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Hospital plots leadership path in MS research

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- Memorial Healthcare's neurology department is growing and engaged in cutting-edge research
- New blood tests for MS patients are being tested that will help doctors pinpoint stage of disease and best drug to slow debilitating effects
- Multi-disciplinary team approach cuts testing and diagnosis process to one day



Rany Aburashed, D.O.

Neurologist Rany Aburashed, D.O., is leading Memorial Healthcare's clinical renaissance and putting it on the map nationally by pioneering clinic-based research on a new blood test for multiple sclerosis on thousands of patients.

Memorial Healthcare, a small 161-bed rural referral center in central Michigan, is believed to be the only hospital in the U.S. where the Simoa Analyzer MS blood test technology is being tested, Aburashed said. There are about 100 universities that are testing the MS blood test technology on animals, experts said.

Aburashed also has helped to create Memorial's Institute for Neurosciences and Multiple Sclerosis that offers patients a multi-disciplinary approach to MS care that is in effect, "one-stop shopping" for co-located neurology, orthopedics, rehabilitation and wellness programs.

"The Europeans tend to be ahead of us in terms of research into MS. They are much more aggressive after the disease and treatment," Aburashed said. "When we saw more and more evidence from the European data on neurofilaments that was not only predictive of MS but also was predictive of (how effective is the) drug working. I realized this was going to the future of MS care over the next five years and we had to have it."

While the MS blood test using "neurofilament light chain" technology, or NfL, is still under clinical trials in the U.S. and not approved by the U.S. Food and Drug Administration, it is also widely being researched in Europe.

The blood test detects NfL, a structural protein that forms part of the internal skeleton of neurons. When brain neurons are damaged or dying, the protein leaks out into the fluid that covers the brain and spinal cord. From there, the brain and spinal fluid goes into the bloodstream.

By hard work and determination, Aburashed earlier this year won approval from the hospital's institutional review board to test the NfL technology in a five-year trial. He also was able to secure the machine to test NfL, the Simoa Analyzer, from Quanterix Corp, a Billerica, Mass.-based biotech company.

Memorial purchased the Simoa Analyzer for about \$150,000 and plans to spend \$500,000 this year on overall neurology research. Neurologists also are garnering research grants for various studies.

But to fund the cutting edge research that also helped to recruit like-minded neurologists meant the hospital would need to dramatically increase clinical neurology revenue. Since 2014, Memorial has invested about \$4.3 million in its neurology department, excluding capital costs, that includes staff, physicians and facility operations.

"We need neurology volume growth to support the research," said Brian Long, Memorial's CEO. "We are excited about offering research not just for this community, but for the larger community of Michigan and the region, even potentially nationally and beyond."

Long said Memorial doesn't have the deep pockets of larger health systems such as the University of Michigan or Henry Ford Health System. "We have to do that in a way that makes sense financially. We have to manage that growth and the research where it is an asset for us," said Long, adding that so far the plan is working.

Research is underway at Memorial using the NfL technology and the Simoa Analyzer that will help neurologists understand what drugs and what treatments work best on individual patients because each one is at a different stage of the disease and requires different medications.

Since 2010, the number of FDA approved drugs for MS has grown from five to more than 15. "We've had literally 11 new drugs over the last 10 years," Aburashed said. "And the differences we have been able to apply certain treatments, certain new cutting edge treatments."

But deciding on the right drug, whether it is a mild drug or a strong drug, is more the art of medicine, he said.

Because using NfL and the Simoa Analyzer to test blood is still investigational, Aburashed and other neurologists at Memorial are not yet making treatment decisions based on the test results. However, they do use the test results to supplement the standard of care for MS patients, he said.

Still, Memorial is individualizing patient care by analyzing blood samples of at least 450 patients over the last four months using the NfL technology and the Simoa Analyzer. "Every patient we see now is tested," Aburashed said.

"We have the most prospective (looking ahead) neurofilament data I think in the world at this stage," Aburashed said. "With everything we are doing to diagnose patients, neurofilament was the next piece to our puzzle."

Aburashed said tracking patients based on the results of their blood test will add critical information to the treatment process. "We believe there is a way to categorize these patients at the beginning of their disease," he said

The blood test results will help doctors tell what stage the disease is at, he said.

"Now when we look at a patient at day one, we can get a broader picture of where that patient is in the disease process," Aburashed said.

"We are not putting them at risk (with a strong medication) they don't need, but we're not putting them at risk for the disease because of fear" of not being as aggressive as needed with medication, he said.

"This is aimed at individualizing a patient's care and getting them on the right drug early," Aburashed said.

Aaron Boster, M.D., medical chief of neuroimmunology and founder of the OhioHealth Multiple Sclerosis Clinic in Columbus, said what Aburashed and Memorial are doing is revolutionary and will improve outcomes of patients with MS.

Boster met Aburashed at a medical conference several years ago and they began to trade notes about how they believed MS diagnosis and treatment needed to be improved for the 21st century.

Memorial has a good chance at helping the MS community discover a biomarker for MS similar to what the hemoglobin HbA1c3 biomarker test did for the diagnosis and treatment of diabetes, Boster said.

"Our field of MS desperately needs better biomarkers. It is a measure that gives us insight into the disease process," said Boster, a national MS expert and researcher. "We talk with humans, take a history, do physical

exams. Now, the best biomarker we have is the MRI. It is like taking a picture of the outside structure of a house. You don't know what is going on in the kitchen."

"NfL will revolutionize the entire field and will literally change everything," Boster said. "I can draw blood and tell you if you soon will have an attack. Now, we wait for you to have clinical problems before we can see what's happening."

Memorial also is one of a few hospitals in the nation that uses NeuroQuant, a software program that analyzes a brain MRI to improve the early detection and treatment of MS, dementia, Alzheimer's disease and epilepsy. It was developed by CorTechs Labs in San Diego.

"Let's say we are getting diagnosed. We get an MRI and see a couple of (brain) lesions (an area of tissue that has been damaged through injury or disease). We do the blood test and your NfL might come in at 40 and mine comes in a seven," said Aburashed, adding that higher numbers indicate more severe MS.

"Looking at the data retrospectively might tells us that you at 50 in 10 years are probably in big trouble. Tells us that me at seven probably doing fantastic," he said.

MS blood test numbers also give neurologists information on whether to use mild, moderate or very strong MS drugs, Aburashed said. "Mild drugs gives the patient the least amount of risk, but it also gives the the disease more room to progress," he said.

Multi-disciplinary approach to MS treatment

Most hospitals have neurology, orthopedics, physical therapy and wellness programs, but the majority don't have an integrated approach to diseases where all specialists consult together on difficult patient cases. Telemedicine and co-location of doctors has made it easier specialists to consult and work together.

"(Hospitals and clinics) might have multidisciplinary programs but they don't do it all in one day like we do," Aburashed said. |We have point of service comprehensive care. We are building our program to be one where a patient comes and we will see you on that day and take you through the process."

Aburashed said he has studied the multi-disciplinary approach used at such leaders as the Cleveland Clinic and the Mayo Clinic. Several other hospitals in Michigan have similar approaches, including Henry Ford and the University of Michigan.

Like others on the cutting edge, Memorial takes a full multidisciplinary approach including consultation, imaging, lab testing and rehab, Aburashed said.

In 2014, Boster developed a similar interdisciplinary care model using neurologists, orthopedists and wellness providers at OhioHealth. The 12-hospital health system's MS Clinic cares for 4,000 families each year, he said.

Boster said using a multi-disciplinary approach to MS "is, unfortunately, still unusual. The academic model for caring for MS may not be the best approach as it turns out. The structures of most academic environments are siloed and bureaucratic. It takes an innovative health care system to appreciate the patient and family to break down those silos and barriers."

Besides neurologists and orthopedic specialists, Boster said physical and speech therapists, social workers and other allied health workers contributing to patient care is a vast improvement over traditional approaches.

"You have MRI one day, speech therapy another day, a separate appointment for social workers and a fourth appointment for a discussion of clinical trials and I just took up half your vacation," Boster said.

"Rany's shop is similar to what we constructed here. All care is integrated into one clinic visit. We put patient in the center and bring specialists to see them," said Boster, who added he decided to become a neurologist specializing in MS when he was 12 years old and has been a neurologist 15 years.

"My uncle was very poorly cared for. I promised my mother I would do it better," said Boster. "I am really impressed with Rany. His shop has become destination for all of Michigan from Detroit to Grand Rapids (and they are competing) with Wayne State, University of Michigan and Spectrum Health."

How Memorial diagnoses MS patients

Typically, neurologists talk with MS patients, take a medical history, have patients explain their limitations and review an MRI to complete the evaluation.

"We would examine them and I would look at their MRI. If the MRI was stable and the exam was stable, we would say even if the patient said, 'I'm getting worse or I can't walk well,' we would say, ' You're stable. Your drug is working,'" Aburashed said.

That was the typical intake and conversation. Memorial has added a few additional tests since 2015 for repeat MS patient visits.

Four years ago, Memorial added NeuroQuant software to the MRI technology that identifies the amount of shrinkage of the brain and helps measure MS progression. NeuroQuant software also can be used to improve the early detection and treatment of dementia, Alzheimer's disease and epilepsy.

Few hospitals have such technology, Aburashed and Boster said.

"We've added another piece to the puzzle. I can look at lesions with the MRI. Now I can look at atrophy (shrinkage of brain volume)," Aburashed said.

Each year, Boster said normal brains shrinks by about 0.2 percent, but patients with MS have brains that shrink more, at least 1 percent per year.

"Measuring brain volume enhances our understanding of what is going on," Boster said. "With an MRI, I can see patient with MS and see no new spots but with NeuroQuant I can see accelerated brain shrinkage and I know we are not winning."

Memorial also added two physical therapy-type tests for MS. One is called "the 25-foot time blocks." Patients are timed on the amount of seconds it takes to walk 25 feet.

"We've treated you with drug 'X' and now you're walking the 25 feet in six seconds, or maybe the opposite is happening. You were walking in six seconds then and now you're getting worse," Aburashed said. "It tells us maybe we should change medications."

Another test used on MS patients is the "nine hole peg" that measures how long it takes to place the little golf tees into the holes in a small triangle board.

Next steps?

Soon, Aburashed hopes in a couple of years, neurologists will be using the NfL blood testing technology that can help diagnose the stage an MS patient is in, giving critical information on the strength of the medication to be prescribed.

"We can adjust the drugs based on all these test. Once the blood test is approved it will completely change the way we practice neurology in the world" for not only MS, but also dementia, Alzheimer's disease and epilepsy, Aburashed said.

If all continues to go well, Aburashed said he foresees adding 10 more neurologists to Memorial's neurosciences institute over the next five years and possibly 40 over the next decade, plus adding two to four neurology satellite clinics. Long said it is feasible if neurology volume continues to grow and research advances continue.

"We will have nine (in December). I don't think having 20 neurologists is a stretch in five years, achievable," Aburashed said. "It has to be manageable growth, sustainable and can't put the department at risk."

Aburashed said he believes the sky is the limit for Memorial once MS research advances and its multi-disciplinary team gains experience and patient volume continues to grow.

"Why can't we have a system of neurologic care here in Michigan that is renowned across the world where if you get a neurologic illness, you go to our group?" he said.

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