TAVR in an Integrated Academic Health System: Clinical and Financial Considerations

Daniel I Simon, MD, FACC, FAHA, FSCAI
President, University Hospitals Cleveland Medical Center
Hellerstein Chair and Professor of Medicine
Case Western Reserve University School of Medicine


Seidman Cancer Center
University Hospitals

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Grant/Research Support	Medtronic Foundation
Consulting Fees/Honoraria	Medtronic, HeartFlow
Major Stock Shareholder/Equity	
Royalty Income	
Ownership/Founder	Sujana Biotech
Intellectual Property Rights	Sujana Biotech

Objectives

- Academic health system and cardiovascular service line
- Overview TAVR program (minimalist)
- Team design
- Economic considerations
- Lesson learned

Summary (1)

- $4 billion health system in NE Ohio
- 1.1 million unique patients treated annually in 15-county primary and secondary market
- 15 hospitals, 40 ambulatory centers
- ~1800 employed physicians
- ACO (5th largest in the U.S.)
- Volume, market share, and revenue/margin growth
- $180M in research funding ($97M NIH, largest clinical trial site in Ohio with 1,014 active trials)

UHACO: 5th Largest ACO in the Nation

HealthData Management

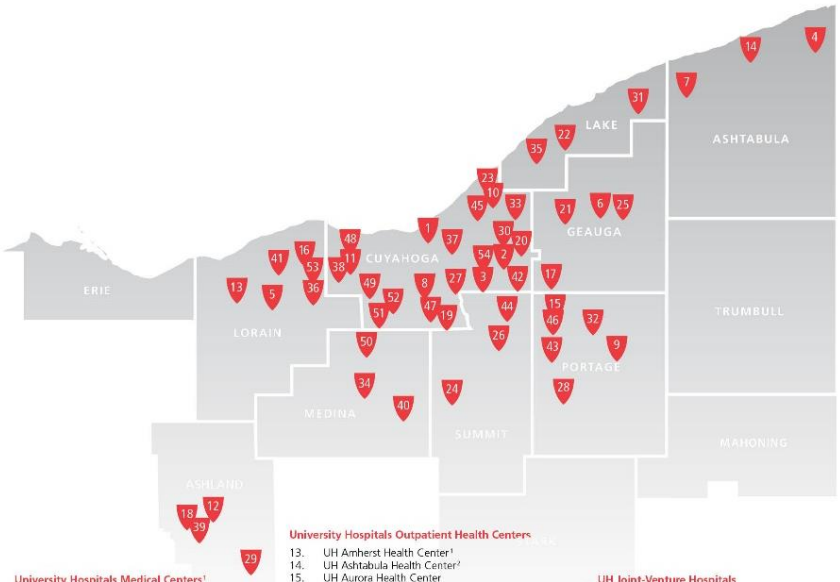
Rank	Organization	Approximate Membership	City	State
1	Banner Health Network	460,000	Phoenix	Arizona
2	Advocate Physician Partners	423,350	Downers Grove	Illinois
3	Ochsner Accountable Care Network, LLC	420,244	Jefferson	Louisiana
4	UnityPoint Health	340,000	Des Moines	Iowa
5	**University Hospitals Accountable Care Organization**	**300,800**	**Shaker Heights**	**Ohio**
6	Partners Healthcare	245,000	Needham	Massachusetts
7	MissionPoint Health Partners	233,310	Nashville	Tennessee
8	Integrated Health Network of Wisconsin	215,000	Brookfield	Wisconsin
9	MaineHealth Accountable Care Organization	178,000	Portland	Maine
10	New England Quality Care Alliance	170,000	Braintree	Massachusetts

Source: Health Data Management: "30 of Nation's Largest ACOs" http://www.healthdatamanagement.com/list/30-of-the-nations-largest-acos#slide-1

Summary (2)

- Comprehensive cardiovascular service line
- System-wide access (24 sites)
- >165 employed and independent physicians, surgeons, anesthesiologists, and radiologists
- Strong system commitment with local access to experts
- Disruptive technologies (95 active clinical trials following 3,000 patients)
- Highest quality

Local Access. Personalized Care.



University Hospitals Medical Centers[1]

1. UH Case Medical Center
   UH Rainbow Babies & Children's Hospital
   UH Seidman Cancer Center
   UH MacDonald Women's Hospital
2. UH Ahuja Medical Center
3. UH Bedford Medical Center, a campus of UH Regional Hospitals
4. UH Conneaut Medical Center[2]
5. UH Elyria Medical Center
6. UH Geauga Medical Center
7. UH Geneva Medical Center
8. UH Parma Medical Center
9. UH Portage Medical Center
10. UH Richmond Medical Center, a campus of UH Regional Hospitals
11. UH St. John Medical Center, a Catholic hospital
12. UH Samaritan Medical Center

University Hospitals Outpatient Health Centers

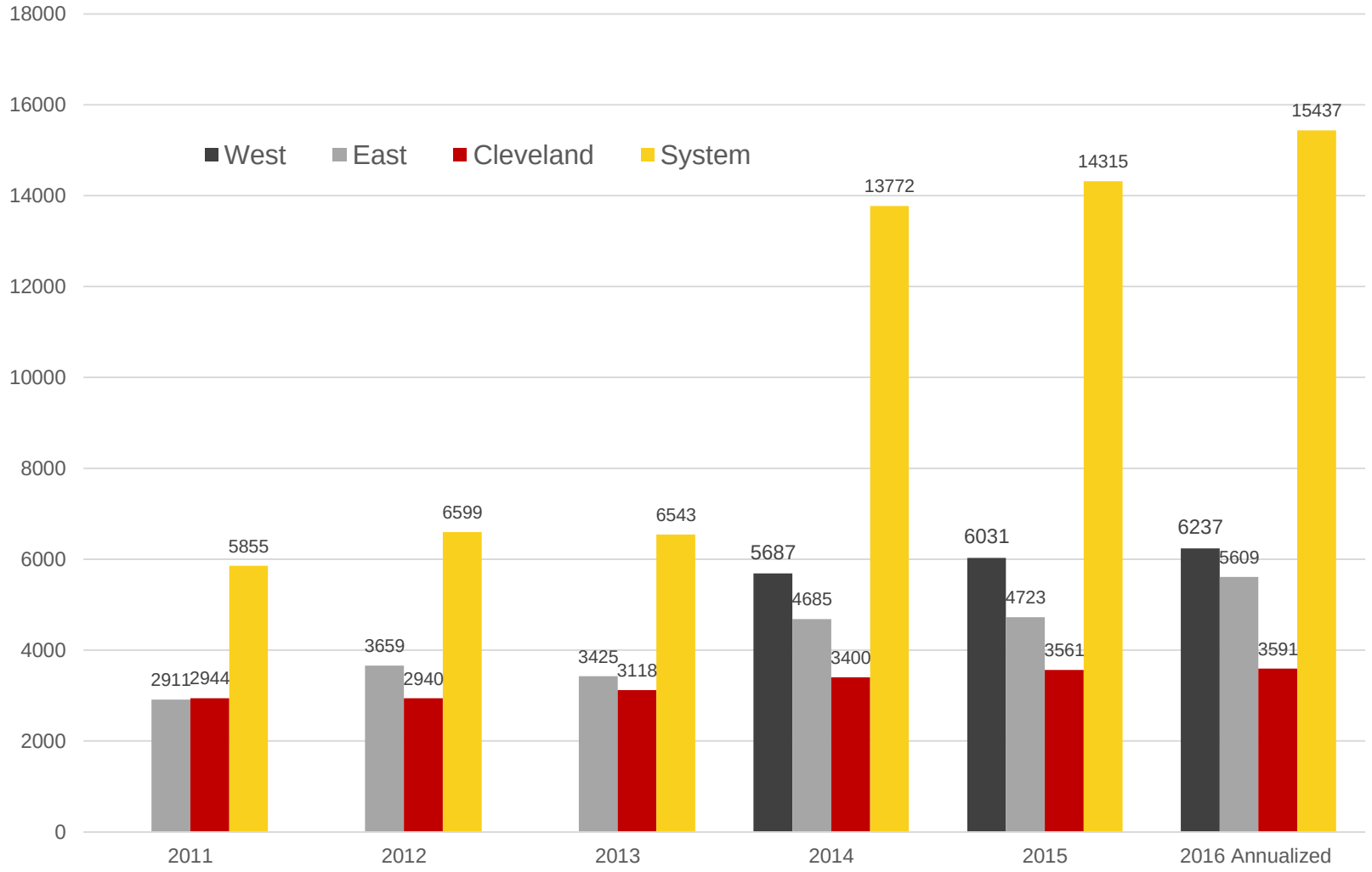
13. UH Amherst Health Center[1]
14. UH Ashtabula Health Center[2]
15. UH Aurora Health Center
16. UH Avon Health Center[1]
17. UH Bainbridge Health Center
18. UH Baney Road Health Center
19. UH Broadview Heights Health Center[1,2]
20. UH Chagrin Highlands Health Center[2]
21. UH Chesterland Health Center
22. UH Concord Health Center[2]
23. UH Euclid Health Center
24. UH Fairlawn Health Center[2]
25. UH Geauga Health Center
26. UH Hudson Health Center
27. UH Independence Health Center
28. UH Kent Health Center
29. UH Kettering Health Center
30. UH Landerbrook Health Center
31. UH Madison Health Center
32. UH Mantua Health Center
33. UH Mayfield Village Health Center
34. UH Medina Health Center[2]
35. UH Mentor Health Center[2]
36. UH North Ridgeville Health Center *(opening 2017)*
37. UH Otis Moss Jr. Health Center
38. UH St. John Health Center
39. UH Samaritan Health Center
40. UH Sharon Health Center
41. UH Sheffield Health Center
42. UH Solon Health Center
43. UH Streetsboro Health Center[2]
44. UH Twinsburg Health Center[1,2]
45. UH University Suburban Health Center
46. UH Walden Health Center
47. UH Wellpointe Health Center
48. UH Westlake Health Center[2]
49. UH Urgent Care partnering with Southwest General Brook Park[2]
50. Southwest General Brunswick Medical Center[1]
51. Southwest General Strongsville Medical Center[2]

UH Joint-Venture Hospitals

52. Southwest General Health Center[1]
53. UH Avon Rehabilitation Hospital, a Joint Venture with Kindred Healthcare
54. UH Rehabilitation Hospital, a Joint Venture with Kindred Healthcare

[1] 24-hour emergency department
[2] Urgent care center

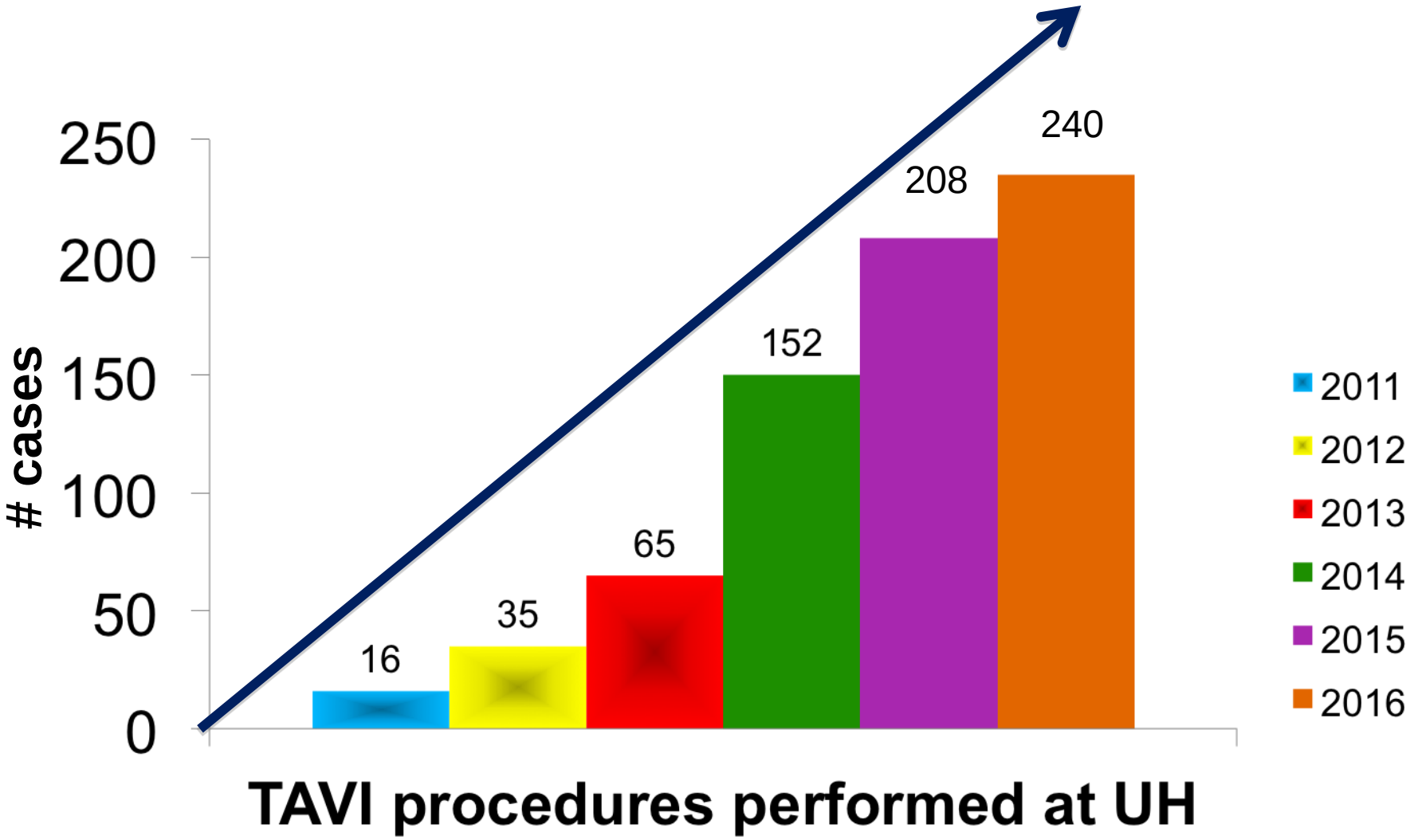
UH System Cath Lab Volume 11 hospitals, 8 PCI (2 non-SOS)



Valve & Structural Heart Disease Program

- Early experience in Porto, Portugal and U of Catania, Sicily
- 1st UH TAVR implanted March 2011
  - CoreValve U.S. Pivotal Trial
  - CoreValve Continued Access Trial
  - CoreValve Expanded Use Trial
  - CoreValve SURTAVI Trial (intermediate risk)
  - Medtronic TAVR in Low Risk Patients
- Team infrastructure grew as the clinical volume increased
- Center-of-Excellence with optimal practices/minimalist courses
- Proctored > 100 cases in USA and overseas

UH Harrington HVI TAVR Volume



UH Harrigton HVI TAVR Program

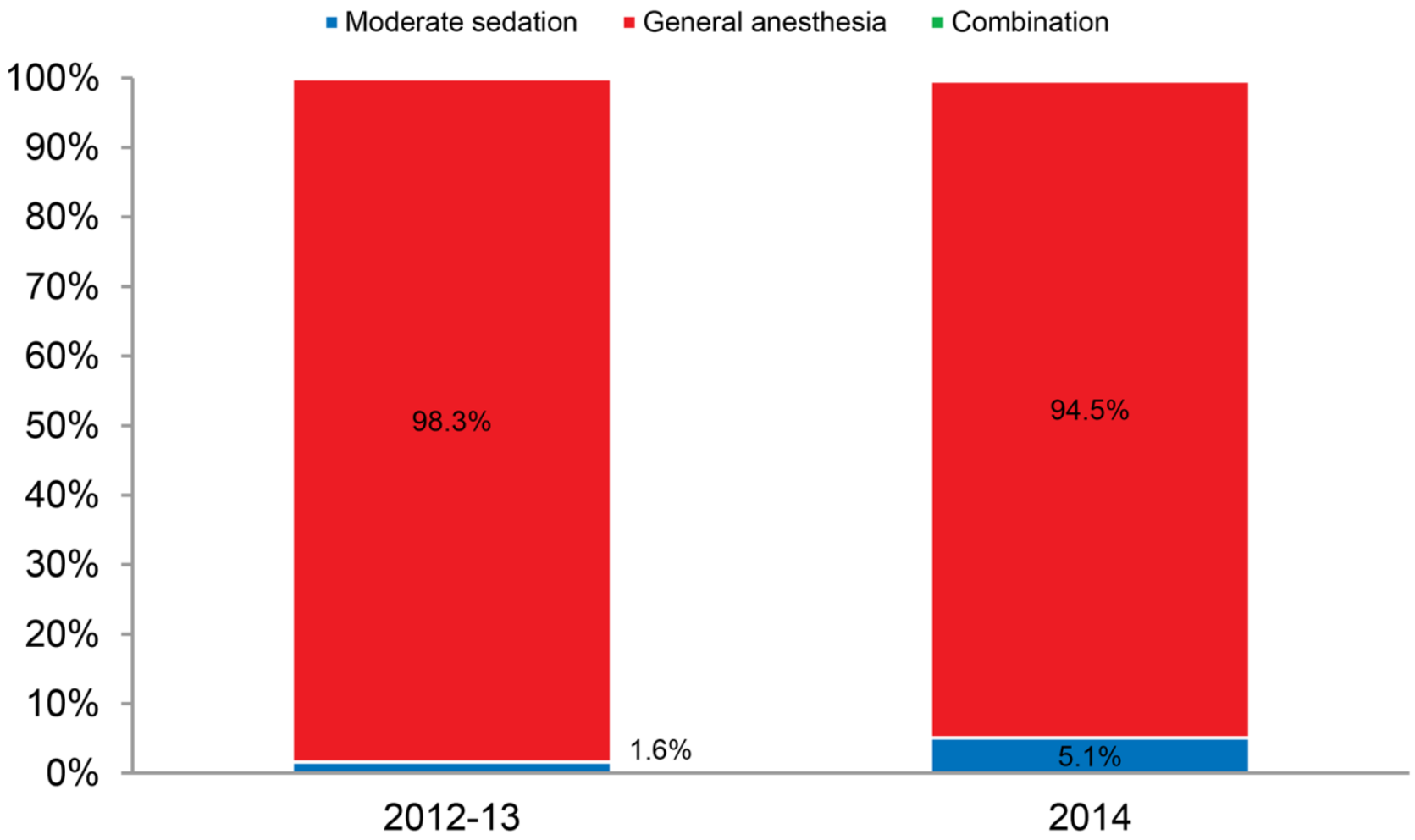
- > 700 implants performed to date.
- In 2015-2016: 95% of the procedures performed in the Cath Lab under local anesthesia and moderate conscious sedation.
- UH team is reference for optimal TAVR practices (minimalist) in the US.
  - Edwards Center-of-Excellence for minimalist approach
  - >100 proctored cases in the USA and Japan

Outcomes Following Transcatheter Aortic Valve Replacement in the United States

Michael J. Mack, MD; J. Matthew Brennan, MD, MPH; Ralph Brindis, MD, MPH; John Carroll, MD; Fred Edwards, MD; Fred Grover, MD; David Shahian, MD; E. Murat Tuzcu, MD; Eric D. Peterson, MD, MPH; John S. Rumsfeld, MD, PhD; Kathleen Hewitt, MSN; Cynthia Shewan, PhD; Joan Michaels, RN; Barb Christensen, RN; Alexander Christian; Sean O'Brien, PhD; David Holmes, MD; for the STS/ACC TVT Registry

Characteristics	Overall (n = 7710)	High Risk (n = 6151)		Inoperable (n = 1559)	
		Trans-femoral (n = 3833)	Nontrans-femoral (n = 2318)	Trans-femoral (n = 1139)	Nontrans-femoral (n = 420)
Procedure location					
Hybrid operating room	4391 (57)	2099 (55)	1515 (65)	545 (48)	232 (55)
Hybrid catheterization laboratory	2165 (28)	1124 (29)	516 (22)	410 (36)	115 (27)
Catheterization laboratory	1050 (14)	549 (14)	272 (12)	162 (14)	67 (16)
Procedure status					
Elective	6873 (89)	3401 (89)	2052 (89)	1039 (91)	391 (91)
Urgent/emergent	832 (11)	430 (11)	265 (11)	98 (9)	39 (9)
Reason for procedure					
Procedure aborted	200 (3)	147 (4)	13 (0.6)	35 (3)	5 (1)
Cardiopulmonary bypass used	315 (4)	73 (2)	183 (8)	38 (3)	21 (5)
Type of anesthesia					
General anesthesia	7565 (98)	3730 (97)	2304 (99)	1113 (98)	418 (100)
Moderate sedation	126 (2)	95 (2)	5 (0.2)	25 (2)	1 (0.2)

Anesthesia of Patients Undergoing TAVR



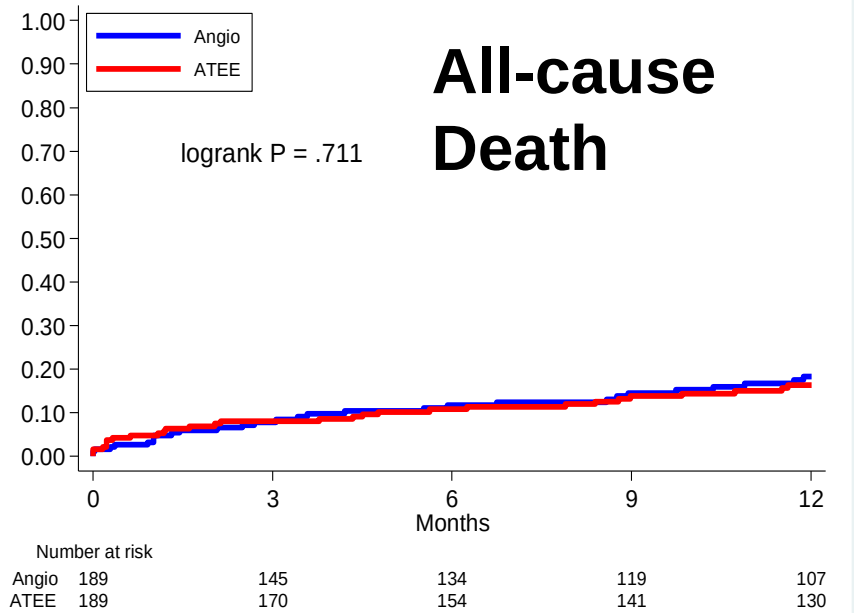
Holmes DR et al. *JAMA*. 2015;313:1019-1028

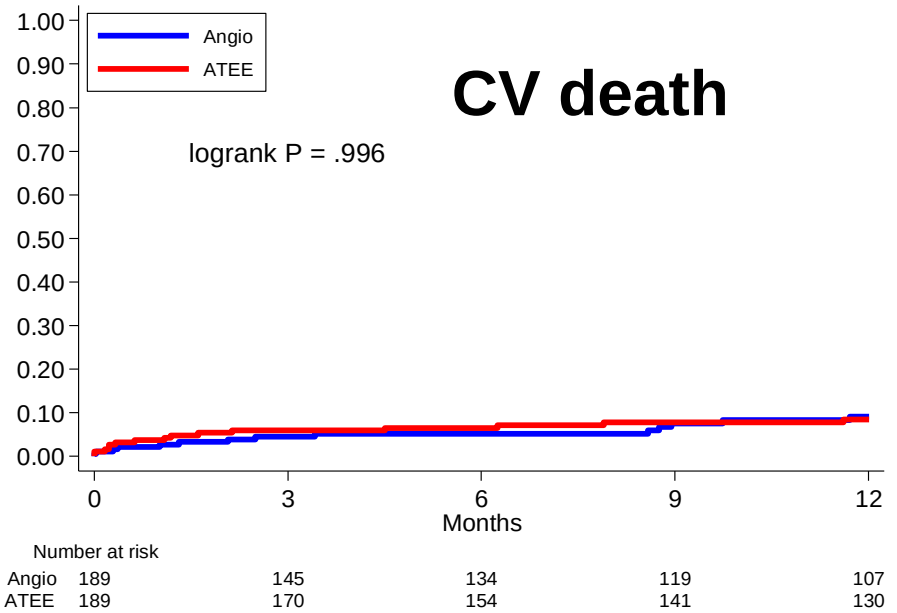
Minimalist TAVR

- "Minimized invasion" and procedural optimization
- Cath lab
- No Foley
- No Arterial Lines
- No Swan-Ganz
- No TEE
- Cath Lab RN for conscious sedation only. No Anesthesia team present in the room (only if initially decided by the heart team due to potential pre-procedural concerns ~3% of cases).

Minimally Invasive Strategy

TAVR performed under Angio + TEE vs. Angio guidance





Attizzani GF, Ohno Y, Barbanti M et al Am J Cardiol. 2015

Post-TAVR Protocol

- 4-6 hours of bed rest post-procedure
- Out of bed walking 6 hours post-procedure
- Pacemaker (IJ) removed in the cath lab if no conduction disturbances during the procedure, otherwise left in place until telemetry assessment next morning.

LOS Reduction

- **UH data**: LOS of 3.0 [2.0,5.0] vs. 6.0 [3.5,8.0] days for the MIS vs. conventional strategy (p<0.001)

Attizzani GF et al. Am J Cardiol. 2015

Characteristics	Overall (n = 7710)	High Risk (n = 6151)		Inoperable (n = 1559)	
		Trans-femoral (n = 3833)	Nontrans-femoral (n = 2318)	Trans-femoral (n = 1139)	Nontrans-femoral (n = 420)
Intensive care unit duration, median (IQR), h	46 (25-77)	34 (24-64)	54 (29-115)	37 (24-71)	55 (28-102)
Hospital duration, median (IQR), d[d]	6 (4-10)	5 (4-9)	8 (6-12)	5 (4-9)	8 (6-11)

Mack M, et al. JAMA 2013

Mortality Outcomes

- UH data: 30-day mortality 4.3% vs. 4.4% for MIS and conventional strategy, respectively (P=NS)

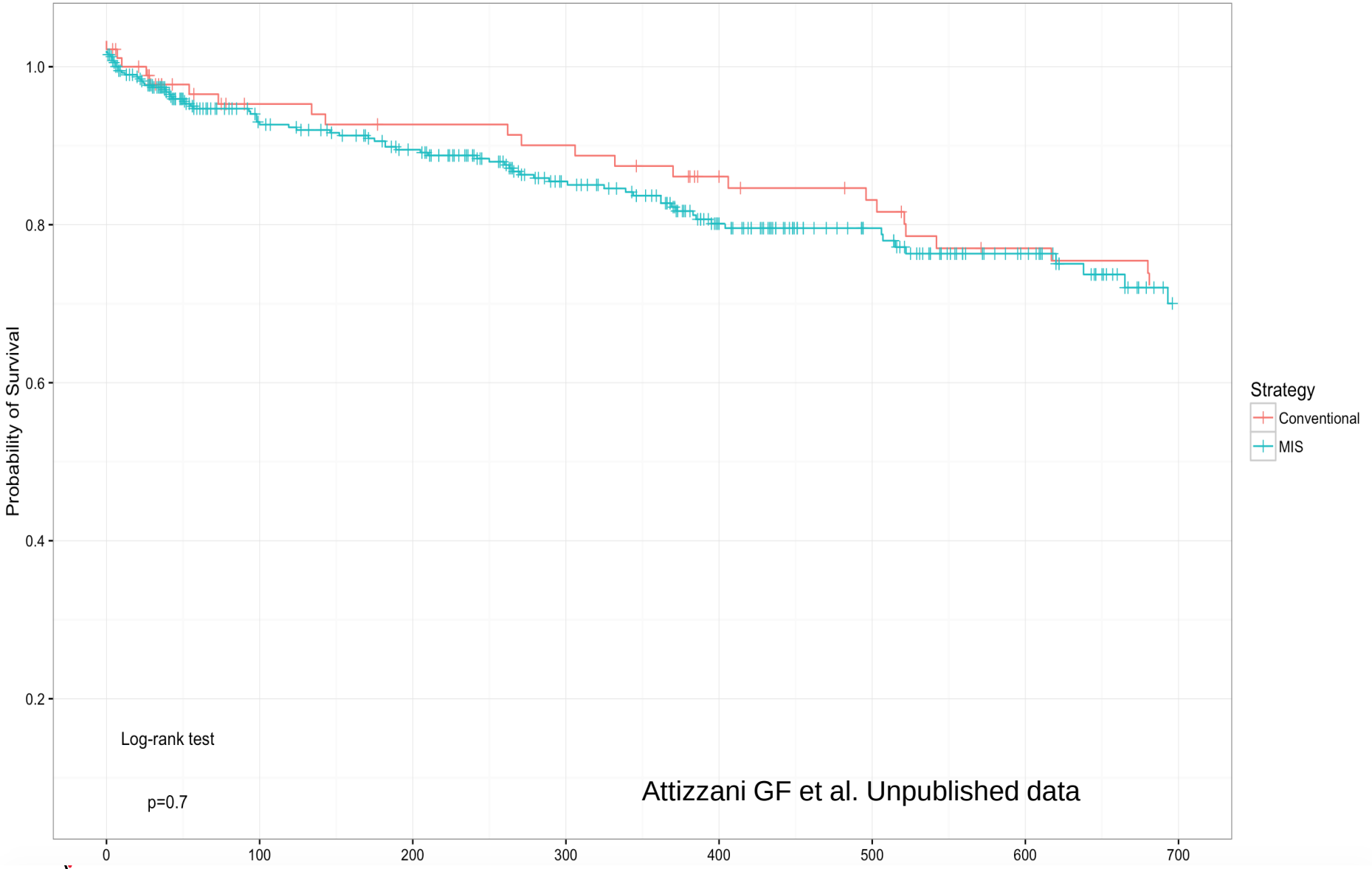
Attizzani GF et al. Am J Cardiol. 2015

Table 4. 30-Day Clinical Outcomes[a]

Outcomes	Overall (n = 3528)	High Risk (n = 2834)		Inoperable (n = 694)	
		Trans-femoral (n = 1687)	Nontrans-femoral (n = 1147)	Trans-femoral (n = 489)	Nontrans-femoral (n = 205)
Death	243 (7.6)	77 (5.0)	112 (10.8)	30 (6.7)	24 (12.6)

Mack M et al. JAMA 2013

Transfemoral cases 2011-Sep 2016



Transfemoral Cases 2011 – Sep 2016

Transfemoral Cases 2011-Sep 2016	MIS	Conventional Strategy	P
N	454	93	
Length of stay (median [IQR])	**3.00 [2.00, 5.00]**	**6.00 [4.00, 8.00]**	**< 0.001**
Intraprocedural death, n (%)	7 (1.6)	3 (3.3)	0.493
Mortality 30 days, n (%)	12 (2.6)	4 (4.3)	0.598
Stroke 30 days, n (%)	6 (1.3)	0 (0.0)	0.570
TIA 30 days, n (%)	0 (0.0)	1 (1.1)	0.379
Procedural.success, n (%)	453 (99.8)	93 (100.0)	1
Pericardial tamponade, n (%)	2 (0.4)	4 (4.3)	0.007

Attizzani GF et al. Unpublished data

Total Costs: Minimalist vs. Conventional

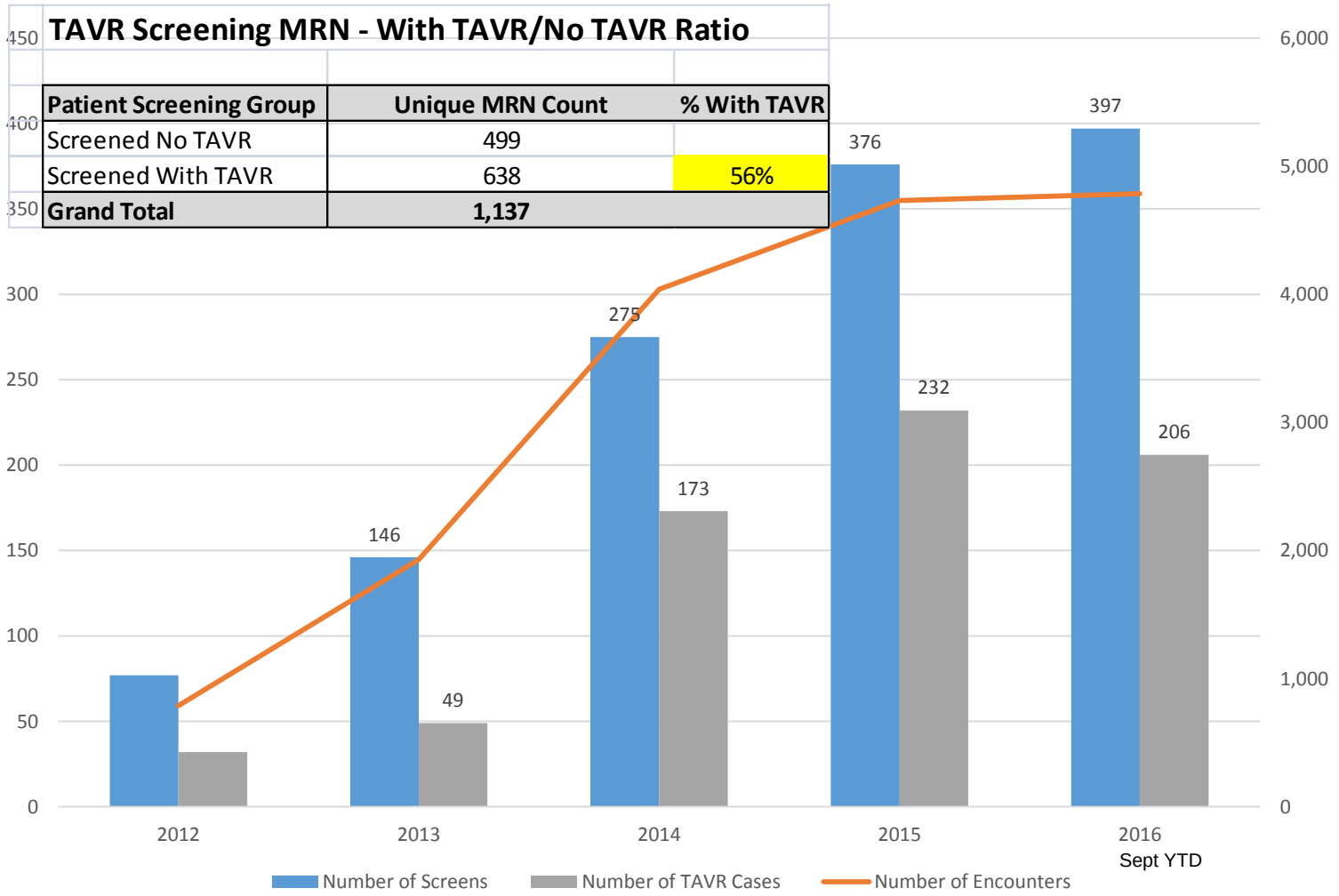
- Compared with more invasive procedures performed in the OR, MIS led to a mean **$16,000 reduction** in total costs per procedure, largely driven by reduction in LOS

Attizzani GF, et al. Am J Cardiol. 2015

TAVR Financial Analysis (1)

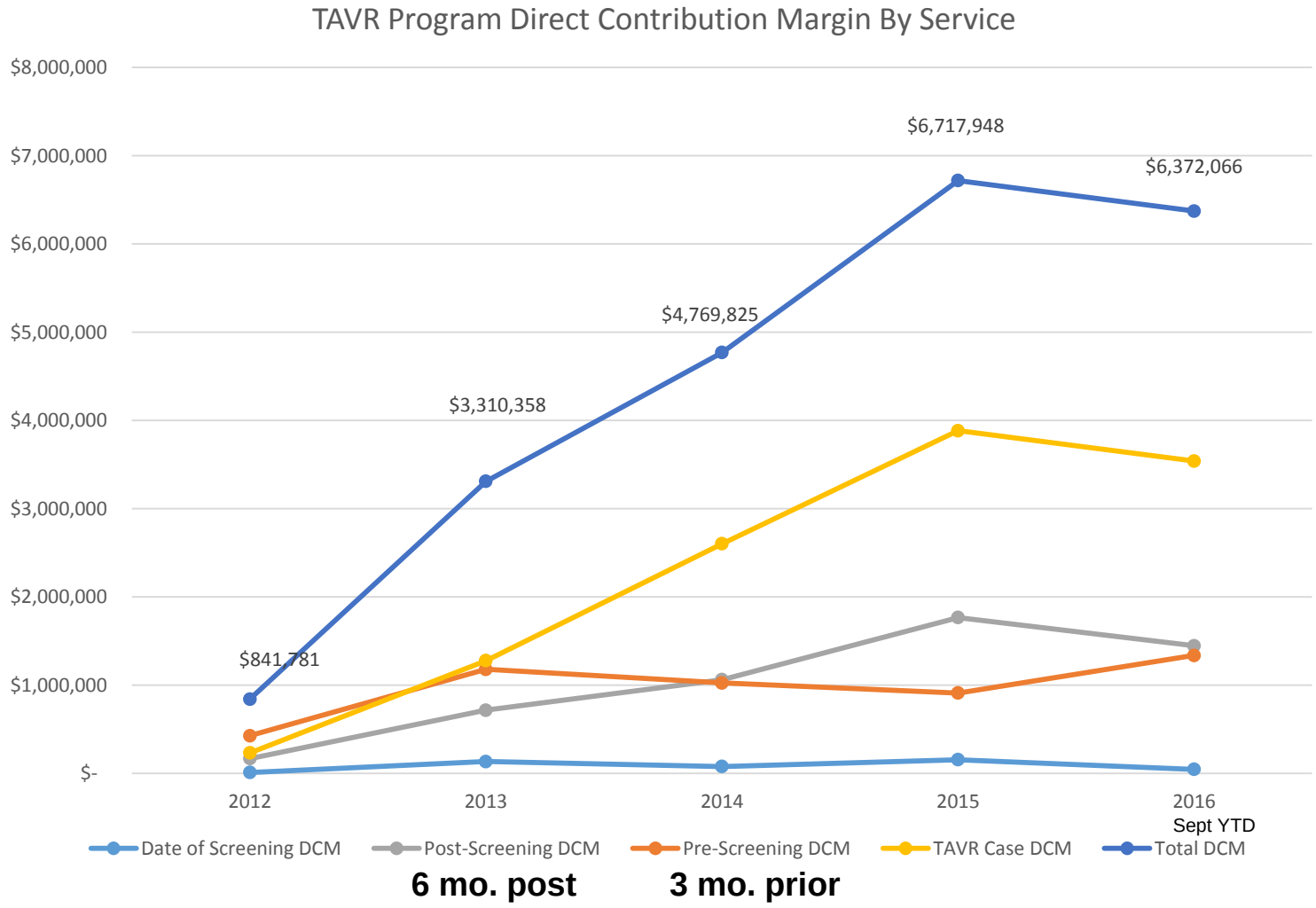
TAVR Screening MRN - With TAVR/No TAVR Ratio

Patient Screening Group	Unique MRN Count	% With TAVR
Screened No TAVR	499	
Screened With TAVR	638	56%
Grand Total	**1,137**	



TAVR Financial Analysis (2)

Direct Contribution Margin by Point of Service



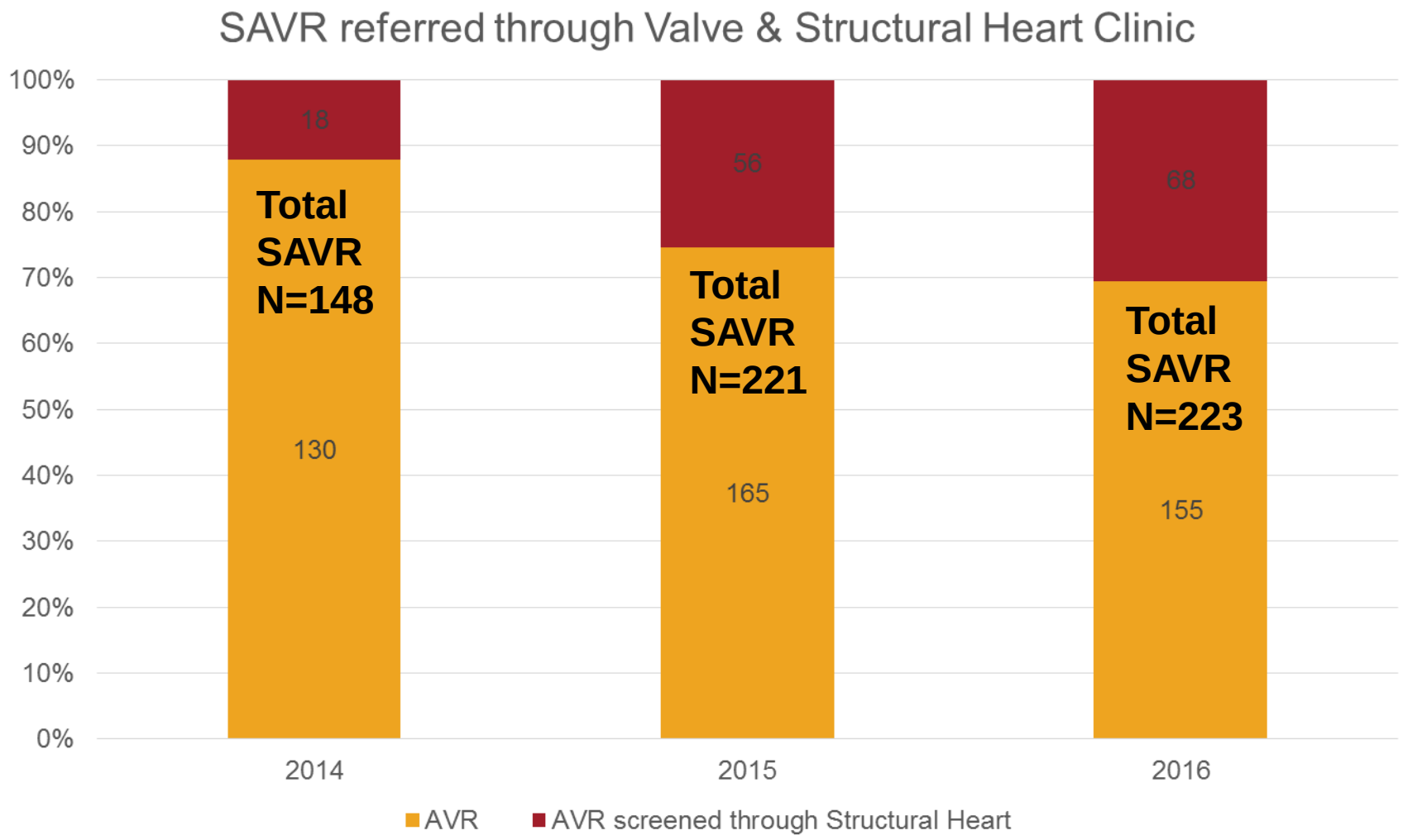
TAVR Financial Analysis (3)
Direct Contribution Margin by Point of Service

TAVR Program Consolidated Financials					
					Sept YTD
	2012	**2013**	**2014**	**2015**	**2016**
Number of Screens	77	146	275	376	397
Number of Encounters	788	1,930	4,038	4,731	4,784
Number of TAVR Cases	32	49	173	232	206
Total Volumes	**897**	**2,125**	**4,486**	**5,339**	**5,387**
Date of Screening DCM	$ 11,724	$ 134,550	$ 79,544	$ 156,435	$ 46,546
Pre-Screening DCM	$ 427,787	$ 1,179,614	$ 1,025,703	$ 911,462	$ 1,337,113
Post-Screening DCM	$ 169,489	$ 717,662	$ 1,062,281	$ 1,766,597	$ 1,447,606
TAVR Case DCM	$ 232,781	$ 1,278,532	$ 2,602,297	$ 3,883,454	$ 3,540,801
Total DCM	**$ 841,781**	**$ 3,310,358**	**$ 4,769,825**	**$ 6,717,948**	**$ 6,372,066**

3 mo. prior

6 mo. post

SAVR Impact


SAVR referred through Valve & Structural Heart Clinic
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
18
Total SAVR N=148
130
56
Total SAVR N=221
165
68
Total SAVR N=223
155
2014
2015
2016
AVR
AVR screened through Structural Heart

Building the Valve & Structural Heart Team

2011

- Interventional Cardiologist x 2
- Cardiac Surgeon
- Nurse Practitioner
- Research Nurse

- Total = 5 members

2014

- Interventional Cardiologist x 2
- Cardiac Surgeon x 3
- Advanced Fellows x 2
- Nurse Practitioner x 2
- Research Nurse
- Research Data Specialist
- Program Scheduling Coordinator
- Nurse Manager

- Total = 13 members

2016

- Interventional Cardiologist x 2.5
- Cardiac Surgeon x 3
- Advanced Fellows x 2
- Nurse Practitioner x 3
- Research Nurse Hybrid / Assistant Nurse Manager
- Research Data Specialist
- Program Scheduling Coordinator
- Nursing Director Hybrid / Research Director

- Total = 16 members

The Valve & Structural Heart Clinic Experience

Monday	Tuesday	Wednesday	Thursday	Friday
Valve Clinic 4-8 New Patients **Procedure Day** **1 case**	**Procedure Day** 2 cases	**Procedure Day** 2 cases	Valve Clinic/ **Procedure Day** 2 cases 4 New Patients 6 Post - TAVR	Valve Clinic 4-8 New Patients 6-8 Post – TAVR ***Procedure Day (inpatient?)***

***** We do TAVR Procedures EVERY day of the week *****

We have moved away from the “TAVR Tuesday” model

Referral-to-Procedure Time

- Patients are evaluated within 7-10 days of initial intake

- Patients are treated within 3 weeks of initial evaluation

- Patients are admitted into the hospital day of procedure

- Average length of stay = 2.7 days (some patients sent home next day)

~ 4.5 weeks from initial visit to discharge

Patient experience and expectations

- **Appointments**
  - 3 to 4 appointments (including TAVR procedure day)

- **Testing**
  - Coordination of testing and consult visits to optimize/reduce visits
  - Dedicated TAVR testing schedules in echo, CT, and cath lab
  - Encourage local testing

- **Communication**
  - Structural Heart Welcome Packet
  - Structural Heart Team Line / Pager

Post-procedure expectations

- **Hospital stay**
  - Development of post-care clinical care-path to promote early mobilization and discharge
  - Engaging CICU and unit floor
  - Continuing to evaluate every patient's unique needs

- **Follow up**
  - Setting expectation to discharge home
  - Follow up 48hr post-discharge phone call and 1 week clinic visit
  - TVT follow up 30 days, 1 year

Referral Physician Network

- ***Communication, Communication, Communication***
- Participate in heart team meetings
- Community screening valve clinics (Ahuja Medical Center, Elyria Medical Center)
- Physician outreach by the structural heart team in the community

Lessons Learned

- Adopt best practices. Seek OUS models of care.
- Team building is a continuous process: Evaluate your programs needs annually.
- The ***"Team"*** is not only the Structural Heart Team. As the volume increases, impact on other touch points surfaces as well as ability to provide timely treatment.
- Constant program evaluation: Review your clinical outcomes, TVT, and M&M review.
- Senior leadership engagement: Program support and alignment of Institute goals. Financial analysis should be performed annually.