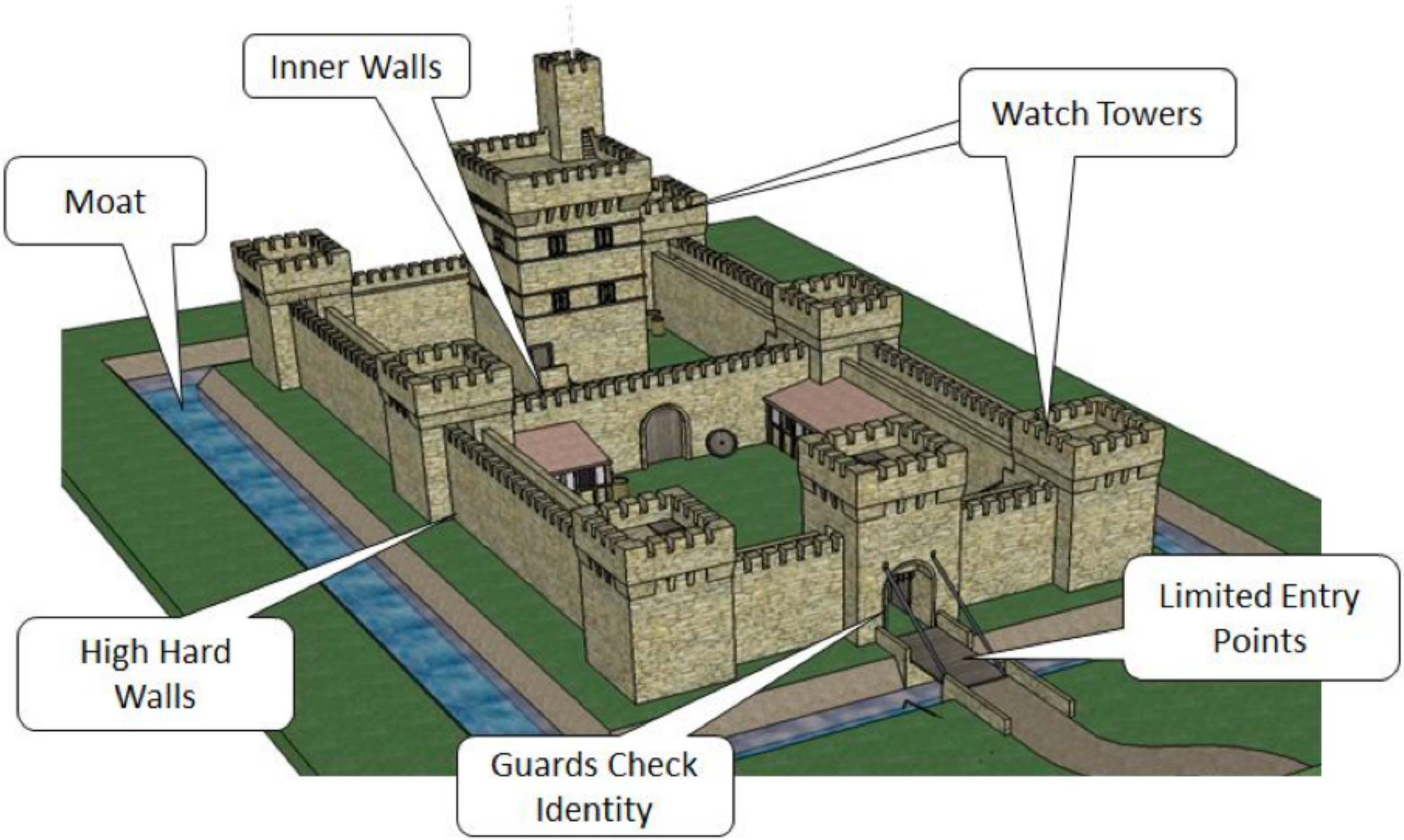
TAVI FOR LOW RISK PATIENTS

Is it a business for the cardiac surgeon?

Augusto D'Onofrio

Gino Gerosa

Department of Cardiac, Thoracic and Vascular Sciences, University of Padua, Italy


Inner Walls
Watch Towers
Moat
High Hard Walls
Limited Entry Points
Guards Check Identity

One-year outcomes of patients with severe aortic stenosis and an STS PROM of less than three percent in the SURTAVI trial

Patrick W. Serruys[1]*, MD, PhD; Rodrigo Modolo[2], MD; Michael Reardon[3], MD, PhD; Yosuke Miyazaki[4], MD, PhD; Stephan Windecker[5], MD, PhD; Jeffrey Popma[6], MD, PhD; Yanping Chang[7], MS; Neal S. Kleiman[3], MD; Scott Lilly[8], MD, PhD; Hafid Amrane[9], MD, PhD; Piet W. Boonstra[9], MD, PhD; Arie Pieter Kappetein[7], MD, PhD; Yoshinobu Onuma[4,10], MD, PhD; Lars Søndergaard[11], MD, PhD; Nicolas van Mieghem[4], MD, PhD

1. International Centre for Circulatory Health, NHLI, Imperial College London, London, United Kingdom; 2. Department of Cardiology, Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands; 3. Houston Methodist DeBakey Heart and Vascular Center, Houston, TX, USA; 4. Thoraxcenter, Erasmus Medical Center, Rotterdam, the Netherlands; 5. University Hospital Foundation, Bern, Switzerland; 6. Beth Israel Deaconess Medical Center, Boston, MA, USA; 7. Medtronic, Minneapolis, MN, USA; 8. Department of Cardiology, Ohio State University Wexner Medical Center, Columbus, OH, USA; 9. Department of Cardiothoracic Surgery, Medisch Centrum Leeuwarden, Leeuwarden, the Netherlands; 10. Cardialysis Clinical Trials Management and Core Laboratories, Rotterdam, the Netherlands; 11. The Heart Center, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark

	STS <3%				
	TAVI		SAVR		
	# Subjects (# Events)	K-M rate (%)	# Subjects (# Events)	K-M rate (%)	*p*-value
Number of subjects	131		123		
All-cause mortality or disabling stroke	2 (2)	1.5%	8 (9)	6.5%	0.0421

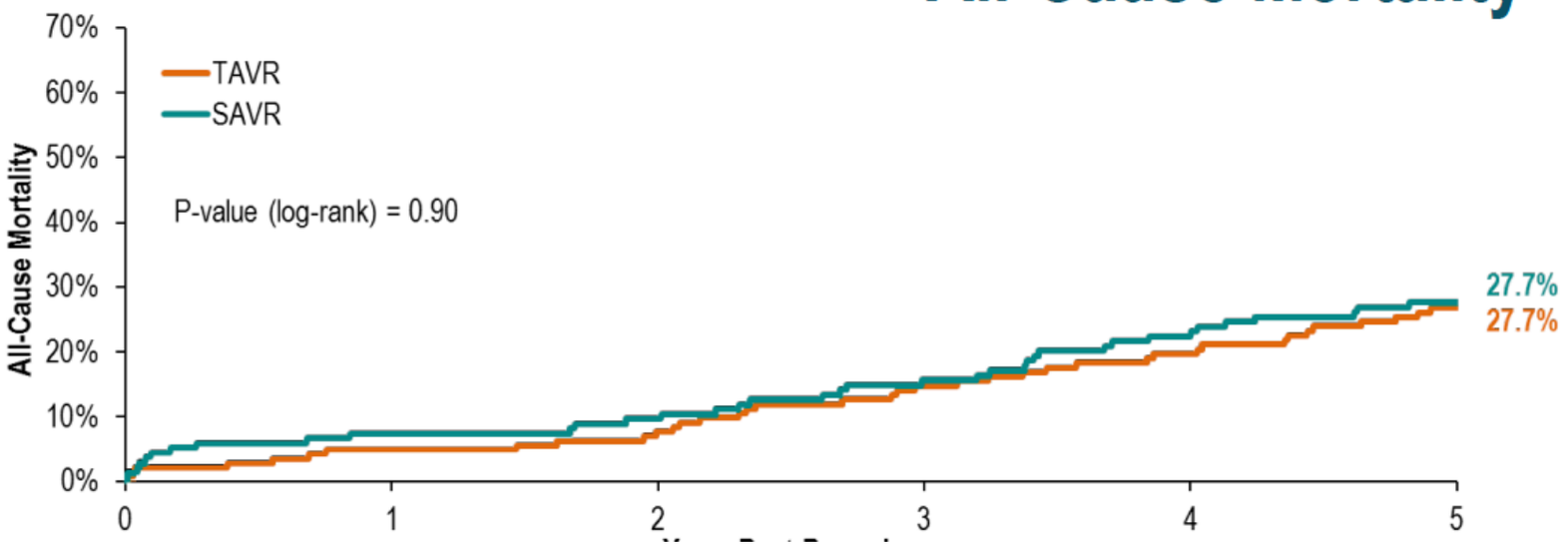
Five-Year Outcomes From the All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial in Patients with Severe Aortic Valve Stenosis

H. Gustav Hørsted Thyregod, MD, PhD
Department of Cardiothoracic Surgery
Copenhagen University Hospital, Denmark

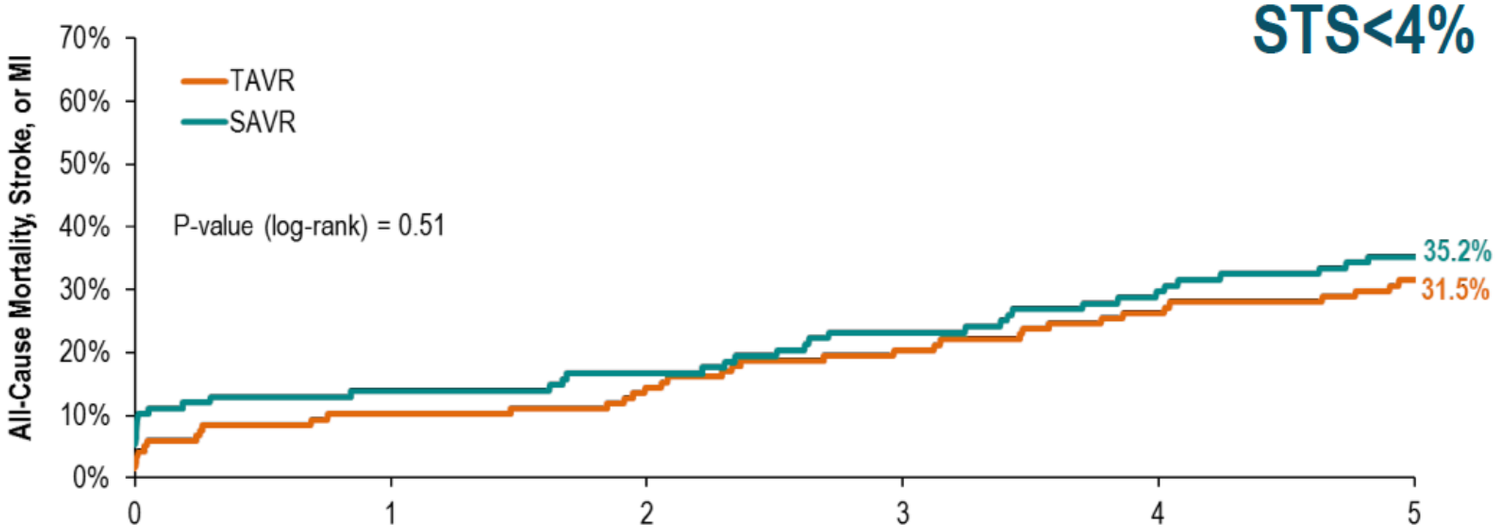
On behalf of the NOTION Investigators

ACC.18

All-Cause Mortality



All-Cause Mortality, Stroke, or MI: STS<4%




I STARTED A
NEW EXERCISE
ROUTINE
EVERY DAY I DO
TAVI

Cardiac surgery evolution

- Beating heart commissurotomy → Cardiac Surgeon
- Conventional AVR → Cardiac Surgeon
- Minimally invasive AVR → Cardiac Surgeon
- Sutureless/Rapid deployment AVR → Cardiac Surgeon
- Valve repair → Cardiac Surgeon
- **TAVI** → **?**

Update del documento di posizione della Società Italiana di Cardiologia Interventistica (SICI-GISE) sui requisiti minimi per ospedali ed operatori che eseguono procedure di impianto transcatetere di protesi valvolare aortica

GIORNALE ITALIANO DI CARDIOLOGIA
Organo Ufficiale di
Italian Federation of Cardiology
Società Italiana di Chirurgia Cardiaca

G ITAL CARDIOL | VOL 19 | SETTEMBRE 2018

REQUISITI DELL'OPERATORE E DELLA STRUTTURA

Per svolgere il ruolo di primo operatore (team leader) di TAVI transfemorale o transucclavia occorrono i seguenti requisiti[1,32,33]:

1. Essere primo operatore da almeno 5 anni nell'esecuzione di coronarografie, PCI, cateterismi cardiaci e impianto di pacemaker temporanei.
2. Eseguire più di 75 procedure di PCI/anno (in un centro con un numero totale di oltre 400 PCI/anno). Inoltre, l'operatore deve essere in grado di eseguire procedure diagnostiche e interventistiche attraverso l'accesso radiale e femorale e utilizzare dispositivi di recupero endovascolare.
3. Aver eseguito come primo operatore:
   - valvuloplastiche aortiche,
   - pericardiocentesi (elettive o in urgenza).
4. Avere esperienza nella risoluzione di complicanze periferiche.

=

EMODINAMISTA

Clinical Outcomes After Transcatheter Aortic Valve Replacement Using Valve Academic Research Consortium Definitions

A Weighted Meta-Analysis of 3,519 Patients From 16 Studies

Philippe Généreux, MD,*† Stuart J. Head, MSc,‡ Nicolas M. Van Mieghem, MD,§ Susheel Kodali, MD,* Ajay J. Kirtane, MD, SM,* Ke Xu, PhD,* Craig Smith, MD,* Patrick W. Serruys, MD, PhD,§ A. Pieter Kappetein, MD, PhD,‡ Martin B. Leon, MD*

New York, New York; Montréal, Québec, Canada; and Rotterdam, the Netherlands

Table 4 VARC: Prosthesis-Related Complications

Outcomes	Reported Rate, Min, Max, %
Failure to deliver or implantation of the valve in the correct position	0.8, 5.6
Multiple valve implanted	0.6, 4.1
AVA ≤1.2 cm^2	0.0, 9.7
Mean gradient >20 mm Hg	0.0, 2.9
Moderate to severe AR	0.0, 30.0
Valve embolization	0.0, 5.6
Valve in valve	0.0, 9.0
Conversion to open surgery	0.0, 5.6
Repeat procedure for valve dysfunction	0.0, 4.1
Unplanned CPB	0.0, 1.9
Coronary obstruction	0.0, 3.0
LV perforation	0.2, 0.8
Tamponade	0.6, 4.6
Annulus rupture	0.3, 0.8
Aortic rupture	0.8, 1.0
Aortic dissection	0.9, 1.7
Endocarditis	0.3, 1.1
Valve thrombosis	0.0, 2.7
LVOT rupture	0.6
VSD	0.6

Why…?

- Does the cardiac surgeon performing TF-TAVI need to be able to perform emergency PCI and treat peripheral complications using catheters

BUT

- The interventional cardiologist performing TF-TAVI doesn’t need to be able to establish emergency CPB and perform (at least) median sternotomy?

Update del documento di posizione della Società Italiana di Cardiologia Interventistica (SICI-GISE) sui requisiti minimi per ospedali ed operatori che eseguono procedure di impianto transcatetere di protesi valvolare aortica

GIORNALE ITALIANO DI CARDIOLOGIA
Organo Ufficiale di
Italian Federation of Cardiology
Società Italiana di Chirurgia Cardiaca

G ITAL CARDIOL | VOL 19 | SETTEMBRE 2018

REQUISITI DELL'OPERATORE E DELLA STRUTTURA

Per svolgere il ruolo di primo operatore (team leader) di TAVI transfemorale o transucclavia occorrono i seguenti requisiti[1,32,33]:

1. Essere primo operatore da almeno 5 anni nell'esecuzione di coronarografie, PCI, cateterismi cardiaci e impianto di pacemaker temporanei.
2. Eseguire più di 75 procedure di PCI/anno (in un centro con un numero totale di oltre 400 PCI/anno). Inoltre, l'operatore deve essere in grado di eseguire procedure diagnostiche e interventistiche attraverso l'accesso radiale e femorale e utilizzare dispositivi di recupero endovascolare.
3. Aver eseguito come primo operatore:
   – valvuloplastiche aortiche,
   – pericardiocentesi (elettive o in urgenza).
4. Avere esperienza nella risoluzione di complicanze periferiche.

ACC CLINICAL DOCUMENT

2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults With Aortic Stenosis

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. 69, NO. 10, 2017

ISSN 0735-1097/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jacc.2016.12.006

5.3.1.5. Anticipated Complication Management

The roles and responsibilities of each individual person during the TAVR procedure should be clearly defined. The team leader is usually an interventional cardiologist for transfemoral TAVR procedures, whereas a cardiothoracic surgeon usually is team leader for transapical and transaortic procedures or if a subclavian approach is required.

MULTISOCIETY EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT

2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement

A Joint Report of the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons

One of the cornerstones of the success of transcatheter valve programs is partnering between cardiologists and cardiac surgeons, the underlying principle being that no one individual, group, or specialty possesses all the necessary skills for optimal patient outcomes (13,17). The success of these programs depends on a group of professionals, each with their own skillset, working together to provide the best possible patient-centered care (13,18).

. For the purpose of this document, the term "TAVR proceduralist" refers to either interventional cardiologists or cardiac surgeons. These clinicians should possess extensive knowledge of valvular heart disease (VHD), including the natural history of the disease, hemodynamics, appropriate diagnostics and imaging, optimal medical therapy (particularly of comorbidities), application and outcome for both TAVR and SAVR, procedural and perioperative care, and long-term follow-up (21).

MULTISOCIETY EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT

2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement

A Joint Report of the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons

Table 4: Requirements for New TAVR Programs
2018 Criteria

The proposed TAVR proceduralist for a new TAVR program should document the following:

- Prior TAVR experience with participation in 100 transfemoral TAVRs lifetime, including 50 TAVRs as primary operator
- Being board eligible or certified in either interventional cardiology or cardiothoracic surgery
- Certification of device-specific training on device(s) to be used.

Table 5: Requirements for Continued Certification for Existing TAVR Programs
2018 Criteria

Optimal program characteristics include documentation of multidisciplinary approach and patient access to all forms of therapy for aortic valve disease (TAVR, SAVR, and medical therapy) using an SDM process.

- For all patients with aortic stenosis meeting criteria for valve replacement, there should be documentation of the following:
  - An evaluation completed by both a cardiac surgeon and cardiologist with knowledge and experience in both TAVR and SAVR;
  - Education of patients regarding the treatment recommendations and options;
  - The use of an SDM process incorporating patient preference.
- For patients undergoing TAVR, there should be documentation of an evaluation by 1 surgeon involved in the TAVR program.
  - For this requirement to meet CMS coverage criteria, the NCD recommendation of evaluation by 2 surgeons for all patients having TAVR should be updated.

MULTISOCIETY EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT

2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement

A Joint Report of the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons

The MDT should be codirected by an interventional cardiologist and a cardiac surgeon, both of whom are responsible for meeting programmatic quality metrics and credentialing as outlined in Tables 1, 2, and 4. The MDT, however, goes well beyond this

The field of percutaneous repair of cardiac structural abnormalities has advanced rapidly in the last decade. Training for TAVR should occur by 1 of 2 pathways: 1) a formal training program incorporated into cardiology fellowship or cardiovascular surgical residency or 2) formal proctorship wherein an established interventional cardiologist or cardiac surgeon participates in an established TAVR program under the tutelage of an experienced team.

MULTISOCIETY EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT

2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement

A Joint Report of the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons

Surgeons 7/16

WRITING COMMITTEE

Joseph E. Bavaria, MD, FACC, FACS§ *Co-chair*

Carl L. Tommaso, MD, FACC, MSCAI‡ *Co-chair*

Ralph G. Brindis, MD, MPH, MACC, FSCAI†

John D. Carroll, MD, FACC, MSCAI†

G. Michael Deeb, MD, FACC, FACS*

Ted E. Feldman, MD, FACC, MSCAI‡

Thomas G. Gleason, MD, MS, FACC, FACS§

Eric M. Horlick, MD, FSCAI‡

Clifford J. Kavinsky, MD, PhD, FACC, MSCAI‡

Dharam J. Kumbhani, MD, SM, FACC, FSCAI†

D. Craig Miller, MD, FACC, FACS*

A. Allen Seals, MD, FACC†

David M. Shahian, MD, FACC, FACS§

Richard J. Shemin, MD, FACC, FACS§

Thoralf M. Sundt, III, MD, FACC, FACS*

Vinod H. Thourani, MD, FACC, FACS§

ACC CLINICAL DOCUMENT

2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults With Aortic Stenosis

A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents

Writing Committee

Catherine M. Otto, MD, FACC, *Co-Chair*
Dharam J. Kumbhani, MD, SM, FACC, *Co-Chair*
Karen P. Alexander, MD, FACC
John H. Calhoon, MD, FACC
Milind Y. Desai, MD, FACC
Sanjay Kaul, MD, FACC
James C. Lee, MD
Carlos E. Ruiz, MD, PhD, FACC
Christina M. Vassileva, MD, FACC

Task Force on Clinical Expert Consensus Documents

James L. Januzzi, Jr, MD, FACC, *Chair*
Luis C. Afonso, MBBS, FACC
Brendan M. Everett, MD, FACC
Jonathan Halperin, MD, FACC
Adrian Hernandez, MD, FACC
William Hucker, MD, PhD
Hani Jneid, MD, FACC
Dharam J. Kumbhani, MD, SM, FACC
Eva M. Lonn, MD, FACC
Joseph Marine, MD, FACC
James K. Min, MD, FACC
Pamela B. Morris, MD, FACC
Robert Piana, MD, FACC
John Puskas, MD, FACC
Karol E. Watson, MD, FACC
Barbara S. Wiggins, PharmD, AACC

Surgeons 3/25

Update del documento di posizione della Società Italiana di Cardiologia Interventistica (SICI-GISE) sui requisiti minimi per ospedali ed operatori che eseguono procedure di impianto transcatetere di protesi valvolare aortica

Giuseppe Tarantini, Giovanni Esposito, Giuseppe Musumeci, Chiara Fraccaro, Anna Franzone, Battistina Castiglioni, Alessio La Manna, Ugo Limbruno, Alfredo Marchese, Ciro Mauro, Stefano Rigattieri, Fabio Tarantino, Caterina Gandolfo, Gennaro Santoro, Roberto Violini, Flavio Airoldi, Remo Albiero, Manrico Balbi, Giorgio Baralis, Antonio Luca Bartorelli, Francesco Bedogni, Alberto Benassi, Andrea Berni, Giulio Bonzani, Alessandro Santo Bortone, Giuseppe Braito, Carlo Briguori, Elvis Brscic, Paolo Calabrò, Ivan Calchera, Maurizio Cappelli Bigazzi, Francesco Caprioglio, Fausto Castriota, Carlo Cernetti, Cinzia Cicala, Paolo Cioffi, Antonio Colombo, Virgilio Colombo, Gaetano Contegiacomo, Alberto Cremonesi, Maurizio D'Amico, Mauro De Benedictis, Alessandro De Leo, Maurizio Di Biasi, Domenico Di Girolamo, Emilio Di Lorenzo, Carlo Di Mario, Marcello Dominici, Federica Ettori, Maurizio Ferrario, Massimo Fioranelli, Dionigi Fischetti, Gabriele Gabrielli, Arturo Giordano, Pietro Giudice, Cesare Greco, Ciro Indolfi, Ornella Leonzi, Corrado Lettieri, Bruno Loi, Nicola Maddestra, Niccolò Marchionni, Cinzia Marrozzini, Massimo Medda, Bindo Missiroli, Luigi My, Jacopo Andrea Oreglia, Cataldo Palmieri, Paolo Pantaleo, Saro Roberto Paparoni, Guido Parodi, Anna Sonia Petronio, Luigi Piatti, Emanuela Piccaluga, Carlo Pierli, Andrea Perkan, Antonino Pitì, Arnaldo Poli, Angelo Bruno Ramondo, Maurizio Alessandro Reale, Bernhard Reimers, Flavio Luciano Ribichini, Roberta Rosso, Salvatore Saccà, Cosimo Sacra, Andrea Santarelli, Gennaro Sardella, Gaetano Satullo, Filippo Scalise, Massimo Siviglia, Leonardo Spedicato, Amerigo Stabile, Corrado Tamburino, Tullio Nicola Maria Tesorio, Salvatore Tolaro, Fabrizio Tomai, Carlo Trani, Renato Valenti, Orazio Valsecchi, Giuseppe Valva, Ferdinando Varbella, Carlo Vigna, Luigi Vignali, Sergio Berti

Surgeons 0/104

… e l'HEART TEAM???

American Board of Thoracic Surgery
Operative Case Index Requirements

For 5/2 or 5/3 residents starting thoracic training on or after July 1, 2017
For I-6 residents starting PGY 5 on or after July 1, 2017
For 4/3 residents starting thoracic training on or after July 1, 2017

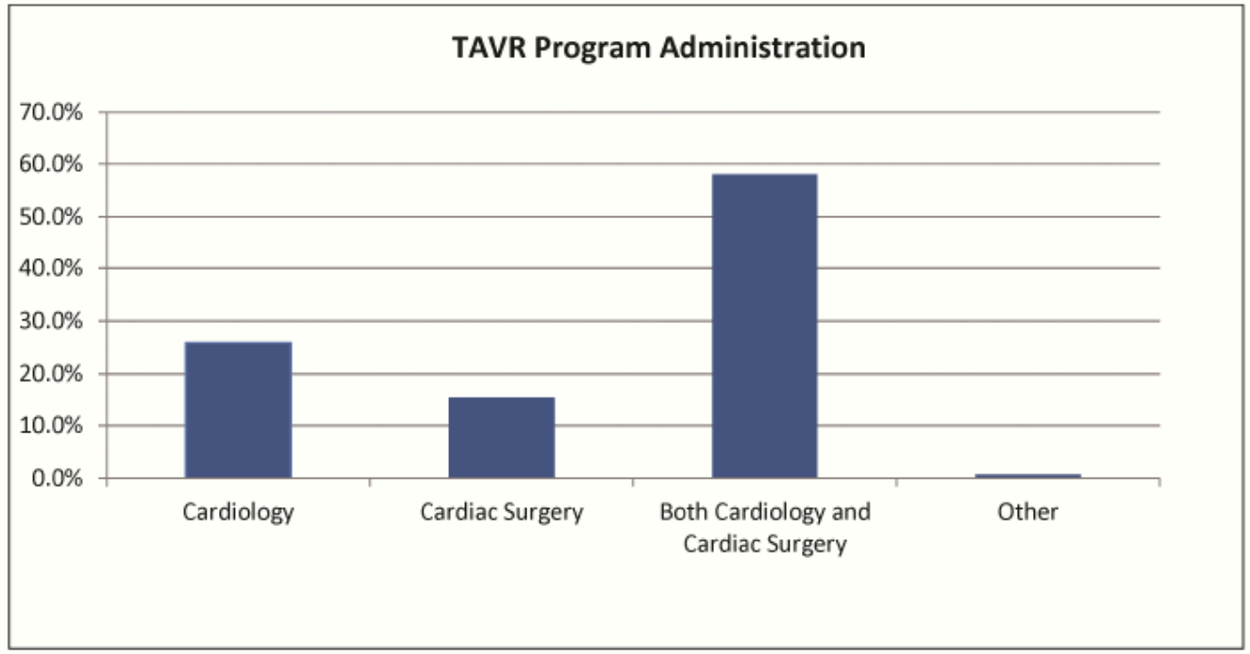
Cardiac Focused Total	Cardiac Focused Subtotal	Requirements	General Thoracic Focused Subtotal	General Thoracic Focused Total
		CONGENITAL HEART DISEASE		
	5	Primary surgeon		
	15	First assistant	10	
20		**Subtotal Congenital Heart Disease**		**10**
		ADULT CARDIAC		
60		**Acquired Valvular Heart Disease**		30
	25	Aortic Valve Repair/Replacement	15	
	15	Mitral Valve Repair/ Replacement	5	
	5	Tricuspid Valve Repair/Replacement, Annuloplasty	5	
	5	TAVR as primary		
	10	TAVR as assistant	5	
80		**Myocardial Revascularization**		35
	15	**Re-Do Sternotomy**** **Can be double-counted with any Cardiac procedure	5	
15		**Interventional Wire-based Procedures**		5
	5	Left Heart Catheterization, PCI, TEVAR, Mitral Clip		
	10	Intra-aortic Balloon Pump	5	

STS SPECIAL REPORT

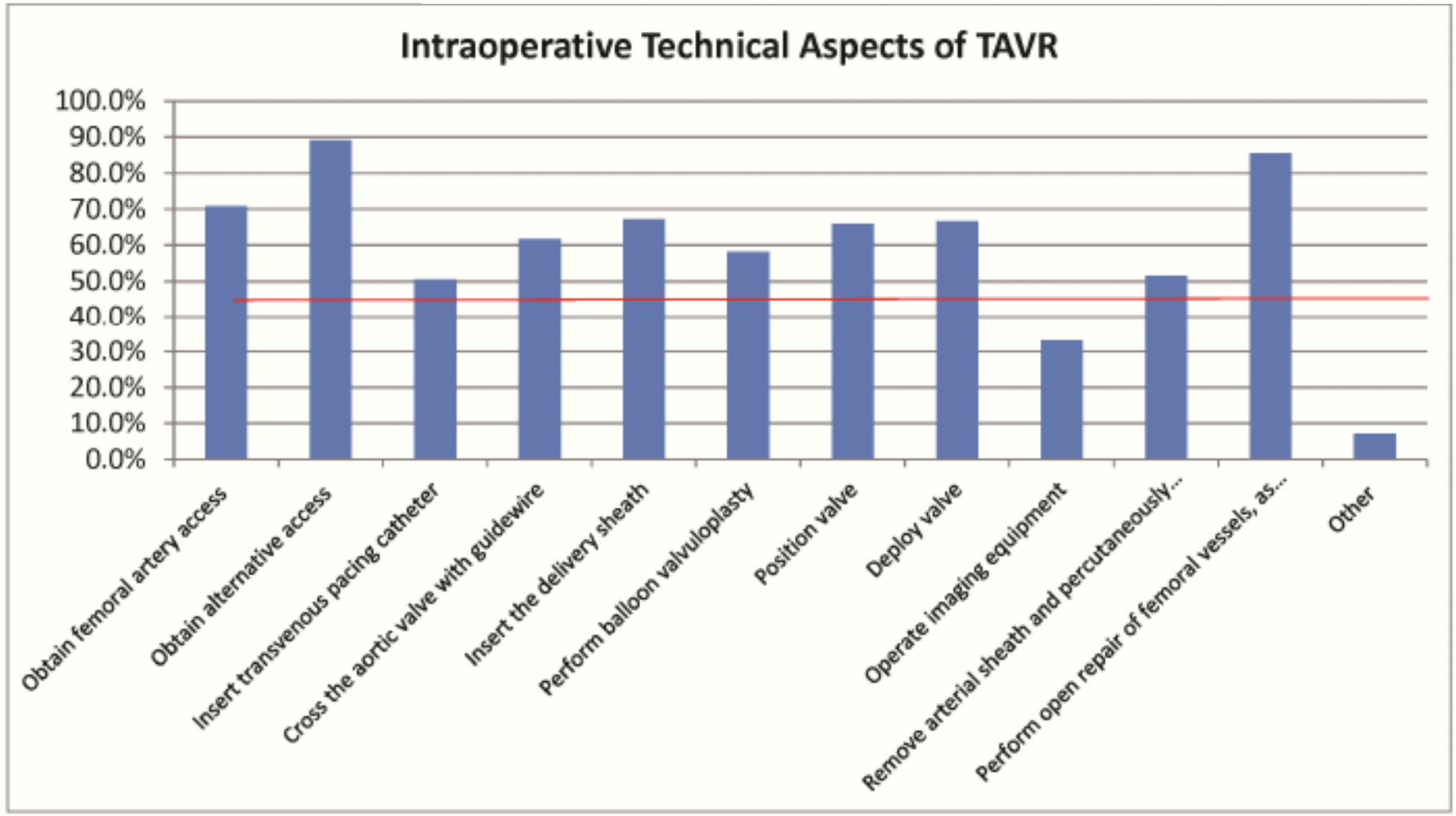
Surgeon Involvement in Transcatheter Aortic Valve Replacement in the United States: A 2016 Society of Thoracic Surgeons Survey

Joseph E. Bavaria, MD, Richard L. Prager, MD, Keith S. Naunheim, MD,

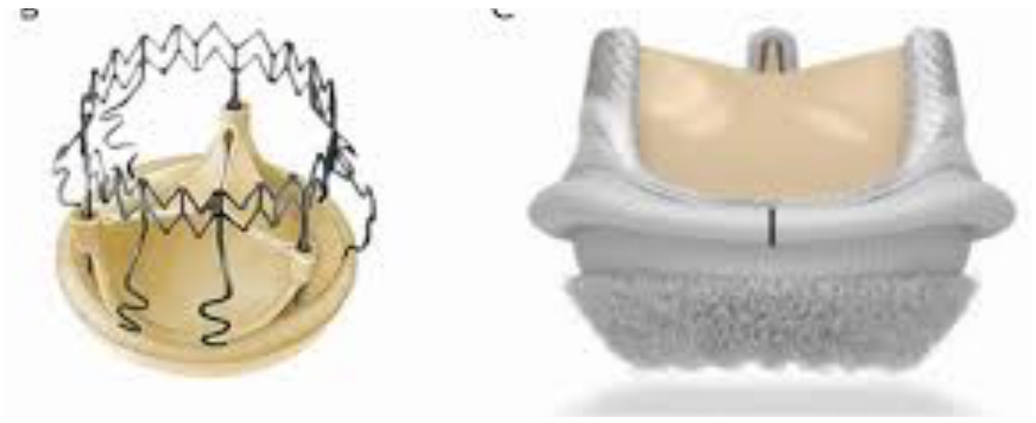
(Ann Thorac Surg 2017;104:1088–94)

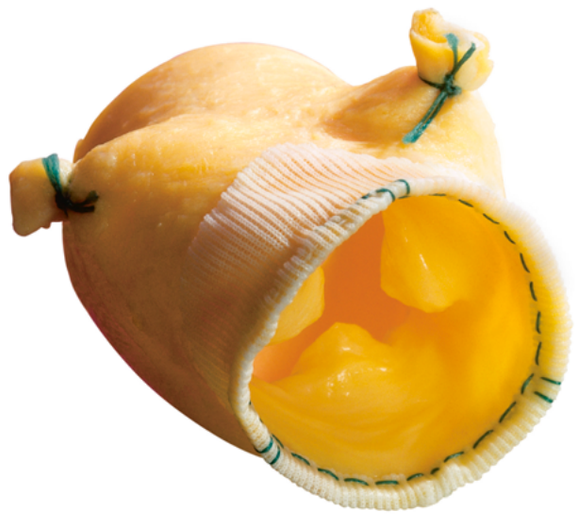


Cardiac surgeons who perform transcatheter aortic valve replacement (TAVR) regularly participated in all aspects of intraoperative procedure, except operating imaging equipment.

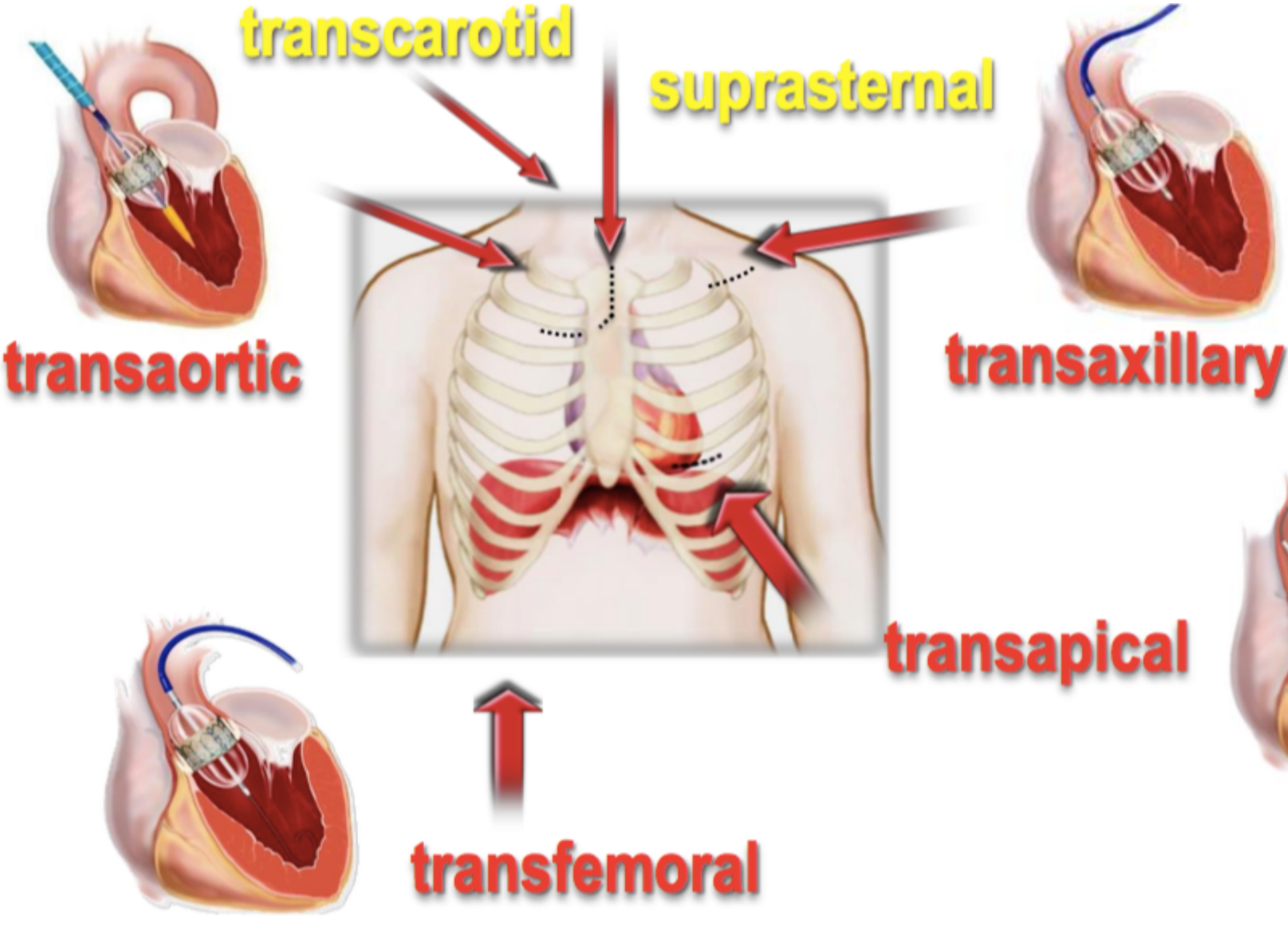


Surgeon's armamentarium (1)

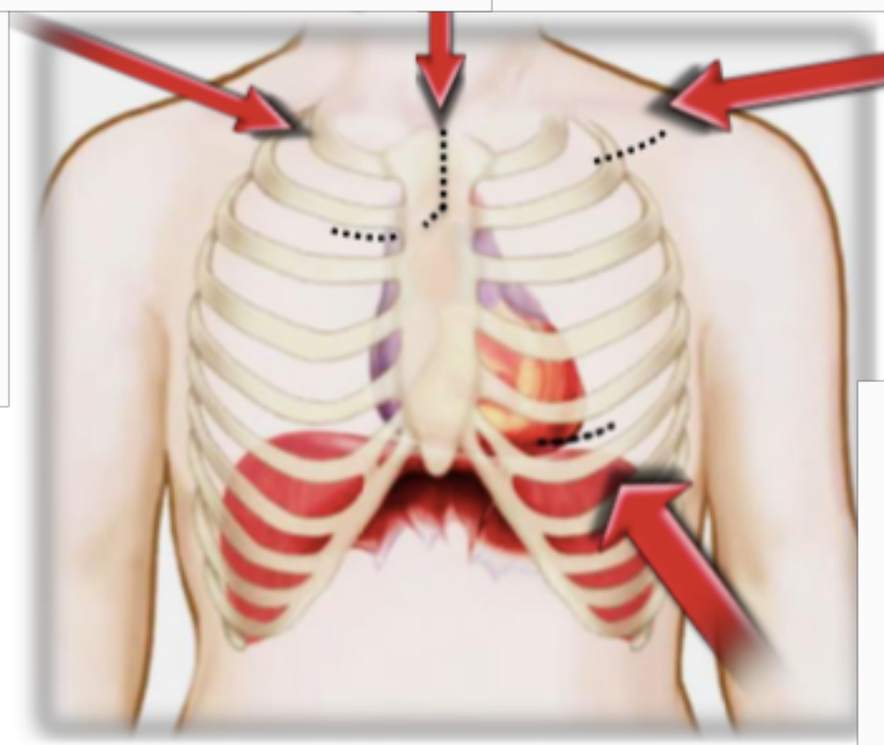




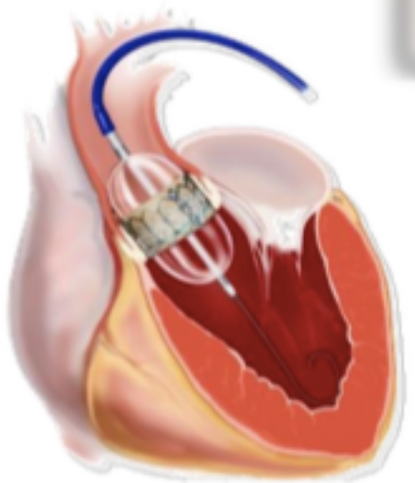
Surgeon's armamentarium (2)



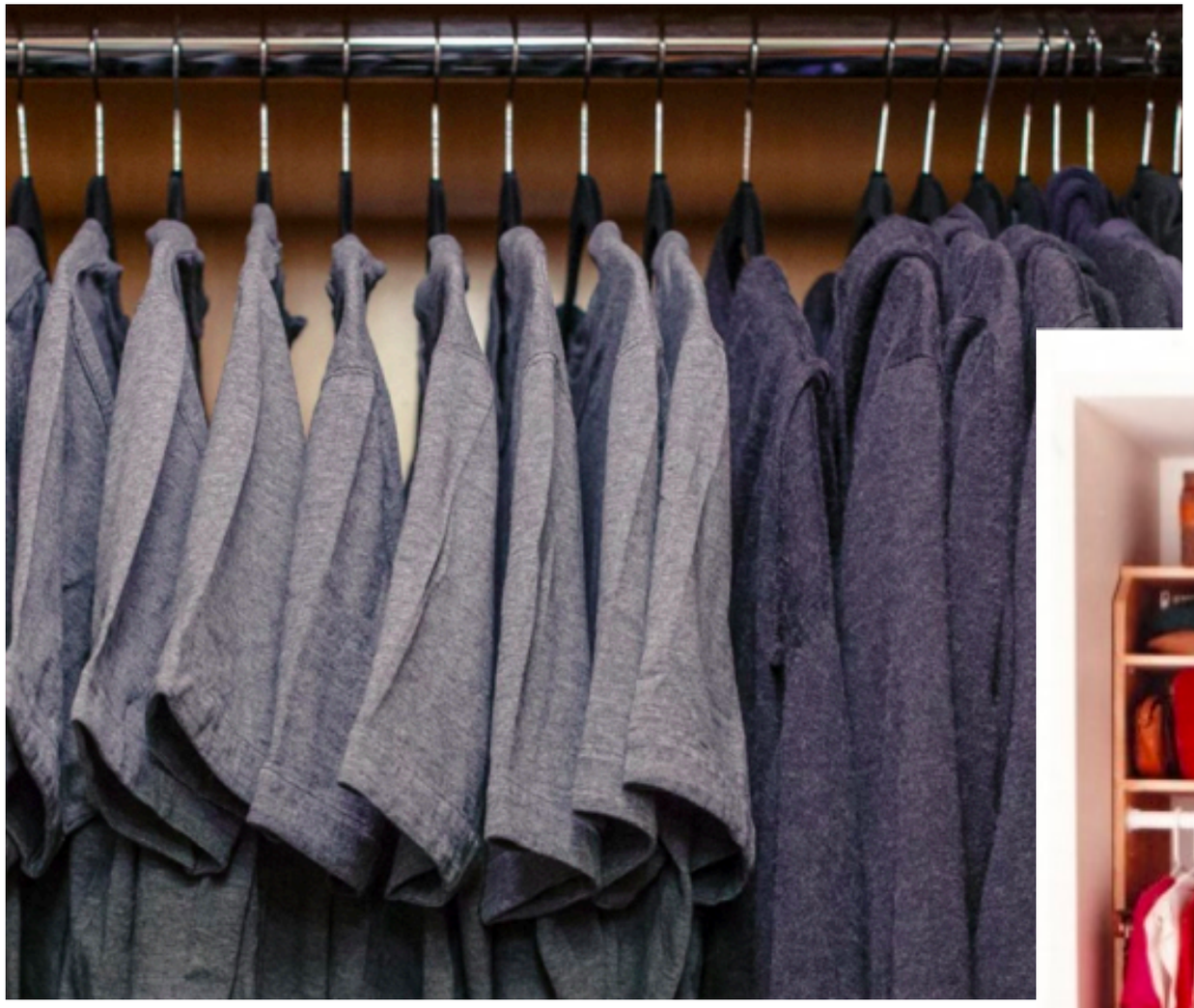
Interventional cardiologist's armamentarium



transaxillary



transfemoral



… I STILL BELIEVE IN THE HEART TEAM

TAVI FOR LOW RISK PATIENTS

IT MUST BE a business also for the cardiac surgeon!!!

Augusto D'Onofrio

Gino Gerosa

Department of Cardiac, Thoracic and Vascular Sciences, University of Padua, Italy

Adherence of Catheterization Laboratory Cardiologists to American College of Cardiology/American Heart Association Guidelines for Percutaneous Coronary Interventions and Coronary Artery Bypass Graft Surgery

What Happens in Actual Practice? (*Circulation*. 2010;121:267-275.)

Edward L. Hannan, PhD; Michael J. Racz, PhD; Jeffrey Gold, MD; Kimberly Cozzens, MA;
Nicholas J. Stamato, MD; Tia Powell, MD; Mary Hibberd, MD; Gary Walford, MD

- Indications for CABG (According to guidelines)
  - CABG recommended in 53%
  - PCI recommended in 34%
  - Medical therapy recommended in 12%

- Indications for PCI (According to guidelines)
  - PCI recommended in 94%
  - CABG recommended in 4%
  - Medical therapy recommended in 2%

Conclusions—Patients with coronary artery disease receive more recommendations for PCI and fewer recommendations for CABG surgery than indicated in the American College of Cardiology/American Heart Association guidelines. (***Circulation*. 2010;121:267-275.**)

Process quality in TAVI

- No matters who performs TAVI, only results count
- Analysis of internal results
- Optimization of the program based on these results
- Shared decision making with patients and families
- Unbiased counselling

Journal of the American College of Cardiology
© 2012 by the Society for Cardiovascular Angiography and Interventions, the American Association for Thoracic Surgery, the American College of Cardiology Foundation, and the Society of Thoracic Surgeons
Published by Elsevier Inc.

Vol. 59, No. 22, 2012
ISSN 0735-1097/12/$36.00
doi:10.1016/j.jacc.2012.02.016

COMPETENCE STATEMENT

Multisociety (AATS, ACCF, SCAI, and STS) Expert Consensus Statement: Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part 1: Transcatheter Aortic Valve Replacement

Table 1. Transcatheter Aortic Valve Replacement: Criteria for New and Existing Programs

New Programs	
Institutional Interventional Program	1,000 cath/400 PCI per year[a]
TAVR Interventionalist	100 Structural procedures lifetime or 30 left sided structural per year of which 60% should be balloon aortic valvuloplasty (Left sided procedures include EVAR, TEVAR, BALLOON AORTIC VALVE (BAV), aortic valve (AV) and mitral valve (MV) prosthetic leak closures and ventricular septal defect [VSD] closures). (atrial septal defect/patent foramen ovale (ASD/PFO) closure are not considered left sided procedures) Suitable training on devices to be used
Institutional Surgical Program	50 Total AVR per year of which at least 10 aortic valve replacement (AVR) should be high-risk (STS score ≥6) Minimum of 2 institutionally-based cardiac surgeons in program (more than 50% time at hospital with surgical program)
TAVR Surgeon	100 AVR career, at least 10 of which are "high-risk" (STS score ≥6) or 25 AVR per year or 50 AVR in 2 years and at least 20 AVR in last year prior to TAVR initiation Experience with, and management of, peripherally inserted cardiopulmonary bypass Experience with open retroperitoneal exposure of, and surgical intervention on, the iliac arteries Suitable training on devices to be used
Training	Cardiologists must be board certified/eligible in interventional cardiology Surgeons must be board certified/eligible in thoracic surgery **Additional operators who are trained or experienced in structural heart disease, and have unrestricted hospital privileges in structural procedures, may also be part of the interventional operating team with the interventional cardiologist and cardiovascular surgeon**
Existing Programs	
Institutional	Programs in existence >18 months: 30 TAVR (total experience) Programs in existence <18 months: 2 per month
Training	Cardiologists must be board certified/eligible in interventional cardiology Surgeons must be board certified/eligible in thoracic surgery **Additional operators who are trained or experienced in structural heart disease, and have unrestricted hospital privileges in structural procedures, may also be part of the interventional operating team with the interventional cardiologist and cardiovascular surgeon**

Clinical guidelines and position paper

FIC Federazione Italiana di Cardiologia
Italian Federation of Cardiology

Updated clinical indications for transcatheter aortic valve implantation in patients with severe aortic stenosis: expert opinion of the Italian Society of Cardiology and GISE

Ciro Indolfi, Antonio L. Bartorelli, Sergio Berti, Paolo Golino, Giovanni Esposito, Giuseppe Musumeci, Sonia Petronio, Corrado Tamburino, Giuseppe Tarantini, Gianpaolo Ussia, Corrado Vassanelli, Carmen Spaccarotella, Roberto Violini, Giuseppe Mercuro and Francesco Romeo

Complications of TAVI procedures

Before a transcatheter approach is raccomended to intermediate-risk patients, some partially issues should be taken into account:

- the risk of PPI;

- the presence of a bicuspid valve

- the need for TAVI in TAVI or PCI after TAVI.

The most serious acute complications every operator should be aware of to recognize them in a timely fashion and to set forth the proper management strategy.

Vascular perforation/rupture of the ilio-femoral axis with retroperitoneal hemorrhage
Aortic rupture (arch or annulus) during device delivery/implantation
Cardiac tamponade related to RV perforation (pacing lead), LV perforation (super stiff wires, delivery system whiplash) or aortic root perforation (improper valve release, delivery system)
Coronary ostium obstruction (valve frame, dislodged calcified native cusp)
Acute severe aortic regurgitation

LV, left ventricle; RV, right ventricle.

Who is the "owner" of the *technique*?

- Cardiac surgeons have been performing **IMPLANTATION** of prostheses in aortic position with many different **APPROACHES**:
  - Median sternotomy
  - Ministernotomy
  - Right thoracotomy

- Since evolving technologies have started to enable to **IMPLANT** a prosthesis in aortic position through a *(simple)* transcatheter (*transfemoral)* APPROACH, cardiac surgeons have been reluctant

OWNERSHIP

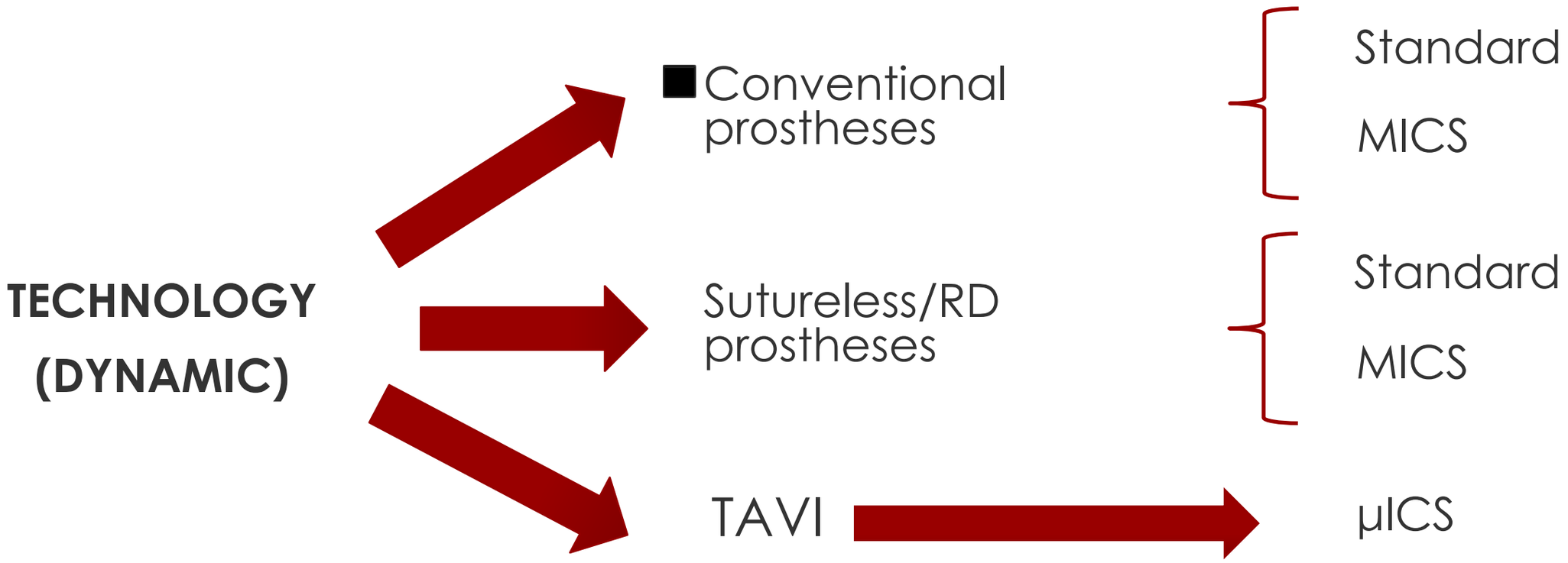
?

- Beating heart commissurotomy → Cardiac Surgeon
- Conventional AVR → Cardiac Surgeon
- Minimally invasive AVR → Cardiac Surgeon
- Sutureless/Rapid deployment AVR → Cardiac Surgeon
- Valve repair → Cardiac Surgeon
- **TAVI** → **Interventional Cardiologist**

Technique vs. technology

TECHNIQUE (STATIC)

- The treatment of severe aortic valve stenosis is the ***IMPLANTATION*** of a prosthesis in aortic position



The cardiac surgeon has to partecipate to:

PRE-OPERATIVE RECRUITMENT → Planning with the patient the best strategy

INTRA-OPERATIVE PROCEDURE → Perform the procedure in any possible way and approach, changing plans if necessa

POST-OPERATIVE → Handling of all the possible complications
(ECMO; conversion to full sternotomy, vascular complications..

HOTTEST DATA

- A Low risk patient implies such a perfect implant of the prosthesis. NO Complication is admitted!

- SAVR should be mandatory in case of PVL for low risk patient (whereas mortality rate for Low risk patient SAVr is <1%)

- The conversion to full sternotomy has to be warranted if the the result is not satisfatictory.

REVIEW

Annals of Internal Medicine

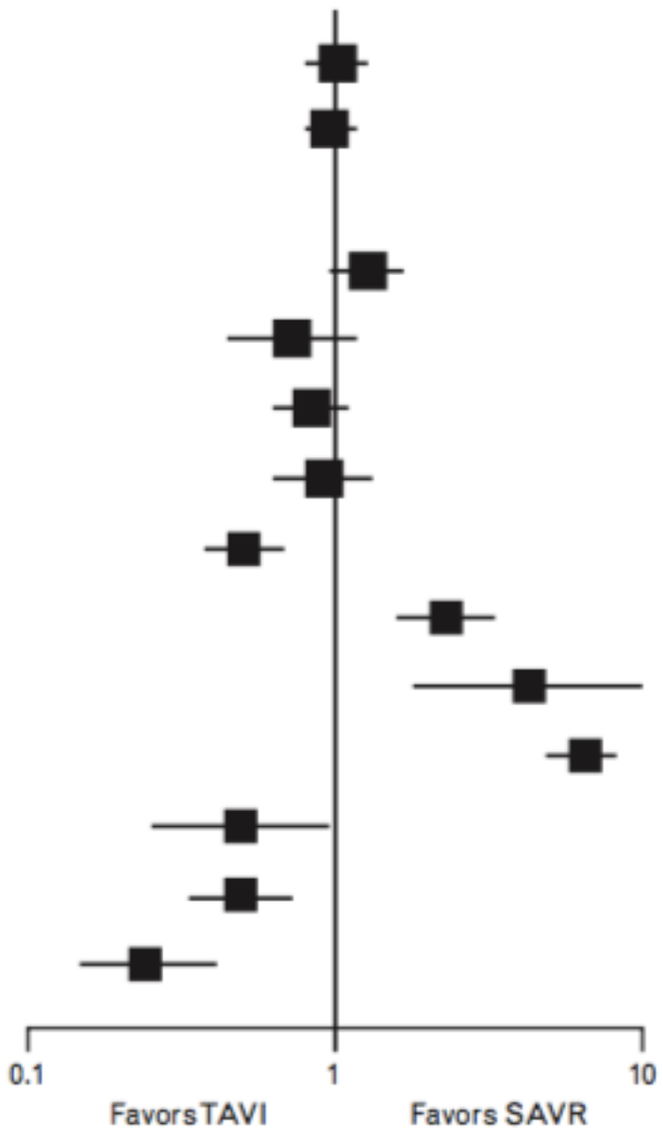
Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement

A Systematic Review and Meta-analysis

Giuseppe Gargiulo, MD*; Anna Sannino, MD*; Davide Capodanno, MD, PhD; Marco Barbanti, MD; Sergio Buccheri, MD; Cinzia Perrino, MD, PhD; Piera Capranzano, MD; Ciro Indolfi, MD, PhD; Bruno Trimarco, MD; Corrado Tamburino, MD, PhD; and Giovanni Esposito, MD, PhD

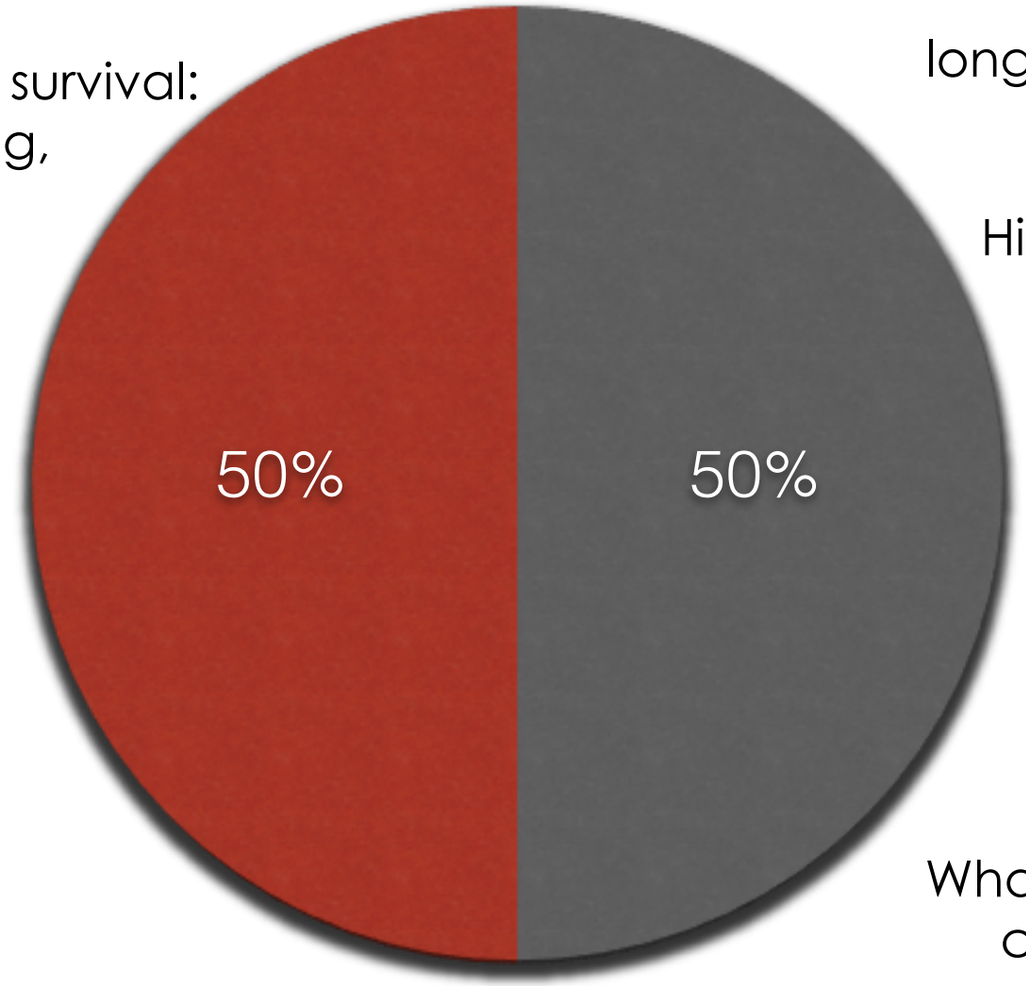
Forest plot for all outcomes in patients with intermediate risk

	Studies, *n*	Patients, *n*	OR (95% CI)	*P*	I^2, %	P_{int}
Primary outcomes						
Early all-cause mortality	35	16 386	1.01 (0.81–1.26)	0.90	37	0.14
Midterm all-cause mortality	23	11 222	0.96 (0.81–1.14)	0.64	40	0.48
Secondary outcomes						
Long-term all-cause mortality	10	5505	1.28 (0.97–1.69)	0.08	62	0.01
Early CV mortality	10	6656	0.73 (0.45–1.19)	0.18	33	0.41
Early stroke	30	14 236	0.84 (0.64–1.09)	0.17	18	0.24
Midterm stroke	9	7433	0.92 (0.62–1.35)	0.63	53	0.46
Early MI	19	11 835	0.51 (0.38–0.69)	0.001	0	0.33
Early PM implantation	25	13 086	2.32 (1.62–3.31)	0.001	67	0.76
Early vascular complication	15	11 167	4.32 (1.82–10.3)	0.001	81	0.12
Early paravalvular leak	15	7631	6.66 (5.26–8.45)	0.001	0	0.61
Early major bleeding	14	9808	0.49 (0.26–0.95)	0.04	96	0.45
Early AKI	15	9809	0.50 (0.34–0.73)	0.002	65	0.35
Early NOAF	9	6087	0.24 (0.15–0.40)	0.001	77	0.35



Is TAVI legitimate in Low risk patients?

Reduced compliations impacting survival:
AKI; life-threatening bleeding,
disabling strokes



long term durability?

Higher rate of AV block and
definitive PM implant

Vascular complications

Predictable procedure
(more than PCI)

What about bicuspid valves and
concomitant procedures ?

Currently major indication is high-risk or inoperable AS

TAVI indication is and will be expanded (intermediate/lower risk)

Current RCTs for intermediate/low-risk pts are biased & most initiated/funded by industry

- ***Physician-initiated RCTs are necessary – isolated TAVI vs. sAVR***

- ***The TAVI 'heart-team' plays a key role in clinical practice***

- ***TAVI can be performed with high procedural success rates***

- ***There is a (substantial) institutional learning curve***

- ***There are valve-specific complications & limitations***

- ***Long-term durability data are still rare***

- ***Will CV surgeons play a key role in TAVI ?***

European Heart Journal

Issues More Content ▾ Publish ▾ Purchase Advertise ▾ About ▾

Volume 37, Issue 28
21 July 2016

Article Contents

EDITOR'S CHOICE FAST TRACK

Outcomes of transfemoral transcatheter aortic valve implantation at hospitals with and without on-site cardiac surgery department: insights from the prospective German aortic valve replacement quality assurance registry (AQUA) in 17 919 patients

FREE

Holger Eggebrecht ✉; Maike Bestehorn; Michael Haude; Axel Schmermund; Kurt Bestehorn; Thomas Voigtländer; Karl-Heinz Kuck; Rajendra H. Mehta

Eur Heart J (2016) 37 (28): 2240-2248. **DOI:** https://doi.org/10.1093/eurheartj/ehw190
Published: 17 May 2016 **Article history** ▾

Although patients undergoing TAVI at hospitals without on-site CS department were older and at higher predicted perioperative death risk, major complications, and in-hospital mortality were not statistically different, suggesting the feasibility and safety of Heart Team-based TAVI at non-CS sites.

What would cardiologists like to be th of the heart surgeon in the heart te (…as far as guidelines require it..

- Confirm decisions they have already taken

- Confirm indications they have already given

- Stand-by while they perform procedures

Editorial
Shifting a Paradigm of Cardiac Surgery: From Minimally Invasive to Micro-Invasive

The Journal of Heart Valve Disease 2015;24:528-530

Augusto D'Onofrio, Gino Gerosa

Division of Cardiac Surgery, University of Padova, Padova, Italy

We should implement cardiac surgery training with catheter-based techniques and percutaneous structural heart operations.

Whilst our generation will probably be only marginally affected by this ongoing revolution, *for our fellows who are about to start their individual practice in the next four or five years this is going to be a big deal.*

The absence of catheter skills in their training would have detrimental effects, as it would reduce their chances of having an active role in this new era of μICS that they strongly deserve for their passion, sacrifices and commitment to the job.

What should ACTUALLY be the rol
the heart surgeon in the heart tea

- Leading role in case discussion

- Leading role in indications to procedure

- Leading role in performing transcatheter procedures

Requirements for transcatheter Mitral Valve procedure

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Journal of the American College of Cardiology

TABLE I Mitral Valve Institutional and Operator Requirements

Institutional	**1,000 Cath/400 PCI per Year[a]**
Interventionalist	50 Structural procedures per year (including ASD/PFO and trans-septal punctures) Suitable training on devices to be used
Surgical program	25 Total mitral valve procedures per year, of which at least 10 must be mitral valve repairs[b] All cases must be submitted to a single national database
Existing programs	15 Mitral (total experience) Ongoing CME (or nursing/technologist equivalent) of 10 h per year of relevant material All cases must be submitted to a single national database
New programs	Because the indications are not defined, no volume criteria can be proposed yet Assuming approval would be for high-risk cohorts, 10%-15% mortality rate at 30 days, similar to registry or published data 65% 1-year survival rate Ongoing CME (or nursing/technologist equivalent) of 10 h per year of relevant material All cases must be submitted to a single national database
Training	Operator must be board certified in interventional cardiology or board certified/board eligible in pediatric cardiology or similar boards from outside the United States. Cardiac surgeons must be board certified in thoracic surgery, or similar foreign equivalent.

[a]With acceptable outcomes for conventional procedures compared to NCDR benchmarks. [b]Mitral valve procedures should be those done for severe mitral regurgitation. Mitral valve procedures for mild or moderate mitral regurgitation done at the time of other cardiac surgical procedures (AVR, CABG) do not meet this criterion.

Eur J Health Econ
DOI 10.1007/s10198-017-0877-7

ORIGINAL PAPER

The impact of post-procedural complications on reimbursement, length of stay and mechanical ventilation among patients undergoing transcatheter aortic valve implantation in Germany

Klaus Kaier[1,2] · Holger Reinecke[3] · Huseyin Naci[4] · Lutz Frankenstein[5] · Martin Bode[2,6] · Werner Vach[1] · Philip Hehn[1] · Andreas Zirlik[2] · Manfred Zehender[2] · Jochen Reinöhl[2]

Received: 9 July 2016 / Accepted: 7 February 2017

	Reimbursement ($N = 9103$)		reimbursement ($N = 9103$)		likelihood of ventilation >48 h ($N = 9147$)		time of ventilation among ventilated patients ($N = 482$)	
	Unadjusted extra reimbursement (95% CI)	Risk adjusted extra reimbursement (95% CI)	Unadjusted extra length of stay (95% CI)	Risk adjusted extra length of stay (95% CI)	unadjusted odds ratio (95% CI)	Risk adjusted odds ratio (95% CI)	Unadjusted extra length of ventilation (95% CI)	Risk adjusted extra length of ventilation (95% CI)
Stroke	€4125	€3880	4.68	3.03	5.73	5.51	139.61	134.41
	(€1794–€6456)	(€1525–€6235)	(2.72–6.64)	(1.06–5.00)	(3.88–8.45)	(3.66–8.31)	(34.76–244.45)	(13.69–255.13)
Bleeding (>5 RBC)	€12,839	€12,604	14.58	13.54	17.91	16.79	236.08	235.29
	(€10,807–€14,872)	(€10,589–€14,620)	(12.63–16.52)	(11.63–15.44)	(14.30–22.44)	(13.29–21.21)	(180.18–291.97)	(179.55–291.03)
Acute kidney injury	€5963	€5657	7.92	6.63	6.93	6.06	48.36	56.48
	(€4301–€7625)	(€3983–€7330)	(6.16–9.68)	(4.89–8.37)	(5.31–9.05)	(4.61–7.97)	(−14.70 to 111.41)	(−8.79 to 121.75)
PPI	€662	€646	3.54	3.26	1.22	1.23	−5.96	1.01
	(€194–€1130)	(€176–€1117)	(2.92–4.17)	(2.66–3.86)	(0.93–1.59)	(0.93–1.61)	(−74.60 to 62.67)	(−70.71 to 72.73)

- Fermamente convinto che la tavi nei low risk sia il futuro
- Però:
  - PM
  - PVL
  - Sustainability