

A systematic review of transapical aortic valve implantation

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Background: Transcatheter aortic valve implantation (TAVI) through a transapical approach (TAAVI) for severe aortic stenosis becomes the procedure of choice in cases where patients have peripheral artery disease and unfeasible access due to excessive atherosclerotic disease of the iliofemoral vessels and aorta. The present systematic review aimed to assess the safety, success rate, clinical outcomes, hemodynamic outcomes, and survival benefits of TAAVI.

Methods: Electronic searches were performed in 6 databases from January 2000 to February 2012. The primary end points included feasibility and safety. Other end points included echocardiographic findings, functional class improvement, and survival.

Results: After applying the inclusion and exclusion criteria, 48 out of 154 shortlisted potentially relevant articles were selected for assessment. Of these, 26 studies from 24 centers including total number of 2,807 patients were included for appraisal and data extraction. The current evidence on TAAVI for aortic stenosis is limited to observational studies. Successful TAAVI implantation occurred in >90% of patients. On average, the procedure took between 64 to 154 minutes to complete. The incidence of major adverse events included 30-day mortality (4.7-20.8%); cerebrovascular accident (0-16.3%); major tachyarrhythmia (0-48.8%); bradyarrhythmia requiring permanent pacemaker insertion (0-18.7%); cardiac tamponade (0-11%); major bleeding (1-17%); myocardial infarction (0-6%); aortic dissection/rupture (0-5%); moderate to severe paravalvular leak (0.7-24%); cardiopulmonary bypass support (0-15%); conversion to surgery (0-9.5%); and valve-in-valve implantation (0.6-8%). Mean aortic valve area improved from 0.4-0.7 cm² before TAAVI to 1.4-2.1 cm² after TAAVI. The peak pressure gradient across the aortic valve decreased from >70 mmHg to <20 mmHg after TAAVI. One-year survival ranged from 49.3% to 82% and the 3-year survival was 58% in 2 series.

Conclusions: TAAVI appears to be feasible with a reasonable safety and efficacy portfolio. Randomised controlled trials are required to compare transapical *vs.* transfemoral TAVI when both techniques are equally feasible.

Key Words: Transcatheter aortic valve implantation (TAVI); systematic review; aortic stenosis (AS)

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Introduction

Aortic stenosis (AS) is the most common valve disease, and once symptomatic can lead to a decrease in life expectancy (1). Aortic valve replacement (AVR) has long been the definitive therapy in treating symptomatic AS.

However, in the face of an increasingly older population and increasing prevalence of AS, a percentage of patients may not be deemed candidates for surgery due to high surgical risk or other prohibitive risk factors. Transcatheter aortic valve implantation (TAVI) has become an accepted

alternative to surgery in treating severe AS for high-risk or non-operative individuals (2).

TAVI can be performed using several approaches including a retrograde transfemoral (TFAVI), transsubclavian, transaortic, or antegrade transapical. The TFAVI approach is often considered the first choice for TAVI due to its minimal invasiveness and reduced anaesthetic requirement (3). Transapical TAVI (TAAVI) becomes the procedure of choice in instances where patients have excessive atherosclerotic disease of the iliofemoral vessels and aorta, and peripheral access is not feasible. For TAAVI, the balloon-expandable Edwards SAPIEN (Edwards Lifesciences, Irvine, CA) prosthesis with the Ascendra delivery system gained CE (European Conformity) mark approval in 2008. Thereafter, CE mark approvals were granted to the second-generation Edwards SAPIEN XT prosthesis (23-mm and 26-mm valves) and the Ascendra II delivery system in 2010 and the SAPIEN XT 29-mm prosthesis in 2011. Several other devices from different companies (Jenavalve, Jena Valve Inc, Munich, Germany; Embracer, Medtronic Inc, Guilford, CT; Accurate, Symetis Inc, Geneva, Switzerland) have passed “first in man trials” successfully and are being evaluated within multicenter studies (4). The subclavian artery is the other alternative access route when a transfemoral approach is not feasible. The self-expanding CoreValve ReValving system (Medtronic, Minneapolis, MN) is another commonly used valve that can be delivered retrogradely via both transfemoral and trans-subclavian approaches (5).

Despite the growing number of patients undergoing TAAVI each year, there is no comprehensive review assessing the safety and efficacy of this approach. We performed this systematic meta-analysis and review to assess the safety, success rate, clinical outcomes, hemodynamic outcomes, and survival benefits of TAAVI.

Methods

Literature search strategy

A systematic review was performed and six electronic databases including MEDLINE, EMBASE, PubMed, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Database of Abstracts of Review of Effectiveness were searched for original published studies from January 2000 to February 2012. To achieve the maximum sensitivity of the search strategy and identify all studies, we used appropriate free text and

thesaurus terms: “percutaneous” OR “transcutaneous” OR “transcatheter” OR “transarterial” OR “transapical” AND “aortic valve” OR “aortic valve stenosis”. The reference lists of all retrieved articles were reviewed for further identification of potentially relevant studies.

Outcome measures

The primary end points included feasibility and safety (procedural success rate, 30-day mortality, major tachyarrhythmia, bradyarrhythmia requiring permanent pacemaker insertion, myocardial infarction, cardiac tamponade, cerebrovascular accident, conversion to surgery, moderate to severe paravalvular leak, valve-in-valve procedure, emergency percutaneous coronary intervention, aortic dissection/perforation, major bleeding, procedure and fluoroscopy duration, and length of hospital stay). The secondary outcomes included echocardiographic findings (mean aortic valve area before and after TAAVI, peak and mean pressure gradient before and after TAAVI, left ventricular ejection fraction before and after TAAVI), New York Heart Association [NYHA] functional class improvement versus baseline, and survival at 6-month, 1-year, 2-year, and 3-year follow-up reviews.

Selection criteria

Studies eligible for this systematic review included high-risk patients with AS who received TAAVI using the Edwards SAPIEN transcatheter xenograft (Edwards Lifesciences, Irvine, CA). The criteria for patient selection for TAAVI varied among institutions, and the definitions for nonsurgical candidates were not uniform. Experimental or observational studies were included in the present review. Case reports, series with less than ten patients, abstracts, editorials, and expert opinions were excluded. Case series limited to a selected group of patients (redo surgeries, valve-in-valve implantation, etc.) were excluded.

Serial publications reporting accumulating numbers of patients or increased length of follow-up were identified. The publication with the most complete data set from each center was retained. Data was extracted from two papers from each of the two centers that had competing data on the same patient population (6-9).

Data extraction and critical appraisal

Two reviewers (M.R. and J.S.) independently appraised each

included study using a standard form and extracted data on methodology, quality criteria, and outcome measures. All data was extracted and tabulated from the relevant articles' texts, tables, and figures. The quality of studies was assessed using criteria recommended by the National Health Service Centre for Reviews and Dissemination case series quality assessment criteria (University of York, Healington, United Kingdom) (10). Clinical effectiveness was synthesized through a narrative review with full tabulation of results of all included studies. Discrepancies between the 2 reviewers were resolved by discussion and consensus with a third investigator (T.D.Y.).

Intervention

Despite some variations, similar steps are followed in various centers. The operative technique for TAAVI is well described in the literature (11). In brief, an anterolateral mini-thoracotomy is performed in the fifth intercostal space. After pericardiotomy, the left ventricular apex is punctured between two pledgeted purse-string sutures. Balloon valvuloplasty of the stenotic valve is then performed under rapid ventricular pacing. Under guidance of fluoroscopy and transesophageal echocardiography, the valve is then positioned within the aortic annulus and implanted during a second period of rapid ventricular pacing.

Results

Quantity of studies

After removing duplicates, the titles and abstracts of 671 peer-reviewed publications were identified through searching the 6 electronic databases. Initial evaluation of these abstracts identified 151 potentially relevant publications. Manual search of the reference lists identified 3 additional publications of interest. When the inclusion and exclusion criteria were applied to these 154 publications, 48 articles (3,6-9,12-54) remained for assessment (*Table 1*). In total, 25 series presented in 27 studies (3,6-9,21-23,28,30-32,34,37,38,41-45,47-51,53,54) including total number of 2,807 patients were included for appraisal and data extraction (*Table 2*).

Quality of evidence

No randomized controlled trials were identified. Papers presented data on groups of patients who had undergone TFAVI or TAAVI (3,8,9,22,23,31,32,34,38,41-43,45,48-51,53,54), TAAVI only (6,7,28,30,37,44,47), or compared

between TAAVI and open AVR (21). All reports originated from specialized tertiary referral centers. Seven centers reported results of TAAVI in 100 or more (range, 101-575) patients (6-9,28,30,31,38,47). There were five multicentric series (8,31,47,48,51).

Twelve studies reported explicit inclusion criteria (6,7,28,32,41-44,47,48,51,54). The definitions of high-risk patients with AS not suitable for surgical AVR varied among the institutions; for example, age >75 years (6,21); NYHA functional class II or more (48,51); AVA <1 cm² (32,45,48), <0.8 cm² (21,47,51,54); logistic EuroSCORE >20% (9,21,28,41-44,47,48,51,54), logistic EuroSCORE >15% (45), additive EuroSCORE ≥9 (6,7), and/or Society of Thoracic Surgeons score >10% (6,28,41-43,48,51,54). Operative technique was clearly explained in ten studies (21,23,32,37,41-44,48,51). Procedures were performed in either a surgical hybrid suite (7,22,23,28), an angiography suite (21,42,53,54), or in the operating theater (32,37,42,44). The definitions of adverse events were clearly explained in 8 studies (9,32,38,41,42,45,47,51).

Assessment of feasibility

Success of the procedure occurred in >90% of cases in studies that reported this outcome (*Table 2*). Procedural success rate was 92.7% (522/563) in a multicentric European registry (SOURCE registry), with 20 patients (3.5%) requiring conversion to open AVR (8). Valve-in-valve implantation was required in 19 patients (3.3%) in the SOURCE registry to correct malposition or moderate/severe aortic insufficiency after placement of the first valve (8). D'Onofrio *et al.* (47) reported successful implantation in 99% (500/504) of patients undergoing TAAVI in an Italian multicentric registry. Valve-in-valve implantation was performed in 3 patients because of malpositioning of the first prosthesis and 1 patient required conversion to an open AVR after the valve embolized to the left ventricle.

Kempfert *et al.* (6) reported similar device success rates in their first 150 patients (138/150; 92%) compared to the next 149 patients (137/149; 91%) that had undergone TAAVI. Requirement for conversion to AVR or valve-in-valve implantation was similar between earlier and later groups of patients in this series (6).

Assessment of safety

Table 3 summarizes 30-day major adverse events following TAAVI across all studies. The range of these adverse

Centre	Reference	Year	n	Follow-up time	Success rate	Mortality	Morbidity	Conversion to surgery	Neurologic event	Rethoracotomy	Length of stay	Echo findings	Learning curve	Survival	Fluoroscopy and/or contrast data
Leipzig, Germany	Walther (12)	2007	30	27-230 d	x	x	x	x	x	x	x	x	x	x	x
Multicentre, Germany	Walther (13)	2007	59	1-255 d	x	x	x	x	x	x	x	x	x	x	x
Leipzig, Germany	Walther (14)	2008	50	6-18 m	x	x	x	x	x	x	x	x	x	x	x
Leipzig, Germany	Walther (15)	2009	25	1 y	x	x	x	x	x	x	x	x	x	x	x
Leipzig, Germany	Kempfert (16)	2010	29		x	x	x	x	x	x	x	x	x	x	x
Leipzig, Germany	Walther (17)	2010		1 y	x	x	x	x	x	x	x	x	x	x	x
Leipzig, Germany	Kempfert (6)	2011	299	1 y	x	x	x	x	x	x	x	x	x	x	x
Leipzig, Germany	Van Linden (18)	2011	39	1 y	x	x	x	x	x	x	x	x	x	x	x
Leipzig, Germany	Van Linden (19)	2011	261	1 y	x	x	x	x	x	x	x	x	x	x	x
Leipzig, Germany	Walther (7)	2012	299	4 y	x	x	x	x	x	x	x	x	x	x	x
Frankfurt/Main, Germany	Zierer (20)	2008	26		x	x	x	x	x	x	x	x	x	x	x
Frankfurt/Main, Germany	Zierer (21)	2009	21	12±4 m	x	x	x	x	x	x	x	x	x	x	x
Essen, Germany	Thielmann (22)	2009	24	1 y	x	x	x	x	x	x	x	x	x	x	x
Munich, Germany	Bleiziffer (23)	2009	50	6 m	x	x	x	x	x	x	x	x	x	x	x
Berlin, Germany	Pasic (24)	2010	194		x	x	x	x	x	x	x	x	x	x	x
Berlin, Germany	Pasic (25)	2010	175	12 m	x	x	x	x	x	x	x	x	x	x	x
Berlin, Germany	Buz (26)	2011	46	1 y	x	x	x	x	x	x	x	x	x	x	x
Berlin, Germany	Dreus (27)	2011	158	2 y	x	x	x	x	x	x	x	x	x	x	x
Berlin, Germany	Unbehaun (28)	2011	300	30 m	x	x	x	x	x	x	x	x	x	x	x
Berlin, Germany	Unbehaun (29)	2012	358	2 y	x	x	x	x	x	x	x	x	x	x	x
Cologne, Germany	Strauch (30)	2010	30	8 wk	x	x	x	x	x	x	x	x	x	x	x
Multicentre, Canada	Rodés-Cabau (31)	2010	177	8 m	x	x	x	x	x	x	x	x	x	x	x
Ontario, Canada	Osten (32)	2010	30		x	x	x	x	x	x	x	x	x	x	x
Quebec, Canada	Gutiérrez (33)	2009	33	1 m	x	x	x	x	x	x	x	x	x	x	x
Quebec, Canada	Rodés-Cabau (34)	2011	63		x	x	x	x	x	x	x	x	x	x	x
Vancouver, Canada	Webb (35)	2009	55	1 y	x	x	x	x	x	x	x	x	x	x	x
Vancouver, Canada	Ye (36)	2009	26	1 y	x	x	x	x	x	x	x	x	x	x	x
Vancouver, Canada	Ye (37)	2010	71	129±115m	x	x	x	x	x	x	x	x	x	x	x
Vancouver, Canada	Gurvitch (38)	2011	101		x	x	x	x	x	x	x	x	x	x	x
Vancouver, Canada	Higgins (39)	2011	46		x	x	x	x	x	x	x	x	x	x	x

Table 1 (continued)

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Centre	Reference	Year	n	Follow-up time	Success rate	Mortality	Morbidity	Conversion to surgery	Neurologic event	Rethoracotomy	Length of stay	Echo findings	Learning curve	Survival	Fluoroscopy and/or contrast data
Paris, France	Al-Attar (40)	2009	18		x	x	x								
Paris, France	Himbert (41)	2009	24	1 y	x	x	x	x	x		x	x	x	x	
Paris, France	Guinot (42)	2010	28		x	x	x	x	x			x			
London, United Kingdom	Dworakowski (43)	2010	84	12 m	x	x	x		x		x	x		x	
Lausanne, Switzerland	Ferrari (44)	2010	30		x	x	x		x		x	x			x
Bern, Switzerland	Wenaweser (45)	2011	43	1 y	x	x	x		x			x		x	x
Multicentric, European	Thomas (9)	2010	575		x	x	x	x	x			x			
Multicentric, European	Thomas (8)	2011	575	1 y			x		x					x	
Multicentric, Italy	D'Onofrio (46)	2011	179	9±7 m	x	x	x					x	x	x	
Multicentric, Italy	D'Onofrio (47)	2011	504	12 m	x	x	x		x			x	x	x	
Multicentric, France	Elchaninoff (48)	2011	71	1 m	x	x	x		x			x			x
Leiden, The Netherlands	Ewe (49)	2011	59	12 m	x	x	x		x		x	x		x	x
Lund, Sweden	Johansson (50)	2011	30	1 y	x	x	x		x		x			x	x
Multicentric, European	Lefevre (51)	2011	69	1 y	x	x	x	x	x		x	x		x	x
Milan, Italy	Godino (52)	2010	15	6 m	x	x	x		x		x	x		x	
Milan, Italy	Taramasso (3)	2011	16	6.0±6.8 m	x	x	x		x		x			x	
Skejby, Denmark	Nielsen (53)	2011	76	1 y	x	x	x		x					x	
Athens, Greece	Spargias (54)	2011	32	1 y		x								x	
Bolded studies are selected for appraisal and data extraction; Y, year(s), m, month(s), wk, week(s)															

Study	Number assessed TA	Number other routes	Study period	Age, years	Female, %	Logistic EuroSCORE, %	STS score, %	Successful implantation, n [%]	Successful procedure, n [%]	CPB, n [%]	Contrast volume, mL	Fluoroscopy time, min	Procedure time, min
Kempfert (6)&Walther (7)	299	299	0	2006-2010	82±6	70	31±16	12±8	-	-	18 [6.3]	-	-
Early group	150	150	0	2006-2010	82.5±5.7	69	29.4±14	13.5±7.8	-	138 [92]	22 [15]	104±78	94±56
Kempfert (6)	149	149	0	2006-2010	81.8±7.0	71	33.2±17.2	11.4±7.5	-	137 [91]	8 [5]	93±6	84±34
Late group	51	21	30	2006-2007	85±6	71	38±14	-	-	-	-	-	154±33
Thielmann (22)	85	24	15	2005-2008	82.7±5.1	67	52.5±13.4	19.9±7.5	23 [96]	-	1 [4]	222±77	135±28
Bleiziffer (23)	203	50	153	2007-2009	81.5±5.9	78	22.0±14.9	6.3±3.8	-	-	-	116±50	95.4±26.1
Unbehaun(28)	300	300	0	2008-2010	79.6±8.1	68	38.5±19.4	19.1±15.5	-	299 [99.7]	4 [1.3]*-13 [4.3]**	104±52	8.7±5.1
Strauch (30)	-	30	-	2008-2009	82.1 [71-88]	63	19.01 [5.1-77.4]	13.6 [3.2-26]	-	-	1	115±12.9	-
Rodés-Cabau (31)	396	177	168	2005-2009	80±8	66	-	10.5±6.9	-	170 [96]	-	-	-
Osten (32)	46	30	16	2007-2009	79±7	66	25.9	9.5	28 [93]	-	-	-	-
Rodés-Cabau (34)	101	63	38	-	78±9	65	-	8.6±6.5	-	63 [100]	-	12 [10-20]	70±15
Ye (37)	--	71	0	2005-2009	80.0±8.1	62%	34.5±20.4	12.1±7.7	71 [100]	-	-	-	-
Gurvitch (38)	270	101	169	-	81±7	64	-	11.2	101 [100]	98 [97]	-	-	-
Himbert (41)	160	24	74	2006-2008	82±10	33	28±13	18±9	24 [100]	-	-	-	-
Guinot (42)	90	28	62	2006-2009	80±10	39	25±9	16±8	-	27 [96]	0 [0]	-	97 [70-105]
Dworakowski (43)	386	84	382	2007-2009	82.2±0.8	54	23.4±1.5	-	-	83 [99]	3 [3.6]	-	-
Ferrari (44)	30	30	0	2008-2009	80.1±8.7	50	32.2±13.3	-	-	29 [97]	1 [3.3]	5.5±9.1	116.4±31.4
Wenaweser (45)	360	43	157	2007-2010	78±10	44	26±14	6±5	42 [98]	40 [93]	-	198±88	81±31
Thomas (8,9)	1123	575	548	2007-2009	80.7±7.0	56	29.1±16.3	-	-	522/563 [93]	-	-	-
D'Onofrio(47)	504	504	0	2008-2010	81.2±6.5	61	24±16	11±4	-	500 [99]	10 [1.9]	-	-
Elitchaninoff (48)	244	71	173	2009	82.1±7.3	36	26.8±11.6	18.4±12.1	-	-	-	123±70	9.9 ± 10.4
Ewe (49)	104	59	45	-	79.4±8.3	47	22.6±1.9	8.9±3.5	-	-	-	80 [70-109]	5 [4-8]
Johansson(50)	-	30	10	2008-2009	80±6	50	23.5±17	-	-	28 [93]	-	209±100	-
Lefevre (51)	131	69	61	2007-2008	81.9±5.7	51	33.8±14.4	11.8±6.8	62 [95]	-	-	153.8±76.7	131.6±59.3
Taramasso (3)	177	16	159	2007-2010	78.2±6.7	69	33.6±23.2	28.3±15.7	-	16 [100]	-	-	-
Nielsen (53)	100	76	24	2006-2010	80.6±6.7	57	21.5±13.5	-	71 [93]	-	-	-	-
Spargias (54)	91	32	59	2007-2010	81±7	62	27±15	14±8	-	-	-	-	-

TA, transapical approach; CPB, cardiopulmonary bypass; ICU, intensive care unit; CCU, cardiac care unit; STS, Society of Thoracic Surgeons; *emergency CPB; **elective CPB

Study	n	30-day mortality, n [%]	Pacemaker insertion, n [%]	Neurological event, n [%]	Cardiac tamponade, n [%]	Conversion to surgery, n [%]	Valve-in valve (>1 valve), n [%]	Aortic dissection/perforation, n [%]	Paravalvular leak >2+ (II), n [%]	Major bleeding, n [%]	Tachyarrhythmia, n [%]	Myocardial infarction, n [%]	Length of ICU/CCU stay, day	Length of hospital stay, day
Kempfert (6) & Walther (7)	299	26 [8.7]	12 [4]	2 [0.7]	-	6 [2]	-	-	2 [0.7]	6 [2]	-	-	-	-
Early group	150	17 [11.3]	2 [1]	-	-	5 [3]	6 [4]	-	4 [3]	3 [2]	-	-	-	-
Kempfert (6)	149	9 [6.0]	8 [5.4]	2 [1.3]	-	2 [1]	11 [7]	-	9 [6]	1 [1]	-	-	-	-
Late group	21	3 [14]	0 [0]	0 [0]	-	2 [9.5]	-	1 [5%]	5 [24]	-	0 [0]	-	1.0±0.4	5.0±0.9
Zierer (21)	24	5 [20.8]	0 [0]	0 [0]	0 [0]	1 [4]	1 [4]	-	8 [25]	-	2 [8]	-	2±3	12±10
Thielmann (22)	50	4 [8.3]	-	0 [0]	-	-	-	-	-	-	-	-	-	-
Bleiziffer (23)	300	14 [4.7]	19 [7]	3 [1]	-	1 [0.3]	10 [3]	-	-	-	-	-	-	-
Unbehaun (28)	30	4 [13]	-	-	-	2 [7]	-	-	-	-	-	-	4.1±0.6	12.1±0.8
Strauch (30)	177	20 [11.3]	11 [6.2]	3 [1.7]	-	4 [2.3]	5 [2.8]	-	-	-	16 [9.0]	3 [1.7]	-	-
Rodés-Cabau (31)	30	2 [7]	3 [10]	2 [7]	-	-	-	-	-	5 [17]	-	0 [0]	-	10
Osten (32)	63	4 [6]	3 [5]	2 [3]	-	1 [1.5]	1 [1.6]	-	-	-	-	-	-	-
Rodés-Cabau (34)	71	12 [16.9]	6 [8.5]	1 [1.4]	-	-	-	-	4 [5.2]	-	-	-	-	-
Ye (37)	101	13 [12.7]	6 [5.9]	2 [2.0]	4 [3.9]	-	-	4 [3.9]	-	8 [7.9]	12 [11.9]	-	-	-
Gurvitch (38)	24	-	-	0 [0]	2 [8]	-	2 [8]	-	3 [12]	-	-	-	5 [3-8]	12 [9-18]
Himbert (41)	28	2 [8]	1 [4]	0 [0]	3 [11]	0 [0]	-	0 [0]	-	-	4 [14]	1 [4]	4 [3-9]	-
Guinot (42)	84	11 [13.1]	5 [6]	4 [4.8]	-	-	-	-	-	-	-	0 [0]	-	-
Dworakowski (43)	30	3 [10]	-	1 [3.3]	-	-	-	-	3 [10]	-	-	0 [0]	2.4±4	15.1±10.2
Ferrari (44)	43	4 [9.3]	6 [14]	7 [16.3]	3 [7.0]	0 [0]	-	1 [2.3]	-	-	21 [48.8]	-	1 [2.3]	-
Wenaweser (45)	575	59 [10.3]	42 [7.3]	29 [6.3]	-	20 [3.5]	19 [3.3]	5 [0.7]	-	-	-	-	-	-
Thomas (8,9)	504	42 [8.3]	27 [5.3]	15 [3]	-	1 [0.2]	3 [0.6]	-	-	-	-	8 [1.6]	2	9±4
D'Onofrio (47)	71	12 [16.9]	4 [5.6]	2 [2.8]	0 [0]	-	-	0 [0]	-	-	-	-	-	-
Elchaninoff (48)	59	5 [8.5]	2 [3.4]	2 [3.4]	3 [5.1]	-	-	-	-	9 [15.3]	-	-	-	6 [5-8]
Ewe (49)	30	-	0	1	-	-	-	-	-	-	3 [10]	-	7 [3]	-
Johansson (50)	69	13 [19]	2 [3]	1 [1.5]	-	-	-	-	-	8 [11.6]	-	4 [6]	1 [0-56]	11 [0-59]
Lefevre (51)	16	2 [12.5]	3 [18.7]	0 [0]	-	-	-	0 [0]	-	-	-	0 [0]	-	14.8±18.3
Taramasso (3)	76	5 [6.6]	3 [3.9]	1 [1.3]	-	-	-	-	-	-	-	3 [3.9]	-	9.6±7.3
Nielsen (53)	32	2 [6]	-	-	-	-	-	-	-	-	-	-	-	-
Spargias (54)	-	-	-	-	-	-	-	-	-	-	-	-	-	-

events was as following: 30-day mortality (4.7-20.8%); cerebrovascular accident (0-16.3%); major tachyarrhythmia (0-48.8%); bradyarrhythmia requiring permanent pace maker insertion (0-18.7%); cardiac tamponade (0-11%); major bleeding (1-17%); myocardial infarction (0-6%); aortic dissection/rupture (0-5%); moderate to severe paravalvular leak (0.7-24%); cardiopulmonary bypass support (0-15%); conversion to surgery (0-9.5%), and valve-in-valve implantation (0.6-8%). The procedure took between 64 to 154 minutes on average to complete. The reported mean volume of contrast used varied widely between studies (12-222 mL) (*Table 2*). In a series from Leipzig, Germany, less contrast volume, shorter fluoroscopy time and less frequent cardiopulmonary bypass support were required as the procedural team gained experience (6). The mean length of ICU stay varied between 1 to 5 days, while, the mean length of hospital stay ranged from 5 to 15 days (*Table 3*).

Assessment of efficacy

Echocardiographic findings are demonstrated in *Table 4*. Mean aortic valve area improved from 0.4-0.7 cm² before TAAVI to 1.4-2.1 cm² after TAAVI. The peak pressure gradient across the aortic valve decreased from >70 mmHg to <20 mmHg after TAAVI (*Table 4*). In a few series, symptomatic improvement occurred as evidenced by a decrease in NYHA functional class (*Table 5*). The number of patients with NYHA functional class III or IV reduced from 71% (42/59) before intervention to 36% (14/39) in 6 months and to 26% (6/23) in 12 months after TAAVI in one series (49).

The multicentric European PARTNER transcatheter heart valve study (51) showed that the frequency of patients with NYHA functional class III or IV symptoms decreased from 85.5% (59/69) before procedure to 14.7% (5/34) one year after TAAVI. When the EuroQol with EQ-5D UK-TTO rating scale (not specific for cardiac patients) was used to assess the quality of life, only marginal difference was noted in the one-year follow-up (n=20, 0.59±0.30 baseline *vs.* 0.66±0.43 one year after TAAVI; P=0.13). However, the Kansas City Cardiomyopathy Questionnaire (KCCQ), a more specific questionnaire for cardiac patients, showed significant improvement in the quality of life in one year (n=23, 49.6±22.7 baseline *vs.* 77.1±23.4 one year after TAAVI; P=0.0004) (51).

Assessment of survival

One-year survival ranged from 49.3% to 82.5% (*Table 5*).

Mid-term (≥1 year) survival data was recorded in series from 9 centers (*Table 5*) (6,7,22,28,31,37,41,43,47,51). The 3-year survival was 58% in 2 studies (7,37).

Discussion

The worldwide experience in TAAVI is growing. The current systematic review presents the procedural outcomes of 24 series with a total number of 2,724 patients that have undergone TAAVI worldwide. The procedural success rate ranged from 93% to 100% across all studies that reported this outcome (*Table 2*). In the largest series included in this review, Thomas *et al.* (9) reported a 30-day mortality of 10% following TAAVI. The reported 1-year survival was often greater than 70% (*Table 5*), with Walther *et al.* (7) reporting a 3-year survival of 58% in 299 patients who had undergone a TAAVI.

Based on echocardiography and NYHA functional class, TAAVI proved to be efficacious with symptomatic improvement at 6- and 12-month follow-up. However, it remains unclear whether there is a correlation between improvement in valvular hemodynamics and patient's quality of life (2). One study (European PARTNER) was able to demonstrate a significant improvement in the quality of life at 12 months (51), but additional evidence is still needed.

Learning curves play a role in determining an operator's and institute's overall outcomes. In their series of 300 TAAVI patients, Unbehaun *et al.* (28) reported a reduction in overall 30-day mortality from 6% for the first 100 patients to 2% for the last 100 patients. In the same series, the six-month survival rate increased from 84% in the early group to 96% in the late group (28). Similarly, Ye *et al.* (37) reported a 33.3% mortality in the beginning of their cohort and a 12.5% with the remaining patients. Furthermore, Kempfort *et al.* reported decreased 30-day mortality rates from 11% in the first 150 patients to 6% in the next 149 patients receiving a TAAVI. In the same series, the 1-year mortality significantly improved from 30.7% to 21.5% between the two groups (P=0.047) (6). Nevertheless, results from the Italian Registry of Trans-Apical Aortic Valve Implantation (I-TA) suggested no significant differences in outcomes between high- and low-volume centers and between the first and the second 50% of cases (47).

Risk factors for mortality proved to be heterogeneous between studies. When multivariate analysis was performed by Kempfort *et al.*, reduced vital capacity (<70%) and mitral regurgitation (>grade 1) were the only independent

Study	n	Mean aortic valve area before TAAVI (cm ²) ± SD	Mean aortic valve area after TAAVI (cm ²) ± SD	Peak pressure gradient before TAAVI (mmHg) ± SD	Peak pressure gradient after TAAVI (mmHg) ± SD	Mean pressure gradient before TAAVI (mmHg) ± SD	Mean pressure gradient after TAAVI (mmHg) ± SD	LV ejection fraction before TAAVI (%) ± SD	LV ejection fraction after TAAVI (%) ± SD
Kempfert (6)&Walther (7)	299	-	-	-	12	-	8	55±14	56
Early	150	-	-	-	15±6	-	7.9±4	55.4±14.6	55±13
Kempfert (6)	149	-	-	-	17±6	-	9.2±3	55.1±12.3	56±11
Late group	21	-	1.5±0.8	-	-	-	9.6±3.7	-	-
Zlerer (21)	24	-	-	-	-	-	-	52.1±12.8	-
Thielmann (22)	50	0.58±0.2	-	-	-	-	-	-	-
Bleiziffer (23)	300	0.7±0.2	-	-	-	48.5±14.9	-	50.0±13.7	-
Unbehaun (28)	30	-	-	-	-	-	-	-	-
Strauch (30)	177	0.63±0.18	-	-	-	44±17	-	56±14	-
Rodés-Cabau (31)	30	0.6±0.1	1.6±0.6	-	-	52±13	10±3	-	-
Osten (32)	63	0.62±0.21	-	-	-	42±19	-	54±14	-
Rodés-Cabau (34)	71	0.6±0.2	1.4±0.3	-	-	43.6±16.3	10.1±3.9	55.5±12.6	61.2±7.0
Ye (37)	101	-	-	-	-	-	-	-	-
Gurvitch (38)	24	0.65±0.17	1.80±0.48	-	-	48±14	9±4	48±13	-
Himbert (41)	28	0.37±0.09	-	-	-	43±14	-	50±14	-
Guinot (42)	84	-	-	-	-	-	-	-	-
Dworakowski (43)	30	0.7±0.16	-	-	14.1±8.8	60.3±20.9	7.7±4.8	0.526±0.128	0.557±0.105
Ferrari (44)	43	0.6±0.2	-	-	-	44±15	-	49±15	-
Wenaweser (45)	575	-	-	-	-	-	-	-	-
Thomas (8,9)	504	0.53±0.18	-	74.7±23.3	-	47.4±15.4	-	52.4±13.6	-
D'Onofrio (47)	71	0.68±0.17	-	-	-	48±16	-	54±12	-
Elchaninoff (48)	59	0.8±0.2	2.0±0.3	-	-	39±12	8±3	52±14	50±13
Ewe (49)	30	-	-	80±24	-	45±15	-	-	-
Johansson (50)	69	0.6±0.2	1.4±0.4	-	-	46.6±18.6	10.6±6.9	52.8±14.6	56.1±14.8
Lefevre (51)	16	-	-	-	-	42.5±16	-	49.1±12.7	49.67±10.4
Taramasso (3)	76	0.6±0.2	1.6±0.4	76 [27.9]	19 [9.7]	-	-	-	-
Nielsen (53)	32	-	-	-	-	-	-	-	-
Spargias (54)	-	-	-	-	-	-	-	-	-
TAAVI, transcatheter aortic valve implantation; LV, left ventricle									

Study	n	Preop NYHA class III-IV, n [%]	Postop (within 30-day) NYHA class III-IV, n [%]	Late (>6 months) NYHA class III-IV, n [%]	1-year mortality, n [%]	6-month survival, %	1-year survival, %	2-year survival, %	3-year survival, %
Kempfert (6)&Walther (7)	299	299 [100]	-	-	-	-	73	68	58
Early group	150	143 [95.3]	-	-	46 [30.7]	73.3±3.6	69.3±3.8	-	-
Kempfert (6)	149	109 [73.1]	-	-	32 [21.5]	81.2±3.2	78.5±3.4	-	-
Late group	21	-	-	-	5 [24]	-	-	-	-
Zierer (21)	24	-	-	-	-	70.7	61.9	-	-
Thielmann (22)	50	-	-	-	-	73.4	-	-	-
Bleiziffer (23)	300	-	-	-	-	85.8±2.1	82.5±2.4	64.6±4.7	-
Unbehaun (28)	30	-	-	-	-	-	-	-	-
Strauch (30)	177	158 [89.3]	-	-	-	-	78	64	-
Rodés-Cabau (31)	30	30 [100]	-	-	-	-	-	-	-
Osten (32)	63	61 [97]	-	-	-	-	-	-	-
Rodés-Cabau (34)	71	61 [86]	-	-	18 [25]	74±5	72±5	66±6	58±9
Ye (37)	101	82 [81]	-	-	-	-	-	-	-
Gurvitch (38)	24	-	-	-	-	-	74	-	-
Himbert (41)	28	24 [86]	-	-	-	-	-	-	-
Guinot (42)	84	-	-	-	-	-	70	-	-
Dworakowski (43)	30	-	-	-	-	-	-	-	-
Ferrari (44)	43	-	-	-	-	-	-	-	-
Wenaweser (45)	575	-	-	-	-	-	-	-	-
Thomas (8,9)	504	419 [83.1]	-	-	-	-	-	-	-
D'Onofrio (47)	71	53 [75.7]	-	-	-	-	81.4±2.2	71.5±6.2	-
Elchaninoff (48)	59	42 [71.2]	-	-	6 [26]	-	-	-	-
Ewe (49)	30	-	-	-	28 [47]	-	-	-	-
Johansson (50)	69	59 [85.5]	9 [16.1]	5 [15.7]	-	58	49.3	-	-
Lefeuvre (51)	16	-	-	-	-	-	-	-	-
Taramasso (3)	76	-	-	-	12 [17.5]	-	-	-	-
Nielsen (53)	32	-	-	-	-	-	-	-	-
Spargias (54)									
NYHA, New York Heart Association									

predictors of 30-day mortality in a series of 299 patients. Of interest, variables such as age, logistic EuroSCORE >30%, and STS score >15% failed to predict mortality in this series (6). While in the I-TA registry, multivariate analysis identified NYHA class III and IV (OR, 4.43; 95%CI, 1.28-15.40), logistic EuroSCORE >20 (OR, 1.83; 95%CI, 1.02-3.29), creatinine concentration >200 mmol/L (OR, 2.56; 95%CI, 1.07-6.15), and intraoperative complications (OR, 5.80; 95% CI, 2.68-12.55) as independent risk factors for mortality after TAAVI (47).

In a joint position statement published for 2012, the American College of Cardiology Foundation (ACCF) Board of Trustees, American Association for Thoracic Surgery (AATS) Council, Society for Cardiovascular Angiography Interventions (SCAI) Board of Directors, and Society of Thoracic Surgeons (STS) have established a guideline of recommendations in the selection of patients for TAVI, who would be deemed a prohibitive or high surgical risk, yet there are no specific inclusion criteria for TAAVI (55). To our knowledge, there has been no randomized trial reported so far comparing TFAVI versus TAAVI. Despite TAAVI being considered more invasive than TFAVI, preliminary results suggest TAAVI as having less vascular complications, decreased use of contrast or fluoroscopy, and possible different adverse neurologic outcomes. Based on the current literature, TAAVI and TFAVI patients cannot be compared without a significant bias. Ewe *et al.* (49) highlighted the possibility of such a selection bias, noting that TAAVI patients carried a higher perioperative risk compared to TFAVI patients. Similarly, Eltchaninoff *et al.* (48) demonstrated that patients treated by TAAVI had more comorbidities than patients selected for TFAVI in particular more peripheral vascular disease. This invariably increases their mortality risk. Additionally, Nielsen *et al.* (53) observed TAAVI patients to have a greater burden of comorbidity, reflected in a higher EuroSCORE than that of TFAVI patients (21.5% *vs.* 15.9%). The SOURCE investigators (8) also highlighted a higher logistic EuroSCORE (29% *vs.* 25.8%; $P=0.007$) comparing TAAVI *vs.* TFAVI.

In conclusion, based on the results available from more than 2,700 patients gathered in this review, TAAVI can be performed with acceptable safety profiles and reasonable survival outcomes. Furthermore, TAAVI can be chosen as the primary access route, although current common practice uses TAAVI as an alternative when TFAVI cannot be safely performed. Randomised controlled trials are required to

compare TAAVI *vs.* TFAVI as standard primary approaches for TAVI when both techniques are equally feasible.

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