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Results of a prospective randomized multi-centre trial to assess the impact of laboratory-based rapid diagnosis using MALDI-TOF technology on outcomes of patients with bloodstream infection (RAPIDO study)

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Background: Blood stream infections (BSI) remain a major public health and infection problem, with one month mortality rates of approximately 20%. Increasing the speed of diagnosis of BSI may lead to improved patient outcomes - related to earlier use of appropriate chemotherapy. MALDI-TOF technology using direct extraction from blood cultures offers an opportunity to reduce the time to isolate identification compared to standard methods, and therefore may impact on outcomes.

Material/methods: A multi-centre randomised controlled trial was conducted comparing rapid (MALDI-TOF) and conventional diagnosis. Patients were randomised in a 1:1 ratio once a positive blood culture was identified, but prior to assessment of eligibility or seeking consent. The primary outcome measure was all cause 28 day mortality. Secondary endpoints were: seven day mortality, time to resolution of fever, length of hospital stay, antibiotic consumption, acquisition of *C.difficile* infection, time to provision of identification information and time to de-escalation of broad-spectrum antibiotic therapy.

Results: Of 14,298 patients with positive blood cultures, 8628 were randomised, 4312 to MALDI-TOF and 4316 to conventional. After exclusions due to either ineligibility or patients declining consent, 2740 were included in the MALDI-TOF group and 2810 in the conventional group. 28 day survival was 81.5% (2232/2740) in the MALDI-TOF group and 82.3% (2313/2810) in the conventional group (HR 1.05, 95% CI 0.93-1.19, p=0.42). There were no differences in the secondary endpoints,

other than the median time to provision of identification information was reduced in the MALDI-TOF group (35.6 hours vs 54.5 hours, p<0.0001). Sub-group analyses based on clinical significance of the isolate indicated no differences between the groups. Sub-group analyses by the pathogen causing BSI indicated borderline improved survival (p-value for interaction 0.071) in the MALDI-TOF group for *P.aeruginosa* (n=130); HR 0.61, 95% CI 0.33-1.13.

Conclusions: Use of MALDI-TOF to identify bacteria in blood cultures decreased the time of pathogen identification but did not impact on clinical outcomes, with the possible exception of patients with *P.aeruginosa* BSI.

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