AUTOMATED HAND-HELD NERVE CONDUCTION DEVICES: RAW DATA, RAW INTERPRETATIONS

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The use of automated hand-held nerve conduction devices is among the newest and most controversial topics in the field of electrodiagnostic (EDX) medicine.[1,2] These systems use anatomically configured biosensors to perform and record nerve conduction studies. A hand-held device records the responses. The user can then transmit the data to the company where a computer software system analyzes it and automatically provides an "interpretation." Sounds slick and easy, right? There is no question about it: it is slick, and it is easy. But is this method of electrodiagnosis accurate enough to replace the currently acceptable standard of diagnosis for patients with peripheral nerve lesions? Can it really replace a focused history, physical examination, and tailored EDX evaluation performed by a specialist in electrodiagnostic medicine? The NC-stat system, manufactured by NeuroMetrix (Waltham, Massachusetts), is one of the most prevalent of these hand-held devices. According to company documents (www.neurometrix.com), NC-stat is capable of reliably diagnosing a number of peripheral nerve problems, including lumbosacral radiculopathy and carpal tunnel syndrome. In a high-profile article in *The New York Times*, the chief executive of NeuroMetrix was quoted as saying, "We've put the technology in the hands of all physicians, allowing them to replicate the diagnostic accuracy of the specialist."[2] But how true is this? Let us review the evidence.

The U.S. Food and Drug Administration (FDA) has approved marketing of the NC-stat as a "nerve conduction velocity measurement device" (www.neurometrix.com). The most recent FDA 510(k) Summary states that the NC-stat is "substantially equivalent to the TECA TD-10/TD-20 EMG and nerve conduction velocity measurement device." What this means is that nerve conduction measurements obtained using the NC-stat are comparable to those obtained using conventional equipment. An electrical stimulus is delivered, and nerve or muscle compound action potentials are recorded. In other words, the NC-stat is "substantially equivalent" in an engineering sense to conventional equipment. However, neither diagnostic accuracy nor utility (outcomes) of devices are required by the FDA for 510(k) approval, only that the device is substantially equivalent to any other device approved prior to May 28, 1976. A successful 510(k) application means only that the device has received "clearance" for marketing, not that it is approved for use.

For physicians and patients, however, knowing the diagnostic accuracy of a procedure is the most important part. For us, interpretation of the data and the formulation of an accurate diagnosis are paramount in determining the most appropriate treatment for our patients. It is in this arena that there are concerns about the usefulness of the hand-held devices. There are a few studies that support the usefulness of hand-held devices (i.e., NC-stat), but most of these have been industry-sponsored studies with a possibility of significant biases.[3–5] Only a few other independent studies have addressed the diagnostic accuracy of hand-held devices.[6–8]

One study assessed the usefulness of the NC-stat system as a screening tool for carpal tunnel syndrome (CTS) in 1695 workers.[6] Median distal motor latencies (DMLs) obtained with the device were plotted on a frequency histogram using the 95th percentile as the upper limit of normal. These results were compared with the same data interpreted by the automated NC-stat system. The automated reporting system classified 587 workers as having either "borderline" ($n = 221$) or definitely "prolonged" ($n = 366$) DML, whereas the independent analysis indicated that only 81 were abnormal. Thus, the automated system significantly overdiagnosed carpal tunnel syndrome in an

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asymptomatic population of industrial workers. The author concluded that this technology cannot be recommended for screening or diagnosis of CTS in an industrial population.

The most recent study, published in this issue of the journal, assessed the diagnostic accuracy of the NC-stat system in 50 patients with unilateral leg symptoms and 25 asymptomatic control subjects.[7] Because the NC-stat is purported to diagnose accurately lumbosacral radiculopathy (LSR), our study was designed to determine the sensitivity and specificity of NC-stat in comparison to standard electrophysiologic testing. The study was performed in a methodologically rigorous manner by experienced EDX experts at the electromyography laboratory of the Mayo Clinic. All subjects underwent a focused history and physical examination complemented by standard EDX testing [nerve conduction studies (NCS) and electromyography (EMG)]. The same patients also underwent testing with the NC-stat system programmed for general use, utilizing the "Sciatica Protocol." All automated NCS were performed by experienced technicians who were blinded to the findings of standard EDX evaluation. As expected, the NC-stat was able to record raw data (including F-waves) that matched the standard EDX testing. However, the automated interpretations provided by NC-stat, based on non-transparent industry algorithms, showed high sensitivity with an unacceptably low specificity (high false positive rate) for LSR in both symptomatic patients and normal controls. In the patient cohort, the sensitivity of the NC-stat was 0.00 for L4 radiculopathy, 0.69 for L5 radiculopathy, and 0.64 for S1 radiculopathy, but the overall specificity was only 0.14. By standard EDX evaluation, 28 of the 50 symptomatic patients were found to be normal or to have a diagnosis other than LSR; however, NC-stat identified only 4 of these cases, all with normal studies by both standard EDX and NC-stat. Standard EDX testing also identified other important diagnoses in 18% (3 cases of peripheral neuropathy, 1 thoracic radiculopathy, 1 cauda equina syndrome, 2 lumbosacral plexopathies, 1 motor neuron disease, and 1 L3 radiculopathy) that were not identified by the NC-stat testing. The NC-stat system did report finding other conditions in some patients (2 peripheral neuropathies, 1 sensory peripheral neuropathy, 1 sensory polyneuropathy, 1 mild polyneuropathy, and 1 peroneal (fibular) neuropathy), but in all of these cases the standard EDX evaluation was normal.

In the control group (25 subjects), all standard EDX studies were normal; however, NC-stat reported that 18 of these subjects were abnormal (17 LSRs and 1 sensory polyneuropathy). Overall, the specificity for NC-stat testing was just 0.32. NC-stat significantly overdiagnosed LSR in these asymptomatic controls. In conclusion, considering results in both symptomatic and asymptomatic groups, its was demonstrated that the NC-stat, because of extremely low specificity, cannot be recommended as a diagnostic test for patients with lower extremity complaints.

So what does all of this mean? It means that the NC-stat automated computerized NCS device, whose data is churned but whose interpretation resides in a black box, cannot replace the most sophisticated computer available—the human brain! Those of us who practice electrodiagnostic medicine know that the best EDX consultants utilize EDX as an extension of and not a replacement for the clinical history and examination. No automated device can replace the evaluation of patients by a well-trained and qualified practitioner. These points are made with distinct clarity in the 2006 AANEM Position Statement,[9] which states that "electrodiagnostic studies should be performed by physicians properly trained in electrodiagnostic medicine, that interpretation of NCS data alone absent face-to-face patient interaction and control over the process provides substandard care, and that the performance of NCSs without needle EMG has the potential of compromising patient care."

The 2010 CPT Code 95905 allows for billing of automated NCS using preconfigured electrode arrays, uniquely differentiating use of this technology, albeit at a lesser payment level. So, is there any role for these automated tests? Does the high correlation of the raw automated NCS data with conventional NCS data[7] mean there is any use that could be rationalized? The poor performance of NC-stat for lumbosacral radiculopathy suggests that its use would likely lead to a high misdiagnosis rate and potentially inappropriate treatment, including surgery. Similarly, an overly sensitive but not very specific test for carpal tunnel syndrome, or other mono- or polyneuropathies, cannot replace expert use and interpretation of conventional EDX. As recently suggested in a well-conducted, federally funded study of CTS, the automated technology might be better suited for field-based identification of CTS, where sensitivity may be more important than specificity, and that "NC-stat is not designed to replace traditional methods of NCS."[8]

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