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<https://reachmd.com/programs/cme/patient-centric-considerations-for-therapeutic-decisions-in-multiple-sclerosis/12332/>

Released: 03/10/2021

Valid until: 03/10/2022

Time needed to complete: 15 minutes

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### Patient-Centric Considerations for Therapeutic Decisions in Multiple Sclerosis

Announcer:

Welcome to CME on ReachMD. This activity, entitled "Patient-Centric Considerations for Therapeutic Decisions in Multiple Sclerosis" is provided by Prova Education and is supported by an independent educational grant from Biogen, Bristol Myers Squibb, and EMD Serono.

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Dr. Coyle:

An improved understanding of the MS damage process and disability patterns associated with MS has led to support for earlier diagnosis and often more aggressive intervention. We're witnessing an impressive expansion in the MS treatment landscape, but much remains to be accomplished. One critical component of care is the incorporation of best clinical evidence into the personalized management of each patient.

This is CME on ReachMD, and I'm Dr. Patricia Coyle. Today, I'm talking with Dr. Mitzi Williams about how bringing shared decision-making into the management of MS can help us achieve our treat-to-target goals.

Dr. Williams, welcome to the show.

Dr. Williams:

Thank you for having me, Dr. Coyle.

Dr. Coyle:

Dr. Williams, let's dive in. Those of us managing patients with MS are well aware that one size does not fit all. What factors do you consider when making personalized treatment decisions for your patients? Let's briefly consider initial therapy but then shift our focus to those patients for whom a therapy switch should be considered.

Dr. Williams:

Absolutely, so, there are multiple factors that we take into consideration. There are certainly patient factors, including the patient's comorbidity, their age and gender, as well as how they presented with disease. There are disease factors such as the severity of the onset of disease as well as their MRI activity, involvement of the brain stem, as well as other correlative laboratory testing. And then also there are drug factors, so there are 2 major approaches right now to treatment including the escalation versus the induction therapy models. Escalation, meaning we start with low- or moderate-efficacy therapy, and we advance our treatment based on breakthrough disease activity versus induction, which is a bit of a misnomer, but really entails starting with high-efficacy therapy early in an effort to try to really curb disease activity. When we're talking about switching therapy, there are a couple of reasons that we do that. Certainly, if there's breakthrough disease on MRI or clinically, we also look at adherence and we look at tolerability; if there are side effects that the patients can't tolerate or laboratory abnormalities that may cause issues. So this is just a little bit of what we take into consideration, but certainly there are much more things that we consider in treatment decision-making.

Dr. Coyle:

So I agree with you that induction is a bit of a misnomer. I consider induction strategies a subset of highly effective therapies; they're short-lived with regard to taking the medication but change the immune system for a long period of time. Things like oral cladribine or alemtuzumab or autologous hematopoietic stem cell transplant, so they're a very interesting subset of high-efficacy DMTs. I'd also mention my perspective would be that this is really indicating how important communication is with the patient. If we're going to make personalized decisions, we really need to speak to the patient and understand where they're coming from and make them a partner.

Dr. Williams, you mentioned the importance of identifying a range of key factors inclusive of clinical trial data that support the value of a particular agent in your patient. How do we approach that issue if the patient in question is not well represented from the clinical trials? And as part of that, can real-world data support decision-making? If so, can you give an example of how real-world data might be used in the management of individuals with MS?

Dr. Williams:

Yes thank you for that question. So there are many considerations with clinical trial data, and there are many populations that are underserved and not included in our clinical trials, including people from lower socioeconomic status backgrounds, people from ethnic minority groups, as well as advanced age for MS which is considered over the age of 55. So we have to really look to real-world data to give us some of the answers about how the disease may behave, the natural history of disease, as well as how people may respond to different treatments. So an example of this would be looking at some of the sub-analysis data from some of our trials and some of the larger phase 4 or investigator-initiated trials that look at treatment response. So many of the newer trials and studies suggest that treatment response, for instance, for African American and Hispanic Latino patients here in the US may be very similar to what we see in other populations. But I think, ultimately, using real-world data is extremely important, but we also need to work on making our clinical trials more inclusive so that we can use both sets of data to offer our patients the best treatment possible.

Dr. Coyle:

You know, I totally agree with you, and I think minorities are being underserved in the United States. We have data that MS is more severe in Blacks, African Americans, and perhaps in Hispanics. We really owe it to study this and get clear-cut answers, and I applaud companies that are really focusing specific studies and supporting specific studies on minority groups.

For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Patricia Coyle, and here with me today is Dr. Mitzi Williams. We're discussing the management of patients with MS and how we can best make patient-centric decisions that help optimize outcomes for each patient.

We've talked about treatment decisions for patients with MS and efforts to individualize them and make them patient-centric. How exactly is that accomplished? How can we engage our patients in successful shared decision-making over the course of their journey with MS so that we address our treat-to-target philosophy?

Dr. Williams:

Absolutely, so shared decision-making is really about partnership with our patients. So first we have to engage them in discussion and let them know that their voice and their preferences are important. We provide scientific information as well as our knowledge as providers, and they provide their experience as well as thoughts about adherence and concerns inside about side effects of certain therapy options. And once we come up with that discussion together, then we can think of the best treatment for that individual patient. And I also tell my patients that treatment is an on-going conversation, so it's a conversation that we don't just have when we pick a therapy, but we have it at every visit so that we can understand if what we are doing is working or if there are adjustments that need to be made. And I think it's also important to have the same goals in mind. So when we treat to target, we talk about our goals, we talk about how we want to stop relapses, how we want to prevent disability, but we also talk about how the medications may not necessarily improve symptoms that are currently present. And I think that's extremely important because one of the reasons that people discontinue therapy is because they expect it to make them better, and so we have to set those mutual goals up front and work towards reaching those goals together.

Dr. Coyle:

So, really, this emphasizes two key components in approaching the treatment of MS. First of all, it needs to be a shared decision-making with the patient and educated partner in getting their input all along the way. And secondly, to have a treat-to-target, probably minimal evidence of disease activity. And the American Academy of Neurology 2018 Practice Guidelines gave us our walking papers for what is unacceptable breakthrough activity: over 1 year of treatment of clinical attack, worsening on the exam, or 2 or more new MRI lesions. That's our treat-to-target, and if the patient needs that, they're having breakthrough activity, and I think it should trigger a switch discussion.

Dr. Williams, there's a wealth of literature across a range of therapeutic areas related to clinical inertia, also termed "therapeutic inertia."

Could you describe what clinical inertia is and is not, and then how does clinical inertia affect the management of patients with MS?

Dr. Williams:

Absolutely, so clinical inertia is really this inability or failure to advance therapy as needed when there are changes in disease course over time. For example, at a referral center, I've seen many patients who have stayed on suboptimal therapy and continue to have worsening disease, and by the time they're referred to a specialist or referred to another neurologist or by the time their treatment is advanced, they've already suffered significant disability that can't be recovered. So this is a crucial concept with multiple sclerosis because once we have lost function, our medicines really are unable to lead to repair. So we need to treat as early as possible, and if we see any evidence of breakthrough disease, we need to advance or adjust therapy so that we can prevent further long-term disability.

Dr. Coyle:

You know, this is really, virtually an unforgiveable mistake. When we diagnose MS early and we start treatment early, there is a window of opportunity; the data clearly supports that. If the patient is not doing well, we should make a switch, and that's particularly true early on; most patients will declare themselves. And to sit on a patient having permanent injury to their central nervous system when we could make a switch is really poor medicine.

Well, this has certainly been a fascinating conversation, but before we wrap up, Dr. Williams, can you share your one take-home message with our audience?

Dr. Williams:

Yes. If you've seen one MS patient, you have seen *one* MS patient. And we have to look at each patient as an individual, take into account their factors, and make the best treatment decision along with the patient and their care partners for that individual person that's sitting in front of us.

Dr. Coyle:

And I would say, we want every MS patient to have a normal life. That's what I tell them is my therapeutic goal. That means communicating, educating and acting appropriately if they are not responding well.

Well, unfortunately, that's all the time we have today, so I want to thank our audience for listening in and thank you, Dr. Mitzi Williams, for joining me and for sharing all of your valuable insights. It was great speaking with you, today.

Dr. Williams:

Thank you so much.

Announcer:

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