Abstract This paper describes the history of transcatheter aortic valve implantation (TAVI) from its preclinical phase during which visionary pioneers developed its concept and prototype valves against strong head wind to first application in clinical practice (2002) and the clinical and scientific role of an early believer and adopter, the Netherlands (2005).

Keywords Aortic stenosis · TAVI

Introduction

2020 is the year that the Netherlands was to host the annual meeting of the European Society of Cardiology (ESC) whose mission is to reduce the burden of cardiovascular disease through education, congresses, surveys and publishing [1]. We as medical professionals as well as those who are directly or indirectly involved in the deterrence of illness or ailment and/or the delivering of care (e.g. healthcare authorities such as governments, controlling & advisory bodies, insurance companies, medical industry, etc.), should in addition to that statement also be inspired by the US Food and Drug Administration (FDA) that has taken the role and responsibility of ensuring the timely availability of innovative, safe and effective products to the American people [2].

Transcatheter aortic valve implantation (TAVI) is an example of such a technology that has proven to reduce disease burden by improving quality of life and survival in patients with aortic stenosis [3–9]. Because of its minimally invasive nature (local anaesthesia, minimal incision, beating heart procedure, no cardiopulmonary bypass, …) and its undeniable efficacy as it reduces valve stenosis, it has been embraced by physicians, patients and relatives. This enthusiasm is supported by the findings showing overall clinical equivalence between TAVI and surgical aortic valve replacement (SAVR) which necessitates general anaesthesia, extensive surgical trauma, cardiac arrest and cardiopulmonary bypass. TAVI is a disruptive technology and has caused a sea change in cardiovascular
therapy similar to intracoronary stenting 40 years ear-
lier [10].

At the cradle of TAVI are the visionary pioneers in Europe who came up with the idea and had the
courage to introduce TAVI in clinical practice notwith-
standing endless pessimism and even open opposi-
tion. Interestingly, the discussion of added clinical
value and, thus, appropriateness of reimbursement
is still present notwithstanding the consistent find-
ings of the various randomised controlled trials and
numerous multicentre surveys. This contrasts with
the position of the FDA that has granted approval of
TAVI in patients with aortic stenosis at low risk (Au-
gust 2019). It also contrasts with the respected po-
sition of the Netherlands, which ranks fourth on the
Global Innovation Index 2019 (after USA, Switzerland,
and Sweden) and has been in the top ten of all coun-
tries in the world for many years [11]. It also ranks very
highly in matters of social, economic and political sta-
bility, infrastructure and organisation and belongs to
the elected group of high-income countries.

The early 1990s—Henning Andersen, Aarhus,
Denmark

The TAVI story started in February 1989 when Hen-
nning Andersen—inspired by a lecture of Julio Palmaz
on the development of coronary stents—thought of
inserting a biological valve inside a large stent and
to implant this using a balloon-expandable technique
similar to the stent technique described by Palmaz.
Andersen manufactured a stent himself with a diam-
eter of 30 mm using metal wires that he bought in a
hardware store in which he mounted a porcine aor-
tic valve that was crimped onto a second-hand 30 mm
balloon catheter pioneered by Cribier in the 1980s.
The assembly was then inserted into a 41 Fr. intro-
ducer sheath (Fig. 1).

The first implantation on 1 May 1989 in an 80 kg pig
was uneventful. Yet, during subsequent experiments
冠状动脉阻塞和瓣膜栓塞偶有发生。他也发现阻断血流可以防止气球移位，为此他开发了一种带有气球的导管，在共同肺动脉中膨胀。

他在1990年5月19日丹麦心脏病学会（Odense, Denmark）上发表了他的工作，但1990年12月心脏病学会（Stockholm, Sweden）的摘要被拒绝。这也有
生的隆凸部”/CIRCLE

First TAVI via the axillary artery, June 2006.
• First true percutaneous TAVI, October 2006.
• Contribution to TAVI using local anaesthesia.
• Cerebral protection.
Historical Review

Fig. 3 First TAVI in the Netherlands in 2015 and milestones in 2006. Professor Serruys, Dr Kappetein and Dr de Jaegere during the first TAVI in the Netherlands on 15 November 2005. General anaesthesia, surgical cut-down, ECMO, CoreValve 26mm valve. The patient died 12 years later (2017). Inset upper left: Dutch newspaper reporting ‘First heart operation via groin’. Inset lower right: first TAVI via the subclavian artery (30 June 2006), inset lower left: CoreValve press release on 20 October 2006 reporting first full percutaneous TAVI in the world on 12 October 2006

Fig. 4 Briefing before TAVI. Briefing before the first TAVI via the subclavian artery (CoreValve 26mm). Seating in front from right to left: M de Ronde (head nurse), Dr de Jaegere, Dr Kappetein (white coat, back), Professor Serruys. Standing behind Professor Serruys: Dr Klein (anaesthesiologist). Please note the ‘script’ in the hands of attendees summarising all procedural steps and materials that were needed in chronological order during the planned procedure

surgeons provided numerous reasons why this could not work. As he could no longer afford the patented costs, he sought and received support from Stanford Surgical Technologies (SST), a small company founded by cardiothoracic surgeons in San Francisco, which licensed his patent with the promise to develop the technology. Yet, nothing happened. SST became Heartport and concentrated on the development of a less invasive SAVR (port access) while holding the exclusive license agreement. On 21 January 2001, Heartport was acquired by Johnson&Johnson-IS (JJ-IS) but three days earlier (18 January 2001) Heartport had sold the exclusive license agreement to Percutaneous Valve Technologies (PVT).

The balloon-expandable valve story—Alain Cribier, Martin Leon, Stan Rabinovich, Stanton Rowe (PVT)

In the mid-1990s Alain Cribier pioneered aortic balloon valvuloplasty (1985) but, confronted with the high restenosis rate, he presented a similar idea to a number of companies (Fig. 2). He knew that a balloon was capable of disrupting a stenotic aortic valve
and decided to take advantage of the calcification for frame-anchoring. The first cadaver experiment was performed in 1994. The stent was conceptualised together with a cardiac surgeon (Dr Bessou) in such a way that in its crimped configuration (8 mm) it would be possible to deliver it via the femoral artery. Analogous to Andersen's experience, companies were not interested as it was considered: 'ridiculous, impossible and unnecessary'. Yet, Stanton Rowe championed the concept at JJ-IS, which licensed Cribier's ideas and agreed to develop the percutaneous valve. Unfortunately, JJ-IS was at that time (1996) in the midst of acquiring Cordis and nothing happened. Cribier returned to Stanton Rowe and Stan Rabinovich who had both left JJ-IS. They brought Cribier's idea back to Martin Leon which resulted in the creation of PVT (21 July 1999). In search of venture capital, they came into contact with an Israeli company ARAN R&D (June 1999, Jerusalem) who were interested in investing money but also in the development of the valve. Yet, the development of the percutaneous valve necessitated Andersen's patents licensed to SST as they contained the fundamentals around a collapsible and expandable valve for which the PVT series A financing was used (December 2000). Despite negative advice from cardiothoracic surgeons, Medtronic and Boston Scientific subsequently became the main investors. A meeting between PVT and Edwards Lifesciences (TCT, September 2003) led to the acquisition of PVT (12 December 2003) after consent from Medtronic and Boston Scientific [14].

The first animal (non-atherosclerotic) experiments using polymeric valves were performed in August 2000 but without success since there was no anchoring. The choice of healthy animals is understandable but surprising given Cribier's initial experiments with cadaver hearts. Noteworthy is the short time between the animal experiments and the first clinical TAVI (16 April 2002). Cribier was faced with a 57-year-old man in heart failure and a poor left ventricular ejection fraction (10%). To complicate matters, the patient had a failed aorto-bifemoral graft precluding a transfemoral approach for which the valve system was designed. At the risk of jeopardising all the work done, its future and the company the decision was taken to use the valve system via an 'unplanned' antegrade-transseptal route given the patient's fate if nothing was done. In a subsequent feasibility study (36 patients, 2002–2005) the 'success rate' was 75% but paravalvular aortic regurgitation frequently occurred since only one size (23 mm) was available. During this study, the value of rapid ventricular pacing for valve delivery was recognised. Now, so many years after this pioneering work, Cribier says ‘... it is moving to remember the fierce opposition of experts towards this “totally unrealistic and stupid idea” that “would never work”.'

The self-expanding valve story—Georg Boertlein, Rob Michiels, Jacques Sequin (CoreValve)

CoreValve was founded by a cardiothoracic surgeon Jacques Sequin in Paris in 2001 together with a biomedical engineer Georg Boertlein, who both understood the future of a catheter-based minimally invasive aortic valve treatment. In 2001, they found Rob Michiels (managing director of CONSILIUM active in identification, funding and green-housing of start-up technologies) immediately interested, which led to the entire high risk ‘seed round’ of

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**Table 1** Summary start TAVI in the Netherlands

| Year | Month | Day | Hospital  | City      |
|------|-------|-----|----------|-----------|
| 1    | 2005  | 11  | Erasmus MC| Rotterdam |
| 2    | 2006  | 2   | Amphia    | Breda     |
| 3    | 2007  | 6   | St Antonius | Nieuwegein |
| 4    | 2007  | 10  | AMC       | Amsterdam |
| 5    | 2007  | 11  | LUMC      | Leiden    |
| 6    | 2008  | 4   | UMCU      | Utrecht   |
| 7    | 2008  | 26  | MCL       | Leeuwarden|
| 8    | 2008  |     | Catharina | Eindhoven |
| 9    | 2008  |     | Radboud   | Nijmegen  |
| 10   | 2008  |     | UCMC      | Maastricht|
| 11   | 2009  | 5   | UMCG      | Groningen |
| 12   | 2009  | 15  | OLVG      | Amsterdam |
| 13   | 2009  | 2   | Isala     | Zwolle    |
| 14   | 2012  | 13  | MST       | Enschede  |
| 15   | 2013  | 27  | Haga      | The Hague |
| 16   | 2014  | 30  | VUMC      | Amsterdam |

Population of the Netherlands (2018): 17.2 million (population density of 488 people/km²)
Gross domestic product/capita (2018): 53,228$
Hospital beds/1000 people: 5.8 (1990)–4.7 (2009). (USA 3.1 in 2009—source WHO)
CoreValve (mid-2002) and paved the way to the first-in-man in 2004 despite the fact that ‘... well-regarded medical professionals told them that we were crazy and it would be over their dead body if one of these ever got implanted in a patient’.

The CoreValve technology featured a novel leaflet and construction design using porcine pericardium to allow for more compression capability, thereby reducing catheter size and developing a true ‘interventional’ device. CoreValve chose a strategy of restricted use by a small number of centres in Europe that was continued after CE marking in 2007 for the 3rd generation to assure successful maturing of their technology, appropriate training of physicians and to gather additional clinical data for post-approval surveillance later submission to the FDA.

**TAVI in the Netherlands**

The first TAVI in the Netherlands was performed in the Erasmus Medical Center, Rotterdam on 15 November 2005 using the self-expanding CoreValve (Fig. 3). [15] The team first conducted a short animal experiment to get a feel for the catheter system and technique of delivery (September 2005). The product was not CE-marked and, therefore, permission for compassionate use was granted by the Ministry of Health. Given the experimental nature and limited experience, a script was written in which all steps in chronological order were summarised including the materials and responsibility of each team member throughout the procedure (Fig. 4). This was continued during the early years of TAVI (2005–2007), which established a disciplined surgical-type approach in the intervention room that became an undisputable and natural modus operandi. Shortly after this, and in close cooperation with the Erasmus Medical Center, the second TAVI and first inclusion in the CoreValve first-in-man study was performed in the Amphia Hospital, Breda in February 2006 (Tab. 1).

At that time, some sort of circulatory support was recommended. In the first and the second patient (4 April 2006) an extracorporeal membrane oxygenation system was used but replaced by the TandemHeart in the next three as this allowed percutaneous insertion. It was also the period that an interventional radiologist experienced with percutaneous endovascular aortic repair (Lucas van Dijk) trained the team in echo-guided arterial access. This in combination with the use of a percutaneous closure device (Prostar) and the fact it turned out that TAVI could be performed without circulatory support (stable haemodynamics when reducing flow) led to the first fully percutaneous TAVI in the world (12 October 2006, Fig. 3). [16] A milestone that has been adopted world-wide and has become the standard for transfemoral TAVI (TF-TAVI). Of note, this was preceded by another first-in-the-world, namely TAVI via the subclavian artery on 30 June 2006 (Fig. 4), which has become the dominant approach in Radboud University Medical Center.

The next major step was the use of local anaesthesia. This was pioneered in the Netherlands by the team at the Academic Medical Center Amsterdam and first performed in 2010. It was the stepping stone for further simplification of TAVI to a minimalist approach mimicking PCI [17]. Moreover, TF-TAVI is now possible via a two-arterial access only (femoral artery for valve delivery and pacing over the wire, contralateral femoral or radial for pig-tale guidance) [18]. In case of TAVI for failed bioprosthesis, single access (femoral) suffices as the radiopaque structures of the bioprosthesis can be used as reference for valve deployment. During all those innovations, a fully percutaneous TAVI via the axillary artery under local anaesthesia became a reality and was first performed on 13 September 2011 (Fig. 5). In conjunction with the experience gained and improved catheter and valve
Table 2  Peer-reviewed papers (source PubMed, EndNote X9) by Dutch investigators (as of 1 March 2020)

| Year | n | ≥15 | ≥10–15 | 0–10 |
|------|---|-----|--------|------|
| 2007 | 1 | 0   | 1      | 0    |
| 2008 | 3 |     |        | 3    |
| 2009 | 1 |     |        | 1    |
| 2010 | 15| 1   | 1      | 13   |
| 2011 | 13|     |        |      |
| 2012 | 18| 2   | 1      | 15   |
| 2013 | 22| 2   | 3      | 17   |
| 2014 | 36| 5   |        |      |
| 2015 | 30| 2   | 1      | 27   |
| 2016 | 33| 2   | 1      | 30   |
| 2017 | 48| 9   | 0      | 39   |
| 2018 | 48| 6   | 0      | 42   |
| 2019 | 54| 2   | 0      | 52   |
| 2020 | 24| 2   | 0      | 22   |

Total number of publications (n) per year are subdivided by the journal Impact Factor (2019) using the following categories: ≥15, 10–15 and 0–10.

Table 3  PhD theses by Dutch Academic Institutions

| Year | Institute | 1th Promotor | 1th Copromotor | Candidate | Title |
|------|-----------|--------------|----------------|-----------|-------|
| 1    | 2011 EMC  | Serruys      | De Jaegere     | Tzikas    | The role of advanced imaging in TAVI |
| 2    | 2011 EMC  | Serruys      | De Jaegere     | Piazza    | TAVI: from experiment to clinical practice and beyond |
| 3    | 2012 AMC  | Piek         | Baan           | Yong      | Clinical and haemodynamic effects of TAVI |
| 4    | 2013 EMC  | De Jaegere   | Van Domburg    | Nuis      | TAVI: Current results, insights & future challenges |
| 5    | 2014 AMC  | Piek         | Baan           | Van Dijk  | Percutaneous treatment of heart valve disease |
| 6    | 2014 EMC  | De Jaegere   | n.a.           | Van Mieghem | Transcatheter aortic valve therapies: from cutting edge to mainstream |
| 7    | 2014 EMC  | De Jaegere   | Van Domburg    | Van der Boon | Insights into complications of TAVI |
| 8    | 2014 LUMC | Bax          | Delgado        | Katsanos  | Outcomes of TAVI |
| 9    | 2014 UMCM | Prinzen      | Van Gelder     | Houthuizen | Left bundle branch block: controversies in aortic interventions and cardiac resynchronisation therapy |
| 10   | 2014 UMCU | Doevendans   | Stella         | Samim     | TAVI; optimisation of the technique, assessment of complications an future directions |
| 11   | 2015 UMCU | Doevendans   | Stella         | Nijhoff   | Evolving concepts in TAVI |
| 12   | 2016 AMC  | Piek         | Baan           | Wiegerrink | Replacing the valve, restoring flow. Effects of TAVI |
| 13   | 2016 AMC  | Van Bavel    | Marquering     | Elattar   | Quantitative image analysis for planning of aortic valve replacement |
| 14   | 2016 LUMC | Bax          | Delgado        | Ewe       | Aortic valve disease: novel imaging insights from diagnosis to therapy |
| 15   | 2018 AMC  | Piek         | Baan           | Kesteren van | Screening complications and outcome of aortic valve implantation |
| 16   | 2018 EMC  | De Jaegere   | Van Mieghem    | Gils van  | TAVI: insights and solutions for clinical complications and future perspectives |
| 17   | 2018 UMCM | Prinzen      | Houthuizen     | Poels     | Left bundle branch block in TAVI |
| 18   | 2019 AMC  | Piek         | Baan           | Delewi    | Cerebral outcomes in patients undergoing TAVI |
| 19   | 2019 AMC  | Kappetein    | Piazza         | Moyal     | Evolution of transcatheter heart valve technology |
| 20   | 2019 AMC  | Kappetein    | Piazza         | Mylto     | Evolution of transcatheter heart valve technology |
| 21   | 2019 UMCU | Doevendans   | Stella         | Kooistra  | Individualised optimisation of TAVI |
| 22   | 2020 UMCU | Doevendans   | Stella         | Abawi     | Role of novel predictive factors on clinical outcome after transcatheter aortic valve replacement |
| 23   | 2020 EMC  | Mattace Raso | Lenzen         | Goudzwaard | The impact of frailty on outcome after TAVI in older patients |
| 24   | 2020 EMC  | De Jaegere   | Lenzen         | Faquir    | Clinical application of patient-specific computer simulation and advanced imaging in TAVI |

https://www.narcis.nl/search/coll/publication/Language/NL/uquery/TAVI
technology, a program of early discharge was instituted [18–21]. The Netherlands also played an important role in the adoption and evaluation of the use of cerebral protection devices for the prevention of perioperative stroke [22]. Last but not least and perhaps more importantly, the typical Dutch spirit of consultation and collaboration has led to structured multidisciplinary decision-making, planning, execution and evaluation involving medical specialists with various backgrounds and expertise ensuring balanced treatment stratification via the heart-team [23]. Given the outstanding infrastructure in the Netherlands, such as the nationwide prospective registry that was created under the auspices of the Netherlands Society of Cardiology and Cardio-Thoracic Surgery to improve quality of care by monitoring patient demographics and clinical outcomes (BHN-registratie), clinical programs are incorporated into clinical-scientific ones [24]. The TAVI Care and Cure is an example of this [25]. The clinical scientific output of the Netherlands is summarised in Tab. 2 and 3. Beyond the analysis of outcomes and the underlying mechanisms in single, multicentre national and international initiatives and collaborations, research has been initiated to elucidate and predict the interaction between the device and host as well as the role of Artificial Intelligence in TAVI [26–35]. The clinical drive of innovation providing the best possible care to the individual patient and the scientific work (volume and content) of all Dutch medical professionals is an expression of the stimulating environment in which they have the pleasure to live and work.

Acknowledgements The authors express their respect and gratitude to Henning Andersen, Alain Cribier, Stan Rabinovich, Stanton Rowe and Rob Michaels who kindly provided written testimonies of their pioneering work that they allowed us to use for this paper.

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