Meropenem-Vaborbactam (VABOMERE) vs. Best Available Therapy for Carbapenem-Resistant Entero bacteriaeae Infections in TANGO II: Primary Outcomes by Site of Infection

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Abstract

Introduction: CRE infection has become an important public health concern because of limited treatment options. Carbapenem reliance is common and treatment options are limited. Although vancomycin-based regimens have shown some success in CRE infections, the antibiotic treatment landscape is changing.

Methods: TANGO II is a Phase 3, multi-center, randomized, open-label comparative trial designed to evaluate efficacy and safety of M-V vs. BAT in selected infections due to confirmed CRE pathogens. The primary endpoint was composite clinical cure and microbial eradication (MME) at 28 d post-treatment. TANGO II endpoints differed by infection type based on prevailing FDA guideline for CRE infections (i.e. bacteremia, complicated urinary tract infection, or complicated intra-abdominal infection). M-V consisted of meropenem-vaborbactam (1/1) given IV Q2h over 3 h: 54 mg/kg/day of meropenem β-lactam and 70 mg/kg/day of vaborbactam β-lactamase inhibitor combination as monotherapy or in combination with other agents. BAT included mono-combination therapy with polymyxins, carbapenems, aminoglycosides, tigecycline; or ceftazidime-avibactam alone.

Results: 44/280 (15.7%) of 280 patients enrolled were classified as mCRE-MITT with 150 in the M-V group and 130 in the BAT group: 28/150 (18.7%) vs. 16/130 (12.3%) for combined endpoints of clinical cure and microbial eradication (p=0.24), respectively. M-V/Ampicillin vs. BAT showed a statistically significant improvement over BAT; 6/12 (50%) vs. 4/12 (33.3%) for clinical cure (p=0.5), respectively; and 1/12 (8.3%) vs. 0/12 (0%) for MME (p=0.5), respectively, at test of cure. Discontinuation due to adverse events (AEs) was higher in the BAT group: 9/12 (75%) vs. 4/12 (33.3%) for M-V/Ampicillin vs. BAT, respectively (p=0.07).

Conclusions: M-V/Ampicillin showed improved clinical cure vs. BAT in mCRE-MITT for complicated urinary tract infections. These findings are consistent with those of the TANGO I trial and the current ARMISTICE trial. M-V is a potent new option for treatment of CRE in hospitalized patients and expanded the therapeutic options for the treatment of select CRE infections.

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References


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