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Closing the Gap to Care: Assessing CAD and Improving Patient Outcomes with Revascularization

Announcer:
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[CHAPTER 1]

Dr. DeVore:
So today we’re going to discuss an important gap in care that affects multiple aspects of the health system. And what I mean by that is that when we’re not assessing for underlying coronary disease, we might be missing a really important opportunity to improve heart failure symptoms and improve outcomes for our patients, both through medications and revascularization. And these low rates of assessments for coronary disease also highlight an important disparity of care that’s more pronounced in certain subgroups, including Black patients and females. So today, our group is going to explore this gap in care and talk about ways to improve outcomes for our patients using assessments for coronary disease and revascularization for appropriate patients, both in high-risk PCI [percutaneous coronary intervention] and surgical interventions.

This is CME on ReachMD. I’m Dr. Adam DeVore from Duke University.

Dr. Barron:
I’m Dr. Lauren Barron from Texas Heart Institute in Baylor.

Dr. Kapur:
And I’m Dr. Navin Kapur from Tufts Medical Center in Boston, Massachusetts.

Dr. DeVore:
So understanding the assessment for coronary disease in new onset heart failure is a really interesting topic, and I became interested in this for 2 reasons. One, I am a heart failure specialist and a transplant cardiologist at Duke University, and as I started doing this, I was always humbled by the number of patients that we would have undergo transplant and the explanted heart would be reviewed by the pathologists and it would turn out that even patients that we had thought of having a non-ischemic cardiomyopathy would end up having significant coronary disease. I always thought of that as a really interesting problem, and, you know, a lot of those patients had been patients from our clinics that we had seen multiple times and had opportunities to think about coronary disease as leading to worsening heart failure.

The second reason is, I’m a believer in revascularization. I think it’s a great way to really try to find a single pathway that might explain the main issue causing heart failure, and then, also, it’s a unique treatment pathway. I guess the other part of that, though, is if we’re not looking for coronary disease, we’re probably not looking for other aspects that could be causing an underlying cardiomyopathy, like

sarcoidosis or amyloidosis, or even genetic cardiomyopathies where we might want to screen family members.

I know when I first started looking into this as an issue for the heart failure population in general, the largest study on this topic was a retrospective cohort study using claims data of patients with commercial insurance and Medicare. People had a new diagnosis of heart failure, and it would look both during an index hospitalization but then again 90 days later and say how many of these people underwent some assessment, whether it's a stress test or an invasive cath, and tried to understand if that patient had coronary disease.

Well, it turns out, if you are using that approach, that only 18% of patients had an assessment during that index hospitalization. And if you even widen that window out to 90 days after admission, it only increased to 27%.

And so a second study on this topic is actually something that I got to help participate in. I work in the "Get With the Guidelines" heart failure program, and so we thought, you know, what a great way to try to look at this. These are all hospitals across the US. They're participating in quality improvement programs, very focused on heart failure care.

And so in our study, we looked at over 22,000 patients. These were all patients who were admitted to the hospital for the first diagnosis of heart failure, and they had linked Medicare claims. And in our study, it was 40%, or 39% to be specific, of patients underwent an assessment for coronary disease – again, quite low, and certainly lower than, I think, the expected prevalence, and thinking these are all patients with Medicare, all 65 or older. We were also able to kind of look at what are some of the patient factors that are associated with getting an assessment for coronary disease compared with those that weren't, and there were things that – some of them might be a little surprising. Some of the factors associated were younger age; it was more common in patients with a low ejection fraction instead of a preserved ejection fraction; and then some of the others were things associated with underlying coronary disease, like smoking and hyperlipidemia. There was also a predominance for male sex, and so that was the first time we saw this kind of disparity, that it seemed like males were much more likely to undergo an assessment than females, and, you know, that actually comes up again in further literature.

The third study on this topic that I also found really interesting was focused on the VA [Veterans Affairs]. So we've looked at a couple different health systems. This was the VA, a different one, and this looked at a really long cohort. So these were patients that were hospitalized from 2006 to 2017 – over 10 years of data – and asked a similar type of question. If you look at people who are in the hospital with a new diagnosis of heart failure, how many of them are going to be evaluated for coronary disease? And they kind of focused on patients who had an ejection fraction of 40%. And what you found is that about 9,000 patients – only 40% – underwent ischemic evaluation, so very similar to what we had seen in the Get With the Guidelines study. But what I like about it, and the reason why I'm highlighting it, is when you looked at different hospitals within the VA system, you saw a ton of variation. So, you know, some hospitals were really good at this, and some were still kind of figuring that out. The other thing you saw is that over a decade, despite the fact that a lot of things changed from 2006 to 2017, you didn't really see any improvements, right? So we're learning a lot more about revascularization, but it didn't seem like that was translating into people being more interested in trying to look for underlying coronary disease.

The last study I would highlight on this is actually the most recent study. This was published in JACC in 2022, and it again used a commercial – or a claims database of patients with commercial insurance or Medicare Advantage, and it was a very large study including patients from all 50 states. Same idea – let's look at patients with a new diagnosis of heart failure. How many are being tested for coronary disease? And this included data from 2004 to 2019, so they had over 500,000 patients across the US. All of them had insurance, just like these other studies, and only 35% of them underwent an evaluation for coronary disease during the first 90 days. The other reason I highlight this, it's not only a large study, but it also – they were able to take a deep dive on some of those patients factors that were associated with this, and turns out if you were being comanaged by a cardiologist, that was associated with being evaluated. But even there, there was a lot of variability, so it's not a simple fact as, like, if cardiologists are seeing them they're more likely to be cathed. I think it's a little more complicated than that. But they also highlighted a couple other things, including again, males were more likely to be evaluated, but also white race was more likely to be evaluated. So again, you kind of highlight an important disparity in care here.

If you put all these together, that's data on over 650,000 patients across the US, over like a 15-year time span. And one thing that I haven't highlighted very much, but all of those patients had insurance, so we're not even talking about those who have more challenges with access to care. But if you put all those together, only 1 in 3 – a third of patients – are likely to undergo an assessment for coronary disease.

I think that's something we can certainly improve on and I'm hoping that we can have a little bit of a discussion with this, but I'm really interested in the idea of why is this? And I think it's a complex answer. I don't think it's as simple as education. I think almost all clinicians know that coronary disease can lead to heart failure. I think, you know, for most people, testing is available at most hospitals in America, whether it's a noninvasive study or an invasive study. I think there's a growing movement within heart failure, where people

are being much more conscientious about being systematic about making sure patients are on all the right medicines for heart failure, and I think this would be another important aspect of care that could be systematized and really thought of before someone is discharged from the hospital, for example.

Thank you for your attention. I'm looking forward to some discussion here. Dr. Barron, I might start with you. I'm kind of curious what you think when you hear some of these numbers or some of these disparities in care, what resonates with you? What kind of things come to your mind?

Dr. Barron:
I often wonder, when we get patients who have – I'm doing a revasc on someone whose ejection fraction has been suboptimal, has been 40s for a little while, and they're only getting revasc'd when their ejection fraction drops to 35 or less, and they're extraordinarily symptomatic. I often wonder if it dropped precipitously, or it was something that they tolerated and we just didn't really look because it was only a little depressed. Do you think that we're missing the early folks because they're not as symptomatic?

Dr. DeVore:
I think there's lots of opportunity to try to think about this earlier, at the time of diagnosis, and that's where I think the idea that maybe somebody's in the hospital; they get a new diagnosis of heart failure. Sure, we're thinking about they need some type of assessment for coronary disease, but the weekend's coming up, let's try to get them home. They can always do that in the clinic, and then they get to the clinic and it never happens. So I do think that you're right, that there's a lot of opportunity there, instead of just waiting until somebody's sick and they're on their 4th hospitalization. But we have a lot of work to do to figure out how to do that better.

Dr. Kapur?

Dr. Kapur:
Yeah, it's a really great presentation, Adam, and, I think this is a critically important question. You know, we're really the gatekeepers for these patients with heart failure in terms of their assessment. You know, with heart failure, I think it still leaves the door open with angiography in 2 ways. One is, a lot of times patients present with signs and symptoms of congestion and may not necessarily have angina. So I think that's one aspect is patients who present with heart failure symptoms, it should be clear that that's an anginal equivalent until proven otherwise. And that may not be necessarily how we approach things currently.

And then the second aspect of this that I think is worth diving into is, what is the method for assessment of CAD? You know, the noninvasive nuclear stress test versus actually doing coronary angiography, I think, is another nuance that can become important. And is that because we're shying away from early angiography? We're trying more noninvasive methods.

And as you know, those noninvasive methods may miss coronary disease if there's balanced ischemia.

Dr. DeVore:
From my perspective, this is such an important problem that I think we really have to take that next step and think about just making sure we're really looking for an underlying etiology for their cardiomyopathy.

But this has been a great discussion, and I'm looking forward to the next chapter, so thank you both.

[CHAPTER 2]

Dr. Kapur:
Great, thanks very much. My name is Navin Kapur, and I'm from Tufts Medical Center, and I'm going to be talking about Chapter 2: Revascularization in patients with heart failure. In Chapter 1, we discussed the often-delayed evaluation of coronary artery disease and disparities in care. And now we're going to turn toward the use of revascularization, and especially high-risk or a complex revascularization using coronary techniques that have been proven to be safe and effective for patients with multivessel disease and try to understand the data set that supports this approach.

So I think it's important to take a step back and understand the rationale for coronary revascularization in heart failure. There was an excellent editorial back in the early 2000s that helped us understand that when patients come in with ischemic heart disease, which can be in the acute setting of acute MI or in the chronic setting, then these patients tend to do better if they are revascularized. I think it's most evident for patients with acute MI or for acute coronary syndrome, but even for the patients with stable ischemic heart disease, if that disease is left untreated, there is a propensity for those patients to undergo maladaptive remodeling, where the LV [left ventricle] can start to dilate, and then they remodel from an early to a late, and then ultimately to an end-stage period of remodeling, to the point where they're thinned and dilated, and revascularization may no longer be an option for those subjects. So if we get to these patients early enough or in their sequence of remodeling, we can potentially lead to reverse remodeling, stabilization of their maladaptive remodeling, and get them to a better outcome.

And so what do we do with the patient who has reduced ejection fraction, who has multivessel disease who comes in with heart failure symptoms, or who comes in with an acute coronary syndrome? And a lot of these patients, as we talked about in Chapter 1, they do require early angiography or some sort of assessment of CAD. And in those cases, when we do identify complex multivessel disease, now we get to the next step, which is how do we manage these patients? Sometimes the disease is so critical that even during the diagnostic test, we can see hemodynamic compromise for these patients, and so that tells us that these patients are at high risk when we do revascularization.

And so this forms the basis for the hemodynamic rationale for the concept of protected PCI. So in these patients with low EF [ejection fraction], multivessel disease, if they're going to undergo percutaneous coronary revascularization, this is now done in an era where you can put them on a support device and now support them hemodynamically while you complete that revascularization.

And there is a heart team approach and a heart discussion that needs to take place in a lot of these cases when we're doing the assessment. And a lot of this requires that shared decision-making that has really now become standard per guidelines in terms of interventions. But for interventions in the heart failure population in particular, there are multiple unique aspects of that conversation that have to be held.

And a lot of the features that we're talking about – our left main disease, multivessel disease, high anatomic complexity – and then, of course we try to assess their surgical risk as well as their risk for having an adverse event during coronary revascularization in the cath lab. But the current guidelines really are very illustrative. They point out a subset of patients, but there's not really anything beyond that heart team discussion, so we're now left in a data-free zone, and the question is what do we do here? And if you look at the guidelines, the current recommendation for hemodynamic support in that subset of patients, especially the surgical turndown, low EF patient, is not really that supportive, because the level of evidence is quite broad, and so this is a 2b recommendation currently, for hemodynamic support in complex PCI, and this is where the evidence base has to come around. And for those patients who have high surgical risk, that are often considered inoperable and who often have high anatomic risk, they fall into a category where they have no exit, and that's where these guidelines need to change, and we need to build the evidence base for protected PCI.

Now, the PROTECT II trial, which was performed back in the early 2000s, this trial was a landmark study. It was one of the first to look at the concept of hemodynamic support during complex revascularization, and in the intent-to-treat population, there was no difference between Impella and intra-aortic balloon pump used in terms of major adverse events. But when we look at the per-protocol analysis, the 2 curves diverge to the point of becoming statistically significant.

So this opened the field of protected PCI, and then the data generation subsequently has accumulated. And when you look at the PROTECT II population, 64% of that population were not surgical current candidates. So these are that surgical turndowns that put them into that no-exit category.

In the PROTECT III trial – this was a prospective study that basically looked at patients with low EF, that really mimicked the PROTECT II population, but we are now looking at real-world evidence from over 1,100 patients. We were able to try to create a population who we could do a comparison against PROTECT II. And when you look at the PROTECT III patient population – this is real-world data – we see that the in-hospital outcomes, ranging from MACCE, for MI, repeat revasc, vascular complications, and bleeding – all actually showed lower event rates compared to patients in PROTECT II. And my takeaway from these data is that our techniques have advanced so quickly and aggressively over the last 10 years that we're getting better and better at completing revascularization and doing it safer in real-world practice. And you can see here in this slide that 90-day major adverse cardiovascular and cerebral outcomes are also substantially lower in that PROTECT III analysis of a PROTECT II-like population, based on real-world data.

And then more recently, there was another study called the RESTORE EF study. Now this was a multicenter, single-arm, prospective clinical study looking at the change in ejection fraction at 90 days after complex coronary revascularization with protection. And what these authors illustrated was that there was a significant increase in ejection fraction, from 34% up to 44% at 90 days' follow-up and that this was particularly notable in that surgical turndown population, but also seen in the CABG-eligible population. So it's quite a bit of food for thought for the way we're changing the paradigm currently in terms of complex revascularization.

So at this point, I'm going to open it up to comments from Adam as well as from Lauren. I think this is a really exciting time right now in revascularization, especially in heart failure. This field has, I think, been very, very sensitized around protected PCI. What does that mean? Who is this patient population? And I think it would be great to really hear your opinions. I'll start with Adam for your perspective as a heart failure physician in terms of referring patients for PCI.

Dr. DeVore:
Yeah, that was a great presentation, I think, and it's a really nice summary of where the field is going. I think the biggest things that we've seen in our heart failure clinics are there's a much better push about trying to be comprehensive in terms of patients' care. And so

we've been much better about having comprehensive evaluations, so I join the complex PCI meetings where we talk with surgeons, we talk with our interventional colleagues, and we are presenting different patients who might be candidates for this, who might be candidates for that. So I think we're just talking about these patients and the different things we can offer them in a much better way than we were 10 years ago, as you asked. It also helps me understand better, you know, some of the nuances of the approaches that the interventionalists and the surgeons are thinking of for these candidates. So I've really enjoyed that. I think it's really moved the field forward.

Dr. Barron:
So you mentioned a bit about us using bypass in one of the previous chapters, but the thing is that the bypass run is great, but it's like you mentioned – the time period that is immediately after, where they have some stunning, some cardiac stunning, that makes that person with an EDP [end-diastolic pressure] of 6, it makes it concerning, because regardless of how great their vascularization is, if their ventricle is dilated, their coronaries are flat and there's no flow. Doesn't matter if you put a balloon pump, when you have – at this point when I see the patients with the dilated ventricles and they need a revascularization, particularly the acutely dilated, that person needs a vent to offload, and like you, I use an Impella. I use a 5.5 and I have them come off of pump on the Impella, and their ventricle doesn't have to distend. It doesn't even have to do the full job for a few days, until after the postcardiotomy stunning period is up.

Dr. Kapur:
Yeah, I think the use of 5.5 really is a huge opportunity, both for interventionalists and for surgeons. You know, as I had mentioned, I like to do these complete revascularizations on 5.5, especially if they're dilated, mostly because then we can follow also the course afterwards. If these patients don't end up getting to a point where we can decannulate them from the 5.5, you know, we have those options. They are fully supported at that point. If they're a candidate for advanced therapies, we can complete the eval and start thinking about other options for these patients. So I agree with you.

So I'll end the conversation here, and just say thanks to my colleagues for the discussion and for engaging in Chapter 2.

[CHAPTER 3]

Dr. DeVore:
For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Adam DeVore, and with me today are Dr. Navin Kapur and Dr. Lauren Barron. We're discussing early coronary artery disease assessments and revascularization in high-risk patients.

Dr. Barron:
Hey, everyone. I'm Dr. Lauren Barron. I'm at Baylor and Texas Heart in Houston. In the previous chapters, we discussed the treatment gap in the coronary artery disease assessment. We've gone over the use of mechanical circulatory support in the high-risk PCI patients, and now we're going to flip over and look at how this might be used in the revascularization when we're talking about a surgically high-risk patient.

And I'll start with what our societies have given us as far as guidelines. And when we look at the guidelines and we look at patients whose ejection fractions are less than 35% – because in the surgical world, that's what is considered heart failure – we have a list of high-risk features, and these range from everything from how acutely the patient presents and how much support they're requiring to basically anything that makes a patient surgically complex. Immediately that patient gets pushed into the high-risk features, and they're considered high risk for surgery. If that person's disease is based on ischemic cardiomyopathy, then what we know is that people with ischemic cardiomyopathy benefit from revascularization.

And so our guidelines suggest that when you look at a patient, you have to first assess if the CABG [coronary artery bypass grafting] is feasible and if it's indicated. And then once you've decided that it's feasible, that their targets and their anatomy require it and that they work, then you have to decide how you're going to get the patient through the operation. And that's where things get a little bit less sure in our guidelines.

There's a IIb recommendation for advanced mechanical circulatory support, and right now, what we have to offer these patients comes in the form of balloon pump, ECMO, Impella, Tandem Heart. Those are the major 4 that we're using here at Baylor, and that's what we'll go over a little bit later.

So when we look at the data, when we go back and look and see what drives the guidelines, what we found is that in the surgical treatment of ischemic heart disease, and the extension trial at 6 and 10 years, this was 1,000 patients with EFs of less than 35%. This was a randomized trial, and it compared CABG plus medical therapy to medical therapy alone. And what we found is that patients who got revascularization, they had significant improvement in their long-term mortality. So at 10 years, if they had a CABG, they lived longer, and it only took 14 patients to save 1 life, so the number needed to treat was 14. That's great, but we have PCI, and PCI is getting better and better and better, so now we are left with what do we do with patients who are high-risk operatively and could benefit

from revascularization? Should they just go to PCI because it's less demanding on their physiology?

Well, there's a group out of Canada that looked a registry data of almost 3,000 patients with an EF of less than 35%. This was a propensity-matched group, and they looked at CABG versus PCI, and everyone was on optimum medical therapy. What they found was that in the patients with EFs of less than 35%, there were significantly higher rates of mortality, all-cause mortality, mortality from cardiovascular disease, and just morbidity – so things that decreased quality of life and are related to heart disease – in the PCI group. So again, this also favored patients with ischemic heart disease benefit from a LIMA [left internal mammary artery] to LAD [left anterior descending artery]. They benefit from revascularization.

So now we know that patients with ischemic cardiomyopathy, they live longer, they have less morbidity if you can give them surgical revascularization, but that's not the whole story because when we look at the STICH data, the 30-day mortality, the patients with surgical therapy had a 4% 30-day mortality, and the patients with medical therapy had a 1%. So if we know that they need this, then the question becomes, what can we do to optimize these patients to get them through surgery?

We talked about mechanical support a bit. Here at Baylor, what we've started doing in these patients who are high risk, the guidelines suggest that you start with a balloon pump, so if they are isolated to coronary artery disease with no changes and no maladaptive remodeling, then they do pretty well with a balloon pump. But often, these people are quite dilated. Their left ventricle's quite dilated, and they need to be offloaded. So we've been preemptively putting in an Impella 5.5 and offloading these patients.

What that's done for us is it's taken a patient who is coming in with acute heart failure, who may or may not have multisystem dysfunction, we give them support. We offload their ventricle, their renal numbers normalize, their liver doesn't go into shock, and we don't have to give them a lot of fluid or put them on a lot pressors, and so when we start our pump run, I'm starting with a patient who has physiologically got 1 system failure, which is a different ball game than a person who's coming into surgery with multisystem organ dysfunction.

The problem with what I know is good for the patient and what I'd like to do for the patient is there's a gap in data in between. So the STICHES trial excluded people with cardiogenic shock within 30 days and often the patients who present with NSTEMIs [non-ST-elevation myocardial infarctions] or present and then re-present with heart failure, those patients fall into that group. The registry data also excluded patients that had an MI within 24 hours and also all people with end-stage renal disease.

There is a trial that's coming up, it's called the IMPACT trial, and it looks at what happens when you support a patient off of pump through that, maybe, first several days of postcardiotomy shock that we often see, called myocardial stunning, postcardiotomy shock. It's when we look at the ECHO and we say, oh, it's going to get better. Most surgeons look at the ECHO and say it's going to get better. We know this, but we haven't studied how to support through it, and so that is where we're moving to in the next step.

And I think it'll be very interesting, if I could get Dr. Kapur to weigh in on what he thinks about putting these patients with multisystem dysfunction on an Impella support prior to a PCI or a surgical intervention.

Dr. Kapur:
Yeah, I think that's a great – first of all, a great presentation, and that's a great discussion point. The idea of optimizing patients hemodynamically using percutaneous mechanical support, I think, is a really good one. I think if patients are coming into procedures, as we know, in suboptimal condition, congested, with renal dysfunction, hypoperfusion or even moderate hypotension, or requiring vasopressors, they're in a very difficult position, because you're about to initiate ischemic injury. You're about to initiate LV dysfunction or make it worse. And if all of that can be done with the idea of preemptive or early support, especially if you have a day or two of support, it really changes the way the patient looks. The idea of preemptive early mechanical support is leading to better outcomes for patients, ranging from cardiogenic shock all the way to elective PCI, so I think this makes a lot of sense in terms of the approach, and I'm excited to see the initiation and results of the IMPACT study.

Dr. DeVore:
Yeah, I think you both are – first of all, that was a great presentation – but I think you're both hitting on important topic of trying to optimize their hemodynamics before, so I think that's what drives a lot of our decisions, as we're trying to get good numbers, understand exactly where they are, and the reality, I think Navin was alluding to this, but especially in the ischemic patient awaiting revascularization, the medical options are pretty limited, and so that's where mechanical support really comes in.

Dr. Barron:
All right, I think that wraps up our discussion. It's been fantastic. Thank you, guys, for joining me.

Dr. DeVore:
Well, thank you. This has certainly been an enlightening conversation. Before we end this, though, could you each share one take-home

message with our audience? Maybe we'll start with you, Dr. Barron.

Dr. Barron:
I think the take-home is you can't discount the possibility of revascularization via PCI or surgery in a patient with ischemic cardiomyopathy regardless of what their starting point is. It can't be off the table.

Dr. DeVore:
Great. Dr. Kapur?

Dr. Kapur:
Yeah, thanks, Adam. I think my takeaway from this is that you know, these complex patients require discussions, and just like the panel discussions we had today with heart failure, interventional, and cardiac surgery on the table, I think this is where we can get to the best outcomes for our patients and provide hope for those subjects especially for the ones who really are challenged by their underlying condition. So heart team discussion is always the best way to go.

Dr. DeVore:
Couldn't agree more. And my final take-home message is just for those of us who are seeing these patients early on in their disease course, the earlier we can understand what's really driving their heart failure and identify good candidates for revascularization, the better their outcomes are going to be. So we all have to be really kind of incorporating that into our best practices for heart failure management – thinking about medical therapy, but also making sure we've done a great systems-level identification of what might be the underlying etiology and looking for underlying coronary disease.

So unfortunately, that's all the time we have today. I want to thank our audience for joining us. I hope you found that valuable, and I want to thank Dr. Navin Kapur and Dr. Lauren Barron for joining me and sharing their valuable insights. It was great speaking with you today.

Dr. Kapur:
Thank you.

Dr. Barron:
Thank you, everybody, and have a good day.

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