Transcript Details

This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/neurofrontiers/safety-outcomes-in-ms-clinical-trials-examining-comorbidities-and-adverse-events/32705/

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Safety Outcomes in MS Clinical Trials: Examining Comorbidities and Adverse Events

Announcer:
You're listening to *NeuroFrontiers* on ReachMD. On this episode, Dr. Amber Salter will discuss her research on the association between comorbidities and safety in phase III clinical trials for disease-modifying therapies in multiple sclerosis, or MS. Dr. Salter is an Associate Professor of Biostatistics at UT Southwestern Medical Center, and she presented this research at the ACTRIMS Forum 2025. Let's hear from her now.

Dr. Salter:
The goal of our study was to examine the association between comorbidities and adverse events and early trial discontinuation in phase III clinical trials of MS disease-modifying therapies. So over the past 20 years, treatments for MS have grown both in number and in effectiveness, and these trials provide the evidence base used in clinical decision-making. But we know very little about the safety of disease-modifying therapies in those with a comorbidity. So comorbidities, or the presence of another chronic health condition, are common in people with MS, but comorbidity status is not generally reported in disease-modifying therapy trial reports. Additionally, some observational studies have shown that associations with early disease-modifying therapy discontinuation have been observed in people with comorbidity as well.

Our study used 17 phase III clinical trials to look at adverse events, and we found that most of the adverse events that we were interested in were infection-related adverse events. We found that those participants with a greater number of comorbidities were associated with an increased odds of serious adverse events and early trial discontinuation. And after adjusting for multiple demographic and clinical factors, those trial participants with three or more comorbidities had 25 percent increased odds of an adverse event compared to those without a comorbidity and about 20 percent increased odds of early trial discontinuation compared to those without a comorbidity. Additionally, those participants who had a higher burden of psychiatric comorbidities were associated with an increased rate of trial discontinuation as well.

So we think these findings are important for clinical practice. Disease-modifying therapies are increasingly being used in people with MS who are older and have a higher comorbidity burden. And while our study findings warrant further study in a broader MS population, we think that the net benefit of treatment in those with comorbidities needs to be considered in clinical decision-making. We also think that patients with comorbidities in clinical practice may need additional support to prevent early discontinuation of disease-modifying therapies.

So while we have these findings, we think that we still need some studies with longer follow-up to better understand other important safety outcomes, such as the development of cancers or hepatic dysfunction. Additionally, while we've identified participants with comorbidities in these trials, these trial populations include those with milder comorbidities, and our results may underestimate these effects for the wider MS population where comorbidity burden and severity are likely greater.

Announcer:
That was Dr. Amber Salter discussing the association of comorbidities and safety in phase III clinical trials for disease-modifying therapies in multiple sclerosis. To access this and other episodes in our series, visit *NeuroFrontiers* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!