Routine surveillance versus independent assessment by an outcome adjudication committee in assessing patients for sternal surgical site infections after cardiac surgery

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Abstract

Background: Independent data collection and assessment of possible cases by an outcome adjudication committee (AC) is considered the gold standard for clinical trials where surgical site infections (SSI) are an outcome. It is unclear however, if routine infection control surveillance alone is sufficiently accurate to detect SSIs in clinical trials.

Methods: We included all patients undergoing cardiac surgery by sternotomy at two Canadian high-volume centers (Hamilton, ON and Edmonton, AB) over a 4 month period. Surveillance charts were also independently reviewed by a research assistant who, blinded to surveillance results, contacted patients 90 days after surgery, and presented patients flagged for a potential SSI to an AC (three infectious disease physicians and one cardiac surgeon). The accuracy of surveillance with comparison by the AC in identifying deep/organ space SSIs was assessed.

Results: A total of 966 patients were included. There were 12 deep infections identified (1.2%) by surveillance and 11 (1.1%) by the AC. There were disagreements in 7 cases (kappa = 0.692%). Using the AC as the gold standard, the specificity of routine surveillance was 72.7% (95% CI: 64.9-79.3) and sensitivity 99.6% (95% CI: 99.3-99.8), respectively. The four cases that were identified by surveillance but not by the AC were thought to be deep SSI by treating physicians, and could therefore only be identified by a follow-up phone call by the research assistant. The four cases that were identified by surveillance but not by the AC were thought to be deep SSI by treating physicians and could therefore only be identified by a follow-up phone call by the research assistant. The four cases that were identified by surveillance but not by the AC were thought to be deep SSI by treating physicians and could therefore only be identified by a follow-up phone call by the research assistant. The four cases that were identified by surveillance but not by the AC were thought to be deep SSI by treating physicians and could therefore only be identified by a follow-up phone call by the research assistant.

Discussion: Routine surveillance alone did not prove to be sufficiently accurate in identifying deep/organ space SSIs. Adding a phone call at 90 days to routine surveillance however, plus an independent review by an AC of cases identified as deep/organ space infections by routine surveillance, would improve the accuracy and may allow the use of surveillance data as a basis for cardiac surgery clinical trials.

Methods

Inclusion criteria: All patients undergoing cardiac surgery by sternotomy

Setting: Two Canadian high-volume centers over a 4 month period

Routine Surveillance

- Comparison of adjudication of deep and organ/space sternal SSI (s-SSI) by routine surveillance with infection prevention control (IPAC) versus adjudication by an independent research outcomes adjudication committee (AC)
- Routine surveillance by IPAC using CDC/NHSN criteria, patients in-hospital charts were reviewed by trained infection control practitioners 3 months post surgery
- Additional cases identified by AC: charts were also independently reviewed by a research assistant who, blinded to surveillance results, contacted patients 90 days after surgery, and presented patients flagged for a potential SSI to an AC

Adjudication Committee

- All patients undergoing cardiac surgery by sternotomy based on the diagnosis by an attending physician or surgeon that was not considered by the AC due to this patient’s subjectivity

Statistics:

- Sensitivity and specificity and 95% CI of routine surveillance as compared to the AC assessment were calculated
- We defined a priori that routine surveillance would be sufficiently accurate for research purposes if the sensitivity to detect deep and/or organ/space s-SSI was >85% and specificity >99.5%
- Sample size calculation: We required a total of 20 deep and organ/space s-SSIs for a sensitivity of >95% if not more than 1 case was missed by routine surveillance, and a specificity of >99.5% if not more than 4 cases were falsely labelled as events.

Results

Table 1 – Assessment of deep and organ/space s-SSI by routine surveillance versus outcome adjudication committee

<table>
<thead>
<tr>
<th>Site</th>
<th>Both sites (n=422)</th>
<th>Site 1 (n=544)</th>
<th>Site 2 (n=422)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (95% CI)</td>
<td>99.6 (98.9-99.9)</td>
<td>99.5 (98.6-99.8)</td>
<td>99.6 (98.9-99.9)</td>
</tr>
<tr>
<td>Specificity (95% CI)</td>
<td>99.9 (99.5-100.0)</td>
<td>99.9 (99.5-100.0)</td>
<td>99.9 (99.5-100.0)</td>
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</tbody>
</table>

Discussion

- We found an insufficient agreement between routine surveillance by IPAC and an independent review by a study nurse and adjudication by an expert committee to justify the use of s-SSI surveillance data for research purposes.
- The main limitation of routine surveillance was relying on re-admission in the event of deep and/or organ space s-SSI and the lack of active surveillance by contacting patients 3 months post surgery.
- The surgical site infection definition based on the diagnosis of a s-SSI by either an attending physician or surgeon is subjective and was therefore not considered in the review by the AC. This resulted in disagreements between the AC and surveillance as treating physicians tended to err on the side of caution and treating potential s-SSI in the AC: trained personal reviewed clinical events. This may reduce an outcome adjudication in an un-blinded clinical trial and as such such this criterion should be removed from the s-SSI criteria if using the CDC/NHSN definition for research.

Limitations

- We defined independent review by an expert outcome adjudication committee as the gold standard to define s-SSI. Although this is generally considered the preferred approach for adjudication of SSIs in clinical trials, this approach is not necessarily 100% accurate.
- The s-SSI rates was lower than expected, thus, the number of events was lower than assumed for in the power calculation.

Conclusions

Routine surveillance by IPAC cannot be used for research purposes as there is a lack of active surveillance by contacting patients 3 months post surgery, and if needed with the family physician or other health care providers 3 months post surgery, and unless there is an independent blinded AC that reviews all cases labelled s-SSI by routine surveillance.

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