Department of Medicine

Retrospective Review of BioFires FilmArray Gastrointestinal Panels Detection of Multiple Pathogens in Adults Patients.

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Retrospective Review of BioFire's FilmArray Gastrointestinal Panel's Detection of Multiple Pathogens in Adult Patients: A Hypothesis Generating Study

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INTRODUCTION

- Pathogens are only identified in 1.5 to 5.6 percent of stool cultures for acute diarrhea[1]
- Multiplex stool PCR is an accurate diagnostic tool to detect multiple intestinal pathogens in a single sample with rapid turnaround and high sensitivity/specificity
- BioFire's FilmArray Gastrointestinal Panel is an FDA approved syndromic multiplex PCR assay which evaluates stool for 22 common bacterial, viral and parasitic targets
  - *Campylobacter spp., Clostridium difficile toxins, Plesiomonas shigelloides, Salmonella, Yersinia enerocolitica, Vibrio spp., Diarrheagenic E. coli/Shigella, Enteroaggregative E. coli, Enteropathogenic E. coli, Enterotoxigenic E. coli, Shiga-like toxin-producing E. coli, Shigella/Enteroinvasive E. coli, Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia,* Adenovirus, Astrovirus, Norovirus, Rotavirus A, and Sapovirus
- Major advantages include rapid turnaround time, identification of coinfections, high negative predictive value which decreases the use of infection control precautions, and high sensitivity and specificity[2]
- The test's sensitivity ranges between 94.5%-100% and specificity ranges between 97.1-100%[3]
- In studies using multiplex assays there has been a notable increase in the detection of multiple pathogens within one stool sample. One study found as many as 31.5% of stool samples that were positive had multiple pathogens detected; another study found that 18% of immunosuppressed patients with positive stool test were coinfected[3-4]
- Currently the clinical implication of detecting multiple pathogens is poorly understood

METHODS

- The study was designed as a retrospective, descriptive, hypothesis-generating study to evaluate the co-detection of pathogens with BioFire FilmArray Gastrointestinal Panel in an adult community population
- Patients with stool PCR positive for ≥1 pathogen within the date range of 01/01/15-06/30/16 were obtained
- Inclusion criteria was age ≥18 and having a stool PCR with ≥1 pathogen within a community health network in the study date range
- Patients with tests repeated within 14 days of initial sample were excluded from the analysis
- Demographic data at the time of sample collection were obtained

RESULTS

- 710 patients with pathogen detection
- 119 patients with a pathogen detected had >1 pathogen (16.8%)
- Bacterial-viral co-detections were seen in 50.4% of co-detection samples, while 39.5% of co-detections were bacterial-bacterial (Table 1)
- Viral-viral, bacterial-parasitic, and bacterial-parasitic-viral co-detections were less frequent
- Certain organisms when positive on stool PCR testing, had a ≥50% occurrence as a co-detection rather than in isolation:
  - *E. coli* O157:H7 100% (1/1), *P. shigelloides* 83% (5/6), Sapovirus 70.6% (12/17), EAEC 62.9% (22/35), and *Cryptosporidium* 50% (3/6) when positive on stool PCR testing
- The most common patterns of co-detection were Norovirus/C. difficile (19.3%), EPEC/C. difficile (7.6%), EPEC/Campylobacter (5.9%), and EPEC/Norovirus (5.9%) (Table 2)
- Currently the clinical implication of detecting multiple pathogens is poorly understood

Table 1. Organism Classification in Co-Detections

Co-detection Pathogen Classification	Incidence in Co-detections
Bacterial-Viral	50.4% (60/119)
Bacterial-Bacterial	39.5% (47/119)
Viral-Viral	5.0% (6/119)
Bacterial-Parasitic	3.4% (4/119)
Bacterial-Parasitic-Viral	1.7% (2/119)

Table 2. Incidence of Pathogens

Highest Incidence of Co-Detected Pathogens	Incidence
C. difficile, Norovirus	19.3% (23/119)
C. difficile, EPEC	7.6% (9/119)
Campylobacter, EPEC	5.9% (7/119)
EPEC, Norovirus	5.9% (7/119)
C. difficile, EAEC	4.2% (5/119)
EAEC, EPEC	4.2% (5/119)

DISCUSSION

- Our study highlights a high frequency (16.8%) of pathogen co-detection in patients with a positive stool PCR test
- It also suggests that bacterial-viral co-detections are the most commonly identified combination
- The most frequent pathogen-specific combination was Norovirus with *C. difficile* accounting for 19.3% of co-detections
- More information is needed on the significance of co-detections and their treatment
- Further analysis will evaluate the contribution of demographics and immunosuppressing conditions to the likelihood of co-detection

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