Multi-Site Testing With a Point-of-Care Nerve Conduction Device Can Be Used in an Algorithm to Diagnose Diabetic Sensorimotor Polyneuropathy

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OBJECTIVE — We aimed to establish whether multi-nerve testing with a point-of-care nerve conduction device could be used to diagnose diabetic sensorimotor polyneuropathy.

RESEARCH DESIGN AND METHODS — A total of 72 consecutive patients with diabetes underwent a full neurological examination and a concurrent evaluation for nine standard electrophysiological parameters using conventional nerve conduction studies (the reference standard) and a point-of-care device.

RESULTS — Spearman coefficients for correlation of point-of-care and conventional parameters ranged between 0.76 and 0.91 ($P < 0.001$ in all comparisons). Agreement by the method of Bland and Altman was acceptable despite small systematic biases. Fifty subjects (69%) had neuropathy according to conventional criteria. The sensitivity and specificity for the point-of-care device to identify such neuropathy was 88 and 82%, respectively.

CONCLUSIONS — A novel point-of-care device has reasonable diagnostic accuracy and thus may represent a sufficiently accurate alternative for detecting the diffuse electrophysiological criteria necessary to make the diagnosis of diabetic sensorimotor polyneuropathy.

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Universal nerve conduction study testing for suspected neuropathy is not feasible due to limitations in availability of specialized laboratories (1–3). Simplified automated devices usable by nontechnicians have been developed and validated for conditions other than diabetic sensorimotor polyneuropathy (4–6). As such, we aimed to evaluate agreement and accuracy for such neuropathy by a point-of-care device.

RESEARCH DESIGN AND METHODS

— A total of 72 consecutive patients attending the Diabetes and Diabetic Neuropathy Clinic were identified and categorized for diabetic sensorimotor polyneuropathy using a clinical examination and conventional nerve conduction studies. Standardized procedures with the Counterpoint device (Medtronic, Mississauga, Canada) were used to measure conduction according to the standards of the American Association for Neuromuscular and Electrodiagnostic Medicine. Based on the American Academy of Neurology criteria, classification of neuropathy was based on the presence of at least one neuropathic symptom or sign together with electrophysiological polyneuropathy as defined by abnormality of at least two parameters in at least two nerves (7).

The point-of-care nerve conduction studies were performed using the NC-stat system (Neurometrix) designed to perform standard noninvasive nerve conduction studies by nontechnical personnel. Recently described (8), this system consists of single-use flexible biosensor panels, a monitor, docking station, and a remote on-call information system. The repeatability is comparable with conventional methods (9).

We could predict a priori that the point-of-care system has minor technical limitations that interfere with its agreement with conventional studies. First, the device automatically zeros sensory nerve amplitude potential signals <2.1 μV (8,10). Second, the point-of-care system's median motor nerve distal amplitude potential measurement is based on a "volume conduction montage" in which the sensing electrodes are not situated directly over muscle, and therefore the amplitudes are attenuated 5- to 10-fold. This discrepancy was viewed as a limitation, and this parameter was not considered for analysis. The remaining nine parameters were considered sufficient to evaluate for diffuse nerve dysfunction.

Statistical analyses were performed in SAS version 8.02 for Windows (SAS Institute, Cary, NC). Correlation was analyzed using Spearman's coefficients. Agreement was assessed by the method of Bland and Altman for all nine parameters (11,12).

RESULTS

— Of the 72 patients enrolled in the study, 89% had type 2 diabetes, and mean age and diabetes duration were 56 ± 11 and 12 ± 10 years, respectively. In total, 50 patients (69%) met the diagnostic criteria for the presence of neuropathy.

Correlation between conventional and point-of-care nerve conduction studies was very high for all the parameters (Table 1). Examination of plotted regression lines (not shown) demonstrated that a degree of bias exists for all parameters. For example, examination of the plot for the median nerve distal motor latency revealed that most points were situated above the line of unity; thus, on average, the point-of-care value overestimated the conventional nerve conduction value.

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Table 1—*Correlation and agreement (according to the method of Bland and Altman) between the point-of-care and conventional nerve conduction studies in the 72 subjects with diabetes*

Parameter	Spearman correlation coefficient†	Systematic bias*		
		Mean bias	95% CI (in units of measurement)	95% CI (percentage of conventional nerve conduction value)
Median				
Motor latency	0.83	0.36 ms	−0.26 to 0.98 ms	−8 to 28%
Motor F-wave latency	0.76	0.29 ms	−5.24 to 5.82 ms	−22 to 20%
Sensory amplitude	0.90	−5.89 μV	−25.16 to 13.37 μV	−62 to 5%
Sensory latency	0.83	0.43 ms	−0.75 to 1.61 ms	−5 to 34%
Peroneal				
Motor amplitude	0.83	−1.16 mV	−4.50 to 2.19 mV	−85 to 43%
Motor latency	0.83	−0.42 ms	−2.02 to 1.19 ms	−30 to 17%
Motor F-wave latency	0.86	0.74 ms	−6.55 to 8.02 ms	−18 to 11%
Sural				
Sensory amplitude	0.91	−1.55 μV	−5.41 to 2.31 μV	−100 to 33%
Sensory latency	0.87	−0.93 ms	−1.63 to −0.22 ms	−31 to −8%

All parameters are measured at the distal point of the limb. Data for median motor distal amplitude measurements not included owing to the technical limitations of the point-of-care system for measuring this parameter (see RESEARCH DESIGN AND METHODS). *Bias is calculated as a point-of-care nerve conduction value − conventional nerve conduction value. †All Spearman coefficients have $P < 0.0001$.

The degree of such overestimation was +0.36 ms. The third column of Table 1 summarizes the average bias for each parameter. To further explore the variability in systematic bias, the statistical method of Bland and Altman was performed (represented in the fourth and fifth columns). The first of these two columns shows the upper and lower critical values for the 95% distribution of differences between values. For example, for the median nerve motor latency, 95% of values fall within a range of differences as low as −0.26 ms and as high as +0.98 ms. Most parameters fell within ±30% of the conventional values; however, there are exceptions, particularly for measurements that are low in magnitude and higher in variability.

To determine whether the magnitude of bias in these measurements is of clinical significance, we aimed to determine whether the diagnosis of neuropathy would differ significantly if the point-of-care values were used in place of the conventional nerve conduction study values in the diagnostic algorithm. Of the 50 individuals with neuropathy, 44 were classified appropriately using the point-of care system, indicating a sensitivity of 88%. Of the 22 free of neuropathy, 18 were classified appropriately by the point-of-care system, indicating a specificity of 82%. The 10 misclassified subjects had minor electrophysiological abnormality.

CONCLUSIONS — This study demonstrates that a point-of-care device can measure the majority of nerve conduction parameters with reasonable levels of agreement. It can accomplish this through the use of nontechnologist staff in a nonspecialized clinical setting. Furthermore, when all parameters are integrated along with an assessment of signs and symptoms in a diagnostic algorithm for diabetic sensorimotor polyneuropathy, the bias does not appear to be of clinical importance, owing to the sufficient sensitivity and specificity of the device. Despite meeting diagnostic criteria, subjects who were misclassified by the point-of-care system had minor degrees of neuropathy.

The results of this study imply that an unequivocal diagnosis of neuropathy may be feasible in the primary care or diabetes clinic in place of a specialized neurodiagnostic lab. However, a few limitations must be considered. First, a degree of clinical interpretation is still necessary—to what extent this interpretation is made by the remote on-call system or by the examining health care provider remains to be determined. As such, further study is required into a specific clinical protocol for the point-of-care device, and, in particular, further research into investigation of patients with atypical presentations of neuropathy must be pursued. Second, there are technical limitations of the point-of-care system that make interpretation of certain parameters difficult, although this does not seem to interfere with diagnostic accuracy.

Application of this technology in routine diabetes care, particularly given the short turn-around time between testing and receipt of an interpretation, is a promising contribution to efficient, patient-centered care (13,14). However, studies that investigate the implications of false-positive and false-negative results and their impact on cost-effectiveness are needed before widespread application of the technology.

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