PERCORSO INTRAOSPEDALIERO: APPROPRIATEZZA DELL'INDICAZIONE A TAVI

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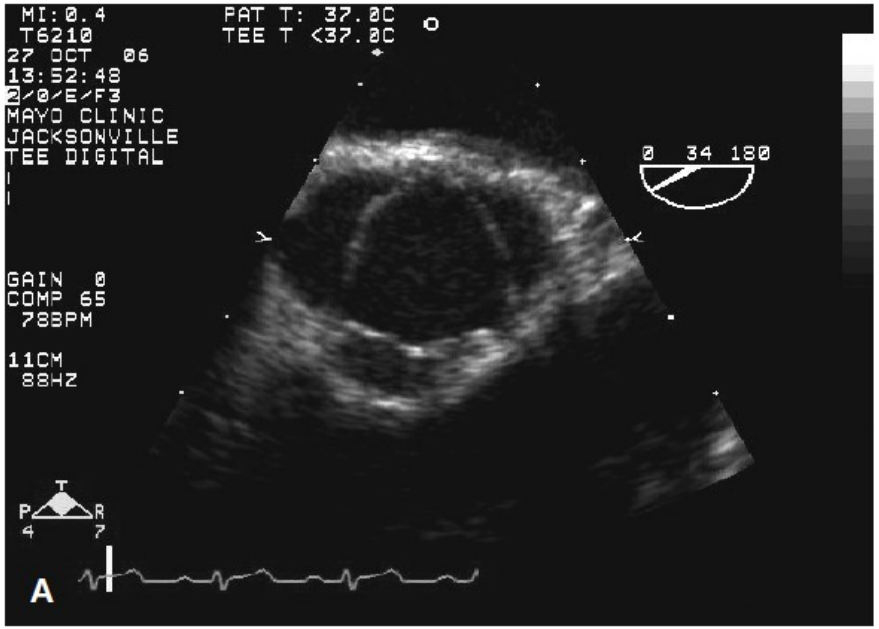
HUMANITAS
GAVAZZENI

Ordine dei Medici Chirurghi
e Odontoiatri
della provincia di Bergamo

MERCOLEDÌ 5 OTTOBRE 2022

STENOSI VALVOLARE AORTICA: QUANDO E COME INTERVIENE IL CARDIOLOGO INTERVENTISTA CON PROCEDURA TAVI

Background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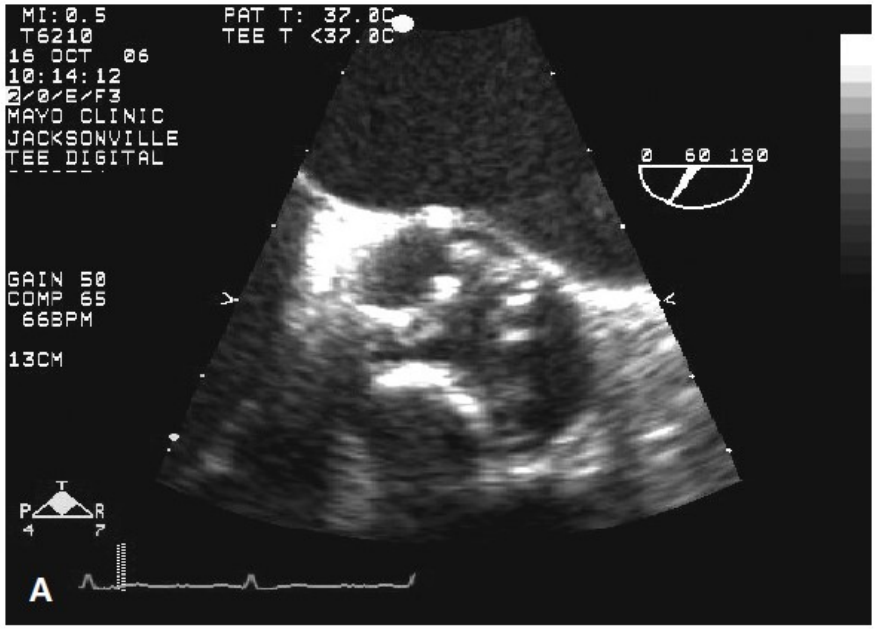
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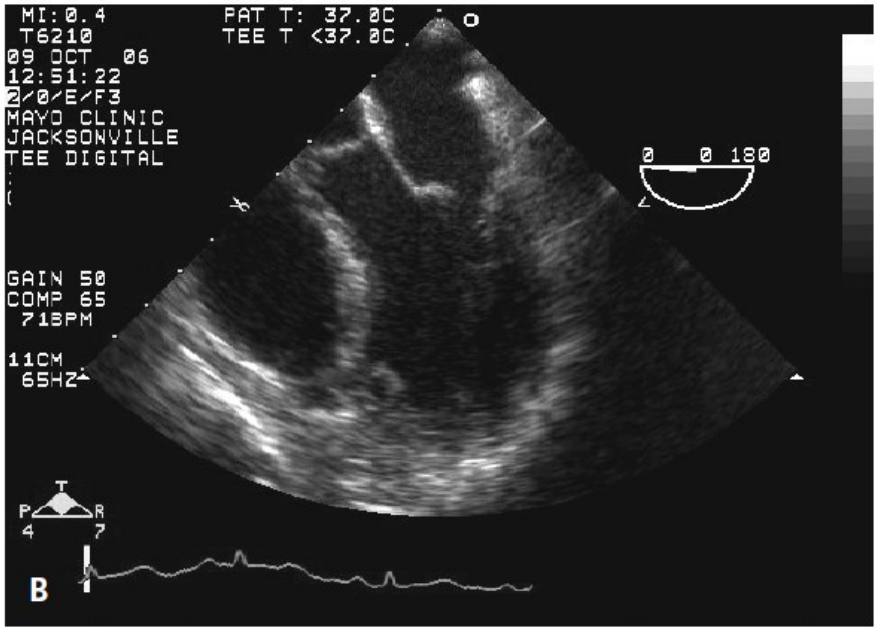
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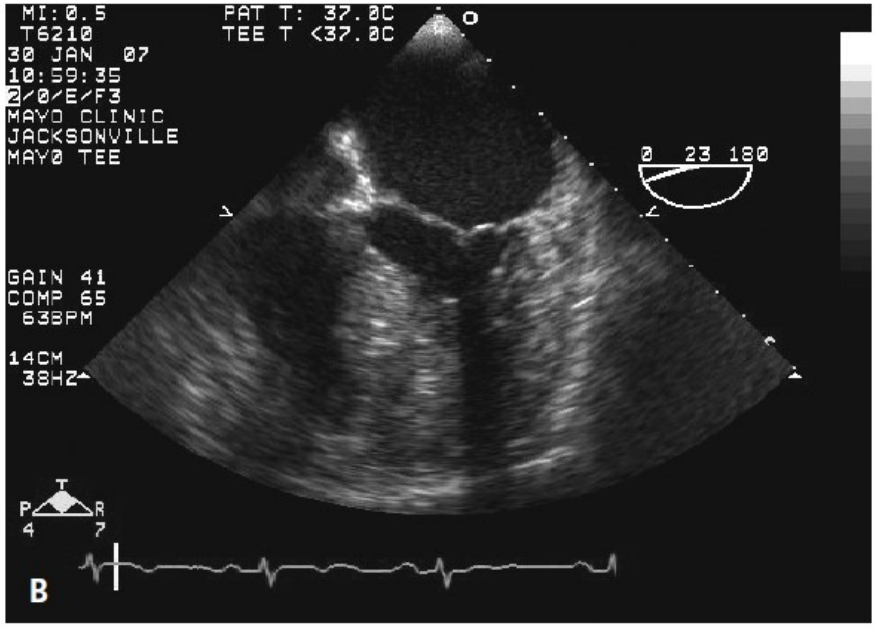
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Background

Aortic Stenosis

By JOHN ROSS, JR., M.D. AND EUGENE BRAUNWALD, M.D.

Supplement V to Circulation, Vols. XXXVII and XXXVIII, July 1968

Aortic stenosis

Blase A Carabello, Walter J Paulus

Lancet 2009; 373: 956–66

Pathophysiology and relation to symptoms

Onset of severe symptoms of aortic stenosis—angina, syncope, and heart failure—remains the major demarcation point in the disease's course (figure 1).[19] The asymptomatic patient has a good outlook even with severe obstruction, whereas an individual with symptoms has a mortality rate of about 25% per year. Thus, knowing how the pathophysiology of aortic stenosis causes symptoms and death is paramount to understanding the disease.

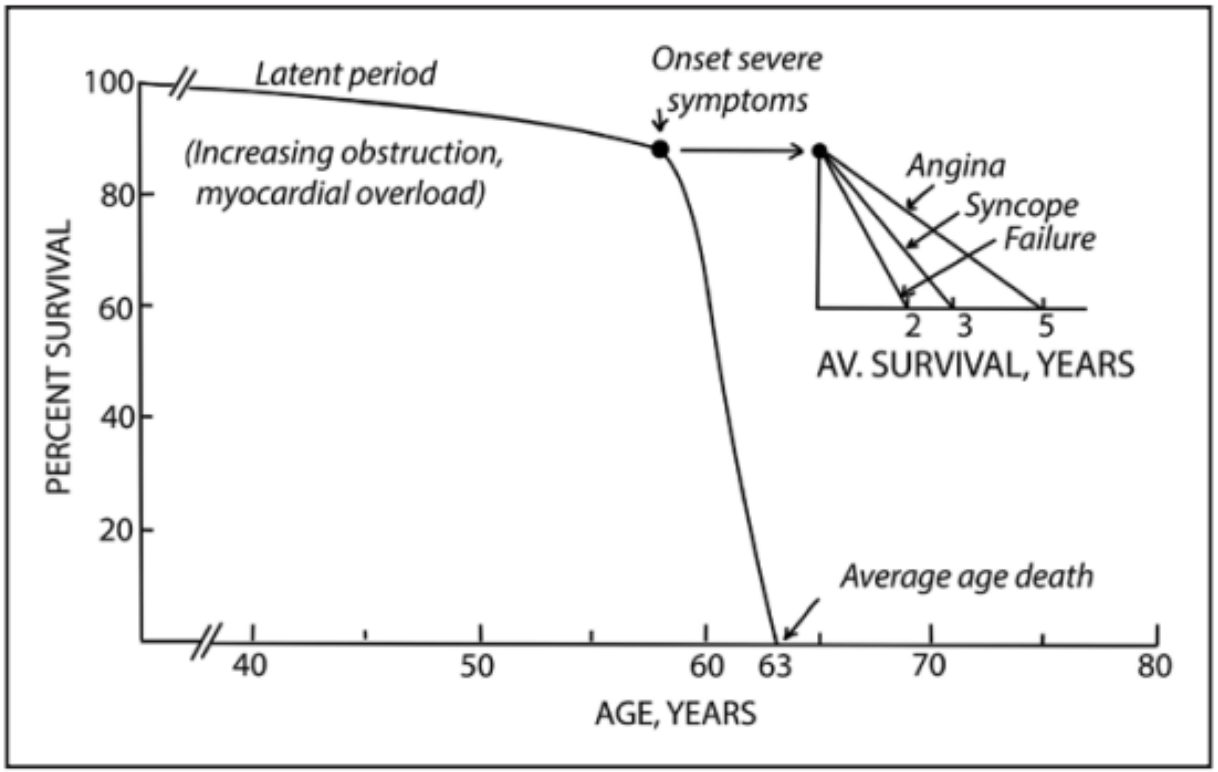

Figure. Valvular aortic stenosis in adults.
Average course (postmortem data). Reproduced from Ross and Braunwald[4] with permission of the publisher. Copyright © 1968, American Heart Association.

Background

Aortic stenosis

Blase A Carabello, Walter J Paulus

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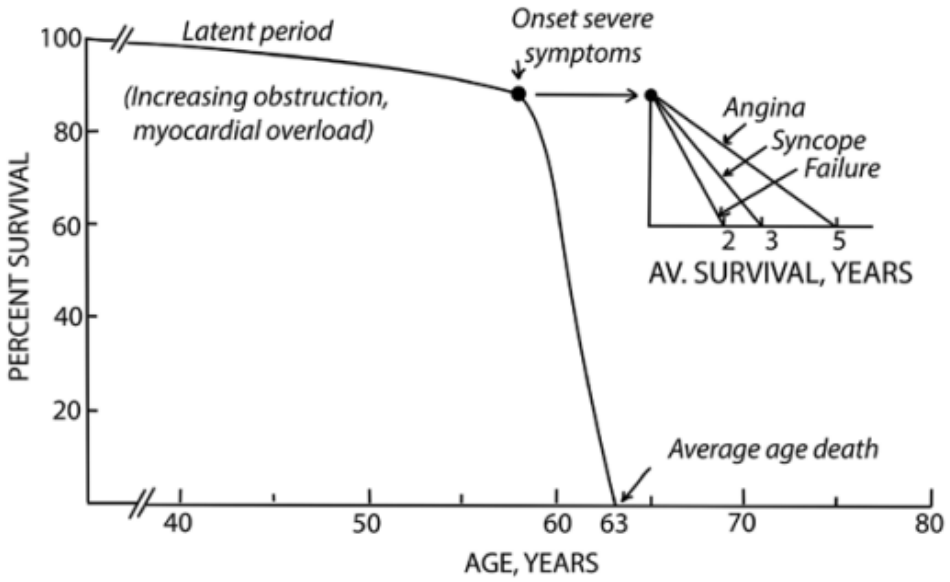
Unfortunately, hypertrophy is a double-edged sword, beneficial in some respects and deleterious in others. Although it helps to preserve ejection performance, hypertrophy also impairs coronary blood-flow reserve, reduces diastolic function, and is associated with increased mortality.[24–30]



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In all other circulatory beds, oxygen delivery to tissues can be augmented by both a boost in blood flow to the region and an increase in oxygen extraction from haemoglobin. The heart is unique among all organs in that its blood flow is received mainly during diastole and oxygen extraction is always close to maximum. Thus, the only way in which the myocardium can match enhanced oxygen demand with increased supply is by boosting coronary blood flow. In healthy individuals, coronary blood flow reserve is 500–800% over resting flow; however, in the presence of concentric hypertrophy, reserve is diminished, usually to about 200–300%.[26] This impairment could be secondary to reduced capillary ingrowth into the hypertrophied myocardium.[27] Additionally, the increased filling pressure needed to distend the thickened ventricular wall compresses the endocardium, further impairing blood flow to that layer of the myocardium. These abnormalities must contribute to the cause of angina in patients who develop it in the presence of normal epicardial coronary arteries. However,

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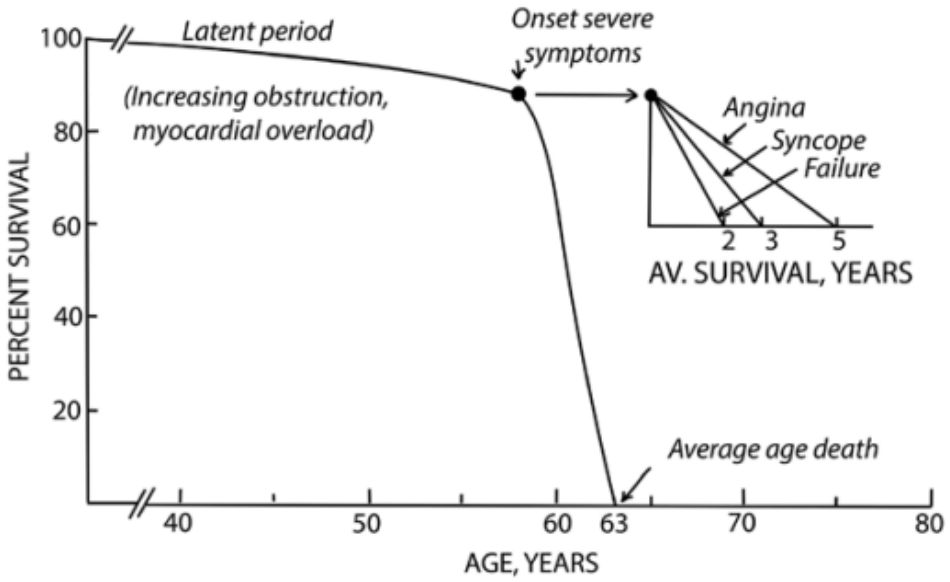

Pathophysiology and relation to symptoms

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syncope usually arises during exercise. In healthy individuals, blood pressure rises during exercise. Blood pressure is equal to cardiac output multiplied by total peripheral resistance. In healthy people, total peripheral resistance falls during exercise but blood pressure increases because cardiac output rises more than total peripheral resistance diminishes. One theory is that the augmented stroke volume that usually accompanies exercise is limited in aortic stenosis by the narrowed outflow orifice. Since there is a requisite decrease in arterial resistance, blood pressure drops leading to syncope. Indeed, a fall in blood pressure during exercise has been noted in patients with aortic stenosis.[43] Other researchers[44] have postulated that the very high intraventricular pressure that develops during exercise in people with aortic stenosis causes a reflex depressor response, in turn causing syncope (ie, vasoplegic syncope). Finally, in some individuals, ventricular arrhythmias potentiated by exercise-induced ischaemia might also produce syncope. Such people are at risk for postoperative

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Aortic stenosis

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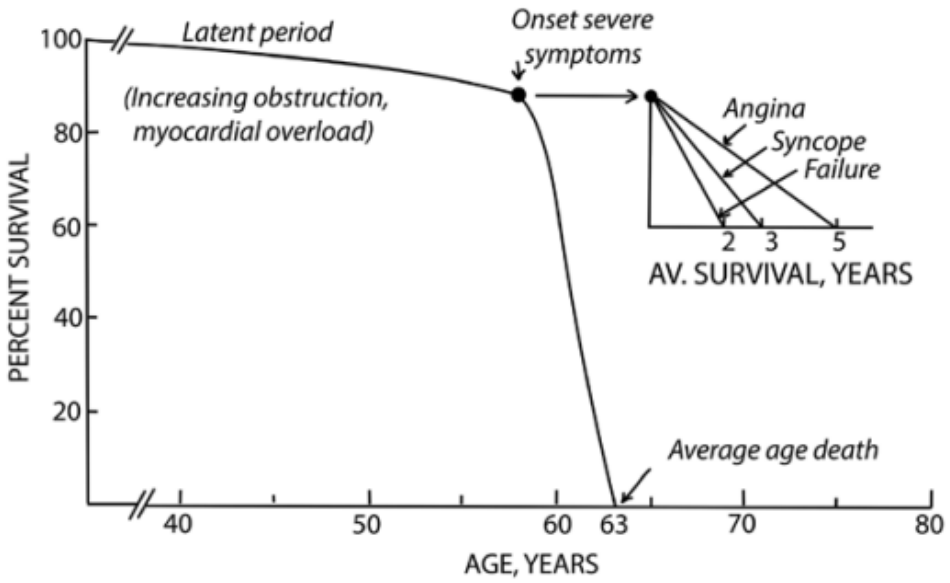


Pathophysiology and relation to symptoms

Onset of severe symptoms of aortic stenosis—angina, syncope, and heart failure—remains the major demarcation point in the disease's course (figure 1).[19] The asymptomatic patient has a good outlook even with severe obstruction, whereas an individual with symptoms has a mortality rate of about 25% per year. Thus, knowing how the pathophysiology of aortic stenosis causes symptoms and death is paramount to understanding the disease.

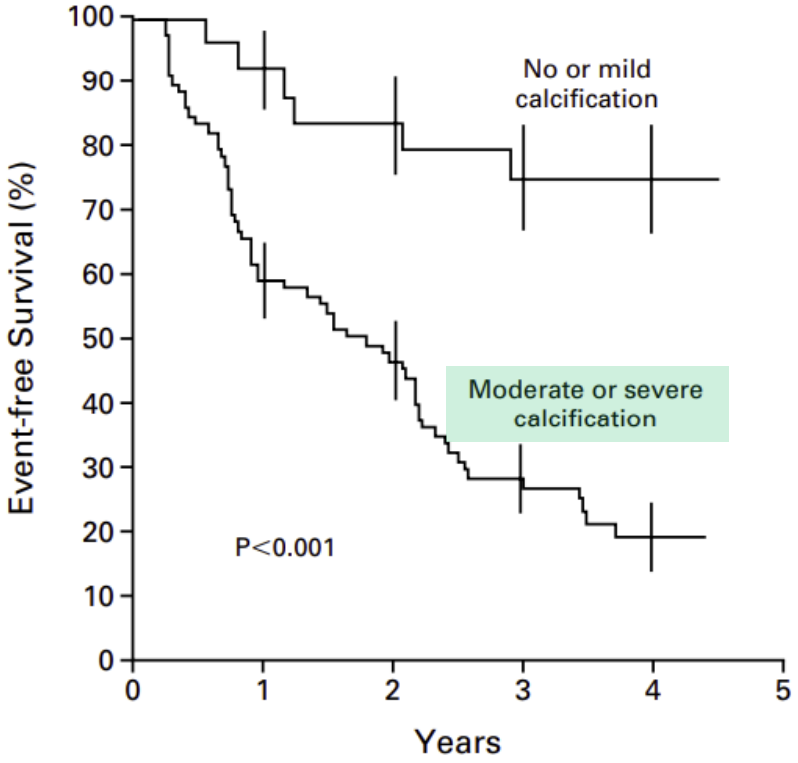
Onset of dyspnoea and other symptoms of heart failure presage the worst outlook for the patient with aortic stenosis. Whereas concentric hypertrophy helps to maintain systolic performance, increased wall thickness impairs diastolic function. Diastole is typically divided into active relaxation and passive filling. During active relaxation, calcium is pumped back into the sarcoplasmic reticulum, causing the contractile interaction between actin and myosin to diminish. In concentric hypertrophy, this process is delayed, in turn holding up the onset of passive filling, shortening the time for blood to pass from the atria to the ventricles.[30] Furthermore, increased wall thickness needs amplified distending pressure to achieve the same diastolic volume as noted in a healthy individual.[31] This augmented diastolic pressure leads to pulmonary congestion and dyspnoea.

Concentric hypertrophy is not compensatory in all cases. In some patients, hypertrophy fails to normalise afterload,[32] allowing the abnormal afterload to reduce ventricular ejection performance, reducing cardiac output, adding to the heart failure syndrome. Eventually, contractile function also fails (figure 2),[33] further restricting ejection

Background

PREDICTORS OF OUTCOME IN SEVERE, ASYMPTOMATIC AORTIC STENOSIS

RAPHAEL ROSENHEK, M.D., THOMAS BINDER, M.D., GEROLD PORENTA, M.D., IRENE LANG, M.D., GÜNTHER CHRIST, M.D., MICHAEL SCHEMPER, PH.D., GERALD MAURER, M.D., AND HELMUT BAUMGARTNER, M.D.



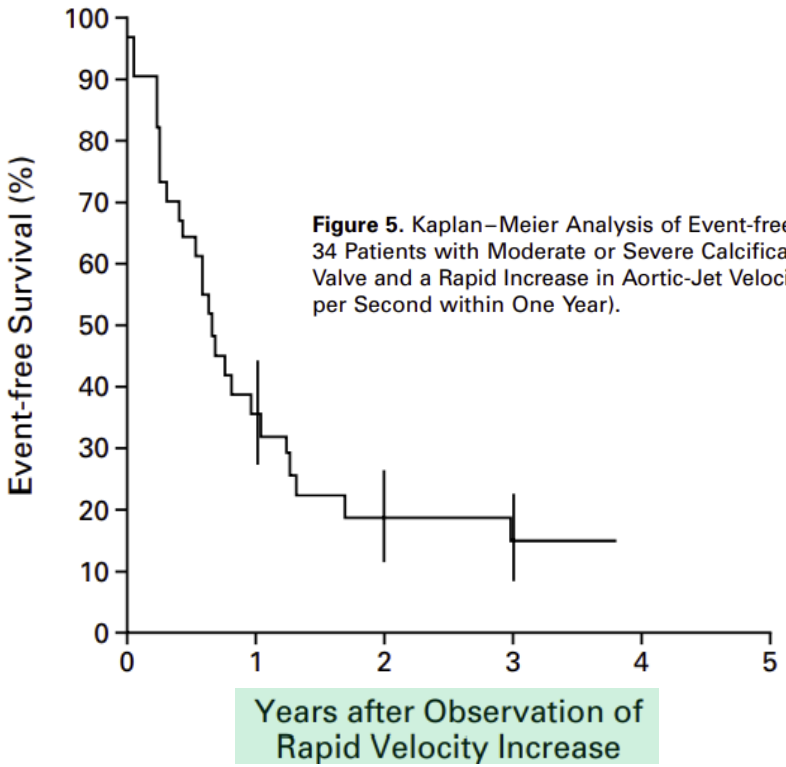


Figure 5. Kaplan–Meier Analysis of Event-free Survival among 34 Patients with Moderate or Severe Calcification of the Aortic Valve and a Rapid Increase in Aortic-Jet Velocity (at Least 0.3 m per Second within One Year).

Conclusions In asymptomatic patients with aortic stenosis, it appears to be relatively safe to delay surgery until symptoms develop. However, outcomes vary widely. The presence of moderate or severe valvular calcification, together with a rapid increase in aortic-jet velocity, identifies patients with a very poor prognosis. These patients should be considered for early valve replacement rather than have surgery delayed until symptoms develop. (N Engl J Med 2000; 343:611-7.)

Circulation

PERSPECTIVE

Aortic Stenosis

Then and Now

Eugene Braunwald, MD

Circulation. 2018;137:00–00.
DOI: 10.1161/CIRCULATIONAHA.118.033408

Background

- In North America and Western Europe, a large majority of adults with severe AS now are older than the patients we dealt with a half-century ago, and they usually have calcific (degenerative) rather than rheumatic disease.
- Despite the improvements in medical therapy for heart failure, the prognosis of patients with severe, symptomatic AS remains poor without the relief of the obstruction.
- Echocardiography and other contemporary imaging techniques permit the identification of patients who, although still in the latent period, are at high risk of early progression to the late stage, that is, who in Wood's words are "just before the onset of (serious) symptoms."[2]
- Transcatheter replacement of the aortic valve represents an enormous advance in the care of these patients.[5]
- The risks of replacement of severely stenotic aortic valves, by both surgery and the transcatheter route, have declined greatly. Early mortality in patients with preserved left ventricular function and without serious comorbidity has fallen to 1% to 4% in most centers, and almost all survivors describe improvement in the quality of their lives. As a consequence, patients are undergoing valve replacement at progressively earlier stages than heretofore.

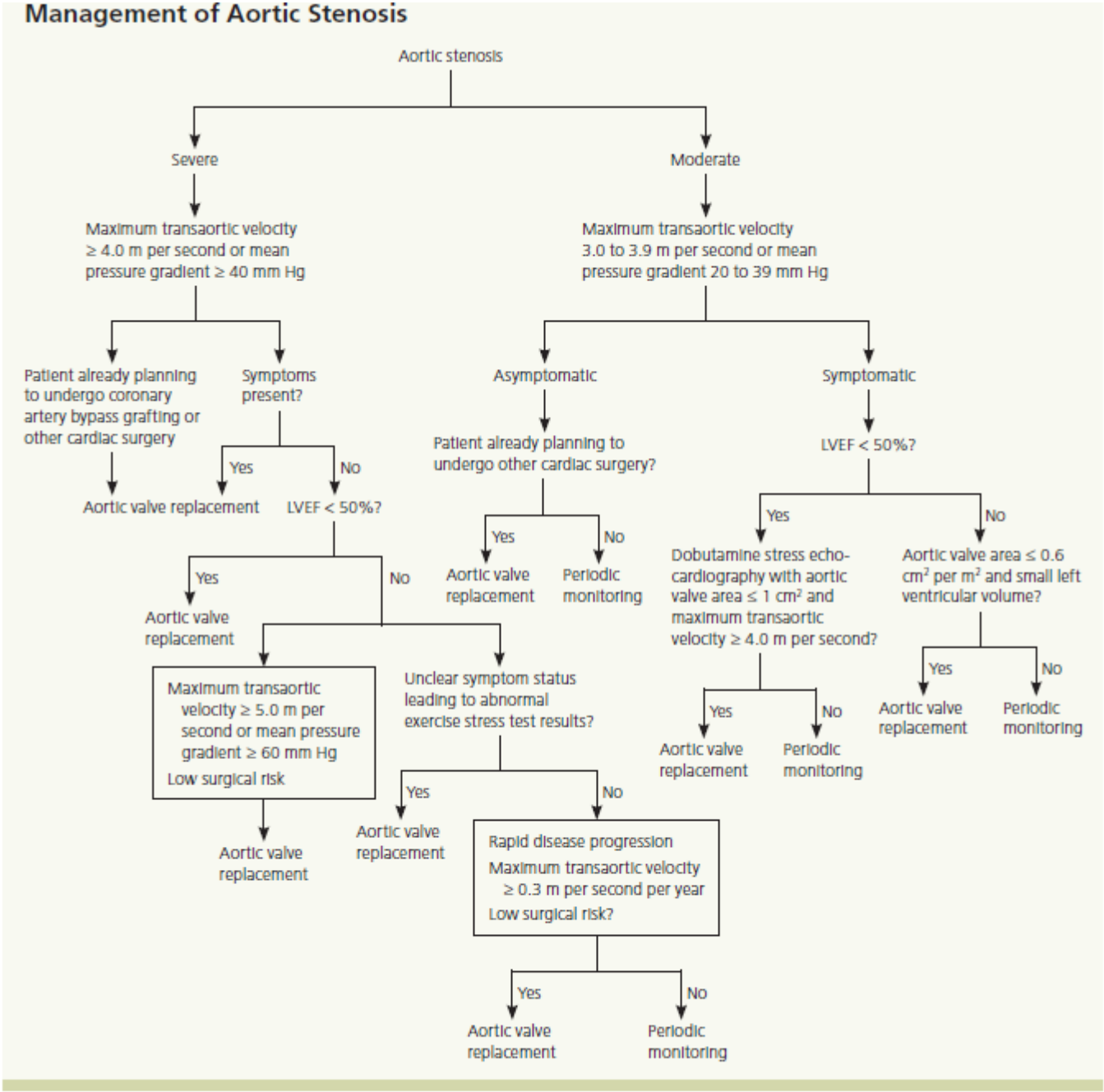


Figure 3. American College of Cardiology/American Heart Association algorithm for the management of aortic stenosis. (LVEF = left ventricular ejection fraction.)

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

	High risk patients*			Inoperable patients		
	TAVI	AVR	P value	TAVI	Control	P value
No of patients	348	351		179	179	
1 year all cause mortality (% (No of events))§	24.2 (84)	26.8 (89)	0.44	30.7 (55)	50.7 (89)	<0.001
1 year stroke rate (% (No of events))¶	8.3 (27)	4.3 (13)	0.04	10.6 (19)	4.5 (8)	0.04

TAVI= transcatheter aortic valve implantation, AVR=surgical aortic valve replacement.

*Hazard ratio with TAVI in high risk patients: 0.93 (95% CI 0.71 to 1.22; P=0.62)

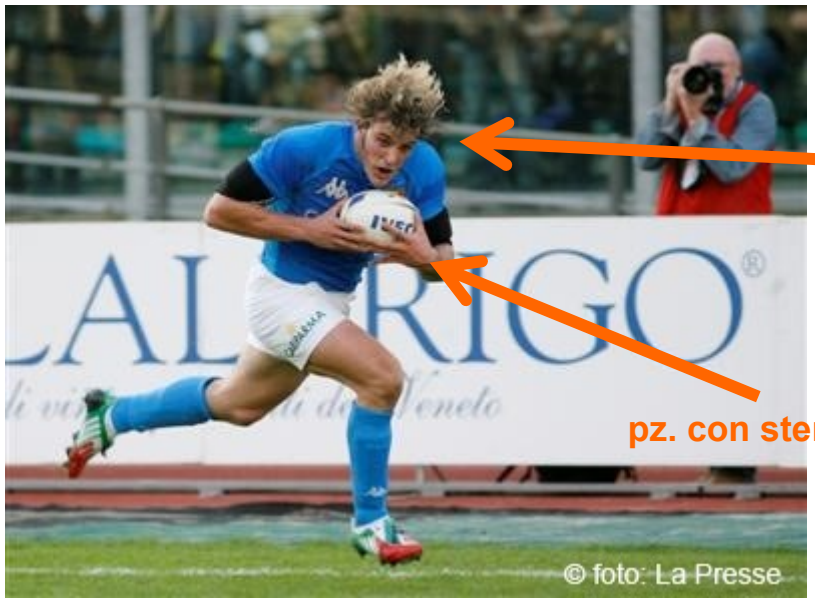
†Hazard ratio with TAVI in inoperable patients (pivotal trial): 0.55 (95% CI 0.40 to 0.74; P<0.001);

‡No P value or hazard ratio was published for the continued access study.

§ Kaplan-Meier estimates.

¶ Includes any stroke and transient ischaemic attack; stroke rate in continued access study includes “major stroke” only.

2009



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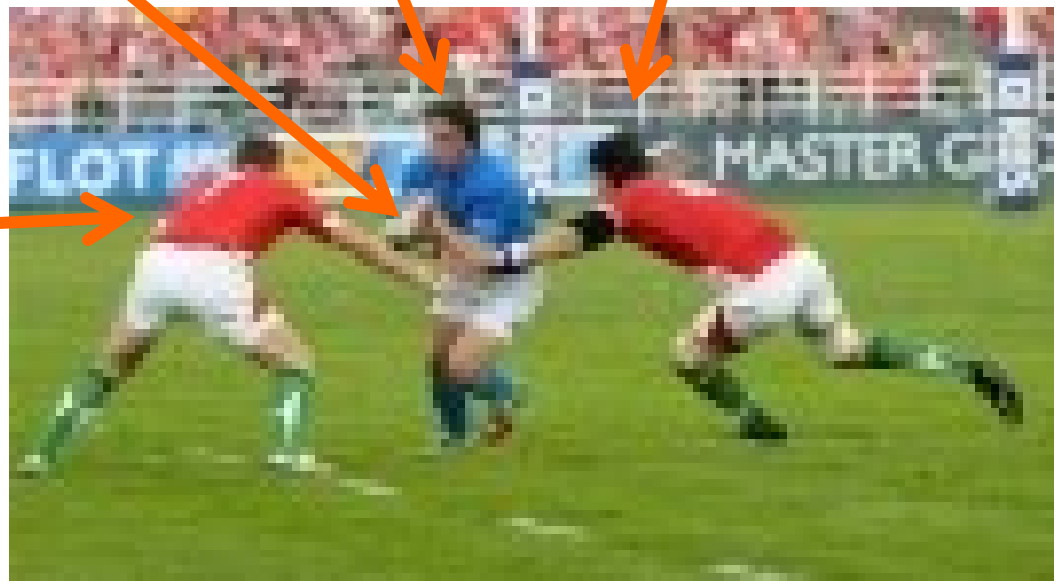

BMJ

BMJ 2012;345:e4710 doi: 10.1136/bmj.e4710 (Published 31 July 2012)

Transcatheter aortic valve implantation (TAVI): risky and costly

Many of the 40 000 transcatheter procedures so far carried out cannot be justified on medical or cost effectiveness grounds. **Hans Van Brabandt**, **Mattias Neyt**, and **Frank Hulstaert** examine why practice has gone beyond the evidence

Hans Van Brabandt *researcher*[1 2], Mattias Neyt *researcher*[1], Frank Hulstaert *researcher*[1]

[1]KCE, Belgian Health Care Knowledge Centre, Administratief Centrum Kruidtuin, Kruidtuinlaan 55, 1000 Brussels, Belgium; [2]CEBAM, Belgian Centre for Evidence-Based Medicine and Branch of the Dutch Cochrane Centre, Leuven, Belgium

Taken together, these results suggest that TAVI can be justified for inoperable patients on clinical grounds, though cost effectiveness calculations are more equivocal. But even this conclusion is thrown into doubt by a follow-up study authorised by the FDA, in which 41 inoperable patients were randomised to TAVI and 49 to standard therapy. This study remains unpublished, and our attempts to gain access to further details have been rebuffed by the FDA and the study sponsor. But the data presented at an FDA meeting on 20 July 2011 showed that the TAVI patients fared worse than those given standard therapy (one year mortality 34.3% *v* 21.6%).[15]

Table 1| **One year mortality and stroke rate in the PARTNER trial13 14 15**

				Inoperable patients				
	High risk patients*			Pivotal trial†			Continued access study‡	
	TAVI	AVR	P value	TAVI	Control	P value	TAVI	Control
No of patients	348	351		179	179		41	49
1 year all cause mortality (% (No of events))§	24.2 (84)	26.8 (89)	0.44	30.7 (55)	50.7 (89)	<0.001	34.3 (13)	21.6 (10)
1 year stroke rate (% (No of events))¶	8.3 (27)	4.3 (13)	0.04	10.6 (19)	4.5 (8)	0.04	2.4 (1)	0 (0)

TAVI= transcatheter aortic valve implantation, AVR=surgical aortic valve replacement.

*Hazard ratio with TAVI in high risk patients: 0.93 (95% CI 0.71 to 1.22; P=0.62)

†Hazard ratio with TAVI in inoperable patients (pivotal trial): 0.55 (95% CI 0.40 to 0.74; P<0.001);

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Based on current evidence, and considering efficient use of limited resources, it is difficult to see how healthcare payers can justify reimbursing TAVI for patients suitable for surgery, given that the risk of stroke is twice as high after TAVI. In addition, TAVI is much more expensive, on average about €20 000 more per patient in our analysis of Belgian data. Based on observational data, the costs during the initial hospital admission, inclusive of an Edwards Sapien valve of €18 000, are on average €43 600 for TAVI versus €23 700 for surgical valve replacement. The average cost of transapical TAVI is higher than for the transfemoral approach (€49 800 *v* €40 900).[26] The


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EDITORIAL COMMENT

Journal of the American College of Cardiology
Vol. 62, No. 11, 2013
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.05.012

Transcatheter Aortic Valve Implantation

A Treatment We Are Going to Need!*

Alec Vahanian, MD, Bernard Iung, MD,
Dominique Himbert, MD

Among the patients denied for surgery, some should not be treated by TAVI because their life expectancy is too short due to comorbidities, and it is unlikely, and probably undesirable, that a larger proportion of such patients will be treated by TAVI in the future because the procedure would not improve their life expectancy or, even more so, their quality of life. We need here to refine the analysis of co-morbidities and especially the evaluation of frailty. Conversely, it is likely that the indication will be extended to lower risk patients because of a better knowledge of the results of TAVI with longer term follow-up and more refined technology. Although we do not yet have sufficient evidence, new trials such as PARTNER (Placement of Aortic Transcatheter Valves) II and SURTAVI (Surgical Replacement and Transcatheter Aortic Valve Implantation) are on the way to answer this question. We also need studies to investigate whether the indications for TAVI can be extended to patients with relative contraindications such as low left ventricular ejection fraction, associated coronary disease, bicuspid valve, bioprosthesis failure, and perhaps aortic regurgitation. Overall, the respective use of TAVI versus surgery will increase in the future, although it is too early to say for certain when and, more importantly, to what extent.

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Aortic Stenosis in the Elderly

Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modeling Study

The number TAVR candidates. Nearly 40.5% of all patients with symptomatic severe AS did not undergo SAVR (Fig. 4B). Possible explanations for the lower than expected rates of SAVR include excessive operative risk, advanced age, comorbidities, and patient preference (21,22). TAVR is a safe, effective, and less invasive treatment strategy for a highly selected proportion of the patients who do not undergo SAVR (23), represented by the 40.3% of patients who underwent TAVR (Fig. 4C). The treatment decisions reflect heart team discussions, in which (interventional) cardiologists and cardiac surgeons combine risk models with additional factors such as frailty, porcelain aorta, and vessel tortuosity (24).

The estimated large number of TAVR candidates has clinical, economic, and social implications. If the index admission costs (US $72,000) of the PARTNER (Placement of Aortic Transcatheter Valves) trial are applied (25), treating all TAVR candidates would represent a budget impact of $13.7 billion in the European countries and $7.2 in North America. At a price of $30,000, the total device turnover would be approximately $8.7 billion.

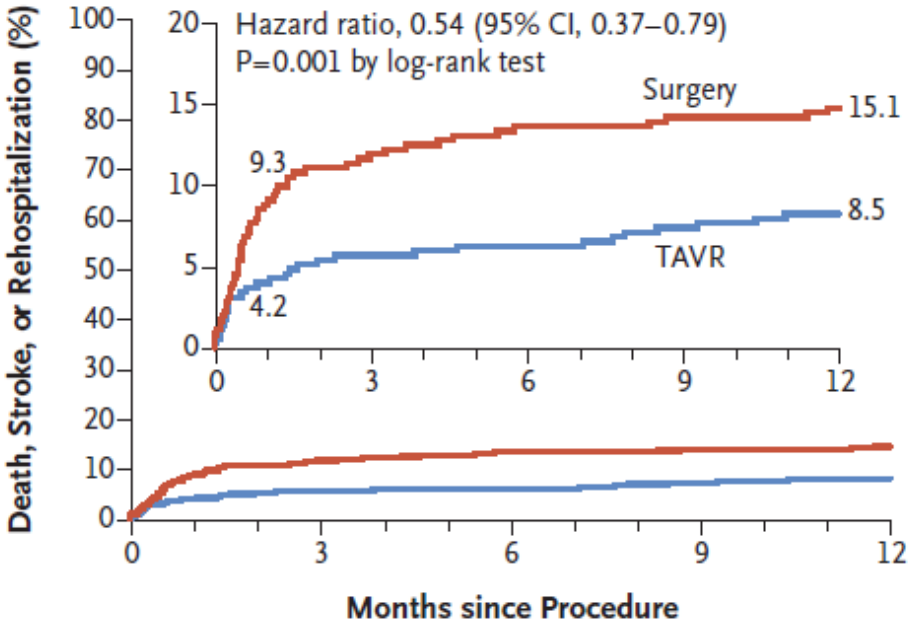
Despite budgetary concerns, current clinical trials are evaluating TAVR for patients at intermediate surgical risk (NCT01314313 and NCT01586910) (9,29). If TAVR proves to be noninferior to SAVR in this population, we estimate that a further 145,000 patients would become TAVR eligible. Indeed, there is some evidence that suggests that TAVR is already being performed in these intermediate-risk patients (18,30). Thus, our estimates of the impact of positive outcomes in the ongoing trials are likely to be conservative. In the future, TAVR may even compete with SAVR in patients at low surgical risk (30,31), a group that comprises 730,000 severe AS patients in the European countries and North America combined.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 2, 2019 VOL. 380 NO. 18

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators*



No. at Risk						
Surgery	454	408	390	381	377	374
TAVR	496	475	467	462	456	451

CONCLUSIONS

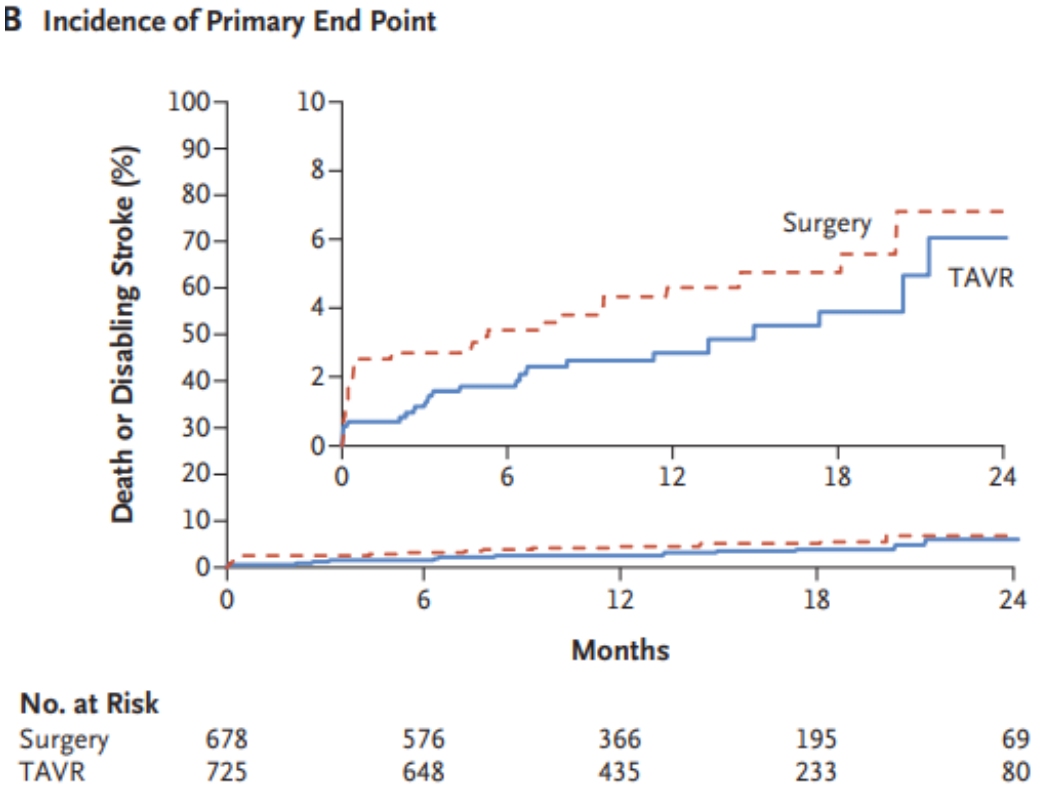
Among patients with severe aortic stenosis who were at low surgical risk, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVR than with surgery. (Funded by Edwards Lifesciences; PARTNER 3 ClinicalTrials.gov number, NCT02675114.)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn III, M.D., John K. Forrest, M.D., Didier Tchétché, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators*



CONCLUSIONS

In patients with severe aortic stenosis who were at low surgical risk, TAVR with a self-expanding supraannular bioprosthesis was noninferior to surgery with respect to the composite end point of death or disabling stroke at 24 months. (Funded by Medtronic; ClinicalTrials.gov number, NCT02701283.)

Transcatheter aortic valve replacement—state of the art and a glimpse to the future: 'the Tailored Approach'

Francesco Bedogni, Alessandro Frigiola, Marco Ranucci, Nedy Brambilla, Rocco Antonio Montone, Mauro Agnifili, Lorenzo Menicanti, and Luca Testa*

European Heart Journal Supplements (2016) **18** (Supplement E), E86–E95
The Heart of the Matter
doi:10.1093/eurheartj/suw017

Transcatheter aortic valve replacement determined a paradigm shift in the treatment of high-risk patients with severe symptomatic aortic valve stenosis. Notwithstanding the impressive results of the first-generation prostheses, a fast-paced technological evolution is taking place to overcome their limitations, in particular the vascular access damage and the paravalvular leak. Nowadays, with the availability of several different devices, the expert operator can select the right prosthesis for the specific anatomical and clinical situation. As 'One does not fit all', the 'Tailored TAVR Approach' we describe will conceivably become the future of this therapy.

Il ruolo dell'Heart Team

Un heart team specializzato è costituito da un gruppo di operatori sanitari qualificati che collaborano per determinare il piano terapeutico migliore per ciascun paziente. Un heart team specializzato si fonda su un approccio multidisciplinare per la selezione del paziente, sfruttando le competenze del cardiologo clinico, dei cardiologi interventisti, dei cardiochirurghi, degli esperti di imaging, degli anestesisti e dell'intero staff del laboratorio di emodinamica e della sala operatoria. Un heart team specializzato potrebbe richiedere delle analisi aggiuntive che contribuiscano a individuare l'opzione terapeutica più appropriata per ciascun paziente.

Il ruolo dell'Heart Team

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STATE-OF-THE-ART PAPER

The Heart Team of Cardiovascular Care

David R. Holmes, Jr, MD,* Jeffrey B. Rich, MD,† William A. Zoghbi, MD,‡ Michael J. Mack, MD,§
Rochester, Minnesota; Norfolk, Virginia; and Houston and Dallas, Texas

The management of complex cardiovascular disease has changed markedly with the development of new strategies of care, an increasing amount of scientific evidence-based data and appropriate use criteria. Applying this plethora of information and synthesizing it for presentation and recommendations to the patient and family have assumed central importance. To facilitate this process of patient centric evidence-based care multidisciplinary Heart Teams have become identified as cornerstones. While specific strategies for implementation of these teams will vary, this broad approach will become the standard of cardiovascular care. (J Am Coll Cardiol 2013;61:903–7) © 2013 by the American College of Cardiology Foundation

Il ruolo dell'Heart Team

STATE-OF-THE-ART PAPER

The Heart Team of Cardiovascular Care

David R. Holmes, Jr, MD,* Jeffrey B. Rich, MD,† William A. Zoghbi, MD,‡ Michael J. Mack, MD,§
Rochester, Minnesota; Norfolk, Virginia; and Houston and Dallas, Texas

In the case of TAVR, the Heart Team consists of the cardiovascular surgeon, the interventional cardiologist, a structural heart disease expert, and imaging specialists, among others. This Heart Team approach has been recommended by multiple specialty societies and is also mandated by regulatory and reimbursement agencies including the U.S. Food and Drug Administration and Centers for Medicare and Medicaid Services based upon several issues (6–8,38). These issues include the facts that there is already an established surgical option, which has been tested over the past 25 years; patients are elderly with multiple comorbidities, making any approach more complicated with higher risks; consideration of TAVR includes evaluation of peripheral arterial access and underlying coronary artery disease, as well as the severity of the aortic stenosis and the presence or absence of LV dysfunction; and, finally, procedural performance improves when both cardiac surgeons and interventional cardiologists perform the procedure together. This combination of facts including the risk/benefit ratio of either surgical AVR, TAVR, or medical therapy requires assessment by a multidisciplinary team to be comfortable with the recommendation to optimize patient care and to educate the patient and the family.

Il ruolo dell'Heart Team

Multidisciplinary transcatheter aortic valve replacement heart team programme improves mortality in aortic stenosis

Dylan R Jones,[1,2] Derek P Chew,[1,2] Matthew J Horsfall,[1] Anthony Ming-Yu Chuang,[1,2] Ajay R Sinhal,[1] Majo X Joseph,[1] Robert A Baker,[3] Jayme S Bennetts,[2,3] Joseph B Selvanayagam,[1,2] Sam J Lehman[1,2]

Jones DR, *et al. Open Heart* 2019;**6**:e000983. doi:10.1136/openhrt-2018-000983

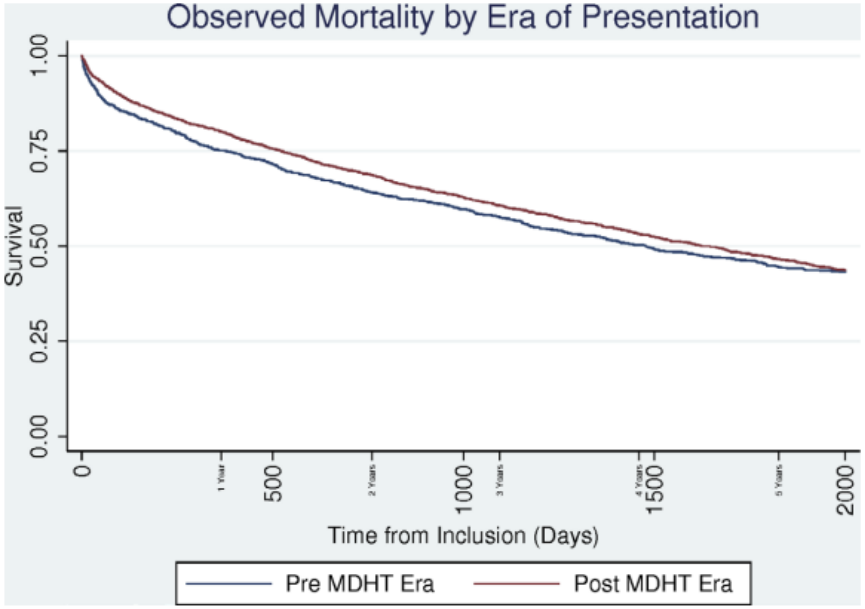


Figure 3 Observed 5-year survival in the population with AS stratified by era of presentation. AS, aortic stenosis; MDHT, multidisciplinary heart team.

CONCLUSIONS

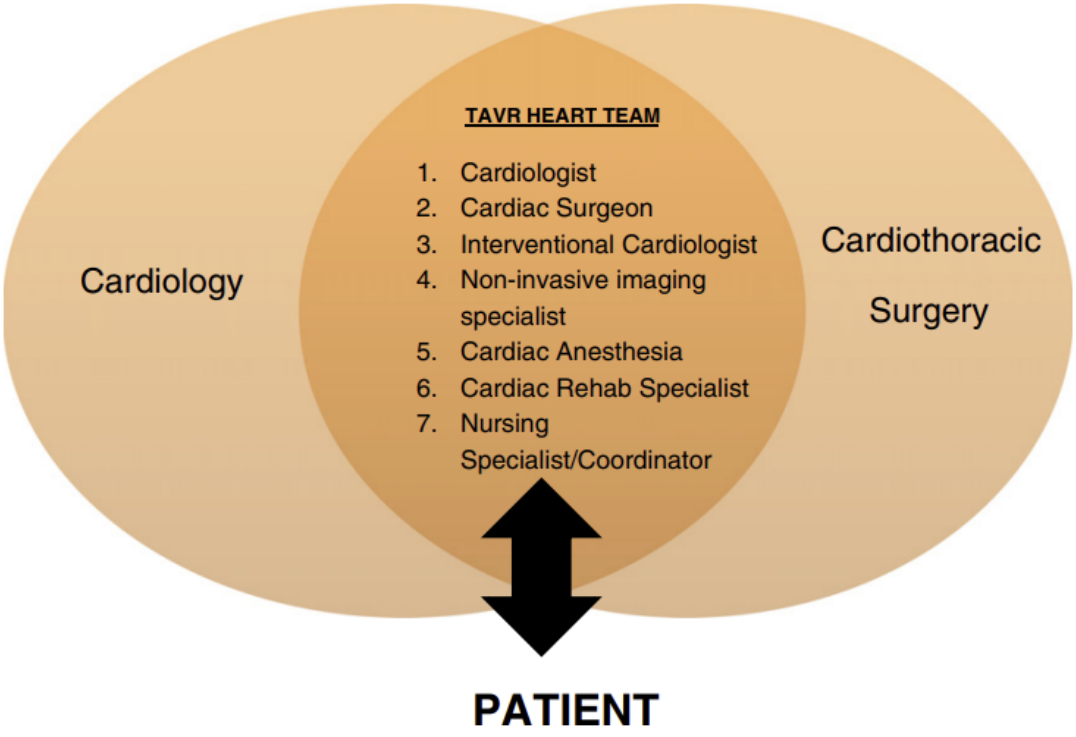
The involvement of an MDHT in a TAVR programme is a class 1C recommendation from both American and European societies as a central concept of AS management, but as far as we are aware, no prior data exist supporting its efficacy.[24] Our data suggest that the addition of TAVR to the long-standing surgical programme for the management of AS along with a functional MDHT is associated with a mortality benefit in the population with severe AS. Even when adjusting for the expansion of the intervention population, a significant mortality benefit remains, possibly due to the MDHT itself, supporting the use of this collaborative method despite the increased organisational difficulty and cost.

Il ruolo dell'Heart Team

Patient Evaluation and Selection for Transcatheter Aortic Valve Replacement: The Heart Team Approach

*Marc Sintek, Alan Zajarias**

PROGRESS IN CARDIOVASCULAR DISEASES 56 (2014) 572–582



Suggested Components of the TAVR heart team. Diagram modified from Holmes et al.

TAVR is successful because of the heart team. The heart team must make careful assessments of patient risk and specific co-morbidities such as renal and pulmonary disease, systolic dysfunction and CAD that have an impact on outcomes. Factors such as frailty are increasingly important to evaluate in the aged TAVR population, and severe fragility may be a contraindication to any procedural reparation of AS. Finally, the complexity of imaging studies needed for patient assessment and operative planning requires a team approach. Patients referred for TAVR are extraordinarily complex and the process of TAVR evaluation is extraordinarily challenging. Without the use of a team, multidisciplinary approach TAVR simply would not be feasible. The heart team will remain a fundamental part of management of TAVR patients, as well as other structural heart disease and complex CVD in the future.

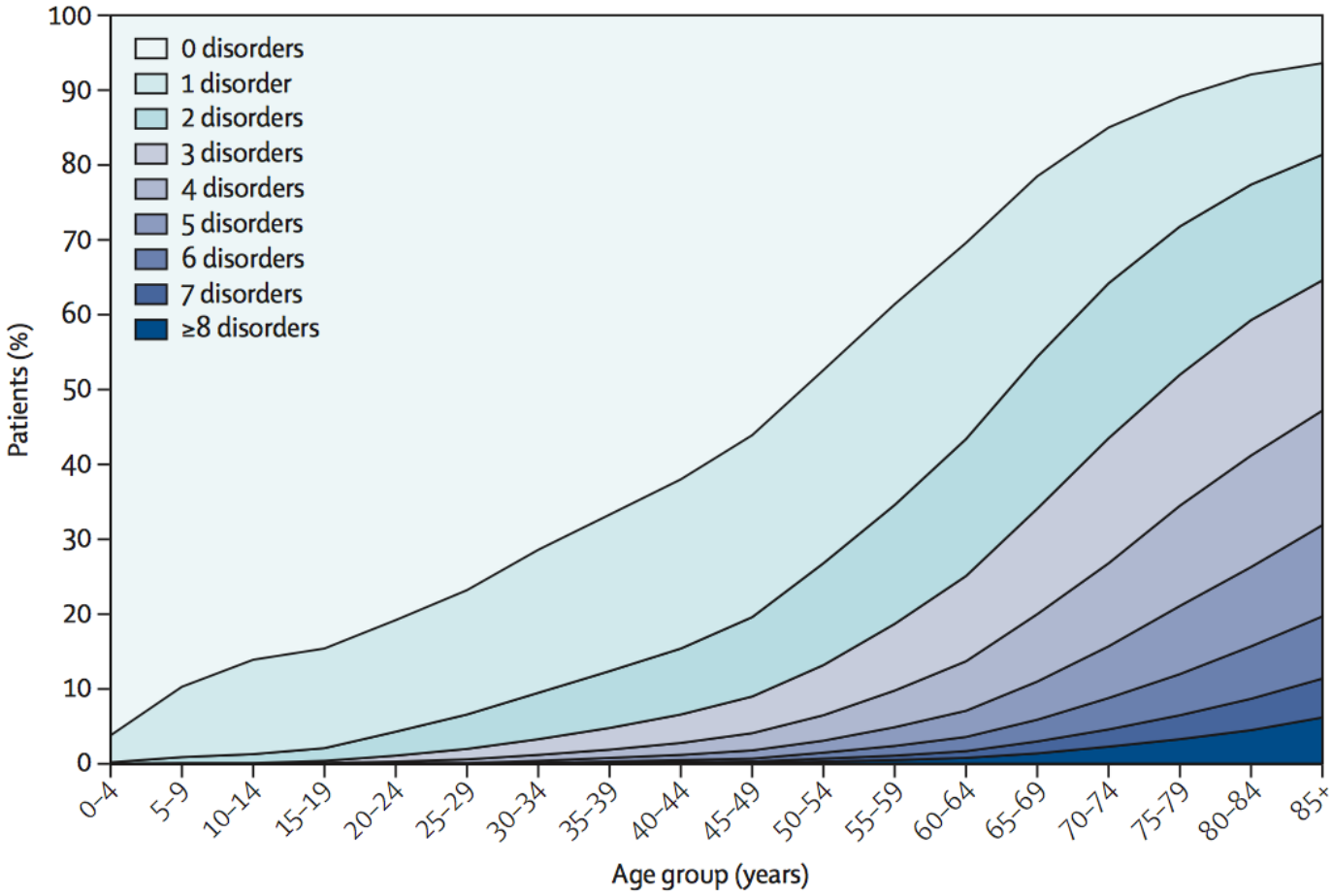
Comorbidities

JAMA | Original Investigation

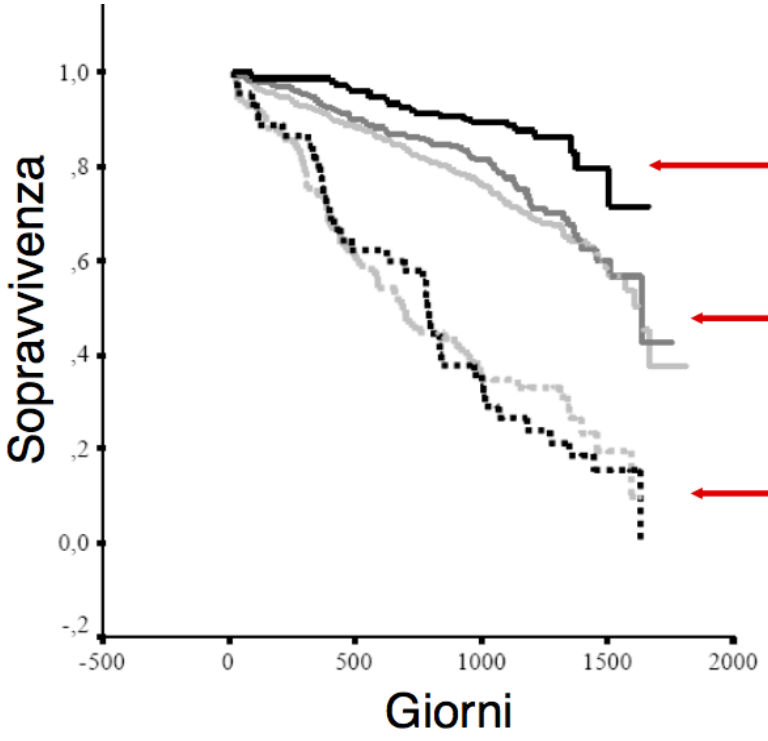
US Spending on Personal Health Care and Public Health, 1996-2013

Joseph L. Dieleman, PhD; Ranju Baral, PhD; Maxwell Birger, BS; Anthony L. Bui, MPH; Anne Bulchis, MPH; Abigail Chapin, BA; Hannah Hamavid, BA; Cody Horst, BS; Elizabeth K. Johnson, BA; Jonathan Joseph, BS; Rouselle Lavado, PhD; Liya Lomsadze, BS; Alex Reynolds, BA; Ellen Squires, BA; Madeline Campbell, BS; Brendan DeCenso, MPH; Daniel Dicker, BS; Abraham D. Flaxman, PhD; Rose Gabert, MPH; Tina Highfill, MA; Mohsen Naghavi, MD, MPH, PhD; Noelle Nightingale, MLIS; Tara Templin, BA; Martin I. Tobias, MBBCh; Theo Vos, MD; Christopher J. L. Murray, MD, DPhil

JAMA. 2016;316(24):2627-2646. doi:10.1001/jama.2016.16885



Disability



No malattie croniche

Malattie croniche (1 o 2+), **senza disabilità**

Malattie croniche (1 o 2+), **con disabilità**

Marengoni A., J Am Geriatr Soc, 2009

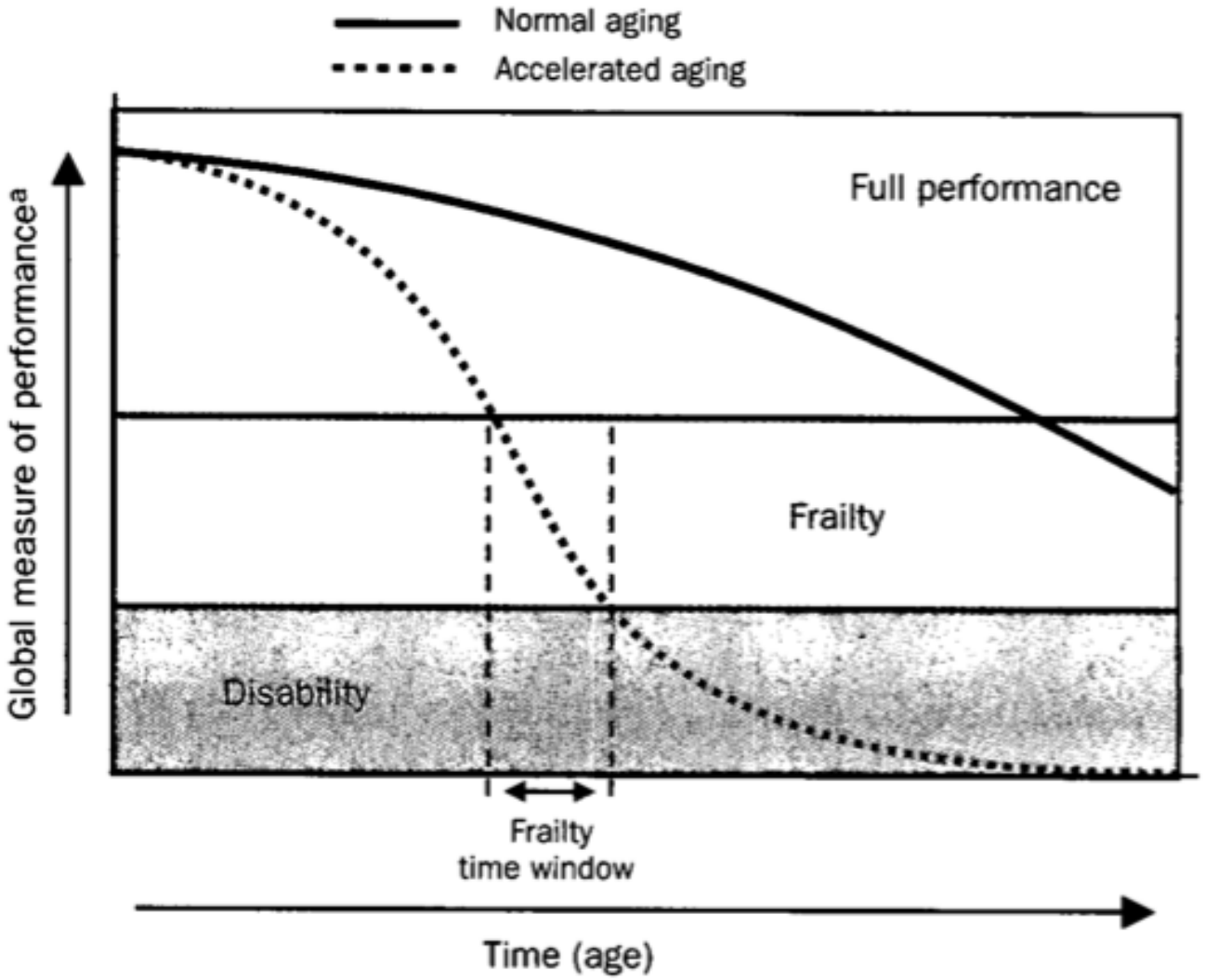
Frailty and disability

REVIEW

Frailty and Its Potential Relevance to Cardiovascular Care

MANDEEP SINGH, MD, MPH; KAREN ALEXANDER, MD; VÉRONIQUE L. ROGER, MD, MPH; CHARANJIT S. RIHAL, MD; HEATHER E. WHITSON, MD; AMIR LERMAN, MD; ARSHAD JAHANGIR, MD; AND K. SREEKUMARAN NAIR, MD

Mayo Clin Proc. 2008;83(10):1146-1153



Frailty

Frailty in elderly people

Andrew Clegg, John Young, Steve Iliffe, Marcel Olde Rikkert, Kenneth Rockwood

Lancet 2013; 381: 752–62
Published Online

Frailty is the most problematic expression of population ageing. It is a state of vulnerability to poor resolution of homoeostasis after a stressor event and is a consequence of cumulative decline in many physiological systems during

- Sindrome multifattoriale, determinata dalla **riduzione della fisiologica riserva funzionale** e della capacità di resistere a eventi stressanti (capacità di omeostasi),
- risultante dal declino cumulativo di molteplici sistemi fisiologici,
- che causa **vulnerabilità agli eventi avversi** ed un elevato rischio di decesso

Walston J et al., J Am Geriatr Soc, 2006

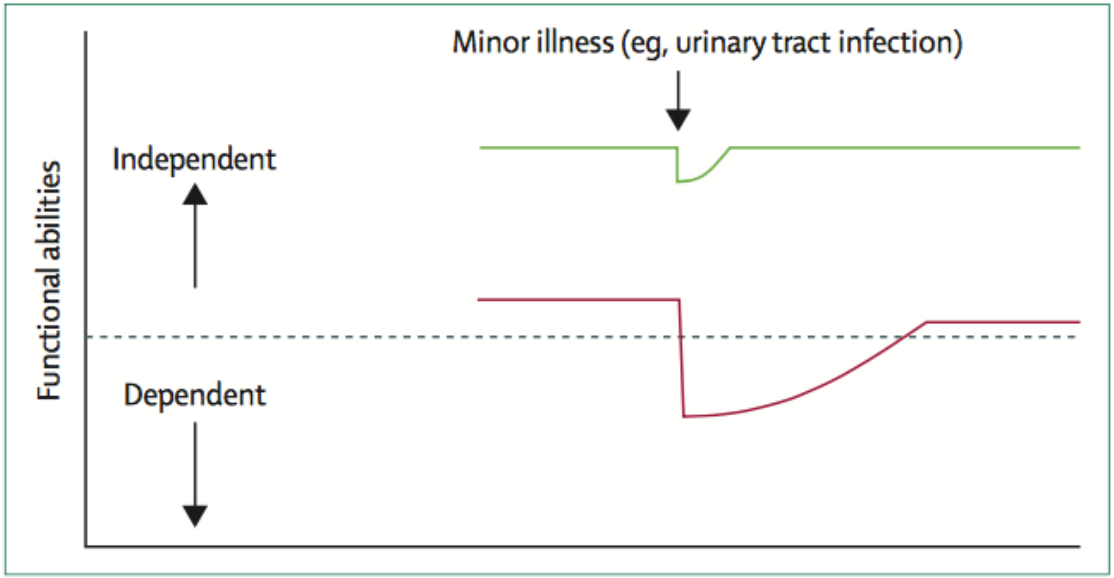
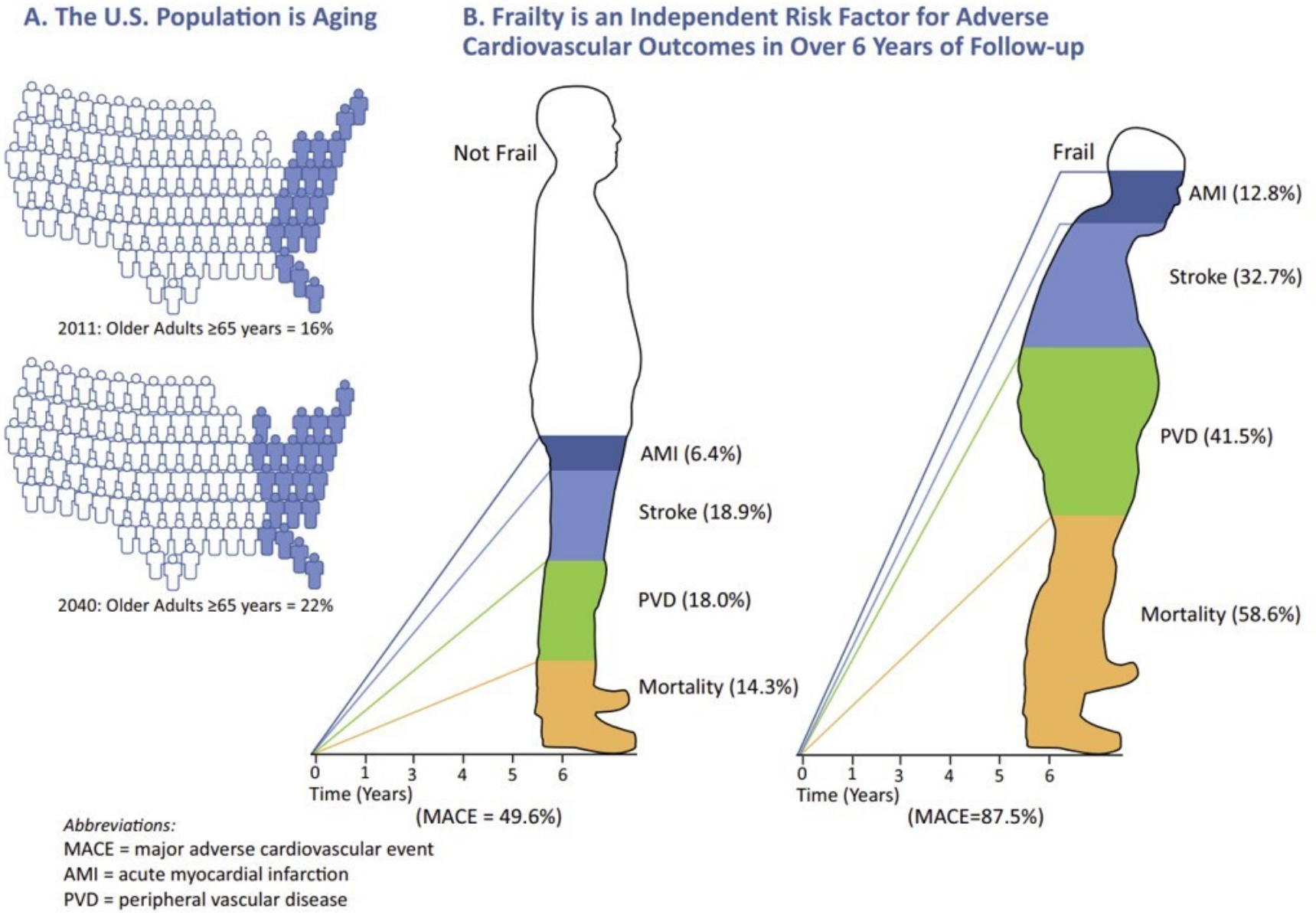


Figure 1: **Vulnerability of frail elderly people to a sudden change in health status after a minor illness**
The green line represents a fit elderly individual who, after a minor stressor event such as an infection, has a small deterioration in function and then returns to homoeostasis. The red line represents a frail elderly individual who, after a similar stressor event, undergoes a larger deterioration, which may manifest as functional dependency, and who does not return to baseline homoeostasis. The horizontal dashed line represents the cutoff between dependent and independent.

Frailty


A. The U.S. Population is Aging
2011: Older Adults ≥65 years = 16%
2040: Older Adults ≥65 years = 22%
B. Frailty is an Independent Risk Factor for Adverse Cardiovascular Outcomes in Over 6 Years of Follow-up
Not Frail
AMI (6.4%)
Stroke (18.9%)
PVD (18.0%)
Mortality (14.3%)
0 1 3 4 5 6
Time (Years)
(MACE = 49.6%)
Frail
AMI (12.8%)
Stroke (32.7%)
PVD (41.5%)
Mortality (58.6%)
0 1 3 4 5 6
Time (Years)
(MACE=87.5%)
Abbreviations:
MACE = major adverse cardiovascular event
AMI = acute myocardial infarction
PVD = peripheral vascular disease

Frailty

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http://dx.doi.org/10.1016/j.jacc.2014.12.042

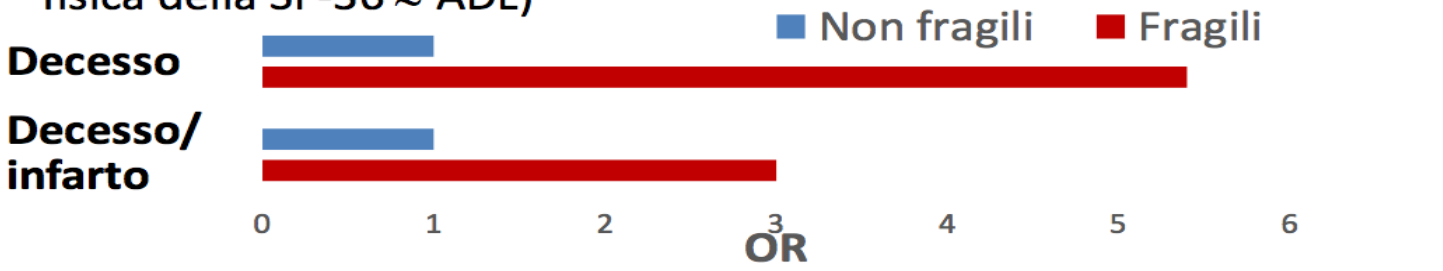
EDITORIAL COMMENT

Which Came First, the Frailty or the Heart Disease?

Exploring the Vicious Cycle*

Kelsey Flint, MD

629 soggetti sottoposti a PTCA (di cui 19% fragili): f/u a 3 anni
Valutazione di fragilità, comorbosità, qualità della vita (componente fisica della SF-36 ≈ ADL)



Variable	C-Statistic (AUC)	C-Statistic Increase	NRI %*	IDI*
Death				
MCRS (rischio cardiovascolare)	0.628			
+Frailty/Intermediate frailty	0.675	0.047	22% (P=0.13)	0.007
+Charlson index for comorbidity	0.671	0.043	34% (P<0.001)	0.016
+Short-form-36 (mental and physical)	0.694	0.066	23% (P=0.010)	0.010
+Frailty, Charlson, and Short-Form-36	0.724	0.097	43% (P=0.007)	0.027

Singh M et al., Circ Cardiovasc Qual Outcomes, 2011

Frailty

Frailty

Patient Evaluation and Selection for Transcatheter Aortic Valve Replacement: The Heart Team Approach

*Marc Sintek, Alan Zajarias**

Division of Cardiology, Barnes Jewish Hospital, Washington University School of Medicine, St Louis, MO

PROGRESS IN CARDIOVASCULAR DISEASES 56 (2014) 572–582

Table 1 – Suggested parameters/tests to evaluate frailty in patients referred for TAVR.

Frailty Test/ Assessment	Description
Grip Strength	Dynamometer; <30 kg in non-obese males and <18 kg in non-obese females abnormal
Gait Speed	>7 s to walk 5 m abnormal
6 min Walk	walk less than 128.5 m during 6 min walk
Comprehensive Assessment of Frailty (CAF)[34]	Grip strength, gait speed, instrumental activities of daily living questionnaire, standing balances test, serum albumin, brain natriuetic peptide and creatinine. Proprietary scoring algorithm used to measure frailty.
Multi-Dimensional Geriatric Assessment (MGA)[21]	Mini-mental state exam, timed get up and go test, basic and instrumental activities of daily living questionnaires. Frailty index score generated and score ≥3 indicated frailty

Conclusion

TAVR is successful because of the heart team. The heart team must make careful assessments of patient risk and specific co-morbidities such as renal and pulmonary disease, systolic dysfunction and CAD that have an impact on outcomes. Factors such as frailty are increasingly important to evaluate in the aged TAVR population, and severe fragility may be a contraindication to any procedural reparation of AS. Finally,

Frailty

Innovations in Care

Practical Implementation of the Coronary Revascularization Heart Team

Carlos E. Sanchez, MD; Vinay Badhwar, MD; Anthony Dota, MD; John Schindler, MD; Danny Chu, MD; Anson J. Conrad Smith, MD; Joon S. Lee, MD; Sameer Khandhar, MD; Catalin Toma, MD; Oscar C. Marroquin, MD; Mark Schmidhofer, MD; Jay Bhama, MD; Lawrence Wei, MD; Sun Scolieri, MD; Stephen Esper, MD; Ashley Lee, MD; Suresh R. Mulukutla, MD

Circ Cardiovasc Qual Outcomes. 2013;6:598-603.

DOI: 10.1161/CIRCOUTCOMES.113.000269

8258002881

Heart Team Additional Data ☐☐☐☐

Patient Name _____

CAD Status

Left Main ○ Yes ○ No

Prox LAD ○ Yes ○ No

2VD ○ Yes ○ No

ThreeVD ○ Yes ○ No

Anomalous Coronary ○ Yes ○ No

Specify: _____

Other Coronary Issue: _____

Valve Status:

Aortic Stenosis: ○ None ○ Mild ○ Moderate ○ Severe

Mitral Stenosis: ○ None ○ Mild ○ Moderate ○ Severe

Mitral Regurgitation: ○ None ○ Mild ○ Moderate ○ Severe

Aortic Insufficiency: ○ None ○ Mild ○ Moderate ○ Severe

Possible Aortic Root Surgery: ○ Yes ○ No

LV Function ☐☐

Syntax ☐☐.☐

STS Score

Mortality ☐☐.☐

Permanent Stroke ☐☐.☐

Reoperation ☐☐.☐

Morbitdity or Mortality ☐☐.☐

Prolonged Vent ☐☐.☐

Long LOS ☐☐.☐

DSW Infection ☐☐.☐

Short LOS ☐☐.☐

Renal Failure ☐☐.☐

Frailty Index

○ Low

○ Intermediate

○ High

○ Unknown

Heart Team Recommendation:

○ Medical Therapy Only

○ PCI Only

○ Hybrid (MidCAB + PCI)

○ CABG only

○ CABG + AV Surgery

○ CABG + MV Surgery

○ CABG + AV Surgery + MV Surgery

○ AV Surgery Only

○ MV Surgery Only

○ PCI + TAVR

○ TAVR Only

○ Other

_____

Cognitive impairment

Predictors of functional decline in elderly patients undergoing transcatheter aortic valve implantation (TAVI)

Andreas W. Schoenenberger[1†], Stefan Stortecky[2†], Stephanie Neumann[1], André Moser[1,3], Peter Jüni[3], Thierry Carrel[4], Christoph Huber[4], Marianne Gandon[2], Seraina Bischoff[2], Christa-Maria Schoenenberger[2], Andreas E. Stuck[1], Stephan Windecker[2*], and Peter Wenaweser[2]

European Heart Journal (2013) **34**, 684–692
doi:10.1093/eurheartj/ehs304

Cognitive Impairment

Cognitive impairment is under-recognised and a significant contributor to frailty.[71] Patients with cognitive impairment at baseline (Mini Mental State Examination score <27) have more than a threefold increased risk of functional decline or mortality at 1-year post-TAVI.[72] Another study showed that for every point gained on the Mini-Mental Test score, the OR of a poor outcome was 0.94 (95% CI [0.90–0.97]; p=0.001).[71]

Cognitive impairment

Predictors of functional decline in elderly patients undergoing transcatheter aortic valve implantation (TAVI)

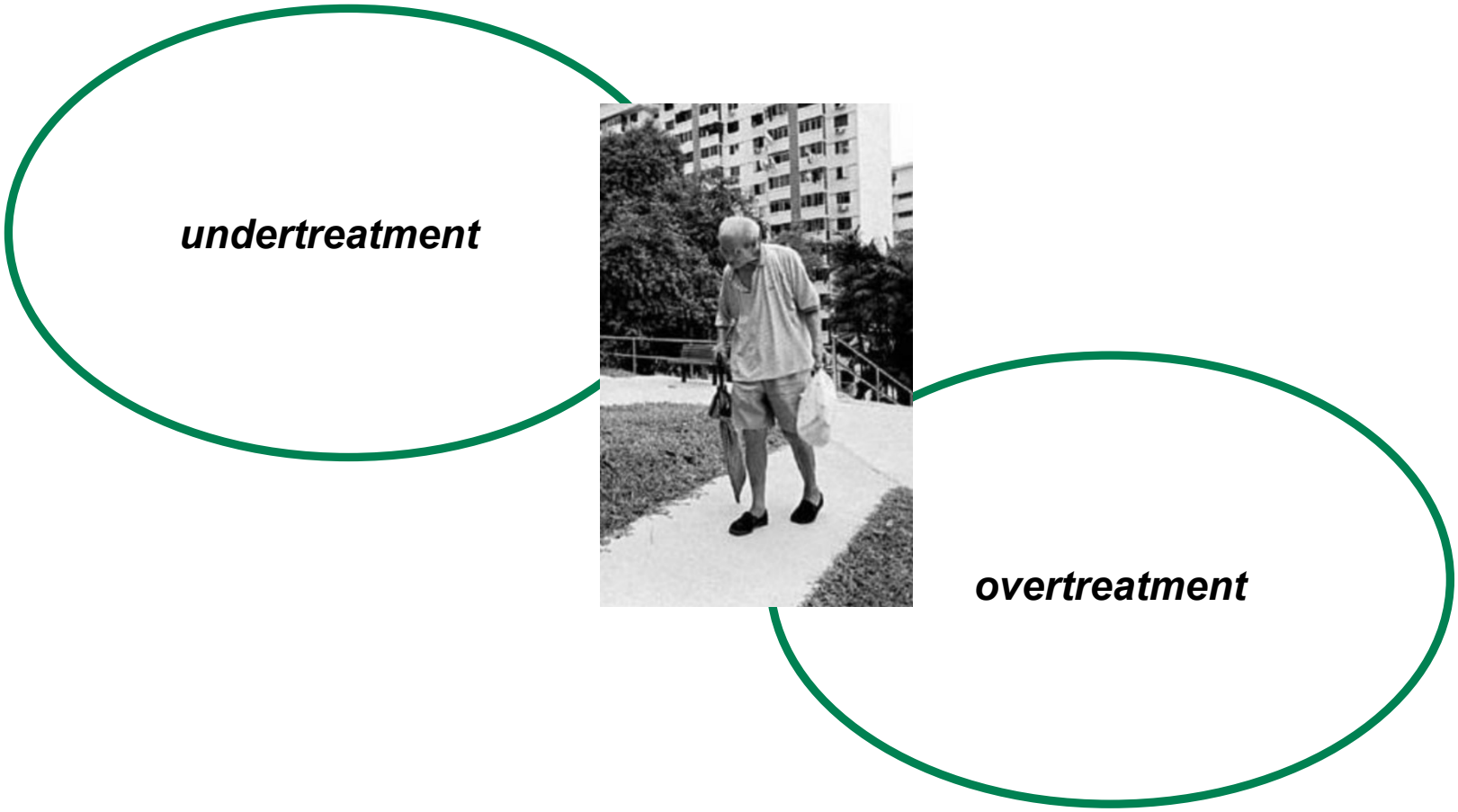
European Heart Journal (2013) **34**, 684–692
doi:10.1093/eurheartj/ehs304

Andreas W. Schoenenberger[1†], Stefan Stortecky[2†], Stephanie Neumann[1], André Moser[1,3], Peter Jüni[3], Thierry Carrel[4], Christoph Huber[4], Marianne Gandon[2], Seraina Bischoff[2], Christa-Maria Schoenenberger[2], Andreas E. Stuck[1], Stephan Windecker[2*], and Peter Wenaweser[2]

ACE-I, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; BADL, basic activities of daily living; CAD, coronary artery disease; IADL, instrumental activities of daily living; LVEF, left-ventricular ejection fraction; MMSE, mini mental state exam; MNA, mini nutritional assessment; STS, Society of Thoracic Surgeons; TUG, timed get up and go test.

Predictor	Functional decline			Functional decline or death		
	OR (95% CI)	*P*-value	NR^2	OR (95% CI)	*P*-value	NR^2
Components of frailty index						
MMSE						
Linear (OR per 3 points decrease)	2.41 (1.23–4.71)	0.01	0.086	2.64 (1.55–4.50)	<0.001	0.150
Dichotomized (<27 vs. ≥27 points)	2.50 (0.94–6.65)	0.07	0.048	3.18 (1.38–7.29)	0.01	0.088
TUG						
Linear (OR per 5 s increase)	1.48 (1.13–1.94)	0.004	0.091	1.64 (1.26–2.12)	<0.001	0.161
Dichotomized (≥20 vs. <20 s)	2.50 (0.95–6.56)	0.06	0.050	4.23 (1.83–9.77)	0.001	0.138
MNA						
Linear (OR per 2 points decrease)	1.30 (0.96–1.76)	0.09	0.032	1.51 (1.09–2.10)	<0.001	0.085
Dichotomized (<12 vs. ≥12 points)	3.32 (1.24–8.87)	0.02	0.087	4.14 (1.77–9.65)	0.001	0.133
BADL						
Linear (OR per 1 point increase)	1.39 (0.86–2.25)	0.18	0.024	1.63 (1.12–2.37)	0.01	0.071
Dichotomized (≥1 limited activity)	1.71 (0.60–4.85)	0.31	0.015	2.44 (1.04–5.76)	0.04	0.049
IADL						
Linear (OR per 1 point increase)	1.45 (1.08–1.94)	0.01	0.093	1.46 (1.13–1.89)	0.004	0.109
Dichotomized (≥1 limited activity)	2.10 (0.74–5.92)	0.16	0.031	2.19 (0.91–5.27)	0.08	0.039
Pre-clinical mobility disability						
Dichotomized (disability vs. no disability)	3.23 (0.99–10.59)	0.05	0.078	3.69 (1.33–10.24)	0.01	0.108

undertreatment or overtreatment?



overtreatment

SPECIAL ARTICLES

The End of the Disease Era

Mary E. Tinetti, MD, Terri Fried, MD

Am J Med, 2004

Abstract

The time has come to abandon disease as the focus of medical care. The changed spectrum of health, the complex interplay of biological and nonbiological factors, the aging population, and the interindividual variability in health priorities render medical care that is centered on the diagnosis and treatment of individual diseases at best out of date and at worst harmful. A primary focus on disease may inadvertently lead to undertreatment, overtreatment, or mistreatment. The numerous strategies that have evolved to address the limitations of the disease model, although laudable, are offered only to a select subset of persons and often further fragment care. Clinical decision making for all patients should be predicated on the attainment of individual goals and the ll modifiable biological and nonbiological factors, rather atment, or prevention of individual diseases. Anticipated rated and individualized approach range from concerns blems to "this is nothing new" and "resources would be better spent determining the underlying biological mechanisms." The perception that the disease model is "truth" rather than a previously useful model will be a barrier as well. Notwithstanding these barriers, medical care must evolve to meet the health care needs of patients in the 21st century.

Overtreatment – la teoria degli opposti estremismi
soggetti in buone condizioni, con qualità di vita soddisfacente
soggetti fragili, in equilibrio precario tra salute e disabilità

overtreatment

ONLINE FIRST

Eliminating Waste in US Health Care

Donald M. Berwick, MD, MPP
Andrew D. Hackbarth, MPhil

The need is urgent to bring US health care costs into a sustainable range for both public and private payers. Commonly, programs to contain costs use cuts, such as reductions in payment levels, benefit structures, and eligibility. A less harmful strategy would reduce waste, not value-added care. The opportunity is immense. In just 6 categories of waste—overtreatment, failures of care coordination, failures in execution of care processes, administrative complexity, pricing failures, and fraud and abuse—the sum of the lowest available estimates exceeds 20% of total health care expenditures. The actual total may be far greater. The savings potentially achievable from systematic, comprehensive, and cooperative pursuit of even a fractional reduction in waste are far higher than from more direct and blunter cuts in care and coverage. The potential economic dislocations, however, are severe and require mitigation through careful transition strategies.

JAMA. 2012;307(14):1513-1516
Published online March 14, 2012. doi:10.1001/jama.2012.362 www.jama.com

Here is a better idea: cut waste. That is a basic strategy for survival in most industries today, ie, to keep processes, products, and services that actually help customers and systematically remove the elements of work that do not.

overtreatment

ONLINE FIRST

Eliminating Waste in US Health Care

Donald M. Berwick, MD, MPP
Andrew D. Hackbarth, MPhil

JAMA. 2012;307(14):1513-1516
Published online March 14, 2012. doi:10.1001/jama.2012.362

Table. Estimates of Annual US Health Care Waste, by Category[a]

	$ in Billions					
	Annual Cost to Medicare and Medicaid in 2011[b]			Annual Cost to US Health Care System in 2011		
	Low	Midpoint	High	Low	Midpoint	High
Failures of care delivery	26	36	45	102	128	154
Failures of care coordination	21	30	39	25	35	45
Overtreatment	67	77	87	158	192	226
Administrative complexity	16	36	56	107	248	389
Pricing failures	36	56	77	84	131	178
Fraud and abuse	30	64	98	82	177	272
			402	558	910	1263
				21	34	47

"il fato ha concesso all'umanità una coperta così pietosamente insufficiente, che nel tirarla sopra una parte del mondo, lascia scoperta l'altra parte"

(Rahindranath Tagore, Il battello d'oro, 1893)

overtreatment

The Lancet Commissions

Published Online
November 7, 2016
http://dx.doi.org/10.1016/
S0140-6736(16)31599-9

Essential medicines for universal health coverage

Veronika J Wirtz, Hans V Hogerzeil*, Andrew L Gray*, Maryam Bigdeli, Cornelis P de Joncheere, Margaret A Ewen, Martha Gyansa-Lutterodt, Sun Jing, Vera L Luiza, Regina M Mbindyo, Helene Möller, Corrina Moucheraud, Bernard Pécoul, Lembit Rägo, Arash Rashidian, Dennis Ross-Degnan, Peter N Stephens, Yot Teerawattananon, Ellen F M 't Hoen, Anita K Wagner, Prashant Yadav, Michael R Reich*

Executive summary

Essential medicines satisfy the priority health-care needs of the population. Essential medicines policies are crucial to promoting health and achieving sustainable development. Sustainable Development Goal 3.8 specifically mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a central component of Universal Health Coverage

For this report, the Commission developed a new model-based global estimate of the total financing that would be needed to achieve universal access to a basic package of essential medicines in low-income and middle-income countries (LMICs). A costing model was developed on the basis of disease prevalence, current or projected consumption of medicines, and international reference prices. Using two consumption scenarios, the Commission estimated that between US$77·4 and $151·9 billion (or $13 to $25 per capita) is required to finance a basic package of 201 essential medicines (378 dosage forms) in all LMICs. Yet in 2010, the majority

**"il fato ha concesso all'umanità
una coperta così pietosamente
insufficiente, che nel tirarla
sopra una parte del mondo,
lascia scoperta l'altra parte"**

**(Rahindranath Tagore,
Il battello d'oro, 1893)**

Il ruolo dell'Heart Team

The heart team approach to transcatheter aortic valve implantation: What has been done and what is to be expected

Gustavo Pires-Morais*, Vasco Gama

Rev Port Cardiol. 2017;36(11):819–821

In parallel with risk stratification is the development of new tools for predicting clinical futility, and this entails looking at the patient from a different angle. Futility can be defined by the combination of death and/or absence of improvement in functional class during short-term follow-up post-procedure (six months to one year). Other definitions are possible and this is still a hotly debated topic. Factors influencing futility of treatment include non-cardiovascular conditions such as chronic lung disease (CLD), advanced chronic kidney disease and frailty, and various cardiovascular conditions, including reduced left ventricular ejection fraction, pulmonary hypertension, low trans-aortic gradient, low-flow state or severe organic mitral regurgitation.[12] An analysis of futility has been performed for a Portuguese TAVI population of 340 patients with a mean STS score of 5.67±4.17%. The authors found that age, CLD, New York Heart Association functional class ≥III prior to the procedure and a non-transfemoral approach were predictors of futility for this population.[13] Apart from its clinical impact, analysis of futility is also closely related to the healthcare costs of TAVI.

Slow medicine è una rete di professionisti che si riconoscono nei principi di una medicina sobria, rispettosa, giusta.

Sobria	*Fare di più non vuol dire fare meglio*
Rispettosa	*Valori, aspettative e desideri delle persone sono inviolabili*
Giusta	*Cure appropriate e di buona qualità per tutti*

www.slowmedicine.it

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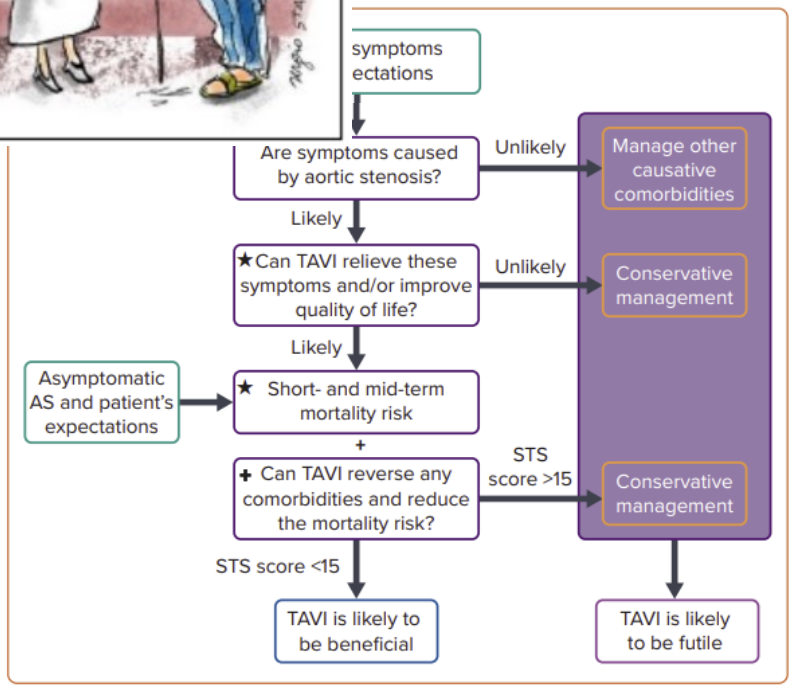
examines the contribution of pre-existing

Determining Benefit Versus Futility of Transcatheter Aortic Valve Implantation



Futility

Futility in Transcatheter Aortic Valve Implantation: A Search for Clarity

Kush P Patel [1,2] Thomas A Treibel [1,2] Paul R Scully,[1,2] Michael Fertleman [3] Samuel Searle,[4]
Daniel Davis [4] James C Moon [1,2] and Michael J Mullen[1,2]

Interventional Cardiology 2022;17:e01. **DOI:** https://doi.org/10.15420/icr.2021.15

Although transcatheter aortic valve implantation (TAVI) has revolutionised the landscape of treatment for aortic stenosis, there exists a cohort of patients where TAVI is deemed futile. Among the pivotal high-risk trials, one-third to half of patients either died or received no symptomatic benefit from the procedure at 1 year. Futility of TAVI results in the unnecessary exposure of risk for patients and inefficient resource utilisation for healthcare services. Several cardiac and extra-cardiac conditions and frailty increase the risk of mortality despite TAVI. Among the survivors, these comorbidities can inhibit improvements in symptoms and quality of life. However, certain conditions are reversible with TAVI (e.g. functional mitral regurgitation), attenuating the risk and improving outcomes. Quantification of disease severity, identification of reversible factors and a systematic evaluation of frailty can substantially improve risk stratification and outcomes. This review examines the contribution of pre-existing comorbidities towards futility in TAVI and suggests a systematic approach to guide patient evaluation.

Figure 1: Decision-making Algorithm for Determining Benefit Versus Futility of Transcatheter Aortic Valve Implantation

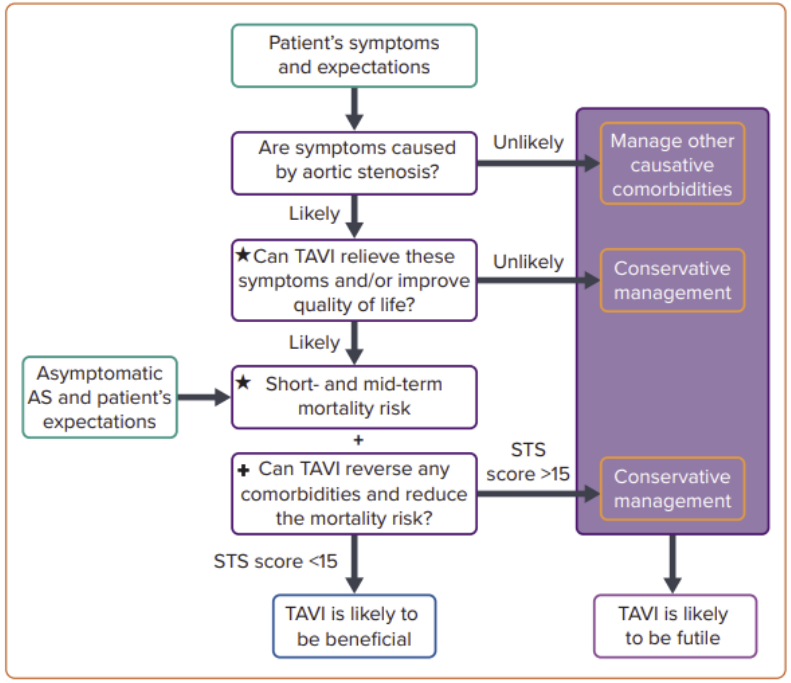


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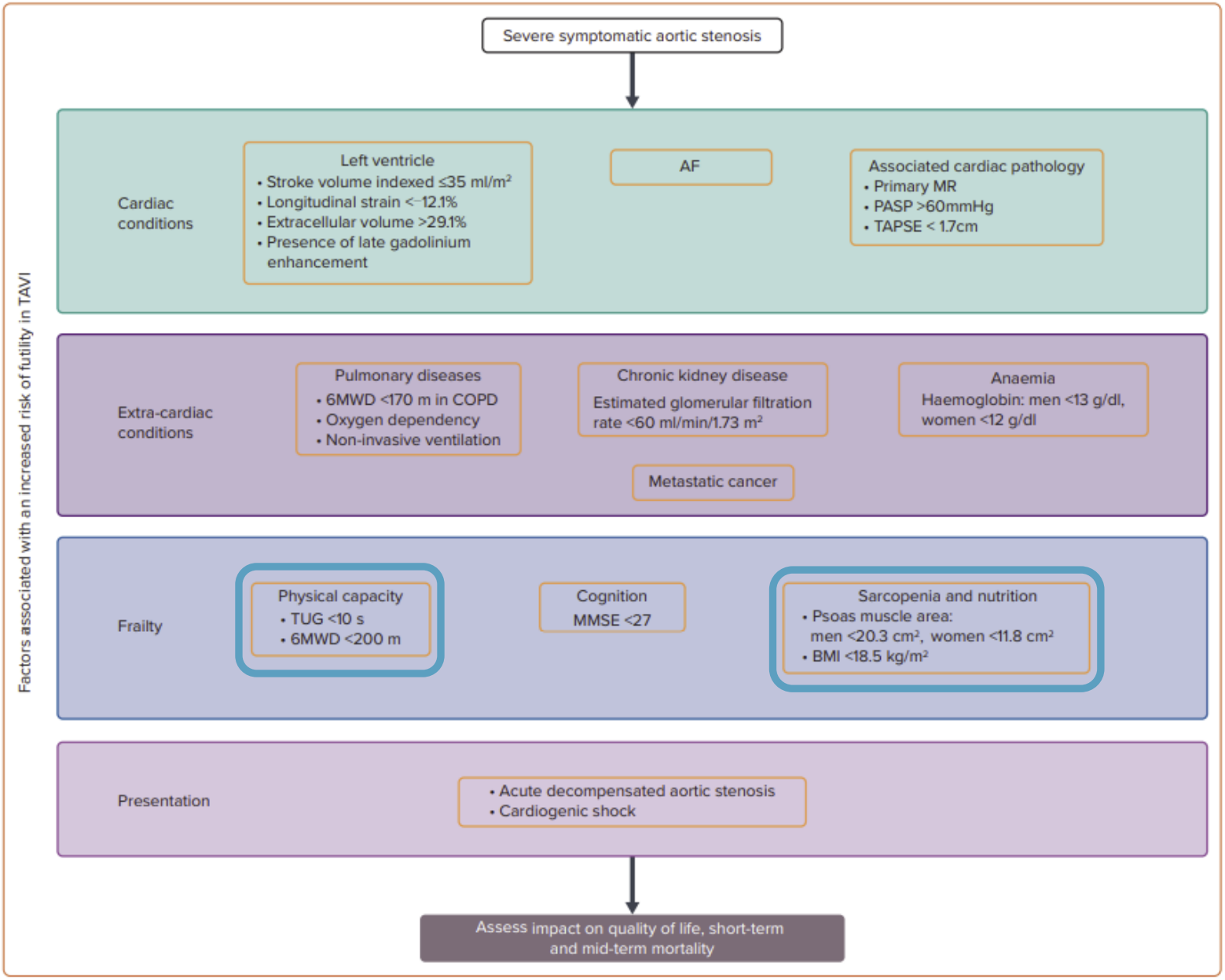
Figure 2: Factors Associated With an Increased Risk of Futility in Transcatheter Aortic Valve Implantation

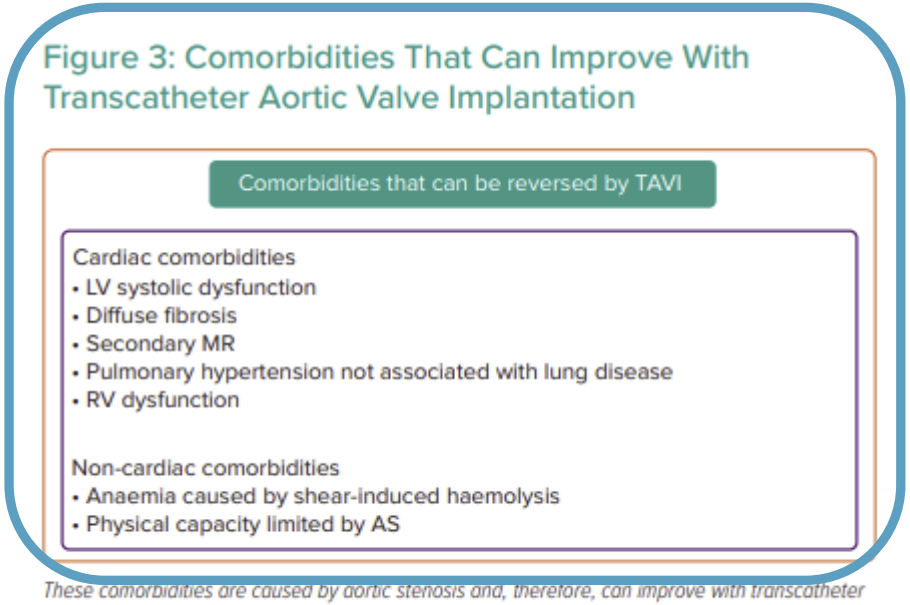


Futility

Futility in Transcatheter Aortic Valve Implantation: A Search for Clarity

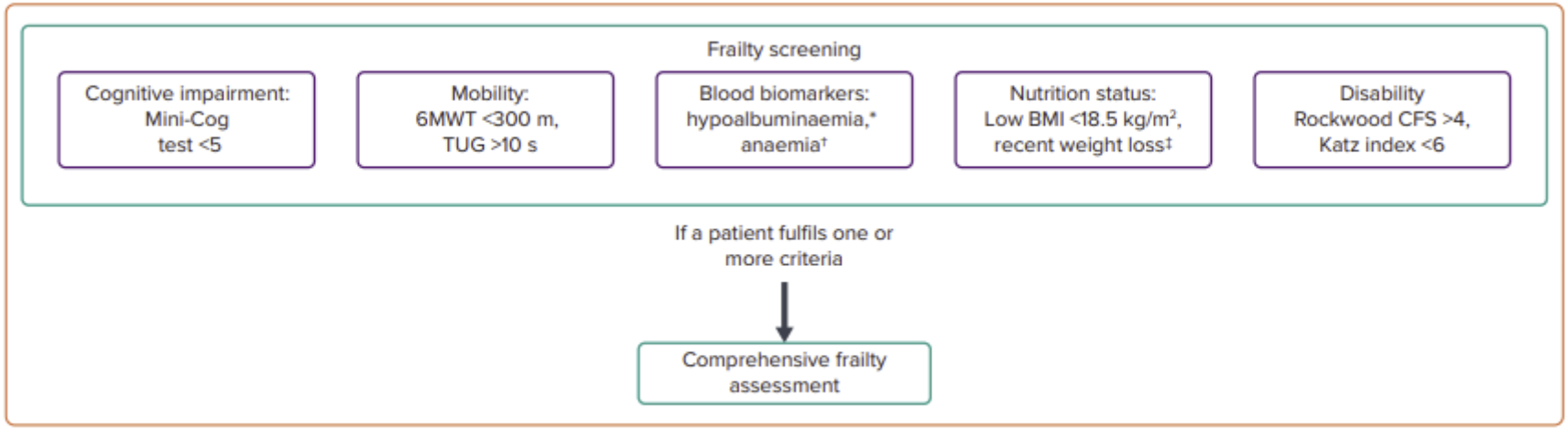
Interventional Cardiology 2022;17:e01. DOI: https://doi.org/10.15420/icr.2021.15

Figure 3: Comorbidities That Can Improve With Transcatheter Aortic Valve Implantation



These comorbidities are caused by aortic stenosis and, therefore, can improve with transcatheter aortic valve implantation. However, improvement is dependent on multiple factors. AS = aortic stenosis; LV = left ventricular; MR = mitral regurgitation; RV = right ventricular; TAVI = transcatheter aortic valve implantation.

Figure 4: Screening for Frailty



*If a patient meets any of these frailty criteria, a comprehensive frailty assessment is recommended. Each assessment has examples of assessments that are simple, quick to perform and routinely used among transcatheter aortic valve implantation patients. *Defined as serum albumin <3.5 g/dl; †defined as haemoglobin in men <13 g/dl and in women <12 g/dl; ‡defined as >5% loss in weight over the past 6–12 months. 6MWT = 6-minute walk test; CFS = clinical frailty score; TUG = Timed Up and Go test.*

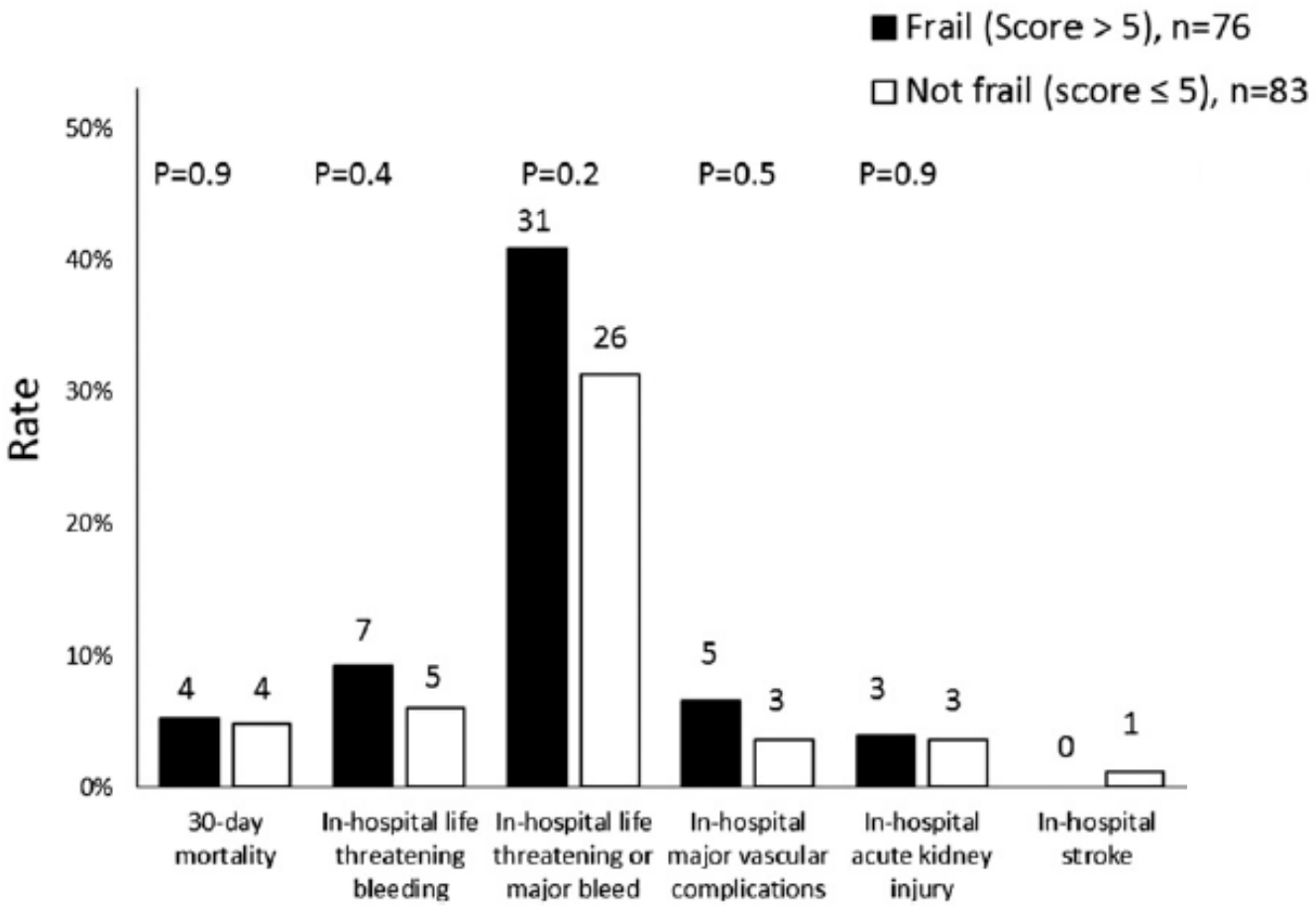
The Impact of Frailty Status on Survival After Transcatheter Aortic Valve Replacement in Older Adults With Severe Aortic Stenosis

A Single-Center Experience

Philip Green, MD,* Abigail E. Woglom, RN,† Philippe Genereux, MD,* Benoit Daneault, MD,* Jean-Michel Paradis, MD,* Susan Schnell, ACNP-C,‡ Marian Hawkey, RN,* Mathew S. Maurer, MD,* Ajay J. Kirtane, MD,* Susheel Kodali, MD,* Jeffrey W. Moses, MD,* Martin B. Leon, MD,* Craig R. Smith, MD,*† Mathew Williams, MD*†

Table 1. Components of Frailty Score

Frailty Domain	Measure	Frailty Score
Slowness	15-ft walk gait speed (m/s)	Quartiles (0–3)
Weakness	Grip strength (kg)	Sex-based quartiles (0–3)
Wasting and malnutrition	Serum albumin (g/dl)	Quartiles (0–3)
Inactivity	Katz activities of daily living	Any dependence = 3, Independent = 0



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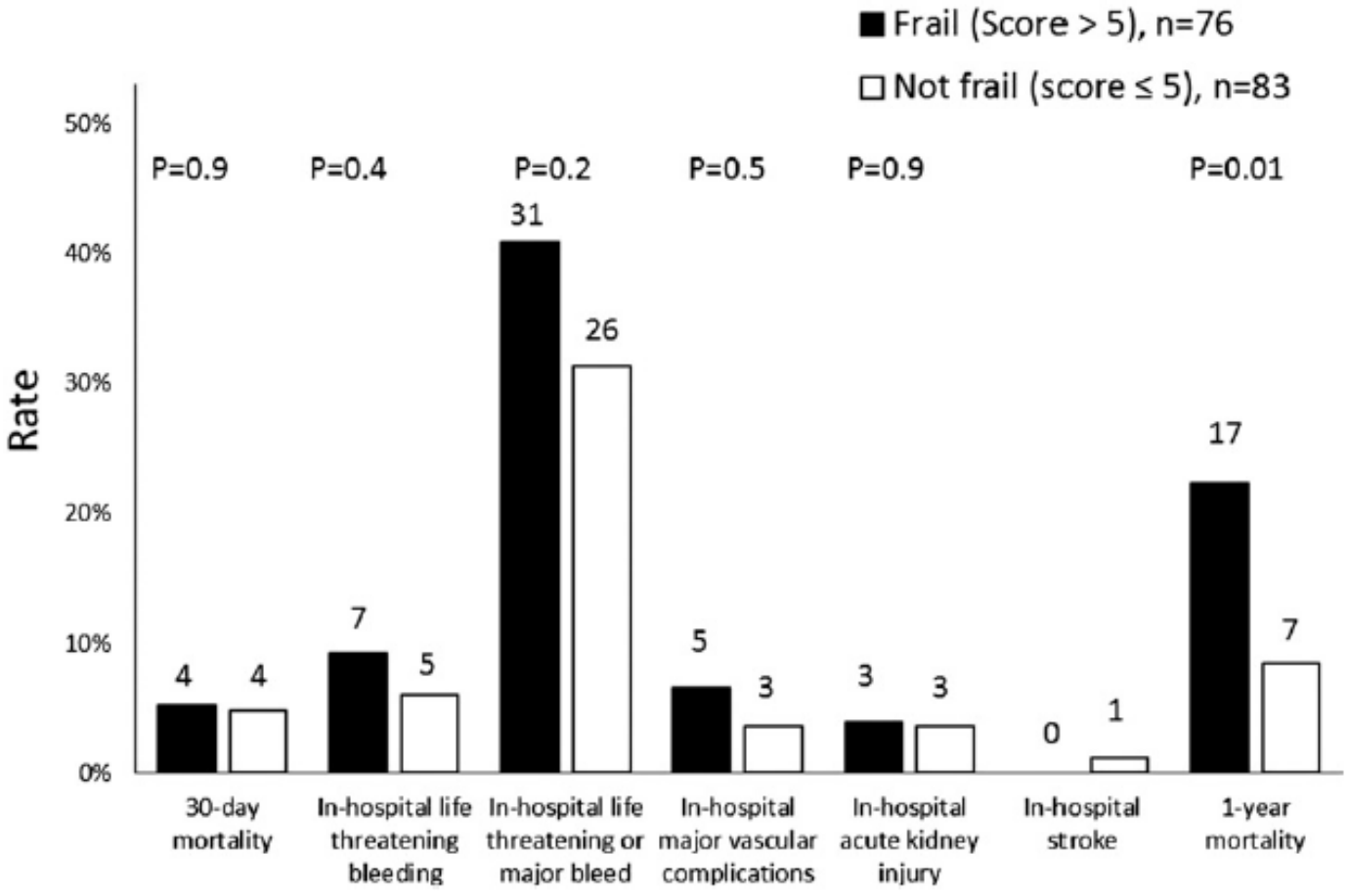
Conclusions Frailty was not associated with increased periprocedural complications in patients selected as candidates to undergo TAVR but was associated with increased 1-year mortality after TAVR. Further studies will evaluate the independent value of this frailty composite in older adults with aortic stenosis. (J Am Coll Cardiol Intv 2012;5:974–81) © 2012 by the American College of Cardiology Foundation



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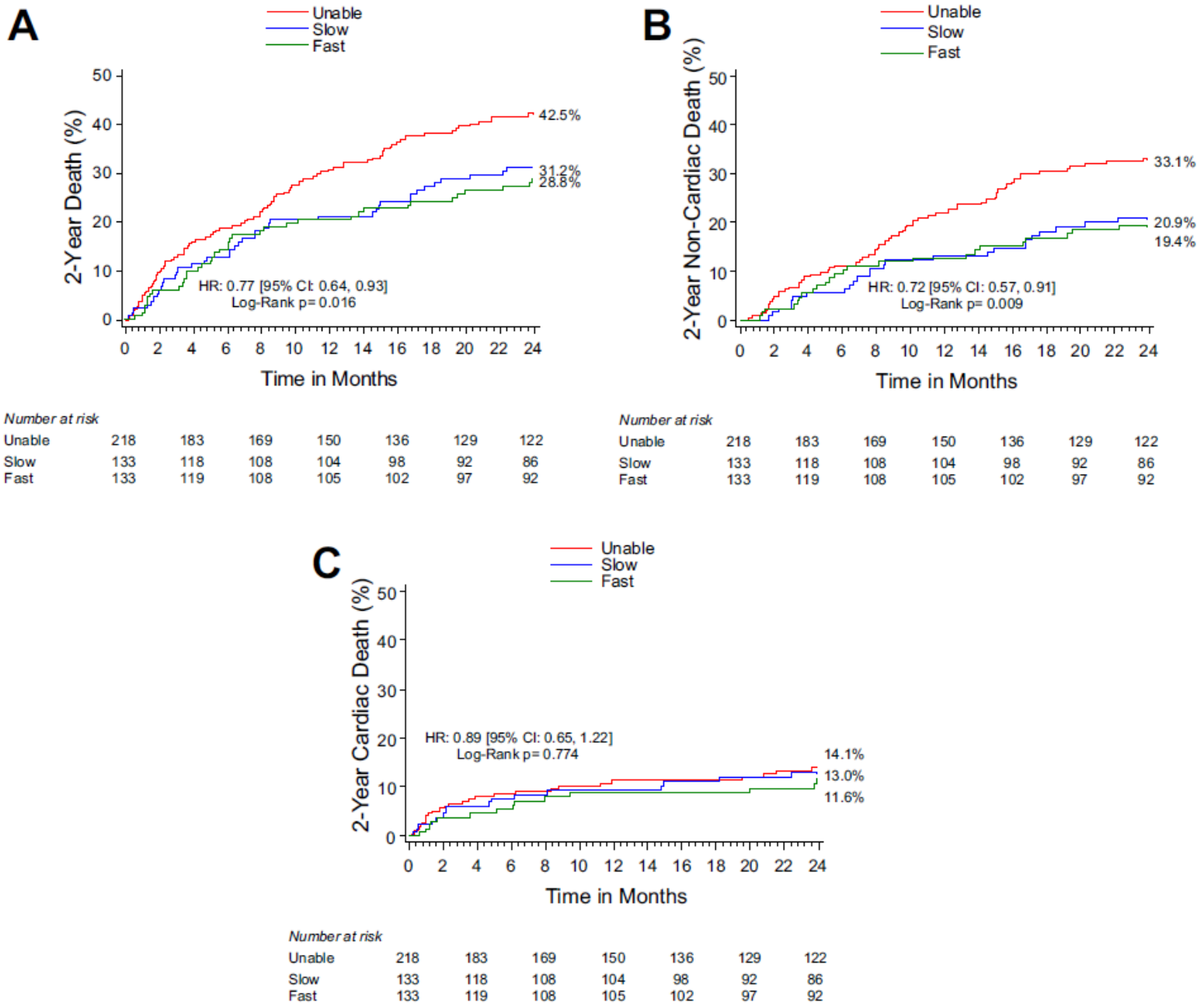
Relation Between Six-Minute Walk Test Performance and Outcomes After Transcatheter Aortic Valve Implantation (from the PARTNER

Philip Green, MD[a], David J. Cohen, MD, MSc[b], Ph
Suzanne V. Arnold, MD, MHA[b], Maria Alu, MM[a],
Michael J. Mack, MD[e], Samir Kapadia, MD[f], D
Mathew R. Williams, MD[a], Susheel Kodali, MD[a], Mart

Am J Cardiol 2013;112:700–706



Relation Between Six-Minute Walk Test Performance and Outcomes After Transcatheter Aortic Valve Implantation (from the PARTNER Trial)

Philip Green, MD[a], David J. Cohen, MD, MSc[b], Philippe Généreux, MD[a], Tom McAndrew, MS[a], Suzanne V. Arnold, MD, MHA[b], Maria Alu, MM[a], Nirat Beohar, MD[c], Charanjit S. Rihal, MD[d], Michael J. Mack, MD[e], Samir Kapadia, MD[f], Danny Dvir, MD[g], Mathew S. Maurer, MD[a], Mathew R. Williams, MD[a], Susheel Kodali, MD[a], Martin B. Leon, MD[a], and Ajay J. Kirtane, SM, MD[a,*]

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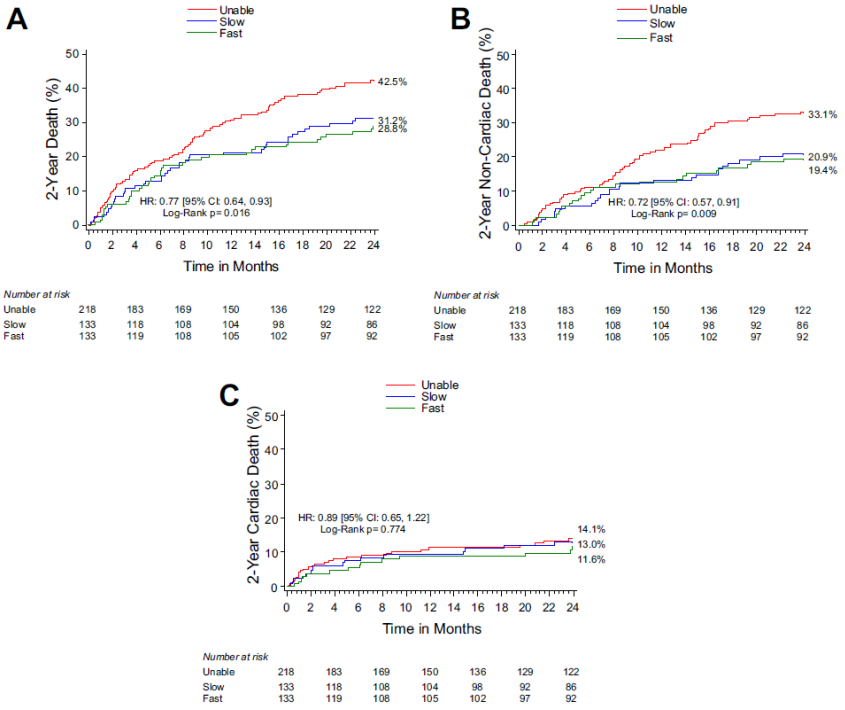

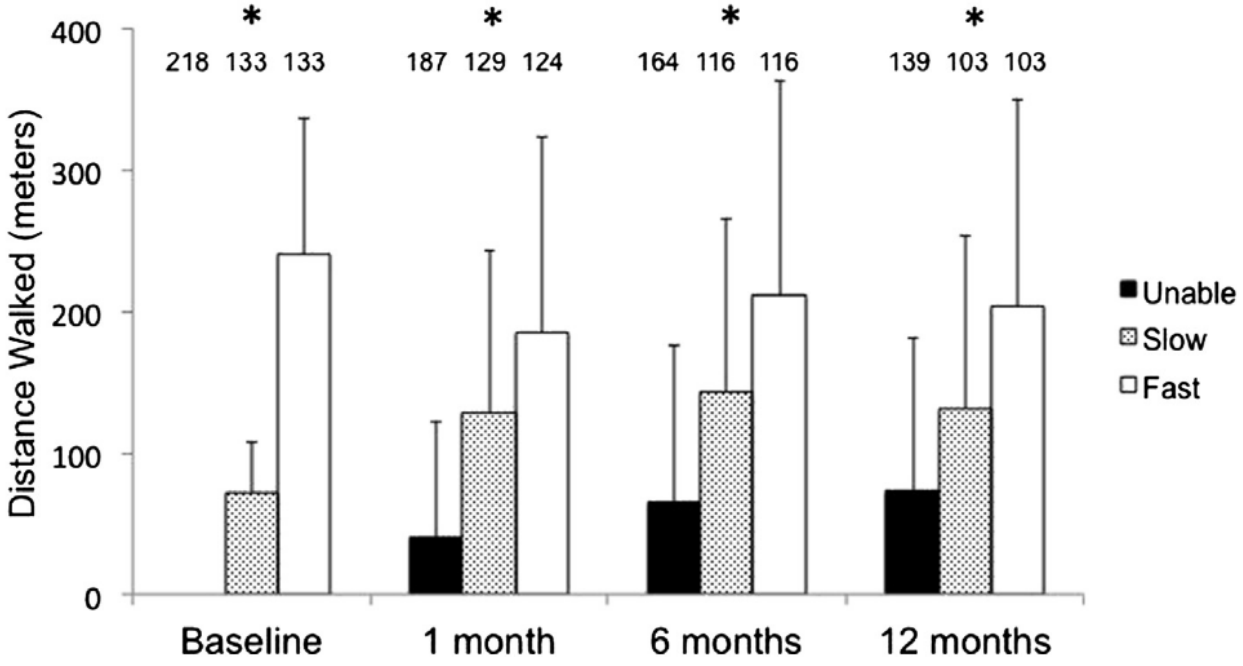

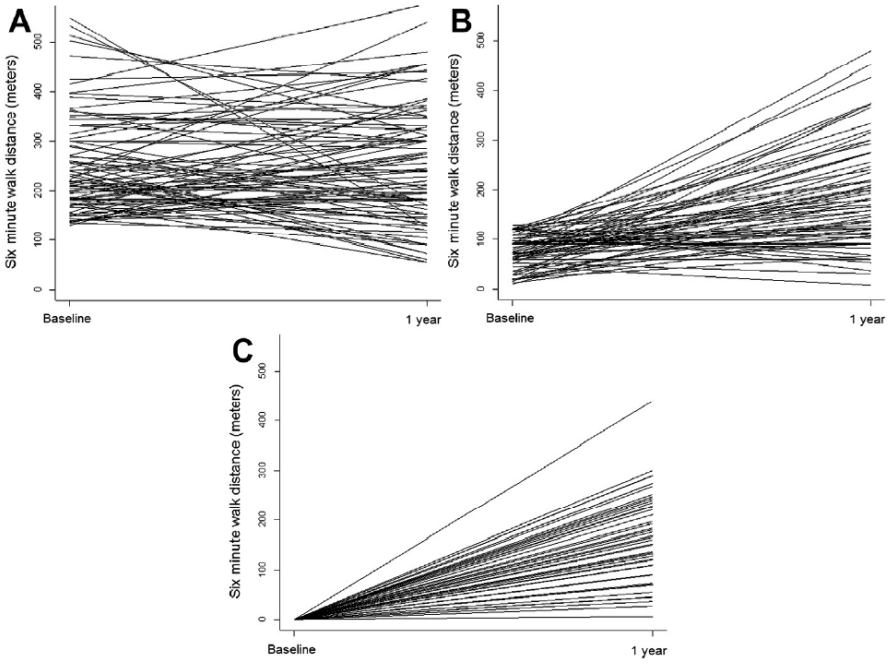

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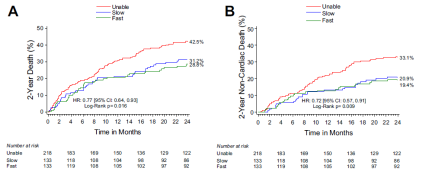
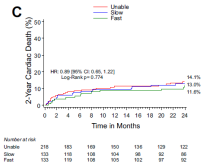
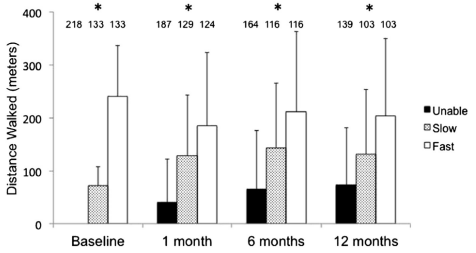
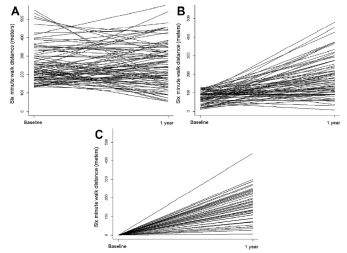
Am J Cardiol 2013;112:700–706

Finally, the high mortality rates seen after TAVI among inoperable patients enrolled in the PARTNER trial (43.3% at 2 years) have motivated clinicians to attempt to identify patients in whom TAVI would be considered "futile."[2] Our study does not suggest that TAVI is futile in those who are unable to walk. Rather, despite the high mortality rate seen among those unable to walk, those who do survive after TAVI actually experience the greatest improvement in walking distance. In contrast, the overall decrease in walking performance after TAVI seen among the fastest walkers at baseline may reflect either regression to the mean or a "ceiling effect" in which factors other than AS per se limit walking speed for this cohort. Among such patients, it is therefore important to ensure that AS is truly severe to ensure that TAVI would be expected to provide a meaningful survival benefit.









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EDITORIAL COMMENT

The heart team approach to transcatheter aortic valve implantation: What has been done and what is to be expected

Abordagem da *Heart Team* à TAVI: o que tem sido feito e o que se espera

Gustavo Pires-Morais*, Vasco Gama

Although the TAVI and SAVR groups appear to have performed well in the population analyzed by Costa et al., there is still room for improvement, as the authors recognize. The fact that many patients died (12% of the study population) while awaiting heart team assessment or TAVI itself is a reminder of the severity of these patients and that appropriate strategies need to provide a more timely response from the healthcare system.

PDTA pazienti con stenosi aortica candidabili a TAVI (IMPIANTO TRANSCATETERE DI VALVOLA AORTICA PERCUTANEA)

Con riferimento alle nuove linee guida europee del 2021 (6), TAVI e SAVR vengono considerate due metodiche complementari. L'intervento chirurgico (SAVR) è raccomandato nei pazienti con età inferiore a 75 anni ed a basso rischio chirurgico (STS-PROM risk score o EuroSCORE II <4%) o non candidabili a TAVI con classe di raccomandazione I e livello di evidenza B. L'intervento transcatetere (TAVI) è, raccomandato nei pazienti con età superiore o uguale a 75 anni od a rischio chirurgico "aumentato" (STS-PROM risk score o EuroSCORE II >8%), o non candidabili a chirurgia con classe di raccomandazione I e livella di evidenza A. Per i pazienti che non rientrano in queste categorie, la scelta deve essere effettuata in base alle caratteristiche individuali, anatomiche e procedurali.

	A FAVORE DI TAVI	A FAVORE DI SAVR
Caratteristiche cliniche		
Basso rischio chirurgico	-	+
Alto rischio chirurgico	+	-
Età minore	-	+
Età maggiore	+	-
Precedente chirurgia cardiaca	+	-
Fragilità severa	+	-
Endocardite attiva o sospetta	-	+
Caratteristiche anatomiche e procedurali		
TAVI fattibile per via transfemorale	+	-
Accesso transfemorale difficoltoso o impossibile da reperire e SAVR fattibile	-	+
Accesso transfemorale difficoltoso o impossibile da reperire e SAVR fattibile	+	-
Sequele di radiazioni toraciche	+	-
Aorta a porcellana	+	-
Alta probabilità di mismatch protesi paziente (AVA <0.65 cm^2/m^2 BSA)	+	-
Deformazione toracica severa o scoliosi	+	-
Dimensioni dell'annulus aortico non compatibili con TAVI	-	+
Valvola aortica bicuspide	-	+
Morfologia valvolare non favorevole a TAVI (es. rischio di ostruzione coronarica, pesanti calcificazioni dei lembi/LVOT)	-	+
Trombo in aorta o in LV	-	+
Patologie cardiache concomitanti che richiedano l'intervento chirurgico		
CAD severa richiedente rivascolarizzazione	-	+
Patologia mitralica primaria severa	-	+
Patologia tricuspidale severa	-	+
Dilatazione/aneurisma della radice aortica e/o dell'aorta ascendente	-	+
Ipertrofia settale richiedente miectomia	-	+

PDTA pazienti con stenosi aortica candidabili a TAVI (IMPIANTO TRANSCATETERE DI VALVOLA AORTICA PERCUTANEA)

Come indicato dalle Linee Guida internazionali, la decisione di sottoporre un paziente a procedura di TAVI deve essere effettuata da parte di un apposito Heart Team (…)
Questo il percorso concordato: il paziente considerato candidabile a TAVI (criteri conformi alle Linee Guida) verrà proposto in sede Heart Team, da uno qualsiasi dei partecipanti alla riunione, per discussione collegiale. Di ogni paziente andranno forniti dati clinici, ecocardiografici (trans-toracico e se occorre trans-esofageo) con accurata valutazione gradienti e diametro anulare, angiografici (coronarografia) e di imaging avanzato (angio-TAC mirata per studio anello aortico ed accessi arteriosi periferici), nonché ogni altra eventuale documentazione che si riferisca alle comorbidità in essere del paziente.
Durante la discussione l'Heart Team si propone di indirizzare a TAVI i pazienti con le seguenti caratteristiche:

- Età maggiore di 80 anni
- Clinica legata alla stenosi valvolare manifesta come classe funzionale New York Heart Association (NYHA) > 3, oppure con moderato o grave deterioramento della funzione ventricolare sinistra con una frazione di eiezione (FE) <40%;
- Gradiente medio >40 mmHg e/o area valvolare aortica indicizzata <0.6 cm2/m2;
- Intervento chirurgico convenzionale controindicato o con rischio aumentato (riferimento EuroSCORE logistico, score STS, indici di fragilità o caratteristiche anatomiche sfavorevoli).

PDTA pazienti con stenosi aortica candidabili a TAVI (IMPIANTO TRANSCATETERE DI VALVOLA AORTICA PERCUTANEA)

Si considereranno controindicazioni all'intervento di TAVI tutte quelle indicazioni che, a seguito della discussione collegiale ed analitica della situazione clinica generale del paziente, dovessero mettere in dubbio l'efficacia clinica della procedura. In particolare, si considerano fattori rilevanti a tale proposito la presenza di:

- Aspettativa di vita inferiore a un anno
- Concomitanti gravi valvulopatie con indicazione ad intervento cardiochirurgico
- Endocardite attiva e malattie infettive in atto
- Presenza di masse intra-ventricolari
- Demenza senile o altri gravi stati irreversibili di compromissione cognitiva
- Per l'approccio transapicale: malattia polmonare severa
- Per l'approccio transapicale: apice del ventricolo sinistro non accessibile

Journal of the American Heart Association

ORIGINAL RESEARCH

Temporal Trends and Drivers of Heart Team Utilization in Transcatheter Aortic Valve Replacement: A Population-Based Study in Ontario, Canada

Gil Marcus, MD; Feng Qiu, MSc; Ragavie Manoragavan, BSc; Dennis T. Ko, MD, MSc; Gabby Elbaz-Greener, MD, MHA; Jennifer C. Y. Chung, MD; Maneesh Sud, MD; Michael E. Farkouh, MD, MSc; Mina Madan, MD; Stephen E. Fremes, MD, MSc; Harindra C. Wijeysundera, MD, PhD

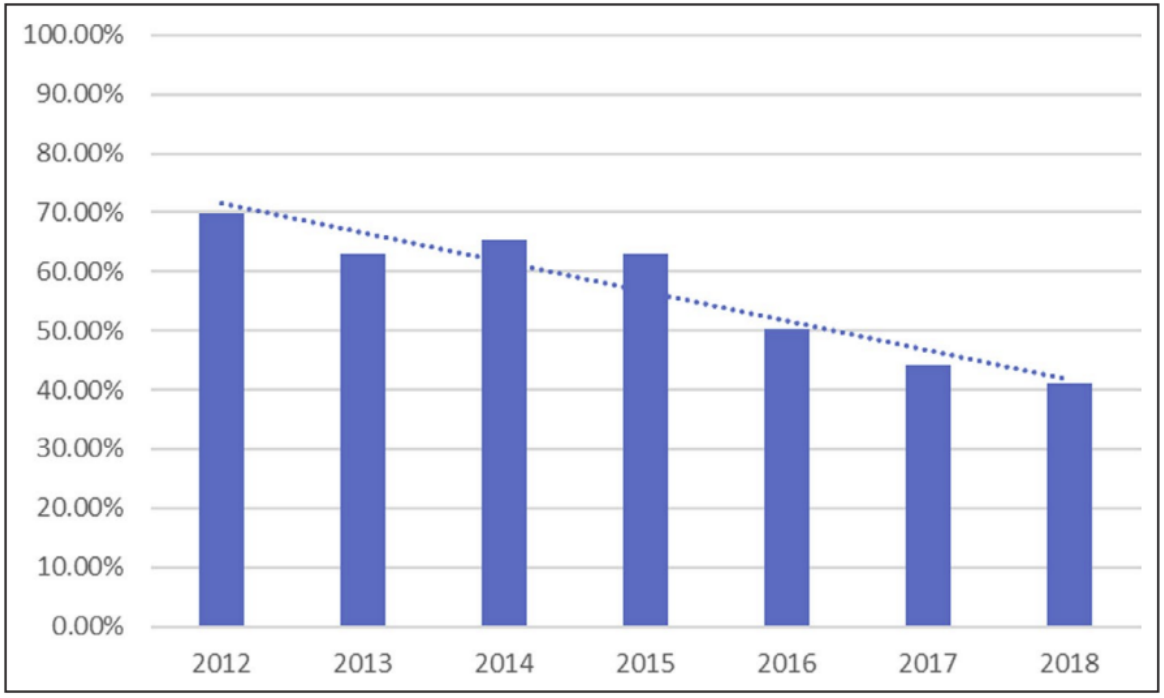

Figure 2. Temporal trend of Heart Team utilization 2012 to2018.
A statistically significant decline in Heart Team utilization for TAVR referrals was seen over the years

CLINICAL PERSPECTIVE

What Is New?

- A substantial decline in Heart Team utilization for TAVR candidates was observed over time.
- This decline in TAVR use was associated with increasing maturity of TAVR programs, and it did impact treatment allocation—thus we believe reflects a more selective use of the Heart Team in cases where it is likely to affect treatment decisions.

What Are the Clinical Implications?

- These findings challenge the current recommendations to utilize a Heart Team for every TAVR candidate.


Grazie!