Comparing outcomes between surgical aortic valve replacement and transcatheter aortic valve implantation

Transcatheter aortic valve implantation (TAVI) has been introduced for the treatment of high-risk patients with symptomatic aortic stenosis. Surgical aortic valve replacement (SAVR) provides the therapeutic armamentarium for all complex valvular pathologies and is the established gold standard. TAVI has initially been restricted to non-operative patients. The extension of this treatment modality to less complex patient populations warrants a thorough comparison of safety and efficacy vis-à-vis SAVR. Perioperative mortality of SAVR for high-risk subpopulations such as octogenarians, patients with impaired LV function or previous sternotomy ranges from 5 to 19%. Peri-interventional mortality rates for TAVI amount to 6–23%. Reported stroke rates average 2–5% with both treatment modalities. While TAVI does not require cardiopulmonary bypass or general anesthesia, the spectrum of peri-interventional complications is extended to vascular access site complications as well as atrioventricular conductance disturbances. Results from randomized trials are necessary to prove safety and efficacy of TAVI compared with SAVR.

KEYWORDS: aortic stenosis, endovascular, surgical aortic valve replacement, transcatheter aortic valve implantation

The prevalence of valvular heart disease increases substantially as the population ages and is associated with impaired survival (Figure 1) [1]. The natural course of symptomatic aortic stenosis portends a poor life expectancy once symptoms of angina, syncope or heart failure ensue (Figure 2) [2]. More recent data indicate an impaired prognosis even in asymptomatic patients [3,4]. Aortic valve replacement using surgical techniques has been shown to effectively alleviate symptoms and improve survival and represents one of the most frequently performed cardiac surgical procedures (Figure 3). However, up to a third of patients are said not to undergo surgery [5,6] due to advanced age, comorbidities and depressed left ventricular function, recent myocardial infarction or severe concomitant coronary artery disease [9].

Valvular heart surgery has been introduced into clinical practice in the early 1960s shortly after the establishment of cardiopulmonary bypass. Within only one decade, two categories of heart valves were established – mechanical and biological valve prostheses. The caged ball valve design applied in the first mechanical valve prostheses (St Jude Medical) in the 1990s. Despite continuous efforts to advance heart valve technology, mechanical prostheses retain a substantial risk of thromboembolism and anticoagulation-related bleeding, while structural deterioration remains the principal concern of biological valves. Technical refinements of valvular design went in parallel with efforts to elaborate minimally invasive surgical approaches. Following demonstration of the feasibility of transcatheter implantation of heart valves in aortic and pulmonary position in experimental models [13,14], Cribier performed the first transcatheter aortic valve implantation in man in 2002 [15], whereas Bonhoeffer reported the first transcatheter pulmonary valve implantation also in 2002 [16]. The antegrade approach of transcatheter aortic valve implantation via femoral vein access, trans-septal puncture, passage of the left atrium and mitral valve was soon replaced by the retrograde approach via the femoral artery [17,18] and complemented by an antegrade surgical approach via direct transapical access [17,19].

Surgical aortic valve replacement (SAVR) is the current gold standard in the treatment of severe, symptomatic aortic stenosis owing to its proven safety and efficacy record over several decades in large patient populations with a wide spectrum of aortic disease. Conversely, transcatheter aortic valve implantation (TAVI) was only recently introduced into clinical practice and currently undergoes evaluation of safety...
Transcatheter aortic valve implantation has been introduced as an alternative treatment for valvular aortic stenosis particularly in the subset of patients deemed at increased risk of SAVR. Consequently, patients assigned to this novel treatment strategy were primarily recruited from the patient population previously considered inappropriate candidates for open heart surgery. Both excitement and controversy surround this new treatment option as it provides a less invasive strategy appealing to both patients and physicians, while it has to prove safety and efficacy during short- and long-term follow-up vis-à-vis the established gold standard of SAVR.

**Surgical aortic valve replacement**

Aortic valve replacement through a standard median sternotomy or via minimally invasive approaches through a limited sternotomy or lateral thoracotomy shares the common necessity of cardiopulmonary bypass and mechanical ventilation. Surgical access facilitates concomitant interventions and hence provides treatment for the entire spectrum of valvular heart disease. Thus, aortic regurgitation due to dilatation or dissection of the ascending aorta can be managed in a similar way as well as concomitant mitral valve pathology or surgical revascularization of coronary arteries. Young patients with a long life-expectancy qualify for mechanical valve prostheses with prolonged durability and a lower risk of valve-related reinterventions. Conversely, patients aged 65 years and older frequently undergo implantation of bioprosthetic heart valves as event-free survival is similar to mechanical prostheses, and the risk of bleeding and thromboembolic complications substantially lowered. Compared with current transcatheter strategies, not only is SAVR the current gold-standard treatment for severe aortic stenosis, but TAVI also provides the therapeutic armamentarium for all complex cardiac pathologies (beyond isolated aortic stenosis).

**Patient population**

Valvular aortic stenosis is the most common pathology leading to SAVR worldwide. SAVR has been shown superior to a conservative treatment strategy in symptomatic patients and recent data suggest the same for asymptomatic individuals. Given the dismal prognosis of the natural course of symptomatic aortic stenosis, SAVR represents the treatment of choice ever since its introduction and is widely applied across different patient populations. Notwithstanding, SAVR requiring cardiopulmonary bypass, an open sternotomy and general anesthesia is associated with perioperative complications such as death and stroke as well as prolonged ventilation and hospitalization time particularly in high-risk and frail patients. In addition, porcelain aorta, exposure to radiation therapy and previous cardiac operations such as coronary artery bypass surgery are associated with an increased risk of adverse events.

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**Figure 1. Prevalence of valvular heart disease by age.** (A) Frequency in population-based studies and (B) in the Olmsted County community. Adapted with permission from [72].
■ Safety of SAVR
Perioperative mortality of isolated SAVR in the overall population averages 3%, whereas the mortality for combined SAVR and coronary artery bypass grafting (CABG) amounts to 5% [101]. Perioperative outcome of high-risk subpopulations is predominantly derived from retrospective analyses. Published data of SAVR in high-risk populations can be categorized into those focusing on elderly patients aged 80 years or older (Table 1) [22–36], patients with reduced left ventricular ejection fraction (Table 2) [37–45], patients with increased risk according to EuroSCORE [36,46], or patients with previous sternotomy (Table 3) [47,48]. Concomitant coronary artery bypass grafting has been associated with an incremental risk in some but not all of these studies [25,35,41].

■ Safety of SAVR in octogenarians
Perioperative mortality in patients 80 years of age or older has been reported in the range from 4.3 [25] to 19% (Table 1) [25]. Several studies consistently identified urgent surgery [27,30,33,36], pre- [35] and post-operative [29] renal failure as independent predictors of increased mortality. Moreover, reduced left ventricular ejection fraction, severe congestive heart failure (NYHA functional class IV) [27,30], and pulmonary hypertension have been shown to increase in-hospital mortality [36]. Most reports also indicate an increased risk of procedural mortality with SAVR and concomitant CABG.

Likosky et al. observed a procedural stroke risk of 2.1% in patients aged 80–84 years and of 4.6% in patients older than 85 years of age [35]. These findings correspond well with previous reports of octogenarians undergoing SAVR.

The diagnosis of peri-interventional myocardial infarction following SAVR is difficult and usually requires either new Q waves or the elevation of creatinine kinase-MB in association with persistent ST segment changes [24,29,30,32,34]. Six studies reported on the incidence of peri-procedural myocardial infarction with a low frequency ranging from 0 to 4% (Table 1) [24,29,30,32,34,49].

■ Safety of SAVR in patients with impaired left ventricular function
The impact of impaired left ventricular function on clinical outcome after SAVR has been addressed in several studies with perioperative mortality ranging from 5 [31] to 18% [37] (Table 2). A multicenter study of 217 patients (71 ± 8 years) with low-flow/low-gradient aortic stenosis (left ventricular ejection fraction [LVEF] ≤35% and mean gradient ≤30 mmHg) reported a perioperative mortality of 16% in the overall population. However, the investigators noted a decrease in mortality from 20% in the decade 1990–1999 to more recently 10% in the period from 2000 to 2005 [39].

In a retrospective analysis of 76 patients with LVEF less than or equal to 30%, the incidence of perioperative stroke amounted to 5% in the isolated SAVR cohort and to 8% in the SAVR cohort with concomitant CABG [47]. Multivariate analysis identified low-flow/low-gradient aortic stenosis as an independent predictor of postoperative stroke in this study. Sharony et al. reported a perioperative stroke rate of 5.8% in their cohort of 260 patients with an LVEF less than or equal to 40% [43]. The overall stroke rate was 2.8-fold higher than the risk that was observed in the group with normal left ventricular function. Multivariate analysis identified peripheral vascular disease, previous history of cerebrovascular disease and diabetes as independent predictors of stroke [43].

The occurrence of perioperative myocardial infarction has not been addressed in patients with impaired LVEF undergoing SAVR.

■ Safety of SAVR in patients with previous cardiac surgery or increased EuroSCORE
Several reports have focused on the perioperative risk of SAVR after previous sternotomy (Table 3). Perioperative rates of death range from 4.6 to 8.4% [47,48,50,51] and of stroke from 1.2 to 5.2% [48,50,51].

One study investigated the outcome of redo-SAVR in a cohort of 71 octogenarians that was compared with a control group matched for age,
sex and year of aortic valve replacement. The study cohort underwent concomitant CABG in 20% and mitral valve replacement in 6% of patients. Mortality within 30 days amounted to 15.5% but did not differ significantly between the study cohort and the controls [52]. These findings are conflicting with data from Langanay and colleagues who identified redo-SAVR as independent predictor of in-hospital mortality [27].

Grossi et al. prospectively collected results of 731 high-risk patients as defined by a linear EuroSCORE greater than 7% undergoing isolated SAVR. While mean linear and logistic EuroSCORE predicted a 30-day mortality of 9.7 and 17.2%, respectively, in this population, actual in-hospital mortality amounted to 5.7 and 3.4% of patients suffered from stroke [46]. Another study evaluated outcome of octogenarians undergoing isolated SAVR at a single institution with a particular focus on risk stratification by EuroSCORE [36]. Patients were categorized into low-risk (log EuroSCORE ≤10%), moderate-risk (log EuroSCORE >10 to <20%) and high-risk groups (log EuroSCORE ≥20%).

In-hospital mortality was 7.5% in the low-risk group (n = 107), 12.6% in the moderate-risk group (n = 103) and 12.5% in the high-risk group (n = 72).

**Efficacy of SAVR**

Surgical aortic valve replacement looks back to a long tradition of heart valve surgery using various prostheses and different surgical approaches and data on long-term survival after SAVR in octogenarians is available. The largest published cohort of octogenarians observed actuarial survival rates after 1, 3, 5 and 8 years of 89, 79, 69 and 46%, respectively [22]. Actuarial survival analysis of 345 octogenarians undergoing SAVR with a follow-up of 40 ± 33 months showed that 61% of patients at 5 years and 21% of patients at 10 years were alive [33]. Melby et al. observed an actuarial survival rate of 82% at 1 year, 70% at 3 years and 56% at 5 years during a mean follow-up of 4.2 ± 3.3 years [29], whereas Kolh et al. reported a 5-year survival rate of 73 ± 7% (mean follow-up 58.2 months) in 220 consecutive octogenarians undergoing SAVR [21]. Similar findings were reported by Unic et al. (actuarial survival rate at 1 year and 5 years of 92 ± 1% and 66 ± 5%) [25] and Filsoufi et al. (1-year survival: 90.3 ± 2.1%; 5-year survival: 63.8 ± 4.8%; mean follow-up 3.6 ± 2.5 years) [32]. Urgent procedures were independently associated with late mortality in two studies [30,36]. Moreover, previous stroke [36], prior myocardial infarction [30], postoperative stroke [29] and congestive heart failure [34] resulted in adverse long-term outcome.

**Transcatheter aortic valve implantation**

Transcatheter techniques for aortic valve implantation circumvent the need for cardiopulmonary bypass and general anesthesia. Currently, two valve types have received CE approval and each has been implanted in more than 10,000 patients worldwide. The Edwards-SAPIEN prosthesis consists of a balloon-expandable, stainless steel stent with a valve made of bovine pericardium, which currently can accommodate an aortic valve annulus of 18–25 mm (23 and 26 mm prosthesis). The 23-mm Edwards-SAPIEN prosthesis can be delivered through a 22-Fr transfemoral sheath, whereas the 26-mm valve requires a 24-Fr sheath. The Edwards-SAPIEN prosthesis can also be delivered through a

**Figure 3. Effect of surgical aortic valve replacement on survival.**
Adapted with permission from [21].
### Table 1. Perioperative outcome of surgical aortic valve replacement in octogenarians (≥80 years).

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient (n)</th>
<th>Age (years)</th>
<th>EuroSCORE add/log</th>
<th>Concomitant CABG (n/%)</th>
<th>Perioperative outcome (30 day/in-hospital)</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mortality (n/%)</td>
<td>Myocardial infarction (n/%)</td>
</tr>
<tr>
<td>Asimakopoulos (1997)</td>
<td>1100</td>
<td>82 ± 2</td>
<td></td>
<td></td>
<td>73 (6.6%)</td>
<td></td>
</tr>
<tr>
<td>Gilbert (1999)</td>
<td>103</td>
<td>83 ± 3</td>
<td></td>
<td>25 (24%)</td>
<td>19 (19%)</td>
<td>17 (17%)</td>
</tr>
<tr>
<td>Alexander (2000)</td>
<td>345</td>
<td>83 ± 2</td>
<td></td>
<td>345 (100%)</td>
<td>10.1%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Chiappini (2004)</td>
<td>115</td>
<td>82 ± 2</td>
<td></td>
<td>44 (38%)</td>
<td>10 (8.5%)</td>
<td>4 (3.8%)</td>
</tr>
<tr>
<td>Unic (2005)</td>
<td>242</td>
<td>83 ± 3</td>
<td></td>
<td>148 (61%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Langanay (2006)</td>
<td>442</td>
<td>83 ± 2</td>
<td>86 (19%), 5 MV (1%), 7 aorta (2%)</td>
<td></td>
<td>33 (7.5%)</td>
<td></td>
</tr>
<tr>
<td>Melby (2007)</td>
<td>245</td>
<td>84 ± 3</td>
<td></td>
<td>140 (57%)</td>
<td>22 (9%)</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Kolh (2007)</td>
<td>220</td>
<td>83</td>
<td></td>
<td>58 (26%)</td>
<td>22 (10%)</td>
<td>10 (4%)</td>
</tr>
<tr>
<td>Bose (2007)</td>
<td>68</td>
<td>83 ± 3</td>
<td>8.6 ± 1.2/12.0 ± 5.9</td>
<td>31 (46%)</td>
<td>13%</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Gulbins (2008)</td>
<td>236</td>
<td>83 ± 3</td>
<td>10.2 ± 1.9/19.4 ± 10.8%</td>
<td>215 (91%), 21 MV (9%)</td>
<td>22 (9.3%)</td>
<td></td>
</tr>
<tr>
<td>Filsoufi (2008)</td>
<td>231</td>
<td>83 ± 3</td>
<td>23 ± 16% (log)</td>
<td>110 (48%)</td>
<td>12 (5.2%)</td>
<td>2 (0.9%)</td>
</tr>
<tr>
<td>De Vincentis (2008)</td>
<td>345</td>
<td>82 ± 2</td>
<td></td>
<td>150 (43%), 39 MV (11%)</td>
<td>26 (7.5%)</td>
<td></td>
</tr>
<tr>
<td>Thourani (2008)</td>
<td>88</td>
<td>83 ± 2</td>
<td></td>
<td>0%</td>
<td>5 (5.7%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Likosky (2009)</td>
<td>1390</td>
<td>59%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leontyev (2009)</td>
<td>282</td>
<td>83 ± 3</td>
<td>16.2 ± 11.9 (log)</td>
<td>0%</td>
<td>30 (10.6%)</td>
<td></td>
</tr>
</tbody>
</table>

*add: Additive; AVR: Aortic valve replacement; CABG: Coronary artery bypass grafting; log: Logistic; MV: Mitral valve.*
transapical sheath (27 Fr). The Medtronic CoreValve revalving system consists of a three-level self-expanding nitinol stent, which houses a valve made of porcine pericardium. The valve comes in two sizes (26 and 29 mm) and can accommodate an aortic valve annulus from 19 to 27 mm. Both, the 26- and 29-mm Medtronic CoreValve prostheses are delivered through an 18-Fr sheath, which allows access via the femoral or subclavian artery.

Patient selection
While SAVR slowly progressed from low- to high-risk patient populations, the opposite phenomenon is observed with TAVI, which was initially restricted to non-operable or high-risk patients and is slowly being extended to less complex patient populations. Moreover, certain anatomical features in terms of aortic valve dimension and peripheral access have to be fulfilled precluding eligibility of all patients for this treatment modality. Notwithstanding, technical refinement and growing experience have already led to an expansion from high-risk to lower-risk patients.

Safety of TAVI
The first 50 patients at 30 days amounted to 12% in the first 50 patients undergoing TAVI in the first 50 patients undergoing TAVI. Thus, mortality with increased levels of experience was also demonstrated by improved long-term outcomes and operator experience was also demonstrated by improved long-term outcomes. The latest series including 30 and 80 patients, respectively, 80 years of age and a surgical risk assessment by means of the logistic EuroSCORE greater than 20%. Data from the initial feasibility studies by Cribier et al. documented successful transcatheter implantation of 27 out of 33 patients (82%) and showed a 30-day mortality of 22% (six patients) in those with successful implantation [53]. Subsequent studies reported separate results for the transcatheter and transapical transcatheter access. Webb et al. published initial experience with the balloon-expandable Edwards-SAPIEN prosthesis [54] whereas Grube et al. investigated outcomes with the self-expandable Medtronic CoreValve prosthesis delivered by the transapical route [55]. Procedural success was achieved in 86 and 74% in these early series including 50 and 86 patients, respectively, which decreased to 8% in a later cohort [57].

Table 2. Perioperative outcome of surgical aortic valve replacement in patients with impaired left ventricular ejection fraction.

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient (n)</th>
<th>Age (years)</th>
<th>Patient characteristics</th>
<th>EuroSCORE add/log</th>
<th>Concomitant CABG (n/%)</th>
<th>Perioperative outcome (30 day/in-hospital)</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connolly (1997)</td>
<td>154</td>
<td>73 ± 10</td>
<td>LVEF ≤35%</td>
<td>14 (9%)</td>
<td>10 (18%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Powell (2000)</td>
<td>55</td>
<td>73 ± 9</td>
<td>LVEF ≤30%</td>
<td></td>
<td>3 (8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pereira (2002)</td>
<td>68</td>
<td>70 ± 9</td>
<td>LVEF ≤35%, mean gradient ≤30 mmHg</td>
<td>16 (31%)</td>
<td>4 (8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tarantini (2003)</td>
<td>52</td>
<td>69 ± 12</td>
<td>LVEF ≤35%</td>
<td>16 (31%)</td>
<td>4 (8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sharony (2003)</td>
<td>260</td>
<td>73 ± 10</td>
<td>LVEF ≤40%</td>
<td>25 (9.6%)</td>
<td>15 (5.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quere (2006)</td>
<td>66</td>
<td>68 ± 9</td>
<td>LVEF ≤40%, mean gradient ≤40 mmHg</td>
<td>25 (9.6%)</td>
<td>15 (5.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levy (2008)</td>
<td>217</td>
<td>71 ± 8</td>
<td>LVEF ≤35%, mean gradient ≤30 mmHg</td>
<td>8.9 ± 2.7 (add)</td>
<td>34 (16%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clavel (2008)</td>
<td>44</td>
<td>67 ± 10</td>
<td>LVEF ≤40%, gradient ≤30 mmHg</td>
<td>30 (68%)</td>
<td>18%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pai (2008)</td>
<td>58</td>
<td>72 ± 12</td>
<td>LVEF ≤35%</td>
<td>59% (14% MV)</td>
<td>9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chikwe (2009)</td>
<td>76</td>
<td>71</td>
<td>LVEF ≤30%</td>
<td>36 (47%)</td>
<td>9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levy (2008)</td>
<td>217</td>
<td>71 ± 8</td>
<td>LVEF ≤35%, mean gradient ≤30 mmHg</td>
<td>8.9 ± 2.7 (add)</td>
<td>34 (16%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clavel (2008)</td>
<td>44</td>
<td>67 ± 10</td>
<td>LVEF ≤40%, gradient ≤30 mmHg</td>
<td>30 (68%)</td>
<td>18%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pai (2008)</td>
<td>58</td>
<td>72 ± 12</td>
<td>LVEF ≤35%</td>
<td>59% (14% MV)</td>
<td>9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chikwe (2009)</td>
<td>76</td>
<td>71</td>
<td>LVEF ≤30%</td>
<td>36 (47%)</td>
<td>9%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

add: Additive; AVR: Aortic valve replacement; CABG: Coronary artery bypass grafting; log: Logistic; LVEF: Left ventricular ejection fraction.

Table 2. Perioperative outcome of surgical aortic valve replacement in patients with impaired left ventricular ejection fraction.
### Table 3. Perioperative outcome of surgical aortic valve replacement in patients with previous sternotomy, Redo-SAVR or high EuroSCORE.

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient (n)</th>
<th>Age (years)</th>
<th>Patient characteristics</th>
<th>EuroSCORE add/log</th>
<th>Concomitant CABG (n/%)</th>
<th>Perioperative outcome (30 day/in-hospital)</th>
<th>Mortality (n/%)</th>
<th>Myocardial infarction (n/%)</th>
<th>Stroke (n/%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potter (2005)</td>
<td>162</td>
<td>64 ± 15</td>
<td>Redo-AVR</td>
<td></td>
<td>41 (25.3%)</td>
<td>8 (4.9%) 0 2 (1.2%)</td>
<td>[51]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eitz (2006)</td>
<td>71</td>
<td>80–84 (90.2%); ≥85 (9.8%)</td>
<td>≥80 years and cardiac reoperation of AV</td>
<td>CABG: 14 (19.7%); MVR: 4 (5.6%)</td>
<td>11 (15.5%)</td>
<td>[52]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Davierwala (2006)</td>
<td>216</td>
<td>59 ± 14</td>
<td>Redo-SAVR</td>
<td></td>
<td>4.6%</td>
<td>0.9% 4.6%</td>
<td>[50]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grossi (2008)</td>
<td>731</td>
<td>&gt;80 (44%)</td>
<td>EuroSCORE &gt;7</td>
<td>9.7/17.2%</td>
<td>0%</td>
<td>57 (7.8%)</td>
<td>[46]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Khaladj (2009)</td>
<td>130</td>
<td>60–84 (75%)</td>
<td>Previous sternotomy</td>
<td>12 ± 3/32 ± 21%</td>
<td>0%</td>
<td>2 (5%)</td>
<td>[47]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LaPar (2010)</td>
<td>191</td>
<td>67 ± 13</td>
<td>Previous sternotomy</td>
<td></td>
<td>58 (30.4%); MV: 22 (11.5%); Aortic root: 9 (4.7%); tricuspid valve: 5 (2.6%)</td>
<td>16 (8.4%) 10 (5.2%)</td>
<td>[48]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Perioperative outcome of transcatheter aortic valve implantation.

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient (n)</th>
<th>Age (years)</th>
<th>Patient characteristics</th>
<th>EuroSCORE add/log</th>
<th>Perioperative outcome (30 day/in-hospital)</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cribier (2006)</td>
<td>27</td>
<td>80 ± 7</td>
<td>High risk for conventional surgery</td>
<td>Add 12 ± 2</td>
<td>Mortality (n/%) 6 (22%) Myocardial infarction (n/%) Stroke (n/%)</td>
<td>[53]</td>
</tr>
<tr>
<td>Webb (2007)</td>
<td>50</td>
<td>82 ± 7</td>
<td>High risk for conventional surgery</td>
<td>Log 28%</td>
<td>6 (12%) 1 (2%) 2 (4%)</td>
<td>[54]</td>
</tr>
<tr>
<td>Grube (2007)</td>
<td>86</td>
<td>82 ± 6</td>
<td>≥80 years + EuroSCORE ≥20 or ≥75 years + EuroSCORE ≥15</td>
<td>Log 21.7 ± 12.6%</td>
<td>10 (12%) 1 (1%) 9 (10%)</td>
<td>[55]</td>
</tr>
<tr>
<td>Cribier (2008)</td>
<td>136</td>
<td>82 ± 7</td>
<td>≥80 years + EuroSCORE ≥20 or ≥75 years + EuroSCORE ≥15 or ≥65 years + severe comorbidities</td>
<td>Log 23.1 ± 15.0%</td>
<td>17 (12.5%) 3 (2.2%) 6 (4.4%)</td>
<td>[58]</td>
</tr>
<tr>
<td>Webb (2007)</td>
<td>50</td>
<td>82 ± 7</td>
<td>≥75 years + EuroSCORE ≥15 or ≥65 years + severe comorbidities</td>
<td>Log 23.1 ± 13.8%</td>
<td>52 (8.0%) 4 (0.6%) 12 (1.9%)</td>
<td>[56]</td>
</tr>
<tr>
<td>Himbert (2009)</td>
<td>75</td>
<td>82 ± 8</td>
<td>EuroSCORE ≥20% or STS ≥10%</td>
<td>Log 26 ± 13%</td>
<td>19 (11.3%) 1 (0.6%) 3 (4%)</td>
<td>[64]</td>
</tr>
<tr>
<td>Ye (2009)</td>
<td>80</td>
<td>80 ± 9</td>
<td>High risk for conventional surgery</td>
<td>Log 37 ± 20%</td>
<td>6 (23%) 1 (4%) 1 (4%)</td>
<td>[64]</td>
</tr>
<tr>
<td>Piazza (2008)</td>
<td>646</td>
<td>81 ± 7</td>
<td>≥75 years + EuroSCORE ≥15 or ≥65 years + severe comorbidities</td>
<td>Log 25.3%</td>
<td>3 (6.5%)</td>
<td>[74]</td>
</tr>
<tr>
<td>Thielmann (2009)</td>
<td>39</td>
<td>81 ± 5</td>
<td>EuroSCORE &gt;30%, STS ≥15%</td>
<td>14.2 ± 3.6/44.2 ± 12.6%</td>
<td>17.9%</td>
<td>[75]</td>
</tr>
<tr>
<td>PARTNER EU</td>
<td>61 TF</td>
<td>82 ± 5</td>
<td>Log EuroSCORE &gt;20% and/or STS ≥10% or severe comorbidities</td>
<td>Log 25.7 ± 11.5%</td>
<td>5 (8.1%) 1 (1.6%) 2 (3.2%)</td>
<td>[60]</td>
</tr>
<tr>
<td>SOURCE Registry</td>
<td>463 TF</td>
<td>81.7</td>
<td>Log 25.7%</td>
<td>Log 29.7%</td>
<td>29 (6.3%) 11 (2.4%) 16 (2.6%)</td>
<td>[59]</td>
</tr>
</tbody>
</table>

vascular injury was documented in 8.0% of patients with a transfemoral access and 3.5% of patients with a transapical approach in the study by Webb and colleagues using the Edwards Sapien prosthesis [57]. Himbert et al. found a vascular complication rate of 11% in 51 transfemoral and 24 transapical patients (12 and 8%, respectively) also using the Edwards Sapien prosthesis [64]. Perforation or damage to vessels, myocardium or valvular structures were observed in 15.0, 9.1, 19.7 and 17.9% in the REVIVE, REVIVAL and PARTNER EU trial for transfemoral access with the Edwards Sapien valve, respectively [59]. By contrast, the Expanded Evaluation Registry of the third-generation CoreValve Revolving System documented vascular access site dissection or tear in only 12 out of 646 patients (1.9%) [56]. Definitions of vascular complications vary across different reports and may contribute to differences in incidence and outcome. The Rotterdam group observed that the incidence of vascular complications ranged from as low as 4% to as high as 13% when applying different definitions to 99 consecutive patients following CoreValve implantation [65]. The transapical approach was associated with access complications in 9–20% in the REVIVAL TA, PARTNER EU and TRAVERCE TA studies [59]. The SOURCE registry reported an incidence of major vascular complications of 10.6% after transfemoral and 2.4% after transapical implantation of the Edwards Sapien valve [59]. Whereas access site complications were associated with adverse outcome in the transapical cohort of the SOURCE registry, transfemoral access was no longer a predictor of mortality, which was attributed to a learning curve in complication management. Three recent studies addressed vascular complications following TAVI. In a cohort of 45 consecutive patients from France, four patients (8.5%) suffered vascular complications necessitating vascular surgery; no significant differences between the Medtronic CoreValve and Edwards-SAPIEN prostheses were observed [66]. A somewhat higher vascular access complication rate was documented in 54 patients undergoing transfemoral implantation of the Edwards-SAPIEN prosthesis. Five patients (9.3%) with vascular rupture required surgical repair, whereas four patients (7.4%) with arterial dissection were managed with endovascular stents. However, no differences in hospital mortality or length of stay were observed in patients with and without vascular complications [67].

Transcatheter aortic valve implantation is associated with a higher incidence of postoperative aortic regurgitation compared with conventional stented or stentless aortic valve replacement (moderate AR in 8 vs 0 vs 0%, respectively, \( p<0.0001 \)) [68]. In 74 patients undergoing TAVI using the balloon expandable device paravalvular aortic regurgitation grade 2/4 or more was observed in 21% [69]. The clinical significance of these findings is still under debate.

**Efficacy of TAVI**

Transcatheter aortic valve implantation is still in the early stages of clinical investigation. Although promising midterm results are
accumulating long-term data are currently lacking. Using the Edwards SAPIEN prosthesis, Webb and colleagues reported 1- and 2-year survival rates of 74 and 61%, respectively, and identified transapical access and chronic renal failure as predictors for increased mortality [57]. The incidence of valve-related adverse events during follow-up was rather low. In the PARTNER EU study, a similar 1-year survival rate of 78% was observed [70]. Using the Medtronic CoreValve Revalving system, Grube and colleagues reported a survival rate of 68% at 1 year [58].

Symptomatic and functional improvement following TAVI is impressive. An increase in functional class has been shown as early as 30 days after the intervention and appeared sustained over time. Thus, 77 (78%) of 99 patients were found to be in NYHA functional class I or II at 1-year follow-up in the study of Webb et al. [57]. These findings have been corroborated by a similar improvement of NYHA functional status from 3.3 ± 0.5 preprocedure to 1.7 ± 0.7 postprocedure in the cohort reported by Grube et al., which remained stable over the duration of 12 months [58].

### Direct comparison of SAVR & TAVI

Comparing crude, unadjusted outcome in contemporary studies point to similar perioperative mortality in high-risk patients undergoing SAVR and TAVI (Figure 4). A small registry of 66 consecutive patients (mean age of 83 ± 6 years) with severe aortic stenosis reported outcome according to treatment allocation to conservative management, SAVR, TAVI or balloon valvuloplasty following a multidisciplinary consensus. A total of 27 patients were considered low-risk and underwent SAVR. Among the remaining 39 high-risk patients, 12 underwent TAVI, seven balloon valvuloplasty, four SAVR and 16 medical treatment. There were three hospital deaths in patients undergoing TAVI, two in those treated medically, and one following SAVR without
Comparing surgical aortic valve replacement with transcatheter aortic valve implantation

significant differences among groups [70]. A two-center, prospective cohort study compared baseline characteristics and 30-day mortality between TAVI and SAVR in consecutive patients undergoing invasive treatment for aortic stenosis. A total of 1122 patients were included with 114 patients undergoing TAVI and 1008 patients undergoing SAVR. The crude mortality rate was higher in the TAVI group (9.6 vs 2.3%) yielding an odds ratio (OR) of 4.57 (95% CI: 2.17–9.65). Compared with patients undergoing SAVR, patients with TAVI were older, more likely to be in NYHA class III and IV, and had a considerably higher logistic EuroSCORE and more comorbid conditions. In patients with sufficient overlap of propensity scores, adjusted OR ranged from 0.35 (0.04–2.72) to 3.17 (0.31–31.9). In patients with insufficient overlap, an increased odds of death was associated with TAVI compared with SAVR irrespective of the method used to control confounding, with adjusted OR ranging from 5.88 (0.67–51.8) to 25.7 (0.88–750). Approximately a third of patients undergoing TAVI were found to be potentially eligible for a randomized comparison of TAVI versus SAVR. The authors concluded that TAVI could be associated with either substantial benefits or harms and that randomized comparisons of TAVI versus SAVR were warranted to address these issues (Figures 5–7) [71].

One randomized trial assessing the role of TAVI is currently underway. The Placement of Aortic Transcatheter Valve Trial Edwards-SAPIEN Transcatheter Valve (PARTNER US) study completed enrollment of more than 1000 patients who underwent assessment of operability for SAVR and technical feasibility to implant an Edwards-SAPIEN prosthesis. Patients deemed operable were allocated to cohort A and subsequently screened for feasibility of transfemoral access. If transfemoral access was deemed feasible, patients were randomly assigned to treatment with SAVR or TAVI using the Edwards-SAPIEN prosthesis implanted via the transfemoral route. In case transfemoral access was not possible, patients were randomly assigned to SAVR or TAVI using the Edwards-SAPIEN prosthesis implanted via the transapical route. Preliminary results are expected to be released by the end of 2010.

**Conclusion & future perspective**

The concept of TAVI is appealing and disruptive with the potential to revolutionize the field of interventional cardiology to a similar degree as the advent of percutaneous transluminal coronary angioplasty more than three decades ago. Smaller delivery catheters, larger prostheses, ability to reposition and retrieve devices, and alternative access routes will all but eliminate technical barriers for TAVI in the near future. Randomized clinical trials are either underway or in the planning phase in order to establish the scientific foundation for the appropriate use of TAVI vis-à-vis both SAVR and medical treatment in various patient populations. The possibility for transcatheter valve-in-valve implantation is not only an attractive treatment for degenerated bioprostheses, but will also permit surgeons to more liberally use bioprostheses instead of mechanical heart valves in younger patients.

**Financial & competing interests disclosure**

Peter Wenaweser and Stephan Windecker are both proctors for Medtronic CoreValve and Edwards and received honoraria from Medtronic CoreValve and Edwards. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patients received or pending, or royalties. No writing assistance was utilized in the production of this manuscript.

**Executive summary**

- The prevalence of valvular heart disease increases substantially as the population ages.
- Surgical aortic valve replacement is the established gold standard and provides the therapeutic armamentarium for all complex valvular pathologies.
- Perioperative outcome of high-risk populations, such as octogenarians, patients with reduced left ventricular ejection fraction, or previous sternotomy is associated with a considerably higher perioperative mortality risk ranging from 5 to 19%.
- Transcatheter aortic valve implantation for severe aortic stenosis, which circumvents the need for cardiopulmonary bypass and general anesthesia, was initially restricted to non-operative or high-risk patients and is slowly being extended to less complex patient populations as per-interventional outcomes improve.
- Randomized clinical trials are underway to establish the scientific foundation for the appropriate use of transcatheter aortic valve implantation vis-à-vis surgical aortic valve replacement.
Papers of special note have been highlighted as:

* of interest

**Bibliography**

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* of interest

35. In a cohort study of consecutive patients undergoing aortic valve surgery, perioperative mortality among 419 patients 80–85 years of age was 6.7%, and 11.7% in 156 patients aged 85 years or over. Among the patients undergoing aortic valve replacement and concomitant coronary artery bypass grafting, perioperative mortality among 577 patients 80–85 years of age was 9.5 and 8.5% in 238 patients at least 85 years old, respectively. Median survivorship for patients undergoing isolated aortic valve replacement was 6.8 years (80–84 years) and 6.2 years (85+ years) for patients undergoing concomitant coronary artery bypass grafting, median survivorship was 6.8 years (80–84 years) and 7.1 years (85+ years), which was similar to the life expectancy of the general population from actuarial tables.
In a large multicenter series of 217 patients operated for low-flow/low-gradient aortic stenosis (ejection fraction $\leq$35% and mean gradient $\leq$30 mmHg), perioperative mortality was 16% and decreased from 20% (1990–1999 period) to 10% (2000–2005 period). Predictors for perioperative mortality were high EuroSCORE, very low mean gradient and ejection fraction. New York Heart Association Functional class III or IV, history of congestive heart failure, and multivessel coronary artery disease. In addition, in a subgroup, the absence of contractile reserve in dobutamine stress echocardiography was strongly associated with perioperative mortality.


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Among 646 patients with a mean age of 81 ± 6.6 years and a logistic EuroSCORE of 23.1 ± 13.8% undergoing transcatheter aortic valve implantation using the third-generation CoreValve, survival success and 30-day clinical outcome was 97%, 30-day mortality was 8% and the combined end point of death, stroke and myocardial infarction was 9.3%.


Among 168 patients undergoing transcatheter aortic valve implantation at a single institution using the Edwards Sapien prosthesis (median age 84 years, logistic EuroSCORE 28.6%) overall success rate was 94.1%, 30-day mortality was 11.3% and survival at 1 year was 74%.


Website

Society of Thoracic Surgeons National Cardiac Surgical Database
www.sts.org