A Pocket-size Device to Detect Autonomic Neuropathy

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Abstract

Background:
Diabetic autonomic neuropathy (DAN) is a very frequent complication in the diabetic population (type 1 and type 2 diabetes), and patients may suffer debilitating symptoms from various organ systems. In the less symptomatic and even in the asymptomatic condition it severely impacts health. Testing for DAN is currently time-consuming and costly due to the technical setups available today, therefore the examination may not be offered regularly. The purpose of this study was to evaluate the clinical performance of a pocket-size device for detecting DAN by measuring heart rate variability (HRV).

Method:
Ten healthy young males and eight type 1 diabetes patients suffering symptomatic DAN were selected. The standardized spectral analysis equipment VariaPulse TF3® (Sima Media, Olomouc, Czechoslovakia) was used as a reference method for evaluating a prototype of the pocket-size device according to a specified protocol. HRV, inhalation/exhalation ratio (E:I) (deep breathing test), and 30:15 ratio (response going from lying to standing) were measured using both methods. Statistical calculations were performed.

Results:
The correlation between the two devices was $R^2 = 0.98$ and $R^2 = 0.81$ when 30:15 ratio and E:I were measured, respectively. Bland-Altman plots showed suitable agreement between the two devices, substantiated by 95% limits of agreement of the differences of ±0.014 and ±0.033 when 30:15 ratio and E:I were measured, respectively.

Conclusions:
The pocket-size device was fully interchangeable with the hitherto-used, research-based setup. It proved highly suitable for ambulatory testing of autonomic nervous function and may facilitate screening for DAN according to Danish and international recommendations.


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Abbreviations: (DAN) diabetic autonomic neuropathy, (DSP) digital signal processor, (E:I) inhalation/exhalation ratio, (ECG) electrocardiogram, (HRV) heart rate variability, (SD) standard deviation

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