PLATELET FUNCTION TESTING: LABORATORY TESTS AND QUALITY CONTROL

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Platelet function testing is essential to diagnose many common bleeding disorders and it has emerging roles in evaluating response to anti-platelet therapy [1]. The available tests for an assessment of platelet function range from point-of-care (predominantly to study drug effects) and other simplified assays, to more complex tests of aggregometry, granule contents and release. Presently, many clinical laboratories that assess platelet function by aggregometry do not offer additional tests to diagnose common congenital platelet disorders, such as secretion defects [1]. Recently, there have been a number of initiatives to standardize the use and performance of platelet function tests in various setting, including the standardization of more complex tests such as light transmission aggregometry (LTA) [1]. These initiatives reflect an increased recognition that like other assays, platelet function tests require standardization of their uses and application, methodologies, performance, interpretation and quality monitoring [1-5]. Initiatives by the Platelet Physiology Scientific Subcommittee (SSC) of the International Society of Thrombosis and Haemostasis (ISTH) addressed platelet function tests for the evaluation of aspirin resistance [2]. ISTH initiatives also provided recommendations on the appropriate use of the Platelet Function Analyzer, PFA-100® in the evaluation of platelet function disorders.[3] The Clinical and Laboratory Standards Institute (CLSI) released a proposed guideline on platelet function testing that covers the preanalytical, analytical and postanalytical components of platelet function testing, but not test interpretation.[5] This has provided clinical laboratories with updated views on acceptable practices for platelet function assessments. New ISTH guidelines are anticipated for the evaluation of light transmission platelet aggregometry (LTA). In general, the recommendations from these different initiatives have relied on expert opinion and concensus, where scientific evidence is lacking to guide practices for platelet function testing. Although many platelet function tests require rapid processing of fresh blood samples, a number of organizations have initiated proficiency testing exercises for platelet function disorders. Results from exercises that have used normal samples, spiked with or without inhibitors of platelet function, have generally shown wide scatter among participants. The North American Specialized Coagulation Laboratory Association (NASCOLA) has had some success with proficiency testing exercises, using real clinical cases, to evaluate the diagnosis of dense granule deficiency (by electron microscopy) and to interpret results of LTA assays [1]. These exercises have confirmed the need to external quality assurance for platelet function tests. Some important issues that clinical laboratories must consider for quality assurance of platelet function tests include: how normal (and abnormal) internal and external quality control samples are used for assay monitoring; which parameters to report for different assays; how to establish appropriate reference ranges for result interpretation [6]; how to test platelet function in individuals that have a reduced platelet count [6]; what abnormalities can be considered clinically significant; the ideal number and concentrations of agonists for aggregometry and release assays; and how to keep up with the changing literature (e.g. on using platelet function tests to assess responses to drugs) [1-3]. The presentation will include highlights from recent NASCOLA EQA exercises on platelet disorders and some unpublished data from a prospective study that illustrates the important diagnostic utility of LTA for diagnosing bleeding disorders and different models to optimize result interpretation.

References

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