# 1

# Introduction

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With the dramatic reduction of rheumatic disease and the increase in life expectancy, valvular diseases are now mostly degenerative in industrialized countries [1]. Calcific aortic stenosis (AS) is the most common heart valve anomaly, with a largely age-dependent prevalence, a calculated annual incidence rate in the range of 4–5‰ in general populations and a marked increase up to 6% in patients ≥75 years of age [2, 3].

Surgical aortic valve replacement (SAVR) was previously the only option available to patients with symptomatic, severe aortic stenosis, without which a median survival of ~2 years was to be expected [4].

After the first-in-human transcatheter aortic valve implantation (TAVI) performed by Alain Cribier in 2002 [5], the treatment strategy for patients with symptomatic aortic stenosis has been revolutionized. In over 15 years, penetration of TAVI has grown exponentially, as a result of accruing evidence demonstrating safety and efficacy, and reduced invasiveness compared with SAVR.

Favorable outcomes of TAVI were documented in randomized clinical trials among compassionate and inoperable cases [6], then comparing outcomes with SAVR in high-risk patients [7–9] and more recently in intermediate-risk populations [10, 11]. On the basis of such evidence, guidelines from both American Heart Association (AHA)/American College of Cardiology (ACC)/Society of Thoracic Surgery (STS) [12] and after the Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial [11], European Society of Cardiology (ESC)/European Association of Cardio-Thoracic Surgery (EACTS) [13] recommend SAVR for symptomatic AS in low-risk patients, TAVI in patients deemed not suitable for surgery; in patients >75 years old at intermediate surgical risk (STS or EuroSCORE II ≥4), guidelines recommend that the decision between SAVR and TAVI should be made by the Heart Team, with TAVI "being favored" in elderly patients suitable for transfemoral access (Table 1.1).

Moreover, TAVI devices have expanded to include several valve design options, allowing a dramatic increase in the number of patients who might benefit from this evolving technology [14].

TAVI systems can be currently divided into balloon-expandable valves, self-expanding valves, or devices with a controlled-release deployment method (Figure 1.1). At present,

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**Table 1.1** Current recommendations for TAVI in patients with aortic valve disease.

| Patient profile, as assessed by the Heart Team | ACC/AHA/STS guidelines [12] | ESC/EACTS guidelines [13] |
|---|---|---|
| Severe AS, inoperable | Class I, LOE A | Class I, LOE B |
| Severe AS, high surgical risk | Class I, LOE A | |
| Severe AS, intermediate surgical risk[a]<br>STS score or Euroscore II ≥ 4% | Class IIa, LOE B | Class I, LOE B[b] |
| Severe AS, low surgical risk[a]<br>STS score or Euroscore II < 4% | Not recommended<br>SAVR: class I, LOE A | Not recommended<br>SAVR: class I, LOE B |
| Bioprosthetic valve failure | Class IIa, LOE B | Reasonable alternative if the patient is at increased surgical risk |

LOE = level of evidence.
STS = Society of Thoracic Surgeons; score calculator is available at http://riskcalc.sts.org/stswebriskcalc/#/calculate.
EuroSCORE = European System for Cardiac Operative Risk Evaluation; score calculator is available at http://www.euroscore.org/calc.html.
[a] Without other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation.
[b] The decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics, with TAVI being favored in elderly patients suitable for transfemoral access.

the most robust clinical data and resultant market share have been dominated by the SAPIEN and CoreValve devices, both currently commercialized with their third-generation systems.

As techniques are continuously evolving to treat younger patients and lower-risk populations, aside from the long-term durability of the valve systems, procedural safety will become the focus of newer-generation devices [15] (Figures 1.2 and 1.3). However, despite improvements in device technology, specific complications remain and warrant dedicated consideration.

During the early TAVI period, vascular complications, systemic embolization with periprocedural neurological events, conduction disturbances, aortic annular rupture, valve migration, and paravalvular regurgitation were main concerns [16]. Newer valve designs have been engineered to reduce other major events. The radial force has been increased, recapturability has been ameliorated, steerability and softness of the systems have been further improved. Sheaths have been reduced to decrease vascular complications. A skirt has been added on the outside of the valve frame to seal paravalvular leaks. Together with technical improvement, operator expertise and multimodality imaging have increased the accuracy of TAVI planning, minimizing the risk of most adverse events (Figure 1.2), that have a relevant impact on survival, anyway [17, 18]. For instance, the risk of coronary occlusion, first contained through careful planning and with the use of coronary protective strategies during valve deployment, has now a renewed interest with the growing use of TAVI as a valve-in-valve treatment in patients with degenerated bioprosthetic aortic valves [19]. Embolic protection devices have been introduced to reduce the occurrence of cerebrovascular complications, but the clinical translation of such benefit is still controversial [20]. Moreover, concern has arisen on the risk of leaflet thrombosis [21], and the optimal antithrombotic strategy is currently the aim of several clinical randomized trials.

| | Sapien 3 (Edwards) | Evolut R (Medtronic) | Evolut Pro (Medtronic) | Acurate (Boston Scientific) | Portico (Abbott St Jude) | Lotus Edge (Boston Scientific) | Allegra (NVT) | Centera (Edwards) | Jena Valve (JenaValve) | Myval (Meril) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Valve tissue** | BP | PP | PP | PP | BP | BP | BP | BP | PP | BP |
| **Frame** | CC | NiTi | NiTi | NiTi | NiTi | NiTi | NiTi | NiTi | NiTi | NiCo |
| **Deployment** | B–E | S–E | S–E | S–E | S–E | M–E | S–E | S–E | S–E | B–E |
| **THV size** | 20–23–26 –29 | 23–26–29–34 | 23–26–29 | S–M–L | 23–25–27 | 23–25–27 | 23–27–31 | 23–26–29 | 23–25–27 | 20–21.5–23 24.5–26– 27.5–29– 30.5–32 |
| **Sheat size** | 14*–16* Fr | 14–16 Fr | 16 Fr | 14*–18–19 Fr | 18–19 Fr | 18–20 Fr | 18 Fr | 14* Fr | 18 Fr | 14* Fr |
| **Advantages** | External PET skirt to reduce PVL | Resheathable up to 80% deployment | Resheath up to 80% deployment; external pericardial wrap to increase anulus/valve contact | Low permanent pacemaker requirement | Resheath up to 85% deployment | Fully repositionable Reduced LVOT interaction | Resheathable up to 70% deployment | Resheath up to 85% deployment Motorized delivery. PTFE skirt to reduce PVL | Active fixation for use in aortic regurgitation | External PET buffing to minimize PVL |

**Figure 1.1** Currently available CE-approved TAVI systems. BP = bovine pericardium; PP = porcine pericardium; CC = cobalt-chromium; NiTi = nitinol (nickel-titanium); B-E = Balloon-expandable; S-E = Self-expandable; M-E = mechanically expandable; THV = transcatheter heart valve; PET = polyethylene terephthalate; PVL = paravalvular leak; LVOT = left ventricular outflow tract.
*expandable sheat.

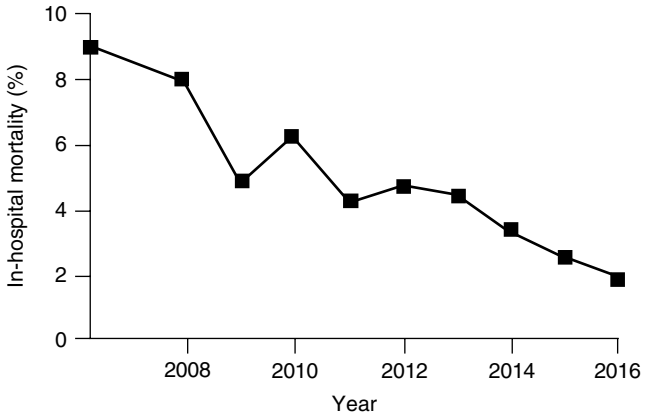


**Figure 1.2** Temporal trends in the incidence of in-hospital mortality rates in patients undergoing TAVI.

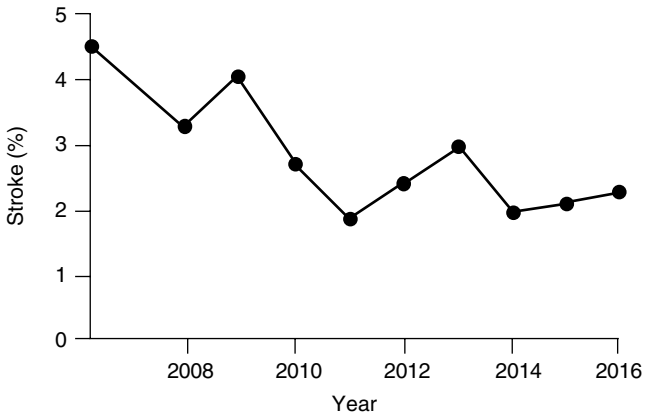


**Figure 1.3** Temporal trends in the incidence of stroke rates in patients undergoing TAVI.

The present monography is a practical handbook devoted to the optimization of TAVI procedures, through a focused containment of complications. Through an integrated evaluation of the clinical status, imaging techniques and laboratory findings, authors will provide readers with clear messages on preventive and therapeutic recommendations.

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