WORKSHOP ON THE VALIDATION OF THE HEPARIN-INDUCED-PLATELET-ACTIVATION ASSAY (HIPA)

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Heparin-induced thrombocytopenia (HIT) is a limb- and life threatening immunological complication of heparin treatment in up to 3% of patients receiving heparin for more than five days. Based on clinical criteria it is often difficult to distinguish HIT from other reasons causing thrombocytopenia or new thrombotic events. Most assays for diagnosis of HIT are functional assays measuring platelet activation following incubation of platelets from healthy donors with patient serum and heparin. Nine laboratories, interested in laboratory diagnosis of HIT performed a workshop to validate the heparin-induced-platelet-activation assay (HIPA). Eight sera (5 sera of patients with clinically typical HIT, 2 sera of healthy blood donors and 1 serum of a patient with heparin-independent platelet activation) were investigated in this workshop. It was not given any clinical information about the sera. Two laboratories obtained correct results in 100% of samples, 4 laboratories in 88% of samples, 1 laboratory in 75% of samples, 1 laboratory in 63% of samples and 1 laboratory in 50% of samples. It was possible to demonstrate that the HIPA-test gives reproducable results in trained laboratories. Two thirds of the laboratories had none or only one discrepant result. However, if the assay is not well established it might lead to false negative as well as false positive results. We therefore strongly recommend to include standardized positive and negative controls in the assay. In conclusion, the HIPA test is a reproducable and valuable diagnostic tool for detection of antibodies associated with heparin-induced thrombocytopenia in the hand of specialized laboratories.

Workshop zur Validierung des Heparin-induzierten Plättchen-Aktivierungstestes (HIPA)