Safety and Feasibility of Intravascular Lithotripsy for Treatment of Common Femoral Artery Stenoses

Pr Marianne Brodmann, MD
Univ. Klinik für Innere Medizin
Medizinische Universtität Graz

Disclosure

Speaker name: Marianne Brodmann, MD

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I have the following potential conflicts of interest to report:

☒ Consulting

Medtronic, BD BARD, Spectranetics, Intact Vascular, Soundbite Medical, Biotronik, Bayer, Daiichi Sankyo, Böhringer Ingelheim, Astra Zeneca

Calcification in CFA Disease

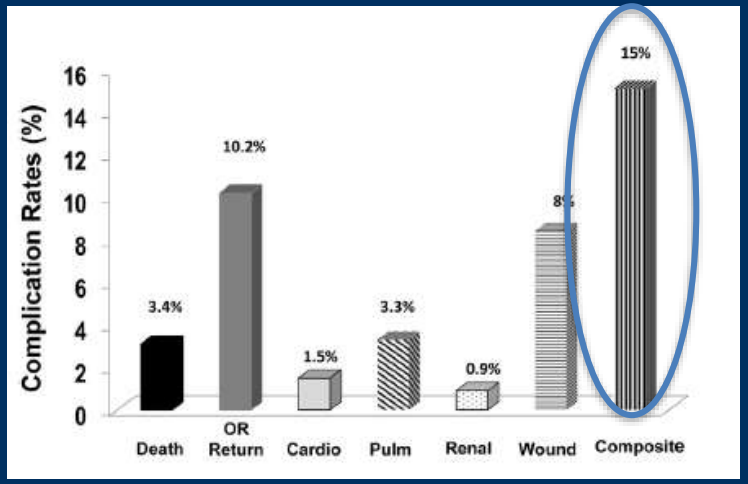
- Calcification is a key underlying factor in CFA disease
- Common Femoral Endarterectomy (CFE) is the standard of care for common femoral artery stenosis
- CFE is associated with good long-term patency, but
  - It is not a benign procedure
  - Not all patients are candidate
  - It is associated with extended LOS
- Endovascular interventions are growing in acceptance and have
  - High technical success rates
  - Lower reintervention rates

Common Femoral Endarterectomy (CFE): Is Not A Benign Procedure

- A review of almost **2000 cases from the National Surgical Quality Improvement Program** database revealed:
  - Post operative complications are not rare
    - 15% composite rate of morbidity and mortality
  - Not all patients are ideal candidates for CFE

Postoperative complications after common femoral endarterectomy

Nguyen, B, et al, J of Vasc Surg, 2015; 61(6): 1489-1484

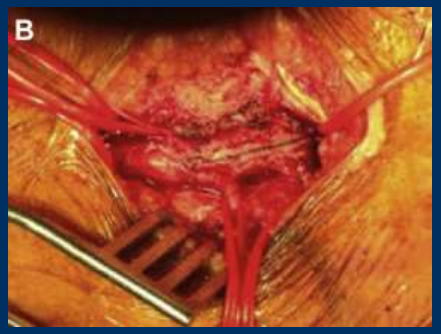


Predictors of wound complications

Predictor	P-Value
Operation Time	.0002
Weight	< .0001
Female	.0009
Diabetes	.03
Dialysis	.0016
Chronic Steroid Use	.0074

Common Femoral Endarterectomy (CFE): Patient Selection and Considerations

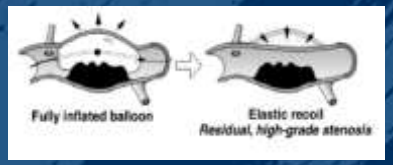
- Not all patients are good candidates for CFE:
  - History of healing wound problems
  - Obesity
  - Focal, calcified stenosis
  - Elderly
  - Concomitant external iliac or sfa disease
  - Physiologic high risk (for surgery)
- CFE can have a average length of stay of 4 + 5.8 days[1]



1. Bao-Ngoc,, et al. J of Vasc Surg, 2013; 1152

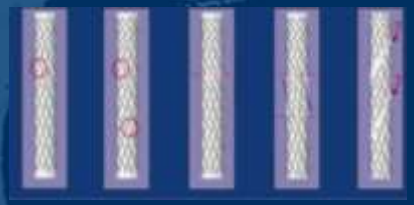
Challenges with Current Endovascular Options

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 address calcium 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 System

How IVL Cracks Calcium In Situ

Expanding and collapsing vapor bubble creates a short burst of **sonic pressure waves**.

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

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

The Shockwave IVL System consists of an IV pole-mountable generator, a connector cable, and a catheter that houses an array of lithotripsy emitters enclosed in an integrated balloon.

Peripheral IVL System: Clinical Programs

DISRUPT PAD I	DISRUPT PAD II	DISRUPT BTK	DISRUPT PAD III	Observational Registry
Pre Market	Post Market	Post Market	Post Market	Post Market
Single Arm	Single Arm	Single Arm	Randomized	Single Arm
N = 35	N = 60	N = 20	N = 400	N = 1000
2014	2015	2017	2017	2017

Study Completed | **Enrolling**

Objective: To study the safety and effectiveness of the IVL System in the treatment of *calcified*, stenotic femoropopliteal or infrapopliteal peripheral arteries.

Common Femoral Case Series

Objective: Evaluate the safety and effectiveness of peripheral IVL to deliver localized lithotripsy to calcified, stenotic common femoral arteries

Design:

- Initiated in 2015 with Prospective Data collection, additional 2 sites added with retrospective data collection 2017-208
- Core lab adjudicated

Sites & Subjects: 21 patients, 3 sites

- Medical University of Graz, Graz Austria
- St. Franziskus Hospital, Muenster Germany
- Heart Hospital of Austin, Austin Texas

Baseline Demographics

Baseline Characteristics	N = 21
Age, years, mean ± SD	71.9±10.1
Male Gender, % (n)	76.14% (16)
Rutherford Class, %	
RC 1	4.7%(1)
RC 2	9.5% (2)
RC 3	52.3 % (11)
RC 4	23.8% (5)
RC 5	9.5.% (2)
RC 6	0.0 % (0)

Pre-procedure	N = 21
Reference vessel diameter, mm, mean ± SD (range)	6.1± 0.8 (4.5-7.5)
Mean luminal diameter, mm, mean ± SD (range)	1.7 ± 0.7 (0.0-2.8)
Diameter stenosis, % mean ± SD (range)	72.3% ± 12.8 (50.2-100.0)
Lesion length, mm, mean ± SD (range)	37.8 ± 16.7 (12.0-72.7)
Calcified length, mm, mean ± SD (range)	61.6 ± 30.7 (25.4-143.0)
Calcification[†], % (n)	
Moderate	28.6% (6)
Severe	71.4% (15)

Core lab adjudicated

Brodmann, et al, *Manuscript Submitted*

Procedural Details

- 100% Successful IVL delivery with no pre-dilatation
- 86% Procedures were combined IVL + DCB

Procedural Characteristics	Study Subjects N = 21
Pre-dilatation, %	0.0% (0)
Successful IVL delivery	100.0% (21)
IVL Pulses mean ± SD (range)	140 ± 58 (60-300)
Mean pressure, atm, mean ± SD	6.3 ± 1.4 (4.0-7.0)
Adjunctive Technology, % Drug-Coated Balloon Atherectomy Stand-alone IVL	 85.7% (18) 4.7% (1) 9.5% (2)
Length of Stay (days)	2

Core lab adjudicated

Brodmann, et al, *Manuscript Submitted*

Outcomes

No vascular complications including flow-limiting dissections, perforation, distal embolization or stenting

Final Procedure	N=21
Mean luminal diameter, mm, mean ± SD (range)	4.8±1.1 (2.8-6.5)
Diameter stenosis, % mean ± SD (range)	21.3% ± 10.7 (5.1-40.0)
Acute gain, mm, mean ± SD (range)	3.1± 1.3 (0.7-5.5)
Dissection Flow-limiting (Grade D-F)	0% (0)
Stents	0% (0)
Perforation	0% (0)
Distal embolization	0% (0)
Thrombus	0% (0)
No reflow	0% (0)
Abrupt closure	0% (0)

Core lab adjudicated

Brodmann, et al, *Manuscript Submitted*

Case Example: CFA Lesion

Pre-procedure

90% Stenosis
11.98 mm length

IVL Catheter

6.5mm IVL balloon

Final

10% Stenosis
Acute Gain 5.5mm

Case Example: CFA Lesion

Pre-procedure

72% Stenosis
29.01 mm length

IVL Catheter

7.0mm IVL balloon

Final

11% Stenosis
Acute gain 4.5 mm

Summary: IVL Provides an Endovascular Option for CFA Disease

- Early experience shows promising results of IVL in highly calcified CFA arteries
  - Low residual stenoses and high acute gain
  - No vascular or angiographical complications such as flow-limiting dissections, provisional stenting, perforation, slow or no reflow
- Results from early CFA experience have similar results in both acute performance and safety as seen in Disrupt PAD I/II and BTK studies

- IVL:
  - May be a viable option for patients that are not good surgical candidates
  - Won’t prohibit future surgical interventions if required
  - May improve hospital efficiency and cost effectiveness with a reduced LOS compared to surgical intervention
- Early experience shows promising results of IVL in highly calcified CFA arteries

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