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# Brachiocephalic artery access in transcatheter aortic valve implantation: a valuable alternative: 3-year institutional experience

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## Abstract

**OBJECTIVES:** With the expanding use of transcatheter aortic valve implantation (TAVI), we have encountered increasing numbers of patients without ideal femoral access. Although many alternatives have been described, vascular access and access-related complications remain a point of concern. We report our series of 20 patients undergoing TAVI via brachiocephalic artery access.

**METHODS:** Between September 2011 and May 2014, we performed 107 consecutive CoreValve bioprosthesis implantations, of which 20 were by the brachiocephalic approach due to unfavourable iliac or femoral anatomy.

**RESULTS:** No vascular or access-related complications were seen. Procedural feasibility, device success and early safety, as defined by the Valve Academic Research Consortium-2 criteria, were good, at 100, 95 and 95%, respectively. No stroke, transient ischaemic attack, acute kidney injury, major vascular or major bleeding complications were observed. At a mean follow-up of 497 days, the 1-year survival rate is 75.0%. Echocardiography at discharge confirmed moderate paravalvular regurgitation in 1 patient and mild paravalvular leakage in 3 patients, and no paravalvular leak more than moderate was seen. Echocardiography at discharge, 6 months and 1 year after TAVI confirmed persistent low mean transvalvular gradients (9, 9 and 10 mmHg, respectively).

**CONCLUSIONS:** TAVI implantation through the brachiocephalic artery is safe and feasible. The distance between the point of access and the aortic valve annulus is short, improving catheter stability and implant site accuracy. We consider it to be a valuable alternative in patients without femoral access.

**Keywords:** Aortic valve stenosis • Transcatheter aortic valve implantation • Alternative access • Brachiocephalic artery • Innominate artery

## INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is now generally accepted as treatment for patients with severe aortic valve stenosis, not suitable for surgical aortic valve replacement because of a high risk of operative mortality [1–3]. Being less invasive, transfemoral implantation is the most widely adopted technique for retrograde TAVI, yet some patients do not have suitable femoral anatomy, due to small-calibre vessels, excessive peripheral or aortic atherosclerosis, severe tortuosity or previous peripheral arterial stenting or surgery [4, 5]. As vascular and access site-related complications influence the outcome in percutaneous transfemoral TAVI procedures [4, 6–9], multiple alternative approaches such as transapical, direct aortic, subclavian, axillary and carotid access have been extensively described in the literature and are currently successfully used worldwide [5, 6, 10–17]. All of these various ‘alternative’ TAVI access routes have

applications but also limitations and, therefore, a patient-tailored strategy with a preprocedural access decision remains essential.

In our search of alternative retrograde approaches in implanting the CoreValve<sup>®</sup> bioprosthesis (Medtronic, PLC, Dublin, Ireland), we started to use the brachiocephalic (or innominate) artery access in 2011 [18]. In this paper, we describe our results from the first 20 TAVI procedures with a brachiocephalic artery approach performed between September 2011 and May 2014.

## MATERIALS AND METHODS

### Access decision protocol

The work-up for TAVI patients in our centre and the factors determining the most ideal access route have been previously described

in detail [18]. Preprocedural imaging by means of coronary angiography, echocardiography, duplex ultrasound of the carotid arteries and multidetector computed tomography (MDCT) scan is performed. We routinely use electrocardiogram (ECG)-triggered MDCT images for obtaining precise measurements of the aortic valve annulus and root, minimizing motion artefacts in measuring the aortic root dimensions in the different phases of the cardiac cycle [19]. A non-ECG-gated MDCT is performed from the supraclavicular level to the level of the common femoral artery in order to investigate the anatomy of the aorta, and supra-aortic and iliofemoral vessels. Special attention is given to limiting the image acquisition time and minimizing the contrast dose. Curved multiplanar reformation is used for investigating the degree of atherosclerosis and possible arterial stenosis, and 3D volume-rendered images are routinely used for evaluation of the general morphology and tortuosity of the vessels and their relationship to the surrounding tissues.

The optimal TAVI access route is selected individually, based primarily on the anatomical features presented by preprocedural imaging. As we follow the femoral-first strategy, our primary choice remains the least invasive percutaneous transfemoral approach. In case of poor iliofemoral access, for any reason, we first opt for the suprasternal brachiocephalic artery; if unsuitable, our next option is the direct aortic or brachiocephalic access via partial upper sternotomy.

Several conditions should be fulfilled to be eligible for brachiocephalic artery access in TAVI.

The brachiocephalic artery should be large enough to accommodate the 18-Fr delivery sheath, ensuring a sheath-to-artery ratio of <1. Avoiding complete arterial occlusion minimizes any potential risk of periprocedural cerebral ischaemia. A minimum diameter of 8 mm as measured on MDCT scan is recommended [18]. The artery should show no major diameter-reducing calcifications. Ostial atherosclerotic plaques may be present in the brachiocephalic artery, but, as long as they are not diameter-reducing (beyond 8 mm on MDCT scan), this does not preclude the brachiocephalic access. Atherosclerotic brachiocephalic or carotid artery plaques without significant stenosis or previous carotid surgery are not absolute contraindications for the brachiocephalic TAVI access.

The bifurcation of the brachiocephalic artery into the right subclavian and right common carotid artery can be situated either behind the sternum or higher cranially. The need for partial sternotomy can be determined preoperatively: if the brachiocephalic artery bifurcation reaches the level of the upper one-third of the sternal manubrium, the brachiocephalic artery can be accessed suprasternally. In case of a more caudal bifurcation, situated behind the sternum, a partial upper J-shaped sternotomy without opening the pericardial or pleural cavity can be performed (Fig. 1).

Another important feature to be evaluated on MDCT is the position of the brachiocephalic artery in relation to the aortic valve annulus and the surrounding tissue. The distance from the potential point of brachiocephalic artery access to the aortic valve annulus should be at least 6 cm, as this distance is needed for full deployment of the current CoreValve delivery system. Specific attention is also given to the surrounding structures of the brachiocephalic artery; an enlarged thyroid or soft tissue retraction after previous cervical surgery or radiation therapy can impede brachiocephalic artery access, but are not absolute contraindications.

## Procedure and surgical technique

As previously described [18], the procedure is performed under general anaesthesia with continuous cerebral oximetry monitoring by means of bilateral frontal cerebral tissue oxygen saturation measurement with the Fore-sight cerebral oximeter (CAS Medical Systems, Inc., Branford, CT, USA). Depending on the need for partial sternotomy to access the brachiocephalic artery, a 4-cm vertical cervical (upwards from the sternal jugulum) or presternal incision (over the sternal manubrium) is made. After surgical exposure of the brachiocephalic artery, patent cerebral perfusion is assessed by 1-min external brachiocephalic artery occlusion while observing cerebral oximetry signals. In case of decrease in cerebral oximetry, alternative TAVI access should be considered, minimizing the risk of periprocedural cerebral ischaemia. Subsequently, surgical purse-string sutures are placed on the anterior side of the brachiocephalic artery (Fig. 2), and the 18-Fr sheath can be introduced over a stiff wire crossing the aortic valve. The rest of the TAVI procedure is performed per the standard technique. Upon closure of the vessel, no arterial reconstruction or vascular clamping is needed.

## Clinical end-points

Data concerning the composite end-points of device success, early safety, 30-day clinical efficacy and time-related valve safety were prospectively collected, as defined by the Valve Academic Research Consortium (VARC)-2 criteria [20]. Special attention was given to vascular access and access site-related complications.

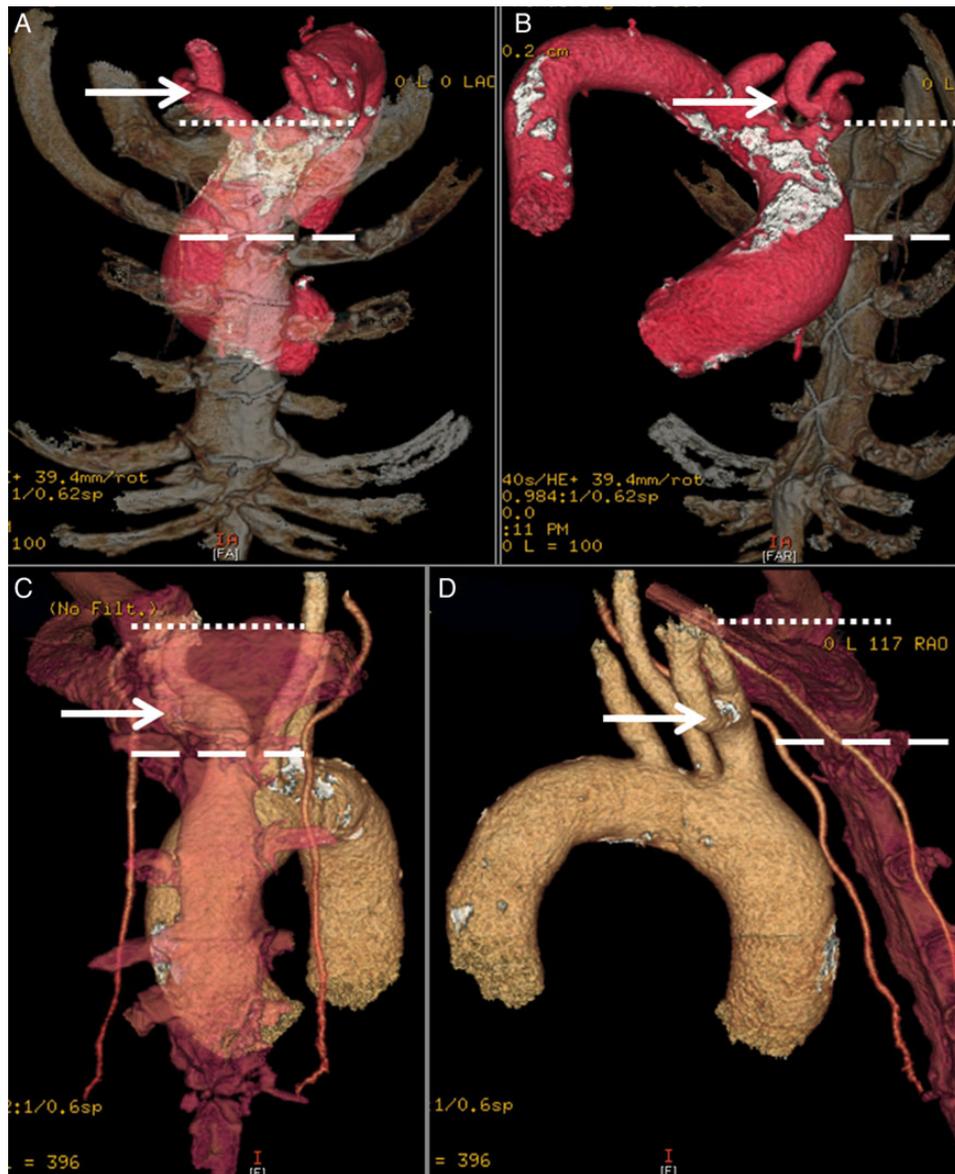
All patients provided written informed consent for the use of their procedural and follow-up data, and approval was obtained from our hospital's local ethics committee.

## RESULTS

### Study population

Between September 2011 and May 2014, 107 consecutive CoreValve TAV implantations were performed in our centre. Of these, 20 patients (18.7%) were implanted by the brachiocephalic artery approach as preprocedural imaging demonstrated unfavourable iliofemoral access. Table 1 summarizes patient characteristics. Mean age was 79 years, patients were predominantly male (75%) and all at high risk for mortality if treated by surgical aortic valve replacement with a mean logistic EuroSCORE of 27.46% and a mean STS-Predicted Risk of Mortality score of 7.17%. Ninety percent of patients were in New York Heart Association functional class III or IV. All patients were diagnosed with severe degenerative aortic valve stenosis: aortic valve area ranged from 0.4 to 0.86 cm<sup>2</sup> (mean 0.65 cm<sup>2</sup>) with mean transvalvular gradients between 17 and 69 mmHg (mean 43 mmHg) and peak transvalvular gradients between 30 and 109 mmHg (mean 66 mmHg). Left ventricular ejection fraction ranged from 27 to 85% (mean 51%).

Table 2 reports the main reasons patients were selected for the brachiocephalic artery approach. All patients had either excessively calcified or small-calibre peripheral vessels, previous peripheral arterial interventions or a combination of pathologies. Of the total, 30% of the patients presented with a porcelain ascending aorta, thereby impeding direct aortic TAVI access. In addition, 60% of patients had undergone coronary artery bypass grafting (CABG),



**Figure 1:** Anatomical landmarks in the decision for partial upper sternotomy. (A and B) Bifurcation of the brachiocephalic artery to the right subclavian and the right common carotid artery reaches the level of the upper one-third of the sternal manubrium, indication for the suprasternal approach. (A) Frontal view; (B) right lateral view. (C and D) More caudal brachiocephalic artery bifurcation, situated behind the osseous structures, indication for partial upper J-shaped sternotomy or manubriotomy. (C) Frontal view; (D) right lateral view. Dotted line: upper border of the manubrium; striped line: manubriosternal junction; arrow: brachiocephalic bifurcation

and most (91.7%) had proven patent grafts on angiography, either *in situ* left internal mammary artery (LIMA) grafts or vein grafts with proximal anastomoses on the ascending aorta, correspondingly inhibiting subclavian or direct aortic TAVI access. All brachiocephalic arteries were large enough, as measured on MDCT (mean diameter 9 mm, range 7–12 mm), to introduce the 18-Fr sheath without complete occlusion.

### Procedure feasibility

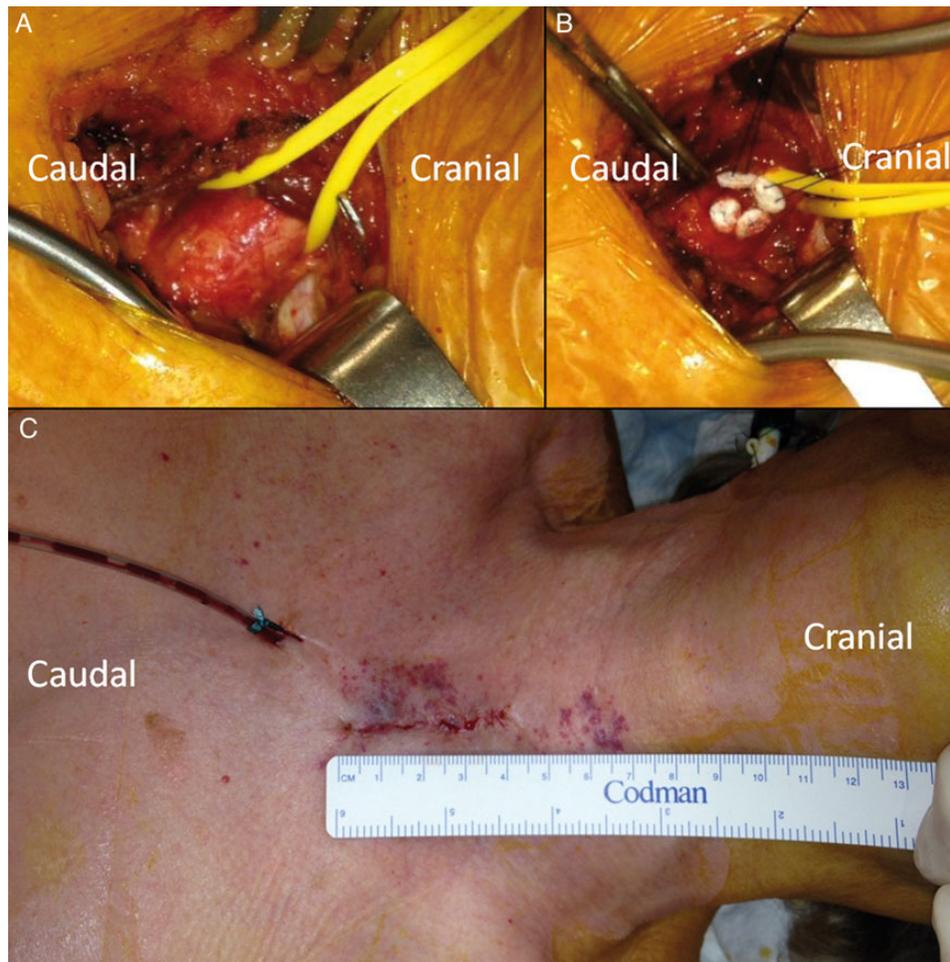
The brachiocephalic TAVI approach was successful in all 20 patients. We did not see any significant decrease in cerebral oximetry values upon external occlusion of the brachiocephalic artery. Access was obtained suprasternally in 15 patients. In the remaining 5 cases, partial upper sternotomy was performed without

opening the pericardium or pleural cavity. No periprocedural cerebral or cardiac ischaemia was seen. No conversion to full sternotomy was needed. All valves were positioned correctly. We encountered no vascular access or access-related complications.

### Early safety

The 30-day survival rate was 95%. In 1 patient, periprocedural occlusion of a patent venous graft resulted in electrical instability and, despite urgent re-stenting of the vein graft, cardiogenic shock persisted.

No periprocedural clinically assessed haemorrhagic or ischaemic stroke or transient ischaemic attack (TIA) was seen. No acute kidney injury was noted, based on serum creatinine levels and urinary output data. No life-threatening bleeding or major



**Figure 2:** Perioperative images. (A) Brachiocephalic artery after surgical dissection; (B) purse-string sutures in place before introducing the 18-Fr delivery sheath; (C) postoperative result.

**Table 1:** Baseline patient characteristics

	n = 20
Age (years)	79.2 ± 8.0
Male sex	15 (75)
Body surface area (m <sup>2</sup> )	1.85 ± 0.2
Log EuroSCORE (%)	27.46 ± 18.4
STS-PROM score (%)	7.17 ± 4.6
New York Heart Association class III/IV	18 (90)
Aortic valve area (cm <sup>2</sup> )	0.65 ± 1.9
Peak gradient aortic valve (mmHg)	66.2 ± 28.6
Mean gradient aortic valve (mmHg)	43.4 ± 16.9
Left ventricular ejection fraction (%)	51.0 ± 15
Coronary artery disease	11 (55)
Carotid artery disease	11 (55)
Chronic obstructive pulmonary disease	6 (30)
Diabetes	5 (25)
Chronic renal failure	5 (25)

Variables expressed as mean ± standard deviation, or number (%).  
EuroSCORE: European System for Cardiac Operative Risk Evaluation;  
STS-PROM: Society for Thoracic Surgeons-Predicted Risk of Mortality.

**Table 2:** Indications for the brachiocephalic approach

	n (%)
Poor iliofemoral access	20 (100)
Severe atherosclerosis	18 (90)
Previous vascular intervention	6 (30)
Small calibre <6 mm	1 (5)
Hostile groins post radiotherapy	1 (5)
Porcelain aorta	6 (30)
Previous CABG	12 (60)
Patent left internal mammary artery graft	11 (91.7)
Patent vein graft on the ascending aorta	11 (91.7)

Variables expressed as number (%).

vascular complications were encountered. All minor access-related complications were seen at the site of the secondary, femoral artery access: one femoral arterio-venous fistula and five femoral artery haematomas were diagnosed. None of these minor access-related vascular injuries necessitated further intervention.

Two patients required transfusion of 1 unit of packed red blood cells because of a haemoglobin level <9 mg/dl without an overt bleeding aetiology. In 2 patients, diagnosed with a right bundle branch block before the TAVI procedure, implantation of a permanent pacemaker within 2 days post TAVI was necessary because of a new third-degree atrioventricular block.

Table 3 summarizes the early safety end-points as described by the VARC-2 criteria [20].

The mean length of hospital stay was 9 days (range 5–15 days). Echocardiography at discharge showed only 1 patient with moderate paravalvular aortic valve regurgitation, and 3 patients with mild paravalvular leakage. Mean gradients at discharge were overall low [mean 9 mmHg (range 6–14 mmHg)]. No other TAVI-related complications were seen.

## Clinical efficacy

At a mean follow-up time of  $497 \pm 256$  days, the survival rate is 85.0% at 6 months and 75.0% at 1 year. Mortality during follow-up was neither procedure- nor valve-related. Causes of death were respiratory infection, a cerebral tumour and bleeding after thrombolysis. No valve-related dysfunction was seen at follow-up. Echocardiography at 6 weeks, 6 months and 1 year after TAVI showed a mild, clinically insignificant rise in mean gradients over the aortic valve prosthesis (9, 9 and 10 mmHg, respectively) and stable effective orifice areas (EOA) of the aortic valve (1.31, 1.36 and  $1.43 \text{ cm}^2$ , respectively) without presence of any paravalvular aortic regurgitation more than moderate. No aortic valve reinterventions of any kind were required until now. Follow-up data are given in Table 4 and Fig. 3.

**Table 3:** 30-day safety and clinical efficacy end-points

	n = 20
All-cause mortality	1 (5)
All stroke (disabling/non-disabling)	0
Life-threatening bleeding/major vascular complication	0
Acute kidney injury	0
Coronary artery obstruction	0
Valve-related dysfunction	0
Aortic regurgitation > moderate	0
New permanent pacemaker implantation	2 (10)

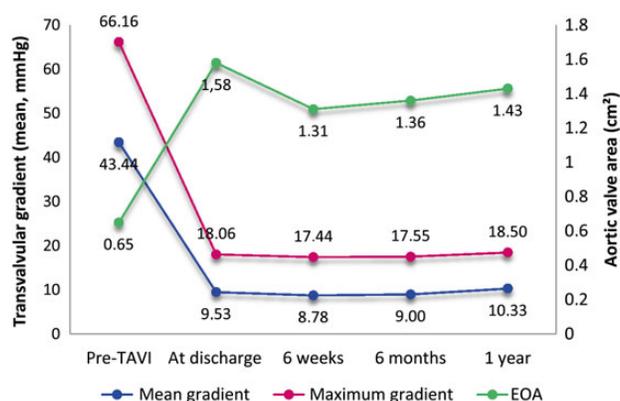
Variables expressed as number (%).

## DISCUSSION

The results of our series show that brachiocephalic artery access in TAVI is safe and feasible in patients with poor peripheral femoral arterial access. Early mortality rates are low, with an overall 30-day mortality rate of 5.0%. We saw no vascular or access-related complications at the brachiocephalic access site. No closure devices, vascular clamping or arterial reconstruction is needed. The distance between the entry point of the delivery catheter and the aortic valve annulus is short, increasing stability during valve delivery and improving accuracy in deployment.

As the brachiocephalic artery is larger than the subclavian or carotid, the risk of periprocedural ischaemia (cerebral, brachial or even cardiac in case of patent LIMA grafts) due to complete arterial occlusion after insertion of the TAVI introducer sheath is low. Furthermore, by not touching or clamping the carotid artery directly, we feel there is less risk of direct intracerebral embolization in case of the presence of atherosclerotic carotid plaques. We do not use embolic protection filters, and in this series we did not encounter any clinically assessed stroke or TIA.

The low morbidity and mortality confirm that alternative access routes such as the brachiocephalic approach can have results similar to, or even better than, those seen in the transfemoral access. When compared with the Belgian TAVI registry, our early results are similar to those of patients treated transfemorally, with a 30-day survival rate for the CoreValve TAVI-treated patients of 91% [21]. In comparison to results of the ADVANCE study [22] (CoreValve TAVI via transfemoral, subclavian or direct aortic access), 30-day mortality is comparable. However, early safety and clinical efficacy appears to be even better in our series. These



**Figure 3:** Valve haemodynamics at follow-up post TAVI. TAVI: transcatheter aortic valve implantation; EOA: effective orifice area.

**Table 4:** Follow-up data

	Discharge	6 weeks	6 months	1 year
Survival (n/total, %)	19/20 (95.0)	19/20 (95.0)	12/15 (80.0)	10/14 (71.4)
All-cause mortality (cardiovascular/non-cardiovascular) (n)	1/0	1/0	1/2	2/2
Mean transvalvular gradient (mmHg)	$9.53 \pm 2.79$	$8.78 \pm 2.72$	$9.00 \pm 4.28$	$10.33 \pm 5.78$
Maximum transvalvular gradient (mmHg)	$18.06 \pm 5.21$	$17.44 \pm 6.23$	$17.55 \pm 7.70$	$18.50 \pm 10.07$
Effective orifice area of the aortic valve prosthesis (cm <sup>2</sup> )	$1.58 \pm 0.33$	$1.31 \pm 0.34$	$1.36 \pm 0.31$	$1.43 \pm 0.32$

Variables are expressed as mean  $\pm$  standard deviation, or number (%).

results are also consistent with the results of other, larger registries and the PARTNER (Placement of AoRtic TraNscathetER) trial, with comparable 30-day mortality rates in high-risk patients between 3.3 and 6.3%, but with major vascular complications in up to 15.3% of patients treated transfemorally [3, 9, 23].

Other existing alternative approaches for TAVI all have their limitations. The transapical approach is nowadays widely used but is more invasive as it requires a limited thoracotomy, and may not be an ideal solution for patients with severe left ventricular dysfunction or chronic respiratory disorders [5, 7, 15, 24]. Furthermore, not all currently used TAVI prostheses can be delivered antegrade. We believe that transapical TAVI should be reserved for patients in whom less invasive approaches are not deemed feasible.

Direct ascending aortic TAVI access is another alternative [5, 12, 16] but it requires a limited sternotomy or anterior thoracotomy. In a short ascending aorta, the distance between the catheter entrance point and the aortic annulus may also be too short, and complete deployment of the valve outside the sheath can be impeded. In patients with previous CABG, the risk of harming patent retrosternal vein grafts in approaching the ascending aorta exists. To overcome this problem, the Suprasternal Aortic Access System (Aegis surgical Ltd, Dublin, Ireland) was recently introduced, intended for suprasternal direct aortic TAVI approach [25]. Though early results of the direct aortic TAVI approach appear promising, early and long-term clinical efficacy and safety in a larger cohort of patients are to be investigated, as results of the multicentre, prospective registries are awaited.

If direct aortic TAVI access is contraindicated, subclavian access is offered as an alternative [5, 13]. Subclavian TAVI can be performed either left- or right-sided, although the left-sided approach is preferred in case of a more horizontal configuration of the ascending aorta. In our early experience, we experienced that in patients with poor femoral access, the subclavian arteries were often tortuous, calcified or small, risking vascular complications if used as TAVI access. Caution should be taken in patients with patent mammary artery grafts after previous CABG [5]. As we encountered 1 case of periprocedural cardiac ischaemia due to a patent LIMA graft occlusion after introducing the TAVI delivery sheath into the left subclavian artery, we have now totally abandoned this approach.

Another alternative for TAVI is the carotid artery approach, as first described by Modine *et al.* [14]. Surgical carotid artery access is well known and easily performed, and the access point can be surgically controlled. However, we believe that the calibre of the carotid arteries is often small, thereby with the risk of the TAVI delivery sheath being occlusive and increasing the probability of cerebral ischaemia during implantation of the valve.

A disadvantage we encounter in performing valve implantation by the brachiocephalic artery approach is that the length of the currently utilized 18-Fr delivery sheaths is often less ideal for central arterial access. A shorter sheath might increase stability even more during valve delivery and implantation.

## Study limitations

This study is a single-centre study, limited by the small size of the study population and the use of only one type of transcatheter aortic valve prosthesis. If we want to be able to really compare the results of brachiocephalic approach to the other alternative TAVI access sites, a larger, prospective study with the use of multiple different retrograde TAVI devices is needed.

## CONCLUSION

The amount of patients treated by retrograde TAVI is restricted by anatomical limitations, especially for the most commonly used transfemoral approach. Access and access site-related complications in TAVI remain a key point of concern. Despite continuous evolutions in delivery sheath profile and the ongoing development of new vascular closure devices [6], alternative approaches to transfemoral access have to be explored.

We are convinced that the brachiocephalic approach is a safe and feasible retrograde approach for TAVI if the transfemoral access is contraindicated, provided that the preprocedural MDCT scan shows a suitable brachiocephalic artery. The most important feature in TAVI access decisions is the individual tailoring of the access approach to the specific needs of each patient.

**Conflict of interest:** Johan Bosmans is a part-time clinical proctor for Medtronic CoreValve.

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