

A Pocket-size Device to Detect Autonomic Neuropathy

Niels Ejksjaer, M.D., Ph.D.,¹ Jesper Fleischer, M.Sc., BME,² Jacob Fleischer, M.D.,³
Poul Erik Jacobsen, M.D.,⁴ Per Logstrup Poulsen, M.D., DMSci,¹ Hans Nygaard, DMSci⁵

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, Olumouc, 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.

J Diabetes Sci Technol 2008;2(4):692-696

Author Affiliations: ¹Aarhus University Hospital, Department of Medicine M (Diabetes & Endocrinology) and Clinical Research Units, Aarhus University Hospital, Aarhus, Denmark, ²Medicus Engineering Ltd, The Engineering College of Aarhus, Aarhus, Denmark, ³Soendersoe General Practice, Soendersoe, Denmark, ⁴Department of Endocrinology, Aarhus University Hospital, Aalborg, Denmark, ⁵Center of Biomedical Engineering, The Engineering College of Aarhus, Aarhus, Denmark

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

Keywords: autonomic neuropathy, cardiac, complications, diabetes, neuropathy, risk stratification

Corresponding Author: Niels Ejksjaer, M.D., Ph.D., Aarhus University Hospital, Department of Medicine M (Diabetes & Endocrinology) and Clinical Research Units, Aarhus University Hospital, Denmark, email address niels.ejksjaer@as.aaa.dk