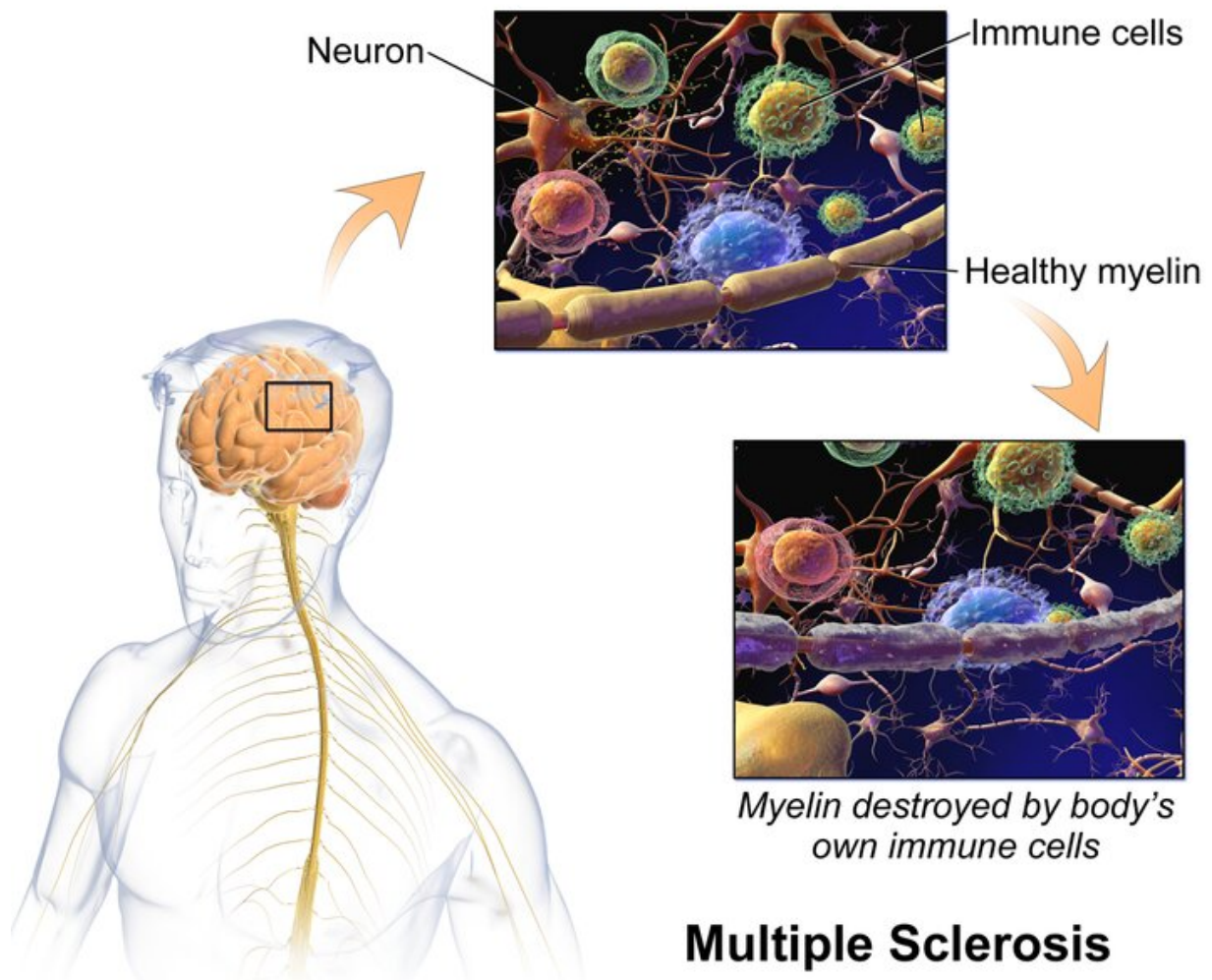


Older MS patients who discontinue medications experience worsening of their disease

December 3 2021, by Ellen Goldbaum



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In recent years, new drugs to treat multiple sclerosis have significantly improved both the quality of life and longevity for patients with MS. Many of them now live well into their 60s and 70s, a significant improvement from just a generation ago when few patients lived to be 70.

Despite these advances, the prevailing standard of care with MS is to discontinue the [anti-inflammatory medications](#) in [patients](#) in their 50s and 60s because of a lack of efficacy as patients age. Due to the diminishing returns, most clinicians do not justify subjecting patients to the significant risks of these disease-modifying therapies (DMTs), which commonly suppress the immune system, if there is little-to-no benefit to taking them.

Now, a study published in *Multiple Sclerosis and Related Disorders* and led by University at Buffalo researchers provides evidence that discontinuing medications in older and previously stable patients results in new disease worsening/progression.

The results are of interest in light of the growth in the population of older MS patients in recent years and concerns about how best to treat them.

"Our results raise important questions about the accepted practice of discontinuing medications once MS patients are in their 50s and 60s," said Dejan Jakimovski, MD, Ph.D., first author on the paper and research assistant professor in the Department of Neurology in the Jacobs School of Medicine and Biomedical Sciences at UB. He conducts research at UB's Buffalo Neuroimaging Analysis Center (BNAC).

Bianca Weinstock-Guttman, MD, SUNY Distinguished Professor of Neurology at UB, director of the Jacobs Comprehensive MS Center for Treatment and Research at UBMD Neurology, and director of the New

York State MS Consortium, is corresponding author.

"It's generally accepted that these [older patients](#) won't benefit with the currently available disease-modifying medications," Jakimovski explained, "but some of the studies that those conclusions were based on involved older medications. There are better DMTs now, and [clinical trials](#) have also improved. It's becoming a real issue: Do we treat these older progressive MS patients, and do the currently available medications work?"

Disease progression seen in up to a third of previously stable patients

The UB study was conducted on 216 patients who are part of the New York State MS Consortium, a statewide MS registry—and one of the nation's largest—of some 10,000 current or historically enrolled patients. These patients, with an average age of 50 at the start of the study, had discontinued their medications and were monitored for an average of 4.6 years.

Out of those patients, 53 previously stable patients (32.9%) experienced disability worsening/progression after they discontinued their [medication](#). This occurred both in patients with relapsing-remitting MS, a stage where patients experience flare-ups of symptoms that subside and improve, as well as in secondary progressive MS, a more advanced stage where no inflammatory activity is present and where symptoms gradually worsen and accumulate.

"The value of our paper is that it shows that it's not an insignificant number of previously stable MS patients who have disease progression after discontinuing their therapy," said Jakimovski. He noted that this is in sharp contrast to some other studies, which suggest that fewer than

10% of older MS patients will have new relapses and subsequent disease worsening/progression after discontinuing the MS therapy.

"The assumption has been, why treat someone to prevent acute inflammatory attacks if those attacks are no longer happening in the aging MS population?" Jakimovski said. "But our paper shows that even though the attacks are not clinically evident or seen on MRI studies, there is more disability progression without medication."

Age at discontinuation was not a factor

The study, which followed adult patients of all ages, revealed that disease worsening and progression occurred regardless of the patient's age when medications were discontinued. Patients who experienced [disease progression](#) were between 21 and 82 years old.

The fact that these patients were stable prior to discontinuing their medications and then declined after they stopped taking them is also important, Jakimovski explained.

"We selected patients who were previously clinically stable," he said. "This preselection criterion is important because usually these DMT discontinuations occur in patients who have been stable for a long time and no new activity is expected. The rate of disability worsening was not different between patients that stopped their medication, regardless if they were younger or older than 55 years old.

"Moreover, these changes also occurred in both relapsing-remitting and progressive MS patients," he continued. "In particular, up to 40% of the previously stable progressive patients experienced disability worsening after drug discontinuation."

But the amount of disability seen in the patients in the study as measured

by the Expanded Disability Status Scale (EDSS), which evaluates disability in MS patients, was significant, Jakimovski said. The disability worsening in the study was determined based on common MS trial criteria, which necessitates an increase in the EDSS of at least one point when there is less disability (0 to 5.5) and an increase of .5 for patients with an EDSS above 5.5.

The types of disability progression seen in a third of the patients included decline in a range of various functions, including the ability to walk unassisted, bladder and bowel control, balance, visual acuity, sensory symptoms and cognitive functioning.

The researchers also found that patients with an EDSS of six were more likely to experience disease worsening/progression than those with lower disability status.

A limitation of the study that the researchers acknowledge is that they didn't utilize an age-matched control group that continued taking their medications. "The main caveat could be that these patients were going to have this progression regardless of whether or not they discontinued their medications," said Jakimovski. "However, these limitations are still not sufficiently explaining the significant progression in a large percentage of the patients."

He added that a larger comparison trial is currently ongoing (Discontinuation of Disease Modifying Therapies in Multiple Sclerosis—DISCO-MS trial) and the results may provide greater insight and further guidelines for MS clinicians.

More information: Dejan Jakimovski et al, Discontinuation of Disease Modifying Therapies is Associated with Disability Progression Regardless of Prior Stable Disease and Age, *Multiple Sclerosis and Related Disorders* (2021). [DOI: 10.1016/j.msard.2021.103406](https://doi.org/10.1016/j.msard.2021.103406)

Provided by University at Buffalo

Citation: Older MS patients who discontinue medications experience worsening of their disease (2021, December 3) retrieved 11 May 2024 from <https://medicalxpress.com/news/2021-12-older-ms-patients-discontinue-medications.html>

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