Abstract

Background

The BioFire FilmArrary GI Panel Assay is a highly sensitive PCR-based diagnostic test capable of detecting 22 different gastrointestinal pathogens from stool specimens. The predominant pathogens associated with hospital-acquired gastroenteritis are *Clostridioides difficile* and Norovirus, both of which can be assayed individually with PCR-based tests performed at UCHealth. Previous studies favor a cost-saving '3-day rule,' that restricts ordering culture-based stool testing on inpatient adults following the 3rd day of hospitalization. However, the previous studies performed a limited analysis of pathogens using predominantly culture-based assays. Furthermore certain patient groups may be at high risk for developing nosocomial diarrhea with less common organisms, which may go undetected if the 3-day rule were enforced for the GI panel assay. Thus there is a need to validate whether the 3-day rule is appropriate for restricting the use of the GI panel assay for the evaluation of nosocomial diarrhea.

Hypothesis

The aim of this study was to define the appropriate use of the GI panel assay for the evaluation of hospital-acquired diarrhea in adult patients. We hypothesized there would be a decreasing yield in the detection of gastrointestinal pathogens (excluding C. difficile and Norovirus) by the FilmArray GI Panel assay when testing hospitalized adult patients more than 3 days following hospital admission, compared to those tested within the first 3 days of hospitalization or those tested as outpatients.

Methods

This is a two-part study. Part one is a retrospective study of the yield of the FilmArray GI Panel in detecting GI pathogens from outpatient and inpatient adults greater than or equal to age 18 tested between June 2016 and June 2017 at the UCHealth Molecular Laboratory. Part two is an observational study intended to analyze risk factors associated with a positive GI PCR assay in those inpatients tested more than 3 days following hospitalization. Clinical data was collected on 118 cases (positive GI PCR > 3d) and randomly-selected 118 controls (negative GI PCR > 3d). We used Fisher's exact test to compare proportions of positive and negative tests among inpatient and outpatient patients, patients who were or were not immunocompromised, and patients with or without medical co-morbidities.

Results

We found that the types of pathogens detected and the positive yield of the GI panel assay was similar between outpatients (689/1958 assays, 35.2% positive) and inpatients tested during the first three days of hospitalization (538/1601 assays, 33.6% positive). In contrast, of the 586 tests that were performed on adults hospitalized for greater than 3 days, 486 were negative for all pathogens, and 125 analytes were positive from 118 tests (due to tests positive for more than one enteropathogen). Of the 118 positive tests performed, 85 were positive for C. difficile and 7 were positive for Norovirus, leaving only 26 of the 586 assays (4.4%) positive for pathogens other than C. difficile or Norovirus.

Conclusions

Based on the results of our retrospective study, the University of Colorado Hospital implemented restrictions on the use of the BioFire FilmArray GI PCR panel in 2018, that conformed to a '3-day rule,' which restricts ordering of GI PCR tests on inpatient adults following the 3rd day of hospitalization. A subsequent observational study to determine the clinical significance of the GI PCR findings is presently underway.