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Closing Gaps in Care for Patients with T2D & CV Disease

Dr. Buse:
While many medications are currently available to reduce the risk of cardiovascular events, several barriers have led to certain newer diabetes medications being significantly underused in clinical practice, and these barriers continue to cause gaps in care for patients with type 2 diabetes and atherosclerotic cardiovascular disease. How can we combat these barriers and reduce gaps in care?

Dr. Buse:
Welcome to *Diabetes Discourse* on ReachMD. I'm Dr. John Buse. And joining us to share highlights from the COORDINATE study, which was recently published in JAMA, is Dr. Jennifer Green, who is a professor of medicine at Duke University in Durham, North Carolina.

Jennifer, thanks for speaking with me today.

Dr. Green:
Thanks. I'm really happy to be here.

Dr. Buse:
So let's start with some background. What are some of the primary gaps in care for patients with type 2 diabetes in atherosclerotic cardiovascular disease? And particularly, which ones did you look at?

Dr. Green:
Well, there are too many to cover in today's discussion, but we were most interested as a group here at Duke in the utilization of what we know are very, very effective therapies to reduce the risk of future cardiovascular events in a high-risk patient population primarily comprised of people with type 2 diabetes and established atherosclerotic cardiovascular disease. And I will tell you that similar to what many other surveys have shown, when we looked at a very large database of what were completely insured patients, we found that the utilization of these very effective cardiovascular risk reduction strategies was very, very low. And yes, part of what we looked at were the rates of use of some of the newer medicines to reduce cardiovascular risk in people with type 2 diabetes, like the SGLT2 inhibitors and GLP-1 receptor agonists, but we really were interested in a broader spectrum of risk reduction interventions, so we also looked at the use of ACE or ARB by this patient population as well as rates of high-intensity statin use.

And so, when we looked at how well people were treated based on prescriptions for these kind of three key elements of care, what we found was actually disturbing, and only about 3 percent of people were on all three of what we consider to be at present the foundations of risk reduction in people with diabetes and cardiovascular disease, and almost 40 percent of people were on none of those interventions. So it became clear, or clearer shall we say, that we need to focus on actually translating what we know are effective therapies from clinical trials into the clinical care setting, so that was the driving force behind COORDINATE-Diabetes.

Dr. Buse:
Very good. So I imagine you did a lot of thinking about how you're going to intervene with clinics. Why don't you tell us a bit about how you thought about the process and then what you actually did with regards to the interventions in the clinics that were randomized in this study?

Dr. Green:
Sure. So, we were really interested in focusing on cardiology clinics. If you look in the United States at where people with type 2 diabetes and cardiovascular disease receive their care, of course most of the time, they're cared for by primary care physicians, but the next most common group of doctors that they see are cardiologists, so they're really sort of a group that has tremendous potential to

alter the care in a favorable way for these high-risk patients. Only a tiny sliver of people with type 2 diabetes in the United States actually see an endocrinologist, so we decided we were going to work on the cardiologists and work on them to get them to, first of all, be aware of these deficiencies in care and to work with them to figure out how we could narrow these therapeutic gaps, and the trial was a randomized trial where we actually randomized the sites themselves. So we randomized cardiology clinics who were engaged with the study to our intensive intervention or to essentially their usual care practices, and the intervention for the group with which we were engaged very closely had three main components. First, we met with them at first in person, but then during COVID it changed to a virtual meeting. We talked with them about their local practices for delivery of care. We identified what their obstacles to the delivery of guideline-based care might be, so we started there. As a next step or the second of the three interventions, we talked with them about strategies to overcome those barriers. As you might glean from the name of the trial, we asked them to coordinate their practices, their care delivery practices with other care providers, such as clinical pharmacists or midlevel providers, and in particular, they needed to identify a specialist who was very interested in diabetes care, so it was team building and planning to change their prescribing practices. And then finally, during the course of the study, we routinely gave them feedback about how their patients who were also enrolled in the study were being treated and how many of them were on all three of these important therapies: again, the high-intensity statin, an ACE or ARB, or an SGLT2 inhibitor or GLP-1 receptor agonist. And so we gave them feedback. We were available to answer questions that they might have about particular case management strategies if necessary, but those were really the three main elements of the intervention, all of which I would point out should be reproducible within most if not all, healthcare settings.

Dr. Buse:
Wonderful. For those just turning in, you're listening to Diabetes Discourse on ReachMD. I'm Dr. John Buse, and today I'm speaking with Dr. Jennifer Green from Duke about the COORDINATE study, which looked at medication usage in patients with type 2 diabetes and cardiovascular disease.

So, turning to the results, what was the primary outcome of the study?

Dr. Green:
The primary outcome of the study was a comparison of the percentage of patients enrolled at either the intervention clinics or the usual care clinics who were on all three key therapies at 12 months of follow-up, although I will say there were a small percentage of people who, due to COVID, were only followed for six months, so in those patients we used their six-month data. But again, the percentage of individuals at those, clinics who were on, again, high-intensity statin, ACE or ARB or an SGLT2 inhibitor or GLP-1 receptor agonist.

And I'm very happy to say that we did find at the end of the day that about 38 percent of patients who were enrolled at the intervention clinics were on all three of these interventions. Remember, our background work had suggested that only about 3 percent of such patients were cared for in that fashion. And usual care prescribing practices had improved too, but they only increased to 14.5 percent, so we had about a 23, 24 percent absolute difference in utilization of these effective therapies between the intervention and the usual care arms.

Dr. Buse:
Yeah. And you know, I reviewed the paper. It's really beautifully done. And it seems that for each of the interventions separately, there was an improvement in the intervention group, so it's not like people got unfocused and didn't do the high-intensity statin and the ACE inhibitors when they were thinking about SGLT2 inhibitors and GLP-1 receptor agonists. For each of the therapies, they were advanced more in the intervention group. Did I interpret that correctly?

Dr. Green:
Yeah, absolutely, because, you know, the effects of one class of drug really can't replace these others. I mean, when the trials of the newer medications were conducted, people were, for the most part, on effective sort of background more traditional risk-reduction therapy, so all of these are important. You can't focus on one to the detriment of the others. I will say though that when we look at the components of this three-point outcome and how they change during the course of the study, there was the greatest increase in prescription of SGLT2 inhibitors and GLP-1 receptor agonists, but that's probably because utilization was so low to begin with. They sort of had more room for improvement shall we say.

Dr. Buse:
Yes. And I think I know the answer to this, but I didn't see anything about cardiovascular outcomes. Is that something that we'll hear about later, or not even a focus of this trial, just on implementation?

Dr. Green:
Well, cardiovascular outcomes were collected. There was no adjudication, so this was as reported by the clinics that were enrolled in the trial, and, and we knew going into the study that we didn't have enough patients. The trial was not powered and would not accumulate enough cardiovascular events to really demonstrate a reduction in the risk of these actual cardiovascular events during one-

year of follow-up. We did, however, perform an analysis looking at rates of actual cardiovascular events. There was a large cardiovascular composite outcome that was analyzed, and the hazard ratio for the rates of these cardiovascular events in the intervention trial compared to the usual care trial was 0.79, which is reduced by the extent to which you might expect it to be through these various interventions. But you know, we did not have enough power for this difference or this reduction in risk of cardiovascular outcomes to be statistically significant. So it's consistent with what we would expect to see, but we cannot claim that what occurred in this number of patients during the year of follow-up altered healthcare outcomes, but certainly, that would be the goal.

Dr. Buse:
Understood. How do you think these results will impact the use of evidence-based therapies in clinical practice? Or to put it another way, what would you recommend to our colleagues that are listening now with regards to how to move forward with this evidence?

Dr. Green:
Well, we do actually have a website where many of the materials that we used to communicate with the healthcare providers at the involved sites and some materials that we used to educate and support patients who were enrolled in the study at those sites. We have that information available if people are interested in introducing similar programs to enhance delivery of guideline-based care in their local settings, and we plan to update those tools over time so that the information remains contemporary and fit for ongoing use. So that's one thing is that we hope that this information will be understood to be relatively straightforward and readily reproducible.

Now, the other take-home message from this is that, you know, we really made significant inroads in improving delivery of care, but when you think about it, only having about 40 percent of people at very high risk on these three treatment modalities is still pretty low. It's much better than it was when the patients and clinics were enrolled in the trials, but there's still very significant room for improvement, so we need to think about other types of healthcare providers who are, shall we say, touching these patients, who are caring for these patients, other care settings, such as inpatient hospitalizations where we can think about ways to customize, but hopefully reproduce what we've seen in this current trial, so that we can get as many people as possible on these effective therapies.

Dr. Buse:
Wonderful. So there's room for COORDINATE II and COORDINATE III future trials.

Dr. Green:
Absolutely.

Dr. Buse:
All right. So, before we close, Jennifer, do you have any final thoughts you'd like to share with the audience?

Dr. Green:
Yes. Please feel free to go to the COORDINATE-diabetes website. It should be very easy to find. And, if there are any questions about how we did what we did, you can reach out to us, and we'd be very, very happy to support you and answer any questions that you might have.

Dr. Buse:
It's always such a pleasure to talk to you. You're so clear and precise in the way you explain things. With those thoughts in mind, I'd like to thank my guest, Dr. Jennifer Green, for sharing highlights from the COORDINATE study and how it may impact clinical practice in the care of patients with type 2 diabetes and atherosclerotic cardiovascular disease.

Jennifer, it was a pleasure speaking with you today.

Dr. Green:
Thank you very much for having me.

Dr. Buse:
For ReachMD, I'm Dr. John Buse. To access this episode and others from our series, visit ReachMD.com/DiabetesDiscourse where you can be Part of the Knowledge. Thanks for listening.