

# Use of DCB in BTK Con

**At Least Not Yet!**



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# Disclosure

Speaker name: Gary Ansel, MD

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I have the following potential conflicts of interest to report:

**Consulting** Medtronic, BSC, Cook Med. WL Gore, Abbott Vasc. CR Bard, Phillips

Employment in industry

Stockholder of a healthcare company

Owner of a healthcare company

**Other(s)**

Royalties: Cook Medical,

I do not have any potential conflict of interest

# When Not to Adopt a Technology

- Not enough data on efficacy
- Cant afford unproven technology
- Possible Safety Concerns



# Big Data Deficit

- There are several single center data sets but come on these are biased! Can you say Renal Denervation! “Randomized core lab controlled”
- Why was true CLI excluded from all SFA IDE trials and no one reports incidence of toe amputations?
- What Happened in the 1 multicenter randomized, core lab controlled CLI trial?



# BIG DATA DEFICIT

**TABLE 4** 12-Month Efficacy Endpoints

	<b>IA-DEB</b>	<b>PTA</b>	<b>p Value</b>
Late lumen loss,* mm	0.605 ± 0.775	0.616 ± 0.781	0.950
Binary restenosis*	41.0 (25/61)	35.5 (11/31)	0.609
Occlusion rate	11.5 (7/61)	16.1 (5/31)	0.531
Longitudinal restenosis†	62.7 ± 56.2	93.2 ± 60.8	0.167
Clinically driven TLR (AFS subjects)	9.2 (18/196)	13.1 (14/107)	0.291
Clinically driven TLR (all ITT subjects)	11.9 (27/226)	13.5 (15/111)	0.682

Values are mean ± SD or % (n/N). \*Angiographic cohort (core lab analyzed). †Mean % of stenosis length versus treated lesion length (angiographic cohort).

AFS = amputation-free survival; TLR = target lesion revascularization; other abbreviations as in [Table 1](#).

# Cant Afford Unproven Technology

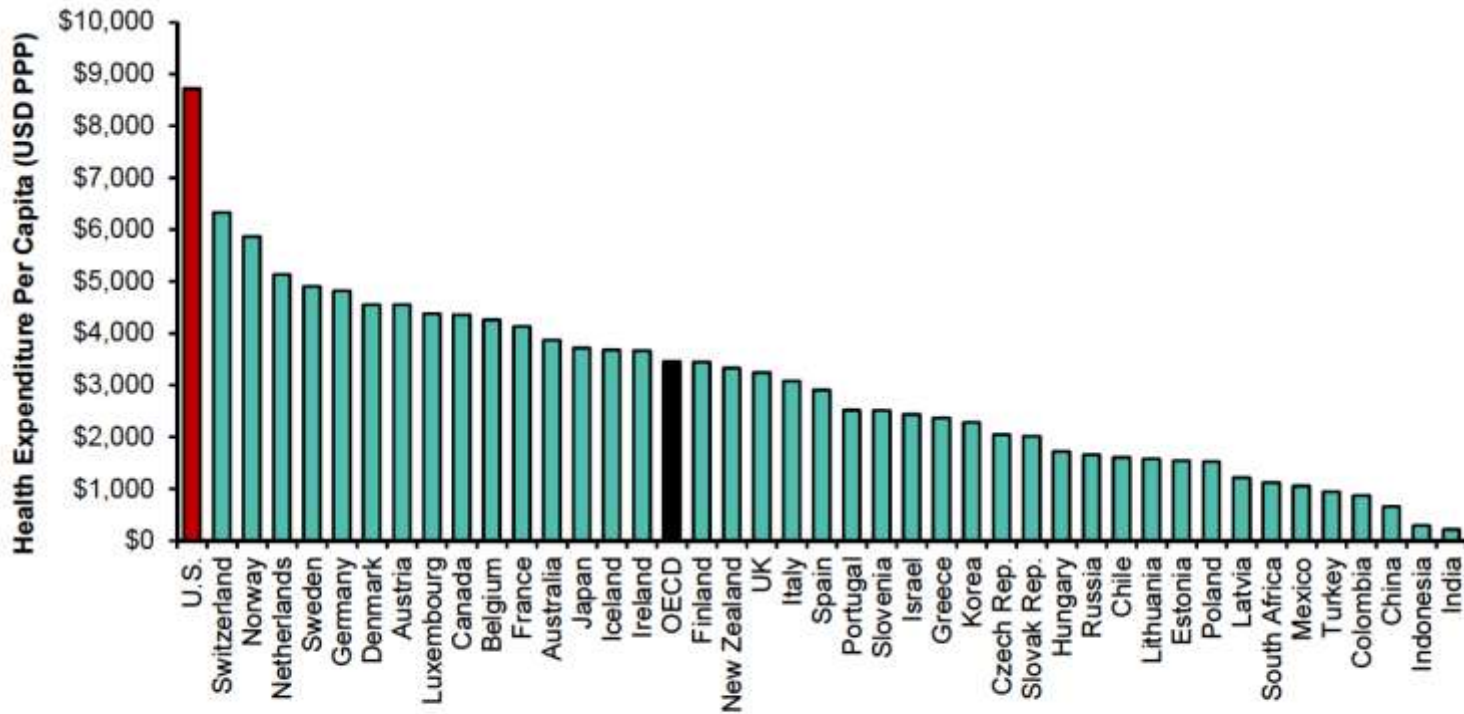


- If Surgery could not beat POBA in CLI
- Then How can any technology beat POBA?
- Say Basil Very Slowly
  
- Wasting money here takes it from there



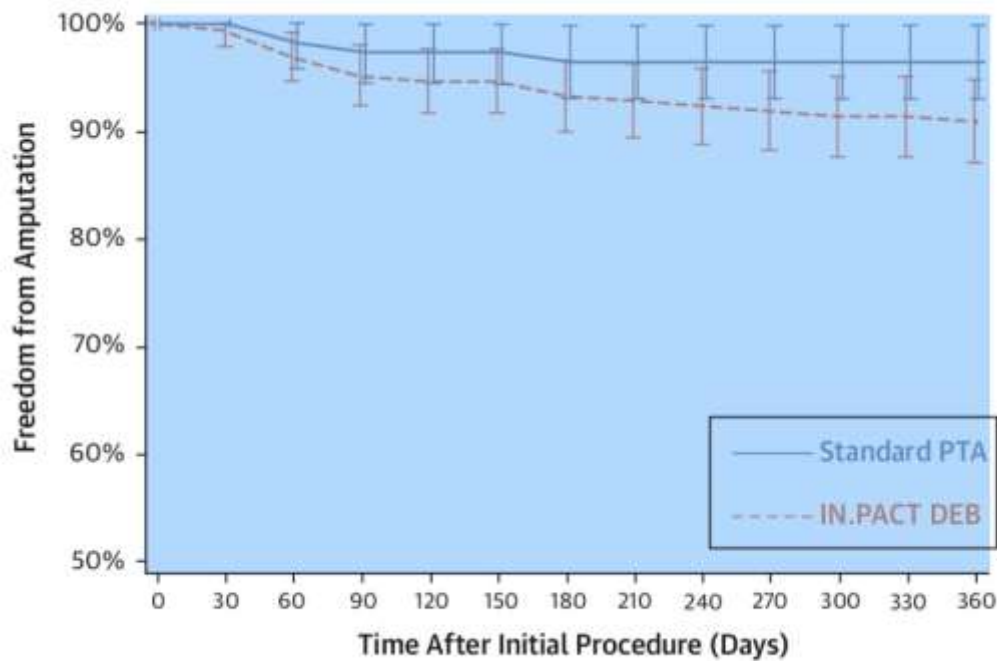


# Health Expenditures Per Capita



Source: OECD Health Statistics 2015 (2013 data or nearest year), Bernstein analysis

# Possible Safety Concerns?

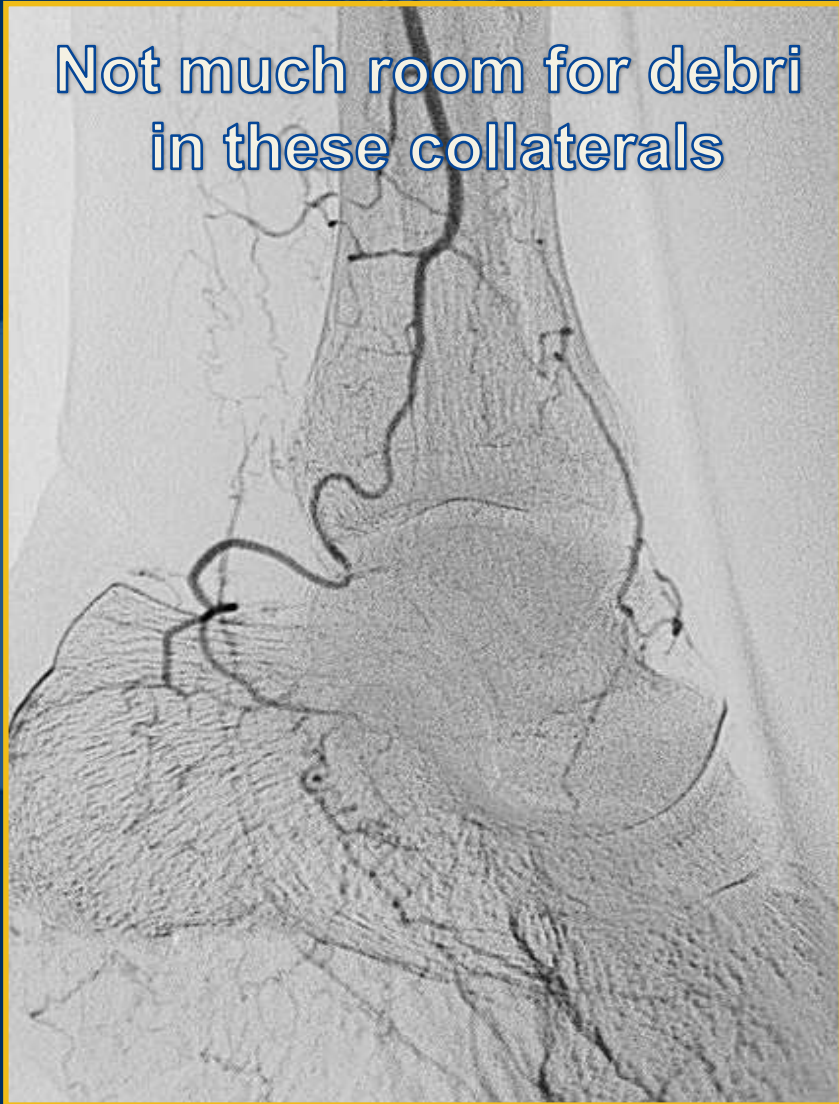


Zeller et al JACC 2014:1568-76

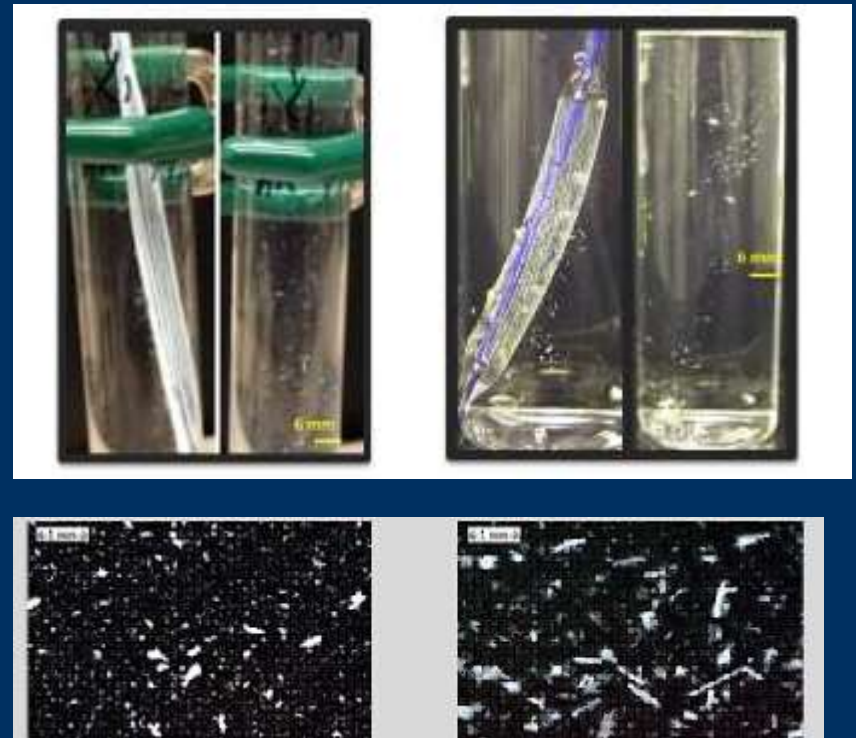


# Possible Safety Concerns?

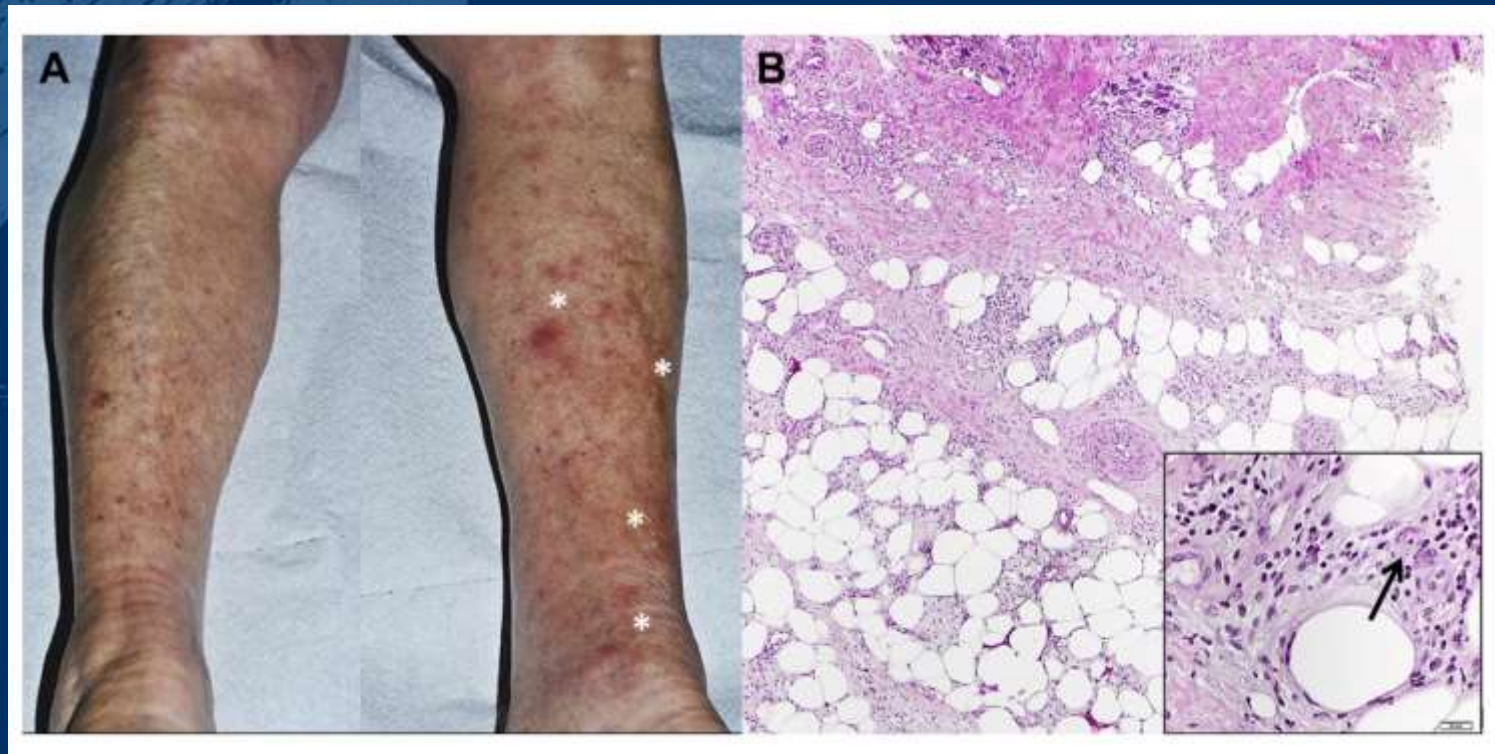
Not much room for debris  
in these collaterals



Current Generation DCBs  
Debris



# Case Report of Paniculitis after DCB



# Summary

## Why We Should Not Adopt DCB in CLI Yet

- We don't have enough data on efficacy!
- We cant afford unproven technology!
- There are possible Safety Concerns!



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