

Suma Shah, MD- Public Comment for PRGLAC Task Force

Multiple sclerosis (MS) is a chronic autoimmune condition primarily affecting young adults. Internationally, there is a growing body of evidence to suggest an increasing gender ratio with time to an estimated 3-4:1. As there are numerous uncertainties faced by young women of childbearing age who are living with this chronic condition, it has become critical to define a clear approach to questions of disease management during pregnancy. Currently, there are no disease modifying therapies (DMTs) that are deemed safe (FDA pregnancy class A) during conception and pregnancy. As a result of the limited available data, management decisions for MS patients during pregnancy are made more difficult.

A few weeks ago, I met a 27-year-old woman in consultation for multiple sclerosis. She had been recently diagnosed with MS and wanted to speak to a specialist about how this diagnosis would affect her ability to start a family. As a provider serving patients with multiple sclerosis and neuroimmunologic disease, this was not the first time this subject had been broached. Currently, navigating this conversation not only requires knowledge of the latest breakthroughs in care for our patients but also the expertise in extrapolating that evidence to our young female population. This extrapolation results in an uncertainty that lends itself to an array of answers. Patients are often left confused or questioning the validity of provider recommendations, especially when different MDs are recommending differing advice.

Unfortunately, dedicated research to the pregnant and breastfeeding population is still lacking. During my fellowship year, I've spent the several months reviewing the available literature for therapy options for patients who would like to become pregnant, are pregnant, or are postpartum. The available information is limited. There are fields of medicine (e.g rheumatology, oncology) that seem to be a step ahead of us in gathering information regarding outcomes after treatment with certain disease modifying medications, but even this is not enough. The gold standard of research in medicine is the randomized controlled trial but, as a group, medical researchers have not successfully convinced themselves to do so for the pregnant population.

One of the questions I am frequently asked is: How have other patients in similar circumstances responded to treatment with disease modifying therapies during pregnancy? We could start there. Though this would be more of a retrospective analysis of past experiences, it may help guide where to focus our energies going forward. Additionally, in the last decade the available treatments for multiple sclerosis have nearly doubled. There is a shift towards immunomodulatory therapy as first-line care. As the arsenal of treatments for MS grows, so should our understanding of how it can be used for unique populations.

This morning, I received a message from a patient who has decided to stop breastfeeding so that she may resume therapy. I'll be seeing her this week to discuss options but cannot help but wonder: couldn't there be a way to allow her to breastfeed while still treating her safely? The implications of medication exposure to a nursing child seem to directly conflict with the desire to breastfeed. Reconciling this takes thoughtful, educated reflection on the risks and benefits of management options, but we need data for that.

Ultimately, the care of our patients with MS becomes about doing so with the least risks (both from the treatments themselves and possible disease relapse). The stakes are high: the lack of MS therapy may

result in weakness, sensory changes, overall functional impairment. In contrast, we do not want to expose any future children to medications that may put their health in jeopardy.