European Heart Journal (2012) **33**, 2388–2400
doi:10.1093/eurheartj/ehs220

REVIEW

Clinical update

Transcatheter aortic valve implantation 10-year anniversary: review of current evidence and clinical implications

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Received 26 April 2012; revised 21 June 2012; accepted 26 June 2012; online publish-ahead-of-print 31 July 2012

Surgical aortic valve replacement (SAVR) is currently the standard of care to treat patients with severe symptomatic aortic stenosis (AS) and is generally accepted to alleviate symptoms and prolong survival. Based on the results of randomized trials, transcatheter aortic valve implantation (TAVI) is the new standard of care for patients with symptomatic AS who are deemed 'inoperable'. Debatably, TAVI is also an alternative to SAVR in selected patients who are at high risk but operable. As we approach 10 years of clinical experience with TAVI, with over 50 000 implantations in 40 countries, a review of the current literature and clinical outcomes with this rapidly evolving technology is appropriate.

Keywords Aortic stenosis • TAVI • TAVR

Introduction

Symptomatic severe aortic stenosis (AS) has a poor prognosis when treated medically and inevitably leads to functional deterioration, heart failure, and death.[1] Surgical aortic valve replacement (SAVR) is currently the standard of care and is generally accepted to alleviate symptoms and prolong survival, but ~30% do not undergo SAVR.[2] However, since Dr Alain Cribier pioneered the first transcatheter aortic valve implantation (TAVI) procedure in 2002,[3] this relatively new technique has been used extensively in over 40 countries accumulating to >50 000 implantations.[4–19] With results from the randomized Placement of AoRTic TraNscathetER Valves (PARTNER) trial,[20] TAVI is now the standard of care for extremely high risk or 'inoperable' patients and is a valid alternative to surgery for selected high-risk but 'operable' patients with symptomatic AS.[21] Currently, two different TAVI devices are widely used: the balloon-expandable Edwards SAPIEN Transcatheter Heart Valve (Edwards Lifesciences, Irvine, CA, USA) and the self-expanding Medtronic CoreValve™ (Medtronic, Minneapolis, MN, USA) (*Figure 1*). Both devices received CE Mark approval for European commercial sale in 2007, and the Edwards SAPIEN valve received FDA pre-market approval in the USA in November 2011. As we approach 10 years of clinical experience with TAVI, a review of the current literature and clinical outcomes is appropriate.

Initial experience

First-in-man, initial reports, and feasibility studies

Cribier and co-workers[3] performed the first TAVI in an inoperable patient in 2002 using a transeptal antegrade approach and a balloon-expandable aortic valve prosthesis, demonstrating the feasibility of percutaneous valve implantation. The antegrade approach

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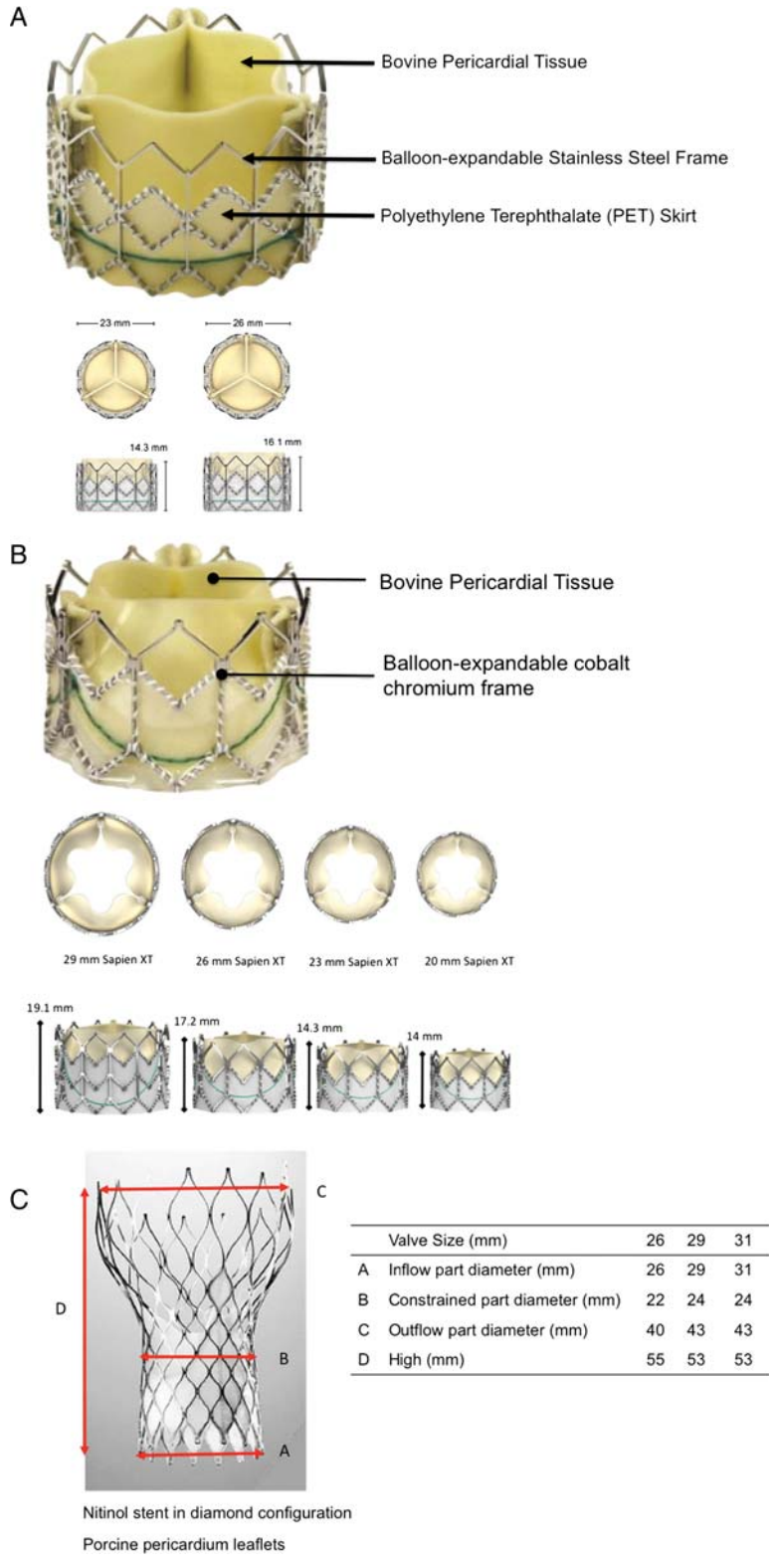

	Valve Size (mm)	26	29	31
A	Inflow part diameter (mm)	26	29	31
B	Constrained part diameter (mm)	22	24	24
C	Outflow part diameter (mm)	40	43	43
D	High (mm)	55	53	53

Figure 1 (*A*) Edwards-SAPIEN Transcatheter Heart Valve (Edwards Lifesciences). (*B*) Edwards-SAPIEN XT Transcatheter Heart Valve (Edwards Lifesciences). (*C*) Medtronic CoreValve™ (Medtronic).

Table 1 Multicentre feasibility studies

Study	Enrollment	Number of patients	Approach	Device	Procedural success	30-day mortality
I-REVIVE/RECAST[6]	2003–2005	26	Transseptal	Edwards SAPIEN	85% (22/26)	16.7% (6/36)
		7	TF	Edwards SAPIEN	57% (4/7)	
Grube et al.[9]	2005–2007	86	TF	CoreValve	74% (64/86)	11.6% (10/86)
TRAVERCE[26]	2006–2008	168	TA	Edwards SAPIEN	95.8% (161/168)	14.9% (25/168)
REVIVAL[24,25]	2006–2008	40	TA	Edwards SAPIEN	100% (40/40)	12.5% (7/40)
	2005–2006	55	TF	Edwards SAPIEN	87% (48/55)	7.3% (4/55)

TF, transfemoral; TA, transapical; I-REVIVE, Initial Registry of EndoVascular Implantation of Valves in Europe trial; RECAST, Registry of Endovascular Critical Aortic Stenosis Treatment trial; REVIVAL, PeRcutaneous EndoVascular Implantation of VALves trial; TRAVERCE, The initial multicentre feasibility trial for TA-AVI.

was further explored,[22] coinciding with the first-in-man retrograde experience of a self-expanding prosthesis (CoreValve™).[23]

Larger series quickly followed, with early experiences of small initiatives using both the balloon-expandable Cribier valve (Edwards Lifesciences Inc.) and the self-expandable CoreValve™ system.[9,19] The devices showed a procedural success rate of ~80%.

After these single-centre experiences, several larger multicentre feasibility studies were initiated first in Europe and later in the USA.[6,24–26] These studies showed that transapical (TA) and transfemoral (TF) TAVI in high-risk patients was feasible and could be performed with a high procedural success rate and a 30-day mortality of ~10–15% (*Table 1*).

Registries

Edwards registries

Several large European and Canadian registries have been published, showing excellent short- and mid-term results after TAVI using both the TF and TA devices.[12,15] The largest registry reported to date is the SOURCE (SAPIEN Aortic Bioprosthesis European Outcome) registry.[17,18] Overall, 1038 patients were enrolled at 32 European centres and were treated with either a TF ($n = 463$) or TA approach ($n = 575$). Patients treated by TA had more comorbidities at baseline than TF patients, resulting in a significantly higher EuroSCORE (European System for Cardiac Operative Risk Evaluation) (29.1 vs. 25.7%; $P < 0.001$). Procedural success was 95.2 and 92.7% and 30-day mortality was 6.3 and 10.3% in the TF and TA populations, respectively. The major limitations of this registry were that >70% of the enrolling centres had no prior experience with TAVI and all adverse events were site-reported without core lab analysis. In early 2011, 1-year results were published, demonstrating a 1-year survival of 76.1% overall, 72.1% for TA and 81.1% for TF patients. Among the surviving patients, 73.5% were New York Class Association (NYHA) class I or II.[17]

CoreValve™ registries

A number of large dedicated CoreValve registries have been reported; generally, these have been somewhat larger than Edwards registries.[14,16] Promising 3-year results were recently reported by Ussia *et al.*[27] and although not yet published, the results of the ADVANCE CoreValve™ registry were presented recently.[28] ADVANCE represents a 100% monitored 'real-world' experience, with a core laboratory and an independent clinical events committee adjudicating events. The registry included 1015 patients from 44 experienced (>40 prior procedures) centres between March 2010 and July 2011. The mean logistic EuroSCORE was 19.2%. At 30 days and 6 months, the rate of all-cause mortality was 4.5 and 12.8%, respectively, with cardiac mortality of 3.4 and 8.4%, respectively. ADVANCE provides insights into contemporary TAVI data of experienced operators, and is a benchmark for comparing outcomes.

Mixed national registries

In 2011, results from four mixed CoreValve™ and Edwards European national registries have been reported, mostly using the TF and TA routes (*Table 2*).[4,8,29,30] Overall, patients included in these registries were at high-risk according to surgical risk models; mean EuroSCORE 18–30%. These registries showed 1-year survival rates ranging between 71.9 and 81.6%. The UK registry reported the longest follow-up; survival was 73.7% at 2 years.[30] Several of these national initiatives performed access-route comparisons and reported that survival was generally higher in patients treated through the TF route.[4,30] However, it should be noted that a transfemoral-first approach is often advocated, which may introduce selection bias and an unfair comparison between the two access routes.[31]

Recently, the largest registry to date was reported by the FRANCE 2 (FRench Aortic National CoreValve and Edwards) investigators.[32] They included 3195 patients treated between January 2010 and December 2011 at 34 centres. The registry reflects contemporary real-life use of available TAVI devices in patients at high surgical risk; the Edwards SAPIEN and the Medtronic CoreValve devices were used in, respectively, 66.9 and 33.1%. The transfemoral approach was most popular (74.6%), followed by transapical (17.8%) and subclavian (5.8%), while 1.8% underwent some other approach. The procedural success rate was 96.9% and 1-year survival in patients was 76.0%.

Randomized trials

Completed trials

While registry reports are of crucial value to assess 'real-world' use of TAVI, more rigorous assessments are available from the

Table 2 Clinical outcomes after TAVI according to access site and device type: major published data

Authors	Type of study	Number of patients	STS (%)	Logistic EuroScore (%)	Follow-up (months)	Procedural success rate (%)	Mortality 30-day (%)	Mortality 1-year (%)	Major access complications 30-day (%)	Stroke 30-day (%)	Need for new PPM (%)
Edwards SAPIEN: TF											
Lefevre *et al.*[12]	Registry	61	11.3	25.7	12	95.4	8.2	21.3	16.4	3.3	1.8
Eltchaninoff *et al.*[8]	Registry	95	17.4	25.6	1	98.3[a]	8.4	–	6.3	4.2	5.3
Himbert *et al.*[11]	Registry	51	15.0	25.0	12	90.0	8.0[b]	19.0	12.0	6.0	6.0
Rodes-Cabau *et al.*[15]	Registry	162	9.0	–	24	90.5	9.5	25.0	13.1	3.0	3.6
Thomas *et al.*[17,18]	Registry	463	–	14.5	1	95.2	6.3	18.9	22.9	2.4	6.7
Leon *et al.*[20]	RCT	179	11.2	26.4	12	–	5.0[c]	30.7[c]	16.2	6.7[d]	3.4
Bosmans *et al.*[4]	Registry	99	–	29.0	12	97.0	6.0	18.0	–	2.0	4.0
Smith *et al.*[21]	RCT	244	11.7	29.1	12	–	3.3[c]	22.2[c]	14.0	3.7[d]	3.7
Edwards SAPIEN: TA											
Walther *et al.*[26]	Feasibility study	168	–	27.0	12	95.8	15.0	37.0	1.2	2.0	2.3
Svensson *et al.*[25]	Feasibility study	40	13.4	35.5	6	87.5	17.5	–	–	5.0	–
Lefevre *et al.*[12]	Registry	69	11.3	33.8	12	96.4	18.8	50.7	5.8[e]	1.5	3.8
Eltchaninoff *et al.*[8]	Registry	71	18.4	26.8	1	98.3[a]	16.9	–	5.6[f]	2.8	5.6
Himbert *et al.*[11]	Registry	24	18.0	28.0	12	100	16.0[b]	26.0	8.0	0	4.0
Rodes-Cabau *et al.*[15]	Registry	177	10.5	–	1	96.1	11.3	22.0	13.0[f]	1.7	6.2
Thomas *et al.*[17,18]	Registry	575	–	16.3	1	95.7	10.3	27.9	4.7	2.6	7.3
Bosmans *et al.*[4]	Registry	88	–	33.0	12	97.0	14.0	37.0	–	8.0	6.0
Smith *et al.*[21]	RCT	104	11.8	29.8	12	–	3.8[c]	29.0[c]	3.8	6.8	3.9
D'Onofrio *et al.*[7]	Registry	504	11.0	26.3	24	99.0	8.3	18.8	–	3.0	5.4
Medtronic CoreValve™: TF											
Tamburino *et al.*[16]	Registry	663	–	23.0	12	98.0	5.4	15.0	2.0	2.5 [g]	17.4
Bosmans *et al.*[4]	Registry	133	–	25.0	12	98.0	11.0	22.0	–	4.0	22.0
Grube *et al.*[10]	Registry	86	–	21.6	1	88.0	12.0	–	–	10.0	–
Piazza *et al.*[14]	Registry	646	–	23.1	1	97.2	8.0	–	1.9	1.9	9.3
Eltchaninoff *et al.*[8]	Registry	66	21.3	24.7	1	98.3[a]	15.1	–	7.5	4.5	25.7
Petronio *et al.*[13]	Registry	460	–	19.4	6	98.4	6.1	11.4	2.0	1.7	16.1
Buellesfeld *et al.*[5]	Registry	126[ξ h]	–	23.0	24	72.6	15.2	28.1	–	9.6	26.2
Medtronic CoreValve™: SC											
Eltchaninoff *et al.*[8]	Registry	12	21.0	24.6	1	98.3[a]	8.3	–	8.3	0	25.0

Continued

Table 2 *Continued*

Authors	Type of study	Number of patients	STS (%)	Logistic EuroScore (%)	Follow-up (months)	Procedural success rate (%)	Mortality 30-day (%)	Mortality 1-year (%)	Major access complications 30-day (%)	Stroke 30-day (%)	Need for new PPM (%)
Bosmans *et al.*[4]	Registry	8	–	25.0	12	98.0	11.0	0	–	4.0	22.0
Petronio *et al.*[13]	Registry	54	–	25.3	6	100	0	6.7	0	1.9	18.5
Zahn *et al.*[29][i]	Registry	697	–	20.5	1	98.4	12.4	–	19.5	2.8	39.3[j]

TAVI, transcatheter aortic valve implantation; TF, transfemoral; TA, transapical; SC, subclavian; STS, Society of Thoracic Surgeons; EuroSCORE, European System for Cardiac Operative Risk Evaluation; RCT, randomized controlled trial; PPM, permanent pacemaker.
[a]Global procedural success rate including Edwards SAPIEN TF, Edwards SAPIEN TA and Medtronic CoreValve TF and subclavian was 98.3%.
[b]In-hospital mortality.
[c]Intention-to-treat mortality rate.
[d]Major and minor stroke.
[e]Vascular-related complications.
[f]Apex-related complications.
[g]1-year.
[h]124 patients received a TF approach and 2 an SC approach.
[i]Outcomes reported together: 566 (81.2%) Medtronic CoreValve™ TF, 22 (3.2%) Medtronic CoreValve™ SC, 106 (15.2%) Edwards SAPIEN TF.
[j]Medtronic CoreValve™ 42.5%, Edwards SAPIEN 22%.

first multicentre, randomized clinical PARTNER trials (Placement of Aortic Transcatheter Valves; ClinicalTrials.gov Identifier: NCT00530894) (*Figure 2*).[20,21]

As the first of two parallel trials was completed, the results of PARTNER IB showed that TF TAVI was superior to standard therapy in patients not deemed candidates for surgery.[20] The primary endpoint of all-cause mortality was markedly reduced by 46% ($P < 0.001$). Recently reported 2-year outcomes showed continued encouraging results (*Figure 3A*).[33] At 2 years, the primary endpoint of all-cause mortality was reduced from 67.6% in the standard treatment arm to 43.3% in the TAVI arm ($P < 0.001$).

The PARTNER cohort IA compared TAVI with SAVR and met its non-inferiority endpoint: the all-cause 1-year mortality in the TAVI group was non-inferior to the SAVR group (24.2 vs. 26.8%; $P = 0.44$; $P = 0.001$ for non-inferiority).[21] Some concerns were raised with regard to neurologic events that were somewhat higher with TAVI than SAVR at 30 days (5.5 vs. 2.4%; $P = 0.04$) and 1 year (8.3 vs. 4.3%; $P = 0.04$). Although the recently published 2-year results showed that stroke rates were similar for TAVI and SAVR during 1 and 2 years with a hazard ratio of 1.22 (95% CI 0.67–2.23, $P = 0.52$), the issue of stroke warrants further investigation and should not be underestimated (*Figure 3B* and *C*).[34] The rate of the composite of all-cause death and stroke was encouragingly nearly identical after TAVI (37.1%) and SAVR (36.4%) at 2 years ($P = 0.85$).

Ongoing trials

In the USA, a randomized trial is currently ongoing to evaluate the safety and efficacy of the Medtronic CoreValve™ in the treatment of severe symptomatic AS in patients at high or extreme risk for SAVR (ClinicalTrials.gov Identifier: NCT01240902). The trial consists of two arms. Patients in a high-risk arm will be randomized between SAVR and TAVI; the primary endpoint consists of all-cause mortality at 1 year. An extreme risk arm will function as an observational arm in which a composite of all-cause mortality and major stroke is the primary endpoint.

As a sequel to the PARTNER I trial, a second randomized trial (PARTNER II) is currently ongoing. It was designed to investigate the performance and outcomes after TAVI with the next-generation Edwards SAPIEN XT valve, model 9300TFX, as well as the new low-profile 18-Fr NovaFlex™ delivery catheter in patients deemed non-operable (ClinicalTrials.gov Identifier: NCT01314313) (*Figure 4A*). Given the results of the control arm in PARTNER IB, it has been judged that a study comparing TAVI against a 'medical management' control group is no longer ethical.[35] Consequently, an 'old device' vs. 'new device' non-inferiority trial was designed. Enrolment began in January 2011 and it is anticipated that primary endpoint results will be published mid-2013.

In Denmark, a phase 2 randomized trial evaluating TAVI in patients ≥70 years of age started enrolment in December 2009 (ClinicalTrials.goc identifier: NCT01057173). The trial will randomize a total of 280 patients to TAVI ($n = 140$) and SAVR ($n = 140$). The primary endpoint is the composite of all-cause death, myocardial infarction, and stroke at 1 year and is scheduled to be completed late 2013.

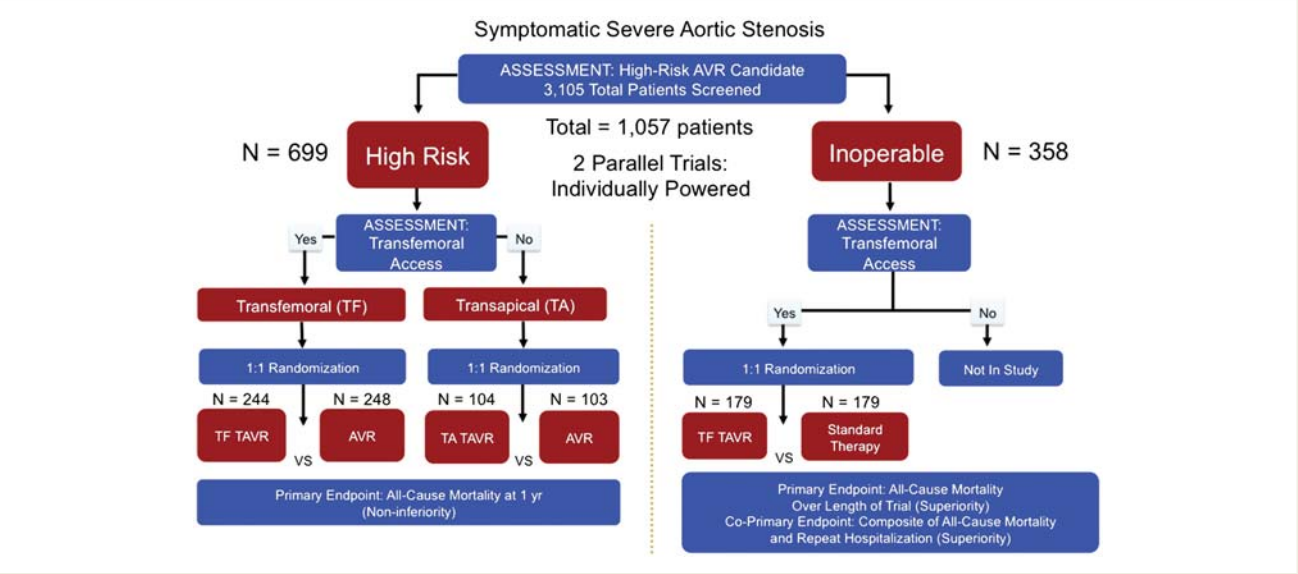

Figure 2 PARTNER trial I design.

In an attempt to expand the indication of TAVI to lower-risk patients, the PARTNER IIA trial will be randomizing patients between TAVI with the SAPIEN XT valve and SAVR in intermediate risk patients (ClinicalTrials.gov Identifier: NCT01314313) (*Figure 4A*). Similarly, the prospective randomized, international SURTAVI trial will randomize 1900 intermediate risk patients between TAVI with the Medtronic CoreValve™ and SAVR at ~80 centres throughout the USA, Canada, Europe, and Australia (ClinicalTrials.gov Identifier: NCT01586910) (*Figure 4B*).

Cost-effectiveness

Since TAVI has been shown to be superior to standard medical therapy and non-inferior to SAVR and is increasingly being used in current practice, the incremental costs and cost-effectiveness of this therapy warrant evaluation.

In the PARTNER IB trial, the mean cost for TF TAVI was $42 806 which accumulated to $78 542 for the initial hospitalization and $106 076 at 1 year.[36] Compared with medical therapy, TAVI was ~$52 455 (95% CI, $40 635–$64 275) more expensive at 1 year, but quality of life was significantly better in patients who underwent TAVI. This resulted in an incremental cost-effectiveness ratio of $50 212 per life-year gained, and $61 889 per quality-adjusted life-year (QALY). The authors rightfully concluded that for patients not candidates for surgery in the USA, TAVI increases (quality-adjusted) life-years at reasonable costs similar to other cardiovascular technologies.

In the PARTNER IA trial, similar costs were found in TF patients as compared with the PARTNER IB trial; $71 955 for the index hospitalization and $94 206 at 1 year, which was comparable to patients who underwent SAVR ($74 452 and $96 417, respectively). However, there was only a minor gain in the number of life-years (0.065: 95% CI, 0.011–0.125) and QALYs (0.068: 95% CI, 0.017–0.123) in comparison with SAVR. Through bootstrap analysis it was concluded that TF TAVI cost was <$50 000 per QALY in 74.7% of times, clearly demonstrating cost-effectiveness in the USA. Patients who could not undergo TF due to anticipated vascular and/or bleeding complications were randomized between TA TAVI ($n = 101$) and SAVR ($n = 91$). The index hospitalization was more expensive in the TA group, although not significantly so ($90 548 vs. $79 540, $P = 0.08$). At 1-year follow-up, costs accumulated to a mean of $107 779 for TA and $98 183 for SAVR, with a small detriment in life-years (−0.015: 95% CI, −0.103–0.080) and QALYs (−0.070: 95% CI, −0.151–0.012). Therefore, TA TAVI was found to be a less attractive alternative to SAVR, although this conclusion has been somewhat criticized because the analysis was not powered and operators were little experienced.[31]

Alternative access sites

Like the TA approach, a subclavian approach allows patients with unfavourable iliofemoral anatomy or extensive disease to be treated with TAVI. Petronio *et al.*[13] recently reported a series of 54 patients, showing a procedural success rate of 100%, a procedural mortality of 0, a 30-day mortality of 0%, and 6-month mortality of 9.4%. No specific vascular complications for subclavian access were reported. The subclavian approach is usually performed with the self-expanding CoreValve™ system and can be fully percutaneous.[37]

Recently, a transaortic approach with direct access to the ascending aorta though an anterior minithoracotomy has been advocated. Access is gained through a J-shaped partial upper sternotomy or using a small right thoracotomy through the intercostal space. Avoidance of LV apical injury or inadequate healing along with reduction in post-operative pain and its associated impairment of respiratory dynamics are potential advantages of this novel approach. Encouraging results have been published from

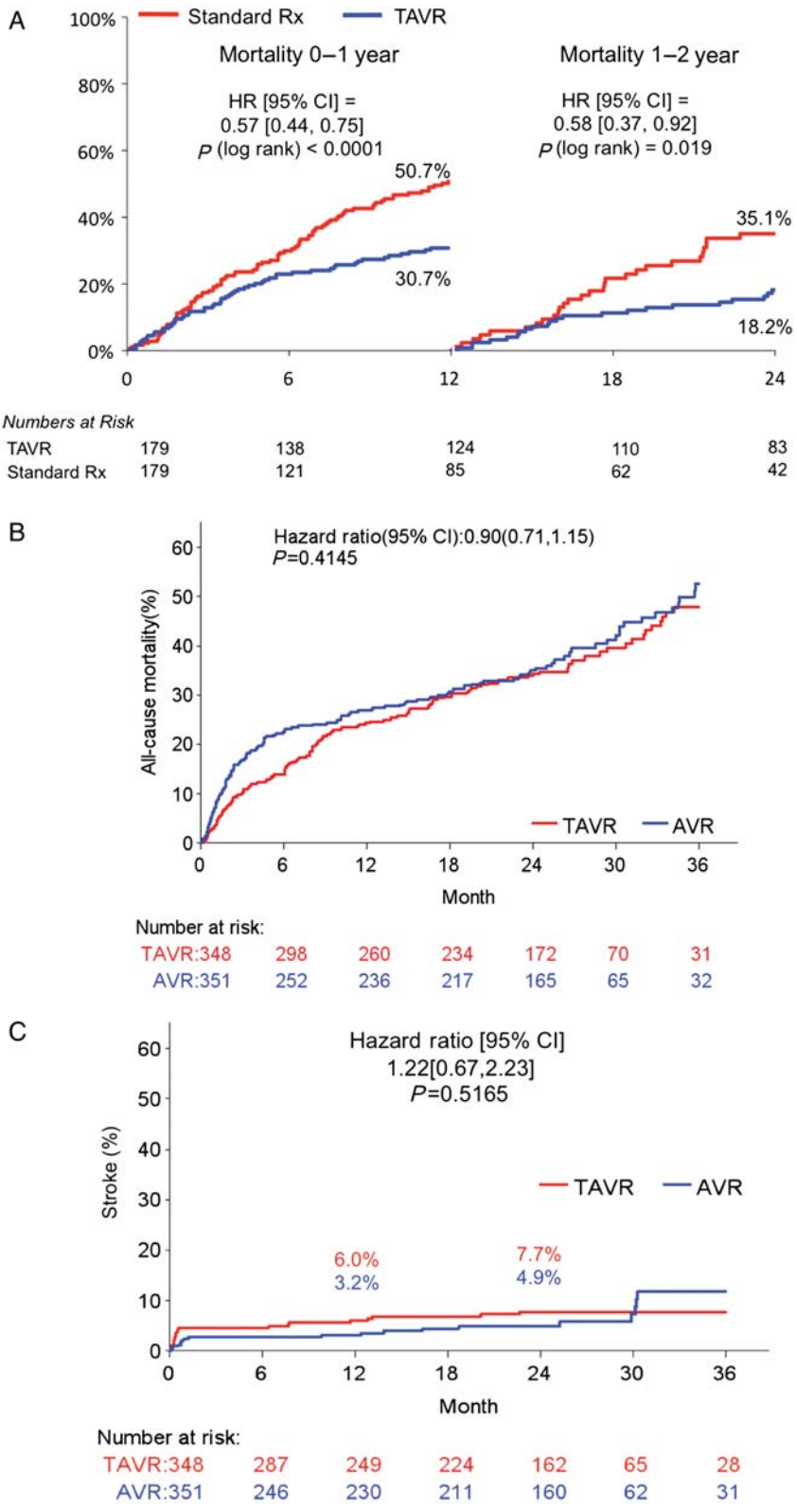

Figure 3 (*A*) Two-year with 1-year landmark analysis of all-cause mortality Kaplan–Meier curve in PARTNER trial cohort 1B. Reprinted with permission from Leon and colleagues[20] and Makkar and colleagues.[33] (*B*) Two-year all cause-mortality Kaplan–Meier curve in PARTNER trial cohort 1A. Adapted with permission from Kodali and colleagues.[34] (*C*) Two-year stroke Kaplan–Meier curve in PARTNER trial cohort 1A. Adapted with permission from Kodali and colleagues.[34]

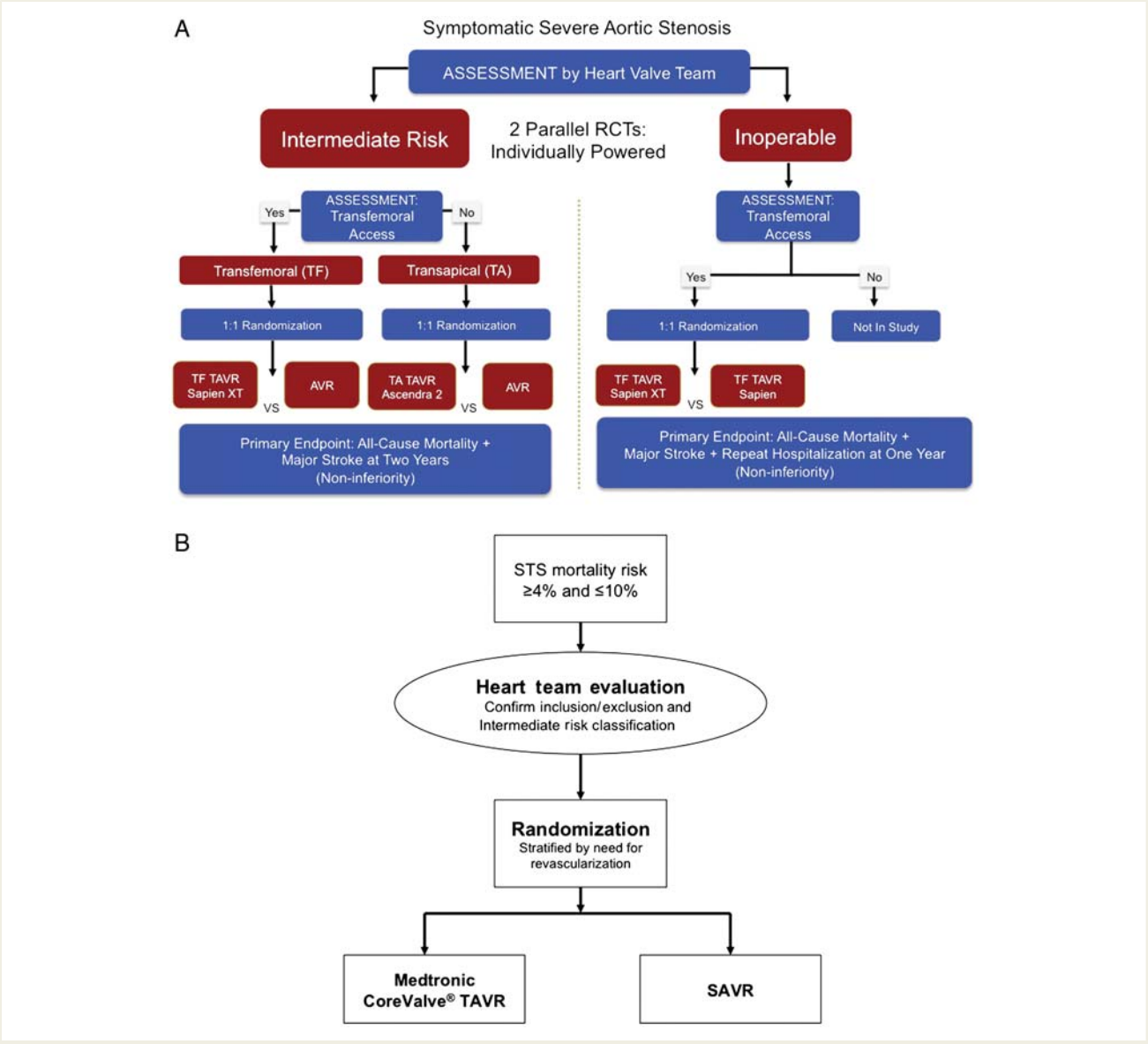

Figure 4 (*A*) PARTNER trial 2 design. (*B*) SURTAVI trial design (provided by Medtronic on 26 April 2012).

small series using both devices.[38,39] It may be suitable for patients with unfavourable iliofemoral and subclavian anatomy and in whom a TA approach is considered too risky (chest deformity, severe respiratory disease or low ejection fraction). Also, TAVI via the carotid artery has been proposed. In such cases, it is crucial to evaluate the cerebral arteries, carotid and vertebral arteries, and circle of Willis, to assess the risk of ischaemic stroke.[40]

Valve-in-valve for failing bioprostheses

Since 2007, when the first TAVI was implanted in a failing surgical aortic bioprosthesis in order to avoid redo surgery, interest in this concept has grown and feasibility and safety have been established.[41,42] Piazza and colleagues[43] published a series of 20 patients (mostly TA: 16/20) and reported successful implantation in 18 of 20 patients and in-hospital mortality in 3 patients. Indeed, transcatheter heart valves have also been implanted in failing mitral prostheses or even annuloplasty rings, and failing tricuspid prostheses, expanding the potential use of devices originally developed for the aortic position.[44,45]

Knowledge of the basic construction, dimensions, and potential failure modes of the surgical bioprostheses is of paramount importance for this technique to succeed. Various complications such as coronary obstruction and device embolization may be implicated with certain surgical bioprostheses but not others.[46] Also, small surgical bioprostheses (e.g. 19 mm) may not respond

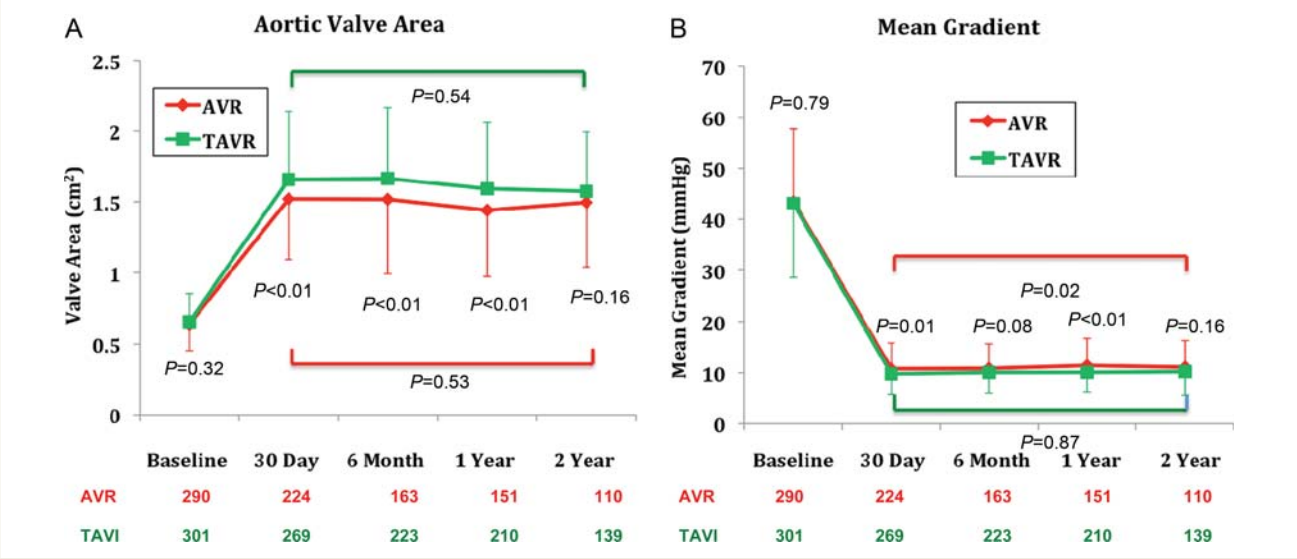

Figure 5 Two-year time trends in haemodynamics after TAVI vs. SAVR. Adapted with permission from Kodali and colleagues.[34]

well to valve-in-valve implantation because of device constraint within the rigid bioprosthesis and incomplete stent expansion, frequently leading to prosthesis–patient mismatch.[47,48]

The presence of a functioning mitral prosthesis may further complicate device delivery, although a recent report has shown that optimal valve positioning through a TA approach should be technically achievable with modifications of the 'classic' procedure.[49]

Efficacy and long-term outcomes

Symptom improvement

Improvement in cardiac symptoms and functional class has been reported at short- and medium-term after TAVI.[14,18,20,21,50] However, functional assessment of the population currently eligible for and treated with TAVI is difficult, mainly because of their multiple co-morbidities.[51]

Three-year follow-up data have been published and are consistent with lasting improvement in cardiac symptoms.[52] While 86% of patients were in NYHA class III or IV at baseline, 93% of surviving patients were in NYHA class I/II at 3-year follow-up. Similarly, the PARTNER trial showed that patients treated with TAVI compared with patients treated with standard medical therapy have better symptom control at 1 year.[20] Indeed, the 1-year rate of NYHA class III or IV was 25.2% for the TAVI group compared with 58.0% for the standard medical therapy group ($P < 0.001$).

Valve durability and haemodynamic performance

TAVI has demonstrated excellent immediate and short-term durability of the prosthesis that is comparable to SAVR, sustaining to 3 years.[14,15,18,20,27,34,52] Actually, data suggest that transcatheter heart valves have greater valve areas and lower gradients than surgical bioprostheses (*Figure 5*),[34,53] which could reduce the prevalence of prosthesis–patient mismatch.[54] For both the Edwards SAPIEN and Medtronic CoreValve™ there was no evidence of structural or non-structural valvular deterioration, stent fracture, deformation, or valve migration.

Predictors

As emphasized throughout the manuscript, many of the listed complications are predictors of short-term and/or long-term mortality. As current randomized trials are moving towards evaluating TAVI in a lower-risk patient population (SURTAVI, PARTNER 2) with a longer life expectancy, prediction of mid- and long-term outcomes (≥1 year) will become increasingly important. Some predictors should be similar to the surgical literature, but the mounting TAVI experience has shown that the incidence and ratio may vary significantly between the two therapies. For example, paravalvular leakage is more common after TAVI than after SAVR and has been identified as a potential significant predictor for long-term mortality.[34]

Table 3 provides a summary of independent predictors of mortality that have been identified in previous studies. Due to the relative infancy of TAVI and the lack of large databases for SAVR,[55] it is likely that additional predictors will come to light over the years. Furthermore, accurate hazard ratios of predictors cannot be given at the current time, due to the severe heterogeneity between studies.

Lessons learned

Patient selection

One of the critical aspects of TAVI we have learned so far is that patient selection is crucial but cumbersome due to inaccuracy of current risk models to predict outcomes in high-risk patients.[56] Several variables that have shown to be predictive are not

Table 3 Independent predictors of long-term mortality after TAVI

Advanced age
Smoking
Logistic EuroSCORE
STS score
Calcium score
Baseline renal failure
Baseline anaemia
Pulmonary hypertension
COPD
Liver disease
Prior stroke
Post-procedural PVL ≥2+
Myocardial injury
Systematic inflammatory response syndrome
Major vascular complication
Acute kidney injury
Early experience with TAVI

TAVI, transcatheter aortic valve implantation.

included, such as frailty, liver disease, and the presence of a porcelain aorta. Decision making should therefore not be based exclusively on clinical risk scores. Instead, it is accepted that the heart team can better judge patient eligibility for TAVI or SAVR. Such a team is dynamic and can include general cardiologists, interventional cardiologists, surgeons, imaging specialists, neurologists, anaesthesiologists, geriatricians, and other specialists.[57,58]

Besides the decision to treat by means of TAVI or SAVR, one must consider multiple access approaches. Frequently, a 'transfemoral-first' attitude is advocated and comprehensive screening of the peripheral arteries and aorta by angiography or preferably by multislice CT-scan (MSCT), is necessary to assess feasibility.[59] MSCT also allows for evaluation of left ventricular dimensions and function, and other potential diseases (e.g. coronary artery disease), which can further help to contemplate feasibility, safety, and efficacy.

Sizing

Accurate preoperative annular sizing is one of the main predictors of a successful TAVI procedure. Several modalities have been proposed for accurate sizing. At first, trans-thoracic and/or trans-oesophageal echocardiography were used to decide which size valve would best be implanted to achieve procedural success with limited or no residual para-valvular aortic regurgitation. More recently, the use of three-dimensional and even four-dimensional MSCT has been shown to be most effective in sizing for TAVI.[60,61] In contrast to trans-esophageal echocardiography, it is non-invasive and has a high reproducibility.[62] Recent studies have shown that the area-derived diameter and basal ring average diameter of the annulus are the most suitable

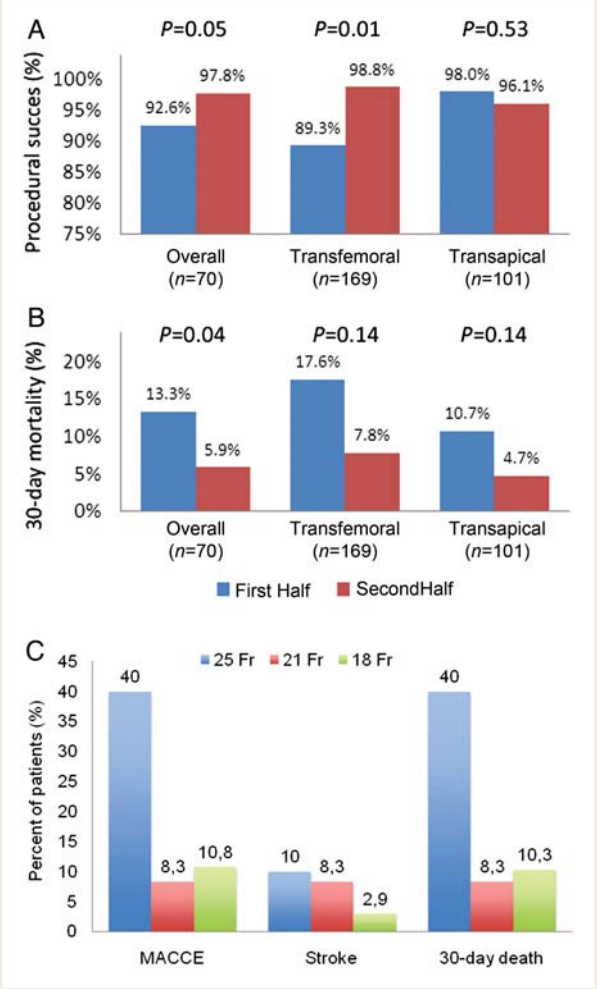

Figure 6 Effect of the learning curve on procedural success (*A*) and 30-day mortality (*B*) after TAVI. Data from Gurvitch and colleagues.[63] (*C*) Single centre experience on 136 patients comparing three generations of CoreValve™ devices. Data from Grube and colleagues.[64]

measurements for valve-sizing. Nevertheless, oversizing of the transcatheter heart valve in relation to the annulus size remains necessary to obtain procedural success with limited aortic regurgitation.

Learning curve

Understanding the importance of patient selection, utilizing better anatomical screening to clarify both the aortic root and iliofemoral geometry, and the development of new devices have led to notable improvements in outcome over time. A report highlighting the importance of the learning curve in 270 patients showed that procedural experience was an independent predictor of 30-day survival.[63] Furthermore, the procedural success rate has significantly increased (*Figure 6*);[63,64] the use of contrast volume use and radiation doses has decreased;[65] and procedural complications have declined.[66]

Conflict of interest: P.G. has received consulting fees/honoraria from Edwards Lifesciences. D.W. and J.W. have received consulting fees from Edwards Lifesciences and St Jude Medical. M.R.W. and S.K. have received consulting fees from Edwards Lifesciences. A.P.K. is a member of the steering committee for the SURTAVI trial. M.B.L. is a nonpaid member of the Scientific Advisory Boards of Edwards Lifesciences and Medtronic Vascular. The other authors report no conflicts of interest.

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