

Multicentre Study of Effectiveness of MANTA closure device after Percutaneous Femoral Access for EVAR and TEVAR

Dammrau R. A. 1,2,3, Kalmykov E.L. 1

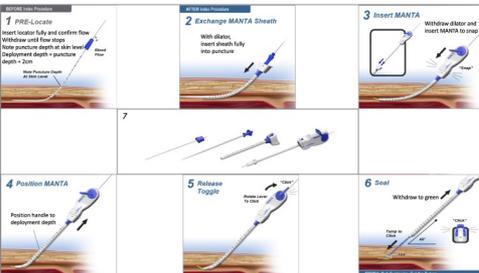
1:Vascular and Endovascular Surgery, Katharinen Hospital Frechen, 2: Cardiothoracic Surgery, Helios Klinikum Siegburg
3: Vascular and Endovascular Surgery, Helios University Hospital Wuppertal 

Introduction

With the development of endovascular therapy with the use of big diameter sheaths or cannula there are now several techniques of closure available to allow percutaneous treatment. Percutaneous access for EVAR and TEVAR can reduce the operation time and the number of local complications, more over its improves a cosmetic results.

Manta Closure Device

The MANTA® Device is the first commercially available biomechanical vascular closure device designed specifically for large bore femoral arterial access site closure.1 Available in 14 Fr. and 18 Fr., a single MANTA® Device effectively closes femoral arterial access sites following the use of sheaths ranging from 12 Fr. to 25 Fr. O.D.



Study

Methods: A retrospective multicenter study with 3 participating hospitals was performed.

A total number of 212 patients was included in the study.

All 212 patients were treated between April 2017 and October 2021 for abdominal aortic aneurysms and thoracic aortic pathology as dissections or aneurysm. There were 33 females and 179 males.

The mean age was 68±6 years. In all patients the procedure was done through femoral access one or both sides, we used 12-24F sheaths for graft implantation. The primary effectiveness endpoint was a technical success, freedom of acute bleeding and thromboembolic events.

After intervention in all cases were used groin elastic bandage for 24 hours.

Puncture Technique: The common femoral artery was punctured in a 45 degree angle under duplex ultrasound to confirm the puncture side at the anterior wall of the vessel outside of calcified plaques. We used in all cases the dryseal sheath from Goremedical which has a hydrophilic coating. With small vessels we prepared the sheath with propofol outside.

Results: Technical success of MCD implantation was 100%. In two cases was groin hematoma after 24 hours, no revision was necessary. After interventions no major vascular access site complications requiring surgical treatment was diagnosed.

No thrombotic or embolic complication during hospitalisation were detected. No any local aneurysm in 6 month were detected.

Patients	212	100%
males	179	84,4
females	33	15,6
mean age	68±6 years	
sheaths	12-24 french	
Technical success of MCD implantation	100%	
Major complications (acute bleeding, acute lower limb ischemia due to thromboembolic events)	0	0
Local complications follow up 6 months	2 No complications	0,94% 0

Discussion

In a series of 212 consecutive patients treated with EVAR or TEVAR we had remarkable low complications. One of the reasons for this seems to be the puncture technique, as we use non calcified vessel wall the closure device seals better. The immobilisation and consequent compression bandage helps too.

Conclusion

MANTA closure device is safe, effective and easy to use for vascular access with big sheaths and allows percutaneous aortic graft implantations..

References:

- Schaefer A, Sarwari H, Reichenspurner H and Conradi L (2021) A Novel Plug-Based Vascular Closure Device for Percutaneous Femoral Artery Closure in Patients Undergoing Minimally-Invasive Valve Surgery. Front. Cardiovasc. Med. 8:682321. doi: 10.3389/fcvm.2021.682321
- Kmiec L, Zerditzki M, Schmid C, Debl K, Sossalla S, Hilker M, Holzamer A. Evaluation of the MANTA Vascular Closure Device in Transfemoral AVI. Thorac Cardiovasc Surg. 2021 Jun 27. doi: 10.1055/s-0041-1730972. Epub ahead of print. PMID: 34176110.
- Case BC, Yerasi C, Forrestal BJ, Kumar S, Musallam A, Chezaz-Azerrad C, Khalid N, Shlofmitz E, Khan JM, Satler LF, Ben-Dor I, Rogers T, Waksman R. Real-World Experience of the MANTA Closure Device: Insights From the FDA Manufacturer and User Facility Device Experience (MAUDE) Database. Cardiovasc Revasc Med. 2021 Jun;27:63-66. doi: 10.1016/j.carrev.2020.11.023. Epub 2020 Nov 20. PMID: 33402323.