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Percutaneous access and closure using the MANTA vascular closure device in Trans-axillary Transcatheter Aortic Valve Implantation

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Running title: Percutaneous transaxillary TAVI with MANTA

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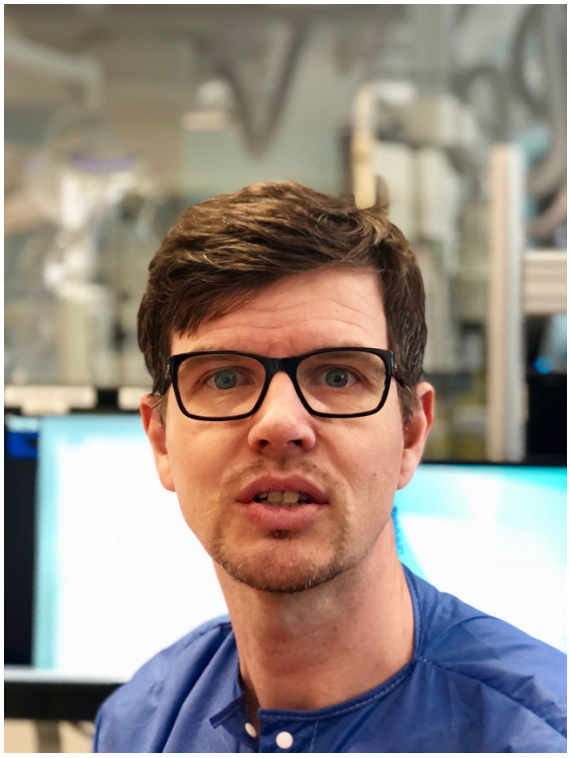
Portrait of Andreas Rück



Classifications

TAVI

Vascular Closure Device

Access site

Subclavian

Abbreviations:

TAVI	Transcatheter Aortic Valve Implantation
VCD	Vascular Closure Device
TAx	Transaxillary
TF	Transfemoral

Introduction

The transaxillary (TAx) arterial access is used for Transcatheter Aortic Valve Implantation (TAVI) when the transfemoral (TF) access is inappropriate.

The TAx access is traditionally performed through surgical cut-down, with the patient under general anaesthesia. More recently a percutaneous TAx procedure has been developed [1]. At our centre, a modified percutaneous TAx approach has been used as alternative access since 2017 using the novel MANTA (Essential Medical, Malvern, PA) vascular closure device (VCD) to achieve haemostasis [2]. MANTA is approved for vascular closure after TF TAVI but there are is so far limited experience with MANTA VCD in percutaneous transaxillary access.

Methods

The aim was to assess the safety and efficacy of percutaneous access trans-axillary artery access TAVI using the MANTA VCD to achieve haemostasis.

This single-centre, retrospective study examined all 16 cases of percutaneous TAx access TAVI at our centre between June 2017 and November 2018. No eligible patients were excluded from analysis.

Percutaneous TAVI was preferably performed via the left axillary artery. The technique is similar to the Hamburg technique [1] and has been described previously [2]. A 0,035” 260 cm hydrophilic wire (Glidewire, Terumo, Tokyo, Japan) was placed from an ipsilateral 6F radial artery sheath and snared out (Amplatz Gooseneck, Medtronic, Minneapolis, MN) through a 8F femoral artery sheath. Ultrasound-guided micro-puncture of the axillary artery was followed by 6F arterial sheath insertion. An Amplatz Ultrastiff 0,035” wire (Cook Medical, Bloomington, IN) was placed in the ventricle and the 18-20F arterial sheath was introduced to

the aortic arch. An Evolut R or Evolut PRO self-expanding valve prosthesis (Medtronic, Minneapolis, MN) was delivered after pre-dilatation. A 6-7 mm balloon was inserted over the hydrophilic wire from the radial sheath to a position in the axillary artery distal to the puncture point. Thereafter the delivery system and large bore sheath was removed and a 18F MANTA VCD was deployed to the arteriotomy site in the same fashion as in TF access. The success of the haemostasis and absence of stenosis was checked immediately with a contrast injection. If there was overt bleeding, the 6-7 mm balloon was inflated to get temporary haemostasis, followed by a covered stent (VIABAHN, Gore Medical, Newark, DE) over the arteriotomy site, using the wire from the femoral access. Unfractionated heparin was administered to maintain an activated clotting time of 250-300 seconds, which could be reversed with protamine in case of bleeding.

Data was collected from the Swedish TAVI registry, hospital records, radiological examinations from the procedures and pre-procedural examinations of the access arteries. Outcomes were analysed according to VARC-2 [3] defined endpoints if not stated otherwise.

The study was approved by the Ethics board in Stockholm and performed in accordance with the Helsinki declaration and did not require the patients' written consent.

Results

The study population was typical for TAVI (average age 83 years, Society of Thoracic Surgeons Risk Score for mortality 7%). 75% were female. The minimal axillary artery diameter on the used side was 5,6 mm (less than 5,5 mm in eight patients). Left-sided axillary access was used in 15 of 16 patients, and general anaesthesia was used in the first 12 patients, with the last 4 treated with local anaesthesia only. 14 patients were treated with the EvolutR system and 2 with the EvolutPRO system. All valves were delivered through sheaths, the

most common being 18F. All cases used predilatation of the aortic valve. Average fluoroscopy time was 33 minutes and contrast volume 85 ml.

The MANTA VCD was used in 15 of 16 patients. In one patient the operator used a covered stent as primary haemostasis method without prior attempt at reaching haemostasis with MANTA. There was a minor vascular complication consisting of closure device failure in 47%. In the first eight patients, the MANTA failed in three, and in the last seven patients, the MANTA failed in four. In all cases a covered stent was deployed successfully, and there was no need for vascular surgery. There was no stenosis in the final angiogram of the axillary artery access site.

There was one case of major vascular complication in combination with major bleeding, a dissection of the axillary artery distal to the vascular closure device, which was solved by stenting.

There were two other major bleedings not associated with the transaxillary access (haematuria after a urinary catheter, and bleeding after a central venous catheter).

One patient suffered a large post-operative ultimately fatal stroke. There was no other 30-day mortality.

Discussion

We studied the first 16 cases at our institution of transaxillary TAVI with percutaneous access. Almost half of the patients did not achieve immediate haemostasis with the MANTA VCD. Although placement of a covered stent solved the problem and only one case of major bleeding was associated with the access site, this is a much higher failure rate than in transfemoral TAVI [4].

Reasons for this higher failure rate in TAx TAVI might be that manual compression of the access site is more difficult in the transaxillary access. It is also possible that a routine balloon occlusion of the access site for 5-10 minutes after MANTA deployment would have reduced the number of failures. In half of the patients the axillary artery diameter was less than 5,5 mm, which is lower than the recommended artery size for MANTA, and might contribute to a higher failure rate. (figure 1)

In the largest published experience with vascular closure device after TAx TAVI another closure device (Proglide, Abbott, Abbott Park, IL) had a lower failure rate [1].

Since two of three major bleeding complications were not related to the transaxillary access site but to urinary and central venous catheters, performing the procedure under local anaesthesia in a more minimalist way might decrease bleedings.

Limitations

This is a small single-centre experience which might limit the generalizability.

Conclusions

Percutaneous transaxillary TAVI using the MANTA VCD was associated with a high failure rate, although placement of a covered stent achieved haemostasis in all cases.

Impact on daily practice:

This study shows that percutaneous access and closure in transaxillary TAVI is safe. However, the MANTA vascular closure device seems to have limitations in transaxillary access.

Funding: None

Conflicts of interest:

Andreas Rück has received lecture honoraria, research support and proctor fees from Boston Scientific and Edwards Lifesciences.

Daniel Eriksson, Dinos Verouhis and Matthias Corbascio have no conflicts of interest.

Nawzad Saleh and Rickard Linder have received lecture honoraria and proctor fees from Boston Scientific.

Magnus Settergren has received lecture honoraria and proctor fees from Abbott, Boston Scientific, Medtronic, WL Gore and Edwards Lifesciences.

References

1. Schäfer U, Deuschl F, Schofer N, Frerker C, Schmidt T, Kuck KH, Kreidel F, Schirmer J, Mizote I, Reichenspurner H, Blankenberg S, Treede H, Conradi L. Safety and efficacy of the percutaneous transaxillary access for transcatheter aortic valve implantation using various transcatheter heart valves in 100 consecutive patients. *Int J Cardiol*. 2017;232:247–54.

2. De Palma R, Rück A, Settergren M, Saleh N. Percutaneous axillary arteriotomy closure during transcatheter aortic valve replacement using the MANTA device. *Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv*. 2018;92:998–1001.

3. Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, van Es G-A, Hahn RT, Kirtane AJ, Krucoff MW, Kodali S, Mack MJ, Mehran R, Rodés-Cabau J, Vranckx P, Webb JG, Windecker S, Serruys PW, Leon MB, Valve Academic Research Consortium (VARC)-2. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document (VARC-2). *Eur J Cardio-Thorac Surg Off J Eur Assoc Cardio-Thorac Surg*. 2012;42:S45-60.

4. De Palma R, Settergren M, Rück A, Linder R, Saleh N. Impact of percutaneous femoral arteriotomy closure using the MANTATM device on vascular and bleeding complications after transcatheter aortic valve replacement. *Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv*. 2018;92:954–61.

Figure legend

Figure 1. Angiographic images of the left axillary artery. Panel A: deployment of the MANTA vascular closure device (red arrow), from the radial access a 7 mm balloon (blue arrow) is positioned over the hydrophilic wire. Panel B: good haemostasis, red arrow shows the metal marker on the MANTA device.