SCAI Fellows Course Case

Retrieval of a Locked Helex septal occluder device

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Case Report

- 45 year fireman (6’2”’) without prior medical problems presented with right sided hemiparesis one week after varicose vein stripping.
- MRI demonstrated a left anterior cerebral artery occlusion.
- Treated with tissue plasminogen activator (tPA).
- Transcranial Doppler showed a Spencer grade 5 shunt.
- Lower extremity ultrasound demonstrated a greater saphenous vein occlusive thrombus.
- Transesophageal echocardiography revealed a PFO. He refused randomization in the RESPECT multi-center clinical trial but agreed to percutaneous PFO closure to prevent further neurologic sequelae.
Case Report

- An 8-French Acuson AcuNav intracardiac echo (ICE) probe was used to guide the placement of a Helex 25mm septal occluder device across the inter-atrial septum
Case Report

- Five minutes after release of the device, the right atrial disk was observed to have slipped off of the limbus of the septum secundum and was now resting in the PFO tunnel.
Case Report

- The position and width of the device within the PFO tunnel was felt to be stable enough to remain within the PFO until fibrous tissue formed to seal the tunnel.
Case Report

- A transthoracic echo was performed the following week and at one month. These showed the device was in a stable position on the interatrial septum without a residual shunt.
- The patient was asymptomatic. He returned for a TEE at three months, our standard protocol.
- The TEE revealed a patent foramen ovale without visualization of the device.
• On fluoroscopy, the device had embolized to the descending abdominal aorta near the renal arteries.

• The patient was brought back to the catheterization lab 3 days later and percutaneous retrieval of the Helex device and PFO closure was performed.
Case Report

- Two 8-French sheaths were placed in the right femoral vein and a 6-French sheath was placed in the left femoral artery.
- 3000 units of intravenous heparin was administered.
- The arterial site was “preclosed” using two Perclose Proglide closure devices.
- A 10 French Flexor sheath was inserted into the femoral artery and placed caudal to the device.
Multiple views of the device were obtained in order to identify the position of the LA and RA islets.
Case Report

• A 6-French multipurpose diagnostic catheter with a 12-20mm EnSnare, followed by a 6-French JR4 diagnostic catheter with a 35mm gooseneck snare was used to capture the left atrial eyelet, successfully releasing the locking loop and allowing the device to unravel.
Mechanism of Retrieval

- The Helex device is a single nitinol wire covered by polytetrafluoroethylene (PTFE) with a LA eyelet, center eyelet and RA eyelet.
- A locking loop from the left atrial side to the right atrial side holds the device together after deployment.
- The Helex device has a white retrieval cord which allows for retrieval of devices which do not lock appropriately.
The embolized Helex device was retracted into the Flexor sheath. The right atrial eyelet (narrow arrow) hooked on the distal tip of the sheath (wide arrow).
The patient’s PFO was closed uneventfully with a 30mm Amplatzer (AGA Medical) cribriform device. The patient was discharged home the same day. He has done well for 3 years.
Conclusions

• The migration of the Helex device off the limbus of the septum secundum, into the PFO tunnel ultimately resulted in embolization of the device.

• Percutaneous retrieval of a locked Helex device is easiest with a stiff tip 10-French sheath, such as the Flexor sheath, a gooseneck snare and capture of the left atrial eyelet to allow the device to unlock.
Mechanism of Retrieval

- Devices that are not locked can also be retrieved with a snare and the Helex delivery sheath.
- Devices that are locked are much more difficult to retrieve.
- Helex devices can embolize to the pulmonary arteries, cardiac chambers or aorta.
- Successful retrieval requires understanding the mechanics of the Helex device and knowledge of potential retrieval methods.
This experience was helpful in this subsequent case:

**Sizing issues during PFO Closure**

38yo man in active military duty had a stroke with mild residual numbness. Workup found no obvious cause for stroke and a PFO was present. No hx of migraines. Unable to take anticoagulants and remain in military. Thus he refused to be randomized.
Doppler flow thru PFO

Balloon sizing
PFO diam= 12mm
25mm Helex superior edge does not extend over the septum secundum.

No “Pac-man” sign

What would you do now?
30mm Helex Device
Take Home Points

1. Despite balloon sizing, the 25mm Helex did not cover or splay over the septum secundum. The device could slip into and through the PFO tunnel.

2. The 30mm device covered the septum secundum. Despite not being as strong of a spring as the smaller 25mm device, it showed no echo contrast passing across the septum.

3. However....
Larger Helex device size associated with greater frequency of residual shunting

- 106 patients with Helex device
- 95 patients had TCD every 3 months after PFO closure
- Average time of the PFO closure occurred at month 5.2 ± 3.5
- Helex 30mm device demonstrated the lowest closure rate = 60%