

Understanding Real-World Clinical and Economic Burden of Different Devices Strategies for the Endovascular Treatment of Symptomatic Peripheral Arterial Disease in Japan: A Real-World Claims Data Analysis Protocol

Poster Code:
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Yirong Chen, PhD¹; Eric Secemsky, MD, MSc²; Michael R Jaff, DO³; Qingxia Hao, MSc⁴; Bruce Crawford, MA, MPH⁵; **Thathya V Ariyaratne, PhD⁶**
¹ Vista Health, Singapore, Singapore, ² Smith Center for Outcomes Research in Cardiology, Beth Israel Deaconess Medical Center, Boston, MA, USA, ³ Boston Scientific Corporation, Marlborough, MA, USA, ⁴ Vista Health, Beijing, China, ⁵ Vista Health, Tokyo, Japan, ⁶ Boston Scientific Corporation, Asia Pacific, Singapore

BACKGROUND

Peripheral artery disease (PAD) is associated with substantial clinical and economic burden worldwide, driven by high rates of hospitalizations, recurrent interventions, and associated comorbidities such as cardiovascular events.^{1,2}

Endovascular procedures, including balloon angioplasty and stenting, are common methods for the treatment of symptomatic PAD in patients who do not respond to lifestyle modifications and pharmacological therapies.^{3,4}

The drug-coated balloon (DCB) delivers an anti-proliferative drug directly to the vessel wall during balloon inflation, eliminating the need for a permanent implant.⁵ Among stent-based interventions, two types are commonly used – bare-metal stent (BMS) and drug-eluting stent (DES).

OBJECTIVE

This study aims to evaluate the clinical and economic outcomes of PAD patients undergoing endovascular revascularization procedures (EVP) with DES, BMS, and DCB in Japan using real-world data.

METHODS

- Design:** Retrospective cohort study
- Database:** The Medical Data Vision (MDV) is a hospital claims database comprised of anonymized hospital data from 532 hospitals, which cover approximately 30% of acute phase hospitals and data for a total of 50.29 million people in Japan
- Study population:** The analysis includes eligible PAD patients who underwent the first EVP (index procedure) with DES, BMS, or DCB from January 2019 to August 2023, and had at least one claim during the 12-month baseline and 12-month follow-up periods
- Study cohort:**
 - ✓ **DES only:** Patients with at least one DES used in the first EVP and without any BMS or DCB use in the index hospitalization
 - ✓ **BMS only:** Patients with at least one BMS used in the first EVP and without any DES or DCB use in the index hospitalization
 - ✓ **DCB only:** Patients with at least one DCB used in the first EVP and without any DES or BMS use in the index hospitalization
- Statistical analysis:**
 - ✓ Descriptive analyses will be conducted. Continuous variables will be summarized using mean and standard deviation (SD). Categorical variables will be summarized using frequency and percentage.
 - ✓ Adjustments through propensity-score matching will be applied to compare the DES, BMS, and DCB cohorts.

CONCLUSIONS

- The results provided an overview of patient and procedural characteristics among PAD patients undergoing EVP with DES, BMS, and DCB in Japan.
- Further analyses will evaluate clinical and economic outcomes after adjustment for baseline differences in real-world settings.
- Future work, including review of medical notes, may help ensure balanced baseline characteristics for robust outcome comparisons.

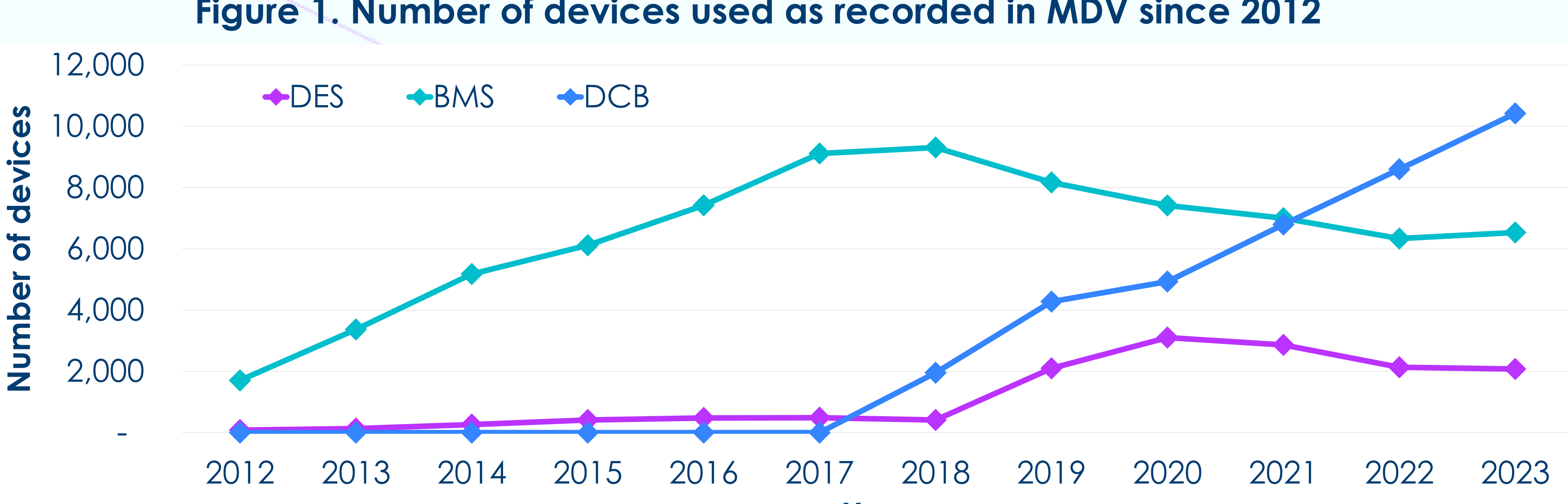
LIMITATIONS

- Claims data are subject to limitations such as misclassification of codes, which may underestimate or overestimate disease prevalence and treatment outcomes.
- Patients are represented with different patient identifiers when they go to different hospitals; therefore, it is not possible to track patients across different hospitals.

RESULTS

- The number of recorded DES and DCB devices used in the MDV data started to increase substantially from 2019 and 2018, respectively; conversely, the number of recorded BMS devices used decreased slightly from 2019 (Figure 1).

Figure 1. Number of devices used as recorded in MDV since 2012



Year	DES	BMS	DCB
2012	0	1,800	0
2013	0	3,500	0
2014	0	5,200	0
2015	0	6,200	0
2016	0	7,500	0
2017	0	9,200	0
2018	0	9,500	2,000
2019	2,000	8,200	4,500
2020	3,200	7,500	5,000
2021	3,000	7,000	7,000
2022	2,200	6,500	8,800
2023	2,100	6,600	10,500

- A total of 20,317 patients treated with DES (n=2,858), BMS (n=9,863), and DCB (n=7,596) were included in the analysis (Table 1).
- The most common comorbidities and their frequencies are reported in Table 1.
- Patients used an average of 1.4 DES and BMS devices, and 1.3 DCB devices for their index procedure. About 70% of patients used only one device during the index procedure, while about 20% of patients used two devices, and the rest used more than two (Table 1).

Table 1. Baseline patient characteristics

	DES (N = 2,858)	BMS (N = 9,863)	DCB (N = 7,596)
Age, Mean (SD)	75.9 (9.2)	74.4 (9.0) *	75.5 (9.4) *
Sex			
Male	1,974 (69.1%)	7,781 (78.9%) *	4,907 (64.6%) *
Female	884 (30.9%)	2,082 (21.1%)	2,689 (35.4%)
Modified Charlson Comorbidity Index (CCI)			
Mean (SD)	2.2 (1.9)	2.0 (1.9) *	2.3 (2.0) *
Medical history			
Hypertension	2,020 (70.7%)	7,046 (71.4%)	5,453 (71.8%)
Hyperlipidaemia	1,672 (58.5%)	6,176 (62.6%) *	4,659 (61.3%) *
Diabetes mellitus	1,824 (63.8%)	5,524 (56.0%) *	5,160 (67.9%) *
Congestive heart failure	1,338 (46.8%)	4,281 (43.4%) *	3,749 (49.4%) *
Chronic kidney disease	808 (28.3%)	1,926 (19.5%) *	2,583 (34.0%) *
History of amputation			
Minor	93 (3.3%)	179 (1.8%) *	248 (3.3%)
Major	136 (4.8%)	284 (2.9%) *	342 (4.5%)
Number of devices used in the index procedure			
Mean (SD)	1.4 (0.6)	1.4 (0.7)	1.3 (0.6) *
1 device	2,035 (71.2%)	7,185 (72.8%)	5,532 (72.8%)
2 devices	635 (22.2%)	2,058 (20.9%)	1,814 (23.9%)
≥3 devices	188 (6.6%)	620 (6.3%)	250 (3.3%)

- During index hospitalisations, more preparation devices, such as cutting balloons and PTA balloons, were used in the DES and DCB cohorts than in the BMS cohort (Table 2).

Table 2. Vessel /Lesion preparation during index hospitalisation

	DES (N = 2,858)	BMS (N = 9,863)	DCB (N = 7,596)
Use of vessel /lesion preparation during index hospitalisation			
Cutting balloons	212 (7.4%)	366 (3.7%) *	1,004 (13.2%) *
PTA balloons	2,482 (86.8%)	6,778 (68.82%) *	5,564 (73.25%) *
Non-slip element scoring balloons	364 (12.7%)	1,094 (11.1%) *	2,041 (26.9%) *

- Vessel /lesion preparation device use provided an indication of vessel calcification, highlighting potential differences in baseline patient characteristics.
- The unadjusted median (IQR) cost (JPY, Million) of an index EVP using only DES, BMS, and DCB was JPY 1.27M (0.70M), JPY 0.98M (0.57M)*, and JPY 1.0M (0.48M)*, respectively.
- Future comparisons of clinical and economic outcomes should account for baseline differences (Table 1), which can be addressed through matching the baseline patient and procedural characteristics.

* Statistically significant at the 0.05 level when compared with the DES cohort

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