How We Did It: An Experience From a Published Article Using ACS-NSQIP Data

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Disclosure

• None
Acknowledgment: Henry Ford Hospital NSQIP Researchers

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Clavien Class IV and V Complications for Laparoscopic vs Open Colectomy Using NSQIP Data and Risk Adjustment

Shawn Webb MD, Ilan Rubinfeld MD, Vic Velanovich MD, M Horst MD, Craig Reickert MD

2011 Annual Scientific Session of the Society of American Gastrointestinal and Endoscopic Surgeons, San Antonio, TX
March 30-April 2, 2011
Question

• Will laparoscopic colectomy result in fewer more severe complications than open colectomy?
Data needed

- Laparoscopic colectomy patient data
- Open colectomy patient data
- Identification of the occurrence of severe complications
- Identification of sources of bias

- Will NSQIP provide these types of data?
<table>
<thead>
<tr>
<th>Laparoscopic Colectomy</th>
<th>Open Colectomy</th>
<th>Need for conversion not recorded</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 44204</td>
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<td>• 44151</td>
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<tr>
<td></td>
<td>• 44155</td>
<td></td>
</tr>
</tbody>
</table>
## How to Define “Severe” Complications?

### Clavien Classification

### TABLE 1. Classification of Surgical Complications

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td>Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.</td>
</tr>
<tr>
<td>Grade II</td>
<td>Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.</td>
</tr>
<tr>
<td>Grade III</td>
<td>Requiring surgical, endoscopic or radiological intervention.</td>
</tr>
<tr>
<td>Grade IIIa</td>
<td>Intervention not under general anesthesia.</td>
</tr>
<tr>
<td>Grade IIIb</td>
<td>Intervention under general anesthesia.</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Life-threatening complication (including CNS complications)* requiring IC/ICU management</td>
</tr>
<tr>
<td>Grade IVa</td>
<td>Single organ dysfunction (including dialysis).</td>
</tr>
<tr>
<td>Grade IVb</td>
<td>Multiorgan dysfunction.</td>
</tr>
<tr>
<td>Grade V</td>
<td>Death of a patient.</td>
</tr>
<tr>
<td>Suffix “d”</td>
<td>If the patient suffers from a complication at the time of discharge (see examples in Table 2), the suffix “d” (for “disability”) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.</td>
</tr>
</tbody>
</table>

*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.
CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

Which NSQIP Collected Complications Fit this Definition?

- Septic Shock
- Q-wave Infarct
- Cardiac Arrest
- Pulmonary Embolism
- New need for dialysis
- Reintubation
- Prolonged Ventilation
- Mortality
Sources of Bias We Could Identify in NSQIP Data

Patient-Related
- ASA Class
- Gender
- Preoperative functional status
- Preoperative albumin
- Inpatient status

Disease-Related
- Emergency case
- Wound Class
Sources of Bias that We Could Not Overtly Eliminate

Disease-Specific
- Cancer
  - Obstruction
- Diverticulitis
  - Perforation
  - Obstruction
- Colonic hemorrhage
  - Diverticular disease
  - Angiodysplasia
- Volvulus
- Inflammatory Bowel Disease
- Polyposis Syndromes

Patient-Specific
- Degree of severity of co-morbid condition
  - Heart failure
  - COPD
  - Renal insufficiency
  - Cognitive dysfunciton
  - Etc., etc.

Surgeon-Specific
- Trained to do lap colectomy?
- Judgment as to best approach?
How PUF Data was Accessed and Manipulated

- Participant Use Files accessed via ACS website
- Data Use Agreement Signed and Followed
- Years 2005-2008 were available at the time
- Data downloaded from the website in SPSS
- Data was manipulated in SPSS
- A data set was constructed combining the 4 years of data
Statistical Analysis

Univariate Analysis
• Chi-squared analysis

Multivariate Analysis
• Multiple logistic regression
  – Dependent variables: each complication individually
  – Independent variables: the operation type and each identified source of bias
Results

- NSQIP database 2005-2008, n=635,265 operations tracked
- 45,645 patients underwent colectomy
  - 12,455 laparoscopic colectomy
  - 33,190 open colectomy
### Results: Clinical Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Laparoscopic (n=12,455)</th>
<th>Open (n=33,190)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>60.0</td>
<td>62.9</td>
</tr>
<tr>
<td>Mean LOS</td>
<td>6.4 days</td>
<td>11.25 days</td>
</tr>
<tr>
<td>Mean OR time</td>
<td>175 minutes</td>
<td>160 minutes</td>
</tr>
<tr>
<td>Gender, Male</td>
<td>48.4%</td>
<td>47.9%</td>
</tr>
</tbody>
</table>
## Clavien IV and V Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Lap (n=12,455)</th>
<th>Open (n=33,190)</th>
<th>Univariate $\chi^2 (p&lt;0.001)$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q-wave infarct</td>
<td>0.2%</td>
<td>0.5%</td>
<td>2.99</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>0.3%</td>
<td>1.2%</td>
<td>4.27</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0.4%</td>
<td>1.0%</td>
<td>2.27</td>
</tr>
<tr>
<td>Reintubation</td>
<td>1.4%</td>
<td>4.5%</td>
<td>3.22</td>
</tr>
<tr>
<td>Prolonged Vent</td>
<td>1.6%</td>
<td>8.9%</td>
<td>5.95</td>
</tr>
<tr>
<td>Septic Shock</td>
<td>1.5%</td>
<td>5.6%</td>
<td>3.88</td>
</tr>
<tr>
<td>Dialysis</td>
<td>0.3%</td>
<td>1.6%</td>
<td>4.67</td>
</tr>
<tr>
<td>Mortality</td>
<td>1.1%</td>
<td>5.8%</td>
<td>5.52</td>
</tr>
<tr>
<td>Any Clavien IV or V</td>
<td>3.6%</td>
<td>15.4%</td>
<td>4.87</td>
</tr>
</tbody>
</table>
## Risk Adjustment

<table>
<thead>
<tr>
<th>Complication</th>
<th>Multivariate Regression OR (p&lt;0.001)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q-Wave infarct</td>
<td>1.63</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>2.21</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>1.87</td>
</tr>
<tr>
<td>Reintubation</td>
<td>1.57</td>
</tr>
<tr>
<td>Prolonged ventilation</td>
<td>1.77</td>
</tr>
<tr>
<td>Septic Shock</td>
<td>1.64</td>
</tr>
<tr>
<td>Dialysis</td>
<td>1.94</td>
</tr>
<tr>
<td>Mortality</td>
<td>1.54</td>
</tr>
<tr>
<td>Any Clavien IV or V</td>
<td>1.74</td>
</tr>
</tbody>
</table>
Paper Writing and Submission

- Shawn Webb (Colorectal Surgery Fellow) completed first draft
- Revisions and queries put forth by co-authors
- Paper presented at SAGES (lots of interests by moderators and audience)
- Final draft submitted to Surgical Endoscopy
- Relatively minor criticisms and revision requests by reviewers
- Paper accepted for publication
Using National Surgical Quality Improvement Program (NSQIP) data for risk adjustment to compare Clavien 4 and 5 complications in open and laparoscopic colectomy

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Keys for Successful Research using ACS-NSQIP PUF Data

• Have a good question or hypothesis
• Make sure PUF data can provide the answer
• Understand how to do the queries necessary to obtain the required data
• Understand biases in the data
• Use statistical methods to account for known biases
• Understand limitation of PUF data
• Choose the forum in which to present data wisely
• Be prepared to answer lots of questions and criticisms