

# CORE TM and AFM

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[00:00:00] **Roberta Pesce:** Welcome back, everyone, for our next talk on the Core TM and AFM study. I am joined by Dr. Kyle Blackburn, Assistant Professor in the Department of Neurology at UT Southwestern, and 2018 SRNA James T. Lubin fellow. He's going to tell us a little bit more about the research he's conducting on TM and AFM through the CORE TM study. Dr. Blackburn, thank you for being here and over to you.

[00:00:32] **Dr. Kyle Blackburn:** Thanks, everyone. I know we're getting towards the end today but I'm happy to speak with you and tell you about this opportunity that we have to kind of meaningfully contribute to the research surrounding TM and AFM. So, the reason for a study like Core TM, this registry, to come about is really a lack of robust data on the outcomes of idiopathic transverse myelitis, and that's really due to a number of factors. For one, this is a relatively uncommon condition, so collecting large numbers of patients has been difficult over time. It's also important to note that the definitions for transverse myelitis are a little bit out of date, and I actually just saw a typo here. They were last updated in 2002, not 2004.

[00:01:36] So we are using definitions that really haven't been updated since the discovery of aquaporin-4, or MOG, and that creates a lot of problems. Some of the old data may be a little bit inconsistent for that reason. And then I also want to highlight inconsistent data collection. So what we have, there actually have been a few studies that have attempted to do this on a larger scale, but the best they've been able to do is look through old records of people who had a diagnosis of transverse myelitis and use very rough measures to assess outcome, and one of them I show you on the right here is the modified Rankin scale which, so there's zero, and actually there is a level five, which is severe disability, and in between are different levels of what they define as disability, and really what they're referring to is motor recovery.

[00:02:30] That's really what this is heavily geared towards, so it's kind of a rough measure. It doesn't really give us the comprehensive picture of what somebody has gone through. So, to date there have been several attempts to quantify TM outcomes, but they have not been very large, and they've been very rough. So that's where we stepped in. And this project largely spurned out of a project that Ben Greenberg, one of my mentors, was launching, called Capture, and he was trying to learn about pediatric cases within a certain time frame. And actually, follow them over time. And because there was a lot of interest in doing something even in a larger scale, we created this study which is called the comprehensive outcome registry exploring transverse myelitis or CORE TM.

[00:03:21] So, our goal with this study is to collect information from individuals with TM and AFM who have been diagnosed, and review MRI scans and really do as best we can a comprehensive assessment. The beautiful thing about studies like this we've actually had to get very creative about how we do this because this is an uncommon condition and people are relatively spread out and can't always travel to places like Dallas. We have actually tried to make this a study that can be done remotely, and I'll explain that later.

[00:03:56] And for this specific study we have really opened it up to anyone with a diagnosis of TM or AFM that has access to the MRI scan that was used to diagnose their condition, and that there is no age or cutoff. So, you could have had TM 20 years ago and if you can access your MRI scan and your records, you'd be eligible to enroll. So, I wanted to kind of cover a few of the aims. To kind of, and really one of the biggest ones is to try to gain a full understanding of how TM and AFM have impacted individuals in a comprehensive fashion and kind of guide the needs of this community.

[00:04:39] So as I said before, a lot of studies have focused on mobility and motor function as really the best measure they could collect. But we know that there are a lot of other symptoms at play here and I just listed a few of them here that need to be assessed and I need to understand them better and when they're quantified, that oftentimes helped guide treatments, and further study. And then of course the second aim of this study is to assess the diagnostic accuracy making a diagnosing spinal cord issues can be quite difficult. If you guys were hearing part of my talk, you can see there's a lot of twists and turns to it as we talked about.

[00:05:22] And this is a study out of the Mayo Clinic that actually shows that occasionally people who come to us with the diagnosis of idiopathic transverse myelitis as we review the case in detail, we can actually many times change that diagnosis. So, we are actually doing this also to see what the diagnostic accuracy is, to see in the community how people are being diagnosed and what the diversity of diagnosis may be. So, to give you a little bit more information, about how the study is conducted, I really have two different cohorts here and then there's cohorts means groups of people.

[00:06:02] In addition to pediatric and adult patient cohorts, patient groups. But we're also dividing people based upon when their TM occurred relative to when they enrolled. So, for people that have had TM with an onset of greater than two years ago, this is kind of the workflow. You express interest in the study, and I'd show you how you would go about that. And then you fill out an informed consent, so we send you a consent form and some information about the study through that. You have the opportunity to ask these questions, about the study and about logistics.

[00:06:39] Once you've signed the consent form, we've received it we give you instructions on how to send the MRI scan and medical records to our center. Once we receive those, we send surveys electronically. The surveys that we're sending take about I think a lot of people told me really about half an hour or less to complete. And if you have all of your information in front of you it can even take a little bit longer. Now, for people, we're trying to explore long-term outcomes so to do that I added a second data collection for people who are less than two years from onset.

[00:07:23] So they would go through the same process, express interest, fill out the consent, submit MRI scans, and CDs. Submit MRIs and medical records. And then they would fill out surveys and then 2 years later would complete most of the surveys again. We're trying to see, have there been any improvements, is there any change in your condition, and really just trying to make sure that we understand the long-term impact of this disease on the individual. So, as we're getting into the iceberg and diving through, the surveys are going to cover a lot of information so they're going to ask names, but they're going to ask for information about your diagnosis and your treatment.

[00:08:10] They're going to give, there's a measure of mobility included and that's the Patient Derived Disease Steps. It's at least a question about your current mobility status. But there's going to be questions about depression and anxiety, pain, bladder function, and a series of other psychosocial functions as well really trying to know how TM or AFM has impacted these measures. So, kind of we'll walk through the process again.

[00:08:39] For people that are interested in participating in the CORE TM and AFM registry, beforehand it's often helpful to go and collect your medical records. Really the most, if you were hospitalized, that is the extent of the records we need. When you were diagnosed what treatments were administered? We're really going to be looking at those things. Looking at your exam at the time of hospitalization. But we understand some people weren't hospitalized. It wasn't recognized until many months later so in those situations it's helpful just to have neurology notes. Either way if there were CSF studies done, we certainly want to see CSF studies. If there's blood work that's been done, we certainly want to take a look at the blood work. And see if it was a comprehensive evaluation.

[00:09:27] And then of course one of the big requirements is the MRI scan and the reason is we have to be able to confirm there is indeed an injury to the spinal cord. We have to be able to look at the images and see. So, we asked that everyone who participates in the study send us the images on a CD from the time of diagnosis. And we also recommend these are sent via a service that will allow you to track. This is a big medical center so we want to be able to know when it reached our center and oftentimes you can find out where and that helps us track things down in case something gets lost on the way home. So. And that's really the end of this portion.

[00:10:13] If you are interested in the study, I would love it. We certainly want participation. If you could gather your records, gather your MRI scan and this is the e-mail address that you can express interest through, and that is at [coretm@utsouthwestern.edu](mailto:coretm@utsouthwestern.edu). And that's really all I have to say about this right now. We've been running this for a few years, we're very excited whenever anyone expresses interest, and we certainly try to help facilitate as much as we can getting medical records and getting everything together. But I'm happy to answer any questions anyone has about our registry.

[00:10:55] **Roberta Pesce:** Great. Thank you so much Dr. Blackburn. We appreciate your talk. I'm just checking with the team, whether there are any questions that came in...

[00:11:09] **Dr. Kyle Blackburn:** Sure

[00:11:10] **Roberta Pesce:** ...live. Let's see. Yes. Community question: Have you considered utilizing PCORnet in recruiting participants for CORE TM?

[00:11:23] **Dr. Kyle Blackburn:** PCORnet? We haven't yet. It's something that we may explore in the future though.

[00:11:33] **Roberta Pesce:** Okay, sounds good. There's another one, sorry. This is the beauty of live events. Here we go. Is there a website link for the CORE TM study?

[00:11:47] **Dr. Kyle Blackburn:** So, there's not a specific website link. There is information available, I know, on the SRNA website. Certainly, we can eventually get a link and throw that in the chat. Really the best way to if you wish to find out more information about the study, whenever an e-mail is sent, we usually send an e-mail that provides, one, consent, and, two, fairly good overview of the study. So, I'd be happy to share our e-mail if you just reach out to us.

[00:12:20] **Roberta Pesce:** Perfect. They're coming in so I'm moving frenetically to try and get them all covered. Is it possible to check if we've already done this?

[00:12:29] **Dr. Kyle Blackburn:** Sure! It would be very easy. If you wanted to send an e-mail just saying, "Hey. I think I may have tried to sign up for this," I'm happy to check and see if we have you in our system.

[00:12:41] **Roberta Pesce:** Perfect. Kyle, would love to join the study, can you take UK participants?

[00:12:49] **Dr. Kyle Blackburn:** That's a great question. So, we actually have enrolled people with records from the UK before, so it's definitely possible. If you can get hold of your MRI scan and get the medical records, we'd love to have anyone that has records available in English for review.

[00:13:07] **Roberta Pesce:** Perfect. Does it matter how old the MRIs from onset are, and if you had one every 3 to 4 years would you want them too, so you can compare them, for example?

[00:13:18] **Dr. Kyle Blackburn:** That's a good question. We really the main MRI scans we are focused on is the MRIs that were obtained at the time of diagnosis. Certainly, if you wanted to send others, we would have those available. If there was for example if the MRI was thought to be normal but then was clearly thought to be abnormal later, that's certainly something we would take into consideration and review but some people as part of their evaluation have had MRIs every few years, as this person's asking, we don't necessarily need all of those. We just need really the ones that secured the diagnosis and TM.

[00:14:01] **Roberta Pesce:** Alright, thank you. Other questions: There's often costs for individuals to get their own records. Do you have an option to submit a form for the hospitals to send you records, images at no cost to the participants?

[00:14:15] **Dr. Kyle Blackburn:** Yeah, that's a good question and unfortunately that has been a tough one for us. We have occasionally helped patients fill out a form so that we can request them if they were a patient at UT Southwestern and they wanted to participate. Because we've established a doctor/patient relationship. But for people who were interested outside of the UT Southwestern network, it is a little bit more challenging for me to do that because we're actually asking for these records for research and not for clinical purposes. So unfortunately, sometimes the person would have to take on those costs.

[00:14:52] **Roberta Pesce:** Thank you. There's another one that just came in: What if the MRI scans showed spinal damage, but the diagnosis came a lot later?

[00:15:01] **Dr. Kyle Blackburn:** That's okay. I would want to see the MRIs that showed the damage and in terms of records for this specific individual, certainly seeing, one of the things we are looking at as well is, what was the initial diagnosis? So, if you're in an emergency room, we're seeing it fairly commonly for people to be diagnosed with Guillain-Barré, so in this instance, it may be helpful to get the MRI and the records from the initial evaluation and then the subsequent evaluation that led to the diagnosis of transverse myelitis. We would certainly be interested in those.

[00:15:40] **Roberta Pesce:** Great. Another one. "What if those with relapsing TM with MRIs undertaken at initial presentation and 5 months after?" Yeah, so this is a question.

[00:15:51] **Dr. Kyle Blackburn:** Yeah, that's a really interesting question. And relapsing certainly somebody who's been diagnosed with TM is welcome to submit these, and if they have had true relapses and that's been confirmed on imaging, we would take a look. That's an interesting situation where we would want to

make sure that as we review the record, we think that we agree with the diagnosis, but we would certainly be interested in enrolling and seeing the imaging.

[00:16:19] **Roberta Pesce:** Okay, thank you. I think we still have some time.

[00:16:22] **Dr. Kyle Blackburn:** Yeah.

[00:16:23] **Roberta Pesce:** Here's another one. I think you're getting to the top three of most questions submitted at this point. "My lesion was very small, missed in the hospital. I got a diagnosis of idiopathic transverse myelitis 2 months later after an additional MRI. Would you want all of these initial scans?"

[00:16:46] **Dr. Kyle Blackburn:** It's a good question, and I think in instances like this, it's always a good idea to send more information rather than less so that we can feel comfortable we've got out what we need to secure the diagnosis as we review. I would absolutely be interested in seeing the first MRI at this case, and if a follow-up one showed something more prominent, that would be great as well. We'd be happy to see both of those.

[00:17:17] **Roberta Pesce:** Great, thank you. Another one is coming in. I'm adding it as we speak. I haven't looked at it yet, so let's look at it together! Is there a formal research application that we can submit to our consultants to explain the study we are wishing to participate in?

[00:17:34] **Dr. Kyle Blackburn:** That is a good question. We have had one or two clinicians offer interested asking if their patients could participate in a study, and we certainly bring this up. There is not a formal research application at this time, but what we can do is provide you with the same information that we can provide you with the information, and you can share it with your team. Based upon the use of consultants, I'm going to speculate this person is not from the US. That's not commonly how the neurologists are referred to. And we've actually in the UK done this where another neurologist reached out, and we shared information on the study with them. So, you can certainly do that. We can give you the information we have that they can review. You can share that with them. We don't mind

[00:18:27] **Roberta Pesce:** Great. Alright. I think we've reached the end of the questions. I don't see any new ones popping in, so thank you so much, Dr. Blackburn, for your time today and for giving this very comprehensive talk about the research that is being conducted. Thank you for your time.

[00:18:47] **Dr. Kyle Blackburn:** Thank you all. I hope to see some e-mails.

[00:18:50] **Roberta Pesce:** Sounds good. Bye.