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Transcutaneous aortic valve implantation using the carotid artery access: Feasibility and clinical outcomes

Implantation transcutanée d'une valve aortique en utilisant l'abord carotidien : faisabilité et données de suivi

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KEYWORDS
Transcatheter aortic valve implantation;
Aortic stenosis;
Common carotid artery;
Femoral artery;
Peripheral artery disease

Summary
Background. — Transcarotid access is an alternative route for transcutaneous aortic valve implantation (TAVI) in patients with impossible transfemoral access.
Aims. — We evaluated the safety, effectiveness and early and late clinical outcomes of CoreValve® implantation via the common carotid artery.
Methods. — Eighteen patients (10 men, 8 women; mean age 84 ± 5 years) at high surgical risk (mean EuroSCORE II 16 ± 13%) with significant peripheral artery disease underwent TAVI via common carotid artery access under general anaesthesia. Mean aortic valve area was 0.64 ± 0.13 cm^2 (0.36 ± 0.07 cm^2/m^2).
Results. — At a mean follow-up of 605 ± 352 days, two patients (11%) had died in hospital, on days 6 and 20, as a result of sepsis with multiorgan failure ($n = 1$) or pneumonia ($n = 1$). There were no perioperative deaths, myocardial infarctions or strokes. Perioperative prosthesis

Abbreviations: CCA, common carotid artery; CT, computed tomography; TAVI, transcatheter aortic valve implantation.

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embolization occurred in one patient (6%), requiring implantation of a second valve. In-hospital complications occurred in four patients (23%): blood transfusion for transient significant bleeding at the access site in one patient (6%); permanent pacemaker implantation in two patients (11%); and pericardial drainage in one patient (6%). The rate of event-free in-hospital stay was 66%. Post-procedural echocardiography showed very good haemodynamic performance, with a mean gradient of 8 ± 3 mmHg. Moderate paravalvular leak was present in one patient (6%). Mean intensive care unit stay was 48 ± 31 h; mean in-hospital stay was 7 ± 3 days.
Conclusion. — TAVI performed by transcarotid access in this small series of severely ill patients was associated with a low incidence of complications, which were associated with the procedure itself rather than the access route.

MOTS CLÉS
Implantation transvalvulaire d'une valve aortique ;
Sténose aortique ;
Artère carotide commune ;
Artère fémorale ;
Artériopathie périphérique

Résumé
Justification. — l'abord transcarotidien est une alternative à la voie transfémorale pour la mise en place d'une prothèse valvulaire aortique par voie transcutanée (TAVI).
Objectif. — nous avons évalué la sécurité, l'efficacité ainsi que les évènements à court et moyen termes après implantation d'une valve CoreValve, en utilisant la voie de l'artère carotide commune.
Méthode. — 18 patients, 10 hommes, 8 femmes, d'âge moyen 84 ± 5 ans, à haut risque chirurgical (EuroScore II moyen 16 ± 13) porteurs d'une artériopathie périphérique significative ont bénéficié d'un TAVI en utilisant la voie de l'artère carotide commune, sous anesthésie générale. La surface valvulaire aortique moyenne était de $0{,}64 \pm 0{,}13$ mc^2 (soit une surface aortique indexée à $0{,}36 \pm 0{,}07$ cm^2/m^2).
Résultats. — lors d'un suivi moyen de 605 ± 352 jours, deux patients (11%) sont décédés pendant la phase hospitalière à J6 et J20 du fait d'un sepsis lié à une défaillance multiviscérale (1 patient) et du fait d'une pneumonie (1 patient). Il n'y a pas eu de décès péri-opératoire, d'infarctus du myocarde ou d'accident ischémique cérébral. L'embolisation péri-opératoire de la prothèse a été observée chez un patient soit 6% nécessitant l'implantation d'une seconde valve. Les complications en phase hospitalière sont survenues chez 4 patients soit 23%.: transfusion globulaire pour un saignement transitoire au site d'accès chez un patient (6%), implantation permanente d'un pacemaker chez 2 patients (11%), et drainage péricardique chez un patient (6%). Le taux actuariel de survie sans évènement est de 66% lors de ce suivi évolutif de près de deux ans. L'échographie post-procédurale a montré la performance hémodynamique satisfaisante avec un gradient moyen post-procédural de 8 ± 3 mmHg. Une régurgitation paravalvulaire modérée a été décrite chez un seul patient (6%), le séjour moyen en soins intensifs au décours de l'intervention était de 48 ± 31 heures, et la durée de séjour hospitalier de 7 ± 3 jours.
Conclusion. — le TAVI par voie carotide commune dans cette série préliminaire de patients porteurs de sténose aortique sévère avec des comorbidités majeures semble sûr avec une incidence faible de complications. Les complications sont dominées par celles liées à la procédure elle-même et ne sont pas liées à la voie carotidienne.

Background

TAVI has emerged as a current routine alternative procedure for treating severe aortic valve stenosis in patients who are inoperable and at high surgical risk [1]. Transfemoral access is the most commonly used route [2—6]. However, patients with limited vascular access caused by severe calcification or tortuosity, previous iliofemoral surgery, type B aortic dissection or surgically treated type A aortic dissections may not be candidates for transfemoral access. For these patients, the need for TAVI has led to the development of transapical, transaortic and transaxillary/transsubclavian alternatives. Generally, a patent left internal thoracic artery coronary bypass graft precludes left transsubclavian access because of the risk of coronary hypoperfusion by the 18 F delivery sheath positioned in the left subclavian artery. An implantable pacemaker/defibrillator in the subclavian region may also restrict transsubclavian access. Transapical or transaortic accesses both require thoracotomy or mini-sternotomy. Transcarotid access has been slowly gaining popularity as an alternative in the growing TAVI arena when other routes are not feasible. The purpose

of our prospective study was to assess the feasibility and safety of transcarotid access for a specific group of patients.

Methods

Patient selection

Since November 2012, 18 consecutive patients (10 men and 8 women) with peripheral artery disease and severe symptomatic aortic stenosis underwent the TAVI procedure via transcarotid access. These patients were not eligible for cardiac surgery because of multiple co-morbidities and a high perioperative risk. Each patient was selected for TAVI after multidisciplinary heart team evaluation. All patients underwent routine preoperative coronary angiography, transthoracic echocardiography and contrast-enhanced cardiac computed tomography (CT). Transcarotid artery access was chosen when transfemoral access was not suitable because of severe peripheral arteriopathy, major tortuosity or previous iliofemoral surgery. The patency and anatomy of the carotid artery were evaluated preoperatively with contrast-enhanced CT. All patients had preoperative functional assessment of the carotid artery by transcranial Doppler examination.

Procedure

Procedures were performed by a multidisciplinary team that included anaesthesiologists, interventional cardiologists and cardiac surgeons, with patients under general anaesthesia and transoesophageal echocardiographic monitoring. Aspirin 100 mg/day was started the day before the procedure, without additional antiplatelet agents. Patients received 1.5 g of cefuroxime by intravenous injection immediately before the incision. All procedures except one were performed via the right common carotid artery (CCA). After intravenous injection of 5000 U of unfractionated heparin, a surgical cut-down of the right CCA was performed, and an 18 F sheath was inserted directly into the right CCA for introduction of the valve delivery system (CoreValve® ReValving System; Medtronic, MN, USA). Cerebral oximetry monitoring was performed during the procedure, based on near infrared spectroscopy during the procedure to detect ischaemic cerebral complications. An aortic root pigtail catheter was advanced through a 5 F arterial sheath in the femoral artery for angiographic visualization. A temporary pacemaker lead was inserted via the femoral vein through a 6 F sheath. A stiff wire (Safari™ pre-shaped TAVI guidewire; Boston Scientific, Marlborough, MA, USA) was used for guiding the valve. No balloon aortic valvuloplasty was performed before TAVI implantation. After the valve was delivered, the sheath was retrieved, and the CCA was surgically purged and repaired with the aid of a 6-0 polypropylene suture. A drain was inserted, and the incision was closed (Figs. 1 and 2). Patients were then transferred to the intensive care unit. Transthoracic echocardiography was used to assess the prosthetic valve function on day 1 and during follow-up at 1 and 6 months.

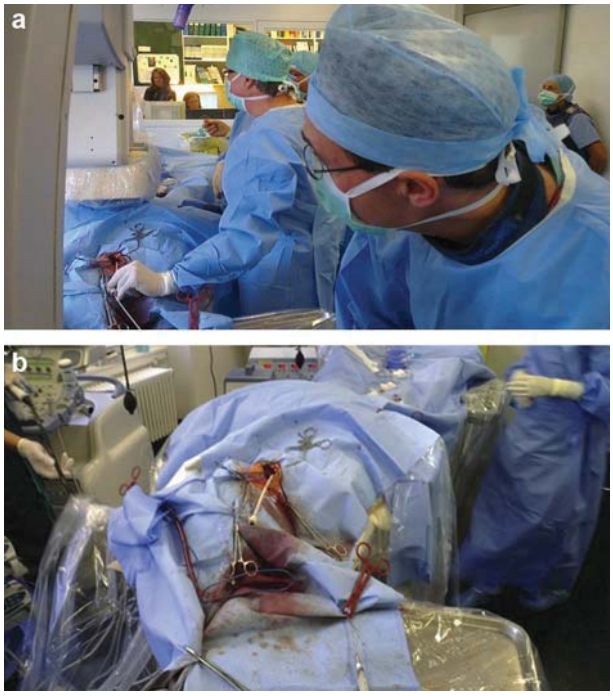

Figure 1. a: positions of the operators, with the first operator on the left and the second operator on the right: it is evident that only the first operator sees the fluoroscopy; the material has to be improved for this access; b: picture of the access site after valve implantation, just before sheath removal by the surgeon.

Results

Overall, 18 consecutive patients ineligible for transfemoral access (10 men, 55%; eight women, 45%), with a mean EuroSCORE II of 16 ± 13% and significant peripheral artery disease, underwent TAVI for severe symptomatic aortic stenosis via right CCA access under general anaesthesia. The mean age was 84 ± 5 years and the mean aortic valve area was 0.64 ± 0.13 cm^2 (0.36 ± 0.07 cm^2/m^2). Baseline patient characteristics and preoperative demographic data are summarized in Table 1. As shown in Table 2, seven patients with a mean EuroSCORE II < 10% were considered for TAVI, although

Table 1 Preoperative demographic data and baseline patient characteristics (n = 18).

Age (years)	84 ± 5
Men	10 (55)
Body mass index (kg/m^2)	26 ± 4
New York Heart Association class III/IV	10 (55)
Pacemaker carrier	3 (17)
Peripheral vascular disease	18 (100)
Renal failure	11 (61)
History of coronary artery bypass graft	2 (11)
Left ventricular ejection fraction (%)	56 ± 16
Aortic annular surface (cm^2)	0.65 ± 0.12
EuroSCORE II (%)	16 ± 13

Data are expressed as mean ± standard deviation or number (%).

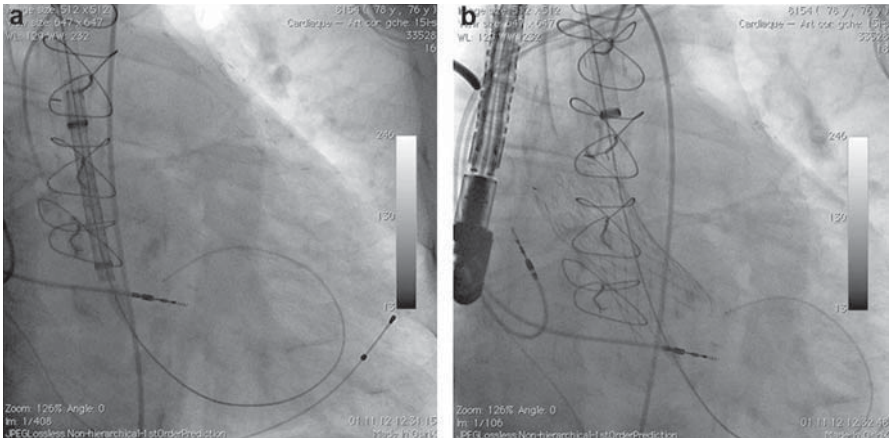

Figure 2. a: position of the sheath immediately before deployment of the valve; the vertical position of the catheter facilitates the delivery of the prosthesis; b: prosthesis after deployment.

Table 2 EuroSCORE II individual data ($n = 18$).

Patient	EuroSCORE II (%)
1	22
2	15
3	8
5	5
5	16
6	16
7	15
8	5
9	5
10	31
11	27
12	51
13	6
14	12
15	6
16	7
17	17
18	28
Overall mean ± standard deviation	16 ± 13

they were below the threshold. Four patients among them categorically refused an open heart operation, two patients had a porcelain aorta, and one patient had history of radiation for lymphoma. Data, complications and safety outcomes were collected in hospital at 30 days, 6 months and 1, 2 and 3 years (Tables 3 and 4). Prosthesis implantation was uneventful in this series of patients. Transcarotid introduction of the delivery sheath was successful, and accurate deployment of the device was achieved in all cases. No carotid dissections occurred during the procedures.

At a mean follow-up of 605 ± 352 days, two patients (11%) had died, as shown in Table 3. There were no intraoperative deaths. There was one in-hospital death on day 6 of an 85-year-old patient with very poor preoperative condition (EuroSCORE II 51, left ventricular ejection fraction 25%), caused by sepsis and low cardiac output syndrome with multisystem organ failure. The second death occurred in an 83-year-old patient known to have monoclonal

Table 3 Procedural data and in-hospital data and complications ($n = 18$).

Variable	*N* (%)
Procedural data	
Procedural success	18 (100)
Valve malpositioning	1 (6)
Carotid dissection	0 (0)
Conversion to open surgery	0 (0)
Acute renal failure	0 (0)
Major access site bleeding	1 (6)
Procedural mortality	0 (0)
Permanent pacemaker for complete AV block	2 (11)
Postimplantation mean gradient (mmHg)	8 ± 3
Aortic regurgitation grade III/IV	0 (0)
Intensive care unit stay (h)	48 ± 31
In-hospital stay (days)	7 ± 3
In-hospital events	
Death	2 (11)
Myocardial infarction	0 (0)
Stroke	0 (0)
MACCE	2 (11)

Data are expressed as number (%) or mean ± standard deviation. AV: atrioventricular; MACCE: major adverse cerebrovascular or cardiovascular events.

Table 4 Late safety endpoints in mean follow-up (605 ± 303 days; $n = 18$).

Variable	*n* (%)
All-cause mortality	2(11)
New York Heart Association class III/IV	0(0)
Myocardial infarction	0(0)
Stroke and TIA	0(0)
MACCE	2(11)

MACCE: major adverse cerebrovascular or cardiovascular events; TIA: transient ischaemic attack.

gammopathy of undetermined significance, who died on day 20 because of pneumonia and sepsis. There was no myocardial infarction as assessed by clinical symptoms, periprocedural cardiac biomarker measurements, electrocardiograms and ventricular wall motion echocardiography analysis. There was no stroke or transient ischaemic attack as assessed by clinical criteria. Prosthesis embolization in the ascending aorta occurred in one patient (6%) perioperatively, and required implantation of a second valve. No prosthesis thrombosis, endocarditis or other complication associated with prosthetic valve implantation was observed. Additional in-hospital complications occurred in four patients (23%). One patient (6%) with active cirrhosis required a blood cell transfusion for transient severe bleeding at the vascular access site. One patient (6%) required pericardial drainage because of tamponade at the time of temporary pacemaker removal. Third-degree atrioventricular block requiring permanent pacemaker implantation occurred in two patients (11%). Event-free in-hospital stay was 66%. Postprocedural echocardiography showed very good haemodynamic performance of the CoreValve®, with a mean gradient of 8 ± 3 mmHg. There was no prosthetic valve stenosis or prosthesis-patient mismatch at the 1- and 6-month echocardiography assessments. Moderate paravalvular leak was present in one patient (6%). The mean intensive care unit stay was 48 ± 31 h and the mean in-hospital stay was 7 ± 3 days (Table 3).

Discussion

TAVI is widely accepted as a therapeutic option for patients with symptomatic severe aortic valve stenosis at high surgical risk because of multiple co-morbidities. TAVI, using the Medtronic CoreValve®, was associated with significantly lower mortality at 1 year when compared with conventional aortic valve replacement in patients at high surgical risk [7]. Transfemoral access is generally considered to be less invasive, and is thus the most widely used access for TAVI, with ongoing improvements in technical feasibility, including reduced sheath profiles and automated closure percutaneous devices. However, given the high incidence of vascular disease in TAVI candidates, an alternate access route is required when iliofemoral artery access is problematic, because of severe arteriopathy, tortuosity or previous surgery.

In many centres, the transapical route is well established as a second option, as its use is supported by feasibility data with favourable clinical outcomes [8—10]. The short distance between access and deployment sites facilitates valve insertion and placement. However, the need for thoracotomy and left ventricular cannulation may not be suitable for certain patients with severe left ventricular dysfunction or lung disease. Moreover, bleeding complications, lateroapical hypokinesia and ventricular aneurysm formation have been reported [6,11,12].

In 2010, Modine et al. reported the first experience of a successfully performed TAVI through the left CCA, complicated by retrograde dissection of the latter and the ascending aorta, leading to transient hemiparesis [13]. Later, Modine et al. further reported successful implantation of a self-expanding valve via transcarotid access, with one transient ischaemic attack (7%) and no vascular access site complications as early outcomes in a series of 12 patients [14]. More recently, Azmoun et al. reported no cerebrovascular events or access site complications in a series of 19 patients undergoing TAVI of both self-expanding and balloon-expandable valves via transcarotid access under local anaesthesia [15]. To date, further available data seem to confirm the safety and feasibility of this access site [16,17]. Furthermore, a first report of valve-in-valve implantation for degenerated stentless aortic root conduits with severe regurgitation via transcarotid access has described three uneventful cases [18].

In the present series of 18 consecutive patients, we have shown that transcarotid access might be a suitable alternative access for TAVI with excellent outcomes when transfemoral or other access site routes are not feasible. Prosthetic valve positioning and release control are easier and the transcarotid approach offers greater movement precision compared with the transsubclavian or transaortic routes as a result of the shorter distance and the direct trajectory between the carotid artery and the aortic annulus. Furthermore, transcarotid access is feasible in patients with a previous coronary artery bypass graft, who are at risk of myocardial hypoperfusion when a transaxillary approach is employed.

In our prospective study of this small series of patients there were no cerebrovascular ischaemic events. Stroke is a main concern in TAVI procedures [19], and is caused by cerebral embolic events from valvular calcifications or aortic atheroma. As the transcarotid access does not include instrumentation of the aortic arch, and the carotid artery is surgically purged after sheath retrieval, cerebral embolization events can be reduced. In our study, access-site complications occurred in one patient with active cirrhosis, and involved major bleeding of the access site, requiring a blood cell transfusion event. There were no intraoperative deaths in our series. One in-hospital death occurred on day 6 in an 85-year-old patient in poor preoperative condition, with a EuroSCORE II of 51 and a left ventricular ejection fraction 25%, and was the result of sepsis and multisystem organ failure. The second death, on day 20, was in an 83-year-old patient known to have monoclonal gammopathy of undetermined significance, and was the result of pneumonia and sepsis. Both deaths were unrelated to the transcarotid access procedure itself.

Study limitations

An important limitation of the current prospective study was the small size of the population, which undermined the statistical power of the study. These preliminary data do not allow us to draw any definite conclusions regarding the safety of this access site route.

Conclusion

TAVI performed by transcarotid access in this small series of aged and severely ill patients was feasible with a low incidence of short- and long-term complications. These complications were related to the procedure itself and not

to the access route. Our results highlight growing interest in a larger confirmatory study.

Sources of funding

None.

Disclosure of interest

The authors declare that they have no competing interest.

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