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Original Article:

Approaches for Transcatheter Aortic Valve Replacement: A Systematic Review and Meta-Analysis

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Abstract: Introduction: Retrograde transfemoral and antegrade transapical approaches are mostly used for transcatheter aortic valve replacement. This meta-analysis is designed to assess the performance of the transfemoral and transapical approach. Methods: A systematic search was conducted using MEDLINE, PubMed, EMBASE, Current Contents Connect, Cochrane library, Google Scholar, Science Direct, and Web of Science. Original data was abstracted from each study and used to calculate a pooled odd ratio (OR) and 95% confidence interval (95% CI). Results: Only 14 studies comprising of 6965 patients met full criteria for analysis. The mean duration of hospitalisation and procedure duration were similar among the 2 cohorts. The 30 days mortality (OR: 0.70, 95% CI: 0.531-0.921), the need for haemodialysis (OR: 0.29, 95% CI: 0.157-0.525) and one year mortality (OR: 0.72, 95% CI: 0.564-0.927) were lower in the transfemoral cohort. The frequency of stroke at 30 days and new pacemaker insertion were comparable. However, the prevalence of vascular complication (OR: 2.88, 95% CI: 1.821-4.563) was higher in the transfemoral group. The incidence of aortic regurgitation (OR: 1.25, 95% CI: 0.844-1.855), valve embolization (OR: 2.00, 95% CI: 0.622-6.448), major bleeding incidence rates (OR:0.77, 95% CI: 0.488-1.225), coronary obstruction (OR:0.74, 95% CI:0.234-2.311), myocardial infarction (OR: 0.75, 95% CI: 0.28-2.00), conversion to open cardiac surgery (OR: 0.29, 95% CI: 0.062-1.343) and successful implantation (OR: 0.67, 95% CI: 0.394-1.149) were comparable in the two cohorts. Conclusions: In the absence of a randomized controlled study, the ability to discriminate true differences is challenging. Even though the complications rate was much lower in transfemoral group as compared to transapical group, the current literature does not support a clear superiority of one approach to TAVR over the other.

Key Words: Transcatheter aortic valve replacement; Access approaches; Transfemoral; Transapical; Aortic stenosis

Introduction:
Transcatheter aortic valve replacement (TAVR) is a fairly recent development, performed for the first time in 2002.(1) The last decade has seen an exponential growth in the application of this technology in higher-risk populations. Many patients deemed inoperable for AVR have been treated successfully by TAVR. Results of recent randomized prospective trials demonstrate both the future promise and current problems of the TAVR approach. The PARTNER Trial Investigators(2-6) have shown that in patients with aortic stenosis who are at high risk for operative complications and death, surgical aortic valve replacement and balloon-expandable transcatheter replacement were associated with similar mortality at 30 days and 1 year and produced similar improvements in cardiac symptoms. These findings indicate that transcatheter replacement is an alternative to surgical replacement in a well-chosen, high-risk subgroup of patients with aortic stenosis. At the present time TAVR is indicated in the presence of high risk according to current position statements from the European Society Cardiology and European Association Cardiothoracic Surgery.(7) The Nordic Aortic Valve Intervention (NOTION) trial,(8) PARTNER II trial, MEDTRONIC COREVALVE® U.S. PIVOTAL trial, COREVALVE vs. SAVR-DENMARK TRIAL and SURTAVI trial are underway or are expected to start aiming to investigate the effectiveness of TAVR in younger and lower-risk patients. Retrograde transfemoral and antegrade transapical approaches are mostly used for implantation. The purpose of this study was to evaluate the feasibility and compare the results for the transfemoral and transapical approach.

Methods:
Study Protocol: We followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses PRISMA guidelines where possible in performing our systematic review.(9) We performed a systematic search through MEDLINE (from 1950), PubMed (from 1946), EMBASE (from 1949), Current Contents Connect (from 1998),

Cochrane library, Google scholar, Science Direct, and Web of Science to February 2013. The search terms included "transcatheter aortic-valve replacement (TAVR)", "transfemoral approach", "transapical approach", AND "approaches for TAVR", which were searched as text word and as exploded medical subject headings where possible. No language restrictions were used in either the search or study selection. The reference lists of relevant articles were also searched for appropriate studies. A search for unpublished literature was not performed.

Study Selection: We included studies that met the following inclusion criteria:

- Studies identifying the population of patients undergoing transcatheter aortic-valve replacement.
- Studies comparing the outcomes of various approaches for transcatheter aortic-valve replacement and reporting original data (or odds ratios).

Data Extraction: We performed the data extraction using a standardized data extraction form, collecting information on the publication year, study design, number of cases, total sample size, population type, country, continent, mean age and clinical data. The event rate and confidence intervals were calculated.

Statistical Analysis: Pooled odds ratio and 95% confidence intervals were calculated using a random effects model.(10) We tested heterogeneity with Cochran's Q statistic, with $P<0.10$ indicating heterogeneity, and quantified the degree of heterogeneity using the I2 statistic, which represents the percentage of the total variability across studies which is due to heterogeneity. I2 values of 25, 50 and 75% corresponded to low, moderate and high degrees of heterogeneity respectively.(11) The quantified publication bias using the Egger's regression model,(12) with the effect of bias assessed using the fail-safe number method. The fail-safe number was the number of studies that we would need to have missed for our observed result to be nullified to statistical non-significance at the $p<0.05$ level. Publication bias is generally regarded as a concern if the fail-safe number is less than $5n+10$, with n being the number of studies included in the meta-analysis.(13) All analyses were performed with Comprehensive Meta-analysis (version 2.0).

Results:

The original search strategy 421 retrieved studies (Fig 1). The abstracts were reviewed and after applying the inclusion and exclusion criteria, articles were selected for full-text evaluation. Of the articles selected, only 14 studies (6965 patients) met full criteria for analysis and are summarised in Table 1. The years of publication ranged from 2009 to 2013.

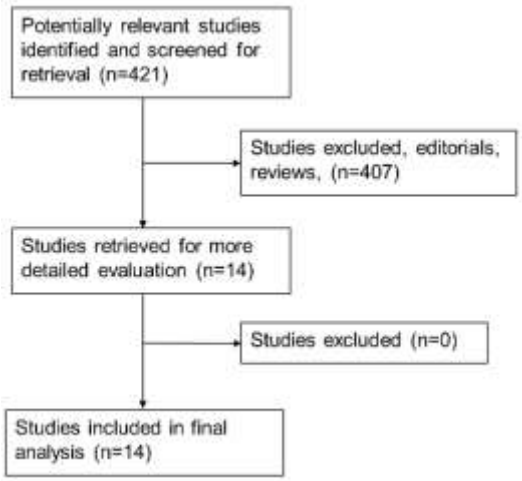

Figure 1: Flow of Included Studies

Table 1: Characteristic of the Studies Included in the Meta-Analysis

Author	Country	Year	Approach	Patients
Himbert et al(34)	France	2009	Trans-femoral	51
			Trans-apical	24
Rodes-Cabau et al(35)	Canada	2010	Trans-femoral	168
			Trans-apical	177
Thomas et al(36)	Europe	2010	Trans-femoral	463
			Trans-apical	575
Ewe et al(37)	The Netherlands	2011	Trans-femoral	45
			Trans-apical	59
Lefevre et al(38)	Germany	2011	Trans-femoral	61
			Trans-apical	69
Moat et al(39)	United Kingdom	2011	Trans-femoral	599
			Non Trans-femoral	271
Gilard et al(40)	France	2012	Trans-femoral	2293
			Trans-apical	567
			Trans-subclavian	184
Witkowski et al.(41)	Poland	2011	Trans-femoral	13
			Trans-subclavian	6
			Trans-apical	11
Bleiziffer et al(42)	Germany	2009	Trans-femoral	153
			Trans-apical	50
Němec et al(43)	Czech Republic	2012	Trans-femoral	15
			Trans-apical	15
Johansson et al(44)	Sweden	2011	Trans-femoral	10
			Trans-apical	30
Schymik et al(45)	Germany	2012	Trans-femoral	174
			Trans-apical	126
Lange et al(46)	Germany	2011	Trans-arterial	285
			Trans-apical	127
Smith et al(47)	Multicentre study	2011	Trans-femoral	240
			Trans-apical	104

The mean duration of hospitalisation and procedure duration were similar among the 2 cohorts (10.9 vs. 11.8 days, P value=0.56 and 116.675 vs. 128 minutes, P value= 0.47 respectively). The mean fluoroscopic exposure was higher in transfermoral cohort however did not achieve statistical significance. (25.433 vs.12.833 minutes, P value=0.07). The mean amount of contrast agent injected was greater in the transfermoral cohort attained statistical significance (207.1 vs.143.56, P value=0.003)

The 30 days mortality (OR:0.70, 95% CI:0.531-0.921), the need for haemodialysis (OR: 0.29, 95% CI:0.157-0.525) and one year mortality (OR:0.72, 95% CI: 0.564-0.927) were lower in the transfemoral cohort. The frequency of stroke at 30 days and new pacemaker insertion were comparable. However, the prevalence of vascular complication (OR: 2.88, 95% CI: 1.821-4.563) was higher in the transfemoral group. The incidence of aortic regurgitation (OR: 1.25, 95% CI: 0.844-1.855), valve embolization (OR: 2.00, 95% CI: 0.622-6.448), major bleeding incidence rates (OR:0.77, 95% CI: 0.488-1.225), coronary obstruction (OR:0.74, 95% CI:0.234-2.311), myocardial infarction (OR: 0.75, 95% CI: 0.28-2.00), conversion to open cardiac surgery (OR: 0.29, 95% CI: 0.062-1.343) and successful implantation (OR: 0.67, 95% CI: 0.394-1.149) were comparable in the two cohorts.

Heterogeneity and publication bias

The heterogeneity of outcomes has been summarized in Table 2. The reason for significant heterogeneity may be attributed to different population groups. No publication bias was detected using the Egger's regression model.

Table 2: Overall odds ratio and 95% CI				
Outcome	OR	95%CI	I2	P value(I2)
30 days mortality	0.70	0.531-0.921	28.18	0.17
One year mortality	0.72	0.564-0.927	57.67	0.01
Stroke 30 days	0.95	0.698-1.29	0.00	0.63
Aortic regurgitation	1.25	0.844-1.855	42.42	0.01
Vascular complication	2.88	1.821-4.563	55.39	0.02
New pacemaker	1.08	0.872-1.338	0.00	0.90
Major bleeding	0.77	0.488-1.225	45.95	0.12
Need for hemodialysis	0.29	0.157-0.525	0.00	0.42
Conversion to open cardiac surgery	0.29	0.062-1.343	60.93	0.02
Successful implantation	0.67	0.394-1.149	0.00	0.56
Coronary obstruction	0.74	0.234-2.311	0.00	0.67
Valve embolization	2.00	0.622-6.448	2.50	0.38
Myocardial infarction	0.75	0.28-2.00	25.16	0.26

Table 3:				
		Femoral	Trans-apical	P value
Duration of hospitalisation [days]	Mean	10.914	11.8	0.56
	SD	2.957	4.288	
Procedure duration [min]	Mean	116.675	128	0.47
	SD	51.035	67.874	
Fluoroscopy duration [min]	Mean	25.433	12.833	0.07
	SD	12.89	7.059	
Amount of contrast agent(ml)	Mean	207.1	143.56	0.003
	SD	51.916	48.541	

Discussion:

Transfemoral approach

The transfemoral route is the first choice of approach in the vast majority of centres performing TAVR procedures. As stated above, an accurate evaluation of the iliofemoral anatomy is of major importance in determining the appropriateness of this approach for each individual patient. The procedure is performed in a catheterization laboratory or a hybrid operating room. Although surgical cut-down was the technique used for the transfemoral approach at the beginning of the TAVR experience, most centers are now using a fully percutaneous technique for this approach. This strategy makes it possible to avoid the use of general anaesthesia, especially if the procedure is performed without transesophageal echocardiographic guidance.(14)

Transapical approach

The transapical approach was first reported as an alternative to the transfemoral approach in 2006 by Litchenstein et al(15) The approach requires a small left lateral thoracotomy and a direct puncture of the left ventricular apex. The first-in-human CoreValve® implantation by the transapical approach was performed in Germany.(16)

Advantages of the transapical approach include the avoidance of using large catheters though the iliofemoral system, aortic arch, ascending aorta, and aortic valve; improved coaxility of the valve prosthesis within the aortic annulus, which can be especially helpful in cases of horizontal aorta;(17) and the possibility of obtaining very accurate transesophageal echocardiographic images for valve positioning, which might lead to a reduction in the amount of contrast used during the procedures.(17) The main disadvantages are the need for a thoracotomy; a greater degree of myocardial injury, owing to the apical perforation of the left ventricle;(18) and the potentially life-threatening bleeding complications associated with the surgical repair of the apex**.**

Transaortic approach

The use of the transaortic approach through a small right or mid sternotomy was suggested as an alternative approach with the Corevalve®, ASCENDRA and Edwards systems.(19-26) Although requiring sternotomy, this approach avoids the use of large catheters through the iliofemoral system and aortic arch, and avoids puncture of the ventricular apex.

Subclavian approach

The left subclavian approach has emerged as an alternative to the transfemoral approach with the CoreValve® system.(27, 28) A surgical cut-down is needed to isolate the subclavian artery (usually the left vessel). The very short distance between the vascular access and the native aortic valve might be associated with better control of the CoreValve® prosthesis during positioning and deployment. However, any injury of the subclavian artery would translate into a major intrathoracic bleeding that might be difficult to control. Tamburino et al(29) reported the use of the subclavian approach in up to 20% of the patients included in the Italian registry.

Transaxillary approach

First-in-human CoreValve® implantation by the transaxillary approach(30) was reported in 2009. Like the subclavian approach, a surgical cut-down is performed to isolate the left axillary artery, and the sheath and delivery catheters are advanced through the axillary artery. The potential advantage of this approach versus the subclavian approach is that any injury to the axillary artery could be easily repaired with no major clinical consequences, as compared with the potentially life-threatening consequences of a subclavian-artery injury. Indeed, and unlike in iliofemoral vessels, occlusion of the axillary artery would be compensated by the collateral circulation between the thyrocervical trunk of the subclavian artery and the subscapular artery.

Specific risks

Stroke

Stroke is one of if not the most devastating complication that can occur during TAVR. Recently a meta-analysis was published by the Cardioangiological Center Bethanien, Frankfurt (31) comprising of 53 studies including a total of 10,037 patients undergoing transfemoral, transapical or trans-subclavian TAVI for native aortic valve stenosis. Patients were 81.5±1.8-years-old and had a mean logistic EuroSCORE of 24.77 ± 5.60%. Procedural stroke (<24 h) occurred in 1.5±1.4%. The overall 30-day stroke/TIA was 3.3±1.8%, with the majority being major strokes (2.9±1.8%). During the first year after TAVR, stroke/TIA increased up to 5.2±3.4%. Comparing three groups of patients, TF Corevalve™, TF Edwards SAPIEN™, and TA Edwards Sapien™, the results of the meta-analysis show that the TF Corevalve™ (n=3226, mean logistic Euroscore of 22%) had a stroke rate of 3.1±2.2%, the TF Edwards SAPIEN™ (n=1,733, mean logistic Euroscore of 26%) had a stroke rate of 4.2±2.2%, and the TA Edwards Sapien™ prosthesis (n=2,482, mean logistic Euroscore of 29%) had a stroke rate of 2.7±1.4%. Our analysis demonstrated that stroke at 30 days (OR: 1.01, 95%CI: 0.729-1.389) was similar in both cohorts.

Vascular complications

The risk of access related morbidity such as vascular injury must also be taken into account for patients undergoing TAVR. The safety of the TA approach was shown in the multicenter PREVAIL TA study on 150 patients, of whom only one patient (0.7%) suffered an access related complications.(32) Vascular complication were significantly higher in the transfemoral cohort with an odd ratio of 2.88.

Inflammatory response

In a total of 40 patients evaluated by the Stähli et al,(33) a retrospective study that assessed levels of high-sensitive C-reactive protein (hs-CRP) and leukocyte counts following 'uneventful' AVR and TAVR. Four groups of matched patients were compared (AVR; transapical and transfemoral Edwards SAPIEN [TA ES and TF ES, respectively]; and transfemoral Medtronic CoreValve [TF CV]). A postprocedural increase of both hs-CRP levels and leukocyte counts was observed (P<.001) with peak levels 48 hours after the procedures. Comparing treatment groups, hs-CRP levels at 48 hours were significantly higher following AVR and TA ES compared to TF ES and TF CV (P<.04). Leukocyte counts at 48 hours were higher following TA ES compared to TF ES and TF CV (P<.03). Multivariate analysis incorporating both hs-CRP levels and leukocyte counts confirmed significant differences for all measurements over time (P<.001). Furthermore, the treatment group significantly influenced postprocedural hs-CRP levels and leukocyte counts (P<.001).

Limitations

Obviously, all retrospective studies have the disadvantage that can be overcome only by a prospective, randomized controlled trial. In the absence of a randomized controlled study, the ability to discriminate true differences between the approaches to TAVR is clearly limited by an inherent patient selection bias. Nearly all physicians consider the transfemoral route as the preferred approach due to the perception that it is less invasive and generally avoids surgical incisions. The transapical approach is used when peripheral vascular access is poor or impossible. Thus, those patients selected for the transapical approach comprise a group of patients more likely to have a disseminated vasculopathy with an increased risk for death and complications.

With growing experience in TAVR and the development of improved valves and smaller delivery sheaths, a reduction in peri-procedural complications can be expected. The current literature does not support a clear superiority of one approach to TAVR over the other. Recognizing that approximately half of all deaths in this high risk group of TAVR patients are non-cardiac, factors other than TAVR technology are obviously important. Multidisciplinary collaboration with improved patient selection and advanced technology will promote progressive safe application of this promising technique.

In conclusion, the cardiovascular teams at major referral centres will jointly decide and perform the optimal therapies individualized to each patient's risk stratification. With growing experience, complications with TAVR may be avoided by proper patient selection and skilful management. Other complications, when they occur, require a specific treatment algorithm to avoid delay in decision making. A considerable number of complications after TAVR require surgical treatment. Therefore, the ideal environment for TAVR procedures is a hybrid operating room, where a multidisciplinary team of surgeons, cardiologists, and anesthesiologists is best fitted to meet the current needs associated with TAVR technology. Cross training of cardiologists and surgeons, who are actively and jointly performing all therapies will be the future. This will lead to a new speciality of a structural heart interventionist to treat high risk patients.

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