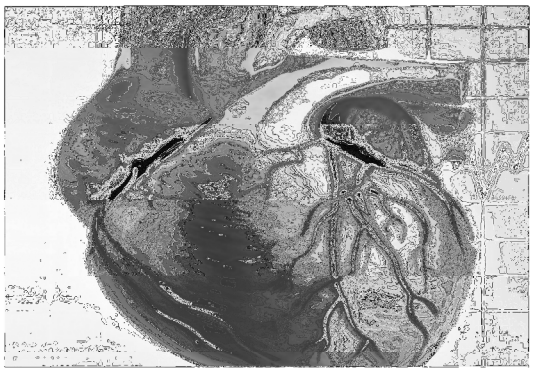
Oklahoma Heart Institute

Managing the Interventional Patient: PFO & ASD

Lauren Stegemann, APRN-CNS

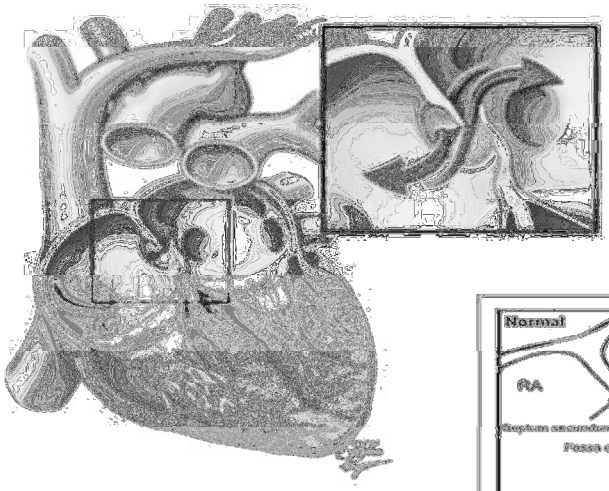
No Disclosures

Overview

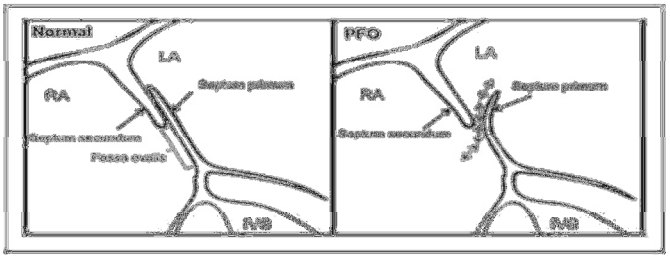


- Anatomy & Pathophysiology review
- What Can Be Done?
- Work-Up
- Pre-Procedure
- Intra-Procedure
- Post-Procedure
- Post-Discharge Care

Patent Foramen Ovale

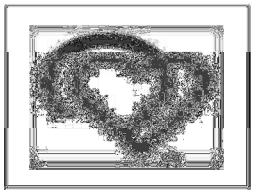


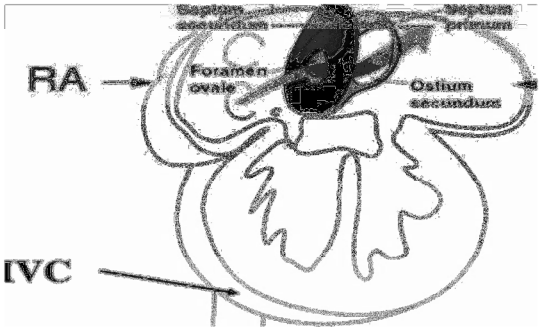
- Associated with stroke
- Right-to-left shunting can allow for paradoxical emboli
- 40% of patients with cryptogenic stroke



A patent foramen ovale is a flap-like opening between the right and left atria. We care about it because of its association with stroke. In fetal circulation, the foramen ovale functions to allow the oxygenated blood from the mother to pass from the right side of the heart to the left, bypassing pulmonary circulation. This picture shows the septum secondo and this flap, the septum primum, that allows for that right to left flow of blood. At birth, the pressures on the left side of the heart become greater than the right, which pushes the septum primum against the septum secondo; they usually by 6 months but at least by age 2 to form the fossa ovalis. In about 25% people, this fusion does not occur which leaves the patient with a patent foramen ovale. Most people with this defect are asymptomatic. However, if there is any right to left shunting across the defect this opening can allow for paradoxical emboli, where venous emboli to pass into arterial circulation, and if they travel to the brain, they can lead to a stroke In patients who have had a cryptogenic stroke, or stroke of unknown origin, the prevalence of PFO rises to 40%. PFOs may also be associated with migraine and vascular headaches.

Atrial Septal Defect
Ostium Secundum

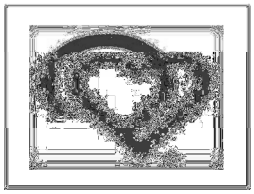


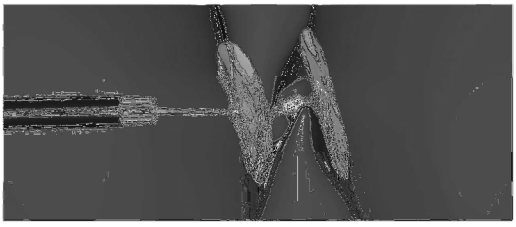


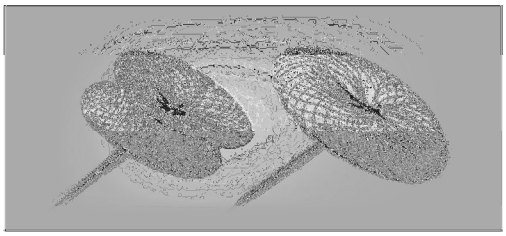
- 75% of all ASDs
- Primarily left-to-right shunting, can progress to right-to-left
- Can lead to RV failure and pulmonary hypertension
- Exercise intolerance, dyspnea, fatigue
- Risk for paradoxical embolism

Atrial septal defects are true holes in the heart; they account for one third of all congenital heart defects. There are three types: ostium primum, ostium secondum, and sinus venosus. Ostium secundum defects are the kind we can close percutaneously and they are about 75% of all ASDs. The picture shows the ostium secondum, another fetal cardiac structure that is centrally located on the atrial septum like the foramen ovale. This defect is caused by either a septum secundum that is too small to cover the ostium secundum or an excessively large ostium secundum that the septum secundum can't cover. So, too little a cover or too big a hole. These patients will have shunting between the two sides of the heart, the amount and direction of shunting depends on the size of the defect and the compliance of the ventricles and can change over time. The shunting is primarily left-to-right but the can have transient right-to-left shunting. Overtime this can cause RV failure and pulmonary hypertension. Depending on the hemodynamic effect, these patients can be symptomatic with exercise intolerance, dyspnea, fatigue and heart failure symptoms; this usually happens later in life. They can also have atrial arrhythmias. Like the PFO, these patients are at risk for paradoxical embolism and there may be some correlation to migraine headaches.

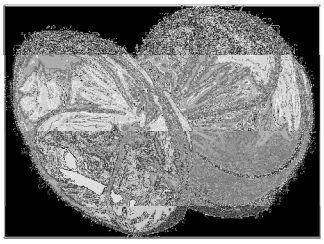
What Can Be Done?
PFO





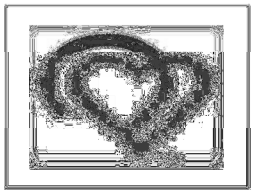


- Prevent recurrent stroke
  - Life-long anticoagulation
  - Closure with device

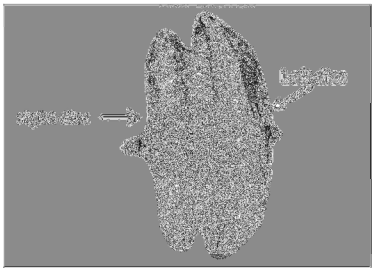


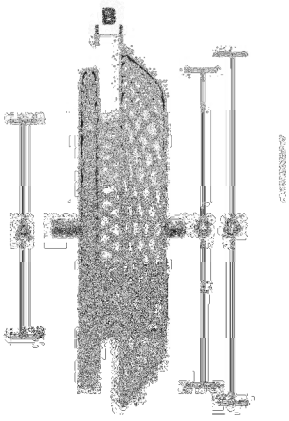
To prevent recurrent stroke in patients with a PFO, the patient can either take life-long anticoagulation which does carry a bleeding risk, or we can close PFOs percutaneously with a septal occluder device. That device sandwiches the atrial septum to close off the communication between the left and right sides of the heart.

What Can Be Done?
ASD



- Prevent RV overload, stroke
- Septal occluder device

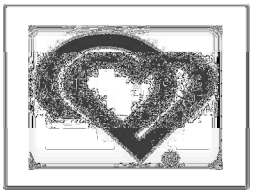


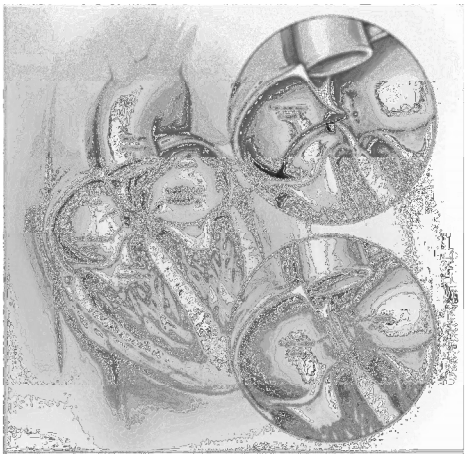


In ASD patients, to prevent progression of those changes to the right ventricle from that shunting of blood and also to protect against stroke, again, we can close that defect percutaneously to cut off the communication between the two sides of the heart. And if you notice, the types of devices used are different depending on the defect.

Who Gets Closed? PFO

- Paradoxical embolism
- Right-to-left shunting
- High risk features:
  - Atrial septal aneurysm
  - Mobile interatrial septum
  - Size ≥ 2 mm

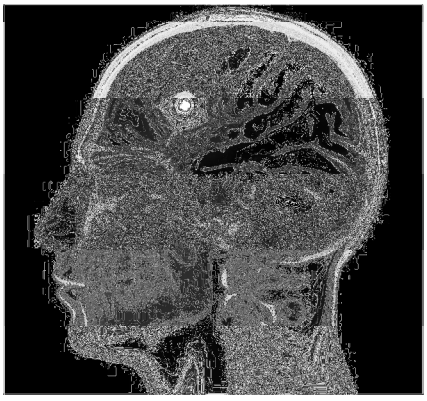




Patients who would benefit from closure of their PFO are those who have had a paradoxical embolism, such as a cryptogenic stoke, for secondary stroke prevention. High-risk features include an atrial septal aneurysm, a mobile interatrial septum with excursion of the septum >10 mm, and a size >2mm during Valsalva. Closure is recommended for those under 60, as that's the population that was studied, but those over 60 can be closed if they have strong evidence for a paradoxical embolism such as DVT or if they are contraindicated or opposed to lifelong anticoagulation.

PFO Guidelines

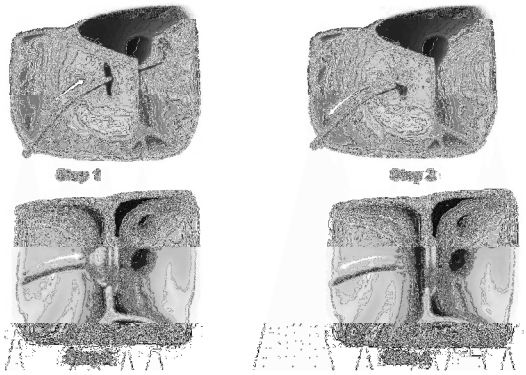
- Guidelines need updating
- RESPECT: Reduction in recurrent stroke with PFO closure versus medical therapy
- Meta-analysis of three early trials: PFO closure superior to medical therapy
- CLOSE, REDUCE: Lower risk of recurrent stroke with PFO closure versus antiplatelet therapy



Of note, the current guidelines for closure will likely be seeing an update based on some recent trials. In 2013, RESPECT, the largest PFO trial, was a randomized trial that showed a 50% reduction in recurrent stroke with closure versus medical therapy. In 2016, there was a meta-analysis of three early PFO closure trials that found PFO closure superior to medical therapy. There were also a couple of randomized controlled trials that came out last year, CLOSE and REDUCE that both showed that patients who underwent PFO closure had a lower risk of recurrent stroke compared to antiplatelet therapy.

Who Gets Closed?
ASD

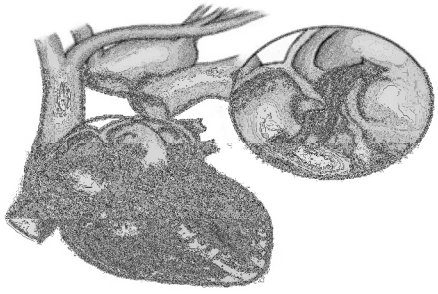
- Paradoxical embolism
- Significant left-to-right shunting
- RV volume overload
- Asymptomatic or symptomatic



For ASDs, again, closure is recommended for a paradoxical embolism to prevent recurrent stroke. Its also indicated with significant left-to-right shunting and/or signs of RV volume overload. These patients do not have to be symptomatic to be closed.

Contraindications

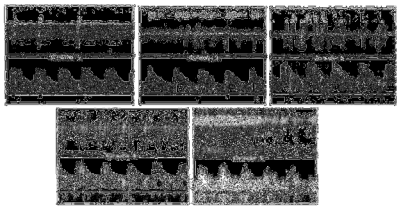
- Contraindication to antiplatelet therapy
- Too large a defect
- Atrial thrombus
- ASDs:
  - Inadequate tissue rim
  - Eisenmanger syndrome: right-to-left shunting, irreversible pulmonary hypertension

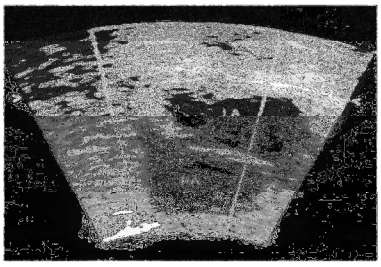


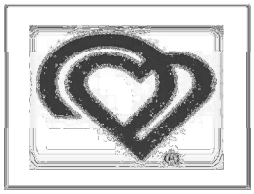
Patients you would not want to close would be those who cannot take antiplatelet therapy, those with defects that are too large for the device to cover without causing other problems like erosion. If the patient had an atrial thrombus you would want to avoid this procedure. For ASDs, you would not want to close them if you lacked an adequate rim of tissue on which the device sits, again to avoid erosion. And if the patient has progressed to have right-to-left shunting with irreversible pulmonary hypertension, or Eisenmanger syndrome, you do not want to close these patients because they can have acute right heart failure if you were to close their shunt.

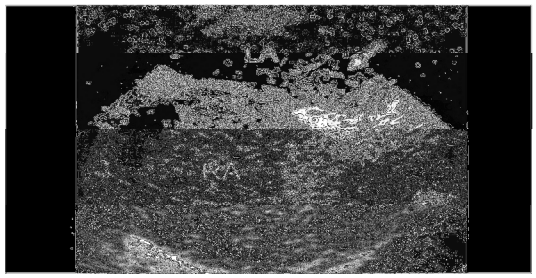
Work-Up

- 30-day event monitor
- TTE with bubble study
- TEE with bubble study
- PFO: Transcranial Doppler
- ASD: Right heart catheterization









Patients typically get evaluated for a PFO or ASD in the setting of a paradoxical embolism. To rule out other causes of stroke, the patient will have a 30-day event monitor to rule out atrial fibrillation as a source. If a patient has unexplained RV overload, that would be another reason to look for an ASD. The first study these patients will typically get is a transthoracic echocardiogram with color Doppler imaging to detect shunting as well as a bubble study. With a bubble study, agitated saline contrast is injected into a peripheral vein; the study is positive if one or more bubbles are seen in the left heart within 3 cardiac cycles. Valsalva maneuver and cough can enhance the shunting during the study. These patients will also undergo TEE, again with a bubble study, which allows for confirmation and better visualization of the defect, such as the size of the defect, length of PFO tunnel and presence of an atrial septal aneurysm. It also can evaluate the defect for suitability for closure. Transcranial Doppler can be used in PFOs to detect the magnitude of right-to-left shunting. This is one of the most predictive tests for risk of paradoxical embolism and its very sensitive foe detecting right-to-left shunting. For this study, a Doppler probe is placed over the middle cerebral artery, agitated saline is injected, and the amount of bubbles that make it up to the brain before and after Valsalva are measured to give you a grade of shunting. ASD patients will also undergo a right heart catheterization to evaluate the degree of shunting and right heart pressures. It can also assist is helping determine if the defect is suitable for closure.

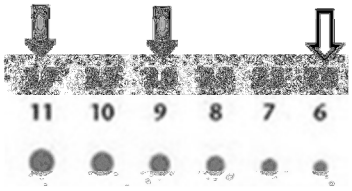
Pre-Procedure

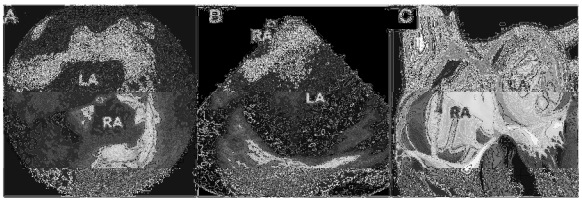
- Physical exam
  - PFO: no findings
  - ASD
    - RV heave
    - Wide, fixed split S2
    - No murmur from defect itself
- Pre-procedure labs: BMP, CBC, PT/INR, PTT
- Medications:
  - Aspirin & clopidogrel
  - Antibiotics

There are no abnormalities that can be detected on the physical exam with a PFO. With an ASD with large left-to-right shunting, there can be a right ventricular heave, wide, fixed splitting of S2 when sitting or standing, and a split S1. The shunting across the ASD itself cannot be heard but they can have several other murmurs from the hemodynamic effect of the defect. These patients will have the usual labs drawn before the procedure. The patient will be loaded with aspirin and clopidogrel that day and will also receive IV antibiotics both immediately prior to implanting the device as well as post-procedure for SBE prophylaxis.

PFO/ASD Closure Procedure Overview

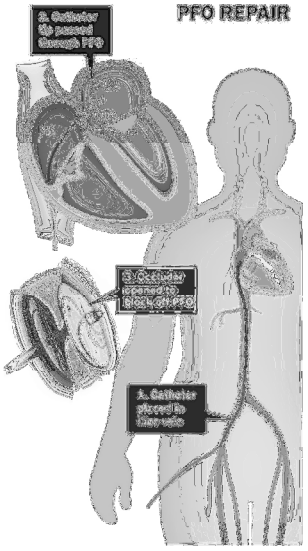
- Moderate conscious sedation
- Heparin anticoagulation
- Bilateral femoral venous access
- Intracardiac and transthoracic echo





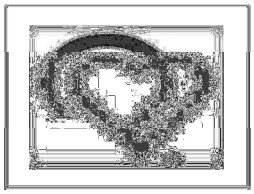
This procedure is done under moderate sedation and the patient is anticoagulated with heparin. Bilateral femoral venous access is used; one side for the device delivery, and the other is for intracardiac echo, or ICE. They are larger bore access sites than you would see for a typical cardiac catheterization. Usually patients getting a left heart catheterization will have a 6 fr sheath. These procedures require typically 9 fr and 11 fr sheaths. The ICE catheter allows for confirmation of the defect and to help with sizing and device placement. Limited transthoracic echo is also used to help with placement and assess for pericardial effusion and also look fo any interference of the device with the valves during implantation.

PFO/ASD Closure Procedure Overview

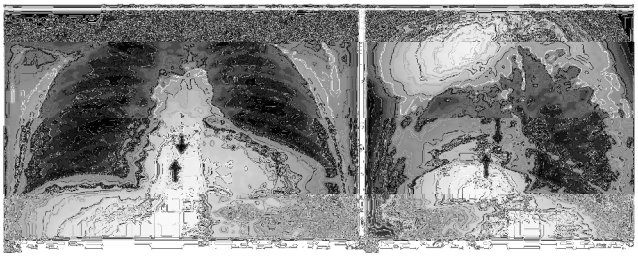


The device itself is housed within its delivery catheter; the catheter is advanced across the defect into the left atrium and one disc of the device is deployed and it get seated against the septal wall. Then the other side of the device can be deployed on the right atrial side of the septum to sandwich and occlude the defect. Before the device is released from the delivery catheter, they push and pull on the device to make sure its not going to go anywhere. If the device is not appropriately seated or sized, it can be pulled back into the delivery catheter. If the placement looks good, the device is released. Following the procedure, the sheaths are removed while the patient is fully anticoagulated and hemostasis is obtained. Typically, our patients will have figure-of-eight sutures at the access sites.

Post-Procedural Care & Testing

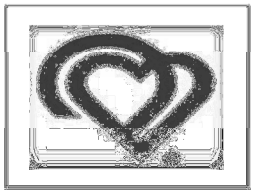


- Overnight stay
- Groin checks, suture removal
- Monitor for arrhythmias
- Next morning:
  - 2-view CXR
  - Limited echo with bubble study

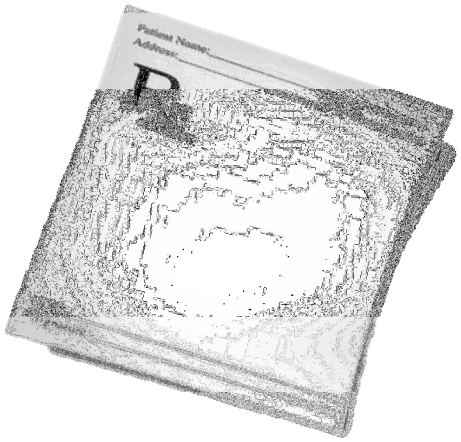


These patients all stay overnight following their closure. The sutures are typically removed the evening of the procedure and the patient will have bed rest and neurovascular checks as they typically do after cardiac catheterization. These patients can have hematomas and other access site complications. The patient is monitored on telemetry for arrhythmias as these patients can have new onset atrial fibrillation, PVCs and PACs from the device moving around. The following morning, the patient will have a 2-view chest x-ray to serve as their new baseline so if they were to go to a facility without echo capability, they can evaluate for device embolization. They also have a limited echo with bubble study done to assess device placement as the highest risk for device embolization is in the first 12 hours. The patient will typically go home late morning to early afternoon.

Post-Discharge



- Usual wound care
- Aspirin 81mg & clopidogrel 75 mg daily x 6 months
- SBE prophylaxis x 6 months



These patients require the usual wound care for post cardiac catheterization. They're instructed to monitor for bleeding, signs of infection or signs of vascular compromise and to keep the access sites clean and dry. These patients will require dual antiplatelet therapy with aspirin and clopidogrel for 6 months while the device is endothelialized . These patients also require subacute bacterial endocarditis prophylaxis for 6 months following closure, again while the device is endothelialized, so they would need antibiotics 30 minutes prior to any dental work or surgery.

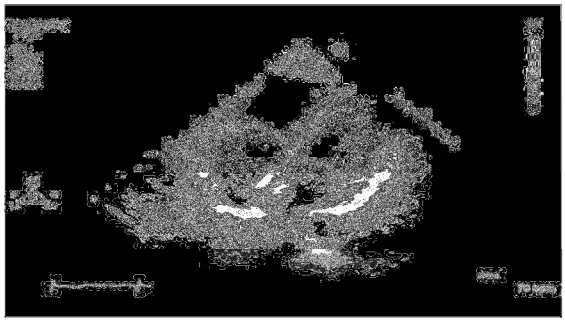
Restrictions

- No lifting >10 lbs. x 5 days
- No lifting > 20 lbs. x 2 weeks
- No jarring activities x 1 month
- No running x 2 months

These patients will have more restrictions post-procedure than your usual heart cath patient. The first 5 days, we don't want them lifting greater than 10 pounds in addition to not lifting greater than 20 pounds for two weeks. They are also not supposed to engage in any jarring activities for a month or running for 2 months. This is all to prevent device embolization. So, no trampolines, water skiing, horseback riding, wrestling, et cetera. We do have pre-printed instructions with all this information available to give our patients upon discharge.

Post-Procedure Testing

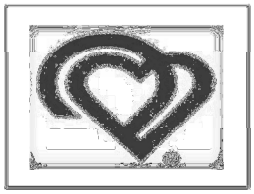
- Limited echo with bubble study
  - 1 week
  - 1 month
- Full echo with bubble study
  - 6 months
  - 12 months



These patients also need testing after they leave the hospital. They will have a limited echo with bubble study at 1 week and 1 month after closure to make sure the device hasn't embolized. They will have a full echo with bubble study at 6 months to make sure there's no thrombus on the device and that it's safe to stop the antiplatelet therapy and at 12 months following closure, making sure there's not been any erosion from the device. If they've had a particularly large device implanted, they may also have echos at 2 and 5 years looking for device erosion.


Thank you!

References



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