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Techniques and Procedures

PIGTAIL CATHETER INSERTION ERROR: ROOT CAUSE ANALYSIS AND RECOMMENDATIONS FOR PATIENT SAFETY

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☐ **Abstract—Background: Small-caliber chest tubes are used to treat pneumothorax and pleural fluid collections. Although commonly considered a less invasive alternative to large-caliber thoracostomy tubes, small-caliber tubes have a high complication rate. Emergency physicians must be familiar with common and dangerous procedure complications associated with these devices and have a systematic and rapid approach to identify and solve malfunctions. Structured root cause analysis can facilitate identification of problems. Methods: We reviewed the medical literature for complications of small-caliber chest tubes and searched the U.S. Food and Drug Administration (FDA) database for complications of a specific pigtail catheter kit. Using a structured root cause analysis (RCA), we examined two cases of retained pigtail catheter obturators resulting in catheter malfunction and unresolved pneumothorax. Results: We identified common complications of pigtail catheters from the medical literature, as well as 28 reports to FDA of complications with the kit used in the analyzed cases; ours were the only reports of the obturator error. RCA identified multiple contributing factors, including unrecognized and novel radiographic clues, human errors, communication breakdown, device design, and opportunities for improved systematic procedural approach. Discussion: We discuss factors identified in RCA and regulatory considerations relevant to emergency physicians, including FDA reporting mechanisms. Conclusions: A structured review of complications of pigtail catheter insertion revealed opportunities for improved patient safety. We highlight a preventable error in insertion of a percutaneous catheter and describe radiographic features to enhance error detection. Improved design, systematic processes for device insertion and troubleshooting, and enhanced provider education could reduce the risk of medical device errors. An end-of-procedure time-out including instrument counts and systematic assessment of device function is a generalizable patient safety measure for bedside procedures.**

☐ **Keywords—patient safety; medical devices; imaging; medical errors; pneumothorax**

INTRODUCTION

Small-caliber chest tubes are used to treat pneumothorax and pleural fluid collections. Clinicians, diagnostic radiologists, and interventional radiologists must be familiar with common and dangerous procedure complications associated with these devices and have a systematic and rapid approach to identify and solve malfunctions. We previously reported an error with insertion of a pigtail catheter and described a root cause analysis (RCA) (1). As a consequence, the manufacturer modified the kit to include more explicit warning instructions to reduce the risk of similar errors. Here we report an additional error in insertion with the same percutaneous catheter kit and identify radiographic features as well as additional specific and generalizable design and process features that could improve patient safety.

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CASE REPORTS

Case 1

A 43-year-old man with sarcoma presented with dyspnea. Chest x-ray study (Figure 1A) demonstrated left pneumothorax and metastatic disease. The patient's respiratory distress worsened, and a 14.0-Fr catheter (Wayne Pneumothorax Tray, Cook Medical, Bloomington, IN) was placed (Figure 1B). A series of chest x-ray studies were obtained due to unresolved symptoms, each showing residual pneumothorax. Chest computed tomography (CT) confirmed the catheter position in the pleural space (Figure 2A). Ultimately, the catheter obturator, used to stiffen and straighten the catheter for insertion, was found not to have been removed as intended. The obturator was then removed, but the function of the catheter could not be restored, and a larger thoracostomy tube was placed. The error was reported through the institution's electronic safety reporting system and disclosed to the patient's family.

Case 2

A 40-year-old male patient presented after a motor vehicle collision. Chest x-ray study revealed a pneumothorax, and a 14.0-Fr catheter (Wayne Pneumothorax Tray) was placed. Approximately 30 min later, the patient's symptoms had not improved, and the obturator was found within the catheter. Removal of the obturator resolved the pneumothorax and patient symptoms. The error was disclosed to the patient and reported through the institution's safety reporting system.

After each event, the device errors and risks were reported to the U.S. Food and Drug Administration (FDA) and to the device manufacturer.

METHODS

We conducted a review of the literature with the aid of a trained reference librarian (acknowledgement: Leila Ledbetter, MLIS. Research and Education Librarian, Duke University Medical Center Library. DUMC 3702, Durham, NC 27710 leila.ledbetter@duke.edu) to further understand the frequency and type of complications of small-caliber chest tubes. We also searched the FDA online database, Manufacturer and User Facility Device Experience (MAUDE), which includes reports filed through the MedWatch Program, to assess the frequency of the observed error and other complications of the catheter used in the cases reviewed (2).

The events were analyzed using a standard RCA (Table 1) (3). We also examined the errors using previously published design, engineering, and human factors analyses (3–11). The RCA was conducted by a board-certified emergency physician with 17 years of postresidency experience and prior RCA expertise, a board-certified general surgeon and surgical critical care physician with 13 years of posttraining experience, a board-certified emergency physician and emergency medical services physician with 4 years of posttraining experience, and a postgraduate year (PGY)-3 emergency medicine resident. The former two physicians were not involved in the analyzed cases and thus could provide an unbiased review; the latter two physicians were involved in one of the two cases and thus, could provide insights based on their personal experiences with the procedure and medical device.

Our Institutional Review Board exempts case series of three or fewer from review. Informed consent was obtained from the patient's legally authorized representative (case 1) and patient (case 2).

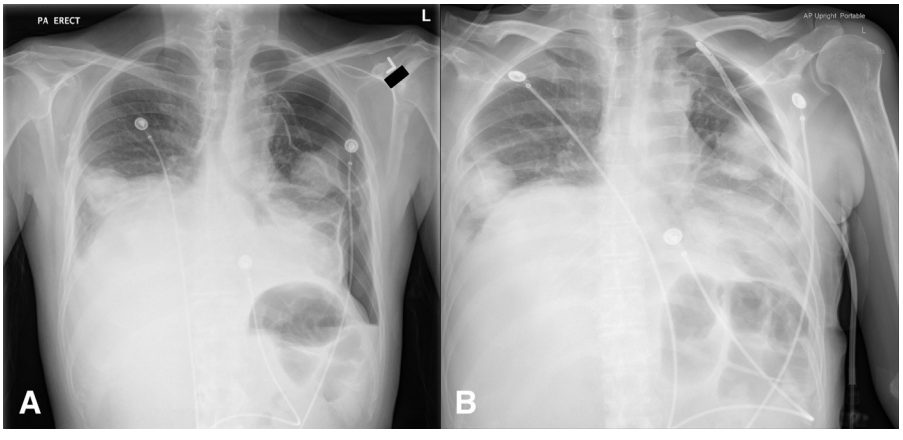

Figure 1. Clues to retained catheter obturator. (A) Initial chest radiograph. A left pneumothorax is present. (B) A 14.0-Fr pigtail catheter (Wayne Pneumothorax Tray; Cook Medical, Bloomington, IN) has been inserted. Several radiographic clues exist to indicate that the catheter is not correctly inserted. These are examined in subsequent figures. The catheter does not have the expected "pigtail" curved shape at its tip, but rather is straight. The obturator is visible within the intrathoracic portion of the catheter and extends out of the extracorporeal portion.

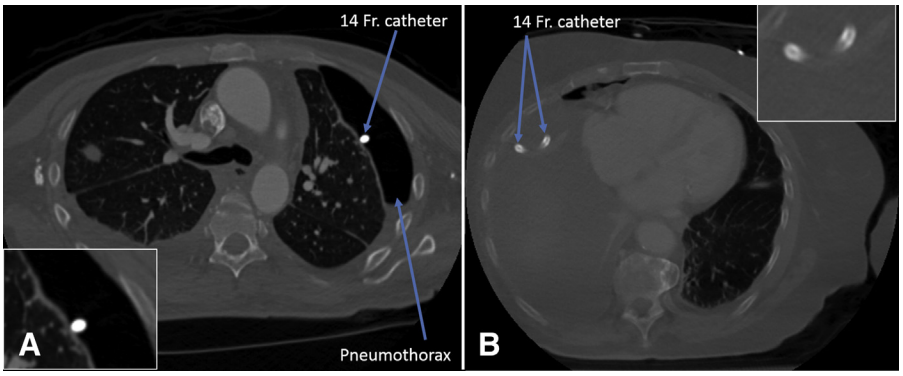

Figure 2. Computed tomography appearance. (A) At left, patient with retained catheter obturator. The 14.0-Fr catheter is visible in cross section, within the pleural space. A pneumothorax is visible. Of note, the catheter appears solid (inset, lower left), not hollow, even on window settings that typically highlight air—another indication that the obturator remains in place. (B) A different patient, with the same catheter type inserted, without the obturator. The catheter tip is curled as expected and also appears hollow (see inset, enlarged, upper right). Both images are depicted with bone windows (C570/W3077).

RESULTS

We searched the medical literature for pigtail catheter complications; most of the described complications are categorized by the types of injuries or complications occurring (e.g., hemothorax, infection, organ injury, failure of the catheter), without much additional information about the features of the equipment or procedure leading to the complication (12). Although commonly considered a less-invasive alternative to large-caliber thoracostomy tubes, small-caliber tubes have a high complication rate, including infection (cellulitis 3%, empyema 3%), catheter dislodgment (2%), catheter malfunction (4%), pneumothorax (6%), and, more rarely, bleeding and injury to adjacent organs such as the liver (12). Immediate complications of the insertion procedure are less well characterized, providing limited information about risks of specific equipment or procedural steps.

Our search of the FDA MAUDE database found that from July 1, 2000 to July 31, 2019, 28 reports were filed on the "Wayne Pneumothorax Tray." The reports included stopcock issues, anatomic misplacement, guidewire unraveling/fracture, reversal of the Heimlich valve, retained obturator, needle issues, catheter displacement, and catheter decomposition (1–4,8). Some reports seem to duplicate the same medical event, perhaps representing reports from the medical provider and manufacturer (the latter having a legal reporting mandate once aware of an

Table 1. Root Cause Analysis of Events, Following a Standard Agency for Health Care Research and Quality Rubric

Root Cause	Application to the Case
Communication problems	Instructions for insertion are insufficient to avoid common procedural errors.
Inadequate information flow	The admitting treatment team was not present during initial placement of the catheter. The emergency department (ED) procedure note did not include step-by-step details of the procedure, as is common in surgical procedure notes.
Human problems	Operator lacked familiarity with the specific device. Radiologists reviewing images may not have known the catheter identity and therefore its expected radiographic appearance.
Patient-related issues	Patients presenting to an ED with trauma or severe symptoms such as dyspnea create a sense of urgency that can undermine a systematic and methodical approach to procedures. Ironically, the emergency environment exemplifies the necessity for a systematic approach applied uniformly to avoid error.
Organizational transfer of knowledge	A system or checklist to ensure that all procedure steps were correctly completed did not exist. No system existed to troubleshoot a malfunctioning catheter.
Staffing patterns/work flow	Multiple health care provider teams (ED, inpatient, surgical consultants) were involved in the care of the patients, also contributing to communication challenges.
Technical failures	The device instructions and design contributed to the error. The device lacks a pictorial list of steps to insert it safely. The presence of the Luer lock connector on the obturator allows incorrect connection. The obturator is inconspicuous in color and is not obvious when left in place in the circuit.
Inadequate policies and procedures	No institutional policy exists mandating prior training on exact medical device to be used. No standard algorithm exists to troubleshoot a malfunctioning device. Postprocedural time-out is not mandated in institution.

Table 2. Stages in Identification and Mitigation of a Medical Error

Stage	Events in the Cases Described
Occurrence of the error	Obturator incorrectly left in place in the chest pigtail circuit.
Patient harm	Pneumothorax persisted, with unresolved symptoms.
	Patient underwent multiple radiographs and catheter manipulations.
	Patient underwent insertion of a large chest tube to replace the malfunctioning pigtail catheter.
Identification/detection	The treatment teams ultimately noted that the obturator was left in place, obstructing the catheter lumen.
Mitigation of patient harm	The obturator was removed/the pigtail catheter was replaced by a large bore thoracostomy tube, which improved the pneumothorax.
Disclosure	The patient or legally authorized representatives were informed.
Reporting and surveillance	Providers reported the error through the health system safety reporting system – in one instance, this was the only means by which the original operators became aware of their error.
	Providers reported error to U.S. Food and Drug Administration (FDA) and manufacturer.
	This error was reviewed by the Emergency Department operators (physicians and residents) after being notified of the error.
Root cause analysis	Physician operators considered the causes using a standard rubric (Table 1).
System modification	Potential users of the device in the health care system were warned of the potential risks of the device.
	Education was performed.
	Postprocedural time-outs, instrument counts, and systematic tests of function/troubleshooting processes were proposed.
	Consideration was given to alternative devices.
Regulatory action/reform	The FDA was informed of the error and device risks.
Engineering/manufacturing reforms	The manufacturer was contacted by the authors and discussions were held about device labeling and redesign. The manufacturer also received a report from the FDA.

error). Our RCA identified multiple contributing factors (Tables 1–3), including human errors, unrecognized radiographic clues, communication breakdown, systematic procedural approach, and device design. Table 1 summarizes RCA findings. Table 2 applies stages in identification and mitigation of a medical error. Table 3 illustrates application of engineering principles to the error.

Figures 1–4 demonstrate radiographic clues to retained catheter obturator. Figures 5 and 6 illustrate design features contributing to the errors. Figure 7 illustrates a systematic approach to troubleshooting a chest tube, which could be applied uniformly at the end of the procedure and when functional issues arise.

DISCUSSION

Radiographic Appearance, Expected and Abnormal

We identified several radiographic features of retained catheter obturator (Figures 1–4). The expected appearance of the pigtail catheter on chest radiograph is its namesake: a curled configuration resembling a pig's tail (Figures 2–4). With the catheter obturator in place, the catheter has an unexpectedly straight appearance (Figures 1, 3, 4). In addition, the obturator is radiographically visible, creating a "tube within a tube" appearance on chest radiograph (Figure 3). When the obturator is removed as intended, this radiographic finding is not evident (Figure 3).

Table 3. Heuristics for Usability Problems in Medical Devices (10)

Heuristic	Application to the Pigtail Catheter
Visibility of system state	The catheter obturator is hidden within the catheter, and its presence is difficult to recognize. The color of the obturator is inconspicuous.
Minimalist	The obturator and dilator have unnecessary Luer lock connectors that serve no function and create the opportunity for erroneous connection of the system.
Minimize memory load	The system design forces the user to remember to remove the catheter obturator; the system would not need to rely on user memory if the unnecessary Luer lock adapters were removed, preventing incorrect connection.
Prevent errors	Connector design facilitates incorrect assembly of system; redesign could prevent error from occurring.
Clear closure	Instructions do not include an end-of-procedure sequence of actions to confirm function of the catheter and retrieval of all disposable components.
Help and documentation	Instructions for insertion could be improved with a visual checklist and instrument count diagram for use during the procedure.

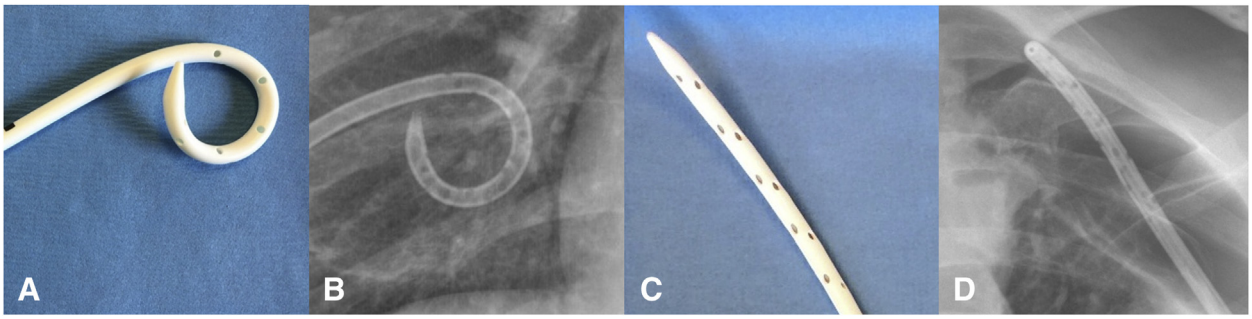

Figure 3. Physical and radiographic appearances of catheter, correct and incorrect. (A) Photograph, *without* the stiffening obturator in place. The catheter tip assumes its namesake "pigtail" shape. (B) Radiographic appearance, *without* the stiffening obturator device in place. The "pigtail" shape is visible. The catheter appears hollow [compare with (D)]. (C) Appearance with stylet in place (straight). The pigtail shape is absent. (D) Radiographic appearance with the stiffening obturator in place. The catheter appears unexpectedly straight. A "tube within a tube" appearance is present, because the obturator fills the normal lumen of the 14.0-Fr catheter [compare with (B)].

On chest CT, the abnormally straight appearance of the catheter is evident on scout images (Figure 4) when the obturator is in place. On planar cross-sectional CT images, the catheter appears solid with the obturator in place, rather than having an expected air-filled channel (Figure 2). CT also demonstrates whether the catheter is appropriately located in the pleural space.

Additional systematic improvements for radiographic detection could be implemented. Images of the expected and incorrect radiographic appearances could be included in the kit to guide the user. Given the large number of catheters in clinical use, a radiologist not informed of the specific device may not recognize the absence of the expected pigtail radiographic configuration. Communication with the radiologist to identify the specific catheter placed could enable the radiologist to recognize an unexpected appearance. The device could also be printed with radiographically visible, unique identifiers to guide clinicians and radiologists.

Human Error

Human error played a role in the occurrence and duration of these errors, though the duration itself points to the subtlety of the errors. The operators did not recognize the radiographic abnormalities immediately after catheter placement; nor, apparently, did other clinical providers and radiologists (in case 1, for nearly 48 h and through multiple radiographic assessments). The treatment teams did not recognize the cause of the chest tube malfunction.

Training and experience with small-caliber chest tube insertion and management likely played a role in the occurrence of the errors and the delay in their recognition. In one of the two cases, the primary operator was a PGY-3 resident; his prior experience included simulation laboratory and tissue laboratory insertions but not insertion during patient care. During the procedure, he was supervised by a board-certified emergency physician. The patient was admitted to an oncology medical service where the pigtail device is frequently used in patients, but it is unclear whether the providers caring for the patient had personal experience inserting the device, which might have improved their recognition of the cause of the catheter malfunction. The obturator error we describe is not highlighted as a risk in the manufacturer's training materials; improvements in training with a focus on high-risk steps might reduce the likelihood of repeat occurrences.

A systematic approach to the assessment of chest tube malfunction might have enabled more rapid detection and resolution of the error (Figure 7).

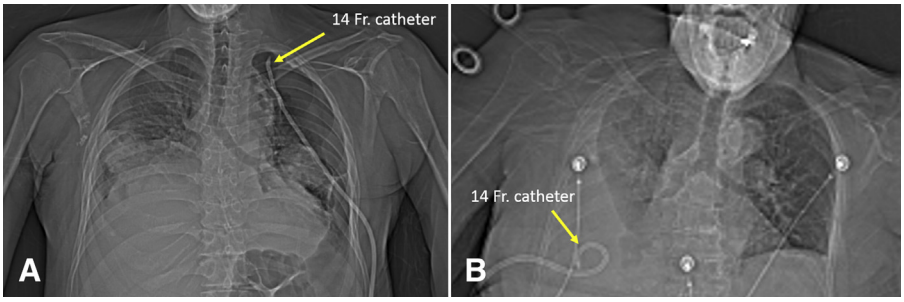

Figure 4. (A) Computed tomography scout image from patient 1 shows a straight catheter tip, an indication that the catheter obturator remains in place. (B) A different patient, with the 14-Fr catheter correctly inserted without the catheter obturator in place, shows the expected curled "pigtail" shape.

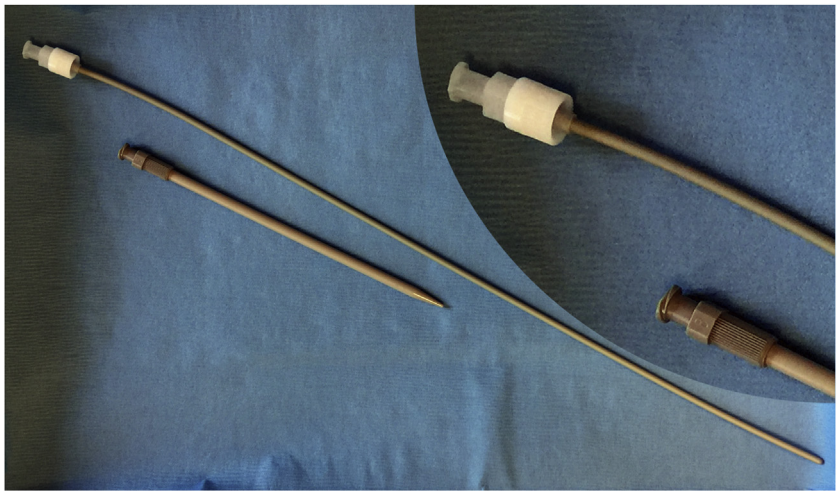

Figure 5. Luer-lock connectors on the catheter obturator and tissue dilator serve no essential purpose, but create a risk of the error observed in this case. The external drainage tube can be inadvertently connected to these devices, rather than to the 14-French catheter.

Engineering/Device Design

We evaluated the device with a usability heuristics model and identified several design features that create latent risks for the observed errors (6,10).

Inadvertent retention of the obturator defeats the function of the catheter. The obturator obstructs the catheter lumen and the 19 side ports, leaving only the smaller terminal opening patent. This single remaining port may be susceptible to occlusion *in vivo*.

Medical devices should be designed using a "minimalist" approach, eliminating unnecessary steps and functions, and applying "interfaces that make errors impossible" (10). The catheter at hand violates these

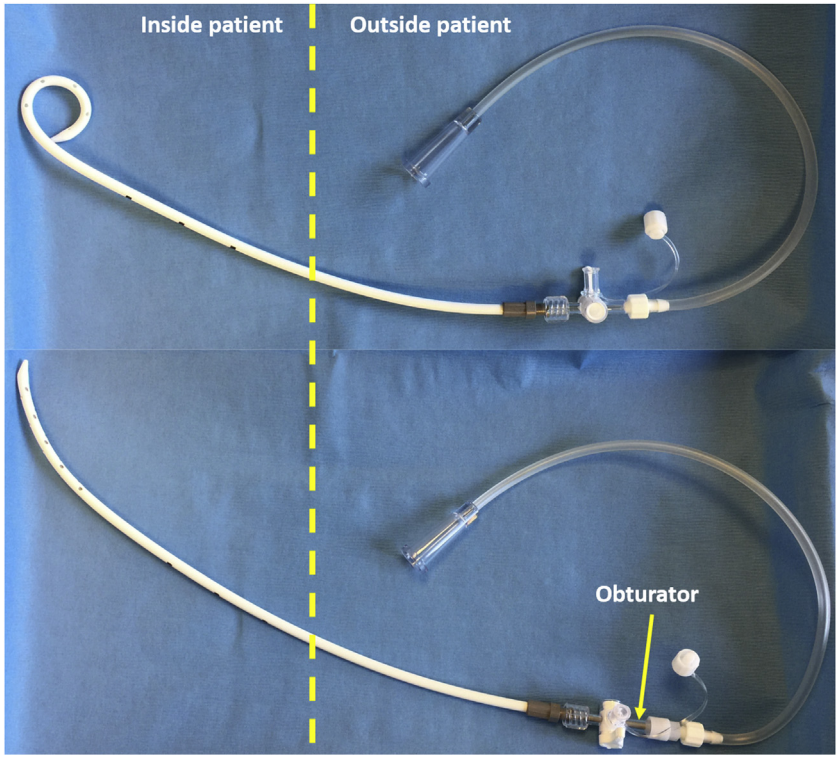

Figure 6. The assembled catheter and external drain tubing, without the obturator (top) and with the obturator (bottom). The portion of the assembly outside the patient appears nearly identical, as the obturator is an inconspicuous gray color and is hidden within the catheter.

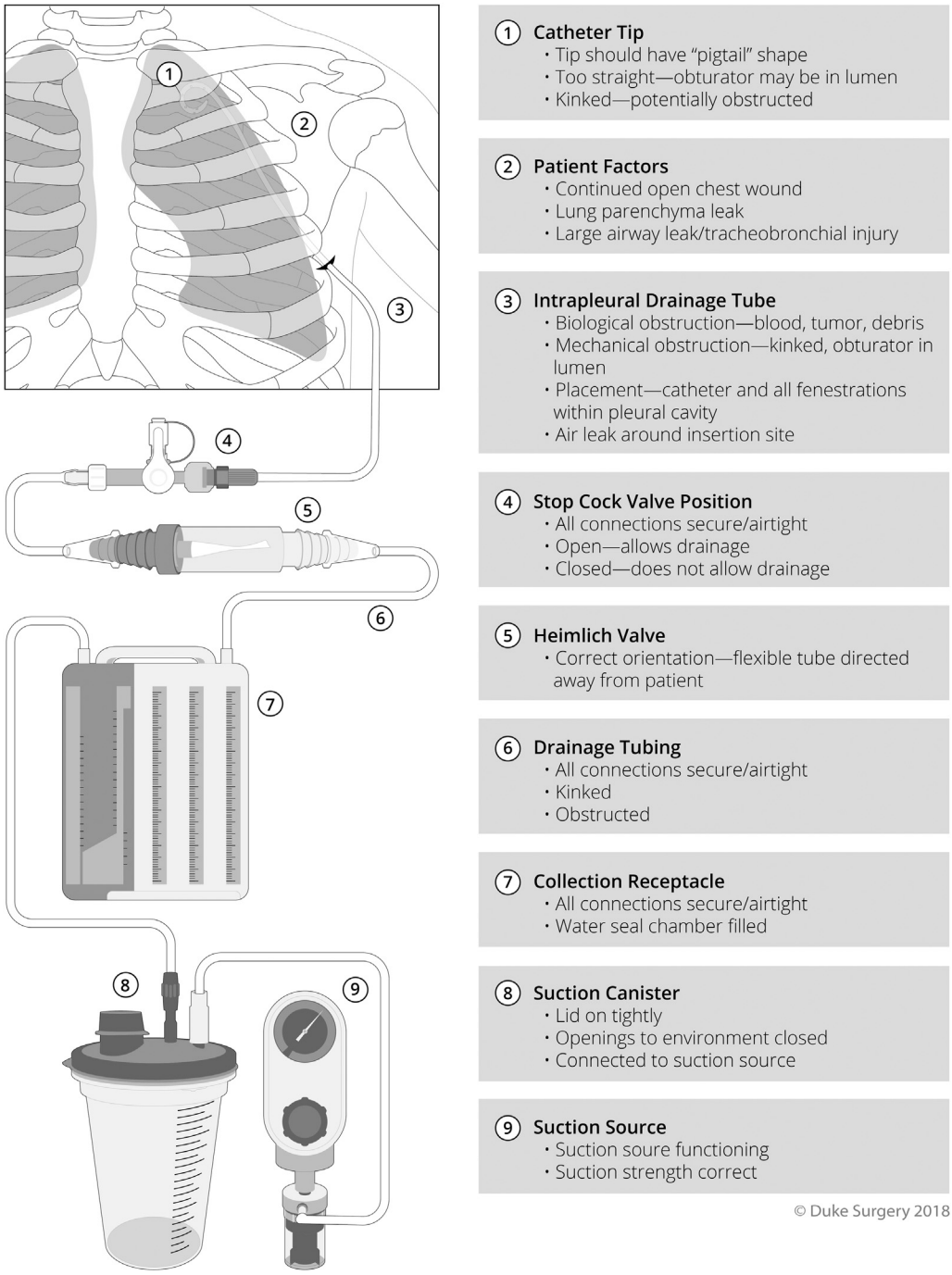

Figure 7. A systematic approach to troubleshooting chest tubes. Attribution: Illustrated by Megan Llewellyn, MSMI, CMI; copyright Duke University 2019; with permission under a CC BY-ND 4.0 license. megan.llewellyn@duke.edu

principles because the obturator unnecessarily has a Luer lock connector that is compatible with drainage tubing, enabling an operator to commit the error of connecting these two components, rather than forcing removal of the obturator prior to drainage tube connection (Figure 5). This Luer lock connector serves no essential purpose in the kit and could be eliminated, preventing the error. The tissue dilator has an identical unnecessary Luer lock connector.

"Visibility of system state" is essential for safety in medical devices, but violated in the kit described (10). The obturator is inconspicuous when in place within the catheter (Figure 6). This facilitates operator error, as an operator may not notice that the obturator has not been

removed. Both the obturator and the tissue dilator are an inconspicuous gray color; attention could be called to these devices with a warning hue to indicate that they should be removed or discarded. The obturator could be made more radiographically apparent to increase the likelihood that it would be recognized by a radiologist or clinician if inadvertently left in place.

"Minimizing memory load" is another key usability and safety tenet (10). A warning label or more explicit instructions could be provided to prevent the error from occurring, by specifically calling the operator's attention to this possible error. A sterile copy of the instructions or figures could be included in the kit; currently, the instructions are affixed to the nonsterile exterior of the kit and available online (13). The instructions do state "remove the wire guide and catheter obturator" but do not call attention to the risk of inadvertent retention of the obturator.

Procedural Approach

Systems to Prevent and Detect Error. Complex multistep procedures create risk of errors of commission or omission, even for skilled and experienced operators. Use of surgical safety checklists has been shown to decrease morbidity and complications from surgical procedures (14). A list of key procedural actions with images could be included in the kit for reference. In addition to the widely implemented preprocedural time-out, evidence-based lessons from surgical practice could improve safety (14,15). A postprocedural time-out could include an instrument count to prevent foreign bodies from being left inadvertently within a patient. For each kit, items that are intended to be discarded could be labeled clearly and checked against a diagram or list. End-of-procedure systematic assessment for function (Figure 7) could identify functional problems and solutions. These steps also satisfy the "clear closure" heuristic, in which the completion of a task is explicit (10).

Regulatory Considerations

The FDA monitors postmarketing adverse clinical events for medical devices through a reporting system, which is voluntary for clinicians and consumers. Manufacturers are required to share reports they receive from health care professionals or consumers (4). We reported the occurrence of the events to the FDA and also to the manufacturer. Other kits by multiple manufacturers may have similar designs creating comparable risks; manufacturers and the FDA could assist in identifying these. Clinicians should be aware of their vital surveillance role in reporting device-related concerns to the FDA and manufacturers; without this reporting function, serious patient safety concerns may remain unrecognized and unaddressed.

Limitations

The actual rate of the described obturator error and other complications is impossible to determine with current data, as both the numerator (complications) and denominator (number of attempted chest tube placements) are unknown. We believe that the cases presented are sentinel events, important to proceduralists and providers caring for patients undergoing small-caliber thoracostomy. Anecdotally, we have heard from other providers of similar complications in other institutions. Our review of the literature did not reveal other similar reports, but under-recognition and under-reporting are possible, perhaps even likely. An operator may fail to self-report an error that is recognized and corrected. Clinicians may be unaware of reporting mechanisms, including institutional safety reporting systems and the FDA database.

CONCLUSIONS

We highlight a preventable error in insertion of a percutaneous catheter and describe radiographic features to enhance error detection. Improved design, systematic processes for device insertion and troubleshooting, and enhanced provider education could reduce the risk of medical device errors. An end-of-procedure time-out including instrument counts and systematic assessment of device function is a generalizable patient safety measure for bedside procedures.

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