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117. Adjunctive Daptomycin in the Treatment of staphylococcus Aureus Bacteremia

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DASH

Session: O-23. Hot Clinical Trials

Background: Bloodstream infections (BSI) caused by methicillin-susceptible *Staphylococcus aureus* (MSSA) are associated with significant morbidity and mortality. The objective of our study was to determine whether daptomycin given in combination with an anti-staphylococcal beta-lactam improved outcomes in MSSA BSI.

Methods: A randomized, double blind, placebo-controlled trial was performed at two academic hospitals in Montreal, Canada. Patients ≥ 18 years of age with MSSA BSI receiving either cefazolin or cloxacillin monotherapy were considered for inclusion. In addition to the standard of care treatment, participants received a 5-day course of adjunctive daptomycin or placebo. The primary outcome was the duration of MSSA BSI in days.

Results: Of 318 participants screened, 115 were enrolled and 104 were included in the intention to treat analysis (median age 67 years; 34.5% female). The median duration of bacteremia was 2.04 days among patients who received daptomycin versus 1.65 days in those who received placebo (absolute difference 0.39 days, p=0.40). A modified intention to treat analysis involving participants who remained bacteremic at the time of enrollment found a median duration of bacteremia of 3.06 days among patients who received daptomycin versus 3.0 days in those who received placebo (absolute difference 0.06 days, p=0.77). Ninety-day mortality in the daptomycin arm was 18.9% vs. 17.7% in the placebo arm (p=1.0). There were no significant differences in the proportion of patients who developed renal failure, hepatotoxicity, or rhabdomyolysis between groups.

Conclusion: Among patients with MSSA BSI, the administration of adjunctive daptomycin therapy to standard of care treatment did not shorten the duration of bacteremia.

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118. Eliminating Blood Culture Contamination with an Initial-specimen Diversion Device

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Background: Blood samples obtained via traditional venipuncture can become contaminated by superficial and deeply embedded skin flora. We evaluated the hospital-wide use of an initial-specimen diversion device (ISDD) designed to shunt these microorganisms away from the culture bottle to reduce blood culture contamination (BCC) and sequelae: false-positive central line-associated bloodstream infections (CLABSIs), repeat blood culture draws, inappropriate antibiotic usage, increased patient length-of-stay and misdiagnosis. The study aimed to show the proportion of blood cultures containing contaminants drawn by phlebotomy staff using the ISDD versus those drawn using traditional methods. Nursing staff continued to use traditional methods to draw blood cultures in the emergency department (ED) and from inpatients.

Methods: Over a four-month trial at Stanford Health Care (SHC), 4,462 blood cultures were drawn by phlebotomy staff using the ISDD (Steripath Gen2, Magnolia Medical Technologies) in the ED and from inpatients; 922 blood cultures were obtained by phlebotomy staff using standard methods. Additionally, 1,413 blood cultures were drawn by nursing staff using standard methods. The number of matched sets (2 bottles [aerobic/anaerobic] plus 2 bottles [aerobic/anaerobic], with total volume 40 ml) obtained through traditional methods and by the ISDD were recorded. Contaminants were defined by the National Healthcare Safety Network (NHSN). In addition, sets in which 1 out of 4 bottles contained vancomycin-resistant *Enterococcus* (VRE) or *Candida* sp. were also recorded, even though these are not considered contaminants by the NHSN.

Results: Of 4,462 blood cultures obtained using the ISDD there were zero contaminants found (BCC rate 0%) versus 29 contaminated sets using traditional methods (BCC rate 3.15%). Twenty-eight contaminants were observed from nursing staff blood culture draws (BCC rate 1.98%). Zero false-positive CLABSIs were associated with use of the ISDD for the trial period. No matched sets containing 1 of 4 bottles with VRE or *Candida* sp. were observed.

Table: Stanford Health Care blood culture collection methods and contamination events (March 15, 2019 - July 21, 2019)

	Matched Sets	Contaminated Sets	Contamination Rate	False-Positive CLABSIs
Standard Method (Nursing Staff)	1,413	28	1.98%	0
Standard Method (Phlebotomy)	922	29	3.15%	1
Standard Method (Combined)	2,335	57	2.44%	1
ISDD (Phlebotomy)	4,462	0	0.00%	0

Conclusion: The trial results encourage adoption of the ISDD as standard practice for blood culture at SHC.

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119. A Respiratory Syncytial Virus Prefusion F Protein (RSVPreF3) Candidate Vaccine Administered in Older Adults in a Phase I/II Randomized Clinical Trial Is Well Tolerated

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Background: RSV is a common cause of respiratory acute illness in older adults (OA). We evaluated safety and reactogenicity of RSVPreF3 candidate vaccine in young adults (YA) and OA.

Methods: In this phase I/II, placebo-controlled, multi-country trial (NCT03814590), YA aged 18–40 years were randomized 1:1:1:1 and received 2 doses of Low-, Medium- or High-dose of RSVPreF3 non-adjuvanted vaccine, or placebo, 2 months apart. Following favorable safety evaluation, a staggered enrolment with 2 steps followed in OA aged 60–80 years, who were randomized 1:1:1:1:1:1:1:1:1 to receive 1 of the 9 RSV vaccine formulations containing Low-, Medium- or High-dose of RSVPreF3 non-adjuvanted or adjuvanted with $AS01_E$ or $AS01_B$, or placebo (same schedule). Safety/reactogenicity up to 1 month post-dose 1 are reported here.

Results: Exposed set was comprised of 48 YA and 1005 OA. Within 7 days post-dose 1, any solicited/unsolicited adverse event (AE) ranged from 58.3% to 83.3% across YA vaccinees (placebo YA: 58.3%) and from 29.9% to 84.2% across OA vaccinees (placebo OA: 33.7%) (Fig 1). Pain was the most common solicited local AE, being reported in ≤ 58.3% of YA (placebo YA: 0.0%) and at higher rates in the adjuvanted groups (≤ 75.7%) vs non-adjuvanted groups of OA (≤ 14.1%) and placebo OA (4.1%) (Fig 2A). Of solicited general AEs, fatigue (YA: ≤ 41.7% in vaccinees vs 50.0% in placebo; OA: ≤ 48.5% in vaccinees vs 16.3% in placebo) and headache (YA: ≤ 33.3% in vaccinees vs 16.7% in placebo; OA: ≤ 27.7% in vaccinees vs 8.2% in placebo) were most commonly reported (Fig 2B), while fever ≥ 38.0 °C was observed in ≤ 3.0% of OA vaccinees (placebo OA: 0.0%). Grade 3 solicited local and general AEs were observed in OA only, with erythema (≤ 4.9% in vaccinees vs 0.0% in placebo) and fatigue (≤ 2.0% in vaccinees vs 1.0% in placebo) being most common (Fig 2). No serious AEs (SAEs) were reported in YA. A number of 11 OA reported a SAE within 1 month post-dose 1, but none was fatal or assessed as vaccine-related. No clinically significant abnormalities occurred in hematological/biochemical parameters in any group.

Figure 1. Percentage of participants presenting at least one type of solicited/unsolicited adverse event (AE) within 7 days post-dose 1