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Reliability of a new point-of-care portable coagulometer for PT-INR test performed in the hospital anticoagulation clinic

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Background: Recently, a new coagulation point-of-care testing (POCT) system, the microINR portable coagulometer (Instrumentation laboratory-IL, Italy), has been introduced for assessing PT-INR in capillary whole blood samples of patients on oral vitamin K antagonist (VKA) therapy.

Aims: This study was aimed to evaluate the precision and accuracy of this POCT coagulometer.

Methods: Capillary whole blood PT-INR by using POCT device were assessed in 288 patients on oral VKA therapy. At the same time, citrated blood was withdrawn for comparing citrated plasma PT-INR results obtained from a laboratory conventional method (ACL TOP700, IL, Italy).

Results: Significant correlations were observed between POCT and laboratory PT-INR (rho = 0.96, $P < 0.001$, n = 288). For all determinations, the agreement analysis by using Bland Altman plot revealed that the mean differences between POCT system and laboratory method was: 0.05 ± 0.4 INR ($P < 0.01$). The 95° limits of agreement ranged from -0.7 to 0.85 INR ($P < 0.001$). Across different POCT PT-INR ranges, the following mean differences were observed: < 2.0 INR (n = 20), 0.03 ± 0.24 INR; 2 to 3 INR (n = 83), 0.10 ± 0.29 INR; 3 to 4 INR (n = 83), 0.09 ± 0.33 INR; > 4 INR (n = 102), -0.04 ± 0.44 INR. In addition, for these different ranges significant correlations between POCT and laboratory PT-INR were observed (at least, $P < 0.01$). Regarding between-cartridge imprecision analysis, the coefficient of variation (CV) within day was: CV=3.2%. The Integrated Quality Control for the guaranteed reliability of system did not failed.

Conclusion: These data show that the POCT system microINR provides precise and accurate results that are significantly comparable with plasma laboratory PT-INR.

Disclosure of Interest: None declared.