Retrospective Chart Review of Symptoms of Patients Tested for *Clostridium difficile*

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**Background**

- *Clostridium difficile* is an enteric microorganism, a component of normal intestinal microbiota with the potential to cause diarrheal disease.
- Infection rates have increased over the last 30 years to epidemic levels. In 2011 there were an estimated 453,000 cases of CDI in the United States and 29,300 deaths.
- Diagnosis of CDI is usually done with nucleic acid amplification testing (NAAT) for *C. difficile* toxin genes. NAAT carries a risk of false positive results as the presence of *C. difficile* toxin gene does not distinguish between asymptomatic carriage and CDI.
- In 1996, Katz et al. created a clinical screening tool:
  - Positive if diarrhea ≥ 3 episodes, with abdominal pain or antibiotic use.
  - Negative Predictive Value: 94%.
- Twenty years later, we believe this clinical decision tool is worth revisiting with increased incidence of CDI and improved testing methods. Our aim is to determine the current applicability of the Katz et al. 1996 clinical decision tool for CDI.

**Methods**

- Retrospective cross-sectional chart review at Midwestern teaching hospital; variables of interest entered into standardized electronic data collection form.
- Inclusion criteria: all patients tested for CDI between June 1, 2016 and May 31, 2017.
- Exclusion criteria: critical data missing from chart, a previous positive *C. difficile* toxin in the last 8 weeks, or age < 18 years.
- Variables of interest: presence and amount of diarrhea, abdominal pain in past 24 hours, antibiotic use in past 30 days prior to testing, any prior positive testing for CDI, length of hospital stay prior to testing, patient age and sex.
- Diarrhea was considered significant if ≥ 3 episodes in 24 hour period. Katz screen was positive if a patient had significant diarrhea AND either abdominal pain OR antibiotic use.
- A positive CDI test was determined by a positive result on our facility’s PCR-based assay for *C. difficile* toxin.
- Analysis was conducted using SAS® v9.4 (Cary, N.C.).

**Results**

- Initial review of 810 of 2149 total charts (37.7%) has been completed.
- 69 (8.5%) were ineligible for analysis:
  - 46 (66.7%) due to prior positive CDI test in past 8 weeks.
  - 21 (30.4%) due to incorrect records.
  - 2 (2.9%) due to age < 18 years.
- 741 charts analyzed initially; 85 (11.5%) tested positive for CDI.
- 389 of 741 initial charts (52.5%) included all data required for analysis.
- 21 (3.0%) due to incomplete records.
- 46 (66.7%) due to prior positive CDI test in past 8 weeks.
- Of eligible charts, 39 of 389 (10.0%) had positive CDI test results (see Table 1).
- The Katz screen was positive in 146 of 389 (37.5%) cases, the distribution of data is shown in Table 2.
  - Sensitivity: 56.4%.
  - Specificity 64%.
  - Positive Predictive Value: 15.1%.
  - Negative Predictive Value: 93.0%.

<table>
<thead>
<tr>
<th>Test</th>
<th>Positive</th>
<th>Negative</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>60.1</td>
<td>61.0</td>
<td>0.77</td>
</tr>
<tr>
<td>Sex (% male)</td>
<td>41.0</td>
<td>48.6</td>
<td>0.37</td>
</tr>
<tr>
<td>Diarrhea in past 24 hours (% positive)</td>
<td>76.9</td>
<td>54.9</td>
<td>0.008</td>
</tr>
<tr>
<td>Amount of diarrhea (mean episodes)</td>
<td>4.8</td>
<td>2.8</td>
<td>0.009</td>
</tr>
<tr>
<td>Significant diarrhea (% positive)</td>
<td>59.0</td>
<td>39.7</td>
<td>0.02</td>
</tr>
<tr>
<td>Abdominal pain (% positive)</td>
<td>56.4</td>
<td>52.6</td>
<td>0.67</td>
</tr>
<tr>
<td>Antibiotic use (% positive)</td>
<td>74.4</td>
<td>63.1</td>
<td>0.17</td>
</tr>
<tr>
<td>Length of stay (≥ 3 days)</td>
<td>48.7</td>
<td>35.1</td>
<td>0.10</td>
</tr>
<tr>
<td>Previous positive (% positive)</td>
<td>15.4</td>
<td>2.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Katz criteria (% positive)</td>
<td>56.4</td>
<td>35.4</td>
<td>0.01</td>
</tr>
</tbody>
</table>

**Table 1: Characteristics of patients with positive and negative CDI tests.**

**Discussion**

- Katz et al.3 found a sensitivity, specificity, positive predictive value and negative predictive value of 80%, 45%, 16% and 94%, respectively.
- In comparison, our results were 56%, 64%, 15% and 93%, respectively, with *+ LR of 1.59, - LR of 0.67.*
- Discrepancies could result from variations in testing methodology and prevalence of CDI, compared to the1992 study population.
- Negative predictive value remains a relative strength. If this screening tool were applied to our population, there would have been 243 (62.5%) fewer tests, but 17 (43.6%) positive results may have been missed, though the significance of these is unknown.
- Limitations of our work include the few positive tests, the paucity of data and the reliance on presumably accurate charting.
- Future efforts: further data analysis, crucial variables in predicting CDI test results, and the development of a new predictive model.

**Acknowledgements/References**

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**References**


Table 2: 2x2 table of Katz tool and CDI test result.