Cost Economic Evidence:

What do DCB's deserve? The US Case Example

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Disclosures

Company	Consultant	Research	Speaking Representative
Abbott Vascular	X		X
Asahi Intecc	X		X
Bard	X		
Boston Scientific	X	X	
Cardinal-Cordis	X		
Cook Medical	X	X	X
CloSys		X	
Cardiovascular Systems Inc.	X	X	X
Daiichi Sankyo	X	X	
Gore	X	X	X
Intact Vascular	X	X	X
Lake Region Medical	X	X	X
Medtronic	X	X	X
Mercator Med-Systems	X	X	X
Penumbra	X	X	X
Philips- Volcano	X	X	X
Roxwood Medical	X		
Shockwave Medical	X	X	
Terumo	X		X

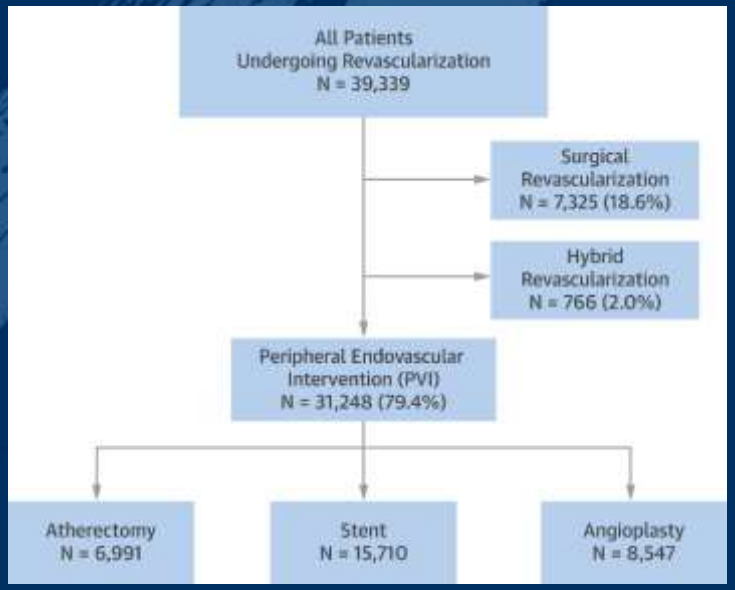
Where we often stand…

- Increasingly complex patients
- Multitude of available diagnostic and treatment option
- Abundance of data, but also data gaps
- Fiscal concerns

Where we want to go…

- Clear data
- Individual and optimized treatment
- Value based care

Reimbursement Changes Can Drive Trends in Practice

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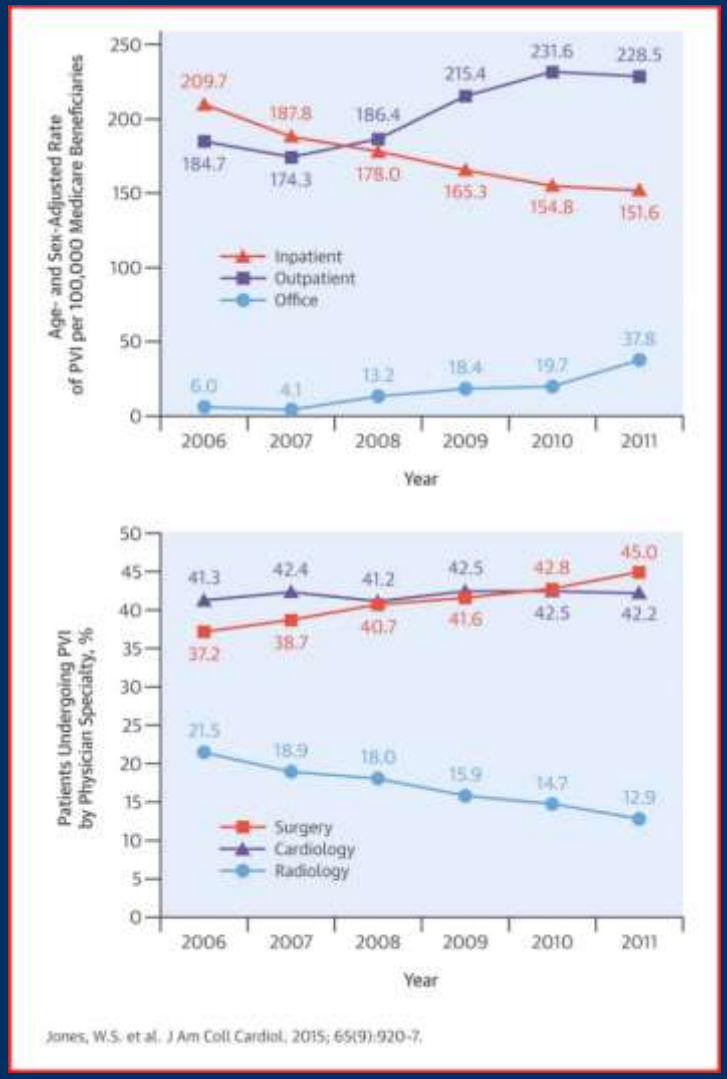
NEWS

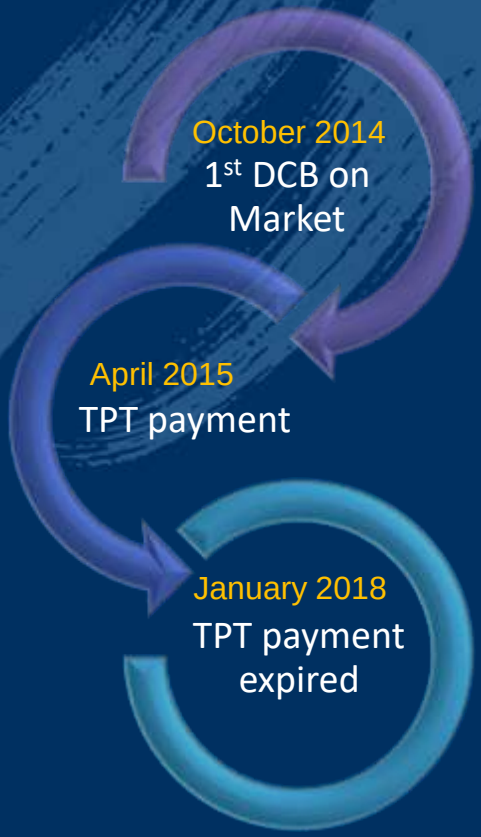
Surge in Outpatient PAD Procedures Linked to Change in Medicare Reimbursement

https://www.tctmd.com/news/surge-outpatient-pad-procedures-linked-change-medicare-reimbursement



W. SchuylerJones et al., JACC 2015

Case Example: DCB's in the USA



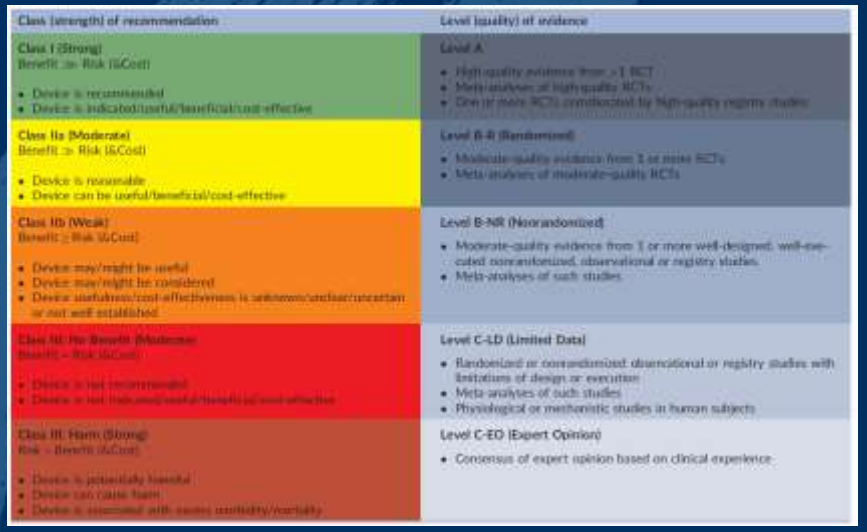
Background

To facilitate access to new and truly innovative devices, the United States Centers for Medicare & Medicaid Services (CMS) grants transitional pass-through (TPTs) payments on an application basis. TPTs are designed to enable adequate payment while additional cost data are collected.

- ✓ On April 1, 2015, the CMS established a TPT payment to outpatient hospital usage of DCB platforms.
- ✓ On January 1, 2018, the TPT payment for DCB reimbursement by the CMS expired.
- ✓ Three DCBs are currently approved for use in the US: Lutonix (Bard Peripheral Vascular, Inc.), In.Pact Admiral (Medtronic), and Stellarex (Philips IGTD). The expiry of the TPT applies to all outpatient hospital DCB applications.

DCB's – Clear Data for Effectivity

SCAI consensus guidelines for device selection in femoral-popliteal arterial interventions



Class (strength) of recommendation	Level (quality) of evidence
Class I (Strong) Benefit ≫ Risk (&Cost) • Device is recommended • Device is indicated/useful/beneficial/cost-effective	Level A • High-quality evidence from ≥1 RCT • Meta-analyses of high-quality RCTs • One or more RCTs corroborated by high-quality registry studies
Class IIa (Moderate) Benefit ≥ Risk (&Cost) • Device is reasonable • Device can be useful/beneficial/cost-effective	Level B-R (Randomized) • Moderate-quality evidence from 1 or more RCTs • Meta-analyses of moderate-quality RCTs
Class IIb (Weak) Benefit ≥ Risk (&Cost) • Device may/might be useful • Device may/might be considered • Device usefulness/cost-effectiveness is unknown/unclear/uncertain or not well established	Level B-NR (Nonrandomized) • Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized, observational or registry studies • Meta-analyses of such studies
Class III: No Benefit (Moderate) Benefit = Risk (&Cost) • Device is not recommended • Device is not useful/beneficial/cost-effective	Level C-LD (Limited Data) • Randomized or nonrandomized observational or registry studies with limitations of design or execution • Meta-analyses of such studies • Physiological or mechanistic studies in human subjects
Class III: Harm (Strong) Risk ≫ Benefit (&Cost) • Device is potentially harmful • Device can cause harm • Device is associated with excess morbidity/mortality	Level C-EO (Expert Opinion) • Consensus of expert opinion based on clinical experience

Strong level and high quality of evidence supporting the use of DCB in Fem-pop interventions

TABLE 3 COR[a] and LOE for device selection as the *Intended Definitive Therapy* in the femoral-popliteal arterial interventions

	PTA	Specialty balloons	BMS (Self-expanding)	DES	DCB	Covered stents	Laser atherectomy	Directional atherectomy	Orbital/ Rotational atherectomy	Excisional/ aspiration atherectomy
1. CFA bifurcation lesion	IIB C-LD	IIB C-EO	IIA B-R	IIA C-EO	IIA C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO
2. Above knee popliteal lesion	III: NB B-R	III: NB C-EO	IIA A	I B-R	I A	IIB B-R	III: NB C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO
3. Ostial SFA lesion	IIB B-R	IIB C-EO	IIA A	I B-R	I A	III C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO
4. Focal SFA lesion	IIB A	III: NB C-LD	IIA A	I B-R	I A	IIB B-R	III: NB C-LD	III: NB C-LD	III: NB C-LD	III: NB C-LD
5. Intermediate SFA lesion	III: NB B-R	III: NB C-LD	IIA A	I B-R	I A	IIB B-R	III: NB C-LD	III: NB C-LD	III: NB C-LD	III: NB C-LD
6. Diffuse SFA lesion	III: NB B-NR	III: NB C-EO	IIA B-NR	I B-NR	I B-R	IIA B-R	III: NB C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO
7. Moderate to severe calcified, focal lesion	IIB B-NR	IIB C-LD	IIA C-LD	I C-LD	I C-LD	IIB C-EO	III: NB C-LD	III: NB C-LD	III: NB C-LD	III: NB C-LD
8. Moderate to severe calcified, intermediate lesion	III: NB B-NR	III: NB C-LD	IIA C-LD	I C-LD	I C-LD	IIB C-EO	III: NB C-LD	III: NB C-LD	III: NB C-LD	III: NB C-LD
9. Moderate to severe calcified, diffuse lesion	III: NB B-NR	III: NB C-LD	IIA C-EO	I C-EO	I C-LD	IIA C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO
10. Chronic total occlusion, focal lesion	IIB B-R	III: NB C-EO	IIA B-R	I B-R	I B-R	IIB C-LD	III: NB C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO
11. Chronic total occlusion, intermediate lesion	III: NB B-R	III: NB C-EO	IIA B-R	I B-R	I B-R	IIB B-R	III: NB C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO
12. Chronic total occlusion, diffuse lesion	III: NB B-NR	III: NB C-EO	IIA C-LD	I B-NR	I B-NR	IIA B-R	III: NB C-EO	III: NB C-EO	III: NB C-EO	III: NB C-EO
13. ISR, focal lesion	IIB B-R	III: NB C-LD	III: NB C-EO	IIB C-LD	I B-R	IIB C-LD	IIA B-R	III: NB C-EO	III: H C-EO	III: NB C-EO
14. ISR, intermediate lesion	III: NB B-R	III: NB C-LD	III: NB C-EO	IIA C-LD	I B-R	IIB B-R	IIA B-R	III: NB C-EO	III: H C-EO	III: NB C-EO
15. ISR, diffuse lesion	III: NB B-NR	III: NB C-EO	III: NB C-EO	IIA C-LD	I B-R	IIA B-R	IIA B-R	III: NB C-EO	III: H C-EO	III: NB C-EO

Feldman et al., Catheter Cardiovasc Interv. 2018;1–17.

DCB's – The Argument for Cost Effectiveness

A primary outcome in a recent cost-effectiveness analysis was patency at 2 years, which includes primary, primary assisted, and secondary patency.

At 2 years, DCB was the dominant strategy with the highest patency and lowest cost of any strategy.

Table IX. Two-year cost analysis

Index procedure	Overall patency at 2 years, %	Cost per patent limb, $	ICER
DCB	89	10,153.08	
POBA	83	11,552.20	Dominated
DES	87	14,702.00	Dominated
BMS	80	15,034.29	Dominated

BMS, Bare-metal stent; *DCB*, drug-coated balloon; *DES*, drug-eluting stent; *ICER*, incremental cost-effectiveness ratio; *POBA*, plain old balloon angioplasty.

Sridharan et al., Cost-effectiveness analysis of drug-coated therapies in the SFA , JVA, January 2018

How Would Decrease in Reimbursement Impact DCB Use?

We hypothesize that

1) De-incentivizes physicians to use DCBs, leading to altered treatment for PAD, including
2) increased atherectomy usage,
3) increased stent usage (BMS and DES), and
4) a shift toward balloon angioplasty (BA) treatment.
5) This might potentially mean limited patient access to care

Study Setup

Design

- DESIGN: Retrospective, comparative, single center study
- OBJECTIVE: DCB utilization in 2017 (with PTC) versus 2018 (without PTC)

Patients treated for PAD involving the SFA or popliteal artery

Group 1 July-Dec 2017 With PTC (n=209)	Group 2 Jan-Jun 2018 No PTC (n=180)

Patient Demographics

	N=209 2017	N=180 2018
Male gender	113 (54.1%)	93 (51.7%)
Age	67.2 ± 12.7	69.3 ± 9.8
Hypertension	184 (88.0%)	162 (90.0%)
Hyperlipidemia	158 (75.6%)	151 (83.9%)
Diabetes Mellitus	120/208 (57.7%)	98 (54.4%)
Hx of CAD/CVA	132 (63.2%)	109 (60.6%)
Smoking	N=207	N=178
Never	38 (18.4%)	35 (19.7%)
Current	64 (30.9%)	45 (25.3%)
Former	105 (50.7%)	98 (55.1%)

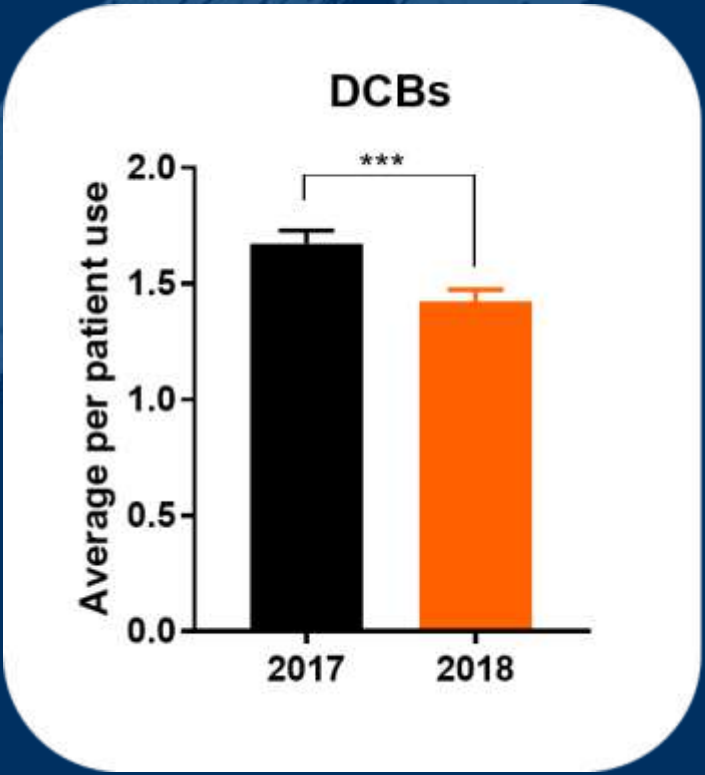
Lesion and Procedural Characteristics

2017 Lesions n=235 in 209 patients
2018 Lesions n=195 in 180 patients

	2017	**2018**
Lesion length (mm)	135.2 ± 109.1	139.6 ± 102.6 (n=189)
RVD (mm)	5.6 ± 0.7	5.6 ± 0.6
%DS Baseline	90 ± 10	90 ± 10 (n=191)
% Residual Stenosis post treatment	10 ± 10	10 ± 10 (n=190)

Per lesion unless specified

Results Part 1: DCB Use



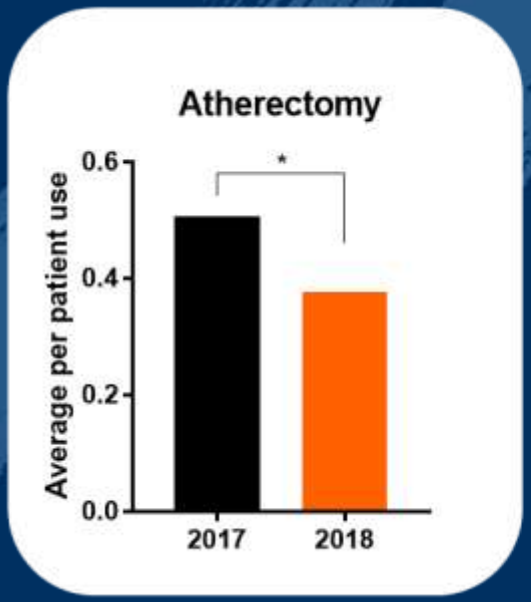
350 DCBs were used in 209 patients sampled with the pass through code (PTC) in 2017 (1.675 DCBs/pt)

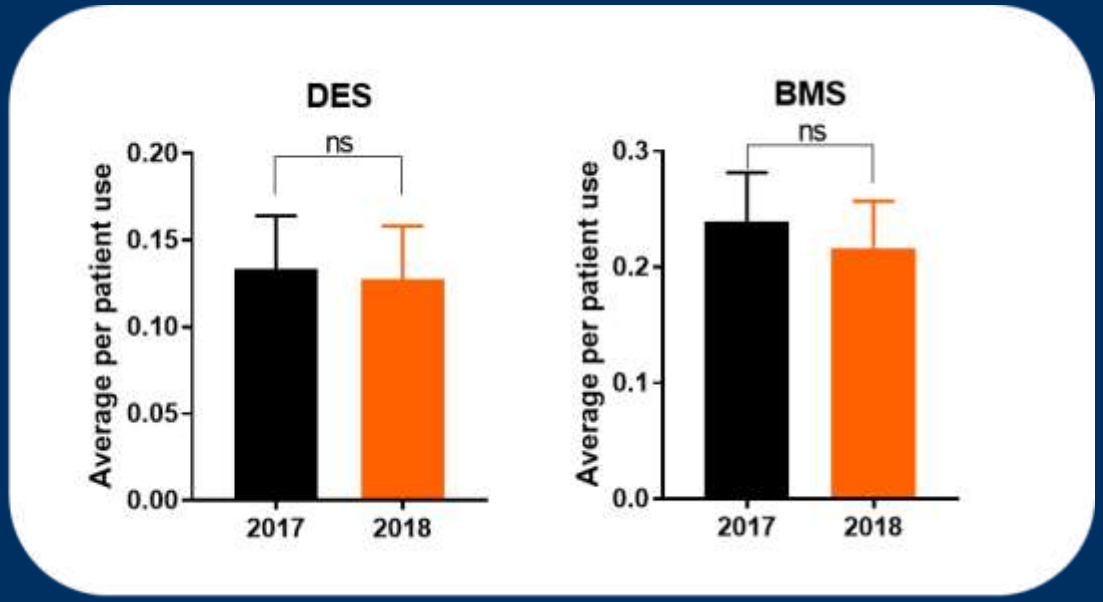
256 DCBs were used in the 180 patients sampled without the PTC in 2018 (1.422 DCBs/pt)

There was a 15.07% reduction in DCB usage per patient without the PTC

Shown are the mean DCBs used per patient + the standard error of the mean (SEM). Performed was a non-parametric t-test (Mann-Whitney test) to compare the non Gaussian distributed data.

Results Part 2: Other Treatment Options





- 106/209 patients treated with atherectomy in 2017 (50.72%). 68 /180 patients treated with atherectomy in 2018 (37.78%) → a 25.51% reduction in atherectomy.
- 27 DESs/209 patients in 2017 (0.1292 DES/pt) and 23 DESs/180 patients in 2018 (0.1278) → no obvious change in DES use
- 50 BMSs/209 patients in 2017 (0.2392 BMS/pt). 39 BMSs/180 patients in 2018 (0.2167 BMS/pt) -> a non significant 9.433% reduction in BMS use

For atherectomy, the average use per patient is shown, to test for statistical significance, a Fisher's exact text was performed.
For DES and BMS, the mean number of stents/patients and the SEM are shown, non-parametric t-tests (Mann-Whitney) were performed.

Next Steps

- Determine if this shift in treatment is owed to other treatment strategies such as balloon angioplasty.
- A detailed look at lesion characteristics that might influence the average DCB use per patients, such as lesion length, to better judge the observed differences
- Determine procedure cost and comparing readmission rates.
- In a world increasingly focused on the value of care, this study provides preliminary insights on the impact of DCB reimbursement changes and their utilization in treating PAD.

Conclusions

The use of DCBs to treat Fem-Pop PAD is supported by a host of high quality data. In addition, cost-analysis over 2 years provides an argument for their cost-effectiveness

The recent drop of the CMS transitional pass-through (TPTs) payment could however impact their use

How this might impact practice and possibly outcomes remains to be seen. Studies like the herein presented one will hopefully shed light and provide insights into how we can move to a truly value-based solution

Cost Economic Evidence:

What do DCB's deserve? The US Case Example

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