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The 2-Point Signal: Apply \geq 2-Point Rule

Dr. Wolfe:

Well, thanks for joining us on CE on ReachMD. I'm Dr. Gil Wolfe. Here with me today is Dr. Christyn Edmundson.

Today, we're talking about one of the simplest tools we have for gauging treatment responses in generalized MG, the MG-ADL. It's a quick 8-item scale that assesses the patient's perspective on disease symptoms, so it's a patient-reported outcome.

A greater than 2-point change in the MG-ADL is more than just a number; it's a validated threshold that helps us know when it's time to act. Let's start with the basics. How do you use the 2-point MG-ADL threshold in your practice, Dr. Edmundson, and what makes it such a useful marker for response or for relapse?

Dr. Edmundson:

Absolutely, great question. So, I really like the MG-ADL because it really does rely on the patient to describe how their life is being impacted on a day-to-day basis by their myasthenia symptoms. It's something that I often use to guide therapy when patients have escalating MG-ADLs. I'll use that as a flag to escalate their therapy, and if they have declining MG-ADL scores, I usually see that as a success and maybe even a trigger to pull back from therapy, depending on how well they're doing.

The really important thing about the MG-ADL score is using it consistently, right? So, it's something that I do at every clinic visit with every patient, and then as I'd even mentioned in one of the prior episodes, we'll oftentimes use it between visits if a patient is calling in to report changes specifically worsening in their symptoms.

I really like the 2-point rule, which is a 2-point change in the MG-ADL reflecting either meaningful improvement or meaningful decline in a patient's myasthenia gravis. And it's because this 2-point rule has been validated through sensitivity and specificity analyses. Using that 2-point cutoff as a marker for improvement or decline really sort of gives you the best trade-off of attributes to predict clinical improvement or decline. So, you can be pretty confident that if a patient's MG-ADL score has improved by 2 points, that clinically they're doing better, whereas if it's worsened by 2 points, then they're clinically doing worse.

This scale also demonstrates a strong correlation with a lot of physician-rated measures, for instance, the QMG, which is a standardized physician-directed examination that results in a score. It's a great measure, but very cumbersome to do. I really never do it outside of clinical trials.

As well as the MGC, as well as quality of life measures. So, those MG-ADL scores really also correlate with physical examination and quality of life outcomes for patients.

In general, the MG-ADL has a lower floor effect compared to the QMG, making it actually a little bit more sensitive for detecting leftover symptoms in patients with mild disease activity.

So, in summary, I really like the MG-ADL. I use it sort of every patient of every visit and use that 2-point rule, that 2-point threshold as a cutoff for reliably indicating improvement or decline in myasthenic control.

Dr. Wolfe

One thing I might add, the MG-ADL is really a simple tool. It can be administered by a research coordinator or a physician or some other healthcare provider with the patients responding. There actually are studies where they've looked at, once patients are trained—and it doesn't require a lot of training; it's an 8-item scale—that their scoring is as reliable with a little bit of training as actually it being driven by a healthcare provider. And the time involved, no matter who's administering it, really can come down to about a minute and a half once people are familiar with the scale. So, it's really pretty easy to do. It's served as the primary outcomes we've measured in all these pivotal registration trials as well. So, it's just something that I do routinely for every one of our MG patient visits. And obviously, we're doing it in the clinical trials as well, since it's serving, usually, as a primary outcome measure.

The other thing that I might add is we've talked about quite a few different outcome measures, the MG-ADL, the MGC, which is the MG composite, the quality of life 15r, the QMG.

Just so everyone knows, the lower your score on these scales, the better you're doing. So, a 0 is the perfect score on all of these scales, and then they build up from there, depending on how bad your disease severity is.

With that, we'll wrap up this episode. Thanks so much for listening.