Results. 1289 ITT patients were randomized (LEE n = 646; MOX, n = 643). Most patients in both groups achieved ECR at Day 3, with further increases through Day 7 and sustained efficacy through LFU (Fig 1). In mITT patients, IACR success rates at EOT/TOC/LFU were 87.1/85.0/83.2% with LEE and 88.1/87.1/86.1% with MOX; results were consistent in CE patients. The proportions of ITT patients with resolution of all baseline signs/symptoms of CABP increased similarly by visit in both treatment groups (Fig 2). Most patients did not achieve complete sign/symptom resolution until TOC, with fever generally being the first and cough the last to resolve. There was no apparent relationship between ECR and age, gender, renal status, SIRS, PORT, prior antibiotic use, baseline pathogens, typical/atypical pathogens, or mono/polymicrobial pathogens. The high percentage of patients at LFU with baseline symptom resolution suggests that symptom resolution was sustained.

Conclusion. In this pooled analysis, efficacy results were similar by visit in the LEE and MOX groups, with high ECR rates maintained through LFU. LEE will provide a potential new effective systemic monotherapy alternative to fluoroquinolones for the empiric treatment of CABP.

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2235. Fecal Biomarkers for Clostridioides difficile Infection in Cancer Patients Adilene Olvera, MPH MLS (ASCP)1; Eduardo Yepes Guevara, MD;2 Kevin W. Garey, PharmD, MS, FASHP3; Ryan J. Dillon, MSc;4 Pablo C. Olkhuysen, MD, FACR, FIDSA5; The University of Texas MD Anderson Cancer Center, Houston, Texas;6 University of Houston College of Pharmacy, Houston, Texas;7 Merck & Co., Inc., Kenilworth, New Jersey

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Background. The diagnosis of C. difficile infection (CDI) relies on using a nucleic acid amplification test (NAAT) followed by confirmatory toxin enzyme immunoassay (EIA). This study examined the utility of fecal biomarkers and C. difficile bacterial quantity (BQ) in differentiating patients with true infection (NAAT+/EIA+) from patients with colonization (NAAT+/EIA-). The enterotoxigenic (ET) ribotypes in the context of C. difficile ribotypes.

Methods. We studied 136 patients with diarrhea and CDI identified by NAAT in stools for which a confirmatory toxin A, B, EIA was performed. Calf IL-8, IL-1β, calprotectin, and lactoferrin were studied by ELISA.

Results. Stools were EIA+ in 36/136 (26%) of the cohort. Although ST patients had a higher Charlson co-morbidity index when compared with the other two groups (P < 0.002), demographic characteristics and symptoms at the time of presentation were similar between groups regardless of CDI status. Most common ribotypes identified included FI60 and FI04-020. Ribotype distribution differed according to oncologic diagnosis as determined by the Shannon diversity index. There were fewer distinct C. difficile ribotypes in the SCT (n = 8) vs. ST (n = 15) and H (n = 15) groups (P < 0.001 and P < 0.002, respectively). BQ were higher in EIA+ than EIA− across all strata (log of BQ/mg 2.38 ± 1.49 vs. 0.92 ± 1.28, P < 0.001). Similarly, higher levels of fecal IL-8 (1.72 ± 1.9 vs. 0.83 ± 1.6 ng/mL), IL-1β (3.74 ± 13.7 vs. 1.21 ± 4.6) and calprotectin (14.9 ± 27 vs. 6.1 ± 6.8 mg/mL) levels were seen in EIA+ patients. While IL-8, IL-1β, and calprotectin were increased in EIA+ ST, IL-8 was also significantly increased in CDI in the SCT group. A sensitivity analysis using ROC curves, revealed that BQ resulted in a greater area under the curve than fecal markers of inflammation (A = 0.77, P < 0.001, 95% CI [0.67–0.86]).

Conclusion. In this study in cancer and immunocompromised patients, C. difficile bacterial burden regardless of infecting ribotype and fecal cytokines showed to be a helpful assay in distinguishing true CDI from colonization.

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2236. Stool-Derived Inflammatory Mediators Serve as Biomarkers of Severity in Clostridium difficile Infection
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