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GDMT Is Working Fine, so Why Add More Therapies for Patients With HFrEF?

Opening:
Welcome to CE on ReachMD. This activity, titled **"GDMT is Working Fine, so Why Add More Therapies for Patients with HFrEF?"** is provided by **Medcon International**.

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Dr. Lam:
Today we'll discuss which patients may benefit from additional evidence-based therapies. This is Continuing Education on ReachMD, and I'm Dr. Carolyn Lam.

I'm delighted to have with me Dr. Johann Bauersachs, a very experienced heart failure trialist and clinician and a good friend.

Johann, let's start with discussing a case, shall we?

So say we have a typical patient, 68-year-old gentleman with chronic HFrEF. His EF is about 30%, and this is due to coronary artery disease, and he's being followed in our outpatient heart failure clinic. He's got comorbidities of type 2 diabetes. He has a systolic blood pressure around 120 and eGFR of around 56.

Despite contemporary quadruple guideline-directed medical therapy, he is symptomatic with the New York Heart Association Class II to III and requires a loop diuretic. By the way, he also has a CRT-D in place. His last hospitalization for heart failure was 15 months ago, and his natriuretic peptide today is elevated at 2,400 NT-proBNP.

So, Johann, what are your thoughts on this patient?

Dr. Bauersachs:
Thank you, Carolyn. So this is a patient we see in our daily clinical practice quite often. It's an example of a patient that seems to be stable, but at the end we know that these patients, even when they seem to be stable, that they have an elevated risk for cardiovascular death or all-cause mortality, even when they are in New York Heart Association Class II and when they are treated with devices and guideline-directed medical therapy. So that means that even this so-called optimized therapy does not eliminate risk, and we have to be careful, and we have to do our best to improve their outcomes.

And he, for example, was hospitalized around 1 year ago, and he also has elevated NT-proBNP levels. And this indicates that there is a pretty high residual risk also for mortality and another heart failure hospitalization. And therefore, I think we need additional therapies also for these patients.

And vericiguat may be an option for these patients because we could show in the VICTOR study recently that patients that were pretty stable, that didn't have a heart failure hospitalization in recent times, that they still had a pretty high mortality risk and that vericiguat was able to reduce cardiovascular death and also an all-cause mortality in these patients.

Patients that seem to be stable with heart failure with reduced ejection fraction, they are not really stable.

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Dr. Lam:
You know, Johann, you said it so well. In fact, I believe in our universal definition of heart failure, we have actually removed the word "stable" from the lexicon. You know, we refer to heart failure with terms similar, unfortunately, to cancer stages because we realize that it is also a very chronic, deadly disease like cancer.

So we talk about the symptoms being in remission, but we don't say "stable," isn't it? And I think our experience really tells us that these patients can manifest with high-risk situations. Again, I love the way you pointed out the high-risk features in this patient, which was the NT-proBNP—2,400 to me is like a signal. Watch out, right? That is high. Also, this interesting requirement of an oral diuretic. I would love your thoughts there. You know, if you have a patient in an outpatient clinic who now is requiring more and more oral diuretics, what does that mean to you?

Dr. Bauersachs:
I think this is a very important point, Carolyn, you made. So these patients quite often do not go to the hospital for recompensation of decompensated heart failure, but they have more congestion; they have more dyspnea. And then on an outpatient basis in these patients, then diuretics are increased and the dosage is increased, and then we can stabilize to some extent the patient. And this is also a worsening heart failure event. Because an increase in diuretic dose means that the patient had a problem and that he needed more diuretics. And this is clearly an indicator of an increased risk for decompensation, also for mortality.

Dr. Lam:
Yeah, I couldn't agree more. And exactly, we need to recognize when a patient is requiring more and more diuretics, that is a sign of worsening, and that is a sign that we probably have to—not probably—that we have to improve on the current regime.

So a patient like this on quadruple GDMT already has a CRT-D in place. You mentioned the VICTOR trial and adding vericiguat. Perhaps we should talk about is this a new mechanism that vericiguat is working by? And does it come with any—what's the cost of adding something like that? Is there side effects we need to worry about and so on?

Dr. Bauersachs:
So in fact, the stimulation of soluble guanylate cyclase with vericiguat is an additional mechanism which we can tackle and which we can use to improve outcomes in patients with heart failure with reduced ejection fraction.

And it's really easily compatible with the current medications. We know from the large studies, from VICTOR and also from VICTORIA, that you can add this medication easily to guideline-directed medical therapy, and it's easy to use. You have only one-per-day regimen. So you start usually with a 2.5 mg vericiguat and then increase to 5 mg and 10 mg, and it's quite easy once daily.

And it's also important that you don't have a problem with eGFR, you don't have worsening kidney function, you don't have hyperkalemia, and you also have only a very small effect on blood pressure. Almost no drop in blood pressure in most patients. So it's easy to use, and it helps. And what's also possible, now we have the data from VELOCITY, and VELOCITY did show that you must not start in all patients with a 2.5 mg, but you can directly go to 5 mg and then you have only one dosing step from 5 to 10 mg, and then you are on the optimal dose. And the vast majority of patients in the studies, they were able to tolerate these dosages of 10 mg vericiguat and with the starting 5 mg going up to 10, so you have no problem. Also for your patient and in this patient, I think, with a blood pressure of 120 systolic blood pressure, I would have absolutely no problem to directly start with the 5 mg.

Dr. Lam:
Oh, that is so great. Thank you for mentioning VICTORIA as well.

For those just tuning in, you are listening to Continuing Education on Reach MD. I am Dr. Carolyn Lam, and here with me today is Dr. Johann Bauersachs. We're discussing our next move where GDMT is not enough for our patients.

I do think the totality of the evidence is really, really, very, very strong. Vericiguat is already approved in your region and in my region, based on the VICTORIA trial, and together VICTORIA and VICTOR, I mean, it's really convincing. These have randomized more than 11,000 patients with HFrEF across the spectrum of the presentation, right, from a very recent worsening heart failure event, including a recent hospitalization, all the way to those like in VICTOR, who have a remote event or may not have even been hospitalized for HFrEF before. And when we looked at the pooled data, there was a strong, consistent signal of benefit on the composite endpoint of cardiovascular death or heart failure hospitalization, the traditional endpoint that we use in heart failure. That with adding a very easy-to-use regime, as you've said, right? A single dose, once a day, oral, very safe, no new safety signals coming out.

When we looked at the totality of the data, do you think this is time to call this a fifth pillar, I mean, Johann, right? If we have a patient, whether they are near the recent hospitalization or far away, it seems that we can prevent some very important clinical outcomes.

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What do you think?

Dr. Bauersachs:
Yeah, thank you for mentioning these broad possible indications. So really, we have patients that were pretty stable, if we can call them stable, in the VICTOR study. They didn't have a heart failure hospitalization recently, and they profited, and they profited especially regarding mortality.

I think this very important point that mortality could be reduced in these patients that seem to be stable. And on the other hand, we have the patients that are at high risk for a cardiac decompensation or that may have had a cardiac decompensation or an outpatient increase of diuretic dosages. They profited very clearly in the VICTORIA study, and they had in the VICTORIA study, in fact, a significant reduction of hospitalizations for heart failure. And so across the whole spectrum of heart failure with reduced ejection fraction, we have excellent data for vericiguat. It's not so easy to announce the next pillar because here, clearly, also the guideline committees have to add and we have to weigh all the evidence.

But when you see these 2 large trials, more than 11,000 patients, both in the similar direction with reduction of mortality and heart failure hospitalization and heart failure outpatient events. So it's really a drug that we should use much more often than we do now.

Dr. Lam:
Yeah, exactly. Especially when there's no sort of safety drawback.

It works by a completely different mechanism. Augmenting the good things, right, of cyclic GMP in these patients, which the other GDMT don't target in the same way. So I really appreciate what you just said. In fact, our group did a network meta-analysis of all the clinical trials in HFrEF that have been performed, including VICTOR and VICTORIA, and it did look like the quintuple therapy, the 5. Really, it reduced cardiovascular mortality or reduced all-cause mortality by almost 70% compared to no treatment. Can you imagine? That's how far we've come. That it's just really, really fantastic to be at this point, again, not to rest on our laurels, but to remember that it is important to get these effective therapies to our patients.

Maybe I could ask you in this last few minutes, Johann, what would be your take-home message to the audience?

Dr. Bauersachs:
My take-home message for you is that we should go for the guideline-directed medical therapy in all patients. We should not forget device therapy, especially when patients, after several months of guideline-directed medical therapy, do not improve above the 35% left ventricular ejection fraction.

Then we have to think about device therapy with CRT, especially in the patients with a left bundle branch block, and also ICD, and clearly, we should not only stick with 4 pillars that we already have and optimize this, but we should do more and we should do more for our patients, especially at higher risk.

These are the patients we had here in the case vignette. For example, patients with elevated NT-proBNP, patients with a heart failure decompensation, they are not stable even when they seem to be stable. So please care for these patients, increase the dosages, add additional medications that have been proven to reduce mortality and hospitalization even when they seem stable.

Dr. Lam:
Yeah, I think very hard to add to that. Very clear and important message. I think I would only say, too, please, it's our duty to recognize when the patient is getting into risk of worsening, and as we've discussed, when a patient needs more oral diuretics, even as an outpatient, recognize that early as a high-risk feature rather than waiting for the catastrophic event of a hospitalization or an emergency visit.

So it really behooves us, I think, now that we have effective therapies, to treat our patients with the best.

So thank you very, very much for this important discussion. It is all the time we have today. I really want to thank you, Johann. I also want to thank our audience for listening in. Thank you for all the valuable insights that have been shared.

Dr. Bauersachs:
And thank you very much, Carolyn.

Closing:
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