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CASE REPORT

Late Pseudoaneurysm After Access Site Closure with Manta in Transfemoral Aortic Valve Implantation

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Introduction: Access site vascular complications in transfemoral transcatheter aortic valve implantation (TF-TAVI) are still a major concern. Recently, a novel collagen plug based closure device (Manta) was introduced. The results from the first reports on Manta are very promising, but not much is known about the long-term patency.
Report: A case of late pseudoaneurysm after access site arterial closure with Manta in TF-TAVI is described. The patient presented five weeks after left sided TF-TAVI with pain and claudication like symptoms in the left leg. CT angiography revealed a pseudoaneurysm at the puncture site. The patient was successfully treated by vascular surgery.
Discussion: The results from recent peri-operative reports on the Manta vascular closure device (VCD) are promising, but not much is known about the long-term patency. In the present report a patient is described who developed a pseudoaneurysm several weeks after access site closure with Manta. To the authors' knowledge, no such late access site complications after use of the Manta VCD have been reported previously.

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INTRODUCTION

There has been a development towards a minimalist approach to TF-TAVI and percutaneous vascular closure devices (VCD) are used even in large diameter arterial access of 14—22 French (Fr).[1] However, access site bleeding and vascular complications in TAVI are still a major concern.[2]

Recently, a novel closure device (Manta, Essential Medical Inc., USA) has been introduced in Europe.[3,4] The Manta is a collagen based vascular plug for post-procedure closure of large bore access sites. Briefly, the Manta consists of an intra-arterial toggle and an extravascular collagen plug and a stainless steel suture lock which keeps the toggle and the collagen plug together. The Manta is delivered in 14 and 18 Fr, for punctures of 10—22 Fr.[3]

The results from the first reports on Manta are very promising, but not much is known about the long-term patency. To the authors' knowledge, there are two studies presenting 30 day data,[5,6] whereas others present peri-operative results.[3,4]

REPORT

A 73 year old male with aortic stenosis was admitted to Oslo University Hospital, Ullevaal, Oslo, Norway, for TAVI. The patient's medical history included hypertension, diabetes, and atrial fibrillation. The patient had aortocoronary surgery in 1992. Because of increasing chest pain and dyspnoea (NYHA 2, CCS 2), coronary angiography was performed. The angiogram showed a patent left internal mammary artery to left anterior descending artery, patent aortocoronary graft to the CX while the graft to the RCA was occluded. Echocardiography revealed a high grade aortic stenosis with mean gradient of 45 mmHg, aortic valve area 0.5 cm^2, and ejection fraction 34%. STS/ACC TAVR risk score was 2.46.

Left common femoral artery (CFA) access was chosen. The smallest lumen diameter in the left CFA was 7.4 mm. Calcification was graded as moderate to severe.

CFA puncture was made by a highly experienced interventional cardiologist under fluoroscopy using a J-tip wire at the puncture level, introduced by an ipsilateral peripheral puncture. The puncture site was distal in the CFA. A Sentrant 16 Fr sheath was used and sheath size/CFA ratio was 0.72. TAVI was successfully performed using a Medtronic Evolut PRO 29 mm valve. The patient received intravenous

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heparin and activated clotting time was 345 s. Vascular closure was started after reversing the heparin effect with intravenous Protamine 50 mg. The 16 Fr access site was sealed using a 14 Fr Manta, without any visible bleeding on post-procedural angiography. The next day a biventricular pacemaker was implanted because of an AV block III. Otherwise the procedure was uneventful, and the patient left the hospital on the third post-TAVI day. There was no unexpected discomfort or bleeding from the puncture site. The patient was prescribed acetylsalicic acid (ASA) 75 mg/day and NOAC (apiksaban 5 mg × 2).

Five weeks after the TF-TAVI procedure the patient was admitted to Akershus University Hospital with increasing discomfort from the left groin and claudication symptoms. CT angiography was performed and showed a pseudoaneurysm at the 16 Fr access site in left CFA (Fig. 1). The aneurysm compressed the underlying artery and there was also a dissection distal to the puncture site. The decision was taken to perform vascular surgery, which was successful. The patient received five units of blood products in total. The post-operative course was uncomplicated and the patient was discharged home on post-operative day three. Three months post TAVI the patient is asymptomatic from the left leg.

Ethical considerations

The patient signed written informed consent to publication of the case.

DISCUSSION

Vascular complications and large haemorrhage volume are associated with prolonged hospital stay and increased morbidity and mortality,[2,7] and access site complications constitute a major part of the total number of vascular complications during TF-TAVI. Thus, low complication rates are of great importance for any new vascular closure device introduced. The first reports on Manta VCD are promising, but not much is known about long-term patency. There are two studies presenting 30 day data,[5,6] whereas others present peri-operative results.[3,4] In a recent registry study, an increased number of access site complications was

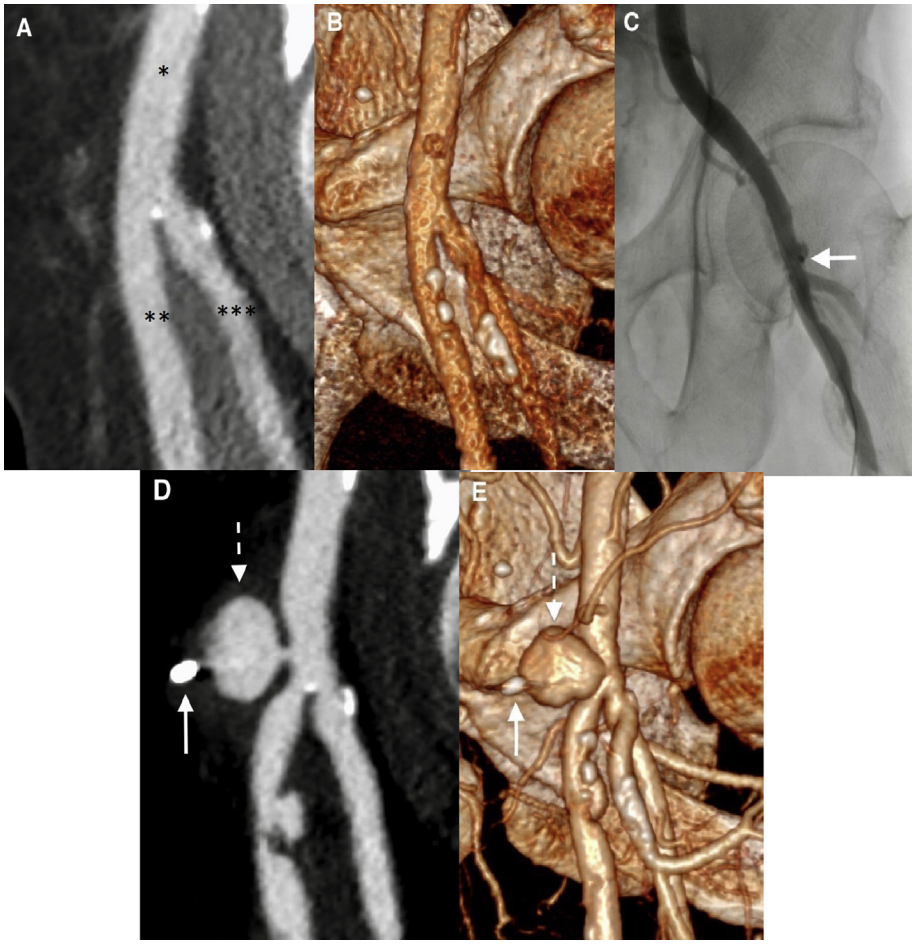

Figure 1. (A,B) CT angiography of left femoral artery pre TAVI. (A) Multiplanar reformat and (B) volume rendering. (C) Angiography after TAVI. Vascular closure with Manta, without any bleeding at the puncture site. Solid arrow indicates steel suture lock well apposed to the arterial wall. (D,E) CT angiography 7 weeks post TAVI. (D) Multiplanar reformat and (E) volume rendering at puncture site. Manta suture lock (solid arrow) anterior to the pseudoaneurysm (stapled arrow). * Indicates common femoral artery, ** superficial femoral artery, and *** deep femoral artery. The same anatomical region is displayed in (B)—(D).

reported in Manta compared with ProGlide during the index hospital stay.[8] The present report describes a patient who experienced a pseudoaneurysm five weeks after access site closure with the Manta VCD. To the authors' knowledge, no such late access site complications after use of the Manta VCD have been described previously. The 14 Fr Manta is acceptable for use in up to 16 Fr sheath size,[9] which applied in the present patient. This mismatch in size may perhaps have contributed to late formation of the pseudoaneurysm. Until this is resolved, 18 Fr Manta should be used for 16 Fr puncture sites. The present patient had calcification in the pelvic arteries, but the access site itself was not calcified on the anterior wall. In addition to ASA, the patient was also prescribed NOAC because of atrial fibrillation. Otherwise there were no severe risk factors for access site vascular complications. The patient's BMI was 26 and the sheath size/CFA ratio was 0.72, indicating a low risk of access site vascular complications.[2]

After finishing the TAVI procedure an angiogram is done to confirm satisfactory closure of the large bore puncture site. If there are any clinical puncture site complications before discharge, duplex ultrasound or CT angiography is performed. Late complications, such as the one described in this report are uncommon. Therefore, control imaging is not routinely performed. It is suggested, however, that when new vascular closure devices are introduced into clinical practice, duplex ultrasound should be performed one week after the procedure.

The present case report describes a patient who experienced a pseudoaneurysm five weeks after access site closure with the Manta, so observations should also be made for possible pseudoaneurysm in patients presenting with discomfort from the arterial access site for some weeks after percutaneous arterial large bore closure.

CONCLUSION

There is limited knowledge on the long-term patency of the Manta VCD. The present case report reinforces the need for vigilance for pseudoaneurysms in patients presenting with discomfort from the arterial access site up to several weeks after percutaneous arterial large bore closure with the Manta. In the present patient, a 14 Fr Manta was used in a 16 Fr sheath size. This mismatch in size may have contributed to the late pseudoaneurysm reported here. Until this sizing issue is resolved, 18 Fr Manta should be used for 16 Fr puncture sites.

Limitations

Angiography at the end of the TAVI procedure was performed in only one projection. No bleeding or other complication was seen, but a second projection may have given additional information. There were no symptoms from the puncture site before discharge, so no further imaging was done. The patient was admitted five weeks after the TAVI procedure, but the exact onset of symptoms is not clear.

Future directions

Completion angiography to confirm successful closure of percutaneous large bore vascular punctures should be done in two orthogonal projections. When a new vascular closure device is introduced into clinical practice, duplex ultrasound should be performed at one week. Clinicians should be aware of possible pseudoaneurysm in patients presenting with discomfort from the arterial access site up to several weeks after closure with the Manta VCD.

CONFLICTS OF INTEREST

None.

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