**MHIF FEATURED STUDY:**

# CLBS16-P02 FREEDOM Study

**OPEN and ENROLLING:**

**EPIC message to *Research MHIF Patient Referral***

| CONDITION: | PI: | RESEARCH CONTACTS: | SPONSOR: |
|---|---|---|---|
| Coronary Microvascular Dysfunction without obstructive Coronary Artery Disease (CAD) | Jay Traverse, MD | **Jane Fox, RN**<br>Jane.Fox@allina.com \| 612-863-6289 | Caladrius Bioscience |

**DESCRIPTION:** Blinded randomized study comparing IC delivery of apheresis derived (after G-CSF administration) autologous CD34+ cells versus placebo.

Reduced CFR is a risk factor and these are patients with chronic chest pain thought to be secondary to microvascular dysfunction. This disease adversely affects women; typical patients experience angina without obstructive coronary artery disease (CAD).

## CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Age > 18
- Experiencing  angina > 3 times a week
- No obstructive CAD
- CCS Class II-IV

Exclusion

- Active Inflammatory or autoimmune disease
- Sickle Cell disease
- LVEF < 30%

# DEMONSTRATING THE VALUE OF IMAGING: THE ROLE OF OUTCOMES RESEARCH AND BIG DATA IN CARDIAC IMAGING

**Jordan B. Strom, MD, MSc, FACC, FASE**
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**Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology**
**Assistant Professor of Medicine, Harvard Medical School**

**May 24, 2021**

Beth Israel Deaconess Medical Center | Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology | HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

# Disclosures

**Grant support:** NIH/NHLBI K23, Edwards Lifesciences (Co-PI), HeartSciences, Ultromics

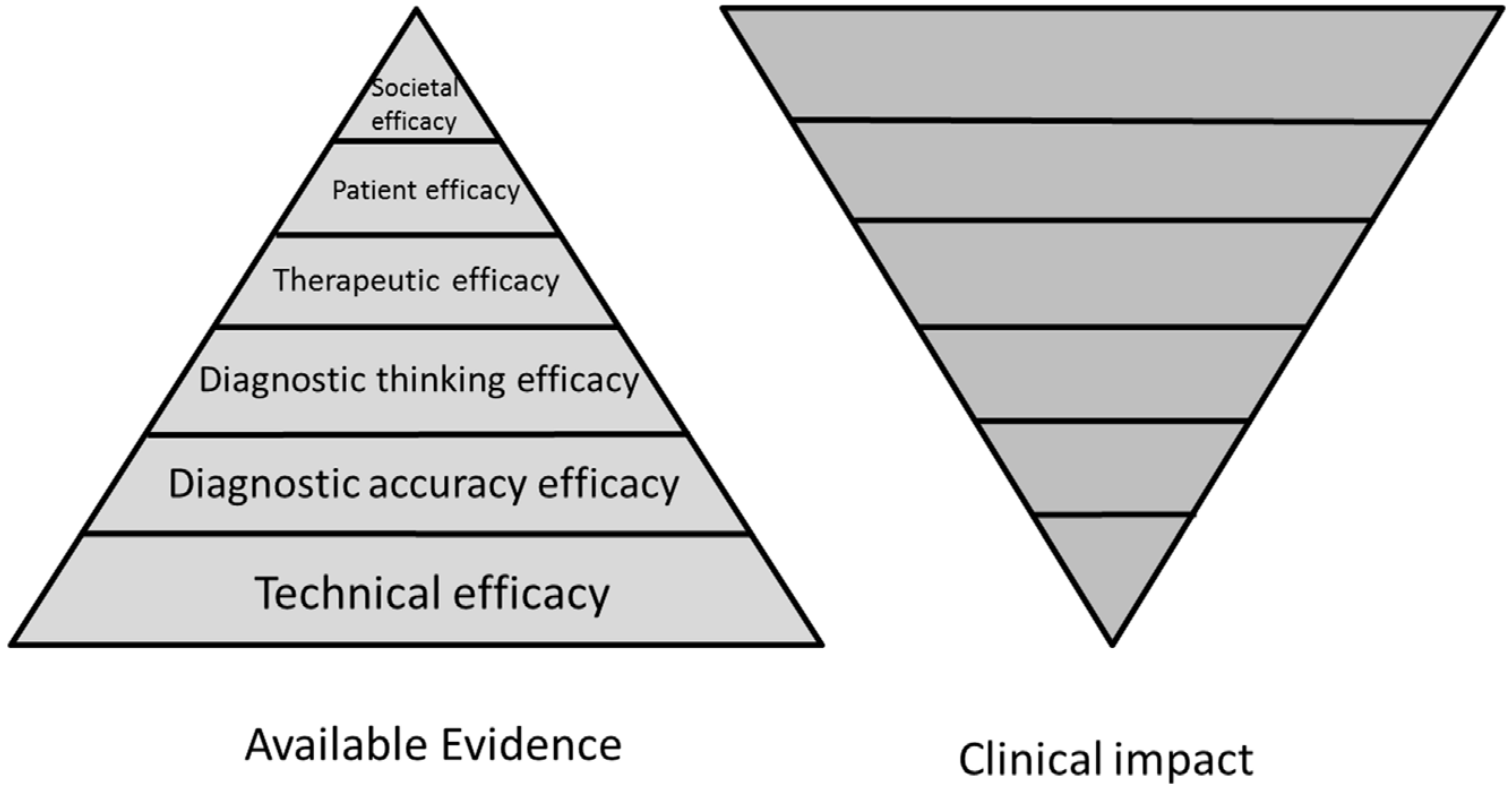
**Consulting:** Philips Healthcare, Bracco

**Speaker's Bureau:** Northwest Imaging Forums

**Other:** ASE Board of Directors (2021-22), JRC-DMS Board of Directors (2019-2022)

Wallbridge, Resp Medicine, 2018

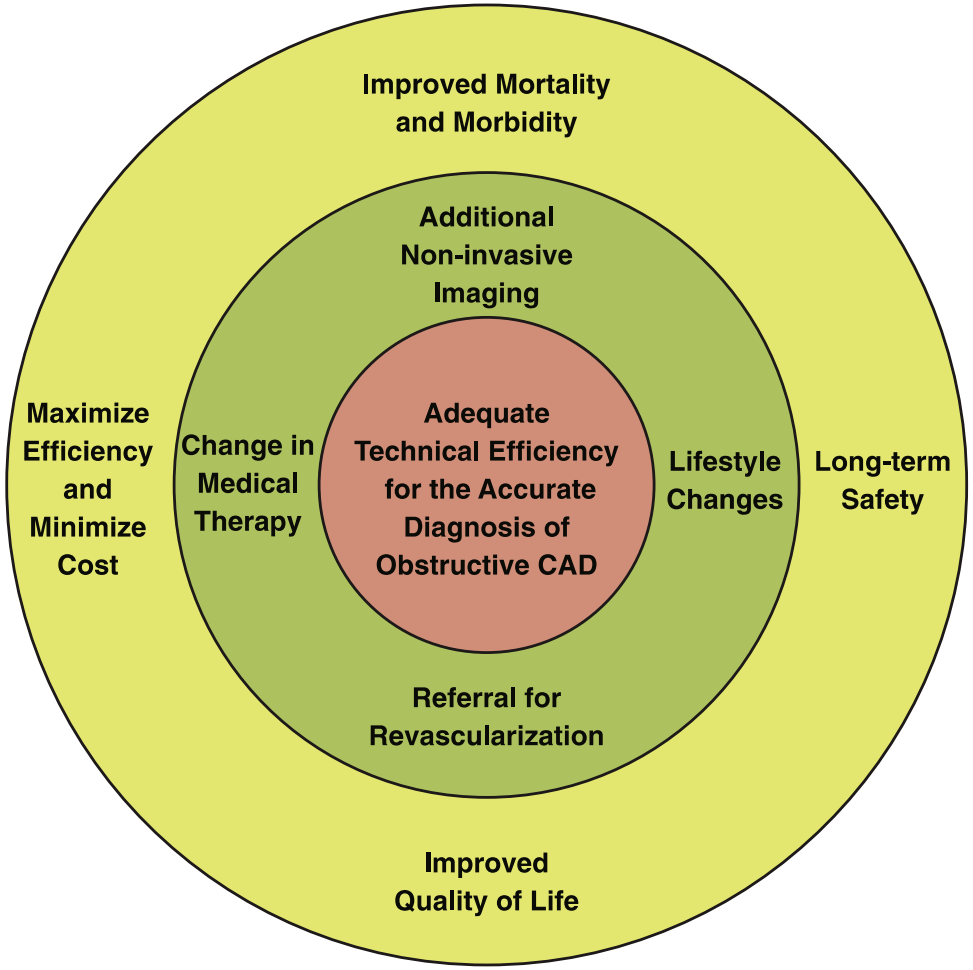
# The Hierarchy of Imaging Evidence
## The Thornbury and Frybeck Pyramid



Fordyce, JACC Imaging, 2017

# The Hierarchy of Imaging Evidence

## The Fordyce and Douglas Circle



Adapted from Wallbridge, Resp Medicine, 2018

# The Hierarchy of Imaging Evidence

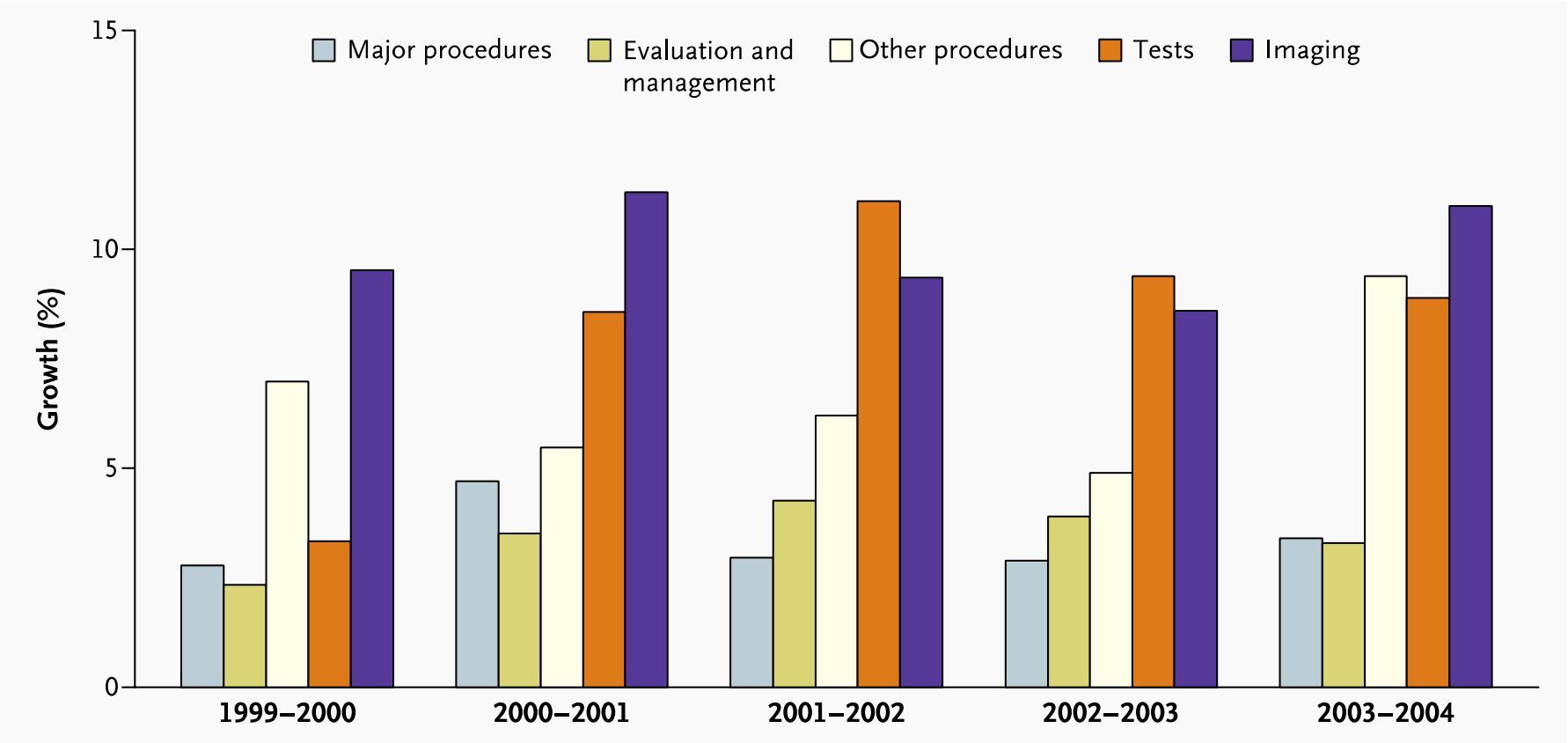
## Domains of Diagnostic Evidence

| Domain | Questions |
|---|---|
| **Test Attributes** | Can the test detect the target condition |
| | Is the test accurate? |
| | Is the test reproducible? |
| | Is the test available? |
| **Clinician Behavior** | Does the test alter clinical diagnosis? |
| | Does the test alter clinical management? |
| **Health Outcomes** | Does the test alter patient outcomes? |
| | Does the test improve resource utilization? |
| | Is the test cost-effective? |

Iglehart, NEJM, 2006

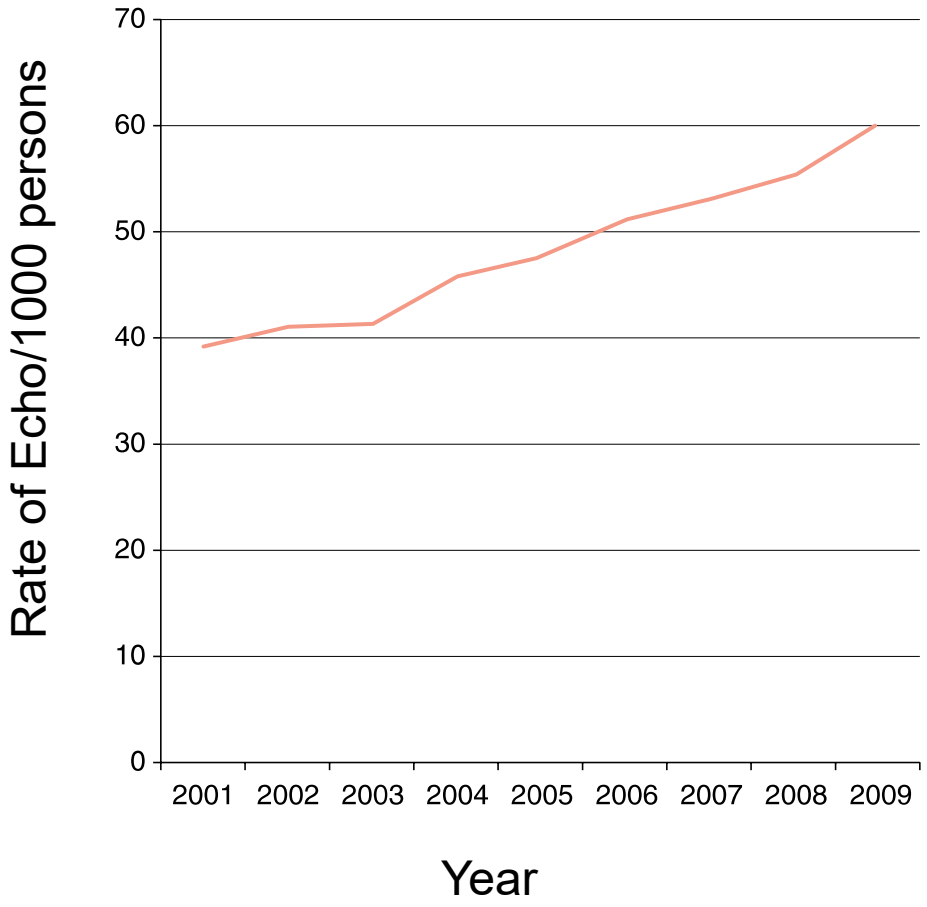
# Why do imagers need to demonstrate value?

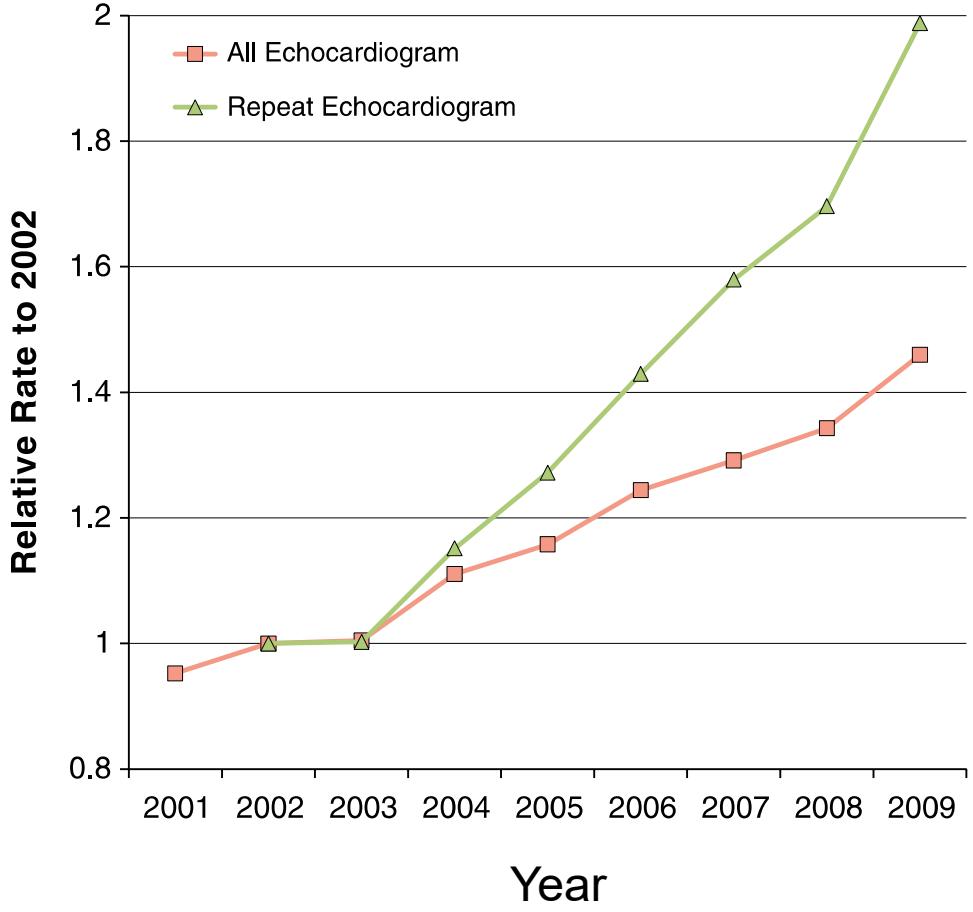
## Growth in Volume of Physician Services per Beneficiary, 1999-2004



Blecker, JACC Imaging, 2013

# Why do imagers need to demonstrate value?
## Trends in Imaging: the Scene from Canada



Blecker, JACC Imaging, 2013

# Why do imagers need to demonstrate value?
## Trends in Imaging: the Scene from Canada

**Table 2. Characteristics of Repeat Echocardiograms in Ontario**

| | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|---|---|---|
| Number of echocardiograms | 371,356 | 382,187 | 431,716 | 459,692 | 504,581 | 536,655 | 571,520 | 630,692 |
| Percent repeats | 18.5 | 18.4 | 19.1 | 20.3 | 21.3 | 22.6 | 23.5 | 25.3 |
| Adjusted rate of repeat (per 1,000 people) | 7.6 | 7.6 | 8.7 | 9.7 | 10.9 | 12.0 | 12.9 | 15.1 |
| Repeats (%) performed by same physician | 43.4 | 45.3 | 46.3 | 45.6 | 48.0 | 47.6 | 46.5 | 46.5 |
| Number of persons with echocardiogram | 338,055 | 348,181 | 390,220 | 413,157 | 449,277 | 474,264 | 500,432 | 543,772 |
| Percent of persons with repeat echocardiogram | | | | | | | | |
| 0 repeat | 83.4 | 83.5 | 82.8 | 81.7 | 80.9 | 79.5 | 79.0 | 77.5 |
| 1 repeat | 13.7 | 13.5 | 13.9 | 14.8 | 15.3 | 16.4 | 16.5 | 17.3 |
| 2 repeats | 2.5 | 2.5 | 2.7 | 2.9 | 3.1 | 3.3 | 3.6 | 4.0 |
| 3 repeats | 0.4 | 0.4 | 0.5 | 0.5 | 0.6 | 0.6 | 0.7 | 0.9 |
| ≥4 repeats | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 | 0.3 |

> 1/2 of all echocardiograms were performed by a different physician

Adapted from Blecker, JACC Imaging, 2013

# Why do imagers need to demonstrate value?
## Trends in Imaging: the Scene from Canada

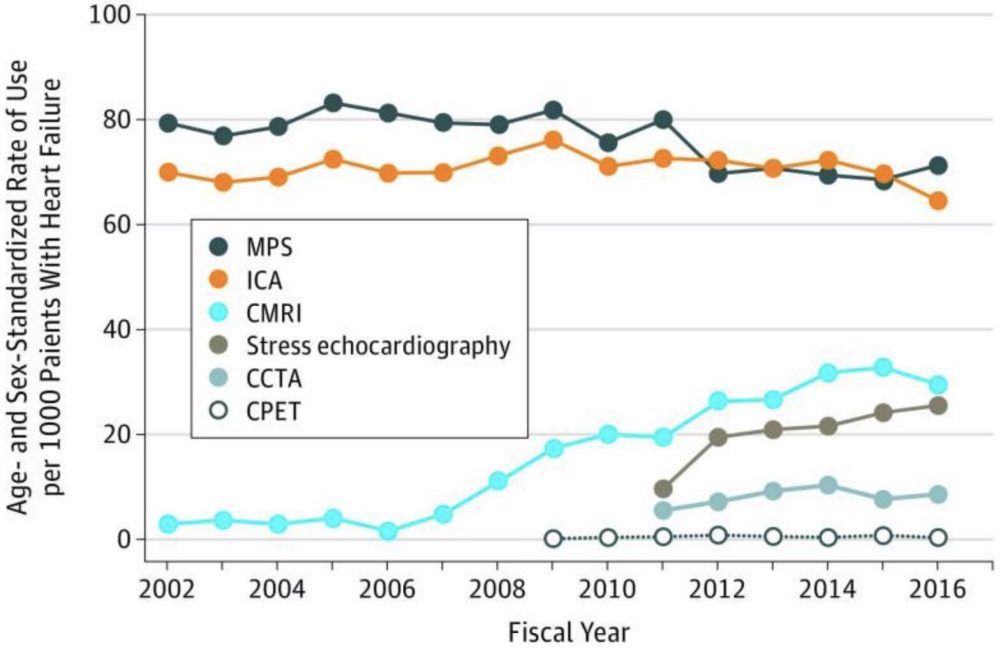
Annual rate of change per year (%):

| Parameter | Cardiology | Internal Medicine | Radiology |
|---|---|---|---|
| Physicians billing echo - no. | 3% | 3% | - 6% |
| Echo - no. | 8% | 6% | 1% |
| Echos per physician – mean | 5% | 3% | 8% |
| Repeat Echo - no. | 13% | 11% | 16% |
| Repeat echo per physician - mean | 9% | 8% | 27% |

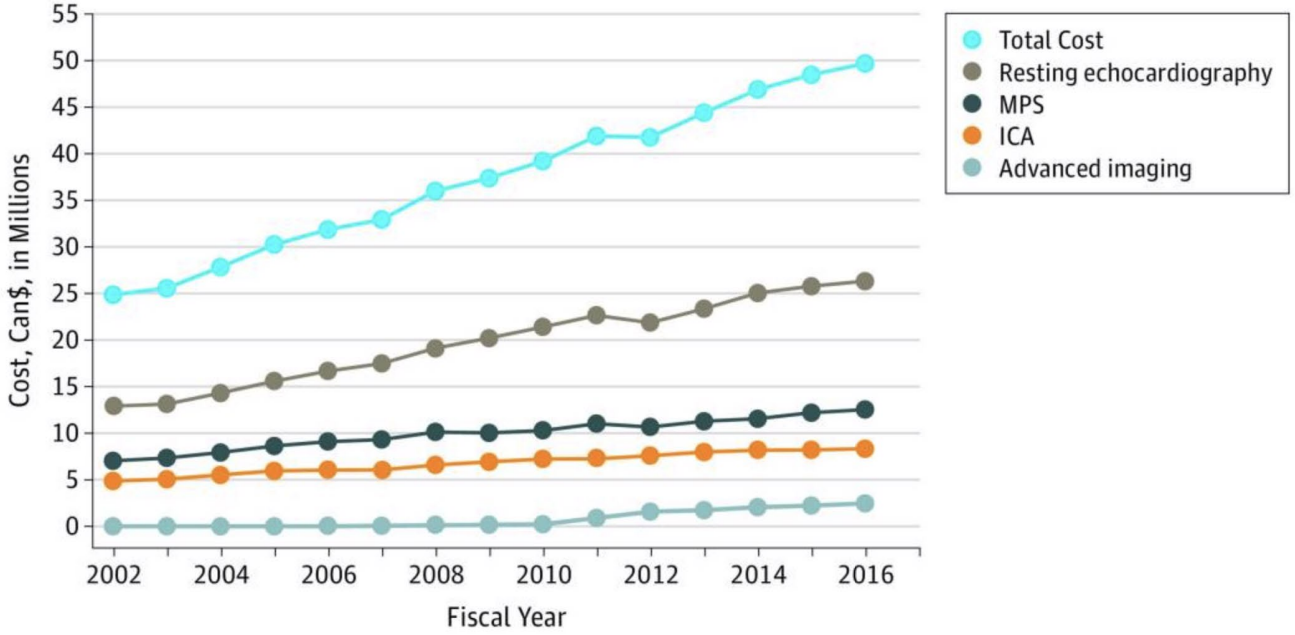
Braga JR, JAMA Open, 2019

# Why do imagers need to demonstrate value?
## Trends in Imaging: the Scene from Canada

### Utilization of Multimodality Imaging



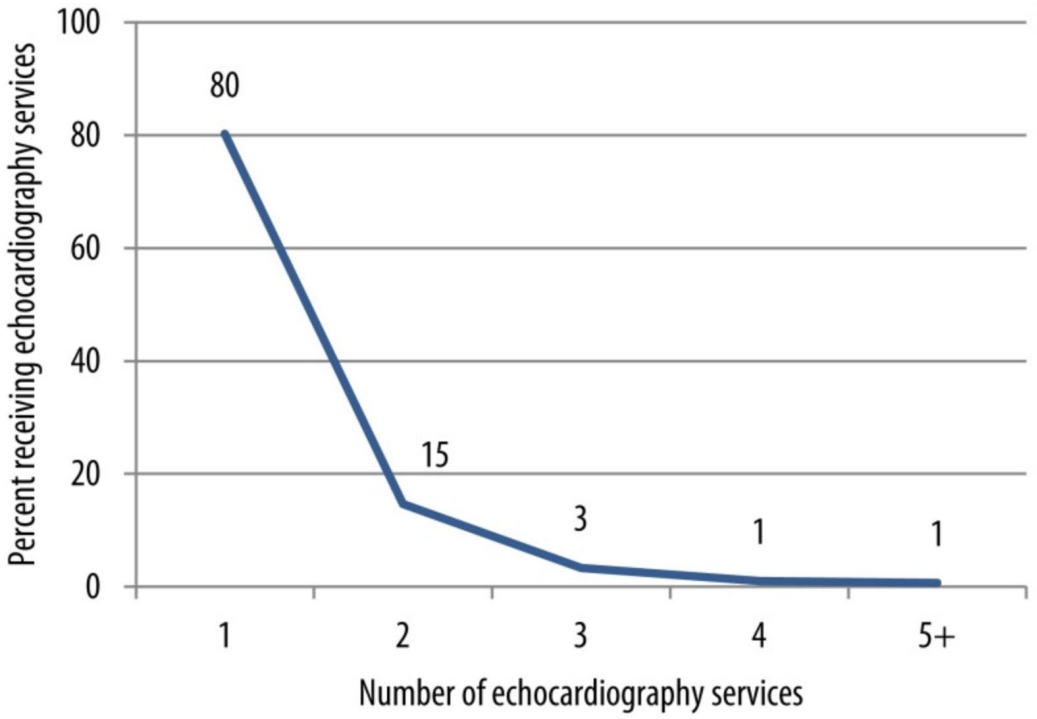

### Costs of Multimodality Imaging

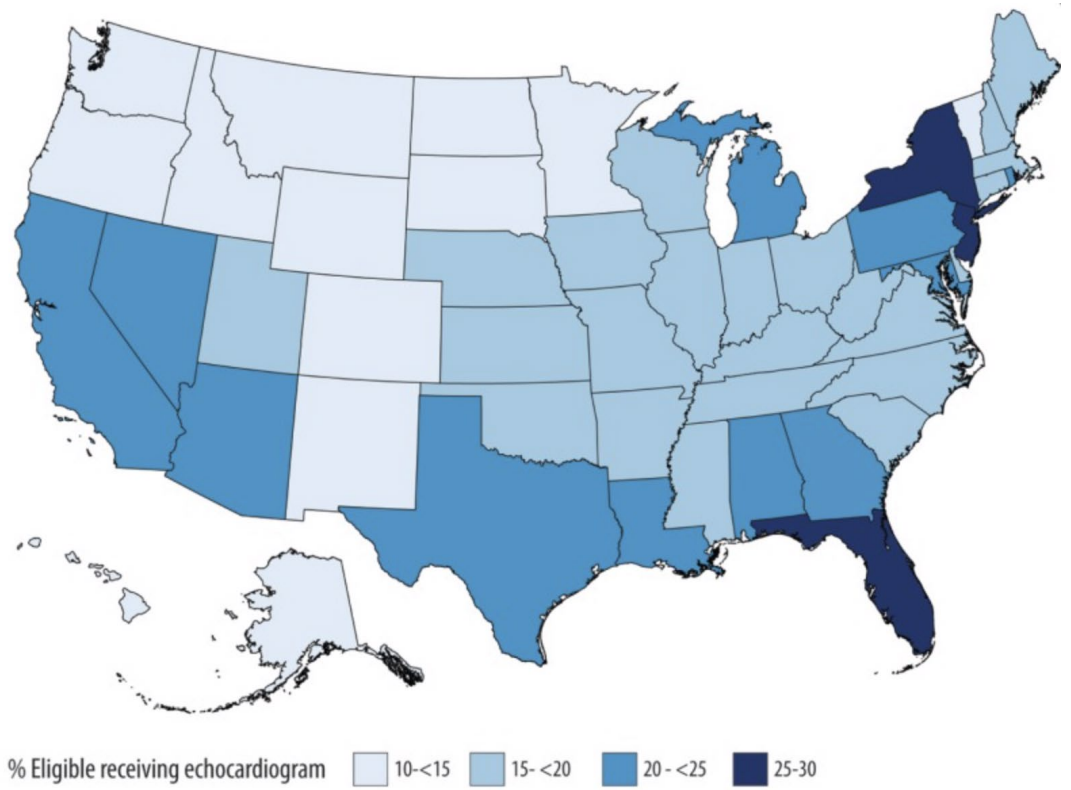


Virnig BA, AHRQ Data Points, 2011

# Why do imagers need to demonstrate value?

## Trends in Imaging: Back to the US in 2011



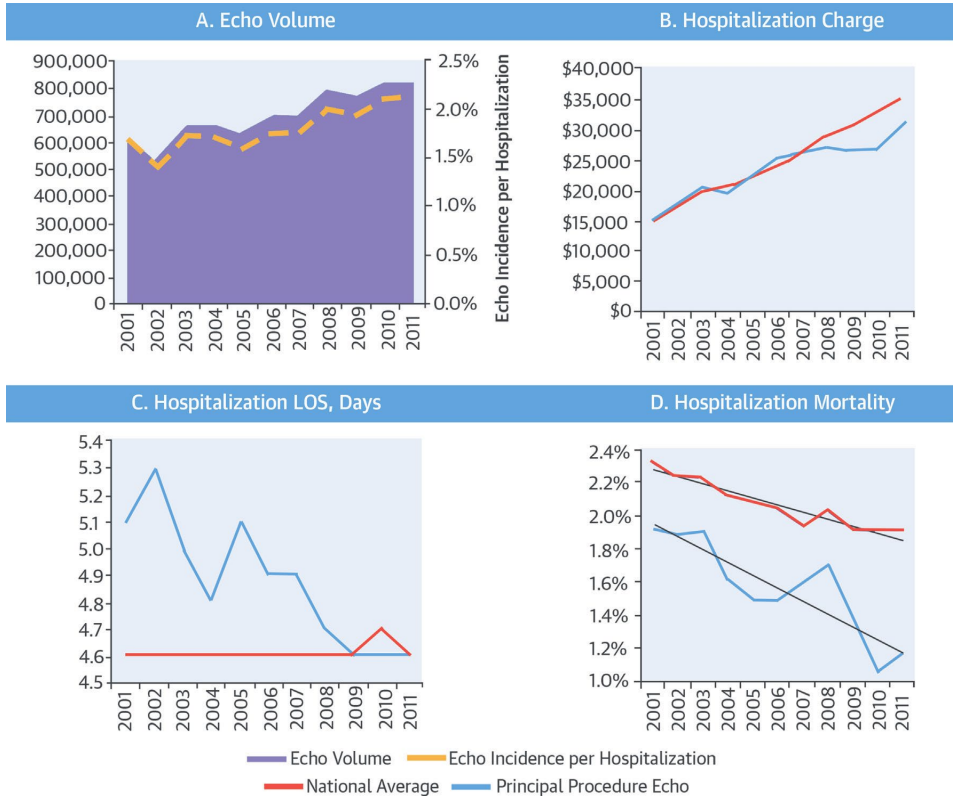



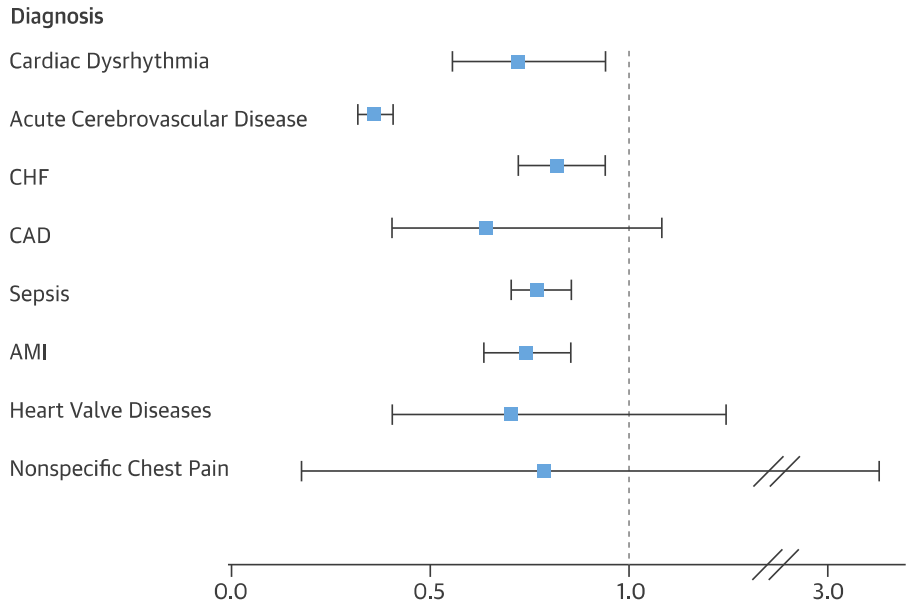

**80% of Medicare FFS beneficiaries receive at least one echo per year and 15% receive two**

Papolo A, JACC, 2016

# Why do imagers need to demonstrate value?

## The Mortality Effect: Caution Advised




Echo only performed in 8% of HF hospitalizations

**The problem: individuals must survive long enough to receive an echo**

Strom JB, JASE, 2019

# Why do imagers need to demonstrate value?
## The Mortality Effect: Caution Advised

SPECIAL ARTICLE

### Demonstrating the Value of Outcomes in Echocardiography: Imaging-Based Registries in Improving Patient Care



Jordan B. Strom, MD, MSc, Varsha K. Tanguturi, MD, Sherif F. Nagueh, MD, Allan L. Klein, MD, and Warren J. Manning, MD, *Boston, Massachusetts; Houston, Texas; and Cleveland, Ohio*

- Underutilization is harder to measure than overutilization
- It is hard to separately value proper diagnosis vs. treatment (e.g. ICDs and LVEF)
- Impact of mistakes is harder to measure – what is ground truth?
- Imagers nevertheless need to study outcomes to justify the cost and inconvenience of testing

# How do imagers demonstrate value?
## Value of Linking Outcomes to Imaging

**Uses of Imaging as a Biomarker**
- Pre-operative risk stratification
- Guide shared decision making
- Guide use of treatments or other diagnostic tests
- Understand cardiac structure and function

**Uses of Imaging as Raw Data**
- Images as High Resolution Data Arrays

**Use of Imaging as a Surrogate Outcome**
- Provide outcomes (e.g. LV mass, LGE) for trials and other studies

**Use of Outcomes to Understand Variation in Imaging**

**Use of Outcomes to Identify Areas of Underutilization in Imaging**

**Use of Outcomes to Define Normality in Imaging**
- Example: ageing and diastolic function

# How do imagers demonstrate value?
## Why Big Data?

- Outcomes of interest to cardiology are generally uncommon.
- Central limit theorem – unless collected in a biased manner, imaging measurements in large numbers will approach population means.
- Technology advances have made large data analysis feasible.
- Large, multicenter registries can improve generalizability of results and can improve understanding of subgroups.
- Large data repositories are increasingly being built through human interactions with the healthcare system, though relatively few have been linked.

Strom JB, JASE, 2019

# How do imagers demonstrate value?

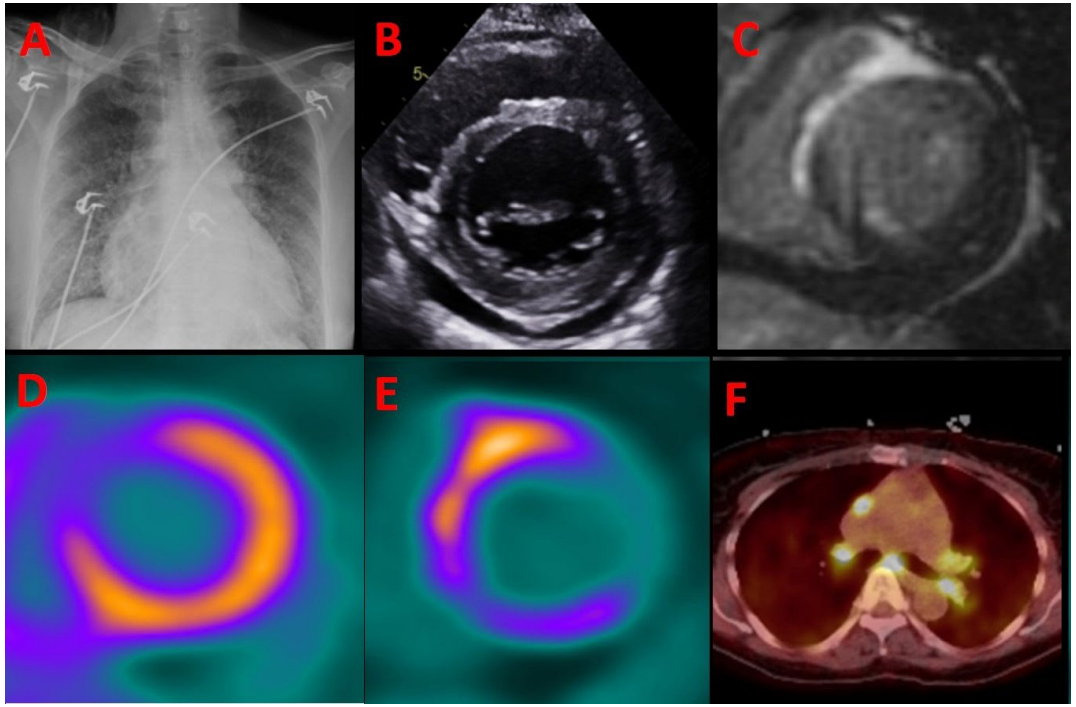
## Sources of Data

| Data source | Outcomes data: Advantages and disadvantages | Echocardiographic data: Advantages and disadvantages |
|---|---|---|
| Patient self-report | • Well-validated and reliable questionnaires available<br>• Difficult to capture in practice | • Patient self-report of imaging data is not validated and likely biased by recall |
| Electronic health records | • Detailed patient information (e.g., diagnoses, testing, treatments)<br>• Outcomes may be incompletely recorded or captured<br>• Challenging to extract information<br>• Privacy concerns involving data access and sharing across sites | • Predominant source of large aggregated imaging data<br>• Site variation in acquisition and recording of data<br>• Frequently includes nonstructured data<br>• Variables may require mapping across sites<br>• Interoperability and privacy concerns limit sharing across sites<br>• Frequent missing data |
| Clinical trials | • Gold standard for evaluation of efficacy<br>• Detailed, adjudicated outcomes<br>• May lack generalizability and expensive to conduct | • Imaging data often adjudicated at central core laboratories<br>• May lack generalizability and expensive to conduct<br>• Limited number of subjects with echocardiograms and limited data obtained from images |
| Registries or cohort studies | • May enroll generalizable, "real-world" populations<br>• Relies on site participation, complete and accurate data entry, and inclusion of generalizable populations | • Large echocardiography databases (e.g., ImageGuideEcho registry) in development<br>• May enroll generalizable, "real-world" populations<br>• Relies on site participation, complete and accurate data entry, and inclusion of generalizable populations<br>• Variables collected may differ by site |
| Administrative billing claims | • Capture of outcomes across sites<br>• Cost and billing data included<br>• Few repositories of multipayer claims<br>• Subject to coding errors and incomplete capture of number and severity of comorbidities | • Claims for echocardiographic examinations contain cost and billing data<br>• Limited information on imaging variables<br>• Few repositories of multipayer claims<br>• Subject to coding errors and incomplete capture of number and severity of comorbidities |
| Mobile or wearable technology | • Provides near continuous or continuous physiologic information<br>• Few metrics are validated against clinical outcomes<br>• Proprietary control limits access to data | • None currently available for echocardiography |
| National health/vital status repositories | • Source of death information across sites (e.g., National Death Index or Social Security Death Master File)<br>• Comprehensiveness and data quality vary | • None currently available for echocardiography |

Photo source: ACC.org

# How do imagers demonstrate value?
## Unique Challenges with Imaging Data

- Data only actionable if diagnosis/misdiagnosis recognized
- Large amounts of missing data
- Hierarchical data structures
- Large amounts of collinearity
- Differences in variable names and conventions
- Data entry errors
- Different study types within a given modality (e.g. TEE, TTE, stress echo)




- Large amounts of unstructured data
- Size and complexity of images
- Referral bias
- Imaging “leakage”

# How do imagers demonstrate value?
## Existing Registries: Institutional Registries and BIDMC

**ENCOR (2000-2018)** – 271,618 echocardiograms on 135,792 individuals

- Linked to 26,163 deaths in SSDI
- Linked to 100% Medicare FFS claims from 2003-2017
  - Includes information on 133,168 echocardiogram reports from 64,063 individuals
  - Claims algorithms used to generate 23 clinical covariates (e.g. hypertension, smoking, diabetes), and 20 outcomes (e.g. MACCE, AKI, acute MI, HF, stroke)


**MIMIC (2003-2018)** – Contains clinical and lab data from > 60,000 ICU admissions

- MIMIC-III features 350,000 de-identified chest x-ray DICOM images linked to patient information and clinical data from over 260,000 ED visits
- MIMIC-IV (in development) will add 145,000 TTEs, 980,000 ECGs

# How do imagers demonstrate value?
## Existing Registries: Others

### Foundations and Non-for-profit Companies

- SCMR Registry - > 62k CMRs
- ImageGuide Registry (ASE and ASNC)
- UK Biobank
- National Echo Database Australia (NEDA)
  - > 40 million echocardiographic reports
  - 14 clinical laboratories
  - 60,000 deaths

### Governmental Federated Data Networks

- Sentinel network
- PCORNet
- NIH Collaboratory

Blumenthal S., eGEMS, 2017

# How do imagers demonstrate value?
## Existing Registries: Challenges

The National Quality Registry Network (NQRN) surveyed 152 societies/associations:

- Response Rate 52%
- 32% spent $1-9.9 million per year
- Average registry had 3 FTEs
- 88% used manual data entry
- 18% linked to external data sources
- Mostly used for QI, benchmarking, and clinical decision support
- Cost, interoperability, and vendor management were barriers to continued development

| MEASURE TYPES | USING TODAY | PLANNING TO USE |
|---|---|---|
| Process | 86% (30/35) | 6% (3/35) |
| Outcome | 74% (26/35) | 20% (7/35) |
| Safety | 62% (21/34) | 26% (9/34) |
| Structure | 46% (16/35) | 9% (3/35) |
| Patient-reported outcome | 47% (16/34) | 29% (10/34) |
| Utilization | 41% (14/34) | 38% (13/34) |
| Other | 12% (4/33) | 9% (3/33) |
| Cost | 6% (2/34) | 53% (18/34) |
| Personalized medicine | 6% (2/33) | 15% (5/33) |

# How do imagers demonstrate value?
## Defining a Field: Outcomes Research in Cardiac Imaging

A multidisciplinary field that seeks to:

1. Evaluate the relationship of cardiac structure and function to health outcomes
2. Evaluate the use of imaging to guide medical decision making and prognostication
3. Understand the use, cost, and sources of variation of cardiac imaging in practice
4. Identify optimal imaging intervals and the cost-effectiveness of diagnostic strategies related to imaging.
5. Conduct trials of diagnostic imaging strategies.

These goals are accomplished through a hybrid of methods including epidemiology and biostatistics, cost effectiveness, and data science techniques (e.g. machine learning, database management) and using a variety of data sources including registries of structured or unstructured images or image reports, trials, claims, and multicenter registries.

# A use case of imaging registries
## Moderate Aortic Stenosis

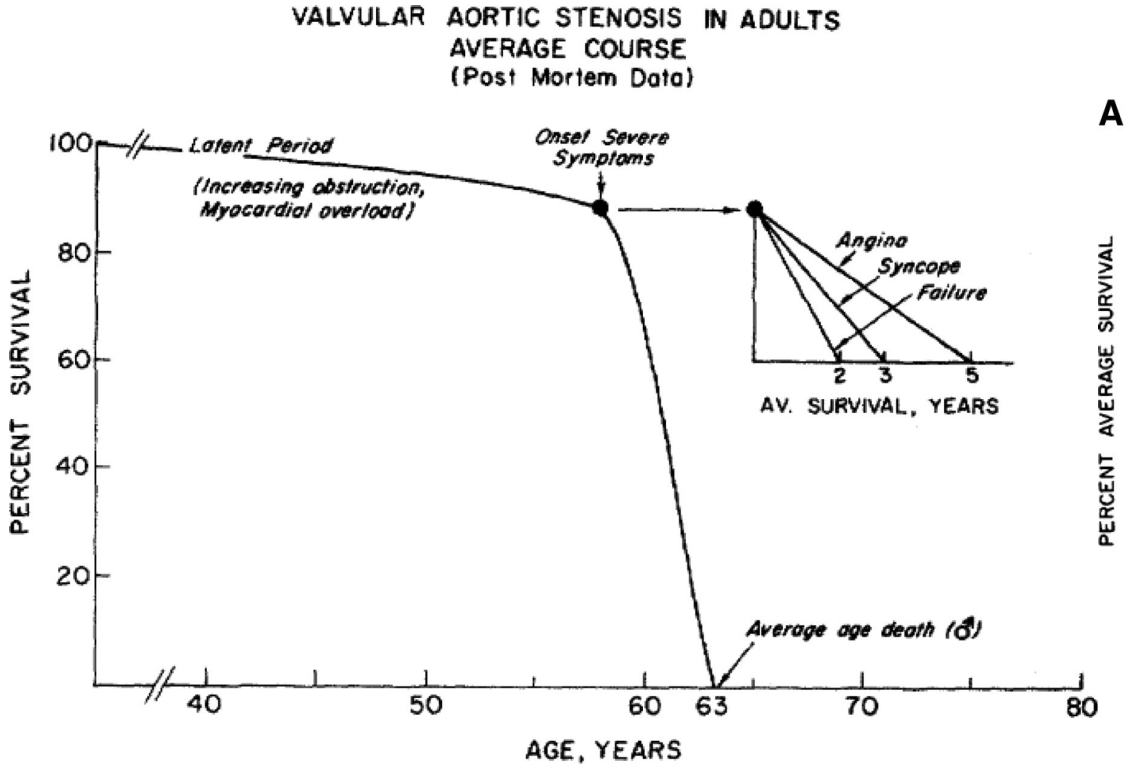
72 year old M with HTN, HL, DM2 and moderate AS (AVA 1.3 cm2) who presents with dyspnea on exertion x 1 year.

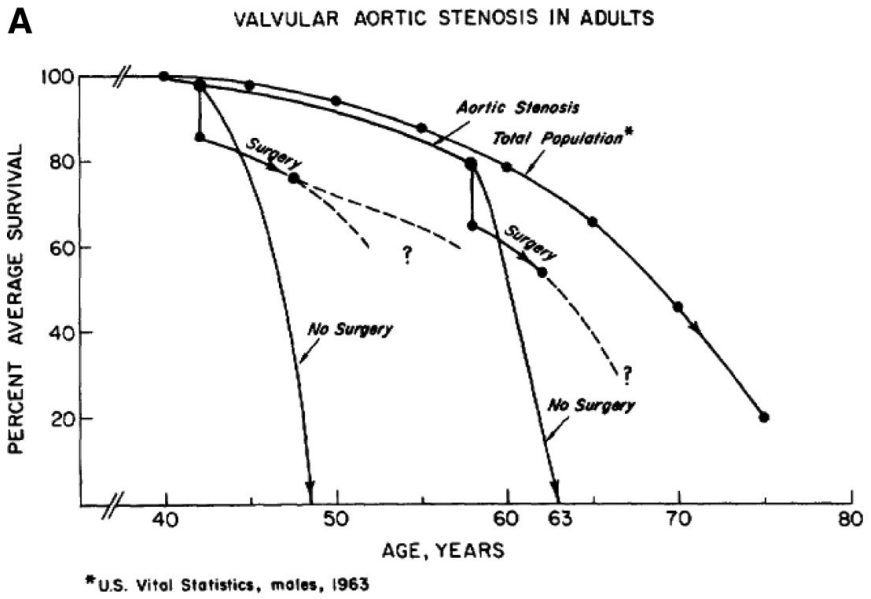
- TTE with no significant AS progression (AVA 1.2 cm2) but LVEF 35%
- Coronary angiography without obstructive CAD
- ETT with limiting dyspnea at 5 METs, no ECG changes, no changes on TTE
- CPET demonstrates cardiac limitation

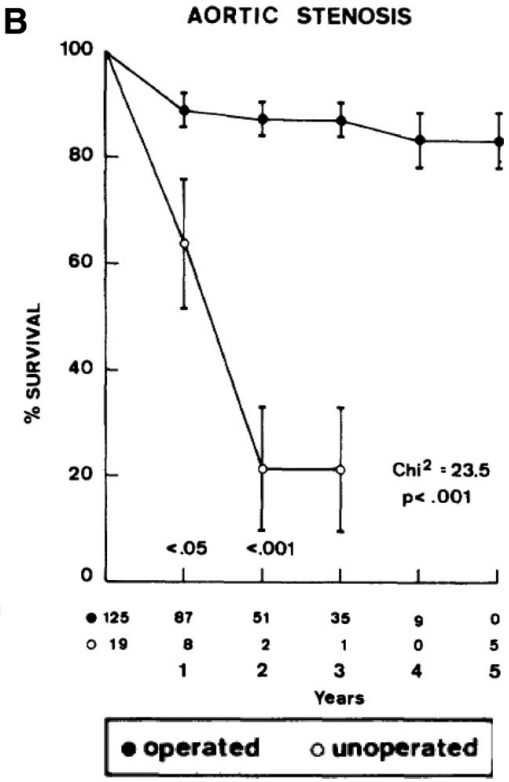
**Should we consider AVR in moderate AS?**

Ross and Braunwald, Circulation, 1968

# A use case of imaging registries
## Natural History of Severe AS



# A use case of imaging registries

## Natural History of severe AS

| Author | Title | N Value | Journal and Year |
|---|---|---|---|
| Pellikka et al | The Natural history of Adults with Asymptomatic, haemodynamically significant Aortic Stenosis | **N = 143** | JACC 1990 |
| Otto et al | Prospective Study of Asymptomatic Valvular Aortic Stenosis. Clinical, echocardiographic and exercise predictors of outcome | **N = 123** | Circulation 1997 |
| Pellikka et al | Outcomes of 622 patients with asymptomatic haemodynamically significant Aortic Stenosis | **N = 622** | Circulation 2005 |
| Lancelloti et al | Risk Stratification of Moderate to Severe Aortic Stenosis | **N = 163** | Heart 2010 |
| Lancelloti et al | Outcomes for Patients with Asymptomatic Aortic Stenosis followed in heart centres | **N = 1375** | JAMA Cardiology 2018 |

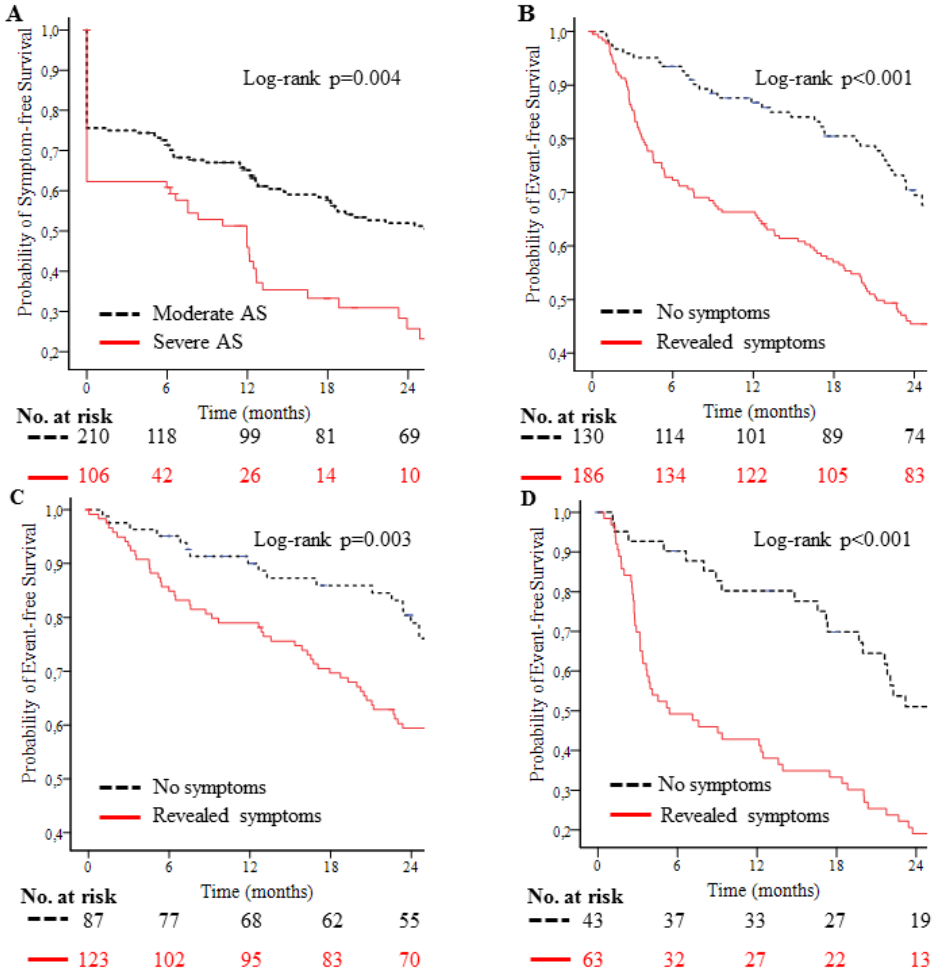
Saeed, BMJ, 2018

# A use case of imaging registries
## What is the risk of moderate AS?

316 asymptomatic patients with moderate to severe AS underwent ETT (mean age 65, 67% men):

Outcome of mortality (67% CV related) or AVR

Followed for 3 years




During serial testing, symptoms identified in 55% with moderate AS

**Symptom free survival at 24 months:**

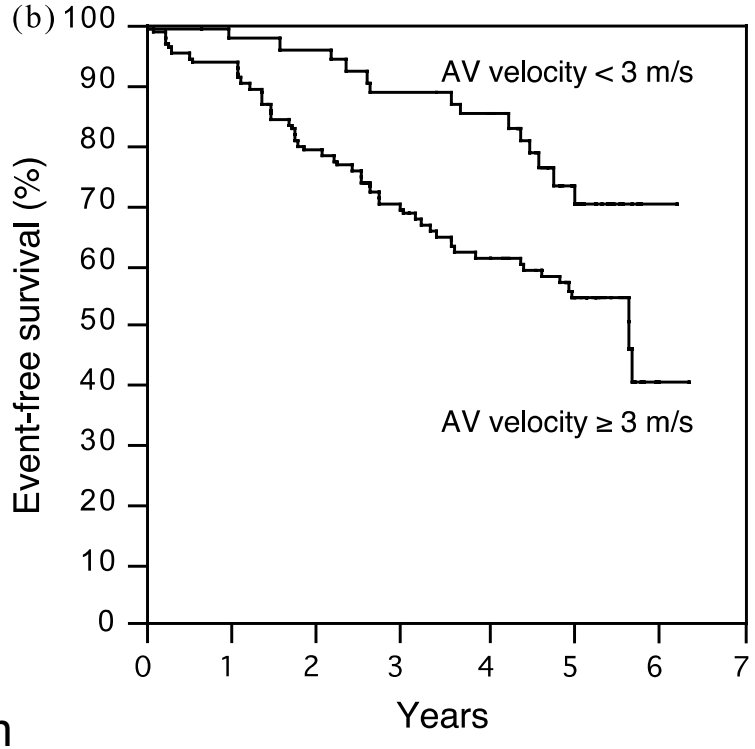
Moderate AS: 52% ± 4%
Severe AS: 26% ± 6%

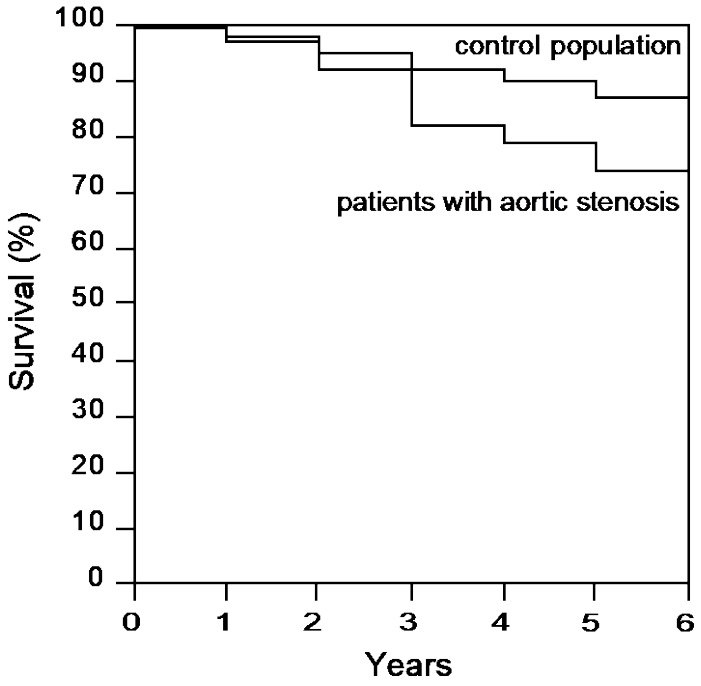
Rosenhek, EHJ, 2004

# A use case of imaging registries
## What is the risk of moderate AS?

176 asymptomatic patients (58 ± 19 years; 41.4% female) with mild-moderate AS (peak AV velocity 2.5-3.9 m/s):

- 48 ± 19 month follow-up
- Evaluated hemodynamic progression
- Outcome: death or AVR
- Compared with age-, gender- matched controls




34 deaths (15 CV deaths)
Severe AS only in 7/15 premortem
One with SCD

**Event-free survival only 55% ± 5% at 5 years if velocity > 3 m/s**

# A use case of imaging registries
## What is the risk of moderate AS?

Rosenhek, EHJ, 2004
Kennedy, JACC, 1991
Yechoor, JTCS, 2013
Van Gils, JACC, 2017
Chizner, AHJ, 1980
Horstkotte, EHJ, 1988
Livanainen, AJC, 1996
Otto, Circulation, 1997
Rosebo, NEJM, 2008
Minners, EHJ, 2013
Kearney, Int J C, 2012
Lancellotti, JAMA Card, 2018
Strange, JACC, 2019

| Author | Years | N | Echo or Cath | AV parameter | Follow-up | Event free survival |
|---|---|---|---|---|---|---|
| Horstkotte and Loogen | 1978-1988 | 236 | Cath | 0.8 – 1.5 (AVA) | 10 years | 80% at 10 years |
| Chizner | 1980 | 42 | Cath | 0.71-1.09 (AVA) | 64.4 months | 57% mortality at 3 years (56% SCD) |
| Kennedy | 1980-1985 | 66 | Cath | 0.7-1.2 (AVA) | 35 months | 59% at 4 years |
| Kearney | 1988-1994 | 55 | Echo | 1-1.5 (AVA)<br>or 25-40 mmHg (MG) | 6.5 years | 23% at 5 years |
| Otto | 1989-1995 | 68 | Echo | 3-4 m/s (peak velocity) | 2.5 years | 66% at 2 years |
| Livanainen | 1990-1991 | 26 | Echo | 0.9-1.2 (AVA) | 4 years | 65% at 4 years |
| Rossebo | 2001-2002 | 948 | Echo | 3-4 m/s (peak velocity) | 5 years | 49.1% at 5 years |
| Minners | 2001-2002 | 948 | Echo | 3-4 m/s (peak velocity) | 4 years | 94.1% at 4 years |
| Lancellotti | 2001-2014 | 1375 | Echo | 1-1.5 (AVA) | 8 years | 30% at 8 years |
| Yechoor | 2006 | 104 | Echo | 1-1.5 (AVA) | 22 months | 15% at 5 years |
| Van Gils | 2010-2015 | 305 | Echo | 1-1.5 (AVA) | 4 years | 39% at 4 years |
| Strange | 2000-2017 | 241, 303 | Echo | 1-1.5 (AVA) | 5 years | 56% at 5 years |

# A use case of imaging registries
## What is the risk of moderate AS?

# Excess Mortality Associated with Progression Rate in Asymptomatic Aortic Valve Stenosis



Giovanni Benfari, MD, Stefano Nistri, MD, PhD, Federico Marin, MD, Luca F. Cerrito, MD, Luca Maritan, MD, Elvin Tafciu, MD, Ilaria Franzese, MD, Francesco Onorati, MD, Martina Setti, MD, Michele Pighi, MD, Andrea Rossi, MD, and Flavio L. Ribichini, MD, PhD, *Verona and Vicenza, Italy*

# A use case of imaging registries
## Moderate Aortic Stenosis

Braunwald, Circulation, 2018
Mack, NEJM, 2019

Circulation

PERSPECTIVE

**Aortic Stenosis**

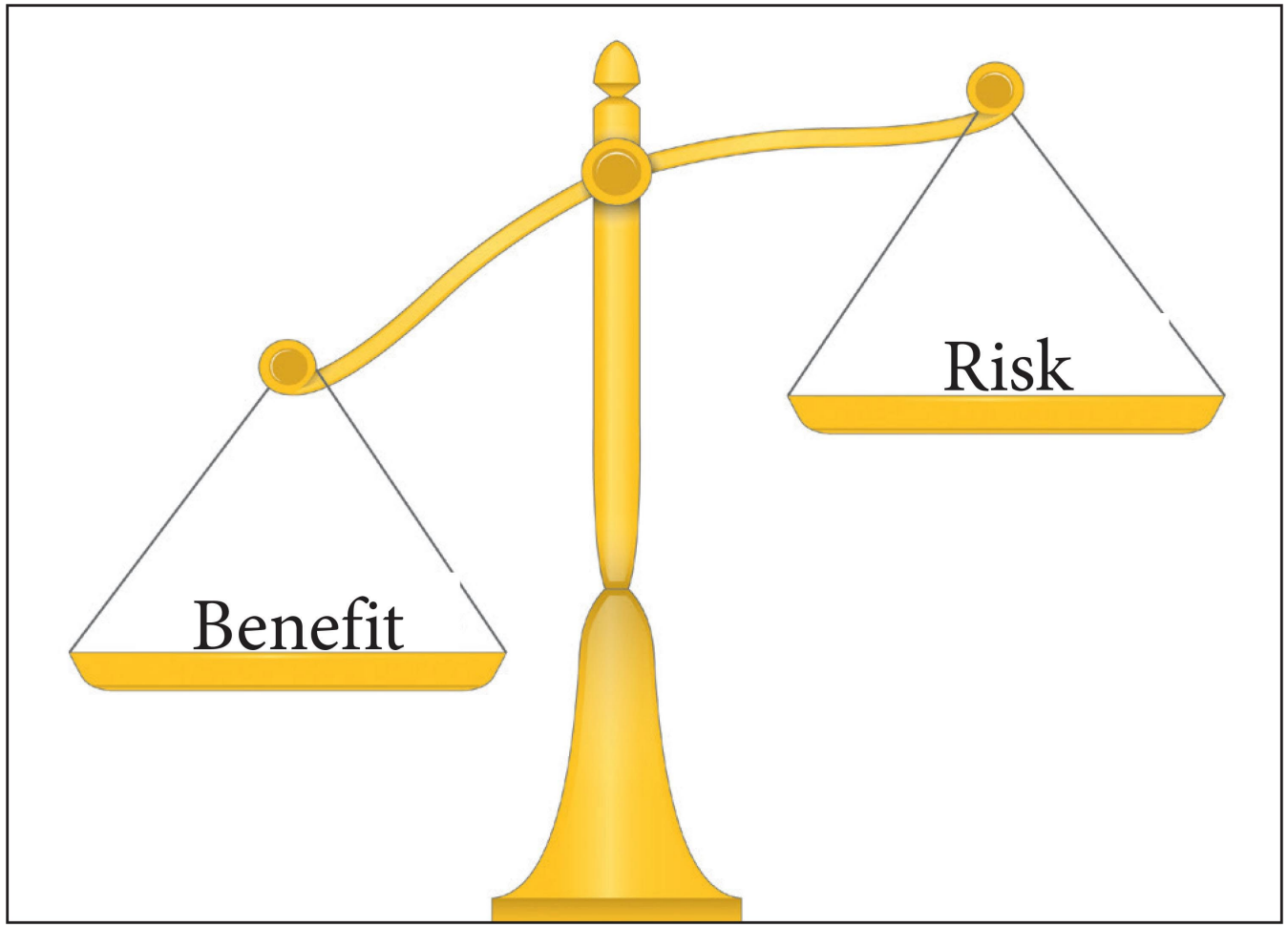
**Then and Now**

Historical operative mortality for AVR = ~ 15%

Current operative mortality in low-risk TAVR population = ~1%

Slide courtesy of Geoff Strange

# A use case of imaging registries
## Moderate Aortic Stenosis




**Does risk/benefit now favor early intervention?**

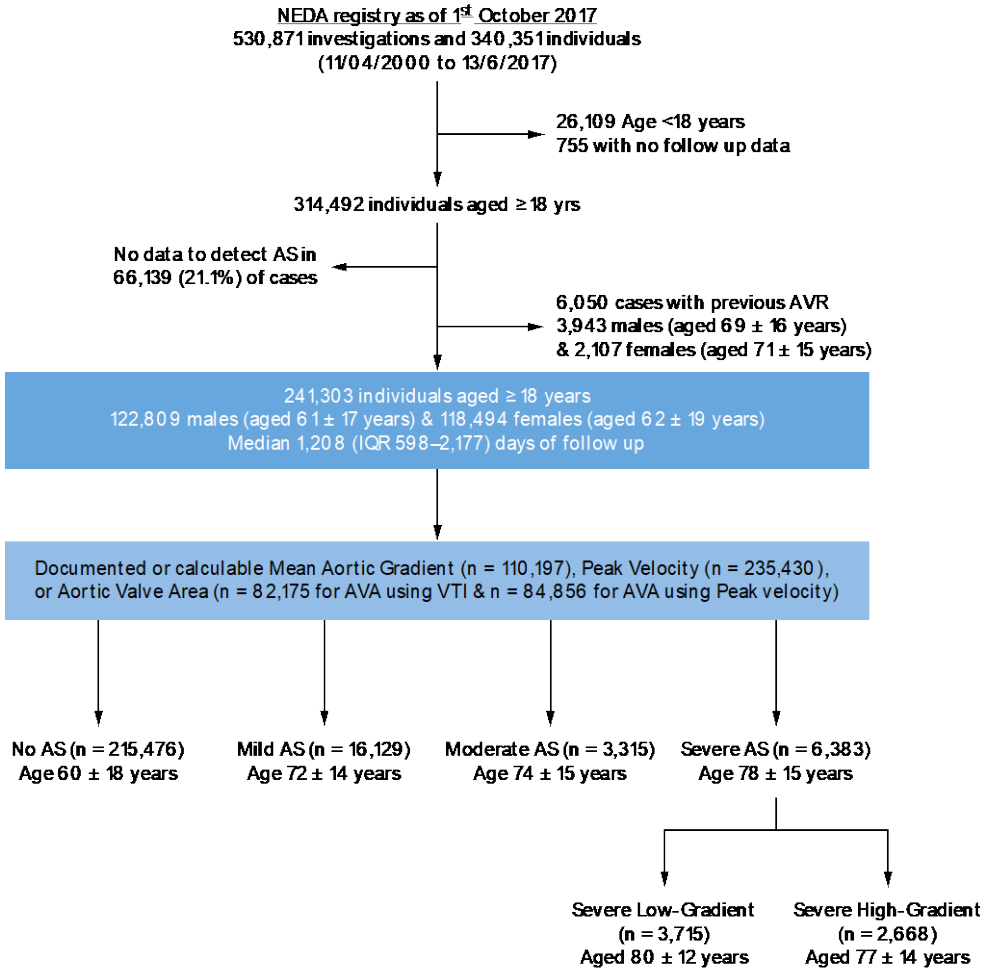
**Moderate AS trial:**
TAVR UNLOAD trial - Sapien 3 THV in HF, moderate AS (AVA 1-1.5 cm2), and HF

**Asymptomatic severe AS trials:**
-EARLY-TAVR trial
-EVoLVeD trial
-AVATAR trial
-ESTIMATE trial
-RECOVERY trial (very severe: Vmax > 5 m/s)

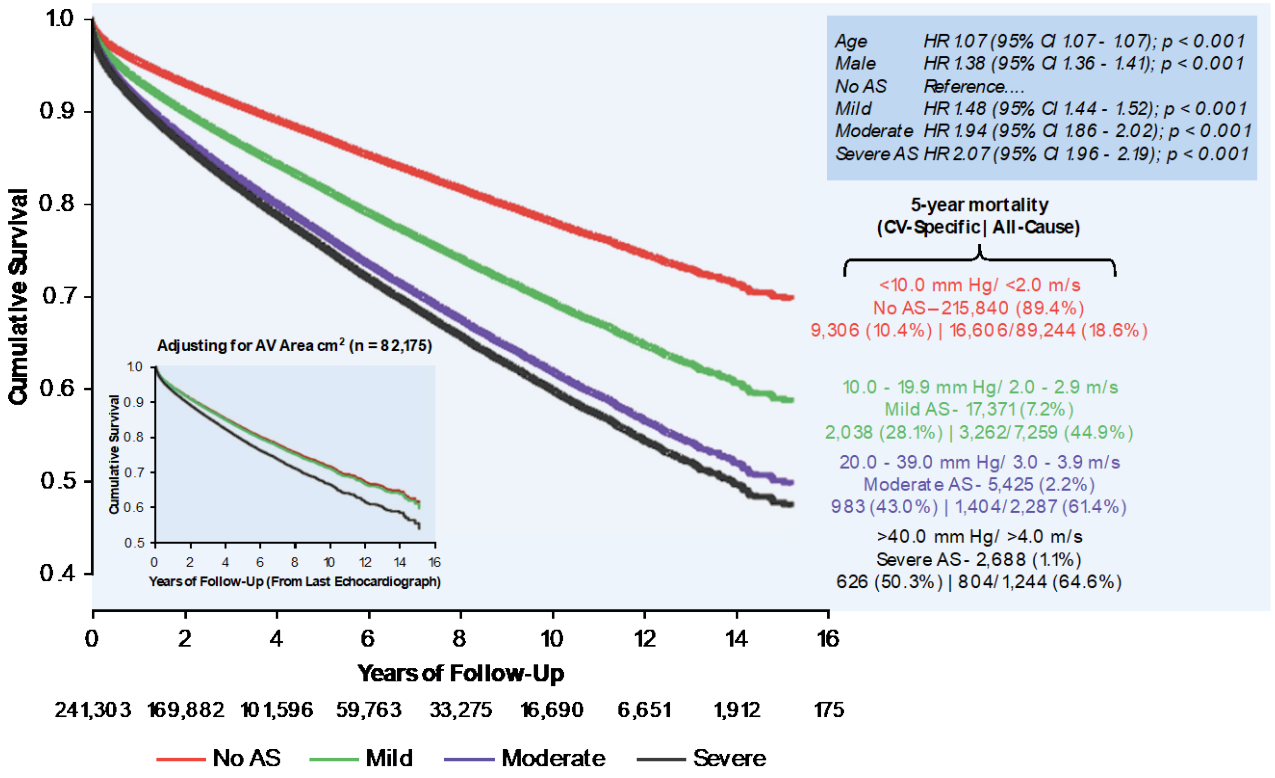
Strange, JACC, 2019

# A use case of imaging registries

## Moderate Aortic Stenosis: The Final Nail?




Adjusted for age, sex, AR, LVEF SVI




**Mortality inflection at MG = 20 mmHg**

# A use case of imaging registries
## Moderate Aortic Stenosis: Size Does Matter

STUDY FOLLOW-UP. All individuals were followed up from the date of their last recorded echocardiogram to the point of death or being censored alive at the census point. The pattern of all-cause and cardiovascular-related mortality during >1 million person-years of follow-up (derived from 44,235 case-

**Is the moderate AS the issue or the company it keeps?**

1. All those in Rosenhek and Lancellotti studies who had AVR had severe AS pre-operatively.
2. Noncardiac death high in moderate AS group as well.

**BUT**

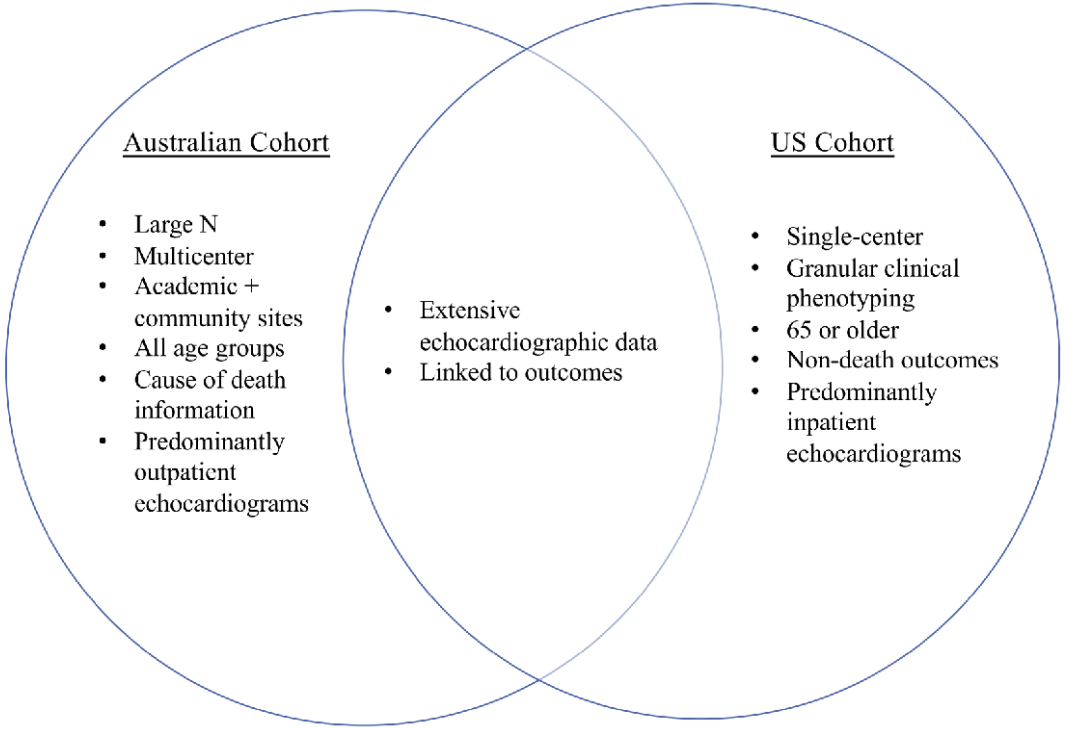
1. Moderate AS still associated with higher mortality than age-, sex-, and comorbidity-adjusted controls.
2. Half of deaths in Rosenhek study did not have severe AS
3. If there is an associated SCD risk in moderate AS, it is likely small and large numbers are needed for detection.
4. Ascertainment bias: those with OHCA may not present to medical attention; autopsies rarely performed.
5. Confirmation bias: we don't associate moderate AS with mortality.

# A use case for imaging registries

## Moderate Aortic Stenosis: the iENHANCED-AS study

**Redefining the clinical consequences Aortic Stenosis:**
**The International ENHancing the ANalysis of Clinical Events & Death in Aortic Stenosis (I-ENHANCED-AS) Study**

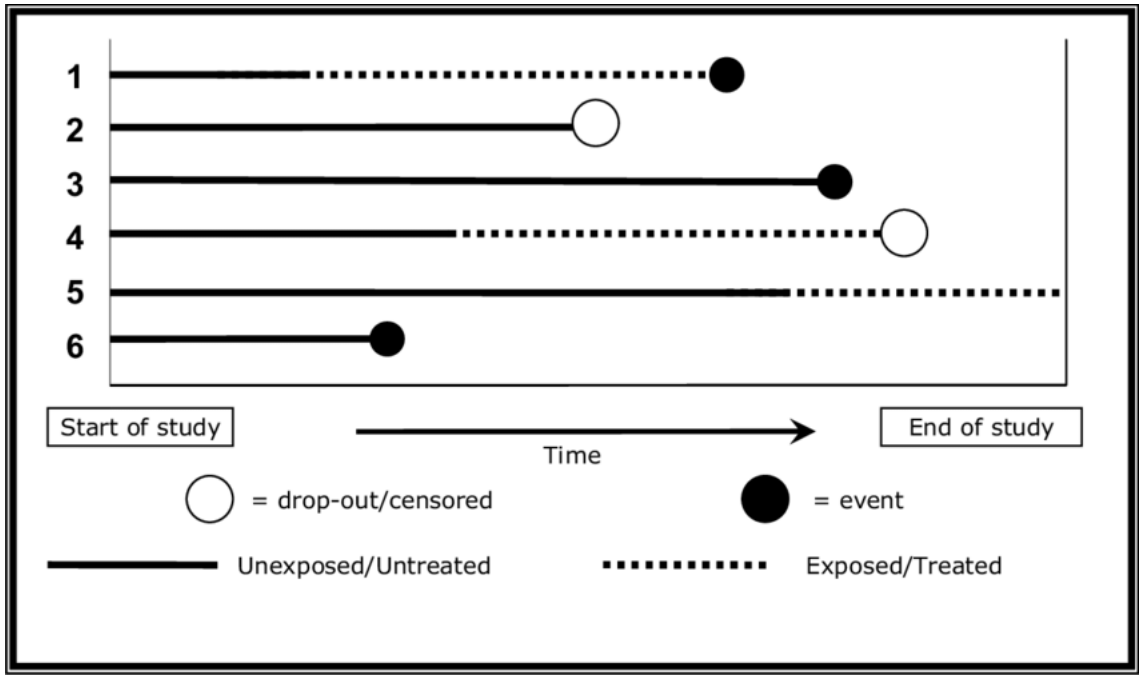
**Co-PIs: Geoff Strange (NEDA), Jordan Strom (Smith Center)**



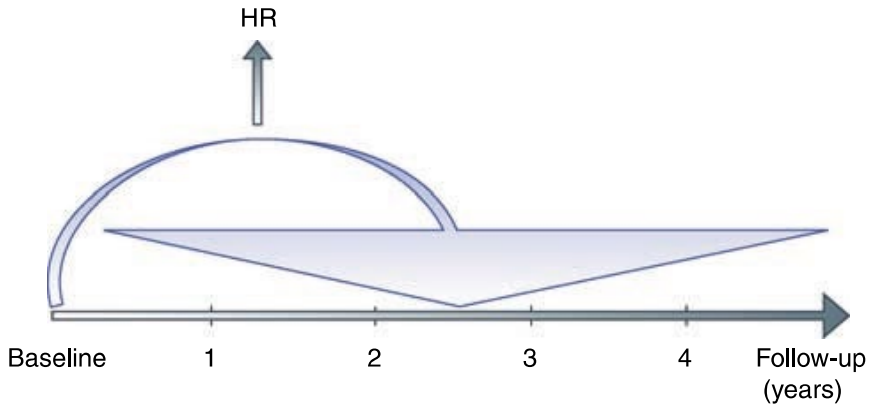
Dekker, Kidney International, 2008

# A use case for imaging registries

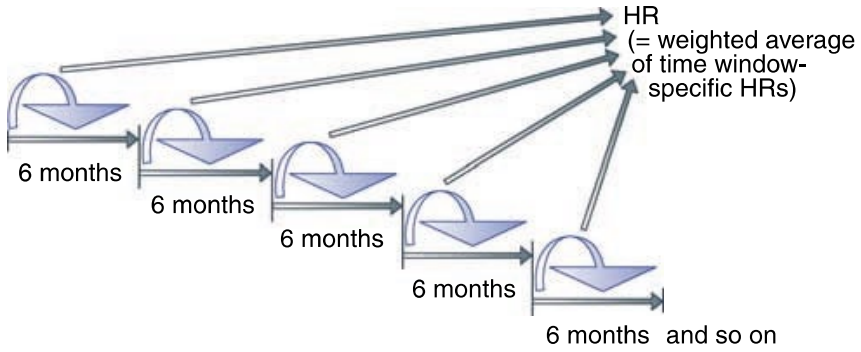
## The iENHANCED-AS study: Time-Dependent Covariates




Example Survival Plot




Time-invariant interpretation




Time-varying interpretation

**Individuals with AS are only given "credit" for the alive time they spend in each severity stage**

# A use case for imaging registries
## The iENHANCED-AS study: Results

**ENCOR-CMS / NEDA v2.0**

***Equivalent Linked Data (2000-2017)***

**135,481 echocardiograms from 66,846 people (US cohort) /**
**1,077,145 echocardiograms from 631,824 people (Australian cohort)**

→ 17,428 / 31,468 Non-study period
→ 4,445 / 125,606 No AV profiling

**44,973 / 474,750 people with Aortic Valve profiling**

→ 12,634 / 243,023 Aged <65 years
→ 1,081 / 18,405 Prior AVR

**393 / 5,454 people aged ≥ 65 years with native Aortic Valve → AVR**
**127 / 2,422** all-cause deaths over **633 / 38,000** person-years follow-up

**30,865 / 217,599 people aged ≥ 65years with native Aortic Valve on last echo**
**14,481 / 89,054** all-cause deaths over **97,576 / 1.1 million** person-years follow-up

**Peak AV Velocity (30,810 / 211,635) or Mean AV Gradient (5,063 / 118,133) to determine grade of AS according to hemodynamic profile as per clinical guidelines**

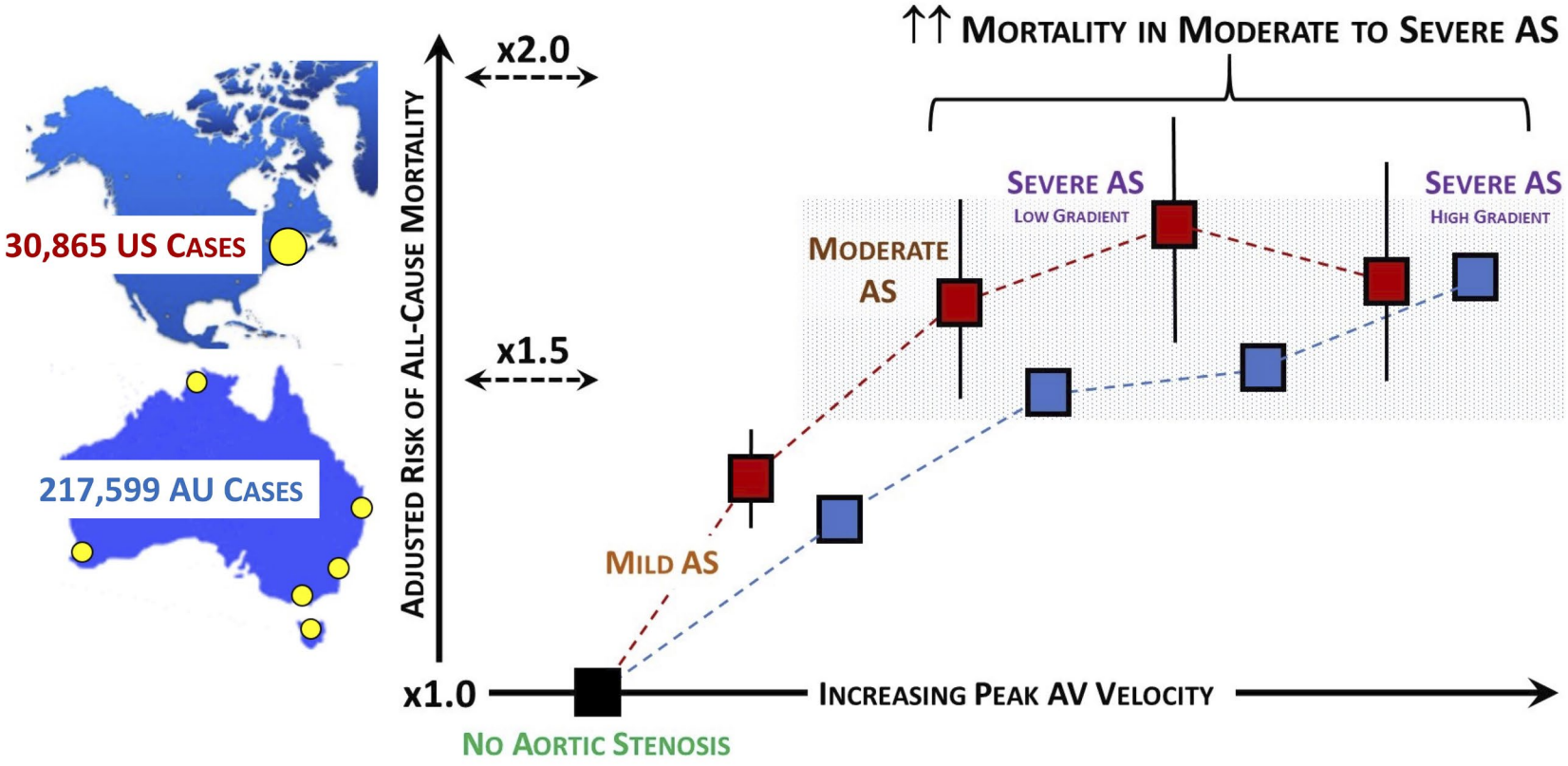
| No AS | Mild AS | Moderate AS | Severe AS |
|---|---|---|---|
| 26,682 / 173,776 | 2,440 / 27,921 | 1,198 / 10,789 | 545 / 5,113 |

**AVA measurements in 3,976 / 104,689 cases to reclassify [1] severe AS if AVA <1.0 cm²**

| No AS | Mild AS | Moderate AS | Severe Low-Gradient AS | Severe High-Gradient AS |
|---|---|---|---|---|
| 26,682 / 173,776 | 2,326 / 26,426 | 728 / 7,717 | 584 / 4,567 | 545 / 5,113 |

Strom et al. (in press)

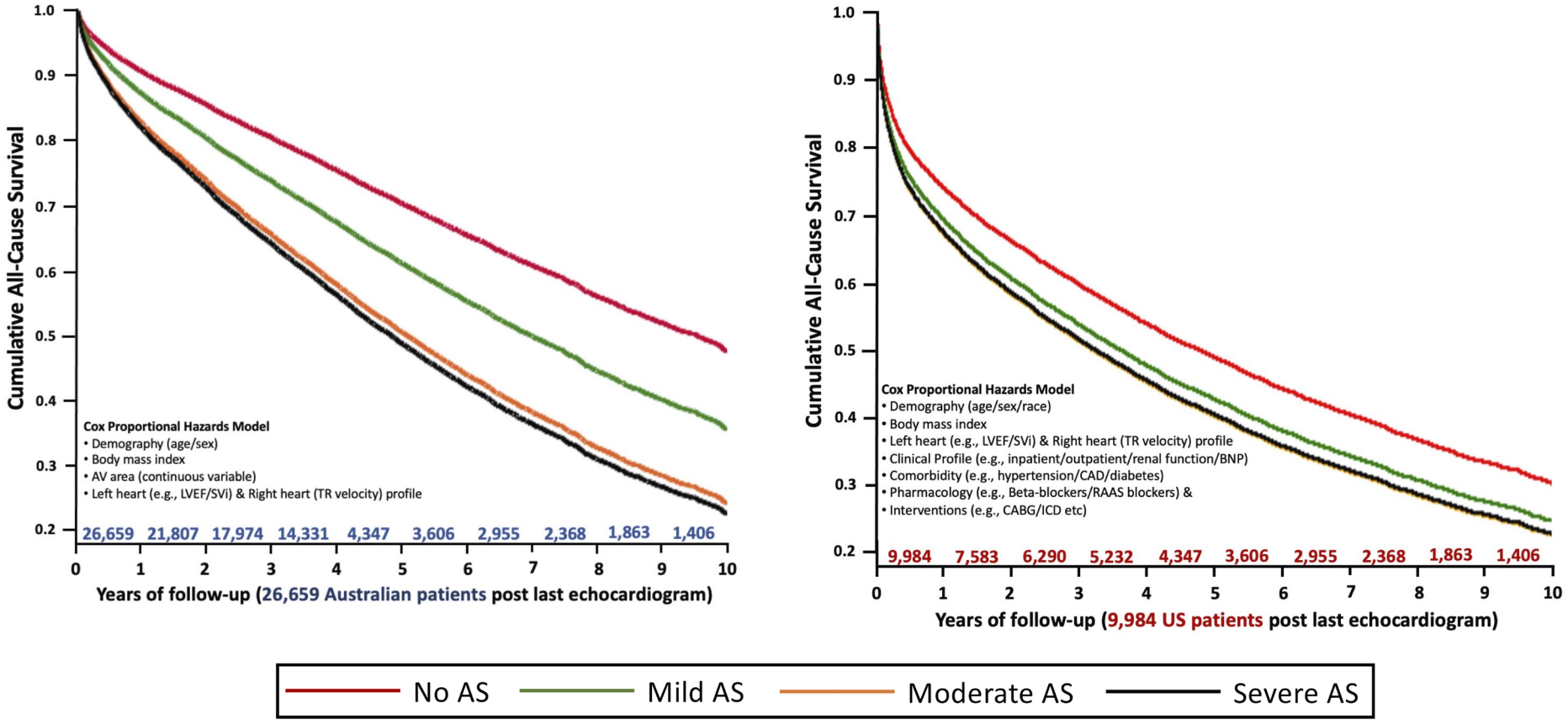
# A use case for imaging registries
## The iENHANCED-AS study: Results



Strom et al. (in press)

# A use case for imaging registries

## The iENHANCED-AS study: Gradient-based classification

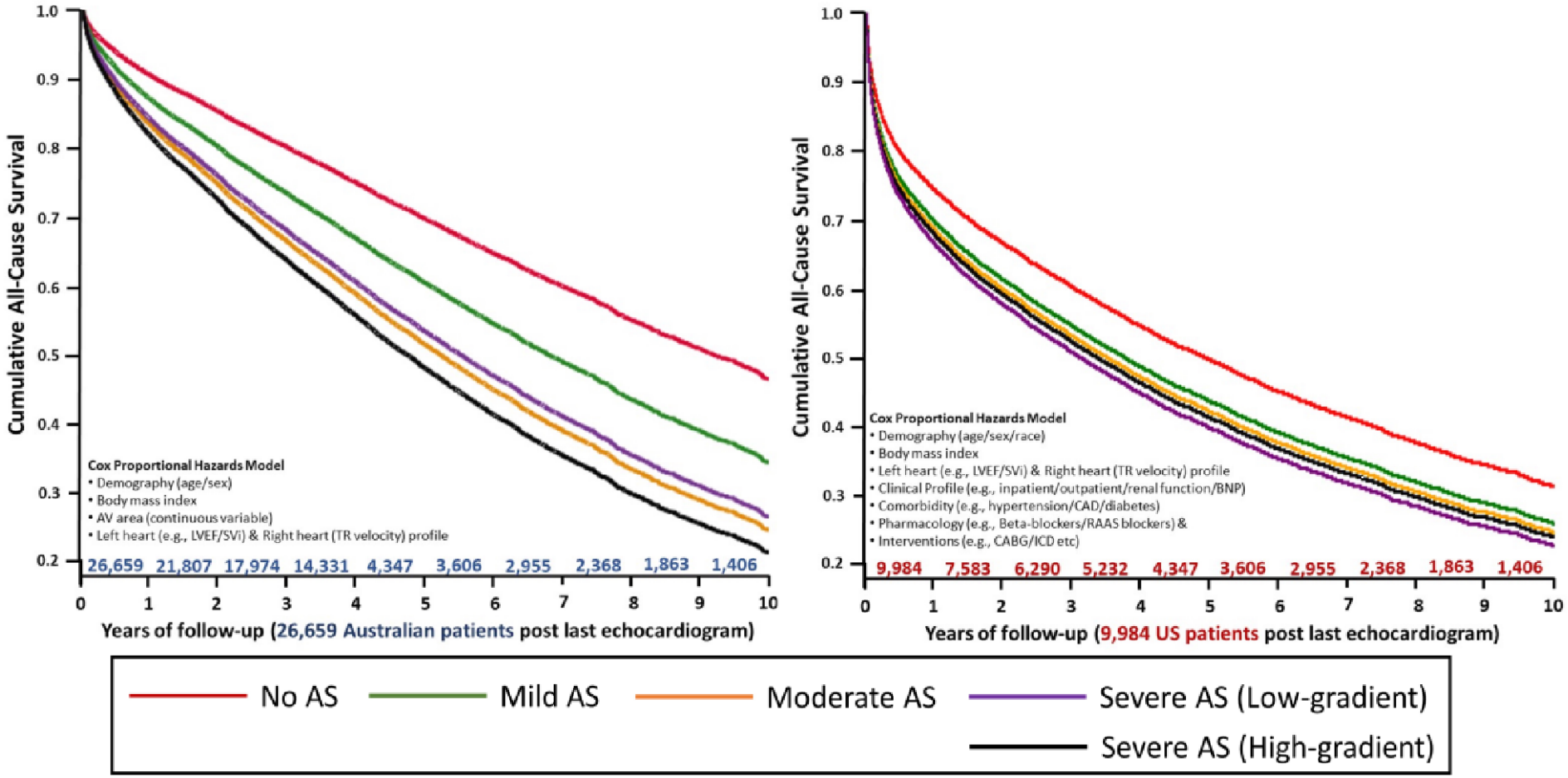





Beth Israel Deaconess Medical Center | Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology | HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

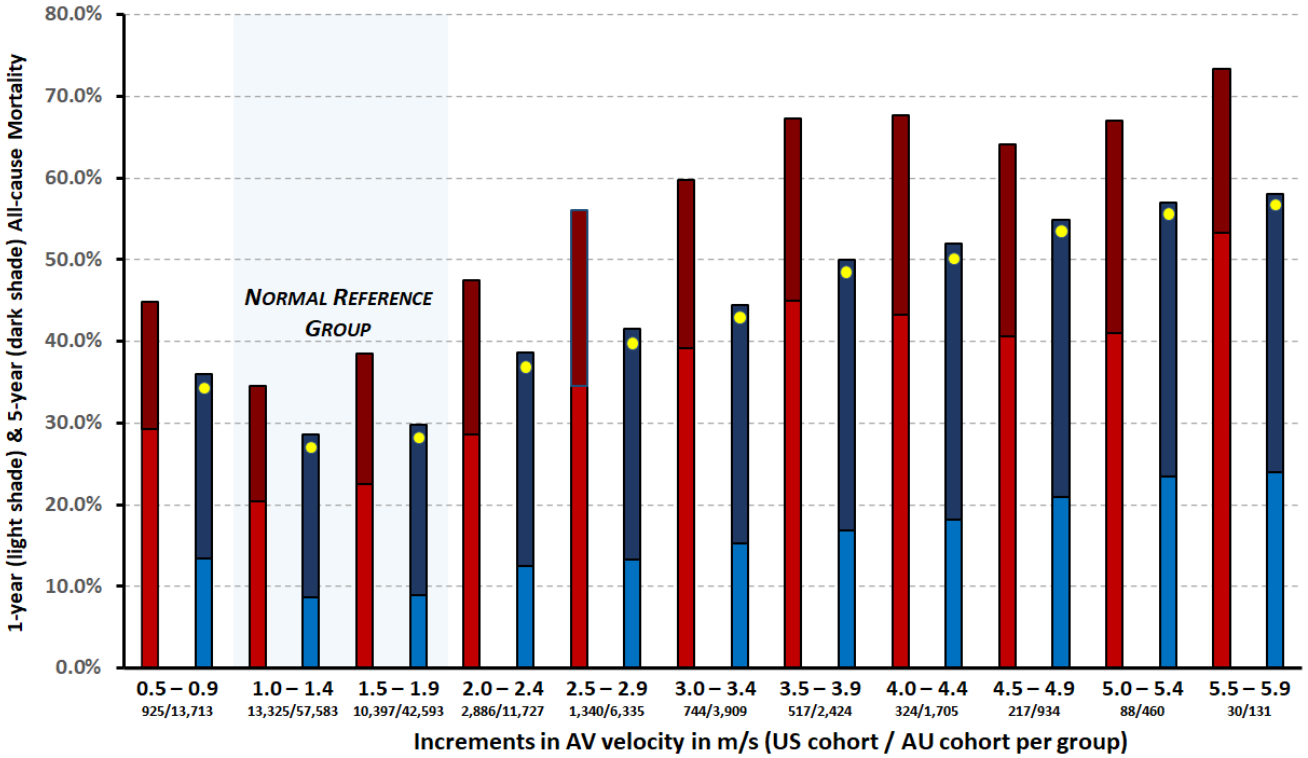
# A use case for imaging registries

## The iENHANCED-AS study: AVA-based classification



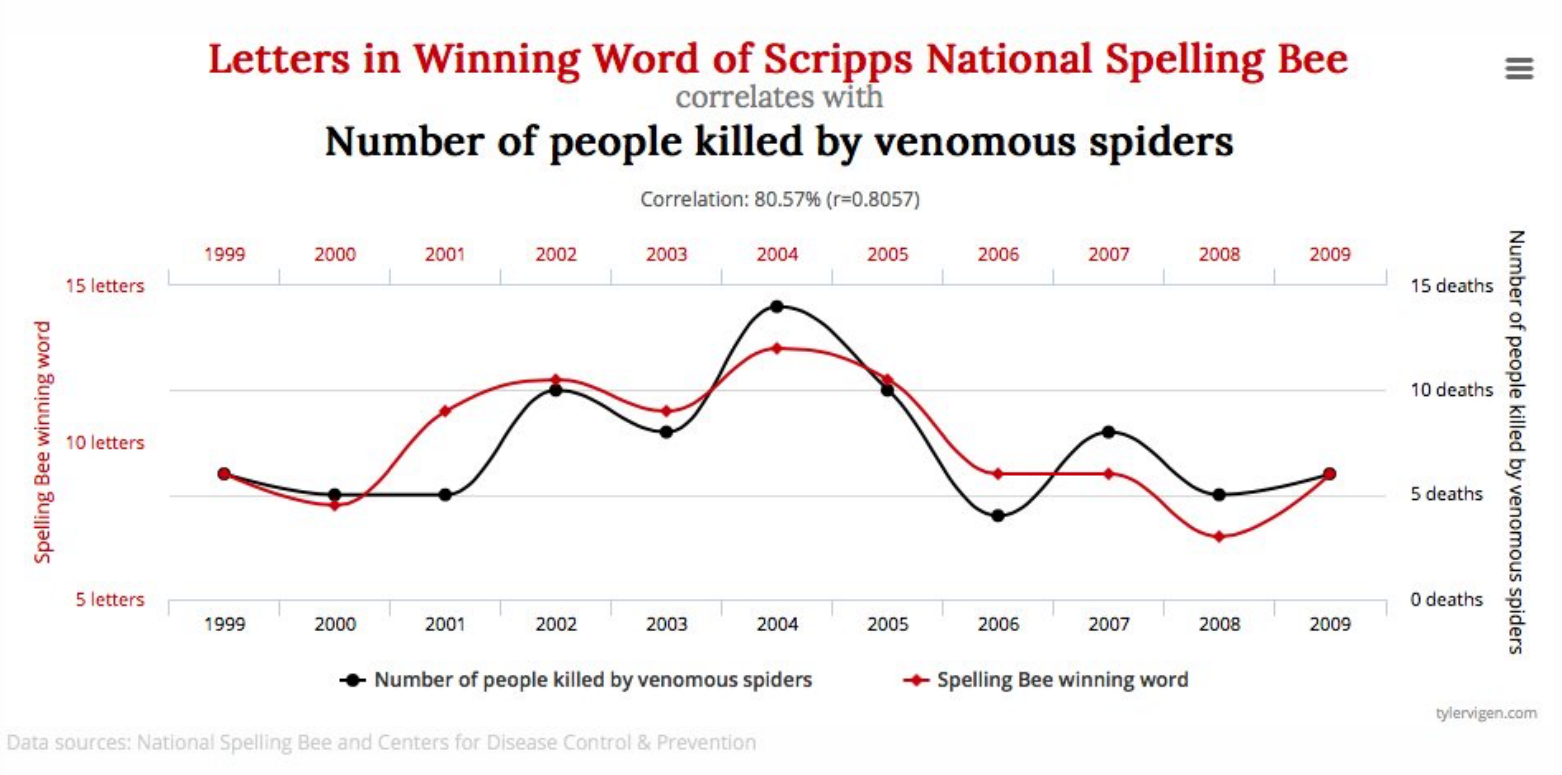
# A use case for imaging registries
## The iENHANCED-AS study: Results

- Results consistent across subgroups:
  - First vs. last echo as baseline
  - Adjusting & not adjusting for time in stage
  - CV-specific death (AU cohort)
  - Age < 65 (AU cohort)
- Interaction by CAD/HF status
  - Significant interaction by prevalent HF and CAD
- Importance of gradients to risk
- Impact of sex and race on risk



Source: tylergiven.com

# The case for imaging registries
## iENHANCED AS – Caution: Not a Prescription




**Correlation ≠ Causation.** | **Risk ≠ Benefit from AVR**

# Summary

- Rising costs of cardiac imaging have forced the hand of imagers to justify the value of imaging
- Imaging registries, especially when linked with outcomes, can be used to demonstrate value. through better risk stratification and prognostication for patients, pathophysiologic insights into diseases, and understanding of care gaps and variation in imaging.
- Outcomes research in cardiac imaging is a unique discipline with a distinct set of methodologies, challenges, and questions.
- Aortic stenosis represents a powerful and important use case for use of such methodologies to answer clinically relevant questions, but results must be interpreted cautiously.

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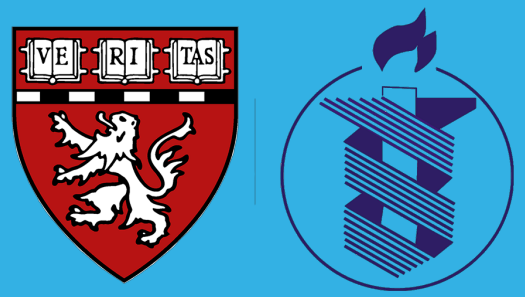


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