OBSERVATIONAL STUDY

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Patient, Operator, and Procedural Characteristics of Guidewire Retention as a Complication of Vascular Catheter Insertion

Nicholas Kassis, MD[1]
Laith Alkukhun, MD[2]
Kathleen Kravitz, RN[3]
Carolyn Miclea, BSN[3]
Amanjit Gill, MD[4]
Chiedozie I. Udeh, MBBS[5]
Piyush Mathur, MD[5]
Aaron C. Hamilton, MD[6]
Sean P. Lyden, MD[7]
Samir R. Kapadia, MD[3]
Umesh N. Khot, MD[3]

OBJECTIVES: Guidewire retention after intravascular catheter insertion is considered a "never event." Prior reports attribute this complication to various characteristics including uncooperative patients, operator inexperience, off-hour or emergent insertion, and underutilization of ultrasound guidance. In this descriptive analysis of consecutive events, we assessed the frequency of patient, operator, and procedural factors in guidewire retention.

DESIGN: Pre-specified observational analysis as part of a quality improvement study of consecutive guidewire retention events across a multihospital health system from August 2007 to October 2015.

SETTING: Ten hospitals within the Cleveland Clinic Health System in Ohio, United States.

PATIENTS: Consecutive all-comers who experienced guidewire retention after vascular catheter insertion.

INTERVENTIONS: None.

MEASUREMENTS AND MAIN RESULTS: Data were manually obtained from the electronic medical records and reviewed for potential contributing factors for guidewire retention, stratified into patient, operator, and procedural characteristics. A total of 24 events were identified. Overall, the median age was 74 years, 58% were males, and the median body mass index was 26.5 kg/m^2. A total of 12 (50%) individuals were sedated during the procedure. Most incidents (10 [42%]) occurred in internal jugular venous access sites. The majority of cases (13 [54%]) were performed or supervised by an attending. Among all cases, three (12%) were performed by first-year trainees, seven (29%) by residents, three (12%) by fellows, and four (17%) by certified nurse practitioners. Overall, 16 (67%) events occurred during regular working hours (8 AM to 5 PM). In total, 22 (92%) guidewires were inserted nonemergently, with two (8%) during a cardiac arrest. Ultrasound guidance was used in all but one case.

CONCLUSIONS: Guidewire retention can occur even in the presence of optimal patient, operator, and procedural circumstances, highlighting the need for constant awareness of this risk. Efforts to eliminate this important complication will require attention to issues surrounding the technical performance of the procedure.

KEY WORDS: catheters;medical errors;never event; vascular access devices

Central venous catheter (CVC) insertion is a ubiquitous practice among healthcare professionals owing to its multipurpose use for delivering medications, parenteral nutrition, and hemodialysis, as well as for numerous diagnostic and therapeutic procedures (1). The Seldinger technique, in which a CVC is introduced over a guidewire, is the predominant insertion strategy in current practice, born over the past several decades as a means to decrease the mechanical (pneumothorax, arterial

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KEY POINTS

Question: Which patient, operator, and procedural factors are associated with guidewire retention as a complication of intravascular catheter insertion?

Findings: In this prespecified, descriptive observational analysis of 24 guidewire retention events, affected patients were predominantly nonobese and noncoagulopathic, and in equal split, under preprocedural sedation. The majority of events occurred under the supervision or directly by an experienced attending, during regular working hours, in nonemergent circumstances, and under ultrasound guidance.

Meaning: Guidewire retention can occur under optimal patient, operator, and procedural conditions, emphasizing the need for fixed awareness of this risk and for focused efforts on standardizing and optimizing technical procedural performance.

puncture, and hematoma), thrombotic, and infectious complications associated with CVC insertion (1, 2). Since its emergence, however, there have been incident reports of retained guidewires (3–12), with an estimated prevalence of nearly one in every few thousand cases (7, 11, 13). Although the majority do not cause any major complications (10–12) and are promptly removed endovascularly (14–16), rare cases can lead to arrhythmia/heart block (17, 18), hemothorax (19), tangling in an inferior vena cava filter (20, 21), cardiac tamponade (22–24), pulmonary embolism (25), and death (25). In response, the National Quality Forum labeled guidewire retention as a serious reportable event, and effectively in 2008, the Centers for Medicare and Medicaid Services substantially reduced payments to hospitals for the care of patients who experienced these events (26, 27). Further, the National Patient Safety Agency of the United Kingdom released a 2009/2010 report identifying guidewire retention as a "never event among 26 others defined as "a serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers"(28).

Prior case reports and series suggest several factors associated with guidewire retention. These include patient variables such as obesity (6, 11), coagulopathy, and lack of cooperation (5); operator features such as inattention (7, 11, 12), fatigue (12, 29), inexperience (5, 6, 12, 13, 29, 30), and inadequate supervision (5); and procedural circumstances including poor guidewire design (5–7, 13, 31), lack of ultrasound guidance (11), and procedural urgency due to patient instability (5), for instance, during cardiopulmonary arrest (7, 32). In response to these perceived deficiencies across multiple tiers within the system, various institutions have proposed or implemented preventative and corrective measures including sedating disoriented patients (33), further educating and supervising trainees (5, 7, 33), and increasingly utilizing ultrasound guidance (33).

Despite these efforts, cases of guidewire retention continue to occur, indicating that such processes may not sufficiently address the root causes and predispositions to this "never event." In this descriptive analysis of consecutive guidewire retention events across 2007–2015, we aimed to assess the frequency of the previously proposed patient-, operator-, and procedural-related factors thought to be associated with the occurrence of guidewire retention.

MATERIALS AND METHODS

This is a prespecified observational study as part of a quality improvement initiative identifying consecutive events of guidewire retention that occurred as a complication of vascular catheter insertion within the Cleveland Clinic Health System in Ohio between August 2007 and October 2015. The Cleveland Clinic Health System comprises the main academic teaching hospital and nine community hospitals within the broader Ohio community. Cases were identified utilizing the Cleveland Clinic Safety Events Reporting System (SERS), a robust event reporting process available to all caregivers within the enterprise, which is designed to facilitate patient and caregiver safety, performance improvement, cost containment, and loss control. Data were obtained by manual review of the electronic medical records, and factors contributing to these events were determined and stratified into those related to the patient, operator, and procedural scenario (**Fig. 1**). This study was reviewed and approved by the Cleveland Clinic Institutional Review Board (study 16-636, approved May 12, 2016,"Patient, Operator, and

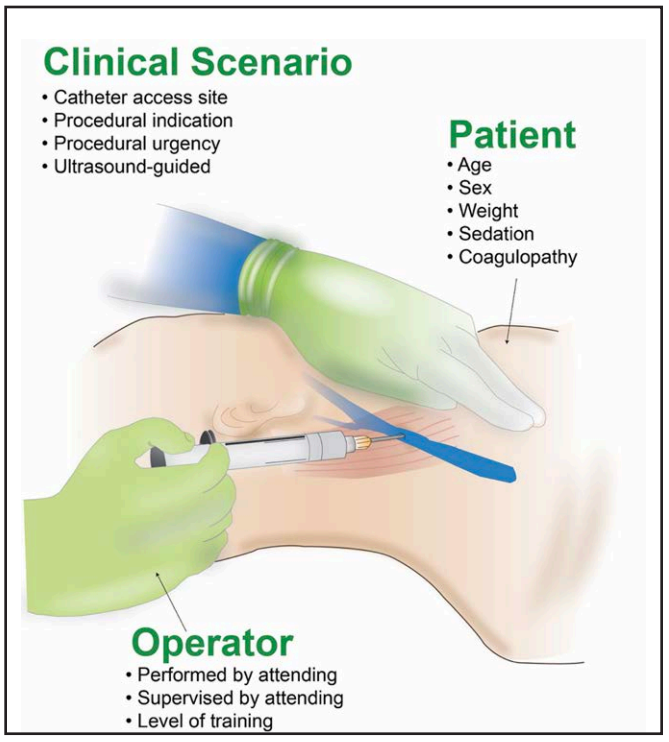

Figure 1. Study features hypothesized to contribute to guidewire retention after intravascular catheter insertion, stratified into patient, operator, and procedural factors.

Procedural Characteristics of Guidewire Retention as a Complication of Vascular Catheter Insertion"), and written informed consent was waived. All procedures were followed in accordance with the ethical standards of the responsible committee on human experimentation within our institution and with the Helsinki Declaration of 1975.

Patient-related factors included age, sex, body mass index, presence of coagulopathy as defined by the use of anticoagulation or an elevated international normalized ratio, and cooperation as assessed by use of preprocedural sedation. Operator-related variables included level of operator training and supervision as well as timing of intravascular catheter insertion with respect to the academic year and to regular working hours, defined as 8 AM to 5 PM on Monday through Friday. The procedural circumstances surrounding catheter insertion included the type of intravascular catheter and associated catheter access site, procedural indication such as presence of circulatory shock or cardiopulmonary arrest, procedural urgency, incident location, and use of ultrasound guidance. Elective cases were defined as catheters inserted during an elective surgery/procedure or a peripherally inserted central catheter placed due to difficulty obtaining peripheral intravenous access. Urgent cases included catheters placed prior to emergent surgeries and those inserted in the emergency department or ICU for resuscitation or delivery of vasoactive agents. Emergent cases consisted of catheters that were inserted during a cardiopulmonary arrest or a code situation. Additional collected data included the documented complications of guidewire retention, the method of retrieval, and any causative factors suggested in the SERS.

Continuous variables were summarized using median (interquartile range), and categorical variables were reported as numbers (percentages).

RESULTS

A total of 24 events of guidewire retention after catheter insertion were identified. **Supplemental Table 1** (http://links.lww.com/CCX/B119) details the observed incidence of the studied features categorized into those related to the patient, operator, and procedural circumstances. Among the cohort, the median age was 74 years, 58% were males, and the median body mass index was 26.5 kg/m^2. Twelve (50%) of the patients were sedated, and 18 (75%) were noncoagulopathic.

At the operator level, the majority of cases (13 [54%]) were performed or supervised by attending physicians. Overall, 13 (54%) procedures were completed by a resident or fellow-in-training, of which six (25%) were supervised and three (13%) were performed by postgraduate year 1 trainees. Among all cases, four (17%) were completed by certified nurse practitioners. In total, 16 (67%) events occurred during regular shift hours. A total of two (8%) events were observed in July, the first month of the academic year, and nine (38%) cases transpired during the second half of the academic year.

With regard to procedural factors, most incidents (10 [42%]) occurred in internal jugular venous access sites, which correspond to the preferred access site due to lower thrombotic and pneumothorax complications (1, 34, 35). Retained wires were inserted electively in eight patients (33%), urgently in 14 patients (58%), and emergently in two patients (8%) during a cardiac arrest. The majority of events (15 [62%]) occurred in the ICU, and the incident location was split equally between the main academic teaching hospital and community hospitals. Ultrasound guidance was used in all but one case, which was an arterial catheter insertion.

The retained guidewire was recognized and removed within the first few hours after catheter insertion in all but two events. One patient had the guidewire removed 2 months after insertion of an internal jugular Swan-Ganz catheter that was placed during combined aortic valve replacement and coronary artery bypass grafting surgery. The postoperative chest radiograph obtained 1 hour later revealed a retained guidewire; however, this was not identified by the medical staff until the patient returned for a follow-up visit with a provider 2 months later. The patient, who was asymptomatic at the time, was then readmitted for percutaneous removal of the retained guidewire, which measured 45.5 cm in length and extended from the superior vena cava to the inferior vena cava into the right internal iliac vein. The guidewire was removed in its entirety by vascular surgery via the left transfemoral approach using a hooking technique with a Varrel Contralateral Flush catheter with snaring from the same sheath. It appeared intact without fracture or fragmentation. No complications or harms to the patient occurred.

The second patient did not have the guidewire removed. It was initially placed when the patient presented with acute right limb ischemia requiring thrombolysis and stenting of an occluded proximal popliteal and distal superficial femoral artery. Postprocedural X-ray demonstrated a small, retained wire; however, this was not identified by medical staff until 10 months later during a follow-up visit with vascular surgery who confirmed its retention via Duplex studies. In light of good flow throughout the vessel without evidence of stenosis, palpable pulses on examination, and likely epithelization of a portion of the wire that abutted the vessel wall, the decision was made in conjunction with the patient to forgo wire retrieval and, instead, continue antiplatelet therapy and follow-up with repeat Duplex studies. The wire was not visualized on imaging 1 year later or during recanalization with angioplasty of an occluded superficial femoral artery stent 3 years later. No complications of wire retention were observed in this case.

Among all 24 events, complications were observed in two patients. Given lack of intravenous access, one patient underwent placement of a left upper extremity peripherally inserted central catheter via the left basilic vein using ultrasound guidance at bedside in the ICU. During the procedure, the guidewire loosened and migrated to the right ventricle. The patient was then transferred to the special procedures suite to retrieve the retained guidewire. Multiple attempts of percutaneous retrieval were unsuccessful, and during these attempts, the patient experienced respiratory failure requiring intubation. Once the patient was medically stabilized, the wire was surgically removed from the upper extremity via venous cutdown by vascular surgery.

The other patient underwent recurrent ventricular tachycardia ablation via the subxiphoid approach, which was complicated by unsuccessful withdrawal of a 0.035-inch Wholey™ (Medtronic, Minneapolis, MN)) wire from the pericardial space, requiring the use of a 5-Fr dilator to straighten out the wire. This resulted in the wire fracturing and the distal end (estimated 12–15 cm in length) looping through the diaphragm with additional portions in the pericardium and posterior mediastinum. This led to liver laceration and perihepatic bleeding that tracked down the right paracolic gutter into the pelvis, ultimately causing circulatory shock. In a shared-decision discussion with the patient, family, and the medical, radiology, and surgical teams, the decision was made to treat conservatively without removing the guidewire as the benefits did not appear to outweigh the risks of a sternotomy.

No deaths were observed as a direct sequelae of guidewire retention. Potential causes for guidewire retention were described via the SERS in six cases; three of these were attributed to the guidewire fragmenting or fracturing (one as described above and two with attempted wire removal during peripherally inserted central catheter placement): one to difficulty in gaining intravenous access, one to loss of guidewire control, and one to difficulty in retrieving the guidewire.

DISCUSSION

In this prespecified, descriptive observational analysis of 24 guidewire retention events that occurred as a complication of vascular catheter insertion within a large health system from 2007 to 2015, we observed the following principal findings (**Fig. 2**). First, affected patients were predominantly nonobese and noncoagulopathic, and in equal split, under preprocedural sedation. Second, the majority of events occurred under the supervision or directly by an experienced attending physician and during regular working hours. Third, the overwhelming preponderance of cases was performed

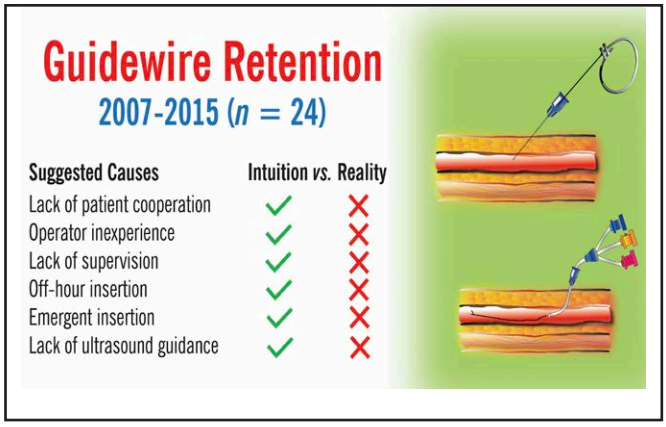

Figure 2. Observed discrepancies between perceived causative factors and incident characteristics of 24 consecutive guidewire retention events across a multihospital health system.

in nonemergent circumstances and under ultrasound guidance. These findings suggest that guidewire retention can occur even with optimal patient, operator, and procedural conditions, emphasizing the need for fixed awareness of this risk and for focused efforts on standardizing and optimizing technical procedural performance.

Our study highlights the limitations of relying on intuitive beliefs. We instinctively speculated that a lack of patient cooperation (5), operator inexperience (5, 6, 12, 13, 29, 30), absence of ultrasound guidance (11), and emergency situations (5, 7, 32) were commonly associated with guidewire retention. However, these assertions are inconsistently substantiated by objective data (36, 37) and may be subject to "intuition bias," a cognitive bias described as the improper and exaggerated tendency to depend on immediate intuition for decision-making (38). We must depend on analytic evidence to further elucidate the factors related to guidewire retention. Duncan et al (39) demonstrated this successfully by surveying interns to identify failure modes for retained guidewires; they subsequently developed and required interns to complete a data-driven safety improvement curriculum comprised of online and hands-on training modules, which ultimately reduced this complication. It is our core recognition that guidewire retention is not directly attributable to one factor, but rather to aligned deficiencies across multiple levels, including technical challenges and intrinsic human error (3).

In the absence of clear patient, operator, or procedural scenario factors, guidewire retention reduction efforts should focus first on the technical performance of the procedure. It is critical to stress proper catheter insertion techniques as they relate to maintaining guidewire control. These include confirming guidewire visibility prior to advancing the catheter, inserting the guidewire to a set centimeter mark and maintaining that position while inserting the catheter, assuring the catheter is not advancing in tandem with the guidewire, holding the proximal tip of the guidewire at all times until its removal from the vessel, and inspecting the guidewire for design or manipulation defects if it does not pass freely into the vessel (7, 40, 41). Surprisingly, most training resources and practice guidelines fail to highlight the importance of these principles (1, 42–44). In the future, these fundamental routines must be incorporated and emphasized within standardized training (39).

The study findings prompted our institution to modify our approach to mitigate and manage retained guidewires by standardizing and implementing several redundant strategies and sharing these with the appropriate departments including the ICU, anesthesiology, radiology, and vascular surgery. We emphasized that all patients and all operators, irrespective of experience or specialized expertise, are at risk of this event when placing any vascular catheter using the Seldinger technique. Accordingly, we recommended preventative measures such as encouraging operator mindfulness, stressing guidewire control during catheter advancement by supporting the guidewire with the three fingers of the non-advancing hand, utilizing landmarks to push the catheter forward, and employing guidewires with markings. We further shared additional safety measures such as a catheter checklist, with a boxed reminder of "remember the guidewire," and a wire count at the end of the procedure to ensure early retrieval (3, 6, 7, 45). Finally, there was a concerted effort to routinely acquire X-ray imaging after catheter placement not solely to confirm correct positioning but also to explicitly rule out retained guidewires (7). Guidewire retention did not discriminate by patient, operator, or procedural feature, and thus, we strongly encourage a multipronged and dynamic approach.

As the complication is rooted in technical challenges, ergonomic and mechanical advances in intravascular catheter insertion may altogether prevent guidewire retention. For instance, developing guidewires with distinct brightly colored proximal ends may alert operators at all times of its absence (6). Additionally, designing

guidewires that are unable to directly pass through catheters after their insertion (i.e., capping at the hub) may prevent inadvertent loss of wire control among operators. However, any change in the design of the catheter or the wire would need to be evaluated to demonstrate that these changes do not introduce alternative risks in the procedure or to the patient. More precise and methodical review of the procedural steps is likely the simplest and most effective means to avoid this complication. Novel improvements in device technology may further solve the issue. The National Health Service of the United Kingdom implemented WireSafe™ (Venner Medical Technologies, Singapore) following its regulatory approval, which is a locked procedure pack engineered to eliminate guidewire retention by relying on the guidewire to unlock its contents (suture, suture holder, and antimicrobial dressings) in order to complete the procedure (46). In a forced error randomized controlled simulation study, this technology proved effective in preventing such events (36). Such progress in device development is promising and jointly with various coordinated safety, quality, and educational measures may help entirely eliminate this "never event."

This study was subject to the inherent limitations of a retrospective, descriptive analysis, including the inability to assign causality to these incident events. We did not consider the measured effect of each patient-, operator-, and procedural-related features on controls of successful, uncomplicated vascular catheter insertion. Our study cannot determine the incidence of guidewire retention due to the unavailability of an accurate measurement of the total number of vascular procedures performed at our institution. Additionally, data on guidewire retention events after October 2015 were not collected given that the study period was prespecified as part of a quality improvement analysis. Further, there was potential for recall bias in the operators when documenting the reasons for guidewire retention in the SERS.

CONCLUSIONS

Challenging our understanding of factors thought to contribute to guidewire retention as a complication of vascular catheter insertion, our findings reveal that all patients and operators are at risk of guidewire retention when the Seldinger technique is employed. Centers should focus on encouraging operator mindfulness, stressing critical procedural techniques, optimizing guidewire design, and ensuring quality measures such as checklists, wire counts, and postprocedural imaging. The adoption of universal precautions with every catheter placement to ensure guidewire control has the promise of eliminating the occurrence of this important adverse event.

1 *Division of Cardiology, Lifespan Cardiovascular Institute, Warren Alpert Medical School of Brown University, Providence, RI.*

2 *Knight Cardiovascular Institute, Oregon Health & Science University, Portland, OR.*

3 *Department of Cardiovascular Medicine, Heart, Vascular and Thoracic Institute, Cleveland Clinic, Cleveland, OH.*

4 *Department of Diagnostic Radiology, Cleveland Clinic, Cleveland, OH.*

5 *Department of Intensive Care and Resuscitation, Anesthesiology Institute, Cleveland Clinic, Cleveland, OH.*

6 *Department of Internal Medicine, Cleveland Clinic, Cleveland, OH.*

7 *Department of Vascular Surgery, Cleveland Clinic, Cleveland, OH.*

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For information regarding this article, E-mail:khotu@ccf.org

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