Analytical evaluation of the Aspect-Plus ST2 test, a lateral flow immunoassay: is the clinical cut-off still acceptable?

A. Mewis¹, T. Pilate¹, P. Dendale²

(1) Jessa Hospital, Clinical Laboratory, Stadsomvaart 11, 3500 Hasselt, Belgium
(2) Jessa Hospital, Cardiology / Heart Centre Stadsomvaart 11, 3500 Hasselt, Belgium

Purpose:
Soluble ST2 (sST2) measurement has proven to be an additive prognostic marker to clinical variables and other well-established cardiac markers in patients with acute and chronic heart failure. Furthermore serial measurement of sST2 in heart failure patients can be useful for monitoring response to therapy. There are several commercially available enzyme-linked immunosorbent assays (ELISA) for measurement of sST2 in human plasma. Recently a more easily applicable and faster method has been developed: the Aspect-Plus ST2 lateral flow immunoassay. We performed an analytical validation of the Aspect-Plus ST2 test evaluating the reproducibility, linearity and correlation with an ELISA method.

Methods:
We evaluated the reproducibility of the Aspect-Plus ST2 test using a low and high level of external quality controls. We then assessed the linearity by conducting a dilution series with low- and high-concentration patient sample pools. Finally we performed a correlation study with the Presage ST2 ELISA assay (Critical Diagnostics, San Diego, United States) comparing 54 samples from 22 cardiac patients with dyspnea.

Results:
Within-run coefficients of variation of the Aspect-Plus ST2 test were 11.9% for the low control level and 10.9% for the high control level. The assay was linear across its measurement range using six different analyte concentrations between 20.4 ng/mL and 212.3 ng/mL. Passing and Bablok regression analysis showed a small constant and proportional bias between the Presage ST2 ELISA assay (variable x) and the Aspect-Plus ST2 test (variable y) with an intercept of -12.06 ng/mL (95% CI: -19.25 to -7.16) and a slope of 1.11 (95% CI: 1.02 to 1.23). Spearman’s coefficient of rank correlation was 0.94. At the proposed cut-off value of 35 ng/mL there was a negative bias of 8 ng/mL. Accordingly a shift in the cut-off value to 27 ng/mL could be advisable if the Aspect-Plus ST2 test were to be implemented.

Conclusions:
The Aspect-Plus ST2 test was demonstrated to be a reliable and easily applicable alternative to current ELISA assays for the measurement of sST2, an attractive new marker for heart failure.