

The New Indicator Test (NEUROPAD) in the Assessment of the Staged Severity of Diabetic Neuropathy

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Background and aims: The new indicator test for sudomotor function (Neuropad[®]) has been shown to be a highly sensitive and reproducible tool for the diagnosis of diabetic peripheral neuropathy. The aim of this study was to examine the utility of the indicator test in the assessment of the staged severity of diabetic neuropathy. **Patients and methods:** This study included 120 type 2 diabetic patients (58 men) with a mean age of 67.3±5.9 years and a mean diabetes duration of 13.1±3.2 years. Neuropathy was diagnosed and staged by clinical examination and nerve conduction study, according to the Michigan classification system (Feldman et al, 1994). Patients were also examined with the indicator test, applied on the plantar aspect of the feet. Time until complete colour change of the test was recorded and stratified into deciles according to the spread of measurements in the study population. **Results:** Neuropathy was staged as class 0 in 37 patients, class 1 in 44 patients, class 2 in 28 patients and class 3 in 11 patients. Time until complete colour change was 436.5±62.9, 740±88.1, 1192.5±161 and 1817.3±127.4 seconds in patients staged as class 0, 1, 2 and 3 respectively (p=0.001). Use of a threshold lower than 530 seconds until complete colour change had 97.3% sensitivity and 100% specificity for diagnosis of class 0. Use of a threshold lower than 1000 seconds until complete colour change had 100% sensitivity and 97.4% specificity for class 1 neuropathy. A threshold lower than 1440 seconds had 92.9% sensitivity and 100% specificity for class 2 neuropathy. A threshold above 1440 seconds had 100% sensitivity and 99% specificity for class 3 neuropathy. A highly significant (Kendall's tau-b= 0.848, p=0.001) correlation was shown between time until complete colour change of the test and Michigan class of neuropathy. **Conclusions:** It appears that the indicator test contributes substantially to the assessment of the staged severity of neuropathy. There is excellent agreement between the indicator test and the Michigan classification system. These results suggest a role for the indicator test in the assessment of diabetic neuropathy.