Take 3 – Practical Practice Pointers© October 29, 2018 Edition

A-Fib Follow-up, Gardasil, Air Travel in Pregnancy

Follow-up on Atrial Fibrillation (AF) and Questions from Colleagues

1) AF – Pacemaker Candidates and Watchman Procedure

I received 2 questions from colleagues this week as a result of last week's Take 3 focus on atrial fibrillation.

Question:
"How do we know when a patient is a candidate for ablation or a pacemaker?"

Answer:
I reached out to Carl Musser, MD, one of our Carilion Cardiologists with expertise in electrophysiology, for his input. Here is his reply: *"I would recommend that you refer any patient you suspect has symptomatic atrial fibrillation (paroxysmal or persistent) directly to Cardiac Electrophysiology and we can then determine if they are a candidate for ablation. The guidelines now advocate for ablation as first line therapy for symptomatic paroxysmal atrial fibrillation and although the recommendations aren't as strong for persistent AF, AF ablation can be considered in this setting often in conjunction with anti-arrhythmic drug therapy. Options for permanent AF are really limited to rate-control therefore unless you are having difficulty with maintaining acceptable rate control in which case pacemaker with AV junction ablation might be useful, it is unlikely we would have much to offer."*

Question:
"Many of my patients, especially those with bleeding risk, are being offered the WATCHMAN procedure. What can you tell us about this procedure and is there anyone in the region performing it?"

Answer:
The WATCHMAN Device is a parachute-shaped, self-expanding device that closes the left atrial appendage (LAA) for patients who have AF. It was tested in several studies that showed the device was a good alternative treatment for patients who cannot tolerate treatment with warfarin. I reached out to Jason Foerst, MD, one of our Carilion Clinic Interventional Cardiologists who regularly performs this procedure, for his input.

Here is his reply:
"Atrial fibrillation places patients at increased risk of thromboembolic events including TIA/CVA. The majority of the thrombus originates in the left atrial appendage (LAA) and sealing off the LAA has been proven to mitigate the stroke risk in patients deemed unsuitable for long term oral anti-coagulation. There were two large randomized trials against warfarin that let to FDA approval of the WATCHMAN device in 2015.

The procedure is minimally invasive but does require general anesthesia due to the use of a TEE probe. Access is a 14F sheath in the right femoral vein, transseptal puncture, and device delivery to the LAA. Patients are monitored overnight and home the next day. We then typically resume oral anti-coagulation (DOAC or warfarin) for 45 days and then repeat TEE. If device well sealed with no thrombus then stop anti-coagulation and

start asa/clopidogrel for remainder of 6 months post implant at which point will convert to aspirin monotherapy.

We are glad to see these patients. In EPIC, order REF164 (structural heart) or to me directly and make reason a-fib."

My Comment:
Thank you for these questions! It is wonderful to know that we have such options for the highest quality care for our patients regionally. For those readers outside of Carilion, I encourage you to contact your referral cardiologist to learn what is available in your region.

References:
Carilion Video Interview with Jason Foerst, MD (click "learn more"): Link
Video on Device Implantation: Video

From the FDA

2) FDA Expands Gardasil to Include Adults Up to Age 45

The FDA recently approved a supplemental application for the 9-valent human papillomavirus vaccine (*Gardasil 9*) to include women and men aged 27 through 45 years.

The CDC estimates that every year about 14 million Americans become infected with HPV. About 12,000 women are diagnosed with cervical cancer and about 4000 women die from cervical cancer caused by certain HPV viruses. HPV is also associated with several other forms of cancer affecting men and women. It is estimated that receiving the vaccination prior to becoming infected with the HPV types covered in the vaccine has the potential to prevent more than 90% of HPV-related cancers.

In 2014, the FDA approved Gardasil 9, which covers the same four HPV types as the original Gardasil approved in 2006 as well as 5 additional types. Gardasil 9 was first approved for use in males and females aged 9 through 26 years.

According to the FDA, in a study in roughly 3200 women aged 27-45 followed for an average of 3.5 years, Gardasil was 88% effective in preventing the combined endpoint of persistent infection, genital warts, vulvar and vaginal precancerous lesions, cervical precancerous lesions, and cervical cancer related to HPV types covered by the vaccine. The FDA indicated that the effectiveness of Gardasil 9 in men 27-45 is inferred from the data for women as well as that from younger men and some immunogenicity data for men ages 27-45. In those studies, the regimen was 3 shots over 6 months. The most commonly reported adverse reactions were injection-site pain, swelling, redness, and headaches.

My Comment:
I have received questions from both colleagues and patients concerning this, as it was well-publicized on at least some news wires (big $$ here!). Although there is no reason to think approval won't happen, remember this has not been reviewed by the ACIP nor has yet made the list of "recommended adult immunizations" from the CDC. Thus, insurance coverage is likely to not occur until this happens. Having recently diagnosed

a patient with an HPV-related cancer of the head and neck region, this recommendation hits “close to home.”

Reference:
FDA News Release – October 5, 2018: Release

From the American College of Obstetrics and Gynecology (ACOG)

3) Air Travel During Pregnancy

ACOG recently updated their 2009 Committee Opinion regarding air travel for pregnant women. In the absence of obstetric or medical complications, pregnant women can fly safely, observing the same precautions for air travel as the general population. Because severe air turbulence cannot be predicted and the subsequent risk for trauma is significant should this occur, pregnant women should be instructed to use their seat belts continuously while seated. Despite a lack of evidence associating lower extremity edema and venous thrombotic events with air travel during pregnancy, certain preventive measures can be used to minimize these risks, including use of support stockings and periodic movement of the lower extremities, avoidance of restrictive clothing, occasional ambulation, and maintenance of adequate hydration. For most air travelers, the risks to the fetus from exposure to cosmic radiation are negligible.

Air travel is not recommended at any time during pregnancy for women who have medical or obstetric conditions that may be exacerbated by flight or that could require emergency care. The duration of the flight also should be considered when planning travel. Pregnant women should be informed that the most common obstetric emergencies occur in the first and third trimesters.

Most commercial airlines allow pregnant women to fly up to 36 weeks of gestation. Some restrict pregnant women from international flights earlier in gestation and some require documentation of gestational age. For specific airline requirements, women should check with the individual carrier.

My Comment:
Though I recognize many of our Take 3 readers no longer practice obstetrics, we still care for both pregnant women and women of childbearing age, and for many, this information with be personally helpful. The advice for DVT prevention certainly applies to car travel as well.

Reference:
ACOG Committee Opinion No. 746: Air Travel During Pregnancy. Obstetrics and Gynecology 2018, 132 (2): e64-e66. Link

Feel free to forward Take 3 to your colleagues. Glad to add them to the distribution list.

Mark

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