

CASE SERIES OF WATCHMAN FLX LEAKS AND INNOVATIVE CLOSURE METHODS

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Background:

Atrial fibrillation puts affected individuals at an increased risk of stroke due to the propensity for clot formation. Specifically, in patients with nonvalvular atrial fibrillation (NVAF), the majority of clots are formed within the left atrial appendage (LAA) due to a combination of fibrosis, inflammation, and blood flow stasis. Consequently, obliteration or occlusion of LAA in NVAF is considered an effective measure for stroke prevention. In addition to a risk of thrombus formation for endocardial devices, incomplete appendage exclusion is a drawback shared by any closure technique (percutaneous, hybrid, or surgical) targeting the LAA. We present 2 cases of WATCHMAN FLX leaks and innovative closure techniques used for LAA leak closure.

History and Physical:

<u>Case 1:</u> Patient is a 83 year old female with a medical history of Atrial Fibrillation, Recurrent CVA. Patient has had multiple previous CVAs despite being on various anticoagulants. Hematology was closely following the patient. After extensive workup and multidisciplinary approach, a shared decision was made to perform LAA occlusion with watchman device. Follow up TEE status post watchman showed multiple 5mm leaks which communicated to the tip of LAA. We then did a successful implant of Left atrial appendage TERUMO coils and Vascular Plugs for persistent left atrial appendage leak occlusion.

Case 2: Patient is a 71 year old male with a medical history of ESRD s/p renal transplant, CAD, Atrial fibrillation, Anemia deemed high bleeding risk for OAC use. After multidisciplinary approach, a shared decision was made to perform LAA occlusion with watchman device. Follow up TEE status post watchman showed a persistent leak of > 5mm with connection into the distal tip of the LAA. We then did a successful implant of the AMPLATZER PFO 18/25mm occluder device for persistent left atrial appendage leak occlusion.

Imaging:

Leak closure with TERUMO coils and Vascular Plugs on the left, Leak closure with AMPLATZER PF0 18/25mm occluder device on the right





Indications for Intervention:

Atrial Fibrillation with recurrent strokes

Multiple 5mm leak status post watchman device implantation

Persistent leak after LAA closure

Intervention:

Case 1: The area overlying the right and left groin was prepped and draped in the usual sterile fashion. The right femoral veins were then accessed with a needle with direct real time ultrasound guided visualization of puncture and guidewire access and was saved with a printout in the paper chart. 2 guidewires were then placed in the right femoral vein with the above approach. A long 10F sheath was placed in the left femoral vein and an Agilis sheath was

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placed in the right femoral vein. ICE catheter was inserted through the 10F venous sheath & advanced into the right atrium. The TS puncture for LA access with the Agilis was low and anterior and a mid puncture was also performed through which the ICE was advanced into the LA. Subsequent boluses of IV heparin were administered to achieve a target ACT of 300s throughout the duration of the left sided procedure. A 5F BERN catheter was advanced through the Agilis and the leak above the WATCHMAN device was accessed easily. This was guided with ICE imaging as well. Contrast injection opacified the leak which clearly communicated to the tip of the LAA. At this point a TERUMO framing coil was then advanced. TERUMO hydrogel coils were then advanced. After multiple coils were placed a 6 mm Vascular Plug on the anterior and the posterior leaks using the microcatheter to advance the Cordis MP2 delivery catheter. The leak was fully occluded and final contrast showed full leak closure with distal contrast hang up confirming full seal.

Case 2: The area overlying the right and left groin was prepped and draped in the usual sterile fashion. Ultrasound guidance was used to assist with access. ICE catheter was inserted through the 9 F venous sheath & advanced into the right atrium for monitoring transeptal, monitoring for complications and assessing watchman position. TEE was used for LAA anatomy and final leak measurements and position. Both sheaths were placed in the right femoral vein. A 6 Fr right radial artery was placed in the wrist and a carotid Artery sentinel protection was placed under fluoroscopy and position to prevent any embolic debris escaping to the brain. A 16 French sheath was placed in the RFV and using the bayliss transeptal sheath, the Bayliss transeptal needle, the transeptal access was obtained and was exchanged over a long wire for an CRYOFLEX sheath. We then advanced a Cordis into the LAA and various cine views were taken. TEE was previously placed and views were obtained to size the device. There was a leak > 5mm with connection into the distal tip of the LAA. We decided on a AMPLATZER PFO 18/25mm occluder device. Using the de-sheathing technique a device was extruded and then advanced into position and tug test and contrast images showed good placement. After confirming position, stability there was no leak and device was released.

Learning points of the procedure:

Residual leaks are common after LAA closure, with <u>1-year follow-up of the PROTECT AF</u> <u>trial</u> showing that nearly one-third of patients who had been implanted with the Watchman device had incomplete occlusion of the appendage. Coils, plugs, and occluders have emerged as potentially useful tools for closure of peridevice leak following LAAO. Transcatheter LAA leak occlusion using endovascular coils appears to be a safe, effective, and promising approach in patients at high echo time risk with incomplete LAA closure. In our first patient with multiple leaks, it was challenging to use TERUMO coils and Vascular Plugs to occlude the leaks. In our second patient with leak >5 mm with anatomic features which do not meet the manufacturer's requirements for LAA occluding device, off-label use of AMPLATZER PFO Occluder seems to be an another great alternative for LAA leak closure. It is crucial that we continue to find innovative solutions to emerging challenges in transcatheter interventions.