# Trocar-Related Safety Events in Minimally Invasive Surgical Procedures: Risks for Organ and Vascular Complications





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trocar is a hollow device used during minimally invasive surgery that serves as an entry port for optical scopes and surgical equipment. Insertion of this device into the body is determined using anatomical landmarks taking into consideration the patient's history and physical attributes, e.g., scars or abdominal size. Insertion of the first trocar is the time of highest risk of injury. Intestinal and vascular injuries are two potentially life-threatening injuries that can occur. A retrospective review of trocar-related events submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) between January 1, 2014, and June 30, 2020, identified 268 events. Internal organ and vascular injuries accounted for 81.0% of events; trocar site skin integrity injuries, bleeding/hemorrhage, and hernias accounted for 17.2% of events; and vasovagal responses accounted for 1.9% of events. Internal injuries occurring during the initial insertion of the trocar, Veress needle, or incision in preparation for a trocar insertion was reported in 64.5% of events. Adhesions were identified in 13.5% of internal injury events. Many internal injury events identified a single injury; however, in 17 instances patients sustained two trocar-related injuries. Conversion to open surgery, return to the operating room during the same admission, postoperative intensive care unit admission, ambulatory surgical facility transfer to a hospital, readmission, postdischarge return to the operating room, and death are outcomes identified in the event reports.

**Keywords:** patient safety, trocar, Veress needle, laparoscopy, robotic surgery, laceration, perforation

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Compared to open surgical procedures, minimally invasive surgery (e.g., laparoscopic, thoracic, or arthroscopic) results in reduced recovery time, decreased scarring, and shortened length of hospital stay. These procedures begin with the surgeon inserting one or more trocars, i.e., devices with hollow tubes that serve as entry ports into the body for optical scopes and surgical equipment. <sup>2,3</sup>

There are different methods used when placing the initial trocar into the body:

- 1. Inserting a Veress needle to create space between the abdominal wall and the organs (i.e., pneumoperitoneum) using carbon dioxide gas (i.e., insufflation) to reduce the chances of the trocar touching the organs.
- 2. Inserting a sharp-bladed trocar directly into the body without a pneumoperitoneum.
- 3. Creating an opening into the body via a surgical incision to insert a blunt-edged (i.e., Hasson) trocar.
- Inserting an optical trocar that provides views of the layers of the abdominal wall and organs on a monitor as cuts are made when entering the abdominal cavity.<sup>2,4,5</sup>

Most minimally invasive surgical procedures are completed without an iatrogenic injury (i.e., injury caused during medical treatment). However, insertion of the initial trocar is the time when the highest risk of injury usually occurs. Two common, potentially life-threatening injuries that usually occur during initial trocar insertion are vascular and intestinal injuries. Hese injuries are the leading causes of death during laparoscopic procedures. An analysis of Pennsylvania Patient Safety Reporting System (PA-PSRS) event reports, hereafter referred to as "reports," was performed to find out what types and frequency of trocar-related safety events have occurred in minimally invasive surgeries within Pennsylvania hospitals and ambulatory surgical facilities (ASFs).

# Methods

We queried PA-PSRS free-text data fields using keywords "trocar," "trochar," "laceration," "Hasson," "Seldinger technique," "laparoscopy," "obturator," "Veress," and "Veress needle" to identify minimally invasive surgical, trocar-related safety events that occurred between January 1, 2014, and June 30, 2020.

A two-step process refined the initial data set.

• A second keyword search<sup>b</sup> of the free-text data fields narrowed the number of potentially appropriate

- reports. Manual review of these reports determined inclusion in the final data set.
- A manual review of the remaining reports identified additional trocar-related reports not captured in the keyword search. The exclusion criteria applied during this review comprised the following conditions: equipment issues such as defective trocars, broken specimen bags, and sterilization issues such as biofilm or tissue found on trocars; lost surgical specimens that mentioned a trocar; aborted procedures due to contraindications such as administration of anticoagulants prior to surgery; ophthalmologic procedures that used trocars; and reports that contained the word "trocar" within another term, such as electrocardiogram, retrocardiac, and dextrocardia. All non-trocar-related reports were excluded.

### Results

# **Demographic Analysis**

The data query identified 810 reports. Review and analysis of the report descriptions narrowed the final dataset to 268 tro-car-related reports. Women accounted for 79.9% (214 of 268) of the reports and men accounted for 20.1% (54 of 268). The median patient age was 51.5 years, interquartile range is 39–65 years old (25<sup>th</sup> percentile and 75<sup>th</sup> percentile). The majority of these events occurred in a hospital (95.1%; 255 of 268); the remaining 4.9% (13 of 268) occurred in an ASF.

# **Qualitative Analysis**

### **Surgical Procedures**

All 268 reports were surgical procedures. In 69.8% (187 of 268) of the reports, the surgical procedure was identified. Gynecological procedures accounted for 47.6% (89 of 187), followed by cholecystectomies 17.1% (32 of 187) and hernia repairs 9.6% (18 of 187). In total, we identified 12 categories of surgical procedures. See **Figure 1**.

# **Trocar-Related Categories**

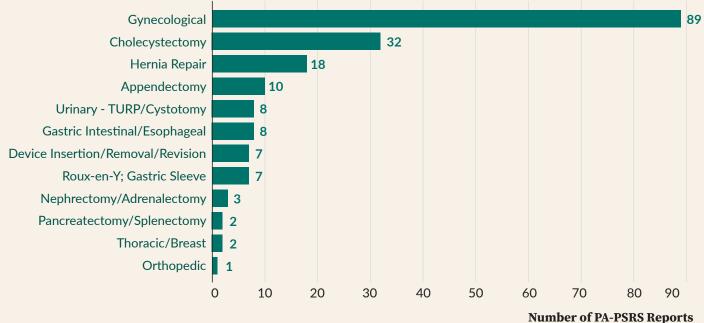
We identified three groups of safety events surrounding the use of trocars and Veress needles: internal organ and vascular injuries 81.0% (217 of 268), hereafter referred to as "internal injuries;" trocar site injuries 17.2% (46 of 268); and vasovagal responses 1.9% (5 of 268).

# **Internal Injuries**

Many PA-PSRS report descriptions identified circumstances with internal injuries based on when they happened; 62.7% (136 of 217) occurred during the initial insertion of the trocar

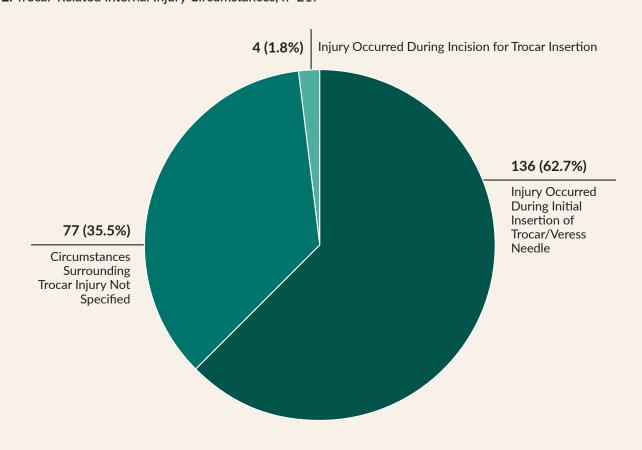
Minimally Invasive Surgical Procedures

Figure 1. Minimally Invasive Surgical Procedures With Trocar-Related Injuries, n=187\*†



<sup>\*</sup>There were 81 reports with no procedure specified.

Figure 2. Trocar-Related Internal Injury Circumstances, n=217



<sup>&</sup>lt;sup>a</sup>PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety-related incidents and serious events in accordance with mandatory reporting laws outlines in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002). <sup>13</sup> All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

<sup>&</sup>lt;sup>b</sup>Keywords for the second search: "perforation", "laceration", "injury", "perforated", "puncture", "injure", "nicked", "bleed", "hemorrhage", "pierce", "damage", and "hematoma".

Vasovagal response, or syncope, is a medical term for a sudden temporary drop in heart rate and blood pressure, causing fainting or passing out. It occurs when the vagus nerve, the part of your nervous system that regulates heart rate and blood pressure, responds to an event, such as extreme emotional duress.<sup>14,15</sup>

<sup>†</sup>Device insertion/removal/revision category are comprised of events involving abdominal ports, pleural drainage catheters, peritoneal dialysis catheters, ventral peritoneal shunts, and central lines.

or Veress needle, 1.8% (4 of 217) occurred when the incision used in preparation for the trocar insertion was made, and 35.5% (77 of 217) of the reports did not specify the circumstances when the trocar injuries occurred. See **Figure 2.** 

In 92.2% (200 of 217) of internal injury reports, one injury per patient was noted; however, 7.8% (17 of 217) described patients who sustained two internal injuries. In total, we identified 234 internal injuries across 217 reports. Below are examples of report descriptions.

During an exploratory laparoscopy procedure, while placing the trocar, two enterotomies [i.e., bowel injuries] were made to the small bowel. The trocars were removed, and the procedure was converted to open to repair the enterotomies.

Patient has history of abdominal surgeries. During a laparoscopy for multiple gastrointestinal procedures, trocar placement went into the bowel. Multiple small bowel enterotomies occurred. There was no place where the bowel was not adhered to the abdominal wall.

Patient for laparoscopic hysterectomy. Vital sign changes noted immediately after the surgeon placed the trocar through the umbilicus. Procedure immediately converted to open incision due to massive bleeding from a punctured aorta. Two additional surgeons were consulted for repair and found a small bowel injury as well. Patient was transferred to ICU post-operatively.

This analysis led to identifying the types of internal injuries. Intestinal injuries occurred most frequently (40.2%; 94 of 234), followed by bladder and kidney injuries (17.1%; 40 of 234), and vascular injuries (12.8%; 30 of 234).

Bladder perforations accounted for 97.5% (39 of 40) of bladder and kidney injuries. In 61.5% (24 of 39) of patients with a bladder injury a foley catheter was used to allow the bladder to heal. The remaining 38.5% (15 of 39) of reports did not state whether a foley catheter was used. More than half (57.5%; 23 of 40) of these injuries occurred during the initial insertion of the trocar. The remaining 42.5% (17 of 40) of reports did not indicate when the injuries occurred.

Figure 3. Number and Location of Trocar-Related Internal Injuries, n=234

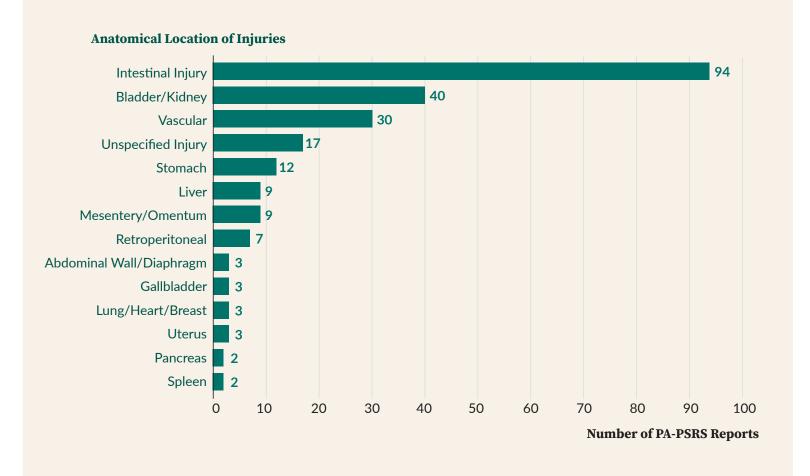
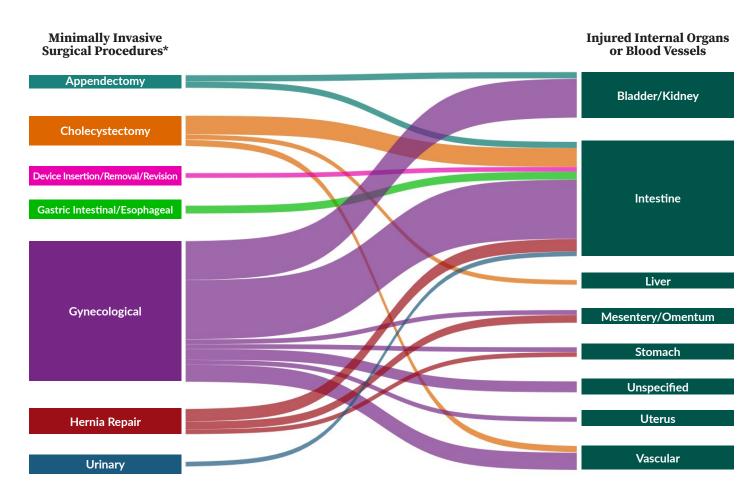


Figure 4. Surgical Procedures and the Associated Internal Injuries



\*This diagram shows paired links between the surgical procedures and the affected organ or blood vessels. The links represent three or more reports in each category shown. The thickness of the links is proportional to the number of reports underlying that specific relationship. Links representing one or two reports between the columns are not presented here. For example, urinary procedures had fewer than three reports in the vascular and bladder/kidney injury categories.

The 30 vascular injuries were described in 29 reports. One patient sustained two vascular injuries. An analysis revealed injuries to the aorta occurred 33.3% (10 of 30) of the time, iliac artery 20.0% (6 of 30), epigastric artery or vein 13.3% (4 of 30), mesenteric artery or vein 13.3% (4 of 30), vena cava 3.3% (1 of 30), and arterial bleeding site not specified 16.7% (5 of 30). Eighteen of the 29 vascular events (62.1%) reported an injury happening during the initial insertion of a trocar or Veress needle.

Figure 3 displays the number and location of all internal injuries.

To understand the link between the surgical procedures and the affected internal injuries, a Sankey diagram was created. The links between the two columns are based on three or more reports in each category shown. See **Figure 4.** 

### **Outcomes**

Surgical outcomes were identified in 44.7% (97 of 217) of the internal injury reports. They were grouped by changes in the

procedure, additional care provided during the same admission, additional care postdischarge, or death. Many reports noted more than one outcome. See **Figure 5**.

In 69.1% (67 of 97) of reports that described the decision to convert the surgery to an open procedure, intestinal injuries were the most frequent reason (52.2%; 35 of 67) followed by vascular injuries (19.4%; 13 of 67).

In 6.5% of the reports (14 of 97), patients required ICU care postoperatively. Fifty percent (7 of 14) of these patients experienced a vascular injury. The two reported deaths also occurred in patients with a vascular injury.

Six of 13 (46.2%) reports submitted by ASFs identified patients who were transferred to a hospital for additional surgery, evaluation, and monitoring.

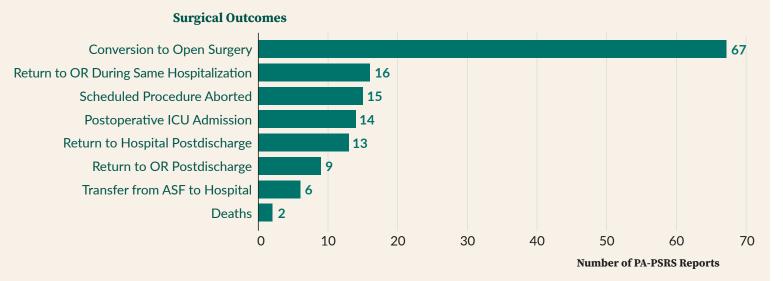
Nearly three-quarters (69.2%; 9 of 13) of the patients that returned to the hospital postdischarge returned to the operating room (OR).

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<sup>&</sup>lt;sup>d</sup> PA-PSRS does not provide patient identifiers. When we use the word patient, we are referring to the person receiving care described in the event report. There is no way for us to confirm each patient is unique.

eTotal does not add up to 100% due to rounding.

Figure 5. Internal Injury Outcomes, n=97 Reports\*



\* The 141 outcomes were described in 97 reports. Many patients experienced more than one of these outcomes.

Adhesions played a role in patient outcomes. They were noted in 16.1% (35 of 217) of the reports, and in 40% (14 of 35) of these reports, the description acknowledged a history of adhesions or expectation of possible adhesions based on the patient's prior surgical history. The remaining reports do not identify the presence of adhesions *a priori* and/or did not state the patient's past surgical history.

Intestinal injuries accounted for 65.7% (23 of 34) of these patient injuries and 69.5% (10 of 23) had their procedure converted to an open surgery. Four of the 34 (11.8%) patients returned to the hospital and the OR for a bowel perforation and/or resection.

# **Trocar Site Injuries**

Trocar site injuries included skin integrity issues, infections, bleeding/hematomas, and hernias. Skin integrity issues accounted for 56.5% (26 of 46) of the trocar site reports. Many of these reports identified minor injuries such as abrasions, bruising, skin tears, lacerations, and a potential burn.

Trocar site bleeding and hematomas were grouped together and accounted for 26.1% (12 of 46) of these reports. Eleven of these 12 patients returned to the OR to address the underlying cause for the bleeding or hematoma. Trocar site hernias occurred in 7 patients (15.2%). One patient with hernia had an adhesion. Below are report descriptions.

Patient had laparoscopy. In the post-acute care unit, a nurse discovered a hematoma developing at an abdominal trocar site. The patient returned to the operating room for evacuation of the fluid.

Patient returned to the hospital two weeks after robotic prostate surgery with complaint of fluid leaking from the abdominal incision. Patient returned to the operating room to close the leaking trocar site. Patient had laparoscopic cholecystectomy [i.e., gallbladder removal]. Patient returned to the emergency department after discharge with abdominal pain and low-grade fever. Imaging showed a small bowel obstruction due to an incarcerated umbilical hernia, [i.e., bowel trapped in the abdominal wall] through the trocar site. Patient returned to the operating room where it was found the bowel had returned to the abdominal cavity. The connective tissue around the trocar site was closed and patient was admitted.

Patient had laparoscopic appendectomy and was discharged home the same day. Four days after the procedure, patient presented to the emergency room with nausea, vomiting, and abdominal pain. Patient returned to surgery to repair a trocar site hernia. The bowel was incarcerated but still viable.

### **Outcomes**

Trocar site outcomes were described in 43.5% (20 of 46) of these reports. They were grouped by additional care provided during the same admission or return to the hospital postdischarge.

Returning to the OR during the same admission due to trocar site bleeding or hematomas was described in 50% (10 of 20) of the reports with outcome descriptions. One report described a patient with trocar site bleeding that received ICU care postoperatively. Nine reports described patients returning to the hospital postdischarge of which 77.8% (7 of 9) went back into surgery. All 7 patients had trocar site hernias. Two trocar site skin infections were reported. One patient returned to the hospital due to a trocar site infection.

# Vasovagal Responses

Five reports described vasovagal responses to the insertion of the trocar. Cardiac arrest occurred in 60.0% (3 of 5) and unstable vital

signs, e.g., diaphoresis, unresponsive (noncardiac arrest), and respiratory arrest (i.e., stopped breathing) occurred in 40.0% (2 of 5) patients. All five reports described the patients were successfully resuscitated and/or stabilized. One patient was observed in the ICU overnight. All five procedures were aborted.

Patient scheduled for minimally invasive surgical procedure. During placement of the trocar, the patient's heart rate dropped then went asystolic [i.e., heart stopped beating]. CPR was successfully performed, and the procedure was aborted. Evaluation post-operatively showed this was likely a vasovagal response from the trocar placement.

After inserting the trocar, the patient stopped breathing. Chest x-ray showed no evidence of pneumothorax, (i.e., collapsed lung). The procedure was aborted, and patient was evaluated post-operatively.

# Discussion

Most patients have no complications following minimally invasive surgery. However, there are times when injuries may exist and go undetected until a later time postdischarge.<sup>6</sup> This situation can lead to health emergencies.

Our data shows intestinal injuries were the most frequently reported injury with some requiring readmissions. Delays in diagnosing intestinal injuries are a recognized issue that can lead to life-threatening illness and death.<sup>2, 3, 11</sup> We have reports of patients with intestinal injuries returning to the hospital and OR postdischarge requiring additional care.

The two next most frequent injuries, bladder and vascular, provided information that deviated from the literature. Urinary injuries have been identified as more likely to occur during the insertion of a second trocar.<sup>3</sup> Our reports described close to 60% of bladder injuries occurred during the insertion of the initial trocar. Regarding vascular injuries, they usually occur during the initial insertion of a trocar or Veress needle.<sup>7, 9</sup> Our data shows almost two-thirds of the vascular injuries occurred during the initial insertion.

Two patient characteristics that can affect laparoscopic surgical outcomes and internal injuries are abdominal adhesions and body size. Abdominal adhesions are bands of scarlike tissue that form between two or more organs or between organs and the abdominal wall. They are common and often develop after abdominal surgery. Adhesions and scarring can result in organs such as the intestine adhering to the abdominal wall or other organs, increasing the likelihood of the trocar/Veress needle perforating or nicking an organ during insertion. In the same of the same of the same organ during insertion.

Body size is an important consideration during minimally invasive procedures<sup>4-8, 17-21</sup> because anatomical landmarks of the aorta to the umbilicus vary with body size.<sup>18, 20-22</sup> Thin patients are at higher risk for complications such as vascular or intestinal injuries during the initial trocar insertion due to a small amount of space between their abdominal wall, organs, and major vessels.<sup>4,5, 20</sup> Patients who are obese, depending on their abdominal girth and weight, have challenges due to the size of their panniculus, (i.e., excess fatty tissue in the lower abdomen), and the hospital's or ASF's ability to have the appropriately sized equipment to successfully carry out the surgery.<sup>18,19,21</sup>

### **Trocar Site Injuries**

Trocar site injuries identified in this analysis included bleeding/hematomas, hernia, and skin injuries/infections. Trocar site bleeding and hematomas may not be noticed immediately. A couple of reports described vital sign changes and drops in hemoglobin and hematocrit postoperatively that signaled further investigation. Issues such as fascia bleeding and possible arterial bleeders were identified, and all but one case required a return to the OR to address the hematoma and control the bleeding.

Another serious issue is postoperative trocar site hernias. They may be asymptomatic<sup>23-26</sup> or require emergency surgery.<sup>24,25</sup> Left unattended they can result in incarcerated hernias (i.e., bowel is trapped in the abdominal wall),<sup>27</sup> strangulated hernias (i.e., trapped bowel and blood is cut off to the bowel),<sup>28</sup> bowel obstructions,<sup>27,29</sup> and necrotic bowels.<sup>30</sup> One study identified umbilical incisional hernias occurred three to 36 months (mean, 8.8 months) after the operation.<sup>28</sup> The literature surrounding potential hernia development postoperatively addresses the impact of trocar size.<sup>3,23-25,27,31-34</sup> Hernias are more likely to occur when a 10 mm or larger trocar is used,<sup>23,24,27,31,33,35</sup> yet, they can form when 5 mm trocars are used.<sup>23,24,27,31,34,35</sup> Body size also plays a role in hernia formation. Obese patients are at higher risk of hernias because of increased intra-abdominal pressure.<sup>27</sup>

Skin injuries ranged from red marks and skin tears to lacerations and abrasions. The report descriptions indicated that these were minor injuries. The 2 infections were addressed with antibiotics.

# Vasovagal Responses

Cardiac arrests and reduced pulmonary compliance can occur with the insufflation of carbon dioxide (CO2) in the peritoneum.<sup>36,</sup> <sup>37</sup> There is a paucity of information regarding patients who have a vasovagal response with the insertion of the trocar. Yong et. al. identified vagal responses as a potential cause for cardiac arrest due to rapid peritoneal distension with CO2 insufflation and identified cases of pelvic organ manipulation leading to severe vagal responses.<sup>37</sup> One case study identified what was believed to be a case of a severe vagal reaction and asystolic cardiac arrest triggered by manipulation of the patient's gallbladder.<sup>38</sup> While this report was not associated with a trocar insertion, it was also believed not to be associated with CO2 insufflation in the peritoneum. Our reports described situations of cardiac arrest and unstable vital signs as occurring when the trocar was inserted. There was no mention of CO2 insufflation. Reports with a cardiac arrest when CO2 was inserted into a patient's abdomen were excluded from this data set.

# General Safety Measures to Reduce the Risks of Trocar-Related Safety Events

The general safety measures listed below provide ways to identify, address, and mitigate circumstances that can increase the likelihood of injuries. One statement found in the literature suggested selecting patients at low risk for complications.<sup>2</sup> This goal is hard to achieve. Surgeons are faced with patients who present with comorbidities (i.e., patients with one or more chronic health conditions)<sup>39-41</sup> that raise the likelihood of injuries.

Obesity is a good example. Between 1999 and 2018, the prevalence of obesity increased from 30.5% to 42.4% and the prevalence of severe obesity increased from 4.7% to 9.2%.  $^{42}\,\rm This$  population has challenges with the size of their abdominal girth along with an

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increased risk for many serious health conditions such as hypertension (i.e., high blood pressure), diabetes, heart disease, gall-bladder disease, sleep apnea, and stroke.<sup>43</sup> Even with the higher risk of injury, it has been identified that patients who are obese benefit from minimally invasive surgery compared to undergoing laparotomy (i.e., open surgery).<sup>18,21</sup>

Incorporating these safety measures can assist the physician in weighing the risks and benefits of performing minimally invasive surgery versus open surgery and making the appropriate recommendation of care for the patient.

- Screen patients for history of surgical procedures; medical comorbidities (e.g., respiratory function in patients who are obese, obstructive sleep apnea, or history of smoking) and conditions that increase the likelihood of intra-abdominal adhesions (e.g., prior open or laparoscopic surgical procedures, endometriosis, pelvic inflammatory disease, or inflammatory bowel disease); and history of adhesions<sup>3, 4, 7, 21</sup>
- Consider patients with more than two prior abdominal procedures at higher risk of having an inadvertent enterotomy<sup>12</sup>
- Identify high-risk patients (e.g., patients with prior open or laparoscopic surgery) and tailor consent appropriately<sup>17</sup>
- Evaluate patient's body type prior to beginning the procedure<sup>5,7</sup>
- Prior to surgery, determine if the size of available surgical equipment (e.g., Veress needle or trocars), along with standard equipment (e.g., blood pressure cuffs or stretchers) are the right size for patients who are obese<sup>19,21,44,45</sup>
- Consider strategies to reduce chances of injury during trocar insertion, e.g., Palmer's point for patients who are either thin or morbidly obese 5,6,8,18,20,21 and patients at risk of adhesions 2,5,6,20
- Evaluate alternative entry sites and techniques based on history, body size, and procedure<sup>2,7</sup>
- Seek consultation from experienced colleagues regarding questions about addressing concerns when caring for high-risk patients prior to starting the procedure<sup>12</sup>
- Investigate preoperative ultrasound, which has been shown to help identify the presence and location of adhesions in high-risk patients prior to laparoscopic surgery<sup>46-49</sup>
- Maintain a low threshold for imaging or investigation in the postoperative period when there is a high suspicion of injury<sup>17</sup>
- Arrange at minimum to have a general surgeon on standby in case of emergency patient complications.
   When possible, have specialty surgeons (e.g., vascular and/or gastrointestinal) on standby<sup>2,17</sup>
- Be vigilant in observing for injuries and upon recognition of injury immediately apply appropriate surgical management; check and recheck suspected areas of injury<sup>2,12</sup>
- Report adverse events involving the use of trocars through the Food and Drug Administration's voluntary adverse event reporting program<sup>50</sup> and, for Pennsylvania facilities, report adverse events to PA-PSRS.

- Patient education safety measures:
  - o Encourage patients to:
    - Ask their surgeon about alternative procedures<sup>2</sup>
    - Carefully read all preoperative and postoperative materials<sup>2</sup>
    - Seek clarification of any unclear or confusing instructions<sup>2</sup>
    - Seek medical attention immediately if signs or symptoms of complications develop<sup>2</sup>
  - Provide patients with information about signs and symptoms of any unrecognized trocar injury after the procedure, such as trocar site hernia<sup>2,7,49,51</sup>
  - Offer clear explanations to the patient in the written consent and information given regarding the risks and potential complications, including serious risks associated with laparoscopic surgery and possibility of conversion to laparotomy if clinical circumstances dictate or repairs to bowel, bladder, or blood vessels are necessary<sup>2,4,6,7,21,49,51</sup>
  - Counsel patients about individual risk related to their body mass index<sup>6,7</sup>

There are a couple of evidence-based suggestions about closure of trocar sites and hernias.

- Fascial closing is recommended when using 10 mm or larger trocars<sup>3,23,52</sup>
- There are mixed results regarding closing the fascia around the trocar site of a 5 mm trocar versus leaving it open<sup>23,24,27,35,52</sup>

# Limitations

The narrative section of event reports submitted to PA-PSRS are provided by healthcare staff as an open-ended story. The information provided in these report descriptions varies, thereby limiting certain information and conclusions. For example, reports can include long descriptions about the procedure, injury, and circumstances surrounding the injury, or may be a short sentence with very little detail. Patient weight is also unknown, limiting conclusions about body size in relation to a vascular injury. Infection reporting requirements also vary. Pennsylvania hospitals report infections to the Centers for Disease Control and Prevention's National Healthcare Safety Network, whereas ASFs report infections to PA-PSRS. Therefore, the total number of trocar site infections is unknown. The paucity of data on patients who had similar procedures coupled with possible underreporting of trocar injuries prevents calculating complication rates. Finally, information about complications arising from these injuries in the future, such as delays in identification of an intestinal injury, may be reported but there is no direct link of future events with earlier reports. The only way a future event is captured and linked with a prior surgery is when the reporter provides detailed information such as the initial surgical date, procedure performed, type of trocar, and high-risk situations.

# **Conclusions**

No surgical procedure is without risks. Our analysis revealed intestinal injuries and complications were the most frequent patient safety event associated with laparoscopic trocar insertions. Urinary and vascular injuries were the next two most frequent patient safety events, respectively. The general safety measures presented in this article offer risk reduction strategies for surgeons to consider when encountering patient conditions that can increase the chance of an injury. One risk reduction strategy we identified involves educating patients about their procedure and engaging them in a discussion with their surgeon. This interaction provides patients an opportunity to express preferences about their care and making informed decisions. 53,54 It has been shown that engaged, knowledgeable patients have better health outcomes and better care experiences. 54,55 Surgeons can use patient information gained preoperatively to weigh the risks and benefits of performing minimally invasive surgery versus open surgery and make the appropriate recommendation of care for their patients. Suggestions for future research on this topic include updated complication rates, as current available rates date back to the 1990s and 2000s. Updated complication rates can help identify trends based on current evidence-based practices. Another area of research is the impact of patient education and engagement on patient choices and outcomes.

# **Notes**

This analysis was exempted from review by the Advarra Institutional Review Board.

### References

- 1. American Institute of Minimally Invasive Surgery. Benefits of Minimally Invasive Surgery 2020 [cited 2020 28 August]. Available from: https://aimis.org/benefits-of-minimally-invasive-surgery/.
- 2. Fuller J SW, Ashar B, Corrado J,. Laparoscopic Trocar Injuries: A Report from a U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) Systematic Technology Assessment of Medical Products (STAMP) Committee: FDA Safety Communication. In: FDA, editor. Silver Sping, MD2003.
- 3. Hindman NM KS, Parikh MS,. Common Postoperative Findings Unique to Laparoscopic Surgery. RadioGraphics. 2014;34(1):119-38. doi: https://doi.org/10.1148/rg.341125181.
- 4. Krishnakumar S TP. Entry Complications in Laparascopic Surgery. *J Gynecol Endosc Surg*. 2009;1(1):4-11. doi: 10.4103/0974-1216.51902. PubMed Central PMCID: PMCPMC3304260.
- 5. Djokovic D GJ, Thomas V, Maher P, Ternamian A, Vilos G, L:oddo A, Reich H, Downes E, Rachman IA, Clevin L, Abrao MS, Keckstein G, Stark M, van Herendael B. ·Principles of Safe Laparoscopic Entry. *Eur J Obstet Gynecol Reprod Biol.* 2016;201:179-88. doi: http://dx.doi.org/10.1016/j.ejogrb.2016.03.040.
- 6. Royal College of Obstetricians and Gynaecologists. Preventing Entry-Related Gynaecological Laparoscopic Injuries: Green-top Guideline No. 49. 2008.

- 7. Alkatout I. Complications of Laparoscopy in Connection with Entry Techniques. *J Gynecol Surg.* 2017;33(3):81-91. doi: 10.1089/gyn.2016.0111.
- 8. Thepsuwan J HK, Wilamarta M, Adlan AS, Manvelyan V, Lee CL,. Principles of Safe Abdominal Entry in Laparoscopic Gynecologic Surgery. *Gynecol Minim Invasive Ther.* 2013;2:105-9.
- 9. Belena JM NM. Postoperative Complications of Laparoscopic Surgery. *Int J Clin Anesthesiol*. 2014;2(3):1034-9.
- 10. Jacobson MT OS, Milki A, Nezhat C,. Laparoscopic Control of a Leaking Inferior Mesenteric Vessel Secondary to Trocar Injury. *JSLS*. 2002;6(4):389-91. PubMed Central PMCID: PMCPMC3043438.
- 11. LeBlanc KA EM, Corder III JM,. Enterotomy and Mortality Rates of Laparoscopic Incisional and Ventral Hernia Repair: A Review of the Literature. *JSLS*. 2007;11(4):408-14. PubMed Central PMCID: PMCPMC3015847.
- 12. Binenbaum S GM. Inadvertent Enterotomy in Minimally Invasive Abdominal Surgery. *JSLS*. 2006;10:336-40.
- 13. Karadag MA CK, Demir A, Bagcioglu M, Kocaaslan R, Kadioglu TC,. Gastrointestingal Complications of Laparoscopic/Robot-Assisted Urologic Surgery and a Review of the LIterature. *J Clin Med Res.* 2015;7(4):203-10. doi: http://dx.doi.org/10.14740/jocmr2090w.
- 14. Mayo Clinic. Vasovagal Syncope 2018. Available from: https://www.mayoclinic.org/diseases-conditions/vasovagal-syncope/symptoms-causes/syc-20350527.
- 15. Cedars Sinai. Vasovagal Syncope 2020. Available from: https://www.cedars-sinai.org/health-library/diseases-and-conditions/v/vasovagal-syncope.html.
- 16. National Institute of Diabetes and Digestive and Kidney Diseases. Abdominal Adhesions 2019 [cited 2020 27 August]. Available from: https://www.niddk.nih.gov/health-information/digestive-diseases/abdominal-adhesions.
- 17. O'Donovan OP VA. Complications of Laparoscopic Surgery. *Obstet Gynaecol Reprod Med.* 2017;27(7):213-7.
- 18. Biswas N HP. Review Surgical Risk From Obesity in Gynaecology. *Obstet Gynecol*. 2011;13:87-91. doi: 10.1576/toag.13.2.87.27651.
- 19. American College of Obstetricians and Gynecologists. Gynecologic Surgery in the Obese Woman: Committee Opinion. 2015. p. 1-5.
- 20. la Chapelle CF BW, Rademaker BMP, van Barneveld TA, Jansen FW,. A Multidisciplinary Evidence-Based Guidelines for Minimally Invasive Surgery: Part 1: Entry Techniques and the Pneumoperitoneum. *Gynecol Surg.* 2012;9(3):281-82. doi: 10.1007/s10397-012-0731-y. PubMed Central PMCID: PMCPMC3401300.
- 21. Scheib SA TIE, Green IC, Fader AN,. Laparoscopy in the Morbidly Obese: Physiologic Considerations and Surgical Techniques to Optimize Success. *J Minim Invasive Gynecol*. 2014;21:182-95. doi: http://dx.doi.org/10.1016/j.jmig.2013.09.009.
- 22. Hurd WW BR, DeLancey JOL, Pearl ML,. The Relationship of the Umbilicus to the Aortic Bifurcation: Implications for Laparoscopic Technique. *Obstet Gynecol.* 1992;80:48-51.
- 23. Dincel P BF, Goksu M,. Causes of Asymptomatic Trocar

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- Site Hernia: How Can it be Prevented? North Clin Istanbul. 2015;2(3):210-14. doi: 10.14744/nci.2015.50479.
- 24. Gogacz M KA, Winkler I, Adamiak A, REchberger T, Phillipe K,. Suture or Not to Suture? Trocar-Site Bowel Herniation as a Rare Complication after Trocar Placement in Laparoscopic Surgery: Case Report and Review. *Clin Surg.* 2018;3.
- 25. Karampinis I LE, Hetjens S, Vassilev G, Galata C, Reissfelder C, Otto M,. Trocar Site HERnias after Bariatric Laparoscopic Surgery (HERBALS): A Prospective Cohort Study. *Obes Surg*. 2020;30:1820-26.
- 26. Rossi A MD, Witte S, LynSue J, Haluck RS, Rogers AM,. An Expanded Retrospective Review of Trocar Site Hernias in Laparoscopic Gastric Bypass Patients. *J Laparoendosc Adv Surg Tech.* 2017;27(6):633-5. doi: 10.1089/lap.2016.0483.
- 27. Tonouchi H OY, Kobayashi M, Kusunoki M, Trocar Site Hernia. ARch Surg. 2004;139:1248-56.
- 28. Coda A BM, Ferri F, Mattio R, Ramelini G, Poma A, Quaglino F, Filippa C, Alberto B, Incisional Hernia and Fascial Defect Following Laparoscopic Surgery. *Surg Laparosc Endosc Percutan Tech.* 2000;10(1):34-8.
- 29. Phillips E SD, Towfigh S,. Working Port-Site Hernias: To Close or Not to Close? Does it Matter in the Obese? Bariatric Times. 2011;8(6):24-30.
- 30. Delmonaco P CR, La Mura F, Morelli U, Migliaccio C, Napolitano V, Trastulli S, Farinella E, Giuliani D, Desol A, Milani D, Di Patrizi MS, Spizzirri A, Bravetti M, Sciannameo V, Avenia N, Francesco S, . Trocar Site Hernia After Laparoscopic Colectomy: A Case Report and LIterature Review. *Int Sch Res Notices*. 2011:1-7. doi: 10.5402/2011/725601.
- 31. Karthik S AA, Shibumon MM, Pai MV, Analysis of Laparoscopic Port Site Complications: A Descriptive Study. *J Min Access Surg.* 2013;9(2):59-64.
- 32. Kang DI WS, Lee DH, Kim IY,. Incidence of Port-Site Hernias After Robot-Assisted Radical Prostatectomy with the Fascial Closure of Only the Midline 12-mm Port Site. *J Endourol*. 2012;26(7):848-51. doi: 10.1089/end.2011.0630.
- 33. Nofai MN YA, Hamdan FF, Oudat AH,. Characteristics of Trocar Site Hernia after Laparoscopic Cholecystectomy. 10. 2020:2868. doi: https://www.nature.com/articles/s41598-020-59721-w.
- 34. Chorti A AS, Michalopoulos A, Papavramidis TS,. Richter's Hernia in a 5-mm Trocar Site. *SAGE Open Med Case Rep.* 2019;7:1-4. doi: DOI: 10.1177/2050313X18823413.
- 35. Yamamoto M ML, Zaritsky E,. Laparoscopic 5-mm Trocar Site Herniation and Literature Review. *JSLS*. 2011;15:122-6. doi: DOI: 10.4293/108680811X13022985131697.
- 36. Atkinson TM GG, Togioka BM, Jones DB, Cigarroa JE,. Cardiovascular and Ventilatory Consequences of Laparoscopic Surgery. *Circulation*. 2017;135:700-10. doi: 10.1161/ CIRCULATIONAHA.116.023262.
- 37. Yong J HP, Runciman WB, Coventry BJ,. Bradycardia as an Early Warning Sign for Cardiac Arrest During Routine Laparoscopic Surgery. *J Qual Health Care*. 2015;27(6):473-78. doi: 10.1093/intqhc/mzv077.

- 38. Valentin MD TN, Dolgin C,. Recurrent Asystolic Cardiac Arrest and Laparoscopic Cholecystectomy: A Case Report and Review of the Literature. JSLS. 2004;8:65-8.
- 39. Centers for Disease Control and Prevention. Chronic Diseases in America: US Department of Health and Human Services; 2019 [cited 2020 16 September]. Available from: https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm.
- 40. National Council on Aging. Health Aging. Washington DC: National Council on Aging; 2014. p. 2.
- 41. Akinyemiju T JM, Moore JX, Pisu M,. Disparities in the Prevalence of Comorbidities Among US Adults by State Medicaid Expansion Status. *Prev Med.* 2016;88:196-202. doi: http://dx.doi.org/10.1016/j.ypmed.2016.04.009.
- 42. Centers for Disease Control and Prevention. Adult Obesity Facts 2020 [16 September 2020]. Available from: https://www.cdc.gov/obesity/data/adult.html.
- 43. Centers for Disease Control and Prevention. Adult Obesity Causes and Consequences 2020 [16 September 2020]. Available from: https://www.cdc.gov/obesity/adult/causes.html.
- 44. Gardner LA GC. Class III Obese Patients: Is Your Hospital Equipped to Address Their Needs? *PA Patient Saf Advis*. 2013;10(1):11-8.
- 45. Kukielka E. How Safety Is Compromised When Hospital Equipment Is a Poor Fit for Patients Who are Obese. *Patient Saf.* 2020;2(1):49-54. doi: 10.33940/data/2020.3.4.
- 46. Tu FF LG, Hartmann KE, Steege JF, Preoperative Ultrasound to Predict Infraumbilical Adhesions: A Study of Diagnostic Accuracy. *Am J Obstet Gynecol.* 2005;192:74-9. doi: 10.1016/j. ajog.2004.07.034.
- 47. Minaker S MC, Hayashi A,. Can General Surgeons Evaluate Visceral Slide with Transabdonimal Ultrasound to Predict Safe Sites for Primary Laparoscopic Port Placement? A Prospective Study of Sonographically Naive Operators at a Tertiary Center. *Am J Surg.* 2015;209:804-9.
- 48. Kothari SN FL, Lambert PJ, Mathiason MA,. Use of Transabdominal Ultrasoundto Identify Intraabdominal Adhesions Prior to Laparoscopy: A Prospective Blinded Study. *Am J Surg.* 2006;192:843-7. doi: 10.1016/j.amjsurg.2006.08.055.
- 49. Society of American Gastrointestingal and Endoscopic Surgeons (SAGES). Diagnostic Laparoscopy Patient Information From Sages. 2015.
- 50. U.S. Food and Drug Administration. MedWatch: The FDA Safety Information and Adverse Event Reporting Program 2020 [cited 2020 15 Oct]. Available from: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.
- 51. Royal College of Obstetricians and Gynaecologists. Diagnostic Laparoscopy: Consent Advice No. 2. 2008.
- 52. la Chapelle CF BW, Bongers MY, van Barneveld TA, Jansen FW,. A Multidisciplinary Evidence-Based Guidelines for Minially Invasive Surgery: Part 2 Laparoscopic Port Instruments, Trocar Site Closure, and Electrosurgical Techniques. *Gynecol Surg.* 2013;10:11-23. doi: 10.1007/s10397-012-0776-y.