



Transcript:

A Clinical Assessment of Peripheral Artery Disease for Those on the Primary Care Spectrum

Intro

[00:01] Hello and welcome to the Peripheral Arterial Disease webinar about the Clinical Assessment of PAD for those on the Primary Care Spectrum. My name is Eileen Walsh. I'm a professor at the College of Nursing University of Toledo, and I've had a long standing history in taking care of patients with cardiovascular disease, not only in the outpatient areas but in the inpatient area as well as rehabilitation settings for both cardiac and vascular patients. Peripheral arterial disease affects more than 200 million adults worldwide and over 8.5 million in the United States. Although it's a serious risk factor for coronary artery disease and cerebral vascular disease, PAD remains largely an overlooked condition. Hopefully together we can change that. Janssen pharmaceuticals is a proud sponsor of the American Heart Association's efforts to educate healthcare practitioners about PAD. So let's get started. I wanted to share this slide because I have no disclosures, but others who had participated in the development of the first slide deck are included on this slide.

Objectives

[01:05] The objectives for today are really three-fold. The first one is to recognize PAD is a common vascular disease that is associated with functional impairment and increased risk of major cardiovascular events as well as amputation.

The second objective is to review the diagnostic approach to PAD, the history, the physical exam, the ankle brachial index, and when and which additional diagnostic testing is simply recommended.

The third objective is to review the medical therapy for the patient with PAD.

Guidelines

So today I'm going to be focusing on the 2016 AHA American College of Cardiology guidelines on the Management of Patients with Lower Extremity Peripheral Artery Disease. While you might be wondering why these guidelines, these concepts, and there are three pertained truly to the first objective of the program, and that is to help you understand the PAD is a highly prevalent disease. If we look to the graph to the right, you'll see that both men and women are significantly affected by PAD.

[02:09] In the N-HANES data, that was a US population. 14.5 percent of the individuals who were over age 70 had PAD. If we look at the GetABI that was a study conducted in Germany, so they're in the ambulatory care population there. Those individuals were 65 years and older, 21 percent had PAD and then as we look to partners, we had individuals, all comers, if you will, who were 70 years of age and older in the ambulatory care population as well as the younger cohort, ages 50 to 69 if they were diabetic or had a smoking history and we actually found 29 percent prevalence of PAD.

So the take-home messages are these and that is that in the PAD effects really 8.5 million Americans and that is anybody age 40 years and older. Additionally, if we look at the global impact worldwide, 202 million people were living with PAD in the year, 2010, approximately 70 percent of those as well [03:15] were in low or middle income countries.

Why These Guidelines?

So why these guidelines? We're looking again at another concept in that is a PAD is a high cardiovascular risk, high mortality condition. If you look at the graph you'll see on the vertical axis, these are evident event-free survival, and then on the horizontal axis to time after baseline, so there are sharp declines, whether or not the patient is symptomatic, asymptomatic or simply doesn't know if they have PAD. Additionally, if we look at the San Diego population study done by Michael Criqui and colleagues, there was a threefold increase in all-cause mortality with PAD as well as a sixfold increase if we looked at cardiovascular related mortality. Also, the ABI Collaborative Collaboration founded for each of the Framingham risk categories. If someone had an ABI less than 0.9, they had twice the cardiovascular event in death rate and one of the take home points is at the bottom of this slide and that is the Reach Registry that if we look at five PAD patients, one of those approximately has had a stroke, [04:23] a myocardial infarction, has been hospitalized for a cardiovascular event, or has died of a cardiovascular cause on an annual basis.

Then what about concept three, which again pertains to PAD. This is perhaps more important for the patient because it affects their day to day life. PAD truly is a morbid disease, is a major risk factor for lower extremity amputation. Approximately five percent of individuals with claudication in five years can end up with an amputation, and that's even astronomically increased if the person has critical limb ischemia to the tune of 30 to 40 percent per year. Quality of life significantly impairs PAD and even more so than those patients who have heart failure or who has sustained a recent heart attack. Functional impairment is very common. Patients who are in the rehabilitation program or simply in the clinic just can simply not walk the distance that they used to. [05:26] They have also a change in their walking velocity and this is

regardless of what the leg symptoms that they manifest with. And lastly, patients with PAD are at an increased risk of depression.

A Little History

So we're going to chronicle back in time just a little about the history in 2005. The first PAD, if you will, guideline was actually published. This was groundbreaking because PAD had not received much attention in the literature up until this time. One of the problems, however, was that there were close to 200 pages and more than 1300 references, and the other problem was that it covered not only PAD but aneurysmal disease, not only in the aorta, but peripheral aneurysms, renal mesenteric disease, as well as fibromuscular disease. This was however a landmark because it did help to create a national awareness of PAD for public and healthcare professionals.

2011 Guideline Update

The other thing that happened then in 2011 was new PAD guideline.

[06:28] That was simply an update and the reason for the update is that there were new guidelines to address specifically the Ankle Brachial Index for PAD, PAD medical management and also revascularization and a different approach to aneurysm repair.

2016 Guideline Update

So now we're up to the 2016 guidelines which we're going to focus on with this presentation. Some of the things to just address will be really the scope of the document and that is it was limited purposely to lower extremity PAD. The aim of the guideline was really to be a contemporary guideline and also to have recommendations that will be based on current treatment, current evidence, and specifically peer reviewed manuscripts and articles in the, in preparing the guideline, a guideline writing committee was established. The intention was to make sure it was interdisciplinary in nature as well as individuals who had relationships with industry being carefully addressed and assessed.

[07:36] So there was a rigorous process to follow through with any of the relationships with industry and if indeed there was a relationship, we were asked not to vote on any of those sections which applied to the guidelines. You'll see in another slide that the participants were nominated from a variety of organizations, very, very interactive in interdisciplinary in nature. So not only was vascular medicine nursing, surgery, Interventional Cardiology, interventional radiology, were all part in part at the table. This is a listing, if you will, of all the individuals who participated on the guideline writing committee. You will see there are many individuals, here. And we also did have a lay member. I did want to mention that and highlight it. If you look here

on the collaborating organizations, you'll see the logos and you'll see again reiterating the variety in the scope of the organizations that were all dedicated to the care of patients with PAD.

Methodology

So really what has changed with the American Heart Association, ACC guidelines for 2016 will truly the look and the format has really changed, so instead of having large amounts of texts and reading another textbook, they are actually little knowledge bites, if you will, and there's a variety of evidence in summary tables to help sort through the evidence.

[08:58] The other key thing is that the scientific rigor was definitely used to make sure that we had a complete analysis of the evidence and we also had to grade the evidence using a, b, and c, which we'll talk about specifically in another slide. All of the evidence stated to have supporting tables and references as well. So, if you look here at this guideline, you'll see if you look at the PAD 2016 Guideline, you'll see all of the various sections that were included in the guideline. So, it really covered a broad extent of care delivery for patients with PAD as well as critical limb ischemia. We're going to focus on the PAD today in this Webinar. So, um, in order to actually look specifically at the guidelines, it's really helpful to see what indeed class of recommendation and level of evidence was used with this particular guideline that is, you can see we have five specific classes and as you all well know, the class pertains to the strength of the recommendation and then five levels of evidence.

[10:06] And this might be a little atypical in terms of what you're used to because we have two levels for B and two levels for C. See as we walk through some of these, you'll see that the strength of the recommendation, the primary factors here tend to be the benefit versus the risk. So does the benefit outweigh the risk you can readily see class one is strong, so the benefit definitely does outweigh the risk and that is highly recommended and should be performed or administered. If you draw your attention down to the latter classes here, you'll see that for both class two we have a no benefit and we also have a harm and in this case the no benefit is one in which the benefit and the risk are shared equally so it's not recommended or not found to be useful or effective, and then class three where we do have some harm and I will point that out where the risk is greater than the benefit and in those instances, can be potentially harmful and should not be performed or administered.

[11:08] So what about the level, as I alluded to before, there's five levels so you can see to go from a to c and the first one is level a. those typically come from randomized control trials or Meta analyses of the high quality randomized controlled trials. We also have level B for randomized as well as non-randomized studies. And lastly, level C. Level C has two specific categories, one for limited data. And then we also have EO for expert opinion. So, consensus of

expert opinion based on clinical practice was indeed considered throughout the grading of this evidence. So let's take a look here at some of the specific sections within the guideline. What we're going to focus on right now is the history and physical exam, the ankle brachial index, physiological testing that's conducted in the vascular lab, anatomical imaging and assessing PAD patients for disease and other vascular beds or territories.

Step 1: Identify Patients at Risk

[12:10] So one of the key things is to look at identifying the patients. So who truly is at risk. Well, I previously reviewed what the literature has showed us in terms of age. So patients at risk are those individuals who correlate with that. So anyone who is 65 years or older, the younger cohort, ages 50 to 64 years with any risk factor, they can have diabetes. They would maybe have a history of smoking, hyperlipidemia, or high blood pressure or simply a family history of PAD. Also, those very younger individuals, if they happen to be diabetic and have one additional risk factor for atherosclerosis. And the last group of patients who are at increased risk of PAD or those individuals with known atherosclerotic disease and another vascular bed or territory such as coronary, carotid, Subclavian, Renal Mesenteric, or the abdominal aorta. So what did we come up with from a class and a level of recommendation?

[13:11] You can see that they're all class one and that any patient truly at increased risk, and I'd mentioned those patients and the foregoing slide, they truly need to have a comprehensive medical history obtained, a review of symptoms to assess for exertional leg symptoms including claudication, any other walking impairment, ischemic rest pain or non-healing wounds.

The Vascular Exam

Additionally, the patients at increased risks should also undergo vascular examination, including pulse examination, as well as auscultation for bruits and truly the inspection of legs and feet. As we look at this slide, you can readily see the cartoon of the individual here where we have to auscultate for bruits and palpate pulses. This is so important and you'll see that we can have differences in terms of arm pressures and typically we use 15 to 20 millimeter difference as a suggestion that there's some type of subclavian stenosis in the patient. You'll also see alluded to in this particular diagram.

[14:12] Take the socks off and we'll talk a little bit about that in another minute, so it is very important to incorporate in your exam a thorough vascular exam, so all pulses should be checked and also looking for bruits. Take the socks off, as I said, are so important. I know in the PARTNERS STUDY it was difficult even in populations where we had a high degree of diabetics. Oftentimes those patients didn't even have their socks off, so it is so important because obviously if you don't have the socks off, you can't check the pulses. It's also important not only

for pulse checks, but also to look for any bony deformities, callus formation or anything that would predispose the individual to having an ulcer or peripheral neuropathy. Tissue loss with either wounds or gangrene is also important as well as early signs of infection. Another key thing to address is the importance of having a systematic, consistent grading scale for pulses.

[15:11] Oftentimes they're reported in the literature and then used in the hospital setting in varying ways, but we would recommend that the grading system be adopted so that zero obviously is absent and that's pretty true in most cases. But we use the one for diminished, 2 for normal and 3 is bounding. Some individuals have a four-point scale, but this meaning a four+ scale with five actual points, but we're recommending that it really be a four point scale so that we're talking the same language. So what about the summary of the evidence for the physical exam? There are a few things just to point out to make, um, make it clear that is if you have a non healing, a leg, a leg wound, it should conjure up in your mind that there might be the need for intervention and the patient might have critical limb ischemia. Also too, anytime there's an abnormal physical finding,

[16:06] So for instance, if somebody has an abnormal pulse from side to side or a bruit as auscultated that will simply increase the likelihood that they do indeed have PAD. Another important point is that the converse is true. So if you find that there are normal pulses throughout, there's no bruits, it's likely that that patient doesn't have PAD. Another important factor is that in many individuals, they have a congenitally absent Dorsalis pedis pulse so that the posterior tibial pulse tends to be more specific and a better assessment in terms of sensitivity and specificity for PAD. And the last thing to just point out the normal capillary refill and if you have a normal skin temperature, you cannot rule out PAD. So the bottom line is that the physical exam is not perfect. It in fact, it is imperfect to diagnose PAD. So we do need to confirm these findings and one of the ways we can do that is with the ABI or ankle brachial index or TBI, which stands for toe brachial index.

[17:12] The other important point to mention is it a normal physical exam does not completely rule out PAD. If there's a high clinical suspicion. So hence we have to use our intuition to make sense if the symptoms may be indicative, if of um, disease.

Step 2: Identify Red Flags

So what about, um, identifying the red flags in some of the red flags. Really come from what we just talked about, the physical exam. So if there is an abnormal pulse, is there a vascular bruit? Do they have non healing wounds that are visible? Is, are there signs of gangrene? Another kinds of things that you can look forward to would be elevating the legs. So if someone has

pallor when the leg is elevated or simply if they have dependent rubor when the leg is in a dependent position, those can be indicative similarly of PAD and also the history, um, which we have have of claudication or any of those not typical symptoms of claudication.

[18:11] And many patients don't have typical claudication. Anybody who has impaired walking function or ischemic rest pain simply should be a red flag to you for further followup. So one of the important things is to talk just for a moment about classic claudication, because classic claudication although we learn all about it, it truly is the exception rather than the rule for patients with PAD. So if we look at this diagram, you can readily see the shades of blue there and classic claudication is only 11 percent. So in the partners program approximately just shy of 2000 patients, if they had an ABI, which was indicative of PAD less than 0.9, you can see that only 11 percent of the individuals truly had what we call classic claudication. So that classic claudication is shown in the slide to your right. That is when patients complain of fatigue, discomfort, a cramping sensation, it just tightens up in their calf muscle.

[19:08] So it typically comes down with exercise and it's relieved by rest. Oftentimes patients wouldn't be able to walk in the mall, they can't walk out to their mailbox to get the mail, etc. That's classic claudication. BuT you'll see from the diagram that most people do not have classic claudication. The majority, more than 50 percent, have atypical leg pain. And about a third have no pain at all.

Step 3: The Resting ABI

So another step in the diagnosis. And one of the cornerstones we actually use to diagnose PAD is actually an ankle brachial index. The ankle brachial index is basically the ratio of the ankle pressure to the arm pressure and we'll use the systolic pressure. So what you can see in the cartoon here to your left, you will see the right arm, left arm, right and left ankle respectively. And then an actual ratio. What we typically do is have the patient rest for at least five minutes if that's possible.

[20:09] And then we walk through the ankle brachial index by getting the pressure in the right arm. Then moving to the right ankle, the left ankle, and the left arm. That's the the mechanism and method in terms of obtaining the pressures. So we take then the higher brachial pressure, right or left. and in this case it would be the 120 on the right arm. And then we take the higher of the dorsalis pedis or posterior tibial respectively in each of the right or left arm extremities. And we come up with an ankle brachial index, so what you can see from this example here, that 120 is the higher of the arm pressure, so that would go in the denominator. And then in the numerator we take each of the respective, um, pressure and we use the higher, once again of

the right ankle for the height and the higher of the left ankle to come up with an ankle brachial indices for each of the legs.

[21:10] You can see that the patient, um, who's depicted with this diagram here has a .57 ankle brachial index on the right. So obviously there is a difference and they're not getting adequate blood flow to their leg. Additionally, the bottom bullet point addresses that there are other types of procedures that can be done. We do segmental leg pressures, which is wrapping a blood pressure cuff around the various segments of the leg. And also some other in looking at doppler studies, plus seismographic waveforms. I'm also to localize the actual location of the disease within the vascular tributary. So what about the recommendation then for a resting ankle brachial index to help with the diagnosis? It has a class one recommendation. You can see that there's not a lot of randomized control trials, but um, we do recommend that in patients who have a history or physical exam findings that they do indeed have a resting ankle brachial index with or without segmental pressures and waveforms.

[22:16] Additionally, we also recommend, and I would like to highlight this, that the ABI results should be reported systematically. So we had a lot of discussion about this and the abnormal was truly ABI less than or equal to 0.9. Borderline is in between 0.91 and 0.99, normal 1.0 to 1.4 or if they're non-compressible vessels such as we'll see with a diabetic, the ankle brachial index typically is erroneously high. And that's above 1.4. So this I did want to highlight because again, to reiterate, we would like to have a standard classification system. There been many proported in the literature, but this is what we would like to use for normal, abnormal, borderline or non-compressible. Moving right along to the other recommendation here. I did want to highlight that there's no benefit. If you look at the very last recommendation, if there's a patient not at risk of PAD and there's no history or physical examination findings suggestive of PAD, then we don't recommend that the ABI be performed.

[23:25] If you would like more detail about the ankle brachial index, there is a very nice scientific statement. You can look this up and it will be very helpful in terms of further augmenting your knowledge.

Diagnostic Testing

Now we're moving onto diagnostic testing for the patient with suspected lower extremity PAD. This is, this - could, this type of testing is typically done in the vascular lab, not necessarily at the bedside, although some of the studies can be done then. And some of the physiologic testing and the Class I recommendation here is that any patient with exertional, non joint related leg symptoms and normal or borderline resting ABI, they should really undergo an exercise treadmill ABI. So unlike the resting one that we just talked about where somebody rests and

then they have their blood pressure, their, um, their blood pressure and their arms and their systolic pressure in their legs checked, they are actually mimicking the claudication by walking on the treadmill.

[24:26] So this is actually a Class I recommendation. Similarly in patients with an abnormal resting ABI, the exercise treadmill can be used to look at functional status as well. So this is just a picture of some of the worksheets that can be used in the various labs. We use all different worksheets to depict what the treadmill test does show. So if we take a moment and look, you'll see a patient here in the bottom corner walking on the treadmill with a nurse there or technician, and you'll see the resting ABI in the box above. The right is .48, which is already low as well as the left .58, which is low. You can see that immediately after walking, they drop all the way down to zero. This patient was able to walk a full five minutes, but they were complaining of severe pain in both in both calves.

[25:23] It was burning and you can readily see that I'm on the diagram here, that the blood, the pressures not only the blood pressure in the arm, which is the systolic pressure noted in blue with the, as well as the pressure for the right and left leg. You can see that it took some time to actual recover or go back to normal. So the treadmill tests can be very useful in terms of diagnosing and, helping one to establish their treatment regimen for the patient, especially when it comes to vascular rehab. Critical limb ischemia is another condition we should just mention and typically by definition it is characterized by more than two weeks, ischemic rest pain, non healing wound ulcers or gangrene. It can be in one or it can be in both legs. That's a term that implies chronicity and we want to distinguish that from acute limb ischemia.

[26:24] One of the key things too that can be used is some other diagnostic testing, the toe brachial index, TCPO₂ and also skin perfusion pressure. So we're going to take a minute and talk a little bit about the toe brachial index because that is something to focus in on. As you can readily see here in this picture, you'll see the toe and then a probe as well in a blood pressure cuff. We use very small blood pressure cuffs around the toe. And the reason for this is that that the tiny, tiny digital vessels are, um, are small and those likely are not calcified. So in an individual who is diabetic, and if we had an erroneous ankle brachial index, say for instance, that came up to be 1.4, that would indicate that the vessels were non-compressible. Hence we needed to get a more accurate picture of the vascular flow in that patient's leg.

[27:20] So we would use, um, the small cuff and do a similarly obtain a pressure. In this case though, the normal toe brachial index is greater than 0.7. So we would get similarly the ratio to toe pressure to the brachial pressure. Now one of the key things to mention is this particular example that's shown here, and this is an example to show why the ankle brachial index is

flawed in some individuals. If we take and look over at the right ankle brachial index and the left one here, you'll see waveforms. They look almost the same, although the ankle brachial index is different. So the problem with these is that the tracings don't match the pressures at all. There's a disconnect between them. And that's because again, the vessels are non-compressible so you can't get an accurate portrayal of the real flow within that leg.

[28:18] So what's needed, in this case, it's an arterial duplex to look at the multiple levels of disease perhaps in this individual that's 73 years old with leg wounds. So, um, if we looked at the recommendation, then the Class or Recommendation is I or II for getting toe brachial indices done. So anytime we have somebody who has an ABI greater than 1.4, then truly TBI should be measured because we want to make sure we have an accurate description and an accurate treatment plan then for that patient. Additionally, if anybody has a normal or borderline ABI, additional testing can be helpful either the toe brachial index, PCPO₂ or skin perfusion pressures as well.

[29:13] Now we're going to just change to diagnostic testing, which is imaging. We can look from the left to the right. And as we pan this slide, you'll see a duplex examination here. This is the popliteal artery. We'll also look at mr, mra, digital subtraction angiography additionally, and when we look at the specifics here for anatomical imaging options for patients, we know that the duplex exam is the least expensive, there's no dye obviously, so no radiation. Um, and we, we do know that it's helpful, but it's not a perfect roadmap for the patient. Typically we use the duplex for followup in patients and maybe as a preliminary test prior to some of the other diagnostic regimens. If we look at MRA it's, it's, um, no ionizing radiation, which is a plus, however, it does require a high degree of expertise and it can overestimate the percent of stenosis and in those patients who have concomitant cardiac as well as peripheral disease, if they happen to have a pacemaker, that certainly is a contra- indication. CT angio, um, can be helpful.

[30:25] It does require contrast. So we need to protect those patients with renal impairment and um, it is readily available at most institutions. So that is one of the benefits. And then if we look at DSA, digital subtraction arteriography, that truly is the gold standard, it's invasive as we all know, it does require contrast and radiation exposure, which again can be harmful to some of our patients who have concomitant disease in other areas such as the renal, um, such as renal disease. So imaging, if we look then at the recommendations you'll see the Class I recommendations readily for the top two. That is duplex ultrasound, CT or MRI is useful to help diagnose anatomic lesions, especially when we're considering that patient going to the OR for revascularization. So That's the key factor here. So if somebody's going to be revascularized, the testing, especially if it's invasive, would be indicated. If you scroll your eyes down to the latter

one, there is harm that we've put as a classification and that is that if someone has simply asymptomatic peripheral arterial disease, anatomic assessment of the patient should really not be performed. So invasive or noninvasive angiography should not be performed for the anatomic assessment of patients with asymptomatic disease.

[31:56] These next two slides are algorithms that are listed in our guidelines. They're very helpful. They're the, the nice things, a quick to refer-to that you might want to keep on a card or have downloaded to your, um, as an app. This diagnostic testing specifically here on the screen is for suspected PAD. You'll see that all of this specific areas are listed as yes-no decision points in terms of where the patient is with the typical findings and what we would recommend in terms of followup that dovetails with the guidelines. So you'll see in here some recommendations and alluding to the tables. Those tables are all in the guidelines, clearly stated. This next slide is for diagnostic testing for suspected critical limb ischemia. So in this case, patients need to have decisions made more promptly and certain parameters are a little bit different based on, whether or not they have wounds, et cetera.

Medical Therapy

[32:58] So now let's take and change our thought process here and look at some of the medical therapy for the patient with PAD. If we look at anti-platelets, you'll see that antiplatelet therapy does have a Class I, high level, a level A evidence. So there's randomized controlled trials that antiplatelet therapy with aspirin alone or clopidogrel alone is truly recommended to reduce those secondary events, either a heart attack, stroke, or vascular death, death in patients with PAD. Also, you'll see as you scroll down through here, the dual antiplatelet therapy. So that's a combination of aspirin and clopidogrel can be effective in reducing the risk of cardiovascular ischemic events in patients with symptomatic PAD, even though it's not well established. It can be useful.

[33:51] Then if we look on some of the other, um, therapies here, oral anticoagulation, I did want to address this. We have a Class II recommendation, level B evidence, that if we do use anticoagulation therapy, it is indicated to improve patency, that is after somebody has had a bypass, so they might've had an autogenous vein bypass graft or a prosthesis or prosthetic bypass graft. It's uncertain whether it's useful, but it can be helpful. The one thing to point out however is if we look at the class select recommendation, it's harmful if anticoagulation is used to reduce the risk of cardiovascular ischemic events in patients with PAD, so we would advise that it should not be used. There's high level evidence that that can cause harm to patients, so anticoagulation should not be used to reduce risk of cardiovascular ischemic events in PAD patients. If we take a look at this slide, you'll see all of the associated risk factors that patients have typically with cardiac disease or peripheral arterial disease.

[35:04] So statins are recommended for patients with PAD. There's a Class I level A as well as antihypertensives. Antihypertensives can be helpful in reducing the patient's risk of a further stroke, a further myocardial infarction, heart failure, or cardiovascular death. Specifically, the ACE inhibitors and ARBs can be effective to reduce risk in those patients as well. Glycemic control is so important. If you have a patient with peripheral arterial disease, it's often that they also are diabetic, so if they have those two diseases, it really needs to be carefully managed with the entire healthcare team that's addressing both diseases. Glycemic control definitely can be beneficial to those patients who have limb-related outcomes as well. Smoking cessation, this goes without saying, but there is a Class I recommendation for helping individuals quit smoking. They need to be advised at every visit. That's a level A as well as helping patients to find a plan to assist them and quitting smoking or refer to a smoking cessation program if you happen to have one available within your area. Another key thing is that patients with PAD should avoid exposure to environmental smoke at work, home and in public places.

[36:37] Now, what about some of the other medications that have been used? You'll readily see that one of the key ones is Cilostazol: Class 1, level of evidence A. Cilostazol has been an effective therapy. It improves symptoms and has been shown to help patients with PAD increase their walking distance if they've had claudication. You'll see though, however, that Pentoxifylline as well as any chelation therapy is not effective. It's not beneficial, therefore not recommended. Also the use of homocysteine lowering with vitamin B complex vitamins not indicated or recommended for patients with PAD. There's really no benefit to that. So what about minimizing tissue loss in patients with PAD? We want to help them so that they don't have to help them avoid further sequelae with bad feet. So one of the key things, and this is a Class I recommendation, although we really don't have evidence, but it makes common sense to think that those patients who have PAD also diabetes, they really should be counseled about performing an exam on their foot and how to actually do that.

[37:51] In each of the counseling visits, you see the patient. In addition, those patients really do need to have prompt diagnosis and treatment and to avoid amputation. In patients with any type of foot infection, they need to be referred promptly to the interdisciplinary teams so that they can be treated appropriately. And also it's reasonable to counsel patients with PAD about PAD without diabetes to conduct a foot exam and healthy foot behaviors. And we do recommend twice a year foot examinations by a clinician. We think that's reasonable for patients with PAD. And of course the literature does, um, that's based on expert opinion. Okay. Well, what about structured exercise therapy? You can see it that it's a Class I recommendation and we do have level A and level B, for exercise interventions. The problem is though that many places do not have exercise programs for patients with peripheral arterial disease.

[\[39:01\]](#) We do recommend that and there's a new writing guideline that will help, um, help address those specific issues and help clinicians such as yourself provide exercise to patients. So in patients with claudication supervised exercise is recommended. It helps improve the functional status, the quality of life, and the leg symptoms that patients experience. The program should be discussed as a treatment option before revascularization is considered. Also, um, in patients with PAD, it can be either structured community-based or home-based exercise program. They also need to have behavioral changes, um, change techniques, talk to them as well to help improve their ability to walk better and of course their functional status. And lastly too, in patients with claudication, it doesn't necessarily mean that they always have to walk on a treadmill. We have seen good results with studies if they were able to use an upper body ergometry if they were cycling or doing any other activity that promoted and improved their functional status and ultimately their walking ability.

Screening in Other Vascular Beds

[\[40:11\]](#) So now in terms of, um, the focus here and the next few slides is just disease and other atherosclerotic, um, territory's besides the patient with PAD. So what we're looking at here is disease in the subclavian area. And as we indicated before, anytime there is a difference in blood pressure, arm, blood pressure of 15 to 20 millimeters of mercury, difference between the right and the left, it's likely that there might be a subclavian artery stenosis. In those particular patients with PAD, they should have a bilateral arm blood pressure at least once during the initial assessment. Obviously we get there when we do an ankle brachial index, but it should be done early on. If somebody has an abdominal aortic aneurysm, a screening duplex ultrasound for AAA, abdominal aortic aneurysm, is reasonable in patients who have symptomatic PAD. Now, why is that true? Because PAD has been demonstrated as a risk factor for abdominal aortic aneurysm.

[\[41:21\]](#) Additionally, there are recommendations in other published works, about the screening of the general population and then screening of patients if they have a family history or if they do not have a family history. Then there are also other territories where the vascular blood flows such as coronary carotid and the renal arteries. And in those particular cases, screening for asymptomatic atherosclerosis in other beds. If we really just focus in on the bullet point number three, there's really no evidence to demonstrate that if we screen everybody with PAD for asymptomatic disease in other beds it improves clinical outcomes, hence that's not, um, advised. And lastly, I just wanted to focus a few minutes on the evidence gaps in future research that we identified as the guideline writing committee. There are several specific areas that might intrigue you where we need future research directives in looking at patients with PAD. For example, and I won't read each of these but [\[42:29\]](#) one of the key things would be to have basic science and

translational studies to truly understand more thoroughly the vascular biology of endovascular therapies and bypass grafting. We need to develop new methods to prevent re-stenosis especially after people have a revascularization procedure. Other kinds of things would be to advance on what we know about the diagnostics to determine what PAD truly is. We need to have randomized controlled trials to look at the value of using the ankle brachial index to identify asymptomatic patients, to look at therapies to reduce cardiovascular risks. We also need comparative effectiveness studies to determine the optimal antiplatelet therapy for prevention of cardiovascular and any limb-related events in these patients. And further, you'll see on other lists here. One of the key things to highlight is that we do have different types of registries that are used by all of our societies.

[\[43:29\]](#) What we need to do is truly look at the impact of those registries, the appropriateness of use, and the outcomes on the patients. That would be very helpful. In addition, comparative and cost effective studies on the different techniques that we use from an endovascular perspective to treat, treat claudication as well as critical limb ischemia. And in the middle you'll see one of the examples of society for vascular surgery has used SVS wifi limb classification system and that's one of the systems that's used where symptoms, the anatomic factors and specific patient factors that can be used to actually predict clinical outcomes and optimized treatment. We need more of those. We need to validate what we do have and, and follow up. And importantly, um, too at the very top, we need to look at the role of dietary interventions in addition to statins and other other therapies to improve and perhaps modify the natural history of PAD.

[\[44:27\]](#) So lastly, I wanted to just point out some of the advocacy priorities. There are simply only three. I'm pleased to announce that the second one here, ensuring access to supervised exercise programs for patients with PAD has truly been addressed. Medicare coverage has been issued since March of 2017. We're currently working on writing guidelines to help define what a supervised exercise program should indeed entail for the patient with PAD. So stay tuned for those results. Also, the other advocacy priorities, if we looked at number one, we can see that the availability of the ankle brachial index is the initial diagnostic test. Not all areas within the country or clinical sites or office practices have the availability to have a doppler to be able to do the ankle brachial index. So looking at that, um, would be key. And number three would be the incorporation of patient-centered outcomes into the process of regulatory approval of new medical therapies and revascularization.

[\[45:32\]](#) So basically we're not just looking at how well did the intervention treat the actual lesion, but truly what was the impact on that particular patient? Did it truly affect the functional parameter? Did it affect their quality of life so we can really say that it's helpful to the patient with peripheral arterial disease? So in summary, I hope I've given you a broad perspective of the

scope of the 2016 guidelines. We've touched upon many of these specific areas somewhat. Thank you so much for joining us today for this webinar. Again, my name is Eileen Walsh and I'm thankful that you were able to participate with us today and indeed thankful as well to Janssen pharmaceuticals for being a proud sponsor of the American Heart Association's efforts to educate healthcare practitioners about PAD. If you would like to watch this webinar again or if you'd like to show it to your colleagues, visit the link at heart.org/managingPAD. Thank you again and have a great day.