29th ECCMID Amsterdam, Netherlands 13 – 16 April 2019

The congress of ESCMID

P0246 Investigation of *Clostridium difficile* positive and negative samples using an ultra-sensitive toxin detection assay and BIOFIRE FILMARRAY Gastrointestinal Panel

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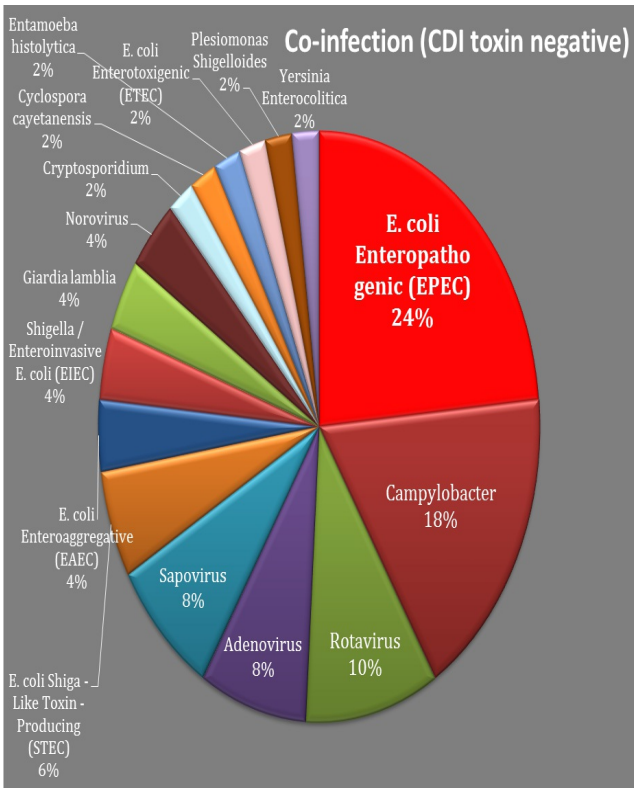
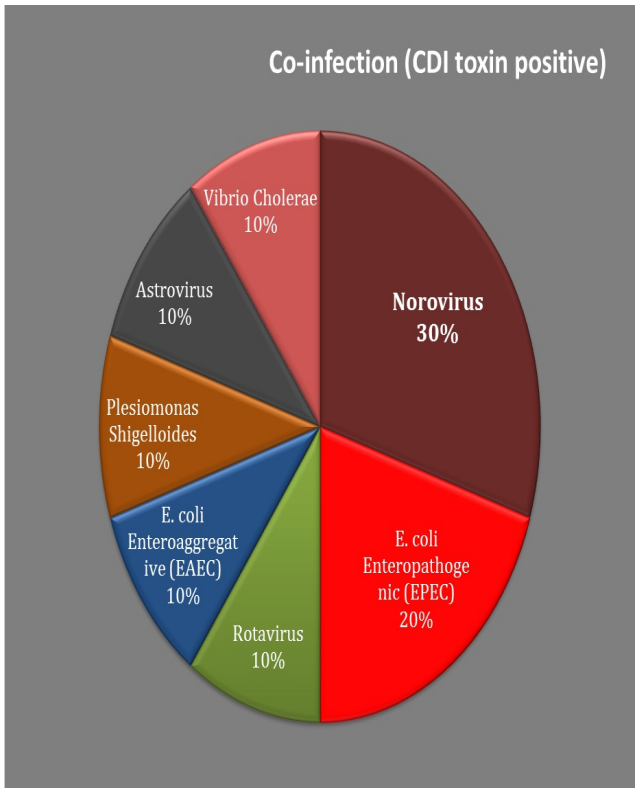
Background: ESCMID guidelines recommend that CDI should be diagnosed by two-stage testing (GDH EIA or NAAT for toxin gene (CDTg) followed by toxin detection). Ultra-sensitive toxin detection assays, such as SIMOA, have recently been developed. In addition, molecular highly multiplexed gastric-pathogen panels offer the opportunity to investigate a wide array of potential co-infections, and potential alternate causes of diarrhoea. We investigated these two new tools in diarrhoeal patients with/without CDI.

Materials/methods: Sites testing both in-patient and community samples were recruited from countries across Europe (1 site/3 million population). On two selected days, all diarrhoeal faecal samples (regardless of test requested) were sent to the European coordinating laboratory (ECL) for testing: cell-cytotoxin neutralisation assay (CCNA), cytotoxigenic culture (CTC), and isolate ribotyping. Selected samples (CCNA and/or CTC positive plus a negative control from the same site) were tested using the SIMOA (France) and BioFire GI (Leeds) assays. Results between SIMOA, BioFire and CCNA were compared.

Results: To date, 169 samples have been tested with BioFire and 93 with SIMOA. All the CCNA positive samples were positive with SIMOA; 16 samples were SIMOA positive/CCNA negative; 14/16 were also CTC positive and 13/15 were toxin gene positive (BioFire). 57/169 samples were positive for another organism by bioFire; the most commonly detected pathogens (BioFire) in community samples were *Campylobacter* sp. (32% n=6/19) and Enteropathogenic *E.coli* (EPEC) (21% n=4/19), whilst in hospital samples they were EPEC (24% n=9/38) and rotavirus (16%n=6/38). In CCNA positive samples the most common co-pathogen was norovirus (30.0%). The commonest alternative potential causes of diarrhoea (CCNA negative samples) were predominately EPEC (23.5% n=12/51) and *Campylobacter* sp. (18% n=9/51).

Conclusions: SIMOA may be more sensitive for CDI detection as some CTC positive samples were *C. difficile* toxin positive by SiMoA but not by CCNA. This suggests that the levels of toxin in these samples may be below the limit of detection of the CCNA. Correlation between the results of ultra-sensitive toxin assays and clinical patient data are lacking, so this is an important subset to include in a case/control study. BioFire GI panel showed that co-infecting pathogens differed between hospital and community samples.


Co-infection (CDI toxin negative)
E. coli Enteropathogenic (EPEC) 24%
Campylobacter 18%
Rotavirus 10%
Adenovirus 8%
Sapovirus 8%
E. coli Enteroaggregative (EAEC) 4%
E. coli Shiga - Like Toxin - Producing (STEC) 6%
Shigella / Enteroinvasive E. coli (EIEC) 4%
Giardia lamblia 4%
Norovirus 4%
Cryptosporidium 2%
Cyclospora cayetanensis 2%
Entamoeba histolytica 2%
E. coli Enterotoxigenic (ETEC) 2%
Plesiomonas Shigelloides 2%
Yersinia Enterocolitica 2%


Co-infection (CDI toxin positive)
Norovirus 30%
E. coli Enteropathogenic (EPEC) 20%
Rotavirus 10%
E. coli Enteroaggregative (EAEC) 10%
Plesiomonas Shigelloides 10%
Astrovirus 10%
Vibrio Cholerae 10%