SSC 2017 Abstract Submission

A STANDARDIZED FUNCTIONAL ASSAY FOR ROUTINE RELIABLE HIT DIAGNOSIS: A POTENTIAL ALTERNATIVE TO THE SEROTONIN RELEASE ASSAY

Brigitte Tardy[1,2], Aurelie Montmartin[2], Michele Piot[1], Fatima Alkhalfioui[3], Hubert Maes[3], Bernard Tardy [1,2] and GFHT-HIT Study Group

[1] Université de Lyon, 42023 Saint-Etienne, France, Inserm U1059 SAINBIOSE, SAINT-ETIENNE, France

[2]INSERM CIC 1408, FCRIN-INNOVTE, CHU Saint-Etienne, SAINT-ETIENNE, France.

[3]Emosis, 11 rue de l'industrie, 67400 Illkirch-Graffenstaden, France.

Background: Reliable diagnosis of HIT remains a major clinical concern. Screening tests are highly sensitive but lack specificity, while confirmatory tests lack standardization and are not widely available.

Aims: Our objective was to evaluate the performance of a novel functional flow cytometric assay (FCA) vs. clinical expert opinion and the serotonin release assay (SRA).

Methods: Plasmas of 228 patients included (after signing the informed consent) in a multicenter study "HIT Score" (NCT00748839) were randomly selected: 106 with a positive HIT diagnosis and 122 with a negative HIT diagnosis, as defined by the expert' opinion adjudication. The experts expressing the opinions used in this study were blinded to SRA results. SRA and FCA were centrally performed. Here, we present a modified FCA based on a method previously described by B.Tardy-Poncet during 24th congress ISTH (2015), with a time to results of about 90 min, simplified reagent handling, and a standardized procedure for analyzing and interpreting the results.

Results: The FCA performed as well as the gold standard SRA when both tests were compared to clinical expert opinion. The sensitivity and specificity of the FCA vs. expert opinion were respectively 83% (95% CI: 75-90) and 97% (95% CI: 93-100). The sensitivity and specificity of the SRA vs. expert opinion were respectively 88% (95% CI: 81-94) and 97% (95% CI: 93-100). The sensitivity and specificity of the FCA vs. the SRA were respectively 85% (95% CI: 78-93) and 94 % (95% CI: 89-98).

Conclusion: This new FCA gave results similar to those of the SRA for HIT diagnosis, without requiring either radioactivity, or profound expertise in flow cytometry. Based on these results, the new FCA may be conveniently used in routine practice as a reliable test for HIT diagnosis.

Abstract: A-859-0083-02425

+33 (0)3 66 32 63 26
www.emosis-diagnostics.com
11 rue de l'industrie
Illkirch-Graffenstaden (France)