Presentation Type:
Poster Presentation - Top Poster Award
Subject Category: *C. difficile*

Efficacy and Safety of Investigational Microbiome Drug SER-109 for Treatment of Recurrent *Clostridioides difficile* Infection

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Background: Antibiotics targeted against *Clostridioides difficile* bacteria are necessary, but insufficient, to achieve a durable clinical response because they have no effect on *C. difficile* spores that germinate within a disrupted microbiome. ECOSPOR-III evaluated SER-109, an investigational, biologically derived microbiome therapeutic of purified Firmicute spores for treatment of rCDI. Herein, we present the interim analysis in the ITT population at 8 and 12 weeks. **Methods:** Adults ≥18 years with rCDI (≥3 episodes in 12 months) were screened at 75 US and CAN sites. CDI was defined as ≥3 unformed stools per day for <48 hours with a positive C. difficile assay. After completion of 10–21 days of vancomycin or fidaxomicin, adults with symptom resolution were randomized 1:1 to SER-109 (4 capsules × 3 days) or matching placebo and stratified by age (≥ or <65 years) and antibiotic received. Primary objectives were safety and efficacy at 8 weeks. Primary efficacy endpoint was rCDI (recurrent toxin+ diarrhea requiring treatment); secondary endpoints included efficacy at 12 weeks after dosing. **Results:** Overall, 287 participants were screened and 182 were randomized (59.9% female; mean age, 65.5 years). The most common reason for screen failure was a negative *C. difficile* toxin assay. A significantly lower proportion of SER-109 participants had rCDI after dosing compared to placebo at week 8 (11.1% vs 41.3%, respectively; relative risk [RR], 0.27; 95% confidence interval [CI], 0.15–0.51; p-value <0.001). Efficacy rates were significantly higher with SER-109 vs placebo in both stratified age groups (Figure 1). SER-109 was well-tolerated with a safety profile similar to placebo. The most common treatment-emergent adverse events (TEAEs) were gastrointestinal and were mainly mild to moderate. No serious TEAEs, infections, deaths, or drug discontinuations were deemed related to study drug. **Conclusions:** SER-109, an oral live microbiome therapeutic, achieved high rates of sustained clinical response with a favorable safety profile. By enriching for Firmicute spores, SER-109 achieves high efficacy while mitigating risk of transmitting infectious agents, beyond donor screening alone. SER-109 represents a major paradigm shift in the clinical management of patients with recurrent CDI. Clinicaltrials.gov Identifier NCT03183128. These data were previously presented as a late breaker at American College of Gastroenterology 2020.

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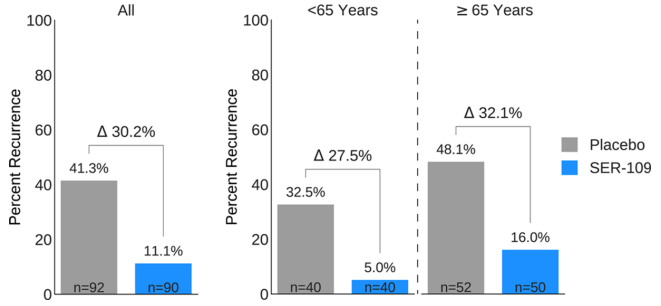

Figure 1.

Presentation Type:
Poster Presentation - Top Poster Award
Subject Category: CAUTI

Impact of Female External Urinary Catheter on Indwelling Catheter Use and Catheter-Associated Urinary Tract Infection Rates

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Background: Catheter-associated urinary tract infections (CED: TIs) are one of the most prevalent healthcare-associated infections. They can lead to bacteremia and increased length of stay, healthcare costs, and mortality. Indwelling urinary catheter (IUC) prevention bundles, nurse-driven removal protocols, and the use of external catheters can help reduce CED: TIs. However, female external urinary catheters (FEUCs) have only recently become widely available. FEUCs were introduced at our institution in July 2017. The purpose of this study was to evaluate the impact of FEUC on IUC utilization ratio and overall CED: TI rate in an 844-bed teaching hospital in southeastern Michigan. **Methods:** We retrospectively evaluated the utilization ratio of FEUCs (female FEUC days per patient days ×1,000) and female IUCs (IUC days per patient days ×1,000), and labia hospital-acquired pressure injury (HAPI) rate due to FEUC from July 2017 through June 2019. We compared the overall (male and female) CED: TI rate per 1,000 IUC days in the preintervention period (January 2016 to June 2017) to the postintervention period (July 2017 to June 2019). **Results:** In total, 4,013 FEUCs were placed during the intervention period. The utilization ratio of FEUC increased by 59% and the utilization ratio of female IUC decreased by 13% over the course of the 2 years. Only 1 HAPI was reported during the observation period at a rate of 0.025% (1 of 4,013). The overall CED: TI rate decreased from 1.60 to 1.40 (P = .372). **Conclusion:** Introduction of a FEUC was associated with a decrease in the IUC utilization ratio in female patients with minimal adverse events; however, there was no significant difference in the overall CED: TI rate.

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