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PROCALCITONIN (PCT). COMPARISON OF TWO ASSAYS FOR PCT SERUM MEASUREMENT: IMMUNOCHROMATOGRAPHIC POINT-OF -CARE TESTING (POCT) VERSUS CONVENTIONAL IMMUNOASSAY

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Background: PCT is a highly sensitive and specific biomarker of sepsis. Its measurement is used in the differential diagnosis of infections, severe bacterial infections monitoring and decision-making on the need, duration and effectiveness of antibiotic therapy.

The aim of this study is to compare a point of care testing (POCT) assay for PCT quantification with a conventional system located in the laboratory, taken as a reference method to evaluate the diagnostic capability of the new assay.

Methods: PCT measurements were performed in 58 serum samples extracted daily from 9 severe burn patients. Samples were analysed in parallel with both assays. The reagents used for each method were:

-Elecsys 2010 autoanalyzer (Roche Diagnostics, Germany), based on an electrochemiluminescence assay (ECLIA) with Elecsys BRAHMS PCT reagents.
-Semiautomatic POCT Reader Analyzer e-Diagnosis (Tecil), based on a rapid test gold immunochromatography colloidal assay (GICA).

Two batches of e-Diagnostics reagents were used. The correlation of both techniques was evaluated applying the Passing-Bablok test and to compare differences between the two methods a Bland-Altmann graphic was performed. ROC curves were also made to find out the e-Diagnosis method discrimination ability for standard cut-offs previously set for decision-making. Statistical analyses were conducted using software from MedCalc v.14.8.1.

Results: Data obtained were separated in two groups according to the cut-off points: 0.5 ng/mL for antibiotic use and 2ng/mL for sepsis diagnosis. Taking the ECLIA method as reference, the results obtained for the POCT technique were:

-Cut-off 0.5 ng/mL:
False positive: 0; false negative: 0. Sensitivity: 100%. Specificity: 100%. Proof accuracy: 100%
-Cut-off 2 ng/mL:
False positive: 16; false negative: 0. Sensitivity: 100%. Specificity: 63.3%. Proof accuracy: 81.65%

The agreement and correlation for the 58 samples analysed was:

-Agreement coefficient: 0.7816
-Confidence Interval (95%): 0.6683-0.8595
-Pearson ρ: 0.8359

Conclusions: The POCT Reader e-Diagnosis analyzer has demonstrated an excellent diagnosis capability (sensitivity = 100%) as well as a notable discrimination ability for bacterial infection (specificity = 100%), which may support an effective choice of the antibiotic therapy.

The POCT Reader e-Diagnosis analyzer allows a comfortable and safe measurement of PCT with results available to physicians in 15 minutes at the point of patient care.