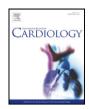
Contents lists available at ScienceDirect

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International Journal of Cardiology



journal homepage: www.elsevier.com/locate/ijcard

Letter to the Editor

Device stratified comparison among transfemoral, transapical and transubclavian access for Transcatheter Aortic Valve Replacement (TAVR): A meta-analysis



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ARTICLE INFO

Article history: Received 31 October 2013 Accepted 28 December 2013 Available online 9 January 2014

Keywords: Aortic stenosis TAVR Access site Transubclavian Transfemoral Transapical

Transcatheter Aortic Valve Replacement (TAVR) is a treatment option for high-risk patients undergoing aortic valve replacement. It associated to decreased mortality in 20% when compared to standard therapy and equivalent mortality as compared to surgical replacement [1].

The overwhelming majority of reported results for TAVR are from transfemoral access followed by transapical and transubclavian or axillar access. Currently mainly two devices are used for TAVR procedures, the Edwards Sapien (ES) valve and the CoreValve (CV) [2].

It is unknown if different vascular access for TAVR would lead different outcomes. Therefore, we aimed to investigate the optimal TAVR access for ES and CV devices by reviewing and comparing 30-days outcomes in TAVR among transfemoral, transapical and transubclavian/ transaxillary approaches using the same valve. This is justified because studies have shown different outcomes between the Edward Sapiens valve and the CoreValve device. For instance, the CoreValve has been implicated in a higher rate of post-procedural new pacemaker implantation. On the other hand, Edward Sapiens valves seem to be associated with a higher rate of surgical conversion [3].

¹ Both share the first authorship.

We systematically searched PubMed, EMBASE, and Cochrane Central Register for studies with symptomatic aortic stenosis patients who underwent TAVR through transfemoral, transapical or transubclavian/ axillar access from January 2006 to August 2013. Searched terms were: ("aortic stenosis" OR "transcatheter aortic" OR "TAVI" OR "TAVR") and ("transfemoral" OR "transapical" OR "transaxillary" OR "transubclavian").

Studies that reported the outcomes of interest stratified by different access routes and devices were included and those studies that (1) used only one access route; (2) did not specify which access or valve was used; and (3) overlapped patient populations from another study were excluded. Primary outcome was 30-day mortality. Secondary outcomes were in-hospital or 30-day incidence of stroke, new pacemaker implantation, vascular complications and renal failure requiring dialysis.

Data extraction was completed by four authors (DG, RNC, PC and FN), reporting to the coordinator (AB). Disagreements were resolved by consensus and by the senior author (EDM).

The statistical analysis was performed according to the Cochrane Collaboration Review. We used Review Manager 5.1 for treatment effect estimation of odds-ratio (OR). We defined $l^2 < 50\%$ as low heterogeneity and fixed effect analysis when l^2 was less than 50% and p value at least 0.10; otherwise we used random effect.

Search results yielded 778 studies. Final analysis was made with seven studies [4–10]. A total of 1526 patients received transfemoral access, 882 transapical and 228 transubclavian access. Baseline characteristics of compared groups in individual studies were similar, with the notable exception of a lower prevalence of peripheral vascular disease found in the transfemoral group and a higher Logistic EuroScore. There was or no differences among transapical and transfemoral.

The transfemoral vs. transapical analysis was made with 882 transfemoral and 771 transapical (Fig. 1A–E). All patient studies used exclusively ES. The transapical group presented with increased odds for 30-day mortality (OR 1.54; 95% CI 1.09–2.16; p = 0.01). There was no significant difference among groups for stroke incidence (OR 0.92; 95% CI 0.51–1.67; p = 0.78) and new pacemaker implantation (OR 1.17; 95% CI 0.78–1.75; p = 0.44). However, transapical route presented with a decreased odds of vascular complications (OR 0.31; 95% CI 0.22–0.42; p < 0.001). On the other hand, patients who had TAVR through a transapical access had a significant increase in the odds of renal failure (OR 4.42; 95% CI 2.21–8.83; p < 0.001).

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^{0167-5273/\$ –} see front matter © 2014 Elsevier Ireland Ltd. All rights reserved. http://dx.doi.org/10.1016/j.ijcard.2013.12.162

The transfemoral vs. transubclavian analysis was composed with 761 transfemoral and 228 transubclavian patients who only received CV device (Fig. 2A–D). Overall, there was no significant difference for 30-day mortality (OR 0.64; 95% CI 0.31–1.32; p = 0.23), stroke (OR 0.74; 95% CI 0.27–2.01; p = 0.55) and new pacemaker implantation (OR 0.88; 95% CI 0.58–1.35; p = 0.56). However, there was a decreased risk of vascular complications (OR 0.53; 95% CI 0.29–0.95; p = 0.03) in the transubclavian group. Due to the lack of data in individual studies and different outcome definitions, incidence of post-procedural renal failure could not be assessed in the transfemoral versus transubclavian comparison.

Prior literature suggested that transapical access was related to a higher incidence of 30-day mortality, renal insufficiency and stroke (reference if space). We only confirmed the first two when gathering the data. Our analysis also suggests a significantly increased risk of vascular complications in the transfemoral group compared to both transapical and transubclavian access since femoral access involves percutaneous vascular access only. The first one was expected due to the nature of the transapical technique, but the transubclavian result was unexpected.

There was no difference for stroke or pacemaker implantation among the different types of access which means that valve type other than access route might play a more important role for those complications.

Our study indirectly suggests that transubclavian may be a better access than transapical to patients unable to receive transfemoral implants as there was no increase in mortality and there was actually a decrease in vascular complications. It is important to notice that most of the available data refers to the initial generations of the TAVR devices and that the newer and coming ones are smaller. The original ES valve requires 22 to 24 fr sheaths, the CV requires 18 fr sheaths and the third generation of ES valves is expected to require 14-frame sheaths; this is expected to change the profile of patients unable to receive transfemoral valves and the incidence of vascular complications.

A) 30 Day Mortality

	Transapical		Transfemoral		Odds Ratio		Odds Ratio		
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% C	M-H, Fixed, 95% Cl		
Eltchaninoff 2011	12	71	8	95	10.5%	2.21 [0.85, 5.74]			
Ewe.2011	5	59	5	45	9.6%	0.74 [0.20, 2.73]			
Rodes-Cabau.2010	20	177	16	168	26.8%	1.21 [0.60, 2.42]			
Thomas. 2011	59	575	29	463	53.1%	1.71 [1.08, 2.72]			
Total (95% CI)		882		771	100.0%	1.54 [1.09, 2.16]	•		
Total events	96		58						
Heterogeneity: Chi ² = 2.42, df = 3 (P = 0.49); l ² = 0%									
Test for overall effect: 2	Z = 2.46 (F	0.01 0.1 1 10 100 Favors Transapical Favors Transfemoral							

Significantly increased odds for overall 30-day mortality in transapical compared to transfermoral access (p=0.01).

B) Stroke

	Transapical		Transfemoral		Odds Ratio		Odds Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% C	I M-H, Fixed, 95% Cl	
Eltchaninoff 2011	2	71	4	95	14.8%	0.66 [0.12, 3.70]		
Ewe.2011	2	59	2	45	9.8%	0.75 [0.10, 5.57]		
Rodes-Cabau.2010	3	177	5	168	22.5%	0.56 [0.13, 2.39]		
Thomas. 2011	16	575	11	463	52.9%	1.18 [0.54, 2.56]		
Total (95% CI)		882		771	100.0%	0.92 [0.51, 1.67]	•	
Total events	23		22					
Heterogeneity: Chi2 = -	1.01, df = 3	B (P = 0	.80); l ² = 0%	6				
Test for overall effect:	Z = 0.27 (F	P = 0.78	5)				0.01 0.1 1 10 100 Favors Transapical Favors Transfemoral	

No significant difference between stroke incidence in the transapical and transfemoral groups (p=0.78).

C) Pacemaker Implantation

	Transapical		Transfemoral		Odds Ratio		Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% C	M-H, Fixed, 95% Cl
Eltchaninoff 2011	4	71	5	95	9.2%	1.07 [0.28, 4.15]	
Ewe.2011	2	59	2	45	5.0%	0.75 [0.10, 5.57]	
Rodes-Cabau.2010	11	177	6	168	13.2%	1.79 [0.65, 4.95]	+
Thomas. 2011	42	575	31	464	72.6%	1.10 [0.68, 1.78]	-
Total (95% CI)		882		772	100.0%	1.17 [0.78, 1.75]	•
Total events	59		44				
Heterogeneity: Chi2 =	0.93, df = 3	B (P = 0	.82); l ² = 0%	6			
Test for overall effect: $Z = 0.77$ (P = 0.44)							0.01 0.1 1 10 100 Favors Transapical Favors Transfemoral

No significant difference in new pacemaker implantation between transapical and transfemoral groups (p=0.44).

Fig. 1. Comparison among transfermoral and transapical access. Vertical line: "no difference" point between the transapical and transfermoral groups; squares = odds ratio for each study (the size of each square denotes the proportion of information given by each study); diamond = pooled odds ratios from all studies; horizontal lines = 95% confidence interval (CI).

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