



STATE OF THE ART

The roadmap to transcatheter aortic valve implantation



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Received 25 November 2019; accepted 5 September 2022

Available online 21 March 2023

KEYWORDS

Percutaneous aortic valve;
Aortic stenosis;
Review

Abstract Nearly 300 years after the first description of aortic valve obstruction, it has taken less than two decades of randomized clinical trials (RCTs) for transcatheter aortic valve implantation (TAVI) to become a recognized strategy for patients with aortic stenosis.

The high density of recent publications makes it easy to ignore the history that led to the development of this procedure. Knowing the evolution of a diagnostic or therapeutic technique improves critical reasoning, prevents repeated mistakes, paves the way for future research and contributes to an insightful perspective on the subject. Nevertheless, it should not overshadow the findings of recently published RCTs, which still are the mainstay of clinical practice.

In this timeline review, the authors aim to recap the development of TAVI, combining the pathophysiology of aortic stenosis and the initial concept of TAVI with the roadmap of clinical trials that led to the generalization of the TAVI procedure.

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PALAVRAS-CHAVE

Válvula aórtica percutânea;
Estenose aórtica;
Revisão

O percurso até às válvulas aórticas percutâneas

Resumo Após cerca de 300 anos da primeira descrição de uma obstrução da válvula aórtica, menos de duas décadas de estudos randomizados decorreram até a válvula aórtica percutânea (VAP) ser uma estratégia terapêutica reconhecida para doentes com estenose aórtica.

Com a elevada densidade de estudos recentes é possível negligenciar a perspetiva histórica que originou este procedimento. Conhecer o fundamento histórico que sustenta uma técnica terapêutica ou diagnóstica melhora o raciocínio clínico, previne a repetição de erros do passado,

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define os estudos do futuro e permite enriquecer a perspetiva sobre o tema. No entanto, o conhecimento histórico não se deve sobrepor aos estudos randomizados mais recentes, que continuam a ser o pilar principal das decisões feitas na prática clínica.

Nesta revisão temporal, pretende-se delinear uma linha temporal da história da VAP, combinando o desenvolvimento do conhecimento da patofisiologia da estenose aórtica e a sequência de descobertas que originou o conceito inicial da VAP, com o percurso de estudos clínicos que levaram à globalização deste procedimento.

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Introduction

Given the negative impact of time constraints in clinical practice, and the exponential growth of publications on transcatheter aortic valve implantation (TAVI), it is tempting to focus attention on the most recent data, ignoring the history that led to the development of this procedure. However, understanding the major breakthroughs of the past not only improves critical thinking, but also avoids repeated mistakes and paves the way for future research.¹

In this article we aim to identify the main timeline of our understanding of the pathophysiology and management of aortic stenosis (AS) that ultimately led to the TAVI procedure, and the cascade of clinical trials that assured its position in the treatment of AS.

Historical overview of aortic stenosis

The first TAVI procedure was performed in 2002 by Alain Cribier,¹⁰ but the history of TAVI starts with the history of AS. Arguably, the first description of aortic valve obstruction was given in 1663 by Lazare Rivière,³ in which he characterized a patient with progressive dyspnea, leg edema and a “pulse small, irregular, with every variety of irregularity” – probably a patient with heart failure, atrial fibrillation and the weak and late (*parvus et tardus*) peripheral pulse of AS. Despite medical therapy, the patient’s condition progressively worsened until he “suffered from the greatest difficulty in breathing (...), the “swelling of the legs increased so that the thighs were involved” and on “the eighth day, he died in the hours of evening”. In the autopsy report, Rivière described that “in the left ventricle of the heart, round caruncles were found like the substance of the lungs, the larger of which resembled a cluster of hazel nuts and filled up the opening of the aorta”. These clusters were most likely vegetations on the aortic valve, projecting into the aorta.⁴

This connection between endocarditis and calcification of the aortic valve was unquestioned until the first half of the 19th century.⁵ In 1846, Charles Ewald Hasse stated that “ossification cannot invariably be ascribed to endocarditis” and proposed a degenerative process behind aortic valve calcification. Over the years, this degenerative etiology was increasingly recognized and, in 1904, Möenckeberg

described the histological features of valve degeneration and explained the “close relationship between this disease and the senile form of atherosclerosis”.⁶

In the first half of the 20th century, AS was established as a distinct clinical entity. In 1937, Contratto and Levine recognized angina, dyspnea and syncope as the cardinal symptoms of the disease and sudden death as one of the three major causes of death (the others being endocarditis and heart failure).⁷ In 1939, Dry and Willius stated that “symptoms are likely to remain in abeyance for many years, but with the onset of myocardial failure the outlook becomes serious”, suggesting that a clinically silent period of the disease preceded the onset of rapidly progressive and difficult-to-treat heart failure.⁸ In 1964, Ross and Braunwald identified a link between the clinical syndrome and prognosis, with heart failure presaging the worst life expectancy.⁹ During that era, left ventricular dilatation and dysfunction was associated with rapid disease progression¹⁰ and patients with heart failure and preserved left ventricular function (diastolic dysfunction) were recognized as having a different survival outcome.¹¹

Surgical aortic valve replacement (SAVR) evolved alongside characterization of the clinical syndrome. After the first heterotopic valve implantation in 1952 by Charles Hufnagel, the advent of heart-lung machines with extracorporeal circulation enabled the first annular SAVR to be performed in 1960 by Dwight Harken.^{12–14} Following poor long-term results with valvuloplasty (decalcification, commissurotomy and other procedures that attempt to restore the valve cusps) and prosthetic tricuspid implants, the first successful SAVR was performed with a ball-cage valve. Combined with other small series, Effler et al. published a study of 224 patients with satisfactory results with the Starr-Edwards ball-valve prosthesis, favoring SAVR as the first-line therapy for severe AS,¹⁵ although high operative mortality was the principal limiting factor to the procedure, mostly related to the complexity of the operation and perioperative care.¹⁶ It became clear that the benefits of SAVR needed to be balanced against the risks of the procedure, with intervention being reserved for cases in which there was likely to be prognostic benefit.

The focus therefore turned to risk stratification and patient selection. This considered, on one hand, the prognostic benefit of surgery: it was consensual that the prognosis after symptom onset was ominous,^{17,18} as

opposed to the lack of agreement concerning asymptomatic patients.^{19–25} After 1968, SAVR was recommended after the onset of symptoms in patients with AS.²⁶ On the other hand there was the patient's surgical risk: a significant number of higher-risk patients were not suitable for surgery. In the 1980s, age over 70 years was considered a high-risk feature for cardiac surgery,²⁶ and subsequently the EuroHeart survey revealed that nearly one third of symptomatic patients were not suitable for valvular surgery.²⁷ Therefore, a less invasive approach was required for this large group of inoperable patients.

The concept behind transcatheter aortic valve implantation

The concept of percutaneous valves is not new. The first percutaneous aortic valve was implanted almost half a century before the first TAVI procedure. In 1965, Davies and colleagues used a parachute-like temporary aortic valve, implanted under the aortic annulus, to stabilize a patient with severe aortic regurgitation, as a bridge to SAVR.²⁸ Catheter-mounted valves were studied in animal models of acute aortic regurgitation,^{29,30} but the system did not evolve into a full-fledged implantable valve.

The first percutaneous treatment for AS took place in 1985, when Alain Cribier performed the first transcatheter aortic balloon valvuloplasty in a 72-year-old patient. The initial series showed promising results, with a significant increase in valve area, reduction in aortic gradients, rapid improvement of performance status and no severe complications.³¹ The short- to medium-term effects of valvuloplasty were interesting, but it became clear that it was still associated with significant short-term morbidity.³² The restenosis rate at one year was high,^{33–35} and the natural history and prognosis of AS patients did not change.³⁶ Thus, a more definitive, long-term solution was required.

From the routine observation that balloon valvuloplasty could open calcified aortic valves in a circular fashion, allied with the stentless bioprosthesis technology from SAVR, the initial concept emerged of an expandable stent containing a valve that could be implanted inside the native aortic valve.²⁶ The first successfully implanted transluminal stented valve in an animal model was developed by Henning Rud Andersen, who prepared a porcine aortic valve in an expandable metallic stent compressed around a deflated balloon catheter.³⁷ Unpublished autopsy studies by Cribier showed that such stents could be easily opened and would adhere to the calcified aortic valve.²

In the 1990s and early 2000s, animal studies confirmed that implantation of such valves was a feasible and safe procedure, without the risk of coronary flow obstruction if correct valve orientation and implantation plane were assured.^{37,38} The first transluminal stented valve in humans, however, was implanted in 2000, when Philipp Bonhoeffer placed a stented valve in a pediatric patient with a degenerated right ventricle-to-pulmonary artery conduit.³⁹

On April 16, 2002, Cribier and colleagues performed the first TAVI in a 57-year-old patient with severe AS and refractory cardiogenic shock.² The patient had a left ventricular ejection fraction of 14%, complicated with subacute leg ischemia due to severe peripheral artery disease and an

occluded aortofemoral bypass. He was not eligible for cardiac surgery and after failed sustained results with balloon valvuloplasty, was proposed for TAVI. The bovine valve (three pericardial leaflets), mounted within a balloon-expandable stent, was implanted under conscious sedation with an anterograde transseptal approach through the femoral vein. No major complications were reported following the procedure. Minimal paravalvular regurgitation (PVR) was observed with normal mitral valve function and coronary flow. At 48 hours, the valve displayed excellent function with gradual improvement of hemodynamic and echocardiographic features. Nonetheless, the patient died 17 weeks after the procedure due to non-cardiac complications.

Original studies on high-risk patients undergoing transcatheter aortic valve implantation

The first successful TAVI was the real-life proof of concept that set the tone for the main randomized controlled trials (RCTs), which initially focused on the feasibility of TAVI in extreme-risk patients. These trials can be classified according to the valve delivery system: balloon-expandable valves (BEV, mainly Edwards® SAPIEN), self-expanding valves (SEV, mainly Medtronic® CoreValve) and mechanically-expandable valves (MEV, mainly Boston Scientific® Lotus). Furthermore, patients can be divided according to risk strata into extreme/inoperable, high-, intermediate-, and low-risk, based on the EuroSCORE I or II, or Society of Thoracic Surgeons Predicted Risk of Mortality scores.

The first trials for inoperable patients were cohort B of the PARTNER trial (PARTNER B) (2010)⁴⁰ to assess BEV and the CoreValve Extreme Risk Pivotal Trial (2014)⁴¹ for SEV. In PARTNER B, patients were randomly assigned to receive TAVI or optimal medical therapy, while in the non-randomized CoreValve Pivotal Trial, TAVI was compared with a prespecified objective performance goal. Both valve systems clearly improved symptoms, aortic area and gradients and, most significantly, decreased mortality at one-year follow-up.

Results from PARTNER B were sustained up to five years, with symptomatic relief and decreased mortality. Moreover, valvular structure and function were not significantly disrupted. However, in this landmark trial, TAVI was associated with a higher 30-day risk of stroke.^{42–44}

Cohort A of the PARTNER trial (PARTNER A) (2011)⁴⁵ and the U.S. CoreValve High Risk Study (2014),⁴⁶ for BEV and SEV, respectively, targeted high-risk surgical patients. Both randomized up to 700 patients to TAVI or SAVR with a bioprosthetic valve. In both trials, TAVI was non-inferior to surgery regarding all-cause mortality at 30 days and at one-year follow-up. Major stroke rates were similar in both procedures. Each strategy was associated with a different subset of complications: TAVI was prone to vascular complications, significant PVR and pacemaker implantation, while SAVR was associated with major bleeding, acute kidney failure and atrial fibrillation.

Both trials have published data up to five-year follow-up, with similar functional and mortality endpoint results.^{47–51} These trials also revealed a significant association between moderate-to-severe PVR and increased long-term mortality.

Progression to lower-risk patients

The PARTNER 2 (2016)⁵² and SURTAVI (2017)⁵³ trials addressed the intermediate-risk group. PARTNER 2A used the SAPIEN XT valve (BEV), while SURTAVI used the CoreValve or Evolut-R valves (SEV). Both trials randomly assigned up to 2000 patients to TAVI or SAVR and followed them for 24 months. These valves were associated with similar short- and long-term mortality in SAVR and TAVI patients. The tendency towards different complications following TAVI and SAVR remained the same in these intermediate-risk patients and similarly, significant PVR was associated with long-term mortality. At five years of follow-up, death and stroke endpoints remained similar between the groups in the PARTNER 2 trial. Still, rehospitalization, reintervention and at least mild PVR was more frequent in the TAVI group.⁵⁴

The first trial to include low-risk patients was NOTION (2015)⁵⁵ for SEV. This study of 280 patients in northern Europe (82% low-risk patients) displayed comparable results regarding all-cause mortality and other major endpoints for TAVI and SAVR at one- and five-year follow-up. Although valve areas and gradients were better in TAVI at five-year follow-up, PVR and pacemaker implantation were significantly more frequent.⁵⁶

PARTNER 3 (2019)⁵⁷ and an interim analysis of the Evolut Low Risk Trial (2019),⁵⁸ for BEV and SEV respectively, enrolled low-risk patients. Evolut Low Risk employed a 24-month primary endpoint (death or stroke) and the results were inferred using Bayesian statistics. Both trials displayed low mortality at one-year follow-up for both TAVI and SAVR. Interestingly, in PARTNER 3, there were no significant differences between the two procedures concerning the classic adverse effects (pacemaker implantation within 30 days, significant PVR and major vascular complications). Nonetheless, new conduction disorders, such as left bundle branch block, and mild PVR was still more frequent following BEV. Importantly, only one-year valve durability results are available in low-risk, usually younger, patients.

Development of new delivery methods

MEV were developed in order to decrease significant PVR and to increase the implantation accuracy associated with early TAVI models. These valves are repositionable and retrievable when in final position and contain an adaptive polyurethane/polycarbonate outer seal to minimize PVR. REPRIS (2014)^{59,60} and REPRIS II (2014)^{61–63} were single-arm studies that assessed MEV in a total of 131 patients. All the valves were correctly implanted and partial or total resheathing was successfully performed in 40 patients in total. No moderate-to-severe PVR was seen at one-year follow-up.

Studies directly comparing transcatheter aortic valve systems

Cross-trial comparisons between valve systems are potentially hazardous, due to differences in population selection and trial designs.

The CHOICE trial (2014)^{64–66} randomly assigned 241 patients to receive the SAPIEN XT or CoreValve. The BEV displayed higher implantation success due to a lower rate of valve replacement and moderate-to-severe PVR compared to the SEV cohort, but forward flow valve dynamics were superior with the SEV. No significant differences regarding hard endpoints were seen in up to five years of follow-up.

REPRIS III (2018)^{67,68} randomized up to 900 patients to receive a MEV or SEV (CoreValve Classic in about half of the patients). This non-inferiority trial showed similar mortality at two-year follow-up. The MEV showed better results in terms of disabling stroke, valve migration, need for reintervention, functional class and PVR. Conversely, the SEV revealed better valvular areas and aortic gradients, in addition to lower rates of thrombosis and pacemaker implantation.

The SCOPE I trial (2019)⁶⁹ randomly assigned up to 700 high-risk surgical patients to a BEV (SAPIEN 3) or SEV (ACURATE neo/TF). The selected endpoint combined early safety and clinical efficacy at 30 days. The ACURATE neo/TF SEV showed a higher rate of acute kidney failure and significant PVR but also better valvular areas and aortic gradients.

In the PORTICO IDE trial (2020),⁷⁰ 750 high- and extreme-risk patients were randomized to the Portico resheathable SEV system or any other commercially available valve. The former was non-inferior regarding death or stroke at one year of follow-up but was associated with higher rates of mortality and vascular complications at 30 days.

Finally, SOLVE-TAVI (2020)⁷¹ randomized 447 high-to-intermediate risk patients to an SEV (Evolut R) or a BEV (SAPIEN 3). The valve systems were equivalent regarding the primary endpoint of all-cause mortality, stroke, moderate to severe regurgitation or pacemaker implantation at 30-day follow-up.

Gaps and future challenges

As TAVI approaches 20 years of in-human experience, with favorable results in RCTs with patients of all risk strata, there are still important challenges to overcome. Firstly, patients with abnormal valve anatomies were excluded from the main trials. This is particularly important in younger, low-risk patients, in whom a bicuspid anatomy may be more prevalent. Secondly, there is still scope to decrease complications, such as those related to vascular access, conduction disturbances or significant PVR. TAVI-related complications are tending to decrease in successive generations of trials, arguably in part due to advances in valve structure and delivery systems and increased operator experience. Thirdly, large-scale studies directly comparing valves are lacking. The largest RCT comparing two TAVI systems is the REPRIS 3 trial, and only small trials compared older models of BEV and SEV. Fourthly, there have been no large-scale RCTs addressing the optimal management of coronary artery disease and severe AS. The implications of coronary artery bypass grafting and percutaneous coronary intervention on top of SAVR and TAVI, respectively, may be different, and should be addressed in an RCT. Fifthly, TAVI has only been compared with bioprosthetic surgical valves, hence the use of TAVI in younger patients, for whom a mechanical prosthesis would be suitable, has not been studied. Sixthly, the

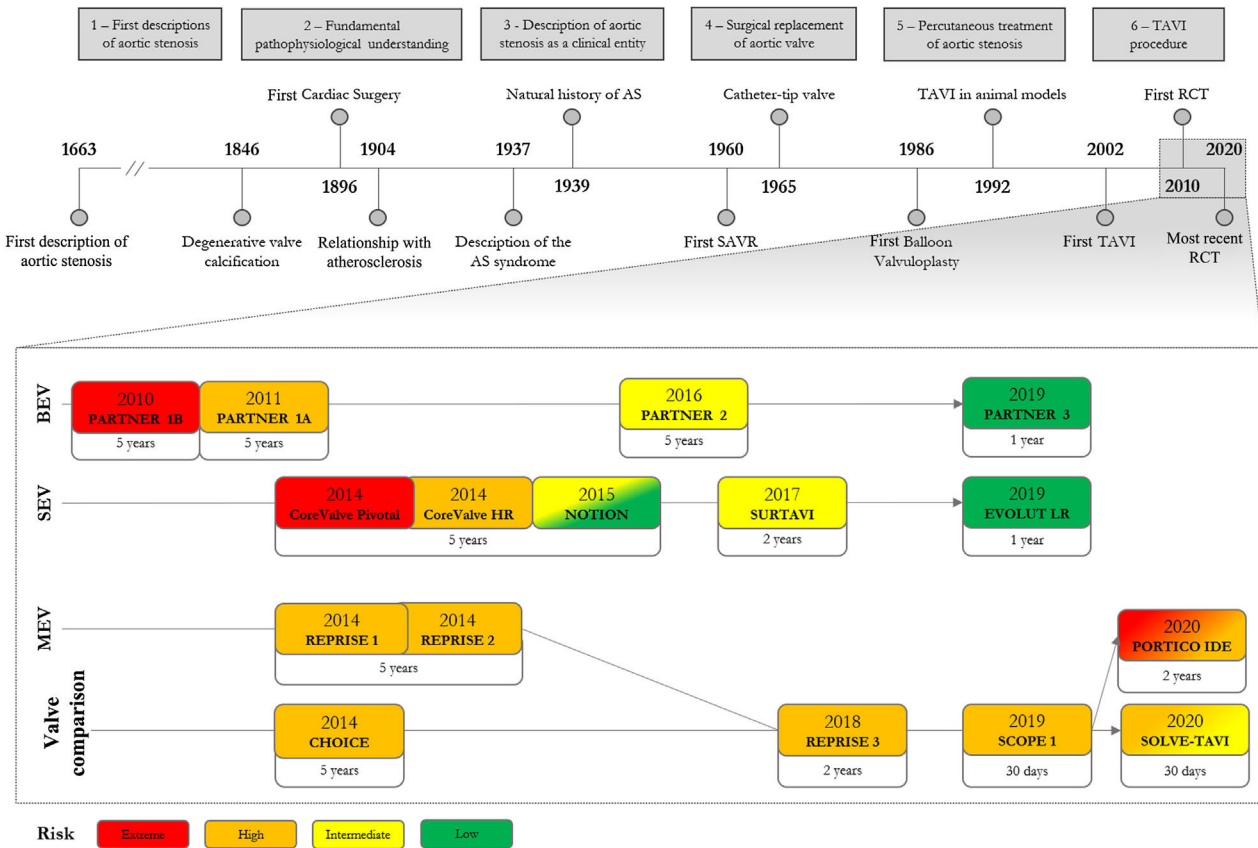


Figure 1 The roadmap to transcatheter aortic valve implantation. Above is the overall timeline of events since the first case descriptions of aortic stenosis. Below is the timeline of the major randomized clinical trials organized by valve type and patient risk, also displaying the longest follow-up study available to date. AS: aortic stenosis; BEV: balloon-expandable valve; HR: high risk; LR: low risk; MEV: mechanically-expandable valve; RCT: randomized clinical trial; SAVR: surgical aortic valve replacement; SEV: self-expanding valve; TAVI: transcatheter aortic valve implantation.

role of TAVI in asymptomatic patients with severe AS and decreased left ventricular function is unknown.⁷² Finally, there is a lack of data on long-term valve durability, which is particularly important when treating low-risk patients with a longer life expectancy.

Conclusion

TAVI may be a recent approach to treat AS, but it tells a centuries-old story. Looking back at this roadmap, it is easy to see the increasing density of publications over the years, especially after the index TAVI procedure in 2002. More than 300 years after the first description of aortic stenosis, only a decade has passed since the first RCT in extreme-risk patients. The subsequent cascade of RCTs has progressively led to the current position of TAVI in the heart team discussion as a therapeutic option for the management of patients with aortic stenosis of all risk strata (Figure 1).

Conflicts of interest

The authors have no conflicts of interest to declare.

References

- Cordell E. The importance of the study of the history of medicine. *Med Library Hist J.* 1904;2:268–82.
- Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation.* 2002;106:3006–8.
- Rivière L. *Opera Medica Universa. Observationum medicarum, centuria IV, observatio XXI, Cordis Palpatio pulsus inequalitas. Lungduni: Sumptibus Antoni Celler; 1663. p. 83.*
- Major R. Notes on the history of endocarditis. *Bull Hist Med.* 1945;17:351–9.
- Cutler DM, Deaton AS, Lleras-muney A. The determinants of mortality. National Bureau of Economic Research; 2006.
- Möenckeberg JG. Der normale histologische Bau und die Sklerose der Aortenklappen. *Arch F Pathol Anat.* 1904;176:472–514.
- Contratto A, Levine S. Aortic stenosis with special reference to angina pectoris and syncope. *Ann Intern Med.* 1937;10:1636–53.
- Dry T, Willius F. Calcareous disease of the aortic valve. *Am Heart J.* 1939;17:138–57.
- Ross J, Braunwald E. Aortic stenosis. *Circulation.* 1968;38:61–7.
- Wagner S, Selzer A. Patterns of progression of aortic stenosis: a longitudinal hemodynamic study. *Circulation.* 1982;65:709–12.

11. Dineen E, Brent BN. Aortic valve stenosis: comparison of patients with to those without chronic congestive heart failure. *Am J Cardiol.* 1986;57:419–22.
12. Gott VL, Alejo DE, Cameron DE. Mechanical heart valves: 50 years of evolution. *Ann Thorac Surg.* 2003;78:2230–9.
13. Harken DE, Soroff H, Taylor W, et al. Partial and complete prostheses in aortic insufficiency. *J Cardiothorac Surg.* 1960;40:744–62.
14. Harken DE, Taylor WJ, Lefemine AA, et al. Aortic valve replacement with a caged ball valve. *Am J Cardiol.* 1962;9:292–9.
15. Effler D, Favaloro R, Groves L. Heart valve replacement. *Ann Thorac Surg.* 1965;1:14–21.
16. Russo M, Taramasso M, Guidotti A, et al. The evolution of surgical valves. *Cardiovasc Med.* 2017;20:285–92.
17. Chizner MA, Pearle DL, Antonio C. The natural history of aortic stenosis in adults. *Am Heart J.* 1980;99:419–24.
18. Lombard T, Selzer A. Valvular aortic stenosis: a clinical and hemodynamic profile of patients. *Ann Intern Med.* 1987;106:292–8.
19. Turina J, Hess O, Sepulcri F, et al. Spontaneous course of aortic valve disease. *Eur Heart J.* 1987;8:471–83.
20. Selzer A. Changing aspects of the natural history of valvular aortic stenosis. *N Engl J Med.* 1987;317:91–8.
21. Kelly TA, Rothbart RM, Cooper CM, et al. Comparison of outcome of asymptomatic to symptomatic patients older than 20 years of age with valvular aortic stenosis. *Am J Cardiol.* 1988;61:123–30.
22. Frank S, Johnson A, Ross J. Natural history of valvular aortic stenosis. *Br Heart J.* 1973;35:41–6.
23. Rapaport E. Natural history of aortic and mitral valve disease. *Am J Cardiol.* 1975;35:221–7.
24. Pellikka PA. The natural history of adults with asymptomatic, hemodynamically significant aortic stenosis. *JACC.* 1990;15:1012–7.
25. Braunwald E. On the natural history of severe aortic stenosis. *JACC.* 1990;15:1018–20.
26. Cribier AG. The Odyssey of TAVR. *Tex Hear Instit J.* 2014;41:125–30.
27. Iung B, Baron G, Butchart EG, et al. A prospective survey of patients with valvular heart disease in Europe: the Euro Heart Survey on Valvular Heart Disease. *Eur Heart J.* 2003;24:1231–43.
28. Davies H. Catheter-mounted valve for temporary relief of aortic insufficiency. *Lancet.* 1965;285:250.
29. Moupoulus SD, Anthopoulos L. Catheter-mounted aortic valves. *Ann Thorac Surg.* 1976;11:423–30.
30. Phillips SJ, Ciborski M, Freed P, et al. A temporary catheter-tip aortic valve: hemodynamic effects on experimental acute aortic insufficiency. *Ann Thorac Surg.* 1976;21:134–7.
31. Cribier A, Savin T. Percutaneous transluminal valvuloplasty of acquired aortic stenosis in elderly patients: an alternative to valve replacement? *Lancet.* 1986;327:63–7.
32. Percutaneous balloon aortic valvuloplasty. The NHLBI Balloon Valvuloplasty Registry. *Circulation.* 1991;84:2383–97.
33. Letac B, Cribier A, Koning R, et al. Results of percutaneous transluminal valvuloplasty in 218 adults with valvular aortic stenosis. *Am J Cardiol.* 1988;62:598–605.
34. Safian RD, Berman AD, Diver DJ, et al. Balloon aortic valvuloplasty in 170 consecutive patients. *N Engl J Med.* 1988;319:125–30.
35. Feldman T, Glagov S, Carroll JD. Restenosis following successful balloon valvuloplasty: bone formation in aortic valve leaflets. *Cathet Cardiovasc Diagn.* 1993;29:1–7.
36. O'Neill W. Predictors of long-term survival after percutaneous aortic valvuloplasty: report of the Mansfield Scientific Balloon Aortic Valvuloplasty Registry. *JACC.* 1991;17:193–8.
37. Andersen H, Knudsen L. Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs. *Eur Heart J.* 1992;13:704–8.
38. Boudjemline Y, Bonhoeffer P. Steps toward percutaneous aortic valve replacement. *Circulation.* 2002;105:775–8.
39. Bonhoeffer P, Boudjemline Y, Saliba Z, et al. Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction. *Lancet.* 2000;356:1403–5.
40. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med.* 2010;363:1597–607.
41. Popma JJ, Adams DH, Reardon MJ, et al. Transcatheter aortic-valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. *JACC.* 2014;63:1972–81.
42. Kapadia S, Pichard AD, Douglas PS, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. *N Engl J Med.* 2012;366:1696–704.
43. Kapadia SR, Tuzcu EM, Makkar RR, et al. Long-term outcomes of inoperable patients with aortic stenosis randomly assigned to transcatheter aortic valve replacement or standard therapy. *Circulation.* 2014;130:1483–92.
44. Kapadia SR, Leon MB, Makkar RR, et al. 5-Year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet.* 2015;6736:1–7.
45. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med.* 2011;364:2187–98.
46. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med.* 2014;370:1790–8.
47. Kodali S, Williams MR, Smith CR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med.* 2012;366:1686–95.
48. Mack MJ, Leon M, Smith CR, et al. 5-Year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet.* 2015;385:2477–84.
49. Reardon MJ, Adams DH, Kleiman NS, et al. 2-Year outcomes in patients undergoing surgical or self-expanding transcatheter aortic valve replacement. *JACC.* 2015;66:113–21.
50. Deeb GM, Reardon MJ, Chetcuti S, et al. 3-Year outcomes in high-risk patients who underwent surgical or transcatheter aortic valve replacement. *JACC.* 2016;67:2265–74.
51. Gleason TG, Reardon MJ, Popma JJ, et al. 5-Year outcomes of self-expanding transcatheter versus surgical aortic valve replacement in high-risk patients. *JACC.* 2018;72:2687–96.
52. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2016;374:1609–20.
53. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2017;376:1321–31.
54. Thourani VH. Five-year outcomes from the PARTNER 2A trial: transcatheter vs. surgical aortic valve replacement in intermediate-risk patients. In: Present TCT 2019. 2019, 09.
55. Thyregod H, Steinbrüchel D, Ihlemann N, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis. 1-Year results from the all-comers NOTION randomized clinical trial. *JACC.* 2015;65:2184–94.
56. Thyregod H, Ihlemann N, Jorgensen T, et al. Five-year clinical and echocardiographic outcomes from the Nordic Aortic Valve Intervention (NOTION) randomized clinical trial in lower surgical risk patients. *Circulation.* 2019;139:2714–23.

57. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;380:1695–705.
58. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med*. 2019;380:1706–15.
59. Meredith IT, Worthley SG, Whitbourn RJ, et al. Transfemoral aortic valve replacement with the repositionable Lotus Valve System in high surgical risk patients: the REPRISE I study. *EuroIntervention*. 2014;9:1264–70.
60. Gooley R, Worthley SG, Whitbourn RJ, et al. Final results from the REPRISE I study: five-year clinical outcomes with the repositionable and fully retrievable LOTUS valve system. *EuroIntervention*. 2018;14:1180–2.
61. Meredith IT, Walters D, Dumonteil N, et al. Transcatheter aortic valve replacement for severe symptomatic aortic stenosis using a repositionable valve system. *JACC*. 2014;64:1339–48.
62. Meredith IT, Walters D, Dumonteil N, et al. 1-year outcomes with the fully repositionable and retrievable lotus transcatheter aortic replacement valve in 120 high-risk surgical patients with severe aortic stenosis. *JACC*. 2016;9:376–84.
63. Dumonteil N, Walters D, Worthley SG, et al. Final 5-year outcomes of the REPRISE II study: long-term outcomes with the fully repositionable and retrievable lotus transcatheter aortic valve. *J Am Coll Cardiol*. 2018;72. B6-suppl B. A.
64. Abdel-Wahab M, Mehilli J, Frerker C, et al. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. *JAMA*. 2014;311:1503–14.
65. Richardt D, Landt M, Jose J, et al. 1-Year outcomes after transcatheter aortic valve replacement with balloon-expandable versus self-expandable valves. *JACC*. 2015;66:791–800.
66. Abdel-Wahab M. Five-year outcomes after TAVI with balloon expandable vs. self expandable valves: results from the CHOICE randomized clinical trial. In: Presented at EuroPCR. 2019.
67. Feldman TE, Reardon MJ, Rajagopal V, et al. Effect of mechanically expanded vs self-expanding transcatheter aortic valve replacement on mortality and major adverse clinical events in high-risk patients with aortic stenosis: the REPRISE III randomized clinical trial. *JAMA*. 2018;319:27–37.
68. Reardon MJ, Feldman TE, Meduri CU, et al. Two-year outcomes after transcatheter aortic valve replacement with mechanical vs self-expanding valves: the REPRISE III randomized clinical trial. *JAMA*. 2019;02:1–7.
69. Lanz J, Kim W, Walther T, et al. Safety and efficacy of a self-expanding versus a balloon-expandable bioprosthesis for transcatheter aortic valve replacement in patients with symptomatic severe aortic stenosis: a randomised non-inferiority trial. *Lancet*. 2019;S0140:32220–2.
70. Makkar RR, Cheng W, Waksman R, et al. Self-expanding intra-annular versus commercially available transcatheter heart valves in high and extreme risk patients with severe aortic stenosis (PORTICO IDE): a randomised, controlled, non-inferiority trial. *Lancet*. 2020;396:669–83.
71. Thiele H, Kurz T, Feistritz HJ, et al. Comparison of newer generation self-expandable vs. balloon-expandable valves in transcatheter aortic valve implantation: the randomized SOLVE-TAVI trial. *Eur Heart J*. 2020;41:1890–9.
72. Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J*. 2017;38:2739–86.