAR Sheath

Post-IVL and successful AAA

Case Highlight:
- Patient was to receive an 18Fr AAA graft
- Highly Calcified Iliac limited the options for a safe delivery of the AAA Graft
- IVL chosen to prep and modify the calcified vessels in order to enable passage of the graft

Why IVL?
- IVL has been shown to safely and effectively treat calcified Iliacs in advanced of EVAR & TEVAR delivery, allowing safe delivery[1]
- Complication rate with IVL in Pre-EVAR/TEVAR use is very low with a no perforations and no stents placed[1]

Outcome
- Post-IVL iliac arteries allowing safe passage of a the 18Fr AAA graft
- No complications (dissections, perforations, emboli)

1. Foteh M, The use of intravascular lithotripsy to facilitate the delivery of aortic endovascular grafts in calcified iliac arteries, Charing Cross 2019

Conclusions

- IVL is a unique therapy which allows safe, effective treatment of heavily calcified peripheral vessels, possibly reducing risk of complications
- Minimal learning curve, embolic protection not necessary
- Allows treatment of lesions which have historically required surgical revascularization (no-stent areas)
- May be used to facilitate large bore access (TAVR, EVAR, TEVAR) through diseased iliac arteries

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