LumiraDx™ Case Study

Evaluation of the Accuracy of LumiraDx INR Test in patients taking Phenprocoumon as VKA Therapy

Introduction

The LumiraDx INR Test is a point of care *in vitro* diagnostic system for the quantitative determination of Prothrombin Time expressed as International Normalised Ratio (INR) at the point of care (POC).

INR is the preferred test for monitoring patients on vitamin K antagonist (VKA) therapy. It is a standardised measurement of the rate at which blood clots, calculated from the quantitative measurement of PT in capillary blood.[1]

The most commonly prescribed VKA's are Coumadin (Warfarin), Phenprocoumon (Marcumar®, Falithrom®) and Acenocoumerol and within Europe, there are country to country differences in preferential vitamin K antagonist (VKA) prescription. In Germany and surrounding countries, Phenprocoumon is the most commonly prescribed.

Aims

A study was conducted in a German clinic to compare INR results obtained in with patients taking Phenprocoumon determined using the LumiraDx INR Test and fingerstick blood samples, with those obtained with paired plasma samples on the reference methods: ACL Elite Pro and Sysmex CS-5100.

Methods

The study was conducted at Klinik am See, Rehabilitation Clinic for Cardiovascular Diseases, Rüdersdorf, Berlin with Professor Heinz Völler. It was an observational, cross-sectional study with 102 subjects (24 female and 78 male) taking Phenprocoumon across the age range of 36 - 88 years. Devices used were CE marked for INR measurement, and tests conducted by healthcare professionals.

In the first part of the study, venous whole blood samples were taken from 25 subjects and prepared to plasma. The frozen plasma samples were shipped to the LumiraDx UK Ltd laboratory in Stirling, UK, for paired analysis of INR using the LumiraDx INR Test and the IL ACL ELITE Pro (Instrumentation Laboratory) laboratory reference system. In the second part of the study, a comparison of capillary whole blood INR (direct fingerstick application) from 77 subjects were determined by LumiraDx INR Test and compared to venous plasma INR determined by the two laboratory reference methods, IL ACL Elite Pro and Sysmex CS-5100.

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"The study showed a strong correlation between the results obtained by the LumiraDx INR Test with those from the two laboratory reference methods (r=0.949; r=0.950)."

Results

In Part 1 of the study, the 25 plasma samples were tested in replicates of two on the LumiraDx INR Test device and the IL ACL ELITE Pro reference instrument. The accuracy of result agreement was determined between the two instruments, and the INR results from the LumiraDx INR Test were plotted against the results from the reference method. Results showed a high agreement between the two methods (r = 0.981). (*Fig. 1*)

In Part 2 of the study, the accuracy of INR result agreement was analyzed between capillary whole blood samples measured with the LumiraDx INR Test in situ at the coagulation clinic with paired venous plasma samples measured with the IL ACL ELITE Pro (n =74) and the Sysmex CS-5100 (n=73) reference instruments measured at the reference laboratories. The results from the LumiraDx INR test showed strong correlation to both the IL ACL ELITE Pro (r=0.949) and the Sysmex CS-5100 (r=0.950) across the INR range 1.3–5.2.

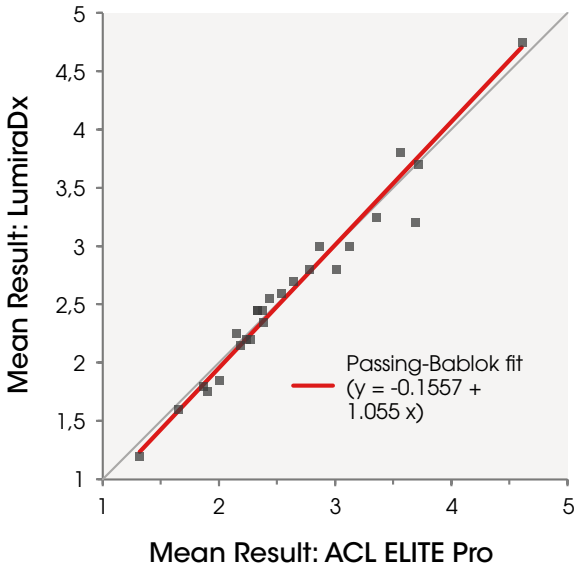

Figure 1.
Analysis of plasma samples (part 1 analysis) from 25 subjects.

Conclusions

Results were found to agree with those from the OPTIMAL[2] study which included subjects on Coumadin (Warfarin), and demonstrated no difference in LumiraDx INR test results when patients are taking either Phenprocoumon or Coumadin as VKA therapy. The LumiraDX INR Test can be used by healthcare professionals at the POC to provide reliable INR monitoring of patients who are receiving vitamin K antagonists.

1. Shikdar S, Bhattacharya PT. Normalized Ratio (INR). StatPearls (Updated 2018 Oct 27). Available from: https://www.ncbi.nlm.nih.gov/books/NBK507707/
2. Tait RC, Hung A, Gardner RS. Performance of the LumiraDx Platform INR Test in an anticoagulation clinic point-of-care setting compared with an established laboratory reference method. Clin Appl Thromb Hemost. 2019;25:1076029619890423

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