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ABSTRACT

Background: The growth of laparoscopic surgery has increased the use of laparoscopic electrosurgical devices based on radiofrequency current. Despite an improvement in most post-operative outcomes, the use of these devices can be associated with inadvertent thermal or mechanical injuries, also called accidental punctures and lacerations (APLs). APLs can occur through either operator error or system error, including insulation failure or capacitive coupling resulting in stray energy burns. Our aim was to estimate the incidence and—as a result—the impact of laparoscopic APLs.

Methods: A retrospective analysis of the Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID) was performed for 2009 in California (CA) and Florida (FL). ICD-9 codes and current procedural terminology were used to query for five common general surgery procedures: appendectomy, cholecystectomy, fundoplication, gastric bypass, and gastroplasty with these procedures cross-referenced for

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any secondary procedure at the time of the initial surgery indicative of APLs. The χ² test was used for comparisons where appropriate.

Results: Overall, 192,794 primary laparoscopic procedures were identified in the HCUP database in CA and FL in 2009, with a similar procedure frequency distribution between CA and FL. Six hundred ninety-four procedures were complicated by APL. Gastric bypass and fundoplication were more commonly associated with APLs.

Conclusion: In this retrospective analysis of procedures performed in CA and FL, the estimated incidence of APL was 3.6 per 1000 cases. Patient morbidity and mortality were likely related to both pilot-error injuries and stray energy burns during laparoscopy. Possible solutions to reduce surgical complications from APL include educational programs to reduce pilot error and the incorporation of fail-safe technologies to eliminate stray energy burns, such as active electrode monitoring and use of non-radiofrequency current (true cautery).

INTRODUCTION

The growth of minimally invasive (laparoscopic and robotic) surgery has increased the use of laparoscopic electrosurgical devices. Modern laparoscopic surgery has been shown to provide improved postoperative outcomes including decreased post-operative pain, reduced length of hospital stay, and faster return to work. Laparoscopic electrosurgical devices are essential tools in minimally invasive (laparoscopic and robotic) surgery given their ability to cut and fulgurate tissue with continuous low-voltage current, dampened current, and a combination of the two. However, radiofrequency-based electrosurgical devices are also associated with risks due to current diversion, including inadvertent thermal or mechanical injury. There are two primary causes of iatrogenic injury with the use of radiofrequency-based electrosurgical devices: pilot error and system error. Pilot error can occur from either mechanical perforation or thermal injury from a hot instrument inadvertently placed near tissue by the operating surgeon. Laparoscopic thermal injuries due to pilot error (not instrument malfunction) are likely skill-based or related to the operator’s knowledge of their tools. On the other hand, system errors such as stray energy burns outside of the laparoscopic field are not related to surgeon skill; these are caused by the current design of a monopolar instrument, which causes either insulation failure or capacitive coupling between conductive materials, including surgical instruments, human tissue, and the metal of the cannula. Regardless of the etiology, these stray energy injuries can result in clinically significant morbidity and mortality. Classiﬁed as hospital-acquired conditions (HAC) of the type accidental puncture and laceration (APL), these complications are used to grade health systems, hospitals, and individual surgeons. Importantly, some studies estimate that up to 50% of APLs are due to stray energy burns, suggesting that the design of the electrosurgical instrument, and not the surgeon, creates risk for the patient. However, it is essential for the surgeon and public alike to understand the epidemiology of laparoscopic thermal injuries and to create education systems and instrument designs that reduce their frequency. In this study, we aimed to estimate and describe the epidemiology of APLs during laparoscopic and robotic procedures using two large public databases from California (CA) and Florida (FL).

MATERIALS AND METHODS

A retrospective analysis of both inpatient and ambulatory data was performed using the Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID) for 2009 in California (CA) and Florida (FL) (https://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp). HCUP is a series of federal databases derived from administrative data that present encounter-level, clinical, and non-clinical information (all listed diagnoses and procedures, discharge status, patient demographics, and charges for patients). International Classification of Diseases, 9th Revision (ICD-9) and current procedural terminology (CPT) were used to query for five common general surgery procedures: appendectomy, cholecystectomy, fundoplication, gastric bypass, and gastropasty (Appendix 1). Patients undergoing these procedures were then cross-referenced for any secondary procedure (using ICD-9 codes) at the time of the initial surgery that might be indicative of accidental injuries from pilot error and stray energy burns, including perforation of intestine and suture of laceration of the stomach, duodenum, small intestine, or large intestine, among others (Appendix 2). The χ² test was used for comparisons where appropriate. Data analysis was performed using SAS® Version 12.1 (SAS Institute Inc., Cary, NC) and Epi Info™ Version 7.1.5.2 (Centers for Disease Control and Prevention, Atlanta, GA). Since this study used publicly available, de-identified data, it was exempt from IRB approval.
There were 192,794 primary laparoscopic procedures identified in the HUCP database in CA and FL in 2009. In both states, the most commonly performed procedures included cholecystectomy and appendectomy. While the procedure frequency distribution was similar between CA and FL, the distribution of case type was significantly different between the states (Table I). Six hundred ninety-four procedures (0.4% of 192,794 patients undergoing a primary procedure) were complicated by APL based on the second-operation procedure code. In California, 414 (0.4%) APLs were identified after 115,256 procedures, and in Florida, 280 (0.4%) APLs were noted after 77,538 procedures. Gastric bypass and fundoplication procedures, and in Florida, 280 (0.4%) APLs were noted after 77,538 procedures. Gastric bypass and fundoplication were more commonly associated with APL: gastric bypass (CA: 19.9, FL: 26.0 APLs per 1000 procedures) and fundoplication (CA: 14.3, FL: 11.0 APLs per 1000 procedures). A significantly greater proportion of APLs occurred with gastric bypass in Florida (p=0.03). None of the other differences in APL between the states were statistically significant. Assuming that 50% of all APL injuries were due to energy-device design (based upon previous estimates), we can estimate that 1.8 APLs per 1000 cases were associated with non-operator error, resulting in re-operation in CA and FL, respectively.

This retrospective study reviewed common laparoscopic surgeries using a large inpatient and outpatient dataset to determine the rates of surgical complications from APLs. Every year in the United States, over 3,000,000 laparoscopic procedures are performed, and an estimated 85% of these procedures use monopolar energy with radiofrequency current. Several studies on stray energy burns have estimated that there are approximately 1 to 5 APLs per 1000 procedures that are severe enough to require reoperation. Our overall APL rate of 3.6 APLs per 1000 procedures, with an estimated 1.8 APLs per procedure due to stray energy burns, is consistent with these previous studies. We found that bariatric and foregut surgeries (gastric bypass and fundoplication) had higher rates of APL. As bipolar and ultrasonic energy are the preferred energy devices used in gastric bypass surgery, the increased frequency of APLs may not be entirely attributable to stray monopolar energy and might reflect the complexity of the operation. Stray energy burns due to capacitive coupling are less likely with bipolar radiofrequency energy-based devices, but can still occur. However, thermal injury resulting from inadvertent tissue contact with the hot surfaces of bipolar and ultrasonic instruments can also cause APLs. Interestingly, the most commonly performed laparoscopic procedures, cholecystectomy and appendectomy, had a lower rate of stray energy injuries. We hypothesize that increased operator experience (secondary to the relatively high numbers of operations performed per surgeon), minimal amount of shaft contact with the bowel, and comparatively minimal bowel manipulation in these procedures could explain the low frequency of stray energy burns. The potential morbidity and mortality associated with APLs have been well-recognized. Educational programs, like the Fundamental Use of Surgical Energy program (FUSE) developed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), have the potential to decrease pilot error by increasing the understanding of electrosurgical principles and the limitations of this technology. As suggested by other authors, directing surgeons to this program early in their training could be particularly effective. In addition to reducing pilot error, strategies to reduce system error might also reduce the burden of APL. Methods to decrease electrosurgical system errors have been described previously. In addition to these system checks, technological improvements in monopolar electrosurgical devices may help eliminate system errors, such as Active Electrode Monitoring (AEM) and true cautery devices. AEM devices use metal electrical shielding along the shaft of the instrument that prevents
Electromagnetic fields from transmitting energy outside the intended operative field. Capacitive coupling and insulation failure are eliminated and therefore the risk of stray energy injuries is greatly reduced. In addition, any stray energy is monitored and relayed to the electrosurgical unit (ESU). If a dangerous amount of stray energy is detected, the AEM monitor stops the flow of energy to the instrument. While this technology can reduce clinically relevant stray energy burns, surgical practice has been slow to implement it. Similarly, true cautery-based energy devices theoretically eliminate any electromagnetic field within the surgical field, but clinical proof of the validity of this technology is not yet available. An additional factor that must be taken into account is the power use during routine surgery. Small bowel burns can occur from capacitive coupling at 3.8 J of energy, with a 2.2-second activation time, which equates to an electrosurgical generator power setting of just 8.4 watts. Under typical surgical circumstances, appropriate coagulation and hemostasis cannot occur below generator power settings of about 10 W. The typical power settings used in most scenarios, including those mentioned in this study, are in the range of 30W – 40W.

Both pilot error injuries and stray energy burns during laparoscopy can result in patient morbidity and mortality. In our retrospective analysis of cases in CA and FL, the incidence of APL was 3.6 per 1000 cases. Educational programs to reduce pilot error and the incorporation of fail-safe technologies to eliminate stray energy burns, such as active electrode monitoring or true cautery devices, are possible solutions to reduce surgical complications from APL. Their value remains to be tested in clinical studies.

Appendix 1
Primary Procedure Codes

The following procedure codes were used to identify the primary procedure:

<table>
<thead>
<tr>
<th>Laparoscopic Procedure</th>
<th>ICD-9 Codes</th>
<th>CPT Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendectomy</td>
<td>47.01; 47.11</td>
<td>44970, 44979</td>
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<tr>
<td>Cholecystectomy</td>
<td>51.23, 51.24</td>
<td>47562, 47563, 47564, 47570, 47579</td>
</tr>
<tr>
<td>Fundoplication</td>
<td>44.67 43279, 43280, 43281, 43289</td>
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<tr>
<td>Gastric Bypass</td>
<td>44.38 43644, 43645</td>
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</tr>
<tr>
<td>Gastroplasty</td>
<td>44.68 43283</td>
<td></td>
</tr>
</tbody>
</table>

REFERENCES

AUTHORS’ DISCLOSURES
The authors declare that they have no conflicts of interest.
Appendix 2
Secondary Procedure Codes

The following secondary procedure codes (ICD-9-CM) were used in this analysis, as they are indicative of abdominal injury during the procedures:

- a. 569.83 - Perforation of intestine
- b. 07.44 - Repair of adrenal gland
- c. 39.3 - Suture of vessel
- d. 39.59 - Other repair of vessel
- e. 41.95 - Repair and plastic operations on spleen
- f. 44.61 - Suture of laceration of stomach
- g. 44.69 - Other repair of stomach; Inversion of gastric diverticulum
- h. 46.71 - Suture of laceration of duodenum
- i. 46.73 - Suture of laceration of small intestine, except duodenum
- j. 46.75 - Suture of laceration of large intestine
- k. 46.79 - Other repair of intestine
- l. 48.71 - Suture of laceration of rectum
- m. 48.79 - Other repair of rectum: repair of old obstetric laceration of rectum; Inversion of gastric diverticulum
- n. 50.6 - Repair of liver
- o. 51.71 - Simple suture of common bile duct
- p. 51.79 - Repair of other bile ducts: closure of artificial opening of bile duct NOS; Suture of bile duct NOS
- q. 51.91 - Repair of laceration of gallbladder
- r. 52.95 - Other repair of pancreas: Fistulectomy of pancreas; simple suture of pancreas
- s. 54.63 - Other suture of abdominal wall: suture of laceration of abdominal wall
- t. 54.64 - Suture of peritoneum: secondary suture of peritoneum
- u. 54.72 - Other repair of abdominal wall
- v. 54.73 - Other repair of peritoneum: suture of gastrocolic ligament
- w. 54.74 - Other repair of omentum: epiplorrhaphy; graft of omentum; omentopexy; reduction of torsion of omentum
- x. 54.75 - Other repair of mesentery: mesenteric placation; mesenteropexy
- y. 55.81 - Suture of laceration of kidney 12
- z. 55.89 - Other repair of kidney
- aa. 56.62 - Suture of laceration of ureter
- bb. 56.89 - Other repair of ureter: graft of ureter; replacement of ureter with ileal segment implanted into bladder
- cc. 57.81 - Suture of laceration of bladder
- dd. 57.89 - Other repair of bladder: bladder suspension, not elsewhere classified; cystopexy
- ee. 58.71 - Suture of laceration of bladder
- ff. 58.79 - Other repair of bladder: bladder suspension, not elsewhere classified; cystopexy

The following secondary procedure codes (ICD-9-CM) were used in this analysis, as they are indicative of bladder injury during the procedures:

- a. 57.81 - Suture of laceration of bladder
- b. 57.89 - Other repair of bladder: bladder suspension, not elsewhere classified; cystopexy
- cc. 58.71 - Suture of laceration of bladder
- dd. 58.79 - Other repair of bladder: bladder suspension, not elsewhere classified; cystopexy

The following secondary procedure codes (ICD-9-CM) were used in this analysis, as they are indicative of bladder injury during the procedures:

- a. 57.81 - Suture of laceration of bladder
- b. 57.89 - Other repair of bladder: bladder suspension, not elsewhere classified; cystopexy

- a. 57.81 - Suture of laceration of bladder
- b. 57.89 - Other repair of bladder: bladder suspension, not elsewhere classified; cystopexy