**AMERICAN HEART ASSOCIATION**

**Moderator: Anastasia Pargulski**

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**12:00 p.m. ET**

Operator: This is Conference#:41264739

Operator: Hello and welcome to today’s webcast. My name is (William) and I will be your event specialist today. All lines have been placed on mute to prevent any background noise and please note that today’s webcast is being recorded.

During the presentation we’ll have a question and answer session, you can ask text questions at any time like clicking the green Q and A icon in the lower left hand corner of your screen, type your question in open area and click submit.

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For optimal viewing and participation please disable your pop-up blockers. And finally should you need technical assistance at the best practice we first suggest you refresh your browser.

If that does not resolve the issue please click on the support option in the upper right hand corner of your screen for online troubleshooting. It is now my pleasure to turn today’s program over to (Steve Dental). The floor is yours.

(Steve Dental): Thank you (Will) and good afternoon and welcome to the American Heart Association and American Stroke Association “Give Us The Guidelines” National webinar. Today’s session we will review new technologies and left atrial appendage closure. Are you ready?

For our call today we are fortunate to have as our presenter Dr. Jonathan Piccini, Dr. Piccini is a clinical cardiac electrophysiologist and associate professor of medicine at Duke University Medical Center and Duke Clinical Research Institute.

His research interests include the conduct of clinical trials and the assessment of cardiovascular therapeutics from the care of patients with heart rhythm disorders.

At present he is the director of the EP clinical trials program and arrhythmia core laboratory at Duke University and serves on the executive committee of the American Heart Association’s “Give Us the Guidelines” atrial fibrillation registry program.

He is an associate editor for the American Heart Journal and serves on the editorial board of heart rhythm and the Journal of cardiac electrophysiology.

He’s a principle investigator of the data and coordinating center for ORBIT-AF, a 25,000-patient registry focused on quality of care, improving outcomes in patients with atrial fibrillation.

He is also the PI of the genetic AF clinical trial, the first clinical trial to study genotype corrected rhythm control therapy for atrial fibrillation. Dr. Piccini has more than 140 publications in the field of heart rhythm medicine.

Clinically his focus is on the care of patients with atrial fibrillation and complex arrhythmias with particular emphasis on catheter ablation.

During today’s session he will – Dr. Piccini will share detailed information on development of nonpharmacological therapy for stroke prevention and left atrial fibrillation.

(In his low share) at the conclusion of today’s formal presentation you will have an opportunity to ask question and everyone’s line will be on mute.

But you can post via the question and answer icon on the lower right of your screen and we will do the – our best to address all questions during the call.

And at the end there will be a short survey, please take a few moments to answer the questions as it will help ensure that these calls remain relevant to you.

Thank you again for your participation today and Dr. Piccini I will hand things over to you. Thank you.

Jonathan Piccini: Great (Steve). Thanks for (head) introduction, more simply my name is Jon, I am a cardiac EP at Duke and majority of my practice focuses on treatment of atrial fibrillation and I am very happy to have the chance to talk to you about what I think is a very exciting and very timely topic and that’s left atrial appendage closure for stroke prevention.

And we have a little bit of a delayed start and due to some informational technology challenges and so we have my desktop shared with you all so hopefully we can play a lot of these videos that I have embedded through my PowerPoints.

But if pictures of my children come up of them terrorizing each other or throwing snowballs, we’ll know that my screensaver has (got) between us in the content.

So please I apologize upfront for any technical glitches and if you have a problem seeing the content or any problems whatsoever during the broadcast please promptly (send) a message to let us know.

So here are my disclosures. It is important to understand that I received research grant to serve as consultant to several companies that either manufacture or market products aimed at stroke prevention.

This is the first main content slide and it’s just to remind us what the three primary treatment goals in atrial fibrillation are which are to prevent – first and foremost to prevent stroke, to control the heart rate and to eliminate symptoms and improve quality of life.

And for anyone that deals with atrial fibrillation frequently you say well gosh Jon why do you even bother including this slide, this is like the no brainer slide and one of the reasons I’ve included is there’s been a recent survey done by the European Heart Rhythm Association where they served eight patients with atrial fibrillation asking them if they understood their goals of care.

As well as some other surveys administered by different atrial fibrillation support groups and what rings through and clear is that patients with atrial fibrillation are very often unaware of what the actual goals of therapy are.

And so I think it’s now a critical part of any (invasive) encounter, just remind patients that the importance of preventing stroke controlling the heart rate and eliminating symptoms and restoring quality of life.

And we all know that one of the worst sequela of atrial fibrillation is strokes and between anywhere from 15 to 20 percent of all strokes were due to atrial fibrillation and if we ask what percentage of strokes in elderly patients are due to atrial fibrillation it’s even higher, one in four, 25 percent of all strokes.

Stroke is the leading cause of death and disability and it is projected to be the leading cause of death and disability after myocardial infarction by the year 2020 and fortunately we do have good (pools) to prevent stroke.

And we have had them for a while and this slide shows you all the randomized clinical trials of warfarin which demonstrated that warfarin – those (stressed) with warfarin is highly effective for the prevention of stroke and compared with placebo reduces the risk of stroke by over 60 percent.

And there certainly has been an evolution in therapy so we know that – recently we know that the nonvitamin K antagonist for anticoagulants are superior to aspirin and patients who can’t tolerate warfarin.

And we know that the nonvitamin K antagonist relative to warfarin from data and a large (met) analysis also suggest that the (know act) agents provide superior safety and efficacy relative to warfarin when we look at all of the aggregate evidence or perhaps the most important part of that beneficial effect is on the safety side where we see avoidance of intracranial bleeding relative to warfarin.

And you know a lot of times these talks degenerate into oh let me show you slide after slide of really bad news and there is reason for some optimism and good news.

And this slide shows you from an analysis published in (gem) internal medicine that the good news is that oral anticoagulation had steadily improved in patients with atrial fibrillation since the early 90s.

And fortunately the incident of ischemic stroke has decreased since the early 90s so we are making progress of course just because we’re headed into the right direction doesn’t mean we can’t do better.

Well what are the ways with – in which we can do better, well my problem is that not everyone can take an oral anticoagulant whether it’s warfarin or whether it’s (see no act) and these are data from the ORBIT AFib registry looking at practices across the United States.

And in this national sample we see that 13 percent of patients have a contraindication oral anticoagulation so before we even get out of the gate we already have 13 percent of patients who aren’t going to be able to benefit from these medications.

Well what about warfarin, well we know that even in patients who can tolerate warfarin we know that the time of therapeutic range is not optimal and so as you can see here a significant portion of patients have a relatively low amount of time in the therapeutic range and so even for patients on dosages of warfarin we have room for improvement.

But how (white) might we improve, I think the (no acts) are one new class of drugs that can be helpful but what’s another way and another way would be to provide a nonpharmacologic method of preventing stroke and showing here on the left is an autopsy specimen of a left atrial appendage where it’s – with a dense thrombus in the distal aspect and shown in the right panel is a transesophageal echocardiographic image, you can see the Mercedes Benz sign of the aortic root here.

Here is the left atrial appendage and the arrow was pointing to this guy here and this not tissue, this is a thrombus.

Well you know what is the evidence for the basis that we believe the vast majority of strokes in atrial fibrillation are due to clots in the left atrial appendage and this is a very elegant study from the Beth Israel Deaconess Hospital in Boston where some investigators performed transesophageal echocardiograms in patients who had a recent stroke versus patients who do not have a recent stroke.

And what they saw was that the patients who had atrial fibrillation in a recent stroke the prevalence of left atrial appendage (drawn) by was much higher and the prevalence of slow flow as observed by spontaneous echo contrast was much higher. Here is the series of images that get shown a lot.

What this four-panel figure is showing you is an actual stroke event that was observed in real time during a transesophageal echocardiographic examination so here in panel A you see the thrombus, the thrombus starts to move, the thrombus leaves the appendage and now the appendage has no more thrombus and unfortunately shortly after these images were recorded the patient had a thromboembolic stroke.

So shown here is some metaanalytic work or systematic review by (black shown O’Dell) where they looked at a series of autopsy studies and what they found based upon all of these different reports was that in patients without rheumatic heart disease 201 out of 222 thrombi were located in the left atrial appendage.

So you know these are the reason why we (sit) – we say that the majority of stroke due to atrial fibrillation is caused by clots in the left atrial appendage and who is this (what) the atrial appendage guy anyway or gal, well I tell my patients left atrial appendage is kind of like a junk closet, everyone has a junk closet at home right, you never want to be in it, it’s usually not very clean, it usually doesn’t get good circulation of air.

And it is an outpouching from the anterolateral primordial left atrium and we used to call it the vestigial structure because we really didn’t know what it’s purpose but today we know that it’s a very potent source of atrial natriuretic peptide which is important for volume balance and we know that the left atrial appendage had several important roles in maintaining atrial compliance and diastolic function.

Here’s another picture of that left atrial appendage and here it is on a cartoon representation and the problem is is that when the heart goes in atrial fibrillation and flow in the atria is slow, stagnant blood can form clots in the left atrial appendage and then those clots can leave the appendage as I show you in this prior esophageal echocardiogram images and caused a stroke.

The first line of defense against this problem is to thin the blood so that clots don’t form in the first place but we know as we’ve shared that many patients can’t tolerate an oral anticoagulant. This is a fun slide.

This shows you what a lot of investigators have been up to lately and that’s categorizing the different appendage (safe) and this is kind of like when you’re a little kid and you lay down on a nice clear day and look at the sky.

And said well that cloud looks like a giraffe and that cloud looks like an elephant, well if you look at pictures of the appendage some will look like cacti, some will look at chicken – will look like chicken wings, some will look like (wind stocks).

And some will look like cauliflower or broccoli and if that (uterus) have now been going on to images, I am looking at the type of atrial appendage and seeing if that correlates with stroke and in this study if patients who just had an AFib ablation may found in a case control study that chicken wing morphology was associated with the occurrence of stroke more than other forms or other types or shapes of left atrial appendages.

However in this study nonchicken wing morphology was associated with the higher risk of stroke so in this study if you have a chicken wing type of appendage your odds ratio for stroke was actually much lower.

So this is really exciting, it’s a fun thing to think about, can the shape of someone’s appendage tell us about their risk for future cardiovascular events but you know we’re probably a little early on in this science and so we have a lot of questions and not a lot of good answers as has been demonstrated by some of the conflicting data.

I’ll give you a couple of seconds to process the (stroke) slide. OK well this brings us to left atrial appendage occlusion so since this left atrial appendage or junk closet is the cause for about 90 percent of strokes in patients with atrial fibrillation is there another way we can prevent stroke besides giving patients blood thinners.

And one way to do that might be to close off the appendage so clots can’t get in there and form and then leave the appendage in travel to the brain and cause a stroke and this slide shows four devices.

Now if we were giving this talk in Europe all four of these devices would be available to us but in the United States there are only two devices available for commercial use, the WATCHMAN device which has been studied in several randomized clinical trials.

This is the WATCHMAN device here and then the LARIAT suture closure device which requires both an endocardial and epicardial approach which is available on market.

It has not been evaluated in any randomized controlled trials that has been completed and published and we’ll talk about these two devices a little bit further. Well let’s first talk about the WATCHMAN device.

Here’s the WATCHMAN device seated in the left atrial appendage. The idea here is that the device endotheliosis and then there’s no blood communication between the appendage and then main body of the left atrium.

The device had several barbs that helped it fixated to the tissue and the (TFE FiberCap) that helps facilitate endothelialization and occlusion. (On the next) frame is the self-expanding nitinol frame.

It’s delivered via 12-French delivery system and sizing is important, there are five available sizes and it requires that when the device is placed in the appendage that it is compressed a little bit and that’s important for both preventive of – prevention of blood flow around it as well as the security of the device.

So not to get too deep into the details, the very first clinical trial to evaluate the use of this WATCHMAN device was to protect AF trial and the protect AF trial was designed to demonstrate the efficacy and safety of this device and patients who were eligible for warfarin who had a CHADS score of more than 1 were randomized on to the WATCHMAN device or dose adjusted warfarin.

And there are couple exclusion criteria and so if you had class 4 heart failure or you had an abbreviated life expectancy or you had an appendage that wouldn’t accommodate the WATCHMAN device you were not eligible for this clinical trial.

And for the statistic gurus in the audience this trial is also notable because it was one of the first trials conducted with an (off) priority (Dasein) analysis among cardiology trials which isn’t really important.

But we can talk about that if anyone has any questions and the primary efficacy endpoint meeting did it work was the composite of all stroke cardiovascular deaths, (this then again) blows in a transischemic attack and the primary safety endpoint, a.k.a., was it safe was life threatening bleeding including pericardial effusion requiring drainage, bleeding in the central nervous system and GI bleeding requiring transfusion.

And here is the device schema, if you did get the device you were treated with dose-adjusted warfarin or Coumadin for 45 days or six weeks after the device while it endothelialized.

You had a transesophageal echocardiogram at the six-week time point to see if the seal was good and if it was you were able to come off warfarin and go to Clopidogrel and aspirin and then eventually you can – those patients came off Clopidogrel.

Here’s another way to look at it. Here’s the device arm. So the subject gets an implant, six weeks of warfarin, if the seal was good they go to aspirin and Plavix and then at six months they take aspirin only whereas the comparator patients were on dose-adjusted warfarin the entire study period.

And whether we see so in the primary safety analysis is you could see in this very first clinical trial there were some safety event associated with the implantation of the WATCHMAN device and if you think about it that’s not at all unexpected.

We know from other left atrial procedures like catheter ablation complications do occur. If you look in longer follow up though we see that the curves kind of come together and what it showed was that in terms of overall safety there was no significant evidence that one treatment was worse than the other.

If we look at the primary efficacy endpoint did it work again the (noninferiority) criteria was matched so another way to say that is the WATCHMAN device did not perform any worse than the control group and if anything numerically (as in) in the follow up the WATCHMAN device looked a little bit better but this was only part of the story.

When they looked at quality of life in PROTECT AF it wasn’t necessarily that the WATCHMAN led to dramatic improvement in patients’ quality of life but continued oral anticoagulation was associated with worst quality of life in the control arm.

And certainly I think this information speaks to most of us who have a (dib clinics) because we know that patients don’t like taking blood thinners all the time.

If you ask the question so there was the PROTECT AF trial, there was a registry and then there was the second trial called (Prevail) which we won’t spend a lot of time talking about today but as time has gone on the implant success rate has increased significantly and a recent registry show it is pretty close to 98 percent overall.

And then you’d say well you know kind of the purpose of all this is to get people off the blood thinner so how successful is that and again if you look at the most recent clinical trial 99 percent were off blood thinner so again most patients are getting a good seal and are able to come off medical therapy.

One thing that we always want to do in clinical trials is look at long term data whenever we can and what was really interesting is when they looked at long term freedom from (death) in the PROTECT AF study there appear to be an advantage with the WATCHMAN device.

And so you say well how is that, how you know why would a left atrial appendage occlusion device save lives and the reason for that is is that obviously if you’re not on a blood thinner you might have a lower risk of hemorrhagic stroke or bleeding and indeed that’s what we see when we metaanalyze all of the randomized control data available for the WATCHMAN device.

When we look at all stroke it’s neutral and when we look at ischemic stroke if anything there’s a little bit more ischemic stroke in the WATCHMAN group and that makes sense because patients are on an oral anticoagulant and we might expect an oral anticoagulant, would have some ancillary benefits and nonleft atrial appendage (drawn) by protection as well.

But when you get down to it the avoidance of major bleeding and the avoidance of hemorrhagic stroke appears to be what gives WATCHMAN it’s overall beneficial profile.

So a big question that we often get asked in clinical practice is as well you know we have this patient who can take any oral anticoagulant, could we consider doing a left atrial appendage closure procedure on that patient and these data starts to get at that clinical question.

So this is a registry of I believe a little under 150 patients who could not take any oral anticoagulant whatsoever and 93 percent had prior hemorrhage or bleeding diathesis and they did not get any warfarin after implant and their observed stroke rate was 1.7 percent and their stroke rate that they should have experienced based on their (trans vast for) was 7.3.

So these were just suggestive but they suggest that patients who have a complete contraindication may also benefit from device therapy and I think most of us intuitively think that these would be the patients who benefit the most right because they don’t have any other options, they truly cannot take an oral anticoagulant.

It’s just important to remember here in this blue box, these are data from the Oxfordshire community stroke project that shows that not all stroke in atrial fibrillation patients are due to large thromboembolic events and that makes sense right, no one thinks that AFib is while it gives you an increased risk of thromboembolic events no one suggest that atrial fibrillation gives you magical protection against small vessel strokes or vascular disease strokes.

So we would expect the WATCHMAN device to perform at less than 100 percent because we know there are strokes in patients with atrial fibrillation that are caused by mechanisms other than left atrial appendage thrombus.

So we talked about the LARIAT device. I am going to talk about the two devices now in a little bit more detail now that we’ve reviewed the randomized evidence. There’s no randomized evidence for the LARIAT device.

There are some observational data that have been published and in the LARIAT device a catheter is introduced in the pericardium and a catheter is introduced across the interatrial septum and there is a magnet on each catheter that connect.

And then a lasso or suture is advanced over the left atrial appendage and its inches off the left atrial appendage and this actually leads to death and shrinkage of the left atrial appendage when it’s interesting it also appears to lead to a lower incidence or a lower burden of atrial fibrillation so it also appears to have some effects that help maintain sinus rhythm in some patients after the procedure.

This is a video that one of my colleagues from Germany and Dr. (Horsevert) share it with me, you can see here the LARIAT suture is being positioned over the appendage and here is that suture being tied down around the appendage.

It’s important to note that as I mentioned there have been no completed randomized clinical trials so there is one that is just getting off the ground right now that is looking at this therapy. The FDA has released a safety advisory because there have been some patients who’ve had pericardial bleeding or left atrial appendage rupture with this device.

It does require both epicardial and endocardial access so if someone had bypass surgery or previous cardiac surgery they’re generally not considered a candidate for this approach. There are also surgical methods of closure in addition to oversewing the atrial appendage which is controversial.

There are now some devices that have been showing an observational series to have higher closure rates. This is the (aperture) clip which is a glorified (hairbreadth) that goes over the left atrial appendage.

It can be inserted through an open approach or through a thoracoscopic approach and this is a slide from Dr. (Mark Fionod). So what did the guideline say, certainly (I get) with the guidelines call we always want to talk about the guidelines.

It’s important to note that most of the guideline statements that speak to left atrial appendage closure occurred before the complete release of all the clinical trial data.

So in the American Heart Association, American College of Cardiology guidelines the only statement really that speaks to this is regarding surgical closure or in this case excision so surgical excision, removal of (left atrial) appendage maybe considered in patients undergoing cardiac surgery with the grade of evidence of 2B and a level of (evident C) so not based on clinical trial – randomized perspective clinical trial data.

So how do we put all this information together and I know we’re going a little quickly but I also want to make sure we have time for questions at the end.

So you know we know that patients with nonvalvular atrial fibrillation who have one or more risk factors for stroke are at increased risk for stroke and we know that those benefit – patients benefit from oral anticoagulation and they should be treated with an oral anticoagulant.

We know that using oral anticoagulants in these patients saves lives and prevent strokes. But what if they have a bleeding event? Well if it’s a reversible cause of bleeding like it is due to a polyp in the colon or some other reversible cause they should probably get that treated and then go back to oral anticoagulation.

But if they have intracranial bleeding or some irreversible cause of bleeding like diffuse angiodysplasia of the bowel then that patient is a good candidate for left atrial appendage closure.

And if the patient is going to have cardiac surgery then it would make sense for them to have surgical closure but we know that generally is not the case and most of our patients were seen in clinic.

If there is nonindication for surgery that patient can undergo percutaneous closure and ideally if they can take warfarin for 45 days they would be eligible or if they have prior (CT) surgery precluding the use of the lasso they could receive and endocardial occlude device.

But if they can’t take oral anticoagulation, if you feel comfortable with the observational data from Europe maybe they could receive an endocardial occlusion device or perhaps alternatively perhaps they should undergo epicardial suture closure as we’ve previously described.

Well you know the left atrial appendage occlusion device that is FDA approved is the WATCHMAN device, the approval came last spring and now there’s a national coverage determination that was just published in the past couple of weeks to month.

And the national coverage determination says if you have a CHADS score of 2 or higher or CHADS VASc score of 3 or higher you’re suitable for short-term warfarin but you can’t take long-term anticoagulation and there’s evidence of formal shared decision making interaction between the patient.

And an independent noninterventional doctor using an evidence-based decision making tool then you are a good candidate for the WATCHMAN device and left atrial appendage closure.

I think the number of risk factors, the suitability for short term anticoagulation and the inability to take long term anticoagulation are all pretty straightforward but what is this we’re talking about, what is formal shared decision interaction, what does that mean.

And so there are several of these out there, one is from the National Institute for Health and Care Excellence in the U.K. and in general what these tool is trying to do is illustrate the patients what life might be like without treatment where all the green smileys are patients who don’t have a stroke and the red faces or red frowns are people who have an AF related stroke and if they get treated with the blood thinner here are the red faces with the stroke.

As you can see this decreases the risk of stroke and here in yellow are the people who would have had a stroke but now otherwise won’t because they’re on therapy and these tools go through all the potential situations with the patient.

So they can see what the magnitude of benefit is and that way they have a way to incorporate how they fell about the benefits and how they feel about the risks in a way that’s a little more quantified and shared between physician and patient.

So I thought it might be helpful to talk about the case – a case, this is one of our patients that – one of my patients from clinic. A 74-year-old woman on – who had atrial fibrillation, heart failure, a mildly – a mild reduction in her ejection fracture of 45 percent, a recurrent gastrointestinal bleeding.

She had the (Chaz vast square) of 6 so she was a very high risk patient. And she had persistent AF and we did pulmonary (date) and isolation with rotor mapping and rotor ablation and she was actually in sinus rhythm but we all know that the reality is that AFib ablation is not a durable long-term cure and we know that stroke risk is not always rectified.

And she continued to have recurrent hospitalization for GI bleeding requiring coil embolization and surgery and on top of that she had a cavernous cerebral aneurysm and she could tolerate short periods of warfarin but she continued to have bleed and so we discussed the possibility of WATCHMAN implantation with her.

She understood the risks and benefits. Her neurosurgeon was in favor of it. Her cardiologist was in favor of it. I certainly was in favor of it and perhaps most importantly the patient was very, very much in favor particularly after having been admitted to the ICU with life threatening bleeding on more than one occasion.

So I am going to show some videos. Hopefully they will project. Here is our outer sheath for the WATCHMAN device and this is a pigtail catheter and we’re making the contrast injection in the left atrial appendage and we can see our target lobes that we’re going to put our WATCHMAN device in.

I am going to play that one more time. Here is another injection and you can see here there’s the secondary lobe of the appendage and then here’s the primary lobe and you can also see that the patients had percutaneous intervention of coronary artery in the past.

After we make a series of detailed measurements from both the (TEE) images and our fluoroscopic images we’re now ready to release the device and what you’re going to see on this next video is that the device stays fixated, we slide back the sheath and that allows the watchman device to open up and when it’s implanted people often say it looks like an upside down strawberry so hopefully will show that to you right here.

Here’s the sheath coming back, the WATCHMAN device is expanding and here you go, here’s your strawberry shape. This is the fixation rod. If you rotate this counterclockwise (left the Lucy) the device becomes free from the catheter.

I am going to show the deployment one more time in case you were looking at your iPhone and returning a page quickly. Here’s a shot of that device fully deployed in the left atrial appendage from a different view. And there’s our final picture of device after we took away the retaining wire.

Here’s an echocardiogram and you can see here’s the device and there’s no flow or leak around the device and that was the case in multiple echocardiographic views. This is a 3D echo image looking at the opening of the appendage. You can see the device here. Here’s all the spokes on the device.

Here’s the central face where that retaining wire was. And we can see that the device is stable here and again this confirmed the absence of any significant leak around the device.

When the patient comes back at 45 days or six weeks we repeat the transesophageal echocardiogram and as long as there’s no leak around the device or the leak is greater than 5 mm the patient at that point in time can come off their oral anticoagulant.

It’s important to understand that in any clinic that’s devoted to left atrial appendage closure it’s not a one size fits all.

So you have to consider multiple different treatment options for patients who present. This was a 67-year-old man that I saw who had prior stroke and had a fall in his garage and had a subdural hemorrhage on warfarin.

And the patient actually have prior surgery before and the left atrial appendage was not removed at that time. And so we did a CT scan to assess his candidacy and his left atrial appendage measurements were 52 x 34 mm which is larger than the WATCHMAN device will accommodate and since the patient had prior cardiothoracic surgery he couldn’t get a LARIAT and these dimensions weren’t suitable for LARIAT closure either.

So we referred this patient for a surgical addressment of his left atrial appendage and so we referred him for potential (at secure) clip placement versus other surgical means of closure. And you know at most centers this technology is getting rolling off the ground.

What I thought would be helpful for everyone is if I share the slide with you of some of our very first patients we saw in our left atrial appendage program here at Duke and you can see that several of these patients had severe bleeding episodes that required craniotomy or multiple hospitalizations in the intensive care unit.

One patient have a GI bleed with the hemoglobin of 5. His anticoagulation was stopped. He had a stroke while off anticoagulation and was put on a (no act) and continued to have a fall in hemoglobin. Another patient with a (chance vast) score of 5 had paroxysmal atrial fibrillation and on oral anticoagulation.

He had multiple episodes of genitourinary tract bleeding that required three-way irrigation and aggressive management.

And aside from this patient who we recently did these early patients and our subsequent patients have all been able to get off their oral anticoagulant, meaning that their six-week transesophageal echocardiograms looked good and in follow up they were doing very well and their Clopidogrel could be stopped.

It’s also important to mention that sometimes you’re going to see patients like this gentleman who had multiple TIAs despite an oral anticoagulant and was also having difficulty with chronic thrombocytopenia.

Many patients when they learn about these procedures, their risks with the procedure, their risks with continued medical therapy, I’d like to either take some time to make a decision or decide that they want to continue with medical therapy and that’s the whole purpose that shared decision making so important.

At the end of the day these are shared decisions we’re making with our patients. So in conclusion the majority of stroke in atrial fibrillation is due to left atrial appendage thrombus formation.

In modern therapeutic times about one in eight patients cannot tolerate an oral anticoagulant and left atrial appendage closure is a coherent, safe and effective strategy for many patients who cannot tolerate long term oral anticoagulation.

And with that I’d like to thank all of you for your attention this afternoon. I think we have some time for questions. I’d also like to thank the American Heart Association (got the) guidelines program for supporting these webinar series.

I’ve enjoyed the ones that I’ve attended as an audience member and I hope that this has been a valuable use of your time this morning or lunchtime depending upon where you are in the country.

Male: Thank you Dr. Piccini and (Will) please remind the audience on how to submit questions?

Male: Yes at this time we would like to take any questions you might have for us today. To ask a question via the Web click the Q and A button in the lower left hand corner of your screen, type the question in open area and click submit.

Male: I am a little worried and I am worried that people weren’t able to see the slides.

Male: Yes there was – some people had some delays but.

Male: OK.

Male: Yes, they’re – I am just waiting for other questions to roll in as to content with regards to the presentation. So first question it – comes from Northern Westchester Hospital, any problem with loss of the function you mentioned about left atrial appendage, also can you get MRI head after closure device.

Male: You know so those are great questions so let me take the first one. What do we know about loss of function of the atrial appendage. This is an area where there’s a lot of active ongoing investigation.

But if we just look at the clinical course of patients after suture ligation where after closure in cardiothoracic surgery those patients don’t appear to have experienced any deleterious outcomes.

Some patients as I alluded to actually experienced a decrease in the amount of atrial fibrillation they have but this is a very important ongoing area of investigation, understanding the long term changes and outcomes associated with left atrial appendage ligation.

It’s important to note that when you use a closure device as opposed to the suture or the clip you’re not eliminating blood – the blood supply of the appendage so presumably in the WATCHMAN patients where you’re just blocking opening of the appendage presumably the endocrine component of the left atrial appendage it’s still functioning in those patients.

And then the last question I mean this is always the moving target but just like patients who received intracoronary stents can undergoing an MRI imaging so too can patients who get a left atrial appendage occlusion device.

Male: Another great question, are there recommendations on what materials should be included in the patient decision discussion and who should be doing this?

Male: Well I’ll give you answer from the centers for Medicare services so they would say that the key pieces are those that are present in some of the existing guideline or existing tools that they cite and the (nice) guideline is one of those.

They’re – excuse me, the (nice) tool is one of those. There is also one from the NCDR that is available as well and you’ll see if you go into those tools you’ll see that the majority focuses on the patient’s perception of the importance of the efficacy or the ability of the device to prevent strokes and then the safety of the device so the likelihood that the patient could experience an adverse event.

Those are the main issues so basically ability to reduce stroke changes with respect to bleeding and then potential patient – potential complications.

Who should be doing it I think is a great question. I think the reality is is that when patients are referred for left atrial appendage occlusion they usually come to clinic having multiple conversations, first with their primary care physician, second with their referring cardiologist.

So they’ve already started to have these conversations and I think that shared decision tool I agree it’s best employed. Now who should employed I think is an open question. One might argue and be it national coverage decision does is that you want an unbiased physician. So someone who’s not an interventionalist.

I don’t have a real argument with that. Although I would say that sometimes understanding the specifics of the procedure makes the difference to some people so some people hearing about the procedure is a very important part of their shared decision making and so they may not get that piece until they visit with someone who does do the procedure.

But I think one great thing about this national coverage decision is we’re going to see how the use of the shared decision tools affects patient decision making.

And so I think not only is this an opportunity for us to help make patients more informed about their treatment decision it’s also a huge opportunity for us as cardiovascular professionals to understand the – to understand how these tools can impact clinical practice, patient decisions and even downstream outcomes.

Male: Another question, are there any immediate risk clinician should monitor for after implementation of the WATCHMEN device and hold on a second, question just.

Male: Let me take that one first while you’re looking for the other question (Steve) so.

Male: OK.

Male: We admit these patients overnight to our cardiovascular short stay unit. So they stay one night with us.

We do a chest x-ray the next morning to make sure the device is safe and sound where it’s supposed to be and just like any patient who has large sheath in the groin we are watching carefully for any signs of femoral bleeding.

But their overnight observation is very similar to someone who undergoes catheter ablation of atrial fibrillation.

Male: And what happens to (ANT) production with left atrial appendage closure devices?

Male: So we’ve – I think we’ve answered this one already. So if you ligate the appendage with a LARIAT or if you sew it off or if you put a clip that eliminates the blood supply there’s an acute release of atrial natriuretic peptide levels and that can lead to the so-called atrial storm after LARIAT closure.

With WATCHMAN and some of the other devices that are used in Europe like the (coherence) device and the St. Jude device as well as the WATCHMAN you’re not eliminating the blood supply to the atrial appendage myocardium so presumably the (AMP) production and secretion of those blood – of those myocardial cells continues unaltered.

Male: So do you still recommend the anticoagulation for patients identified with new atrial fibrillation and do patients have an option for the atrial appendage intervention if they do not want to be on anticoagulation.

Male: So that’s a great question. It’s one of the you know $10,000 questions here so to be clear in case it didn’t come out in my comments I think the vast majority of cardiovascular specialists and electrophysiologists would say that oral anticoagulation remains first line therapy and it is the preferred therapy with the patient who has nonvalvular atrial fibrillation and additional risk factors for stroke.

The national coverage decision furthermore stipulates that patient should be in higher risk and may you know for their purposes they really want to see a CHADS (vast) score of 3 or higher.

And then let me address the final question, what about someone with new onset atrial fibrillation who says right out of the gate I don’t want to take an oral anticoagulant.

I think that it is reasonable to engage in a discussion of shared decision making process with that patient and if one of the reasons that they don’t want to be on long term anticoagulation is because they have you know significant anxiety over that or they have fears over their ability to be compliant due to an occupational risk or some other consideration, then I think in rare circumstances using this device shortly after someone is diagnosed is not unreasonable although I think it’s going to be a very rare situation.

However, even that patient is still going to need to be anticoagulated during the procedure and in the six weeks following the procedure so it doesn’t completely get that patient out of some anticoagulation.

And I think those are great questions and the answer to those questions are probably going to change as we move forward and learn more about this procedure and the long term outcomes associated with this procedure as well as the nonvitamin K antagonist oral anticoagulants.

Male: So we are at top of the hour and I want to be in cognizant of everyone’s time and apologize for those questions that we could not get to.

But on behalf of the American Heart Association and American Stroke Association we really would like to thank all our people that have attended, our call for your valuable time and participation.

And a special thanks to Dr. Piccini for his expertise on this subject and really providing a phenomenal presentation. So again thank you for attending and we look forward to talking to you again in the future. Thanks everyone.

Operator: Thank you all our participants for joining us today. We hope you found this webcast presentation informative. This does conclude our webcast. You may now disconnect. Everyone have a great day.

**END**