

Comparison of Two Quantitative Methods for Determination of Dabigatran Concentration: Diluted Thrombin Time Test and Innovance Dabigatran Test in Real Life Patients Treated with Dabigatran

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Background: Clinical application of dabigatran does not require routine therapeutic monitoring. However, there are special clinical situations in which measurement of dabigatran concentration in circulation should be performed using specific quantitative methods.

Aims: The aim of this study was to compare two quantitative methods for dabigatran concentration i.e. commercial chromogenic Innovance Dabigatran assay (DTI) and in house optimized coagulometric diluted thrombin time (dTT) test.

Methods: Dabigatran concentrations were determined in 38 patients using two methods on BCS XP coagulation analyzer (Siemens Healthineers, Germany): Innovance Dabigatran assay (Siemens Healthineers, Germany) with drug specific calibrators (Siemens Healthineers, Germany) and dTT test as an in house applied protocol with thrombin time reagent (BC Thrombin, Siemens Healthineers, Germany) calibrated with commercial dabigatran calibrators (Diagnostica Stago, France). Passing-Bablok regression and Bland-Altman methods were used for method comparison and Wilcoxon test was used to test differences between pairs of samples. The study was funded by the Croatian Science Foundation as part of the research project IP- 2016-06-8208.

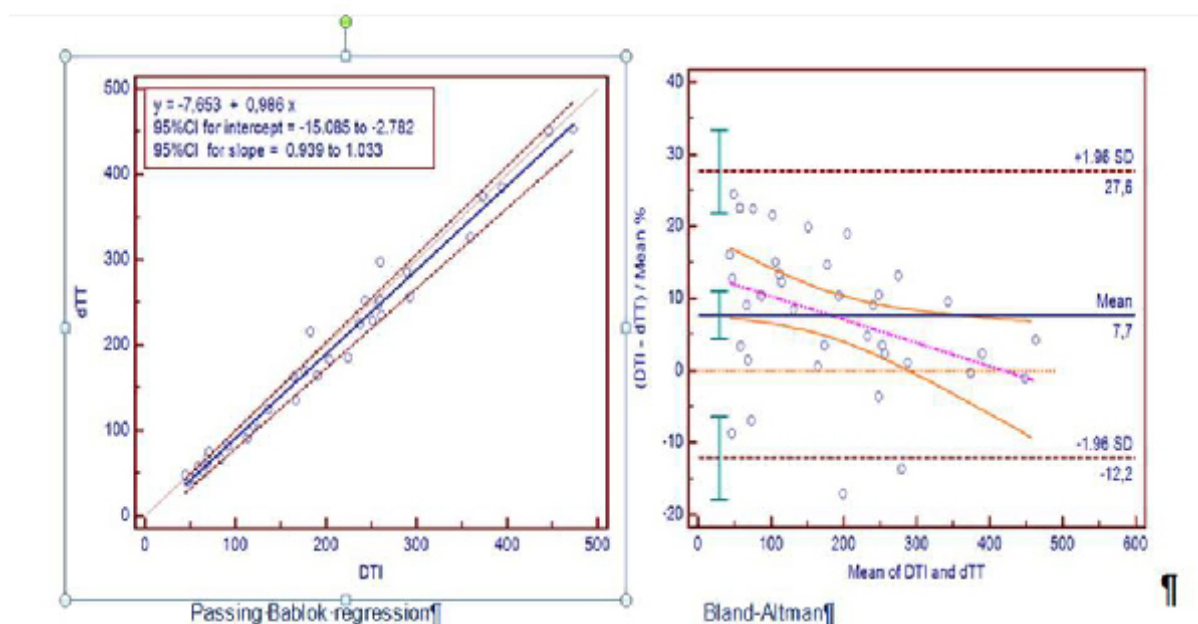
Results: Passing and Bablok regression analysis ($y = -7.653 (-15.085 \text{ to } -2.782) + 0.986x (0.939 \text{ to } 1.033)$) revealed constant difference between two methods (Figure 1). Bland-Altman analysis showed statistically significant mean difference of 7.7% ($P < 0.001$) between dTT assay compared with DTI. Further, comparison of the results for dabigatran concentrations using DTI and dTT assays showed statistically significant difference ($P = 0.0002$), but without clinically significant difference (Table 1).

Conclusions: Although two evaluated methods for quantitative determination of dabigatran concentration showed significant constant difference, that difference is not clinically significant, so both can be used interchangeably. However, commercial DTI assay could be recommended as a method of choice for quantitative measurement of dabigatran concentration, since it has much wider measurement range without sample dilution (up to 500 ng/mL) compared to dTT assay (up to 256 ng/mL), uses chromogenic principle and time of testing is much shorter.

Method	Dabigatran concentration (ng/mL) Median (95%CI); IQR

Diluted thrombin time (dTT) test	163.5 (95 – 228) 68 – 252
Innovance Dabigatran (DTI) test	171 (114 – 240) 70 – 259
P	0.0002

[Table 1. Results of dabigatran concentrations measured with two methods in real life patients treated with dabigatran (n= 38)]



[Figure 1. Passing-Bablok regression and Bland-Altman methods for comparison of two methods (dTT and DTI) for dabigatran concentration measurement.]

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