

Moore - PFO Device Doctor

Monday, August 24, 2009

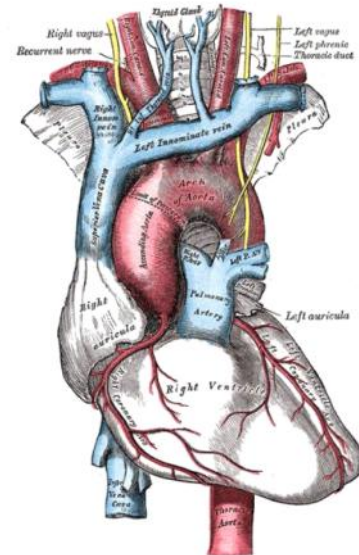
Walk through the decision process

Look at TEE

Do you know Al Burdulis? Worked on suture based PFO closure device at Abbott/Percluse

Questions

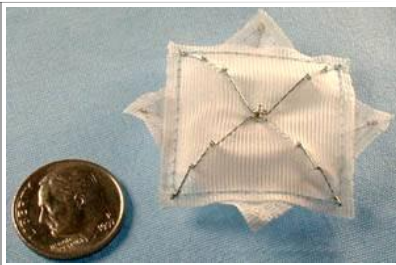
- o Where did the clot come from?
 - We know the clot went through the atrial septum - but what caused the clot? Clot usually caused by turbulent flow either due to PFO flap or generally slow flow in the Right Atrium (RA). RA is generally the end of the line for the circulation system so flow is usually worst there
 - o Am I at risk for heart attack? ...enter the left atrium, and travel out of the heart and to the brain (causing a [stroke](#)) or into a coronary artery (causing a [heart attack](#)).
 - o I think it has to do mainly with location of the various vessels that take off from the aorta outside the LV. Coronary arteries (which feed the heart and are the source of heart attacks) take off from the "root" of the aorta at a near 90 deg angle the three arteries that go to your arms and head are at the top of the aortic arch and are directly in the path of the ventricular exit (BAD DESIGN!) so it is more likely that a clot will go there vs making a 90 deg turn and head to your heart muscle
 - Dr Moore
 - o It is pretty rare to have a cerebellar stroke
 - o The fact that this clot went to the artery headed to the cerebellum may indicate that the PFO wasn't the cause
 - o It was a small clot that took a very strange route to the head



o Device



Amplatzer -



Star Flex (next gen after cardioseal) - Dr Moore doesn't use this for this hole

Third Device - Gortex - Helix

- Both are mesh nitinol (Shape memory) devices with Dacron material on them or in them. I believe the amplatzer was the first device on the market (For ASD not PFO) na Cardioseal followed ask Dr moore if there is conclusive data on one vs the other
- Is device designed for my PFO size? On Cleveland Clinic web site, it talks about a "determination of the device will fit the hole"
 - o Cardio Seal vs. Amplatzer devices - what's the difference?
 - o Dr Moore: depends on the size, shape of the PFO
- How long will device last? 50 years?
- What is the risk of erosion and/or hemorrhaging?
 - o Dr Moore
 - ◆ We have 20 years of good data
 - ◆ If there is erosion, it's usually due to the device not being put in correctly
 - ◆ But you want this device to last 50-60 years
- Are devices now FDA approved for my situation? Do you have to be involved in clinical trial?
 - o Dr Moore
 - ◆ Until we know which strategy is better, we recommend thinners, not surgery
 - ◆ First time event, not on medication, start on medication. If you have an additional stroke or problems with medication, then OK.
- o Procedure
 - Describe surgery to me (with a model)
 - o Dr Moore
 - ◆ Tube in femoral vein

◆ <http://www.youtube.com/watch?v=LxcTOrLvr94&NR=1>

- Dr Moore - Risks
 - Very Rare - Air bubble - you are given strong blood thinners
 - ◆ Left side of heart - could go to heart, brain
 - ◆ This has never happened, minor issues with 1 patient
 - 3-5% risk
 - ◆ 5-7% patients
 - ◇ Abnormal heart rhythms, skipped heart beats
 - ◇ 1% need some medication after - but none permanently
 - ▶ 6-9 month
 - ◆ Migraine / Ocular Migraine
 - ◇ Reduction of migraines 60--70%
 - ◇ Don't usually close holes based on migraines alone
 - ▶ The ONE study where PFO fixes were applied to migraine sufferers ONLY did NOT have an effect on the migraines, the closure didn't really matter
 - ◇ Some patients have **new** migraines but these last for 1 to 1.5 years
 - ◆ Foreign body in system - body forms clots
 - ◇ Stay on blood thinner after procedure
 - ◇ 1/400 before blood thinners, now 1/1000 develop clots on device, usually treated with stronger blood thinners, goes down to zero after device covered completely (not sure, but think so)
- How often do you operate on adults?
 - Dr Moore - 1/3 of 1400 patients are adults
- How long is procedure?
 - 2.5 Hours
- The procedure does not involve by-pass, but how am I put "out"?
 - You can stay awake if you like
- Would there be a certain time period they want to wait after the stroke
 - Usually wait because we cause fluid shifts
 - There is also mild sedation - but you can be awake
 - During procedure you get heparin to thin blood
 - ◆ Heparin and coumadin - OK?
 - In my case, there's no emergency to operate soon, so we'd wait 3-4 months
- Dr Moore - What is recovery time?
 - 1 day in hospital - to make sure femoral artery heals
 - 2 weeks, don't lift anything heavy
 - That's it!
- Dr Moore - Pre- and Post-Device
 - Do I remain on aspirin or blood thinners?
 - No
 - Endocarditis risk before and after PFO fix?
 - What is [prophylactic therapy](#)? Prophylactic therapy is "just in case" therapy, or "plan ahead" therapy where you are not symptomatic but get a drug/device/treatment anyway (like taking baby aspirin even if you haven't had a heart attack or history of potential heart attack)
 - Does the closed PFO w/ device constitute an abnormality?
- Dr Moore - Percutaneous (Device) vs. Surgery - what's your thought?
 - Surgery
 - Surgery is a longer recovery
 - Surgery SEEMS more definitive (to me) more of a piece of mind thing than really, but again what is the incidence of stroke after each treatment?
 - Surgical repair is THE gold standard for any defect
 - Surgery - Moore feed-back
 - ◆ 99.9% effective in closing hole
 - ◆ Of all heart surgery, this is easiest
 - ◆ 70 years of intra-cardiac repair, longer track record
 - ◆ Stop the heart - by-pass
 - ◇ Very good, very safe
 - ◇ Mortality should be zero
 - ◇ Stroke should be zero
 - ◇ Would definitely want to wait after stroke
 - ◇ Recovery time
 - ▶ Hospital 3-4 days
 - ▶ 2-3 week recovery
 - ◇ Controlled study for surgery vs. PFO device fix
 - ▶ Main issues were not death/stroke
 - ▶ Surgery had more complications - 15-20%

- ▶ Surgery more involved, mainly due to surgery itself
 - Collapse lung, infection, chest tube to drain fluid
- PFO size
 - Mine is at the slightly bigger spectrum - "stretched" PFO
 - Little squirt "always sneaks through"
 - Not big enough to affect lungs or risk of heart attack
- Clot and stroke
 - Clot can come from anywhere - neck, heart, legs
 - If all congenital, blood stuff negatives
 - ◆ Legs or pelvis - lower body veins
 - Posterior strokes - tougher to have happen
 - ◆ Since it is so rare to have clot go through, maybe stroke risk is very low
- Strategy to achieve "no more stroke"
 - We do not know right now which strategy is better
 - Just starting to understand controlled
 - ◆ 3 studies in progress now to test "head to head" blood thinners vs. PFO device
 - ◆ 2-3 years away from getting data
 - ◆ Blood thinners - key points
 - ◇ With thinners, this is the "end of discussion"
 - ◇ Right in theory, right in practice as well
 - ▶ Coumadin works well, very safe
 - ◇ Reduction of stroke is dramatic - 80-95% reduction
 - ◇ But NOT perfect
 - ◇ Small percentage DO have strokes
 - ◇ Forget to take medicine, blood levels change
 - ◇ We used to test for 3 genetic issues, now we test for 8, 10 years from now we'll test for 50?
 - ▶ Where do I fall? Is it the PFO or do I have a congenital defect that has nothing to do with PFO?
 - ◇ With family members (cousin, nephew) forming clots, this raises issue of possible genetic issue
 - ◆ Close PFO with device
 - ◇ 20 years on implants, 750 total, Dr Moore = 1400 closures
 - ◇ 100% of getting the device in
 - ◇ 97-98% hole closure rate
 - ▶ Why not 100% - growth doesn't happen, device not the right size, not put in correctly, etc
 - ▶ Sometimes have additional holes - very rare
 - ◇ Works well, reduces risk substantially
 - ◇ 80-95%
 - ◇ Small % do - Why? Two reasons:
 - ▶ PFO didn't matter
 - ▶ Device makes clot
 - ◆ Middle ground - Dr Moore prefers this (but is this the standard line to patients who want the procedure?)
 - ◇ Next 3-5 years there will be substantially more information
 - ◇ Continued development of slicker, safer or "bulky" implants
 - ◇ This will probably be an advantage, but not sure
 - ◇ You have a lifetime ahead of you, the information may get better
 - ◇ No extenuating circumstances, not 110% clear that PFO caused this
 - ◇ Dr Moore puts us on a list, will let us know in year or two if things change
 - ◇ Pub Med - National Institutes of Health - medical library
 - ▶ Studies that need volunteers:
 - ▶ <http://clinicaltrials.gov/ct2/show/NCT00697151>
 - ▶ <http://clinicaltrials.gov/ct2/show/NCT00562289>
 - ▶ <http://www.nlm.nih.gov/medlineplus/ency/article/007418.htm>