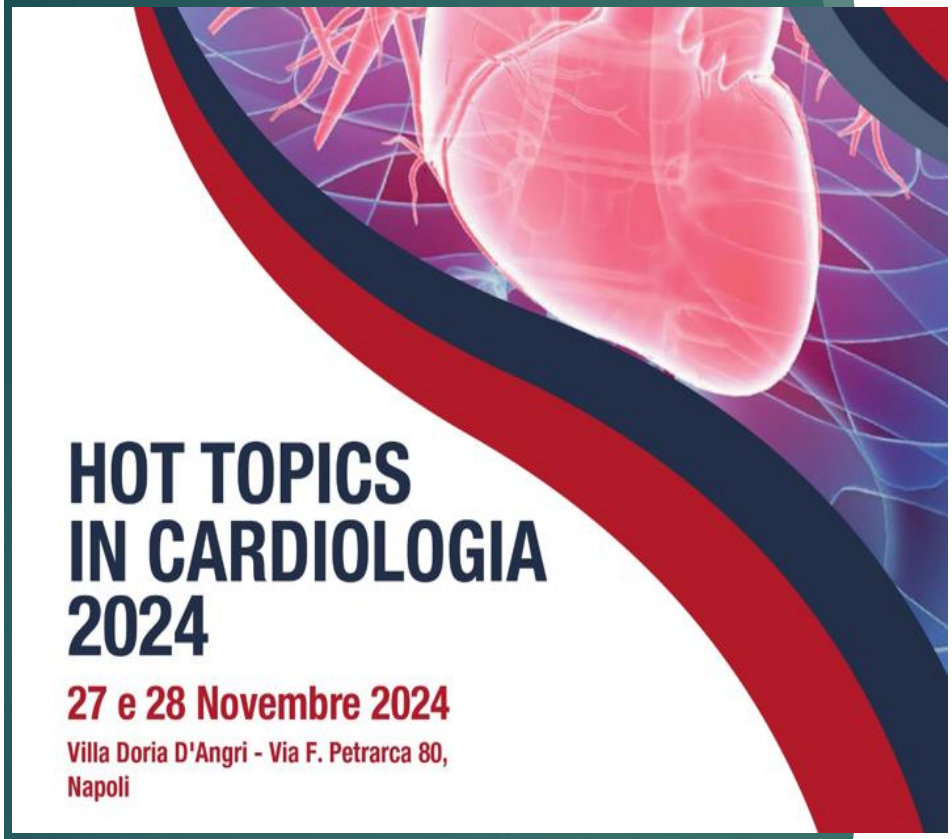


PROSPETTIVE FUTURE NELL'INTERVENTISTICA VALVOLARE

TAVI AT HOME

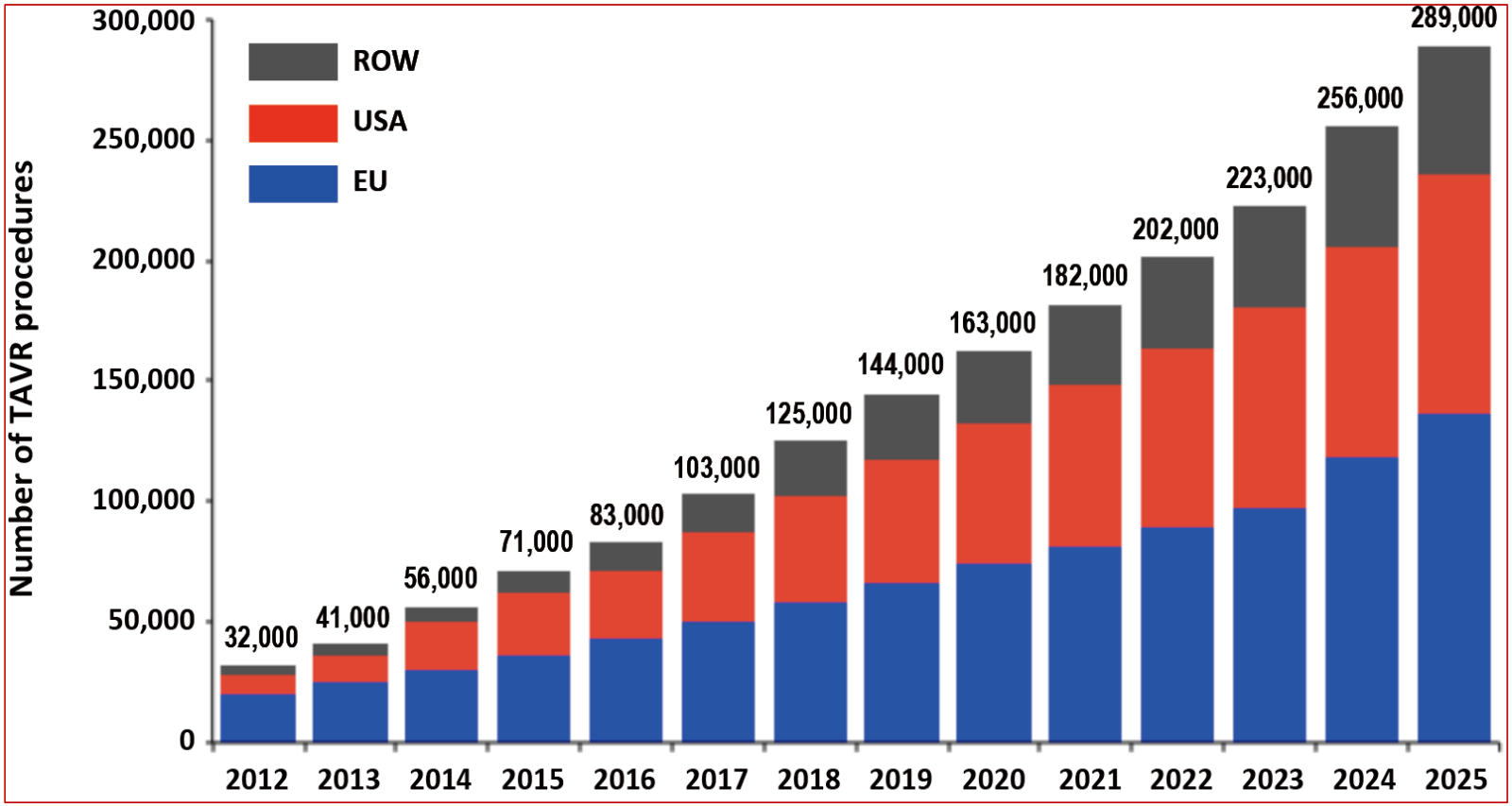
TAVI AT HOME

Fabio Tarantino

SSD Cardiologia Interventistica e Strutturale
Forlì-Cesena
AUSL della Romagna

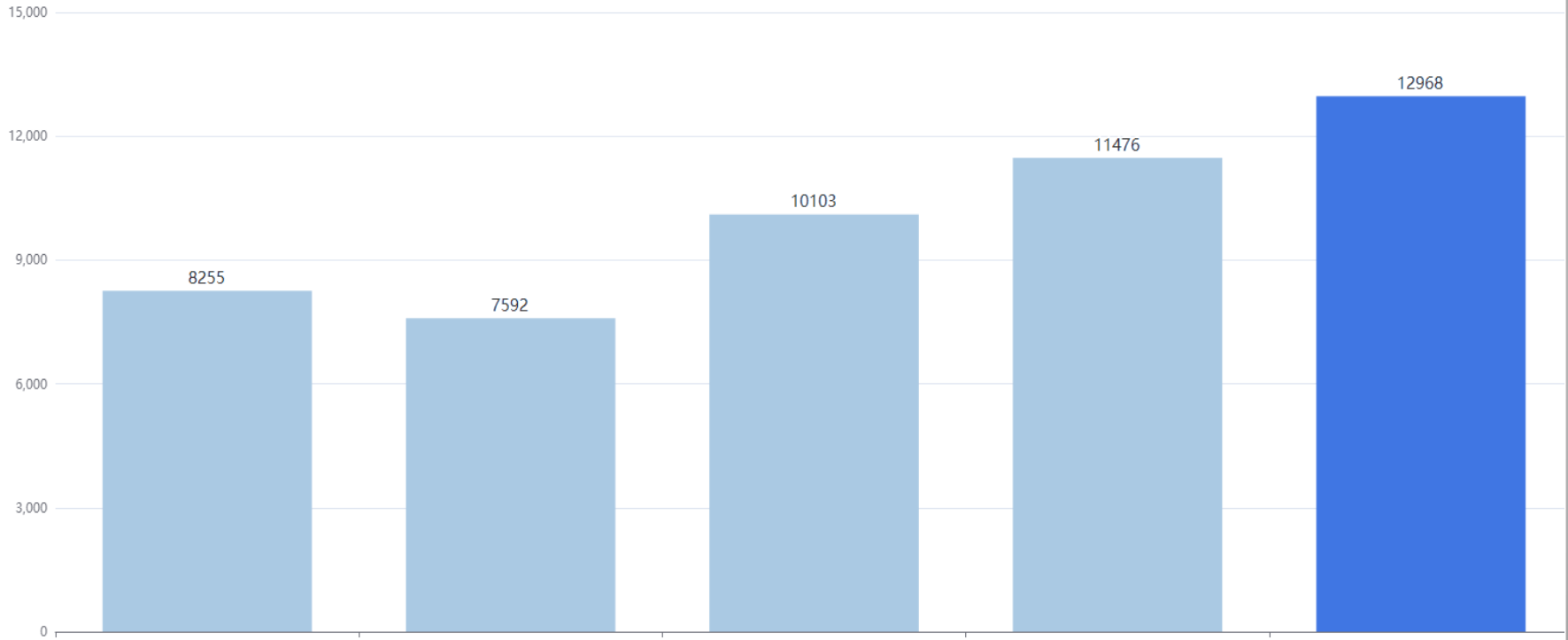
TAVR: real word

An ongoing increasing trend



Sharma T. *et al*. *J Am Coll Cardiol. 2022;80:2054–2056*

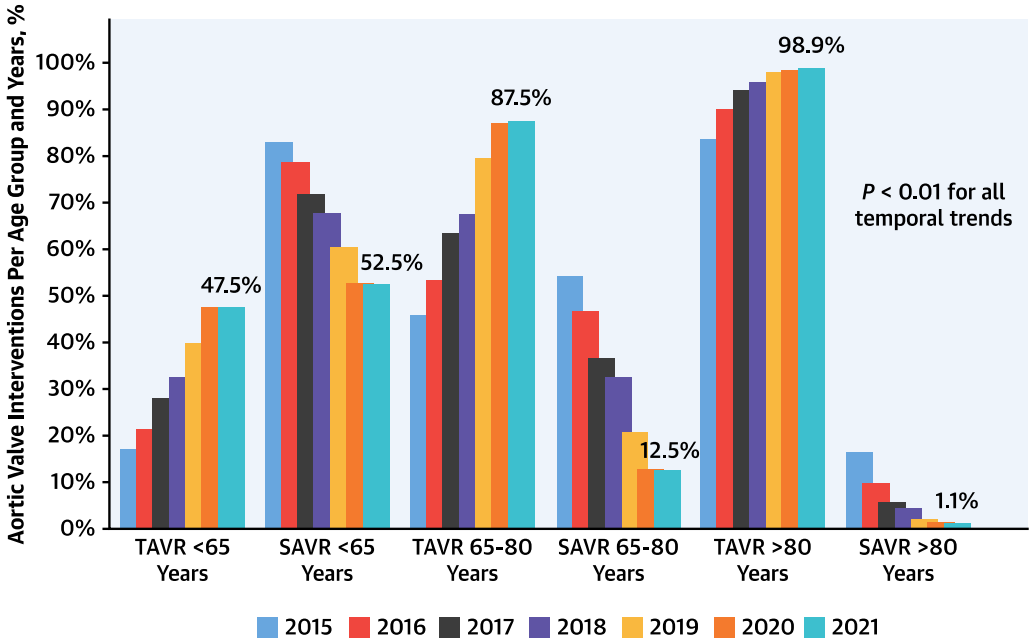
TAVI: Serie storica Italia



	2019	2020	2021	2022	2023
DELTA % ANNO PREC.	0.0%	-8.73%	24.85%	11.96%	11.51%

TAVI: real world

TAVI has become **the mainstay** of treatment in degenerative AS.

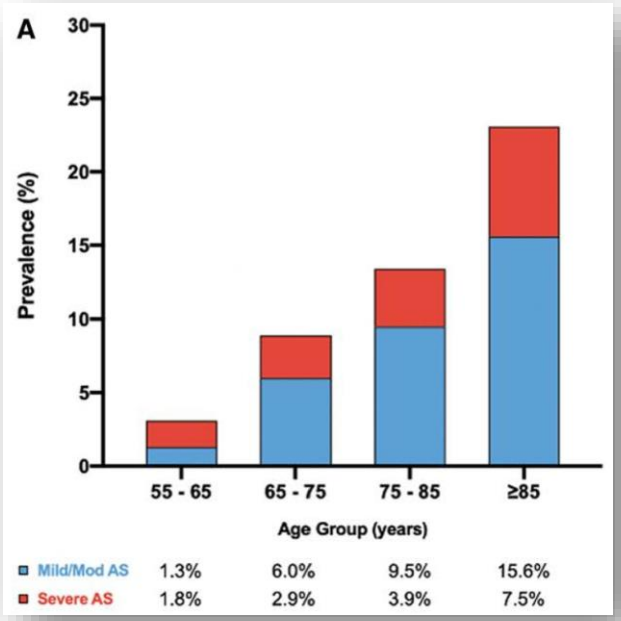


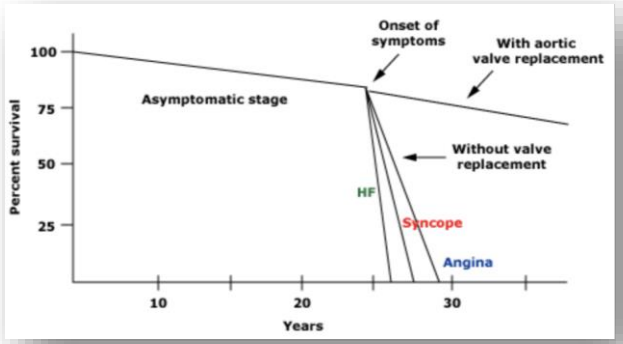
Sharma T. *et al*. *J Am Coll Cardiol. 2022;80:2054–2056*

Over the last 20 years, the **indications for TAVI** have rapidly **expanded.**

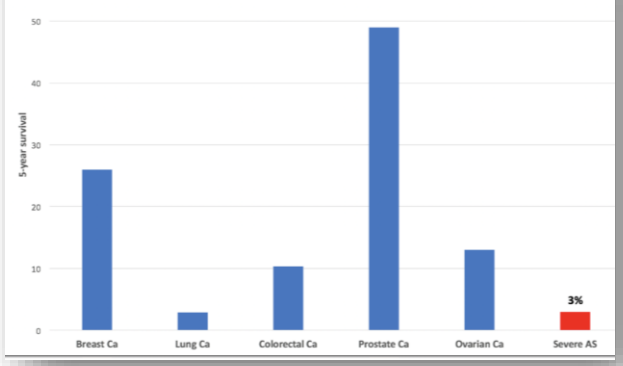
Symptomatic Aortic Valve Stenosis
Clinical and Epidemiological Emergency

Increasing prevalence and poor prognosis





3% sopravvivenza a 5 anni per SAO severa

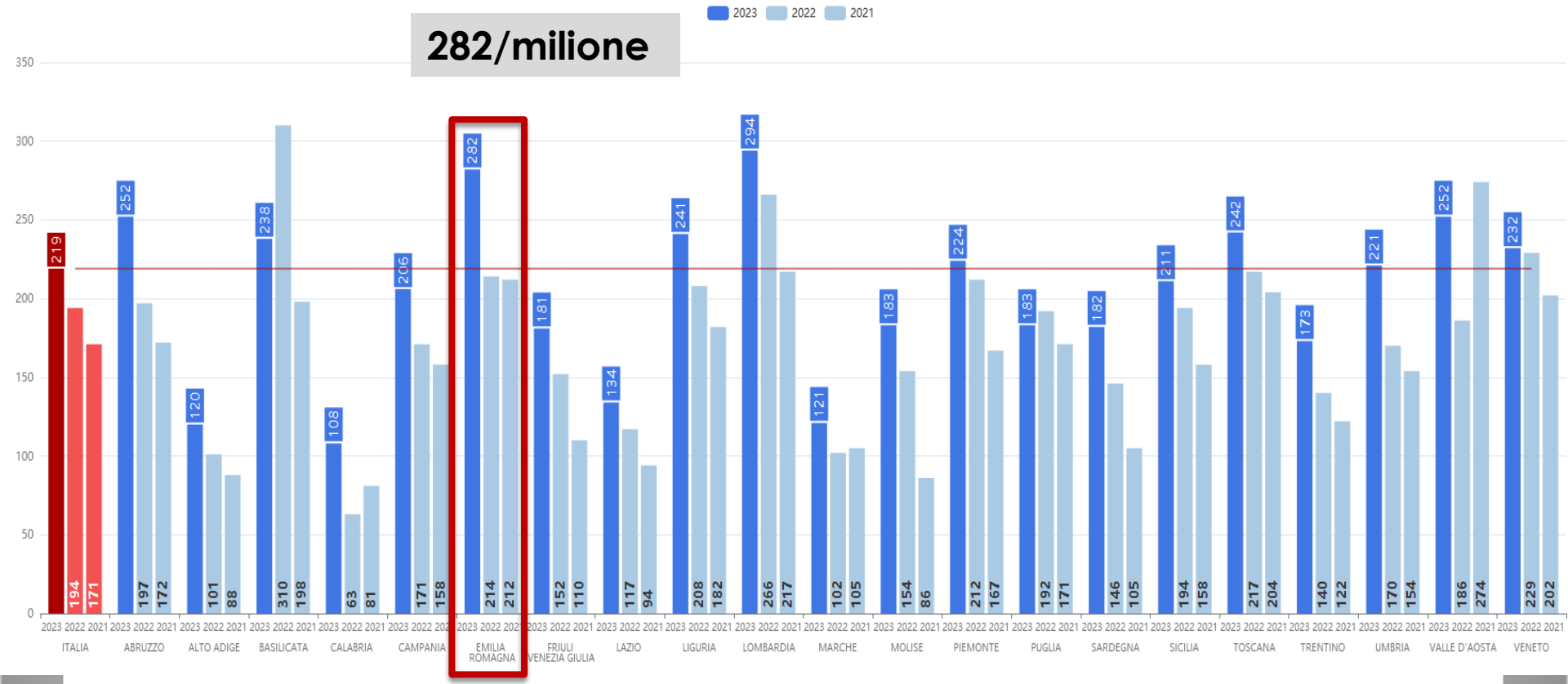


Prognosi a 5 anni delle più comuni neoplasie metastatiche e della SAO in UK

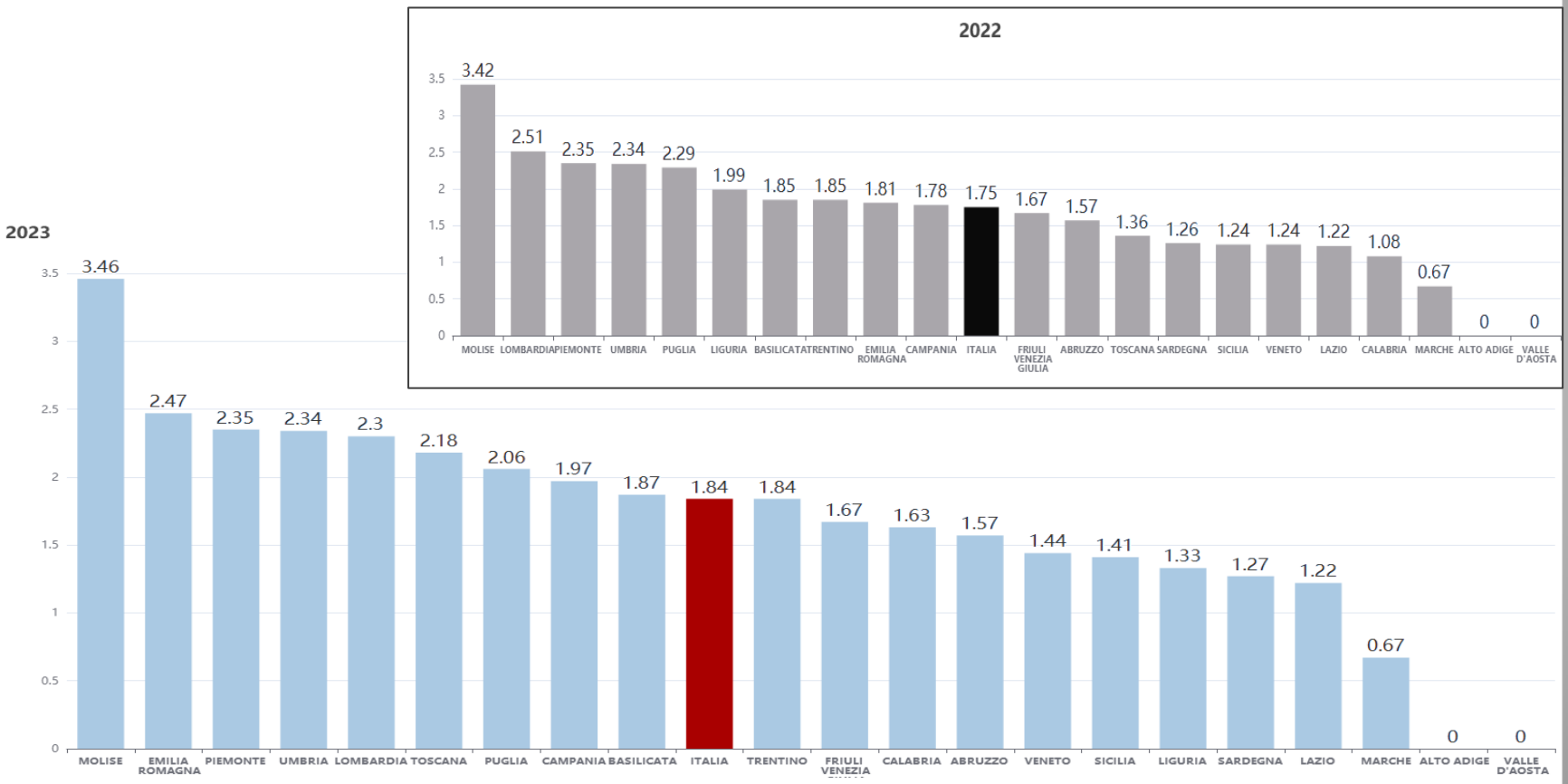
Ali N, et al. *Open Heart* 2021; 8e001547
. doi:10.1136/openhrt-2020-001547

TAVI/1.000.000 Abitanti: Italia e Regioni 2021-22-23

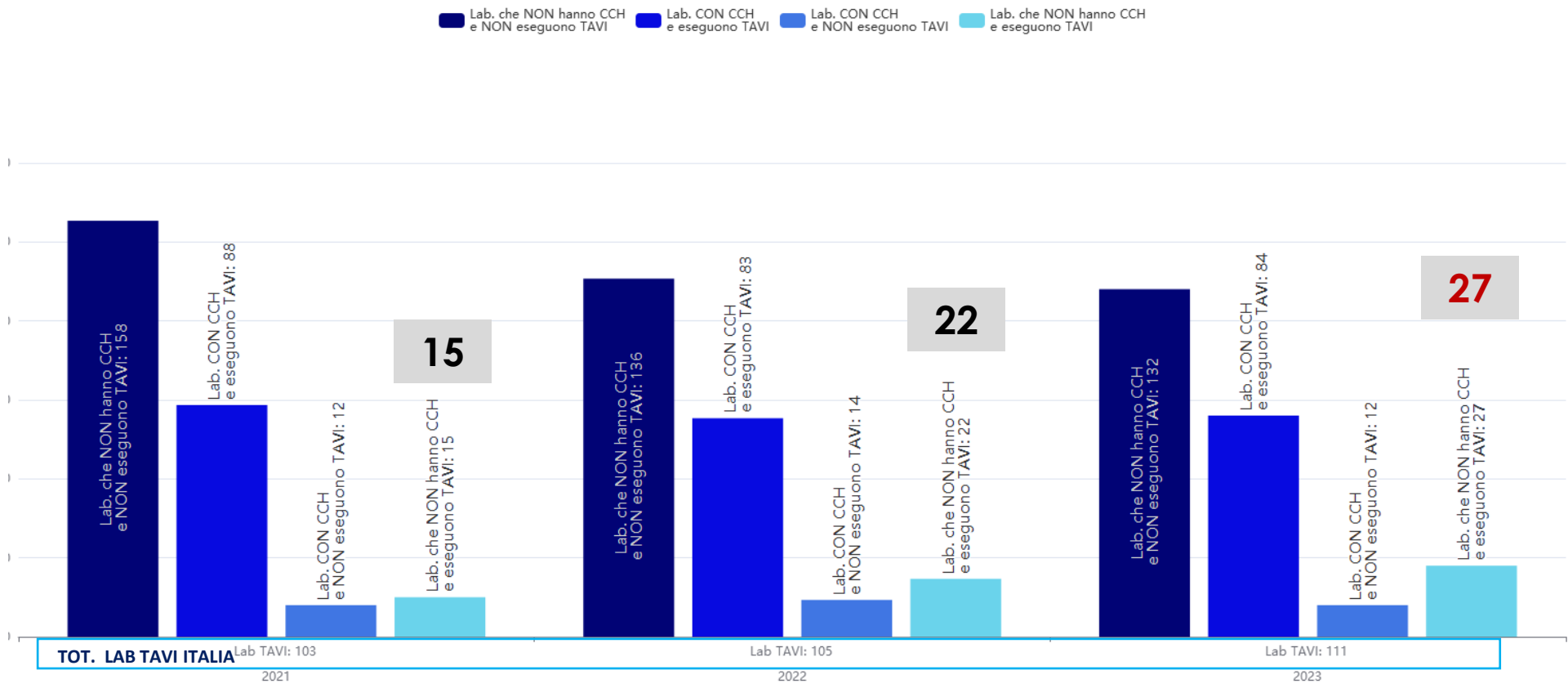
282/milione



Laboratori TAVI/1.000.000 Abitanti: Italia e Regioni 2023



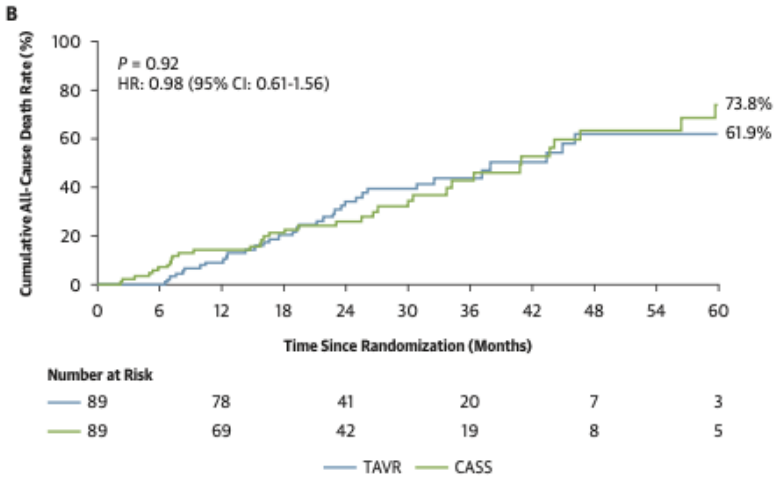
Laboratori che eseguono TAVI e presenza di CCH on site



TAVI: recent data

Transcatheter Aortic Valve Replacement in Patients With Systolic Heart Failure and Moderate Aortic Stenosis

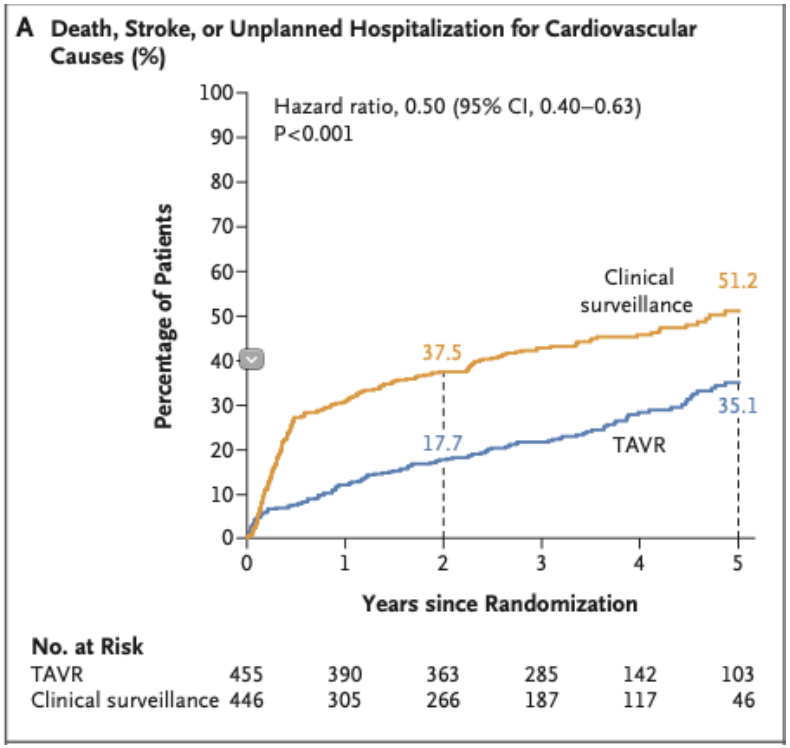
TAVR UNLOAD



43% dei pazienti in Tp medica sottoposti a TAVR entro i 12 mesi dalla randomizzazione.

Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis

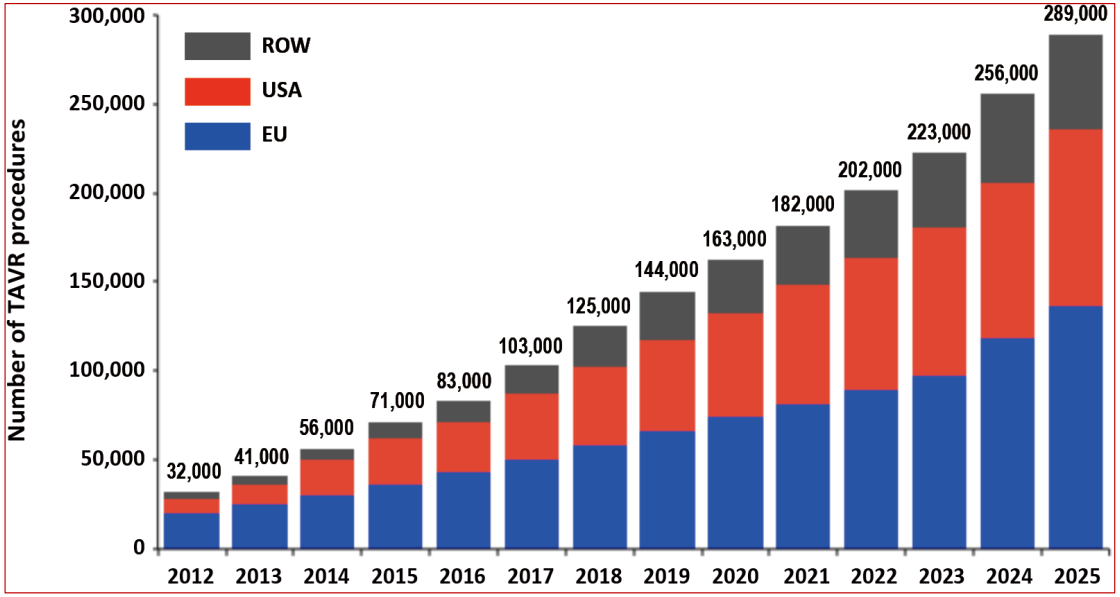
P. Généreux, A. Schwartz, J.B. Oldemeyer, P. Pibarot, D.J. Cohen, P. Blanke, B.R. Lindman, V. Babaliaros, W.F. Fearon, D.V. Daniels, A.K. Chhatriwalla, C. Kavinsky, H. Gada, P. Shah, M. Szerlip, T. Dahle, K. Goel, W. O'Neill, T. Sheth, C.J. Davidson, R.R. Makkar, H. Prince, Y. Zhao, R.T. Hahn, J. Leipsic, B. Redfors, S.J. Pocock, M. Mack, and M.B. Leon, for the EARLY TAVR Trial Investigators*



TAVI: in the future

The number of **TAVI** is projected to **increase in the future.**

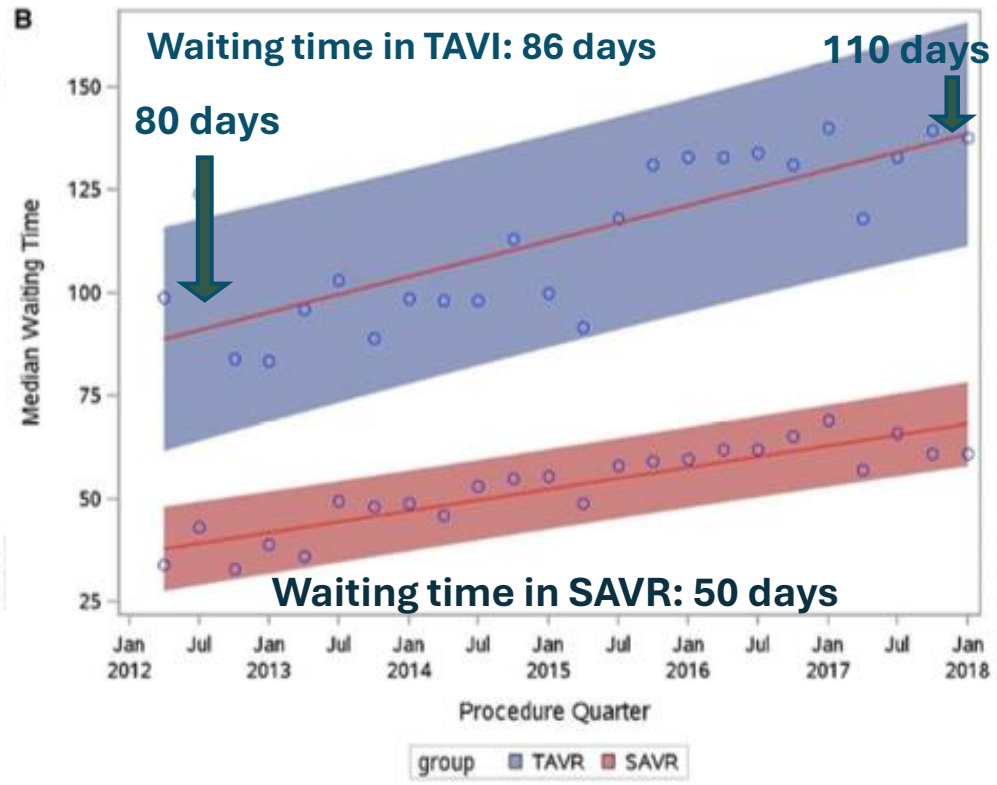
An ongoing increasing trend



Cesna, S. *et al.*. *J. Thorac. Dis.* 2017; 9(6): 1432-1436

Exponential growth in TAVI could overcome the centres capacity

TAVI supply

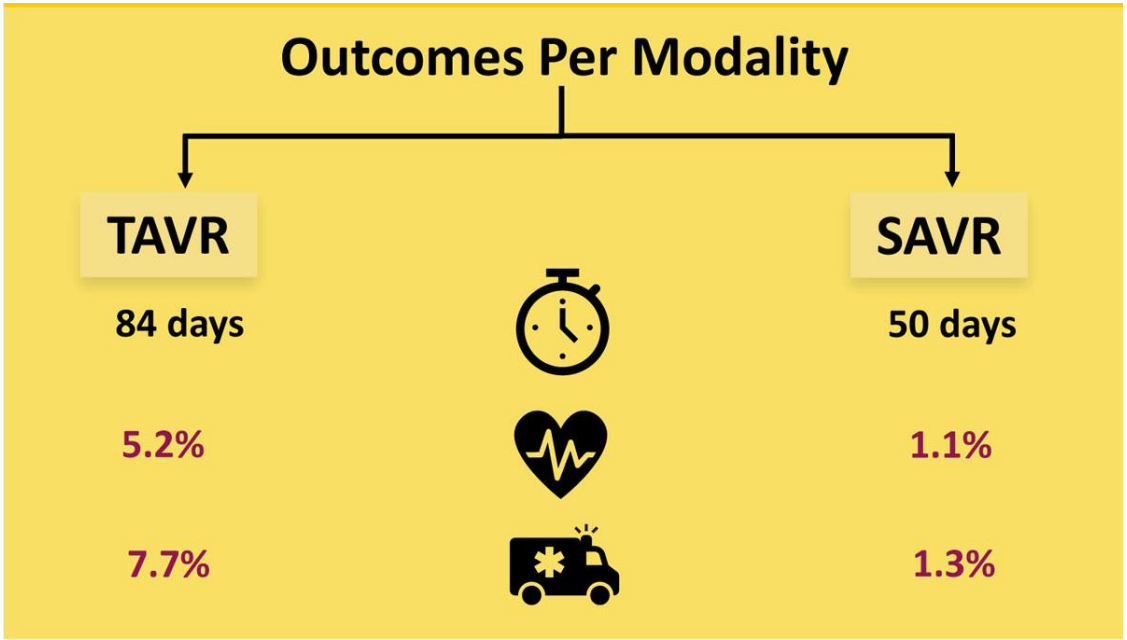


- 8098 patients;
- The increase in number of **TAVI procedures was not in keeping** with the increasing number of **referrals**;
- This large mismatch between demand and supply results in increase waiting-list.

Albassam O et al. Circ Cardiovasc Interv. 2020 Nov;13(11):e009297.

Long waiting-list

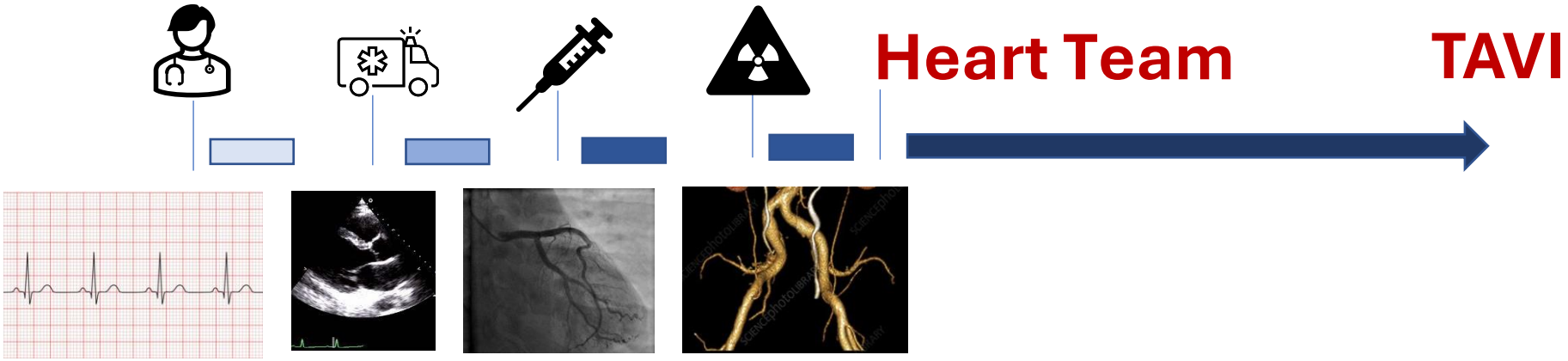
- In the early TAVI era, **10-14%** patients died on waiting-list;
- In more recent study the cumulative probability of **mortality** was **5.2%** and **HF hospitalization** rate **7.7**% in TAVI patients.



Albassam et al. *Circ Cardiovasc Interv*. Nov. 2020

Circulation: Cardiovascular Interventions

Waiting List



Waiting list work-up

Fast-track pathways

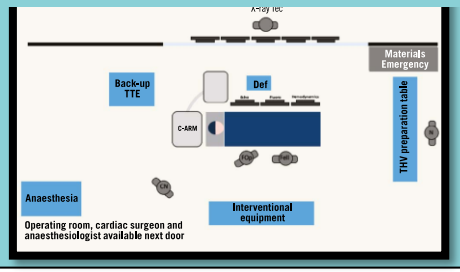
Increase awareness of Ao valve disease

Simplify and facilitate access to the procedure

?

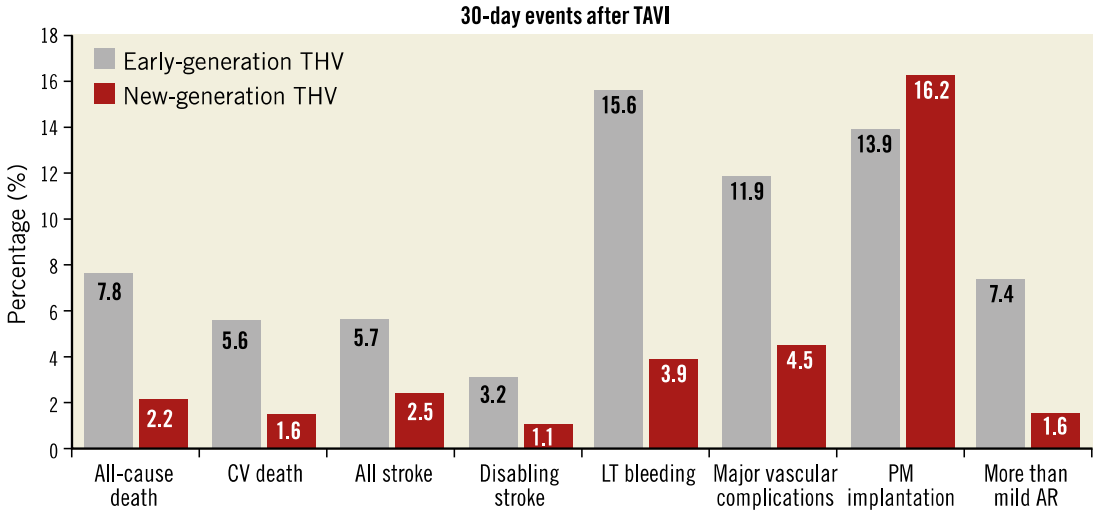
Minimalist TAVI

Increase Hospital beds turnover

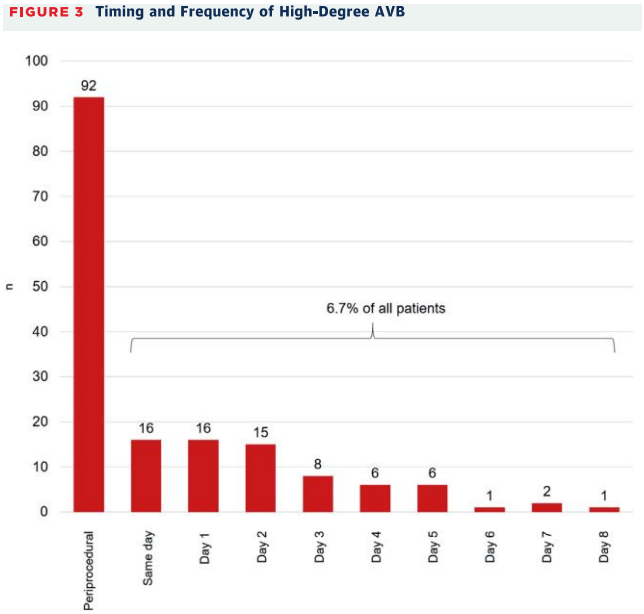


Waiting list work-up

Fast-track pathways & minimalist TAVR



Barbanti M, Webb JG, Gilard M, Capodanno D, Tamburino C. Transcatheter aortic valve implantation in 2017: state of the art. *EuroIntervention*. 2017 Sep 24;13.



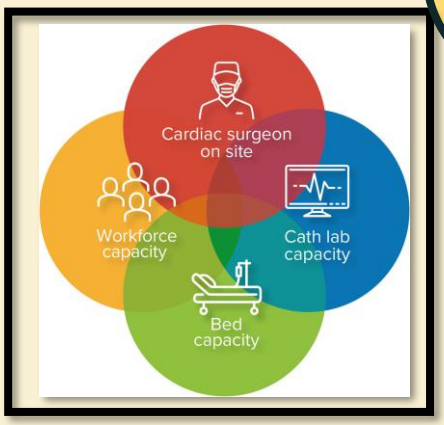
The Electrocardiogram After Transcatheter Aortic Valve Replacement Determines the Risk for Post-Procedural High-Degree AV Block and the Need for Telemetry Monitoring

Stefan Toggweiler, MD,[a] Stefan Stortecky, MD,[b] Erik Holy, MD,[c] Katarzyna Zuk, MD,[b] Florim Cuculi, MD,[a] Fabian Nietlispach, MD,[c] Zaid Sabti, MD,[a] Raluca Suciu, MD,[c] Willibald Maier, MD,[c] Peiman Jamshidi, MD,[a] Francesco Maisano, MD,[c] Stephan Windecker, MD,[b] Richard Kobza, MD,[a] Peter Wenaweser, MD,[b] Thomas F. Lüscher, MD,[c] Ronald K. Binder, MD[c]

Waiting list work-up

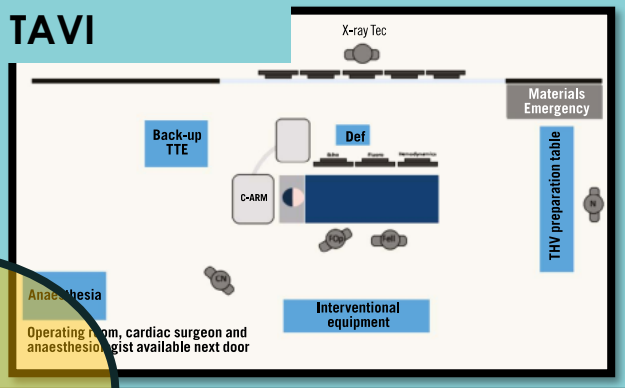
Fast-track pathways

VALVE FOR LIFE
An EAPCI initiative



?

Minimalist TAVI



Heart Valve Centers capacity

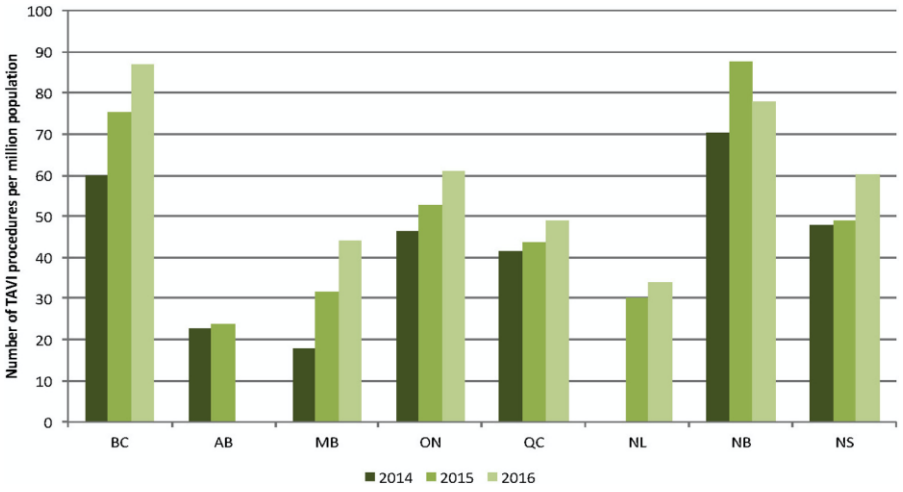
Increase volume capacity ?

Canadian Journal of Cardiology 36 (2020) 844–851

Clinical Research

Inequity in Access to Transcatheter Aortic Valve Replacement: A Pan-Canadian Evaluation of Wait-Times

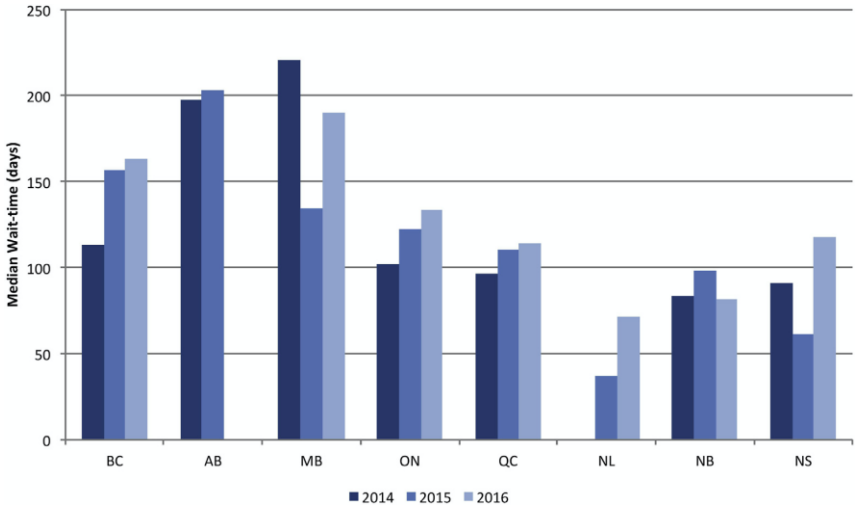
Harindra C. Wijeysundera, MD, PhD,[a,b,c] Kayley A. Henning, MPH,[b] Feng Qiu, MSc,[b] Corey Adams, MD, MMSc,[d] Faisal Al Qoofi, MD,[e] Anita Asgar, MD, MSc,[f] Peter Austin, PhD,[b,c,g] Kevin R. Bainey, MD, MSc,[h] Eric A. Cohen, MD,[a] Benoit Daneault, MD,[i] Stephen Fremes, MD,[a] Malek Kass, MD,[j] Dennis T. Ko, MD, MSc,[a,b,c] Laurie Lambert, PhD,[k] Sandra B. Lauck, PhD,[l] Kendra MacFarlane, MSc,[m] Syed Najaf Nadeem, MD,[n] Garth Oakes, PhD,[o] Vernon Paddock, MD,[p] Marc Pelletier, MD,[q] Mark Peterson, MD,[r] Nicolo Piazza, MD,[s] Brian J. Potter, MD,[t] Sam Radhakrishnan, MD,[a] Josep Rodes-Cabau, MD,[u] Olga Toleva, MD,[j] John G. Webb, MD,[l] Robert Welsh, MD,[h] David Wood, MD,[v,w] Graham Woodward, MSc,[o] and Rodney Zimmermann, MD[x]



32% TAVR procedural volume at Hospital with onsite CS
(46.3 TAVR -> 60.9 TAVR/1.000.000)

27% waiting time

Marked variation between Provinces

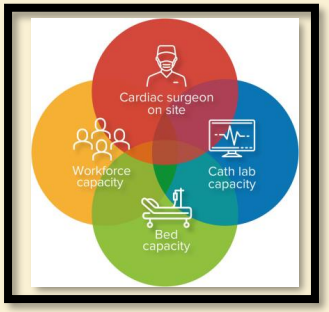


Waiting list work-up

Fast-track pathways

VALVE FOR LIFE
An EAPCI initiative

Heart Valve Centres



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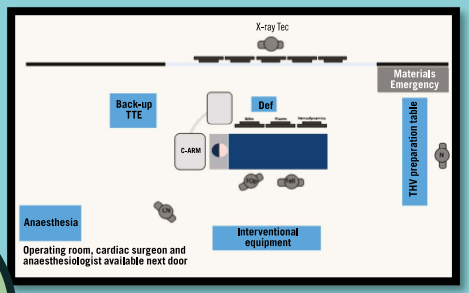
Minimalist TAVI



TAVI AT HOME

Solutions to improve TAVI supply ?

Extend TAVI in Centres without cardiac surgery on site ?

Guidelines

Aortic valve interventions must be performed in Heart Valve Centres that declare their local expertise and outcomes data, have active interventional cardiology and cardiac surgical programmes on site, and a structured collaborative Heart Team approach.

I	C

ESC European Society of Cardiology
European Heart Journal (2021) 00, 1–72
doi:10.1093/eurheartj/ehab395

ESC/EACTS GUIDELINES

2021 ESC/EACTS Guidelines for the management of valvular heart disease

TABLE 11 Structure of Primary and Comprehensive Valve Centers

Comprehensive (Level I) Valve Center	Primary (Level II) Valve Center
Interventional procedures*	
TAVI–transfemoral	TAVI–transfemoral
Percutaneous aortic valve balloon dilation	Percutaneous aortic valve balloon dilation
TAVI–alternative access, including transthoracic (transaortic, transapical) and extrathoracic (eg, subclavian, carotid, caval) approaches	
Valve-in-valve procedures	
TEER	
Prosthetic valve paravalvular leak closure	
Percutaneous mitral balloon commissurotomy	

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Developed in collaboration with and endorsed by the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons

TAVI without on site surgery

Any evidence ?

Transcatheter Aortic Valve Replacement Without On-Site Cardiac Surgery

Ready for Prime Time?

Miriam Compagnone, MD,[a] Gianni Dall'Ara, MD, PhD,[a] Simone Grotti, MD,[a] Andrea Santarelli, MD,[b] Marco Balducelli, MD,[c] Carlo Savini, MD,[d,e] Fabio Felice Tarantino, MD,[a] Marcello Galvani, MD[a,e,f]

https://doi.org/10.1016/j.jcin.2023.09.020

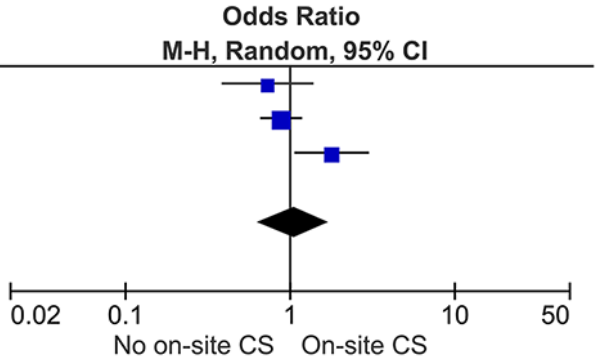
Meta-analysis: TAVI without onsite CS

- **3 comparative studies** TAVI with vs without on-site CS;
- A total of **21173** patients, of which 1800 patients (**8.5%**) group without on-site CS. The outcome was **short-term mortality;**
- Mean age 81 years and LogES>21%.

	No on-site CS		On-site CS			Odds Ratio	
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**	**Year**
Eggebrecht 2014	11	178	104	1254	26.7%	0.73 [0.38, 1.38]	2014
AQUA 2016	50	1332	703	16587	41.8%	0.88 [0.66, 1.18]	2016
Egger 2018	20	290	61	1532	31.6%	1.79 [1.06, 3.01]	2018
Total (95% CI)		**1800**		**19373**	**100.0%**	**1.05 [0.64, 1.71]**	
Total events	81		868				

Heterogeneity: Tau² = 0.13; Chi² = 6.45, df = 2 (P = 0.04); I² = 69%

Test for overall effect: Z = 0.18 (P = 0.85)

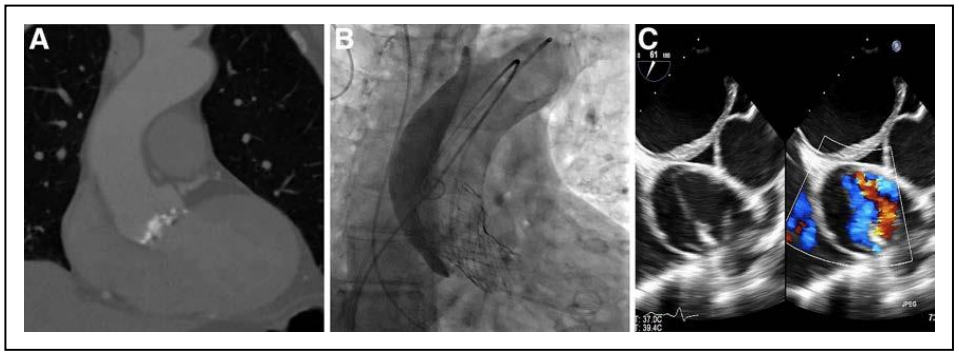


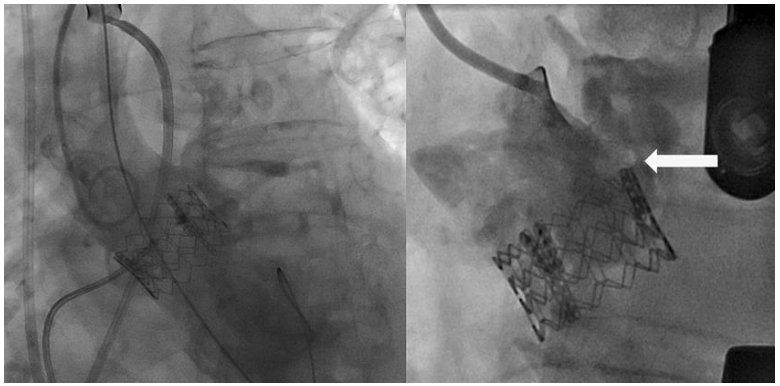
Transcatheter Aortic Valve Replacement Without On-Site Cardiac Surgery

Ready for Prime Time?

Miriam Compagnone, MD,[a] Gianni Dall'Ara, MD, PhD,[a] Simone Grotti, MD,[a] Andrea Santarelli, MD,[b] Marco Balducelli, MD,[c] Carlo Savini, MD,[b,c] Fabio Felice Tarantino, MD,[a] Marcello Galvani, MD[a,e,f]

Why we need on site cardiac surgery ?





- Annular rapture
- Aortic dissection
- Valve migration and embolization
- Coronary obstruction
- Ventricular perforation
- Mitral valve damage

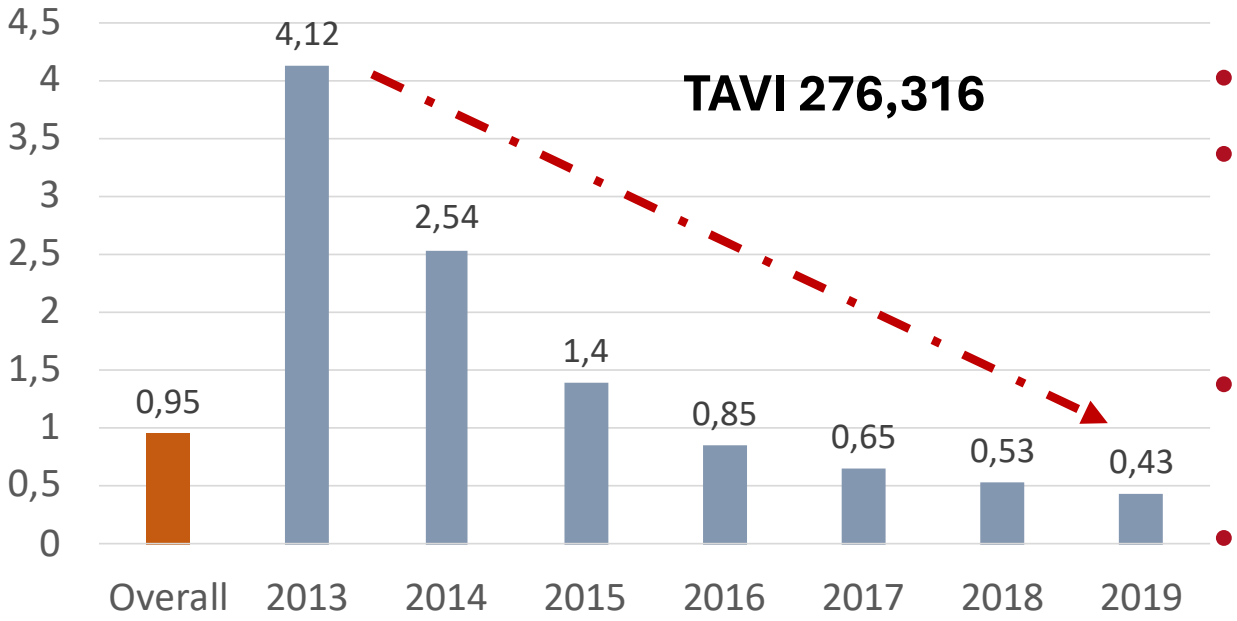
Valve Academic Research Consortium 3: Updated Endpoint Definitions for Aortic Valve Clinical Research

VARC-3 WRITING COMMITTEE: Philippe Généreux,[a] Nicolo Piazza,[b] Maria C. Alu,[c] Tamim Nazif,[c] Rebecca T. Hahn,[c] Philippe Pibarot,[d] Jeroen J. Bax,[e] Jonathon A. Leipsic,[f] Philipp Blanke,[f] Eugene H. Blackstone,[g] Matthew T. Finn,[c] Samir Kapadia,[h] Axel Linke,[i] Michael J. Mack,[j] Raj Makkar,[k] Roxana Mehran,[l] Jeffrey J. Popma,[m] Michael Reardon,[n] Josep Rodes-Cabau,[o] Nicolas M. Van Mieghem,[p] John G. Webb,[q] David J. Cohen,[r] Martin B. Leon[c]

Emergent cardiac surgery

STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement

John D. Carroll, MD,[a] Michael J. Mack, MD,[b] Sreekanth Vemulapalli, MD,[c] Howard C. Herrmann, MD,[d] Thomas G. Gleason, MD,[e] George Hanzel, MD,[f] G. Michael Deeb, MD,[g] Vinod H. Thourani, MD,[h] David J. Cohen, MD, MSc,[i] Nimesh Desai, MD, PhD,[j] Ajay J. Kirtane, MD, SM,[k] Susan Fitzgerald, MSN, RN,[l] Joan Michaels, MSN, RN,[l] Carole Krohn, BSN, RN,[m] Frederick A. Masoudi, MD, MSPH,[a] Ralph G. Brindis, MD, MPH,[n] Joseph E. Bavaria, MD[j]



- Operator **expertise**;
- Less frequent use of the **trans-apical access**;
- Development of **new devices**;
- **Imaging techniques**.

Emergent cardiac surgery

- In a registry including 10,314 TAVI,(January 2021 and June 2023) the rate of ECS was **0.2%** after SAPIEN 3Ultra Resilia valve implantation.

STRUCTURAL

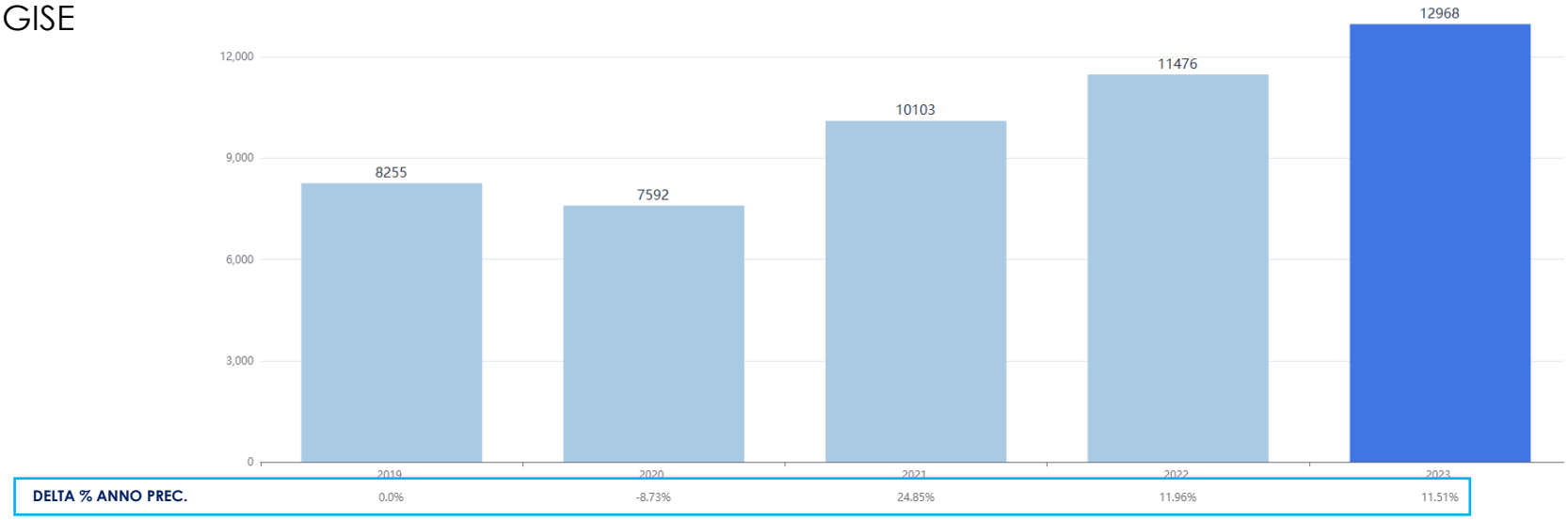
Real-World Outcomes for the Fifth-Generation Balloon Expandable Transcatheter Heart Valve in the United States

Curtiss T. Stinis, M
JACC: Cardiovascular Intervention VOL. 17, NO. 8, 2024
APRIL 22, 2024:1032–1044

Need to emergent cardiac surgery

TAVI	2019 8255 pt	2020 7592 pt	2021 10103 pt	2022 11478 pt	2023 12968 pt	TOTALE 50396
CCH conversion	16 (**0.2%**)	22 (**0.3%**)	14 (**0.1%**)	19 (**0.2%**)	23 (**0.2%**)	94 (**0.2**%)
Compl. Vasc.	119 (1.4%)	214 (2.8%)	478 (4.7%)	435 (3.8%)	424 (3.3%)	1670 (3.3%)
Compl. Vasc. surgery	-	109 (1.4%)	166 (1.6%)	112 (1.0%)	113 (0.9%)	500 (1.2%)

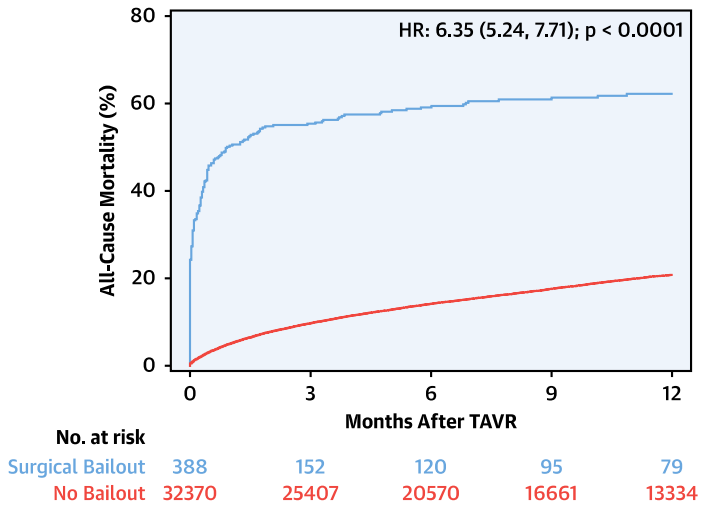
Audit GISE

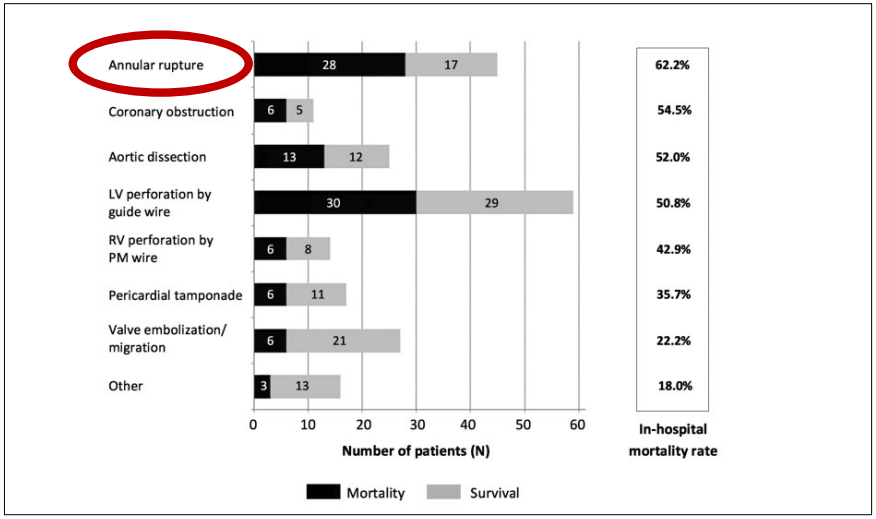


Outcome of Emergent Cardiac Surgery

- ECS is associated with significantly worse outcomes, even in the optimal setting including CS;
- **50% in-hospital mortality.**

Incidence and outcomes of emergent cardiac surgery during transfemoral transcatheter aortic valve implantation (TAVI): insights from the European Registry on Emergent Cardiac Surgery during *TAVI* (EuRECS-TAVI)





Incidence and Outcomes of Surgical Bailout During TAVR

Insights From the STS/ACC TVT Registry

Andres M. Pineda, MD,[a] J. Kevin Harrison, MD,[b] Neal S. Kleiman, MD,[c] Charanjit S. Rihal, MD,[d] Sucheel K. Kodali, MD,[e] Ajay J. Kirtane, MD,[f] Martin B. Leon, MD,[e] Matthew W. Sherwood, MD,[f] Pratik Manandhar, MS,[c] Sreekanth Vemulapalli, MD,[b] Nirat Beohar, MD[a]

TAVI AT HOME

TAVI at Home

Transfemoral **T**ranscatheter **A**ortic **V**alve **I**mplantation (TAVI) **At H**ospital without on-site cardiac surgery: early clinical **O**utco**ME**

Studio interventistico, multicentrico ed a singolo braccio.

Obiettivo dimostrare la **sicurezza** e **l'efficacia** della TAVI in centri con caratteristiche HUB per l'emergenza cardiologica in assenza cardiochirurgia on-site.

TAVI AT HOME

SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Unità Sanitaria Locale della Romagna

TAVI at Home

200 PATIENTI

20 PATIENTI

First step

- **AUSL Romagna – Forlì**
- **AUSL Romagna – Ravenna**
- **AUSL Romagna – Rimini**
- **Hospital Del Mar – Barcellona**
- **Ospedale 'F. Miulli' – Bari**

Interim analysis

- Saranno ammessi al massimo **4 eventi** per considerare la percentuale di mortalità ancora nel range di variabilità di quella standard.

180 PATIENTI

Second step

- AORN Cardarelli, Napoli
- ASST Fatebenefratelli Sacco, Milano
- Ospedale Cardinal Massaia, Asti
- ASST Rhodense-Rho, Milano

TAVI AT HOME

SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Unità Sanitaria Locale della Romagna

TAVI at Home

TAVI AT HOME

SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Unità Sanitaria Locale della Romagna

Endpoint primario → Mortalità a 30 gg

Endpoint secondario → Successo tecnico → Singole componenti del successo tecnico

Valve Academic Research Consortium 3: Updated Endpoint Definitions for Aortic Valve Clinical Research

VARC-3 WRITING COMMITTEE: Philippe Généreux,[a] Nicolo Piazza,[b] Maria C. Alu,[c] Tamim Nazif,[c] Rebecca T. Hahn,[c] Philippe Pibarot,[d] Jeroen J. Bax,[e] Jonathon A. Leipsic,[f] Philipp Blanke,[f] Eugene H. Blackstone,[g] Matthew T. Finn,[c] Samir Kapadia,[h] Axel Linke,[i] Michael J. Mack,[j] Raj Makkar,[k] Roxana Mehran,[l] Jeffrey J. Popma,[m] Michael Reardon,[n] Josep Rodes-Cabau,[o] Nicolas M. Van Mieghem,[p] John G. Webb,[q] David J. Cohen,[r] Martin B. Leon[c]

Technical success (at exit from procedure room)

- Freedom from mortality
- Successful access, delivery of the device, and retrieval of the delivery system
- Correct positioning of a single prosthetic heart valve into the proper anatomical location
- Freedom from surgery or intervention related to the device* or to a major vascular or access-related, or cardiac structural complication

TAVI at Home

CRITERI DI INCLUSIONE

Età **≥ 75** anni

Pazienti con **rischio proibitivo**

Accesso **transfemorale**

Consenso informato

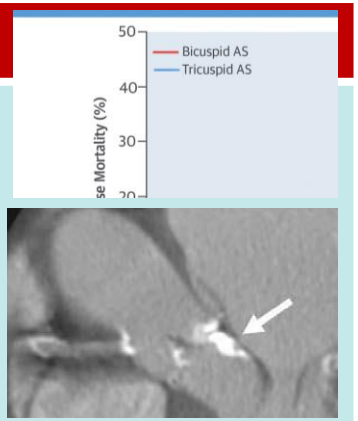
CRITERI DI ESCLUSIONE

Bicuspidi

VIV

Alto rischio complicanza strutturale maggiore

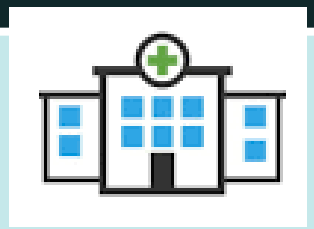
(calcificazioni LVOT, osti coronarici bassi)



VARC-2 .A. P. Kappetein et al. European Journal of Cardio-Thoracic Surgery 42 (2012) S45–S60.

TAVI at Home

CARATTERISTICHE DEI CENTRI



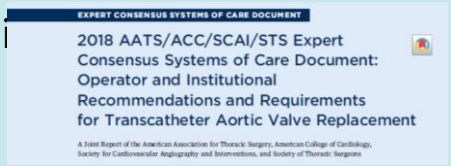
Presente regolare attività di TAVI con sistemi organizzativi differenti
> **36 TAVI/anno** (3/mese preferibilmente > 5/mese)
Terapia intensiva III livello
Chirurgia vascolare
Cardiochirurgia in rete con percorso di trasferimento in emergenza entro 60 minuti

CARATTERISTICHE DEGLI OPERATORI

Presente un **Team Leader**

- **≥ 30 TAVI/anno** da primo operatore da > **3 anni**
- Esperienza sul coronarico, sull'uso dei device endovascolari e sulla gestione di complicanze periferiche

Formazione di **infermieri** e **tecnici** per preparare i pazienti, utilizzare i di
gestire le complicanze periprocedurali

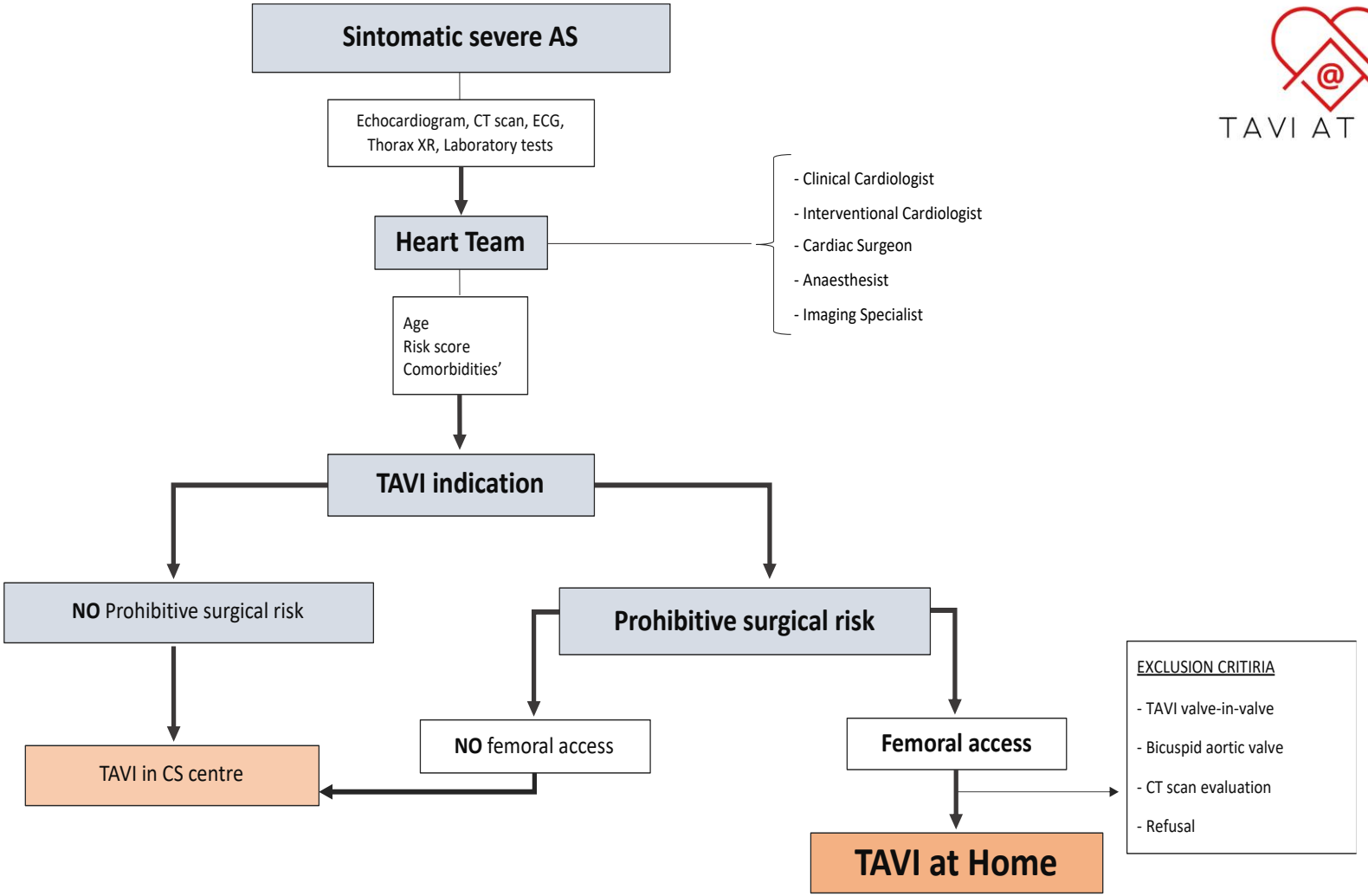

EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT

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, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

[Updated SICI-GISE position paper on institutional and operator requirements for transcatheter aortic valve implantation]
G Ital Cardiol (Rome). 2018 Sep;19(9):519-529.

TAVI at Home


Sintomatic severe AS
Echocardiogram, CT scan, ECG, Thorax XR, Laboratory tests
Heart Team
- Clinical Cardiologist
- Interventional Cardiologist
- Cardiac Surgeon
- Anaesthesist
- Imaging Specialist
Age
Risk score
Comorbidities'
TAVI indication
NO Prohibitive surgical risk
Prohibitive surgical risk
TAVI in CS centre
NO femoral access
Femoral access
EXCLUSION CRITIRIA
- TAVI valve-in-valve
- Bicuspid aortic valve
- CT scan evaluation
- Refusal
TAVI at Home

TAVI at Home

200 PAZIENTI

42 TAVI ESEGUITE

5 TAVI PROGRAMMATE

First step

- **AUSL Romagna – Forlì**
- **AUSL Romagna – Ravenna**
- **AUSL Romagna – Rimini**
- **Ospedale 'F. Miulli' – Bari**
- **Hospital del Mar, - Barcellona (ESP)**

20 PAZIENTI

Interim analysis

- Saranno ammessi al massimo **4 eventi** per considerare la percentuale di mortalità ancora nel range di variabilità di quella standard.

Second step

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- ASST Fatebenefratelli Sacco, M
- Ospedale Cardinal Massaia, As
- ASST Rhodense-Rho, Milano

180 PAZIENTI

TAVI AT HOME

TAVI at HOME: patients characteristics

Variable	Overall, n=20 (%)
Age	
Median (range)	87 (80-93)
Sex	
Male	13 (65)
Female	7 (35)
Prohibitive risk classification (according Varc-2 consensus)	
Porcelain aorta	5 (25)
Fragility	9 (45)
Presence of a patent graft of an internal mammary artery crossing midline and/or adherent to posterior table of sternum	6 (30)
High surgical risk	10 (50)

TAVI AT HOME

TAVI at HOME: patients characteristics

Variable	Overall, n=20 (%)
Clinical features	
High blood pressure	16 (80)
Dyabetes	5 (25)
Prior myocardial infarction	4 (20)
Prior coronary artery bypass graft (CABG)	5 (25)
Prior aortic valvuloplasty	10 (50)
Symptoms	
Syncope	2 (10)
Coronary acute syndrome	2 (10)
Dyspnea	20 (100)
NYHA classification	
Class II	6 (30)
Class III	10 (50)
Class IV	4 (20)

TAVI AT HOME

TAVI at HOME: procedure details and complication

Variable	Overall n=20 (%)
Procedure	
Performed	20 (100)
Valve type	
Balloon expandable	7 (35)
Self-expanding	13 (65)
Technical success	
Yes	19 (95)
No	1 (5)
Uncorrected positioning of a single prosthetic heart valve into the proper anatomical location	1 (5)
Complications	
Bleeding	6 (30)
Type 1	4 (20)
Type 2	1 (5)
Type 3	0 (0)
Type 4	1 (5)
Acute neurological events	1 (5)
TIA	1 (5)
Stroke	0 (0)
Myocardial infarction	1 (5)
Vascular complications	2 (10)
Major	1 (5)
Minor	1 (5)
Valve malposition	1 (5)
Valve migration	1 (5)
New permanent pacemaker implantation	5 (25)
New onset atrial fibrillation	1 (5)
Rehospitalization	1 (5)
Other	1 (5)

Variable	Overall, n=20 (%)
Procedure	
Performed	20 (100)
Procedural death	0
Follow-up	
Performed	16 (80)
Death during follow-up	0
To be performed	4 (20)

TAVI AT HOME

Take-Home messages

Performing TAVI in qualified **Centres without on-site CS** could be possible and may have significant **advantages**:

- **shortening wait time** for TAVI, which could **reduce** the waiting-list **mortality** and morbidity;
- not performing TAVI with low-procedural risk in **Valve Centres** may increase their availability for more complex procedures;
- TAVI without CS backup could also be important to ensure **equal access** to treatment, particularly in Countries where the number of Valve Centres is limited.

TAVI-at-HOME messages

- ✓ The TAVI at Home study expresses the **current need to increase the volume of TAVI**
- ✓ It represents an **effective and reproducible organizational model** consisting of HUB hemodynamic centers that perform TAVI with CCH in a network
- ✓ The **correct selection of patients in the Heart Team** and the adequate expertise of the centers/operators are fundamental
- ✓ In addition to **reducing waiting lists**, it will be possible to lighten the overload of the Heart Valve Centers

Grazie !!