RECONSIDERATION OF TAVR NCD

"QUALITY NOT QUANTITY"

MEDCAC Meeting, July 25, 2018

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Disclosures

- Medical Director, Cardiac Catheterization Lab, Providence Saint John's Health Center, Santa Monica
- No pharma or device company board or advisory positions
- No conflicts in reference to this subject

TAVR NCD REQUIREMENTS
1/7/13

- 2 CV Surgeons approve
- Heart team model
- Hospital infrastructure:
  - On-site CV surgery program
  - Cath lab or Hybrid room
  - Echo
  - ICU
  - "Appropriate volume requirements per applicable qualifications…"

- NATIONAL COVERAGE DECISION (NCD) FOR TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) (20.32) 1/7/13

TAVR NCD REQUIREMENTS 1/7/13

- Hospital without previous TAVR experience
  - ≥ 50 SAVR (10 high risk) the prior year
  - ≥ 1000 caths including ≥ 400 PCIs / year
  - ≥ 2 CV surgeons with
    - ≥ 100 career SAVRs (10 high risk)
    - ≥ 25 AVRs in 1 year or 50 in 2 years

- TAVR NCD 20.32

TAVR NCD REQUIREMENTS 1/7/13

- Interventional Cardiologist (IC) experience
  - ≥ 100 lifetime structural cases; or:
  - ≥ 30 left-sided structural cases / yr, at least 60% BAV
  - ASD and PFO excluded
  - Watchman / LAA closure not included

- TAVR NCD 20.32

TAVR NCD REQUIREMENTS 1/7/13

- Other requirements:
  - National registry participation
  - Procedure done as team with IC and CV Surgeons together

TAVR NCD REQUIREMENTS 1/7/13

- Hospital with previous TAVR experience
  - ≥ 2 CV Surgeons
  - ≥ 20 TAVRs in prior year or 40 / 2 years
  - ≥ 1000 caths including ≥ 400 PCIs

NCD Revision is Needed

- Procedure “experimental” and then “newly approved” → commonplace
- Procedure risk has decreased
- Intermediate risk patients now approved: low risk soon?
- Outcomes have improved

Presumptions

- Volume of a procedure predicts quality
  - e.g., PCI volume predicts PCI quality
- Volume of a procedure predicts quality of an unrelated procedure
  - e.g., PCI volume predicts TAVR quality
- TAVR is a modification of SAVR
- TAVR is a high-risk procedure with frequent surgical conversion

NCD Presumptions

- Applicable in 2018 for TAVR?
- Examine:
  - Volume and quality for cardiac cath
  - Volume and quality for PCI
  - Volume and quality for CABG
  - Volume and quality for LVAD
  - Volume and quality for cath/PCI/SAVR → TAVR

Cath Volume Does Not Predict Quality

- 2012 ACCF/SCAI Consensus Doc: “Using minimum case volumes as a surrogate for quality presumes that a high procedural volume equates to a high skill level...the relationship between procedural volume and outcome remains controversial.”
- Recommend quality assurance, not volume criteria

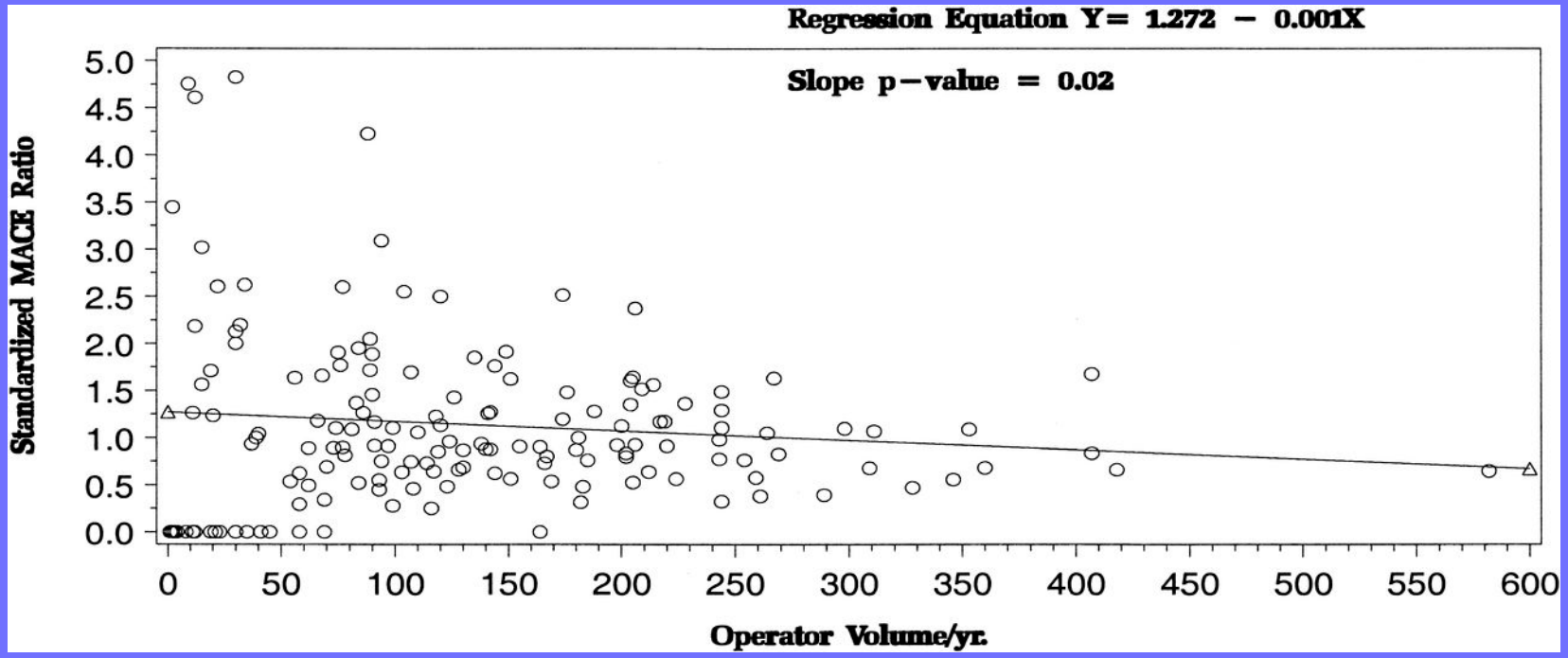
2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards. Bashore et al. JACC 2012;59:2221-2305

PCI Operator Volume and Quality

- Moscucci:
  - 18,504 consecutive PCIs in 2002
  - 165 operators
  - 14 hospitals
  - “relationship between operator volume and in-hospital mortality is no longer significant, relationship between volume and any adverse outcome is still present”

Relationship Between Operator Volume and Averse Outcome in Contemporary Percutaneous Coronary Intervention Practice. Moscucci et al. JACC 2005;46:625-632

Individual Operator Volume vs. MACE



Mauro Moscucci et al. JACC 2005;46:625-632

PCI Volume and Mortality: UK

- UK Cohort Study: 93 hospitals
- 427,467 PCIs
- No correlation of volume and quality/outcome (mortality)

Total Center Percutaneous Coronary Intervention Volume and 30-Day Mortality. O'Neill et al. Circ Cardiovasc Qual Outcomes 2017;10e003186/CIRCOUTCOMES.116.003186.

PCI Volume and Quality

- 2007 ACCF/AHA/SCAI Update on PCI:
  - 400 case threshold for mortality and emergency CABG: NY + Michigan registries
  - HOWEVER: based on NYS registry from 1999
  - “Advancements in technology…in part offset the adverse institutional volume-outcome relationship”

ACCF/AHA/SCAI 2007 Update of the Clinical Competence Statement on Cardiac Interventional Procedures. King, et al. JACC 2007;50:82-108

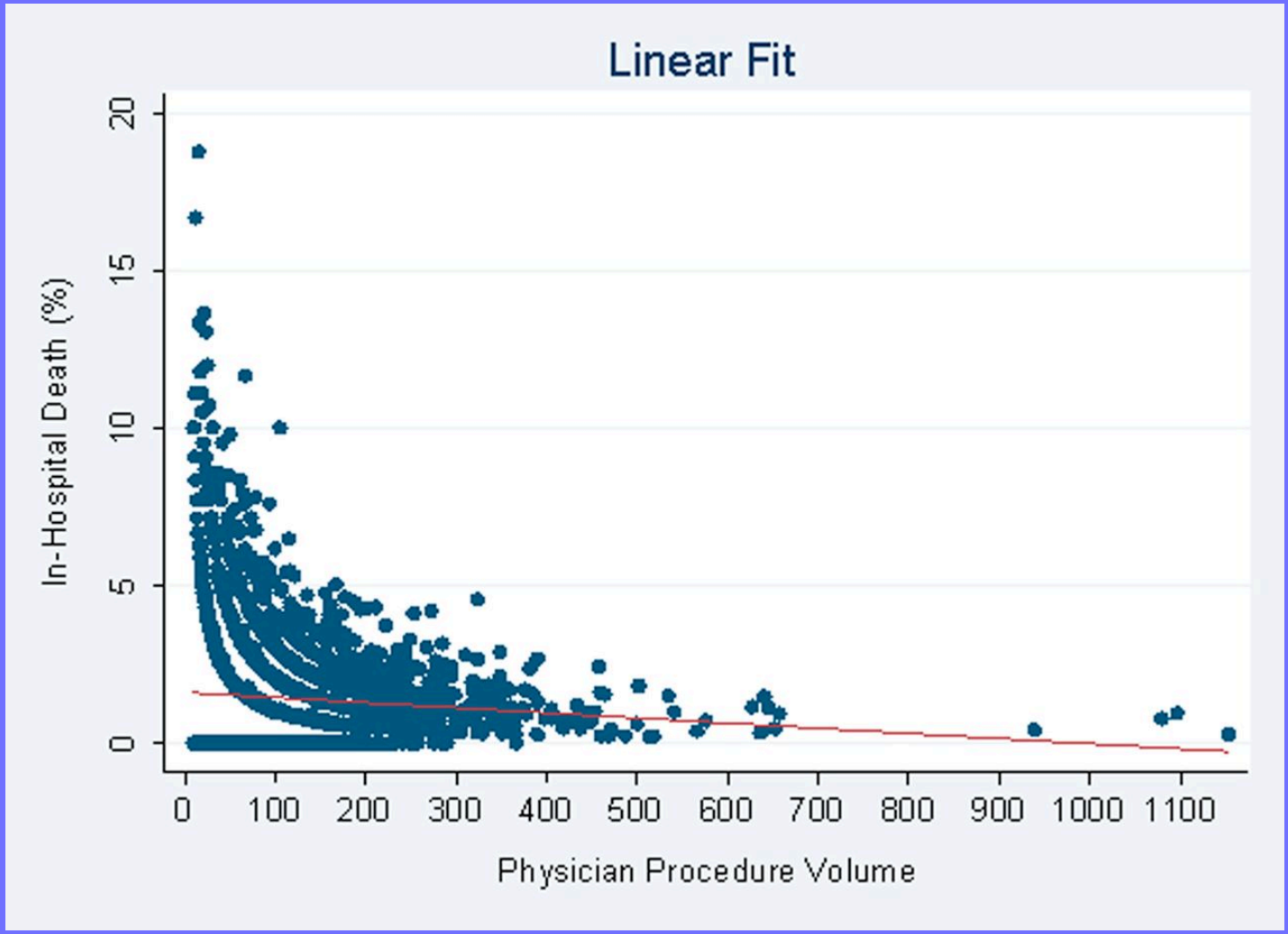
PCI Hospital Volume and Quality

- 2013 Update on PCI:
  - Data from 1995 – 2003
  - Correlation, “but moderate heterogeneity existed” in hospital volume quality relation
    - Pre-stent correlation present
    - Stent-era: some correlation
  - Now discuss 200 PCIs/year as cutoff for quality, but also recognize quality as important

PCI Operator Volume and Quality

- 2013 Update on PCI:
  - Individual operator volume and quality correlation
  - However, this correlation is statistical: significant heterogeneity exists

ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures. Harold et al. JACC 2013;62:357-96



$R^2 = 0.0057$

John G. Harold et al. JACC 2013;62:357-396, ACCF/AHA/SCAI

JACC

PCI Operator Volume and Quality

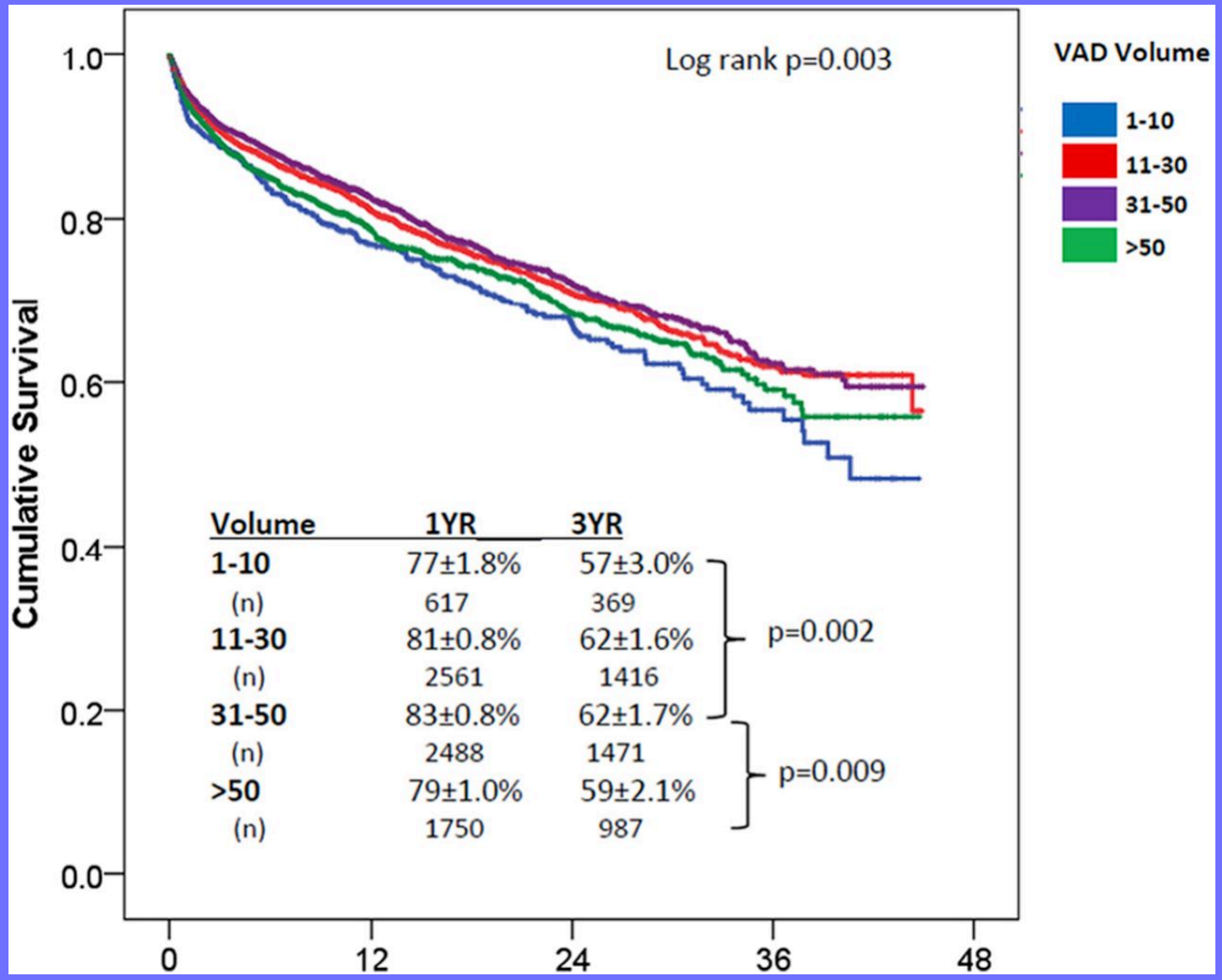
- 2013 Update on PCI:
  - "Overall, it is the opinion of the writing committee that the available evidence does not send a loud signal supporting a consistently strong relationship between operator caseload and mortality."

ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures. Harold et al. JACC 2013;62:357-96

LVAD: Volume and Quality

- INTERMACS Registry: Cowger studied outcomes after LVAD IN 7,419 patients
- Compared ≤ 10, 11-30, 31-50 and > 50 implants/year
- CMS requires ≥ 10 LVAD or artificial hearts/yr
- Conclude: low volume → worse survival

- Impact of Center Left Ventricular Assist Device Volume on Outcomes after Implantation. Cowger et al. JACC Heart Failure 2017;5:691-699



Jennifer A. Cowger et al. JCHF 2017;5:691-699

Cowger LVAD Post-Hoc Analysis

- Dr. Shih-Ting Chiu, Biostatistician, Medical Data Research Center, Providence Health and Services, Portland, Oregon
- Article conclusion is not supported by the data

California Valve Surgery

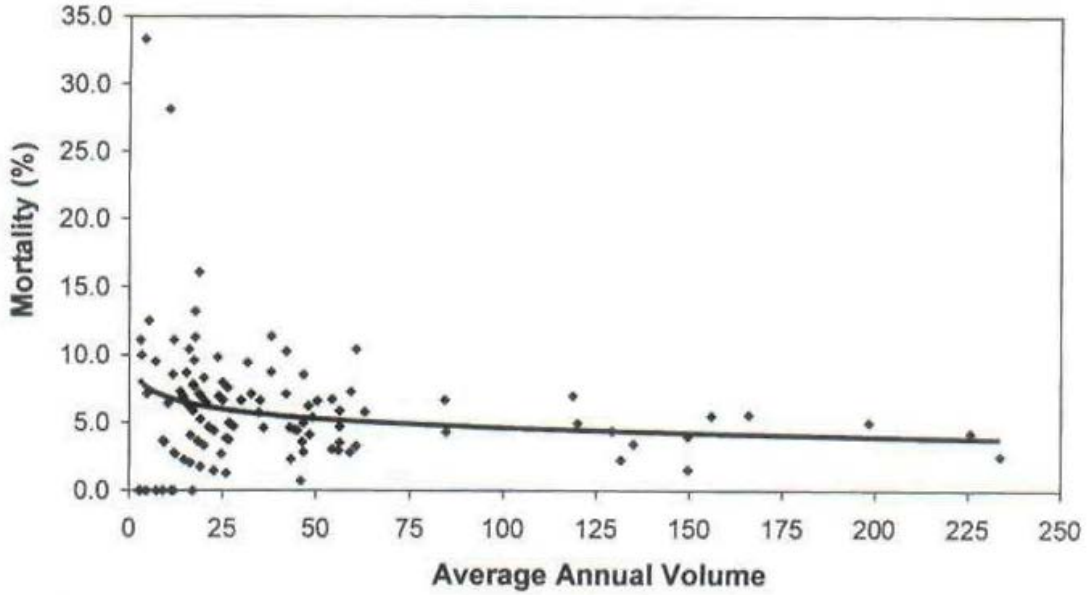


FIG. 3. VALVE-only. Scatter plot of average annual volume *versus* 3-year mortality. Logarythmic trendline calculated by MS Excel.

Relationship of Hospital Volume to Outcome in Cardiac Surgery Programs in California.
Carey et al. So. Cal ACC Presentation Jan 2002

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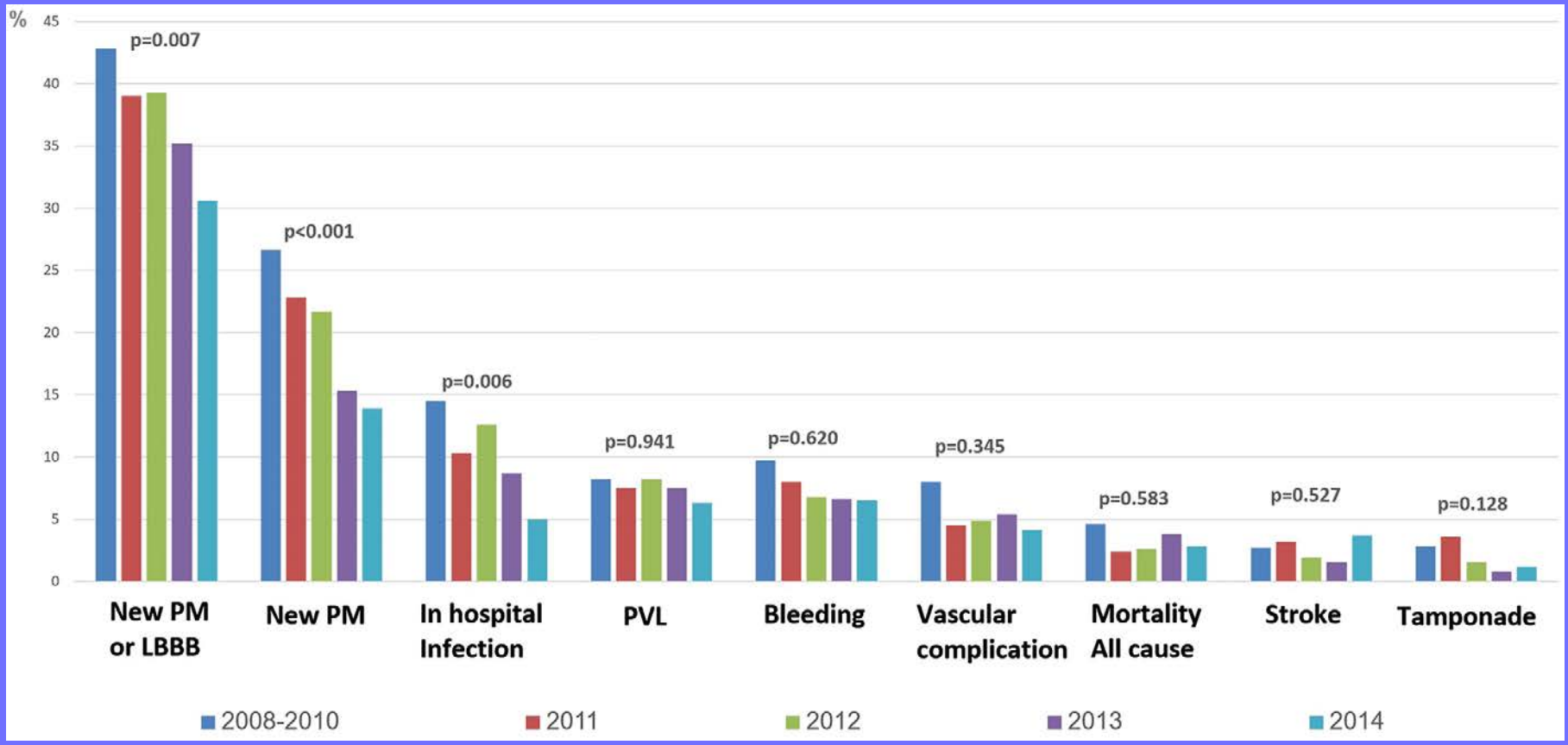
QUALITY OUTCOME IMPROVEMENT OVER 6 YEARS



Landes et al. Temporal trends in transcatheter aortic valve implantation, 2008–2014: patient characteristics, procedural issues, and clinical outcome, Clin Cardiol: 40;82-88, First published: 26 October 2016, DOI: (10.1002/clc.22632

Surgical Conversion for TAVR for 45,395 Cases

		# cases	%
1246	**Conversion open heart surgery**	**220**	**0.5**
1247	Reason	220	100.0
1248	Valve dislodged to aorta	13	5.9
1249	Valve dislodged to left ventricle	9	4.1
1250	Ventricular rupture	51	23.2
1251	Annulus rupture	39	17.7
1252	Aortic dissection	13	5.9
1253	Coronary occlusion	19	8.6
1254	Other	76	34.6

ACC Registry, Q4 2016 → Q3 2017

TAVR NCD: RECONSIDERATION IS NEEDED

- Presumption that volume confers quality is debunked
- TAVR streamlined with lower risks
- In the age of EHR and Registry Data, quality is measurable
- Quality, not volume should be the determinant of CMS approval of TAVR programs and operators

National Volume Trends and TAVR NCD:

- Due to outcomes research and adherence to AUC: PCI volume is decreasing nation-wide:
  - Should a program with quality TAVR stop if their PCI volume appropriately drops below 400?
  - Is there motivation to unnecessarily perform PCI to maintain TAVR status?
  - Should a program performing 350 PCIs find 10 new docs to do 5 cases each to reach 400?

National Volume Trends and TAVR NCD:

- Due to TAVR, Surgical AVR volumes are decreasing
  - TAVR is a Cardiac Cath Lab procedure: no relation to SAVR quality
  - Should a quality TAVR program stop doing TAVR if surgical volume drops?
  - Motivation for unnecessary Surgical AVR to maintain TAVR status

Benefits of TAVR NCD Revision

- Patient and family convenience
- Improved care quality: patient's MD and RN team maintain continuity of care in their hospital
- Improved outcomes, since quality, not simply volume, will determine sites

Rational TAVR NCD

- Quality, not volume, should determine program initiation and maintenance
- Operator training is key, but:
  - Recommend including Watchman and other newer structural cases in IC or CV Surgeon qualification
  - Case numbers: (100 lifetime or 30/year) include TAVR, mClip, TMVR etc., LAA occluder, PFO/VSD/ASD closure
- Trained and privileged in cath, PCI, peripheral, structural

Voting Questions: Hospitals without prior TAVR

1. SAVR Volume Threshold: quality, not volume
2. PCI Volume Threshold: quality, not quantity
3. Volume requirements of SAVR/PCI do limit access to TAVR, and should be revoked

Voting Questions: Hospitals with prior TAVR experience

4. SAVR quality, not volume should be required to maintain a TAVR program
5. PCI quality, not volume, should be required to maintain a TAVR program
6. Using volume criteria limit patient access, increase the chance of lower quality, and increase patient inconvenience and risk.

CV SURGEON: TO BEGIN TAVR

7. CV Surgeons who perform TAVR should be skilled at TAVR, as TAVR is not a minor modification of SAVR, but rather a catheter based, cath lab procedure. SAVR skillset is not translatable. Quality outcomes and experience should determine surgical requirements (e.g., direct Aortic or LV delivery) for TAVR, not volume.

Interventional Cardiologist to begin TAVR

8. IC OPERATOR TRAINING AND EXPERIENCE IS KEY. TRAINING SHOULD INCLUDE SUFFICIENT CASES OF TAVR, AND OTHER STRUCTURAL HEART CASES REQUIRING MULTI-MODALITY IMAGING AND CATHETER SKILLS, INCLUDING TAVR, ASD, PFO AND VSD CLOSURE, WATCHMAN/LAA OCCLUDER, AND MITRAL VALVE INTERVENTION

Interventional Cardiologist to begin TAVR

8. IC OPERATOR SKILLSET TO INCLUDE:
   - STRUCTURAL HEART
   - CORONARY ANGIOGRAPHY
   - PCI
   - PERIPHERAL ANGIO AND INTERVENTION

Maintenance of Proficiency for TAVR Programs

9. Volume should be replaced with quality criteria for maintenance of a TAVR program:
   a) for the Surgeon
   b) For the Interventional Cardiologist
   c) For the team

Hospital Volume Criteria Create Barriers for Patients

a) Geography, e.g., travel in Los Angeles and rural

b) – e) Gender, ethnicity, race and socioeconomic: local factors

f) Provider preference: limited by volume criteria

g) Hospital setting: community hospitals more likely excluded

CONCLUSION

- QUALITY SHOULD DETERMINE TAVR PROGRAM SITES
- VOLUME CRITERIA ARE OUTMODED AND DO NOT GUARANTEE QUALITY
- QUALITY CRITERIA WILL IMPROVE PATIENT ACCESS AND CARE
- IN THE ERA OF ELECTRONIC RECORDS AND DATA REGISTRIES QUALITY CAN BE MEASURED
- THE TIME FOR CHANGE IS NOW

THANK YOU FOR YOUR ATTENTION AND CONSIDERATION

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