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(866) 423-7849

Addressing Gaps and Disparities in the Care of HFrEF – Now What?

Dr. Butler:
Greetings, I'm Dr. Javed Butler, President of the Baylor Scott and White Research Institute in Dallas, Texas, and Distinguished Professor of Medicine at University of Mississippi in Jackson, Mississippi. I'm delighted to give this short presentation on "Addressing the Gaps in Care for Patients with Heart Failure and Reduced Ejection Fraction, Now What?"

So we have seen that the guidelines continue to evolve as more and more evidence continues to accumulate. At this point, the guidelines give a Class I recommendation for heart failure with reduced ejection fraction for quadruple therapy based on substantial evidence of mortality and morbidity benefit with RAS inhibitors preferably angiotensin receptor-neprilysin inhibitor over an ACE inhibitor or an ARB, an evidence-based beta-blocker, MRA, and an SGLT2 inhibitor and diuretic as needed. If patients fail on those medications or have certain specific other indications, there are a whole series of other medications like for instance vericiguat for worsening heart failure and hydralazine nitrates in African American patients and ivabradine in those patients who have a persistent high heart rate.

So there are multiple therapy options that are available for these patients. More so, the guidelines have continued to evolve and even patients with heart failure and mildly reduced ejection fraction, patients also have the same quadruple therapy indicated, though it's a Class II indication because it is based on secondary analysis of the data. So what is at stake when we talk about these foundational therapies? So we are not talking about a few weeks or a few months of extra survival. If you look at the cumulative benefit of quadruple therapy with ARNI, beta-blocker, aldosterone antagonist, and an SGLT2 inhibitor, we are talking about a whopping 75%, approximately 75% relative risk reduction and approximately a 25% absolute risk reduction for a number needed to treat of only four to reduce one mortality event. And we are not even talking about hospitalization, one mortality event with two years worth of treatment.

So how are we doing it? If we had such potent therapy that can substantially change the natural history of the disease, how are they being implemented? So there are multiple data from Europe, from US, from Asia, multiple registries that say that the translation into clinical care is not very effective. Let me quickly go over the data from the CHAMP registry. And the reason why I specifically like to give the results of the CHAMP registry, this was before SGLT2 inhibitors were indicated, so we are not looking at quadruple therapy, but we are looking at triple therapy, is because we had longitudinal data and we asked clinicians at these sites. So one, this was a broad representation, academic sites, private practice sites, cardiology sites, primary care sites. And this data cut was over 3,500 patients, but we specifically asked that there's a lot of times things are not easily understood in the electronic health record because of documentation issues. So you just tell us that if somebody is not on any therapy, give any reason no matter whether or not it's an absolute good reason or not, but even subjective intolerances, any reason for which the therapy is not given. We will take that away from the denominator so that we can have a true denominator of how effectively we are treating these patients. And it turns out that unfortunately, the results were not spectacular. Triple therapy with RAS inhibitor, beta-block, and MRA was seen in less than 25% of the patients. 25% of the eligible patients were on triple therapy. And remember that triple therapy with ACE inhibitor, beta-block, and an MRA are all generic therapy so you don't have the high cost of care issues as well. And then on top of that, if you actually focus not only on the triple therapy, but also on the appropriate target doses of the therapy, that was seen in single digits less than 10% of the patients. So huge opportunities for improvement in care.

To partially support that, the guidelines have substantially changed the way they recommend medical therapies. So in the past, there

was a very strict sequencing recommendation that do this first, do that later. But we also realize that it doesn't make sense to have a very strict sequencing recommendation because one, sequencing is a historical construct, not a biologic construct as history of medicine that you had ACE inhibitors tested in the '80s and beta-blocker '90s and then ARNIs and then SGLT2 inhibitor two years ago. But there's no biologic reason that you have to prime the heart with one medication before you give another medication. Also, how can you have a standardized sequencing algorithm for every single patient you see? Because not all the patients are same. Some patients have high blood pressure, low blood pressure, congestion, potassium issues, creatinine issues, atrial fibrillation, heart rate, so there's a lot of things that the clinician keep into consideration when making the decisions. So the emphasis now in order to improve these gaps that exist in care is to de-emphasize on the historical sequencing and to match the drugs that are given, match the patient to the drugs that you have to give and you can start with anything, but the emphasis is on time, try to get all of these drugs on board as soon as possible.

We have also realized that some of these medications may actually help other medication be better tolerated. So for instance, if somebody is congested, they may not tolerate beta-blockers, but both ARNI and an SGLT2 inhibitor have diuretic properties that may make beta-blockers better tolerated. Those patients with borderline high hyperkalemia, potassium levels, may not tolerate MRA, but SGLT2 inhibitors lower the risk of hyperkalemia and may increase tolerability to MRAs. And then finally, the focus is to give all four foundational therapies sooner before you worry about uptitrating the doses, but it's very important still to uptitrate the dose of RAS inhibitors and beta-blockers, but first, give the therapies. So there are multiple schema suggested by different groups. Dr. Packer and Dr. McMurray had an algorithm. I had the pleasure of writing one with Dr. Greene and Dr. Fonarow, but the gist is basically the same and that is that use your best judgment matching patient characteristics to get patients on all appropriate therapies. There are multiple strategies that have been potentially utilized, including nurse practitioner clinic, pharmacist clinic, the reminder system, electronic health record reminder system, dedicated GDMT clinic, telehealth visit, phone visit, navigators, focus on in-hospital discharge, transition planning, participation in quality improvement registry. So there's a lot of different ways by which we can improve that. And in doing so, we're certainly giving rapid foundational therapy, improve the chances of left ventricular reverse remodeling, improvement in ejection fraction, reduction in heart failure hospitalization, certain cardiac death, overall mortality, as well as improvement in quality of life in very short timeframe. And what is at stake? So if you think about it, there are these beautiful data published in Lancet that if you are on dual medical therapy with ACE inhibitors and beta-blockers, not placebo, but dual therapy, and if you convert that into quadruple therapy with ARNI, beta-blocker, MRA, and SGLT2 inhibitor, we are estimating about extra six years, six years of extra survival. So there's a lot of benefit and hopefully, all of these gaps that we have identified we can bridge with some of these clinical implementation strategies. Thank you so much.