Cardiac Resynchronization Therapy CAC Transcript

Dr. Lisa Banker:

Now I'm going to repeat what I have spoken to all of you before. That is that I have just started the recording of this Contractor Advisory Committee Meeting in compliance with CMS. For the record, prior to doing so, I announced that Palmetto GBA would make an audio recording of the Contractor Advisory Committee Meeting, and I did consent on behalf of Palmetto GBA. Okay, so we're going to proceed to our discussion. You all have the key questions, and if possible, we want to get your interpretation of the rating of the evidence that supports the opinions that you're going to express today. For question number one, I'll throw this out to Dr. Merchant, first. We ask the question; how do you rate the quality of evidence supporting the use of CRT in patients with a QRS duration that's less than 130 milliseconds?

Dr. Merchant:

There's a sub-question there that says, "Should CRT be contraindicated?" I don't know if you want me to continue and answer that.

Dr. Lisa Banker:

Yeah, yeah. I think that'd be fine because I did provide sort of a sub-question saying should CRT be contraindicated in people with low QRS durations less than 130 milliseconds?

Dr. Merchant:

Yeah, I mean, by and large I think that's probably true. I think data from both Echo CRT, Resync, and a handful of other studies haven't shown any consistent benefit to CRT with QRSs less than 130. The one caveat I would say is occasionally for the folks where you anticipate AD node ablations, but that's a separate situation. For native QRS less than 130, I think there's little role, and the evidence probably suggests that it is not beneficial.

Dr. Lisa Banker:

Okay, and you would say the evidence for that is ... ?

Dr. Merchant:

Four.

Dr. Lisa Banker:

Okay, great. Dr. Powell. Any input on this question for us, your opinion as well?

Dr. Powell:

Yeah, thank you. I agree with Dr. Merchant. I think there is one other exception category, and that's patients who were studied in the BLOCK HF trial, and that was a trial of patients with ejection fraction less than 50% who had a second or third degree AV block, or a long first degree AV block, and were expected a case more than 40% of the time than ventricle, so that study randomized patients to CRT or standard right ventricular pacing, and showed reduced heart failure events in patients who received CRT, so that would be the one other exception category is patients which you have less than 50% who are anticipated to have greater than 40% facing the ventricle.

Dr. Lisa Banker:

Am I correct that that's largely based on the fact that they're going to have to pace so significantly?

Dr. Powell:

Yes, that's correct.

Dr. Lisa Banker:

Okay. And again, you feel the same sort of evidence confidence?

Dr. Powell:

Yes, and that was a randomized prospective trial, so yeah, I would say since there's a randomized prospective trial to support it in that population, and that's to try to avoid the detrimental effects of right ventricular pacing. Some patients will have worsening heart failure with right ventricular pacing and that can be avoided with CRT.

Dr. Lisa Banker:

Okay. Dr. Whalen, your input?

Dr. Whalen:

Yeah, I would agree with that. Essentially, chronic RV pacing places those patients out of that less than 130 millisecond category. The problem is that the time of the implant, nobody knows for sure exactly how much RV pacing will ensue after a device is implanted. That can depend on pacing algorithms, it can depend on the vendor and what kind of avoidance of ventricular pacing algorithms there are, so the challenge is that once that device is in, and once the patient is settled out, they clearly meet criteria for CRT but the documentation upfront is based on a high likelihood for RV pacing, which leaves a sort of nebulous inclusion. I agree, those patients clearly benefit from CRT. It's a matter of sort of documenting all of that upfront.

Dr. Lisa Banker:

Okay, so sort of doubling back just a little bit, am I interpreting you all correctly that at least in terms of a native, narrow QRS, in other words less than 130 milliseconds, no one really seems to question that that would potentially obviate a need for CRT, and in fact that CRT might be detrimental in that particular group?

Dr. Powell:

Yeah, it's Brian Powell, but I think what you're getting at is if a patient has a QRS less than 130 milliseconds and is not expected to pace in the ventricle, then CRT would not be indicated.

Dr. Lisa Banker:

Dr. Rose, do you have anything to add?

Dr. Rose:

No, I would agree with what has previously been mentioned. I think that the call out of the Block Heart Failure trial for the expectation of pacing is important but otherwise I certainly concur with the opinions expressed.

Dr. Lisa Banker:

Okay, great. I will mention, too, if this is okay, I'm going to read a little bit into the record. Dr. Stambler was supposed to be with us tonight and had an unavoidable emergency, so just for my purposes, he answered these questions for me, and essentially, he agreed that CRT would not be indicated in patients with a QRS less than 130 milliseconds with a rating of four on that. He mostly quoted European Society Cardiology guidelines in that regard. Roshitska's study and Cleveland's study. He did note a post hoc analysis in the FOCRT trial that identified a subgroup with a QRS duration less than 130 milliseconds who might benefit from CRT, specifically those with a high ratio of QRS duration to left ventricular end-diastolic volume, but it was really an observation in his mind and it was going to need a prospective trial, and he didn't seem to be able to give that much weight in terms of forward decisions.

Dr. Lisa Banker:

Based on that comment, do you all have anything else to add for this first question?

Dr. Whalen:

Nothing on my end.

Dr. Powell:

Brian Powell again. If I could just point out that the trial that he was referring to is patients who are not expected a pace, so these would be primary prevention ICV implants, for example, on patients who are not expected to pace on ventricles. They have normal AV node conduction, and if they have a QRS less than 130 I think that we're all in agreement that those patients should not have CRT. But just want to make it clear, there is randomized trial patients who are expected to pace on the ventricle because they have second or third degree AV block, or a long PR interval, and if their EF's less than 50%, there is randomized trials showing there is benefit of CRT.

Dr. Lisa Banker:

Okay. Thank you.

Dr. Lisa Banker:

Question number two, I'll start with you, Dr. Powell. This was how do you rate the quality of evidence supporting use of CRT in heart failure patients with EF less than 35% but with non-bundle branch block, and QRS durations in that a little more gray range of 130 to 149 milliseconds? And then I ask a few sub-questions. First of all, is QRS morphology an important defining parameter for CRT use? Secondly, based on the review of the evidence, should this group of patients that I just mentioned have CRT restricted to symptomatic heart failure? In other words, class three ambulatory four. And then is there any basis for CRT to have some sort of restrictive parameter put on it that you would use it in this class of patients based on the number of times, the frequency that they're getting hospitalized for their heart failure?

Dr. Powell:

Yeah, those are good questions.

Dr. Lisa Banker:

I'll start with you, Dr. Powell.

Dr. Powell:

Sure. As far as the first question, "Is QRS morphology a defining parameter for CRT use?" Yes, I do agree that the patient population that was pointed out here does have a lower likelihood of benefit than patients with non-bundle branch block. For the second question, "Should this group be restricted to patients with class three and ambulatory class four?" Yes, I agree that would follow the appropriate use guidelines. The third question, "Should CRT in such a group be limited to patients on actual medical therapy, yet are still being frequently hospitalized?" That, I have not seen that criteria used in randomized trials, so I think that would be a little bit outside of the clinical trial evidence or guidelines to have a requirement that patients have been frequently hospitalized.

Dr. Lisa Banker:

Okay, and so at least for the first couple sub-questions, you would rate your evidence on that as sounds like fairly strong?

Dr. Powell:

Yes, that's correct, yeah. For, "Is QRS morphology a defining parameter?" Yes, I would say probably a four or five for that. And the second question, yes, I would give that a five for the second question.

Dr. Lisa Banker:

Okay. Dr. Merchant?

Dr. Merchant:

Yeah, I mean, I generally agree with what Dr. Powell was just saying, and the challenge here is that I think, at least from my point of view, is QRS morphology a defining parameter? Yes, I would probably put that as a four. The challenge is I think that we're seeing a lot of data recently from the Chicago group and others looking at left septal mapping, and I think a lot of what we think of as being true left bundle branch block on EKG is not necessarily always the case. There are IVDCs that have a preponderance left bundle delay. Sort of, this is a very heterogeneous group, right? And that's why I hedge a little bit on saying not all non-left bundles are the same. I think our ability to clearly say who has true left bundle branch block and who doesn't is maybe not as good as we thought it was even a few years ago, but by and large I do think QRS should be a defining parameter, particularly in this sort of 130 to 149, and generally I agree. I think given all of the caveats with how subjective NYJ class can be, these should generally be used for people who have symptomatic heart failure. I mean, all three of these, I generally agree with what Dr. Powell just said. The frequent hospitalization is not a criteria that I'm aware of that has been utilized as any part inclusion in any randomized trials.

Okay. Let me try as an internist to pin you down a little bit. You spoke to the variability, and as far as what is really the left bundle branch block, and you know, how much of a preponderance of that is with a left bundle branch block? Would there be any way that you could think of to better classify some sort

of restriction on this group of patients to make sure that the right people are getting CRT versus not, if you kind of follow what I'm saying? That's always the difficulty with policy is how to be appropriately inclusive and yet have some sort of guard rails up.

Dr. Merchant:

Agreed. You know, I'll tell you what I use in clinical practice. For people who have right bundle branch blocks, or variations of right bundle branch block, I tend not to use CRT in this range. People who have IVCDs and others that sort of fall into more gray area, particularly if it's a little bit wider, in the 140s, and not in the ischemic, I tend to probably use CRT a little bit more, but if I were going to exclude anything I think I would exclude the true right bundle branch blocks in this area, rather than sort of lumping all the non-left together.

Dr. Lisa Banker:

Okay. That's helpful. Let me ask this question, too. Would you expect your colleagues in their documentation, say they had that IVCD that they thought had a preponderance of left bundle branch block involvement, more so than maybe was being indicated, would you expect them to be documenting that in a note to explain why they're proceeding with CRT?

Dr. Merchant:

I think so. I try to document that kind of thought process. I think it's a reasonable thing, particularly with the QRS in this mid-range.

Dr. Lisa Banker:

Okay. Dr. Whalen, what say you on this question?

Dr. Whalen:

Well, I would agree with most of what's been said. I think the challenge here is the difference between applying clinical research outcomes to the individual patient sitting in front of you, and although the non-left bundle patients are certainly less likely to respond than a left bundle with 160 milliseconds, in the non-ischemic, there are still responders within that group, so withholding the therapy altogether is a challenging thing when you're talking about sitting in front of the patient. There's a lot of variables that go into what makes a left bundle, and even left bundles that look the same on the surface that can be withheld for over a decade, that those are heterogeneous, and where the lead goes relative to the latest activated site has as much to do with response to CRT as the pattern of conduction itself, so I think the challenge here is what is good for a group is easy to say when you're looking at a non-ischemic young patient with symptomatic heart failure. They might take a 20 or 30 or 40% response rate for an acceptable risk. I do think that is reasonable, to expect the clinician to document it as such. We know that ischemic have a lower response rate than non-ischemic. We know that non-left bundles have a lower response rate than left bundles. I think that's got to be in some hands in the informed consent process between the provider and the patient.

Dr. Lisa Banker:

Okay, great points. Dr. Rose, I'm sure you see these patients with these types of issues. What do you think?

Dr. Rose:

I agree with what's been said. You know, it just seems to me that rather than classifying it as left bundle and non-left bundle, I wonder if it's more helpful clinically to define it as non-right bundle because it does seem to be such a heterogeneous group from true left bundle to these non-specific intraventricular conduction delays, and as it's been said, the wider the QRS in those categories, we've got evidence of improved outcome, so I agree with what Dr. Powell lead with in terms of the answers to the three questions, but you know, again, agree with the comments that have been said that it isn't just pure left bundle. I think that the intraventricular conduction delays that are non-specific, so long as they're predominately not right bundle, there should be opportunity for CRT.

Dr. Lisa Banker:

Okay. I think that's very helpful, so it sounds like all of you would say for a right bundle branch block you'd be much less inclined, whereas there's some wiggle room clinically for that gray area with this heterogeneity of the left bundle branch manifestation.

Dr. Rose:

I would agree.

Dr. Powell:

Yeah, I agree there.

Dr. Lisa Banker:

Thanks. Let's move on to question number three, and I'll have Dr. Whalen start with this one. This question was how do you rate the quality of evidence for the use of CRT in patients who have left bundle branch block, a QRS greater than 150 milliseconds, and therein a heart failure class that goes down to two? In other words, two, three, or ambulatory four. The sub-questions are is CRT justifiable for these types of patients, and in addition, would you ever expand to class one heart failure? And if so, what sort of evidence would you use to support that?

Dr. Whalen:

Well, so I think we have certainly some evidence that early CRT is helpful and effective in these patients. I think the number of patients in these studies has been small. I think that we are moving in a direction where this is where we're headed, but I don't think the data supports the true class one patient, although I will say in my practice most of these patients with a low EF and class one heart failure, if you really put them on a treadmill and push them a bit, I think we overestimate the number of these patients that are asymptomatic. Yes, and I'll intervene here as well based on Dr. Stambler's responses. He made the same point that sometimes he will actually take a patient who's said to be a class one, and get them on an exercise treadmill to find out if, in fact, that's true. Because patients often sort of minimize their patients when speaking to their doctors, so I think that's a good point. Dr. Merchant, what would you say on this one?

Dr. Merchant:

Yeah, I agree with what Patrick and Bruce alluded to already. In fact, I would even go a little bit further. I mean, the number of patients who are enrolled that are true class ones interact, or is small, but by and large I tend to think that there's little to be gained from having a wide left bundle branch block with

cardiomyopathy even if you're minimally symptomatic at baseline. I mean, based on everything we know about the contribution left bundle to worsening heart failure over time, reversed from modeling with CRT, I actually for wide left bundles more than 150 tend to be pretty aggressive even in the setting of minimal symptoms, so I think a treadmill to try to elicit symptoms is a good idea but I'm generally looking for a reason to put CRT into these folks, not a reason to avoid it.

Dr. Lisa Banker:

For those truly wide left bundle branch blocks, I mean these ones that are no doubt about on this 150s, you are saying you would easily feel comfortable expanding that to a class one heart failure patient just to prevent that loss over time?

Dr. Merchant:

Yeah, to prevent that loss. We know that reverse remodeling, there's something lost, I think, in the time that it takes for your ventricle to dilate, for heart failure symptoms to progress, and I think CRT is about as well situated to meliorate a left bundle with QRS more than 150, and I tend to think that it should be applied for class ones.

Dr. Lisa Banker:

Okay. And Dr. Powell?

Dr. Powell:

Yeah, I agree with the comments that were made. You know, there were a small number of patients in matted CRT. They did, per class when they were restricted to ischemic cardiomyopathy for the enrollment criteria, non-ischemic had to be two or greater, but I think for these wide QRS left bundles with low EF, most of them are going to go on to be class two or three eventually, so if you don't implant CRT up front, then you're likely to end up bringing the patient back for a second procedure for an upgrade, so I think it's reasonable to offer that to even the class one patient with a very wide left bundle.

Dr. Lisa Banker:

Okay. Dr. Rose?

Dr. Whalen:

I think they have the most to benefit. You know, for the lowest risk. Certainly, they have the largest area under the curve in terms of time to enjoy benefit of optimal therapy.

Dr. Lisa Banker:

Okay. And was that Dr. Rose?

Dr. Whalen:

No, I'm sorry, that was Whalen.

Dr. Lisa Banker:

Dr. Rose, do you have anything to add?

Dr. Rose:

No, I mean, just to also say it as Dr. Powell said, that there are some data from matted CRT, but I think the principal point and looking ahead at some of the questions that are coming up comes back to the subjectivity of the New York Heart Association classification versus when you really test these patients subjectively with other measures. Most of the time you will find that these patients indeed had a higher functional class.

Dr. Lisa Banker:

Okay. All right. We'll move ahead to question four, and I will toss this out to Dr. Merchant. I know that some of these questions will start to get a little repetitive and feedback on each other, but would you agree that New York Heart Association class is a differentiating factor for being a candidate for CRT, and if so, I threw this in, do you think that's an important thing for colleagues to document what the New York Heart Association class is? Since it's used so frequently in the various trials, in one way or another.

Dr. Merchant:

Yeah, you know, I think you can probably imagine. I tend not to think that it should be a differentiating factor. I think it's important to take into consideration, but I tend to put much more stock into the more objective parameters. QRS duration, QRS morphology, ventricular dimensions, ejection fraction. I mean, NYHA class is helpful. It certainly has been used as an inclusion criteria. But as many have already said, it's very subjective. There's lots of data to this. There's a lot of in-observable variability for the reasons we mentioned. I think patients often under report their symptoms. And it's obviously variable, right? You could be class two today, a few months later be class three, kind of slide up and down the scale, so I think it's helpful but it's probably among the things that I think is least critical in terms of determining CRT candidacy, in my mind, compared to the other objective things that we've talked about.

Dr. Lisa Banker:

Okay. Dr. Powell?

Dr. Powell:

Yeah, you know, I think those are good points. When I read some of the written questions, I had put yes, that I felt the New York Heart Association class was important, but I guess based on our previous question that we just discussed, the more I think about it as we're expanding into class one patients, I guess I still lean a little bit toward, I think it'd be reasonable to have New York Heart Association documented because I guess if you have a patient with a left bundle and a QRS of, let's say, 135, and they're class one, there would be less of an argument for CRT in that population. I mean, in the primary prevention ICV population, the New York Heart Association class was clearly in all the trials, and most patients who are thinking about CRT were also looking at primary prevention ICVs, so I lean a little bit more toward, yes, I think it'd be reasonable to include that in the medical record.

Dr. Lisa Banker:

Okay. And I think that's a good point. It's totally understanding the variability that there would be between patients on New York Heart Association class, and even within a single patient over time, it still provides some sort of window into the things that were considered by the implanting physician and it gives some sort of sense about where that patient clinically sits. That was sort of a little reasoning behind the question. Dr. Whalen?

Dr. Whalen:

Yeah, I agree with what has been said. I would add to that, if you're going to assess efficacy of your therapy, having a baseline is important, so I think the implanting physician documenting the class of heart failure prior to implant is at least the internally controlled metric to look at response to CRT, and especially as we look at left bundle, His bundle pacing, as we look at multi-site pacing, as we look at optimizing devices, having some clear objective measure of response is an important part of delivering the therapy.

Dr. Lisa Banker:

Okay. Thank you. And Dr. Rose, you have anything to add?

Dr. Rose:

No, I agree with what's been said. I guess the only thing I would say that, sometimes these come down to chart reviews, and I think if the implanter doesn't expressly say New York Heart Association but is otherwise providing an accurate verbal description of the patients' symptoms, that that should be acceptable.

Dr. Lisa Banker:

Okay. Understood. And we'll move on to question number five, and I will throw this out. I'm losing track here. I think this one will go to Dr. Powell. How do you rate the quality of evidence? Let me see, I'm skipping. How do you rate the quality of evidence regarding the use of CRT in patients who have class one heart failure, left bundle branch block, with a QRS greater than 150, and an EF less than 30% on optimal medical therapy with an ischemic cardiomyopathy etiology? I appreciate your input on this because I think this is something I struggle with a little bit, the difference between the ischemic cardiomyopathy basis versus the non.

Dr. Powell:

Yeah, that's a good question. There's some overlap with question number three from earlier, where in the meta CRT trial they did enroll class one ischemic patients, and there was in the overall trial where they put class one and class two together, there was a benefit from CRT over not having CRT, so kind of like our discussion earlier, granted it was a smaller number of patients who were class one, but the overall group showed some benefit. I think for the same reasons we discussed previously these patients often go on to progress to class two and three, so I think it's reasonable to offer CRT to that group.

Dr. Lisa Banker:

Okay. And Dr. Merchant?

Dr. Merchant:

Yeah, I agree with all of that. I mean, there's no question that the non-ischemic as a group tend to respond better than the ischemic, but even then with two left bundle branch block QRS greater than 150 on good medical therapy, I think CRT's undoubtedly a useful adjunct, particularly knowing that many of these people would progress to develop worsening symptoms over time.

Dr. Lisa Banker:

Okay. Dr. Whalen?

Dr. Whalen:

I would agree. I would also add that I think a lot of the patients with true left bundle branch block, and ischemic heart diseases, have non-ischemic cardiomyopathy in the setting of chronic coronary disease, and that those are not mutually exclusive diagnoses.

Dr. Lisa Banker:

Okay, so sort of a mixture of both a NCs, you're saying?

Dr. Whalen:

Yes.

Dr. Lisa Banker:

Okay. Dr. Rose?

Dr. Rose:

Dr. Whalen took my point away from me. That's what I was going to contribute. No, but I think it's an astute observation. You know, we are claiming this dichotomy between ischemic and non-ischemic when it's much more nuanced in these patients, and we do have data, as Dr. Powell pointed out, with respect to matted CRT in the New York Heart Association class ones, if indeed they are truly class one, as has already been said.

Dr. Lisa Banker:

How strong do each of you feel as far as the quality of that evidence, the strength of it?

Dr. Merchant:

Probably give it a four. I mean, there was a relatively small group as part of a larger randomized trial.

Dr. Powell:

I would say the same thing. A four.

Dr. Rose:

Yeah, I mean, I think on the strength of matted CRT, it's got to be a four.

Dr. Lisa Banker:

Okay.

Dr. Whalen:

I agree and I would say logistically this is a relatively low risk population and it's a small number of patients, so I don't foresee us getting better data out than this.

Dr. Lisa Banker:

Okay. Point well taken. I'm going to ask kind of maybe a dense question, but why the delineation of the EF less than 30% and this group, whereas it tends to be less than 35% in so many others? Is it just the way the studies fell out, or ... ?

Dr. Powell:

Yeah, that was the predefined, how they decided to enroll patients. It wasn't that they had patients enrolled with EF between 31 and 35% that didn't do well. It wasn't that. But they just decided when they designed the trial to use an EF cutoff of 30%. I'm not sure what their rationale behind that was.

Dr. Lisa Banker:

Oh, it was just that particular inclusion criteria for that trial.

Dr. Powell:

That's correct.

Dr. Lisa Banker:

Okay. All right, well, thank you. I guess we'll move on to number six, and let's see. Now that I've moved through these I'm definitely starting to lose my track. I think it's Dr. Whalen. I'm going to pick on you to be the first one to lead off. How do you rate the quality of evidence in support of CRT for this patients with EFs less than 50% but not in need of pacing?

Dr. Whalen:

Yeah, I think that as it stands now, I think the BLOCK HF data in the patients that are going to require pacing is firm, but in the absence of pacing I don't typically offer CRT to this patient population.

Dr. Lisa Banker:

Okay.

Dr. Whalen:

I assume you mean between 50 and 35% or 50 and 40%.

Dr. Lisa Banker:

Right, so without a pacing need, you would just sit tight with those people and follow.

Dr. Whalen:

Yeah, I mean, from a pragmatic standpoint, we offer His bundle pacing and left bundle pacing if we think they're going to benefit from resynchronization and physiologic, you know, AV synchrony and such.

Dr. Lisa Banker:

Okay. Dr. Merchant?

Dr. Merchant:

Yeah, I mean, strictly speaking, I agree there's not good data here. I will say that I have put CRT pacers into people with that mid-range EF of 35 to 50, particularly non-ischemic with through wide left bundles. I mean, they don't seem to be all that frequent. I have used CRT on them. My gut sense is that they probably respond relatively well if they have heart failure symptoms. I certainly wouldn't do it for somebody who's asymptomatic with an EF of 40 or 45%, but I'll be the first to admit that that's not based on any good data. It's very much extrapolation of other processes, physiologic data, but there's really not good data to support that.

Dr. Lisa Banker:
Okay. Dr. Powell?

Dr. Powell:

Yeah, I agree with what's been said. If there's, I can't really say it better than Dr. Whalen said it, if they're not going to pace and their QRS is less than 130 milliseconds, then I would not recommend CRT. If they are going to pace and their QRS is less than 130 milliseconds, or their EF is less than 30%, then there would be an indication for CRT.

Dr. Lisa Banker:

Okay. Dr. Rose?

Dr. Rose:

I agree with what's been said.

Dr. Lisa Banker:

Okay. All right, so we're moving on to question number seven. I think I'm back to Dr. Merchant. How do you rate the quality of evidence in support of CRT for patients with EFs in the 35 to 50% range, and they have a need for pacing. And then there were multiple sub-questions here. Would the potential for preserving EF sort of outweighs the risks of the complications that would go along with CRT lead implants and so forth? Secondly, how would you rate the quality of evidence in support of CRT used for patients with EFs less than 50% and class four heart failure? And then rating the quality of evidence in support of CRT with EFs less than 50%, and class four heart failure, and with left bundle branch block rated at 130?

Dr. Lisa Banker:

And I don't know how you guys keep all this stuff straight, but how you can answer that question, I'd appreciate it.

Dr. Merchant:

Sure. EF 35, 50, with need for pacing, so this gets to that BLOCK HF sort of group, and I mean it is a fair question in terms of, you know, the increased procedural complexity, battery life, whatever the case may be. By and large, I tend to think of RV pacing as a dose response, which may or may not be the case, but you started to see a reduction in hard outcomes of BLOCK HF in the longer term follow-up. It was in the original New England Journal paperwork, sort of some softer heart failure events, so for people who are relatively younger who I think are going to spend the next five, 10, 15 years, who knows how long,

potentially exposed to RV pacing in this sort of mid-range EF, I tend to favor CRT with the idea that they may be exposed to RV pacing for a longer period of time. Folks who are older, higher risk, or maybe that risk benefit analysis doesn't make as much sense, you know, I think there may be less to be gained from CRT, and I think the follow-up in the BLOCK HF was in the order of six or seven years by the time you started to see the curves diverge, so I tend to make a little bit of a discrimination based on how old or young the patient is and what their other comorbidities are, which I know is subjective and hard to put into terms from a regulatory point of view. But that's sort of my thought process on that from BLOCK HF data. The quality of evidence for CRT, EF less than 50%, in class three to four. I assume here we're still talking about need for pacing?

Dr. Lisa Banker:

Yes.

Dr. Merchant:

Well, I guess C is for left bundle, so if B is related to pacing, then I think it's the same sort of thing where if they've got more advanced heart failure symptoms and need pacing, then I tend to favor CRT. The seven, C, let's see. CRT with EFs less than 50%, heart failure symptoms and a left bundle greater than 130. I mean, I think that C here is a little bit like what we were talking about in the prior question where there's not very good data to support CRT for a de novo left bundle branch block in that mid-range of 35 to 50. The data's really for RV pacing, so yeah, I mean, I don't think there's very good data to support it regardless of the QR restoration.

Dr. Lisa Banker:

Okay. And Dr. Whalen?

Dr. Whalen:

Yeah, I guess I don't have a whole lot to add to that. I think similar to what was previously said, we look at the likelihood of EF decline, likelihood of clinical improvement, how much life the patient has in front of them, how vigorous and active they are. I do think RV pacing, if the EF is depressed to begin with, tends to be pretty predictable in its decline. It's much harder to predict the patients who have a good EF but aren't going to tolerate it, or the patients who have a good EF that will tolerate it, so I don't have a whole lot to add on this one, I'm afraid.

Dr. Lisa Banker:

Okay. Dr. Rose, any comments?

Dr. Rose:

Nothing substantive to add. I think Dr. Merchant and Dr. Whalen have really discussed the issue in detail.

Dr. Lisa Banker:

Dr. Powell?

Dr. Powell:

Yeah, I agree with the comments that have been made. The BLOCK HF trial is really the primary trial to support CRT so I think any patient that meets to inclusion-exclusion criteria of that trial would be appropriate for CRT, and there was a question previously about is there a clinically meaningful benefit, that might've been an earlier version of the questions that were sent out, and I do think it's a clinically meaningful benefit with heart failure hospitalizations reduced and lower mortality.

Dr. Lisa Banker:

Okay. All right. Moving ahead to question number eight, we'll toss this out to Dr. Powell. How do you raise the quality of evidence to support a requirement for at least 40% expected RV pacing in order to proceed with CRT, and how should that expectation be documented if you even agree with it?

Dr. Powell:

Yeah, so it's a good question. There is data out there supporting that greater than 40% right ventricular pacing was detrimental, so my main input here would be that oftentimes when we see a patient in the clinic, we usually won't be able to say, "This patient's going to pace 53% of the time." But our notes might say something like, "The patient's expected to have frequent ventricular pacing," or it might say, "the patient has heart block and is going to pace frequently." Or it might use the words like, "a majority of the time," but we often don't put a specific number in our note, so I wouldn't say that it was an inappropriate implant just because someone didn't specifically have their note greater than 40%.

Dr. Lisa Banker:

Okay. Dr. Rose?

Dr. Rose:

No, I would agree. I mean, I think that I don't know how clinicians can know precisely what the exact frequency will be. I think it's got to be a clinical judgment and I think it's incumbent upon the physician to document that that this would be frequently needed, but I don't think a numerical value is relevant.

Dr. Lisa Banker:

Okay. Dr. Merchant?

Dr. Merchant:

Yeah, I agree totally. I typically tend to use the terminology anticipated high burden RV pacing and then left the high burden not specified any further for the reasons everybody else has mentioned.

Dr. Lisa Banker:

Okay. And Dr. Whalen?

Dr. Whalen:

Yeah, I agree.

Dr. Lisa Banker:

Okay. I know Dr. Stambler was mentioning, I don't know if this has any pertinence, but he was saying he recommended RV pacing, or that any RV pacing greater than 20% with a pace QRS greater than 150 for at least three months would be a good support for an upgrade to CRT, and then he mentioned, I thought pertinently, that the David trial, which is I think what most of this is based upon, is that for every 10% increase in RV pacing that increase the risk of death or heart failure or hospitalization by 16%. He did bring up the intrinsic RV study that the best outcome was when the right ventricular pacing was between 10 and 19%, whereas increased RV pacing at 20% or above was predictive of death or heart failure hospitalization, so again kind of emphasizing I think maybe that those thresholds for pacing actually have to be fairly low. Any commentary on any of that? Okay.

Dr. Whalen:

I would-

Dr. Powell:

Yeah, I agree. I think those are ... go ahead, Patrick.

Dr. Whalen:

I was just going to say I think those thresholds going down is a natural recourse of the therapy maturing, getting easier to apply, successful implants being higher, complication rates being lower. I think it's a natural consequence that that number's going to move down with time.

Dr. Powell:

Yeah, I agree, and I was just going to briefly say that I think that the comments that were just made kind of outline the reason for not having a specific number being required, but just some kind of frequent ventricular pacing or high burden as has been mentioned.

Dr. Lisa Banker:

Yeah, at least there's some documentation that you anticipate that they're going to have to pace more than you want them to, obviously, so okay. Moving onto number nine, let me throw this out to Dr. Whalen. How do you rate the quality of evidence in support of CRT implementation for patients with A-fib, with heart failure, and with left bundle branch block, QRS durations greater than 130 milliseconds?

And if you feel the evidence is strong, again I threw in a question, should the provider be required to document what their strategy is?

Dr. Whalen:

I do think the evidence is strong as long as the therapy is delivered, so if atrial fibrillation is not controlled and CRT is not delivered effectively, then you're not getting the benefit of resynchronization. This is a hard one because this is a dynamic process that changes with a natural history of atrial fibrillation, things like catheter oblation for atrial fibrillation and AV node oblation obviously greatly impact the need for pacing and the capacity to deliver CRT, and often we're faced with implanting a device while the natural history of atrial fibrillation is still playing out.

Dr. Whalen:

And so I think if you are going to implant CRT in the A-fib population, you need to have a strategy for allowing them to pace which is either going to be controlling them either pharmacologically or definitively with AV node oblation, or rhythm controlling them allowing them to track sinus rhythm, and we're not unfortunately blessed with very effective pre-hand knowledge about how effective the treatment strategy for rhythm control is going to be in these patient populations, so I think the problem with this is it requires sort of guessing what comes next.

Dr. Lisa Banker:

Yeah, which I'm sure is difficult at times. Dr. Powell?

Dr. Powell:

Yeah, I think CRT implantation is reasonable in patients with atrial fibrillation in the left bundle and QRS greater than 130 milliseconds. I think that it's really standard of care to adjust medications and therapy to get a higher percentage of biventricular pacing, and it's such a standard of care that we often don't document in our notes, so I would say that having a requirement that someone outlines a plan prior to implant should not be required because it's just standard of care. It's kind of, as we see patients, this is just kind of accepted. We know we have to do it so we might not think to actually spell it out in our notes.

Dr. Lisa Banker:

Okay. Dr. Merchant?

Dr. Merchant:

Yeah, I agree with most of what's already been said. I'll frequently try to document some kind of plan moving forward, ANC arrhythmic, cardioversion, or whatever the case may be to deal with A-fib, but I don't know that in and of itself for justifying the use of CRT that that additional plan to address AFIB necessarily should be a hard and fast documentation requirement.

Dr. Lisa Banker:

Okay. Dr. Rose, any thoughts?

Dr. Rose:

I agree with what I heard. I actually just got kicked off the call for a second so I just logged back on. You know, I think that it's just standard practice to suppress arrhythmias and control rate, and I agree, I don't think that that needs to be separately called out in the criterion for documentation, per se.

Dr. Lisa Banker:

Okay. We'll move on to question number 10. If I'm skipping in any order here, no offense intended, honestly. I had this sort of planned out and then I had some participants ducking out so I'm just kind of making it on the fly here, but let's go with Dr. Merchant.

Dr. Merchant:

Yeah, it's a fair question. Again, like most things, I think a lot of this depends on how much are they pacing. Assuming that they're pacing all the time or quite a bit, I'll generally look for a change in EF of

more than 10%. I feel like sometimes 5%'s within the margin of error for any given reader, so 10% or a drop to less than 40% are sort of the numbers that I use in my head, assuming they started out at a relatively normal EF.

Dr. Merchant:

But again, it also depends on how much they're pacing, and where they started out in the first place. But assuming they started for normal, I tend to use less than 40% or drop off more than 10%, and that's what a handful of other upgrade studies have looked at.

Dr. Lisa Banker:

Okay, and is my understanding correct that there's really no voluminous evidence basis for this question, really, whatsoever? I think that's coming on the next frontier, right?

Dr. Merchant:

Yeah, I mean, it is true that most of the studies that have looked at CRT upgrade response rates have been relatively small, single center. I'm not aware of any real randomized data looking at the upgrade population, but most of the study's single center. In fact, some of our data have used something along the line of a drop in EF of more than 10% or less than 40%, so that's what I go by, but it is true that there's not nearly as robust an evidence base here to guide the inclusion.

Dr. Lisa Banker:

Okay. Dr. Rose, what's your practice?

Dr. Rose:

Well, I'm not an electrophysiologist, but as a clinical cardiologist I would agree with what's been said that there isn't a robust evidence base to draw from in terms of the decline in ejection fraction. Certainly if EF is less than 35%, then CRT is indicated. I think as you get into that sort of gray zone, you know the BLOCK AF data, I think are probably applicable. But there aren't randomized data to my knowledge to really help guide us. I think it's clinical judgment.

Dr. Lisa Banker:

Okay. Dr. Whalen?

Dr. Whalen:

Yeah, I agree with that. I tend to be motivated in the patient population by symptoms first, by a drop in EF second, and I would say that absolute loss of 10% or 40% or less are, I think, very reasonable standards.

Dr. Lisa Banker:

Okay. Dr. Powell?

Dr. Powell:

Yeah, I agree with comments that have been made. There isn't a lot of clinical trial data to really give us an absolute number for this. I think if there was a requirement put out saying that a specific number, it would be hard to back that with any evidence, and I'm not really sure that there's a standard of care out

there for an absolute drop in EF. Personally, I would favor looking more at the absolute EF measurement. If the EF is less than 50% and someone felt there was a clinical indication to upgrade to CRT, then the data to support it with the BLOCK HF trial, so personally I would look at the absolute EF being abnormal as opposed to a certain percentage drop in EF.

Dr. Lisa Banker:

Okay. I'm just going to throw this out there. Did Dr. Coleman join by any chance? Okay. I didn't want to be ignoring him if he had managed to get on the line. We're down to our last couple of questions. Number 11, Dr. Powell, your expert opinion on current recipients ... I hear this bandied around quite a bit, where it seems like E-pacer physicians get a little frustrated at times with sort of the restrictions to CRT only being used at least 40 days after an MI, so this is really sort of a general puerile question. What's the evidence related to this? How strong is it? Is it a reasonable standard to follow?

Dr. Powell:

Yeah, I think waiting 40 days after MRI for CRT is correct. The one exception would be is if a patient has another indication for pacing, so for example if they have an acute MI, and they have complete heart block, and need to have a pacemaker implanted, and their EF is less than 50%, then that would be an indication for CRT where they're going to require a pacemaker anyway, but outside of that for CRT just to treat heart failure, I think waiting at least 40 days after MI is appropriate.

Dr. Lisa Banker:

I wanted to ask about that scenario that you brought up, because that seems to be one that percolates up more than I would think it would, and that is that in the setting of an MI the patients have enough problems that they do need that pacemaker, and you know, maybe they've got that 45% or 40% EF and you don't know where that's going to go in the future. I mean, is there any evidence to really support that that's the correct thing to do? But I know the offset of that is you hate to not do it and then tell that person they need an upgrade to CRT in 40 days, too, so I appreciate both sides of it, but any thoughts on that?

Dr. Whalen:

I would say I have a much lower threshold to add an LV lead at the time of pacemaker implant than I do to implant an ICV in that early window, where the EF may recover. I think if you're going to be pacing these folks, then an LV lead is a reasonable thing to do. I think the harder decision is in the patients who haven't been on medical therapy for heart failure, and their EF is low, and do they need an ICV? I think that's a much harder clinical decision for me.

Dr. Lisa Banker:

Is there good evidence? I'm asking all of you, is there any good solid evidence to say that that's really a reasonable thing to do in these MI patients who need a pacemaker, that you should just go ahead and within that CRT versus just letting the scenario play out?

Dr. Merchant:

Well, as you alluded to-

Dr. Whalen:

I think if they're likely-

Dr. Merchant:

As the rubber really meets the road ... go ahead.

Dr. Whalen:

I was just going to say, I think if they're likely to pace, or they have a very wide left bundle, you're potentially giving them therapy that will harm them, or withholding helpful therapy, and exposing them to risk without the benefit.

Dr. Lisa Banker:

Okay. Who did I miss there ... ?

Dr. Rose:

This is Rose. I mean, I think this sort of gets back to the BLOCK HF, or pardon me, Block Heart Failure trial. You know, if they've got complete heart block after infarct and chances are, and to the point that they need ventricular pacing, then you're talking about chronic right ventricular pacing, and I think we can certainly look at the Block Heart Failure data in that regard, so I agree with Dr. Whalen that having a low threshold for a left ventricular lead and CRT ought to be considered in that cohort.

Dr. Lisa Banker:

Okay. Dr. Powell?

Dr. Powell:

Yeah, I agree completely. I'm unaware of any trials that look specifically at the early post-MI population, but I think the best thing we have to go from is the BLOCK HF trial, which the addition of right ventricular pacing alone is harmful, so CRT can be helpful or prevent worsening heart failure in the future, so I think that's the exception are those patients who are going to require ventricular pacing post-MI, that if they're not going to require ventricular pacing, it's best to wait.

Dr. Lisa Banker:

And if this were being questioned for CRT, you'd have no choice but to wait, the way current policy is written. Is that true?

Dr. Merchant:

Yeah, it does put you in a little bit of a bind. I mean, I think, and there was an HRS consensus statement a few years ago that addressed some of these scenarios that fall outside of these clinical trial guidelines, but even in that document, the sense was that if people have a pacing indication early on, practically speaking, you have to implant a device to get them safely out of the hospital. Even if they've recently had an infarct, it'd probably make sense to put the CRT in up front, knowing the detrimental impact of RV pacing and our inability often to predict what someone's clinical trajectory is going to be when they've just recently had an infarct, so I think this really is mostly a practical issue with getting people out of the hospital who need pacing and putting the CRT upfront versus having to wait and bring them back, which also exposes them to incremental risk of infection or whatever else the case may be.

Dr. Lisa Banker:

Okay. Did everyone get a chance to respond to that one? I think they did. Okay. And question number 12, this deals with non-ischemic cardiomyopathy in CRT. Again, to me it seems to be one of those aggravating situations of being asked to wait three months post-cardiomyopathy diagnosis, nine months post-cardiomyopathy diagnosis. I think of that common clinical scenario, I guess that goes along with this, where someone comes into the hospital, they sort of present newly with some degree of heart failure symptoms, or maybe not, maybe it's incidentally found on echo, but you find your awful EF, you find this 30, 35% EF, and what do you do with that person long term?

Dr. Lisa Banker:

Dr. Whalen?

Dr. Whalen:

Well, you know, I think that's a difficult question to answer with absolute certainty. I find patients have a strong opinion on this in terms of their interest in device therapy. We look at their initial response, you can look at non-invasive measures of scar and other things to guide you. If they have an initial, very robust improvement on medical therapy, then watching and waiting is often very reasonable. I will say I move towards implanting in general devices in patients who I think are going to benefit from CRT earlier than I would in somebody who's just getting a primary prevention ICV, just because I think you're getting quality of life in addition to protection from ventricular arrhythmias.

Dr. Lisa Banker:

Okay. Dr. Merchant?

Dr. Merchant:

Yeah, I agree totally with that. I think generally for non-ischemic ventricular that have wide left bundles, I tend to implant those who are CRT candidates early, and I'm generally pretty willing to wait nine months or even longer on a primary prevention ICV if people are uptight regarding medical therapy, but I tend to try to implant CRT earlier, particularly in those who have more dilated ventricles, who are younger, who maybe are a little more separate at the outset.

Dr. Lisa Banker:

Okay. And Dr. Powell?

Dr. Powell:

I think from a coverage decision standpoint, there is data to support waiting three months after initial diagnosis of non-ischemic cardiomyopathy because some patients will improve with medical therapy and their ejection fraction will improve the point where they're above 35% and outside of the range for primary prevention CRT-D device. Waiting beyond three months, I'm not aware of clinical trial evidence that would support that you would need to wait beyond three months. I think that there are patients who get like a cardiac MRI for example, and you can see they have a huge percentage of scar burden, and you know they're not going to get better. Waiting an additional nine months is not in the patients' best interest, so my thoughts would be data would support waiting three months after an initial diagnosis.

Dr. Lisa Banker:

Okay. Dr. Rose?

Dr. Rose:

Yeah, I would agree. I mean, I think nine months is really too long, particularly with the advent of some of the tools we have, as Dr. Powell mentioned, with cardiac MRI, we can get a pretty good look at what's likely to happen, and in general there can be spontaneous or facilitated recovery in three months with appropriate medical therapy, but my clinical sense is once you get past three months, if people have been aggressively managed, you're kind of where you're going to be and I don't know that you gain anything more over those next six months except incremental risk to the patient.

Dr. Lisa Banker:

Okay. Am I hearing y'all correctly that, at least throwing out some sort of modified guard rail there, saying, "Hey, it's reasonable for this new diagnosis to take three months," get them on appropriate medications, and then make decisions at the conclusion to some reasonable therapy to decide whether to proceed with CRT, that's not an unreasonable stance, correct?

Dr. Whalen:

I think that's reasonable.

Dr. Powell:

That's reasonable.

Dr. Whalen:

With the caveat that, if medical therapy isn't going to be tolerated, or MRI scar burden is very unlikely to recover, those might be patients that aren't going to be able to wait as long.

Dr. Lisa Banker:

Okay. Dr. Coleman, did you join by any chance?

Dr. Coleman:

Yes, I'm on the line, now.

Dr. Lisa Banker:

Okay.

Dr. Coleman:

Sorry about that.

Dr. Lisa Banker:

No, that's completely understood. The life of a physician, unfortunately. Let's see. I'm trying to decide how to best handle this. Let me throw out this scenario, because in general everyone on the call has pretty much agreed with each other, across the board pretty much. Let me take this opportunity to throw out just one scenario that I was thinking about, and it's probably been answered one way or

another, but I want to throw it out. A patient with persistent A-fib, if they maintained a normal sinus rhythm, they've got like a 40% DF and they've got left bundle branch block, let's say a QRS of 140, is that a person who does not need CRT?

Dr. Lisa Banker:

And I guess you could answer first, Dr. Coleman, since you just came on.

Dr. Coleman:

Yeah, I would say it depends. If they have significant heart failure symptoms, they might benefit from CRT pacing with an EF in that range, but if their symptoms are very well controlled and they're in sinus rhythm and they just have a left bundle with an EF of 40, they may not necessarily benefit from CRT pacing until they start to display their worse symptoms.

Dr. Lisa Banker:

Okay.

Dr. Coleman:

Of heart failure.

Dr. Lisa Banker:

How about the other docs on the call? Your thoughts on that scenario?

Dr. Powell:

I agree.

Dr. Whalen:

That's a tough scenario given there.

Dr. Merchant:

Only point I was going to make is that depending on what the QTE looks like, I often feel more comfortable up-titrating dofetilide in people who have a device just because the risk of cause dependent arrhythmias is lower and sometimes that factors into the decision to put in a pacer or a CRT pacer, but some of that would depend on the renal function, underlying QTEs, is it a male or a female? Dofetilide, I think, sometimes gets to be a little bit more tricky for those reasons.

Dr. Lisa Banker:

Okay. And then I think the second part to my question, I added in then heart failure symptoms, and if that same patient were clearly symptomatic of heart failure, it sounds like then you guys would be very inclined to go ahead with CRT therapy. Would you agree with that, Dr. Whalen?

Dr. Whalen:

I would, I think for two reasons. One, I think you'd get better long-term arrhythmia monitoring for AF management. A lot of these patients have subclinical burden of arrhythmia that exacerbates their heart failure. I think it'd be safer from a drug management standpoint in terms of preventing cause-dependent

arrhythmias, and I think you have very reasonable evidence in a non-ischemic with a wide left bundle that their EF will recover in terms of optimizing their heart failure.

Dr. Lisa Banker:

Okay. Dr. Rose, Dr. Merchant? Anyone else?

Dr. Rose:

It's Rose. I agree with what's been expressed.

Dr. Lisa Banker:

Okay.

Dr. Powell:

And it's Brian Powell. I think if the patient had tachycardia syndrome or some indication for pacing, then CRT would be appropriate. If they did not have any greater carrier, in the indication for pacing, then I would not be inclined to implant a device.

Dr. Lisa Banker:

Okay. And I think, Dr. Coleman, for purposes of you getting on, I think the first two questions were the ones that probably generated the most conversation, so I think I'm just going to pose those first two questions for you and then let you lean in with anything else that you probably wanted to say on this topic. The first question to you was how do you rate the quality of evidence supporting the use of CRT in patients with a QRS less than 130 milliseconds, and do you see any role for doing CRT in those types of patients?

Dr. Coleman:

I don't. I mean, there's minor evidence suggesting that in certain people it might be beneficial but I think that by and large the evidence does not support it and the evidence that is out there is not high quality evidence.

Dr. Lisa Banker:

Okay. That's helpful. And then the second question was how do you rate the quality of evidence supporting use of CRT in heart failure patients who have EF less than 35%, but they have the non-left bundle branch block scenario, and a QRS duration in that 130 to 149 sort of range? You know, that's where the evidence just varies a lot, and all of its sort of 2B to 3 across the board. Just wondering what you thought about that.

Dr. Coleman:

Yeah, same thing. I've never been extremely convinced by the evidence for non-left bundle in that range. It's not terribly convincing. Those are the types of patients that it might not be a bad idea to put a EF lead in if you think there's a high probability that they're going to progress with their heart failure or their QRS is going to continue to prolong, or they're going to be dependent on their device for pacing. If they have a high chance of independence for a high burden of pacing, then I think CRT would definitely play a role.

Dr. Lisa Banker:

Okay. Did you have any other burning thoughts that you wanted to convey, Dr. Coleman, on just the topic in general?

Dr. Coleman:

Not in particular. I mean, I agree with, I think when I came on y'all were discussing timing for, was that for non-ischemic or was it for ischemic evaluation of EF?

Dr. Lisa Banker:

Another good question we bandied about a little bit was what's the difference between these ischemic cardiomyopathies and needing CRT, and why is the cutoff EF less than 30% for them versus the non-ischemic? And we were talking about the time course on those non-ischemic cardiomyopathies, whether it was reasonable to kind of give them good therapy for three months before you pull the trigger on CRT?

Dr. Coleman:

Yeah, yeah, I think three months is a good timeframe.

Dr. Lisa Banker:

Any specific observations? Do you see ischemic cardiomyopathy patients as being different from non-ischemic cardiomyopathy patients in terms of CRT? Or are the decision points sort of the same?

Dr. Coleman:

For the most part, I feel like the decision points are very similar. But I mean, we do know that there's going to be probably a differential rate of response between the two different populations, but you never know on the front end who those patients are so you have to offer the therapy if they meet the indications.

Dr. Lisa Banker:

Got you. Well, I think I ran through most of my scenarios. Anything else that you guys can think of to pass along to me? Anything else we didn't touch on today that we really should have touched on with regard to CRT therapy? Okay. Well, I guess we'll close it there, then. I think each of you would be fine if we needed to do any follow-up questions with you or contact you. I think all five of you are open to getting a random email or something with a question. Is that correct?

Dr. Whalen:

Yeah, that's fine.

Dr. Rose:

Absolutely.

Dr. Merchant:

Sure.

Dr. Coleman:

Yes, anytime.

Dr. Powell:

Yes.

Dr. Lisa Banker:

Well, great. I really appreciate it. Your brainpower amazes me and I appreciate the expertise that you've given us today, and most of all your time. I know it's asking a lot, so Palmetto GBA thanks you for that.

Dr. Powell:

I guess I have just one quick comment about kind of an up and coming thing that may come across your radar, and that is that sometimes we'll use, and Dr. Whalen brought this up a little bit earlier, that sometimes we'll use His bundle pacing now instead of traditional left ventricular coronary sinus leads, so sometimes we'll plug the His bundle lead into the left ventricular port of a cardiac resynchronization device, so as that's been done I hope that hasn't raised any flags from the coverage standpoint, but I just wanted to bring that up that that is a newer thing in the last five years or so that's being done more frequently.

Dr. Lisa Banker:

My understanding is that can be very difficult for all of you, sometimes, to get that implanted appropriately, and to identify the correct place to get it into the His bundle. Do you expect that's going to get easier with time as equipment, technology, gets better?

Dr. Powell:

Yeah, it sure is. The delivery equipment is improving so I do think it'll get better with time.

Dr. Lisa Banker:

Okay. Anyone else? Any comments? All right, well, I think I'll let you have your evening back and you can get to dinner. Again, we really appreciate this.

Dr. Whalen:

Thanks so much. Have a good night.

Dr. Rose:

Thanks so much.

Dr. Merchant:

Thank you. Have a good night.

Dr. Rose:

Appreciate it. Bye-bye.

Dr. Coleman:

Thank you.

Dr. Lisa Banker:
Thank you and bye-bye.

Dr. Powell:
Thank you.

Dr. Lisa Banker:
Thank you.