Hospitals Without Investigational Device Exemptions Have Worse Outcomes After PMEGs: These Are Often Unreported

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Disclosures

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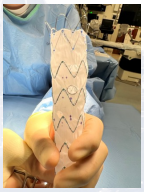
Background

- Fenestrated and Branched Repairs (F/BEVAR) have been adopted by many centers in the US
  - Investigational Device Exemption Studies
  - Custom-made devices
  - Physician Modified Endografts
- Published data is primarily limited to patients treated as part of IDE studies (Aortic Research Consortium)



Background

- Trends in practice of F/BEVAR in the United States is unknown
  - Prevalence of F/BEVAR
  - Center specific volume
- Perioperative and long-term mortality rates for patients treated with F/BEVAR outside of an IDE is not clear

How Can We Study This?

- Medicare claims (100% Fee for service) 2016-2023
  - CPT codes used to identify all patients who underwent endovascular treatment of the visceral aorta using 2+ visceral artery endoprosthesis from 2016-2023
  - ICD-10 codes used to determine indication for repair
- Identified all hospitals with IDE studies and their corresponding start and end dates
  - Classified all centers as IDE or non-IDE sites based on clinicaltrials.gov and tax (EIN) identifiers

Centers with IDEs

eTable 3. Facilities with investigational device exemptions (IDE) for performing F/BEVAR

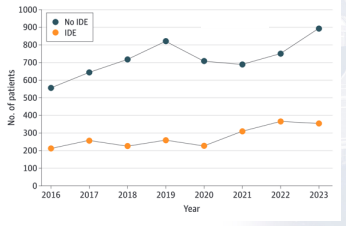
Center Name	Physician	IDE	IDE Type	Earliest Date start	Date end
Cleveland Clinic	Matthew Eagleton, Behzad Farivar	Yes	CMD, PMEG	2001	2020
University of San Francisco	Timothy Chuter, Warren Gasper	Yes	CMD, PMEG	2005	Current
University of Washington	Benjamin Starnes, Matthew Sweet	Yes	CMD, PMEG	2011	Current
Northside Hospital Atlanta	Joseph J. Ricotta II	Yes	PMEG	2012	2015
Baptist Health South Florida	W. Anthony Lee	Yes	CMD, PMEG	2012	Current
University of North Carolina	Mark Farber	Yes	CMD, PMEG	2012	Current
Weill Cornell Medicine	Darren Schneider	Yes	CMD, PMEG	2013	2020
UT Southwestern Medical Center	Carlos Timaran	Yes	CMD, PMEG	2014	Current
Mayo Clinic	Gustavo Oderich	Yes	CMD, PMEG	2014	2019
University of Alabama at Birmingham	Adam Beck	Yes	CMD, PMEG	2014	Current
University of Massachusetts	Andres Schanzer	Yes	CMD, PMEG	2014	Current
Harbor-UCLA Medical Center	Rodney White	Yes	PMEG	2015	Current
UTHealth Houston	Gustavo Oderich	Yes	CMD, PMEG	2019	Current
University of Pennsylvania	Darren Schneider	Yes	CMD, PMEG	2020	Current
Dartmouth Health	David Kuwayama, Bjoern Suckow	Yes	PMEG	2020	Current
Massachusetts General Hospital	Matthew Eagleton	Yes	CMD, PMEG	2020	Current
Beth Israel Deaconess Medical Center	Marc Schermerhorn	Yes	PMEG	2021	Current
University of Southern California	Sugku Han	Yes	PMEG	2021	Current
Medstar Washington Hospital Center	Javairiah Fatima	Yes	PMEG	2021	Current
Minneapolis Heart Institute Foundation	Jesse Manunga	Yes	PMEG	2022	Current
University of California San Diego	Andrew Barleben	Yes	PMEG	2023	Current
University of South Florida / Tampa General Hospital	Dean Arnoutakis	Yes	PMEG	2023	Current

CMD, custom-made device; PMEG, physician-modified endograft.

Methods

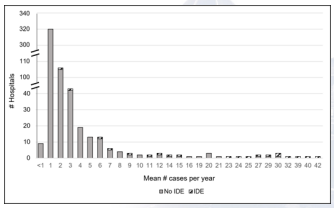
- Mapped trends in the use of F/BEVAR in the US over time
- Compare outcomes for patients treated at centers with vs. without IDEs
  - 30-day & mid-term (3-year) mortality
- Assessed center specific volume & outcome relationship
  - High volume: > 9 F/BEVARs
    - Based on European analysis and ESVS guidelines

F/BEVAR is Increasing with Time



Center-Specific Volume

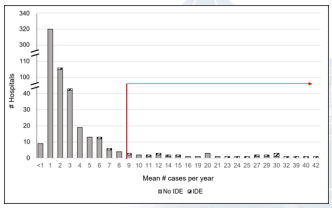
Median Cases Per Year
- IDE: 22.3
- Non-IDE: 1.2



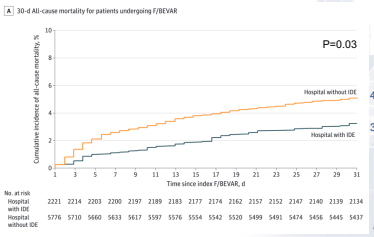
Center-Specific Volume

Median Cases Per Year
- IDE: 22.3
- Non-IDE: 1.2

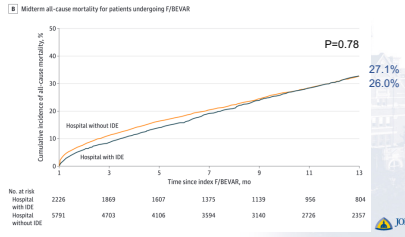
High Volume (>9/year)
- IDE: 74%
- Non-IDE: 7%



30-Day Mortality



3-Year Mortality



Adjusted Mortality Risk

Covariate	30-Day Mortality aOR (95% CI)	Mid-Term Mortality aHR (95% CI)
Hospital IDE Status		
IDE	0.47 (0.32, 0.69)	0.81 (0.69, 0.95)
No IDE	Ref	Ref

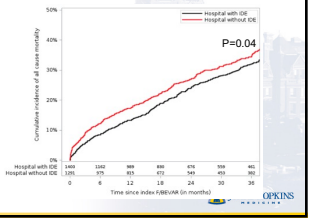
Adjusted for patient age, sex, race, area deprivation index, diabetes, hypertension, dyslipidemia, CHF, CAD, PAD, CKD/ESKD, COPD, smoking, population density of residence, census region of residence, indication for repair, # vessels treated, extent of repair

Sensitivity Analysis: 4 Vessel F/BEVAR

30-Day Mortality
- IDE: 2.4%
- Non-IDE: 5.0%
- aOR 0.41 (95% CI 0.24-0.70)

3-Year Mortality
- IDE: 32.0%
- Non-IDE: 36.4%
- aHR 0.83 (95% CI 0.69-1.00)

N=2,691

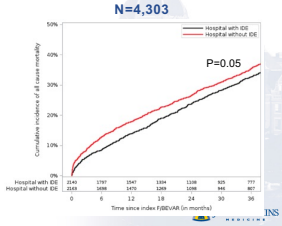


Sensitivity Analysis: High-Volume Centers

30-Day Mortality
- IDE: 3.0%
- Non-IDE: 5.2%
- aOR 0.54, 95% CI 0.37-0.80

3-Year Mortality
- IDE: 32.7%
- Non-IDE: 35.4%
- aHR 0.81, 95% CI 0.66-0.98

N=4,303



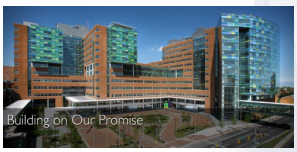
Summary

- The utilization of F/BEVAR is increasing significantly with time
  - Majority of cases are performed outside of IDE studies and at low volume centers
- F/BEVAR at non-IDE sites are associated with higher 30-day mortality
  - True for 4-vessel devices
  - True among high-volume centers

Conclusions

- The increasing use of F/BEVAR suggests a clear need for ready access to more complex aortic devices
- Identification of process measures from IDE sites may help achieve more equity in patient outcomes
- Given differences in mortality between IDE and non-IDE sites, transparent outcome reporting is critical to ensuring high quality of care as novel devices come to market

Thank You



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