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PCR/ESI-MS vs. SeptiFast vs. blood culture in blood stream infections

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Background: Blood culture (BC) is considered the gold standard of the microbiological sepsis diagnostic. However, this method lacks sensitivity, especially for slow-growing or fastidious microorganisms, and there is often a substantial time delay. During recent years, molecular technologies for detection of microorganisms from whole blood have been made available. The aim of this observational study was to evaluate the accuracy of the novel IRIDICA BAC BSI assay (Abbott) based on PCR combined with electrospray ionization mass spectrometry (PCR/ESI-MS) in comparison to SeptiFast (SF; Roche), which is a well-established molecular test, and BC in patients with suspected blood stream infections (BSI) from the emergency department and internal medicine wards.

Material/methods: Patients fulfilling at least two SIRS criteria were prospectively included. BCs and EDTA whole blood used for BAC BSI and SF were from the same blood draw. BAC BSI and SF were compared to BC and all three tests to a constructed reference complying with an adapted BSI diagnosis according to the ECDC criteria of hospital acquired infections established for point prevalence studies. Thus, the constructed reference was based on clinical data, radiological findings as well as detection of bacteraemia/fungaemia by at least one of the tests upon exclusion of cases of contamination.

Results: One hundred ninety three episodes with valid test results have been analysed. The overall positivity rate was 35.2% and the overall concordance between the three tests was 75.3%, whereas the highest concordance of 88.5% was observed between the two molecular tests. The sensitivity, specificity, PPV and NPV in comparison to BC were 77.8%, 83.0%, 61.4%, 91.5% for BAC BSI and 71.1%, 91.5%, 74.4%, 90.1% for SF. The respective values of the three tests in comparison to the constructed reference are shown in Table 1. BAC-BSI presented with 0.899 ROC-AUC, whereas BC and SF showed statistically significantly lower ROC-AUCs (0.795, p=0.017; 0.792, p=0.018; Hanley & McNeil test). In six cases, slow- or non-growing microorganisms e.g. *Legionella pneumophila*, *Rickettsia typhi*, *Mycoplasma pneumoniae*, *Nocardia* spp. have been identified solely by BAC BSI.

Conclusions: Both molecular techniques may represent a valuable add on to BC-based BSI diagnosis. PCR/ESI-MS, in particular, was shown to improve the diagnostic capacity for BSI with rare and fastidious pathogens.

Table 1. Test performance characteristics in comparison to the constructed reference

	BC	**SF**	**BAC BSI**
Sensitivity	66.2%	63.2%	83.8%
Specificity	92.8%	95.2%	96.0%
PPV	83.3%	87.8%	91.9%
NPV	83.5%	82.6%	91.6%