EVALUATION OF A NEW RAPID TEST FOR DETECTION OF ANTI PF4-HEPARIN ANTIBODIES IN HIT DIAGNOSIS

Transfusion Center, Legnano General Hospital, Legnano (Milan), Italy.
* Clinical Chemistry Laboratory, Lecco Hospital, Lecco, Italy

INTRODUCTION: The heparin-induced thrombocytopenia (HIT) is an adverse complication of heparin treatment with a platelet count fall higher than 30% and a high risk of thrombotic events. The diagnosis is made by laboratory tests and clinical criteria. There are many commercially available methods to detect antibodies against PF4/heparin complex, which are involved in the disease pathogenesis.

AIM: to evaluate a new rapid test, lateral-flow immunoassay (LFI-HIT) for the detection of IgG anti-PF4/polyanion complexes, distributed by Stago (STic EXPERT® HIT) and not requiring dedicated instrumentation.

MATERIALS AND METHODS

The LFI-HIT test requires only 10 min and the presence of antibodies against PF4/polyanion-complexes becomes visible as a coloured test line in T (test) position and in C (control) line respectively. The evaluation of positivity is visual and a cut off coloured line is provided in an enclosed Evaluation Card (fig.1-3).

We have compared two immunological test (new method LFI-HIT and ELISA ASSERACHROME® HPIA-IgG – Stago) with a functional test in flow cytometry according to Denys et al. (Thrombosis Research, 2008).

We have analyzed 33 patients from Transfusion Center, Legnano Hospital and Clinical Chemistry Laboratory, Lecco Hospital. All patients were on therapeutic or prophylactic doses of heparin for more than 5 days, their platelet count fell higher than 50% and had a 4T'score of 4 point or more. We also analyzed 15 patients (control group) that received therapeutic or prophylactic heparin treatment without a significant platelet count fall.

RESULTS:

11 samples were positive with LFI-HIT, 17 were positive with ELISA and 8 with functional assay respectively. In control group only 1 sample was positive with LFI-HIT, 2 with ELISA but all samples were negative with the functional assay.

The sensitivity and specificity of immunological assays (LFI-HIT and ELISA) was respectively 100% and 88% for LFI-HIT and 87.5% and 60% for ELISA, whereas the functional assay was considered as the ultimate gold standard.

The positive predictive value (PPV) was 73% for new test LFI-HIT and the negative predictive value (NPV) was 100%.

The positive predictive value (PPV) was 41% for ELISA and the negative predictive value (NPV) was 94%.

4 patients had thrombotic events confirmed by diagnostic imaging and had a positive functional assay.

RESULTS:

11 samples were positive with LFI-HIT, 17 were positive with ELISA and 8 with functional assay respectively. In control group only 1 sample was positive with LFI-HIT, 2 with ELISA but all samples were negative with the functional assay.

The sensitivity and specificity of immunological assays (LFI-HIT and ELISA) was respectively 100% and 88% for LFI-HIT and 87.5% and 60% for ELISA, whereas the functional assay was considered as the ultimate gold standard.

The positive predictive value (PPV) was 73% for new test LFI-HIT and the negative predictive value (NPV) was 100%.

The positive predictive value (PPV) was 41% for ELISA and the negative predictive value (NPV) was 94%.

4 patients had thrombotic events confirmed by diagnostic imaging and had a positive functional assay.

RESULTS:

11 samples were positive with LFI-HIT, 17 were positive with ELISA and 8 with functional assay respectively. In control group only 1 sample was positive with LFI-HIT, 2 with ELISA but all samples were negative with the functional assay.

The sensitivity and specificity of immunological assays (LFI-HIT and ELISA) was respectively 100% and 88% for LFI-HIT and 87.5% and 60% for ELISA, whereas the functional assay was considered as the ultimate gold standard.

The positive predictive value (PPV) was 73% for new test LFI-HIT and the negative predictive value (NPV) was 100%.

The positive predictive value (PPV) was 41% for ELISA and the negative predictive value (NPV) was 94%.

4 patients had thrombotic events confirmed by diagnostic imaging and had a positive functional assay.

RESULTS:

11 samples were positive with LFI-HIT, 17 were positive with ELISA and 8 with functional assay respectively. In control group only 1 sample was positive with LFI-HIT, 2 with ELISA but all samples were negative with the functional assay.

The sensitivity and specificity of immunological assays (LFI-HIT and ELISA) was respectively 100% and 88% for LFI-HIT and 87.5% and 60% for ELISA, whereas the functional assay was considered as the ultimate gold standard.

The positive predictive value (PPV) was 73% for new test LFI-HIT and the negative predictive value (NPV) was 100%.

The positive predictive value (PPV) was 41% for ELISA and the negative predictive value (NPV) was 94%.

4 patients had thrombotic events confirmed by diagnostic imaging and had a positive functional assay.

CONCLUSION:
The new LFI-HIT may be a suitable tool for the rapid exclusion of HIT without a dedicated instrumentation, with good sensitivity and specificity. Test line can be sometimes weak, which may cause sometimes an uncertain interpretation in non-expert operators, also because the cut off coloured line is also very pale. The ELISA test, that was considered the immunological reference test, is confirmed to be very sensitive but less specific. The functional flow cytometric assay is manageable and may serve as ultimate confirmatory test.