TAVR Update: New Insights and Perspectives from the U.S. National STS/ACC TVT Registry

Joseph E. Bavaria, MD
STS/ACC TVT Registry Steering Committee Chairman (2017-2020)
Past-President of STS (2016-17)
Roberts-Measey Professor and Vice-Chair of Cardiovascular Surgery at the University of Pennsylvania
Disclosures

- STS-ACC Transcatheter Valve Therapy (TVT) Registry Steering Committee Chairman
- Co-Chair of the 4-Society TAVR Institutional and Operator Writing Committee (ACC/STS/AATS/SCAI)
- Site Investigator in Transcatheter Valve Trials or Consultant
  - W.L. Gore: Cardiac & Aortic Teams
  - Edwards Lifesciences: PARTNER family of Trials, Commence Trial
  - Abbott/St. Jude: Portico, Trifecta Trials
  - Medtronic: SURTAVI Intermediate Risk Trials
- Founders Shares and Equity holder in CardiAQ TMVR (sold to Edwards in Oct 2015 with no financial conflict presently)
Disclosures

• I love TAVR!!
History of the TVT Registry

The STS/ACC TVT Registry™, created by a collaboration between the Society for Thoracic Surgeons (STS) and the American College of Cardiology (ACC), monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures – emerging treatments for valve disease patients.

TVT = Transcatheter Valve Therapy
The Need for a **National Clinical Registry**

Value of TVT: The Key to Sustainability

- **Hospital System**
  - QA/QI
  - Site Performance
  - National Benchmarks
  - AUC

- **A Clinical Knowledge Machine**
  - Key to US Learning Health Care System

- **A Source of Data for Patients**
  - Decision-Aids
  - Public Reporting

- **Medical Device Industry**
  - Expansion of Indications
  - Imbedding CA and PAS Studies
  - Regular Comprehensive Reports

- **A Component of Regulatory and Reimbursement Reform**
Multiple Stakeholders

Professional Societies
Government agencies
Hospital Networks
Device Industry
University Analytic Centers
Health Media

TVT Registry Stakeholders

- STS
- NHLBI
- Hospital Systems
- Device Companies
- Patient Advocacy
- ACC
- CMS
- FDA
- Media
- US News
- AATS & SCAI
- ACC
- CMS
- FDA
- US News
- AATS & SCAI
- Media
- STS
- Hospital Systems
- Device Companies
- Patient Advocacy
- ACC
- CMS
- FDA
- Media
- US News
- AATS & SCAI
- STS
- Hospital Systems
- Device Companies
- Patient Advocacy
- ACC
- CMS
- FDA
An Update of the Data Collected in the Three Modules

Transcatheter aortic valve replacement (TAVR)
Transcatheter mitral valve repair (MitraClip)
Transcatheter mitral valve replacement (Valve-in-Valve)

CMS Mandated
“Science tells us what we can do; Guidelines what we should do; & Registries what we are actually doing.”

Lukas Kappenberger MD
Heart Rhythm Society Policy Conference
Washington DC 2005
An Update of the Data Collected in the Three Modules

Transcatheter aortic valve replacement (TAVR)
Transcatheter mitral valve repair (MitraClip)
Transcatheter mitral valve replacement (Valve-in-Valve)

CMS Mandated
• Last 2 years 115 new sites
• New sites opening are most frequently in close proximity to existing sites
• Whether or not new sites meet current NCD requirements is unknown
• First Wyoming TAVR site to open in 2020
TVT Registry Sites since new NCD

• US has 1 TAVR site for every 70,000 people over the age of 65 years. More than ANY other country
Sites Enrolled in the TVT Registry as of October 16, 2019

Steady Growth each year
TVT National Volumes Data: Snapshot of U.S. TAVR Practice Patterns
Commercial TAVR Submitted to the TVT Registry

Over 250,000 TAVR Patients are in Registry. Anticipate >70,000 in 2019

TVT Registry Datamart Data as of 10/16/19
<table>
<thead>
<tr>
<th>Transcatheter Therapy Modules in TVT Registry</th>
<th>Current Number of Sites Performing Treatment</th>
<th>2018 Patient Volume in USA</th>
<th>2018 Mean Number of Procedures per Site</th>
</tr>
</thead>
</table>
| **TAVR**
Native and Valve-in-Valve                  | 642                                        | 63,361                    | 105                                    |
| **Transcatheter Mitral Valve Repair**
(MitraClip)                                 | 355                                        | 7,230                     | 20                                     |
| **Transcatheter Mitral Valve Replacement**
(Sapien Valve-in-Valve and Valve-in-Ring)   | 184                                        | 937                       | 5                                      |
| **Transcatheter Tricuspid Valve Repair and Replacement**
(2020?)                                    | TBD                                        | TBD                       | TBD                                    |

Sept. 1, 2019
The Aortic Valve “Universe” in the USA

TAVR, for the First time, in 2019 surpassed SAVR in all its forms. Surpassed Isolated AVR in 2016.

Linked TVT and STS Data. From the STS/ACC TVT Steering Committee Represents approx. 93% and 97% of SAVR and TAVR respectively.
The predominant etiology is age-related Degenerative AS. Therefore Age statistics have changed minimally with Intermediate Risk patients. But ....
TAVR Age
(25th and 75th percentiles)

Average age of Low Risk trials = 74 years

Table 1. Characteristics of the Patients at Baseline.5

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TAVR (N=496)</th>
<th>Surgery (N=414)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age — yr</td>
<td>73.3±5.8</td>
<td>73.6±6.1</td>
</tr>
<tr>
<td>Male sex — no. (%)</td>
<td>335 (67.5)</td>
<td>323 (77.1)</td>
</tr>
<tr>
<td>Non-white race or ethnic group — no. (%)†</td>
<td>38 (7.7)</td>
<td>45 (9.9)</td>
</tr>
</tbody>
</table>

Table 1. Characteristics of the Patients at Baseline.7

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>As-Treated Analysis</th>
<th>Intention-To-Treat Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TAVR (N=715)</td>
<td>Surgery (N=718)</td>
</tr>
<tr>
<td>Age — yr</td>
<td>74.1±5.8</td>
<td>73.6±5.9</td>
</tr>
<tr>
<td>Female sex — no. (%)</td>
<td>260 (36.0)</td>
<td>229 (33.8)</td>
</tr>
</tbody>
</table>
TVT Registry

TAVR and TAVR ViV Procedures

V-in-V is an important part of TAVR: approx. = 7%

TVT Registry Datamart Data as of 10/16/19
Expansion of TAVI into Intermediate Risk. Absolute Number of patients with extreme and high risk remains substantial

Few Low Risk in 2018 but .....
TAVR

Median LOS in Days

(25th and 75th percentiles)

LOS reductions becoming less
**TAVR In-Hospital Mortality Risk Score**

(Median, 25th and 75th %)

- 2012: 6.3%
- 2013: 4.1%
- 2014: 4.0%
- 2015: 5.0%
- 2016: 4.5%
- 2017: 4.2%
- 2018: 4.0%

*Based on TVT Registry TAVR in-hospital mortality risk score*

Mean TAVR risk is similar for 3-years but range has narrowed ... interesting!
STS SAVR Risk Score Patients Undergoing TAVR
(Median, 25\(^{th}\) and 75\(^{th}\) %)

Lower Risk Patients each year
TAVR Access Site

Source: STS/ACC TVT Registry Database as of Jul 17, 2017

TF Dominates: >95% in 2018: Good for Patients
Concurrent and 30-Day PCI with TAVR Procedure

- Steady and Reasonable
Real World TAVR Clinical Outcomes
TAVR: In Hospital
Major and Life-Threatening Bleed

Complications continue to decrease, however completely flat for 3 years
TAVR Stroke
In-Hospital, 30 Day, and One Year Stroke

Stroke Rates are Very Flat; No real change ..... VERY Important if we’re going into Low Risk!
TAVR Stroke: In-Hospital, 30 Day, and One Year Stroke

Risk-adjusted stroke model completed and results reported to all TAVR sites quarterly.

Use of cerebral protection is now captured by TVT Registry
TAVR - 30 Day Dialysis

Very good. Rates are Very Flat; No real change in 3 years ..... VERY Important if we’re going into Low Risk!
TAVR Mortality

In-Hospital, 30 Day, and One Year Mortality

5.7% 5.2% 4.1%

2.9% 2% 1.7% 1.5%

7.5% 7% 6%

4.4% 3.2% 2.8% 2.6%

Steadily improving National results.
30 day mortality a bit flat recently
TAVR - All Cause Readmission
(Readmitted for any reason, valve or not valve related)

Wow!! Not sure what to make of this?? 81 year old natural history? CHF admissions? Poor selection nationally? ..... Terrible!! ..... And not improving over 3 years
Alive and Well At One Year After TAVR

(among 1-year survivors with complete KCCQ*)

79.3% 76.4% 76.2% 76.7% 78.4% 80.0%

0% 10% 20% 30% 40% 50% 60% 70% 80% 90%

2012 2013 2014 2015 2016 2017

This is pretty good. No Change in 6 years
BUT it’s nice that 80% SELF REPORT that they are better

1-Yr KCCQ >= 60 and no more than a 10 unit decrease in KCCQ score from baseline to 1 year
TAVR Disposition

Source: STS/ACC TVT Registry Database as of Jul 17, 2017

This is Excellent!
TAVR Disasters:
Three Major Procedure Events

About 2.0% Catastrophe rate: Stable x 3 years
Location of TAVI Procedures: where are they being performed?

- 64% in 2014
- 63% in 2015
- 61% in 2016
- 58% in 2017
- 57% in 2018

Hybrid OR Suite: 26% in 2014, 27% in 2015, 27% in 2016, 27% in 2017, 27% in 2018

Hybrid Cath Lab: 11% in 2014, 10% in 2015, 12% in 2016, 14% in 2017, 15% in 2018

Cath Lab: 10% in 2014, 10% in 2015, 12% in 2016, 14% in 2017, 15% in 2018
TAVR
New Pacemaker after TAVR (Excludes PPM pre TAVR)

<table>
<thead>
<tr>
<th>Year</th>
<th>In Hospital Pacemaker</th>
<th>30 Day Pacemaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>9.1%</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>10.9%</td>
<td>12.9%</td>
</tr>
<tr>
<td>2015</td>
<td>11.0%</td>
<td>13.2%</td>
</tr>
<tr>
<td>2016</td>
<td>11.9%</td>
<td>13.1%</td>
</tr>
<tr>
<td>2017</td>
<td>9.9%</td>
<td>11.9%</td>
</tr>
<tr>
<td>2018</td>
<td>9.4%</td>
<td>11.8%</td>
</tr>
</tbody>
</table>
New (excludes PPM pre TAVR) In Hospital and 30-Day Pacemaker

30 day = 11.8% **NEW** pacemakers. Important as it is well known that pacemaker in younger patients (Low Risk?) die earlier!

**NO CHANGE IN 6 YEARS**
### Other Clinical Events Intermediate Risk

At 30 Days (As Treated Patients)

<table>
<thead>
<tr>
<th>Events (%)</th>
<th>S3HR Overall (n=583)</th>
<th>S3HR TF (n=491)</th>
<th>S3HR TA/TA (n=92)</th>
<th>S3i Overall (n=1076)</th>
<th>S3i TF (n=951)</th>
<th>S3i TA/TA (n=125)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Vascular Comps.</td>
<td>5.0</td>
<td>5.3</td>
<td>3.3</td>
<td>5.6</td>
<td>5.9</td>
<td>3.2</td>
</tr>
<tr>
<td>Bleeding - Life Threatening</td>
<td>6.3</td>
<td>5.5</td>
<td>10.9</td>
<td>5.4</td>
<td>4.4</td>
<td>12.9</td>
</tr>
<tr>
<td>Annular Rupture</td>
<td>0.2</td>
<td>0.3</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial Infarctions</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.3</td>
<td>0.3</td>
<td>0</td>
</tr>
<tr>
<td>Coronary Obstruction</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0</td>
</tr>
<tr>
<td>Acute Kidney Injury</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
<td>1.6</td>
</tr>
<tr>
<td>New Permanent Pacemaker</td>
<td>13.0</td>
<td>13.2</td>
<td>12.0</td>
<td>10.1</td>
<td>10.4</td>
<td>7.2</td>
</tr>
<tr>
<td>Aortic Valve Re-intervention</td>
<td>1.0</td>
<td>0.8</td>
<td>2.2</td>
<td>0.7</td>
<td>0.8</td>
<td>0</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>0.2</td>
<td>0.2</td>
<td>0</td>
<td>0.1</td>
<td>0.1</td>
<td>0</td>
</tr>
</tbody>
</table>

Corroboration: TVT Data Consistent ....In the S3i TF group, the Partner 2 “BEST GROUP” = 10.4% Pacemakers - 1000 patients
TAVR: 2018 NYHA Data

Note: 30 day NYHA excludes 25% of pts with missing NYHA

These are good results
The Big Question in the U.S. Regarding TAVR: Is There a Significant Volume – Outcome Relationship??

National Policy Recommendations:
Post-MEDCAC Meeting: Analyses on Volume-Outcome Relationship in TAVR

United States Procedure Volume and Outcomes in Transcatheter Aortic Valve Replacement

Sreekanth Vemulapalli, MD,1,2 John D. Carroll, MD,3 Michael J. Mack, MD,4 David Dai, PhD,2 Zhuokai Li, PhD,2 Andrzej S. Kosinski, PhD,2,5 Dharam J. Kumbhani, MD, SM,6 Carlos Ruiz, MD,7 Vinod H. Thourani, MD,8 George Hanzel, MD,9 Thomas G. Gleason, MD,10 Howard C Herrmann, MD,11 Ralph G. Brindis, MD, MPH,12 Joseph E. Bavaria, MD13

J Am Coll Cardiol 2019;73:427–40

NEJM; 2019
United States Procedure Volume and Outcomes in Transcatheter Aortic Valve Replacement

Sreekanth Vemulapalli, MD, John D. Carroll, MD, Michael J. Mack, MD, David Dai, PhD, Zhuokai Li, PhD, Andrzej S. Kosinski, PhD, Dharam J. Kumbhani, MD, SM, Carlos Ruiz, MD, Vinod H. Thourani, MD, George Hanzel, MD, Thomas G. Gleason, MD, Howard C Herrmann, MD, Ralph G. Brindis, MD, MPH, Joseph E. Bavaria, MD

Approximately 27% Risk Reduction in high volume vs the lowest volume centers

Sensitivity Analysis Excluding 12-Month Start-up Period at Each Hospital
30 Day Composite Major Outcomes Related to Site Annual Volume

2016-2017 Complete One-Year Data from STS-ACC TVT Registry

Frequency of Major Complications %

- Major Vascular Complications
- Major Bleeding
- Mortality

P<0.001
Is the Data any **Good**?
Is it **Reliable**?
Is the Data any **Good**?

Is it **Reliable**?

10% of all sites are **AUDITED** each year per Steering Committee Resolution!
National Audit Program

Evaluates accuracy and reliability

• Assesses proper and complete reporting of cases
• Voluntary

2018 Results (Draft Results)

• Base and Follow Over Accuracy = 91.5%
• Overall Follow Up Accuracy = 90.7%
• 30 Day Follow Up Accuracy = 92.4%
TAVR Module Data Completeness

KCCQ and Follow-Up
DQR Submission Status

A “Red” status indicates the submission (one quarter/timeframe) is not included in the benchmark statistics. Data is not displayed in the quarterly column.

A “Yellow” status indicates the submission (one quarter/timeframe) is not included in the benchmark statistics. Data is displayed in the quarterly column, but is not included in the “My Hospital R4Q” summary. The data has not passed the overall completeness assessment checks.

A “Green” status indicates the submission (one quarter/timeframe) is included in the benchmark statistics. The data has successfully passed all data assessment and completeness checks.
TVT Registry Base Submissions
Green Yellow Red Status
2014-2018

2015: 91%, 9%
2016: 92%, 8%
2017: 97%, 3%
2018: 97%, 3%
2019 Q1: 98%, 2%
TVT Registry Follow Up Submissions
Green Yellow Red Status
2014-2018

[Bar chart showing percentage for each year from 2014 to 2019Q1]
TAVR - 30 Day Follow Up Completed

Some follow up assessment 21-75 days after TAVR

80% 85% 89% 90% 91% 92% 92%

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

2012 2013 2014 2015 2016 2017 2018 Q1

30-day Follow up is a Standard of Care. It is Malpractice not to know what happened to your patient at 30 days after a procedure!!

Comparison: STS Database 30-day mortality >98%
TAVR
Baseline KCCQ Completed

<table>
<thead>
<tr>
<th>Year</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>24%</td>
<td>74%</td>
<td>87%</td>
<td>90%</td>
<td>91%</td>
<td>92%</td>
<td>93%</td>
</tr>
</tbody>
</table>
Baseline and One Year KCCQ Complete

Among One Year Survivors

<table>
<thead>
<tr>
<th>Year</th>
<th>KCCQ Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>66%</td>
</tr>
<tr>
<td>2015</td>
<td>67%</td>
</tr>
<tr>
<td>2016</td>
<td>70%</td>
</tr>
<tr>
<td>2017</td>
<td>71%</td>
</tr>
</tbody>
</table>
Data Completeness Becomes Essential if Institutional and Operator Volume Requirements are Replaced with Quality Metrics

Will Updated TAVR NCD Address This Problem of Sites Not Submitting Complete and Accurate Data?
STS/ACC TVT Registry
Mortality and Morbidity
Composite Risk Model for TAVR

Nimesh D. Desai MD PhD
On behalf of the TVT Risk Modeling Subcommittee
TVT Risk Model: Global Rank Methodology

- In-Hospital or 30-day mortality
- In-Hospital or 30-day stroke
- In-hospital or 30-day VARC major or longterm/disabling bleed
- In-hospital sig creatinine increase or 30 day new dialysis (AKI III)
- In-hospital or 30-day moderate/severe peri-valvular leak (PVL)
- None of the above
STS/ACC TVT Registry “New Stuff”

What new ideas, devices, knowledge, and research are “informing” the TVT??
Collecting Data on New Techniques is Becoming Very Important for the TVT Registry

1. **Cerebral protection** using one FDA approved device: Sentinel
   - to address the not “insignificant” stroke rates despite new TAVR technology and lower risk patients

2. **Fracturing of sewing rings** of surgically implanted prosthetic valves during V-in-V treatment for degenerated bioprosthetic valves
   - To address the problem of small surgically implanted valves/ and prosthetic-patient mismatch

3. **Catheter-based electrosurgery techniques** to lacerate valve leaflets and reduce risks of obstruction from TAVR and TMVR implantation
   - **BASILICA**: Technique applied to aortic leaflets of native and bioprosthetic valves to prevent coronary obstruction
   - **LAMPOON**: technique applied to anterior leaflet of mitral valve to prevent LVOT obstruction

4. **Vascular Access** using the transcaval (IVC to aorta) technique for TAVR
TVT Registry Updates

• Embolic protection and bioprosthetic valve fracture is captured in the device table in v2 (current version)

<table>
<thead>
<tr>
<th>Device 1 Used (^{6225})</th>
<th>(Refer to Master Device List)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device 2 Used (^{6225})</td>
<td>Note: Code all valves, embolic protection, valve fracture and support devices</td>
</tr>
</tbody>
</table>
Cerebral Protection

- Stroke is a devastating complication of interventional procedures and surgery.
- The development of “cerebral protection” devices to capture the embolic debris released during these treatments is potentially a major advancement, but with an evidence-base that is “evolving”.
- The FDA approval of the first such device, Sentinel, has provided a unique opportunity for TVT Registry to gather clinical use.

Cerebral Protection and TVT Registry

- Data element added in January 2018 (Version 2).
- 3867 cases of TAVR using Sentinel performed at 82 sites have been entered into the TVT Registry.

Version 3 update will have the following data element:

```
Embolic Protection Deployed: O No  O Yes  → If Yes, EP Device: _____________ see device list
```
Bioprosthetic Valve Fracture During Valve-in-valve TAVR: Bench to Bedside

John T Saxon,1,2 Keith B Allen,1,2 David J Cohert1,2 and Adnan K Chhatriwalla1,2

1. Saint Luke’s Mid America Heart Institute, Kansas City, MO, USA; 2. University of Missouri - Kansas City, Kansas City, MO, USA

Figure 1: Technique of High-pressure Balloon Inflation to Perform Bioprosthetic Valve Fracture

(1) A high pressure stopcock connects the valvuloplasty balloon to a syringe of dilute contrast and an inflectator. (2) The syringe is used to inflate the balloon manually. (3) The stopcock is turned so that the syringe is off and the inflectator is on. (4) The inflectator is dialed to the desired pressure, until the bioprosthetic valve fractures or the balloon ruptures.

Figure 2: Fractured 21 mm Mitroflow Bioprosthetic Valve

Figure 3: A: Baseline Appearance of 23 mm Magna BFV after Deployment of 26 mm Medtronic Evolut R THV. B: Initial Balloon Inflation During BFV. C: Appearance of BFV and Balloon after BPV Ring Fracture. Note the Visible Release of the Balloon Waist and Expansion of BFV Compared to (B). D: Final Appearance after VIV TAVR and BFV
Fracturing of sewing rings of surgically implanted prosthetic valves during V-in-V treatment for degenerated bioprosthetic valves

Under-Reporting?
Efforts being made to educate site data coordinators to assess whether or not fracturing is being done.
“Transcaval Access for Transcatheter Aortic Valve Replacement in People With No Good Options for Aortic Access”

- ClinicalTrials.gov Identifier: NCT02280824
- Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
- Principal Investigator: Robert J Lederman, M.D. at NHLBI
TVT Registry v3 updates

Concomitant Procedures Performed:  
- PCI
- LAAO
- Permanent Pacer
- Mitral Valvuloplasty
- Vascular Stent
- BASILICA
- LAMPOON
- Alcohol Septal Ablation
TVT Registry v3 updates

- Transcaval access will have its own data element
TVT Registry v3 updates

• Bioprosthetic valve fracture

<table>
<thead>
<tr>
<th>Valve-in-Valve Procedure</th>
<th>O No (degenerative native valve)</th>
<th>O Yes (degenerative bioprosthetic valve)</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Yes, BVF Attempted with High Pressure Balloon Dilation</td>
<td>O No</td>
<td>O Yes</td>
</tr>
<tr>
<td>If Yes, Timing of BVF</td>
<td>□ Pre-implant □ Post-implant</td>
<td>If Yes, Valve Observed To Be Fractured</td>
</tr>
</tbody>
</table>
STS/ACC TVT Registry Research

Over 30 Manuscripts Published and 30 in preparation
Early pacer implantation is a common complication following TAVR. It is associated with a higher mortality and a composite of mortality or heart failure admission at one year.
Incidence, Predictors, and Outcomes of Prosthesis-Patient Mismatch in 62,125 TAVR Patients

An STS/ACC TVT Registry Report

Presented 2018 TCT showing worse outcomes with TAVR PPM. Severe PPM in 12% of all TAVR

Howard C. Herrmann, MD
University of Pennsylvania
Philadelphia
The Process of Updating TVT Registry Sites of These Changes in Data Collection

- Identify changes on Data Collection Form
- Announce on TVT website
- Review at every monthly webinar.
- Place a tag line on the signature for all questions coming into TVT
- Remind valve coordinators at industry meetings
- Reinforce at National NCDR and STS AQO Meetings
TAVR – C
(What does C stand for?)
As of March 1, 2019 There is Only One TAVR – C Site in US
First Canine TAVR Performed in the World at Colorado State Ft. Collins CO with UC Health Interventional Cardiologists Drs. Justin Stroke and Brad Oldemeyer assisting Dr. Brian Scansen, a Veterinarian Interventional Cardiologist. Data not entered into TVT Registry because case lacked KCCQ results.
“Science tells us what we can do; Guidelines what we should do; & Registries what we are actually doing.”

Lukas Kappenberger MD
Heart Rhythm Society Policy Conference
Washington DC 2005
Conclusions

1. The National STS/ACC TVT Registry is the largest source of TAVR (and TMV repair) information in the world. ... (FDA = “A National Treasure”)

2. The data from the TVT is used by multiple Stakeholders throughout the country

3. The TVT Registry continues to inform the world of “Real World” TAVR outcomes, not just trial data.
   1. Getting better in some areas
   2. Static in other areas

4. The TVT is now using the data to develop TAVR and TMVR risk models and Composite Outcome measures. These will be the basis for CMS suggested Public Reporting of Outcomes by institution and transparency.

5. The STS/ACC TVT is REALLY Big Data.... Mandated data entry by Law in the U.S. (100% participation)
Questions?
Mitral Repair Module of TVT Registry

MitraClip Currently Only Technology
TVT National Volumes Data:
Snapshot of U.S. Leaflet Clip Practice Patterns
Leaflet Clip
Sites and Records Submitted

Significant continued growth in Clip procedures 25-30% annually
Sites are static but 355 is a lot!
Leaflet Clip

Median LOS in Days
(25th and 75th percentiles)

Steady Improvement
Leaflet Clip Age
(25th and 75th percentiles)

Elderly, Don’t anticipate much difference with FMR approval??
Leaflet Clip
Demographics

Very steady and slightly improving each year: Actually a reasonable percentage of 80 year olds in America
Leaflet Clip Procedure Indications
Reasons for Determination of Prohibitive Risk

<table>
<thead>
<tr>
<th>Year</th>
<th>Fraility</th>
<th>Hostile Chest</th>
<th>SLD</th>
<th>Porcelain Aorta</th>
<th>Unusual Circumstances</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>49.8%</td>
<td>2.0%</td>
<td>7.6%</td>
<td></td>
<td>22.3%</td>
</tr>
<tr>
<td>2015</td>
<td>51.0%</td>
<td>3.1%</td>
<td>1.3%</td>
<td></td>
<td>59.0%</td>
</tr>
<tr>
<td>2016</td>
<td>53.1%</td>
<td>1.0%</td>
<td>1.4%</td>
<td>1.2%</td>
<td>27.7%</td>
</tr>
<tr>
<td>2017</td>
<td>55.5%</td>
<td>1.0%</td>
<td>1.2%</td>
<td>1.0%</td>
<td>30.3%</td>
</tr>
<tr>
<td>2018</td>
<td>59.0%</td>
<td>1.0%</td>
<td>1.4%</td>
<td>1.0%</td>
<td>28.0%</td>
</tr>
</tbody>
</table>

Legend:
- Blue: Fraility
- Red: Hostile Chest
- Green: SLD
- Purple: Porcelain Aorta
- Cyan: Unusual Circumstances

Source: National Cardiovascular Data Registry (NCDR)
Leaflet Clip
STS Operative Mortality Risk

Fairly High Risk for open Mitral Surgery

STS MV Repair >=6%  STS MV Replacement >= 8%

2014: 47%  2015: 45%  49%  2016: 41%  46%  2017: 39%  43%  2018: 38%  42%
Leaflet Clip
Mitral Valve Disease Etiology

“Mixed” Lesions growing: ... Changes with FMR in future

STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY
Real World Leaflet-Clip Repair
Clinical Outcomes
Leaflet Clip Mortality
In Hospital 30 Day and One Year

Interesting: No change or improvement in 30-day mortality in 5 years ...... but quite low
Leaflet Clip Stroke
In-Hospital 30 Day and One Year Stroke

Interesting: No change or improvement in 30-day stroke in 5 years ..... maybe even worsening .... But still quite low
### Leaflet Clip
#### 2018 NYHA Data

<table>
<thead>
<tr>
<th>Class</th>
<th>Baseline</th>
<th>30 Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing</td>
<td>33.1%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Class I</td>
<td>24.2%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Class II</td>
<td>29.9%</td>
<td>14.5%</td>
</tr>
<tr>
<td>Class III</td>
<td>60.4%</td>
<td>11.0%</td>
</tr>
<tr>
<td>Class IV</td>
<td>1.8%</td>
<td>22.0%</td>
</tr>
</tbody>
</table>

*Good Clinical result nationally*
Leaflet Clip Morbidity: 30 Day Outcomes


* Among non-missing follow-up
Leaflet Clip – Alive and Well*
(among 1-year survivors with complete KCCQ)

*1-Yr KCCQ $\geq$ 60 and no more than a 10 unit decrease in KCCQ score from baseline to 1 year

*Among 2,368 pts
Leaflet Clip
Baseline KCCQ Completed

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>71%</td>
</tr>
<tr>
<td>2015</td>
<td>83%</td>
</tr>
<tr>
<td>2016</td>
<td>82%</td>
</tr>
<tr>
<td>2017</td>
<td>85%</td>
</tr>
<tr>
<td>2018</td>
<td>85%</td>
</tr>
</tbody>
</table>
New Techniques, Not Investigative Devices, in Transcatheter Valve Treatment

- Physicians see first-hand problems-adverse events that arise in their patients in the trenches of clinical care.
- The spirit of innovation is alive to come-up with solutions.
- New techniques often use existing technologies on the shelves of cath labs.
- “Beneath” the radar screen of FDA approval.
- Surgeons for years have developed new surgical techniques in such a fashion.
- These new techniques have been studied using formal research proposals, listing in ClinicalTrials.gov, and with NIH funding.
- When to add them as data elements in the TVT Registry is an important issue.
- How to add them as data elements is an additional issue.
**Other TVT Registry V3 updates**

### CTA Findings

<table>
<thead>
<tr>
<th>AV Annulus Size Assessment Method</th>
<th>CTA (2D)</th>
<th>TTE</th>
<th>TEE</th>
<th>Angiography</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AV Annulus Diameter:</strong></td>
<td>Min: _____ mm</td>
<td>Max: _____ mm</td>
<td>AV Annulus Area: _____ mm²</td>
<td>AV Annulus Perimeter: _____ mm</td>
</tr>
<tr>
<td>AV Calcification:</td>
<td>None</td>
<td>Minimal</td>
<td>Moderate/Severe</td>
<td>Not documented</td>
</tr>
</tbody>
</table>

### Dobutamine Stress Test Findings

- **Dobutamine Challenge Performed**: No, Yes
- If Yes, **Flow Reserve Present**: No, Yes
- If Yes, **Aortic Stenosis Type**: Truly severe aortic stenosis, Pseudo-severe aortic stenosis, Severity not documented