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Common carotid artery access for transcatheter aortic valve implantation

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Abstract

Transcatheter aortic valve implantation (TAVI) is an alternative method of treatment for severe symptomatic aortic stenosis in patients who are at high risk of surgical aortic valve replacement (AVR). In randomised clinical trials TAVI was shown to be superior to standard medical therapy in a cohort of inoperable patients and non-inferior to AVR in high-risk operable patients. Additionally, in a recent trial with self-expandable prosthesis use, TAVI was associated with lower mortality compared with surgery. Usually, femoral arteries are the most common vascular access to deliver the bioprosthesis; however, in some cases (up to 20%) this route may not be applied because of significant peripheral artery disease or tortuosity. In this article, we present the first two TAVI procedures in Poland performed via the left common carotid artery.

Key words: transcatheter aortic valve implantation, aortic stenosis, common carotid access, transcarotid

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is an alternative way of treating patients with severe symptomatic aortic stenosis. The target group for whom this method is dedicated consists of patients with predicted high perioperative mortality risk during standard aortic valve replacement (AVR) surgery and those who are deemed inoperable. In the randomised PARTNER trial, TAVI showed superior results in terms of all-cause and cardiovascular mortality when compared with conservative approach in an inoperable group of patients. Most importantly though, in the second arm of this study, patients with high surgical risk were randomised to conventional AVR or to TAVI. In this subgroup TAVI has shown to be non-inferior in terms of short-term as well as three-year mortality [1, 2]. Moreover, in a recent trial with self-expandable prosthesis use, TAVI proved to be superior even to AVR in terms of short-term mortality [3]. The 2012 European Society of Cardiology guidelines on valvular disease acknowledged the significance of this method in the management of high-risk patients with severe aortic stenosis [4].

The most commonly used approach for implantation of both self- and balloon-expandable prosthesis devices, accounting for up to 80% of cases, is through the femoral artery, preferably with the use of vascular closure devices (e.g. Prostar XL, Proglide), which makes this procedure less traumatising and minimally invasive. Unfortunately, due to calcified atherosclerotic lesions in the iliofemoral arteries or aortic aneurysms or severe tortuosity of the vessels, not all patients can undergo transfemoral TAVI. In these patients alternative access sites have been implemented — left subclavian artery, ascending aorta (direct aortic approach), or antegrade transapical approach. Again, all of these approaches pose some technical and clinical difficulties, which sometimes may prove prohibitive in different subgroups of patients. Patent arterial or venous grafts in trans-subclavian and direct aortic route, and scar tissue in the apical segments of the myocardium when using transapical route are some examples of those situations. To

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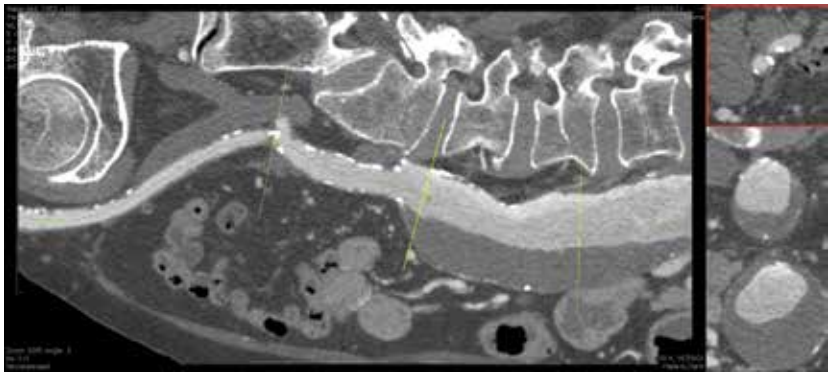

Figure 1. Multi-sliced angio-computed tomography image showing longitudinal and transverse views of large abdominal aneurysm and calcified common iliac artery

meet the needs of a very diversified group of patients with different concomitant conditions new, alternative access has been introduced. In this study we present the first two TAVI procedures in Poland performed with the use of the left common carotid artery (both on 11 December, 2014).

CASE 1

The first patient is a 74-year-old female who underwent coronary artery bypass grafting (CABG, left interior mammary artery to left anterior descending artery and saphenous venous grafts to right coronary artery and marginal branch) with ascending aortoplasty (due to aneurysm) and AVR with bioprosthetic aortic valve (Hancock II 21 mm). She was admitted to our department four years after surgery due to severe functional status deterioration in the preceding four months with chest pain and dyspnoea (from New York Heart Association [NYHA] class I to III). On echocardiography signs of severe aortic stenosis were found with aortic valve area (AVA) of 0.45 cm^2, V max 4.3 m/s, peak gradient 73 mm Hg, and mean gradient 37 mm Hg. The patient had no systolic dysfunction, with left ventricular ejection fraction of 60%. Her medical history also included abdominal and thoracic aortic aneurysm (Fig. 1), hypertension, chronic kidney disease, hypothyroidism, right-sided mastectomy, and gastrointestinal bleeding. Moreover, she was recently diagnosed with early-stage operable colorectal cancer. During control angiography both venous and arterial grafts where found patent, with no de novo lesions, and the bioprosthetic valve was visualised (Fig. 2). Predicted perioperative mortality risk according to Society of Thoracic Surgeons (STS) score was 4.3%. The Heart Team considered her a high-risk patient and referred her for valve-in-valve TAVI. Before the procedure multi-sliced computed tomography and Doppler ultrasonography was performed showing carotid and vertebral arteries with no significant atherosclerotic lesions (Fig. 3).

TAVI was performed in a hybrid operating room under systemic heparinisation, general anaesthesia with transoesophageal echocardiography guidance, cerebral oximetry

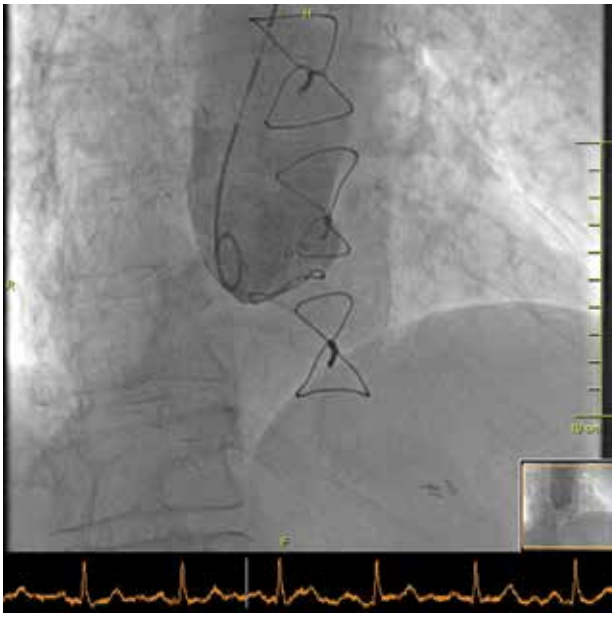

Figure 2. Aortogram showing widened ascending aorta (status after aortoplasty) and characteristic metal elements of Hancock II 21-mm bioprosthesis

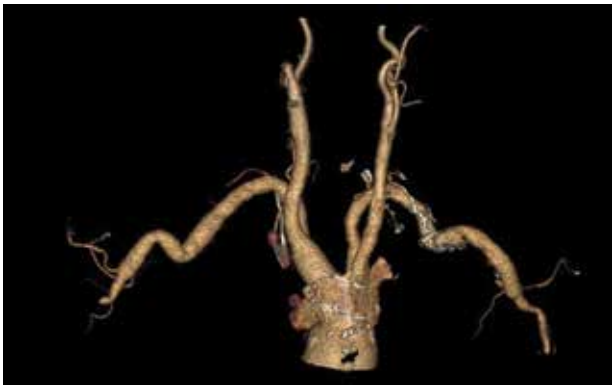

Figure 3. Favourable left carotid artery anatomy in multi-sliced angio-computed tomography

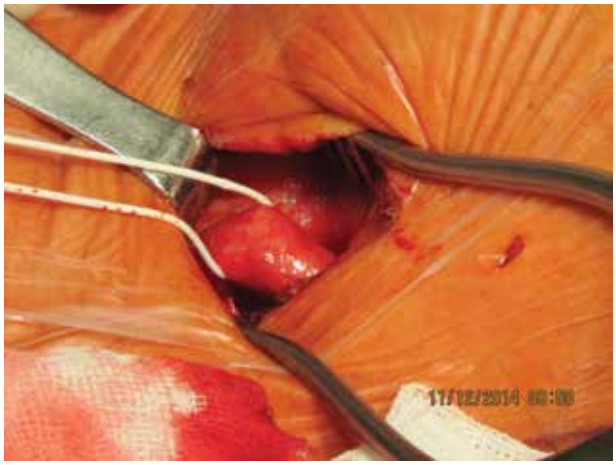

Figure 4. Surgical exposure of the left common carotid artery

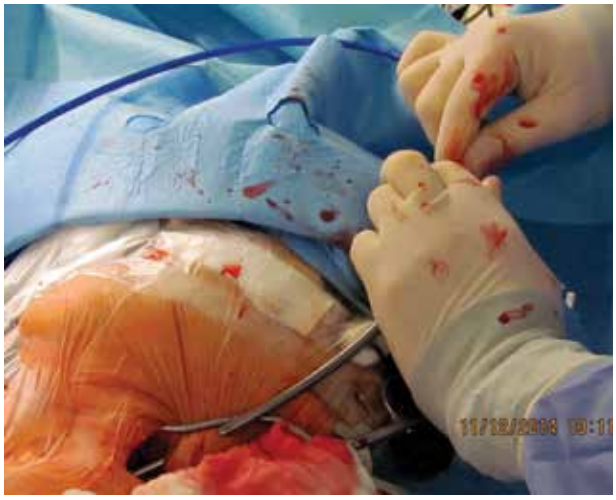

Figure 5. Sheathless delivery of Evolut R 23 mm through left carotid artery over previously placed stiff Amplatz wire across Hancock II into left ventricle

measurement (Fore-Sight, CAS Medical Systems), and transcranial Doppler monitoring (TCD, DWL Doppler Box with QL 2.10 software). The proximal left common carotid artery was exposed through a small latero-cervical incision, 2 cm above the left clavicle (Fig. 4). One 5-0 Prolene continuous purse-string suture was made on the anterior wall of the artery. The common carotid artery was punctured and a 6 F sheath was positioned in the carotid artery through a contraincision in the upper part of the surgical access. In contrast to all other approaches, in order to minimise the time of potential brain hypoperfusion, using the low-profile 6 F sheath, a straight-tip guidewire was advanced through the Hancock II into the left ventricle and then exchanged to a Super Stiff Amplatz guidewire. Then an Evolut R 23 mm valve was introduced through a 14 F sheathless delivery system (Fig. 5). The valve was then carefully placed and deployed within the previously implanted

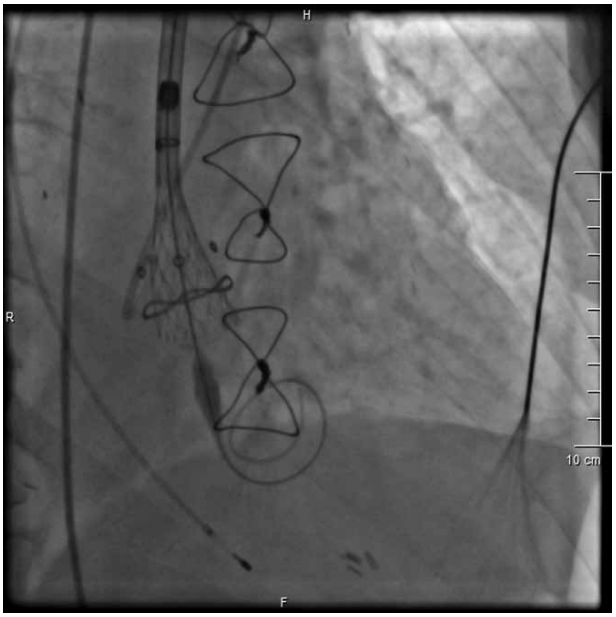

Figure 6. Positioning of Evolut R 23-mm bioprosthesis within the frame of Hancock II

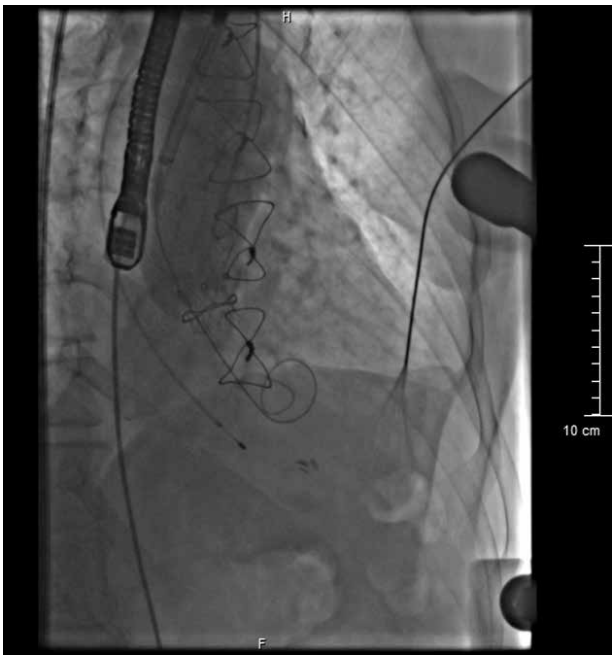

Figure 7. Control angiography showing good final position of self-expandable bioprosthesis within previously surgically implanted Hancock II. No signs of aortic regurgitation

surgical prosthesis (Fig. 6). Due to the straight delivery route and short distance from access site to annulus level, there was excellent control during frame flaring with no need to reposition. Control angiography revealed good positioning and no aortic regurgitation (Fig. 7). After implantation the common carotid artery was sutured without any stenosis (Fig. 8).

Figure 8. Common left carotid artery sutured without stenosis just after implantation and removal of delivery system

The cerebral oximetry monitoring used to assess the patient's cerebral tissue oxygen saturation status during the procedure showed stable recordings with no episodes of hypoperfusion. TCD monitoring on the left middle cerebral artery (MCA) lasted for 65 min and revealed 160 high intensity signals (HITS), mostly recorded during prosthesis deployment. Due to the technical aspects of the procedure, 14 min of low flow in the left MCA was observed (TIBI, thrombolysis in brain ischaemia grade 1) (Fig. 9). Most importantly, during and after the procedure clinical and radiological (Fig. 10, diffusion-weighted magnetic resonance imaging [DW-MRI]) examination did not reveal any pathological changes.

No conduction disturbances were observed immediately after TAVI or during hospital stay. On control transthoracic

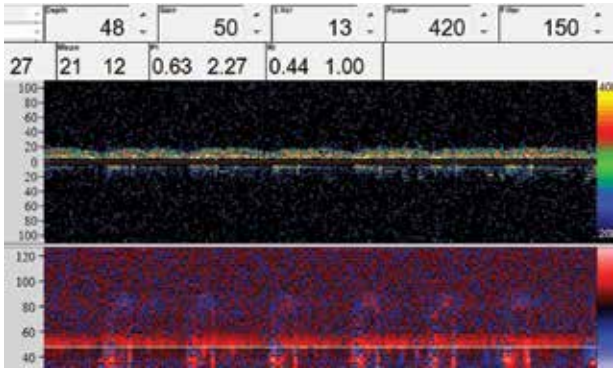

Figure 9. Transcranial Doppler monitoring recording showing an episode of low flow in the left middle cerebral artery during 14 F delivery system insertion

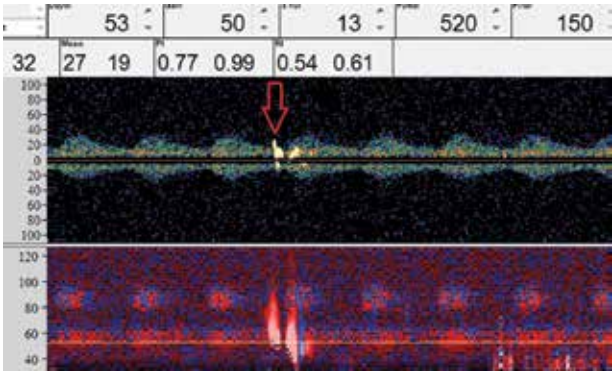

Figure 11. Transcranial Doppler monitoring reveals high intensity transient signal (red arrow)

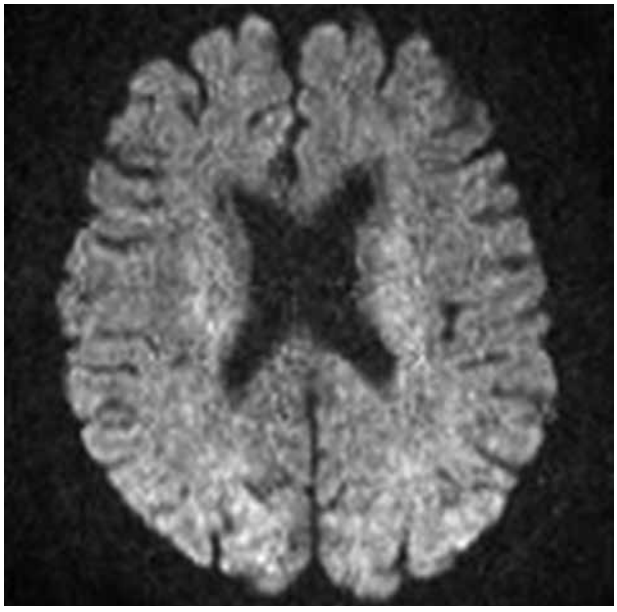

Figure 10. Diffusion-weighted magnetic resonance imaging performed on day 3 after the procedure, showing no ischaemic lesions

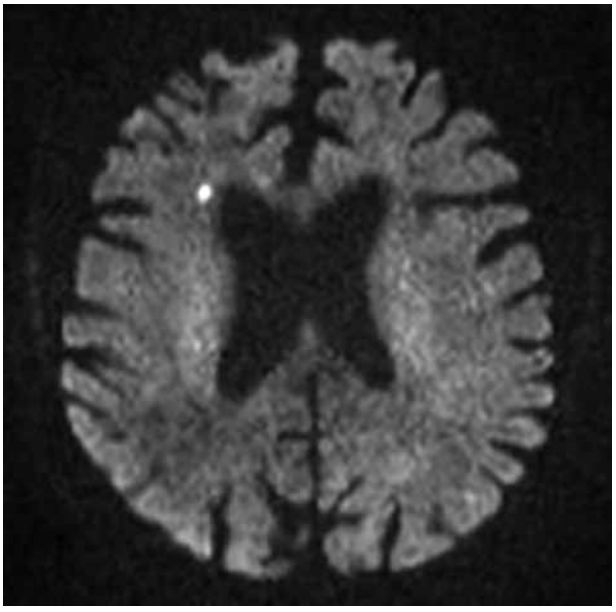

Figure 12. Diffusion-weighted magnetic resonance imaging with small subcortical ischaemic lesion in right frontal lobe

echocardiography (TTE), AVA improved to 1.1 cm^2 and pressure gradients were 44 mm Hg (maximal) and 21 mm Hg (mean). The stenosis in general changed from severe to moderate (due to the limiting surgical valve inner diameter) but with noticeable improvement in functional status (NYHA III to I). The patient was discharged home on day 7 after TAVI in good clinical condition. Currently she has been admitted for colonic surgery.

CASE 2

A 84-year-old male patient with aortic stenosis and coronary artery disease who three months earlier underwent CABG in one of the territory hospitals (left internal mammary artery to left anterior descending) with no AVR, due to intraoperative diagnosis of porcelain aorta. His clinical status worsened in the preceding two months and he had heart failure symptoms in functional class NYHA III. When admitted to our centre the patient's surgical wound of the sternum was not fully healed with signs of infection. We performed control angiography, which showed severe atherosclerotic lesions in iliac arteries and patent left internal mammary artery graft with no lesions in native coronary arteries. Transthoracic and transoesophageal echocardiography confirmed the presence of severe aortic stenosis with AVA 0.8 cm^2, V max 4.5 m/s, peak gradient of 86 mm Hg, and mean of 47 mm Hg. The patient also had several other comorbidities, and his perioperative mortality risk was 8.8% by STS score. The Heart Team referred him to TAVI after surgical treatment of the sternal wound. After one month the wound was cleaned, it healed without any markers of infection, and the patient was admitted once again for an elective TAVI. Prior to the procedure the patient had an angio-computed tomography and Doppler ultrasonography showing carotid and vertebral arteries with no significant atherosclerotic lesions. Similar monitoring tools, antithrombotic prophylaxis, and surgical technique were applied as in case 1. Differently, due to the 24 mm native annulus diameter, a 29 mm CoreValve was delivered via 18 F regular sheath (Cook) with only a trace paravalvular leak after deployment.

As in case 1, cerebral oximetry recordings remained stable throughout the procedure. During 72 min of TCD monitoring 200 HITS and 9 min of low flow (TIBI-1) in left MCA was observed (Fig. 11). Patient did not suffer from any signs of clinical stroke but his follow-up DW-MRI at day 3 revealed small new ischaemic lesion in the right front lobe (Fig. 12). The number of HITS per hour did not vary greatly: 147 vs. 167 between case 1 and 2, respectively; nor did the median number of HITS per hour significantly differ between transcarotid access and other approaches for TAVI (own data, not published). The silent ischaemic lesion discovered in right subcortical area of frontal lobe in this patient is probably of thrombotic origin because prolonged low flow was observed only on the left side.

After the procedure there was no new onset of advanced atrioventricular block requiring permanent pacemaker. Control TTE showed AVA of 1.6 cm^2 and reduced transvalvular pressure gradients (max 12 mm Hg and mean 5 mm Hg). The patient improved clinically to class I NYHA. Hospitalisation after TAVI was uneventful and the patient was discharged home in good condition on day 6 after the procedure.

DISCUSSION

Transcatheter treatment of symptomatic severe aortic stenosis represents a major development in valvular disease management. Improvement of survival and quality of life in elderly, frail patients with several comorbidities observed everyday in clinical practice and confirmed in clinical trials was hardly imaginable 10 years ago. From early experiences, transfemoral delivery of bioprosthesis, with automated closure percutaneous devices (or relatively easy surgical cut-down), and frequently without general anaesthesia remains the gold standard of TAVI. However, about one-fifth of patients referred to TAVI cannot undergo transfemoral TAVI due to various vascular limitations. For a long time the only alternative approach for this subgroup was the antegrade transapical approach, current use of which is limited due to significant invasiveness (especially in those with scar tissue in the apical region), increased bleeding complications, and a tendency for higher overall mortality. Later, trans-subclavian (transaxillary) access was implemented; however, this technique is not advisable in cases with tortuous anatomy and patent internal mammary grafts, and may pose significant risk when bleeding is expected. Similarly, certain reservations exist with direct aortic approach, especially in patients after CABG with functioning coronary grafts and so-called "hostile" chests, e.g. after irradiation or mastectomy.

All of these potential drawbacks of different non-femoral approaches make transcarotid access a valuable alternative for a substantial proportion of TAVI-eligible subjects. The first implantation through the left common carotid was performed successfully and reported by Modine et al. in 2010 [5]. Larger data sets published thereafter by Modine's group and others prove that this mode of access (even in patients after ipsilateral carotid atherectomy, and also via right carotid) is associated with excellent procedural results and low complication rate [6–9]. Moreover, as also demonstrated above, especially in our case 1, due to the short distance between the puncture site and the annulus level, even with difficult baseline anatomy (small diameter degenerated surgical valve), excellent control of deployment can be achieved with no need for troublesome frame repositioning and supposedly with lower risk of paravalvular leakage.

The procedural technique is quite similar to other femoral and non-femoral approaches; however, unlike those, in order to minimise the potential low flow to the brain larger sheaths should be placed for as short a time as possible, only after

crossing the stenosed valve with stiff wire. In our cases, to the best of our knowledge, for the first time TCD monitoring was implemented, which is a more sensitive and selective tool for brain perfusion compared with cerebral oximetry. In both patients, when larger devices were introduced (14 F Evolut R system in case 1 and 18 F sheath in case 2) a significant hypoperfusion in the corresponding left middle cerebral artery was recorded; however, most importantly it did not translate to any corresponding drop in cerebral oxygenation, suggesting compensating increased flow in this region through small arteries and/or collaterals. Nevertheless, this observation further supports the use of the current technique, which shortens the time of large sheath placement in the common carotid.

Each TAVI procedure, irrespective of access type, can be associated with cerebrovascular complications, mostly of embolic or thromboembolic origin, and usually taking place during prosthesis deployment or valvuloplasty. Due to this observation, different protection devices have been gaining ground, and the recently presented results from the CLEAN-TAVI trial are beginning to prove their efficacy (data not published). In light of this, transcarotid access can be perceived as being even somewhat protective for cerebrovascular circulation. On the other hand, prolonged placing of large catheter in the left or right carotid artery can potentially cause hypoperfusion in the corresponding area of the brain, if collateral perfusion is too scarce. Pure anatomical assessment of cerebrovascular circulation (e.g. in MRI) before the procedure, although not precluded, does not provide us with any conclusive findings as different anatomical variants of the circle of Willis can be found and small collaterals cannot be visualised [10].

However, there are preventive measures that should be taken into account before and during the procedure. Firstly, after favourable morphology of the left or right transcarotid access site is evidenced in computed tomography scan and Doppler ultrasonography, cerebral oximetry and possibly (although not mandatory) TCD monitoring is advised during the procedure. When the procedure is performed with local anaesthesia, with cautious sedation, neurological status can also be monitored with simple methods known from best surgical practices during carotid thromboendarterectomy. Secondly, as mentioned above, minimising the time of a large introducer or delivery system is crucial, especially in those with potentially low collateral flow. The number of such cases is potentially very small, and the problem of hypoperfusion will further decrease with the reduction in the delivery system dimensions; however, since we cannot identify those patients up-front, this preventive measure should be taken into consideration as the most important.

CONCLUSIONS

In conclusion, transcarotid access, although in early development, seems to be a promising new means of transcatheter delivery of aortic valve prostheses, and if the safety and efficacy of this route are proved also in larger observations one may expect growing numbers of such procedures in Poland in 2015 and beyond.

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Conflict of interest: *none declared*

References

1. Leon MB, Smith CR, Mack M et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med, 2010; 363: 1597–1607. doi: 10.1056/NEJMoa1008232.
2. Smith CR, Leon MB, Mack MJ et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med, 2011; 364: 2187–2198. doi: 10.1056/NEJMoa1103510.
3. Adams DH, Popma JJ, Reardon MJ et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med, 2014; 370: 1790–1798. doi: 10.1056/NEJMoa1400590.
4. Vahanian A, Alfieri O, Andreotti F et al. Guidelines on the management of valvular heart disease (version 2012). Eur Heart J, 2012; 33: 2451–2496. doi: 10.1093/eurheartj/ehs109.
5. Modine T, Lemesle G, Azzaoui R, Sudre A. Aortic valve implantation with the CoreValve ReValving System via left carotid artery access: first case report. J Thorac Cardiovasc Surg, 2010; 140: 928–929. doi: 10.1016/j.jtcvs.2010.03.001.
6. Modine T, Sudre A, Delhaye C et al. Transcutaneous aortic valve implantation using the left carotid access: feasibility and early clinical outcomes. Ann Thorac Surg, 2012; 93: 1489–1494. doi: 10.1016/j.athoracsur.2012.01.030.
7. Pozzi M, Grinberg D, Obadia J et al. Transcatheter aortic valve implantation using the left transcarotid approach in patients with previous ipsilateral carotid endarterectomy. Catheter Cardiovasc Interv, 2015; 85: E203–E209. doi: 10.1002/ccd.25779.
8. Azmoun A, Amabile N, Ramadan R et al. Transcatheter aortic valve implantation through carotid artery access under local anaesthesia. Eur J Cardiothorac Surg, 2014; 46: 693–698. doi: 10.1093/ejcts/ezt619.
9. Rajagopal R, More RS, Roberts DH. Transcatheter aortic valve implantation through a transcarotid approach under local anesthesia. Catheter Cardiovasc Interv, 2014; 84: 903–907. doi: 10.1002/ccd.25367.
10. de Borst GJ, Moll FL. Status of the circle of Willis and intolerance to carotid cross-clamping. Eur J Vasc Endovasc Surg, 2013; 45: 113. doi: 10.1016/j.ejvs.2012.11.029.

Dostęp naczyniowy przez tętnicę szyjną w przezcewnikowej implantacji zastawki aortalnej

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Streszczenie

Przezcewniowa implantacja zastawki aortalnej (TAVI) jest alternatywną metodą leczenia ciężkiej objawowej stenozy aortalnej u pacjentów z grupy wysokiego ryzyka klasycznej chirurgicznej wymiany (AVR). W randomizowanych badaniach klinicznych udowodniono, że TAVI jest skuteczniejsze u pacjentów nieoperacyjnych i porównywalne z leczeniem chirurgicznym u chorych z grupy wysokiego ryzyka operacyjnego. Najpowszechniejszym dostępem naczyniowym do wszczepienia bioprotezy jest tętnica udowa, jednak u części pacjentów (do 20%) nie może być wykorzystana ze względu na istotne zmiany miażdżycowe lub kręty przebieg. W niniejszej pracy przedstawiono pierwsze dwa przypadki TAVI w Polsce wykonane z dostępu przez lewą tętnicę szyjną.

Słowa kluczowe: przezcewniowa implantacja zastawki aortalnej, tętnica szyjna, dostęp naczyniowy

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