ABSTRACT

Diagnosis of Clostridium difficile infection (CDI) via nucleic acid amplification testing (NAAT) for toxin genes may result in over diagnosis in patients who are only colonized, leading to unnecessary treatment; however, the added value of other diagnostic modalities is currently unclear. The purpose of this study was to determine whether addition of toxin enzyme immunoassay (EIA) to specimens already tested by NAAT would differentiate patients with CDI from those who were colonized by C. difficile.

METHODS

As part of routine diagnostic workup, unformed stool specimens are tested by the hospital laboratory for the presence of C. difficile toxin B gene using the Cepheid Xpert C. difficile/Epi Assay (PCR). For this study, stool samples, randomly selected based on investigator availability from January to May 2017, were subsequently tested with the Alere C. DIFF QUIK CHECK COMPLETE (EIA) to evaluate for the presence of glutamate dehydrogenase (GDH) and toxins A and B. The EIA results were not provided to the treating clinicians. All corresponding medical charts were reviewed while blinded to the EIA results for the following factors: severity of symptoms, 3 or more unformed stools within a 24-hour period, antibiotic use within 90 days of symptom onset, prior history of C. difficile treatment for CDI, improvement of symptoms with treatment, and colonoscopy findings if performed. Since there is no gold standard to diagnose CDI, these factors were used to categorize patients into three groups: (1) CDI likely, (2) CDI unlikely, and (3) CDI indeterminate.

RESULTS

A total of 60 stool samples were tested from 60 patients. Clinical categorization of the patients and the associated test results are shown in Table 2. Clinical sensitivities for PCR, GDH EIA, and toxin EIA were 100%, 81%, and 38%, and clinical specificities were 77%, 64-77%, and 86%, respectively, as shown in Table 1.

CONCLUSIONS

At our institution, the addition of GDH/toxin A&B EIA to the already performed PCR results did not help differentiate Clostridium difficile infection from colonization

19.2% (5/26) patients with likely CDI, who were PCR-positive but GDH and toxin EIA negative still benefited from treatment for CDI

REFERENCES

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