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Patent Foramen Ovale Closure Devices for Preventing Recurrent Cryptogenic Strokes

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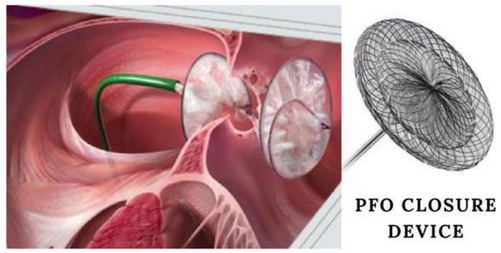
Introduction:

A patent foramen ovale (PFO) is a hole in the atrial septum used for fetal circulation. After birth, this hole usually closes to increase blood pressures within the heart. In 25% of the world's population, the septum never fully closes. A PFO causes a right to left shunt where emboli can travel from the venous side to the arterial side causing a stroke. Cryptogenic strokes are unexplained in origin but may be caused by a PFO. (Kern, 2016)

Treatment Options:

Surgical Closure requires a thoracotomy and cardiopulmonary bypass. This treatment option is rarely chosen, unless the patient is already receiving another open cardiovascular procedure. 73% of the surgical patient's still have recurrent cryptogenic strokes due to incomplete PFO closure. (Saver, 2018)

PFO DEVICE:



The image above demonstrates a PFO closure device

https://www.openpr.com/news/1031493/global-pfo-closure-device-market-poised-to-take-off-by-2023.html

The Amplatzer device is a double-disk nitinol mesh and polyester fiber device that sits on either side of the septal defect. (Kern, 2016)

This design has caused significantly less complications than other devices.(Saver, 2018)

Drug Therapy Compared to Device Closure

Six randomized clinical trials were conducted comparing medical drug therapies to a PFO closure device. Each trial looked at different combinations of treatment options with different drug therapies and devices. (Saver, 2018)

The RESPECT Trial conducted in 2013 was the first trial that showed a significant impact in reducing recurrent cryptogenic strokes by 45 percent, making the closure device the standard of treatment. (Saver, 2017)

Trials conducted from 2017 to 2018 such as the DEFENSE-PRO Trial further developed PFO device methods over medical drug therapy alone. It was found to be more significant for patient's who have an aneurysmal atrial septum and a PFO. (Saver, 2018)

Case Study:

The patient is a 62-year-old male with a history of cerebrovascular disease and hypertension. He had a recent Cerebrovascular Accident (CVA) and was found to have a PFO.

Pre-Op Imaging Studies:

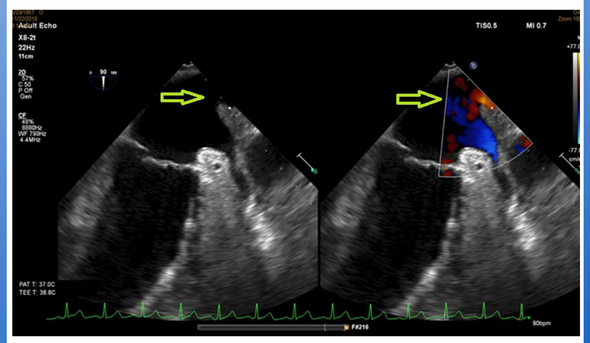
CT with intravenous contrast:

- Used to determine size and shape of defect. (Pathan, 2018)

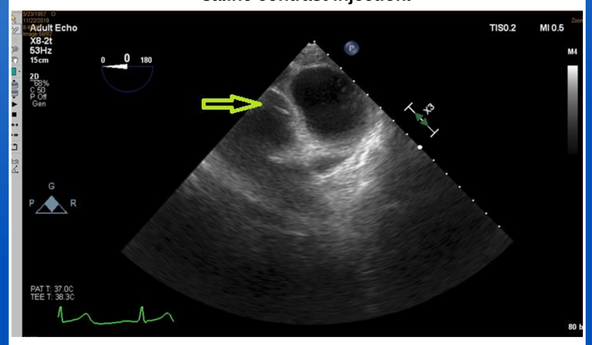
No malignancy identified in the chest, abdomen or pelvis. No concerning findings.

Transesophageal Echocardiogram (TEE):

- Used to evaluate the atrial septum before, during and after the procedure. (Pathan, 2018)



The Image above demonstrates a presence of a small right to left shunt through the PFO while at rest by saline contrast injection.

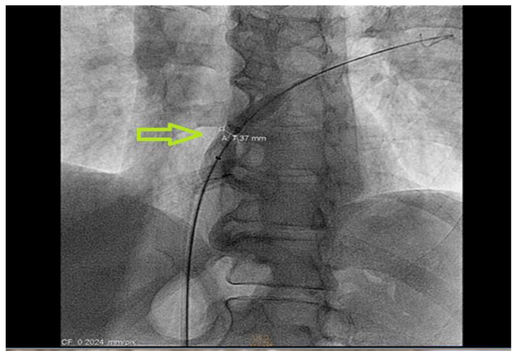


The image above demonstrates the atrial septal defect. This image shows a mildly aneurysmal atrial septum and no mass or thrombus present on atrial appendage.

The patient was considered for a PFO closure device due to his recurrent cryptogenic strokes. All other test performed were considered normal.

PFO device insertion:

The patient was given mild sedation and a local anesthesia to both groins. Vascular access was obtained in both femoral veins. A Swan-Ganz Catheter was introduced to evaluate right heart pressures and blood saturations. A 5 Fr multipurpose catheter was used to cross the PFO and was positioned in the pulmonary vein. The catheter was replaced with a 9 Fr sheath and advanced across the defect with an Amplatzer wire. The PFO was evaluated with a sizing balloon to determine what size device would be used. (Kern, 2016)



The image above demonstrates the sizing balloon measuring the size and shape of the defect

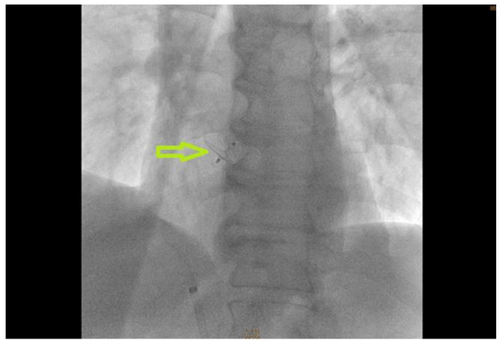
After sizing the defect, a 25 mm Amplatzer PFO occluder device was prepared and passed through the delivery sheath. The left atrial disk was deployed, and the right atrial disk was deployed. Fluoroscopy and an intracardiac echo were used to determine correct placement. The Minnesota Wiggle Test was also performed to determine accurate placement and sizing.

The Minnesota Wiggle Test is performed to ensure the device is stable enough to be released. The physician gently pushes forward and pulls backwards on the Amplatzer wire. Successful placement is determined by the lack of movement of the device in either direction. (Kern, 2016)

The device is released off the delivery wire using a pin vise, rotating the wire in a counterclockwise motion. (Kern, 2016)

The device was detached and a bubble study with Valsalva maneuver was performed to assess for shunting. (Kern, 2016)

PFO Device deployed:



The Image above depicts the deployed closure device

Post procedure patient care:

The long 9 Fr sheath was replaced with a short 9 Fr sheath and secured with a figure of 8-stitch to be removed later

- Limited TEE study before discharge
  - no atrial shunt demonstrated
- Infective endocarditis prophylaxis for at least 6- 12 months
- Recommended 81 mg of Aspirin per day indefinitely.
- Recommended Clopidogrel 75 mg at least 3 months.
- Follow-up TEE appointment at 3 months. If closure is complete, Plavix may be stopped.

Conclusion:

There are several treatment options used to treat cryptogenic strokes in patients who have a patent foramen ovale. Open surgical procedures prove to be unnecessary due to the harm it can cause to patient. Medical drug therapy alone still puts the patients at risk to have recurrent ischemic strokes because the physical problem is not being treated. PFO closure devices when combined with medical drug therapies have been found to significantly impact the rate of recurrent cryptogenic strokes in PFO patients.

Because of the success in the RESPECT Trial, the FDA approved the PFO occluder as a viable treatment option on October 28, 2016. (Mojadidi, 2018)

This option is continuously being studied in attempt to further advance it making it more effective for future patients. This life saving treatment significantly improves the quality of life for recurrent cryptogenic stroke patients.

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