

[MUSIC PLAYING]

KRISHNA : I would like to start with the importance of transradial adaptation for cardiac catheterization and coronary
TUMMALAPALLI: interventions because there are tremendous advantages from a patient perspective. So one request I would make is for you to reserve your questions till the end of my presentation.

So what I like to do is in the next to 45, 50 minutes, I will focus more on the clinical aspect rather than the technical and procedural aspects of transradial cardiac catheterization, and bring all of us up-to-date to what's happening in the latest trials, et cetera.

So I'd like to start with a patient that I took care of a little less than two years ago. This patient is a 55-year-old gentleman who went to a local hospital on April 2, 2017 with chief complaints of shortness of breath and chest pain. So he did have a documented history of coronary artery disease. He had stenting of the left anterior descending artery, at that time in Cleveland Clinic in 2011.

He also has hyperlipidemia. And important to note is he does have myotonic dystrophy, meaning he is very weak, and tired, and experiencing severe fatigue. He's also a little noncompliant with medications.

So when he was at the local hospital, as you can see in the EKG, the EKG does show sinus bradycardia and sinus arrhythmia. And you can see that there is a slight suggestion of these ST elevations in II, III, and aVF and the T-wave inversions in lead I and aVL, and with T-wave inversion in V2. The borderline Q-waves in the inferior leads, but not significant. So a diagnosis of acute coronary syndrome and possible STEMI was made. And patient was taken to the cardiac catheterization lab at the local hospital.

So that showed here, as you can see, the catheter in the left main coronary artery, you have left anterior descending artery coming this way. His previous stent was at this location. So it may be hard to see, but this patient does have a critical stenosis-- 90%-- at the beginning of the stent and also the distal end of the stent.

So it was diagnosed that this patient has acute ischemic syndrome involving the left anterior descending artery. That was their diagnosis. And they were able to place a long stent in the left anterior descending artery, clouding those two lesions. And it was successful. And then patient had a good result in the LAD.

And this cardiologist happens to be a femoral operator with experience of 20 years plus. But, for some reason, unable to engage the right coronary artery selectively. So they did not visualize the right coronary artery. So they thought the infarct vessel is taken care of and patient was transferred to their ICU. So in the ICU, the patient was not getting better. He was still ill. He was becoming bradycardiac, progressively hypotensive, and now the troponin jumps to 3.0 and CPK-MB went up to 50.

So they thought maybe what they are dealing with pulmonary embolism. A chest CT was performed at that time to rule out pulmonary embolism, which was negative. Patient was given the standard therapy for acute coronary syndrome, including aspirin, ticagrelor, heparin drip, and dopamine drip.

So then they thought maybe right coronary's involved because they could not visualize the right coronary. Maybe it was a right coronary involvement with the artery infarction causing hypertension. Though this patient was taken back to the cath lab next day by a different cardiologist, who is also a femoral operator, and again, with the experience, they again could not visualize selectively the very coronary artery.

The best they could do was to put a pigtail catheter into the aorta that kind of showed maybe there's a dominant right coronary artery on this side. And when they used the Amplatz catheter, they came as close as the right coronary ostium, and there was some suggestion of maybe high-grade stenosis, but selectively could not be engaged.

This is not a criticism on the cardiologists that they could not engage the right coronary because sometimes it does happen when you are dealing with femoral arterial approach, could be significant tortuosity in the iliac vessels. Sometimes the cardiologist does not have control of the catheter, so sometimes it becomes impossible to engage the right coronary, especially if it is anomalous in origin.

In this case, it happens to be anomalous origin as you can see, the origin of the right coronary artery coming from the anterior aspect to near the left coronary cusp. So they thought the patient is not improving. So they thought the best option would be to send the patient to Shadyside Hospital for possible single-vessel bypass surgery in this case.

So when we received the patient, this patient was in cardiogenic shock. Patient had the intra-aortic balloon, 1 to 1 augmentation, and he was intubated. He was also sedated. He was on multiple vasopressors, norepinephrine, dopamine, heparin-- that was continued.

And the surgery was evaluating the patient, and we were consulted to perform a TEE in this patient to make sure we are not dealing with any tricuspid incompetence or mitral incompetence causing worsening of his clinical picture. So that's when we got involved with this patient care. So I performed the TEE, and as you can see, the TEE measures. Here is the right atrium, and right ventricle is here, and there is some tricuspid incompetence.

The left ventricle, our function is not terrible. There's not much mitral incompetence, so the valve-allowed regurgitation does not explain. If you look at the right ventricle, the right ventricle is enlarged and some dysfunction noted. So the clinical impression now is resolved because of the right coronary involvement, and artery infarction, and cardiogenic shock on that basis.

Surgeons were hesitant to take this patient for a single-vessel bypass surgery because the high-risk nature of the clinical situation, the mortality would be very high. So I thought maybe we will give it a try to see what happens if we attempt the right coronary engagement from the radial approach.

So again, because of these challenges, we thought maybe a radial approach might save the open-heart surgery for this patient-- might be better. And I performed the radial catheterization on this patient. It was possible to engage with a 6 French Amplatz catheter into the dominant right coronary artery.

You can see the ostium. And this was predilated. There was a critical lesion in the proximal portion, so we put a long stent in the proximal portion of the dominant right coronary artery. It is a huge right coronary and has a good opening. We put a 3-millimeter long 28-millimeter stent.

So to complete the story on this patient, he did have prolonged course at Shadyside Hospital. His cardiogenic shock slowly improved. Yeah, he was in respiratory failure. He failed extubation attempts couple of times, and subsequently, he ended up with tracheostomy. He also had GI bleeding, atrial fibrillation.

And finally, after 10 days of aggressive therapy-- this part of the credit definitely goes to our critical care team, and he was discharged to cardiac rehab, Mercy Rehabilitation, 10 days later. And this patient did well since the rehab. And I see him now every six months, and is doing very well, walking, talking. His LV function has improved, RV function has improved.

So the point in this case would be that this case really illustrates the importance of knowing radial approach. I believe that radial approach did make a difference in this patient. That approach needs to be considered when femoral approach is incomplete or unsuccessful before we call the surgeons. So in a critically ill patient, in this case, it did make a difference.

So to expand further, we are not only doing radial arterial catheterization, so now we are expanding into other areas like, in this case, there's ulnar approach here, ulnar puncture is seen here. Sometimes we need bilateral access, particularly if we are trying to open a totally occluded vessel, CTO intervention.

We need one catheter-- in this case, happens to be at the left radial to engage and inject into the left coronary, for example, if there's a total right coronary occlusion, to get an angiogram and look at the collaterals where the artery occluded. And then to deliver the stent, we use the bigger guide catheter through the ulnar artery.

So we are using sometimes bilateral radial artery access, and the new trend now that's coming up is so-called the distal radial approach, where instead of using at the typical radial site, we are able to puncture at the distal radial, so-called the snuff box radial, and that's also taking progress.

And the advantage of this, theoretically, that there will not be any forearm hematomas and AV fistulas, and problems like that. So one might ask, why do we have to change from femoral lateral approach, which has been worked so well for the last three decades, and why do we have to switch the approach?

And I will answer that, but I will tell you that the United States is lagging behind in the adaptation of radial approach. If you look at the worldwide experience, UK, France, Norway, Malaysia, the adaptation is 70% to 80%. And some places in Canada, the adaptation is more than 90%. They are also similar in Japan, South Korea, and places like that.

So if we just look at the UK and the US experience here, it is represented with graphs. Let's look at the US experience. In 2007, Dr. Sunil Rao has compiled in NCDR registry that in the United States, we are doing 1.3% of the PCI procedures where radial artery in 2007.

Now, that has improved, and now in 2018, we are up to 40% range, and this is expected to grow. And in 2020, although the slide here says 80%, I suspect it'll be about 50% range. And UK, actually, much more ahead in this curve than the United States.

So again, the point here is that for interventional cardiologists who have been doing procedures from femoral artery for the last three decades, to change into a radial approach would be so-called considered as a disruptive technology. So always the question comes, why do we have to do it? Why not just stick with the femoral artery approach? Are there any benefits of radial? Is radial approaches as effective as femoral? Because femoral, we have been doing for 30 years.

And there's also a doubt-- is the stroke risk higher with the radial? Because we are going most of the time from right radial approach, and the innominate artery is right there. And if you disrupt the plaque, patient may go into a stroke. So is there a stroke risk higher in radial? And what about the risk to the arm? Most people are right-handed. Is it safe to do a right radial approach?

And can we do it in STEMI patients? You know, we have the pressure off due to balloon time. Can we meet those guidelines? So all these questions linger, so any new technology wants to replace the old technology has to prove that all of these can be done with radial approach.

So I hope in the next 30 minutes, I would present the data, and based on the literature, evidence-based, not just personal opinion-- evidence-based data to show that all of these are possible with radial arterial approach.

So one of the main reasons we do want to switch from femoral to radial is this. You know, you have this patient, a large hematoma, ecchymosis-- this is not a pleasant thing for the patient or anybody. And the local complications, the femoral arterial access is significant. It is anywhere from 2% to 10%.

And this could range from minor complications to even major complications. The major complications are pseudoaneurysm, large hematoma requiring blood transfusions, AV fistula, and even the horrendous complication one might encounter with femoral arterial approaches, retroperitoneal hematoma.

Retroperitoneal hematoma is very serious, and it is fatal in certain cases. In addition to that, the femoral vein and femoral nerves are close by, and the nerve damage can take place. And sometimes thrombosis can happen if the femoral artery happens to be small, or by mistake, if we puncture, not the common femoral, but the superficial femoral or deep femoral.

So there are many complications, and the complication rate still persists. It's not zero. It's similar arterial approach. Even if you use ultrasound technique or micropuncture technique, still the complication rate is higher. So that is the reason why the whole radial adoption-- adaptation was taking place.

So we know that the radial arterial approach reduces these kinds of puncture site and bleeding complications. This was shown as early as in 2004. This is a compilation of total randomized trials, including 3,200 patients. And as you can see, the entry site complications is much in favor of radial arterial approach.

And we also know clinically that the women have much higher chance of bleeding complications with any percutaneous procedure. And that is shown here. They not only have a higher rate of bleeding complications, but they get much higher benefit also by switching from femoral arterial to radial arterial approach.

So we are still adapting, as you can see. But still, this is not a new procedure. This has been going on, the radial adaptation, for the last three decades. And the first paper was published in 1989 by Dr. Campeau. So he put his experience, a hundred patients, using 5 French catheters. There were 12 failures, but one person really largely occlusion and major bleeding.

Another question that comes up in international cardiology is if we cannot do femoral, why not do brachial arterial approach. That's what we used to do 40, 50 years ago, by using a brachial cutdown. And from there, some people are using brachial puncture technique.

The problem with the brachial arterial puncture is that you are actually risking both the radial and ulnar arteries at the same time. So if there is a big complication like thrombosis or stenosis of the brachial artery, you are risking entire arm.

So reviewing the literature, to my knowledge, there is only one paper that actually was published comparing the radial approach to femoral approach to brachial approach, and this was the ACCESS trial that was published in 1997. And in this trial, the major entry-site bleeding complications were none with the transradial, 2% with transfemoral, and, in fact, 2.3% with transbrachial. So transbrachial is not a good alternative to transfemoral.

So coming back to the arterial anatomy and why this concept has started, very briefly, you have this deep palmar arch and the superficial palmar arch, as contributed by radial as well as ulnar arteries. And so the idea was that if you punctured the radial artery, even if you lose it, there the circulation is intact. And also the radial arteries on the top of a bone, easy to get hemostasis.

There's no important vein. There's no important nerve next to the radial artery. So the damage to any other structures would be less. And traditional thinking was that we had to make sure that the palmar arch circulation is intact before we do radial artery. So we used to do this so-called modified Allen's test or a Barbeau test to make sure that the arch is intact.

So baseline, you have the oximeter for the thumb. You have nice waveform, and when you occlude with your fingers, both radial and ulnar arteries, you lose your saturation waveform. And then when you release the ulnar, still compressing the radial, you have resumption of this, your waveform, so telling you that it is intact.

In the past several years, we used to check this, and then if there is an abnormal test, then we did not do radial arterial approach. However, that theoretical concern is no longer valid, and many experts in the field, they do not routinely check Allen's test or Barbeau test. If there is a radial pulse, they proceed.

The reasons are multiple reasons for that. One would be from the anesthesia literature, where the anesthesiologist routinely put radial arterial lines on critical ill patients and anesthesia patients-- they don't check Allen's test. And then we also knowing it from the 1980s surgical literature that the surgeons used to actually resect part of the radial artery and use that as a conduit for a bypass.

So none of those patients had left-arm ischemia. So we don't routinely check Allen's test. This is, again, in a more scientific fashion was proven. This is a very elaborate, elegant study which, actually, what they did was they divided patients into three groups-- normal Allen's test, intermediate Allen's test, and abnormal Allen's test.

They checked the capillary blood lactate level from the thumb during and after the procedure. They check the hand-grip strength. They check the discomfort as described by the patient. And also they check the ulnar count-- when they inject dye into the radial sheath, how long does it take for the ulnar artery to show up on the angiogram.

So when they looked at systematically, there's really no correlation, whether you have an abnormal Allen's test or a normal Allen's test, all these points are all over the place, indicating that there's no role of Allen's test now to do or not to do radial arterial approach.

And looking at a different way, we have experience, worldwide experience, of more than 650,000 patients who had radial arterial approach, not counting the minor complications. Yes, complications do occur with the radial arterial approach, but mostly they are small hematomas and ecchymosis, some discomfort, pain in the beginning, but no major complications. So there's only one in the literature. One hand ischemia was reported because of the occluded radial artery, and that was handled with a balloon angioplasty in that case.

So clearly, with all this data, that we can clearly say that the radial arterial approach reduces bleeding complications. Now, the most important question is what is the problem with bleeding complication after a PCI, for example. So next two slides will tell us that anytime we have a patient with PCI, and ends up having bleeding complication, that increases the mortality and morbidity.

So this slide shows clearly that, as the complexity of our patient increases, the bleeding incidents also increases. So a fairly stable angina patient, overall bleeding rate is 2.1%. So if you have a non-STEMI and a STEMI patient, the rate goes up. STEMI patients, it can be as high as 12.7%.

And we also know that there are two types of access-- the two types of bleeding that patient might encounter. One is a non-access site. The other one is the access site. So by changing the approach from femoral to radial, we can affect the access-site bleeding. We can reduce or almost eliminate the access-site bleeding.

But the non-access site bleeding, mostly GI bleeding, that we had to change by changing our pharmacotherapy. And we are making progress in that by not giving IIb/IIIa inhibitors as we used to give 15, 20 years ago. Now we are uploading patients with dual antiplatelet therapy, even in acute coronary syndrome and STEMI patients, not giving IIb/IIIa's, and that is reducing the non-access site complications.

So to emphasize the problem with bleeding after PCI, here is the OASIS Registry, OASIS, and CURE, three trials that showed that if the patient has bleeding after a PCI, the death rate goes up, the myocardial infarction rate goes up, and the stroke rate goes up. So it's a bad happening for our patient to have it bleeding after a PCI procedure.

So more elegantly shown here is the impact of myocardial infarction and a major bleeding in our patients after a PCI. So if you have an MI or bleeding within the 30 days after PCI, so what happens to their death rate over next one year? So that has been shown here. The bottom line here is, if you just have a major bleeding after PCI, the mortality rate is 3.4.

So if you just have an MI, your patient had an MI after PCI, mortality 8.6. OK, sorry. If you do not have an MI or major bleeding, the mortality is 3.4%. So if you have a MI, it's 8.6%. If you have a major bleed, 12.5%. But if you have both, MI and major bleeding, your mortality, they're as high as 28%.

So any of these things that we can impact would be beneficial to this patient. So that's where the international randomized trials will come in place for us to really believe that radial arterial approach does make a difference in these two components. So I like to go briefly about these trials.

MORTAL trial is the one that was published around 2010, retrospective analysis of 38,000 patients, the transradial approach reduced bleeding, complications, and reduction in transfusion rate by 50%. And it also reduced mortality from 3.9% to 2.8%. But this is a retrospective study, but we will get to some randomized prospective trials.

So one of the landmark large patient-population trial was the RIVAL trial which was published in 2011. And this actually changed my practice. I think it's about 2011 that I switched my practice from femoral to radial approach. So what they're trying to determine was if the radial was a similar arterial access for angiography and PCI, can it reduce the composite endpoint of death, myocardial infarction, and non-bypass related bleeding.

And all patients are acute coronary syndrome patients. Larger number of patients, 7000 patients, divided into 3,500 radial access, and femoral arterial access, 3,500 patients. So the primary outcome, as we said, composite endpoint. They have also prespecified their secondary endpoints. We will look at them. Those are also valid in this group.

In the RIVAL trial, the definition of bleeding was more than 5 grams loss of hemoglobin. And in the overall trial, there's no statistically significant difference between the primary endpoint and secondary endpoint. So it was then, when they analyzed the subgroup analysis, what they found was, if you look at the major vascular access site complications individually, there's a clear difference favoring radial approach, 1.4% to 3.7%.

And if you also use the older definition of a serious bleeding, which is hemoglobin drop of more than 4 grams, then also this rate, if this radial approach reduced those bleeding complications. And the interesting subanalysis in this trial showed that it's clearly showed here that if the patient presents with STEMI, actually the primary endpoint was met.

So remember, these are all ACS patients, that include some non-STEMI, STEMI, unstable angina and STEMI patients. So if the patient present with STEMI, and you do radial approach, the primary endpoint was met. And also, the radial volume by the center, so if people are doing a lot of radials, the highest volume center, they also met-- the primary endpoint was met.

So the point is that if a institution and an individual is committed to doing radial, it has to be a full-time commitment to the radial approach. But if you look at the only vascular complications, it doesn't matter whether you do high volume, medium volume, or low volume, they all had reduction in their vascular complications from the radial approach.

So vascular complications, it didn't matter whether you have STEMI or non-STEMI, there is improvement. Death-- STEMI patients, there's a improvement in the death, so very important results. So the primary outcome appeared to be lower with radial compared to femoral in high-volume radial centers and STEMI patients. The radial had fewer major vascular complications with similar PCI success.

So next few slides, I want to discuss three more important trials. Very quickly, this one is a, again, multi-center STEMI-ACS patient group study as from Europe. 1,000 patients-- they are all STEMI patients. They were all referred for primary PCI or rescue PCI. Cardiogenic shock patients were also included. So their combined endpoint was met. The transfemoral rate was 21%, transradial 13.6%. Mortality was better with transradial, and bleeding was much better with the transradial.

And STEMI-RADIAL is up here again, another trial, including only STEMI patients. It's a randomized trial with 700 patients that they looked at. Their primary endpoint definition was 30-day bleeding and access-site complications. So they have met their primary endpoint-- transfemoral 7.2% and transradial 1.4%. Mortality was similar, but the investigators commented that there were only 700 patients to really account for the mortality benefit.

The other common question comes also is, can we achieve the door-to-balloon time? If you have a patient with STEMI in the emergency room, can you do quickly, within 90 minutes, do the radial arterial approach and do the angiogram to put a stent? And there are many, many trials which show, yes, it can be done.

I wanted to share one trial here. This is a non-randomized, a single center, Montreal Heart Institute experience, about 500 patients. They are all comers with STEMI, and within that one year, 2007 to 2008, the access site was operator-driven, and they showed the time to puncture, time to revascularization, door-to-balloon time, ischemia time, they're all similar with both groups.

But the interesting finding here was, if you look at the major adverse cardiac events, and that, they are all in favor of radial arterial approach. We still don't know the exact mechanism of why there is a mortality benefit by just switching from femoral to radial. Several theories have been postulated. One would be, like we said, there's less bleeding, so less bleeding leads to improved mortality in these patients.

And the other postulation was that, with the radial approach, because there's no puncture-site bleeding, you will not interrupt our antithrombotic/antiplatelet therapy in those patients. Maybe that has a benefit as well. But we still do not know the exact mechanism of why death rate is affected by switching from femoral to radial.

Here is just a share, another patient of mine. This was several years ago. This patient came in with inferior-wall STEMI. Patient is about 425 pounds, so I thought it's best to avoid all the groin complications. Took the pictures of the left coronary angiogram. Left is good, and then the right coronary is completely occluded right here.

So we're able to put the balloon, open stent, so STEMI also-- STEMI patients can easily be taken care of by a radial arterial approach. And in this particular patient, I believe that all the femoral access-site complications have been avoided. And the Harvard study done a few years ago showed that the higher the BMI, the higher the puncture-site complications if you go with femoral arterial approach. So higher BMI patients would clearly benefit from radial arterial approach.

So this is one of the last trials I'm going to discuss, which is very important trial. This is a MATRIX trial published in 2015. So this, again, alleviates some of the concerns that the femoral operators might have, that, are we causing more strokes by switching to radial approach.

So this is the largest trial, and this is a randomized, superiority trial. When they designed the trial, they wanted to prove that radial is superior. 8,404 patients from 74 centers-- it's an international trial. The primary endpoints were major adverse cardiac events and net adverse cardiac events. And they also looked at all-cause mortality, stroke, MI, bleeding.

So the results are listed here. The MACE was reduced by 15% relative reduction. This particular one did not reach statistical significance, but the net adverse cardiac events were reduced by 17%, reached the statistical significance. Stroke rate was same in these two groups, alleviating our concern that just because we go through the-- closer to the innominate artery doesn't mean that there will be more strokes. So the stroke rate is exactly equal in these two groups.

And there's also 33% reduction in the bleeding. And if you look at just all-cause mortality, there's 28% reduction. So this is a very positive trial indicating that the radial is superior to femoral arterial approach. So in summary, we looked at the RIVAL trial. It's the landmark trial, 2011 trial-- clearly showed vascular complications are better.

The RIVAL STEMI-ACS trial showed at 30-day endpoints, bleeding and mortality are better. STEMI-RADIAL showed bleeding and vascular complications, along with net adverse cardiac events, are better with radial. And we didn't talk about the STEMI SAFE-PCI which was a smaller trial. Others, the US-based multi-center trial, Shadyside also participated.

It did show overall-- it's a women-only trial-- overall, women did better with radial in terms of bleeding complications. But in PCI group, it did not meet statistical significance. And we talked about the MATRIX-- MACE and NACE are better, and radial is superior.

So one other concern the femoral operators might have is, are we exposing the operator and the cath lab staff, and also the patients, for higher radiation because we are taking a longer time. And there are several studies to show that, as the radial central volume increases, the operator experience increases, all these things are coming down the exposure to radiation.

So there are all the curves, the utility of the contrast agent, everything is coming down. And there are also many other techniques that we could use to lower the radiation. Simply by placing the arm closer to the body, so it would be like similar to femoral arterial distance, and by using shields, using extension tubing, things like that.

So with all that trials, I think it's clear that the radial arterial approach is better compared to femoral. But there are many other clinical advantages as well to the patients and for the practitioners. So here is one advantage-- that you have a patient with atrial fibrillation on Coumadin. You don't really need to stop Coumadin. INR 2 and 2.5, even 3-- with INR 3, you could perform radial arterial approach, and there's no problem with bleeding.

If you are concerned about patient having stroke-- and sometimes stopping Coumadin for three days can result in a stroke-- so there is no need to stop anticoagulation, and the bleeding will be less, so you could be liberal with our antithrombotic and anticoagulant therapies.

Staff preference-- nursing staff would really love it if a radial patient comes to their care, as opposed to the femoral patient. And it's very ideal for our patients who have musculoskeletal problems, like back pain. They're obese. They can't lie down flat, you know, who are at higher risk of bleeding.

We used to think that-- here are some of the contraindications. We used to think that ischemic Allen's test was a contraindication, but as I have shown you, the concern of ischemia for the arm is very, very less. So we don't routinely check nowadays, the Allen's test or Barbeau test. We proceed if there's a radial arterial pulse.

We also used to think that the AV fistula, if the patient is-- dialysis patient has AV fistula, we used to say that we should avoid radial approach because, in case, if one arm fistula fails, patient has the other side, you can get the fistula. But the UK, last year, they have presented a large experience from larger data of patients, that it really did not matter whether you do radial approach or not in dialysis patients.

The concept was that, even if the patient needs fistula on the same arm, it was the view, it will be much higher, and we are puncturing the radial artery much distal location. So it will not impact the ability to have a fistula on the other arm. So the only contraindications that I could probably say are that if a patient has scleroderma, Raynaud's phenomenon, then I would probably avoid.

So right-heart catheterization also can be done from the arm. So we do this routinely. Right now we have, at Shadyside Hospital, several operators who do radial arterial approach in there, and they also do from the antecubital approach, right-heart catheterization. So if somebody needs right or left-heart cath, there's no reason to go for the groin.

So another question comes-- so can we use the radial approach on all comers, all patients? Yes, we can. We can do in STEMI, as I showed you. Note the balloon time is same. We can do in bypass patients. There are techniques to visualize the LIMA and vein grafts from the radial approach. We can do complex anatomy like left main disease, calcified lesions, bifurcation lesions.

And there also, several techniques double up to even engage the larger diameter guide catheters for a radial approach in a sheathless fashion, so even if the patient needs ROTABLATOR, you could do from the radial arterial approach.

So with all these advantages, the reduction in bleeding, vascular complications, enhance patient comfort, with all of these that I re-mention, I think that is now overwhelming data that I will present in the next four slides that the radial is definitely superior to femoral arterial approach.

And these next few slides are courtesy of Dr. Gilchrist from Hershey Medical Center. So here is the-- if you look at the major vascular complications, these are all important trials as listed here, and the radial approach fares better for reduction of vascular complications, and for major bleeding, reduction of major bleeding, again, all these trials. Radial arterial approach is better.

And now imaging evidence is telling us that even mortality is better if you do radial arterial approach. And we are all familiar with the concept of a number needed to treat. So based on the data, that it reduces vascular complications, reduces bleeding, and reduces mortality, so here is a way to look at it. If you take 100 patients and switch from femoral to radial arterial approach, if you look at their vascular complications, the number to treat is 21. That means by switching from one approach to the other, five extra patients will be happier.

So major bleeding-- so if you take, again, same thing, number to treat is 47. So two patients will be happy because they don't have major bleeding. Mortality reduction-- number to treat is 100. So if you treat-- if we switch-- this is for acute coronary syndrome, not for a stable patient-- so if we switch from femoral to radial for acute coronary syndrome, one extra life can be potentially saved.

And look at it another way, the cost-benefit analysis of radial approach. So we're all familiar with-- the way to read this chart is-- it might be too small to read from there, but I'm sure these slides all will be available to you to review. So the way to read this is, which treatment is more efficacious? If the dots fall on the left side, therapy is more efficacious. If they fall on the right side, less efficacious. And these dots are representing here where the number needed to treat.

So just to give you an example of here, so we don't think twice for giving statins for hyperlipidemic patients for primary prevention. So if you'll straighten that out, the number needed to treat, to prevent one death, is 680 patients. So let's take a look at the radial access to number needed to treat to prevent one death is 100 patients.

Similarly, we don't think twice for giving Coumadin for atrial fibrillation patients. So coming in for atrial fibrillation patient, number needed to treat is 62. So a BP control, for example, so look at BP control for diastolic pressure less than 115-- number needed to treat, 158.

So based on all of these analysis here, benefits of radial access is falling in a favorable position, that it is important to consider this. And based on all of these advantages, there are actually-- have been guideline changes. And if you look at the 2018 European Society of Cardiology, they have-- look, they have placed radial access is recommended as the standard approach, unless there are overwhelming procedural consideration-- Class I, Evidence Level A.

And recently at the American Heart Association meeting a couple of months ago, in 2018, the AHA put a scientific statement that the radial-first approach is strongly recommended in all patients, but a graduated level of center and operator experience is recommended. And I would submit that, at Shadyside, we do have that experience for the center and also for several operators here who are working.

And the last point is patient comfort. Now look at this patient that I had not too long ago. Patient has back pain, hip pains, cannot lay down flat, neck pain. So all we did was we gave two pillows for the neck, and we used this wedge so the patient can comfortably put the legs on the wedge, relax, and we did the procedure from there, a radial arterial approach.

So I think based around all of these case examples, scientific data, and the literature, I think the time has come for clinicians to see their patients when they are referring to consider radial arterial approach as opposed to the femoral arterial approach for all the benefits that we have mentioned.