



# NEUROLOGISTS RESPOND AS NEW NEURODIAGNOSTIC TEST INVADES THE GENERAL MARKET

By Orly Avitzur, MD

## ARTICLE IN BRIEF:

- ✓ Neurologists question the efficacy of a new neurodiagnostic testing tool that is increasingly being done by non-neurologists.

When a patient scheduled to undergo a radiofrequency rhizotomy went to Salem, MA, neurologist Sanford M. Levy, MD, for a second opinion, he determined that her complaints were actually due to hip disease. "Her diagnosis of lumbosacral radiculopathy was based on findings from a device that showed an absent F-wave," recalled Dr. Levy. After she was properly diagnosed, he added, her condition improved with a simple injection of steroids into the hip.

When he confronted the local physician who had sent the report, he discovered that the person doing the testing was a young woman who normally functioned as a file clerk. The doctor admitted that his employee had received little training with the instrument — an NC-stat® monitor — sold to his office by the manufacturer, NEUROMetrix, Inc.

"The patient had not had a neurological examination," Dr. Levy said. "People without the skills to do or interpret the procedure are being given the responsibility of diagnosing difficult problems, and physicians are being asked to treat these patients based on incorrect conclusions."

## CORRECTION:

"From Harlem to Kansas City, Programs to Close Gaps in Stroke Care" (May 16, page 17) incorrectly identified the hip-hop music program in which the Harlem Hospital Center participates. The Hip-Hop Elementary School Stroke program is sponsored by the National Stroke Association, not the American Stroke Association.

## CLARIFICATION

Dr. Lawrence Huntoon, author of "The Problem with Third Party Care," (Jan. 3, page 4) — a *Viewpoint* on why he opted out of a third party practice — responded to a letter

## WHAT ARE THESE DEVICES?

The NC-stat® device "is basically a miniature, battery-powered nerve conduction system that stimulates nerves and records standard nerve conduction data," Harvard Medical School Associate Professor of Neurology Seward B. Rutkove, MD, told *Neurology Today*. Dr. Rutkove, a member of the NEUROMetrix Neurology Advisory Board, explained: "By pushing a button on the NC-stat®, the device automatically ramps up the stimuli until a supramaximal response is obtained. The data are collected and downloaded to the company where a computer automatically processes the results and identifies where (within a range of normal) it falls."

"The standardization removes some of the mystery and variability inherent in most nerve conduction measurements," said Dr. Rutkove, Director of the Clinical Neurophysiology Fellowship at Brigham and Women's Hospital. "NEUROMetrix mines the F-wave data by using more detailed F-wave attributes than the standard minimum latencies that most electromyography (EMG) labs measure," he noted. "Here, you have a clear set of normal values that are applied in a consistent fashion across the board, and the report, including waveforms, is immediately sent back to the tester."

## WHY ARE NEUROLOGISTS CONCERNED?

If this product is so revolutionary, why are listservs brimming with commentary from neurologists across the country suggesting that certain uses of the device aren't good for patient care?

by Dr. Laura Boylan (March 7, page 4), who wrote that his practice is not entirely third-party free if he refers patients for tests that get reimbursed by insurers elsewhere. Dr. Huntoon wrote in: "This is a totally false statement...I accept no payment whatsoever from any third party. ...Medicare and other patients may have the misconception that just because I am third-party free that means that they cannot receive reimbursement for anything else they need, including things I may order — provided by someone else, not me. The key is that it is provided by someone else, not me."



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Most concerns relate to the clinical context. Neurologist R. James Hawley, MD, knew that orthopedist and internist colleagues were performing nerve conduction tests in their offices in the Christiansburg, VA, area, but he was nevertheless surprised to see a report diagnosing radiculopathy in the absence of needle EMG. "The nerve data on a patient with pretty obvious L5 radiculopathy were probably accurate," he concluded, "but the assertion that F-waves without EMG are helpful in diagnosing radiculopathy is presently unsupported."

"The use of F-waves to evaluate for radiculopathy is controversial," Dr. Rutkove admitted. "They are rather nonspecific measurements being potentially affected by abnormalities anywhere along the course of the nerve fibers," he said. "And because no needle EMG is performed, common forms of cervical radiculopathy cannot be evaluated at all," he noted, adding that in the legs, F-waves are used only to evaluate L5 and S1 radiculopathies; L4 and higher levels cannot be assessed.

Although for motor studies, the tool can capture distal latency, amplitude, and F-wave, it does not record conduction velocity on a variety of nerves — a problem, said Dr. Rutkove, if you are looking to diagnose a median neuropathy in the forearm or a peroneal neuropathy at the fibular head.

Jeremy M. Shefner, MD, PhD, also a member of the NEUROMetrix Neurology Advisory Board, said, "In its current

incarnation, I think this technology has a role when a particular diagnosis has a high pre-test probability — examples might be carpal tunnel syndrome in patients seen in a rheumatology office, or neuropathy in a diabetes clinic." Dr. Shefner, Neurology Professor and Chair at the State University of New York Upstate, added, "More complicated patients are probably not appropriate for evaluation with this system."

## NEED TO REDO TESTING

But neurologists assert that if studies do not offer essential diagnostic information, it puts them in the position of needing to repeat tests. Neurologist Richard A. Spitzer, MD, of Pasadena, CA, recently felt obliged to repeat a study on a patient with painful diabetic neuropathy. He was concerned that the referring doctor would infer that Dr. Spitzer was critical of his diagnostic procedure, and might stop sending more patients. Also, in running his own diagnostics, Dr. Spitzer thought he might upset the patient and risk the chance that the insurer would not cover what appeared to be redundant tests.

"But to understand this patient I felt I needed to conduct my own study," he said, explaining, "the NEUROMetrix report provided partial and incomplete information. I don't see how anyone can produce a legitimate electrodiagnostic study without needle EMG, nerve conduction velocities, and a good working knowledge of peripheral neuroanatomy."

Neurologists and physiatrists trained in the nuances of electrodiagnostic medicine say they need to select components of these tests based on good clinical evidence. They question whether any system should be used by untrained personnel, even by physicians, if they lack requisite clinical and academic training.

## ANALYSIS OF THE DATA

When an out-of-state relative of his called neuromuscular expert Eric L. Logigian, MD, recently, she was concerned about several diagnoses she was given after an NC-stat® test. He asked to see the report. The Director of the EMG Laboratory and Professor of Neurology at the University of Rochester Medical Center admits that although he had heard about the technology, this was the only study he has reviewed.

The 80+ year-old-patient had com-

plained of low back pain and numbness in the legs and hands. "Working through the possible causes, including spinal stenosis, entrapments and polyneuropathy, can be challenging even to neurologists," said Dr. Logigian, who added that rather than referring the patient for a neurological consultation, her internist ordered an NC-stat® test that was performed in his office. "The patient had eight motor conduction studies with F-wave, but with stimulation only at distal sites (thereby precluding determination of conduction velocities, blocks, or dispersion) and five distal sensory studies," he said. "The computer-generated summary was 'reviewed' and signed by her internist."

When Dr. Logigian studied the data, he noted that some F-waves were mis-marked; others were marked correctly but called "very prolonged," when they were, in fact, normal for height and age. "And because F-waves are apparently overemphasized by this technology," said Dr. Logigian, "the flawed interpretation included a long list of possible diagnoses (some highly unlikely) that obfuscated rather than clarified the cause of the patient's symptoms."



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"For example, the 'very prolonged' (but actually normal) median F-wave latency of 32 msec was 'suggestive of' a C8 and T1 radiculopathy, a brachial plexopathy, a proximal median neuropathy, or polyneuropathy, while the 'very prolonged' (but actually normal) bilateral minimum ulnar F latencies of 31-33 msec were 'consistent with' bilateral ulnar neuropathy at the elbow, bilateral brachial plexopathy and bilateral C8 and T1 radiculopathy," he explained. "Bilateral L5 and S1 radiculopathies were similarly suggested in the legs based on 'very prolonged' (but mis-marked and actually normal) tibial and peroneal F responses of 52-57 msec," he said.

"This patient received maximal



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billing but minimally helpful information," said Dr. Logigian. Although he concedes that the technology may be innovative and interesting, he said that the crux of the problem lies in the manner in which the technology is used. "Given the limitations of relying on F-waves for nerve conduction proximal to the ankles or wrists, and the absence of conduction velocity and needle EMG data, the interpretations are fraught with pitfalls even if the data are gathered and analyzed correctly, which was not done in this case," he said.

"Furthermore, electrodiagnostic testing works best as an extension of the neurological examination," Dr. Logigian continued, "when it is focused and interpreted in light of the patient-specific neuromuscular clinical context, requiring knowledge and experience that is beyond most primary care providers."

"A lot of family practitioners and internists are doing it here," said St. Charles, IL, neurologist Nicholas L. Schlageter, MD. He reported that fraud investigators from Blue Cross Blue Shield have come to one area neurologist's office asking why primary

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care doctors are billing for nerve conduction studies. "I have had patients referred to me after these tests by orthopedists who wanted proper tests to be done before surgery," he explained. "I think any test performed by an untrained physician is a threat to patient care," he added.

"The AANEM [American Association of Neuromuscular and Electrodiagnostic Medicine] position is that trained physicians should supervise nerve conduction studies and perform needle EMGs and that the two tests should be performed together in the majority of cases," said AANEM Executive Director Shirlyn A. Adkins, JD. An AANEM position paper published earlier this year stated: "Without the information provided by the needle EMG examination, valuable data that may be essential in establishing an accurate diagnosis is missing" (*Muscle Nerve* 2006;33:436-439).

However, Dr. Shefner pointed out that there are no AANEM guidelines that state which specific technology should be used. The AANEM guidelines state that all electrodiagnostic evaluations should be performed by a physician trained in electrodiagnostic medicine, but, he added: "This standard is not currently being met, and this particular device does not attempt to address this problem."

Dr. Rutkove proposes that since a practice assistant or nurse can be trained to perform the studies, there is the advantage of substantially increasing patient throughput. "A relatively untrained person can do a simple carpal tunnel study while the physician is working out the details of a complex plexopathy in the lab next door using a traditional system," he suggested.

#### THE IMPACT ON NEUROLOGY

While NEUROMetrix has a strict policy not to market the product to non-physicians, said Dr. Rutkove, other compa-

nies, also getting into the game, may not follow suit. "For instance, XLTEK has just come out with a product that appears to be aimed at a larger audience," he said. "Keeping electrodiagnosis firmly under the purview of neurologists may be ideal from our standpoint as neurologists, but ongoing advances in technology and automation may make this an unrealistic expectation."



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It remains to be seen whether it will be possible to continue to package and sell neurodiagnosis into a do-it-yourself box. While these products are being promoted as a means to expedite diagnosis at the point of care, many neurologists argue that they result in the devolution of one of the specialty's most essential tools of the trade. Only trained physicians can truly understand what data should be collected, and how to best interpret it, in order to avoid missing nerve muscle and nerve disorders and root disease.

Dr. Logigian concluded: "Although the NC-stat® onCall report does state several times that 'electrodiagnostic results supplement the patient examination,' and 'clinical correlation required,' the strong financial incentives for neurologically-naïve primary care providers are such that this technology could begin to overturn this time-honored approach to diagnosis of neuromuscular problems to the detriment of patients." \*

#### SPIKE IN PROCEDURAL CODES FOR NERVE TESTING

The Centers for Medicare and Medicaid Services frequency data shows a 17.49 percent increase between 2004 and 2005 for motor nerve conduction studies with "F-wave" (95903) in comparison to a 0.86 percent increase in one limb EMG (95860).

"The disproportionate increase in nerve conduction studies is most likely related to users with automated devices because needle testing is not part of their system," said Marc R. Nuwer, MD, PhD, Professor of Neurology at the University of California-Los Angeles, who has been tracking utilization data for the past fourteen years. A rise in use of nerve conduction codes of this magnitude will likely trigger reviews by private carriers as well. Dr. Nuwer suspects that some carriers may choose to bundle these automated nerve conduction velocities (NCVs) with Evaluation and Management codes, as has already been proposed by one in Washington state. "We hope that this proposed rule does not spread to all NCVs; carriers may take restrictive actions if the rate of NCVs continues to skyrocket like this," reflected Dr. Nuwer.

#### EDITOR'S NOTE:

Dr. Seward B. Rutkove and Dr. Jeremy M. Shefner, members of the NEUROMetrix Neurology Advisory Board disclosed that they had a financial interest in NEUROMetrix, Inc.