

Trans-subclavian Access in Transcatheter Aortic Valve Implantation (TAVI): an Elegant Alternative for Non-ideal Candidates to the Transfemoral Access Method

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Trascatheter aortic valve implantation (TAVI) has emerged as an alternative treatment for patients with severe aortic stenosis that are considered to be at high or prohibitive surgical risk.¹ While the transfemoral approach has been considered to be the primary approach in the vast majority of centres and studies, non-optimal iliofemoral vessel characteristics preclude the safe placement of sheaths in a large number of patients. In addition to the small size of the iliofemoral arteries, approximately one-third of TAVI candidates present with significant peripheral vascular disease.¹

were treated with the subclavian approach using the CoreValve[®] system, and all of procedures were performed under general anaesthesia and used dissection. Despite the small sample size, the study demonstrated device success in all cases, with only one major access site complication. This single complication was also related to the single death in the report. In addition, no cerebral events were reported at the 30-day follow-up. Interestingly, these results are comparable with other CoreValve[®] subclavian registries (Table 2).

See page 247

Accordingly, other alternative approaches such as the transapical, subclavian/axillary, and transaortic access methods have been developed in recent years. The transapical approach has been the most frequently used alternative to the transfemoral approach when using the balloon-expandable Edwards SAPIEN valve (Edwards Lifesciences, Irvine, CA, USA) (> 50% of cases in the SOURCE registry; Table 1). Currently, and even with the use of lower profile sheaths, transapical TAVI is still performed in more than 30% of patients.^{4,7,10,11} However, the transapical approach is not an option for patients receiving the CoreValve[®] system (Medtronic, Inc. – Minneapolis, USA), and as a consequence, access methods such as the subclavian/axillary and transaortic approaches have also been developed. As highlighted in Table 1, over 90% of procedures using the CoreValve[®] system have been performed transfemorally, and approximately 5%-8% have been performed with the subclavian/axillary approach.

In the current issue of the **Revista Brasileira de Cardiologia Invasiva**, Brito Júnior et al.¹² reports TAVI results using the subclavian access method gathered from the Brazilian Registry of TAVI. Among the 277 patients included in this registry, 8 patients (2.9%)

Apart from registries and the small sample series, there are currently no randomized data comparing the transfemoral or transapical approaches to the subclavian approach. However, a recent propensity-matched analysis has compared the procedural and two-year results of the subclavian access method (n = 141) to those of the femoral approach (n = 141).¹³ The aforementioned study included all consecutive TAVI patients utilizing the subclavian access with the 18 F CoreValve[®] prosthesis. These patients were matched on the basis of baseline clinical characteristics (except peripheral vascular disease) to a transfemoral cohort. Both groups showed similar procedural success rates (97.9% for subclavian access vs. 96.5% for transfemoral access; P = 0.47), major vascular complications (5% vs. 7.8%, respectively; P = 0.33), life-threatening bleeding events (7.8% vs. 5.7%, respectively; P = 0.48), and combined safety endpoints (19.9% vs. 25.5%, respectively; P = 0.26). Nonetheless, the subclavian group had lower rates of acute renal failure/stage 3 (4.3% vs. 9.9%, respectively; P = 0.02), minor vascular complications (2.1% vs. 11.3%, respectively; P = 0.003), and all types of bleeding events related to vascular complications. Survival at 2 years was similar in both groups (74% ± 4% vs. 73.7% ± 3.9%, respectively; P = 0.78). It should be noted that the subclavian approach was related to longer procedure times, although fluoroscopy times were similar for both approaches.

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TABLE 1
Number of Cases Using Various Access Sites in Transcatheter Aortic Valve Implantation (TAVI) Registries

Study	n	Valve n (%)	Transapical n (%)	Transfemoral n (%)	Trans-subclavian/axillary n (%)	Transaortic n (%)
Australian ²	428	CoreValve®	–	404 (94.4)	24 (5.6)	–
Belgian ³	328	CoreValve® 141 (43), SAPIEN® 187 (57)	CoreValve® (0), SAPIEN® 88 (47)	CoreValve® 133 (94), SAPIEN® 99 (53)	CoreValve® 8 (6)	–
Canadian ⁴	345	Cribier, SAPIEN®, SAPIEN XT®	177 (51.3)	168 (48.7)	–	–
FRANCE 2 ⁵	3,195	SAPIEN® 2,137 (66.9), CoreValve® 1,058 (33.1)	567 (17.7)	2,361 (73.9)	184 (5.8)	83 (2.6)
German ⁶	697	SAPIEN® 109 (15.6), CoreValve® 588 (84.4)	26 (3.7)	644 (92.4)	22 (3.2)	5 (0.7)
SOURCE ⁷	1,038	SAPIEN®	575 (55.4)	463 (44.6)	–	–
SOURCE XT ⁸	2,600	SAPIEN XT®	871 (33.5)	1,628 (62.6)	7 (0.3)	94 (3.6)
Meta-analysis ⁹	4,871	CoreValve® 1,649 (33.9), SAPIEN® and SAPIEN XT® 3,222 (64.1)	CoreValve® (0), SAPIEN® 1,840 (57.1)	CoreValve® 1,510 (91.6), SAPIEN® 1,382 (42.9)	CoreValve® 133 (8.1), SAPIEN® (0)	CoreValve® 6 (0.3), SAPIEN® (0)

TABLE 2
Main Results from the Subclavian Approach Cohort from Transcatheter Aortic Valve Implantation (TAVI) Registries

Study	n	Number of centers	Follow-up	Age, years	Logistic EuroSCORE, %	Procedural success, %	Vascular Complications, %	30-day survival, %
FRANCE 2 ⁵	184	33	1 year	82.2	20.3	96.7	10.8*	89.9
Italian ¹³	141	10	2 years	83	23.7	97.9	12.1*	94.3
British ¹⁴	35	8	30 days	80.6	25	100	2.9 [†]	–
Netherlands ¹⁵	22	1	30 days	–	–	95	9 [†]	95
French ¹⁶	17	4	30 days	71	34	100	0	88.2
Brazilian ¹²	8	4	9 months	84	32	100	12.5*	87.5

* Major and minor vascular complications; [†] Major vascular complications.

Overall, the data, which include registries, small sample sizes and propensity-matched analyses, suggest that the subclavian approach is an interesting alternative to the transfemoral route for TAVI and should be considered especially in patients whose clinical situations preclude

the femoral approach, such as severe calcification, severe tortuosity, and small vessel diameter. In addition, when considering the subclavian access approach, a careful analysis of the subclavian anatomy should be performed to obtain a minimum diameter > 6 mm, in order to avoid

circumferential calcifications and severe tortuosity, and to search for the presence of previous ipsilateral pacemakers. Lastly, while the presence of previous coronary artery bypass graft (CABG) surgery, including the left internal mammary artery (LIMA), is considered to be a formal contraindication, Modine et al.¹⁷ have recently demonstrated the feasibility and safety of the subclavian approach in 19 patients with prior CABG and a patent LIMA. However, a minimal subclavian diameter of 7 mm and sheath removal during valve placement is recommended in these cases to avoid the occurrence of myocardial ischemia.

In conclusion, the transfemoral approach is not possible in a high proportion of TAVI candidates. Several prior studies have shown that the subclavian approach using the CoreValve[®] system is a good alternative for TAVI candidates that are not well-suited candidates for transfemoral TAVI, a finding corroborated by the study by Brito Junior et al.¹² Future randomized studies are needed in order to evaluate the potential superiority of this approach compared to other alternative approaches, as well as to the transfemoral approach.

CONFLICT OF INTEREST

Josep Rodés-Cabau is a consultant for Edwards Lifesciences (Irvine, USA), and for St. Jude Medical Center (St Paul, USA). Henrique Barbosa Ribeiro declare no conflicts of interest.

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