

INTER-ASSAY AGREEMENT TO DEFINE INADEQUATE CLOPIDOGREL RESPONSE

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Background: There is accumulating data showing a marked inter-individual response variability to clopidogrel and patients with inadequate response have an increased risk of adverse ischemic events. Several definitions of inadequate clopidogrel responsiveness have been used based on different assays and cut-off values of platelet reactivity. However, the degree of concordance between these definitions in identifying inadequate clopidogrel responders has been poorly explored.

Methods: Three platelet function assays were tested: light transmittance aggregometry (LTA), flow cytometric analysis of intraplatelet vasodilatorstimulated phosphoprotein (VASP), and the point-of-care VerifyNow P2Y12 system. Platelet function analyses were performed in patients during the maintenance phase of clopidogrel therapy. LTA was performed with 20 µmol/L ADP stimuli and reported as maximal percentage aggregation. The VASP and VerifyNow P2Y12 assays results were reported as P2Y12 reactivity index (PRI) and P2Y12 reaction units (PRU), respectively. Inadequate clopidogrel responders were defined with 3 definitions that have been previously associated with adverse outcomes: maximal ADP-induced platelet aggregation > 50%, PRI >50% and PRU > 240. Agreement analyses among these definitions were performed.

Results: A total of 151 blood samples were evaluated. Maximal ADP 20-induced aggregation > 50% showed a good degree of concordance both with PRI > 50% (kappa 0.77) and PRU > 240 (kappa 0.71). A total of 34/111 (30.6%) patients defined as good responders based on the VerifyNow P2Y12 assay reports were poor responders based on the LTA **Results:** There was a relatively lower degree of concordance between PRI > 50% and PRU > 240 (kappa 0.64). A total of 50/111 patients (45%) defined as good responders using the VerifyNow P2Y12 assay were poor responders based on the VASP results.

Conclusions: Although there is a good degree of agreement between the point-of-care VerifyNow P2Y12 system and more technically sophisticated techniques such as LTA and VASP in evaluating clopidogrel responsiveness, this may fail to identify a considerable number of inadequate responders defined according to these other assays.