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National Multiple Sclerosis Society

> MS Learn Online Feature Presentation

## CLIMB Study Featuring: Dr. Tanuja Chitnis

>>Kate Milliken: Hello, I'm Kate Milliken, and welcome to MS Learn Online. The CLIMB study is a long-term study of how MS changes over time. Joining me for this discussion is Dr. Tanuja Chitnis. Dr. Chitnis is the director of the Partners Pediatric MS Center at the Massachusetts General Hospital to Children, and she is an assistant professor in neurology at Harvard Medical School, and the medical director of the CLIMB Study at the Partners MS Center at Brigham and Women's Hospital in Boston. Welcome to MS Learn Online, Dr. Chitnis.

>>Dr. Tanuja Chitnis: Thank you.

>>Kate Milliken: So, what is CLIMB, the CLIMB Study? What does it stand for?

>>Dr. Tanuja Chitnis: So, the CLIMB Study stands for Comprehensive Longitudinal Investigations at the Brigham Women's Hospital.

>>Kate Milliken: And what is the study?

>>Dr. Tanuja Chitnis: The study is a natural history study of approximately 2,000 MS patients who are followed over a 10-year period, and there is no intervention, so they are treated according to their physician's wishes. But we merely collect information about their neurological status, their MRI status, and also biological samples, such as blood and genetic samples.

**>>Kate Milliken:** So, out of some of the results you've gotten from the CLIMB Study, what are a few that you have found particularly interesting?

>>Dr. Tanuja Chitnis: We found that smoking is actually a risk factor for developing more progressive or earlier progressive disease. We have also found that 12% of our patients may develop something called malignant MS, which means having a disability score of 6 within five years, or walking with a cane within five years. And we've identified some risk factors including smoking, including being a man as risk factors for malignant MS. And these may be a patient group that needs attention or more aggressive treatment earlier.

In addition, we found -- we studied benign MS patients. We found, depending on how you define benign MS, which usually is defined as a disability score of 3 within 10 or 15 years, we found that those patients do tend to still have difficulty with some cognitive and patient reported outcome measures. If we use a more conservative definition of benign MS, such as an EDSS of 1 or 1.5 within 10 years, then those patients seem to do better overall. So, I think we have to be very careful in how we're defining benign MS.

>>Kate Milliken: Who is eligible to be part of the CLIMB Study?

>>Dr. Tanuja Chitnis: So, anyone with a diagnosis of MS who is willing to be followed at the Partners MS Center, and is willing to have neurological exams before and every 6 to 12 months, and an MRI every year, as well as blood draws once a year. So, it's a fairly simple procedure.

**>>Kate Milliken:** So, when you started the CLIMB Study in 2001, I'm sure you had parameters that you were working with to commence the study. Have those parameters changed in terms of what you're giving the people in the study?

>>Dr. Tanuja Chitnis: Yes, that's a very good question. So, initially we began by studying things like dates of disease onset and relapse rates in patients and, as well, treatments, of course, and disability scores. We've added MRI and patients have standardized MRI's performed on an annual basis. As well, we have added blood draws on an annual basis, and genetic testing was added a little bit later on. So, most of our patients have all of these studies or tests performed.

In addition, a number of patients have quality of life or patient reported measures included, and we think that this is a very important way of assessing a patient's response to treatment or just a perception of how they're doing, and we can correlate this with other more standard neurological measures.

>>Kate Milliken: So, the testing is continuing to evolve.

**>>Dr. Tanuja Chitnis:** Exactly. And we're adding questionnaires and taking away things as we move along, and try to answer new and more exciting questions.

>>Kate Milliken: One of the things that has come up recently that has become kind of a hot topic are biomarkers and how they are making a difference in people, how people are diagnosed, how disease-modifying therapies are distributed to patients. Do biomarkers come into effect with your work?

>>Dr. Tanuja Chitnis: Absolutely. So, we are studying a number of biomarkers including something called antigen arrays, which is basically about 500 proteins or peptides spotted on a microchip, and that way we can get a signature of antibody responses from a patient's serum or spinal fluid, if available. And we have found that there is a signature differentiating MS from healthy controls and as well there are some proteins that seem to differentiate primary-progressive MS patients from those with relapsing-remitting MS. So we are hoping to take these results further and understand – these will help us to understand why progression occurs, as well it may help us understand and/or identify treatment responders to certain treatments.

**>>Kate Milliken:** Thank you so much for your time, Dr. Chitnis. This is Kate Milliken for MS Learn Online. Thank you for joining us.