Preventing Surgical Stapler Adverse Events: A Simulation-Based Curriculum

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Part I

SURGICAL STAPLER RISKS
What Can Go Wrong?
Background: Literature

- Low reported rates of malfunction, but potentially catastrophic results
- Reports to FDA MAUDE database 2003-2012: 97 deaths, 3,436 injuries, and 2,817 malfunctions
- May be due to device malfunction or use error

Chan et al., 2000; Yano et al., 2013; Boggi et al., 2009; Deng et al., 2009
Stapler Failure Modes

• **Division without ligation**
  - Missing stapler cartridge
  - Missing staples
  - Overriding safety mechanism and firing used cartridge

• **Malformed staple lines**
  - Firing over existing staples/clips
  - Incomplete firing stroke
  - Manufacturing defect

• **Stapler locking** before or after firing leading to tissue injury when stapler is removed

• **Partial or no cutting**

• **Damage of nearby tissue** during stapler insertion or removal

Chan et al., 2000; Deng et al., 2002; Hsi et al., 2007
Background: Spot RCA Database

- 12 relevant RCAs (13 events) involving non-skin closure surgical staplers

### Type of Surgery

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary surgery</td>
<td>7</td>
</tr>
<tr>
<td>Laparoscopic nephrectomy</td>
<td>3</td>
</tr>
<tr>
<td>Bowel surgery</td>
<td>3</td>
</tr>
</tbody>
</table>

### Patient Outcome

- **Death**: 4 events
- **Survived - transfusion**: 5 events
- **Survived - no transfusion mentioned**: 3 events
Stapler Event Root Causes

- Poor teamwork/communication
- Change of shift
- Lack of educational opportunities
- Over-scheduling

- Lack of education or familiarity with instrument

- Poor visualization of structure to be stapled
- Friable tissue characteristics

- Stapler misfire
- Misalignment of stapler
Hazard Avoidance and Mitigation

Prior to surgery:

- Evaluate potential devices prior to purchase
- Ensure surgeons have their preferred devices
- Implement systematic training on surgical devices
- Make provisions for practice time
Hazard Avoidance and Mitigation

*During surgery:*

- **Identify** devices, use issues, and possible adverse outcomes during preoperative briefing
- Establish **proximal control** and **pause** (“Step Back”) prior to stapling large blood vessel
- **Examine** stapler prior to firing
- Avoid **stapling over clips** or existing staple line
- **Visually inspect** staple line prior to dividing tissue
- Avoid **forcefully freeing** the tissue if stapler locks up
- Utilize standardized procedure for **investigation of misfires**
Part II

SIMULATION-BASED TRAINING
Learning Gap

- No systematic training program for surgical devices
- “See one, do one, teach one”
- No routine trial of new devices
- No provisions for routine practice with surgical devices
Training Objectives

- Familiarize users with correct operation of tool
- Teach users best practices
- Teach users possible failure modes and responses
- Demonstrate severe failures
Methodology

- Participants: Surgeons, nurses, technicians
- Site: Required clinical team training events
- Design: Optional hands-on activity
  - Initial survey
  - Surgical stapler simulation activity
  - Post-training survey
Pre-Training Survey

- Demographics
- Training/Experience
- Stapler ease of use
- Experiences with stapler failures
- Knowledge of stapler failure modes
Pre-Training Survey

- Demographics
  - Gender
  - Age
  - Height/weight
  - Dominant hand
  - Glove size
  - Specialty
  - Most common case with stapling device

- Training/Experience
- Stapler ease of use
- Experiences with stapler failures
- Knowledge of stapler failure modes
Pre-Training Survey

• Demographics
• Training/Experience
  • Year most recent training completed
  • Last time you used a surgical stapler
  • Frequency of use of various models
  • Did you have specific stapler training during your residency? Have you since?
• Stapler ease of use
• Experiences with stapler failures
• Knowledge of stapler failure modes
Pre-Training Survey

• Demographics
• Training/Experience
• Stapler ease of use
  • How easy/difficult to you find it to close a surgical stapler?
  • Fire a surgical stapler?
  • Have you ever required assistance with using a surgical stapler?
• Experiences with stapler failures
• Knowledge of stapler failure modes
Pre-Training Survey

- Demographics
- Training/Experience
- Stapler ease of use
- Experiences with stapler failures
  - Have you ever encountered failures with surgical staplers?
  - Did you report the failure and secure the stapler?
  - Have you ever heard of other people encountering failures?
- Knowledge of stapler failure modes
Pre-Training Survey

- Demographics
- Training/Experience
- Stapler ease of use
- Experiences with stapler failures
- Knowledge of stapler failure modes
  - If you were advising residents, what stapler problems would you tell them to look out for?
  - What would you advise them to do to avoid these problems?
Post-Training Survey

• Knowledge of stapler failure modes
  • If you were advising residents, what stapler problems would you tell them to look out for?
  • What would you advise them to do to avoid these problems?

• As a result of training…
  • I am more aware of possible stapler problems
  • I am more proactive regarding stapler safety

• This training…
  • Would be beneficial to other surgeons
  • Was worthwhile

Strongly Disagree
Neither Agree nor Disagree
Strongly Agree
Summary

• Low reported rates of adverse events related to surgical staplers, but outcome may be catastrophic
• Simulation is a good medium for training because hazards may be demonstrated without risk to patients or providers
• Stapler simulation training will be piloted at clinical team training events in the VA
References


Thank you